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Authors: Jonna Wilén
Kjell Hansson Mild
Ronnie Lundström

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Non-Ionising Radiation in Swedish Health Care

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SSM perspektiv

Bakgrund

Inom sjukvården används alltmera teknik som exponerar patienter för icke-joniserande strålning vid diagnostik och terapi. Ofta används sådan teknik som ett alternativ till och ibland i kombination med metoder som exponerar för joniserande strålning.

Huvudsyftet med studien var att identifiera och beskriva hur icke-joniserande strålning används inom hälso- och sjukvård, samt att undersöka förväntade exponeringsnivåer, identifiera eventuella hälsorisker och identifiera kunskapsluckor inom området. Icke-joniserande strålning refererar här till icke-joniserande elektromagnetisk strålning med frekvenser från 0 Hz upp till 3,0 PHz, inkluderande elektromagnetiska fält, optisk strålning och mekaniska vågor såsom ultraljud.

SSM har saknat en samlad kunskap kring de metoder och exponeringsnivåer som använder icke-joniserande strålning inom sjukvården. Bland annat EU:s vetenskapliga råd SCENIHR (har numera bytt namn till SCHEER) har pekat på behovet av forskning om potentiella hälsoeffekter inom detta område. Studien var alltså viktig för att få ett underlag för att bedöma behovet av ytterligare säkerhetsåtgärder inom området, identifiera kunskapsluckor och också för att få ett bättre underlag för att besvara frågor angående säkerhet och eventuella risker.

Resultat

Inga hälsorisker eller allvarliga säkerhetsbrister har identifierats. Däremot är de exponeringsnivåer som används många gånger på en nivå där det finns en tydlig biologisk påverkan och ibland kan även akuta symtom upplevas, detta är dock ofta helt avsiktligt för att få önskad effekt och av övergående natur.

Författarna har identifierat ett behov av att förbättra hälsovårdspersonalens kunskap om risker och säkerhet vid användning av icke-joniserande strålning samt pekar på vikten av tydlighet när det gäller vilken organisation/myndighet som ska tillhandahålla sådan information.

Rapporten indikerar också att ett robust forskningsunderlag för närvarande saknas för att bedöma möjliga långsiktiga hälsorisker med användning av exempelvis MRI, TMS och ultraljud. Den kunskap och forskning som finns tillgänglig tyder dock inte på några betydande hälsorisker med nu aktuella exponeringsnivåer.

Relevans

Rapporten stöder Strålsäkerhetsmyndighetens tidigare uppfattning att de tillämpningar med icke-joniserande strålning som används i sjukvården inte utgör några kända hälsorisker. När metoder som bygger på icke-joniserande strålning ersätter metoder som bygger på joniserande strålning ökar patientsäkerheten, under förutsättning att syftet med undersökningen eller behandlingen uppnås.

Behov av vidare forskning

Trots att det idag inte påvisats några hälsorisker med icke-joniserande strålning inom sjukvården (UV undantaget) anser myndigheten att ytterligare forskning är angelägen kring långsiktiga effekter på patienter vid i första hand de metoder som ger en exponering runt de nivåer där tydlig tillfällig biologisk påverkan eller akuta övergående symtom kan uppträda, detta gäller exempelvis MRI och TMS.

Mera kunskap är också önskvärd avseende långsiktiga effekter av ultraljudsexponering av foster.

Ytterligare forskning behövs också för att undersöka möjliga negativa effekter av ultraljud i kombination med kontrastmedia.

I takt med att det blir vanligare med hybridmetoder där olika strålslag kombineras blir det angeläget att följa forskning kring potentiella hälsorisker med detta.

Projektinformation

Kontaktperson SSM: Torsten Augustsson
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Authors: Jonna Wilén, Kjell Hansson Mild and Ronnie Lundström
Department of Radiation Sciences, Umeå University, Umeå, Sweden

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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.

SSM 2017:37

Non-Ionising Radiation in Swedish Health Care

Jonna Wilén, Kjell Hansson Mild and Ronnie Lundström

Department of Radiation Sciences,
Umeå University, Umeå, Sweden

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Content

1. Sammanfattning

Studien har gjorts på uppdrag av Strålsäkerhetsmyndigheten med huvudsyftet att identifiera och beskriva hur icke-joniserande strålning (NIR) används inom hälso- och sjukvård, men också att undersöka förväntade exponeringsnivåer, identifiera eventuella hälsorisker och identifiera kunskapsluckor inom området. NIR refererar här till icke-joniserande elektromagnetisk strålning med frekvenser från 0 Hz upp till 3,0 PHz, inkluderande elektromagnetiska fält, optisk strålning och mekaniska vågor såsom ultraljud.

I studien har vi kartlagt medicinska tillämpningar där NIR används inom Västerbottens läns landsting (VLL; två länssjukhus och över 30 vårdcentraler), Kalmar läns landsting (KLL och 3 länssjukhus) och Karolinska Universitetssjukhuset i Stockholm (KUH).

Vi har använt publicerad litteratur och rapporter från myndigheter som International Commission on Non-Ionising Radiation Protection (ICNIRP), the Food and Drug Administration (FDA), Health Canada, och i vissa fall egna mätningar för att undersöka exponeringsnivåerna för patienter och personal och jämfört dem med dessa riktlinjer och vår nuvarande kunskap om möjliga hälsoeffekter. Även behandlingsrekommendationer från Läkemedelsverket och nationella riktlinjer från Socialstyrelsen har ingått i vår kartläggning. Vidare har vi konsulterat medicintekniska ingenjörer främst inom VLL för att få hjälp med att kategorisera medicinsk utrustning, och annan sjukvårdspersonal för eventuella riktlinjer för användning av utrustningen. Rapporten är indelad i tre sektioner; elektromagnetiska fält, optisk strålning och ultraljud.

Exponering för elektromagnetiska fält sker i vården främst vid diagnostik och terapi. Tre tillämpningar har identifierats som kan medföra hög exponering för patienter och personal, vilket innebär att akuta hälsoeffekter inte kan uteslutas: magnetisk resonanstomografi (MRT), transkraniell magnetisk stimulering (TMS) och diatermi, där potentiella akuta effekter som t ex sensoriska effekter och värmeeffekter kan förekomma, ibland dock avsiktligt för diagnos/behandling.

När man använder optisk strålning såsom klass 3 och 4 lasrar för terapi eller kirurgiska ingrepp och UV behandlingar måste akuta effekter som oavsiktliga brännskador och fotoreaktion från laserexponering och erytem och påverkan på ögonen under UV behandlingen undvikas.

Ultraljud är i allmänhet att betrakta som ett säkert alternativ vid såväl diagnostiska som terapeutiska tillämpningar men risk för termiska och mekaniska effekter måste ändå alltid övervägas.

Kartläggningen av medicinsk utrustning hos de ingående sjukhusen/landstingen visade att i stort används samma typ av medicinteknisk utrustning används på de olika sjukhusen men med vissa undantag. Som ett exempel var antalet diagnostiska ultraljudsutrustningar som används på KLL, KUH och VLL, 98, 515 och 206, respektive. Motsvarande siffror för MRT var 2, 22 och 6. Enligt vår inventering var antalet diatermienheter 54, 259 och 202.

Vi har också försökt att uppskatta antalet MRI undersökningar i Sverige baserat på siffror från VLL. Vi har extrapolerat fram att ungefär 400 000 till 450 000 undersökningar utfördes under 2016. För andra applikationer var det inte möjligt att göra samma typ av uppskattning på grund av spridd användning av utrustning på många kliniker och avsaknaden av strukturerad rapportering.

Vår slutsats utifrån litteraturstudien och uttalanden från organisationer och myndigheter är att det finns en brist på kunskap om långsiktiga effekter av MRT och ultraljud. Eftersom det har blivit vanligare att använda hybridtekniker där kombinationen av

exempelvis joniserande strålning och magnetiska fält tillämpas (t ex PET-MR) behövs mer kunskap om möjliga hälsoeffekter vid kombination av olika exponeringar. Det finns också andra kombinerade tekniker såsom ultraljudsaspiration där tillämpningar finns som kombinerar skärande och koagulerande effekter från ultraljud och diatermi. Till exempel diskuterar både ICNIRP och SCENIHR behovet av mer kunskap om diagnostiska tekniker såsom MRI och ultraljud i kombination med kontrastmedel. Vi har inte täckt kombinationer explicit i rapporten, men hybridtekniker finns på vissa svenska sjukhus, t ex PET-MR och ultraljudsaspiration.

Vår slutsats är att regleringen av yrkesmässig exponering för NIR täcks väl av gällande arbetsmiljöföreskrifter och dessa gäller också för medicinsk användning. Tillämpningen och kunskapen om detta kan emellertid vara bristfällig inom sjukvården.

Det finns gott om europeiska standarder för medicintekniska produkter som bl a ställer krav på att visuellt rapportera patienternas exponeringsnivåer för till exempel MRI och ultraljud. Denna information används ofta vid MR undersökningar, särskilt när patienter med medicinska implantat eller andra situationer som kräver lägre exponering ska behandlas.

Vi har inte kunnat kartlägga hälsovårdspersonalens kunskap inom risker och säkerhet av NIR, men vi konstaterar baserat på litteratur och efter samråd med personalen, att detta är ett område som bör förbättras. ICNIRP anger i en sammanfattning från en workshop att utbildning av personal som använder NIR är nödvändig speciellt för de som använder klass 3 eller 4 laser. Deras slutsats är att särskilda riktlinjer för patienter kunde vara användbara, men att det inte är uppenbart att det krävs särskilda riktlinjer för personalen. De konkluderar också att information till användarna krävs, men att detta är komplicerat då användningen är utbredd på många olika kliniker.

Vi har till viss del funnit information om säkerhetsaspekter i samband med NIR från myndigheter som Strålsäkerhetsmyndigheten, Socialstyrelsen, och Läkemedelsverket men detaljerad information om specifika medicinska ingrepp saknas.

Slutligen drar vi slutsatsen att för att förbättra kunskaperna om säkerhetsaspekter för NIR i hälso- och sjukvårdssektorn, finns behov av tydlig, evidensbaserad information från tillförlitliga källor och det borde vara uppenbart för användaren vilken organisation/myndighet man kan vända sig till för information.

2. Executive summary

The study was done as an assignment from the Swedish Radiation Safety Authority. The main aims of the study were to identify and describe methods that use non-ionising radiation (NIR) in health care, to examine anticipated exposure levels for each application and frequency range, to identify possible health hazards, and to identify knowledge gaps in the field. In this report NIR refers to electromagnetic radiation with frequencies from 0 Hz up to 3PHz. This range includes ultraviolet light, visible light, infrared light, radio waves, and mechanical waves such as ultrasound.

In this study we have mapped applications using NIR within Västerbotten County Council (VCC: two county hospitals and over 30 primary health care centres), Kalmar County Council (KCC: 3 county hospitals), and Karolinska University Hospital in Stockholm (KUH).

We have used published literature and reports from authorities such as the International Commission on Non-Ionising Radiation Protection (ICNIRP), the Food and Drug Administration (FDA), and Health Canada. In some cases, we have used our own measurements to investigate the exposure levels for patients and staff, and have compared those with the present guidelines and our present knowledge of possible health effects. We have also used treatment recommendations from the Medical Product Agency and national guidelines from The National Board of Health and Welfare. We have consulted medical engineers, mainly at VCC, for help in categorization of medical equipment and other medical professionals for guidance on the use of the equipment. This report is divided into three sections: electromagnetic fields, optical radiation and ultrasound.

Exposure to electromagnetic fields is mainly used in health care for diagnosis and therapy. Three applications were identified as “high exposure to patients and staff,” i.e., acute effects cannot be ruled out. These areas are: magnetic resonance imaging (MRI), transcranial magnetic stimulation (TMS) and electro surgery, where potential acute effects such as sensorial effects or heating effects might occur - sometimes intentionally for diagnosis.

When using optical radiation, such as class 3 and 4 lasers for therapy or surgical procedures, and when using UV treatments, acute effects such as unintentional burns, photo reactions from laser exposure, erythema and effects on the eyes during UV treatment need to be avoided.

Ultrasound is generally regarded as a safe alternative for diagnostic as well as therapeutic applications but the risk for thermal and mechanical effects still need to be taken into consideration.

Our survey of the medical equipment at the included hospitals showed that essentially the same type of medical equipment, with some exceptions, is used throughout Sweden. As an example, the numbers of diagnostic ultrasound apparatuses reported in use at KCC, KUH and VCC are 98, 515 and 206, respectively. The corresponding numbers for MRI are 2, 22 and 6. Our inventory showed that the number of electro surgical units (ESU), which seems to be one of the most common applications in health care using NIR, are 54, 259 and 202, respectively.

We have also tried to estimate the number of MRI procedures performed in Sweden based on figures from VCC. We extrapolated that approximately 400 000 to 450 000 procedures were performed in Sweden in 2016. For other applications, it was not possible to do the same type of estimation due to the widespread use of equipment at many clinics and lack of structured reporting.

We conclude, based on the literature review and statements from organisations and authorities, that there is a lack of knowledge regarding long-term effects of MRI and ultrasound. Since it has become more common to use hybrid techniques, i.e., where a combination of ionising radiation and magnetic fields (PET-MR) is used for diagnostics, more knowledge on the combination of different exposure levels is needed. There are also combined techniques, such as ultrasound aspiration where applications exists that combine the cutting/coagulation effect of ultrasound and ESU. At an workshop arranged by ICNIRP workshop and also SCENIHR discussed the need for more knowledge about diagnostic techniques such as MRI and ultrasound in combination with contrast media. We have not covered combinations explicitly in this report, but some hybrid techniques do exist at some Swedish hospitals, e.g., PET-MR and ultrasound-aspiration techniques.

We conclude that the regulation of occupational exposure to NIR is well covered. However, the appliance and knowledge about this might be sparse.

There are many European standards for medical devices that require the devices to visually report the exposure levels to the patients. e.g., MRI and ultrasound. This information is commonly used for MRI procedures, especially when patients with medical implants or other issues demand lower exposure.

We have not been able to survey the health care professionals' knowledge about the risks and safety measures in NIR, but we conclude, based on literature and after consulting staff, that this is an area that should be improved. ICNIRP also states in a workshop summary of non-ionising radiation in medicine that training of staff using NIR is necessary and that training for class 3 or 4 laser is essential. They conclude that specific guidelines for patient exposure would be useful, but that it is not obvious that special guidelines for staff are needed. They also conclude that information to users is required, but due to the widespread use of NIR, this is a complex subject.

We have found information, to some extent, about safety issues in relation to NIR from the authorities such as the Swedish Radiation Safety Authority, The National Board of Health and Welfare, the Swedish Work Environment Authority and the Medical Products Agency. Unfortunately, detailed information on specific medical procedures is missing.

Finally, we conclude that to improve the knowledge in safety aspects of NIR in the health care sector, there is a need for clear, evidence-based information from reliable sources, and it should be obvious to the user which source to address.

3. Background

Non-ionising radiation (NIR), e.g., ultrasound imaging, laser surgery, and UV-light treatments, have been used for a long time in health care. Some more recently introduced applications include Magnetic Resonance Imaging and Transcranial Magnetic Stimulation which is used to treat depression.

This document covers the use and safety of non-ionising radiation in health care. NIR refers to electromagnetic radiation with frequencies from 0 Hz up to 3,0 PHz, including ultraviolet light, visible light, infrared light, electric and magnetic fields, radio frequency fields, and mechanical waves such as ultrasound. ICNIRP [1] has recently published a statement on diagnostic devices using NIR, and they used the same division of NIR. In this report, we also include the use of NIR for therapeutic use.

Within the electromagnetic spectrum, NIR is situated below the ionising radiation band that includes X-rays (Figure 1). NIR has less energy than ionising radiation and cannot remove electrons from atoms, i.e., NIR cannot ionise (except for part of the UV band). NIR is sub-grouped into different frequency or wavelength bands. The different subgroups have different effects on the body and require different protection measures.

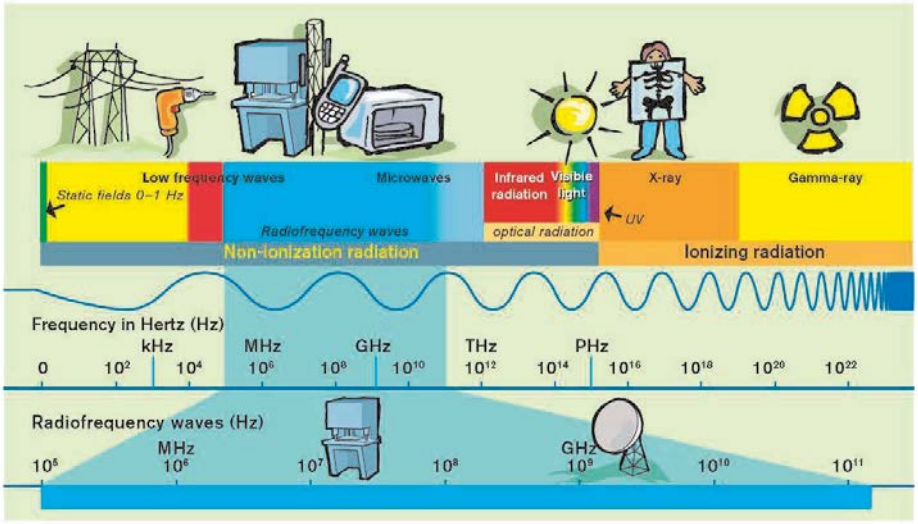

Figure 1. The electromagnetic spectrum. Illustration Gunilla Guldbrand

3.1. Aim of the study

This study was done as an assignment from the Swedish Radiation Safety Authority and the main aims of the study were:

- to identify and describe methods that use non-ionising radiation in health care.
- to examine anticipated exposure levels for each application and frequency range.
- to identify possible health hazards, and
- to identify knowledge gaps in the field.

In addition, the report discusses the need for continued activities in the area, such as:

- To identify and stimulate research that aims to investigate possible health risks with the use of NIR.
- To propose appropriate structure platform for further analyses.

4. Methods

Initially we investigated applications using NIR within Västerbotten County Council (VCC, which has two county hospitals and over 30 primary health care centres) by the use of the VCC inventory database (Maximo). Search terms (translated into English) were magnet stimulation, MRI, surgical diathermia, laser, ultrasound, light treatment, and UV. We also recruited a reference group of biomedical engineers at VCC, who have the responsibility for customer support, product service and maintenance with respect to all equipment listed in the inventory and, thus, could help us identify applications using NIR.

We have used published literature, both peer-reviewed scientific literature and reports mainly from authorities such as the International Commission on Non-Ionising Radiation Protection (ICNIRP), the Food and Drug Administration (FDA), Health Canada, and product datasheets from the manufactures. Our aim was to investigate the exposure levels and to compare those with the present guidelines and our present knowledge of possible health effects. When available, we have also used treatment recommendations from the Medical Product Agency and national guidelines from The National Board of Health and Welfare. In some cases, we have added data from our own measurements of the exposure (UV, MRI and surgical diathermia). From the literature search and from personal communications with users and manufacturers we have tried to get a perspective over new or coming techniques using NIR. In this case we focused on applications, which are close to introduction or which have recently been introduced into the Swedish health care sector.

This project has primarily focused on the equipment routinely used in health care. Equipment that uses power in direct contact with the patient has been excluded, except for those that produce considerable electric or magnetic fields such as, e.g., surgical diathermy. This project has focused on the patient's exposure, but when required, it has also examined exposure to the staff.

The work has been divided into these subareas:

- Electromagnetic field (0-300 GHz) in health care including applications using static-magnetic field, low-frequency magnetic and electric fields, radiofrequency fields, e.g., for transcranial magnetic stimulation (TMS), MRI and electrosurgical devices.
- Optical radiation including:
    - Visible light (400-780 nm) such as laser and light treatments
    - Ultraviolet light (100- 400 nm) such as UV treatment and UV disinfection units
- Ultrasound for diagnostics and therapy in health care.

For the broader picture of the use of NIR in health care in Sweden, we also established contact with two other County Councils/hospitals, chosen to represent a larger and a smaller County Council in Sweden, i.e. Kalmar County Council (KCC; 3 county hospitals), and Karolinska University Hospital in Stockholm (KUH). We have also collected the same information as from VCC from their inventory databases. The products have then been grouped into:

- UV therapy units
- Neonatal phototherapy units
- Electro surgical units (ESU)
- Transcranial magnetic Stimulation (TMS)
- Laser (Laser doppler, surgical laser, laser welding)
- Magnetic resonance imaging (MRI) units

- Ultrasound (diagnostic ultrasound, ultrasonic blood flow meters, surgical ultrasound, ultrasound heating, dental ultrasonic scalers and laboratory devices)

An effort has also been made to collect reported accidents in relation to NIR in the deviation management system. Questions about the safety management systems at VCC, KCC, and KUH have also been asked. The questions were (translated to English):

1. How is the safety work organised for devices that emit non-ionizing radiation (including ultrasound)?
2. How do you think your safety work functions at the hospital today for NIR equipment? What works well or badly? Do you have any suggestions on how safety procedures should be improved?
3. Are safety issues concerning NIR included during the decision to acquire new equipment?
4. Are you performing your own measurements on how much NIR is emitted by the equipment to patients or to staff? If yes, how is this work organised? If not, do you engage external consultants, suppliers or someone else?
5. It is argued in the literature that knowledge about the risks for both patients and personnel in the use of NIR equipment is deficient? Do you agree with this?
6. Both technical and medical training for handling equipment is usually provided by the supplier upon delivery. The question is how can staff skill level be maintained over time? What happens, for example, after technical updates, or when new personnel are introduced?

We have also investigated national as well as international guidelines on NIR that could be applied to patients and personnel. We have also searched for published information on safety aspects of NIR in health care from the Swedish National Board of Health and Welfare, Swedish Radiation Safety Authority and the Medical Products Agency. We have tried to briefly identify knowledge gap on safety and the use of NIR in health care mainly from published literature form authorities, but also in some cases from published scientific literature.

5. Non-ionising radiation in health care

The survey at the three hospitals/county councils with primary health care facilities showed rather similar types of medical products independent of the hospital. However, the number of devices within each product category varied considerably. A summary of the survey is given in Table 1. However, there might be misclassifications within each category due to different methods used to classify the medical products among the different hospitals. Some of the product categories that we would expect to find at each hospital have obviously not been included in the survey, probably due to other category names that were not included. These categories are marked with "not included" (n.i.).

Table 1. Summary of surveys at Kalmar County Council (KCC, Karolinska University Hospital (KUH), Stockholm and Västerbotten City Council (VCC)

	KCC	KUH	VCC
UV therapy units	4	25	30
Neonatal phototherapy units	11	36	21
ESU	54	259	202
TMS	-	5	5
Laser	5	28	27
Laser Doppler	n.i.	4	7
Surgical laser	5	19	18
Laser welding (laboratory)	-	-	2
MR units	2	22	6
Ultrasound	109	624	853
Diagnostic ultrasound	98	515	206
Ultrasonic blood flow meters	n.i.	68	166
Surgical ultrasound	7	26	40
Ultrasound heating	4	9	72
Laboratory devices	-	6	3
Dental ultrasonic scalers	-	-	366

A search within the VCC deviation management system database did not give any conclusive information about NIR-related accidents/deviations, but events such as ferromagnetic objects in the MRI scanner room, burns after UV phototherapy treatment and burns after surgical procedures due to metallic objects close to the patient while using ESU were found after closer scrutiny in the database. In general, NIR-related accidents are not easy to find within the system. We suspect an underreporting due to lack of routines that demand reporting and because it is not clear if the accident was in relation to NIR. Therefore, we did not go any further with these analyses.

The questions about the safety management systems, which were asked to biomedical engineers at VCC, KUH and KCC, gave mixed results. Some sites reported that the safety management works well, but that there are areas that could be improved, especially the transfer of knowledge to new colleagues. It was also pointed out that the biomedical engineers do not get enough education from the manufactures about safety issues. The engineers (N= 4) that answered these questions all had different areas of work (UV, laser, MRI, etc.), so their answers are not conclusive for the whole county council or hospital, but their answers give an indication of the situation. Below is a summary of the questions and answers.

1. *How is the safety work organised for devices that emit non-ionizing radiation (including ultrasound)?*
   From the answers we conclude that there are different routines in different hospitals. In some places a person from the medical technical department is responsible for the safety aspects for the use of US and laser, whereas in other hospitals it is not clear how safety work is handled.
2. *How do you think your security works today at the hospitals for NIR equipment? What works well or badly? Do you have any suggestions on how security work should be improved?*
   Again, a very diverse picture on the safety work was obtained. Some said it is working well, but in other places it is not clear where the main responsibility lies.
3. *Are safety issues concerning NIR included in connection with the procurement of new equipment?*
   In some cases the safety issues are addressed but not in all.
4. *Are you performing your own measurements of how much NIR equipment emits to patients or staff? If yes, how is this work organised? If not, do you engage external consultants, supplier or someone else?*
   In some hospitals regular controls are made for UV and light treatment, but others have no such controls.
5. *It is argued in the literature that the knowledge of the risks for both patients and personnel in the use of the equipment is insufficient. Do you agree with this?*
   In general they agree that the knowledge about risks are low with respect to UV, but safety in the use of laser and eye surgery is high.
6. *Both technical and medical training for handling equipment is usually provided by the supplier upon delivery. The question is how the level of skill is maintained among the personnel over time. What happens, for example after technical updates, or when new users are introduced?*

At the delivery of new equipment a short education by the manufacturer is usual. Older staff members educate the new staff members. It is pointed out that a continued education is also needed.

