

DENTAL

Midmark Mobile True Definition™ Scanner

USER MANUAL



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Introduction

WARNING

United States Federal law restricts this device to sale by or on the order of a licensed dentist or physician; sale by or on the order of any other person is prohibited.

Product Description

The The Midmark True Definition Scanner Mobile System is a digital impressioning system consisting of a tablet computer with integral touchscreen and carrier/stand, a lightweight optical wand, and an accessory isolation transformer. The Scanner is designed to be easily transported from one operatory to another. It may be operated from a countertop or suspended from a range of available mounting accessories.

The scanning wand is a hand-held optical device that captures high-resolution video images, in real time, as the patient is being scanned. The wand contains an optical system comprised of low intensity LEDs, a light sensor, lenses and supporting electronics. The wand is connected to the computer processing unit with a high-speed data transfer cable. The wand is designed to easily maneuver inside the mouth and capture video imagery. The video images are converted to 3-D data sets and displayed in real time.

Via its wireless interface, the tablet computer uploads the 3-D scans to the Midmark Connection Center. The Midmark Connection Center provides a secure web portal, for any parties specifically identified by the clinician, to download the necessary data and complete the prescribed workflow.

The scanner facilitates creating a digital model of the oral anatomy, replacing the work of processing a model from a traditional impression.

Accessory items include a contrast spray to be applied to the patient's teeth and a battery powered sprayer.

Principles of Operation

Overview

The operator of the Scanner applies a contrast spray to the patient's teeth, preparation areas, or oral anatomy and then scans the sprayed areas. The wand and software work together to capture high-resolution images, creating 3-D models in real time.

During creation of the 3-D models, the image data is simultaneously stored to the hard drive. 3-D models are transferred from the system to the Midmark Connection Center using a standard PC wireless network hardware. Industry Standard Secure Sockets Layer (SSL) protocol is used to secure data transfer of 3-D models. The system's software User Interface includes password, screen locking and logging features to comply with U.S. and international patient health information privacy requirements.

Depth Encoding by the Optical Device

The intraoral scanning wand contains four main parts: a lens assembly, an imaging sensor, illuminating LEDs and firmware. The assembly includes three optical channels, which produces three separate views of the scanning region. Each view has a slightly different perspective due to geometric parallax. This parallax encodes 3-D information in the video images. A full 3-D replica of the oral anatomy is constructed from these video images, displayed to the user in real time, and uploaded to the Midmark Connection Center.

Wireless Network Connection

Many dentist office's will have an existing internet network with a wireless router that is either store-bought or supplied by the location's Internet Service Provider (ISP). The customer must have a Wireless Network available at their site prior to installing the scanner.

- A Wireless Access Point (WAP) must be available for the System to be associated (connected) to.

- A Dynamic Host Configuration Protocol (DHCP) or Static IP address may be used and must have available IP addresses for the System.
- Reduced wireless activity may be observed in lead-lined rooms, rooms which limit positioning of the System and/or operatories over 15 meters (45 feet) from the WAP.

Battery Management Best Practices

The scanning, case processing, and upload functions of the scanner demand significant power from the system's battery. The Scanner is capable of scanning multiple cases on a fully charged battery. The number of cases will vary depending on the amount of idle time spent on battery prior to scanning, and also will vary depending on the duration of the scanning time for the cases. The case processing and upload functions of the Scanner are executed only while the scanning unit is attached to the power connection.

To ensure that cases upload as quickly as possible, and to ensure there is always sufficient battery charge to complete a scan, it is recommended to plug into the power connection and recharge the battery between cases.

Indications

The Scanner is an optical impression system used to record the topographical characteristics of the dentition and/or full arch and preparation areas (including features such as implant scan locators fixtures, braces, brackets, etc.). In addition, it can record the topographical characteristics of the oral anatomy (such as soft tissue, gingivae and palate). The three-dimensional (3-D) model generated from the scan may be further used for the design and manufacturing of dental restorations including implant supported prostheses and partial frameworks and can be used to design and manufacture physical models of the teeth. It may also be used to create orthodontic appliances, retainers and accessories.

