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Abstract

Ultrasound is utilized for many purposes in medicine, beauty care, industry and consumer products. In the past years, the use of ultrasound has increased particularly in the field of beauty care, where it has applications such as skin cleansing, fat removal and facilitating conditioner absorption. At worst, the use of ultrasound may have serious health effects, and therefore ensuring safety is essential. Factors that significantly affect safety include equipment technology, the skills of the user, the instructions provided and the state of health of the customer.

The medical use of ultrasound is subject to the Radiation Act (592/1991). The Radiation Act specifies no limits to ultrasound exposure. The safety of medical equipment is also regulated by the Act on Healthcare Equipment and Supplies (629/2010). Nowadays, limiting the non-medical ultrasound exposure of members of the public is necessary, as the use and applications of ultrasound in consumer products and beauty care services have increased significantly. Limitations to ultrasound should be taken into account in the major overhaul of the Radiation Act.

The health effects of ultrasound have been discussed in overviews by international specialist organizations. The International Commission on Non-Ionizing Radiation Protection (ICNIRP) and the World Health Organization have assessed the health effects of airborne ultrasound. Nowadays, particularly in beauty care, ultrasound exposure occurs in direct skin contact, and the effects of ultrasound may reach the entire body. Many international organizations, including the World Federation for Ultrasound in Medicine and Biology (WFUMB), the Advisory Group on Non-Ionizing Radiation (AGNIR) and the Strahlenschutzkommission (SSK) have made recommendations for the safe use of ultrasound in exposure through skin contact.

This report presents the purposes of use of ultrasound, its health effects and the international recommendations for limiting exposure to it. The report pays special attention to the use of ultrasound in beauty care and offers a suggestion for limiting non-medical exposure to ultrasound in the upcoming Radiation Act. In addition, the report specifies the contraindications that should be taken into account in ultrasound treatments in beauty care.

Contents

1 Introduction

The aim of this project was to establish ways to ensure the safety of ultrasound in beauty care and other non-medical applications, as well as to seek ways to organize regulation, regulatory control and guidance appropriately to prevent health risks from the use of ultrasound without imposing unnecessary restrictions to practices. The results of the project are intended to be utilized in the major overhaul of the Radiation Act. The report briefly describes the use of ultrasound and the technology of equipment that produces ultrasound, as well as possible health hazards, legislation and standardization. In addition, a short chapter has been dedicated to discussing infrasound and its safety.

2 Basic information on ultrasound

2.1 What is ultrasound?

Ultrasound refers to mechanical waves with frequencies higher than the upper audible limit of human hearing (> 20 kHz). Ultrasound always requires a medium to propagate, using pressure variations for propagation. Ultrasound propagates well in liquid media, but will not propagate through a vacuum. The shape of the ultrasound beam depends on the geometry and frequency of the source. In practical applications, ultrasound normally contains several frequencies. The beam can be modified, which is utilized especially in diagnostic applications.

In addition to the frequency, describing an ultrasound field requires knowledge of the sound pressure, referring to the difference between the ambient atmospheric pressure and the local pressure caused as a sound wave passes the observation point. The attenuation of ultrasound depends on the frequency and the properties of the medium, and may therefore not occur predictably and evenly. At the interface of media, a part of the ultrasound is reflected, while some is refracted as it propagates to the other side of the interface. Ultrasound's behavior on the interface depends on the properties of the media. On the interface of the bone, reflection is strong, and at an air interface, ultrasound is almost entirely reflected. For ultrasound imaging and procedures, coupling gel is placed between skin and the transmitter in order to improve the propagation of ultrasound inside the body.

In practical applications, the ultrasound wave is typically focused by using a suitably shaped source or a lens or some other means. Focusing the wave improves the resolution in diagnostics. Due to the greater intensity achieved through focusing, ultrasound may also be used to break selected targets, such as kidney stones. Detailed information on the basics of ultrasound is available in reports by HPA and SSK (HPA 2010, SSK 2012) and Leighton's publication (2007).

The article by INIRC (1985) covers the definitions, quantities, units and terminology concerning protection from non-ionizing radiation. Ultrasound has been included in non-ionizing radiation. The quantities used to establish exposure limits for ultrasound are acoustic intensity (W/m^2) and, for airborne ultrasound, sound pressure (dB).

2.2 Purposes of use of ultrasound

Ultrasound is utilized for various purposes in the fields of medicine, beauty care services, industry and consumer products. In the last few years, new types of applications have been introduced at an increasing pace. The difference between medical and beauty care-related procedures is somewhat ambiguous, as the same procedures are performed for both medical and cosmetic purposes, sometimes also with the same equipment. Examples of purposes of use of the equipment are listed below, adapted from the Ahmadi publication (2012).

Medical applications of imaging and treatments include:

- ultrasound scans (e.g., fetuses and internal organs)
- ultrasonic drug delivery (sonophoresis, phonophoresis)
- dental cleaning, removal of dental calculus and root canal therapy
- different types of removals and lithotripsy (including kidney stones and gallstones, blood clots)
- surgery
- ocular surgery
- fat removal
- the absorption of medicinal substances.

Beauty care applications include:

- skin scrubbing
- fat removal
- hair removal
- skin cleansing
- the absorption of conditioners.

Industrial applications include:

- ultrasound cleaning
- soldering
- welding plastic and metal
- processing and polishing parts
- material quality control.

Home use applications include:

- ultrasound washers
- door openers
- remote controls
- burglar alarm systems
- pest repellants
- guidance devices for the blind
- fetal heartbeat monitoring device.

Other applications include:

- 3D and 4D imaging of the fetus for non-medical purposes
- localization and navigation in water and air (SONAR and SODAR).

2.3 Effects of ultrasound on the human body

Airborne ultrasound primarily affects the external organs of the body, such as ears and eyes. In medical and beauty care-related procedures, equipment utilizing ultrasound is used with direct skin contact. The treatment head of the device is typically moved around during the procedure. The equipment's effects on the body are either based on the tissue warming up (thermal effect) or the cavitation phenomenon.

Thermal effect

When used at higher frequencies, the effect ultrasound has on the tissue is based on heating. The thermal effect normally becomes dominant when the frequency is increased from kilohertz (kHz) to megahertz (MHz) levels. Equipment based on the utilization of the thermal effect can be used with focused high power. These devices are often called HIFU (high intensity focused ultrasound) or HITU (high intensity therapeutic ultrasound) devices, and they have been used in surgical procedures for years (Lindberg 2013).

Cavitation

Ultrasound waves are propagated through tissue via pressure variations. When being propagated through liquid, ultrasound may produce bubbles and cause them to grow, vibrate or collapse. This phenomenon is called cavitation. One of the uses for the phenomenon is beauty care-related fat removal, the aim of which is to cause fat cells to collapse by inducing microbubbles in them. Equipment based on the use of cavitation normally operates at very low frequencies (kHz), and the effect can usually be achieved with low power levels.

