User’s guide for

- Single film feeder
- Multi-film feeder

Serial numbers
200,000 to 209,999

NOTE

The digitizers do not include application specific software (Picture Archiving and Communications [PAC] system, Teleradiology, Oncology Systems, or Computer Aiection [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.filmdigitizer.com

Sales: 1-800-471-SCAN or
1-800-471-7226
Email: sales@VIDAR.com

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

EC REP

Emergo Europe
Molenstraat15
2513 BH, The Hague
The Netherlands

E-mail: service@emergogroup.com

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.

Acceptable shipping conditions

- Temperature: –15° 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: 15°C to 30°C (60°F to 85°F)
- Relative humidity: 20% to 85%, non-condensing
- Atmospheric. pressure: 697 to 1013hPa (10,000 to 0ft)

Electrical supply

- Voltage: 100 to 240 VAC
- Current: 1.0 to 0.42 A
- Frequency: 50 to 60 Hz

Safety and compliance information

5RA9

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 3rd edition.

Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of IEC 60606-1-1 or IEC 60601-1 3rd 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. 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.

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. See Appendix Patient Vicinity for minimum distance between this product or the host computer and a 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:

Contents

Intended Use

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

Note: The SIERRA 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

Operating

the SIERRA *Advantage* film digitizer

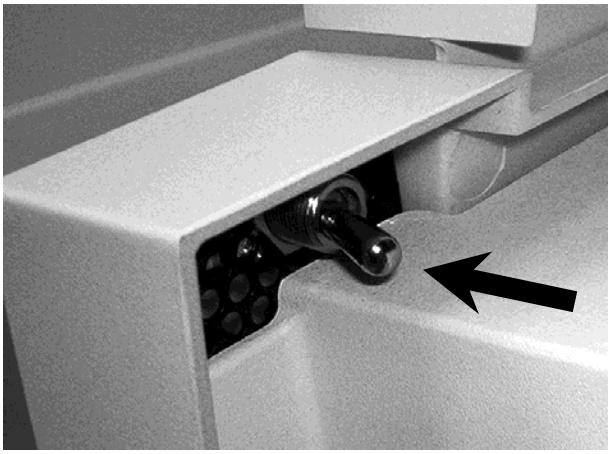
Apply power—then leave on continuously

If the film digitizer is already on and ready to scan (LED on the front of the digitizer is solid green), then skip this section.

1. 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.

2. Turn on the digitizer (the switch is located behind the upper right corner of the digitizer body).



3. Observe the LED on the front of the digitizer: the LED should flash light blue for several minutes. This indicates the digitizer is performing internal tests and calibration.

4. When the LED stops flashing and remains solid green, turn on the PC.

   The digitizer is now ready to scan films.

> **Note:** Normally, **do not turn off the digitizer**. Leave it on continuously. Turn the PC on and off as needed.

CAUTION: X-ray images displayed on a computer monitor are representative only. Dimensional and grayscale inaccuracies may result from the build-up of tolerances in the digitizer, the display board and the computer. For this reason, special precautions must be exercised when taking measurements from the digitized image. Please refer to the user's manual for your digitizing software for more information.

About films

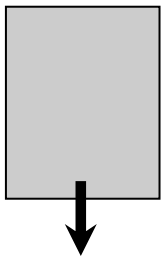
The SIERRA *Advantage* handles standard radiograph films up to 14" x 17" (35.5cm x 43cm).

With multi-film SIERRA *Advantages*, you can feed multiple films (up to 10), and you can mix film sizes ranging from 8" x 10" (20.5cm x 24.5cm) to 14" x 17" (35.5cm x 43cm) in one stack—as long as you follow the rules below.

IMPORTANT: Remove stickers, tape, staples, paper clips, etc. from films before scanning. These may cause serious film feeding problems. Failure to remove extraneous items from films will void your warranty.

Load films just as you would view them on a light box, with these qualifications:

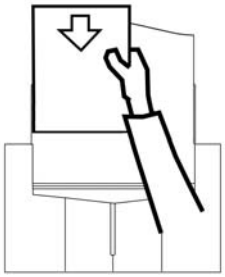
- Films 8" x 10" (20.5cm x 24.5cm) or larger should be fed in portrait orientation, as shown here:



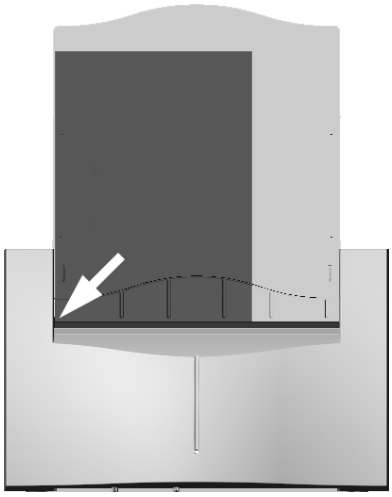
- Films smaller than 8" x 10" (20.5cm x 24.5cm) must be fed one at a time.

Using the single film feeder

Note: The digitizer cannot scan films smaller than 5" x 7" (12.7cm x 17.8cm).



1. Ensure the LED on the front of the digitizer is solid green.



2. Hold the film in front of you as you would view it on a light box.

3. Place the film into the slot **BEHIND the blue area**.

   The blue area is defined by a lip and a groove on the top edge of the digitizer where the feeder is attached. Place a single film directly behind the blue area.

