Optima™ **XR220amx X-Ray System**

Operator Manual

54400222-1EN

Rev 1 DRAFT 11092010

IMPORTANT!...X-RAY PROTECTION

X-Ray equipment if not properly used may cause injury. Accordingly the instructions herein contained should be thoroughly read and understood before you attempt to place this equipment in operation. The General Electric Company, Healthcare Division, 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 or his assistant to take adequate precautions to prevent the possibility of authorized or unauthorized persons carelessly, unwisely, or unknowingly exposing themselves or others to direct or secondary radiation.

It is important that everyone having anything to do with x-radiation be 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 Ave., Bethesda, MD 20814, and of the International commission on Radiation Protection, and take adequate steps to insure protection against injury.

It is assumed that all persons authorized to use the equipment are cognizant of the danger of excessive exposure to x-radiation and the equipment is sold with the understanding that the General Electric Company, Medical Systems Division, its agents, and representatives have no responsibility for injury or damage which may result from exposure to x-radiation.

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

CTRL+SHIFT+F to search using Search Index (faster)

Medical Device Directive

This product complies with the following requirements:

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

The location of the CE mark label on the equipment is in the service system manual.

European registered place of business:

> GE Healthcare SCS
> Quality Assurance Manager
> 283 rue de la Minière
> 78530 BUC France

Green QSD 1990 Standard issued by MDD (Medical Devices Directorate, Department of Health, UK).

Medical Device Good Manufacturing Practice Manual issued by the FDA (Food and Drug Administration, Department of Health, USA).

Underwriters' Laboratories, Inc. (UL), an independent testing laboratory.

Canadian Standards Association (CSA).

International Electrotechnical Commission (IEC), international standards organization, when applicable.

GE Healthcare reserves the right to make changes in specifications and features shown herein, or discontinue the product described at any time without notice or obligation.

The original language of this manual is English.

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Contact Information

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Revision History

Revision History

Revision Number	Pages Affected	Description of Change
1 DRAFT 21 Oct 2010	All	Preliminary Copy

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Chapter 1: Introduction

The equipment is intended for use by qualified personnel only.

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

This Operator Manual should be kept with the equipment and be readily available at all times. It is important for you to periodically review the procedures and safety precautions. It is important for you to read and understand the contents of this manual before attempting to use this product.

This chapter explains the purpose and design of this Operator Manual. It provides information on the organization, chapter format, and graphic conventions that identify the visual symbols used throughout the manual.

Purpose Of This Manual

This manual is written for health care professionals (namely, the radiologic technologist) to provide the necessary information relating to the proper operation of this system. The guide is intended to teach you the system components and features necessary to use it to its maximum potential. It is not intended to teach radiology or to make any type of clinical diagnosis.

Prerequisite Skills

This guide is not intended to teach radiology. It is necessary for you to have sufficient knowledge to competently perform the various diagnostic imaging procedures within your modality. This knowledge is gained through a variety of educational methods including clinical working experience, hospital based programs, and as part of many college and university Radiologic Technology programs.

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Safety Information

Please refer to Chapter 2: Safety and Regulatory in this manual. The Safety chapter describes the safety information you and the physicians must understand thoroughly before you begin to use the system. Note that you will find additional safety information throughout your Learning and Reference Guide. If you need additional training, seek assistance from qualified GE Healthcare personnel. The equipment is intended for use by qualified personnel only. This guide should be kept with the equipment and be readily available at all times. It is important for you to periodically review the procedures and safety precautions. It is important for you to read and understand the contents of this guide before attempting to use this product.

Safety Notices

Safety notices are used to emphasize certain safety instructions. This guide uses the international symbol along with the danger, warning, or caution message. This section also describes the purpose of a Note.

DANGER   **Danger is used to identify conditions or actions for which a specific hazard is known to exist which <u>will</u> cause severe personal injury, death, or substantial property damage if the instructions are ignored.**

WARNING   **Warning is used to identify conditions or actions for which a specific hazard is known to exist which <u>may</u> cause severe personal injury, death, or substantial property damage if the instructions are ignored.**

CAUTION   **Caution is used to identify conditions or actions for which a <u>potential hazard</u> may exist which will or can cause minor personal injury or property damage if the instructions are ignored.**

IMPORTANT!   An Important comment calls your attention to items that affect your workflow or image quality but do not involve the safety of people or equipment.

Note: A Note provides additional information that is helpful to you. It may emphasize certain information regarding special tools or techniques, items to check before proceeding, or factors to consider about a concept or task.

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Manual Organization

The manual is organized by chapters to provide information about specific functions. The following list provides an overview of the chapters' contents.

- Chapter 1: Introduction provides basic information about the Operator Manual itself.

- Chapter 2: Safety and Regulatory contains the detailed safety information operators and the physicians must understand thoroughly before using the system. Note that you will find additional safety information throughout the Operator Manual. If you need additional training, seek assistance from qualified GE Healthcare personnel.

- Chapter 3: General Information describes features and functions that apply to the whole system: such as start up, shutdown, and system messages.

- Chapter 4: Moving and Positioning

- Chapter 5: System Battery Charging

- Chapter 6: Quick Steps provides an overview of common tasks.

- Chapter 7: System Hardware Overview describes the overall system, hardware, and available accessories.

- Chapter 9: Worklist describes the process of adding, deleting, and selecting procedures from the system.

- Chapter 10: Image Acquisition describes the process of selecting and performing exams.

- Chapter 11: Image Viewer describes the features and functions for adjusting and viewing acquired images.

- Chapter 12: Image Management describes the features and functions to find and organize acquired images and exams.

- Chapter 13: Digital Detector describes the advanced digital detector

- Chapter 14: Set Preferences describes the features and processes to configure the system.

- Chapter 15: Quality Assurance and Maintenance describes the process to conduct checks on the detector(s) to ensure continued image quality.

- Appendix A: Login Administration describes how to administer the login options of the system, such as adding and removing users or groups.

- Appendix B: Specifications provides the technical specifications of the system.

- Appendix C: Messages on Display

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Graphic Conventions and Legends

The table below describes the conventions used when working with menus, buttons, text boxes and keyboard keys.

Table 1-1 Conventions for menus, buttons, text boxes, and keyboard keys

Example	Describes
Select	Marking an option in a group of check boxes or radial buttons Choosing an option from a drop-down list Activating a tab Highlighting row items
Press [START EXAM]	Pressing a button on a screen.
Press ENTER	Pressing a key on the keyboard.
Press CTRL+ALT+DELETE	Pressing a combination of keys on the keyboard. The key that should be pressed first is listed first.
Press and hold SHIFT	Pressing and holding down a key on the keyboard.
In the Matrix text box,...	The name of text box in which you can select or type text or the name of a drop-down list from which you select an option.
Type DICOMAE in the...	Text you enter into a text box.
Select Preferences > Worklist.	The path of selecting option(s) in a tree structure.

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Software User Interface Controls

This manual refers to "controls" that appear on the software screens. The table below describes the most common controls that appear on the software user interface.

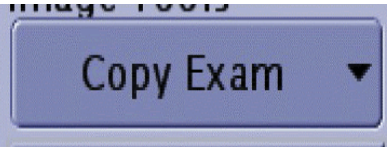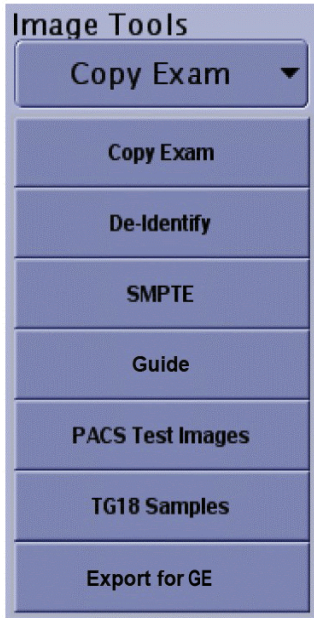**Table 1-2** Common software user interface controls
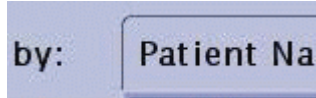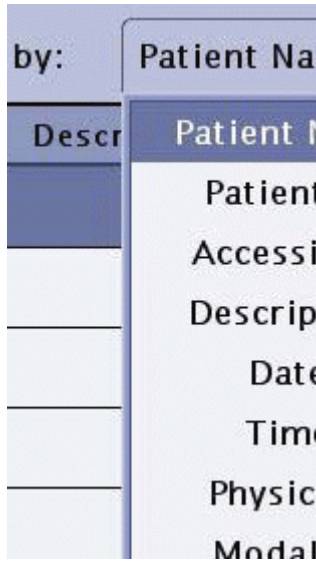
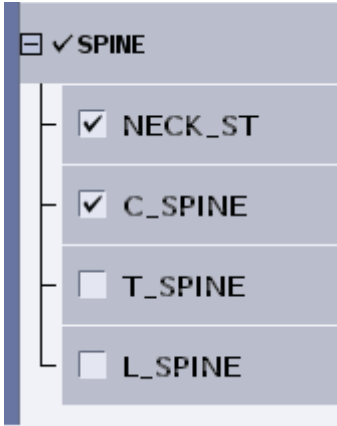| Control and Description	Examples	
Button Screen buttons look and act like physical buttons on equipment. A single button performs a specific action, such as opening a new screen or saving settings. A group of two or more buttons provides a choice of settings. The dark blue color indicates which button or buttons are selected.	A single button to start an exam	Two buttons to select the focal spot Focal Spot :
Drop down list Drop down lists open to reveal several options, but only one option may be selected at a time. Drop down lists may be included on a button or a text box. The presence of a drop down list is indicated by a down-pointing arrow on the right side of the control.	A list from a button Closed Copy Exam Open Image Tools Copy Exam Copy Exam De-Identify SMPTE Guide PACS Test Images TG18 Samples Export for GE	A list from a text box Closed by: Patient Na Open by: Patient Na Descr Patient N Patient Accessi Descrip Date Tim Physic Modal

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Table 1-2 Common software user interface controls

Control and Description	Examples	
Tab Tabs are similar to the tabs on file folders. They categorize related information on a single screen. Pressing on a tab reveals the information related to that tab. Pressing on another tab hides the previous information and reveals a different set of information.	A tab to move between two screens 	
Checkbox Checkboxes indicate selection. A single checkbox shows that an option is active. Multiple checkboxes show that several options are selected.	A single checkbox 	Multiple checkboxes
Text box Text boxes allow information to be entered using the keyboard.	Text boxes 	

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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 Optima XR220amx is a self-contained, battery-operated mobile radiographic imaging system 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.

The Optima XR220amx is indicated for use on adult and pediatric patients for general-purpose diagnostic radiographic examinations and procedures. Its mobility enables generating radiographic images of human anatomy in all general-purpose x-ray diagnostic procedures within radiology departments, emergency rooms, intensive care units, operating rooms, pediatrics, orthopedics and clinical environments. This may include 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 Optima XR220amx is intended to take exposures utilizing film or CR, however the Optima XR220amx utilizes the GE Universal Radiographic Detector, which is intended to replace radiographic film screen systems in all general purpose diagnostic procedures, for digital radiography (DR). The flat panel detector provides increased functionality to enable images of patients of all sizes, and can produce comparable quality images with as little as half the dose of traditional CR cassettes and other flat panel detectors with lower DQE.

The system is 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. The system has medical applications ranging from but not limited to gastrointestinal examinations, cranial, skeletal, thoracic, and lung exposures as well as examination of the urogenital tract.

⚠️

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 Health-care 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.

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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.

