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Federal Department of Home Affairs FDHA
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Magnetic field mats

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This fact sheet deals with magnetic field mats that are connected to the mains during operation. The information in this fact sheet does not apply to magnetic field mats with built-in permanent magnets that do not require a power supply.

Magnet field mats are used in medicine for therapeutic treatments of various disorders. For private use these mats are also used as recreational and wellness equipment so as to increase for example general wellness or to help the body to recover more quickly after sporting activities.

The strong magnetic fields generated by the magnetic field mats exceed in some cases the international recommended limit values. Consequently, health risks cannot be unequivocally ruled out for long-term use. Also, according to the present state of knowledge, the health benefit associated with these mats has not been proven.

People who use the magnetic field mats should therefore respect the following precautionary measures:

- Do not use magnetic field mats for recreational and wellness purposes.
- Children and pregnant women should not use magnetic field mats .
- Persons with a pacemaker or another electronic medicinal implant should not use magnetic field mats , as this could lead to a malfunction of the implant.
- Make sure that you follow closely the manufacturer’s instructions in regard to the lying position and position yourself on the mats as indicated in the instruction manual.
- The efficacy of these mats has not been scientifically proven.
- The costs of the magnetic field mats are not reimbursed by the health insurance companies.
- If you decide to use a magnetic field mat, it is advisable to use one that is approved as a medical device.
- It is advisable to use magnetic field mats under the supervision of a medical professional who specialises in magnetic field therapy.

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1 Purpose of magnetic field mats

1.1 Design and Operation

Magnetic field mats are available in various sizes. This depends on whether they are designed for treating the whole body or for individual areas of the body. Both the whole body and partial body mats contain coils, through which flow the pulsed low frequency electric currents. These currents generate magnetic fields that permeate the body of the treated person. These magnetic fields again generate electric currents in the electrically conductive body of the person and if sufficiently intense can provoke physiological effects.

Signal form, frequency, magnetic field strength and coil arrangement differ depending on the manufacturer of the mats. The coils are either spiral in shape (Figure 1, mats 1 and 3) or are formed by a plurality of pairs of coils of differing power (Figure 1, mat 2).

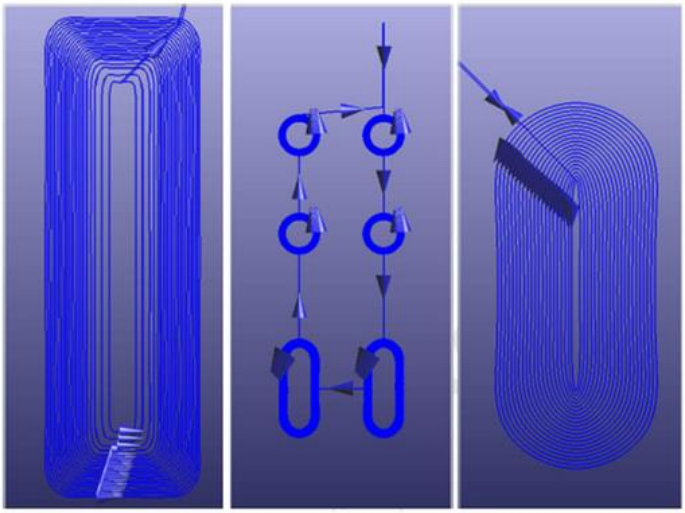

Figure 1: Arrangement of the coils of three different magnetic mattress pads.

1.2 Purpose

Therapeutic magnetic field mats are recommended by the manufacturers for the treatment of various disorders such as arthritis, rheumatism, headaches, asthma or osteoporosis. According to the manufacturers, these mattresses can also be used as recreational and wellness equipment so as to increase general wellness or to help the body to recover more quickly after sporting activities. Magnetic field mats are sold or rented for home use as well as for use under medical or therapeutic supervision.

1.3 Applications

Magnetic field mats generally offer a number of application programmes that differ in intensity and duration and are recommended for different symptoms or medical conditions.

Magnetic field mats are designed in such a way that the person being treated lies directly on the mat or the mat is positioned during use under the bed mattress. The length of the treatment can be between 15 minutes and several hours.

2 Risks and benefits of magnetic field mats

The Federal Office of Public Health (FOPH) commissioned various studies in order to assess both the benefits (chapter a. Effectiveness and Benefits of Magnetic Mattress Pads) as well as the risks (chapter b. Risk Assessment of Magnetic Mattress Pads) of Magnetic Mattress Pads.

