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Generic Safety Directions for Agfa HealthCare Imaging Products

► Purpose of this Document

This Generic Safety Directions document comprises the general safety relevant information including relevant environmental and occupational safety instructions for the Service Engineer.

It is valid for all Agfa HealthCare Imaging Products.

► Document History

Edition. Revision	Release Date	Changes compared to previous Version 1.5:
1.6	03-2016	• Updated the list of used icons. Refer to section 2. • Added safety note for modifications. Refer to section 22. • Extended instructions for Protected Health Information (PHI) and security information. Refer to section 26.

► Referenced Documents

Document	Title
Not applicable	Not applicable

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► Manufacturer

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WARNING:

Improper operation or service activities may cause damage or injuries.

(1) Read the "Generic Safety Directions" prior to attempting any operation, repair or maintenance task on the equipment.
Refer to Document ID 11849633.

(2) Strictly observe all safety directions within the "Generic Safety Directions" and on the product.

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1 Disclaimer

The installation and service of equipment described herein is to be performed by qualified personnel who are employed by Agfa HealthCare or one of its affiliates or who are otherwise authorized by Agfa HealthCare or one of its affiliates to provide such services.

Fitters, engineers and other persons who are not employed by or otherwise directly affiliated with or authorized by Agfa HealthCare or one of its affiliates are directed to contact one of the local offices of Agfa HealthCare or one of its affiliates before attempting installation or service procedures.

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Agfa HealthCare makes no warranties or representation, expressed or implied, with respect to the accuracy, completeness or usefulness of the information contained in this document and specifically disclaims warranties of suitability for any particular purpose.

Agfa HealthCare shall under no circumstances be liable for any damage arising from the use or inability to use any information, apparatus, method or process disclosed in this document.

Agfa HealthCare is not liable for resulting consequences, damages or injuries if you don't operate the product correctly or if you don't have it serviced correctly.

Agfa HealthCare reserves the right to change the product, the characteristics and its documentation without further notice to improve reliability, function or design.

NOTE:

In the United States, Federal Law stipulates that medical devices should only be sold to, distributed and used by or by order of a licensed physician.

2 Used Icons

Icon	Signal Word and Situation
	**CAUTION**: Hazardous situation which, if not avoided can lead to a minor injury to a user, engineer, patient or any other person.
	**WARNING**: Hazardous situation which, if not avoided, can lead to a potential serious injury to a user, engineer, patient or any other person.
	**DANGER**: Direct, immediate danger: If not avoided, it can lead to a serious injury to a user, engineer, patient or any other person
	Instruction to avoid damage to equipment and/or environmental pollution.
	Prohibition to avoid damage to equipment and/or environmental pollution.
	IMPORTANT: Highlights very important actions which have to be carried out to prevent malfunction.
	NOTE: • Indicates advice to facilitate the following step or action without having a direct influence on the step or action. • Highlights unusual points. • Indicates background information. • Can be used to explain or highlight displays of the graphical user interface.

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3 Labels

3.1 CE Mark

CE Mark 	This product carries the CE Mark. The CE Declaration (CE Conformity) becomes invalid if the product is changed without explicit consent of the manufacturer! This applies to all parts, not only to safety elements.

3.2 Labels

For the meaning of the labels in and on the product refer to:

- The corresponding product or system User Manuals and
- The figure below, with a list of possible service activity related labels and their meaning. To prevent injuries or damage to the equipment, follow the instructions on the label or the related service instructions.

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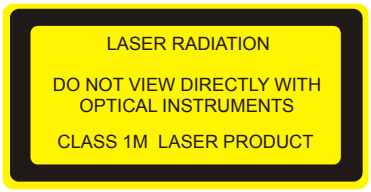
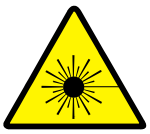
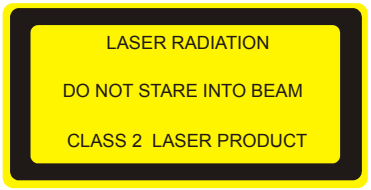
3.3 Labels concerning Laser Radiation

According to its classification, laser radiation can lead to eye and skin injuries. Each laser source is classified from class 1 to class 4, based on standard DIN EN 60825-1:2007.