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

Figure 2-1 Incline Limits
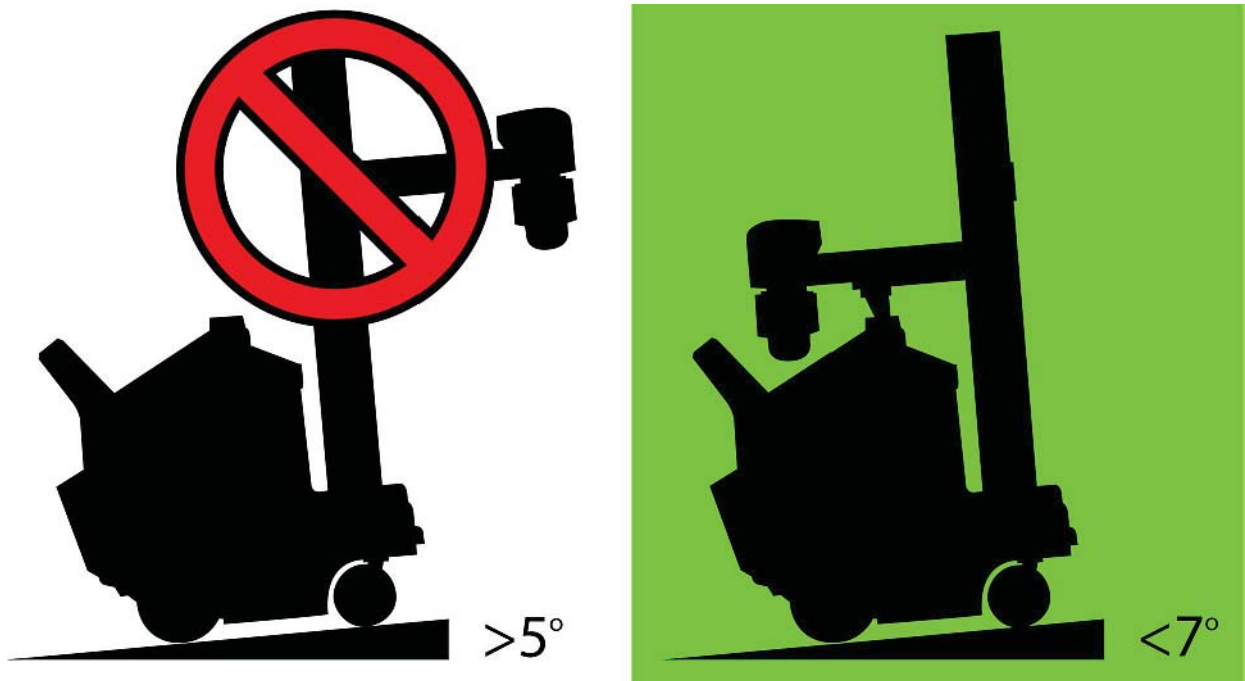
Good Operating Practices

- Wear a lead apron while performing an x-ray exam.
- Step back at least 6 feet (1.8 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.

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- 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.

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

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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.

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![warning icon]

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 icon]

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.**

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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.

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⚠️

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.

Maximum Attenuation Equivalent mm AL or Percent

Item	mm Al or Percent
Collimator without spectral filters at 70kV	TBD
Permanent tube assembly filtration at 75 kV	0.9mm
Tube housing minimum filtration at 150 kV	TBD
Detector Housing at 100 kV	TBD
Standard Grid: 6:1 grid ratio horizontal	35%
Optional Grid: 8:1 grid ratio horizontal	35%

Patient Positioning Warnings

⚠️

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

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

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).

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
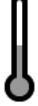
Component	Warning
System	⚠ **WARNING** **Potential Pinch Point:** TBD

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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.

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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

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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.

Table 2-7 Ground types

Symbol	Description
	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.
	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.

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Table 2-8 Collimator descriptions

Symbol	Description
	Indicates the collimator blades are open. The controlled blades are shown in thicker lines.
	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 in the table below.

Identification Plate

Figure 2-2 Typical identification plate
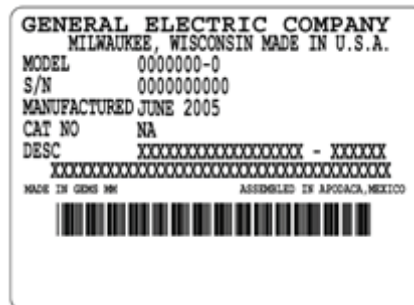
Figure 2-3 Typical identification plate

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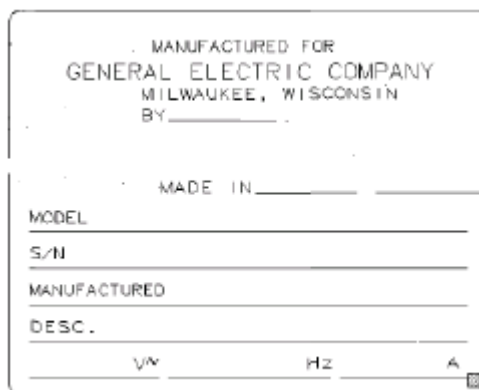
NRTL Listed Label

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 2-4 ETL Listed Label

Identification and Compliance Plate Locations

The table below identifies the type of compliance plates and their location on your system.

Table 2-9 System identification and compliance plates

Component	Plate Type
TBD	TBD

System Identification Plate

Figure 2-5 System Identification Plate TBD

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Table 2-10 System Identification Plate

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

Figure 2-6 System Identification Plate (DHHS)
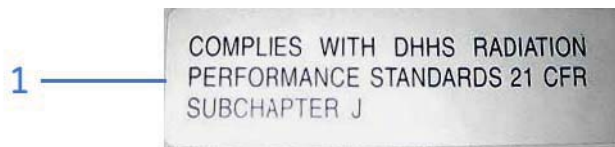
Table 2-11 System Identification Plate (DHHS)

Number	Text
1	Complies With DHHS Radiation Performance Standards 21 CFR Subchapter J

Figure 2-7 System Identification Plate (ETL)

Table 2-12 System Identification Plate (ETL)

Number	Text
1	ETL Classified

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Table 2-12 System Identification Plate (ETL)

Number	Text
2	**Medical Equipment**

X-Ray Tube Identification Plates

Figure 2-8 X-Ray Tube Identification Plate 1 TBD

Table 2-13 X-Ray Tube Identification Plate 1

Number	Text
1	**GE BE Private Ltd**
2	**Model**
3	**Serial Number**
4	**Manufactured**
5	**Focus**
6	**Description**
7	**Tube Insert Maximum Potential Anode to Cathode**
8	**Tube Insert Minimum Filtration:** **Aluminum Equivalent at::**
9	**Whitefield, Bangalore-66. Made in India.**

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Figure 2-9 X-Ray Tube Identification Plate 2 TBD

Table 2-14 X-Ray Tube Identification Plate 2

Number	Text
1	GE BE Private Ltd
2	Model
3	Serial Number
4	Description
5	Tube Insert Maximum Potential Anode to Cathode
6	Tube Insert Minimum Filtration: Aluminum Equivalent at::
7	Made for: General Electric Company, Milwaukee, Wisconsin
8	Whitefield, Bangalore-66. Made in India.

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Collimator Identification Plate

Figure 2-10 Collimator Identification Plate TBD

Table 2-15 Collimator Identification Plate

Number	Text
1	**Model Number**
2	**Serial Number**
3	**(Manufacturer)**
4	**This Product Complies With DHHS Radiation Performance Standards 21 CFR Subchapter J, Applicable At Date of Manufacture**
5	**Manufactured (Month/Year)**
6	**Filtration**
7	**Localizer Light: TBD**
8	**Made in TBD**

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Detector Identification Plates

Figure 2-11 Detector Identification Plate 1 TBD

Table 2-16 Detector Identification Plate 1

Number	Text
1	Manufactured For
2	General Electric Company Milwaukee, Wisconsin
3	by
4	Model
5	Serial Number
6	Manufactured
7	Description
8	Made In (Name of Country)
9	(Month and Year)
10	(Description of Detector)

Figure 2-12 Detector Identification Plate 2 TBD

Table 2-17 Detector Identification Plate 2

Number	Text
1	**Manufactured for** **GE Healthcare by**
2	**Model Number**
3	**Serial Number**
4	**Manufactured**
5	**Description**
6	**(Month and Year)**
7	**(Description of Detector)**

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Collimator Label

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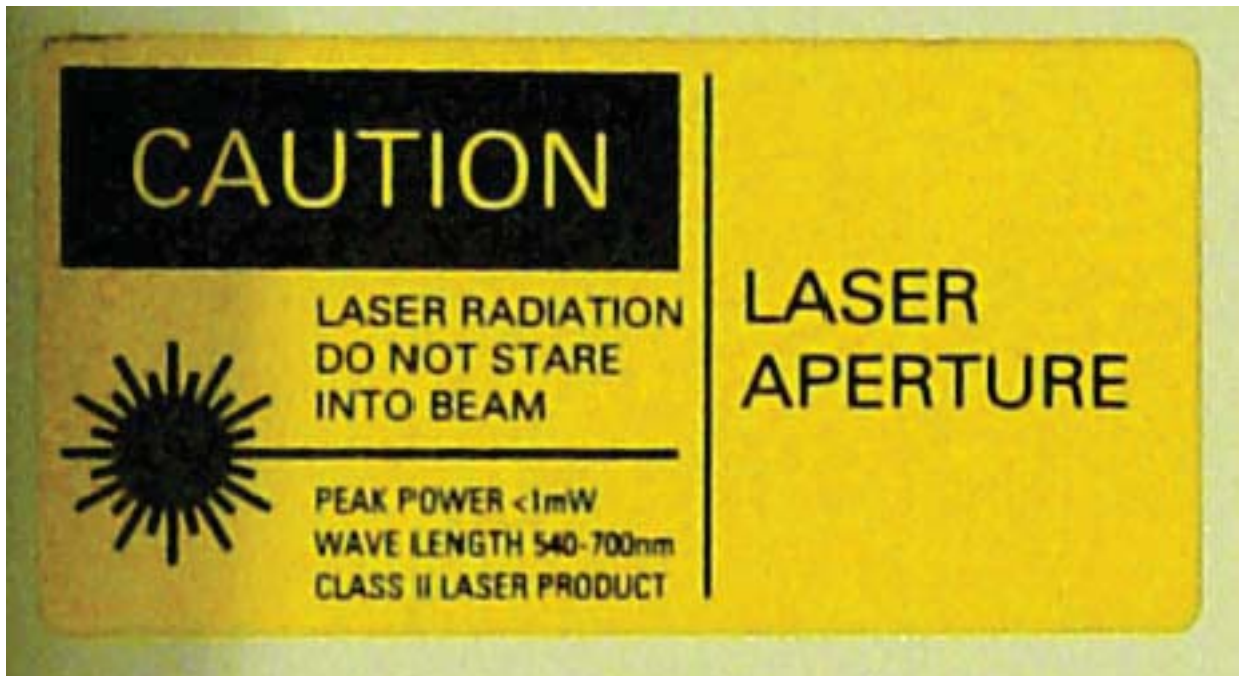
Digital Detector Labels

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 2-13 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 2-14 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 2-15 Battery Disposal symbol

Pb/Cd/Hg

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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 2-16 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 2-18 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

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Table 2-18 Dose Chart

Expected receptor Default Dose (µGy) at 80 kVp is less than:	Equivalent Film Speed
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.**

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Chapter 3: General Information

This chapter explains some of the basic operations and features of the Mobile X-ray Unit.

Quick Highlights

User Interface

- Optimized GUI – Technique, image acquisition and display tools in a single integrated user interface: Image preview display covers over 50% of the screen
- Commonly used tools pallet available in all image processing screens
- Edit/copy exam to reprocess images without additional patient exposures
- Reprocessing of images allow multiple "looks" selection with configurable display parameters
- Pre-programmed techniques per anatomy and patient size
- Image text annotations are supported with configurable font size for display and print
- Usage reporting tools by individuals and user groups
- System Health dashboard for system status
- Independent system status and system battery charge indicators

Productivity

- "Stand-by" mode eliminates boot up cycles and allows exposure within 25 seconds of system activation
- Exposures can be taken and processed while the unit is plugged in and charging
- Smart Charge automatic charging algorithms allow the system to be re-charged even if batteries are not fully drained
- System can be driven within 4 seconds of activation

Digital Detector

- Wireless connectivity from detector to system
- Lightweight detector enclosure designed for mobile use, weighs less than 4.5 kg (10lbs) including battery
- Detector is battery operated with rechargeable and exchangeable batteries – Back-up tether included
- Detector battery charges automatically while the detector is in the bin
- System can be used without the detector for manual film or CR exposures

Workflow

- Modality Perform Procedure Step (MPPS; SPS/PPS configurable)
- Automated and customizable image transfer to PACS and printers
- Worklist auto-refresh (configurable)
- Can reprocess images post acquisition and during an exam
- MWL remains visible until the next refresh, even if the network connection is lost

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Chapter 13: Digital Detector

This section outlines the basic detector functions, usage, care, and specifications.

Detector Overview

Detector primary functions are:

- To convert x-ray data into digital image data
- To transfer the digital data to the system for processing and display

The detector is an x-ray imaging device. It consists of an array of 2024 x 2024 pixels (40.4 x 40.4 cm). Each pixel is attached to a data acquisition circuit that converts incoming x-ray signal to 14-bit digital data.

