

Gendex expert® DC

User Manual

Manual del usuario

Benutzerhandbuch

Manuale d'uso

Manual de l'opérateur



Intraoral X-ray System

GENDEX

User Manual

English



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Warning



X-ray equipment may cause injury if used improperly.

It is extremely important that you be fully acquainted with all 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 Avenue, Suite 800, Bethesda, MD 20814.

Personal radiation monitoring and protective devices are available. You are strongly urged to use them to protect against unnecessary X-ray exposure.



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.

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.

Classification

The Gendex expert DC is UL Class I Type B equipment (UL60601-1:2003).

Authorized Representative

Your Gendex dealer will assist you in placing the Gendex expert DC in operation.

For dealer opportunities or customer service, contact the following:



European Representative
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Bismarckring 39
Biberach, Germany
Tel.: +49 7351 / 56 - 0
Fax: +49 7351 / 56 - 1488

GENDEX Dental Systems
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Language

The original language of this manual is English.

Overview

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



Note: If training is needed, a Gendex expert DC dealer will provide training.

This chapter presents the following sections:

- Users
- About this Manual
- Explanation of Symbols
- System Components
- Safety

1.1 Users

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

1.2 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.

1.3 Explanation of symbols on technical labels



Type B: Protection against electric shock (UL60601-1:2003)



Consult written instructions in this User Manual



X-ray Source Assembly



Warning X-ray
This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed.



X-ray Emission



Mains Hot Wire



Mains Neutral Wire



Earth Ground



Electronic Equipment
Do not recycle into normal trash

1.4 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

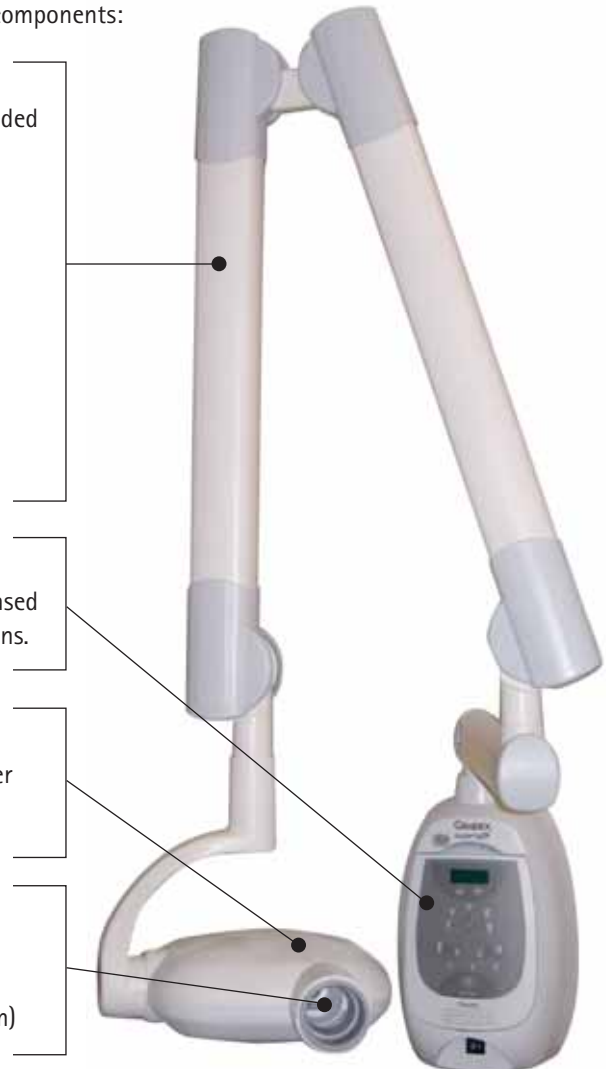
Allows the user to set specific exposure values based on the anatomical area and view system conditions.

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)



1.5 USB connection

The Gendex expert DC features an integrated universal serial bus (USB) connection. The USB is a pass-through connection designed to work with the Gendex expert DC USB Extender Kit and the VisualiX eHD sensor system. The Gendex expert DC USB Extender Kit is the only reliable way to implement the USB option. No other USB cables, USB active extensions, or USB hubs are supported with this system.

For more information about the USB connection, refer to the Gendex expert DC USB Extender Kit (Part Number 112-1220G1).

1.6 Safety

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

Radiation Safety

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.

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.

