Remanufacture of medical imaging devices

Abstract

The remanufacture of medical imaging devices such as X-ray equipment, CT scanners and MRI scanners has been identified as a strong market in the USA and a growing market in Europe.

Both original equipment remanufacturing (OEM) and third party remanufacture occur. Third party remanufactured equipment is often destined for developing countries or for use in veterinary medicine, with standards and any warranty provided varying by company. OEM remanufacture of imaging devices is increasing, with the remanufactured devices destined for mainstream hospitals. Remanufacture by OEM is also company specific, but usually returns the equipment to the standard of new and provides a strong warranty offer.

The UK (NHS) makes practically no use of remanufactured imaging systems, instead buying all equipment as new. Potentially there are opportunities for financial and environmental savings to be made in this area.
Overview

The term ‘medical devices’ covers some 8000 different types of product. The market is a relatively stable one, largely separate from the flux of economic cycle. Government spending on healthcare tends to remain the same or increase year on year as to do otherwise would be unpopular with the general public. In the UK, in 2003 the National Health Service (NHS) spent around £1.5 billion on purchasing medical equipment and medical supplies. Health spending in the EU averages 8-9% of GDP, with 10% of the workforce employed in this sector.

The market is a global and highly competitive one, with a high emphasis placed on continuing research and development. Such a focus, while ensuring that improved devices are constantly entering the market, also means that equipment can date quickly and health organisations find themselves under pressure to update to and use the latest equipment.

Regulation of Medical Devices

Medical devices have been regulated in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA), a government agency, in accordance with EC Medical Devices Directives (MDD) since June 2002. The regulations concern either new devices placed on the market, or devices that have been refurbished and returned to the market as ‘new’. Otherwise a device is considered to be second hand and would come under general consumer legislation.

A manufacturer must demonstrate that a device satisfies the regulation criteria, which vary according to the nature of the device. Manufacturers can self declare that very simple (class I) devices meet the requirements and issue a certificate of conformity. The regulations for sterile/measuring devices and medium to high risk devices (class I sterile, class II and class III) require the manufacturer to use a Notified Body to assess the device. The Notified Body must ensure that the device is safe, that it performs as the manufacturer intended and that the risks associated with its use are acceptable. Then a certificate of conformity can be issued, the device is marked with the CE symbol and it can be marketed throughout the European Union. The Notified Body’s identification number will

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2 Department of Health 2004
3 COCIR, Facts and Figures www.cocir.org
4 Keynote report, Medical Equipment Market Report, 2003
5 MHRA website: www.mhra.gov.uk
6 Advise from MHRA direct. General consumer legislation such as the Sale of Goods and Trades Description Acts and the General Product Safety Regulations.
appear alongside the CE mark. Such a system places the onus on manufacturers to meet the requirements for the devices they produce

**R**em**manufacture of Medical Devices**

It is important to note that the words ‘remanufacture’ and ‘refurbish’ have significantly different meanings when applied to medical devices within the EU. This difference is defined within EU regulations. When a medical device is refurbished it is repaired, cleaned and updated to relevant safety standards. Such procedures take it back to the original state and scope of the device when it was placed on the market as a new item: i.e. it is of the same standard as a new item. Thus its conformity, as defined under the EU regulations, is ensured and it retains its CE marking.

A medical device is remanufactured when the repairs and updates take the scope and state of the device beyond its original position i.e. it is ‘better’ than a new device. At this point it essentially becomes a different device and must reapply for conformity and for a CE marking. Remanufacture as defined in the MDD is rare in Europe, while refurbishment is reasonably well established and is a growing area. Both activities are good examples of remanufacture as defined by the Centre for Remanufacture and Reuse.

The definitions of remanufacture and refurbishment are less strict in the USA, and so the two terms are used more interchangeably. The definition of a remanufacturer, used for the first time by the Food and Drug Administration (FDA) in 1996, states that “any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that changes the finished device's performance or safety specifications or intended use” is a remanufacturer. Remanufacturers in the USA are bound by the Good Manufacturing Practices guidelines, as are all OEM manufacturers.