The detector is constructed from a metal case. The front face contains a graphite x-ray imaging window. The back face contains safety warnings.

Panel

The panel consists of a thin-film amorphous silicon integrated circuit on a glass substrate with a cesium iodide scintillator. The scintillating material absorbs the x-rays and converts the energy to light. The light is converted into a charge that is digitized by the detector electronics.

Electronics

The primary function of the readout electronics is to convert the charge into digital image data. This data is then transmitted to the system through a wireless link or an ethernet connection.

Physical Appearance / Finish

The detector unit is designed to be installable as 1) an external patient access/contact surface and 2) a non-external patient access/contact surface.

Detector surfaces have been treated with a finish to allow a smooth and easily cleanable surface. Care shall be taken to protect the surface from scratches.

Nameplates and Markings

A label on the back of the detector contains the GE part number.

Detector Handling

The device contains sensitive electronics that are susceptible to vibration, shock, drop, and impact.

When handling the device, use the handle and/or use both hands to manipulate the detector into the correct anatomical position for the exam.

⚠️

WARNING   **Do not swing the device into hard surfaces, especially corners, as this may scratch the cover, create an image quality artifacts, or damage the electronics inside.**

Special Instructions if the detector is dropped: Inspect the exterior for any possible cracks. Run Detector Check to test the detector. It will be clear if the electronics are not functioning. Other possible failures may include communication problems, image quality degradation, and loss of power. If any or all of these occur, call your GE Service Representative.

- Do not drop objects onto the detector.
- Do not use the detector as a stretcher to lift a patient.
- Do not drop the detector at any time.
- Do not prop the device on an edge, against wall or bed. Keep detector in cradle, bucky, or other GE-supplied container.
- Do not place other objects or patients on the detector if it is not on a flat surface, as shown in .
- Do not use unapproved chemical cleaners.
- Do not immerse detector into water or other liquids.
- Do not use a defibrillator while patient remains in contact with detector.
- Do not place objects on detector if it is not lying flat
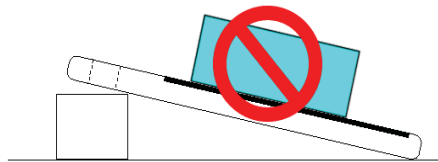
Detector surfaces have been treated with a finish to provide a smooth and easily cleanable surface. Take care to protect the surface from scratches.

⚠️

WARNING   **Extra precautions should be taken if the device will be exposed to excessive amounts of bodily fluids or liquids.**

The detector is designed to prevent some liquids or particulate matter from getting inside the cover. It can sustain a temporary splash or spray, but it is not designed to be immersed in liquid (not even temporarily).

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Hardware Overview

Figure 13-1 Front of the Digital Detector
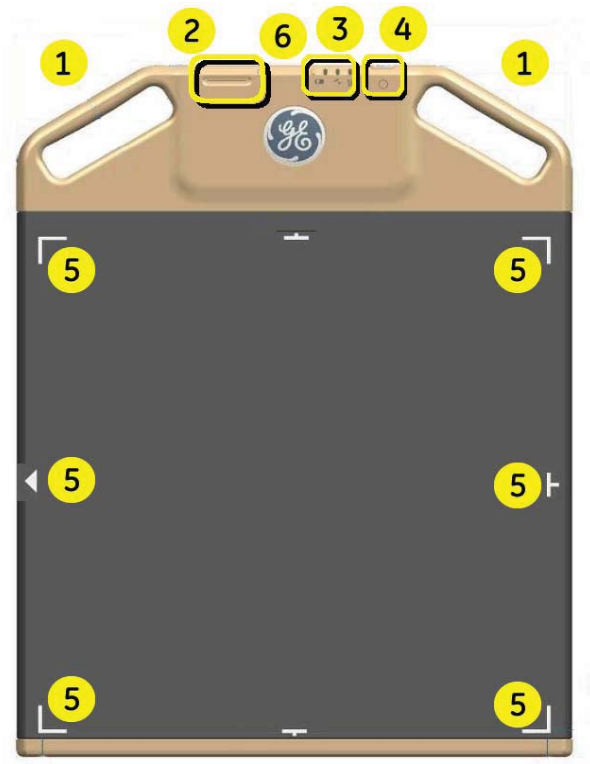
Table 13-1 Front of the Digital Detector

Item	Description
1	Handles
2	Battery
3	Indicator Lights
4	Pushbutton
5	Detector Active Visible Area (inside the white marks)
6	Antenna (inside the detector)

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Figure 13-2 Labels on the Front of the Digital Detector

Table 13-2 Labels on the Front of the Digital Detector

Item	Description
1	Centerline
2	Do not defibrillate (IEC 5841 w/line)
3	RF transmitter (IEC 5140)
4	Ths side toward X-ray source (IEC 5338)

Figure 13-3 Labels on the Back of the Digital Detector
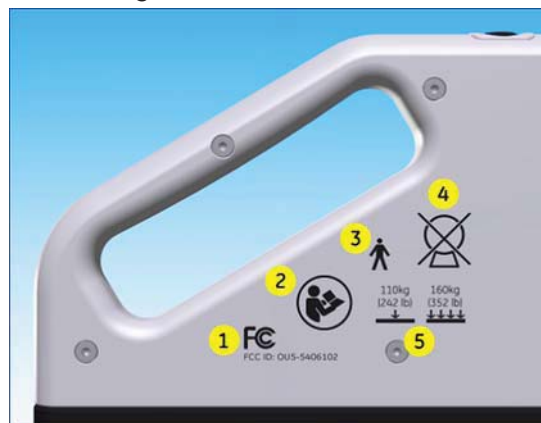
Table 13-3 Labels on the Back of the Digital Detector

Item	Description
1	FCC Approval and FCC ID Number (OU5-5406102)
2	Refer to Instructions (ISO 7010-M002)
3	Type B Applied Part (IEC 5840)
4	Do not X-ray this side (IEC 5338 with cross)
5	Maximum applied weight: 110kg (242 lb) concentrated; 160kg (352 lb) distributed

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Figure 13-4 Detector Docking Connector

Table 13-4 Detector Docking Connector

Item	Description
1	Detector Docking Connector

Figure 13-5 Detector Top

Table 13-5 Detector Top

Item	Description
1	Pushbutton: Push to toggle between normal mode and sleep mode.
2	Indicator Lights
3	Detector ID Insert - See Chapter 14: Set Preferences-Adding A New Detector Identified By Color and Shape
4	Battery

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Item	Description
5	Battery Latch

Battery and Tether Connection

The battery and the tether plug share the same connector. Only one of these can be plugged in at a time.
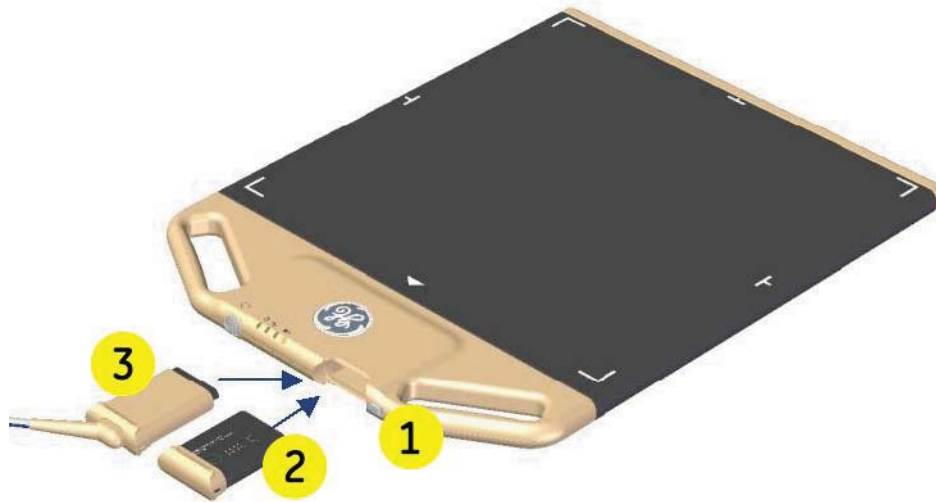
Figure 13-6 Detector Battery and Tether

Table 13-6 Detector Battery and Tether

Item	Description
1	Latch
2	Battery
3	Tether

Tether

Handling

To ensure maximum tether life, follow these guidelines:

- Treat the tether with care.
- Clean the tether regular with an approved chemical. Refer to for more information.
- Untwist the tether periodically. The colored stripe on the tether shows if it is twisted.
- Do not jerk or pull on the tether. For example, do not pull on the tether to free it from under a wheel (especially if the tether is twisted).
- Do not step on the tether.
- Do not run over the tether with the unit, cart, table or other equipment.
- Do not use the tether as a handle.

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- Do not bend or fold the tether sharply, especially at the points where the tether connects to the detector and to the unit.

Use

The tether should be kept with the mobile system at all times. It can be stored in the storage compartment. Use the tether under these conditions:

- Low Digital Detector battery or no Digital Detector battery. Tether the system to continue imaging.
- Connectivity issues between the Digital Detector and the system. If you lose an image and are unsure of the reason, you can use the tether to make sure the next image is transferred.
- Complete loss of connectivity between the Digital Detector and the system. You can use the tether until your Service Engineer can diagnose and repair the problem.

Detector Grid

The Digital Detector grid is integrated with a holder that fits the detector exactly. The grid fits over the detector handle and has raised edges to fit around the detector. Once together, you may handle the grid and detector as one unit.

The arrows on the grid surface show the direction of the grid lines, which run horizontally.
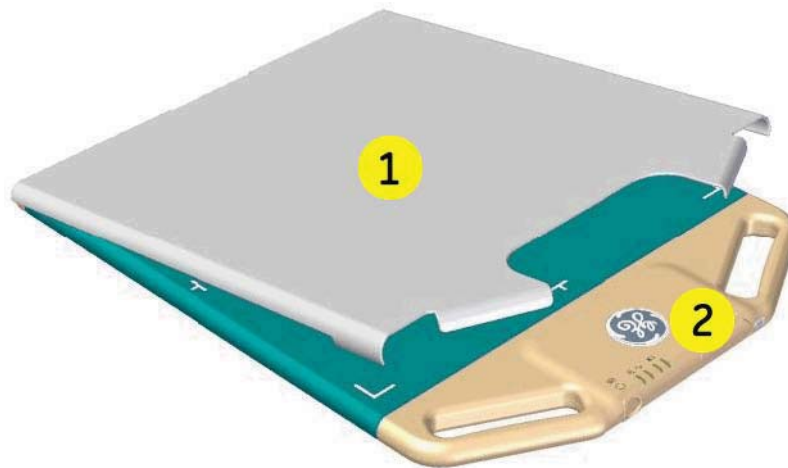
Figure 13-7 Detector Grid

Table 13-7 Detector Grid

Item	Description
1	Grid (6:1 grid ratio horizontal is standard, 8:1 grid ratio horizontal is optional)
2	Detector

The detector automatically detects when the grid is properly in place. If the grid has been improperly placed on the back of the detector, the detector will not function. The detector reports to the system when the grid is attached to or detached from the detector.

Grid Attachment

The bottom edge of the detector should be placed into the bottom lip of the grid holder while held in the vertical position with the carbon graphite cover (on the front of the detector) facing the inside of the grid holder. Then press the detector into the top edge of the grid holder. Be careful to not pinch your fingers or clothing when assembling.

While in use, keep a firm grasp on both the grid holder and the detector. The markings for the active area are clearly shown on the exterior surface of the grid holder.

Grid Handling

The grid is a sensitive device containing delicate mechanical structures. It is made of very thin pieces of lead (Pb) and interspersed with Aluminum (Al).

- Do not drop the grid.

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- Do not allow objects to hit/impact the grid.
- Do not immerse grid in water or other liquid.
- Do not peel labels or vinyl covering.
- Inspect the grid for physical damage before use.
- Clean the grid regularly (between each patient) with an approved chemical. Refer to for more information.

Use

On, Off, and Sleep Modes

Off

The detector only turns off when the Digital Detector battery is removed. There is no OFF button.

Sleep

- When the Digital Detector is on, push the black standby button and hold down for four seconds. The Digital Detector will go into the Sleep Mode. Press for one second to wake up from the sleep mode.
- When placed into the bin, the Digital Detector battery will begin charging and the Digital Detector will go into the Sleep Mode.

