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Applications of electric, magnetic and electromagnetic fields (EMF) in humans for non-medical purposes

Recommendation by the German Commission on Radiological Protection with scientific background

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Anwendungen elektrischer, magnetischer und elektromagnetischer Felder (EMF) zu nichtmedizinischen Zwecken am Menschen

Empfehlung der Strahlenschutzkommission mit wissenschaftlicher Begründung

Preface

In recent years there has been a sharp rise in the use of electric, magnetic and electromagnetic fields (EMF) on humans. Such sources include regular consumer devices as well as devices originally intended solely for medical applications.

In view of this trend, in March 2017 the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) asked the German Commission on Radiological Protection (SSK) to assess the risks involved in EMF applications in humans for non-medical purposes, taking into account the health effects of specific devices, and to develop professional requirements for the use of such devices in humans.

In order to comply with this advisory mandate, the German Commission on Radiological Protection formed a working group attached to the 'non-ionising radiation' committee. The working group consisted of the following members:

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1 Introduction

In recent years there has been a significant increase in the use of ultrasound devices, lasers and other optical sources of radiation (e. g. Intense Pulsed Light, IPL) for cosmetic and other non-medical purposes, as well as a sharp rise in the use of electric, magnetic and electromagnetic fields (EMF) on humans. Such sources include regular consumer devices as well as devices originally intended solely for medical applications. They are used, for instance, to reduce fat (lipolysis), to 'tighten the skin', to remove hair, and are also marketed as a means of improving brain, nerve and muscle activity. In view of this trend, the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) asked the German Commission on Radiological Protection (SSK) to assess the risks involved in EMF applications in humans for non-medical purposes.

On this topic, a study has already been conducted on behalf of the Federal Office for Radiation Protection (BfS) (Dürrenberger et al. 2018). This study is a systematic survey of devices used for application of EMF, plasma and ultrasound for non-medical purposes in humans, the standards that such devices must meet before reaching the market, as well as side effects and risks documented in specialist literature, by notification offices and in the media. The study also provided recommendations, chiefly with regard to regulatory requirements and the need for further research. These recommendations largely align with the evaluation provided in the present recommendation. As a result, the 'Ordinance on protection against the harmful effects of non-ionising radiation in human applications' (NiSV 2018, Article 4) was drafted to provide a regulatory framework and will come into effect at the end of 2020.

The present recommendation includes an evaluation of conventional device types as well as applications of electric, magnetic and electromagnetic fields (including static fields) in humans. Due to the broad range of devices and applications available, it was not possible to include every type of device and every kind of EMF application in humans. It was also beyond the scope of this recommendation to include device-specific warnings (e. g. for people with implants) issued by the manufacturers, device-specific information about possible adverse effects (e. g. thermal effects of EMF applications during pregnancy) provided by manufacturers, and device-specific information about contraindications (e. g. transcutaneous electrical nerve stimulation (TENS)). Device-specific information provided by manufacturers should always be observed together with the present recommendation before using a device for human application.

A key assessment criterion is whether thresholds for biological effects, i. e. the respective field strengths and SAR values within a tissue above which biological effects are evident, are exceeded during application. The following differences need to be taken into account when assessing the risk associated with these thresholds. The acute biological effect could be a nuisance, for example, when impeding the sensory function with little impact on health, as is the case with magnetophosphenes occurring from 2 mT to 10 mT at frequencies from 10 Hz to 50 Hz. In the radiofrequency range, however, direct thermal tissue damage may occur if SAR limits are exceeded. This is why users outside of the medical field, even trained persons, should refrain from exceeding the associated thresholds (see Annex A-1).

In addition, this recommendation sets out the professional requirements for the use of such devices in humans. The EMF applications under consideration involve deliberate human exposure to EMF so as to achieve an intended effect (principal intended effect – term used in the non-official translation of the Medical Devices Act from 2002). Apart from the principal intended effect, direct or long-term unintended effects may occur which may or may not have a detrimental effects on a person's health.

There are two categories for devices or, more specifically, EMF sources used in applications for non-medical purposes:

1. Devices that enter the market as consumer devices subject to corresponding product safety requirements.
2. Devices declared as medical devices, which however can be used for non-medical purposes.

Devices in the first category are governed by product safety requirements intended to ensure that consumers are safeguarded when using devices as intended, i. e. that the benefits of such applications outweigh the negligible risks involved. Product safety requirements are based on the hitherto scientifically proven acute health risks of EMF, and do not include any possible effects of long-term applications.

Devices in the second category often emit extremely high EMF which are needed to achieve the principal intended effect for medical purposes. As a result, the risks involved are much greater. However, the requirements for medical devices and their use in medical applications ensure that the devices achieve their principal intended effect, in turn justifying any potential risks. Moreover, the available medical expertise and additional specific medical requirements help to optimise the risk-benefit balance. In contrast, the use of such devices for cosmetic or other non-medical purposes does not require any qualification of the user.

Fundamentally, this evaluation is based on thresholds for effects which, when exceeded, can lead to tissue reactions (thresholds for effects denote the values above which biological effects are evident, see ICNIRP 1998). In addition, thresholds above which a health risk cannot be excluded are also important, which is why the following questions will be investigated in this recommendation:

- Which devices intended for medical purposes must not be used for non-medical purposes under any circumstances?
- Which non-medical applications fall in which risk category and may be performed subject to what requirements and restrictions, particularly in terms of expertise?

2 Recommendation by the SSK

The risks associated with applications involving electric, magnetic and electromagnetic fields (EMF) are primarily assessed on the basis of knowledge available about their health effects (described in Annex A-1). This includes in addition to scientifically proven acute effects also indications of possible long-term effects, e. g. childhood leukaemia or neurodegenerative diseases in adults stemming from low-frequency magnetic fields, for which it is not possible to perform a quantitative assessment based on the knowledge available. These indications are used as an additional risk assessment criterion.

The following criteria are used to estimate the health risks:

- Exposure: extent of exposure to EMF compared to the ICNIRP guidelines (field strength, frequency).
- Invasivity: extent of potential tissue damage (see Section 3.1.2.2).
- Required professional qualification of the user which can range from device-specific training to medical (or an equivalent level of) expertise.

The risk assessed on the basis of these criteria is classified as low, medium or high. Corresponding measures and/or recommendations are provided if the risk is medium or high.

This classification is also used to estimate the relevance of unquantifiable additional health risk criteria, particularly the kind of target person, scope, duration of application, and indications of possible long-term effects. A high exposure coupled with long-term application, for example, is associated with a higher health risk than a short-term application. The additional criteria should make it easier to assess applications comprehensively and in a more differentiated manner.

The three criteria – exposure, invasivity and required professional qualification of the user – form the basis for assessing the potential risk and for determining obligatory protective measures which need to be defined in a regulatory framework to an extent deemed proportionate to the risk. The additional criteria are more difficult to quantify and are only of secondary importance to the intended regulatory framework. Due to the broad range of devices and applications available, the following recommendations do not include every type of device and every kind of EMF used for applications in humans; instead, a list is provided which is by no means exhaustive.

With this in mind, the German Commission on Radiological Protection recommends the following when using EMF for non-medical applications:

- Applications with a potentially high health risk should be reserved for medical purposes, e. g. hyperthermia, thermoablation, electroporation-based therapies for cancer, cancer therapy with tumour-specific frequencies, tumour-treating fields (TTFields), magnetic resonance imaging (MRI), transcranial magnetic stimulation (TMS), neurostimulation of the central nervous system for pain and lipolysis.
- Applications with a potentially medium health risk, such as diathermy, transcutaneous electrical nerve stimulation (TENS), electrical muscle stimulation (EMS) and radiofrequency (RF) epilation, should be linked to qualification requirements (expertise) and limited to commercial use. These applications are contraindicated for persons with active implants.
- It is not advisable to use the above applications privately due to the inherent adverse health effects.
- Adverse health effects following frequent and/or prolonged applications should be systematically recorded and researched.

Table 8 in Section 3.3.2 provides a differentiated assessment of individual applications.

3 Scientific background

3.1 Evaluation concept and measures

The following concept developed by SSK serves to evaluate the EMF applications described here in terms of their possible health risks.

3.1.1 Evaluation basis

The basic restrictions for the general public recommended by the International Commission on Non-Ionizing Radiation Protection (ICNIRP) in its guidelines are used to assess the possible risks of EMF applications (described in Annex A-2).

The basic restrictions recommended by ICNIRP (ICNIRP 1998, ICNIRP 2009, ICNIRP 2010) are based on frequency-dependant thresholds for biological effects (nerve and muscle stimulation and/or electrically induced heat) at different frequencies which were gleaned from

extensive literature research and also evaluated by the ICNIRP for their health effects. Basic restrictions were set using this data and by applying reduction factors at different frequencies. Exposures can generally be declared safe by complying with these basic restrictions, in turn excluding any possible adverse health effects. Conversely, it is not possible to exclude adverse health effects as a result of exposures exceeding these basic restrictions. Applying reduction factors when setting basic restrictions helps to account for the highly varied sensitivity and tolerance of individuals, and to include any risk groups. The reduction factors are calculated in line with current scientific knowledge and in such a way that even highly sensitive individuals will not experience any biological effects from exposures remaining below the basic restrictions.

However, most of the devices covered in this recommendation need to exceed the ICNIRP basic restrictions to achieve their intended effect. Exposures fall in two categories:

a) Exposure exceeds the basic restrictions, but remains below the thresholds for biological effects, thus not representing a universal health risk to the general public. However, there may still be a health risk for highly sensitive individuals, e. g. persons with perturbed thermoregulation, older people, ill people, and children.

b) Exposure exceeds the thresholds for biological effects; hence it must be assumed there is a health risk to the general public.

Since the thresholds for effects can vary widely from individual to individual, a quantitative limit between the ranges specified in a) and b) can only be drawn in the order of magnitude.

These uncertainties make it extremely difficult to provide general recommendations on using EMF for applications in humans, particularly for non-medical applications. Also there is only a limited amount of evidence available for certain conceivable long-term effects:

– Limited experience is available for category b) from medical applications involving stimulation currents such as prolonged use of nerve stimulator implants. Tissue samples were taken from five deceased Parkinson's disease patients who received continuous stimulation from intracranial stimulation electrode implants for up to twelve years. So-called fibrous, gliotic changes and macrophages were present in the immediate vicinity of the electrodes along with a minimal reactive astrocyte and perivascular lymphocytic infiltration (De Vloo et al. 2018). Unlike transcranial stimulations lasting up to 30 minutes at a time, this method involves non-invasive stimulations at much higher localised intensities which last all day and are administered over the course of many years. As a result, electrically induced brain tissue damage is not anticipated for transcranial stimulations.

– MRI scans are performed so often that it leads to a large number of both healthy and ill people being scanned. The electromagnetic field exposures during MRI scans are covered by category a), sometimes even category b), and occur simultaneously as a result of extremely high fields in the static magnetic field, in the low-frequency magnetic field, and in the radiofrequency field. Despite the large number of people scanned, their generally good medical monitoring, and the EMF exposures typical of such scans, there have been no studies on the long-term effects on patients and test subjects. However, acute adverse effects, such as nausea, dizziness and a metallic taste in the mouth are reported (Heinrich et al. 2013). In addition, unfavourably chosen parameters may provoke localised exposure increases and, as a result, adverse temperature increases with higher tissue conductivity occurring, e. g. due to certain tattoo ink ingredients or conductive implant structures with pointed geometries (as is the case with metal bone nails or pacemaker electrodes).

There is a clear need for research on possible long-term effects, particularly as the experiences described above in the first hyphenated-list item indicate possible effects which are yet to be systematically investigated and reliably documented. Given the arguments repeatedly raised about possible long-term effects, such investigations are explicitly recommended. To date, long-term effects are not deemed as having been demonstrated, which is why the ICNIRP guidelines for limiting exposure are based on observing acute effects.

Particular attention should be paid to potential health risks for groups of people especially worthy of protection who exhibit low thresholds for acute biological effects and for whom there are certain indications of long-term effects, e. g. childhood leukaemia in connection with low-frequency magnetic fields as described in A-1.2.2).

Section 3.2 provides a list of medical and non-medical applications in humans involving EMF. The reason for including medical applications is that many of them are also used for non-medical purposes because there is no clear regulatory framework in place. The principal intended effects, level of evidence, and EMF exposures are provided for each application. The health risk for an application is then assessed by comparing the exposure with the basic restrictions as well as the proven risks and unintended effects. Where appropriate, the risks described in detail in Annex A-1 are also to be considered.

This assessment only refers to risks. It does not provide any risk-benefit assessments, although explicit reference is made to the need to conduct such analyses for certain applications.

This assessment is by no means exhaustive, but seeks to include as many different applications as possible along with their associated health risks, while also anticipating applications which may be developed in the future.

3.1.2 Health risk assessment criteria

3.1.2.1 EMF exposure

EMF exposure is the crucial criterion for the assessment of the health risk of human applications involving EMF (Table 1). It is also the only criterion which allows a quantitative assessment by comparing it with the ICNIRP basic restrictions and thresholds for acute effects, i.e. directly observable biological effects (see Section 3.1.1).