6. Electromagnetic fields in health care

Exposure to electromagnetic fields (EMF) is used in health care mainly for diagnostic and therapeutic purposes. The equipment used emits EMF that are much stronger than what is normally encountered in our daily environment. This leads to exposure of the patients undergoing examination or treatment and the staff, e.g., physiotherapists, surgeons, radiologists. Electronic equipment, including medical implants, can also be affected by the EMF.

The main interaction mechanism during exposure to EMF with frequencies up to 100 kHz in humans is the induction of electric currents. For frequencies between 100 kHz and 10 MHz, the effect is both induced currents and heat, and for frequencies above 10 MHz, the effect is seen only as heat.

To protect against these effects there is an EU directive [2] and a Swedish standard [3] which limit exposure to protect against known, immediate and negative effects in the staff and the patients. These limits are listed in the form of maximum induced electric field and the maximum heat load in the form of so-called SAR (Specific Absorption Rate). SAR is given in units of Watts per kilogram of tissue (W/kg). Since these limit values are not directly measurable quantities, the limits have also been expressed as action values which are directly measurable quantities, such as electric field and magnetic field.

The first tactile effects of exposure to EMF at low frequencies are nerve and muscle spasms. At higher frequencies, the effects are not as clear – such as a feeling of heat, discomfort and a behavioural impact, much like having a mild fever. The strength of the EMF when these effects begin to occur is well known and is the basis of the current limits.

If the EMF exposure is below the limits, according to our knowledge available today, there are no risks associated with the exposure, either in the long or short term. However, research has shown that EMFs can exert an effect on biological systems below these limit values. The mechanisms by which this occur, and if these effects are hazardous to humans, are not known, see further SCENIHR [4]. Low-frequency magnetic fields, such as that from power lines, have been classified by the WHO's IARC cancer expert bodies as a possible carcinogen, class IIB [5]. Radiation from mobile phones is still a current research question. The IARC has stated that it is not possible to rule out the possibility that there is an increased risk of brain tumors with prolonged use of mobile phones and has also classified their use as a class IIB carcinogen [6].

The safety management with the use of EMF in healthcare attracted attention in a workshop organized by ICNIRP, and a summary is given by Sienkiewicz [7].

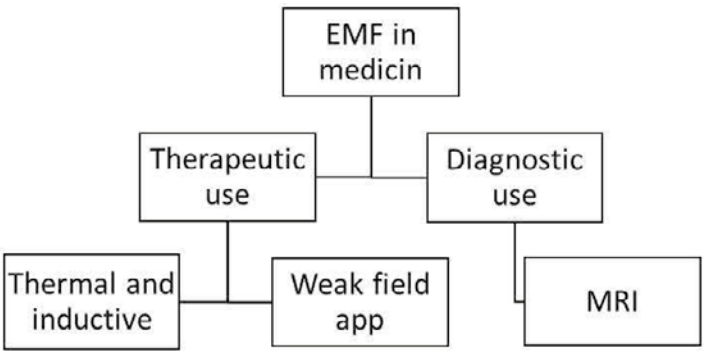

Figure 2. Division of electromagnetic field within the healthcare system.

The use of electromagnetic fields within the healthcare system can be divided into two main areas: therapeutic and diagnostic. This is illustrated in Figure 2. With regard to the

therapeutic division, low-frequency magnetic fields are used to induce currents in tissues and higher frequencies are applied to produce heat. For example, induced current is used for Transcranial Magnetic stimulation (TMS), and heat development is used in diathermy, either in the form of short-wave diathermy, microwave diathermy or electro surgery. Weak fields, with either low or high frequencies, are not used to any great extent in Sweden but are present in many places abroad. See further Markov [8] about bone and wound healing, cancer therapy, effect on microcirculation, and electroporation.

6.1. Magnetic resonance imaging

The Magnetic Resonance Imaging (MRI) technique plays a significant role in the diagnostic portion of health care today. This is because MRI is flexible in terms of what tissue properties need to be examined, it has high resolution and a very good soft tissue contrast. MRI is used for a wide range of applications, neuroimaging, cardiac imaging, musculoskeletal imaging, spectroscopy and functional imaging to mention a few. The number of areas where MRI is introduced increases and one of the recent areas where MRI has been introduced is modern radiation therapy where MRI is introduced for planning, positioning the patient, but also to monitor the treatment effect.

In Sweden today we have an estimated 150 MR cameras. We asked about the number of MRI investigations performed at the University Hospital in Umeå during 2016. Together on both cameras there were a total of 6,342 investigations performed, 3,374 on the 3 T system and 2,968 on the 1.5 T camera. It is estimated that during 2017 the total number of investigations may reach about 6,600 investigations.

At the county hospitals in Lycksele and Skellefteå there is one MR camera at each hospital and during 2016 they performed 2214 and 3817 investigations, respectively.

A rough estimate would be that on each camera in clinical use about 10 patients could be scanned per day and with about 300 operating days per year a total number could be (150x3000) about 400,000-450,000 patients undergoing MR examination. The total number of patients may be somewhat less since some patients are getting multiple scans.

A large number of people are exposed to the EMF associated with the camera. In addition to this, even the staff that handles the camera becomes exposed in different cases depending on the role they have in the investigation. Besides from the cameras used in the daily diagnostic there are also units in use in research and in radiation therapy where a combination of PET and MR is used.

The electromagnetic fields associated with MR scanners have been studied closely [9], and have been discussed at length [10] and therefore only a brief summary is given here.

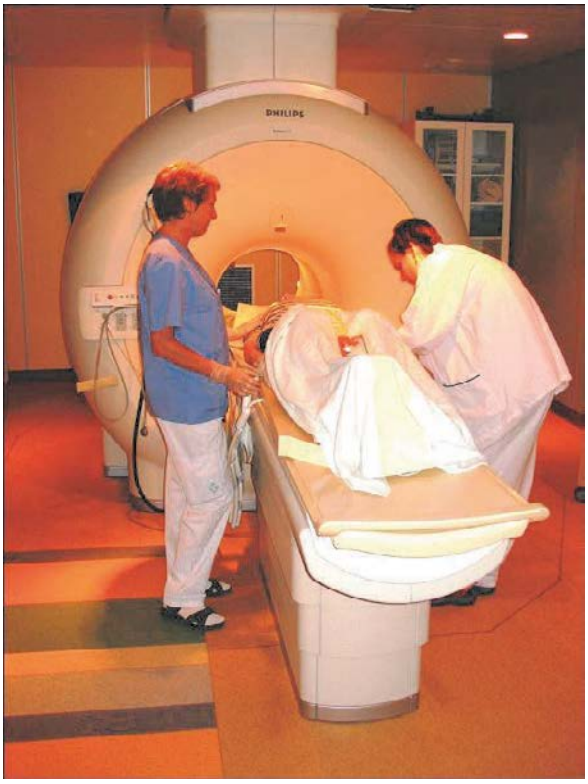

Figure 3. Preparation of a patient before entering the magnet for an MRI investigation. Photo: Jonna Wilén.

6.1.1. Static magnetic fields

MR scanners in clinical use have superconducting magnets, and these usually have a cylindrical opening or bore. The static magnetic field has a flux density of 1.5-3 T. A smaller number of systems are in use in research institutions worldwide, and these use static fields up to 9.4 T. In Lund, there is now a national common research MR working at 7 T. Due to the active shielding, especially for scanners with higher field strengths, the field declines rapidly with the distance from the scanner. The field is only significant within 0.5 m from the bore opening. However, this means that the static magnetic field gradient is steep, which can be of significance for the staff moving around the magnet. There is a requirement that the 0.5 mT contour (5 Gauss) around the magnet should be marked, or that access to that area is restricted. This is to prevent interference with the function of implanted pacemakers and cardioverter defibrillators. This contour is usually located inside the MRI scanner room.

When a person moves in the static field gradient in the MR room, electric currents will be induced in the body, and therefore the movement should be controlled and not too fast.

So-called open systems provide far greater access to the patient and facilitate interventional procedures. In such systems, the static field is usually around 0.2-1 T.

The static magnetic field is always on, regardless of whether an MR scan is in progress or not. This means that anyone who moves around the scanner will be exposed to a room-varying magnetic field, caused by movement in the static field, and its gradient.

6.1.2. "Switched" gradient field

A “switched” gradient field is used for image coding, and this is emanating from three separate coils in the three directions within the scanner (Figure 4). The "switch mode" gradient field is only active when a scan is to be performed and it is switched on and off to indicate the area of diagnostic interest and spatially encode MR signals. Fast sequences are used to catch rapid biological events, like movement of the heart. The faster the sequence the larger time derivate of the gradient field is required. The amplitude is of the order of mT with fast rise and fall times, tens to hundreds of µs. Typically, the gradient in the region of interest may be 25-50 mT/m and the maximum value (maximum amplitude divided by the rise time, slew rate) can be 100-200 T/m/s within the picture area. The gradient field in modern systems can be as high as 100 mT/m with a slew rate of 800 T/m/s. The wave forms of the gradient field are complex and are not periodic, but can be characterized by the primary frequencies in the range of kHz. In the figures below we show some examples of waveforms of the applied current in the gradient coils.

The limiting factor for the patient exposure is the electric potential induced in the patient’s nerve fibres that can lead to peripheral nerve stimulation (PNS). To avoid this a limit of about 20 T/s - which should not be exceeded - has been given as a rheobase value. However, for shorter pulse duration higher values can be allowed [3]. This also applies when the patient is moved into position in the camera. The speed of the movement must be limited in order not to cause nerve excitation.

Occupational exposure to the gradient field may be significant, especially near the bore opening. Wilen et al. [11] measured the rms value of the field up to 0.1 mT at 0.3 m from the centre of the magnet opening. From their data dB/dt values of 70 T/s could be calculated in that position. The magnitude of the magnetic gradient field and its derivative time depend on the pulse sequence used.

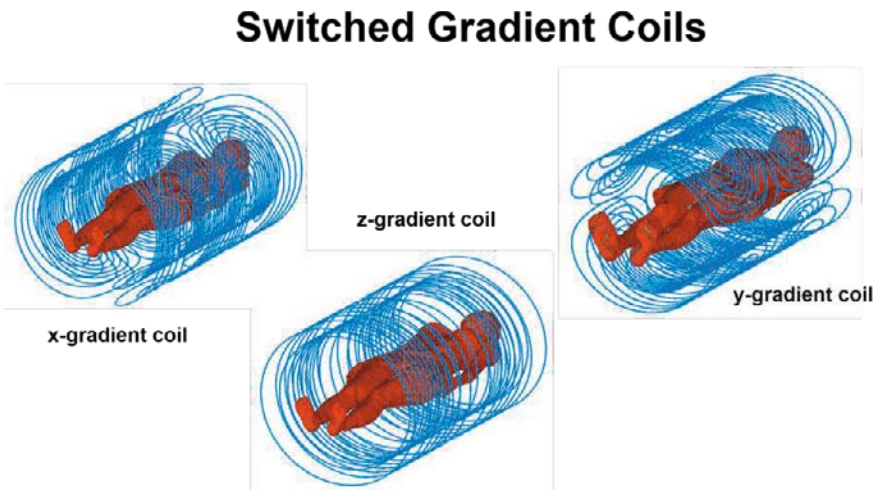

Figure 4. Illustration of the three coils for the switched gradient magnetic field. Courtesy of Jeff Hand, King´s College, London.

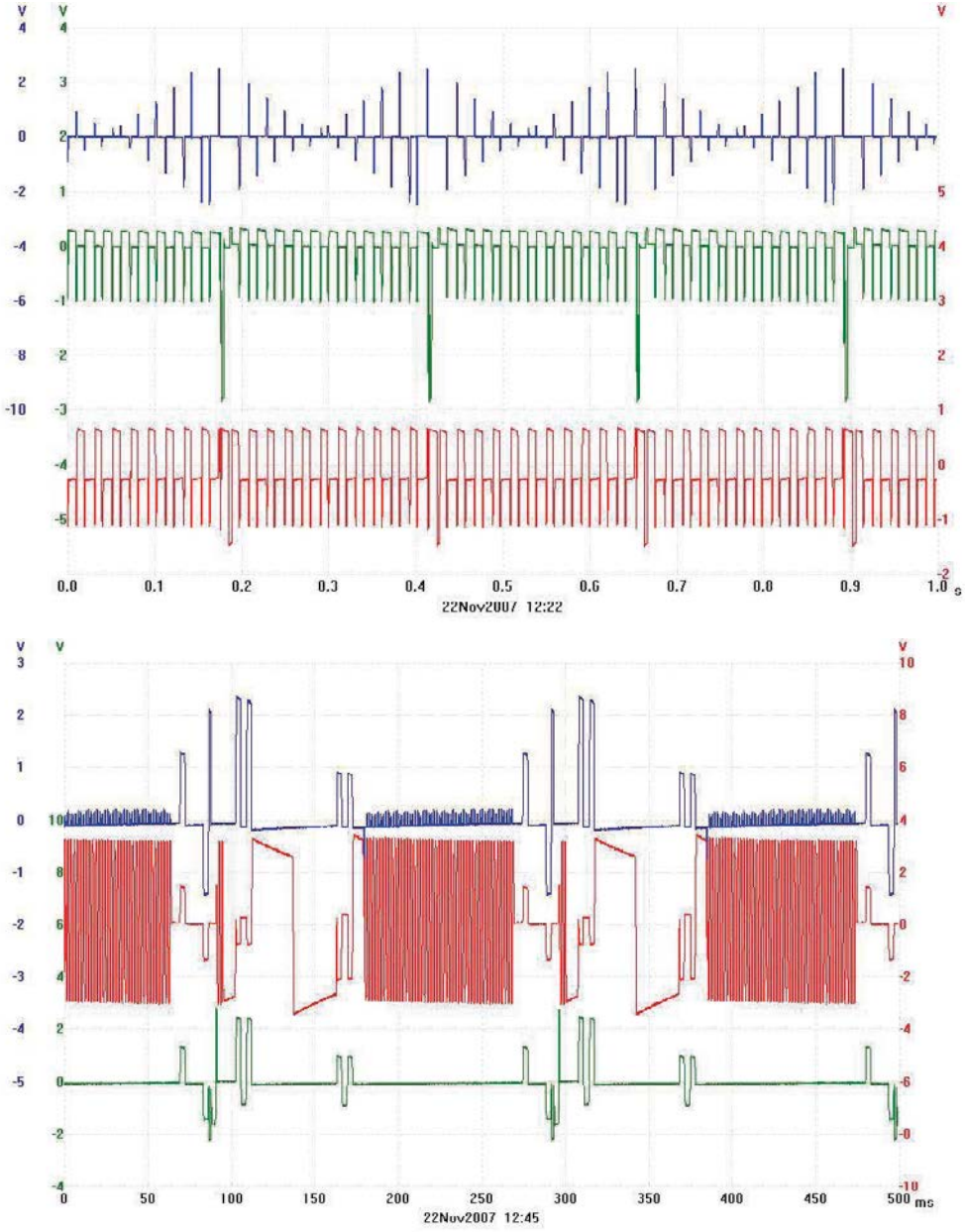

Figure 5. Measurements of current in the three gradient coils for two different sequences. The top sequence is a T2 weighted Turbo Spin Echo, and the bottom is an Echo Planar Imaging sequence. From Wilen et al. [11]

6.1.2.1. Ripple from the gradient field

Magnetic field exposure during an MRI scan is determined in large part by the gradient field from the three gradient coils. What was not known in the past was that there is a ripple overlaid on the signal with a frequency around hundreds of kHz. This gives a contribution to the time derivate, dB/dt, which can be higher than what is specified in the manual. Usually the values are up to tens of T/s, but the ripple can provide significantly higher values than that. Sundström et al. [12] measured the ripple on a Siemens Espree 1.5 T and found values of up to 56 T/s. When equivalent measurements were done on a Philips 3 T, the ripple was negligible. Thus, it is different between different machines. In order to fully characterize exposure, it is necessary to take into account the ripple effect.

6.1.3. Radiofrequency magnetic fields

An RF magnetic field is usually created with a body coil integrated into the scanner, which produces a circularly polarized magnetic field called B_1. For systems with cylindrical openings with 1.5 or 3 T, it is usually a coil in the form of a "bird cage" to provide an area around isocentre of the scanner where the B_1-field is spatially homogeneous. For open MRI scanners with the static field vertically, the RF B_1 field is often produced by a pair of planar coils placed above and below the patient. Only the magnetic field component is required for the MRI, and the electric field, E, is generally low except in the vicinity of the coil windings. Exposure to RF B_1 outside the bore is generally low since the field falls off quickly outside the transmit coil. An exception will be for employees who perform interventional procedures, especially in open scanners, where their hands and arms, and possibly head, can be exposed to levels that are like those to which the patients are exposed. The RF field has a frequency of about 42 MHz/T, meaning that for a 3-T scanner the frequency is approximately 126 MHz.

Various RF-pulse sequences are used depending on what contrast is required, and thus, the SAR value of each pulse sequence, is different. Usually, during clinical scanning, many different sequences are used to get the appropriate information. Based on our own measurements the peak values for the RF B_1 can reach 10 A/m and more. Since the duty cycle can be about 1%, the SAR values in pulses can be rather high, in comparison with the limit values. With a whole-body average SAR value around 1 W/kg, the peak of the pulse can reach 100 W/kg. This type of exposure has not been studied with regard to health effects. There is very little information available on high peak pulses because nearly all research on RF has involved only the average values and thermal effects.

The switch mode gradient field and the RF field is only activated during MRI procedure, and both the patients and personnel who are in the room during the scan will be exposed.

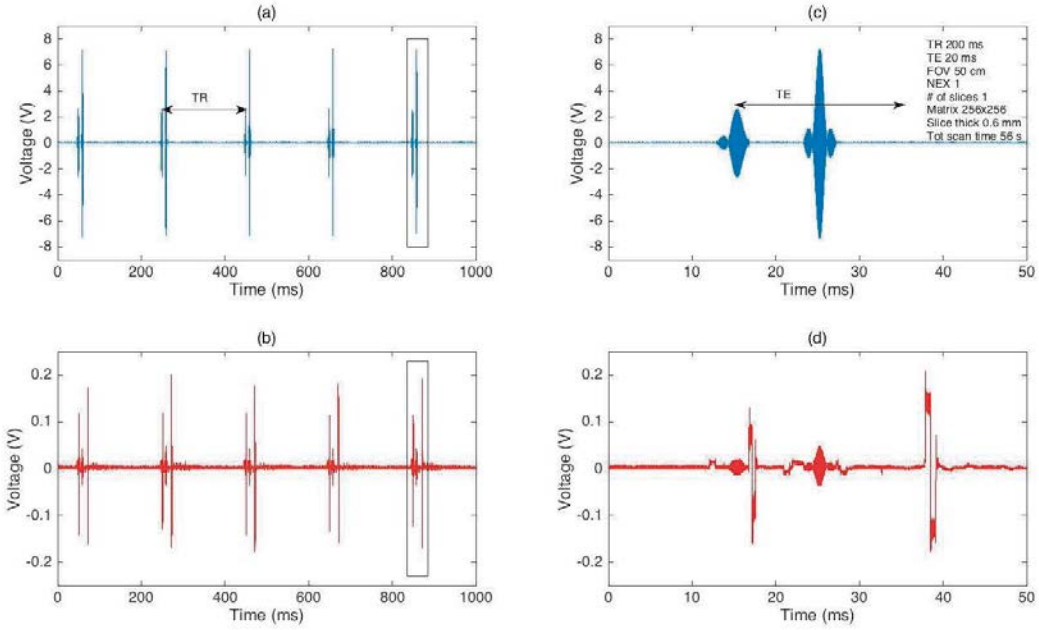

Figure 6. RF pulses are shown in the upper figure in blue, and the pulsed gradient field appears in the lower figure in red. Measurement is from a spin-echo sequence, oscilloscope photos show time derivate dB/dt, and the magnetic field in the form of induced voltage is measured in a pick-up coil. The pictures to the right show a magnified view of the 90 and 180 degree spin echo pulse pair with accompanying pulsed magnetic fields. From Frankel et al. [13]

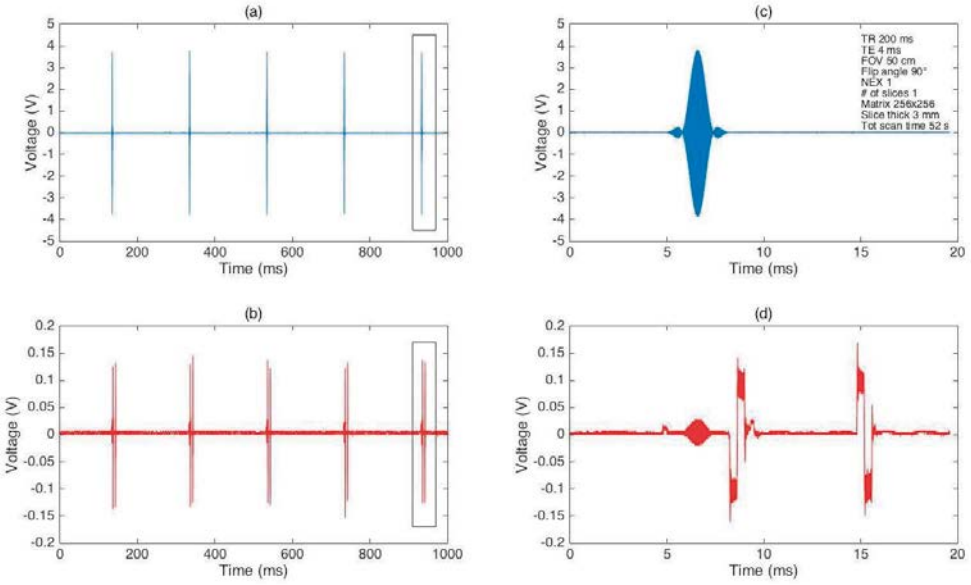

Figure 7. RF Pulse is shown in the upper figure in blue and the pulsed gradient field in the lower in red. The measurements are from a "spoled gradient echo sequence". The picture to the right is an enlarged part of the sequence. From Frankel et al. [13].

6.1.4. Exposure near MRI scanners

Beside the patient also the operator will be exposed to the magnetic fields near the scanner, mainly the static magnetic field that is always switched on. In some circumstances when personnel are present during scans, for instance during anaesthetic procedures when the patient needs to be monitored, the personnel are also exposed to stray fields from the switched gradient field and to some extent also the radiofrequency field. Several recent studies have examined the occupational exposure of people working with MRI. de Vocht et al. [14] measured both static and time-varying magnetic fields, and found that the time-weighted exposure levels were within the ICNIRP guidelines [15], but peak exposure limits were exceeded during certain procedures. Keevil [16] discussed the induced current density from movements in a static field, and he found that although the limit was set at 40 mA/m^2 according to [15] values up to 200--400 mA/m^2 could be measured. The limit can be exceeded if one is closer than 0.5-1 m from magnet opening. For the gradient field the limit value was 10 mA/m^2, and here values could be measured over 200 mA/m^2 inside the magnet during scanning.

Karpowicz and Gryz [17] studied exposure to static magnetic fields (SMF) during scanning. Measurements near a 1.5 T MRI magnet revealed that SMF exposure from different scanners depends on both the SMF magnet, the scanner design and the work organization. During a routine examination of a patient, nurses were exposed to SMFs exceeding 0.5 mT for approximately 1.5-7 min, and up to 1.3 min for SMF exceeding 70 mT. The average values for exposure to SMF were 5.6-85 mT, with a mean of 30 mT.

Chiampi and Zilberti [18] have developed a computational procedure to evaluate the internal E-field induced by movement in the static magnetic field gradient. For further details see Wang et al. [19]. ICNIRP [20] recently came with recommendations for mitigation of the induced electric field due to the movement of the static field. Working near an MRI scanner inevitably leads to an induced electric field in the body due to the

movement in a strong static magnetic field. The value given in the ICNIRP guidelines [20] is the same as that for induced field from ELF fields, namely 1.1 V/m. This is then translated to a reference value for the time derivative, dB/dt, as 2.7 T/s. Fatahi et al. [21] measured dB/dt in a study in which 5 MRI researchers moved around a 3 T and a 7 T scanner in a controlled way. They found large variations among the five people, but occasions that exceeded the limit were often similar, 30% of 60 scenarios. Further studies of this are needed to develop guidelines for adopting some simple precautionary rules for staff behaviour around MRI scanners to avoid exceeding the limits.

