



**DITTA** GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION

# Medical Device Refurbishment

*healthcare in a circular economy*

AHC-AHWP Joint Workshop  
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Seoul, South-Korea

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# REFURBISHMENT OF MEDICAL SYSTEMS

In the context of this presentation “Refurbishment of Used Medical Systems” is defined as:

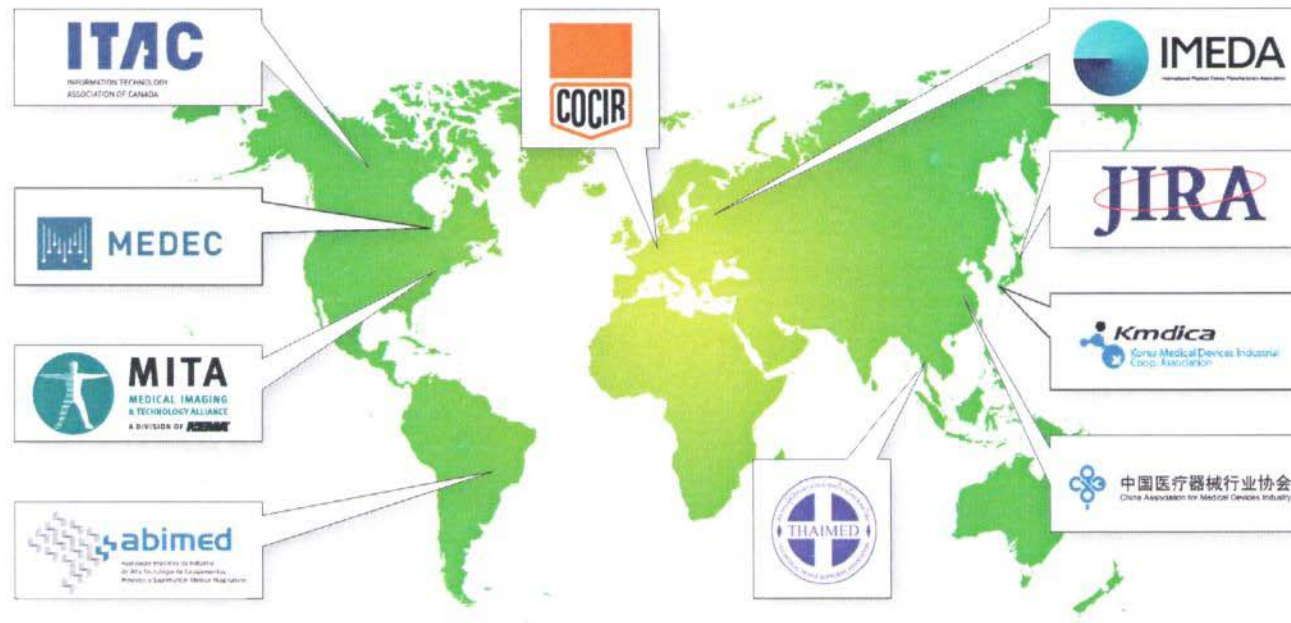
“The process to restore used equipment or systems into a condition of safety and effectiveness comparable to when new. This includes actions such as repair, rework, update and replacement of worn parts with original parts. All actions are performed in a manner consistent with product specifications and service procedures defined by the manufacturer for that equipment or system without significantly changing the equipment’s or system’s performance, safety specifications and/or changing intended use as in its original registration”

- Similar terms with sometimes different regulatory implications are used around the world.
- DITTA focus is on the process as defined above, rather than on the term used to define it.



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# DITTA is the Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association.





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Healthcare is evolving.  
Dramatically.



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# We're getting older and sicker

An increasing population in the developed world is projected to be chronically ill.

