

CDR Wireless / SDX Software User Guide

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Notice to Customers in European Countries

For customers in European countries, additional information about the CDR Wireless system is provided below. Refer to the following table as well as to other information in this User Guide for an explanation of symbols on CDR Wireless hardware.

| AUS | В | DK | FIN | The \textcircled{O} symbol indicates that the use of |
|-----|-----|----|-----|--------------------------------------------------------------------------|
| | D | GR | IRE | 2.4 GHz devices is restricted in the countries crossed out on this table |
| Ι | LUX | NL | Р | However, the CDR Wireless system |
| Е | S | | | has been designed to comply with these |
| СН | | | | European countries. |

Compliance Statement and Safety Issues

FCC Compliance Statement

Changes or modifications not expressly approved by Schick Technologies could void your authority to operate this equipment. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

Check CDR Wireless Sensor before Using It

Before each usage, check the CDR Wireless Sensor for any signs of physical damage or defect. Make sure the battery pack is attached securely to the Sensor. Before taking X-rays, refer to the CDR Positioning System User Guide for guidelines on using Sensor sheaths, holders, and tabs. The CDR Positioning System User Guide is distributed with Sensor Holder kits and is also available on our website.

Secure Protective Covers to Base Station Connector Panels

If you choose to position the Antenna / Receiver and SDX USB Interface separately (undocked), you must add the protective covers to the connector sides of these devices. These covers reduce the risk of accidental contact with cable connectors. Refer to the CDR Wireless / SDX Software Installation Guide for assembly instructions.

Observe Proper Handling, Storage, and Disposal for Batteries

Your CDR Wireless Sensor is equipped with disposable batteries that have been packaged and protected at the factory. Be sure to read the special instructions relating to battery usage and follow all of the guidelines for storage and disposal.

Do not use Snap-A-Ray Holders with CDR Wireless Sensors

Any type of clamping holder, or equivalent instrument, can exert damaging pressure on the Sensor case, including the material and components enclosed inside. This type of damage is not covered by warranty. As an alternative, use our Universal Holders for proper and safe Sensor positioning.

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.

Radio Frequency (RF) Interference Considerations

Although the CDR Wireless / SDX equipment is designed to provide a reasonable degree of protection from electromagnetic interference according to International Electrotechnical Commission (IEC) 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 can be used only at a minimum distance of 5 feet (1.5m) from any part of the SDX equipment.

Any instrumentation or equipment for professional use located near CDR Wireless / SDX systems must conform to Electromagnetic Compatibility regulations appropriate to this type of equipment. 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 electric line.

Do Not Stack CDR Wireless Equipment or Connect it to Items that are Not Part of the System

CDR Wireless / SDX equipment should not be used adjacent to or stacked with other equipment, nor should other items be connected to it that are not part of the system. If adjacent or stacked use is necessary, normal operation shall be observed and verified in that configuration.

Observe Proper Handling and Placement for CDR Wireless Sensors

As with any dental device or instrument placed intraorally, proper care must be taken when using CDR Wireless 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, damage, or accidentally swallow the Wireless Sensor during the X-ray examination.

Explanation of Symbols

Some symbols on the SDX USB Interface label identify the system as having met the requirements for sale within the United States and for export internationally. The "CE" symbol is an example of this type of mark. The remaining symbols provide either technical or directive information, as described below.

| Symbol | Description |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | Indicates Class II equipment. |
| Ť | Indicates Type BF equipment. |
| | Indicates an attention to customers to consult accompanying documents for more information. |
| | Indicates that under certain ambient environmental conditions (especially low humidity), this device may be susceptible to electrostatic discharge (ESD). Appropriate care and handling must be observed to avoid damage. |
| ((r <u>`</u>)) | Indicates that the CDR Wireless Sensor is a source for non-ionizing radiation |
|))@((| Green LED located on the Antenna / Receiver. Displays Receiver status conditions |
| (()) | Green LED Located on the SDX USB Interface. Displays Receiver status conditions |
| | Orange LED located on the SDX USB Interface. Displays SDX USB Interface status conditions |

Label Locations

Sensor Label

Refer to the following figure for labels and / markings found on the CDR Wireless Sensor.



Battery Package Label

Refer to the following figure for labels and / markings found on CDR Wireless Sensor Battery Packages.

| Label | Description |
|---------------------------------------------------------------------------------|--------------------------------------------|
| Schick Technologies, Inc. Long Island City, NY P/N: B1240100 MFG: 2003 | Regulatory Markings and Manufacturer Label |

Antenna / Receiver Module Label

Refer to the following figure for labels and / markings found on the Antenna / Receiver Module (CDR Wireless System only).

| Label | Description |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| CONFORMS TO UL STD. 2601-1. CERTIFIED TO CAN.CSA C22.2 NO.601.1 CDRW RECEIVER MODULE P/N B2600210 S/N xxxxx MFR xxxx SCHICK TECHNOLOGIES, INC. L.I.C., NY III01 | Regulatory Markings and Manufacturer Label (located on bottom) |

SDX USB Interface Module Label

Refer to the following figure for labels and / markings found on the SDX USB Interface Module.

| Label | Description |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| CONFORMS TO UL STD. 2601-1. CERTIFIED TO CAN.CSA C22.2 NO.601.1 CDRW USB INTERFACE MODULE P/N B2600200 S/N XXXXX MFR XXXX SCHICK TECHNOLOGIES, INC. L.I.C., NY III01 | Regulatory Markings and Manufacturer Label (located on bottom) |

Terms Used in this Document

Base Station Antenna / Receiver

Receives, via wireless RF link, the image acquired from the CDR Wireless Sensor and sends it to the CDR Wireless / SDX USB Interface. The device is powered from the computer's USB port.

CDR-W (CDR Wireless)

Describes the wireless implementation of the CDR imaging system manufactured by Schick Technologies.

CDR2000 Sensor

Captures the image created when the Sensor is exposed to radiation from an SDX or other X-ray source and transmits the image over wired link.

CDR Software (CDR DICOM for Windows)

Provides advanced features for image acquisition, review, manipulation, printing, and storage.

CDR Wireless Sensor

Captures the image created when the Sensor is exposed to radiation from an SDX or other X-ray source and transmits the image over wireless RF link.

CDR Wireless / SDX Interface Driver

Name on the CD-ROM containing the driver for the SDX USB Interface.

CDR Wireless / SDX USB Interface

Communicates, via wired USB link, with attached computer hardware, enabling acquired images to be displayed on a computer monitor or other display system. The device is powered from the computer's USB port. Also contains a Sensor configuration cradle used to set the CDR Wireless Sensor's transmission channel and can be used for Sensor diagnosis. (*A shortened name, SDX USB Interface, is used in text.*)

CDR Wireless / SDX Utility

Configures and diagnoses CDR-W and SDX systems. (A shortened name, SDX Utility, is used in text.)

RF (Radio Frequency)

Alternating current waveform suitable for wireless transmission.

RJ (Registered Jack)

RJ-45 is the connector type at each end of the Category 5 cable used in the CDR-W system to convey data between the Antenna / Receiver and the SDX USB Interface when they are not connected to each other.

SDX (Schick Dental X-ray)

Describes the Intra-oral X-ray Source and supported hardware and software from Schick Technologies, Inc.

SDX USB Interface

Shortened name of CDR Wireless / SDX USB Interface.