   When the SIERRA *Advantage* detects the film, it *stages* the film—it pulls the film in about 1" (2.5cm), then pushes the film back out about 1/2" (1.25cm).

CAUTION: If the film is not staged properly, do not manually pull the film out of the digitizer. Instead, use the scanning application's "eject" command to remove the film.

Note: When a film has been staged, it is in the digitizer's light path. The ADC (Automatic Digitizer Calibration) feature requires that the light path be clear of the film for proper background calibration of the digitizer. The digitizer will automatically adjust the film's position to properly proceed with ADC. Depending on the location of the film's leading or trailing edge, and the length of time the film has been blocking the light path, the film will be: a) pushed up, b) pushed down, or c) ejected to remove the film from the light path.

4. Using your scanning software, execute the **Scan** command.

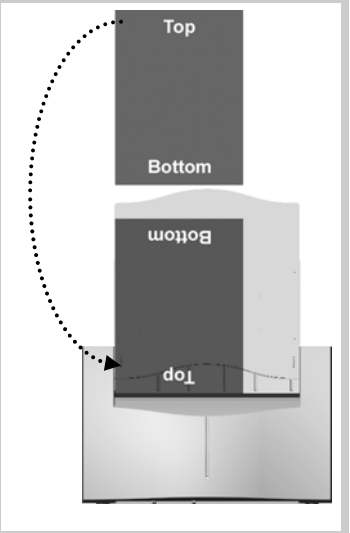
   The LED will flash green rapidly, indicating the scan is in progress.

   When the scan is complete, the LED will return to solid green.

Note: After the scan, the film may or may not be ejected—your scanning software determines what happens. If the software's **Auto Eject** function is activated, the film will drop into the exit tray. Otherwise, the lower rollers in the scanner will hold the film until one of the following occurs:

- Another film is detected.
- You manually eject the film from the software.
- The ADC process begins by ejecting the film.

Note: Proper orientation of the film during loading depends on the scanning application program you are using. Some scanning programs rotate images 180° for display. If images appear upside down, you may be able to set the default orientation in the scanning application. If this option isn't available, then insert films into the digitizer upside down, as shown here.



Using the multi-film feeder

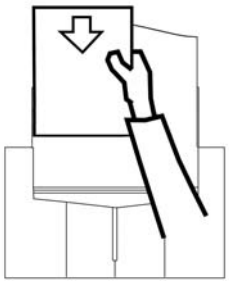
The SIERRA *Advantage* with multi-film feeder can accept stacks of **up to 10** films of mixed sizes. It can also accept single films.

CAUTION: Do not load more than 10 films at one time.

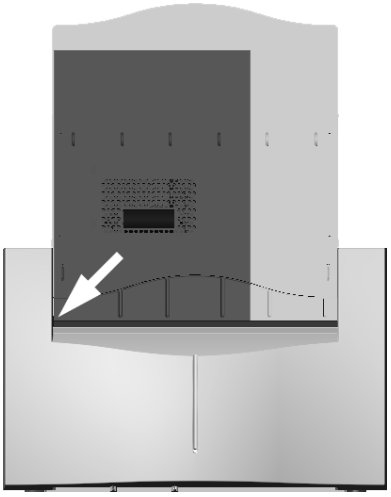
1. Ensure the LED on the front of the digitizer is solid green.

2. Hold the film stack (or single film) in front of you as you would view the films on a light box.

   Films at the back of the stack are digitized first.



Note: The digitizer cannot scan films smaller than 5" x 7" (12.7cm x 17.8cm). When loading small films, the vertical dimension must be at least 7" (17.8cm).



3. Align the left edge of the film stack with the film guide on the left edge of the feeder.

4. Place the film stack **IN the blue area**.

   The blue area is defined by a lip and a groove below the feed tray. Place the film stack in front of the feeder inside the groove of the blue area.

Note: If you are digitizing a single film, place the film either behind the blue bar or on the blue bar depending on the instructions from your scanning application. If no instructions are given, place the film on the blue bar.

Note: When a film has been staged, it is in the digitizer's light path. The ADC (Automatic Digitizer Calibration) feature requires that the light path be clear of the film for proper background calibration of the digitizer. The digitizer will automatically adjust the film's position to properly proceed with ADC. Depending on the location of the film's leading or trailing edge, and the length of time the film has been blocking the light path, the film will be: a) pushed up, b) pushed down, or c) ejected to remove the film from the light path.

5. Using your scanning software, execute the **Scan** command.

   The LED will flash green rapidly, indicating the first scan is in progress.

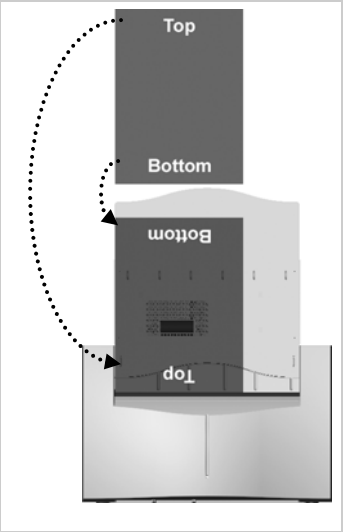
   When the first scan is complete, the second film will be scanned and so forth, until the last film has been scanned.

   When the entire batch has been scanned, the LED will return to solid green.

