Chapter 2

Safety and Regulatory

This chapter explains the safety considerations, general equipment and patient related precautions, and the symbols used for the safe operation of your equipment. This chapter also includes information about the emergency procedures.

This chapter presents the concepts necessary to successfully operate your system safely.

X-Ray Protection

X-ray equipment if not properly used may cause injury. Accordingly, the instructions herein contained should be thoroughly read and understood by everyone who will use the equipment before you attempt to place this equipment in operation. GE Healthcare, will be glad to assist and cooperate in placing this equipment in use.

Although this apparatus incorporates a high degree of protection against x-radiation other than the useful beam, no practical design of equipment can provide complete protection. Nor can any practical design compel the operator to take adequate precautions to prevent the possibility of any persons carelessly exposing themselves or others to radiation.

It is important that everyone having anything to do with x-radiation be properly trained and fully acquainted with the recommendations of the National Council on Radiation Protection and Measurements as published in NCRP Reports available from NCRP Publications, 7910 Woodmont Avenue, Room 1016, Bethesda, Maryland 20814, and of the International Commission on Radiation Protection, and take adequate steps to protect against injury.

The equipment is sold with the understanding that GE Healthcare, its agents, and representatives have no responsibility for injury or damage which may result from improper use of the equipment.

Various protective material and devices are available. It is urged that such materials or devices be used.

FCC Statement of Conformance

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Indications for Use

The GE Automatic Mobile X-Ray (AMX) Series: Brivo XR285amx, Optima XR200amx, Optima XR220amx are intended to take exposures utilizing film or computed radiography (CR), however the Optima XR220amx utilizes the GE Wireless Detector, which is intended to replace radiographic film screen systems in all general purpose diagnostic procedures, for digital radiography (DR).

Brivo XR285amx, Optima XR200amx, Optima XR220amx are self-contained; battery operated mobile radiographic imaging systems designed to generate diagnostic radiographic images (medical x-rays) that may increase the ability to detect disease or injury early enough for a medical problem to be managed, treated, or cured. Medical x-rays are used in many types of examinations and procedures, some examples include: x-ray radiography (to find orthopedic damage, tumors, pneumonias, foreign objects).

The series are indicated for use on adult and pediatric patients for general-purpose diagnostic radiographic examinations and procedures. Its mobility enables general-purpose radiographic procedures throughout the clinical environment, or as needed within the emergency, intensive care, premature birth ward, cardiac and operating departments, for patients that may not be able to be moved or in cases where it is unsafe or impractical to move them to a traditional RAD room.

The systems are indicated for taking radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts with the patient sitting, standing, or lying in the prone or supine position.

These devices are not intended for mammographic applications.

WARNING: United States Federal law restricts this device to sale by or on the order of a physician.

Contraindications

This device is not intended for mammographic applications.

Users

The targeted clinical users include qualified trained doctors, radiographers, or radiologic technologists (RTs) working in various locations. Locations may include orthopedic clinics, radiology imaging centers, hospital radiology departments, or hospital orthopedic departments.

Safety

The electrical wiring of the relevant rooms complies with all national and local codes, as well as the Regulations for the electrical equipment of buildings published by the Institution of Electrical Engineers. All assembly operations, extensions, re-adjustments, or repairs must be carried out by qualified service representatives. Any modifications must be carried out by GE Healthcare Technologies authorized service representatives. The equipment must be used in accordance with the instructions for use.

WARNING: This X-Ray unit may be dangerous to patient and operator, unless safe exposure factors, operating instructions and maintenance schedules are observed.

To be used by authorized personnel only.

WARNING: Electric Shock Hazard! Do not remove covers. The system contains high voltage circuits for generating and controlling X-rays. Prevent possible electric shock by leaving covers on the equipment. There are no operator serviceable parts or adjustments inside. Only trained and qualified personnel should be permitted access to the internal parts of this equipment.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING: All assembly operations, extensions, re-adjustments, or repairs must be carried out by qualified service representatives. Any modifications must be carried out by GE Healthcare Technologies authorized service representatives.

WARNING: Electric shock hazard. To prevent possible electric shock, do not insert fingers inside the RJ 45 connector (Ethernet port).

WARNING: Radiographic equipment must be operated by qualified personnel and only after sufficient training.

WARNING: Do not use in an oxygen-rich environment or around other flammable or explosive gases.

WARNING: **This equipment is not rated for use in the presence of flammable gases.**

CAUTION: **Always be alert to safety when you operate this equipment. You must be familiar enough with the equipment to recognize any malfunctions that can be a hazard. If a malfunction occurs or a safety problem is known to exist, do not use this equipment until qualified personnel correct the problem.**

CAUTION: **This mobile X-ray Unit is not normally connected to protective earth ground while in use. For the safety of the patient and operator, only devices that are certified to the appropriate safety standards for medical devices and in good working order are to be used in proximity to this X-ray Unit.**

CAUTION: **THIS SYSTEM IS NOT DESIGNED FOR USE IN CLOSE PROXIMITY TO A DEFIBRILLATOR!**

Never use a defibrillator on a patient that remains in contact with the digital detector or any part of the mobile x-ray system. This system must be treated as a conductive surface and moved well away from a patient before defibrillation is attempted. If any part of the mobile x-ray system remains in contact with a patient when the defibrillator is discharged, voltage may be conducted through the patient's body and into the system. This may be hazardous to anyone who may come in contact with the system, and could damage the detector.

Always consult the instructions for use of any defibrillator that may be used on a patient being imaged by this digital mobile x-ray system.

