



FONA CDRelite Sensor and USB Interface User Guide

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Contents

1. Overview	1
1.1. Purpose	1
1.2. Indications for Use	1
1.3. System Description	1
1.4. Replaceable Cable	2
1.5. PC Workstation Description	2
1.6. Relationship with Current FONA Sensors	4
2. Hardware	5
2.1. Connecting Cables to the FONA CDRelite USB Interface Module	5
2.2. Installing the FONA CDRelite USB Interface Module Holder	6
3. Software	8
3.1. What You Will Need to Complete this Section	8
3.2. Before You Start Installing Software	8
3.3. Setup with Windows Vista	9
3.4. Sensor Calibration File Installation	11
3.5. Image Enhancement	11
3.6. CDR AutoDetect	15
3.7. Using the CDR Elite Utility	17
4. LED Indicators	22
4.1. FONA CDRelite USB Interface Module Indications	22
5. Operation	23
5.1. Operating the System	23
5.2. Using Your FONA CDRelite Sensor	24
5.3. Acquiring X-ray Images with Keyboard Shortcuts	29
6. Protective Measures	30
6.1. Introduction	30
6.2. Cleaning and Disinfecting	30
6.3. Recommended Disinfectants	31
7. Maintenance	32
7.1. Visual Inspection	32
7.2. Damaged Sensor	32
7.3. Periodic Maintenance	32
8. Cable Replacement	33
Appendix A. Reference	40
A-1. Removal and Replacement	40
A-2. Part Numbers	40
A-3. Summary of Specifications	41
A-4. Leakage Current Statement	42

A-5. EMC Tables	43
Appendix B. Troubleshooting Tips	46
B-1. Introduction	46
B-2. Troubleshooting Table	46

List of Figures

Figure 1. FONA CDRelite USB Interface Module Cable Connections	5
Figure 2. FONA CDRelite USB Interface Module Holder.....	6
Figure 3. Enhancements: Smooth (top) and Edge High (bottom)	13
Figure 4. Enhancements: Edge Low (top) and None Applied (bottom)	14
Figure 5. FONA CDRelite USB Interface Module LED and Connector Views	22

List of Tables

Table 1. Description of FONA CDRelite USB Interface Module Cable Connections	5
Table 2. FONA CDRelite USB Interface Module LED Indications.....	22
Table 3. Proper Sensor Removal from Protective Sheath.....	25
Table 4. Examples of FONA CDRelite Sensor-to-Image Orientation.....	26
Table 5. Keyboard Shortcuts	29
Table 6. Orderable Item Part Numbers	40
Table 7. Specifications.....	41
Table 8. Guidance and Manufacturer's Declaration - Electromagnetic Emissions.....	43
Table 9. Guidance and Manufacturer's Declaration - Electromagnetic Immunity	43
Table 10. Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the FONA CDRelite USB Interface Module	45

Safety Issues

Check FONA CDRelite Sensor and USB Interface Module before Using Them

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

To help ensure proper hygiene and to protect against infectious disease, refer to Section 6, Protective Measures, and observe all device cleaning and patient protection recommendations specified there.

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

When the FONA CDRelite 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.

Follow All Instructions to Ensure Cable Replacement Procedures are Performed Correctly

Follow all instructions to ensure the successful replacement of your FONA CDRelite cables. When performing the cable replacement procedure, it is especially important to tighten the screws that attach the cable to the Sensor by turning them *at least one-quarter revolution clockwise after initial resistance or until they cannot be turned any further*. An improperly attached cable may cause an intermittent connection and prevent the Sensor from operating effectively. Refer to Section 8, Cable Replacement, for complete instructions.

Use Only USB Cables Approved for the FONA CDRelite System

For normal operation of your FONA CDRelite system and to ensure compliance with regulatory EMC and EMI standards, use only the USB cables described and specified for your system. Refer to Section 2.1, Connecting Cables to the FONA CDRelite USB Interface, for details. EMC and EMI information may be found in the appendix, Section A-5, EMC Tables.

Do Not Connect Items that are Not Part of the System

Only items specified for use with the FONA CDRelite 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.

RF Interference Considerations

Although the FONA CDRelite 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 FONA CDRelite Sensor and Interface Module.

Any instrumentation or equipment for professional use located near the FONA CDRelite 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.

Installers to Ensure that FONA CDRelite Sensor and USB Interface Module Operate Optimally

Installers must ensure that the FONA CDRelite 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 FONA CDRelite Sensor and USB Interface Module are installed as described in this User Guide and shall perform the appropriate procedures therein.

Only Dentists or Authorized Designees Are Permitted to Operate the System

To ensure the correct use of the FONA CDRelite 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.

Ensure Proper System and PC Workstation Installation and Operation

The FONA CDRelite 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.

Operate the FONA CDRelite Sensor and USB Interface Module as Directed

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

Protect Sensor from Potential ESD Damage

Like other electronic devices, your FONA CDRelite 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 FONA CDRelite 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.

Always Use Sheaths with Sensors









Use approved sheaths every time the Sensor is used. **Never use the Sensor without a protective sheath. Never use a damaged sheath. Always dispose of the sheath after every patient.**

Protective sheaths are single-use devices and must not be reused under any circumstance. Reuse of single-use devices/instruments may cause them to become contaminated, compromise their intended function, and result in patient and user infection, injury and/or illness.

Explanation of Symbols

Sirona Dental 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)
	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
	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
	Indicates that this product meets North American safety standards. The ETL 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
	Indicates that the product has been tested and evaluated to meet the electrical safety requirements, according to IEC 60601-1, for electronic products sold within Brazil
	Indicates that this product conforms to European Union Medical Devices Directive (MDD) 93/42/EEC
	Indicates that this product does not contain toxic and hazardous substances or elements above the maximum concentration values, and that it is an environmentally-friendly product which can be recycled and reused

Label Location

This label can be found on the FONA CDRelite 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. Sirona Dental and its Dealers are committed to complying with the Directive.

WEEE Marking

All Sirona Dental 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, Sirona Dental 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, Sirona Dental or its Dealers will fulfill its obligations for the management of WEEE from users other than private households.