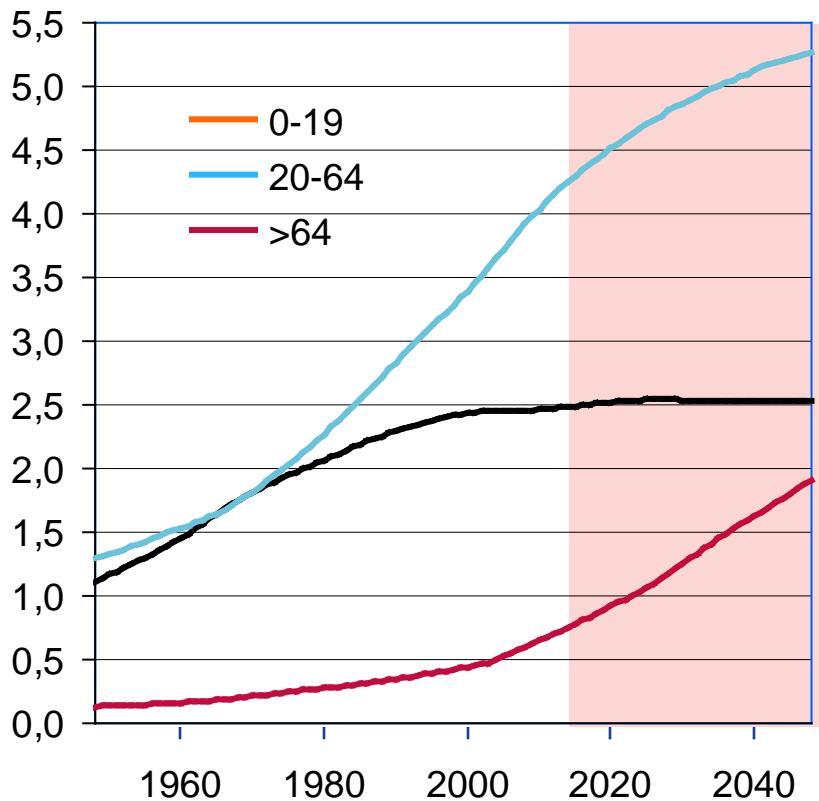




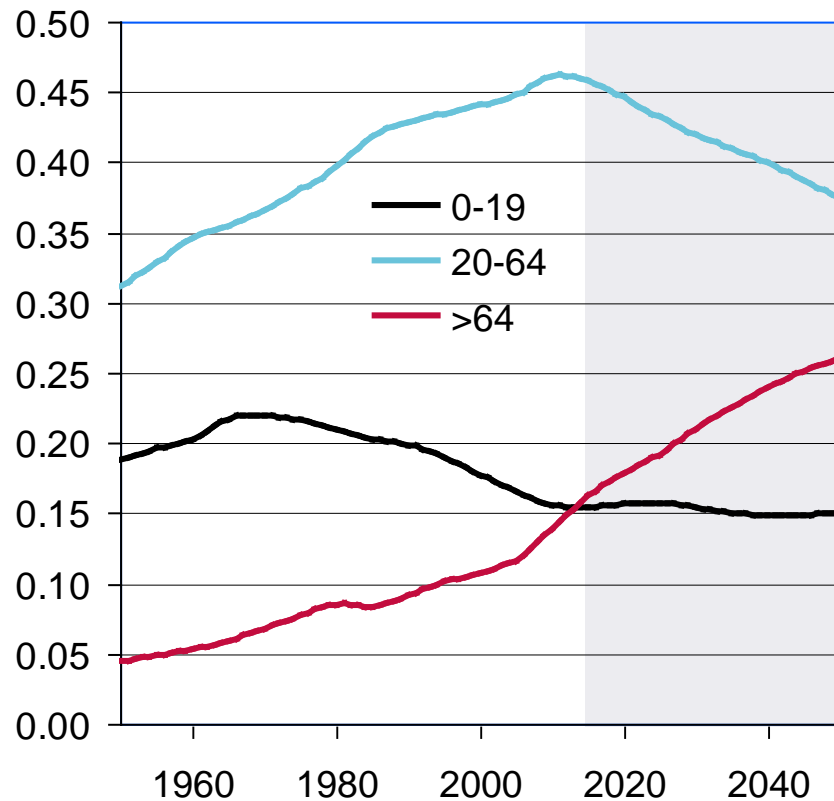
# The world population grows and ages

In Billions

### World population by age group, 1950-2050



### Europe population by age groups, 1950-2050



Source: UN, 2006 Revision of World Population Prospects,  
[http://www.un.org/esa/population/publications/wpp2006/FS\\_ageing.pdf](http://www.un.org/esa/population/publications/wpp2006/FS_ageing.pdf)



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# We don't take good care of ourselves

Obesity, heart disease and cancer are global health issues that are worsened by the way we live.





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# Demand for care is growing

There are simply not enough nurses and doctors to cope with our growing (and aging) population. Rising healthcare costs are unsustainable.







