

# CDR Elite Sensor and USB Interface User Guide

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November 24, 2008

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### Check CDR Elite Sensor and USB Interface Module before Using Them

Before each usage, check the outer surface of the CDR Elite Sensor and USB Interface Module for any signs of physical damage or defect. CDR Elite Sensor and USB Interface Module surfaces should have a smooth finish, with no evidence of chipping or damage. If detected, contact your local distributor of Schick Technologies products for further instructions.

To help ensure proper hygiene and to protect against infectious disease, refer to the Protective Measures section of this document and observe all device cleaning and patient protection recommendations specified there.

### **Operate the CDR Elite Sensor and USB Interface Module as Directed**

Always use the CDR Elite Sensor and USB Interface Module in accordance with the directions and recommendations contained in this User Guide. Do not attempt to modify the CDR Elite Sensor and USB Interface Module or use it in system configurations not specified in this document.

# Do Not Touch Exposed Connectors on Non-Medical Equipment and the Patient at the Same Time

When the CDR Elite Sensor and USB Interface Module are in use, avoid touching exposed connectors on non-medical electrical equipment and the patient at the same time. The human body is capable of conducting electrical current and may cause a shock hazard to patients if appropriate safety practices are not observed.

### **RF Interference Considerations**

Although the CDR Elite Sensor and USB Interface Module are designed to provide a reasonable degree of protection from electromagnetic interference, according to IEC International regulations, they must be installed at an adequate distance from electricity transformer rooms, static continuity units, two-way amateur radios and cellular phones. To ensure proper operation, the latter (meaning, electricity transformer rooms, static continuity units, two-way amateur radios and cellular phones) can be used only at a minimum distance of 5 feet (1.5m) from any part of the CDR Elite Sensor and Interface Module.

Any instrumentation or equipment for professional use located near the CDR Elite Sensor and USB Interface Module must conform to Electromagnetic Compatibility regulations, to which the EMC tables in this document's Appendix serve as guidance. Non-conforming equipment, with known poor immunity to electromagnetic fields, may not operate properly unless they are installed at a distance of at least 10 feet (3m) and supplied by a dedicated electrical line.

### Apply Recommended Procedures for Cleaning the Equipment

Safe and proper operation of the equipment requires following a regular schedule of preventive maintenance. Refer to "Protective Measures" in this document for details.

### Do Not Connect Items that are Not Part of the System

Only items specified for use with the CDR Elite Sensor and USB Interface Module are to be connected to it. The device should not be used adjacent to other equipment that is not part of the system. If, however, use with adjacent equipment is necessary, normal operation should be observed and verified in that configuration.

# Installers to Ensure that CDR Elite Sensor and USB Interface Module Operate Optimally

Installers must ensure that the CDR Elite Sensor and USB Interface Module provides the user with the optimal use of the equipment. This includes, but is not limited to, ensuring that the system operates as described in this document. Installers must also ensure that the system presents no physical obstacles or hazards during operation and when not in use. To verify this requirement, installers shall confirm that the CDR Elite Sensor and USB Interface Module are installed as described in this User Guide and shall perform the appropriate procedures therein.

### Ensure Proper System and PC Workstation Installation and Operation

The CDR Elite Sensor and USB Interface Module have been determined to be in accordance with international safety standards and are deemed suitable for use within the patient area, which extends from the patient for a distance of 5 ft (1.5m). To comply with these standards, do not operate non-medical equipment (such as a PC workstation) inside the patient area. Outside the patient area, the presence of approved non-medical grade equipment and Listed / Approved / IEC 60950-1 certified Information Technology Equipment (ITE) computer equipment is acceptable.

The host computer (PC workstation) should be CE-approved and conform with the Low Voltage [73/23/EC] and EMC Directive [89/336/ERC]. Also, to help ensure optimal performance, ensure that all software programs residing on the workstation are virus-free and have been adequately tested so they will not impact imaging applications after installation.

### Only Dentists or Authorized Designees Are Permitted to Operate the System

To ensure the correct use of the CDR Elite Sensor and USB Interface Module in a clinical environment, for purposes that correspond to its intended design and application, only dentists, or their designees, are authorized to operate the system.

### Protect Sensor from Potential ESD Damage

Like other electronic devices, your CDR Elite Sensor is susceptible to electrostatic discharge (ESD), particularly when the device is used in or around carpeted areas or low-humidity environments. During cable replacement, when Sensor contacts are exposed, it is especially important to protect the device from potential ESD damage. Touching a metal

surface prior to replacing the CDR Elite cable will reduce the risk of damaging Sensor components by accidental static discharge. The use of anti-static floor mats or floor treatments (for example Staticide 2005/2002) will also help eliminate static build-up in your office.

### Wait for Appropriate Prompts before Operating X-ray Source

To avoid exposing the patient to unnecessary X-rays, ensure that the CDR exam window viewbox is flashing green (default color) in AutoTake mode, or that the message, "Waiting to take X-ray," is displayed before triggering the X-ray Source.

# **Explanation of Symbols**

Schick Technologies' products display a number of markings which indicate compliance with regulatory requirements or which provide information in accordance with applicable technical standards.

The symbols and their descriptions are provided below.

Symbol	Description
	Indicates Class II equipment in accordance with applicable medical device safety standards (IEC/EN/UL 60601-1)
<b>†</b>	Indicates Type BF equipment in accordance with applicable medical device safety standards (IEC/EN/UL 60601-1)
	Indicates an attention to users to consult accompanying documents (this User Guide) for more information
CE	Conforms to European Union Medical Devices Directive (MDD) 93/42/EEC
C Rent American	Indicates that this product meets North American safety standards. The TUV mark is a Nationally Recognized Testing Lab (NRTL) marking and indicates conformance with UL 60601-1 and CAN/CSA STD C22.2 NO 601.1-M90
X	Indicates that in the European Union, at the end of product life this device must be disposed of in accordance with the requirements of the Waste Electrical and Electronic Equipment (WEEE) directive 2002/96/EC

### Label Location

The Schick logo and the following label can be found on the CDR Elite Interface Module.



# Waste Electrical and Electronic Equipment

### Background

The European Union's Waste Electrical and Electronic Equipment (WEEE) Directive (2002/96/EC) has been implemented in member states as of August 13, 2005. This directive, which seeks to reduce the waste of electrical and electronic equipment through re-use, recycling, and recovery, imposes several requirements on producers. Schick Technologies and its Dealers are committed to complying with the Directive.

### WEEE Marking

All Schick products subject to the WEEE Directive and shipped after August 13, 2005 will be compliant with the WEEE marking requirements. These products will be identified with the "crossed-out wheeled bin" WEEE symbol shown below, as defined in European Standard EN 50419, and in accordance with WEEE Directive 2002/96/EC.



This "crossed-out wheeled bin" symbol on the product or its packaging indicates that this product must not be disposed of with other unsorted municipal waste. Instead, it is the user's responsibility to dispose of Electrical and Electronic Equipment (EEE) by handing it over to a designated collection point for the reuse or recycling of waste electrical and electronic equipment. The separate collection and reuse or recycling of Electrical and Electronic waste equipment will help to conserve natural resources and ensure that it is recycled in a manner that protects the environment and human health. For more information about where you can drop off your waste equipment for recycling, please contact your local officials.

### Reporting

According to the WEEE Directive, Schick Technologies or its Dealers will ensure that information needed to calculate the financial obligations with respect to EEE products will be provided as required.