2.1 Effectiveness and Benefits of Magnetic Field Mats

2.1.1 Method

The Swiss Tropical and Public Health Institute (Swiss TPH) was mandated by the FOPH to carry out a literature study on the therapeutic effects of magnetic field mats [1]. This review of the literature solely included randomised double-blind studies. This study type involves part of the participants in the study being treated with magnetic field mats that were switched on (the intervention group), the other part, however, with mattresses that were switched off (the placebo group). Allocation to both groups was randomised. Neither the participants in the study nor those conducting the tests knew who was being treated with magnetic fields and who was not. The review took into account only peer-reviewed studies that were published up to the end of March 2010 in a scientific journal.

The systematic literature search in various scientific databanks found a total of 155 publications on the use of electrotherapeutic methods. Thirteen of these studies related to the use of magnetic field mats and met the above described criteria. In most of the other studies, smaller devices for magnetic uses on individual areas of the body, or other electrotherapy methods were investigated. As one of the studies on the use of magnetic mattress pads had been published twice, a total of twelve publications were evaluated.

2.1.2 Results

In the twelve studies the use of whole body magnetic field mats was investigated for the following symptoms:

- arthritis of the knee (3 studies)
- arthritis in the area of cervical vertebra (1 study)
- fibromyalgia (widespread muscular pain) (1 study)
- perception of pain (2 studies)
- Heart rate variability in healthy persons (1 study)
- wound healing and microcirculation (2 studies)
- chronic fatigue in persons suffering from multiple sclerosis (2 studies)

The four studies on arthritis of the knee or cervical vertebra produced conflicting results in regard to pain reduction. Three studies indicated a decrease in pain, but only one study included a subsequent control after four weeks. At this point in time a treatment effect was no longer detectable. In regard to the desired improvement of the functionality of the joint, the results were not uniform and showed individual effects that, however, were not identical in all studies.

The single study on fibromyalgia patients pointed to a decrease of the impairments due to the disease and to the level of pain after three weeks of using a magnetic mattress pad. The subsequent control after twelve weeks demonstrated only slight improvements.

In both studies relating to pain perception, no difference was observed between treated and untreated persons.

Only twelve patients participated in each of the two studies on wound healing and microcirculation. There were no differences between those who had used the magnetic mattress pads and those who had not been exposed to magnetic fields.

The results of the studies on fatigue in patients suffering from multiple sclerosis were not consistent either: In one of the two studies an improvement was observed after twelve weeks' use of magnetic mattress pads, in the other investigation, however, the persons of the intervention group were less tired than those not exposed to magnetic fields only immediately after each use of the magnetic mattress pad.

The study of the heart rate variability showed overall no changes by the use of magnetic field mats.

The results of the 12 studies are again summarised in Table 1.

Table 1: Overview of the results of the 12 evaluated studies of the systematic literature search

Clinical picture	**number of studies**	**number of participants**	**Results**	
			Positive effects	**no effects**
Arthritis of the knee	3	158		No significant and lasting effects
Arthritis in cervical vertebrae	1	32		No lasting effects
Fibromyalgia	1	56	Indications of short-term improvements in regard to pain and impairment	
Pain perception	2	100		No difference between treated and untreated persons
Heart rate variability	1	27		No changes
wound healing and microcirculation	2	24		No improvement
Fatigue in MS patients	2	37	Study 1: improvement in fatigue after 12 weeks	Study 1: no immediate improvement and none after 6 weeks
		24	Study 2: improvement in fatigue immediately after use	Study 2: no lasting improvement

In summary, these studies do not show any compelling evidence for the value and efficacy of magnetic field mats.

2.2 Risk assessment for the use of magnetic field mats

2.2.1 Limit values for magnetic fields

The "International Commission on Non-Ionizing Radiation Protection" (ICNIRP) is a scientific commission recognised by the World Health Organisation WHO and the European Union. It assesses the impact of electromagnetic fields on health and delivers recommendations for limit values [2]. The ICNIRP recommended limit values form the basis for the EU Council Recommendation [3]. It forms the fundamental requirements for the safety of electrical products in Europe and Switzerland with regard to their electromagnetic fields. Although magnetic mattress pads, which are approved as medical devices, do not have to meet these limit values, their risk potential is nonetheless gauged using these limit values. This is particularly so, as the above described literature study shows that no benefit is to be expected.