On

- When the Digital Detector is in the Sleep Mode, push the black standby button and hold down for one second. The Digital Detector will automatically wake up and be ready to use for exposures in 10 seconds.
- When pulled out of the bin, the Digital Detector will automatically wake up and be ready to use for exposures in 10 seconds.

Detector Alignment

To aid in proper alignment of the detector with respect to the X-ray source, there are alignment marks centered on the front side (imaging side) of the detector. The arrow represents the default heads-up display orientation.

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Indicator LED's

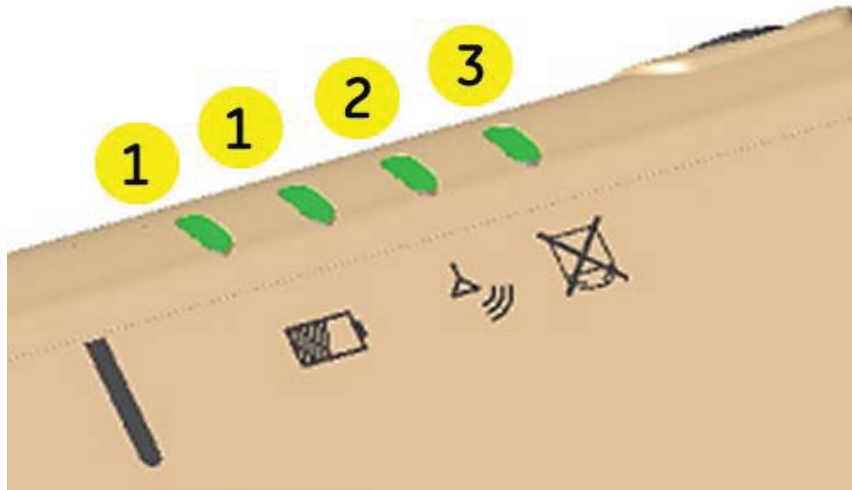**Figure 13-8** Indicator LED's

Table 13-8 Indicator LED's

Item	Description
1	Battery LED's • Green, Green: Battery more than 75% remaining • Off, Green: Battery remaining between 25% and 75% • Off, Yellow: Battery remaining between 10% and 25% • Off, Red: Battery less than 10% remaining • Off, Off: Detector in sleep mode
2	Wireless Link LED • Green: Wireless Link Connected • Red: No Wireless Link • Off: Detector in sleep mode
3	Detector LED • Green: Detector Ready • Off: Detector Off (in sleep mode) • Red: Detector Fault Condition

The various states of the Indicator LED's are shown in the illustrations below.

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Figure 13-9 Battery more than 75% remaining; Wireless link connected; Detector ready

Figure 13-10 Battery remaining between 25% and 75% ; Wireless link connected; Detector ready

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Figure 13-11 Battery remaining between 10% and 25% ; Wireless link connected; Detector ready

Figure 13-12 Battery less than 10% remaining; Wireless link connected; Detector exposure not allowed

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Figure 13-13 Battery more than 50% remaining; No Wireless link; Detector exposure not allowed

Figure 13-14 Detector off (in sleep mode)

Figure 13-15 Detector fault condition

In this condition the battery LED's may be lit to show the condition of the battery.

Electro-magnetic Interference

The detector has been designed and tested to meet all IEC regulations in regard to electro-magnetic (EM) susceptibility (and EMC).

However, there are no regulations for low frequency EM fields. All flat panel detectors have some suscep-tibility to these EM fields.

This detector is robust to EM fields up to 0.1mG over a broad low frequency range (DC - 250kHz).

It has been found that some common equipment in clinical environments can generate EM fields well over 0.1mG. Some measurements have shown 4mG field strengths which can cause artifacts on x-ray images.

EM fields are reduced by the square of the distance between the EM source and the detector. Thus, mov-ing the EM source twice as far away will reduce the field strength by 4 times.

General suggestions:

- Keep IV pumps, patient monitoring, feeding pumps 1 meter or more away from any detector surface.
- Consider turning off equipment that cannot be moved.
- Change the patient or detector orientation /position to maximize distance from any equipment.
- Turn on the EMI Reduction feature. See the Preferences chapter for information on how to do this.

Possible sources of EM fields:

- IV pumps

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- Monitors
- Feeding pumps
- Patient monitors
- ECG equipment
- EMG equipment
- Infusion pumps
- RF ablators
- Powered surgical equipment
- Heaters
- Air conditioners
- Refrigerators

Cleaning

All exterior surfaces—detector, tether, and grid—should be cleaned after each exam.

- The detector and grid must be allowed to dry before use.
- Do not leave disposable wipes or cleaning cloths on the detector or grid for more than 60 seconds.
- Let the detector dry at least 60 seconds between cleanings.

The following chemicals and products have been tested and approved by GE for cleaning the GE Portable DR Detector, grid, and tether.

- Cidex OPA
- Oxivir
- Super Sani-Cloth Germicidal Wipes
- Bleach (50% solution)

Specifications

Detector Size and Weight

Table 13-9 Detector size and weight specifications

Item	Specification
Overall detector size • Including handle • Not including tether	Thickness: 27mm Width:452mm Height:580mm
Image Size The active area of the x-ray panel	2024 x 2024 pixels or 40.4 x 40.4 cm
Weight Not including the tether or grid	9.9lbs (without battery) Battery: 0.38lbs

Environmental Contraints

This section describes the environmental conditions that the detector is designed to withstand.

⚠️

CAUTION   **Operation or storage outside of these constraints may cause damage to the detector.**

Table 13-10 Environmental Constraints

Item	Operating Environment Constraints	Non Operating Environment Constraints
	This column contains additional operating environmental constraints, within which the subsystem function and performance capabilities shall be in compliance.	This column defines additional Non-operating environmental constraints, within which the subsystem function and performance capabilities shall be in compliance, when returned to the operational state, within operating environment conditions.

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Item	Operating Environment Constraints	Non Operating Environment Constraints
Ambient • Temperature • Humidity • Pressure	• External ambient temperature range: +10 °C to +30 °C. • Rate of temperature change: 10 °C per hour • Ambient humidity range: 10% to 80%, non condensing. • Rate of humidity change: 30% per hour. • Atmospheric pressure (altitude) range: -400 meters to +3000 meters relative to sea level.	• External ambient temperature range: 0°C to +50 °C. • Rate of temperature change: 20 °C per hour • Ambient humidity range: 5% to 95%, non condensing. • Rate of humidity change: 30% per hour. • Atmospheric pressure (altitude) range: -100 meters to +15,000 meters relative to sea level (to support pressurized transport)
Mechanical Stress & Vibration Forces	The detector assembly shall not be exposed to operating vibration spectrum exceeding the following parameters: • Type: Random • Frequency Range: 20 to 350 Hz • Magnitude: 0.006g2 /Hz at 10-350 Hz • Duration: 8 hours/axis (x, y, z)	The detector assembly shall not be exposed to non-operating vibration spectrum exceeding the following parameters: • Type: Random • Frequency Range: 10 to 2000 Hz • Magnitude: 6 m/s2 RMS or 0.02g2 /Hz at 10-2000 Hz • Duration: 15 minutes/axis (x, y, z)
Shipping & Storage Environment	Not applicable.	The non-operating shipping conditions shall be -20 to +60 with the detector and packing. The shipping container shall protect the detector from vibration of 2 Grms for 8 hours in the x, y, and z axes, random vibration from 10 to 2000 Hz such that the image quality is not degraded. Cargo hold during shipment shall be within the atmospheric pressure range of 700-1100hPa

CTRL+SHIFT+F to search using Search Index (faster)

Appendix A: Login Administration

Login and Logout

The login feature requires you to login to access the system and can be turned on or off by your administrator or Field Engineer.

How your site uses this feature depends on if your site has a central user repository to which the system is connected. Sites with networks are referred to as Enterprise systems, those without are referred to as stand-alone systems. This feature can be used with either configuration, although some features are more applicable to enterprise systems.

1. At the login screen, type your assigned login name.
   - This name is assigned by your system administrator.

Note: If you need to log in quickly for emergency purposes only, press [Emergency Login].

Note: Logging off does not prohibit other users from logging in. Logout is designed to protect patient privacy, not stop approved users from logging in. When you or another user logs back in, the system returns to its last known state.

2. Press in the Password area and type in your password.

3. Press [Login].

Figure A-1 Login Window

4. To logout of the system, press [Shutdown].
   - The Shutdown window appears.

5. Press [Logout User].

6. Press [OK].

- The system logs you out and waits for the next login.

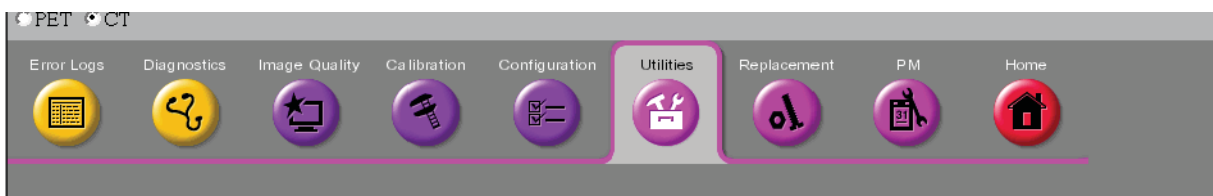# Configure HIPAA (EA3) Properties

After logging in, the component will display the Application Tab. On this tab, you will be able to configure EA3 application properties.

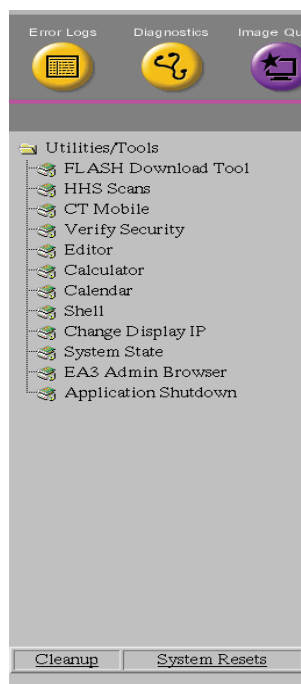1. Press [Utilities].

Figure A-2

2. Press Service [Launch] on the System Utilities screen.
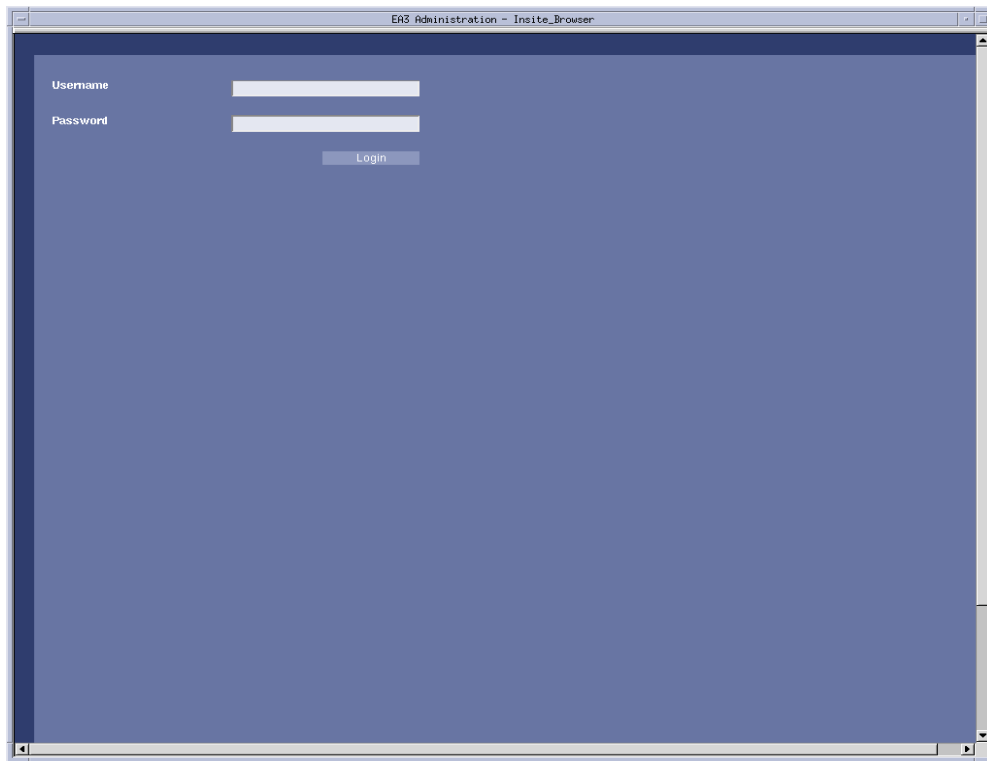
Figure A-3 Service Toolbar