### WEEE from Users other than Private Households

According to the WEEE Directive, Schick Technologies or its Dealers will fulfill its obligations for the management of WEEE from users other than private households.

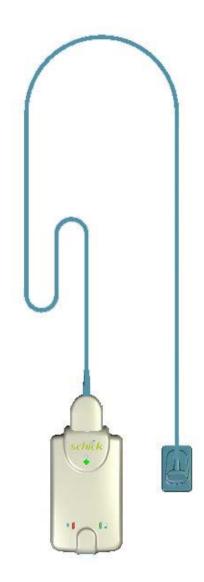
Furthermore, as required by the WEEE Directive, in order to determine unequivocally when the equipment was put on the market, the maufacturer's date is placed on the equipment.

### Information for Reuse Centers, Treatment and Recycling Facilities

As required by the WEEE Directive, Schick Technologies or its Dealers will provide reuse, treatment, and recycling information for each type of new EEE put on the market within one year of the date in which the equipment is put on the market.

Information will include the different EEE components and materials as well as the location of substances in these items. The information will be provided as a printed document or in electronic media (on CD-ROM or by web download, for example)

# CDR Elite Sensor and USB Interface Module



CDR Elite Sensor with CDR Elite USB Interface Module

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# 1. Overview

### 1.1. Purpose

The CDR Elite Sensor and CDR Elite USB Interface Module represent the latest advances in our intraoral sensor technology and provides the following advantages:

- Improved image resolution based on smaller pixel size
- Sensor calibration disks no longer required
- Greater resistance to kinking for improved cable flexibility
- Improved resistance to interference from other electronic devices
- Serviceable Sensor cable is standard with all CDR Elite Sensors
- New options for image enhancement.

### 1.2. Indications for Use

The CDR Elite Sensor is to be used as part of an intraoral image acquisition system and is indicated for individuals requiring intraoral dental examinations.

### **1.3.** System Description

The CDR Elite Sensor is connected to the CDR Elite Interface Module, which is connected via a USB A-B cable (supplied separately) to a compatible PC workstation. The workstation runs a compatible Windows operating system and also provides the power source for the device. Additional details on the PC workstation may be found in Section 1.5. Additional details on the USB cable may be found in Section 2.1.

Support for the CDR Elite Sensor is provided by compatible software programs such as CDR DICOM for Windows, EagleSoft, and Patterson Imaging. Section 1.5 lists the software versions compatible with the CDR Elite system.

The CDR Elite Sensor includes a detachable holder so the device can be mounted either by screws to a wall or to another stable surface. Details on installing the CDR Elite USB Interface Module holder may be found in Section 2.2.

### 1.4. Replaceable Cable

The CDR Elite Sensor Imaging System is designed to meet the practical, timely needs of dental professionals. For this reason, CDR Elite Sensor sizes 1 and 2 support a replaceable-cable design that enables customers to make immediate, in-office replacements of failed cables. Manufactured for safe and reliable operation, the replaceable cable provides appropriate strain relief, molded protection from electronic contacts and components, and easy installation. Details on replacing CDR Elite cables may be found in Section 2.3.

### 1.5. PC Workstation Description

The PC workstation connects to the CDR Elite USB Interface Module via USB cable (supplied seperately) and serves as the host for CDR DICOM or other compatible imaging software products. The workstation provides the capability to display, manipulate, store, and print images acquired from CDR Elite Sensors.

Getting the best results from your CDR system begins with having a computer system suitable for capturing and displaying intraoral images. *For optimum performance*, we recommend the following:

- 1. Compatible operating systems
  - Windows XP Pro and XP Pro x64 Edition, Windows Vista and Vista x64 Edition
- 2. Compatible imaging applications
  - CDR DICOM for Windows 3.5 SR1 and higher, EagleSoft 14.0 and higher, and Patterson Imaging 14.0 and higher.
- 3. Pentium D processor or Intel Core2Duo processor
- 4. 2 GB RAM
- 5. 250 GB hard drive Raid Level 1 (practice-specific, depends on number of patients)
- 6. Intel USB chipset with at least 2 powered USB 2.0 ports (USB 1.1 also supported)

### **1.6. Relationship with Current CDR Sensors**

If your current workstation supports CDR Sensors, it will also support CDR Elite Sensors. If both CDR and CDR Elite Sensors are connected to the same workstation, they are detected automatically (by CDR AutoDetect, as described in Section 3.7), and you can work with either Sensor type.

The CDR Elite USB Interface Module that connects the CDR Elite Sensor to the workstation via USB 2.0 cable is unique to the CDR Elite Sensor type, however. This means that you will not be able to swap CDR Remote Modules with CDR Elite Interface Modules. To avoid any possible mismatch, the CDR Elite Module Interface enclosure is specifically designed for the CDR Elite Sensor and will not accommodate any other Sensor type for which it was not intended.

### 2.1. Connecting Cables to the CDR Elite USB Interface Module

**IMPORTANT!** Do not connect the CDR Elite USB Interface Module and cable to your computer until after you have successfully run the setup program. Procedures for installing these files are supplied in Section 3, "Software."

The USB cable used with the device has a Series "A" USB plug on one side and a Series "B" USB plug on the other. The "A-type" plug connects to any available USB port on the computer. The "B-type" plug connects to the CDR Elite Interface Module.

USB Cable Connectors	Schick Part Number	Cable Length
"B-type" USB Connector (Connects to Synergy Interface Device)	B2250150	5 meter (16.5 feet)
	B2250151	2 meter (6.5 feet)
"A-type" USB Connector (Connects to Computer)	B2250152	0.5 meter (1.6 feet)

An illustration of the CDR Elite Sensor and CDR Elite USB Interface Module are shown in Figure 1. For a description of cable connections to the device, refer to Table 2.

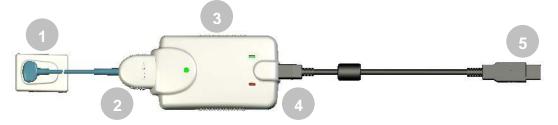


Figure 1. CDR Elite USB Interface Module Cable Connections

Table 2. Description of CDR Elite USB Interface Module Cable Connections

Number	Description
1	CDR Elite Sensor
2	CDR Elite Sensor cable connection
3	CDR Elite Interface Module
4	USB cable connection ("B" connector end of USB cable connects here)
5	USB cable connection ("A" connector end of USB cable connects to PC)

### 2.2. Installing the CDR Elite USB Interface Module Holder

The CDR Elite USB Interface Module holder is designed for several mounting options: (1) Wall-mounted with fastening hardware, or (2) Attached to a wall or other acceptable bonding surface with Velcro adhesive. When installing your CDR Elite USB Interface Module choose a location that offers easy access and visibility during patient exams.



Figure 2. CDR Elite USB Interface Module Holder

### 2.2.1. Wall-Mounting Option (with Fasteners)

**IMPORTANT!** When choosing a location for the holder, make sure there are no electrical wires or connections that could be contacted accidentally when drilling.

Install the holder by fastening it to a wall or other flat surface, as follows:

- 1. Remove the CDR Elite USB Interface Module from its holder.
- 2. Position the holder on a smooth stable flat surface. Using the holes on the back of the holder as guides, fasten the holder securely to the wall using 2 (#4) dry wall screws (supplied) or other hardware appropriate to the mounting surface.

