User Manual

expert DC

Intraoral X-ray System

GENDEX
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Chapter 1 Introduction

System Components

The Gendex Expert DC consists of the following components:

Articulated Arm

The tubehead can be positioned with an extended reach.

The 8” (20cm) cone has a reach of:

- 59” (149cm)
- 69” (175cm)
- 79” (200cm)

The optional 12” (30cm) cone has a reach of:

- 55” (140cm)
- 65” (165cm)
- 75” (191cm)

Master Control Touch Panel

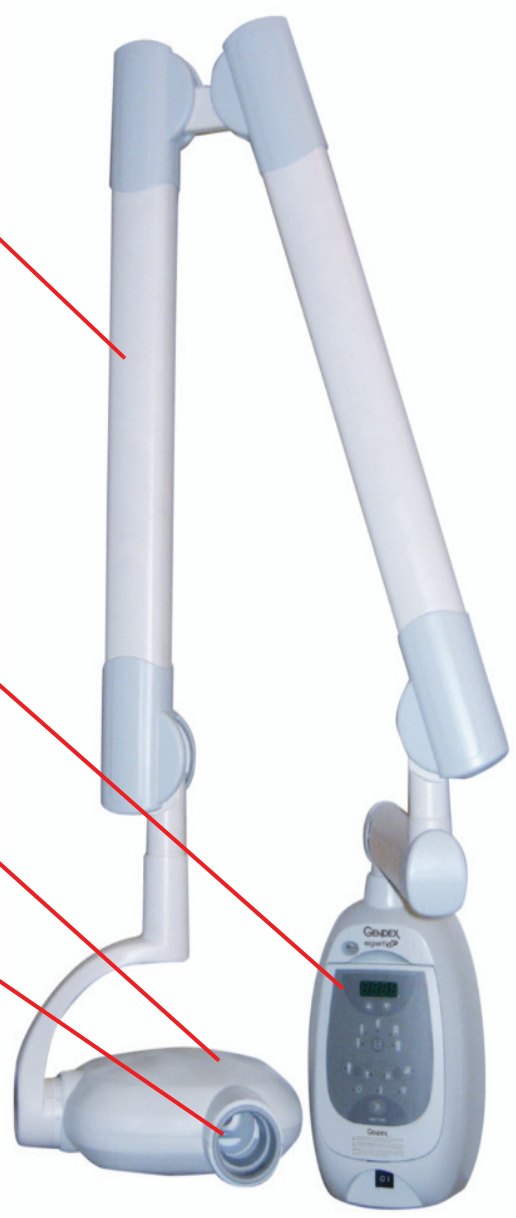
Allows the user to set specific exposure values based on the anatomical area and view system conditions.

Tubehead

- Focal spot indicated by raised features on cover
- Secondary operator controls

Cone

- Standard 8” (20cm) focal length
- Optional 12” (30cm)
- Optional – Rectangular 8” (20cm) or 12” (30cm)



Intended Use

The Gendex Expert DC is a high frequency X-ray system designed to produce gray scale intraoral images to film or digital receptors.

Users

This manual is intended for trained dental professionals and authorized Gendex Dealer Technical Representatives.

About This Manual

This manual provides information and instructions to enable users to operate the Gendex Expert DC in a safe and effective manner. Before operating the Gendex Expert DC, users must read this manual completely and adhere to all warnings and cautions described in this manual.

Service

Any user maintaining or servicing the Gendex Expert DC unit will void the warranty.

Gendex strongly recommends that only authorized Gendex dealers maintain and service the Gendex Expert DC.

Copyright

Chapter 2 Safety Items

This manual contains original instructions by Gendex Dental Systems for the safe set-up, use and maintenance of the Gendex Expert DC.

Safety

This system features continuous operation (stand-by mode). X-rays are emitted only when the exposure handswitch button is pressed.

With correct handling and installation, proper maintenance and servicing will ensure safe and efficient operation. The equipment must never be used if there are any electrical, mechanical, or radiation defects whatsoever.

Refer to the Installation Manual for the recommended maintenance activities (for example, checking wear and tear on cables, belts, and gears).

Modifications and additions to the equipment must be carried out only by personnel or third parties that are expressly authorized by, and must comply with the applicable legal requirements as well as with the generally accepted technical regulations.

Prior to operating the Gendex Expert DC, all laws, regulations, and preventative measures must be carefully read and addressed for the following conditions:

- Radiation
- Electrical
- Explosion
- Mechanical

Tubehead Leakage

The tubehead contains mineral insulating oil. Such oils are potentially harmful in case of ingestion or contact with skin or eyes. In case of a defect or fault, an oil leak can occur. Avoid direct contact with the oil and do not inhale its vapors. Call your local Service Representative to repair the problem.

In case of minor leaks, the oil can be wiped away with a dry cloth, wearing protective gloves and flush eyes with copious amounts of water.

Articulated Arm Leakage

The Articulated Arm contains grease. The grease is not harmful and proposes only a slight irritation risk in the unlikely event of contact with skin or eyes. In case of a defect or fault, leakage of grease can occur. Call your local Service Representative to repair the problem.

In case of minor leakage, the grease can be wiped away with soap and water and flush eyes with copious amounts of water.

Radiation Safety

X-ray equipment may cause injury if used improperly. The instructions contained in this manual must be read and followed when installing, servicing, or operating the Gendex Expert DC. The Expert DC provides a high degree of protection from unnecessary X-radiation. However, no practical design can provide complete protection, nor prevent operators from exposing themselves or others to unnecessary radiation. It is important that you become fully acquainted with applicable government radiation protection regulations. Many provisions of these regulations are based on the recommendations of the National Council on Radiation Protection and Measurements. Recommendations for dental X-ray protection are published in NCRP Report Number 35 available from NCRP Publications, 7910 Woodmont Ave., Suite 800, Bethesda, MD 20814, or at www.ncrp.com. Personal radiation monitoring and protective devices are available. You are urged to use them to protect against unnecessary X-radiation exposure.

Only qualified and authorized personnel may operate the equipment while observing all laws and regulations pertaining to radiation protection.

The operator must remain 6 ft. (2m) from the focal spot and the X-ray beam for operator protection. The operator must use all radiation protection devices, accessories, and procedures available to protect the patient and operator from radiation.