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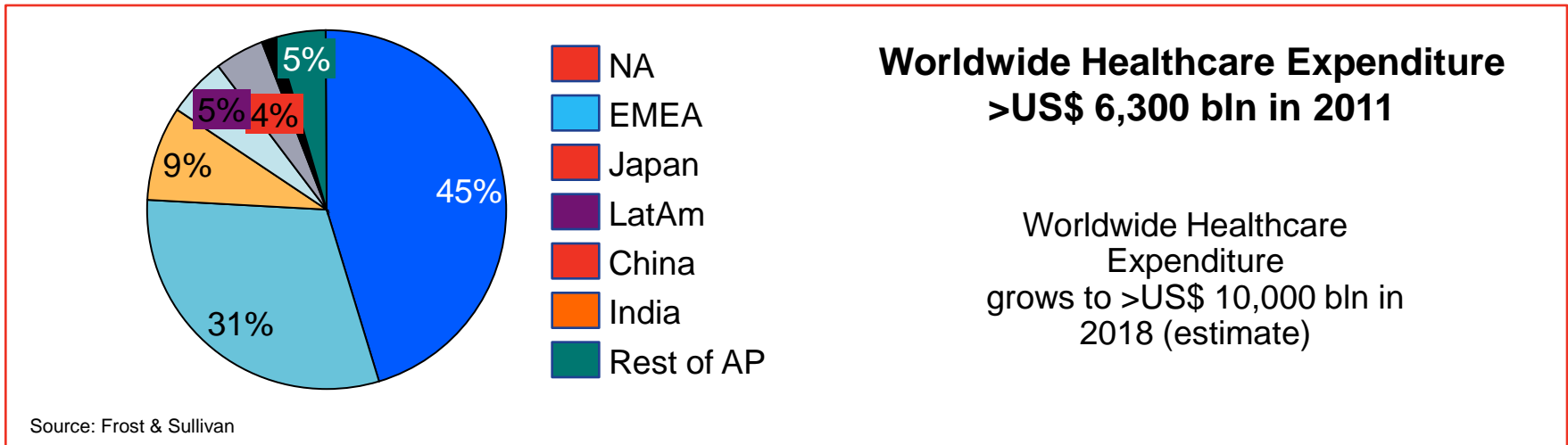
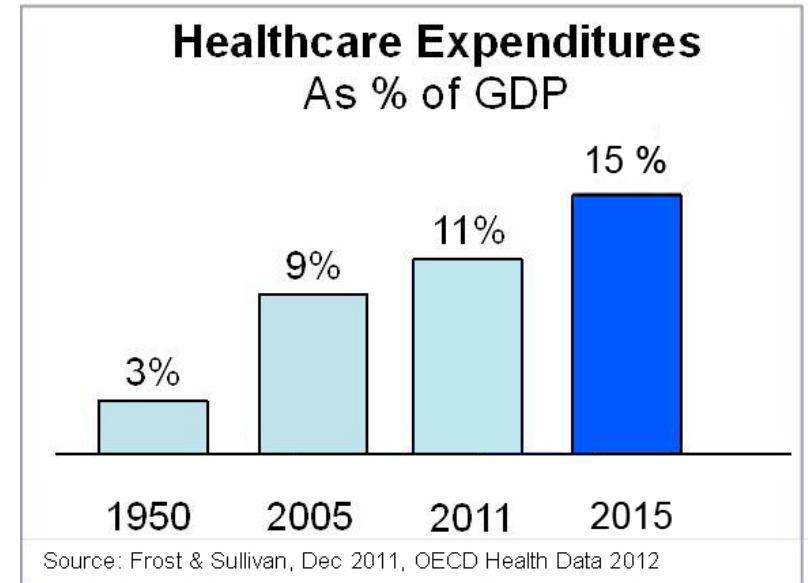
# The rate of change is accelerating

New product innovation introduces both complexity and promise. We need another kind of innovation as well, one that is financially sustainable.





# Healthcare, the world's largest service sector



## Worldwide Healthcare Expenditure >US\$ 6,300 bln in 2011

Worldwide Healthcare  
Expenditure  
grows to >US\$ 10,000 bln in  
2018 (estimate)

