



IAMERS

INTERNATIONAL ASSOCIATION
OF MEDICAL EQUIPMENT
REMARKETERS & SERVICERS

ETHICS • PROFESSIONALISM • SERVICE

Responsible Handling of Pre-owned Medical Diagnostic Imaging Equipment

**labeling, sales, transfer, refurbishment, and maintenance
of diagnostic imaging equipment into secondary markets**

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Forward

Today, across the world the rising cost of health care is a major problem. Providing proper and reasonable access to health care is expensive and for most countries the cost of health care is spiraling out of control. Technology and its rapid advance are often blamed for the increasing expense associated with the provision of health care services. We believe if managed properly available technology can be cost effectively implemented and managed to support the application of cost effective health care for all. This White Paper will provide a view to the cost effective implementation and management of clinically effective and affordable technology application in the fastest growing segment of health care, medical imaging.

Medical Imaging is the key to our modern health care system of diagnosis and treatment management. Over the past decade the use of medical imaging has advanced and we have witnessed double digit annual increases in its use by physicians seeking non-invasive diagnostic and therapy management information.

Medical Imaging technology takes many forms and all of it requires capital to acquire, maintain and operate. These costs have been rising with the introduction of new equipment bringing more and more features. Although new equipment with new features can be attractive, we believe that there is a diminishing return on the investment after reaching a certain level of performance. To manage the escalation of health care services will require that we manage better the global asset of available medical imaging equipment. Making the best use of this equipment will prove a benefit to patients and providers alike.

We are IAMERS, The International Association of Medical Equipment Remarketers and Servicers. In this White Paper we will detail a program that makes the best use of available medical imaging technology, does so in a safe and clinically efficacious manner and helps mediate the escalation of health care costs caused by medical imaging while making it affordable to expand the availability of imaging services to more people needing the diagnostic services.

Since 1993 the safe, cost effective and ethical supply of pre-owned medical imaging equipment for use around the world has been a top priority of IAMERS members. IAMERS is currently made up of 150 member companies located around the globe. IAMERS members sell X-ray, CT, MRI, Ultrasound, Nuclear, PET and Mammography and all forms of medical imaging equipment. Our members are remanufacturers, refurbishers, brokers, independent service organizations, original equipment manufacturers, financiers and transporters of pre-owned medical imaging equipment.

Not all companies dealing in pre-owned medical equipment choose to join IAMERS and not all qualify for membership. To become a member of IAMERS and display the IAMERS seal on your business you must first meet certain business standards of ethical operation for consideration as a member. Once qualified for membership you must agree to be bound by a code of ethics and fair dealing.

IAMERS members are the best and most experienced providers of pre-owned medical imaging instrumentation and services in the world. The placement of thousands of pieces of cost effective, clinically appropriate, high quality and safe pre-owned medical imaging equipment by our members over the past 16 years puts us in a unique position to comment on and propose avenues that provide the broadest availability to medical imaging resources in the most cost effective way.

In the past year there has been a lobbying effort to increase regulation, and/or industry guidelines, on the sale and ultimately the use of pre-owned medical imaging equipment. This effort has taken the position that there is a need to improve the delivery of pre-owned medical imaging devices by adopting new quality standards for delivery, service and personnel. In addition the introduction of technology at its current pace is said to be reason for shortening the useful life of instrumentation being used in the field. IAMERS at its very core stands for high quality delivery of instrumentation and business practices. However, to add standards that effectively remove useful and capable equipment from the market when the cost of health care is increasing uncontrollably seems foolhardy and potentially life-threatening to those in need of affordable imaging services.

IAMERS would like buyers and sellers to know:

- IAMERS members support quality practices and implement them within their businesses.
- IAMERS members offer reliable, safe and cost effective pre-owned diagnostic medical imaging instrumentation.
- IAMERS members are able to successfully sell and provide service for pre-owned medical imaging equipment.

