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by **sirona**

CDR PlusWire
User Guide

REF B1051067

Sirona Dental, Inc.
30-30 47th Avenue
Long Island City, NY 11101
USA

(718) 937-5765
(718) 937-5962 (fax)

EC REP Sirona Dental GmbH
Sirona Straße 1
5071 Wals bei Salzburg
Austria

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To avoid potential damage to CDR PlusWire Sensor components during cable replacement, always disconnect the Sensor and its cable from the CDR Remote, or CDR Remote HS, or SDX Sensor Interface. When performing cable replacement, always work outside the patient area, using the tools and materials supplied by Sirona Dental.

CAUTION: Be Sure to Disconnect the CDR PlusWire Sensor from the CDR Remote, or CDR Remote HS, or SDX Sensor Interface before Performing Cleaning and Disinfecting Procedures

To avoid potential damage to CDR PlusWire Sensor components during cleaning and disnfecting, always disconnect the Sensor and its cable from the CDR Remote, or CDR Remote HS, or SDX Sensor Interface.

Check CDR PlusWire Sensors before Using Them

Before each usage, check the outer surface of the CDR PlusWire Sensor for any signs of physical damage or defect. The surface of the CDR PlusWire Sensor should have a smooth finish, with no evidence of chipping or damage. If detected, discontinue use of that sensor and contact your local distributor of Sirona Dental products for further instructions.

The CDR PlusWire cable should be checked for any damage in the shielding, such as exposed or frayed shields or broken connections to solder points. If detected, discontinue use of that cable and contact your local distributor of Sirona Dental products for further instructions.

Always Use Sheaths with CDR PlusWire Sensors

Use Sirona Dental positioning products and sheaths every time the CDR Plus Wire 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.

Operate CDR PlusWire Sensors as Directed

Always use CDR PlusWire Sensors in accordance with the directions and recommendations contained in this User Guide. Do not attempt to modify CDR PlusWire Sensors or use them in system configurations not specified in this document.

Observe Proper Handling and Placement for CDR PlusWire Sensors

As with any dental device or instrument placed intraorally, proper care must be taken when using CDR PlusWire Sensors to ensure they are handled and positioned properly. Practitioners should observe standard guidelines, use recommended holders and other Sensor positioning elements, and follow accepted clinical methods to make sure that the patient does not bite down on or damage the Sensor during the X-ray examination.

Before taking X-rays, refer to <u>both</u> the Sensor Care Guide and the CDR Positioning System User Guide for guidelines on using Sensor sheaths, holders, and tabs. Inspect the sheath after placing it on the Sensor to verify proper fit and integrity. The CDR Positioning System User Guide is distributed with Sensor Holder kits and is also available on our website, www.schickbysirona.com.

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

When the CDR PlusWire Sensor is 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.

Apply Recommended Procedures for Cleaning the Equipment

To ensure proper hygiene practices 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. Following a regular schedule of preventive maintenance will help ensure the safe and proper operation of the equipment.

Do Not Connect Items that are Not Part of the System

Only items specified for use with CDR PlusWire 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 CDR PlusWire equipment is designed to provide a reasonable degree of protection from electromagnetic interference, according to IEC International regulations, it 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 PlusWire.

Any instrumentation or equipment for professional use located near the CDR PlusWire 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 dedicated electrical line.

Only Dentists or Authorized Designees Are Permitted to Operate the System

To ensure the correct use of CDR PlusWire Sensor 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

Installers to Ensure that CDR PlusWire Operates Optimally

Installers must ensure that CDR PlusWire provides the user with the optimal use of the equipment. This includes, but is not limited to, ensuring 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 CDR PlusWire Sensors are installed as described in this User Guide and shall perform the appropriate procedures therein.

Ensure Proper System and PC Workstation Installation and Operation

CDR PlusWire Sensors 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 feet (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 / 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]. 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. Equally important is a reliable strategy for backing up data and image files to ensure this information can be properly restored in the event of data loss or corruption.

Protect Sensor from Potential ESD Damage

Like other electronic devices, your PlusWire 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 PlusWire 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.

