FIELD TEST MANUAL



CDR Elite Wireless System User Guide

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Contents

| 1. | CDR Elite Wireless System | 1 |
|--|---|----------------------------|
| 1.1. 1.2. 1.3. 1.4. | Purpose Indications for Use System Description Wireless Interface | 1 1 1 2 |
| 2. | Hardware | 3 |
| 2.1. 2.2. 2.3. 2.4. | CDR Elite Sensor Power and Transceiver Counter Top Dock PC Workstation | |
| 3. | Software | 6 |
| 3.1. 3.2. 3.3. 3.4. 3.5. 3.6. 3.7. 3.8. 3.9. | Setup with Windows 7 Setup with Windows Vista Setup with Windows XP Wireless Monitor WiFi Configuration Utility Upgrade Utility PAT and PC Workstation Pairing Resend Last Image CDR AutoDetect and PAT Devices | |
| 4. | Controls and LED Indicators | 24 |
| 4.1. 4.2. | Counter Top Dock Power and Transceiver Device | |
| 5. | Operation | |
| 5.1. 5.2. 5.3. 5.4. 5.5. | Preparing CDR Elite Sensors for Wireless Usage Configuring the PAT Pairing the PAT to a PC Workstation Using Sensor Sheaths and Holders Taking X-rays | 30 30 31 34 35 |
| 6. | Protective Measures | |
| 6.1. 6.2. 6.3. 6.4. | Introduction Sensor and PAT Cleaning and Disinfecting CTD Cleaning Recommended Disinfectants | |
| · . | | |
| Ŏ. | | |

| 8.1. | Damaged Sensor | 40 |
|------|-----------------------------|----|
| 8.2. | Sheath and Battery Disposal | 40 |
| 8.3. | Battery Replacement | |
| 8.4. | Upgrades and Diagnostics | |
| 8.5. | Image Exposure Issues | 41 |
| 9. | Reference | |
| 9.1. | System Summary | |

List of Figures and Tables

| Figure 1. CDR Elite Wireless System Connections | 3 |
|---|----|
| Figure 2. CDR Elite Wireless Firmware Upgrades Tab | 21 |
| Figure 3. CDR Elite Wireless Pattern Tests Tab | 21 |
| Figure 4. CTD Connections and LEDs | 24 |
| Figure 5. PAT Pushbutton Switch and LED Indicator | 25 |
| Figure 6. CDR Elite Wireless Device LED Color Range during Operation | 26 |
| Figure 7. CDR Elite Wireless Device LED Color Range during Upgrades and Diagnostics | 26 |
| Figure 8. CDR Elite Wireless PATs Docked to CTD | 27 |
| Figure 9. CDR Elite Wireless PAT Not Docked to CTD (No Sensor Connected) | 28 |
| Figure 10. CDR Elite Wireless PAT Not Docked to CTD (Sensor Connected) | 29 |
| Figure 11. Wireless Monitor Menu Items | 32 |
| Figure 12. PAT Management List of Paired and Available PATs | 32 |

| Table 1. CDR Elite Wireless PAT LEDs (PAT Docked to CTD) | 27 |
|---|-------|
| Table 2. CDR Elite Wireless PAT LEDs (PAT Not Docked to CTD - No Sensor Connected). | 28 |
| Table 3. CDR Elite Wireless PAT LEDs (PAT Not Docked to CTD - Sensor Connected) | 29 |
| Table 5. CDR Elite Wireless System Summary | 42 |
| Table 6. Wireless Interface Characteristics | 42 |
| Table 7. Environmental Specifications | 42 |
| Table 8. Compliance Specifications | 43 |
| Table 9. Guidance and Manufacturer's Declaration - Electromagnetic Emissions | 43 |
| Table 10. Guidance and Manufacturer's Declaration - Electromagnetic Immunity | 44 |
| Table 11. Recommended Separation Distance between Portable and Mobile RF Communica | tions |
| Equipment and the System | 46 |

B1051080 Rev. - (DRAFT)

Notice to Customers in European Countries

For customers in European countries, additional information about the CDR Elite 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 Elite Wireless hardware.

| AUS | В | DK | FIN | The $\textcircled{0}$ symbol indicates that the use of 2.4 |
|------------------------|-----|----|-----|---|
| $\left \right>\right $ | D | GR | IRE | GHz devices is restricted in the countries crossed out on this table. |
| Ι | LUX | NL | Р | However, the CDR Elite Wireless system has |
| Е | S | | | and can be used in all European countries. |
| СН | | | | |

FCC Compliance Statement

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.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The maximum wireless signal rate for the system is derived from IEEE Standard 802.11a/b/g specifications. Actual data throughput will vary. Network conditions and environmental factors, including the volume of network traffic, building materials, and construction, and network overhead, may lower actual data throughput rate. Environmental conditions will adversely affect wireless signal range.

Observe Proper Handling, Storage, and Disposal for Batteries

Your CDR Elite Wireless PAT is equipped with disposable lithium ion batteries. Be sure to read and understand the special instructions relating to battery usage and follow all of the guidelines for usage, storage, and disposal. Improper use can result in serious injury, fire, or death.

Do not short circuit, disassemble, or modify the batteries. Do not place them near high-temperature locations. Do not place the batteries in fire or apply heat to them. Do not subject the batteries to strong impacts or shocks. Do not expose the batteries to water or allow them to get wet. A fire extinguisher must be used if a lithium ion battery is burning. Do not use water.

Check Sensor Before Using It

Before each usage, check the Sensor for any signs of physical damage or defect. 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.

Radio Frequency (RF) Interference Considerations

Although the CDR Elite Wireless System 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 equipment.

Any instrumentation or equipment for professional use located near the CDR Elite Wireless system 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.

Installers to Ensure that CDR Elite Wireless System Operates Optimally

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

Ensure Proper System and PC Workstation Installation and Operation

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

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

Only Dentists or Authorized Designees Are Permitted to Operate the System

To ensure the correct use of the CDR Elite Wireless system 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.

Operate the CDR Elite Wireless System as Directed

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

Protect Sensor from Potential ESD Damage

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

Do Not Use Snap-A-Ray Holders with 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.

Observe Proper Handling and Placement for Sensors

As with any dental device or instrument placed intraorally, proper care must be taken when using 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.

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

The CDR Elite Wireless system 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.

Wait for Appropriate Prompts before Operating X-ray Source

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

Explanation of Symbols

Some symbols on the 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.



