报废电子设备再制造研究—以MRI和X-Ray扫描仪为例

（申请清华大学工学博士学位论文）

培 养 单 位： 环境学院

学　　科： 环境科学与工程

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二〇一八年四月

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盖比

Remanufacturing approach of end-of-life electronics by MRI&X-Ray scanners

Dissertation Submitted to

Tsinghua University

in partial fulfillment of the requirement

for the degree of

Doctor of Philosophy

in

Environmental Science and Engineering

by

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April, 2018

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摘 要

制造技术的快速发展和消费者对产品质量要求的提高引起电气和电子设备（EEE）更新换代越来越快、寿命也越来越短，因此废弃电气电子设备（WEEE 或电子废物）的产生量也急剧增加。论文通过阐述电子和医疗制造业的再制造概念，梳理工业界和学术界在减少电子废物数量方面所采取的措施，并进行案例分析，得到了有价值的结论，研究成果对延长电子产品的生命周期，降低环境负荷具有重要的技术支撑。

基于再制造理念，通过 WEEE 的产生与环境损耗相互作用分析，论文得出了在再制造概念下解决电子废物问题的技术思路。互联网收集可取代传统收集，企业对企业（B2B）的模式可有助于医疗设备的再制造。材料、零部件和产品的再利用表明再制造在保护环境、节约资源、提升废弃产品价值方面具有很大的应用潜力。

由于材料利用率高、翻新过程简单以及高能源节约率（32%），同时原始设备制造商（OEM）可使用现有技术进行再制造，因此医疗器械具有很大的翻新潜力。本文从立法及市场准入的角度探索了医疗器械翻新在全球范围内的接受程度，发现翻新和新医疗设备的市场主要集中在美国、欧洲和中国。

论文研究了通过翻新实现能源节约和环境影响/效益的潜力，提出了废弃医疗设备处理的另一方案。调查了核磁共振成像（MRI）设备和 X 射线设备的翻新过程，基于 18 个因素评估了翻新过程带来的环境影响。由于 X 射线双平面系统在所有医学影像设备中的翻新率最低（63%），因此评估了其翻新过程中涉及的八类能源消耗的累积能量需求（CED）。X 射线双平面系统的翻新可节约 211 MWh 的能耗，其中材料供应可节约 79%、单元制造可节约 66%、组件装配可节约 85%、系统装配可节约 77%。这些设备最多可运行 10 年，但其功能可通过翻新可再延长 5 年。通过案例研究，并结合该领域存在的主要问题，相关结果可有助于医疗装备学术研究和引导行业的发展。

关键词：非正规回收，再制造，翻新，电子废物，生命周期评价

Abstract

Owing to the rapid expansion of manufacturing, innovation and consumer demand, there has been a vast improvement in various electronic equipment, so the amount of waste electrical and electronic equipment (WEEE, or e-waste) generated has also increased proportionally to production. The main objective of this research is to disclose the remanufacturing concept which can be adopt by the electronic manufacturing and healthcare manufacturing industry. A part of this thesis reveals differential steps debated by industry as well as academia in assets to reduce the amount of e-waste.

The generation of waste electrical and electronic equipment (WEEE) interacts with the environmental depletion. In this case, we gave the examples of addressed issues under the concept of remanufacturing. The online collection opportunity eliminates the classical collection, and implements along with business to business (B2B) approach which is commonly used in the remanufactured servers and medical devices. The material reuse (recycling), component sustainability, reuse (part harvesting), product reuse (after repair/remanufacturing) indicates the recovery potential using remanufacturing tool for a better conservation of resources adding more value to the products.

Because of rapid sales growth in the past few years, medical devices present a potential for refurbishment. With high material utilization, easy refurbishment processes, and high energy savings (32%), original equipment manufacturers (OEMs) anticipate that existing technologies can be re-used, thanks to a complete refurbishment approach. A conducted global overview regarding medical devices refurbishing acceptance from a legislative and market access was analyzed. The covering market access for refurbishment and new devices addresses to United States, Europe, and China market.

This study reflects the potential for energy savings and environmental impacts/benefits through a refurbishing process, demonstrating another option for the use of medical devices approaching end-of-life. We investigated the refurbishment process for Magnetic Resonance Imaging (MRI) and X-Ray systems, evaluating the environmental impacts of 18 factors influenced by the process. We assessed the cumulative energy demand (CED) only for an X-Ray biplane system, which has the

lowest refurbishing percentage (63%) among all medical imaging devices. This CED study covered 8 types of savings involved throughout the refurbishment process. The 211 MWh savings resulting from a CED analysis from original manufacture to the refurbishing process was attributable to: material supply 79%, unit manufacturing 66%, components assembling 85%, system assembly 77%, etc. These devices operate for a maximum of 10 years, but their functionality can be extended another 5 years through refurbishment. We examined the actual market situation, including the effects of module lifetime, the residual value, and the availability of these devices, offering an alternative solution to approach used devices.

Keywords: Informal recycling, Medical Devices, Remanufacturing/Refurbishing, e-waste, LCA

CONTENT

Chapter 1 INTRODUCTION

Electronics are driving our lives from the last decades in a more accelerated process of social communication at a global level. Electrical and Electronic Equipment are defined by the EU as being equipment which are dependent on electric currents, electromagnetic fields between 1000 V in an alternating current and 1500 volts for direct current according with Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE). The diversity of Electrical and Electronic Equipment (EEE) had increased at the same time exponentially with the possibility of communication. Currently, most equipment is transforming in Waste Electrical and Electronic Equipment (WEEE or e-waste) which give an important amount of concern regarding the generation and recyclability of this type of product.

Waste Electrical and Electronic Equipment (WEEE) worldwide generation (Figure 1.1) should be reduced in the near future by implementing methods of remanufacturing and recycling[1]. According to current estimations, the collection rate of 85 % of WEEE generated is broadly equivalent to a collection rate of 65 % of the average weight of EEE placed on the market in the three preceding years[2].

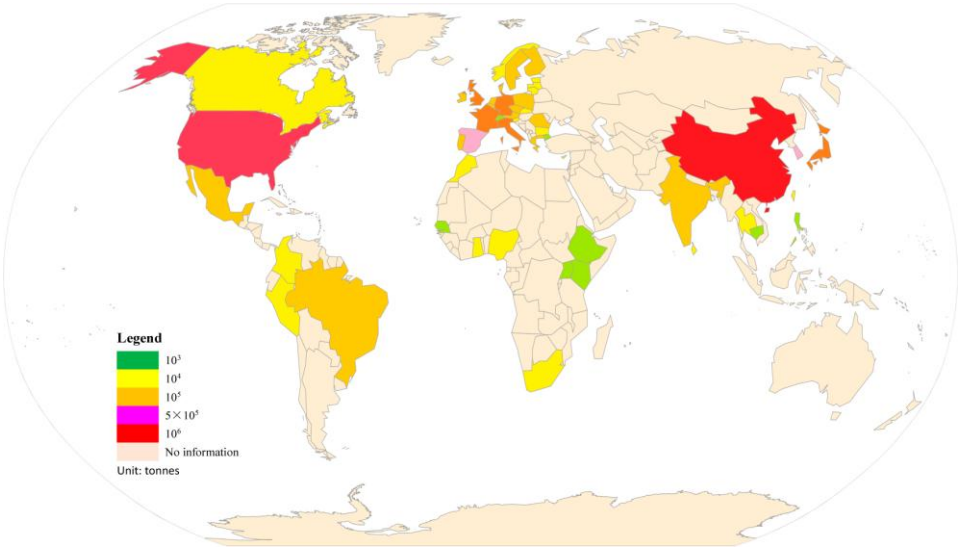

Figure 1.1 Sources of e-waste generation[3].

Electronic manufacturing, innovations, and the variety of electronic products have significantly expanded in the last three decades, which have a significant impact on WEEE generation. In EU, the annual WEEE amount is growing between 3-5%

(waste/year). In 2012 alone, the total sum of treated e-waste was 3.6 million tons, of which 2.6 million tons were recovered (Eurostat,2016). The international commerce, resource depletion, and the miniaturization of components/products had enforced the e-waste legislation/policies to be changed in different countries, depending on their economic development and region. However, WEEE becomes a global issue because of the quick maturation of electronics, the low recycling rate in some cases, the utilization of raw materials, and the pollution effects around the globe[4–6].

The recycling of e-waste on the global level is just 13% (Reck and Graedel, 2012; Gold, 2010) which reveals that informal recycling, artisanal mining of e-waste, eco-design, manufacturing, international markets, and the economic potential of buyers play a crucial role in material recovery, the recycling rate, and environmental problems. Among these, the informal recycling, electronic cannibalism, and in some cases, the impossibility of re-update leads to increasing e-waste, see Figure 1.2.[4,9,10].

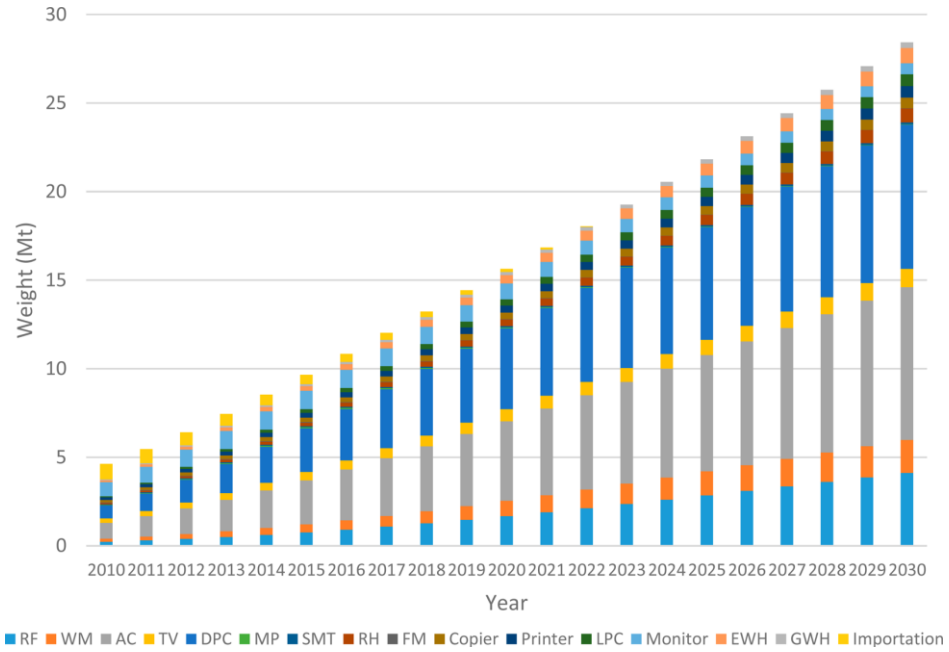

Figure 1.2 WEEE generation in China.[11]

The results of this evidence prompted the development of new strategies in order to implement e-waste eradication in an efficient way through the adoption updating potential from the stage of manufacturing-modeling[12] adopting remanufacturing.

1.1 Research background and significance of this research

Remanufacturing is another way to do manufacturing through updating, which can help to reduce waste from landfill, and incineration giving another destination to the products transforming them in “like-new” for another utilization.

The products undergo a life cycle that is defined by the speed of upgradability, the potential of being remanufactured or recycled, the market growth, and the consumers[13] (Figure 1.3).

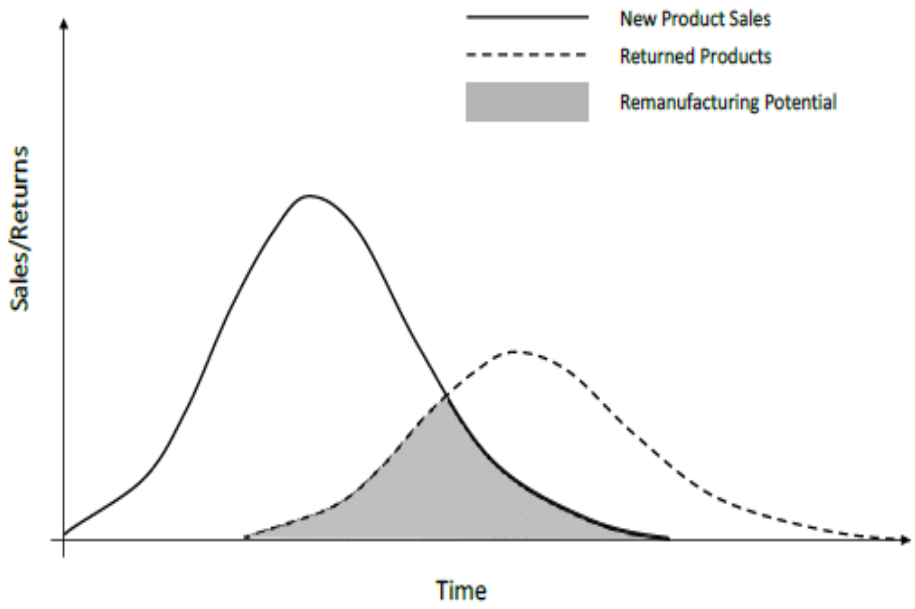

Figure 1.3 Volume of demand (product sales) and return rate over the life cycle of a product, with potential for remanufacturing highlighted through the overlap of the two curves[14].

Remanufacturing increases the utilization of recovered systems and components avoiding the recycling processes while reducing the raw materials by increasing the waste value thought product update in case of used electronics. A worldwide distribution of WEEE and remanufacturing situations described in annex 1 represent the current general status in this field according to the literature. Sixty percent of non-hazardous waste is produced by manufacturers, which demands the implementation of legislation to reduce the environmental impacts of products. In these cases, a remanufacturing strategy plays a crucial role for original equipment manufacturers (OEMs) and for the remanufacturer [15,16].

Remanufacturing is considered to be another option to reduce the e-waste generated by updating the old products to a new stage of use, and offering warranty like a new one.

Globally, the subject has not been discussed intensely, but was tried to be implemented starting with customers and ending with the design for reusability and updatability for the automotive and heavy machinery industry. The literature of specialty is digging the issue concerning the subject, trying to give more transparency and understanding. For instance, in case of servers, copy machines and unknown medical devices refurbishing outputted Magnetic Resonance Imaging (MRI) and X-Ray scanner, their situation is uncertain in terms of energy saving, management process, upgrade possibility, etc.

OEMs produce different devices, components, and assemble with clear specification for the final products in order to differentiate their products from the other outsiders that can influence the price of products by reducing their final sale price. In the way of selecting their technology for determining the potential of remanufacturing, the strategy is developed to give the possibility of replacing some components by the owner or to be redirected to recyclers or remanufacturers at the end of its lifecycle[17,18]. In this case, the remanufactured products represent just 60-70% of the original price as compared to a new product. The production expenses for the remanufacturer represent 35-60% of the final original cost[19]. Among all these factors, sustainability for the remanufacturing industry represents an important global issue[20].

However, the eco-design improvement represents an efficient and effectiveness development to update approached end-of-life product longevity[21]. This concept of reuse, re-update and support of the sustainable manufacturing, consumption and socio-environmental belongs to a Circular Economy (CE) concept.

1.1.1 Circular Economy interaction

In the current linear extractive industrial model, circular economy (Figure 1.4) aspires to specify development, concentrating on mutual benefits. In fact,, encouraging the traditional economic activities to gradually help design products in a manner to reduce waste. Certain transitions such as from fossile fuels to renewable energy sources build an economic, and socio-circular capital for a better environment based on on three principles:

1) Reduce waste and pollution throught design;

2) Extending life of products and materials in use (remanufacturing option);

3) Restore certain systems (remanufacturing option).

The concept of circular economy was first raised by the Ellen Macarthur Foundation in 2008. Later, once the European Union adopted the concept implementing as an environmental solution for waste reduction, and eco-efficiency; reestablishing the connectivity between economy and ecology[22,23].

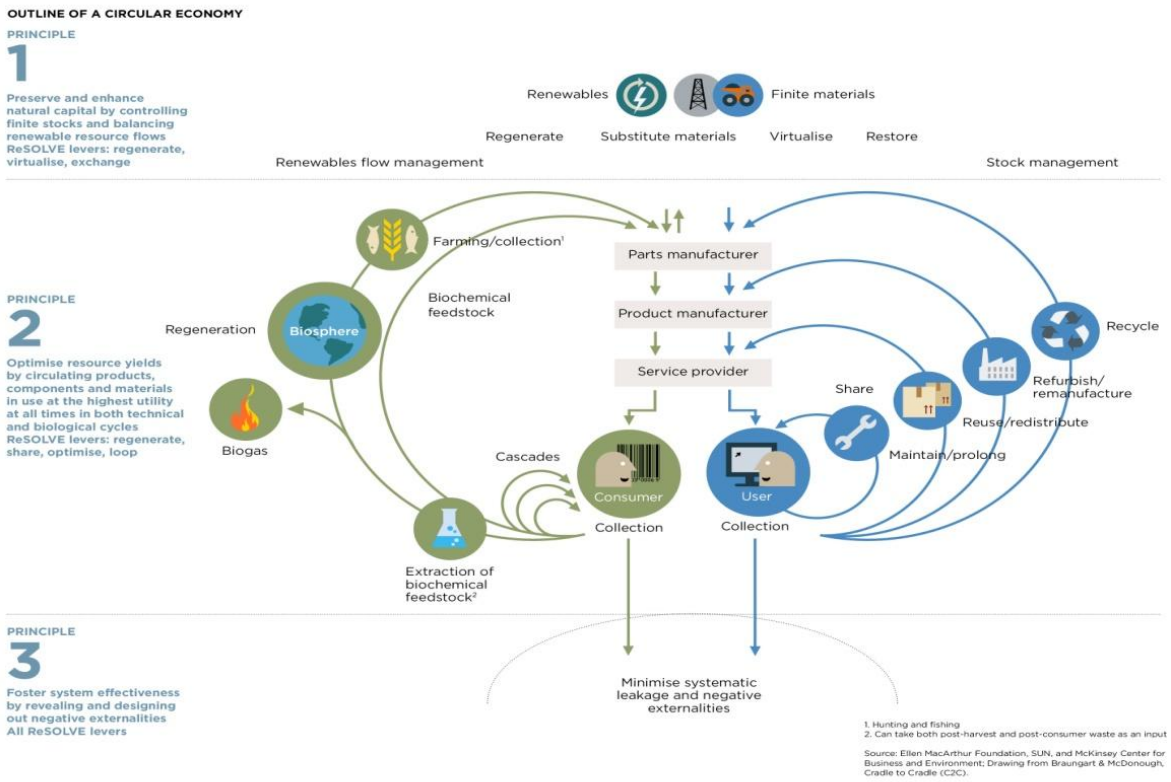

Figure 1.4 Circular Economy diagram by Ellen Macarthur Foundation[24]

Furthermore, in a study conducted in 2009, the European center for remanufacturing and reuse elaborated on the benefits, barriers, and potential areas to implement the concept[25]. The range of applicability raised by Ellen Macarthur Foundation starts with an efficiency versus effectiveness balance for conceptual implementation, and applicability fields (electronics, automotive, textile, and plastic) [24]. An example of circular implementation and economical sustainability is thought remanufacturing/refurbishing process as in the case of medical devices[26], which does not appear to be debated and recognized worldwide(chapter 6). Furthermore, the Sustainable Developing Goals (SDG) were promoted, realized and implemented in the agenda by the United Nations for 2030. For instance, the three pillars of the sustainable goals (Environment, Social, Economic) include Circular Economy (CE) as a sustainable

way to reduce different types of consumptions (energy, resources) fulfilling certain goals from the agenda. Furthermore, this research deployed the benefits of sustainability through a remanufacturing/refurbishing procedure respecting a circular cycle of the product described by CE.

1.1.2 Definition of remanufacturing

Remanufacturing is a process of recovering/bringing used or worn-out products to a ''like-new'' functioning condition, offering an equal functional warranty like a new product and reducing the environmental impacts, waste generation, landfill and the levels of raw materials used in production[27–32].

1.1.3 Remanufacturing Emplacement regarding WEEE

Through all economic, sustainable design, and technical remanufacturing processes, the concept of remanufacturing will develop and improve. According to particular description of the concept of remanufacturing expresses the understanding of the assessment model for creating a sustainable applicability in industry and product reusability to reduce the waste that will/can be generated (Figure 1.5) [33].

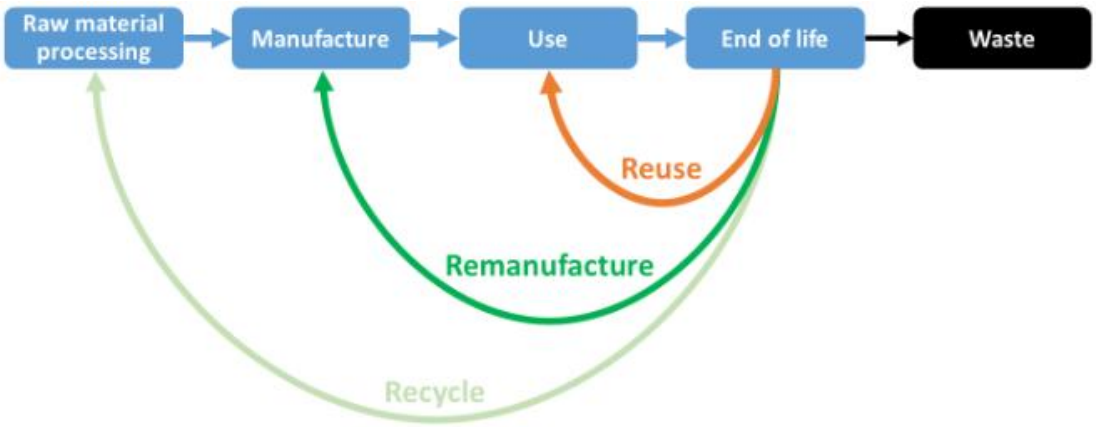

Figure 1.5 Remanufacturing emplacement[34]

Also, these decisions demonstrate how to handle the waste. The reserve supply chains (RSC) and end-of-life (EOL) are required to understand the original equipment manufacturers' (OEM) strategic plans (ex: XEROX, IBM, and SIEMENS)[35]. Their objective is to recover their products and resell them after or before the product reaches the end of life stage, and protects the environment [36,37].

1.1.4 Medical equipments remanufacturing/refurbishing

Healthcare is prohibitively expensive for a large option of the population. In an effort to reduce costs, healthcare providers may resort to practices that may not match international standards and potentially compromise safety. Many hospitals have been re-sterilizing instruments and devices labeled for ‘single use’ by manufacturers[38].

Remanufacturing/refurbishing favors medical equipment that are designed to have a long lifespan, that are non-invasive, that require significant R&D investment, and that are capital intensive to build and purchase [39].

Remanufacturing andrefurbishing play an important role in keeping a piece of equipment functioning (Table 1.1) for as long as it is needed or until it becomes obsolete because of technological advancements or because of functional redundancy[40,41].

Table 1.1 Examples of medical divisions[40]

Medical division	Type of equipment
Anesthesia	Face masks, patient monitoring equipment
Endoscopy/laparoscopy	Range of implements and equipment
Hearing aids & audiometry	Instruments to aid hearing and diagnoses hearing loss
Hospital capital fixed plant	Body scanners, linear accelerators to x-ray apparatus
Hospital supplies & disposables	Sterilisers, gloves, needles, syringes to sample holders
Implantable devices	Miniaturised instruments such as pacemakers
In-vitro diagnostics & kits	Kits (lab-in-a-box)
Infusion & inhalation therapies	Instruments to dispense drugs or nutrients
Invasive surgery	Surgical tools and disposable
Prosthetics and artificial joints	Implants or limb replacements
Ultrasound	Imaging, diagnostic and treatment devices

In the EU, OEMs reportedly resell approximately 80 % of the medical devices they receive back from customers as trade-ins; the remaining 20 % are sold for spare parts[19]. One of medical devices will be refurbished by third-party operators, while the other will be sold for spare parts by brokers[17]. The main refurbished medical devices are Magnetic Resonance Imaging (MRI), Computer Tomography (CT), X-Ray scanners, and Positron Emission Tomography–Computed Tomography (PET-CT).

Producers and remanufacturers of medical devices worldwide and world known: Toshiba, Siemens, Philips, and General Electric.

According to the OEMs investigation of the European Coordination Committee of the Radiological, Electro-medical, Health ICT and Radiotherapy Industry (COCIR) network, the main barriers were the quality of the feedstock available and legislative restrictions.

These barriers to remanufacturing are more significant than labor costs, and the availability of technology and product knowledge. Independent third-party operators reported their remanufacturing activities were constrained by the quality of the feedstock, by the lack of technology, and by product knowledge, high labor costs, and lack of experts.

In the EU, a differential approach to legislative implementation among union states is different, and is an improvement after-sale services accessed by OEM's or other parties regards refurbished systems can be challenges. Finding suitable dealers and networking information are also barriers that face third-party refurbishers operating in this market[42]. Restrictions to market access to used and remanufactured devices raised by the governments of different countries are having an decisive role for the remanufactured products worldwide, especially in Asian countries. These types of equipment are forbiden to be used[43,44].

All the administrative and technical implementations regarding medical devices' remanufacturing are guided by directives and regulations. The most relevant ones are:

1) USA - 21 CFR 820.3 (FDA – Food and Drug Administration, CFR – electrical Code of Federal Regulation);
2) EU-Medical Device Regulation – MDR 2017/745;
3) China Management Regulations on the Recycling and Disposal of Waste Electrical and Electronic Products.

Currently, the remanufacturing/refurbishment of medical devices is less known in the academic literature from various aspects due to data unavailability and confidentiality issues from certain parties. This study reveals certain benefits related to environmental aspects and savings of the remanufacturing process. Furthermore, an approachable legislative situation between new and approached end-of-life devices is revealed to enforce the concept model sustainability.

1.1.5 The importance of remanufacturing

According to the prevailing legislation, an example is given by the European's End-of-Life Vehicle and Waste Electrical and Electronic Equipment (WEEE) directives[2,45]. It is required that OEM's handle their products' EOL by finding suitable solutions for reducing waste and environmental issues caused by their products (implementation of the take back recovery system). Because of these effects, the implementation of remanufacturing helps more industries and businesses create new jobs, and enhance economic development [(ex: from 2009 and 2011 in the United States had increased the number of jobs and financial growth have increased by 15% to at least 43 billion USD[35]]. In 2012, in The International Trade Commission, the number of jobs was approximately 180,000 [45]. The decision has driven the remanufacturing industry towards legislative regulation, and material and energy conservation**.** Altogether, this describes an entire chain from material flow to recycling and can be called a value recovery strategy after the end of life (Table 1.2, and Figure 1.5).

A product recovery plan implemented in the EU between 2005 to 2014 plays an important role in the WEEE reduction which has been mentioned in technical literature within this field. Figure 1.6 reveals the statistics among literature studies availability in the WEEE field from EU[46].

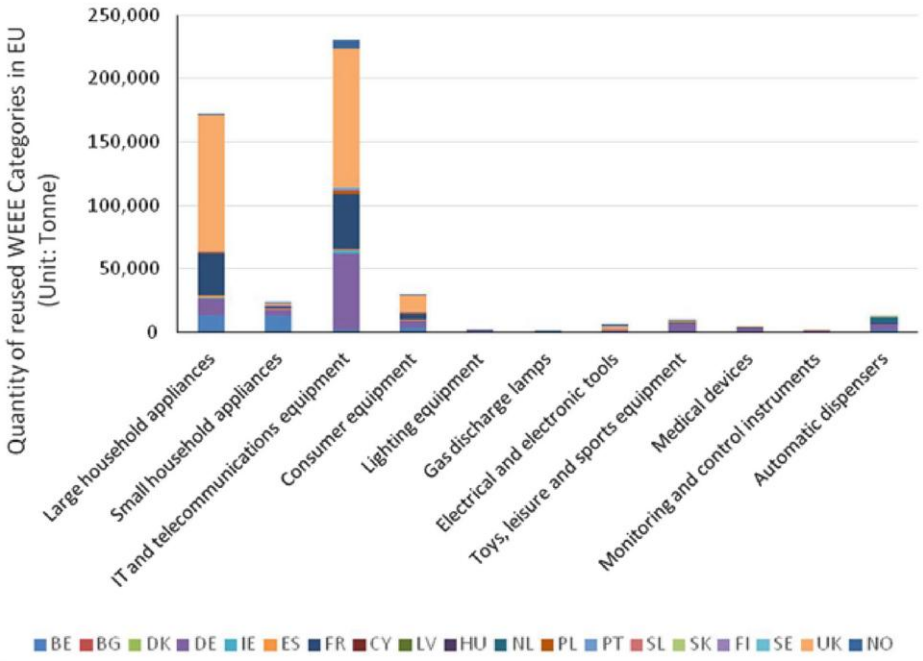

Figure 1.6. Situation of reused EEE for EU comunity between 2005 to 2014[46].

The supply chain of the EOL introduces remanufacturing as one of the main joints in the chain.