### 2.2.2. Wall-Mounting Option (with Adhesive)

Install the CDR Elite USB Interface Module by attaching it with Velcro adhesive to a wall or other flat surface, as follows:

- 1. Remove the CDR Elite USB Interface Module from its holder.
- 2. Cut and trim a piece of Velcro adhesive (not supplied) to the size of the back of the Remote. Remove one half of the tape and attach it to the CDR Elite Interface Module.
- 3. Locate an accessible, stable, and flat surface for the module. Apply the other half of the Velcro adhesive in that location and attach the module securely.

### 2.3. Cable Replacement

**IMPORTANT!** Always disconnect the Sensor from the CDR Elite USB interface during cable replacement to avoid potential damage to Sensor components. Close CDR DICOM or any other imaging application (EagleSoft or Patterson Imaging) prior to starting cable replacement. When performing cable replacement, always work outside the patient area, using the tools and materials supplied and / or recommended by Schick Technologies.

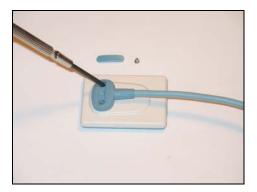
**IMPORTANT!** Like other electronic devices, your CDR Elite Sensor is susceptible to electrostatic discharge (ESD), particularly when the device is used in or around carpeted areas or low-humidity environments. During cable replacement, when Sensor contacts are exposed, it is especially important to protect the device from potential ESD damage. Touching a metal surface prior to replacing the CDR Elite cable will reduce the risk of damaging Sensor components by accidental static discharge. The use of anti-static floor mats or floor treatments (for example Staticide 2005/2002) will also help eliminate static build-up in your office.

### Step 1

- A. Please clean and dry your hands before performing this procedure. Do not wear gloves since the powder inside them could be deposited on sensor contacts while replacing the cable.
- B. Make sure the Sensor is placed securely on a clean, moisture-free surface.
- C. Using an appropriate dental instrument, such as a scaler, *carefully* lift and remove the tab cover from the back of the Sensor cable. Dispose of the tab cover as a new one will be used when the new cable is attached.



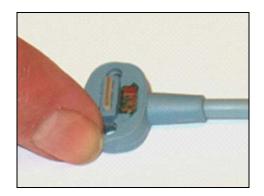
- A. Using the screwdriver provided, loosen and remove the 2 screws that secure the cable to the Sensor. Dispose of the screws as new ones are supplied.
- B. Remove the cable from the Sensor.

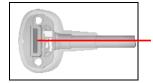


### Step 3

- A. Remove the new cable from the replacement kit.
- B. Verify that the small elastomeric strip is in its slot in the cable. Ensure proper seating by applying a small amount of finger pressure across the strip. Skip ahead to step 4.
- C. *If the elastomeric is missing*, take a spare elastomeric (supplied) and insert it into the cable slot. Apply a small amount of finger pressure evenly across the strip and continue with the next step.

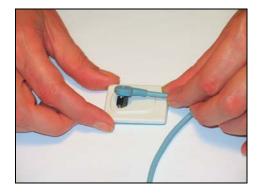
**IMPORTANT!** The elastomeric must be seated properly in its slot for the Sensor to function.





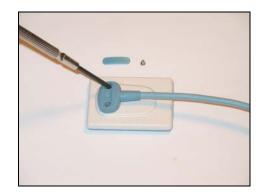
Elastomeric shown in place

- A. Align the new cable to Sensor as shown, making sure that the Sensor keying feature connects to the corresponding key in the cable assembly.
- B. When properly aligned, the cable fits the back of the Sensor evenly and the metal area on the sensor should be completely covered by the cable.

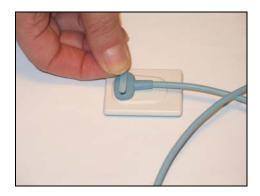


### Step 5

- A. Holding the cable to the Sensor, insert one of the screws into its hole.
- B. Using the small screwdriver, loosely tighten one of the screws. Do the same with the other screw.
- C. When secured, fully tighten both screws.



- A. Place the new tab cover over the screw slot and press evenly. You should hear a soft click when the cover closes. Also verify that the tab cover fits evenly in its slot.
- B. Cable replacement is complete.



## 3. Software

### 3.1. What You Will Need to Complete this Section

To expedite software installation, please have the following items available:

- CDR Elite Interface Driver CD
- CDR Elite USB Interface Module
- USB 2.0 A-B Cable (supplied separately)

### 3.2. Before You Start Installing Software

**IMPORTANT!** Please do not connect the CDR Elite USB Interface Module and USB cable to your computer until after you have installed the device driver. Procedures for installing these files can be found on the following pages.

The software component to accompany the your CDR Elite USB Interface Module installation consists of the CDR Elite USB Interface Module driver. You must install this driver successfully to ensure proper operation of your CDR Elite Interface Module.

Installation differs slightly between Windows XP and Windows Vista operating systems, so you should follow the procedures that refer to your particular system. (Procedures can be found on subsequent pages.) If you're not sure which operating system is installed on your computer, right click on the My Computer icon on your desktop and select Properties (pressing the Windows Start (IP) and Break keys will also display System Properties).

### 3.3. Setup with Windows Vista

### Step 1

- A. Insert the CDR Elite USB Remote Driver CD.
- B. Click **Run setup.exe** when prompted at the Autoplay message window.
- C. Click "Allow" when the message, "An unidentified program wants access to your computer" is displayed.

🥔 AutoPlay	
DVD Drive (E:) 070	0514_1134
Always do this for software	and games:
Install or run program	
Run setup.exe Publisher not specified	
General options	
Open folder to view files using Windows Explorer	
Set AutoPlay defaults in Contro	ol Panel

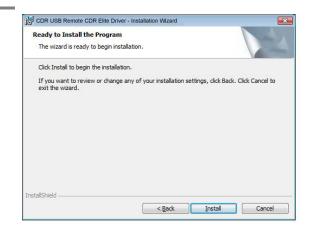
### Step 2

Click Next to begin the setup process.



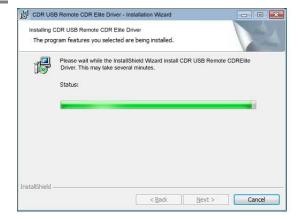
### STEP 3

### Click Install.



### Step 4

Setup will copy the drivers to your workstation.



- A. Click Finish.
- B. Connect the CDR Elite USB Interface Module to your computer. When you do, you will receive a momentary message saying that new hardware has been installed and is ready for use.
- C. Remove the CDR Elite USB Remote Driver CD.



### 3.4. Setup with Windows XP

### Step 1

- A. Insert the CDR Elite USB Remote Driver CD. Setup should start automatically. If it doesn't, click Start, Run, and then enter d:\ setup.exe at the command line (if your CD drive is a letter other than "d", use that letter instead).
- B. Click **Next** to begin the setup process.

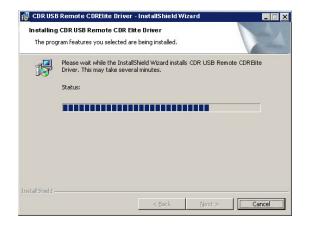
CDR USB Remote CDREIit	e Driver - InstallShield Wizard	×
	Welcome to the InstallShield Wizard for CDR USB Remote CDRElite Driver	
	The InstallShield(R) Wizard will install CDR USB Remote Synergy Driver on your computer. To continue, click Next.	
Z	WARNING: This program is protected by copyright law and international treaties.	
	< Back [ Cancel	

### Step 2

# Click Install.

### Step 3

Setup will copy the drivers to your workstation.