Waste Electrical and Electronic Equipment

Background

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

WEEE Marking

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



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

Reporting

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

WEEE from Users other than Private Households

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

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

Information for Reuse Centers, Treatment and Recycling Facilities

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

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

Label Locations

CDR Elite Wireless PAT Battery Package Label



CDR Elite Wireless Remote Module Label



CDR Elite Wireless Counter Top Dock Label



SCHICK TECHNOLOGIES, INC. 30-30 47 Ave, L.I.C., N.Y., 11101, USA MFR XX/XXXX S/N XXXXX

Lithium Ion Battery Packaging Label



CDR Elite Wireless System Shipping Label

CDRElite WIRELESS SYSTEM

SCHICK TECHNOLOGIES, INC. 30-30 47th Ave, L.I.C., N.Y., 11101, USA P/N 2400100

| Temperature | Humidity | Pressure |
|--------------------------------------|---------------|--------------------|
| 50° F to (+10° C) to 104° F (+40° C) | Less than 75% | 700hPa to 1060 hPa |

Terms Used in this Document

CDR DICOM

Schick Technologies software that provides advanced features for image acquisition, review, manipulation, printing, and storage.

CTD

(Counter Top Dock) Charges PAT batteries and is used for initial configuration and firmware upgrade functions.

CDR Elite Wireless System

Describes a wireless implementation of the CDR imaging system, using CDR Elite Sensors and other CDR Elite Wireless-specific components, including an integrated sensor / holder system, manufactured by Schick Technologies.

CDR Elite Wireless System Interface Driver

Name on the CD containing the driver for the CTD USB Interface.

PAT

(*Power and Transceiver*) Provides power to, and receives image data from, the CDR Elite Sensor, and transfers images wirelessly to the PC workstation.

Upgrade Utility

Enables in-office updates of Sensor and PAT firmware, performs image pattern tests, and reports wireless access point status.

USB

(Universal Serial Bus) Plug and play interface between host computer and connected USB-compatible devices.

Wireless Monitor

Opens the PAT Status and PAT Management windows and is used when enabling or disabling PAT-to-workstation pairing and when displaying status information regarding detected PATs, including signal strength, battery level, availability for pairing, and Sensor serial number.

WiFi Configuration Utility

Configures the CDR Elite Wireless PAT to be detected by, and ready for use on, the user's wireless network.

Special Note about the Field Test Manual

This user guide makes reference to features and implementations not currently found in the system under pre-certification review.

For convenience, these differences are highlighted in bold when they appear in text and are summarized below:

Hardware

- Battery removal and replacement by the user is not available
- The integrated sensor / holder system is not available
- The wireless adapter is not available

Software

- The driver CD is not supplied (drivers are pre-installed)
- The Upgrade utility is not available
- The Resend Last Image feature is not available
- Double-clicking to perform pairing is not available
- Showing paired PATs in bold or dim letters is not available
- The low battery message is not available

1.CDR Elite Wireless System

1.1. Purpose

The CDR Elite Wireless system represents the latest advances in our intraoral sensor technology and provides the following advantages:

- Wirelessly acquires and transmits intraoral X-ray images
- Expands the product options of the CDR Elite sensor
- Leverages the capabilities of in-office wireless networks
- Provides an integrated sensor / holder system for stable alignment and positioning during image acquisition.

1.2. Indications for Use

The CDR Elite 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.

1.3. System Description

The CDR Elite Wireless system includes the CDR Elite Sensor, which is used for intraoral imaging; the Power and Transceiver (PAT) device, which is used to provide power to the CDR Elite Sensor, and the Counter Top Dock (CTD), which is used primarily to charge the PAT battery. (*Please Note: Use only the WALL Model WMMPU12*, 103 power supply with the CTD.) The PAT and CTD also provide additional functions and are described separately in Section 2.2. and Section 2.3, respectively.

The CDR Elite Wireless system acquires X-ray images and transmits them to the PC workstation through an 820.11 b/g compliant WiFi access point. Temporary memory storage in the PAT enables images to be retransmitted, potentially recovering from severe interferences that may occur while the PAT and the sensor are in use.

1.4. Wireless Interface

A WiFi-compliant wireless access point provides the connection between the PAT device and the PC workstation. The wireless interface must be TCP/IP-based and compatible with 802.11b/g protocols for transferring data.

2. Hardware

A simplified diagram of the CDR Elite Wireless system is shown below (Figure 1).



Figure 1. CDR Elite Wireless System Connections

2.1. CDR Elite Sensor

The CDR Elite Sensor provides improved image resolution based on smaller pixel size, eliminates the need for separate sensor calibration disks, implements additional changes to reduce electronic interference from other devices, and offers new options for image enhancement.

When used in the CDR Elite Wireless system, the CDR Elite Sensor replaces the replaceable Sensor cable with a wireless adapter. The wireless adapter (not available in the field-test version of the CDR Elite Wireless system) and the Sensor cable are interchangeable, enabling customers to select the technology that best fits their clinical environment and their individual preferences. For details on how to change your standard CDR Elite Sensor to the CDR Elite Wireless configuration, please refer to Section 5.1.

2.2. Power and Transceiver

The Power and Transceiver (PAT) provides power to the CDR Elite Sensor, contributes to the process of acquiring an image, and transfers the image to the PC workstation, where it can be displayed, reviewed, and stored.

The PAT is also responsible for monitoring the strength of the rechargeable Lithium cell battery located in this module. Battery strength is reported by the Wireless Monitor, a separate utility distributed with CDR Elite Wireless software.

For upgrading the PAT when new features are available, an Upgrade utility is distributed with CDR Elite Wireless software. This utility also includes image pattern tests and status information for troubleshooting purposes.

For details on how to upgrade the PAT firmware or to perform troubleshooting, please refer to Section 7.

2.3. Counter Top Dock

The Counter Top Dock (CTD) charges the PAT battery when the PAT is inserted into one of three connector slots on the station. Up to three PATs can be charged concurrently. When the PATs are not in use, the CTD also serves as a convenient storage unit.

PLEASE NOTE: Use only the WALL Model WMMPU12D-103 power supply with the CTD.

When placed in the CTD, the PAT is said to be in its "docked" position, where upgrade and diagnostic functions can be performed, as needed, over USB cable or wireless connection.

The WiFi Configuration utility, which is described in more detail later in Section 3.5, is the software interface that enables customers to perform firmware upgrades and other diagnostic tests of the PAT and the Sensor.

2.4. PC Workstation

The PC workstation (CE-approved computer system conforming to the Low Voltage [73/23/EC] and EMC Directive [89/336/ERC]) connects to the USB Interface of the CTD via a compatible USB cable and serves as the host for CDR software and utilities. For safety, connect the cable from the 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 Elite Wireless hardware. Recommended system requirements for the PC workstation are listed below:

- Windows 7 (Home Premium, Professional, Ultimate) and Windows 7 x64 Edition; Windows Vista (Home Premium, Business, Ultimate) and Vista x64 Edition, and XP Professional and XP Professional x64 Edition.
- CDR DICOM for Windows 3.5 SR1 and higher, EagleSoft 14.0 and higher, and Patterson Imaging 14.0 and higher.
- Pentium D processor or Intel Core2Duo processor
- 2 GB RAM
- 250 GB hard drive Raid Level 1 (practice-specific, depends on number of patients)
- Intel USB chipset with at least 2 powered USB 2.0 ports (USB 1.1 also supported).