2.4 Information provided by ultrasound equipment concerning exposure

The safe use of ultrasound equipment requires information about the properties of the devices. These properties include the preset values set by the user, as well as the information the device provides to the user during use. Requirements for these properties have been set especially in standards concerning medical equipment.

The IEC 60601 series of standards includes three standards that address the safety requirements of ultrasound equipment. These are IEC 60601-2-5 (physiotherapy equipment) (IEC 2009), IEC 60601-2-37 (ultrasonic medical diagnostic and monitoring equipment) (IEC 2007a) and IEC 60601-2-62 (high intensity therapeutic ultrasound (HITU) equipment) (IEC 2013a). All three standards contain the chapter "Accuracy of controls and instruments and protection against hazardous outputs", describing which parameters should be indicated to the user.

Physiotherapy equipment with continuous power must indicate the output power and the effective intensity. Physiotherapy equipment with modulated amplitude must display the temporal-maximum intensity and the temporal-maximum output power.

The parameters listed above are subject to the following accuracy requirements:

- The output power shall not differ more than ±20% from the actual value.
- The effective intensity shall not differ more than ±30% from the actual value.
- The effective radiating area shall not differ more than ±20% from the actual value.
- The maximum effective intensity of any treatment head shall not exceed 3 W/cm^2. The limitation applies also in the case of a device failure as specified in the standard.

Physiotherapy equipment must include a timer with a maximum timing not exceeding 30 minutes. The accuracy of the timer shall be better than ±10% of setting.

The standard on ultrasonic medical diagnostic equipment states that if a device is not capable of exceeding the thermal index (TI) 1.0 on soft tissue or bone, it is not necessary for the device to indicate the thermal index to the user. This also applies to diagnostic equipment used on the skull area. If a ultrasound diagnostic device is not capable of exceeding the mechanical index (MI) 1.0 through any method of use, it is not necessary to indicate the mechanical index. In case a device is capable of exceeding any of the index values mentioned above, the index must be indicated starting at value 0.4. The increment for the display of any index shall be no more than 0.2.

According to standard IEC 60601-2-62 (IEC 2013a), high intensity therapeutic ultrasound equipment must always display the expected temperature rise at the ultrasound focus point during the treatment, the entry power, the effective intensity of the entry power, an indication in case cavitation occurs at the target location, the level of the reflected power, and the thermal equivalent time.

The technical report IEC/TR 62799 by IEC (IEC 2013b) presents alternative quantities that would offer better tools for describing the thermal effect of medical diagnostic equipment than the currently used TI. The technical report is fairly recent, and it can be assumed that the employment of new quantities is still at an experimental stage. For instance, the TETI (thermally equivalent time index) might offer a good indicator for thermal effects, as it takes time into account as well as the temperature, thus providing an improved way of indicating exposure.

2.5 Measuring ultrasound

Ultrasound that impacts the body can be measured in a water tank using a hydrophone. The measurement system is presented in figure 1. Calibrated devices for low frequencies are not easily available. Additional information on carrying out the measurements is available in parts 1–3 of the standard IEC 62127 for medical applications (IEC 2007b+c+d).

The costs of the measurement systems have been estimated in a report commissioned by Strålsäkerhetsmyndigheten (SSM), the Swedish radiation protection authority (Lindberg 2013). According to the estimate, the price of a commercial hydrophone falls between EUR 7 000 and EUR 24 000, depending on the manufacturer. According to the authors of the report, HIFU devices should be measured with a fiber optic sensor.

The standard IEC 61828 (IEC 2001) describes methods that can be used to specify the properties of the ultrasound field of a focused ultrasound device.

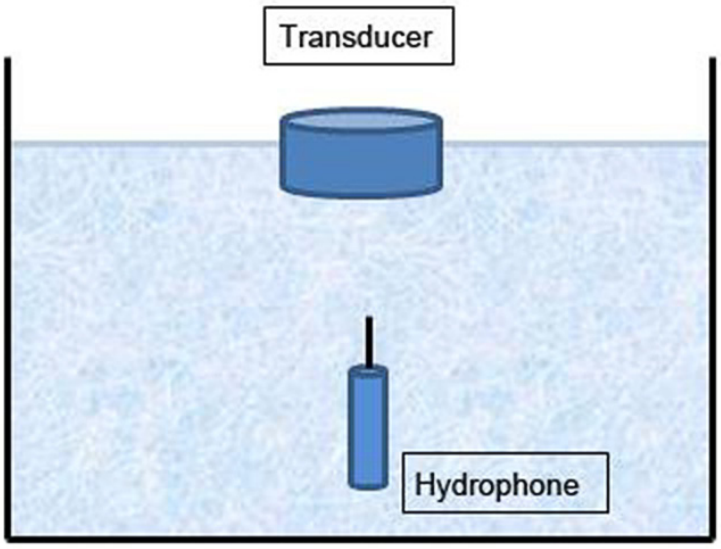

Figure 1. Measurement system based on the use of a hydrophone. Figure from the report by SSM (Lindberg 2013).

3 Use of ultrasound in beauty care

Uses of ultrasound in beauty care include skin cleansing, facilitating conditioner absorption, skin rejuvenation and fat removal. In beauty care-related applications, the treatment head transmitting ultrasound is in direct contact with the body, allowing the ultrasound to penetrate into the body. The aim of the treatments is to induce a mechanical or thermal effect on the body through the use of ultrasound, leading to the desired results. For instance, in skin rejuvenation treatments, the objective is to warm the hypodermic layers and thus impact the skin's collagen production. The aim of fat removal is to use ultrasound to break up the subcutaneous fat layer (cavitation), which should allow metabolism to process the fat out of the body in time.

In recent years, the use of these devices has increased, and will likely continue to increase. The equipment is constantly developing, and new types of applications are introduced to the market every year at an increasing pace.

3.1 Frequency of use and number of devices

Radiation and Nuclear Safety Authority (STUK) oversees the use of non-ionizing radiation in beauty care services. Operators are not subject to any reporting or permit requirements. However, surveillance and interest group cooperation provide relatively comprehensive information on the frequency of use.

The Swedish radiation protection authority SSM conducted a survey on the beauty care-related ultrasound devices available in the Swedish market (Lindberg 2013). Ten devices were discovered, nine of which operated at frequencies between 25 and 40 kHz and one at a frequency of 200 kHz. Other technical specifications (e.g., intensity, focal depth, constant/pulsing signal) were hard to find. In addition to ultrasound, all but one of the devices also utilized RF radiation, laser or both.

