

Page 1 - Intro

My Name is Michael Schmit and I am the Remanufacturing Technology Director for GE Healthcare. I have worked in various Manufacturing and Engineering roles over the past 17 years with GE and the last 6 have been completely focused on Remanufacturing. I would like to thank the Commission for the opportunity to speak today on the topic of Remanufacturing for the Healthcare Market.

Page 2 – Scope

I will start by talking about the scope of the Remanufacturing Medical Equipment Industry. The most common Medical Equipment that is remanufactured includes Magnetic Resonance (MR), Computed Tomography (CT), X-Ray (XR), Interventional Cardiology (IC), PET/CT, Nuclear Imaging (NUC) and Ultrasound (U/S). Reman in this industry is certainly practiced by the Top 4 OEM's (GE, Siemens, Philips, and Toshiba) as well as 100+ small to medium sized businesses across the United States. The graph on the right side of the page displays data from a Frost & Sullivan study of revenues for Reman Medical Equipment sold in the US from 2010 to 2015. Revenues in 2010 were \$563M with a projected 5% Compound Annual Growth Rate through 2015 for the major modalities. The major customers included hospitals, imaging centers and private practices. From a global standpoint, 50% of the market is in the US and European Union. The projected growth is more substantial in emerging markets in Asia and Latin America than in the US and European Union economies.

Page 3 – Expanding Healthcare Affordability

On page 3, I will talk to Remanufacturing's linkage to Healthcare Affordability. Remanufacturing of Medical Imaging Equipment creates a cascade of trade which expands affordability of Healthcare. The graphic on the left side of the page shows the process. Typically, a customer has an original system that was sold to them 3-5 years prior. Either because the system has reached end of lease terms or the customers simply wants to upgrade to the latest technology, they decide to trade-in the piece of medical equipment. The value of that trade-in, or core, allows the customer to invest in new technology. The trade-in comes back to our factory. Our trained professionals go through an extensive process to ensure the product is remanufactured and meets the original manufacturer's performance, safety and image quality specifications. The product is backed by full service support, product surveillance and warranty like a new system at a significant price reduction to the customer. Keep in mind that the systems that come back as trade-ins, or cores, for medical equipment do so because they are coming off lease or because of turn over to new technology. They are typically not defective systems that need to be repaired and made to work again. They are working systems that have yet to meet end of life and will go through a thorough testing processes before being sold to the next customer.

Page 4 – Industry Trends

Next I will discuss Medical Equipment Remanufacturing Trends. The current market place trends in the US for Healthcare seem to be favorable for the Remanufacturing Industry. Declining reimbursement for imaging procedures leads to a need for lower priced Remanufactured Medical Imaging equipment since customers are looking for value offerings to meet their needs. Technology innovation continues to drive quick turnover of equipment which lends itself to Remanufacturing. Imaging Centers and Private Practices have been consolidated and taken over by larger Hospitals. This has allowed for excess core availability for Remanufacturing processing.

Page 5 – Global Markets

In my last slide, I will talk about Global Markets and Barriers to trade for Reman Medical Imaging Equipment. In the pie chart on the left of the slide, I have displayed data form the US Dept of Commerce International Trade Administration

Global Import Regulations for Pre-owned Medical Devices 6th Ed. It shows that although 61 countries have open borders to the importation of Remanufactured Medical Equipment, 24 restrict shipments to non-public customers, 16 have other restrictions to importation and 5 countries have complete bans. The types of barriers to trade are varied and are summarized in the text block on the right of the page. They include outright bans, High Tariffs or Fees, Public Institution Bans, special certification requirements, Excessive Documentation (which may sometimes include requests of proprietary information), Equipment Age restrictions (for instance in Columbia, Reman equipment older than 5 years cannot be imported into the country), and bans on equipment that competes with locally produced devices.

I would like to talk to a couple of the examples that the Medical Equipment Reman Industry has struggled with over the past several years. China is a classic example for many industries regarding Reman including Healthcare. There is a complete ban on the importation of used medical equipment. Even though the remanufactured medical equipment meets all of the safety, performance and Image Quality Standards of when it was originally produced, because it has used content, it is classified as "used" and not allowed to be imported into China. This is especially ironic since there is such a significant need for low-cost high quality medical equipment as China is working towards meeting its healthcare objectives to supply Healthcare to the rural communities. Another good example is Brazil. ANVISA has published a new proposed regulation that would not allow the importation of Remanufactured medical imaging equipment unless it was originally produced in Brazil. In effect, this would shut down the US exports we have today shipping into Brazil for Remanufactured Medical Equipment. Today in Brazil, it is not permitted to import Remanufactured medical equipment that competes with locally produced goods. Therefore, no one is allowed to import Remanufactured X-ray equipment since there is a local producer within the country. Other high end equipment such as PET/CT and MR are allowed to be imported today but it is just a matter of time until that market opportunity will also be eliminated. Furthermore, it is not allowed to ship cores or as-is medical equipment into Brazil, even if the intent is to Remanufacture within the country.