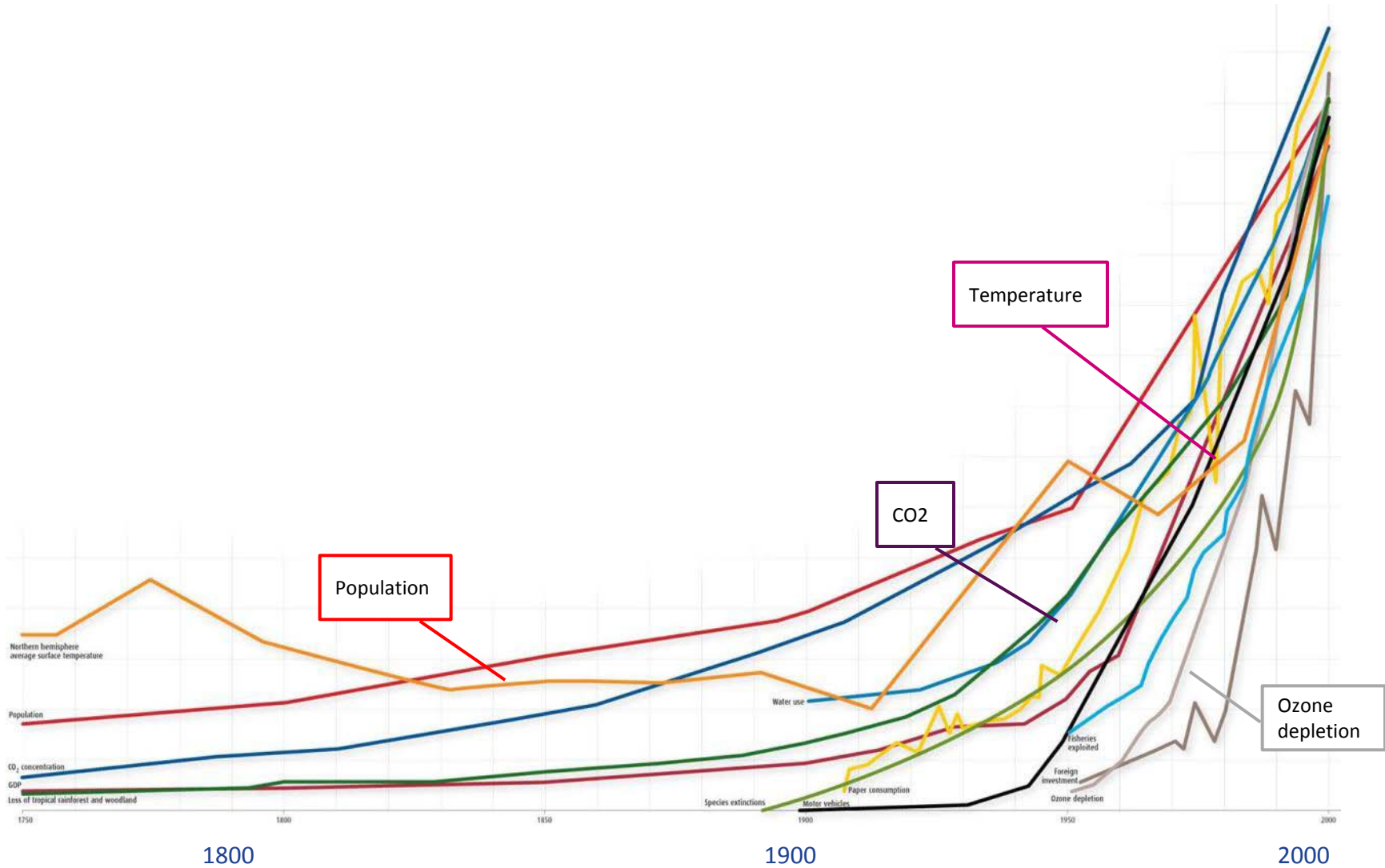


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Our global economy is evolving  
as well.  
Exponentially.

