Self-Regulatory Initiative
EcoDesign of Energy using Products
for Medical Imaging Equipment

19 October 2009

Executive Summary

COCIR believes in being proactive about EcoDesign in the medical device industry. COCIR was the first trade association to develop its own internationally-recognized standard for integrating EcoDesign into the product design and development process.

COCIR fully supports the EuP Directive aims and objectives and commits to proactively participate in the EuP Directive through this Self Regulatory Initiative. Medical devices are tightly regulated under the Medical Devices Directive to ensure that they achieve their primary function of improved patient healthcare. Indeed, the requirements in Annex VIII Clause 8 of the EuP Directive are directly relevant to medical devices, because this Clause specifically requires that Self-Regulatory Initiatives

> *"shall be consistent with the economic and social dimensions of sustainability. The **protection of consumers'** interests (**health, quality of life** and economic interests) **shall be integrated**."*

Nevertheless, COCIR companies believe that there are further opportunities to improve the environmentally conscious design of medical devices, while continuing to take advantage of new technologies for better and earlier diagnosis, more effective, successful patient treatment and completely new treatments.

COCIR, on behalf of its member companies, presented initial proposal for a Self-Regulatory Initiative to the EuP Consultation Forum meeting on 28 May 2008. This present document outlines detailed proposals for the scope, approach and timeline established by the established EuP Steering Committee.

Product Scope:

This Self-Regulatory Initiative is focusing on the industry sector on medical imaging equipment for human applications, which comprises the following modalities:

- Computer Tomography (CT),
- Ultrasound,
- X-Ray,
- Magnetic Resonance Imaging (MRI),
- Nuclear Medicine.

Endorsement:

Current COCIR company members represent at least 80% of the sales of each of these modalities in Europe. This Self-Regulatory Initiative was endorsed by 11 companies. A EuP Steering Committee was constituted by representatives of those 11 companies in September 2008 in order to establish a consensus on how to manage this project and get consensus on various aspects.

Establishment of a common methodology:

To develop and test the methodology and approach for this Self-Regulatory Initiative, COCIR initiated a review of the products groups listed above in the product 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. It was determined to start in 2009 with the ultrasound product. The experience gained from this pilot will enable EuP Steering Committee to apply this methodology and approach to a second modality in 2010, third in 2011, and so on.

Assessment on Environmental criteria for the Pilot Modality (Ultrasound):

An assessment was performed based on Life Cycle Assessment and Annex 1.3 of the EuP Directive (refer to *Appendix 6*).

Life Cycle Assessment data showed that, on average, energy consumption during the use phase accounts for about 83% of the total life cycle environmental impact of ultrasound products where the "use phase" is defined as the time when the equipment is in use by the customer (the total time from when they received the equipment to the time that they dispose of it). In view of this, the EuP Steering Committee decided to focus on energy consumption in the use phase to begin with. Some environmental aspects are already covered by legislation such as RoHS, REACH, WEEE etc. Other environmental aspects will be considered in future phases of this Self-Regulatory Initiative.

Market Relevance:

COCIR has gathered industry data from all COCIR participating companies selling ultrasound products and analyzed the trends for average energy consumption of new products in 2005, 2006, 2007 and 2008. Based on this trend analysis, participating companies were able to predict that under a 'business as usual' scenario, the average energy consumption for new ultrasound products placed on the market would stay the same in 2008, 2009 and 2010 at 762 kWh per unit per year.

More than "business as usual":

Since 2008, based on customer needs to improve image accuracy to get better diagnostic and therapeutic results, innovative powerful imaging techniques satisfied this request. As a result, energy consumption increased. However, companies were able to avoid this energy increase trend by continuing efforts in EcoDesign programmes already in place which resulted in getting energy consumption flat.

The Self-Regulatory Initiative will deliver added value (more than 'business as usual') by setting a target to further reduce the energy consumption of new ultrasound products (pilot) placed on the market by 6% between 2010 and 2012 (this is the targeted industry average agreed by the EuP Steering Committee). Using 2005 as a baseline, this is equivalent to reducing the average energy consumption of new ultrasound products placed on the market in 2012 by 25% compared to 2005.

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,
- Develop metrics to measure the energy efficiency of ultrasound equipment.

Compliance with legal requirements for Self-Regulatory Initiative (ref Annex VIII of EuP Directive):
Appendix 3 highlights how the medical imaging industry sector ensures all regulatory requirements in Annex VIII of the EcoDesign of Energy using Products (EuP) Directive 2005/32/EC are incorporated into the initiative.

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1 Introduction

Founded as a non-profit trade association in 1959, COCIR represents the Radiological, Electromedical and Healthcare IT industry in Europe. As such, COCIR members[1] play a driving role in developing the future of healthcare both in Europe and worldwide. COCIR is committed to supporting its members and communicating 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 devices and healthcare IT systems without compromising the safety of patients and users. We encourage the use of advanced technology to support healthcare delivery worldwide. COCIR's key objectives include promoting free worldwide trade of medical devices and maintaining the competitiveness of the European health sector.

For more information: www.cocir.org.

A vast majority of products manufactured by COCIR members are medical devices and as such are regulated through the Medical Devices Directive[2] (a New Approach Directive). All products sold in Europe must be CE marked to prove compliance to this Directive. This directive requires that manufacturers comply with Essential Requirements and have a Quality Management System in place to ensure products are designed, produced and put on the market through an established and robust way. It covers also post-market surveillance principles.

1.1 COCIR Core Competencies

Those competencies are as follows:

- **Market Statistics** (Medical Imaging and Healthcare IT Intelligence Centre): COCIR established more than 10 years ago a platform to gather market statistics data very useful to better understand the global coverage and providing COCIR members with data per product groups and per country. Focus is on Diagnostic Imaging and Healthcare IT. As of today data are collected from COCIR company members on a quarterly basis (sales and orders) for more than 50 countries. Those data are accessible to COCIR companies including their figures into the process. The application used is robust and includes confidentiality rules. A study was performed in 2009 on Age Profile more specifically for CT, MRI and Nuclear Medicine

- **eHealth:** COCIR is actively involved in all discussions linked to eHealth. Refer to COCIR Position Paper providing 10 Recommendations (http://www.cocir.org/uploads/documents/-24-cocir_pp_ehealth_rel_short.pdf).

- **Contribution to sustainable healthcare** with Institutions and other stakeholders (Europe). Refer to COCIR White Paper on sustainable Healthcare systems (http://www.cocir.org/uploads/documents/-24-cocir_pp_ehealth_rel_short.pdf).

- **Regulatory Activities and Standardisation** (EU and Global). COCIR is involved in various activities linked to regulatory framework affecting Medical Devices in Europe and

[1] ***COCIR Company Members:*** *Agfa-Healthcare, Aloka, Bosch, Canon Europe, GE Healthcare, Hitachi Medical Systems Europe, IBA Ion Beam Applications, IBM, Intel, iSoft, Carestream Health, Fujifilm, Elekta, Medison, Konica, Microsoft, Philips Healthcare, Siemens Healthcare, Shimadzu, Toshiba Medical Systems Europe, T-systems*
COCIR National Associations Members: *AGORIA (Belgium), Assobiomedica (Italy), SNITEM (France), ZVEI (Germany), SPECTARIS (Germany) HHT (Netherlands), FENIN (Spain), Swedish MedTech (Sweden), AXREM (UK), FiHTA (Finland), TipGorDer (Turkey), AMDM (Hungary)*

[2] *See Council Directive 93/42/EEC of 14 June 1993, OJ No L 169/1 of 1993-07-12.*

globally. With regards to standardisation refer to COCIR Position Paper (http://www.cocir.org/uploads/documents/-38--608-cocir_vision_and_recommendations_on_standardisation_5_june_2009.pdf).

- **Environment** (EU and Global). In 2000 COCIR created the Focus Group Environmental Affairs. Main tasks: Collecting environmental information, sharing best practices and driving innovative solutions to reduce adverse environmental impacts. COCIR has long track records showing its leadership in this domain for Medical Devices.

1.2 COCIR Initiatives in the field of environment

COCIR has taken several initiatives in the environmental domain introducing EcoDesign Initiatives in different ways:

- **2000**, From the beginning COCIR is developing solutions to integrate the approach of "Integrated Product Policy". In the front is the idea "Thinking in life cycles". COCIR supported solutions for "Gathering information from supply chain regarding substances", "Take back used Products", "Refurbished Systems" and very first version of "Environmental Product Declarations".

- **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 equipments. International Electro-technical Commission (IEC) published the International Standard IEC 60601-1-9: Environmentally Conscious Design of Medical Electrical Equipment in July 2007. The standard provides a systematic approach for product designers to address all life cycle aspects when they design new medical devices.

- 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)[3], COCIR member companies participated in an Integrated Product Policy project with the Hamburg authorities and hospitals. Operators and manufacturers of medical devices jointly developed a standardised list of criteria for ecological product information to allow hospitals to make a balanced ecological and economical purchasing decision.

- 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 effectively refurbish equipment to ensure quality, safety and effectiveness of medical imaging equipments. Evidence-based data are showing this process contributing to a Recycling Economy[4]. A version 2, endorsed by MITA (US Trade Association) and JIRA (Japanese Trade Association), was published in September **2009.** In addition, COCIR published its 1st Industry Standard (http://www.cocir.org/uploads/documents/-560-cocir_industry_standard1806.pdf).

- COCIR published in **2008** a **guide** on REACH requirements for component suppliers and equipment manufacturers http://www.cocir.org/uploads/documents/32-697-guide_to_reach_requirements_for_component_suppliers_and_equipment_manufacturers.pdf.

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

[4] *It has been verified that the typical reduction of energy input due to refurbishment of used medical equipment compared with the manufacturing of a new piece of equipment is 100% for a new device to only 27% for the refurbished device. An estimated 1, 6 billion Euros are spent on refurbished equipment globally, 50% of this is sold in the U.S. and the EU alone. Source: COCIR internal data.*

- 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. 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. This initiative is benefiting not only COCIR members but also to all electronic industries. This initiative is hosted by COCIR but includes a vast list of industries in the electronic domain. An EuP Steering Committee has been established and is continuing to monitor progress of this tool. For more information: www.bomcheck.net.

1.3 COCIR's ambition continued through EuP Initiative

COCIR, furthering the past intensively, explored opportunities and took a number of initiatives (refer to previous section) to improve the environmental performance of medical imaging equipment. In the same spirit our industry continues its effort to maximize efficiency of the equipment and services while contributing to a greener environment. Our vision as a responsible, sustainable and highly innovative industry sector is to cover environmental aspects early in the process from research and development through production, comprising also post-production throughout the total life cycle of our products.

COCIR member companies fully supports the **EuP Directive**[5] aims and objectives and commits to proactively participate in the EuP Directive through this Self-Regulatory Initiative (hereafter: *Initiative*) for medical imaging equipment.

COCIR supports the approach as outlined through the following Recitals 16 and 17:

(16) Priority should be given to alternative courses of action such as self-regulation by industry where such action is likely to deliver the policy objectives faster or in a less costly manner than mandatory requirements,

(17) Self-regulation, including voluntary agreements offered as unilateral commitments by industry, can provide for quick progress due to rapid and cost-effective implementation, and allows for flexible and appropriate adaptation to technological options and market sensitivities.

COCIR, on behalf of its member companies, presented its initial proposals for this Self-Regulatory Initiative to the EuP Consultation Forum meeting on **28 May 2008**. The EuP Consultation Forum welcomed this approach because it could achieve the same overall objective as an implementation measure but would avoid potential negative business impact. In particular, the EuP Consultation Forum emphasised that "*regulation would risk hampering innovation in the medical equipment sector, where technology evolves rapidly*" [6].

Based on this positive feed-back, COCIR decided in **September 2008** to establish an independent EuP Steering Committee in order to further develop this Initiative and take proactive actions.

Strategic Directions and Action Plan (see *Appendix 1*) was the basis to get formal engagement from participating companies to engage in this process. The governance of this committee is provided in *Appendix 2.*

[5] *Directive 2005/32/EC of July 2005 establishing a framework for the setting of EcoDesign requirements for energy-using products.*

[6] *Minutes from Consultation Forum of 28 May 2008, CF-2008-15-EC.*

This present document provides the industry's detailed proposal for the scope, approach and timeline of this Self-Regulatory Initiative. *Appendix 3* highlights how COCIR's proposal complies with all regulatory requirements in Annex VIII of the EcoDesign of Energy using Products (EuP) Directive 2005/32/EC.

2 Scope of Self-Regulatory Initiative

2.1 Product scope

Modern medical equipment offers a broad range of possibilities for the improvement of healthcare. Technological innovation has multiplied the possible efficiency gains to be achieved by healthcare entities from the consequent use of medical technology as well as the potential benefit for patients.
New procedures are in general less invasive and pose less risk for patients. Diagnosis and therapy are more effective and accurate.
Modern CT, MRI, PET-Nuclear Medicine and Angiography medical imaging technology improves the quality of healthcare services and offers many possibilities for rationalization.

This Self-Regulatory Initiative covers medical imaging equipment for human applications, these are:

- Computer Tomography (CT)[7],
- Ultrasound[8],
- X-Ray[9],
- Magnetic Resonance Imaging (MRI)[10],
- Nuclear Medicine[11].

