

# Installation Guide for

# **VIDAR** *Dental Film Digitizer*

Serial numbers  
210,000 to 219,999



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### 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.

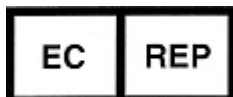


365 Herndon Parkway  
Herndon, VA 20170 U.S.A.

**Phone:** 1-703-471-7070  
**Fax:** 1-703-471-7665  
**Internet:** [www.filmdigitizer.com](http://www.filmdigitizer.com)

**Sales:** 1-800-471-SCAN or  
1-800-471-7226  
Email: [order@3dsystems.com](mailto:order@3dsystems.com)

**Technical Support:**  
1-800-471-SCAN or 1-703-471-7070  
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**Emergo Europe**  
Prinsessegracht 20  
2514 AP The Hague  
The Netherlands

**E-mail:** [europe@emergogroup.com](mailto:europe@emergogroup.com)

**Caution:** No operator-serviceable parts inside. Refer servicing to qualified personnel.  
**Achtung:** Gehäuse nicht öffnen. Wartung und Reparatur nur durch Elektrofachkräfte.  
**Attention:** Aucune pièce ne peut être remplacée par l'utilisateur. Toute opération de maintenance doit être effectuée par une personne qualifiée.  
**Atencion:** Acceso interno solo autorizado a personal técnico cualificado.  
**Attenzione:** Non aprire. Rivolgersi a personale qualificato.

## 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.

## Acceptable shipping conditions

- Temperature: -15° to +60°C (5° to +140°F)
- Relative humidity: 20% to 85%, non-condensing
- Atmospheric pressure: 500 to 1060hPa (+18,000 to -1,200ft)

## Operating conditions

- Temperature: 15°C to 30°C (60°F to 85°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: 1.0 to 0.42 A
- Frequency: 50 to 60 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.).

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 3<sup>rd</sup> 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<sup>rd</sup> 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 manufacture.

Do not position the product so that it is difficult to disconnect the product from mains power supply.

Mains power may be removed from the product by disconnecting the power cable at the bottom of the product. 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.

This product is not suitable for use in a patient environment. Do not use the product or the host computer in the vicinity of a patient. Do not touch the product or the host computer while touching the patient.

The use of portable or mobile communications equipment and/or the presence of strong electromagnetic and/or x-ray fields may interfere with proper operation of this product. This product should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, verify normal operation in the configuration in which it will be used. Should such interference occur, the user is required to provide adequate isolation between the digitizer and the source of the interference. Isolation is typically achieved by moving the digitizer away from the source of the interference.

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:



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# Intended Use

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The VIDAR dental film digitizer is used for making digital copies of x-ray film commonly used in dental practices. Images captured with this device are intended for use in primary, secondary and over-reading applications. The target users of the device are medical professional or trained staff.

# Unpack

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In this chapter, you will:

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

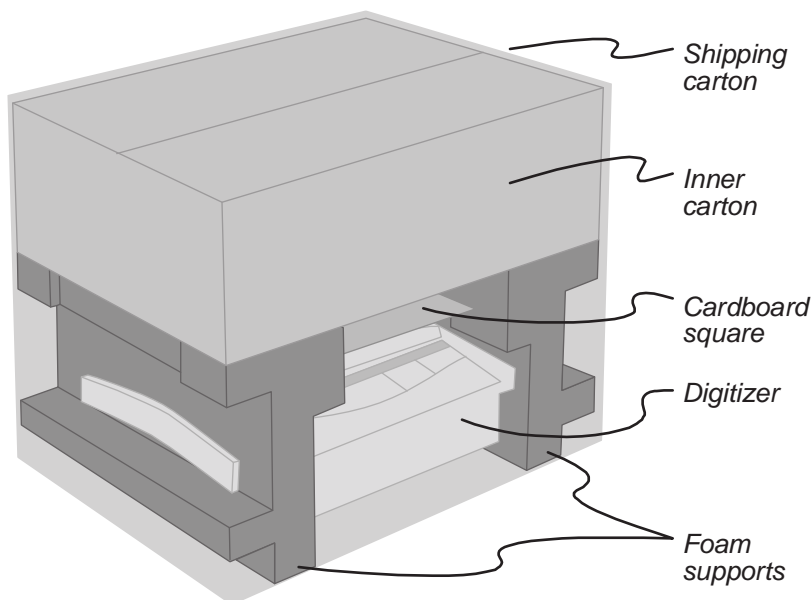
## 1. Look for Damage

Before unpacking the Dental 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](mailto:medtech@3dsystems.com).
- Notify VIDAR Medical Support at 1-703-471-7070.

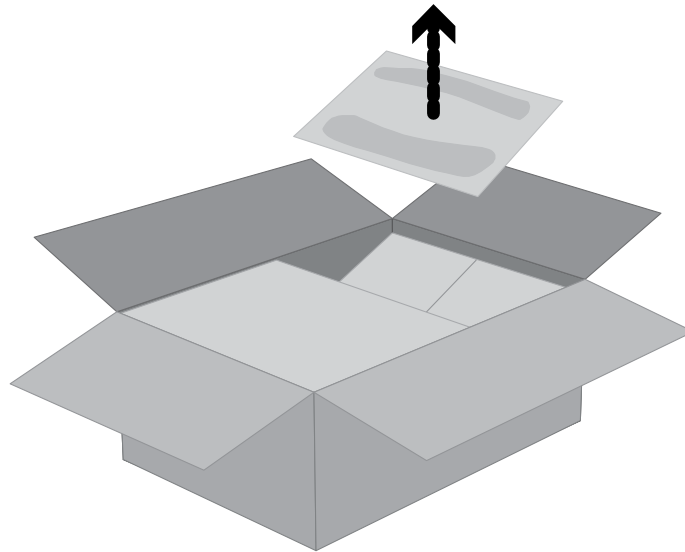
### What's inside the shipping carton?



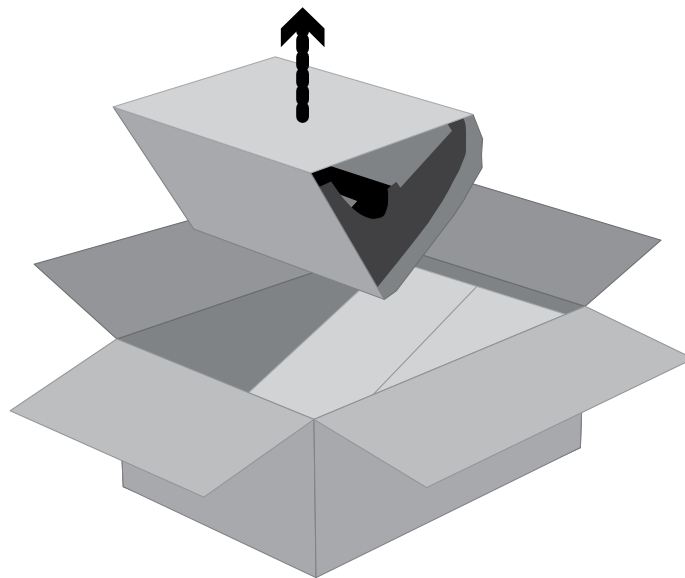
## 2. Unpack the shipping carton

**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.

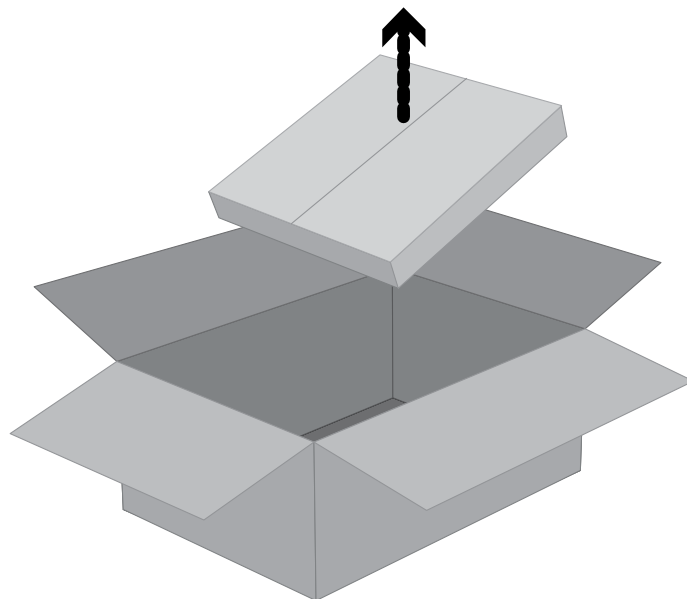
- a. Remove the inner carton from the shipping carton. Open the inner carton.
- b. Remove the envelope.