SDX Utility

Shortened name of CDR Wireless / SDX Utility.

USB (Universal Serial Bus)

Plug and play interface between host computer and connected USB-compatible devices.

Wireless / SDX Interface

Name of CDR Wireless / SDX USB Interface in Windows Device Manager.

1.CDR Wireless System

1.1. Overview

This section describes the operation and use of CDR Wireless Sensors, SDX USB Interface, and Antenna / Receiver in the CDR Wireless System.

Please Note: For information on using CDR2000 Sensors and CDR Wireless Sensors in the SDX Intra-oral X-ray System, refer to Section 2. For a description of product names and acronyms, refer to the list of terms in the front of the manual.

1.1.1. Purpose

The following elements are part of an electronic imaging system, manufactured by Schick Technologies, that transmits X-ray dental exams over wireless link.

- CDR Wireless Sensor
- SDX USB Interface
- External Antenna / Receiver
- Drivers and application software.

1.1.2. Indications for Use

The CDR Wireless system is intended for any dental practice that uses X-ray equipment for intraoral diagnostic purposes. It can be used by trained dental professionals for patients receiving intraoral X-ray examinations and produces digital images that can be displayed, enhanced, printed, and saved.

1.1.3. Important Setup Reminders

- Images acquired with CDR Wireless Sensors are transmitted to the Antenna / Receiver over RF link. If active during image transmission, other devices using RF or microwave technology (wireless Local Area Networks, wireless telecommunication devices, microwave ovens) may interfere with the optimal performance of your CDR Wireless System. For best results, run the Real-Time RF Environment Test for information about potential RF interference, or turn off other wireless or microwave devices when using your CDR Wireless Sensor. If these devices must remain on, they will cause less interference the further they are from the Antenna / Receiver.
- 2. Correct placement of the Antenna / Receiver with respect to the CDR Wireless Sensor is essential. Be sure to follow the positioning information found in this document when establishing the optimal location for the Antenna / Receiver. As a general rule, place the Antenna / Receiver facing the patient, as close as practically possible to the patient chair where the Sensor will be used. Optimally, the distance between the Sensor and the Antenna / Receiver should not exceed 6 feet (1.8 meters).

Refer to the CDR Wireless / SDX Software Installation Guide for more information on antenna positioning.

3. As with any dental X-ray procedure, stabilizing the Sensor in the correct intraoral position is critical for diagnostic quality images. To achieve stable Sensor positioning during X-ray exams, use the appropriate tabs and holders available with the CDR system. Equally important is for the patient to remain completely still as X-ray images are acquired. CDR Wireless Sensors are more sensitive to motion during the examination, so be sure to remind your patients as you take X-ray images.

1.2. Hardware

The hardware elements of the CDR Wireless system (**Figure 1**) consist of the CDR Wireless Sensor (with battery pack), Antenna / Receiver, and SDX USB Interface, a compatible PC workstation, and interconnecting cables. The Antenna / Receiver and the SDX USB Interface can be attached directly to each other or connected by network cable; in this case when they are connected together, the term "CDR Wireless Base Station" will be used.



- 2 SDX USB Interface
- 3 CDR Wireless Sensors
- 4 PC Workstation

Figure 1. CDR Wireless System

1.2.1. CDR Wireless Sensor

The CDR Wireless Sensor provides FM digital data to the Antenna / Receiver over the 2.4 GHz frequency band. Three, user-selectable channels are available to minimize interference from other RF devices and to provide optimal communication in practices where multiple CDR Wireless Sensors are in use.

Power for the CDR Wireless Sensor is provided by a water resistant, non-rechargeable battery package located on the back (non-active pixel area) of the Sensor. Battery status is displayed on the Sensor using a single window, dual LED display. (For more information about the CDR Wireless Sensor LEDs and their indications, refer to **Table 1**.) Battery level information is also available in the Sensor Monitor dialog box (**Figure 10**), where RF channel number, battery level, signal quality, and Sensor information can be found.

Please Note: When detached from the Sensor, place the battery pack on its back with the terminals facing upwards. Ensure that no conductive object contacts the battery terminals to prevent accidental discharge.

The Sensor ON / OFF switch is part of the battery package. Turn the Sensor on and off by pressing lightly on the button shown below. The CDR Wireless Sensor must be turned ON to capture X-ray images. The Sensor will turn itself OFF automatically if no X-ray exposures are detected for approximately 5 minutes.



Figure 2. CDR Wireless Sensor with Battery Pack Removed

1.2.2. Antenna / Receiver

The CDR Wireless Base Station is composed of the Antenna / Receiver and SDX USB Interface. The Antenna / Receiver receives the radio frequency status and image data signals from the CDR Wireless Sensor, demodulates the signals, and transfers the information to the SDX USB Interface. The LED located near the base of the Antenna indicates power and Receiver activity.

The Antenna / Receiver can be positioned separately from the SDX USB Interface to enhance signal reception. Nominally, the Antenna / Receiver should be within 6 feet (1.8 meters) of the CDR Wireless Sensor and facing the patient for best results. The Antenna can be pivoted forward-and-back and rotated from left-to-right to achieve optimum reception.

Please Note: The side of the Antenna indicated by the symbol shown in **Figure 3** identifies the active side of the Antenna. This side must face the patient.

¥

Figure 3. Symbol Designating Active Side of Antenna

The Antenna / Receiver and SDX USB Interface are shipped connected directly to each other ("docked"). Two screws are used to secure the units. Remote mounting of the Antenna / Receiver from the SDX USB Interface is optional, and may be desirable depending on a number of factors (including physical layout of the office and / or RF reception). The base of the Antenna contains molded areas to allow for wall- and ceiling-mounted options.

When the Antenna / Receiver is mounted remotely, the two screws securing the Antenna / Receiver to the SDX USB Interface must be removed allowing the two units to be unplugged from each other. (The location of these screws is shown in **Figure 4**.) A standard computer network modular Category 5 cable with RJ-45 connectors may be used to connect the Antenna / Receiver to the SDX USB Interface.







Figure 5. Antenna / Receiver

1.2.3. SDX USB Interface

The SDX USB Interface connects the CDR hardware to the computer via standard USB port. It also provides channel selection for CDR Wireless Sensors, performs Sensor diagnostics, and supports field upgrades of the firmware for the unit itself, the Antenna / Receiver, and CDR Wireless Sensors. When opened, the translucent compartment lid permits access to the Sensor cradle (used for RF channel configuration and diagnostics) and a storage slot for a battery pack. When closed, the compartment lid serves to protect the Sensor and battery pack when not in use.

Dual LEDs are located on the exterior of the SDX USB Interface and report power and status information about the unit and the CDR Wireless Sensor currently in use. LED indications have several states to reflect various states of operation. For more information about the SDX USB Interface LEDs and their indications, refer to **Table 3** on page 16.

The SDX USB Interface can be wall-mounted, either "docked" with the Antenna / Receiver itself, or located some distance from the Antenna, via Category 5 cable with RJ-45 connectors. For details on installation options, refer to the CDR Wireless / SDX Software Installation Guide.



