VIDAR Systems Corporation



Installation Guide for Use With Windows XP & Windows 7

Advantage Series (Serial Numbers 340000 to 369999)

DiagnosticPRO[®] Advantage DosimetryPRO[®] Advantage CAD PRO[®] Advantage



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Terms denoted by the trademark symbol (TM or [®]) used in this publication are trademarks or service marks registered in the United States or other countries.

NOTE

The digitizers do not include application specific software (Picture Archiving and Communications [PAC] system, Teleradiology, Oncology Systems, or Computer Aided Detection [CAD] software). The manufacturer of the application software will determine specific indications for use. These third-party software packages or complete systems are approved separately from a regulatory perspective.

The digitizers are marketed as a component to application software development companies, who will incorporate the digitizer into their respective PACS or Teleradiology, CAD system(s). The software developer is ultimately responsible for detailing the Contraindications for the PACS System (or Teleradiology software package) or Oncology Systems as a whole, including the digitizer.





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Caution: No operator-serviceable parts inside. Refer servicing to qualified personnel.
Achtung: Gehäuse nicht öffnen. Wartung uno reparatur nur durch eletrofachkräfte.
Attention: Aucune piece ne peut etre remplacee par l'utilisateur. Toute operation de maintenance doit etre effectuee par une personne qualiee.
Atencion: Acceso interno solo autorizado a personal tecnico cualificado.
Attenzione: Non appire. Rivolgersi a personale qualificado.

Radio Frequency Emissions

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area can cause harmful interference, in which case the user will be required to correct the interference at his or her own expense.

Product compliance testing was conducted using VIDAR shielded cables. Modifications to the digitizer or the VIDAR shielded cables or the use of cables other than those available from VIDAR could void the user's authority to operate the equipment.

Storage/Shipping conditions

- Temperature: -18° to $+60^{\circ}$ C (0° to $+140^{\circ}$ F)
- Relative humidity: 20% to 85%, non-condensing
- Atmospheric pressure: 500 to 1060hPa (+18,000 to -1,200ft)

Operating conditions

- Temperature: 10° C to 35° C (50° F to 95° F)
- Relative humidity: 20% to 85%, non-condensing
- Atmospheric pressure: 696 to 1013hPa (10,000 to 0 ft)

Electrical supply

- Voltage: 100 to 240 VAC
- Current: 0.75 to 1.5 A
- Frequency: 47 to 63 Hz

Safety and compliance information





MEDICAL –GENERAL MEDICAL EQUIPMENT AS TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH: CAN/CSA C22.2 No.601.1-M90, IEC 60601-1, UL 60601-1, ANSI/AAMI ES60601-1(2005, 3RD Ed.), CAN/CSA-C22.2 No.60601-1(2008). IEC 60601-1:2005(3RD Ed.). 5RA9

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (i.e. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the system standard IEC 60601-1-1 or IEC 60601-1 3rd edition.

Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of IEC 60606-1-1 or IEC 60601-1 3^{rd} edition. If in doubt, consult the technical services department or your local representative.

This product is rated for continuous use.

This product is in the Ordinary Equipment Class. It provides no protection against the ingress of water.

This product is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or with nitrous oxide.

Class I Medical Device; No Applied Parts. This product provides Class I medical device protection against electrical shock.

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

Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "HOSPITAL ONLY" or "HOSPITAL GRADE".

WARNING: Do not modify this equipment without authorization of the manufacturer.

Do not position the product so that it is difficult to disconnect the product from the Mains Power Supply.

Mains power may be removed from the product by disconnecting the power cord at the rear of the product or unplugging the power cord from the wall outlet.

Power cords used with this device in North America must be rated by Underwriters Laboratories for hospital use.

Power cords used with this device in Europe must meet the requirements of IEC 227 Designation 53 or IEC 245 Designation 53.

Correct and safe operation of the digitizer requires familiarity with information that is not marked on the product. The following symbols indicate that the operator should consult the manual for additional information:

This Class 1 LED device is safe under reasonably foreseeable conditions of operation.

