User Manual

Digital Intraoral Sensors

Table of Contents

Chapter 6 - Use

Chapter 7 - Specifications and Standards

Chapter 8 - Diagnostics

Appendix A - Accessories

Appendix B - EMC Information

Chapter 1 Introduction

This User Manual contains original instructions by Gendex Dental Systems for safe set-up, use and maintenance of the Gendex GXS-700.

It also contains technical specifications of the system and basic information on how the system works.

Please read this manual carefully before starting to use the device, paying particular attention to warnings, especially safety warnings.

Intended Use of the Device

The GXS-700 is a USB-driven digital sensor which is intended to acquire dental intraoral radiography images. The GXS-700 shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intraoral radiographs. The GXS-700 can be used either in combination with special positioning devices to facilitate positioning and alignment with the X-ray beam, or it may also be positioned by hand with the assistance of the patient.

Product Description

An X-ray image sensor (CMOS) is positioned in the patient's mouth just like intraoral film. There is no electrical or physical connection between GXS-700 and the X-ray generator. Images are automatically acquired when X-rays are present in a dose which is perceptible to the sensor.

Digital X-ray images are quickly displayed on the screen. Images can be optimized for viewing via imaging software, stored as image files, and printed out on a suitable printer if desired. VixWin Platinum is one example of a dedicated software that employs a number of utilities for optimizing viewing and printing of images.

The GXS-700 must be connected to a PC running on a Windows operating system through the standard USB port (Universal Serial Bus). See the "System Configuration" paragraph for details.

Conventions Used in the Manual

The following conventions are used to bring the operator's attention to important information:

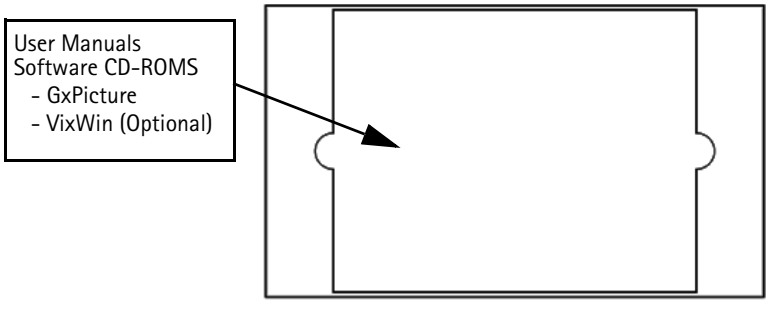
⚠	**Warning** Alerts the operator that failure to follow the procedure could cause bodily injury or death.
⚠	**Caution** Alerts the operator that failure to follow the procedure could cause damage to the equipment or cause loss of data.
Important:	Provides advice for the operator regarding use of the device or a process.
NOTE:	Highlights important or unusual points.

Unpacking the GXS-700 System Components

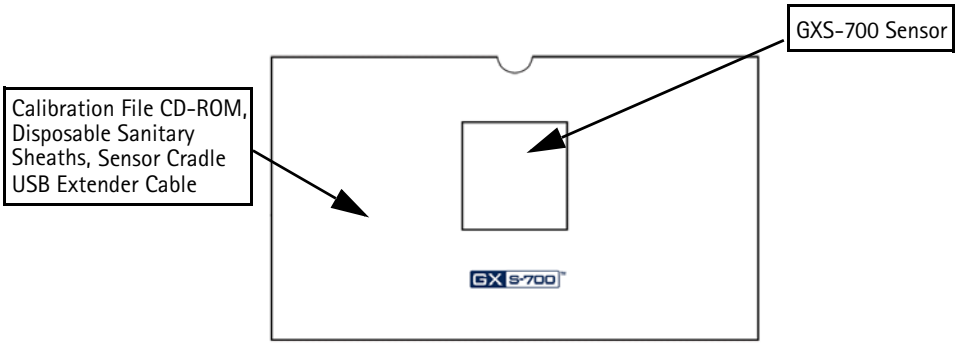
The GXS-700 system is carefully inspected and packaged prior to shipment. If the GXS-700 system was shipped to you, please remove the contents of the shipping container and be sure to identify and directly locate each of the system components shown below.

NOTE: Report any damaged components to the shipping company and any missing components to your dealer within 24 hours of receiving the shipment.

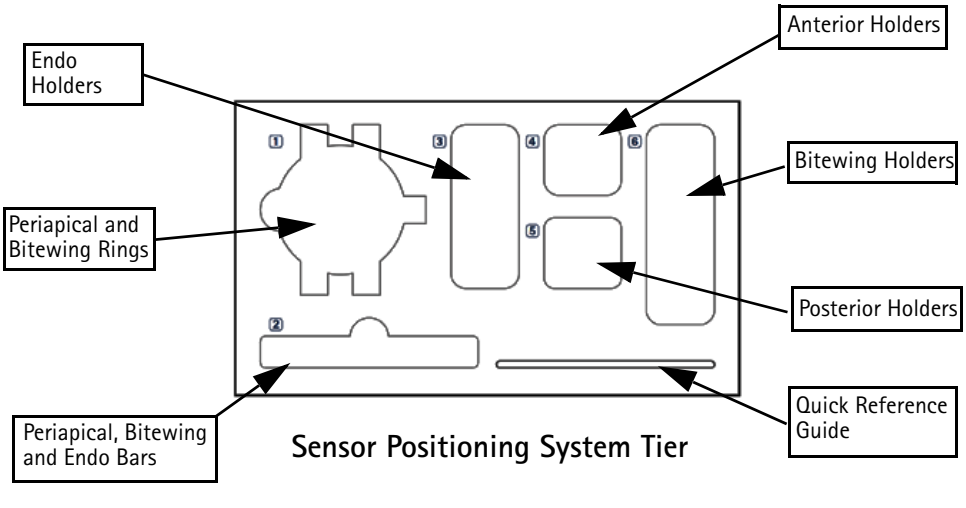
Contents of each Package Tier



Documentation and Software Tier



Sensor and Accessories Tier



Sensor Positioning System Tier

System Components

Digital Intraoral Sensor

The GXS-700 sensors are USB-driven digital intraoral sensors based on a CMOS technology that has been specifically designed for dental applications. The GXS-700 sensors are available in two formats: size 1 (active area: 20x30mm) and size 2 (active area: 26x36mm).

