Refurbished Medical Imaging Devices

Dossier

for the Government of the Socialist Republic of Vietnam

Prepared by
DITTA "Good Refurbishment Practices" Working Group

February 2019

Objective

This dossier on “Refurbished Medical Imaging Devices” has been prepared on the occasion of a roundtable discussion on “Good Refurbishment Practice & Import of Refurbished Medical Imaging Devices to Vietnam” and a meeting with the Deputy Prime Minister of Vietnam, H.E. Mr Vu Duc Dam with DITTA in Hanoi in April 2019.

About DITTA

DITTA is the united global industry voice for diagnostic imaging, radiation therapy, healthcare ICT, electromedical and radiopharmaceuticals. Our members are national and regional industry associations representing more than 600 medical technology manufacturers, responsible for designing and producing technologies and services such as medical X-ray, computed tomography, ultrasound, nuclear imaging, radiation therapy and magnetic resonance imaging.
DITTA has ten working groups including the “Good Refurbishment Practice” (GRP) working group which is focused on medical imaging devices. The companies being represented in the GRP working group are original equipment manufacturers (OEMs) who are best positioned to develop and implement refurbishment processes for their medical imaging devices.

Contact persons

Mr. Susumu Uchiyama (uchiyama@jira-net.or.jp)
- Secretary, DITTA GRP working group
- JIRA, Japan

Mr. Michael Schmit (Michael.Schmit@med.ge.com)
- Chair, DITTA GRP working group
- GE Healthcare, USA

Ms. Patricia Gehrlein (patricia.gehrlein@siemens-healthineers.com)
- Vice-Chair, DITTA GRP working group
- Siemens Healthineers, Germany

Ms. Nguyen Quynh Hoa (nguyen-thi-quynh.hoa@siemens-healthineers.com)
- Vietnam Representative, DITTA GRP working group
- Siemens Healthineers, Vietnam

Table of content

1. How is the term refurbishment defined in the medical device industry?

Definition according to IEC PAS 63077: “Refurbishment: process or combination of processes applied during the expected service life to restore used medical imaging equipment to a condition of safety and effectiveness comparable to when new.

Note 1 to entry: Refurbishment can include activities such as repair, rework, replacement of worn parts, and update of software / hardware but shall not include activities that result in regulatory submissions.”

2. What kind of medical imaging devices are refurbished and what are they used for?

Refurbishment of medical imaging devices is an established practice in the medical imaging device industry and has been for more than two decades. It is applied to medical imaging devices for professional use in all healthcare segments, including Magnetic Resonance, Computed Tomography, Molecular Imaging, X-ray Products and Ultrasound. These imaging devices are required for diagnostic imaging and image guided therapy in clinics as well as medical centers, and are used, for example, for mammography screening, diagnostic and interventional radiology, neuroradiology, cardiology, and surgery.

3. How does a refurbished medical imaging device differ from a used medical imaging device?

	New Medical Imaging Devices	Refurbished Medical Imaging Devices according to IEC 63077 PAS	2nd hand Medical Imaging Devices refurbished by non-OEMs or sold non-refurbished by dealers
OEM test instructions	✓	✓	No
Declaration of Conformity (DoC)	issued	confirmed [1)]	No
CE - mark (e.g. in EU)	issued	confirmed [2)]	Confirmation not possible
Post-market surveillance	✓	✓ [3)]	No
QMS ISO 13485	✓	✓ [4)]	No
Performance and safety test	✓	✓ [5)]	No

Source: own illustration

4. How is the safety and effectiveness of a refurbished medical imaging device ensured?

The refurbishment process consists in not only repairing, hardware/software update, replacement of worn parts with original parts but also safety and performance tests based on the original manufacturer's specification. This process ensures the safety and effectiveness of the device.

5. What is the difference between refurbishment and remanufacturing?

Outside the medical equipment industry, the terms remanufacturing and refurbishment are often used as synonyms.

Within the medical equipment industry, in the United States we must consider the term remanufacturer as defined by the U.S. Food and Drug Administration:

In the USA, the Food and Drug Administration defines 'remanufacturer' as *"(…) any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that **significantly changes** the finished device's performance or safety specifications, or intended use."* (CFR 21 Part 820)

This means that in the medical equipment industries there are differences between refurbishment and remanufacturing. The most important aspect is that for refurbished medical (imaging) equipment there is **no significant change** of the performance or safety specifications, or in the intended use of the equipment compared to the specifications the manufacturer defined for the relevant new equipment.