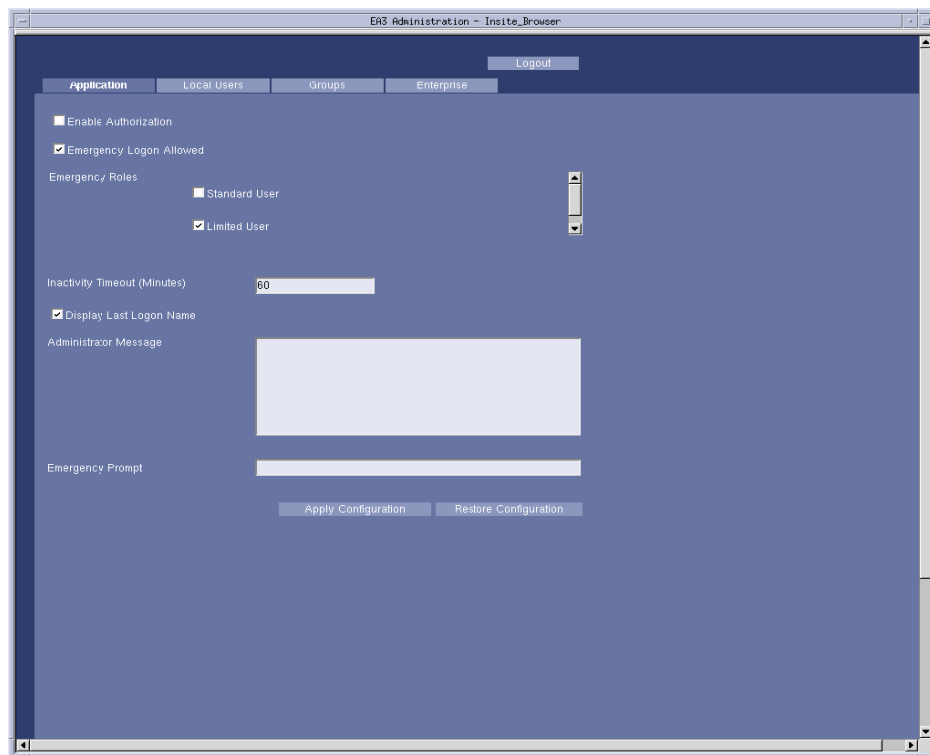3. Select EA3 Admin Browser

Figure A-4 EA3 Admin Browser

- This brings up the Administration Screen.

Figure A-5 Administration Tab

4. Enter your Username and Password.

5. Press [Login].

CTRL+SHIFT+F to search using Search Index (faster)

Figure A-6 Applications Screen

6. Make your desired selections.

- The following configurations can be made on this tab:

    – Enable Authorization - Whether or not to enable authorization. If authorization is enabled, anyone logging in through EA3 (both local and enterprise users) must have a role. Anyone without a role will be denied access if authorization is turned on. Note that the role the user has doesn't matter for logging into EA3 (however, some other EA3 client applications can decide which roles can login)

    – Emergency Logon Allowed - Whether or not to allow emergency access. If EA3 is used in GUI mode, this decides whether or not to display the Emergency login button. If this is disabled, emergency user access is prevented.

    – Emergency Roles - The roles assigned to the emergency user. The defaults allow an admin to assign a Standard user role, Limited User role, or both roles.

    – Inactivity Timeout (minutes) - The amount of time (in minutes) that must elapse without any mouse/keyboard, etc. activity before a timeout is generated. When a timeout is generated, the EA3 logon screen is displayed. This value can be any positive integer, or it can be 0. If the value is 0, this indicates NO inactivity timeout (there will never be a timeout event regardless of how much time has elapsed).

    – Display Last Logon Name - Whether or not to display the username of the last user that has logged in on the EA3 logon screen.

    – Administrator Message - Under certain circumstances / error conditions, the user of EA3 is asked to contact an administrator. This field allows the administrator to specify contact details for himself / herself and a custom message.

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– Emergency Prompt - The text that will be displayed to any user logging in as emergency. The user is asked to enter information (usually their actual user name). This text is the text that will appear in that prompt for information.

7. Press [Apply Configuration].

- To make a configuration change, make the necessary changes on the fields, and press the Apply Configuration button. If there was a problem with making the changes (such as an invalid value or a problem contacting the back-end Servlet) you will see a message box indicating this error with a description of the error. If the changes are successful, after the 'Apply Configuration' button is pressed, then you will see a brief message indicating that the changes were applied in a green label. If at any time, you want to revert your changes to what is currently saved on the back-end, you can press the Restore Configuration button. This will undo any changes that you have made that have not yet been saved by pressing the Apply Configuration Button. (Once you press the 'Apply Configuration' button and get the confirmation label, the changes have been applied).

Configure Local Users

The second tab on the EA3 Administration Component is the Local Users tab. On this tab, you can add users, remove users, change user group memberships, change user names, change user passwords, lock / unlock users, force users to change their password on next login, etc. Below is a screen-shot of the EA3 Administration Component Local Users Tab:

1. Select the Local Users tab.

Figure A-7 Local Users Tab
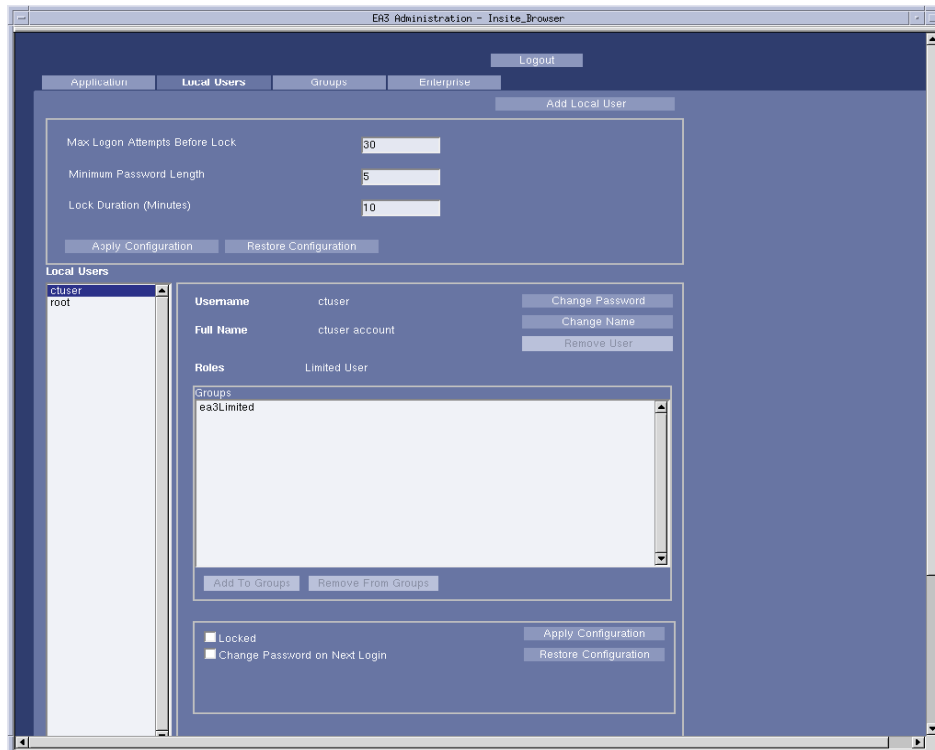
2. Select the choices you wish to have selected.

    *   Max Logon Attempts Before Lock - The number of failed login attempts a user can make before their account is locked for a certain number of minutes. When a user account is locked, that user will not be allowed to login, even if they provide the correct username/password combination. Either the specified time must elapse before the user can login again, or a user with ADMIN role must login to the EA3 Administration component to unlock the user. Note that locking only applies to local users (enterprise user locking is managed by the enterprise server)

    *   Minimum Password Length - The minimum length of a new password for a user. Note that if a password is below the minimum password length already, setting this value will have no effect on the password. For example if your password is 8 characters, and someone changes the minimum password length to 10 characters, the 8 character password is still ok. However, next time the user changes their password, they will have to choose a password that is 10 characters or greater. Note that minimum password length only applies to local users (password length restrictions for enterprise users are managed by the enterprise server)

    *   Lock Duration (Minutes) - The number of minutes a user stays locked for if they become locked because of failed login attempts.

- Apply Configuration - Use the Apply Configuration button to save changes.
- Restore Configuration - Use this button to undo any changes that have not been saved yet. If there are any errors, you will get a popup box describing the error. If it is successful, you will see a green label appear with confirmation information.

Note: Users can become locked in one of two ways.

- The user enters too many incorrect passwords. In this case, the user will be locked out for a certain amount of time, even with a correct password. Once the time has elapsed, the user can attempt a login again. An administrator can unlock this user before the lock duration time has elapsed by un checking Locked under the Local User tab when a user is selected.

- The administrator forcefully locks the user account. In this case, the lock duration does not apply to a user who was forcefully locked by and administrator. They are locked until the administration unlocks them.
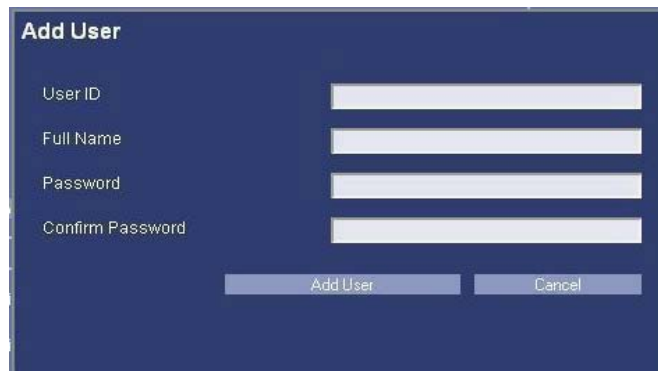
3. Press [Apply Configurations].

Add a Local User

Once a user is added, it is automatically highlighted in the Local Users list box on the left-hand site, and it is 'in context'. Once a user is in context, all information and buttons in the center panel (i.e. Username, Full Name, Roles, Change Name, Change Password, Remove User, Groups list box, Add To Groups Button, and Remove From Groups button) refer to that user.

1. Press [Add Local User].
   - When this button is pressed a popup panel is displayed.

2. Enter the new User ID (which must be unique).

3. Enter a Full Name.

4. Enter a Password.

5. Enter the Confirmed Password.
   - If any errors are encountered, you will receive an error messagebox. If you receive the error messagebox, changes were not committed to the database, and you can correct your errors and try again. Possible errors that can be encountered when adding a user are:
     - User ID already exists in the local user database (Choose a different unique username)
     - Password does not meet the minimum length requirements (Choose a longer password)
     - Password and Confirm Password box do not match (Make sure the passwords match)

6. Press [Add User].

Figure A-8 Add User Screen

CTRL+SHIFT+F to search using Search Index (faster)

Change a User Password

You can select a user to be 'in context' by pressing on the user's id in the 'Local Users' list box on the left side. Only one user can be in context at a time, and if you attempt to choose multiple users, EA3 will select the top-most user that is selected. Once a user is 'in context', you can make any necessary modifications to that user.

Note: When you first navigate to the Local Users tab, EA3 will put the first listed local user 'in context' automatically. If there are no local users then there will be no user in context, and all of the buttons in the center panel will be disabled until a user is added.

1. Select User.

2. Press [Change Password].

   • This brings up a popup panel with two textboxes for the password.

3. Make changes to the password.

4. Press [Confirm Change].

   • If you do not want to make the change, simply press Cancel.

   • If the password doesn't meet the minimum length requirements, you will receive an error message-box. If this occurs, your changes were not saved. Simply make the necessary corrections, and press Confirm Change again.

Figure A-9 Change Password

Change a User Full Name

1. Select User.

2. Press [Change Name].

3. Make changes to the name.

4. Press [Confirm Change].
   - If you do not want to make the change, simply press the Cancel button.

Figure A-10 Change Name

Remove a User

1. Select User.

2. Press [Remove User].

3. Press [Confirm Removal].
   - If you do not want to make the change, simply press the Cancel button.

Figure A-11 Confirm Removal

Add or Remove a User from a Group

All of the groups to which this user belongs are listed in the Groups list box.

