Characterization, treatment proposal and metal recovery in waste of active implantable medical devices

Caracterização, proposta de tratamento e recuperação de metais dos resíduos dos dispositivos médicos de implante ativo

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Abstract: This study analyses the feasibility of active implantable medical devices waste treatment. After contacts with some responsible for the management of these devices in Portugal, it is possible to verify that none have a treatment process for this devices after been used, so they are stored in the hospitals or they can be delivered to the patience, if requested. The number of devices implanted increase every year and consequently the quantity of waste produced is higher, so is important propose an efficient treatment process for this waste. With the aim of development an efficient treatment process was realized a characterization of active implantable medical devices. Several analyses of the devices’ components were realized with special attention on printed circuit board because of its complexity and high economic value. The results indicate that printed circuit board from active implantable medical devices present quantities of precious metals, particularly gold (Au), superiors of printed circuit board of other electronic devices. It is possible to conclude that exist technology able to valorize the active implantable medical devices waste, since these are subject to a pretreatment (disinfection) after their explantation.

Keywords: Active implantable medical device, Metal recovery, Printed circuit boards, Waste electric and electronic equipment, Precious metals.

Palavras-chave: Dispositivos médicos de implante ativo, Recuperação de metais, Placas de circuito impresso, Resíduos de equipamento eléctrico e eletrónico, Metais preciosos.

1. Introduction and objectives

Population growth is more pronounced every day who leads to the rise of consumption, generating many problems in relation to treatment and final destination for the waste produced. With the improvement of life conditions, more waste is generated, particularly hospital waste, turning to several legal and social issues, in relation to environmental effective treatment solutions.

The technology industry growth leads to inordinate use of metals and ensure their supply is seen as critical (UNEP, 2010). In addition, that fact leads to an increase of waste electric and electronic equipment (WEEE) which rounds 8.3 to 9.1 million metric tons with an annual increase of 3–5% in twenty seven countries of European Union (Huisman et al., 2008).

Despite the implementation of waste electrical electronic equipment and the Restriction of Hazardous Substances (RoHS) directives, to properly manage ever-growing stream of WEEE, the most of developing countries not introduce these directives yet (European Parliament, 2003).

Medical devices are contained on 8th category of EEE in the directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on WEEE, which states that recycling goals shall not apply to “medical devices and in vitro diagnostic medical devices, where such devices are expected to be infective prior to end of life, and active implantable medical devices” (article 2, point 4, paragraph g), where pacemakers and implantable cardioverter defibrillator (ICD) are included. Due this fact, there’s no actual solution to recycle these devices.
The hospital waste is divided in four groups (Agência Portuguesa do Ambiente, 2011), in which, groups I and II obey in an efficient way the current waste management hierarchy, while groups III and IV, after a previously treatment, are sent for incineration or landfill.

The active implantable medical devices (AIMD), after explantation and disinfection, belong to group III. According to European Waste Catalogue (EWC) (Ministério da Economia, da Agricultura, Desenvolvimento Rural e Pescas, da Saúde e das Cidades, Ordenamento do Território e Ambiente, 2004), these devices are classified in chapter 18 of this catalogue and they do not represent a specific waste flow. Therefore, it arises the necessity to identify their components, in particular relevance for metals components, with the aim of development an efficient process of treatment.

It’s known that precious and special metals are decisive for increasing devices functionality and then is expectable that the use of gold and other technology metals grow further. Electronics represents 12% of total annual mine production of gold. Their efficient recovery from electronic scrap represents a significant potential recycling source. Gold’s demand had an increasing during the last decade, not only due to the jewelry market, but also due to the increasing uses of gold in industrial, as well as medical devices (Hagelüken & Corti, 2010).

Printed circuit boards (PCB) are the essential parts of electronic devices and hold the major fraction of metals present in WEEE. PCBs are particularly rich in copper and precious metals with high economic potential (80% of the total intrinsic value even though the amount is less than 1 wt. %, such as gold (Park & Fray, 2009). Every year 300 ton of gold are used in electronic components such as integrated circuits, contacts and bonding wires (Hagelüken & Corti, 2010).

The rigid PCB multilayers are fabricated from copper-clad dielectric materials. The dielectric consists of an organic resin reinforced with fibers. The organic media can be of a wide formulation and include flame-retardant phenolic, epoxy, polyfunctional epoxy, and polyimide resins (Harper & Sampson, 1994). Multilayer circuits are produced by building a structure of conductive layers and are filled with the same metallization in a separate screening step (Minges & Committee, 1989).

The gold is not deposited on the PCB surfaces directly but on an aluminum or titan pre-coat layer (Harper & Sampson, 1994). Conductors that use gold are easily bonded and when alloyed with small amount of platinum or palladium, it is easy to solder and form reliable joints (Minges & Committee, 1989).

In AIMD are included the pacemaker, the ICD and others. In this study only pacemakers and ICDs were included.

A pacemaker is an electronic biomedical device that can regulate the human heartbeat when its natural regulating mechanisms break down. The durability of these devices varies from 5 to 10 years due the degree of battery’s use. In Portugal, the annually average number of implanted devices is about 7200 (Direção Geral de Saúde, 2013).

The pacemaker’s motherboard contains all the electrical circuitry of the pacemaker and using hybridization, all components are combined to form a single complex circuit, allowing the use of materials which cannot be included in a monolithic integrated circuitry. The primordial conductor used in pacemakers is gold because of its stable and inert status, does not oxidize or migrate (Minges & Committee, 1989).