NOTE: The Gendex Expert DC Intraoral X-ray unit provides a high degree of protection from unnecessary radiation. However, no practical design can provide complete protection nor prevent operators from exposing themselves or others to unnecessary radiation.

All the safety and operating instructions should be read before the device is operated. Follow operating and use instructions.

Electrical Safety

Covers on the Gendex Expert DC equipment should only be removed by qualified and authorized service personnel.

The Gendex Expert DC must be used in areas that comply with all applicable laws and recommendations pertaining to electrical safety used for medical purposes (IEC, US National Electrical Code, or VDE standards concerning provisions of an additional protective earth (ground) terminal for power supply connection).

This equipment must always be electrically disconnected from the mains electrical supply before cleaning or disinfecting.

The Gendex Expert DC equipment is classed as ordinary medical equipment without protection against ingress of liquids. Water or any type of liquid cannot leak inside the Gendex Expert DC as it may cause corrosion and short-circuit the equipment.

Explosion Safety

The Gendex Expert DC must not be used in the presence of flammable or potentially explosive disinfecting gases or vapors, which could ignite causing personal injury and/or damage to the equipment. If such disinfectants are used, the vapor must be allowed to disperse before using the equipment.

Mechanical Safety

If complete safeguarding of the Gendex Expert DC is not possible, extreme care must be taken to ensure that no body part, especially fingers, or clothing of the operator or the patient can be trapped or injured by any part of the equipment. Make sure that fingers are not caught or pinched in the articulated arm when closing it.

Proper Disposal of Electronic Equipment

NOTE: The following information is valid in the European Union. If you wish to discard this product, please contact your local authorities or dealer and ask for the correct method of disposal.

This symbol on the products and/or accompanying documents means that used electrical and electronic products should not be mixed with general household waste.

For proper treatment, recovery, and recycling, please take these products to designated collection points where they will be accepted on a free-of-charge basis. Alternatively, in some countries, you may be able to return your products to your local retailer upon the purchase of an equivalent new product.

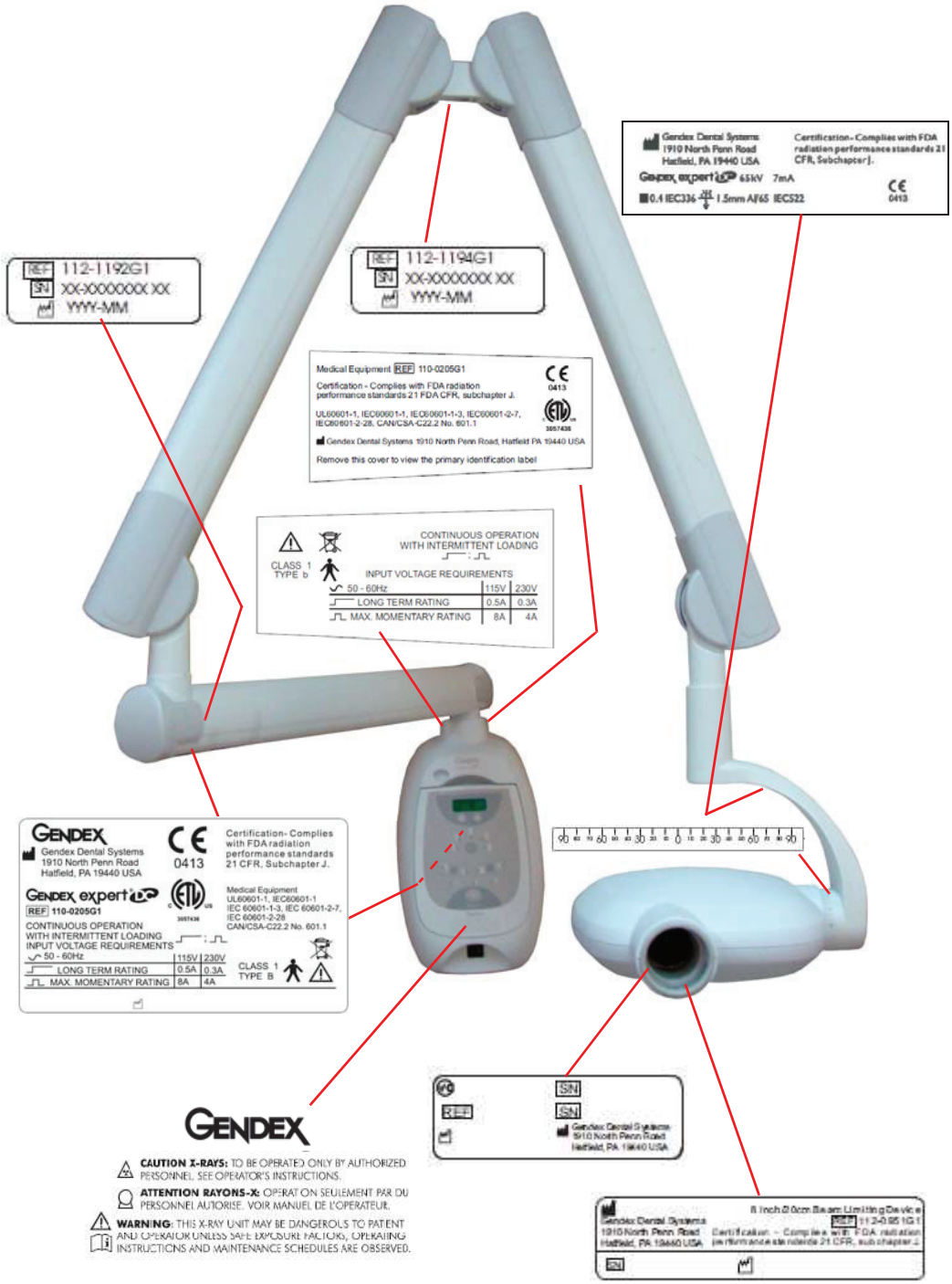
Disposing of this product correctly will help to save valuable resources and prevent any potential negative effects on human health and the environment which could otherwise arise from inappropriate waste handling.

Please contact your local authority for further details of your nearest designated collection point. Penalties may be applicable for incorrect disposal of this waste in accordance with national legislation.

NOTE: For Business users in the European Union
If you wish to discard electrical and electronic equipment, please contact your dealer or supplier for further information.

