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Authors: Frida Lindberg
Mattias Mårtensson

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Aesthetic ultrasound devices

Current state of knowledge and suggested measurement set-up for characterization of exposure

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Abstract
This report concerns the ultrasound devices used for the aesthetic purposes of body contouring and fat reduction (ablation of adipose tissue). Such devices have recently become more frequent on the Swedish market. These ultrasound devices are currently not medically regulated in Sweden and little is known about their safety and potentially harmful exposure when using them.

This report aims to provide relevant information about present guidelines and scientific results in the area, a survey of the Swedish market and also recommendations on how to characterize the ultrasound emitted by these devices. This information provides an important basis for possible future regulatory actions.

All aesthetic ultrasound devices found on the Swedish market use low-frequency non-thermal ultrasound. These types of devices (with one exception) have not yet been studied in peer-reviewed publications and the technical specifications from the suppliers are often incomplete. Consequently, there is a need to evaluate the devices in order to gain adequate knowledge about possible risks associated with their use.

Ultrasound exposure should be characterized by its frequency and acoustic pressure. It has not been fully investigated whether the mathematical equation for the mechanical index is valid for the low frequencies used by aesthetic ultrasound equipment on the Swedish market. In this report, two different hydrophone measurement set-ups for characterization of ultrasound exposure are proposed. The most common reason behind adverse events or exposure of non-target tissue regions is most likely handling errors by the operator. Hence, only characterization of the ultrasound field does not necessarily imply the safe use of aesthetic ultrasound devices.

It is recommended that the Swedish Radiation Safety Authority and the Swedish Medical Products Agency discuss their respective future responsibility and how aesthetic ultrasound devices should be regulated.

Abstrakt
Denna rapport (Ultraljudsapparatur för estetiskt bruk – rådande kunskapsläge och förslag på mätuppställning för exponeringsbedömning) behandlar ultraljudsutrustning som används i estetiskt syfte för kroppsskulptering och fettreducering. På senare tid har denna typ av apparatur blivit vanlig på den svenska marknaden. De ligger idag utanför det medicintekniska regelverket och kunskapen kring säkerhet och exponeringsrisker är begränsad.

Syftet med denna rapport är att sammanställa relevant information kring befintliga riktlinjer och vetenskapliga studier inom området, kartlägga den svenska marknaden och beskriva hur en karakterisering av ultraljudet från dessa utrustningar kan utföras. Informationen utgör ett

viktigt underlag inför en eventuell reglering på området. Alla estetiska ultraljudsutrustningar som identifierades på den svenska marknaden var av typen ”low-frequency non-thermal ultrasound”. Den sortens utrustning har ännu inte utvärderats (med ett undantag) i vetenskapliga studier och de tillhörande tekniska specifikationerna är ofta inte kompletta. Följaktligen finns ett behov av att utvärdera dessa för att få kunskap om möjliga risker kopplade till deras användning.

Ultraljudsfältet bör karakteriseras utifrån dess frekvens och akustiska tryck. Det är inte fullt utrett om den matematiska formeln för parametern mekaniskt index är giltig för de låga frekvenser som används av estetiska ultraljudsutrustningar på den svenska marknaden. I denna rapport presenteras två olika förslag på möjliga hydrofon-mätuppställningar för karakterisering av ultraljudsexponering. Sannolikt är orsaken till vävnadsskada från estetiska ultraljudsutrustningar handhavandefel, vilket innebär att enbart karakterisering av ultraljudsfältet inte i sig medför säker användning.

Författarna rekommenderar Strålsäkerhetsmyndigheten och Läkemedelsverket att föra en diskussion om hur ansvarsfördelningen ska se ut i framtiden när det gäller tillsyn av området.

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Authors: Frida Lindberg and Mattias Mårtensson
Royal Institute of Technology, KTH, School of Technology and Health

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This report concerns a study which has been conducted for the Swedish Radiation Safety Authority, SSM. The conclusions and viewpoints presented in the report are those of the author/authors and do not necessarily coincide with those of the SSM.

Content

1. Introduction

Liposuction is one of the most commonly performed cosmetic surgical procedures. However, lately several less invasive methods have advanced on the aesthetic market, such as laser therapies, radiofrequency and ultrasound based techniques [Jalian et al., 2012; Jewell et al., 2011].

This report concerns the ultrasound used for the aesthetic purposes of body contouring and ablation of adipose tissue. The frequency and intensity of this ultrasound differs from the ultrasound used in medical imaging systems and for physical therapy. Medical ultrasound imaging systems typically generate waves of high frequency (range 1-20 MHz) and low intensity (< 1 W/cm^2). Also therapeutic ultrasound is normally of high frequency and lower intensity.