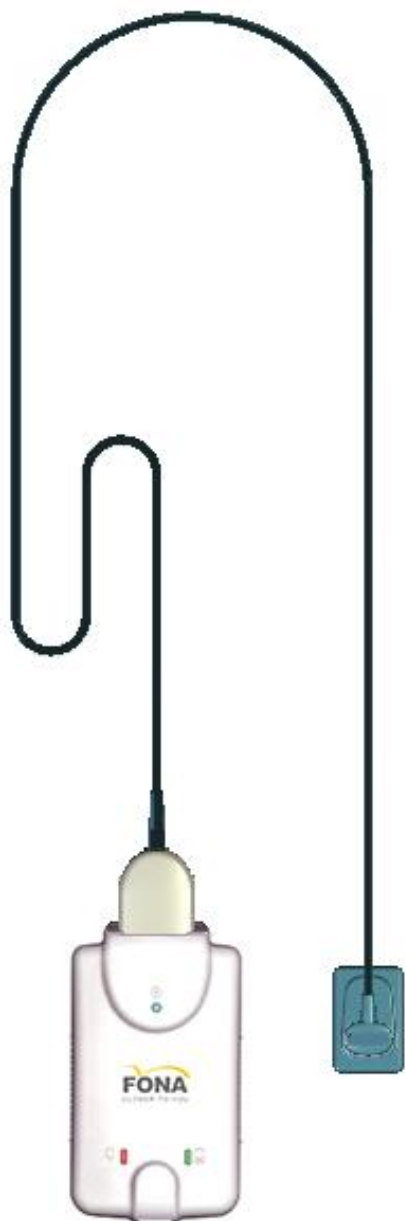
Furthermore, as required by the WEEE Directive, in order to determine unequivocally when the equipment was put on the market, the manufacturer's date is placed on the equipment.

Information for Reuse Centers, Treatment and Recycling Facilities

As required by the WEEE Directive, Sirona Dental 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).

FONA CDRelite Sensor and USB Interface Module



FONA CDRelite Sensor with FONA CDRelite USB Interface Module

1. Overview

1.1. Purpose

The FONA CDRelite Sensor and FONA CDRelite 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 FONA CDRelite Sensors
- New options for image enhancement.

1.2. Indications for Use

The FONA CDRelite 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 FONA CDRelite Sensor is connected to the FONA CDRelite 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 FONA CDRelite Sensor is provided by compatible software programs such as FONA OrisWin. Section 1.5 lists the operating systems compatible with the FONA CDRelite system.

The FONA CDRelite 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 FONA CDRelite USB Interface Module holder may be found in Section 2.2.

1.4. Replaceable Cable

The FONA CDRelite Sensor Imaging System is designed to meet the practical, timely needs of dental professionals. For this reason, FONA CDRelite 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 FONA CDRelite cables may be found in Section 8.

1.5. PC Workstation Description

The PC workstation connects to the FONA CDRelite USB Interface Module via USB cable (supplied separately) 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 FONA CDRelite Sensors.

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

1.5.1. Client or Standalone

- Windows 7 and Windows 7 x64, Windows Vista SP2, and Vista x64
- Intel i7 or equivalent
- 4 GB RAM
- 256 MB graphics card
- 500 GB hard drive (practice-specific, depends on number of patients)
- Intel USB 2.0 or 3.0.

1.5.2. Server

- Windows Server 2003 R2 (SP1 minimum) and Windows Server 2008 R2
- TCP/IP networking protocols (for DICOM Servers)
- 4 GB RAM (recommended)
- 1 TB (recommended).

NOTE: To achieve maximum image transfer-to-display time, we recommend quad-core processors, 8 GB RAM, Windows 7 operating system, and 512 MB graphics card. Recommended minimum display resolution is 1280x1024.

1.6. Relationship with Current FONA CDRelite Sensors

If your current workstation supports FONA CDRelite Sensors, it will also support FONA CDRelite Sensors. If both FONA CDRelite and FONA CDRelite Sensors are connected to the same workstation, they are detected automatically (by CDR AutoDetect, as described in Section 3.6), and you can work with either Sensor type.

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

2. Hardware

2.1. Connecting Cables to the FONA CDRelite USB Interface Module

IMPORTANT! Do not connect the FONA CDRelite 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 FONA CDRelite

Interface Module. cable part numbers and lengths are listed below:

- B2250150 - 5 meters (16.5 feet)
- B2250151 - 2 meters (6.5 feet)
- B2250152 - 0.5 meter (1.6 feet)

IMPORTANT! For normal operation of your FONA CDRelite system and to ensure compliance with regulatory EMC and EMI standards, use only the USB cables described and specified for your system.

The FONA CDRelite Sensor and FONA CDRelite USB Interface Module are shown in Figure 1. Cable connections are described in Table 1.



Figure 1. FONA CDRelite USB Interface Module Cable Connections

Table 1. Description of FONA CDRelite USB Interface Module Cable Connections

Number	Description
1	FONA CDRelite Sensor
2	FONA CDRelite Sensor cable connection
3	FONA CDRelite 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 FONA CDRelite USB Interface Module Holder

The FONA CDRelite 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 FONA CDRelite USB Interface Module choose a location that offers easy access and visibility during patient exams.

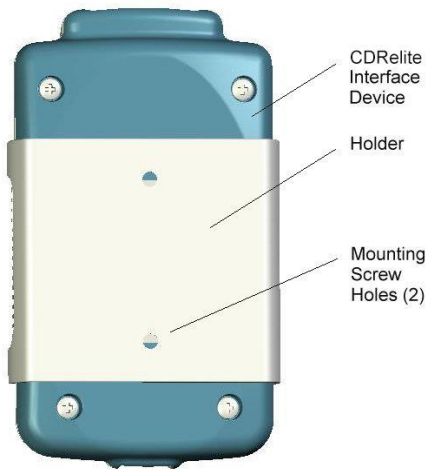


Figure 2. FONA CDRelite USB Interface Module Holder

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 FONA CDRelite 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.
- 3 . Remove the FONA CDRelite USB Interface Module from its holder

2.2.2. Wall-Mounting Option (with Adhesive)

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

- 1 . Remove the FONA CDRelite 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 FONA CDRelite 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.

3. Software

3.1. What You Will Need to Complete this Section

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

- FONA CDRelite Interface Driver CD
- FONA CDRelite USB Interface Module
- USB 2.0 A-B Cable (supplied separately)

3.2. Before You Start Installing Software

IMPORTANT! Please do not connect the FONA CDRelite 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 FONA CDRelite USB Interface Module installation consists of the FONA CDRelite USB Interface Module driver. You must install this driver successfully to ensure proper operation of your FONA CDRelite Interface Module.

Installation differs slightly among the Windows operating systems, so you should follow the procedures that refer to your particular system.

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 (⊞) and Break keys will also display System Properties).

3.3. Setup with Windows Vista

STEP 1

- A. Insert the FONA CDRelite 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.