Size 1 Sensor

Size 2 Sensor

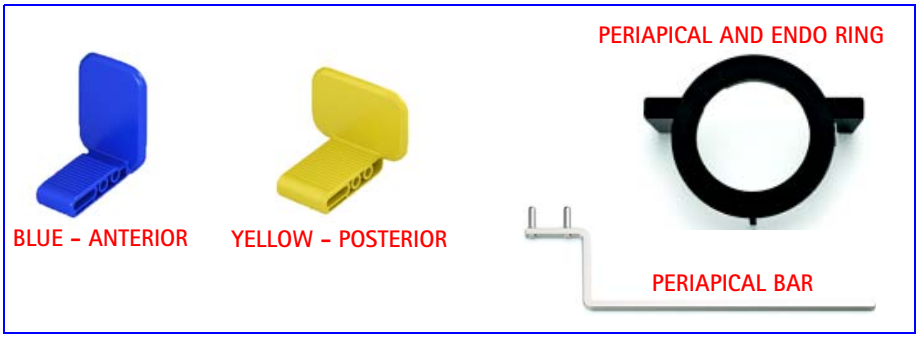
USB Connector

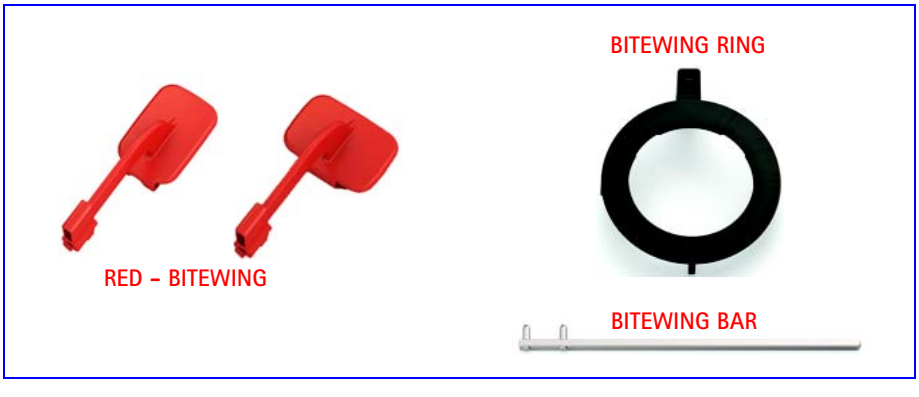
USB Cable Label
(typical)

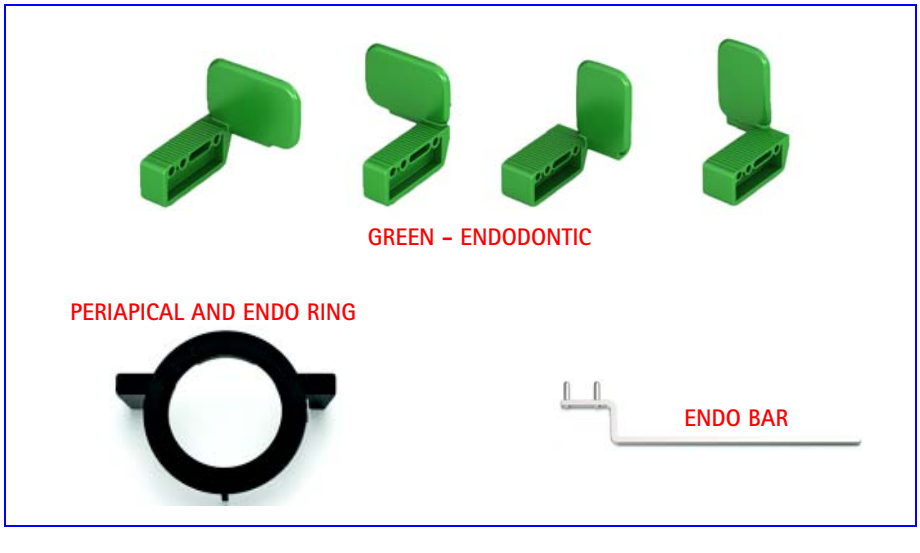
USB Connector
(cable not shown)

GXS-700 Intraoral Positioning Devices

Specifically designed to support the sensor and align it with the X-ray beam and with the teeth of the upper and lower jaws.

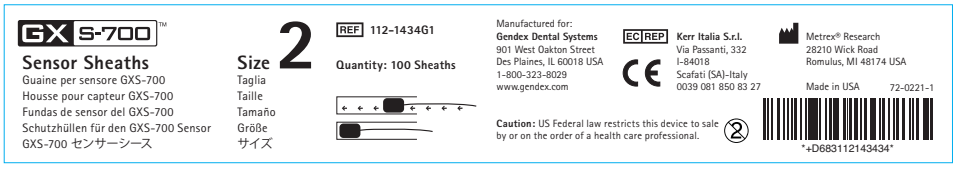






Disposable Sanitary Sheaths

Used as a barrier for the sensor. Supplied in a package of 100 pieces.



Cables

1. 3 foot (1m) USB extender cable.

Sensor Cradle

Designed to provide a safe and secure storage solution for GXS-700 sensors.

Software CD-ROMs

1. GxPicture CD containing GxPicture installation files and utilities.
2. Calibration Files CD containing the sensor calibration files.
3. Optional: VixWin Platinum CD (installation and utilities) and VixWin Platinum User Manuals (multiple languages).

Documentation

1. GXS-700 User Manual
2. GxPicture Quick Install Guide
3. Optional: VixWin Platinum User Manual

Chapter 2 Safety and Disposal Procedures

The device must be installed and used in accordance with the safety regulations and instructions for use supplied in this User Manual, for the purposes and applications for which it is intended.