3.2 Ultrasound cavitation-based procedures in Finland

In spring 2016, STUK conducted a survey on the services provided by cosmetologists in Finland. The survey covered beauty care service providers and medical clinics offering ultrasound cavitation. The survey was conducted via an internet search. The survey found a total of 81 beauty care service providers with websites containing the words cavitation and ultrasound. More than half (50) of the service providers only mentioned ultrasound and cavitation without specifying which devices or techniques they employed. The rest mentioned the device or its manufacturer, or the name was available in a device photo depicting the service. Five service providers also mentioned the frequency at which the device operates.

Terminology in the field varies, which is why, in some cases, it was not clear whether the service offered was actual ultrasound cavitation or just fat removal performed with the use of RF technology, as the word "cavitation" is sometimes erroneously used as a synonym for fat removal.

Mentions of the contraindications of the treatments varied. A total of 31 operators mentioned pregnancy as an obstacle to the treatment on their websites, or stated that it must be otherwise taken into account, such as by asking for a doctor's approval for the treatment. The websites of 48 operators contained no mention of the contraindications whatsoever. Two websites could not be accessed due to a data security alert. In addition to the websites, the contraindications of the treatments may be covered at the place of treatment. This was not clarified. The treatment counter-indications mentioned on the websites of beauty care service providers are listed in Appendix 3.

The survey also covered medical clinics and other healthcare units offering ultrasound cavitation treatments. All of them mentioned the device used to perform the treatment. As far as the topic was addressed on the websites, it seems that beauty care service providers and healthcare units use different equipment. The treatment counter-indications mentioned on the websites of medical clinics are listed in Appendix 4.

In September 2016, STUK ran an internet search to collect information on the prices of ultrasound cavitation treatment. The search was targeted at the same group of operators found when searching for enterprises offering ultrasound cavitation. The treatment fees varied between EUR 40 and EUR 400 for the treatment of a single area. Increasing the number of treated areas in one treatment session normally reduced the average price, as did a series of several treatment sessions. The highest price for a single session was EUR 2 900, comprising treatment on 10 different areas. Some of the service providers stated that to ensure safety, no more than two areas can be treated during a single treatment session. Some of the service providers determined the price of the service on the basis of the time used on the treatment.

3.3 Accident cases in Finland

Finding information on the harmful health effects encountered in beauty care is difficult. There are no registers of equipment or treatment places, and in practice, operators do not report accidents or close-call situations to authorities. Thus, it is difficult to form a reliable image of accident cases and their number. Some cases of skin burns related to ultrasound use in Sweden and Norway have come to STUK's knowledge thanks to cooperation between authorities. No cases have been reported in Finland.

4 Possible health effects

Airborne ultrasound is nearly entirely reflected on the skin surface. Ultrasound can be coupled into the body keeping the source of exposure in direct contact with the skin, allowing the effects of ultrasound to reach the entire body. The effects of ultrasound on humans vary depending on whether the exposure is airborne or occurs via skin contact (Leighton 2007, HPA 2010).

The health effects of ultrasound depend on the frequency and power level used. The effects are normally linked to threshold values, which means that they only occur when exposure exceeds a certain level. Sections 4.1–4.3 present possible effects caused by airborne exposure and exposure via skin contact, with a separate section on the exposure of pregnant women. The Ahmadi publication (2012) contains a list of the biological effects of both airborne and skin contact exposure.

4.1 Airborne exposure

Airborne ultrasound primarily affects the external organs, such as ears and eyes. Reported harmful effects include hearing loss, pain sensations, vertigo and tinnitus (WHO 1982, IRPA 1984, Lawton 2001, HPA 2010).

4.2 Exposure through skin contact

Various types of health effects are possible when ultrasound is conducted into the human body via a transducer in direct skin contact. The effects largely depend on the method used, the power level and frequency, as well as the properties and temperature of the tissue. The effects have been extensively discussed in many compilation articles and reports (NCRP 2002, Leighton 2007, O'Brien 2007, Humphrey 2007, HPA 2010, SSK 2012). Different types of health effects collected from these publications are presented below, taking into account comments by medical experts. All effects are not listed; instead, the point is to offer examples of the different types of possible effects. The examples do not address the likelihood or seriousness of the effects.

Harmful health effects are only caused if certain levels are exceeded. Possible cellular effects of ultrasound include tissue inflammation, blisters forming and damage to blood vessels and the nervous system. In addition, excess temperature rise caused by ultrasound may cause pain and result in necrosis in the tissue. Necrosis may also occur in tissue that has not been deliberately exposed. For example, due to bone's high ultrasound absorption rate, bone necrosis may be caused by treatments that are targeted at a certain area of the body (e.g., buttocks and thighs) at frequent intervals.

Ultrasound can impact the movement of substances inside the body. This can be taken advantage of, as is the case in ultrasound-assisted drug distribution, conducted at frequencies of 20–100 kHz (low-frequency sonophoresis) to substances with a high molecular weight, and at frequencies higher than 700 kHz to substances with a low molecular weight (Polat 2011).

Ultrasound can also be used to heat up tissue. The temperature rise has uses in, for instance, traditional physiotherapy, which is covered in the healthcare standards sections of this report. If the treatment is not performed appropriately, the temperature rise may be too excessive. This may cause pain and lead to tissue damage. Rapidly rising temperature may even result in necrosis in the tissue. Rapidly heating up the skin may cause changes to the tissue, such as trabecular tightening (Wall 1999). One of the harmful health effects of temperature rise is tissue inflammation. This may also occur if, for instance, fat cells have been mechanically damaged.

The vibration may cause mechanical damage to the cell membrane, cell or cellular structure. This is made more likely by high ultrasound pressure and power levels, such as when using HIFU devices

for extracorporeal shockwave lithotripsy (ESWL) in health care. This effect is used deliberately in medical treatment, but it can also be utilized in beauty care. Related harmful effects may include cellular damage, structural damage and internal bleeding. They are most likely when the area to which ultrasound is applied contains tissue and/or structures that do not require treatment. For instance, this may occur when the area to be treated is large, or ultrasound penetrates too deep or has not been sufficiently focused.

Momentary cavitation may cause cell membranes to open up and/or be damaged and cells and tissue structure to be destroyed. If this occurs, the tissues of the gas exchange system, such as the lungs and gas-containing liquids, are especially at risk. Small gas bubbles that already exist within the tissue, for instance, at the borders of lungs, may cause cavitation even at the ultrasound levels used for diagnostic purposes. This may cause damage to small vessels, which may result in microbleeding.

4.3 Exposure of pregnant women

Ultrasonography is widely used as an imaging technique during pregnancy, offering medical professionals detailed information about the fetus. Little research data is available on how the scanning affects the fetus, and the possibility of long-term effects cannot be excluded with certainty. However, the power levels used for imaging have not been found to have harmful health effects (HPA 2010). Medical ultrasound examinations (including scans of the fetus) are conducted in large numbers (a total of 640 000 examinations in Finland in 2015) (Suutari 2016). Neither STUK nor the physicians consulted for this report have knowledge of cases involving harmful health effects.