[7] *Computed tomography, or CT, is a medical imaging method employing tomography created by computer processing. Digital geometry processing is used to generate a three-dimensional image of the inside of an object from a large series of two-dimensional X-ray images (slices) taken around a single axis of rotation.*

[8] *Ultrasound is an imaging technique used to visualize subcutaneous body structures including tendons, muscles, joints, vessels and internal organs for possible pathology or lesions. Ultrasound, also known as obstetric sonography, is commonly used during pregnancy and is widely recognized by the public. There is a plethora of diagnostic and therapeutic applications practiced in medicine (incl. in cardiology, anesthesiology, urology, gastro-enterology, vascular, etc).*

[9] *X-Ray, is obtaining diagnostic information by using imaging techniques based on X-radiation directed through the patients body to produce images (radiographs) on photographic film or a fluoroscope. X-ray photon energy would typically be in the energy range of 30-150 keV. Radiography is used to produce images of disease in all parts of the body. In case of Computerized radiography (CR) photographic film is replaced by a charged plate, from which charge is knocked off by exposure to X-rays. The resultant image is read by a laser beam, then stored digitally or printed out. Digital radiography (DR) in which X-ray images are acquired in digital format, allowing the storage of images on hard disk and their subsequent retrieval and interpretation using TV monitors.*

[10] *Magnetic Resonance Imaging, or MRI, is primarily a medical imaging technique most commonly used in radiology to visualize the internal structure and function of the body. MRI provides much greater contrast between the different soft tissues of the body than computed tomography (CT) does, making it especially useful in neurological (brain), musculoskeletal, cardiovascular, and oncological (cancer) imaging.*

[11] *Nuclear medicine is a branch or specialty of medicine and medical imaging that uses radioactive isotopes (radionuclides) and relies on the process of radioactive decay in the diagnosis and treatment of disease. In nuclear medicine procedures, radionuclides are combined with other chemical compounds or pharmaceuticals to form radiopharmaceuticals. These radiopharmaceuticals, once administered to the patient, can localize to specific organs or cellular receptors. This unique ability of radiopharmaceticals allow nuclear medicine to diagnose or treat a disease based on the cellular function and physiology rather than relying on the anatomy.*

2.2 Participating companies

To date, the following companies have formally committed their full support for the Self-Regulatory Initiative, including a signed statement from the CEO or Company Officer of each company and formal agreement to share all costs for the Initiative:

- Agfa HealthCare (www.agfa.com/en/he/landing/index.jsp), hereafter: Agfa
- Aloka Holding Europe AG (www.aloka.com), hereafter: Aloka
- Elekta AB (www.elekta.com), hereafter: Elekta
- FujiFilm (www.fujifilm.com/products/medical), hereafter: FujiFilm
- General Electric Healthcare (www.gehealthcare.com/worldwide.html), hereafter: GEHC
- Hitachi Medical Systems (www.hitachi.com/products/business/bio.html), hereafter: Hitachi
- Ion Beam Applications SA (www.iba-worldwide.com), hereafter: IBA
- Medison Europe (www.medison.com), hereafter: Medison
- Philips Healthcare (www.medical.philips.com), hereafter: Philips
- Siemens Healthcare (www.medical.siemens.com), hereafter: Siemens
- Toshiba Medical Systems Corporation (www.toshiba-medical.eu), hereafter: Toshiba

Participation to this Self-Regulatory Initiative is open to all other companies placing medical imaging equipment on the European market (refer to *Appendix 2*).

For the purpose of this Self-Regulatory Initiative and documentation, all current and future companies participating, i.e. committed to the proposal presented in this initiative, are defined as *participating companies* or *participants*. A Memorandum of Understanding (MoU) including AntiTrust guidelines for industry self-regulation has been developed so that any company can join the initiative (refer to *Appendix 4).*

2.3 Market relevance

Medical imaging equipment are playing an important role in contributing to enhancing the quality of life of citizens during the whole complete care cycle (prevention, diagnostic, therapy and care).

Table 1 hereafter is providing an overview on market value, market coverage, current participating companies and status on remaining ones.

Market value and market coverage are activities monitored over the past 10 years through the COCIR Imaging Market Statistics Focus Group. Also refer to Age Profile Edition 2009 published recently (http://www.cocir.org/uploads/documents/-609-new_members_ws_-_del._3_-_cocir_age_profile_17_june_2009.pdf).

Table 1: Medical Imaging - EU market share for modalities within the scope of this Initiative

		2008 Market Value[i12]	Estimated EU Market Coverage[ii13]	Participating companies	Other targeted companies[14]
Computer Tomography (CT)		**630 M€**	**100 %**	GEHC, Hitachi, Philips, Siemens, Toshiba	None[15]
Ultrasound		**839M€**	**80 %**	Aloka, GEHC, Hitachi, Medison, Philips, Siemens, Toshiba	Esaote Medical, Sonosite, Mindray, Ultrasonix, Zonare
X-ray	**Cardio (45%)**	**381 M€**	**100 %**	GEHC, Philips, Siemens, Toshiba	None[15]
	Others (55%)	**490 M€**	**82 %**	GEHC, Hitachi, Philips, Siemens, Toshiba, Agfa, Shimadzu, Canon	Approx. 50 companies incl. Hologic, Konica, Mindray
Magnetic Resonance Imaging (MRI)		**769 M€**	**100%**	GEHC, Hitachi, Philips, Siemens, Toshiba	None[i15]
Nuclear Medicine (SPECT[16], PET[17])		**224 M€**	**100%**	GEHC, Philips, Siemens	None[15]

The EuP Steering Committee managing this Initiative established a general methodology described in section 3 with the principle to work on a specific product group as pilot to validate the methodology (pilot developed in section 4).

2.4 Baseline determination

The EuP Steering Committee decided to choose 2005 as the baseline for this Self-Regulatory Initiative because:

- 2005 is the date of implementation of the EuP Directive,
- Reliable data on power consumption and total numbers of units sold in Europe from 2005 onwards is available within companies.

3 General Methodology

The general principle/concept is based on the fact that not all products groups can be considered at the same time due complexity of those products. Those capital investment products require specific attention to review all phases during their life cycle including design and development phases.

Thus the principle adopted is based on a 6 steps approach over three years. Those steps have to be performed for each modality under the principle of continuous improvement. EuP Steering Committee decided to engage in one modality per year.

The *Table 2* hereafter is representing how the process would work.

[12] *COCIR Imaging Market Statistics source*
[13] *COCIR Imaging Market Statistics source*
[14] *COCIR plans to contact those companies over time*
[15] *To COCIR knowledge*
[16] ***Single photon emission computed tomography (SPECT)*** *is a nuclear medicine tomographic imaging technique using gamma rays, it is able to provide true 3D information. This information is typically presented as cross-sectional slices through the patient, but can be freely reformatted or manipulated as required.*
[17] ***Positron emission tomography (PET)*** *is a nuclear medicine medical imaging technique which produces a three dimensional image or map of functional processes in the body.*

The industries approach to this Initiative comprises **six steps**:

Step 1: Screening to determine which modality should be addressed next

The principle of this step is to select one modality each year looking at various aspects such as environmental criteria as per Annex 1.3 of EuP Directive, LCA, R&D, production lines, post-production phases, installed base, innovations and customer requirements healthcare needs.
Ultimately, the EuP Steering Committee will decide on consensus based which modality will be considered next.
Note: the 1st modality chosen as a pilot is ultrasound (refer to section 4).

Step 2: Identify the most significant environmental aspects for the specific modality

Participating companies agreed to use Life Cycle Assessment (LCA) data and environmental criteria as listed in Annex 1.3 of the EuP Directive to identify the most significant life cycle environmental aspects for each of the modality.
Note: *Appendix 5* shows how this analysis was documented for ultrasound equipments.

Step 3: Gather baseline data for target setting (specific to each modality)

a) Come to an agreement and standardized approach for data gathering on most significant environmental aspects

A standardized approach is developed by the EuP Steering Committee for collecting data on the most significant environmental aspects. This approach might be specific to each modality.

b) Gather data for most significant environmental aspects and new product sales

Participating companies use a spreadsheet tool to gather data from companies on the most significant environmental aspect and new product sales.
Note: for ultrasound equipment the spreadsheet is in *Appendix 8*.

c) Identify and review technology trends

EuP Steering Committee identifies and reviews key technology trends for the dedicated modality that have an impact on the most significant environmental aspects during the use phase.
Note: the example for ultrasound modality is described in section 4.2.

Step 4: Set target and objectives for most significant environmental aspects

EuP Steering Committee use the analysis of key technology trends and trends in the most significant environmental aspects for new products to set a target and objectives for the modality. The target is set in relation to the 2005 baseline, for achievement in three years time. The objective is set by consensus at EuP Steering Committee.

Step 5: Integrate target into design and development of new products

Once the target has been established by the EuP Steering Committee (refer to step 4), participating companies have to implement this target into the design and development of their new products. Participants plan to achieve this target by:

- 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*,
- Develop metrics to measure energy efficiency,
- Any other means that might be specific to the participating company.

Note: the example for ultrasound modality is described in section 4.5.

Step 6: Monitor and report / publish annual progress

The EuP Steering Committee will draft annual progress report indicating the achievements compared to the initial target agreed. The participating companies may decide to communicate to their customers by using the standardised list of criteria which were developed under a German Integrated Product Policy[18] (IPP) project for ecological product information allowing hospitals to make a balanced ecological and economical purchasing decision.

At the end of step 6 the steps 2 and 3 will be repeated on the same modality and the outcome with possible new target(s) on the most significant environmental aspects(s) for the next three year period re-assessed.

Starting in 2010, EuP Steering Committee will annually select a next modality. Participating companies will start working through the six steps for this new modality and so forth.

[18] *In 2006, COCIR companies participated in an Integrated Product Policy (IPP) project with the Hamburg authorities and hospitals. Operators and manufacturers of medical devices jointly developed a standardized list of criteria for ecological product information to allow hospitals to make a balanced ecological and economical purchasing decision. See also Appendix 8, Example of Environmental Product Declaration. Learn more about the IPP project „Environmental Product Information for Diagnostic Imaging Devices" on the Internet at www.ipp-medizintechnik.hamburg.de/en*

Table 2: Application of the COCIR 6 steps methodology

	2009	2010	2011	2012	2013	2014	2015	2016	20xx
Period 1									
1. Screening to determine which modality should be addressed next	Ultrasound was selected	Select second modality	Select third modality	Select Fourth modality					
2. Identify the most significant environmental aspect	Ultrasound	Second modality	Third modality	Fourth modality	Fifth modality				
3. Gather baseline data for target setting.	Ultrasound	Second modality	Third modality	Fourth modality	Fifth modality				
4. Set target and objectives for most significant environmental aspect	Ultrasound	Second modality	Third modality	Fourth modality	Fifth modality				
5. Integrate target into design and development of new products		Ultrasound	Second modality	Third modality	Fourth modality	Fifth modality			
6. Monitor and report every year progress		Ultrasound	Ultrasound and 2nd modality	Ultrasound and moda-lity 2 and 3	Ultrasound and moda-lity 2-4	All modalitie s	All moda-lities	All moda-lities	All moda-lities
Period 2									
2. Identify the most significant environmental aspect				Ultrasound	Second modality	Third modality	Fourth moda-lity	Fifth moda-lity	
3. Gather baseline data for target setting.				Ultrasound	Second modality	Third modality	Fourth moda-lity	Fifth moda-lity	
4. Set target and objectives for most significant environmental aspect				Ultrasound	Second modality	Third modality	Fourth moda-lity	Fifth moda-lity	
5. Integrate target into design and development of new products					Ultrasound	Second modality	Third moda-lity	Fourth moda-lity	
Periods 3-x									
Steps 2-5 for periods 3-x									

4 Pilot for Ultrasound Modality

4.1 Screening (step 1 of the general methodology)

To develop and test the methodology and approach for this Self-Regulatory Initiative, participating companies initiated a 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. It was determined to start in 2009 with the ultrasound product.

The experience gained from this pilot will enable COCIR to apply this methodology and approach to a second modality in 2010, third in 2011, and so on.

All contributing manufacturers worked on an initial screening of all the modalities in scope and concluded to select ultrasound for the pilot. This for the following reasons:

- Inspection of *Table 1* in section 3 shows that by choosing ultrasound, the Self-Regulatory Initiative will include the largest number of COCIR member companies in the pilot.
- COCIR member companies represent 80% of all ultrasound units sold in the EU, the remaining vendors are known.
- COCIR members have a good understanding of environmental aspects and opportunities to reduce environmental impacts for ultrasound devices.
- Ultrasound equipment is much less complex compared to other modalities in the medical imaging sector. So, with this example it is easier and faster to learn and to develop the methodology and to establish company internal processes to assess environmental aspects, create targets and to change technologies. Also, it is important to understand, that these processes will have big impacts to all core business processes in particular product life cycle management, supply chain and customer relationship management.

Appendix 4 provides a description of ultrasound equipment.

4.2 Most significant environmental aspect: Focus on energy consumption in the use phase (step 2 of the general methodology)

Participants of this Initiative used simplified Life Cycle Assessment (LCA) tools and the environmental criteria listed in Annex 1.3 of the EuP Directive to assess the different stages in the life cycle of ultrasound products and to identify the most significant environmental aspect.

The LCA data presented in *Appendix 6* shows that, energy consumption during use phase is the biggest environmental aspect (about 83% of the total life cycle environmental impact of ultrasound products). Materials procurement accounted for ~12% of the total life cycle environmental impact, manufacturing accounted for ~2,5% and distribution accounted for ~2%. *Appendix 6* includes an assessment of ultrasound equipment against the environmental criteria listed in Annex 1.3 of the EuP Directive.

Some of these environmental criteria are already being addressed through existing industry initiatives. For example, in 2007 COCIR published Guidelines on Good

Refurbishment Practice (GRP) for Medical Electrical Equipment to ensure that used medical equipment is safely and reliably returned to active service contributing to a Recycling Economy. In 2009 COCIR strengthened the adoption of good refurbishment practices by publishing the Guidelines as an Industry Standard.

The assessment also identified whilst there are regulatory drivers in place to reduce many of the environmental aspects listed in Annex I section 1.3 of the EuP Directive, there are currently no regulatory drivers for reducing the energy use during the use phase. For example:

- The RoHS Directive[19] and REACH Regulation[20] are reducing the use of hazardous substances in new product designs. 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, enabling manufacturers to reduce the environmental aspects of new product designs,
- 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,
- The Packaging Directive[22] is reducing the used of hazardous materials in packaging, reducing the volume and weight of packaging and increasing end-of-life recycling of packaging.

This assessment of ultrasound equipment against the environmental criteria listed in Annex 1.3 of the EuP Directive confirms that the most significant environmental aspects for ultrasound equipment are:

- Energy consumption during the use phase,
- Materials procurement.

In view of this, participants have decided to focus for the modality of ultrasound on energy consumption in the use phase to begin with.

In addition, we note that materials procurement accounts for approximately 12% of the total life cycle environmental impact. We have included a representative selection of examples in *Appendix 7* to highlight activities that participants are already undertaking to address materials procurement aspects in the design of new ultrasound equipment. These include:

- 31% reduction in product volume and 25% reduction in product weight (see *Appendix 6*, case study 1),
- 10% reduction in packaging weight (see *Appendix 6*, case study 2),
- 16% reduction in overall product weight and 9% reduction in packaging weight (see *Appendix 6*, case study 3). The Initiative will consider setting targets for product

[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.*

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

[22] *Directive 94/62/EC on Packaging and Packaging Waste.*

weight and packaging weight of ultrasound products from 2012. Other environmental aspects will also be considered in future phases of the Initiative.

4.3 Energy consumption data gathering (steps 3. a & b of the general methodology)

Clause 4, Annex VIII of the EuP Directive requires participants to set quantified and staged objectives which are *"set in clear and unambiguous terms, starting from a well-defined baseline".* Clause 4 also requires that *"it must be possible to monitor compliance with the objectives in an affordable and credible way using clear and reliable indicators"*.

The EuP Steering Committee decided to choose 2005 as the baseline for this Initiative because:

- 2005 is the date of implementation of the EuP Directive,
- Reliable data on power consumption and total numbers of units sold in Europe from 2005 onwards is available within companies.