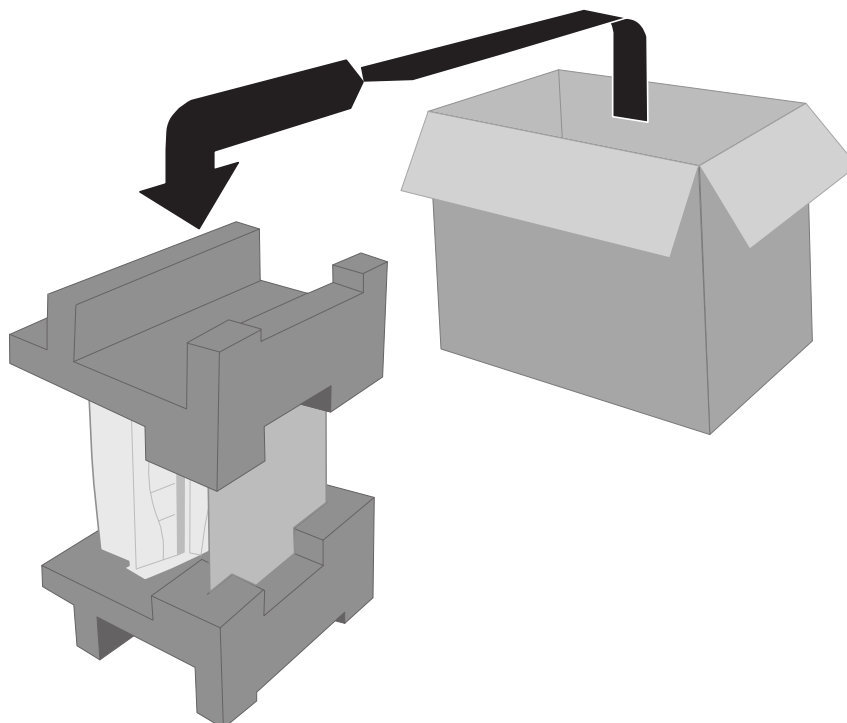
- c. Remove the wrapped stand.



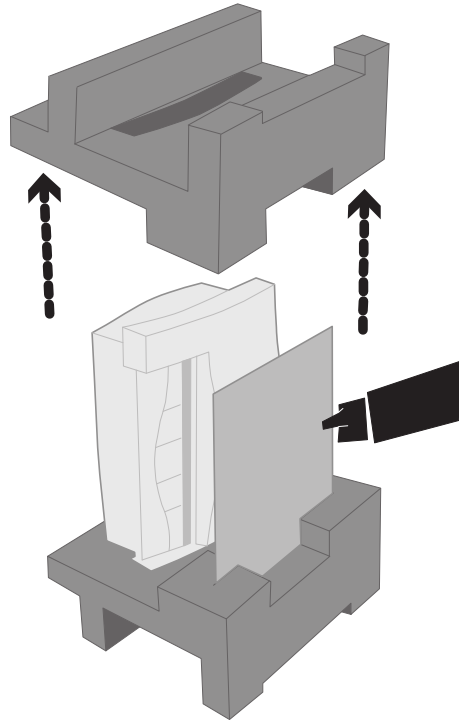
d. Remove the accessories box.



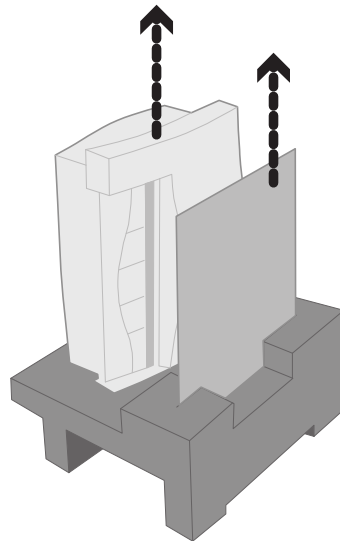
e. Lift both foam supports— with the items they are supporting —from the shipping carton, then stand everything on one support.



- f. Hold the cardboard square while removing the upper foam support.



- g. Remove the cardboard square. Then remove the film digitizer and place it securely on a horizontal surface.


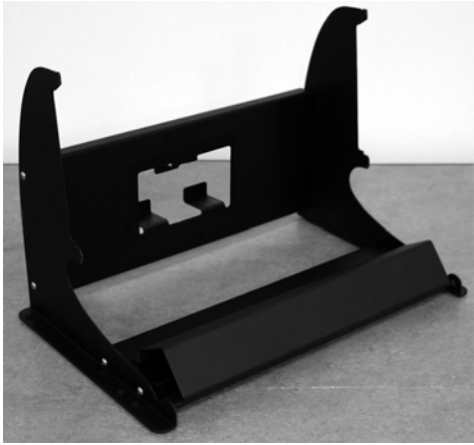
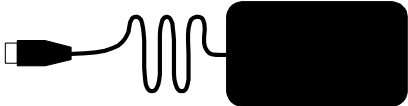



**IMPORTANT:** Save all the packing materials. If you need to ship the digitizer later, you should repack the digitizer in the original materials by reversing the procedure described here. Failure to properly pack, or failure to use VIDAR authorized shipping materials, will void the product's warranty,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

# 3. Identify the Parts

Check carefully to ensure you received the items listed below.

## Standard Items

✓ Description	(Note: items are not shown to same scale.)
<input type="checkbox"/> Dental Film Digitizer	
<input type="checkbox"/> Stand	
<input type="checkbox"/> Power Adapter. Contact Service Provider or Vidar Systems Corp for PN.	
<input type="checkbox"/> Electrical power cord USA Medical Power Cord, P/N 4043 or Euro-Style Power Cord, P/N 2104	
<input type="checkbox"/> VIDAR Dental Film Digitizer Installation CD	
<input type="checkbox"/> TWAIN 7.1 Installation CD	
<input type="checkbox"/> USB Cable, VIDAR part number 4618	
<input type="checkbox"/> 3 Plastic X-ray mounts (carriers for intraoral films)	
<input type="checkbox"/> Declaration of Conformity	

## Optional Items

- | ✓                        | Description                       |
|--------------------------|-----------------------------------|
| <input type="checkbox"/> | Third-party software instructions |

## 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

View the digitizer from the front to locate the power switch behind the top right corner.



### Power Switch Labeling

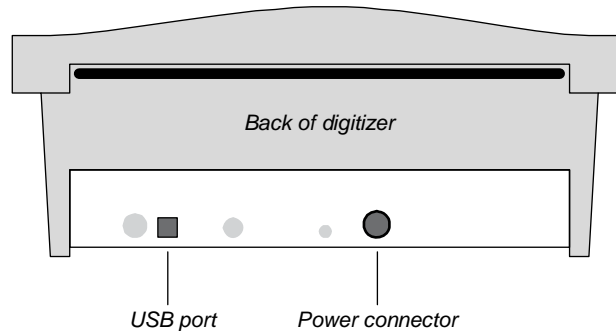
The label pictured below appears on the left front top side of the digitizer to assist you in locating the power switch.