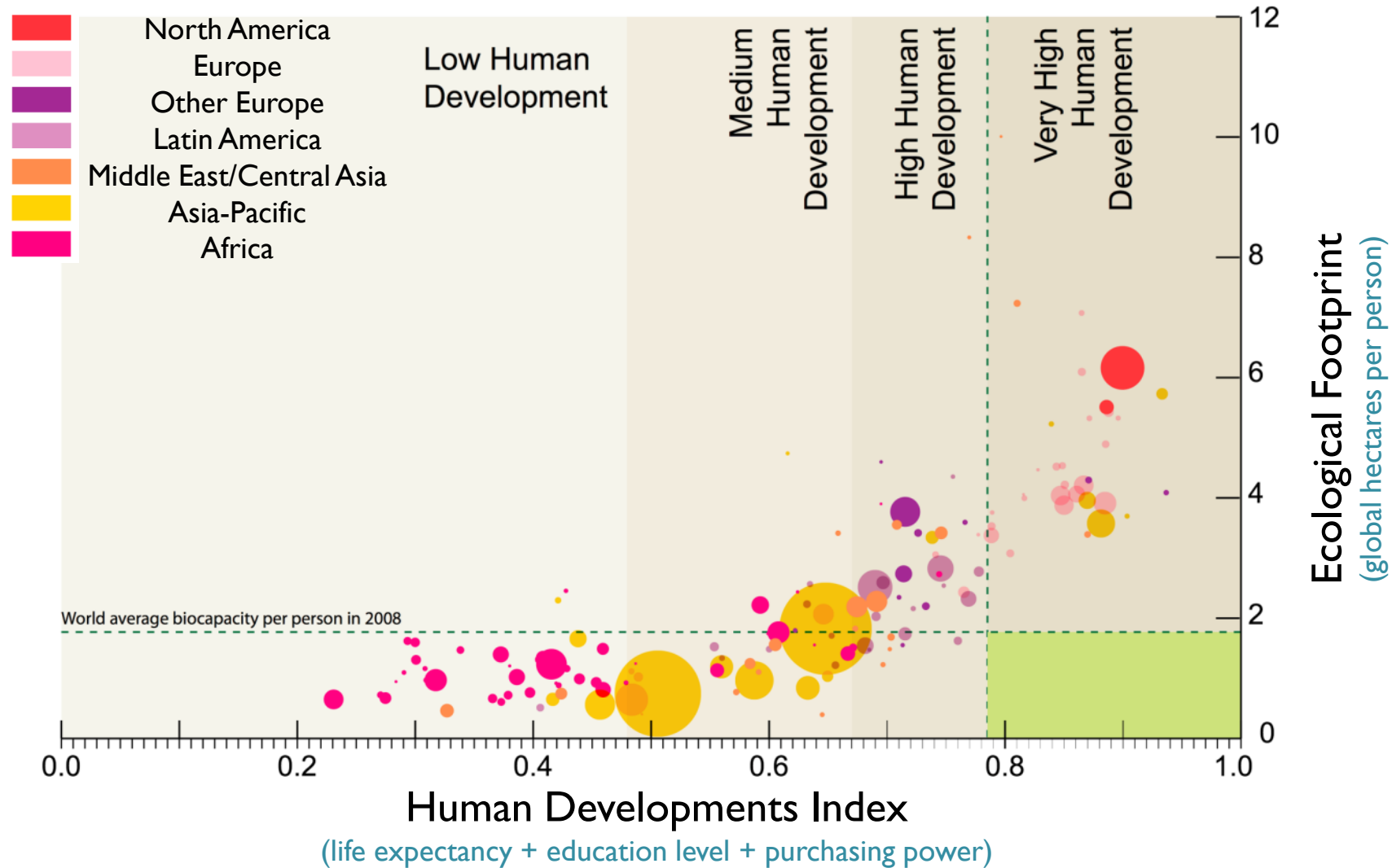


# BUT IS IT SUSTAINABLE?





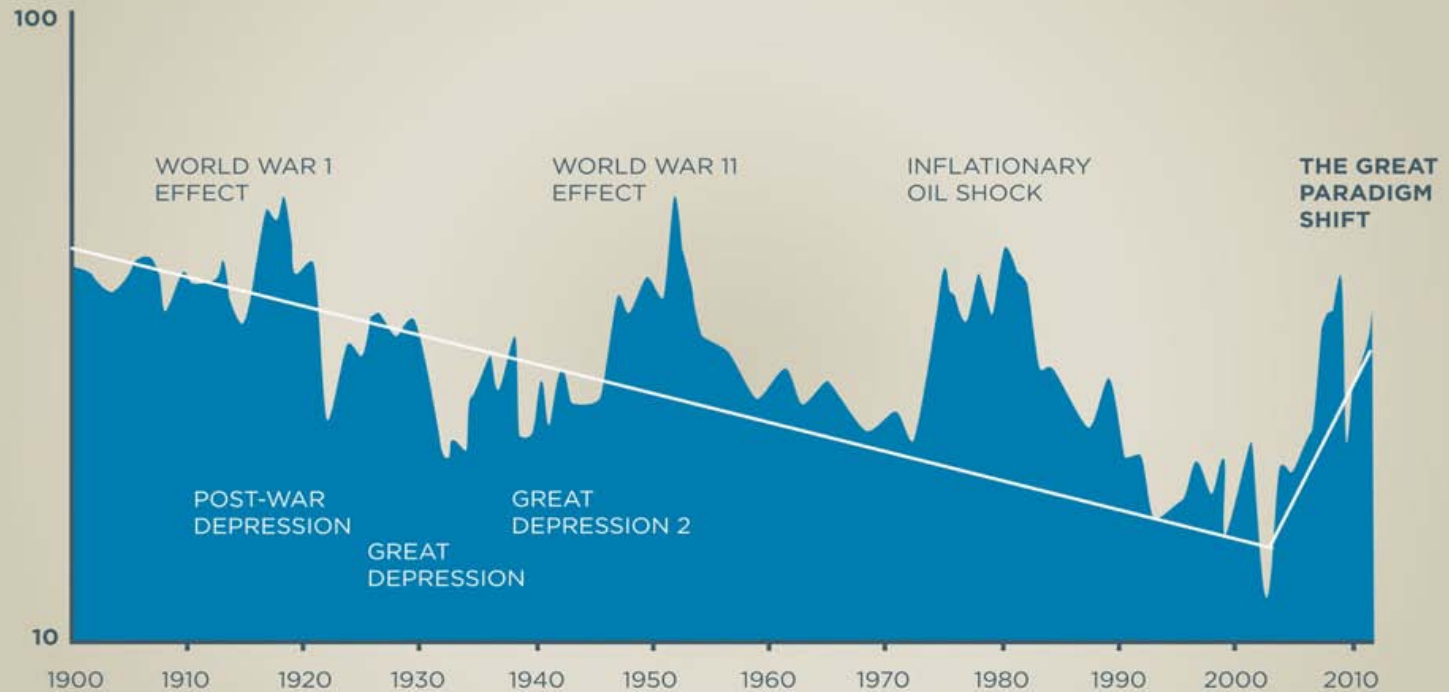
# ECONOMIC DEVELOPMENT COUPLED TO NEGATIVE ECOLOGICAL IMPACT