The ICNIRP basic restrictions define the exposure range deemed fundamentally safe. This is why product safety regulations (harmonised standards) based on the recommendation by the Council of the European Union (EC 1999) call for consumer products to be withheld from the market if they cause exposures exceeding the basic restrictions. However, this does not apply to medical devices, which is why special measures are needed when medical devices are used for non-medical applications, particularly if exposure exceeds the corresponding thresholds for effects. This may lead to an acute health risk, meaning that such products should only be used for non-medical applications as an exception, weighing up the risks against the benefits beforehand, and in line with corresponding restrictions.

Table 1: Health risk due to EMF exposure

Health risk	**Description**
High	EMF exposure exceeds the threshold for acute effects, possibly leading to an acute risk
Medium	EMF exposure is below the threshold for effects but exceeds the basic restrictions, possibly leading to an acute risk for sensitive groups of people (people with perturbed thermoregulation, older people, ill people, and children)
Low	EMF exposure is below the basic restrictions for proven effects and thus deemed safe

3.1.2.2 Invasivity

According to the EU regulation on medical devices (EU 2017), the term 'invasive device' means a device which, in whole or in part, penetrates inside the body, either through a body orifice (any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma) or through the surface of the body. In this recommendation, invasivity includes both the tissue damage which can occur when applying electrodes, and the damage caused by the application itself. Depending on the extent of the tissue damage it is classified as being medium or high. The criterion is not applicable if there is no invasivity as defined above (Table 2).

Except in medical care, invasive applications (such as electrode implantations and tissue removal) must only be performed as an exception and subject to appropriate training requirements (e. g. in cosmetics studios).

Table 2: Health risk due to the invasivity of an application

Health risk	**Description**
High	Invasive application such as surgically implantable electrodes and tissue removal
Medium	Minimally invasive application such as transdermal needle electrode placement or introduction of electrodes via body orifices
n/a	Criterion not applicable; non-invasive as defined above

n/a: not applicable

3.1.2.3 Required professional qualification

The level of professional qualification needed for applications in humans varies depending on the exposure, invasivity and several other factors linked to the health risk. By way of example, a highly invasive application requires medical or an equivalent level of expertise. EMF sources which may pose a health risk require device-specific training so the user is able to estimate and minimise exposure and its associated risks as accurately as possible. The higher the required qualification, the higher the health risk if the user does not hold the required qualification (Table 3).

Table 3: Health risk due to not holding the required qualification

Health risk	**Description**
High	The application must be performed by a licensed physician.
Medium	The application requires training in a healthcare profession related to the application along with device-specific and application-specific expertise.
Low	The application requires prior instruction.

3.1.2.4 Additional criterion: Uncertainties / duration of the application

The ICNIRP guidelines for limiting exposure are not linked to a defined exposure time (except for a 6-minute averaging time for the assessment of thermal SAR exposure). There is little substantiated scientific data available on potential long-term applications and repeated applications. Among other things, this is due to the difficulty of finding a method to conduct such studies as well as the pace at which new technologies are being developed. As a result, it is not possible to exclude unknown long-term effects both above and below the basic restrictions. The non-existence of such long-term effects cannot be proven purely on a logical basis, and there is very little evidence for their existence, in turn rendering the situation unproven from a scientific perspective. Naturally, assessments of the associated real or fictitious risk as a means of precaution differs for EMF applications depending on whether they are used in medical or non-medical applications. This is why prolonged non-medical exposures should be investigated for weak indications of possible long-term effects of EMF, e. g. childhood leukaemia or neurodegenerative diseases in adults stemming from low-frequency magnetic fields. Here, it should be noted that this involves indications rather than evidence, meaning that recommendations are of a precautionary nature (see, e. g., the WHO assessment and recommendations for childhood leukaemia in chapter 13 (WHO 2007)).

EMF used for non-medical applications in humans are associated with further uncertainties, e. g. due to improper use, particularly when it comes to applications involving medical devices. Medical applications are subject to strict requirements, e. g. clinical studies must be performed beforehand to demonstrate their effectiveness and to exclude or minimise adverse effects. Besides that, there is direct medical supervision with applications performed according to protocols defined in advance. There are no such measures in place for non-medical applications.

In view of the aforementioned uncertainties, it is difficult to quantify a risk, which is why relevance for the health risk assessment is only classified as being high, medium or low (Table 4). A high exposure coupled with long-term application, for example, is associated with a higher health risk than a short-term application. However, the duration of the application is generally negligible for a very low exposure.

Table 4: Relevance of the additional criterion 'uncertainties and duration of application' when assessing the health risk

Relevance for assessing the health risk	**Description**
High	Long-term application Indications of negative effects which may lead to a high health risk under certain circumstances.
Medium	Repeat application Indications of negative effects which may lead to a medium health risk under certain circumstances.
Low	Brief or single application No indications of negative effects or uncertainties which may lead to a health risk.

3.1.2.5 Additional criterion: Target persons and scope

The type of target person for an EMF application is not a direct criterion when assessing the health risk. It does, however, serve as an additional criterion which may enhance or alleviate the present risk. In addition, target persons define the protective aim of the measures and the implementation options.

The environment and modalities of an application define the scope as well as the options available to implement certain measures, e. g.:

- Commercial applications involving third parties – requirements possible at the time of application (mode of operation, training, reporting requirement).
- Private applications – only product-related measures possible (product information, operating instructions, limited market availability).
- Medical applications – no measures necessary.

Table 5: Relevance of the additional criterion 'target persons and scope' when assessing the health risk

Relevance for assessing the health risk	**Description**
High	Target persons: children Private application
Medium	Target persons: probands (e. g. in scientific studies involving high-field MRI Commercial application (can be supervised)
Low	Target persons: adults Medical application

3.1.2.6 Additional criterion: Indirect effects of EMF and technical questions regarding electromagnetic compatibility (EMC)

EMF can affect electronic medical devices such as pacemakers. This represents a health risk which must be taken into consideration (Table 6).

Table 6: Assessment of the health risk resulting from technical EMC

Risk	**Description**
High	A health risk from EMC has been demonstrated or is anticipated due to EMF exposure characteristics.
Medium	A health risk from EMC cannot be ruled out.
Low	No anticipated health risk from EMC.

3.1.3 Possible recommendations and measures

3.1.3.1 Prohibition and limitations

Applications of EMF in humans which fall under the highest risk category as per the three key criteria (exposure, invasivity, required professional qualification of the user) should be prohibited for non-medical purposes or only permitted as an exception and subject to stringent requirements, e. g. appropriate training and/or immediate supervision by a physician (see Sections 3.1.3.2 and 3.1.3.3). One such example is lipolysis.

Applications with a medium or, in exceptional cases, a high risk should only be performed by persons with proof of qualification, and respectively the corresponding EMF device may only be supplied to persons with proof of qualification. Treatment should only take place in a commercial environment which can be supervised, and should be subject to additional requirements (see Section 3.1.3.3). Such applications should be prohibited for private persons.

3.1.3.2 Requirements for commercial applications

EMF applications in humans with a medium or partially high risk based on the key criteria which, under certain circumstances, present a positive risk-benefit ratio, should be permitted

for commercial use subject to certain requirements so as to minimise the potential risk involved. Such requirements should be binding and supervised.

Commercial applications are performed in an environment which can be supervised and where it is possible to enforce certain requirements linked to commercial trading licences.

Possible requirements include:

- qualification
- operating and maintenance rules and requirements
- supervision of EMF devices
- a risk-benefit analysis
- information for customers
- reporting in case of an incident

3.1.3.3 Information

Information is always the first and foremost measure, be it a standalone measure or in tandem with other measures. Providing information can be a voluntary or mandatory measure. In any case, it should be tailored to the target group to ensure that those persons understand the information provided. Potential types of information include:

- Warnings, advice or instructions for consumer products.
- Dissemination of information from authorities or designated information centres regarding the current state of research in the field and the level of knowledge available about potential risks.
- Obligatory information to be provided to customers about the risks and adverse effects.
- Exchange of information between the various information centres and instances regarding problematic liaisons, e. g. when handling the topic of electromagnetic compatibility.

3.1.3.4 Qualification

User qualification is just as important as information when it comes to minimising the health risk involved in EMF applications in humans. This should be the decisive aspect of any requirement (see Section 3.1.3.3). Section 3.3.3 provides professional qualification requirements which should be met by users to ensure that such devices are used safely in humans.

3.1.3.5 Reporting an incident – vigilance

In a medical environment, the medical devices regulation (MPG 2002) requires incidents and unexpected events to be reported. Similar non-medical applications should also be subject to the same reporting requirement. A central reporting office for incidents makes a great deal of sense here, particularly as such applications are new and often introduced according to protocols which differ from those originally envisaged and tested.

3.1.3.6 Risk-benefit analysis for non-medical applications

A risk-benefit analysis should be performed for every EMF application in humans. This can be required specifically for commercial applications. Private persons should also be in a position to understand or carry out a risk-benefit analysis; hence it is important to provide information that is easy to understand.

3.1.3.7 Research, reporting and monitoring

EMF applications in humans are a relatively new field that is being researched intensively with new technologies being developed at pace. This is why it is extremely important to constantly monitor and report on these developments. It is also important to demand and subsidise research on the potential risks of such technologies.

3.1.3.8 Private applications, market supervision

Regulation by public authorities is not possible for private applications. In view of this, regulatory measures must have been performed before devices (consumer products or freely available medical devices) are manufactured or enter the market. Here, it should be noted that highly sensitive persons (persons with perturbed thermoregulation, older people and ill people) and children have access to and can use such products. Products with a high risk to health during use should come with corresponding warnings and instructions on how to use them safely. Protective equipment should be available where necessary. Restricting market availability is an option for products assumed to have a high or medium health risk.

Information or warnings about the risk of self-application should especially be provided with freely available and potentially hazardous medical devices known to be used for non-medical purposes.

Market supervision should help ensure that corresponding measures are taken to minimise health risks.

3.2 EMF applications in humans

3.2.1 Thermal methods

Radiofrequency electromagnetic fields of sufficient strength can heat tissue in a biologically effective manner, the physical mechanism being based on ohmic losses due to the tissue's alternating current conductivity. Biological effects are to be expected from a temperature increase of one kelvin at the latest. Depending on the application and frequency, the effects can range from heating an extremely localised area of a few millimetres to heating larger areas or even the entire body. Literature does not provide a clear distinction between the three methods described below, i. e. diathermy, hyperthermia and thermoablation, which is why the following descriptions of each term only include their respective main fields of application.

3.2.1.1 Diathermy

Diathermy is a form of physical therapy which uses strong radiofrequency EMF for localised tissue heating to aid circulation, muscle relaxation, etc. Its main benefit compared to infrared or red-light heat treatment is that it penetrates deeper, with the level of tissue penetration depending largely on the skin-effect and hence on frequency. Devices either use electrodes placed on the skin or antennas. Typical output power lies in the range of 100 W to 200 W, with frequencies ranging from 100 kHz to several GHz. Devices designed for internal electrosurgical procedures use electrodes which are applied to perform sclerotherapy, tissue ablation, and to destroy tumour tissue. Some of these devices are known as diathermy devices, but should rather be classified as thermoablation devices due to the method involved.

Classification of exposure

The electromagnetic fields and specific absorption rates (SAR values) involved in diathermy exceed the thresholds for effect.

3.2.1.2 Hyperthermia

In tumour treatment hyperthermia seeks to increase the body temperature to a sufficient level, i. e to overheat tissue against the body's heat-regulation system.

Hyperthermia is mainly used in combination with radiotherapy, and sometimes with chemotherapy (Datta et al. 2015).

The mechanisms underlying hyperthermia with EMF have been the subject of intense research since the 1970s. According to the current level of knowledge, the following mechanisms are involved, individually or combined:

- cell protein denaturation due to heat,
- increase in perfusion: hyperthermia leads to improved circulation and thus improved oxygen supply to the tumour, in turn enhancing the therapeutic effect of radiotherapy,
- repair process impairment: protein denaturation is assumed to impair DNA repair mechanisms. DNA damage caused by radiation cannot be repaired, and
- heat shock protein generation to activate the body's own immune system.

The aim is to achieve the desired temperature (typically 43 °C in 90 % of the tumour tissue) and to maintain this temperature during treatment (typically one hour) while minimising the effects to the surrounding healthy tissue. Frequencies of 100 MHz to 2.5 GHz are used depending on the type of tumour and its depth within the body. Multiple antennas are placed in different positions around the tumour to focus the electromagnetic fields on the tumour tissue. With some deep tumours, and when treating larger areas where extremely strong EMF are used (over 1,000 W, SAR values of 60 W/kg in the tumour), this treatment is performed in an MRI scanner under constant surveillance and temperature monitoring. Magnetic resonance imaging (MRI) can use specific sequences to spatially resolve the temperature measurement. This is already performed in clinical applications to monitor focused ultrasound therapy.

Classification of exposure

The electromagnetic fields and specific absorption rates (SAR values) involved in hyperthermia exceed the thresholds for effect by far.