1. Press [Add To Groups] or press [Remove From Groups].
   - This brings up a popup panel that lists all of the groups that this user is eligible to be added to. If there are no groups that this user is eligible to be added to, you will get an error message box instead of the popup panel. Once you get the popup panel, simply select all of the groups to which you want to add this user (you can select as many as you want at one time).

2. Press [Add Membership] or press [Remove Membership].

Figure A-12 Add Groups

Figure A-13 Remove Group

CTRL+SHIFT+F to search using Search Index (faster)
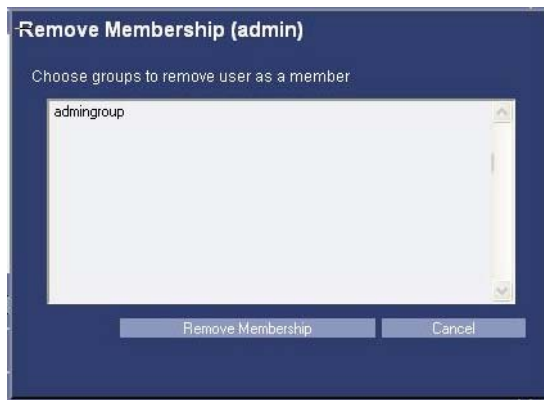
Change User Roles

Users roles cannot be directly changed from the Local Users panel. Roles are actually associated with groups, and users belong to groups. In order to change the roles for a user, you must change the roles of a group to which that user belongs.

Locking / Unlocking a User

Once a user is in context, you can see if the user is locked by looking at the status of the Locked checkbox in the bottom panel. If this is checked, then the user cannot login even with a correct password.

1. To unlock the user, uncheck the checkbox, and press Apply Configuration button.

2. To lock a user, check the checkbox and press the Apply Configuration button.

Note: If Emergency User is enabled, you can still login through Emergency User while the system is lock.

Force a User to Change Password on Next Login

Often times if you are an administrator, you would like to force a user to change his or her password the next time they login for security reasons. You can do this using EA3.

1. Select User

2. Check the Change Password on Next Login checkbox in the bottom panel.
   - If this is checked, then the user will be asked to change their password on the next successful login.

Note: Once the user changes the password on the next login the check will be removed from this user.

Some fields may not be selectable if the following conditions occur.

- For Users:
  - Permanent - If a user is permanent, they can never be removed. When a permanent user is in context, the 'Remove User' button will be disabled.
  - Content Not Editable - If a user is flagged as this, then their group memberships cannot be changed. When a 'content not editable' user is in context, the 'Add To Groups', and Remove From Groups' buttons are disabled.
  - Password not changeable - If a user is flagged as this, then the password cannot be changed, and the 'Change Password' button will be disabled.
- For Groups:
  - Permanent - If a group is permanent, it can never be removed. When a permanent group is in context, the 'Remove Group' button will be disabled.
  - Content Not Editable - If a group is flagged as this, then its group members cannot be changed (neither added nor deleted). When a user belongs to a Content Not Editable group, this user cannot be removed from the group (therefore, the group name will not show up when you press 'Remove From Group'). When a user does not belong to a Content Not Editable group, this user cannot be added to the group (therefore, the group will not show up when you press 'Add To Group').

CTRL+SHIFT+F to search using Search Index (faster)

- – Role Not Editable - If a group is flagged as this, then the Roles associated with that group cannot be changed. This property itself does not have a direct impact on what you can do on the Local Users tab.

Configure Groups

The third tab on the EA3 Administration Component is the Groups tab. On this tab, you can add local groups, add enterprise groups, remove local groups, remove enterprise groups, change group roles, and change group memberships.

1. Press [Groups].

Figure A-14 Groups window

CTRL+SHIFT+F to search using Search Index (faster)
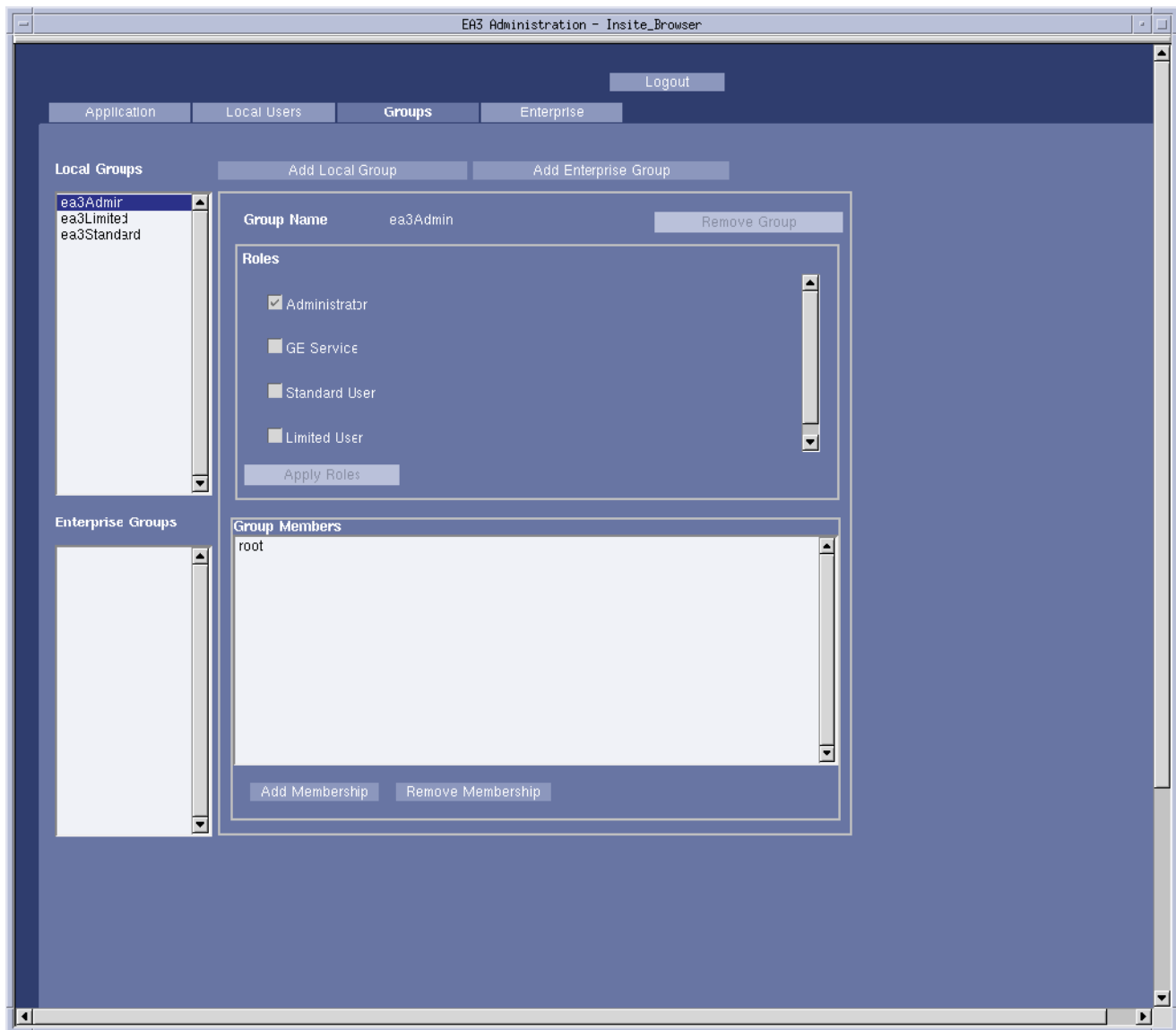
Add a Local Group

1. Press [Add Local Group].
    - When this button is pressed a popup panel is displayed.

2. Enter the new group's name (which must be unique).
    - If any errors are encountered, you will receive an error message box. If you receive the error message box, changes were not saved to the database, and you can correct your errors and try again. Possible errors that can be encountered when adding a group are:
      - Group name already exists in the database
      - Application session timeout
    - Once a local group is added, it is automatically highlighted in the Local Groups list box on the left-hand site, and it is highlighted. Once a group is highlighted, all information and buttons in the center panel (i.e. Group Name, Remove Group Button, Roles checkboxes, Apply Roles button, Group Members list box, Add Membership button, and Remove Membership button) refer to that group.

Figure A-15 Add Group

3. Press [Add Group].

Add a Enterprise Group

Adding an Enterprise group is quite similar to adding a local group.

1. Press [Add Enterprise Group].
    -

2. When this button is pressed a popup panel is displayed.
    - If any errors are encountered, you will receive an error message box. If you receive the error message box, changes were not saved to the database, and you can correct your errors and try again. Possible errors that can be encountered when adding a group are:
      - Group name already exists in the database
      - Application session timeout

3. Press [Add Group].
    - Adding an enterprise group doesn't actually add a group to the Enterprise directory server. What it does is give EA3 the ability to manage roles for that group, which should already exist on the Enterprise directory server. So, for example, if you add a group 'All Employees' as an Enterprise group to

CTRL+SHIFT+F to search using Search Index (faster)

EA3, and assign that group with the STANDARD role, then any enterprise user that logs in through EA3 and belongs to the 'All Employees' group will have the STANDARD role.

- You cannot manage the group memberships for Enterprise groups. This is managed by the directory server, not EA3. Therefore, whenever an Enterprise group is in context, both the 'Add Membership' and 'Remove Membership' buttons will be blocked out. This doesn't mean that no one belongs to the Enterprise groups, just that this is managed by the directory server and not EA3.

- Once an enterprise group is added, it is automatically highlighted in the Enterprise Groups list box on the left-hand site, and it is 'in context'. Once a group is in context, all information and buttons in the center panel (i.e. Group Name, Remove Group Button, Roles checkboxes, Apply Roles button, Group Members list box) refer to that group.

Figure A-16 Add Enterprise Group

Manage a Group

You can select a group to be highlighted by pressing on the group's name in either the 'Local Groups' or the 'Enterprise Groups' list box on the left side. Only one group can be highlighted at a time, and if you attempt to choose multiple groups, EA3 will automatically select the top-most group that is selected. Once a group is highlighted, you can make any necessary modifications to that group.

Note: When you first navigate to the Groups tab, EA3 will put the first listed local group highlighted automatically. If there are no local groups, then EA3 will put the first listed enterprise group highlighted automatically. if there are no local groups or enterprise groups, then there will be no group highlighted, and all of the buttons in the center panel will be disabled until a group is added.

Remove a Group

1. Once a group is highlighted, press [Remove Group].
   - This brings up a popup panel asking you to confirm the removal of the group.

2. If you want to remove the group, press [Confirm Removal].
   - If you do not want to remove the group, simply press [Cancel].

CTRL+SHIFT+F to search using Search Index (faster)

Figure A-17 Remove Group

Change Group's Roles

Once a group is highlighted, check or uncheck the checkboxes for the Roles you want to give to this group, and press [Apply Roles]. There is a green label confirmation as usual for successfully applied roles. If there is a failure on the back-end (i.e. a problem writing the roles configuration changes), you will receive an error message box with information.

Add Memberships

1. Once a group is highlighted, press [Add Membership].
    *   This brings up a popup panel that lists all of the users that are eligible to be added to this group. If there are no users eligible to be added to this group, you will get an error message box instead of the popup panel. Once you get the popup panel, simply select all of the users that you want to add to this group (you can select as many as you want at one time).

2. Press [Add Membership].
    *   If you do not want to remove the group, simply press [Cancel].

Remove Memberships

1. Once a group is highlighted, press [Remove Membership].
    *   This brings up a popup panel that lists all of the users that are eligible to be removed from this group. If there are no users eligible to be removed from this group, you will get an error message box instead of the popup panel. Once you get the popup panel, simply select all of the users that you want to remove from this group (you can select as many as you want at one time).

2. Press [Remove Membership].
    *   If you do not want to remove the group, simply press [Cancel].

Configure Enterprise Tab

The last tab on the EA3 Administration Component is the Enterprise tab. On this tab, you can configure the properties necessary to make a connection to an Enterprise directory server (i.e. MSAD, Novell, etc.).

The Enterprise Tab is used by the site's IT (Information Technology) or GE Service personnel. It provides connectivity to the site's user database. If you do not have a network established in your hospital or clinic, this tab will not be used.