Table 1.2 End-of-life options[12,47]

EOL Option	Description
Landfill	Dispose-of a product, or its parts, in a landfill
Recycle	Recover material from the product or its parts. Any value because of the form of the product or its part is destroyed
Resell	Sell product or its parts on used market as is
Repair/Refurbishment	Fix the product or its parts to some specified standard and sell them on the used market
Remanufacturing	Re-make the product or its parts by using a mixture of recovered and replacement parts, so that it meets the "like-new" specification (i.e. identical warranty to that for a new product)

This reflects that the implementation of different strategies adopted in Table 1.2 shows multiple perspectives used to understand the feasibility for industry in case of WEEE. The examples collected from literature include reserve supply chain, policy, and

design for remanufacturing, process optimization, business model, and government decision in regards to remanufacturing and refurbishing of used electronic and medical devices.

The most common method used in this field is to understand how the concept has been adopted in different parts of the world from the academic and industrial point of view. As an example, in some countries such as China, the main problems of remanufacturing are still relevant in the electronic remanufacturing industry, see figure 1.7[48].

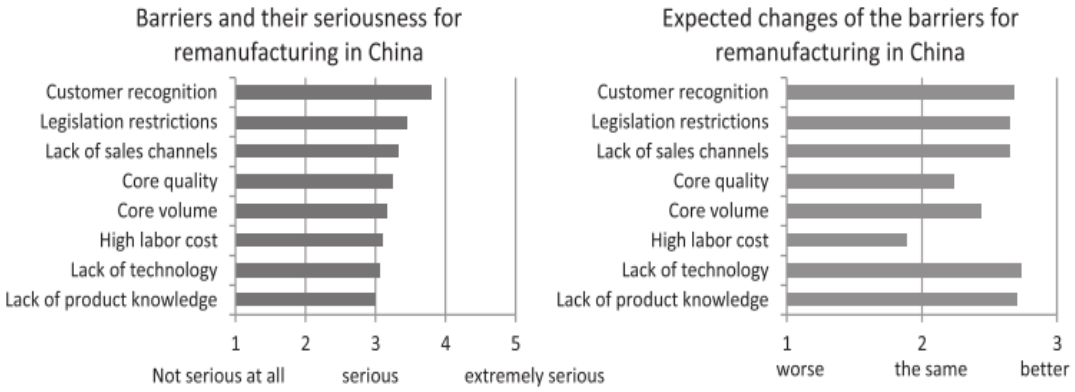

Figure 1.7 Rank of overall barriers and their expected changes[48]

In this research, certain barriers are concluded to demonstrate the sustainability of the process processing OEM data exposed in academic format. The bottoms of certain un-clarities of remanufacturing process will be demonstrated utilizing certain tools as LCA, demonstrating the interconnectivities among energy savings and environmental impacts of the process. Overall barriers mentioned above will be debated and demonstrated as unit availabilities (core), lack of channels, technology and product recognition.

1.2 Research questions and research objectives

In this research, the topic of interest is the assessment of whether to conduct remanufacturing in order to reduce the WEEE generation for a circular economy support. After consulting the field literature and manufacturer's remanufacturer's perspectives, it was decided to focus on the three pillars known as environment, social and sustainability which were missed by literature, and necessary to support certain concepts as Circular Economy and UN-Sustainable Developing Goals.

Analyzing the electronic products' evolution and medical devices from the material, physical structure, legislative changes, and company's issues remanufacturing can be improved. All these factors can give a better understanding of the possibilities for product destination of implementing remanufacturing for end-of-life products such as copy machines, servers, and medical devices to be considered as more sustainable. To achieve the goals of this Ph.D. research the following questions have drawn the results:

A) How the management assessment of remanufacturing, components status, and upgradability potential can retrogress WEEE generation?

The purpose of these research questions is to identify the concept model, ideologies and product/components status for remanufacturing implementation. These questions focus on three types of products such as servers, copy machines and medical devices covered by the research. The investigation is based on literature review, software and experimental analysis, and field investigation. According to these findings, the management assessment can be implemented as an example for companies and policy makers.

B) What is the energy savings and its extension to environmental benefits involved in the refurbishing process, with a particular interest in medical devices in the existent market?

The research question aims to identify the evolving and sustainable benefits of the remanufacturing/refurbishing process focusing on medical devices. Furthermore, a market assessment was conducted to understand the technical situation and availability of the approached end-of-life product. Therefore, the market assessment and technical sustainability can support the environmental impacts and coat the remanufacturing/refurbishing process.

C) What is the status and implication of the current market among new and remanufactured/refurbished electronic legislative (directives) from the European Union, the USA, and China in terms of medical devices?

The last question intends to define the actual perspective behavior regarding new and remanufactured product involvements from a legislative aspect for medical device sector. In this case, the private sector and governments can overview the current status of the legislative approaches as a guideline considering the physical status and update possibilities.

1.3 Scope of the study

As the thesis conceptual framework is explained, the first step is to identify the remanufacturing interactions and background to have a better knowledge about the concept placement. This is crucial due to the fact that the role of the process and involvements, roots with other operations and businesses engaging different needs. Only by having different approaches for concept models can an operation or process be sustainable. These facts will be discussed in the following chapters of the study to have a better approach on remanufacturing/refurbishing process and its implications.

First, the study described in Chapter 3 presents a conceptual model approach to WEEE problem utilizing the remanufacturing operation. The operation is emplaced and viewed in the problematic frame of waste generation adopting the concepts of circular economy, reuse, reverse management, and a decoded description through copy machines.

Second, Chapter 4 of this study focuses on conservation approaches by viewing the collection, product physical status, and upgrade opportunities of used electronic products. This concept will expose the operation system of certain industries. Furthermore, in Chapter 5, a cumulative energy demand (CED) and an LCA investigation was conducted to support the remanufacturing/refurbishing process for this green environment and a diverse savings benefits. This study focused on medical devices as Magnetic Resonance Imaging (MRI) and X-Ray scanners due to their high value in terms of social aspects, material saving and operational sustainability.

For having a complete frame of the research, Chapter 6 enhances an overview of the medical device market, policies/regulations on new and refurbished medical device. This section attempts to understand the operational placement in US, European Union and China as examples of quality approach for a strong enforcement in Circular Economy concept, guidance for governments - companies and a future research approach.

Chapter 2 METHODOLOGY

There are various elements that are essential for the research methodology. First, the methodological framework provides the understanding of the research approach. Second, details of the study area, regards of the provenience of research data, product/process acceptance, field-data collection, and experimental analysis will supplement the methodological framework. Third, the combined research framework can address a bigger range of products regarding medical devices, and can aid in understanding the remanufacturing/refurbishing process and benefits.

2.1 Research methodology

This study was conducted in China at Tsinghua University containing three parts of research (desk, laboratory and field investigation), and Europe that were focused on different aspects of the researched topic. The desk approach was covered through the literature review, and through debates at different conferences and collaborative meetings with international organization as European Coordination Committee of the Radiological, Electro-medical, Health ICT and Radiotherapy Industry (COCIR) Belgium, and affiliated companies to the organization.

The laboratory work was fulfilled at Tsinghua University, the School of Environment in the field of Waste Management focusing on different aspects of the Remanufacturing process. More or less, the experimental approach was conducted at the School of Environment and other faculties that were able to facilitate certain devices needed to conduct the research. To complete the circle, the field investigation was conducted at five remanufacturing companies, and at one collection company of used Electrical and Electronic Equipment.

Two companies were based in China (IBM remanufacturing and Taolv collection of used WEEE), and the others in Europe as Concept Group by Xerox and three manufacturers of medical devices from COCIR group. The manufacturing companies of medical devices decided not to reveal their identity due to confidentiality reasons.

Furthermore, regulatory implications made by this study are summarized in an environmental analysis that supports the engineering study.

Moreover, a regulatory introduction to remanufacturing/refurbishment will be drafted, as well as an engineering study regarding material properties status and operational process.

The frame and waterfall (Figure 2.1) of the research is presented below, and after that, each point will be explained and articulated. The research questions will incorporate experimental or theoretical research that will help answer the questions.

The research will be concluded in two parts that are significant to all three questions:

1) Experimental:

a) Material stage analysis (plastic covers, and PCB's).

2) Theoretical:

a) WEEE remanufacturing perspectives;

b) Description of remanufacturing/refurbishing process and implication;

c) Different interaction acquiring remanufacturing potential;

d) Regulatory overviews.

The Waterfall Methodology, figure 2.1.

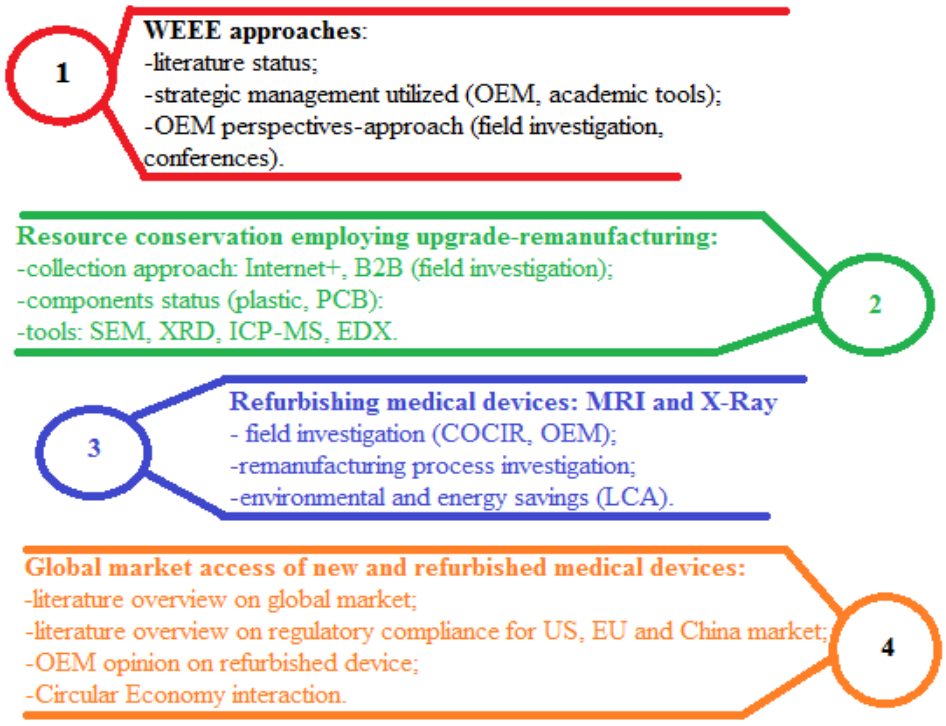

Figure 2.1 Methodology frameworks

2.2 Study area

This study was conducted in China and Europe, focusing on the remanufacturing/refurbishing process and its benefits from the environmental aspects. Furthermore, it has been considered a general overview for the regulatory and upgradability aspects that embrace the remanufacturing process to exemplify his sustainability. A cumulative energy demand calculation (CED) using LCA software (Gabi) determinates the impacts and involvements of the process for different factors.

The entire study can provide useful information for certain companies/manufacturer, policymakers and governments in order to support the remanufacturing process towards a circular economy.

2.3 Market assess (Product/Process acceptance)

A discussion of the remanufacturing/refurbishing process, and of the market access for end-of-life and new medical device is addressed. The process is explained in detail and in correlation with the current worldwide situation in this field. The regulatory investigation was conducted for the US, Europe and China markets.

2.4 Data collection

The data collection consists of the literature analysis, the field investigation as well as LCA approaches in order to ensure its precision.

2.4.1 Literature analysis

This analysis was conducted utilizing research articles published in certain international journals from several fields of interest according to the type of experimental investigation. Mostly, the searched fields of interest were related to the following: circular economy, medical devices, WEEE, remanufacturing and waste management for used electrical and electronic equipment.

Another contributive base of the theoretical research was the reports from international organizations as United Nations, Basel Convention, COCIR, DITTA, governmental websites news, and certain academic events.

2.4.2 Field investigation (Industry)

The aggregated methods used in this research are shared in three main parts: collection, remanufacturing management, and remanufacturing/refurbishing process. All the information generated herein has been collected from the field. In the collection section, a Chinese company from Shenzhen called Taolv Iinformation Technology Company is described, from which the data has been collected and processed. They collect, test and sell secondhand mobile phones and tablets. Taolv is a leading third party internet transaction platform for Waste/secondhand mobile phones, which aims to build a B2B reverse supply chain, set up standard collection flow, and break through information, material and fund flow, and realize the green, technical and intelligent collection.

In the second part, the data from the remanufacturing section had been compiled from two remanufacturing companies: A-two medical devices manufacturer and remanufacturer in Europe and B – IBM servers in China and copy machines at Concept Group by Xerox in United Kingdom - Glasgow. Company group A had offered their information during the investigation visit at the remanufacturing facility in Europe. Currently, company group A does not have any kind of remanufacturing activity in China due to the legislative restriction. The data from company B had been collected on the spot at their facility remanufacturing in Zhejiang Province, China and UK and was compared to the data from the company A. The process of remanufacturing had been explained and investigated step by step by all companies, resulting in our described analysis for understanding of the internal managerial activity process steps of remanufacturing in case of servers and medical devices. Other aspects were debated with the European Coordination Committee of the Radiological, Electro-medical, Health ICT and Radiotherapy Industry (COCIR) Belgium in regards to the worldwide situation of medical devices. All companies are leaders in the remanufacturing industry with a high reputation for quality and technical and fiscal sustainability of their products.

2.4.3 LCA analysis – “Gabi” software

The LCA investigation was conducted at one of the remanufactured companies in Europe utilizing the real imputed data offered by the manufacturer. Due to

confidentiality reasons, the imputed data was not allowed to be revealed in the manuscript except in the results section**.**

The investigation was conducted with the LCA software ''Gabi'' included in the assembly of refurbishing process evaluating the environmental impacts of 18 factors influenced by the process**.** The evaluated devices under LCA were a Magnetic Resonance Imaging (MRI) and an X-Ray.

Covered factors included the following climate change, ozone depletion, terrestrial acidification, freshwater and marine eutrophication, human toxicity, photochemical oxidation, particular matter form, terrestrial and freshwater and marine eco-toxicity, ionizing radiation, water depletion, agricultural and urban land occupation, natural land transformation, water and land and fossil depletion.

2.4.4 Cumulative Energy Demand – CED

A cumulative energy demand (CED) study covered eight types of savings that were involved throughout the refurbishment and manufacturing process. The study was conducted only for the X-Ray medical device to illustrate that the device with the lowest remanufacturing percentage can have a significant attribute to several types of savings. This part of the research compared the differences between a new and refurbished medical device. The range of savings was focused on material supply, business trips, transportation, unit manufacturing, components assembling, system assembling, usage, and end-of-life.

The calculations were made in Excel with the imputed data from the manufacturer for each procedure (manufacturing and refurbishing). Due to data confidentiality and mutual agreements among parties, only the results of the study will be uncovered.

2.5 Experimental Analysis

The experimental aspect of this research is designed to expose the used material properties represented as body parts from various products. The investigated components were plastic cases and PCB's belonging to different monitors utilized as desk components from a PC or integrated in a desk surveillance console for a MRI, X-Ray or other medical device. The investigations were executed in certified laboratories from School of Environment and School of Material Science in Tsinghua University, China.

In the experimental procedure, certain monitoring and testing devices were used for exploring the chemical composition of materials, mechanical properties (extrusion), and surface properties (visual status). In certain cases, the samples were compared between old and new body parts, and year of production.

2.5.1 Sample collection

The samples utilized for this study were purchased online from different sources. The pallet range and diversity of devices were used just as monitors from certain manufacturers and year of production. The manufacturers (brands) were chosen in conformity with the conducted field investigations observing the type (model) and brand used by manufacturers in their sales portfolio and the product availability. The samples (monitors, PCB's) were purchased from secondhand markets in Beijing, China and the new products (monitor, PCB's) from certain electronic shops in Beijing.

2.5.2 Sample processing for tests (plastic, PCB's)

The plastic sample procedures were conducted to be prepared for the SEM and XRD inspection. The preparation procedure includes four gendered fazes such as dismantling, shredding and sifting. Each faze requires high attention due to the electric mechanical and toxic powders emanating from the instruments in the moment of processing.

The Dismantling procedure was established utilizing different types of instrumentation such (Figure 2.2) as scrolls, cutting devices and wire molding/disassemble instruments for wires connections. The instruments required mechanical force to be used and electric sources for their functionality.

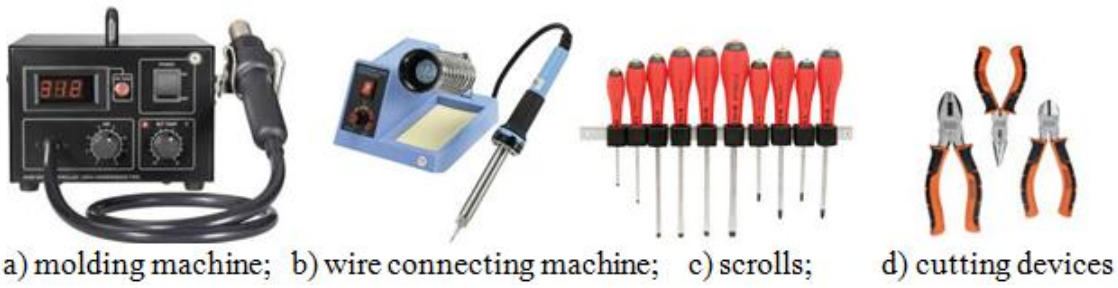

Figure 2.2 Dismantling instrumentation

The Crushing method had, in the assemble, just one device-the blade shredder (Figure 2.3) that was connected to an electric source. The shredded plastic pieces were mixed with liquid hydrogen to freeze them in order to have certain granulation of the

plastic, and to avoid the material molding point due to the particular friction and elasticity properties engaged in the shredding operation. The shredding timing was repeated depending on the granulation required by the XRD device. In case of PCB's, the items were just cut and introduced in the shredder.

Figure 2.3 Blade shredder

The Shifting procedure (Figure 2.4) was introduced to generate a suitable granulation for plastic and PCB's powder utilized in the XRD machine.

Figure 2.4 Shifting instruments

2.5.3 Tensile test – extrusion

The Tensile test provided a good base to demonstrate the mechanical properties and changes of plastics. The non-destructive test examined the material extrusion capacity using a tensile meter M350-10 AT/CT following the ISO527 standard for plastic.

2.5.4 Scanning Electron Microscopy (SEM)

The SEM is a type of electro-microscope that can detect the surface of a material producing imaging of the sample by scanning to a microevolution focusing on electrons.

2.5.5 Field Emission Scanning Electron Microscope (FESEM) Hitachi S-4500

Measure the texture of the surface, determinate with FESEM at 15kW electron acceleration.

2.5.6 Leaching toxicity-sulfuric acid and nitric acid (HJ/T299-2007)

The resulted powder from smelting consisted of 100g in a ratio of 10:1 (L/Kg) with liquid. The next step was the solution containing sulphuric acid, nitric acid, and distilled water that was equilibrated at 3.5 pH and mixed with the plastic powder in separate recipients for 18h using a stirring machine. Every four hours, the stirring machine was stopped to release the accumulation of gasses from the recipients, and then was restarted. Subsequently, the mixture had been separated (liquid from solid) using a vacuum filter separation method. The filter is a silicon membrane with a thickness of 40μm. Instrumentation used in the leaching experiment included the following: vacuum pump, laboratory bottles, pH meter, filters, lab funnels, lab coats, scale, pipette, and a homogenizer.

To identify the elements from the leaching solution an inductively coupled plasma mass-spectrometry (ICP-MS) has been used as an instrument with the capacity to detect mass spectrometry, detecting several metals and non-metals at different concentrations.

Figure 2.5 Leaching flow analysis

2.5.7 X-ray diffraction (XRD)

X-ray diffraction was used to study the anatomical structure, the internal composition, and the physical properties of different materials. In this study, it was used to determinate the material composition for printed circuit board (PCB's) from certain electronic devices as monitors. The purpose of this investigation was to determine the element composition as hazardous elements in the PCB's. The test contained three samples belonging to different categories of PCB's as new PCB from a new monitor, used PCB from a secondhand monitor, and solid residue from a used PCB.

The main focus of the study was on the following elements: copper-Cu, silicon-Si, lead-Pb, cadmium-Cd, and aluminums-Al.

Chapter 3 REMANUFACTURING APPROACHES FOR WEEE

3.1 Introduction

Remanufacturing is giving another option to the products, by transforming them to "like-new".

Recycling and remanufacturing increase the utilization of recovered materials or used and reconditioned components to reduce the raw material consumption and increasing the waste value. A worldwide distribution of WEEE and EEE remanufacturing situation is described in Figure 3.1 according with the literature. This represents the current status of EEE remanufacturing related with the technological potential, regulations and governmental or private affiliations with remanufacture. The 60% non-hazardous waste that had been produced by manufacturers demands the implementation of legislation to reduce the environmental impacts of these products [49–52]. In these cases remanufacturing strategies play a crucial role for original equipment manufacturers (OEMs) and remanufacturer[53].

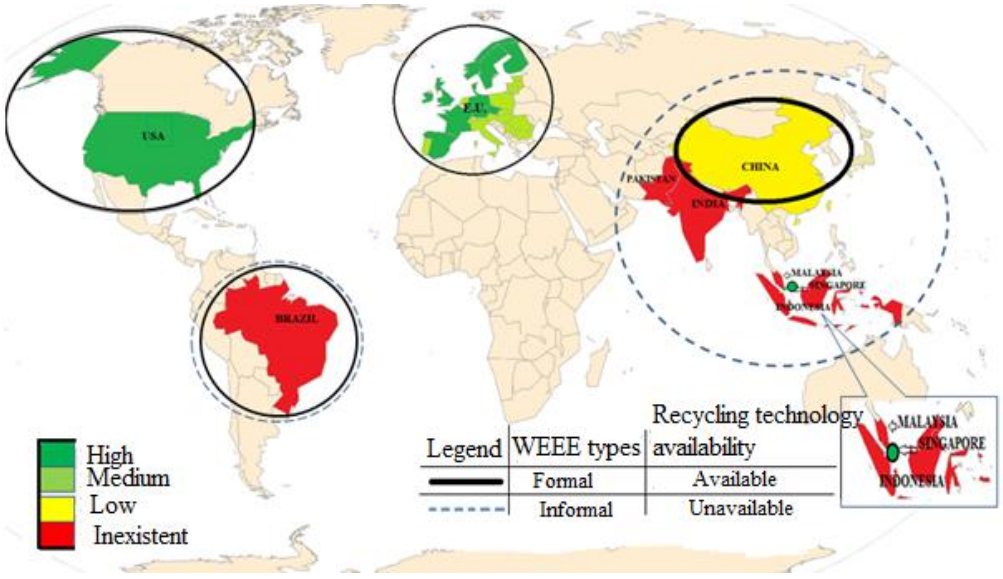

Figure 3.1 Worldwide distribution of the remanufacturing status. Note: Data source of the assembled map are from the appendix content.

OEMs produce different components with their own specification for the final products to differentiate their products from those produced by competitors, which can

affect the price of products by reducing their final sale price. In regards to select their technology for determining the potential of remanufacturing, the strategy is developed in order to give the possibility of replacing some components by the owner or to be redirected to recyclers or remanufacturers at the end of its lifecycle[17,54]. In this case, the remanufactured products represent just 60-70% of the original price compared to a new product. The rehabilitation expenses for the remanufactured products are estimated to represent 35-60% of the original cost of production[19]. Among all these factors, sustainability for the remanufacturing industry represents an important global interest[53,55].

However, the eco-design is helping to improve the efficiency and effectiveness of development for updating products longevity [21]. Remanufacturing is a process of recovering/bringing used or worn-out products to a “like-new” functional condition, offering an equal functional warranty like a new product and reducing the environmental impacts, waste generation, landfill and the levels of raw materials used in production[27–32]. This chapter will articulate the remanufacturing typologies from different aspects, as implementation strategies, and provided a strategic solution for used EEE and WEEE sustainability.

3.2 Remanufacturing emplacement

Through all economic, sustainable design, and technical remanufacturing processes, the concept of remanufacturing will develop and improve. According to[33], the particular description of the concept of remanufacturing expresses the understanding of the assessment model, in order to create a sustainable application in industry and product reusability to reduce the waste that will/can be generated.

Also, these determinations demonstrate how to handle the waste. Explained by[35], the reserve supply chains (RSC) and end-of-life (EOL) are parameters required to understand the original equipment manufacturers' (OEM) strategies. As a producer and remanufacturer of electronics and medical devices [ex: (XEROX-copy machine), (IBM-servers), and (SIEMENS-medical devices)] demonstrate the importance of (RSC, OEL and OEM) in their remanufacturing activity . Their objective is to recover their products and make profits before and after the product reaches the stage of the EOL and protect the environment [36,37].

According to the prevailing legislation, an example is given by the European's End-of-Life Vehicle and WEEE directives[2,45]. It is required for OEM's to handle their products' EOL by finding suitable solutions for reducing waste and environmental issues caused by their products (implementation of the take back recovery system)[56].

The above effects, reflect the implementation of remanufacturing which helps more industries and businesses to create new jobs, and develop their economy. For example, from 2009 and 2011 the United States increased the number of jobs and financial growth by 15% to at least 43 billion USD [35]. According to the International Trade Commission, in 2012, the number of jobs was approximately 180,000)[45]. However, the factors that drive the remanufacturing industry include legislative regulation, as well as material and energy conservation. All, together, this describes an entire chain from material flow to recycling and can be called a value recovery strategy after the end-of-life (Table 3.1). The supply chain of the EOL products introduces remanufacturing as one of the main joints in the chain which can be state in Figure 3.2.

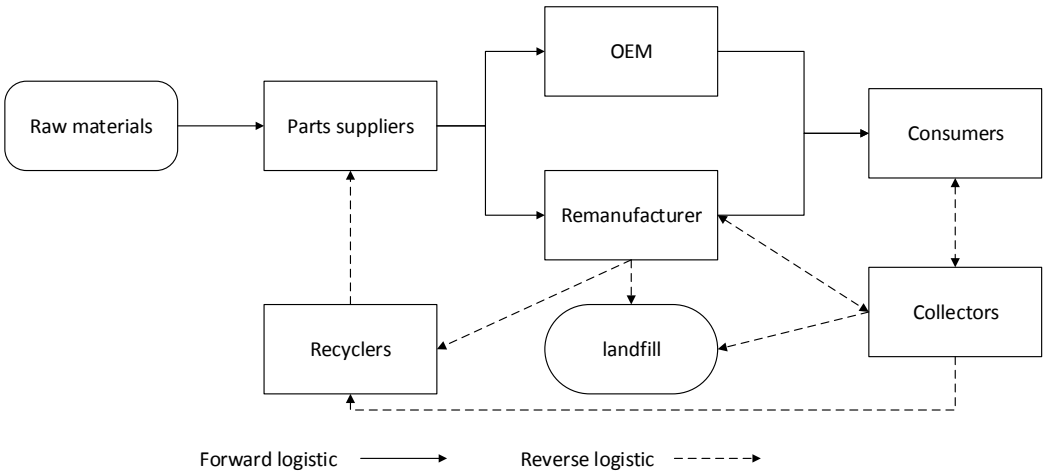

Figure 3.2 Materials and equipment chain with its forward and reverse destination. Note: SC represents supply chain; Modified from[35].

This chapter reflects the implementation of different strategies used in remanufacturing concepts, which show multiple perspectives used to understand the feasibility for the remanufacturing industry in the case of WEEE. The examples collected from the literature include reserve supply chain, policy, as well as design for remanufacturing, process optimization, business model, and marketing decision. In addition, this research illustrate, the intention to determine what are the most common methods being used in this field, to understand how the concept is adopted in different parts of the world, from the academic and industrial point of view.

Table 3.1 Types of destination places for End-of-life (EOL)[12,47].

EOL Option	Description
Landfill	Dispose of a product, or its parts, in a landfill
Recycle	Recover material from the product or its parts. Any value depends on the form of the product, or its parts, and if it destroyed or not
Resell	Sell product, or its parts, on used market as it is
Repair/Refurbishment	Fix the product, or its parts, to some specified standard and sell them on the used market
Remanufacturing	Re-make the product, or its parts, by using a mixture of recovered and replacement parts so that it meets the "like-new" specification (i.e. identical warranty to that for a new product)

Furthermore, these have been an influence on the remanufacturing process and business competition for the market requirements resulting that the WEEE forecasting, reuse, and remanufacturing potential is having an impact on reverse management [57,58].

3.3 Methods and data

3.3.1 Data collection from conferences

The data for this chapter has been collected and debated during the international trade show for remanufacturing[59], in the IcoR Remanufacturing conference in Amsterdam in June 2015, and the Remanufacturing Summit Beijing 2016. During the events, most of the exhibitions have consisted of the automotive remanufacturing and electronic remanufacturing issues. The most qualitative event was attendees of the workshop of IBM, from ICoR Amsterdam. The remanufacturing problems of used EEE and WEEE had been discussed and in such a way to understand the changing from the managerial point of view to a technical point. Cannibalism and material recovery plays an important role in the WEEE reduction, which has been discussed in trades and technical literature within this field(Linton 2008).