**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.

## Back Panel

View the digitizer from the back to identify connectors on the panel.



## 5. If Anything is Missing...

Immediately contact your VIDAR supplier or send e-mail to [medtech@3dsystems.com](mailto:medtech@3dsystems.com).

## 6. Record Important Information and Activate Your Product Warranty

- Locate the “Warranty information and customer survey” form on the Dental Film Digitizer CD.
- Print the “Warranty information and customer survey.”
- In the “Product information” section, record this information:
  - Product you are registering (Dental Film Digitizer).
  - Digitizer serial number.
- Complete the form.
- Mail or fax the form to VIDAR Systems Corporation

Warranty information and customer survey for VIDAR film digitizers		 <small>480 Spring Park Place Hawthorne, NJ 07035 USA Phone: (201) 471-5075 • Fax: (201) 471-1940 E-mail: <a href="mailto:medtech@3dsystems.com">medtech@3dsystems.com</a></small>	
<b>Instructions:</b> 1. Call your dealer for the kit. 2. Fill in. 3. Make a copy for your records. 4. Mail or fax to VIDAR.			
<b>Warranty information</b>			
Date: _____			
<b>System integrator information</b>			
<b>System integrator administrative contact</b>			
Name	Title		
Company name	Telephone no.		
E-mail address	Fax no.		
<b>System integrator technical contact</b>			
Name	Title		
Company name	Telephone no.		
E-mail address	Fax no.		
<b>Shipping information</b>			
Company name			
Street address			
City	State	Postal code	
Country	Telephone no.	Fax no.	

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](mailto:medtech@3dsystems.com)

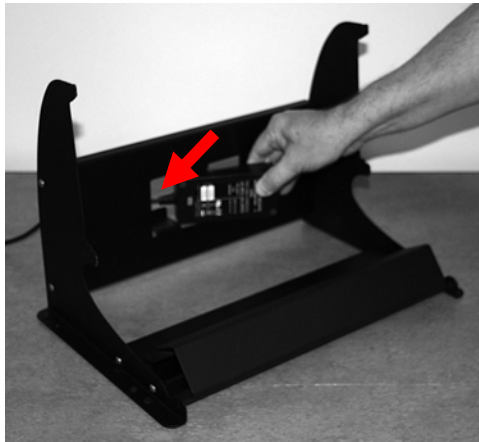
When you contact VIDAR, you will need to provide:

- The unit's serial number.
- Your name, company and contact information.
- Where you purchased the digitizer.

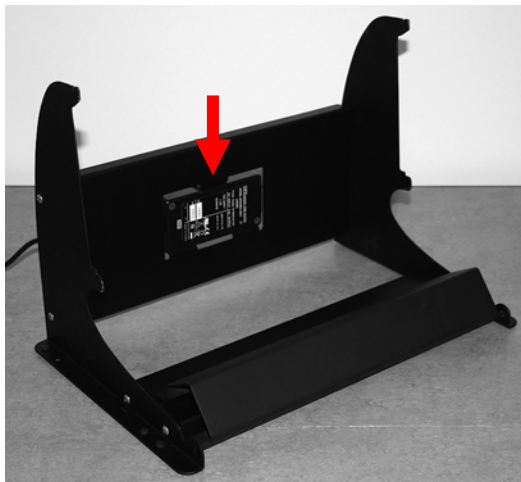
# Assemble the Digitizer

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

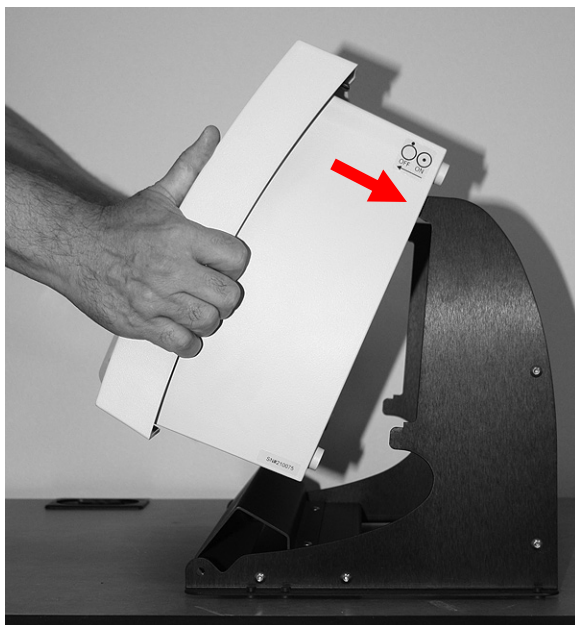
1. Feed the power supply's DC cable through the opening in the stand back.



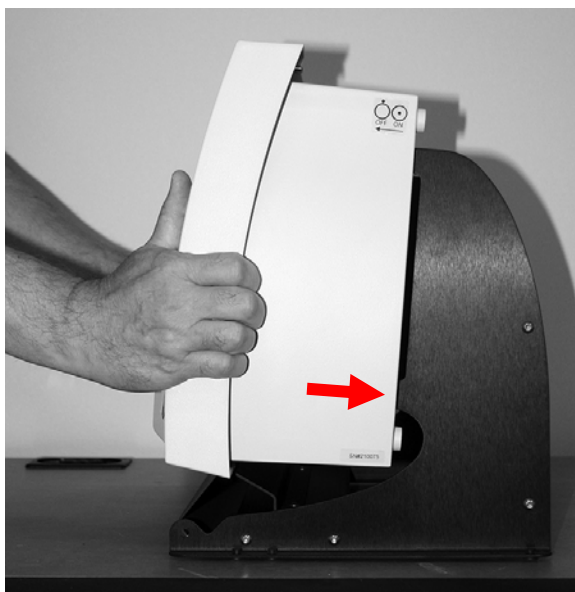
2. Orient the power supply with its label toward you, the push the power supply into the opening in the stand back. When fully in place, the front of the power supply should be flush with the front of the stand back.



3. Grasp the digitizer by its sides. Slide the digitizer's upper mounting slots over the upper tabs on the stand (as shown below). Ensure that the slots drop into the notches in the tabs.



4. Rotate the bottom of the digitizer toward the stand, so the digitizer's lower mounting slots slide over the bottom tabs on the stand (as shown below).



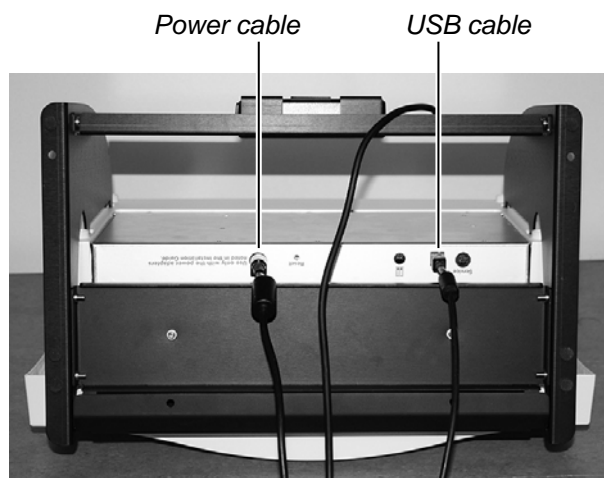
5. From behind, grasp the digitizer (not the stand!) as shown below.