IAMERS also wishes for the medical imaging device marketplace to know that in a world of economic fluctuations and year-to-year double digit growth of health care costs that the sale and purchase of pre-owned medical imaging devices results in:

- Necessary cost containment when IAMERS members offer safe and clinically efficacious pre-owned equipment and service options.
- Proper recycling of medical imaging devices that can and are used for many years in primary, secondary and tertiary hospitals and clinics.
- The extension of the clinical and physical useful life of the equipment, contributing to the availability of important clinical imaging services where there may have been none because of the cost of newer equipment.

IAMERS wishes to address certain statements made in the marketplace about the usefulness, efficacy of the equipment and the companies that provide the pre-owned medical imaging devices:

In the past some lobbyists have stated that there has been recent “regional dumping” of equipment in parts of the world. Statements of this type are unfortunate and not supportive of the end user market or of the small businesses that serve them with cost effective, safe and clinically efficacious pre-owned medical devices. IAMERS is

unaware of any such “dumping” of equipment. The FDA has stated, in substance, that there were no recent records from the refurbished marketplace of adverse events.

Imposing unnecessary regulations will most certainly cause an escalation in the cost of medical imaging which in turn will contribute to the further escalation of health care cost. Should such regulations be implemented, reducing the number and type of pre-owned imaging equipment it is clear that access to quality health care will be limited in those areas where capital budgets are not available for the sale of new capital equipment.

IAMERS members and their customers welcome any new regulations that truly advance the availability of useful and safe instrumentation. However, regulations that do nothing to advance the availability of cost effective health care are considered counter productive and valueless by IAMERS members.

For many years IAMERS members have struggled installing and upgrading equipment as access has been routinely restricted to the very software, documentation and other information that would result in the best possible installation and use of the pre-owned medical imaging device. IAMERS welcomes a cooperative effort that allows all buyers of pre-owned equipment to be able to have the latest and best upgrades and performance for the equipment they purchase and use in local markets. Restrictions on such information about proper handling, upgrades, recalls and other such quality information should be made available to refurbishers, remanufacturers, and end users too; as a way to determine if the equipment they are buying or already possess is going to perform at the latest release as specified by the OEM.

In this White Paper you’ll learn about IAMERS, its members, the marketplace we serve and how important we are to the delivery of safe, cost effective and clinically efficacious medical imaging technology to those end users where new is not an option due to the economy or other capital restrictions. IAMERS members serve the medical imaging market and are important contributors to a solution that will slow the present health care inflation, and expand healthcare utilization.

Respectfully,



Diana Upton
President
IAMERS

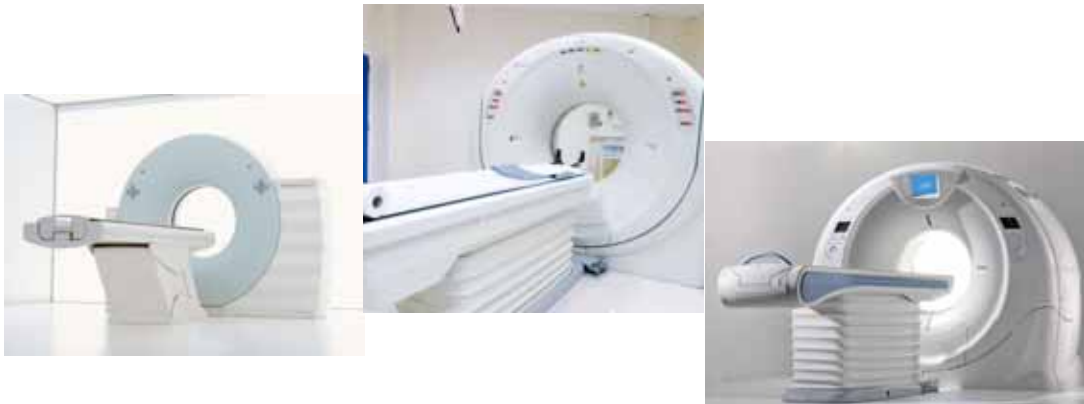
Overview: Medical Equipment/Care Costs Are Exploding

Over the past decade the pace of technology introduction for medical imaging instrumentation has been faster than in any other time. All areas of imaging from acquisition to display have been affected.

