

CADENT



EID-2 Optical Impression Device

Operation Manual

iTero Mobile Cart
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April 18, 2007

Optical Impression System for Computer Assisted Design and Manufacturing
(510K exempt under 21 CFR 872.3661)

DIGITAL IMPRESSION DEVICE

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SYMBOLS



Caution! - Wherever this symbol appears on the device, it is recommended to refer to the instructions in this Operator's Guide.



Applied part type B. Any component on which this symbol appears is electric isolation type B.

CLASS 1 LASER COMPLIANCE



Class 1 Laser Product

This product complies with "21 CFR 1040.10" and "EN 60825-1".

FCC COMPLIANCE



This device complies with Part 15 of FCC Rules, and operation is subject to the following two conditions:

- 1) This device may not cause harmful interference.
- 2) This device must accept any interference received, including interference that may cause undesired operation.

FCC Warning

Modifications to the device that are not expressly approved by the manufacturer may void your authority to operate the device under FCC Rules.

CSA COMPLIANCE



This device complies with the following CSA standard for Canada and the USA:

UL Std No. 60601-1 – Medical Electrical Equipment Part 1: General Requirements for Safety.

WARNINGS

POWER

- ⇒ An internal battery backup unit will supply AC power to the system in the event of a power shortage. Therefore, power is present in the internal hardware components even when the system is unplugged from the wall. To ensure that power is removed from all components, follow these instructions:
 - Close all files and applications.
 - Press the front POWER switch to shutdown the system.
 - Press the MAIN POWER SHUT OFF switch on the back of the cart.
 - Unplug power cable from the wall socket.
- ⇒ To restore power, plug in the power cable and press the MAIN POWER SHUT OFF switch. The system will beep to indicate return of power.
- ⇒ According to Department of Transportation (DOT) regulations, the system must be shipped with internal battery leads disconnected. Please note that battery leads should be disconnected and reconnected by authorized Cadent technicians only.
- ⇒ Power is supplied to the system via an isolation transformer.

WIRELESS LAN

- ⇒ The system comes equipped with a Wireless LAN unit. Using standard wired communications will violate the AC mains power isolation.

SCANNER

- ⇒ Scanner emits red laser light (660 nm Class 1) as well as a multi-colored LED light. Normal usage of the scanner does not present any danger to the eye. However, the doctor should refrain from shining the light directly into the patient's eyes.
- ⇒ The scanner cable should be handled with care. Avoid stepping on the scanner cable, rolling over the cable with the cart wheels, knotting, or over-twisting the scanner cable.
- ⇒ The scanner head contains fragile parts and should be handled with care. Before starting to work, be sure to read the instructions in Chapter 3 for disinfecting the scanner and replacing the disposable sleeve.

GENERAL

- ⇒ Be careful not to block any of the air vents on the cart.
- ⇒ Refrain from opening any closed components. Except for the replacement of batteries in the mouse and foot pedal, all closed components should be serviced by authorized Cadent technicians only.
- ⇒ The system is intended for indoor usage only and should not be exposed to direct sunlight.
- ⇒ Due to its weight, the system should be lifted and loaded by two or more persons.

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Chapter 1: Introduction

Overview

The EID-2 functions as a digital impression system for scanning preparation teeth in the doctor’s office and uploading the digital files to Cadent for further processing and CNC crown production. This Operator’s Guide explains how to operate the system, and also describes the system’s hardware components and features.

Chapter 1: Introduction	Overview of the iTero digital crown production process.
Chapter 2: Operating Instructions	Essential instructions for working with the EID-2 system.
Chapter 3: Cleaning & Maintenance	Instructions for cleaning & maintenance of hardware components.
Appendix A: Hardware Specifications	List of hardware specifications.

The Digital Crown Production Process

Below are listed the major steps involved in Cadent’s iTero Service for digital crown production.

STEP 1: Prepare Tooth and Perform Digital Scan

Perform tooth preparation in conventional fashion. Then use the system to perform a high-resolution digital scan of the tooth. Upon completion of the scanning process, place a temporary crown on the patient tooth.

STEP 2: Upload Case to Cadent

Upload the case to Cadent for processing based on your choice of materials and color. Cadent receives the case, performs crown design, and then sends the case to the lab technician for viewing and editing.

STEP 3: Lab Review

The lab technician receives the case, performs any desired changes to crown design, and sends the updated case back to Cadent for production. (If necessary, one or more additional rounds of changes may be performed between Cadent and the lab before proceeding to step 4.)

STEP 4: Cadent Production

Cadent receives the case from the technician, performs a final check, and then sends the case to CNC production.