The LED illumination system consists of 16 Class 1 LEDs, a mirror system to spread the light, and a diffuser to distribute the light approximately uniformly across an area of 2.4 sq in (15.5 sq cm). Light from the LED illuminator may be indirectly observed in the digitizer's film entry and exit areas.





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DiagnosticPRO[®] Advantage & DosimetryPRO[®] Advantage (Red)

Installation Guide



Intended Use

VIDAR's x-ray film digitizers are intended for making digital copies of medical x-ray films.

Note:

- The DiagnosticPRO Advantage with ClinicalExpress or other DICOM standard software meet or exceed ACR and DICOM standards for use of secondary capture images for consultation, review and final interpretation. Images captured as DICOM MG are to be used as reference or comparison only, and not for primary diagnosis.
- Mammography images captured as DICOM MG are to be used as reference or comparison only, and not for primary diagnosis.

Unpack

In this chapter, you will:

- Unpack and inspect the digitizer's parts.
- Identify the digitizer's parts.

1. Look for Damage

Before unpacking the Digitizer, examine the shipping carton for damage.

If the carton is damaged:

- Notify the shipper immediately.
- Take photographs of the damage.
- Send pictures and description of damage to <u>medtech@3dsystems.com</u>.
- Notify VIDAR Medical Support at 1-703-471-7070.

2. Unpack the shipping carton

IMPORTANT: Save all the packing materials. If you need to ship the digitizer later, you should repack the digitizer in the original materials by reversing the procedure described here. Failure to properly pack, or failure to use VIDAR authorized shipping materials, will void the product's warranty, and will likely result in costly repairs.

Remove items from the shipping carton in the order shown below.



Note: For clarity, this illustration does not show the plastic bags surrounding the digitizer and feeder.

IMPORTANT: Save all the packing materials. If you need to ship the digitizer later, you should repack the digitizer in the original materials by reversing the procedure described here. Failure to properly pack, or failure to use VIDAR authorized shipping materials, will void the product's warranty, and will likely result in costly repairs.

3. Unpack the Accessory Box

a. Remove these items from the accessory box:



b. Then remove these items from the accessory box:



4. Unwrap

- a. Unwrap all items.
- b. Remove the foam block from the rear of the digitizer base:



IMPORTANT: Save the carton and all packing materials. If you need to ship the digitizer later, you **must** repack it using the original wire ties, plastic bags, foam supports and cartons. Instructions for repacking are provided in the "Packing the film digitizer for shipment" section of this manual.

5. Identify the Components

✓	Item
	Digitizer base
	Exit tray
	Film feeder
	Film support bar
	Stand
	Power cord: 115V (p/n 4043-001) <i>or</i> 230V (p/n 2104-006)
	Important Safety Information card (on film feeder)
	Quick setup card
	USB cable: 6 foot (p/n 4618)
	VIDAR Advantage Pro Series Installation & Users CD



Digitizer Base



Exit Tray

Film Support bar





6. If Anything Is Missing...

Immediately contact your VIDAR supplier.

7. Activate Your Product Warranty

Complete the warranty information/customer survey form at the back of this manual and mail it to VIDAR Systems Corp.

If your digitizer needs service, this information should be on file at VIDAR.

Contact VIDAR Technical Support if you have any questions about installing or using your VIDAR film digitizer: Phone: +1.800.471.SCAN (+1.800.471.7226) +1.703.471.7070 outside the U.S. E-mail: medtech@3dsystems.com

NEXT: Go to "Setting up" \Rightarrow

Setting Up

The digitizer must be placed on a counter or tabletop.



Identify Important Features

Look over the digitizer base and locate the features shown in this section. You will need to know where these features are when you assemble the digitizer.



Digitizer base, rear view

Assemble the Digitizer

- 1. Place the stand on a solid, flat surface (such as a table).
- 2. Place the digitizer base on the stand as shown below. Tighten the thumbscrews on the bottom of the stand to secure it to the digitizer.