When connecting the CTD via USB cable 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.

3. Software

CDR Dicom is an imaging application that provides the software interface between the CDR Elite 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, available on our website, for more details.

For information regarding other compatible imaging programs, such as EagleSoft and Patterson Imaging, please refer to the documentation supplied with those products.

Several software utilities that are specific to the CDR Elite Wireless System have been developed to provide configuration, monitoring, and diagnosis of CDR Elite Wireless system. Information regarding the *Wireless Monitor* (Section 3.4), *WiFi Configuration Utility* (Section 3.5), and *Upgrade Utility* (Section 3.6) can be found in the pages that follow.

The USB device drivers for the CDR Elite Wireless CTD are available via the Internet or by manually installing them from the CDR Elite Wireless Interface Driver CD. (Please note that the driver CD is not supplied with the field-test version of the CDR Elite Wireless system.) Refer to the following procedures when installing the USB drivers. These procedures differ slightly depending on the particular Windows operating system on the PC Workstation.

B1051080 Rev. - (DRAFT)

3.1. Setup with Windows 7

Step 1

- A. Connect the CDR Elite Wireless CTD to a spare USB port on your PC.
- B. If an Internet connection is available, Windows 7 will silently connect to the Windows Update website and install the appropriate driver. If the driver is installed automatically, stop here and do not continue with this procedure as driver installation is complete.
- C. If a suitable driver is not found automatically, continue with the following steps.

NOTE: The device name and the driver path shown in the screenshots that follow are provided as examples and will differ in your installation.

STEP 2

- A. Click on the Windows Start button and select the Control Panel.
- B. Click on Hardware and Sound.
- C. Click on Device Manager under Devices and Printers.





Step 3

- A. When the Device Manager opens, click on Other Devices, which displays the device (in this example TTL232R), with a yellow exclamation symbol.
- B. Right-click on the device and select Update Driver Software from the menu.

STEP 4

- A. Insert the CDR Elite Wireless Driver CD. If the setup wizard starts automatically, just close or cancel it.
- B. Click on "Browse my computer for driver software."

| TTL2 | Update Driver Software |
|-----------|---------------------------|
| Ports (CC | Dirabla |
| Processo | |
| Sound, v | Uninstall |
| Universa | Scan for hardware changes |
| | Properties |

| + | Search automatically for updated driver software Windows will search your computer and the Internet for the latest driver software for your driver, unless you've disabled this feature in your device installation settings. | |
|---|--|--|
| • | Browse my computer for driver software Locate and install driver software manually. | |
| | | |

Step 5

- A. Click the Browse button, or type into the Browse box, the exact path where the drivers are located. In this procedure, they reside on the CD.
- B. Click Next.

| Bro | wse for driver software on your computer |
|-------|--|
| Searc | ch for driver software in this location: |
| RIVE | RS\CDM 2.04.16 WHQL Certified\CDM 2.04.16 WHQL Certified 🔻 Browse |
| + | Let me pick from a list of device drivers on my computer This list will show installed driver software compatible with the device, and all driver |
| | sonware in the same category as the device. |

Step 6

A progress bar is displayed while the driver software is being installed.

| | | | × |
|---------------|-------------------------|--|----------|
| 🌀 🧕 Update Dr | iver Software - TTL232R | | |
| Installing d | river software | | |
| | | | |
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| | | | |
| | | | |
| | | | |

Step 7

- A. A confirmation screen is displayed after a successful installation.
- B. Click Close.



STEP 8

Install the USB Serial Port by repeating steps 3 through 7, as described previously.

| | × |
|---|-------|
| 🥥 🤰 Update Driver Software - USB Serial Port (COM3) | |
| | |
| Windows has successfully updated your driver software | |
| Windows has finished installing the driver software for this device | |
| 102 0-010-0 | |
| Senal Port | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | Close |
| | |

A. Returning to the Device Manager, a new device, USB Serial Controller, has been added under Universal Serial Bus Controllers. Also, a new device, USB Serial Port (COM 3), has been added under Ports (COM & LPT).

NOTE: Not all devices will install to COM3. The COM port allocation is determined by the next free COM port designated in the PC registry.

B. Driver installation is complete. Remove the CDR Elite Wireless Driver CD.

| ⊳ 🖑 Ports (COM & LPT) | | | | |
|---|--|--|--|--|
| Processors | | | | |
| 5 4 Sound, video and game controllers | | | | |
| b Image System devices | | | | |
| a 📲 Universal Serial Bus controllers | | | | |
| 🏺 Intel(R) 82801EB USB Universal Host Controller - 24D2 | | | | |
| 🏺 Intel(R) 82801EB USB Universal Host Controller - 24D4 | | | | |
| 🏺 Intel(R) 82801EB USB Universal Host Controller - 24D7 | | | | |
| 🏺 Intel(R) 82801EB USB Universal Host Controller - 24DE | | | | |
| 🏺 Intel(R) 82801EB US82 Enhanced Host Controller - 24DD | | | | |
| 🏺 USB Root Hub | | | | |
| 🏺 USB Root Hub | | | | |
| 🏺 USB Root Hub | | | | |
| 🏺 USB Root Hub | | | | |
| 🏺 USB Root Hub | | | | |
| 🛶 🖶 USB Serial Converter | | | | |

3.2. Setup with Windows Vista

Step 1

- A. Connect the CDR Elite Wireless CTD to a spare USB port on your PC.
- B. If an Internet connection is available, Windows Vista will silently connect to the Windows Update website and install the appropriate driver. If the Windows New Hardware Found wizard starts after driver installation, follow those prompts until complete.
- C. If a suitable driver is not found automatically, continue with the following steps.

Step 2

- A. If there is no available Internet connection, or if Windows Vista is configured to ask before connecting to Windows Update, the Found New Hardware screen is displayed.
- B. Click on "Locate and install driver software (recommended)."



Step 3

Click on "I don't have the disc. Show me other options."



NOTE: The device name and the driver path shown in the screenshots that follow are provided as examples and will differ in your installation.

