Independent Assurance Report

Ecodesign Steering Committee Secretariat ("COCIR")
Brussels

Limited assurance engagement on the preparation process of selected data of the Status Report of the SRI for Medical Imaging Equipment under the Ecodesign Directive (the "SRI Status Report") for the year 2011

Engagement: 0.0638534.001

pwc

INDEPENDENT ASSURANCE REPORT

To the Ecodesign Steering Committee Secretariat ("COCIR") of the Self-Regulatory Initiative ("SRI") for Medical Imaging Equipment under the Ecodesign Directive, Brussels

We have been engaged to perform a limited assurance engagement on the preparation process of selected data of the Status Report of the SRI for Medical Imaging Equipment under the Ecodesign Directive (the "SRI Status Report") for the year 2011.

Responsibility for SRI Status Report 2011
The Ecodesign Steering Committee of the SRI is responsible for the preparation of the SRI Status Report in accordance with the six step methodology as stated in the SRI V1 (for ultra-sound imaging equipment) and SRI V2 (for MRI and future modalities):

- Step 1: Gather baseline data
- Step 2: Prioritization and selection of next modality
- Step 3: Identification of significant environmental aspect(s) for the selected modality
- Step 4: Derive environmental targets and objectives for the selected modality
- Step 5: Implementation into company processes
- Step 6: Monitoring and reporting

This responsibility includes the selection and application of appropriate methods to prepare the annual SRI Status Report and the use of assumptions and estimates for individual SRI disclosures which are reasonable in the circumstances. Furthermore, the responsibility includes designing, implementing and maintaining systems and processes relevant for the preparation of the SRI Status Report.

Practitioner's Responsibility
Our responsibility is to express a conclusion based on our work performed as to whether any matters have come to our attention that cause us to believe that the preparation process for the data in the SRI Status Report 2011 marked with the logo ✓ has not been, in all material respects, in accordance with the above mentioned SRI six step methodology. We also have been engaged to make recommendations for the further development of the reporting of the SRI based on the results of our assurance engagement.

Within the scope of our engagement we did not perform any procedures on the data that have been submitted by the member companies to the Ecodesign Steering Committee Secretariat (COCIR). Thus, we provide limited assurance on the preparation process of the SRI Status Report 2011 by COCIR, but not on the respective data.

We conducted our work in accordance with the International Standard on Assurance Engagements (ISAE) 3000. This standard requires that we comply with ethical requirements and plan and perform the assurance engagement under consideration of materiality to express our conclusion with limited assurance.

In a limited assurance engagement the evidence-gathering procedures are more limited than in a reasonable assurance engagement, and therefore less assurance is obtained than in a reasonable assurance engagement.

The procedures selected depend on the practitioner's judgement. Within the scope of our work we performed amongst others the following procedures:

- Inquiries of personnel at the Ecodesign Steering Committee Secretariat (COCIR) responsible for the preparation of the SRI Status Report regarding the process to prepare the Report and the underlying internal control system;
- Inspection and sample testing of the systems and process documentation for collection, analysis and aggregation of the selected data;
- Recalculation of the aggregation and KPIs calculation for selected data;
- Analytical procedures on selected data;
- Inspection of documents regarding the description of the SRI six step methodology (SRI V2) and its application to MRI as detailed in 'Magnetic resonance Equipment (MRI) - Study on the potential for environmental improvement by the aspect of energy efficiency' and 'Magnetic Resonance – Measurement of energy consumption'.

Conclusion
Based on our limited assurance engagement, nothing has come to our attention that causes us to believe that the preparation process for the data in the SRI Status Report 2011 marked with the logo ✓ has not been, in all material respects, in accordance with the above mentioned SRI six step methodology.

Emphasis of Matter - Recommendations
Without qualifying our conclusion, we make the following recommendations for the further development of the reporting of the Self-Regulatory Initiative for Medical Imaging Equipment under the Ecodesign Directive:

- Refine reporting contents according to stakeholder needs
- Develop a policy to require the SRI members to submit assurance certificates for annual sales data and data on the environmental aspects in scope for each modality
- Improve documentation of controls
- Develop a formal timeline and sanction mechanisms in case of non-compliance for all phases of preparation of the SRI Status Report

General Terms of Engagement
We issue this report on the basis of the engagement agreed with the Ecodesign Steering Committee Secretariat (COCIR), which comprises the attached General Terms of Engagement for Wirtschaftsprüfer and Wirtschaftsprüfungsgesellschaften as of 1 January 2002, which are also applicable to third parties.

Munich, 14 August 2012

PricewaterhouseCoopers
Aktiengesellschaft
Wirtschaftsprüfungsgesellschaft

Hendrik Fink
Wirtschaftsprüfer (German Public Auditor)

ppa. Heinke Richter

Annexes

SRI Status Report 2011

General Engagement Terms for Wirtschaftsprüfer and Wirtschaftsprüfungsgesellschaften as of January 1, 2002

SELF-REGULATORY INITIATIVE FOR MEDICAL IMAGING EQUIPMENT

STATUS REPORT 2011

COCIR

SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

FOREWORD

COCIR Members have always played a driving role in developing environmental friendly healthcare technology in Europe and worldwide. Reducing the environmental aspects and impact of our products, while improving the quality of care for patients, reducing healthcare costs and granting wider access to state-of-the-art medical equipment is our principal goal in this industry sector.

COCIR Members started integrating environmental considerations into the development of medical devices long before the entry into force of the Ecodesign Directive in 2005. Further, in 2008, COCIR Members proactively signed a Voluntary Agreement to improve environmental performance through ecodesign, even though at that time medical equipment had not been included in the first ecodesign directive working plan.

With this Self-Regulatory Initiative, which sets clear targets, COCIR Members have made a public declaration to the European Commission EU Member States and NGOs to continuously improve the environmental performance of medical equipment through the entire life cycle, starting from the concept and design phase through to equipment end-of-life, while continuing to deliver benefits to patients.

The European Commission welcomed this Self-Regulatory Initiative during the first COCIR SRI Annual Forum in March this year and the process leading to official acknowledgement by the Commission is expected to be concluded by the end of 2012.

We strongly believe that the COCIR Self-Regulatory Initiative will succeed in its objectives and will provide the medical technology industry with new tools to better deal with the environmental challenges we are now facing. We are also believing, that medical devices from COCIR members can provide strong benefits for healthcare and can increase environmental efficiency at the same time.

K.J. Haydon

Kevin Haydon
COCIR President

F. Schröder

Freimut Schroeder
SRI Steering Committee Chair

Nicole Denjoy
COCIR Secretary General

REPORT OVERVIEW

The Status Report on the Self-Regulatory Initiative for medical imaging devices, published annually by the Ecodesign Steering Committee presents information and results achieved by the participating Companies.

This SRI Status Report 2011 consists of 8 main parts:

Part 1 offers a general introduction to the self-regulatory initiative, describing the development of the methodology from the first proposal in 2009 (SRIv1), to the final methodology (SRIv2) submitted to the European Commission and the Consultation Forum early in 2012 for official acknowledgement.

Part 2 lists news and results of the work of the Steering Committee and the Expert Groups in 2011.

Part 3 explains in brief the content of the six steps of the SRIv2 methodology. More details on the methodology are available in the SRIv2 documentation (www.cocir.org – "greening at COCIR" section).

Part 4 shows the results achieved in 2010 by participating companies in the pilot on ultrasound equipment according to the SRIv1 methodology. The chapter also offers a brief overview of the SRIv1 methodology.

Part 5 displays the results of the SRIv2 methodology applied in 2010 to all the modalities in scope of the Self-regulatory Initiative. Step 1 and step 2 of the methodology allowed to define a Priority List based on LCA data provided by companies.

Part 6 presents the results of the application of the methodology to Magnetic Resonance Imaging equipment that have been identified as priority one for their environmental impact. The target set by the Steering Committee according to the SRI methodology is presented together with the market fleet average in 2011, the year chosen as reference. The "MRI measurement of the energy consumption" methodology is also briefly introduced.

Part 7 summarizes the findings of the on-going project on Computer Tomography equipment. The ecodesign target will be developed during 2012 and presented to the EC and the Consultation Forum in March 2013.

Part 8 presents briefly the lesson learnt in 2011 in the process of setting ecodesign targets for Magnetic resonance equipment.

Appendix provides for a review of the environmental aspects identified as most relevant for Ultrasound and MRI equipment against Annex 1.3 of the Ecodesign Directive. It also lists some cases of Ecodesign applied to modalities in scope.

This first SRI Status Report 2010 presents the processes developed by the Steering Committee and the results achieved for Ultrasound and MRI equipment in 2010. Each following year a new modality will undergo the methodology steps and targets and results will be added to the Status Report. By 2014/2015 all the modalities will be covered and will be subject to the continuous improvement cycle established by the methodology itself.

Data and figures marked with the ✓ logo have been in the scope of the PWC review (see page 42 for additional information).

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COCIR

Founded as a non-profit trade association in 1959, COCIR[1] represents the Radiological, Electromedical and Healthcare IT industry in Europe. As such, COCIR members play a driving role in developing the future of healthcare both in Europe and worldwide. COCIR is committed to support its members and communicate with its partners in Europe and beyond on issues which affect the medical technology sector and the health of EU citizens. COCIR also works with various organisations promoting harmonised international standards and regulatory control that respects the quality and effectiveness of medical equipment and healthcare IT systems without compromising the safety of patients and users. COCIR encourages the use of advanced technology to support healthcare delivery worldwide. Key objectives are to include and to promote free worldwide trade of medical equipment and to maintain the competitiveness of the European health sector.

COCIR ENVIRONMENTAL FOCUS GROUP

Founded in 2000 COCIR ENVI Focus Group has taken several initiatives in the environmental domain introducing Ecodesign Initiatives in different ways:

- **2002 - 2007**, in the field of **International Standardisation**: COCIR member companies contributed to the development of an internationally-recognized standard integrating Ecodesign into the product design and development process for all electromedical equipment. International Electro-technical Commission (IEC) published the International Standard IEC 60601-1-9
- In **2006**, in the field of **Integrated Product Policy**, as advocated by the EU's Action Plan on Sustainable Consumption and Production and Sustainable Industrial Policy (SCP/SIP)[2], COCIR member companies participated in an Integrated Product Policy project with the Hamburg authorities and hospitals.
- Keeping up with the latest inventions in medical technology often involves replacing equipment in medical practice before it reaches the end of its useful life. COCIR published in **2007** a version 1 of **Good Refurbishment Process** (GRP) describing in 5 steps how manufacturers can effectively refurbish equipment to ensure quality, safety and effectiveness of medical imaging equipment.
- COCIR published in **2008** a **guide** on REACH requirements for component suppliers and equipment manufacturers
- In **2008**, COCIR launched a **web-based database for substances declarations under REACH, RoHS, Batteries and Packaging directives called BOMcheck**. This centralized open-access database provides a cost-effective approach for manufacturers to work with their suppliers to reduce hazardous substances in products.

GREENING AT COCIR

More detailed information on COCIR initiative in environmental domain could be found on COCIR website www.cocir.org at "Greening at COCIR" section.

[1] *For more information: www.cocir.org.*

[2] *See COM(2008) 397, Brussels, 16.7.2008.*

PARTICIPATING COMPANIES

The following companies participate in the SRI for Medical Imaging Equipment for the modalities they market in EU.

Table 1: Participating Companies

	Magnetic Resonance MRI	Computer Tomography CT	Nuclear Medicaine NM	Radiology X-RAY	Ultrasound US
Agfa HealthCare				⌑	
Aloka					⌑
Elekta				⌑	
Fujifilm				⌑	
GE Healthcare	⌑	⌑	⌑	⌑	⌑
Hitachi Medical Systems Europe	⌑	⌑			⌑
IBA Ion Beam Applications			⌑		
Philips Healthcare	⌑	⌑	⌑	⌑	⌑
Samsung Medison Europe					⌑
Siemens Healthcare	⌑	⌑	⌑	⌑	⌑
Toshiba Medical Systems Europe	⌑	⌑		⌑	⌑

PART 1

1. GENERAL INTRODUCTION TO THE SELF-REGULATORY INITIATIVE FOR MEDICAL IMAGING EQUIPMENT

The Energy Related Products (Ecodesign) Directive, 2009/125/EC, enables the EC to set Ecodesign requirements through new regulations for any group of products which uses energy.
In 2007, Medical Devices were identified as a "Priority A" product group by the EC for future regulation. To avoid adverse business impacts (unnecessary costs and loss of flexibility in product design), COCIR reached a consensus with the EC to develop an alternative approach allowed under the Ecodesign Directive Annex VIII (Self-Regulatory Initiative for an industry sector).

1.1. SELF-REGULATORY INITIATIVE V1

During the EC Consultation Forum[3] meeting on **28 May 2008** COCIR presented its first proposal for an industry-led Self-Regulatory Initiative. The EC welcomed this alternative approach as it could achieve the same overall objective as an implementing regulation but would avoid potential negative business impact. In particular, the EC emphasised that "*regulation would risk hampering innovation in the medical equipment sector, where technology evolves rapidly"*.

Based on this positive feedback, COCIR decided in **September 2008** to establish the Ecodesign Steering Committee *(hereafter: Ecodesign SC)* in order to further develop this Initiative and develop the methodology.

In **May 2009** the developed methodology (*hereafter SRI v1*) was applied to ultrasound products in a pilot project to gather experience from practical implementation.

In **November 2009** the methodology and the pilot project on ultrasound products was presented to the Consultation Forum. Comments were gathered for further improvements.

In **2010** COCIR and the Steering Committee worked on the SRI v1 to update and improve it taking into account the comments received from the Members of the Consultation forum, the EC and the lessons learnt from the Ultrasound pilot project.

1.2. THE NEW METHODOLOGY SRIV2

The result of the thorough analysis and review is the SRIv2 6 step methodology which the Steering Committee considers to address all concerns.

The SRIv2 has been submitted to the European Commission and Consultation Forum in January 2012 and the Consultation phase closed on 5th March 2012. The Steering Committee expects the SRIv2 to be officially acknowledged by the Commission by the end of 2012.

[3] *Article 18 of the Ecodesign Directive (2009/125/EC) establishes a "Consultation Forum" (CF) which allows stakeholders to be informed and consulted on the implementation of the Directive. The Forum is limited to 60 members, including 27 representatives of EU Member State, 3 representatives of EEA Member States, 30 stakeholders (Stakeholders have been selected by the EC following anopen call for interest).*

PART 2

2. NEWS AND DEVELOPMENTS 2011

During 2011 the Steering Committee worked on Magnetic Resonance Equipment, the modality identified by the methodology as the one with the highest priority, to define ecodesign targets.

2.1. METHODOLOGY FOR THE MEASUREMENT OF THE ENERGY CONSUMPTION OF MRI DEFINED

The Steering Committee defined in 2011 a methodology for the measurement of the energy consumption of Magnetic Resonance equipment. On the basis of the methodology Companies producing MRI (see table 1) defined measurement campaigns and in June 2011 started to measure their equipment. The process took several months. All MRI except a few models were measured by the end of 2011.
The data has been used to define the baseline 2011, i.e. the average performance of the market weighted against the sales.
The data has also been used as input for the study on improvement potentials.