CAUTION: **It is the User's responsibility to provide the means for audio and visual communication between the Operator and the patient.**

CAUTION: **If you suspect any electromagnetic interference affecting or caused by the unit, call service. Portable and mobile RF communications equipment can affect medical electrical equipment.**

CAUTION: **Use only manufacturer recommended equipment and accessories.**

CAUTION: **Front bumper will stop movement of the mobile system when engaged. The system will stop when the release handle is released.**

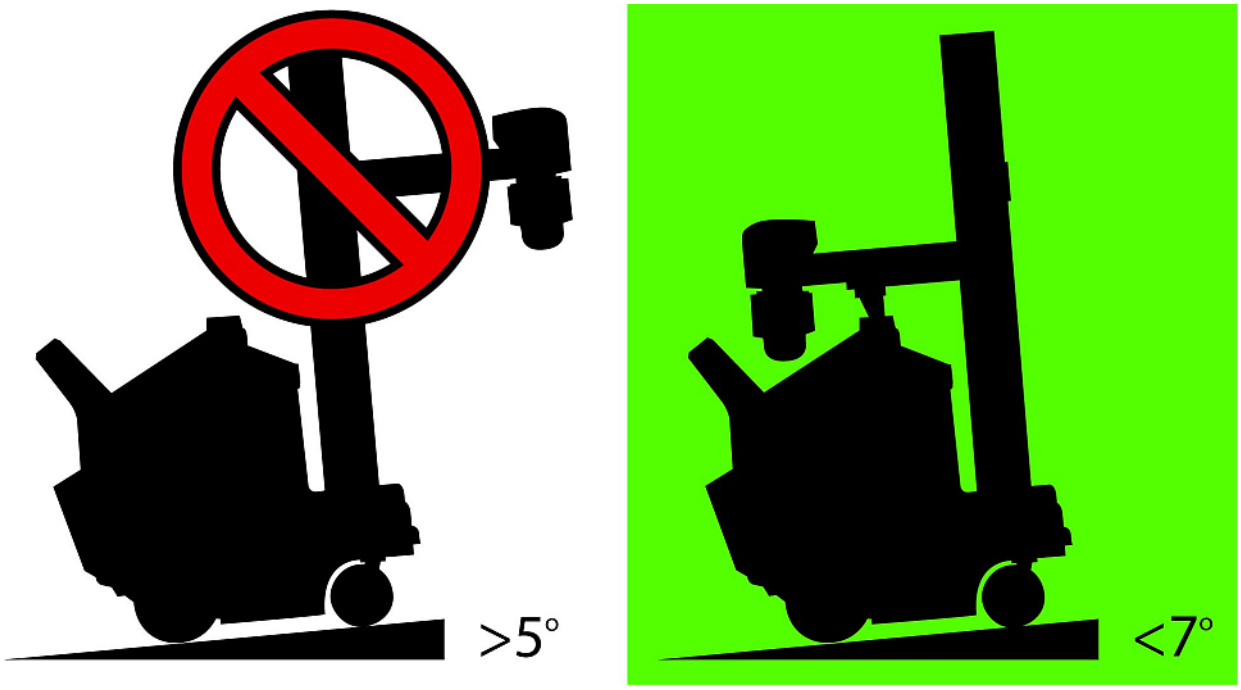
CAUTION: **The connection of equipment or transmission networks other than as specified in these instructions can result in electric shock hazard. Alternate connections will require verification of computability and conformity to IEC/EN 60601-1-1 by installer.**

CAUTION: **There is a cable-counterpoise assembly in the tube support column which makes the tube easy to move and position. This assembly includes a mechanical safety device. In the unlikely event that the tube becomes very difficult to move vertically on the column, please contact your service personnel as the mechanical safety device may have been activated.**

NOTE: If such an event occurs, it may be accompanied by a loud noise.

CAUTION: **Observe equipment limitations when moving the mobile system up or down an incline.**

Figure 2-1 Incline Limits



Good Operating Practices

- Wear a lead apron while performing an x-ray exam.
- Step back at least 2 meters from the tube or to the full extension of the hand switch cord before making an exposure.
- Always use the proper field sizes and technic factors for each procedure to minimize x-ray exposure and produce the best diagnostic results.
- GE Healthcare strongly suggests reducing radiation dose to As Low As Reasonably Achievable (ALARA) in all patients, whenever it is determined that an x-ray exposure is necessary.
- It is recommended that all users receive proper training in applications before performing them in a clinical setting. Please contact the local GE representative for training assistance. ALARA training is provided by GE Application Specialists. The ALARA education program for the clinical end-user covers basic x-ray principles, possible biological effects, ALARA principles, and examples of specific applications of the ALARA principle.
- Check the digital display carefully before making an exposure: verify that the selected technique is the intended technique. Pay particular attention to the placement of the decimal point in the mAs setting to insure that whole numbers are not mistaken for an intended mAs fractional number.
- Ask visitors to step outside the room during an exposure.
- Use gonadal shields for patients whenever possible.
- Be sure to read and follow the maintenance schedule outlined in the Maintenance and Service section of this manual.
- Under most conditions, cumulative radiation dose to the operator will not exceed recommended maximum permissible levels. However, as with all radiation-producing devices, a qualified radiation expert should evaluate situations involving frequent exposures using high kVp and mAs technics to determine if extra protective devices are necessary.
- The protocols supplied with the system represent examples for procedures commonly conducted in radiography. Based on the needs of a particular practice, these protocols may be modified to optimize factors such as image quality or dose reduction.

Know the Equipment

Read and understand all of the instructions in this Operator Manual before attempting to use the product.