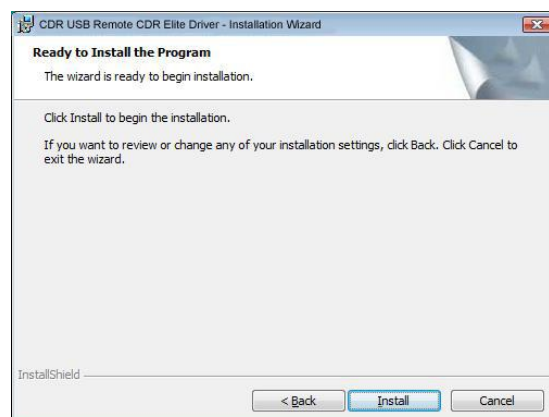
STEP 2

Click **Next** to begin the setup process.



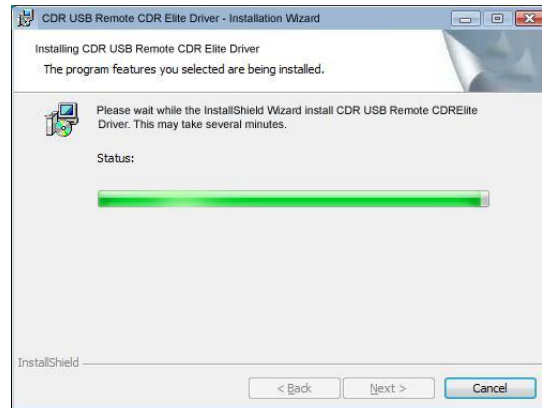
STEP 3

Click **Install**.



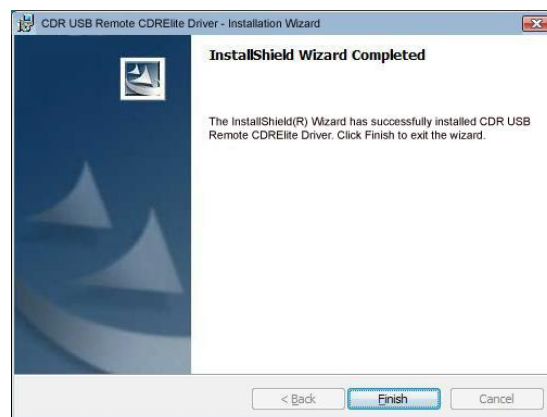
STEP 4

Setup will copy the drivers to your workstation.



STEP 5

- A. Click **Finish**.
- B. Connect the FONA CDRelite 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 FONA CDRelite USB Remote Driver CD.



3.4. Sensor Calibration File Installation

Calibration data for FONA CDRelite 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 FONA CDRelite system cables are connected securely.
2. Start imaging software, which 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.

3.5. 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.

3.5.1. 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.

3.5.2. 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.

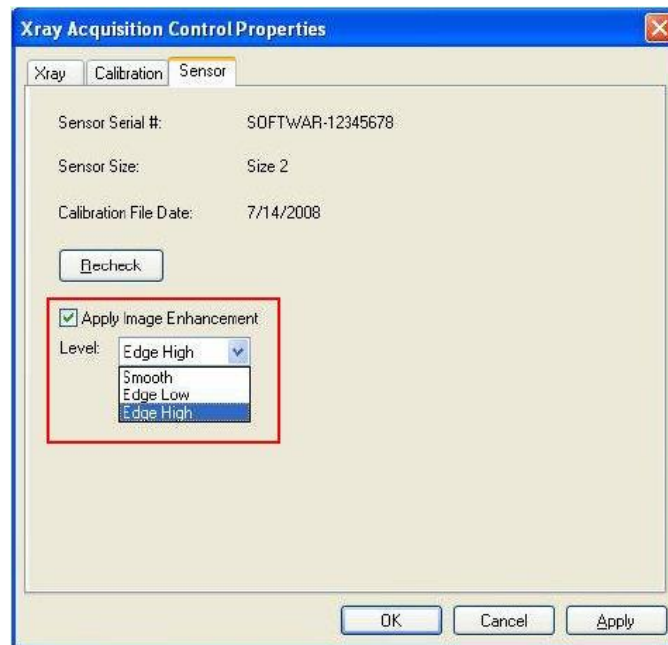




Figure 3. Enhancements: Smooth (top) and Edge High (bottom)



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

3.6. CDR AutoDetect

The CDR AutoDetect feature instantly recognizes when a different Schick intraoral USB device used with X-ray image acquisition is connected — including standard, high-speed (HS), and FONA CDRelite modules — skipping the step of manually selecting a new Schick USB device before using it.

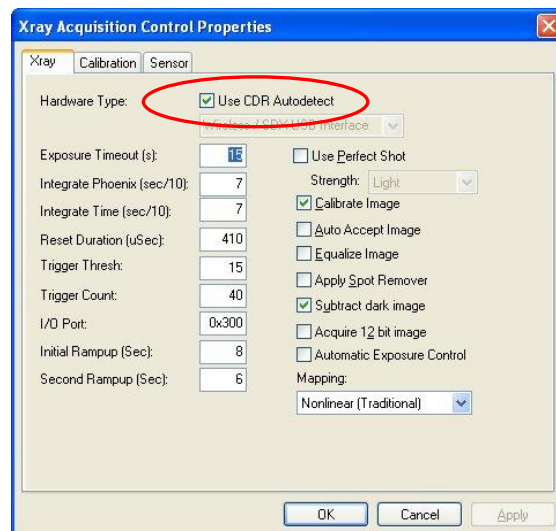
CDR AutoDetect will be most useful for offices that employ a mix of Schick USB modules and Sensors and use them interchangeably within one or several operatories.

3.6.1. 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.

3.6.2. 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.



3.6.3. How FONA USB Devices are Detected

CDR AutoDetect requires that the FONA CDRelite USB (or Remote HS) device be connected for the system to recognize it. Once the USB device is connected, we say that it is “known” by CDR AutoDetect, which informs the imaging program to begin using that device. If no Schick intraoral USB device for X-ray acquisition is connected, a notification window reports this when the CDR DICOM application starts.

3.6.4. Changing FONA 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.



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.