Note: After the scan, the last film may or may not be ejected—your scanning software determines what happens. If the software's **Auto Eject** function is activated, the film will drop into the exit tray. Otherwise, the lower rollers in the scanner will hold the film until one of the following occurs:

- Another film is detected.
- You manually eject the film from the software.
- The ADC process begins by ejecting the film.

Note: Proper orientation of the film during loading depends on the scanning application program you are using. Some scanning programs rotate images 180° for display. If images appear upside down, you may be able to set the default orientation in the scanning application. If this option isn't available, then insert films into the digitizer upside down, as shown here.



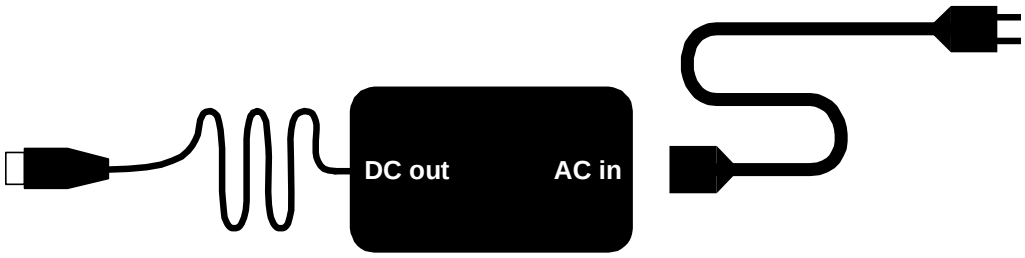
Troubleshooting

the SIERRA *Advantage* film digitizer

Normal operation

LED indication	Condition
Flashing light blue	Digitizer calibrating, please wait.
Flashing dark blue	See “Error conditions” in the “In case of difficulty” section, later in this chapter.
Solid green	Ready to scan.
Flashing green	Scan in progress.

Power adapter information



CAUTION: Only use the power supply adapter as supplied by your Service Provider or Vidar Systems Corp.

In case of difficulty

How to use this section:

1. Look through the left columns to find a description of the problem you are having.
2. Follow the instructions (in order) in the "Corrective action" column. If the one corrective action doesn't solve the problem, then carry out the next corrective action.
3. When the instruction is "Get qualified technical help," then:
   a. Contact your system integration specialist (the company or person that installed your VIDAR film digitizer).
   b. If your system integration specialist isn't available, then contact VIDAR Customer Support (medtech@VIDAR.com). Please record system information before calling, and have it available when calling.

Tip: Check www.filmdigitizer.com for current troubleshooting information, tools and software updates.

Error conditions

LED indication	Condition	Corrective action
Flashing dark blue.	Normalization error.	1. Clean lamp diffuser (see "Cleaning the diffuser" in the "Cleaning and maintaining" chapter, later in this manual). ***or if that doesn't solve the problem...*** 2. Replace lamp (instructions are provided with the Lamp Cartridge Replacement Kit, VIDAR part number 18629-001). ***or if that doesn't solve the problem...*** 3. Get qualified technical help.
No LED...	and scanner functions correctly.	Get qualified technical help.
No LED...	and scanner does not function.	1. Ensure that power cable is properly plugged into digitizer (power cable connects to bottom of digitizer). If digitizer then appears normal, wait for solid green LED, then reboot PC. ***or if that doesn't solve the problem...*** 2. Ensure that electrical power cord is properly plugged into power adapter. If digitizer then appears normal, wait for solid green LED, then reboot PC. ***or if that doesn't solve the problem...*** 3. Get qualified technical help.

continued

Operational problems

Symptom	Corrective action
Film tilts or skews during scanning.	1. Ensure individual films are loaded properly: bottom edge of film parallel to rollers, left edge of film up against digitizer body—as far left as it will go. (Review "Loading a single film" in "Operating" chapter.) 2. (*Multi-film feeder only*) Ensure multiple films are loaded properly: place films in front of blue area. 3. Ensure pickup roller is clean (see "Cleaning the multi-film feed tray," later in this chapter). 4. Ensure idler rollers spin freely. 5. If problem persists, get qualified technical help. 6. Remove any foreign matter from film entrance slot.
After film is loaded and staged properly, a few minutes later film is pushed out of staging area.	When film is staged, it is over digitizer's light path. SIERRA's ADC (Automatic Digitizer Calibration) feature requires that light path be clear for proper background calibration. Thus, if film remains in digitizer for more than 5 minutes, it will be pushed up 1/4" (0.6cm) to clear light path. Later, when you execute your software's **Scan** command, film will be re-staged before it is digitized.
Digitizer has been off for several days. First film misfeeds or jams.	Run three or four films through digitizer: load films one at a time, then eject each one (or perform a scan on each film, but this takes longer).
Can't turn digitizer on or off. Can't find power switch.	The on/off switch is located behind the upper right corner of the digitizer body (when viewed from the front). If the digitizer is mounted on the table-top stand, look at the digitizer from the rear to see the switch.
Multi-film feed tray won't feed films.	The multi-film feed tray must be connected to the digitizer with the multi-film feed tray cable. The cable is located above the digitizer body, on the left side (when viewed from the front). Ensure the cable is present. Ensure one end of the cable is plugged into the jack on the multi-film feed tray, and the other end is plugged into the digitizer. After checking cable and connections, restart digitizer, then restart PC after LED turns green.
After applying power, LED on front keeps flashing light blue.	After power is applied, digitizer normally requires about 7 minutes to normalize and calibrate, during which time the LED will flash light blue. If LED flashes light blue for more than 15 minutes, turn digitizer power off and on again (as described later in this chapter), then reboot PC.
Streaks in image	Clean LED cartridge diffuser (see "Cleaning the diffuser" in the "Cleaning and maintaining" chapter, later in this manual).