A spreadsheet tool (contained in *Appendix 8*) was developed to gather baseline data for 2005 and trend data for 2006, 2007, and 2008. Participants provided confidential sales data and power consumption data to the COCIR Secretariat for each model of ultrasound equipment they place on the EU market in each of these years. COCIR consolidated the confidential spreadsheet data from each company into a single master spreadsheet for analysis.

4.3.1 Calculation of annual energy consumption of mains power units

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

- Scanning / ready to scan (system already booted up). This is defined as the average power consumption for a system which is actively scanning or ready to scan in any scanning mode,
- Standby (need to boot up the system). This mode is defined a system which is ready to boot up/resume operation from a reduced power consumption standby state. A Standby mode may not be supported by all products,
- Off/hibernation. This mode is defined as a system which is switched off but still plugged into mains and with the circuit breaker on.

This data was 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.

4.3.2 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 would 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 per day.

Accordingly, COCIR 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 Annual sales and annual energy consumption in 2005, 2006, 2007 and 2008

Table 3 provides consolidated data for total annual sales and total annual energy consumption of new ultrasound products that participants put on the market in EU Member States in 2005, 2006, 2007 and 2008. These data are used to calculate the average annual energy consumption for new products put on the market each year. *Table 3* further includes participants trend data (predictions) for 2009 and 2010 considering implemented EcoDesign programmes (which represents 'business-as-usual') explained in section 4.3.5.

Figure 1 compares the annual sales each year as a percentage of 2005 annual sales, with the annual energy consumption as a percentage of 2005 annual energy consumption. This shows that the average annual energy consumption for new products put on the market fell in 2006 and 2007 compared to 2005. In 2008, however, this trend changes significantly – average annual energy consumption for new products put on the market stayed approximately the same in 2008 compared to 2007.

Figure 1: Annual sales and annual energy consumption for new ultrasound products compared to 2005 baseline

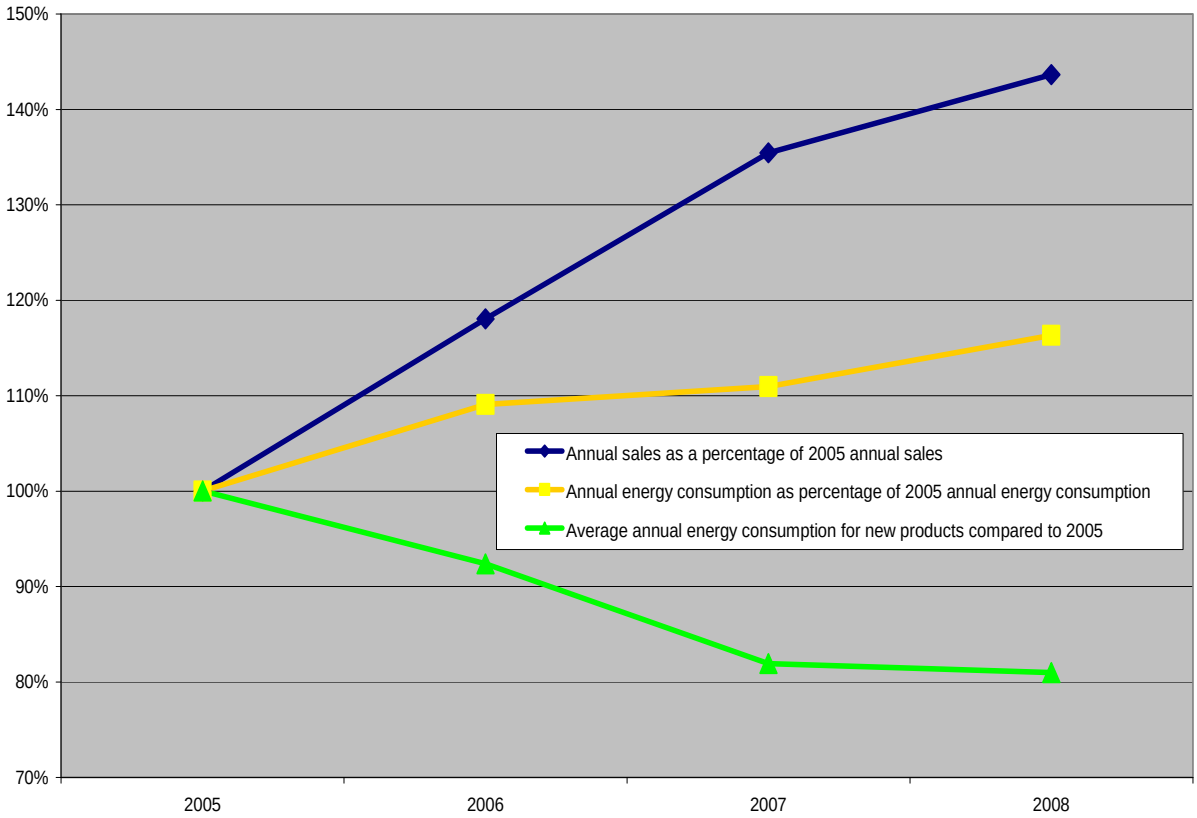


Table 3: Consolidated data for the total annual sales and total annual energy consumption of new ultrasound products placed on the market by participating companies in EU Member States in 2005, 2006, 2007 and 2008, and participants trend data (predictions) for 2009 and 2010 considering implemented EcoDesign programmes (which represents 'business-as-usual' for imaging medical devices).

	Total annual sales	Total annual sales as a percentage of 2005 annual sales	Total annual energy consumption in kWh for new products	Total annual energy consumption for new products as a percentage of 2005 annual energy consumption	Average annual energy consumption for new products in kWh	Average annual energy consumption for new products compared to 2005
2005	14,475	100%	13,628,343 kWh/year	100%	942 kWh/unit/year	100%
2006	17,088	118%	14,864,054 kWh/year	109%	870 kWh/unit/year	92%
2007	19,604	135%	15,121,116 kWh/year	111%	771 kWh/unit/year	82%
2008	20,791	144%	15,851,000 kWh/year	116%	762 kWh/unit/year	81%
2009	*20,800*	*144%*	*15,851,000*	*116%*	*762 kWh/unit/year*	*81%*
2010	*20,800*	*144%*	*15,851,000*	*116%*	*762 kWh/unit/year*	*81%*

4.3.4 Analysis of trend data for 2005, 2006, 2007 and 2008

Figure 1 shows that average annual energy consumption for new products fell notably in 2006 and 2007 compared to 2005. In 2008, however, this trend changes significantly as average annual energy consumption for new products stayed approximately the same in 2008 compared to 2007.

As discussed in section 4.2, this change reflects the three major competing technology trends which have affected energy consumption of ultrasound equipment since 2005:

- Increased market share of laptop products and handheld products which has reduced energy consumption,
- Development of more powerful imaging techniques which has increased energy consumption,
- Reductions in energy consumption from existing EcoDesign programmes.

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 and 2007. In 2008, however, the market for new laptop and handheld products remained the same. The overall energy consumption for new products stayed the same in 2008, as the impact of more powerful imaging techniques (which has increased energy consumption) was balanced by reductions in energy consumption from existing EcoDesign programmes (see section 4.4.3).

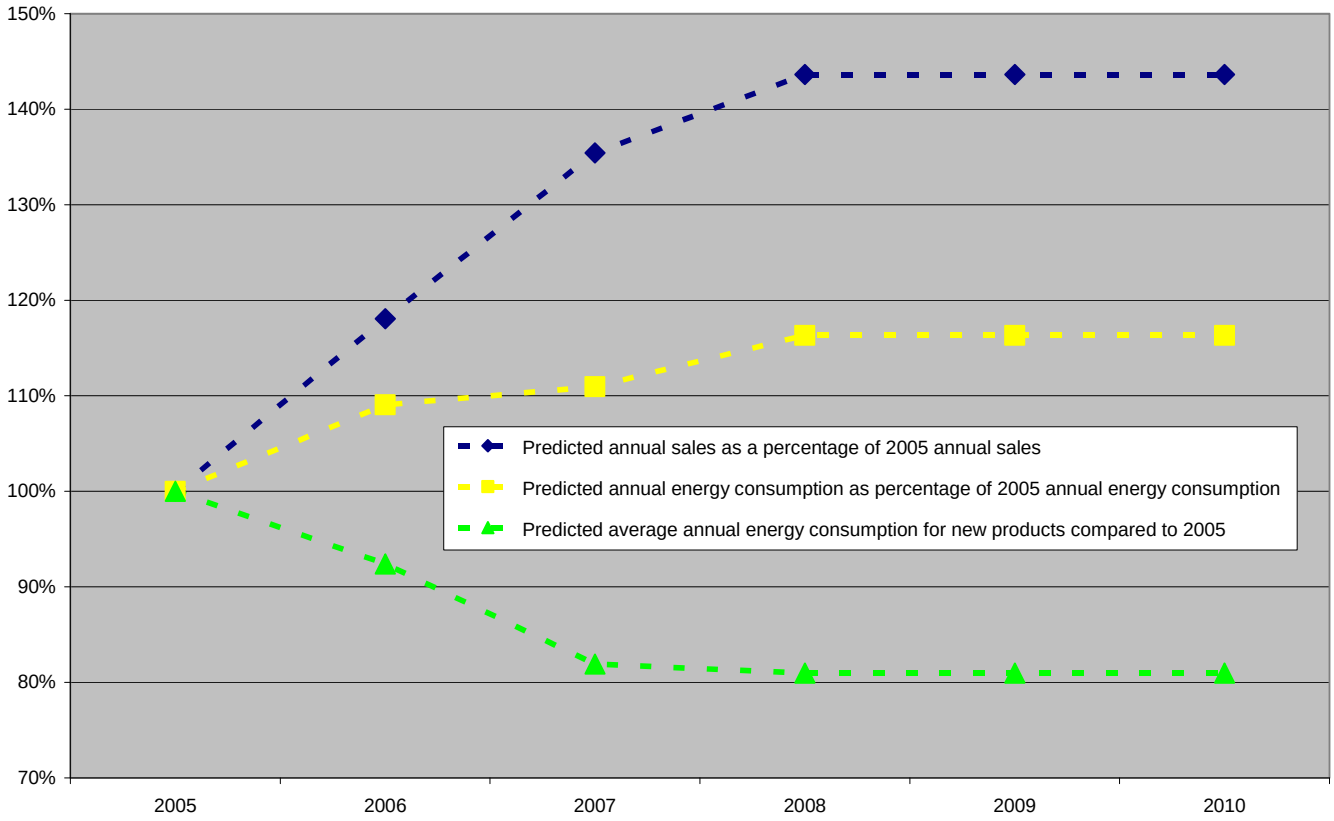
4.3.5 Predicted trends for 2009 and 2010

Most economists predict that the global recession will last at least until the middle of 2010. Accordingly, COCIR predicts in *Table 3* that total EU annual sales of ultrasound equipment will stay the same in 2009 and 2010.

Under the current trend, COCIR predicts that the impact of more powerful imaging techniques will continue to balance out the reductions in energy consumption from existing EcoDesign programmes. This represents ‘business-as-usual’ for radiological and imaging medical devices.

Therefore, COCIR predicts that under a ‘business-as-usual’ scenario the annual energy consumption for new products will stay the same in 2009 and 2010, compared to 2008 at 762 kWh per year.

Figure 2: Current EcoDesign efforts (which represents 'business-as-usual') for ultrasound trend predictions for 2009 and 2010



4.4 Identification and review of technology trends affecting energy consumption (step 3.c of the general methodology)

There are three major competing technology trends which have affected energy consumption of ultrasound equipment since 2005:

- Increased market share of laptop products and handheld products which has reduced energy consumption,
- Development of more powerful imaging techniques which has increased energy consumption,
- Reductions in energy consumption from existing EcoDesign programmes.

4.4.1 Increased market share of laptop products and handheld products

In 2005 the medical device industry introduced the first laptop ultrasound products, followed by the first handheld ultrasound products. The new, low energy consumption, portable products weigh around 5kgs and can provide similar imaging power and capabilities to older generation systems weighing up to 200kgs. The products were very popular from the outset and continued to gain a larger and larger share of the market in 2006 and 2007.

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 significantly in 2006 and 2007.

In 2008, however, the market for new laptop and handheld products reached saturation. The market share of laptop and handheld products remained the same in 2008 and so the overall energy consumption for new products stayed the same in 2008. This was only to be achieved due to existing EcoDesign programmes: The impact of more powerful imaging techniques (which has increased energy consumption) was balanced by general reductions in energy consumption through iterative improvements in product design, i.e., concentrated EcoDesign efforts.

4.4.2 Development of more powerful imaging techniques

There have been several significant new developments in ultrasound imaging technology since 2005. As a result, ultrasound equipment has become an even more powerful tool for healthcare professionals, to enable better and earlier diagnosis of patient symptoms and therefore more successful patient treatment and outcomes. These new, more powerful imaging techniques have lead to increased energy consumption for imaging modules in new design ultrasound equipment introduced since 2005.

New analogue front end technology launched in 2008 will lead to future decreases in energy consumption for signal processing modules in new design ultrasound equipment. Due to the timescales required for product development and regulatory approvals, however, new design equipment which makes use of this new energy saving technology is unlikely to be available for sale in the EU until 2010.

Increased computing power

Scan convertors in older generation ultrasound equipment were based on electronics hardware which was designed and built into the ultrasound unit. New design ultrasound equipment introduced in the past few years now use PC computers to carry out these scan convertor functions. This has led to a massive increase in the calculation power of ultrasound equipment, which has resulted in significant improvements in image quality. In particular, the use of PC computers has enabled the use of more advanced signal technologies and more powerful image analysis packages. Both of these factors, however, have lead to significantly increased energy consumption of imaging modules in ultrasound equipment.

Signal multiplexing technology

The increased computing power of new design ultrasound equipment has enabled the use of advanced signal multiplexing technology. In older generation ultrasound equipment, the number of signals that could be processed simultaneously was limited to the number of wires (known as channels) that could be connected to the ultrasound transducer probe. For example, an older design ultrasound unit with 128 channels is capable of firing 128 elements simultaneously in a transducer probe – the analogue signal from each transducer element travels down a separate wire to the ultrasound unit.

Signal multiplexing technology was developed in the telecommunication industry to enable several phone calls to be transmitted using one wire. This multiplexing process is now widely used in new design ultrasound equipment and enables multiple analogue signals to be combined into one signal for transmission down a single channel from the probe to the ultrasound unit. The signal is then be de-multiplexed at the ultrasound unit, to re-create the multiple analogue signals. This massively increases the number of signals which can be processed simultaneously by the ultrasound unit, in some cases by a factor of 10 or more.

Processing this increased number of signals requires more computing power, which in turn increases the energy consumption of imaging modules in ultrasound equipment.