IEC Equipment Classifications

This product is a mobile general purpose radiographic x-ray system. The following equipment classifications are applicable to this product:

- Equipment classification with respect to protection from electric shock: Class I
- Degree of protection from electric shock: Type B
- Degree of protection against ingress of liquids: IPX0
- Degree of Safety in the presence of Flammable Anesthetics Mixture with air or with oxygen or with nitrous oxide: Not suitable for use in the presence of Flammable Anesthetics Mixture with air or with oxygen or with nitrous oxide.
- Mode of operation: Continuous with intermittent loading

Electromagnetic Immunity

WARNING: Power line anomalies or electrostatic discharges to the system may cause a CD write failure error. A new CD should be used and the image re-written.

Radiation Safety

Always use the proper technical factors for each procedure to minimize X-ray exposure and to produce the best diagnostic results. In particular, you must be thoroughly familiar with the safety precautions before operating this system. Default techniques are designed to optimize the image processing parameters.

CAUTION: There should be no people other than the patient in the room during x-ray exposure. If circumstances require another person to enter the room while x-ray exposures are planned or possible, that person should wear a lead apron in accordance with accepted safety practices.

Radiation Protection

Because exposure to X-ray radiation may be damaging to health, use great care to provide protection against exposure to the primary beam. Some of the effects of X-ray radiation are cumulative and may extend over a period of months or years. The best safety rule for X-ray operator is “Avoid exposure to the primary beam at all times”.

Any object in the path of the primary beam produces secondary (scattered) radiation. The intensity of the secondary radiation is dependent upon the energy and intensity of the primary beam and the atomic number for the object material struck by the primary beam. Secondary radiation may be of greater intensity than that of the radiation reaching the film. Take protective measures to safeguard against it.

An effective protective measure is the use of lead shielding. To minimize dangerous exposure, use such items as lead screens, lead impregnated gloves, aprons, thyroid collars, etc. The lead screen should contain a minimum of 2.0 mm of lead or equivalent and personal protective devices (aprons, gloves, etc.) must contain a minimum of 0.25 mm of lead or equivalent. For confirmation of the local requirements at your site, please refer to your “Local Radiation Protection Rules” as provided by your Radiation Protection Advisor.

WARNING: While operating or servicing x-ray equipment, always keep a distance not less than 2 meters from the focal spot and X-ray beam, protect body and do not expose hands, wrists, arms or other parts of the body to the primary beam.

Monitoring of Personnel

Monitoring of personnel to determine the amount of radiation to which they have been exposed provides a valuable cross check to determine whether or not safety measures are adequate. It may reveal inadequate or improper radiation protection practices and potentially serious radiation exposure situations.

The most effective method of determining whether or not the existing protective measures are adequate is the use of instruments to measure the exposure. These measurements should be taken at all locations where the operator, or any portion of the body may be exposed. Exposure must never exceed the accepted tolerable dose.

A frequently used, but less accurate, method of determining the amount of exposure is the placement of film at strategic locations. After a specified period of time, develop the film to determine the amount of radiation.

A common method of determining whether personnel have been exposed to excessive radiation is the use of personal radiation dosimeters. These consist of X-ray sensitive film or thermoluminescent material enclosed within a holder that may be worn on the body. Even though this device only measures the radiation which reaches the area of the body on which they are worn, they do provide a reasonable indication of the amount of radiation received.

Emergency Procedures

It is not always possible to determine when some components, such as the X-ray tubes, are nearing the end of their operating lives. These components could stop operating during a patient examination.

WARNING: The facility must establish procedures for handling the patient in case of the loss of radiographic imaging or other system functions during an exam.

Safe Operation Precautions

General Use Warnings

WARNING: **For continued safe use of this equipment, follow the instructions contained in this Operator Manual. Study this guide carefully before using the equipment and keep it at hand for quick reference. You may print this manual to have a paper copy available within the Radiology department.**

WARNING: **Only qualified personnel trained in the operation of this equipment should run this system. Read and become familiar with all instructions in this manual before using this equipment If further assistance is needed, please contact GE.**

WARNING: **It is the responsibility of the owner to make certain that only properly trained, fully qualified personnel are authorized to operate the equipment. A list of authorized operators should be maintained.**

WARNING: **Check for obstructions before moving the system; do not drive the system into or onto fixed objects.**

WARNING: **It is the responsibility of the operator to ensure the safety of the patient at all times. The patient should be monitored by visual observation, use of proper patient positioning, and the use of appropriate protective devices.**

CAUTION: **Keep the patient in full view at all times and never leave the patient unattended.**

CAUTION: **Please carefully monitor all equipment motion to prevent collisions. Pay attention during operation to prevent possible injuries that could result from collision of the power-driven equipment parts with other moving or stationary items likely to be in the environment.**

WARNING: **Perform periodic maintenance to ensure continued safe use of the equipment. Follow recommended preventative maintenance schedule as outlined in the documentation provided with your system.**

CAUTION: **Make sure any other accessories or materials are not located in the primary X-ray beam during exposure that could result in bad image quality.**

CAUTION: **Always use GEHC recommended accessories to ensure best performance and to avoid possible hazards.**

WARNING: **Do not load non-system software onto the system computer.**

WARNING: **For accessories used in combination with diagnostic X-ray equipment, be aware of the possible adverse effect arising from materials located in the X-ray beam.**

CAUTION: **This equipment may only be operated indoors. Operation outdoors is in violation of 47 U.S.C. 301 and could subject the operator to serious legal penalties.**

Patient Positioning Warnings

CAUTION: **To avoid patient injury, always assist the patient as needed at the beginning or end of an exam.**

CAUTION: **Make sure that patient connected lines, tubes, etc. do not become pinched or pulled.**

WARNING: **Hot Surface! Take care not to burn yourself or the patient by contact with the x-ray tube housing or the collimator lamp housing during extended use.**

Digital Detector Warnings

CAUTION: Do Not Drop.