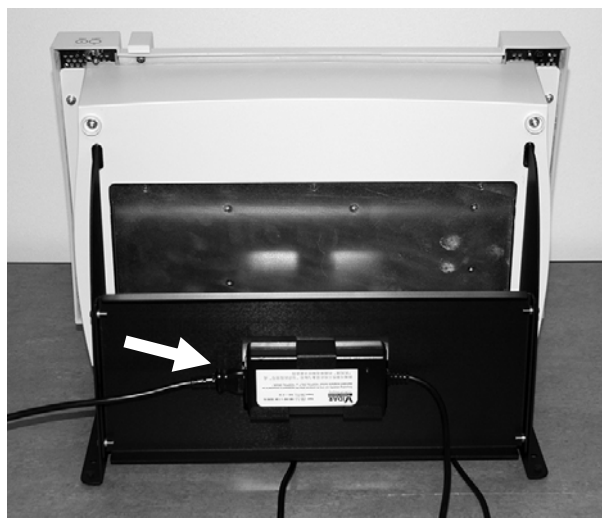
6. Tilt the digitizer away from you and gently place the front of the digitizer on the table.



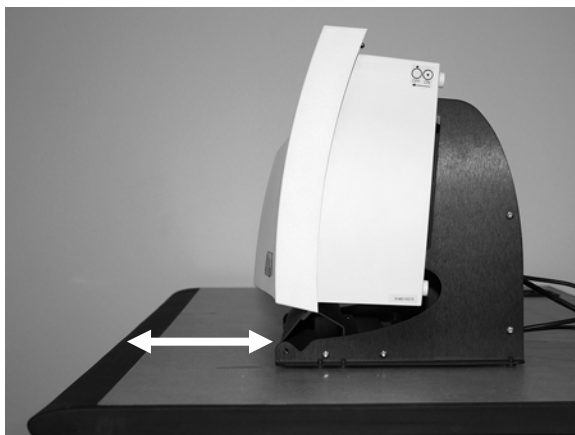
7. Connect the power cable and USB cable to the bottom of the digitizer.



8. Grasp the digitizer (not the stand!), then tilt it and the stand back onto the stand's feed.
9. Plug the power cord into the power supply.



10. Place the digitizer with stand where you will be using it. The stand should be several inches back from the edge to provide a resting place for emerging films.



# Install Device Drivers and Toolkit for Windows 7

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

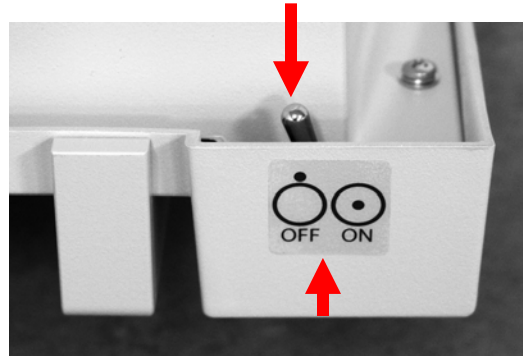
**Note:** Installation instructions for Windows XP are provided in the next chapter.

## 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 behind the upper right corner.



### Power switch labeling

The label pictured above appears on the right top side of the digitizer to assist you in locating the power switch.

**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 was designed to provide compatibility between VIDAR Dental Film Digitizers and Windows 7 (both 32-bit and 64-bit). 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

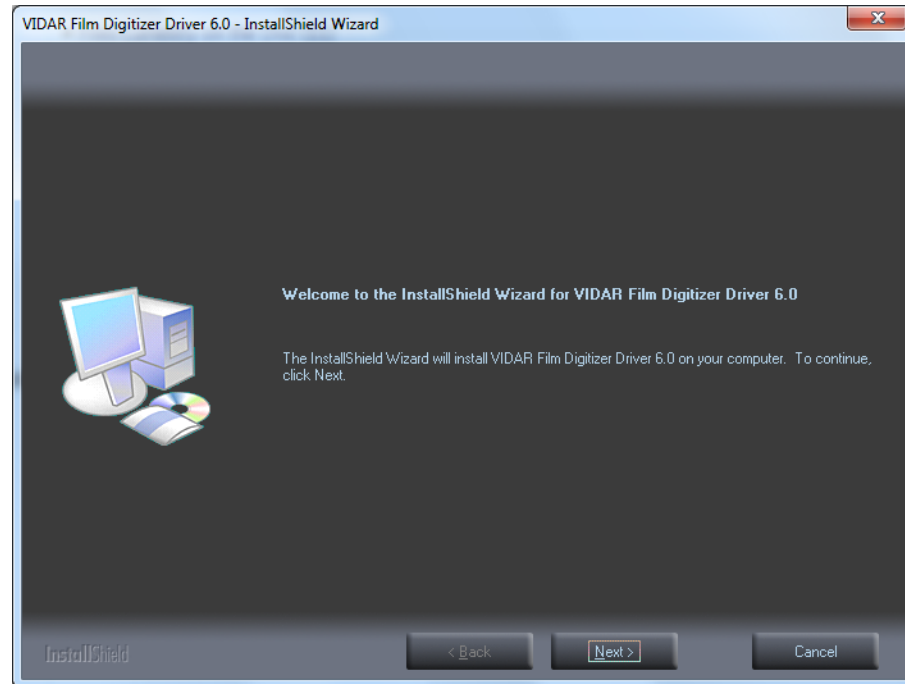
**Note:** The computer must be running Windows 7 Professional 32-bit or 64-bit.

**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.

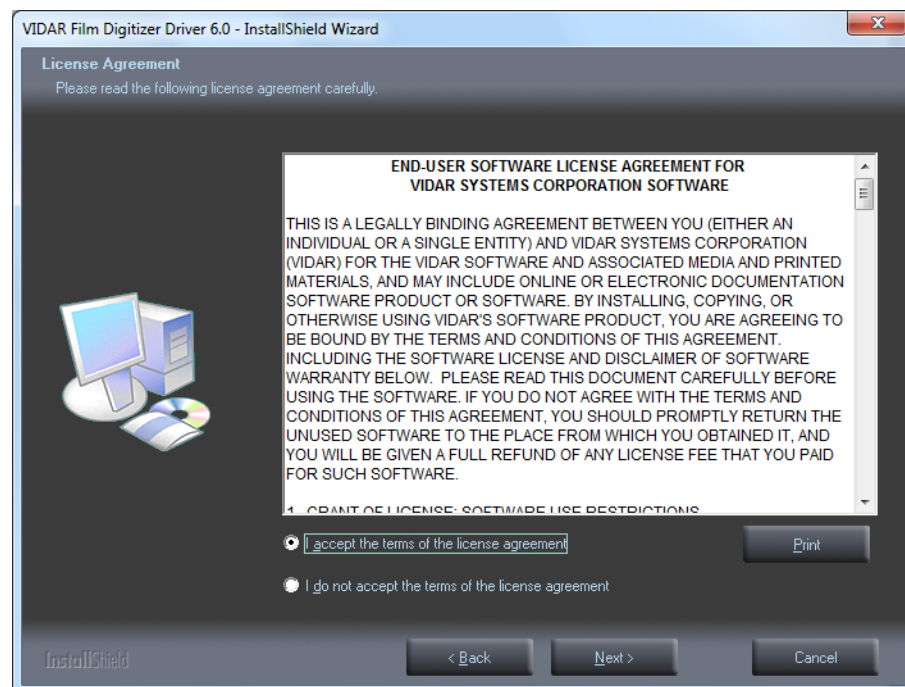
You will need the VIDAR Dental Film Digitizer Installation CD.

- 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 Dental Film Digitizer Installation 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.

