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 2010

Engagement: 0.0603881.001

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 2010.

Responsibility for SRI Status Report 2010
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 ultrasound imaging equipment) and SRI V2 (for other 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 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 data for the year 2010 of the SRI Status Report 2010 marked with the logo ✓ have not been prepared, in all material respects, in accordance with the above mentioned SRI 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 2010 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 and approval of the SRI six step methodology (SRI V2).

Conclusion
Based on our limited assurance engagement, nothing has come to our attention that causes us to believe that the data in SRI Status Report 2010 marked with the logo ✓ have not been prepared, 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:

- 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
- Enhance the internal control system and improve documentation of underlying processes for data gathering at COCIR
- Develop 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, 29 July 2011

PricewaterhouseCoopers
Aktiengesellschaft
Wirtschaftsprüfungsgesellschaft

Michael Werner

Hendrik Fink

Wirtschaftsprüfer (German Public Auditor)

SELF-REGULATORY INITIATIVE
FOR
MEDICAL IMAGING EQUIPMENT

STATUS REPORT 2010

AUGUST 2011

Executive Summary

This Status Report, published annually by the Ecodesign Steering Committee Secretariat, presents information and results achieved by the Companies participating to the Self-Regulatory Initiative for Medical Imaging Equipment under the Ecodesign Directive (2009/125/CE).

This SRI Status Report 2010 consists of 6 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), amended in 2010 according to the comments received by stakeholders and to the lessons learnt with the practical implementation of the pilot on ultrasound imaging equipment started in 2009.

Part 2 lists the latest sections added to the SRIv2 and the initiatives of the Steering Committee in 2010.

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 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 offers an overview of the on-going application of the methodology to Magnetic Resonance Imaging equipment that have been identified as priority one for their environmental impact. Step 3 allowed to identify energy consumption during the use phase as the most relevant environmental aspect. The definition of functional units and typical use scenarios already developed by industry expert groups are presented in this report, while the definition of feasible and ambitious reduction targets is not yet completed and not presented.

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.

TABLE OF CONTENTS

1. GENERAL INTRODUCTION TO THE SRI FOR MEDICAL IMAGING EQUIPMENT 4
1.1. Self-Regulatory Initiative V1 4
1.2. The Ecodesign Consultation Forum 4
1.3. Lessons Learnt from the pilot ultrasound 5
1.4. New sections added to the generic methodology in 2010 6
1.5. The new methodology SRIv2 7
2. NEWS AND DEVELOPMENTS 2010 8
2.1. Verification of SRI methodology and priority list by third party consultancy 8
2.2. Active investigation on environmental impact of modalities on EU market 8
2.3. Methodology applied to MRI in 2010 8
2.4. Additional internal expert at COCIR to handle centrally SRI 8
2.5. External audit procedure developed and third party consultancy hired 8
3. THE SRIV2 METHODOLOGY 9
3.1. Scope 9
3.2. Step 1: Gather baseline data 10
3.3. Step 2: Prioritization and selection of next modality 10
3.4. Step 3: Identification of significant environmental aspect(s) for the selected modality 10
3.5. Step 4: Derive environmental targets and objectives for the selected modality 10
3.6. Step 5: Implementation into company processes 11
3.7. Step 6: Monitoring and reporting 11
4. ULTRASOUND IMAGING EQUIPMENT PILOT PROJECT 12
4.1. General Description of ultrasound equipment 12
4.2. Market coverage 13
4.3. SRIv1 Methodology for Ultrasound 13
4.4. COCIR Status Report on pilot ultrasound performance 16
4.5. Interpretation of annual sales and annual energy consumption 17
4.6. Achieving the pilot ultrasound energy reduction target
5. ANNUAL STATUS REPORT GENERIC METHODOLOGY 19
5.1. Gather baseline data for all modalities in scope (STEP 1) 19
5.2. Prioritization and selection of the next modality (STEP 2) 20
5.3. Identification of significant environmental aspect (STEP 3) 21
6. MAGNETIC RESONANCE IMAGING EQUIPMENT 22
6.1. General description of Magnetic Resonance equipment 22
6.2. Market coverage 22
6.3. Identification of significant environmental aspect for MRI 23
6.4. Derive environmental targets and objectives (STEP 4) 24
INDEPENTENT ASSURANCE REPORT 29
APPENDIX 31
1. ULTRASOUND IMAGING EQUIPMENT 31
1.1. Case studies: Ecodesign applied to US equipment 31
1.2. Review against Annex 1.3 of Ecodesign Directive 334
2. MAGNETIC RESONANCE IMAGING EQUIPMENT 378
2.1. Review against Annex 1.3 of Ecodesign Directive 378
3. EPD - ENVIRONMENTAL PRODUCT DECLARATION 42
4. GLOSSARY OF TERMS 43

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.*

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 European Commission (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 European Commission 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 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 Ecodesign Consultation Forum

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 States
- 3 representatives of EEA Member States
- 30 stakeholders

30 organizations representing all interested stakeholders (such as business federations, environmental protection groups, consumer organizations) were selected out of the numerous applicants to the call for applications launched by the Commission and closed on 31st March

2006. The group is open for observers from candidate and EFTA countries and from organizations which are not official members but have a legitimate interest in the discussion.