3.3.2 Data collection from literature

The literature reveals that the availability of documentation related with used electronics, and WEEE remanufacturing worldwide has shrunk to recycling, as seen in Figure 3.3[61]. Using Scopus to search for studies conducted between 1990 and 2016, associated with environmental issues and processing technology, with the key words of WEEE reuse, WEEE recycling, and WEEE remanufacturing, resulted in 987 closely related papers. Among these, 840 papers were related to the WEEE recycling situation, 112 papers related to WEEE reuse, and just 35 papers related to WEEE remanufacturing. All data suggests that the lack in the WEEE remanufacturing aspect is poorly represented and should receive more research focus.

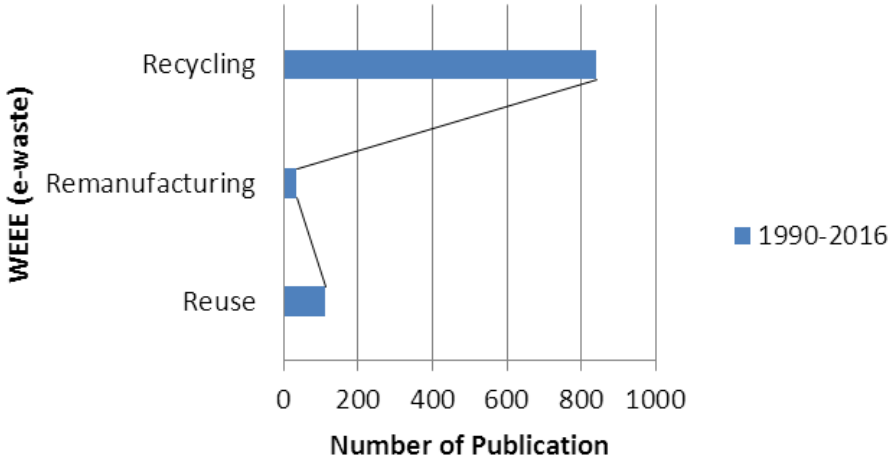

Figure 3.3 Situation of WEEE remanufacturing literature based on SCOPUS.

During the ICoR IBM workshop, all participants contributed to the general understanding of the current situation in the field from different viewpoints, and expressed their needs regarding remanufacturing problems across the globe. The research includes the main points of the researchers from workshop that were debated and analyzed.

3.3.3 Case study

This research took several examples from literature and the cases of remanufacturing companies of copy machine as Concept Group by XEROX UK, servers by IBM and SIEMENS healthcare (medical devices) are mentioned. This fact will articulate the remanufacturing typologies from different aspects, as implementation strategies, and a strategic solution for sustainable global WEEE management, which can

contribute to the remanufacturing concept. Because the remanufacturing is not sustainable with all the products, the profitability decreased in some cases as concluded, the chapter exemplify a case of copy machine remanufacturing from Concept Group by XEROX UK.

3.4 Results and discussion

3.4.1 Remanufacturing implementation from different points of view

The literature review provides examples to differentiate the perceptions used by different companies to achieve various goals. The diversifications of the perceptual objectives were made for diverse objectives to facilitate the remanufacturing companies.

3.4.1.1 Overview of circular economy for remanufacturing

The analysis that had been done in the circular economy (CE) are focusing on the energy consumption, material flow (3R rule implementation), closed loop systems, and eco-design[61,62]. This reveals that at the micro-level of waste reduction everything changes. In the case of China's leapfrog development, the environmental policy had been implemented, and the CE started to increasingly work in a sustainable economic growth from 2002 riveting on energy consumption, resource and waste problems, environmental degradation, and conservation among other things [63]. [64]estimated that the CO_2 emissions are growing at a rate of 7.5% annually in China, and were approximated to be 7693 million tons (Mt) in 2010.

In the developing countries, such as China, the impact of the manufacturing industry is playing an important role to germinate other industries such as recycling, while adopting the 3R rule [63]. The necessity of customization is increasing and at the same time, the materials are used, recycled, and then resold on different markets with less value for the customer demand. Product revolution, technology development, and policy implementation affect remanufacturing concepts of green-products life-cycle for entering in the supply chain of production/updating [65,66].

In theory, the mathematical and software analysis Life Cycle Assessment (LCA), Cost Benefit Analysis (CBA), Life Cycle Cost (LCC) are incorporated to actualize and improve the remanufacturing scheme to minimize the environmental impact and to step-up the sustainability of the remanufacturing system[67–69]. The fuzzy, multi-aim of

remanufacturing does not only help companies to develop but even to generate new perspectives for the consumers, clarify the connection among new and recycled materials, production/selling cost, machine yield, energy consumption, and CO_2 emissions[70]. The examples from the literature review have been implemented in Asia, Europe, and the USA.

3.4.1.2 The status of original equipment supplier and manufacturer

Independent remanufacturers and contractors in remanufacturing industry have different opinions regarding the use of concepts like, Original Equipment Manufacturing (OEM's), and Original Equipment Suppliers (OES) in the field. For example, in Europe, remanufacturing is considered as being connected with the production line depending on the remanufactured product[52,71]. However, the U.S. considers that strategies should be deployed to increase the employment rate and after which, the outsourced/ contracted companies need to increase and help the remanufacturing process. Beside, both ideas in the OEMS were used and were adopted by automotive and electronic companies in U.S.[45]. Usually, the remanufacturing concept depends on the generic activities (Figure 3.4), product routing and process, and product types/company.

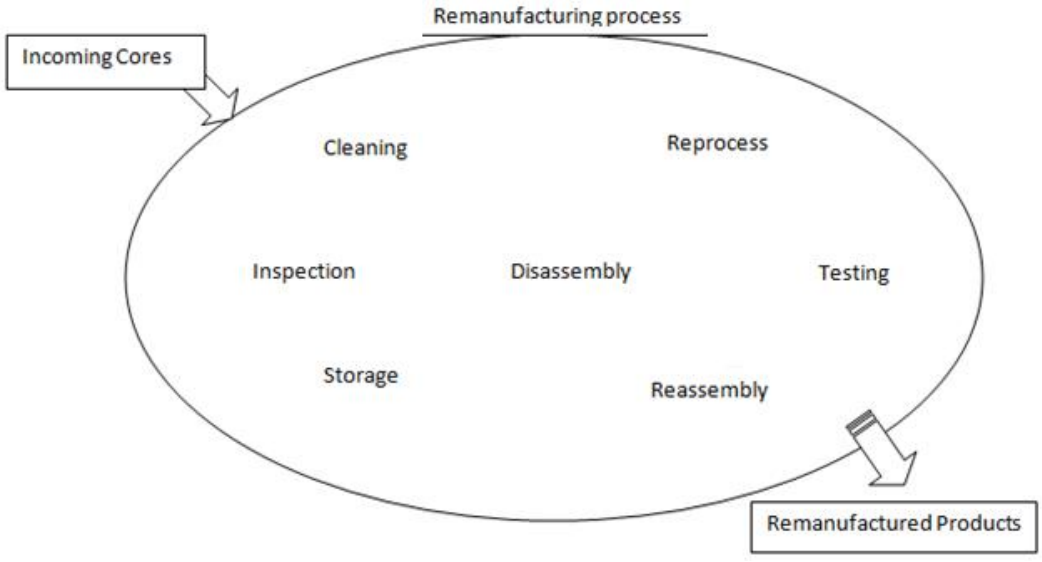

Figure 3.4 Illustration of Generic Remanufacturing Processes (GRP)

All of the activities shown in the Figure. 3.4 are different from product to product depending on testing modalities, software update and missing/replacing parts of the

product. This activity depends on the product quality, supply/demand, and technology migration. Among these, remanufacturing cost can be between 45%-65% depending on the product and marketplace which can be comparable with a new product[45].

Developing the remanufacture concept the remanufacturing industry takes into consideration profitability, environmental sustainability, legislative regulations, marketing and perception, process design optimization, materials and energy conservation, business model and job creation according to IBM and academia description [37]. The sustainability of the factors mentioned before involves, in a manner, the understanding of a particular barrier and the motives that affect the remanufacturing industry, not only in the process of adaptability to legislation and production, but also recycling of different products.

3.4.1.3 Methods of remanufacturing implementation and examples

A suitable case is the Chinese remanufacturing industry lacks where the EEE interest is spreading to manufacturing and recycling rather than used EEE or WEEE remanufacturing[72,73].

In the cases of the technical design, market factor and legislation for electronic remanufacturing on the Chinese market the (MIIT – Ministry of Industry and Information Technology), in 2012, establish a catalog to guide the research institutes and companies. The Chinese situation reveals that even if the manufacturing industry is well developed and the variety of products and accessibility of EEE components are handier, remanufacturing companies are insignificant being only five in the whole country [48]. One of the most relevant examples of sustainability is the IBM server remanufacturing facility plant in Shenzhen that has been open since February 2012 and being the IBM 22nd facility in the world. The main objective of IBM is IT remanufacturing with a rate of remanufacturing of 10.000 units/year and viability of 90% [36]. In the Chinese markets, the remanufactured products, which include IBM as well, have percentage ranges from 40 to 80% of the new product introduced for sale. The basic issues that had been discussed in the studies by scholars and governmental organizations reveal that the main barriers in China are environmental, ethical responsibilities, costumer orientation/recognition, and strategic implementation [32,48].

On the other hand, the main objective is to restore non-functioning products to a new condition while reducing WEEE and the consumption of raw materials with

standards of a quality level that are equivalent to the new product and can offer a warranty level as well. [72]explain the difficulties of having a proper direction of e-waste after they expire and the differences between DfRem (design for remanufacturing) and e-waste remanufacturing capacity which varies. In the case of China being the largest producer of electronics and importer of e-waste in the world, there is poor development in the electronic remanufacturing sector which is considerably unknown and an untried solution, which is becoming quite a challenge to undertake[48,72,74].

Basically, remanufacturers have to choose their process methodology and perspectives. Other authors,[75] suggested in their research, different types/tools of the methodology used by remanufacturers and academia, sustainable development extension have different descriptions and dissimilar perspectives on remanufacturing.

Methods, types/tools:

1) Remanufacturing and Product Profile (REPRO2);

2) Close Loop Environmental Evaluation (CLOEE);

3) Environmental Impact Simulator (EIS);

4) Remanufacturing Decision-Making Framework (RDMF);

5) Remanufacturing Network Design Modeling (RNDM);

6) Research for efficient Configuration of Remanufacturing Enterprises (reCORE);

7) Fuzzy multi-objective linear programming (FMOLP);

8) Remanufacturing cleaning method.

Comparing their research and other case studies, this research extracted the most common ones that are used in industry and academia for management implementation in the remanufacturing industry. The profit maximization for reverse logistics and product design problems in case of remanufacturing, are plausible in practice[76,77]. By making future adjustments in the network and allowing gradual changes to a better flexibility, remanufacturing is incorporating different perspectives. Multi-period models demonstrate to have a better flexibility than the static one[20,78]. For example, the logistic network design of remanufactured washing machines, in Germany, can save the cost of transportation between facilities which is explained by[79].

Different perspectives on remanufacturing are implemented in the closed loop supply chain to understand the remanufacturing concept as followed in Table 3.2.

Table 3.2 IBM remanufacturing perspectives.

Remanufacturing and sustainable development	Remanufacturing like a system
Technical feasibility: Materials, methods, man, machine, energy, and information, are included	Design for remanufacturing
Economic aspects: LCA, cost, product recovery, disassembling, cleaning and washing, reconditioning, recovery, etc...	Reserve supply chain(RSC), acquisition/relationship, reserve logistics
Social aspect: attitude, orientation, behavior, warranty	Information flow in the remanufacturing: Composition of the product; Magnitude and uncertainty of the return flow; Market of remanufactured product; Information about how product returns
Environmental aspects	Employees knowledge and skills; The remanufacturing operation; Commercialization of the remanufactured products

Depending on the product being remanufactured, each company chooses a different strategy in their approach to remanufacturing. For example, NEOPOST in France reviled by [80] adopted the same strategy as the Concept Group by XEROX from Glasgow UK regarding the recovery of printers after the EOL. On average, they recovered 90% after a usage period of 4-5 years. In this period, they also offered technical support to their remanufactured products.

The main pillar of the returning products is very well developed by Concept Group by having a database that can provide all the information about the product type, client, technical situation of the product, and location according with CG. By using these systems, even Neopost expresses that the raw material consumption from remanufactured products can reduce the environmental impact by 37%, depending on the types of undertaken products. All the products were considered as being converted in an economical and sustainable fashion using complex algorithms which demonstrate

the big gap between return, recycling (rate, cost) and CO_2 emission. Several researchers have demonstrated the differences between these factors presented in Table 3.3.

An important factor of these aspects is how the returned items are represented like a variable with a specific quality. Different parameters like demand, return and stochastic lead have a qualitative and quantitative influence on the cost and quality. All these influence the recyclability, economical cost for recycling, and environmental protection [18].

Table 3.3 WEEE sustainability potential[18,81]

Items	Recycling rate	Recycling cost	Disassembly time (min)
Fan controller	0	21.77	0.93
Cable	4.00	35.31	26.4
PCI board	0	3.24	3.0
HDD	27.27	-114.51	4.2
FDD	9.09	-15.83	18.0
CDD	18.18	-55.83	18.0
Switch	0	21.09	15.6
Big fan	18.18	-42.29	28.2
Big fan cover	1.82	35.71	27.6
Small fan	9.09	-2.29	28.2
Inside switch	0.91	20.69	15.6
Speaker	5.45	35.31	28.2
Memory	0	6.51	4.8
Motherboard	0	75.09	56.4
Total	93.99	40.61	302.4

3.4.2. Strategic solutions for sustainable global WEEE management

Future reusability, another branch of the remanufacturing implementation, had demonstrated an important goal in minimizing scrap recycling[82]. In the previous examples, can observe that end-of-life management before remanufacturing and management strategies to develop a proper sustainability for remanufacturing, involve not just a proper generation of product updating but also environmental friendly manufacturing[44,83,84].

In this section, is discussed what is needs to be done for managing waste from the point of view of electrical and electronic businesses and what are their needs/issues for managing strategies required for a sustainable WEEE on a global basis. The remanufacturing in the WEEE sector, specifically the automotive and aerospace sectors, is more developed and more profitable[85]. However, the automotive and aerospace sectors are challenged by the updated/remanufactured products of the electronics, such as board computer, controllers, safety systems, and other specific electronics[86,87]. [88]highlighted the exiting challenges that are commonly found in the WEEE remanufactured equipment, and remanufacturing processes, such as: inspection, cleaning, disassembly, reprocessing, reassembly, testing, facilitating the remediation of WEEE storage, pollution and energy consumption.

WEEE from the remanufacturing side has two main camps (i) Operational level, a conglomeration of activities that smoothly flows from EOL of the product to the remanufactured processes. (ii) Management strategies, which engage the circular economy, asset reuse, plans, policies, and tactics for ensuring the profitability of the remanufacturing.

In the following part, these decisions are included as if the electronic manufacturer would remanufacture the used EEE and WEEE from an OEM perspective or other private companies. All these had been debated with the IBM Global Asset Recovery Services and academia from different countries as in the annual ICoR workshop. Here the key discussions had been concentrated on reverse management, design for remanufacturing and reuse selection, while trying to optimize the real situation at the moment.

3.4.2.1 Reverse Management

The concerns for reverse management lay within the general idea that legislation appears to be blanketed by particular models. The transportation of waste is one of the general problems. This is, not just from the logistical point of view, but it even concerns the diversity of the waste involved. In these cases, the industry can be supported by the government and consumers. Among these, there is a potentially manufactured product that can be considered waste at a particular stage in its life cycle. The data, provided by the producer for the consumer and remanufacturer at the same time, would be about the product characteristics or the possibility of recovery after the EOL cycle.

It is important to articulate that the life cycle, which will be provided by the producer, can influence the policy makers to change the legislation regarding e-waste recovery from the electronic users. The general idea of waste designation and the lack of specific legislation for remanufactured products will change, thus giving a better opportunity for reversing the chain for reusability if the legislation for remanufactured products will be for their benefit. Group members put forward the case that joining value streams (between companies) would be difficult to achieve because of the business competition that prohibits co-operation between different companies. This is having an impact on the economic level for them.

Reverse management is currently dictated by particular models, depending on the product complexity. Thus, creating new models to encourage collection for remanufactured products will be a challenge. The increasing complexity of parts has had an adverse effect on the management process.

3.4.2.2 Design for remanufacturing

Different mechanical or electrical parts from different areas of the product can be remodeled/readapted to increase the life cycle and decrease waste. The key factor here, are the outsourcers, which provide solutions to the producer for updating the products in an economical way, equal to cost, complexity, and capabilities of a new product.

Remanufacturing strategies, in advice with the sustainability for remanufacturing have to increase the relations between the remanufactured and original equipment manufacturer (OEM) to reduce the price of producing via economy/sale.

Among these, the high production and updating of the products/design have an important role in changing the public reaction/behavior to the new products, even if the price is different, depending on the product category (new/re-manufactured). In regards with cost, quality, and capacity, the aspiration for manufacturing products having a statistical concept of efficiency versus flexibility is represented. Both of them are influenced by the supply and demand chain, giving a balance to the remanufacturing demand to be a higher-care for a low price.

An example is the copiers that are sold by Concept Group by Xerox UK to their original consumers or go to the sales market to begin their new life cycle, while offering a warranty and service at the same time. The logistic system of Concept Group is a partially closed loop, and some copiers go through more than one life cycle, as shown in

Figure 3.5. All their products are separately monitories before ending as a use product by the producer and in this way can be categorized more efficient as profitable or non-profitable for remanufacturing. The figure reveals two channels designated for the products as rivers logistic and remanufacturing.

The connection between them is given by the possibility of upgrading the electrical equipment, which has a shorter lifespan and a decrease of performance during the life cycle. From the IBM point of view being in the situation of the producer and remanufacturer, this type of situation is improved by offering a guarantee for the remanufactured products.

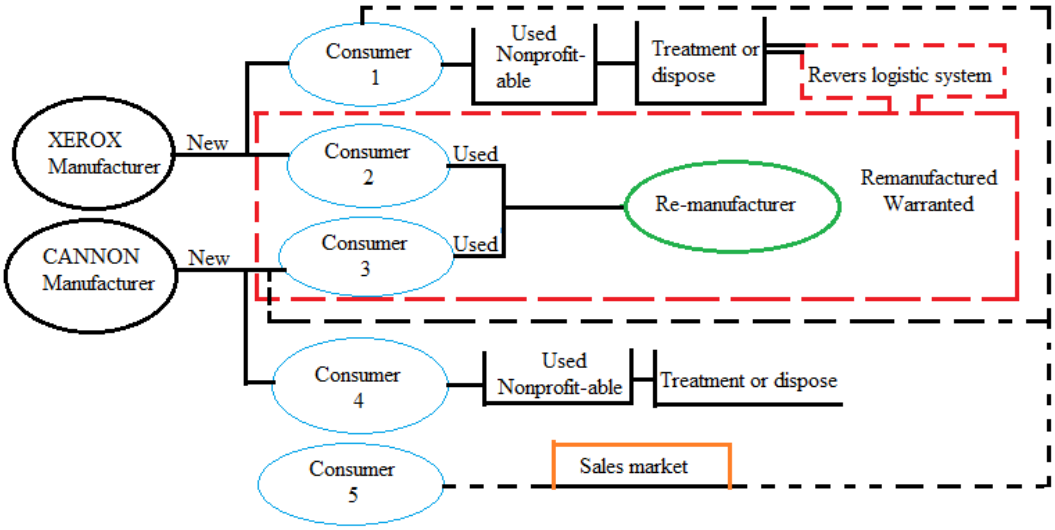

Figure 3.5 The logistic system of copiers' remanufacturing in Concept Group by Xerox UK

IBM, SIEMENS, and Concept Group by XEROX, offers in their new remanufactured products the last upgrading, which means new interface and software, hardware, guarantee, and efficiency.

The big issue for these companies is the design of upgrade, which has a short lifecycle, not just for the entire product, but even for the small components. The high complexity of the components requires more investments in the graphic and technological design and production, which can affect directly or indirectly the product price but also even the business. In the case of IBM being in the position of the producer and remanufacturer at the same time, the adjustment to upgrade an old product is less expensive and simpler according to the IBM.

In the case of laptops' and medical equipment's high construction complexity and lower possibility of remanufacturing, not to mention, the emergence of new products or

technological and political problem, the possibility of reselling is lower, in some developed countries.

3.4.2.3 Reuse selection

One of the most important factors in the regression of used electronics begins with verification/validation upon arrival and discusses the difficulties and the practicalities involved in the process of verification and validation [89].

For instance, the concept of verifying a standardized product against the process of verifying a customized product was discussed. Also, the fact that the level of validation required is such that the product must be shown to exceed the threshold of classification, where it would be defined as a solid waste or introduced into the category of recoverable products [90].

Forecasting successfully engages in WEEE management; good forecasting models are required for a better sustainability [91]. The point raised about this subject was the buyback option from IBM on equipment installed on sites, which would be required to be made a model basis (specific decision) and not a carpet buyback approach. The access to information is included to increase waste management of WEEE, and more information is required to be shared between the relevant bodies. The relevant bodies are the producers, third party waste management organizations such as remanufactures, and the policy makers to resolve the issues between different stages of remanufacturing and EOL [36,92].

From business to business and business to customer, the case was put in discussion that potential reuse operators may need to be differentiated, depending on the application/person or organization that is forecast to receive the re-used products (re-used products in this instance is a generic term used to describe the resulting product that has been subject to an EOL process)[93,94].

Understanding that the value for the manufacturer/provider represents the full cost model (which goes from cradle to grave) would generally need to be required as a first step in understanding the value provided by the manufacturer. For a potential manufacturer to:

a) Conduct EOL strategies such as repair, recondition, remanufacture, etc...

b) Provide necessary information to allow others to carry out these practices smoothly and efficiently;

c) Design products intending to carry out an EOL process such as remanufacture (thus products avoid costly disposal) while providing the cost model analysis as a requirement;

d) Product life management is not necessarily aligned with re-use of a product.

The points raised here, touches essentially the current modeling of products that include product re-uses (or successive products re-use options). It may be the case that new or existing life management operations/plans need to be created or altered to cater large product reuse operations to small reuse operations[39,95].

3.4.3 Practical execution of remanufactured copiers' machine

This chapter also illustrate an example of a copier remanufactured, made by Concept Group (CG), which is a subsidiary company of Xerox. They give the technical supports to CG, to make sure that the remanufacture processes are completed effectively and the quality of remanufactured copiers could be guaranteed. Meanwhile, they remanufacture some models of Cannon's copiers like IRC 30380 and IRC 20880 for more profit. CG takes back used Xerox or Cannon copier from the consumers and remanufactures them, then sells them to the original or new consumers. As a result, there is a partially closed reverse logistic loop between the manufacturers and the consumers, and CG is the link between. The process to realize their remanufacturing: disassemble, clean/ refinish/ rebuild/ mend, reassemble which lasts about 10 hours and are represented in figure 3.6. Here is reveal the entire chain of the remanufactured process to understand the general decomposition of a Xerox machine and the steps that each component is having.

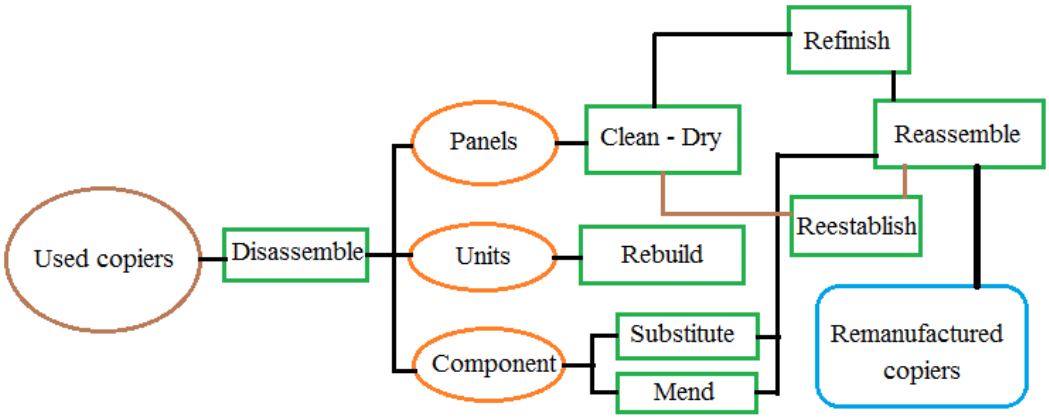

Figure 3.6 The copiers' remanufacturing process in CG

All copiers are disassembled to a very high degree (Figure 3.7 a). First, the straight external panels, the paper pickup section, control panel, process units, fuel sections, transport sections are taken off from the machine and are cleaned. Finally, all the subassemblies and components are disassembled individually and manually. Usually, each machine will be disassembled into more than 20 parts, which could be cleaned, refinished, rebuilt or replaced easily, to satisfy the needs of remanufacture process.

Figure 3.7 a) The disassembled individual parts of copier. b) One of the sensitive components in copiers.

Some of the easily broken components like the fusing rollers and pick-up rollers would be substituted by new ones which are brought from OEMs. Buying a drum unit from the manufacturers (for example, Canon) would cost about 250 USD. Meanwhile, CG spends only 60$ if it takes out the drum blade (the easily broken components) to replace it with a new one from the OEMs. The components in the copiers are complex, and the total number of components in each copier is about 50 to 100, and they are composed of plastic, leather, metal and some other materials. In all the operations, there are no used special tools to deal with the sensitive parts (figure 3.7 b.) during the disassembly process.

Experienced technicians are trained by Xerox with one at each branch, for six months to get used to the different models and techniques to disassemble, rebuild, and adjust the copiers. This upholds the quality of the remanufactured products in CG. After the used copiers are remanufactured, they undergo a run test, copies test, and the final electrical safety test. Meanwhile, all the copiers essentially work the same way, and use roughly the same components, so the remanufacturing is similar, and there are no technical problems to remanufacture different models or brands of copiers.

Also, the broken components in CG, which cannot be remanufactured (i.e. brought back to at least 'as new' condition), are substituted by the new ones from the OEMs, rather than different manufacturers. From the perspective of environmental protection,

more energy and resources are saved compared to the simple recovery of the material from copiers, as would be in the case with recycling.

The development of design, for joining other components during design and manufacture, makes the copiers much easier to remanufacture compared with the ones from many years ago. In addition, the stability of the copier technical development and the similar construction of different models and brands, make the remanufacturing of copiers much easier, and the economical-efficiency greater than other electrical and electronic products [79].

3.5 Summary

This chapter presents the existing operations of diverse approaches applied in remanufacturing models, which illustrate various viewpoints suggested to know the clear picture of remanufacturing feasibility for used electronic and WEEE industry. The key findings of this review are the elaboration and description of the different typologies of concepts and strategies that are used by the remanufacturer and their issues in the industry. This can be understood that not only just the concept of how to do remanufacturing will have an important role but also in which direction the operations should be applied to have a better sustainability from different sides. Currently, the policy makers are trying to develop new strategies for helping the companies to increase the remanufacturing process, reduce the environmental pollution, and raw materials reduction. The case of Chinese market debated in the case of the statically situation give a description of the possibility to implement remanufacturing by linking directly with the manufacturing. Future more recommendations can exemplify the CE concept if the OEM and remanufacturing industry connect each other as business to business and business to consumer. The exemplification reviled by the certain companies, US and Europe can strongly support other developing countries and companies to implement remanufacturing in a sustainable way creating jobs and reducing WEEE. Avoiding the main barriers as environmental issues and consumer recognition by implementing a good management, eco-design and reuse selection to increase the potential of the buy-back concept.

As a general overview, on all discussed examples and descriptions about the remanufacturing in this chapter, it can be concluded that remanufacturing industry could be suitable, if it will be implemented in the developed and developing country as well.

These are given as example by Xerox Group UK and IBM (China) remanufacturing by introducing the monetarize system at their products and increasing the possibility to regress old products and waste generation.

This chapter will help researcher to know the exiting situation worldwide of remanufacturing from the technological and legislative emplacement aspect. Different situation, cases, assumptions and modalities are reviled for a stronger sustainability of the remanufacturing in different countries. In other hand, the future development of the electronic industry will need to be more concern about their waste and they should consider all the aspects for a better functionality and life cycle of their e-products. Therefore, the detail work should be conducted to establish the perception of developing countries regardless remanufacturing potential, and proper implementation in different growing industries such as electronic manufacturing.

Chapter 4 RESOURCE CONSERVATION EMPLOYING UPGRADE-REMANUFACTURING FOR USED PRODUCTS

4.1 Introduction

The most prominent accessories and utilities in our daily life have changed the aspects of living and communication. From the moment when the information and communication technology (ICT) expanded, the world became more interconnected through a diversity of devices. The reflection of Moore law, observed that the updating of packed components from an integrated circuit board is doubling every 18 months, increasing the electronic manufacturing, used/ WEEE generation and informal recycling[96,97].

