VIDAR Systems Corporation

*Advantage*PRO Series

Installation Guide for Use With Windows 7, 8 & 10

Advantage Series (Serial Numbers 340000 to 369999)

DiagnosticPRO® *Advantage*
DosimetryPRO® *Advantage*
CAD PRO® *Advantage*

VIDAR
systems corporation
A 3D Systems Company

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.
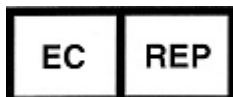
VIDAR systems corporation — A 3D Systems Company

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 (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: 50 to 60 Hz

Safety and compliance information

CLASSIFIED Ⓒᵁᴸᵁˢ

5RA9

CE

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 60601-1-1 or 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 60606-1-1 or 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 access the disconnect switch (power switch) on the back of the unit.

Mains power may be removed from the product by turning off the power switch on the back of the unit.

Power cords used with this device in North America must be rated by Underwriters Laboratories for hospital use.
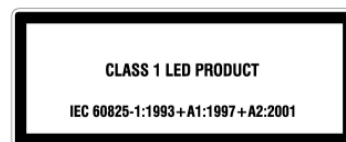
Power cords used with this device in Europe must meet the requirements of IEC 227 Designation 53 or IEC 245 Designation 53.

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.

> **CLASS 1 LED PRODUCT**
> IEC 60825-1:1993+A1:1997+A2:2001

Contents

DiagnosticPRO® *Advantage*

&

DosimetryPRO® *Advantage* (Red)

Installation Guide

VIDAR
systems corporation
The Image of Reliability

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. Mammography images captured as DICOM MG are to be used as reference or comparison only.*

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

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

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 medtech@3dsystems.com.
- 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.
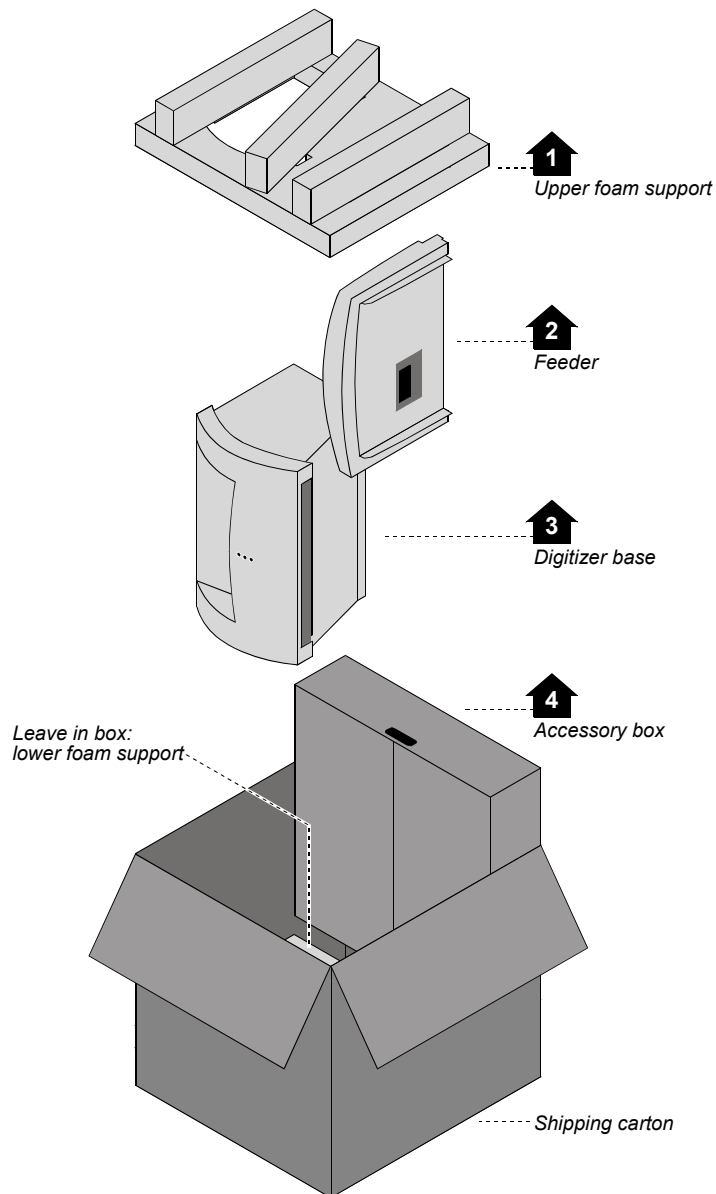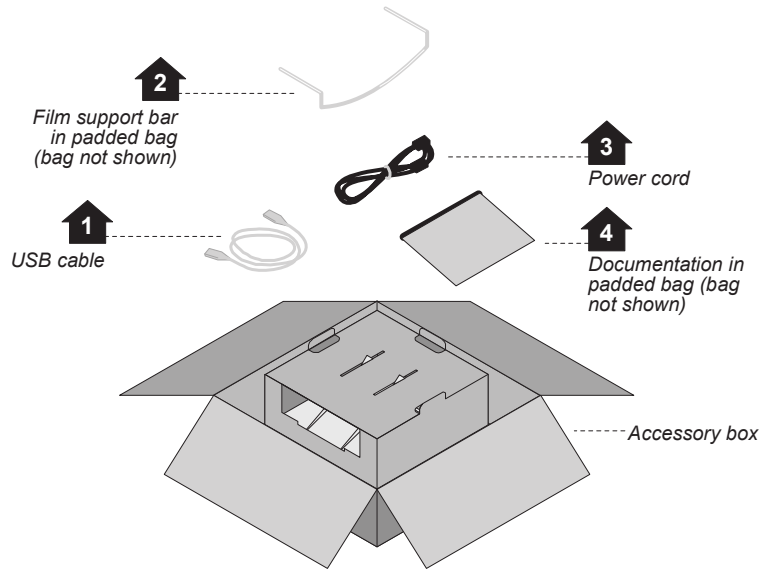
1 Upper foam support

2 Feeder

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

3 Digitizer base

4 Accessory box

Leave in box:
lower foam support

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.

3. Unpack the Accessory Box

a. Remove these items from the accessory box:
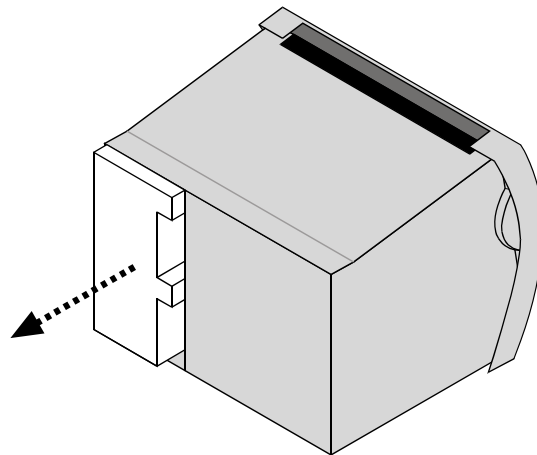

2 Film support bar in padded bag (bag not shown)

3 Power cord

1 USB cable

4 Documentation in padded bag (bag not shown)

Accessory box

b. Then remove these items from the accessory box:

5 Cardboard retainer

6 Exit tray

Note: For clarity, this illustration does not show the plastic bag surrounding the exit tray.