The remanufacture/refurbishment of medical devices in the USA is well developed, with this market being by far the largest worldwide. This is due to a range of factors including a lack of negative association with remanufactured equipment, and a medical system that is not financed directly from central government, so is therefore more business orientated.

To avoid confusion, the term ‘refurbish’ will be used in this report from this point on to describe a medical device reaching the end of its first life, being repaired and refurbished back to a state and scope that is the same as its state when new, and subsequently being made available for purchase. Such a device retains

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7 FDA website, www.fda.gov/CDRH/DEVADVICE/32.html#remanufacturers
its CE award which is considered to be essential by OEM remanufacturers in Europe.

Whether a medical device is appropriate for refurbishment often depends on its intended lifespan. Although the refurbishment and reuse of single-use medical devices occurs, with proponents citing economic and environmental benefits, the risks of compromised function, incomplete decontamination and re-sterilisation, a lack of retesting and the possibility for cross-contamination has led the MHRA to advise against the reuse of such devices.\(^8\) Thus most single use devices are disposed of after they have been used once.

Devices that are commonly refurbished have generally been designed to have extended use periods, many operating for thousands of cycles. Examples include imaging devices such as X-ray equipment, CT, MRI and ultrasound scanners and surgical equipment that can be repeatedly re-sterilised.

There are two distinct groups which refurbish medical devices. In the first group refurbishment is performed by the OEM. Such refurbished products are generally offered back into the medical institutions of the developed world. The second type is where refurbishment is carried out by a separate third-party, and the devices are often sold into veterinary medicine, or to medical institutions in developing countries.

The worldwide market for refurbished medical systems is estimated to be worth over a billion dollars annually, with an expected growth rate of 10% each year.\(^9\)

### Refurbishment of Medical Devices by the OEM

Many of the large medical manufacturing companies offer refurbished imaging systems. Such systems are ideal for refurbishment as they are non invasive, involve a considerable capital outlay to purchase and represent a significant manufacturing investment. Leading medical device manufacturing companies that advertise refurbished systems in their literature are Siemens, GE and Philips.

Examples of such refurbishment systems include:

**Siemens Medical Proven Excellence Programme**

Siemens started its ‘refurbished systems’ (RS) group in the late 1990s.\(^{10}\) Generally the larger scanning machines, such as angiography, radiology,

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\(^8\) Device Bulletin, Single-use Medical Devices: Implications and Consequences of Reuse, October 2006.

ultrasound, magnetic resonance, X-ray systems and molecular imaging are refurbished and offered back into the market for 30% less than the cost of a new system. Most systems are sourced from Siemens customers who are obtaining an upgraded system, with trade-in having been accepted for over seven years.

Siemens uses a five stage quality process to remanufacture its systems:

1. **Selection** - appropriate systems are inspected, tested and evaluated: they must be under eight years old and spare parts must be available for the next five years. The software and hardware must be upgradable to the most current version.
2. **De-installation**: the instrument is packed in its original packaging material and transported back to a Siemens refurbishment factory, either in Forchheim in Germany, or Chicago in the USA.
3. **Refurbishment**: the equipment is cleaned, disinfected and repainted. Worn parts are replaced with Siemens spares; all components and subsystems are checked and the latest software and hardware are installed. The system is then customised as required, all components and subsystems are tested using the original test equipment and procedures for new systems, and then the whole system is subjected to a quality acceptance test. If successful the system receives the “Proven Excellence” seal.
4. **Reinstallation**: after transportation to the customer the systems are installed by professional service partners. Application training is available, and the “Proven Excellence” certificate is handed to the customer.
5. **Warranty**: “Proven Excellence” systems have a warranty equivalent to a new system which covers any defects for twelve months, and guarantees the availability of spare parts for a minimum of five years. The full range of service contracts, financing options and qualified contact persons are made available to the customer.