- A. Click Finish.
- B. Connect the CDR Elite USB Interface Module to your computer. When you do, you will receive a momentary message saying that new hardware has been installed and is ready for use.
- C. Remove the CDR Elite USB Remote Driver CD.



### 3.5. Sensor Calibration File Installation

Calibration data for CDR Elite Sensors is programmed directly into the Sensor so a separate calibration disk CD is no longer needed.

To install the calibration file, perform the following steps.

- 1. Verify that all CDR Elite system cables are connected securely.
- 2. Start CDR DICOM for Windows. CDR DICOM will automatically detect the Sensor and determine whether a calibration file has been installed for this Sensor previously. If the calibration file was not installed already, it will be copied from the Sensor itself.
- 3. A message will be displayed momentarily, "Reading sensor calibration file . . . please wait." Installation is completed in approximately 10 seconds.

### 3.6. Image Enhancement

New options are available to enhance the appearance of X-ray images before they are displayed on your monitor. There are 3 options — Edge High, Edge Low, and Smooth — and the names themselves describe the enhancements they perform. For sample X-rays that illustrate the effects of these enhancements, please refer to Figure 3 and Figure 4. Using these options is discretionary, so you can try each of them and select the one that works best for you. Alternatively, you can choose to turn off these enhancements, if you prefer.

Please note that the image enhancements, when applied, cannot be undone or changed, nor will they affect images you have acquired already.

### 3.6.1. Enabling Image Enhancement

Image Enhancement is enabled by default with the Edge High option selected. If, however, it has been disabled and you wish to re-enable it, open the X-ray acquisition options page (in CDR DICOM, browse to the System menu, select X-ray Settings, click on the Sensor tab, and mark the Apply image Enhancement checkbox). The other enhancements, Smooth and Edge Low, are available from the drop-down menu. After selecting the option you want, click Apply, and click OK to close the X-ray acquisition options page.

### 3.6.2. Disabling Image Enhancement

Image Enhancement can be disabled at any time by clicking the "Apply Image Enhancement" checkbox again, which removes the checkmark. When the checkbox is cleared, all of the enhancements are unavailable.

Xray Ca	alibration	Sensor					
Sensor	Serial #:		SOFT	WAR-1234	45678		
Sensor	Size:		Size 2				
Calibrati	ion File D	ate:	7/14/2	2008			
Rea	heck						
Пес							
	-	Enhancer	ient				
Level:	Edge H	A5010	<u>~</u>				
	Edge L	ow					
	Ballacabella						

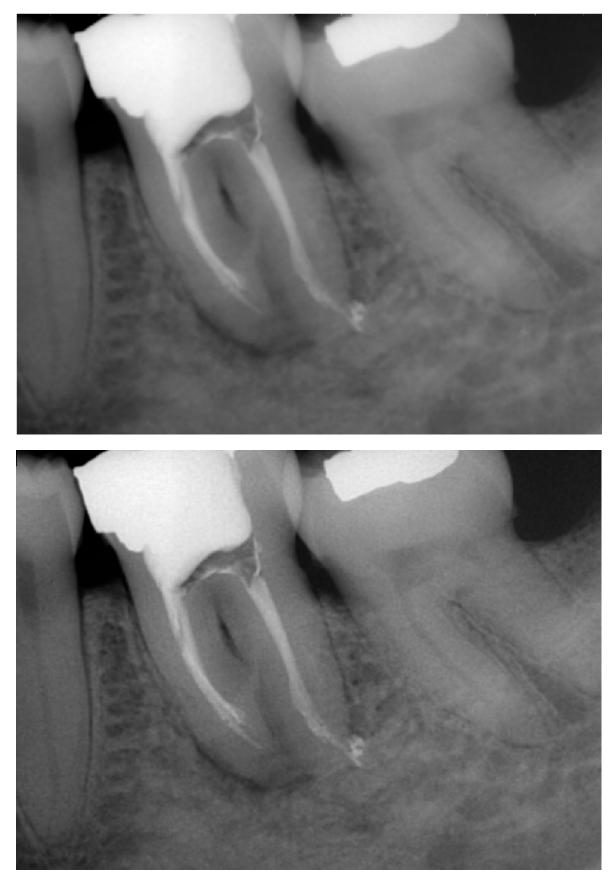


Figure 3. Enhancements: Smooth (top) and Edge High (bottom)

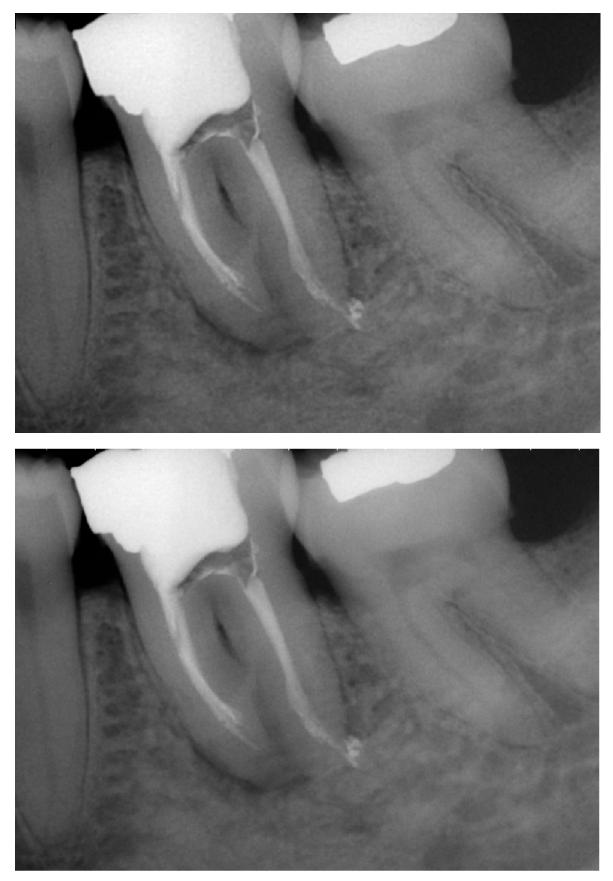


Figure 4. Enhancements: Edge Low (top) and None Applied (bottom)

### 3.7. CDR AutoDetect

The CDR AutoDetect feature instantly recognizes when a different Schick USB device is connected — including standard, high-speed (HS), and CDR Elite modules, and Wireless / SDX interfaces — skipping the step of manually selecting a new Schick USB device before using it.

CDR AutoDetect will be most useful for offices that employ a mix of Schick USB modules and Sensors and use them interchangeably within one or several operatories.

### 3.7.1. Enabling CDR AutoDetect

CDR AutoDetect is enabled by default. If, however, it has been disabled and you wish to re-enable it, open the X-ray acquisition options page (in CDR DICOM, browse to the System menu and select X-ray Settings). If unchecked, click on the CDR AutoDetect to mark the checkbox and enable this option. You might also notice that the Hardware Type drop-down box becomes unavailable, as detection of Schick USB devices and Sensors will now be performed automatically.

