



2019 Refurbished Medical Devices Market in **North and Latin Americas**



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Report by FIME

“ The refurbished medical equipment market contributes to grand societal challenges by reducing waste and conserving resources; increasing access to healthcare in markets with increasing healthcare cost pressure; and offering economic benefits from extending the lifecycle value of manufactured equipment and creating new jobs, growth and investment. ”

European Union, August 2017.

What are medical devices?

Medical devices:

- are used on humans
- have therapeutic benefits
- generally have a physical or mechanical effect on the body or are used to measure or monitor functions of the body

Medical devices are a key part of modern healthcare, and medical equipment manufacturers are crucial players within the healthcare system value chain, working especially closely with universities, research institutions, clinics, hospitals and pharmaceutical companies.

Who are the key players within the global refurbished medical equipment market?

These include:

- OEMs (Original Equipment Manufacturers)
- Parts and components suppliers
- Service providers, distributors and remarketers
- Industry associations

Source:
“REFURBISHMENT OF
MEDICAL EQUIPMENT:
Report on promising
KETs-based product nr. 4”,
European Union,
August 2017

A global perspective

According to a recent report by Markets & Markets, the global refurbished medical devices market is expected to reach USD 11.91 billion by 2021, at CAGR of 12.7% from 2016 to 2021.

Within the product categories, the medical imaging equipment segment was estimated to hold the largest share of the refurbished medical equipment market in 2016.

A matter of regulation

According to a blog post by TforG.com (an IQVIA company) titled Sustainable Medtech: An overview of the Refurbished Medical Equipment Market, a key factor to the refurbished medical device market is the matter of regulation.

Ironically, according to the blog, many of the lower income nations categorically inhibit the entry of refurbished or used products, through stringent or impeding regulations. Meanwhile, many high-income nations - who have the most advanced medical equipment already - are also setting forth regulatory frameworks to optimise the entry of refurbished products.

The blog continues: "Arguably, the lesser developed nations perhaps do not have the administrative and technical resources to ensure a quality control system and therefore avoid the market altogether. Nonetheless, the fact that refurbished equipment can be 100% equivalent to its identical unused version, yet at a price 20-60% lower than the original price, make it the optimal solution to underdeveloped, under-resourced national healthcare systems."

Drivers

TforG.com identifies the following as key factors and drivers shaping the refurbished medical market:

- Population growth, greying societies, and the increased demand upon healthcare systems; increase of morbidities and chronic conditions
- Hospital budget constraints, forcing care providers to seek alternative and more financially viable and sustainable procurement options
- Immense price-quality value; 20-60% cheaper than new equipment
- Greater focus and prioritisation of developing nations on their healthcare delivery, and a rising demand for medtech accordingly
- Difficulties in reimbursing medical care; inefficiencies in reimbursement mechanisms
- Growth of privatisation across nations all over the world
- Activities being undertaken by refurbishing companies to expand production facilities and supply networks in various country markets, both developed and developing

- Increase of joint ventures and partnerships across the sector
- Changing perception of resource utilisation
- Growing popularity of recycling practices, awareness of ecological damages to the planet
- Quicker return on investment for hospitals, which allows for more regular updates of equipment
- Advances in technological skills in refurbishing, to guarantee quality and safety in cost-effective ways
- Increases of warranty and post-sale services being offered with refurbished products/sales contracts, boosting the positive perception/consumer confidence and reliability of the supplier
- Interconnectivity and easier access through online marketing and sales
- "Older" refurbished equipment is more likely to be known by the users, which saves costs and resources to train personnel and avoids error, increasing patient safety
- No unexpected inherent product malfunctions, as the product has already been on the market for a while

Challenges and Market Inhibitors

TforG.com also highlights certain challenges to the prevalence and global growth of refurbished medtech markets:

- A lack of international standards and harmonisation of protocols in regards to quality, technological, marketing and sale controls
- Inadequate reimbursement mechanisms
- Unsupportive import laws and regulations
- Potential lack of sale/servicing support and availability of spare parts when necessary
- Reliability of suppliers and product quality, which again closely ties in with perception, and the previous point of being able to offer warranties and post-sale services





Market Synopsis – North Americas

US market dominance

According to a report by Fitch Solutions, the US will remain the world's largest market for medical devices, accounting for around two-fifths of the global market Fitch Solutions forecast and project that the medical device market will register a 2017-2022 CAGR of 5.1 %, which will take the value to USD198.5billion.