Ultrasound used for aesthetic purposes (body contouring) can be divided into two different categories; the first one is ultrasound of very low frequency (kHz) and relatively low intensity aimed to cause cavitation in the adipose tissue cells (also referred to as *nonthermal* ultrasound). This effect is further described in the next chapter. The second category is focused ultrasound with very high intensity aimed to ablate the adipose tissue by heating (referred to as High Intensity Focused Ultrasound or HIFU). This technique has been used for decades for the purpose of non-invasive treatment of tumors in various organs.

Although the noninvasiveness of these techniques appears favoring, there is little known about the safety and efficiency of using these aesthetic ultrasound devices and only a few clinical studies have been carried out so far, especially in the low-frequency range. The lack of knowledge about the function of the aesthetic ultrasound devices leads to questions about the subsequent biological effects and possible harmful exposure to non-target tissues. Today these ultrasound systems are not classified as medical devices in Sweden, and hence free from medical device regulations.

1.1 General aim

The work of this report aims to support the Swedish Radiation Safety Authority with relevant information of the present guidelines and scientific results in the area, a survey of the Swedish market and also recommendations of how to characterize the ultrasound emitted from these devices.

The work is divided into three separate parts:

Part I – Present regulations, guidelines and literature
The first part includes a summary of present regulations and guidelines for aesthetic ultrasound devices together with relevant scientific publications and documented clinical studies where these devices have been used or evaluated.

Part II – Aesthetic ultrasound in Sweden
The second part aims to provide a survey of the different aesthetic ultrasound devices currently on the Swedish market, including the technical specification such as ultrasound frequency, intensity and if the devices use ultrasound in combination with laser and/or radio frequency.

Part III - Characterization of aesthetic ultrasound
The third part describes the parameters that are considered relevant to measure in order to characterize exposure and risk of using ultrasound for cosmetic purposes. This section further includes a suggestion of the required equipment to measure the proposed parameters and an estimated cost of the equipment.

The outcome of this report is aims to provide the suggestion for future assessment of tissue exposure and risk identification. Note that, this report does not aim to investigate the cosmetic function of these devices.

2. Background

This section describes information relevant for this report regarding regulation about medical devices and ultrasound safety.

2.1 Definition

In contrast to other products, the medical devices are subject to strict premarketing and post marketing controls. In Sweden, aesthetic ultrasound devices are not classified as medical products.

The regulation and surveillance of medical products are under the jurisdiction of the Medical Product Agency (Läkemedelsverket). Their work is governed by the European medical device directive (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices). The European medical device directive defines a medical device as:

"Medical devices are defined as articles which are intended to be used for a medical purpose. The medical purpose is assigned to a product by the manufacturer."

However, even though a product is not claimed to have a medical purpose, the Medical Product Agency might anyway, in order to assure safety, classify it as a medical product. This is usually done when the use of a product is considered to be associated with great risks; one such example is breast implants. The manufacturers of aesthetic ultrasound devices does not claim that their products have medical purposes and the Medical Product Agency have not considered aesthetic ultrasound devices to be associated with risks serious enough to classify them as medical devices.

In the Unites States, the Food and Drug Administration (FDA) has the responsibility to decide if a product should be classified as a medical product [Food and Drug Administration, 2011]. When it comes to aesthetic ultrasound devices the FDA have identified a sufficient number of risks to classify aesthetic ultrasound devices as medical devices. Furthermore, the FDA classifies aesthetic ultrasound devices as medical devices of class II. In the Class II Special Controls Guidance Document for aesthetic ultrasound devices FDA define aesthetic ultrasound devices as:

"*A Focused Ultrasound Stimulator System for Aesthetic Use is a device using focused ultrasound to produce localized, mechanical motion within tissues and cells for the purpose of producing either localized heating for tissue coagulation or for mechanical cellular membrane disruption intended for non-invasive aesthetic use*"

In this report the Focused Ultrasound Stimulator Systems mentioned above will be referred to as *aesthetic ultrasound devices* [Food and Drug Administration, 2011]. When referring to devices causing heating, the term *high-intensity focused ultrasound devices* will be used, and when referring to devices causing mechanical cellular membrane disruption by cavitation, the term *low-frequency non-thermal focused ultrasound devices* will be used.

2.2 General safety in medical ultrasound

2.2.1 Intensity

The intensity of an ultrasound field is the amount of acoustic power passing a given cross-sectional area. The SI unit for intensity is W/m^2, but often is mW/cm^2 or

W/cm^2 used. In general it is difficult to measure the intensity of an ultrasound field directly, why instead the intensity often is calculated from the acoustic pressure, which can be measured by a hydrophone. To make this calculation, an assumption about the instantaneous intensity, I, must be made, saying that it is related to the instantaneous acoustic pressure, by the following relationship:

$$\mathrm{I} = \frac{\text{Acoustic pressure}^2\ (\mathrm{Pa}^2)}{\text{Acoustic impedance}\ (\mathrm{Pa}*\mathrm{s/m})} \quad (1)$$

Where the acoustic impedance, measured in Rayls (Pa*s/m), is defined as ρ times c (ρ = density of water, c = speed of sound in water). This approximation is used in most international standards (IEC62127-1, 2007) [Shaw et al., 2012].