STEP 4

- A. Insert the CDR Elite Wireless Driver CD. If the setup wizard starts automatically, just close or cancel it.
- B. Click on "Browse my computer for driver software (advanced)."

| Windo | ws couldn't find driver software for your device |
|---------------|---|
| ◆ C W W | teck for a solution ndows will check to see if there are steps you can take to get your device rding. |
| → Bi La | owse my computer for driver software (advanced) cate and install driver software manually. |
| | |

Step 5

- A. Click the Browse button, or type into the Browse box, the exact path where the drivers are located. In this procedure, they reside on the CD.
- B. Click Next.

| Browse for o | driver software on your computer | | | |
|------------------|----------------------------------|---|--------|--|
| Search for drive | r software in this location: | | | |
| C:\Users\ | Desktop\CDM 2.00.00 (Certified) | - | Browse | |
| Include subf | olders | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

STEP 6

A progress bar is displayed while the driver software is being installed.

| Found New Hardware - TTL23 | 32R Tester | | |
|-----------------------------|------------|--|--|
| Installing driver software. | - | | |
| | _ | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

Step 7

- A. A confirmation screen is displayed after a successful installation.
- B. Click Close.

| | × |
|--|-------|
| Found New Hardware - USB Serial Converter | |
| The software for this device has been successfully installed | |
| Windows has finished installing the driver software for this device: | |
| USB Serial Converter | |
| <u> </u> | |
| | |
| | |
| | |
| | |
| | Close |

STEP 8

- A. Install the USB serial port by repeating steps 3 through 7, as described previously.
- B. A confirmation screen is displayed after a successful installation.
- C. Click Close.



Step 9

- A. Open the Device Manager (Windows Start button > Control Panel > System and Maintenance > System > Tasks).
- B. Select View > Devices by Connection. The device appears as a USB Serial Converter with an additional COM port identified as a USB Serial Port.

NOTE: Not all devices will install to COM3. The COM port allocation is determined by the next free COM port designated in the PC registry.

C. Driver installation is complete. Remove the CDR Elite Wireless Driver CD.

Ports (COM & LPT)
 Communications Port (COM1)
 Printer Port (LPT1)
 USB Serial Port (COM3)

3.3. Setup with Windows XP

Step 1

- A. Connect the CDR Elite Wireless CTD to a spare USB port on your PC.
- B. If an Internet connection is available, Windows XP will silently connect to the Windows Update website and install the appropriate driver. If the Windows New Hardware Found wizard starts after driver installation, follow those prompts until complete.
- C. If a suitable driver is not found automatically, continue with the following steps.

Step 2

- A. When the Found New Hardware screen is displayed, select "No, not this time" when prompted to connect Windows Update.
- B. Click Next.





STEP 3

- A. Select "Install from a list or a specific location (Advanced)."
- B. Click Next.



STEP 4

- A. Insert the CDR Elite Wireless Driver CD. If the setup wizard starts automatically, just close or cancel it.
- B. Select "Search for the best driver in these locations."
- C. Click the Browse button, or type into the Browse box, the exact path where the drivers are located. In this procedure, they reside on the CD.
- D. Click Next.

Step 5

Click Continue Anyway if prompted by the message screen about Windows testing.

| lease cho | ose your search and installation options. |
|-----------------------|---|
| <u>⊚</u> <u>S</u> ear | that the best driver in these locations. |
| Use to paths | re check boxes below to limit or expand the default search, which includes local and removable media. The best down for and will be installed. |
| | Search removable media (light CD.B.D.M.) |
| V | Include this location in the search |
| | C:VCDM 2.02.04 |
| O Dan'i | search. I will choose the driver to install. |
| Choo the d | e this option to select the device driver from a list. Windows does not guaranter ver you choose will be the best match for your bardware. |
| | |

| Hardwa | ire Installation |
|--------|---|
| ⚠ | The software you are installing for this hardware: USB Serial Converter |
| | has not passed Windows Logo testing to verify its compatibility with this version of Windows. [Tell me why this testing is important] |
| | Continuing your installation of this software may impair or destabilize the correct operation of your system either immediately or in the future. Microsoft strongly recommends that you stop this installation now and contact the hardware vendor for software that has passed Windows Logo testing. |
| · | Continue Anyway STOP Installation |

STEP 6

A progress bar is displayed while the driver software is being installed.



STEP 7

- A. A confirmation screen is displayed after a successful installation.
- B. Click Finish.

| Found New Hardware Wiz | ard |
|------------------------|---|
| | Completing the Found New Hardware Wizard The wizerd has first-ed installing the software for: USB Serial Converter USB Serial Converter |
| | KBack Finish Cancel |

STEP 8

- A. Install the USB serial port by repeating steps 3 through 7, as described previously.
- B. A confirmation screen is displayed after a successful installation.
- C. Click Finish.



- A. Open the Device Manager (Windows Start button > Control Panel > System > Hardware).
- B. Select View > Devices by Connection. A new device, USB Serial Converter, has been added under the USB Root Hub of the USB Universal Host Controller. Other new devices, USB Serial Ports COM3 and COM4, have been added also.

NOTE: Not all devices will install to COM3. The COM port allocation is determined by the next free COM port designated in the PC registry.

C. Driver installation is complete. Remove the CDR Elite Wireless Driver CD.





3.4. Wireless Monitor

The Wireless Monitor is included with CDR Elite Wireless software and is installed automatically. When the workstation is turned on, the Wireless Monitor initializes automatically and remains active until the workstation is turned off.

The Wireless Monitor consists of two tabs:

- PAT Status: Reports the battery level of the PAT to which the workstation is currently paired and the signal strength of a currently connected CDR Elite Sensor with wireless adapter. (If the sensor is not connected, or detected, no signal strength information is displayed.)
- PAT Management: Lists all detected PAT devices, their serial numbers, signal strengths, battery levels, and the Sensors and workstation IP addresses where they are connected, and their availability for pairing.

A sample screen of the Wireless Monitor is shown below.



A sample screen of the PAT Status window is shown below.



A sample screen of the PAT Management window is shown in Figure 12.

PAT pairing, which is a term to describe how PATs and workstations connect to transfer images wirelessly, is discussed in more detail later in Section 5.

3.5. WiFi Configuration Utility

The WiFi Configuration utility enables customers to configure the CDR Elite Wireless PAT to communicate with their computer network. Configuring the PAT is necessary before using the device with imaging applications.

A sample screen of the WiFi Configuration utility is shown below. For additional information and instructions regarding the utility, please refer to Section 5.

| 🔲 WiFi Configuratio | n Utility | | | | × |
|---|------------------|-------------------------|-------|---------------------------------|-------|
| Ports detected | M | | | Refresh Po | rts |
| Networks availab | le | | R | efresh Netw | vorks |
| | Name | Secu | urity | Signal | |
| marconi schickcorp schickguest marconi-3comWEP marconi-3com | | Yes Yes Yes No | | 184 169 169 189 190 | |
| | | | | More | |
| PAT serial number: | 000B6CB4F94EEric | | | | |
| Network Name: | marconi | | | | |
| Password: | ***** |] | | | |
| IP Address: | 192 168 0 239 |] | 🗸 Dy | namic IP | |
| Read | Write | | | | |

3.6. Upgrade Utility

Please note that use of the Upgrade utility is not available in the field-test version of the CDR Elite Wireless system.