Modifications and/or additions to the GXS-700 must be made exclusively by Gendex personnel or by parties expressly authorized for the purpose by Gendex. Any modifications or additions must always comply with standards and generally recognized rules of good workmanship.

Electrical Safety

The product must be used only in rooms or areas which comply with all laws and regulations applicable to electrical safety in medical premises, such as CEI standards regarding use of an additional ground terminal for potential connections.

The GXS-700 sensor conforms to safety standard IEC 60601-1.

Gendex GXS-700 sensor is not suitable to be operated in oxygen rich and/or explosive environments.

All IT components electrically connected to the GXS-700 sensor must conform to IEC 60950-1.

Normally, the IT components are placed OUTSIDE the patient environment. IT components placed INSIDE the patient environment, due to customer site requirements, must also conform to IEC 60601-1.

IEC 60601-1 defines the "Patient environment" as "any volume in which intentional or unintentional contact can occur between a Patient and parts of the ME Equipment or ME System or between a Patient and other persons touching parts of the ME Equipment or ME System."

Always check sensor prior to use.

WARNING

Do not continue to use the GXS-700 if there is visible damage to the sensor housing and/or cable.

X-ray Protection

The rules of dental radiography still apply to digital X-ray systems. Please continue to use protection for your patients. As a clinician, clear the immediate area when exposing the sensor.

Prevention of Cross-Contamination

To help prevent cross-contamination between patients, place a new hygienic barrier on the sensor for each new patient. The hygienic barrier must cover the sensor and at least 3-4 in. (7-10 cm) of the cable.

Product Disposal

The GXS-700 sensor contains a small amount a lead, similar to the lead foil used in a dental intra-oral X-ray film. Please contact your dealer or supplier for further information about product disposal at the end of the product's lifetime.

Prevention of Environmental Contamination

Dispose of sheaths and other consumables following the normal dental office procedure for biomedical waste.

Chapter 3 System Configuration

Personal Computer Requirements

	Minimum System Requirements	Recommended
Operating System	Microsoft® Windows® XP with service pack SP3	Microsoft® Windows® 7 Professional 32 and 64 bit
Processor	Intel Celeron® M 1.6 GHz	Intel® Core™ 2 Duo 2.4 GHz
Memory	512 MB	2 GB
Hard Disk	40+ GB	120+ GB
Display Setting	800 x 600	1024 x 768 at 32 bit true color
Video Memory	1+ MB	128+ MB
Ports	USB 2.0	USB 2.0
Standards	In compliance with the UL/IEC/EN 60950-1 standard	In compliance with the UL/IEC/EN 60950-1 standard

NOTE: Gendex GXS-700 is a USB certified device and shall be used with USB compliant cables suitable for high speed/USB 2.0 components. Certified USB cable extenders are available from Gendex. Certified powered USB active hubs can also be used to extend the distance to the USB host/computer. The length of the cable connection to the hubs or between hubs shall not exceed 5m.

CAUTION

Using non-USB compliant cables or hubs, or exceeding the maximum count of USB hub devices for extending the distance, can degrade the immunity of the GXS-700 sensor to electromagnetic fields or increase the emission of electromagnetic fields from the sensor.

Hard Disk

The choice of hard disk capacity depends on the number and size of images to be stored. Intraoral images vary in size from 4.7 MB (uncompressed TIFF images with a Size 2 sensor) to 100 KB (JPEG/JFIF with 50% compression). A 20 GB hard disk is normally capable of satisfying the requirements of the average user. To guarantee data security, however, it is preferable to allow for duplication to provide back-ups of files containing diagnostic images and information.

Backup

Spare copy to permit recovery of data if lost. The database of patients and images should be copied frequently (e.g. once a week) onto a removable mass storage device (removable hard disk, CD-ROM, Pen-drive etc.). You may use the back-up functions offered by Microsoft® software or directly copy files of data and images onto a removable device.

Application Software

Some diagnostic imaging software, practice management software or other third-party software may have different minimal system requirements. Refer to the requirements of the specific software in its User Manual.

Important: If the GXS-700 System is used with imaging software other than VixWin Platinum, then the Intended Use of that software needs to include **dental intra-oral x-ray**.

Chapter 4 Installation

GXS-700 is normally set up on a Personal Computer (PC) by a professional system integrator or a software house. We advise against non-professional installation and configuration of the GXS-700.

Installation of Software Driver

Before connecting the USB cable, carefully follow the procedure described below:

1. Install a compatible imaging software (such as VixWin Platinum) on the PC, following the installation and configuration procedures contained in the imaging software Operator Manual.

   Important: If upgrading to a new version of VixWin Platinum, make sure that all acquisition and viewing workstations are upgraded to the latest version of the VixWin software. Otherwise, image quality differences could be observed on the same image depending on which workstation is used to display it. Other imaging software packages may require similar action; consult the appropriate Operator Manual or technical support resource.

2. Check that the installed imaging software (such as VixWin) is NOT runnning.

   Important: GxPicture should NOT be installed for DEXIS and Dentrix Image imaging software.

3. Insert the GxPicture CD supplied with the GXS-700 system in the CD-ROM drive and follow the Windows "Guided Installation" instructions provided. The GxPicture CD contains the USB driver for the GXS-700 system.

4. Once the GxPicture installation is complete, insert the Calibration File CD supplied with the GXS-700 system in the CD-ROM drive and follow the Windows "Guided Installation" instructions provided.

5. When the software installation is complete, connect the sensor to the computer and follow the instructions on the screen. When you have completed the installation procedure, the icon representing the GXS-700 driver will appear in the Windows System Tray.

   NOTE: If nothing happens in the 10 seconds after you have inserted the GxPicture or Calibration File CD in the CD-ROM, the CD-ROM auto-run has been disabled on the computer. It is necessary to manually launch the "Setup" file which can be found in the main directory of the ActiveX Driver CD-ROM.

6. Using GxPicture, ensure that the status icon indicates the ready state (green icon) which verifies that the sensor is recognized (see "Status Icon" on page 5-1).