In conclusion, I would like to thank the Commission for the opportunity to contribute to the discussion of Remanufacturing. It's great to see that that the study has a sector focus on Healthcare as Remanufacturing is a well-established practice in this industry. Thank you again and I am looking forward to continued dialogue on this very important topic.

ITC Public Hearing Discussion

Washington, DC

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Michael Schmit



imagination at work



Medical Imaging Equipment Reman Scope

Medical Imaging Equipment is Remanufactured by the Top 4 OEM's as well as 100+ small to medium size businesses.

Magnetic Resonance Imaging (MR)

Computed Tomography (CT)

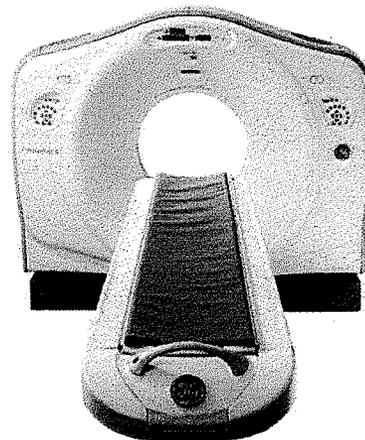
X-Ray (XR)

Interventional Cardiology (IC)

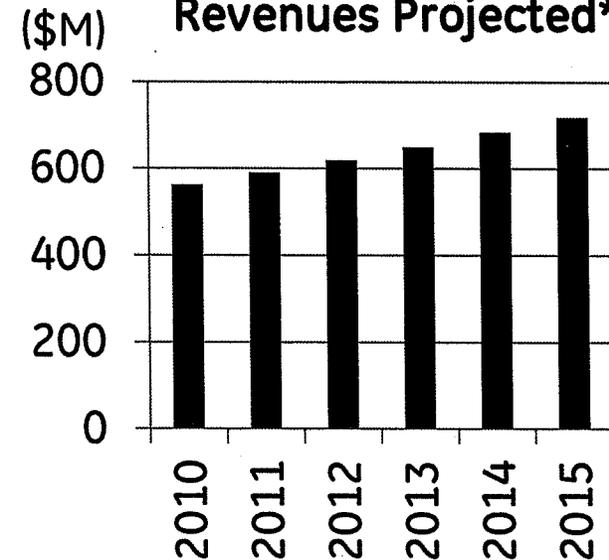
PET/CT

Nuclear Imaging (NUC)

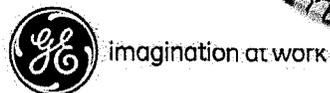
Ultrasound (U/S)