7 Stand

Accessory box
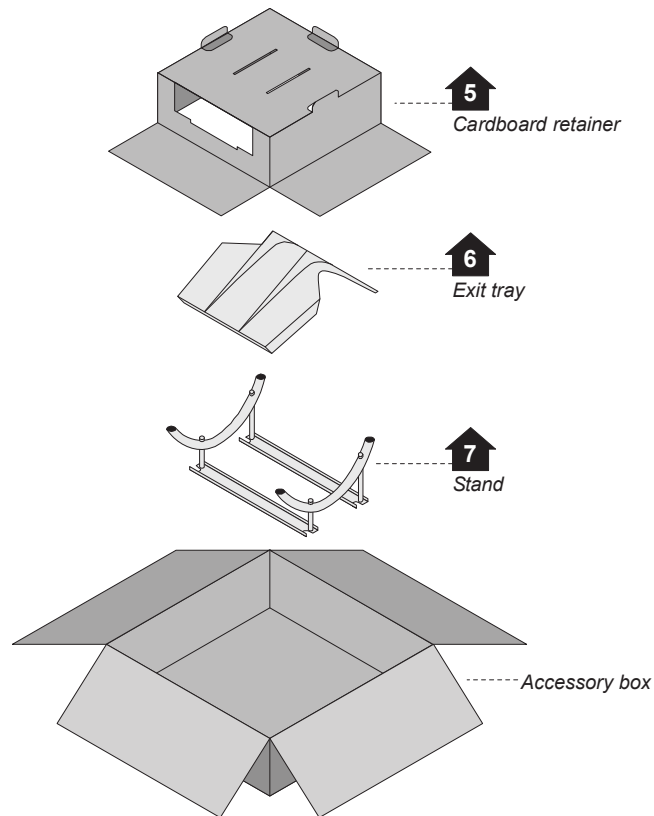
4. Unwrap

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) *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

Exit Tray

Film Support bar

Stand

Film Feeder

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" ⇨

Setting Up

- The digitizer must be placed on a counter or tabletop.

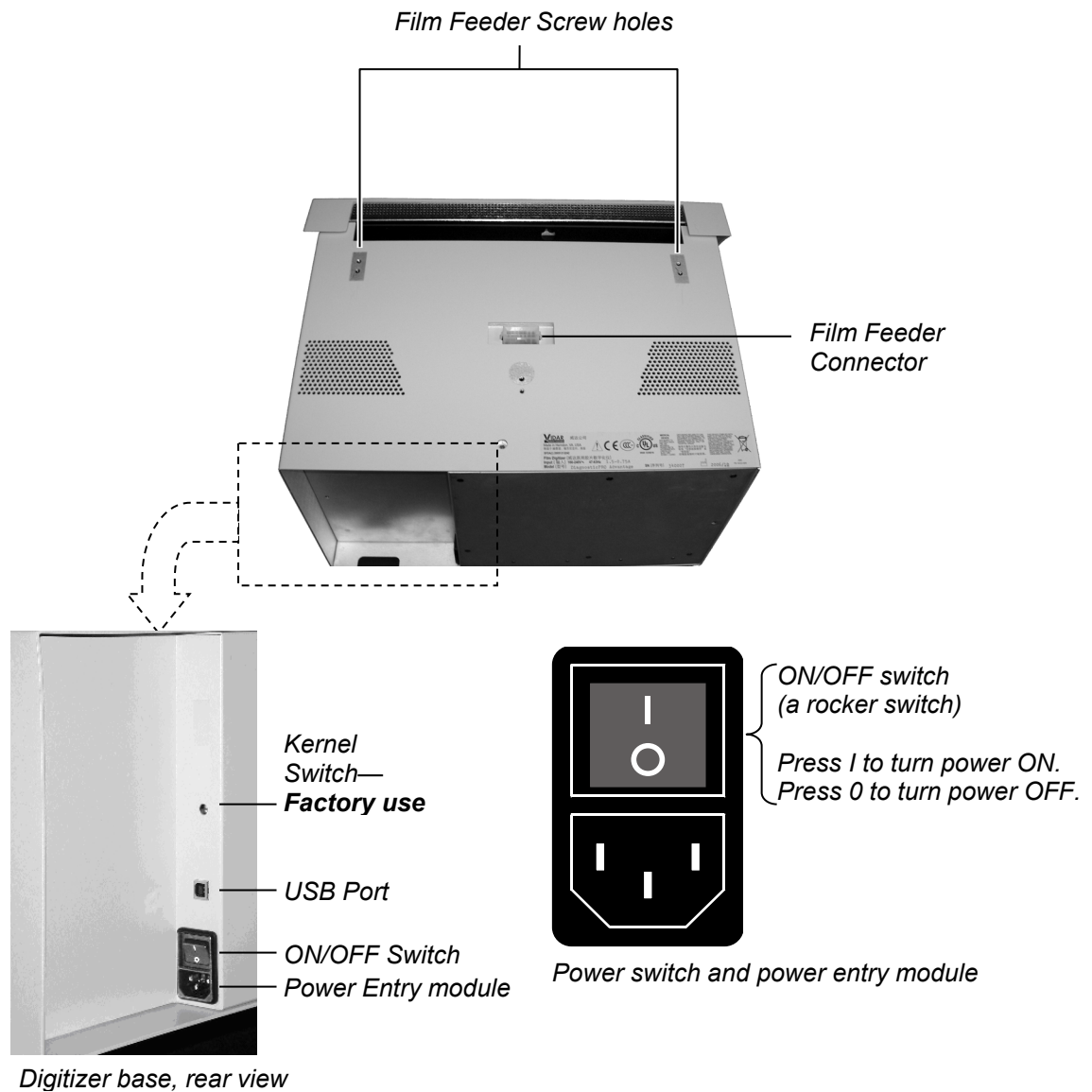- The digitizer is not intended to be used in a Patient Environment.

SAFETY WARNING

Never place the digitizer on the floor.

1. 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.

Film Feeder Screw holes

Film Feeder Connector

Kernel Switch—
Factory use

USB Port

ON/OFF Switch

Power Entry module

ON/OFF switch (a rocker switch)

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

Power switch and power entry module

Digitizer base, rear view

2. 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.
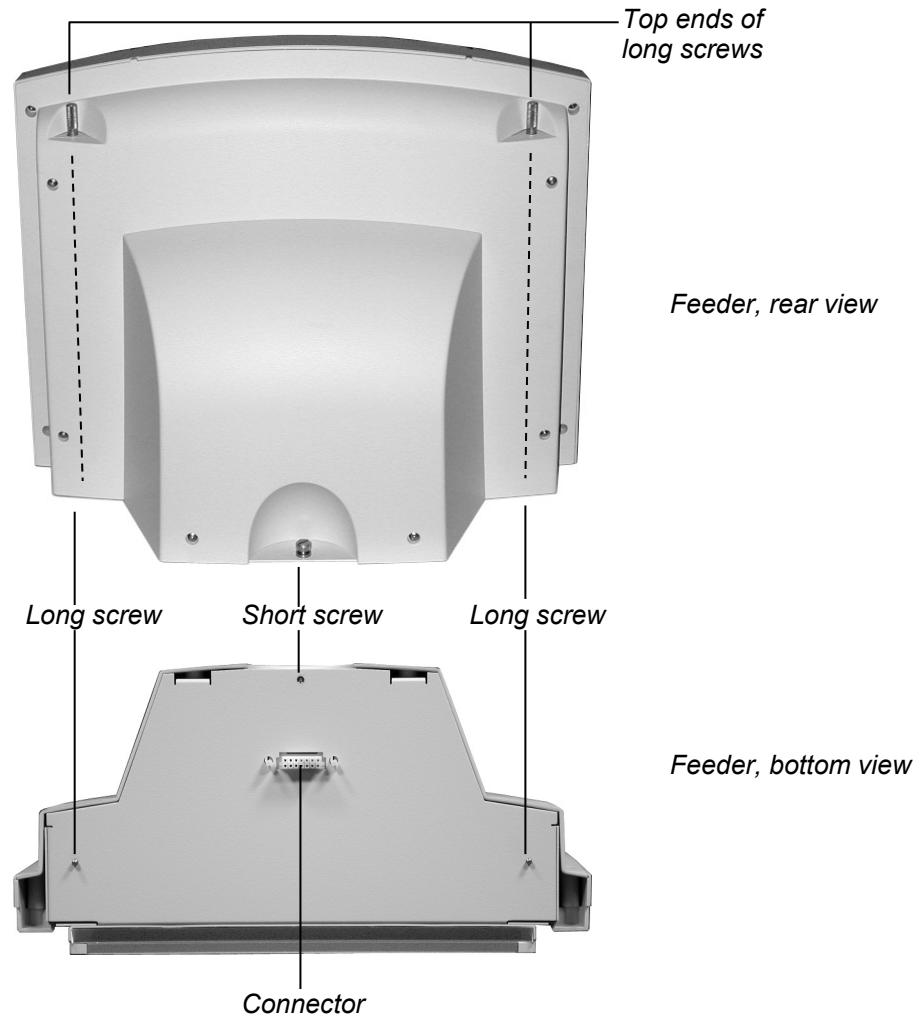
Front view   *Side view*