After the Consultation Forum Meeting in November 2009 the SRI Steering Committee went back to review the methodology and the pilot ultrasound on the basis of the received comments. Additional comments were received by mail from CF members after the meeting.

The main points were to:

- Include more quantitative data
- Add the stock figures in units
- Include company specific targets by modality
- Follow the MEEuP[3] methodology more closely
- Commit more systematically to use an Environmental Product Declaration (EPD)
- Establish ongoing procedure for targets beyond 2012
- Allow to refine the methodology over time, and
- Systematically indicate the sources of data.

1.3. Lessons Learnt from the pilot ultrasound

Furthermore, the SC reviewed the pilot for difficulties that occurred in the implementation of the pilot methodology. An example was that there had been different assumptions on the EU countries to be included. This issue was due to the expansion of the European Union[4] within the scope of time in which data had been collected. The reported data has therefore been refined and validated by an established consultancy (PE International).

The experience gained from this pilot enabled the expert members of the Ecodesign Steering Committee to review the pilot methodology and approach. In the following are the main lessons learnt and how they are addressed in the new SRIv2 methodology.

- **Standard Operating procedures:** COCIR internal Standard Operating Procedures including responsibilities and timelines have been developed to ensure a systematic and accurate completion of the SRI procedure.
- **Modality selection:** the modality selection is now based on company internal Life Cycle Assessment data and the resulting impacts are weighted with the available sales units of each modality
- **Documented LCA**: applied Life Cycle Assessment Methodologies are documented and thus the scope of the aspects that are accounted for is explicitly integrated
- **Environmental aspect selection**: the environmental aspect to be targeted is selected through a ranking of the top three environmental aspects. This allows for separate risk

[3] The methodology developed by the EC to run the preparatory studies under the Ecodesign Directive.

[4] Difference in EU 25 versus EU 27 countries

assessments, a greater transparency on the impact of the top aspects and objective reasoning for the selection of the aspect with the highest impact.

- **LCA boundaries harmonized**: the boundaries of the modality will be fully harmonized since the industry will develop a common definition for each modality before targets are defined. This common definition includes all relevant consideration on the key parameters such as product features, use hours, typical applications, and patient throughput. This data is based on practice experience from each company and aims to allow accounting for a utility unit of the modality.
- **Target setting:** target setting is now based on a mix of target scenarios (Business as Usual, Best Available Technology and Best not yet Available Technology) and the front-runner approach to prove the ambition of the proposed target. The target proposed to the Consultation Forum will remain an industry goal to be achieved, however, each company will have its own target to achieve.
- **Innovation cycle**: The target will apply for the duration of one innovation cycle, depending on the typical innovation cycle of each modality. After the target is completed, the generic process will start over again.
- **Annual reporting:** The progress in reaching the target will be published annually to ensure the industry reaches its target and the Stakeholders to verify that the industry is acting according to their promises.
- **External verification:** a process for verification by a third independent party has been developed to ensure the accuracy of the reported data.
- **Non-compliance procedure**: an initial version of non-compliance procedure has been added.

1.4. New sections added to the generic methodology in 2010

During 2010 new sections have been developed and added to the methodology

1.4.1. Guidance to risk assessment

A risk assessment procedure has been developed to respond to Clause 8 of Annex VIII of the Ecodesign Directive 2009/125/EC, securing an integrated approach that protects equally the interests of consumers, healthcare, quality of life and economic interests.

This Risk Assessment assesses the impacts on future developments, which may be expected from the restriction of the respective top-ranked aspects, throughout all member companies, company sites, facilities, operations, and products. Therefore, this method provides a common approach across all member companies to evaluate and dedicate a measure of risks and significance for respective aspects, impacts, and obligations for innovations to ensure a truly sustainable development as defined in the Directive 2009/125/EC.

1.4.2. Non-compliance procedure developed

A procedure for non-compliance with defined targets has been developed and added. The procedure foresees different levels of action in case a participating company or the whole industry is not able to meet the targets. Sanctions are provided for companies not able to reach targets. They will not be allowed to show the SRI Ecodesign Label.
The future Ecodesign SRI Label will be the key element of the non-compliance procedure to ensure maximum efforts by all the participating companies in achieving the proposed targets.
The design and set-up of the Ecodesign SRI Labeling system, detailed rules and functioning scheme is part of the 2011 working plan.

1.4.3. Change procedure developed (for products and companies)

New procedures have been developed to allow new companies, whether already member of COCIR or not, to join the initiative and the scope to be extended to new product groups. New companies could join the Initiative any time but could not participate for modalities for which targets have been already set and are in the process of achieving them. That is necessary to grant data comparability.

1.4.4. Environmental Product Declaration

A common format for an environmental product declaration has been developed and added to the SRI v2 (see also Appendix 3 of this report). The EPD will be used by companies, on a voluntary basis, to show the environmental performance of their products and to allow greater transparency to all interested stakeholders.