2.2. EXTERNAL STUDY ON IMPROVEMENT POTENTIALS FOR MRI.

The SC mandated an external consultancy, PE International, to run a study to identify a methodology to quantify the improvement potentials of MRI equipment. PE International was also given the task to collect data from companies and to apply the methodology. The study has been submitted to the Consultation Forum and the EC in March 2012 and has been discussed during the 1st Annual Forum meeting on the SRI for medical imaging equipment on 28 March 2012.

2.3. ECODESIGN TARGETS FOR MRI DEVELOPED

Ecodesign targets have been defined in 2011 and refined in 2012 according to the SRI methodology (see part 3). The results have been presented in the "Ecodesign Target for Magnetic Resonance Equipment" report, submitted to the EC in March 2012 and discussed with the EC and the Consultation Forum on March 28 during the 1st Annual Forum meeting on the SRI for medical imaging equipment.

2.4. FIRST ANNUAL FORUM MEETING HELD ON 28 MARCH 2012

On March 28, the Steering Committee presented to the EC and the Consultation Forum the results of the work performed in 2011 on Magnetic Resonance equipment.

2.5. COCIR WEBSITE UPDATED. ALL RELEVANT DOCUMENTATION AVAILABLE FOR DOWNLOAD

Following the 1st annual forum meeting the COCIR website has been updated. All the publicly available documentation has been uploaded in the "greening at COCIR" section. A reserved area has been set up for the Consultation Forum Members where additional documentation is available for download.

PART 3

3. THE SRIV2 METHODOLOGY

The SRI methodology is the process participating companies shall follow to set ecodesign targets for their products and ensure that they are achieved.

The purpose of the SRI methodology is to:

- Provide a transparent and continuous process to control the application of ecodesign targets while protecting company confidential information.
- Set a priority sequence for the equipment evaluation.
- Identify top environmental aspects.
- Set environmental targets.
- Systematically engage stakeholders.
- Monitor and report progress.

The SRI methodology is based on six key steps. The iterative process allows the member companies to offer their confidential internal life cycle assessment data for each modality, life cycle stage and aspect selection processes. This provides a comprehensive analysis which any one single approach could not achieve.

3.1. SCOPE

The SRIv2 methodology applies to the following imaging equipment:

- Magnetic Resonance Imaging equipment (MRI)
- Computer Tomography (CT)
- Nuclear Medicine (NM)
- X-ray
- Ultrasound (US)

Every year at least one new modality is selected until all modalities in scope have been chosen.

After a modality has been selected (via the priority list resulting from Step 1 and 2), it will remain in the continuous improvement circle (Steps 3 to 6). This means that once a modality has been selected and the industry has achieved the target to minimize the aspect with the highest environmental impact and potential for improvement, another assessment of the most significant aspects will be done.

3.2. STEP 1: GATHER BASELINE DATA

The purpose of the first step is to establish a baseline for prioritization and improvement. The method of the first step is to collect Member Company Life Cycle Assessment (LCA) data on products in scope of the SRI.

The provided information in Step 1 contains typical LCA data per modality and company, including the defined use scenarios, functional units, impact categories and intended use, the percentage of life cycle contribution, the individual environmental load per modality related to the corresponding LCA method, as well as an plausibility check based on expert expectations on the future capacity for innovation of the modality.

3.3. STEP 2: PRIORITIZATION AND SELECTION OF NEXT MODALITY

The purpose of the second step is to analyse the baseline data in order to prioritize the modalities for evaluation. The method of the second step is to rank the environmental load and other data from each modality.

3.4. STEP 3: IDENTIFICATION OF SIGNIFICANT ENVIRONMENTAL ASPECT(S) FOR THE SELECTED MODALITY

The purpose of the third step is to analyse and prioritize the three most significant environmental aspects contributing to the total environmental impact of the selected modality. The method of the third step is to rank the data on the top three environmental aspects, including the percentage of their contribution to the total life cycle.

3.5. STEP 4: DERIVE ENVIRONMENTAL TARGETS AND OBJECTIVES FOR THE SELECTED MODALITY

The purpose of the fourth step is to define a common modality and derive Ecodesign target(s). The method of the fourth step is to develop a common definition and thus basis for measurement. Based on these comparable figures the target scenarios are calculated.

In the second phase of this step, the SC Secretariat uses the collected values to calculate the target scenarios:

- Best available technology as Baseline (BAT),
- Business as usual (BAU),
- Best not yet available technology (BnyAT)
- Beyond Business as usual.

Based on these ranges, the Ecodesign SC decides on a feasible industry reduction target. Before it is integrated into the companies design targets, the industry target is proposed to the Consultation Forum for endorsement.

The results of this step are two types of targets:

- **Individual company targets:** These are absolute improvement targets that each company can derive from their reported value against the average result of the business as usual scenario. It remains at the company's own discretion to publish this individual target.
- **Industry target:** this target is achieved by the relative improvement of the total industry compared to the Baseline.

3.6. STEP 5: IMPLEMENTATION INTO COMPANY PROCESSES

The purpose of the fifth step is the integration of the Ecodesign target(s) into the internal company processes. The translation of the target(s) into the company internal product design process remains up to the individual member.

3.7. STEP 6: MONITORING AND REPORTING

The purpose of the sixth step is to monitor and report on the achievement of the industry target. The method of the sixth step is to calculate the averages of the annually reported impact values and comparison to the Baseline. The status of each modality and the progress that the companies are making is annually reported to the Stakeholders with this SRI Status Report.

PART 4

4. ULTRASOUND IMAGING EQUIPMENT PILOT PROJECT

When COCIR and the participating companies started to develop the Self-Regulatory Initiative, the methodology and approach was a new terrain for all. Participating companies initiated a first non-standardised review of the products in scope to establish the product of initial focus for a pilot, to develop the industry baseline for energy trending, and to establish targets and timing. The final choice of ultrasound imaging equipment was based on the following reasons:

- Ultrasound equipment is manufactured by the majority of the COCIR participating companies in the Self-Regulatory Initiative (Aloka, GEHC, Hitachi, Samsung Medison, Philips, Siemens and Toshiba). The inclusion of many manufacturers could steep the learning curve.
- COCIR members have a good understanding of environmental aspects and opportunities to reduce environmental impacts for ultrasound equipment. Most of the manufacturers are engaged in Life Cycle Analysis projects and focus on the Ecodesign of their products (examples of ecodesign applied to Ultrasound products are reported in Appendix).
- Ultrasound equipment is much less complex, including fewer components compared to other modalities in the medical imaging sector. Taking ultrasound as example was easier and faster to learn and to develop a methodology, to establish company internal processes to assess environmental aspects, create targets, and to change technologies.

4.1. GENERAL DESCRIPTION OF ULTRASOUND EQUIPMENT

Ultrasound is an imaging technique used to visualize subcutaneous body structures including tendons, muscles, joints, vessels and internal organs for possible pathology or lesions. Obstetric ultrasound is commonly used during pregnancy to check on the development of the fetus.

Ultrasound uses a piezoelectric transducer encased in a probe to send pulses of sound into the body. The sound wave is partially reflected at each point in the body where a tissue interface results in a change in density. The time it takes for the echo to travel back to the transducer is measured and used to calculate the depth of the tissue interface causing the echo. The greater the difference in density, the larger the echo is.

The sound is focused either by the shape of the transducer, a lens in front of the transducer, or a complex set of control pulses from the ultrasound scanner machine. This focusing produces an arc-shaped sound wave from the face of the transducer. The wave travels into the body and comes into focus at a desired depth.

Typical ultrasound scanners operate in the frequency range of 2 to 18 megahertz, hundreds of times greater than the limit of human hearing. The choice of frequency is a trade-off between spatial resolution of the image and imaging depth. Superficial structures such as muscles, tendons, testes, breast and the neonatal brain are imaged

Figure 1: ultrasound equipment

at a higher frequency (7-18 MHz), which provides better axial and lateral resolution. Deeper structures such as liver and kidney are imaged at a lower frequency 1-6 MHz with lower axial and lateral resolution but greater penetration.

4.2. MARKET COVERAGE

The ✓7 companies[4] participating in the ultrasound pilot project have a total turnover in Europe[5] in 2011 of ✓788[6] million euros. These companies cover 82%[7] of the European[6] market.

Table 2: Ultrasound - EU[8] market data

Modality	2009 Market Value	2010 Market Value	2011 Market Value	Estimated EU Market Coverage
Ultrasound (US)	✓801 M€	✓814 M€	✓788 M€	82%

4.3. SRIV1 METHODOLOGY FOR ULTRASOUND

Participating companies developed a generic process to be followed for the pilot ultrasound. A detailed description of each process phase is described in the SRIv1.

4.4. TARGET SETTING

The industry Ecodesign SC has set a target to reduce by 2012 the average annual energy consumption per unit of new ultrasound products placed on the market by 25% compared to the 2005 baseline. The target was set on the basis of an expert judgment on realistic feasibility to improve the already existing ecodesign programs.

To reach the 25% target, according to table 3, participating companies should reduce the average annual energy consumption per unit by ✓14,5% from 2009 to 2012.
The average annual energy consumption per unit will be reduced despite new products will have increased functionality and will deliver even more healthcare benefits to patients.

The target to reduce average annual energy consumption of new ultrasound products placed on the market by ✓14,5% between 2009 and 2012 translates to a reduction in average annual energy consumption from ✓808 kWh per unit per year in 2009 down to ✓691 kWh per unit per year in 2012.

Based on predicted EU27 annual sales in 2012 by COCIR companies of 22.316[9] units, this is equivalent to a total energy saving of 2.610.972 kWh for 2012 compared to 2009. This is equivalent to 885 ton[10] of CO_2.

[4] *SRI Member : Aloka, GEHC, Hitachi, Samsung Medison, Philips, Siemens, Toshiba.*
[5] *Countries included: Estonia, Latvia, Lithuania, Bosnia, Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania, Serbia, Slovakia, Slovenia, Ukraine, Portugal, Spain, Denmark, Finland, Norway, Sweden, Ireland, UK, Austria, Belgium, France, Germany, Greece, Italy, Netherlands, Switzerland*
[6] *COCIR SHARE internal market statistics data base. Data are based on the fiscal year.*
[7] *Estimation provided by companies based on SHARE data*
[8] *COCIR Imaging Market Statistics source (SHARE). Countries included: Estonia, Latvia, Lithuania, Bosnia, Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania, Serbia, Slovakia, Slovenia, Ukraine, Portugal, Spain, Denmark, Finland, Norway, Sweden, Ireland, UK, Austria, Belgium, France, Germany, Greece, Italy, Netherlands, Switzerland*
[9] *Estimated sales in 2012 to be equal to pre-crisis sales volume in 2008*

Participating companies plan to achieve this target by setting the following objectives:

- Increased focus on Ecodesign in the product design and development process. For example, considering the use of the International Standard IEC 60601-1-9: Environmentally Conscious Design of Medical Electrical Equipment
- Specify and design product components and parts with much less energy consumption
- Using new technologies (e.g. Green IT equipment)

4.5. COCIR STATUS REPORT ON PILOT ULTRASOUND ACHIEVEMENTS

The Ecodesign Steering Committee calculated the average annual energy consumption for new products put on the market for the years 2005 to 2011. The data is used to assess whether companies are achieving the interim targets and are therefore on track to achieve the final pilot modality target.

As shown by table 3, in 2011 the annual average energy consumption per unit for ultrasound equipment slightly increased to 737 kWh/unit.

✓**Table 3:** achievements in the Ultrasound Pilot Project

Year	Total annual sales	Total annual sales as a % of 2005 annual sales	Total annual energy consumption of all new products sold	Total annual energy consumption of all new products as a % of 2005 annual energy consumption	Actual average annual energy consumption of all new products sold in kWh (per unit and year)	Actual average annual energy consumption of all new products compared to 2005	Targeted average annual energy consumption of all new products sold	Targeted annual energy consumption of all new products compared to 2005
	Units[11]		kWh[12]		kWh/unit year		kWh/unit year	
2005	17099	100%	15.757.081	100,00%	922	100,00%	-	
2006	20260	118%	17.536.665	111,29%	866	93,9%	-	
2007	21526	126%	17.193.454	109,12%	799	86,7%	-	
2008	22316	130%	16.606.971	105,39%	744	80,8%	-	
2009	17273	101%	13.975.406	88,69%	808	87,8%		
----------Entry into force of SRI for Ultrasound equipment----------								
2010	19030	111%	13.589.213	87,96%	**728**	**79,0%**	769	**83,5%**
2011	21672	127%	15.969.315	101,35%	**736,9**	**80,0%**	730	**79,2%**
2012							**691**	**75,0%**

[10] Conversion factor gCO2/kWh = 339. Average value for Europe 27 in 2009. Source: CO2 Emissions from Fuel Combustion (2011 Edition), IEA, Paris.The conversion factor has been updated to 2009 value compared to the Status Report 2010 where the 2008 value has been used.

[11] Units sold each calendar year provided by Companies

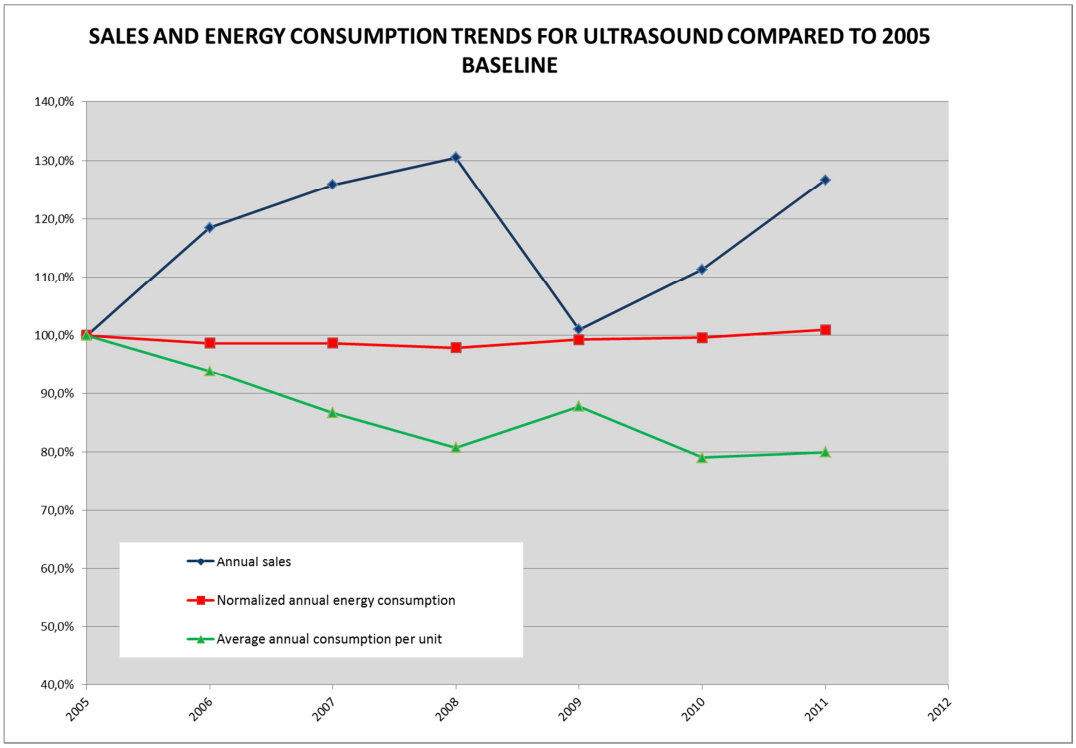
[12] Energy consumption for each model placed on the market in the calendar year provided by Companies

4.6. INTERPRETATION OF ANNUAL SALES AND ANNUAL ENERGY CONSUMPTION

Table 3 provides consolidated data for total annual sales and total annual energy consumption of new ultrasound products that participating companies put on the market in EU Member States from 2005 to 2011.
✓Figure 2 compares the annual sales each year as a percentage of 2005 annual sales, with the average annual energy consumption for new products put on the market which shows a decreasing trend from 2006 to 2008 compared to 2005.