These limit values are based on scientifically proven acute effects that occur with humans when their exposure to electrical or magnetic fields exceeds a certain level. The limit values for allowable exposure of the general population for low frequency fields are 50 times lower than this value. Acute effects of very strong low frequency magnetic fields can affect both the central as well as the peripheral nervous systems. The central nervous system includes the brain and the spinal cord. The peripheral nerves include the cranial nerves, nerves in the wall of internal organs and all nerves that emanate from the spinal cord to other parts of the body.

The ICNIRP fundamentally differentiates two categories of limit values: basic restrictions and derived reference levels. The basic restriction in the low frequency region is related to electric currents that are generated in a body (body currents) by exposure to a magnetic field and which produce acute effects on the functions of the nervous system. However, as these body currents cannot be directly measured, the derived reference levels tend to be used in practice because they can be measured as the electrical or magnetic field without the person being present. If these magnetic field reference levels are respected then the current in the body of an exposed person is mostly below the basic restriction. If, however, the reference level is exceeded, then compliance with the basic restriction must be checked. This is possible with inter alia complex computer simulations.

The limit value recommendations do not take account of potential long-term effects, as the ICNIRP has rated the proof for damaging effects of long-term exposure to weak electromagnetic fields as inadequate.

2.2.2 General effects of magnetic fields on health

Strong low frequency magnetic fields can provoke unwanted neural stimuli and muscle contractions and thereby cause malfunctions, such as e.g. muscle cramps. The ICNIRP recommended limits permit magnetic fields to be only so great that the electrical currents produced in the body are at least a factor of 50 below the excitation threshold.

In our environment, for example in the proximity of high voltage lines or other current carriers, magnetic fields are produced that are far below the limit values recommended by the ICNIRP. Some epidemiological studies have shown an increased risk of leukaemia in children due to these weak but long term magnetic field exposure (<0.4 µT (microtesla)) from high voltage lines [4, 5].

In addition, some epidemiological studies indicate that long term exposure at home or at work to magnetic fields in the range of 1 µT could increase the risk of suffering from Alzheimer disease [6, 7]. 2009). Moreover, there are some studies in which correlations between the use of electric devices such as electric blankets, hair dryers and electric razors and the risk of certain tumour diseases have been observed [8, 9].

2.2.3 The measurement of magnet fields with magnetic field mats

The magnetic fields of three of the magnetic field mats available on the Swiss market were measured by the Zurich University of Applied Sciences on behalf of the FOPH [10].

The three therapeutic magnetic field mats were surveyed at a distance of 1.5 cm, 10 cm and 30 cm above the mattress for each of the highest intensity levels. The average magnetic field strength at a distance of 1.5 cm above the surface was found to be 17 to 94 µT (microtesla) depending on the mattress, thereby exceeding the reference level for the general population. The maximum magnetic field strengths reached between 133 and 461 µT, depending on the mattress, thus exceeding the reference level by 5 to 11 times (Table 2).

Table 2: Magnetic fields for three different mats at a distance of 1.5 cm

	Average magnetic field strength	**Maximum magnetic field strength**	**Exceeds the international limit value by**
Mat 1	94 µT	461 µT	11 times
Mat 2	47 µT	170 µT	9 times
Mat 3	17 µT	133 µT	5 times

Figure 2 shows the maximum measured magnetic field as a function of the distance.