7. From the GXS-700 GxPicture dialog box, select the "Image Setting" tab and select the desired settings.
8. Close the installation by taking phantom images using the GXS-700 sensor (see "Image Quality Assurance" on page 6-6).

Chapter 5 GxPicture Software

Status Icon

In the Windows System Tray (portion of the "application bar" next to the "system clock", available in all releases of Microsoft® Windows® operating systems) an icon appears representing the status of the sensor. Each icon identifies a different status, as listed below.

- **SENSOR WITH GREEN BACKGROUND** icon indicates correct functioning of all connected sensors. GXS-700 is ready to capture images.

- **SENSOR CROSSED OUT IN RED** icon indicates there is no connection to the computer and/or is unavailable for image acquisition. No GXS-700 is detected.

- **SENSOR WITH BLUE BACKGROUND** icon indicates the sensor is transferring the image to the PC.

Important: If no status icon appears, CHECK THAT YOU HAVE INSTALLED THE SOFTWARE DRIVER CORRECTLY. GXS-700 cannot operate without the driver.

Right Click the status icon to access the configuration panel containing information about the sensor, software release and image settings of the sensor in use, which may be useful when requesting technical support.

NOTE: Detailed instructions for verification or installation of software drivers are supplied in the Microsoft® Windows® manual. Inexperienced users should ask specialized personnel to install software drivers.

CAUTION

Always check that the green icon is displayed before making exposures to ensure correct operation.

GxPicture Options

Important: GxPicture should NOT be installed for DEXIS or Dentrix Image imaging software.

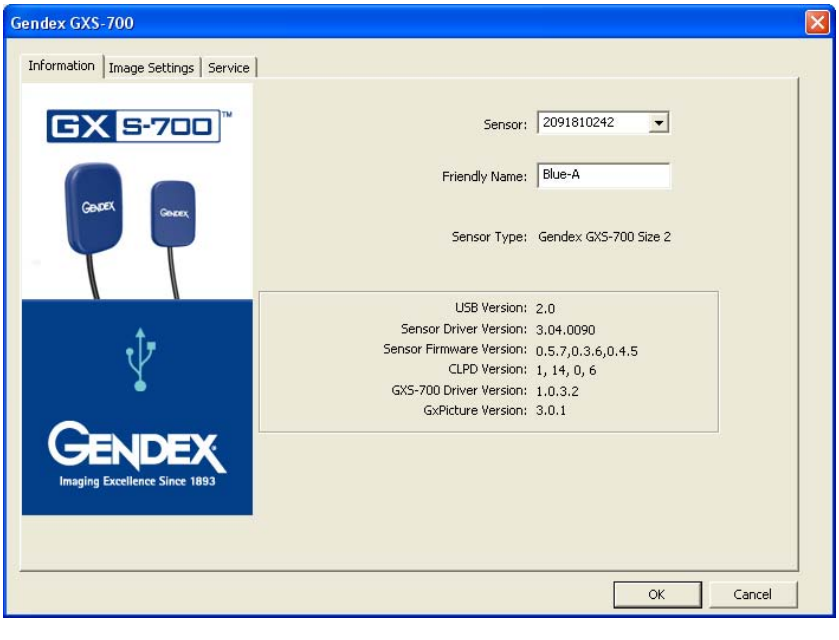
Status Icon

Right click the GXS-700 Status Icon (lower right corner of desktop) to access the three available GxPicture options:

- Information
- Image Settings
- Service

Information

The information dialog displays all currently connected sensors. Friendly Names can be assigned to sensors. Specific information, including version and status information, is displayed for each connected sensor.



Multiple GXS-700 Sensors

Multiple GXS-700 sensors are supported on a single PC (and GxPicture installation).

In the event of multiple sensor installation, after each sensor is connected, the user is responsible to verify that it is recognized and communicating with the PC.

Important: To do so,

- right click on the Status Icon (as above)
- select the information dialog
- confirm that the newly installed sensor is available to be selected according to its serial number on the Sensor drop-down list.

If the newly connected sensor does not appear on the list, make sure the USB port that the sensor is plugged into is connected to the PC on which the installation of GxPicture is running (and is not, for example, on a USB hub which is connected to a different PC). If the sensor is connected to the correct PC but does not appear on the Sensor drop-down list, contact Gendex technical support for further assistance.

Operators of DEXIS or Dentrix software should consult the appropriate software user manual for the procedure that verifies the presence of a connected sensor. If required, contact Customer Support (contact info provided in that manual).

Image Settings

Important: VixWin software does not use GxPicture Optimizer settings described below. Refer to the VixWin User manual for image settings within VixWin software.

This dialog allows:

- Effective pixel size / bite depth of the image data is accessible via GxPicture
- Selection of initial values of displayed settings: Gamma, Brightness, and Contrast
- Activate and configure automatic image optimization.