continued

Symptom	Corrective action
LED is off, in spite of using proper power-on procedure described later in this chapter.	1. Ensure wall outlet is providing AC power: obtain another electrical device known to be working, and plug it into that AC wall outlet. ■ If other device doesn't work, AC power is not available at that wall outlet. Get help from building services. ■ If other device does work, AC power is available from that outlet. Go to step 2. 2. With power applied to digitizer, look into digitizer film entrance slot. If you see light coming from inside digitizer, power is on. For this condition (LED off, internal light on), get qualified technical help. 3. If you have another SIERRA *Advantage* film digitizer, try its power adapter. ■ If digitizer works with other power adapter, original power adapter is defective. Obtain replacement VIDAR SIERRA *Advantage* power adapter from your system integration specialist. **Do not substitute any other power adapter.** ■ If digitizer does not work with a known good power adapter, get qualified technical help. **CAUTION: Using a non-approved power adapter will void the warranty.**
Film starts and stops during scanning.	1. Increase memory allocation for scanning software. (Especially if scanning at high resolutions, memory allocation must be sufficient to accept data stream from digitizer.) 2. If scanning to disk, ensure sufficient space is available on disk drive. 3. Ensure PC has enough memory available to support scanning application. Close applications not needed for image acquisition from digitizer. 4. If problem persists, get qualified technical help.
Digitizer stops scanning and PC locks up.	1. Reset entire system. Remember that USB protocol requires that digitizer be powered before PC. a. Turn digitizer off. b. Shut down PC and turn it off. c. Turn digitizer on. d. After digitizer LED turns solid green, turn on PC. 2. Launch scanning software on PC, then try scanning again. If problem persists, get qualified technical help. 3. Check for correct device driver installation.
Digitizer was working properly, but after installing (or reinstalling) the scanning application there are Toolkit errors or the digitizer is not detected on the USB bus.	1. If you installed a new scanning application, or if you reinstalled the existing application, the older Toolkit (vscsi32.dll) may have been installed. Run the VIDAR Drivers and Toolkit Installation CD (see appropriate section in the "Installing device drivers" chapter). 2. If problem persists, contact medtech@VIDAR.com.

continued

Symptom	Corrective action
Digitizer is not listed in Windows Control Panel > Scanners and Cameras.	1. Update to or reinstall STI drivers. See the “Install device drivers and toolkit” chapter of the “Installation Guide for SIERRA *Advantage*.” 2. Check all USB cables and connectors.

Turning the digitizer on and off

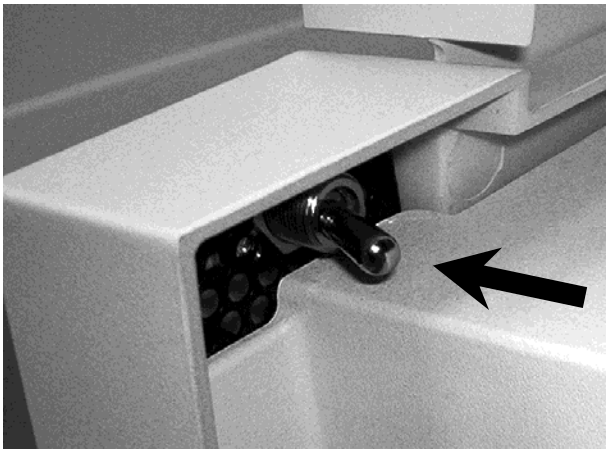
WARNING

Do not apply power by plugging the DC power connector into the digitizer while the power adapter is live. Do not remove power by unplugging the DC power connector from the digitizer while the power adapter is live. Either of these actions could permanently damage the digitizer, the power adapter or both.

Note: SIERRA *Advantage* was designed to be powered continuously. Under normal conditions, the digitizer should remain on at all times.

Use only the power switch to turn the digitizer on or turn it off:

The power switch is located behind the upper right corner of the digitizer (when viewed from the front).

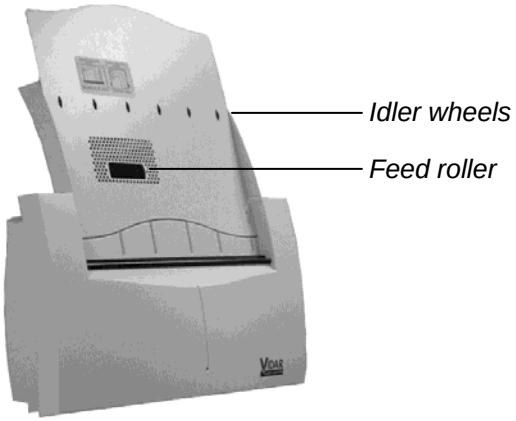


Cleaning and maintaining

the SIERRA *Advantage* film digitizer

Cleaning the multi-film feed tray

After extensive use, dust or lint particles may build up on the feed roller and idler wheels.



To remove residue, loop a piece of light adhesive tape (such as Scotch® Magic™ Tape) around your fingers with the adhesive side out, then gently pat the roller and wheels as you turn them.