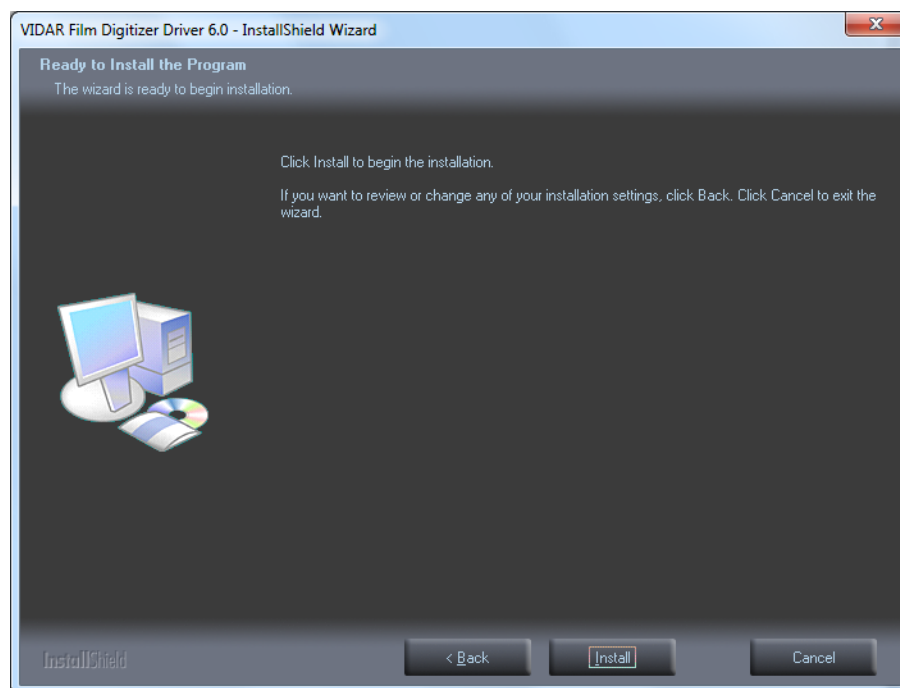
- d. In the first screen, click **Next >**.



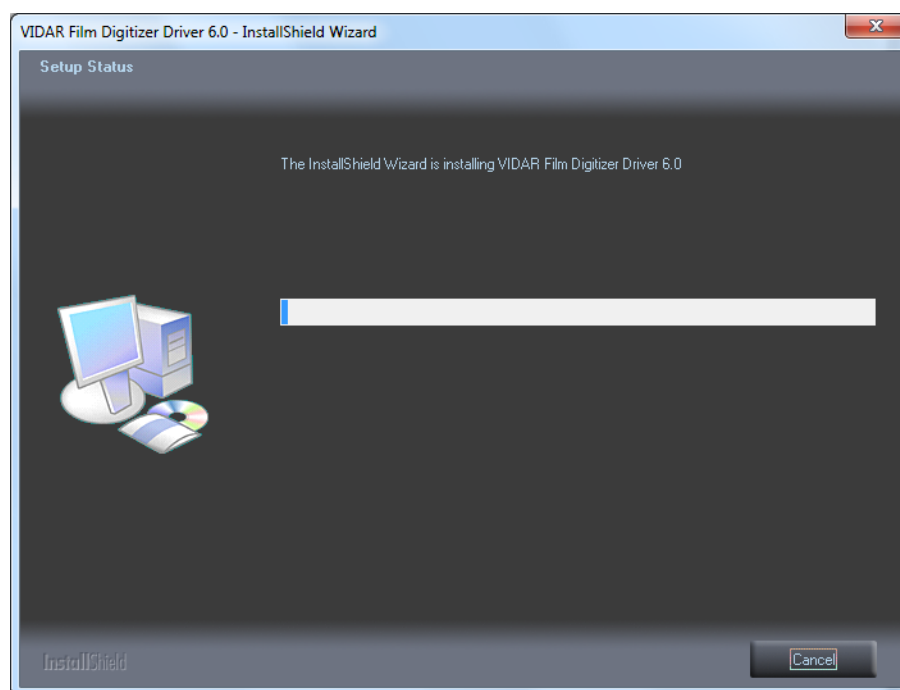
- e. In the **License Agreement** screen, activate **I accept the terms of the license agreement**, then click **Next >**.



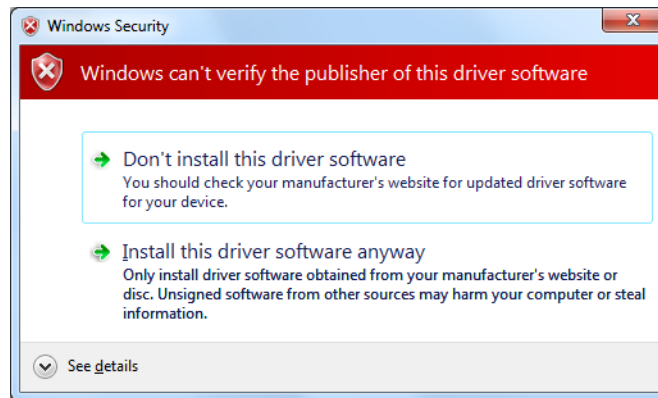
- f. In the **Ready to Install the Program** screen, click **Install**.



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



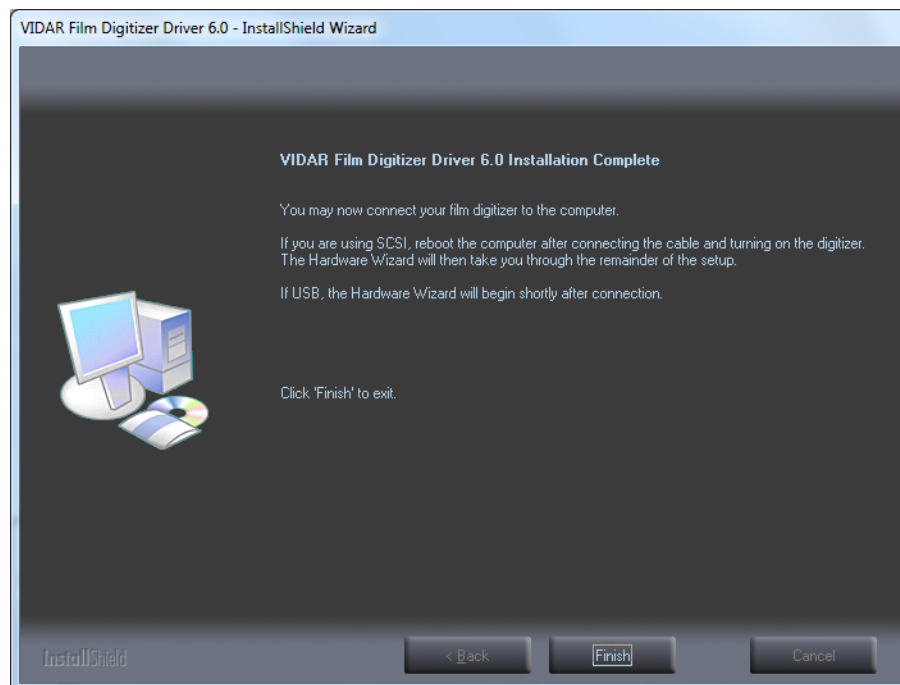
- h. The **Windows Security** window will appear. Click **Install this driver software anyway** each time it appears.



- 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.