The Upgrade utility enables wireless upgrades of firmware or other files in either the CDR Elite Sensor or the PAT, to provide updates, including new features, and for system status and diagnostic purposes.

The Upgrade Utility performs the following:

- Upgrades firmware in the PAT by USB link when the PAT is docked to the CTD
- Upgrades firmware in the CDR Elite Sensor by wireless link when the PAT is outside the CTD ("undocked")
- Performs pattern tests to simulate image transmission
- Reports PAT status and wireless access point information.

The pattern tests performed by the Upgrade utility include:

- The PAT test of the Sensor connection by sending a preset number of image patterns to the workstation. (*The actual image patterns are not displayed during the test.*)
- The Sensor test of image transmission by sending a preset number of image patterns to the PAT. (*The actual image patterns are not displayed during the test.*)
- The PAT test of the wireless link by sending a preset number of image patterns to the workstation. *(The actual image patterns are not displayed during the test.)*

If all image patterns are sent and received properly, the utility reports that the test was completed successfully. A pattern that fails to be sent or received properly indicates a hardware problem and further troubleshooting is required. Contact your local distributor of Schick Technologies products for further instructions.

| Web Serve | r and Ungra | de Utility | | | | |
|---------------------------|---------------------------|-------------------|----------|-----------------|--------|-----------------|
| Web Serve | r una opgra | ac othey | | | | |
| Firmware upgrades | Pattern tests | Status | Support | | | |
| | | | | | | |
| Cirmurana Una | wadaa | | | | | |
| Close your imaging progra | i dues | re is connected | | | | |
| close your imaging progra | an and make sure an nardw | are is connected. | | | | |
| PAT Flash | | | PAT FPGA | | Sensor | |
| | 6 | | | 6 | | ~ |
| | 0 | | | 0 | | |
| | Current version | | | Current version | | Current version |
| | | Browse | | Browse | | Browse |
| | | Biowac | | Elonoc. | | Biowse |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | P | efresh Close | | |

Figure 2. CDR Elite Wireless Firmware Upgrades Tab

| Web Serve | er and Upgra | de Utility | | | | | |
|-------------------------|-----------------------------|-------------------|----------|--------------|--------|------|--|
| Firmware upgrades | Pattern tests | Status | Support | | | | |
| | | | | | | | |
| Pattern Tests | | | | | | | |
| Close your imaging prog | ram and make sure all hardw | are is connected. | | | | | |
| WiFi | Test | | PAT FPGA | Test | Sensor | Test | |
| | | | P | efresh Close | | | |

Figure 3. CDR Elite Wireless Pattern Tests Tab

3.7. PAT and PC Workstation Pairing

To acquire an image on any PC workstation, a specific PAT must be "paired" with that workstation. Any sensor can be connected to the paired PAT device and used to acquire X-ray images.

A workstation will only receive images from its paired PAT device. The PAT will only transmit to the computer to which it is paired. If there is no paired PAT device when the imaging application is started, you will be prompted to select a PAT device for pairing.

3.8. Resend Last Image

Please note that the Resend Last Image feature is not available in the field-test version of the CDR Elite Wireless system.

The Resend option can be triggered manually by the user via the imaging software. The option can be controlled at a checkbox on the Xray Acquisition Control Property page.

Image resend is supported in both Autotake and non-autotake (manual) modes. Only the last acquired image can be retransmitted, although it can be retransmitted multiple times, if necessary.

If a PAT device is turned off (manually or automatically), the last acquired image can no longer be retransmitted.

3.9. CDR AutoDetect and PAT Devices

The CDR AutoDetect feature instantly recognizes when Schick intraoral devices are connected. Like Schick high-speed (HS) remotes, PAT devices are supported by this feature, enabling customers to skip the step of manually selecting a new Schick device before using it.

If the CDR Elite Wireless device is selected at the default device in the CDR DICOM property page, and if the PAT is already paired, both the Wireless Monitor icon and the AutoDetect Server icon will appear in the System tray.

| Xray Calibration Sensor | |
|---|--|
| Hardware Type: Exposure Timeout (s): Integrate Phoenix (sec/10): Integrate Time (sec/10): Reset Duration (uSec): Trigger Thresh: Trigger Count: I/O Port: Initial Rampup (Sec): Second Rampup (Sec): | ✓ Use CDR Autodetect Marconi Wireless PAT 15 ✓ Use Perfect Shot 7 Strength: Light 7 ✓ Calibrate Image 410 Equalize Image 15 Apply Spot Remover 40 ✓ Subtract dark image 0x300 Acquire 12 bit image 8 Automatic Exposure Control 6 Mapping: Nonlinear (Traditional) ▼ |

4. Controls and LED Indicators

4.1. Counter Top Dock

There are three connectors for PATs to dock with the CTD. Near each connector is a green indicator that illuminates and remains on when a PAT is connected. When there are no PATs connected, these LEDs are off.

Additional LEDs, located to the right and left of the docking LEDs, are illuminated when power is available to the CTD. There are two possible sources of power to the CTD:

- External power (*Please Note: Use only the WALL Model WMMPU12*-103 power supply with the CTD.)
- USB power

External power is supplied by a wall outlet and is normally connected to charge any PATs that may be connected to the CTD.

USB power is supplied via cable to a PC workstation and is normally disconnected except when diagnostic testing or upgrades are needed.

The following illustrations and tables provide information about the controls and indicators of the CDR Elite Wireless CTD.



Figure 4. CTD Connections and LEDs

4.2. Power and Transceiver Device

A multi-purpose pushbutton switch on the PAT controls power to the device and turns it on or off. When the PAT is on, pressing and holding the pushbutton for 2 to 3 seconds turns it off. If the PAT is off, pressing the pushbutton turns the device on immediately.

The LED located at the back of the PAT displays a range of colors and flashing patterns depending on the status and the functions being performed by the PAT. The LED also provides ongoing visual feedback regarding the battery charge required for operation. With CTD usage, the LED will reflect the consumption of battery charge as it approaches the orange and red colors.

We **strongly** recommend recharging the battery before it reaches the color red, for the following reasons:

- When the LED displays red, it means that there may not be sufficient battery charge to complete image acquisition and display, thus exposing the patient to unnecessary radiation.
- A battery whose charge has been completely consumed will require a longer period to recharge.

With normal usage, recharging the CTD battery will take approximately one hour. If the battery charge is significantly low, or completely exhausted, the typical time to fully recharge it may be as long as three hours.