CAUTION: Device weighs 4,536g (10.0 lbs. with battery).

CAUTION: Do not use a defibrillator while patient remains in contact with detector.

CAUTION: Maximum load is 110kg (242 lb) concentrated; 160kg (352 lb) distributed. Do not exceed these maximum load limits.

CAUTION: Operate the detector within the temperature range of 10° C to 35° C. Store the detector within the temperature range of 0° C to 50° C (maximum change 50° C per hour).

CAUTION: This equipment may only be operated indoors. Operation outdoors is in violation of 47 U.S.C. 301 and could subject the operator to serious legal penalties.

Pinch Points and Crush Hazard Summary

This section lists the potential pinch points or crushing hazards that exist for the system.

Table 2-1 Pinch Points and Crush Hazard Summary

Component	Warning
System	**WARNING: Potential Crush Hazard: Take care not to drive the system over cables or over a person's foot.**
Drive Handle	**WARNING: Potential Pinch Point: Always grasp the drive handle in such a way that neither hand can be pinched between the handle sections.**

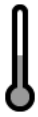
Component	Warning
Park Latch	 **WARNING: Hand Crush Hazard: Keep your extremities and the patient's extremities away from the Park Latch.**
Column	 **WARNING: Potential Pinch Points: The vertical column may create pinch points during up and down motion.**
Column Arm	 **WARNING: Potential Pinch Points: The column arm may create pinch points during motion.**
X-ray Tube and Collimator	 **WARNING: Potential Pinch Point: The area where the tube connects to the arm may create a pinch point when the tube is rotated. Operators should keep their hands on the collimator handle and keep patient clear while rotating the tube.**

Symbols

This section explains the symbols used on this system and in its accompanying documents.

Special Notices

Table 2-2 Special notices

Symbol	Description
	Dangerous voltage. This indicates an avoidable, dangerous, high voltage hazard.
	This symbol on the equipment indicates the operating instructions should be consulted to ensure safe operation.
	Hand crushing hazard. This symbol indicates that serious injury to the hand may occur.
	Follow operating instructions. This symbol directs you to consult this manual for more information.
	No stepping or standing on unit. The component on which the symbol appears cannot support the weight of a person. Damage to equipment or injury may occur if the unit is stepped or stood upon.
	Maximum load. This symbol indicates that the component has a maximum weight limit. Damage to equipment or injury may occur if the maximum weight is exceeded.
	Operating temperature. This symbol indicates that the component must be within a minimum and maximum temperature range in order to operate. Damage to equipment may occur if equipment is used at temperatures outside of the specified range.

X-ray Tube Operational Symbols

The table below describes the operational symbols for the system such as X-ray emissions and collimator locations.

Table 2-3 Operational symbols

Symbol	Description
	X-ray emission is used to indicate the X-ray tube head is emitting X-rays. Take adequate precautions to prevent the possibility of any persons carelessly, unwisely, or unknowingly exposing themselves or others to radiation.
	X-ray source assembly is used to indicate a reference to an X-ray source assembly.
	X-ray tube is used to indicate a reference to the X-ray tube, e.g., to mark the surface of a grid, which is to be oriented towards the X-ray tube.
	Identifies controls or indicators associated with the selection of a small focal spot or the connection for the corresponding filament.
	Identifies controls or indicators associated with the selection of a large focal spot or the connection for the corresponding filament.

System Power On and Reset

The table below describes the power controls of the system.

Table 2-4 Power controls

Symbol	Description
	The POWER ON button is used to turn on the power to the system. ■ ON: Green ■ STANDBY: Blue

Electrical Type

The table below describes the electrical protection rating based on system type.

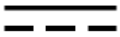
Table 2-5 Electrical type

Symbol	Description
	Type B Equipment indicates the equipment provides a particular degree of protection against electrical shock regarding leakage current and protective earthing per IEC60601-1.

Electrical Current

The table below describes the symbols for the different types of electrical current that may be used on your system.

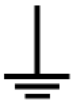
Table 2-6 Electrical current types

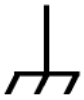
Symbol	Description
	Alternating Current indicates the equipment is suitable for alternating current only.
	Direct Current indicates the equipment is suitable for direct current only.
	Both direct and alternating currents indicate the equipment is suitable for both direct and alternating current.

Ground

The table below describes the different types of grounding that may be used in your system.

Table 2-7 Ground types

Symbol	Description
	Functional Earth (ground) Terminal indicates a terminal directly connected to a point of a measuring supply or control circuit or to a screening part, which is intended to be earthed for functional purposes.
	Noiseless (clean) earth (ground) identifies any terminal of a specially designed earthing system where noise from earth of leads will not cause a malfunction of the equipment.

Symbol	Description
	Protective earth (ground) identifies any terminal which is intended for connection of an external protective conductor to protect against electrical shock in case of a fault.
	Frame or chassis identify the frame or chassis terminal.
	Equipotentiality identifies terminals that bring the various parts of equipment or systems to the same potential when connected together. These terminals are not necessarily at earth (ground) potential. The value of the potential may be indicated next to the symbol.

Collimator

The table below describes the collimator controls and the radiation field.

Table 2-8 Collimator descriptions

Symbol	Description
	Control for indicating radiation field by using light.
	Identifies controls for opening the collimator blades, or indicates partially or fully open state.
	Identifies controls for closing the collimator blades, or indicates closed state.
	Indicates the collimator blades are closed. The controlled blades are shown in thicker lines.
	Indicates the collimator blades are open. The controlled blades are shown in thicker lines.