In cases of cosmetic treatments involving power levels high enough to cause health effects to the tissue, it is possible that also the fetus is affected. Thus, for instance, undergoing a cavitation treatment for fat removal during pregnancy may also result in harmful health effects to the fetus.

5 International recommendations

This chapter covers recommendations made by the most important international and national organizations concerning the airborne and skin contact-based use of ultrasound. A separate section has been dedicated to the devices used for medical purposes, as they are most widely used. Ultrasound has been utilized in health care for decades. The health effects of ultrasound are also best known in the field of health care, as many medical devices make use of the impacts that ultrasound has on tissues (e.g. gall stone lithotripsy).

ICNIRP (International Commission on Non-Ionizing Radiation Protection)

ICNIRP, the International Commission on Non-Ionizing Radiation Protection, makes recommendations for limitations on non-ionizing radiation. ICNIRP has published guidelines on limits of human exposure to airborne ultrasound (IRPA 1984). According to the guidelines, public exposure should be limited by keeping the sound pressure level under 70 dB at a frequency of 20 kHz, and under 100 dB at frequencies between 25 and 100 kHz. ICNIRP has started preparing new ultrasound guidelines. According to the leader of the group (Zenon Sienkiewicz), the target schedule for the guidelines' first version, which will be sent out for external comments, is fall 2017. The guidelines will likely also address exposure via direct skin contact. ICNIRP has published a statement on diagnostic devices using non-ionizing radiation (ICNIRP 2017), which also discusses medical ultrasound scans.

WHO (World Health Organization)

The World Health Organization studied the health effects of ultrasound in the Environmental Health Criteria 22 report published in 1982 (WHO 1982). WHO is currently working on an update to the ultrasound statement in collaboration with ICNIRP.

WFUMB (World Federation for Ultrasound in Medicine and Biology)

WFUMP is an international organization dedicated to the development of ultrasound use. The organization's activities include supporting international cooperation and distributing scientific knowledge concerning ultrasound. The organization has nearly 50 000 expert members, including physicists, researchers, engineers and sonographers. Among the members of the WFUMB is the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB). The members of EFSUMB, in turn, include national organizations from many European countries, such as the British Medical Ultrasound Society (BMUS).

WFUMB's publications include the following statements on ultrasound safety (http://www.wfumb.org/safety-statements/):

- The use of Doppler ultrasound should be restricted during weeks 11–14 or earlier in pregnancy by ensuring that the TI ≤ 1.0 and exposure time is kept as short as possible. The exposure time should normally be no longer than 5–10 minutes and should never exceed 60 minutes.
- The organization disapproves of the use of ultrasound for the sole purpose of providing keepsake or souvenir images of the fetus, unless the images are taken during a clinical examination. The use of ultrasound for non-medical purposes is not recommended unless carried out for education, training or demonstration purposes. When used for non-medical purposes, the TI should be less than 0.7 and the MI less than 0.3.

AGNIR (Advisory Group on Non-Ionising Radiation)

AGNIR is an independent advisory group on non-ionizing radiation. It reports to the English health authority Public Health England (PHE).

Commissioned by the Health Protection Agency (HPA), the predecessor of the PHE, AGNIR conducted a comprehensive study on the use and possible health effects of ultrasound (HPA 2010). The report also contains a comprehensive list of recommendations and limitations currently applied. Figure 2 contains a summary of the different sound pressure levels utilized in different applications.

The report by HPA also discusses the issue of fetal imaging. The report states that there is no reason to limit the clinical imaging of the fetus and the souvenir images created for the parents as a by-product. Carrying out the scans for the sole purpose of creating a souvenir image for the parents to keep is a different matter. The HPA also emphasizes that imaging requires expertise and training. According to the HPA, the popularity of this type of imaging is increasing, but it can be hard to justify as it offers no clinical benefits. According to HPA's recommendation, ultrasound scans should only be carried out by medical professionals who have been trained in ultrasound safety. Moreover, if something unusual is discovered from the scan, they are able to offer advice and the necessary instructions. As the scans have not been clearly proven to pose a health risk, future parents must make the decision of whether or not they want to have the images.

AIUM (American Institute of Ultrasound in Medicine)

AIUM is a multi-disciplinary medical association with a membership comprising more than 9 000 physicians, sonographers, researchers, students and other health care providers. AIUM is committed to promoting the safe and efficient use of ultrasound in medicine by training professionals and members of the public, conducting research, preparing recommendations and granting accreditations.

According to AIUM (Fowlkes 2008), a temperature rise of 2°C from the normal 37°C temperature induced with ultrasound does not cause any adverse biological effects during an exposure period of 50 hours (Fowlkes 2008). If the temperature rises 2–6°C above normal, the harmful biological effects become time-dependent. This dependency is presented in the formula:

$$6 - \frac{log_{10}(\frac{t}{60})}{0.6} \quad (1)$$

If the temperature rises more than 6°C, the time dependency is strengthened:

$$6 - \frac{log_{10}(\frac{t}{60})}{0.3} \quad (2)$$

A formula has been specified for exposure of less than five seconds:

$$9 - \frac{log_{10}(\frac{t}{60})}{0.3} \quad (3)$$

In formulas 1, 2 and 3, time t is indicated as seconds. Figure 3 contains a graphic presentation of the relationship between temperature and time, which has been derived from these formulas.

The formulas above are not applicable in situations in which radiation is targeted at a fetus. The fetus may develop serious developmental disorders if ultrasound increases its temperature by 4°C for a time longer than five minutes.

NCRP (National Council on Radiation and measurement)

In the United States, ultrasound has been used in health care and beauty care for a long time. NCRP has published three reports concerning ultrasound exposure (primarily related to medical imaging) and its health effects. The most recent of the reports (NCRP 2002) also covers other effect mechanisms in addition to those related to temperature increase.

Health Canada

Health Canada is the Canadian federal department responsible for maintaining and improving public health in Canada.

Health Canada (2001) has published recommendations for the use of ultrasound in diagnostics and medical, industrial and commercial applications. According to the recommendations, in medical use, the mechanical index produced by the device should be equal to or less than 1.9, and the derated spatial-peak temporal average intensity ($I_{spta.3}$) equal to or less than 720 mW/cm². For devices targeting ultrasound at the eye, the

equivalent recommended maximum values are 0.23 and 50 mW/cm², respectively. For monitoring the fetal heartrate, the maximum recommended value is 20 mW/cm². According to the report, temperature increase poses a risk to the fetus when the following exposure durations are exceeded:

- 39°C: 60 minutes
- 40°C: 15 minutes
- 41°C: 4 minutes
- 42°C: 1 minutes
- 43°C: 0.25 minutes.