Product Manuals from Sirona Dental

The contents of this manual are subject to change without prior notice. For the latest version of this user guide and other product manuals from Sirona Dental, please consult our website: www.schickbysirona.com

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
CE	Conforms to European Union Medical Devices Directive (MDD) 93/42/EEC
(crossed-out wheeled bin symbol)	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
ETL LISTED 9801284	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

Label Location

The following sample label can be found on the edge-card connector of CDR PlusWire cable assembly.

Warning: This will void the warrantee.
1) Pulling on cable when disconnecting sensor from remote.
2) Clamping sensor or cable with hemostat.

MFG: XX/XXXX Schick Technologies, Inc. L.I.C., NY 11101
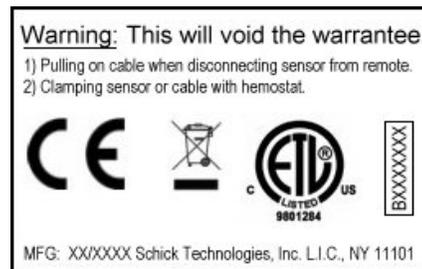
Waste Electrical and Electronic Equipment

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 on its packaging indicates that this product must not be disposed of with other unsorted municipal waste. Instead, it is user's responsibility to dispose of EE waste equipment 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 & 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 enable the date upon which the equipment was put on the market to be determined unequivocally, a mark on the equipment will be placed to specify that the equipment was put on the market after August 13, 2005.

Information for Reuse Centers, Treatment and Recycling Facilities

After August 13, 2005, and 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)
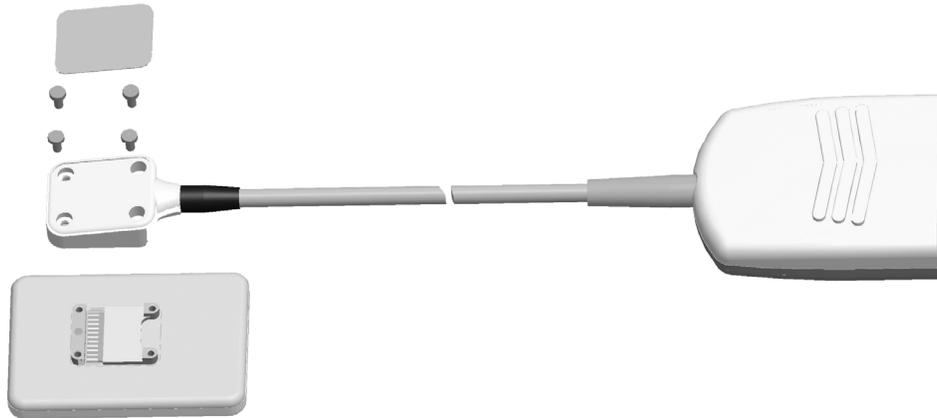
CDR PlusWire Expanded View
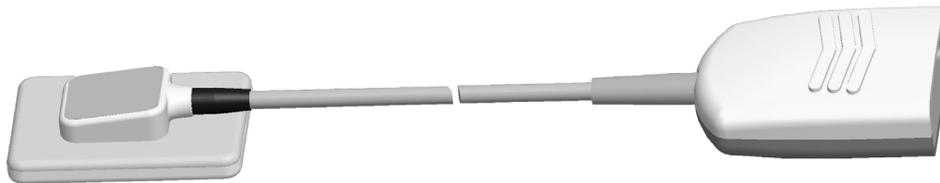
CDR PlusWire Completed Installation

1. Overview

1.1. Purpose

Designed with the convenience of replaceable cables in mind, *CDR PlusWire* enables customers to perform in-office Sensor cable replacements.

1.2. Indications for Use

CDR PlusWire 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

CDR PlusWire is connected by its edge-card connector to the CDR Remote Module (firmware revision 34 or higher), CDR Remote HS, or the Sensor interface on the SDX Intraoral X-ray system. These USB devices (or, in the case of SDX, its USB interface) are connected by appropriate USB cable to a compatible PC workstation,[1] running Windows Vista or Windows XP. When CDR PlusWire cables are replaced, a utility is used to read / write Sensor data from one cable to another.