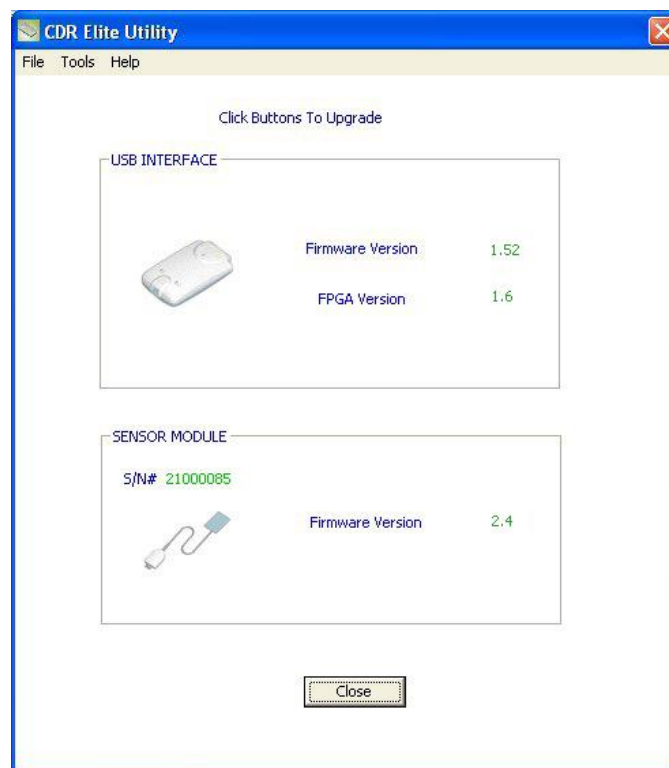
3.7. Using the CDR Elite Utility

3.7.1. Introduction

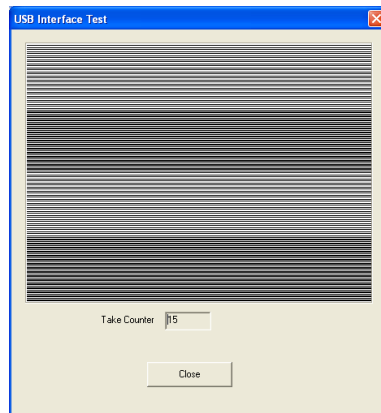
The CDR Elite Utility is installed during the CDR Elite Driver setup program. This tool can be used to accomplish the following:

- 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.)*



3.7.2. USB Interface Test



The CDR Elite USB Interface Test checks the connection between the *FONA CDRelite 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.

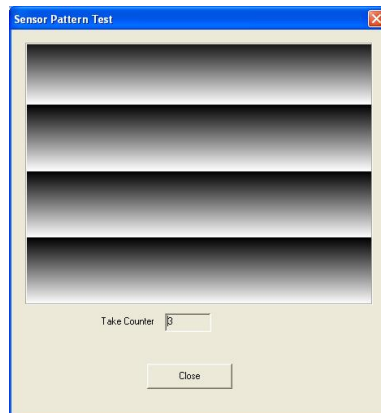
A count of at least 10 test pattern images is usually sufficient to determine if there are USB problems that would cause poor test patterns to be generated. The absence of any test pattern (blank image window), or the appearance of distorted lines, indicates a problem between the *FONA CDRelite Interface* 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 FONA CDRelite device or its USB connector, or the USB cable and / or port, or corrupt firmware inside the FONA CDRelite device. Additional troubleshooting can be performed if another FONA CDRelite USB device is available. In this case, connecting a different FONA CDRelite device to the USB cable and repeating the USB Interface Test may help to identify the possible cause of the problem.

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

STEP	ACTION
1	Close CDR DICOM (if running)
2	Verify that FONA CDRelite USB Interface is connected to the host computer.
3	Start the CDR Elite Utility (Start > All Programs > CDR DICOM for Windows > CDR Elite Utility).
4	Click Tools > USB Interface Test.
<i>Note: After a momentary pause, a test pattern is displayed. The orange LED on the FONA CDRelite USB Interface blinks as the test pattern scrolls.</i>	
5	Click Close to exit this test.
6	Click Close to exit the CDR Elite Utility.

3.7.3. Sensor Pattern Test



The CDR Elite Sensor Pattern Test checks the connection between the *FONA CDRelite 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.

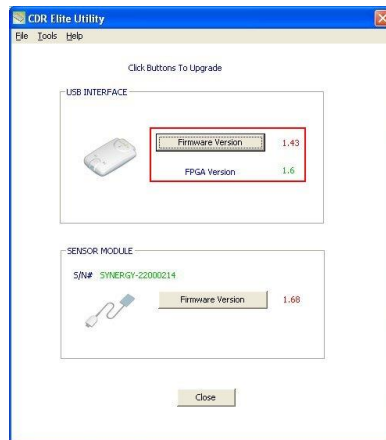
A count of at least 10 test pattern images is usually sufficient to determine if there are USB problems that would cause poor test patterns to be generated. The absence of any test pattern, or (blank image window) or the appearance of distorted lines indicates a problem between the *FONA CDRelite Interface 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 FONA CDRelite device or its Sensor connector, or the Sensor cable, or corrupt firmware inside the FONA CDRelite device. Additional troubleshooting can be performed if another FONA CDRelite Sensor is available. In this case, connecting a different FONA CDRelite Sensor to the FONA CDRelite USB Interface and repeating the Sensor Pattern Test may help to identify the possible cause of the problem.

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

STEP	ACTION
1	Close CDR DICOM program (if running)
2	Verify that FONA CDRelite USB Interface is connected to the host computer.
3	Start the CDR Elite Utility (Start > All Programs > CDR DICOM for Windows > CDR Elite Utility).
4	Click Tools > USB Interface Test.
<i>Note: After a momentary pause, a test pattern is displayed. The orange LED on the FONA CDRelite USB Interface blinks as the test pattern scrolls.</i>	
5	Click Close to exit this test.
6	Click Close to exit the CDR Elite Utility.

3.7.4. USB Interface Firmware Upgrades



Field updates to the FONA CDRelite USB Interface can be accomplished by installing new firmware.

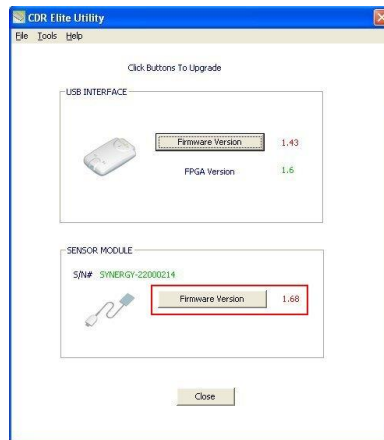
When new firmware is available, it is typically provided with a software release and becomes part of the update to your existing system.

Whenever version information is displayed with red lettering, we recommend that you perform the upgrade, referring to the procedure

that follows. Perform the following steps to upgrade FONA CDRelite USB firmware.