According to the UN data, from the released rapport in 2015 for the year of 2014, an approximated amount of 41.8 million metric tons (Mt) of e-waste was generated which consisted 3 Mt small IT devices, 11.8 Mt large equipment, and 7 Mt cooling and freezing equipment [98]. In most of the cases, the open dumping areas are related to the informal recycling, dismantling, discharging of hazardous substances from EEE [99–102].

Because of the chemical and mechanical characteristics e-waste and used electrical and electronic equipment can have another option to be regressed to a new product or raw material with less hazardous environmental effect using remanufacturing procedure.

Different solutions of the WEEE global issue can solve the problem in other manners being more or less efficient as the recycling option[103]. This chapter reveals how technology, market potential, and electronic design can contribute to a better collection of the waste and how remanufacturing is implemented, exemplifying of an efficient collection system and internal remanufacturing scheme of used equipment as servers and medical devices. In the traditional scheme of electronic collection system the complexity and time duration per transaction of used equipment is too slow and too complicated. A new practice of collection developed in China is “Internet + logistics” collecting waste/used mobile phones, tablets, and monitors. The aim of internet transactions is to build a business to business (B2B), reverse supply chain, not a business to consumer (B2C) standard collection flow, and break through information to a sustainable and fast collection reducing costs and giving more value to the WEEE.

This base strengthens the material and fund flow, realizing a breakthrough in the typical industrial chain of the electronic collection. A better collaboration between B2B cuts the corridors of a slow typical collection, helping the user and receiver (remanufacturing company) of used equipment to receive the product in a shorter time and physically diagnose. The case of server remanufacturing in China and healthcare remanufacturing of medical equipment in Europe are proper examples highlighting the availability to maximize the resource value.

Remanufacturing is more sustainable than material recycling offering a new possibility to the product to be reintegrated in the life chain avoiding the transformation of components, parts and assembles in secondary materials and again in a new product[17,53,104]. This is giving the possibility to reduce the CO2 emission, raw material, and energy consumption plus environmental degradation[104,105]. However, to support the benefits of reusing for remanufacturing illustrate the internal composition and physical status of the plastic circuit board (PCB) and plastic cases of two monitors. Overall, the experimental parts uncover the already discussed composition of WEEE products which degrade the environment and avoided raw material consumption. All of this can be avoid by using the proper tools as remanufacturing and reuse of subassemblies via Internet of Things (IoT) upgradability with Banana pi (card sized single-board computer) for a universal range of new and use equipment.

This chapter is organized as follows. Section (I) a worldwide introduction of e-waste generation and markets approach and possibilities. In section (II) is presented the methodology of collection by using new methods as internet application, (B2B) remanufacturing to maximize resource value and physical status for selection of subassembly for reuse and upgradability. In section (III) we describe the research results which are followed by section (IV) discussion of the study. In particular, shows that IT contributes to increasing the collection and resource conservation.

4.2 Methodological framework

The aggregated methods used in this research are shared in three main parts: collection, remanufacturing management and experimental analysis. All the information generated herein has been collected from the field. In the collection section, a Chinese company from Shenzhen called Taolv Information Technology Company is described,

from which the data has been collected and processed. They collect, test and sell secondhand mobile phones and tablets. Taolv is a leading third party internet transaction platform for Waste/secondhand mobile phones, which aims to build a B2B reverse supply chain, set up standard collection flow, and break through information, material and fund flow, and realize the green, technical and intelligent collection.

In the second part, the data from the remanufacturing section had been compiled from two remanufacturing companies: A – medical devices manufacturer and remanufacturer in Europe and B – servers in China. Company A had offered their information during the visit at the remanufacturing facility in Europe. At this moment company A doesn't have any kind of remanufacturing activity in China due to the legislative restriction. The data from the company B had been collected on the spot at their facility remanufacturing in Zhejiang Province, China and compared with the data from the company A. All the process of remanufacturing had been explained step by step by both companies, resulting our described analysis for a general understanding of the internal managerial activity of remanufacturing process in case of servers and medical devices. Both companies are leaders in the remanufacturing industry with a high reputation for quality and technical and fiscal sustainability of their products.

For the experimental part, different methods had been used to identify the physical and chemical characteristics of the electronics. Several analyses had been made as XRD, SEM, ICP-MS and leaching. The experimental samples and materials had been gathered from electronic markets in Beijing, China. They represent a description of existent statues – surface, chemical composition, from plastic and PCB to realize that the applied updating and resource conservation thought IT devices applicability can extend the life cycle of existent products postponing the recycling process.

4.3 Case studies

The investigated companies in this study generate another view regardless to the traditional collection system and the new opportunistic approaches from China and Europe. The waterfall of the manuscript describes a new collection system rather the conventional one [106] and remanufacturing introduction and management for servers and medical devices. This path gave a meaningful approach to conserve the existent equipment and reuse specific parts/components avoiding recycling.

4.4 Collection

Informal recycling and transboundary movements of electronics are one of the key factors in the regression of electronics and open dumping. Considering the informal recycling is having the potential we decided to exemplify the collection system implemented in Shenzhen, China by Taolv which is a leading third-party Internet+ transaction platform for waste/used mobile phones, tablets, aims to build a B2B reverse supply chain. They are one of the 25th specific enterprises with this profile in China, collecting approximately 1/5 (60 million, units) of discharged mobile phones in the country. The company is supervised by the Chinese authorities and requested to give balance reports regarding quantity and product destination. According to Ministry of Industry and Information Technology (MIIT), the discarded mobile phones add up to 250 million in 2016. Their activity unfolds where as in 10 of the biggest cities in China, such as Beijing, Shanghai, Shenzhen, etc., where Guyiu is the direct intermediary between seller and purchaser providing the special services (Table 4.1) as shown below.

Table 4.1 Service facilities provided by Taolv

Services provided by Taolv	
Seller	Purchaser
Sorting (different price/product)	Stable source from seller
Auction (price negotiation with seller)	Reliable trade channel
List of products they sell	Full time IT management
Logistic subsidy	High-efficient dismantling technology
Quick transaction (3 days)	Pre-pay financial service
Monitoring the transaction online	Logistics

Their implemented methodology of work succeeded to reduce the general cost of several key sectors in the collection and transaction chain (Table 4.2) as shown below. Among these, the requirements for supply chain and collection are simply eliminating some disadvantages, such as: lack of standards; too many steps in the logistics chain; information asymmetry (imbalance); impossibility of fragmentation of different kinds of items; stable supply and less variety for downstream plants.

The total cost reduction (45%) achieved is specified in this table according to the various cost categories. It is concluded that application of IT brings cost reductions for a wide variety of activities needed for appropriate collection.

Table 4.2 Internal cost reduction

Sectors	Taolv cost reduction (%)	Reduction factors
Combine information	10	Metal market price, online transportation - transaction
Warehouse cost	10	Depositing period maximum tree days
Storage risk	7	Technical accidents, retard delivery
Integrated logistics	5	Courier delivery for income/outcome of products
Accelerate the turnover of the capital	3	Transaction speed and efficiency
Bulk collection	10	Reducing the conventional collection points
Total reduce cost	45	

Breakthrough the traditional recycling and collection chain in China, Taolv succeeded to eliminate several steps, such as door to door collection, recycling points, classified recycling, region recycling and cross region recycling. In their collection scheme, just three steps are mentioned, namely: starting with consumers, collectors and the direct link between Taolv platform and the purchaser (Figure 4.1).

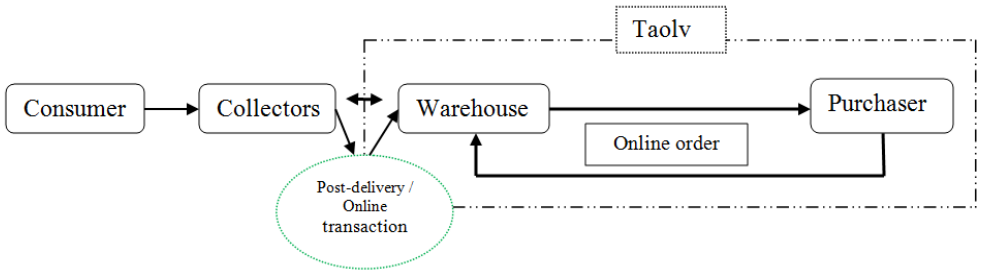

Figure 4.1 Taolv collection, distribution system

The Taolv shortcut is more effective than the standard one, having an internal time of delivery of the selected and sorted equipment of just three days from the moment of receiving. From the point of acceptance of the transaction containing the used or second-hand device, till the delivery, see the Taolv flow of products (Figure 4.2) is followed.

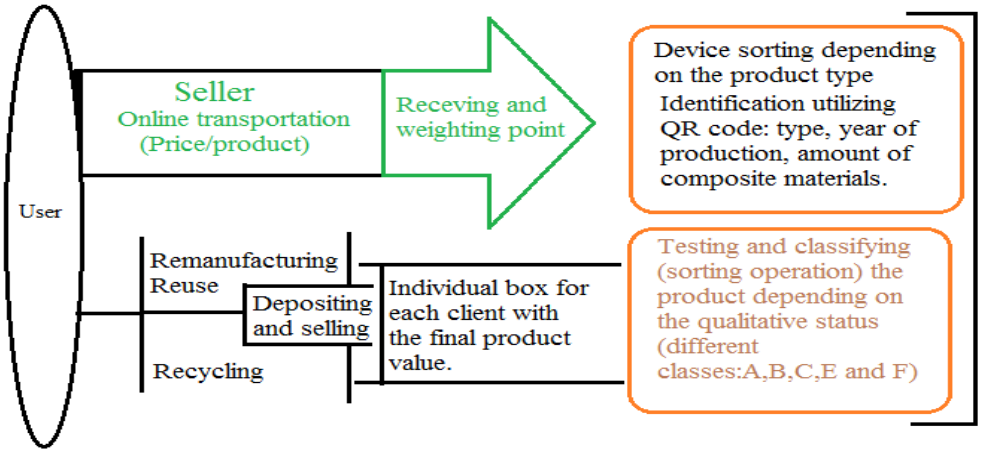

Figure 4.2 Flow of goods from seller to purchaser mane by Taolv company

The first step is the online transaction between the owner of used electronics and collecting company (Taolv) where general price before the technical inspection of the device is discussed. In this general price includes the international metal exchange transaction of the precious metals/materials in the moment of the selling and purchasing (Table 4.3).

Table 4.3 International exchange metal transaction price

Product category	Latest price	Unit
High configuration capacitance screen	22.5-24.0	RMB/piece
Medium configuration capacitance screen	13.0-14.0	
Low configuration capacitance screen	7.5-8.5	
CDMA	9.1-9.5	
Middle-end Nokia	14.0-15.0	
High-end Nokia	24.0-25.0	

After the online transaction has been completed the device is shipped to the collector by a usual courier. At the collector base, the device is firstly weighed (Figure 4.3) and identified by scanning the code bar (QR code) from the phone and using special sorting machine incorporated with software which generates all the characteristics of the product (Figure.4.4).

Figure 4.3 Reception and weighting of the products (mobile phones, tablets)

Figure 4.4 Identification machine for type of product and model reading the QR code

The software is updated with the existent database of manufacturer regarding material percentage (gold, copper, aluminum, plastic, etc.) for each brand and model of the device (mobile phone, tablet). After the identification, the devices are tested from the electrical and physical status (screen, cables, covers and components,) to generate a better classification depending on the physical defects detected (Figure 4.5). Furthermore, the tested device is characterized in certain classes of quality (A-good, B-satisfactory, C-less satisfactory, D-spare parts only, F- material recycling), after this reevaluating the product and offering the seller the final price of the device according with the deffects sheet (a balance sheet containing the reusable parts) (Table 4.4).

Figure 4.5 Testing and classification operation

Table 4.4 Balance sheet for individual product diagnose

Components name	Number	Unit	Class of quality
Large size screen cell phone	32	pcs	E
Weight of small size screen bar cell phone	0.3	pcs	F
Weight of clamshell cell phone	0.05	kg	F
Apple 4	1	kg	F
Huawei c2800	1	pcs	A
BBK y31	1	pcs	F
High configuration capacitive screen	11	pcs	E
Low configuration capacitive screen	9	pcs	E
Medium configuration capacitive screen	1	pcs	E

The destination of the collected products are shipped to the reuse, remanufacturing and recycling companies from China with an oscillating price of the product depending on the international metal exchange of precious metals, physical characteristics and product quantity(kg in case of recycling). This type of collection can be implemented in different countries with a lower infrastructure of collection points recycling or remanufacturing. This method upstands the traditional collection due to online, public or privets distribution with a direct connection between the owner of the used product

and remanufacturing/recycling company. In this case remanufacturing and recycling companies are facilitated to obtain the best quality for the incoming products (an already sorted, tested and diagnosed product).

4.5 Remanufacturing introduction of B2B (business to business) and overview of the internal management model

Remanufacturing in big lines is seen as one of the most environmentally friendly of ''end of life'' treatments for a saturated product. If the remanufactured product will avoid substitution for new product, and therefore to avoid energy consumption, with a new product manufacturing. In the remanufacturing needs, some products of the return stream have this sufficient residual value. If the remanufacturing firm can recover and upgrade the equipment, incomes some products with a real residual value at its end of life or before it, and can give a predicament to the remanufacturer[107]. The fact that in most of the cases a remanufacturing operation is made by original equipment manufacturer (OEM), in the case of medical devices and electronic equipment is offering better possibility to be upgraded for a lower cost and technological effort.

This had been observed in the present study, both company A its medical equipment (an example from Europe applied in the United States as well), and company B having the objective server remanufactured (an example from China).

The statistical operation regarding remanufacturing is quite different and significant, while the remanufacturers. In the United States is more or less $50 billion in the industry and 73000 firms. In China, so far only has in total 75 general pilot firms in the remanufacturing industry, but more activity is expected to follow in the years to come [31,85].

Both of the companies (A and B) have a large worldwide experience and recognition in the remanufacturing industry with more or less activity (company A) on the Chinese market. In their internal framework of remanufacturing, they mutually respect more or less the same general steps in a B2B business of this profile. In our example, is mentioning the relative and common technical activities that are implemented in their framework and the benefits of their remanufactured products.

Company A, a European healthcare manufacturing and remanufacturing/refurbishment company is implementing their B2B remanufacturing

business in Europe and United States with big success, having a special program offering a chance to the pre-owners equipment to extend the end of life of their products by remanufacturing [108].

Company B started the remanufacturing activity in China in 2013, and they are focused just on servers. The global history of the company helps them to adapt quickly to the Chinese market occupying the server supply starting from the government and finishing with banks [36].

In both cases, the strategic core of their framework is divided into five common steps which represent the water flow of the remanufactured product starting and finishing with the product owner (Figure 4.6).

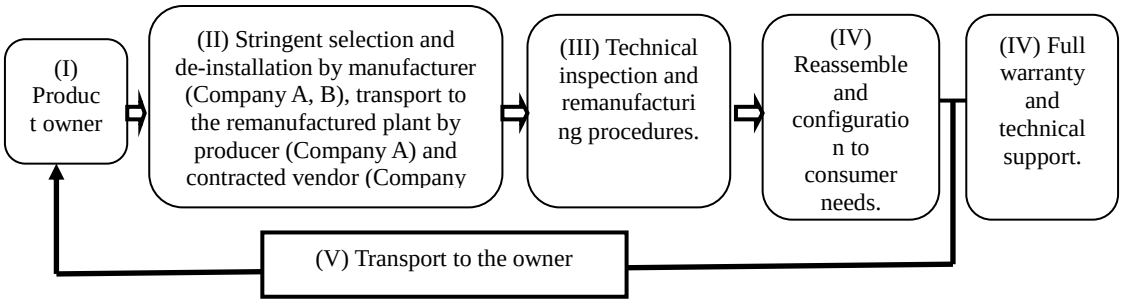

Figure 4.6 Flow scheme of the remanufactured product

Starting from the first step, each and everyone of them is starched in other technical and logistical activities in the remanufacturing process. All the products that designate to be remanufactured are already recorded, regarding their location and technical status by the producer or leaser in some cases. However, if the owner is doing the request for re-updating, he is contracting directly the manufacturing in addition to remanufacturing.

The stringent selection and references (step II) depend on the technical condition, age and service history of the product. If the item respects all the technological characteristics, it is de-installed and packaged by the manufactured company and shipped directly to the remanufacturing plant. In the case of company B, a special vendor makes the shipment, such as Sunjet China specialized in transporting special equipment's.

The fact that the machines have a high value means that after their arrival they are introduced directly in the warehouse for a pre-inspection conducted by a technical expertise to determine the real status of the equipment (step III). Subsequently the following main procedures are implemented, such as de-installation, cleaning,

replacement, updating, and warranty. A detailed process underway is represented in Figure 4.7 where the technical flows (step III and IV) of the remanufactured product of Company A and Company B are shown.

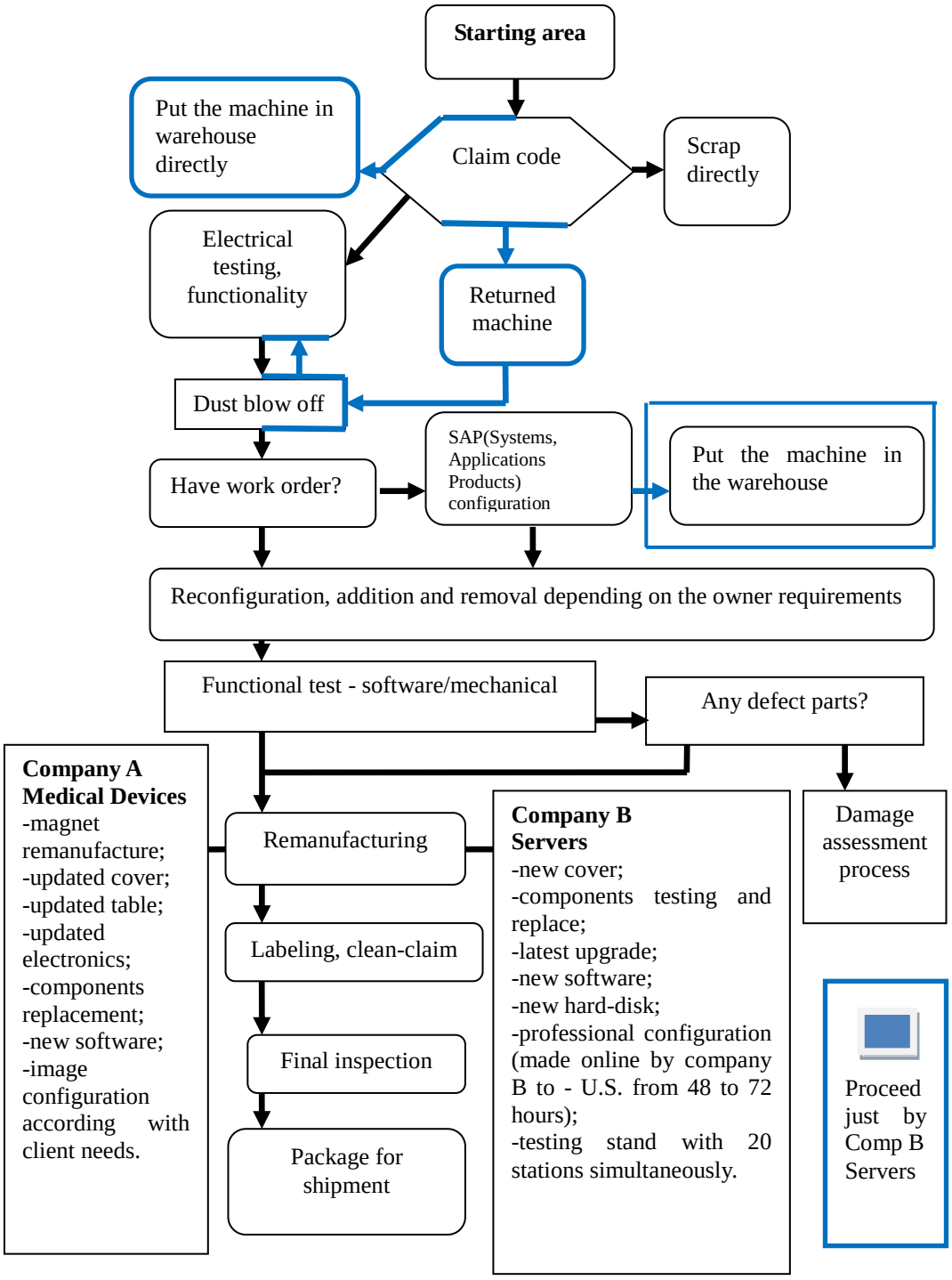

Figure 4.7 Internal process of remanufacturing for servers and medical equipment (Company A and B)

Fulfilling the remanufacturing steps and transferring the equipment back to the owner or to a new one it requires a maintenance process depending on is nature and specifications. For example, servers don't need a very special attention from this point of view, just a monetarization of the technical functionality. Company B is providing full technical support for their devices after the warranty as well.

The other hand, company A requires more strict attention regarding remanufacturing and maintenance to his medical equipment for the reason that it can produce severe magnetically radiation for the operator and patient, electrocution and contaminations can appear. However, these are avoided if the owner respects the planned maintenance (daily, weekly, periodically), cleaning and disinfection of the required parts. The most known products that are remanufactured by company A are Computer Tomography (CT), X-ray and Magnetic Resonance Imaging (MRI).

The initial equipment is designed to be disposed or remanufactured for a technical re-update being advantageous in terms of value and in resource conservation. To avoid the disposal, remanufacturing option jumps to equilibrate the balance giving more benefits to the used equipment like medical devices and servers. The key benefits of remanufacturing this type of devices are not outstanding just from an environmental benefit but outputs the clinical functionality, quality, performance and appearance of new product simultaneously. The full configuration needed by the client is offered at an excellent financial value, lower than a new product flipping the environmental preservation and raw material consummation. Overall the availability on the market in case of medical devices is significant having a high potential to maximize the resource value consumption. As an example, Figure 4.8 exemplyfy a computed tomography on a worldwide scale from the past years revealing the situation of this product and future WEEE generation. The devices which are on the market between the age of 1 to 5 years will have more value if it will be remanufactured between the aged of 6 to 10 years having a high economical value as a remanufactured product rather an e-waste device. From Figure 4.8 is visible that in the next 1 to 5 years the density of the equipment will increase as proportionally with the waste generation if the remanufacturing concept will not be aplicable anywhere.

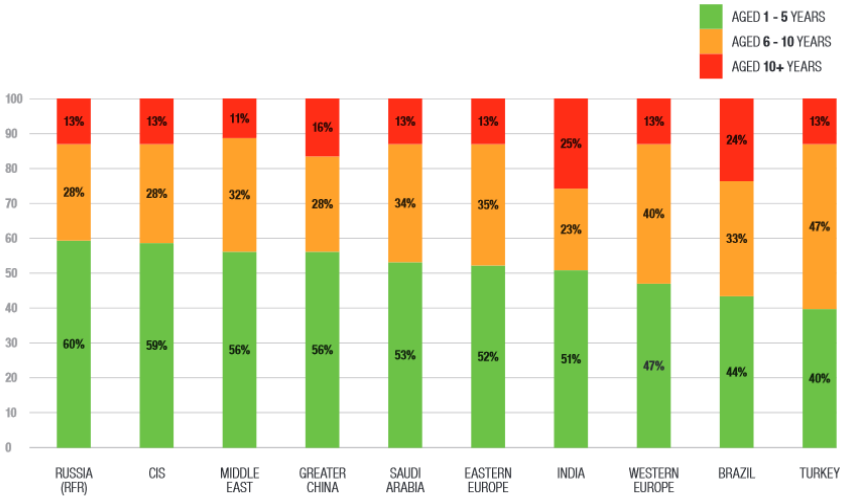

Figure 4.8 Worldwide age overview of an computer tomography [109]

Remanufacturing procedure can be considerate as cooperation linked in a B2B chain, shorting the traditional logistical manipulation of certain use equipment. Company A and B give an approach by implementing their strategy directly with their clients reducing the possibility of e-waste generation in a big scale with proper management. Researchers giving a description of materials and remanufacturing sustainability for different products sustain the importance of this study[104,110]. The main output of this research section deliver a new approach for a better sustainability of collection and managerial remanufacturing procedure being an exemplification for the standard ones [19,20,47,76,81,111,112].

4.6 Material status of used plastic

The experimental purpose of this section is to measure to what extent the actual status of plastic and PCBs from used electrical/electronic devices or e-waste can substitute parts harvesting for reuse or remanufacture to avoid informal recycling [113]. The state of reusing had been heavily discussed in the literature having different opinions related to the components quality, material safety, and equipment durability[114]. If discharged products can be combined with harvesting parts correlated with remanufacturing option enter in consideration after the visual and technical inspection (an example of Taolv Company) of the product/component guided to its end of life stage or being reintegrated again in the close loop chain by updating its physical status by

hardware or software. The example discussed here is about measuring the replicability of PCB materials. In order to do so for the blended material (PCB) analysis, had been choose to use an x-ray diffraction (XRD) for PCB composition, ICP-MS and scanning electron microscopy (SEM) with energy dispersive x-ray spectroscopy (EDX) to identify the surface status and elements composition of the plastic case.

In the examples, the start is by identifying if the surface of the plastic case is having a changeable deviation of surface status by using SEM inspection. After that, the examination will categorize the existing concentration and presents of different elements from the plastic cases focusing on Pb, Si, Cd, As, Al, Ti, Fe, and Hg knowing the negative effects. The method that being used is solid waste extraction for leaching toxicity-sulfuric acid and nitric acid (HJ/T299-2007). The resulted leaching solution has been described by the ICP-MS test and resulted in Figure 4.16. Leaching procedure will help to describe the eventually discharged elements from the e-waste in the environment and the capacity of regression for used equipment/components.

4.7 Material acquisition

In the experiments given have been choose two LCD monitor from different years of production and manufacturer. The purpose to choosing just an old and new monitor is just to be able to exemplify the difference of the internal composition of a specific product as monitor. A Mingsu LCD 2016 monitor is the latest product from this company and was aquired from an electronics shop in the Chinese market. The Apple monitor and PCB board had been acquire from a collector of electronic equipment in Beijing China [115].

4.8 Blending procedure from used plastic and PCB

For the x-ray diffraction analysis, the samples had been used in solid and powder state following the experimental flow from Supporting information (Figure 4.9). After the collection and disassembly of rudimentary tools (scroll, scissor, and nippers), the monitors had been divided into two categories: plastic and PCB. The plastic samples were cut from the plastic case body of the monitors having a diameter of 0.5 cm^2 for the EDX, SEM inspection. The textures of the surface were exanimate using a Hitachi S-4500 field emission scanning electron microscope (FESEM) whit 15kW electron

acceleration. The plastic samples were given a conductive coating of gold to prevent the electro-charging of the samples. The PCB particles had been prepared using a usual crusher for 60 seconds, and after shifted to a screening of 0.5 mm to give a proper consistency to the samples for the XRD scrutiny.

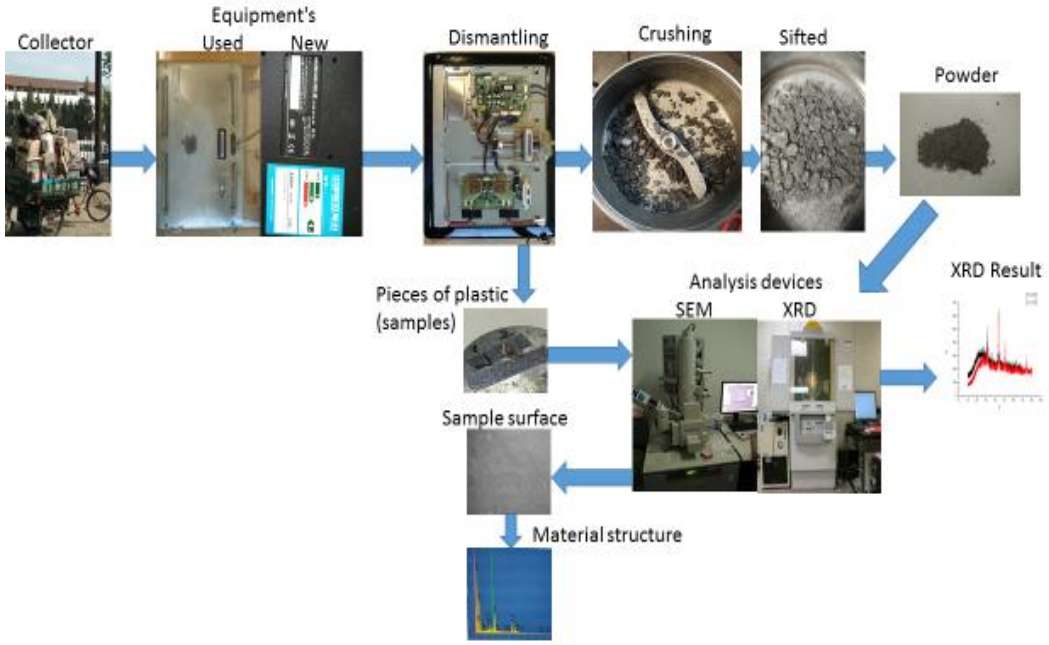

Figure 4.9 Experimental analysis flows

4.9 Leaching Procedure using sulphuric acid and nitric acid for toxicity determination from used plastic

Before the leaching experiment the plastic cases had been crushed separately in powder using a smelter. The amount that had been converted is 200g from each product freeze with liquid nitrogen for a better diffraction during the smelting procedure. The liquid nitrogen had been used because the material compositions of the cases were elastic and prevented the decomposition in the smelter. From the resulted powder we use 100g in a ratio 10:1 (L/Kg) with liquid.