Thumbscrews (2)   *Longer portion toward front*
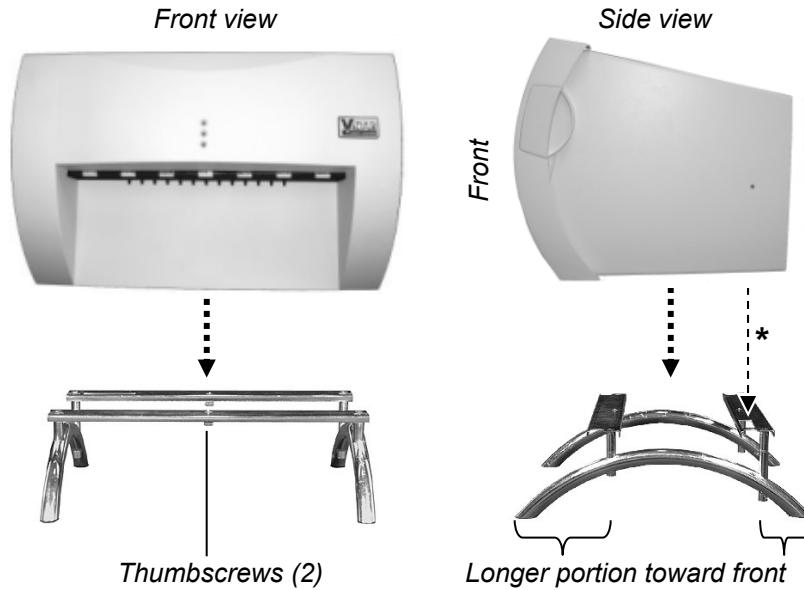
**Vent in bottom of base
must be over cutout in stand*

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.
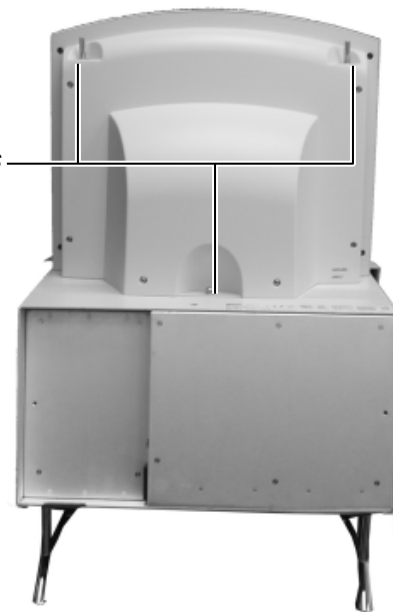
Top ends of long screws

Feeder, rear view

Long screw   *Short screw*   *Long screw*

Feeder, bottom view

Connector

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.

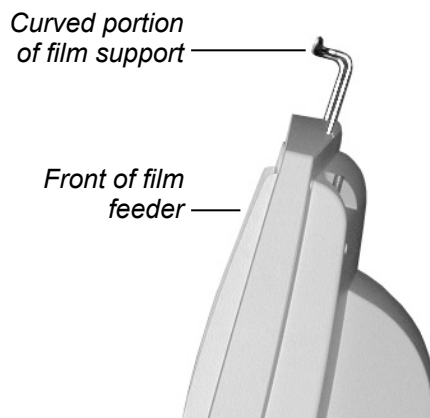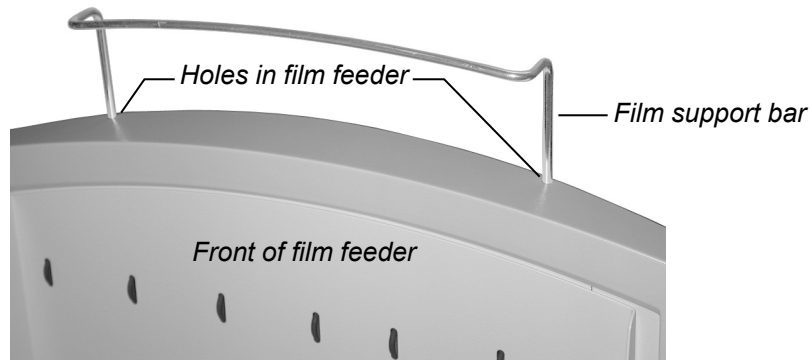- Tighten each screw a few turns, then repeat until all are finger tight.

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.

Roller shaft
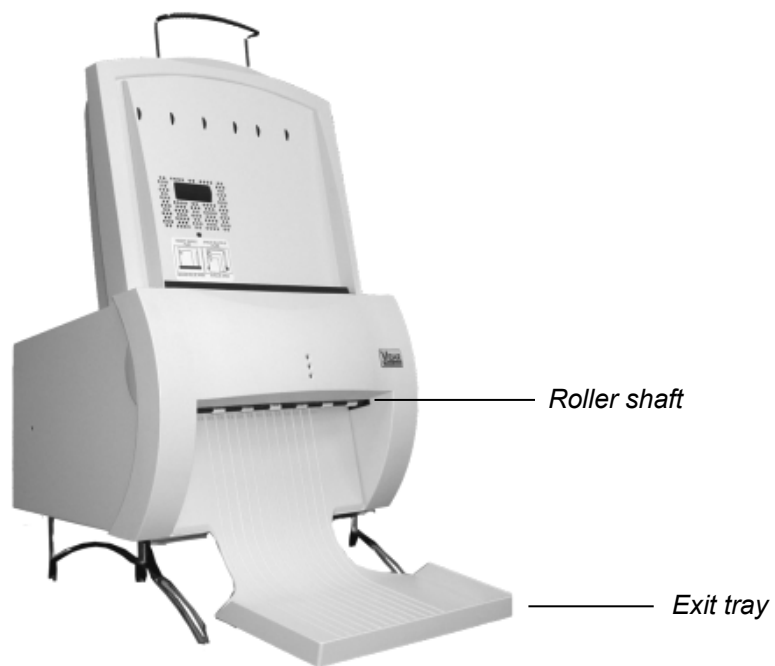
Exit tray

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.

Holes in film feeder ——— *Film support bar*

Front of film feeder

Curved portion of film support ———

Front of 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.