6. In the context of the EU-Vietnam Free Trade Agreement: can a refurbished medical imaging device be considered a "remanufactured good" as defined in the EU-Vietnam FTA?

Yes. In the EU-Vietnam Free Trade Agreement "remanufactured goods" are defined as follows:

*A **remanufactured good** means a good in HS chapters 84, 85, 87, 90 and 9402, except Annex [Z] that:*

a) is entirely or partially comprised of parts obtained from goods that have been used beforehand; and

b) has similar performance and working conditions as well as life expectancy compared to the original new good and is given the same warranty as the new good.

This definition also applies to refurbished medical imaging devices as it does not refer to the significant changes in the performance or safety specifications, or in the intended use of the devices.

Therefore, DITTA welcomes that the EU-Vietnam FTA considers the equal treatment of remanufactured goods and would support a practical implementation in the context of refurbished medical imaging devices.

7. How does the refurbishment process look like?

The refurbishment process consists of five essential steps: selection, de-installation, refurbishment, installation and warranty & after-sale service.

1) *Selection*: The careful selection of the used medical imaging devices for refurbishment ensures that only devices with flawless maintenance, performance and safety records are eligible for refurbishment. A very important element to consider is that such devices are in the ownership of the refurbisher. By making the selection process an essential first step of the whole process, the foundation is built to ensure the traceability of the device in the closed-loop take back system.

2) *De-installation*: Used medical devices are de-installed by qualified personnel at the customer site in a non-destructive manner and are then shipped to the refurbishment facility. In this step the used medical devices are still in a working condition. To prevent damage during shipment, the refurbisher must make sure that the original manufacturer instructions and packing materials are used.

3) *Refurbishment*: During the refurbishment process, according to IEC 63077 all actions are performed in a manner consistent with product specifications and service procedures defined by the manufacturer. All steps in the process are performed by trained experts using original manufacturer's specifications. The refurbishment process is thorough and well documented. The safety and quality test are the same test as for a new medical imaging device. As part of this process, the refurbisher has to make sure that all safety-relevant updates that were issued during the time since the product's original shipment are installed. OEMs can update refurbished devices with the latest software versions. Medical imaging devices that are refurbished according to IEC PAS 63077 are labeled indicating when they have been refurbished. Putting the label close to the original label is requested by the standard.

4) *Installation*: For the installation of the refurbished product it is made sure that product customization, re-installation and training are done according to customer needs. The same start-up and performance checks as for any new device are performed.

5) *Warranty & After-sale service*: Just like with new devices, refurbished medical imaging devices come with a warranty period and after-sale service are made available in the country where the device is sold. Warranty time, spare party availability and service contracts depend on the offers by the OEMs.

8. What is IEC PAS 63077?

IEC PAS 63077 “Good refurbishment practices for medical imaging equipment” has been published by the International Electrotechnical Commission (IEC) in 2016. It describes and defines the process of refurbishment of used medical imaging devices to a condition of safety and effectiveness comparable to when new and without significantly changing the equipment’s performance, safety specification and/or intended use as in its original registration.

In January 2018 it has been accepted within IEC to further develop IEC PAS 63077 into IEC 63077. IEC 63077 will be an international standard.

9. Where did the idea to have “Good refurbishment practices for medical imaging equipment come from and how did you arrive to have IEC PAS 63077?

In 2007, COCIR published its first Green Paper on the principle of “Good Refurbishment Practices”, followed by a “Good Refurbishment Practices Industry Standard” document in 2009. In 2009, the industry associations COCIR (EU), JIRA (Japan), and MITA (USA) released a joint “Good Refurbishment Practice” Green Paper filling a need in the global healthcare market for safe and effective refurbished medical equipment.