Figure 6. SDX USB Interface

1.2.4. PC Workstation

The PC workstation (CE-approved computer system conforming with the Low Voltage [73/23/EC] and EMC Directive [89/336/ERC]) connects to the SDX USB Interface via a compatible USB cable and serves as the host for CDR software and utilities. For safety, connect the cable from the SDX USB Interface to Listed / Approved / Certified Information Technology Equipment (ITE) computer equipment only. The workstation provides the capabilities to display, manipulate, store, and print images acquired with CDR Wireless hardware. Recommended system requirements for the PC workstation is listed below:

- Compatible operating system (Windows 2000 or XP)
- Minimum of 64 MB RAM
- Minimum of 20 MB free disk space (to install CDR software)
- Minimum of 20 GB free disk space (to store X-ray images you acquire or convert to DICOM format)
- Available USB port

When connecting the SDX USB Interface to the PC workstation, we recommend the use of a 1 meter (3.28 feet) USB cable (28AWG/2C and 20 AWG/2C) with the "/2c" designation marked along the cable, typically at either end and close to the connector. The "/2c" designation is the USB spec designation for power connectors inside the cable, and is a requirement for this system.



Figure 7. USB Connector and Cable Marking

1.3. Software

CDR software provides the interface and control between the CDR Wireless System hardware and the computer. It provides the customer with advanced features for acquisition, display, manipulation, storage, and printing of acquired X-ray images. Please refer to the CDR DICOM User Guide for more details.

Functions specific to the CDR Wireless System have been added to CDR software to provide configuration, monitoring, and diagnosis of system components. General information on the Sensor Monitor and SDX Utility can be found in this section. For more details about using these tools during system installation, refer to the CDR Wireless / SDX Software Installation Guide.

1.3.1. Configuring CDR Wireless Sensors

To select Wireless Sensors as the default Sensor type in CDR DICOM software, you should access the appropriate settings in CDR Options. Each time you change from one type of Sensor to another (Wireless or CDR2000) in CDR Wireless systems, it will be necessary to repeat this step, which is described in the following paragraph. By interchanging CDR2000 and Wireless Sensors in a CDR Wireless system, you effectively choose the USB hardware that supports the Sensor you will use (either the Wireless / SDX Interface or the CDR2000 USB Remote). In comparison, SDX systems are able to dynamically recognize the type of connected Sensor — Wireless or CDR2000 — without having to make this selection in CDR Options.

To prepare CDR DICOM software for either CDR2000 or CDR Wireless Sensors, open CDR DICOM software (if it is not running already), and click **System** > **Options** to display the acquisition settings. Click on the Acquisition Modules tab, select the X-ray module, and click Properties (**Figure 8**). Use the Hardware Type drop-down box (X-ray tab) to select either CDR2000 USB Remote (for CDR2000 Sensors) or Wireless / SDX Interface (for CDR Wireless Sensors). Click OK to close the Properties sheet. Click OK to exit CDR Options.

Until you modify this setting again, the hardware type you chose will remain the default for the current and subsequent CDR DICOM sessions.

| ^o rint Configuration | Directories | Institutio |
|---------------------------------------------|----------------------|-------------------|
| General | Windows A | equisition Module |
| Installed Acquisition I | Modules | |
| Module | Modality | |
| 🕷 Xray | 10 | |
| 💼 Video | XC | Add |
| 😎 Panoramic | PX | - |
| 📥 Scanner | ОТ | <u>H</u> emove |
| | - Auto Take | |
| | Charl when April | ication starts |
| U seducero loto | Statt When Appl | Contern statist |
| Hardware Info | Final Interval (and) | 1 - |
| <u>H</u> ardware Info | Flash Interval (sec) | 1 - |
| Hardware Info | Flash Interval (sec) | 1 - |
| <u>H</u> ardware Info Properties | Flash Interval (sec) | 1 - Stop |
| <u>H</u> ardware Info <u>P</u> roperties | Flash Interval (sec) | 1 V Stop |

Figure 8. CDR System Options

1.3.2. SDX Utility

The SDX Utility (wstools.exe), accessible from the Windows Start menu and listed in the CDR DICOM for Windows program group, identifies, diagnoses, and resolves configuration and communication issues in or between the Sensor and the CDR Wireless Base Station.

The SDX Utility can be used to perform the following tasks:

- Select the Sensor and Receiver RF channel
- Perform firmware upgrades
- Read version information
- Perform diagnostic tests
- Register Wireless Sensors

The first three tasks are immediately accessible from the SDX Utility screen (**Figure 9**). The remaining items — diagnostic tests and Wireless Sensor registration — open separate, Wireless Sensor-related tools, so click on the appropriate button (RF environment, Sensor Monitor, or Register Sensors) to display them.

The RF environment test and Wireless Sensor registration are especially useful during the initial installation of the CDR Wireless System, so you will find more information about these tools in the CDR Wireless / SDX Software Installation Guide. For more information on Sensor Monitor settings, including Wireless Sensor locking, continue with the next paragraph.

| Sensor info | USB interface | Sensor | Receiver |
|--------------------------------------|------------------|------------------|------------------|
| BSL revision: Firmwara ravision: | Read info | Read info | Read info |
| CPLD revision: | Test interface | Upgrade firmware | Upgrade firmware |
| Benal number. Date of production: | Upgrade firmware | Upgrade CPLD | |
| OEM code: Type: | Upgrade CPLD | | |
| Size: | Set RF cl | hannels | Wireless system |
| A/idth: | 🗖 Match channels | Reset | RF environment |
| Height | Sensor 0 - | Apply | |
| Receiver info | Receiver 0 - | Apply | Sensor monitor |
| Firmware revision: 2.4 | | | Register Sensors |
| USB interface info | | | 4 |
| Firmware revision: 2.3 | | | |
| CPLD firmware revision: 2.2 | | | F×it |

Figure 9. SDX Utility (CDR Wireless Sensor Detected)

1.3.3. Sensor Monitoring

The Sensor Monitor (**Figure 10**) provides real-time reporting of the CDR Wireless Sensor, shows the current status of several elements required for proper operation, and enables registered Wireless Sensors to be locked to the current workstation (useful when multiple Wireless Sensors are active at the same time). Under certain conditions the Sensor Monitor will be displayed automatically, or it can be started from the SDX Utility.

- The Sensor Monitor will be displayed automatically when CDR DICOM is started and the CDR Wireless hardware type is selected. The Sensor Monitor can be minimized, but it will remain active in the System Tray until the CDR DICOM application is closed.
- The Sensor Monitor can also be displayed using the SDX Utility. In Windows XP, click the Windows Start menu > All Programs > CDR DICOM for Windows > SDX Utility (the steps for other operating systems will differ). At the SDX Utility Screen, click Sensor Monitor. The Sensor Monitor can be minimized, but it will be removed from the System Tray if you click on any other button in the Information Screen. To display the Sensor Monitor again, click on the Sensor Monitor button.

Status information displayed on the Sensor Monitor will vary with usage and environment — there are no perfect measurements, but customers should try to obtain and maintain the highest levels attainable. In the event of partial image corruption due to RF interference, CDR software will identify those areas on the displayed image so that dental professionals can evaluate whether another exposure is required.



Figure 10. Sensor Monitor

Checkboxes on the Sensor Monitor provide important selections for customers with the following setups: when multiple CDR Wireless Sensors share the same RF channel, and when CDR Wireless Sensors are used with more than one CDR Wireless Base Station. For information on why these checkboxes are important, refer to the following paragraph.