STEP	ACTION
1	IMPORTANT! Close CDR DICOM (if running).
2	Verify that FONA CDRelite USB Interface is connected to the 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.
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.
6	Verify that the USB Interface firmware and FPGA version numbers should be listed in green. If not, please contact your local distributor.
7	Click Close to exit the CDR Elite Utility.

3.7.5. Sensor Module Firmware Upgrade



Field updates to the FONA CDRelite Sensor can be accomplished by installing new firmware.

When new firmware is available, it is typically provided with a software release and becomes part of the update to your existing system.

Whenever version information is displayed with red lettering, we recommend that you perform the upgrade, referring to the following

procedure. Perform the following steps to upgrade FONA CDRelite Sensor firmware.

STEP	ACTION
1	IMPORTANT! Close CDR DICOM (if running).
2	Verify that FONA CDRelite USB Interface is connected to the 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.
5	Verify that the Sensor Module firmware version number is listed in green. If not, please contact your local distributor.
6	Click Close to exit the CDR Elite Utility.

4. LED Indicators

4.1. FONA CDRelite USB Interface Module Indications

The FONA CDRelite 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 2.

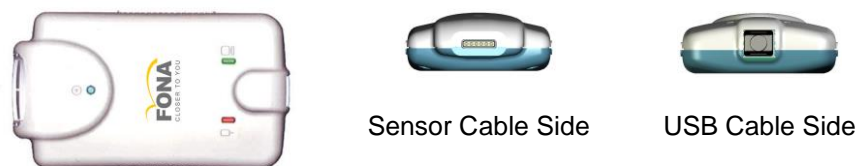





Figure 5. FONA CDRelite USB Interface Module LED and Connector Views

Table 2. FONA CDRelite USB Interface Module LED Indications

No.	SENSOR	CDR DICOM	GREEN LED 	AMBER LED 	GREEN LED 	STATUS
1	Connected	Running	ON	Blinking every ½ - 1½ secs.	ON	Ready for image acquisition
2	Connected	Running	ON	OFF	ON	Image acquisition
3	Connected	Not Running	OFF	OFF	ON	Start CDR DICOM to prepare for image acquisition
4	Connected	Not Running	OFF	ON	OFF	Cable short or over-current condition. Replace Sensor cable. Replace Sensor if problem persists.
5	Connected	Running or not running	OFF	ON	Blinking	Low current condition. Replace Sensor cable. Replace Sensor if problem persists.
6	Connected	Running or not running	OFF	ON	OFF	Over current condition. Replace Sensor cable. Replace Sensor if problem persists.
7	Not connected	Not running	OFF	ON	OFF	Connect Sensor and start CDR DICOM

NOTE: FONA CDRelite 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 FONA CDRelite Interface Module.
- 3 . Connect the “A-type” end of the USB cable to the PC workstation.
- 4 . Connect the FONA CDRelite Sensor edge-card to the FONA CDRelite Interface Module.
- 5 . The amber LED on the USB side of FONA CDRelite 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 FONA CDRelite 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. For other imaging software, please refer to those instructions instead.

5.1.2. Power Off

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

5.2. Using Your FONA CDRelite Sensor

5.2.1. Sensor Sheaths and Holders

Sheaths and the appropriate holders are required for FONA CDRelite 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 necessary 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 FONA Sensor holders, please refer to the FONA Positioning System User Guide, distributed with Sensor Holder kits and also available on our website.

5.2.2. Sensor Cleaning and Disinfecting

Before using the FONA CDRelite 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 FONA system. When positioning the Sensor, the inverse pixel box located on the FONA CDRelite Sensor can be used to determine the orientation of the resulting image.

Table 3. Proper Sensor Removal from Protective Sheath









Examples	Actions
	<p>1. Keeping the Sensor attached to the positioning tab and aiming bar, grasp the aiming bar where it joins the Sensor.</p>
	<p>2. Still grasping the bar underneath the sheath, use your thumb to start pushing the distal tip of the Sensor out of the sheath.</p>
	<p>3. Continue pushing the Sensor away from the closed, tight end of the sheath.</p>
	<p>4. As the Sensor is pushed into the wider area of the sheath, be careful to prevent the Sensor from falling on the floor. Handle both Sensor and cable gently.</p>

Table 4. Examples of FONA CDRelite Sensor-to-Image Orientation

Sensor Location	Sensor Orientation	Inverse Pixels (Circled) and Image Orientation
Patient's left side		 <i>Left Bitewing</i>
Patient's upper jaw		 <i>Anterior Periapical, Maxillary</i>

5.2.4. Taking X-rays

NOTE: Refer to the CDR DICOM User Guide, P/N 1057010, for detailed information on the use and operation of CDR DICOM software. For other imaging software, please refer to those instructions instead.

STEP 1

Start CDR DICOM from the Windows **Start** button or by clicking the shortcut to CDR DICOM for Windows on your desktop.

STEP 2

When the CDR exam window appears, click on **New Exam** under the **File** menu or just click the **New Exam** button on the toolbar.

STEP 3

- 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.
- B. To customize an X-ray series for the current exam, click **Edit Series**, which opens the Edit Viewset dialog box. (Reusable, customized series can be created at the **Series > New Intraoral Series** menu.)
- 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 FONA positioning 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. *As a guideline, FONA Sensors require 85% less dosage than D-speed film.*

STEP 5

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

- A. In AutoTake mode, activate the X-ray source. The message, "Reading Image from Sensor" appears momentarily.
- 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 next X-ray image, repeat this procedure starting at Step 5.

5.3. Acquiring X-ray Images with Keyboard Shortcuts

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

Table 5. Keyboard Shortcuts

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 FONA CDRelite USB Interface Module from the Sensor and the USB cable before performing any cleaning procedures.

The FONA CDRelite 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 FONA CDRelite 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 FONA CDRelite 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 hygienic 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 FONA CDRelite Sensor with a hygienic barrier. Before using the FONA CDRelite 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 FONA CDRelite 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 wipe the Sensor and cable with the disinfecting product recommended in Section 6.3. Do not expose the Sensor cable connectors to any amount of liquid.
- 8 . Allow the liquid disinfectant to remain on the Sensor for 30 seconds.
- 9 . Repeat steps 7 and 8. When the Sensor has been wiped two times, continue with the following steps.
- 10 . Remove potential chemical build-up from the Sensor by wiping it with a sterile lap sponge saturated with de-ionized water.
- 11 . Use a sterile 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 other dental product suppliers.

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

7. Maintenance

7.1. Visual Inspection

Like all electrical equipment, the FONA CDRelite 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 FONA CDRelite 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.