In 2010, this activity further resulted in the transfer of the working group on “Good Refurbishment Practices” (GRP) at COCIR to the global medical imaging devices association DITTA. The feedback to the COCIR industry standard triggered the idea within the DITTA GRP working group to further develop an international standard on GRP. From 2014 to 2015 the DITTA GRP working group completely reworked the COCIR industry standard. With the support of DITTA, the US medical imaging and technology alliance MITA managed to develop and publish the out-come of this rework as NEMA / MITA 1-2015 standard in February 2016. At the same time, in 2016, DITTA released an updated Green Paper on the GRP. The Green paper describes how the standard might be applied.

In addition, DITTA (via MITA and ANSI, the American National Standards Institute) filed a request to the International Electrotechnical Commission (IEC) to publish the content of NEMA / MITA 1-2015 standard as an IEC PAS. A Publicly Available Specification (PAS) is a standardization document in a preliminary stage to an IEC standard. The objective of a PAS is to speed up the process of standardization. PASs are often produced in response to an urgent market need.

Later in 2016, IEC published IEC PAS 63077 – content wise identical to NEMA / MITA 1-2015. In 2017, DITTA (via MITA and ANSI) filed a request (a new work item proposal (NWIP)) to IEC to set up an IEC working Group on GRP to transfer the IEC PAS 63077 into the IEC 63077 standard. In January 2018, a positive vote was announced by the relevant committee at IEC to set up this working group and develop the PAS document into a full IEC 63077 standard. In October 2018, the so-called “committee draft for voting” (CDV) of IEC 63077 was submitted to IEC. The voting period for the CDV

will end on 8 March 2019. In case of a positive vote, the publication for IEC 63077 would be expected for summer 2019.

10. Which original equipment manufacturers refurbish medical imaging devices?

Original Equipment Manufacturers (OEMs) that refurbish medical imaging devices are for example Philips, GE (General Electric) Healthcare, and Canon Medical Systems Corporation which are all active at DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association.

By having the knowledge about the design and production of the medical imaging devices the OEMs are best positioned to also develop and implement refurbishment processes for their medical imaging devices to offer refurbished medical imaging devices to their customers.

11. How much cheaper is a refurbished medical imaging device on average?

Refurbished medical imaging devices can be offered at a lower price than the comparable new ones. It is difficult to give a general statement on the cost savings comparing the price of a new medical imaging device with a refurbished one. The cost savings vary depending on the product and its configurability, the refurbisher and the country. It can therefore range between 10% and 50% of a corresponding new device.

12. At what age does a medical imaging device usually gets refurbished?

Based on calculations by Siemens Healthineers, on average, a CT scanner is bought back to be refurbished after 7 years of clinical use; MRI systems are, on average, bought back to be refurbished after 9 to 10 years of clinical use. Philips experiences a similar term for Image Guided Therapy equipment.

This is when customers usually decide to buy a new medical imaging device. There are various triggers for customers to invest in a new medical imaging device, which vary for example depending on the customer segment (e.g., high-end research customers who are driven by innovation cycles) or regional conditions (e.g., age-dependent reimbursement regulations).

13. What is the product lifetime of a refurbished medical imaging device?

IEC PAS 63077 states the requirement for the refurbisher of having the competency and spare parts available for a refurbished medical imaging device. With a proper maintenance and available spare parts, a refurbished medical imaging device can have the same product life time as a new device. As for new medical imaging devices, a warranty condition and the availability of spare parts will be provided by the refurbisher.

14. What are the major markets for refurbished medical imaging devices?

In 2017, according to calculation by DITTA, refurbishment of medical imaging devices accounted for global revenue of approximately 980 million USD. The major markets for refurbished medical imaging devices are the USA (46%) and the European Union (24%). Other markets to which DITTA members regularly sell refurbished medical imaging devices are for example Japan, South Korea, Russia, Mexico and India. Those healthcare providers that decide to use refurbished medical imaging devices have been very happy to report that these devices provide the required image quality and, at the same time, offer substantial cost savings.

15. In which ASEAN countries are refurbished medical imaging devices sold?

In the ASEAN region sale is allowed in Malaysia, Singapore and the Philippines.

16. How are refurbished medical imaging devices regulated and tested in other markets, e.g. in the USA, the European Union and other Asian countries?

The DTTA GRP working group has prepared summary text for the following countries and regions: USA, Europe, Japan, Malaysia, Singapore, South Korea, Philippines.

In addition to these summary text, please also find a more comprehensive table as an annex to this dossier.