The intensity of an ultrasound field varies in different points. This is due to several factors. It depends on whether the transmitted ultrasound is continuous or if it constitutes of discrete pulses, the attenuation of the ultrasound pulse, and if the ultrasound field is focused. Therefore, when calculating the intensity, in order to describe the ultrasound field, both temporal and spatial averaging and peak values are used.

2.2.2 Cavitation effects

Ultrasound is a mechanical wave that propagates through soft tissues by means of oscillating pressure. The rapid change in pressure can generate micro-bubbles within tissues when used in medical applications. If the pressure is sufficiently high the generated micro-bubbles may collapse. The collapsing of a micro-bubble generates a water jet that could induce tissue damage. The generation of micro-bubbles is called *cavitation effects*; either if they collapse or not. If the generated micro-bubble collapses it is called inertial or unstable cavitation, whilst it is called non-inertial or stable cavitation if it doesn't collapse.

2.2.3 Indices

When evaluating risks associated with the use of medical diagnostic ultrasound, i.e. ultrasound emitted from devices classified as medical devices and used for imaging purposes, two factors are considered: the thermal effects and the mechanical effects. In order to quantify these effects, the parameters mechanical index (MI) and thermal index (TI) have been introduced. The definition of these parameters and details how to characterize ultrasound fields from medical diagnostic ultrasound are given in IEC62359 from the International Electrotechnical Commission (IEC).

2.2.4 Mechanical Index

The purpose of the MI is to indicate the probability of inertial cavitation and is defined by:

$$\mathrm{MI} = \frac{\text{Peak negative pressure}\ (\mathrm{Pa})}{\sqrt{\text{Center frequency of the pulse}\ (\mathrm{Hz})}} \quad (2)$$

Today cavitation is not believed to occur at MI values below 0.7.

2.2.5 Thermal Index

The TI is defined as the ratio of the output power of the transducer and the power required to raise the temperature of the tissue by 1 °C. TI is defined by:

$$TI = \frac{\text{Output power from transducer (W)}}{\text{Power to raise the temperature of the tissue 1 °C (W)}} \quad (3)$$

The presence of bone tissue influences how much the temperature raise. Thus, different values of the needed power to raise the temperature 1°C (the denominator in (3)) are used for different anatomical situations. Therefore, there are three TI models: one that should be used for uniform soft tissue (TIS), one when there is bone tissue in or close to the focal zone of the ultrasound field (TIB), and one when bone tissue is present just under the surface of the skin (TIC). Values higher than 0.7 are considered to increase the risks of damages related to heating.

2.2.6 Comments about MI and TI

The MI and TI ratios are based on many assumptions, for instance about tissue properties, and therefore only represents approximations about the likelihood of inducing negative biological effects to tissues subjected to ultrasound.

When the peak negative pressure and the acoustic output values are measured, hydrophones in water tanks are often used. Since the attenuation of ultrasound is very low in water and about 0.5 dB/cm/MHz in soft tissue, the measurements would yield incorrect values. In order to compensate for this, the values are adjusted (sometimes called derated). However, the measured values are not compensated by the factor 0.5 dB/cm/MHz. Instead is the measured values compensated by the factor 0.3 dB/cm/MHz. This is considered to represent a worst case scenario situation with a possible echo free region in the path of the ultrasound wave.

3. Method

This section describes the methodology used to access the relevant information needed for the different parts of this report.

The PubMed MEDLINE database was used in a search to access relevant scientific articles for the literature study included in the first part regarding present regulations, guidelines and literature. The following search terms were used:

(high intensity focused OR low frequency OR nonthermal OR safety OR noninvasive) AND (ultrasound OR ultrasonic) AND (aesthetic OR contour* OR cosmetic OR sculpt*) NOT (assisted* OR skin OR tumor OR doppler)*

The asterisk indicates that all possible prefix or suffix combinations are searched. Using these search terms 120 references were identified of which 21 were considered to be relevant for this report.

Further, the FDA, the American Institute of Ultrasound in Medicine (AIUM), the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) and Svensk Elstandard were contacted for information about current publications and guidelines concerning aesthetic ultrasound.

To access aesthetic ultrasound devices available on the Swedish market the, needed for the second part of this report, web search engine Google was used. The following search terms were used:

(kavitation OR fettreducering OR behandling)AND (ultraljud)

Any possible distributors or aesthetic clinics without information about their devices/treatments on the internet were not visible in this search. All distributers and manufacturers that could be identified were contacted either via mail or by phone. They were asked to provide detailed information regarding the technical specification of their device, information about the manufacturer and if they knew of any research or product testing that supported the method of their device.

4. Results

This section presents the results obtained during the three parts of this report.