1.5. The new methodology SRIv2

The result of the thorough analysis and review is the SRIv2 generic 6 steps methodology, which is applicable to all modalities in scope. With each of the generic six steps and the accordingly developed Standard Operating Procedure, as well as the establishment of a non-compliance procedure, a common approach on an Environmental Product Declaration (EPD) and the inclusion of an external third party review to ensure the accuracy of the reported data, the Steering Committee aimed to address all concerns.

Even before submitting the new SRIv2 to the European Commission and to the Consultation Forum, the SRI member companies have concurrently started to gather available LCA data, initiating the iterative process to select the next modality.

PART 2

2. NEWS AND DEVELOPMENTS 2010

During 2010 the Steering Committee worked in parallel on other aspects complementing the SRIv2 Methodology.

2.1. Verification of SRI methodology and priority list by third party consultancy

In July 2010 the Steering Committee hired an external independent consultant, PE International, specialized in sustainability to run a verification of the Ultrasound Pilot methodology and the SRIv2 six step methodology in particular regarding step 1 and 2.
The results of the review have been taken into account and the content of the SRIv2 modified accordingly.

2.2. Active investigation on environmental impact of modalities on EU market

The Steering Committee started in 2010 to apply the new methodology to investigate all the modalities in the scope. LCA data was gathered according to the methodology and processed to define a priority list. This report 2010 shows the results of Step 1 and 2 of the methodology and the priority list.
MRI – Magnetic Resonance Imaging Equipment has been identified as the first modality to be targeted for the reduction of environmental impact.

2.3. Methodology applied to MRI in 2010

Already in 2010, even if the methodology was not yet endorsed by the European Commission, the Steering Committee started the third step of the methodology to identify the most significant environmental aspect of MRI. Data showed that energy consumption is the most significant environmental aspect.

In the second half of 2010 an Expert Group on MRI was created to perform the fourth step of the methodology that will deliver staged reduction targets to be met in a 5 years cycle (innovation cycle for MRI equipment). At the date of publication of the present report, the work is still on-going.

2.4. Additional internal expert at COCIR to handle centrally SRI

In 2010 the Steering Committee decided to hire a new resource in the role of COCIR Environmental Affairs Manager to provide a full time central support to the Ecodesign SC Secretariat handling the SRI. The new Manager started his activity in COCIR on middle January 2011.

2.5. External audit procedure developed and third party consultancy hired

In 2010 the Steering Committee decided to hire an external audit firm (PriceWaterhouseCoopers) to review selected data in the annual SRI Status Report for 2010, 2011 and 2012, to ensure that the selected data has been aggregated and calculated by the SC Secretariat in accordance with guidance developed in the SRI V1 and V2. The contract with PriceWaterhouseCoopers was signed in February 2011. The review statement is added to the present report.

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 equipment (MRI)
- Computer tomography (CT)
- Nuclear medicine (NM)
- X-ray
- Ultrasound (US)

The table summarizes the companies participating in the SRI for Medical Imaging Equipment and the modalities marketed in EU.

	MRI	CT	NM	X-RAY	US
Agfa HealthCare				⌑	
Aloka					⌑
Elekta				⌑	
Fujifilm				⌑	
GE Healthcare	⌑	⌑	⌑	⌑	⌑
Hitachi Medical Systems Europe	⌑	⌑			⌑
IBA Ion Beam Applications			⌑		
Philips Healthcare	⌑	⌑	⌑	⌑	⌑
Samsung Medison Europe					⌑
Siemens Helthcare	⌑	⌑	⌑	⌑	⌑
Toshiba Medical Systems Europe	⌑	⌑		⌑	⌑

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

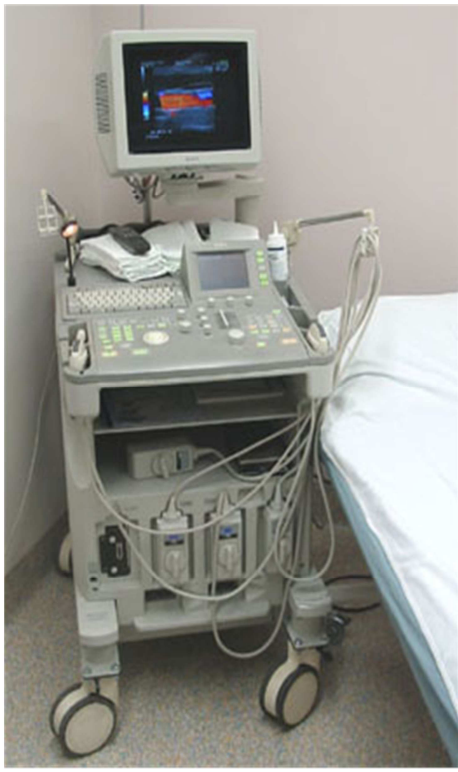


Figure 1: ultrasound equipment

resolution of the image and imaging depth. Superficial structures such as muscles, tendons, testes, breast and the neonatal brain are imaged 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.