CAUTION:

- **Do not** use any type of cleaning solvent on the feed roller and idler wheels, as this could damage these components and cause improper operation.
- **Do not** use tape with a strong adhesive, such as packing tape or strapping tape.
- **Do not** use tape requiring the adhesive to be wetted, such as brown paper packing tape.

Cleaning the diffuser

Note: Use this procedure only when you observe streaks in images, or when the digitizer's LED flashes dark blue.

Note: Use this procedure only for SIERRA *Advantage* digitizers with serial numbers between 200,000 and 299,999.

IMPORTANT: You must follow these instructions when cleaning the diffuser. Deviation from these instructions will void the product's warranty and will likely result in costly repairs.

You will need:

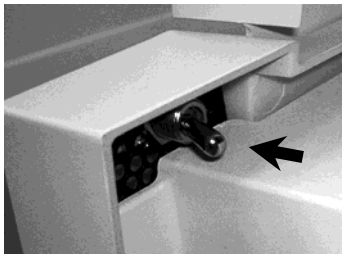
- #2 (medium) Phillips screwdriver.
- Soft cloth to protect front of digitizer.
- Lint-free wipes (VIDAR part number 15194).

1. Shut down system.

a. Shut down and turn off PC.

b. Turn digitizer power switch off.

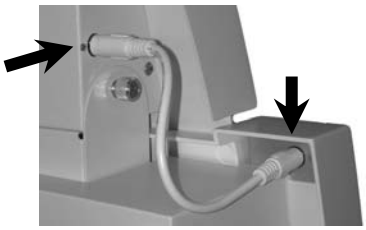
c. Disconnect digitizer power adapter cord from wall outlet.



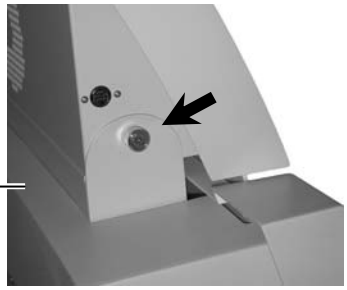
2. Unmount digitizer.

a. Disconnect power cable and SCSI cable from bottom of digitizer.

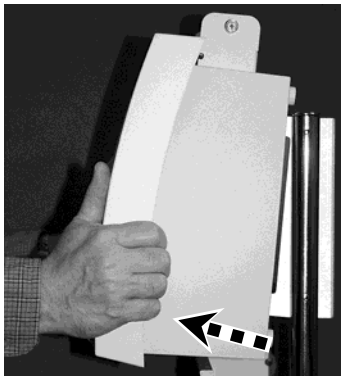
b. If unit has a multi-film feed tray, disconnect cable from both digitizer and multi-film feed tray.



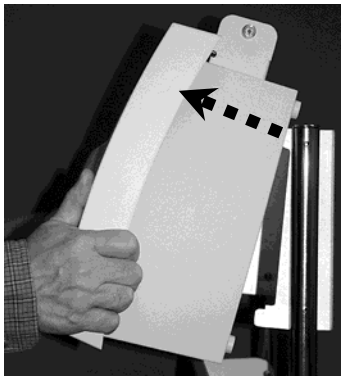
c. Loosen thumbscrews holding feed tray (one on each side, above digitizer body), then remove feed tray: tilt forward and lift up.



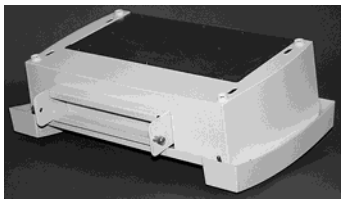
d. Stand in front of digitizer. Grasp digitizer on both sides. Pull bottom of digitizer toward you...



then lift up and off mounting bracket.

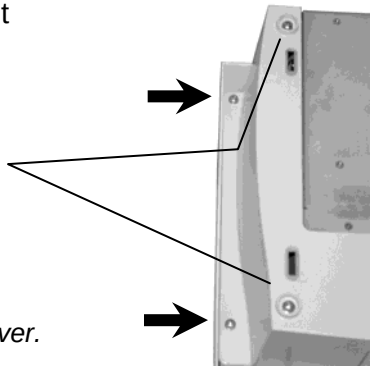


e. Place digitizer face down on soft cloth on table. Top should be toward you.



3. Open digitizer.

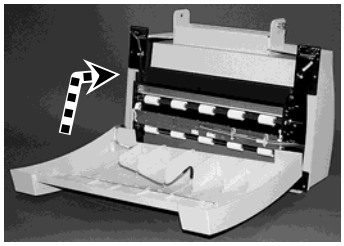
a. Remove four screws securing front cover (two screws shown here by arrows; other two are on opposite end of front cover).



Do not
remove four screws in feet on rear cover.

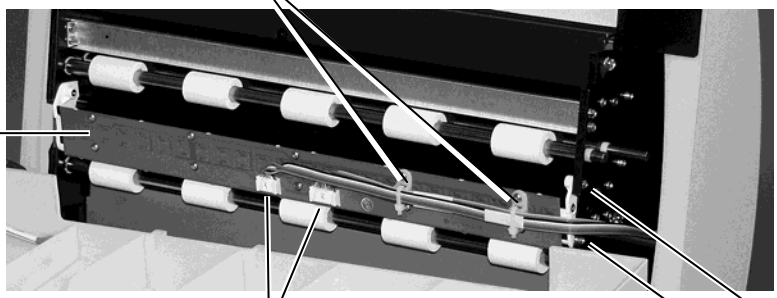
b. Lift main unit up (out of cover) and place on table near cover.