*Vent in bottom of base must be over cutout in stand

- 3. Attach the feeder to the digitizer:
 - a. Note the three screws protruding from the bottom of the feeder. These mate to holes in the digitizer base. Two of the screws are very long—their tops ends are near the top of the feeder.

Also note the connector on the bottom of the feeder. It mates to the connector on top of the digitizer base.



b. Place the feeder on top of the digitizer, and slide the feeder connector into the digitizer connector.



- c. On the rear of the feeder, tighten the three screws to secure the feeder to the digitizer base.
 - You may need to move the feeder slightly to get the screws started in the holes.
 - Tighten each screw a few turns, then repeat until all are finger tight.

4. Install the exit tray by hooking it over the notched plastic edge just below the rollers. When the exit tray is properly positioned, it will be parallel to the roller shaft.



Properly installed exit tray

5. Insert the film support bar legs into the two holes on the film feeder's top edge. The film support bar's curved center portion must face the front of the film feeder.





IMPORTANT: Do not lift or carry the digitizer using the film support bar.

Warning

Before you begin the installation procedure, turn off all power to the computer and peripherals.

Précaution

Avant de commencer la connexion, assurez vous que votre ordinateur soit bien éteint.

Advertencia

Antes de continuar con la instalación, favor de apagar su computadora y periférico.

Warnung

Vor dem Installieren den Computer und angeschlossene Geräte ausschalten.

Connect the Power Cord

1. Connect the power cord to the digitizer's Power Entry Module (PEM), located on the rear of the digitizer.



2. Connect the other end of the power cord to a grounded power outlet.

Note: The film digitizer has an auto-sensing power supply. When you apply power, the digitizer will detect the voltage and set itself for proper operation.

NEXT: "Device Driver and Toolkit Installation Guide" \Box



CAD PRO[®] Advantage

Installation Guide



Unpack

In this chapter, you will:

- Unpack and inspect the digitizer's parts.
- Identify the digitizer's parts.

1. Look for Damage

Before unpacking the film digitizer, examine the shipping carton for damage.

If the carton is damaged, notify the shipper immediately.

IMPORTANT: Save the carton and all packing materials. If you need to ship the digitizer later, you **must** repack it using the original wire ties, plastic bags, foam supports and cartons. Instructions for repacking are provided in the "Packing the film digitizer for shipment" section of this manual.

2. Unpack the Shipping Carton

Remove items from the shipping carton in the order shown below.



3. Unpack the Accessory Box

- a. Remove these items from the accessory box:

b. Then remove these items from the accessory box:



4. Unwrap

- a. Unwrap all items.
- b. Remove the foam block from the rear of the digitizer base:



c. Locate the foam wedge on the bottom of the feeder.



d. Remove the wedge from the feeder as shown below.



IMPORTANT: Save the carton and all packing materials. If you need to ship the digitizer later, you **must** repack it using the original wire ties, plastic bags, foam supports and cartons. Instructions for repacking are provided in the "Packing the film digitizer for shipment" section of this manual.

5. Identify the Components

- ✓ Item
- Digitizer base
- Exit tray
- 50 sheet film feeder
- Dever cord: 115V (p/n 4043-001) or 230V (p/n 2104-006)
- □ Important Safety Information card (on film feeder)
- Quick setup card
- USB cable: 6 foot (p/n 4618)
- □ VIDAR Advantage Pro Series Installation & Users CD



Digitizer base





50 sheet feeder

6. If Anything Is Missing...

Immediately contact your VIDAR supplier.

7. Activate Your Product Warranty

Complete the warranty information/customer survey form in the front of this manual and mail it to VIDAR Systems Corp.

If your digitizer needs service, this information should be on file at VIDAR.

Contact VIDAR Technical Support if you have any questions about installing or using your VIDAR film digitizer: Phone: +1.800.471.SCAN (+1.800.471.7226) +1.703.471.7070 outside the U.S.

E-mail: medtech@3dsystems.com

NEXT: Go to "Setting up" \Box

Setting Up

The digitizer must be placed on a counter or tabletop.



Identify Important Features

Look over the digitizer base and locate the features shown in this section. You will need to know where these features are when you assemble the digitizer.