6.1.4.1. Reduced exposure

During most clinical scans, standard sequences are used, and often several sequences are needed for obtaining the required information. However, it is possible to reduce the exposure for the patient in some cases and many MRI scanners do have special protocols to reduce exposure for instance when the sound level needs to be lowered or also for some scanners when medical implants are present.

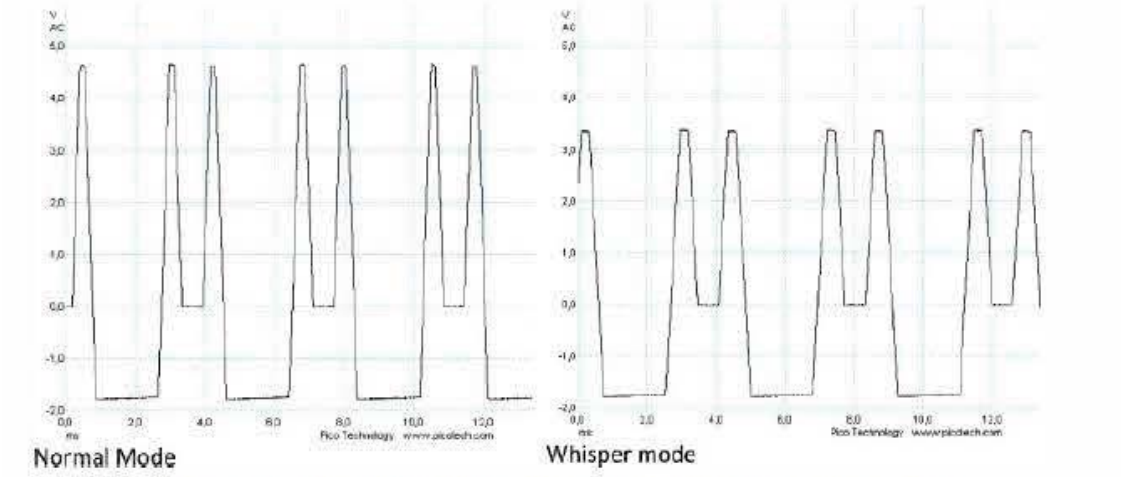

Fig. 1. The gradient current for the Trufi sequence in normal and whisper mode. (the Y-axes are expressed in Volts where 100 A = 1 V).

Figure 8. The change that occurs when the so-called Whisper mode is used on a Siemens MRI camera. By changing the rise and fall times of the fast gradient pulses, the exposure from dB/dt can be reduced with 1.5 times. An oscilloscope recording of current in one of the gradient coils during a Trufi sequence is shown. The scale is in Volts with converting factor 100 A = 1 V. From Wilen et al. [11].

6.1.5. Limits and regulations

Safety aspects for the use of MR have been described in several studies [22-25].

There are limits and rules for the exposure of patients as well as staff who may be exposed during an MRI examination. For the patient's safety it is necessary to comply with the standard [3]. Its adoption was intended to ensure the safety of patients undergoing an MRI examination as well as the professionals who work with MR. The standard sets both technical requirements on the equipment and on the organization of the work with MR. For the staff, the new regulations from the Swedish Work Environment Authority on electromagnetic fields also apply [26].

When it comes to gradient fields, the patient is to be protected from peripheral nerve stimulation (PNS), and this is done by restricting the induced electric field in the body. For that, both pulse intensity and duration are taken into account. This can then be

translated into a restriction on the time derivative of the gradient magnetic field, dB/dt. The standard [3] also defines operating modes for MR systems: *normal operating mode*, *first level of control* and *second level of control* based on level of SAR and dB/dt.

In *normal operating mode* the apparatus shall be set so that it does not exceed 80% of the threshold value of the PNS, and in a *first level controlled mode* it can go up to 100%. To go to this setting requires a specific action from the operator in order to clarify that the patient or operator now is entering a special risk position.

To protect the patient against undesirable temperature rise during an MR scan, there are also limits on how much the body temperature may rise. Normally, it should not be more than 0.5ºC, but in *first level controlled mode* it can be allowed to reach 1°C, and for special cases which require a permit (*second level controlled mode*), even higher levels can be allowed. These temperature rises have since been translated into the SAR values that are allowed, and in the *normal operating mode*, they should be kept at SAR < 2 W/kg. In *the first level controlled mode*, levels can go up to 4 W/kg whole body. These values are time averages over a 6-minute period. For times shorter than 10 s it is allowed to go up to two times these SAR values.

The standards also address the static magnetic field, and here the normal case is ≤ 3 T, and in special cases one can go higher. The audio level inside the machine is also restricted. The standard also discusses how to manage patients with various medical implants, but more on this in a separate section. Also the definition of controlled environment is defined by the standard were for instance the 0.5 mT limit apply due to potential risk to implants. To enter the controlled environment special authority need to be applied.

The Swedish Work Environment Authority has adopted the EU directive on regulations for protection from 1 July 2016. An exception is made for MR work so that exposure can exceed the limit values if the exposure occurs in connection with the installation, testing, operation, development and maintenance of, or research on, equipment for MRI for patients in healthcare. The exemption only applies to §§ 9--13 in the provision, and the other sections should be followed, and this applies in particular to the requirement that the employer must inform and educate the staff about the risks which can occur and how to work safely in order to avoid these [26].

For certain types of surveys, for example, when rapid processes are to be studied, it may happen that the patient can feel gentle nerve twitches in superficial nerves, which are caused by current induced in the body from the gradient field. The risk of nerve excitation is greatest when fast processes are applied, e.g., when rapidly changing gradients are used for functional imaging of the brain with MRI or for the diagnosis of stroke. Heating effects can occur when the number of RF pulses per unit time is high, such as in the anatomical image where detail resolution is important.

6.1.6. Risks and effects of MRI exposure

An MRI examination is not entirely risk-free. Because very strong magnetic fields are used, from static up to radio frequency, there are risks that require attention both before and during the investigation.

Static fields. A person inside the examination room moves in the strong gradient of the static magnetic field, and this will induce currents in the body - the faster the movement the higher the current. These currents may lead to subjective feelings, depending on how sensitive the person is. Symptoms include dizziness, nausea, headache, and an experience

of “curved” space [27-30]. ICNIRP has issued guidelines for induced electric fields from movement in a static field [20].

These symptoms become more common the stronger the static field is [28]. Today the greatest strength of a human MR scanner in Sweden is 7 T. It is actively shielded for static field, which means that the static magnetic field does not reach far away from the bore, but it also has the implication that the gradient the patient passes through when inserted into the opening is stronger than that found in non-shielded scanners. This higher static magnetic field gradient therefore increases the risk of symptoms for the patient. To reduce the risk for patients the speed of the patient table is adjusted due to the static magnetic field gradient to avoid symptoms.

Switched gradient field. The gradient field used in the MR is in the range of what can be tolerated before the experience of nerve excitation. Patients can experience slight nerve twitching on body parts that come closest to the solenoid coils, i.e. arms and legs that touch the walls of the magnet where the field is strongest. Setsompop et al. [31] have discussed the nerve stimulation thresholds and how different slew rates influences the quality of the picture, and a comprehensive study on nerve excitation and changing magnetic field has been done by Reilly [32].

Radiofrequency field. The intensity of the RF field is on the verge of what can be tolerated in the form of heating of the body without an increase in body temperature more than 1^{o}C. The strength is usually given in terms of how much energy is absorbed per kilogram, SAR, and levels of single W/kg may lead to harmful local elevations of temperatures, and cause a general increase in body temperature. Therefore, the scanner warns when too high SAR values are being applied.

The risk for burn injuries is especially great if the person comes too close to the walls of the magnet, since the RF field will increase with distance to the coil. Therefore, it is recommended that an insulation of at least 2-cm thickness is placed near the wall to prevent burns. At high SAR levels it is also important not to form closed loops with body parts, such as the arms over the head and the hands or knees against each other. Special consideration must be given to patients with poor body control, such as babies who do not sweat, and others with impaired circulation.

Reddig et al. [33] have given a list of estimated absorbed energy during scanning with different MR protocols. The mean whole body SAR value varies from 0.3 W/kg in a cardiac scan with a contrast agent to 2.6 W/kg for a lumbar spine scan. Including the time of the scan the energy absorbed ranges from 182 J/kg to 2,818 J/kg.

Implant. Passive implants, such as orthopaedic implants, can lead to a concentration of the radio frequency field and thus provide a very local harmful warming, something that is not detected until it is too late because the heat sensors in the body are superficial.

For active implants, such as pacemakers and defibrillators, the risks are that they can concentrate the radio frequency field, but also that its function may be affected. For the whole area around the implants, it may be helpful to have access to a medical specialist who has a good overview of the area and can provide advice in cases of doubt.

All patients are reviewed for contraindications prior to MRI scanning where possible implants are investigated carefully. All implants are categorized as *MR-safe*, *MR-Conditional* or *MR-Unsafe.*

Implants that are categorised, as *MR-Safe* is completely non-magnetic, non-electrically conductive, and non-RF reactive, and it is safe to perform MR scanning. *MR-Conditional* implants may contain magnetic, electrically conductive or RF-reactive components that are safe for operations in special conditions such as for instance a certain level of SAR, dB/dt or static magnetic field strength. Some implants are categorised as *MR-Unsafe*

which means that due to their ferromagnetic material pose a significant risk to the patient and MR scans are prohibited.

This information is available through the manufacturer of the implants but it is a hard and time consuming task to investigate this for each patient. Therefore, many hospitals have developed their own implant data-bases where also routines for especially MR conditional implants are stated. To keep these data bases updated is an important task for the safety organisation and might be especially challenging for smaller hospitals with few MR physicists. There have therefor been discussions about possible national databases to help especially the smaller clinics. There do exist some commercially available data bases but these are not complete. Also resources such as safety hand books are available, see for instance [34]

It is imperative that the first contact with the patient for an MRI examination includes a questionnaire on which implants the patient has, and this should then be followed up before the examination. This can cause problems with people who do not remember what implants they have and when the operation history is missing.

Mattei et al. [35] looked at the effect of the movement near the MRI scanner bore for people with a pacemaker or an implantable cardioverter defibrillator. They found that motion in and around an MR scanner can induce significant voltage, which would be enough to be misinterpreted by the implant and thus lead to inappropriate changes in its function. Persons with these implants, including MR-conditional systems, should not enter the MRI room, except in case of an examination under specified conditions.

Pregnancy and scanning. There are currently no established long-term effects of *in utero* MR scans, but account must be taken of RF heating and noise level. In England it is recommended that pregnant staff should avoid being in the room during scanning and that one should select sequences that minimize RF noise. This is also done in common practice at Swedish hospitals, but there exist no guidelines for this from Swedish authorities.

6.1.6.1. Indirect effects

Static fields. In a static field there is the projectile risk. The field is so strong that ferromagnetic objects can be dragged into the magnet with such great force that damage to the people who happen to be in the way can be life-threatening. It is important that all people entering the examination room such as staff, relatives and patients are controlled carefully so that no ferromagnetic objects are brought into the room. Incidentes have occurred when, e.g., trolleys, IV stands and office chairs, have been affected by the magnetic field, attracted to and stuck to the magnet [25].

This type of accident can be very dangerous in terms of injuries, but can also lead to a huge loss of investigative time. To remove the object from the magnet, it may be necessary to turn off the magnetic field by releasing the helium gas that keeps the magnet cooled to the superconducting temperature. Replenishment of helium and rebooting takes at least a week.

It is also important that patients (and personnel who will be present in the MR room) have been screened for various implants. The static field can exert force on an implant that is somewhat ferromagnetic, and it can thus be moved out of position with unwanted consequences. It should be noted that the implants that are considered safe for 3 T may not be safe for a 7 T machine [36].

Gradient field. The most common problem that occurs due to the gradient field is the level of noise caused by vibrations in the wires in the gradient coils. It is a requirement that personnel in the room during scanning have hearing protection, and patients must be

provided with protection. Sometimes a double hearing protection is put on the patient. Audio levels can range from 85 to 95 dBA.

6.1.6.2. Possible long term effects

Some studies have demonstrated genotoxic effects in cells after exposure to an MR scan [37-39], while others could not demonstrate any effects [40, 41] The MRI sequences used in those studies are clinically available and routinely used in heart and brain scans. In Reddig et al [33], patients undergoing clinical CT scans were used as positive controls, and the authors found nearly a doubling of DNA double strand breaks 5-30 minutes after the CT scan as compared with before the CT scan. There was no evidence of DNA damage after the MRI examinations.

In a recent paper by Foster et al. [42] those studies were criticized on the grounds that many lacked a positive control, sham exposure and blinding in the analysis work. They suggest that the results should be confirmed with studies with the same end points but with higher statistical power and more rigorous design.

In recent studies from Utrecht University [43-45] risk assessments for MRI workers have been carried out. They found an association between MRI-related occupational SMF exposure and an increased risk of accidents leading to injury, and for commute-related (near) accidents during the commute from home to work found that radiographers using intrauterine devices (IUDs) and were occupationally exposed to stray fields from MRI scanners reported abnormal uterine bleeding more often than their co-workers without an IUD, or nonexposed co-workers with an IUD. In particular, radiographers present inside the scanner room during image acquisition showed an increased risk. These findings points to the need for further research to find out if staff working close to MRI scanners are at increased health risk.

Recently a report from an EU Committee, the SCENIHR (Scientific Committee on emerging and newly identified health risks) [4], gave a review of the area of EMFs and health. They also give recommendations on health effects of MR fields. They recommend long-term prospective and retrospective cohort studies of personnel exposed to high-gradient fields in the operation of MRI units, and this is a high priority issue. As there have been reports on DNA damage in patients after an MRI scan, therefore additional studies investigating genotoxic effects of MRI examinations in either patients or volunteers should be done.

The challenges with the exposure assessment for epidemiological studies of MRI personnel have been discussed in a publication of a COST BM0704 group [46].

6.1.7. Organizational aspects of safety for MRI system

Personnel working with MR must receive adequate training on the various incidents that can occur in different contexts including direct effects such as movement induced symptoms, heating effects but also indirect effects such as possible risk for implants and ferromagnetic objects. For instance, if a patient starts feeling bad during a scanning and must quickly be taken out of the magnet, certain precautions are needed. If a fire is detected on the premises, the firefighters must be informed about the risks with the static field since they are likely to carry ferromagnetic equipment. If there is need for an emergency stop and a quench of the magnet, helium might leak out in the room, and the oxygen level can become low. Information about this must exist. At the MRI clinics, to our experience the safety management works quite well and the introduction of the regulation [26] will also improve this further. It is more challenging to make the safety management work for personnel that are not primary situated at the MRI clinics, such as

cleaning personnel, anaesthetist and other groups that rather seldom, enters the scanner room.

In a recently published document by Hand et al [47] recommendations on how to allocate the responsibility for safely working with MR are given. The organizations behind the document is European Federation of Organization of Medical Physics (EFOMP) and they recommend the introduction of a number of positions for the operative responsibility, such as:

MR Medical Director (MRMD) or MR Research Director (MRRD), MR Safety Officer (MRSO), and MR Safety Expert (MRSE). It is assumed that MRMD, MRRD and MRSO are part of the organization that performs the actual scanning, while MRSE can be an external person.

MRMD or MRRD shall, among other things, oversee the safe execution of the MRI scan on each patient/person being investigated in the system. MRMD/MRRD shall be available to the operators of the MR system when the system is available. MRMD/MRRD shall ensure that appropriate human security and quality programs are implemented, as well as a risk assessment performed for MR facility.

MR Safety Officer (MRSO) is often carried out by the senior Radiographer. Multiple MRSOs can be appointed provided that only one is responsible at a given time. He/she shall be easily accessible to operators of MR system at all times when MR facility is accessible. The role also involves managing the risks posed by MR equipment and monitoring the measures taken to protect against such risks.

MR Safety Expert (MRSE). This position is expected to serve as a resource for the MRMD/MRRD or MRSO. MRSE is often an MR physicist, but others with the appropriate technical MR expertise could also fill this role.

MRSE roles include giving advice on construction, scientific, and administrative aspects of safe use of MRI equipment, to provide the Security Council with regard to non-routine MRI procedures for individual substances and groups of substances, such as implants, metallic foreign bodies, tattoos and other similar issues.

By implementing something like the above, then also requirements in the Swedish work environment authority's new regulation: electromagnetic fields, applicable from mid-2016, can be fulfilled.

6.1.8. Conclusion

There is an increasing number of patients, including children and young adults, who are examined with MRI, and MRI scanners with stronger magnetic fields have become more common. Therefore, the question of possible long-term effects on patients has been raised. There are no epidemiological studies on large groups of patients who have undergone MRI scans. MRI is used increasingly in paediatric imaging diagnosis. A study on the effects of MRI exposure in children is recommended by the SCENIHR [4] with high priority.

SCENIHR also recommends studies investigating possible cognitive effects of exposure to magnetic gradient field of employees working in the immediate vicinity of the MRI equipment.

The question about how to deal with patients with various types of medical implants is something that could be addressed in a national database which is accessible to all.

Overall there is a need for education and training of the personnel involved in MRI investigations. This should be organized in such a way that new staff members can easily get the training and information about the safety aspects. Implementing the safety management system suggested by [47] and described above, might be one way to go.

6.2. Electro surgery

Electro surgical units (ESU) is the most common medical-technical equipment in our hospitals using EMF. Only at VCC, there are 202 different ESU registered the corresponding figures for KUH and KCC are 254 and 54, respectively.

Radiofrequency energy is used in several surgical procedures, not only in medical care but also in dental care. In most cases, a small active electrode applicator and a flat electrode (also known as the ground electrode or return pad) are used. The ground electrode returns to the generator (monopolar configuration). The active electrode provides a high current density and serves as a cutting or coagulating instrument by applying a current with sinusoidal or pulsed waveform, and the frequencies are about 0.3 to 5 MHz. A widely used minimally invasive electro surgical procedure is radiofrequency ablation, which is routinely used in oncology, cardiology and otorhinolaryngology.

In a study of 6 ESU, Marco and Maggi [48] found that close to the equipment the fields were quite high, but at a distance of 0.5 m from the machine, the electrical field strength fell to 32-57 V/m and the magnetic field strength fell to 0.2-0.8 A/m. In the worst case at maximum reading, the surgeon's hands were exposed to RF field with the magnetic field strength of 0.75 A/m and the electric field strength at 400 V/m. Significantly higher values were measured by Liljestrand et al [49] and they also noted that the fields are produced not only by the active electrode but also of the return pad and cable.

The system uses different sequences depending on whether the intention is to cut or coagulate. Several different modes exist, and Table 2 gives examples of this. See also below from Wilén [50].

Measured peak values of the voltage at electrode tips are between 1 to 4 kV. The highest values are obtained when using coagulating mode. Wilén [50] also concludes by noting that when using ESU, both surgeons and other professionals that come close to the active cable are exposed to radiofrequency fields in excess of the guidelines specified by the ICNIRP [15]. They point out that further studies and calculations must be made to ensure that the ICNIRP specified "basic restrictions" are not exceeded.

The ICNIRP's values are now accepted as a Swedish regulation by the SWEA [26]. Laboratory tests show that shielding of the active conductor gives a substantial reduction of the electric field around the conductor and can thus be a possible way to move forward to reduce exposure using ESU. According to one of the manufacturers of diathermy equipment, there is one system on the market that has shielding, but the users think it is too clumsy to use and it lacks smoke exhaust. Therefore, on the Swedish market only non-shielded electrodes are used.

Based on measurements by Wilén [50] the use of ESU with unshielded electrodes leads to exposure to electric fields in excess of the action levels given in the EU directive on occupational exposure to EMF and thereby also the new Swedish regulation. The question then is raised if also the underlying limits are exceeded, and to answer this further studies and investigations need to be done.

The limits are set both as instant values not to be exceeded, and for the frequencies used here the E-field action value is 610 V/m. This should also be combined with a time

average value of 610/(frequency in MHz) for thermal effect. The first value is to protect against nerve stimulation and here the limit is set at $3.8 \times 10^{-4} \times f$ (f in Hz). In the thermal case the limit is set in SAR values: whole body 0.4 W/kg, head and torso 10 W/kg and extremities 20 W/kg.

It is not likely that the time averaged SAR values will be exceeded, but that needs to be shown. For induced E field, further investigations in form of measurements and calculations are needed to ensure that the limit is not exceeded.

In the case study SWEA refers to in connection with the regulation: "the use of this device is likely not to exceed the Exposure Limit Value (ELV) for the surgeon or other hospital staff "[51] . However, this assertion is completely at odds with the measurements made by Wilén [50], where she found a risk that the action values could be exceeded.

Table 2. Description of the evaluated VIO 300 d modes.

	Wave form	Max. The RF peak Voltage (Vp)		Max. output power (W)	No. of period in the pulse
AUTOCUT	CWA	740		300	-
HIGH CUT	CW	950		300	-
DRY CUT	PMB	1450		200	7
SOFT COAG	CW	190		200	-
	SWIFT COAG	PM	2500	200	3
FORCED COAG	PM	1800		120	2
SPRAY COAG	PM	4300		120	1

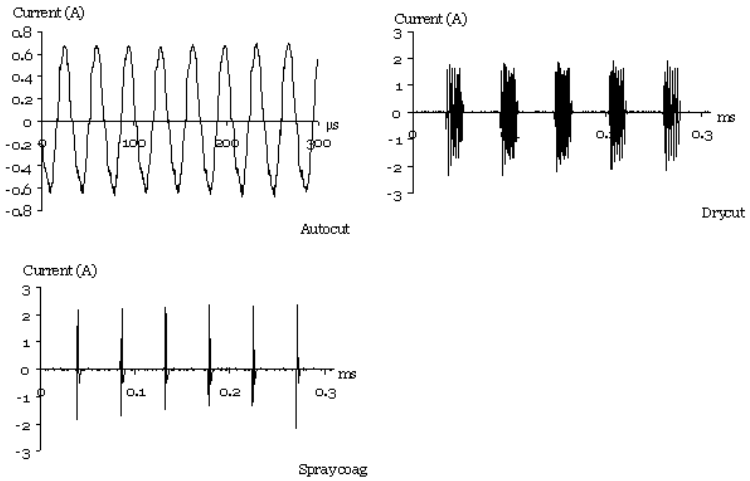

Figure 7. Oscilloscope scans from measured current in the active cable for AUTOCUT (8/300), DRYCUT (8/200) and SPRAYCOAG (2/120). From Wilén [50].

6.2.1. Indirect effects of surgical diathermy.

From a medical routine at the Department of Anesthesia in the Region of Jämtland/Härjedalen on risks related to the use of surgical diathermy [52], we pick up parts of it below.

The use of surgical diathermy can be risky for both the personnel and patients. When the high frequency current flows in one part of the patient's body, there is a risk of burns. The greatest risk occurs if the return current is spread over a too small area, due to poor contact with the neutral electrode. It may also be other metal surfaces the patient is in contact with which can take over a part of the return current.

For example, a surgical table, due to its large size, has sufficient capacitance to ground a lead current and can therefore cause burns. ECG connectors, due to the capacitance of the amplifier and cables, can lead a significant amount of the electrosurgical current. ECG electrodes should be attached as far as possible from the diathermy electrodes so that they do not lie between the active and the neutral electrode of the diathermy apparatus.

The risk of current concentration during surgery in the vicinity of electrically conductive orthotics (surgically implanted metal objects such as metallic prostheses) and pacemakers is particularly important. The risk for burns increases with increasing current and power during the surgery. The lowest possible setting must therefore be used. If the patient has an active implant, such as pacemaker, bipolar cautery should be used first. Pacemaker or pacemaker electrodes must not, however, be between the surgical site and the neutral electrode. If the patient has an implantable defibrillator (ICD) the defibrillation function should be switched off during the operation.

There are also risks for explosion and fire. When the diathermy generator is used, sparks may occur. Therefore, flammable aesthetic gases should not be used, and flammable liquids, such as rubbing alcohol which could accumulate, e.g. in the navel, must have evaporated before the diathermy apparatus is used. Even the risk of ignition of bodily gases should be taken into account, especially at the opening of a dilated gas-filled colon.

6.2.2. Education

It is our experience from talking to medical staff and manufacturers that the knowledge about all the different settings on diathermy equipment is quite low among surgeons. The education of new surgeons is usually done on a word of mouth basis, i.e., the older ones tell the younger ones how to do it. The knowledge about the EMF emission from the equipment is very rudimentary, and precautionary measures are seldom applied, such as avoiding to place the cable close to the body or medical equipment.

6.2.3. Conclusion

In [51] the problem with EMF from electrosurgical devices are dealt with. They find very low values for the electric field compared with our own measurements [50]. We found that under certain settings and waveforms, the use of surgical diathermy with unshielded electrodes leads to exposure to electric fields in excess of the action levels given in the EU directive on occupational exposure to EMF and thereby also the new Swedish regulations, AFS 2016:3. The question then is raised if also the underlying limit values are exceeded, and to answer this further studies and investigations need to be done. To reduce the exposure, both to the staff and to the patient, shielded cables would be a solution. Then both the active cable, as well as the cable to the neutral electrode, would be shielded.