The table below lists the meaning of the different laser classes. Note the detailed instructions in the user manual and technical documentation.

Class #	Meaning	Example Label
Class 1:	Not dangerous to the human eye, even when using optical instruments. Can nevertheless produce irritating effects, especially with low ambient light conditions.	
Class 1 M:	Not dangerous to the human eye if no optical instruments (magnifying glass or binocular) are used. Can nevertheless produce irritating effects, especially with low ambient light conditions.	
Class 2:	Dangerous to the human eye for intentional staring into the beam. Not dangerous for short term exposure < 0,25 seconds. Using optical instruments does not increase the risk of eye injury. Can even for short term exposure < 0,25 seconds produce dazzling and irritating effects, especially with low ambient light conditions.	 

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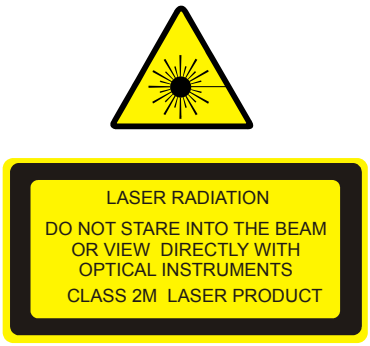
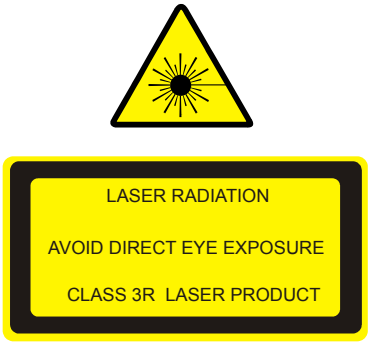
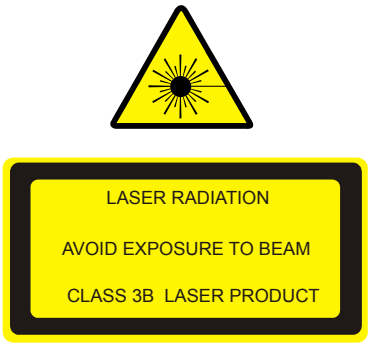
Class #	Meaning	Example Label
Class 2M:	Dangerous to the human eye when staring into the beam or when using optical instruments (magnifying glass or telescope). No hazard for short term exposure < 0,25 seconds (aversion response of the eye) without use of optical instruments. Can produce dazzling and irritating effects even for short term exposure < 0,25 seconds, especially at low ambient light conditions.	
Class 3R:	Possibly dangerous to the human eye for direct view into the beam. Risks of an eye injury is increasing with duration of exposure. Can produce dazzling and irritating effects, especially with low ambient light conditions.	
Class 3B:	Normally dangerous to the human eye for direct view into the beam. Viewing diffuse reflections is normally not dangerous. Risk of small skin injuries or ignition of explosive material if the power of the laser beam is close to the upper limits of class 3 B.	
Class 4:	Dangerous to the human eye for direct view into the beam or viewing diffuse reflections. Very often class 4 lasers also implicate a fire hazard.	

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4 Product Complaints

Any service person who has any complaints or has experienced any dissatisfaction in the quality, durability, reliability, safety, effectiveness or performance of this product must notify Agfa HealthCare by the Agfa HealthCare complaint procedure.
If the product malfunctions and may have caused or contributed to a serious injury of a patient or an accident or if there are any hazards which may cause an accident, Agfa HealthCare must be notified immediately by telephone, fax or written correspondence to the following address:
Agfa Service Support - local support addresses and phone numbers listed on:
www.agfa.com

As an alternative, contact the Corporate Communication Department:

Agfa-Gevaert N.V.
Septestraat 27
2640 Mortsel, Belgium.
Fax +32 3 444 4485

5 References

Technical Documentation is available via Agfa HealthCare Library and your local Agfa HealthCare support organization.

Access to the Agfa HealthCare Library:

https://healthcare.agfa.net/irj/portal/library

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6 Intended Use

This Agfa HealthCare product should only be operated in a hospital or clinical radiological environment by qualified staff.