# COMMODITY PRICES GOING UP FAST

## COMMODITY INDEX PARADIGM SHIFT?



CREDIT: GMO





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# SEPTEMBER 2010: THE ELLEN MACARTHUR FOUNDATION IS LAUNCHED





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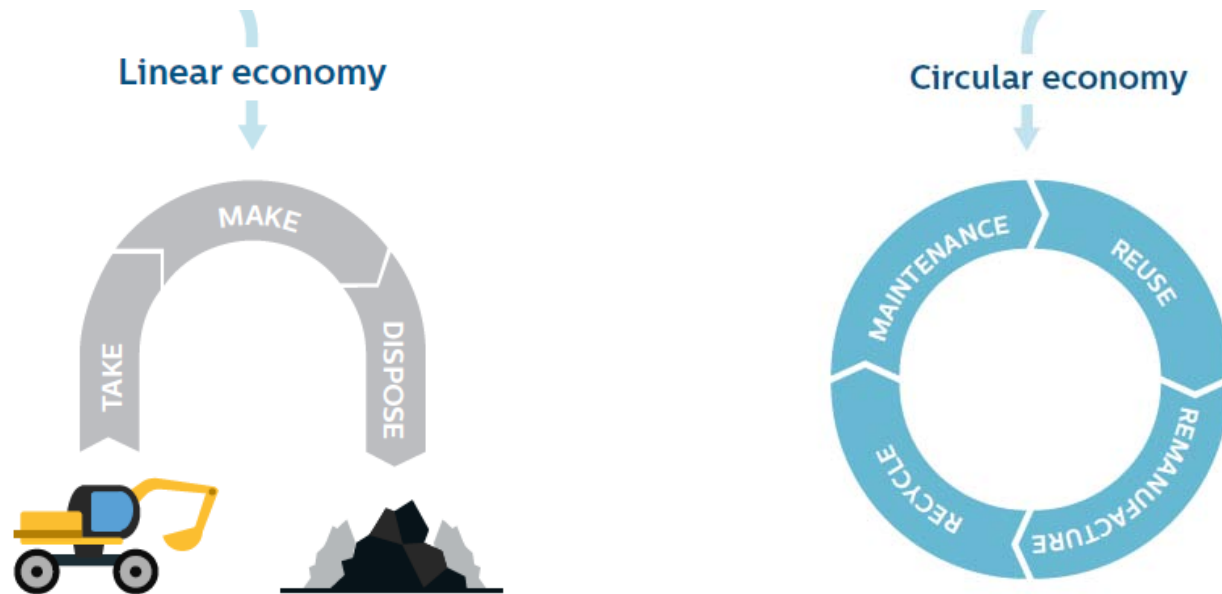
# THE CIRCULAR ECONOMY 100 - PLATFORM OF LEADING COMPANIES







# CIRCULAR ECONOMY IS ALL ABOUT RETAINING VALUE



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

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

Product refurbishment, improving reusability and new business models away from product ownership, will help us in the right direction.