3.2.1.3 Thermoablation

Thermoablation and radiofrequency ablation (the latter is also known as electrocautery, and both are sometimes classified as diathermy) are both extreme forms of hyperthermia and always used to damage cells directly and subsequently induce cell necrosis. Cell structures to be coagulated and/or reduced are targeted and heated to over 60° C, leading to irreversible protein denaturation and coagulative necrosis. Thermoablation is suitable, e. g. for reducing atrium pacemaker cells in the event of cardiac arrhythmias, or it can be used for general treatment of tumours up to 3 cm or 4 cm in size, e. g. kidney, lung and liver tumours.

The cells are generally heated by EMF at frequencies of 400 kHz to 460 kHz (radiofrequency ablation) or 0.9 GHz to 2.5 GHz (microwave ablation). The extremely small electrodes or antennas are placed on or, in the case of minimally invasive procedures, in the tissue to be treated.

Classification of exposure

At present, only the medical field uses the term thermoablation to describe the above mentioned applications. However, it cannot be ruled out that the method could be advertised by the cosmetics industry in the future. Some detailed descriptions for electrolipolysis allude to thermoablation, also in combination with other procedures such as laser treatments. The electromagnetic fields and specific absorption rates (SAR values) involved exceed the thresholds for effect by far.

3.2.2 Electroporation-based therapies for cancer

Electroporation-based therapies use the effects that sufficiently strong electric fields have on cell membrane permeability. The temporary opening of cell membrane pores makes it easier for chemotherapy and gene therapy drugs to penetrate and destroy the cells. Extremely strong fields lead directly to cell death.

At present, there are four electroporation-based therapies for cancer which are at different stages of research and application:

- electrochemotherapy (ECT)
- electrogene therapy (EGT)
- irreversible electroporation (IRE) and
- electroporation using nanosecond pulsed electric fields (nsPEFs)

3.2.2.1 Electrochemotherapy (ECT)

Two projects (Marty et al. 2006, Colombo et al. 2008) conducted within the scope of the fifth and sixth EU Framework Programmes for Research and Technological Development were responsible for the majority of ECT's development and subsequent breakthrough. These projects led to the development of the Cliniporator® medical device and a standardised, optimised application protocol. To date it has been used to successfully treat more than 4,000 patients with cutaneous and subcutaneous tumours. ECT is typically performed with non-permeable or low-permeable chemotherapeutic drugs such as Bleomycin and Cisplatin. Numerous clinical studies have shown that ECT has an average response rate of 80 % for full tumour destruction of cutaneous and subcutaneous tumours, compared to 30 % when performing chemotherapy on its own (Marty et al. 2006).

ECT uses monopolar, direct current, with short and intense electric pulses. The protocol prescribes applications involving square-shaped pulses with a pulse width of 100 µs and a frequency of 1 Hz to 5,000 Hz. Normally, treatments are performed with eight pulses applied via needle or plate electrodes with electric fields of 400 V/cm generated between the electrode pairs. Needle electrodes are arranged in a linear fashion when treating small lesions, while hexagons are suggested for larger tumours and metastases.

3.2.2.2 Electrogene therapy (EGT)

EGT is nowhere near as well developed as ECT. It aims at creating conditions under which systemically administered DNA in the form of plasmids or vectors are ideally absorbed by the tumour cells, not the normal tissue. There are only a few clinical studies available on this as the response mechanisms have not yet been fully understood (Calvet and Mir 2016), e. g. how large molecules such as (plasmid) DNA can diffuse through the relatively small membrane pores. 61 of the clinical gene therapy studies carried out in 2016 involved EGT.

The same EMF are used for both ECT and EGT, although they differ significantly in terms of pulse shape and duration depending on whether ECT or EGT is being performed. EGT uses combinations of short (intense) and long (less intense) pulses as prescribed by a common protocol (André et al. 2008), while ECT uses a pulse duration of 100 µs which leads to transient permeabilisation of the tumour cell membranes. The latter pulses are several hundred milliseconds long and, as with electrophoresis, guide the DNA to the cells opened by way of electroporation, in turn enabling gene expression of the DNA in the tumour cell.

3.2.2.3 Irreversible electroporation (IRE)

IRE uses stronger EMF than ECT or EGT which lead to irreversible pore formation and increased permeability of the cell membranes. As a result of this, an overdose of calcium ions passes from the extracellular space to the inner cell, in turn destroying their homeostasis. An acute lack of energy then leads to tumour tissue death. IRE does not involve the injection of chemotherapy or gene therapy drugs into the tumour tissue, thus making it a form of tumour ablation or specific tumour tissue necrosis. IRE has several benefits over thermoablation: e. g. IRS is a non-thermal method, meaning that it can also be used close to heat-sensitive blood vessels.

When performing IRE, EMF of up to 3,000 V and 50 A are generated between two electrodes at a distance of 0.5 cm to 5 cm from one another. Treatment requires 70 to 90 pulses ranging from 90 µs to 100 µs. Due to the strong EMF involved, IRE is generally performed under general anaesthesia with complete muscle relaxation and synchronized with the cardiac refractory period.

3.2.2.4 Nanosecond pulsed electric fields (nsPEFs)

nsPEF is the latest form of electroporation-based therapy. Tumour ablation is performed using extra-strong and ultrashort pulsed EMF (approx. 3,000 kV/m to 4,000 kV/m with a frequency of 2 Hz and a pulse duration of 100 ns). A single treatment lasting one minute (100 pulses) is sufficient for a full tumour ablation. nsPEF is still at an experimental stage, although a large number of the preclinical in vivo and in vitro studies and individual pilot studies on humans (Beebe et al. 2018, Breton and Mir 2011, Vadlamani et al. 2019) present very good results so far. They show that nsPEF not only leads to cell death, but, much like EGT, also initiates a systemic immune response. The mechanisms involved have not been sufficiently examined, but experiments to date indicate electrodynamic effects as a result of electrically charging parts of the cell structures.

Classification of exposure

Exposures from electroporation-based therapies for cancer exceed the thresholds for effects by far.

3.2.3 Other EMF-based cancer therapies

Over the last ten years, a number of publications have appeared with regard to EMF inhibiting metastatic spread (see below). Clinical studies were primarily conducted on two applications:

3.2.3.1 Tumour-treating fields (TTFields) (working group involving Eilon Yoram Palti, Israel)

TTFields are used to treat brain tumours by applying electric fields at medium frequencies (100 kHz to 300 kHz) via two pairs or electrodes attached to the patient's skin, the localization of the tumour being essential for the placement of the electrodes. Electric field strengths of 100 V/m to 300 V/m are applied to the skin, leading to electric field strengths exceeding

150 V/m and SAR values of more than 7.5 W/kg in the target areas in the brain (Lok et al. 2017). Electric field strengths in the tumour exceed the therapeutic threshold of 100 V/m (up to 220 V/m) (Wenger et al. 2015). The skin temperature remains below 41° C (Lok et al. 2015). Treatment is administered continually (18 hours per day) using a portable TTFields system operating at 200 kHz and producing a maximum voltage of between + 50 V and -50 V. The system holds FDA approval as a medical device for treating cancer with EMF (Swanson et al. 2016).

The TTFields system has been used in several clinical studies, primarily for patients presenting with glioblastoma tumours. The largest of these studies was a randomised clinical phase III study with around 1,000 patients (Stupp et al. 2012). The only unwanted effect observed were small skin irritations beneath the attached electrodes. The study reported mitotic impairment and influence on the immune system as response mechanisms (Swanson et al. 2016). Clinical studies on other types of tumour are still ongoing (Burri et al. 2018, Mun et al. 2018).

3.2.3.2 Tumour-specific frequencies (working group involving Boris Pasche, USA)

Tumour-specific frequencies are used to treat cancer. Fields with a carrier frequency of 27.12 MHz are modulated at frequencies of 100 Hz to 21 kHz, the modulating frequencies being determined by the specific responses of the patient's cancer cells (Barbault et al. 2009). Frequencies higher than 1 kHz are typically used here. Patient treatments involve a spoon-like tongue electrode used at home for up to one hour at a time and up to three times per day. The electrode imparts amplitude-modulated fields (AM-EMF) at several tumour-specific frequencies, with only a few side effects observed, such as drowsiness and mucosal inflammation (Zimmerman et al. 2013). The whole-body SAR is 0.2 mW/kg to 1 mW/kg with a peak SAR of 0.15 mW/kg to 0.35 W/kg (Jimenez et al. 2018).

Classification of exposure

Both applications are used in cancer therapy, but clinical phase III studies have only been completed for TTFields on glioblastoma patients. These studies did not ascertain any negative health effects. TTFields cause electric field strengths of 100 V/m to 300 V/m in the body. The ICNIRP basic restriction for this frequency range depends on the frequency and is between 13.5 V/m and 40 V/m, meaning that it is exceeded by a factor of around 10. As a reduction factor of 10 was used to derive the basic restriction (for peripheral nerve stimulation), the electric field strengths must be around the level of the threshold for effect. Correspondingly, the SAR value here is 7.5 W/kg, which exceeds the threshold for effect at 4 W/kg.

The tumour-specific frequencies reach SAR values below the basic restriction of 2 W/kg. The effectiveness of this treatment is yet to be proven unequivocally.

3.2.4 Magnetic resonance imaging (MRI)

Magnetic resonance imaging (MRI) is an imaging procedure which is particularly well suited to imaging soft tissues and organs. It is a commonly used procedure for cross-sectional imaging of the body with a high soft-tissue contrast. Physicians can use these images to assess organ structures and apply suitable sequences to evaluate functional parameters such as circulation or diffusion. MRI scans of the entire body are known as whole-body MRIs, although MRIs are generally only used to image individual parts of the body.

MRI scans expose both the patient and, particularly with interventional procedures, staff to electromagnetic fields. There are three types of electromagnetic fields:

- a static magnetic field for spin orientation,

- switched magnetic gradient fields for spatial coding (moderate speed, in the low frequency range) and
- pulsed radiofrequency field for spin excitation.

The static magnetic field of clinical MRIs typically uses field strengths of 1.5 T to 3.0 T, although more recent scanners also use field strengths of up to 7.0 T. At present, there is a trend towards higher static magnetic fields with the aim of improving the signal-to-noise ratio, in turn providing more detailed information. MRIs used for research purposes currently use scanners with field strengths of 7.0 T to 10.5 T. The first devices for humans using field strengths of 11.7 T are due to be rolled out in 2019. MRIs used in animal studies currently emit field strengths of up to 21.1 T.

Here, it is important that the excitation frequencies used to initiate spin are proportional to the strength of the static magnetic field, and that wavelength λ in human tissue is reduced correspondingly at higher field strengths.

As the frequency increases, the energy absorbed from the radiofrequency field also rises, leading to an increase in heat input, which is reflected in the SAR value. This is why permissible SAR limits (see below) are reached earlier at higher static field strengths and also why SAR limits may be exceeded due to inhomogeneity in the SAR distribution, with the resulting excessive temperature possibly causing excessive thermal loading of the body or (local) tissue damage (Quick 2010). The gradients may lead to burns from the induced currents, especially at the edge of the field and if loops arise due to skin-to-skin contact. Staff are trained to avoid this when positioning patients, and it also forms part of the manufacturer's safety operating instructions and induction.

High-field MRIs may cause short term physiological effects. By way of example, several users or subjects in studies using field strengths of 7 T to 9.4 T reported feeling dizzy and nauseous, seeing flashes of light (magnetophosphenes), and/or experiencing a metallic taste in the mouth. These effects are deemed harmless and cease to occur when the person leaves the magnetic field or when movement within the magnetic field halts (Kangarlu et al. 2004, Mühlenweg et al. 2008, Theysohn et al. 2008, Heilmaier et al. 2011, Rauschenberg et al. 2014). Such phenomena without any loss in perception have also been observed in recent studies involving field strengths of 1.5 T to 7.0 T (Heinrich et al. 2013).

The maximum permissible values for the different fields are laid down in the Recommendations by the U.S. Food and Drug Administration (FDA 2014), the International Electrotechnical Commission (IEC 2015), the SSK (SSK 2002) and the International Commission on Non-Ionizing Radiation Protection (ICNIRP 2009).

The following applies to time-varying magnetic gradient fields:

The main aspect to consider here are adverse effects on the conduction system. The recommended values have been selected such that in normal operating mode, the gradient system shall operate at a level that does not exceed 80 % of the directly determined mean threshold for peripheral nerve stimulation (PNS), where the threshold for PNS is determined as the onset of sensation. In first level controlled operating mode, the gradient system shall operate at a level that does not exceed 100 % of the directly determined mean threshold for PNS. In general, the cardiac muscle stimulation threshold is at least one order of magnitude greater than that of PNS, and the limits in normal and first level controlled operation mode have been selected so as to always avoid cardiac stimulation (induction of an ectopic heartbeat or cardiac arrhythmia). Sensitive or motor neurostimulation is also not uncommon, and can lead to unpleasant sensations or rhythmic limb twitching.

The following applies to radiofrequency fields used to initiate spin:

The main aspect to consider here is the thermal effect on the whole body and the local thermal effect on individual organs/tissues. Basic restrictions are provided both for the maximum increase in core body temperature and for maximum local tissue temperatures. For this reason, the U.S. Food and Drug Administration (FDA 2014), the International Electrotechnical Commission (IEC 2015) and the International Commission on Non-Ionizing Radiation Protection (ICNIRP 2004) have stipulated SAR limits ([W/kg]) which may also be exceeded when complying with the stated maximum temperatures and under controlled conditions.