1.3.3.1. Sensor Monitor Checkbox: Sensor Locked

In practices where multiple CDR Wireless Sensors are operating, the "Sensor Locked" checkbox helps customers manage the Wireless Sensors used with workstations. As there are only three RF channels to choose from, the operation of more than three CDR Wireless Sensors in practices will mean that some CDR Wireless Sensors, if active at the same time, will be transmitting images to their Base Stations using the same RF channel.

While this is a normal and expected use of the CDR Wireless system (particularly in larger practices), the Sensor Locked checkbox enables customers to select a specific, CDR Wireless Sensor from a list of registered Sensors for a particular Base Station. (*The currently detected Sensor will always appear at the top of the list, even if it has not been registered.*)

In effect, the Base Station ignores all images except those sent by the CDR Wireless Sensor that is "locked" with it and identified by serial number in the Sensor Monitor. This selection helps ensure that an image sent by a CDR Wireless Sensor is received by the Base Station expecting it. (*For details on registering Wireless Sensors using the SDX Utility, refer to the CDR Wireless / SDX Software Installation Guide.*)

To summarize, there are three points to keep in mind when marking this checkbox:

- 1. This checkbox is intended primarily for practices where multiple CDR Wireless Sensors share the same RF channel.
- 2. Any registered Wireless Sensor can be locked, selected, and unlocked using the Sensor locked checkbox.
- 3. In practices where several CDR Wireless Sensors are active, noisy RF conditions could result in the display of the "Another Sensor is on the same channel" message in CDR. Marking the Sensor locked checkbox and selecting the Wireless Sensor you wish to use with the workstation will resolve this situation. If you have already locked the Wireless Sensor, this message will appear to alert you that other Wireless Sensors are active on the same channel.



Figure 11. Selecting Registered Wireless Sensors

1.3.3.2. Sensor Monitor Checkbox: Base Station Disabled

When using CDR Wireless Sensors with more than one Base Station, leave the "Base Station disabled" checkbox <u>blank</u> in the Sensor Monitor of the Base Station receiving the images and the checkbox <u>filled</u> in the Sensor Monitor of the other Base Station(s). When disabled, the Base Station ignores all images sent by any CDR Wireless Sensor — the Base Station without the checkmark is then clearly designated to receive images.

To summarize, there are two points to keep in mind when marking this checkbox:

- 1. To receive images from any CDR Wireless Sensor, leave the Base Station Disabled checkbox blank.
- 2. To ignore images from all CDR Wireless Sensors, mark the Base Station Disabled checkbox. In the case where several Base Stations are sharing the same CDR Wireless Sensor, the "Base Station disabled" box should be checked for all Base Stations except the one with which the CDR Wireless Sensor will communicate.

1.4. Controls and LED Indicators

1.4.1. CDR Wireless Sensor

1.4.1.1. Controls and Indicators

The following illustration and table provide information about the controls and indicators of the CDR Wireless Sensor. When the battery package is attached to the Sensor, the single pushbutton turns the Sensor on and off.



Figure 12. CDR Wireless Sensor Controls and Indicators

When the CDR Wireless Sensor is turned ON, LEDs on the back of the Sensor display battery status information as well as the particular RF channel number (1, 2, or 3) to which the Sensor is set. By observing these initial LED indications, you can help verify that your Sensor is ready for use.

- Sensor LEDs blink green only (battery OK)
- Sensor LEDs blink green and red (battery OK, but starting to run low)
- Sensor LEDs remain red (replace battery)

As battery power decreases, the LEDs will blink and stay red for longer periods until they remain steady red, indicating that it is time to replace the battery. An additional source of battery level information is the Sensor Monitor, which can be found in the System Tray of your workstation.

Checking the LEDs also helps make the exam setup process more efficient — enabling you to change the battery, if necessary, <u>before</u> you start taking intraoral images. If, during an X-ray exam, battery power becomes low, you will receive a low-battery message on your computer screen. To avoid reductions in image quality, we recommend changing the battery whenever the low-battery message is displayed.

LEDs also report whether a RF channel is selected — the Sensor must be set to one channel number (the same) as the Antenna / Receiver for proper communication. More information about LED indications can be found in **Table 1**.

| Action | Visual Indications | | Status | | |
|-----------------------------|--------------------------------------|-----------------------------|------------|---------------------------------------------------|------------------------------------------------------------|
| Action | Green LED | Red LED | RF Channel | | Battery |
| | ON and blinking RF channel status | OFF | Ch. 1 | 1 long, 1 short | |
| | | | Ch. 2 | 1 long, 2 short | |
| Turn on Sensor | | | Ch. 3 | 1 long, 3 short | ОК |
| | ON (steady, no blinking) | OFF | None | 1 long only (Channel not set or RF problem) | |
| | Blinking every 6 seconds | OFF | OK | | OK |
| Sensor on | ON | OFF | OK | | OK |
| | ON | ON (See Note) | ОК | | Battery power low (See Note) |
| Turn off Sensor | ON momentarily and then OFF | ON momentarily and then OFF | OK | | ОК |
| Sensor off or not available | OFF | OFF | OFF | | Battery power depleted or battery OK (Sensor is off) |

NOTE: As battery power decreases, the LEDs will blink and then stay red for longer periods until they remain steady red, indicating that it is time to replace the battery.

1.4.2. Antenna / Receiver

Once a good RF link has been established with the CDR Wireless Sensor, no additional configuration is needed. There are no On / Off controls on the device.

1.4.2.1. Controls and Indicators

The following illustration provides information about the connections and indicators of the Antenna / Receiver.





| Table 2. Antenna / Receiver LED Indication |
|--------------------------------------------|
|--------------------------------------------|

| Green LED | |
|-----------|--------------------------------------------|
|))@((| Status |
| ON | Antenna is on (power on) |
| OFF | Antenna is off (no power) or not connected |

1.4.3. Interface

When the cable connection is made between the SDX USB Interface and the Antenna / Receiver (not required if the two units are docked together) and between the SDX USB Interface and the PC Workstation (required), no additional configuration is needed. There are no On / Off controls on the device. LEDs located on the unit provide status information about the system and the CDR Wireless Sensor currently in use. Refer to **Table 3** for details.

1.4.3.1. Controls and Indicators

The following illustration provides information about the connections and indicators of the SDX USB Interface.



Figure 14. SDX USB Interface Connections



Figure 15. SDX USB Interface Indicators

| Green LED | Orange LED | |
|------------|---------------------|------------------------------------------------------------------------------|
| (Receiver) | (SDX USB Interface) | Otatus. |
| (i)) | | Status |
| ON | OFF | USB cable connected, Sensor not detected |
| OFF | ON | Error condition |
| ON | ON | USB cable connected, Sensor detected |
| ON | Blinking rapidly | Sensor is acquiring image and transmitting it to computer across USB |
| OFF | OFF | USB cable not connected if CDR is running, or USB driver is not installed |

Table 3. SDX USB Interface LED Indications

1.5. Using Your CDR Wireless Sensor

1.5.1. Sensor Sheaths

Please Note: To place sheaths and holders properly, please refer to the CDR Positioning System User Guide, distributed with Sensor Holder kits and also available on our website.

Sheaths and the appropriate holders are required for CDR Wireless Sensors. New sheaths and Sensor holders (disposable type) are required for each new patient and must be disposed of properly after patient use. Sheaths for CDR Wireless Sensors must be sealed before use to ensure proper patient protection.