Digitizer base, rear view

Assemble the Digitizer

1. Place the digitizer base on a solid, flat surface (such as a table).



- 2. Attach the feeder to the digitizer:
 - a. Note the three screws protruding from the bottom of the feeder. These mate to holes in the digitizer base. Two of the screws are very long—their tops ends are near the top of the feeder.

Also note the connector on the bottom of the feeder. It mates to the connector on top of the digitizer base.



b. Place the feeder on top of the digitizer, and slide the feeder connector into the digitizer connector.



c. On the rear of the feeder, tighten the three screws to secure the feeder to the digitizer base.

Screws-

- You may need to move the feeder slightly to get the screws started in the holes.
- Tighten each screw a few turns, then repeat until all are finger tight.



3. Install the exit tray by hooking it over the notched plastic edge just below the rollers. When the exit tray is properly positioned, it will be parallel to the roller shaft.



Properly installed exit tray

Connect the Power Cord

1. Connect the power cord to the digitizer's Power Entry Module (PEM), located on the rear of the digitizer.



2. Connect the other end of the power cord to a grounded power outlet.

Note: The film digitizer has an auto-sensing power supply. When you apply power, the digitizer will detect the voltage and set itself for proper operation.

NEXT: "Device Driver and Toolkit Installation Guide"



Device Driver and Toolkit

Installation Guide



Install Device Drivers and Toolkit for Windows 7

The USB driver is required for all installations to assure that the computer communicates with the digitizer.

Note: Installation instructions for Windows XP are provided in the next chapter.

1. Apply Power to the Digitizer

a. Ensure the PC is turned off.

Note: Always turn on the digitizer before turning on the computer. This enables the computer to recognize the digitizer.

b. Turn on the digitizer. The on/off switch is located on the back of the digitizer.



Digitizer base, rear view



ON/OFF switch (a rocker switch)

Press I to turn power ON. Press 0 to turn power OFF.

Power switch and power entry module

c. Wait for all three LEDs on the front of the digitizer to turn green.

About the VIDAR Drivers

The VIDAR driver was designed to provide compatibility between VIDAR Advantage Series Digitizers and Windows 7 (both 32-bit and 64-bit). Features of this driver include:

■ Installation/setup wizard for easy and consistent installation.

2. Install the VIDAR Drivers

Note: The computer must be running Windows 7 Professional 32-bit or 64-bit.

Note: These instructions have been successfully tested on a wide range of Windows 7 systems. In rare instances, you may have difficulty installing the VIDAR driver. If that happens, try again after logging on as Administrator, or as a user with Administrator rights.



If you are using RIT 113 or Varian Software, **DO NOT USE THIS CD**.

You will need the VIDAR Advantage Pro Series Installation & Users CD.

- a. Be sure the digitizer is turned ON and all three LEDs are green, but that it is NOT connected to the PC. Wait until you are prompted to connect the digitizer to the PC.
- b. Turn on the PC.
- c. Insert the **VIDAR Advantage Pro Series Installation & Users CD** into the CD-ROM drive. Browse to the CD and double-click on *19090-002 VIDAR_Driver_6.0 Online Install Package.exe* on the CD to install the driver.

d. In the first screen, click **Next** >.



e. In the License Agreement screen, activate I accept the terms of the license agreement, then click Next >.



f. In the **Ready to Install the Program** screen, click **Install**.



g. The Setup Status screen will appear. Wait while the files are installed.



h. The **Windows Security** window will appear. Click **Install this driver software anyway** each time it appears.



i. When prompted Would you like to install this device software?, click Install.



j. InstallShield will indicate that installation is complete. However, the driver installation is not complete.



k. Earlier, you connected a USB cable to the digitizer. Now, attach the connector on the other end of that cable to a USB 2.0 port on the computer.

Note: Wait 30 seconds after you connect the digitizer before you launch the Demoscan program. This ensures the computer has recognized the new hardware and has installed the driver properly.

1. On the desktop, double-click the **DemoscanEx** icon.



m. The window shown below will appear. This indicates that the digitizer is communicating with the computer.