3. 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"** ⇨

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

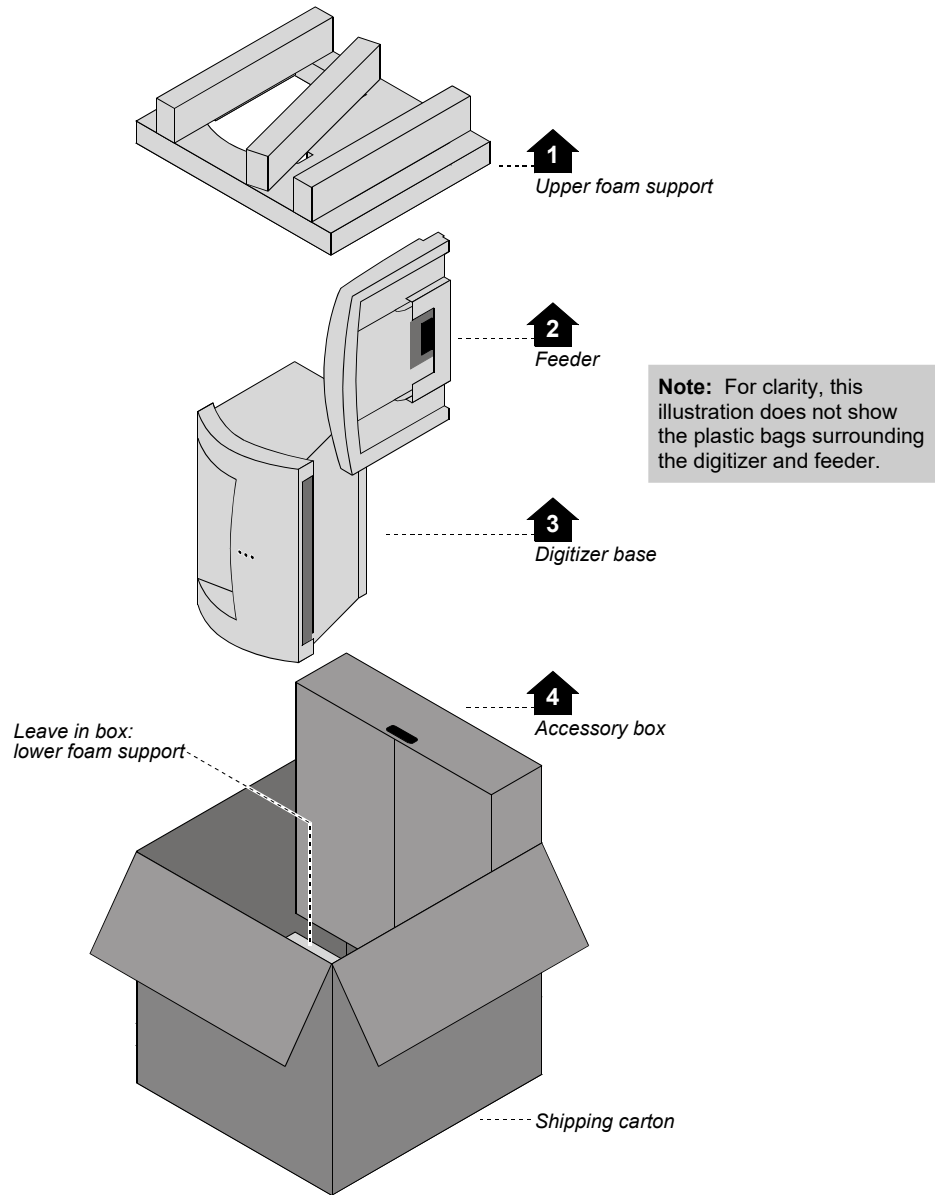Before unpacking the film digitizer, examine the shipping carton for damage.

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.
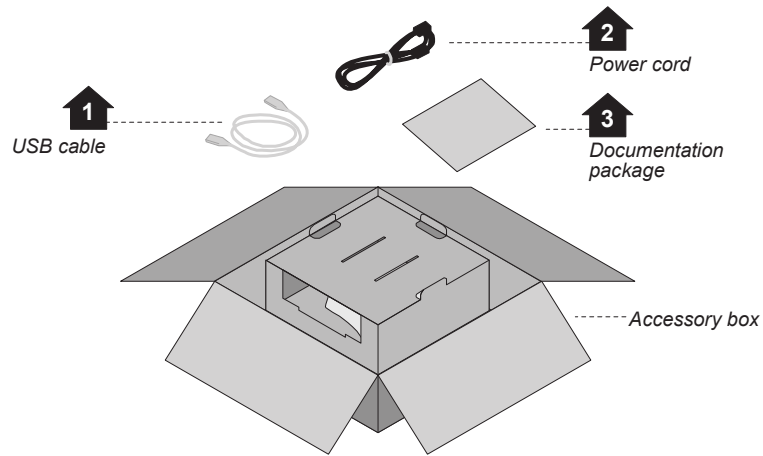
2. Unpack the Shipping Carton

Remove items from the shipping carton in the order shown below.
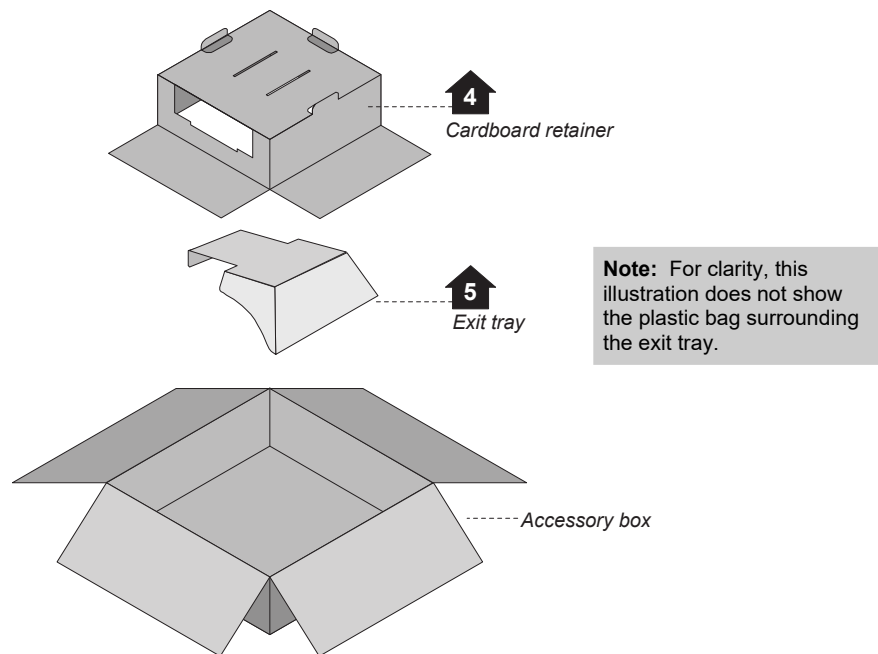
1 Upper foam support

2 Feeder

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

3 Digitizer base

4 Accessory box

Leave in box: lower foam support

Shipping carton

3. Unpack the Accessory Box

a. Remove these items from the accessory box:

1 USB cable

2 Power cord

3 Documentation package

Accessory box

b. Then remove these items from the accessory box:

4 Cardboard retainer

5 Exit tray

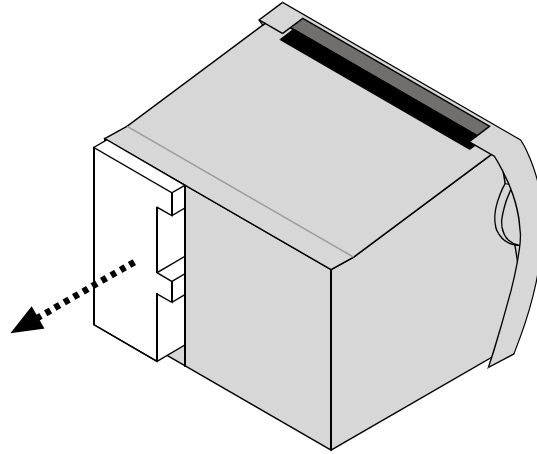**Note:** For clarity, this illustration does not show the plastic bag surrounding the exit tray.
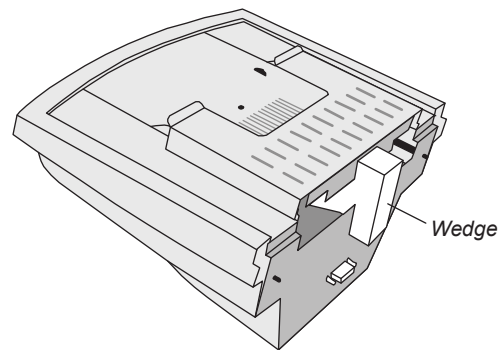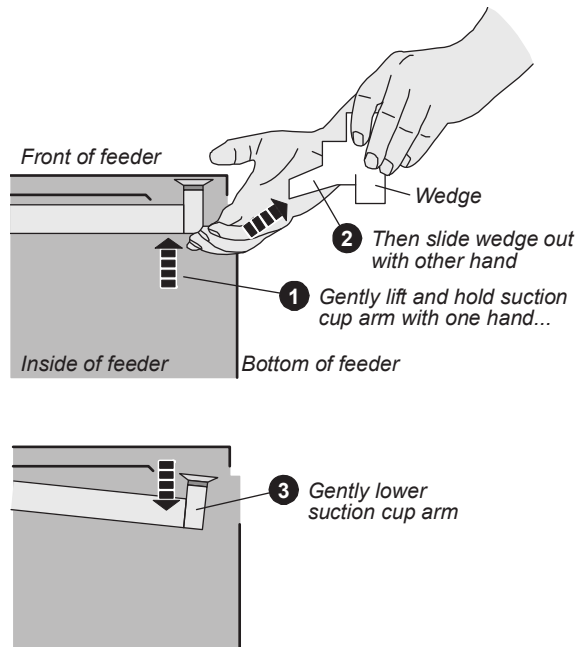
Accessory box