1.4. PC Workstation Description

The PC workstation connects to CDR PlusWire via USB cable (supplied seperately) and CDR Remote, or CDR Remote HS, or SDX Intraoral X-ray Sensor Interface. The workstation serves as the host for CDR DICOM or other compatible imaging software products. Imaging software applications such as CDR DICOM provide the capability to display, manipulate, store, and print images acquired from CDR Sensors.

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[1] USB cables are available from Sirona Dental at the following lengths: 5 meter (B2250150), 2 meter (B2250151), and 0.5 meter (B2250152).

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

1. Compatible operating system (Windows Vista/Windows XP)
2. Intel Pentium D or Intel Core 2 Duo processors
3. 2 GB RAM
4. Minimum 250 GB hard drive Raid Level 1 free disk space (practice-specific, depends on the number of patients)
5. Available USB port (USB 2.0 recommended for CDR Remote HS devices).

2. Installing the CDR PlusWire Sensor

2.1. What You Will Need to Complete this Section

To expedite installation, please have the CDR PlusWire Sensor (Starter) Kit available (Size 2 Sensor: P/N B1205000, or Size 1 Sensor: P/N B1105000), which includes the following items shown below:

1. CDR PlusWire Sensor and Cable
2. Mini-CD containing the Sensor Calibration File
3. Sensor holster, sheaths, and these instructions
4. CD PlusWire Utility CD *(You will not need this CD if you are installing the CDR PlusWire Sensor for the first time. It is only needed when replacing cables.)*

The contents of the starter kit are shown below.

Sensor and Calibration CD (inside case)

Sensor care guide

Sensor holster

CDR PlusWire Cable

Sensor sheaths

CDR PlusWire Utility CD
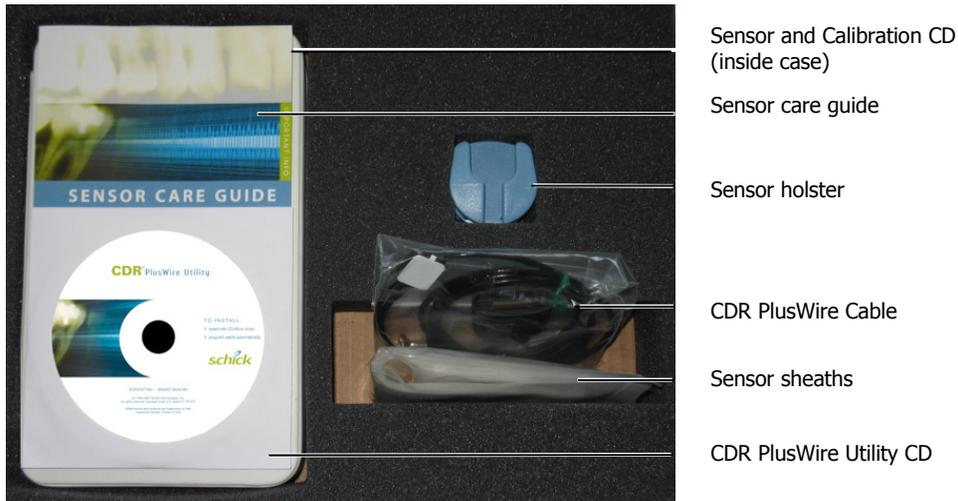
2.2. Connecting the CDR PlusWire Sensor

Perform the following steps to connect the Sensor to the appropriate CDR Interface.

1. Connect the USB cable from the CDR Remote, or CDR Remote HS, or SDX USB interface to the PC workstation.
2. Connect the CDR PlusWire Sensor to the CDR Remote, or CDR Remote HS, or SDX Sensor interface.
3. Turn on the PC workstation used with CDR DICOM, EagleSoft, Patterson Imaging, or other intraoral imaging application.
4. Continue with Section 2.3 to install the Sensor calibration file.

2.3. Sensor Calibration File Installation

If you are using CDR PlusWire Sensor for the first time, you will need to install the calibration file created specifically for the Sensor. In the future, if you decide to use the Sensor on a different workstation, you must ensure that the calibration file is either physically installed there, or is accessible to that workstation.