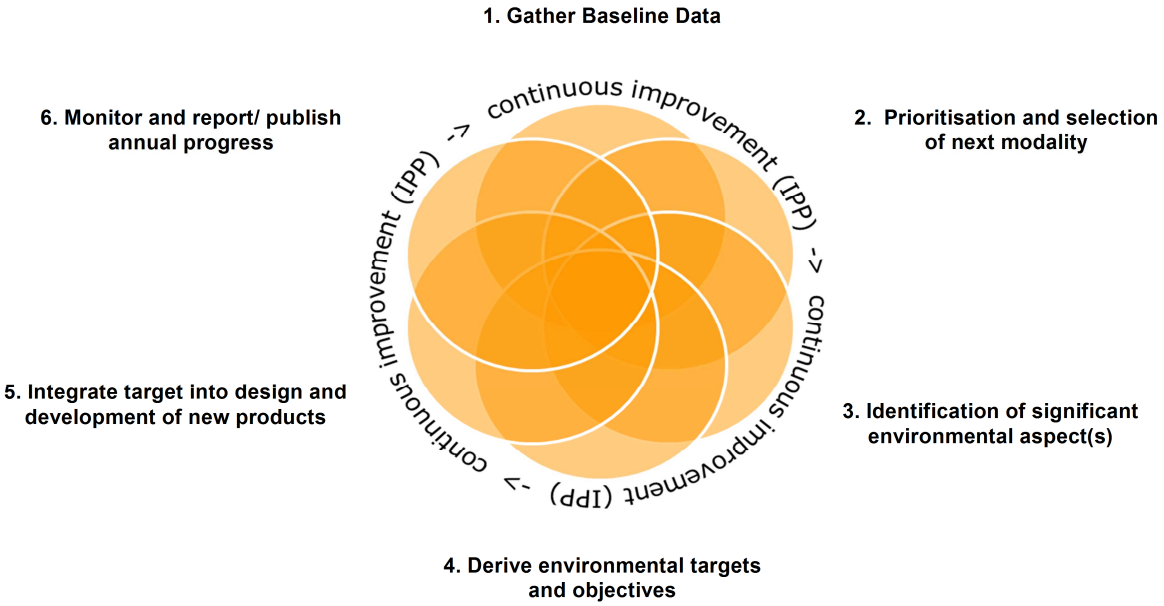
4.2. Market coverage

The ✓7 companies[5] participating in the ultrasound pilot project have a total turnover in Europe[6] in 2010 of ✓814[7] million euros. These companies cover 82%[8] of the European[6] market.

4.3. SRIv1 Methodology for Ultrasound

Participating companies developed a generic process to be followed for the pilot ultrasound. It is shown in Figure 2 below. A detailed description of each process phase is described in the SRIv1.

Figure 2: COCIR's generic process developed in 6 Steps of the Self-Regulatory initiative to secure continuous improvement of the product-related Ecodesign of their products



[5] *SRI Member : Aloka, GEHC, Hitachi, Samsung Medison, Philips, Siemens, Toshiba.*
[6] *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*
[7] *COCIR SHARE internal market statistics data base. Data are based on the fiscal year.*
[8] *Estimation provided by companies based on SHARE data*

4.3.1. Data gathering

Baseline data for 2005 and actual data for 2006, 2007, 2008, 2009 and 2010 have been collected with the spread sheet template presented in the SRIv2.
All participants provided confidential sales data and manufacturer's data about power consumption for each model of ultrasound equipment they place on the EU market for each reporting year (2005-2010) to the SC Secretariat. The SC Secretariat consolidated the individual company data for analysis.

4.3.2. Calculations of energy consumption

On the basis of the data gathered from participating companies, the SC secretariat calculates the energy consumptions for ultrasound products according to the use scenarios and criteria defined below.

Calculation of annual energy consumption of mains power units

For mains power units, the power consumption is provided in kW for the following modes:

- Scanning/ready to scan (system already booted up).
- Standby (need to boot up the system).
- Off/hibernation.

This data is used to calculate the total annual energy consumption for each mains power unit by assuming the following standard use scenario:

- 6 hours operation per day,
- 6 hours standby per day,
- 5 days usage per week, for 52 weeks per year.

This standard use scenario is in line with practical experience of how ultrasound units are typically used in hospitals in Europe.

Calculation of annual energy consumption of battery power units

The batteries used in ultrasound equipment are very similar to batteries used in a typical laptop computer. These batteries typically provide 2.5 hours of running time before they require to be recharged.

In practice, a battery power unit is most likely be trickle charged between uses, rather than being used until reaches a 100% discharged state before recharging. Over the course of a typical day (comprising 6 hours operation and 6 hours standby), this is equivalent to charging the battery from 100% discharged state three times.

Accordingly, member companies provided the energy consumption in kWh to charge the battery from a 100% discharged state. This data was used to calculate the total annual energy consumption by assuming that:

- The daily power consumption for a battery powered ultrasound unit is equivalent to charging the battery three times per day from 100% discharged state,
- 5 days usage per week, for 52 weeks per year.

4.3.3. Target setting

The industry Ecodesign SC has set a target to reduce 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 1, 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 22316[9] units, this is equivalent to a total energy saving of 2.610.972 kWh for 2012 compared to 2009. This is equivalent to 874 ton[10] of CO_2.

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)

[9] Estimated sales in 2012 to be equal to pre-crisis sales volume in 2008

[10] Conversion factor gCO2/kWh = 335. Average value for EOCD Europe in 2008. Source: CO2 Emissions from Fuel Combustion (2010 Edition), IEA, Paris.