3D / 4D image analysis packages

Advanced signal multiplexing technology has enabled a massive increase in the number of signals that can be processed simultaneously by the ultrasound unit. In turn, this has enabled the adoption of considerably more powerful image analysis packages. These provide a substantial increase in diagnostic capabilities, compared to the two dimensional (2D) images generated by older ultrasound equipment. New design ultrasound equipment has added not only a third dimension (3D) of depth but also the fourth dimension (4D) of time.

One example is the new image analysis packages which have been developed for 4D left ventricular (LV) analysis to support cardiac resynchronization therapy (CRT). This image analysis package generates a model of the LV using 3D datasets, subdivided into volumetric elements. The resulting colour-coded display of the contraction pattern of ventricles helps healthcare professionals mark the volumetric changes and timings of the contractions. This 4D imaging technique is more accurate and reproducible compared to conventional 2D technology and enables healthcare professionals to better select the appropriate patient groups for CRT, resulting in greater efficiency and cost savings.

Another example is using real-time 3D ultrasound systems combined with endocardial border tracking algorithms to considerably reduce heart examination times. Heart failure is a major cause of mortality, morbidity and hospitalisation and is also extremely expensive to cure. Real-time 3D ultrasound imaging enables health care professionals to reduce all four issues.

Providing these considerably more powerful image analysis packages requires more computing power, which in turn increases the energy consumption of imaging modules in ultrasound equipment.

New analogue front end (AFE) chips reduce energy consumption per channel

Current design ultrasound equipment uses analogue front end (AFE) chips which handle two channels per chip. New, more efficient AFE chips were launched in 2008 by Texas Instruments (AFE58xx family) and Analog Devices (AD9272 and AD9273). These AFE chips handle eight channels per chip and this leads to an overall reduction in the power consumption per channel by up to 20%. Due to the timescales required for product development and regulatory approvals, however, new equipment which makes use of this new energy saving technology is currently not available for sale in the EU.

4.4.3 Energy reduction from existing EcoDesign programmes

For aspects of ultrasound design where there are no new technical innovations such as the more powerful imaging techniques discussed above, then existing EcoDesign programmes already lead to reductions in energy consumption from one product generation to the next. The reductions in energy consumption from these existing EcoDesign programmes have generally balanced out the increases in energy consumption from uptake of more powerful imaging techniques (see also section 4.3.4).

As a result, when the market share for laptop units and handheld units remained the same in 2008, the overall energy consumption for new products also stayed the same. This is because the impact of more powerful imaging techniques (which has increased energy consumption) was balanced by reductions in energy consumption from existing EcoDesign programmes.

4.5 Targets and objectives to reduce energy consumption (steps 4 and 5 of general methodology)

The trend figures presented above predict that with already existing EcoDesign programmes (which represents 'business-as-usual' for medical imaging equipment) industry achieves average energy consumption for new products staying the same in 2008, 2009 and 2010 at 762 kWh per year.

The industry Self-Regulatory Initiative has set a target to additionally reduce the average energy consumption of new ultrasound products placed on the market by 6% between 2010 and 2012. Using 2005 as a baseline, this is equivalent to reducing the average energy consumption of new ultrasound products placed on the market in 2012 by 25% compared to 2005. This target is based on total energy consumption of new products only. It does not take into account that new products have increased functionality and deliver even more healthcare benefits to patients. In section 4.5.2 COCIR outlines its plans to develop energy efficiency targets for new products, which would capture increases in functionality of new products compared to energy consumption.

The target to reduce average energy consumption of new ultrasound products placed on the market by 6% between 2010 and 2012 translates to a reduction in average energy consumption from 762 kWh per year down to 706 kWh per year in 2010. Based on predicted EU annual sales in 2012 by COCIR companies of 20,800 units, this is equivalent to a total annual energy saving of 1,165,000 kWhrs. This is equivalent to 624,000 kg of CO_2 per year.

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),
- Develop metrics to measure the energy efficiency of ultrasound equipment. This new metrics will allow having a link between the total energy consumption and the benefit of ultrasound devices to support saving lives.

The medical imaging equipment industry would like to communicate the design challenges and technology trends or cycles behind any new ultrasound product. Thus, the 6% energy reduction between 2010 and 2012 is not business as usual, but will be the result of focused design efforts to achieve these improvements. The EU Action Plan on energy Efficiency and particular the EcoDesign Directive 2005/32/EC have a long term view, which can only be achieved by one step at a time.

Competing technology trends have affected energy consumption of ultrasound equipment since 2005. This correlation is in particularly strong for complex high-tech products. While the generally innovation driven healthcare technology sector is committed to respond to the increased requirement of a clinical environment delivering e.g. better image quality in a shorter time, manufacturers at the same time are continuously reducing energy use, achieving already balanced energy consumption compared to previous, less powerful models.

Another important aspect of technology trends are the 'innovation breakthroughs '. Similar to other mature and sophisticated technologies, improvements in the ultrasound domain come in cycles. These need time and considerable investment and are often marked by innovation breakthroughs. The ultrasound industry is working on its next breakthrough

comprising increased technical requirements as well as EcoDesign aspects towards more energy efficient products.

Last but not least, the 'business-as-usual' scenario. Under the current trend, COCIR predicts that the impact of more powerful imaging techniques will continue to balance out the reductions in energy consumption from existing EcoDesign programmes. This, representing 'business-as-usual' for the medical imaging equipment industry, already reflects manufactures efforts e.g. EcoDesign programmes at a time when EuP did not exist yet. In other words, healthcare equipment vendors were actively working on environmental aspect of product design putting them in a leadership position positively influencing also the market.

4.5.1 Increased focus on EcoDesign in the product design and development process

This Initiative will create an even greater focus and importance for EcoDesign in participating companies. In response, participating companies will use a range of approaches to increase the depth and breadth of EcoDesign integration into product design and development. Participating companies may choose to implement the International Standard IEC 60601-1-9: Environmentally Conscious Design of Medical Electrical Equipment.

This standard, published in July 2007, provides a practical and robust framework for medical device design to:

- Identify and prioritize the significant environmental aspects of the product across all of its life cycle phases,
- For significant environmental aspects, establish and document EcoDesign targets to reduce adverse environmental aspects,
- Use a risk management based approach to evaluate EcoDesign options,
- During the product conception and design specification phases, consider innovative emerging or alternative design technologies and/or solutions that can significantly reduce adverse environmental aspects,
- Assess the actual environmental performance of the final prototype against the EcoDesign targets. Any deviations from the targets must be documented for consideration in future designs,
- In the documentation accompanying the product, provide instructions for minimizing the product's environmental aspects during normal use and disposal at the end of life,
- List substances and materials that can be recovered and recycled from the product.

This approach is in line with the Integrated Product Policy (IPP) approach developed by the European Commission in 2001.[23]

[23] *For more information please visit the EC website at http://ec.europa.eu/environment/ipp/home.htm.*

4.5.2 Develop metrics to measure the energy efficiency of ultrasound equipment

The technology trends which have affected the energy consumption of ultrasound products since 2005 are discussed in section 4.2. This section also highlights that the most significant technology trend which will affect energy consumption of new products placed on the market in 2010, 2011 and 2012 will be new imaging technology. New, more powerful imaging techniques will lead to increased energy consumption for imaging modules in new designs.

The participants plan to analyse the affect of this trend on the overall energy consumption for new products by developing metrics to measure the energy efficiency of ultrasound equipment. It will involve developing metrics for the healthcare benefits that these new, more powerful imaging techniques provide. For example, for some types of ultrasound equipment this may involve developing a metric for improved image quality. For other types of equipment this may involve developing a metric for reduced scanning times. This may in turn require a metric for the number of patients that can be treated per day, or the amount of time that ultrasound equipment spends in standby mode whilst the images are being analysed.

These metrics will enable the participating companies to measure the healthcare benefits provided by new, more powerful imaging techniques. The participants will compare the healthcare benefits with the average energy consumption to measure the energy efficiency of new products. In the future, the participants will set targets to increase the energy efficiency of new products, as this provides a better measure for how healthcare products contribute to sustainability.

4.6 Monitoring & reporting/publishing average energy consumption of new products placed on the market (step 6 of the general methodology)

The participants will use the Excel spreadsheet tool contained in *Appendix 8* to gather confidential sales data and power consumption data from participating companies for each model of ultrasound equipment they put on the EU market in 2009, 2010, 2011 and 2012.

These confidential data provided by the participating companies are already externally audited and so these data do not require additional auditing for this Self-Regulatory Initiative:

- Sales data are extracted from financial management systems which are already externally audited to comply with financial regulations,
- Power consumption measurements are required by IEC 60601 to demonstrate compliance with the Medical Devices Directive, which is externally audited. Compliance with IEC 60601 is a central part of the annual external audit of the company's Quality Management System to maintain certification to ISO 13485.

EuP Steering Committee Secretariat's role is to consolidate these confidential Excel spreadsheets from each company into a single master Excel spreadsheet for analysis. This simply involves copying each company's individual Excel spreadsheet into the master Excel spreadsheet.

4.6.1 Calculation of annual energy consumption of mains power units

For mains power units, participating companies will provide the power consumption in kW for the following modes (see also section 4.3.1):

- Scanning / ready to scan (system already booted up). This is defined as the average power consumption for a system which is actively scanning or ready to scan in any scanning mode,
- Standby (need to boot up the system). This mode is defined as a system which is ready to boot up/resume operation from a reduced power consumption standby state. A Standby mode may not be supported by all products,
- Off/hibernation. This mode is defined as a system which is switched off but still plugged into mains and with the circuit breaker on.

This data will be used to calculate the total annual energy consumption for each mains power unit.

4.6.2 Calculation of annual energy consumption of battery powered units

Participating companies will provide the energy consumption in kWh to charge the battery from a 100% discharged state, as detailed in section 4.3.2. This data will be 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.

4.6.3 Reporting performance against energy consumption targets

EuP Steering Committee will analyze the consolidated master Excel spreadsheet to calculate the total annual sales and total annual energy consumption of new ultrasound products that companies put on the market in EU Member States in 2009, 2010, 2011 and 2012. These data will be used to calculate the average annual energy consumption for new products put on the market in each of these years. EuP Steering Committee will use these data assess whether companies are achieving the interim targets and are therefore on track to achieve the final target to reduce the average energy consumption of new ultrasound products placed on the market by 6% between 2010 and 2012.

EuP Steering Committee will use the reporting table in *Table 4* (see section 6) to report annual performance against the interim energy targets and final 2012 target to the European Commission and the Consultation Forum. For example, the performance reporting table to assess whether companies have met the interim target for 2010 will be issued by EuP Steering Committee Secretariat to the European Commission in 2011, based on 2010 data.

5 Sustainability

Annex VIII Clause 8 requires that Self-Regulatory Initiatives

> *"shall be consistent with the economic and social dimensions of sustainability. The **protection of consumers'** interests (**health, quality of life** and economic interests) **shall be integrated**."*

The participants shall ensure that the environmental design targets which are set under the Self-Regulatory Initiative are environmentally sound with regard to other environmental aspects of medical devices. The participants have verified that the target to reduce average energy consumption of new ultrasound products placed on the market by 6% between 2010 and 2012 will not result in an increase in other environmental aspects of ultrasound products. For example, achieving this energy reduction target will not result in increased materials procurement aspects for new ultrasound products.

Regarding other elements of sustainability, it is important to note that new medical devices are designed to give better and earlier diagnosis, more effective and successful treatment and completely new treatments. In other words, the primary function of a medical device is to protect consumers' health and quality of life. Therefore, Clause 8 requires that this primary function of ultrasound equipment must be taken into consideration when setting objectives (Clause 4), and when monitoring and reporting performance (Clause 7).

Section 4.4 highlights the significant new developments in ultrasound imaging technology which have been achieved in recent years. As a result, ultrasound equipment has become an even more powerful tool for healthcare professionals, to enable better and earlier diagnosis of patient symptoms and therefore more successful patient treatment and outcomes. These new, more powerful imaging techniques have led to increased energy consumption for imaging modules in new designs introduced since 2005, and this has balanced out the general reductions in energy consumption achieved by iterative improvements in product design. As a result, under a 'business as usual scenario' the overall energy consumption for new products would stay the same in 2008, 2009 and 2010.

Under this Self-Regulatory Initiative, the healthcare industry will aim to overcome the increased energy consumption in imaging modules, by making energy savings in other aspects of ultrasound equipment design. However, if new, even more powerful imaging technology is developed in the next few years, the Medical Devices Directive obliges the medical device industry to implement this new state-of-the art technology.

As part of this Self-Regulatory Initiative, the participants will continue to monitor the development of new imaging technology and determine whether it is compatible with the requirement of delivering improved consumers' health and quality of life. The participants will inform the European Commission at the earliest opportunity if the need to implement new imaging technology will affect the healthcare industry's ability to meet the target to reduce average energy consumption of new ultrasound products placed on the market by 6% between 2010 and 2012. In this case, the participants would propose revised energy consumption targets for discussion with the European Commission.

6 Monitoring and reporting

Monitoring and reporting will be posted periodically on COCIR's public website.
For ultrasound, detailed process is described in section 4.6.

Additionally, participating companies may publish product related "Environmental Product Declarations", with a similar content of the result of the IPP-Project in Hamburg in 2006 (See also *Appendix 9*).

Process is described hereafter into the *Flow Chart 1*.