To achieve stable Sensor positioning during X-ray exams, use the appropriate tabs and holders available with the CDR system. When positioning the Sensor, the inverse pixel box located on the CDR Wireless Sensor can be used to determine the orientation of the image exposure (**Table 4**).

1.5.2. Taking X-rays

Perform the following steps to take an X-ray using CDR DICOM 3.0.1 or later CDR DICOM software. If you are using a different image acquisition program, refer to documentation supplied with that product.

- 1. Start your image acquisition program (CDR DICOM or Eaglesoft) and either create a new exam or open a patient record.
- 2. The acquisition software recognizes the Sensor and enters AutoTake or Manual mode, depending on your system settings.
- 3. The Sensor Monitor opens, showing the battery level of the detected Wireless Sensor and RF signal quality.
- 4. Perform patient setup and Sensor positioning steps.
- 5. When the exam window viewbox blinks with the appropriate visual prompt (green by default during AutoTake mode), activate the X-ray source (SDX or other).
- 6. When acquisition is complete, the image appears in the zoom window.
- 7. CDR advances to the next empty frame automatically. To take another image, reposition the Sensor and Holder if needed and repeat this procedure starting at Step 4.

| Sensor Location | Inverse Pixels (Circled) and Sensor Orientation | Inverse Pixels (Circled) and Image Orientation |
|------------------------|----------------------------------------------------|------------------------------------------------|
| Patient's left side | schick | Left Bitewing |
| Patient's upper jaw | CDRWreess schov | Anterior Periapical, Maxillary |

Table 4. Examples of CDR Wireless Sensor to Image Orientation

2.SDX System

2.1. Overview

This section describes the operation and use of CDR2000 and CDR Wireless Sensors in the SDX Intra-oral X-ray System, which includes the SDX X-ray Source, integrated Antenna and Receiver, and SDX USB Interface.

Please Note: For information on using CDR Wireless Sensors in the CDR Wireless System, refer to Section 1. For a description of product names and acronyms, refer to the list of terms in the front of the manual.

2.1.1. Purpose

The following are elements of an electronic imaging system, manufactured by Schick Technologies, that transmits X-ray dental exams over a wired or wireless RF link.

- SDX Intra-oral X-ray Source
- CDR2000 Sensors
- CDR Wireless Sensors
- Internal Antenna and Receiver
- SDX USB Interface
- Drivers and application software.

2.1.2. Indications for Use

The SDX system is intended for any dental practice that uses the SDX Intra-oral X-ray equipment for intraoral diagnostic purposes. It can be used by trained dental professionals for patients receiving intraoral X-ray examinations and produces digital images that can be displayed, enhanced, printed, and saved.

2.1.3. Important Setup Reminders

- 1. Images acquired with CDR Wireless Sensors are transmitted to the SDX Antenna and Receiver over RF link. If active during image transmission, other devices using RF or microwave technology (wireless Local Area Networks, wireless telecommunication devices, microwave ovens) may interfere with the optimal performance of the system when using CDR Wireless Sensors. For best results, run the Real-Time RF Environment Test for information about potential RF interference.
- 2. As with any dental X-ray procedure, stabilizing the Sensor in the correct intraoral position is critical for diagnostic quality images. To achieve stable Sensor positioning during X-ray exams, use the appropriate tabs and holders available with the CDR system. We also recommend the use of SDX-compatible Sensor Positioning Arms with CDR Wireless and CDR2000 Sensors.

2.2. Hardware

The SDX Intra-oral X-ray system, which includes the SDX X-ray source, Timer Module, Extension and Scissors arms, and Keypad, supports CDR2000 and CDR Wireless Sensors and provides an optimized digital solution for CDR customers. **Figure 16** provides an illustration of these items.



Figure 16. SDX System (Wall-Mounted Installation)

2.2.1. CDR2000 Sensor

The CDR2000 Sensor provides digital data transmission conveyed via strain-relieved 2meter cable terminating in an edgecard connector and compatible with the interface located on SDX enclosure cover.

2.2.2. CDR Wireless Sensor

The CDR Wireless Sensor provides FM digital data to the Antenna / Receiver over the 2.4 GHz frequency band. Three, user-selectable channels are available to minimize interference from other RF devices and to provide optimal communication in practices where multiple CDR Wireless Sensors are in use.

Power for the CDR Wireless Sensor is provided by a water resistant, non-rechargeable battery package located on the back (non-active pixel area) of the Sensor. Battery status is displayed on the Sensor using a single window, dual LED display. (For more information about the CDR Wireless Sensor LEDs and their indications, refer to **Table 1** on page 13.) Battery level information is also available in the Sensor Monitor dialog box (**Figure 10** on page 10), where RF channel, signal quality, and Sensor information can be found.

Please Note: When detached from the Sensor, place the battery pack on its back with the terminals facing upwards. Ensure that no conductive object contacts the battery terminals to prevent accidental discharge.

The Sensor ON / OFF switch is part of the battery package. Turn the Sensor on and off by pressing lightly on the button shown below. The CDR Wireless Sensor must be turned ON to capture X-ray images. The Sensor will turn itself OFF automatically if no X-ray exposures are detected for approximately 5 minutes.



Figure 17. CDR Wireless Sensor with Battery Pack Removed

2.2.3. SDX USB Interface

The SDX USB Interface connects the CDR hardware to the computer via standard USB port. It also provides channel selection for CDR Wireless Sensors, performs Sensor diagnostics, and supports field upgrades of the firmware for the unit itself, the Antenna / Receiver, and CDR Wireless Sensors. When opened, the translucent compartment lid permits access to the Sensor cradle (used for RF channel configuration and diagnostics) and a storage slot for a battery pack. When closed, the compartment lid serves to protect the Sensor and battery pack when not in use.

Dual LEDs are located on the exterior of the SDX USB Interface and report power and status information about the unit and the CDR Wireless Sensor currently in use. LED indications have several states to reflect various states of operation. For more information about the SDX USB Interface LEDs and their indications, refer to **Table 5** on page 27.

The SDX USB Interface can be wall-mounted. For details on installation options, refer to the CDR Wireless / SDX Software Installation Guide.



Figure 18. SDX USB Interface

2.2.4. PC Workstation

The PC workstation (CE-approved computer system conforming with the Low Voltage [73/23/EC] and EMC Directive [89/336/ERC]) connects to the SDX USB Interface via a compatible USB cable and serves as the host for CDR software and utilities. For safety, connect the cable from the SDX USB Interface to Listed / Approved / Certified Information Technology Equipment (ITE) computer equipment only. The workstation provides the capabilities to display, manipulate, store, and print images acquired with CDR Wireless hardware. Recommended system requirements for the PC workstation is listed below:

- Compatible operating system (Windows 2000 or XP)
- Minimum of 64 MB RAM
- Minimum of 20 MB free disk space (to install CDR software)
- Minimum of 20 GB free disk space (to store X-ray images you acquire or convert to DICOM format)
- Available USB port

When connecting the CDR Wireless / SDX USB Interface to the PC workstation, we recommend the use of a 1 meter (3.28 feet) USB cable (28 AWG/2C and 20 AWG/2C) with the "/2c" designation marked along the cable, typically at either end and close to the connector. The "/2c" designation is the USB spec designation for power connectors inside the cable, and is a requirement for this system.



