Installation guide for

DiagnosticPRO™ *Edge*
Windows 7, 8, & 10

■ Multi-film feeder

Serial numbers
380,000 to 389,999

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.

VIDAR systems corporation
A 3D Systems Company

365 Herndon Parkway
Herndon, VA 20170 U.S.A.

Phone: 1-703-471-7070
Fax: 1-703-471-7665
Internet: www.vidar.com

Sales: 1-800-471-7070 or
1-800-471-7226
Email: order@3dsystems.com

Technical Support:
1-800-471-7070 or 1-703-471-7070
E-mail: medtech@3dsystems.com

EC | REP

Emergo Europe
Prinsessegracht 20
2514 AP, The Hague
The Netherlands

> **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°C (0° to +140°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 (60°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: CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC 60601-1:2005+A1:2012 Edition 3.1. ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012.

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 Edition 3.1.

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 60601-1 Edition 3.1. 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 cable at the rear of the product. The Mains power may also be disconnected by unplugging the power cord from the external power supply adapter 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.
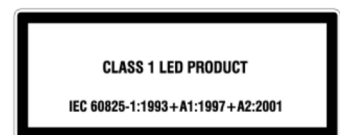
Power cords used with this device in Europe must meet the requirements of IEC 227 Designation 53 or IEC 245 Designation 53.

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 20 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.

CLASS 1 LED PRODUCT

IEC 60825-1:1993+A1:1997+A2:2001

Contents

Intended Use

The DiagnosticPRO *Edge* digitizer is used for making digital copies of medical x-ray film, including printed and radiographic film.

The target users of these devices are medical professionals or trained staff for use as secondary capture images for consultation, review, and final interpretation.

The devices are indicated for the digitization of mammography images for review and analysis, but not as the sole basis for screening or diagnosis.

> **Note:**
>
> The DiagnosticPRO *Edge* with ClinicalExpress or other DICOM standard software meets or exceeds 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.

Notice to Users

In the event of any serious incident occurring in relation to the device please report to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Unpack the digitizer

In this chapter, you will:
- Unpack and inspect the digitizer's parts.
- Identify the digitizer's parts.

1. Look for damage.

Before unpacking the DiagnosticPRO *Edge* film 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 medtech@3dsystems.com.
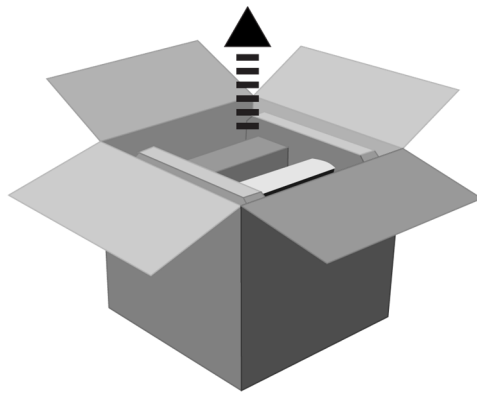- Notify VIDAR Medical Support at 1-703-471-7070.

2. Unpack the shipping carton.

> **IMPORTANT:** Save all 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.
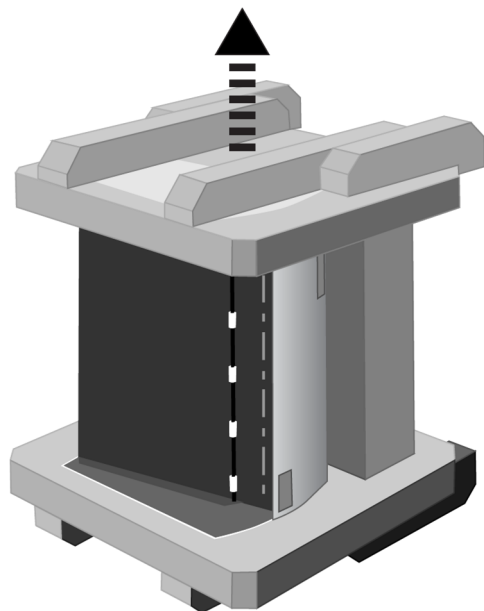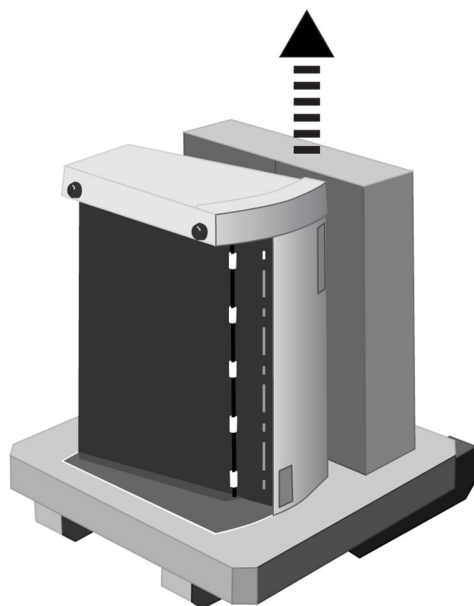
a. Remove the accessory box.
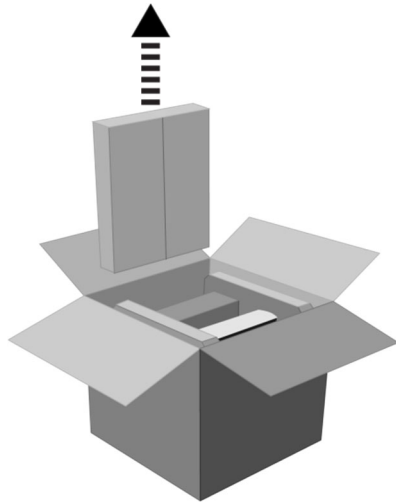
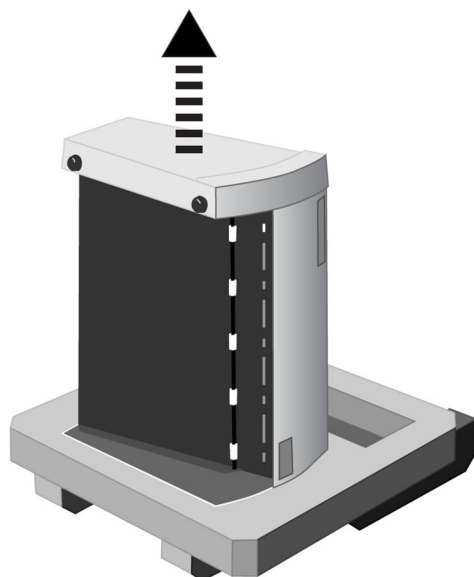b. Lift the digitizer, feeder box and foam end caps—together—out of the shipping container.