Health Canada (1991) recommends that contact with a powerful source of ultrasound should always be avoided in industrial and commercial activities. The publication contains recommendations on reaching this objective. Table 1 contains the Health Canada (1991) recommendations as limiting values for airborne ultrasound.

Standards concerning ultrasound devices (IEC/CENELEC)

Some of the standards published by the International Electrotechnical Commission (IEC) and the equivalent European organization European Committee for Electrotechnical Standardization (CENELEC) cover safety factors related to the use of ultrasound. Part 1 of the standard IEC 60601 on medical equipment specifies general safety instructions to all medical electrical equipment (IEC 2005). The related standards on medical ultrasonic equipment do not set exposure limits to ultrasound (IEC 2009 and IEC 2007a).

In the IEC/EN standards for medical equipment, the safety requirements are based on the following different quantities depending on the purpose of use of the device:

- For physiotherapy equipment (60601-2-5), the effective output intensity per area, 3 W/cm².
- The safety effects of medical diagnostic equipment (60601-2-37) are assessed through the mechanical index (MI) and the thermal index (TI). The indexes are calculated using formulas 4 and 5, which are presented in standard IEC 62359 (IEC 2010). According to current knowledge, cavitation will not occur if the MI is below 0.7. A specification of the mechanical index in frequencies under 500 kHz (Figure 6) is presented in the Ahmadi publication (2012).
- There are separate standards for surgical operations, dental calculus removal and lithotripsy.
- For some devices, such as extracorporeal shock wave lithotripsy and HIFU equipment, no standards are available (Duck 2007).

The standard IEC 62359 (IEC 2010) describes the tests used to specify the indexes.

$$MI = \frac{peak\,rarefactional\,pressure\ (MPa)}{\sqrt{pulse\,medium\,frequency\ (MHz)}} \tag{4}$$

$$TI = \frac{transmitter\,output\,power\ (W)}{the\,power\,required\,to\,achieve\,1°C\,increase\,in\,the\,temperature\,in\,tissue\ (W)} \tag{5}$$

$$MI_{LF} = \frac{peak\,rarefactional\,pressure\,(MPa) - ambient\,pressure\ (MPa)}{\sqrt{pulse\,medium\,frequency\ (MHz)}} \tag{6}$$

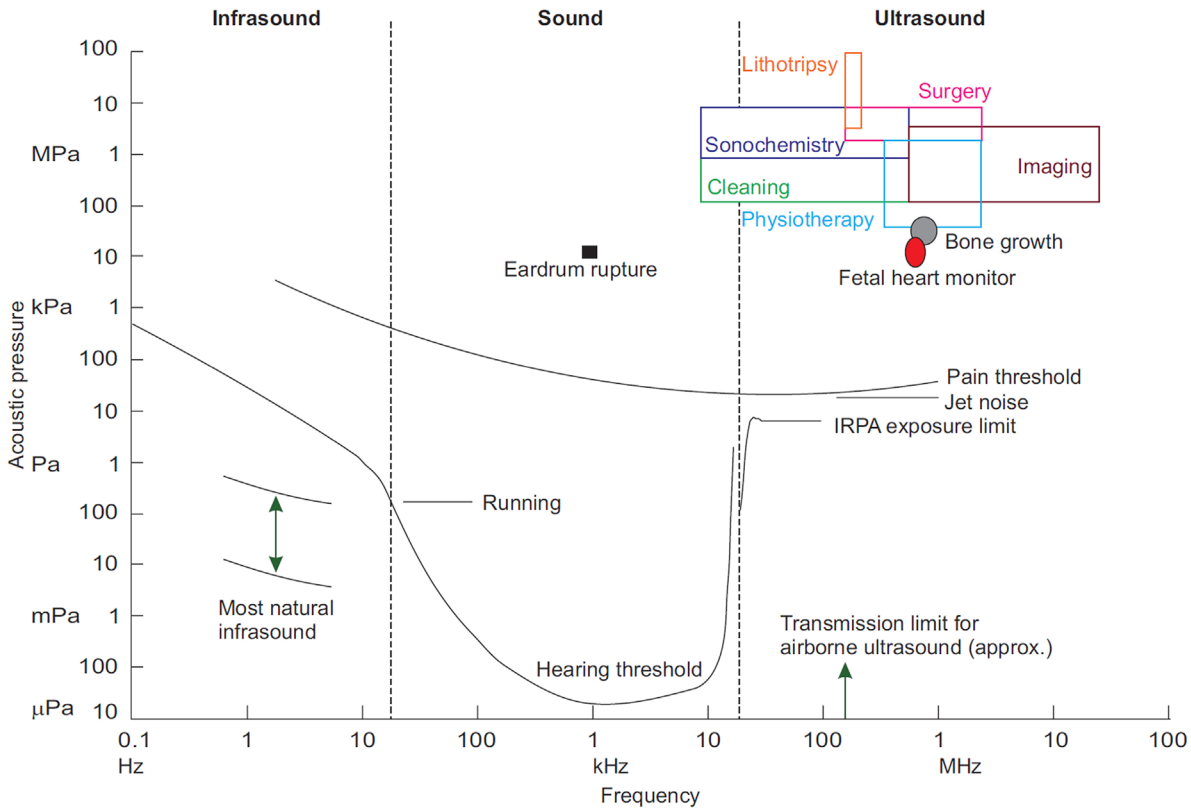

Figure 2. Sound pressure levels and applications as functions of frequency. Figure from the HPA report (2010).