These major changes in technology have not been without cost for the hospital/radiology buyer's of this equipment. As technology has advanced the cost of acquisition has advanced as well. Today a new CT or MRI scanner offered by an original equipment manufacturer (OEM) can cost well in excess of \$1 million. These high capital equipment costs have had a self-limiting effect on the acquisition by hospitals and radiology clinics of new instrumentation and the expansion of diagnostic and therapeutic services to underserved areas. With limited budgets, the caregiver must decide whether the purchase of new equipment is cost effective.

With the expansion of the demand for diagnostic and therapeutic applications and the rising cost of new medical devices, pre-owned equipment is a way to bridge the gap between the expansion of medical services and the increasing cost of new instrumentation.

Suppliers of pre-owned medical imaging equipment must take care to ensure that they are serving their customers in an ethical and professional manner as they provide and service high quality medical imaging devices. IAMERS continues today with the purpose of delivering quality equipment and services through member education, end user education and an enforceable code of ethics and professionalism.



Who Belongs to IAMERS?

IAMERS, the *International Association of Medical Equipment Remarketers and Services*, was formed in 1993 by industry leaders with the goal of building a non-profit organization in which members, buyers and sellers of pre-owned medical imaging devices, could be distinguished from others by their professionalism and business ethics

requirements as administered by the group. As a condition to continued membership, IAMERS holds all members to these high standards of ethics and professionalism, with a written Code of Ethics. All members must agree to the Code in order to join IAMERS.

IAMERS is an international trade association whose members largely include sellers and servicers of pre-owned medical diagnostic imaging equipment. It is the only organization of its type, worldwide. IAMERS member companies have extensive experience serving a very important segment of the clinical diagnostic and therapy marketplace. Without IAMERS members bringing quality, safe and clinically efficacious pre-owned medical imaging equipment to providers of diagnostic and therapy services, significant segments of the medical imaging market would be underserved because the cost of new equipment would be out of reach of available capital funds.

IAMERS acts as a liaison to various government agencies for its members. The organization works to stay abreast of changing regulations and to support the regulators as they learn about the value of pre-owned medical imaging equipment and the important place this equipment fills throughout the world.

IAMERS interacts regularly with the United States Food and Drug Administration (FDA), the United States Department of Commerce, and other agencies here and abroad. The information gathered is transferred to its members so they can be current with industry changes and the latest thinking for the delivery of the best medical imaging devices. IAMERS provides ongoing educational programs for its members and it performs a public relations service as it educates suppliers and the end user marketplace in the importance of pre-owned medical imaging devices to the delivery of quality health care and the control of escalating health care costs.

In early 1997, IAMERS participated in the AAMI/FDA task force for the purpose of developing guiding principles for the sale of pre-owned equipment and was recognized for its contribution to the responsible sale of pre-owned medical equipment.

IAMERS members represent the major vendors and small businesses refurbishing, marketing and servicing pre-owned medical imaging equipment. Often these businesses are former employees of the OEMs. They bring their training and experience learned while at the OEM; adding entrepreneurship to better serve another aspect of the market. The OEMs continue to rely upon IAMERS members for expertise in installation, servicing, and deinstallation. IAMERS members continue to enjoy a productive relationship with their industry partners.

IAMERS members are experienced companies making substantial contribution to the pre-owned medical imaging marketplace ensuring the availability of safe, quality, cost effective medical imaging devices.

Why Does IAMERS Circulate this Position Paper?

Some claims have been made within the industry as to the alleged recent “major dumping” of pre-owned equipment in various regional markets. IAMERS believes such claims have no basis in fact and are self-serving. Such claims serve only to frighten buyers and sellers of pre-owned diagnostic imaging equipment and suggest that purchasing used equipment is unsafe.

Some speculate that the claims are being made to achieve certain competitive advantages and to cause hospitals or other potential purchasers to refrain from doing business with sellers of pre-owned equipment. Others believe that these claims are being made to encourage further regulation of pre-owned medical equipment, the byproduct of which will result in the attrition of small businesses and the limitation of available sellers to only the largest competitors, the original equipment manufacturers.