It would also be of interest to find out about the education level of safety aspects for the use of surgical diathermy. Furthermore, the knowledge of laws and limits applying to the use of surgical diathermy is also to a large extent missing.

6.3. Short-wave and microwave diathermy

Diathermy is used in physical therapy for the treatment of acute or chronic orthopaedic and inflammatory conditions. The therapeutic effect comes from the heat produced in the tissues due to the absorption of electromagnetic energy at high frequencies. Short-wave diathermy uses 13.56 MHz or 27.12 MHz in a continuous form or pulsed mode. Microwave diathermy uses primarily 2.45 GHz, but there are devices that work at 434 MHz. Studies for the evaluation of exposure to diathermy has mainly focused on occupational exposure by physical therapists, and we do not know of any study of patients who had undergone the diathermy. During the treatment a temperature rise is wanted, so clearly the SAR values will be dozens of W/kg during the treatment period, which may be up to 30 minutes.

A measurement of 20 physical therapy departments throughout the United Kingdom and 36 different diathermy units showed that at the distance of 0.15-0.2 m the electrical field strength for a continuous wave was generally over 500 V/m and sometimes as high as 5000 V/m when using capacitive electrodes. The magnetic field strength at the same distances was 0.5-2.0 A/m [53], and the authors suggested that the operator should maintain a distance of at least 1 m from the unit, cables and electrodes. These measurements are completely in line with what we found already in the 70s, and the devices have not changed much since then [54]

In a recent survey of 10 short-wave diathermy devices that operated at 27.12 MHz, it was noted, however, that the field fell below the reference level for occupational exposure in the ICNIRP guidelines [55] at 2 m for capacitive electrodes and at 1 m for inductive equipment [56] For microwave diathermy, the measurements on about 11 units have shown that if the operator is at a 1-m distance from 2.45 GHz and 434 MHz applicators,

and if there are no large metal objects in the vicinity that can reflect radiation, then the fields are within the reference levels for occupational exposure [57].

A numerical study has shown that short wave diathermy can cause relevant unintended exposure of tissues, such as eyes, central nervous system and gonads, if certain output levels are exceeded for specific applicators, as in the treatment of head, shoulder or hip [58].

The use of this form of EMF therapy is very limited in Sweden today, and has been replaced by ultrasound. See more about that in the section about Ultrasound.

6.4. Transcranial Magnetic stimulation

Transcranial Magnetic Stimulation (TMS) is used both as a diagnostic instrument and for therapy. However, it is not yet widespread in Sweden, and today TMS equipment is available only at some psychiatric clinics for the treatment of depression and at clinical neurophysiology departments where TMS is used for diagnosis of nerve damage.

TMS is a technology based on the induction of an electric field inside the brain by application of an external magnetic field with rapid rise and fall times. The induced electric field in the brain has been calculated when different coils are used for the treatment. Mai and Ueno [59] reported E fields of the order of tens to hundreds volts per meter and the induced current density was estimated at tens of A/m^2. In this case an excitation is wanted, but it should be compared with the limits given for occupational exposure in the EU directive EU2013/13 which is 1.1 V/m.

This field can depolarize neurons or modify cortical excitability by selecting the appropriate parameters for stimulation and the duration of the treatment session. This has behavioural consequences and therapeutic potential [23]. However, a recent review Klooster et al. [60] states that the mechanisms of action of neuro stimulation still remains incompletely understood. They give the present understanding of the induced electric fields with the use of a figure-eight coil.

An experimental study has assessed the exposure of the operator during a TMS treatment session with a figure-eight coil, a pulse repetition frequency of 5 pulses, and stimulus intensity of 60-80% of the level that provides direct nerve excitation. The level at the operator exceeded the EU directive reference levels for magnetic fields at a distance of approx. 0.7 m from the coil [61].In a numerical study [62], it was confirmed that staff working with TMS treatments can be exposed to magnetic fields exceeding the ICNIRP's guidelines [15] and the SWEA’s new regulations [26]. The conclusion was that the use of a figure-eight coil results in a smaller leakage field and thus lowers the induced current density in the TMS operator compared with circular coils. The authors suggest that the operational staff should not be within 1.1 m from the TMS coil and suggests that robot-controlled TMS systems should be used instead of hand-held devices.

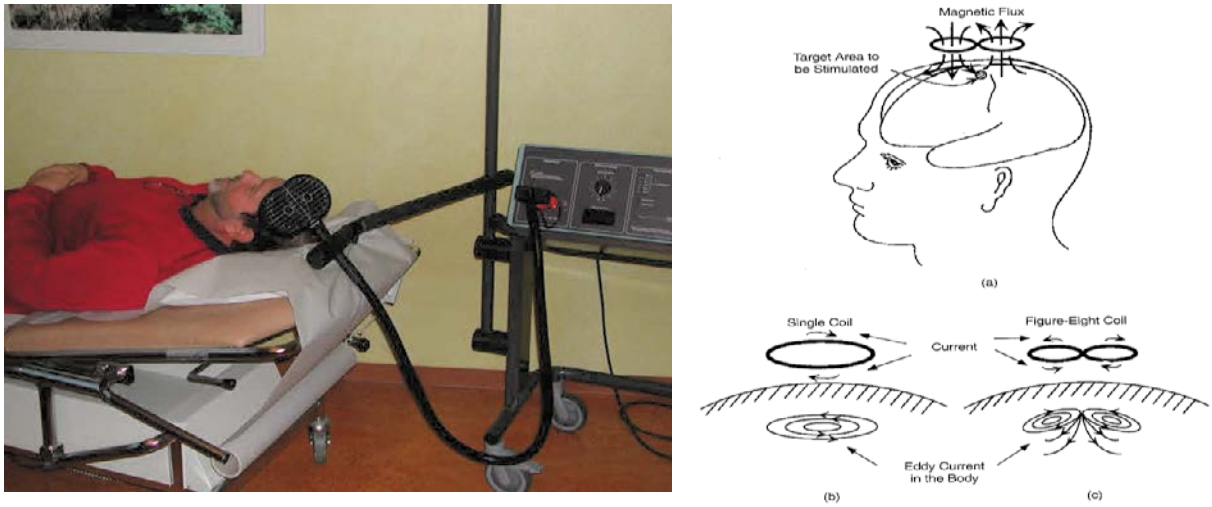

Figure 9. TMS treatment with a Figure-8 coil. To the left a schematic illustration of the induced current from the pulsed magnetic field. The peak dB/dt can reach several tens of kT/s and the current density is of the order of tens of A/m2. Photo Kjell Hansson Mild. Illustration with courtesy of Professor Shoogo Ueno, Tokyo.

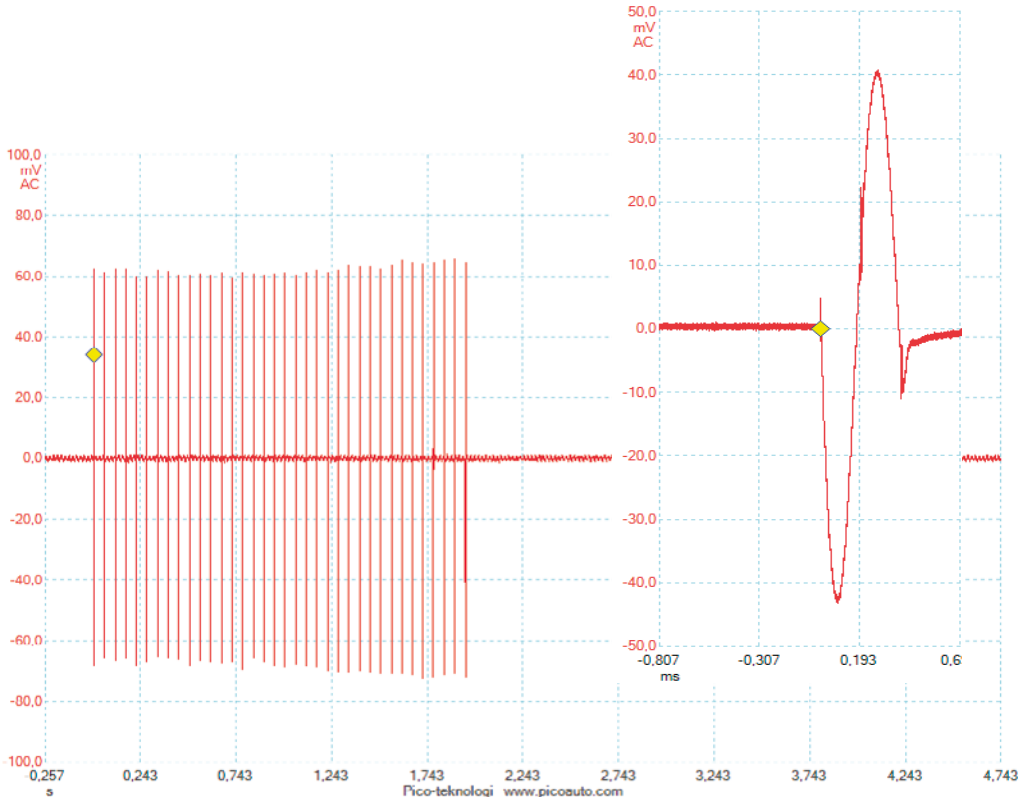

Figure 8. Oscilloscope scans from measurement on MagVenture rTMS system with a coil Cool-B65 (MagVenture A/S, Inc. 303 Perimeter Center North, Suite 300, Atlanta, GA 30346, United States). Cool-B65 coil is a figure-eight coil. Pulse length is 300 µs, repetition frequency 10 Hz, 37 pulses per sequence, 21 seconds between pulse showers, and 80 showers per treatment. From [63]

6.4.1. Limit values and safety

Given the very strong pulsed magnetic fields used in the TMS treatment, there is a clear need for safety procedures and recommendations for management. Training requirements for the staff who manage the TMS apparatus are also important.

There is a need to protect personnel against unwanted exposure, and TMS treatment is subject to the SWEA regulations on exposure to electromagnetic fields [26]. The regulation has far-reaching requirements on training and information for those who may be exposed at the level of the limits, and this includes TMS treatment. We will return later to this issue in our summary with recommendations.

The Food and Drug Administration (FDA) in the United States has released recommendations for what information the manufacturer shall provide, we do not have similar requirements in Sweden. Our experience after having visited a number of institutions, which provide TMS treatment, is that the knowledge of what a TMS apparatus actually does and potential risks with magnetic field exposure is very limited.

The patient receives a high exposure that is intended to lead to nerve excitation. It is therefore necessary that the personnel operating the apparatus is well acquainted with how the TMS functions, and that particular attention must be given to certain groups of patients. Also here, patients with implants are in need of special attention before a possible treatment.

6.4.2. Use of TMS in healthcare

Use of TMS in healthcare is not widespread. Yet. For diagnostics it is used in neurophysiological investigations, but the number of investigations is not great. From personal information from the staff at VCC it was estimated that 50-100 patients per year are investigated with the use of TMS. In psychiatry, clinical treatment with the use of TMS is only done in two places in Sweden, Skellefteå and Eksjö. The former had over 600 patients in the last half year undergoing treatment for depression. In other places, such as Uppsala, Linköping, Lund, Gothenburg, and Stockholm, treatment with TMS is used in research of this treatment.

The Swedish Medical Products Agency states in a background document [64] that today there is only moderate scientific support for use of TMS for depression. This view is shared by van Belkum et al [65], and in their review article on the treatment of depression with TMS they write: The mode of action of this new technique is however largely unknown.

A group of European experts [66] established guidelines for therapeutic use on repetitive TMS regarding pain, movement disorders, stroke, amyotrophic lateral sclerosis, multiple sclerosis, epilepsy, consciousness disorders, tinnitus, depression, anxiety disorders, obsessive-compulsive disorder, schizophrenia, craving/addiction, and conversion. They found a sufficient body of evidence to accept with level A (definite efficacy) the analgesic effect of high-frequency (HF) rTMS to the primary motor cortex (M1) contralateral to the pain and the antidepressant effect of HF-rTMS to the left dorsolateral prefrontal cortex (DLPFC). They also stated that professionals carrying out rTMS protocols should undergo rigorous training to ensure the quality of the technical realization, guarantee the proper care of the patients, and maximize the chances of success. Finally, they predict that under these conditions, the therapeutic use of rTMS should be able to develop or increase in the coming years.

The National Board of Health and Welfare has issued a referral edition about the use of repetitive TMS as an alternative treatment for depression. [67] The method is new, but it has been used with positive effects on persons with medium to severe depression. The side effects have been light. This may lead to an increase in the application of TMS to treat depression.

6.5. Magnetic fields in incubators

Premature babies often have a need for care in a neonatal intensive care unit. Here a stable thermal environment can be offered, which makes it easier for the child to maintain a suitable body temperature. Warming of the incubator will give rise to magnetic fields inside the incubator, and it has previously been seen that the 50 Hz magnetic field levels can be several μT in incubators. Epidemiological studies have observed an association between magnetic field exposure and childhood leukemia [5]. They have also found impacts on heart rate variability in children treated in incubators, and as a possible explanations the elevated magnetic field levels have been suggested [68].

There are several papers published where measurement of the magnetic fields in incubators have been presented. In a recent master thesis [69] careful measurements were made to identify the low-frequency magnetic fields in and around two types of incubators (Dräger 8000 IC and Giraffe OmniBed) as well as peripherals thereto. In the older incubator model, Dräger 8000 IC, measured values of 50 Hz magnetic field were between 1.0 and 8.1 μT inside the incubator. In the newer model, Giraffe OmniBed, flux density ranged between 0.2 and 5.8 μT. The mean value from long-term registrations in the incubators was 1.9 μT for Dräger incubators and 0.2 μT for Giraffe incubators.

Given that the IARC classified low-frequency magnetic fields as class IIB [5], possibly carcinogenic, and that the Swedish authorities issued a precautionary approach with regard to exposure to magnetic fields, this should be taken into account with regard to the choice of incubators Possibly, one could imagine that the Radiation Safety Authority along with the National Board of Health should speak out about this in a joint statement.

6.6. Magnetic fields from induction loop pad

Hearing aids usually have two operating modes, one for normal use and one for use with a so-called hearing loop. By switching over the device to the latter mode in premises with inductive loop hearing, the subject can hear what is being said over the public address system. There is also equipment with induction loop systems for home use that can be connected to the TV set. In its simplest form, it is a simple induction coil with about 10 turns of wire, and this coil is located either under the seat cushion or on top of it. The loop pad is connected via a single amplifier to the TV and amplification level will be set at a level so that the magnetic field at the ear is at 0.5 μT. We recently made measurements [70] and found that the magnetic field could reach several tens of μT over the body. In Sweden today, it is estimated that approximately 20,000 loop pads are in use. These inductors are also beginning to be given to children who may be exposed to these relatively strong low-frequency magnetic fields several hours per day. Perhaps one should apply the precautionary principle and seek some other solution with less exposure because of the IARC rating IIB for this kind of exposure. Even for pregnant women, different solutions should be considered.

6.7. Active implantable medical devices

Active implantable medical devices can be divided into two categories, namely, for diagnosis and for treatment. The first category includes those devices that are used for monitoring physiological events. Such devices are inserted into the patient's body for *in-vivo* monitoring of critical physiological processes, such as cardiac function (electrocardiographic (ECG)), hemodynamics (venous oxygen saturation SvO2, blood pressure), body thermoregulation (temperature), and metabolic dysfunction (blood sugar level) [71-73]. The second category of devices includes those used for the treatment of a disease, a dysfunction or a deterioration, such as different neuromuscular micro stimulators, [74, 75], drug-infusion pumps [76], micro electro-mechanical systems (MEMS), cochlear implants [77] and visual prostheses [78].

Unfortunately, despite the increased use of active implantable medical devices within or on the body, the Specific energy Absorption Rate (SAR), current density, or fields in tissues, is not always reported even if it should be reported. However, there are reports of implants, either for biotelemetry [79-82] or for wireless transmission [83-85], that do give the SAR and current induced in the patient's tissues. They also provide an indication of the maximum current that must not be exceeded in order to comply with the ICNIRP guidelines [15].

6.7.1. Cochlear implants

The implanted Cochlear Implant (CI), which is used for compensating for a severe hearing damage, uses weak radio-frequency electromagnetic fields for the transmission of sound from the external part to the implanted part. Recently Kalakoti et al [86] reported about two independent cases of glioblastoma (GBM), an elderly man in the United States and a middle aged woman in Sweden. Both had a cochlear implant (CI), and the tumours were located in the immediate vicinity of the implant. The authors discuss the possibility that the tumors may have been caused by the radiofrequency fields used during the function of the implant. At present we do not know the levels of the signal current.

Today, we have about 3,700 users of CIs in Sweden (S. Friberg, VLL, personal communication), but it will be difficult to follow up because patients who require a CI generally have a high level of co-morbidity due to high age or the conditions which caused their deafness such as meningitis, rubella or trauma. More information about possible long-term effects may become available by studying a particular group of children. Since about 2002 children at ca. 10 kg weight or about 10-12 months of age with particularly sever hearing deficiency receive bilateral CIs. As of 2016-01-01 there were 738 bilateral CI users under 18 years of age in Sweden (S. Friberg, VLL, personal communication).

6.8. Other applications

In addition to what we have discussed so far, there are several new fields of application using EMF in healthcare, but several of these are currently not yet in use in Sweden.

Treatment of glioblastoma by exposure to alternating electric fields has been started, see e.g., Wong et al [87] for an overview. Kirson et al [88] used the technology on cell cultures, animals, and a clinical study with 10 brain tumor patients. They found that the method, which used alternating electric fields, was an: "effective new treatment modality which effectively slows down tumor growth in vitro, in vivo and, as demonstrated here, in human cancer patients." See also Giladi et al. [89].

The project, COST EMF-MED, COST Action BM1309: European network for innovative uses of EMFs in biomedical applications (EMF-MED) (http://cost-emf-med.eu/), with a working group has been working on the treatment and diagnosis of cancer using both low-intensity and high-intensity EMF. The group is headed by Gerard c. Van Rhoon of Erasmus MC Cancer Institute, Rotterdam, The Netherlands.

Another working group is looking at applications and procedures based on stimulation with EMF on excitable and non-excitable tissues. The group is led by Lluis Mir, CNRS, France.

An application that is not used in Sweden but that is common in other countries is hyperthermia treatment against cancer. The idea is that the cells will heat up to over 45°C, which they cannot tolerate. Hyperthermia treatment is usually combined with other forms of therapy. It produces heat by microwaves or ultrasound. See further [90] for a review of the working method.

6.9. General comments on the use of EMF in health care

As we have shown, the highest exposure to EMF in health care can occur in connection with the use of MR, TMS and ESU. In all three cases patients are exposed to such high levels that acute effects are possible. Also staff can be exposed in excess of the existing exposure limits, and actions are required to ensure the safety of the staff working with these kinds of equipment.

For the patients undergoing examination or treatment, there is also a risk in connection with the use of the above techniques. Among those at particular risk are patients with implanted medical implants, e.g., pacemaker or defibrillator, or passive devices, e.g., metallic knees or hips. The knowledge of which implants can be regarded as *MRI safe* is not widespread. It would be valuable if this database could be transferred into a national database available for the staff at all MRI units in Sweden.

However, the recent published rules from the SWEA will put demands on the use of EMF also in health care from an occupational perspective. The recommendation on how to allocate the responsibility for safely working with MR as given by the different organisations of professionals is an interesting approach. We think it is worthwhile to consider to introduce something similar to other medical applications using high levels of EMF as stated above (electro surgery and TMS).

The knowledge of safety aspects of EMF among personnel in Sweden has not been studies or described, but the new rules from SWEA do demand education of staff of this. A study from New Zealand on MRI technologists highlighted inconsistencies in safety practices regarding intra-orbital metallic foreign body [91]. In a study from Ghana [92] among MRI staff at a teaching hospital revealed some lacks of fundamental knowledge about safety issues such as restrictions on entering the scanner room, screening patients and staff for ferrous material before entering the room. They conclude that the study revealed a huge training gap in the use of MRI equipment.

As we have pointed out in the section on research recommendations, the latest SCENIHR report [4] recommends long-term prospective and retrospective cohort studies of personnel exposed to high-gradient field in the operation of MRI units. The DNA damage in patients after an MRI scan should be further investigated. A study on the effects of MRI exposure in children is also on the list from SCENIHR. For TMS the effect of using this type of treatment for depressions needs further studies.

There are quite many studies published lately on the effect of pulsed magnetic field (PEMF) on various diseases such as carpal tunnel syndrome [93], rotator cuff disease [94], and knee osteoarthritis [95] . PEMF has also been used to stimulate bone healing for non-union fractures. However, to our knowledge PEMF is not used in ordinary health care in Sweden, but we cannot rule out if it is applied in some research projects.

7. Optical radiation

Optical radiation defined as electromagnetic waves from 180 nm to 3 mm (UV, visible light and IR) has been used in health care for different purposes for a long time. Light treatments of neonatal, UV treatments of skin diseases and laser for diagnostics, treatments and surgery are some examples. We have divided this section into light treatments, laser and UV.

The European Parliament and the Council of the European Union has adopted a directive that lays down minimum requirements for the protection of workers from risks to their health and safety arising or likely to arise from exposure to artificial optical radiation during their work [96]. The Directive refers to adverse effects from exposure to the eyes and skin. Adherence to the exposure limits, as set out in Appendix II of the Directive, should provide a high level of protection from side effects that may result from exposure to laser radiation. The Directive also introduces measures protecting workers from the risks associated with optical radiation to the eyes and to the skin. These measures are intended not only to ensure the health and safety of each worker on an individual basis, but also to create a minimum basis of protection for all workers to avoid possible distortions of competition. The corresponding Swedish provision for workers' exposure to artificial optical radiation is solely based on the EC Directive 2006/25 [97, 98]. The Commission has also published a non-binding guide to good practice for implementing the Directive 2006/25/EC in order to help employers to better understand the technical provisions of this Directive [99].

7.1. Light treatments in health care

Visible light is used in health care for treatment purposes, such as in dentistry where blue light is used to harden dental materials and in neonatal care where blue light is used to treat high bilirubin levels in newborns. In both cases, there are special luminaires designed for these purposes, and below is a description of the technologies.

7.1.1. Neonatal phototherapy

Some newborns produce such high levels of bilirubin in the blood (hyperbilirubinemia) that it must be treated to avoid toxic reactions that can lead to severe brain damage. In the 1950s it was discovered that children who resided in daylight or sunlight at neonatal departments showed less yellowing of the skin. In the 1960s methods of phototherapy were developed as a treatment to reduce high levels of bilirubin by transforming it into water-soluble, non-neurotoxic so-called bilirubinisomerer [100].

Research has shown that the treatment efficiency is greatest with the use of blue-green wavelength range (400-520 nm with a peak at 460 nm) [101]. In Sweden approximately 5% of all new born children are treated with phototherapy [102].

There are several different phototherapy instruments on the market today. The newest equipment uses LED lighting that emits blue light to an optical fibre, which is built into a soft plastic mattress that is placed under the child. Other equipment use fluorescent lamps that emit blue light. Incubators or luminaires with metal halide lamps or filtered halogen lamps with optical fibres are also used. A review of twelve common phototherapy devices [103] showed that the spectral distribution differs considerably between different light sources (LED, metal halide and fluorescent lamps). Generally, the LED lighting produces high spectral irradiance in the blue wavelength range (peak value around 460 nm),

whereas the wavelength of fluorescent tubes can vary considerably, with a peak around 420 nm or with a widespread spectrum.

Pinto et al. [103] measured the spectral irradiance at a distance of 20 cm from the middle of the luminaire and found a very great variability (0.2 to 8600 W/m^{2}sr). Therefore, the effectiveness of treatment could differ significantly between the different types of phototherapy light fixtures and the distance between the luminaires and the newborns. Appropriate knowledge about the specific technique/luminaire which is available is also suggested by [7].

Halogen produces more heat than LED. This is also a factor to consider in the treatment of newborns. Continuous temperature registration may be necessary, especially for halogen lamps, to ensure that the environment is safe for the baby [104].

7.1.2. Other types of phototherapy

Other types of phototherapy are also used in medical health care. For the treatment of acne vulgaris, acid-mediated photodynamic therapy uses visible light, wavelength 400-600 nm, together with an acidic gel to treat acne vulgaris. This method is used in Sweden at dermatological clinics, and we found a couple of devices in the inventory. According to [105, 106], reactions such as stinging and erythema have been reported.