c. Place the group on one foam end cap. Lift off the upper foam end cap.

d. Remove the feeder box from the lower end cap.

e. Remove the digitizer from the lower end cap.

IMPORTANT: Save all 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. Identify the parts.

Check carefully to ensure you received the items listed below.

Standard items

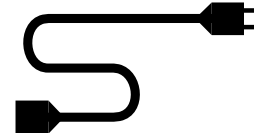| ✓	Description	(**Note:** items are not shown to same scale.)
☐	DiagnosticPRO *Edge* film digitizer	
☐	Multi-film feed tray	
☐	Film tray	
☐	Power Adapter. Contact Service Provider or Vidar Systems Corp for P/N	
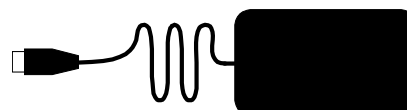
✓	**Description** (**Note:** items are not shown to same scale.)
☐	Electrical power cord China Power Cord, P/N 4635
☐	Multi-film feed tray cable, VIDAR part number 4200-001 (if unit has multi-film feed tray)
☐	Quick start guide card
☐	VIDAR DiagnosticPRO *Edge* Installation CD
☐	USB Cable, VIDAR part number 4618-002

Optional items

✓	**Description**
☐	Third-party software instructions (not supplied for the market in China)
☐	Lint-free wipes, VIDAR part number 15194 (package of 10)

4. Identify important features

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

Power switch

The power switch is located on the front of the digitizer.

To turn digitizer ON:
Press and release power switch.

To turn digitizer OFF:
Press and hold for two seconds.

> **CAUTION:** The digitizer power switch is used to disconnect the 24 volts from the external power adapter to the digitizer, and therefore applies power to and removes power from the digitizer only. The external power adapter is still a source of electrical current as long as it is plugged into an electrical outlet.

Rear panel

View the digitizer from the rear to identify the USB port and power connector.

USB port

Power connector
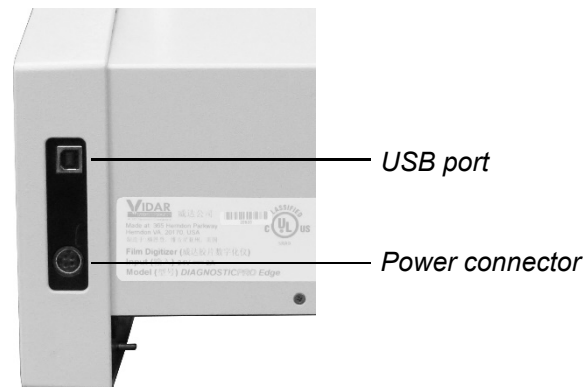
5. If anything is missing...

Immediately contact your VIDAR supplier or send e-mail to medtech@VIDAR.com.

6. Record important information and activate your product warranty.

a. Locate the "Warranty information and customer survey" form on the DiagnosticPRO *Edge* CD.

b. Print the "Warranty information and customer survey."

c. In the "Product information" section, record this information:
    - Product you are registering: DiagnosticPRO *Edge*.
    - Digitizer serial number.

d. Complete the form.

e. Mail or fax the form 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

When you contact VIDAR, you will need to provide:
- The unit's serial number.
- Your name, company and contact information.
- Where you purchased the digitizer.

Assemble the digitizer

1. Place the digitizer base on a table. Orient the digitizer base with the back toward you.
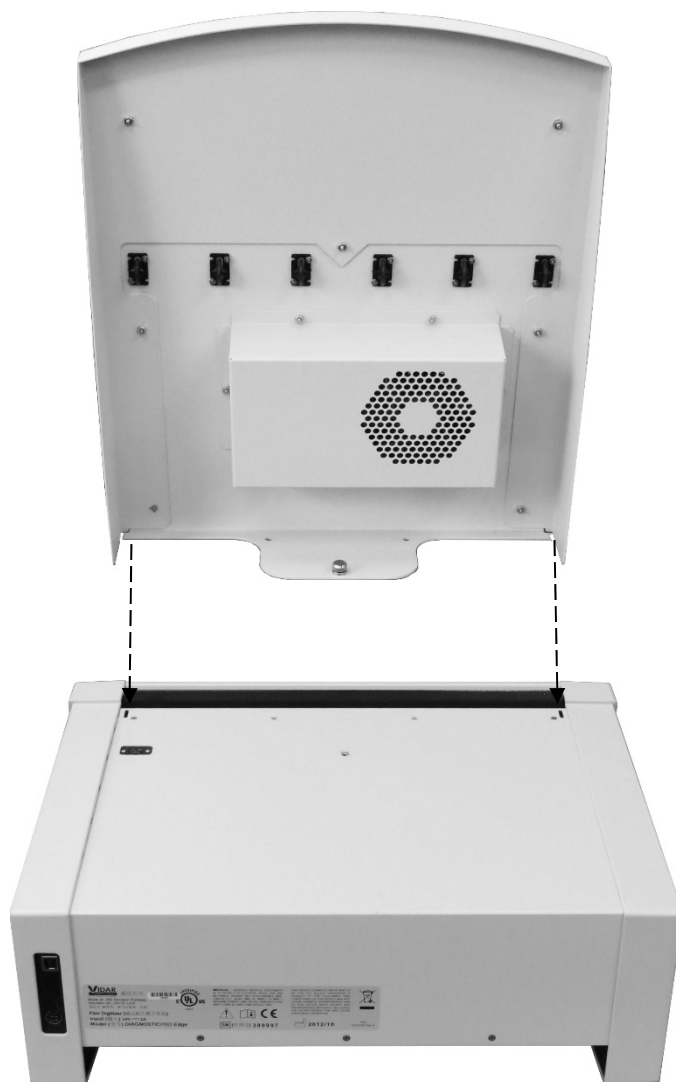
   Notice the two slots on top of the digitizer base.