Setup and Operation

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 Master Control Settings
- Default Exposure Values (Anatomical Exposure Times) Tables

2.1 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 (D)1; 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	<p>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.</p> <p>The optional, longer 12" (30cm) cone is used to sharpen the X-ray image if the paralleling technique is used.</p> <p>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.</p>
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	<p>The default bitewing setting can be changed to one of the following selections:</p> <ul style="list-style-type: none"> • Incisor • Bicuspid • Bitewing • Lower Molar • Upper Molar

Master control touch panel

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

1. **Exposure Time Display:** Allows the user to view the anatomical exposure time and system information
2. **Time Selector:** Allows the user to adjust the anatomical exposure time up ▲ or down ▼ to a specific value. The time up ▲ arrow and the time down arrow ▼ allow the user to override the anatomical exposure time.
3. **Anatomy Selection (Anatomical Time Selector):** Allows the user to select the desired tooth area. When the tooth area is selected, the unit automatically displays the anatomical exposure time for the desired area.
4. **Patient Selector:** A toggle function that allows the user to select an adult or a child patient. Depending on the selection made, the unit automatically modifies the anatomical exposure time.
5. **Imaging Type Selector:** A toggle function that allows the user to select between the use of film or a digital imaging receptor. Depending on the selection made, the unit automatically modifies the anatomical exposure time.
6. **Ready Indicator Lamp:** Indicates that the On switch has been pushed and the unit is ready for operation.
7. **Cool-Down Indicator Lamp:** Warning light. This lamp will illuminate when the tubehead becomes heated; indicating that the tubehead needs to cool before the next exposure can be taken.
8. **Radiation Indicator Lamp:** Warning light. This lamp will illuminate when the exposure button is pressed and X-ray radiation is being produced.
9. **Push-Button Exposure Switch:** Allows the user to activate an exposure on the master control touch panel.
10. **Coil-Cord Exposure Switch (Not Shown):** Allows the user to exit the operatory and then activate an exposure.
11. **Quickset™ Tubehead Control:** Allows the user to select the anatomical exposure times directly at the tubehead. Also, allows the user to select the patient type. The selections are indicated according to the corresponding LED light.
12. **On/Off Power Switch:** Switching to the On position supplies power to the unit. The Ready Indicator Lamp on the master control touch panel indicates that the unit is ready for use.



2.2 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 the master control touch panel

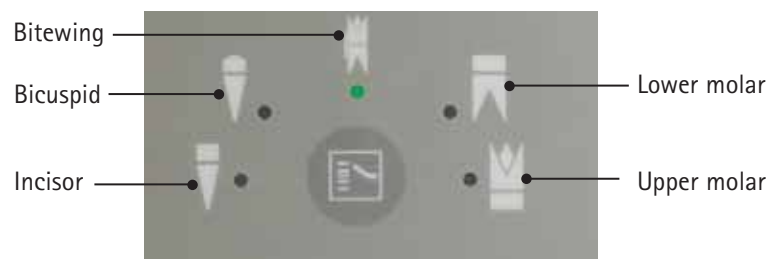
To set up the master control touch panel, follow the procedure.

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.

2.3 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.



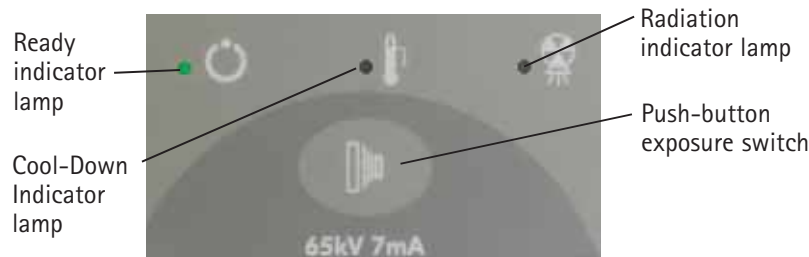
Warning: Use extreme care when adjusting the articulated arm to avoid placing your fingers in areas where they may be potentially pinched while you are moving the arm. Also, do not allow the tubehead to hit the wall after returning the arm to the storage position.

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.

2.4 Customize master control settings

The factory default settings can be customized.

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

To 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.