C DemoscanEx	- 0 ×	J
		ך
***** WELCOME to DEMOSCAN ***** ***** Version: 1.0.24.0 *****		
A development package from VIDAR Systems Corporation.		
VIDAR Toolkit Version: 6.0.25.0 WARNING: There was a problem with enabling logging.	=	
VIDAR Film Digitizer found at id = 0		l
Film digitizer information:		1
Digitizer model: Dental Film Digitizer		ł
Serial Number: 210002 Firmware version number: 6.25 Hardware version number: 128		
Resolution 0 = 75 Resolution 1 = 150 Resolution 2 = 300 Current resolution = 300 Optical resolution = 300		
Maximum width in inches = 13.00		
Bit depth 0 = 8 Bit depth 1 = 12 Bit depth 2 = 16 Current bit depth = 16		
Fixed line time = 16		
Dark Enhance not available. Line Filter not available. Maximum number of films = 1 Film backup available.		
Translation tables are limited to Linear and LOG. Translation table locations 0 and 1 set to LOG.		
Single unloadMedium<> command to eject film.		
No feeder found. Lamp type is a white LED full width cartridge.		
Time since power-up or reset = 169:59:49 (hrs:mins:secs) Time since last forced calibration = 169:54:54 (hrs:mins:secs)		
Enter the bit depth or q to quit then press <enter>: _</enter>		
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n. Press Q on the keyboard, then press ENTER.

The digitizer is now ready to operate. Please refer to the "User's Guide for VIDAR Advantage Series Digitizers" for operating instructions.

You may need to install other application software to run the digitizer.

Note: While the digitizer works with both 32-bit and 64-bit versions of Windows 7, it only works with 32-bit image processing applications.

In the Windows 7 Computer Management window, the digitizer is listed under Jungo.



Install Device Drivers and Toolkit for Windows XP

The USB driver is required for all installations to assure that the computer communicates with the digitizer.

Note: Installation instructions for Windows 7 are provided in the previous chapter.

1. Apply Power to the Digitizer

a. Ensure the PC is turned off.

Note: Always turn on the digitizer before turning on the computer. This enables the computer to recognize the digitizer.

b. Turn on the digitizer. The on/off switch is located on the back of the digitizer.



Digitizer base, rear view



ON/OFF switch (a rocker switch)

Press I to turn power ON. Press 0 to turn power OFF.

Power switch and power entry module

c. Wait for all three LEDs on the front of the digitizer to turn green.

About the VIDAR Drivers

The VIDAR driver was designed to provide compatibility between VIDAR Advantage Series Digitizers and Windows XP. Features of this driver include:

- Installation/setup wizard for easy and consistent installation.
- Scanners and Cameras Control Panel, which provides a common interface for still image devices.

2. Install the VIDAR Drivers

Note: The computer must be running Windows XP SP3.

Note: These instructions have been successfully tested on a wide range of Windows XP systems. In rare instances, you may have difficulty installing the VIDAR driver. If that happens, try again after logging on as Administrator, or as a user with Administrator rights.



If you are using RIT 113 or Varian Software, **DO NOT USE THIS CD**.

You will need the VIDAR Advantage Pro Series Installation & Users CD.

- a. Be sure the digitizer is turned ON and all three LEDs are green, but that it is NOT connected to the PC. Wait until you are prompted to connect the digitizer to the PC.
- b. Turn on the PC.
- c. Insert the **VIDAR Advantage Pro Series Installation & Users CD** into the CD-ROM drive. Browse to the CD and double-click on *19090-002 VIDAR_Driver_6.0 Online Install Package.exe* on the CD to install the driver.

d. In the first screen, click **Next** >.



e. In the License Agreement screen, activate I accept the terms of the license agreement, then click Next >.



f. In the **Ready to Install the Program** screen, click **Install**.



g. The Setup Status screen will appear. Wait while the files are installed.



h. The VIDAR Driver Install window previews the next steps. Click Next >.