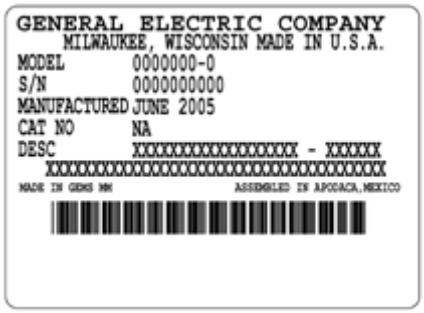
Symbol	Description
	Indicates the use of laser radiation.

Identification and Compliance Plates

Product identification labels can be found on the system. The types of system identification compliance plates are located below.

Identification Plate

Figure 2-2 Typical identification plate



NRTL Listed Label

The Nationally Recognized Testing Laboratory (NRTL) label indicates that the assembly is listed or recognized by a nationally recognized testing laboratory (i.e. ETL, UL, CSA).

Figure 2-3 ETL Listed Label

Identification and Compliance Plate Locations

Figure 2-4 System identification and compliance plate Locations

System Identification Plate

Figure 2-5 System Identification Plate

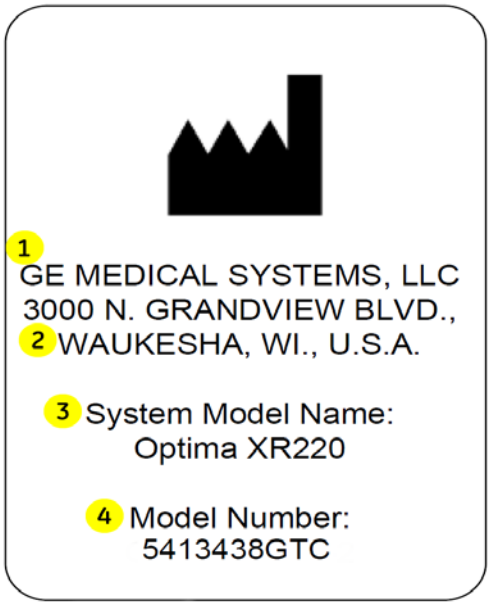


Table 2-9 System Identification Plate

Number	Text
1	GE Healthcare, LLC
2	3000 N. Grandview Blvd. Waukesha, WI USA
3	System Model Name
4	Model Number

Standard Identification Plate

Figure 2-6 Standard Identification Plate

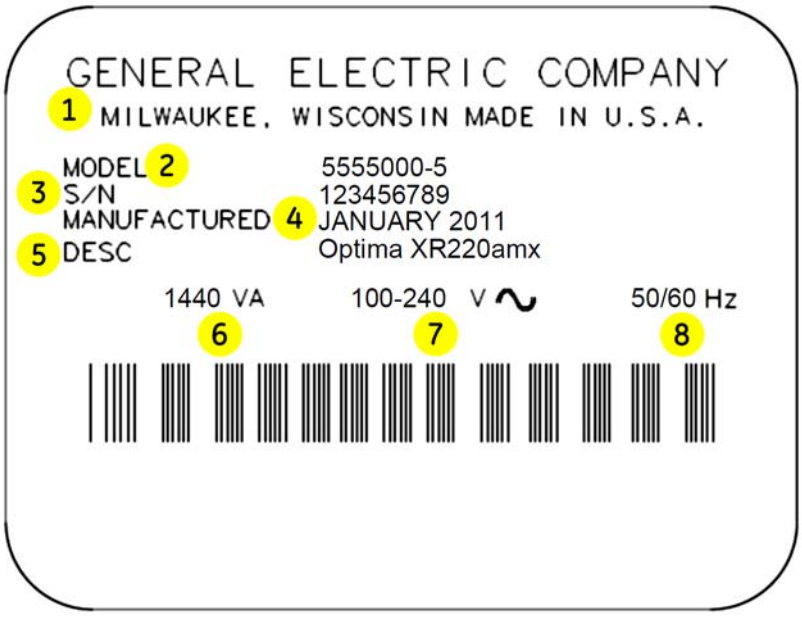


Table 2-10 System Identification Plate

Number	Text
1	General Electric Company Milwaukee, Wisconsin. Made In USA
2	Model
3	Serial Number
4	Manufactured
5	Description
6	1440 VA
7	100-240 VAC
8	50/60 Hz

Figure 2-7 System Label (CISPR 11)

Table 2-11 System Label (CISPR 11)

Number	Text
1	CISPR 11 / EN 55011
2	CLASS: A GROUP: 1
3	CLASSE: A GROUPE: 1
4	The operating instructions should be consulted to ensure safe operation.
5	Refer to Instructions (ISO 7010-M002)
6	RF transmitter (IEC 5140)

System Label (Chassis)

Figure 2-8 System Label (Chassis)

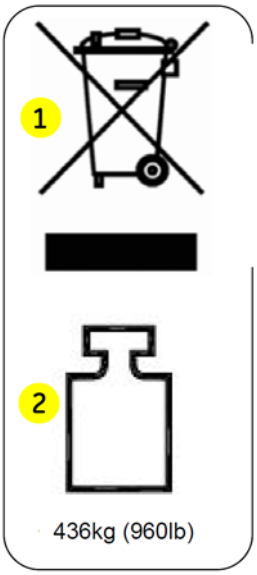


Table 2-12 System Label (Chassis)

Number	Text
1	Dispose of Separately
2	Weight of System

Figure 2-9 System Identification Plate (ETL)