The remanufacturing process adheres to EN ISO 13485: 2003 which ensures Quality Management Systems are used by Medical Device Manufacturers and ISO 14001: 1996 which is an international standard for an effective Environmental Management System. The refurbishment systems also participate in the voluntary EU Eco-Management and Audit Scheme (EMAS).
GE Healthcare’s GoldSeal Programme

The GE GoldSeal Programme has been operating for 10 years. GE Healthcare offer pre-owned, refurbished, computed tomography systems, functional imaging systems, magnetic resonance systems, ultrasound and X-ray systems. These are generally selected from off-lease or trade-in arrangements, from GE services sites. They are inspected in the field to assess their suitability by GE Field Engineers, transported in OEM packaging and remanufactured by GE trained technicians, with OEM replacement parts. At the subsequent installation site planning is assured to meet GE specifications and the equipment is reinstalled by GE Field Engineers. At all stages of the process the team who provide sales support for new device purchase provide the same level of support for refurbished device purchase.

GE have three different strands of devices, each offering a different level of refurbishment and warranty.¹⁶

“GS Class” is the premium refurbished offering with systems fitted with brand new magnets, gantries, X-ray tubes and cameras. Components that aren’t replaced must undergo a rigorous test certification process. GS Class systems are easily upgradable in the future and each system is provided with a full warranty.

- “GoldSeal Certified” devices have been refurbished and undergone a rigorous testing procedure. Each system is offered with a same-as-new GE warranty.

“Gold Xtend” pre-owned systems are inspected, restored and tested to ensure devices conform to original specifications and functionality. Such systems are offered with limited warranty and a five year guarantee.

Philips’ Diamond Select Programme

The Philips Diamond Select Programme offers pre-owned refurbished systems at a reduced market price compared to new systems. CT, MR, cardiovascular X-ray, general X-ray, nuclear medicine and ultrasound systems are all available through this programme.

Systems for refurbishment are sourced from models that are being phased out in the middle of their working life, as well as showroom and demonstration models. Philips personnel inspect, test and, if selected for the programme, de-install the system and transport it to a Philips refurbishment centre – several exist in the USA and in Europe. The systems are cleaned, disinfected and repainted. Old and failed parts are replaced with the latest replacements and software is updated to the latest versions as are any vacuum components, X-ray tubes and

¹⁶ GE GoldSeal website.
image intensifiers. The systems are then tested to original specifications. The subsequent purchasing process, the installation and after sale service offered are the same as for new equipment, as are the warranties offered.\textsuperscript{17,18}

In 2005 Philips Medical Systems was presented with Frost and Sullivan’s (a growth consulting company) Customer Service Leadership Award for its excellence in the field of European refurbished medical imaging systems.\textsuperscript{19} This award demonstrates the growing significance of refurbished systems in the medical device market.

Although such refurbishment programs fit very well within the environmental policies of the OEMs, often this situation is a happy coincidence. The primary driving force behind OEM refurbishment of medical devices is to provide the best patient care at affordable prices. Considering that in mature markets the purchase of a new piece of equipment is almost always to replace an old system, there is a sizeable supply of older equipment with considerable residual value that can be refurbished and returned into patient care rather than being scrapped. The environmental considerations are growing in importance for the OEMs and their customers, so it is likely this issue will develop into a driving factor, but it is not a significant one yet.

**Refurbishment of medical devices by a third party**

An alternative to OEM refurbishment of medical devices involves the purchase of medical devices by third parties. Such third parties will either refurbish the devices, or simply sell them on. The first category provides genuine refurbishment, while the second category may more accurately be described as brokers.

Many third parties who perform refurbishment have considerable expertise. Best practice involves replacing broken and worn parts with OEM parts, bringing in OEM trained engineers to perform repairs if that knowledge is lacking, providing manuals for the devices where appropriate and providing a warranty on the items. The warranties provided ranged between thirty days and one year for the companies identified through this work. This best practice is voluntary as no industry standards exist for this work.

Medical devices which are subsequently refurbished are bought from some NHS hospitals, private hospitals and vets’ practices. Alternatively they may be bought

\textsuperscript{17} Technology news: Refurbished equipment, Philips promotional brochure

\textsuperscript{18} Philips’ website: \texttt{http://www.medical.philips.com/main/products/refurbished_eqp/program/}

\textsuperscript{19} Philips’ website: \texttt{http://www.medical.philips.com/main/news/content/file_882.html}
through auction houses, as many NHS hospitals will not sell their end-of-life equipment directly.