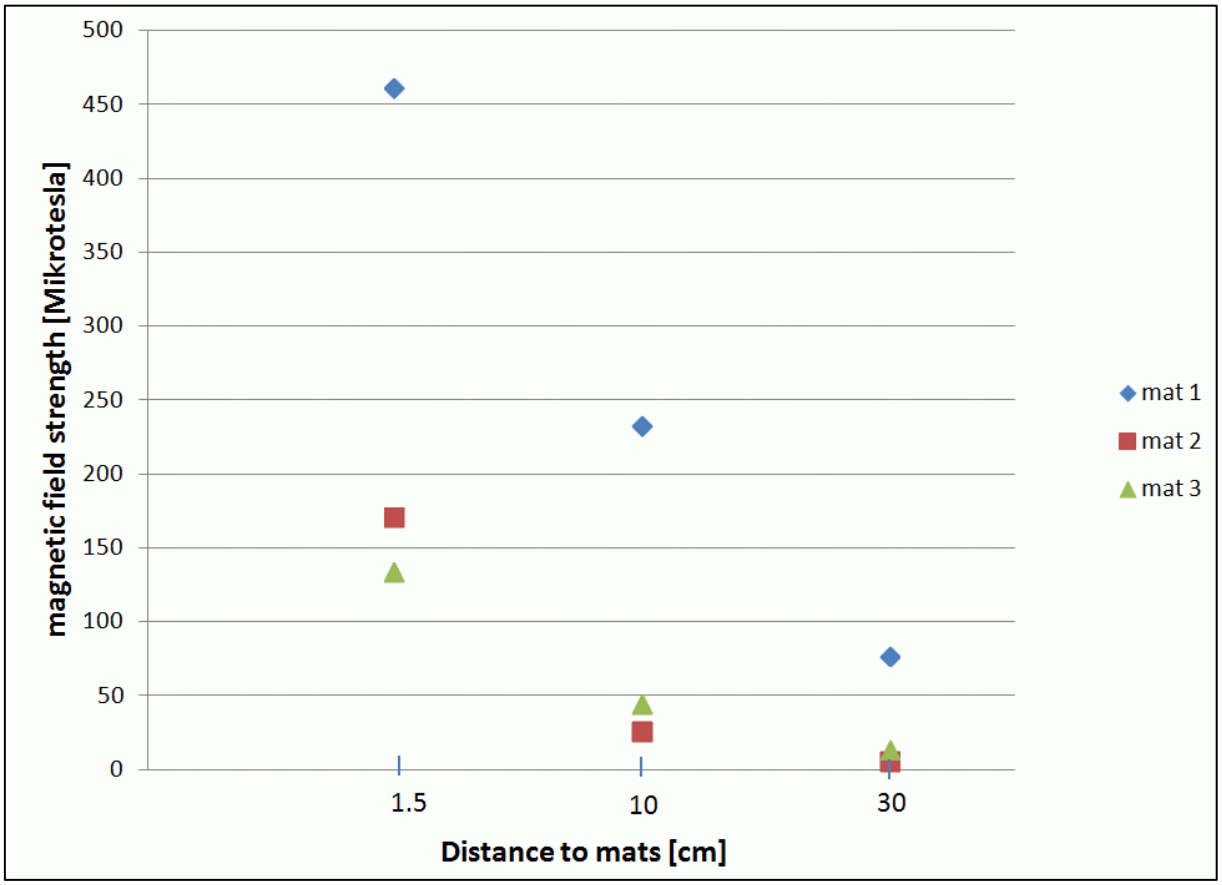

Figure 2: Maximum magnetic fields of the three mats as a function of the distance

Figure 3 shows the distribution of the maximum magnetic fields on the three mats. The measurements show that the exposure increases significantly towards the middle of the mat.

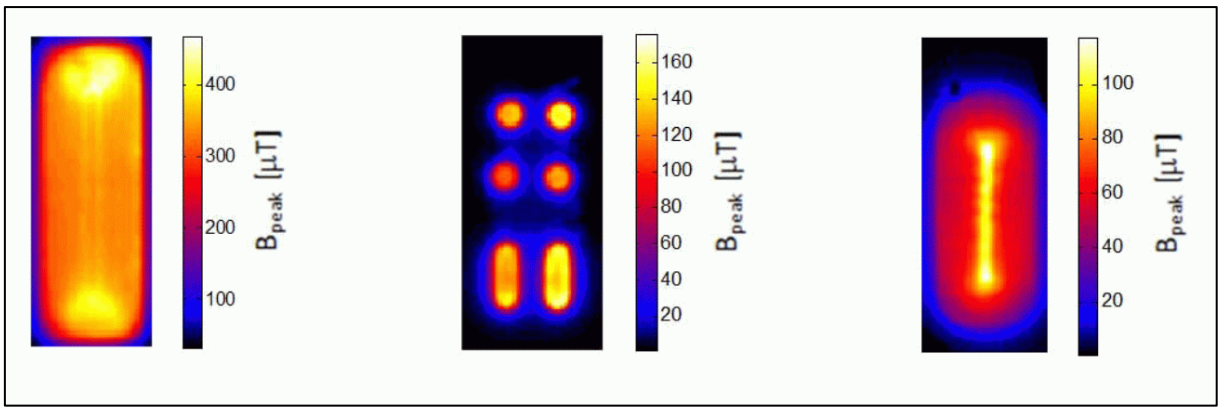

Figure 3: Comparison of the maximum magnetic flux density of the three magnetic mattress pads at a distance of 1.5 cm

As the reference level was exceeded by all mats, additional tests were carried out to determine whether the magnetic fields of the three mats also exceeded the basic restrictions.