It must only be operated according to its specifications and its intended use. Any operation not corresponding to the specifications or intended use may result in hazards, which in turn may lead to serious injuries or fatal accidents (for example electric shocks). AGFA will not assume any liability whatsoever in these cases.

Make sure that the product is constantly monitored in order to avoid inappropriate handling, especially by children.

The product must only be installed and put into operation under the specified conditions.

The intended use statement of the product or system is listed in the User Manual of the product or system.

7 Intended User

This manual is written for Agfa trained Field Service Engineers and Clinical Application Specialists, trained users of Agfa HealthCare products and trained diagnostic X–Ray clinical personnel who have received proper training. Users are considered as the persons who handle the equipment as well as the persons having authority over the equipment.

8 Qualifications for Operation and Service Tasks

This technical documentation describes adjustments and routines which must only to be performed by qualified technical personnel.

The Agfa (trained) Field Service Engineers and Clinical Application Specialists must have received adequate Agfa HealthCare training on the safe and effective use of the product and applicable environmental and occupational safety matters before attempting to work with it. Training requirements may vary from country to country.

Agfa trained Field Service Engineers and Clinical Application Specialists must make sure that training is received in accordance with local laws or regulations that have the force of law.

Your local Agfa HealthCare representative can provide further information on training.

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9 Environmental and occupational Safety Instructions

Each Agfa trained Field Service Engineer and Clinical Application Specialist:

- Must make his or her personal contribution to improve safety and protect the environment.
- When working on a customers site, has a duty to take reasonable care to avoid injury to himself or herself or to others who may be affected by their acts or omissions.
- Is obligated to adhere strictly to regulations and instructions.
- Shall familiarize himself or herself with the provisions of the Agfa Healthcare Health, Safety and Environment Policy and any specific rules or procedures relating to occupational safety at work and the protection of the environment.
- Shall promptly report any near misses, accidents, incidents or dangerous occurrences to their line manager and co-operate fully in any investigation.
- Shall co-operate with company management on matters relating to health, safety and environment and, where appropriate, discuss with and / or assist their manager in resolving matters relating to health, safety and environment.
- Shall ensure that any company equipment issued to them, or, for which they are responsible, is correctly used and properly maintained.
- Shall wear protective equipment whenever instructed or if it is recommended to do so.
- Shall be responsible for good housekeeping in the area in which he or she is working.
- Shall report situations, which could put them at risk, on either company or customers' premises, to their manager or supervisor; and, if warranted, directly and in confidence, to the Health and Safety Coordinator, Global HSE* Manager, or ultimately to the Managing Director.
  * **H**ealth, **S**afety and **E**nvironment
- Shall report any injuries, diseases or dangerous occurrences to his or her line manager.
- Shall report any accidents, incidents or near misses to his or her line manager.
- Shall report any situation of which he or she is aware that is potentially dangerous.
- Shall comply with any health surveillance procedure instituted for his or her benefit or for compliance with regulations.

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10 Connections to other Equipment

Agfa HealthCare equipment must only be used in combination with other Agfa HealthCare equipment or components if these are expressly recognized by Agfa HealthCare as compatible. A list of such equipment and components is available from Agfa HealthCare service on request.

Changes or additions to the equipment must only be carried out by persons authorized to do so by Agfa HealthCare. Such changes must comply with best engineering practice and all applicable laws and regulations that have the force of law within the jurisdiction of the hospital.

Connections to other equipment:

WARNING:

Accessory equipment not complying with the safety requirements of this product may lead to a safety hazard.

Consult the technical documentation before making any connections to other equipment.

Consideration relating to the choice of accessory equipment shall include:

- Use of the accessory equipment in the patient vicinity.
- Evidence that the safety certification of the accessory equipment has been performed in accordance with the appropriate IEC 60601-1 and IEC 60601-1-1 harmonized national standard.

In addition all configurations must comply with the medical electrical systems standard IEC 60601-1-1. The party that makes the connections acts as system configurer and is responsible for complying with the systems standard.

If required, contact your local service organization.

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11 Accessories and Spare Parts

Parts and accessories replacement:

WARNING:

Hazards may be introduced because of component failure or improper operation.