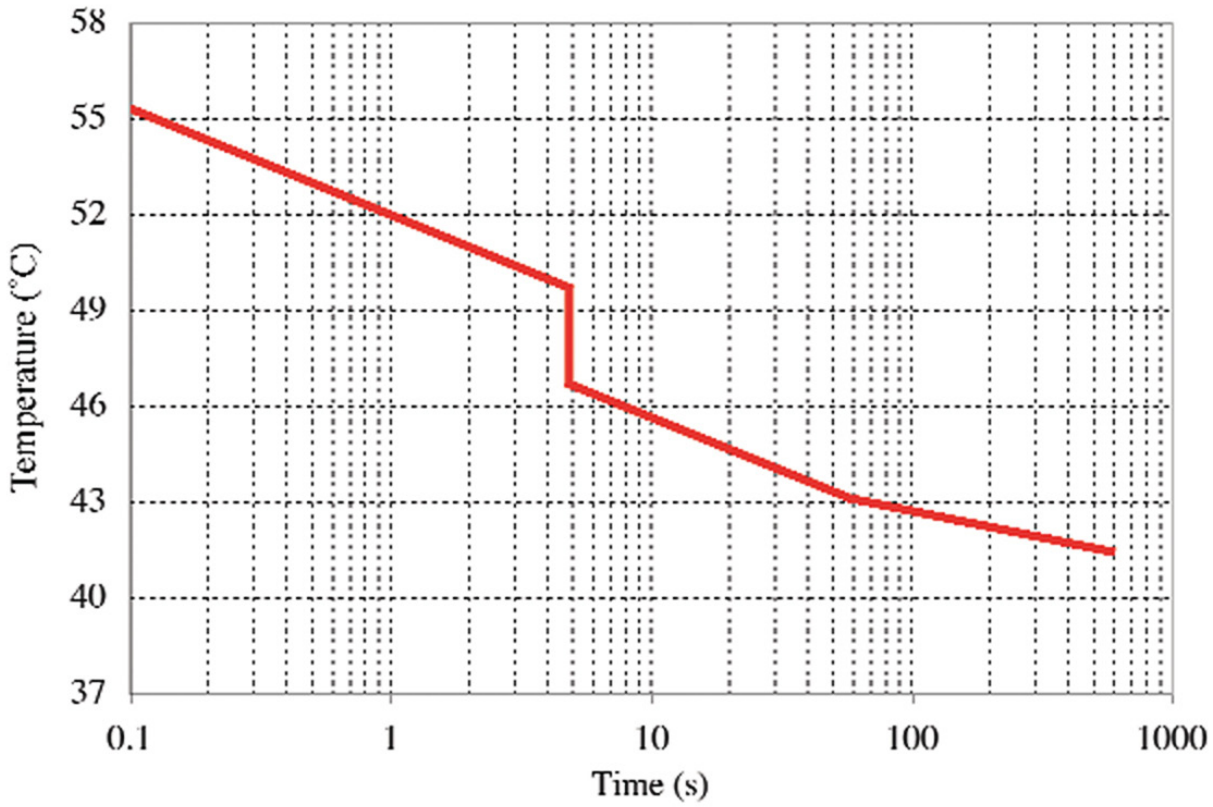

Figure 3. A graphic presentation of the relationship between temperature and time, indicating the conservative limit for exposure times, when the target of exposure is not a fetus. The figure is from the AIUM report (Fowlkes 2008), taken from the article by O'Brien et al. (2008).

Table 1. Health Canada's (1991) recommendations as the limiting values for airborne ultrasound. The limiting values are indicated in decibels, using sound pressure 20 µPa as the reference level. The frequencies are indicated for 1/3-octave bands.

1/3-octave band [kHz]	Sound pressure level limiting value [dB]
16	75
20	75
25	110
31.5	110
40	110
50	110

6 Regulation and control

The division between medical and cosmetic treatments is not straightforward, as some procedures are performed for both purposes. Thus, in many countries, both types of treatment are governed by the same norms.

6.1 Legislation in Finland

The medical use of ultrasound is subject to the Radiation Act (592/1991). The Radiation Act specifies no limits to ultrasound exposure. The safety of medical equipment is also regulated by the Act on Healthcare Equipment and Supplies (629/2010). The general provisions in the Consumer Protection Act (920/2011) are applied to the safety of consumer products and services. Currently, the Radiation Act contains no regulations related to the topic at hand. The draft of the Radiation Act currently being prepared covers non-medical exposure to ultrasound.

No uniform legislation or practices exist at EU level concerning the non-medical use of ultrasound. The directive concerning medical devices (EU 1993) will be replaced with an EU regulation (EU 2016) in the near future. The current version of the regulation also covers cosmetic devices. The application restrictions do not directly refer to ultrasound, but, depending on the interpretation, equipment such as ultrasound devices used for fat removal may be interpreted as high-energy equipment, thus falling within the regulation's scope of application. The EU regulation 1223/2009/EC on cosmetic products (EU 2009) discusses substances and mixtures used in contact with the external parts of the human body. Thus, the regulation is not applied to cosmetic devices impacting the internal parts of the body, or the treatments carried out using the devices.

According to statements STM/970/2014 and STM/985/2016 by the Finnish Ministry of Social Affairs and Health, demanding cosmetic treatments should only be carried out at health care units, regardless of whether they are conducted for aesthetic or medical reasons. Treatments such as ultrasound-based fat removal can be regarded as demanding cosmetic treatments.

6.2 Legislation in other countries

In Sweden, ultrasound equipment used for beauty care are not classified as medical devices, and they are not controlled by Läkemedelsverket, the authority responsible for monitoring medicinal substances. If necessary, Läkemedelsverket can classify a device as medical, if it deems that the use of the device involves great risks. The Swedish radiation protection authority SSM is also working to clarify the safety issues related to ultrasound, including the necessity of surveillance. In Sweden, it has been suggested that all treatments of this type should be banned for people under 18 years of age.

In Germany, the Strahlenschutzkommission published a report and proposal concerning the medical and non-medical use of ultrasound in 2012 at the commission of Bundesamt für Strahlenschutzin (BfS) (SSK 2012). The proposal included suggestions for bans or warnings concerning the use of ultrasound in imaging and treatment for non-medical purposes. Among the suggestions was the proposal to ban the use of HIFU equipment in beauty care when treatment is carried out for non-medical purposes. The proposal also mentioned introducing certifications for the users of the devices in order to ensure that those carrying out the procedures have sufficient knowledge and skills concerning ultrasound treatment. Based on information acquired from Bundesamt für Strahlenschutz in September 2016, the legislation is currently being prepared.

In France, a legal ban was introduced in 2011 prohibiting cosmetic fat removal procedures utilizing focused ultrasound, laser equipment, infrared radiation or radio frequency radiation

(Légifrance 2011). The law was amended in 2012, lifting the ban on the use of focused ultrasound, infrared radiation or radio frequency radiation. In France, a decree is currently being prepared to prohibit non-medical imaging of fetuses (EU notification 2016).

In Italy, a draft decree has been introduced addressing cosmetic treatments on the basis of medical equipment standards. The draft is very detailed and contains guidelines and requirements specifically for each type of device (EU notification 2015).

In the United States of America, ultrasound has been used in health care and beauty care for a long time. The US Food and Drug Administration (FDA) has classified aesthetic ultrasound equipment as sufficiently high-risk to be regarded as medical equipment and processed in accordance with medical standards, falling under risk class II (FD 2011a, FDA 2011b).

In Canada, the requirements for medical radiation appliances are specified in two acts: the Food and Drugs Act (Canada 2016a) and the Radiation Emitting Devices Act (Canada 2016b). The decrees Medical Devices Regulations (Canada 2016c) and Radiation Emitting Devices Regulations (Canada 2016d) are also related. References 2016a, 2016b and 2016c cover medical devices in general and do not set any detailed requirements. Part XIII of reference 2016d concerns ultrasound therapy equipment. For these equipments, the set maximum value of ultrasound intensity is 3 W/cm^2 (temporal and spatial average). Besides this limit, the focus of the requirements is on ensuring that the parameters indicated on the devices are correct and that the warning markings on the devices are appropriate.