4.1 Present regulations, guidelines and literature

As described in the Background the FDA has classified aesthetic ultrasound devices as medical devices of Class II Special controls and has developed a guidance document (Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use) to support the classification for industry and government [Food and Drug Administration, 2011]. This document is available at the FDA homepage.

Except for FDA's guidelines, no published guidelines for aesthetic ultrasound devices were found in either the US or Europe. The AIUM states that they have no published guidelines today but "body contouring" will be included in the IEC work on HIFU standards in the future. The EFSUMB have not published anything on this topic, but state that this is currently under consideration.

The standards for safety and essential performance of all medical electric equipment are set out in the IEC 60601 series. Part 2-5 deals with ultrasound for physiotherapy equipment and part 2-37 includes ultrasound for diagnostic and monitoring equipment. Neither surgical nor aesthetic applications of HIFU are included. For HIFU, exposure is allowed which is sufficient to cause the desired destructive effect on the tissue. Protection from the non-target tissue regions is achieved entirely from appropriate placement of the beam [Duck, 2007].

The organisation SEK Svensk Elstandard is responsible for standardization in the field of electrotechnology and is a member of IEC. SEK Svensk Elstandard has published standards based on the IEC standards regarding the use of ultrasound devices. These standards may not be applicable for the low-frequency range; the standards are claimed to be valid for frequencies over 0.5 MHz. SEK Svensk Elstandard states that it is unclear today whether the standards should be applied in the lower range as well.

4.1.1 Literature and clinical studies

A limited number of clinical reports and publications were found through the literature search on PubMed MEDLINE database. A few more articles were added to the results through reference material from some of the manufacturers.

In a review article on noninvasive body contouring, the device *UltraShape Contour I* from Syneron and Candela is described as the first system for non-thermal aesthetic ultrasound launched commercially and as the device with the most peer-reviewed articles and worldwide clinical experience [Mulholland et al., 2011]. This is in accordance with the understanding of the authors of this report. In the majority of clinical and pre-clinical studies found on *low-frequency non-thermal focused ultrasound devices*, the device UltraShape was used. However, these studies had in general relatively small sample groups and the most commonly investigated parameters were the reduction of waist circumference and blood values including levels of triglycerides and cholesterol, pre and post treatment/s with the aesthetic ultrasound device. In several of the studies performed on human subjects cases of adverse events were reported, such as blisters and erythema. [Ascher, 2010; Brown et al.,

2009; Chang et al., 2013; Moreno-Moraga et al., 2007; Shek et al., 2009; Teitelbaum et al., 2007].

Considering HIFU devices for aesthetic use, the device called LipoSonix by Medicis Technology Corporation occurs more frequent than other devices in clinical studies. A difference from the clinical studies based on *low-frequency non-thermal focused ultrasound devices*, is that in the Method-section of almost all the aesthetic HIFU studies it is stated the minimum thickness of the subcutaneous adipose tissue of the patient group included. [Gadsden et al., 2011; Garcia et al., 2013; Jewell et al., 2011; Jewell et al., 2011; Jewell et al., 2012; Shalom et al., 2013; Solish et al., 2012]

Further it should be noted that in the majority of the studies found the authors either declared supported funding of the studies and/or some kind of conflict of interests (e.g. consulting fees, employment or board memberships).

There are very few studies that aim to quantify the cavitation effect in adipose tissue using aesthetic ultrasound devices. In a study aimed to analyse at what pressure cavitation is initiated at different frequencies, excised porcine fat were exposed to ultrasound of different frequencies in the range of 0.5-3.4 MHz. The results showed that inertial cavitation was always initiated at 0.5 MHz for pressures greater than 1.6 MPa [Kyriakou et al., 2011]. The pressure needed to cause cavitation for frequencies lower than 0.5 MHz is however unknown.

Only one study was found with the aim to evaluate the biological effect on adipose tissue using low-frequency ultrasound (37 – 42 kHz). In this study, ultrasound intensities of 1.8 – 2.5 W/cm^2 were used on excised human adipose tissue. The results showed increasing weight loss over time after the exposure reaching maximum weight loss at 18 h from the end of the exposure. A histological evaluation of the exposed adipose tissue showed alterations in the tissue characteristics and destruction of collagen fibres. [Palumbo et al., 2011]

4.2 Aesthetic ultrasound in Sweden

Ten different aesthetic devices were found on the Swedish market. For three of the devices, the manufacturers could be identified. All the devices that were found use low-frequency (< 0.5 MHz), non-thermal ultrasound. In total, 9 out of 10 devices use ultrasound within the frequency range 25-40 kHz. Only the device UltraShape is outside this range with a frequency of 200 kHz.

