INDUSTRY SELF-COMMITMENT IN THE ECODESIGN OF MEDICAL IMAGING EQUIPMENT

Riccardo Corridori

COCIR –European Coordination Committee of Radiologic, Electromedical and Healthcare IT Industry

Abstract: The objective of this paper is to illustrate the achievements and results of the COCIR Self-Regulatory Initiative (SRI) in the ecodesign of medical equipment. COCIR, the European coordination Committee of the Radiological, Electromedical and healthcare IT Industry launched in 2008 a SRI with the European Commission in compliance with the requirements specified by the ErP directive, to reduce the environmental impact of medical imaging equipment through ecodesign.
The initiative, officially acknowledged in 2012 by the EU Commission has already provided significant results and the findings have been already used in the project, launched by the European Commission, to develop criteria for the Green Public Procurement of medical devices.

1. THE COCIR SRI

Companies in the medical technology sector have always been very proactive in addressing environmental aspects at the design stage, maintaining a balance with performances and safety of medical devices. Environmental impacts created in the product life cycle such as manufacturing by production, distribution, use and at the product's end of life can be best managed/addressed during the product specification and design phase. At this stage, all environmental impacts, occurring in the product life cycle, can be taken into account.

With the publication of the Ecodesign Directive in 2005 and the definition of the first implementing measures, COCIR companies realized that the Directive approach, if applied to medical devices, would have brought limited benefits but would have hampered flexibility in the adoption of design solutions to achieve the best possible clinical performances. Therefore COCIR companies came together in 2008 to define and launch a project for a voluntary initiative, based on the long experience in ecodesign, to be proposed to the European Commission as an alternative to regulatory requirements. COCIR companies were sure they could have achieved the same results with this initiative or even better, than any implementing measure with mandatory regulatory requirements on ecodesign.

During the EC Consultation Forum meeting on 28 May 2008 COCIR presented its first proposal for an industry-led Self-Regulatory Initiative on ecodesign of medical imaging equipment.

After a first complete version in 2011, many rounds of comments and thanks to the results of a pilot project focused on ultrasound equipment, the COCIR SRI was submitted to the European Commission and Consultation Forum in January 2012. It has been officially acknowledged by the EC in November 2012. In 2013 an updated and improved 3rd version has been published by COCIR.

The SRI applies to the following imaging equipment:

- Magnetic Resonance Imaging equipment (MRI)
- Computed Tomography (CT)
- Nuclear Medicine (NM)
- X-ray
- Ultrasound (US)
- Therapy equipment (starting from 2016)

Since 2010, every year, a new modality is brought into focus of the methodology for the definition of ecodesign goals.

2. THE SRI METHODOLOGY

The SRI methodology [1] is the methodology participating companies follow to set ecodesign targets for their products and ensure that they are achieved.

The purpose of the SRI methodology is to:

- Provide a transparent and continuous process to control the application of ecodesign targets while protecting company confidential information.
- Set a priority sequence for the equipment evaluation.

- Identify top environmental aspects.
- Set environmental targets.
- Systematically engage stakeholders.
- Monitor and report progress.

The SRI methodology is based on six key steps.

1. Gathering of baseline data
2. Prioritization
3. Identification of environmental aspects
4. Definition of environmental goals
5. Implementation into company processes
6. Monitoring and reporting

3. MEASUREMENT OF ENERGY CONSUMPTION

Step 3 of the SRI methodology identified, through the use of Life Cycle Analysis, that energy consumption during the use phase represent the most significant environmental aspect of medical imaging devices. Therefore the methodology focused on defining energy consumption and on setting ecodesign goals for the reduction of energy usage.

The definition of standards for the measurement of the energy consumption and the definition of an energy efficiency index are the key elements for the achievement of environmental improvements.

Unlike for other electric and electronic equipment, no international or recognized standards have been developed for the measurement of energy consumption of medical devices. This is due to the fact that the most important aspect driving purchasers' choice is the clinical performance rather than the energy consumption. Nonetheless in recent years the concept of "running costs" over the life time has become more common and therefore higher attention has been given to energy aspects considering the raise in electricity costs.