### **3.7.2. Disabling CDR AutoDetect**

CDR AutoDetect can be disabled at any time by clicking the checkbox again, which removes the checkmark. By disabling CDR AutoDetect you will need to return to this property page when switching different hardware types on the same workstation and manually select the new device from the drop-down menu.

Exposure Timeout (s):       Image         Integrate Phoenix (sec/10):       7         Strength:       Light         Integrate Time (sec/10):       7         Reset Duration (uSec):       410         Trigger Thresh:       15         Apply Spot Remover         Trigger Count:       40         I/O Port:       0x300         Acquire 12 bit image         Initial Rampup (Sec):       6         Mapping:         Nonlinear (Traditional)	Integrate Phoenix (sec/10): 7 Strength: Light
---	---

### 3.7.3. How CDR USB Devices are Detected

CDR AutoDetect requires that both the USB device <u>and</u> the Sensor be connected to each other for the system to recognize them. If the USB module is connected, but not the Sensor, they will be unrecognized by CDR AutoDetect. Once the USB device and Sensor are connected, we say that they are "known" by the AutoDetect feature, which informs the imaging program to begin using that device.

Only the Wireless / SDX system behaves differently, meaning that connecting just the USB device is sufficient for CDR AutoDetect to recognize it.

### 3.7.4. Changing CDR USB Devices

When a known USB device is plugged into the system, a notification window appears momentarily, indicating that the device was just detected and has become active.



It is also possible to interact with the CDR AutoDetect feature by clicking on the notification window when it appears or by double-clicking on the CDR AutoDetect icon that is present in the Windows system tray when CDR AutoDetect is enabled. Performing this action will display a pop-up dialog that lists all the "known" USB devices currently connected to the system.

Device Na	me		
	Remote HS	_	
CDR Elite			

When the imaging software is loaded initially, or when CDR AutoDetect is initially turned on, the system will populate the dialog with all known currently connected devices. If several devices are listed, the one that is highlighted signifies the currently active device. To select a different device using the monitor, select the device (highlighting it), and then click the Select Device button.

### 3.8. Using the CDR Elite Utility

### 3.8.1. Introduction

The CDR Elite Utility is installed during the CDR Elite Driver setup program. This tool can be used to accomplish the following:

- Perform USB Interface tests
- Perform Sensor Pattern tests
- Perform USB Interface firmware upgrades
- Perform Sensor Module firmware upgrades

A sample screen of the CDR Elite Utility is shown below. (*Please note that the version numbers shown in the picture below are examples only and may differ from those reported for your system.*)

CDR E	ite Utility			
File Tools	Help			
		s To Upgrade		
	ODB INTERFACE			
	6.	Firmware Version	1.43	
		FPGA Version	1.6	
	SENSOR MODULE			
	S/N# synergy-21000085			
	S.	Firmware Version	1.68	
		Close		

### 3.8.2. USB Interface Test

The CDR Elite USB Interface Test checks the connection between the CDR Elite USB Interface and the host computer. During this check, a test pattern appears with alternating sections of black and white rows. A counter located below the image window updates as the pattern is generated.

A count of at least 10 test pattern images is usually sufficient to determine if there are USB problems that would cause poor test patterns to be generated. The absence of any test pattern (blank image window), or the appearance of distorted lines, indicates a problem between the CDR Elite Interface and the host computer to which it is connected.

There may be one or more reasons for poor test patterns, which can be the result of a problem with the CDR Elite device or its USB connector, or the USB cable and / or port, or corrupt firmware inside the CDR Elite device. Additional troubleshooting can be performed if another CDRPanElite USB device is available. In this case, connecting a different CDR Elite device to the USB cable and repeating the USB Interface Test may help to identify the possible cause of the problem

### **USB Interface Test**

Perform the following steps to start the USB Interface diagnostic test.

Step	Action			
1	Close the CDR DICOM or EagleSoft program (if running)			
2	Verify that CDR Elite USB Interface is connected to the host			
2	computer			
3	Start the CDR Elite Utility (Start > All Programs > CDR			
U	DICOM for Windows > CDR Elite Utility).			
4	Click Tools > USB Interface Test.			
	After a momentary pause, a test pattern is displayed. The orange on the CDR Elite USB Interface blinks as the test pattern scrolls.			
	1			
5	Click Close to exit this test.			
6	Click Close to exit the CDR Elite Utility.			

### 3.8.3. Sensor Pattern Test

The CDR Elite Sensor Pattern Test checks the connection between the CDR Elite USB Interface and the Sensor. During this check, a gradient test pattern appears with repeating sections. A counter located below the image window updates as the pattern is generated.

A count of at least 10 test pattern images is usually sufficient to determine if there are USB problems that would cause poor test patterns to be generated. The absence of any test pattern, or (blank image window) or the appearance of distorted lines indicates a problem between the CDR Elite Interface and the Sensor to which it is connected.

There may be one or more reasons for poor test patterns, which can be the result of a problem with the CDR Elite device or its Sensor connector, or the Sensor cable, or corrupt firmware inside the CDR Elite device. Additional troubleshooting can be performed if another CDRPanElite Sensor is available. In this case, connecting a different CDR Elite Sensor to the CDR Elite USB Interface and repeating the Sensor Pattern Test may help to identify the possible cause of the problem.

Sensor Pattern Test

Perform the following steps to start the Sensor Pattern diagnostic test.

Step	Action			
1	Close the CDR DICOM or EagleSoft program (if running)			
2	Verify that CDR Elite USB Interface is connected to the host			
	computer			
3	Verify that the Sensor is attached to the USB Interface.			
4	Start the CDR Elite Utility (Start > All Programs > CDR			
	DICOM for Windows > CDR Elite Utility).			
5	Click Tools > Sensor Pattern Test.			
	Sensor Pattern Test			
6	Click Close to exit this test.			
7	Click Close to exit the CDR Elite Utility.			

### 3.8.4. USB Interface Firmware Upgrades

Field updates to the CDR Elite USB Interface can be accomplished by installing new firmware. When new firmware is available, it is typically provided with software release and becomes part of the update to your existing system. In the event you are prompted to upgrade CDR Elite USB firmware, perform the steps provided below.

### USB Interface Firmware Upgrade

Perform the following steps to start the USB Interface firmware upgrade.

Step Action IMPORTANT! Close the CDR DICOM or EagleSoft program 1 (if running) Verify that CDR Elite USB Interface is connected to the host 2 computer Start the CDR Elite Utility (Start > All Programs > CDR 3 DICOM for Windows > CDR Elite Utility). 4 If the firmware version number is listed in red, click the Firmware Version button to upgrade. The firmware version number will change to green letters when the upgrade is completed successfully. 5 If the FPGA version number is listed in red, click the FPGA Version button to upgrade. The firmware version number will change to green letters when the upgrade is completed successfully.

Pictured below is an example of the CDR Elite Utility, with the firmware upgrade buttons for the USB Interface highlighted.

	CDR Elite Utility
	Click Buttons To Upgrade
	USB INTERFACE
	Frmware Version 1.43 FPGA Version 1.6
	SENSOR MODULE S/N# SVNERCV-22000214 Firmware Version 1.68
	Close
6	Verify that the USB Interface firmware and FPGA version
	numbers are listed in green. If not, please contact your
	distributor of Schick Technologies products for additional
	information.
7	Click Close to exit the CDR Elite Utility.