The market for such devices in the UK is largely restricted to private hospitals and vets’ practices. Much of the refurbished equipment is sold to developing countries.

**Trends**

The most significant driver in the field of medical devices is developing new technology. The pace of advancing technology in this field is rapid. The intervals between the purchase of superior systems are shortening, and a greater number of devices with significant use periods still remaining are being returned to the OEMs or bought by third parties to sell on.

As part of the changing market place many of the OEMs’ offerings contain elements of a servitisation business model, although this term is never used. For example rather than selling an imaging device in isolation, service maintenance contracts are provided as part of the offering. This level of service is often provided irrespective of whether the device is new or refurbished. It is likely such service offerings will continue to be an important part of the service offered by OEMs.

There is enormous pressure on all medical institutions to provide the best patient care at the lowest possible price and this is an issue which can only increase in importance in the future.

Environmental considerations, especially with regard to waste, are increasingly significant but are currently addressed at the disposal stage of a device’s product life, rather than through the whole life cycle process. Waste concerns are likely to grow, and refurbished medical devices are potentially one way to address some of the areas of concern.

The market for medical devices in the UK is driven by the NHS, with specific purchasing initiatives driven by the individual Trusts, with support provided by NHS Supply Chain and PASA.
Use of Refurbished Medical Devices

OEM refurbishing programmes aim to supply the higher end of the medical device market, focusing on publicising the quality of the products and the quality of the service to the purchasers. At the same time they stress that purchasing such items from third party refurbishers may not yield the same quality of product.

Siemens reports that it has experienced an increase in demand for refurbished systems; in 2005 over 800 refurbished systems were purchased, where as in 2002 only half this number were sold. Although these figures are encouraging, use of refurbished medical devices varies greatly worldwide. OEM and third party refurbished devices are common in the USA, with its privatised health care system. In Europe, Germany has the largest incidence of using OEM refurbished devices, in part facilitated by a state payment system that pays a set fee per activity performed, irrespective of the equipment used to perform it. The activity of brokers is also particularly strong in Germany. Some use of OEM refurbished devices occurs in France, also in Spain and Italy. In the UK no specific examples of use of OEM refurbished devices in NHS hospitals were identified.

Some countries have placed restrictions on the import of pre-owned and refurbished medical devices. Turkey and China were both identified as countries that have banned imports of pre-owned medical devices. There are many other countries which place restrictions on the import and sale of pre-owned refurbished medical devices. This is largely in reaction to the import of sub-standard medical devices that have proved detrimental to a country’s health service in the past.

COCIR is the ‘European Coordination Committee of the Radiological, Electro-medical and Healthcare IT Industry’. It has recently produced a green paper entitled “COCIR Good Refurbishment Practice (GRP)” which has been written by its members with refurbishment programmes and was released for consultation in November 2007. The aim of this guide is to identify and outline good refurbishment practice. COCIR intends this guide to help healthcare providers distinguish well refurbished devices from poor quality ones, to inform governments about GRP for their regulatory work and to motivate industry to improve the safety and effectiveness of used medical equipment by creating process standards. COCIR is also engaged in discussions with the Chinese to promote refurbished medical devices that are of an appropriate standard and covered by adequate warranties.

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Barriers to Refurbished Medical Devices in the UK

Significant barriers exist in the UK which currently prevent the widespread adoption of refurbished medical devices. The NHS dominates all medical related markets in the UK. Thus if the NHS does not use refurbished medical devices, there is a dramatic impact on the availability of such systems for the minority members of the healthcare industry.

Current funding patterns within the NHS mean there is no long term, centrally agreed replacement programme for imaging equipment. Therefore when the opportunity to replace equipment arises, a Trust often seeks to purchase the most advanced system available within the budget. This may be over-specked initially, but can go some way to ‘future-proofing’ the equipment. Advanced equipment can also be a positive draw when trying to attract new staff members or research opportunities.