7.1.3. Dental curing lamp

The use of direct, light-cured, resin-based composite materials have increased rapidly during the last decades in Sweden and in other countries, and this has almost completely replaced amalgam in dental practice [107]. By applying visible light, often in the blue region, with a certain radiant energy and wavelength, the composite material quickly polymerizes and hardens. The effect can be achieved with different light sources: tungsten halogen, plasma arc curing (PAC), laser and light-emitting diodes (LED). Based on our survey among the three different county councils in Sweden, LED is dominating the Swedish market, but there are still halogen lamps available.

There are many reports showing that the irradiance from commercially available Light Curing Units (LCU), derived from the manufacture's reports, varies greatly with respect to wavelength and irradiance, e.g. see [108-110] where irradiance from 0.1 kW/m^2 to 20 kW/m^2 with a wavelength spectrum between 380 to 510 nm are found. With the introduction of LED LCUs it has been less common with wavelengths within in the UV range, but halogen tungsten LCU can have part of its spectrum within the UVA range. There are also some direct resin-based composite materials with absorption peaks in the UVA range [111] that demand LCUs with enough intensity within the UVA range.

Many modern LCUs offer a range of modes where the irradiance, and sometimes the wavelength, can be modified by choosing different modes from the LCU. The irradiance is often lowered by pulsing the light in various frequencies or by alternating between high and low power, and there are also modes that will ramp up the irradiance in a distinct step up to a certain level. Manufactures offer different techniques to modify the irradiance [108]. The possibility to vary the wavelength will make it possible to use a wider range of photo initiators. Previously, halogen LCUs, which have a wider wavelength range (including UVA), worked with a wide range of materials. The introduction of LEDs that often have a narrower spectrum (often without any UVA), has demanded that the operator has knowledge about the spectrum of the specific LCU and the specific resin composite.

The LCU is handheld and the light is applied through a rather small opening directly to the composite material in the tooth. The crucial parameters for correct polymerization of the composite are the radiant energy expressed as J/m^2, and that the light spectrum is matched to the optimal wavelength for the specific composite. The radiant exposure needed for commercially available composite can vary between approximately 6 J/m^2 to 48 J/m^2 [107, 112]. Other factors that affect the curing quality are, e.g. the distance between the tooth and the active tip of the LED, the size of the area/volume to be cured, the volume of the composite material in the filling, and the size of the active tip of the LED. It is therefore impossible to state a specific curing time to achieve a high quality curing of the composite. The operator needs to have good knowledge about these factors, including the characteristics for the LCU being used and the absorption peak of the composite material.

7.1.3.1. Safety aspects of dental curing lamps

The intensity of the curing light has increased during recent years to increase the efficiency and to decrease the total curing time. McCusker et al. [109] measured the "weighted irradiance" (probably the E_v weighted by the $L(\lambda)$, author note) and the maximal exposure time (t_{max}) during direct exposure at different distances. A comparison with the former ICNIRP guidelines for incoherent light [113] showed that depending on the LCU used, the calculated t_{max} at 10 cm distance (which is comparable with the distance between the tip of the LCU and the eyes of the patient) varied between 0.2 min and 12 min. At 30 cm (comparable to the distance to the operator) t_{max} between 22 min to 120 min was calculated. During normal operation, direct exposure to the patient's or operator's eyes are not common.

McCusker et al. [109] also measured the reflected light by introducing brackets of both metallic and composite material and measured the reflected irradiance at a distance of 10 cm. The results showed that the t_{max} for the most reflecting bracket was 62 min. Labrie et al. [114], however, showed that for palatal position of the LCU (the LCU is placed under the front teeth with the light in the direction of the operator's eyes) for some of the more powerful LCUs, the t_{max} could be as low as 6 s at a distance of 30 cm based on blue light hazard and the ICNIRP [113] guidelines.

The dental light-curing procedure is a handicraft. The operator needs experience in the technique and knowledge about factors such as choice of light unit and curing time to achieve high quality curing and to reduce risks. Santini and Turner [115] showed in a questionnaire study that in the UK, the knowledge of resin-based composite material and the light curing technique is poor. A large fraction of the respondents, 112/181, did not know about the features on their LCUs, e.g., low vs- high intensity, the spectrum characteristics, and this indicates poor knowledge in the field. There also seems to be a confusion about whether the LCU emits UVA or only visible light. [111]. Many reports recommend the dentist to use eye protection to avoid blue light hazards during a working day and advise the dentist not to just look away from the light [107, 109, 111, 116]. Bruzell [111] also stresses the need to choose the protective eyewear carefully since the transmission can vary greatly (0.0001-20%).

7.1.4. Disinfection techniques using blue light.

For many years UV light has been used for disinfection purposes in health care, but during recent years visible violet-blue light in the range of 405 nm has been tested as a means of disinfecting air and surfaces and hospital rooms. [117, 118] The technique is called high-intensity narrow-spectrum (HINS) light, and targets intracellular porphyrins, which are photosensitizers that absorbs 390 - 425 nm light and produce reactive oxygen

species. The efficacy is lower than UV-C light, but it can be used in areas occupied by patients. In one study, continuous HINS light showed a 27 to 75 % reduction in surface contamination by staphylococci compared with control areas [119]. The authors also state that the level of exposure from this type of equipment is safe for humans and is in line with the requirements, i.e., ICNIRP [120], due to the rather low effect and large area of exposure. However, we have not found any published literature where compliance with the present guidelines has been measured.

7.2. Laser in health care

Laser has been used in medicine for diagnostic or therapeutic purposes for several decades, the first application was demonstrated within ophthalmology and dermatology in the early 1960s [121]. In dermatology, lasers are used for treatment of tumours and tattoos and for hair and birthmark removal. In ophthalmology, lasers are for instance used to reattach the retina, to reshape the cornea and for treatment of macular degeneration. Lasers are also found within cosmetics but these applications are not within the scope of this survey. The number of laser-based applications is steadily growing in medicine leading to an increasing number of patients and health care professionals exposed to laser radiation.

7.2.1. Basic types of lasers in medicine

There are basically 7 different types of lasers used in healthcare, namely solid-state lasers, diode lasers, CO_2 lasers, argon and krypton ion lasers, excimer lasers, dye lasers, and free electron lasers [122].

The solid-state ruby laser emits red light (≈ 694 nm) and common applications are for the removal of tattoos and birthmarks. The neodymium-based Nd: YAG[1] solid state laser (λ = 1064 nm) is widely used in urology, pulmonology, and gastroenterology [123-125]. The erbium-ion based Er:YAG solid-state laser (≈3 μm) with pulse energies between 10 and 3000 mJ, duration of 100 μs to 1 ms, and repetition rates of about 50 p/s, is found in dentistry since it can work as a dental drill. The holmium-based solid state laser (Ho:YAG) (2.1 μm, pulse energies between 0.2 and 3 J, maximum repetition rates up to about 30 Hz, and average power up to 45 W) is used for incisions in cartilage and bone, endoscopic and open ablation of tissue, arthroscopic or percutaneous orthopaedics, recanalization of vessels, and for lumbar laser disc decompression [123, 126]. Diode lasers (630-980 nm) with an output power range up to 1 W are frequently employed as diagnostic or therapeutic instruments, or as positioning tools for other medical devices (eg. MR, CT) [122, 127]. Diode lasers are used to illuminate structures in biological tissues and determine the speed of moving particles (e.g., erythrocytes), for fluorescence diagnostics and for photodynamic therapy (PDT). Various tissue reactions can be induced, such as hyperthermia, coagulation, and vaporization. The carbon dioxide (CO_2) laser (9–11 μm) is suitable for surgical applications, involving the cutting and vaporization of tissue [122]. Argon and krypton ion lasers emit light between 250 and 530 nm and 350 to 800 nm, respectively [128]. Their output power is between 5 and 10 W and most applications are found in ophthalmology, dermatology, and photodynamic therapy (PDT). The excimer laser is a pulsed gas laser emitting in the UV wavelength

[1] YAG – Host crystal of Yttrium Aluminium Garnet

range from 157 to 351 nm [129] commonly used within photorefractive keratectomy (PRK), Laser in situ keratomileusis (LASIK) in ophthalmology, and laser angioplasty. Unlike most other lasers, dye lasers offer the possibility of shifting the output wavelength [130, 131]. The wavelength range for one dye is 50–100 nm, and it is possible to cover the range from 400 to 900 nm by employing presently available dyes. Typical applications in medicine are in laser lithotripsy and dermatology.

A free electron laser (FEL) generates tuneable radiation with wavelengths ranging from microwaves over visible and ultraviolet light up to x-rays. FEL is used as a surgical tool in ophthalmology (corneal tissue), otolaryngology, and neurosurgery (e.g., tumor ablation), or generalized wound healing via photovasodilation [122]. Other areas of application are in medical research, such as spectroscopy studies of biological micromolecules, inactivation of pathogenic microorganisms and development of methods for the use of optical coherence tomography (OCT) imaging in diagnostic applications [132].

7.2.2. Laser therapy

An application of interest is Laser-Induced Thermal Therapy (LITT), which is an emerging technique to treat primary and metastatic tumours in the brain, liver or elsewhere, where they are hard to reach with conventional surgery [133-139]. According to Rahmathulla et al. [137] two main types of lasers are used, i.e. the continuous-wave Nd:YAG laser or the diode laser with wavelengths of 1,064 nm and 800–980 nm, respectively. Typical laser output levels are between 6 to 15 W [134, 140]. LITT is performed by implanting a laser catheter, quite often guided by other means (e.g., with ultrasound or real-time MRI), into the tumour and heating it to temperatures high enough to kill it. The catheter is implanted using advanced computer imaging techniques. The laser is guided through the catheter and allows the surgeons to limit thermal energy delivery only to the tumour. Most patients can go home the day after treatment and can quickly return to normal activities. LITT therapy is minimally invasive. It typically requires only a 2-millimeter incision and takes only a few minutes to perform. LITT can also help patients who do not respond to stereotactic radiosurgery or have radiation necrosis (tissue death caused by radiation treatment).

Photodynamic therapy (PDT), sometimes called photochemotherapy, is a form of phototherapy involving light (such as laser) and a photosensitizing chemical substance, used in conjunction with oxygen to elicit cell death (phototoxicity). For an extensive review, see Jamil and Berlien [141]. A photosensitizer drug is injected that gets concentrated only in tumour cells a few hours after injection. When the laser beam is directed toward the tumour area (cancer) it causes selective death of the cancer cells with minimal damage to the surrounding normal tissues. In addition, PDT has the ability to kill microbial cells, including bacteria, fungi and viruses [142]. It is used clinically to treat a wide range of medical conditions such as macular degeneration, psoriasis, atherosclerosis, acne, cancers (e.g., lung, bladder, prostate, and skin) and has also shown some efficacy in anti-viral treatments, including herpes [141-144]. It is recognised as a treatment strategy that is both minimally invasive and minimally toxic. Photosensitizers have been employed to sterilise blood plasma and water to remove blood-borne viruses and microbes. It has also been considered for agricultural uses, including herbicides and insecticides. PDT reduces the need for delicate surgery and lengthy recuperation, and there is minimal formation of scar tissue and disfigurement.

7.2.3. Laser surgery

During surgery, laser is used to cut tissue instead of using an ordinary scalpel. The laser beam vaporizes soft tissue with high water content. Typical surgical lasers include CO_2, erbium, dye, argon, and Nd:YAG lasers. In dermatology and plastic surgery lasers are used to treat various skin conditions such as scars, vascular and pigmented lesions. Laser surgery is commonly used in ophthalmology for treatment of refractive errors as well as non-refractive conditions. For example, LASIK is used for correction of near and far-sightedness in vision, photorefractive keratectomy (PRK, LASEK) is used to reshape the cornea without cutting a flap with a scalpel, and laser thermal keratoplasty improves near vision by placing a ring of concentric burns in the cornea. Examples for treatment of non-refractive conditions are photoretherapeutic keratectomy (PTK) in which opacities and surface irregularities are removed from the cornea, and laser coagulation to cauterize blood vessels in the eye to treat various conditions. Other medical areas where laser application is found useful is in foot and ankle surgery, oral and dental surgery, gynaecology, genitourinary, general and thoracic surgery, otorhinolaryngology, orthopaedic, neurosurgery and gastro-intestinal medicine. For a more extensive review of laser applications in surgery, see [145-151].

7.2.4. Laser diagnostics

The characteristics of laser light are well suited for non-invasive exploration of tissue structure and high resolution imaging for diagnostic purposes. Among methods used for diagnostic purposes are optical coherence tomography (OCT), auto-fluorescence bronchoscopy (AFB), fibred confocal fluorescence microscopy (FCFM), fluorescence lifetime imaging microscopy (FLIM), diffuse reflectance, Raman spectroscopy, optical molecular imaging (OMI), optical imaging, Laser Doppler Flowmetry (LDF) and Laser Doppler perfusion Imaging (LDI). Some of these applications are briefly summarized and referenced below.

Optical coherence tomography (OCT) is an established medical imaging technique that typically uses NIR light to capture micrometre resolution three-dimensional images from e.g. biological tissue. OCT is based on low-coherence interferometry and the use of long wavelength light allows it to penetrate into the scattering medium. Confocal microscopy, which is another optical technique, typically penetrates less deeply into the sample but with higher resolution. Depending on the light source (e.g. super luminescent diodes, ultra short pulsed lasers, and super continuum lasers) OCT has achieved sub-micrometre resolution with sources emitting over a ~100 nm wavelength range. OCT is used across several medical specialties including ophthalmology, cardiology, dermatology, rheumatology, and oncology is also widely used in medical research [152-158].

The optical molecular imaging (OMI) concept is based on optical imaging and diagnosis of pathologic tissue changes. Such imaging and diagnosis is focussed on observing and visualising tissue areas in the molecular range by means of disease-specific dyes. The laser light source must have a wavelength within the NIR spectral range between 650 and 1200 nm. Optical imaging offers various medical applications including for instance the detection and evaluation of superficial dermatome, squamous cell carcinoma, tumours of the base of the tongue, hyperplasia, dysplasia, bronchial carcinoma and malignous glioma [159-162]. Optical imaging is also used for the diagnosis and monitoring of inflammatory rheumatoid diseases or intra-operative monitoring of cardiac ischemia [163, 164].

Fluorescence-lifetime imaging microscopy (FLIM) is an imaging technique for producing an image based on the differences in the exponential decay rate of the fluorescence from a fluorescent sample [154, 165-167]. The lifetime of the fluorophore signal, rather than its

intensity, is thus used to create the image. FLIM can be used in confocal microscopy, two-photon excitation microscopy, and multiphoton tomography. The method uses a light source that is pulsed or modulated at high frequency (up to 500 MHz) such as an LED, diode laser or a continuous wave source. FLIM is primarily used as a method to detect photosensitizers in cells and tumours, in clinical multiphoton tomography to detect intradermal cancer cells as well as pharmaceutical and cosmetic compounds. FLIM imaging is particularly useful in neurons, where light scattering by brain tissue is problematic for ratio metric imaging. Laser florescence imaging allow the early detection and quantification of initial caries formed around orthodontic brackets minimizing the damage of caries lesions in orthodontic patients [168].

Raman spectroscopy is used to observe vibrational, rotational, and other low-frequency modes in a system. The method relies on inelastic scattering (Raman scattering) of monochromatic laser light emitted in the visible near infrared, or near ultraviolet range. Raman spectroscopy has a wide variety of applications in biology and medicine. It has for instance been used to confirm the existence of low-frequency phonons in proteins and DNA and used as a non-invasive technique for real-time, in situ biochemical characterization of wounds [154]. Raman signals are however weak why imaging requires high laser power (typically >10 mW), very sensitive detectors and long data acquisition times (> 30 minutes). This imaging technique is thus unsuitable for clinical applications [154].

Laser Doppler flowmetry (LDF) and Laser Doppler perfusion Imaging (LDI) are methods that use the Doppler shift in a laser beam to measure the velocity in transparent or semi-transparent fluid flows or the linear or vibratory motion of a reflecting surface. Beams of collimated, monochromatic, and coherent laser light with wavelengths in the visible spectrum (λ 390–750 nm) are used to ensure coherence. Typically, He-Ne, Argon ion, or diode lasers are used. LDF/LDI is used as a technique to partially quantify blood flow in human tissues such as skin. The beam from a low-power laser (usually a laser diode) penetrates the skin sufficiently to be scattered with a Doppler shift by the red blood cells and return to be concentrated on a detector. These measurements are useful to monitor the effect of exercise, drug treatments, environmental, or physical manipulations on targeted micro-sized vascular areas. The technique is also being used in clinical otology for the measurement of tympanic membrane (eardrum), malleus (hammer), and prosthesis head displacement in response to sound inputs of 80 to 100 dB. It also has potential use in the operating room to perform measurements of prosthesis and stapes (stirrup) displacement. Important clinical application is also found in dermatology since malignant skin tumours have higher perfusion than benign nevus and basal cell carcinomas. When measuring the blood perfusion there is a possibility to differentiate between various types of skin tumours.

Endothelial dysfunction is one of the key events in the development of atherosclerosis and has been confirmed in patients with cardiovascular related diseases. Owing to its accessibility, the skin microcirculation is frequently used as a model to assess the general condition of the endothelium. Blood perfusion imaging (i.e. LDF, LDI), in combination with iontophoresis, post-occlusive reactive hyperaemia or thermal challenge, has been proven to be an excellent tool for endothelial function studies [169]. Another important clinical application is the assessment of the skin blood flow response to a provocation in diabetic patients. Already in its early stages, the diabetic disease impairs the sympathetic nervous system, which controls skin blood flow. Stimulating the microcirculation, either by a drug or cold exposure, and then measuring the vascular response with LDF, LDI, LASCA or similar technology allows for a quantification of the sympathetic control function [170, 171].

In addition, measuring perfusion in wound healing is useful for several disciplines, such as diabetes care, surgery and geriatrics medicine. Infections and inflammation of the wound increases the perfusion that is easily detected with laser Doppler technology. For instance, leg ulcers and wounds can be monitored easily and without physical contact, which is a benefit regarding contamination and discomfort issues. Burn wounds are not always easy to judge clinically. Early assessment of burn depth is crucial to avoid unnecessary surgery or potential hypertrophic scarring. The status of the skin microcirculation reflects the burn depth and changes in the skin blood flow over time will reveal the wound healing potential. Increased activity indicates that the microcirculation is functioning and that there is a higher degree of wound healing potential [172].

Laser Doppler imaging (LDI/LDF) or Laser Speckle Contrast Analysis (LASCA) is used to follow vascular changes in order to monitor or understand the underlying mechanisms. These applications use laser radiation within the waveband of about 630-785 nm. One example of application is to diagnose or monitor disturbances in finger microcirculation due to Raynaud's syndrome. The phenomenon is characterized by a vasospasm in the extremities as a response to cold temperatures or other sympathetic stressors, for example noise. LDF, LDI and LASCA has also proven useful to distinguish between secondary and primary Raynaud, as well as differentiating between established and early disease [173, 174].

In orthodontics, LDF has found its application in assessing the vitality of the tooth during or prior to undergoing orthodontic treatment [168].

7.2.5. Biological effects of laser radiation

The scientific literature that addresses the biological effects of exposure to optical radiation such as lasers is very comprehensive. The reports published by the European Commission [1, 7, 99, 175] provide extensive and very good overviews of the current state-of-the-art regarding biological effects and other aspects of laser radiation.

Adverse health effects of laser radiation are the result of one or more biophysical interaction mechanisms (i.e. photochemical, thermal, thermo-acoustic) that vary depending on wavelength and exposure duration. It is clear that an exposure to laser radiation may cause adverse health effects across the entire optical spectrum from ultraviolet (λ >180 nm) in to the far infrared (λ <10^3 μm). The injury threshold varies greatly across the optical spectrum due to biological and structural differences of tissues and organs that are potentially at risk. Skin and eyes are the main target for health effects, and wavelength plays an important role regarding which part of the skin or eye that absorbs the radiation most and which type of interactions are involved. Exposure to short wavelength ultraviolet laser radiation is most important for photochemical effects whereas thermal effects are most dominating in the infrared region. Some examples of photochemical effects are erythema (reddening of the skin), conjunctivitis, photokeratitis (corneal inflammation) and cataract. The primary effect of visible and near infrared laser radiation is damage to the retina. The retina is very susceptible to radiation in the region (i.e. λ 400-1400 nm) because of the transparency of the ocular media and the focussing properties of the eye. In the mid- and far-infrared part of the optical spectra (i.e., λ >1.4 μm) laser radiation primarily damages the cornea.

The biological effects of laser radiation can broadly be divided into acute and chronic. In general, acute effects will only occur if the exposure exceeds a threshold level. This critical exposure level usually varies among individuals. Most exposure limits are based on studies of thresholds for acute effects, and derived from statistical consideration of these thresholds. Therefore, exceeding an exposure limit will not necessarily result in a

health effect. The risk for getting an adverse health effect will increase as exposure levels increase above the exposure limit defined in the EU Directive [96]. However, persons who are abnormally photosensitive may suffer adverse effects at levels below the exposure limits. In general, the long-term effects of repeated and chronic exposures to laser radiation in general are not well understood. Chronic effects often do not have a threshold below which they will not occur. Risks for adverse health effects may thus be reduced through lower daily exposure levels.

7.2.6. Laser applications in Swedish health care

An inventory of laser equipment in Västerbotten County Council (VCC; one university, two county hospitals and over 30 primary health centres), Kalmar County Council (KCC; 3 county hospitals), and Karolinska University Hospital in Stockholm (KUH) was conducted. The inventory showed that a relatively small number of laser-based devices are available and used in these counties (Table 3).

At VCC about 28 laser devices are listed in the inventory (excluding accessories such as various probes), and most of them are located at the University Hospital in Umeå. The corresponding figures for KCC and KUH are 10 and 27, respectively. Listed devices at all hospitals and county councils sites are predominantly of the type Nd:YAG, Ho:YAG, CO_2 or diode lasers plus and laser Doppler devices for blood flow investigations. Most laser equipment is of class 1 and 2. Only a few laser equipment belongs to class 3 and 4 which can be found within clinical specialties such as ophthalmology, dermatology, basic research, applied research and surgery.

The daily exposure dosage for an individual operator who uses various types of laser equipment is not easy to determine. Some reasons for this are the uncertainties regarding laser beam intensity, dispersion, coverage and risks for un-wanted reflections. In addition, the daily exposure duration varies considerably between operators. It should be noted that a direct exposure to a beam from laser of class 4 (Table 4) is instantly harmful for an unprotected eye or naked skin. To be able to address this issue properly a more in-depth exposure analysis needs to be done.

Table 3. Inventory of the total number of laser units at VCC, KCC and KUH

Medical area	VCC (n=27)	KCC (n=10)	KUH (n=27)
Annestesiology		1	
Biomedical engineering	2		3
Cardiology			1
Clinical Physiology	1		2
Dermatology	3		6
Neurology	1		1
Endocrinology			1
Obstetrics/Gynaecology			1
Odontology	2		
Ophthalmology	12	8	4
Otorhinolaryngology	1		3
Paediatrics			1
Clinical research	3		
Surgery	2	1	1
Urology	1		2
Geriatrics			1

7.2.7. Safety regulations and guidelines

Lasers and devices with lasers are classified by the strength of the laser, distribution, wavelength and what the risks are in normal use. Laser safety classification can be found in the non-binding guide to good practice for implementing Directive 2006/25/EC [99]. The Swedish Radiation Safety Authority has adopted the definition of the different laser safety classes, and these are presented in Table 4. Note that permission from the Swedish Radiation Safety Authority is required for using laser pointers in the laser class 3R, 3B and 4. No permit is required for lasers in the lower classes. In addition, each laser must be labelled with its laser safety class. Lasers in class 2 and above must also have a laser warning triangle and an "alert" symbol. The text should be printed with black text on a yellow background.

The international Commission on Non-Ionizing Radiation Protection (ICNIRP) has published guidelines on limits of exposure to laser radiation of wavelengths between 180 nm and 1000 μm [175]. The purpose of these guidelines is to establish the maximum levels of exposure to laser radiation that are not expected to cause adverse biological effects to the eyes and skin. The presented exposure limits apply to wavelengths from 180 nm to 1 mm and to exposure durations between 100 fs and 30 ks (about 8 h). The guidelines apply to all human exposure to optical radiation emitted by lasers. The exposure limits for lasers were derived on the basis of a robust set of experimental damage threshold data, which describe the dose-response relationships for the biological effects of laser radiation on the eye and skin. These damage-threshold doses depend on the wavelength, exposure duration and spot size. Presented exposure threshold limits should be used as guidelines for controlling human exposure to laser radiation.

Table 4. Laser safety classification as defined by the Swedish Radiation Safety Authority (www.ssm.se).