### 3.8.5. Sensor Module Firmware Upgrade

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Field updates to the CDR Elite Sensor can be accomplished by installing new firmware. When new firmware is available, it is typically provided with software release and becomes part of the update to your existing system. In the event you are prompted to upgrade CDR Elite Sensor firmware, perform the steps provided below.

**Sensor Firmware Upgrade** Perform the following steps to start the Sensor firmware upgrade.

Step	Action				
1	IMPORTANT! Close the CDR DICOM or EagleSoft program				
	(if running)				
2	Verify that the CDR Elite Sensor is connected to the USB				
	Interface host computer				
3	Start the CDR Elite Utility . (Start > All Programs > CDR				
	DICOM for Windows > CDR Elite Utility).				
4	If the firmware version number is listed in red, click the				
	Firmware Version button to upgrade. The firmware version				
	number will change to green letters when the upgrade is completed successfully.				
	ed below is an example of the CDR Elite Utility, with the Sensor le button highlighted.				
	S CDR Elite Utility				
	Elle Iools Help				
	Click Buttons To Upgrade				
	USB INTERFACE				
	Firmware Version 1.43				
	FPGA Version 1.6				
	SENSOR MODULE				
	S/N# SWIERGY-22000214 Firmware Version 1.68				
	Close				
	1				
5	Verify that the Sensor Module firmware version number is listed				
	in green. If not, please contact your distributor of Schick				
	Technologies products for additional information.				
6	Click Close to exit the CDR Elite Utility.				

# **4. LED Indicators**

### 4.1. CDR Elite USB Interface Module Indications

The CDR Elite USB Interface Module has three LED indicators: amber, green (USB cable side), and green (Sensor cable side) for reporting its functional status. The location and description of the LEDs is shown in Figure 5 and described in Table 3.



Figure 5. CDR Elite USB Interface Module LED and Connector Views

Sensor	CDR DICOM	Green	Amber LED	Green 于	Status
Connected	Running	ON	Blinking every <sup>1</sup> / <sub>2</sub> - 1 <sup>1</sup> / <sub>2</sub> seconds	ON	Ready for image acquisition
Connected	Running	ON	OFF	ON	Image acquisition
Connected	Not Running	OFF	OFF	ON	Start CDR DICOM to prepare for image acquisition
Connected	Not Running	OFF	ON	OFF	Cable short or over- current condition. Replace Sensor cable.
					Replace Sensor if problem persists.
Connected	Running or	OFF	ON	Blinking	Low current condition. Replace Sensor cable.
	not running				Replace Sensor if problem persists.
Connected	Running or	OFF	ON	OFF	Over current condition. Replace Sensor cable.
	not running				Replace Sensor if problem persists.
Not connected	Not running	OFF	ON	OFF	Connect Sensor and start CDR DICOM

Table 3. CDR Elite USB Interface Module LED Indications

NOTE: CDR Elite USB Interface Module is considered connected for the cases described in the above table.

# 5. Operation

### 5.1. Operating the System

#### 5.1.1. Power On

- 1. Turn on the PC workstation used with imaging applications.
- 2. Connect the "B-type" end of the USB cable to the CDR Elite Interface Module.
- 3. Connect the "A-type" end of the USB cable to the PC workstation.
- 4. Connect the CDR Elite Sensor edge-card to the CDR Elite Interface Module.
- 5. The amber LED on the USB side of CDR Elite USB Interface Module blinks momentarily if CDR is running. The green LED on the same side will also be illuminated.
- 6. The green LED on the Sensor side of the CDR Elite USB Interface Module illuminates also and remains steady on, indicating proper current condition for the Sensor.
- 7. Continue with Section 5.2 for step-by-step instructions on acquiring X-ray images with CDR DICOM software.

### 5.1.2. Power Off

- 1. Disconnect the USB cable from either the CDR Elite USB Interface Module or the PC workstation.
- 2. Power is removed from the CDR Elite USB Interface Module and Sensor, and the green LED on the Sensor side of the CDR Elite USB Interface Module is turned off.

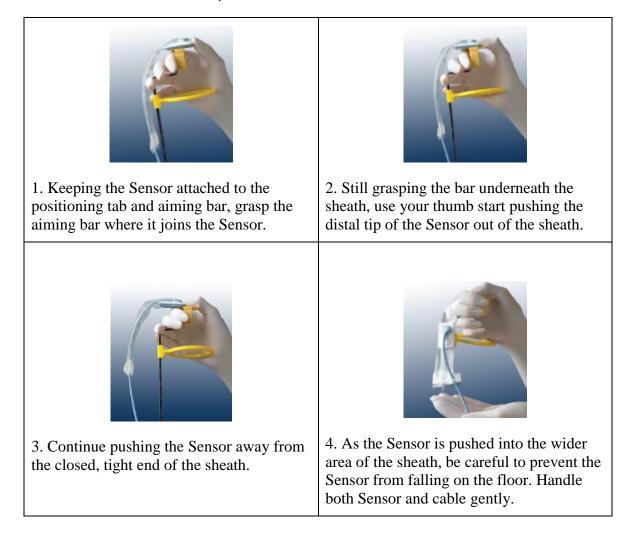
# 5.2. Using Your CDR Elite Sensor

### 5.2.1. Sensor Sheaths and Holders

Sheaths and the appropriate holders are required for CDR Elite Sensors. New sheaths and Sensor holders (if they are the disposable type) are required for each new patient and must be disposed of properly after patient use.

Before using a new sheath, select one that is appropriate for the size of the Sensor. You may find that the sheath seems slightly undersized, which is necessory to provide a secure barrier around the Sensor. Once you have selected the sheath, slide the Sensor into it.

Using an appropriate Sensor positioning system, adjusting the X-ray setting depending on intraoral position, and placing the X-ray source as close as possible to the imaging area of the Sensor: all of these contribute towards obtaining quality digital X-ray images. For proper placement and usage of CDR Sensor holders, please refer to the CDR Positioning System User Guide, distributed with Sensor Holder kits and also available on our website.



#### Table 4. Proper Sensor Removal from Protective Sheath

### 5.2.2. Sensor Cleaning and Disinfecting

Before using the CDR Elite Sensor the first time, and before every new patient, please perform the protocol described in Section 6.2.

### 5.2.3. Sensor Positioning

To achieve stable Sensor positioning during X-ray exams, use the appropriate tabs and holders available with the CDR system. When positioning the Sensor, the inverse pixel box located on the CDR Elite Sensor can be used to determine the orientation of the resulting image.