The following illustrations provide information about the controls and indicators of the CDR Elite Wireless PAT.



Figure 5. PAT Pushbutton Switch and LED Indicator



Figure 6. CDR Elite Wireless Device LED Color Range during Operation

(Full Battery Charge in Green to Low Battery Charge in Red)

Colors in this range are specific to battery charge during Upgrades and Diagnostics



Figure 7. CDR Elite Wireless Device LED Color Range during Upgrades and Diagnostics

(Full Battery Charge in Blue to Low Battery Charge in Red)



Figure 8. CDR Elite Wireless PATs Docked to CTD

Table 1. CDR Elite Wireless PAT LEDs (PAT Docked to CTD)

| Action | LED Indications | Pushbutton Settings |
|-------------------------|--|---------------------|
| Battery charging | Changes from Red to Green | _ |
| Connected to USB | _ | _ |
| Pairing | Solid | Power Off, Pairing |
| Connected to WiFi | One long pulse followed by two short flashes | Power Off |
| No WiFi connection | Short flashes every N seconds | Power Off |
| PAT upgrade (idle) | Pulse every N seconds | Power Off |
| PAT upgrade (active) | Rapidly flashing every N seconds | Locked |
| Sensor upgrade (idle) | — | — |
| Sensor upgrade (active) | — | — |
| Diagnostics (idle) | Pulse every N seconds | Power Off |
| Diagnostics (active) | Rapidly flashing every N seconds | Locked |
| Acquiring image | Rapidly flashing every N seconds | Locked |
| Transferring image | Rapidly flashing every N seconds | Locked |



Figure 9. CDR Elite Wireless PAT Not Docked to CTD (No Sensor Connected)

Table 2. CDR Elite Wireless PAT LEDs (PAT Not Docked to CTD – No Sensor Connected)

| Action | No Sensor Connected | | | |
|-------------------------|--|-------------------------------------|---|---|
| | LED Indications | | Pushbutton Se | ettings |
| PAT Off | No LED illuminated | | If On, press and hold for 2 - 3 seconds to turn Off | |
| PAT On | Short flashes eve | ry N seconds | If Off, press to turn On | |
| Pairing | Solid | | Power Off, Pairing | |
| Battery in use | "Breathing" (Flash | ning steady) | Power Off | |
| Connected to WiFi | One long pulse followed by two short flashes | | Power Off | |
| No WiFi connection | Short flashes every N seconds | | Power Off | |
| PAT upgrade (idle) | _ | | _ | |
| PAT upgrade (active) | _ | | _ | |
| Sensor upgrade (idle) | — | | _ | |
| Sensor upgrade (active) | — | | — | |
| Diagnostics | FPGA Pattern Transfer | Rapidly flashing every N seconds | Locked | Press for more than 2 seconds and release before 6 seconds |
| Acquiring image | — | — | Locked | |
| Transferring image | — | — | Locked | |
| Retransmitting image | Rapidly flashing every N seconds | | Locked | |

B1051080 Rev. - (DRAFT)



Figure 10. CDR Elite Wireless PAT Not Docked to CTD (Sensor Connected)

Table 3. CDR Elite Wireless PAT LEDs (PAT Not Docked to CTD – Sensor Connected)

| Action | Sensor Connected | | | |
|-------------------------|----------------------------------|--|--------------------------------|---|
| | LED Indications | | Pushbutton S | ettings |
| PAT Off | No LED illuminate | ed | Press to turn On | |
| PAT On | Short flashes eve | ery N seconds | Press and hold seconds to turr | for 2 - 3 Off |
| Pairing | Solid | | Power Off, Pair | ring |
| Battery in use | Changes from Gr | een to Red | _ | |
| Connected to WiFi | "Breathing" (Flash | ning steady) | Power Off | |
| No WiFi connection | Short flashes every N seconds | | Power Off | |
| PAT upgrade (idle) | _ | | — | |
| PAT upgrade (active) | _ | | — | |
| Sensor upgrade (idle) | Pulse every N seconds | | Power Off | |
| Sensor upgrade (active) | Rapidly flashing e | every N seconds | Locked | |
| Diagnostics | Sensor Pattern Transfer | Rapidly flashing every N seconds | Locked | Press for more than 2 seconds and release before 6 seconds |
| Acquiring image | Rapidly flashing every N seconds | | Locked | |
| Transferring image | Rapidly flashing e | every N seconds | Locked | |
| Retransmitting image | Rapidly flashing every N seconds | | Locked | |

5. Operation

5.1. Preparing CDR Elite Sensors for Wireless Usage

Please note that the wireless adapter is not available in the field-test version of the CDR Elite Wireless system.

If your CDR Elite sensor has its replaceable cable attached, this must be removed and replaced with the CDR Elite Wireless adapter so the Sensor can be used wirelessly.

5.2. Configuring the PAT

Configuring the CDR Elite Wireless PAT with the WiFi Configuration Utility is necessary before using the device with imaging applications.

5.2.1. How to Configure the PAT

- 1. To do this, insert the PAT into the CTD, which is physically connected the host PC via the USB cable.
- 2. Start the WiFi Configuration Utility (Windows Start > Program Files > Schick Technologies > Shared Files > InitalUtility.exe).
- 3. At the WiFi Configuration Utility, under the Ports Detected menu, select the number on the CTD corresponding to the slot where the PAT is connected.
- 4. Select the wireless network from the Networks Available window and type in the name and password for this network.
- 5. Pressing the *Write* button completes the configuration. Every PAT device must be configured at least once, using this utility.

5.3. Pairing the PAT to a PC Workstation

To acquire an image on any PC workstation, a specific PAT must be "paired" with that workstation.

5.3.1. How to Pair a PAT to a Workstation

- 1. Turn on the PAT device.
- 2. Click on the Wireless Monitor icon located in the Windows System Tray and select PAT Management (Figure 11).
- 3. Select the desired PAT device from the list of PAT devices (Figure 12).
- 4. To select a PAT device for pairing, it must not be paired with any other workstation and its Status in the PAT Management window must be available. If the PAT is paired with a workstation that is different than the one desired, click on the Wireless Monitor at the workstation where it is currently paired, press the Unpair button in the PAT Management window, and continue with the next step.
- 5. Click the Pair button or double-click the PAT entry to start the pairing process. (Please note that doubleclicking to perform pairing is not available in the field-test version of the CDR Elite Wireless system.)
- 6. The "Please press pairing button" message, and the selected PAT device LED steady on, indicates that the button on that PAT device must be pressed to confirm the pairing.
- 7. Press the PAT button momentarily for approximately 1 second to complete the pairing process. This action also closes the pairing confirmation message.
- 8. The paired PAT entry is listed in bold letters on the PAT device list for this workstation and will be dimmed on the PAT device list for all other workstations. (Please note that showing paired PATs in bold or dim letters is not available in the field-test version of the CDR Elite Wireless system.)