As a next step was the solution containing sulphuric acid, nitric acid, and distilled water was equilibrated at 3.5 pH and mixed with the plastic powder in separate recipients for 18h using a stirring machine. Every 4hr the stirring machine was stopped to release the accumulation of gasses from the recipients and start over. Subsequently, the mixture had been separated (liquid from solid) using a vacuum filter separation method. The filter is a silicon membrane with a thickness of 40 μm.

4.10 Results and discussions

4.10.1 Experimental analysis

The existent literature examining the composition of old electronics for the recycling process it didn't change in the last decades having more or less the same structure[116]. The examination of the old and new material utilized in the manufactured equipment deliver an unchanged situation of their status. The examination of plastic and PCB materials observed that the inorganic composition of the PCB (plastic circuit board) is changing comparing over the production year in different concentrations. Being exposed to erosion and the identified elements are mostly the same presented in both of the samples. The chemical composition and crystal structure described by the XRD analysis for each product (Figure 4.10-4.12) had shown out a decreasing or increasing of some crystal faces depending on the year of production. Heavy metals as lead (Pb), mercury (Hg), chromium (Cr), and cadmium (Cd) had been discovered in a disorientated position according to XRD results and in combination with other elements. XRD test can not precisely identify chloride compounds. The biggest shade of the effect is dominated by the copper (Cu), aluminum (Al), gold (Au), and silicones (Si) present in a higher percentage on the scale in all samples. The SEM result describes in (Figure 4.13) the initial stage of the plastic case from a new and used monitor; the analysis demonstrated whether the original status of the material is proper to be remanufactured or recycled.

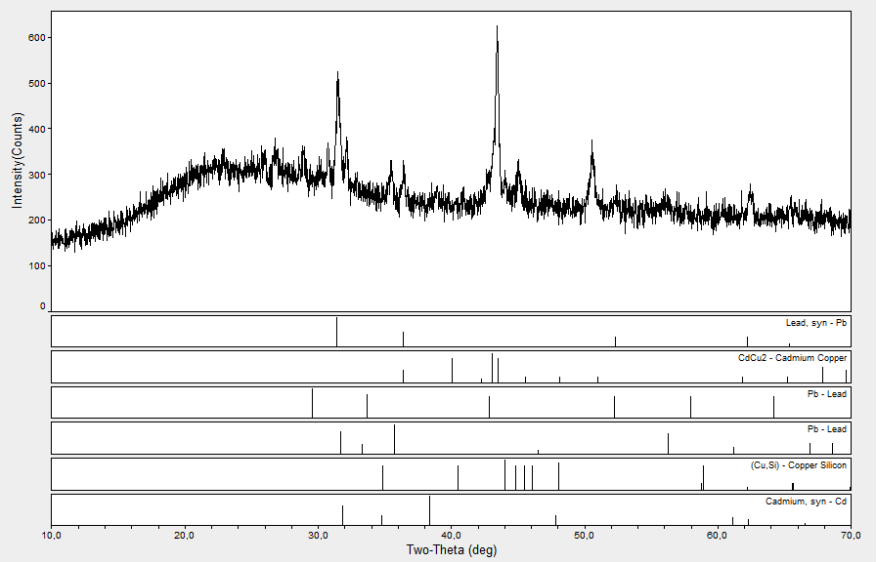

Figure 4.10 X-ray diffraction from the solid residue of new monitor (New monitor 2016)

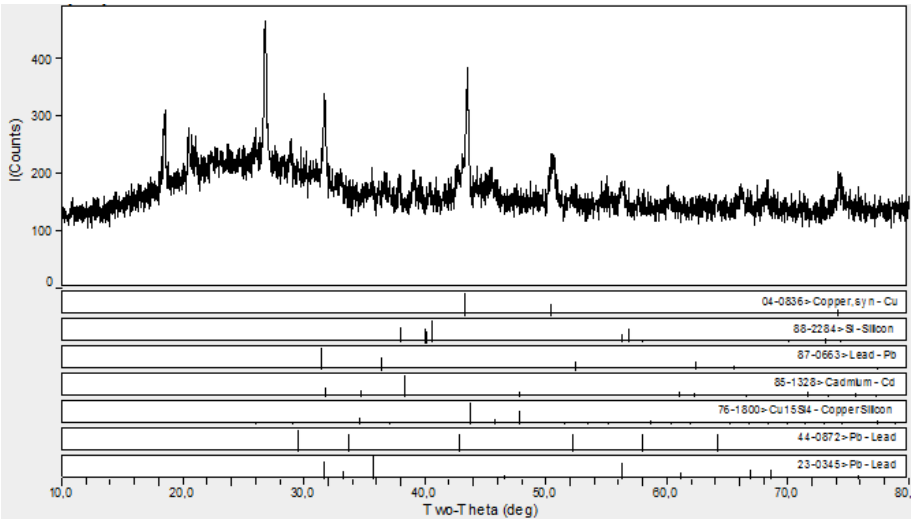

Figure 4.11 X-ray diffraction from the solid residue of used PCB monitor (Old monitor 2001)

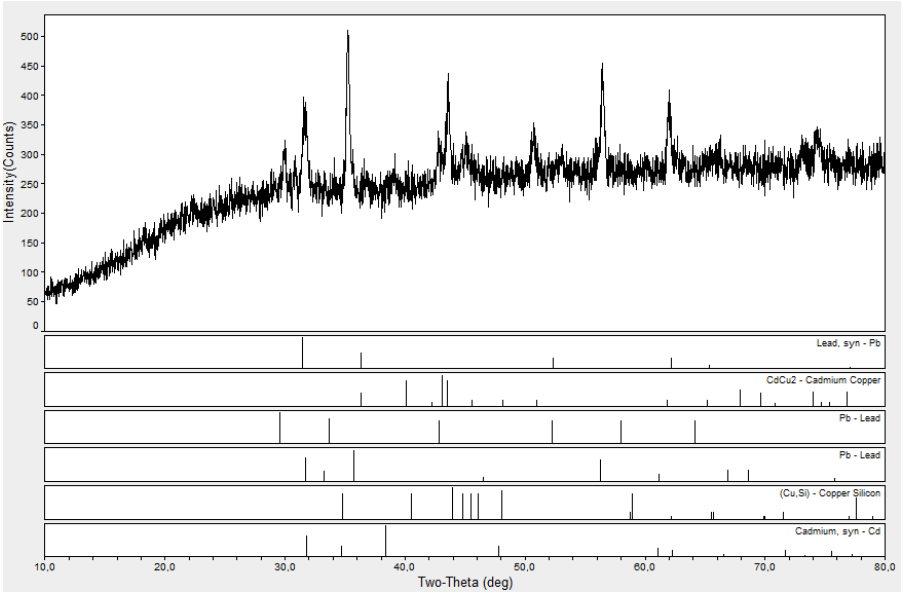

Figure 4.12 X-ray diffraction from the solid residue of waste PCB

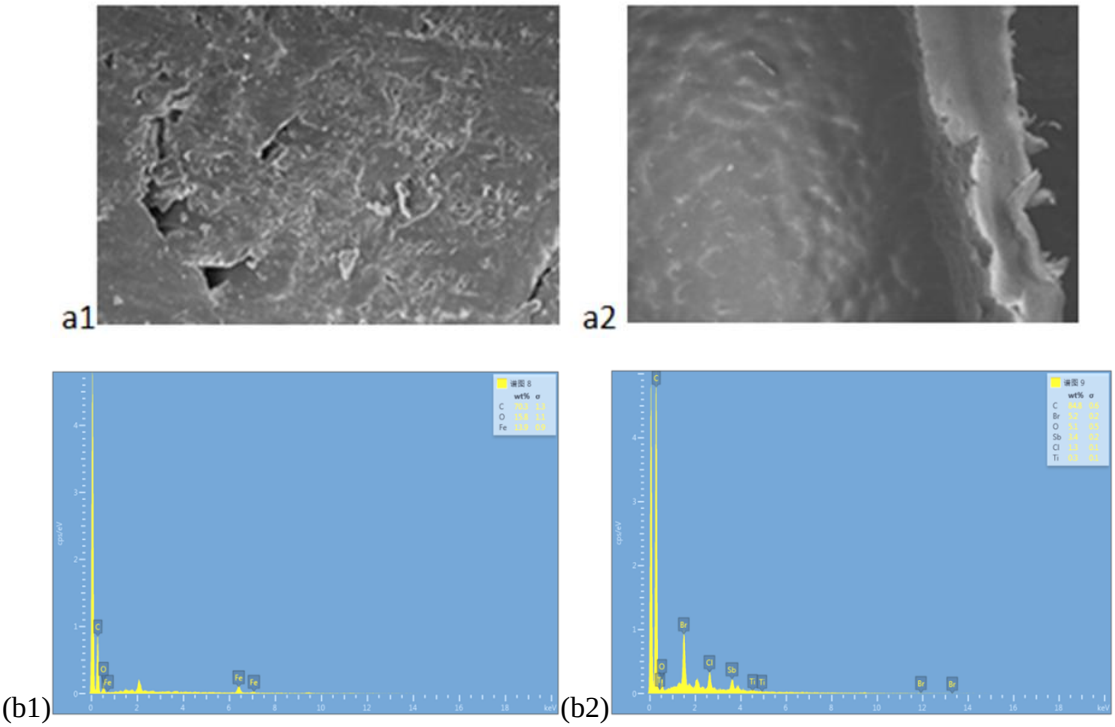

Figure 4.13 (a) Scanning Electron Microscope (SEM) (a1) new monitor, (a2) old monitor and (b) Energy Dispersive X-Ray Spectroscopy (EDX) image from monitor's plastic cases (b1) new monitor (b2) old monitor

From our SEM result concludes that the new monitor (Mingsu) case is in an appropriate physical stage of use. The old monitor (Apple) cover had been zoomed at a resolution of 300X on a scale of 100µm where it can be identified several microdefects

(Figure 4.13. a1). Due to the high resolution, it can understand that the status of the surface is not deprecated even though the cracks are prominently existent. This gives the possibility to conclude that the cover is in good shape without any severe deterioration.

EDX images in both cases reflect almost the same chemical composition, identified as carbon, oxides, iron, and titanium elements being common in the composition of the polymers materials. From the experimental results, it can be seen that the chemical composition of PCBs is almost the same containing Cu, Fe, Ti, and Sn. As regards the content of silicon in the new device determine that the other elements are presented but in a reduced concentration, Cu being except. For instance, the result of the plastic cases reveals that some components as the plastic cases of the monitors can be remanufactured even if they have small defects by using small mechanical processes as cleaning and repainting. These needs small financial investment and the result is the same as a new product from an OEM. In the present research, the cover from the Apple monitor has the physical cracks at the surface, but cleaning, polishing, and repainting can remanufacture [117]. In the internal composition of plastic and elements that had been chosen to be exanimated from the products, cases have a different characteristic for almost all equipment's (Figure 4.14). The new monitor (Mingsu) produced in 2016 in China reveals that the amount of the explored elements decreases compared with the old monitor. In the composition of the new monitor, it's determined that Pb, Cd, Ti, and Fe have a total concentration, Hg being decreed just in a very small amount. However the quantity of Hg is not very significant comparing with the other elements Pb, Si, Al, and Fe, but these are substituting the potential of hazardous discharging especially in the case of an old monitor.

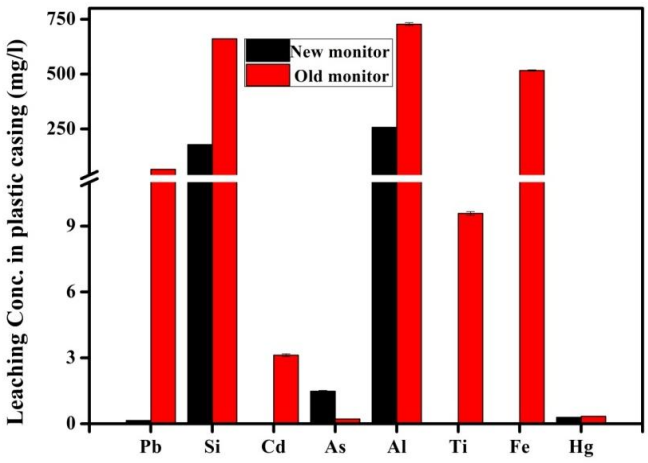

Figure 4.14 ICP-MS result for leaching toxicity of plastic

4.10.2 Technical approach updatability

Overall the physical result pictures the existence and persistence depending on the case of certain toxic or nontoxic elements in the composition of the materials and a good visual overview of the plastic surface. This unchangeable status of plastic composition is suggested by this research as an opportunity for the use of electronics to be updated or be used as reuse parts instead recycling for raw material minimization propose. The possibility of applying upgradability in the case of some electronics as PC, TV, laptops, tablets, mobile phones, and medical devices can be made in two ways: hardware and software. As an overview for these devices, the technical upgradeability can be improved using high-tech extensions as Banana pi (bpi) (Figure 4.15) accessories and IoT (Internet of Things) module [118,119].

Figure 4.15 Internet of Things (IoT) accessories - Banana pi

These can be programmable to deliver different function as intelligent personal assistant being connected through Wi-Fi to the internet and having a knowledge navigation system.[120] Many electronic start-ups came with several project design for their future innovation base on these universal application applicability.[121] Examples of this applicable software are “Siri” from Apple, “Alexa” from Amazon which can be installed in the high-tech as bpi extension. Many developed, developing countries as China are promoting the concept of IoT seeing as the next movement of technology with a very big range of applicability, even in the case of used electronics and medical devices [122]. The above affirmation embraced by the researched companies demonstrates the possibility of upgradability. In case of servers and medical devices, both companies linked the existent technology and previous generation through software updates, and harvesting parts are reconditioning and reuse. The medical device company exemplified and followed international standards for

remanufacturing/refurbishing as good refurbishing practice[123], ISO[124], directives (RoHS)[116] and regional marks (CE, CCC).

More while in this case the remanufacture of medical devices and servers is the next step for a meaningful reduction of waste due to their size and weight (kg) and offer the best conversion of resource and value just implementing a B2B business scheme by upgrading their remanufactured products.

4.10.3 Market assessment

Household and personal appliances (e.g., fridges, oven, TV, monitors, mobile phones) make up 40% of WEEE where large volumes of other equipment such as IT equipment and medical devices remain stoked in private properties and hospitals[106,116]. Homeowners and parties discard an estimated 2 million tonnes of WEEE items in the UK[125]. In Asia, the recycling predominance is familiar with low results described by [3] exemplified by China as the second generator of e-waste and historical linked with the pollution and discharged electronics causing human health issues[126]. On the other hand, collection approached and implemented by Taovl company increase; general collection rate thought the deployed system. Remanufacturing operation and approached in Europe by the medical device remanufacturer and server remanufacturer in China demonstrate the physical and technical implementation[36]. Remanufacturing potential on the Chinese market is lower as in Asia due to the poor regulatory approached by different governments[127]. As an overview, the internet+ collection approach, the implemented remanufacturing operation system as managerial and technical deliver an extension of remanufacturing and reuse to conserve and extend the usage life of a product as a new one (the case of servers and medical devices).

4.11 Summary

In this chapter we identify three avenues to do a better conservation of resources speculating the new opportunity given to used equipment or matured in functionality for a new reintegration in the life cycle. Although the probability of reintegration is lower in the case of EEE, it remains an approach to recover the used resources utilizing remanufacturing instead of recycling and manufacturing.

All company investigate the products which are tested and analyzed before their

entering in the remanufacturing process giving a total description of their physical potential to be regressed for a new circular life cycle. According to Figure 4.10 and the data collected from Company A, this type of devices represents suitable and efficient example of remanufacturing in the future with a lot of value. The value advantage and technical availability for the products are a perfect incorporation in a healthy circular economy view. As has been demonstrate in the experimental section the chemical composition and surface of the plastic is dives from the chemical and visual aspect. This is not a very crucial problem and can be remediated using technical processes for surface remediation as polishing and painting. In case the device is in a good condition and functionality it can be intercalated with other open source device (hardware and software) as Banana bpi or software and interconnectivity as the concept IoT. In this way, the generation of waste WEEE and chemical discharging are delayed.

The new approaches as Banana pi and IoT can revolutionize old equipment giving them a new postponing for an additional few more years of functionality having the same characteristics as a new product. As a future work will want to establish the technical remanufacturing process and sustainability of medical devices. Moreover the cost efficiency of remanufacturing knowing already that the B2B and Internet+ collection is having a tremendous potential being demonstrated by the company A, B and Taolv. Such work can contribute to the development of new collection systems and a positive perspective to promote the adaptation of already existent products by updating with IT systems, extended units for quality products. An IT system can be helpful to allow a better selection of the sub-assembly interconnected with design, technology, and system organizations. In this way, the problems related with e-waste and raw material consumption can be minimized or postponed.

Chapter 5 ENERGY SAVINGS AND ENVIRONMENTAL IMPACTS OF REFURBISHING MRI AND X-RAY SCANNERS

5.1 Introduction

Refurbishment is an environmentally responsible approach that precedes the end-of-life stage. Refurbishment is intended to restore used equipment or systems for an extended use, thus achieving significant savings. Refurbishment avoids resource use (energy and materials) and emissions associated with production of new devices. At the same time, refurbished devices typically sell for ~50-80% of the new product retail price. Therefore, refurbishment can be considered a 'win-win' as it saves money (for the user), increases access to healthcare for patients and saves energy and resources, protecting the environment[128,129].

The leading refurbishing and remanufacturing industries are in the United States (U.S.), where overall exports are $11.7 billion, with aerospace being the largest market, followed by automobiles, information technology (IT) products, energy generators, and medical-devices, which are traded to Europe, Brazil, Mexico, Canada, Singapore, etc.[85]. The ERN (European Remanufacturing Network) anticipates that refurbishing in the EU could achieve an annual value of €70 bn to €90 bn, employing a workforce of 65,000 personnel by 2030, for some industries[40]. In China, refurbishment can be expanded because the necessary technology is readily available[32,130]. Worldwide the most common refurbished/remanufactured products are aircraft parts, medical devices and their components, compressors and electrical motors, toner cartridges, cameras, automobiles and automobile parts, office furniture and equipment, machine tools, tires, and a few others[40,131].

The first condition for refurbishing is that the used product has a significant residual value at the end of life, compared with their raw-material value[132]. The second condition is that the refurbishing companies can acquire the used product in large numbers. The third is that the used product can be refurbished to a like-new condition (in regard to aesthetics, safety, functionality, and updates)[133–135].

The fact that products can have substantial residual value as they approach their end

of life is a predicament for original equipment manufacturers (OEM): if the OEM chooses not to refurbish its product, then it might find itself contending with its own products, refurbished by another firm (third party). To avoid this situation, the Xerox company entered into a contractual agreement with remanufacturer (refurbisher) Concept Group UK, one of their affiliates, to return their photocopy machines directly to them using a tracking system[127]. Medical-device OEMs might be even more suited to adopting refurbishment as part of their commercial strategy, as they possess the knowledge and technical information to ensure safety and performance of the refurbished equipment. Many firms, from several different industrial sectors, have done this, particularly manufacturers of truck tires and photocopy machines (e.g., Caterpillar, Cummins, and afore-mentioned Xerox). This approach helps build long-term relationships with producers and customers. As a conventional technique for providing products to customers, however, refurbishing presents some challenges. The preliminary steps in refurbishment consist in acquiring the used product, transporting it, cleaning it, and testing it. The challenge is to match the supply, the demand, parts availability and quality standards. Therefore, two conditions required for refurbishment are (1) a trained industry (medical device manufacturers), and (2) environmental benefits and resource conservation plus small stock storage costs. In addition, the refurbishing companies need to have an active operative way to reintroduce refurbished products to the market.

The objective of this study was to determine the energy and material savings, and the environmental benefits, obtainable through the refurbishing process, and the market potential of the refurbished products, in particular for medical devices. The exemplification of remanufacturing/refurbishing medical devices is not present in the academic literature, just mentioned by different authors. Revealing our objective many gaps from remanufacturing and circular economy are covered.

5.2 Data collection

The investigation questions that drove the study were:

1) What is the energy savings involved in the refurbishing process, with a particular interest in medical devices, and

2) Can the energy savings potential be expanded, in terms of environmental benefits and recovery of used medical devices, in the existing market?

To address these issues, we investigated Magnetic Resonance Imaging (MRI) and X-Ray biplane systems refurbished in Europe and the U.S. These types of equipment represent the highest economic and material value (residual value) due to their functional accuracy, technical complexity, and weight.

The analysis included the processing steps of refurbishment for both MRI and X-Ray biplane devices, for each step, and eight types of savings in refurbishing as an ensemble. The questions were investigated utilizing a life cycle assessment analysis software ''Gabi'' in use at the investigated OEM's at their facilities. The energy saving was investigated only for an X-Ray device, in terms of cumulative energy demand (CED) consumption. This type of device (X-Ray) was chosen as example, as it represents the lowest percentage of refurbishment (63%) among the commonly refurbished systems, while retaining a high residual value. The refurbishing of MRIs has a refurbishment potential of 90% with an even higher residual value and weight than an X-Ray.

We performed a field analysis at two OEM refurbishing plants in Europe, to consider the primary processing steps deemed necessary to include in the research. Moreover, the study engaged in a non-destructive test on plastic cases from medical device monitors, as an example of sustainable recovery of parts. The non-destructive test examined the material extrusion capacity using a tensile meter M350-10 AT/CT following the ISO527 standard for plastic, and surface-status visualizing with an SEM device. For the refurbishing procedure, the researched products contained the following assemblies: MRI: magnet, patient table, cooling unit, control desk; X-Ray: cabinet, stand, monitors-suspensions, patient table.

The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), Brussels, Belgium, guided this research. Each step from the refurbishing process was split into five categories, developed in figure 5.1. The process represents the managerial and technical steps described by the Good Refurbishing Practice (GRP) Guide and the IEC PAS 63077 (2016)[136], implemented at the researched plant.

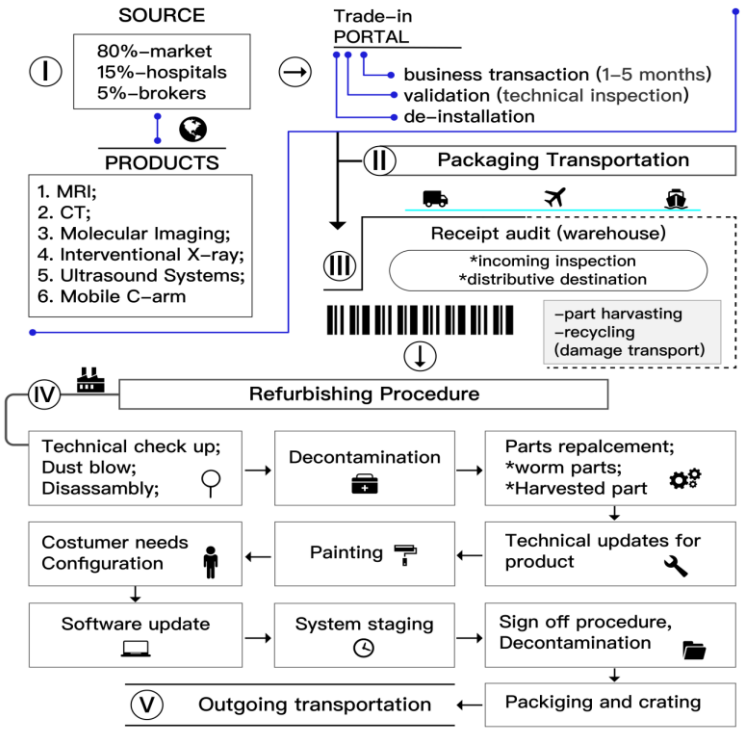

Figure 5.1 Refurbishing processes for medical equipment (MRI and X-Ray)

5.3 Product Life Cycle Analysis

Product life cycle analysis is often utilized in the fields of innovation and research. Many studies and software programs are available to help with the development of new products, complying with the existing standards to guide both researchers and manufacturers.

For this study, we utilized "Gabi" LCA software and field investigation. Refurbishing of medical devices is not well researched by the academic field, because of confidentiality (proprietary rights) among manufacturers of such devices. Yet the existing literature does mention the inclusion of medical devices in the refurbishing approach, as a means of avoiding waste generation[137],[138],[139]. An important and common outcome from product life cycle research is that for most goods, the energy requirements for materials production leads to the need for energy for manufacturing[140]. Also, it has been shown that the refurbishing/remanufacturing process saves both raw materials and energy, compared to manufacturing of an equivalent new device[104].

5.4 Procedure sustainability

Medical equipment is safely and reliably used in active service worldwide, continuing to provide advanced diagnosis and precision treatment. Usage, mechanical stresses, wear and tear on parts, and updated technology, however, lead eventually to the end-of-life of a medical device. On average, the lifetime of medical imaging devices is between 7 and 10 years[141][142]. Only four producers of medical equipment, though, offer refurbishing procedures[40]. The number of refurbished devices is quite low compared with the sales of new products on the global market, resulting in a high number of devices that are not refurbished and are therefore discarded as waste. A comparison between developed and emerging markets (figure 5.2), though, shows an increase of 5.3% in refurbishing, during the past five years (2012–2017) in the emerging markets for refurbished medical devices.

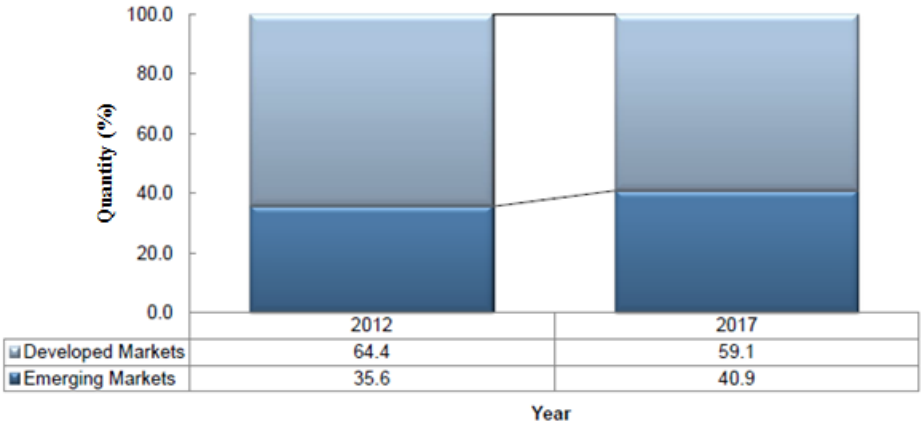

Figure 5.2 Global Medical Imaging Equipment Market: Developed versus Emerging Markets, 2012 to May 2017

Refurbishment is an established activity in the European Union and U.S. healthcare markets, but not in China or Middle Eastern countries, where the below barriers still persist. Overall, the sale of refurbished products remains at a low percentage, according to refurbishing companies and COCIR. The pre-owned market share comes to: 48% in North America, 8% in Latin America, 26% in the EU – Russia, 3% in the Middle East, 15% in Asia, and 3% in Africa[143].

Table 5.1 shows the refurbishing potential of some selected items, for three regions (the Middle East, the EU, and China) based on the number of units installed. The findings demonstrate the numerical potential of refurbishing operations, but also a lack of skilled technicians and engineers in the industry. The number of installed units in

2014 revealed by the World Health Organization (WHO)[144], and the percentage of refurbished devices in 2016, are quite different from those shown in table 5.1. Largely, China for example, does not have any refurbishing plants for medical devices, because of legislative restrictions. Nevertheless, China has an advantage in technological availability from the OEM side. At the Health Industry Summit (tHIS) held in Shanghai, China, in May 2017, about 7000 exhibiting companies from 30 countries were represented. Most of the vendors were Chinese companies or international OEMs based in China[130]. In the Middle East, the legislative situation is similar to that in China, but without the industrial availability. One company investigated in 2017 divulged that they had just recovered 770.73 tons of pre-owned medical devices from the U.S. and the EU.