In 2009, however, this trend changes significantly as average annual energy consumption for new products increased. Again in 2011 a slight increase can be observed.
The changes in the reduction trend reflect the three major competing technology trends which have affected energy consumption of ultrasound equipment since 2005:

- Increased market share of laptop and handheld products with reduced energy consumption
- Development of more powerful imaging techniques with increased energy consumption
- Reductions in energy consumption from EcoDesign.

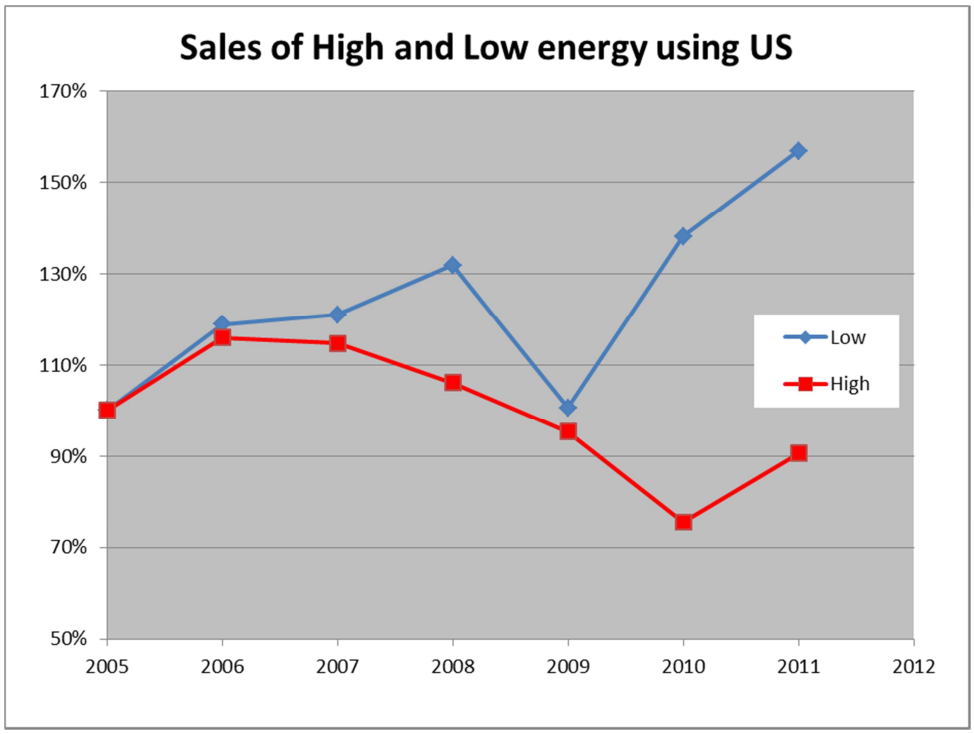


✓**Figure 2:** Annual sales, normalized annual energy consumption[13] and annual average consumption per unit for new ultrasound products compared to 2005 baseline

✓Figure 3 shows how the market demand of equipment with higher energy consumption has significantly increased in 2011 and explains the slight increase in the average energy consumption per unit shown in figure 2. However the increase in sales of new energy saving

[13] *The annual energy consumption depends on products performances but also on sales volume. To compare the annual energy consumption for different years, it has been normalized according to 2005 sales volume.*

technologies has contributed to compensate.



✓**Figure 3:** Sales of high energy using and low energy using ultrasound equipment compared to 2005 baseline

4.7. ACHIEVING THE PILOT ULTRASOUND ENERGY REDUCTION TARGET AND INSURANCE OF A CONTINUOUS IMPROVEMENT

Once the pilot target of reducing the average energy consumption per unit by 25% compared to 2005 has been achieved by 2012, COCIR will include the pilot ultrasound into the established SRIv2 methodology procedure. Ultrasound will be added as the last modality to the Priority List presented in Section 5.2 of this SRI Status Report 2011 and will, from there on, remain in the continuous improvement cycle. Thus, all future Ecodesign targets developed for the next innovation cycle of ultrasound products will be founded on the SRIv2 Methodology.

PART 5

5. SRI GENERIC METHODOLOGY

In 2010 the Ecodesign Steering Committee started to apply the methodology first two steps to all the modalities in scope to identify a priority list.

5.1. GATHER BASELINE DATA FOR ALL MODALITIES IN SCOPE (STEP 1)

Baseline data was gathered according to the template in SRIv2 Appendix 5. According to the product portfolio of the 11 SRI members (see table 1) data has been delivered from the following companies[14]:

- GE Healthcare
- Philips Healthcare
- Siemens Healthcare
- Toshiba Medical Systems Corporation

For the following modalities and sub-modalities:

- Computer Tomography (CT)
- Magnetic Resonance Imaging (MRI)
- Nuclear Medicine
  - NM Conventional
  - NM PET
- X-Ray
  - X-Ray Angio
  - X-Ray Fluoro
  - X-Ray Radio
  - X-Ray Mammography
  - X-Ray Surgery

[14] Only already available LCA data has been provided. According to SRIv2 methodology Step 1 and 2 do not require LCA data to be provided by all the participating companies.

5.2. PRIORITIZATION AND SELECTION OF THE NEXT MODALITY (STEP 2)

The company LCA data from STEP 1 have been consolidated by the SC Secretariat after a plausibility check.

The SC Secretariat calculated two rankings with the provided LCA data:

- The first ranking weights the environmental loads (delivered by the companies in STEP 1) with current units sold in EU (based on SHARE[15] data).
- The second ranking is based on the expert judgements on factors such as feasible technological developments and the complexity of the product, as well as on sales forecasts of the next generation equipment.

The final priority list, see table 4, that is used to select the next modalities is obtained averaging the two previously calculated rankings.

Table 4: Priority list

Modality	Environmental loads ranking 2009	Risk Assesment ranking 20xx*	Average Ranking	Final Ranking
MRI	1	1	1	1
CT	3	2	2,5	2
X-Ray	2	3	2,5	3
Nuclear Medicine	4	4	4	4

*depends on the typical modality innovation cycle

CT has been chosen as second one as the European market coverage of the participating companies is around 100%, while for X-ray it is about 80%. The higher the market coverage, the higher the reduction of environmental impacts that the SRI Initiative could achieve.

According to table 4, the SRI Initiative will focus on the listed modalities in the given sequence, at least one each year.

Thus, MRI is targeted as the first modality under the SRI methodology. This also means that by mid-2012 the group will focus on CT as the second modality and so forth, according to table 5.

Table 5: Timetable for targeting new modalities

	2011	2012	2013	2014	2015
MRI	¤				
CT		¤			
X-Ray			¤		
Nuclear Medicine				¤	
Ultrasound					¤

[15] *SHARE is COCIR's internal market statistics data base.*

5.3. IDENTIFICATION OF SIGNIFICANT ENVIRONMENTAL ASPECT (STEP 3)

Every year a new part is added with a new modality, following the order of the priority list. Each new part for the specific modality includes data on the identification of the top environmental aspect.

PART 6

6. MAGNETIC RESONANCE IMAGING EQUIPMENT

6.1. GENERAL DESCRIPTION OF MAGNETIC RESONANCE EQUIPMENT

Magnetic resonance imaging (MRI) is a medical imaging technique used in radiology to visualize detailed internal structures of the human body. MRI makes use of the property of magnetic resonance of nuclei to create medical diagnostic images.

An MRI machine utilizes superconductor technology by using liquid Helium (below 4.2 Kelvin) to create a powerful magnetic field to align the magnetization of atoms within the body. Radio frequency waves are used to systematically alter the alignment of this magnetization. This causes the nuclei to produce a rotating magnetic field detectable by the scanner. Very powerful magnetic field gradients are needed to cause nuclei at different locations to rotate at different speeds providing the necessary 3-D spatial information.
The information collected is manipulated with high speed mathematical formulas to generate extremely detailed medical diagnostic images.

MRI provides excellent contrast between the different soft tissues of the body, which makes it especially useful in imaging the brain, muscles, internal organs, and cancers. Compared with other medical imaging techniques such as computed tomography (CT) or X-rays, MRI uses no ionizing radiation.

MRI technologies
MRI equipment uses two different technologies to generate the required magnetic field strength that could vary from 0,35 Tesla up to 7 Tesla or even more.

Permanent magnet: permanent magnets are used to generate magnetic field up to 1,2 Tesla. Commonly such models are equipped with non-cylindrical magnets allowing more patient comfort. Non cylindrical magnet MRIs are called "Open MRI".

Superconductive magnet: superconductive electromagnets, cryo-cooled to 4 Kelvin using liquid helium, are used to generate magnetic fields up to 7 Tesla or more. The boiled helium is re-condensed by a cryo-cooler (Gifford-McMahon or pulse tube). The cryo-cooling system cannot be switched off except in case of emergency. This causes the helium to boil off and get lost. Normally superconductive MRIs use cylindrical magnets but sometimes open magnets.

Figure 4: *Open MRI and cylindrical MRI*

Magnetic field strength

The strength of the magnetic field and the power of the gradient coil and the RF senders determine the quality and resolution of the image. High end machines for hospital use are equipped with 3 Tesla magnets. Higher fields equipment, up to 7 Tesla, are actually under development and test and used only for research purposes.

Bore size

The bore diameter is important for patient comfort. Patient suffering from claustrophobia could experience better comfort in larger bores. Moreover, large bores allow the examination of "big" patients suffering from obesity. Nonetheless larger bore size requires the use of more powerful and energy consuming magnet systems and gradient coils, as the field strength decrease with the distance.

Modes

Three modes have been defined for MRI equipment.

Off mode:
The MRI is in the lowest user selectable power state. In superconductive MRIs the magnet needs to be cooled permanently[16]. Therefore the cooling circuitry and the magnet supervision needs to be active.

Ready-to-scan mode:
The MRI is on and ready to acquire an image. All modules are active. However neither gradient pulses nor radio frequency waves are sent or received. The computing system may calculate and display images from raw data previously acquired.

Scan mode:
The MRI is actively scanning the patient by sending high frequency waves as well as gradient pulses and reading the resulting variations in the magnetic field. The computing system acquires the corresponding data and calculates and displays images.

The power consumption of MRI in the three modes is represented in figure 5.

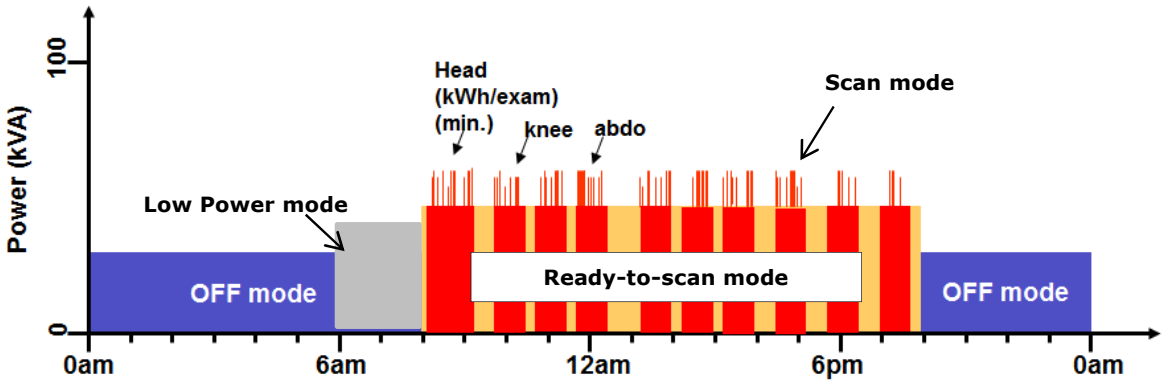


Figure 5: *Exemplary power consumption of MRI*

[16] In case the magnet cooling system is switched off, the helium slowly boils and it is released. The released helium is lost and needs to be replaced by liquid helium. This implies the corresponding cooling and transporting efforts.

Power consumption in different modes

The measurements performed on all models allowed to determine the energy consumption of MRI equipment in the different operating modes, according to the defined use scenario (see chapter 6.5.4).
Even if the variability between different MRI is relevant, the following average values can be identified equipment:

MODE	Average Power Consumption (kW)	Average distribution of daily energy consumption %
Off	9,3	34
Ready to scan	14,6	34
Scan	22,3	32

The power consumption in scan mode cannot be easily measured as it is different for each sequence and moreover it varies extremely during the same sequence as shown by figure 6. For each sequence the average power consumption has to be derived.

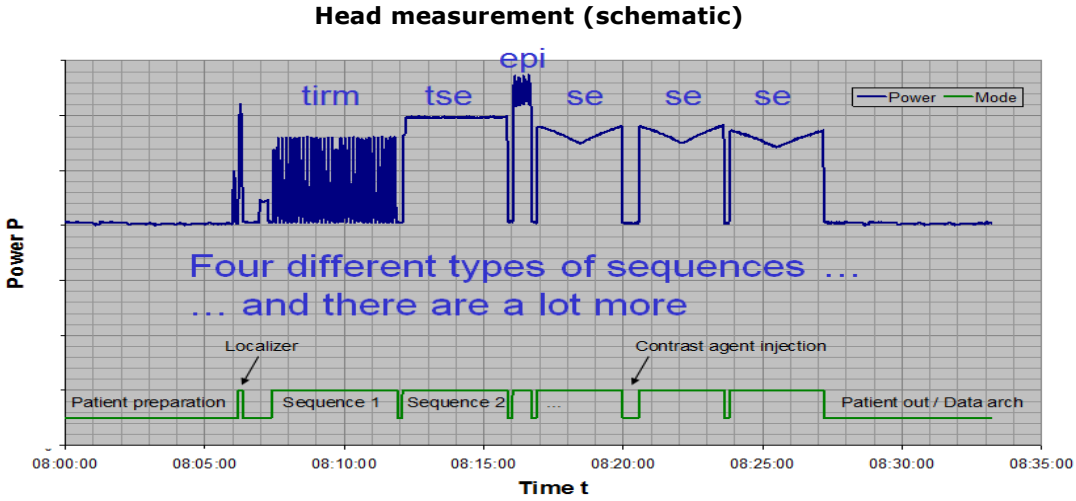


***Figure 6**: Power consumption for different sequences in abdomen examination*

6.2. MARKET DATA

The ✓5 Companies[17] participating in the SRI for the MRI sector represent a total turnover in Europe of ✓643[18] million euros in 2011, covering about 96%[19] of the European market.