Class 1	Lasers Class 1 are harmless even during long-term exposure. Toys with lasers are limited to Class 1, and if the laser beam is red or green a maximum power output of 0.4 mW is standard. Class 1 also covers devices that contain lasers from a higher class, but where the laser is built so that no hazardous radiation can come out. Examples include CD players and laser printers. A person who dismantles this type of product, however, runs the risk of exposure to hazardous radiation.
Class 2	Class 2 only includes lasers that emit visible radiation with a maximum output power of 1 mW. If an unprotected eye is exposed our reflexes will cause us to blink. The natural reaction is quick enough to prevent damage to the retina. Examples of lasers in this class are laser pointers that are used when lecturing.
Class 3R	Permits are required for certain uses. Class 3R lasers emit up to 5 mW of radiation if it is visible. If an unprotected eye is exposed to radiation the exposure limit may be exceeded. However, the risk of injury caused by a short and accidental exposure is small.
Class 3A	This class, 3A, is no longer used, but instead, it is included in Class 3R.
Class 3B	Permits are required for certain uses. This class contains lasers with power between 5 mW and 500 mW. Such lasers may be hazardous to the eye, both through direct exposure and indirect exposure from a reflex. However, a reflection from a matte surface is considered as harmless. Strong green laser pointers and nightclub lasers are examples of products in Class 3B.
Class 4	Permits are required for certain uses. Class 4 includes all lasers that are stronger than Class 3B, i.e. they have a power output of more than 500 mW. Here it can also be dangerous for an unprotected eye to look at an illuminated spot on a matte surface. This class has no upper limit. Lasers in this class can damage the eyes and skin. They also constitute a fire hazard if they have high power. Lasers used for surgery and cutting and lasers for laser shows belong to this class.
Class 1M and 2M	Lasers Class 1M has a power that exceeds the allowed limit in Class 1. This applies to both ultraviolet radiation and visible light to infrared, but in this class, the beam is not focused but dispersed, which means that the limit values for an unprotected eye or unprotected skin will not be exceeded. . However, if the laser beam is focused using magnifying optics then the lasers in this class may damage the eyes. Some lasers used in fibre optic communications belong to this class. M stands for magnifier. Class 2M includes lasers that provide visible light with a higher power than allowed in Class 2, but as in class 1M, they are not focused but dispersed. Consequently, only a small portion, up to 1 mW, of the total beam may hit the eye, which corresponds to a class 2 product.

These guidelines are considered to be adequate for the general population as well as for occupational exposure. However, the threshold limits should not be regarded as sharp demarcations between ‘‘safe’’ and ‘‘dangerous’’ exposure levels. Exposure at levels below the exposure limits should not result in adverse health effects. The limits

incorporate the collective knowledge generated worldwide by scientific research and experience of laser safety, and these limits are based upon the best available published information. The most effective method to control laser hazards to the eye and skin is totally enclose of the laser and all beam paths. For conditions where this is not possible, partial beam enclosure, laser eye protectors, restricted access to beam paths, and administrative controls may be necessary.

The Swedish Radiation Safety Authority has adopted a regulation that provides general advice on laser, strong laser pointers and intense pulsed light [176]. The adopted general advice can be summarised as follows:

- A laser source should be marked with laser safety class (e.g. "Laser Class 3B"), and what standard it meets (eg "EN 60825-1: 2007").
- A laser in laser class 1C, 2, 2M, 3R, 3B or 4 should also be labelled with a laser warning triangle, warning text (eg. "Avoid exposure to laser radiation"), the maximum output power or pulse energy, laser pulse duration and wavelength.
- Lasers in safety class 3R, 3B or 4 should also be labelled with safety information about laser output location and risk distance.
- All markings and safety information should be in Swedish and be in a clear and durable label with black text on a yellow background.
- User manuals for laser products should include information on the issues mentioned above, the required labels, and their positioning on the product.
- User manuals for lasers in safety class 3R, 3B or 4 should also contain technical specifications for personal protective equipment and the technical specification of the laser radiation (e.g., divergence, pulse duration and pulse rate).

The widespread and increasing use of lasers in medicine should be considered as a potential safety problem for staff and patients [7]. Most laser applications for diagnostic purposes are of Class 1 (<0.4mW) and Class 2 (<1 mW) and thus considered harmless for the eye and skin. Laser applications for therapy and surgery include equipment with higher output power, i.e. Class 3B (<5mW), 3R (5-500 mW), and 4 (>500mW) which are associated with a “Low risk to eyes/No risk to skin”, “Medium to high risk to eyes/Low risk to skin”, and “High risk to eyes and skin”, respectively. Issues such as calibration, maintenance and practical handling of the equipment are of great importance in this context. A competent and efficient safety organization and routines must be in place in every health care organization for avoiding negative health effects of laser radiation on patients as well as on operators. Likewise, protection must be given more attention and personnel involved in all aspect of the use of laser equipment for medical purposes should be well-trained and updated on safety issues. For further information regarding different aspects on laser safety, see the comprehensive overview authored by Henderson and Schulmeister [177].

7.3. Ultraviolet light in medical health care

Ultraviolet light is used in health care primarily to treat skin diseases such as psoriasis and eczema but also for sterilization of laboratory equipment. For the UV treatments, narrow band UVB with a wavelength peak at 315 nm or a broadband UVA light is used. Sometimes also a combination of UVA and UVB treatments are given. In UV sterilization procedures UVC is most commonly used.

7.3.1. Medical UV phototherapy treatment

Skin diseases such as psoriasis and eczema can be treated with UV radiation. It uses either narrowband UVB radiation where the lamps emit UV light with the main peak at 310 nm or UVA combined with tablets (psoralens) which are called PUVA treatment. For some eczema treatments combinations of UVB and UVA are used.

The most common types of lamps used are TL01 and PUVA lamps. Both full body and partial body (hand/feet) phototherapy units are used depending on the diagnosis. The full body standing units are covered with fluorescent tubes and during treatment the patient will be positioned inside the unit. Partial body units are commonly adjustable smaller units wherein the patient places their hands or feet. The unit is commonly covered with cloth to avoid radiation to the surroundings.

The dermatologist ordinates a treatment schedule were the initial dose is defined depending on the diagnosis and the sensitivity of the patient (other diseases, skin type, previous UV exposures etc). The treatment dose is then often increased in predefined steps, during the treatment period to achieve highest possible treatment effect and to avoid unwanted side effects such as erythema and burns. The Swedish National Board of Health and Welfare has an ongoing work on a national recommendation for psoriasis treatment and the work is expected to be finished in 2018 (www.socialstyrelsen.se).

The treatment dose is expressed in J/m^2. Depending on the manufacturer the adjustable treatment dose is expressed as J/cm^2, or as a treatment time (minutes, seconds).

For each treatment a nurse sets the dose, but at some clinics the patients themselves set the dose. Some newer UV treatment units provides automatic dose adjustments, were each patient's treatment schedule is pre-programmed and the patient just enter their personal code number at each treatment.

The dominating fluorescent tubes used in medical health care in Sweden are PUVA and TL01, where PUVA emit broadband UVA light and TL01 emit narrow-band UVB (311nm).

7.3.1.1. Potential risks during UV treatments.

Acute potential risks after UV treatment are damage to the skin and eyes and this has also been reported after UV therapy [178-180]. This is also regulated by SWEA for occupational exposure [97, 98] For patient exposure some paragraphs are included in the SSM regulation of sunbeds [181]. The acute health effects that might occur after exposure to UV is skin erythema, or if the exposure is very high; burns with blistering and peeling. The damage occurs first a few hours after irradiation. For the patient, the dermatologist prescribing a specific individual starting dose and a treatment schedule where the treatment does increases in small steps reduces this risk. There is sufficient evidence that long-term exposure UV radiation (UVA; UVB and UVC) causes cancer of the skin, especially malignant melanoma and basal cell carcinoma and UV radiation has therefor been classified as carcinogenic by IARC [182]. PUVA treatment has been classified as carcinogenic by IARC [182], while UVB treatment alone has a weak association to cancer based on epidemiological studies but with also including animal and biological studies IARC states that there are sufficient evidence that also UVB alone are carcinogenic.

Interesting noting is that the Medical Products Agency recommendation for Psoriasis treatment [183] indicates that broad band UVB treatments are considered to be a very safe form of treatment with respect to increased risk of skin cancer, but that animal studies have shown an increased risk of narrow band UVB compared to broad band UVB. They also states that this has not been confirmed among patients treated with narrow band

UVB. The Medical Products Agency also concludes that oral intake of psoralen in combination with UVA treatment is associated with an increased risk of squamous cell carcinoma. They also states that this has not been shown for topical PUVA.

We have previously measured the irradiance in human whole body UV therapy units (unpublished data) and compared those to the hygienic guidelines to UV radiation [181] for the unprotected skin. The maximum exposure time for TL01 fluorescent tubes was calculated to 20 seconds. For PUVA fluorescent corresponding figure was about 20 minutes.

Since the exposure level inside the UV unit is extremely high, especially when using the TL01 (UVB) lamps, personnel should never be inside the units with any parts of their body without protective clothing to avoid overexposure [97, 98]. The measurement procedures to confirm the irradiance, which is also a demand in SSMFS [181] are commonly done with the technician standing inside the full body unit with protective clothing and protective eyewear holding a measurement probe in the hands. Some manufacturers recommend this method. This procedure could potentially be risky since a small opening in the clothing could lead to severe effects on the skin or eyes. At VCC a new method has been developed where the instrument is placed on a tripod inside the full body unit. The measured value is then adjusted to what should have been achieved in a real situation with a person placed inside the unit using an empirical evaluated correction factor.

Potential risks during UV treatment are for instance that the treatment dose is by mistake too high, this is especially important if patients are entering the dose themselves. Other potential risks are that the personnel are exposed to UV, either by mistake during measurement procedures or for instance when helping children during especially hand/feet treatments if protective clothes are not used.

7.3.2. UV disinfection

UV and especially UVC are used to disinfect equipment for instance by using UV cabinets where in the equipment is placed. These are closed processes where UV light is omitted to enter the protective barriers to avoid accidental exposure to the personnel, for instance, by using automatic switch-off irradiated UV light when the door is opened.

There are also open disinfecting techniques, Ultraviolet germicidal irradiation techniques (UVGI), which disinfect the air in for instance health facilities. Upper room installation is used to clean the upper layer of air and in combination with ventilation this could be an effective technique to control airborne infectious particles [184, 185]. During normal operation the UVC light is used in upper room installation and the irradiance levels are not in conflict with present guidelines [185]. There are also open UVC cleaning system that irradiates a larger part of a room and not only the upper layer [186, 187]. Using these devices need special precautions since the exposure level within the room will be above ICNIRP guidelines [188] during irradiation. People should not be inside the room during disinfection, but accidents have been reported. This technique is available in Sweden today and is to our knowledge in limited used at some hospitals. There are also other types of UVC emitting cleaning devices on the market [189, 190] but to our knowledge the usage of those is limited in Sweden today and the technique has also been questioned with respect to cost efficiency and occupational safety [191, 192]. In a recent report from SCHEER [193] UVC lamps are discussed extensively and they conclude that adverse effects to human skin and eyes could be caused by accidental exposure to UVC lamps. This is also regulated in Sweden [97, 98]. In line with IARC [182], SCHEER [193] also

states that UVC radiation can cause cancer, but that quantitative cancer risk from exposure to UVC lamps cannot be obtained due to lack of data.

Since the clinics that are using open UVC systems do not have any former experience of UV light and potential risks it is of importance that the introduction of this technique is done carefully and that the personnel get proper education on the use, the routines and safety when using open UVC systems.

7.4. Summary optical radiation

Light treatments in health care are widespread and the dominating techniques are dental curing lamps and neonatal phototherapy (Table 1). Both techniques have been improved and the usage of LED light has increased. Since LED does not emit UV light the safety improvements is obvious compared to the older halogen technique. But the blue light hazard still needs to be taken seriously and ICNIRP stated in a workshop on non-ionizing radiation in health care that the widespread use of optical radiation in health care suggest that there could be potential safety issues and stressed the importance of staff training, maintenances and calibration and also mentioned protective eye wear as of special importance [7].

The treatment efficiency using LED or halogen lamps for neonatal treatments needs special attention and the knowledge of this at neonatal centres would be of interest to study.

The UV phototherapy units used in health care do, especially for the narrow spectrum UVB (TL01) treatments, produce an effective irradiance that are above the Swedish regulations. It is therefore of importance to have good knowledge of the safety aspects of UV and that the treatment dose is adjusted carefully for each patient and that the irradiance in each unit is checked regularly. Personnel should not be exposed above the limit values and care should therefore be taken during the measurement process as well as during treatment of patients.

Open UVC light used for disinfection in, for instance, operation theatres or in patient rooms has been introduced on the Swedish market and overexposure to personnel can be avoided by carefully using the equipment in line with the manufacturer's instruction.

It would be of interest to study how the safety work at dermatological clinics are organised and how the treatment doses are set and administrated. The knowledge and safety routines among the personnel at other clinics using open UVC light for disinfection purposes would also be of interest to study.

Lasers are used for diagnostic or therapeutic purposes within many medical disciplines such as in ophthalmology, dermatology, oncology, odontology, and clinical physiology. Laser radiation is predominantly absorbed in the outer layers of the body why skin and eyes are the main targets for acute or chronic biological effects. The daily individual exposure dosage for an individual user is not easy to determine. Risk assessment based on exposure threshold limits presented in current provisions and guidelines is consequently difficult to do. The use of laser applications in medicine should be considered a potential safety problem for staff and patients. Safety and protection issues must thus be given more attention to avoid negative health effects due to laser radiation on patients as well as the work force. Personnel involved in all aspects of the use of laser equipment for medical purposes should be well-trained and updated on safety issues.

Based on the result of this review the following research and development needs are identified for medical application using optical radiation in Swedish health care;

- An in-depth risk and safety analysis of current exposures for patients and staff for applications such as class 3 or 4 laser products, UV therapy units and dental curing light
- A better understanding of long-term effects of repeated and chronic exposures to optical laser radiation
- Overview of current safety organisation and safety routines at our Swedish hospitals.
- Inventory of the use of different types of light therapy units for treatments of neonatal phototherapy and the knowledge about the radiation spectrum and its efficiency of treatment outcome.

8. Ultrasound

Medical ultrasound, also called ultrasonography, has been used in medicine for many years and applications can be divided into two main categories - diagnostic and therapeutic ultrasound (sonography).

Historically, one of the first applications of therapeutic ultrasound, the so-called "ultrasonic massage", was introduced by Pohlman and co-workers as a routine procedure in physiotherapy at the end of the1930s [194]. They were able to demonstrate that exposure to ultrasonic waves increased mobility by reducing adhesions between muscles and improved circulation.

Since the early work by Pohlman and co-workers, the area of ultrasound has undergone an incredible technical development, which has led to a steadily increasing number of high performance clinical applications within almost all medical disciplines. The ultrasonic devices have become more sophisticated, more intelligent, provide higher image resolution and colour. High-resolution ultrasonic devices, which provide 3-D colour imaging, have drastically increased the system's applicability. Consequently, the number of patients and health care professionals who are exposed to ultrasonic radiation within health and medical care is also steadily increasing. In addition, new clinical applications of ultrasound are being introduced in new areas. Therefore, it is of utmost importance to maintain vigilance to ensure continued safe and justified usage of these devices for both patients and staff.

The use of ultrasound is divided into two main categories – diagnostic and therapeutic ultrasound and some examples within each category are discussed in the report.

8.1. Basic principles of ultrasound

In medical applications of ultrasound, mechanical waves with frequencies from 20 kHz to 100 MHz are transmitted from the ultrasonic treatment head (also referred to as an applicator) [195] to the body through a special contact medium (ultrasonic gel). Ultrasonic waves, typically produced by one or several piezoelectric elements cased in a plastic housing, require a physical medium for its propagation. The speed of propagation of the transmitted wave (*wave velocity*, Denotation: *c*, SI-unit: m/s) depends on the tissues or structure's acoustic impedance, and that varies between different parts of the body and tissue types. Some part of the ultrasonic wave will be reflected back when entering tissues or structures having different acoustic impedance. Knowledge of wave velocity, degree of tissue absorption, scattering and reflection of the acoustic wave, gives the possibility to predict how the ultrasound will interact with different bodily organs or structures. It is also important to notice that the ultrasonic wave propagates as longitudinal waves in soft tissues whereas hard tissues also support shear waves. The propagating wave will also cause an alternating local pressure on the tissue (Denotation: *p*, SI-unit: Pascal, Pa). The difference between the ambient pressure and the local pressure as the wave passes is called the acoustic pressure, i.e., a compression or rarefaction if the pressure is above or below the ambient pressure, respectively. Biological tissues and fluids can withstand relatively high-pressure levels (several MPa). However, when the critical limits are exceeded, there will be biological effects, e.g., the formation of small gas bubbles. This physical effect is called acoustic cavitation and the phenomenon is believed to be associated with a risk for health. Cavitation develops predominantly when high peak rarefaction pressure levels are present.

According to Whittingham [196], a good lateral resolution requires a narrow ultrasonic beam whereas a good axial resolution requires a wide pulse bandwidth in order to resolve

structures lying close together, side-by-side, or structures behind one another. Both situations are made less risky by using higher frequencies, but the trade-off is that penetration depth decreases with increasing frequency due to absorption and scattering. Therefore, the choice of the optimal frequency for a specific application is most often a compromise. Typical for abdominal examinations on adults and children are 3 MHz and 5 MHz, respectively. About 10 MHz for superficial regions like breast, 30 MHz for intra-vascular scanning and finally about 100 MHz for very superficial applications.

The different modes of ultrasonic scanning, such as A-mode, M-mode, B-mode, 3D and 4D scanning, continuous wave Doppler and Doppler imaging, and their basic features, are extensively reviewed by Whittingham [196]. In the A-mode the ultrasonic beam is typically transmitted to the patient as short pulses of 2 cycles with a maximum pulse repetition frequency that is defined by the need to allow echoes from one transmission to die away before transmitting again. Thus, this limit depends on the speed of sound in the tissue and the maximum depth of interest. For cardiac or abdominal examinations on adults the repetition frequency is typically 2 kHz, but higher frequencies are used for more superficial organs such as the eye. After some processing the echoes are presented as a graph of rectified amplitudes versus time of arrival. This mode, which is not built into all ultrasonic devices, may be useful when information is needed about the depth and structure of an object is wanted. M-mode is an extension of the A-mode, in which a grey-scale-modulated version of the A-scan is swept sideways over the area of interest to provide a graph of target depths versus time. This mode is predominantly used to assess the dynamic behaviour of a structure or an organ (e.g., heart chamber walls), but it is also used in obstetrics for a graphical proof of foetal life. In B-mode imaging, the transmitted beam is scanned sideways across a plane, either by moving the transducer by hand ("static B-Mode) or automatically emanated by the transducer ("real-time" B-Mode). In addition, there are several types of B-mode applicators that are designed for different clinical situations. Linear, curvilinear, radial and compound array are the most common types of applicators for B-mode applications. For ultrasound applications directed towards all soft tissues that are not covered by bone or gas, B-mode real-time scanning is considered as the major imaging modality in medicine.

Three-dimensional scanning (3D), in most cases based on data acquisition that uses B-mode applicators, displays the ultrasonic echoes received within a volume rather than a two-dimensional plane. With high scanning rates it is also possible to achieve real-time 3D imaging. By adding the extra dimension, time, this is called 4D scanning. Ultrasound applications based on continuous wave Doppler (CWD) technology are basically used to study blood flow (perfusion) and for foetal monitoring. A CWD applicator is equipped with two separate transducers – one transmitter and one receiver – both installed in a single house. Since the application is based on the Doppler effect only moving targets, like blood cells and foetal heart walls, can be monitored. A special feature on some B-mode scanners is colour flow imaging (CFI), or colour flow mapping (CFM), where colours represent the Doppler frequency shifts. With this feature it is thus possible to study whether the target object is at rest, moving towards or moving away from the applicator. The magnitude and sign of the Doppler frequency shift will then mirror the flow rate and its direction.

Ultrasound exposure is either described in terms of acoustic pressure (Unit: Pa) or in terms of intensity (Unit: mW/cm^2). For intensity, the most usual parameters are I_{SPTA} (spatial peak, temporal average intensity), I_{SATA} (spatial average, temporal average intensity) and I_{SPPA} (spatial peak, pulse average intensity). According to ter Haar [197], tissue heating is best predicted by I_{SATA}, and when cavitation is of most interest, peak negative pressure is the parameter of most relevance. Some examples of intensities and pressure are shown in Table 5.

Table 5. Characteristics of ultrasound used for some medical applications (based on AGNIR [198]).

Application	Frequency (MHz)	Spatial peak temporal intensity (I_{SPTA}) (mW/cm^2)	Peak or focal rarefactional pressure (MPa)
B-mode	1-15	0.3-990	0.45-5.5
M-mode	3-10	300	>4
Colour Doppler imaging	3-7,5	1000	2.5
Physiotherapy	1	1000	<0.5
Lithotripsy	0,5-10	Very low	>20
HIFU	0.5-5	10^3 - 10^5	10
Bone growth stimulation	1.5	30	0.05
Drug delivery	<2	Various	0.2-8.0

8.1.1. Biological interaction

Ultrasound interacts with biological tissue by mechanical and thermal processes. Thermal and mechanical (non-thermal) effects are thus the main biological response to ultrasound exposure. The amount of transmitted ultrasonic energy, in most cases, is automatically calculated by the ultrasonic device and presented as a thermal index (TI) and a mechanical index (MI) in accordance with an output display standard (ODS). However, the indices are rough estimates that do not take the thermal or mechanical characteristics of the exposed tissue composition into account. The duration of exposure, ultrasound mode, and other factors may raise the intracellular temperature to a hazardous level. The thermal index (TI) is intended to give a rough estimate of the ultrasonic power required to produce a temperature rise of 1°C delivered as a stationary and continuous exposure. There are three sub-indices of TI according to the application. Thermal index in soft tissues (TIS) assumes that only soft tissue is insonated. Thermal index in bone (TIB) assumes bone that is present at the depth where temporal intensity is greatest. Thermal index in the cranium (TIC) assumes that cranial bone is very close to the front face of the probe. A thermal index of 1 indicates a condition during which the rise in temperature would be about 1°C. However, errors in calculating TI values, together with the limitations of the simple models on which they are based, means that TI values can underestimate the temperature elevation by a factor of up to two.

The mechanical index (MI) is an on-screen indicator that gives an estimation of the potential risk for non-thermal bioeffects that include cavitation. MI is thus intended to mirror the likelihood for the occurrence of cavitation. The risk for cavitation depends on the actual tissue's composition and its gas content. The BMUS safety guidelines state that the MI value of 0.3 represents the threshold for the possibility for capillary bleeding in gas-containing organs. An MI value of 0.7 is chosen as the threshold for cavitation. A TI of 0.7 equals an embryonic or foetal exposure limit [199].

According to an overview written by Miller [200] shockwave lithotripsy was the first ultrasonic application that demonstrated significant bioeffects in mammalian tissues as a result of cavitation. These effects included haemorrhage and injury in the kidney [200]. Furthermore, this type of shockwaves may also cause haemorrhage in lung and intestine by activation of pre-existing gas bodies in these tissues. Interestingly, current ultrasound equipment for diagnosis has the capacity to produce pressure amplitudes that are

sufficient for inertial cavitation. However, it seems like the living body normally lacks suitable cavitation nuclei. Ultrasound contrast agent (UCA) gas bodies also provide nuclei for inertial cavitation. Bioeffects from contrast-aided diagnostic ultrasound depend on pressure amplitude, UCA dose, dosage delivery method and image-timing parameters. Microvascular leakage, capillary rupture, cardiomyocyte killing, inflammatory cell infiltration, and premature ventricular contractions have been reported for myocardial contrast echocardiography with clinical ultrasound machines and clinically relevant agent doses in laboratory animals. Similar bioeffects have been reported in intestine, skeletal muscle, fat, lymph nodes and kidney. These microscale bioeffects could be induced unknowingly in diagnostic examinations. However, the medical significance of bioeffects from diagnostic ultrasound with contrast agents is not yet fully understood in relation to the clinical setting.

There is a substantial number of scientific studies related to the interaction between clinical uses of ultrasound in medicine and its effect on biological structures. A search in scientific literature databases, like PubMed and Webb of Science, with key words like (“ultrasound” OR “ultrasonic” OR “sonography”) AND “medicine” OR “diagnostic” OR “therapeutic” results in tens of thousands of references. Reports produced by the Health Protection Agency [198], World Health Organization [201], Health Canada [202], [7], and more recently the International Commission on Non-Ionizing Radiation Protection [1] are recommended for an overview. There are also several review articles recently published that target specific ultrasonic applications within different areas and disciplines in medicine. Some of these will be referred to in the following sections.