Table 5.1 Remanufacturing situation and potential

Category	Product	Average product weight (kg)	Service life (years)	Refurbishment potential (%)	Energy consumption(kw/h)	Installed base (units) 2014			Remanufactured unit's provenience (% in 2016)			OEM technical availability for remanufacturing procedures (%)			OEM remanufacturing plants (numerical)			References
					New	Middle East	EU	China (2016)	Middle East	EU	China	Middle East	EU	China	Middle East	EU	China	
Healthcare Medical Devices	X-Ray	≈4219 Kg (plus 800 Kg of packaging)	8-10	60	≈ 378	82	132	3507 (total imported X-ray devices)	4	19	0	0	100	100	0			[144], [108]
	MRI	≈5500 Kg	8-10	95	326.9	679	2247	355										
	CT	1900 Kg	8-10	85	n/a	1632	2962	914										

Neglecting reusability as a fundamental principle of ecological thinking and circular economy results in a tremendous amount of energy and raw materials being wasted[145]. A good refurbishing practice for Magnetic Resonance Imaging (MRI), and X-Ray biplane detector devices of mixed sizes (30x40cm and 20x20cm) can save up to 30 MWh of energy per ton of refurbished devices. As well other resources as raw materials, manufacturing costs; reduce CO_2 emissions; prevent waste (16,400 tons of waste medical devices were avoided in 2012[143]); support the circular economy; and increase access to healthcare. The energy production costs for MRIs and X-Ray machines can be saved by refurbishing, as represented in the results section of this study, as an overview of cumulative energy demand (CED) efficiency.

5.5 Activity framework

The refurbishing process for medical devices (Figure 5.1) is guided by the Good Refurbishment Practice (GRP) Guide developed by COCIR, JIRA, and MITA in 2009, later adopted by DITTA, and included in 2016 in the IEC PAS 63077. Many companies receive the process certified for EN ISO 13485:2012 & ISO9001:2008 by notified bodies every year.

The refurbishing process can also be applied to those products that are not approaching their end of life; life cycle assessment can be used to determine when it might be appropriate for a product to be refurbished. The complete refurbishing process presents a meticulous and challenging path, as it involves the entire chain of manufacturing and management. The system is circular, starting with the OEM, then the owner of the device (hospital, clinic, etc.), and continuing with the OEM, and ending with a new owner of the refurbished device. It involves taking back, cleaning and decontaminating, testing and repairing reusable parts, replacing unusable ones with new ones, installing updates, cosmetic repairs, re-packaging, transportation and installation, before a refurbished device can be re-sold as an “as-good-as-new” device.

The availability of products for refurbishing, or those in the middle of their working life that could be profitably refurbished, depends first on the location of the product and second on the physical stage of use. For example, an X-Ray with a weight of 4393 Kg transported from a location to the refurbishing site has a particular CED of 0.25 kWh/kg and 1.1 MWh/system. Removing the components, processing, and ending up with a

ready-to-use semi-finished X-Ray device requires the exchange of an average 15% (by weight) of the parts, 30% of the electronics, and 70% of other materials (exact component percentages vary depending on their physical condition). Using the LCA software to determine the suitability of a product's materials for refurbishing can result in a savings of 79%: for example, the estimated 110.3 MWh CED for the materials for a new device can drop to a CED RS (RS-refurbished system) of 23.6 MWh.

According to the refurbishing companies we investigated, 80% of the collected used products are coming from different markets [(research institutes, private clinics), (the EU and the U.S. separately)], 15% from hospitals and 5% from third parties (brokers).

There are legal and regulatory barriers to refurbishment in the healthcare industry, such as the RoHS Directive, the REACH regulation, the Medical Device Regulation and the Basel Convention – Technical Guidance on transboundary movements of e-waste.[146,147] Under these barriers, the process of global trading in used medical devices such as MRIs and X-Rays is restricted and occurs only in limited regions like Europe and the U.S, according to COCIR and the refurbishing companies investigated in this study. The refurbishers often complained about the limited availability of used systems in the EU and the U.S., and their inability to obtain used equipment, including MRIs (Figure 5.3(a)) and X-Rays (Figure 5.3(b)) suitable for refurbishment, from other regions. The unavailability of trade-in devices as complete integrated products results in the loss of materials (Table 5.2), devices being recycled rather than re-used, material reconversion (recycling) of raw material, and unnecessary duplication of manufacturing. These limitations, taken together, decrease the quality of materials, and increase the demand for energy and other resources to manufacture new products,[148] adding to CO_2 emissions and environmental degradation.

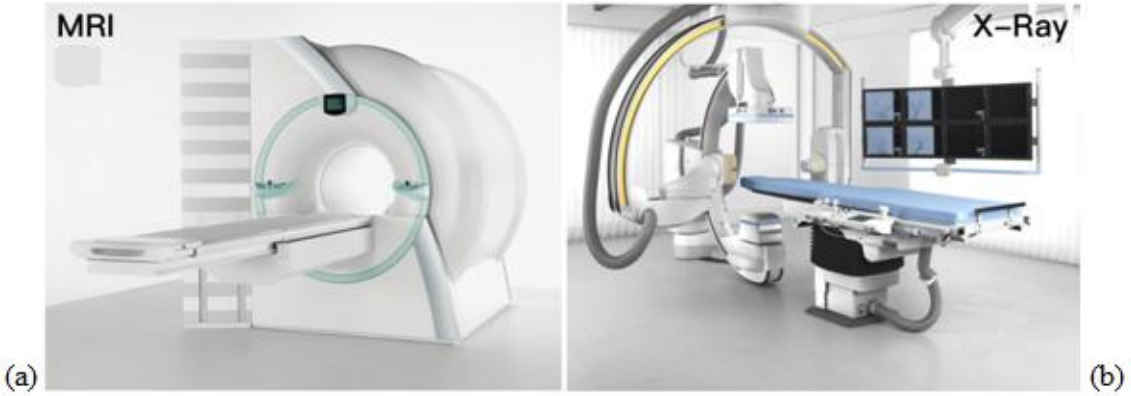

Figure 5.3 Medical devices: a) Magnetic Resonance Imaging (MRI), b) X-Ray

Table 5.2 Components of used devices: a) Magnetic Resonance Imaging (MRI), b) X-Ray

FIGURE 3 (a) MRI – 3T	FIGURE 3 (b) X-Ray
Ferrous alloy, steel – 47%	Ferrous alloy, steel – 52%
Nonferrous metals and alloys – 32%	Nonferrous metals and alloys – 18%
Critical substances – 2.4%	Critical substances – 0.88%
Other materials – 0.36%	Other materials – 0.38%
Organic substances – 0.016%	Organic substances – 0.73%
Plastic – 13%	Plastic – 23%
Inorganic materials, ceramics – 5.1%	Inorganic materials, ceramics – 3.4%
Precious metals – 0.0039%	Precious metals – 0.0042%
Other metals and semi materials – 0.12%	Other metals and semi materials – 1.2%

5.5.1 Trade-in portal (Step I)

The first aspect considered in the refurbishing process is the physical depreciation and real residual value of a product on the market. The window of opportunity for refurbishing MRI and X-Ray business units (BUs) is between 7 and 9 years of functionality, due to software and design incompatibilities between newer and older models. After this, medical devices are no longer refurbish. This represents a condition regarding their safety and performance.

The trade-in validation includes analysis of the maintenance history and a technical inspection (search for defects). Also taken into consideration are the age of the device, its residual value (Figure 5.4), and the costs of de-installation and transportation.

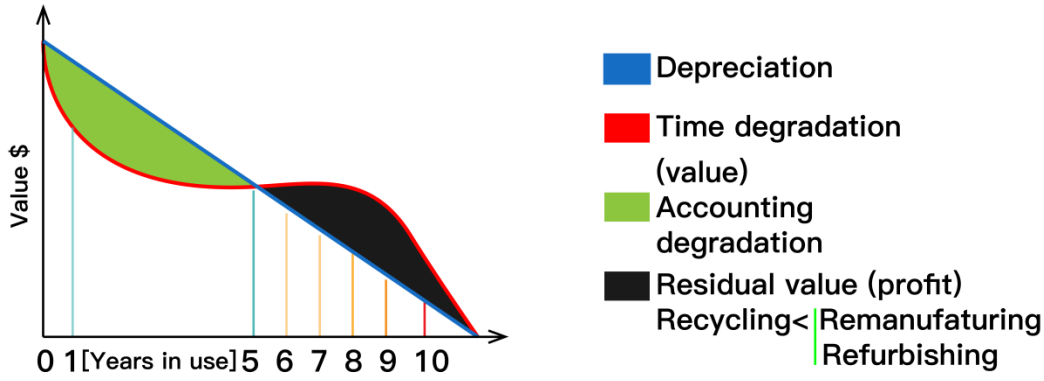

Figure 5.4 Product depreciation considerations

5.5.2 De-installation

De-installation is performed by the professional team from the refurbishing company (OEM), respecting the Quality System Regulation (QS)/Good Manufacturing Practices (GMP) - 21 CFR Part 820.3(l) , RoHS 2 directive.[149, 150] The relevant requirements are applied to cables, pipes, wiring, PCBs (printed circuit boards) and other components, depending on their specifications. Generally, for an X-Ray device, the cables are 50% reusable in the new refurbished device; the other half are recycled.

Business travel costs are included in the cost of de-installation, which varies depending on the total number of employees at the refurbishing facility and the number of devices refurbished. In our case, a specific CED of 6 MWh/employee was generated. This is based on the total weight of an X-Ray device (typically, 4393 Kg), with an additional 800 Kg for the packaging.

5.5.3 Incoming transportation (Step II)

After the trade-in process is finished and the de-installation has been completed, the system proceeds to the refurbishment facility. By using the original shipment pallets, frames and carriers, the protection of the device against damages is ensured during its transportation to the refurbishing facility. Generally, the CED for the transportation of an X-Ray is 1.1 MWh/system. This takes into account a mix of transportation modes: terrestrial (rail and truck), water (cargo ship), and air (cargo aircraft). For this study, we used a figure of 0.9 MWh/system for incoming units (components or devices), since some component used for refurbishment is already present at the refurbishing site.

5.5.4 Receipt audit (Step III)

After the arrival of the system at the refurbishing facility (Figure 5.5 a), an incoming report is generated, to confirm the integrity and completeness of the packaged unit. Because of the complexity of the systems, the report includes a detailed description sheet for various aspects of the process (transportation, technical issues, integrity, maintenance history, total weight, etc.). An MRI device is subjected to a functionality test (phantom test- Figure 5.5b) before being de-installed and shipped. In case of damage sustained during transportation, the deteriorated packaged components are directed to the parts recovery area for repair or recycling of the units.

(a)  (b) 

Figure 5.5 a) Receipt audit b) Phantom test MRI and X-Ray

5.5.5 Disassembly (Step IV)

Following unpackaging the systems are cleaned and prepared for disassembly. This procedure is different for each type of device. An MRI system contains a scanning system or magnet (static magnetic field coils, gradient coils, RF (radio frequency) coils, a computer, and recording hardware. Each electromagnet contains 1500 litres of helium (the refrigerant), and during transportation from the location to the refurbishing facility and other operations, there is an estimated helium loss of 2% per day. An MRI magnet, therefore, is diverted to the field service where it is directly connected to a cooling device to recover helium (Figure 5.6a).

(a)  (b) 

Figure 5.6 a) Magnet cooling system; b) X-Ray C-arm

An X-Ray device is transferred to a disassembly area (Figure 5.6 b), because it has more components: a workstation, operation console, monitor suspension, patient table, C-arms, X-Ray detectors and DTA (data acquisition system) cabinets. The entire assembly is first sent, via electrical forklifts and lifters, to a designated area for testing, accumulating in the process a transportation CED of 0.2 MWh/system. From this point, the components are separated and sent to either a decontamination-and-cleaning or a component-assembly area, generating an additional transportation CED of 0.8 MWh/system. (Actually, most MRI and X-Ray systems are received already disassembled except for the MRI magnet and a few other components, which are relatively compact units).

5.5.6 Decontamination and cleaning

The objective of decontamination and cleaning is to eliminate or prevent the growth of organisms capable of causing infections (Figure 5.7 b). The operation takes place in an isolated room (Figure 5.7 a) for all types of assembling, including pipes, cabinets, and components made of plastic, fiberglass, or iron, etc.

(a)  (b) 

Figure 5.7 a) Decontamination and cleaning room; b) MRI counting status at arrival (prior to cleaning)

5.5.7 Parts replacement, refurbishing system

Defective or worn-out parts are replaced with new original parts from the manufacturer or refurbished parts. In the case of an MRI, the most commonly replaced part is the exterior (aesthetics), to improve the appearance prior to a new quality reinvestigation. The magnet is refilled with helium; the magnet's functionality is checked and replaced in case of any minor technical deviations from the functionality standards. The X-Ray biplane, due to its higher number of components, requires more attention for the assembling and disassembling procedures. The patient table for both devices (MRI and X-Ray) is reconfigured and readjusted (Figure 5.8) with new mechanical and electrical components, to prevent physical failure. The covering of the patient table usually is replaced with a new one (90% of cases) or repaired (10% of cases).

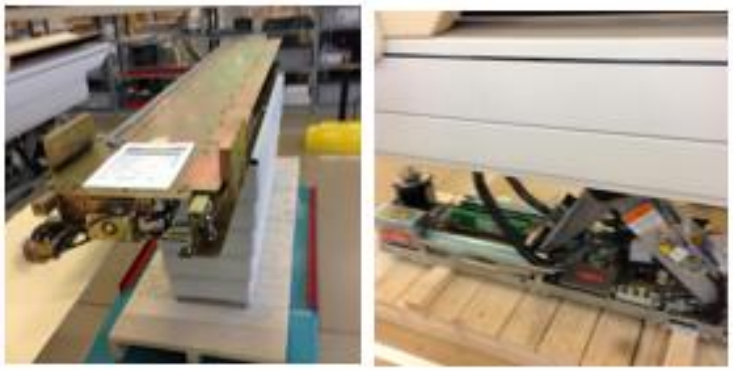

Figure 5.8 Patient table in the replacement stage

The monitors and command desk may be replaced, depending on the functionality and client requirements. If the system is in the OEM's possession, 50% of the monitors will be replaced, depending on the luminosity and image clarity. An X-Ray device uses two types of screens: LCD or LED, with a size varying between 56'' and 58'' or larger, specially designed for medical use. The monitors are held by a support called a "mani suspension" divided (Figure 5.9) into 1, 2, 3, 4, 6, or 8 flex visions (positions). Usually, at least half of the mani suspension's connectivity cables are replaced. The client usually chooses the command desk control from the refurbished or new catalogue.

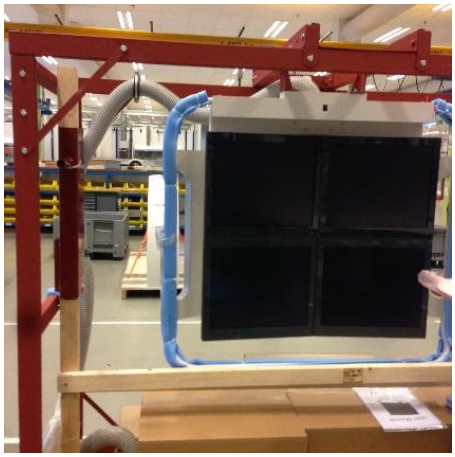

Figure 5.9 New mani suspension with 4 flex visions

The cabinets (Figure 5.10a) represent the core of the X-Ray device and are split into three units: a cooling unit; an “M” (control unit), “B” or “K” (imaging unit); and an x-ray electric-power generator. In the case of an MRI, the cabinets (imaging and cooling) are incorporated into the control desk (imaging) and an additional room for the cooling system. The cooling cabinet (unit 1) of the X-Ray device is configured as a cooling system and its controllers. The cooling system (Figure 5.10b) is designed with an oil tank (5 liters) and compressor. The oil is changed in the refurbishing process, and the used oil is sent to recycling. Controllers are verified, recalibrated or replaced, depending on the functionality and maintenance report. The “M” cabinet (unit 2) (Figure 5.10c) represents the data storage and video imaging control. The imaging units in the refurbishing process are replaced and the old ones used for testing in the refurbishing plant, or recycled.

Data from the incorporated hard disk of the imaging unit is deleted using Blanca software, and each piece is wiped seven times successively and then reused (Figure 5.10e). The same process is applied to the imaging unit of the MRI system.

The X-Ray power-generator cabinet (unit 3) (Figure 5.9d) represents a backup power supply for the entire X-Ray system (in case of blackouts).

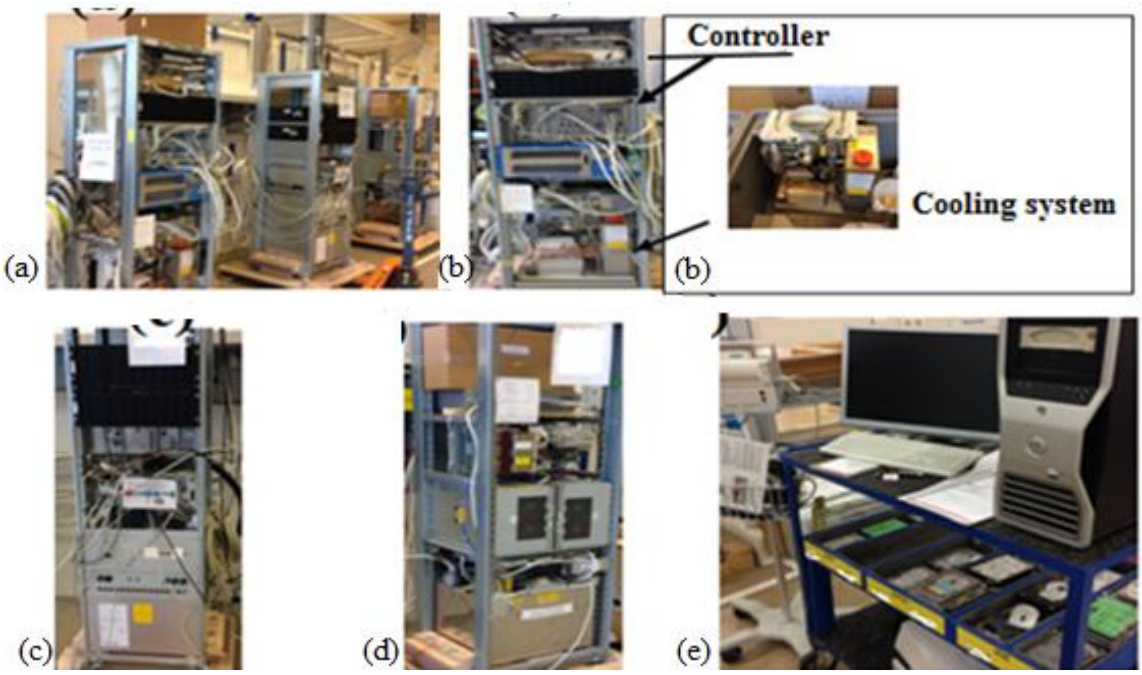

Figure 5.10 a) X-Ray cabinets; b) Cooling system; c) Imaging system; d) Generator; e) Data protection eraser stand

Manufacturing the X-Ray unit involves interconnectivity among several component manufacturers and transportation providers, with final installation of the device at the client site. A newly manufactured X-Ray unit would generate a CED of 67.2 MWh, due to these activities, which also have an environmental cost (the use of fossil fuels, metals, and water; and CO_2 generation from the materials needed in the manufacturing process). In this case, the refurbishing process compensates for some of the depletion produced by the original production process. A refurbished X-Ray device, even taking into account the disposal costs, has a total CED of 23 MWh; this includes the exchanged parts (633 Kg), electronics (190 Kg) and other materials (443 Kg). This represents a 66% reduction, compared to the cost of new manufacture. The specific CED for the mass (Kg) is 91 kWh/Kg for the electronics and 13 kWh/Kg for the other materials. Percentage contributions of environmental variables, for refurbishing, include metal depletion (0%), fossil fuel consumption (1%), water depletion (1%) and human toxicity (6%) (Figure 5.17).

For MRIs the environmental impacts are similar, but occasionally higher because an MRI device weighs more and requires more material consumption for manufacturing. Both devices, though, have climate-change and ozone-depletion effects, in the

refurbishing process, with an impact of 27% for climate change for an MRI and 4% for an X-Ray; for ozone depletion, 29% for an MRI and 3% for an X-Ray. In the manufacturing process the ionizing radiations [(x-ray, Gamma rays, ultraviolet part) depending on the system function and designation of functionality], from the components movement, manufacturing, testing and assembling extend the exposure to ionizing radiation throughout refurbishing processing. The ionizing radiation from the materials needed in the refurbishing process diminishes substantially due to the shorter assembly time and the extended use of the refurbished unit (although these values can vary significantly among individual units). The total environmental impact of ionizing radiation generated by the LCA software for a refurbished MRI was 25%; for an X-Ray, 2%.

5.5.8 Technical product updates

Safety updates, and FCOs (field change orders), can be applied to a certain percentage of EOL devices, depending on the technical and architectural designs of the system. Generally, the ability to update a medical device in a refurbishing process depends on the production year (product age group) and historical background of the individual system. The OEM can improve the technical aspects of a system by replacing the EOL components and software. From an aesthetic perspective the design is not modified; but the processes of replacing, repairing, painting and cleaning result in a total savings, for the entire procedure, of 85% (18.6 MWh) for an X-Ray: a refurbished device has a cumulative energy demand, for these procedures, of 3.3 MWh; this compares with a CED of 21.9 MWh for a newly manufactured one.

5.5.9 Painting and aesthetics

The system is completely repainted in the original colors, using the manufacturer’s specification and procedures, to bring it to a perfect cosmetic condition. The process includes dust removal (Figure5.11 b-1), cleaning (Figure5.11 b-2), polishing (Figure5.11 b-3, surface remediation/adjustment (Figure 5.11 b-4), and painting (Fig.5.11 b-5), creating the aesthetics and quality of a new product (Figure 5.12).

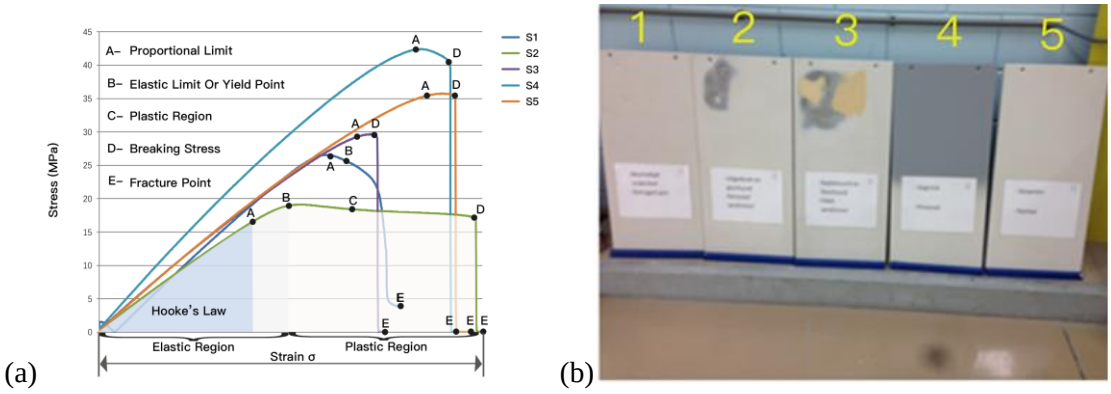

Figure 5.11 a) Extrusion results from plastic tensile test (monitor cases); b) Metal plate stage during painting procedure

The parts reconditioned in this phase include the outer coating and several plastic components from the body, the C-arms, and the patient table.

Figure 5.12 Body parts after repainting; a) MRI cover; b) Patient table components c) C-arm reconditioned

In order to determine whether the refurbished products had plastic components with good cosmetic and other qualitative properties, we tested five covers of LCD monitors, from different years (Sample=S-year S1 from2016, S2 from2010, S3 from2008, S4 from2012, and S5 from2011) and vendors. All the samples were purchased from the second-hand electronic market in Beijing, China.[115] (The investigated company told us that they use the same brand of monitors for these medical devices as for computers, but made especially for the medical devices industry, with a higher image quality.) The extrusion result (Figure 5.11 a) shows that all of the five samples had excellent tensile strength and elasticity with a high breaking stress (point) between 17 to 40 MPa, even

though they were from different vendors and production years.

From the SEM spectrometry image (Figure 5.13) it can be seen that all five samples had perfect surfaces, examining them at resolutions of X25µm and X100µm at a working distance of 8mm. No surfaces of the samples displayed any cracks at any resolution, indicating a high quality of the surface, which can be eventually reconditioned. Because of the procedures we used to prepare the samples for the SEM test (cutting them from the monitor body), the edges of the samples were examined to determine the fibrous structure of the shear. We found, comparing sample S1 with S2, and S3 with S4, that the samples all had different compositions, and the fibrous structures were not similar (Figure 5.13). This result shows that although the material compositions differ, the refurbishing procedure can work on all of them, extending the life of units approaching EOL.

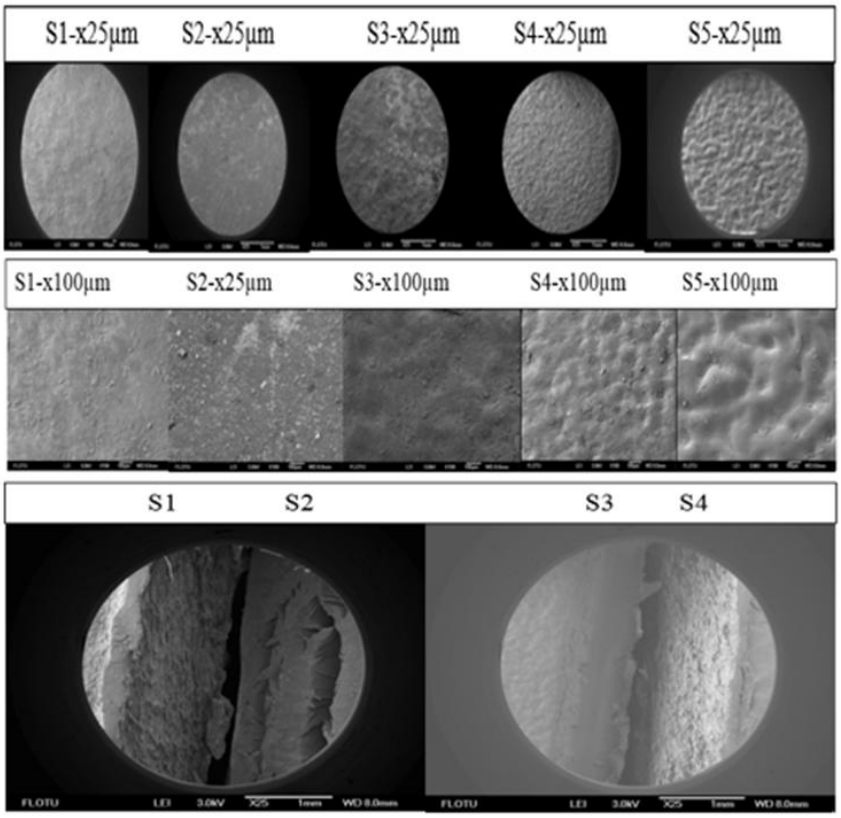

Figure 5.13 Scanning Electron Microscope results

The same reconditioning approach can be performed on metal plates (metal covers of the device body or additional assemblies) giving as high an aesthetic quality as a new one and decreasing the environmental impacts of different kinds of toxicities, oxidations,

and eutrophication. The most common materials used for manufacturing the body are iron, various alloys, plastic, and fiberglass. Fiberglass represents the highest polluting toxicity in the manufacturing and recycling process, affecting human health dramatically.[151,152] The particulate matter generated by the manufacturing process (polluted dust mixed with water or other oils and solvents) are regressed through the refurbishing process. In the refurbishing process all the components made from this material are restored, retreated and painted (Figure 5.11) reducing all the above-mentioned risks. As a validation of our investigation, the LCA revealed a particulate matter (PM) generation from the total refurbishing process of just 4% for the X-Ray and 31% for the MRI, in the refurbishing process compared to original manufacturing.

In addition, the weight of the C-arms makes the repair and reconditioning worthwhile because this can decrease the environmental impacts of metal and fossil-fuel depletion in addition to reducing energy consumption (Figure 5.11c).

5.5.10 Customer needs configuration and software updates

The latest technology is applied to the refurbished devices, from safety updates to the operating software. The company configures the refurbished systems to match the end-user's (client's) needs, making use of a wide range of catalog options. All such updates require adherence to applicable regulations (ISO13485, ISO14791, 21CFR820, 21CFR Port 11) and compliance with the software updates for a product, taking into consideration architectural design, the life-cycle model, required verification (maintenance), and the software quality/model.

The complete assemblage of an X-Ray biplane (wt., 4219 Kg) represents a diverse range of components having different shapes, material compositions, and technical complexities, with a specific CED of 5 MWh. The total CED required for a refurbished system comes to just 21.1 MWh, compared to 92.1 MWh for a new system, representing a 77% savings.

5.5.11 System staging

After the refurbishment at the component level, each system is assembled (Figure 5.14) for calibration, functionality, performance and deficiencies testing. All applicable systems, safety features, and Image Quality (IQ) are measured, within specific standards

as defined in the preventive maintenance manual or imaging testing manual, according to the manufacturers' specifications.