16.1 USA

In the United States, refurbished medical devices are permitted to be sold and placed on the market. As a general rule, a refurbished medical device, just as a new medical device, must possess a relevant premarket clearance or authorization in order to be placed on the market (e.g., 510(k) premarket notification for Class II or a Pre-Market Approval (PMA) for Class III).

Refurbished medical devices are also allowed to be imported into the United States, provided that the source site is registered with the FDA as "Foreign Exporter."

The FDA does not define the term refurbishment and refurbishment is deemed a servicing activity.

16.2 Europe

Medical devices - both new and refurbished are regulated by the EU Medical Device Directive (MDD) (93/42/ECC). From on May 2020 the EU Medical Device Regulation (MDR) 2017/745 will be applicable for new and refurbished medical devices. Neither the Medical Device Directive (MDD), nor the Medical Device Regulation (MDR), define refurbishment. MDR's definition on 'fully refurbishing', means the complete rebuilding of a device or the making of a new device from used devices and is thus closer to the definition of remanufacturing. This is not equivalent how refurbishment is defined in IEC PAS 63077. There are no country specific regulations for refurbished medical devices. Medical devices, new and refurbished, in general need to comply to the EU laws and regulations that are applicable at the time they are placed onto the EU market.

16.3 Japan

The import of refurbished medical devices including their spare parts is permitted in case the refurbishment is performed in the facilities which meet JGMP-QMS requirements and shipped from original manufacturer of the original product.

Japanese regulations do not include a specific definition regarding refurbishment. Refurbished medical devices are regarded as a part of used medical devices. New medical devices, used medical devices and the repair of medical devices are regulated. The same requirements of new products are applied to used medical devices including refurbished devices (i.e. compliance to JIS T0601-1:2017).

16.4 Malaysia

The import of refurbished medical imaging devices is permitted with a valid registration certificate. There is a specific policy in place relating to the control of activities on refurbishment of medical devices. It has been outlined in the "Circular Letter of the Medical Device Authority No. 1 Year 2016". In the meanwhile the authorities require a pre-market approval with the technical dossier identical as a new device. In practice, it has been experiences that submission clearance times are very lengthy so far.

Refurbished medical devices require a similar type of registration dossier as a new medical device submission; in addition, the refurbisher must be able to demonstrate that they have followed the GRP process specified by Malaysia Medical Device Authority.

16.5 Singapore

There are no specific regulations on refurbishment. Import of refurbished medical imaging devices can only take place if the product is registered by Health Science Authority. There are no special requirements or restrictions regarding the import of refurbished medical imaging devices.

16.6 South Korea

Every refurbished medical imaging device imported to South Korea shall be tested by Medical Device Importer or Medical Device Manufacturer of the refurbished medical imaging device. If the Medical Device Importer or Medical Device Manufacturer cannot test the refurbished system, a 3rd party test lab may test.

16.7 Philippines

There is no specific regulation that targets refurbished medical imaging devices. However, Import Clearance must be obtained by fulfilling the requirements written in Bureau Order No. 020 s. 2007. In addition, a custom release clearance for all radiation emitting devices is needed.

17. What are the benefits for Vietnam of allowing the import and distribution of refurbished medical imaging devices?

By allowing the import of high quality refurbished medical imaging devices, Vietnam will make a step in the right direction of increased access to affordable and high-quality healthcare for Vietnamese citizens. Refurbished medical imaging devices can be purchased at a lower price than the comparable new ones. In current times of constrained budgets, refurbished medical imaging devices can help Vietnamese hospitals and medical centers with budget restrictions to purchase high-quality devices and replace their used devices or expand their capacity. It is difficult to give a general statement on the cost savings comparing the price of a new medical imaging device with a refurbished one. The cost savings vary depending on the product and its configurability, the refurbisher and the country. It can therefore range between 10% and 50% of a corresponding new device.

By replacing used, outdated devices with refurbished medical imaging devices, and expanding the capacity of hospitals with more affordable equipment, the overall quality of healthcare for Vietnamese patients can be improved, e.g. by providing better diagnosis, which allows for better therapy, increasing chance of survival and lowers the overall costs for the complete care pathway. Safety and effectiveness are the most important aspects to consider with medical imaging devices, including refurbished medical imaging devices.