   Slots

2. Orient the film feeder with the back toward you (multi-film feeder is shown; single-film feeder is similar). You should be able to see the thumbscrew at the bottom rear of the feeder.

   Thumbscrew

3. Insert the tabs on the bottom of the feeder into the slots on the digitizer base.

4. Tighten the thumbscrew to secure the feeder to the base.

Thumbscrew
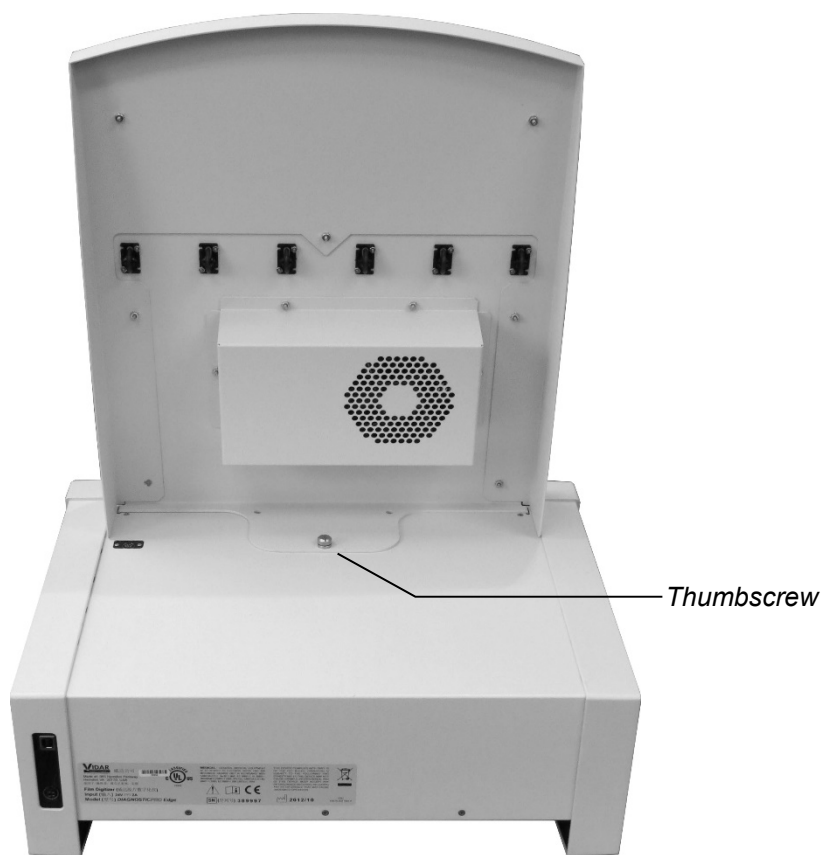
5. Connect the multi-film feeder cable between the feeder and digitizer base as shown below.

Multi-film feeder cable

6. Go to "Placing the digitizer on a table," the next chapter in this manual.

Place the digitizer on a table

1. Select a working location for the film digitizer. Consider the following points when selecting a suitable location:
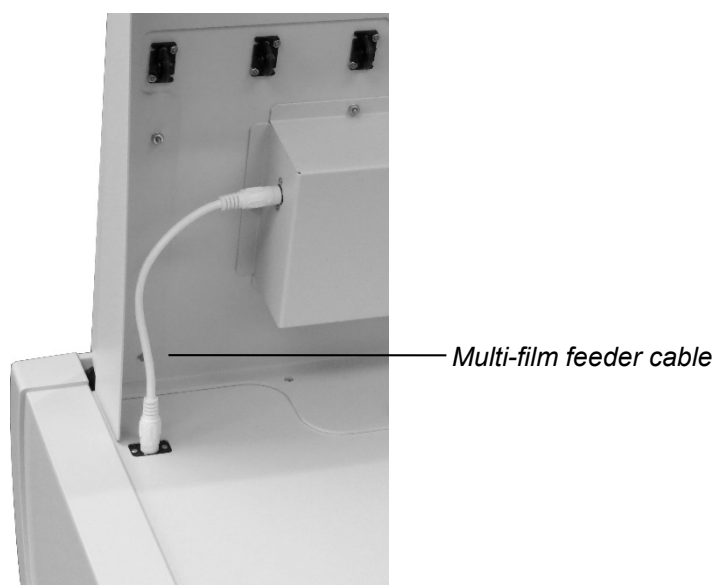
   - The digitizer is not intended to be used in a Patient Environment.

   - The digitizer can only be used on a desk, countertop, table or other physically stable surface not more than 36" (91cm) high.

   > **SAFETY WARNING**
   >
   > The digitizer **must** be placed on mechanically secure horizontal surface, such as a desk or countertop not more than 36" (91cm) high and with no more than a 5° tilt.
   >
   > The digitizer **must not** be placed on the floor.
   >
   > VIDAR Systems Corp. is not liable for any damages or injuries to persons or property associated with improper placement or use of the digitizer.

   - The digitizer must be within 6 feet (1.8m) of an electrical outlet.

   - The USB cable must be able to connect to both computer and digitizer.

   - The digitizer must be away from high traffic areas.

2. Place the digitizer in the location you have selected. Ensure the digitizer is stable (for example, it should not rock when touched).