To install the calibration file, perform the following:

1. Ensure that the physical connection between the CDR PlusWire Sensor and the CDR Remote, or CDR Remote HS, or the SDX Sensor interface is secure. Also, verify that the USB cable connection between the CDR Remote, or CDR Remote HS, or the SDX USB interface and the PC workstation is secure.
2. Insert the mini-CD calibration disk. Make sure the serial number on the disk is the same as the serial number of the Sensor. The Sensor serial number is on the Sensor itself, above the area where the cable connects to the Sensor.
3. Click **Yes** when prompted to install the Sensor calibration file. The calibration file installs automatically.
4. Click **OK** to close the message box confirming that the calibration file installed successfully.
5. Repeat these steps on every workstation where the Sensor is used.
6. Continue with Section 2.4 on page 5 for steps on using the CDR PlusWire Sensor with CDR DICOM software. (To create patient exams and to acquire intraoral images in other imaging applications, refer to the documentation supplied by those manufacturers.)

2.4. Using the CDR PlusWire Sensor with CDR DICOM

> NOTE: Refer to the CDR DICOM User Guide, P/N B1051047, for detailed information on the use and operation of CDR DICOM software.

STEP 1

Start CDR DICOM from the Windows **Start** button or the CDR DICOM shortcut 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. (Re-usable, 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. **Never use the Sensor without a protective sheath.** Select a positioning holder specific to the intraoral area intended for exposure and apply it to the sheath. Attach 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, and the location of the Sensor in the oral cavity. *As a guideline, CDR Sensors require 85% less dosage than D-speed film.*

STEP 5

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 you are 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.

2.5. Acquiring X-ray Images with the Footpedal

Optional serial footpedals (P/N B2501100) are available to navigate view boxes inside a patient exam and to control the capture of X-ray images. Refer to the following table for actions associated with footpedal operation.

Table 1. Footpedal Actions	
Desired Action	**Use Pedal**
Select a view box	Green
Take an X-ray (manual mode)	Amber

2.6. 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 keyboard shortcuts available to navigate patient exams and to acquire images in CDR.

Table 2. 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]

2.7. Disconnecting the CDR PlusWire Sensor

To disconnect the Sensor, unplug it from the CDR Remote Module, CDR Remote HS, or SDX USB Interface. When disconnecting the Sensor, grasp the edge-card, *not the cable*, and pull gently.

Be sure to store the Sensor safely and appropriately when not in use. The Sensor Care Guide, P/N B1010017, supplied with the Sensor and available from our website, contains important information on this topic.
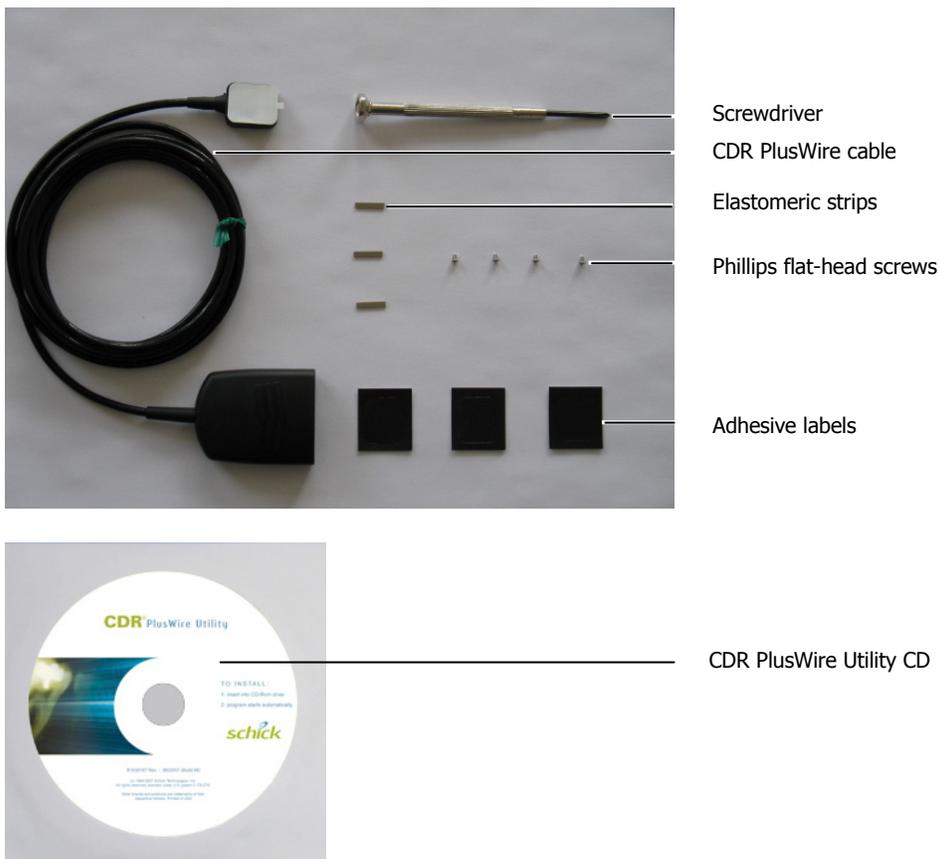
3. Replacing the CDR PlusWire Cable