Classification of exposure

The electromagnetic fields, particularly those in MRI environments with limited access, often exceed the ICNIRP basic restrictions and sometimes reach or exceed thresholds for effect. To date, there have not been any reported cases of irreversible, i. e. cumulative, effects resulting from repeated applications when complying with the recommended restrictions.

3.2.5 Transcranial magnetic stimulation (TMS)

Neurons can be excited by applying electric stimulation to the outer scalp. Two immediate effects can be observed: stimulation of the cerebral cortex induces muscle twitching, while stimulation of the visual cortex leads to short flashes of light (phosphenes). High current flow gradients (transcranial electrical stimulation – TES) are required to generate these phenomena (Merton and Morton 1980). Direct above threshold stimulation of the skin's pain receptors makes this application very painful for the recipient. Five years after the introduction of TES, Transcranial magnetic stimulation (TMS), which is painless, was introduced in 1985 (Barker et al. 1985).

TMS is based on Faraday's principle of electromagnetic induction. Magnetic stimulation is used to transport the current pulse through the skin and skullcap without any pain, with the artificial change of potential in a neuron causing its discharge.

A current of ~8,000 A for 100 µs to 200 µs is needed to induce muscle twitching or phosphenes, with the coil's magnetic flux density peaking at around 2.5 T. TMS is a standard procedure in clinical neurophysiology and used to determine the so-called central motor conduction time. Stimulation is generally followed by a silent period, which is also known as a virtual lesion and is particularly common with repetitive transcranial magnetic stimulation (rTMS). As well as being used for patient therapy, rTMS is also known for its applications in cognitive neuroscience (Rossini et al. 2015).

There are a number of different devices produced by different manufacturers. By way of example, TMS reaches the following values:

- peak magnetic induction → up to around 3.5 T
- frequency → up to 100 Hz
- pulse width → biphasic up to approx. 400 µs

At least 15,000 publications about TMS have been released since 1985.

rTMS can also be used for therapeutic applications. Low rTMS frequencies of < 1 Hz can create a silent period, e. g. in epilepsy patients, while higher frequencies > 5 Hz lead to stimulation, as is the case with strokes, for example (an overview is available in (Rossini et al. 2015)). Since 2007, the main focus has been on applications where patients undergoing treatment for depression receive 3,000 pulses per session at a frequency of 10 Hz for a period of four weeks (O'Reardon et al. 2007). This procedure was first approved in the U.S. and is refinanced there by health insurance companies. rTMS is also covered by health insurance companies in

Germany as a form of outpatient treatment for patients with depression, and is listed under OPS code 8-632 (Operation and Procedure Classification System – OPS). In many cases, this avoids the need to perform electroconvulsive therapy. As is the case with drug therapies, not every patient responds to this form of treatment and the failure rate is 40 %. The simple assumption of 'the higher the dose, the higher the effect' has not borne out (Gamboa et al. 2010). The optimisation of doses, stimulation intervals and co-application of psychotropic drugs and psychotherapy are currently being investigated. Therapy may also fail because TMS can only generate tangential rather than radial currents in the brain (cortical column cosine (C3) model of TMS efficacy) (Seo et al. 2016)), leading to stimulation of the surface of the gyri.

Recently developed devices have an extended parameter range, currently up to 1 kHz at very low intensities (Peterchev et al. 2014). rTMS is considered a safe application provided limits for certain parameters are complied with. If exceeded, they can trigger epileptic seizures (Hellwag and Jacobi 1802). These limits may be intentionally exceeded, but only under general anaesthesia, to induce therapeutic seizures (magnetic seizure therapy alongside electroconvulsive therapy for patients with severe depression) using devices around four times more powerful which are designed specifically for psychiatric clinics. Tissue heating of the brain by a single-pulse TMS is very small and is estimated to be definitely less than 0.1 °C, particularly as the brain's high circulatory rate provides for swift removal of any generated heat (Rossi et al. 2009). The International Federation of Clinical Neurophysiology is planning an update of the Rossi guideline 'Safety, ethical considerations, and application guidelines for the use of transcranial magnetic stimulation in clinical practice and research' in 2019 (Rossi et al. 2009). At present, there are no major new aspects to take into account.

Classification of exposure

The electromagnetic fields exceed the ICNIRP basic restrictions and sometimes reach or exceed the thresholds for effect to produce the intended therapeutic effect. To date, there have not been any studies on the possible adverse effects of a long-term application on healthy subjects.

3.2.6 Neurostimulation in the treatment of pain

Pain perception is a biological phenomenon which must be generated by the brain within what is known as a pain network that also includes various areas of the brain and the spinal cord. Depending on the targeted area (motor cortex, thalamus, spinal cord, etc.), there are a series of invasive and non-invasive stimulation options to reduce pain perception. The benefit of invasive, implanted devices is the option to deliver continuous, permanent stimulation, whereas transcranial or transcutaneous spinal procedures are typically limited to application periods of around 30 minutes. As a result, non-invasive procedures rely on generating after-effects which continue once stimulation is halted. Nevertheless, transcranial stimulation procedures to reduce pain following treatment for depression are associated with the second-best evidence level (Lefaucheur et al. 2014, Lefaucheur et al. 2017). Here, a number of different invasive and non-invasive stimulation procedures are used. The main procedure in use is deep brain stimulation where frequencies of 130 Hz are applied 24 hours per day. The electric pulsed permanent fields reach a local maximum of 30 $\mu C/cm^2$. Weak transcranial electrical stimulation (see below) with a maximum current of 4 mA has an amplitude around ten times lower, with stimulation generally not lasting longer than 30 minutes per day. Epidural spinal cord stimulation is also a neuromodulatory, reversible intervention procedure for patients with chronic pain that is resistant to therapy. This pain may be neuropathic (i. e. the pain arises directly in peripheral nerves, e. g. after injuring or compressing a nerve) or non-neuropathic and the result of stimulating pain receptors in the tissue, e. g. the skin. The third cause is a lesion or illness, generally in the pain network of the central nervous system, e. g. the thalamus. This is also known as central pain syndrome.

In general, this is treated by way of neurosurgical interventions with a tiered approach. The first step is to implant electrodes with connections outside of the body and then providing external stimulation for up to two weeks. If the pain does not subside, the electrodes can be removed again. If a clear improvement is observed, a stimulator is then implanted, e. g. below the collarbone (Antal et al. 2017a, Antal et al. 2017b). The initial spinal cord stimulation (SCS) operates at frequencies of around 40 Hz to 70 Hz. More recent high-frequency SCS uses frequencies of around 10 kHz. This form of treatment is considered to be more efficient and avoids paraesthesia (Kapural et al. 2016). It involves the use of 30 µsec pulses at an intensity adapted to suit the patient.

The S3 Guideline from July 2013 by the Association of the Scientific Medical Societies in Germany (AWMF 2013) provides the following indications: complex regional pain syndrome, failed back surgery syndrome, therapy-refractory angina pectoris and occlusive peripheral arterial disease, generally with the remark ‘recommendation open’.

Spinal cord stimulation can also be performed non-invasively with weak effects, e. g. using direct-current stimulation (Priori et al. 2014). Cyclical 30 Hz stimulation is used for paraplegic patients to enhance robotic-controlled, reflex locomotor activity (Minassian et al. 2016). The maximum current used here was 170 mA. The electrodes were placed below the waist where paralysed patients no longer feel pain. In normal study subjects, the tolerable pain threshold was around 25 mA.

Classification of exposure

The electromagnetic fields exceed the ICNIRP basic restrictions and sometimes reach or exceed the thresholdsof effect to produce the intended therapeutic effect. Due to their invasivity (risk of injury, infection, etc.), invasive applications are associated with a higher health risk than non-invasive, transcutaneous applications.

3.2.7 Bioresonance

Bioresonance involves the use of electrodes to measure the body’s own electrical activity and then use electrodes to intensify and invert signals returned to the body (‘negative feedback’). Bioresonance therapy is a form of alternative medicine that has not been scientifically proven to be effective.

Classification of exposure

The intensities/currents of the signals fed back to the body are well below the basic restrictions.

3.2.8 Neuroresonance / Biofeedback

Biofeedback is a mind-body technique used for a multitude of psychosomatic complaints. Here, patients receive feedback about physical states and changes which are normally (barely) imperceptible. This is designed to enhance self-efficacy in people suffering from depression, fear or pain. As a form of biofeedback, neurofeedback is an instrument-based behavioural therapy. With biofeedback, patients learn and train self-regulation of brain activity.

Classification of exposure

Biofeedback does not typically involve EMF exposure.

3.2.9 Applications involving low-frequency pulsed EMF (PEMF)

The use of non-invasive magnetic fields, or magnetic field therapy, is a form of alternative medicine where patients are exposed to a low-frequency, pulsed electromagnetic field (PEMF). Here, the magnetic field is generated using a mat filled with coils. The person undergoing

treatment either lies down directly on the mat, or the mat is placed under the mattress of a bed during the application. Different applications may last between 15 minutes and several hours.

The coil arrangement used in magnetic field mats and the magnetic field characteristics vary from manufacturer to manufacturer. In general, several different applications are available for each symptom or complaint, each varying in terms of magnetic field strength, signal type, frequency and duration of application.

Manufacturers recommend magnetic field mats to treat a wide range of conditions such as osteoarthritis, rheumatism, headaches, asthma or osteoporosis, and to enhance overall well-being. Magnetic field mats are sold or rented out both for use at home and under medical or therapeutic supervision. Correspondingly, they are declared a medical device or 'consumer product' when they enter the market.

A number of studies were conducted to provide evidence of the therapeutic effects of magnetic field mats, as is required for a medical device to receive a declaration of conformity, but the studies were of poor quality. The only systematic literature review on the therapeutic effects of magnetic field mats was conducted by the Swiss Tropical and Public Health Institute (TPH) on behalf of the Federal Office of Public Health (FOPH) (Hug and Röösli 2012). Only twelve randomised double-blind trials out of a total of 155 publications on pulsed electromagnetic fields used for therapeutic purposes published up until 2011 met the required quality criteria and were subsequently reviewed. The publications focused on a broad range of different symptoms: osteoarthritis of the knee or the cervical spine, fibromyalgia, pain perception, skin ulcer healing, multiple sclerosis-related fatigue, or heart rate variability and well-being. The application protocols and follow-up were also handled very differently. Some studies reported an improvement in symptoms, while others did not see any difference at all when compared with the control groups. Taken together, these studies do not provide any consistent and convincing evidence of the benefit and efficacy of magnetic field mats. Although none of the studies reported any acutely adverse effects when using magnetic field mats, not one of them was aimed specifically at investigating any possible adverse effects or adverse long-term effects.

Two more recent studies of high quality deliver the same inconsistent results. In one of the more recent randomised, double-blind studies published in 2018, 70 subjects were used to determine the influence of a magnetic field application (2.05 Hz, 25.3 μT) on acute ischaemic muscle pain. The magnetic fields had no specific effect on acute ischaemic muscle pain, while the contribution of the placebo effect was considerable (Szemerszky et al. 2018). A separate phase II pilot study published in 2015 on the use of magnetic fields (4 Hz to 12 Hz) involving 20 patients with chemotherapy-induced polyneuropathy saw a significant reduction in pain in both hands and in the feet (Geiger et al. 2015).

As an individual magnetic field application takes a relatively long time (up to several hours) and is repeated many times over prolonged periods, a risk-benefit analysis should also include any possible long-term effects.

There are only two studies available on the long-term effects of magnetic field applications, both of which were conducted by the Women's Health Initiative (WHI) in the U.S. These large-scale cross-sectional studies involved postmenopausal women whose cardiovascular diseases, cancer and osteoporosis were investigated in connection with a number of different influencing factors, including the use of magnetic field mats. The study conducted by Abel et al. in 2007 involved 90,000 women and showed a significant, 36 % higher prevalence of endometrial cancer in women who used magnetic field mats for 20 years or more (Abel et al. 2007). Other studies from 2015 involving the same population did not find any link between the use of magnetic field mats and the prevalence of thyroid cancer (Kato et al. 2015). These cross-

sectional studies were unable to determine the exact exposure and dose-response relationship, meaning that only a limited validity can be attached to them.

The Swiss Federal Office of Public Health (FOPH) commissioned the Zurich University of Applied Sciences to measure the magnetic fields of three magnetic field mats available on the Swiss market (Jaermann et al. 2011).

The main frequencies measured were as follows: 3.8 Hz, 15 Hz and 210 Hz for the first mat, 32 Hz, 210 Hz and 1,667 Hz for the second mat, and 3 Hz, 24 Hz and 238 Hz for the third mat. The signals measured in all of the magnetic field mats exhibited a triangle wave. The various programmes offered by each mat differ in terms of how each signal is emitted over time, their amplitude, the number of signal peaks, and the frequency at which individual signal packets are repeated.