3. Go to "Final assembly," the next chapter in this manual.

Final assembly

Connect the USB cable and power supply

> **CAUTION:** Power the digitizer **only** with the power supply adapter provided by your Service Provider or Vidar Systems Corp.

1. Connect the USB cable to the USB port on the back of the digitizer. Do not connect the USB cable to the PC until instructed later.
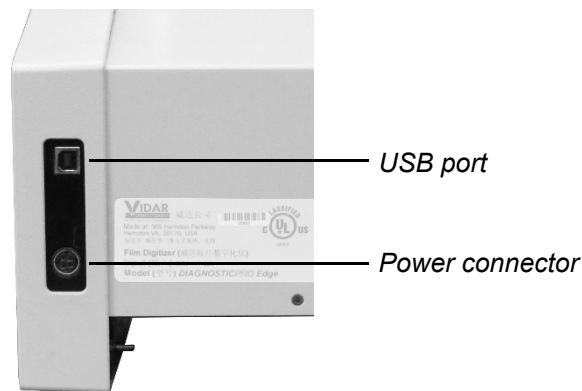
2. Connect the power adapter's cable to the power connector on the back of the digitizer.

3. Connect the electrical cord to the power adapter.

4. Place the power adapter, power cable and electrical cord where they will not be a hazard.

Install the exit tray

1. Slide the exit tray into the digitizer, keeping it high, then drop it down and slide it back toward you so the notches fit over the internal pins.
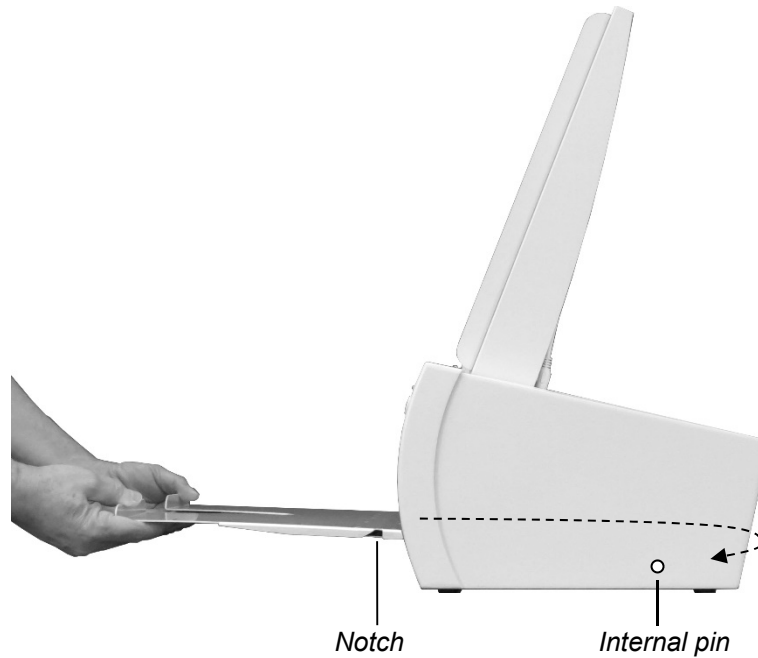
Notch   *Internal pin*

2. When properly positioned, the exit tray will protrude a small distance from the digitizer, and it can't be pulled out without lifting it off the internal pins.

Exit tray in position
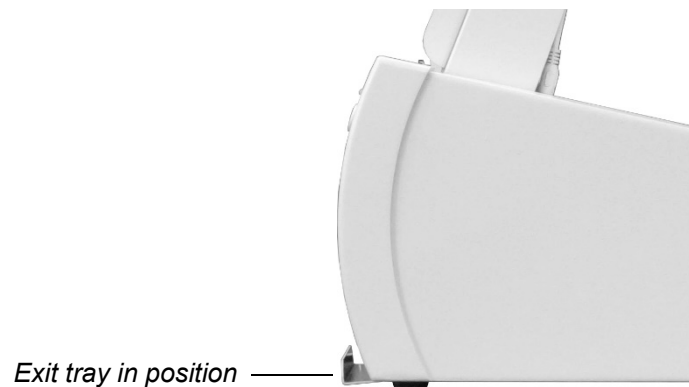
Install Device Drivers for Windows 7, 8, and 10

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

1. Apply Power to the Digitizer and the PC

a. Ensure the PC is turned **off**.

> **Note:** Always apply power to 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 front of the digitizer.

To turn digitizer ON:
Press and release power switch.
To turn digitizer OFF:
Press and hold for two seconds.

> **Note:** The digitizer power switch is used to disconnect the 24 volts from the external power adapter to the digitizer, and therefore applies power to and removes power *from the digitizer only*. The external power adapter is still a source of electrical current as long as it is plugged into an electrical outlet.

c. Observe the LED on the front of the digitizer: the LED should flash light blue for a little over 5 minutes. This indicates the digitizer is performing internal tests.

d. When the LED stops flashing and remains solid green, proceed to step 2.

About the VIDAR Drivers

The VIDAR driver is designed to provide compatibility between VIDAR DiagnosticPRO *Edge* Digitizers and Windows 7, 8, and 10 (both 32-bit and 64-bit). Features of this driver include:

- Installation/setup wizard for easy and consistent installation.
- Scanners and Cameras Control Panel (32-bit only), which provides a common interface for still image devices.

2. Install the VIDAR Drivers

Note: The computer must be running Windows 7, 8, & 10 Professional 32-bit or 64-bit.

Note: These instructions have been successfully tested on a wide range of Windows 7, 8, and 10 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.