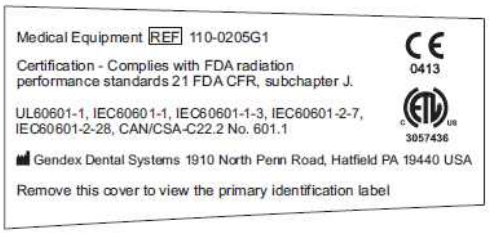
Location of Identification Labels

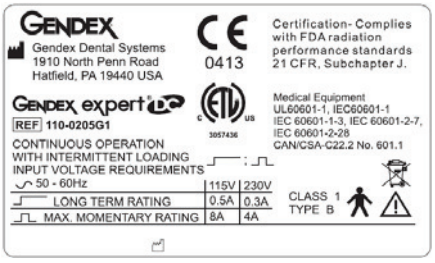
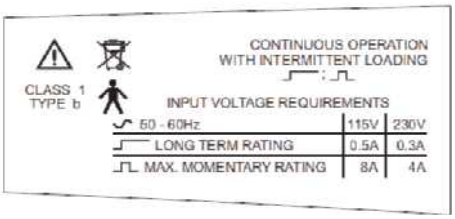
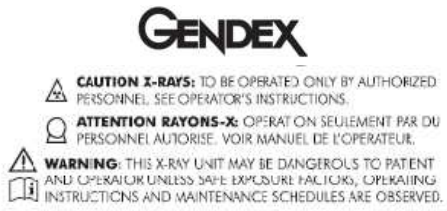
The Gendex Expert DC Tubehead, Master Control, and Cone have identification labels that specify the model number, serial number and applicable product approval listings. On specified components, subject to U.S. Government Radiation Performance Standards 21 CFR, Subchapter J, a certification statement is included with other required information.



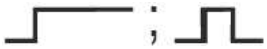
System Labels

The following labels are attached to the system.

Label	Description
	Medical Equipment REF 110-0205G1 Certification - Complies with FDA radiation performance standards 21 CFR, Subchapter J. UL 60601-1, IEC 60601-1, IEC 60601-3, IEC 60601-2-7, IEC 60601-2-28, CAN/CSA - C22.2 No. 601.1 Remove this cover to view the primary identification label.
	**Caution X-Rays:** To be operated only by authorized personnel. See operator's instructions. **Warning:** This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.
	8 inch/ 20 cm Beam Limiting Device Certification - Complies with FDA radiation performance standards 21 CFR, sub chapter J.

	Continuous Operation with the Intermittent loading input voltage requirements Long Term Rating Max. Momentary Rating Certification - Complies with FDA radiation performance standards 21 CFR, subchapter J. Medical Equipment UL 60601-1, IEC 60601-1, IEC 60601-3, IEC 60601-2-7, IEC 60601-2-28, CAN/CSA - C22.2 No. 601.1
	Class I Type B Continuous Operation with Intermittent Loading Input Voltage Requirements Long Term Rating Max. Momentary Rating
	**Caution X-Rays:** To be operated only by authorized personnel. See operator's instructions. **Warning:** This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.
	Certification - Complies with FDA radiation performance standards 21 CFR, Subchapter J.

	**IEC Label** Type B: Protection against electrical shock (IEC 60601-1)
	**Caution** Consult written instructions in this Manual.
	**Warning** This X-Ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed.
	**Warning** Electrical Hazard, Authorized Personnel only.
	**X-Ray Generator**
	**Recycle Label** Dispose of in accordance with your country's requirements. There is material in the system that must be separately collected and recycled in accordance with the European Waste Electrical and Electronic Equipment (WEEE) Directive.
	**Earth Ground**
L	**Mains Hot Wire**
N	**Mains Neutral Wire**
	**X-ray Emission**
REF	**Model Number/Revision**
SN	**Serial Number**

	Manufactured Date
	Manufactured Location
	Tube Head
	Continuous; Intermittent

Compliance with Applicable Standards

The Gendex Expert DC is ETL Class 1 Type B equipment (UL60601-1).

The Gendex Expert DC complies with the following standards:

- General (electrical/mechanical) safety:
- UL60601-1 File Number: 3191665BOX-002
- Medical Equipment with respect to electrical shock, fire and mechanical hazards only in accordance with UL60601-1, IEC60601-1, CAN/CSA C22.2 NO,601.1-M90, and to the following particular standards, IEC60601-2-7 IEC60601-2-28, IEC 60601-1-2.
- Radiation protection IEC60601-1-3 Radiation protection/X-ray equipment.

The certified components of the Gendex Expert DC system comply with Radiation Performance Standards 21 CFR, Subchapter J, at the time of manufacture.

WARNING

The equipment must be installed and operated in accordance with the safety procedures and operating instructions given in this manual and in the Gendex Installation Manual for the purposes and applications for which it was designed.

The equipment must only be installed, and operated in accordance with the safety procedures and operating instructions given in the Operator's Manual and in this Installation Manual for the purposes and applications for which it was designed.

Modifications and/or additions to the equipment may only be carried out by Gendex or by third parties expressly authorized by Gendex to do so. Such changes must comply with legal requirements as well as with the generally accepted technical rules.

It is the responsibility of the user to ensure that existing legal regulations regarding installation of the equipment with respect to the building are observed.

Chapter 3 Master Control

The Gendex expert DC Master Control Touch Panel contains a microprocessor. The microprocessor enables and controls exposure values for film and digital imaging receptors.

This chapter presents the following sections:

- Master Control Function
- Setup
- Operation
- Customize Settings
- Default Exposure Values (Anatomical Exposure Times) Tables

Master Control Function

The Gendex expert DC Master Control Touch Panel provides the following function:

- Preset anatomical time settings
- Single button selection for patient type
- Single button selection for film or digital imaging receptor
- Customization capability

Preset anatomical time settings allow the user to choose technique values corresponding to imaging type, anatomical area, or patient type selections.

The anatomical time settings are based on the following criteria:

- Media type exposure time – Film speed (SP) D, E, F or digital imaging PhotoStimulable Phosphor System (PSP) – digital D1; Charged Coupled Device (CCD) or Complementary Metal Oxide Semiconductor (CMOS) Systems – D2
- Intraoral anatomy area – Incisor, Bicuspid, Bitewing, Lower Molar, Upper Molar
- Patient type – adult or child

The values (exposure times with associated intraoral anatomy areas) are preset at the Gendex factory. The factory default settings are indicated (an LED light appears next to each default selection) on the master control touch panel when the touch panel is initially turned on for normal operation.