7.2. Damaged Sensor

In the event of obvious physical damage to the Sensor, customers shall discontinue use of that Sensor, substitute another FONA CDRelite Sensor (if available), and contact their local 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 FONA CDRelite USB Interface Module are undamaged
- Check that there is no external damage to the FONA CDRelite USB Interface Module which could compromise its ability to operate safely

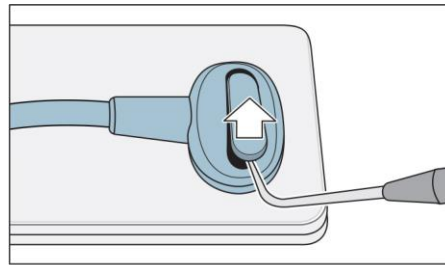
8. Cable Replacement

IMPORTANT! Always disconnect the Sensor from the FONA CDRelite USB interface during cable replacement to avoid potential damage to Sensor components. Close CDR DICOM (or other imaging software) 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 Sirona Dental.

IMPORTANT! Like other electronic devices, your FONA CDRelite 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 FONA CDRelite 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.

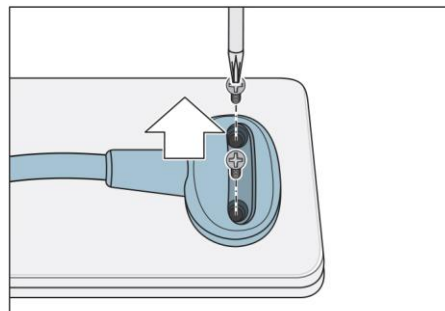
STEP 1

- 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 a dental instrument, 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.



STEP 2

- 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.

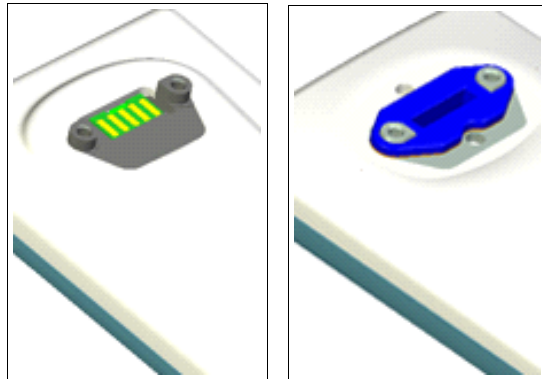


STEP 3

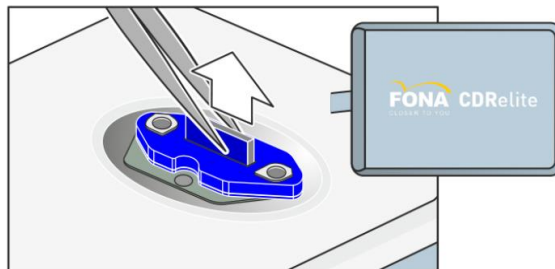
- A. After removing the cable, the area above the contacts should be completely clear. Remove the white elastomeric if it is dislodged accidentally from previous cable.

If the Sensor does not have a blue frame, remove one from the FONA CDRelite spare parts kit and place it into position. When positioned correctly, the flat side of the frame will be facing up.

NOTE: FONA CDRelite parts are blue.

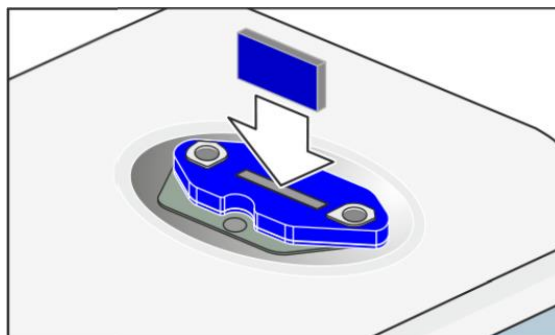


- B. Using tweezers, take a new (blue) strip from the FONA CDRelite spare parts kit and insert the strip into its slot in the Sensor.



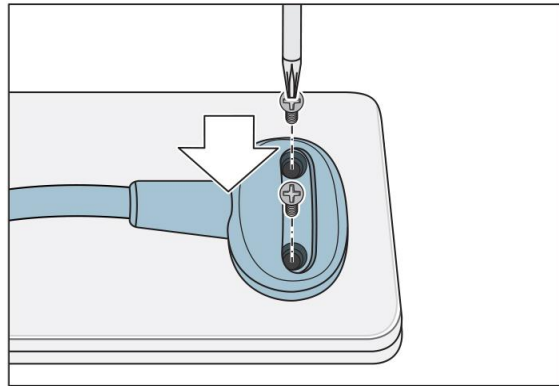
- C. After inserting the strip, apply a small amount of finger pressure to ensure the elastomer is seated squarely in the slot.

IMPORTANT! The elastomeric strip must be seated squarely in the slot for the Sensor to function.



STEP 4

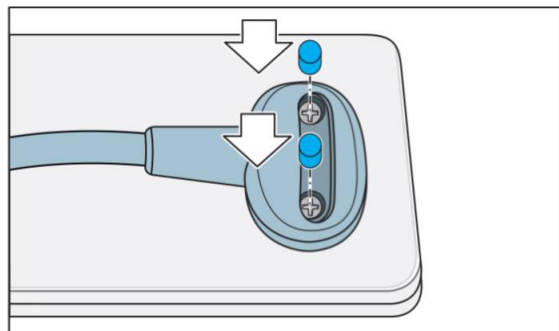
- A. Remove new cable from the replacement kit.
- B. Align the new cable to Sensor as shown, making sure that the Sensor keying feature connects to the corresponding key in the cable assembly.
- C. When properly aligned, the cable fits the back of the Sensor evenly and the metal area on the Sensor is completely covered by the cable.
- D. Holding the cable to the Sensor, insert one of the screws into its hole.
- E. Using the screwdriver, tighten the first screw just until you feel some resistance. Repeat this action for the second screw.
- F. Returning to the first screw, fully tighten it; then, fully tighten the second screw



IMPORTANT! Make sure that both screws are securely tightened before continuing.

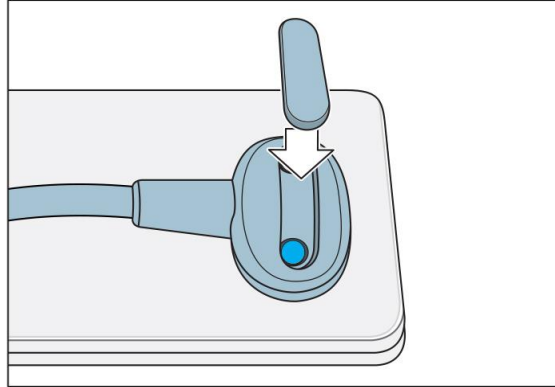
STEP 5

- A. Using tweezers, remove a gel disk from its paper backing and place it over one of the screws you just tightened. Make sure that the gel material completely covers the screw.
- B. Remove another gel disk and repeat this action for the second screw.