- Replace defective parts with Agfa HealthCare original spare parts.
- Use only tools and measuring instruments which are suitable for the procedure.
- Only approved Agfa HealthCare accessories must be used. For a list of compatible accessories contact your local Agfa HealthCare organization or www.agfa.com.

12 Compliance

Directive for HealthCare Imaging Products:
Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
(OJ No L 169/1 of 1993-07-12)

- ANNEX I - ESSENTIAL REQUIREMENTS - GENERAL REQUIREMENTS The products are designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users.

- ANNEX II - EC DECLARATION OF CONFORMITY: Full quality assurance system ISO 13485

- ANNEX X - CLINICAL EVALUATION: The clinical evaluation follows a defined and methodologically sound procedure.

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Applied standards for Agfa HealthCare Imaging medical electrical equipment:

NOTE:

Equipment delivered by Agfa HealthCare is not necessarily classified as medical electrical equipment. For details refer to the related user and /or service manual.

- IEC 60601-1, Ed. 3: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ISO 14971:2000, Medical devices – Application of risk management to medical devices
- IEC 60601-1-2, It specifies the manufacturer of the ME (**M**edical **E**lectrical) equipment or ME system provides information to the responsible organization that is essential in determining the suitability of the ME equipment or ME system for the electromagnetic environment of use, and in managing the electromagnetic environment of use to permit the ME equipment or ME system to maintain basic safety and provide its essential performance without disturbing other equipment.

Additional standards for documentation:

IEC 82079 Ed. 1: Preparation of instructions for use - Structuring, content and presentation

Harmonization:

Global Harmonization Task Force (GHTF) http://www.imdrf.org

This document has been prepared to comply with Study Group 1 guidance document of the Global Harmonization Task Force (GHTF) to assist development of a consistent, harmonized definition for a medical device that could be used within a global regulatory model and would offer significant benefits to the manufacturer, user, patient or consumer, and to Regulatory Authorities and support global convergence of regulatory systems.

IECEE CB SCHEME:

The IECEE CB (Certification Body) Scheme is the world's first truly international system for acceptance of test reports dealing with the safety of electrical and electronic products. It is a multilateral agreement among participating countries and certification organizations. Agfa has produced a CB test report and claims national certification in all other member countries of the CB Scheme.

Details see: www.iecee.org

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Radiation of radio frequency:

CAUTION: For USA only:

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the service manual, may cause interference to radio communication.

NOTE:

This product has been tested and found to comply with the limits for a Class A computing device pursuant to Subpart B of Part 15 of FCC Rules, which are designed to provide reasonable protection against such interference when operated in a commercial environment.

Operation of this equipment in a residential area is likely to cause interference.

The user will be required to take all necessary measures to correct the interference at his own expense.

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13 Safety Directions for Operation

Accessibility of the mains power switch:

CAUTION:

Do not obstruct the mains power switch.

Position the Agfa HealthCare product so that it is possible to disconnect the mains power connection.

- Before operating the device or system e.g. for verification of an installation, repair or preventive maintenance activity, refer to the safety notes in the relevant user manual.
- Under certain conditions the Agfa HealthCare product will show a display containing a message. This message will show that either a problem or action has occurred or that a requested action is required or cannot be performed. The user must read these messages carefully. They will provide information on what to do. This will be either performing an action to resolve the problem or to contact the Agfa HealthCare service organization. Details on the contents of messages can be found in this technical documentation.
- All images created using any image technology can show artifacts which could be confused with diagnostic information. If there is any doubt that the diagnostic information could be corrupted, additional investigations must be performed to get clear diagnostic information.
- Ventilation openings must not be covered.
- If you notice conspicuous noise or smoke, disconnect the product immediately from the mains.
- Do not pour water or any other liquid over the device.
- If a system malfunction causes an emergency situation involving the patient, operating personnel or any system component, activate the emergency stop for the system concerned. All motor driven system movements will be stopped.
- Do not store any magnetic media near or on devices, which produce magnetic fields, since stored data may be lost.

Explosive environment:

DANGER:

Risk of explosion.

Never operate this device in zones where there are flammable anesthetics or oxygen which may cause an explosion.

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Usage of an un-interruptible power supply:

WARNING:

Images can be lost due to power failure.