Reman Med Equip US Revenues Projected*

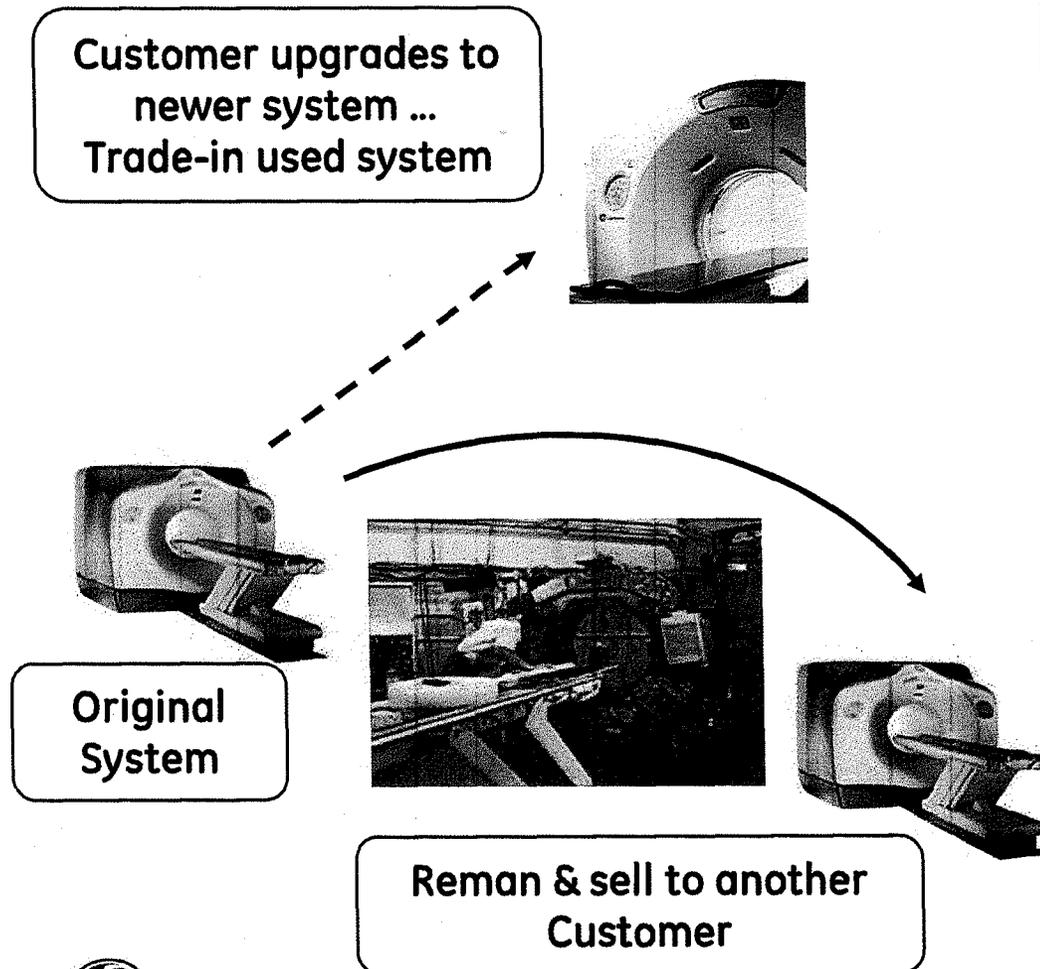


*Data from Frost & Sullivan Landscape Market Study for the Remarketing of MRI, CT, PET-CT, General X-Ray, Ultrasound, Cardiovascular, and Nuclear Medicine Equipment in the U.S. for GE Healthcare.



Expanding Healthcare Affordability

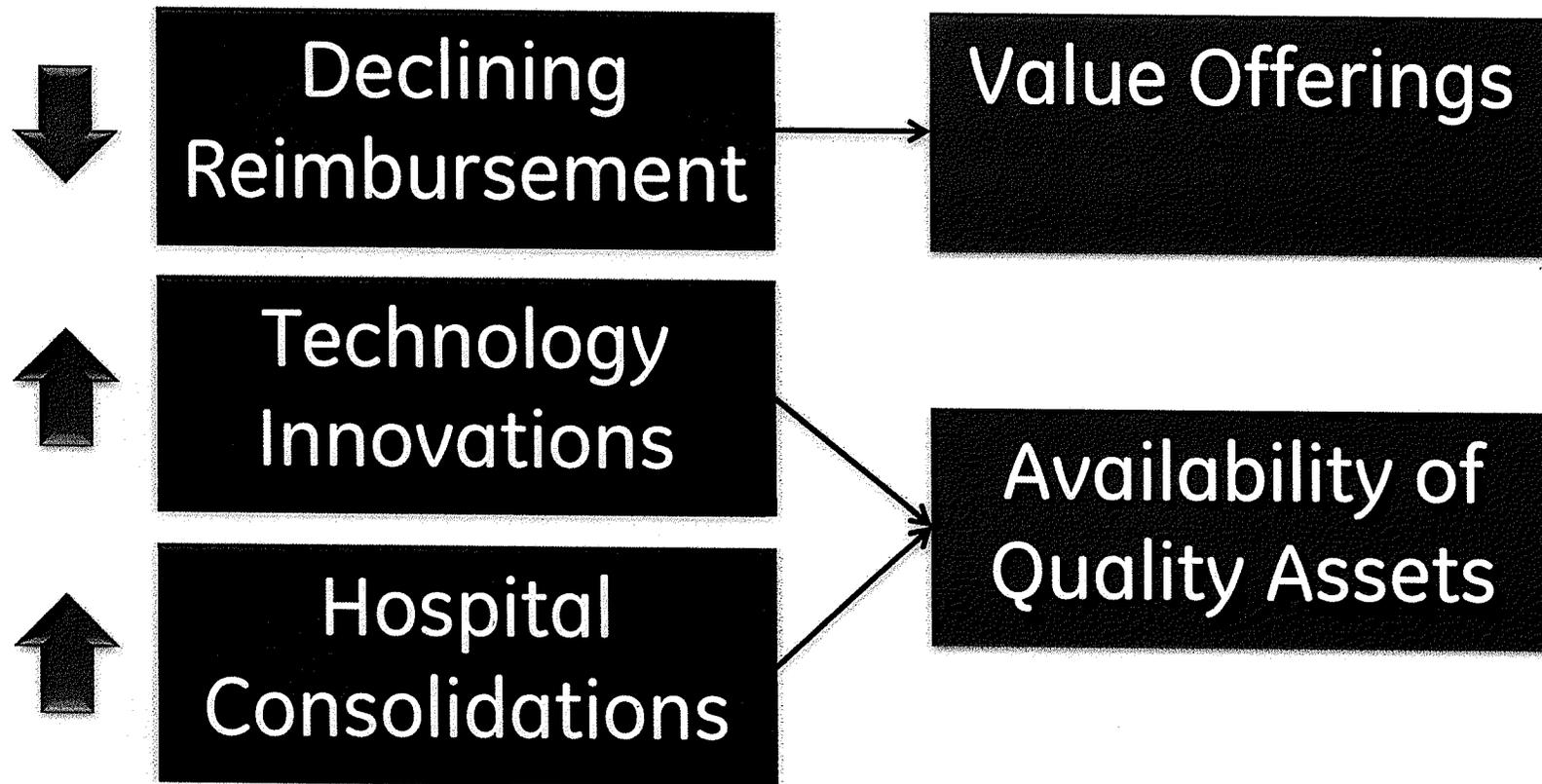
Remanufacturing supports technology upgrade and value needs