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.

Wedge

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

Front of feeder

Wedge

2 *Then slide wedge out with other hand*

1 *Gently lift and hold suction cup arm with one hand...*

Inside of feeder   **Bottom of feeder**

3 *Gently lower suction cup arm*

> **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.
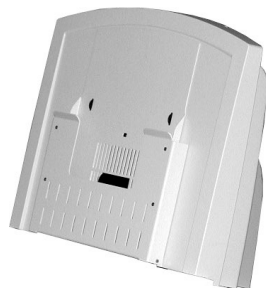
5. Identify the Components

✓	Item
☐	Digitizer base
☐	Exit tray
☐	50 sheet film feeder
☐	Power 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   *Exit tray*

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:
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> 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" ⇨

Setting Up

- The digitizer must be placed on a counter or tabletop.

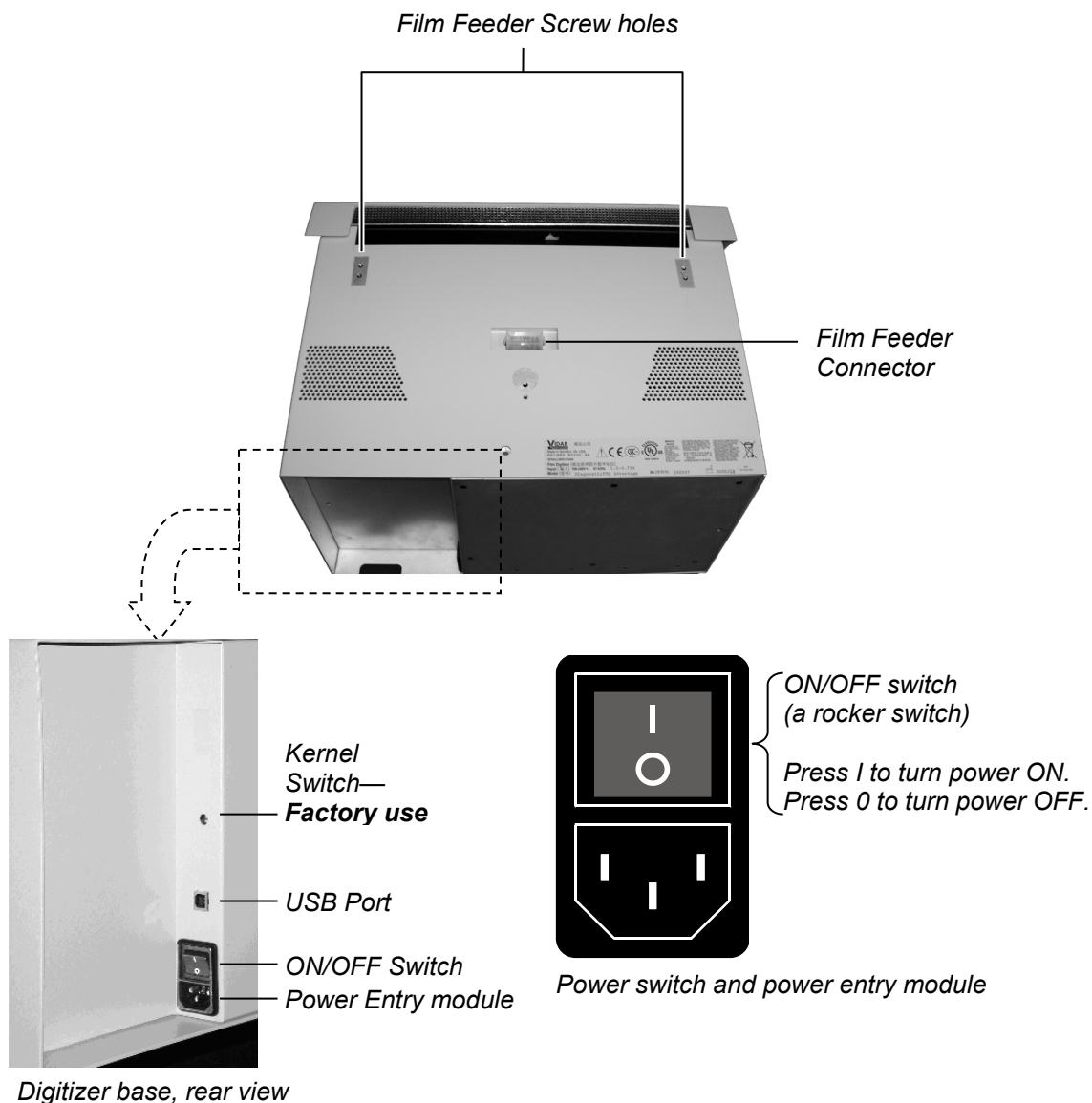- The digitizer is not intended to be used in a Patient Environment.

SAFETY WARNING
Never place the digitizer on the floor.

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1. 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.

Film Feeder Screw holes

Film Feeder Connector

Kernel Switch—
Factory use

USB Port

ON/OFF Switch
Power Entry module

Digitizer base, rear view

ON/OFF switch (a rocker switch)