IAMERS has no knowledge of the “recent dumping” of pre-owned equipment and does not believe that this occurred. IAMERS believe that further industry guidelines proposed as a response to the non-existent “dumping” of pre-owned medical equipment are without merit and may serve to limit the companies available to refurbish and market and service pre-owned devices thus limiting their availability in markets where the available budget for equipment is unable to meet the capital demands of new equipment. IAMERS further believes by implementing such regulations and reducing the availability of safe and cost-effective equipment will further contribute to health care inflation.

Budget constraints within the industry prevent many who serve large populations in many world markets from purchasing new equipment. With the use of well-maintained pre-owned equipment, patient needs can be addressed without unnecessary expense. For certain market segments, pre-owned may be the only way to deliver such diagnostic imaging procedures in a cost-effective manner.

To keep this equipment available and at the highest level of performance IAMERS seeks to encourage sharing of manuals, upgrades, software keys and passwords.

IAMERS believes through proper guidelines, and adherence to existing standards the industry can, and does, police itself without the wholesale adoption of new regulations.

IAMERS believes safe, high-quality pre-owned equipment can be purchased without additional regulations; and without restricting buyer choices to new equipment only. Pre-owned affordable medical imaging equipment helps halt health care inflation and makes available patient services which would not be available at the cost of new equipment or used equipment if provided by the OEM only.

Defining the IAMERS Member – Industry Participants

IAMERS members include OEMs, lessors, sellers, servicers, and brokers of pre-owned diagnostic imaging equipment. While all IAMERS members are involved in pre-owned diagnostic imaging equipment, their business description varies, as noted.

- OEM
- Broker
- Parts distributor
- Refurbisher
- Remanufacturer
- Install/Deinstall provider
- Service provider (ISO)
- Shared service provider
- Financial institution
- Shipping company
- Insurance provider
- Consultant
- Buyer



Since its inception sixteen (16) years ago, IAMERS has sought to promote the ethical, safe and cost effective sale of refurbished medical imaging equipment. IAMERS has been engaged in a continuous conversation with its members, the industry, regulatory bodies and end-users on how best to achieve these goals. As a result of the efforts of IAMERS, and other industry proponents, there have been no adverse events reported concerning the misuse of refurbished medical equipment devices in recent years.

Existing Standards within the Industry

There are many rigorous industry standards in existence within our industry. If the seller is a remanufacturer, the equipment status is often guided by such standards as ISO¹ and GMP which cover the full range of remanufacturing. Within the US those companies that remanufacture are registered with the FDA. Adoption of additional standards above and beyond those all ready in place is redundant and just adds to the cost of providing the equipment. These costs are passed on to the people least able to afford them.

There is a distinction between remanufactured and refurbished. Remanufactured devices may have a different intended use. Refurbished devices are most likely applied in the same specialty and over time are upgraded to meet current OEM specifications for that device.

In an effort to educate its members and the purchasers of pre-owned medical imaging devices IAMERS recommends to its members, the labeling of equipment based on the following descriptions.

As Is, Where Is

“*As is, where is*” systems are unchanged.

Refurbished

Refurbished systems retain their original identity and are essentially repaired and/or upgraded in a manner which could be achieved by field service personnel or in a facility capable of such repairs or upgrades. Refurbished systems include those systems which have received software upgrades or basic improvements consistent with the life cycle of the product. The system complies with the original level of function and at least meets the original OEM specified specifications; or the OEM specified path of upgrades. This is consistent with the extended life cycle as proposed by the OEM.

Cosmetically Enhanced

System is basically *as is, where is*; but has been painted and/or cosmetically improved. No repairs or upgrades have been done.

Remanufactured

Remanufactured systems would be newly built systems using rebuilt, repaired or new parts which allow the system to perform substantially different than the original system.

This category will rarely, apply to IAMERS members and their equipment. When applicable, the IAMERS member would have a remanufacturing registration in place. In such a case, they would already label their equipment. Labeling requirements of those with an existing remanufacturing registration would already be addressed.

¹ **About ISO** - ISO (International Organization for Standardization) is the world's largest developer and publisher of International Standards. ISO is a network of the national standards institutes of 157 countries, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system.