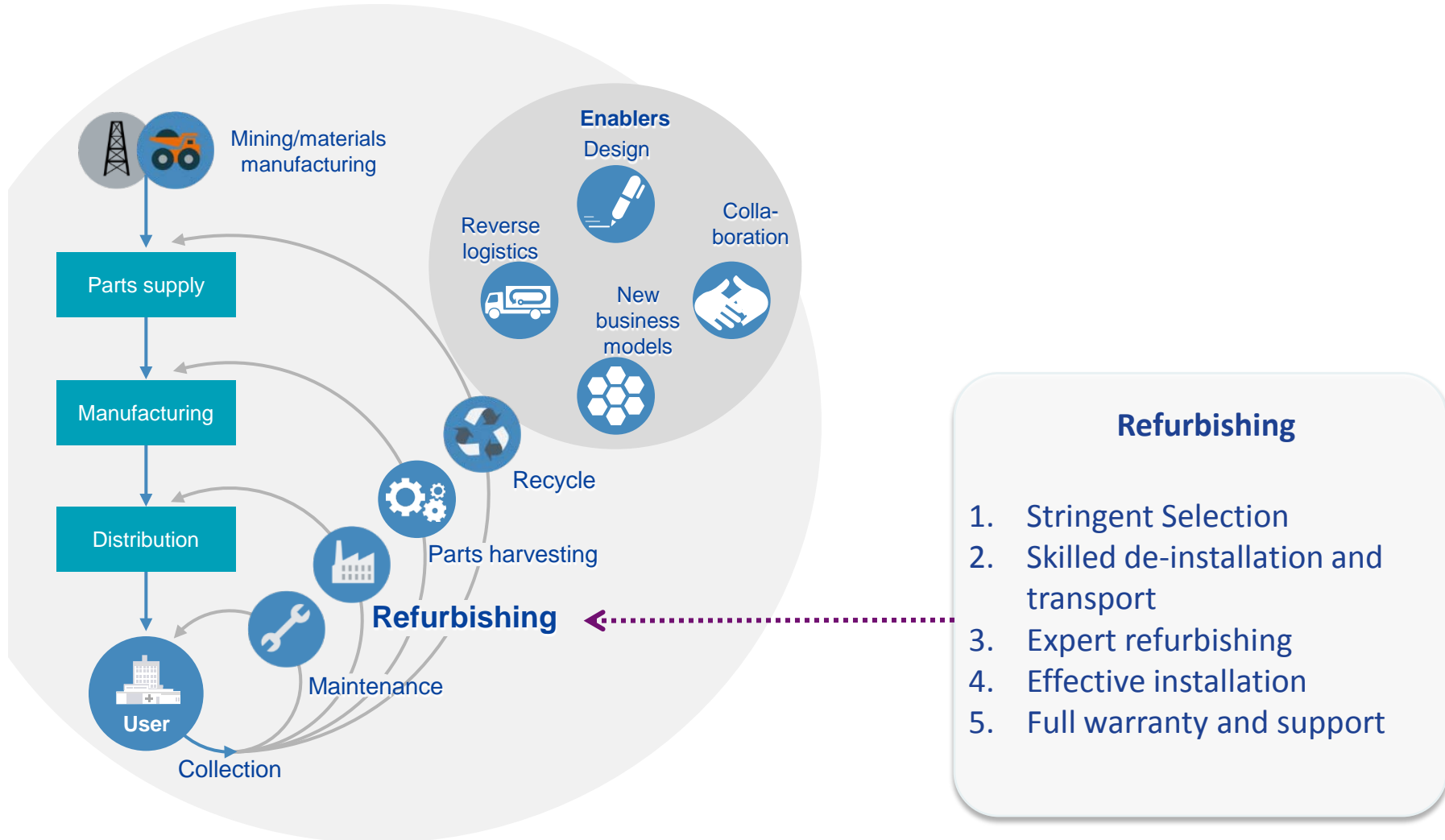


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So how does this affect  
healthcare and our industry?



# LOOPS AND ENABLERS OF A CIRCULAR ECONOMY FOR MEDICAL DEVICES\*



\* Specifically capital goods like medical imaging machines. Not referring to single use medical devices.



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# REFURBISHED MEDICAL IMAGING EQUIPMENT

## Economy solution

- ✓ Typically 70-80% of new price

## High Performance

- ✓ Previous or current generation products

## Risk Free Investment

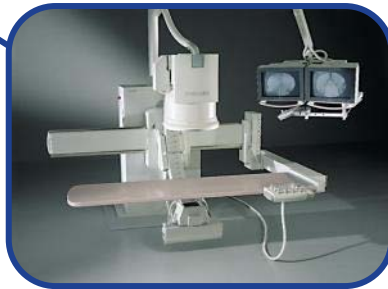
- ✓ Same as new warranty
- ✓ Service back-up





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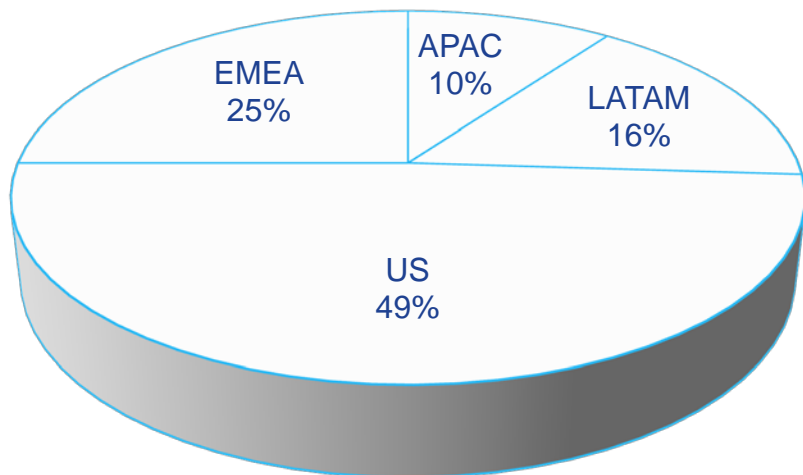
# APPLIES TO DIFFERENT TYPES OF MEDICAL IMAGING EQUIPMENT