8.2. Diagnostic ultrasound

With diagnostic ultrasound, or medical sonography or ultrasonography, we mean the use of an ultrasound-based imaging technique for visualizing muscles, tendons, soft tissues, internal organs, and more. With this imaging technique it is possible to non-invasively capture size, structures and pathological lesions [196]. Diagnostic applications include predominantly imaging within medical disciplines like of anaesthesiology, obstetrics, gynaecology, angiology, ophthalmology, cardiology, emergency medicine, surgery (e.g., head, neck and colorectal), neonatology, neurology, pulmonology, orthopaedics, gastroenterology, urology and superficial structures. More and more, ultrasound is becoming a very useful application within the fields of emergency and trauma medicine. Furthermore, there is a growing interest for ultrasound applications that can be used for diagnostic purposes on patients

Obstetric ultrasound, or obstetric sonography, is nowadays routinely administered in parental prenatal appointments to check/confirm date of the pregnancy, foetal viability, location of the foetus and placenta, and indications of physical abnormalities and conditions that may be harmful to the mother or the baby. The safety of obstetrical ultrasound has been extensively reviewed by Houston and co-workers [203]. They concluded in their review that most scientific studies conducted between 1970 until 2009 support the idea that this imaging modality using ultrasound is generally safe for the foetus and the mother. In a vast majority of the rewieved articles no associations were found between the use of ultradound and birth weight, Apgar score, childhood cancer, soft tissue and bone sarcoma, school performance, vision, and more. However, it is important to note that this conclusion was predominantly based on data obtained using ultrasound euqipment with far less output level than that which is available today. Houston et al. [203] state that modern ultrasound technology, such as the use of Doppler, 3-D and 4-D applications, has significantly higher output potential compared with older equipment. Higher output levels will of coarse increase the risk for thermal and

mechanical side effects. Interestingly, Kieler et al. [204] have reported the possibilty that prenatal ultrasound may lead to an increased nonright-handedness in males. Also, the increased public demands for keepsake imaging also raises safety concerns. Thus, additional research is needed on the use of more modern equipment before any far-reaching conclusion regarding the safety of obstetrical ultrasound can be made.

Ultrasound is also used in neonatology for basic assessment of intra-cerebral structural abnormalities, bleeds, ventriculomegaly (a brain condition that occurs when the lateral ventricles are dilated) or hydrocephalus and anoxic insults (Periventricular leukomalacia). The ultrasound can be performed through the soft spots in the skull of a newborn infant (fontanel) until these completely close at about 1 year of age and form a virtually impenetrable acoustic barrier for the ultrasound. The most common site for cranial ultrasound is the anterior fontanel. The smaller the fontanel opening, the poorer quality of the image.

Within the field of oncology, high-frequency ultrasound of anatomical structures in the head and neck, such as lymph nodes and salivary glands, may provide a detailed image. Diagnostic ultrasound imaging is also used as a modality for evaluation, preoperative planning, ultrasound-guided operations and postoperative surveillance of tumours and lesions among patients with different types of benign and malignant conditions in the head and neck [205-211].

Ultrasound is an essential diagnostic tool in cardiology by which the function of heart ventricles and valves can be visualised. Furthermore, intravascular ultrasound is used to assess patency and possible obstruction of arteries, to diagnose deep vein thrombosis and to determine the extent and severity of venous insufficiency [212-216].

In pulmonology, transbronchial needle aspiration is an established method for sampling mediastinal lymph nodes to aid in the diagnosis of lymphadenopathy and in staging lung cancers. Real-time endobronchial ultrasound (EBUS) guidance is a method that may increase the ability to sample these nodes and hence to determine a diagnosis [217]. EBUS probes are applied to standard flexible endoscopic probes and used by pulmonologists to allow for direct visualization of endobronchial lesions and lymph nodes prior to transbronchial needle aspiration. Another application of EBUS is for staging of lung cancer allowing for lymph node sampling without the need for major surgery. There are also several other applications in use in this field.

Sonographic applications are extensively used in urology for examination in a variety of clinical situations. Some examples are checking for signs or symptoms that may be referred from the kidney, bladder and scrotal regions, the amount of fluid retained in a patient’s bladder and to give diagnostic information regarding suspected abnormal structures, testicular cancer, incontinence and obstructed defecation [218]. Ultrasound is also used not only to diagnose kidney stones or kidney crystals (nephrolithiasis) but also for therapeutic intervention to break them up. Pelvic sonography is performed either internally or externally where the former is performed either transvaginally for women or transrectally for men [219].

In ophthalmology the most prevalent use of ultrasonography is to obtain globe length in order to calculate corrective lens power requirements. According to Harrie [220], ocular ultrasound currently stands as the principal diagnostic tool for a number of conditions within the eye and as a supplement to the radiologic imaging capabilities of MRI and CT scanning within the orbit. Other applications include the measurement of tumours including choroidal melanomas, visualization of lens dislocation, and detection of retinal detachment [121, 220, 221]. Ultrasound is especially useful when the fundus is obscured from visualization with slit lamp and laser interferometry as in patients with dense cataracts [220]. The use of ocular ultrasonography may result in earlier detection of

ocular melanoma [220]. Ultrasound allows improved visualization of structures that are obscured by opaque substances (such as dense cataracts or vitreous haemorrhage), and real time information regarding conditions such as retinal detachment.

Nowadays, ultrasonography is considered as an invaluable and patient-safe technique in orthopaedic practice [203, 222-224]. Technological developments regarding higher resolution and better image quality have increased the number of clinical applications. The use and benefits with ultrasound in clinical orthopaedics is extensively reviewed by Blankstein [225]. In summary, musculoskeletal ultrasonography is used for evaluation of soft tissue damage, tendon structures, dynamic examination in motion and the assessment of articular structures and diseases. Orthopaedic ultrasound is very useful when investigating rotator cuff tears, inflammation, tendinitis, impingement syndrome, frozen shoulder, tennis elbow, biceps muscle, carpal tunnel syndrome, Baker cyst, and much more.

Emergency ultrasound or point-of-care ultrasound (POCUS) is the application of ultrasound at the point of care to make immediate patient-care decisions. POCUS is used in a wide variety of specialties and has steadily increased in use as ultrasound equipment has become more compact and portable [226, 227]. Emergency ultrasound is used to quickly diagnose a limited set of injuries or pathologic conditions where conventional diagnostic methods would either take too long or would introduce greater risk to a person. Some examples are detection of abnormal fluid or air collection in the torso, intrauterine pregnancy, abdominal aortic aneurysm, pericardial effusion and tamponade, cardiac activity, deep vein thrombosis, soft-tissue infection, and foreign bodies. Therefore, emergency ultrasound provides useful guidance and has become a very common emergency department procedure.

Ultrasound has become an important and frequently used diagnostic imaging tool in all specialties in dentistry, such as in the fields of dental scanning, caries detection, dental fractures, soft tissue and periapical lesions, maxillofacial fractures, periodontal bony defects, gingival and muscle thickness, temporomandibular disorders, and implant dentistry. For an extensive review and further references, see Marotti et al. [228].

The implementation of diagnostic ultrasonic applications has revolutionized the modern practice of surgery and has become one of the most integral parts of the surgeon’s clinical practice. Unique qualities, such as non-invasiveness, portability, and rapidness, easily repeatable and steadily increasing resolution and accuracy, make this technology especially suitable for use in bedside or emergency settings, in intensive care units, in preoperative settings and in the operating theatre. For extensive reviews and further references, see [229-232].

Through the introduction of microbubble UCA it became possible to dynamically detect tissue flow of both the macro and microvasculature [233]. In the beginning only Laser Doppler detection was available, but the clinical applications of UCA scanning are expanding rapidly because several microbubble-specific modes have been developed. For instance, with perfluoro-containing microbubbles the distribution of contrast within the microcirculation can be performed in real time. This can be done at low acoustic pressures (MI < 0.3) so that the microbubbles are not destroyed and scanning can continue in real time. This allows characterisation of focal liver lesions with similar precision as the use of contrast CT and MRI, and therefore further imaging may not necessary. Examination of renal and splenic lesions is other examples for the usefulness of other applications.

8.3. Therapeutic ultrasound

With therapeutic ultrasound we mean the use of ultrasonic devices for treatment of diseased or injured body organs or structures. The frequency range for therapeutic ultrasonic applications is from 20 kHz to about 3 MHz. Higher frequencies are used for diagnostic applications. Therapeutic ultrasound is a continuously expanding field and new clinical applications are being developed constantly. In a recent review some historical perspectives of therapeutic ultrasound and its progress in the field since the early 1990s are presented [234]. Major and rapid developments have been made during the last decades regarding transducer technology and computer software for control, data analysis and imaging technologies [197]. This has made it possible to implement a vast number of ultrasonic applications that nowadays are routinely used in health and medical care, such as in the fields of physiotherapy, orthopaedics, surgery, chemotherapy, and drug delivery. More recently therapeutic ultrasound is also being used in lithotripsy, and high intensity focused ultrasound is being used in cancer therapy (HIFU).

Therapeutic ultrasound is applied using a transducer (or applicator/probe) that is in direct contact with the patient's skin. A specific gel is used between the applicator head and the skin to reduce friction and to assist transmission of the ultrasonic waves. High-power ultrasound can break up stony deposits or tissue, accelerate the effect of drugs in a targeted area, assist in the measurement of the elastic properties of tissue, and can be used to sort cells or small particles for research.

In physiotherapy, ultrasound is predominantly used for treatment of soft tissues. Some examples of conditions for which ultrasound is used are: for acceleration of wound healing, muscle strains, tendonitis, joint inflammation, resolution of oedema, bursitis, rheumatoid arthritis, osteoarthritis, and scar tissue softening [197, 235]. Interestingly, ultrasound was initially considered as an alternative diathermy treatment as a gentle method to produce heating. Positive bioeffects of physiotherapy ultrasound are achieved by thermal effects due to absorption of the sound waves and due to non-thermal effects originating from cavitation, micro-streaming and acoustic streaming. However, the effectiveness of physiotherapy ultrasound for pain, musculoskeletal injuries, and soft tissue lesions has been questioned. For instance, Robertson did not find a relation between the ultrasound dose and therapeutic outcome in her survey of randomised clinical trials [236].

In the area of fracture healing and bone repair, some recent overviews clearly indicate that low-intensity pulsed ultrasound (LIPUS) can significantly stimulate and accelerate radiographic bone healing in fresh fractures. There is some weak evidence that LIPUS supports radiographic healing in delayed unions and non-unions [237, 238]. A study by Griffin and co-worker support the use of LIPUS for treatment of acute fractures [239]. However, the detailed biophysical process by which LIPUS stimulates osteogenesis is still unknown [238]. There is also some evidence suggesting that LIPUS may speed healing of acute tibial fractures [240].

The use of low intensity ultrasound in cancer therapy is a developing field that may be divided in to four major areas, namely sonodynamic therapy, ultrasound-mediated chemotherapy, ultrasound-mediated gene delivery and anti-vascular ultrasound therapy. For an extensive review, see Briefly, the intention when applying sonodynamic therapy is that it will consistently result in the death of cancer cells, and that effect is primarily related to a thermal effect and inertial ((initial??)) cavitation. In each therapeutic modality, theragnostic contrast agents (eg. porphyrins and phthalocyanines) composed of micro-bubbles, play a role in therapy as well as vascular imaging [241]. These agents are important because they give a possibility to monitor the effect of anti-cancer therapy. The underlying mechanisms behind observed bioeffects, or the viability of these therapies in

naturally occurring cancers in larger mammals has been paid little attention despite the fact that this therapy technique could be a useful application for the treatment of cancer patients.

The range of ultrasonic power levels that can be effectively employed in therapy appears to be narrow and this may have hindered past research in the applications in cancer treatment [242]. Moreover, ultrasound can ablate tumours or other tissue non-invasively. This is accomplished using a technique known as High Intensity Focused Ultrasound (HIFU), also called focused ultrasound surgery (FUS surgery). This procedure uses generally lower frequencies than medical diagnostic ultrasound (250–2000 kHz), but significantly higher time-averaged intensities. The treatment is often guided by MRI and referred to as Magnetic Resonance-guided Focused UltraSound (MRgFUS) [243]. Delivering chemotherapy to brain cancer cells and various drugs to other tissues is called acoustic targeted drug delivery (ATDD) [244]. These procedures generally use high frequency ultrasound (1–10 MHz) and a range of intensities (0–20 W/cm^2). The acoustic energy is focused on the tissue of interest to agitate its matrix and make it more permeable for therapeutic drugs [245].

With sonodynamic therapy, cytotoxic activities of certain compounds (sonosensitizers) can be enhanced. The attractive features of this modality for cancer treatment emerge from the ability to focus the ultrasound energy on malignant sites buried deep in tissues and to locally activate a preloaded sonosensitizer. A possible mechanisms of sonodynamic therapy is the generation of sonosensitizer-derived radicals, which initiate chain peroxidation of membrane lipids via peroxyl and/or alkoxyl radicals. The physical destabilization of the cell membrane by the sonosensitizer thereby renders the cell more susceptible to shear forces or ultrasound-enhanced drug transport across the cell membrane (sonoporation). Evidence against the role of singlet oxygen in sonodynamic therapy is discussed. The mechanism of sonodynamic therapy is probably not governed by a universal mechanism, but may be influenced by multiple factors including the nature of the biological model, the sonosensitizer and the ultrasound parameters. The current review emphasizes the effect of ultrasound-induced free radicals in sonodynamic therapy [246].

Doppler ultrasonography. Sonography can be enhanced with Doppler measurements, which employ the Doppler effect to assess whether structures (usually blood) are moving towards or away from the probe, and its relative velocity. By calculating the frequency shift of a particular sample volume, for example flow in an artery or a jet of blood flow over a heart valve, its speed and direction can be determined and visualised. This is particularly useful in cardiovascular studies (sonography of the vascular system. All modern ultrasound scanners use pulsed Doppler to measure velocity.

Contrast-enhanced ultrasound (CEUS) is the application of ultrasound contrast medium to traditional medical sonography. Ultrasound contrast agents rely on the different ways in which sound waves are reflected from interfaces between substances. This may be the surface of a small air bubble or a more complex structure [247]. Commercially available contrast media are gas-filled microbubbles that are administered intravenously to the systemic circulation. Microbubbles have a high degree of echogenicity (the ability of an object to reflect ultrasound waves). There is a great difference in echogenicity between the gas in the microbubbles and the soft tissue surroundings of the body. Thus, ultrasonic imaging using microbubble contrast agents enhances the ultrasound backscatter (reflection) of the ultrasound waves to produce a sonogram with increased contrast due to the high echogenicity difference. Contrast-enhanced ultrasound can be used to image blood perfusion in organs, measure blood flow rate in the heart and other organs, and for other applications.

The Harmonic scalpel, sometimes called an ultrasonic knife, is a surgical instrument used to simultaneously cut and cauterize tissue. Some areas of application are tonsillectomy, thyroidectomy and laparoscopic colorectal surgery [248-251]. The harmonic scalpel uses ultrasonic vibrations at about 55 kHz over a distance of 80 μm that generates heat that causes protein denaturation. The protein denaturation results in a protein coagulum that seals the vessels and assures haemostasis at low temperature [252]. A beneficial feature with this technique is that it causes minimal energy transfer to the surrounding tissue, which potentially limits collateral damage.

8.4. Ultrasound in Swedish health care

A survey of diagnostic ultrasonic examinations performed in Swedish hospitals for the year 2005 show that about 475000 ultrasonic examinations were performed [253]. The average number of examinations is about 53 per 1000 inhabitants in the country as a whole. About 42% of all examinations are related to abdominal organs, 22% to neck and chest organs, urinary and male genitalia, and 17% to musculoskeletal organs and soft tissues. Ultrasound is used in many different medical units, and not only in those specialized in diagnostic imaging, and therefore only a part of the total number of ultrasound examinations is reported in this survey. However, the number of examinations reported by units that specialize in ultrasound can be regarded as reliable. The authors notes that the number of certain types of ultrasound examination performed is larger than that which came forward in the survey. Thus, the survey does not cover all ultrasonic examinations and medical exposures.

An inventory of ultrasonic equipment in different facilities has shown that it is difficult to compare results between sites. The main reason is that equipment name as specifications are entered differently in the different inventories. Keeping this difficulty in mind, the inventory shows that a relatively large total number of ultrasonic systems or devices are currently available and used at these sites, Table 6. In Västerbotten County Council (VCC), including the University Hospital in Umeå, Skellefteå Hospital, Lycksele Hospital and 35 Health Centres, there are about 850 ultrasonic devices listed in the inventory (excluding accessories such as various probes). Although not shown here, the county hospitals in Skellefteå and Kalmar, which are approximately equal in size, report a comparable number of ultrasound devices. Listed devices are found in most medical specialities, although the lists differs somewhat between county councils and hospitals due to their profiles. For instance, odontology is an important profile only for VCC, and that explains the relatively high number of units in the University Hospital in Umeå which includes the Umeå School of Dentistry. As can be seen, ultrasonic equipment is frequently used in medical specialities like obstetrics, gynaecology, intensive care, orthopaedics, cardiology, ophthalmology, paediatrics, urology, clinical physiology and renal medicine. All types of diagnostic (including imaging) and therapeutic ultrasound systems and applications like blood flow meters, bladder scans, laser Doppler perfusion systems, harmonic scalpels (ultrasonic knives), ultrasonic aspirators, foetus sound detectors, and more are available at many sites.

The exposure for the patient or operator of this type of ultrasonic equipment cannot easily be estimated. Patient exposure is easy to follow since the TI and MI is visible on the screen during examination, but to give any general comments on exposure for different diagnostic procedures is nearly impossible since that kind of collected data is missing. The exposure will depend on the medical question, the operator's skills, the equipment, and the transducer used.
For the operator it is also a hard task to estimate their exposure. Firstly, the output level, expressed in mW/cm^2, thermal index (TI) and mechanical index (MI), when operating the

equipment is generally low for diagnostic as well therapeutic applications (see the section "Risk and safety guidelines below). Secondly, the daily exposure duration varies a lot between operators. There are sonographers who have ultrasonic examinations as their main work task and others that use ultrasonic equipment very seldom. This type of analysis also requires measurement of ultrasonic energy that actually is transmitted to the operator. A more comprehensive and in-depth exposure analysis is needed before patient or operator exposure can be addressed properly.

Table 6. Inventory of the total number of ultrasonic units at Västerbotten County Council (VCC), Kalmar County Council (KCC) and Karolinska University Hospital (KUH).

Medical speciality	VCC (n=853)	KCC (n=109)	KUH (n=651)
Anaesthesiology	-	-	49
Biomedical engineering	4	-	20
Cardiology	22	3	59
Company Health	4	-	-
Clinical Trail Unit/Research Centre	5	-	10
Dermatology	3	-	1
Emergency	5	-	34
Geriatrics	2	-	5
Health Centres	160	4	36
Intensive Care	11	6	35
Medicine/Rehabilitation	16	10	3
Neurology	13	-	25
Obstetrics/Gynaecology	54	25	69
Odontology	372	-	-
Oncology	7	2	13
Ophthalmology	27	7	-
Orthopaedics	8	3	10
Otorhinolaryngology	-	2	15
Paediatrics	5	4	31
Physiology	21	5	38
Physiotherapy	11	2	5
Psychiatrics	2	-	3
Pulmonology/Gastro logy	12	-	37
Research & Development	5	1	2
Radiology	5	10	36
Rheumatology	7	2	11
Surgery	43	15	42
Urology	18	9	20

8.5. Biological effects of ultrasound

According to the vast number of scientific original and review articles that exist in the area, the general view is that diagnostic and therapeutic ultrasound applications that are properly performed and with a level not exceeding recommended safety guidelines, pose no known risks to the patient or operator. The reports published by World Health Organization [201], the Advisory Group on Non-ionising Radiation [198], the International Commission on Non-Ionizing Radiation Protection [1], and [7] provides extensive and comprehensive overviews of the current state-of-the-art regarding biological effects of ultrasound. WHO supports the conclusion that ultrasound is harmless by saying "Diagnostic ultrasound is recognized as a safe, effective, and highly flexible imaging modality capable of providing clinically relevant information about most parts of the body in a rapid and cost-effective fashion". AGNIR [198] states in their report that an exposure to ultrasound at high levels can induce biological effects in mammalian tissues through heating, non-thermal mechanism or cavitation. At higher-pressure amplitudes, violent mechanical activity may occur due to inertial collapse of microbubbles (i.e. cavitation) that may lead to biological effects on nearby cells and structures. They mention destruction of kidney stones and induced necrosis of soft tissue as examples. Responses and attributed mechanisms are presented in their report in tabular form and an excerpt is presented in Table 7:2 below. ICNIRP [1] has formulated their corresponding statement regarding risks to patients as “The balance of evidence now available does not point to any serious adverse effects in patients from exposure to diagnostic ultrasound as used in normal clinical practice without the use of ultrasound contrast agents”. Therapeutic ultrasound can undoubtedly cause a wide spectrum of biological effects depending on the intensity and duration of the exposure [197]. Exposures with high intensities (about 1000 W/cm^2) are able to cause instantaneous tissue necrosis, which is an effect that is utilised in oncology. At low intensities (about 100 mW/cm^2), however, any effect is likely to be reversible and/or beneficial.

Regarding risks for biological effects on health professional using diagnostic ultrasound, no studies were found that directly examined these potential health risks [1]. Based on the apparent absence of harmful effects in patients, together with the low ultrasound levels that the operator is exposed to during normal and proper handling of the equipment, no risk would be expected from current exposures. There is, however, a risk for harmful effects on the operator, as well as the patient, if the equipment is not used in a proper way or if the equipment is malfunctioning. It cannot be excluded that a long-term exposure to airborne ultrasound with high sound pressure levels may lead to hearing loss. Our Swedish Work Environment Authority’s provision about noise, AFS 2005:16, contains regulations about both hearing-damaging and disturbing noise. The provision stipulates that levels below 115 dB and 115 dB for the 1/3-octave band 20 kHz and for the band 25-200 kHz, respectively, will not likely cause hearing damage [254]. The AGNIR report [198] recommends an exposure limit for the general public to airborne ultrasound sound pressure levels (SPL) of 70 dB (at 20 kHz), and 100 dB (at 25 kHz and above).

Table 7. Some examples of established (upper part) and possible (lower part) biological effects of exposure to ultrasound (Extracted and modified after AGNIR [198]).

Established biological effect	Attributed mechanism(s)
Local tissue destruction	Heating, boiling, acoustic cavitation
Increased cell apoptosis	Not known
Lithotripsy	Mechanical, acoustic cavitation
Sensation and pain	Acoustic radiation force, heating
Teratology	Heating
Increased foetal movement	Acoustic radiation force
Bone and tissue regeneration	Not known
Degradation of DNA (*in vitro*) (and repair mechanism)	Mechanical, acoustic cavitation, heating
Sonoporesis (*in vitro*)	Acoustic cavitation
Lysis (*in vitro*)	Acoustic cavitation
Capillary damage, ventricular extra-systolic contractions, effects on blood-brain barrier	Acoustic cavitation
Topical drug delivery	Acoustic cavitation

Possible biological effect	Attributed mechanism(s)
Increased incidence of non-right handedness in males following prenatal exposure	Not known
Foetal cortical neuron migration	Not known
Behavioural and cognitive deficits following prenatal exposure	Not known
Increased apoptosis of intestinal cells and decreased cell turnover	Not known

8.6. Risk and safety guidelines

Several authorities, organizations and committees in various countries provide guidelines and recommendations regarding ultrasound equipment and its safety. The initial regulations from U.S. Food and Drug Administration (FDA) 1976 imposed application-specific limits that were divided into ophthalmic, foetal and other (including abdominal, paediatric and small parts), cardiac, and peripheral vessels. The maximal spatial peak time-averaged intensity levels (I_{SPTA}) (i.e. the measure most associated with temperature rise) were set to 17, 94, 430, and 720 mW/cm^2, respectively. When revising its regulations in 1993, the FDA altered its approach to ultrasound safety in such a way that the new regulations combine an overall limit of I_{SPTA} of 720 mW/cm^2 for all equipment having output displays to allow users to employ effective and judicious levels of ultrasound appropriate to the examination undertaken. The new regulations allow an eight-fold increase in ultrasound intensity to be used in foetal examinations [255]. They place considerable more responsibility on the user to understand the output measurements and to use them in their scanning. The output display is based on two indices, the mechanical index (MI) and the thermal index (TI). The FDA regulation allows a mechanical index of up to 1.9 to be used for all applications except ophthalmic (where the maximum is 0.23).

In addition to the FDA, the American Institute of Ultrasound in Medicine (AIUM), World Federation for Ultrasound in Medicine and Biology (WFUMB), European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB), Health Canada, Australian Society for Ultrasound in Medicine (ASUM), and WHO are among other organizations, which review current evidence and recommend clinical applications. The Swedish Radiation Safety Authority also provides recommendations, but only for prenatal diagnosis.