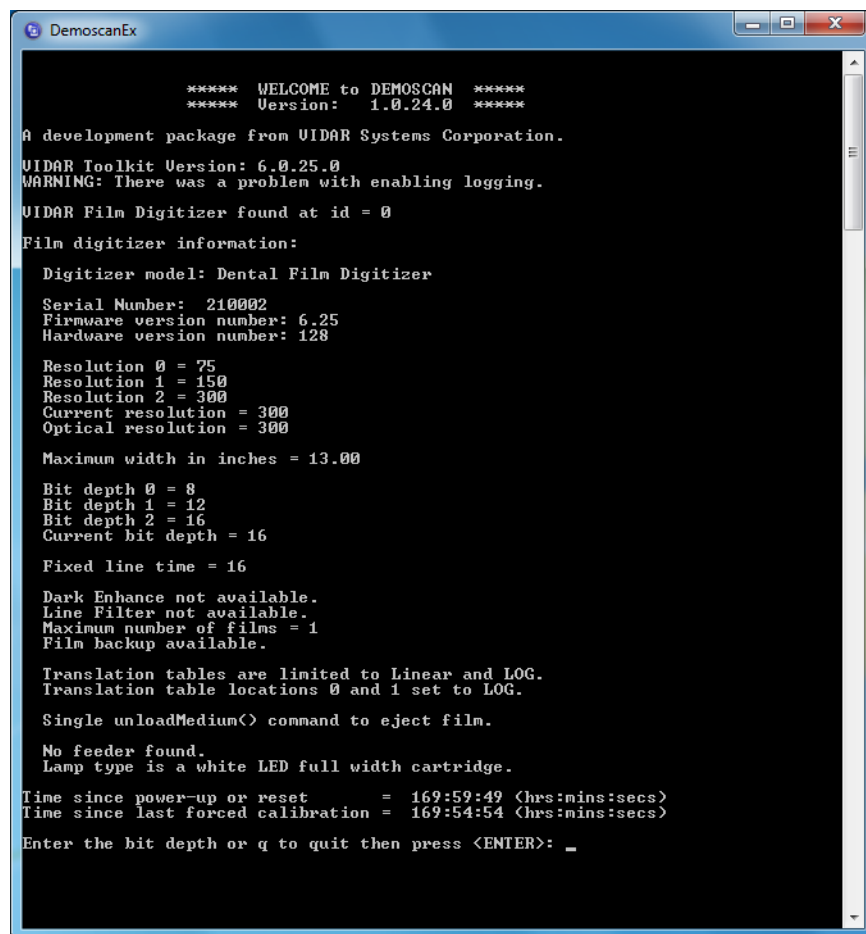
- k. Earlier, you connected a USB cable to the digitizer. Now, attach the connector on the other end of that cable to a USB 2.0 port on the computer.

**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.

- l. 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.

A screenshot of the DemoscanEx application window. The window has a blue title bar with the text 'DemoscanEx' and standard Windows window controls (minimize, maximize, close). The main content area is black with white text. The text displays welcome messages, version information (VIDAR Toolkit Version: 6.0.25.0, Version: 1.0.24.0), and detailed digitizer information for a 'Dental Film Digitizer'. It lists various specifications such as resolution, bit depth, and line time. At the bottom, it prompts the user to 'Enter the bit depth or q to quit then press <ENTER>: \_'.

```
***** 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
Film digitizer information:
  Digitizer model: Dental Film Digitizer
  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>: _
```

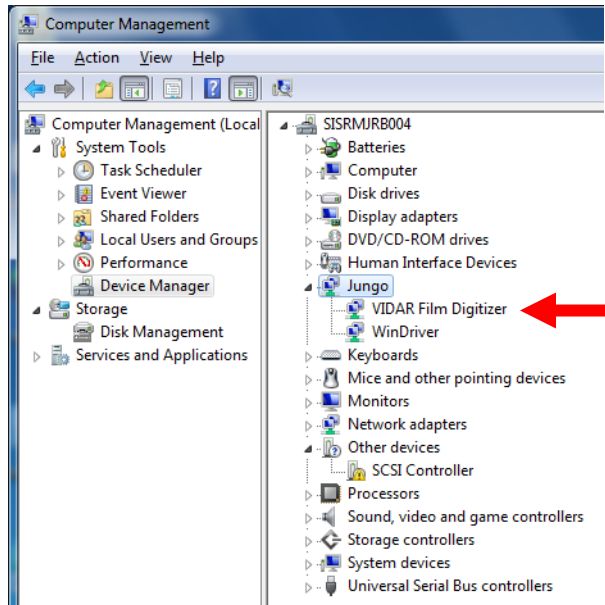
- n. Press Q on the keyboard, then press ENTER.

The digitizer is now ready to operate. Please refer to the “User’s Guide for VIDAR Dental Film Digitizer” 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 film digitizer.

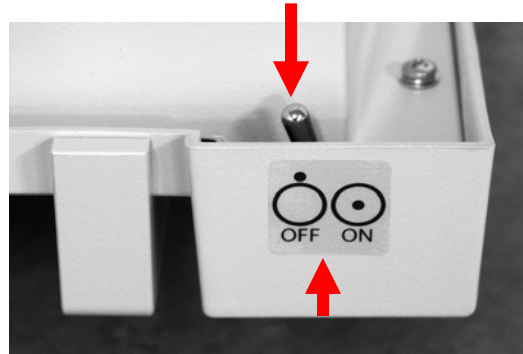
**Note:** Installation instructions for Windows 7 are provided in the previous chapter.

## 1. Apply Power to the Digitizer and the PC

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**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 behind the upper right corner.



### Power switch labeling

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**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 was designed to provide compatibility between VIDAR Dental Film Digitizers and Windows XP SP3. 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

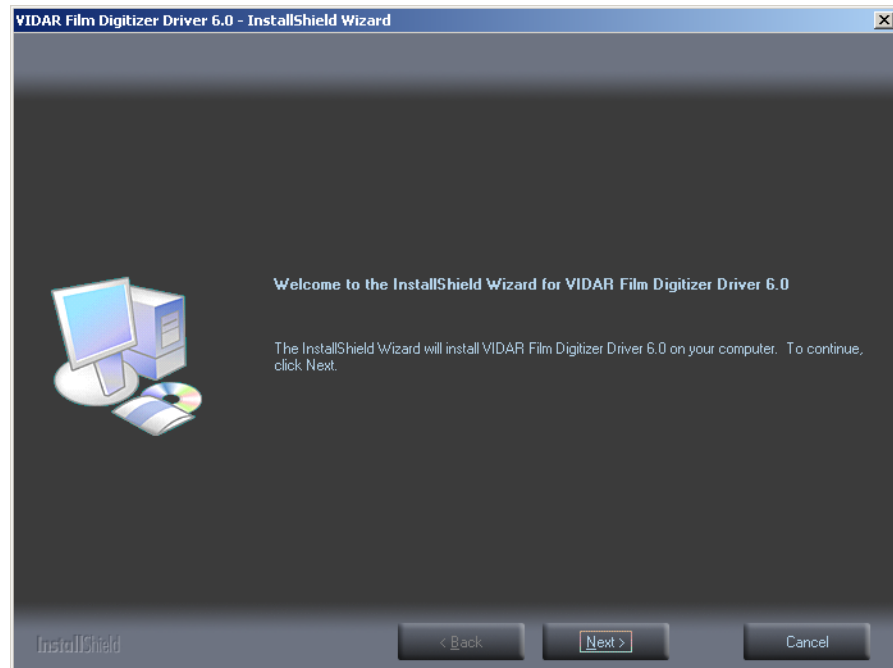
**Note:** The computer must be running Windows XP SP3.

**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.

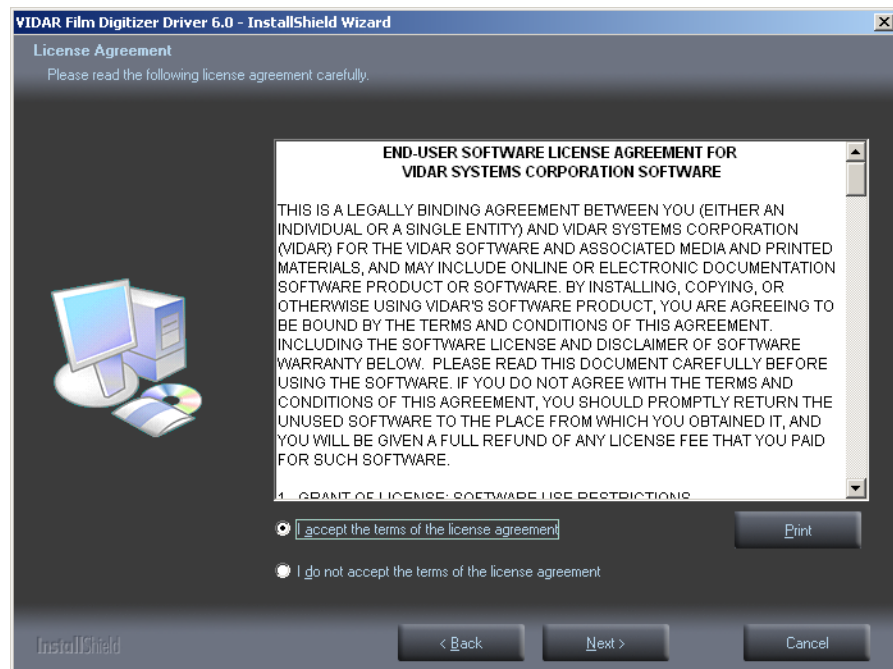
You will need the VIDAR Dental Film Digitizer Installation CD.