3.1. What You Will Need to Complete this Section

To expedite installation, please have a CDR PlusWire Cable Replacement Kit available. The kits are identified by cable length: B1205102 (3-ft cable), B1205101 (6-ft cable), B1205103 (9-ft cable). Each Cable Replacement Kit includes the following items:

1. CDR PlusWire cable assembly (3-, 6-, or 9-foot lengths)
2. CD containing the CDR PlusWire Utility
3. Phillips flat-head screws (0-80)
4. Adhesive-backed black labels
5. Phillips screwdriver
6. Elastomeric strips.

The contents of the cable replacement kit are shown below.

Screwdriver
CDR PlusWire cable
Elastomeric strips
Phillips flat-head screws
Adhesive labels

CDR PlusWire Utility CD

3.2.   Before Replacing the CDR PlusWire Cable

IMPORTANT! Always disconnect the Sensor and its cable from the USB Remote or SDX Sensor interface during cable replacement steps to avoid potential damage to Sensor components. 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 PlusWire 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 PlusWire 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.

We recommend that you make sure that the Sensor is placed securely on a clean, moisture-free surface. The following is a description of compatible CDR Interfaces that can be used with CDR PlusWire.

Table 3. Compatible CDR Interfaces

CDR Remote Module	CDR Remote HS	SDX Sensor Interface

3.3. Description of the CDR PlusWire Utility

The Sensor edge-card does more than just provide the means for the CDR Sensor to connect to USB Remotes or to the Sensor interface on the SDX system. It also includes specific information about the Sensor itself and uniquely identifies it for the purpose of Sensor calibration.

By replacing the Sensor cable, Sensor-specific information could be lost without the ability — supplied by the CDR PlusWire Utility — to read that information from one edge-card connector, and write it to the new edge-card connector. To accomplish this, the utility consists of a few dialog boxes that will prompt you through the entire process.

Refer to Section 3.5 on page 11 for step-by-step directions on cable replacement for the CDR Plus Wire sensor.
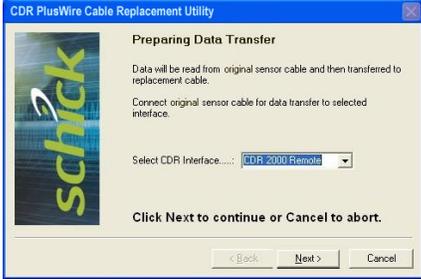
3.4. After Replacing the CDR PlusWire Cable

Any additional items that were not used during the replacement procedure (extra labels, for example, or elastomeric strips) can be retained.

International customers residing in countries where the Waste Electrical and Electronic Equipment (WEEE) Directive has been implemented should contact their local dealers for more information regarding the proper disposal of the failed cable assembly.