Flow Chart 1: Overview of Monitoring & Reporting

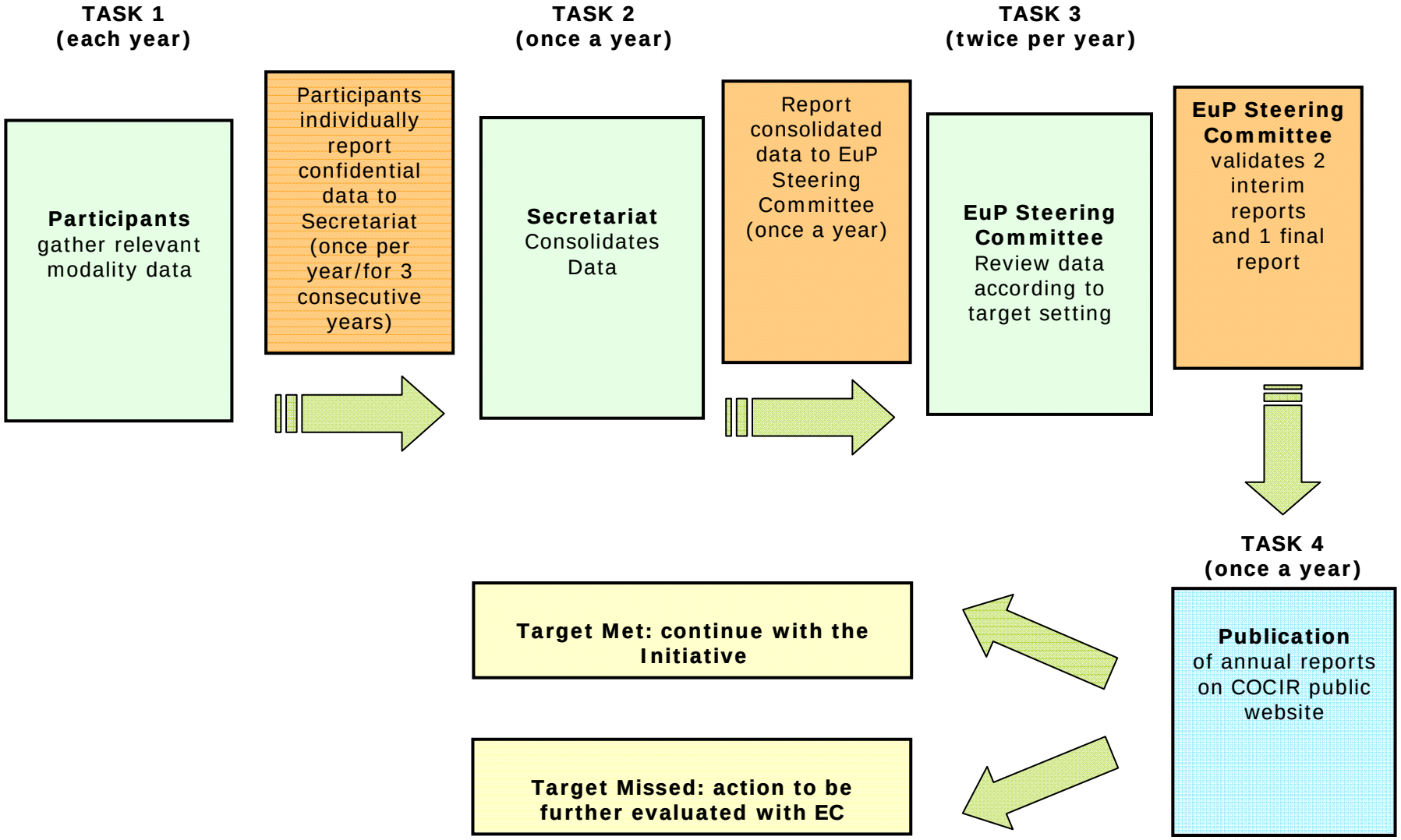
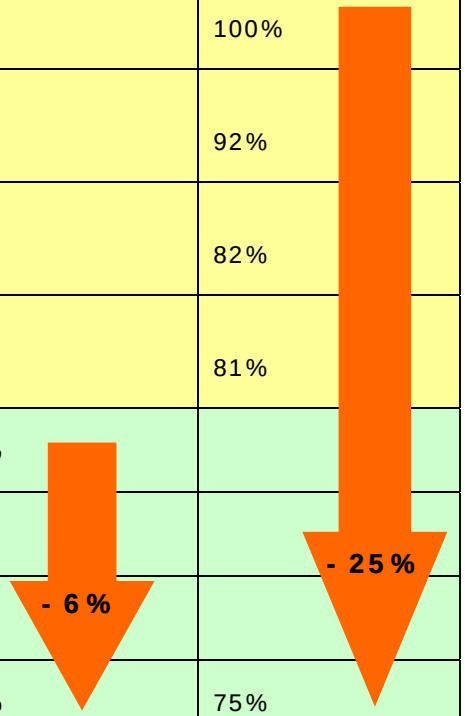


Table 4: Reporting table that COCIR will use to report performance against the interim energy targets and final 2012 target to the European Commission

	Total annual sales	Total annual sales as a percentage of 2005 annual sales	Total annual energy consumption in kWh for new products	Total annual energy consumption for new products as a percentage of 2005 annual energy consumption	Interim targets and **final 2012 target** for average annual energy consumption for new products in kWh	Actual average annual energy consumption for new products in kWh	Interim targets and **final 2012 target** for annual energy consumption for new products compared to 2005	Actual annual energy consumption for new products compared to 2005
2005	14,475	100%	13,628,343 kWh/year	100%		942 kWh/unit/year		100%
2006	17,088	118%	14,864,054 kWh/year	109%		870 kWh/unit/year		92%
2007	19,604	135%	15,121,116 kWh/year	111%		771 kWh/unit/year		82%
2008	20,791	144%	15,851,000 kWh/year	116%		762 kWh/unit/year		81%
2009					*762 kWh/unit/year*		*81%*	
2010					*743 kWh/unit/year*			
2011					*724 kWh/unit/year*			
2012					706 kWh/unit/year		75%	75%



7 Communication Plan

With the annual report COCIR would like to inform all stakeholders comprehensively about COCIR EuP activities, successes, and challenges in an open way. At the same time, the report is intended to initiate a dialogue with stakeholders. COCIR cordially invites all stakeholders to share their thoughts with COCIR.

COCIR welcomes any comments by e-mail to secretariat@cocir.org.

APPENDIX 1: EuP Directive - COCIR strategy and action plan[24]

V2.0

Objective: To reduce regulatory costs and gaining business benefits from the EcoDesign for Energy Using Products (EuP) Directive

1- Status of Medical Devices under the European Union EuP Directive

The EcoDesign Requirements for Energy Using Products (EuP) Directive 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 on an alternative approach EC proposes in the EuP Directive, Annex VIII (Self-Regulatory Initiative for an industry sector).

During the EC Consultation Forum meeting on 28 May 2008 COCIR presented its proposal for an industry-led Self-Regulatory Initiative. The EC welcomed this alternative approach as it could achieve the same overall objective as an implementation 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*"[25].

COCIR's proactive EcoDesign approach would be to voluntarily prove compliance to the International EcoDesign standard IEC 60601-1-9 for electromedical equipment. The EC confirmed at the COCIR General Assembly meeting on 23 October that if COCIR is successful in its Self Regulatory Initiative then the EC will not impose EcoDesign requirements on Medical Devices from 2011.

2- Business impact of doing nothing

If COCIR does not take a pro-active Self-Regulatory approach, EC will then set EcoDesign requirements for Medical Devices most likely around 2011 through additional mandatory regulations. This will result in extra costs, business disruption, diversion of valuable engineering design resources and loss of flexibility in product design (equivalent to 2 to 4% of global annual company turn-over).

3- Costs and benefits of self-regulation

The self-regulatory approach will use the EcoDesign activities that are already ongoing in most of the COCIR companies as the basis for common COCIR targets for EcoDesign. COCIR will establish a robust process to ensure that all individual company data[26] are kept strictly confidential. COCIR will only report anonymous consolidated data to EC. The Self-Regulatory Initiative will be successful only if a whole industry sector of COCIR adheres to it.

There will be costs for managing the established COCIR internal auditable process for setting targets and reporting environmental savings to COCIR. In addition, some companies will have to adapt their systems to gather the necessary data on energy consumption of their products.

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[24] *This document was endorsed by 11 companies already engaged in the Initiative.*

[25] *COCIR Minutes from Consultation Forum of 28 May 2008, CF-2008-15-EC.*

[26] *Nature of data and frequency to be determined by the COCIR Steering Committee (kick-off meeting planned on 28 Jan. 2009.*

These costs will be approximately much less than the extra costs and business disruption which we will incur if we have to respond to requirements set by EC. At the same time, we will gain numerous benefits, including:
• Flexible approach which allows companies to adopt different product design strategies for meeting the targets,
• Longer-term cost savings (mainly in R&D and production),
• Marketing benefits by promoting green image to customers and stakeholders.

4- Product coverage

The product scope for which COCIR members are cumulating at least 80% coverage is as follows:

- Computer Tomography (CT),
- Ultrasound,
- X-Ray,
- Magnetic Resonance Imaging (MRI),
- Nuclear Medicine.

5- COCIR Companies to be enrolled in this programme

The identified companies are as follows:

1. Agfa,
2. Aloka,
3. Elekta,
4. Fujifilm,
5. GEHC,
6. Hitachi,
7. Iba,
8. Medison,
9. Philips,
10. Siemens,
11. Toshiba.

6- COCIR Auditable Process

a) Steps needed:

1. Definition of database
2. Coordination meeting with
   - European Commission (EC)
   - COCIR Members and establishment of a secretariat
3. Establish a reporting format
4. Collection of data from members
5. Issue official reports for EC Consultation Committee

b) Estimated COCIR Budget per annum (expected for 3 consecutive years):

• Internal costs (mainly database): 8.000 €
• External costs (consultancy): 37.000 €
• Communication: 5.000 €

c) Meeting planned for 2009:

- 4-5 internal face to face meetings
- 1 TCON per month
- 4 meetings with EC

7- Actions for CEOs or Company Officers of COCIR companies to take

1. To sign the attached official commitment to the Self-Regulatory approach and send it to COCIR Office.

2. To appoint representative(s) to the COCIR EuP Steering Committee with authority to represent and make decisions for the company on all aspects of the EuP Self-Regulatory approach. This nominated person will represent the company in the Steering Committee that will be established as soon as names of nominees for each company are identified.

8- COCIR EuP Steering Committee

a) Objective and scope for 2009:

The Steering Committee will set the targets and the COCIR Office will aggregate confidential company data to report overall industry performance against the targets initially agreed with EC. IEC 60601-1-9 standard could be the reference document to manage energy consumption in the use phase.

b) Decision-making rule:

All decisions to be taken by the Steering Committee must be reached by consensus.

c) EuP Steering Committee (SC) role and responsibilities:

This Committee will meet regularly to:

1. Define and perform a pilot for a specific product group in 2009,
2. Create common industry targets and approach for measuring performance,
3. Review performance against the targets,
4. Agree any additional costs for managing the auditable process for setting, targets and reporting environmental savings to COCIR,
5. Create a template report, compile the data gathered and notify periodically the progress to EC.

d) Activities to be implemented to build a COCIR Auditable Process (managed through the EuP Steering Committee):

1. Coordinate meetings:
   - with EC,
   - with COCIR members.

   Frequency of those meetings planned:
   - 4-5 face to face Steering Committees meetings,
   - 1 Teleconference per month,
   - 4 meetings with EC.
2. Establish a Reporting Format (through EuP Steering Committee)
3. Database definition and collection of data from members
4. Issue and submit compiled reports to EC Consultation Forum

Appendix: FORMAL ENGAGEMENT FROM PARTICIPATING COMPANIES

(to be signed by COCIR Company Company Officer engaging its company in COCIR activities)

[Company Name] commits to participate in and support the COCIR EuP Self-Regulatory Approach for Medical Devices. We designate _____ to be the representative(s) appointed to the COCIR EuP Self-Regulatory Steering Committee for Medical Devices to represent our company.

_____
Name

_____
Position

_____
Signature

_____
Date

APPENDIX 2: EuP Steering Committee Governance

C O C I R I N T E R N A L P R O C E D U R E

Issue Date: **08 Apr. 2009**	**PG 38 DE**	**COCIR 2009-007** rev.

TITLE: **EuP Steering Committee Governance**			
DISTRIBUTED TO: All participating companies in EuP Steering Committee			
Procedure Owner	**Signature & Date**	**Revision level**	**Reason for revision**
Nicole DENJOY			

1.0 INTENTION

COCIR has demonstrated its leadership in the field of environment through various initiatives including activities at IEC level via the international standard IEC 60601-1-9, efforts developed (guide and web-based application), to help companies complying with REACH Directive, and via the Good Refurbishment Process contributing to recycling economy.
It is COCIR's ambition to continue to develop its innovative technologies while contributing to a greener economy.
This document provides all details on how the EuP Steering Committee is functioning.

2.0 SCOPE

This procedure applies to all companies who have committed to participation in the EuP Self-Regulatory Initiative and who have endorsed the EuP Code of Conduct.
Companies eligible to participate in this activity can be:

- COCIR company members present in the field of medical imaging equipment,
- Companies placing medical imaging equipment on the European market.

The product range considered in this initiative are medical imaging equipment for which COCIR companies cover more than 80% of the total market. This industry sector is mainly including the following product groups, also called modalities:

- Computed Tomography,
- Magnetic Resonance Imaging,
- Ultrasound,
- X-Ray,
- Nuclear Medicine.

Note: Refurbished products are out of the scope of this initiative because that equipment would be refurbished as per their original design.

3.0 MAIN OBJECTIVE

The main objective is to have a clear and transparent process for all relevant stakeholders interested in knowing more about this initiative.

This procedure includes role and responsibilities of participating members who have committed to participate in this initiative.

4.0 PROCEDURE

4.1 Creation of the Steering Committee

Decision to create a Steering Committee for this initiative was taken within the COCIR Environmental Policy Focus Group after all COCIR companies reached a consensus on the scope. This decision was made after COCIR presented its intentions to use the Self-Regulatory Initiative to the Consultation Forum of 28 May 2008.

This Committee will meet regularly to:

1. Define a common methodology for all product groups,
2. Define and perform a pilot for a specific product group in 2009,
3. Create common industry targets and approach for measuring performance,
4. Review performance against the targets,
5. Agree any additional costs where needed and once approved by the EuP Steering Committee,
6. Create a template report, compile the data gathered and notify periodically the progress to EC.

Frequency of meetings planned per year:

- 4 to 6 face to face Steering Committees meetings,
- 1 Teleconference per month.

4.1.1 Constitution

A COCIR Environment Focus Group meeting took place with all interested companies willing to engage in this process. A Strategy and action plan was discussed and subsequently reviewed further. Once a consensus was reached the paper constituted the formal engagement/endorsement COCIR gathered from each participating company willing to contribute. The 1st formal EuP Steering Committee (kick-off) was held on 08 April 2009 in Brussels. The following companies endorsed the strategy and action plan:

1. Agfa,
2. Aloka,
3. Elekta,
4. Fujifilm,
5. GEHC,
6. Hitachi,
7. Iba,
8. Medison,
9. Philips,
10. Siemens,
11. Toshiba.

4.1.2 Election of chair and deputy chairs

The chair and deputy chairs must have been elected:

1. by their company to represent them in this committee and must have a profile and competencies directly linked to EuP Directive and other environmental activities within their companies,
2. By the EuP Steering Committee members.

It was decided to elect one chair and 2 deputy chairs due to the volume of work to be delivered. Volunteering chair and deputy chairs were proposed and vote took place at the kick-off meeting. Those candidates were elected unanimously.

Chair: Mr Freimut Schroeder, Siemens

Deputy Chair 1: Hans van der Wel, Philips

Deputy Chair 2: Beth Hulse /James Vetro, GEHC

Those elected persons can, in case of unavailability, be represented by a designee.

4.2 Budget/Financing

Estimated COCIR Budget per annum (expected for 3 consecutive years 2009, 2010 and 2011):

- Internal costs (mainly database): 8 000 €
- External costs (consultancy): 37 000 €
- Communication: 5 000 €

The budget is managed as an independent project outside the scope of COCIR core budget. This budget is under the ultimate responsibility of the EuP Steering Committee.
The participating companies having endorsed the action plan at the time of the kick-off meeting committed for this investment covering until end 2011.