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

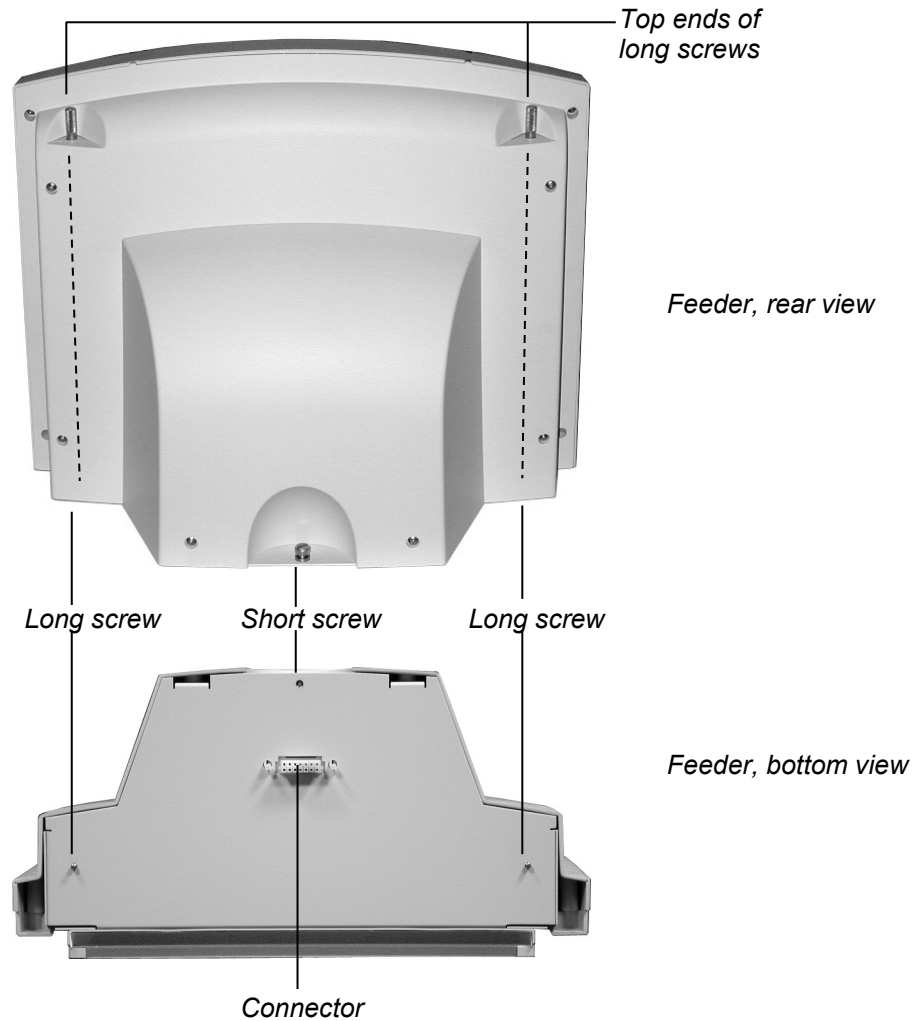*Power switch and power entry module*

2. Assemble the Digitizer

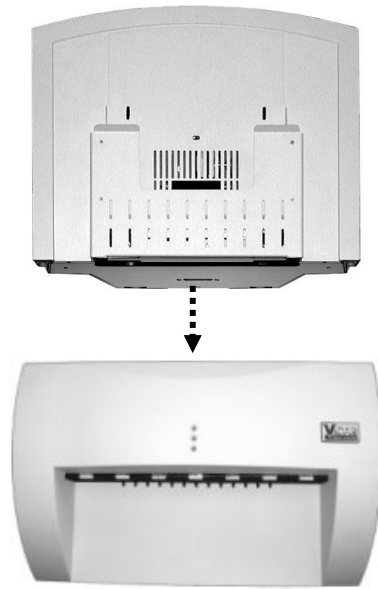1. Place the digitizer base on a solid, flat surface (such as a table).

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.
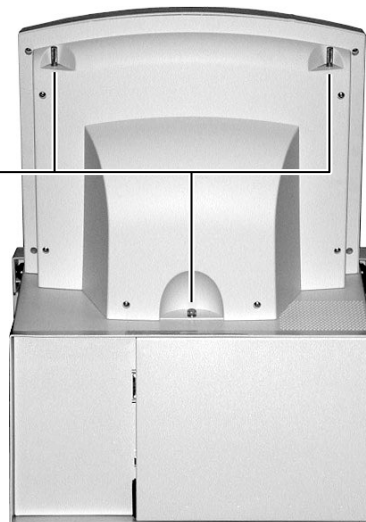
*Top ends of
long screws*

Feeder, rear view

Long screw   *Short screw*   *Long screw*

Feeder, bottom view

Connector

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
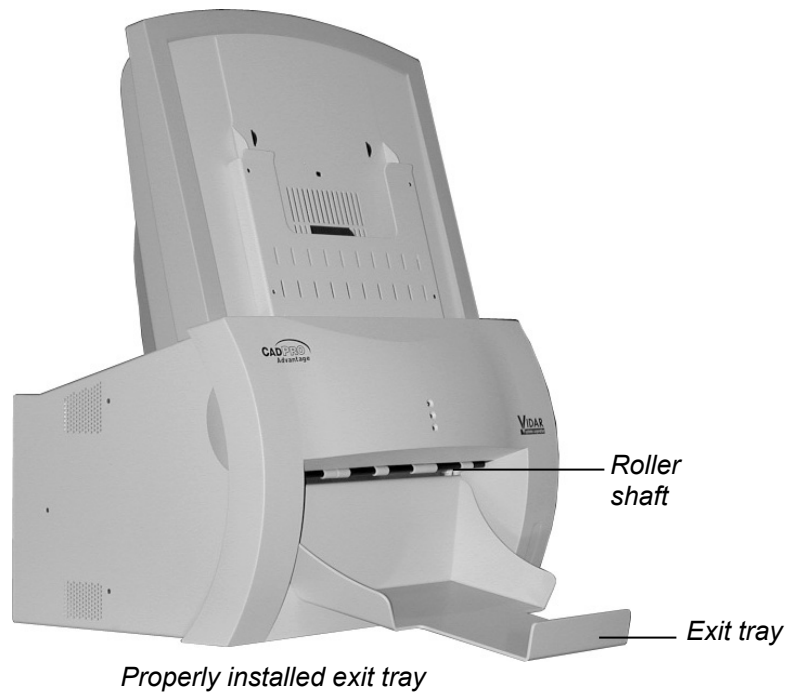
3. Connect the Power Cord

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 Installation Guide"** ⇨

Device Driver

Installation Guide

Install Device Drivers for Windows 7, 8, & 10

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

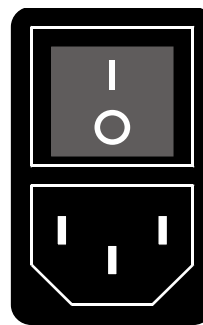## 1. Apply Power to the Digitizer

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.

ON/OFF Switch
Power Entry module

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.

2. About the VIDAR Drivers

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

■ Installation/setup wizard for easy and consistent installation.

3. 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, & 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.