Sensor Location	Sensor Orientation	Inverse Pixels (Circled) and Image Orientation
Patient's left side	School Straight	Left Bitewing
Patient's upper jaw	CDREE schick	Anterior Periapical, Maxillary

Table 5. Examples of CDR Elite Sensor-to-Image Orientation

# 5.2.4. Taking X-rays

	COM User Guide, Schick P/N 1051047, for detailed operation of CDR DICOM software.
STEP 1	
	Start CDR DICOM from the Windows <b>Start</b> button or by clicking the shortcut to CDR DICOM for Windows on your desktop.
Step 2	_
	When the CDR exam window appears, click on <b>New Exam</b> under the <b>File</b> menu or just click the <b>New Exam</b> button on the toolbar.
STEP 3	
	<ul> <li>A. Enter the appropriate patient information and then click on X-ray Series. You may use a pre-defined intraoral series or create a new one.</li> </ul>
	<ul> <li>B. To customize an X-ray series for the current exam, click</li> <li>Edit Series, which opens the Edit Viewset dialog box. (Re-usable, customized series can be created at the Series &gt; New Intraoral Series menu.)</li> </ul>
	C. The numbers in the text boxes correspond to how many target frames (view boxes) are included in this series. You can edit the numbers, creating a series customized with the views you wish to include.
	D. Enter a name for this X-ray series. Click OK.
Step 4	_
	A. Slide an appropriately-sized sheath over the Sensor. Select a CDR holder specific to the intraoral area intended for exposure and place it on the sheath. Attach a positioning arm and aiming ring, as needed
	B. Verify the X-ray exposure settings. Proper technique factors depend on several variables, among them, the type of X-ray tube, the anatomy of the patient, the source-to-Sensor distance, and the location of the Sensor in the oral cavity. <i>As a guideline, CDR Sensors require 85% less dosage than D-speed film.</i>

	-
	IMPORTANT! To avoid exposing the patient to unnecessary X-rays, ensure that the CDR exam window viewbox is flashing green (default color) in AutoTake mode, or that the message, "Waiting to take X-ray," is displayed before triggering the X-ray Source.
	A. If your acquisition mode is set to AutoTake, the first empty view box in the exam is pre-selected and flashes green (default setting). Skip ahead to step 7.
	B. If your acquisition mode is set to manual, select an empty target frame that corresponds to the Sensor's location in the patient's mouth. When the view box is highlighted, click on it again. If using a serial footpedal, press the amber pedal.
Step 6	
	The system is ready to acquire an X-ray image. A "Please Wait" message may appear momentarily.
Step 7	
	<ul> <li>A. In AutoTake mode, activate the X-ray source. The message, "Reading Image from Sensor" appears momentarily.</li> </ul>
	B. In manual mode, activate the X-ray source when the message, "Waiting to take X-ray" appears.
	C. The acquired image appears automatically in the zoom or exam window, depending on system settings.
STEP 8	_
	A. In AutoTake mode, the next empty view box in the series sequence is selected. To acquire the next X-ray image, repeat this procedure starting at Step 7.
	B. In manual mode, close the exam window. To acquire the

# 5.3. Acquiring X-ray Images with the Footpedal

Serial footpedals (Schick P/N B2501100; PDCO P/N 07-0410100) can be used to navigate view boxes inside a patient exam and to control the capture of X-ray images. Refer to the following table for information.

Desired Action	Use Pedal
Select a view box	Green
Take an X-ray (manual mode)	Amber

### 5.4. Acquiring X-ray Images with Keyboard Shortcuts

Intraoral image acquisition can be also accomplished though the use of shortcut keys. Refer to the following table for information.

Desired Action	Use Keys
Select a view box	[Spacebar] or [Page up] or [Page down]
Take an X-ray (manual mode)	[Insert] or [Enter]

# 6. Protective Measures

### 6.1. Introduction

**IMPORTANT!** Be sure to disconnect the CDR Elite USB Interface Module from the Sensor and the USB cable before performing any cleaning procedures.

The CDR Elite Sensor should be thoroughly cleaned after each use. The following cleaning and disinfection recommendations are intended to accomplish intermediate-level disinfection and will prepare the product to be safely used and reused during its life.

The CDR Elite USB Interface Module is not intended to be moved or to come in contact with a patient during clinical use. If the USB Interface Module becomes soiled or comes into contact with a patient, it should be cleaned following the same protocol as the CDR Elite Sensor.

Sensor positioning accessories, such as aiming rings, arms, and holders, should be cleaned and disinfected following manufacturer's instructions. If you are using the Rinn holder system, refer to their product documentation or their website for more information.

Schick's disposable tabs and holders are single-use only, as are the hygenic barriers (sheaths) that are used with them.

### 6.2. Cleaning and Disinfecting

In a clinical use environment, the health care provider should wear protective disposable gloves and cover the CDR Elite Sensor with a hygienic barrier. Before using the CDR Elite Sensor the first time, and before every new patient, the following protocol is recommended:

- 1. Remove and discard all protective hygienic barriers and / or sheaths from the Sensor prior to removing disposable gloves.
- 2. Place the Sensor on a tray covered by a disposable liner, or in a receptacle that can be thoroughly disinfected.
- 3. Remove and discard gloves.
- 4. Wash hands and put on a new pair of disposable gloves.
- 5. Disconnect the Sensor from the CDR Elite Interface Module.
- 6. If the Sensor or cable are visibly soiled (e.g., with blood or saliva), each should be cleaned with a soapy cloth or paper towel, and then dried with a clean lint-free cloth or paper towel.
- 7. Thoroughly spray or wipe the Sensor and cable with one of the disinfecting products recommended in Section 6.3. Do not expose the Sensor cable connectors to any amount of liquid.

- 8. If using a spray disinfectant, allow it to remain on the Sensor for 5 minutes. If using a liquid disinfectant, allow it to remain on the Sensor for 30 seconds.
- 9. <u>Repeat</u> steps 7 and 8. When the Sensor has been sprayed or wiped two times, continue with the following steps.
- 10. Remove potential chemical build-up from the Sensor by wiping it with a lap sponge saturated with de-ionized water.
- 11. Use a dry lap sponge to dry the Sensor or cable, as needed.
- 12. Place the Sensor in a clean environment, ready for next use.
- 13. Reconnect the Sensor.
- 14. Remove and discard gloves.

# 6.3. Recommended Disinfectants

The following surface disinfectant has been found to be effective in achieving a desired level of disinfection and is available from Patterson Dental and other suppliers.

• Cavi-Wipes (Metrex Research, Kerr) or equivalent

# 7. Maintenance

## 7.1. Visual Inspection

Like all electrical equipment, the CDR Elite Sensor and USB Interface Module require not only correct use, but also visual inspection prior to operation, and routine checks at regular intervals. These precautions will help ensure that the CDR Elite Sensor and USB Interface Module operate accurately, safely, and efficiently.

Before operating the system, users shall check it for any signs of physical damage or defect. If detected, contact your local distributor of Schick Technologies products for further instructions.

### 7.2. Damaged Sensor

In the event of obvious physical damage to the Sensor, customers shall discontinue use of that Sensor, substitute another CDR Elite Sensor (if available), and contact their local Schick distributor for further instructions.

### 7.3. Periodic Maintenance

Periodic maintenance is performed as needed, but at least once a month. It consists of various checks performed by the operator or by a qualified service technician.

- Check that the labels are intact, readable, and adhere well to the surfaces on which they are positioned
- Check that all of the cables that connect to the CDR Elite USB Interface Module are undamaged
- Check that there is no external damage to the CDR Elite USB Interface Module which could compromise its ability to operate safely

# **Appendix A. Reference**

### A-1. Removal and Replacement

There are no user-serviceable parts in the CDR Elite USB Interface Module and service of CDR Elite sensors is limited to cable replacement of CDR Elite sensors. Should you experience problems with the CDR Elite products, please contact your local distributor of Schick Technologies products. In the United States, Schick Technologies products are serviced exclusively through Patterson Dental, Inc. Call your local Patterson representative, local Patterson branch, or 1-800-873-7683 for more information.