2.2.4 Simulation of body currents

Body currents that flow in persons exposed to a magnetic field cannot be measured directly; rather they have to be calculated with computer simulations in virtual model persons. The research foundation IT'IS in Zurich, on behalf of the FOPH, carried out these simulations for model persons lying in various positions directly on top of a magnetic field mats. The simulations of the body currents also took into account, besides the exposure to the magnetic field, the gender, age, physical build, anatomy, tissue properties and posture of the following virtual persons:

- Female, 26 years of age, 1.60 m, weight 58 kg
- Female, 26 years of age, 1.60 m, in the third, seventh and ninth month of pregnancy
- Foetus in the third, seventh and ninth month
- Boy, 6 years of age, 1.17 m, weight 20 kg
- Male, 34 years of age, 1.74 m, weight 70 kg

The body currents were simulated in both the peripheral nervous system (PNS) and the central nervous system (CNS).

The results of the computer simulation show for a person who is lying on their back in the middle of the mat that the basic restrictions for body currents in the peripheral body regions are mostly reached or exceeded in all model persons and for all three magnetic field mats (Figure 4). For the central nervous system, the limit values were exceeded only for one magnetic mattress pad (Figure 5).

The highest body currents are induced when the model person is not correctly positioned on the magnetic field mat. The highest body currents in the peripheral body region occur in folds of the skin such as in the armpit or groin. The highest calculated body currents in the central nervous system were in the brain at the back of the head.

Figure 4 and Figure 5 show the body currents that were induced in the pregnant model person in the supine position. Figure 6 illustrates the modelled body currents in unborn children for various growth phases during pregnancy. In mat 1 the body currents in the foetus exceed the limit values in the 7th and 9th month. In the 3rd month the calculated body currents are below the limit value. For mats 2 and 3 the limit values were not reached in any development stage of the foetus. If the pregnant woman lies on her side on the mat, the results are very similar. This is mainly due to the fact that the distance separating the foetus from the mat is similar in the supine and lateral positions.