Figure 19. USB Connector and Cable Marking

2.3. Software

CDR software provides the interface and control between the SDX System hardware and the computer. It provides the customer with advanced features for acquisition, display, manipulation, storage, and printing of acquired X-ray images. Please refer to the CDR User Guide for more details.

Functions specific to the SDX System have been added to CDR software to provide configuration, monitoring, and diagnosis of system components. More information on the use of the Sensor Monitor and SDX Utility during system installation or upgrade can also be found in the CDR Wireless / SDX Software Installation Guide.

2.3.1. Interchanging CDR2000 and CDR Wireless Sensors

CDR Wireless Sensors will automatically be set as the default hardware type when installed, but customers with CDR2000 and CDR Wireless Sensors can change and swap these Sensors at any time, even during an X-ray exam, or while using the SDX Utility.

2.3.1.1. Switching from CDR Wireless Sensor to CDR2000 Sensor

- 1. Turn off the CDR Wireless Sensor.
- 2. Connect the CDR2000 Sensor to the Sensor Interface on the SDX enclosure cover.
- 3. The acquisition software recognizes the CDR2000 Sensor and enters AutoTake or Manual mode, depending on your system settings. The Sensor Monitor, which was active while the Wireless Sensor was detected, closes automatically.
- 4. Perform patient setup and Sensor positioning steps.
- 5. When the exam window viewbox blinks with the appropriate visual prompt (green by default during AutoTake mode), activate the SDX X-ray source.

2.3.1.2. Switching from CDR2000 Sensor to CDR Wireless Sensor

- 1. Unplug any CDR2000 Sensor currently connected to the Sensor Interface on the SDX enclosure cover.
- 2. Turn on the CDR Wireless Sensor (be sure it is set to the same RF channel as the Receiver).
- 3. The Sensor Monitor opens, showing the battery level of the detected Wireless Sensor and RF signal quality.
- 4. Perform patient setup and Sensor positioning steps.
- 5. When the exam window viewbox blinks with the appropriate visual prompt (green by default during AutoTake mode), activate the SDX X-ray source.

2.3.2. SDX Utility

The SDX Utility (wstools.exe), accessible from the Windows Start menu and listed in the CDR DICOM for Windows program group, identifies, diagnoses, and resolves configuration and communication issues in or between the Sensor and Base Station. The SDX Utility can be used to perform the following tasks:

- Read version information
- Perform firmware upgrades

These tasks can be accomplished once the CDR Wireless / SDX Utility is displayed (**Figure 9** on page 9, and **Figure 19** and **Figure 20**). For step-by-step procedures during new system installations or upgrades, refer to the CDR Wireless / SDX Software Installation Guide.

| CDR Wireless / SDX Enabled Utility | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|---------------------------------------------------------|-----|
| Etep Sensor info BSL revision: 1.30 Firmware revision: 1.0 CPLD revision: 1.0 Serial number: 623877 Date of production: 12/02/2002 OEM code: 0 Type: B Size: 2 Width: 900 Height: 641 USB interface info Firmware revision: 2.2 | USB interface Read info Test interface Upgrade firmware Upgrade CPLD | Sensor Read info Upgrade firmware Upgrade CPLD | |
| CPLD firmware revision: 2.2 | | Exit | |
| Wired sensor is detected. | | | NUM |

Figure 20. SDX Utility (CDR2000 Sensor Detected)

| CDR Wireless / SDX Enabled Utility | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| Belp Sensor info BSL revision: 1.30 Firmware revision: 2.0 Serial number: 85361 Date of production: 04/05/2004 OEM code: 0 Type: 7 Size: 2 Width: 900 Height: 640 BSL revision: 1.10 Firmware revision: 2.4 USB interface info Firmware revision: 2.2 CPLD firmware revision: 2.2 | USB interface Read info Test interface Upgrade firmware Upgrade CPLD Set RF of Ø Match channels Sensor 1 ÷ Receiver 1 ÷ | Sensor Read info Upgrade firmware Upgrade CPLD | Receiver Read info Upgrade firmware Wireless system RF environment Sensor monitor |
| , Wireless sensor is detected. | | | NUM |

Figure 21. SDX Utility (CDR Wireless Sensor Detected)

2.4. Controls and LED Indicators

2.4.1. SDX USB Interface

There are no On / Off controls on the device. LEDs located on the unit provide status information about the system and the CDR Wireless Sensor or CDR2000 Sensor currently in use. Refer to **Table 5** for details.

2.4.1.1. Controls and Indicators

The following illustration provides information about the connections and indicators of the SDX USB Interface.



Figure 22. SDX USB Interface Connections



Figure 23. SDX USB Interface Indicators

| Green LED (Receiver) | Orange LED (SDX USB Interface) | |
|-------------------------|-----------------------------------|------------------------------------------------------------------------------------------------|
| | | Status |
| ON | OFF | USB cable connected, Sensor not detected |
| OFF | ON | Error condition |
| ON | ON | USB cable connected, Sensor detected |
| ON | Blinking rapidly | Sensor is acquiring image and transmitting it to computer across USB |
| OFF | OFF | USB cable not connected if CDR DICOM software is running, or USB driver is not installed |

Table 5. SDX USB Interface LED Indications

2.5. Using Your CDR Sensor

2.5.1. Sensor Sheaths and Positioning Elements

Please Note: To place sheaths and holders properly, please refer to the CDR Positioning System User Guide, distributed with Sensor Holder kits and also available on our website.

Sheaths and the appropriate holders are required for CDR2000 and CDR Wireless Sensors. New sheaths and Sensor holders (disposable type) are required for each new patient and must be disposed of properly after patient use. Sheaths for CDR Sensors must be sealed before use to ensure proper patient protection.

To achieve stable Sensor positioning during X-ray exams, use the appropriate tabs and holders available with the CDR system. Compatible positioning arms have been especially designed for use with the SDX X-ray Source. These arms are compatible with standard Rinn-type aiming rings and our set of Sensor holders.

2.5.2. Taking X-rays with SDX X-ray Source

Whether you use CDR2000 Sensors, CDR Wireless Sensors, or both, your SDX system will automatically detect the currently connected Sensor.

2.5.2.1. Using CDR2000 Sensors

- 1. Connect the CDR2000 Sensor to the Sensor Interface on the SDX enclosure cover.
- 2. Start your image acquisition program (CDR DICOM or Eaglesoft) and either create a new exam or open a patient record.
- 3. The acquisition software recognizes the Sensor and enters AutoTake or Manual mode, depending on your system settings. If you were using a Wireless Sensor during the previous exposure, the Sensor Monitor closes automatically.
- 4. Perform patient setup and Sensor positioning steps.
- 5. When the exam window viewbox blinks with the appropriate visual prompt (green by default during AutoTake mode), press the SDX Keypad Exposure button.