You will need the VIDAR DiagnosticPRO *Edge* Digitizer Installation CD.

a. Be sure the digitizer is turned ON and has a stable green light 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 DiagnosticPRO *Edge* Installation CD** into the CD-ROM drive. Browse to the CD and double-click on *19090-003 VIDAR_Driver_6.1 Online Install Package.exe* on the CD to install the driver.

d. In the first screen, click **Next >**.
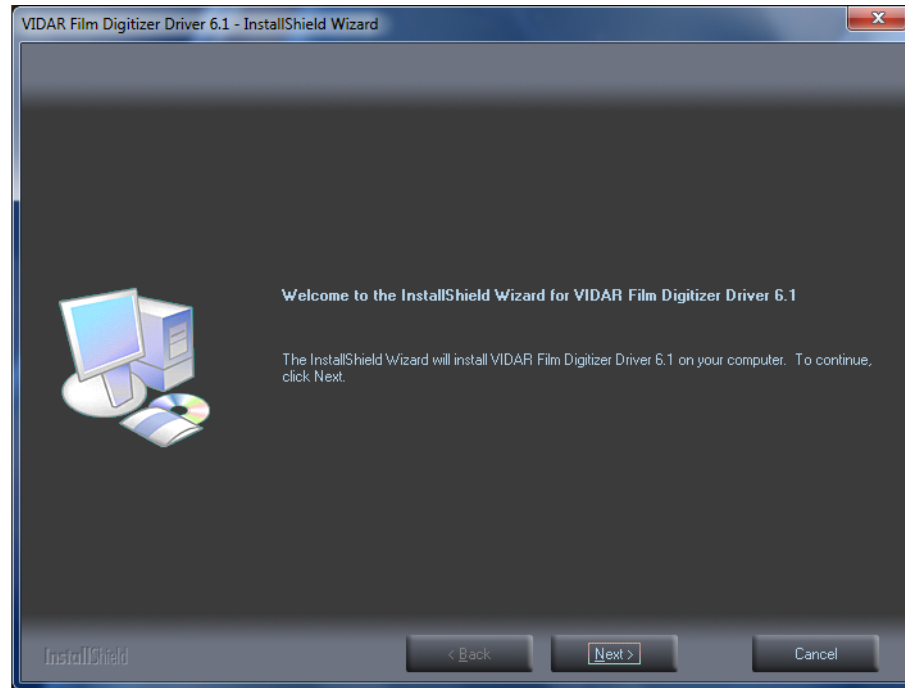
e. In the **License Agreement** screen, activate **I accept the terms of the license agreement**, then click **Next >**.
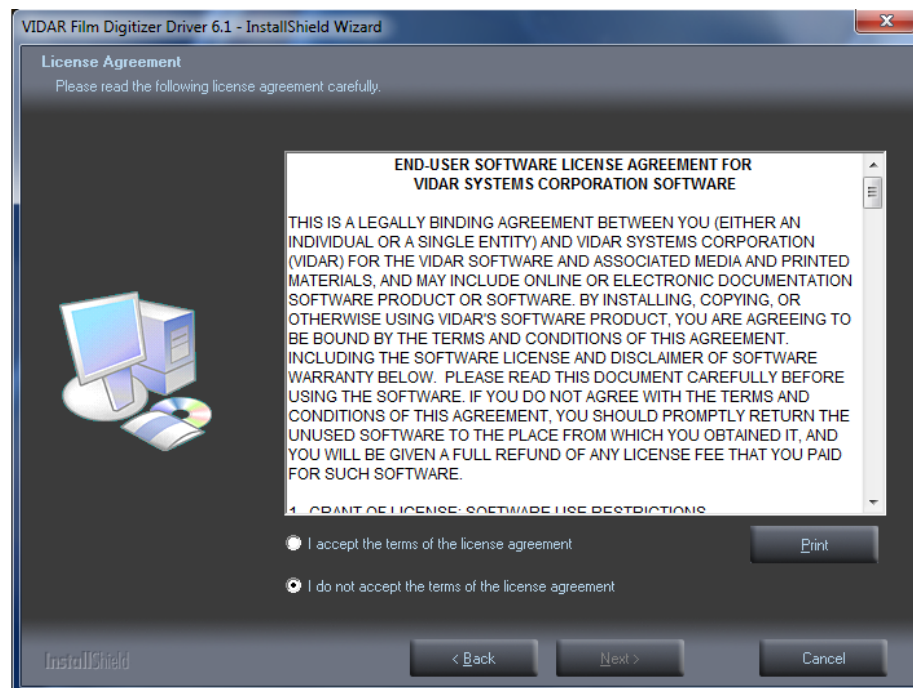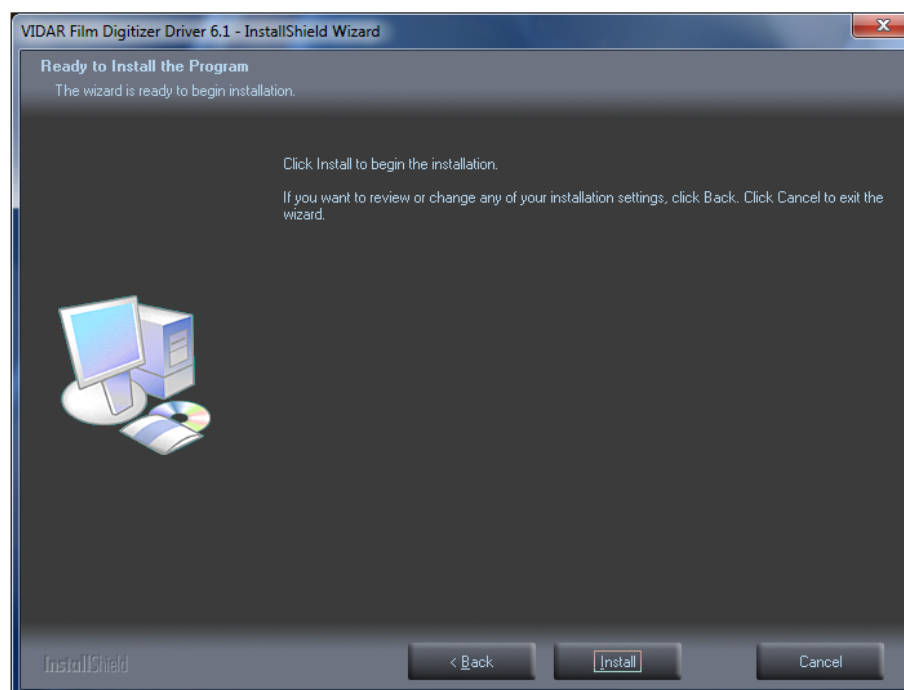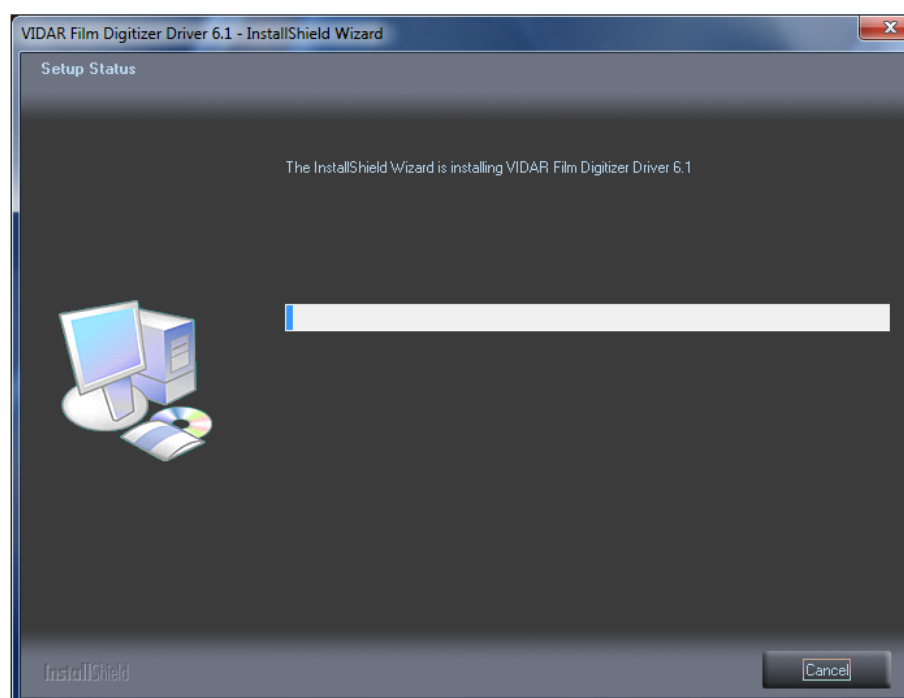
f. In the **Ready to Install the Program** screen, click **Install**.