Any other company willing to engage in this process will be accepted provided they comply with the criteria described in section 4.4.1. Such company will have to pay an annual charge of 3 000€ corresponding to administrative and overall handling of this process implied in this Initiative.

4.3 Rules

4.3.1 Chair/Deputy chairs

The chair and deputy chairs elected have to work in tandem. If the chair cannot attend meetings/telephone conference (TCON) one of the deputy chairs can replace him/her.

4.3.2 EuP Steering Committee Secretariat

Secretariat is ensured by the COCIR Office. Mandated experts could be asked to support partial activities linked to this initiative. In this case the contract must be signed by the COCIR office and the mandated organization once terms and conditions reviewed and approved by the EuP Steering Committee.

4.3.3 Data gathering

The data gathered from each participating company will be compiled by COCIR Office or mandated to an outside source in order include them into consolidated report which would then be published.
Outsourcing will be possible with the condition the mandated organization complies with confidentiality rules described in section 4.3.7.

4.3.4 Participation in Meetings/TCONs

Meetings dates and contents to be covered will be discussed and agreed upon between the chair and secretariat.
All participating companies are recommended to participate in all meetings/TCONs either through their designated representative or an alternative designee
Members of the Consultation Forum (regulatory authorities, EC or NGOs) can participate provided they inform the secretariat in advance. They will be accepted as observers.

4.3.5 Organization of Meetings/TCONs and accessibility

EuP SC secretariat will notify via outlook the participating companies Meeting records will be kept as this constitutes part of the data that can be audited at any time. Those will be posted under COCIR members-only web-site. Specific pass code will be provided to any participating companies as well as members of the Consultation Forum, upon their requests.

4.3.6 Vote

All decisions are taken on consensus basis.

4.3.7 Confidentiality

It is crucial to respect confidentiality rules whenever company data are discussed either through TCONs or face to face meetings or submitted. This means that no specific company name or data shall be mentioned whenever progress is measured on data collection. If a company wants to disclose their own data during conversations with other participating companies, this is exclusively under their own responsibility.

When data is required from all companies and feedback on draft report as well, this is the responsibility of the EuP Secretariat to remind the members in question.

4.3.8 Auditing of EuP Steering Committee

Any interested regulatory authority, NGO or EC members will be allowed to audit the data and other documentation linked to this activity.

4.4 Roles and responsibilities

4.4.1 Participating companies

For companies to be eligible to participate in this initiative they must:

- Sign an official commitment to the Self-Regulatory Initiative and send it to the COCIR Office,
- Appoint representative(s) to the COCIR EuP Steering Committee with authority to represent and make decisions for the company on all aspects of the EuP Self-Regulatory Initiative. This nominated person will represent the company in the Steering Committee.

Participating companies are responsible for:

- providing data when requested by the EuP Steering Committee Secretariat,
- Reviewing draft consolidated report,
- Validating the final report prior to publication.

If feedback is not received by a certain date, it is understood there are no objections from them, process will continue and not be stopped unnecessarily.

4.4.2 Chair & deputy chairs

The chair or deputy chair must allocate sufficient time to prepare the meetings and TCONs with the support of the COCIR Office.

The chair and deputy chairs are eligible to represent COCIR in specific meetings/conferences, provided this is discussed and agreed in advance within the EuP Steering Committee.

4.4.3 COCIR Office

The COCIR Office will ensure that appropriate support is given to this initiative either through the COCIR SG, TRAC manager or administration.

The COCIR office will be responsible for:

- Organizing meetings/TCONs,
- Making sure all participating companies are committed and delivering information/data as required,
- Making necessary appointments with EC upon request,
- Making sure that contracts when needed are validated by the EuP Steering Committee,
- Keep all documentation in separate files for auditing purposes.

4.5 Monitoring and reporting activities

4.5.1 Data collection (quantitative and qualitative)

Collected data cannot be shared with the EuP Steering Committee unless Secretariat has compiled data from
- at least 3 participating companies and
- at least the three companies with the highest market share.

4.5.2 Annual report for publication

This is the responsibility of COCIR Office or mandated external expert to work on the development of the report,

This is the responsibility of the EuP Steering Committee participating companies to review the draft and validate the final report prior making it publicly available. In case participating companies can't respond in time validation has to be ensured ultimately by the EuP Steering Committee Secretariat.

Fair amount of time will be given for review and feedback.

In order to produce a report including necessary data to show evidence that energy saving is effectively done those data must be collected via the EuP Steering Committee Secretariat. Expected average targets for the industry sector will be clearly mentioned.

APPENDIX 3: Compliance with Annex VIII requirements of EuP Directive

Annex VIII Clause 1: Openness to participation

Self-Regulatory Initiatives shall be open to the participation of third country operators, both in the preparatory and in the implementation phases.

Membership of COCIR is open to any company in the Radiological and Imaging, Electromedical and Healthcare IT Industry. Companies who do not wish to become members of COCIR can still participate in this EuP Self-Regulatory Initiative. In this case, COCIR will charge the company a fee to reflect the reasonable costs for the company to participate in the Initiative.

A number of the companies listed in section 2 are third country operators with headquarters located outside the EU, for example, Fujifilm (Japan), GEHC (US), Hitachi (Japan) and Toshiba (Japan). All of these companies are actively involved in the preparatory and implementation phases of this self-regulatory initiative. For example, representatives from these companies attend the Steering Committee meetings held at COCIR offices in Brussels and actively contribute towards the development of the methodology and approach.

Annex VIII Clause 2: Added Value

Self-regulatory initiatives shall deliver added value (more than 'business as usual') in terms of the improved overall environmental performance of the EuP covered.

The trend figures presented in section 4.3 predict that under current EcoDesign efforts (which represents 'business-as-usual' for radiological and imaging medical devices) the average energy consumption for new products would stay the same in 2008, 2009 and 2010 at 762 kWh per year.

The Self-Regulatory Initiative has set a target to additionally reduce the average energy consumption of new ultrasound products placed on the market by 6% between 2010 and 2012. Using 2005 as a baseline, this is equivalent to reducing the average energy consumption of new ultrasound products placed on the market in 2012 by 25% compared to 2005. This target is based on total energy consumption of new products only. It does not take account that new products have increased functionality and deliver even more healthcare benefits to patients. In section 4.4.2 the EuP Steering Committee outlines its plans to develop energy efficiency targets for new products, which would capture increases in functionality of new products compared to energy consumption.

The target to reduce average energy consumption of new ultrasound products placed on the market by 6% between 2010 and 2012 translates to a reduction in average energy consumption from 762 kWh per year down to 706 kWh per year in 2010. Based on predicted EU annual sales in 2012 by COCIR companies of 20,800 units, this is equivalent to a total annual energy saving of 1,165,000 kWhrs. This is equivalent to 624,000 kg of CO_2 per year.

COCIR 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.
- Develop metrics to measure the energy efficiency of ultrasound equipment.

Annex VIII Clause 3: Representativeness

Industry and their associations taking part in a self-regulatory action shall represent a large majority of the relevant economic sector, with as few exceptions as possible. Care shall be taken to ensure respect for competition rules.

Table 1 shows that the participating companies involved in this Initiative represent at least 80% of units sold in the EU for each of the following modalities in the medical imaging equipment sector:

- Computer Tomography (CT),
- Ultrasound,
- X-Ray,
- Magnetic Resonance Imaging (MRI),
- Nuclear Medicine.

This meets the requirement for the Initiative to represent "a large majority of the relevant economic sector". Membership of COCIR is open to any company in the Radiological and Imaging, Electromedical and Healthcare IT Industry. Companies who do not wish to become members of COCIR can still participate in this EuP Self-Regulatory Initiative. In this case, COCIR will charge the company a fee to reflect the reasonable costs for the company to participate in the Initiative.

Industry forums which are designed to share information can give rise to AntiTrust risk, in particular in relation to allegations of collusion by participants in the same market. A violation of the AntiTrust Laws can have serious consequences for COCIR and for companies who become members of the COCIR EuP Self-Regulatory Initiative. Accordingly, all companies who become members of the COCIR EuP Self-Regulatory Initiative are required to comply with the AntiTrust Guidelines contained in *Appendix 4*. The AntiTrust Guidelines specifically prohibit anti-competitive behaviour, for example excluding any companies from becoming members of COCIR and the EuP project.

Annex VIII Clause 4: Quantified and staged objectives

The objectives defined by the stakeholders shall be set in clear and unambiguous terms, starting from a well-defined baseline. If the self-regulatory initiative covers a long time-span, interim targets shall be included. It must be possible to monitor compliance with objectives and (interim) targets in an affordable and credible way using clear and reliable indicators. Research information and scientific and technological background data shall facilitate the development of these indicators.

The trend figures presented in section 9 predict that under current EcoDesign efforts (which represents 'business-as-usual' for radiological and imaging medical devices) the average energy consumption for new products would stay the same in 2008, 2009 and 2010 at 762 kWh per year.

The Self-Regulatory Initiative has set a target to additionally reduce the average energy consumption of new ultrasound products placed on the market by 6% between 2010 and 2012. Using 2005 as a baseline, this is equivalent to reducing the average energy consumption of new ultrasound products placed on the market in 2012 by 25% compared to 2005. This target is based on total energy consumption of new products only. It does not take account that new products have increased functionality and deliver even more healthcare benefits to patients. In section 4.4.2 the EuP Steering Committee outlines its plans to develop energy efficiency targets for new products, which would capture increases in functionality of new products compared to energy consumption.

The target to reduce average energy consumption of new ultrasound products placed on the market by 6% between 2010 and 2012 translates to a reduction in average energy consumption from 762 kWh per year down to 706 kWh per year in 2010. Based on predicted EU annual sales in 2012 by COCIR companies of 20,800 units, this is equivalent to a total annual energy saving of 1,165,000 kWhrs. This is equivalent to 624,000 kg of CO_2 per year.

Participants 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,
- Develop metrics to measure the energy efficiency of ultrasound equipment.

Annex VIII Clause 5: Involvement of Civil Society

With a view to ensuring transparency, self-regulatory initiatives shall be publicized, including through the use of the Internet and other electronic means of disseminating information.

The same shall apply to interim and final monitoring reports. Stakeholders including Member States, industry, environmental NGOs and consumers' associations shall be invited to comment on a self-regulatory initiative.

COCIR will publish the industries Self-Regulatory Initiative document on its website (www.cocir.org). COCIR will also publish the annual performance reporting tables each year on its website.

The EuP Steering Group welcomes comments from the EuP Consultation Forum as this includes wide representation from Member States, industry, environmental NGOs and

consumer associations. In addition to comments during the meeting, COCIR would also welcome any follow-up comments after the meeting by e-mail to secretariat@cocir.org.

Annex VIII Clause 6: Monitoring and Reporting

Self-regulatory initiatives shall contain a well-designed monitoring system, with clearly identified responsibilities for industry and independent inspectors. The Commission services, in partnership with the parties to the self-regulatory initiative shall be invited to monitor the achievement of the objectives.

The plan for monitoring and reporting shall be detailed, transparent and objective. It shall remain for the Commission services, assisted by the Committee referred to in Article 19(1), to consider whether the objectives of the voluntary agreement or other self-regulatory measures have been met.

The monitoring and reporting plan for the medical imaging equipment Self-Regulatory Initiative is presented in detail in section 8. The EuP Steering Committee will use the Excel spreadsheet tool contained in *Appendix 8* to gather confidential sales data and power consumption data from companies for each model of ultrasound equipment they put on the EU market in 2009, 2010, 2011 and 2012.

These confidential data provided by participants are already externally audited and so these data do not require additional auditing for this self-regulatory initiative:

- Sales data are extracted from financial management systems which are already externally audited to comply with financial regulations,
- Power consumption measurements are required by IEC 60601 to demonstrate compliance with the Medical Devices Directive, which is externally audited. Compliance with IEC 60601 is a central part of the annual external audit of the company's Quality Management System to maintain certification to ISO 13485.

COCIR's role is to consolidate these confidential Excel spreadsheets from each company into a single master Excel spreadsheet for analysis. This simply involves copying each company's individual Excel spreadsheet into the master Excel spreadsheet. This simple activity does not require additional auditing for this self-regulatory initiative.

COCIR will analyze the consolidated master Excel spreadsheet to calculate the total annual sales and total annual energy consumption of new ultrasound products that participants put on the market in EU Member States in 2009, 2010, 2011 and 2012. These data will be used to calculate the average annual energy consumption for new products put on the market in each of these years. The EuP Steering Committee will use these data to assess whether participants are achieving the interim targets and are therefore on track to achieve the final target to reduce the average energy consumption of new ultrasound products placed on the market by 6% between 2010 and 2012.

The EuP Committee will use the reporting table in *Table 4* to report annual performance against the interim energy targets and final 2012 target to the European Commission. For example, the performance reporting table to assess whether participants have met the interim target for 2010 will be issued by The EuP Steering Committee to the European Commission in 2011, based on 2010 data.

Annex VIII Clause 7: Cost-effectiveness of administering the Self-Regulatory Initiative

The cost of administering self-regulatory initiatives, in particular as regards monitoring, shall not lead to a disproportionate administrative burden, as compared to their objectives and to other available policy instruments.

This requirement is directed to the European Commission and Members States to ensure that the costs and administrative burden that medical imaging equipment manufacturers incurs through the Self-Regulatory Initiative is not disproportionate compared to other policy instruments.

Annex VIII Clause 8: Sustainability

Self-regulatory initiatives shall respond to the policy objectives of this Directive including the integrated approach and shall be consistent with the economic and social dimensions of sustainable development. The protection of consumers' interests (health, quality of life and economic interests) shall be integrated.

The sustainability aspects of the medical imaging equipment industry's Self-Regulatory Initiative are addressed in detail in section 5. the EuP Steering Committee shall ensure that the environmental design targets which are set under the Initiative are environmentally sound with regard to other environmental aspects of medical devices. The EuP Steering Committee has verified that the target to reduce average energy consumption of new ultrasound products placed on the market by 6% between 2010 and 2012 will not result in an increase in other environmental aspects of ultrasound products. For example, achieving this energy reduction target will not result in increased materials procurement aspects for new ultrasound products.

Regarding other elements of sustainability, it is important to note that new medical devices are designed to give better and earlier diagnosis, more effective and successful treatment and completely new treatments. In other words, the primary function of a medical device is to protect consumers' health and quality of life. Therefore, Clause 8 requires that this primary function of ultrasound equipment must be taken into consideration when setting objectives (Clause 4), and when monitoring and reporting performance (Clause 7).