4.4. COCIR Status Report on pilot ultrasound performance

The Ecodesign Steering Committee calculated the average annual energy consumption for new products put on the market for the years 2005 to 2010. 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 1, in 2010 SRI member companies successfully achieved a ✓79% target compared to the 2005 baseline exceeding the 83,5% target energy reduction for 2010. This result has been achieved thanks to the existing Ecodesign programmes and variations in the market mix of products (see analysis in the next chapter).

✓**Table 1:** 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		kWh		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	88,70%	808	87,8%		
2010	19030	111%	13.589.213	87,95%	**728**	**79,0%**	769	**83,5%**
2011							730	**79,2%**
2012							**691**	**75,0%**

4.5. Interpretation of annual sales and annual energy consumption

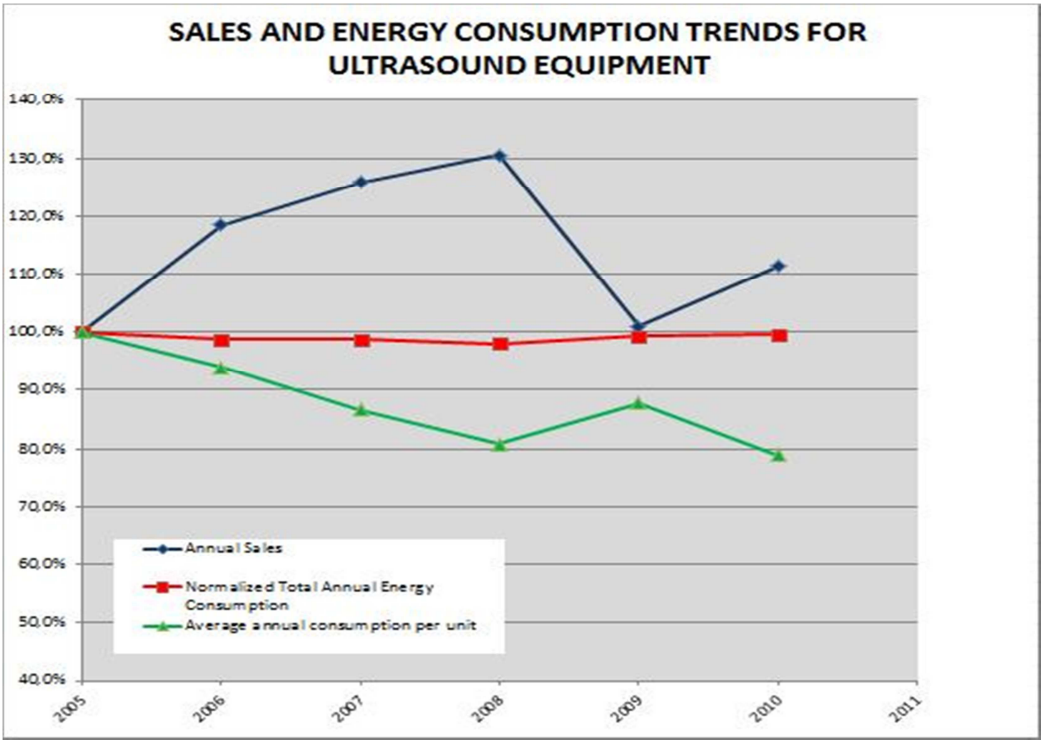
Table 1 provides consolidated data for total annual sales and total annual energy consumption of new ultrasound products that participating companies put on the market in EU Member States in 2005, 2006, 2007, 2008, 2009 and 2010.

✓Figure 3 compares the annual sales each year as a percentage of 2005 annual sales, with the normalized annual energy consumption[11] as a percentage of 2005 annual energy consumption. The average annual energy consumption for new products put on the market 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.
This change reflects 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 existing EcoDesign programmes.

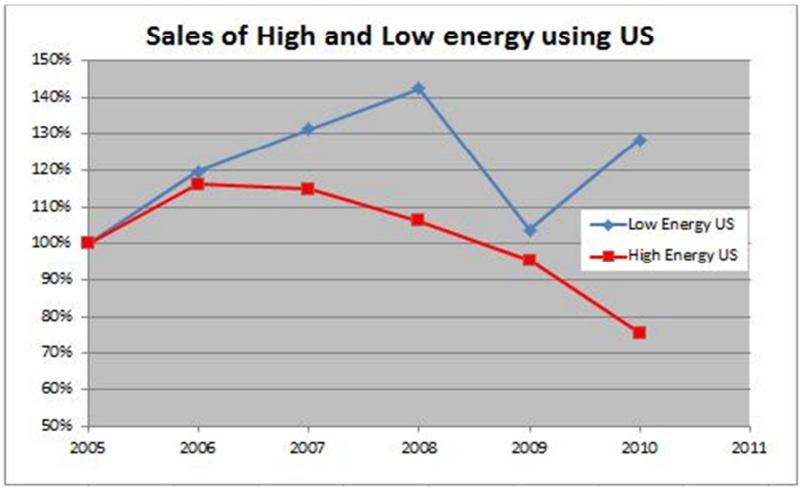
✓**Figure 3:** Annual sales and normalized annual energy consumption for new ultrasound products compared to 2005 baseline



[11] 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.