Table 6: MRI - EU[20] market data

Modality	2009 Market Value	2010 Market Value	2011 Market Value	Estimated EU Market Coverage
Magnetic Resonance Imaging (MRI)	✓708 M€	✓776 M€	✓643 M€	96%

6.3. IDENTIFICATION OF THE MOST SIGNIFICANT ENVIRONMENTAL ASPECT FOR MRI

Magnetic resonance Imaging equipment has been chosen by the Steering Committee as the first modality to be targeted on the base of Step 1 and Step 2 of the methodology as shown in table 4.

According to Step 3 of the methodology as summarized in part 3, the data provided by Companies are used to rank the different environmental aspects. Table 7 shows that energy consumption during the product lifecycle use phase has been identified as the top environmental aspect.

Table 7: Identification of most significant environmental aspect

Identification of most significant environmental aspect		
Aspects	**Average internal ranking**	**Final COCIR Ranking**
Energy use	1	**1**
Non ferrous metals	2	**3**
Ferrous alloys	3	4
Helium consumption	2	**2**
Magnet metals	3	5
Copper in Gradient coil	4	8
Copper: end of life	2	6
Copper: production	3	7

[17] *GE Healthcare, Hitachi Medical Systems, Philips Healthcare, Siemens Healthcare, Toshiba Medical Systems*
[18] *COCIR SHARE internal market statistics data base*
[19] *Estimation provided by COCIR companies based on 2010 SHARE data*
[20] *COCIR Imaging Market Statistics source (SHARE). Countries included: Estonia, Latvia, Lithuania, Bosnia, Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania, Serbia, Slovakia, Slovenia, Ukraine, Portugal, Spain, Denmark, Finland, Norway, Sweden, Ireland, UK, Austria, Belgium, France, Germany, Greece, Italy, Netherlands, Switzerland*

6.4. COMPLEMENTING DOCUMENTATION

This report is completed by the following documentation:

1. **Magnetic resonance Equipment (MRI) - Study on the potential for environmental improvement by the aspect of energy efficiency**

The Ecodesign Steering Committee hired in July 2011 an external consultant with long experience in the field of ecodesign, PE International, to study the potential for improvement of MRI equipment with regard to energy efficiency. The study analyses MRI energy consumption, the allocation of power usage in the different modules during off, ready-to-scan and scan mode and technological solutions to improve the efficiency.
Results of the study are used as input for Step 4 of the SRI methodology for setting the ecodesign target for MRI.

2. **Magnetic resonance Equipment (MRI) - Measurement of energy consumption**

The Ecodesign Steering Committee mandated in October 2010 an Expert Working Group on MRI with the objective to develop a methodology to measure the energy consumption as there are no recognized standards at the moment. The measurement methodology allows company to measure the energy consumption of MRI on a common basis providing comparable data that are used in Step 4 of the SRI methodology.

6.5. MEASUREMENT OF ENERGY CONSUMPTION

The Ecodesign Steering Committee started in October 2010 to develop a methodology to measure the energy consumption of MRI equipment, as there are no available standards that could be used.

The methodology ensures that:

- Results of the measurements are comparable and repeatable
- The measured energy consumption has a strict relation with the real energy consumption in everyday hospital use. Such information is important for hospitals and clinics to understand the real running cost of MRI to plan and allocate correctly their budget
- The procedure does not involve disproportionate costs or resources
- The measurement results allow the determination of all the information that could be considered relevant for the SRI target setting process but could also be useful for MRI users.

A first methodology was defined in May 2011 and Participating Companies started a measurement campaign providing a first set of 5 measured machines. After a deep analysis of the data the methodology was simplified by introducing average values for the ready-to-scan mode durations (see the "Magnetic Resonance – Measurement of energy consumption" document for additional information). Participating companies measured all their MRI models according to the new methodology.

The study on the MRI potential for improvement showed that the energy use in scan mode could not be reduced due to physics of the process which requires a certain amount of energy (see **"Magnetic resonance Equipment (MRI) - Study on the potential for environmental improvement by the aspect of energy efficiency")**.

For the above mentioned reason, the SRI adopted a simplified version of the methodology without measuring the energy consumption in scan modem (for additional information see chapter 6.6.5.).

The methodology has been finalized in February 2012 and is available for download at COCIR website.

6.5.1. Measuring the energy consumption

The energy consumption could normally be calculated by summing the energy consumption in each mode, calculated multiplying the power consumption for each mode for the relative duration:

Energy use= $\mathbf{T}_{off}$*$\mathbf{P}_{off}$ + $\mathbf{T}_{ready\text{-}to\text{-}scan}$* $\mathbf{P}_{ready\text{-}to\text{-}scan}$+$\mathbf{T}_{scan}$*$\mathbf{P}_{scan}$

The power consumption in off mode, servicing mode and ready-to-scan mode can be easily measured. For MRI the following elements are unknown:

$T_{ready\text{-}to\text{-}scan}$: Duration of ready to scan mode
T_{scan} : Duration of scan mode
P_{scan} : Power consumption in scan mode

Those durations depend very much on which examination is performed, the scan speed of the machine and the administrative operations to be performed by doctors during the examination (patient preparation, data input, data archiving, patient positioning, etc.).

While for off mode it is easy to set an average value according to hospital practices, setting average values for the remaining two modes would not allow to take into consideration a very important factor, the "productivity" of the MRI, the number of patients that can be examined per day (see chapter 6.5.5).

6.5.2. System Boundaries

The Ecodesign SC defined the system boundaries (which modules should be included in the measurement and which not) for the measurement of MRI equipment.

In: All system-critical items needed to perform a basic scan, e.g. gradient amplifiers, RF unit, MR coils needed for the specific measurements, reconstruction engine(s), required electronics such power supplies, controllers, console/computer, cryogen compressor, water heat exchanger, patient table, magnet, helium-conservation equipment.

Out: Any equipment and accessories beyond basic product offering and not required for a basic scan, or customer-provided equipment, e.g. optional MR coils, patient vital signs accessories, facility-provided cooling water equipment and hardware for advanced medical applications.

6.5.3. Equipment configuration

To allow comparability of the measurements the Ecodesign SC identified ranges for the values of the most relevant parameters for each one of the defined sequences having an impact on the energy consumption:

- Number of slices
- Field of view
- Slice thickness
- Resolution

- Bandwidth
- Sequence duration

As shown in table 8, a set of parameter has been defined for each sequence. The values have been determined on the basis of the experience of Companies' experts as the most commonly used in hospital practice.

Moreover, the values have been validated according to the following documentation:

- the German "Guidelines of the Federal Medical Council for Quality Assurance of magnetic resonance imaging" (BÄK)
- and the "guidelines on criteria for quality assessment in nuclear magnetic resonance imaging pursuant to § 136 SGB V i.V.m. § 92 SGB V, Section 1 of the Federal Committee of Physicians and Sickness Funds (Quality assessment guidelines for magnetic resonance imaging)

Both documents are available for download at the Greening at COCIR/SRI section of the COCIR website (www.cocir.org).

For each parameter and for each sequence the minimum or maximum value is indicated in the table.

Table 8: abstract of the configuration parameters table. The complete table is available in the "MRI – Measurement of energy consumption" document.

	Number of Slices	FOV(mm^2)	Slc Thk (mm)	Resolution	Bandwidth (Hz/Px, Range)		Sequer Re
	Minimum	Max	Max	Max	Min	Max	
HEAD							
localizer	1	280	8	1,1	290	655	
t2_tirm_tra_dark-fluid_320	28	220	5	0,7	191,0	200	
t2_tse_sag_512	27	250 x 225	5	0,5	122,0	195	
ep2d_diff_3scan_trace_p2	23	240	5	1,9	1132,0	4000	
t1_se_tra_320	28	230	5	0,8	150	160	
t1_se_tra_320	28	230	5	0,8	150	160	
t1_se_cor_320	32	230	5	0,8	150	200	
SPINE							
localizer	5	450	8	1,8	290	655	
t2_tse_sag_512	16	300	3	0,6	160	165	
t1_tse_sag_512	15	300	4	0,6	240	250	
t2_tse_tra_512	20	230	4	0,5	95	195	
t1_tse_tra_448	20	230	4	0,6	110	230	
ABDOMEN							
localizer	5	450	8	1,8	450	655	
t1_fl2d_opp-in_tra_p2_mbh	30	380	6,0	1,5	240	525	
t2_trufi_cor_p2_bh	25	400	6,0	1,4	500	655	
t2_tse_tra_p2_mbh_320	30	380	6,0	1,2	260	395	
t1_vibe_fs_tra_p2_320_bh_pre	64	400	4	1,3	400	785	
t1_vibe_fs_tra_p2_320_bh_arterial	64	400	4	1,3	400	785	
t1_vibe_fs_tra_p2_320_bh_venous	64	400	4	1,3	400	785	
t1_vibe_fs_tra_p2_320_bh_delayed	64	400	4	1,3	400	785	
t1_vibe_fs_cor_p2_bh_288_post	128	400 x 360	4	1,4	600	870	
KNEE							
localizer_tra	3	450	8	1,8	250	656	
localizer sag+cor+tra	3	300	5,0	1,0	250	435	
t1_se_sag_512	32	160	4	0,4	120	150	

6.5.4. MRI Use Scenario

To define the functional unit, the use scenario must first be defined. The use scenario includes applicable use modes, typical customer applications, and equipment capability. Use modes[21] in view of the measurement of the energy consumption are defined as:

> **Off mode**: The system functions into the minimum energy consumption state that the typical user can access e.g. through selection of off or shutdown, at the operator console.
>
> **Ready-to-scan mode**: This mode represents the state of the system during patient handling and/or data evaluation and archiving, between individual scans.
>
> **Scan mode:** The MRI is actively scanning the patient to generate images by sending high frequency waves and gradient pulses and reading the resulting variations in the magnetic field. The computing system interprets the data and generates the images.

To determine the time an MRI system remains in each mode, participants referenced confidential field usage records and estimated average values that could represent daily usage of MRI.

To evaluate the energy consumption the most commonly used examinations were estimated by application specialists. Such values are also supported by external studies such as the "2007 MRI Market Summary Report", May 2008, IMV Medical Information Division[22].
This mix served as the "standard application mix" on which basis specific MRI protocols were defined and performed. Members agreed to use the top 5, normalized to 100% as shown in Table 9.

Table 9: Scan Mode application mix

Diagnostic Application	Normalized Distribution
Head	23,8%
Spine	24,8%
Abdomen	23,8%
Knee	19%
Angio	8,6%

According to companies' experts the following daily usage has been defined:

Off:	12h (Off mode)
Scan, ready-to-scan:	10h (Ready-to-scan + scan mode)
Low power:	2h (Reduced power consumption assumed equal to ready-to-scan)

[21] The low power mode defined in the MRI measurement methodology is not reported here as its power consumption has been assumed equal to ready-to-scan mode.

[22] www.imvinfo.com.

6.5.5. Patient per day

A very important feature of MRI is the patent/day ratio. The patient/day ratio measures the maximum number of patients (or examinations) that a MRI machine could scan in one day according to the examination distribution (use scenario) set as typical by the measurement methodology.

This value is determined by performing each examination (head, spine, abdomen, knee, angio) using phantoms[23] but real patient measurements (e.g. contrast agent injections, table moves, patient breath holds, etc). Using the distribution provided by the use scenario, it is possible to determine how many examinations could be performed in one day (how many patients could be examined per day).

The patient/day ratio is very important for at least 2 main reasons:

- The productivity of the machine represents high value information for the user (hospital/clinic).
- There is a linear correlation between the productivity and the energy consumption. MRI with higher patient/day ratio consumes more energy as shown by figure 7.

This means that MRI with lower performances in terms of patients per day are usually consuming less energy. Reducing the number of patients per day could help reducing the energy consumption of MRI equipment. On the other hand this is not acceptable as Medical Companies are committed to deliver equipment with improved performances/shorter examination times for patients.

As the technological evolution is moving towards machines with faster scan time and higher patient throughput (higher productivity) the energy consumption in absolute value could be expected to grow accordingly.

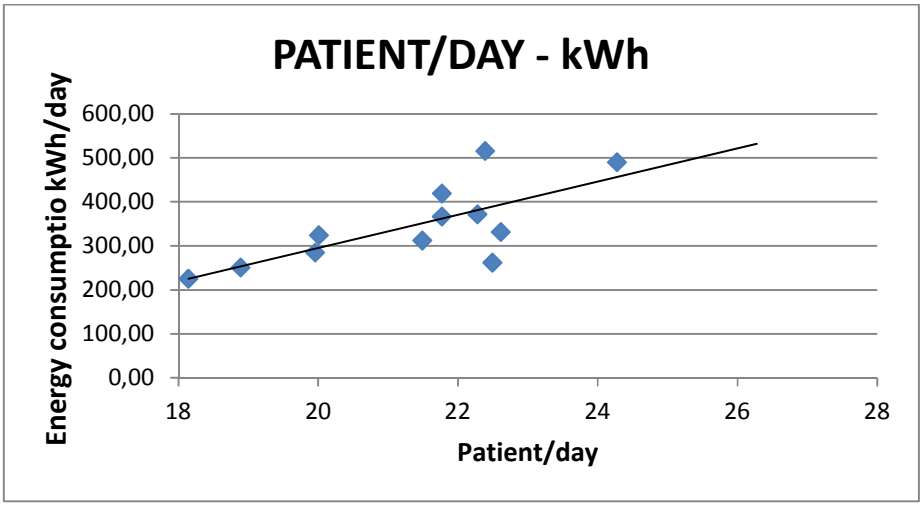


Figure 7: *correlation between patient/day and total energy daily consumption, measured on 12 MRI.*

[23] Phantoms are models made of plastic and fluids that simulate body parts and are used to test and calibrate MRI equipment.

6.5.6. Simplified Measurement methodology

As the Steering Committee decided to measure only the energy usage in off and ready-to-scan mode (see chapter 6.6.5), the "Methodology for the measurement of the energy consumption of MRI" has been applied in a simplified version.
Moreover the energy consumption in low power mode as defined in methodology description has been assumed equal to the energy usage in ready-to-scan mode.

6.5.7. The methodology in brief

The methodology requires and explains how to measure the following data needed for the SRI:

1. Power consumption in off mode
2. Power consumption in ready–to-scan mode
3. Duration of each one of the defined sequences

The duration of each examination is calculated as the sum of the time in scan mode (measured) and the time in ready-to-scan-mode (average value derived by companies' experience and first simulations).