Medical devices have been estimated to contribute to energy consumption in hospitals around 19% (*Source: The Danish Energy Saving Trust "Energy efficiency in hospitals and laboratories"*). The percentage can be even higher in clinics.

Since 2010 COCIR have developed methodologies to measure the energy consumption of MRI, CT and X-ray equipment which are public and available for download at the COCIR website. The definition of such a methodology requires around 1 year of intense work by companies' experts and engineers as results have to be solid, repeatable and comparable.

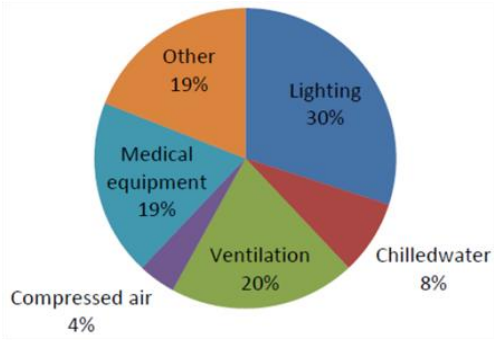

Figure 1: Typical distribution of electricity consumption in hospitals

3.1. Scanning modes and non-scanning modes

Measuring energy usage in low power modes is not very complex as the power absorption is quite constant over time, while in scan modes the task is very complicate. The parameters affecting power usage in scan modes are many, ranging from the physic of the process to the body region to be imaged, to the specific regulations and calibrations of the device to achieve a specific image result. All those parameters have to be defined in such a way to reflect real usage and also to allow all devices to use the commonly defined set of values.

COCIR realized that for certain modalities in particular CT and X-ray, the biggest contribution to energy use during scanning comes from the x-ray tube which absorbs high power but just for a few seconds. COCIR measured the energy consumption in scan mode according to the defined use scenarios and discovered a contribution to the total energy consumption of scan modes between 3 and 10%. Considering the complexity of such measurement, COCIR concluded that excluding scan modes from energy measurement or introducing simplifications in the procedure does not affect too much the results.

4. SETTING INDUSTRY GOALS

4.1. The fleet approach

The COCIR SRI is based on the so called "fleet approach" that significantly differs from the "traditional" approach used so far by Implementing Measures under the Ecodesign Directive.

Targets are not set as threshold level below which the placing on the market is forbidden, but at the level of the whole Medical Industry (participating in the Initiative) and calculated as the average performance (weighted against sales) of the

products placed on the market by participating companies.

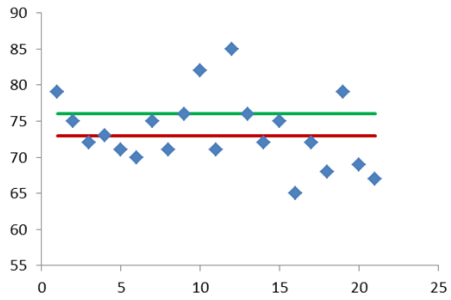

Figure 2: representation of the fleet approach concept

As shown in figure 2, each point represent a specific product model (*x axis*) on the market and its relative environmental performance (*y axis*). The horizontal red line is the market average weighted against sales in the year used as reference. The green line is the market average chosen as target after a certain number of years. While in the classic approach the improvement is ensure by cutting low performing models, the fleet approach allows for the target to be achieved with different instruments.

The methodology provides also for specific company targets that need to be reached by each company to ensure that the industry target is achieved.

4.2. Definitions

The first phase of defining ecodesign goals is the definition of the functional unit(s), product description, mode definitions, system boundaries and typical use scenario(s) to set a common ground on the identification of the impact values of the selected aspect.

4.3. Improvement potential

A specific methodology is used to identify and quantify the maximum improvement potential for the reduction of the energy consumption of the selected modality. The application of the methodology to MRI and CT with the evaluation of the improvement potentials is available on the COCIR website.

With the use of templates and direct interviews, the energy consumption is allocated to the different modules of the modality in the different functioning modes. Experts provide an estimation of the maximum improvement that can be achieved for each module and mode taking into account existing technologies and even technologies which are not yet available (under research or expected to be available at the end of the innovation cycle).