STEP 5: Crown Shipped to Dentist for Fitting

The finished crown is delivered by courier to the doctor's office. The temporary crown can then be removed from patient tooth and the permanent crown fastened in place.




About the iTero Service

Cadent's iTero service has introduced to the dental industry a breakthrough technology in the field of digital crown production. The iTero technology makes it possible to perform an intra-oral digital scan in the office and to produce a precise crown based on the digitally acquired data.

iTero provides important advantages over existing crown-production methods, including powder-free color scanning, greater crown-production accuracy, and immediate feedback during the scanning process. Refer to our website at www.cadentitero.com to learn more about how the iTero Service can save time and money for your practice.

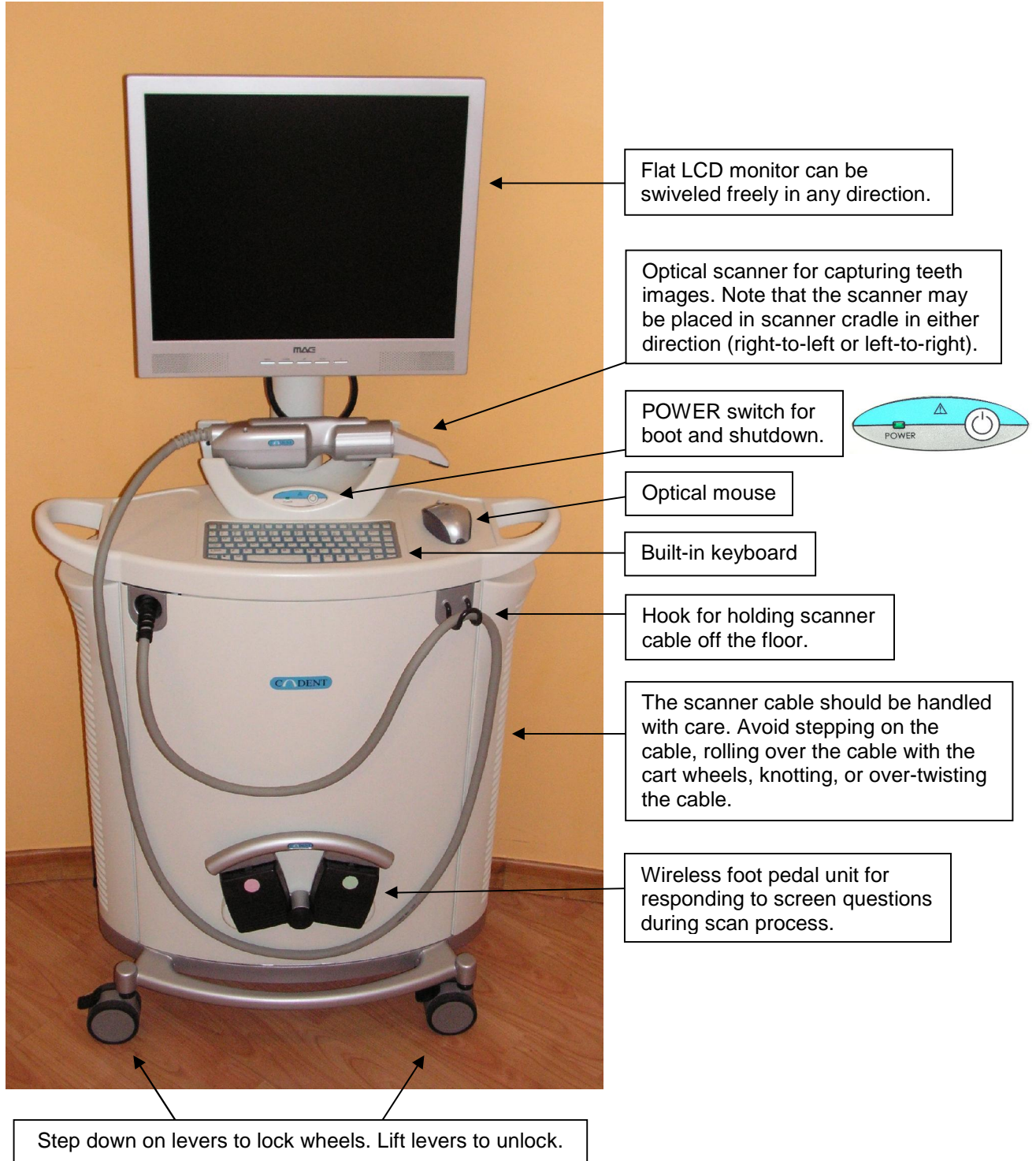
Using the iTero Software

The EID-2 system works together with the iTero software applications.