Besides the frequency of the ultrasound, the technical specification was in general difficult to find or receive from distributors such as intensity, focus depth as well as strength of focusing. Furthermore, it is also unknown if these devices emit the ultrasound in continuous mode or in pulses. Although the device UltraShape is described to deliver the ultrasound in pulses in order to minimize the heating effect [Hotta, 2010] it is not clear if all devices use the same technique. One of the distributers confirmed that their device has only one emitting piezo-electric element.

Values for intensities and focus depths were found for only two devices: 9 W/cm^2 at max depth of 16mm (CaviLipo) and 17 W/cm^2 at a depth of 15 mm (UltraShape). All devices except for one use ultrasound in combination with radiofrequency and/or laser.

The aesthetic ultrasound devices on the Swedish market and the technical specifications are listed in Appendix 1. The information that could not be found is denoted as *unknown*.

4.3 How to characterize aesthetic ultrasound

4.3.1 Parameters

An ultrasound field is defined by its frequency and acoustic pressure. However, the ultrasound field cannot be described by only single measurements of these parameters. There is always a spectrum of frequencies that is emitted from an ultrasound transducer, and since the attenuation of the ultrasound is frequency-dependent, the spectrum will vary with depth. The attenuation itself is a reduction of the acoustic pressure of the ultrasound wave. It is important to point out that the attenuation is not necessary linear from the transducer surface, or in fact predictable at all. This is mainly due to focusing properties that the transducer may have and to some extent interference from reflecting ultrasound waves. The consequence could be areas of both higher and lower acoustic pressures in the ultrasound field, especially in the first few centimeters from the transducer. Both the frequency spectrum and the acoustic pressure can be measured by a hydrophone. A hydrophone provides a voltage waveform on its output and the frequency spectrum is generated through a Fast Fourier transform analysis and the acoustic pressure is given from calibration tables (often provided by the manufacturers).

Information about the frequency and the acoustic pressure could be sufficient for the characterization of the ultrasound field from the aesthetic ultrasound devices. In standards and safety guidance concerning the use of ultrasound devices the parameters MI and TI (described in the Background section) are often used [Duck, 2007; ter Haar, 2011; ter Haar et al., 2011]. In order to assess the risks of mechanical effects, such as cavitation, the parameter MI is used and is related to the acoustic pressure, while the thermal effects are assessed through the parameter TI which is related to the intensity. Since the intensity not can be measured directly it has to be estimated through the acoustic pressure using the plane wave assumption (see the Background section).

The TI formula (3) is considered to be valid for low frequencies (< 500 kHz). However, the calculation of TI for the low-frequency non-thermal ultrasound, which is the most common technique on the Swedish market, is probably of low interest since heating is not the main purpose. For this type of device, MI is theoretically of greater interest, but there is a very important factor here to take in to account. It has recently been suggested that the formula for MI should be modified for frequencies below 500 kHz [Ahmadi et al., 2012]. Ahmadi et al. evaluates a new formula using numerical simulations:

$$\mathrm{MI}_{\mathrm{LF}} = \frac{\text{Peak negative pressure (MPa)} - \text{Ambient pressure (MPa)}}{\sqrt{\text{Center frequency of the pulse (MHz)}}} \qquad (4)$$

The formula in (4) was shown to provide a more accurate index for describing cavitation effects. The ambient pressure is the pressure in the surrounding tissue.

4.3.2 Equipment

For the purpose of characterizing the ultrasound from low-frequency non-thermal aesthetic ultrasound devices, a hydrophone calibrated for low-frequencies is required. Hydrophones that fulfill this criterion are not common neither for medical applications nor for other areas such as for marine use. In order to capture and store data from the hydrophone a system constituting either a dedicated computer with acquisition card or digital oscilloscope with storage function is needed. Depending on the specific solution from the different manufacturers, special equipments such as amplifier, circuit board to connect the hydrophone and possible dedicated software could be further needed. Finally, since the measurements have to be performed in water it is necessary to place the hydrophone inside a water tank. The ultrasound is emitted from the transducer at the surface of the water. Water tanks are seldom provided by hydrophone suppliers and must therefore likely be purchased elsewhere, e.g. a standard aquarium may used for this purpose.

The transducer should preferably be placed at the surface of the water, since the transducers usually cannot be assumed to be waterproof. While hydrophones are designed to operate immersed in water, the hydrophone can be placed deeper in the water tank. See Figure 1.

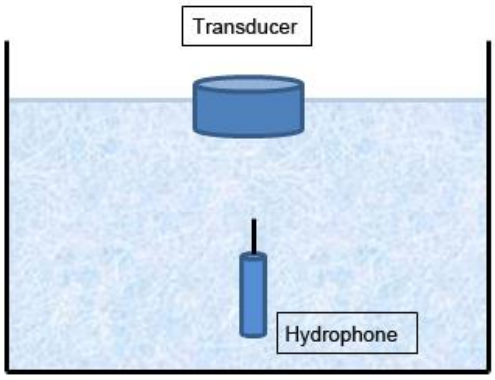

Figure 1 Example of hydrophone-transducer set-up. The transducer is placed at the surface of the water while the hydrophone is immersed in the water.