CAUTION: Keep main unit close to cover. A cable extends between them. ***Do not disconnect cable.***



4. Remove LED cartridge.

a. Cut the two cable ties securing the cables to the LED cartridge.

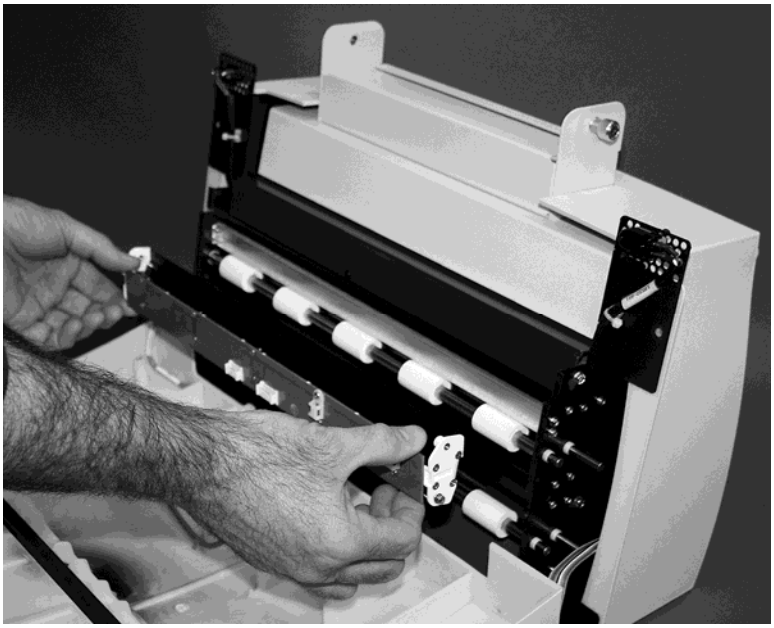


b. Remove the two connectors from the LED cartridge (press in on each latch to release the connector from its socket).

c. Loosen the lower screws at each end of the LED cartridge.

d. Remove the upper screws at each end of the LED cartridge.

e. Grasp both ends of LED cartridge, then pull gently toward you until it is free of main unit frame.

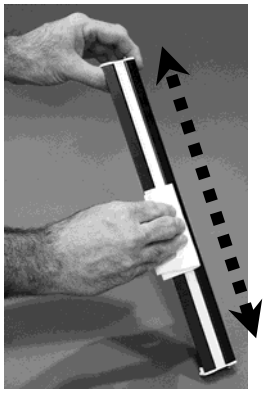


5. Clean diffuser.

Using lint-free wipe, clean entire length of diffuser (white plastic strip) on lamp cartridge.

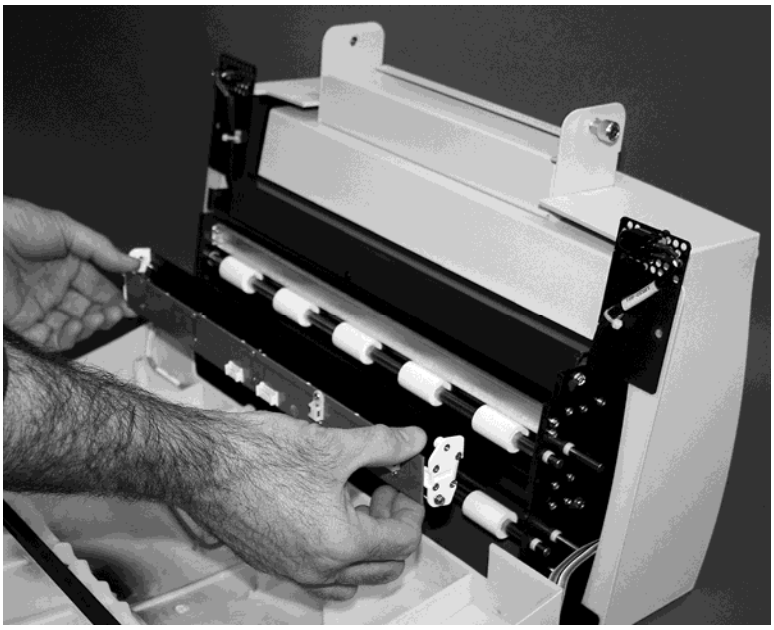
CAUTION: Clean only with lint-free wipes provided by VIDAR (part number 15194). Other cloth or paper wipes will leave fibers on the diffuser, which can affect performance.

After cleaning, do not touch diffuser.



6. Reinstall LED cartridge.

a. Hold LED cartridge in both hands with diffuser facing digitizer, and with cable tie mounts to right.



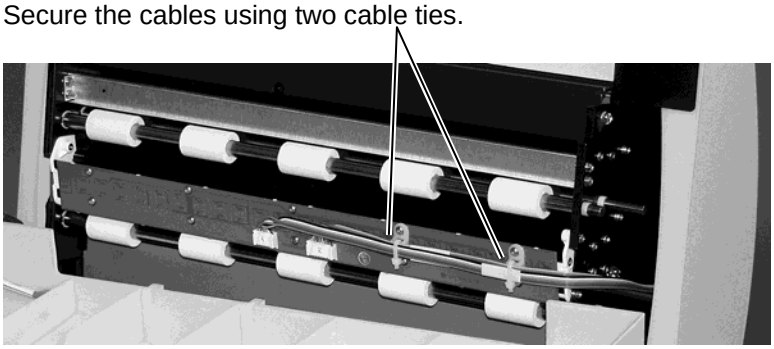
b. Slide LED cartridge into main unit, between the white rollers. The lower screws should slide into slots in the main unit frame.

c. Thread the two upper screws (one on each end) through the main unit frame into the LED cartridge.

e. Tighten the four screws (two on each end) to secure the LED cartridge.