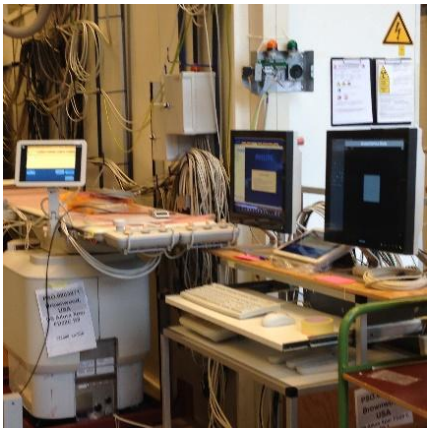

Figure 5.14 Calibration zone

All the testing procedures, according with the abovementioned standards, prepare the entire system for a real functional life of 10 years, according to the investigated OEM. The estimated use phase integrated into the LCA software disclosed a CED consumption of 362.9 MWh, for a usage over ten years.

5.5.12 Documentation and sign-off procedure

A full set of user manuals and updated technical service documentation is provided with every system, and a thorough technical and cosmetic sign-off process is performed before releasing the system for packaging and delivery.

5.5.13 Packaging and delivery (Step V)

OEM expert personnel inspect each component of the system, at both incoming and outgoing shipment centers (Figure 5.15), to verify its decontamination and ensure its safety and integrity during transportation. The outgoing transportation (Step V) to the resale site is performed by qualified transportation companies.

Figure 5.15 Packaging and formatting

Outside the refurbishing process itself, the packaging and delivery operations pass through many shipping routes. As a path through the entire chain of refurbishing, transportation has varying CED values, because transportation includes both product shipments and staff business trips. The cumulative energy demand for transportation, for a refurbished device like an X-Ray machine—including trade-in, de-installation and installation—came to 0.7 MWh. Comparing this to the new appliance CED value of 11.9 MWh gives a 94% savings. And, overall, the CED consumption for a refurbished system reaches a total of 54.6 MWh, even though the entire process may take more time, and require transportation over longer distances, than a new system, which has a CED of 72.7 MWh.

5.6 Discussions

The refurbishing processes described above represent an alternative solution for this type of used electrical and electronic equipment, to extend its life cycle and minimize resource utilization. Over the past few years, e-waste generation has increased significantly, to 7.92 million tons in China, India, and Malaysia alone. Although the waste generated from medical devices and equipment came to just 14.978 tons at the global level,[108] the large size of these devices, and their complexity, make them good candidates for reuse. And, in general, the environmental and economic savings achievable through refurbishing reveals a high percentage of conservation of materials and energy, minimizing the loss of resources.

The results of this research reinforce a similar cumulative energy demand difference, for a new versus a refurbished system, in the case of an X-Ray medical device. Figure

5.16 shows overall savings in materials and energy consumption (MWh) through refurbishing, in the areas of assembly, transportation (including employee business trips), raw materials and environmental impacts.

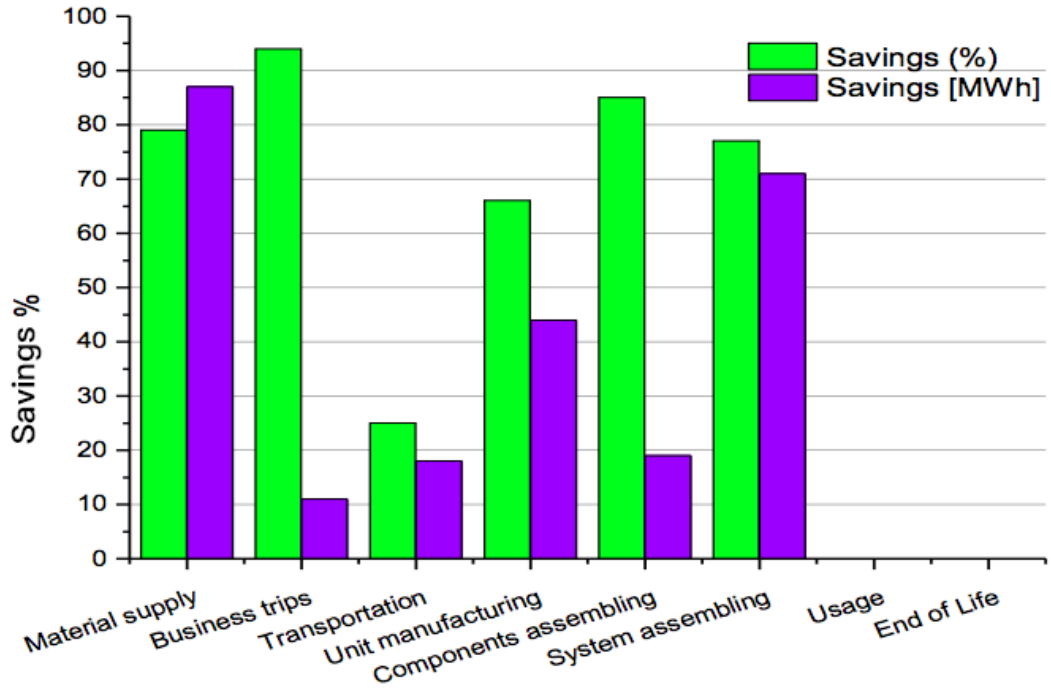

Figure 5.16 Areas producing savings from refurbishing

The CED result utilizing the LCA software indicated a total savings in the refurbishing process of 32% compared to a newly manufactured device, reutilizing 63% of the system and recycling 5%. The highest savings were realized in business trips (94%), components assembly (85%) and material supply (79%) processes, due to the availability of equipment and components at the OEM manufacturing site. The entire chain for taking back used medical devices can take advantage of the distribution channels already in use for new devices. In this way, business trips can be cut, and the transactions between refurbishing companies and clients will be more efficient. If, on the other hand, there is no possibility of refurbishing, and a used product is designated to disposal (recycling, reuse of components) there would be 0% savings and a CED of -38.8 MWh, decreasing the residual value of the EOL product.

The cumulative energy demand savings were identified as being more prominent in the material supply (87MWh), system assembly (71 MWh), and unit manufacturing (44 MWh) processes. This shows that the refurbishing process represents a new path to extending the useful life of a product like a medical device, and could be applied to

other products as well.

Furthermore, this approach to EOL products can limit some of the adverse effects to the environment, human health, and material depletion (Figure 5.16), from several angles, compared with the manufacturing of a new system (NS). The breakthrough between NS and remanufactured systems (RS) for both MRI and X-Ray devices, is the possibility of reuse by upgrading (as an assembly) and conserving high-value material (less metal depletion) in a productive way.

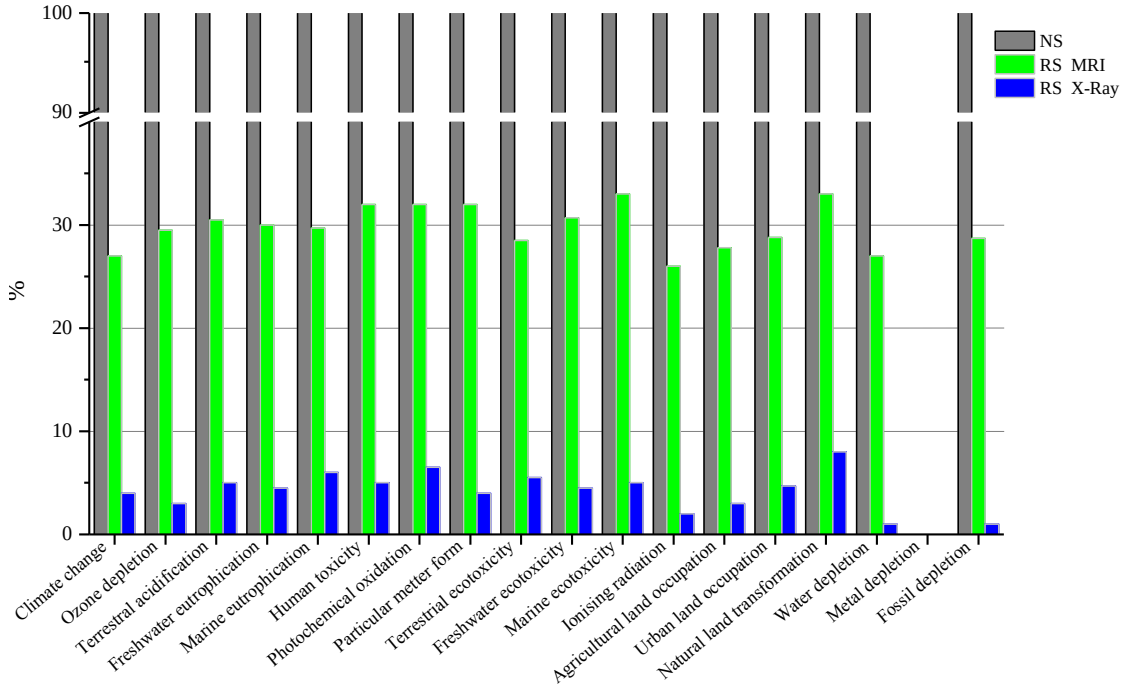

Figure 5.17 Environmental impacts of new systems versus refurbishing procedures

Figure 5.17 shows that where the refurbishing method is implemented for used medical devices (MRI and X-Ray), 18 environmental impacts generated by an NS are reduced. Each step of the refurbishing process has one or more relevant environmental impacts, depending on the procedure. For refurbishing X-Ray devices, the savings from depletion of metals (0%) and fossils (1%) are very low, due to the parts and components reused. The reusability of other parts, though, such as the magnet for the MRI and the C-arms for the X-Ray, decreases the climate-change footprint by 73% for the MRI and 96% for the X-Ray; and the ozone depletion by 71% (MRI) and 97% (X-Ray), simply by avoiding the manufacturing of new components and devices. And components assembly and unit manufacturing operations in the processes of reusing, repairing and reconditioning some components can reduce the freshwater toxicity by 69% (MRI) and

96% (X-Ray), as well as reducing water eutrophication and other environmental impacts.

In general, the environmental impacts of an MRI system are 0-34%, an X-Ray, 0 – 8% (due to its lower weight).

5.7 Summary

An investigation was performed to demonstrate the efficiency of the refurbishing process of X-Ray and MRI devices. A life cycle analysis of cumulative energy demand was performed on eight aspects of the refurbishing process for an X-Ray biplane device. The X-Ray system was chosen as an example to demonstrate that even a system with a low potential for refurbishment still retains a significant residual value, and refurbishment can significantly reduce environmental impacts. A detailed analysis was conducted for both the X-Ray and the MRI, investigating all the refurbishing steps. The total reuse percentage realizable through the refurbishment process is 63% for an X-Ray system and 90% for an MRI, according to our investigation. The total CED resulting from the refurbishment of an X-Ray system was 453 MWh, lower than that for a newly manufactured device (664 MWh): a 211 MWh savings (32%). The focused CED for the refurbished X-Ray system was allocated to eight types of savings (material supply 79% - 87 MWh; business trips 94% - 11 MWh; other transportation 25% - 18 MWh; unit manufacturing 66% - 44 MWh; components assembling 85% -19 MWh; system assembling 77% - 71 MWh; usage- 0%, MWh; end of life 0%, MWh). This analysis indicates significant potential energy savings and environmental impact reduction through refurbishing, compared to new manufacturing. At the same time, there are significant barriers to large-scale implementation. These include a low number of devices available, globally, for refurbishing; legislative gaps and barriers, including regulatory impediments (Basel Convention, various governmental policies), to transboundary movements of used devices; the lack of acceptance of refurbished devices by many countries; an imbalance in the demand/offer ratio; lack of qualified personnel for refurbishing processes; and the unavailability of distributors or refurbishing plants in many regions. There are also concerns by users about safety associated with the use of refurbished devices, that need to be addressed.

Furthermore, according to the recently published medical device regulation (MDR)

in the EU, the establishment, execution, and maintenance of medical devices will now require risk management documentation,[153] providing some additional incentives for refurbishing.

Complete refurbishment of a system executed by OEMs can decrease environmental impacts associated with manufacturing and establish a better surveillance of aftermarket units offering the same high quality and safety as a new device.

In summary, this study indicates a strong potential for refurbishing medical devices, from technological, economic and environmental viewpoints. It has presented an explicit example for developing countries with an industrial potential for contributing to environmental protection, E-waste reduction and a clean and healthful circular economy.

Chapter 6 MARKET PROSPECT ON NEW AND REMANUFACTURED MEDICAL DEVICES COMPLYING WITH CIRCULAR ECONOMY

6.1 Overview of the global market for refurbished medical devices

The refurbishment of medical devices[154] is defined and recognized as a restoring to the original specifications of the product and updated to the latest generation of cosmetics and technical status (end-to-end) of the product. The entire process is considered to fulfil the remanufacturing steps and its quality ‘’as’’ a new product.

The refurbishing process is recommended and recognized by the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), Japan Industries Association of Radiological Systems (JIRA), and Medical Imaging and Technology Alliance (MITA) as an aligning to circular economy. Remanufactured/refurbished medical devices have been viewed as alternate products, and counted to be a scourge to the formal business sector of new equipment. The deficiency of standardized policies and other market issues have prevented the diligent growth for refurbished medical devices.

On the other hand, the negativism received by remanufactured/refurbished medical devices was the end-users regard to safety and policy approaches, which is unmatched in some regions among end-users.

6.1.1 Industry dynamics between original manufacturers versus remanufacturers

The growth of a strong market for refurbished medical devices has become more popular in Europe and the USA, split between the original equipment manufacturers (OEM) and the third party sellers (secondhand and refurbished). Apart from the market share, the original manufacturers are concerned about reputation and clinical enrollment of the existent product on the market acquisitioned by the third party remanufacturers. On the other hand, environmental safety and the remanufacturing process can be doubtful in certain cases due to the technological availability from other remanufacturers for certain products.

6.1.2 Industry challenges

The lack of standardization, policies, regulatory challenges, industry growth, negative outlook of public procurement toward refurbished devices has a negative impact on:

1) recovery, access to used equipment;

2) process emplacement in certain regions;

3) improper possibility to transport used equipments and spare parts;

4) unclear policy description by different countries.

A lack of clear details regarding specific steps and benefits of the remanufacturing/refurbishing process by policymakers discourages the accessibility and acceptance of these products by certain markets.

6.1.3 Regulatory scenario for refurbished medical devices

Worldwide, some countries have different restrictions regarding imports of refurbished medical devices, while others include a complete ban on their import. On the other hand, certain parties (countries) allow unrestricted imports and sales of refurbished medical devices.

However, this does not mean that some countries are allowed to sell refurbished devices without being approved by the relevant regulatory authorities. In the European Union, some countries, such as Romania, have public procurement policies stating that vendors can sell new or refurbished devices under the CE-label.

The countries that have a restriction on imports include different taxes for refurbished and medical devices after a certain age of use, as well as stipulations for the OEM itself, increasing the requirements for the warranty and services. The US, Food and Drug Administration has brought various demands in certain stages, including registration, listing, device history reporting, labeling, and premarket requirements.

In Europe, if the devices should be sold, they need to have a CE mark instead of the US; there is no need to register to the FDA. However, refurbishment could lead to certain growth and benefits as economical, social and environmental.

The following countries have positive regulatory policies that permit the imports of pre-owned medical devices on the same terms as new devices: Australia; Guinea; Morocco; Slovenia; Bahamas; Haiti; Mozambique; Sri Lanka; Barbados; Honduras; Nepal; Switzerland; Belize; Hong Kong; Netherlands; Taiwan; Bolivia; Hungary; New

Zealand; Tanzania; Botswana; Iceland; Nicaragua; Trinidad & Tobago; Cameroon; India; Niger; Tunisia; Chad; Indonesia; Nigeria; Turkmenistan; Chile; Israel; Oman; Uganda; Costa Rica; Jamaica; Panama; Ukraine; Czech Republic; Jordan; Paraguay; United Arab Emirates; Dominican Republic; Kazakhstan; Philippines; Venezuela; Ecuador; Kyrgyzstan; Poland; Yemen; El Salvador; Kenya; Romania; Zambia; Ethiopia; Liberia; Russia; Finland; Luxembourg; Saudi; Arabia; Gabon; Malawi; Serbia and Montenegro; Ghana; Malaysia; Senegal; Guatemala; Mexico*; Singapore.

***** Mexico admits unclassified fairs to end-users, with restrictions on cross-border transactions.

The unrestricted importation of pre-owned devices does not mean that the allowance sales of used medical devices were not approved by regulatory authorities. Furthermore, all the presented countries do not present any revenue in regards to the quality stage of the product for the refurbishing process. The market opportunity depends mostly on the purchasing practice, on the willing of the end-user for refurbishing, and on the technical status of the device. The following list presents certain countries with a high discouragement of procuring the refurbished medical devices for their healthcare public or private sectors.

Countries with discouraging policies to purchase refurbished medical devices include the following: Bahamas; Ghana; Oman; Senegal; Cameroon; Guinea; Panama; Sri Lanka; Chile; Honduras; Paraguay; Tanzania; Costa Rica; Indonesia; Philippines; Uganda; Ecuador; Mexico; Romania; United Arab Emirates; El Salvador; Nicaragua; Saudi Arabia; Venezuela.

A couple reasons that explain why the remafatured/refurbished products or medical devices were seen as being a low product compared to a new one include qualitative and safety perceptions of the policymakers. Other perceptions were related to lower costs of refurbished devices, and were assumed to have lower technical performances compared to a new counterpart. Another concern was estimated that spare parts and proper servicing can be difficult or unavailable to obtain for used medical devices considering the diversity of producers and products. There is another approach and consideration among policymakers that suggests that the refurbishing process be implemented by the OEM and not by another entity such as a third-party for assuring a better guaranteed performance. As a final debate, several healthcare units and regulatory authorities consider refurbished medical devices are low-end technologies that do not ensure proper

safety and quality in the healthcare delivery.

Due to the previously mentioned reasons, various countries restrict the importation of pre-owned medical devices due to safety and exclusion of possible imports of illegal electrical and electronic equipments (WEEE) or hazardous wastes. The mentioned restriction is subordinated to the Basel Convention which refers to the transboardary movements of WEEE. Among all countries, certain restrictions or bans on the imports of pre-owned medical devices generally appeal to at least one of the mentioned issues.

Countries with restrictions on importing pre-owned medical devices include Argentina; Japan; Turkey; Bangladesh; South Korea; Uruguay; Brazil; Moldova; Uzbekistan; Canada; Pakistan; Vietnam; Colombia; Peru; Croatia.

The following countries have placed above on the importing of refurbished medical devices: China; Syria; Egypt; Thailand; Kuwait.

6.2 Regulatory compliance for new, post-market and refurbished medical devices

6.2.1 US – Food and Drug Administration (FDA) compliance to refurbished (remanufacture) medical devices

The demand for refurbished medical devices has increased and transformed to a profitable business with a growing influx of new vendors. This had prompted the FDA to initiate the compliance for pre-owned medical equipments. The perspective of regulations and mandates remains unregulated for the refurbished medical devices[155,156].

The last compliance published by FDA was in 1985 which was revised in 1995, and was named the compliance policy guide (CPG) which contains the following key recommendations, mandates, and requirements.

FDA expresses the compliance to regulatory and legislations for companies that gain the ownership of a device for restoring and refurbishing with a purpose to resell. Remanufacturers/refurbishers must record and comply with the good manufacturing practices (GMPs) for medical devices. The remanufacturer/refurbisher is strongly and clearly requested to disclose the labeling, name and address, and the statement that the medical device equipment was reconditioned or rebuilt (section 300.200(C)). In regards to premarket presentment, the FDA appended “Deciding When to Submit a 510(k) for a

Change to an Existing Device." It suggested the change of labels that distinguishes the device between reuse of single-use-only, submission of a 510(k).

In 1993, the International Association of Medical Equipment Remarketers and Servicers was founded to ensure the need for safe and reliable pre-owned equipment. The remanufacturing of disposables' change of use had been adopted in 1995.

According to the FDA, companies that take in devices from pre-users, single-user from a healthcare supplier and returns them, has changed the intended use from a single to multiple-use respecting the quality, safety (technological and resterilize) are considered remanufactured.

According to the agency, companies that receive pre-used, single-use devices from a health-care supplier, resterilizde them, and returned them to the provider have changed the intended use from single use to multiple-use, and are hence considered remanufacturers.

Quality system regulations for manufacturers became effective on June 1, 1997. A clear definition of remanufacturers in the category of manufacturer stated that a physical person or company that works, conditions or reconditions, renovates, repackages, restores, or other operation that significantly changes the finished device's performance or use qualifies as a remanufacturer according to section 820.3(w). Section 510(k) specifies the safety or other changes in the medical device body or use, functionality, and overall performance.

In case of reuse, the FDA outlines clear mandates in the CPG in regards to the demonstration of the possibility to clean and sterilize. Furthermore, FDA require that the quality of the device should not be affected, and the safety and efficiency concern are fulfilled. Any party that intends to reuse is completely responsible for the safety and efficacy of the medical device.

The Medical Device User Fee and Modernization Act (MDUFMA) requirements in 2002 explain the need for registration, listing, adverse event reporting, labeling and premarket submission requirements report for re-processed single use devices by FDA and Cosmetic Act. Sellers of refurbished or pre-owned medical equipment do not have to be registered with the FDA, but are required to clearly operate up to standards. The FDA and the association for the Advancement of Medical Instrumentation (AAMI) include the need for certification by the original equipment manufacturer (OEM) to validate the safety, performance, quality, and replacement parts in order to fulfill the

requirements for remanufactured/refurbished medical devices.

6.2.2 European Union compliance on CE marking regarding new and refurbish medical devices

The European Union (EU) has established several guidelines regarding new and refurbished medical devices to ensure the safety and health for its countries' members. In 1993, the EU established regulatory compliance polices for the medical device; the Medical Device Directive (MDD) was updated in 1998. The EU bears a CE mark (Conformité Européenne), which asserts that the product complies with the requirements subjected to applicable directives and conformity assessment procedures in order to be used and entered in the European community[153].

In May-2017, the EU had updated the regulatory policy regards medical device compliance changing it from directive to regulation entitled Medical Device Regulation (MDR). The adopted regulation has a period of compliance/transition period of three years until May 2020 in order to access and operate on the EU market and apply to MDR EU 2017/747. The key players or entities in the regulatory process are manufacturers, competent authorities, authorized representatives and notified bodies.

The new regulation requires fulfilled documentation for testing and certification of active Medical Devices:

1) Product certification (EN ISO/IEC 17065 and MDD 93/42/ECC);

2) Product testing (EN ISO/IEC17025 and accreditation CB Scheme/ ILAC-DAkkS);

3) Management System Certification (DIN EN ISO 17021 and MDD 93/42/EEC Annex II, V, VI).

6.2.2.1 Regulatory compliance for refurbished and post-market medical devices

Refurbishment can contribute to different changes to the operational, reability, environmental and safety aspects of the pre-owned medical device. As a result, it is important to align the conformity to the CE marking by the manufacturer by taking legal and regulatory compliance issues into account.

When the refurbished medical device is sold to another user, the manufacturer must check the condition of the documentary support with the new upgrades. A notified manufacturer respects the new MDR, green paper and Good Refurbishing Practice

(GRP). The manufacturer is requested to perform and provide a risk analysis.

The importance of post market surveillance for medical devices is crucial to ensure the technical safety of equipment and safety of the patient. The requirements are almost similar to the MDR. The post-market surveillance system should be planned, established, documented, implemented, maintained, and updated for each medical device. The post-market surveillance system is integrated in the manufacturer management of surveillance for each medical device and analyzes data of quality, safety, and through entire lifecycle of the device.

Data gathered using the post-market surveillance system is used to help the manufacturer update and identify the product stage, labeling, performances and new future possibilities for an extended use.

In the case of product update, there are multiple benefits such as risk determination and improved risk management, clinical evaluation, and summaries for safety and clinical performances. For the identification of needs for prevention, field safety correction action (technical/mechanical/software/evolution evaluation) is needed to improve the usability and safety of the device. These behaviors engage in a constructive contribution to the post-market surveillance of other devices.

6.2.3 China Compulsory Certificate - CCC marking introduction to new medical device access on China market

6.2.3.1 Definition of medical device, in China

Medical devices are defined by the China Food and Drug Administration (CFDA)[157, 158] as: "Any instrument, apparatus, appliance, material, or other article – whether used alone or in combination, including the software necessary for its proper application – that does not achieve its principal action in or on the human body by means of pharmacology, immunology or metabolism, but which may be assisted in its function by such means".

6.2.3.2Market overview

In recent years, China's medical device industry has increased significantly; sales doubled between 2010 and 2014, as shown in Figure 6.1 below. The total sales volume for medical devices came to EUR 2.4 billion in 2001, and by 2014, had reached EUR 36 billion. The largest sales took place between 2013 and 2014: EUR 6.1billion.

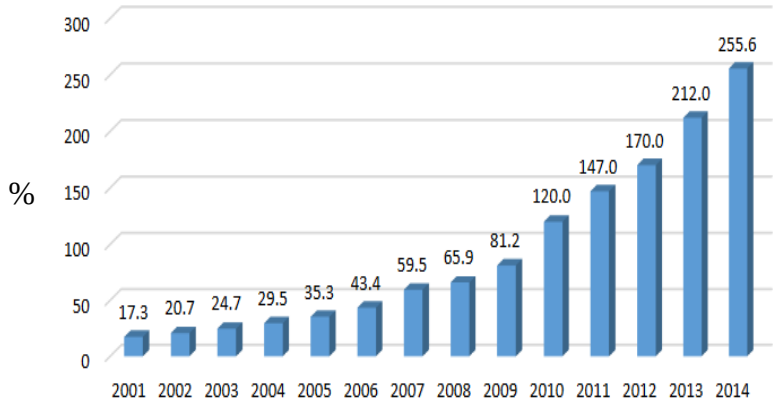

Figure 6.1. Medical device sales in China

In 2014, the total import and export value of medical devices experienced an approximate 4% increase. In 2014, China's total import value of medical devices showed a 5% increase over 2013, but this growth rate was 15% below that in 2013.[159] Diagnostic medical devices totalled approximately 70% of the medical device import value—the highest among all imported medical devices.

In 2014, 35 types of medical devices were imported to China, including: general diagnostic equipment; ultrasound diagnostic apparati; rehabilitation appliances; X-ray tomography instruments; endoscopes for artificial joints; orthopedic equipment; fracture equipment; medical accelerators; medical catheters and Magnetic Resonance Imaging (MRI) equipment.

6.2.3.3 Importing regions

The top three importing regions in China in 2014 were Shanghai, Beijing and Guangdong, with percentages as follows:

1) Shanghai imported over 10%, or 40% of all medical devices imported into China in 2014;

2) Beijing imported over 24% of the total value of medical device imports;

3) Guangdong imported over 11%, in 2014.[159]

Other cities with considerable import values were: Jiangsu, Zhejiang, Shandong, Liaoning, Tianjin, Fujian and Hubei.

6.2.3.4 Responsible authorities for Chinese market product validation

In China, the authority responsible for the safety and authentication/validation of medical devices entering the national market is the China Food and Drug Administration (CFDA), which drafts laws, regulations, rules and policy under the authority of the State Council.

As a general overview, the CFDA covers regulatory guidelines for drug administration and supervision, medical devices, health food, cosmetics, and supervises safety (see Figure 6.2). The CFDA responsibilities for medical device are split between two departments:

1) Department of Medical Device Registration (pre-market approval) – in charge of registration for imported medical devices and domestically produced Class III medical devices, classifications, the implementation of good practices, etc;

2) Department of Medical Device Supervision (post-market supervision) – in charge of analyzing and tracking medical device safety, produces recommendations for testing systems, licensing, checking for defects, etc.

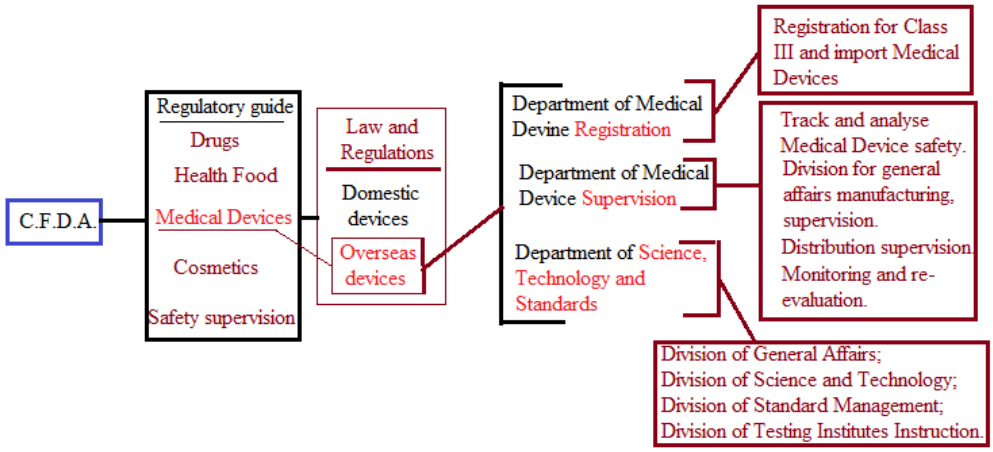

Figure 6.2 China Food and Drug Administration framework for medical device market access

6.2.3.5 Classification of medical devices

In China, medical devices are divided into three classes (I, II and III) based on the risk level of the device (low to high).[160] This classification is used for risk managementbecause different rules are implemented for different classes. The administrative department responsible for medical device classification follows the "Regulation on Supervision and Administration of Medical Devices" – Order 276/2002. In December 2013, the CFDA released a draft amendment for the Classification Rules

for Medical Devices and added a new category for the In-vitro Diagnostic (IVD) reagents. The entire classification process usually takes between 3 and 12 months.