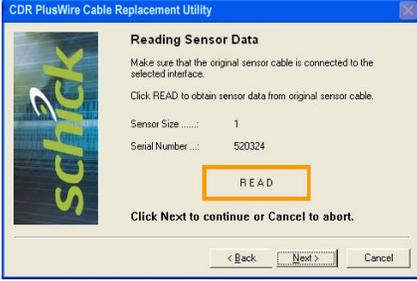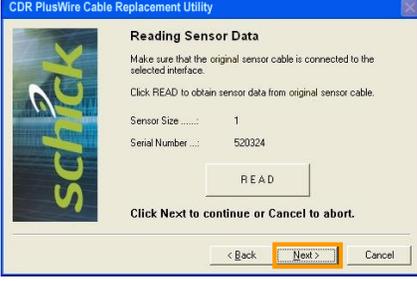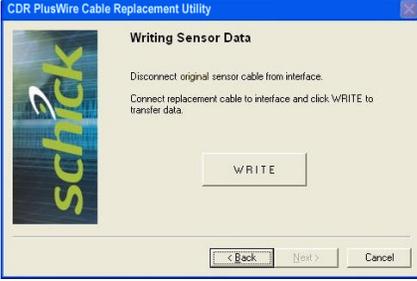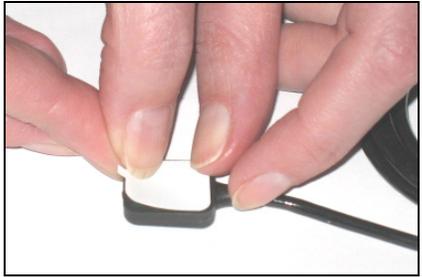## 3.5. CDR PlusWire Cable Replacement

IMPORTANT!: Close CDR DICOM and any other imaging application (EagleSoft or Patterson Imaging) prior to starting the cable replacement procedure.

Step	Directions and Screenshots	
1.	Connect the CDR Sensor with the original cable to the CDR Interface (CDR Remote, CDR Remote HS, or Sensor Interface on the SDX Intraoral X-ray System).	
2.	A. Insert the CDR PlusWire Utility CD at the workstation where the cable is connected. B. Browse to your CD drive and double-click on **CDR PlusWire Cable Replacement Utility.exe**.	
3.	The **Preparing Data Transfer** screen is displayed. The utility will automatically detect the CDR Interface.	
4.	Click **Next**.	
5.	The **Reading Sensor** data screen is displayed. *NOTE:* *Some computers may generate Windows messages stating that "USB Device is not recognized. This message is normal and can be ignored.*	

Step	Directions and Screenshots
6.	Click **Read**. Sensor Size and Serial Number information are displayed
7.	Click **Next**.
8.	Disconnect Sensor with the original cable (to be replaced) from the CDR Interface**.**
9.	Connect the new replacement cable to the CDR Interface. You do not need to have the cable attached to the Sensor for this step.
10.	Verify that the **Writing Sensor Data** screen is displayed. *NOTE: Some computers may generate Windows messages stating that "USB Device is not recognized. This message is normal and can be ignored.*
11.	Click **Write**.

Step	Directions and Screenshots	
12.	The **Data Transfer Successful** screen is displayed.	
13.	Click **Finish** and remove the CD. The new cable is ready to be attached to the Sensor.	
14.	Carefully peel away the black label from the back of the Sensor.	
15.	A. Using the small screwdriver provided, remove the 4 screws and the old cable. B. Remove the old elastomeric strip from the Sensor. C. A new strip is supplied with the new cable (details in next step).	
16.	A. Remove the protective label from the new cable. B. Verify that the small strip, visible when the sticker is removed, remains properly seated.	

Step	Directions and Screenshots
	IMPORTANT! The strip must be seated properly <u>in its slot</u> for the Sensor to function. Verify correct seating by applying a small amount of finger pressure to ensure the strip fits evenly in the slot.	
17.	Align cable to Sensor as shown. Ensure that the keying feature in the Sensor mates with the corresponding keying feature in the cable assembly.	
18.	Attach the replacement cable to the Sensor using 4 screws provided. Tighten screws securely, but do not apply excessive force	
19.	A. Make sure that the area where the label will be applied is clean and dry. B. Use a new label and peel away adhesive backing. C. Position the label over the screws as shown, centering it on the back of the Sensor (adhesive-side down). D. Press down evenly for good contact. Sensor can be used immediately with sheaths and recommended positioning products.	
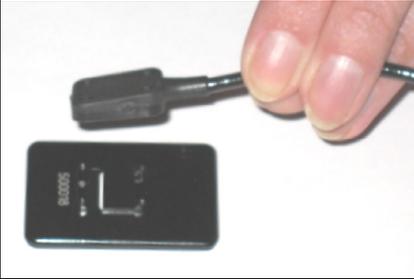
4. Protective Measures

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

CDR Remotes, CDR HS Remotes, and SDX Intraoral X-ray Sensor Interfaces are not intended to come in contact with a patient during clinical use. If they become soiled, whether as a result of contact with a patient or otherwise, they should be cleaned following the same protocol as the CDR PlusWire 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.