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

h. When prompted "**Would you like to install this device software?**" Click **Install**. When installing on Windows 7, 8, & 10, 64 bit the name will appear as **Jungo**
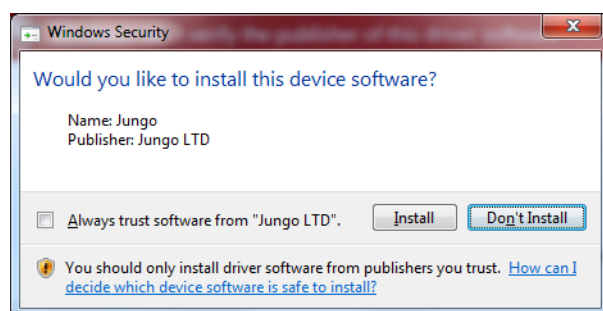
i. When installing on Windows 7, 8, & 10, 32 bit the name will appear as **VIDAR**
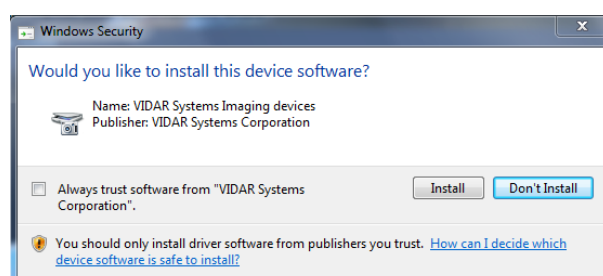
j. InstallShield will indicate that installation is complete. However, the driver installation is not complete.
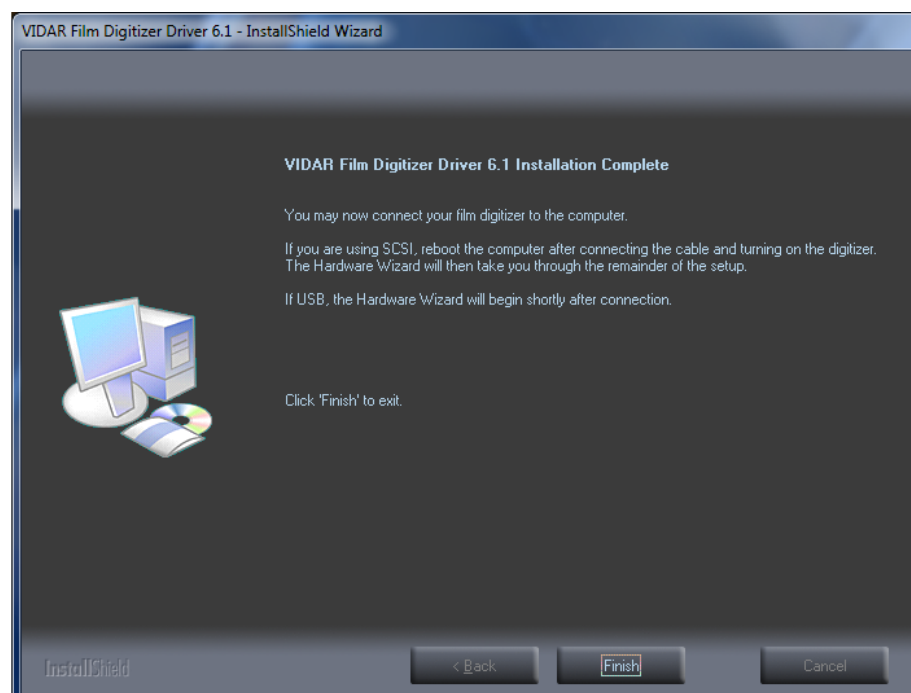
k. Earlier, you connected a USB cable to the digitizer. Now, attach the connector on the other end of that cable to a USB 2.0 or 3.0 port on the computer.