- 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 Dental Film Digitizer Installation 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.

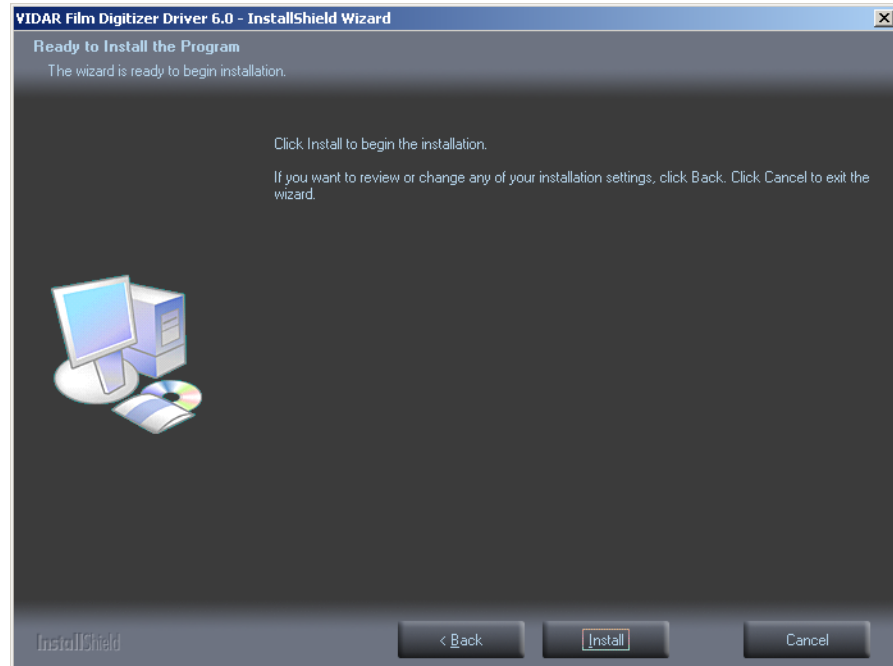
- d. In the first screen, click **Next >**.



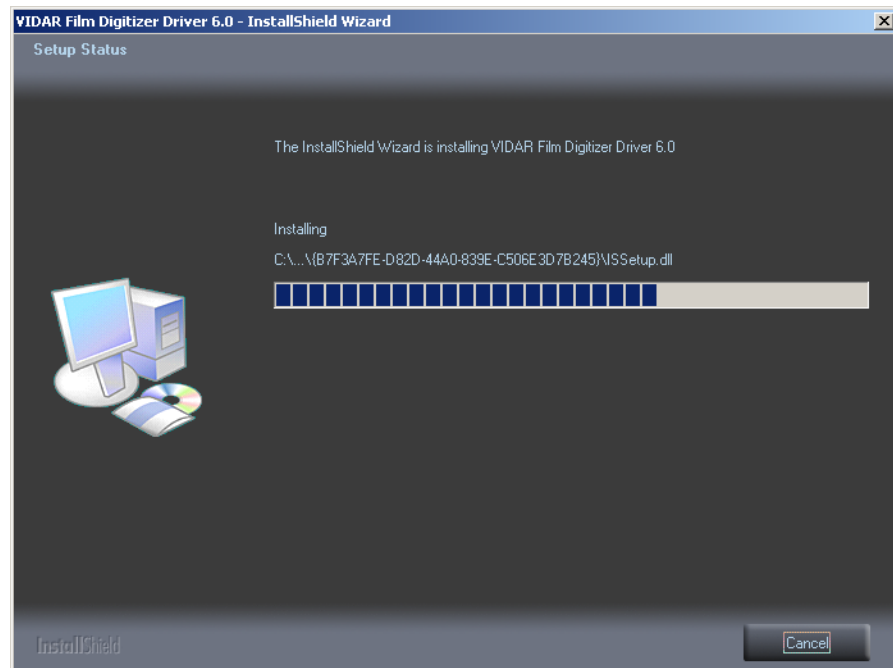
- e. In the **License Agreement** screen, activate **I accept the terms of the license agreement**, then click **Next >**.



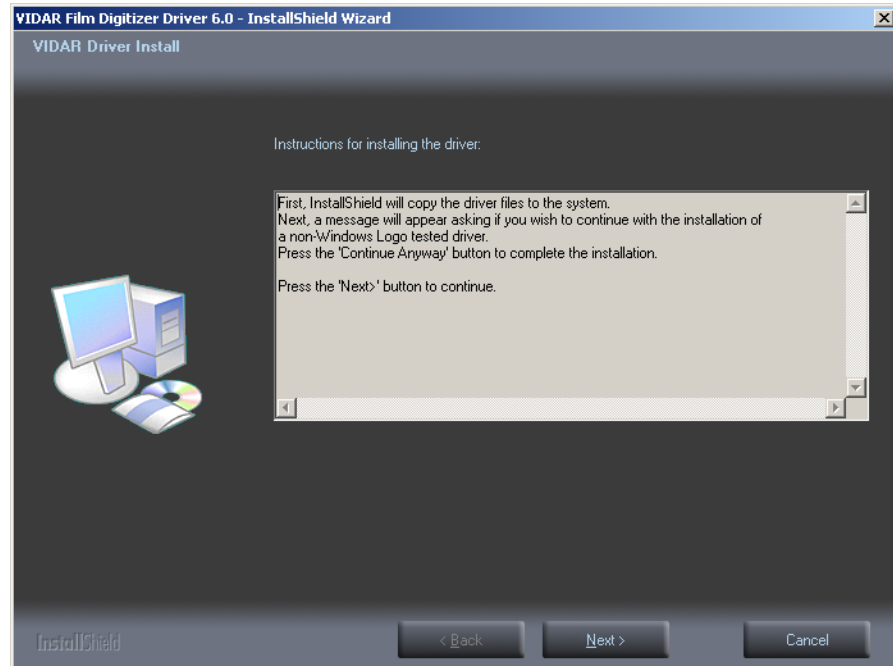
- f. In the **Ready to Install the Program** screen, click **Install**.



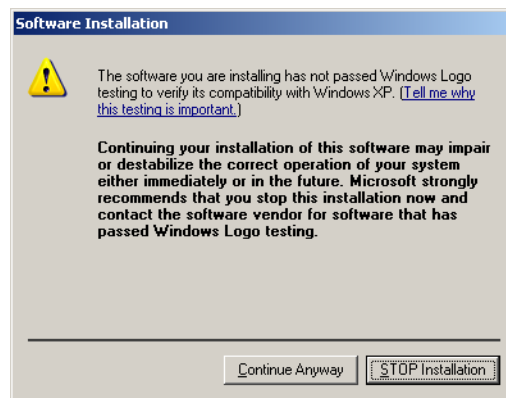
- g. The **Setup Status** screen will appear. Wait while the files are installed.