	<p>The iTero OFFICE application is used for performing 3D color scans of the preparation teeth. The mouse and foot pedals can be used to respond to screen questions during the scanning process. For more information, press F1 to activate the iTero OFFICE help.</p>
	<p>The iTero Case Manager works interactively with iTero OFFICE and handles file communications between the doctor's office and the Cadent Center. For more information, press F1 to activate the iTero Case Manager help.</p>
	<p>The Cadent support icon enables Cadent technical support to provide remote training and support.</p>

Front Features

Basic hardware features are shown below. See Chapter 2 for detailed operating instructions.



Back Features

Basic hardware features are shown below. See Chapter 2 for detailed operating instructions.



Chapter 2: Operating Instructions

This chapter describes the essential operating instructions for booting or shutting down system.

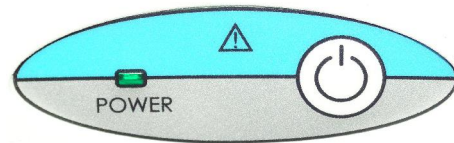
First Time Usage

- (1) Plug the power cord into the wall socket.
- (2) Press the “MAIN POWER SHUT OFF” button on the rear of the cart. System will beep to indicate presence of power.
- (3) Leave the system plugged in for at least 24 hours.

NOTE: For first-time usage it is essential to boot the EID-2 system at least 24 hours prior to the first case scanning to ensure that the battery backup unit is fully charged. This 24-hour charge is also required in cases when the battery backup unit has been emptied (for example, if the system was unattended during a power out). Following the 24-hour charge period, it is recommended to leave the system running 24x7 in order to allow background file transfer with Cadent.

Booting System

- (1) Press the front POWER switch.
- (2) Green POWER LED goes on, PC boots, and MS Windows™ appears.



NOTE: If the green POWER LED does not go on, you may need to press the MAIN POWER SHUT OFF button on the back of the cart. The system will beep once to indicate power has been turned on.

Shutting Down System

- (1) Close all files and applications
- (2) Press the front POWER switch.
- (3) MS Windows™ shuts down, PC turns off, and green POWER LED goes off.

Unplugging System for Short Intervals

Follow these instructions if you need to unplug the system for 10 minutes or less for relocation:

- (1) Save current case in iTero software.
- (2) Attach foot pedal to front of cart.
- (3) Hang scanner cable on cart hook (see picture in Chapter 1).
- (4) Unlock wheels by lifting wheel levers.
- (5) Unplug power cable from the wall socket. **The system will begin to beep.**
- (6) Move system to its new location and plug into wall socket. **The system will stop beeping.**
- (7) Lock wheels by stepping down on wheel levers.
- (8) Resume work where you left off.

Automatic Shutdown

When the cart is unplugged or a power outage occurs, a warning beep will begin. If the system is left unplugged for several minutes, warning messages will appear on the screen and will also be heard through the speakers. As the minutes pass, the status of the battery backup unit will be displayed on the screen. When the battery backup unit is nearly empty (after about 10 minutes), the system will automatically shut down. After an automatic shutdown, it may be necessary to press the front POWER switch once to “wake up” the system.

Main Power Shut Off Before Shipping or Storage

When you need to unplug the cart for an extended period of time, perform these steps:

- (1) Close all files and applications.
- (2) Press the front POWER switch to shut down system.
- (3) Unplug power cable from the wall socket.
- (4) Press the MAIN POWER SHUT OFF switch on the back of the cart to remove power from all internal components.

Restoring Power After Shipping or Storage

To restore power, press the MAIN POWER SHUT OFF switch once and the system will beep to indicate return of power. If the battery backup unit is low or empty (for example, if the system was unattended during a power out), a 24-hour recharge period is required to restore full capacity.

Chapter 3: Cleaning and Maintenance

This chapter describes how to clean and maintain the various hardware components.

Foot Pedal Unit

USING THE PEDALS

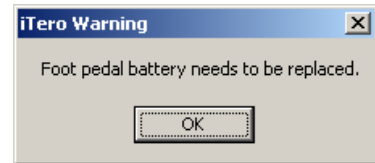
The foot pedal unit contains two pedals for responding to screen questions during scanning. The colors of the two foot pedals match the Pedals dialog in the iTero OFFICE application (red on left, green on right).



CHECKING BATTERY

Pressing either foot pedal turns on the green LED. The battery needs to be replaced if any of the following events occur:

- Pressing a foot pedal causes the LED to blink (or the LED doesn't light up at all).
- Pressing a foot pedal causes no response within the iTero software.
- A warning appears requesting that the battery be replaced.