The default settings or standard factory configuration consists of the following: standard 8” (20cm) focal length cone, bitewing anatomical section, and film media for an adult patient. For all other exposure times, the Gendex Factory Default Time Tables are provided in this chapter.

The standard factory configuration presets can be changed from D-speed film to E-speed or F-speed film, from film to digital, from adult to child, or to a different type of digital imaging system. The standard cone can also be changed to the optional 12” (30cm) cone.

Gendex Factory Defaults

Default Feature	Factory Default Configuration	Can the default setting be changed? Yes/No	Comment
Cone	8” (20cm)	Yes	The 8” (20cm) cone is the standard cone for the Gendex expert DC. The cone can be changed to an optional 12” (30cm) cone or to the optional rectangular 8” (20 cm) and 12” (30cm) cones. The optional, longer 12” (30cm) cone is used to sharpen the X-ray image if the paralleling technique is used. The rectangular cone is used to reduce the X-ray field size to that of the film. Also, the rectangular cone helps reduce radiation to the patient.
Film	D-speed	Yes	The default D-speed film can be changed to E or F-speed film. If film will not be used, the digital option is available.
Patient Type	Adult	Yes	The default adult type patient can be changed to the child patient type.
Anatomy Setting/ Anatomical Exposure Time	Bitewing	Yes	The default bitewing setting can be changed to one of the following selections: • Incisor • Bicuspid • Bitewing • Lower Molar • Upper Molar

Touch Panel

The master control touch panel consists of the following features and functionality:

Exposure Time Display
Displays the anatomical exposure time and system information

Time Selector
Adjust the anatomical exposure time to a specific value. The time up arrow and the time down arrow allows the user to override the anatomical exposure time.

Anatomy Selection (Anatomical Time Selector)
Select desired tooth area. When selected, the unit displays the anatomical exposure time for the area.

Patient Selector
Toggle to select an adult or a child patient. Depending on the selection made, the unit modifies the anatomical exposure time.

Imaging Type Selector
Toggle to select between the use of film or a digital imaging receptor. The unit modifies the anatomical exposure time to suit.

Ready Indicator Lamp
Indicates the On switch was pushed and the unit is ready for operation.

Radiation Indicator Lamp
Warning light illuminates when exposure button is pressed and X-ray radiation is being produced.

Cool Down Indicator Lamp
Warning light. Illuminates when the tubehead becomes heated; indicating that the tubehead needs to cool before the next exposure can be taken.

Push-Button Exposure Switch
Activates an exposure on Master Control touch panel.

On/Off Power Switch
Switching ON/OFF power to the unit. The Ready Indicator Lamp on the master control touch panel indicates that the unit is ready for use.

Coil Exposure Switch
(Not Shown): Exits the operatory and then activates an exposure.

Quickset™ Tubehead Control
Select the anatomical exposure times directly at the tubehead. Also, select the patient type. The selections are indicated according to the corresponding LED light.

Setup

Before operating the Gendex expert DC, you must make the appropriate selections on the master control touch panel. Refer to the Default Exposure Values (Anatomical Exposure Time) Tables in this chapter.

NOTE: The default anatomical exposure times, shown in the Default Exposure Values (Anatomical Exposure Time) Tables, are the factory designated exposure values. Recommended Occlusal image exposure times are also shown in the tables. While there is no setting shown on the master control touch panel for Occlusal images, you can manually set exposure values for Occlusal images by pressing the time up or time down arrows on the touch panel.

Setting Values on Touch Panel

To set up the master control touch panel, follow the procedure.

1. Switch the On/Off power switch to the On position. A green indicator light appears next to the Ready Indicator Lamp on the front of the master control touch panel when the unit is ready for exposure operation.

NOTE: The anatomical exposure time default (the time displayed when the unit is initially turned on) automatically appears on the display.

2. Select the media type (film or digital); press the Imaging Type Selector between the film and computer icons to toggle to the desired media. A green indicator light appears next to the film or digital icon you selected.
3. Select the patient type (adult or child); press the Patient Selector between the adult and child icons to toggle to the desired patient type. A green indicator light appears next to the adult or child icon you selected.
4. Select the anatomical area (incisor, bicuspid, lower molar, upper molar or bitewing); press the Anatomical Time Selector in the center of the anatomy

area to toggle to the desired anatomy you wish to X-ray. A green indicator light appears next to the anatomical section you selected.

5. Check the Exposure Time Display.
    a. If you require a different exposure setting than the factory default value displayed, press the time up or time down arrows on the master control touch panel to change/override the factory setting.
    b. If the factory default value matches the desired anatomical exposure time, proceed to the Operation section.

Operation

CAUTION

If the Cool-Down Indicator Lamp illuminates during normal operation, then the Gendex expert DC tubehead is heated and needs to cool down before an X-ray exposure can be taken.

1. Position the tubehead and cone to the patient using standard accepted positioning procedures.

WARNING

Use extreme care when adjusting the articulated arm to avoid placing your fingers in areas where they may be potentially pinched while you are moving the arm. Also, do not allow the tubehead to hit the wall after returning the arm to the storage position.

2. Use the Quickset Tubehead Control to verify or modify the anatomical exposure settings.
3. When you are ready to take an X-ray, exit the operatory.

CAUTION

In order to comply with regulations and good safety practices, the technique factors must be visible to the operator.

4. Press and hold the Coil-Cord Switch or Push-Button Exposure Switch until the audible signal and X-ray exposure indicator light terminates. While the X-ray

is being emitted, a yellow indicator light appears next to the Radiation Indicator Lamp on the master control touch panel.

NOTE: If you release the Coil-Cord Switch or Push-Button Exposure Switch prior to the completion of an exposure, the process will immediately terminate with a partial exposure; the Exposure Time Display will display an error code (Err0). Press any key, except the Exposure Switch, on the master control panel to clear the error.

5. When the audible signal and X-ray exposure indicator light terminates, return to the operatory and move the tubehead and cone away from the patient.
6. Follow local practices to view and read film or digital X-ray images.

Customize Master Control Settings

The factory default settings can be customized.

Change Default Settings for Film or Digital Speed

You can change the default D-speed film (SP1) to E-speed (SP2) or F-speed (SP3) film, or to digital (PSP digital receptor - D1 or CCD or CMOS digital receptor - D2). The following table captures the film and digital choices to produce quality X-ray images.