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

l. *On a 64-bit system:*

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

    2. The window shown below will appear. This indicates that the digitizer is communicating with the computer.
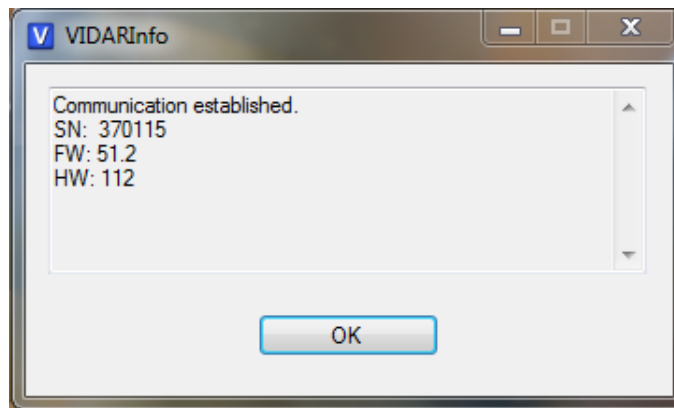
    3. Click "OK" if the Digitizer Information is present on the Screen

    4. *64-bit system only:* In the Windows 7, 8, & 10 **Computer Management** window, the digitizer is listed under **Jungo**.
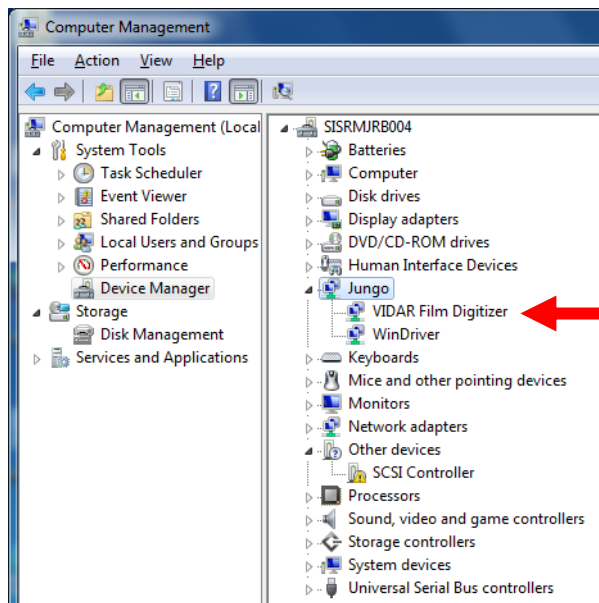
2. *On a 32-bit system:*

    1. **Start > Control Panel > Scanners and Cameras**.

    2. In the device window, <u>right</u>-click **VIDAR Film Digitizer**, then click **Properties** in the pop-up menu.

    3. 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.
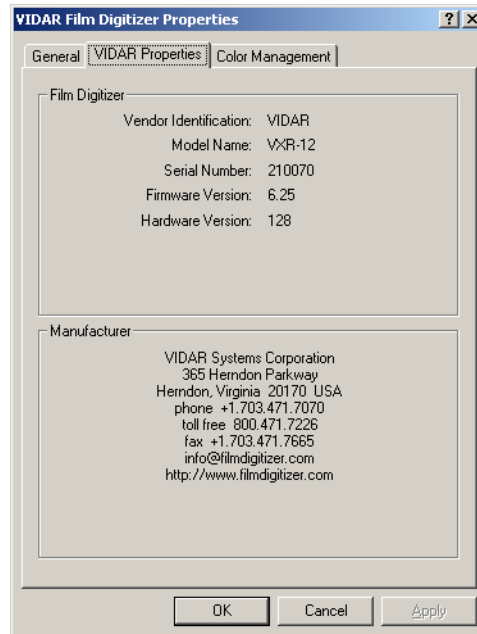
Note that:
- The digitizer will report as "VXR-12" for backward compatibility.
- You may not see the same firmware and hardware version as shown in the window above.
- The serial number will not report if the digitizer was just powered on.

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

5. *32-bit system only:* In the Windows 7, 8, & 10 **Computer Management** window, the digitizer is listed under **Imaging devices**.
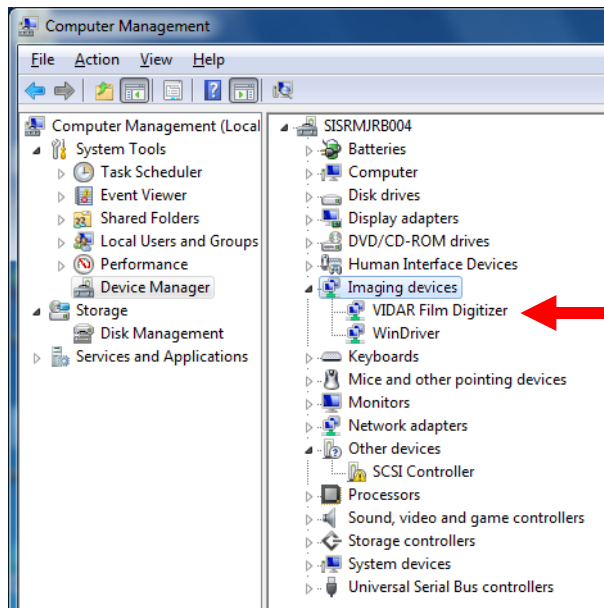
The digitizer is now ready to operate. Please refer to the "User's Guide for DiagnosticPRO *Edge*" for operating instructions.

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, 8, & 10 it only works with 32-bit image processing applications.

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 DiagnosticPRO *Edge* 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		
The DiagnosticPRO *Edge* Digitizer is intended for use in a **professional healthcare facility environment**. 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 CISPR11	Group 1	The Digitizer uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class A	The Digitizer is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

Guidance And Manufacturer's Declaration – Electromagnetic Immunity Enclosure Port

The DiagnosticPRO *Edge* Digitizer is intended for use in a **professional healthcare facility environment**. The customer or end user of the Digitizer should assure that it is used in such an environment.