STEP 6

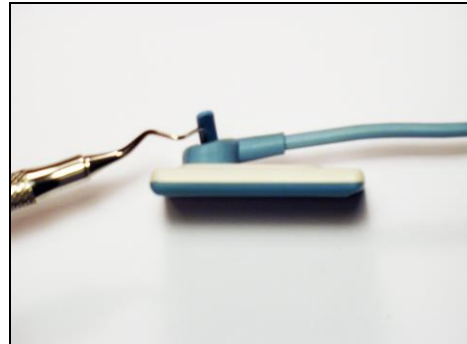
- A. Place the new tab cover over the screw slot and slide it across the slot while applying downward pressure, especially at the middle of the tab.
- B. When the tab completely covers the slot, snap it into place.
- C. Verify that the tab cover fits evenly in its slot. Cable replacement is complete.



PLEASE NOTE: Some Sensors may be equipped with a previous version of the Sensor cable. If the pictures on the preceding pages differ from the cable you are currently replacing, please perform the following procedure instead.

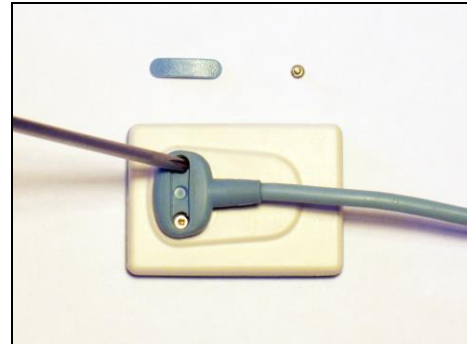
STEP 1

- 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.



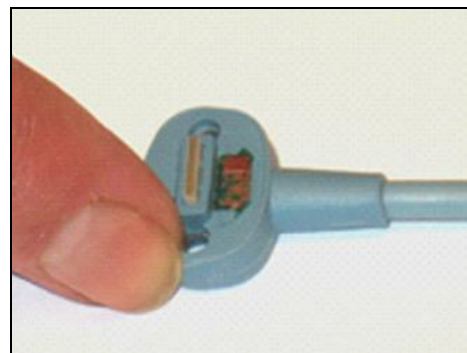
STEP 2

- 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.

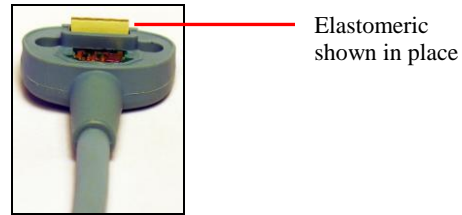


Step 3

- A. Remove the new cable from the replacement kit.
- B. Remove one of the small elastomeric strips provided and insert it **into its slot** in the cable. When inserted properly, the strip will fit securely inside the slot. Ensure proper seating by applying a small amount of finger pressure across the strip.

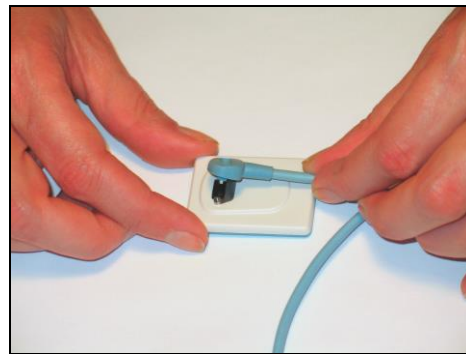


IMPORTANT! The elastomeric must be seated properly in its slot for the Sensor to function.



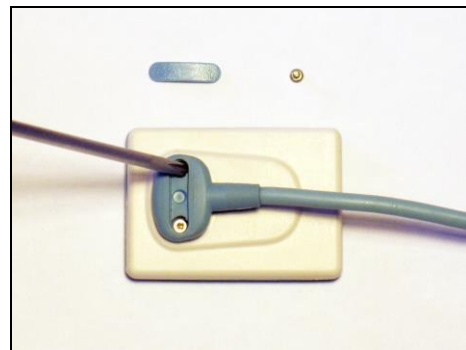
STEP 4

- 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

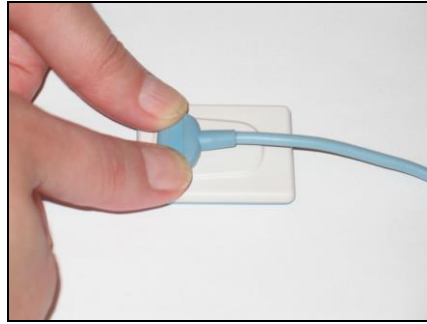
- A. Holding the cable to the Sensor, insert one of the screws into its hole. Using the screwdriver, tighten the first screw just until you feel some resistance. Repeat this action for the second screw.
- B. Returning to the first screw, tighten it fully, turning at least one-quarter revolution clockwise *after feeling initial resistance or until the screw will not turn any further*. Do the same for the second screw.



IMPORTANT! Make sure that both screws are securely tightened before continuing.

STEP 6

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



Appendix A. Reference

A-1. Removal and Replacement

There are no user-serviceable parts in the FONA CDRelite USB Interface Module and service of FONA CDRelite sensors is limited to cable replacement of FONA CDRelite sensors. Should you experience problems with the FONA CDRelite products, please contact your local distributor.

A-2. Part Numbers

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

Table 6. Orderable Item Part Numbers

Item	Part Number	Description	Sensor Cable Length
Size 0 Sensor Kit	B1311000	FONA CDRelite S0 Sensor Kit	6 ft (1.8 meters)
Size 1 Sensor Kit	B1111000	FONA CDRelite S1 Sensor Kit	6 ft (1.8 meters)
Size 2 Sensor Kit	B1211000	FONA CDRelite S2 Sensor Kit	6 ft (1.8 meters)
Cable Kit	B1211110	Replaceable Sensor Cable Kit	6 ft (1.8 meters)

A-3. Summary of Specifications

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

Table 7. Specifications

Item	Value	
EMC/Safety	IEC60601-1:2005 +CORR.1(2006) +CORR.2(2007)	Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance
	IEC60601-1-2:2007	Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility Requirements and tests
	UL60601-1	UL Standard for Safety Medical Electrical Equipment – Part 1: General Requirements for Safety – Edition 1, Issued 2003/04/25
Quality	AAMI TIR12:2004	Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers
	CAN/CSA C22.2 No. 60601.1:08	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
	93/42/EEC	Council Directive of 14/6/ 1993 concerning medical devices amended by directives 98/79/EC (27/10/98); 2000/70/EC(16/10/2000); 2001/104/EC(7/12/2001); 2007/47/EC(5/9/2007)
Classification	Class II, Type BF equipment Not Category AP Equipment 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 Conditions	Ambient temperature range: -40° F (-40° C) to 158° F (+70° C) Relative humidity range: 10 to 100%, including condensation Atmospheric pressure range: 500 hPa to 1060 hPa	
Operating Conditions	Ambient temperature range: 50° F (+10° C) to 104° F (+40° C) 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

FONA CDRelite 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 FONA CDRelite USB Interface Module is connected. Customers are advised to have a qualified electrician perform a leakage test on their equipment before using the FONA CDRelite Interface Module.