The magnetic field strengths were measured at a distance of 1.5 cm, 10 cm and 30 cm from the mat, with the highest level of intensity activated. The mean magnetic field strength averaged over the surface at a distance of 1.5 cm was 94 µT, 47 µT and 17 µT for each mat respectively, while the maximum magnetic field strength amounted to 461 µT, 170 µT and 133 µT respectively.

As the maximum magnetic field strengths for all three mats were relatively high compared to the reference levels (in one case they were exceeded), an additional study was carried out by the IT'IS Foundation in Zurich on behalf of the Swiss Federal Office of Public Health (FOPH) to determine whether the magnetic fields emitted by the three mats exceeded the basic restrictions. To this end, the electric currents induced in the bodies of adults of varying sizes and in the bodies of children were numerically simulated in both the peripheral nervous system (PNS) and the central nervous system (CNS). The results of the computer simulation showed that with all three magnetic field mats and all of the model persons, the basic restrictions for body currents in the peripheral nervous system were generally reached or exceeded. Focusing on the central nervous system, the basic restrictions were only exceeded by one of the magnetic field mats (De Santis et al. 2015).

Classification of exposure

Studies published on magnetic field mats do not provide any convincing evidence of their benefit and efficacy, despite there being a few individual studies indicating the contrary. No negative acute effects were observed during the studies. This was not to be expected, since the magnetic flux density remained below the threshold for muscle and nerve stimulation, despite it exceeding the ICNIRP basic restrictions at times. Nevertheless, there are indications that long-term applications involving PEMF do increase the cancer risk (Abel et al. 2007, Kleinerman et al. 2005). Here, it should be noted that exposure from PEMF applications is a number of times higher than 0.4 µT, i. e. the level at which epidemiological studies found the risk of childhood leukaemia to double.

3.2.10 Peripheral nerve stimulation

3.2.10.1 Electrical muscle stimulation (EMS)

The term electrical muscle stimulation (EMS) requires clarification. The excitation threshold for motor nerves is an order of magnitude lower than direct muscle stimulation. Therefore, when electrodes are attached directly above the muscle the terminal branch of the nerve is excited first, hen the nerve effects muscle contraction via the motor synapse. Direct muscle stimulation without any accompanying nerve stimulation can only be achieved by using a much higher current involving local stimulation with needle electrodes or full nerve severing. Motor nerve stimulation is a standard procedure in clinical neurophysiological diagnostics and used,

e. g. to quantify the slowdown in nerve conduction velocity for what is known as polyneuropathies. The standard values are > 50 m/s for the arms and > 40 m/s for the legs.

Electrical muscle stimulation is used for fitness purposes and in cosmetics (myolifting). Instead of going running three times per week or training hard at the gym, electrical muscle stimulation causes muscles to contract without any deliberate movement on the part of the person being stimulated. This can promote muscle growth and increase muscle mass (Albrecht 2018). Conversely, EMS can be used, particularly by athletes, e. g. after suffering a fracture and limb immobilisation, to minimise temporary muscle atrophy.

The electrical stimulation principle initially appears to line up precisely with the process behind deliberate contraction as the stimulator sends an electrical pulse to the nerve fibres, in turn simulating deliberate muscle excitation. In other words: the muscle cannot distinguish between the instructions coming from the brain and those from the stimulator. The parameters available with the various programmes (number of pulses per second, duration of contraction, duration of rest phase, total programme duration) provide the muscles with different types of exertion. Muscles have slow, intermediate and fast fibres, depending on their contraction speed. Sprinters have an abundance of fast fibres, while marathon runners tend to have more slow fibres. Knowledge of human physiology and mastery of the programmes' stimulation parameters enable EMS protocols to be accurately tailored to the intended goal, i. e. building fast or slow muscle fibres.

How does this differ from regular physical training? EMS is of course no substitute for cardiovascular training. EMS is no guarantee for physiological muscle growth. The spinal cord manages muscle excitation in an extremely intelligent manner (Henneman's size principle). An action potential in the motor nerve generates a muscle fibre twitch lasting 100 ms to 200 ms. The motor neurons only start to fire at discharge frequencies of approx. 6 Hz to 8 Hz so as to produce a somewhat constant muscle contraction. An electrical stimulator can replicate this physiological stimulus by first recruiting physiologically small units, followed by larger units. These units then rotate and take over from one another, enabling them to take short breaks. Fast and slow muscle fibres take over, depending on the given task. EMS does not offer such targeted, selective and asynchronous excitation. This lack of precision control is also the main problem when it comes to neurorehabilitation, e. g. if central lesions following paraplegia are to be bypassed by electrically stimulating the muscle. This can sometimes be achieved by implanting ring electrodes which bypass the nerve and enable segmental multi-electrode stimulation.

Acute muscular hypertrophy can trigger structural muscle damage. The light form of this is known as muscle soreness, while the most severe form is known as rhabdomyolysis. Electrical muscle stimulation can force muscle contractions to occur at a level that is not possible at will. This therefore makes structural muscle damage more likely than with normal training. In fact, a 29 % reduction in power was demonstrated following electrical stimulation with 10 Hz dual pulses, with the reduction improving to 19 % on the fourth day after stimulation. 100 Hz stimulation also led to a loss in power, albeit to a lesser extent (Fouré et al. 2014). Muscle damage after electrical stimulation could be localized with magnetic resonance imaging on the second and fourth day after stimulation, both on the surface and in the deep muscle (Fatehi et al. 2017). Muscle biopsies showed an infiltration of macrophages, i. e. a disruption of the z-line, as well as modified desmin staining.

Muscular hypertrophy leads to an increase in the muscle enzyme creatine kinase (CK), which is eliminated by renal excretion. If CK values are too high, the renal tubules may become 'blocked' and, in a worst-case scenario, cause kidney failure. A retention parameter, creatine is the most common laboratory value used to assess renal function. According to the international

clinical practice guidelines for acute kidney injury (AKI), a three-fold creatine increase over initial values is sufficient for classification in the third and most severe stage (Khwaja 2012). After completing a marathon, four out of five runners meet the criteria for AKI stage 1 (Mansour et al. 2017). Their median creatine values increased from 0.81 mg/dL to 1.28 mg/dL one day post-marathon, with the CK increasing from 85 IU/L to 722 IU/L two days post-marathon. When using electrical muscle stimulation on both thighs, the median CK value increased from 171 IU/L to 12,460 IU/L on the fourth day after stimulation (Fouré et al. 2014). This increase may even be higher for whole-body stimulation, which is fairly common nowadays. Rhabdomyolysis and acute kidney injury were already described above. The CK increases decline significantly following multiple whole-body electrical muscle stimulation sessions, with the initial value of (28,545 ± 33,611 IU/L) measured after the first session decreasing 117 times to just 906 ± 500 IU/L after 10 weekly sessions (Kemmler et al. 2015). This means that long-term kidney damage is possible, particularly in the event of prolonged use. To date, there has been no systematic scientific study of these and other long-term effects of EMS on healthy people.

Classification of exposure

The electromagnetic fields exceed the ICNIRP basic restrictions and sometimes reach or exceed the thresholds for effect to produce the intended therapeutic effect. To date, there have not been any studies on the possible adverse effects of a long-term application on healthy subjects. Particularly at the beginning, electrical muscle stimulation performed too intensively may lead to structural muscle damage and CK release impairing kidney function, even leading to kidney failure. While medical applications are subject to medical supervision with the option of monitoring CK levels, this is not the case for non-medical applications.

3.2.10.2 Transcutaneous electrical nerve stimulation (TENS)

Transcutaneous electrical nerve stimulation (TENS) is primarily used for pain therapy. It can also be used to stimulate motor fibres, in turn causing muscle twitch. In pain therapy, the concept is based on the so-called gate control theory (Melzack and Wall 1965) which states that following electrical stimulation of the small fibres in peripheral nerves, the pulses from myelinated fibres, e. g. the sense of touch, are relayed to the spinal cord via so-called C-fibres at such speed that they can influence the pain sensation subsequently induced there. Another mechanism involves the release of endorphins or other neurotransmitters. TENS uses various current stimulation techniques involving supraliminal stimulation of peripheral, non-nociceptive fibres. The upper current limit is generally where electrical stimulation starts to become painful. As a result, the maximum current used in TENS applications remains at a level used very frequently in routine neurophysiological diagnostics without causing unwanted effects. In general, TENS uses square-wave pulses at frequencies of around 1 Hz to 15 Hz or 35 Hz to 100 Hz with a current of about 5 mA to 30 mA. TENS should be used as part of (multimodal) pain therapy tailored to the individual, taking pharmacological and non-pharmacological procedures into account (Treede 2016). This lack of individualisation, which is difficult to achieve in studies, and the extremely high placebo rate for pain interventions are two key reasons why it is not possible to unequivocally document the effectiveness of TENS in clinical studies (Gibson et al. 2017, Johnson et al. 2017).

Classification of exposure

The electromagnetic fields exceed the ICNIRP basic restrictions and sometimes reach or exceed the thresholds for effect to produce the intended therapeutic effect. To date, there have not been any studies on the possible unwanted effects of a long-term application on healthy probands.

3.2.11 Transcranial stimulation

3.2.11.1 Transcranial direct current stimulation (tDCS)

Transcranial direct current stimulation (tDCS) is a very old, reversible, non-invasive and largely pain-free method for performing transcranial electrical stimulation (Hellwag and Jacobi 1802). Direct current is delivered via electrodes on the head to achieve cortical excitability and an alternation of neuronal activity lasting several minutes to several days (Creutzfeldt et al. 1962).

tDCS uses a very low current of around 4 mA and a voltage of about 8 V to 14 V. For this reason it should not be confused with TES described in Section 3.2.5 (Merton and Morton 1980). While TES can generate additional action potential in quiescent nerve cells, tDCS only modulates the spontaneous discharge rate of neurons by depolarising or hyperpolarising the nerve cell membrane depending on the direction of current flow. Stimulation modulates spontaneous neuron activations as a result of a change to the quiescent membrane potential, leading either to activation or inhibition of that area. Transcranial direct current stimulation is therefore suited to spontaneous modulation of cortical activity (online effect), or, if performed long enough (generally > 3 minutes), it can also be used for effects extending beyond stimulation (offline effects). tDCS can be used to enhance or inhibit the brain's neurophysiology (Lefaucheur et al. 2017). However, it is still a matter of dispute as to what extent this applies to the brain's cognitive functions, including perception, behaviour and memory.

The actual intracranial current density achieved depends on a number of factors (electrode size and placement, number and arrangement of electrodes, bone density with possible local bone thinning, gyrus and liquor cerebrospinalis (cerebrospinal fluid – CSF)). Nowadays, computer software, e. g. SimNIBS (freeware), is able to simulate electric fields based on individual MRI images. This is even possible for stroke patients where affected parts of the brain are replaced with cerebrospinal fluid. These calculations were verified in non-human primates and in epilepsy patients with implanted electrodes.

The electric fields measured in the brain following transcranial stimulation amount to 0.5 V/m (Opitz et al. 2016). The brain itself generates local fields of > 4 V/m in the hippocampus and > 15 V/m in epilepsy patients by way of what are known as sharp waves. In view of this, Vöröslakos et al. call for a higher current of ~ 6 mA to ensure efficient stimulation, with (pain) compatibility ensured by using rotating electric fields with 'inter-sectional pulsed stimulation' (ISP) and temporal summation (Vöröslakos et al. 2018).

By way of comparison, the gradients for supraliminal, painless TMS are around 200 µs for fields of around 50 V/m to 100 V/m, with fields on the brain surface greater than those deeper in the brain. The cerebrospinal fluid surrounding the brain is a much better conductor of electricity. To some extent, it conducts the flow of electricity around the gyri, even if the active and reference electrodes are applied to opposite sides of the head. The current's direction, stimulation and inhibition all depend on the polarity (anodal or cathodal current), strength and duration of stimulation. With anodal stimulation where the current strength remains fixed at 1 mA to 2 mA for a period of 10 to 20 minutes, cortical activation continues for up to 90 minutes after tDCS. In fact, this effect can be prolonged for up to 24 hours through the co-application of L-Dopa (Kuo et al. 2008) or by performing fragmented stimulation (13 minutes of anodal tDCS, then a 20 minute break, followed by another 13 minutes of anodal tDCS) (Monte-Silva et al. 2013).

Acceptance of tDCS is better than of rTMS due to the lower risks involved since rTMS can provoke an epileptic seizure (see above), whereas tDCS cannot. Evidence from relevant animal models indicates that brain injury from direct current stimulation (DCS) occurs at predicted brain current densities of 6.3 A/m^2 to 13 A/m^2 which are several times higher than those produced by conventional tDCS. To date, the use of conventional tDCS protocols in human

trials (≤ 40 minutes, ≤ 4 mA, ≤ 7.2 coulombs) has not led to any reports of a serious adverse effect alongside the principal intended effect, or to any reports of an irreversible injury after more than 33,200 sessions and 1,000 subjects with repeated sessions. This includes a wide variety of subjects, including persons from theoretically vulnerable populations such as children (Bikson et al. 2016).