### A-2. Part Numbers

The following table provides customer-orderable part number information for CDR Elite Sensors, cables, and kits.

ltem	Part Number	Description	Sensor Cable Length
Size 0 Sensor Kit	B1307000	CDR Elite S0 Sensor Kit	6 ft (1.8 meters)
Size 1 Sensor Kit	B1107000	CDR Elite S1 Sensor Kit	6 ft (1.8 meters)
Size 2 Sensor Kit	B1207000	CDR Elite S2 Sensor Kit	6 ft (1.8 meters)
Cable Kit	B1207110	CDR Elite Cable Kit	6 ft (1.8 meters)

Table 8. Orderable Item Part Numbers
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# A-3. Summary of Specifications

CDR Elite USB Interface Module is ETL-certified and complies with EMC, safety, and quality standards listed below.

Item	Value		
EMC/Safety	IEC60601-1	UL Standard for Safety Medical Electrical Equipment – Part 1: General Requirements for Safety; Edition 2, Issued: 1998/12/01	
	IEC60601-1-1	Medical Electrical Equipment – Part 1-1: General Requirements for Safety –Collateral Standard: Safety Requirements for Medical Electrical Systems; Edition 2, Issued: 2000/12/01	
	IEC60601-1-2	Medical Electrical Equipment – Part 1-2: General requirements for safety Collateral standard: Electromagnetic compatibility Requirements and tests – Edition 2.1, Issued: 2004/11/01	
	UL60601-1	UL Standard for Safety Medical Electrical Equipment – Part 1: General Requirements for Safety – Edition 1, Issued 2003/04/25	
	AAMI TIR12:2004	Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers	
Quality	CAN/CSA C22.2 No. 601.1	Medical Electrical Equipment – Part 1: General Requirements for Safety - General Instruction No 1; Update No 2; Issued: 1990/01/11	
	EC93/42/EEC	Medical Device Directive	
	IEC60601-4	Medical Electrical Equipment – Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems Consolidated with Amendment 1:1999; Edition 1, Issued: 2000/04/01	
	Class II, Type BF equipment Not Category AP Equipment		
Classification			
	Not Category APG Equipment		
Mode of Operation	Equipment is intended for continuous use		
Additional Notes	Equipment is not suitable for use in the presence of a Flammable Anesthetic Mixture with Air or with Oxygen or Nitrous Oxide.		
Supply Voltage	+5V DC (derived for PC USB port)		
Supply Current	250 mA		
Power Consumption	1.25W		
Dimensions	3.25 x 2.3 x 0.9 in. (1.28 x 0.91 x 0.35 cm)		
Weight	1.8 oz. (50g)		
Transport and Storage	Ambient temperature range: -40° F (-40° C) to 158° F (+70° C)		
Conditions	Relative humidity range: 10 to 100%, including condensation		
	Atmospheric pressure range: 500 hPa to 1060 hPa		

Item	Value
	Ambient temperature range: 50° F (+10° C) to 104° F (+40° C)
Operating Conditions	Relative humidity range: less than 75%
	Atmospheric pressure range: 700 hPa to 1060 hPa
Restricted service statement	Unless otherwise specified, this unit should be serviced only by the manufacturer. It contains no user-serviceable parts.
External power supply	None (power supplied via USB)
Maximum cable length	5 m (5.5 yds)

## A-4. Leakage Current Statement

CDR Elite USB Interface Module complies with the leakage current requirements of IEC 60601-1-1 safety standard. Variations, however, may exist in the construction of computers to which the CDR Elite USB Interface Module is connected. Customers are advised to have a qualified electrician perform a leakage test on their equipment before using the CDR Elite Interface Module.

# A-5. EMC Tables

The following tables provide CDR Elite USB Interface Module compliance information to electromagnetic compatibility (EMC) and electromagnetic immunity (EMI) standards. To ensure conformance, the customer or user must use the CDR Elite USB Interface Module in environments that are consistent with these standards.

The USB cable required with the CDR Elite USB Interface Module must also comply with the same standards. The operation of the CDR Elite USB Interface Module has been independently tested using USB cables identified in Table 1. Compliance to EMC and EMI standards cannot be guaranteed by the use of alternate cables.

Table 10. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

PLEASE NOTE: The CDR Elite USB Interface Module is intended for use in the electromagnetic environment specified below. The customer or user of the CDR Elite USB Interface Module must ensure that it is used in such an environment.

Emissions Test	Compliance	Guidance	
RF emissions CISPR 11	Group 1	The CDR Elite USB Interface Module 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 CISPR 11	Class B		
Harmonic emissions IEC 61000-3-2	Class D	The CDR Elite USB Interface Module is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes.	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies		

#### Table 11. Guidance and Manufacturer's Declaration - Electromagnetic Immunity

PLEASE NOTE: The CDR Elite USB Interface Module is intended for use in the electromagnetic environment specified below. The customer or user of the CDR Elite USB Interface Module must ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	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 610004-4	±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 ± 2kV common mode	± 1 kV differential mode ± 2kV 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	$< 5\% U_T$ (>95% dip in $U_T$ ) for 0.5 cycle	$< 5\% \ U_T \\ _{(>95\% \ dip \ in} \ U_{T)} \\ _{for \ 0.5} \ cycle$	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CDR Elite USB Interface Module requires
IEC 61000-4-11	40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles 70% U <sub>T</sub>	40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles 70% U <sub>T</sub>	continued operation during mains interruptions, it is recommended that the PC workstation to which the CDR Elite USB Interface Module is connected be powered from an uninterruptible power

Immunity Test	IEC 60601 Test Level	Compliance Level	Guidance
	$(30\% dip in UT) \\for 25 cycles \\< 5\% UT \\(>95\% dip in UT) \\for 5 Sec $	$(30\% \text{ dip in } U_T)$ for 25 cycles $< 5\% U_T$ (>95% dip in $U_T$ ) for 5 sec	supply or battery. NOTE: $U_T$ is the AC mains voltage prior to application of the test level.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Mains power quality should be that of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communication equipment should be used no closer to any part of the CDR Elite Interface Module, including its 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	$d = 1.2\sqrt{P} \text{ for 80 MHz to 800 MHz}$ $d = 2.3\sqrt{P} \text{ for 800 MHz to 2.5 GHz}$ Where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation 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.

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 CDR Elite USB Interface Module is used exceeds the applicable RF compliance above, the CDR Elite USB Interface Module should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CDR Elite Interface Module.

 $^{\rm b}$  Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

#### Table 12. Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the CDR Elite USB Interface Module

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

Rated maximum output power of the transmitter (W)	Separation distance according to the frequency of the transmitter (m)	
	150 kHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.30
10	3.8	7.3
100	12.0	23.00

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 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 B.Troubleshooting Tips

## **B-1.** Introduction

In the event you experience a problem with the CDR Elite Sensor or Interface Module, refer to the table of troubleshooting tips found on this page.

In the United States, Schick Technologies products are available exclusively through Patterson Dental, Inc. If the problem persists, please contact the Patterson Technology Center at 877-498-6505.

Outside the United States, please contact authorized international dealer for Schick Technologies products in your country or region.

## **B-2.** Troubleshooting Table

Item	Description	Corrective Action
1	Both green LEDs are off when CDR DICOM is not running.	Cable short or over-current condition. Replace Sensor cable.
2	The green LED on the Sensor side is blinking, whether CDR DICOM is running or not.	Low current condition. Replace Sensor cable.
3	Both green LEDs are off, whether CDR DICOM is running or not.	Over current condition. Replace Sensor cable.

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