The World Federation for Ultrasound in Medicine and Biology (WFUMB) is dedicated to the advancement of ultrasound by encouraging research, promoting international cooperation, disseminating scientific information and improving communication and understanding in the world community using ultrasound in medicine and biology. That federation, that includes more than 50 000 individual physicians, scientists, engineers and sonographers, covers national societies in Asia (AFSUMB), North America (AIUM), Australasia (ASUM), Europe (EFSUMB), Latin America (FLAUS) and Africa (MASU). There are several special committees that are active within WFUMB. The Safety Committee, within the WFUMB, has the role to stay abreast of the state-of-the-art in the field regarding bioeffects and to develop practical advice for operators. The committee periodically publishes policies, statements and recommendations on safety issues. In their latest document [256] the following WFUMB policy and statements were especially highlighted:

1. Policy on live scanning at commercial exhibitions,
2. Statement on the safe use of Doppler ultrasound scans during weeks11-14 weeks or earlier in pregnancy,
3. Policy statement on souvenir imaging of the foetus,
4. Recommendations on nonmedical use of ultrasound, and
5. Clinical safety statement for diagnostic ultrasound: An overview.

Some examples of rules that should be obeyed during live scanning are as fllows: scanning of the eyes, pregnant women and children is forbidden; endoscopic, intracavity and intravascular scanning is forbidden; the use of ultrasonic contrast agents is forbidden; and subjects (models) must give consent by signing a form that explains the non-diagnostic nature of the scan. Pulsed Doppler (spectral, power and colour flow imaging) ultrasound should not be used routinely and when performing its TI should be less than 1.0 and with an exposure time as short as possible and not longer than 60 minutes. Doppler ultrasound examinations should not be performed during the first trimester of pregnancy. Informed consent should be obtained when a student or a health professional is using an ultrasonic instrument for training on a patient or a subject. WFUMB disapproves the use of ultrasound if the only purpose is to provide parents within souvenir images. Use of ultrasound without medical benefit should thus be avoided. Diagnostic ultrasound is considered safe only if used prudently and performed only by competent personnel who are trained and updated in safety matters. It is important that ultrasound devices are appropriately maintained. It is also recommended that the switch-on power for a scanner should be, by default, set to the minimal level necessary for a given examination. In obstetric diagnosis, the default power should not result in a TI above 0.7.

The European Federation of Societies for Ultrasound in Medicine and Biology has published Clinical Safety Statements since 1994 that gives a concise overview of safety in the use of diagnostic ultrasound. The most recent safety statement is from 2011 [257] and it can be summarised as follows. Diagnostic ultrasound has been used for a long time in clinical settings with no proven deleterious effect. However, ultrasound may cause unwanted effects if it is used imprudently. It is pointed out that only competent personnel who are trained and updated in safety matters should perform examinations. It is further stated that ultrasound can produce temperature rises that are hazardous to sensitive organs

and the embryo/foetus. Biological effects of non-thermal origin have so far not been demonstrated in humans, except when a microbubble contrast agent is present. Regarding exposure during pregnancy it is known that an embryo/foetus is particularly sensitive. Since there is very little information currently available regarding possible subtle biological effects of diagnostic levels of ultrasound on the developing human embryo or foetus, care should be taken to limit the exposure time and the thermal and mechanical indices to the minimum commensurate with an acceptable clinical assessment.

In the Canadian guidelines for safe use of diagnostic ultrasound it is concluded that even if there is a negligible risk for injury during an examination in most cases it cannot be valid for every possible condition using currently available equipment [202]. It is therefore the sonographer's responsibility to ensure that the ultrasonic exposure is justified and that the achieved diagnostic information is beneficial compared with the associated risk. The guideline presents 3 general recommendations, summarised as follows:

1. The use of diagnostic ultrasound to obtain information about function or structure in human beings should be restricted to situations in which the medical benefit that may accrue from the diagnostic data outweighs any foreseeable risk.
2. Situations of training, demonstration or research may also provide a medical benefit from diagnostic data that outweighs any foreseeable risk. If the mechanical or thermal index will be greater than 1 in these situations than the subject must be notified and informed about possible risks.
3. Ultrasound should not be used for solely non-medical reasons (e.g., picture of the foetus, sex-determination, commercial purposes)

The British Medical Society (BMUS) has formulated the following key principles for safe use of ultrasound [199];

- Medical ultrasound imaging should only be used for medical diagnosis.
- Ultrasound equipment should only be used by people who are fully trained in its safe and proper operation. This requires:
    - an appreciation of the potential thermal and mechanical bioeffects of ultrasound,
    - a full awareness of equipment settings, and
    - an understanding of the effects of machine settings on power levels.
- Examination times should be kept as short as necessary to produce a useful diagnostic result.
- Output levels should be kept as low as reasonably achievable whilst producing a useful diagnostic result.
- The operator should aim to stay within the BMUS recommended scan times (especially for obstetric examinations).
- Scans in pregnancy should not be carried out for the sole purpose of producing souvenir videos or photographs.

Included are also application-specific guidelines with recommended exposure time and index values for obstetric, neonatal, non-obstetric, non-neonatal, adult trans-cranial scanning, general abdominal, peripheral and other scanning. An example is shown in Figure 10.

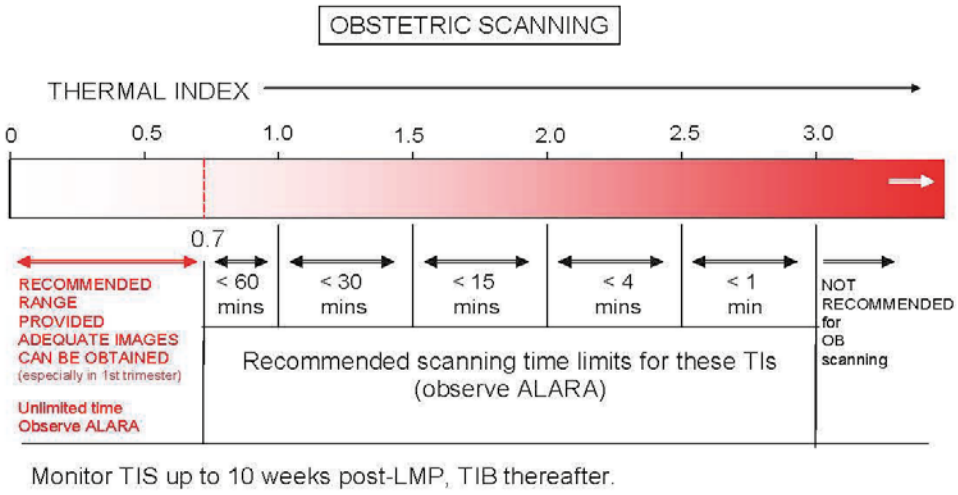

Figure 10. Recommended maximum scanning times for obstetric examinations conducted with different displayed Thermal Indices (TI). From [199].

WHO states in their report, which predominantly focuses on training in diagnostic ultrasound, that ultrasonography has established an enviable safety record [201]. No reports on harmful biological effects due to diagnostic ultrasound had been published at the time for their review. WHOs conclusions and recommendations may be summarised as follows:

1. Appropriate training of the operators of diagnostic ultrasound is the most important requisite for the improvement and rational application of ultrasonography in medical practice.
2. The purchase and use of diagnostic ultrasound equipment should be restricted to those who have successfully completed an adequate training programme or have achieved a proven level of competence in ultrasonography.
3. An appropriate curriculum should be adopted for the general, advanced, and specialized training of medical doctors and allied health professionals who use diagnostic ultrasound.
4. WHO, international governmental and nongovernmental organizations, and professional associations, should be actively involved in the development of training programmes for the use of diagnostic ultrasound.
5. Regular equipment upgrading is essential.
6. The equipment, training, and practice of ultrasonography should be oriented towards local health care problems, and should have a positive effect on the quality of health care in the country concerned.

In the AIUM practice guidelines for the performance of an ultrasound examination in the practice of urology, it is clearly stated that “policies and procedures related to quality control, patient education, infection control, and safety should be developed and implemented in accordance with the AIUM Standards and Guidelines for the Accreditation of Ultrasound Practices” [218]. In addition, ultrasonic equipment used for performance monitoring should comply with this practice and the ALARA principle (i.e., as low as possible) should be considered regarding potential benefits versus risks when conducting examination or treatment [258].

Besides proper and safe usage of ultrasonic equipment by well-trained health professional, there are technical risk factors that must be addressed. For instance, concern has been raised regarding the accuracy of output readings of clinical ultrasound machines. When used in research settings machine calibration is normally considered and checked to ensure accuracy. This is less likely to be the case in practice and even if the equipment undergoes maintenance at regular intervals it may not include an output calibration check. An evaluation of machines used in NHS (National Health Service) practice in Scotland identified almost 70% of the machines' outputs differed from the expected value by more than 30% [259]. Therapy machines more than 10–12 years old and modern dual frequency treatment heads performed particularly badly. Risks associated with poor calibration have also been pointed out by McCabe and Pye [260]. There are incidents that have shown discrepancies between output setting and actual output of therapeutic ultrasound machines. In addition, new machines were found that did not operate at all or operated only at maximum power output irrespective of the chosen setting. Some older machines had not been adequately calibrated since purchase. They suggest that all therapeutic ultrasound machines should be enrolled in a programme of annual calibration. In addition, staff should undertake a weekly quantitative test to ensure the equipment is operating properly in accordance with specifications. This may be done by means of a simple calorimeter or water balance test.

Mårtenson [261] showed in his doctoral dissertation that tomography and ultrasound-based volume measurements may yield disparate measurement results and that tissue Doppler imaging-based ultrasound measurements can be unreliable. He concluded that transducer errors are very common and that annual testing of the transducers is not sufficient to guarantee a faultless function. His dissertation also indicates that the system for checking the function and manufacturing of medical devices in accordance with the EU's Medical Device Directive does not work entirely satisfactorily.

A competent and efficient safety organisation and routines are of outermost importance for avoiding negative health effects of ultrasound on patients and the operators. For the same reason, there is also a need that personnel involved in all aspects of the use of ultrasonic application for medical purposes should be well-trained and updated on safety issues. In Sweden, however, no clear recommendation or reference to international guidelines on the safe use of ultrasound has been made, except for prenatal diagnosis, which makes the safety management of ultrasound unclear.

8.7. Research and development needs

Based on the results of this review, the following research and development needs have been identified for the application of ultrasound in Swedish health care:

- Are there synergistic or additive effects when ultrasonic applications are run in combination with another NIR or IR application?
- Overview of current safety organisation and safety routines at our Swedish hospitals,
- Calibration issues – is poor calibration a safety risk?
- An in-depth analysis of current exposures for patients and staff, and
- Inventory of new applications on their way to becoming implemented.

8.8. Summary

Medical ultrasound, also called ultrasonography, has been used in medicine for many decades and applications are divided into two main categories -- diagnostic and therapeutic ultrasound. The area has undergone an incredible technical development with a steadily increasing number of high performance applications within almost all medical disciplines. In addition, the clinical applications become wider, more sophisticated and intelligent as well as providing higher image resolution and in colour. Consequently, the number of patients that undergo diagnostic and/or therapeutic ultrasound routinely within health and medical care are increasing.

In medical applications of ultrasound mechanical waves with frequencies from 20 kHz to 100 MHz are transmitted from the ultrasonic applicator head to the body, tissue or bodily structure through a special contact medium (ultrasonic gel). These waves will then interact with biological tissue by thermal and mechanical (non-thermal) processes and thus be the main biological response to an exposure to ultrasound. The amount of transmitted ultrasonic energy, in most cases, is automatically calculated by the ultrasonic device and presented as a thermal (TI) and mechanical index (MI). TI is intended to give a rough estimate of the ultrasonic power required to produce a temperature rise of 1°C. MI is an on-screen indicator that gives an estimation of the potential risk for non-thermal bioeffects that include cavitation.

Diagnostic applications include predominantly imaging within medical disciplines like anaesthesiology, obstetrics, gynaecology, angiology, ophthalmology, cardiology, emergency medicine, surgery, neonatology, neurology, pulmonology, orthopaedics, gastroenterology, and urology. Therapeutic applications include use of ultrasonic devices for treatment of diseased or injured body organs or structures in the fields of physiotherapy, orthopaedics, surgery, chemotherapy, and drug delivery and more recently, also in cancer therapy through high intensity focused ultrasound (HIFU).

Since the introduction of ultrasonic application in medicine, there has been no report of injury to patients or to operators from medical ultrasound equipment. Application-specific output limits together with the operator's knowledge of equipment controls and patient body characteristics have been the means of minimizing exposure. The MI and TI provide operators with information that helps them to comply with current safety regulations as well as the ALARA principle, but for Swedish operators no specific regulations or recommendation other than those for prenatal diagnosis exist. It should also be noted that ultrasound examination should only be performed where there is a medical indication. Keepsake images of foetus or gender determination should therefore be avoided if its increases exposure to the foetus.

Besides proper and safe usage of ultrasonic equipment by well-trained health professional, there are also technical risk factors that must be addressed, e.g., accuracy of output readings of clinical ultrasound machines. A competent and efficient safety organisation and routines are of uttermost importance for avoiding negative health effects of ultrasound on patients and staff due to malfunctioning or incorrect usage of ultrasonic devices.

9. Discussion

NIR is widely used for various applications in the health care sector. For instance, ultrasound equipment was found at approximately 25 clinics at VCC and KUH, indicating a widespread use.

We identified the following applications where the exposure levels are high and acute effects for patients are possible: TMS, MRI, ESU, UV treatments, laser therapy and harmonic scalpels in surgery. There are significant risks if the equipment is not used properly. When the exposure limits for occupational exposure have been exceeded for TMS, UV treatments, electrosurgical diathermia, laser therapy, adverse effects have been reported, e.g., burns on the patient's hands/body due to excessive exposure during UV treatment, ferromagnetic objects get stuck in the MRI bore and burns in patient during electrosurgical procedures. However, there are probably more unrecorded accidents or deviations with NIR than with ionising radiation, where there are well functioning routines and requirements to produce accident reports. There are no clear demands from authorities on accident reports when using NIR, and this is also mentioned in [7] where the authors also discuss the generally low reporting of NIR-associated deviations, e.g., ICNIRP and SCENIHR for MRI and ultrasound. There is also a discussion about the lack of knowledge of combined exposure with other agents, since it has become more common with hybrid techniques, where combinations of techniques occur, e.g., ionizing radiation and magnetic fields are used (PET-MRI) for diagnostics [1, 4]. There are also other combined techniques, e.g., ultrasound aspiration, which combines the cutting/coagulation effect from ultrasound and ESU. Sienkiewicz [7] discusses the need for more knowledge about diagnostic techniques such as MRI and ultrasound in combination with contrast media. We have not covered combinations explicitly in this report, but some hybrid techniques such as PET-MRI and ultrasound aspiration techniques exist at some Swedish hospitals. Worth noting is the critique that the report by Sienkiewicz [7] do not provide a systematic review of potential health effects from MRI examination [262]. This is also relevant for NIR in general and since this was beyond the scope of this report, we also conclude that systematic reviews of the scientific literature of potential health effects of NIR used in health care on both patients and workers are warranted.

To be able to control the exposure to the patient or staff during treatment, one needs to have information on the exposure level that is used and how to, if needed, adjust the level. Non-ionising radiation is a complex area where the general knowledge about exposure characteristics in health care is poor. The regulations for optical radiation and EMF are complex with frequency and time dependence that is not easy to interpret. When performing measurements, good knowledge about frequency sensitivity of the instrumentation and source calibration is needed. In our opinion, these aspects are an almost impossible task for a clinic and a biomedical engineering unit to handle today. Therefore, there is a need for practical guidance for specific applications both with respect to demands from the authorities, but also how to succeed with the safety work within the area.

In general, occupational exposure is covered by national legislation, but it is questionable if these regulations are fully implemented in the health care sector. Medical use is covered, to some extent, by national legislation where requirements such as exposure control (UV) and the practitioner's profession (laser, UV) are defined. Beside the Swedish Radiation Protection Act, in which non-ionizing radiation and ultrasound are included in general terms, there are no specific requirements or guidelines on the maximum level of exposure or reference doses for patients during medical procedures. However, in line with

[7], we conclude that this is not a straight forward process, but guidance on how the practical safety management procedures should be performed are needed.

There are many European standards for medical devices that require devices to visually report exposure levels to patients, e.g., MRI and ultrasound equipment. This information is commonly used for MRI procedures, especially when patients with medical implants or other issues, which demand lower exposure levels.

In summary, there are some areas where improvements could/should be made. ICNIRP states in the workshop summary of non-ionizing radiation in medicine [7] that guidelines for staff and training of staff using NIR is essential for class 3 or 4 laser. They also conclude that specific guidelines for patients would be useful

The knowledge of treatment procedures and safety aspects is commonly held by, and passed on from, manufacturers, colleagues, medical physicists and biomedical engineers at the hospital. However, there is no tradition at Swedish hospitals to assign medical physicist to NIR and safety. The knowledge regarding these issues is up to the clinic and the biomedical engineers assigned to the clinics. At each hospital, a medical service and maintenance organization is available to support medical equipment including applications that use NIR. Their basic knowledge about measurements of NIR is obtained from the manufacturers, and we have noticed that there are uncertainties in measurement methods and instrumentation. One way to overcome these difficulties would be to assign a medical physicist/biomedical engineer to NIR who could work as an expert in safety, measurement techniques and help with safety training of staff. This has already been introduced in MRI applications where an MR physicist, often but not always with a background as medical physicist, works as a consultant in safety issues and training of staff.

In general, there are no education programs about NIR, and risks (with the exemption of MR) to our knowledge are sparsely covered in the university programs. The medical physicist programs cover NIR but only to some extent. Lund has a module of 9 ECTS[2], In Umeå approximately 2 ECTS, as part of a 7.5 ECTS course, covers NIR, in Gothenburg approximately 2 ECTS and in Stockholm 0,5 ECTS. MRI is covered by at least 7.5 ECTS at each university, and there are also some elements of Ultrasound within the programs.

Demanding safety training could be one way to increase the knowledge at the clinics, but it is also important that the training recur regularly within the clinic. The hospitals need to have knowledge about the physical aspects of NIR and they need to be able to interpret the regulations and to understand the safety aspects for each specific medical device.

Information about safety issues in relation to NIR in health care, to some extent, can be found on the Swedish Radiation Safety Authority home page, but detailed information on specific medical procedures are missing. We have not found any published information about this from the Medical Products Agency. However, there is some information found in a few national recommendations for treatment of specific diseases from The National Board of Health and Welfare (psoriasis and atopic dermatitis). We suggest that NIR could be integrated in the National Board of Health and Welfare's ongoing work of national recommendations for treatments of specific diseases. At the moment there are 14 final recommendations, and several recommendations in progress. For example, the national recommendations (in progress) for psoriasis describe UV treatment as one option. The recommendations (in progress) for depression describe-rTMS as one option. There will probably be more recommendations in the near future.

[2] ECTS - European Credits Transfer System

We suspect that the training and education of physicians and nurses about NIR is very sparse. Lee and Lee [263] conducted a survey among Irish medical students on their knowledge of ionising radiation safety in healthcare. Their knowledge about radiation safety was limited. For example as much as 74% were not aware of any laws governing the prescription of radiology investigations. We think that the same can be said about the knowledge about non-ionising radiation and the laws and guidelines in this area. It would be of interest to perform a similar study in Sweden, but with NIR as main focus.

Nevertheless, to improve the knowledge in safety and NIR in the health care sector, there is a need for clear, evidence-based information from reliable sources, and it should be obvious to the user where to find that information.

10. General conclusion

NIR is extensively used in health care at many clinics and units for a variety of applications. The exposure to patients and staff needs to be carefully controlled to avoid acute health effects for MRI, TMS, electrosurgical diathermia, UV treatments, laser therapy, and harmonic scalpels in surgery. The knowledge about long-term effects from MRI is sparse. More knowledge regarding the risk for congenital malformations due to ultrasound exposure in utero as well as the risk for adverse effects due to interaction between ultrasound and contrast media is needed. The knowledge is also sparse regarding possible synergistic or additive adverse health effects for hybrid equipment, e.g., when two or more NIR applications are applied simultaneously.

Throughout our work we have noticed that it is hard or nearly impossible to map all different applications - even within a single hospital. Compared to the use of ionising radiation in health care, which is carefully organised with an authorization procedure for each piece of equipment used, the use of NIR in general does not have a dedicated organisation. Our experience is that the quality of safety work differs between clinics and that dedicated, reliable information about safety during use of NIR in medical procedures is sparse. To improve the knowledge in safety and NIR in the health care sector, there is a need for clear, evidence-based information from reliable sources, and it should be obvious to the user which source has the appropriate information.

11. Recommendation for further work

Throughout our work we have identified some areas where more knowledge is needed.

As stated by ICNIRP and SCENIHR, further research is needed to evaluate possible long-term effects for MRI. According to ICNIRP (2017), further research would be useful regarding the risk of congenital malformations due to ultrasound exposure in utero. Further research would also be useful on the potential adverse effects of ultrasound in combination with contrast media.

The putative increased use of rTMS requires analyses of the safety procedures and research of possible negative effects.

It has become more and more common to run two or more NIR applications simultaneously, and it is not known if the combined exposures will have a synergistic or additive adverse effect that need special attention.

It has not been possible within the scope of this project to count or even estimate the number of procedures that are done yearly for the different techniques. We have tried to

extrapolate a figure for MRI, but for other applications the task is impossible. This is partly due to a lack of continued reporting from the individual clinics. For some techniques, such as diagnostic ultrasound, the technique is extremely widespread at many different clinics and no reporting of its use is required. To achieve any reasonable estimation of NIR use, specific clinics/hospitals would have to log all procedures performed within a specific category during a short, well-defined time interval. The same method could be used to record deviations or accidents from a specified medical procedure.

We conclude, based on our own experience in this field, that knowledge about the health effects in relation to the use of NIR in health care is poor. To achieve more precise and convincing evidence a well-designed documentation/investigation is required. This kind of study will require careful consideration with a clear research question and well-chosen study group.

Systematic reviews on scientific literature on health effects from the use of NIR in health care both from a patient but also a worker perspective are also warranted.

Finally we have also identified a lack of dedicated information on the safety aspect for the use of NIR in health care. Health care professionals need a reliable source of information from a major national authority such as the Swedish Radiation Safety Authority, the Medical Products Agency, or the national Board of Health and Welfare. Today it is not obvious where to find information, and the information that is available is sparse.

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13. Abbreviations

AFB	auto-fluorescence bronchoscopy
AGNIR	Advisory Group on Non-Ionising Radiation- Gov.UK
BMUS	British Medical Society
CEUS	Contrast-enhanced ultrasound
CFI	Colour flow imaging
CFM	Colours flow mapping
CI	Cochlear implant
COST	Collaboration in Science and Technology
CT	Computer tomography
DLPFC	Left dorsolateral prefrontal cortex
ECG	Electrocardiography
ECTS	European credit transfer system
EMF	Electromagnetic field
ESU	Electro surgical units
FCFM	Fibred confocal fluorescence microscopy
FDA	Food and Drug Administration, US
FLIM	Fluorescence lifetime imaging microscopy
FUS	Focused ultrasound surgery
HIFU	High intensity focused ultrasound
HINS	High-intensity narrow-spectrum
IARC	International Agency for Research on Cancer
ICD	Implantable defibrillator
ICNIRP	International Commission on Non-Ionising Radiation
IR	Infrared light
I_{SPTA}	Maximal spatial peak time-averaged intensity levels
KCC	Kalmar County Council
KLL	Kalmar läns landsting
KUH	Karolinska University Hospital
LASCA	Laser speckle contrast analysis
Laser	Light Amplification by Stimulated Emission of Radiation
LASIK	Laser in situ keratomileusis
LCU	Light curing units
LDF	Laser doppler flowmetry
LDI	Laser doppler imaging

LED	Light-emitting diode
LED	Light emitting diode
LIPUS	low-intensity pulsed ultrasound
LIPUS	Low-intensity pulsed ultrasound
LITT	Laser-induced thermal therapy
LLLT	Low-level laser therapy
MI	Mechanical Index
MRgFUS	Magnetic Resonance-guided Focused ultrasound
MRI	Magnetic resonance imaging
MRMD	MR medical director
MRRD	MR research director
MRSE	MR safety expert
MRSO	MR safety officer
NIR	Non ionising radiation
OCT	Optical coherence tomography
ODS	Output display standard
OMI	Optical molecular imaging
PAC	Plasma arc curing
PDT	Photodynamic therapy
PEMF	Pulsed magnetic field
PNS	Peripheral nerve stimulation
POCUS	Point-of-care ultrasound
PTK	Photoretherapeutic keratectomy
PUVA	Psoralen and ultraviolet A
RF	radiofrequency
SAR	Specific Absorption Rate
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCHEER	Scientific Committee on Health, Environmental and Emerging Risks
SMF	Static magnetic field
SSM SWEA	Swedish Radiation Safety Authority Swedish Work Environment Authority
T	Tesla
TI	Thermal index
TIB	Thermal index in bone
TIC	Thermal index in the cranium
TIS	Thermal index in soft tissues

TMS, rTMS	Transcranial magnetic stimulation, repetive TMS
UCA	Ultrasound contrast agent
US	Ultrasound
UV	Ultraviolet light
VCC	Västerbotten County Council
WFUMB	World Federation for Ultrasound in Medicine and Biology
VLL	Västerbottens läns landsting

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2017:37

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 300 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

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