Connect the equipment to an un-interruptible power supply (UPS) or an institutional standby generator.

14 Radiation Protection

Only qualified and authorized personnel shall operate any X-Ray system. In this context qualified means those legally permitted to operate this X-Ray equipment in the jurisdiction in which the X-Ray equipment is being used, and authorized means those authorized by the authority controlling the use of the X-Ray equipment. Full use must be made of all radiation protection features, devices, systems, procedures and accessories.

Ionizing radiation can lead to radiation injuries if handled incorrectly. When radiation is applied, the required protective measures must be complied with.

15 Safety Directions for Cleaning and Disinfection

DANGER:

Risk of explosion when using wrong cleaning agent.

Risk of electric shock when cleaning with power ON.

When the equipment is going to be cleaned, be sure to turn OFF the power of each device, and to unplug the power cord from the AC outlet.

Never use anhydrous or high solvency alcohols, benzine, thinner or any other flammable cleaning agent.

- For instructions about cleaning of the device or accessories, refer to the user manual.
- Details about cleaning and disinfection or sterilization methods that may be used on system parts or accessories that can become contaminated through contact with the patient or with body fluids, are referred to within the individual service or user documents.

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16 General Safety Directions for Service Activities

- This system uses high voltage. Consider the respective safety regulations.
- Electrical repairs and connections must only be performed by a qualified electrician.
- Mechanical repairs and connections must only be performed by a qualified technician.
- The safety directions for operation (see section 13) are also valid for all service activities.
- During all service activities observe prescribed local and country-specific requirements (e.g. occupational safety and accident prevention regulations).
- All existing screw connections must be tightened sufficiently firmly, but they may not be overstressed when tightening. There must always be compliance with stated torque values!
- Damaged or missing screws may be replaced only with the same screw types that have the specified hardness rating. Unless a different value is listed in the instructions, all screws used must be hardness rated 8.8.
- All screws must be secured in accordance with the corresponding data.
  If "Loctite" has to be used to secure screws, this is stated in the instructions.
- Any Agfa service PC or tool which is to be connected via RS232, RJ45, USB or other interface to an Agfa device must not be connected to the mains but must be operated on its internal battery or indirect supply (low voltage).

- When handling printed circuit boards (abbr.: PCBs) the following points must be observed:
  - Always switch off the equipment and unplug the power cord, before you disconnect or connect cables on printed circuit boards.
  - When working on PCBs, always wear an anti-static wrist strap. Never touch any parts or components on PCBs with your bare fingers.
  - PCBs have to be kept or transported in their protection bags. Never carry a PCB without protection bag and walk on carpet or plastic floor covering (electrostatic charge).
  - Once the PCB is taken out of its protection bag, it has to be protected from electrostatic charge by a grounded mat.

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General safety note, in case of power ON and cover removed:

DANGER:

Risk of electric shock when working at the device with opened cover and power ON.

Only work at the powered device with opened cover for service purposes, if this is absolutely unavoidable.

Before working at the powered device with opened cover for service purposes,

- first identify the high voltage wires and connectors in the circuit diagram.
- if possible, cover high voltage wires and connectors with insulating material.
- greatest possible care must be taken, never to get in contact with high voltage wires or connectors.

General safety note to check tension before working at the powered-off device:

DANGER:

High voltage. Risk of electric shock.

Before working at the device with opened covers, perform following steps to ensure the device is de-energized:

- Switch off the power at the main power switch.
- Prevent that the device can be switched on by other persons. Example: Put a sign "Don't switch on" in local language to the main switch.
- Use an appropriate tester and confirm that the device is de-energized (0V!).
- Observe additional safety notes at the device and in the specific service documents.
- For devices with capacitors (e.g. X-Ray generator): Confirm by measuring the voltage at the capacitors, that the capacitors are discharged.
- For devices with batteries for power supply (e.g. mobile X-ray unit): Observe special safety notes in the related service manual.

Static discharge at electrical components:

CAUTION:

Static discharge! Electrical components may be destroyed:

For the repair on electrical components, wear a grounding strap (Order number: CM+9 9999 0830 0) around the wrist and connect the other end of this strap on a grounded conducting metal piece.