2.5.2.2. Using CDR Wireless Sensors

- 1. Unplug any CDR2000 Sensor currently connected to the Sensor Interface on the SDX enclosure cover.
- 2. Turn on the CDR Wireless Sensor (be sure it is set to the same RF channel as the Receiver).
- 3. Start your image acquisition program (CDR DICOM or Eaglesoft) and either create a new exam or open a patient record.
- 4. The Sensor Monitor opens, showing the battery level of the detected Wireless Sensor and RF signal quality.
- 5. Perform patient setup and Sensor positioning steps.
- 6. When the exam window viewbox blinks with the appropriate visual prompt (green by default during AutoTake mode), press the SDX Keypad Exposure button.

| Sensor Location | Inverse Pixels (Circled) and Sensor Orientation | Inverse Pixels (Circled) and Image Orientation |
|------------------------|----------------------------------------------------|------------------------------------------------|
| Patient's left side | schick | |
| | | Left Bitewing |
| Patient's upper jaw | CDR Wireless | Anterior Periapical, Maxillary |

Table 6. Examples of CDR Wireless Sensor-to-Image Orientation

Table 7. Examples of CDR2000 Sensor-to-Image Orientation

| Sensor Location | Inverse Pixels (Circled) and Sensor Orientation | Inverse Pixels (Circled) and Image Orientation |
|------------------------|----------------------------------------------------|------------------------------------------------|
| Patient's left side | | Left Bitewing |
| Patient's upper jaw | | Anterior Periapical, Maxillary |

3. Troubleshooting Problems in Digital Images

Please Note: For troubleshooting information related to images acquired with film, please refer to the documents supplied with the SDX Intra-oral X-ray Source. For a description of product names and acronyms, refer to the list of terms in the front of the manual.

3.1. Image Exposure Issues (CDR2000 Sensors)

3.1.1. White Images

Possible causes:

- X-ray Source activated before Sensor was ready
- Remote Module has obsolete firmware
- Exposure setting on X-ray source set too low
- Wrong device driver in CDR Registry.

3.1.2. White Lines or White Pixels

Possible causes:

- Calibration file for Sensor not loaded or not found by acquisition software
- Wrong calibration file for connected Sensor.

3.1.3. Dark Bands

Possible causes:

- Two-prong AC adapter used with laptop computers
- Open ground at AC wall outlet (desktop computers).

3.1.4. No Images

Possible causes:

- Sensor not connected
- Sensor not in path of X-ray source
- X-ray source not active while acquisition software was waiting to take X-ray.

3.2. Image Exposure Issues (CDR Wireless Sensors)

3.2.1. Black or White Lines

Possible causes:

- Interference from other RF devices (such as 2.4 GHz phones, microwave ovens, 802.11 wireless LANs, Sirona Cerec III dental restoration systems, Bluetooth devices)
- Calibration file for Sensor not loaded or not found by acquisition software.

3.2.2. No Image

Possible causes:

- Sensor not detected due to interference from other RF devices (such as 2.4 GHz phones, microwave ovens, 802.11 wireless LANs, Sirona Cerec III dental restoration systems, Bluetooth devices)
- Insufficient battery strength
- Sensor not turned on
- Sensor not placed in path of X-ray source.

4. Maintenance

Please Note: For a description of product names and acronyms, refer to the list of terms in the front of the manual.

4.1. Preventive Actions

The following paragraphs address issues in preventive maintenance.

4.1.1. Sensor Cleaning

If attached to the Wireless Sensor, remove the battery pack before cleaning. To clean and disinfect CDR Sensors (Wireless and CDR2000), apply a small amount of isopropyl alcohol (70%) to a non-abrasive, lint-free cloth and wipe down the Sensor.

If you are cleaning a CDR Wireless Sensor, exercise care around the battery contacts and follow the same procedure for the battery pack. After cleaning, inspect the Sensor and the battery pack to ensure that all surfaces are clean and free of unwanted particles.

Do not use any other medium or approach to clean CDR Sensors (autoclave, cold soak, gas- or heat-sterilize). We recommend cleaning the Sensor at the start of any day in which X-ray exams are scheduled or expected, and whenever a new sheath is used.

4.1.2. SDX USB Interface Cleaning

To clean the SDX USB Interface, apply a small amount of water or isopropyl alcohol (70%), to a non-abrasive, lint-free cloth. Wipe down the unit, exercising care when cleaning around the connectors and contacts. After cleaning, inspect the SDX USB Interface to ensure that all surfaces are clean and free of unwanted particles.

4.1.3. Antenna / Receiver Cleaning (CDR Wireless Systems Only)

To clean the Antenna / Receiver, apply a small amount of water or isopropyl alcohol (70%), to a non-abrasive, lint-free cloth. Wipe down the units, exercising care when cleaning around the connectors and contacts. After cleaning, inspect the Antenna / Receiver to ensure that all surfaces are clean and free of unwanted particles.

4.1.4. Preventive Maintenance

There are no customer serviceable components in the system. However, before operating the system, customers shall check it for any signs of physical damage or defect. If detected, other system units can be substituted if they are available. Contact your local distributor of Schick Technologies products for further instructions.

4.1.5. Damaged Sensor

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

4.1.6. Sensor and Battery Storage

When not in use, one CDR Wireless Sensor and battery pack can be stored in the SDX USB Interface. CDR Wireless Sensors can also be stored in Sensor Holsters, which accommodate one CDR Wireless (or CDR2000) Sensor. Holsters can be mounted with Velcro strips to any clean, flat surface. CDR Wireless Sensors must be stored appropriately, in suitable environments for temperature and humidity.



Figure 24. Storage Options

4.1.7. Sheath and Battery Pack Disposal

Please dispose of used sheaths and depleted battery packs in accordance with local regulations for proper recycling and / or waste disposal. There are no hazardous materials used in the CDR Wireless system and it can be disposed of in accordance with local regulations at the end of its useful life.

4.2. Corrective Actions

The following paragraphs address issues in corrective maintenance.

4.2.1. Battery Replacement

Indications that a battery has failed or is low on power will appear in several ways:

- 1. LED indications on the CDR Wireless Sensor (**Table 1** on page 13)
- 2. Battery Level percentage in the CDR Wireless Monitor dialog box (Figure 10 on page 10)
- 3. CDR software message, "Battery is low", appears in the Sensor Monitor when the Sensor is on. During the low battery condition, the Sensor Monitor will automatically maximize with this message, even if minimized in the System Tray.

If the battery is low on power, it may be possible to complete the current dental exam before replacing the battery, but the battery shall be replaced before the CDR Wireless Sensor is used again. If the battery is depleted, it must be replaced, as the Sensor will not be able to send images to or communicate with the Antenna / Receiver.

To remove the battery pack from the Sensor, please follow the directions in **Table 8**. To install the battery pack on the Sensor, please follow the directions in **Table 9**.

4.2.2. Field Upgrades

If needed, new firmware may be installed to the CDR Wireless Sensor and Base Station. The SDX Utility software is used to upgrade these devices.

For step-by-step procedures on performing field upgrades, refer to the CDR Wireless / SDX Software Installation Guide.

4.2.3. Sensor Diagnostics

If needed, diagnostic information may be obtained using the SDX Utility to identify and resolve problems in the CDR Wireless system.