7 Infrasound

Infrasound is sound with frequencies below the lower limit of human hearing (<20 Hz). In general, the safety of infrasound has been studied very little both on the national and the international level. ICNIRP has no recommendations concerning infrasound, and according to current knowledge, none are being prepared. Moreover, no uniform standards or limitations have been established for infrasound. Infrasound can be used for treatment purposes, for example in physioacoustic therapy. It can also be used as a sonic weapon in military and police use. Recently, discussion about infrasound has arisen due to wind farms, as they cause noise in the infrasound frequency range.

At EU level, infrasound has been addressed as a part of the directive on noise (EU 2003), but no safety limits are set. According to the article by Duck (Duck 2007), the only recommendations available in 2007 were recommendations made by the American Conference of Government Industrial Hygienists (ACGIH 2001). According to the ACGIH guidelines, for frequencies between 1–80 Hz, the sound pressure level should not exceed 145 dB, and the overall SPL should not exceed 150 dB when the commonly used frequency component weighting for audible sound is not applied.

The publication by the Health Protecting Agency (HPA 2010) mentions that Japanese guidelines recommend a limit of 92 dBG for infrasound generated by wind turbines. The G-weighted 95–100 dBG is close to the threshold of perception, whereas 85–90 dBG is normally not audible to humans.

Infrasound does not fall within the scope of application of the Radiation Act. No proposal has been made to include infrasound in the scope of application of the new Radiation Act, as no convincing evidence exists of health effects of infrasound or the related threshold levels. This information would be necessary to establish limitations to exposure. Similarly to ultrasound, both ICNIRP and WHO classify infrasound under non-ionizing radiation.

8 Conclusion and reflection

Safety limits

Based on this survey, the non-medical use of ultrasound in fields such as beauty care involves risks, and the number of applications available is rapidly increasing. Establishing limiting values for exposure is necessary, especially to ensure the safety of consumer services. Internationally approved safety limitations for the non-medical applications of ultrasound are not currently available; therefore, the limiting values for exposure should be established on the national level. The threshold levels of harmful health effects have been assessed in the reports by SSK and HPA (SSK 2012 and HPA 2010), and medical equipment standards also contain useful information. These sources are sufficient for establishing limitations based on scientific evidence.

Appendix 1 contains a proposal for the limitation of exposure to ultrasound. The proposal to limit ultrasound exposure via direct skin contact is based on limiting temperature increase and the mechanical effects. In the decree of the Ministry of Social Affairs and Health (294/2002), limiting electric or magnetic fields with a frequency above 100 kHz (RF radiation) is based on temperature rise. Even though the energy transmitted to the body is produced in different ways for RF radiation and ultrasound, the limitations of both are based on limiting temperature rise. With regards to ultrasound, the mechanical effects caused are also taken into account.

The aim of the levels presented in Tables 2 and 3 of Appendix 1 is to make it easier to determine the exposure to ultrasound via skin contact in non-medical use. The objective of the levels in Table 2 is to ensure that the use of ultrasound causes no harmful health effects. Safety limits proposed by various international organizations (WFUMB, AIUM, SSK, HPA, NCRP) differ slightly from one another. The values in Table 2 are consistent with the proposal by SSK. The limit of the mechanical index would be 0.4. The equivalent limit proposed by WFUMB is 0.3, while NCRP has proposed 0.5. Similarly, the limit of the thermal index would be 0.7, whereas WFUMB has proposed the value 0.5 and NCRP the value 1. When ultrasound exposure exceeds the levels in Table 2, it is necessary to take measures to ensure that no harmful tissue damage or changes to vital functions occur. Safety can be improved by factors such as the equipment technique used, the competence of the user, instructions and monitoring the health of the customer.

As mitigation, a STUK regulation could be applied to cosmetic use if safety of use can be otherwise ensured. The mitigation could be justified by the fact that equipment standards are constantly developing, users are well trained, and there are other means to ensure that no harmful heath effects occur and vital functions are not risked.

The typical energy density levels of ultrasonic applications used in health and beauty care are presented below, along with the action levels proposed in Appendix 1. In addition to the energy density of the treatment period, the local duration must also be taken into account, as it significantly affects the energy received by the tissue. Treatments with the highest energy density last at most a few seconds. Very high power may result in rapid heating of the tissue and tissue necrosis if local exposure lasts too long. HIFU devices are used in medical ultrasound treatment equipment for purposes such as destroying fat cells.

Typical energy density levels of ultrasonic applications include:

- 1000–10 000 W/cm^2: the intensity of HIFU equipment
- 10–30 W/cm^2: lithotripsy
- 2–25 W/cm^2: fat removal through cavitation
- 3 W/cm^2: the maximum allowed intensity of physiotherapy equipment
  0.1–1 W/cm^2: skin cleansing, psoriasis treatment
- 0.1 W/cm^2: proposed intensity level for exposure

targeted at the body
- 0.05–2 W/cm²: physiotherapy treatment
- 0.05 W/cm²: proposed intensity level for exposure targeted at the eyes
- 0.001–0.03 W/cm²: home-use devices meant for monitoring fetal heartbeat.

Of all procedures commonly carried out, at least fat removal cavitation exceeds the ultrasound limitations presented in Appendix 1. Based on the proposal, providing this type of practice as a consumer service would be prohibited. However, the procedures could be carried out by a medical professional. Comments from physicians with expertise in ultrasound support this conclusion. As relevant factors, the physicians mentioned that fat removal cavitation is comparable to surgical procedures, and that for risk management, the user must have in-depth knowledge of anatomy and physiology, which only a trained physician would possess.

It is important to acknowledge multi-use devices (ultrasound and laser and/or RF in the same device) and the special characteristics of both their regulatory control and the exposure they cause. The current Radiation Act (592/1991) and the Ministry of Social Affairs and Health Decree on the Limitation of Public Exposure to Non-Ionizing Radiation (294/2002) do not clearly specify the joint effect of different radiation techniques with relation to the maximum values, as equipment producing more than one type of radiation has not been available before. When preparing the new legislation, the limiting values should be specified to incorporate the joint effect of different types of radiation in the limitations based on temperature rise.

Regulatory control

At the moment, the non-medical use of ultrasound, for instance in beauty care, is governed by the general provisions of the Consumer Protection Act. This means the primary regulatory authority is the Finnish Safety and Chemicals Agency (Tukes). If requirements concerning the safety of ultrasound are added to radiation-related legislation, STUK could take over the regulatory control, as the procedures of operators currently monitored, such as RF or laser treatments, already fall under STUK's authority.

All medical devices are subject to the Medical Devices Act. The supervisory authority of these operators and health care units is the National Supervisory Authority for Welfare and Health (Valvira). Depending on the final scope of application of the pending EU regulation on medical devices (EU 2016), ultrasound equipment could be placed under the scope of application of medical legislation even when used for cosmetic purposes.