Sirona Dental disposable tabs and holders are single–use only, as are the hygenic barriers (sheaths) that are used with them.

4.1. Cleaning and Disinfecting

In a clinical use environment, dental care professionals should wear protective disposable gloves and cover the CDR PlusWire Sensor with a hygienic barrier. Before using the CDR PlusWire 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 Remote, or CDR Remote HS, or SDX X-ray Sensor Interface.

6. If the Sensor or cable is 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 4.2 on page 16. 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 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.

4.2. Recommended Disinfectant

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)

5. Maintenance

5.1. Visual Inspection

Like all electrical equipment, the CDR PlusWire requires 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 PlusWire operates 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 Sirona Dental products for further instructions.

5.2. 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 are undamaged

- Check that there is no external damage to the CDR PlusWire which could compromise its ability to operate safely.

5.3. Damaged or Non-Functioning Sensor

In the event of obvious physical damage to the Sensor, or in the event that cable replacement does not restore the Sensor to proper operation, customers shall discontinue use of the Sensor, substitute another Sensor if available, and contact their local distributor of Sirona Dental products.

In the United States, customers can contact the Patterson Technology Center at 877-498-6505. Outside the United States, please contact the authorized dealer for Sirona Dental products in your country or region.

Appendix A. Reference

A-1. Summary of Specifications

CDR PlusWire is ETL-certified and complies with the following.

Table 4. Specifications

Item	Value	
EMC/Safety	CAN/CSA C22.2 No.601.1-M90	Medical Electrical Equipment Part 1: General Requirements for Safety
	EC93/42/EEC	Medical Device Directive
	IEC60601-1	Medical Electrical Equipment Part 1: General Requirements for Safety
	IEC60601-1-2	Medical Electrical Equipment Part 1: General Requirements for Safety 2.Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
	UL60601-1	Medical Electrical Equipment: General Requirements for Safety
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	
Outer Sensor	(mm) 37 x 24 (size 1); 43 x 30 (size 2)	
Sensor Active Area	(mm) 30 x 20 (size 1); 36 x 25.6 (size 2) ; (mm2) 600 (size 1); 921 (size 2)	
Sensor Thickness	(mm) <5	
Dynamic Range	4096:1	
Weight	1.4 oz. (40g)	
Cable Lengths	(ft) 3, 6, 9	
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	

A-2. Leakage Current Statement

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

A-3. EMC Tables

The following tables provide CDR PlusWire compliance information to electromagnetic compatibility (EMC) and electromagnetic immunity (EMI) standards. To ensure conformance, the customer or user must use the CDR PlusWire in environments that are consistent with these standards. USB cables used with CDR Interfaces must also comply with the same standards.

Table 5. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

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

Emissions Test	Compliance	Guidance
RF emissions CISPR 11	Group 1	CDR PlusWire 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	CDR PlusWire 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 6. Guidance and Manufacturer's Declaration - Electromagnetic Immunity

PLEASE NOTE: CDR PlusWire is intended for use in the electromagnetic environment specified below. The customer or user of CDR PlusWire 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 CDR PlusWire requires continued operation during mains interruptions, it is recommended that the PC workstation to which CDR PlusWire is connected be powered from an uninterruptible

Immunity Test	IEC 60601 Test Level	Compliance Level	Guidance
IEC 61000-4-11	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	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	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	Power frequency magnetic fields should be at levels characteristic of a typical location in 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 CDR PlusWire, 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

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

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

Table 7. Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and CDR PlusWire		

PLEASE NOTE: CDR PlusWire is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of CDR PlusWire can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and CDR PlusWire 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.

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