STOP 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 *19090-003 VIDAR_Driver_6.1 Online Install Package.exe* on the CD to install the driver.
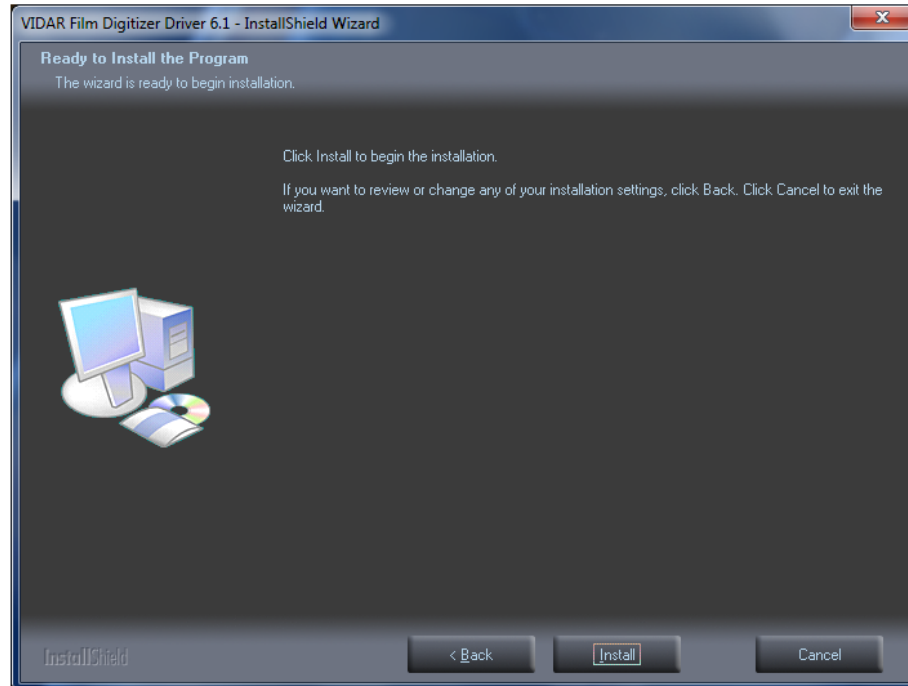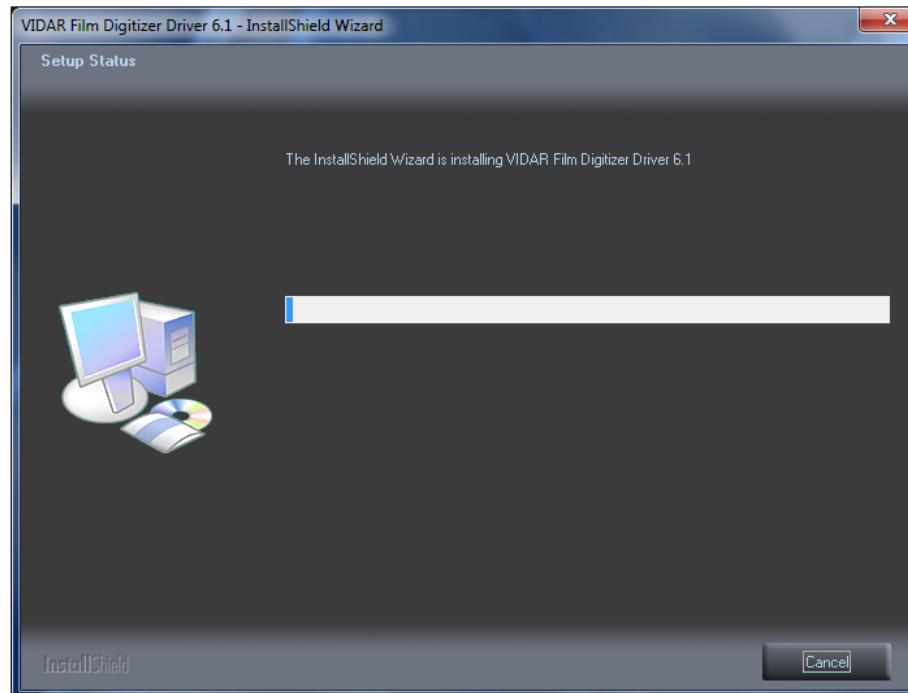
d. In the first screen, click **Next >**.
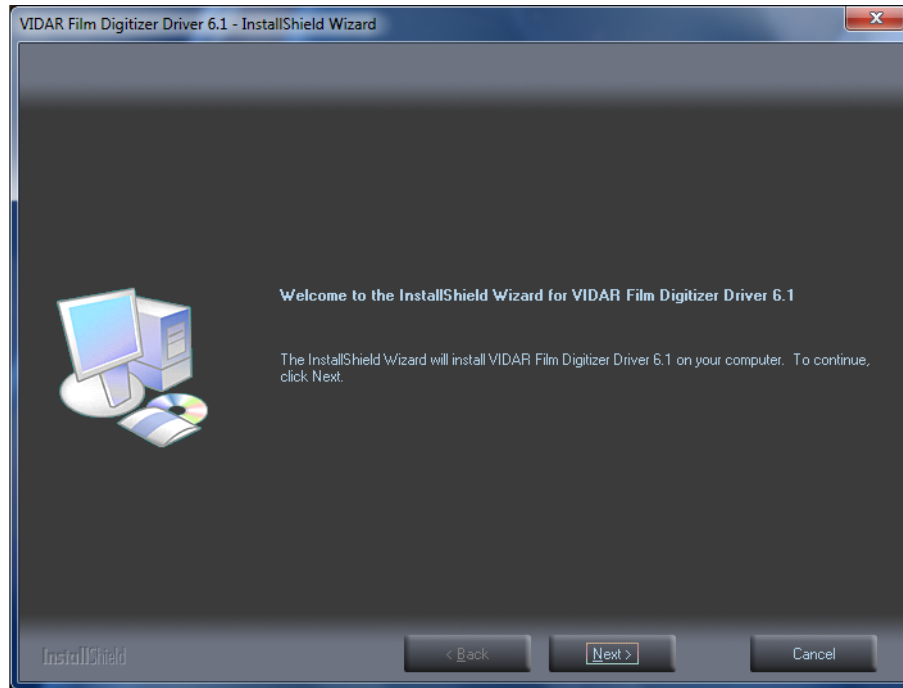
e. In the **License Agreement** screen, activate **I accept the terms of the license agreement**, then click **Next >**.
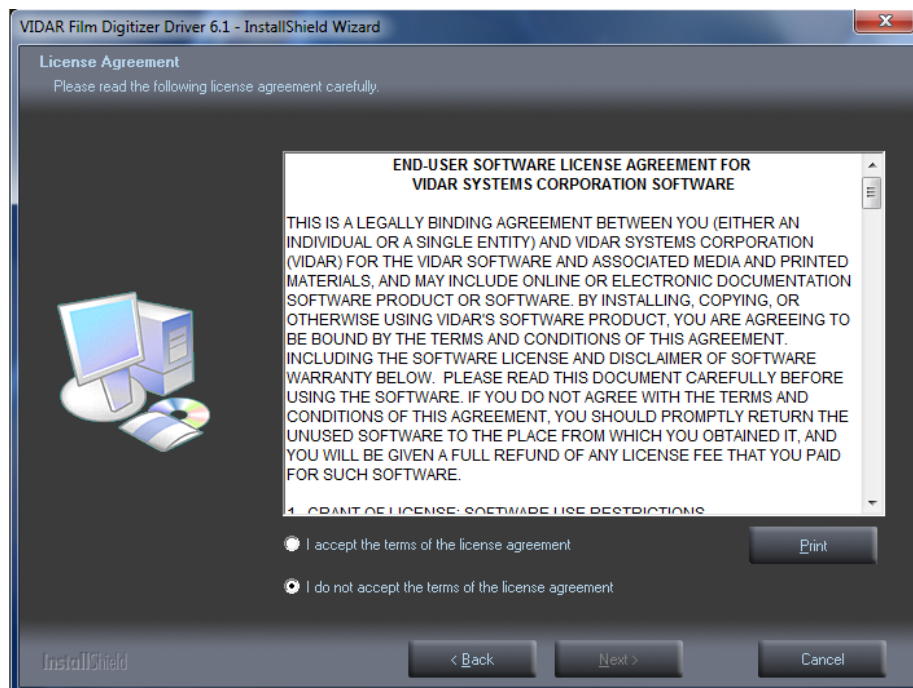
f. In the **Ready to Install the Program** screen, click **Install**.