4.4. Definition of Scenarios

The SRI methodologies calculate 4 scenarios which are used to define the final target. For some scenario more than one methodology has been used to take into account specific situations.

- **Baseline scenario**: This scenario represents the market fleet average in the year chosen as baseline. The fleet average is calculated as the weighted average of the performances of all models placed on the market against sold units.
- **Business as usual (BAU) scenario in 20xx**: This scenario represents the market fleet average in year 20xx under the assumption that no SRI is in place. COCIR defined two methodologies to estimate this scenario which takes into account the expected evolution of the technology, market strategies and existing ecodesign programs.
- **Best not yet available technology (BnyAT) scenario in 20xx:** This scenario represents the market fleet average in 20xx assuming that:
  - All possible improvements have been achieved and
  - All the best available technologies have been used and applied at the same time.

To define this scenario, the data on improvement potentials is used.

- **Beyond business as usual (Beyond BAU) scenario:** This scenario represents the target market fleet average in 20xx assuming that all reasonable improvements have been implemented. 2 methodologies have been defined by COCIR to ensure the scenario is ambitious (better than the BAU scenario) but not unrealistic.

4.5. Definition of the Innovation cycle

The innovation cycle is defined as the time needed to bring a new technology on the market, from the research and testing phase to the regulatory approval. This period is different for each modality and is used as reference for the target achievement.

5. TECHNICAL IMPROVEMENTS VS USER BEHAVIOUR

The analysis of medical device energy consumption and use scenarios showed the importance of user behaviour. With the exception of the ones used in emergency departments, imaging devices are normally used daily for 10/12 hours during working days. Some imaging devices can be switched off when not in use, while others requires to be always operating to be readily available (or in the case of MRI, to maintain the superconductive magnet at its 4 kelvin temperature). Low-power modes are equipped on imaging devices to allow the energy consumption to be reduced as much as possible but their effectiveness is linked to the way such modes are used and operated.

COCIR realized that the potential savings achievable with a correct use of already existing low power modes is far higher than what can be achieved through technical improvements, as shown in table 1 for MRI and CT.

	CT	MRI
Technical Improvements	1,9%	13%
User behaviour	31%-48%	21,8%

Table 1: comparison of reduction in energy consumption achievable with technical improvements or through user behavior

6. RESULTS ACHIEVED BY COCIR SRI

All data and conclusions presented in this chapter together with additional detailed information can be found on the COCIR website and in the SRI Status Report [2].

6.1. Ultrasound

In 2009 COCIR set a target for the ultrasound equipment in the context of a pilot project to achieve by 2012 a 25% reduction in energy consumption compared to 2005, the year chosen as reference. The pilot concluded in 2012.

As shown by figure 3, in 2012 the annual average energy consumption per unit for ultrasound equipment reached 743 kWh/unit against a set target of 691 kWh/unit. In 2013 the average energy consumption per unit decreased significantly to 643 kWh/unit going beyond the set target.

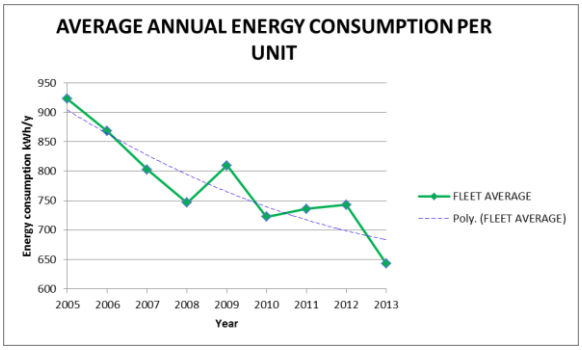

Figure 3: annual market average energy consumption per unit for ultrasound equipment (2005-2013)

6.2. Magnetic resonance

COCIR calculated the 4 scenarios described in chapter 4.4 (see figure 4) and the annual market averages for magnetic resonance. Year 2011 has been chosen as the reference year and an ecodesign target was determined for year 2017 according to the methodology.