Two companies were found that could provide solutions for this purpose. Their solutions are listed below together with cost estimates and comments (a detailed list is provided in Appendix 2):

Solution 1:
Company: Precision Acoustics

Suggested equipment: 1mm needle hydrophone, preamplifier, DC Coupler, Booster Amplifier, Oscilloscope

Total estimated cost: 7780 EUR

Comment: The hydrophone in this solution is thin and will provide a good spatial resolution and can be calibrated to analyze frequencies from 10 kHz up to 20 MHz. The solution does not contain dedicated software for post-processing of the data. This has to be done by exporting the data for example to MATLAB or similar program.

Solution 2:
Company: Brüel&Kjær

Suggested equipment: hydrophone, frontend and software

Total estimated cost: 17 000 – 23 000 EUR

Comment: The hydrophone in this solution can handle the frequency and acoustic power range of interest. The large dimension of this hydrophone (diameter of 21 mm) in combination with short claimed focus distances of the aesthetic ultrasound devices makes this hydrophone less optimal. The advantage of using this solution is its dedicated post-processing software that contains both analyzing and 3D-plotting functions. This software constitutes the main part of the total cost.

Note:
Although no aesthetic ultrasound devices using HIFU were found on the Swedish market, it can be noted that for the purpose of characterizing the ultrasound from HIFU devices a fiber optic hydrophone is to prefer. The company Onda offers such a hydrophone that could be used together with a system, including a water tank and software, which is available at department of Biomedical Engineering, Karolinska Hospital in Huddinge, Sweden. (Estimated cost for Onda fiber optic hydrophone is 236 kSEK.)

5. Discussion

This report aims to support the Swedish Radiation Safety Authority in how to characterize the ultrasound used in aesthetic ultrasound devices in order to assess possible risks. No mandatory European regulations or guidelines for this type of ultrasound devices were found and only a few scientific publications evaluating low-frequency non-thermal ultrasound could be identified.

The manufacturers and distributors have been, with a few exceptions, reluctant to provide basic technical information about their aesthetic ultrasound device, for example about the intensity values and acoustic pressures. This has complicated the possibility to create a complete picture about the current situation for the Swedish market. For that reason it must be noted that there might be aesthetic ultrasound devices on the Swedish market with parameter outside the range presented in the Results. However, this is probably a minor issue since all identified aesthetic ultrasound devices on the Swedish market utilize cavitation which implies similar technical specifications. Furthermore, if a device with different properties would appear, the main solution (Precision Acoustics) can be calibrated for a large range of frequencies and acoustic pressures.

When designing the hydrophone set-up there are several aspects to consider. The choice of hydrophone can affect the spatial resolution (the length between discrete measured points of the ultrasound field). The two hydrophones suggested in the Results have different designs; the Precision Acoustics hydrophone has a diameter of 1 mm while the Brüel&Kjær hydrophone has a diameter of 21 mm. The positioning system for the hydrophone will also affect the spatial resolution; preferably the transducer will be fixed while the hydrophone is repositioned during the measurement. High spatial resolution is a cost issue. A simple solution with millimetre accuracy would not cost more than a few thousand SEK while the cost for high resolution solutions with sub-millimetre precision in all three dimensions will quickly be spiralling. All alternatives will be able to measure peak acoustic pressure but the difference will be the resolution of the acoustic pressure gradient which could be of importance for assessing exposure to non-target tissue.

There are reasons to believe that there are single circular piezo-electrical elements within the transducers of the aesthetic ultrasound systems. For single circular elements there are simple formulas describing the different parts of the ultrasound field (extreme near field, near field and far field). Normally, these formulas indicate the distance to the focus point. However, manufacturers of transducers of aesthetic ultrasound sometimes use acoustic lenses with pleated surfaces, possibly in order to shatter the ultrasound waves. By interference this leads to an uneven ultrasound field with multiple intensity hotspots. To characterize such field the above mentions formulas will not be valid and to assure that the intensity maxima is captured, multiple discrete measurement points are needed.

Further aspects to consider when using the hydrophone set-up are reflections from the tank wall, reverberations between the transducer and the hydrophone and the hydrophone distance from the transducer. Reflections from the tank wall might by interference induce incorrect measurement values. It is suggested that an uneven ultrasound absorbing lining is placed at inside of the tank to minimize such effect, see Figure 2. In contrast to reflections, reverberations are more difficult to handle and should be considered while designing the test protocol. The magnitude of this

effect can be increased by increased pulse repetition frequency and decreased distance to the transducer.
Furthermore, the reverberation issue makes the needle hydrophone (solution 1) more preferable since small size objects generate weaker reverberations than larger objects.