Section 4.2 highlights the significant new developments in ultrasound imaging technology which have been achieved in recent years. As a result, ultrasound equipment has become an even more powerful tool for healthcare professionals, to enable better and earlier diagnosis of patient symptoms and therefore more successful patient treatment and outcomes. These new, more powerful imaging techniques have led to increased energy consumption for imaging modules in new designs introduced since 2005, and this has balanced out the general reductions in energy consumption achieved by iterative improvements in product design. As a result, under a 'business as usual scenario' the overall energy consumption for new products would stay the same in 2008, 2009 and 2010.

Under this Self-Regulatory Initiative, the healthcare industry will aim to overcome the increased energy consumption in imaging modules, by making energy savings in other aspects of ultrasound equipment design. However, if new, even more powerful imaging technology is developed in the next few years, the Medical Devices Directive obliges the medical device industry to implement this new state-of-the art technology.

As part of this Self-Regulatory initiative, the EuP Steering Committee will continue to monitor the development of new imaging technology and whether this is essential to

delivering improved consumers' health and quality of life. The EuP Steering Committee will inform the European Commission at the earliest opportunity if the need to implement new imaging technology will affect the healthcare industry's ability to meet the target to reduce average energy consumption of new ultrasound products placed on the market by 6% between 2010 and 2012. In this case, the EuP Steering Committee would propose revised energy consumption targets for discussion with the European Commission.

Annex VIII Clause 9: Incentive compatibility

Self-regulatory initiatives are unlikely to deliver the expected results if other factors and incentives – market pressure, taxes, and legislation at national level – send contradictory signals to participants in the commitment. Policy consistency is essential in this regard and shall be taken into consideration when assessing the effectiveness of the initiative.

The European Commission has issued a Communication on 16 July 2008–COM(2008) 400- entitled: Public procurement for a better environment. A building block of the 'Action Plan on Sustainable Consumption and Production and Sustainable Industrial Policy (SCP/SIP)' aiming at improving the energy and environmental performances of products.

The Communication, also commonly known as Green Public Procurement (GPP) is an initiative addressing all key industries including "Equipment used in the health sector" and should serve as policy instrument for member states guiding their procurement decisions addressing current energy and health concerns. Although the Communication does not in particular cover energy consumption, it states that "the "core" GPP criteria would be set at the level of the energy efficiency requirements". For the time being, the GPP and developed Training Toolkit with 3 modules are expected to have no effect on the COCIR EuP self-regulatory initiative. Inasmuch as the EuP Steering Committee hopes that the GPP criteria will reflect the findings and proposal of the EuP self-regulatory initiative. The EuP Steering Committee is not aware of any other factors or incentives that could affect the Self-Regulatory Initiative.

APPENDIX 4: MoU including AntiTrust Guidelines for Industry Self-Regulation

SPECIMEN

Memorandum of Understanding

Between

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

And

[Company name] based in .....

[Brussels]

[Date to be completed]

Memorandum of Understanding (MoU)

This Memorandum of Understanding (MoU) is entered into and made effective on this [date] by and between:

I. Parties

1. European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), a non-profit trade association founded in 1959 with seat in Brussels representing the medical technology industry in Europe (referred to in this MoU as "COCIR").
2. [Company name] based in ..... distributing medical imaging equipment in Europe

II. Purpose

Whereas

- COCIR represents the healthcare IT industry voice of its corporate members and its National Trade Associations in Europe and outside when necessary. COCIR acts as a communication channel between its members, the institutions and other regulatory bodies mainly in Europe and outside when necessary;
- COCIR is hosting the EuP Steering Committee that was put in place on 08 April 2008 to coordinate activities of EuP Self-Regulatory Initiative currently covering the industry sector of medical imaging;
- [company name] is distributing medical imaging equipment in Europe comprise in one of the following modalities: Computed Tomography, Magnetic Resonance Imaging, Ultrasound, X-Ray or Nuclear Medicine;
- [company name] is committed to complying with the responsibilities described hereafter.

COCIR and ..... [company name] execute this MoU for the following purposes:

1. To allow [company name] to engage in this initiative
2. To increase market coverage for the specific product group(s)

III. COCIR & [company name] Key roles

III.1 COCIR

COCIR over years has developed through its industry members core competencies on capital investment products in the field of imaging, electromedical and healthcare IT.

COCIR Office will ensure that appropriate support is given to this initiative either through the COCIR SG, TRAC manager or administration.
The COCIR office will be responsible for:

- Organizing meetings/TCONs,
- Making sure participating company is committed and delivering information/data as required,
- Making necessary appointments with EC upon request,
- Making sure that contracts when needed are validated by the EuP Steering Committee,
- Keep all documentation in separate files for auditing purposes.

III.2 [company name]

To be eligible to participate in this initiative the company agrees to:

- Sign this official commitment to the Self-Regulatory Initiative and send it to the COCIR Office,
- Appoint representative(s) to the COCIR EuP Steering Committee with authority to represent and make decisions for the company on all aspects of the EuP Self-Regulatory Initiative. This nominated person will represent the company in the Steering Committee,
- Comply with the AntiTrust guidelines (detailed in Annex to MoU).

Participating companies are responsible for:

- Providing data when requested by the EuP Steering Committee Secretariat,
- Reviewing draft consolidated report,
- Validating the final report prior to publication.

If feedback is not received by a certain date, it is understood there are no objection from the [company name], process will continue and not be stopped unnecessarily.

Participating company agrees to pay an annual charge of 3 000€ corresponding to administrative and overall handling of this process implied in this Initiative. This amount is applicable for 2009, 2010 and 2011 and will be revised by Jan. 2012.

ANNEX TO MoU

Antitrust Guidelines

Industry forums which are designed to share information can give rise to AntiTrust risk, in particular in relation to allegations of collusion by participants in the same market. A violation of the AntiTrust Laws can have serious consequences for COCIR and for companies who become members of the medical imaging equipment Self-Regulatory Initiative (hereafter: *Initiative*). Accordingly, all companies who become members of the Initiative (collectively "Participating Companies") are required to comply with the following guidelines in connection with participation in the Initiative. Prior to any and all meetings associated with the Initiative, or subgroups thereof, the Members in that meeting shall be reminded of these guidelines and their obligation of compliance herewith.

1. The Medical imaging equipment EuP Self-Regulatory Initiative and its committees or activities shall not be used for the purpose of bringing about or attempting to bring about any understanding or agreement, written or oral, formal or informal, express or implied, between and among competitors with regard to their prices, terms or conditions of sale, distribution, volume of production, territories, customers, or credit terms.

2. In connection with participation in the Initiative, there shall be no discussion, communication, agreement or disclosure among Members that are actual or potential competitors, regarding commercially sensitive information, and in particular their prices, discounts or terms or conditions of sale or licensing of products or services, pricing methods, profits, profit margins or cost data, production plans, market shares, sales territories or markets, allocation of territories or customers, or any limitation on the timing, cost or volume of their research, production or sales.

3. Each Member of the Initiative is obligated and expected to exercise its independent business judgment in determining its commercial strategy, including pricing its services or products, dealing with its customers and suppliers, and choosing the markets in which it will compete.

4. Members of the Initiative, in connection with their participation in the Initiative, shall not enter into any agreement or understanding among themselves to refrain, or to encourage others to refrain, from purchasing any raw materials, product, equipment, services or other supplies from any supplier or vendor or from dealing with any supplier or vendor.

5. Members of the Initiative, in connection with their participation in COCIR EuP Self-Regulatory Initiative, shall not attempt to prevent any person from gaining access to any market or customer for goods and services, or attempt to prevent any person from obtaining a supply of goods or services or otherwise purchasing goods or services freely in the market.

COMMITMENT

to COCIR EuP Self-Regulatory Initiative

(to be signed by Company Officer engaging its company in this Initiative)

[Company Name] commits to participate in and support the EuP Self-Regulatory Initiative.

We designate _____ to be the representative(s) appointed to the EuP Self-Regulatory Steering Committee to represent our company.

_____
Name

_____
Position

_____
Signature

_____
Date

Acknowledgement from EuP Steering Committee Secretariat

For COCIR

_____

Nicole Denjoy
Secretary General

_____

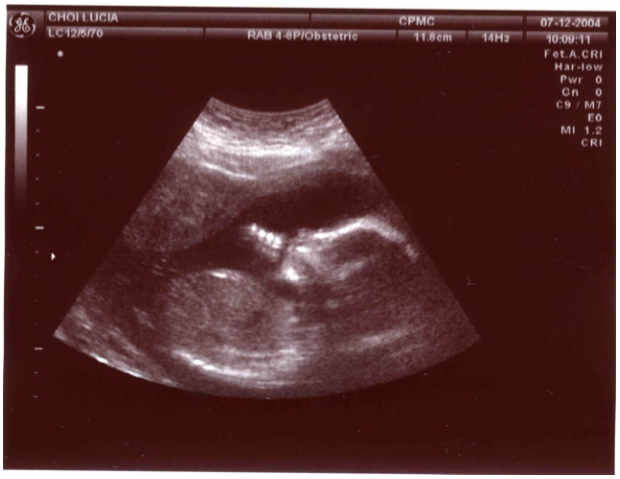
Date Signed

APPENDIX 5: 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 foetus.

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.

Figure 3: Ultrasound cart, linear array transducer and scan image of a foetus



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.

Older technology transducers focus their beam with physical lenses. Newer technology transducers use phased array techniques to enable the sonographic machine to change the direction and depth of focus.

Typical ultrasound scanners operate in the frequency range of 2 to 18 megahertz, hundreds of times greater than the limit of human hearing. The choice of frequency is a trade-off

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

For the purposes of this self-regulatory initiative, the definition of ultrasound includes all low end, medium and high end products and

- Includes the standard/basic probe designed for the system,
- Includes the monitor which is supplied,
- Includes any physically integrated (i.e. built into the ultrasound unit) peripherals (e.g. printers, VCRs, DVD/CD Drives),
- Excludes any stand-alone peripherals (e.g. printers, VCRs, DVD/CD Drives),
- Excludes any stand-alone data archive system,
- Excludes any stand-alone CD/DVD/Video recorders,
- Excludes bone densitometry.

APPENDIX 6: Life Cycle Assessment of ultrasound equipment and assessment against environmental criteria listed in Annex 1.3 of the EuP Directive

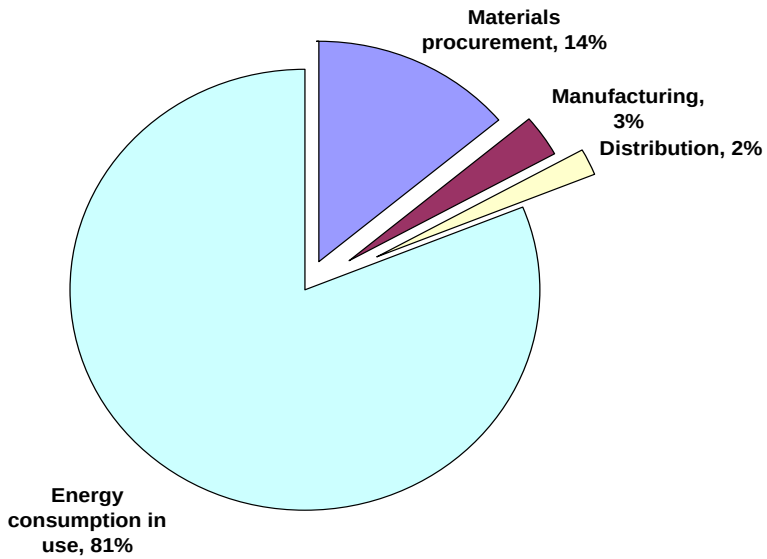
1. Life Cycle Assessment of ultrasound equipment

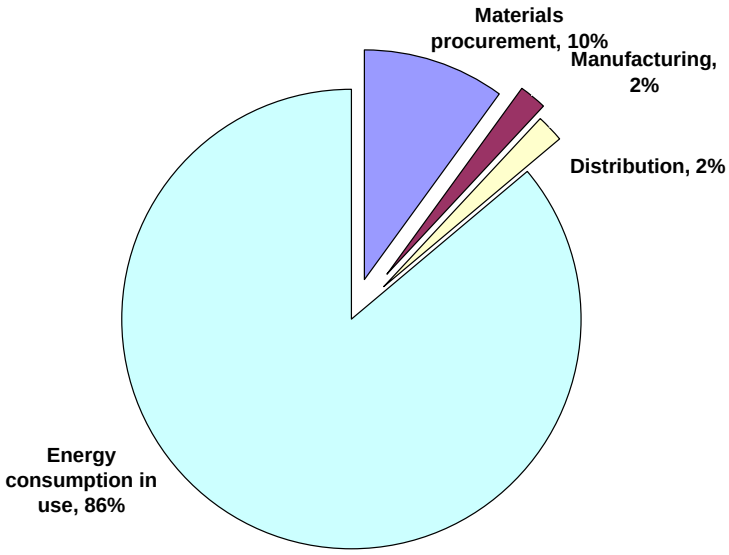
COCIR companies have used Life Cycle Assessment (LCA) methods, e.g. the Eco-indicator 99 impact assessment method (see also www.pre.nl) or Easy-LCA based on LIME, to assess the relative environmental impacts arising from different phases in the life cycle of ultrasound products (see also EuP Directive, Annex 1, Part 1.). These methods (same as all others) are science based impact assessments for LCA and pragmatic EcoDesign tools. They offer a way to measure various environmental impacts, and show a final result in a single score. These environmental impacts include:

- Materials procurement,
- Manufacturing,
- Distribution,
- Use,
- Waste collection and treatment,
- Recycling.

The results of a representative LCA performed for two ultrasound products are shown in *Figure 4.*

Figure 4: Percentage of total life cycle environmental impact (Lime) arising from different stages in the life cycle of two ultrasound products





Ultrasound Product 2

Below *Table 5* highlights that, on average, energy consumption during the use phase accounts for 83% of the total life cycle environmental impact of ultrasound products and that materials procurement accounts for 12%.

In this context participants also want to point out one particularity of accessories which are normally excluded, as it applies to all ultrasound products in the same manner. Adding applied gel and cleaning paper usage to the LCA, the impact of the gel and paper to the total life cycle impact could be as much as 20%, thus considerable[27].

Table 5. Average percentage environmental impact arising from different stages in life cycle of ultrasound products

	Average percentage of total life cycle environmental impact
Energy consumption during use phase	83%
Materials procurement	12%
Manufacturing	2,5%
Distribution	2%
Waste collection and treatment	Less than 1%
Recycling	Less than 1%

[27] Calculation is based on: 15 g gel consisting of 86% tap water, 7% propylene glycol, 6% glycerine, 0.55% carboxymethylene, 0.002% FD&C Blue Dye#1; 20 times/day, 7 days a week, 7 years long (calculated with the Eco Indicator 99 impact assessment method).