An evaluation spreadsheet calculates the following values:
1. Number of examinations per day: calculated from the duration of each examination and the examination distribution in the use scenario during 10 hours daily working time.
2. Energy consumption in off mode: calculated multiplying the power consumption in off mode by 12 hours
3. Energy consumption in ready-to-scan mode: the energy consumption of each examination is calculated multiplying the measured power consumption for the duration of ready-to-scan. The total energy consumption per day is obtained multiplying such values for the number of examinations per day.

All the details and procedures on how to measure the energy consumption are presented in the "Magnet Resonance Equipment (MRI) – Measurement of energy consumption" document, available on the COCIR website in the "Greening at COCIR/SRI" section.

6.5.8. Required resources to perform the measurements

The measurement methodology requires the MRI to be available in a test lab. In alternative the test could be performed in a hospital or clinic.

The following tasks and technicians/specialists are required to measure one specific target MRI equipment:

TASK	TIME	
Compilation of the sequences	4h	Application specialist
Installation of the measurement tool	1h	Electrician
Preparation of the templates	1h	Specialist
Running the sequences	3h	Specialist, Measurement specialist
Measurement of Off mode and de-installation of measurement tool	1h	Specialist, Electrician, Measurement specialist
Data archiving	1h	Application specialist
Data evaluation	4h	Specialist
Total	**20h**	

6.6. ECODESIGN TARGET FOR MRI

6.6.1. SRI methodology for ecodesign target setting in brief

The fourth step of the SRI methodology sets the ecodesign target as the market average performance of the selected aspect, to be achieved in a time equal to the specific innovation cycle.

The SC Secretariat collects from Companies the measurements of all MRI models and, on the basis of the reduction potentials determined by the PE INTERNATIONAL study on MRI, calculates the target scenarios[24]:

- Baseline today
- Business as usual (BAU)
- Best not yet available technology (BnyAT)
- Beyond Business as usual.

Based on these scenarios, the Ecodesign SC decides on a feasible industry reduction target. Before it is integrated into the companies design targets, the industry target is proposed to the Consultation Forum for discussion.

6.6.2. MRI Categories

The Ecodesign SC recognized that MRI equipment has different design intents, for specific clinical applications. The design intents result in energy consumption which is substantially different, due in large part to MR physics. For instance, a growing clinical need is for MRI systems with a large patient access (bore). Since MR physics is based on pulse sequences (switched magnetic field gradients and radio frequency pulses), the power needed for the pulse sequences increases as the diameter increases. Other features relevant to different image quality needs, such as number of data receiver channels, also affect energy consumption. It was recognized that a simple energy metric might cause confusion if systems with different clinical utilities are compared directly. As a result, member companies have developed a categorization table (see table 10).

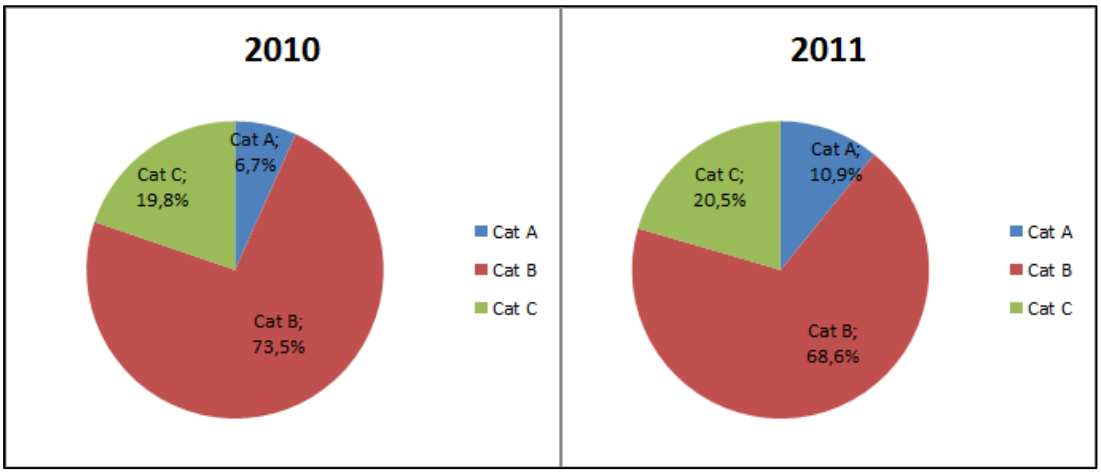
[24] For additional information on scenarios refer to SRIv2 documentation, Appendix V: www.cocir.org

Table 10: MRI Equipment Categorization Table

General information on categories included	– matrix columns represent key differentiation characteristics that differentiate different clinical utilities of a system – each characteristic results in a designated amount of points – total score of all characteristics will determine the overall category that a system belongs to			
Key characteristics	Field strength	1.5T	50	points
		3.0 T	100	points
	Bore size	< 60 cm	10	points
		≥ 60 & < 70 cm	20	points
		≥ 70 cm	30	points
	Maximum Gradient Amplitude per axis	< 35 mT/m	40	points
		≥ 35 mT/m	80	points
	Maximum Slewrate per axis	< 100 mT/m/s	20	points
		≥ 100 mT/m/s & < 150 mT/m/s	30	points
		≥ 150 mT/m/s	40	points
	Patient table	fixed table	10	points
		mobile table	20	points
	Maximum channels	< 16 channels	15	points
		≥ 16 channels & < 64 channels	35	points
		≥ 64 channels	45	points
	Useable FOV cm²	< 40 cm	25	points
		≥ 40 & < 50 cm	35	points
		≥ 50 cm	45	points
Final company model category	**Total points**			
	Clinical model - Category A		**< 220**	points
	Hospital model - Category B		**≥ 220 & < 315**	points
	Research model - Category C		**≥ 315**	points

The MRI units sold in 2010 and 2011 are reported in table 11 in percentage according to the 3 identified categories.

Table ✓ 11: MRI – Distribution of units sold* in 2010 and 2011 in EU[25]



*Open magnet units are not included in the figures as they are not in the scope of the SRI

6.6.3. Scope

The Ecodesign Steering Committee decided to apply the SRI methodology to set ecodesign targets only to category B equipment.

Exclusion of category A

Category A products represent a small percentage of the whole sales in EU as shown by table 11. Most of category A MRIs are open models equipped with permanent magnets that do not require power to generate the magnetic field (no cryo-cooling system). Therefore contribution of category A to the energy consumption of MRI is very limited and the absence of the cryo-cooled magnet reduces also the potential for improvement.

Exclusion of category C

Category C models accounts for 20% of all EU sales. Category C represents high-end models, with increased functionality, mostly used for research purposes. Only a few models are actually commercialized by few companies. If applied, the methodology would open critical issues related to confidentiality of delivered results and certainly would harm innovation.

The required high level performances involve higher energy consumption, due to the high magnetic and gradient field performance, number of receiving channels, bore and field-of-view size. For this reason the potential for improvement is extremely limited and should be investigated with extreme care to avoid that possible technical solutions to reduce the energy consumption (adopted for category B equipment) could compromise the innovation potential.

For the above mentioned reasons the Steering Committee decided not to set targets for such equipment and to evaluate the feasibility of reducing the energy consumption without compromising performances and benefits for patients.

[25] *EU 27 market sold units data provided by Companies for each model placed on the market in calendar year 2010 and 2011*

6.6.4. Functional Unit

The functional unit is the reference ensuring the comparability of power consumption of different products and their developments over time.
As identified by the study on improvement potential for MRI, the functional unit for MRI is the number of patients that can be examined per day. Such number, as already presented, is not fixed a priori but depends on the hospital workflow, the administrative time, the nature of examinations, the required quality and functionality and furthermore the power and performance of the machine. It is determined measuring the duration of each examination (scan time: measured + ready-to-scan time: set) and applying the examination distribution to the 10 hours working time of the machine.

6.6.5. Metric

The energy consumption of MRI is the sum of the energy consumption in the three different modes (off, ready-to-scan and scan).
The initial measurements run on 12 models and the results of the study on MRI potential for improvement have shown that:

1. Measuring the energy consumption in scan mode is complex, expensive and time consuming, as examined in chapter 6.1.

2. The potential for reducing the energy used to perform the scan is limited due to the physics of the process. A certain amount of energy is needed to stimulate the response from the body and to be read by receivers.

3. Improvements could be achieved by defining new technologies that use different sequences. Such improvements could not be recorded by the methodology at the moment, as the sequences are set. Not setting the sequences would render difficult to compare the measurements.

Therefore the Ecodesign Steering Committee **decided to adopt as metric for setting the target for MRI the energy usage per model per day (kWh/unit day) in off and ready-to-scan mode to perform a certain number of examinations according to the use scenario.**

The target is to be expressed as the **average daily consumption per model in off and ready-to-scan mode:**

$$kWh_{(off,\ ready\text{-}to\text{-}scan)}/unit\ day$$

This choice reflects the part of the energy consumption that could be reduced by ecodesign programs and takes into account the productivity of the MRI as the time in ready-to-scan mode is not defined but varies. In fact, even if the ready-to-scan time is defined per examination, the number of examinations per day depends on the total examination time, which account also for the scan time.

6.6.6. Innovation Cycle

The innovation cycle is defined as the time needed to develop new or enhanced products and place them on the market. For medical devices it could vary from 3 years to 7, depending on the complexity of the innovation being brought to market.

The below listed activities for MRI requires:

Research and development	-	1 year
Realization, Verification and Validation	-	3 years
Regulatory Approvals	-	1 year

The innovation cycle for MRI therefore corresponds to 5 years.

6.6.7. Setting the ecodesign target

The SRI methodology for target setting has been developed on the base of the experience gathered with the pilot ultrasound project. In particular the Business-as-usual scenario (BAU) is based on the assumption that that the energy consumption of the modality under consideration will get lower year after year due to existing ecodesign programs and due to the improvements of other technologies according to implementing regulations under the Ecodesign Directive or voluntary measures. This assumption has proven true for the Ultrasound pilot project.

The PE INTERNATIONAL study on MRI shows that this assumption is not true for MRI. New functionalities, larger bore diameters, increased magnetic field strength and more powerful gradient and RF amplifiers are going to increase the energy demand to meet clinical needs of medical care.

Therefore the BAU scenario, defined under the assumption that all companies will reach the front runner today at the end of the innovation cycle, has been redefined for MRI according to the findings of the PE INTERNATIONAL study on MRI improvement potentials and used as the baseline.

According to the findings of PE INTERNATIONAL, the BAU baseline shows an increase in the energy demand which can be mitigated by the reduction of energy usage in the most favorable case (BnyAT) where all possible improvements are implemented at the same time by all companies (extreme assumption not in line with technological limits).

Therefore the BnyAT scenario should be re-defined accordingly as the result of the application of the companies' potentials to the newly defined BAU baseline.

BAU Scenario

PE International estimated in the BAU scenario an increase in energy consumption (off+ready-to-scan) of 16,68% assuming that by 2017, half of the category B product sold on the market will have an energy consumption comparable to the energy consumption of Category C products today.

This estimation has been reviewed with the availability of additional measurement data. Moreover Companies provided the estimation of their own BAU scenario according to the specific corporate strategies.

An increase around 12% in the energy consumption by 2017 has been considered an assumption better reflecting the current trends.

Beyond BAU scenario and correction factors.
According to the experience gathered with the Ultrasound Pilot project the SRIv2 methodology assumes that the front runner is the Company with the lowest potential for improvement. The study on Improvement Potentials coupled with measurement data showed for MRI a different situation. The front runner estimated an improvement potential that is quite high compared to other Companies.

This can be interpreted as the result of extensive research in ecodesign that allows the front runner to foresee the application of technical solutions that are not evident to other companies to improve the energy performances. **This represents an important example of how ecodesign could drive innovation.**

Applying the SRIv2 methodology under this circumstances is not possible, otherwise the industry target will result even higher than what has been estimated as the highest possible improvement.

The Ecodesign Steering Committee decided to use correction factors applied to the individual company maximum improvement to derive the company targets and the Industry targets (weighted average against sales). It has been assumed that companies could achieve 75% of the maximum possible improvement and 50% for the front runner.

Additional information on how the methodology has been adapted to fit MRI can be found in part 8 of this Report.

Scenarios
The four scenarios have been redefined accordingly as:

- **Baseline today**
- **Business as usual scenario according to the SRIv2 methodology**, used as reference value and showing the fleet performance of the front runner.
- **Business as usual (BAU):** scenario for year 2017 where the average daily energy usage per model is expected to be increased around 12% compared to baseline today.
- **Best not yet available technology (BnyAT):** scenario for year 2017 where the average daily energy usage per model is expected to decrease around 5,4% compared to the baseline 2011.
- **Beyond Business as usual:** scenario for year 2017 derived applying correction factors to companies BnyAT where the application of the SRI will compensate the increase in energy consumption due to added functionalities maintaining the energy consumption constant (0,73% decrease compared to the 2011 baseline).

The maximum possible reduction potential identified for each Company is used to calculate the average value, **15,63%**, that is used to define the Best-not-yet-available scenario. The PE International study collected the individual company data that cannot be disclosed due to confidentiality reasons.

The four scenarios calculated on all 14 measured models in category B are indicated in the following table:

Scenario (kWh/unit day)	Company					Average daily consumption in off and ready-to-scan per unit (kWh/d)	Range for setting targets compared to baseline 2011
	A	B	C	D	E		
BASELINE 2011 (kWh/d)	XX	XX	XX	XX	XX	227,4	
BAU 2017 according to SRI methodology	XX	XX	XX	XX	XX	176	Front runner fleet performance
BAU 2017 (kWh/d)	XX	XX	XX	XX	XX	254,9	+12,07%
BnyAT 2017 (kWh/d)	XX	XX	XX	XX	XX	215,2	-5,38%
Beyond BAU 2017 (kWh/d)	XX	XX	XX	XX	XX	225,8	-0,73%

Grey cells: confidential data

The baseline scenario is obtained as the weighted average of the energy performance of all models in $kWh_{(off+ready\text{-}to\text{-}scan)}$/unit·day against the sales[26].

The result means that Companies producing MRI equipment participating in the SRI commit not to increase the energy consumption in off and ready-to-scan mode of the average model in 2017 compared to the 2011 baseline. If the SRI was not in place, the energy consumption would have increased around 12% by 2017.