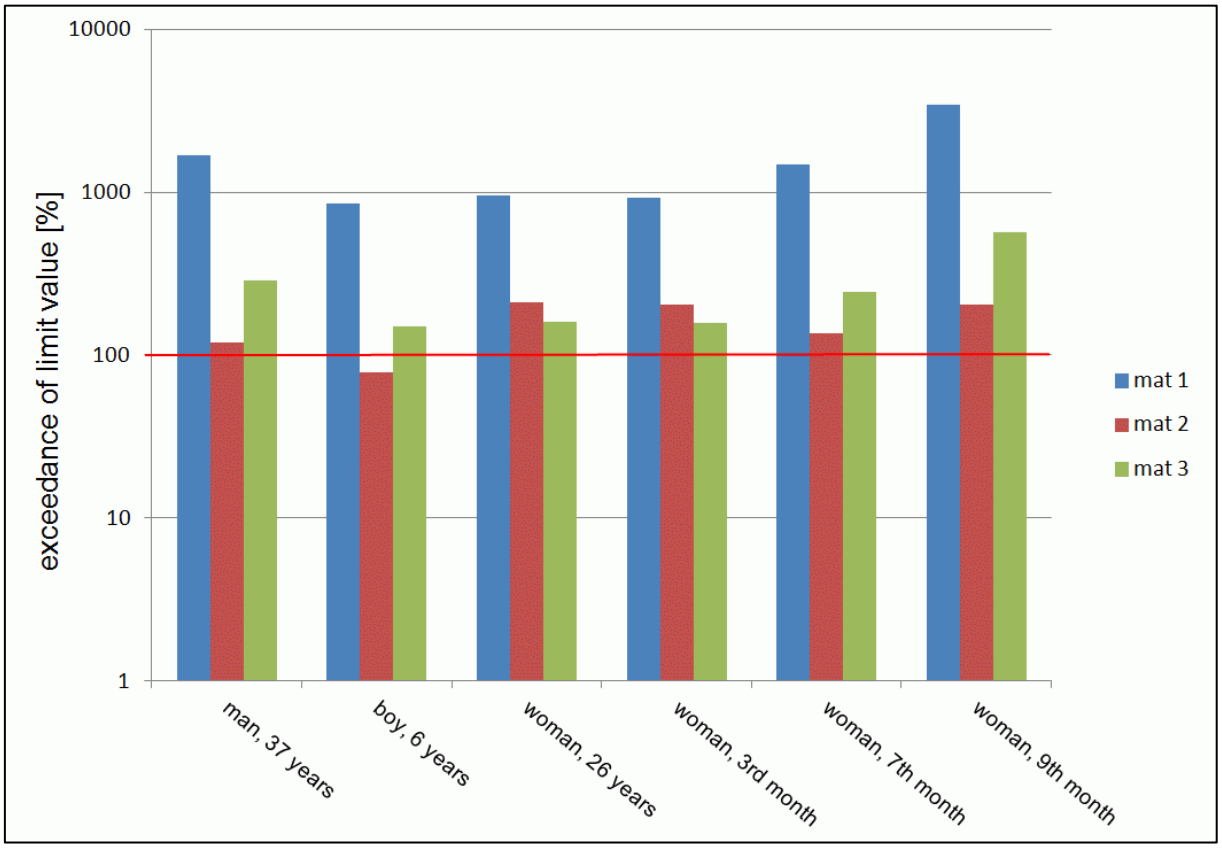

Figure 4: Calculated values expressed as a % limit value for body currents in the whole body (peripheral nervous system PNS) of model persons, who are lying in the middle of the mattress and in the supine position on the magnetic mattress pad. 100% corresponds to the ICNIRP limit value for the general population.

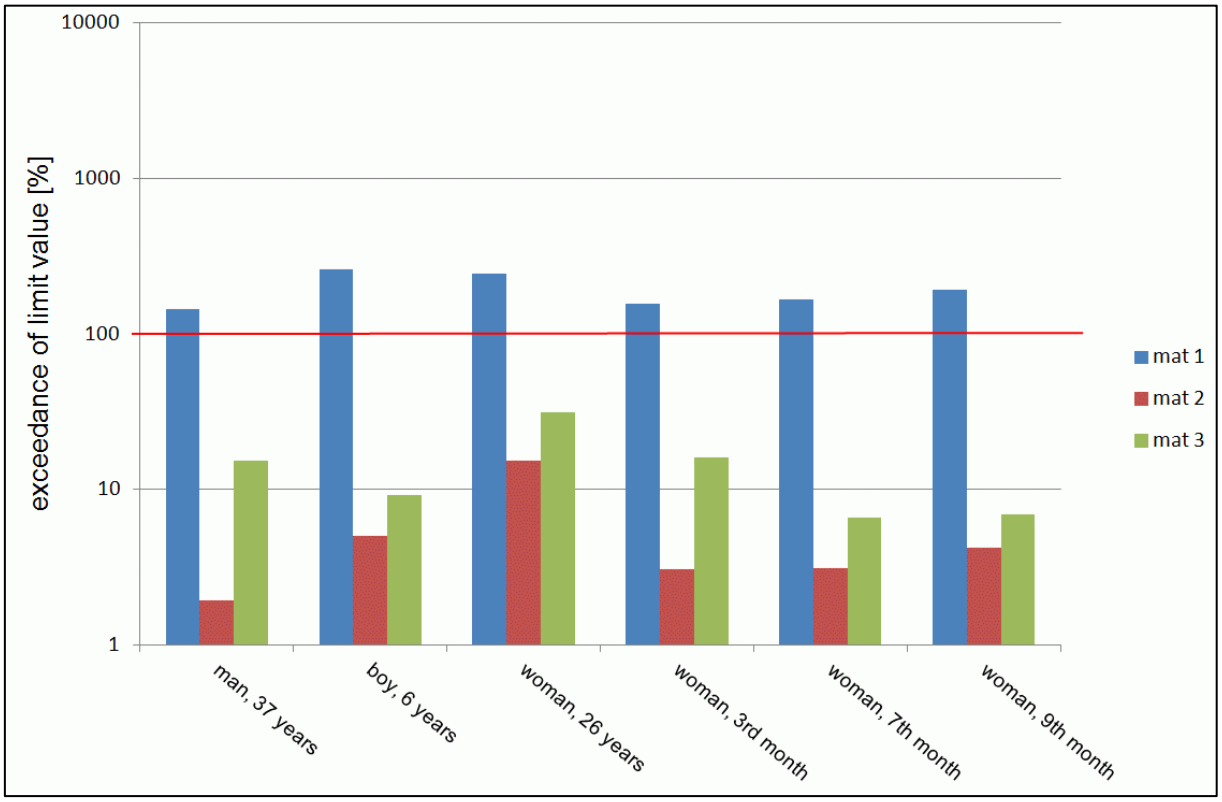

Figure 5: Calculated values expressed as a % limit value for body currents in the central nervous system (CNS; brain and spinal cord) of model persons, who are lying in the middle of the mattress and in the supine position on the magnetic mattress pad. 100% corresponds to the ICNIRP limit value for the general population.