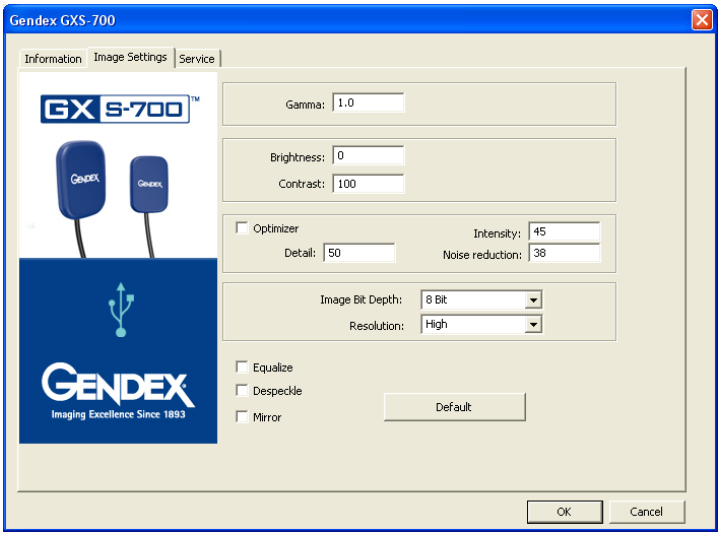


Image Settings

Gamma:	Adjusts image exposure level. (Default: 1.0 - Range: 0.2 to 2.0)
Brightness:	Adjusts image luminance. (Default: 0 - Range: -50 to 50)
Contrast:	Adjusts image tonal range (pixels of highlights and shadows). (Default: 100 - Range: 40 to 250)
Optimize:	Advanced imaging filter which enhances quality of an X-ray image by highlighting morphological details and providing sharpness to the image (Note: The optimizer settings in VixWin Platinum overwrites the Optimizer settings in GxPicture). (Default: Off)
Details:	Adjusts image sharpness. (Default: 50 - Range: 0 to 255)
Intensity:	Adjusts image intensity. (Default: 45 - Range: 0 to 255)
Noise reduction:	Adjusts image graininess. (Default: 38 - Range: 0 to 255)
Image Bit Depth:	Quantifies how many unique shades of gray are available. (Default: 8 bits - Range 8 bit/16 bit).

Resolution: Sets the amount of detail the image holds. Higher resolution means more image detail. (Default: High - Range: Low/High)

Equalize: Enhances image contrast by maximizing the use of the available grayscale. (Default: Off)

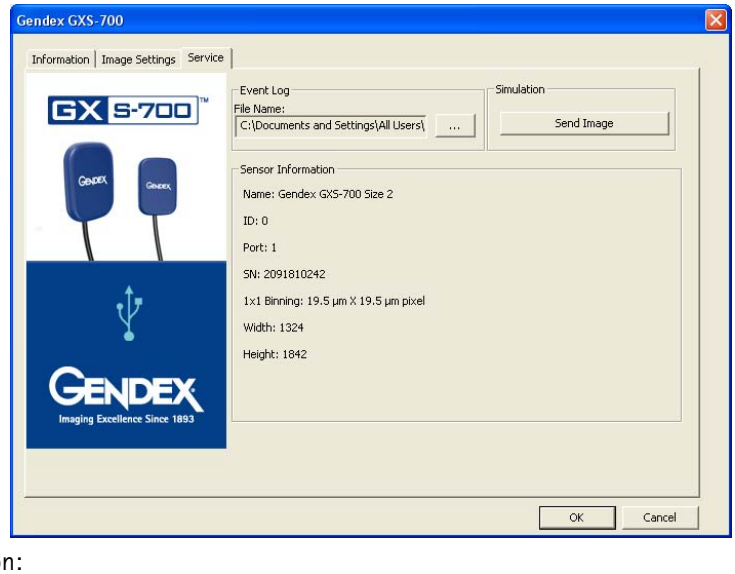
Despeckle: Reduces typical grainy or speckled appearance of X-ray images (Note: results in a small loss in resolution). (Default: Off).

Mirror: Flips image across the vertical axis. (Default: Off)

Service

This dialog allows:

- Change location of the GXS-700 Event Log
- Generate a test image intended to verify the logical connection between GxPicture and the application software.
- Allows activation of a connected sensor to generate a test image to verify connection between the sensor USB and GxPicture and further into the application software.



Send Image Button:

Clicking the Send Image Button tells the Fusion Lib to send a simulated X-ray image from the "sensor" to GxPicture. GxPicture then grabs the simulated image and sends it to VixWin (or 3rd party imaging software). Clicking this button is a way for the user to determine if the GXS-700 system is properly installed.

Chapter 6 Use

Acquisition of Radiographic Images

Turn on the PC that has the GXS-700 installed and launch the imaging software, such as VixWin Platinum (please refer to the software manual for information on the software program).

1. Set the required technical settings (exposure time, etc.) on the X-ray generator (refer to "X-ray Dose / Exposure Time Settings" on page 6-7.
2. Apply a new disposable sheath to the image sensor, making sure that it covers the portion of the cable which may come into contact with the patient.

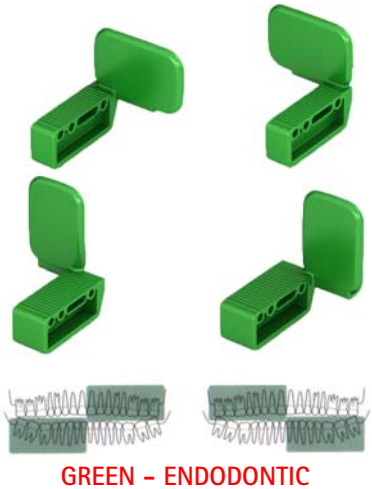
CAUTION

When twisting the disposable covers around the sensor wire, be sure not to twist the wire.

3. Position the sensor appropriately in the part of the mouth to be X-rayed (refer to specific instructions for use).

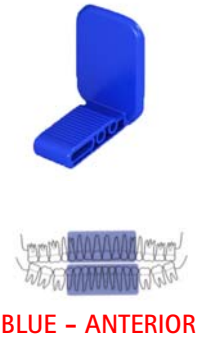
Important: The sensor must be positioned with the sensitive area facing the source of the radiation. The sensitive side of the sensor is marked with the Gendex logo.

NOTE: Use of a sensor positioning device is recommended to guarantee that the sensor is positioned at right angles to the radiation beam and parallel to the tooth. Positioning devices are supplied with the GXS-700 system.