ISO is a non-governmental organization that forms a bridge between the public and private sectors. On the one hand, many of its member institutes are part of the governmental structure of their countries, or are mandated by their government. On the other hand, other members have their roots uniquely in the private sector, having been set up by national partnerships of industry associations.



IAMERS works with many regulatory agencies so its members can quickly adapt to and implement new regulations. One such regulation was implemented in 2007. The US Food and Drug Administration Amendments Act of 2007 as enacted requires the establishment of a Unique Device Identification System for all medical imaging devices.

Unique Device Identification (UDI)

This new system when implemented may require:

- the label of a device to bear a unique identifier, unless an alternative location is specified by FDA or unless an exception is made for a particular device or group of devices
- the unique identifier to identify the device through distribution and use
- the unique identifier to include the lot or serial number if specified by FDA

It is anticipated this new regulation will go into effect in 2010.

A UDI should not be confused with a serial number. IAMERS believes it to be more like the VIN number in a car. Further, IAMERS believes the requirement is the precursor to a post-market surveillance program.

A UDI must logically start with the OEM at the point of manufacture.



A Unique Repository for UDI Transference

Like so many new regulations the regulating agency sets the tone for the regulation but is not always ready to provide the detail that allows for the smooth implementation of the regulation. IAMERS is working closely with its members to find a way to implement this new regulation with its full intent while avoiding the issues that exist between competitors when customer information must be shared as required by a government agency.

IAMERS Proposal for Implementing UDI Regulation.

Software, or a web location, can be created so that a UDI can be monitored throughout the life of the equipment. While the OEM could be the repository for such information, as the equipment UDI logically starts with the OEM. However, sharing customer information with another company may be seen as less than optimal.

IAMERS could act as an independent holder of the site where the information relating to the ever changing UDI could be stored as the device is transferred from one owner to another or as it is altered by recalls, upgrades or other activity that would be reflected in the UDI.

IAMERS could provide a neutral pathway for the OEM's to obtain the contact information should a recall or other critical information need to be transmitted to the end user.

This unique website can be constructed such that confidential information regarding sellers and their customers does not have to be released beyond that required to inform the customer of the event.

Continuous registration of the UDI, which should remain the same throughout the life of the equipment, is the practical pathway to post-market surveillance.

Registering the UDI, and the location(s) of the equipment, throughout the life of the equipment does not have to be a difficult and complex process when implemented through a neutral third party.



Refurbishing & Maintaining Pre-owned Diagnostic Imaging Equipment

In the past year the industry tried to describe the condition pre-owned equipment should achieve to be considered useful, safe and efficacious. The term “As Good As When New” has been suggested. IAMERS and its members believe that this isn’t good enough. In fact as technology advances implementing the As Good As When New designator may result in providing an instrument that is less than others employed in the marketplace.

With the advance of technology these devices are routinely updated with new computers and various software applications to keep them current. Such upgrades and recalls are directly from the OEM. To make the medical imaging device As Good As When New will most likely result in a device that is not current and less useful to the end user.

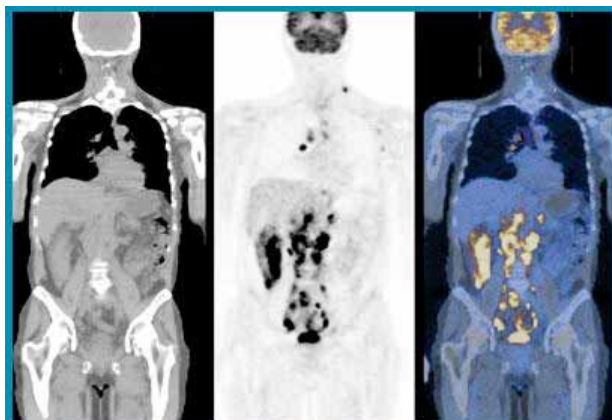
IAMERS proposes the implementation of a standard that has each device be “As Good as It Can be Today”.