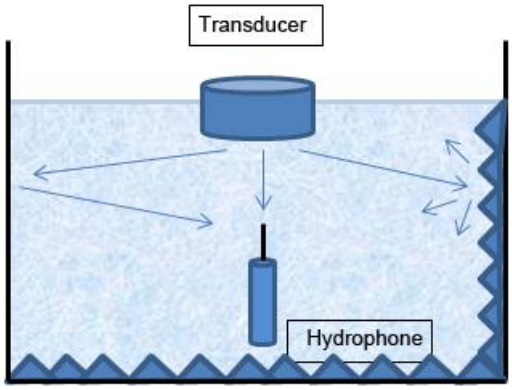

Figure 2 Hydrophone-transducer set-up. On the left side of the water tank there are strong reflections from the tank wall while on the right wall, which is lined with uneven ultrasound absorbing material, the ultrasound reflections are weaker due to both scattering and absorption.

In order to characterize the ultrasound field from aesthetic ultrasound devices, the frequency and the acoustic pressure should be measured, preferably in as many points as possible to achieve good spatial resolution. The intensity could be calculated if the aim is to verify the technical specification of a specific device, since this is a commonly used parameter. The parameter TI is of low interest for the aesthetic ultrasound devices on the Swedish market. However, if HIFU based devices for aesthetic purposes should appear on the Swedish market, TI would be of higher interest. The parameter MI should be used carefully since the standard equation is not valid when used at the frequencies associated with low-frequency non-thermal ultrasound, and there are few studies that have further evaluated this so far.

5.1 Should aesthetic ultrasound devices be classified as medical devices?

This report has been carried out since the Swedish Radiation Safety Authority considers characterizing the ultrasound field from aesthetic ultrasound devices which are used on the Swedish market in order to assess potential harmful exposure. This is not done today by any Swedish authority, neither by any notified body before introduced to the Swedish market since the aesthetic ultrasound devices are not intended for medical use and therefore not classified as a medical product. The manufacturers of aesthetic ultrasound devices clearly point out that their products should not be used with the purpose to treat obesity, most likely in order to avoid the classification as a medical device.

However, the classification does not necessarily have to be based only on the manufacturer's claim of the intended purpose of their product. If the use of a product is considered to have significant risks, the Swedish Medical Product Agency can classify the product as a medical anyway. Further, the decision to not classify a product as medical is not permanent and could be altered in the future. This is something that the Swedish Radiation Safety Authority must weigh before a decision to start evaluating the aesthetic ultrasound devices. It is suggested that the Swedish Radiation

Safety Authority and the Swedish Medical Product Agency discuss and reach a mutual understanding about the responsibility in this area. It is reasonable to believe that the Swedish Medical Product Agency reconsiders their decision and classifies aesthetic ultrasound devices as medical in the future.

In the US, the FDA has identified risks associated with the use aesthetic ultrasound devices and organisations like EFSUMB have new guidelines under consideration for this field. Furthermore, there have been incidents and at least one study reporting adverse events such as development of blisters on the skin [Shek et al., 2009]. Except from the obvious reason that the method itself is not fully investigated and evaluated in independent studies, there can be multiple underlying causes to such adverse events. It could be due to unpredicted output power from the device related to variability in the manufacturing process, which is something that should be assessed according to the requirements by the FDA [Food and Drug Administration, 2011]. Furthermore and likely, the most common reason for adverse events or exposure of non-target tissue regions is handling errors of the operator. Hence, only characterization of the ultrasound field does not necessarily warrants the safe use of the aesthetic ultrasound devices since the user dependent errors will neither be assessed nor improved. When a device is classified as a medical product, there are better premises for safe use since there are demands for instructions from the manufacturer in accordance with the education of the intended user.

5.2 Conclusion

The aesthetic ultrasound devices found on the Swedish market (with exception for the UltraShape device) have not been studied in peer-reviewed publications and the technical specifications from the suppliers are often incomplete. Consequently, there is a need to evaluate these devices in order to achieve adequate knowledge about possible risks associated with their use.

Hydrophones for the purpose of characterizing this type of ultrasound are unusual. In this report, two different hydrophone measurement set-ups are proposed. The ultrasound should be characterized by the acoustic pressure. It is not clear today if the formula for MI is valid for low-frequency ultrasound.

It is recommended that the Swedish Radiation Safety Authority and Swedish Medical Product Agency discuss their respective future responsibility and how these devices should be handled.

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Appendix 1

This section contains a table of the identified aesthetic ultrasound devices in Sweden.