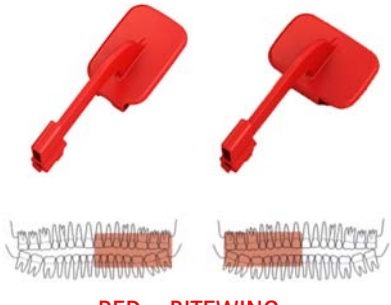


GREEN - ENDODONTIC

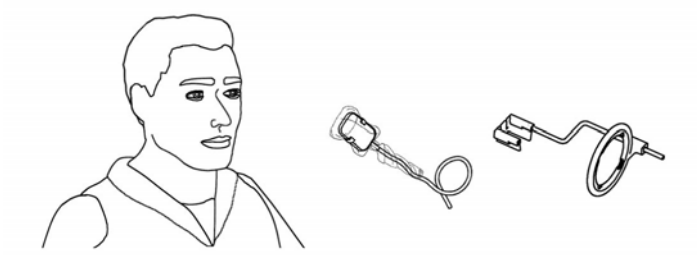
YELLOW - POSTERIOR



BLUE - ANTERIOR



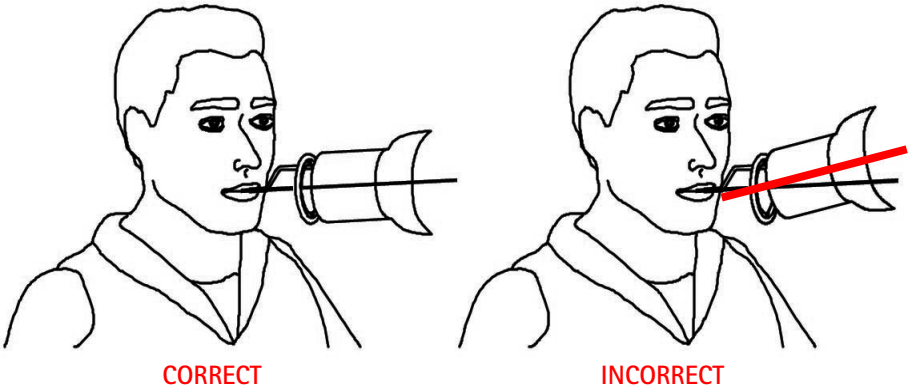
RED - BITEWING



The sensor may alternatively be positioned by hand and held in place by the patient with one finger just like conventional X-ray film. If the positioning device is not used, a wad of cotton wool may be useful for aligning the sensor parallel to the tooth. It may be best to position the sensor by hand in the small mouths of children. Note however, that image quality might be inferior with respect to one attained using an aiming device.

4. Position the X-ray generator as usual for X-ray film.

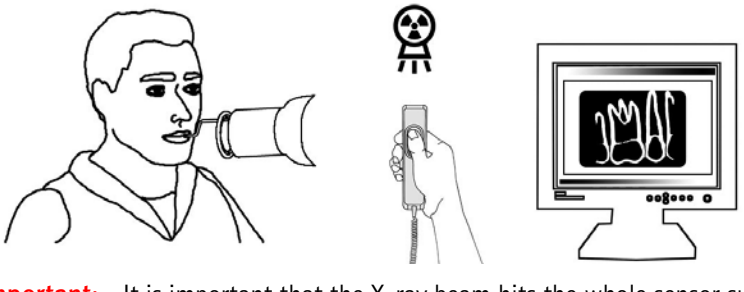
   Use of the parallel technique is highly recommended, with a rectangular cone if possible.



CORRECT INCORRECT

Important: Verify connectivity of the GXS-700.

5. Acquire the image by pressing the X-ray button on your radiography system.



Important: It is important that the X-ray beam hits the whole sensor surface.

Portability

GXS-700 can be easily moved from one dental chair to another. Once disconnected from the USB port of the computer, the sensor may be positioned near a second dental chair and connected to a USB port present nearby.

The USB technology allows easy connection and disconnection of GXS-700 even if the computer is switched on, unless the PC presents particular limitations. No activation or deactivation procedure is necessary with GXS-700, just plug in and out.

Hygiene

It is important to change the disposable sheaths for every different sensor usage and between different patients to prevent risk of cross infection.

Store disposable sanitary sheaths in a clean, dry place not exposed to sunlight or UV rays.

Make sure that used sheaths are disposed of as infected waste which is potentially biologically hazardous.

Important: Disinfect the image sensor before its first use and whenever there is a risk of contamination.

Please follow the sterilization and cleaning instructions in order to avoid damaging the sensors. Disinfection of the X-ray image sensor at the end of each day is recommended even when sheaths are used. To disinfect the sensor:

- Wipe off the sensor surface with a compress moistened in a sterile solution.
- To disinfect with a disinfecting solution carefully follow the manufacturer's recommended immersion time. In any case this immersion should not exceed 12 hours.

CAUTION

Autoclave sterilizers will permanently damage the GXS-700 sensor.

Recommended Disinfecting Solutions

Decontaminate the sensor, cable and holders in accordance with CDC – or your country's (e.g., OSAP) standards – for infection control.

Gendex recommends wiping the GXS-700 sensor with one of the following cleaning agents.

- CaviCide® (Manufactured by Metrex)
- CaViWipes™ (Distributed by Kerr)
- Asepticare (Manufactured by Ecolab)
- Sani-Cloth® Plus (Distributed by Crosstex)
- CIDEX OPA (Ortho-Phthalaldehyd, Distributed in the US by Advanced Sterilization Products)
- FD322 (Manufactured by Dürr)
- Dürr System-Hygiene FD 350 Disinfection wipes Classic (Manufactured by Dürr)
- Isopropyl Alcohol

DO NOT:

- Clean the sensor using non appropriate tools.

The following solutions can be used to decontaminate the holders:

The GXS-700 sensor holders can be sterilized in a steam autoclave using distilled water at temperature of 273°F (134°C) at 216 kPa when bagged or using cold chemical disinfectants (refer to Instructions for Use). However, certain restrictions apply:

- Run the appropriate autoclave cycle according to the manufacturer's specifications for your specific unit.
- Always avoid direct contact of the holders with metal trays, instruments, and heating elements.
- Always place holders in autoclave bags.
- Always situate bagged holders into the autoclave so that they are furthest from the heat source.
- Do not use a chemical autoclave.

Exposing the holders to hot metal and placing them close to heating elements will reduce the lifetime of the holders.

The holders should be sterilized in an autoclave. If the infection control guidelines for your country permit, the holders can be disinfected using the cleaning agents below, following the manufacturer's instructions:

- CaviCide® (Manufactured by Metrex)
- CIDEX OPA (Ortho-Phthalaldehyd, Distributed in the US by Advanced Sterilization Products)
- Asepticare (Manufactured by Ecolab)
- FD322 (Manufactured by Dürr Dental)
- Isopropyl Alcohol

Maintenance

GXS-700 does not require any special maintenance other than regular cleaning and disinfection.