Things to consider:

- Utilize the enterprise capability whenever possible.
- Make sure the enterprise groups are granular enough to restrict protocol edit access.
- The inactivity timeout should be turned on.

1. Press [Enterprise].

Figure A-18 Enterprise Tab

The following configurations can be made on the top box of this tab:

- Enable Enterprise Authentication - Whether or not Enterprise users should be able to log in. If this is unchecked, only local EA3 users will be able to log in. If this is checked, both local users and enterprise EA3 users will be able to log in (although the local EA3 user database will always be tried first).

- Cache Enterprise Users - Whether or not Enterprise users should be cached once they successfully login. If this is checked, then a local record of an Enterprise user is kept. If at any time that user attempts to login again, and for some reason the Enterprise directory server is not available (i.e. network problems), that user will be granted access if they provide the correct password. If this is unchecked, then an Enterprise user will be denied access in the case that the Enterprise directory

CTRL+SHIFT+F to search using Search Index (faster)

server cannot be reached. Note that hashed passwords are cached, the actual password is not cached.

- Enterprise Authentication Latency (Seconds) - The amount of time (in seconds) that the EA3 login process should wait for a response from the Enterprise directory server. Often times, there is a network latency when connecting to servers, and it will be different on different network configurations. If the amount of time is reached without a response from the directory server, the EA3 login process will return a failed login. A value of 5 seconds should be enough time to allow a properly configured directory server to respond, without being too much of an annoyance to the user if the directory server is down (i.e. they will only have to wait at a maximum 5 seconds for the login attempt to return).

- Applying configuration changes on the Enterprise tab top box are the same as mentioned before for the Application tab. Use the Apply Configuration button to commit changes, and the Restore Configuration button to undo any changes that have not been saved yet. If there are any errors, you will get a popup box describing the error.

- Additionally, the actual connection to the Enterprise directory server can be made on this tab. You will be modifying properties in the lower two boxes of the Enterprise tab

Auto Configuration

1. Press [Auto-detect Server Name].

- This attempts to lookup the name of Server Name of the directory server.

- In some environments, EA3 can try to auto-detect the Enterprise Directory Server. This will only work in some environments (i.e. where DNS allows service lookups). This is just a convenience feature, and will sometimes return with an alert that the auto-detect could not find the server. It is not an error if that message is displayed, simply continue with these steps to configure the Server.

2. Enter the Server Name or IP address of the Enterprise directory server that EA3 should connect to, in the Server Configuration box.

Note: The system must be able to resolve any IP address or server name. This means the system must either have DNS enabled or the system must have static information in a hosts file (i.e. /etc/hosts).

3. Choose the Authentication type that the directory server supports.
   - If it is a Microsoft Active Directory Server, most likely you need to choose Kerberos. If it is a Novell eDirectory Server, most likely you need to choose LDAP If you do not know, check with the owner of the directory server for information.
   - If the enterprise server supports SSL connections, check the 'Use SSL' checkbox.

Note: If you use LDAP authentication without SSL, passwords will be sent in the clear. This is not recommended, and the client is alerted if they attempt to configure this way. With kerberos and non-SSL, the authentication is encrypted, but the LDAP traffic is not.

4. Press [Test Connection].
   - This tests to see if the machine can connect to the directory server. If the connection is successful, you will see a label with a 'CONNECTION OK' text next to the Test Connection button.
   - If the connection is not successful, you will see a label with a 'CONNECTION BAD' text next to the Test Connection button.
   - If the connection is bad, then there is a problem connecting to the directory server.

CTRL+SHIFT+F to search using Search Index (faster)

- Possible problems are wrong IP/server name or the system does not have DNS running / cannot resolve the IP address / server name.
- Once the Test Connection procedure indicates that the connection is good,

5. Select the type of directory server (either Microsoft Active Directory, Novell eDirectory, or orhter).

6. Press [Generate Defaults] button.
    - This should populate the Realm Name, Format, DN, Login Attribute, First Name Attribute, Last Name Attribute, and Group Attribute fields with default values for that directory server type.
    - If the directory type is MSAD, both the realm name and the DN should be populated. If the directory type is eDirectory, the realm name will be blank. If you are attempting to configure a directory server that is not MSAD or Novell eDirectory, the configuration will have to be done manually. You'll need to get the correct LDAP property information from the owner of the directory server.
    - If this is a non-MSAD, non-eDirectory server, or is a server with a non-default configuration, it is possible that you may need to change some properties manually. See below for a definition of all of the properties that you can configure.

7. Enter a username and password of a user that resides on the directory server.

8. Press [Login].
    - You will see login result information in the Login Results section on the bottom of the tab.
    - This will indicate if the login was successful or not.
    - Additionally, it will print out the First Name, Last Name, and any group memberships for the user. You may get a warning if First Name, Last Name, or Group Memberships were not found.
    - Getting this warning means 1 of two things:
    - The LDAP properties are mis-configured (i.e. First Name Attribute, Last Name Attribute, and/or Group Attribute)
    - The user doesn't have a First Name, Last Name, or any Group Memberships configured on the Enterprise directory server.
    - If you get these warnings, you may want to talk with the owner of the directory server to make sure you have everything set up correctly.
    - If the test login succeeded and you are satisfied with the first name, last name, and group membership information, then your Enterprise directory server is properly configured.

9. Press [Apply Configuration].
    - This makes the configuration changes. Just like other tabs in the Administration component, pressing Restore Configuration will undo any changed made that have not yet been applied.

Manual Configuration

As mentioned before, if you are connecting to a directory server that is not MSAD or Novell eDirectory, or the directory server you are connecting to has a custom configuration, you may need manually configure some of the properties. Here are definitions of all of the LDAP configuration properties and what they do.

- Format - This is either set to domain or dn. domain is the 'MSAD' way of doing LDAP authentication (i.e <userId>@<realm name>). dn is the other way of doing LDAP authentication, which eDirectory, and

CTRL+SHIFT+F to search using Search Index (faster)

most other directory servers use (i.e. loginAttribute=<userId>,<ldap base dn>). If you are connecting to a non-MSAD directory server, it's pretty safe to say that you should use dn.

- DN - This is the LDAP base DN of the LDAP server to which you are connecting. Usually this is the fully qualified domain name separated by a bunch of 'DC='. For example, if the fully qualified domain name of the directory server is 'example.com', it is likely that the DN will be 'DC=example,DC=com'.

- Login Attribute - This is the LDAP attribute that should be used for the unique identifier of the user. This is what they will use as their user id to login. On MSAD this is 'sAMAccountName, and on eDirectory, it is usually 'cn'. This should be set to whatever the directory server you are connecting to uses as a unique identifier.

- First Name Attribute - This is the LDAP attribute that should be used for the first name of the user.

- Last Name Attribute - This is the LDAP attribute that should be used for the last name of the user.

- Group Attribute - This is the LDAp attribute that should be used to find group memberships for the user. On MSAD, this is 'memberOf'.

Note: EA3 finds all instances of this attribute (not just the first, like it does for other attributes). So if a user belongs to more than one group, EA3 will find all memberships.

Note: Regarding LDAP parameter configurations, EA3 finds the first instance of the configured attribute for a user, except for Group Membership. So, if you configure the First Name attribute to be an attribute that is listed multiple times, EA3 will assume the first one found during an LDAP query is the correct First Name. For Group Membership, EA3 will find all instances of that attribute.

Field Highlighting for changes

No changes are saved to EA3 on the Administration page unless you press an 'Apply Configuration' button on the normal tabs or a 'Confirmation' button on a popup panel.

- For the 'Apply Configuration' buttons, when they are pressed, and successfully commit information to EA3, you will see a brief (5-second) label appear indicating that the changes have been saved. The same things happen when you Restore Configuration (e.g. after you made some changes and want to revert back and you haven't pressed 'Restore Configuration' yet.

Note: If you make changes on one tab (e.g. Application tab), and do not press Apply Configuration, and then you navigate to another tab, your changes will be lost. The next time you navigate to this tab, since the changes were never applied, you will see the old configuration. So, after making changes on a tab, but before navigating to a different tab, you must press Apply Configuration. Also, there are sometimes more than one Apply Configuration button on a given tab, so make sure you press the one associated with the data you changed (the buttons are grouped with the data they manage in a bordered panel).

To help the you understand what fields you may have changed, any changed fields are highlighted with green text / borders, and the Apply Configuration button that must be pressed in order to commit the changes. Below in Figure 5-43 is demonstrating field highlighting. You can see that several fields have changed, and you should press the Apply Configuration button.

Figure A-19 Highlighted Changes
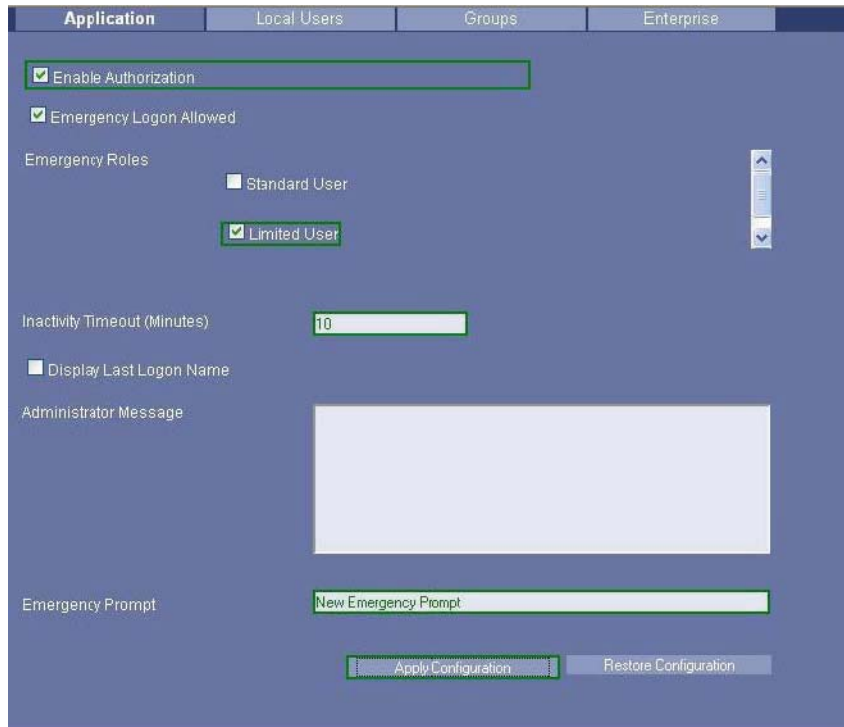
Appendix B: Specifications

Power

- Capable of 100-240V nominal, 50 /60 Hz operation
- System battery status display

System Battery

- Independent component power management and system battery charging algorithms to maximize usage time
- System Battery charge can take 90 typical exams on a single charge
- Maximum charge time of 4 hours to go from 10-100%

X-ray Tube

X-ray Source

- Heat Storage Capacity
  - Anode: TBD Joules (TBD heat units)
  - Tube Unit: TBD Joules (TBD heat units)
- Maximum Heat Dissipation Rate
  - Maximum anode heat units: TBD
  - Maximum Continuous Heat Dissipation: Without Air-circulator: 170W (238 HU/s)
- Focal Spot Sizes 1.3mm/0.6mm
- Target Angle 12.5°
- Anode Rotation Speed (minimal): 3200/min
- Maximum X-ray Tube Current
  - Large Focus: 500 mA
  - Small Focus: 200 mA
- Nominal Voltage (Radiographic): 40 to 150 kV
- Maximum Voltage:
  - Anode to Cathode TBD kVp rectified
  - Anode or Cathode to ground TBD kVp

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Tube Positioning

- The column may be rotated up to ± 270° from the park position
- Tube Angle display and SID measuring tool
- Maximum focal spot 200cm (78.7 in): Height
- Minimum focal spot 62.5cm (24.6 in): Height
- Vertical travel 137.6 cm (54.7 in)
- Minimum horizontal extension center of column rotation to centerline of tube: 70.6 cm (27.8 in)
- Maximum horizontal extension center of column rotation to centerline of tube: 111.8cm (44 in)
- Travel Range of at least 41.2 cm (16.2 in)

High-voltage generator

- Power (kW) 15 standard, 30 optional
- kVp: 50 to 125 in 24 steps (25% up, 20% down)
- mA: 300 maximum
- mAs: 0.2 to 630 in 35 steps
- Allowable tube voltage range deviation: TBD
- Less than 2% low frequency ripple
- Frequency: greater than 100 kHz
- Super resonant inverter with varying frequency
- Maximum exposure time 6 sec. for film/CR, digital exposures limited to 3.6 sec
- Minimum exposure time: 0.4 msec