Displayed on LED	Speed	Media Output	Film and Digital Exposure Times for the Bitewing (Default)
SP1 SP2 SP3	D E F	Film	0.320 0.200 0.125
D1 D2	PSP CCD or CMOS	Digital	0.160 0.080

NOTE: Refer to the Default Exposure Values (Anatomical Exposure Settings) Table in this chapter.

When a different film or digital speed is selected, the unit automatically uses exposure times associated with the new selection.

Prerequisite

Before changing film or digital speed, make sure the unit is turned off.

Change to E-Speed

1. Press and hold the Anatomical Time Selector then turn the On/Off power switch to the On position. The film or digital icon will be flashing and the LED will display SP1, SP2, SP3, D1, or D2. An SP or D setting confirms that the unit is in the media type programming menu.
   a. If the film icon indicator is flashing, no selection is required.
   b. To change to a different media type, press the Imaging Type Selector to toggle to the film icon.

NOTE: When changing the media type, you must quickly press the Imaging Type Selector. If there is no keypad activity for 30 seconds, the unit will not remain in the programming mode, changes will not be saved, and the unit will return to normal operation

2. Press the time up or time down arrows until the LED displays SP2. The SP2 setting confirms that the unit is now set for E-speed film.
3. Press the Anatomical Time Selector again to store the new setting. The new time, 0.200 seconds, will be displayed for the bitewing, (the default anatomical selection).

Change to F-Speed:

1. Press and hold the Anatomical Time Selector then turn the On/Off power switch to the On position. The film or digital icon will be flashing. An SP or D setting confirms that the unit is in the media output programming menu.
   a. If the film icon indicator is flashing, no selection is required.
   b. To change to a different media type, press the Imaging Type Selector to toggle to the film icon.

2. Press the time up or time down arrows until the LED displays SP3. The SP3 setting confirms that the system is now set for F-speed film.

3. Press the Anatomical Time Selector again to store the new setting. The new time, 0.125 seconds, will be displayed for the bitewing, (the default anatomical selection).

Change to Digital D1

NOTE: When the digital icon is selected, the system automatically uses exposure times associated with digital D1 or D2.

1. Press and hold the Anatomical Time Selector then turn the On/Off power switch to the On position. The film or digital icon will be flashing. An SP or D setting confirms that the system is in the media output programming menu.
   a. If the digital icon indicator is flashing, no selection is required.
   b. To change to a different media type, press the Imaging Type Selector to toggle to the digital icon.
2. Press the time up or time down arrows until the LED displays D1. The D1 setting confirms that the system is now set for digital imaging.
3. Press the anatomical time selector again to store the new setting. The new time, 0.160 seconds, will be displayed for the bitewing, (the default anatomical selection).

Change to Digital D2

1. Press and hold the Anatomical Time Selector then turn the On/Off power switch to the On position. The film or digital icon will be flashing. An SP or D setting confirms that the system is in the media type programming menu.
   a. If the digital icon indicator is flashing, no selection is required.
   b. To change to a different media, press the Imaging Type Selector to toggle to the digital icon.
2. Press the time up or time down arrows until the LED displays D2. The D2 setting confirms that the system is now set for a CCD or CMOS type digital imaging receptor.
3. Press the anatomical time selector again to store the new setting. The new time, 0.080 seconds, will be displayed for the default bitewing, (the default anatomical selection).

Change Default Power On Option from Adult Patient to Child Patient

When the Gendex expert DC is first turned on, the adult patient is the default patient type. If desired, the unit can be modified to automatically select the child patient as the default patient type.

To change the factory default, follow the procedure.

NOTE: When a patient type is specified by the user, the unit automatically uses the corresponding exposure time value for the selected patient.

1. Switch the On/Off power switch to the On position. The Ready Indicator Lamp on the front of the
master control touch panel will be lit.
2. Press the Patient Selector until the green light is lit next to the child option.
3. Turn off the Gendex expert DC. The unit will automatically select the child patient option when it is turned on again.

NOTE: The last patient type selected during normal operation will be the default selection at the next startup.

Modify Unit for Optional 12” (30 cm) Cone

The default exposure time values for specific anatomy areas are set at the factory for the 8” (20 cm) cone. These values must be changed if the 12” (30 cm) cone is used.

The exposure times for the 12” (30 cm) cone can be selected by changing an internal electrical setting. However, the modification can only be performed by an authorized Gendex Dealer Technical Representative. Contact your authorized Gendex Dealer Technical Representative to change the 8” (20 cm) cone to a 12” (30 cm) cone.

Default Exposure Values (Anatomical Exposure Setting) Tables

This section presents the default exposure time values for specific anatomy areas (bitewing, lower molar, upper molar, incisor, and bicuspid). Most values have been preset into the Gendex expert DC master control touch panel.

Occlusal exposure values are also shown in separate tables. While there is no setting shown on the master control touch panel for Occlusal exposures, you can manually set the exposure values for Occlusal exposures by pressing the time up or time down arrows on the touch panel.

SP1: D-Speed Film

Anatomy Selected	8“ (20cm) Cone		12“ (30cm) Cone	
	Adult	Child	Adult	Child
Bitewing	0.320 second	0.160 second	0.630 second	0.320 second
Lower Molar	0.320 second	0.160 second	0.630 second	0.320 second
Upper Molar	0.400 second	0.200 second	0.800 second	0.400 second
Incisor	0.200 second	0.100 second	0.400 second	0.200 second
Bicuspid	0.250 second	0.125 second	0.500 second	0.250 second

SP2: E-Speed Film

Anatomy Selected	8“ (20cm) Cone		12“ (30cm) Cone	
	Adult	Child	Adult	Child
Bitewing	0.200 second	0.100 second	0.400 second	0.200 second
Lower Molar	0.200 second	0.100 second	0.400 second	0.200 second
Upper Molar	0.250 second	0.125 second	0.500 second	0.250 second
Incisor	0.125 second	0.063 second	0.250 second	0.125 second
Bicuspid	0.160 second	0.080 second	0.320 second	0.160 second