- i. The **Digital Signature Not Found** window will may appear Each time it appears, click **Yes**. (Note the screen may look a bit different in Windows VISTA.)
- j. The **Software Installation** window will appear. Click **Continue Anyway** each time it appears.

5oftware	Installation
1	The software you are installing has not passed Windows Logo testing to verify its compatibility with Windows XP. (<u>Tell me why</u> <u>this testing is important.</u>)
	Continuing your installation of this software may impair or destabilize the correct operation of your system either immediately or in the future. Microsoft strongly recommends that you stop this installation now and contact the software vendor for software that has passed Windows Logo testing.

k. InstallShield will indicate that installation is complete. However, the driver installation is not complete.



- 1. Earlier, you connected a USB cable to the digitizer. Now, attach the connector on the other end of that cable to a USB 2.0 port on the computer.
- m. The **Found New Hardware** window will appear, indicating that the digitizer is connected to the computer.
- n. Select **Yes, this time only**, then click **Next** >.

Found New Hardware Wizard				
	Welcome to the Found New Hardware Wizard Windows will search for current and updated software by looking on your computer, on the hardware installation CD, or on the Windows Update Web site (with your permission). Read our privacy policy			
	Can Windows connect to Windows Update to search for software? Yes, this time only Yes, now and every time I connect a device No, not this time			
	Click Next to continue.			
	< Back Next > Cancel			

o. On the next screen click **Install the software automatically (Recommended)**, then click **Next >.**

Found New Hardware Wizard
This wizard helps you install software for: VIDAR Film Digitizer If your hardware came with an installation CD or floppy disk, insert it now. What do you want the wizard to do? Install the software automatically (Recommended) Install from a list or specific location (Advanced) Click Next to continue.
< <u>B</u> ack <u>N</u> ext > Cancel

p. Wait while the wizard searches for the driver.

Please wait while the wizard searc	hes	E Contraction of the second se
VIDAR Film Digitizer		
	< <u>B</u> ack <u>N</u> ext >	Cancel

q. The **Digital Signature Not Found** window may appear, click **Yes** each time it appears.



r. When the Files Needed dialog appears, browse to C:\WINDOWS\system32, then click OK

Files Ne	eded	×
	The file 'Vidarusd.dll' on VIDAR Film Digitizer Driver is needed.	ОК
		Cancel
	Type the path where the file is located, and then click OK.	
	Copy files from:	
	C:\WINDOWS\system32	Browse

s. After the driver has been installed, click **Finish**.



- t. Verify that the digitizer drivers are fully installed by checking the device properties at **Start > Control Panel > Scanners and Cameras**.
- u. In the device window, <u>right</u>-click **VIDAR Film Digitizer**, then click **Properties** in the pop-up menu.

v. In the **VIDAR Film Digitizer Properties** window, click the **VIDAR Properties** tab. If the driver is properly installed, the properties will appear and if the digitizer is ready to digitize its serial number will appear. If **Not Ready** appears the digitizer is normalizing.

VIDAR Film Digitizer Properties				
General VIDAR Properties Color Management				
Film Digitizer Vendor Identification: VIDAR Model Name: VXR-12 Serial Number: 210070 Firmware Version: 6.25 Hardware Version: 128				
Manufacturer VIDAR Systems Corporation 365 Herndon Parkway Herndon, Virginia 20170 USA phone +1.703.471.7070 toll firee 800.471.7226 fax +1.703.471.7665 info@filmdigitizer.com http://www.filmdigitizer.com				
OK Cancel A	pply			

Note that:

- The digitizer will report as "VXR-12" for backward compatibility.
- You may not see the same firmware and hardware version as shown in the window above.
- The serial number will not report if the digitizer was just powered on.

w. Click **OK** to close the properties screen.

The digitizer is now ready to operate. Please refer to the "User's Guide for VIDAR Advantage Series Digitizers" for operating instructions.

You may need to install other application software to run the digitizer.

Appendix: Electromagnetic Guidance

Caution: Medical electrical equipment.