Figure 11. Wireless Monitor Menu Items

| 🔏 Wireless Monitor | | | | | | × |
|--|----------------------|---|---|--|---|---|
| Currently Paired PAT: Detected PAT Devices: | de | evice | | | | Pair |
| PAT s/n | Signal | Battery | Sensor | Status | Paired PC | PAT Address |
| 00086CA80DAD PAT-000006 00086CB454C9 00086CB4F94EEric | 48 60 92 88 | 000000000000000000000000000000000000000 | Synergy-12345678 11001419 11001437 Not Connected | Available Available Available Available | 0.0.0.0 0.0.0.0 0.0.0.0 0.0.0.0 0.0.0.0 | 192.168.0.252 192.168.0.155 192.168.1.22 192.168.0.239 |

Figure 12. PAT Management List of Paired and Available PATs

5.3.2. How to Unpair a PAT from a Workstation

- 1. Unpairing a sensor can only be done from the Wireless Monitor on workstation where it is currently paired.
- 2. If a PAT device is turned off, it will become unpaired automatically. (PATs turn off automatically after 5 minutes in an idle state where no image acquisition or pairing has occurred).
- 3. When a PAT device is unpaired, it will be available for pairing with any workstation, if it is still detected by the user's network.

NOTE: If the imaging application is closed, the PAT device <u>will</u> <u>not</u> become unpaired automatically.

5.4. Using Sensor Sheaths and Holders

Please note that the integrated sensor / holder system is not available in the field-test version of the PAT.

Sheaths and the appropriate holders are required for CDR Elite 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 Elite 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 Elite Wireless system. When positioning the Sensor, the inverse pixel box located on the CDR Elite Sensor can be used to determine the orientation of the image exposure.

5.5. Taking X-rays

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

Before performing the following steps, make sure that you have completed the procedures in Section 5.1, Section 5.2, and Section 5.3 to prepare your CDR Elite Wireless system for acquiring and transmitting intraoral X-ray images wirelessly.

- 1. Start your image acquisition program and either create a new exam or open a patient record.
- 2. Press and hold the power button on the CDR Elite Wireless PAT for 2 to 3 seconds.
- 3. The acquisition software recognizes the Sensor and enters AutoTake or Manual mode, depending on your system settings.
- 4. The PAT Status window opens, showing the battery level of the PAT and the signal strength between the PAT and the wireless access point. If a Sensor is connected, its serial number will be displayed also.
- 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), activate the X-ray source.
- 7. When acquisition is complete, the image appears in the zoom window.
- 8. CDR advances to the next empty frame automatically. To take another image, reposition the Sensor with PAT and Holder and repeat this procedure starting at Step 5.

6. Protective Measures

6.1. Introduction

IMPORTANT! Be sure to turn off the CDR Elite Wireless PAT and to disconnect it from the Sensor before performing any cleaning procedures.

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

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

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

6.2. Sensor Cleaning and Disinfecting

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

- 1. Remove and discard all protective hygienic barriers and / or sheaths from the Sensor prior to removing disposable gloves.
- 2. Place the Sensor on a tray covered by a disposable liner, or in a receptacle that can be thoroughly disinfected.
- 3. Remove and discard gloves.
- 4. Wash hands and put on a new pair of disposable gloves.
- 5. Disconnect the Sensor from the CDR Elite Wireless PAT.
- 6. If the Sensor or cable are visibly soiled (e.g., with blood or saliva), each should be cleaned with a soapy cloth or paper towel, and then dried with a clean lint-free cloth or paper towel.
- 7. Thoroughly wipe the Sensor and cable with one of the disinfecting products recommended in Section. Do not expose the Sensor cable connectors to any amount of liquid.
- 8. <u>Repeat</u> step 7. When the Sensor has been sprayed or wiped two times, continue with the following steps.
- 9. Remove potential chemical build-up from the Sensor by wiping it with a sterile lap sponge saturated with deionized water.
- 10. Use a sterile dry lap sponge to dry the Sensor or cable, as needed.
- 11. Place the Sensor in a clean environment, ready for use.
- 12. Reconnect the Sensor.
- 13. Remove and discard gloves.

6.3. PAT Cleaning

IMPORTANT! Be sure to remove the PAT from the CDR Elite Wireless CTD before performing any cleaning procedures.

To clean the PAT, apply a small amount of water or isopropyl alcohol (70%), to a non-abrasive, lint-free cloth. Wipe the unit, exercising care when cleaning around the connectors and contacts and ensure they remain completely dry. After cleaning, inspect the PAT to ensure that its surfaces are clean and free of unwanted particles.

6.4. CTD Cleaning

IMPORTANT! Be sure to disconnect the USB cable and wall-outlet power connector from the CDR Elite Wireless CTD before performing any cleaning procedures.

To clean the CTD, apply a small amount of water or isopropyl alcohol (70%), to a non-abrasive, lint-free cloth. Wipe the unit, exercising care when cleaning around the connectors and contacts and ensure they remain completely dry. After cleaning, inspect the CTD to ensure that its surfaces are clean and free of unwanted particles

6.5. Recommended Disinfectants

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

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

7. Using the Upgrade Utility

Please note that use of the Upgrade utility is not available in the field-test version of the CDR Elite Wireless system.

The CDR Elite Wireless Upgrade Utility can be used to accomplish the following:

- Perform firmware upgrades
- Perform pattern tests
- Display PAT device status
- Display wireless access point information.

8. Maintenance

There are no customer serviceable components in the CDR Elite Wireless system. However, before operating the system, customers shall check 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.

8.1. Damaged Sensor

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

8.2. Sheath and Battery Disposal

Please dispose of used sheaths and depleted batteries in accordance with local regulations for proper recycling and / or waste disposal.

8.3. Battery Replacement

Please note that battery removal and replacement by the user is not available in the field-test version of the PAT.

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

- LED indications on the PAT (see Figure 7)
- Battery level percentage in the Wireless Monitor
- "Battery is low" message appears in the Wireless Monitor when the Sensor is on. **Please note that the low battery message is not available in the field-test version**.

If the battery is low on power, it may be possible to complete the current dental exam, but the battery shall be recharged before the CDR Elite Wireless PAT is used again. If battery power is approaching depletion, meaning that the device cannot hold a charge for more than a few X-rays, the battery must be replaced, as the Sensor will be unable to send images wirelessly.

8.4. Upgrades and Diagnostics

If needed, new firmware for the CDR Elite Sensor and CDR Elite Wireless PAT may be installed using the Upgrade Utility. The Upgrade Utility provides diagnostic and status information as well.