SP3: F-Speed Film

Anatomy Selected	8“ (20cm) Cone		12“ (30cm) Cone	
	Adult	Child	Adult	Child
Bitewing	0.125 second	0.063 second	0.250 second	0.125 second
Lower Molar	0.125 second	0.063 second	0.250 second	0.125 second
Upper Molar	0.160 second	0.080 second	0.320 second	0.160 second
Incisor	0.080 second	0.040 second	0.160 second	0.080 second
Bicuspid	0.100 second	0.050 second	0.200 second	0.100 second

Recommended Occlusal Image Exposure Times for Film Receptors

Film Speed	8“ (20cm) Cone		12“ (30cm) Cone	
	Adult	Child	Adult	Child
SP1: D Speed	0.500 second	0.250 second	1.00 second	0.500 second
SP2: E Speed	0.320 second	0.160 second	0.630 second	0.320 second
SP1: F Speed	0.200 second	0.100 second	0.400 second	0.200 second

D1: Digital (PSP Plate Receptors)

Anatomy Selected	8“ (20cm) Cone		12“ (30cm) Cone	
	Adult	Child	Adult	Child
Bitewing	0.160 second	0.080 second	0.320 second	0.160 second
Lower Molar	0.160 second	0.080 second	0.320 second	0.160 second
Upper Molar	0.200 second	0.100 second	0.400 second	0.200 second
Incisor	0.100 second	0.050 second	0.200 second	0.100 second
Bicuspid	0.125 second	0.063 second	0.250 second	0.125 second

D2: Digital (CCD or CMOS Type Receptors)

Anatomy Selected	8“ (20cm) Cone		12“ (30cm) Cone	
	Adult	Child	Adult	Child
Bitewing	0.080 second	0.040 second	0.160 second	0.080 second
Lower Molar	0.080 second	0.040 second	0.160 second	0.080 second
Upper Molar	0.100 second	0.050 second	0.200 second	0.100 second
Incisor	0.050 second	0.025 second	0.100 second	0.050 second
Bicuspid	0.063 second	0.032 second	0.125 second	0.063 second

Recommended Occlusal Image Exposure Times for Digital Receptors

Digital Receptor	8“ (20cm) Cone		12“ (30cm) Cone	
	Adult	Child	Adult	Child
D1: PSP Plate Receptors	0.250 second	0.125 second	0.500 second	0.250 second

Chapter 4 System Operation

Operating the Device

CAUTION

If the Cool-Down Indicator Lamp illuminates during normal operation, then the Gendex Expert DC tubehead is heated and needs to cool down before an X-ray exposure can be taken.

1. Position the tubehead and cone to the patient using standard accepted positioning procedures.

WARNING

Use extreme care when adjusting the articulated arm to avoid placing your fingers in areas where they may be potentially pinched while you are moving the arm. Also, do not allow the tubehead to hit the wall after returning the arm to the storage position.

2. Use the Quickset Tubehead Control to verify or modify the anatomical exposure settings.
3. When you are ready to take an X-ray, exit the operatory.

CAUTION

In order to comply with regulations and good safety practices, the technique factors must be visible to the operator.

4. Press and hold the Coil-Cord Switch or Push-Button Exposure Switch until the audible signal and X-ray exposure indicator light terminates. While the X-ray

is being emitted, a yellow indicator light appears next to the Radiation Indicator Lamp on the master control touch panel.

NOTE: If you release the Coil-Cord Switch or Push-Button Exposure Switch prior to the completion of an exposure, the process will immediately terminate with a partial exposure; the Exposure Time Display will display an error code (Err0). Press any key, except the Exposure Switch, on the master control panel to clear the error.

5. When the audible signal and X-ray exposure indicator light terminates, return to the operatory and move the tubehead and cone away from the patient.
6. Follow local practices to view and read film or digital X-ray images.

Chapter 5 Additional Customized Film and Digital Options

The Gendex Expert DC Master Control Touch Panel provides the user with the capability to expand film and digital options. The user can set and maintain custom anatomical presets for film and for digital imaging.

This chapter presents the following sections:

- Additional Film and Digital Customization
- Default Exposure Values for Customized Film and Digital Settings (Anatomical Time Setting)
- Restoring Customized Anatomical Exposure Times to Factory Default Values
- Error Conditions

Additional Film and Digital Customization

To customize the preset film or digital options, follow the procedure.

NOTE: You will need to refer to the Default Exposure Values for Customized Programmable Film and Digital Settings (Anatomical Time Setting) in this section in order to input the recommended custom settings.

Prerequisite

Before you change film or digital speed, make sure the unit is turned off.

1. Press and hold the Anatomical Time Selector and the Imaging Type Selector then turn the On/Off power switch to the On position.

2. Release the Anatomical Time Selector and the Imaging Type Selector switches. The LED display will show the current exposure time and you will see the flashing lamps next to the Anatomical Time Selector, Imaging Type Selector, and the Patient Selector. The flashing lights indicate that the unit is in the customized programming mode.
3. The film or digital icon will be flashing.
   a. If the correct film or digital icon is illuminated or flashing, no selection is required.
   b. To change to a different media, press the Imaging Type Selector to toggle to the film or digital icon.

NOTE: If there is no keypad activity for 30 seconds, the unit will not remain in the programming mode, changes will not be saved, and the unit will return to normal operation.

4. Select the anatomical type and the patient type you wish to set.

5. Using the time up or time down arrows, set the exposure value until the desired value is displayed for the anatomical setting, the patient type, and the imaging type you selected.
6. To set additional custom values for anatomical, patient, and imaging values, repeat steps 1 – 5.
7. To exit the programming mode, press the Anatomical Time Selector and then the Imaging Type Selector together to exit and return the unit to operation.

NOTE: The imaging type startup default will be the last selected media output when the programming mode was exited. The patient type default will be the last selected patient type.

Default Exposure Values for Customized Programmable Film and Digital Settings (Anatomical Time Setting)

This section presents the default values for specific anatomical areas (bitewing, lower molar, upper molar, incisor and bicuspid) using custom film and digital imaging options.

Customized Film Factory Setting*

Anatomy Selected	Any Size Cone	
	Adult	Child
Bitewing	0.125 second	0.063 second
Lower Molar	0.125 second	0.063 second
Upper Molar	0.160 second	0.080 second
Incisor	0.080 second	0.040 second
Bicuspid	0.100 second	0.050 second

Customized Digital Factory Setting*

Anatomy Selected	Any Size Cone	
	Adult	Child
Bitewing	0.080 second	0.040 second
Lower Molar	0.080 second	0.040 second
Upper Molar	0.100 second	0.050 second
Incisor	0.050 second	0.025 second
Bicuspid	0.063 second	0.032 second

*Note: Settings are only applicable until they are changed by user selected values from 0.02s to 2.00s

Restoring Anatomical Factory Default Values

To restore the factory default values, follow the procedure.