2. Assessment of ultrasound equipment against environmental criteria listed in Annex 1.3 of the EuP Directive

In addition to the LCA detailed above, COCIR companies used the following 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

Table 6: Assessment of ultrasound equipment against environmental parameter listed in Annex 1.3 of the EuP Directive

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[28] is increasing the recycling of waste equipment at end-of-life which in turn is influencing product design for ease of reuse and recycling, incorporation of used components and use of materials from recycling activities. In 2007 COCIR published Guidelines on Good Refurbishment Practice for Medical Electrical Equipment to ensure that used medical equipment is safely and reliably returned to active service. In 2009 COCIR strengthened the adoption of good refurbishment practices by publishing the Guidelines as an Industry Standard.
(c) consumption of energy, water and other resources throughout the life cycle	Life Cycle Assessment data indicates that energy consumption during use accounts for about 83% of the life cycle environmental impact of ultrasound equipment.
(d) use of substances classified as hazardous to health and/or the environment according to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packing and labelling of dangerous substances (I) and taking into account legislation on the marketing and use of specific substances, such as Directives	The RoHS Directive[29] and REACH Regulation[30] 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 substances declarations web database for REACH, RoHS, Batteries and Packaging

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

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

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

76/769/EEC or 2002/95/EC;	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.

APPENDIX 7: Case Studies to highlight activities that participating companies are undertaking to address materials procurement aspects in design of new ultrasound products

1. 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 5: Previous design Aplio SSA-770A replaced by new design XarioXG in November 2007

Old design Aplio SSA-770A

New design XarioXG SSA-680A introduced November 2007

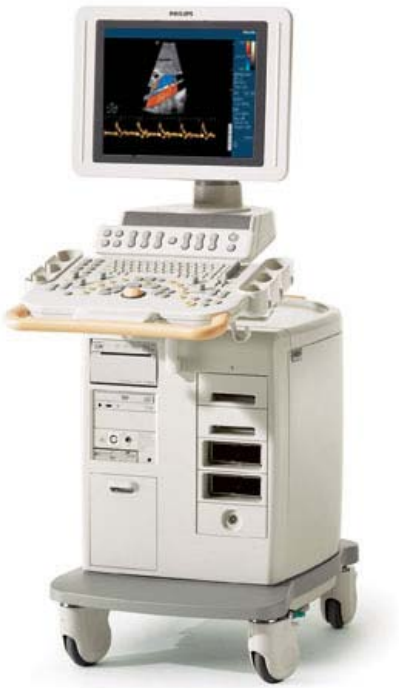
2. Case Study 2: Innovative electronic and mechanical miniaturization technology used in CX50

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.

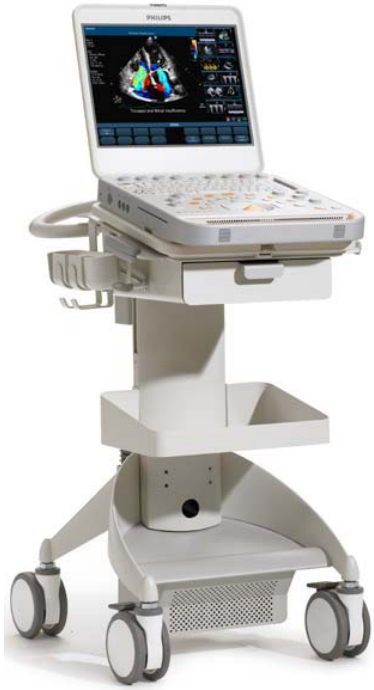
In addition to significant weight reductions where a customer decides to use the CX50 without a cart, the CX50 also delivers the following considerable reductions in environmental impact:

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

Figure 6: Previous design HD11 XE and new design CX50 introduced October 2008



Predecessor design HD11 XE



New design CX50 introduced October 2008

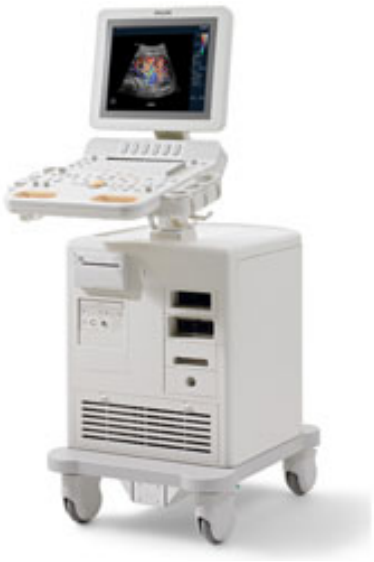
3. Case Study 3: Moving to a flat panel LCD for the newHD7

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 7: Previous design EnVisor 2540 and new design HD7 introduced March 2008

Predecessor design EnVisor 2540



New design HD7 introduced March 2008

APPENDIX 8: Spreadsheet to gather power consumption and sales data for ultrasound units sold in EU

Power consumption and sales data for mains power and battery power ultrasound products

Completed spreadsheet containing all of your mains powered and battery powered ultrasound products must be returned to COCIR **no later than 20 May.**

For example, product 1 may be a battery powered unit in which case you would provide data in rows 8, 9, 15, 18 - 21 and 29 only. Add / delete colums as necessary

– Includes the monitor which is supplied
– Includes any physically integrated (i.e. built into the ultrasound unit) peripherals (e.g. printers, VCRs, DVD/CD Drives)
– Excludes any stand-alone peripherals (e.g. printers, VCRs, DVD/CD Drives)
– Excludes any stand-alone data archive system
– Excludes any stand-alone CD/DVD/Video recorders
– Excludes bone densitometry

Product model number(s) and version numbers (if applicable):	U/S product 1	U/S product 2	U/S product 3	U/S product 4	U/S product 5	U/S product 6	U/S product 7	U/S product 8	U/S product 9	U/S product 10
Number of channels in ultrasound probe:										
Mains power units: Power consumption of the unit in kW										
Scanning / ready to scan*										
Standby (if applicable)*										
Off/hibernation*										
Battery powered units: Energy consumption of the unit in kWh										
Energy consumption in kWh to charge the unit from 100% discharged state										

Number of units sold in Europe since 2005										
	2005									
	2006									
	2007									
	2008									

Mains power units: Power consumption for future planned design if applicable										
Scanning / ready to scan*										
Standby (if applicable)*										
Off/hibernation*										

Battery powered units: Energy consumption for future planned design if applicable										
Energy consumption in kWh to charge the unit from 100% discharged state										

***For this project, please use the following definitions**

Scanning / ready to scan – System already booted up. This is the average power consumption for a system which is actively scanning or ready to scan in any scanning mode

Standby – need to boot up the system. System ready to boot up/resume operation from a reduced power consumption standby state. A Standby mode may not be supported by all products.

Off/hibernation – System off, plugged into mains, circuit breaker on.

APPENDIX 9: Example of Environmental Product Declaration

1. Datasheet

Device name

Ecological product information

Operational data		
Heat output of the device and energy requirement for cooling - at base load * - at maximum load **	 kWh kWh	 In the examination room
Permitted ambient temperature	* C (permitted range)	In the examination room
Permitted moisture level	% rel. moisture level (permitted range)	In the examination room
Noise level - at base load * - at maximum load **	dB(A) dB(A)	Text note on the measurement procedure used Aim: future measurements in accordance with IEC 60601-1-1-32
Energy consumption: - 'Power-on' value*** - at base load * - at maximum load **	 kWh kWh kWh	
Power-on time	Less than 5 mins. (If more specify exact time)	From 'off' until operational status has been reached
Power-off time	Less than 5 mins. (If more specify exact time)	From operational status until completely 'off'

Technical specifications		
Heat recovery interface	Available/Unavailable	
Type of possible cooling	Text note (type of cooling)	
Ability to completely power-off the device is available	Yes/No	
Possible to adjust the height for the operator	Yes/No	If costs are higher: reference
Uniform operational symbols on the device families	Yes/No	Reference to which product family this applies to

Page 1

Radiation		
Measures/techniques for lowering the radiation exposure to x-ray radiation	Text note on reduction technique	
Reductions with regards to the reference value for patients	Reductions in %	
Measures/techniques for lowering exposure to electromagnetic fields	Text note on reduction technique	
Reductions with regards to the treshold for patients	Reductions in %	

Wearable parts and consumables (independent from service contract)

Product (10 to 20)	Service life	Disposal advice

Disposal/material information		
Disposal concept for the device at the end of ist service life	Reference to further information	
Recycling passport for the device	Reference to where it can be found	
Dangerous substance list available (list of substances not included/excluded)	Reference to list	

Page 2

Disinfection		
Non-permitted method of cleaning the device		
- Device overall - Limitations on certain device components	Text note Text note	
Negative list of substance classes incompatible with device disinfection		
- Device overall - Limitations on certain device components	Material classes Material classes	
Able to use the device in a sterile environment	Yes/No	
Size of the surface area to be disinfected	Square centimetre and component to be disinfected	Surface areas with which the operator or patient comes into contact

Additional ecologically relevant information		
Cumulated energy requirement for manufacturing/disposal	MWh, Relation	
Instruction components		
- Information on energy saving - Information on efficient disinfection - Information on appropriate handling of equipment	Yes/No Yes/No Yes/No	

Point of contact

* Base load: the device is operational but no patient examination is taking place
** Maximum load: average value for energy consumption per examination and patient
*** Power-on value: from 'off' until operational status has been reached

Page 3

2. Instructions on filling out the datasheet

The datasheet currently available takes the form of a grid and is to be used for the requesting of ecological product information for diagnostic imaging devices. It was specifically developed for use on ultrasonic and x-ray devices as well as computer and magnetic resonance tomography systems.

The datasheet contains seven categories:

A. Operational data
B. Technical specifications
C. Radiation
D. Wearing parts and consumables
E. Disposal/material information
F. Disinfection
G. Other ecologically relevant information

The individual categories are each subdivided into three columns. The first column contains the points assigned to the overall topics, the second the respective specific details (figures, lists, etc.). There is space in the third column to comment on the respective points, wherever necessary or stipulated.

Explanations to the points mentioned in the individual categories are listed below.

A. Operational data

1. **Heat output of the device and energy requirement for cooling**
   The heat output and the energy requirement for cooling are to be based on the room in which the device is set up (e.g. the examination room). The information is to be given for base and maximum load respectively in kWh.
2. **Permitted ambient temperature**
   The permitted ambient temperature is to be based on the room in which the device is set up (e.g. the examination room). The maximum permitted ambient temperature range for operation of the device is to be given in °C.
3. **Permitted moisture level**
   The permitted moisture level is to be based on the room in which the device is set up (e.g. the examination room). The permitted relative moisture level for operation of the device is to be given in percent.

Page 4

4. **Noise level**

   Information on the noise level is to be given for the base and maximum load. A text note on the measurement procedure used should be located in the comments column.

5. **Energy consumption**

   The energy requirement for reaching operational status from "off". The information is to be given for base and maximum load respectively in kWh.

5. **Power-on time**

   The time interval between 'off' until the device has reached operational status is to be stated here. If this is less than 5 minutes then '<5 minutes' is sufficient information. If the power-on time is more than 5 minutes then a precise timing is to be given.

6. **Power-off time**

   Information is to be given on the time it takes for the device to power-off from operational status until it is completely 'off'. If this is less than 5 minutes then '<5 minutes' is sufficient information. If the power-off time is more than 5 minutes then a precise timing is to be given.

B. Technical specifications

1. **Heat recovery interface**

   It is to be stated here whether an interface is available for heat recovery.
   A Yes or No answer is required.

2. **Type of possible cooling**

   It is to be stated here what time of cooling is possible (e.g. air/water, air/air).

3. **Ability to completely power-off the device is available**

   A Yes or No answer is required.

4. **Possible to adjust the height for the operator**

   A Yes or No answer is required. If increased costs arise as a result of providing the option to adjust the height then a reference is to be given under 'Comments' where information about these additional costs is given.

5. **Uniform operational symbols on the device families**

   A Yes or No answer is required. Furthermore information is to be given on what product groups/device families the information relates to.

C. Radiation

1. **Measures/techniques for lowering the radiation exposure to x-ray radiation**

   Specific measures/techniques are to be described here which are to be implemented on the respective device in order to lower exposure to x-ray radiation.

2. **Reductions with regards to the reference value for patients**

   The lowering of exposure to x-ray radiation with regards to the reference value for patients is to be given here in percent. A detailed listing based on current tests and thereby the possible reduction of x-ray radiation is to be stated.

3. **Measures/techniques for lowering exposure to electromagnetic fields**

   Specific measures/techniques are to be described here which are to be implemented on the respective device to reduce exposure to electromagnetic fields.

4. **Reductions with regards to the reference value for operators**

   The reduction of exposure to electromagnetic fields with regards to the reference value for operators is to be given here in percent.

D. Wearing parts and consumables

1. **Products**

   A listing of all products is required here which are to be included as wearing parts and consumables (independently of the maintenance contract). As a rough definition, all articles are to be listed here which must be exchanged by the customer in order to maintain correct operation of the device, independently of whether a maintenance contract is in place of not.

2. **Service life**

   A guideline value on the estimated service life of the respective product is to be given here. This can be expressed either as a specific period (e.g. six months) or a certain number of times it can be used (e.g. the number of exposures that can be taken with an x-ray tube).

3. **Disposal advice**

   With regards to advice on disposal, information is to be given on how the respective product is to be disposed of at the end of its service life. It is not possible to refer to other publications.

E. Disposal/material information

1. **Disposal concept for the device at the end of its service life**
   A reference is to be given here on where additional information can be found on the disposal concept of the device at the end of its service life.
2. **Recycling passport for the device**
   Reference is to be given here on where the recycling passport can be found.
3. **Dangerous substances list available**
   Reference is to be given here on where the dangerous substances list can be found.

F. Disinfection

1. **Non-permitted method of cleaning the device**
   Specific information is to be provided here on what types of cleaning are not permitted to be carried out on the device (e.g. spray disinfection). Furthermore, information is to be provided on whether certain limitations exist for certain device components. These device components must likewise be named.
2. **Negative list of substance classes incompatible with device disinfection**
   Specific information is to be provided here on what substance classes are not permitted for cleaning the device. Furthermore, information is to be provided on whether certain limitations exist with regards to substance classes for certain device components. These device components must likewise be named.
3. **Able to use the device in a sterile environment**
   A Yes or No answer is required.
4. **Size of the surface area to be disinfected**
   In this regard, surfaces with which the patient or operator comes into contact are to be understood as being surface areas which are to be disinfected. The area of the surface to be disinfected is to be given here in cm^2, as well as the device components which must be disinfected.

G. Other ecologically relevant information

1. **Cumulated energy requirement for manufacturing/disposal**
   The cumulated energy requirement is to be given in MWh.
2. **Instruction components**
   A Yes or No answer is to be given here on whether the following points are a component of the briefing.