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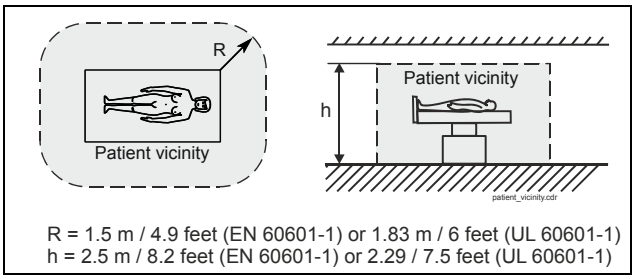
17 Safety Directions for Installation Planning Activities

Install equipment in the patient environment only, if it is classified as “Type B equipment”. Install all equipment outside the patient environment, which is not classified as “Type B equipment”. Refer to the specifications in the user manual of the system or product. For definition of the patient environment see dimensions in the figure below.



R = 1.5 m / 4.9 feet (EN 60601-1) or 1.83 m / 6 feet (UL 60601-1)
h = 2.5 m / 8.2 feet (EN 60601-1) or 2.29 / 7.5 feet (UL 60601-1)

Protecting CR (Computed Radiography) equipment against scattered X-Rays:

WARNING:

Image plate is sensitive for X-rays. Poor image quality possible.

The digitizer and the cassette storage shall be protected against X-ray radiation this way, that the annual dose equivalent at the installation place will not exceed 1 mSv.

Protecting Film-Screen Systems against scattered X-Rays:

WARNING:

Film is sensitive for X-rays. Poor image quality possible.

The film-screen system shall be protected against X-ray radiation this way, that the annual dose equivalent at the installation place will not exceed 1 mSv.

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Accessibility of the power disconnection device:

WARNING:

Electrical device. Shock possible.

- Do not position Agfa equipment so it is difficult to operate the disconnection device when an appliance coupler or separable plug is used as isolation.
- Local and International wiring regulations must be observed. Check all supplies and voltages, currents, trips and fuses with the Hospital facilities department or their engineers.

Fixing equipment at the wall or floor:

WARNING:

Unknown composition of wall or floor structure: Risk of injury or damage:

Hospital management is responsible for the position, location and fixing of all equipment.

Floor load:

CAUTION:

Heavy device may damage the floor covering.

Make sure that the floor covering is solid enough to stand the weight of the device.

Fixing equipment at the ceiling:

CAUTION:

Ceiling construction may be inadequate for fixing of equipment: Risk of injury or damage:

Hospital management is responsible for the position, location and fixing of all equipment.

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18 Safety Directions for Installation Activities

- If not otherwise stated, installation and configuration is performed by Agfa HealthCare trained personnel.
- If damage of the package is visible from the outside contact your local AGFA representative.
- Apart from wearing the required protective clothing, e.g. safety boots and gloves, care must be taken that heavy loads are correctly lifted and carried to avoid injury. The relevant instructions must be complied with. Heavy or awkward loads must be moved by mechanical means or by several people.
- When installing the product be sure that there is either a mains plug or an all-pole circuit breaker in the internal installation fitted near the product and that it is easily accessible.
- If the device has a supplementary protective earth connection: It is recommended to use the supplementary protective earth connection as additional safety measure.
- Defective covers, sharp edges or protruding parts of equipment can cause injuries, if accidentally knocked into. Route cables and position equipment safely.
- This device should be installed behind the institution firewall for network security and anti-virus protection. No ongoing computer virus protection or network security for this medical device is provided (e.g. a computer firewall). Network security and anti-virus provisions are the ongoing responsibility of the user or institution.
- In a system, combine released system components only. Refer to the compatibility information which is referred to from the relevant service manual.

Connection of the device to the power supply:

CAUTION:

Risk of damaging the device by using the wrong power supply.

Prior to connecting the device to the mains:

- Compare the power requirements indicated on the type label with the available power supply in the installation room.
- Check the service manual for the type of input voltage selection, manual or automatic: If manual, select the appropriate voltage and fuses.
- Confirm to use the correct socket and plug for the required power supply.
- Check the equipment will work with the power supply available.