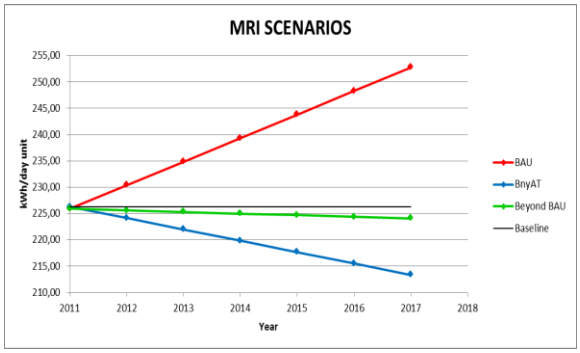

Figure 4: MRI scenarios

In 2013 the daily average energy consumption per unit for MRI equipment decreased from 226 kWh/unit to 209,57 kWh/unit showing a 7,2% reduction compared to 2011.

6.3. Computed tomography

The COCIR assessment on CT showed a very limited improvement potential for the reduction of energy use, focused mainly on low power modes. Considering that low-power modes are rarely used by users (around 70% of CTs are never switched to such modes overnight), the energy savings potential is limited to a 1,9% [3].

The proper use of energy saving modes, on the contrary, can reduce daily energy consumption from 31% to up to 48%.

COCIR concluded that the best way to reduce the environmental impact of CTs is to influence user behaviour through information and training. Therefore, in 2012, COCIR released the "COCIR Guidelines on energy saving: Computed tomography" [3] a brochure highlighting the energy savings that can be easily achieved by users through proper use of energy saving modes

6.4. X-ray

COCIR studied X-ray in 2013 and concluded that the greatest reduction in energy usage can be achieved by influencing the users' behavior through proper education and information about the possible energy savings related to an environmental friendly use.

Already existing Off and LowPower modes could ensure an energy saving between 50,5% and 64,3% of daily energy consumption while technical improvement could achieve less than expected for CT. In figure 5 the energy consumption is reported for 3 scenarios. Each scenario is named according to the mode chosen for the night hours and weekends (e.g. off mode -> scenario Off).

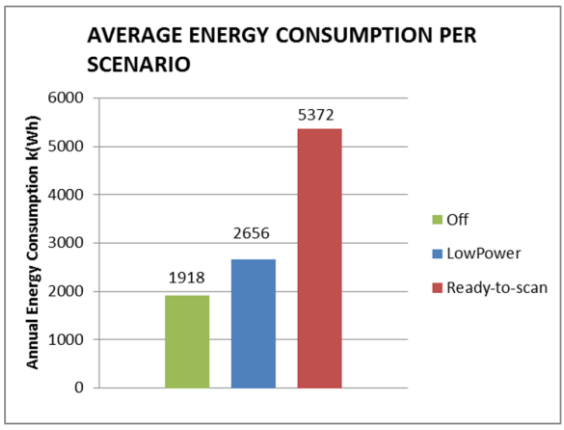

Figure 5: Annual energy consumption of x-ray device per scenario

The use of Off mode during night hours and weekends can save up to 3,45 MWh per year on average per equipment. Nonetheless energy saving options are not widely used by users.

7. GREEN PUBLIC PROCUREMENT

In 2011 the European Commission launched a project for developing a set of criteria for Green Public Procurement of medical devices. GPP is considered a key tool in the context of Integrated Product Policy (IPP) to foster the purchase of "green" products.

COCIR co-operated with the European Commission and the Swedish Environmental Management Council to ensure alignment between the SRI and the criteria to increase the achievements of the COCIR SRI.

The criteria [4], published in 2014, adopted the COCIR energy consumption measurement methodologies for MRI and CT which are publicly available for download at the COCIR website. The use of such methodologies ensures comparability of energy data, allowing, even with some precautions due to the use of pre-determined use scenarios, the comparison between different medical devices.

Moreover, criteria also require that the yearly energy consumption is declared according to different (pre-determined) scenarios to underline how much energy can be saved thanks to proper use of energy saving modes.

In order to allow hospitals to calculate the running costs of the equipment to purchase, COCIR developed simplified formulas to re-calculate energy consumption according to user defined scenarios.

COCIR will cooperate with the European Commission to introduce the new measurement methodology for other modalities like X-ray in the revision of the GPP criteria.