The increased market share of lower energy consumption laptop products and handheld products caused the overall energy consumption for all new products placed on the market to fall in 2006, 2007 and 2008. In 2009, however, the market for new laptop and handheld products fell down while the market for more energy demanding products maintained the same decreasing rate as shown in ✓figure 4.
In 2010 the demand for handheld and laptop products increased significantly while the demand for other products further decreased, thus allowing the average energy consumption per unit to decrease at ✓79% compared to 2005 baseline.

✓**Figure 4:** Sales of high energy using and low energy using ultrasound equipment compared to 2005 baseline



4.6. Achieving the pilot ultrasound energy reduction target and insurance of a continuous improvement

Once the pilot target of achieving additional ✓14,5% to existing EcoDesign programmes 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 2010 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. ANNUAL STATUS REPORT 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 10 SRI members (see 3.1 Scope) data has been delivered from the following companies[12]:

- 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

[12] 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[13] 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 2, that is used to select the next modalities is obtained averaging the two previously calculated rankings.

Table 2: 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 2, 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-2011 the group will focus on CT as the second modality and so forth, according to table 3.

Table 3: Timetable for targeting new modalities

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

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

5.3. Identification of significant environmental aspect (STEP 3)

This first status report "SRI Status Report 2010" covers only data on one modality according to the new methodology. MRI is the modality ranked first place with the highest environmental impact on the EU 27 market.

In future reports, the section will be expanded at least annually by a subsection for each modality in the order of the priority list. E.g. in the SRI Status Report 2011, this section will first include MRI, then CT and so forth.

Each specific modality subsection includes data on the top 3 environmental aspects collected from the individual companies. This data set also includes an internal expert risk assessment on the declared top ranked aspects.

The averages of the results from the single reported aspects to get a ranking of the overall top 3 environmental aspects are calculated by the SC Secretariat. This allows COCIR to identify the most significant aspect.

The offered risk assessments of the companies are used to get an insight on the reduction potential of the top aspects. It is also an opportunity for the industry experts to include their expectations on the impacts of a possible reduction of the respective aspect, in order not to hamper medical innovation. If there is no significant risk for the top aspect, it will be selected for the target setting in STEP 4.

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.

Figure 5: MRI equipment

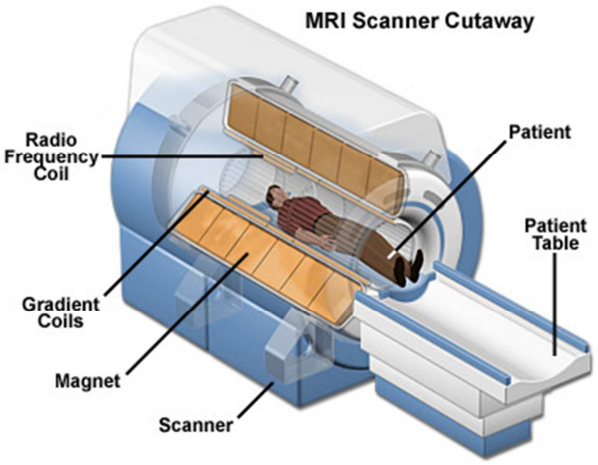
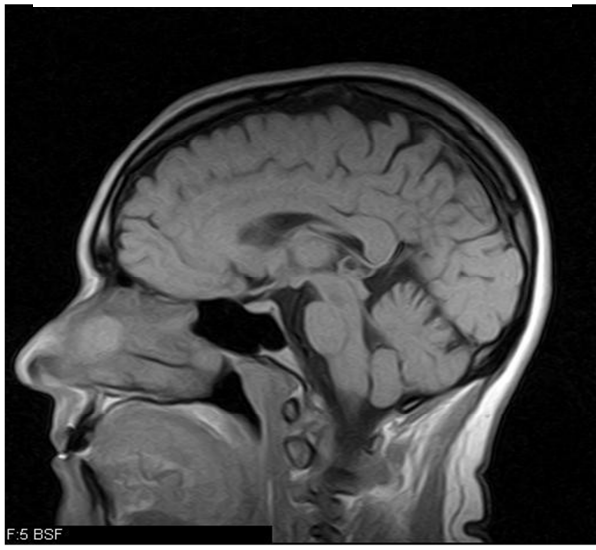


Figure 6: MRI head image



6.2. Market coverage

The ✓5 Companies[14] participating in the SRI for the MRI sector represent a total turnover in Europe[15] of ✓776[16] million euros in 2010 thus covering about 98%[17] of the European market.

[14] *GE Healthcare, Hitachi Medical Systems, Philips Healthcare, Siemens Healthcare, Toshiba Medical Systems*
[15] *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*
[16] *COCIR SHARE internal market statistics data base*
[17] *Estimation provided by COCIR companies based on SHARE data*

6.3. Identification of significant environmental aspect for MRI

Magnetic resonance Imaging equipment has been chosen by the Steering Committee as the first modality to be targeted in 2010 on the base of Step 1 and Step 2 of the methodology as shown in table 2.