8.5. Image Exposure Issues

8.5.1. 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.

8.5.2. 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.

9. Reference

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

9.1. System Summary

Table 4. CDR Elite Wireless System Summary

| Hardware | Description |
|------------------------|---|
| CDR Elite Wireless PAT | 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. |
| CDR Elite Wireless CTD | Recessed configuration cradle with connectors for three PATs. LED for each connector and for USB LED and AC Power LED. |

Table 5. Wireless Interface Characteristics

| Parameter | Description |
|-----------------------|---|
| | |
| Technology | IEEE 802.11b/g, WiFi Compliant |
| Frequency | 2.4-2.4835 GHz (US / Canada / Europe); 2.4-2.497 GHz (Japan) |
| Modulation Technology | DSSS, CCK, OFDM |
| Modulation Type | DBPSK, DQPSK, CCK, BPSK, QPSK, 16QAM, 64QAM |
| Network Access Modes | Ad-Hoc and Infrastructure |
| Wireless Data Rates | 802.11b - 11,5.5,2,1 Mbs; 802.11g - 54,48,36,24,18,12,9,6 Mbs |
| Security Protocols | Disabled, WEP 64 and 128 bit, WPA (TKIP), WPA (AES), WPA2 (AES) |

Table 6. 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. |
| Transport and Storage 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 |

Table 7. 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 IEC60601-1 | Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) Standard for Radio Equipment and Services; Part 1: Common Technical Requirements 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 8. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

PLEASE NOTE: CDR Elite Wireless 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 Elite Wireless 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 | CDR Elite Wireless systems are suitable for use in all establishments including domestic |
| Harmonic emissions IEC 61000-3-2 | Class A | establishments and those directly connected to the public low-voltage supply network that supplies buildings used for domestic |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | purposes. |

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

PLEASE NOTE: CDR Elite Wireless 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 | Compliance | Guidance |
|---|---|---|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact | ±6 kV contact ±4 kV contact ^a | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, |
| | ±8 kV air | ±8 kV air | 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 | < 5% U _T (>95% dip in U _T) for 0.5 CyCle | < 5% U _T (>95% dip in U _T) for 0.5 Cycle | Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued |
| lines IEC 61000-4-11 | < 40% U _T _{(>60% dip in} U _{T)} _{for 5} cycles | < 40% U _T _{(>60% dip in} U _{T)} _{for 5} cycles | operation during mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or |
| | < 70% U _T (>30% dip in U _T) | < 70% U _T (>30% dip in U _T) | battery. |
| | for 25 Cycles | 5% U | voltage prior to application of the |
| | (>95% dip in U _{T)} for 5 SEC | (>95% dip in U _{T)} for 5 SEC | |
| Power frequency (50/60 Hz) magnetic field | 3A/m | 3A/m | |
| IEC 61000-4-8 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 system, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| | | | Recommended separation distance: d=(3.5/3)x√P |

| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | d=(3.5/3)x√P for 80 MHz to 800Mhz d=(7/3)x√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 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 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 system is used exceeds the applicable RF compliance above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.

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

Table 10. Recommended Separation Distance between Portable and Mobile RF Communications Equipment and the System

| Rated maximum output power of the transmitter (W) | Separation distance according to the frequency of the transmitter (m) | | |
|---|---|--------------------------------|--|
| | 150 kHz to 800 MHz d=1.17x√P | 800 MHz to 2.5 GHz 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 | |

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

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

Index

B

Battery Disposal, 40 Handling, Storage, and Disposal Guidelines, iv Replacement, 40

С

CDR AutoDetect and PAT Devices, 22 CDR Elite Sensor, 3 Preparing for Wireless Usage, 30 Sheaths and Holders, 34 CDR Elite Wireless PAT LED Indications PAT Docked to CTD, 27 PAT not Docked, No Sensor Connected, 28 PAT not Docked, Sensor Connected, 29 CDR Elite Wireless System Controls and Indicators, 24 Description, 1 Electromagnetic Emissions, 43 Electromagnetic Immunity, 44 Environmental Specifications, 42 Hardware, 3 Indications for Use, 1 Maintenance, 40 Operation, 30 Overview, 1 Protective Measures, 36 Purpose, 1 Recommended Separation Distance Between Portable and Mobile RF Communications Equipment, 46 RF Frequencies, 42 Specifications, 43 Summary, 42 Taking X-rays with, 35 Wireless Interface, 2 CDR Elite Wireless USB Interface Software, 6 Controls and Indicators, 24 Counter Top Dock Cleaning, 38 Controls and Indicators, 24 Description, 4

D

Damaged Sensor, 40 Dentists or Authorized Designees Only Are Permitted to Operate the System, vi Diagnostics, 41

E

Ensure CDR Elite Wireless System Operates Optimally, v ESD and Protecting Sensors from it, vi

F

FCC Compliance Statement, iv Firmware Upgrades, 41

Η

Hardware, 3

Maintenance, 40

L

Label CDR Elite Wireless Battery Package, xi CDR Elite Wireless CTD, xi, xii CDR Elite Wireless PAT, xi

Μ

0

Operate CDR Elite Wireless System as Directed, vi Operation, 30

Р

PAT Cleaning, 38 PC Workstation, 5 Power and Transceiver Configuring, 30 Controls and Indicators, 25 Description, 4 Pairing with PC Workstation, 22 Procedure for Pairing, 31 Proper System and PC Installation and Operation, v Protective Measures, 36

R

Radio Frequency Interference Considerations, v Reference, 42 Resend Last Image, 22

S

Safety Issues

Ensure CDR Elite Wireless System Operates Optimally, v Only Dentists or Authorized Designees Are Permitted to Operate the System, vi Operate the CDR Elite Wireless System as Directed, vi Proper System and PC Workstation Installation and Operation, v Protect Sensor from Potential ESD Damage, vi Sensor Check before using, iv Cleaning and Disinfecting, 37 Holders, vi Proper Handling and Placement, vi Setup Windows 7, 7 Windows Vista, 11 Windows XP, 14 Sheaths Disposal, 40 Using with CDR Elite Wireless Sensors, 34 Sheaths and Holders Recommendations for, vi Software, 6 Symbols Explanation of, viii

Т

Troubleshooting Black or White Lines, 41 Image Exposures, 41 No Images, 41

U

Upgrade Utility, 20, 39 Introduction, 39 Utility Upgrade, 20 WiFi Configuration, 19

W

Waste Electrical and Electronic Equipment (WEEE), ix WiFi Configuration Utility, 19 Windows 7, 7 Windows Vista, 11 Windows XP, 14 Wireless Monitor, 18 Wireless System Environmental Specifications, 42 Labels for, xi Picture of, 3 Terms Used in Document, xiii NOTES