Immunity test	Test method	Immunity Test Levels Professional healthcare facility environment
Electrostatic Discharge (ESD)	IEC 61000-4-2	± 8 kV contact ± 2 kV, ±4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Table A
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 or 60 Hz

Guidance And Manufacturer's Declaration – Electromagnetic Immunity - Input a.c. power

The DiagnosticPRO *Edge* Digitizer is intended for use in a **professional healthcare facility environment**. The customer or end user of the Digitizer should assure that it is used in such an environment.

Immunity test	Test method	Immunity Test Levels Professional healthcare facility environment
Electrical fast transient / bursts [a) l) o)]	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges [a) b) j) o)] Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV
Surges [a) b) j) k) o)] Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ±2 kV
Conducted disturbances induced by RF fields [c) d) o)]	IEC 61000-4-6	3 V [m)] 0,15 MHz – 80 MHz 6 V [m)] in ISM bands between 0,15 MHz and 80 MHz [n)] 80 % AM at 1 kHz [e)]
Voltage dips [f) p) r)]	IEC 61000-4-11	0 % U_T ; 0,5 cycle [g)] At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° [q)] 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycles [h)] Single phase: at 0°
Voltage interruptions [f) i) o) r)]	IEC 61000-4-11	0 % U_T ; 250/300 cycle [h)]
Note: U_T is the A.C. mains voltage prior to application of the test level.		

Guidance And Manufacturer's Declaration – Electromagnetic Immunity - Input a.c. power Continued:

a) The test may be performed at any one power input voltage within the ME Equipment or ME SYSTEM RATED voltage range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.

b) All the ME EQUIPMENT and ME SYSTEM cables are attached during the test.

c) Calibration for current injection clamps shall be performed in a 150 Ω system.

d) If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

f) ME EQUIPMENT and ME SYSTEMS with a d.c. power input intended for use with a.c.- to – d.c. converters shall be tested using a converter that meets the specifications of the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM. THE IMMUNITY TEST LEVELS are applied to the a.c. power input of the converter.

g) Applicable only to ME EQUIPMENT and ME SYSTEMS connected to single-phase a.c. mains.

h) E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.

i) ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase shall be interrupted one for 250/300 cycles at any angle and at all phases at the same time (if applicable). ME EQUIPMENT and ME SYSTEMS with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A, all phases shall be interrupted simultaneously.

j) ME EQUIPMENT and ME SYSTEMS that do not have a surge protection device in the primary power circuit may be tested only at ± 2kV line(s) to earth and ± 1 kV line(s) to line(s).

k) Not applicable to CLASS II ME EQUIPMENT and ME SYSTEMS.

l) Direct coupling shall be used.

m) r.m.s., before modulation is applied.

n) The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

o) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase and ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase.

p) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase.

q) At some phase angles, applying this test to ME EQUIPMENT with transformer mains power input might cause an overcurrent protection device to open. This can occur due to magnetic flux saturation of the transformer core after the voltage dip. If this occurs, the ME EQUIPMENT or ME SYSTEM shall provide BASIC SAFETY during and after the test.

r) For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the minimum and maximum RATED input voltage. ME EQUIPMENT and ME SYSTEMS with a RATED input voltage range of less than 25 % of the highest RATED input voltage shall be tested at one RATED input voltage within the range.

Immunity to proximity fields form RF wireless communications equipment

The ENCLOSURE PORT of ME EQUIPMENT and ME SYSTEMS shall be tested as specified in Table A using the test methods specified in IEC 61000-4-3.

The frequencies and services listed in Table A are representative examples that are based on RF communications equipment in use at the time of publication of this collateral standard. The test specification does not attempt to cover every frequency and service used in every country. The RISK MANAGEMENT PROCESS should take current communications services into account. Testing should be performed at the additional frequencies identified that are not represented in Table A.

While communication might not be possible when ME EQUIPMENT that includes radio equipment is tested in its bandwidth, the ME EQUIPMENT or ME SYSTEM shall still be able to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE.

Table A- Test specifications for Enclosure Port immunity to RF wireless communications equipment.

The DiagnosticPRO Edge Digitizer is intended for use in a **professional healthcare facility environment**. 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.

Test frequency (MHz)	Modulation [a]	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	Pulse modulation 18 Hz	1,8	0,3	27
450	FM [b] ±5 kHz deviation 1 kHz sine	2	0,3	28
710	Pulse modulation 217 Hz	0,2	0,3	9
745				
780				
810	Pulse modulation 18 Hz	2	0,3	28
870				
930				
1 720	Pulse modulation 217 Hz	2	0,3	28
1 845				
1 970				
2 450	Pulse modulation 217 Hz	2	0,3	28
5 240	Pulse modulation 217 Hz	0,2	0,3	9
5 500				
5 785				

NOTE: If necessary to achieve the Immunity Test Level, the distance between the transmitting antenna and the ME Equipment or ME System may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3

a)   The carrier shall be modulated using a 50% duty cycle square wave signal.
b)   As an alternate to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

The Manufacturer should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation:

$$E = \frac{6}{d}\ \sqrt{P}$$

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

If the ME EQUIPMENT or ME SYSTEM complies with the higher IMMUNITY TEST LEVELS for this test, the 30 cm minimum separation distance (per above table) may be replaced with minimum separation distances calculated from the higher IMMUNITY TEST LEVELS.

Appendix:
Symbols

Symbol	Description
	Indicates a sleep mode or low power state. The switch does not fully disconnect the device from its power supply.
	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.
	Indicates the need for the user to consult the instructions for use.
CLASSIFIED C (UL) US 5RA9	Underwriters Laboratories classification symbol
EC REP	Authorized Representative in the European Community
CE	Compliance to EU Directives
	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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