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Ground potential differences:

CAUTION:

To comply with ISO 60601-1 (annex I) all computers and peripherals must be connected to the same power source.

- Always connect the associated monitor to the same uninterruptible power source as the PC.
- When different combinations of equipment are used in various medical environments a potential difference (V) can exist between the protective earths in different localities. If the protective earthing fails this potential difference can cause a hazard for the operator or for the patient.

Performing the electrical test according to national regulations before putting the equipment into service:

WARNING:

Improper ground connections or too high leakage current may lead to electric shocks.

- After installation, before putting the equipment into service, inform the responsible organization* about the necessity of the electrical test according to national regulations.
  If specific national regulations do not exist: It is recommended to perform the electrical test according to IEC 62353.
- Make sure, that all grounding connections are present.

*Responsible Organization:
Entity accountable for the use and maintenance of a medical equipment or a medical equipment system. The accountable entity can be, for example, a hospital or an individual clinician.

NOTE:

Refer to the Agfa HealthCare Library for system specific IEC 62353 test documents.

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19 Safety Directions for Maintenance and Repair Activities

- This technical documentation identifies the parts on which preventive inspection and maintenance shall be performed by Agfa trained service personnel. For required preventive maintenance frequency refer to the technical documentation or contact local service management.
- In general the device has to be switched off during service activities. Exception: If the device is switched on to perform tests pay particular attention to any hazards due to moving and rotating parts. Avoid lose clothing or finger traps. Switch off the device immediately after the tests.
- Do not turn motors manually. If required, first disconnect the motor from the motor control board.
- Make sure that the power cord does not show any signs of damage.
- After repair work always check that the integrated safety features are not overridden or disconnected.
- If there is any visible damage to the machine casing do not hand-over the product to the customer. First repair the machine casing.

Replacing batteries:

WARNING:

Battery can explode, causing chemical burns.

- Check that batteries are inserted with correct polarity.
- Only use batteries of the same type or an equivalent type as specified by the manufacturer.
- Dispose of empty batteries in compliance with the specifications of the manufacturer.
- When removing batteries from the equipment take appropriate measures to avoid short circuit of the battery:
  Either use tape to cover the two poles of the battery or put the battery back in its original packing and secure the packing by tape.

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Performing the electrical test according to national regulations after repair work:

WARNING:

Improper ground connections or too high leakage current may lead to electric shocks.

- After any repair work which may influence electrical safety of the product, inform the responsible organization* about the necessity of the electrical test according to national regulations.
  If specific national regulations do not exist: It is recommended to perform the electrical test according to IEC 62353.
- Make sure, that all grounding connections are present.

*Responsible Organization:
Entity accountable for the use and maintenance of a medical equipment or a medical equipment system. The accountable entity can be, for example, a hospital or an individual clinician.

NOTE:
Refer to the Agfa HealthCare Library for system specific IEC 62353 test documents.

Performing service activities at devices emitting laser radiation:

WARNING:

Laser radiation. Eye injury possible.

- Strictly observe the warning notes in the service manual of devices emitting laser radiation (See service manual chapter describing Safety Guidelines / General Repair Instructions) and at the corresponding steps of instructions.
- Strictly observe the warning labels at the modules emitting laser light. For the meaning of the labels refer to section 3.3 in this document.
- Do not look into the laser beam.
- Do not open modules containing a laser. Only open modules containing a laser if explicitly instructed to do so.
- Do not keep tools in the laser beam unless explicitly instructed to do so.
- Make yourself familiar with the path of the laser light and the conditions, when the laser beam is switched on. Refer to the functional description in the corresponding service manual.
- Do not operate modules with laser outside the device.

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Sharp edges:

CAUTION:

Sharp edges inside the device: Cut or abrasion possible.

Be careful at maintenance and replacement of parts.

Cleaning optical elements:

CAUTION:

Image artifacts possible after cleaning optical elements.

When cleaning optical elements follow the service manual precisely.

Secured screws:

CAUTION:

Opening screws secured by red lacquer may misalign important device adjustments:

Do not open screws that are secured by red lacquer.

Opening PCs and Workstations:

WARNING:

Electrical shock and damage to the equipment possible.