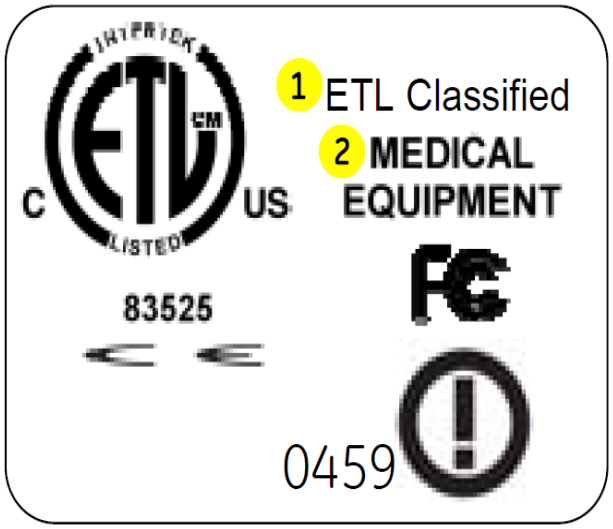


Table 2-13 System Identification Plate (ETL)

Number	Text
1	ETL Classified
2	Medical Equipment

Figure 2-10 System Identification Plate (FCC1)

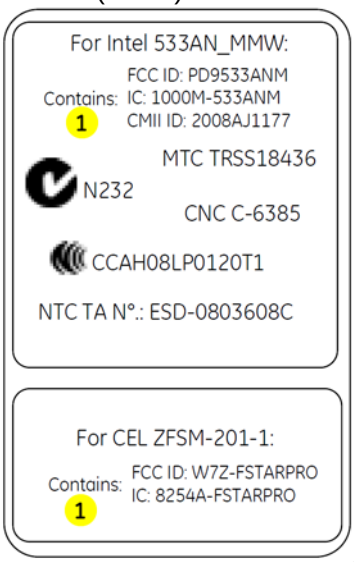


Table 2-14 System Identification Plate (FCC)

Number	Text
1	Contains

Figure 2-11)System Identification Plate (FCC2)

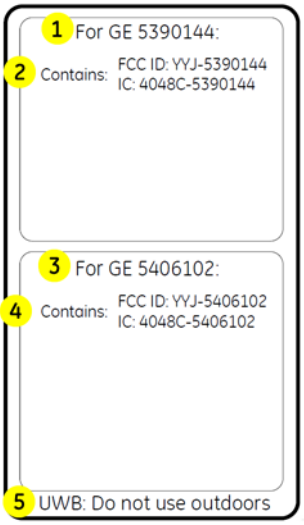


Table 2-15 System Identification Plate (FCC2)

Number	Text
1	For
2	Contains
3	For
4	Contains
5	UWB: Do not use outdoors

Figure 2-12 System Advisory Label

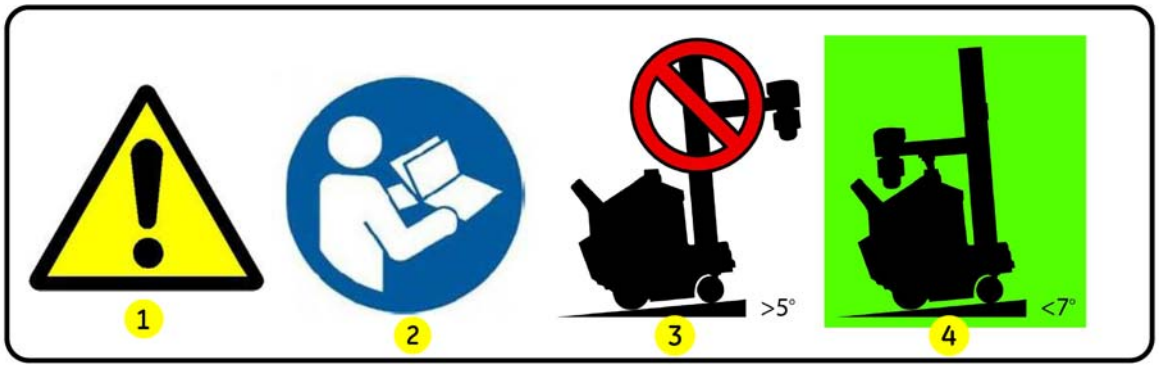


Table 2-16 System Advisory Label

Number	Text
1	The operating instructions should be consulted to ensure safe operation.
2	Refer to Instructions (ISO 7010-M002)
3	Do not drive the system on a grade greater than 5 degrees with the arm extended.
4	It is OK to drive the system on a grade less than 7 degrees with the arm latched in the park position.

Figure 2-13 X-Ray Console Warning

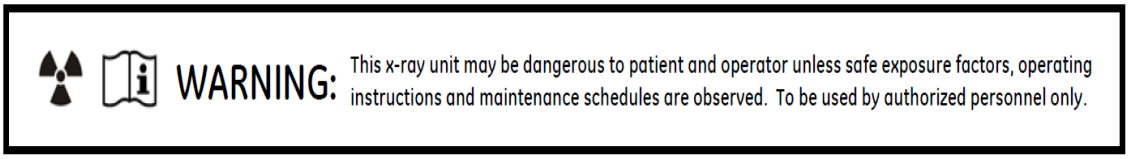


Table 2-17 X-Ray Console Warning

Number	Text
1	WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed. To be used by authorized personnel only.