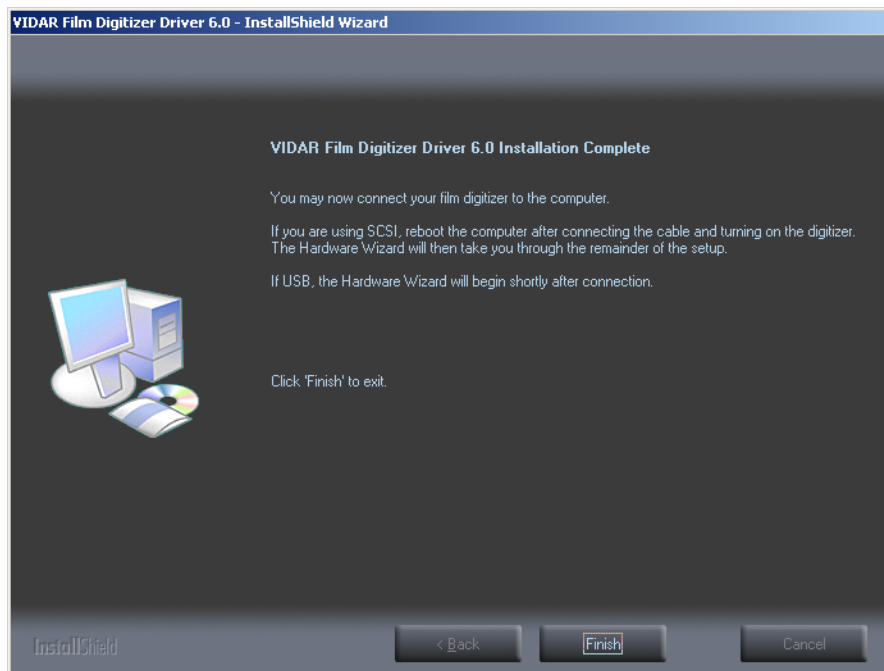
- h. The **VIDAR Driver Install** window previews the next steps. Click **Next >**.



- 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.



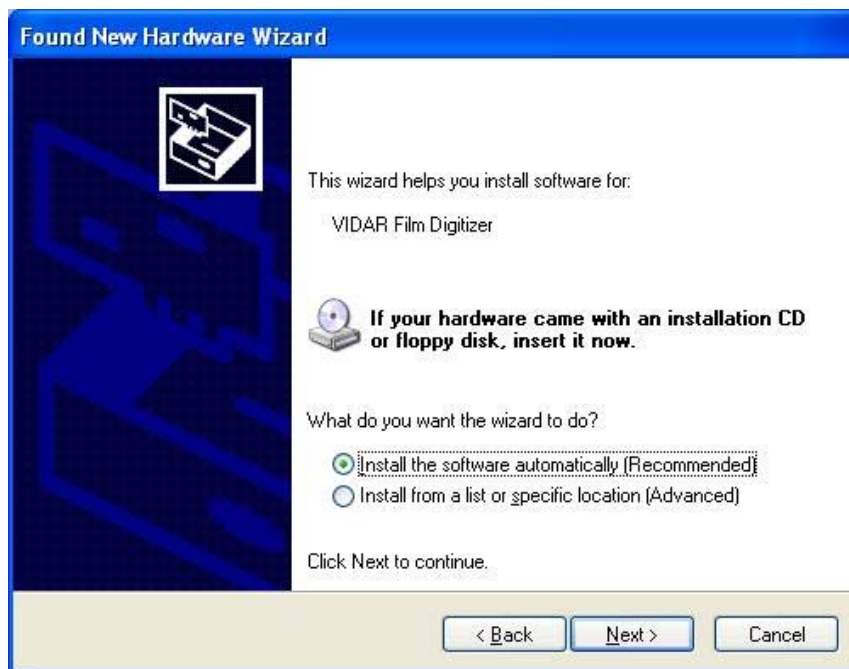
- k. InstallShield will indicate that installation is complete. However, the driver installation is not complete.



- l. 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 >**.



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



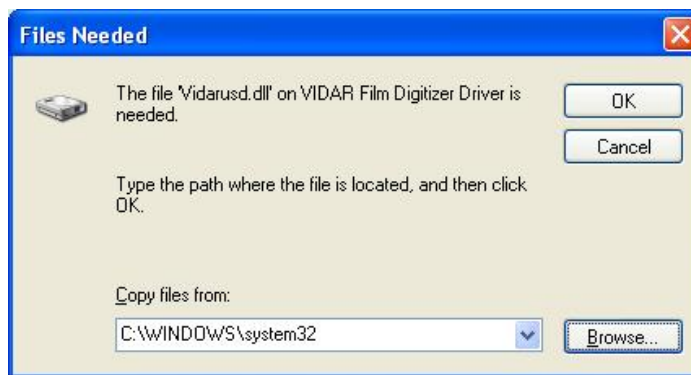
p. Wait while the wizard searches for the driver.



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**

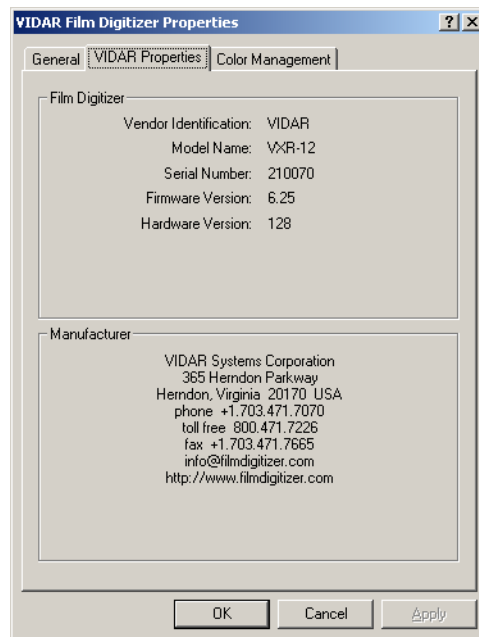


- s. After the driver has been installed, click **Finish**.



- 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, right-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.



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 Dental Film Digitizer” 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 Dental Film 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 VIDAR Dental Film Digitizer is intended for use in the electromagnetic environment specified below. The customer or end user of the Dental Film Digitizer should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR11	Group 1	The Dental Film Digitizer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.  The Dental Film 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.
RF Emissions, CISPR11	Class A	
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ flicker emissions IEC 61000-3-3	Complies	

## Guidance And Manufacturer's Declaration – Electromagnetic Immunity

Table 202

The Dental Film Digitizer is intended for use in the electromagnetic environment specified below. The customer or end user of the Dental Film 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.
Voltage dips, short interruptions and voltage variations on power supply input lines  IEC 61000-4-11	<5 % $U_T$ (>95 % dip in $U_T$ ) for 0,5 cycle  40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles  70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles  <5 % $U_T$ (>95 % dip in $U_T$ ) for 5 sec	<5 % $U_T$ (>95 % dip in $U_T$ ) for 0,5 cycle  40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles  70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles  <5 % $U_T$ (>95 % dip in $U_T$ ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Dental Film Digitizer requires continued operation during power mains interruptions, it is recommended that the Dental Film Digitizer be powered from an uninterruptible power supply or a battery
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 Dental Film Digitizer is intended for use in the electromagnetic environment specified below. The customer or end user of the Dental Film Digitizer should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communication equipment should be used no closer to any part of the Dental Film Digitizer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz  Where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> 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.

<sup>a</sup> 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 Dental Film Digitizer is used exceeds the applicable RF compliance level above, the Dental Film 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.

<sup>b</sup> 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 Dental Film Digitizer

Table 206

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

Rated maximum output power of transmitter  W	Separation distance according to frequency of transmitter, m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23







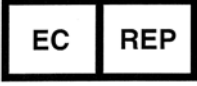


For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the 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
	Indicates the “OFF” condition for a part of equipment; not used to identify the “OFF” position of a switch.
	Indicates the “ON” condition for a part of equipment; not used to identify the “ON” position of a switch.
	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.
	Underwriters Laboratories classification symbol
	Compliance to EU Directives
	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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