According to Step 3 of the methodology as summarized in chapter 3.3, the data provided by Companies are used to rank the different environmental aspects. Table 4 shows that energy consumption during the product lifecycle use phase has been identified as the top environmental aspect.

Table 4: 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

The expert judgment provided by companies shows that there is potential for improvement in the energy consumption of MRI.

6.4. Derive environmental targets and objectives (STEP 4)

In 2010 and 2011, producers of the MRI modality have been meeting to define a common functional unit(s), product description and typical use scenario(s) to set a common ground on the identification of the impact values of the selected aspect. The expert group developed high, medium and low range definitions to reflect the complexity of the products and their respective purposes.

As the definitions are set, the companies will be asked to deliver the values according to the mutual target scenario. Furthermore, the company experts will individually provide feasibility data on the improvement forecast for the respective aspect for the next innovation cycle (successor product). Because of anti-competition laws these data will not be enclosed in the Report.

However, this data serves as the basis for the COCIR Secretariat to calculate the target setting scenarios (Business as usual (BAU), Best available technology (BAT), Best not yet available technology(BnyAT) and BeyondBAU).

In order to derive a target the following actions are needed to define the basis of measurement:

- Define the MRI equipment scope;
- Define product categorizations;
- Define the MRI use scenario based on clinical applications;
- Define the functional unit to be measured.

6.4.1. MRI Equipment Scope

The MRI product scope for the Self-Regulatory Initiative has been defined as follows:

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

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

Figure 7: Components and subsystem included or excluded from the scope of MRI

6.4.2. MRI Product Categorization

Member companies have 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 manipulation of a magnetic field, the power needed to manipulate the magnetic field increases exponentially as the diameter increases. Other features relevant to different image quality needs, such as number of data receive 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 (Table 5) that will be refined according to practical measurement.

Table 5: Initial MRI Equipment Categorization

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

Table 6: example of application of Table 5 to MRI equipment

2011 Data Product Model	Field Strength	points	Bore dia (cm)	points	Maximum Gradient Amplitude per Axis	points	Maximum Slew Rate per Axis	points	Patient Table	points	Channels	points	FOV	points	Final Score
A (example 1)	**1.5**	50	**65**	20	**35**	60	**125**	40	**fixed**	10	**32**	35	**50**	45	**260**
B (example 2)	**3**	100	**70**	30	**65**	80	**125**	40	**fixed**	10	**32**	35	**45**	35	**330**
C		100		10		40		20		20		15		25	**230**
D		100		10		40		20		20		15		25	**230**
E		100		10		40		20		20		15		25	**230**
F		100		10		40		20		20		15		25	**230**
G		100		10		40		20		20		15		25	**230**
H		100		10		40		20		20		15		25	**230**
I		100		10		40		20		20		15		25	**230**
J		100		10		40		20		20		15		25	**230**
K		100		10		40		20		20		15		25	**230**

6.4.3. MRI Use Scenario

To define a functional unit, the use scenario must first be defined. The use scenario includes applicable use modes, typical customer applications, and equipment capability. Use modes have been defined as shown in table 7.

To determine the time an MRI system remains in each mode, participants referenced confidential field usage records and an industry market report ("2007 MRI Market Summary Report", May 2008, © 2008 IMV Medical Information Division, Inc, www.imvinfo.com). Given the use mode definitions and typical use scenarios, and then inspecting various member company systems, the typical power usage allocation was determined.

Table 7: MRI Use Mode Definition.

Mode	Description	Typical time in mode per day (hours)	Estimate of % Energy over Life
Off mode	Lowest power state; requires interaction to make system ready; system circuit breakers on.	12	45
Standby mode	System on, ready to scan, gradient system quiescent.	7 (varies)*	30
Scanning mode	System is activating gradient system and capturing image data.	5 (varies)*	25

** Data for planning purposes only. It will be revised pending baseline performance measurements according to the procedure developed by member companies.*

To evaluate the energy consumed during scanning mode, the most commonly used examinations were determined based on the 2007 MRI Market Summary Report. This mix served as the "standard application mix" on which basis specific MRI protocols were defined and performed to measure for Scanning Mode. Members agreed to use the top 4, normalized to 100%, shown in Table 8.

Table 8: Scan Mode application mix*

Diagnostic Application	IMV © Market Distribution	Normalized Distribution
Spine	26%	33%
Brain	25%	31%
Lower and Upper extremities	20%	25%
Vascular	9%	11%

*This table is just preliminary work in progress. Final results may differ.

6.4.4. Functional Unit

Concerted work is ongoing to determine a functional unit. The functional unit will be the specific basis of the voluntary targets (e.g., litres per kilometer). To ensure openness to participation and competitive action, member companies agree the functional unit must:

- have a sufficient degree of competitive freedom;
- be practical to measure without undue resource burden;
- be independently verifiable;
- be comparable across products and manufacturers;
- address the significant environmental aspect.

6.4.5. Summary

Much progress has been made to define standards of measure for energy consumption of MRI products. The clinical applications, technical makeup and usage of MRI equipment is extremely complex. Member companies have agreed to MR equipment scope, use modes, and standardized clinical applications as shown in this Status Report. Although these dimensions may be altered as new information is brought forward, a solid basis has been formed. A determination of a functional unit that meets the needs of the Eco-Design for Energy-related Products directive can now be achieved.