Table 12: calculated values for year 2010-2011 and forecast until 2017 under the assumption of a linear trend

	Sold units[27]	Total daily energy consumption (kWh)[28]	Average daily energy consumption per unit (kWh/d)	Beyond BAU	BAU
2011	✓385	✓86.887	✓227,4		
2012				226,96	231,81
2013				226,72	236,43
2014				226,49	241,05
2015				226,26	245,68
2016				226,02	250,30
2017				225,79	254,92

[26] *This value differs slightly from the baseline value of the PE INTERNATIONAL study as the study identified the improvement potential of a representative model therefore considering a simple average of the measured models. Therefore the data presented in this report better reflects market reality.*

[27] *Sold units data provided by Companies for each model placed on the market in the calendar year 2011*

[28] *Measured energy consumption data provided by Companies for each model placed on the market in the calendar year 2011. Normalized values against sales will be added from 2012 on.*

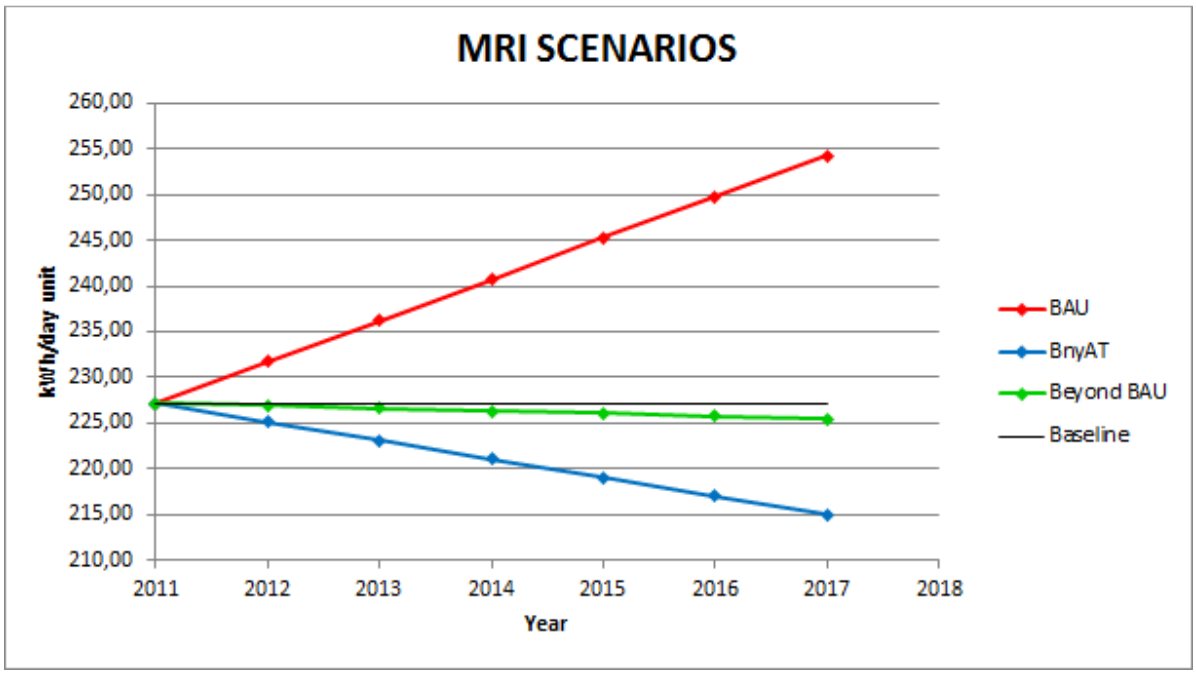


Figure 8: MRI target scenarios

The reduction compared with the BAU baseline implies that the SRI will save in 2017 around 7548[29] kWh per unit sold according to the Beyond as usual scenario, equivalent to more than 2,55 tons of CO_2[30] per year per unit.

6.6.8. Company targets

According to the SRIv2 methodology, each member company adopts an internal company target which enables achievement of the industry target.
Every year the Ecodesign SC Secretariat can evaluate the achievement of each company by comparing the baseline with the measured average performance of all models from each company placed on the market each year.
As the improvement is not a linear process only at the end of the 5 years period it would be possible to evaluate whether the Company targets have been achieved or not.

Member company targets are confidential unless a company wishes to disclose its own.

[29] *Assuming 5 days per week, 52 weeks per year*
[30] *Conversion factor gCO2/kWh = 339. Average value for Europe 27 in 2009. Source: CO2 Emissions from Fuel Combustion (2011 Edition), IEA, Paris.*

6.6.9. Relationship between scan and ready-to-scan kWh

Figure 7 represents the relationship between the energy use in scan mode and the energy use in ready-to-scan mode measured on 12 models.
The linear regression shows a good correlation (R^2=0,77) which allows to determine the total daily consumption of a MRI given the consumption in off and ready to scan mode.

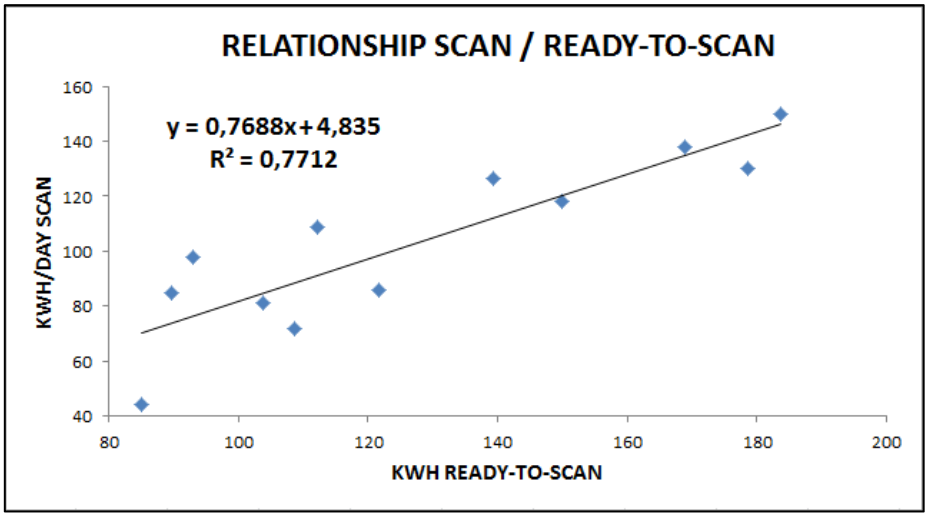


Figure 9: linear correlation between energy consumption per day in scan mode and ready-to-scan mode in 2011

$Scan_{kWh/d}$ = 0,7688 * $Ready\text{-}to\text{-}scan_{(kWh/d)}$ + 4.835

The relationship is valid for year 2011 and will gradually change in time due to the different trends in energy usage in the different modes.

PART 7

7. COMPUTER TOMOGRAPHY

7.1. GENERAL DESCRIPTION OF COMPUTER TOMOGRAPHY[31]

Computed Tomography (CT) is a medical imaging method employing tomography where digital geometry processing is used to generate a three-dimensional image of the internals of an object from a large series of two-dimensional X-ray images taken around a single axis of rotation.

The most prominent part of a CT scanner is the gantry – a circular, rotating frame with an X-ray tube mounted on one side and a detector on the opposite side. A fan-shaped beam of X-rays is created as the rotating frame spins the X-ray tube and detector around the patient. As the scanner rotates, several thousand images are taken in one rotation resulting in one complete cross-sectional image of the body.

The body is positioned on a precision rotational stage and an image is acquired during the rotation at a constant step. The step is usually 0.25 degree to 1 degree (1440 to 360 images). The scan usually covers a rotation of 360 degrees, but for specific applications a limited angle scan can be performed.

Built on these data, it is possible to create a 3D visualization and views from different angles.

Each CT scanner is equipped with grids, collimators and filters to provide shielding against scattered radiation, to define the scan slice and to absorb the low-energy portion of the X-ray spectrum. In this way, both the patient and the examiner are protected.

X-ray tubes used in modern CT scanners have a power rating ranging from 20 to more than 100 kW at voltages of 80 to 140 kV.

7.2. IDENTIFICATION OF THE MOST SIGNIFICANT ENVIRONMENTAL ASPECT FOR CT

Computed Tomography equipment has resulted as the second modality to be targeted in 2012 on the base of Step 1 and Step 2 of the methodology as shown in table 4.

According to Step 3 of the methodology as summarized in part 3, the data provided by Companies are used to rank the different environmental aspects. Table 13 shows that energy consumption during the product lifecycle use phase has been identified as the top environmental aspect, representing around 75% of the impacts on the life cycle of a CT equipment.

[31] https://www.medicalradiation.com

Table 13: Identification of most significant environmental aspect

	Identification of most significant environmental aspect		
Aspects	**Average internal ranking**	**% of total life-cycle**	**Final COCIR Ranking**
Energy use	1	75%	**1**
Non-ferrous metals and alloys	2	11%	**2**
Ferrous metals and alloys	3	6%	**3**

The expert judgment provided by companies' experts shows that there is a potential for improvement, even if limited, in the energy consumption of CT. Risks have been identified regarding the impact on patient throughput and innovation. In particular extreme care should be used to ensure that the energy usage reduction is not going to affect the radiation dose or the development towards lower dosage in the future.

7.3. MARKET DATA

The ✓5 Companies[32] participating in the SRI for the CT sector represent a total turnover in Europe of ✓506[33] million euros in 2011, covering about 96%[34] of the European market.

Table 14: CT - EU[35] market data

Modality	2009 Market Value	2010 Market Value	2011 Market Value	Estimated EU Market Coverage
Computer tomography (CT))	✓581 M€	✓566 M€	✓506 M€	98%

[32] *GE Healthcare, Hitachi Medical Systems, Philips Healthcare, Siemens Healthcare, Toshiba Medical Systems*
[33] *COCIR SHARE internal market statistics data base*
[34] *Estimation provided by COCIR companies based on 2010 SHARE data*
[35] *COCIR Imaging Market Statistics source (SHARE). Countries included: Estonia, Latvia, Lithuania, Bosnia, Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania, Serbia, Slovakia, Slovenia, Ukraine, Portugal, Spain, Denmark, Finland, Norway, Sweden, Ireland, UK, Austria, Belgium, France, Germany, Greece, Italy, Netherlands, Switzerland*

PART 8

8. LESSONS LEARNT IN 2011

8.1. ASPECTS OF THE MEASUREMENT METHODOLOGY TO BE IMPROVED

The MRI measurement methodology is a powerful tool that allows the measurement of energy consumption based on a use scenario that is very close to everyday practice.

Nonetheless the methodology still has some weak points that the Ecodesign Steering Committee is committed to improve in the coming years.

Benefit for patients
In its current form the methodology takes marginally into account the benefits for patients. Companies are working to provide better technologies with improved functions, able to provide better comfort and benefits for patients such as:

- Image quality and resolution
- Integration with other technologies
- Shorter exam durations
- Larger bore diameter
- Noise reduction
- Active magnetic protection screens
- Larger field of view
- Alternatives to the use of contrast agents
- Others

Most of those options require higher energy use that is not reflected by the methodology. An increase in the average energy consumption for MRI due to the increased functionality is not recorded by the methodology but will be shown as an increase in energy usage tout-court.

Duration of examinations
The duration of examinations determines the number of patients that can be examined per day. The patient/day ratio is important as it affects the energy consumption as shown in chapter 6.5.5. The methodology, while able to capture the energy usage is not perfectly suited to capture the development and improvement of exam duration.

Scan time could not be reduced as it is determined by the specific technology as the time needed to reduce the noise and get a clear image. Improvements are limited by the physics of the process. The only way to reduce scan time is to define new sequences that could produce the same image in a shorter time. Unfortunately the methodology does not allow using different sequences than the defined ones. Using new sequences would mean losing data comparability.

The measurement of the time spent in ready-to-scan time is problematic as it depends on the ability of the doctor to perform all the operations. The human factor renders the measurement hardly repeatable and difficult to compare. Therefore the Ecodesign Steering Committee decided to use average values, identical for all the models, determined according to the performed real time measurement and the judgment of experts. This solution, while useful in practice, would not allow taking into account any technical solution that could improve the operation speed, such as new coil systems or larger FOVs which allow the examinations to be performed without the need to reposition the patient.

Therefore the methodology could hardly record improvement of examination speed as, for the above mentioned reasons the main aspects influencing the speed have been set as fixed.

8.2. METHODOLOGY TO SET ECODESIGN TARGETS UPDATED TO FIT MRI

Definition of the BAU scenario
The PE INTERNATIONAL study on MRI shows that this assumption of constant decrease of energy consumption over years is not true for MRI. New functionalities, larger bore diameters, increased magnetic field strength and more powerful gradient and RF amplifiers are going to increase the energy demand to meet clinical needs of medical care.

Therefore the BAU scenario, defined under the assumption of the SRIv2 methodology, has been redefined for MRI according to the findings of the PE INTERNATIONAL study on MRI improvement potentials and used as the baseline.

This assumption has been further refined on the basis of the acquired experience and re-estimated from Companies' specific BAU scenarios, as explained in chapter 6.6.7. This new methodology takes into account company specific strategies and therefore produces estimation closer to reality (around 12%).

As a consequence the BnyAT scenario should be re-defined accordingly as the result of the application of the companies' potentials to the newly defined BAU baseline.

Definition of Industry target
The methodology to define the Industry target (Appendix 5 of the SRIv2) has been developed according to the experience gathered for the US project and under the assumption that the front runner today has the lowest potential to further improve its products compared to other companies. A company that already invested much in energy efficiency will have fewer options to further improve the efficiency compared to another company that invested limited resources in researching efficiency.

The Study on improvement potentials showed that this is not always true, in particular this is not true for MRI, where the experience gathered in many years of research and developments allows the front runners to identify improvement options that are not evident to other companies.

If applied as such the SRIv2 methodology for target setting provides unrealistic results where the front runner would have to bear the highest efforts. Therefore the Steering Committee introduced an updated methodology with the use of **corrector factors** that is explained in chapter 6.6.7.

8.3. DEFINITION OF ENERGY EFFICIENCY

The work on the MRI project showed the impossibility (for now) of setting an energy efficiency index to qualify complex equipment with many functions and taking into consideration performances and benefits for patients at the same time.

8.4. DEFINITION OF THE FRONT RUNNER

Moreover the studies showed the relationship between different aspects and performances of MRI thus influencing the choice of the functional unit. This has a direct consequence on the identification of the front runner which is dependent on the chosen functional unit. There could be a different front runner for each different functional unit.

8.5. NO HISTORIC SERIES OF ENERGY PERFORMANCES

As the measurement methodology has been defined in 2011 for MRI, there are no historical series on energy consumption. Therefore the trends in the energy usage could not be defined as interpolation of the historical data. Reasonable and realistic assumption has been used to determine future scenarios.

INDEPENDENT ASSURANCE REPORT

The Steering Committee mandated an external independent party, PricewaterhouseCoopers AG WPG (PwC) to perform a limited assurance engagement on the preparation process of selected data of the Status Report for the year 2011, in accordance with the International Standard on Assurance Engagements (ISAE) 3000.

Within the scope of PwC work the following procedures, amongst others, have been performed:

- Inquiries of personnel at the Ecodesign Steering Committee Secretariat (COCIR) responsible for the preparation of the SRI Status Report regarding the process to prepare the Report and the underlying internal control system;
- Inspection and sample testing of the systems and process documentation for collection, analysis and aggregation of the selected data;
- Recalculation of the aggregation and KPIs calculation for selected data;
- Analytical procedures on selected data;
- Inspection of documents regarding the description of the SRI six step methodology (SRI V2) and its application to MRI as detailed in 'Magnetic resonance Equipment (MRI) - Study on the potential for environmental improvement by the aspect of energy efficiency' and 'Magnetic Resonance – Measurement of energy consumption'.

PwC concluded that:

"Based on our limited assurance engagement, nothing has come to our attention that causes us to believe that the preparation process for the data in the SRI Status Report 2011 marked with the logo ✓ has not been, in all material respects, in accordance with the above mentioned SRI six step methodology."