For information on using the RF Environment Test to determine RF noise in the operatory, refer to the CDR Wireless / SDX Software Installation Guide.

| Step | Instruction | Illustration |
|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| 1. | Locate the orientation symbol ▲ on the battery package | |
| 2. | Slide the battery along the Sensor guides in the opposite direction of the orientation symbol | |
| 3. | Lift up and remove the battery pack and store it in a proper location Please note: When detached from the Sensor, place the battery pack on its back with the terminals facing upwards. Ensure that no conductive object contacts the battery terminals to prevent accidental discharge. | |

Table 8. Removing the Battery Pack from the Sensor

| Step | Instruction | Illustration |
|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| 1. | Locate the orientation symbol on the battery package ▲ and make sure it is facing the same direction as the corresponding symbol on the Sensor | |
| 2. | Position battery along Sensor guides | |
| 3. | Slide battery package along Sensor guides in the same direction as the orientation symbol until it locks into place. Do not attempt to snap the battery pack down onto the Sensor. This may damage the Sensor and / or battery pack. | |

Table 9. Securing the Battery Pack to the Sensor

5. Reference

Please Note: For a description of product names and acronyms, refer to the list of terms in the front of the manual.

5.1. System Summary

Table 10. CDR Wireless System Summary

| Hardware | Description |
|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CDR Wireless Sensor | 2.4 GHz FM digital data transmission, 3 channels (selectable). Effective Radiated Power of <2 mW. Battery pack with On / Off switch. Single-window, dual LED display. |
| Antenna / Receiver | Remote-mountable or dockable with SDX USB Interface. Equipped with pivotable Antenna. Single LED display for power and transmission status. |
| SDX USB Interface | Dockable with Antenna / Receiver and secured via locking screws. Recessed configuration cradle for one CDR Wireless Sensor and one spare battery pack. USB 1.1 compliant. Dual LED display for power and image acquisition status. |

Table 11. SDX System Summary

| Hardware | Description |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CDR Wireless Sensor | 2.4 GHz FM digital data transmission, 3 channels (selectable). Effective Radiated Power of <2 mW. Battery pack with On / Off switch. Single-window, dual LED display. |
| CDR2000 Sensor | Digital data transmission conveyed via strain-relieved 2-meter cable terminating in edgecard connector and compatible with interface located on SDX enclosure cover. |
| SDX Antenna and Receiver | Enclosed inside and integrated with SDX Intra-oral X-ray System. |
| SDX USB Interface | Recessed configuration cradle for one CDR Wireless Sensor and one spare battery pack. USB 1.1 compliant. Dual LED display for power and image acquisition status. |

Table 12. RF Frequencies

| RF Channel | Frequency | | |
|------------|-------------|--|--|
| 1 | 2417.5 Mhz | | |
| 2 | 2441.75 Mhz | | |
| 3 | 2460 Mhz | | |

Table 13. Environmental Specifications

| Category | Description |
|-------------------|-------------------------------------------------------------------------------------------------------------------------------|
| 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. |

Table 14. Compliance Specifications

| Specification | Description | |
|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| CAN/CSA C22.2 No.601.1-M90 | Medical Electrical Equipment Part 1: General Requirements for Safety | |
| ETSI-EN 301 489-3 | Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) Standard for Radio Equipment and Services; Part 1: Common Technical Requirements | |
| 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 | |

Table 15. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

PLEASE NOTE: CDR Wireless / SDX systems are intended for use in the electromagnetic environment specified below. Users of these systems must ensure they are used in such an environment.

| Emissions Test | Compliance | Guidance |
|--------------------------------------------|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| RF emissions CISPR 11 | Group 1 | CDR Wireless / SDX systems use RF energy only for their 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 A | CDR Wireless / SDX systems are suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage supply network |
| Voltage fluctuations/ flicker emissions | Complies | that supplies buildings used for domestic purposes. |

Table 16. Guidance and Manufacturer's Declaration - Electromagnetic Immunity

PLEASE NOTE: CDR Wireless / SDX systems are intended for use in the electromagnetic environment specified below. Users of these systems must ensure they are used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Guidance |
|-----------------------------------------------|---------------------------------|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Electrostatic discharge | ±6 kV contact | ±6 kV contact | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| IEC 61000-4-2 | | ±4 kV contact ^a | |
| | ±8 kV air | ±8 kV air | |
| Electrical fast transient/burst | ±2 kV for power supply lines | ±2 kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |
| IEC 610004-4 | ±1 kV for input/output lines | ±1 kV for input/output lines | |
| Surge IEC 61000-4-5 | \pm 1 kV differential mode | \pm 1 kV differential mode | Mains power quality should be that of a typical commercial or hospital |
| | $\pm 2kV$ common mode | $\pm 2kV$ common mode | environment. |
| Voltage dips, short | $< 5\% U_T$ | $<$ 5% U_T | Mains power quality should be that of |
| interruptions and voltage variations on power | $_{(>95\%\ dip\ in}\ U_{T)}$ | $(>95\%~dip~in~U_T)$ | a typical commercial or hospital environment. If the user of the SDX |
| supply input lines | for 0.5 cycle | for 0.5 cycle | system requires continued operation during mains interruptions, it is |
| IEC 61000-4-11 | $<40\%~\mathrm{U_T}$ | $< 40\% U_{T}$ | recommended that the SDX system be powered from an uninterruptible |
| | $_{(>60\%\ dip\ in}\ U_{T)}$ | $_{(>60\%\ dip\ in}\ U_{T)}$ | power supply or battery. |
| | for 5 cycles | for 5 cycles | |
| | $< 70\% \ \mathrm{U_T}$ | $< 70\% \ U_T$ | NOTE: U_T is the AC mains voltage prior to application of the test level. |
| | $_{(>30\%\ dip\ in}\ U_{T)}$ | $(\geq 30\%~dip~in~U_T)$ | |
| | _{for 25} cycles | for 25 cycles | |
| | < 5% U _T | $< 5\% U_T$ | |
| | (>95% dip in U_T) | $_{(>95\%dipin}U_{T)}$ | |
| | for 5 Sec | for 5 SEC | |
| Power frequency (50/60 Hz) magnetic field | 3A/m | 3A/m | |
| IEC 61000-4-8 | | | |

| Immunity Test | IEC 60601 Test Level | Compliance Level | Guidance |
|-------------------------------|-----------------------------|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 SDX system, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| | | | $d=(3.5/3)x\sqrt{P}$ |
| Radiated RF | 3 V/m | 3 V/m | $d=(3.5/3)x\sqrt{P}$ for 80 MHz to 800Mhz |
| IEC 61000-4-3 | 80 MHz to 2.5 GHz | | $d=(7/3)x\sqrt{P}$ for 800 MHz to 2.5Ghz |
| | | | 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, ^b should be less than the compliance level in each frequency range. ^c |
| | | | Interference may occur in the vicinity of equipment marked with the following symbol. |
| | | | (((•))) |
| NOTE 1: At 80 MHz and 8 | 800 MHz, the higher freque | ency 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 To avoid damage to electronic components inside, users should not touch the exposed contacts on the Wireless Sensor and the USB Interface before discharging to an earthed object.

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

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

Table 17. Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the SDX System

PLEASE NOTE: CDR Wireless / SDX systems are intended for use in the electromagnetic environment specified below. Users of these systems should ensure they are used in such an environment.

| Rated maximum output power of the transmitter (W) | Separation distance according to the frequency of the transmitter (m) | |
|---------------------------------------------------------|-----------------------------------------------------------------------|--------------------|
| | 150 kHz to 800 MHz | 800 MHz to 2.5 GHz |
| | d=1.17x√P | d=3.3x√P |
| 0.01 | 0.17 | 0.33 |
| 0.1 | 0.37 | 1.04 |
| 1 | 1.17 | 3.30 |
| 10 | 3.69 | 10.44 |
| 100 | 11.7 | 33.00 |

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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