Classes of medical devices:

1) Class I medical devices represent a low level of risk; safety and effectiveness are ensured through routine administration;

2) Class II medical devices represent a medium level of risk, and require safety and effectiveness;

3) Class III medical devices have high levels of risk, and have strict control and safety and requirements. The Regulations for the Supervision and Administration of Medical Devices call for a product to be filed as a Class I medical device before it can be distributed in China. For Class II and Class III medical devices, manufacturers must obtain approval from the CFDA.[160]

A medical device is further classified into one of four categories, depending on its characteristics and in what way it touches the human body. These categories are as follows:

1) Passive human body-contacting medical devices;

2) Passive non-human body-contacting medical devices;

3) Active human body-contacting medical devices;

4) Active non-human body-contacting medical devices.

6.2.3.6 Regulatory bodies

The China Food and Drug Administration (CFDA) is the "administrative and supervisory authority" for medical devices, food, drugs, and cosmetics, in China.

The CFDA: drafts regulations for medical devices; sets classification standards; inspects manufacturing, sales and distribution of medical devices; manages the import of medical devices.

There are a number of departments under the CFDA, including: Department of Medical Device Registration; Department of Medical Device Supervision.

Other organizations involved with the technical evaluation of medical devices and standards include: Center for Medical Device Evaluation; National Institute of Food and Drug Control.

6.2.3.7 Policy and Regulations

There are a number of regulations concerning medical devices in China, but the Regulations for the Supervision and Administration of Medical Devices are the only regulations officially endorsed and approved by the State Council. After the latest version of the regulations was published on 7th March 2014, the CFDA released a series of specific provisions and regulations for medical devices in China. See Table 6.1 for detailed information regarding policies and regulations.

Table 6.1 Regulations and provisions for medical devices in China

Regulations and provisions	Brief description	Full Content
Regulations for the Supervision and Administration of Medical Devices	Class I medical device filing, Class II and Class III registration. (Decree No. 4)	http://www.sda.gov.cn/WS01/CL0784/97814.html
Special Procedures for Approval of Innovative Medical Devices	Defines innovative medical devices, regulates application process, sets documentation requirements and evaluation procedures.	http://www.sda.gov.cn/WS01/CL0845/96654.html
Provision for Supervision and Administration of Medical Device Distribution	Approval and filing procedures, distribution process and storage, and penalties for illegal practices. (Decree No. 8)	http://app1.sfda.gov.cn/WS01/CL0053/103760.html
Provision for Supervision and Administration of Medical Device Manufacturing	Sets conditions for manufacturers in the application process for licenses, including: technical staff, manufacturing equipment, quality control, management systems, post-sales service capacity.	http://app1.sfda.gov.cn/WS01/CL0053/103759.html

Table 6.1 Regulations and provisions for medical devices in China

Regulations and provisions	Brief description	Full Content
Rules on Administration of Manuals and Labeling of Medical Devices	Penalties for misapplying certain rules. (Decree No. 6)	http://www.sda.gov.cn/WS01/CL0053/103758.html
Provision for Administration of Registration of In-vitro Diagnostic Reagents	12 chapters with 90 provisions. Defines In-vitro Diagnostics, regulates registration and filing process and sets requirements for applicants. (Decree No. 5)	http://www.sda.gov.cn/WS01/CL0053/103757.html
Provision for Administration of Medical Device Registration	Issues certificate of validation, good for five years. Class I medical device filing, Class II and Class III registration procedures. Different validation process for innovative medical devices.	http://www.sda.gov.cn/WS01/CL0053/103756.html
Notice on Issuing Directory of Class III Medical Devices that need to Conduct Clinical Trials for Approval	Enumerates all Class III medical devices that require clinical trials throughout registration.	http://www.sda.gov.cn/WS01/CL0087/105374.html
Practice of Quality Management for the Operation of Medical Devices	Outlines the rules of the medical device trading process, including transportation, storage, personnel training, equipment maintenance, record keeping and post-sales service.	http://www.sda.gov.cn/WS01/CL1428/110920.html
Practice of Quality Management for Production of Medical Devices	Enforces the regulations for medical device production process: hardware and software, equipment, quality control, product recall. (Decree No. 7)	http://www.sda.gov.cn/WS01/CL0087/111642.html
Provisions for Medical Device Classification	Newest draft version released in 2015. (Decree No. 15)	http://www.sda.gov.cn/WS01/CL0053/24454.html

Other regulations: MD production: Decree No. 7; MD distribution: Decree No. 8; MD classification: Decree No. 15; MD recall: Decree of MoH No. 82; MD Good Manufacturing Practices; Classification Catalog of MD; Accreditation of MD testing bodies; GB 187 (88 compulsory, 99 recommended); YY 864 (376 compulsory, 488 recommended); (MD – medical device).

6.2.3.8 Regulations for the supervision and administration of medical devices

These regulations are issued in order to guarantee safety by protecting human health. The processes cover research and system development, manufacturing, distribution, use, and supervision of medical devices.

The regulation document contains six chapterscovering General Provisions, Administration of Medical Devices, Administration of Production, Distribution and Use of Medical Devices, Supervision of Medical Devices, Penalties, and Supplementary Provisions (April 1, 2000).

6.2.3.9 Measures for medical device registration

In order to enforcement the registration regulations, the China Food and Drug Administration (CFDA) releases and revises:

1) Medical device registration requirements;

2) Measures for the registration of in vitro diagnostic reagents;

3) Rules for instructions and labeling of medical devices;

4) Measures for the supervision of medical device manufacturing;

5) Measures for the supervision of the distribution of medical devices.

These five measures were adopted on June 27, 2014, and were promulgated on July 30, 2014 as CFDA Order No. 4, Order No.5, Order No.6, Order No.7 and Order No. 8.

The provisions adopted in 2014 for the Provisions for Medical Device Registration contain General Provisions, Essential Requirements, Product Technical Requirements and Registration Testing, Clinical Evaluation, Product Registration, Registration Alteration, Registration Renewal, Product Filing, Supervision and Administration, Legal Responsibilities, and Supplementary Provisions. These are valid for Classes I, II, and III of medical devices, covering 11 regulatory appliances.

6.2.3.10 Regulations for the administration of medical equipment instructions and labels

The CFDA conducts the inspection of instructions. And labels and packaging for nine kinds of medical devices. The inspection is implemented in accordance to:

1) Provisions for the Instructions, Labeling and Packaging of Medical Devices (Order No. 10);
2) Standards related to manufacturers;
3) Import agents, key distributors and users.

These have the objective of disclosing and rectifying significant problems of medical device instructions, labeling and packaging.

The label content should include:

1) Product model and specification;
2) Name and contact information of registrant for imported medical devices;
3) Registration certificate number of the medical device;
4) Manufacturing address and production license number of medical device manufacturer;
5) Manufacturing and production date, service life and expiration date;
6) Power connection;
7) Visual representations and other information, depending on the product;
8) Warning labels;
9) Storage and operation details;
10) Warnings about possible negative effects on the environment and radioactivity/radiation emissions/consequences (in English and Chinese).

6.2.4 Approvals of registration procedures for medical devices

The regulation was adopted by the CFDA as a provision on July 20, 2004 as Order No. 12 (Provisions for the Supervision of Medical Device Manufacturing).

The Provisions contains seven chapters: General Provisions, Application and Approval of Medical Device Manufacturing Enterprise Establishments, Supervision and Inspection, Legal Liabilities and Supplementary Provisions of License Management of Medical Device Manufacturing, and Management of Entrusted Medical Device Manufacturing.

6.2.4.1 Medical device regulatory authorities

In China, there are two authorities that are responsible for medical device registration:

1) China Food and Drug Administration (CFDA – Figure 6.2) responsible for medical devices, drugs, healthcare, certification, cosmetics and food.

2) General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ): responsible for mandatory registration, certification, and inspection for certain devices.

For Class I medical devices in China, importers are required to fill out an application and a notification of filing, but are not required to carry out a clinical trial. In case of Class II and III devices, clinical trials for product approval are required with exemptions for some devices.

The license for trial of a medical device on the Chinese market is valid for a period of five years. To extend the license, the manufacturer has 365 days, but no more. In some cases, a Quality Management System (QMS) may be required for registration.

6.2.5 Classification rules

Medical Device Classification rules:

1) Kits that contain multiple devices will be classified according to the highest-class device;

2) Classification of the device accessories are determined depending on their safety and effectiveness of use;

3) MD software will have the same classification as the device;

4) If a device is revised, it might need re-classification (if its function and/or purpose has changed). Medical dressings are classified as “functional” or “ordinary”;

5) CFDA data base contains the proclaimed device;

6) Classification is based on device structure, operation and conditions of use.

6.2.6 Product Technical Requirements (PTRs)

The manufacturer is obligated to ensure and prepare a Product Technical Requirements (PTR) and Quality Management System (QMS) prior to the registration process, which can be approved by one country, unless it holds an ISO 13485 certificate.

A PTR is draft is based on: Device technical specifications; Applicable standards; Testing requirements (manufacturer's own draft); Required safety and performance specifications; List of testing methods.

6.2.6.1 Types of Testing

For Class I IVDs, the CFDA will accept the foreign manufacturer's testing report.

For Classes II and III, the CFDA requires samples for type testing at the certified testing centers (the same centers as for IVDs). The testing centers will utilize the same testing methods for all the specifications listed in PRT (drafted by the manufacturer).

The CFDA requires the testing center to provide the report and comments from their test results, submitted together with the PRT.

The testing centers are the same as for IVDs (paragraph 3.4).

6.2.7 Product approval for classification and registration

The imported device's classification is approved respecting the regulations and requirements of the National CFDA for Classes I, II, and III.

Class I devices are not required to fulfill the registration procedure; for these, filing the notification application with the CFDA is sufficient. The CFDA review is based strictly on the filing documents, and on the consistency of the legal documents.

Product registration for Class I Devices requires that the application be submitted in the original, or as a notification body in English and simplified Chinese. For legal documents, the CFDA requires the following content in the application:

1) Product risk analysis document;

2) Product Technical Specification/Requirements;

3) Product testing report (manufacturer's testing report or 3rd party report);

4) Clinical evolution report;

5) Key manufacturing information (process, flow chart, materials, etc);

6) Design, artwork, product labels for the minimum selling unit;

7) Legal documents (ISO13485, market authorization approval, authorization letter to the agent in China);

8) Self declaration letter:

9) Letter to CFDA declaring that the requirements for Class I have been fulfilled by the institution;

10) Letter of conformity to Class I of Medical Devices;

11) Declaration that the national and/or industry standards in China have been fulfilled (according to the list of conforming standards);

12) Declaration that all the submitted documents are true.

6.2.7.1 Registration frame for imported medical devices Class II and Class III

The registration procedure for Class III medical devices is represented in figure 6.3.

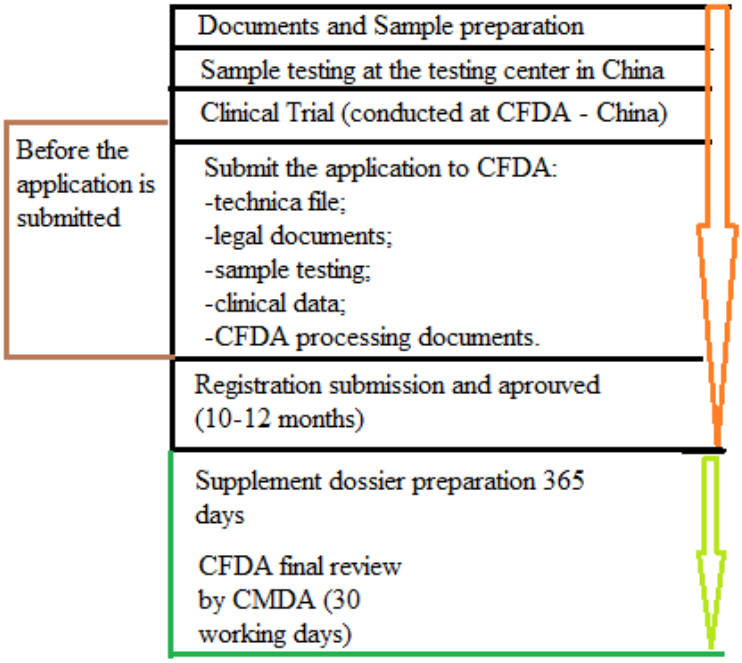

Figure 6.3 Registration framework

6.2.7.2 Dossier requirements for registration

The CFDA requests several types of documents to be attached for submission:

1) Legal Documents;

2) Technical Documents;

3) Testing report issued by CFDA-certificated testing center (the same centers as for IVDs)

4) Documents requested for product registration for imported medical devices:

5) Application form;

6) Legal documents;

7) Safety and efficacy specification list;

8) Summary data: overview; product description; product model; description of the packaging; intended use and contraindications; predicate device, if available; any other relevant information;

9) Research data: product performance, evaluation data; biocompatibility evolution data; biosafety research data; sterilization and disinfection process validation data; shelf and package evaluation data; software validation data;

10) Manufacturing information: manufacturing process description for active/inactive device, and manufacturing site description; clinical evaluation data; product list analysis data; product technical specifications;

11) Registration testing report: testing report issued by CFDA-certified lab; preliminary evaluation comments from testing lab;

12) Artwork for IFU and product label;

13) Self declaration documents.

A supplementary review process may be requested for future information after the technical review by the CFDA. Based on the supplementary notice, additional tests can be requested by the CFDA. The total time granted for the manufacturer to supply the supplementary documents is 365 days.

For Classes II and III medical devices, a local clinical trial is required for product approval. The clinical trial contains a list of exemptions:

1) Exemption will be applied if the manufacturing process is mature and the working mechanisms are clear;

2) Safety and efficacy can be proved by non-clinical evaluation;

3) Safety and efficacy can be proved via clinical trials or data from similar products.

Class II medical devices can be exempted from a batch of clinical trials that are published in CFDA Notice No. 12; these include 488 categories of products. For Class III devices 79 categories are included in the CFDA exemption No. 13. Before conducting a clinical trial, the clinical trial protocol should be validated by the Ethics Committee of the clinical site (CFDA Notice No.14 for Class III).

Good Clinical Practices (GCP) respect the regulation of Medical Device Clinical Trial Requirements for China, and will be performed in accordance with international GDP standards.

Labeling requirements for medical devices are the same as for IVDs, presented

above at paragraph 3.4.

Re-registration requirements that are enrolled before the validity of the product registration will expire within six months. The product registration for a medical device is valid for five years.

Country of origin approval: If the product is not registered in the originating country, it cannot be registered in China.

Raw Materials list required by CFDA is to be provided with information regarding the raw materials used in the medical device.

6.3 Circular Economy interaction with remanufacturing/refurbishing medical devices

The circular economy concept had to be embraced by all the industries, and had to come for a better understanding of how we should consume and protect our values. Due to the growth of the population in the last 100 years and to the increased e consumption/manufacturing speed and standards, we should think to not deplete our planet of its finite resources. In a world where valuable resources are hard to find, a "closing the loop'' of goods becomes more important.

Principles of remanufacturing, refurbishing, recycling, reuse, and leasing are all examples of "closing the loop" to facilitate multiple life-cycles. This will generate a minimal loss of value, energy impact, and material saving (first or primary materials) as well as value. The circular economy framework implemeted by remanufacturers and refurbishers is to increase the material value, to decrease energy savings through extending product life-cycle, and through emmission reduction produced by manufacturers.

Circular Economy extends the life-time of products and upgrades them through technological transformation, through enhancing or extending the clinical capacity, and through optimising the clnical performances of medical device utilizing the refurbished process.

6.3.1 Circular thinking

The literature described and offered many complementary theories to develop and implement a circular economy. A short include from the industry perspective of thinking and implementing the concept is included: regenerative design, performance economy,

industrial ecology, biomimicry and cradle to cradle. From a linear to a circular approach, developing a product for reuse offers many benefits, such as computing the purpose of environment and social aspects and impacts, delivering new businesses and value to the existent products. The roots of the principle of the Circular Economy re-looped the reuse multiple times like a new product, thus creating a positive economic and environmental impact produced by manufacturing. The European Union is developing a circular economy scheme as a socio-economical way to accomplish resource efficiency.

6.3.2 Circular Economy adoption by European Union

The European Commission adopted a Circular Economy in order to stimulate Europe's transition to boost global competitiveness, economic growth, and to generate new jobs. The Circular Economy package covers the whole cycle starting with production and consumption followed by markets, waste management, and secondary raw materials.

The purpose is to "close the loop" of products' lifecycles focusing on recycling and on re-use with benefits to theenvironment and to the economy**.** The proposal in a long-term path is waste management and recycling with the following key elements:

1) Increasing the recycling for municipal and packiging waste by 2030;
2) Reduce, ban and discourage landfilling;
3) Improved definitions for recycling rates throughout the EU;
4) Promote re-use and stimulate raw material use;
5) Incentives to put greener products on the market by adopting recovery, recycling (packaging, batteries, used electric and electronic equipments, medical devices, vehicles).

6.3.3 Healthcare Industry approach to Circular Economy through refurbishing:

The healthcare industry is unlocking value and providing an example for the circular economy principles. In order to create a sustainable world, the healthcare industry supports the transition from a linear to a circular economy possibility and her essential role in any businesses.

The industry aims (Figure 6.4) to uncouple economic growth from the use of natural resources by adopting a circular economy by using the available resources in a

more effective way**.** A primary goal is to promote refurbishment, to design better products to permit updates, to better recyclability, and to create efficient and green products. The secondary goal is to intercalate the existant chain of production with the circular economy goals for better suistainability and job creation.

The refurbishing process entitled by reversing the process of manufacturing gives the technical possibility to update, to recover, to and implement new approaches to certain products.

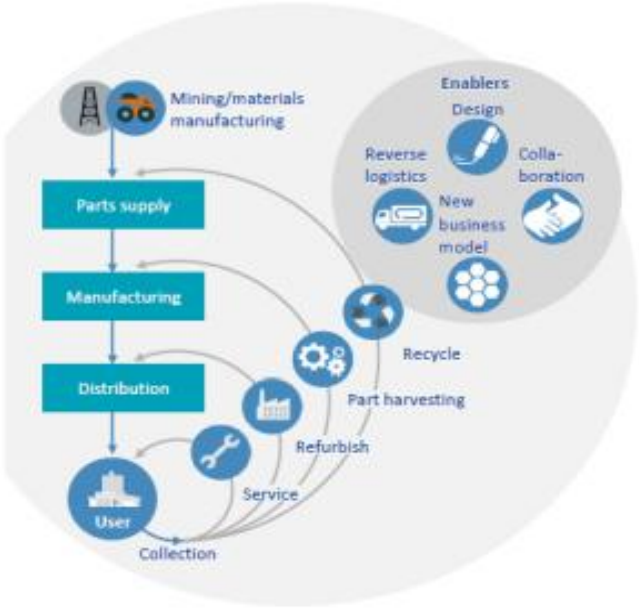

Figure 6.4 Circular Economy frame adopted by OEM

The environment, the economy, and the society/ patient represents the main pillars of sustainability in the healthcare industry for the used medical devices.

1) Environment - reuse through refurbishing is tagged as an effective way to prevent and to preserve approached end-of-life products. Refurbishement prevents waste generation, saves resources and energy, and reduces CO_2 emissions.

2) Economy - with a 480 million euros revenue in 2012, according to DITTA, the refurbishment business adds new jobs and businesses to theeconomy.

3) Society/Patients - refurbished medical devices presents qualitative medical devices as a new device, butat an affordable cost and improves the age profile of installed equipment.

Currently, just Europe and North America represent the higher percentage of the global market for refurbished medical devices. The other markets, such as Asia, Middle

East, Russia, and South America, provide a lower percentage due to market unaccess, and a lack of knowledge on the details in regards to refurbished products and legislative issues.

The refurbishers of medical equipment from across the world generally pocess a broad portfolio of imaging systems that increases the access and quality of healthcare, and the efficiency of installed equipment.

The factory's refurbished portfolio includes the following products: Resonance Imaging; Computed Tomography; Cardio/Vascular or Interventional X-ray; General X-ray; Surgical C-arms; Nuclear Medicine and PET/CT; Mobile Surgery; Ultrasound.

6.4. Summary

This chapter of the study exposes the market access for new and refurbished products in the main world markets. This enforces the perspectives thinking regards product quality and product reorientation for both cases. The healthcare opinion exposes the willingness of responsibility for their products after sale, offering a fare environmental, healthcare access and economic option through a circular approach for used equipments.

Chapter 7 CONCLUSION

7.1 Conclusion

The conclusion consists of the results of different aspects from the research model, based on the diverse elements for remanufacturing/refurbishing process sustainability and fundamental interaction.

As a general illustrations of the internal major surroundings on the remanufacturing process developed, and investigated, this research expose the major existent issues and backgrounds circulating around WEEE, used or end-of-life equipment and medical devices.

As is revealed many countries have a very week legislation and technological possibility to remanufacture especially in Asia. In some countries as China, the remanufacturing concept is developing just for some sectors excluded electronics even if technologically is possible to be implemented. From the legislative aspect the benefits of remanufacturing can be strongly reinforced if the governments accept the challenges and suggestions of other countries, companies and lean from their experiences. A good reverse management, product design and reuse possibility of an e-product can bust the remanufacturing industry supporting the cost reduction, environmental impact/environmental risks and a healthy circular economy.

Foreword offer a description in regards to important interactions of remanufacturing with the regression of used devices focusing on management and strategic approaches to WEEE reduction implementing remanufacturing approach.

In addition a conservation approach emphasizing new ideology of collecting used electronic and updating potential knowing certain material status was conducted and investigated. To emphasize the advantages of remanufacturing/refurbishing process an LCA analysis, and cumulative energy demand was conducted in terms of energy savings and environmental depletion focusing on medical devices as MRI and X-Ray. To illustrate the current legislative regulations or directives concerning new and refurbished medical devices a market access on different zones was pictured.

True the research, a general description illustrates various viewpoints and feasibility for used electronics and the WEEE industry. These aspects can reverse the current implemented management for adopting reuse, remanufacturing and recycling for WEEE.

Reversing the management introducing system tracking by manufacturers on their products, and increasing the possibility to regress adopting eco-design and reuse for e-products can promote remanufacturing and product life-cycle. The description for Asia reveals a significant potential for the remanufacturing operation to be implemented in the region offering an access door for developing countries. Different growing industries can benefit and grow in the field of remanufacturing as the exemplified Xerox Group UK and IBM (China) revealed a stronger sustainability. Furthermore, producers and designers of electronics should consider the new approaches for a life-extension possibility of their e-products.

For a better conservation of resources involves the reintegration in the life cycle of products with higher value such as medical devices and servers, and small value for electronics such as PC, laptops, and tablets in order to offer new life-cycle reintroduction on the market. The classification and inspection of products can reduce, by 45%, the in enveloping the mobile phone collection utilizing ''Internet+'' and B2B scheme method for servers and medical devices. Those methods in the updating process are using remanufacturing procedures that engaged the potential of regression for a new life cycle.

The experimental section demonstrates that certain chemicals (Pb, Si, Cd, As, Al, Ti, Fe, and Hg) and a particular material surface (plastic) are driven from the chemical, and visually do not have major changes except to their element persistence. The functionality of products drove to "an open" source utilization for upgrade utilizing external IoT interconnectivities (hardware and software) as Banana bpi. This results in a delayed discharging percentage of chemicals, raw material consumption, and waste generation.

Foreword, the refurbishing of medical devices, such as the X-Ray and MRI, retain a total reuse percentage of 63% for an X-Ray system, and 90% MRI, according to LCA analysis. A Cumulative Energy Demand from a refurbishment X-Ray system was 453 MWh, which is lower than a newly fabricated device 664 MWh generating savings of 32% (211 MWh).

The CED was allocated to eight types of savings for the refurbished process that were expressed step-by-step for an X-Ray system:

1) material supply 79% - 87 MWh;

2) business trips 94% - 11 MWh;

3) other transportation 25% - 18 MWh;

4) unit manufacturing 66% - 44 MWh;

5) components assembling 85% -19 MWh;

6) system assembling 77% - 71 MWh;

7) usage 0%, MWh;

8) end of life 0%, MWh.

This research section reveals the energy savings, and the environmental impact of diminution utilizing refurbishing in place of recycling. At the same time, significant barriers include a low number of devices available for refurbishing legislative and regulatory impediments persist.

In summary, this study demonstrates a strong potential for refurbishing medical devices, emphasizing certain related environmental benefits and process savings.

Finally, outlining the legislative and regulatory compliances for new and refurbished medical devices can frame the importance of the process and its acceptance on a worldwide scale**.** This will provide an informative background for policymakers and governments in terms of product acceptance on certain markets. Complete refurbishment of a system executed by OEMs can decrease environmental impacts associated with manufacturing and establish a better surveillance of aftermarket units offering the same high quality and safety as a new device.

It has presented an explicit example for developing countries with an industrial potential for contributing to environmental protection, E-waste reduction and a clean and healthful circular economy.

The environmental risk assessed by the remanufacturing/refurbishing exposed thought the environmental impacts and material composition of new systems versus refurbishing systems. This contributes to exemplify the potential for a temporary release, discharge or conservation of certain hazardous compositions, POP’s (Persistent Organic Pollutants’) from the material composition (components) and reducing raw material consumption using remanufacturing.

7.2 Suggestions

In general, this study provides two main suggestion points, which are adumbrated in the following paragraphs:

1. Methodological novelty

Improve the technical methodology and specific literature for regressing used electrical and electronic devices as medical devices, servers and copy machines utilizing the remanufacturing process. Providing this support for developing countries, the legislation and process lack implemented in developed countries can be followed as an example.

2. Environmental and economic approach

Understanding the process and his environmental and economic benefits the developing countries which posses manufacturing enclosure could implement the process for an environmental risk diminution. The circular economy concept can be easier implemented in developing countries with a reach manufacturing industry. This approach will develop other industrial branches correlated with actual manufacturers.

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APPENDIX

Countries	Regulations		Aociations involve in WEEE reduction, recycling, and remanufacturing	Recycling types		Rem. Technology availability	Common equipment rem.	References
	WEEE	Rem.		Formal	Informal			
E.U.	✓	✓	European Rem Network (ERN)	✓	-	✓		(Long et al., 2016; Sthiannopkao and Wong., 2013)
U.K.	✓	✓	Scottish Institute for remanufacture´		-	✓		[25]
U.S.	✓	✓	U.S. International Trade Commission, Remanufacturing Industry Council (RIC)	✓	-	✓	Cartridge; AC;	[85, 162]
China	✓	✓	National Key Laboratory for Remanufacturing	✓	✓	✓	Printers; ICT;	[162, 163]
India	✓	-	Environmental Ministry, Automotive Tyre	✓	✓	-	PC; Mobile phones;	[99, 164, 165]
Brazil	✓	✓	Brazilian Cartridges' Remanufacturers Association (ABRECI)	✓	✓	-	Servers;	[44, 166, 167]
Indonesia	✓	-	Minister of Industry	✓	✓	-	Medical equipment	[59, 168]
Malaysia	✓	-	APEC, Basel Conv.; Ministry of Environment	✓	✓	-		(Centre of Remanufacturing and Reuse, EU.)
Singapore	✓	✓	National Environment Agency	✓	-	✓		[170]
Pakistan	✓	-	Ministry of Industries and Production, Ministry of Environment	✓	✓	-		[171, 172]

ACKNOWLEDGEMENT

I would like to express my sincere appreciation and gratefulness to Prof. Dr. Li Jinhui who was my advisor for the previous four years at Tsinghua University.

Prof. Li always supported me in my academic as well as in my personal life at Tsinghua so that the four years at Tsinghua University have been a remarkable academic and cultural experience.

Furthermore, I would like to thank the industry, and other collaborators from The Nederland, Germany, U.S.A., China, and C.O.C.I.R. - Belgium for their time and valuable support to this topic of this Ph.D. thesis from a practitioner's point of view. I would like to thank the Basel Convention Regional Center, Beijing China for their collaboration and support. It was a great pleasure to work with these high qualified board directors, diplomats, managers, economic experts, engineers, and professors which have given me insights on particular Circular Economy – Remanufacturing fields.

In addition to that, I would like to thank to my family whom support me unconditionally during my study, to Eng. Grigore Parasca and his family, and my dear friends.

Sincerely Gabi 盖比，

God bless you!

声明/PERSONAL STATEMENT

本人郑重声明：所呈交的学位论文，是本人在导师指导下，独立进行研究工作所取得的成果。尽我所知，除文中已经注明引用的内容外，本学位论文的研究成果不包含任何他人享有著作权的内容。对本论文所涉及的研究工作做出贡献的其他个人和集体，均已在文中以明确方式表明。

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