Figure 2-14 X-Ray Console Warning (Canada)

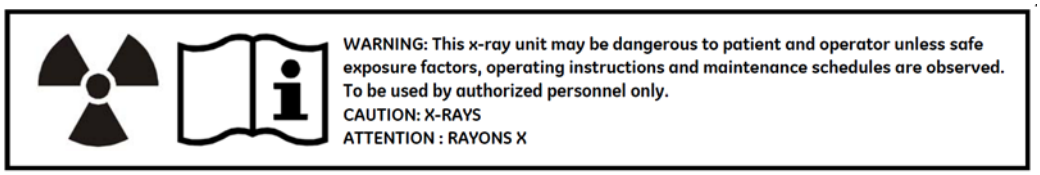


Table 2-18 X-Ray Console Warning (Canada)

Number	Text
1	WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed. To be used by authorized personnel only. CAUTION: X-RAYS ATTENTION: RAYONS X

X-Ray Tube Identification Plates

Figure 2-15 X-Ray Tube Identification Plate 1

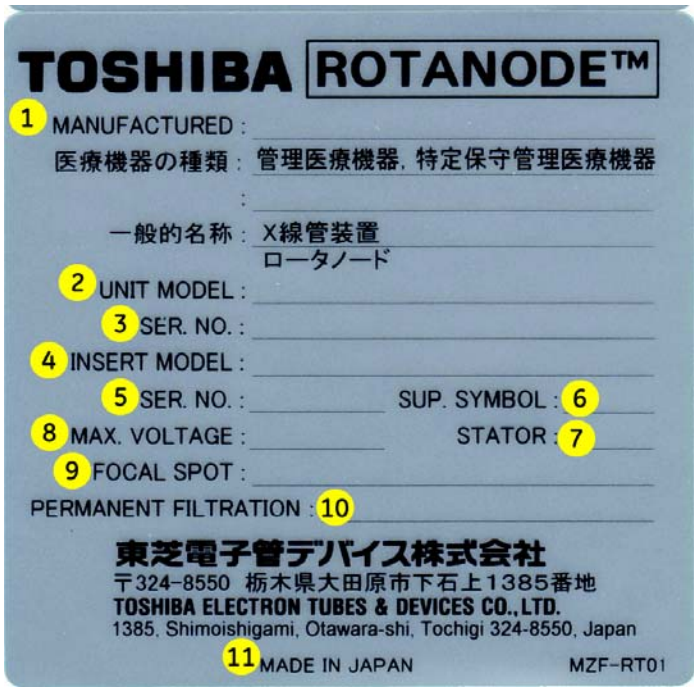


Table 2-19 X-Ray Tube Identification Plate 1

Number	Text
1	Manufactured
2	Unit Model
3	Serial Number
4	Insert Model
5	Serial Number
6	Supplementary Symbol
7	Stator
8	Maximum Voltage
9	Focal Spot
10	Permanent Filtration
11	Toshiba Electron Tubes & Devices Co., Ltd. 1385, Shimoishigami, Otawara-shi, Tochigi 324-850, Japan Made in Japan

Figure 2-16 X-Ray Tube Regulation Label

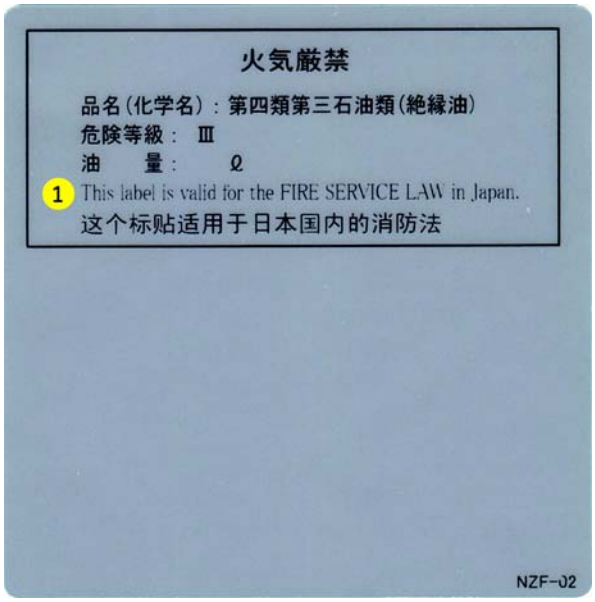


Table 2-20 X-Ray Tube Regulation Label

Number	Text
1	This label is valid for the Fire Service Law in Japan.

Figure 2-17 X-Ray Tube Caution Label (Cable)

Table 2-21 X-Ray Tube Caution Label (Cable)

Number	Text
1	Always have service personnel install or remove the high-tension cable.

Figure 2-18 X-Ray Tube Caution Label (End Caps)

Table 2-22 X-Ray Tube Caution Label (End Caps)

Number	Text
1	CAUTION: Housing end caps must always be mounted to the tube housing assembly properly and correctly for X-ray protection and safety. In any case, the X-ray tube shall not be energized without fixing the cap in such a manner as directed.

Figure 2-19 X-Ray Tube Caution Label (Fragile)

Table 2-23 X-Ray Tube Caution Label (Fragile)

Number	Text
1	CAUTION: Do not impact on this fragile face.