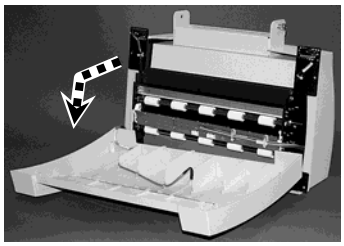
f. Plug the cables into the LED cartridge.

g. Secure the cables using two cable ties.

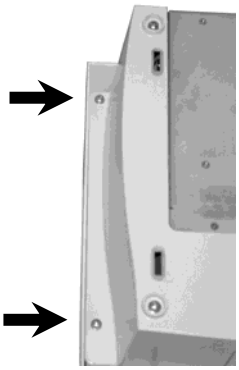


7. Close digitizer.

a. Place main unit in cover.



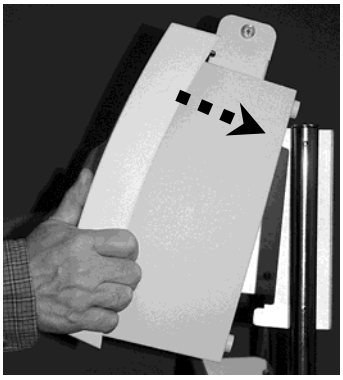
b. Using four screws removed in step 3a, secure front cover to main unit (two screws shown here by arrows; other two are on opposite end of front cover).



8. Mount digitizer.

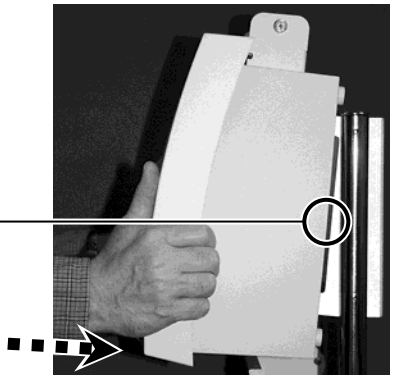
a. Position digitizer with front facing you. Grasp digitizer by both sides.

b. Slide digitizer's upper mounting slots over upper tabs on mounting bracket. Ensure slots drop into notches in tabs.

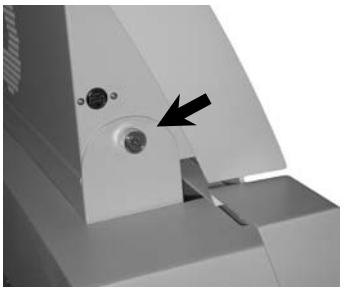


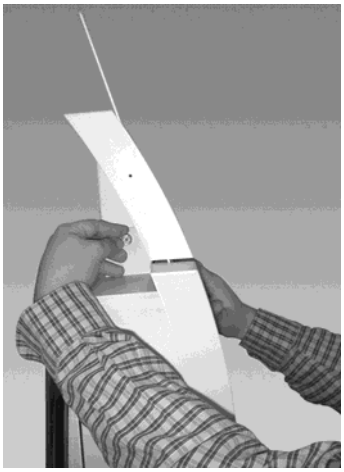
c. Rotate bottom of digitizer toward mounting bracket, so lower mounting slots slide over lower tabs on mounting bracket.

Make sure back side of main unit is parallel to edge of mounting bracket.



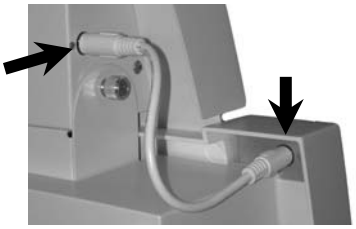
d. Place feed tray in position and hold with one hand while securing with two thumbscrews (one on each side).



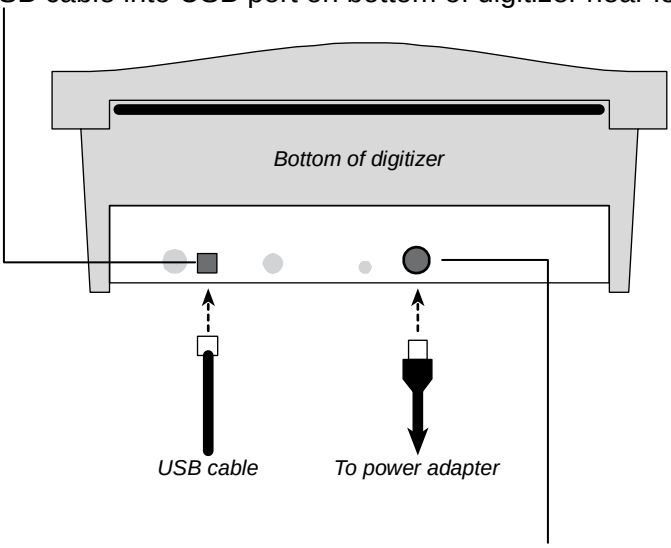


e. If unit has multi-film feed tray, connect feed tray cable to feed tray and to digitizer.