Provided safety guidelines are complied with, TMS and tDCS are safe applications in children and adolescents with various neurological conditions. The incidence of unwanted effects appears to be similar to that observed in adults (Krishnan et al. 2015). However, further studies with longer treatment and follow-up periods are needed to better understand the benefits and tolerance of long-term use of NIBS in children. Software such as SimNIBS allow the calculation of currents required for children which has to be lower due to a thinner skullcap.

Around 30 % (81 out of 264) of transcranial stimulation researchers state that they would consider using tDCS for cognitive self-enhancement. Approximately the same number believe that researchers do in fact use tDCS on themselves for this very purpose (24.8 %, 68 out of 264). 71 % of the researchers believe that tDCS should not be available to the public because improper use may also cause adverse opposite effects. Lay persons do not have detailed knowledge of the technology and potential risks like overdosing or close supervision and oversight by trained professionals (Riggall et al. 2015, Paulus et al. 2016).

Classification of exposure

The electromagnetic fields exceed the ICNIRP basic restrictions, but they lead to neuromodulation rather than nerve stimulation. To date, there are no studies on other effects of non-medical application, e. g. for cognitive enhancement. The effect of a long-term application is unknown.

3.2.11.2 Transcranial alternating current stimulation and transcranial random noise stimulation (tACS and tRNS)

Transcranial alternating current stimulation is similar to tDCS, with the execption of a balanced alternating current flow. While tACS uses sinusoidal alternating current, transcranial random noise stimulation (tRNS) involves a random noise current of up to 4 mA. Application safety increases along with frequency, so that higher currents can be applied. With regard to unwanted effects, the main benefit of tACS and tRNS over tDCS are the higher thresholds for dermal sensation of the current during stimulation (Paulus et al. 2016). Both tACS (Moliadze et al. 2010) and tRNS (Terney et al. 2008) can lead to neuroplastic effects in the brain. In this context, neuroplasticity means a change of excitability of the brain which extends beyond the period of stimulation and is generally limited in time. Depending on the intensity, the effect can be facilitating or inhibiting (Moliadze et al. 2012). A comprehensive overview of data on the effects of tACS and tRNS concludes that they are safe for applications in humans (Antal et al. 2017). Patients receiving electroconvulsive therapy for depression are exposed to a current of around 800 mA to 900 mA, which is at least 100 times higher than the current used in tACS or tRNS (Lee et al. 2016). Tumour-treating fields (see Section 3.2.3.1) involve a frequency of 200 kHz and electrical fields around 10 times higher (100 V/m to 300V/m) being applied for at least 18 hours per day over a period of several months without any known tissue damage attributable to the current used.

Classification of exposure

The electromagnetic fields exceed the ICNIRP basic restrictions, but they lead to neuromodulation rather than nerve stimulation. The effect of a long-term application is unknown.

3.2.12 Lipolysis and treatments for cellulite, acne, scars, etc.

Treatment methods involving radiofrequencies or high frequencies (above 300 MHz) with very short pulses ("Ultra Short High Frequency", USHF treatment methods) can, with the right parameters (frequency, choice of electrode and antenna), cause specific parts of the body or skin layers to heat up, in turn leading to coagulation necrosis. This effect is promoted in both dermatology and cosmetics as a way of reducing fat, treating cellulite, and for a range of other cosmetic applications. This procedure involves heating connective tissue cells to between 41 °C and 44 °C, while temperatures of up to 60 °C are used to damage fat cells, or in the case of thermoablation. Treatments are often offered in tandem, e. g. lipolysis together with subdermal liposuction involving cannulas. There is hardly any neutral scientific literature available for these treatment methods as most of the studies appear to have been sponsored by the device manufacturers. In view of this, no reference is made to any literature covering this field.

Classification of exposure

The promoted methods require exposures far above the thresholds for effect in order to be effective.

3.2.13 Taser (electroshock weapon)

Tasers usually deliver current impulses via needle electrodes in bipolar arrangement to the skin (Kroll and Ho 2009). The effect is mainly based on direct electrical stimulation of nerve fibres leading to uncontrolled muscle twitching and a sensation of pain. Commercial devices are intended for use at distance where the needle electrodes are shot at the target several metres away with thin wires connecting them to the hand-held device. Irrespective of the electric pulses, tasers can cause injury to the eyes or arteries close to the surface of the skin. Wounds can also occur when removing the barbs from the skin. Only security authorities are permitted to use tasers in Germany. However, devices applied directly to the body, i. e. without shooting electrodes, are freely available to persons aged 18 and over if the device is approved by the National Metrology Institute of Germany (PTB) (Kroll and Ho 2009).

In addition, there is a risk of secondary injury from falling, the outcome of which may range from simple scratches to bruising, cuts and contusions, but could also involve more serious injuries such as craniocerebral trauma (Wilke and Grassberger 2013).

A study conducted on behalf of Radio-Canada/the Canadian Broadcasting Corporation showed that four out of the 41 weapons used delivered much higher currents than those stated by the manufacturer. Instead of the stated 3.3 mA peak current, they actually delivered up to 5 mA (Savard et al. 2008).

Classification of exposure

The electromagnetic fields are well above the thresholds for effect. The risk involved with tasers equals that of a weapon.

3.2.14 Radiofrequency and epilation

Epilation is the term used to describe the removal of bodily hair, including the roots. Thermolysis or radiofrequency electrocoagulation is a form of electroepilation where the application of radiofrequency alternating current leads to irreversible sclerotization of the hair follicles. The tip of the probe is heated to cause coagulation of the tissue cells and growth cells in the follicle. Follicles sclerotized in this way can no longer produce any hair. However, it has to be taken into account that this method also leads to destruction of stem cells (responsible for the production of melanocytes) in the bulge region of the hair follicles. It is still unclear as to

what extent this affects the skin's homeostasis and/or whether mutations in cells of the stem cell reservoir are induced.

The current does not react with the hair's melanin, which is why thermolysis, as is the case with all electroepilation procedures, works with all hair and skin colours. The radiofrequency used (13.56 MHz to 40.68 MHz) has a volume-related energy density of 10 J/cm³ to 30 J/cm³ (Godfrey 2013). The application of radiofrequency alternating current leads to far lower, i. e. negligible, nerve excitation than low-frequency alternating current applications (Duncan and Kreindel 2015).

Classification of exposure

Energy densities exceeding the thresholds for effect are required for the method to be effective. Skin burns cannot be fully excluded in this case.

3.2.15 Combined applications and procedures

Combined applications and procedures here are understood to mean where radiofrequency currents are used alongside optical radiation in the form of lasers or incoherent radiation from other optical radiation sources. In principle, the radiofrequency current can either be delivered to the body with monopolar or bipolar electrodes using one or a pair of flat or needle electrodes with a length of approx. 0.5 mm to 3 mm and a thickness of 100 µm to 500 µm. In some cases, only the front part of the electrode in contact with the target tissue is uninsulated while the part in contact with the epidermis is insulated to avoid heating effects as much as possible. This also enables the use of fractional radiofrequency (FRF) where the radiofrequency current is delivered sequentially over a period of time or, ideally, across several points of application below the RF electrode separated by areas where no current is applied. This is performed by inserting needle electrodes into specific parts of the skin, e. g. to bring about tightening and tapering of collagen and elastin fibres. The terms microablation and minimally invasive ablation are also used in this context.

The use of devices combining different technologies in one applicator has largely come about as a result of practical experience. This also applies to an array of devices used consecutively. Practice has shown that the use of optical radiation, i. e. laser radiation sources and other optical radiation sources, on the skin has either proven impossible or the risk of unwanted effects was deemed to be too high. This applies to people with dark or tanned skin (types IV to VI on the Fitzpatrick scale), and to people with light hair (red, grey, blonde or white). An explanation for this is provided in the recommendation by the German Commission on Radiological Protection titled 'Hazard potential of applying lasers and other optical radiation sources to human skin' (SSK 2016).

Combined applications and procedures have not only become commonplace in medical aesthetic clinics, but also in beauty salons, for instance. In addition, there are a number of standalone devices and combination devices for home use which are advertised for a broad range of different applications.

There are two main areas where such devices are used as alternatives in both medical aesthetic applications and in cosmetic treatments: (1) aesthetic plastic surgery to tighten and rejuvenate the skin and to improve the appearance of the skin by way of chemical peeling, and (2) photoepilation for as long as possible hair removal.

According to the literature available on the various forms of energy applied to the skin – including a combination of various heat-generating procedures – certain states, situations and disorders such as photosensitivity, diabetes, consumption of medication, and pregnancy should be excluded from such treatments (Alexiades-Armenakas 2006). Furthermore, the possible

influence, i. e. warming or disturbance of active and passive (metal) implants must also be taken into consideration when applying radiofrequency.

3.2.15.1 Combined applications to improve the complexion

Collagen is constantly replenished in the human skin, but over time this process slows down, meaning that the skin's tissue is no longer supported as well and starts to sag.

To improve effects such as sagging, wrinkles and light damage (i. e. biologically intrinsic or environmental, exogenic skin aging due to thermally induced injury or damage, particularly to the dermis) the chosen applications induce a remodelling of the skin. Neocollagenesis, i. e. the formation of new collagen in the skin, is assumed to be the main mechanism in this process.

The radiofrequency current in the skin may also be responsible for damage to the fat cell membranes. It is also possible that the formation of new fibres containing elastin (elastogenesis) are at least involved in improving the skin's appearance. Treatments may also lead to shrinking of the affected skin tissue.

In an overview of studies conducted between 2003 and 2013, dealing with non-ablative, pure radiofrequency skin applications to improve the loss of elasticity (Araújo et al. 2015), the characteristic parameters and values used were frequencies of 1 MHz to 6 MHz (and 40.68 MHz in one study) with an output power of between 6 W and 330 W. The temperatures produced during such treatments ranged from 35 °C to 45 °C in the epidermis and dermis. Although the pure radiofrequency application is not the subject of consideration here, these studies nonetheless show that there is no standardisation in terms of the parameters used and that manufacturers of such radiofrequency devices do not always provide such information (Araújo et al. 2015). Impartiality from manufacturers' interests is also questionable in some studies.

Nowadays, a number of different combined procedures are used to improve the skin's appearance. Here, IPL devices are combined with radiofrequency applications, using either the non-ablative continuous wave radiofrequency method or the fractional ablative radiofrequency method. The latter combined method involves thin needle electrodes used in pairs to apply radiofrequency current in bipolar arrangement. Here, the needle electrodes are inserted to a certain depth in the skin. Light and current can be applied sequentially or simultaneously depending on the aim of the application. Experience shows that the fractional (discontinuous) radiofrequency method causes a greater sensation of pain than the continuous wave radiofrequency method.

Complications associated with a pure radiofrequency application extend from transient erythema and swelling to structural changes and skin dimpling (AlNomair et al. 2012). The fractional radiofrequency method is also associated with transient risks such as surface crusting, erythematous and nodular papules as well as a deterioration of hyperpigmentation (Gold et al. 2016).

Radiofrequency heating tends to be subject to a non-specific effect largely linked to the impedance of the current-carrying tissue concerned. As a result, the combined application of radiofrequency current and optical radiation requires a lower energy density for the laser or incoherent optical (IPL) radiation. This is due to the additional heating of the target by the radiofrequency current. According to the reports available, this does not produce any negative effect. Only mild erythema and oedemas occur which abate within a day or a few days after application.

Classification of exposure

The electromagnetic fields exceed the thresholds for effect.

3.2.15.2 Combined applications for epilation

As the application of radiofrequency does not depend on chromophores, it can also be used for epilation on darker skin types. The topic of long-term hair removal involving laser radiation at various wavelengths and IPL devices is described in the recommendation by the German Commission on Radiological Protection titled 'Hazard potential of applying lasers and other optical radiation sources to human skin' (SSK 2016), which pointed out that this procedure is biophysically limited when applied to people with dark or tanned skin (types IV to VI on the Fitzpatrick scale), and in people with light hair (red, grey, blonde or white). For epilation to be effective, the optical radiation must penetrate through the epidermis (the keratinized surface epithelium of the skin) so it can be absorbed by the hair follicle. However, this can lead to unwanted effects and complications, particularly in people with dark skin due to a higher melanin concentration. Dark hair, i. e. black and brown hair, contains the highest level of eumelanin, while red hair contains the highest level of pheomelanin, which is also the dominant pigment in people with blonde and light blonde hair. Eumelanin absorbs red and infrared radiation to a greater extent than pheomelanin (Sadick and Laughlin 2004). Grey and, particular, white hair lacks melanin, which is why it does not absorb anything in the red or near-infrared spectrum.

Assuming that the hair follicle, i. e. the structure surrounding the root of the hair and in this way anchoring the hair into the skin, has a higher radiofrequency-electrical conductivity than the area immediately around it, a certain semi-selective heating may occur as a result of a radiofrequency current, irrespective of hair colour (Sadick and Laughlin 2004). The keratin involved in hair shaft composition has, for example, a much lower electrical conductivity than the hair follicle substance, which is why the radiofrequency current ideally flows around the hair shaft to some extent. As intended during epilation, the exogenous heat created by the radiofrequency current leads to a heat transfer into the hair shaft (Yaghmai et al. 2004, Garden et al. 2014).