Clean the monitor screen, mouse and keyboard frequently.

Set monitor brightness and contrast properly. Be sure to use a video mode recommended for use with GXS-700.

Image Quality Assurance

Image quality of the GXS-700 sensor depends on several factors:

- the quality of the X-ray source (kV, focal spot size, distance)
- the alignment of the X-ray source to the anatomic region
- the applied X-ray dose / exposure time
- the settings of the computer monitor

It is recommended that you establish a procedure for periodic review of the image quality. If image quality is not satisfactory, or degrading, please check the contributing system parts as outlined below:

X-ray Dose / Exposure Time Settings

The GXS-700 sensor has been designed to be used with a wide range of dose settings, to allow adjustments of the dose to the specific diagnostic task, and to compensate for under- and over-exposure. As a general recommendation, start by using dose / exposure time settings recommended by your X-ray source manufacturer for digital X-ray sensors.

The GXS-700 sensor can be used with much lower dose / exposure time settings. Nevertheless, low dose operation of a digital sensor in general can result in a grainy image appearance. If the image of the GXS-700 sensor appears grainy, increase the dose settings. If you obtain good results with a particular setting, you might try a lower dose setting to see if you still gain good results.

The GXS-700 sensor can work at higher dose /exposure time settings, if needed for a particular diagnostic task. At high dose / exposure time settings, it might not be possible to distinguish air from soft tissue. Such regions may appear overexposed. If air and soft tissue regions in the image appear overexposed, reduce the dose settings.

Remember, as with standard film, you will need to adjust the duration setting to compensate for tooth type (central incisor to molar) and patient body type (larger adult to small child). Ultimately, the settings you choose should be what you consider to be suitable for your diagnostic needs.

X-ray Sharpness / Contrast

Many parts of the X-ray imaging system contribute to the sharpness and contrast of the image. It is recommended that you use a dental phantom for a periodic assessment of the image quality by performing a side-by-side comparison of an initial dental phantom image to a current dental phantom image.
Dental phantom images should be acquired with fixed settings for X-ray dose (kV, mA, distance), and a fixed and reproducible alignment of the X-ray source and the dental phantom to the Gendex GXS-700 sensor.

NOTE: Contact Gendex technical support for recommendations about commercially available dental phantoms.

Display Image

Refer to the software manual for guidance on how to ensure good display settings and image display properties.

Chapter 7 Specifications and Standards

CAUTION

US Federal law restricts this device to sale by or on the order of a dentist or other licensed practitioner.

Sensor Specifications

Sensor Dimensions (mm)	**GXS-700 Size 1:** 36.9 x 25.4 x 7.7 **GXS-700 Size 2:** 41.8 x 30.6 x 7.8
Sensor Image Area	Indirect converting dental intraoral X-ray sensor 1539 by 1026 pixels for Size 1 1842 by 1324 pixels for Size 2 19.5 µm pixel size
X-ray Parameters	Sensor can be used with dental X-ray generators in the range of 60 to 70 kV; at minimal 40 µGy incident dose
Software Architecture	Operating Systems Supported: • Microsoft® Windows® XP Pro with service pack SP3 • Microsoft® Windows® Vista Business 32-bit with service pack SP2 • Microsoft® Windows® 7 Professional 32 and 64 bit
Electrical Rating	DC 5V, 350 mA max ⎓
Connection to PC	USB 2.0 High Speed
Protection Against Shock	Class II type BF applied part
Mode of Operation	Continuous
Method of Sterilization	Sensor not suitable for sterilization

Environmental Conditions	Humidity	Air Pressure	Ambient Temperature
Usage Gendex GXS-700 sensor is not suitable to be operated in oxygen rich and/or explosive environments	30% to 95%	700 to 1060 hPa	5° to 30°C
Transportation and Storage Transport in the supplied protective package	10% to 95%		-40° to 70°C
EU Classification	Class IIa medical device according to MDD 93/42/EWG		
Protection against water/matter – IP 68			

Product Symbols

BF type device (IEC 601.1 - 1988 and Amendments)

Please refer to the written instructions in this manual.

DC Current (IEC 601.1 - 1988 and Amendments)

This ETL listed mark guarantees that Intertek has certified the product described herein under control number 3187969 to be in compliance with the applicable regulations. Intertek is:

- a Nationally Recognized Testing Laboratory by the Occupational Safety and Health Administration (OSHA) in the United States.
- a Certifying Body in Canada by the Standards Council of Canada.

CE 0086 — The CE symbol ensures that the product herein specified meets the provisions of European Council Directive 93/42 EEC concerning medical devices.

Manufacturer

Date of manufacture

REF — Catalog number

SN — Serial number

Indicates the product should be used only once.
The symbol is found on the packaging for sheaths.

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

NOTE: The information regarding proper disposal is valid in the European Union. For locations outside of the European Union, please contact your local authorities or dealer and ask for the correct method of disposal.

Protection against electrical shock: Class II Equipment.

IP68 — Protection against dust and continuous immersion in water.

Compatibility with Radiographic Generators

GXS-700 is generally compatible with any dental X-ray unit and generator capable of supplying the required range of exposure times and doses.

Follow the instructions of the X-ray generator to set the desired dose range.

The radiation of X-ray tubes is controlled by the settings of:

- Exposure time (msec) or pulses
- Voltage (kV or kVp)
- Current (mA)

Some controls allow for the modification of all of the above, some have fixed settings for current and voltage.

Distance of X-ray Source to Sensor

There is a correlation between the distance of the cone to the sensor and the dose received by the Gendex GXS-700 sensor. The radiation that reaches the sensor decreases with the square of the distance. If you double this distance, you receive only 1/4 of the radiation.