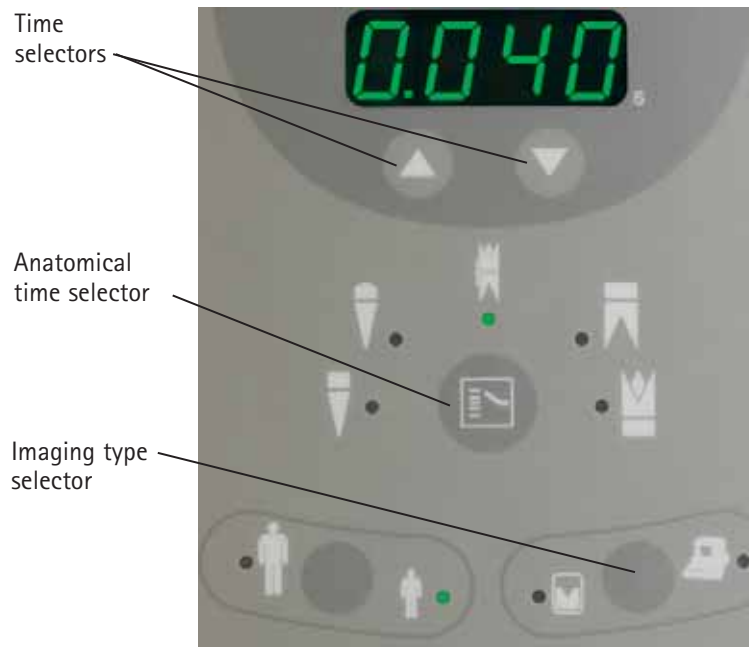


Note: When changing the media type, you must quickly press the Imaging Type Selector. If there is no keypad activity for 30 seconds, the unit will not remain in the programming mode, changes will not be saved, and the unit will return to normal operation

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).

To 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).

To 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).

To 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, 0.160 seconds, will be displayed for the default bitewing, (the default anatomical selection).

Changing the 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.

Modifying the Unit for the Optional 12" (30 cm) Cone

The Gendex expert DC uses the 8" (20 cm) cone. The 12" (30 cm) long cone is recommended when using the paralleling film positioning technique with X-ray positioning devices.

Gendex recommends using the 12" (30 cm) cone when longer exposure times are needed. 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.

2.5 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
SP3: 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
D2: CCD or CMOS Type Receptors	0.125 second	0.063 second	0.250 second	0.125 second

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

3.1 Additional Film and Digital Customization

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

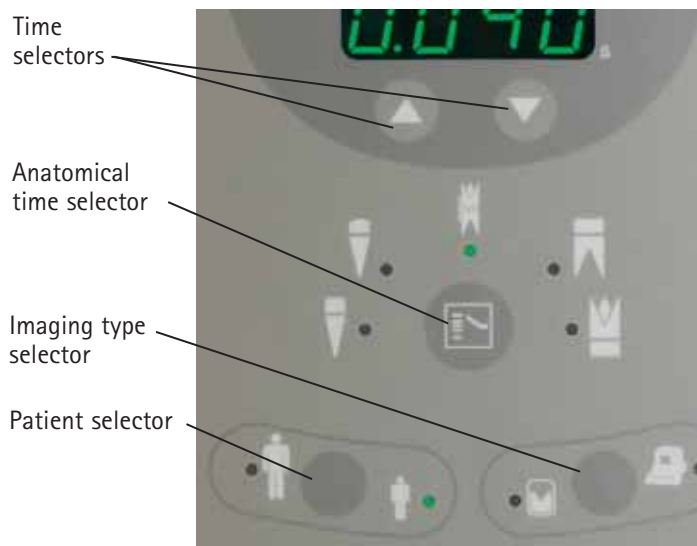


Note: You will need to refer to the Default Exposure Values for Customized Programmable Film and Digital Settings (Anatomical Time Setting) in this section in order to input the recommended custom settings.

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.

3.2 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*

	Any Size Cone	
Anatomy Selected	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*

	Any Size Cone	
Anatomy Selected	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

3.3 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.

3.4 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 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
<p>Err3 flashes on Exposure Time Display</p>	<p>A hardware fault has occurred.</p>	<p>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.</p>
<p>Err4 flashes on the Exposure Time Display</p>	<p>A fault has occurred and terminated the exposure.</p>	<p>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.</p>

Gendex expert[®] DC 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)

4.1 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:	Greater than 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

4.2 Cone specifications

The cone specifications consist of the following:

X-ray Field Size: Containable in a 6 cm diameter circle, measured at the distal end of the installed cone.

Distance from the focal spot to the distal end of the cone is: 8" or 12" (20 or 30 cm).

4.3 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.

4.4 Accuracy of technique factors

The power supply requirements are presented in the following table:

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

4.5 Intraoral X-ray tube housing

Product Data Sheet

Gendex expert DC

The Gendex expert DC housing is designed to operate with the Gendex GX 70-10DC 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.	65 kV	Min.	Max.
Glass	1.27	1.91	0.51	0.65	0.97
Insulating Oil	6.5	7.7	0.08	0.52	0.62
Polycarbonate	16.4	16.7	0.09	1.48	1.50
			Total	2.64	3.09

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

Typical Half 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 12.5°

- Circular cone at 8 inches (200 mm) SSD² 60 mm Dia. +0, -3mm.
- Circular cone at 12 inches (300 mm) SSD² 60 mm Dia. +0, -3mm.
- Rectangular cone at 8 inches (200 mm) SSD² 36mm x 46mm

¹ AHE Aluminum Half value Equivalent correlation

² SSD Source to Skin Distance

Weight: 13.0 lbs. 5.9 kg.