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 2010.

Responsibility for SRI Status Report 2010
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 ultrasound imaging equipment) and SRI V2 (for other 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 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 data for the year 2010 of the SRI Status Report 2010 marked with the logo ✓ have not been prepared, in all material respects, in accordance with the above mentioned SRI 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 2010 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 and approval of the SRI six step methodology (SRI V2).

Conclusion

Based on our limited assurance engagement, nothing has come to our attention that causes us to believe that the data in SRI Status Report 2010 marked with the logo ✓ have not been prepared, 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:

- 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
- Enhance the internal control system and improve documentation of underlying processes for data gathering at COCIR
- Develop 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, 29 July 2011

PricewaterhouseCoopers
Aktiengesellschaft
Wirtschaftsprüfungsgesellschaft

Michael Werner

Hendrik Fink
Wirtschaftsprüfer (German Public Auditor)

APPENDIX

1. ULTRASOUND IMAGING EQUIPMENT

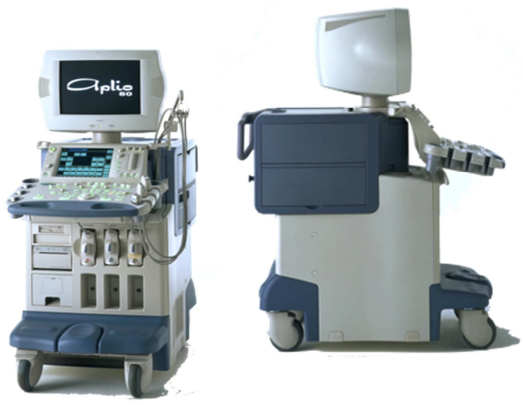
1.1. Case studies: Ecodesign applied to US equipment

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 8: 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

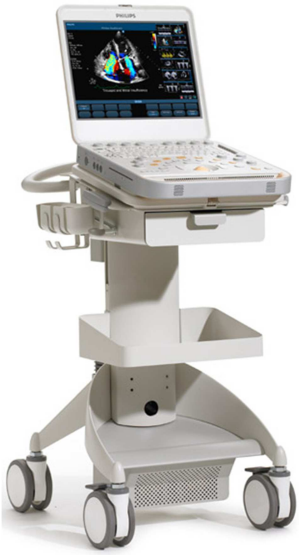
The new CX50 introduced October 2008 has nearly the same cardiology performance and functionality to its predecessor, the HD11 XE, but instead uses innovative electronic and mechanical miniaturization technology for lighter weight and lower power consumption. The HD11 XE is a cart-based system where 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 9: Previous design HD11 XE and new design CX50 introduced October 2008

Predecessor design HD11 XE



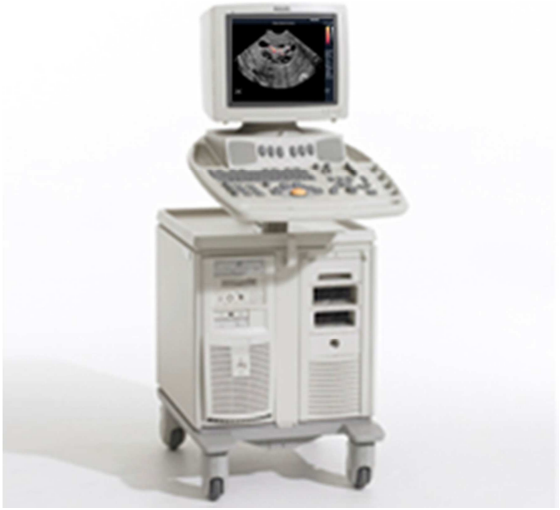
New design CX50 introduced October 2008

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

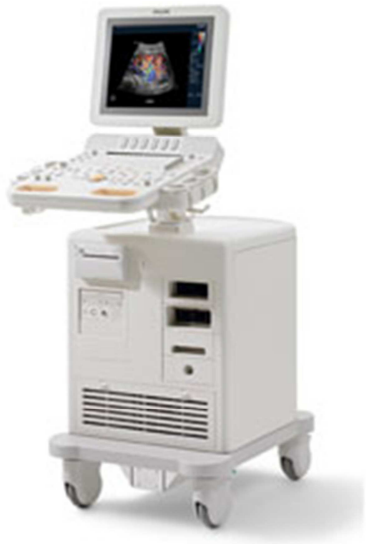
The HD7 was introduced in March 2008 using a 15-inch flat monitor (LCD) instead of a bulky CRT monitor used by the predecessor product EnVisor 2450. Except for this difference in displays, the HD7 is virtually similar in performance, functionality and applications to the EnVisor 2450. As a result of 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 10: 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[18] 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,	The RoHS Directive[19] and REACH Regulation[20] 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.

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

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

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

packing and labelling of dangerous 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[21] 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[22] and REACH Regulation[23] 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

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

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

[23] 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[24]
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

[24] 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".

Additional Ecologically relevant information	Unit
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.

52002 KND
1/2002

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.