A-5. EMC Tables

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

The USB cable required with the FONA CDRelite USB Interface Module must also comply with the same standards. The operation of the FONA CDRelite USB Interface Module has been independently tested using USB cables identified in Section 2.1. *Compliance to EMC and EMI standards cannot be guaranteed by the use of alternate cables.*

Table 8. Guidance and Manufacturer's Declaration - Electromagnetic Emissions


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

Emissions Test	Compliance	Guidance
RF emissions CISPR 11	Group 1	The FONA CDRelite 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	The FONA CDRelite 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.
Harmonic emissions IEC 61000-3-2	Class D	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 9. Guidance and Manufacturer's Declaration - Electromagnetic Immunity

PLEASE NOTE: The FONA CDRelite USB Interface Module is intended for use in the electromagnetic environment specified below. The customer or user of the FONA CDRelite 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 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 ± 2kV common mode	± 1 kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$< 5\% U_T$ (>95% dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ (>95% dip in U_T) for 5 sec	$< 5\% U_T$ (>95% dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FONA CDRelite USB Interface Module requires continued operation during mains interruptions, it is recommended that the PC workstation to which the FONA CDRelite USB Interface Module is connected be powered from an uninterruptible power 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 FONA CDRelite 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	$d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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, ^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 80 MHz and 800 MHz, 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.			

Immunity Test	IEC 60601 Test Level	Compliance Level	Guidance
^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 FONA CDRelite USB Interface Module is used exceeds the applicable RF compliance above, the FONA CDRelite 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 FONA CDRelite Interface Module.			
^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m			

Table 10. Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the FONA CDRelite USB Interface Module

PLEASE NOTE: The FONA CDRelite USB Interface Module is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the FONA CDRelite USB Interface Module can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FONA CDRelite 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 $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
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 FONA CDRelite Sensor or Interface Module, refer to the table of troubleshooting tips found on this page. If the problem persists, please contact your local distributor.

B-2. Troubleshooting Table

Item	Description	Corrective Action
1	Both green LEDs are off when CDR DICOM (or other imaging software) 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 (or other imaging software) is running or not.	Low current condition. Replace Sensor cable.
3	Both green LEDs are off, whether CDR DICOM (or other imaging software) is running or not.	Over current condition. Replace Sensor cable.

Index

A

Acquiring X-ray Images with Shortcuts, 29
Approved USB Cables, iii

C

Cable Connections, 5
Cable Replacement
 Previous Model, 37
Cable Replacement Procedures, iii
Calibration, 11
CDR AutoDetect, 15
CDR Elite Utility, 17
Cleaning and Disinfecting, 30

D

Dentists or Authorized Designees Only Are Permitted
 to Operate the System, iv
Disinfectants, 31
Do Not Touch Exposed Connectors, iii

E

Electromagnetic Emissions, 43
Electromagnetic Immunity, 43
EMC Tables, 43
Ensure Sensor and Module Operate Optimally, iv
ESD and Protecting Sensors from it, v
Explanation of Symbols, vii

F

FONA CDRelite
 Image Enhancement, 11
 Indications for Use, 1
 Purpose, 1
 Replaceable Cable, 2
 Sensor Calibration, 11
 System Description, 1
FONA CDRelite Interface Module
 Connecting Cables, 5
 Hardware Setup, 5
 Holder Installation, 6
 LEDs, 22
 Protective Measures, 30
 Software Setup, 8
 Table of LED Indications, 22
 Using the Device with CDR DICOM, 27
FONA CDRelite Sensor
 Always Use Sheaths with, vi
FONA CDRelite Sensor and Interface Module
 Check before Using, iii
 Cleaning and Disinfecting, 30
 Description of, 1
 Maintenance, 32
 Operation, 23
 Periodic Maintenance, 32
 Picture of, x

Visual Inspection, 32
FONA CDRelite Setup
 Windows Vista, 9

I

Image Enhancement, 11

K

Keyboard Shortcuts, 29

L

Leakage Current Statement, 42
LED Indicators, 22

O

Operate FONA CDRelite Sensor and Interface Module
 as Directed, v
Operating the FONA CDRelite Sensor and Interface
 Module, 23
Orientation of Sensor to Image, 26

P

Part Numbers, 40
Proper Sensor Removal from Protective Sheath, 25
Proper System and PC Installation and Operation, v
Protective Measures, 30

R

Recommended Separation Distance Between Portable
 and Mobile RF Communications Equipment, 45
Recommend Disinfectants, 31
Reference Information, 40
Removal and Replacement, 40
RF Interference, iv

S

Safety Issues
 Always Use Sheaths with FONA CDRelite Sensors,
 vi
 Check FONA CDRelite Sensor and Interface
 Module before Using, iii
 Do Not Touch Exposed Connectors on Non-Medical
 Equipment and the Patient at the Same Time, iii
 Ensure FONA CDRelite Sensor and Interface
 Module Operate Optimally, iv
 Follow All Instructions when Replacing FONA
 CDRelite Cables, iii
 Items Not Part of the System, iv
 Only Dentists or Authorized Designees Are
 Permitted to Operate the System, iv
 Operate the FONA CDRelite Sensor and Interface
 Module as Directed, v
 Proper System and PC Workstation Installation and
 Operation, v

Protect Sensor from Potential ESD Damage, v
RF Interference Considerations, iv
Use USB Cables Approved for FONA CDRelite
System, iii
Wait for Prompts before Operating X-ray Source, v
Setup, 5, 8
Summary of Specifications, 41

T

Troubleshooting Table, 46

U

USB Cable
Picture of, 5

W

Waste Electrical and Electronic Equipment (WEEE),
viii
Windows Vista Setup, 9