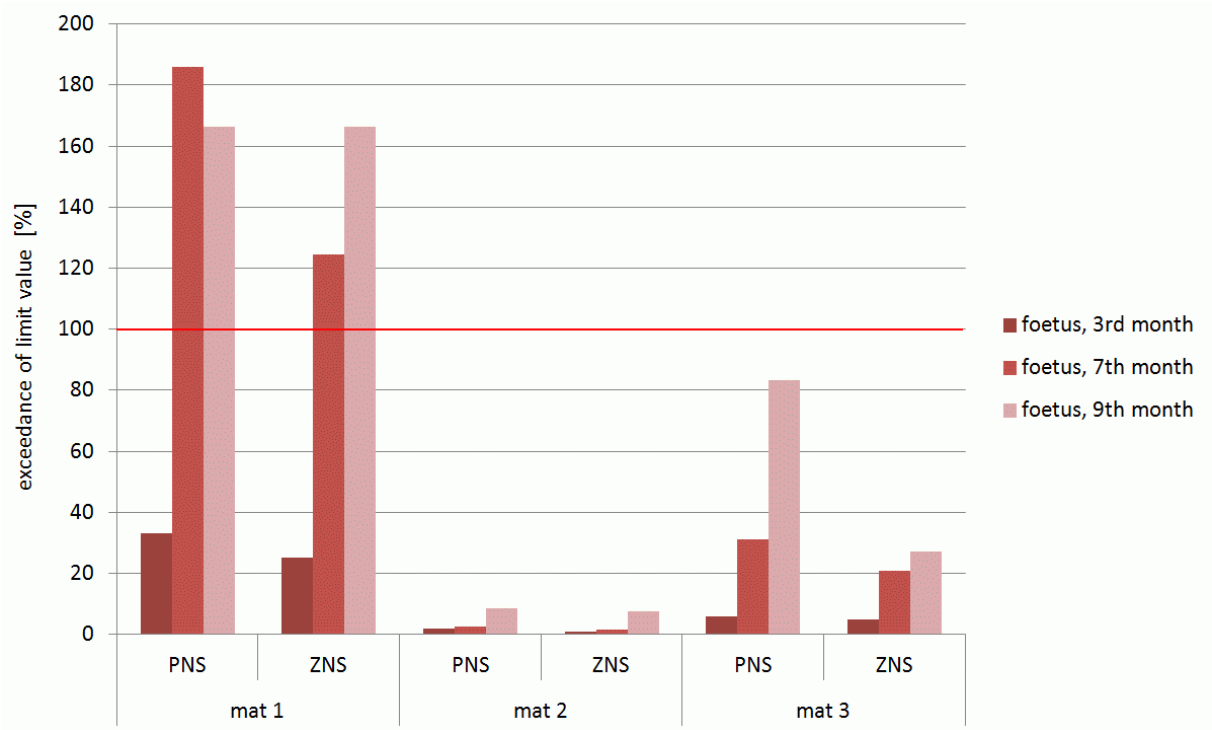

Figure 6: For body currents in the foetus in the whole body (peripheral nervous system, PNS) and in the central nervous system (CNS; brain and spinal cord) when the mother is lying in the middle of the mattress and in the supine position on the magnetic mattress pad. 100% corresponds to the limit value for the general population.

2.2.5 Effect of magnetic field mats on pacemakers:

Caution should be exercised with magnetic field mats that are used at maximum power. Unipolar pacemakers and bipolar pacemakers in unipolar mode are particularly susceptible to interference from magnetic fields

2.2.6 Side effects when using therapeutic magnetic field mats

In the twelve studies evaluated by the Swiss Tropical and Public Health Institute, no acute side effects were reported for the use of magnetic field mats. However, there were no studies that specifically dealt with investigations of side effects. Undesirable long-term effects were not investigated in any study, either.

3 Assessment of the use of therapeutic magnetic field mats

In the case where magnetic field mats are declared as medical devices, they do not have to comply with limit values. However, the manufacturers have to prove that the benefits of their products are greater than the risk accompanying the treatment. According to the systematic literature review man-

dated by the FOPH, at present there are only 12 scientifically published randomised double blind studies on the therapeutic use of magnetic mattress pads (Hug und Röösli 2011). These studies do not provide any overwhelming proof of the benefits and the efficacy of magnetic mattress pads. Moreover, the fields generated by these mattresses are comparatively high and possible health risks from long-term use cannot be assessed. Consequently, the use of magnetic mattress pads cannot be recommended at the present time. In accordance with the precautionary principle, children and pregnant women should avoid using such mattresses.