For instance during a combined application, the skin is cooled, with intended temperatures of 5° C to 15 °C, making the skin's impedance higher than that of the hair to be removed. This difference in impedance can be supported further by ‚preheating' the hair with absorbed energy from optical radiation. The reduction in resistance caused by the increase in temperature plays a key role in ensuring that the effect of the radiofrequency current in the hair follicle is greater than in the epidermis (where no effect of the current is intended). This helps to reduce the side-effects which would otherwise be induced by this procedure.

In a different type of combined device, single infrared pulses with energy densities of 2 J/cm^2 to 4 J/cm^2 at wavelengths of 550 nm to 1,200 nm are applied to an area of approximately 3 cm^2. Simultaneously, a radiofrequency current is applied with a frequency of around 7 MHz and an output power of about 2 W. The IR component uses a repetition rate ranging from 0.5 Hz to 1 Hz, with a 6-ms pulse duration. Breaks of several seconds are taken between individual sessions to allow the skin to cool down. The sessions are conducted over a period of several weeks and may be complemented by so-called maintenance treatments as it is not possible to remove or reduce hair with a single application (Garden et al. 2014).

For the effective epilation of subjects with white and blonde hair by combined use of optical radiation and radiofrequency current optical energy densities of 24 J/cm^2 to 30 J/cm^2 with a wavelength of 680 nm to 980 nm and a radiofrequency energy density of 20 J/cm^3 are used. The pulse durations for the optical radiation and radiofrequency current are 120 ms. In order to

effectively reach deep hair follicles, the radiofrequency current penetration depth is adjusted to approximately 4 mm. Potential pain sensations are suppressed by contact cooling integrated into the applicator at a temperature of, e. g. -4 °C. The application involves passing the applicator over the same part of the skin multiple times. Treatment is halted if erythema occurs and remains for more than a few minutes (Sadick and Laughlin 2004).

Some combined application devices include monitoring by measuring the electrical impedance and/or the radiofrequency electrode temperature.

Classification of exposure (based on the SSK recommendation from 2016)

Although synergistic combination of two forms of energy requires lower amounts of energy to generate the necessary optical radiation and radiofrequency current with the aim of reducing human exposure and thus the risk of unwanted side effects, such applications still exceed known thresholds for optical radiation. It is not possible to provide exact values at present, but a value of around 5 J/cm^2 appears plausible here as the energy density (irradiation) threshold for optical radiation since this value should be enough to destroy a pigmented target (SSK 2016). The application of radiofrequency current in combination with optical radiation during epilation is intended to damage skin appendages. Ultimately, any radiofrequency device can cause injury if it is used improperly during combined applications.

3.3 Summarising evaluation of the described EMF applications

3.3.1 Evaluation of the health risk with measures and recommendations

The health risk of EMF applications for humans should be evaluated on the basis of the criteria described in Section 3.1.2 and summarised in Table 7. The first three criteria (EMF exposure, invasivity and required professional qualification) are key criteria to stipulating obligatory measures and recommendations. They should be defined in a regulatory framework to an extent deemed proportionate to the level of risk.

The additional criteria (see Sections 3.1.2.4 and 3.1.2.6) are more ambivalent, more difficult to quantify, and largely of secondary importance to the regulatory framework discussed here. Consequently, this recommendation only includes legally non-binding arrangements, declarations of intent and guidelines as measures (particularly with a view to providing information), and they are defined for each specific application. The overview in Table 7 provides a qualitative assessment of these criteria as ‘additional criteria’. They are classified in order of health risk, starting with the highest risk, and include the measures and recommendations for each criterion (see examples of evaluations in Section 3.3.2).

Table 7: Evaluation of the health risk with measures and recommendations – overview

Criterion	**Health risk** (cf. Sections 3.1.2.1 – 3.1.2.3)	**Measures and recommendations**
EMF exposure	High	Medical application only Exceptions to commercial applications only subject to strict requirements Private applications should be prohibited
	Medium	Requirements for commercial applications Private application only in exceptional cases Training and device-specific instruction are important to avoid unwanted injury
	Low	No binding measures Provide information if necessary
Invasivity	High	Medical application only
	Medium	Requirements for commercial applications Private application only in exceptional cases Training and device-specific instruction are important to avoid unwanted injury
	n/a	None
Required professional qualification	High	Medical application only Exceptions only subject to supervision by a physician and meeting strict conditions regarding application-oriented additional training
	Medium	Training in a healthcare profession related to the application is required along with device-specific and application-specific expertise These training requirements should be regulated and controlled by law Training opportunities should be provided
	Low	Provide information if necessary

Additional criteria	**Relevance for health risk** (cf. Sections 3.1.2.4 – 3.1.2.6)	**Measures and recommendations**
Duration of application	High	Investigate long-term effects and possible adverse effects Provide information, exchange information and provide training in various forms (especially regarding the current state of scientific knowledge on the risks and associated uncertainties as well as potential voluntary precautionary measures)
	Medium	see 'High'
	Low	None Provide information if necessary
Type of target person/application environment	High	Product-related information Limits for applications involving children if necessary
	Medium	Various requirements can be imposed in connection with controllable applications, e. g. a test person register Training Reporting requirement
	Low	None
EMC	High	Issue a warning Exchange information between various regulatory frameworks Provide feedback Provide information
	Medium	see 'High'
	Low	None

3.3.2 Evaluation and recommendations

The following table provides an evaluation of the applications (described in Section 3.2) according to the specified assessment criteria (described in Section 3.1). The health risk for each of the three main criteria is provided along with a qualitative description of the additional criteria. The table also contains the derived recommendations (described in Section 3.1). It does not replace the assessment and evaluation in Section 3.2.

General contraindication for wearers of active implants should always be taken into consideration for all of the applications set out below, which is why it is not stated explicitly in the evaluation of additional criteria (see Annex A-1 EMC).

Table 8: Evaluation of individual applications using the defined criteria exposure, invasivity, required (and possible lack of) professional qualification and other additional criteria

Application	**Health risk due to**			**Relevant additional criteria**	**Recommendation**
	EMF exposure	**Invasivity**	**Insufficient qualification**		
Diathermy	High	n/a	Medium	Repeated and long-term applications	Requirements for commercial application Expertise Prohibit private application
Hyperthermia	High	n/a	High		Prohibit non-medical application Allow exceptions only subject to strict requirements Prohibit devices from general sale
Thermoablation	High	High	High		Prohibit non-medical application
Electroporation-based cancer therapies	High	High	High	Major uncertainties	Prohibit non-medical application Conduct research
Tumour treating fields (TTFields)	High	n/a	High	Long-term application	Prohibit non-medical application Conduct research
Cancer therapy with tumour-specific frequencies	Low	n/a	Medium	Long-term application	Prohibit non-medical application Provide information
Magnetic resonance tomography (MRI)	High	n/a	High	Long-term application on test persons	Prohibit non-medical application Conduct risk-benefit analysis for test persons Research required on long-term applications / follow-up for test persons

Application	Health risk due to			Relevant additional criteria	Recommendation
	EMF exposure	Invasivity	Insufficient qualification		
Transcranial magnetic stimulation (TMS)	High	n/a	High	Possible adverse effect: epileptic seizure Uncertainties	Prohibit non-medical application Conduct risk-benefit analysis for test persons Research on long-term applications / follow-up for test persons Compliance with generally accepted limits to minimise the risk of epileptic seizures
CNS neurostimulation for pain therapy	High	High	High	Repeated and long-term applications	Prohibit non-medical application
Bioresonance	Low	n/a	Medium	No evidence of effectiveness	None; provide information if necessary
Neuroresonance	Low	n/a	Medium	Repeated application Target persons include children	None; provide information if necessary

Application	Health risk due to			Relevant additional criteria	Recommendation
	EMF exposure	Invasivity	Insufficient qualification		
Magnetic field mats (PEMF)	Medium	n/a	Low	Long-term application (indications of potential cancer risk) Target persons include children and pregnant women No evidence of effectiveness	Provide information Conduct research Provide warnings about use on children and pregnant women
Electrical muscle stimulation (EMS)	High	n/a	Medium	Possible adverse effects: structural muscle damage, renal failure Exclusion criteria: pregnancy; cardiac arrhythmias, epilepsy, tumours in the area of application Uncertainties Repeated applications	Requirements for commercial application Expertise Stimulation intensity for bodybuilding applications should only be slowly increased from session to session and pain similar to that of muscle ache extending beyond regular complaints should always be avoided Prohibit private application Provide information Conduct research on long-term effects
Transcutaneous electrical nerve stimulation (TENS)	High	n/a	Medium	Unwanted effects Exclusion criteria: Pregnancy, cardiac arrhythmias, epilepsy, tumours in the area of application Uncertainties Repeated applications	Requirements for commercial application Expertise Increase in pain from excessive application (> 30 minutes) was described as being dependent upon the intensity of the current. Prolonged applications should therefore be avoided Conduct research on long-term effects

Application	Health risk due to			Relevant additional criteria	Recommendation
	EMF exposure	Invasivity	Insufficient qualification		
Transcranial direct current stimulation (tDCS)	Medium	n/a	Medium	Long-term application Target persons include children and adolescents Uncertainties	Requirements for commercial application Expertise Provide information Limit application on children Prohibit private application Research required on possible adverse effects and long-term effects / follow-up for test persons
Transcranial alternating current stimulation (tACS)	Medium	n/a	Medium	see tDCS	see tDCS
Lipolysis	High	n/a	High		Prohibit non-medical application
Taser (electroshock weapon)	High	n/a	n/a	Additional risk of ‘secondary injury from falling’	Prohibit from general sale
High-frequency epilation	High	Medium	Medium	Possible adverse effect: skin burn	Requirements for commercial application Expertise Prohibit private application
Combined applications	High	Medium	Medium	Possible adverse effect: skin burn	Requirements for commercial application Expertise If the application uses optical radiation, the SSK recommendations on lasers and other optical radiation sources with comparable effects should be taken into account for cosmetic applications (see (SSK 2016) Protective eyewear should be worn Prohibit private application

n/a: not applicable

3.3.3 Professional requirements to ensure the safe use of the above listed devices on humans

3.3.3.1 Basic knowledge and skills

- Knowledge of the biological and physiological effects of EMF
- General knowledge of anatomy, physiology and pathophysiology of the organs and tissue to be treated
- Knowledge of exposures and effects as a basis for conducting a risk-benefit analysis
- Skill to identify the need for referral to a physician
- Knowledge relating to the preparation and follow-up of the treatment area, hygiene and technical/medical aids
- Knowledge of the applicable laws and regulations, in particular the 'Ordinance on protection against the harmful effects of non-ionising radiation in applications in humans' (NiSV 2018, Article 4)

3.3.3.2 Technical knowledge

- of the physical principles of EMF
- of the technology used in EMF devices
- of protective measures for operators and customers or oneself in the event of private application

3.3.3.3 Treatment-specific knowledge and skills

- Knowledge of exclusion criteria, possible adverse effects, risks and alternative methods and technologies
- Knowledge of the treatment plan
- Knowledge of the use of suitable and unsuitable treatment technologies
- Specific practical experience
- Skill to identify incorrect settings and defective devices

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5 Abbreviations and glossary

Ablation	Removal/destruction of body tissue/sclerotherapy
AM-EMF	Amplitude-modulated electromagnetic fields
CAD	Coronary artery disease
CK	Creatine kinase
DCS	Direct current stimulation
Diathermy	Use of strong radiofrequency EMF for localised tissue heating
ECT	Electrochemotherapy
EGT	Electro-gene therapy
ELF	Extremely low frequencies
EMF	Electric, magnetic and electromagnetic fields
EMS	Electrical muscle stimulation
Exposure	Exposure to electromagnetic fields
Failed back surgery syndrome	Persistent pain following back surgery or pain occurring after and as a consequence of surgery.
FRF	Fractional radiofrequency
Hyperthermia	Increasing the body temperature to 39-45°C
Invasivity	An application where a device, in whole or in part, penetrates inside the body, either through a body orifice (any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma) or through the surface of the body (EU 2017). Includes both the tissue damage which can occur when applying electrodes, and the damage caused by the application itself
IPL	Intense pulsed light
IRE	Irreversible electroporation
Lipolysis	Fat-reduction procedure
LLLT	Low-level laser therapy
Magnetophosphenes	Flashes of light due to stimulation of the retina and visual cortex when subjected to low-frequency magnetic fields

MRI	Magnetic resonance imaging
nsPEF	Nanosecond pulsed electric fields
Operant conditioning	Learning process leading from initially spontaneous behaviour to stimulus-response patterns
PAOD	Peripheral artery occlusive disease
Plasma	Partially ionised gas(es) generated by way of high electric voltages
Principal intended effect	The principal intended effect of a medical device in or on the human body is primarily achieved by way of a physical effect (e. g. thermal radiation or electrical stimulus) in contrast to the biochemical effects of pharmaceutical products (MPG 2002, pp. 4-5; https://www.bfarm.de/DE/Medizinprodukte/_node.html).
RF	Radio frequency
RFTT	Radiofrequency thermotherapy
SDSS	Spatially distributed sequential stimulation
Skin effect	Tendency of an alternating current to become distributed within a conductor such that depending on the frequency the charge carrier density is larger near the surface of the conductor than at greater depths
Taser	Electroshock weapon
tDCS	Transcranial direct current stimulation
TENS	Transcutaneous electrical nerve stimulation
tES	Transcranial electrical stimulation
Thermoablation	Extreme form of hyperthermia
Threshold	Field strength or SAR value above which a directly observable (biological) effect may occur
TMS	Transcranial magnetic stimulation
TTFields	Tumor treating fields
Unwanted effect	Effect which occurs alongside the intended principal effect

Annexes

A-1 Effects of EMF on human health

A-1.1 Scientifically proven effects and basic restrictions

ICNIRP has provided guidelines for limiting exposure of the different frequencies of electric, magnetic and electromagnetic fields (EMF), both for the general public and for occupationally exposed persons. Applying reduction factors, these guidelines were derived from thresholds for biological effects and protect against all the scientifically proven (acute) negative health effects of these fields. This recommendation uses the basic restrictions for the general public provided in the guidelines because EMF applications in humans are not restricted to workers. For the sake of completeness, Table 9 (Annex A-2) also provides the basic restrictions for occupationally exposed persons. Basic restrictions in the ICNIRP guidelines for limiting exposure are derived from acute short-term effects which have been relatively well studied. The restrictions cannot simply be applied to long-term effects, which to date remain scientifically unfounded.