Compatibility with Software

The GXS-700 requires the installation and use of GxPicture 3.0.1 or later software in combination either with:

- VixWin Platinum Software 2.0 or later, DEXIS 9.0.2 software or later, or Dentrix Image 5.1 CU1 software or later.

  or

- Application software which has Dental IO Diagnostic Imaging functionality; provided the software is released by the manufacturer for usage with GxPicture software.

Important: If the GXS-700 System is used with imaging software other than VixWin Platinum, then the Intended Use of that software needs to include **dental intra-oral x-ray**.

Chapter 8 Diagnostics

This section supplies information on some simple tests which the user may perform in the event of malfunctioning. Refer to the PC manual and the software manual for information on other types of malfunctions.

System Does Not Acquire X-ray Images

1. Check the GXS-700 USB connection to the PC; ensure that the GxPicture Status Icon is green (see "Status Icon" on page 5-1).
   If not:
   a. Check that the software drivers are installed correctly.
   b. Check that the GXS-700 is not disabled in the software program.
   c. Make sure that the correction file CD for the connected GXS-700 sensors are installed successful.
2. From the "Service" tab on GxPicture (see "Service" on page 5-5) click Send Image to send a test image to the application software. If the test image does not appear within the application software, then check this software installation/settings according the software user manual.
3. Make sure that the active side of the GXS-700 is facing the source of the x-ray and the active area is aligned with the x-ray beam.
4. Check the x-ray exposure settings and ensure that the x-rays were emitted.
5. Contact Gendex Customer Support or your dental dealer.

Operators of DEXIS or Dentrix software should consult the appropriate software user manual. If required, contact Customer Support (contact info provided in that manual).

Appendix A Accessories

	Description	Code	
1	GXS-700 Size 1 Positioner Kit	GXS700H1	
2	GXS-700 Size 2 Positioner Kit	GXS700H2	
3	GXS-700 Size 1 Disposable Sanitary Sheath Pack	112-1433	
4	GXS-700 Size 2 Disposable Sanitary Sheath Pack	112-1434	
5	USB 15' Extender Cable	643-0110	
6	USB 3' Extender Cable	643-0109	
7	GXS-700 Sensor Cradle (for Sizes 1 or 2)	303-0242	Shown with Sensor 
8	Anterior Holder - Size 1	303-0213	Size 1 shown 
9	Anterior Holder - Size 2	303-0221	
10	Posterior Holder - Size 1	303-0214	Size 1 shown 
11	Posterior Holder - Size 2	303-0222	
12	Bitewing Holder - Size 1, Horizontal	303-0215	Size 1 shown 
13	Bitewing Holder - Size 2, Horizontal	303-0223	
14	Bitewing Holder - Size 1, Vertical	303-0216	Size 1 shown 
15	Bitewing Holder - Size 2, Vertical	303-0224	

	Description	Code	
16	Endo Holder - Size 1, UL-LR, Horizontal	303-0217	Size 1 shown 
17	Endo Holder - Size 2, UL-LR, Horizontal	303-0225	
18	Endo Holder - Size 1, LL-UR, Horizontal	303-0218	Size 1 shown 
19	Endo Holder - Size 2, LL-UR, Horizontal	303-0226	
20	Endo Holder - Size 1, UL-LR, Vertical	303-0219	Size 1 shown 
21	Endo Holder - Size 2, UL-LR, Vertical	303-0227	
22	Endo Holder - Size 1, LL-UR, Vertical	303-0220	Size 1 shown 
23	Endo Holder - Size 2, LL-UR, Vertical	303-0228	
24	Bitewing Bar	112-1394	
25	Endo Bar	112-1424	
26	Periapical Bar	112-1395	
27	Bitewing Ring	303-0238	
28	Periapical and Endo Ring	303-0237	

Appendix B EMC Information

The GXS-700 sensor is, like any electronic medical device, subject to electromagnetic interactions with other electronic devices. The information in this chapter addresses this issue.

The EMC information in this chapter is provided for the medical system established by connecting the GXS-700 sensor to a computer. This computer must be compliant with IEC 60950-1 (if located outside the patient environment) or IEC 60601-1 (if located inside the patient environment). Please consult the documentation of the computer for complete EMC information.

Important: Portable/mobile radio frequency communications equipment can affect the function of the GXS-700 sensor as well as any other electronic medical equipment.

GXS-700 is a USB compliant device and shall be used with USB compliant cables suitable for high speed/USB 2.0 cables. Such cables are either marked "USB 2.0" or "USB Hi-Speed." USB certified hubs can be used to extend the distance to the USB host/computer. The length of the cable connection to the hub or between hubs shall not exceed 5 m.

CAUTION

Using non-USB compliant cables or hubs, or exceeding the maximum count of USB hub devices for extending the distance, can degrade the immunity of the GXS-700 sensor to electromagnetic fields or increase the emission of electromagnetic fields from the sensor.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The GXS-700 sensor, used with a compliant computer, is intended for use in the electromagnetic environment specified below. The customer or the user of the GXS-700 sensor should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The sensor 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 sensor 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 emissions IEC 61000-3-3	Complies (*)	

(*) Computer used with the GXS-700 sensor must meet this rating.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The GXS-700 sensor, used with a compliant computer, is intended for use in the electromagnetic environment specified below. The customer or the user of the GXS-700 sensor should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	Complies	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	Complies (*)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Complies (*)	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.	Complies (*)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the GXS-700 requires continued operation during power mains interruptions, it is recommended that the GXS-700 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE 1 U_T is the AC mains voltage prior to application of the test level. (*) Computer used with the GXS-700 sensor must meet this rating.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The GXS-700 sensor, used with a compliant computer, is intended for use in the electromagnetic environment specified below. The customer or the user of the GXS-700 sensor should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the GXS-700 sensor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 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 GXS-700 sensor is used exceeds the applicable RF compliance level above, the GXS-700 sensor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the GXS-700 sensor.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the GXS-700 Sensor

The GXS-700 sensor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the GXS-700 sensor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the GXS-700 sensor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter in Watts	Separation distance according to frequency of transmitter in meters		
	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, 73
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 meters (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.

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