The full Independent Assurance Report issued is provided as a separate document and is available for download on the COCIR public website, at the "Greening at COCIR" section.

APPENDIX

1. ULTRASOUND IMAGING EQUIPMENT

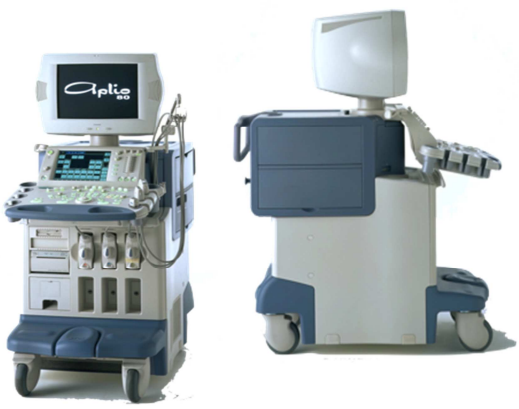
1.1. Case studies: Ecodesign applied to US equipment

Case Study 1: New Design of XarioXG

In November 2007, a manufacturer introduced the new design XarioXG SSA-680A to replace the existing Aplio SSA-770A. In comparison, the new design XarioXG has achieved significant reductions in life cycle environmental impacts including:

- 31% reduction in product volume and 25% reduction in product weight. This was achieved through improved structural design techniques and large-scale field programmable gate arrays (FPGA),
- Energy consumption reduced by 33% by using high-speed CPU to achieve large reductions in start-up times,
- Elimination of PVC-cover.

Figure 10: Previous design Aplio SSA-770A replaced by new design XarioXG in November 2007



Old design Aplio SSA-770A

New design AplioMX SSA-780A introduced October 2009

Case Study 2: Innovative electronic and mechanical miniaturization technology used in CX50

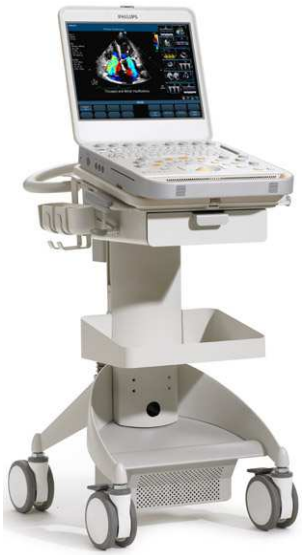
The new CX50 introduced October 2008 has nearly the same cardiology performance and functionality to its predecessor, the HD11 XE, but instead uses innovative electronic and mechanical miniaturization technology for lighter weight and lower power consumption. The HD11 XE is a cart-based system where all the electronics are integrated into a mobile cart. In contrast, the CX50 is a compact, cart-less system similar to a laptop computer. A separate cart is available as a customer option, which can be used to support the CX50 as well as any associated peripherals such as printers.

In addition to significant weight reductions where a customer decides to use the CX50 without a cart, the CX50 also delivers the following considerable reductions in environmental impact:

- Energy consumption in use phase reduced by 31%,
- Packaging weight reduced by 10%.

Figure 11: Previous design HD11 XE and new design CX50 introduced October 2008

Predecessor design HD11 XE



New design CX50 introduced October 2008

Case Study 3: Moving to a flat panel LCD for the new HD7

The HD7 was introduced in March 2008 using a 15-inch flat monitor (LCD) instead of a bulky CRT monitor used by the predecessor product EnVisor 2450. Except for this difference in displays, the HD7 is virtually similar in performance, functionality and applications to the EnVisor 2450. As a result of moving to a flat panel LCD, the HD7 has achieved the following reductions in environmental impact:

- Overall product weight reduced by 16%,
- Packaging weight reduced by 9%.

Figure 12: Previous design EnVisor 2540 and new design HD7 introduced March 2008

Predecessor design EnVisor 2540

New design HD7 introduced March 2008

1.2. Review against Annex 1.3 of Ecodesign Directive

In addition to Step 3, based on LCA considerations, the Ecodesign SC used the environmental parameters listed in Annex 1.3 of the EuP Directive to evaluate the potential for improving the environmental aspects of ultrasound products. This assessment confirms that the most significant environmental aspects for ultrasound equipment are:

- Energy consumption during the use phase
- Materials procurement

Environmental criteria	Assessment of ultrasound equipment against environmental criteria
(a) weight and volume of the product	Life Cycle Assessment data indicates that materials procurement accounts for about 12% of the life cycle environmental impact of ultrasound equipment.
(b) use of materials issued from recycling activities	The WEEE Directive[36] is increasing the recycling of waste equipment at end-of-life which in turn is influencing product design for ease of reuse and recycling, incorporation of used components and use of materials from recycling activities. In 2007 COCIR published Guidelines on Good Refurbishment Practice for Medical Electrical Equipment to ensure that used medical equipment is safely and reliably returned to active service. In 2009 COCIR strengthened the adoption of good refurbishment practices by publishing the Guidelines as an Industry Standard.
(c) consumption of energy, water and other resources throughout the life cycle	Life Cycle Assessment data indicates that energy consumption during use accounts for about 83% of the life cycle environmental impact of ultrasound equipment.
(d) use of substances classified as hazardous to health and/or the environment according to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packing and labelling of dangerous	The RoHS Directive[37] and REACH Regulation[38] are reducing the use of hazardous substances in new product designs. In preparation for this, COCIR companies have already established programs to reduce the amount of hazardous substances, when technologically and economically feasible.

[36] *Directive 2002/96/EC on Waste Electrical and Electronic Equipment*

[37] *Directive 2002/95/EC on the Restriction of the Use of Hazardous Substances in Electrical and Electronic Equipment*

[38] *Regulation 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals*

substances (I) and taking into account legislation on the marketing and use of specific substances, such as Directives 76/769/EEC or 2002/95/EC;	In 2008, COCIR launched the BOMcheck substances declarations web database for REACH, RoHS, Batteries and Packaging compliance. This centralized open-access database provides a cost-effective approach for manufacturers to work with their suppliers to reduce hazardous substances in products. The system improves the quality and availability of substance information across the supply chain and this enables manufacturers to reduce the environmental aspects of new product designs.
(e) quantity and nature of consumables needed for proper use and maintenance;	Life Cycle Assessment data indicates that the environmental impact of consumables used for use and maintenance of ultrasound equipment is negligible compared to other more significant aspects.
(f) ease for reuse and recycling as expressed through: number of materials and components used, use of standard components, time necessary for disassembly, complexity of tools necessary for disassembly, use of component and material coding standards for the identification of components and materials suitable for reuse and recycling (including marking of plastic parts in accordance with ISO standards), use of easily recyclable materials. easy access to valuable and other recyclable components and materials; easy access to components and materials containing hazardous substances;	The WEEE Directive is increasing the recycling of waste equipment at end-of-life which in turn is influencing product design for ease of reuse and recycling, incorporation of used components and use of materials from recycling activities. In 2007 COCIR published Guidelines on Good Refurbishment Practice for Medical Electrical Equipment to ensure that used medical equipment is safely and reliably returned to active service. In 2009 COCIR strengthened the adoption of good refurbishment practices by publishing the Guidelines as an Industry Standard.
(g) incorporation of used components;	The WEEE Directive is increasing the recycling of waste equipment at end-of-life which in turn is influencing product design for ease of reuse and recycling, incorporation of used components and use of materials from recycling activities. In 2007 COCIR published Guidelines on Good Refurbishment Practice for Medical Electrical Equipment to ensure that used medical equipment is safely and reliably returned to active service. In 2009 COCIR strengthened the adoption of good refurbishment practices by publishing the Guidelines as an Industry Standard.

(h) avoidance of technical solutions detrimental to reuse and recycling of components and whole appliances	The WEEE Directive is increasing the recycling of waste equipment at end-of-life which in turn is influencing product design for ease of reuse and recycling, incorporation of used components and use of materials from recycling activities. In 2007 COCIR published Guidelines on Good Refurbishment Practice for Medical Electrical Equipment to ensure that used medical equipment is safely and reliably returned to active service. In 2009 COCIR strengthened the adoption of good refurbishment practices by publishing the Guidelines as an Industry Standard.
(i) extension of lifetime as expressed through: minimum guaranteed lifetime, minimum time for availability of spare parts, modularity, upgradeability, reparability	In 2007 COCIR published Guidelines on Good Refurbishment Practice for Medical Electrical Equipment to ensure that used medical equipment is safely and reliably returned to active service. In 2009 COCIR strengthened the adoption of good refurbishment practices by publishing the Guidelines as an Industry Standard.
(j) amounts of waste generated and amounts of hazardous waste generated	Ultrasound equipment does not generate significant volumes of hazardous or non-hazardous waste during its working life. Recycling of waste equipment at end of life is already addressed under the WEEE Directive. In preparation for the RoHS Directive and REACH Regulation COCIR companies have already established programs to reduce the amount of hazardous substances, when technologically and economically feasible.
(k) emissions to air (greenhouse gases, acidifying agents, volatile organic compounds, ozone depleting substances, persistent organic pollutants, heavy metals, fine particulate and suspended particulate matter) without prejudice to Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery	Ultrasound equipment does not generate emissions to air during its working life.

(l) emissions to water (heavy metals, substances with an adverse effect on the oxygen balance, persistent organic pollutants)	Ultrasound equipment does not generate emissions to water during its working life.
(m) emissions to soil (especially leakage and spills of dangerous substances during the use phase of the product, and the potential for leaching upon its disposal as waste)	Ultrasound equipment does not generate emissions to soil during its working life.

2. MAGNETIC RESONANCE IMAGING EQUIPMENT

2.1. Review against Annex 1.3 of Ecodesign Directive

Annex 1.3 of the Ecodesign Directive lists parameters that have to be taken into consideration for evaluating the potential for improvement of environmental aspects.
In addition to Step 3, based on LCA data provided by companies, the Ecodesign SC used the environmental parameters listed in Annex 1.3 of the EuP Directive to evaluate the potential for improving the environmental aspects of ultrasound products.

Environmental parameters	Assessment of MRI equipment against environmental criteria
(n) weight and volume of the product	Life Cycle Assessment data indicates that materials procurement accounts for about 20% of the life cycle environmental impact of MRI equipment.
(o) use of materials issued from recycling activities	The WEEE Directive[39] is increasing the recycling of waste equipment at end-of-life which in turn is influencing product design for ease of reuse and recycling, incorporation of used components and use of materials from recycling activities. In 2007 COCIR published Guidelines on Good Refurbishment Practice for Medical Electrical Equipment to ensure that used medical equipment is safely and reliably returned to active service. In 2009 COCIR strengthened the adoption of good refurbishment practices by publishing the Guidelines as an Industry Standard.
(p) consumption of energy, water and other resources throughout the life cycle	Life Cycle Assessment data indicates that energy consumption during use accounts for about 75% of the life cycle environmental impact of MRI equipment.
(q) use of substances classified as hazardous to health and/or the environment according to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packing and labelling of dangerous substances (I) and taking into account	The RoHS Directive[40] and REACH Regulation[41] are reducing the use of hazardous substances in new product designs. In preparation for this, COCIR companies have already established programs to reduce the amount of hazardous substances, when technologically and economically feasible. In 2008, COCIR launched the BOMcheck

[39] Directive 2002/96/EC on Waste Electrical and Electronic Equipment

[40] Directive 2002/95/EC on the Restriction of the Use of Hazardous Substances in Electrical and Electronic Equipment

[41] Regulation 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals

legislation on the marketing and use of specific substances, such as Directives 76/769/EEC or 2002/95/EC;	substances declarations web database for REACH, RoHS, Batteries and Packaging compliance. This centralized open-access database provides a cost-effective approach for manufacturers to work with their suppliers to reduce hazardous substances in products. The system improves the quality and availability of substance information across the supply chain and this enables manufacturers to reduce the environmental aspects of new product designs.
(r) quantity and nature of consumables needed for proper use and maintenance;	Life Cycle Assessment data indicates that the environmental impact of consumables used for use and maintenance of MRI equipment is negligible compared to other more significant aspects.
(s) ease for reuse and recycling as expressed through: number of materials and components used, use of standard components, time necessary for disassembly, complexity of tools necessary for disassembly, use of component and material coding standards for the identification of components and materials suitable for reuse and recycling (including marking of plastic parts in accordance with ISO standards), use of easily recyclable materials. easy access to valuable and other recyclable components and materials; easy access to components and materials containing hazardous substances;	The WEEE Directive is increasing the recycling of waste equipment at end-of-life which in turn is influencing product design for ease of reuse and recycling, incorporation of used components and use of materials from recycling activities. In 2007 COCIR published Guidelines on Good Refurbishment Practice for Medical Electrical Equipment to ensure that used medical equipment is safely and reliably returned to active service. In 2009 COCIR strengthened the adoption of good refurbishment practices by publishing the Guidelines as an Industry Standard.
(t) incorporation of used components;	The WEEE Directive is increasing the recycling of waste equipment at end-of-life which in turn is influencing product design for ease of reuse and recycling, incorporation of used components and use of materials from recycling activities. In 2007 COCIR published Guidelines on Good Refurbishment Practice for Medical Electrical Equipment to ensure that used medical equipment is safely and reliably returned to active service. In 2009 COCIR strengthened the adoption of good refurbishment practices by publishing the Guidelines as an Industry Standard.

(u) avoidance of technical solutions detrimental to reuse and recycling of components and whole appliances	The WEEE Directive is increasing the recycling of waste equipment at end-of-life which in turn is influencing product design for ease of reuse and recycling, incorporation of used components and use of materials from recycling activities. In 2007 COCIR published Guidelines on Good Refurbishment Practice for Medical Electrical Equipment to ensure that used medical equipment is safely and reliably returned to active service. In 2009 COCIR strengthened the adoption of good refurbishment practices by publishing the Guidelines as an Industry Standard.
(v) extension of lifetime as expressed through: minimum guaranteed lifetime, minimum time for availability of spare parts, modularity, upgradeability, reparability	In 2007 COCIR published Guidelines on Good Refurbishment Practice for Medical Electrical Equipment to ensure that used medical equipment is safely and reliably returned to active service. In 2009 COCIR strengthened the adoption of good refurbishment practices by publishing the Guidelines as an Industry Standard.
(w) amounts of waste generated and amounts of hazardous waste generated	MRI equipment does not generate significant volumes of hazardous or non-hazardous waste during its working life. Recycling of waste equipment at end of life is already addressed under the WEEE Directive. In preparation for the RoHS Directive and REACH Regulation COCIR companies have already established programs to reduce the amount of hazardous substances, when technologically and economically feasible.
(x) emissions to air (greenhouse gases, acidifying agents, volatile organic compounds, ozone depleting substances, persistent organic pollutants, heavy metals, fine particulate and suspended particulate matter) without prejudice to Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery	MRI equipment does not generate emissions to air during its working life.

(y) emissions to water (heavy metals, substances with an adverse effect on the oxygen balance, persistent organic pollutants)	MRI equipment does not generate emissions to water during its working life.
(z) emissions to soil (especially leakage and spills of dangerous substances during the use phase of the product, and the potential for leaching upon its disposal as waste)	MRI equipment does not generate emissions to soil during its working life.