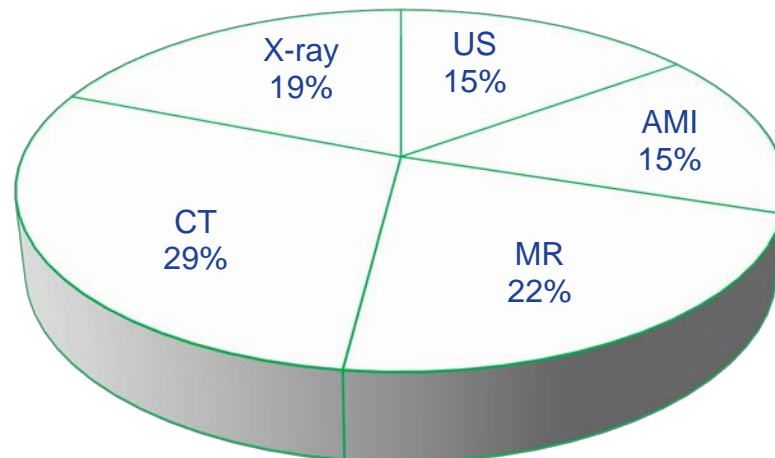


# GLOBAL MARKET FOR PRE-OWNED MEDICAL IMAGING EQUIPMENT

## Sales regions



## Modalities



Total market ~ €1.3 Billion

Historical growth rate ~ 6-8%



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# GLOBAL DIAGNOSTIC IMAGING INDUSTRIES AGREED ON A JOINT POSITION IN REFURBISHMENT



## GRP – Good Refurbishment Practice Position Paper Industry Standard



GLOBAL MEDICAL IMAGING INDUSTRY IS REPRESENTED BY

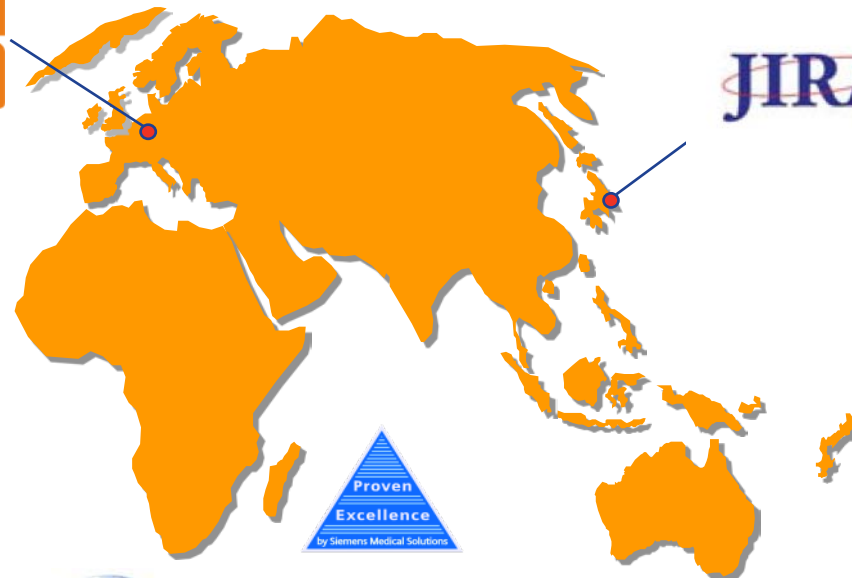


**COCIR INDUSTRY STANDARD**  
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**MEDICAL ELECTRICAL EQUIPMENT  
GOOD REFURBISHMENT PRACTICE (GRP)**

**FOREWORD**

1. COCIR is the union of the European manufacturers, technological and hardware IT industry COCIR is now split from associations, located in USA, representing the medical technology industry technology.
2. COCIR position on refurbishment practices for medical electrical equipment and cannot be considered responsible for any equipment because it has been certified with a COCIR trademark.
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**Philips Diamond Select**  
Refurbished medical imaging equipment



**GOLDSEAL**  
THE GOLD STANDARD  
In Pre-Owned  
Medical Equipment

**TOSHIBA**

# TO GUARANTEE EQUIPMENT SAFETY AND EFFECTIVENESS



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# HARMONIZATION IS CRUCIALLY IMPORTANT



**Asian Harmonization Working Party**  
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

## PROPOSED DOCUMENT

**Title:** Playbook for Implementation of a Medical Device  
Regulatory Framework

**Authoring Group:** AHWP TECHNICAL COMMITTEE (TC)  
OFFICE BEARERS

**Date:** August 5<sup>th</sup>, 2014

Initiatives like this are critical to enable the required flow of goods, needed to provide sustainable access to safe and effective refurbished equipment and affordable healthcare.

Member economies will also need to communicate and coordinate across government bodies to ensure that regulatory controls are optimized with minimal unnecessary overlap and contradiction.

Some non-exhaustive examples of potential existing general controls are:

1. Advertisement and promotion
2. Import-export procedures
3. General business licensing
4. Clinical practice or IVD diagnostic guidelines
5. Environmental controls (e.g. irradiating apparatus, explosives)
6. Disposal procedures (e.g. biohazards)
7. Transboundary movement of used parts and devices for the purpose of repair or refurbishment





# CONCLUSIONS

## Medical Device refurbishment:

- Is a globally growing concept
- Offers economic solutions to help control cost in healthcare
- Makes sense to more and more healthcare providers
- Enhances access to care and contributes to a sustainable future
- Deserves an internationally harmonized approach





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Thank you