- Only open the PC or workstation if explicitly stated in the service manual.
- Unplug before opening.
- Observe anti-static safety regulations.

Replacing fuses:

WARNING:

Replacing fuses by wrong type may lead to fire hazard.

Use only fuses of the exact value and characteristics stated in the service manual or on the device.

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20 Safety Directions for remote Service Activities

Remote Service Activities:

WARNING:

During remote service activities images can be lost.

Inform the customer prior to remote service activities to finish the current work and to stop working on the system.

21 Safety Directions for Transport and Shipment of Spare Parts, Accessories and Devices

- In compliance with transport regulations, all uninterruptible power supplies (UPS) must be shipped with batteries disconnected.
- Use the original packing when returning spare parts, accessories or devices.
- Before returning any spare part with a built in lithium battery remove it and dispose the batteries locally according to local waste regulations.

22 Safety Directions concerning Modifications

Modifications made in products/systems shipped by Agfa HealthCare must not be implemented without written permission from Agfa HealthCare.
This applies in particular to changes which may affect the mechanical and/or electrical safety or radiation-protection properties of a product (e.g. changing of safety distances, removal of locks/instructions etc.).

WARNING:

Improper changes, additions, maintenance or repair of the system can lead to personal injury, electrical shock and damage to the equipment.

Safety is only guaranteed when changes, additions, maintenance or repairs are carried out by an Agfa certified field service engineer. A non certified engineer performing a modification or service intervention on a medical device, acts on his own responsibility and makes the warranty void.

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23 Safety Directions concerning Hazardous Materials

'Hazardous materials' is the designation for substances which can ignite or explode or which are toxic, injurious to health, corrosive or irritating. The “Hazardous Material” instructions must be read and the required protective measures must be complied with when performing work to avoid health risks.

Their properties together with the hazards and protective measures connected with them are identified clearly by symbols and described by the instructions appertaining to the hazardous substances.

24 Recycling

Agfa HealthCare has Recycling Passports available for equipment and CR cassettes. The Recycling Passport explains how to dispose or recycle the equipment or CR cassette at the end of the life cycle.

The Recycling Passports are meant to be used as information for waste treatment partners and companies that want to recycle or dispose end-of-life Agfa equipment and CR cassettes.

To get a copy of the required Agfa HealthCare Recycling Passport please contact your local Sales organization.

25 Waste Disposal

On August 13, 2005, the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, amended by Directive 2003/108/EC, came into force.

The directive on Waste Electrical and Electronic Equipment (WEEE) aims to prevent the generation of electric and electronic waste and to promote the reuse, recycling and other forms of recovery. It therefore requires the collection of WEEE, recovery and reuse or recycling.
This directive has to be implemented into national law by the individual European countries by August 13th 2005.

Due to the implementation into national law, specific requirements can be different within the European Member States.

This symbol on the product, or in the manual and in the warranty, and / or on its packaging indicates that this product shall not be treated as household waste.

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For more detailed information about take-back and recycling of this product, please contact your local Agfa service organization. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources.
If your equipment or replaced spare parts contain batteries or accumulators please dispose of these separately according to local regulations.

26 Erasing Protected Health Information (PHI)

Safeguarding/disposal of Protected Health Information (PHI) in case of parts or device replacement

AGFA HealthCare Field Service Personnel or its authorized affiliates are responsible for safeguarding PHI (patient data) and security information (passwords) during their service activities. In case devices, modules or parts are removed from the customer's site, PHI and security information needs to be properly disposed of. This also applies to the exchange of spare parts, especially to

- parts that are returned to central warehouses for repair or refurbishing and
- parts that are returned for root cause analysis.

Examples for parts or modules that may contain Protected Health Information (PHI) and security information are: Computers, Computer hard disks, CD-ROMs, backup tapes, archive tapes.

Disposal is preferably handled by the data owner, which is usually the customer. If disposal or re-use is however handled by Agfa, any PHI or security information on the product must be made irretrievable. This can be done by physically destroying the storage medium or by securely deleting the information on it.

Safeguarding/disposal of Protected Health Information (PHI) in case of demo systems

After use at a customer, demo systems will contain PHI and security information. Any PHI and security information needs to be deleted or overwritten before removing the system from the customer premises.

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