Collimator

- A pair of independent collimator blades controls the x-ray field
- 180 lux (1000 (Lumen/mt2) light field lamp
- The collimator rotates +/-180 degrees with detents at -180, -90, 0, +90, and +180 degrees
- Full 43cm x 43cm (17 in) coverage at a 100 cm SID to accommodate Film/CR
- Accessory rail for use with optional Al or Cu spectral filters or optional DAP meter

Digital Detector

Physical Characteristics

- Single panel (non-tiled) amorphous silicon detector with a Cesium Iodide scintillator
- Detector battery can take up to 45 exposures per hour and provide enough power for 3 hours of use on a single charge
- Detector can support up to 150Kg (330 lbs) of distributed load for bariatric applications
- Includes 6:1 removable grid
- Includes QAP (Quality Assurance Procedure)
- Dimensions:
  – Length: 23.1 inch (580mm)
  – Height: 17.8 inch (452mm)
  – Thickness: 0.94 inch (24mm)
- Weight:
  – Detector: 4,309 g (9.5 lbs.)
  – Battery: 227g (0.5lbs.)
- Tether Length: 4m
- Image area: 40.4cm x 40.4cm (15.9inx15.9in)
- Active matrix: 2022 x 2022 pixels
- Image Depth TBD Bit
- Raw Image File Size: 8mb
- Pixel Pitch: 200 microns
- Typical Upper Dynamic Range: 7.8mR
- Typical DQE @ 0lp/mm: 68%

Communication

- Wireless point-to-point network between the system and detector for transferring image data
- Communication over wide 500MHz channels to achieve very high data rates
- Low output power to limit range to less than 10 meters to increase safety and spectrum reuse
- Designed to co-exist with 802.11 networks without interference
- Frequency: 3.168-4.752GHz. Uses Band Group 1.
- Max Power Output: -41.3dBm
- Max PHY Data rate: 480 Mbps
- Effective Throughput: 30-70 Mbps
- Standards: WiMedia PHY spec v1.2, WiMedia MAC spec v1.0, Certified Wireless USB spec v1.0

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User Interface

- Integrated 15 in (38.1 cm) touch-screen user interface
- Monitor matrix size 1024 x 768 pixels
- 250GB or greater for storage of more than ~30,000 uncompressed images
- Images can be stored on a CD with the included external CD drive
- USB outlets for external drive, barcode reader, service mouse and keyboard

Networking and DICOM

Worklist can be retrieved from HIS/RIS systems and images can be transmitted through the DICOM interface to printers, archival devices (PACS), servers or review workstations.

- RJ45 10/100/1000 Base T Ethernet port or optional 802.11 a/b/g/n wireless connection
- IHE and DICOM 3.0 compliant services:
    - DICOM IOD generated – DX
    - Image auto send/transfer –DX or CR (support multiple destinations)
    - DICOM storage – SCU
    - DICOM storage commitment SCP, when Fixed IP address is provided (programmable auto-delete function)
    - DICOM modality worklist for HIS/RIS – SCU (with programmable auto refresh)
    - DICOM grayscale print – manual and auto (with print layout options)
    - Multi-format printing
    - DICOM CD-R media exchange (DX only)
    - Verification of connectivity for SCU & SCP services
    - DICOM Modality Perform Procedure Step (MPPS) feedback to the HIS/RIS (SPS PPS) (configurable)
    - VOI LUT burn on send (configurable)

Please refer to DICOM conformance statement for complete definition of supported DICOM services

Drive

- Battery operated
- Self propelled single drive handle control
- Variable speed of up to 5 km/h (3.1 mph) forward and reverse, automatically adjusts to the operator's pace; variable to adjust to the operator's pace.
- Capable of climbing an incline of 7°

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Safety and Compliance

- RoHS Compliant
- Drive Inhibit keypad access for JCAHO compliance
- Password protected access to patient information for compliance with confidentiality regulations
- Automatic safety brake: Operator must press drive controls to allow system movement
- Integrated front bumper stops unit and activates brakes when activated

Mechanical Characteristics

- Overall Width 55.9cm/22in (Includes front bumper)
- Overall Height 194cm/76.4in
- Tube Height in Transport (lookover) 138.4cm/54.4in
- Length: 103.5cm/40.8in
- Overall Length 124.6cm/49.1in (includes handle)
- Weight: 499kg/1,100lbs

Environmental Conditions

System

Temperature	
Operating	+10° C to +35° C
Non-Operating System (except Detector)	-10° C to +45° C
Humidity	
Operating	30% to 75% RH, non-condensing (maximum change 30% per hour)
Non-Operating	25% to 85% RH, non-condensing (maximum change 30% per hour)
Altitude	
Operating	-30 m to +3,000 m relative to sea level
Non-Operating	-30 m to +3,000 m relative to sea level
Atmosphere Pressure	
Operating	106 kPa to 70.1 kPa
Non-Operating	106 kPa to 70 kPa
Audible Noise	
Operating	60 dBA maximum audible noise at any point 1 meter from system
Idle	50 dBA maximum audible noise at any point 1 meter from system

Digital Detector

Temperature	
Operating	+10° C to +35° C
Non-Operating	0° C to 50° C (maximum change 50° C per hour)
Humidity	
Operating	10% to 80% RH, non-condensing (maximum change 30% per hour)
Non-Operating	10% to 95% RH, non-condensing (maximum change 30% per hour)

Options

- 802.11 a/b/h/n - Wireless connectivity to hospital network
  - 802.11 a/b/g/n
  - Wi-Fi Certified
  - Compatible with:
    - 802.11i, Wi-Fi Protected Access 2 (WPA2), WPA
    - 802.1X
    - AES- TKIP
    - 64-, 128-WEP
    - VPN: IPSec –- IKE
    - Management Frame Protection (MFP)
  - EAP Types:
    - LEAP
    - LEAP + 128-WEP
    - LEAP + WPA
    - EAP-TLS
    - EAP-TTLS/MSCHAPv2
    - EAP-FAST
    - PEAP-GTC
    - PEAP/MSCHAPV2 EAP-SIM
- 30 kw Generator
  - Available 30 kW (nominal) option
- Dose Area Product Meter
- Spectral filters
- 8:1 Grids
- Barcode reader
- Repeat Reject Analysis software
  - Optional Repeat/ Reject Analysis tool allows classification and analysis of Repeated / Rejected exposures on the system
- Auto Protocol Assist software
  - Optional Auto Protocol Assist – matches procedure codes from MWL to select anatomy technique

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Appendix C: Messages On Display

Two kinds of messages can appear on the message display on the control cover: status messages and error messages.

Status messages simply inform you of the operating condition of the Definium AMX 700, and look something like this.

Figure C-1 Ready message

Another type of message, called an error message, may appear should a problem occur with the equipment. An error message looks something like this.

Figure C-2 Error message

Note that an error message includes an alphanumeric code, and will display one line at a time.

If an error message appears, follow these steps.

1. Try the function again. If the problem is corrected, and no error message is displayed, proceed as usual.

2. If the error message still displays, turn the unit OFF then back ON.

   ◆ Diagnostics or self-tests are quickly performed when the unit is turned back on.

   ◆ When diagnostics are complete, the following message displays:

   ERROR XXX
   OCCURRED WHEN
   THE UNIT WAS
   LAST OPERATED –
   PROCEED WITH
   ---CAUTION –

3. Now try the function once more. If the problem is corrected, and no error message is displayed, proceed as usual.

4. If the problem persists, call your service representative, and report the code and message shown on the display. This will prepare service for the type of problem encountered and the service required.

Table C-1 lists the status messages and provides a brief explanation of each one.

Table C-1 Status message descriptions

Status Messages	Description
AUTO CAL LIMIT	If this message displays, the unit is at its automatic calibration limit. A service call is recommended to ensure accurate technique and radiographic results. Exposures are not inhibited.
BATTERY TOO HIGH VOLTAGE RECOVERY IS REQUIRED	This message may appear when attempting to take a high technique exposure immediately after removing the unit from charge. Exposure is prevented. Operating the field lamp or driving theDefinium AMX 700 will assist in stabilizing the battery voltage so that the exposure may be made.
BATTERY TOO LOW	This message may appear when attempting to expose when only a few segments remain on the battery charge indicator. This means that the battery does not contain sufficient charge to make an exposure.
CHARGE REQUIRED	Exposure is prevented. Recharging the batteries will eliminate the message and allow exposures.
CHARGE COMPLETE	The charge process is complete, and the battery is fully recharged.
STANDBY	The unit is allowing usage for a maximum of 60 minutes (keyswitch is ON and the unit is plugged in).
CHARGING	The unit is charging.
DRIVES ONLY	All modes are disabled except drive. Service is required.
HEAT WAIT	No exposures can be taken while this message appears (The length of the delay will vary with the selected technique). This message displays while the tube anode is cooling.
kVp MAX	Displayed on the alphanumeric display any time an attempt is made to increase the kVp above125.
kVp MIN	Displayed on the alphanumeric display any time an attempt is made to decrease the kVp below 50.
LIGHT DISABLED FOR COOLING	If the field light is on for over 4 minutes, the light will be automatically turned off to prevent the collimator from overheating. You may activate the field light in about 5 minutes.
mAs MAX	Displayed on the alphanumeric display any time an attempt is made to increase the mAs above320 or above the acceptable energy limit for the x-ray tube anode. The acceptable heat limit is based on the kVp you selected. Note that the kVp setting will always take precedence over the mAs setting. That is, if the technique selected would generate too much x-ray tube heat, the maximum mAs will automatically decrease to permit the selected kVp.
mAs MIN	Displayed on the alphanumeric display any time an attempt is made to decrease the mAs below 0.40.

Status Messages	Description
READY FOR X-RAY	The prep cycle has successfully completed, and an exposure may be taken within the next 30 seconds. (If an exposure is attempted after 30 seconds, the prep cycle must be repeated.)
RECHARGE IMMEDIATELY X-RAY INHIBITED	The estimated usable battery capacity is near 0%. No more exposures may be taken. Although charge is too low to complete an x-ray exam, you'll have enough energy to drive the unit to a correctly rated wall outlet for recharge.
RECHARGE RECOMMENDED	The remaining battery capacity is approximately 10% or less.
RELEASE HANDLE	The Definium AMX 700 was moving faster than the drive motors allow. Release the Drive Handle to clear the message, and then continue with normal operation. This may happen if you push the Definium AMX 700 too hard when driving down a ramp.
RELEASE PREP SW	The prep switch is still depressed (five seconds after an exposure or beyond the 30-second timeout). If taking an exposure, repeat the prep cycle: 1) release the prep switch, and 2) when the message WAIT is no longer displayed, press to prep position again.
RESET AEC CNTROL	Reset the AEC controller. AEC is on, but not enabled. For Example: The (ON) light is flashing on the Automatic Exposure Control (AEC) unit. This indicates the paddle is not connected. Reset the AEC controller. The red reset (GEN) on the Automatic Exposure Control (AEC) unit is lit. This indicates the back-up time is too short. Reset the AEC controller.
REVERSE ONLY	Forward drive is prevented because the safety bumper is in contact with another object. Reverse the unit before proceeding.
TESTING COMPLETE	Power-up diagnostic testing is finished.
WAIT	Wait before taking another exposure. (Displayed when the tube anode has cooled, but before the battery has recovered from the previous exposure.) Although radiographs can be taken, because of low battery voltage they may not achieve the desired kVp technique accuracy.
WAIT/ACT-XX.X	After an AEC exposure the XX.X field will display the actual exposure mAs.
X-RAY DISABLED	This message appears if an attempt to make an exposure occurs while HEATWAIT is displayed.
X-RAY TUBE PARKED	No exposures can be taken with the x-ray tube in the park/transport position.
DETECTOR PARKED	Detector is in the holder. Exposures are inhibited
DIGITAL MODE	System Software is ready for Digital Radiography procedures
FILM MODE ONLY	System can only be used for film procedures

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Status Messages	Description
NO DIG, FILM ONLY	System malfunction and can only be used for film procedures
WAIT FOR DIGITAL	System software is being loaded. Wait for system to boot completely.
SHUTTING DOWN	System PC is shutting down
GOOD-BYE	System PC has shut down
NO DIG RESPONSE	Digital Radiography components are not responding.

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