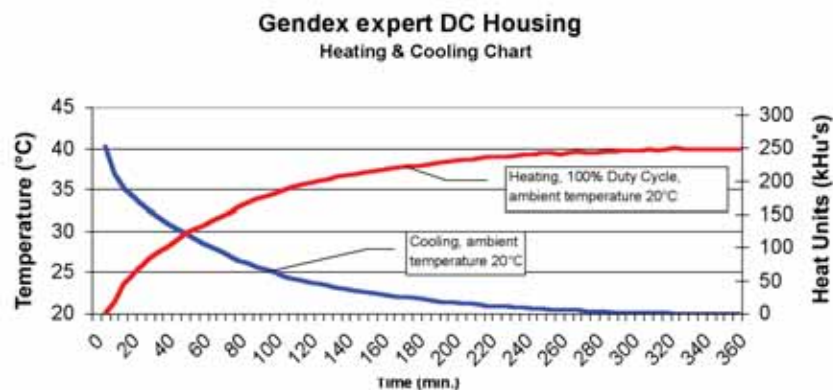
Maximum Head Voltage: Anode to Cathode 65 kV

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.

$$\text{Heat Units} = (\text{kV} * \text{mA} * \text{time in seconds} * 1.4)$$



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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 and Disinfecting

5.1 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.

5.2 Cleaning and disinfecting

The Gendex expert DC can be cleaned and/or disinfected using the following list of commonly used solutions:



Note: Verify the contents of any cleaning or disinfecting solution against the list above before applying it to any surface of the Gendex expert DC.

- Isopropyl alcohol
- Phenylphenl
- Benzyl-P-Chlorophenol
- Iodophor
- Disobutyl phenoxethoxycthyl Dimethyl Benzyl Ammonium Chloride



Warning: Only use bleach or glutaraldehydes occasionally.

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Compliance With Applicable Standards

6

This chapter presents compliance standards.

The Gendex expert DC complies with the following standards:

- General (electrical/mechanical) safety:
- UL60601-1 File Number: E185414
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, IEC60601-2-32, IEC60601-2-7 IEC60601-2-28, IEC60601-1-2.
- 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 User Manual and in the Gendex 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.

X-ray equipment may cause injury if used improperly.

It is extremely important that you be fully acquainted with all 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 Avenue, Suite 800, Bethesda, MD 20814.

Personal radiation monitoring and protective devices are available. You are strongly urged to use them to protect against unnecessary X-ray exposure.



Note: The Gendex expert DC Intraoral X-ray System 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.

6.1 EC Declaration of Conformity



GENDEX DENTAL SYSTEMS
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 Des Plaines, IL 60018-1884
 Phone (847) 364 - 3931
 Fax (847) 718 - 0601

Authorized Representative:
 Kavο Dental GmbH
 Bismarckring 39
 Biberach, Germany

EC Declaration of Conformity

A. Name/Description of product:
 Gendex eXpert DC

REF: Model(s) 110-0207G1 110-0207G2 110-0207G3
 110-0207G4 110-0207G5 110-0207G6

Class: IIb

B. Reference Standards under which conformity is declared:

- IEC 60601-1 W / A1, A2
- IEC 60601-1-1
- IEC 60601-1-2
- IEC 60601-1-3
- IEC 60601-1-4
- IEC 60601-2-7
- IEC 60601-2-28
- IEC 60601-2-32
- IEC 60336
- IEC 60417
- IEC 60552
- IEC 60878
- EN 1041
- EN 980
- ISO 13485

C. GENDEX Dental Systems declares that the products described herein meet all the applicable Essential Requirements of the EC Medical Device Directive 93/42/EEC in Annex I. For Class IIb products described herein, the product is manufactured, inspected, tested, and released in accordance with the approved quality assurance system established in accordance with ISO 13485, and Annex II of the EC Medical Device Directive under the supervision of the British Standards Institution, a Notified Body carrying the Notified Body No. 0086.

Signed: Mari Lambert Date: 3/16/2007
 Mari Lambert, Manager of Regulatory Affairs

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.

- Table 201 - 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.

Table 201 - Guidance and Manufacturer's Declaration - Electromagnetic Emissions

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 A	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 A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

- Table 202 - 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 the user of the Gendex expert DC must ensure that it is used in such an environment

Table 202 - 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.