- ❑ Trade-in Payment Allows Existing Customers to Upgrade
- ❑ Returned system remanufactured and re-certified to original specification
- ❑ Backed by full service support and new warranty
- ❑ Significantly reduced pricing

Medical Imaging Equipment Reman Trends

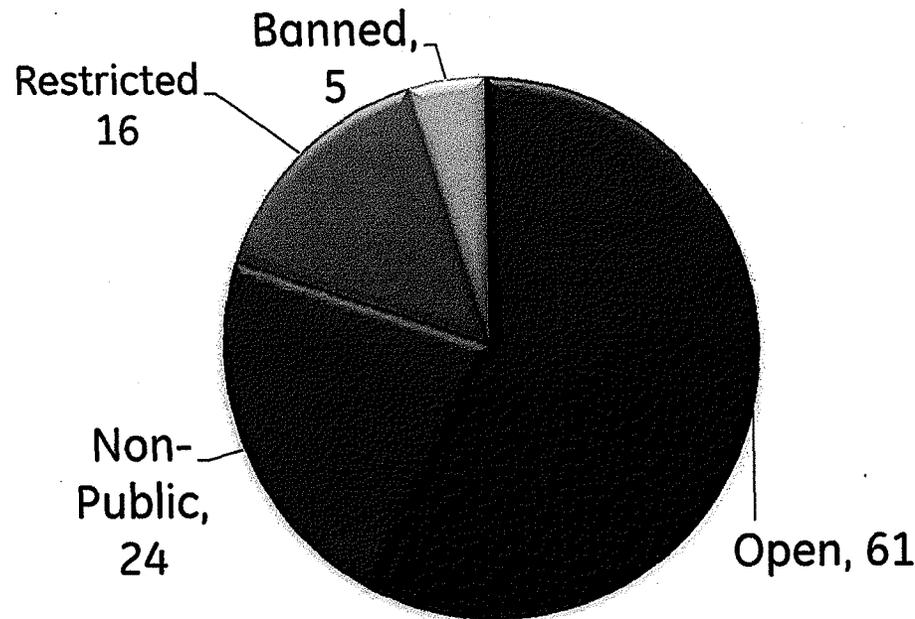
Reman continued growth due to:



Global Markets

Barriers to trade for Reman Medical Imaging Equipment

Country Global Import Status*



Barriers to Trade

- Outright Ban
- High Tariffs or Fees
- Public Institution Bans
- Special Certification Requirements
- Excessive Documentation (including proprietary)
- Equipment Age Restrictions
- Ban on equipment that competes with locally produced devices

*Data from - ITC Global Import Regulations for Pre-Owned (Used and Refurbished) Medical Devices 6th edition