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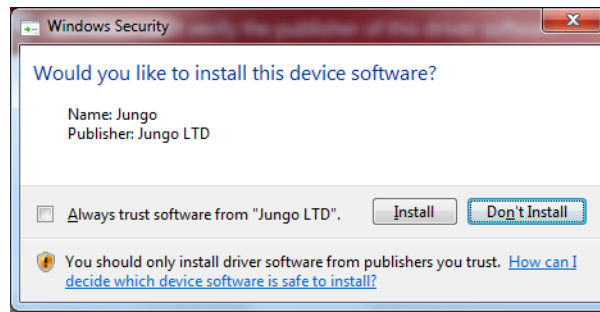
i. When installing on Windows 7, 8, & 10 32 Bit the name will appear as **VIDAR**
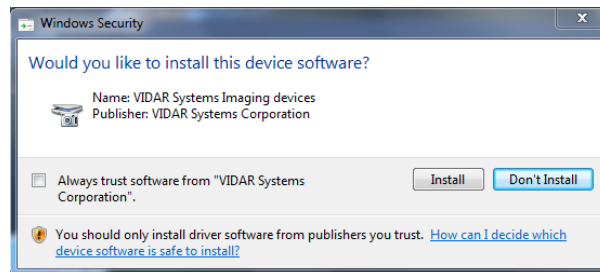
j. InstallShield will indicate that installation is complete. However, the driver installation
    is not complete.
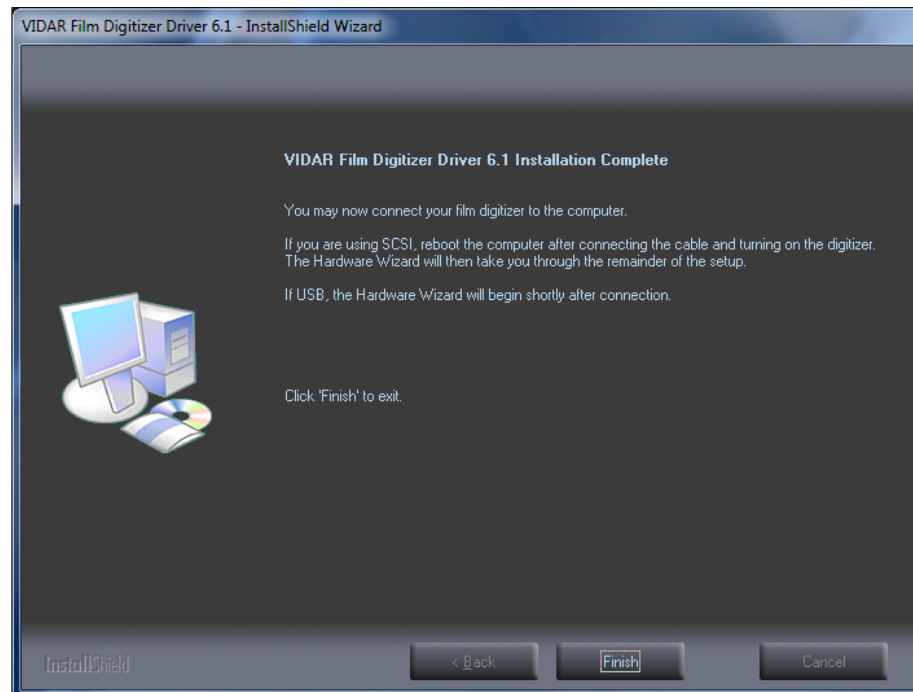
k. Earlier, you connected a USB cable to the digitizer. Now, attach the connector on the
    other end of that cable to a USB 2.0 or 3.0 port on the computer.

> **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. For 64 Bit Windows 7, 8, & 10 On the desktop, double-click the **VIDARINFO** icon.

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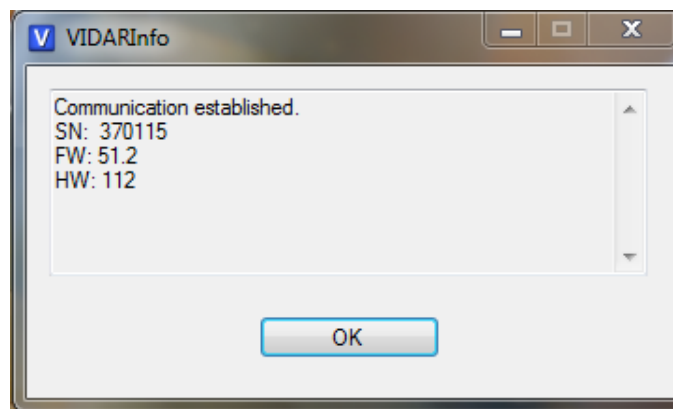
n. "OK" if the Digitizer Information is present on the Screen

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.

> **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.

o.   For 64-Bit, in Windows 7, 8, & 10 **Computer Management** window, the digitizer is listed under **Jungo**.
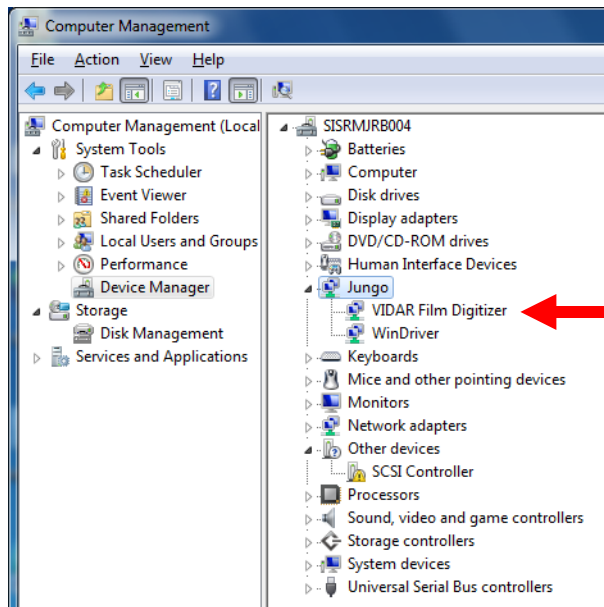
p.   *On a 32-bit system:*

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

2. In the device window, right-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.

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

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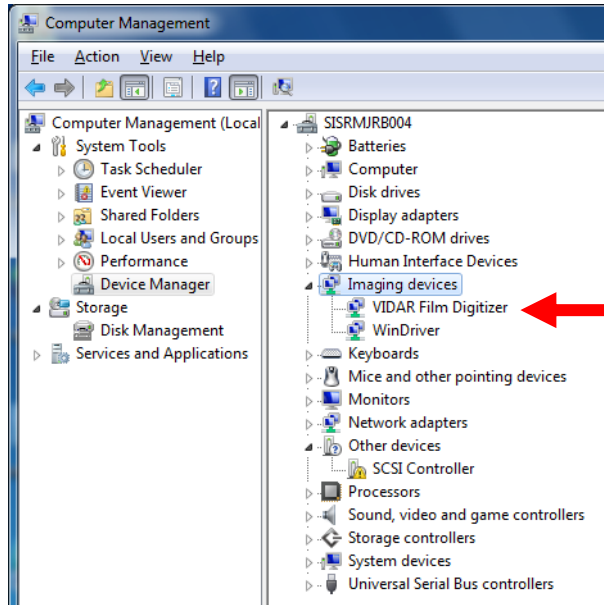
The digitizer is now ready to operate. Please refer to the "User's Guide for DiagnosticPRO *Edge*" for operating instructions.

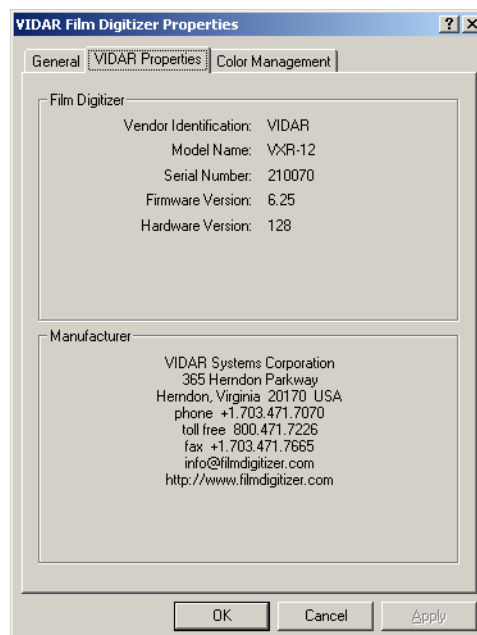You may need to install other application software to run the digitizer.

> **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 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		
The DiagnosticPRO Advantage, DosimetryPRO Advantage (Red) and CAD PRO Advantage Digitizers are 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 Digitizers use RF energy only for their internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class A	The Digitizers are 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 Advantage, DosimetryPRO Advantage (Red) and CAD PRO Advantage Digitizers are 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 Advantage, DosimetryPRO Advantage (Red) and CAD PRO Advantage Digitizers are 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 Advantage, DosimetryPRO Advantage (Red) and CAD PRO Advantage Digitizers are 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 the need for the user to consult the instructions for use.
📖	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.
CLASSIFIED c(UL)us 5RA9	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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