IAMERS believes that what is needed to accomplish the goal of safe and effective marketing and installation of pre-owned equipment in “*as good as it can be today*” condition is to have available on-line or elsewhere to marketers and end-users all specifications, technical requirements, testing procedures, personnel training, special tools and procedures for the equipment so that it can be delivered in “*as good as it can be today*” condition.

IAMERS’ recommendations for refurbishment and proper installation include:

- OEM’s to provide full access to services, to all specifications, service requirements and details for testing, deinstallation, packing, installing, upgrading, descriptions of special tools, software keys, etc.
- OEM’s to make available all service records to the sellers and/or buyers of the equipment.

By providing this information to sellers and buyers alike the goal of high quality, cost effective and technically current equipment could be achieved. The seller would know what to provide, and how to do it; and the buyer could confirm that what was being delivered is of the latest OEM specification.



Buying Pre-owned Diagnostic Imaging Equipment can be the only financial option for many. It can make the difference in the delivery of adequate health care or none at all. The alternative to pre-owned equipment may be no equipment at all.

How can the buyer be secure in the purchase of pre-owned imaging equipment? What protection does the buyer have when buying pre-owned? Is the inspection of the equipment conducted by capable personnel? Can the buyer see service records? These are questions which must be answered. These issues should always be addressed in the Purchase Contract.

Elements of a Purchase Contract for the Sale of Pre-owned Equipment

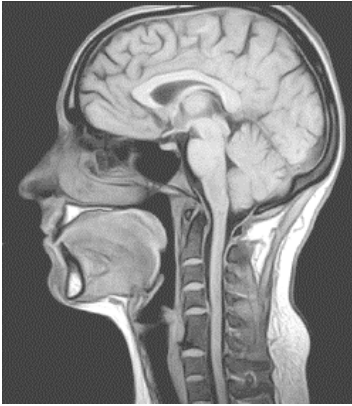
When buying pre-owned imaging equipment, buyers should insist on (and sellers should offer) the following safety mechanisms, fully integrated into the Purchase Contract.

- Inspection of the equipment, where appropriate. Inspection should be conducted by qualified personnel.
- Inspection of the service records pertaining to the equipment. The Purchase Contract should state how, and by whom, the equipment was serviced; and how often.
- Buyer should be able to speak with clinicians regarding the equipment.
- The qualified equipment inspector should be able to speak, if warranted, with the service personnel who worked on the equipment.
- Upgrades and major service events should be identified including when they took place. In some cases a complete description of the upgrade path may be warranted.
- Purchase Contracts should include definitions regarding the nature of the sale such as who is responsible for the deinstallation, who will reinstall the equipment, or was the purchase strictly “*As is, Where is*”.
- Purchase Contracts should indicate whether the equipment is being sold with a warranty.

Cost Containment Should Not Mean a Compromise in Quality.

The latest technology is not available to everyone. Yet, safe and effective technology is available in pre-owned diagnostic imaging equipment. Quality diagnostic imaging procedures can be achieved through pre-owned equipment.





Conclusions

- Pre-owned diagnostic imaging equipment is safe and reliable, if properly maintained.
- IAMERS will continue to encourage the safe and reliable sale of pre-owned medical equipment.
- IAMERS will continue to encourage the ethical sale of medical equipment. IAMERS' Ethics Code continues to be relevant today.
- There is no present need for an international accreditation body which would enforce audits, periodic inspections, and other cost layers upon medical equipment refurbishment. Ample state and federal regulatory authorities already exist to ensure quality sales.
- The encouragement of international accreditation organizations and further regulation will only drive up health care costs, not diminish them.
- Health care equipment is not the sole province of large manufacturers. Small businesses can and should prosper in the medical device industry.
- Defining the equipment within the buyer/seller contract adds clarity. The buyer should always clearly understand what they are buying.
- Remanufactured equipment is not the same as refurbished equipment.
- Brokers provide a necessary link for many customers. Brokers are not refurbishers or remanufacturers, and should not be held to the same standards.
- Access to software and service information provides for better understanding of the specific equipment.
- A universal portal for UDI's can be made possible without compromising confidential information.
- Buying pre-owned diagnostic imaging equipment may be the only option for some budgets.
- Cost containment should not mean a compromise in quality.

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