1. Turn off the Gendex Expert DC.
2. Press and hold the Anatomical Time Selector, the Patient Selector, and the Imaging Type Selector then turn the On/Off power switch to the On position. The LED display and the selector lamps will flash for 5 seconds then function will return to the normal operating mode. The unit will be restored to the factory default values.

Error conditions

The Gendex Expert DC Master Control Touch Panel provides the user with the capability to manage some error conditions.

The green Ready lamp, amber Cool-down lamp and digital Exposure Time Display on the front of Gendex Expert DC Master Control Touch Panel can provide indications that errors have occurred. The following chart provides an explanation of what the indicators mean and the action that is needed to address the condition.

Error Condition Table

Condition	Explanation	Action Required
The amber Cool-down Indicator Lamp comes on and exposure cannot be made	Normal operation by design. Cool-down lamp comes on if too many exposures are made in a short period of time. This feature protects and extends the life of the tubehead.	Wait until lamp goes out; indicates that the tube has properly cooled down.
Err0 flashes on the Exposure Time Display	The exposure has been terminated prematurely. This can be caused by an equipment malfunction or the operator releasing the exposure switch prior to the end of the exposure time selected.	Pressing any key except the exposure switch on the master control touch panel will clear the display and restore normal operation. Care must be taken to press and hold the exposure button until the exposure is finished.
Err1 flashes on the Exposure Time Display	Power Supply voltage was outside of required range: 108V – 132V 198V – 253V	Wait until line voltage returns to normal (indicated by the return to normal display rather than error indication) or have a qualified electrician check the power line.
Err2 is displayed on the Exposure Time Display	Power Supply voltage dropped below the minimum requirement (108V or 198V) during the exposure. The exposure is not terminated but X-ray output may be low.	Pressing any key on the master control touch panel will clear the flashing and restore normal operation. If the problem persists, it is strongly recommended that a qualified electrician check the power line.

Condition	Explanation	Action Required
Err3 flashes on the Exposure Time Display	A hardware fault has occurred.	Reset the unit by turning Off the power switch for 30 seconds and then turning On the power switch. If the problem persists, contact your authorized Gendex Dealer Technical Representative.
Err4 flashes on the Exposure Time Display	A fault has occurred and terminated the exposure.	Pressing any key except the exposure switch on the master control touch panel may clear the Error and restore normal operation. If the problem persists, contact your authorized Gendex Dealer Technical Representative.

Chapter 6 Maintenance

To ensure a safe and functional Gendex Expert DC product, a maintenance program must be established. It is the owner's responsibility to arrange for maintenance service and to ensure that the personnel performing the maintenance are fully qualified to service Gendex Expert DC equipment.

This chapter presents the following sections:

- Equipment Maintenance
- Cleaning

Equipment Maintenance

Calibration and function checks must be performed on the Gendex Expert DC at installation and on a yearly basis. The calibration and function checks are listed in the System and Function Checks section of the Gendex Expert DC Installation manual supplied with the product.

Gendex recommends that cleaning and general maintenance be performed on the Gendex Expert DC on a routine basis.

WARNING

To avoid any potential hazard or danger to operators and patients, contact your authorized Gendex Technical Representative immediately if you experience any unusual operation, mechanical issues, or equipment malfunction.

Cleaning

WARNING

To protect against electrical shock, before cleaning, electrically disconnect the equipment from the mains electrical supply.

The Gendex Expert DC can be cleaned with a damp cloth.

Chapter 7 System Specifications

This chapter presents specifications for the Gendex Expert DC.

Cooling and duty rating specification apply at altitudes up to 12,000 ft. (3,600 m), average relative humidity not exceeding 90 percent, and maximum ambient temperature not exceeding 104 degrees F (40 degrees C).

This chapter presents the following sections:

- Tubehead Specifications
- Cone Specifications
- Power Supply Requirements
- Accuracy of Technique Factors
- Intraoral X-Ray Tube Housing (Product Data Sheet)

Tubehead Specifications

The tubehead specifications consist of the following:

Maximum Rated Tube Potential:	65 kV at 7 mA tube current.
Leakage radiation in the loading state:	Less than 250 micro Gy/h at 1 meter from the focal spot.
Minimum permissible first Half Value Layer (IEC 60601-1-3 (1993)):	1.5 mm Aluminum equivalent
Nominal Focal spot size:	0.4 mm (IEC 336/1993)
Anode angle:	12.5 degrees
Anode heat storage:	7 kHU
Duty cycle:	1:30

Cone Specifications

The cone specifications consist of the following:

1. X-ray Field Size: Containable in a 6 cm diameter circle, measured at the distal end of the installed cone.
2. Distance from the focal spot to the distal end of the cone is: 8” or 12“ (20 or 30 cm).

Power Supply Requirements

The power supply requirements are presented in the following table:

Nominal	Tolerance	Useful Range
120 VAC	± 10%	108 - 132 VAC
230 VAC	+ 10%, -14%	198 - 253 VAC

NOTE: If the line voltage falls outside the range, proper operation may be jeopardized. Contact an electrical contractor in your area.

Accuracy of Technique Factors

The power supply requirements are presented in the following table:

Tube Potential	65 kV ± 3 kV
Current	7mA ± 5%
Time	.02 -.50 Seconds ± .005 Seconds .63 - 2.00 Seconds ± 1%

Intraoral X-ray Tube Housing

The Gendex Expert DC housing is designed to operate with the Gendex insert. The housing has been designed to operate on the Gendex Expert DC high frequency high voltage control, making up the Gendex Expert DC Intraoral Dental X-ray system.

Physical Specifications

Shockproof Housing: Zinc, hermetically sealed under vacuum with high dielectric insulating oil. Inherent to the housing is an expansion chamber designed to provide adequate compensation for the full temperature range.