8. BALANCING PERFORMANCES AND BENEFITS FOR PATIENTS

The COCIR SRI focuses on reducing environmental impacts, in particular energy consumption in the use phase, as it is proven, through LCA, to represent the most significant impact.

Medical devices are complex equipment with a lot of functions, used for saving lives and improving life's quality. Safety for users and patients, and healthcare access are fundamental aspects. In fact, at the design stage, environmental considerations have to be weighed against benefits for patients and users.

Defining an energy efficiency indicator for medical imaging devices is impossible today as the technology is very complex, highly customizable, with an indefinite number of different functions and capabilities which influence the energy usage. Moreover such index should take into consideration the continuous improvement in performances, which, for many modalities, steadily increases the energy consumption, generation after generation. Comparing the energy usage of a 7 years model with a new one with more enhanced imaging capabilities is meaningless.

The experience with the SRI showed that a possible approach is to define a set of indexes, similar to an Environmental Product Declaration (EPD) but also taking into account performances and benefits for users and patients. COCIR is actually working to develop a set of sustainability quantifiable indicators (environment, economy and patient benefits) and the methodologies to quantify them. Such set of indicators is going to solve trade-offs; Higher energy usage can be balanced by higher performances, benefits and economic returns (as shown in figure 6). It is up to the purchaser to decide which aspects to favor.

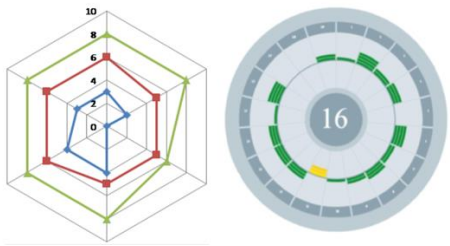

Figure 6: possible ways to graphically represent set of sustainability indicators

The methodology will also allow the aggregation of indicators into a single one, but its usefulness has to be investigated with care

9. REFERENCES

[1] COCIR, "SRI Methodology V3", 2013 http://cocir.org/site/fileadmin/6_Initiatives_SRI/COCIR_SRI_v3_-_Methodology_Final.pdf

[2] COCIR, "SRI Status Report 2013", 2014 http://cocir.org/site/fileadmin/6_Initiatives_SRI/SRI_Status_Report/SRI_Status_Report_2013_15072014f.pdf

[3] COCIR, "Guidelines on energy saving: Computed tomography", 2013 http://cocir.org/site/fileadmin/6_Initiatives_SRI/GoodEnvPractice/COCIR_CT_guidelinesforgoodenvironmentalpractive_19-05-14.pdf

[4] European Commission, "EU GPP Criteria for Electrical and Electronic Equipment used in the Health Care Sector (Health Care EEE)", 2014 http://ec.europa.eu/environment/gpp/eu_gpp_criteria_en.htm

[5] COCIR, "COCIR SRI for medical imaging equipment", 2013 http://cocir.org/site/fileadmin/6_Initiatives_SRI/COCIR_SRI_v3_-_Voluntary_Agreement_Final.pdf

[6] COCIR, "Computed tomography – Measurement of energy consumption: methodology", 2013 http://cocir.org/site/fileadmin/6_Initiatives_SRI/SRI_Status_Report/COCIR_SRI_-_CT_Methodology_for_measurement_of_energy_consumption_-_March2013.pdf

[7] COCIR, "Computed tomography – Study on the potential for environmental improvement by the aspect of energy efficiency", 2013 http://cocir.org/site/fileadmin/6_Initiatives_SRI/SRI_Status_Report/COCIR_SRI_-_Improvement_Potentials_for_CT_Draft_Report_PE.pdf

[8] COCIR, "Magnetic resonance – measurement of the energy consumption: methodology", 2012 http://cocir.org/site/fileadmin/6_Initiatives_SRI/SRI_Status_Report/cocir_sri_-_mri_measurement_of_energy_consumption_2012.pdf

[10] COCIR, "Magnetic resonance – Study on the potential for environmental improvement by the aspect of energy efficiency", 2012 http://cocir.org/site/fileadmin/6_Initiatives_SRI/SRI_Status_Report/pe_international_-_improvement_potentials_for_mri.pdf