3. EPD - ENVIRONMENTAL PRODUCT DECLARATION

The format developed by participating companies enables the individual member companies to systematically use the Environmental Product Declaration to communicate the most significant aspect(s) that the SRI sets for each targeted modality. Additional information on the EPD are available in the SRIv2, appendix 5.

MINIMUM EPD REQUIREMENT including SRI targets and aspects ***Proper definition of "Product" and use phase need to be established***		
SRI CONTENT - mandatory		
SRI	**"Product xxx is part of the SRI Ecodesign Initiative for Medical Equipment to reduce the total energy consumption of units sold by xx % until Year xxxx."**	
	Energy use according to specific scenarios and operating conditions	kWh[42]
Strongly recommended:		
	Energy related	**Unit**
	CO_2 footprint in use phase according to specific scenarios and operating conditions	kg
	Environmentally relevant content/weight information	**Unit**
	Product	
	Weight of product	kg
	Type and number of batteries	list
	Relevant materials content - e.g. list RoHS, REACH SVHC, BoMcheck…	list
	Packaging	
	Weight	kg
	composition	list
	recyclable material content	%
	Additional Ecologically relevant information	**Unit**
	End of life aspects	
	refurbishing program available for the system	yes/no
	re-use of components program available for the system components	yes/no
	cleaning disinfection needed yes/no, if yes which chemicals	yes/no
	Information for user and recyclers (includes WEEE recycling passport info)	describe
Optional		
	Energy related	**Unit**
	Patient throughput for standard operation or energy per analysis	pat/day
	Waste during normal use (hazardous /non-hazardous/predefined categories?)	kg
	Emissions during normal use (hazardous /non-hazardous?)	kg
	Additional Ecologically relevant information	Unit

[42] This unit depends on the targeted environmental aspect. In this case it is "energy use " and thus "kWh". It might also be a material, e.g. "copper" and thus "kg".

	heat dissipation output - operating, stand-by, cooling,	kWh
	start up time	min
	Additional relevant information	Unit
	Power and material saving options (e.g. to previous product)	describe
	Additional End of Life aspects	
	material recycling possibilities, Cradle to Cradle	describe
	ease of dismantling	describe
	Life cycle impact - company specific -	
	% impact per LCA phase (e.g.10% materials, 80% use; specify LCIA method)	%/ describe
	Noise, radiation, vibration, EMC	dB(A)
	Other Health and Safety related information	Unit
	voluntary actions (product and/ or company specific)	describe
	CSR related	describe
	Environmental education	describe

4. GLOSSARY OF TERMS

The Glossary of terms is available at the COCIR website www.cocir.org at the "Greening at COCIR" section.

[Translator's notes are in square brackets]

General Engagement Terms
for
Wirtschaftsprüfer and Wirtschaftsprüfungsgesellschaften
[German Public Auditors and Public Audit Firms]
as of January 1, 2002

This is an English translation of the German text, which is the sole authoritative version

1. Scope

(1) These engagement terms are applicable to contracts between Wirtschaftsprüfer [German Public Auditors] or Wirtschaftsprüfungsgesellschaften [German Public Audit Firms] (hereinafter collectively referred to as the "Wirtschaftsprüfer") and their clients for audits, consulting and other engagements to the extent that something else has not been expressly agreed to in writing or is not compulsory due to legal requirements.

(2) If, in an individual case, as an exception contractual relations have also been established between the Wirtschaftsprüfer and persons other than the client, the provisions of No. 9 below also apply to such third parties.

2. Scope and performance of the engagement

(1) Subject of the Wirtschaftsprüfer's engagement is the performance of agreed services – not a particular economic result. The engagement is performed in accordance with the Grundsätze ordnungsmäßiger Berufsausübung [Standards of Proper Professional Conduct]. The Wirtschaftsprüfer is entitled to use qualified persons to conduct the engagement.

(2) The application of foreign law requires – except for financial attestation engagements – an express written agreement.

(3) The engagement does not extend – to the extent it is not directed thereto – to an examination of the issue of whether the requirements of tax law or special regulations, such as, for example, laws on price controls, laws limiting competition and Bewirtschaftungsrecht [laws controlling certain aspects of specific business operations] were observed; the same applies to the determination as to whether subsidies, allowances or other benefits may be claimed. The performance of an engagement encompasses auditing procedures aimed at the detection of the defalcation of books and records and other irregularities only if during the conduct of audits grounds therefor arise or if this has been expressly agreed to in writing.

(4) If the legal position changes subsequent to the issuance of the final professional statement, the Wirtschaftsprüfer is not obliged to inform the client of changes or any consequences resulting therefrom.

3. The client's duty to inform

(1) The client must ensure that the Wirtschaftsprüfer – even without his special request – is provided, on a timely basis, with all supporting documents and records required for and is informed of all events and circumstances which may be significant to the performance of the engagement. This also applies to those supporting documents and records, events and circumstances which first become known during the Wirtschaftsprüfer's work.

(2) Upon the Wirtschaftsprüfer's request, the client must confirm in a written statement drafted by the Wirtschaftsprüfer that the supporting documents and records and the information and explanations provided are complete.

4. Ensuring independence

The client guarantees to refrain from everything which may endanger the independence of the Wirtschaftsprüfer's staff. This particularly applies to offers of employment and offers to undertake engagements on one's own account.

5. Reporting and verbal information

If the Wirtschaftsprüfer is required to present the results of his work in writing, only that written presentation is authoritative. For audit engagements the long-form report should be submitted in writing to the extent that nothing else has been agreed to. Verbal statements and information provided by the Wirtschaftsprüfer's staff beyond the engagement agreed to are never binding.

6. Protection of the Wirtschaftsprüfer's intellectual property

The client guarantees that expert opinions, organizational charts, drafts, sketches, schedules and calculations – expecially quantity and cost computations – prepared by the Wirtschaftsprüfer within the scope of the engagement will be used only for his own purposes.

7. Transmission of the Wirtschaftsprüfer's professional statement

(1) The transmission of a Wirtschaftsprüfer's professional statements (long-form reports, expert opinions and the like) to a third party requires the Wirtschaftsprüfer's written consent to the extent that the permission to transmit to a certain third party does not result from the engagement terms.

The Wirtschaftsprüfer is liable (within the limits of No. 9) towards third parties only if the prerequisites of the first sentence are given.

(2) The use of the Wirtschaftsprüfer's professional statements for promotional purposes is not permitted; an infringement entitles the Wirtschaftsprüfer to immediately cancel all engagements not yet conducted for the client.

8. Correction of deficiencies

(1) Where there are deficiencies, the client is entitled to subsequent fulfillment [of the contract]. The client may demand a reduction in fees or the cancellation of the contract only for the failure to subsequently fulfill [the contract]; if the engagement was awarded by a person carrying on a commercial business as part of that commercial business, a government-owned legal person under public law or a special government-owned fund under public law, the client may demand the cancellation of the contract only if the services rendered are of no interest to him due to the failure to subsequently fulfill [the contract]. No. 9 applies to the extent that claims for damages exist beyond this.

(2) The client must assert his claim for the correction of deficiencies in writing without delay. Claims pursuant to the first paragraph not arising from an intentional tort cease to be enforceable one year after the commencement of the statutory time limit for enforcement.

(3) Obvious deficiencies, such as typing and arithmetical errors and formelle Mängel [deficiencies associated with technicalities] contained in a Wirtschaftsprüfer's professional statements (long-form reports, expert opinions and the like) may be corrected – and also be applicable versus third parties – by the Wirtschaftsprüfer at any time. Errors which may call into question the conclusions contained in the Wirtschaftsprüfer's professional statements entitle the Wirtschaftsprüfer to withdraw – also versus third parties – such statements. In the cases noted the Wirtschaftsprüfer should first hear the client, if possible.

9. Liability

(1) The liability limitation of § ["Article"] 323 (2)["paragraph 2"] HGB ["Handelsgesetzbuch": German Commercial Code] applies to statutory audits required by law.

(2) Liability for negligence; An individual case of damages

If neither No. 1 is applicable nor a regulation exists in an individual case, pursuant to § 54a (1) no. 2 WPO ["Wirtschaftsprüferordnung": Law regulating the Profession of Wirtschaftsprüfer] the liability of the Wirtschaftsprüfer for claims of compensatory damages of any kind – except for damages resulting from injury to life, body or health – for an individual case of damages resulting from negligence is limited to € 4 million; this also applies if liability to a person other than the client should be established. An individual case of damages also exists in relation to a uniform damage arising from a number of breaches of duty. The individual case of damages encompasses all consequences from a breach of duty without taking into account whether the damages occurred in one year or in a number of successive years. In this case multiple acts or omissions of acts based on a similar source of error or on a source of error of an equivalent nature are deemed to be a uniform breach of duty if the matters in question are legally or economically connected to one another. In this event the claim against the Wirtschaftsprüfer is limited to € 5 million. The limitation to the fivefold of the minimum amount insured does not apply to compulsory audits required by law.

(3) Preclusive deadlines

A compensatory damages claim may only be lodged within a preclusive deadline of one year of the rightful claimant having become aware of the damage and of the event giving rise to the claim – at the very latest, however, within 5 years subsequent to the event giving rise to the claim. The claim expires if legal action is not taken within a six month deadline subsequent to the written refusal of acceptance of the indemnity and the client was informed of this consequence.

The right to assert the bar of the preclusive deadline remains unaffected. Sentences 1 to 3 also apply to legally required audits with statutory liability limits.

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10. Supplementary provisions for audit engagements

(1) A subsequent amendment or abridgernent of the financial statements or management report audited by a Wirtschaftsprüfer and accompanied by an auditor's report requires the written consent of the Wirtschaftsprüfer even if these documents are not published. If the Wirtschaftsprüfer has not issued an auditor's report, a reference to the audit conducted by the Wirtschaftsprüfer in the management report or elsewhere specified for the general public is permitted only with the Wirtschaftsprüfer's written consent and using the wording authorized by him.

(2) If the Wirtschaftsprüfer revokes the auditor's report, it may no longer be used. If the client has already made use of the auditor's report, he must announce its revocation upon the Wirtschaftsprüfer's request.

(3) The client has a right to 5 copies of the long-form report. Additional copies will be charged for separately.

11. Supplementary provisions for assistance with tax matters

(1) When advising on an individual tax issue as well as when furnishing continuous tax advice, the Wirtschaftsprüfer is entitled to assume that the facts provided by the client – especially numerical disclosures – are correct and complete; this also applies to bookkeeping engagements. Nevertheless, he is obliged to inform the client of any errors he has discovered.

(2) The tax consulting engagement does not encompass procedures required to meet deadlines, unless the Wirtschaftsprüfer has explicitly accepted the engagement for this. In this event the client must provide the Wirtschafts-prüfer, on a timely basis, all supporting documents and records – especially tax assessments – material to meeting the deadlines, so that the Wirtschafts-prüfer has an appropriate time period available to work therewith.

(3) In the absence of other written agreements, continuous tax advice encompasses the following work during the contract period:

a) preparation of annual tax returns for income tax, corporation tax and business tax, as well as net worth tax returns on the basis of the annual financial statements and other schedules and evidence required for tax purposes to be submitted by the client

b) examination of tax assessments in relation to the taxes mentioned in (a)

c) negotiations with tax authorities in connection with the returns and assessments mentioned in (a) and (b)

d) participation in tax audits and evaluation of the results of tax audits with respect to the taxes mentioned in (a)

e) participation in Einspruchs- und Beschwerdeverfahren [appeals and complaint procedures] with respect to the taxes mentioned in (a).

In the afore-mentioned work the Wirtschaftsprüfer takes material published legal decisions and administrative interpretations into account.

(4) If the Wirtschaftsprüfer receives a fixed fee for continuous tax advice, in the absence of other written agreements the work mentioned under paragraph 3 (d) and (e) will be charged separately.

(5) Services with respect to special individual issues for income tax, corporate tax, business tax, valuation procedures for property and net worth taxation, and net worth tax as well as all issues in relation to sales tax, wages tax, other taxes and dues require a special engagement. This also applies to:

a) the treatment of nonrecurring tax matters, e. g. in the field of estate tax, capital transactions tax, real estate acquisition tax

b) participation and representation in proceedings before tax and administrative courts and in criminal proceedings with respect to taxes, and

c) the granting of advice and work with respect to expert opinions in connection with conversions of legal form, mergers, capital increases and reductions, financial reorganizations, admission and retirement of partners or shareholders, sale of a business, liquidations and the like.

(6) To the extent that the annual sales tax return is accepted as additional work, this does not include the review of any special accounting prerequisities nor of the issue as to whether all potential legal sales tax reductions have been claimed. No guarantee is assumed for the completeness of the supporting documents and records to validate the deduction of the input tax credit.

12. Confidentiality towards third parties and data security

(1) Pursuant to the law the Wirtschaftsprüfer is obliged to treat all facts that he comes to know in connection with his work as confidential, irrespective of whether these concern the client himself or his business associations, unless the client releases him from this obligation.

(2) The Wirtschaftsprüfer may only release long-form reports, expert opinions and other written statements on the results of his work to third parties with the consent of his client.

(3) The Wirtschaftsprüfer is entitled – within the purposes stipulated by the client – to process personal data entrusted to him or allow them to be processed by third parties.

13. Default of acceptance and lack of cooperation on the part of the client

If the client defaults in accepting the services offered by the Wirtschaftsprüfer or if the client does not provide the assistance incumbent on him pursuant to No. 3 or otherwise, the Wirtschaftsprüfer is entitled to cancel the contract immediately. The Wirtschaftsprüfer's right to compensation for additional expenses as well as for damages caused by the default or the lack of assistance is not affected, even if the Wirtschaftsprüfer does not exercise his right to cancel.

14. Remuneration

(1) In addition to his claims for fees or remuneration, the Wirtschaftsprüfer is entitled to reimbursement of his outlays: sales tax will be billed separately. He may claim appropriate advances for remuneration and reimbursement of outlays and make the rendering of his services dependent upon the complete satisfaction of his claims. Multiple clients awarding engagements are jointly and severally liable.

(2) Any set off against the Wirtschaftsprüfer's claims for remuneration and reimbursement of outlays is permitted only for undisputed claims or claims determined to be legally valid.

15. Retention and return of supporting documentation and records

(1) The Wirtschaftsprüfer retains, for ten years, the supporting documents and records in connection with the completion of the engagement – that had been provided to him and that he has prepared himself – as well as the correspondence with respect to the engagement.

(2) After the settlement of his claims arising from the engagement, the Wirtschaftsprüfer, upon the request of the client, must return all supporting documents and records obtained from him or for him by reason of his work on the engagement. This does not, however, apply to correspondence exchanged between the Wirtschaftsprüfer and his client and to any documents of which the client already has the original or a copy. The Wirtschaftsprüfer may prepare and retain copies or photocopies of supporting documents and records which he returns to the client.

16. Applicable law

Only German law applies to the engagement, its conduct and any claims arising therefrom.