Below is a brief overview of the health effects and resulting basic restrictions for the different frequency ranges.

A-1.1.1 Static magnetic fields

Static magnetic fields physically interact with the body in three ways: magnetic induction (during movement in a static field), magneto-mechanical effects, and influence on radical pairs.

Biological effects on humans are only known for relatively high magnetic flux densities. Above a threshold of 2 T, unpleasant yet reversible sensations may occur, such as nausea, vertigo, magnetophosphenes or a metallic taste in the mouth. To prevent this from occurring, a reduction factor of 5 is used resulting in a basic restriction of 400 mT. This is roughly the level currently achieved with powerful solid-state magnets. The basic restriction is not enough to protect people with implants where a value of 0.5 mT should not be exceeded for technical reasons (ICNIRP 2009).

A-1.1.2 Low-frequency electric and magnetic fields (1 Hz – 100 kHz)

Low-frequency electric fields can electrically charge surfaces, can be perceived by humans, and can be considered unpleasant due to the sensations they induce. Owing to electromagnetic induction, low-frequency magnetic fields can lead to stimulation of the nervous system, the retina, and the muscles. The threshold for electric fields induced in the body is around 4 V/m at below 3 kHz for peripheral nerve stimulation and 50 mV/m at 20 Hz for retina stimulation. Frequency-dependent basic restrictions at frequencies of 10 Hz to 100 Hz, are set at levels that avoid magnetophosphenes which may be felt to be disturbing. At higher frequencies, the basic restriction depends on the threshold for peripheral nerve stimulation. Here, a reduction factor of 5 is used for retina stimulation, and a factor of 10 is used for peripheral nerve stimulation. As internal electric fields of up to 10 MHz may induce nerve stimulation, basic restrictions were set for these frequencies. At frequencies of 100 kHz to 10 MHz, basic restrictions for radiofrequency fields should be respected additionally (ICNIRP 2010).

Since applications are performed directly on or in the body the risk assessment in the present recommendation is based on a comparison of the basic restrictions with the electric fields occurring in the body during application.

When considering devices used for direct stimulation of the nerves and muscles via electrodes, in addition to the basic restrictions for electric fields the reference levels for contact currents must be taken into account. The latter protect against painful shocks and burns, but might not prevent possible unpleasant sensations which are not harmful to a person's health.

A-1.1.3 Radiofrequency electromagnetic fields (100 kHz – 300 GHz)

Radiofrequency electromagnetic fields penetrate into the body and cause tissue heating due to the energy absorbed by the tissue. Temporary heating of the body by less than 1 °C is deemed harmless to a person's health. Such a body temperature increase occurs if the specific absorption rate (SAR), averaged for the whole body volume, reaches 4 W/kg for a period of 30 minutes. By applying a reduction factor of 50, this results in a basic restriction of 0.08 W/kg for whole-body exposure. Parts of the body are allowed to be more highly exposed, in which case the SAR is averaged for 10 g of tissue. At frequencies above 10 GHz, the depth of penetration is so low that only the surface of the skin is affected. In such cases, SAR is not a suitable measure of energy absorption. For this reason, the basic restriction is given as power density at frequencies of 10 GHz or higher (ICNIRP 1998).

A-1.2 Indications of possible long-term effects of electromagnetic fields

A-1.2.1 Static fields

The effects of magnetic fields higher than 4 T have not been sufficiently studied because MRI technology involving high magnetic flux densities is still relatively new. Hence there is a lack of substantiated findings in a number of areas when it comes to research on health effects. There are not enough studies available as to whether strong static magnetic fields have an influence on pregnancy and embryonal development, and the few studies available only involve low magnetic flux densities. However, such knowledge would be important to ensuring the safety of pregnant patients and the medical staff. Nevertheless, this technology is increasingly used in prenatal diagnostic testing.

Several research projects commissioned by the Federal Office for Radiation Protection (BfS) (Hoyer et al. 2012, Zahedi et al. 2014, Zaun et al. 2014) showed that magnetic fields of up to 7 T do not have any negative health effects on male mouse fertility, female mouse pregnancy or embryonal and new-born development. According to a further research project commissioned by the Federal Office for Radiation Protection (BfS) (Heinrich et al. 2013), human testing showed that the test subjects experienced unpleasant sensations, largely vertigo. However, this did not have any effect on cognitive functions, such as reaction time and memory performance. Studies are lacking to determine whether the performance of the medical staff might be impaired to an extent that may pose an indirect risk for patients.

Based on the present state of knowledge, there does not appear to be any health risk due to long-term exposure to static electric fields. According to the SSK statement on field emissions from high voltage direct current (HVDC) power lines (SSK 2013), there is evidence of a non-correlation with effects within the body.

A-1.2.2 Low-frequency electric and magnetic fields

Epidemiological studies have shown that children exposed indoors to magnetic fields exceeding 0.4 μT have a twofold higher risk to develop childhood leukaemia compared to children with no indoor magnetic field exposure (Ahlbom et al. 2000, Kheifets et al. 2010). Based on epidemiological studies published up until 2002, the International Agency for Research on Cancer (IARC) classified extremely low-frequency magnetic fields as being possibly carcinogenic to humans (Group 2B) (Eichholz 2002, IARC 2002). However, epidemiological

studies cannot show any causality between exposure and disease. The IARC mainly arrived at this classification because animal and laboratory studies did not show any reproducible effects which would confirm the hypothesis that low-frequency magnetic fields cause or promote cancer.

Epidemiological studies also indicate that neurodegenerative diseases occur more frequently as a result of high occupational exposure to low-frequency magnetic fields. To this end, Vergara et al. (2013) conducted a meta-analysis involving 42 cohort and case-control studies. An evaluation of 20 of those studies indicated a possible increased risk of occupationally exposed persons developing Alzheimer's disease (Vergara et al. 2013). A possible increased risk of developing Alzheimer's disease was also observed by a Swiss study of the general population living less than 50 m away from a 220 kV to 380 kV high voltage power line (Huss et al. 2009). This risk increases with the time spent living near such power lines. A study from Denmark using much the same approach was not able to confirm the results in full (Frei et al. 2013).

An evaluation of 21 epidemiological studies found an indication of a possible link between occupational exposure to low-frequency magnetic fields and amyotrophic lateral sclerosis (ALS) (Vergara et al. 2013). More recent studies from Switzerland (Huss et al. 2015), the Netherlands (Koeman et al. 2017) and Denmark (Pedersen et al. 2017) confirm this finding. No link was found between ALS and living near high voltage power lines (Seelen et al. 2014), and there was also no evidence of a correlation between magnetic fields and Parkinson's disease (van der Mark et al. 2015) or multiple sclerosis (Feychting et al. 2003).

The statistical correlations observed in epidemiological studies were not confirmed by studies on mechanisms.

An experimental research project conducted by the Federal Office for Radiation Protection (BfS) until 2013 used animal models to determine whether the indications from the epidemiological studies could be confirmed under controlled laboratory conditions. The main result of the molecular-biological, biochemical and histological analyses as well as the behavioural studies showed that low-frequency magnetic fields do not have any negative effect on the progression of Alzheimer's disease and ALS in mice exposed to a magnetic field of 1 mT during their whole lifetime (Liebl et al. 2015).

It should also be noted that daily applications may significantly increase the overall level of magnetic field exposure. Epidemiological studies suggest a correlation between the use of electric devices such as electric blankets, hairdryers and electric shavers and cancer risks in adults (Kleinerman et al. 2005, Abel et al. 2007).

A-1.2.3 Radiofrequency electromagnetic fields

Electromagnetic fields and cancer

Although a number of studies have already been performed, evidence in support of effects remains highly contentious, with hitherto gathered results exhibiting a number of inconsistencies. At the time of preparing this recommendation, there are no scientifically proven additional risks of any type of cancer in children and adults as a result of radiofrequency EMF.

Based on the current state of knowledge, there is limited evidence of a carcinogenic effect (glioma and acoustic neuroma) of radiofrequency electromagnetic fields (mobile phone exposure) in humans. In its assessment from May 2011 (IARC 2013), the IARC/WHO classified radiofrequency electromagnetic fields as 'possibly carcinogenic to humans' (Group 2B on the IARC scale). This classification is based on limited evidence from epidemiological studies on humans and on limited evidence from animal studies in the laboratory. The effect of heating is the main proven biological effect of radiofrequency electromagnetic fields and forms

the basis for the current recommendations. At present, there is no evidence of any adverse health effects of long-term exposure to low radiofrequency fields.

Cataracts

Workers exposed to high-intensity radiofrequency and microwave radiation have reported eye irritation and opacity of the eye lens (cataract). The assumption that such eye damage may occur at intensities which do not represent any thermal risk has not been confirmed by animal studies.

A-1.3 Indirect effects of EMF or electromagnetic compatibility (EMC)

EMF devices for applications in humans may also have an electromagnetic influence on other electrotechnical devices and equipment in the vicinity. If this is the case, it should be classified as technical EMC. In the event that a malfunction or failure occurs due to technical EMC and is thus dangerous for human beings, this can be considered as an indirect effect which should of course also be taken into account. This naturally applies to all active medical implants, meaning that EMF applications should, as a rule, be contraindicated for people with implants.

This is why technical standardisation bodies, particularly those pertaining to occupational safety in Germany, are trying to ensure that people with implants have the same level of protection as the general public when exposed to electromagnetic fields. To this end, the design of at least the most important and most common active implants, e. g. pacemakers and defibrillators, should ensure safe functionality at prolonged exposures to EMF not exceeding the ICNIRP reference levels (ICNIRP 2010). Unfortunately, only a limited number of implants offer such reasonable interference immunity (Heinrich and Börner 2015). Therefore, the intentional use of EMF on people with implants, even when complying with the ICNIRP reference levels, cannot generally be regarded as free from risk. In view of this, corresponding warnings should be issued when performing EMF applications, particularly in the form of relevant information provided in a device’s documentation.

Additional technical scenarios affecting safety are also conceivable in theory, but should be deemed highly unlikely (use of EMF for applications in humans in aircraft, vehicles or intensive care units).

A-2 ICNIRP basic restrictions at different frequencies

Table 9: ICNIRP basic restrictions at different frequencies (values taken from ICNIRP 1998, ICNIRP 2009, ICNIRP 2010)

	Basic restriction (ICNIRP)	
Frequency (f)	**General public exposure**	**Occupational exposure**
0 Hz	**External magnetic flux density**	
Head and trunk	400 mT (people with implants: 0.5 mT)	8 T
Extremities	400 mT	2 T
	Internal electric field (root mean square)	
	Head/CNS:	
1 Hz - 10 Hz	0.1/f V/m	0.5/f V/m
10 Hz - 25 Hz	0.01/f V/m	0.05 V/m
25 Hz - 400 Hz	$4x10^{-4}$ x f V/m	$2x10^{-3}$ x f V/m
400 Hz - 1,000 Hz	$4x10^{-4}$ x f V/m	0.8 V/m
1,000 Hz - 3 kHz	0.4 V/m	0.8 V/m
3 kHz - 10 MHz	1.35x10-4 x f V/m	$2.7x10^{-4}$ x f V/m
	All tissues:	
1 Hz - 3 kHz	0.4 V/m	0.8 V/m
3 kHz - 10 MHz	$1.35x10^{-4}$ x f V/m	$2.7x10^{-4}$ x f V/m
	Contact current (reference levels)	
up to 2.5 kHz	0.5 mA	1 mA
2.5 kHz - 100 kHz	2 x 10^{-4} f mA	4 x 10^{-4} f mA
100 kHz - 10 MHz	20 mA	40 mA
100 kHz - 10 GHz	**Specific absorption rate (averaged for 10g of tissue over 6 min)**	
Whole body	0.08 W/kg	0.4 W/kg
Head and trunk	2 W/kg	10 W/kg
Extremities	4 W/kg	20 W/kg
	Power flux density	
10 GHz - 300 GHz	10 W/m^2	50 W/m^2