Products sold to consumers are currently subject to the general provisions of the Consumer Protection Act. This makes Tukes the primary supervisory authority. Adding ultrasound-related requirements to radiation legislation would allow STUK to act on any dangerous products detected in the market.

The aim should be to avoid unnecessarily restricting cosmetic procedures if they can be carried out safely. However, it is also important to leave more demanding procedures to be carried out by medical professionals. When incorrectly used, equipment such as ultrasound devices used for body modification may cause serious damage in the body.

Pregnant women

There is no evidence to support the notion that ultrasound imaging poses a risk to the fetus. Based on expert comments, it might be sensible to prohibit people without medical training from carrying out fetal ultrasound scans as consumer services. Similarly, the use of 3D devices was only viewed as justified on clear medical grounds. Many organizations (including AIUM, BMUS, FDA, Health Canada, EFSUMB) have reached the same conclusion. According to HPA's recommendation, ultrasound scans should only be carried out by medical professionals who have been trained in ultrasound safety. In France, a decree is being prepared to prohibit the non-medical imaging of a fetus. The report did not mention bans on the non-medical imaging of a fetus in any other European countries.

Cosmetic procedures involving high power levels should not be performed on pregnant women, especially without a trained medical professional overseeing the procedure. This makes it possible to avoid the high risk of harmful health effects involved in these procedures.

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APPENDIX 1 PROPOSAL FOR THE LIMITATION OF EXPOSURE TO ULTRASOUND

Limiting exposure to airborne ultrasound

The harmful health effects of airborne ultrasound can be prevented by limiting sound pressure levels. Limiting values for ultrasound pressure level (SPL) at different frequencies are presented in Table 1.

Table 1. Limiting values for ultrasound pressure level (SPL) at different frequencies. The limiting values are indicated in decibels, using sound pressure 20 µPa as the reference level. The frequencies are indicated in 1/3-octave bands.

1/3-octave band [kHz]	Ultrasound pressure level (SPL) [dB]
20	70
25	100
31.5	100
40	100
50	100
63	100
80	100
100	100

Restricting exposure to ultrasound in direct skin contact

Ultrasound may not cause harmful tissue damage or changes to vital functions due to tissue heating. Temperature rise of not more than one degree can be considered safe regardless of the time of exposure.

In addition, the mechanical impacts of ultrasound (pressure, power, etc.) may not cause harmful tissue damage or changes to vital functions.

When exposing pregnant women to ultrasound, the safety of the fetus must be ensured in particular.

The restrictions presented are not applicable to the medical use of ultrasound.

Ultrasound exposure is defined either through intensity or the mechanical index (MI) and thermal index (TI). Harmful health effects can be safely avoided if the levels presented in Table 2 are not exceeded. When ultrasound exposure exceeds these levels, it is necessary to take measures to ensure that no harmful tissue damage or changes to vital functions occur. Safety can be improved by factors such as the equipment technique used, the competence of the user, instructions and monitoring the health of the customer. Table 3 presents the levels below which harmful health effects are not likely to occur.

Table 2. Levels for ultrasound intensity and the mechanical index (MI) and thermal index (TI), under which no harmful health effects are caused.

Body part	Ultrasound intensity [W/cm²]	Mechanical index (MI)	Thermal index (TI)
Eyes	0.05	0.2	0.7
Other parts	0.1	0.4	

Table 3. The levels of the mechanical index (MI) and the thermal index (TI) below which harmful health effects are not likely to occur.

Mechanical index (MI)	Thermal index (TI)
0.7	1

APPENDIX 2 INDICATIVE LIST OF CONTRAINDICATIONS TO BE TAKEN INTO ACCOUNT IN BEAUTY CARE

The list is based on a survey conducted with medical experts inquiring their opinion on the important contraindications of using ultrasound treatment in beauty care. Contraindications include:

- cardiac pacemaker
- serious cardiovascular diseases
- thrombosis
- vasculitis
- chronic circulation insufficiency
- diabetes
- anticoagulant medication
- renal or hepatic insufficiency or hypothyroidism
- cancer or a tumor
- implants in the treatment area
- morbid obesity
- pregnancy or breast-feeding
- metal implants
- age under 18
- acute infection
- open wounds in the treatment area
- suspicious lymph glands
- previous surgical operations to the abdomen
- scars in the treatment areas
- skin diseases, malignant skin transformation
- numbness
- serious psychological disorders and related medication (e.g., depression)
- osteoporosis.

APPENDIX 3 CONTRAINDICATIONS OF CAVITATION TREATMENTS IN BEAUTY CARE

Contraindications of cosmetic cavitation treatments mentioned on the websites of beauty care service providers:

- coronary thrombosis
- cardiac pacemaker
- cardiac failure
- serious cardiovascular diseases
- aneurysm
- thrombosis
- vasculitis
- chronic circulation insufficiency
- blood clot
- immunological diseases
- hepatitis
- high cholesterol
- anticoagulant medication
- ovarian cyst
- hysterectomy or a surgical operation within the past 12 months
- kidney or liver dysfunction
- renal or hepatic insufficiency or hypothyroidism
- cholelithiasis
- untreated arterial hypertension
- cancer or a tumor
- hysteromyoma
- implants in the treatment area
- diabetes
- epilepsy
- asthma
- morbid obesity
- pregnancy or breast-feeding
- metal implants
- age under 18
- illness or fever
- acute infection or inflammations
- duodenal or gastric ulcer
- open wounds in the treatment area
- suspicious lymph glands
- previous surgical operations to the abdomen
- early phase of period
- skin diseases, malignant skin transformation
- numb area of skin
- damage to middle or inner ear
- tinnitus or equivalent hearing problems
- serious psychological disorders and related medication (e.g., depression)
- anorexia or bulimia
- osteoporosis.

APPENDIX 4 CONTRAINDICATIONS OF MEDICAL CAVITATION TREATMENTS

Contraindications of cosmetic cavitation treatments mentioned on the websites of medical clinics:

- BMI above 30
- morbid obesity
- surgical operation carried out on the treatment area
- subcutaneous fat layer too thin
- severe underlying diseases
- hepatitis
- very high cholesterol
- past or recent coronary thrombosis
- cardiac pacemaker
- implants
- kidney dysfunction
- liver dysfunction
- untreated arterial hypertension
- cancer or a tumor
- being HIV positive
- bleeding tendency or, for instance, Marevan medication
- weakened physical health and metabolism
- infection
- certain skin diseases
- serious diseases of lipometabolism
- immunosuppressive medication
- implants in the treatment area
- diabetes
- epilepsy
- pregnancy or breast-feeding
- age under 18
- age over 65
- illness or fever
- early phase of period.