Collimator Identification Plate

Figure 2-20 Collimator Identification Plate

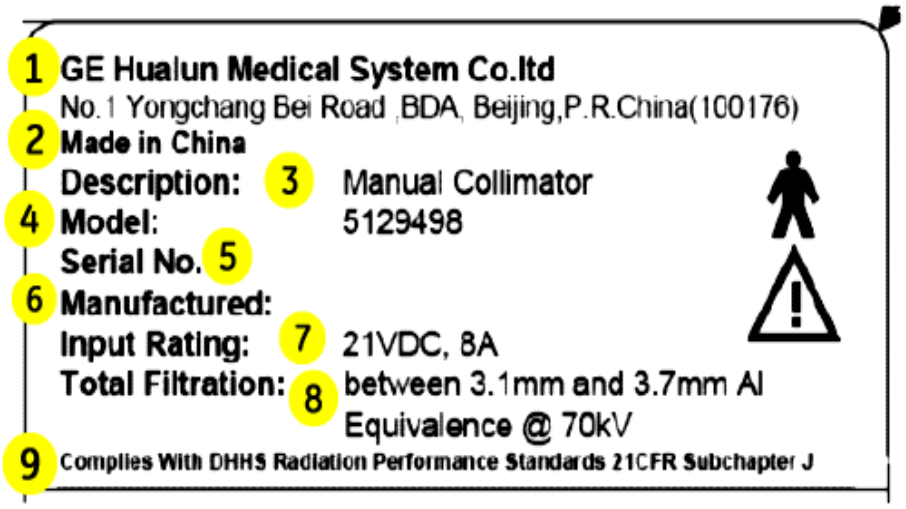


Table 2-24 Collimator Identification Plate

Number	Text
1	GE Hualun Medical systems Co. Ltd. Number 1 Yongchang Bei Road BDA Beijing, PR China 100176
2	Made in China
3	Description: Manual Collimator
4	Model: 5129498
5	Serial Number
6	Manufactured
7	Input Rating: 21VDC, 8A
8	Total Filtration: between 3.1mm and 3.7mm Al Equivalence @ 70kV
9	Complies With DHHS Radiation Performance Standards 21 CFR Subchapter J

Digital Detector Labels

Refer to the Digital Detector chapter for information on the Digital Detector labels.

Regulatory Requirements

NOTE: This equipment generates, uses, and can radiate radio frequency energy. The equipment may cause radio frequency interference to other medical and non-medical devices and radio communications. To provide reasonable protection against such interference, this product complies with emission limits for Group 1 Class A Medical Devices as stated in EN 60601-1-2. However, there is no guarantee that interference will not occur in a particular installation.

NOTE: If this equipment is found to cause interference (which may be determined by switching the equipment on and off), you (or qualified service personnel) should attempt to correct the problem using one or more of the following measures:

- Reorient or relocate the affected devices.
- Increase the space separating the equipment and the affected device.
- Power the equipment from a source different from that of the affected device.
- Consult the point of purchase or the service representative for further suggestions.

NOTE: The manufacturer is not responsible for any interference caused either by the use of interconnect cables other than those recommended or by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the user's authority to operate the equipment.

NOTE: To comply with the regulations applicable to an electromagnetic interface for a Group 1 Class A Medical Device, all interconnect cables to peripheral devices must be shielded and properly grounded. The use of improperly shielded and grounded cables may result in the equipment causing radio frequency interference in violation of the European Union Medical Device directive and Federal Communications Commission regulations.

NOTE: Do not use devices which intentionally transmit radio frequency (RF) signals (cellular phones, transceivers, or radio controlled products) in the vicinity of this equipment, as it may cause performance outside the published specifications.

Keep the power to these type devices turned off when near the equipment.

The medical staff in charge of this equipment is required to instruct technologists, patients, and other people who may be around this equipment, to fully comply with the above requirement.

Installation instructions for this device may be found in Optima XR200amx/220amx Installation Manual 5336113-1EN, which is included with this equipment.

This product complies with the following requirements:

Council Directive 93/42/EEC concerning medical devices when it bears the following CE marking of conformity:

Figure 2-21 CE mark

Disposal of Waste

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

Figure 2-22 Disposal of waste symbol

Battery Disposal

The separate collection symbol is affixed to a battery, or its packaging, to advise you that the battery must be recycled or disposed of in accordance with local or country laws. The letters below the separate collection symbol indicate whether certain elements (Pb=Lead, Cd=Cadmium, Hg=Mercury) are contained in the battery. To minimize potential effects on the environment and human health, it is important that all marked batteries that you remove from the product are properly recycled or disposed.

For information on how the battery may be safely removed from the device, please consult the service manual or equipment instructions. Information on the potential effects on the environment and human health of the substances used in batteries is available at this URL: http://www.gehealthcare.com/euen/weee-recycling/index.html

Figure 2-23 Battery Disposal symbol

Pollution Control Label

The following product pollution control information is provided according to *SJ/T11364-2006 Marking for Control of Pollution caused by Electronic Information Products*.

Figure 2-24 Pollution control symbol

This symbol indicates the product contains hazardous materials in excess of the limits established by the Chinese standard SJ/T11363-2006 Requirements for Concentration Limits for Certain Hazardous Substances in Electronic Information Products. The number in the symbol is the Environment-friendly Use Period (EFUP), which indicates the period during which the toxic or hazardous substances or elements contained in electronic information products will not leak or mutate under normal operating conditions so that the use of such electronic information products will not result in any severe environmental pollution, any bodily injury or damage to any assets. The unit of the period is Year.

In order to maintain the declared EFUP, the product shall be operated normally according to the instructions and environmental conditions as defined in the product manual, and periodic maintenance schedules specified in Product Maintenance Procedures shall be followed strictly.

Consumables or certain parts may have their own label with an EFUP value less than the product. Periodic replacement of those consumables or parts to maintain the declared EFUP shall be done in accordance with the Product Maintenance Procedures.

This product must not be disposed of as unsorted municipal waste, and must be collected separately and handled properly after decommissioning.

Dose Chart

Use the table below to compare film speed to dose values.

Table 2-25 Dose Chart

Expected receptor Default Dose (µGy) at 80 kVp is less than:	Equivalent Film Speed
16.00	100
12.90	125
10.00	160
8.00	200
6.25	250
5.00	320
4.00	400
3.20	500
2.50	640
2.00	800
1.60	1000

CAUTION: **Use the largest possible focal spot-to-skin distance to keep the patient absorbed dose as small as possible.**

CAUTION: **If no technical factors are present in the system for any view, the default settings are:**

- **kV = 50**
- **ma = 100 (fixed setting)**
- **mAs = .05**

These values are placeholders only. No exposures should be made until the user selects values appropriate for the patient size.

CAUTION: **This system source assembly is designed to be used with only the Optima XR220amx tube and collimator. Replacement of either of these components with different types may render the system non-compliant to applicable radiation safety standards and regulations.**