COCIR SELF-REGULATORY INITIATIVE
FOR MEDICAL IMAGING EQUIPMENT

ACTIVITIES AT EU AND INTERNATIONAL LEVEL
• Asian Harmonization Working Party (AHWP) is established as a non-profit organization. Its goals are to study and recommend ways to harmonize medical device regulations in the Asian and other regions.

• DITTA attended the event with 2 presentations on:

  Medical Device Refurbishment
  *healthcare in a circular economy*
DITTA PRESENTATION 1

We don't take good care of ourselves
Obesity, heart disease and cancer are global health issues that are worsened by the way we live.

Demand for care is growing
There are simply not enough nurses and doctors to cope with our growing (and ageing) population. Rising healthcare costs are unsustainable.

BUT IS IT SUSTAINABLE?

CIRCULAR ECONOMY IS ALL ABOUT RETAINING VALUE

A circular economy aims to decouple economic growth from the use of natural resources by using those resources more effectively.

For a sustainable world, the transition from a linear to a circular economy is a necessary boundary condition.

Product refurbishment, improving reusability and new business models away from product ownership, will help us in the right direction.
MALAYSIA
Guidelines for good refurbishment practice for medical devices
Preface

1. Objective

2. Scope

3. Terms and definitions

4. Medical device for refurbishment

5. Organisational framework for refurbishment

6. Refurbishing process

   6.1 Step 1 / Selection of medical device for refurbishment

   6.2 Step 2 / Disassembly, Packaging and Shipment

      6.2.1 Disassembly

      6.2.2 Packaging & Shipment

   6.3 Step 3 / Refurbishment

      6.3.1 Cleaning & Disinfection

      6.3.2 Refurbishment Planning

      6.3.3 Cosmetic Refurbishment

      6.3.4 Mechanical and Electrical Refurbishment and System Configuration

      6.3.5 System Testing

      6.3.6 GRP Declaration (Release)

      6.3.7 Packaging & Shipment

   6.4 Step 4 / Reinstallation of Refurbished Medical Device

   6.5 Step 5 / Professional Services

Conclusion
GOING GREEN
2014

Going Green
CARE INNOVATION 2014

Conference Program

Towards a Resource Efficient Economy
10th International Symposium and Environmental Exhibition
An event to discuss future strategies, meet your clients and form strategic partnerships

November 17 – 20, 2014
Schoenbrunn Palace Conference Centre
Vienna, Austria
COCIR PRESENTATIONS

- Industry Self-Commitment in the Ecodesign of Medical Imaging Equipment
- Refurbishment of Medical Systems – Contribution to Circular Economy and Sustainability
- The Impact of RoHS and REACH on the Medical Device Industry
COCIR SELF COMMITMENT IN ECODESIGN OF MEDICAL IMAGING EQUIPMENT

GOING GREEN 2014: CARE INNOVATION
Vienna, 19 November 2014

Riccardo Corridori
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INDUSTRY SELF-COMMITMENT IN THE ECODESIGN OF MEDICAL IMAGING EQUIPMENT

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Abstract: The objective of this paper is to illustrate the achievements and results of the COCIR SRI (Self-Regulatory Initiative) in the ecodesign of medical imaging equipment. The initiative was launched in 2013 by the European Commission, through the B7-2013-1203 project, to develop a voluntary commitment by industry to reduce the environmental impact of medical imaging equipment through ecodesign.

1. THE COCIR SRI

Companies in the medical technology sector have always been very proactive in addressing environmental aspects at the design stage, including a balance with performance and usability of medical devices. Environmental impact studies are essential in the product life cycle and are increasingly being considered by producers, distributors, and users. Products and services are now evaluated on the basis of environmental impact, reducing the product’s cycle, so they need to be taken into account.

With the publication of the Directive from 2009 and the implementation of the first implementing measures, COCIR companies decided to adapt the Directive approach, if applied to medical devices, would have brought limited benefits but would have jeopardized the adoption of design solutions to achieve the best possible clinical performance. Therefore, COCIR companies came together in 2013 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. The initiative was to be achieved by the companies working closely with regulatory authorities.

During the B7-2013-1203 project, COCIR presented its proposal for an industry self-regulatory initiative on ecodesign of medical imaging equipment. After a first complete version in 2013, many rounds of comments and feedback to the results of a pilot project focused on ultrasound equipment, the COCIR SRI Self-Regulatory Initiative was submitted to the European Commission and Parliament for review. Since 2013, the initiative has been updated and improved and will be published by COCIR.

The SRI applies in the following imaging equipment:
- Magnetic resonance imaging equipment (MRI)
- Computed Tomography (CT)
- Ultrasound devices
- X-ray
- Digital EDI (pixel-based imaging)

Since 2009, every year a new methodology is brought into focus by the methodology for the definition of the new cycle.

2. THE SRI METHODOLOGY

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

The purpose of the SRI methodology is to:
- Foster a transparent and continuous process to control the application of ecodesign impacts while ensuring company confidentiality.
- Set a priority response for the equipment evaluated.
As part of its commitment in the context of the Self-Regulatory Initiative, COCIR developed methodologies for the measurement of the energy consumption of medical devices. Such methodologies allow to measure the energy consumption of medical devices according to specific use scenarios in a repeatable and comparable way. As part of the EU Green Public Criteria for medical devices, the methodologies are designed to provide purchasers with all the information they need to calculate running costs and to choose the best equipment for their needs.

Recognising the importance of a correct user behavior to save energy, COCIR developed Guidelines to provide users with recommendations on how to save energy. The Guidelines also quantify the savings for average equipment in terms of energy and euros.

**Measurement methodology**

**Guidelines for users on saving energy**