There is a pre-conception that refurbished medical devices would be sub-standard and do not provide the best patient care. This, combined with a large capital investment by the UK Government into the NHS over the last decade, may have resulted in the exclusive purchase of new medical imaging systems, whereas in more financially limited periods refurbished systems could be attractive for budgetary reasons.

When a medical device reaches the end of its useful life there are various disposal options. One possibility is to exchange the old system with the OEM as part of the purchase of a new system. Another is to sell old systems to a third party for refurbishment and onward sale. Both of these options allow the residual value of the item to be realised and retained by the hospital. There are many occasions when neither of these options occur, as there exists strong concern in the UK that refurbished medical equipment would be traceable to the original hospital, and some responsibility would be retained should the device malfunction. Therefore end-of-life medical devices are often sold to auction houses to prevent traceability, or sold as scrap. Such an arrangement means that the NHS retains very little of the market value of these items. Sale for scrap also reduces the number of units available for refurbishment by OEMs or third parties.

While there are no specific restrictions against the import and sale of refurbished medical devices in the UK, there appears to be little activity to encourage it either centrally or from equipment manufacturers. A combination of the above barriers combined with low levels of promotion means that very few refurbished medical devices are used in UK hospitals. In general public healthcare systems

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are less receptive to refurbished medical devices than private healthcare systems. Private healthcare institutions often operate on smaller budgets that are more flexible than public ones and a saving made through the purchase of a refurbished system can be used elsewhere in the institution. This may not be the case in the NHS.

The Future

There are two areas where small changes could bring advances in this market:

The sale or exchange of end of life medical imaging devices should be encouraged. This would allow the residual value of the equipment to be released back into a trust’s budget. It would also ensure more equipment is available for refurbishment, almost certainly benefiting secondary markets abroad or in veterinary medicine, and potentially could benefit primary markets. Such an action would help to ensure that working components are retained, rather than simply recycled.

A more long term approach to funding for imaging equipment would enable trusts to evaluate more realistically the requirements of equipment to be purchased and the time frame it will operate for, rather than the current situation where often equipment purchased is over specified for its initial role.
Conclusions

The refurbishment of medical devices does occur, through both OEM and third party arrangements. Medical devices represent considerable inputs of materials and manufacturing, so extending the lifetime of these devices represents a significant saving of resources.

There is a strong market for refurbished medical devices in the USA and a growing market in some European countries. Meanwhile in the UK no instances of refurbished medical devices being purchased for use in NHS or private hospitals were identified.

The quality of the refurbished product offered varies. OEM refurbishing programmes offer the strongest package in terms of service and warranty of the devices. This is a distinct marketing advantage as such systems are intended to re-enter mature healthcare markets in developed countries.

Purchase of refurbished medical imaging systems is a growing market. All the OEM remanufacturers contacted reported increased sales and interest in this area. It is likely that growth in this area will continue. Refurbished imaging systems offer a good opportunity to provide extra equipment at a saving compared to new, whilst maintaining standards of care to the patient and retaining equipment that still has a considerable service lifetime.
Appendix

The term ‘medical device’ covers the range of products from simple items such as dressings, examination gloves and spectacles, through surgical instruments, implantable devices to X-ray systems, ultrasound imagers and CT/MR scanners. It also includes dental equipment.24

Medical devices can be defined as all products used in healthcare for:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception

which do not act primarily through pharmacological, immunological or metabolic means.

Devices are classified according to the level of risk they present to the patient:

- Class I - low risk devices, such as tongue depressors or bandages.
- Class I sterile and/or measuring – low risk devices, such as urine drainage bags or digital thermometers
- Class IIa – medium risk devices, such as IV catheters
- Class IIb implantable – elevated risk devices, such as intraocular lenses or breast implants
- Class III – high risk devices, such as heat valves and reabsorbable implants.

The main purpose of the MDD regulations is to establish a single market through the introduction of controls to regulate the safety and performance of devices throughout the European Union. These Directives replace any existing national systems in Member States.25

24 MHRA website: www.mhra.gov.uk
25 The Notified Body, Bulletin No. 6, Jan 2006, MHRA.