4 Regulation in law

4.1 Reimbursement by the health insurers

Swiss health insurers do not reimburse the costs of magnetic field mats. The legal bases for the reimbursement of products and devices as a standard cover of the health insurance are governed by the law on health insurance (KGV; SR 832.10). The Health Care Benefits Ordinance (KLV; SR 832.112.31) that is based on this law has a list of products and devices that may be covered by the obligatory health care insurance. Magnetic field mats are not in this list.

4.2 Regulations for medical devices

The magnetic field mats examined in this fact sheet were declared by the manufacturers as medical devices pursuant to the ordinance on medical devices (MepV, SR 812.213). Consequently, the manufacturers have to manufacture them in accordance with the applicable regulations and standards and prove a medical benefit or a therapeutic effect. In addition, the products have to be designed and manufactured such that their use under the intended conditions and for the intended purposes neither endangers the clinical state and safety of the patients nor the safety and health of the user or of third parties. An assessment process exists for medical devices. This assessment process is carried out by a notified body that delivers a CE mark and a four digit number for tested products.

Medical devices do not necessarily have to respect the conventional international limit value recommendations that for example apply to domestic appliances. The reason for this is that the benefits and risks associated with medical devices are to be weighed. Limit values may then be exceeded if the treatment has a corresponding benefit, and the consequences of exceeding the limit value are smaller than the benefits of the treatment.

4.3 Regulations for on electrical low-voltage equipment

The medical device Ordinance is not applicable to magnetic field mats without medicinal purposes, such as for example for cosmetic purposes or wellness applications. The safety of electrical low-voltage equipment is regulated in Switzerland by the Ordinance on electrical low-voltage equipment [12]. It stipulates that low-voltage appliances may only be marketed if they comply with the safety objectives of Annex I of the European (EC) Low Voltage Directive [13]. The European directive states that low-voltage appliances must be designed and created in such a manner that protection against hazards is guaranteed when they are used as intended and adequately maintained. To this end, technical measures, among other things, must be defined to ensure that no hazardous radiation is emitted. Manufacturers of low-voltage appliances must obtain a Declaration of Conformity for a product from

the time at which it is brought onto the market; this declaration states that the product complies with these requirements. The requirements for individual products are specified in the technical standards. For the electromagnetic fields created by domestic appliances, the standard “SN EN 62233:2008 Measurement methods for electromagnetic fields of household appliances and similar apparatus with regard to human exposure”, which refers to the standard “ICE 62233:2005” of the same name, applies. According to the standard SN EN 62233:2008, the conformity criteria for compliance with the requirements correspond to the limit recommended by the EU [3]. Manufacturers are responsible for ensuring that their appliances comply with the conformity criteria. In Switzerland, no authority checks whether magnet field mats meet these standards (23.4244 | Mobile phones emit more radiation than permitted. The time has come to check the NIR limits in Switzerland too! | Item of business | The Swiss Parliament – available in German, French and Italian).

5 Technical data of magnetic field mats

Frequency
Low frequency: 50 Hertz (Hz) when the magnetic field mat is switched on
Medium frequency: 0.01 Hz to 20 kHz Kilohertz (kHz) (source: distributor/manufacturer)
Measured: 30 to 250 Hz [10]

Signal forms
The three measured magnetic field mats generate three different signal forms. The duration of the individual signals, the form of the signals and the number of impulses per signal are different. The signals of all the surveyed magnetic field mats are triangular.

The various programmes of each mat differ in the temporal sequence of the individual signals, in the amplitude, in the number of signal peaks or in the repeat frequency of the individual signal packets.

Frequency spectra
The measured magnetic field mats operate principally with very low frequency fields. However, the band width is extended by the triangular signal and the frequency spectrum is broadened by up to 2000 Hertz. In Table 3 are presented the three main frequencies (i=1; i=2; i=3) of a signal packet.

Table 3: An overview of the three main frequencies (i=1; i=2; i=3) of the three magnetic mattress pads

	Mat 1 Frequency [Hz]	**Mat Frequency [Hz]**	**Mat 3 Frequency [Hz]**
i=1	3.8	32	3
i=2	15	210	24
i=3	210	1667	238

6 Literature

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