REPLACING BATTERY

To change the battery, follow the instructions below.

To Replace Battery

1. Open screw and remove battery cover.
2. Take out OLD battery.
3. Press either foot pedal for three seconds.
4. Insert NEW battery.
5. Insert battery cover and tighten screw.

3 Volt
Lithium battery

Type CR2450
or CR2477

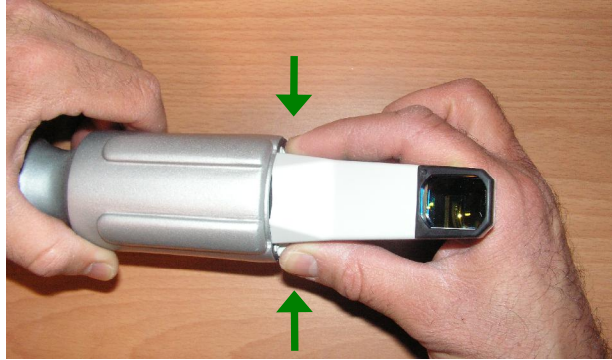


Disinfecting Scanner and Replacing Disposable Sleeve

To avoid cross contamination, it is essential that after each patient you disinfect the scanner and replace the disposable plastic sleeve. First use disinfectant wipes to clean the scanner arm, scanner cradle, keyboard and mouse. Then proceed with the steps below to replace the sleeve.

STEP 1

Press firmly on both sides of the disposable sleeve to release it.



STEP 2

Pull the disposable sleeve slowly off the scanner arm and **discard**.



STEP 3

As you remove the disposable sleeve, a protective metal cover is pulled over the optical surface.



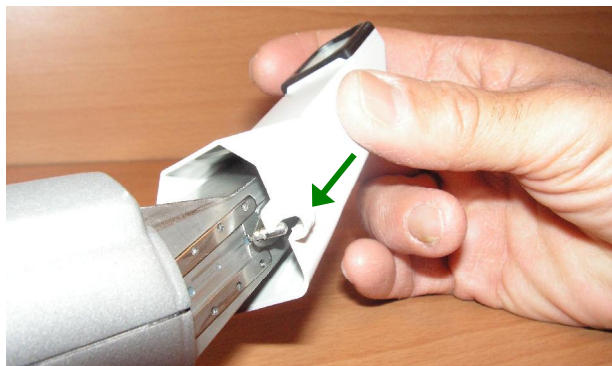
WARNING !!!!

Never touch the optical surface directly with your fingers, as contact may cause damage.



STEP 4

Gently slide on **new sleeve** by aligning metal peg to fit directly into the slot on side of sleeve.



STEP 5

Continue to slide the sleeve slowly onto the scanner arm until it clicks into place.



Cleaning Monitor

- (1) Shut down the system using the front POWER switch to ensure that no power is being supplied to the monitor.
- (2) Lightly dampen a clean white cotton cloth with water and wipe monitor clean.
- (3) Dry the monitor immediately using a clean white cotton cloth.
- (4) If further cleaning is necessary, use a clean cloth to wipe off the monitor with a small amount of alcohol.

- Do not use liquid cleaners, chemicals or aerosol sprays to clean monitor.
- Do not use abrasive cleaning materials such as newspaper or plastics to clean monitor.



Appendix A: Hardware Specifications

ITEM	DESCRIPTION
Monitor	LCD 19" monitor meets FCC and safety approval (UL, CSA, TUV) and operates at 1280x1024 resolution.
Handheld Scanner	Scanner emits red laser light (660 nm Class 1) as well as a multi-colored LED light.
Battery Backup Unit	APC® Back-UPS® ES 725 Broadband
Wireless LAN	DWL-G122™ Wireless USB Adapter produced by D-LINK®. The DWL-G122 provides 2.4 GHz communications using the 802.11g standard for wireless connectivity.
Foot Pedal Battery	3V Lithium coin battery (type CR2450 or CR2477).
Mouse	Optical wireless mouse.
Mouse Battery	A screen message will appear when the mouse battery needs to be replaced. Use 1.5V alkaline LR6 battery (size AA).
Operating Power	115V / 4.5A / 60Hz
Operating Temperature	18° to 30° C 64.4° to 86° F
Storage Temperature	0° to 50° C 32° to 122° F
Humidity	30-90%
Dimensions (including wheels but not including monitor)	Height: 75.2 cm / 29.33 inches Width: 67.0 cm / 26.13 inches Depth: 40.0 cm / 15.60 inches
Weight (including all components)	187.4 lbs 85 kg