EMC (Electro Magnetic Compatibility) must be considered before any medical electrical equipment is installed or put into service. Follow the information in the accompanying documentation when installing and operating the VIDAR Digitizer.

Caution: Portable or mobile RF communication equipment can effect Medical Electrical equipment.

Caution: Using the Digitizer adjacent to or stacked with other equipment may cause interference between the equipment. Before utilizing stacked or adjacent equipment, verify proper functionality of all equipment in the actual configuration in which it will operate.

Caution: Connecting the Digitizer to equipment that is not rated CISPR 11 class A or class B may alter the electromagnetic characteristics.

Caution: In a domestic environment this product may cause radio interference in which case the user may be required to take adequate measures.

Guidance and manufacturer's declaration – electromagnetic equipment

Table 201

The DiagnosticPRO Advantage, DosimetryPRO Advantage (Red) and CAD PRO Advantage Digitizers are intended for use in the electromagnetic environment specified below. The customer or end user of the Digitizer should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance		
RF Emissions	Group 1	The Digitizers use RF energy only for their internal functions. Therefore, its RF emissions are very low and are not likely to cause		
CISPR11		any interference in nearby electronic equipment.		
RF Emissions, CISPR11	Class A			
Harmonic Emissions IEC 61000-3-2	Class A	The Digitizers are suitable for use in all establishments other than domestic and those directly connected to the public low voltage		
Voltage Fluctuations/ flicker emissions IEC 61000-3-3	Complies	power supply network that supplies buildings used for domestic purposes.		

Guidance And Manufacturer's Declaration – Electromagnetic Immunity

Table 202

The DiagnosticPRO Advantage, DosimetryPRO Advantage (Red) and CAD PRO Advantage Digitizers are intended for use in the electromagnetic environment specified below. The customer or end user of the Digitizer 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	+ 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.	
	<5 % UT (>95 % dip in U _T) for 0,5 cycle	<5 % UT (>95 % dip in U _T) for 0,5 cycle		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	40 % U _T (60 % dip in U _T) for 5 cycles 70 % U _T (30 % dip in U _T) for 25 cycles	40 % U _T (60 % dip in U _T) for 5 cycles 70 % U _T (30 % dip in U _T) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Digitizer requires continued operation during power mains interruptions, it is recommended that the Digitizer be powered from an uninterruptible power supply or a battery	
	<5 % U⊤ (>95 % dip in U⊤) for 5 sec	<5 % U⊤ (>95 % dip in U⊤) for 5 sec		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.	
NOTE: U_T is the A.C. mains voltage prior to application of the test level				

Guidance And Manufacturer's Declaration – Electromagnetic Immunity

Table 204

The DiagnosticPRO Advantage, DosimetryPRO Advantage (Red) and CAD PRO Advantage Digitizers are intended for use in the electromagnetic environment specified below. The customer or end user of the Digitizer should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communication equipment should be used no closer to any part of the Digitizer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
Radiated RF	3 V/m	3 V/m	$d=1.2\sqrt{P}$ 80 MHz to 800 MHz
IEC 61000-4-3	80 MHz to 2,5 GHz		$d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> 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 80MHz and 800MHz, the higher frequency range applies.

Note 2: These guidelines may not be applicable 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 Digitizer is used exceeds the applicable RF compliance level above, the Digitizer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Digitizer.

^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 Digitizer

Table 206

The DiagnosticPRO Advantage, DosimetryPRO Advantage (Red) and CAD PRO Advantage Digitizers are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Digitizer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Digitizer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter, m		
W	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
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.

Appendix: Symbols

Symbol	Description
Â	Indicates the need for the user to consult the instructions for use.
- II	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
SRA9	Underwriters Laboratories classification symbol
CE	Compliance to EU Directives
EC REP	Authorized Representative in the European Community
	Indicates the Medical Device Manufacturer
	This symbol on the product indicates that this product must not be disposed of as unsorted municipal waste. Instead it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for recycling of waste electrical and electronic equipment. For more information about where you can dispose of your waste equipment for recycling please contact your local city office, your household waste disposal service or the shop where you purchased the product.

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