Operating Temperature: +50°F to 100°F (+10°C to +40°C)

Storage Temperature: -40°F to 160°F (-40°C to +70°C)

Inherent Filtration:

Material	Thickness/mm.		AHE[1]/mm.	Al. Equivalent	
	Min.	Max.	65kV	Min.	Max.
Glass	1.2	1.6	0.51	0.62	0.82
Insulating Oil	4.5	5.7	0.08	0.36	0.46
Polycarbonate	19.1	19.6	0.09	1.72	1.77
			TOTAL	**2.70**	**3.05**

Radiation Output: Technique 65kV, 7mA, 0.50sec. Source to Detector Distance 229mm (9") 410mR ±125mR (3.55 mGy ± 1.05 mGy)

Typical Half Value Layer: At 65kV 1.9mm Aluminum

Leakage Radiation: Complies to IEC 60601-1-3 IEC Section 29.204 "Leakage Radiation". Maximum continuous power input equals 1,400 heat units per min. (HU/Min.) tube is the limiting factor. HU/Min. = (kV) x (mA) x (1.4) x (Exp. Time (sec) / 60) 1,400 HU/Min. = 65 kV x 0.27mA x 1.4 x 60 sec.

X-ray Coverage: The insert target angle is 16°

- Circular cone at 8 inches (200 mm) SSD[2] 60 mm Dia. +0, -3mm.
- Circular cone at 12 inches (300 mm) SSD[2]60 mm Dia. +0, -3mm.
- Rectangular cone at 8 inches (200 mm) SSD[2] 36mm x 46mm.

[1] AHE Aluminum Half value Equivalent correlation

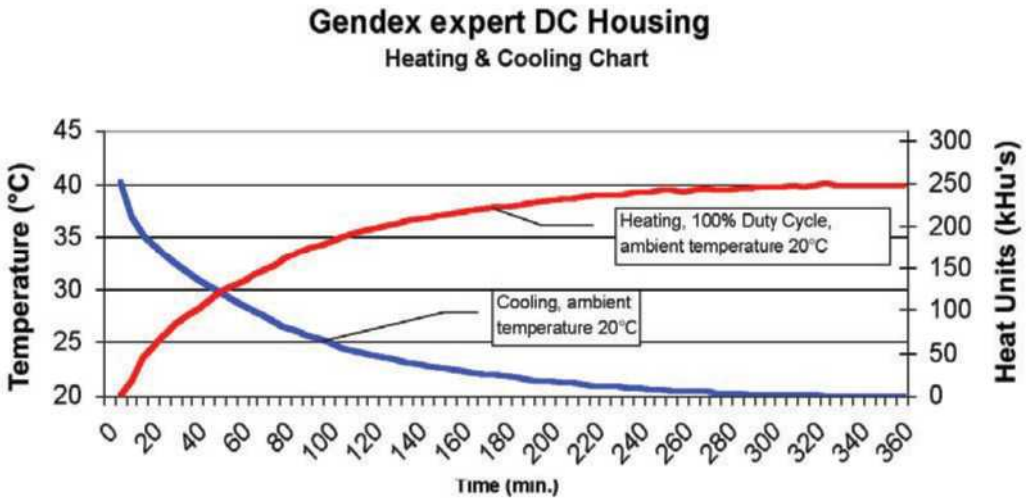
[2] SSD Source to Skin Distance

Weight:	13.0 lbs.	5.9 kg.
Maximum Head Voltage:	Anode to Cathode	65 kV
	Anode to Ground	70 kV

Thermal Characteristics:

- Housing Heat Storage Capacity 250 kHU's (177J)(see graph for more detail)
- Maximum Cooling Rate 3.3 kHU's/Min.

Heat Units = (kV * mA * time in seconds * 1.4)



Chapter 8 Compliance with Applicable Standards

The Gendex Expert DC, classified as Medical Electrical Equipment, requires special precautions regarding EMC and must be installed and put into service according to the EMC information provided in the accompanying product documentation. Portable and mobile RF communications equipment can effect Medical Electrical Equipment. The Gendex Expert DC complies with EMC requirements when used with the cables and accessories supplied with the product. The use of accessories and cables other than those sold by Gendex Imaging and specified as replacement parts for internal components, may result in increased emissions or decreased immunity of the Gendex Expert DC. The Gendex Expert DC should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Gendex Expert DC should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration - electromagnetic emissions -for all equipment and systems (see 6.8.3.201 a) (3).

The Gendex Expert DC is intended for use in the electromagnetic environment. The customer or the user of the Gendex Expert DC must ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The Gendex Expert DC uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Gendex Expert DC is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/flicker emissionsIEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - electromagnetic immunity -for all equipment and systems (see 6.8.3.201 a) 6)).

The Gendex Expert DC is intended for use in the electromagnetic environment specified below. The customer or user must ensure that it is used in such an environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/-6 kV contact +/-8 kV air	+/-6 kV contact +/-8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	+/-2 kV for power supply lines +/-1 kV for input/output lines	+/-2 kV for power supply lines +/-1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/-1 kV differential mode +/-2 kV common mode	+/-1 kV differential mode +/-2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Gendex Expert DC requires continued operation during power mains interruptions, it is recommended that the Gendex Expert DC be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration - electromagnetic immunity -for all equipment and systems that are not life-supporting (see 6.8.3.201 b).

The Gendex Expert DC is intended for use in the electromagnetic environment specified below. The customer or user must ensure that it is used in such an environment.

Guidance and Manufacturer's Declaration –Electromagnetic Emissions

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the Gendex Expert DC, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Gendex Expert DC is used exceeds the applicable RF compliance level above, the Gendex Expert DC should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Gendex Expert DC.
- Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m

Recommended separation distances between portable and mobile RF communications equipment and the equipment or system.

The Gendex Expert DC is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Gendex Expert DC can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Gendex Expert DC as recommended below, according to the maximum output power of the communications equipment.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Equipment or System

Rated Maximum Output Power of Transmitter W	Separation Distance according to Frequency of Transmitter m		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,78
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Equipment Standards

The System was tested and/or evaluated against and found compliant to the following standards/requirements:

IEC 60601-1 W / A1, A2	IEC 60601-2-28
IEC 60601-1-1	IEC 60336
IEC 60601-1-2	IEC 60417
IEC 60601-1-3	IEC 60552
IEC 60601-1-4	IEC 60878
IEC 60601-2-7	ISO 13485

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Signature Manifest

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Quick Approval

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Name/Signature	Title	Date	Meaning/Reason
Martin Rajchel (MARTIN.RAJCHEL)		21 May 2012, 02:03:15 PM	Approved