An ICD is a small device that is placed in the human body, specifically in chest or abdomen. Are used to detect dangerously fast heartbeats and give a lifesaving shock to correct the heart’s rhythm. Like pacemakers that are explained previously, ICD contain a generator containing a computer, battery, and wires called “leads” that go through a vein into the heart. The leads stay in contact with the heart muscle on one end, while the other end is connected to the generator. The battery in the generator lasts an average 5-8 years and must be replaced when it runs out (National Institutes of Health). According to the Portuguese Directorate-General of Health in Portugal in the year 2012 were implanted 888 ICD (Direção Geral de Saúde, 2013).

The aim of this work is the characterization of AIMD to study the feasibility of their treatment.

2. Materials and methods
AIMD, previously disinfected by autoclaving, were collected at several hospitals in the north of Portugal, and then sent to Faculty of Science of the University of Porto (FCUP) laboratory’s where they were identified and weighed. The devices were opened in the physics workshop with a handsaw and a lathe. After opening these devices were examined macroscopically to find out the best way to analyze them with more detail. The separation into three major components appeared to be the best option. The separation in smallest parts was done physically with tweezers and the three main components are: i) Exterior case and electrodes; ii) PCB’s; iii) Batteries as showed in figure 1. All of the components were identified and weighed individually, and were prepared to be analyzed by Scanning Electron Microscopy (SEM).

For analyze of exterior case, the electrodes were manually separated and the two components were analyzed individually. A small piece of the exterior case was selected and prepared with resin in order to be analyzed in Materials Centre of the University of Porto (CEMUP) by SEM technique.

In the workshop of physics, a chainsaw precision was used to make transverse and longitudinal sections in the polymer which coats the electrode.

The PCB’s were prepared with resin to ensure that all conditions were satisfied to be analyzed by SEM technique. The spots analyzed with SEM were previously selected with careful observations in the magnifying glass and the spots analyzed are showed in figure 2. SEM technique does not allow the quantification of materials
present in PCB, so two PCB from pacemakers were selected and grinded in an agate mill to be subsequently sent for an international laboratory (ALS Scandinavia AB) with the aim of quantification the percentage of gold, silver and platinum.

At this time the analysis of batteries was not performed because these components are constituted by hazard materials to public health.

When compared with others type of PCB, these results reveal to be very promising as the quantity of precious metals present in this type of PCB is much higher than in PCB used in other technologies such as laptops and cellphones.

As previously mentioned, the batteries were not analyzed because of their hazard components, but after consulting factsheets about the principal’s manufacturers (Medtronic and St. Jude Medical) it is possible to verify that lithium iodine batteries are used in most recent AIMD’s.

A survey about companies with processes to recycling lithium iodine batteries show that these processes are available in the market.

The results, even considering that the analytic methods had focused in particular components, showed that AIMD are constituted by a relevant quantity of metals with high economic value, such as gold (Au) and silver (Ag), among other metals with lowest economic value (titanium, neodymium, bismuth, cooper, etc.).

3. Results and discussion

The small portion of exterior case analyzed by SEM is constituted by titanium (Ti) with very small inclusions of cooper (Cu).

The results of SEM technique for the electrodes show that they are constituted by a variety of metals with higher incidence in iron (Fe) and manganese (Mn) and lowest incidence in nickel (Ni), chromium (Cr) and others.

The results by SEM technique for PCB show that they have a huge variety of metals in their constitution as showed in figure 3 and 4 as well as in others types of PCB’s (Table 1).

Quantitative analysis were only realized for 3 elements (gold, silver and platinum), and the results showed the presence of 5776 mg of gold (Au), 162 mg of silver (Ag) and 81 mg of platinum (Pt) for each kg of PCB.
Table 1. Typical composition of a Printed Circuit Board (PCB) of Waste Electrical and Electronic Equipment (WEEE) and their respective financial value (Goosey & Kellner, 2002).

<table>
<thead>
<tr>
<th>Component</th>
<th>% mass of each metallic component</th>
<th>% financial of each metallic component</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gold</td>
<td>0.025</td>
<td>65.40</td>
</tr>
<tr>
<td>Palladium</td>
<td>0.010</td>
<td>11.40</td>
</tr>
<tr>
<td>Silver</td>
<td>0.100</td>
<td>4.600</td>
</tr>
<tr>
<td>Copper</td>
<td>0.006</td>
<td>3.700</td>
</tr>
<tr>
<td>Aluminum</td>
<td>0.005</td>
<td>1.100</td>
</tr>
<tr>
<td>Iron</td>
<td>0.001</td>
<td>0.100</td>
</tr>
<tr>
<td>Tin</td>
<td>0.0003</td>
<td>0.400</td>
</tr>
<tr>
<td>Lead</td>
<td>0.0002</td>
<td>0.300</td>
</tr>
<tr>
<td>Nickel</td>
<td>0.0001</td>
<td>0.200</td>
</tr>
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4. Conclusions

The preliminary results allow us to consider that these devices have conditions to be treated in a sustainable way, since they were disinfected after explantation, with particularly incidence in the recovery of the precious metals presents. The survey, which was realized in small scale, will continue with the purpose to determinate the feasibility of the development this project in a larger scale.

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Referências