- Table 204- 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 the user of the Gendex expert DC must ensure that it is used in such an environment.

Table 204. 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	3 V	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.

^a 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.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V₁] V/m

- Table 206- 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.

Table 206- 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

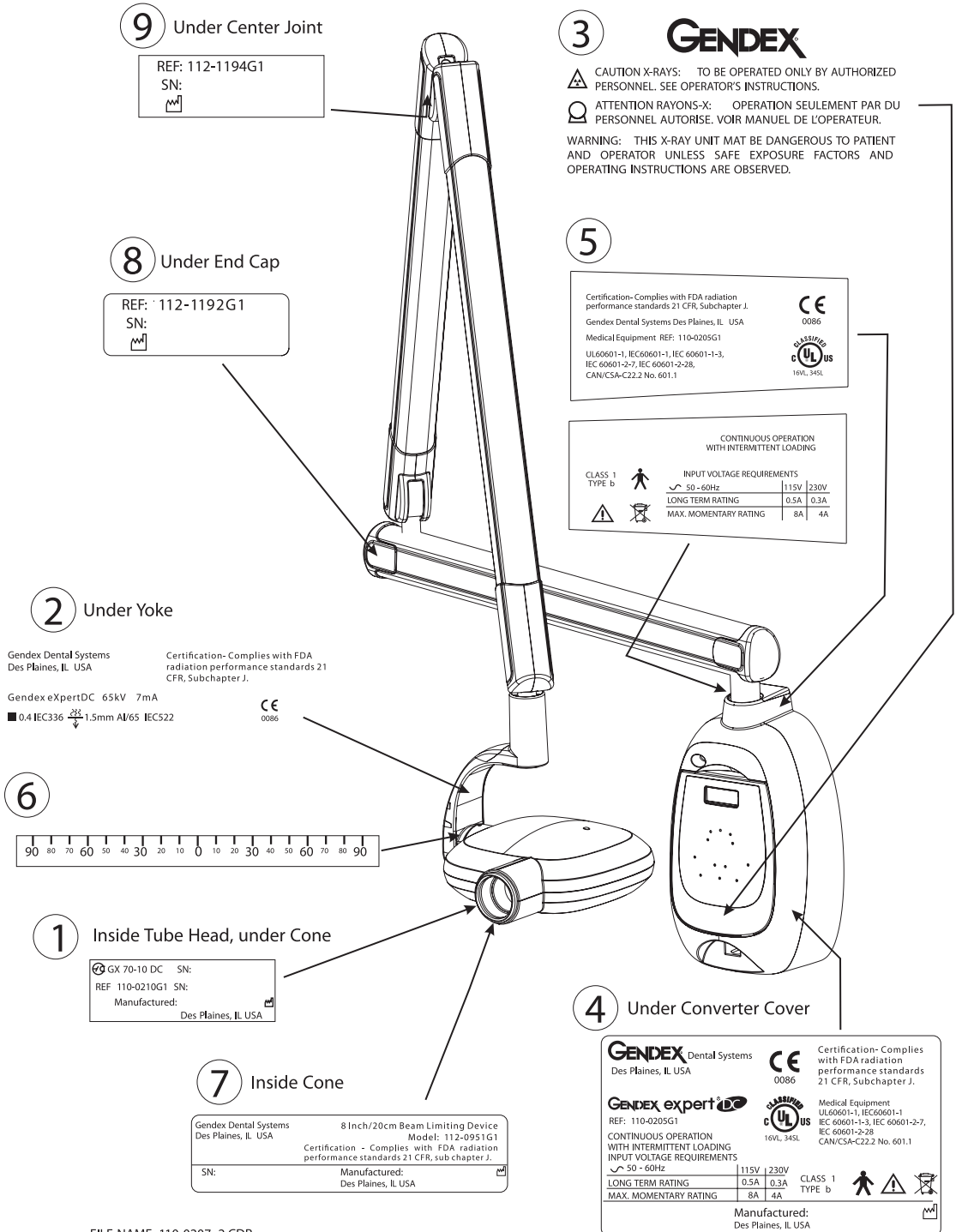
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter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

6.2 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.



FILE NAME: 110-0207_2.CDR

6.3 References

Gendex expert Installation Manual
Gendex Visualix eHD Sensor Manual
Gendex expert DC USB Extender Kit (Part Number 112-1220G1).

6.4 Contact information



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The logo for Gendex, featuring the word 'GENDEX' in a bold, white, sans-serif font with a registered trademark symbol (®) to the upper right of the 'X'. The logo is set against a dark blue background.