Arrow on connector faces up.



f. Plug USB cable into USB port on bottom of digitizer near left side.



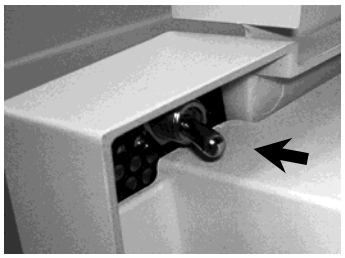
g. Plug power cable into jack on bottom of digitizer to right of center.

9. Return digitizer to service.

a. Assure PC is off.

b. Plug digitizer power adapter cord into wall outlet.

c. Turn digitizer power switch on.



d. Observe LED on front of digitizer:
it should flash light blue for several minutes (indicating digitizer is performing internal tests and calibration).

e. When LED stops flashing and remains solid green, turn on PC.

f. Digitizer is now ready to scan films.

Replacing the LED cartridge

Note: LED cartridges can only be replaced on SIERRA *Advantage* digitizers with serial numbers between 200,000 and 299,999.

Please contact VIDAR Technical Support to order the Lamp Cartridge Replacement Kit, VIDAR part number 18629-001:

- Phone: 1-800-471-SCAN (1-800-471-7226)
  1-703-471-7070 outside the U.S.

- E-mail: medtech@VIDAR.com

Instructions for replacing the LED cartridge are provided with the kit.

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 SIERRA *Advantage* 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 SIERRA *Advantage* Digitizer is intended for use in the electromagnetic environment specified below. The customer or end user of the SIERRA *Advantage* Digitizer should assure that it is used in such an environment.

Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF Emissions CISPR11	Group 1	The SIERRA *Advantage* 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.
RF Emissions, CISPR11	Class A	The SIERRA *Advantage* 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.
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 SIERRA *Advantage* Digitizer is intended for use in the electromagnetic environment specified below. The customer or end user of the SIERRA *Advantage* 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 % UT (>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 % UT (>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 SIERRA *Advantage* Digitizer requires continued operation during power mains interruptions, it is recommended that the SIERRA *Advantage* 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 SIERRA *Advantage* Digitizer is intended for use in the electromagnetic environment specified below. The customer or end user of the SIERRA *Advantage* Digitizer should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communication equipment should be used no closer to any part of the SIERRA *Advantage* Digitizer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
Radiated RF 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,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80MHz and 800MHz, the higher frequency range applies.

Note 2: These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SIERRA *Advantage* Digitizer is used exceeds the applicable RF compliance level above, the SIERRA *Advantage* Digitizer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Digitizer.

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

Recommended separation distances between portable and mobile RF communications equipment and the SIERRA *Advantage* Digitizer

Table 206

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

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter, m		
W	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	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.

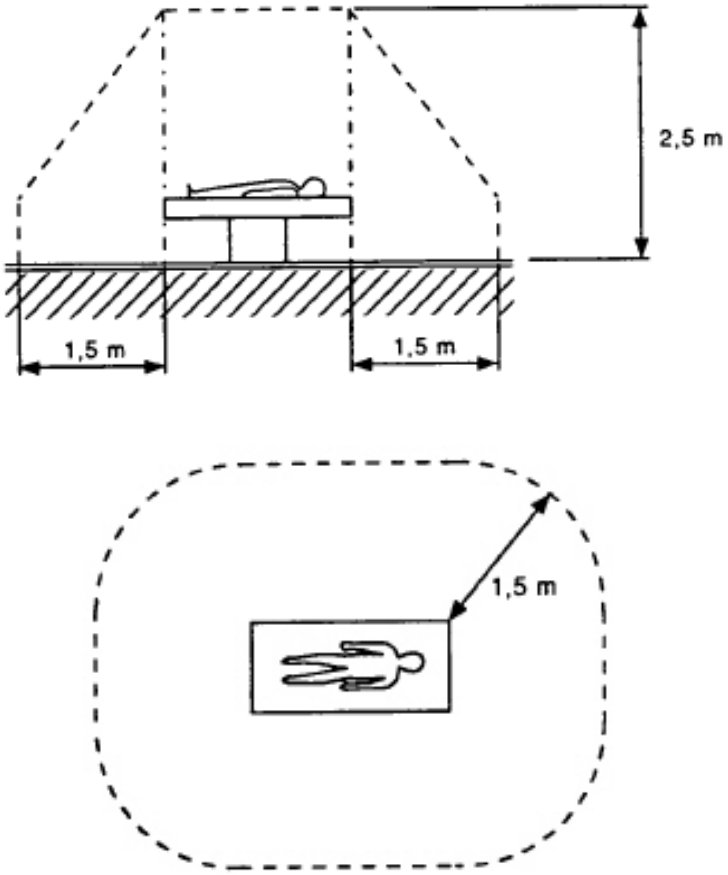
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix:
Symbol

Symbol	Description
	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.
 5RA9	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.

Appendix:
Patient Vicinity



Note: *Dimensions shown are not prescriptive.*

VIDAR Systems Corporation

365 Herndon Parkway
Herndon, VA 20170
+1.703.471.7070 (Phone
+1.703.471.7665 (Fax)
USA Toll Free: 800.471.SCAN

www.vidar.com

VIDAR
systems corporation
A 3D Systems Company