However, US medical device exporters will be faced with a tougher environment in 2019 as global trade is affected by a slowdown in the US economy and ongoing tensions over tariffs. This gives rise to the refurbished medical device market in which North America dominates the global market, due to the high incidence of various diseases, such as cardiovascular disease and cancer, which is a favorable regulatory scenario for the use and sale of refurbished devices.

The USA is currently home to many of the largest refurbishing companies:

- GE Healthcare
- Block Imaging International
- Soma Technology
- DRE Medical
- Integrity Medical Systems
- Radiology Oncology Systems
- Master Medical Equipment

Who regulates the refurbished medical devices market in the US?

The FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the US. In addition, CDRH regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.





Market Synopsis – Latin Americas

An overview of current Latin American markets and regulations for refurbished product importation:

| Country | Requirements | Market demand |
|------------------|--|--|
| Argentina | Refurbished medtech import allowed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Refurbished products (produced in country of origin or in Argentina) require technical assessment certificate approved by Argentine Embassy or Argentine Consulate in export country, or certificate from original manufacturer | Unknown |
| Brazil | Refurbished medtech import allowed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Refurbishment allowed domestically only | Distribution channels, high interest |
| Chile | Refurbished medtech import allowed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Little restrictions | Limited market potential. Maintenance and technical services are important. |
| Colombia | Refurbished medtech import allowed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Various requirements, stringent regulations | Unknown |
| Ecuador | Refurbished medtech import allowed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Warranty obligated, and only allowed for private sector procurement | Unknown |
| Guatemala | Refurbished medtech import allowed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No No restrictions. FDA or CE certifications preferred | Unknown |
| Mexico | Refurbished medtech import allowed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No End-users can import without restrictions. Resalers are restricted. | High potential and large market for equipment with warranty and technical support. |
| Peru | Refurbished medtech import allowed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Limited imports allowed, only by physicians for their own use. | Limited market potential |
| Uruguay | Refurbished medtech import allowed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Registration required with a local company and approval by MoH. Technical documentation of refurbishment required. | Unknown |
| Venezuela | Refurbished medtech import allowed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Only allowed in private sector | Unknown |

Source:
Sustainable medtech: An
overview of the Refurbished
Medical Equipment Market by
TforG, 15 March 2017



Market Synopsis – Latin Americas

1 Argentina

According to US Department of Commerce's Export.gov, until 1994, Argentina prohibited the importation of used or refurbished medical equipment.

Restrictions on imports of used medical equipment are established by Resolution 909/94, Annex II and III of Resolution 748/95, and by Resolution 235/99.

This legislation stipulates the following:

1. Refurbished goods must be accompanied by a certificate issued by the original manufacturer, or by a technical assessment certificate, authenticated by the Commercial Section of the Argentine Embassy or local Consulate.
2. Refurbishment may be done in Argentina by the importer, provided he is the end user. These goods may not be resold.
3. The foreign vendor must ensure the availability of after-sales service and spare parts, provide user's manuals, and have an agent based in Argentina to implement servicing required.
4. Used equipment may not be older than ten years.

Taxation and Duties

Because Argentina belongs to the Latin America trade bloc, Mercosur, all imported medical devices are taxed according to the Mercosur Common External Tariff (AEC). This tariff designates the tax rate, which may range from 0% to 16%. In the case of importing refurbished medical devices, the tax rate ranges from 0% to 24%. When a product is purchased, there is a value-added tax (VAT) equal to 10.5% for new medical devices and 21% for all used or refurbished devices. VAT values are dependent on Cost, Insurance, and Freight (CIF) value.