Device	Manufacturer	Distributor	Frequency ultrasound	Intensity	Focus depth	Comb. RF/laser
Cavi Lipo[1]	Skinrex	FA Import	25-28 kHz	8.5 W/cm^2	Max 16mm	No
Omorphia	Unknown	Victus Medical Clinic	40 kHz	Unknown	Unknown	RF/ laser
SlimFit Pro[2]	Beijing HUAWEI Technology Co. Ltd	Slim Fit Center / Clinic of Scandinavia / Vitasil AB	Unknown	Unknown	Unknown	Unknown
Coax Med	Biotec Italia	Klinikutrustning Sverige AB	28 kHz	Unknown	Unknown	RF
ELMAC Cavity Cell System	Elmac Elettronica	H.O.Ds (House of derma science)	34 kHz	Unknown	Unknown	Unknown
Polarshape	Unknown	Polarkliniken	Unknown	Unknown	Unknown	RF
UltraShape[3]	Syneron and Candela	Kraft Medical	200 ± 30 kHz	17.5 W/cm^2	15 mm	RF
LipoRoyal	Unknown	LM Invest AB	40 kHz	Unknown	Unknown	RF
Multi-Light Plus[4]	Unknown	Unknown	Unknown	Unknown	Unknown	RF/laser
LipoSonix[5]	Solta Medical inc.	MikronMed	2.0 MHz	>1000 W/cm^2	Max 16mm	No

Comments:

[1] According to FA Imports' webb page the CaviLipo is distributed to aesthetic clinics in 27 different cities in Sweden.

[2] This device attracted attention in 2012 due to an episode of the investigating consumer's rights TV-program, "Plus", where the cosmetic effect and the safety of using the device were discussed. Today (Sept 2013) this device is difficult to trace on the Swedish market. The distributors' webb pages are down or inactive and no beauty clinics could be found that offered treatments with this device. It is possible that the SlimFit Pro either is off the market or distributed under a different name.

[3] This device is approved by Health Canada but not FDA and is therefore not distributed in US.

[4] According to Plastikoperationer.net, this is an aesthetic ultrasound device on the Swedish market. However, only one aesthetic clinic could be found that offered treatments with this device but they were not willing to give any further information about the device or the manufacturer.

[5]This is a HIFU device that is available on the Swedish market. However, the distributor MikronMed states that they have no LipoSonix devices currently on the market. This device is approved by the FDA to be distributed on the US market.

Appendix 2

This appendix provides a detailed specification on the equipment solutions for characterizing the ultrasound field from the aesthetic ultrasound devices.

Solution 1:
Company: Precision Acoustics, Hampton Farm Business Park, Higher Bockhampton, Dorchester, Dorset DT2 8QH, UK Telephone**:** +44 (0) 1305 264669 Email**:** technical@acoustics.co.uk

Item	Description	Cost (EUR)
Hydrophone	1mm needle hydrophone probe with PA calibration (1-20MHz in 1MHz increments) (Commodity Code:9027804590)	1,475.00
Preamplifier	Submersible preamplifier for Precision Acoustics hydrophones. (Commodity Code:9027804590)	1,255.00
DC Coupler	DC Coupler with power supply. (Commodity Code:9027804590)	220.00
Booster Amplifier	Hydrophone Booster Amplifier. (CommodityCode:9027804590)	2,210.00
Oscilloscope	Oscilloscope: Manufacturer-- model number 3012A (Commodity Code:9030201090)	2,500.00
Total cost		7780.00

Solution 2:
Company: Brüel&Kjær Sound & Vibration Measurement A/S · DK-2850 Nærum · Denmark Telephone: +45 7741 2000 · www.bksv.com · info@bksv.com

Item	Description	Cost (EUR)
Hydrophone	Type 8104, frequency range 0.1Hz to 120 kHz	
Frontend	3-ch. Input Module LAN-XI 102.4 kHz Type 3052	
Software	Software for PULSE™	
Total cost		17,000-23,000

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The Swedish Radiation Safety Authority has a comprehensive responsibility to ensure that society is safe from the effects of radiation. The Authority works to achieve radiation safety in a number of areas: nuclear power, medical care as well as commercial products and services. The Authority also works to achieve protection from natural radiation and to increase the level of radiation safety internationally.

The Swedish Radiation Safety Authority works proactively and preventively to protect people and the environment from the harmful effects of radiation, now and in the future. The Authority issues regulations and supervises compliance, while also supporting research, providing training and information, and issuing advice. Often, activities involving radiation require licences issued by the Authority. The Swedish Radiation Safety Authority maintains emergency preparedness around the clock with the aim of limiting the aftermath of radiation accidents and the unintentional spreading of radioactive substances. The Authority participates in international co-operation in order to promote radiation safety and finances projects aiming to raise the level of radiation safety in certain Eastern European countries.

The Authority reports to the Ministry of the Environment and has around 270 employees with competencies in the fields of engineering, natural and behavioural sciences, law, economics and communications. We have received quality, environmental and working environment certification.

Strålsäkerhetsmyndigheten
Swedish Radiation Safety Authority

SE-171 16 Stockholm
Solna strandväg 96

Tel: +46 8 799 40 00
Fax: +46 8 799 40 10

E-mail: registrator@ssm.se
Web: stralsakerhetsmyndigheten.se