2 Brazil

Export.gov highlights that Brazilian regulations are strict in relation to pre-owned medical products. Products must be refurbished by OEM, using original spare parts and having the same performance and guarantee as new equipment. Resellers of used equipment have very limited market access in Brazil.

3 Chile

According to IAMERS, importation of used/ refurbished medical equipment is allowed, however, market potential is limited and maintenance and technical service may be an issue.



4 Colombia

According to IAMERS, the importation of refurbished medical devices is allowed but must meet a significant amount of requirements.

5 Ecuador

Importation is only allowed in private clinics and hospitals, estimated to occupy 30 % of the market. Any used equipment must be refurbished and have at least a one year warranty, according to IAMERS.

6 Mexico

According to IAMERS, Mexico has a strong market for refurbished medical equipment when it is accompanied by a warranty and technical support.

7 Peru

IAMERS highlights that no importation of used and refurbished medical equipment is allowed. Only physicians requiring equipment for their own use will be permitted to import one type of equipment per year.

8 Uruguay

IAMERS confirms that imports of refurbished medical equipment are authorised in Uruguay. All medical equipment, new, refurbished and/or recycled need to be registered by a local company and approved by the Ministry of Public Health prior to importation. Refurbished equipment needs to have a Technical/ Refurbishing Protocol (full contact information of the company which refurbished the equipment must be provided).

9 Venezuela

According to the IAMERS, importation is allowed, but Government organisations, who are one of the major buyers, are not allowed to purchase them.

What FIME 2019 exhibitors say



An Informa Experience

What are the major factors driving growth in the refurbished medical equipment market in LatAm and North America?



The top two factors driving growth in the refurbished medical equipment are heightened awareness and consumer confidence. Internet marketing, social media, and word-of-mouth referrals combine to drive awareness of the many benefits of refurbished equipment. As more medical professionals equip their facilities with high quality refurbished equipment, their colleagues take notice. Knowing that friends and associates are saving thousands of dollars on equipment gives new prospective buyers the confidence to reach out directly to refurbished equipment suppliers to enjoy those same benefits.



Kary L. VanArsdale, Ed.D., Director of International Sales, Avante Health Solutions.



As a seller of capital equipment, we provide refurbished radiation oncology and diagnostic imaging equipment throughout the Americas. Cost of equipment is the key factor driving the growth of refurbished equipment in both North and South America. In most Latin American countries, reimbursement rates are generally low, and the only feasible way for private clinics and centers to operate profitably is with refurbished CT's, MRI's, Linear Accelerators, and PET CT's. In the US, while reimbursement rates are higher, many rural centers lacking density of population can only operate profitably with refurbished equipment, since they don't have the patient load (and hence the revenues) to support more expensive, new equipment. Increasingly, clinics and hospitals throughout the Americas are learning that refurbished equipment is safe, reliable, and often cheaper to service than newer equipment. While new equipment may be optimal for larger, wealthier centers, state run facilities, and dense population markets, we find that refurbished equipment is critical for supplying life-saving care in many other markets.



John V. Vano, President, Radio Oncology Systems



For Soma Technology, one of the biggest drivers driving growth in the refurbished medical market place is the large consolidation among the IDNs and the excessive cost of the new devices being brought to the market by the large OEM. For Soma, when you buy from a large reputable source that is ISO 13485:2016 certified you get the best of both worlds. You get the latest refurbished equipment with the same parts and labour warranty and aftermarket support at a fraction of the cost. Overseas there were always budget constraints, but a lot of those constraints have also become reality in the domestic marketplace, due to the baby boomers and the limited budgets facing healthcare systems on a yearly basis. Also, a testament to this is that the large OEM like Philips, GE Healthcare and Siemens have been establishing large refurbishment facilities, especially in the imaging arena to capture part of this multi-billion-dollar market segment.



Peter Leonidas, President & CEO, Soma Technology, Inc.

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