Contraindications

The product is not intended for uses outside its labeled indications for use.

Intended User Profile: Job Type, Training, and Experience

Trained professionals (dentists, orthodontists, dental assistants, and dental hygienists) in dental offices are the primary users.

The sales force and trainers are secondary users. It is expected that any secondary users using the product in-vivo will have had appropriate training for such (e.g., they were previously dental assistants). They are expected to have training in prevention of cross-contamination and disinfection procedures.

Other users may include individuals in dental training (dental school or dental assistance training) working under the supervision of dental professionals.

Midmark True Definition Scanner Components

The system consists of hardware components and embedded software. All system components are suitable for use within the patient environment. The system also uses accessories (Midmark High-Resolution Scanning Spray and Midmark High-Resolution Sprayer) to achieve its intended purpose.

Hardware Components:

The major hardware components of the scanner, include a tablet computer in a mobile form.

Carrier Assembly:

The carrier consists of a plastic and aluminum frame acting as a countertop stand with handles for positioning, transporting, and protecting the tablet computer. The carrier provides an interface to a mounting system. This enables the clinician to customize the system's integration into the operatory with a range of accessories by using a VESA (Video Electronic Standards Association) mount plate to attach to a floor stand or double-hinged arm, clamped to the dental unit.

WARNING

Use only the isolation transformer and power adapter provided by Midmark to power and recharge the tablet.

WARNING

The isolation transformer and power adapter must be used together.

Computer:

The Scanner integrates a tablet computer with an integral Touchscreen and wireless capability.

Software:

The system's embedded software captures high-speed video data and reconstructs a digital impression. It is based on a Fedora Linux Kernel. The user may not modify the software or operating system or install any additional applications on the system. Application software updates are managed by Midmark.

Power:

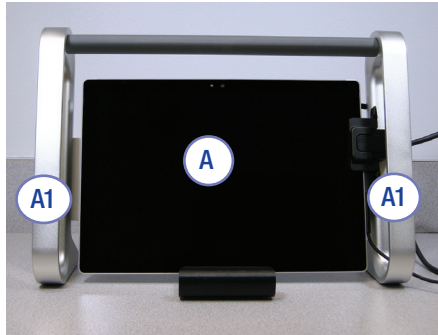
A qualified (UL listed) stand-alone isolation transformer is provided together with a small power supply component for the tablet computer. These **MUST** be used together.

The Scanner is intended to operate routinely while connected to power. Users may elect to equip multiple locations with the Midmark supplied or recommended isolation transformer and power supply component to simplify transport. In this case, it is expected these parts are incorporated into the operatories in a semi-permanent fashion.

The Scanner can be operated, for brief periods, from its internal battery. This provides a flexible alternative for multiple locations and busy schedules. However, it is intended to be connected to an electrical mains power source most of the time.

Scanning Wand:

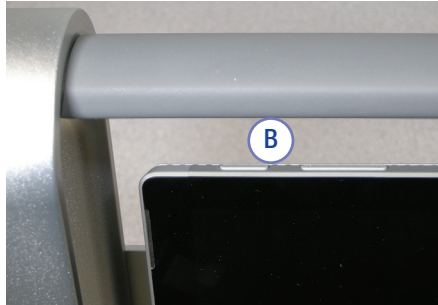
The scanning wand is a hand-held optical device that captures high-resolution video images, in real time, as the patient is being scanned. The wand is connected to the computer via a high-speed USB 3.0 data transfer cable. The wand contains optics and sensor electronics to capture images in real time to be processed by the computer processor. The wand is considered the applied part of the Scanner.



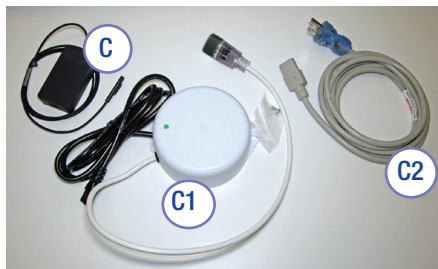
Callouts for Figure 1

A Tablet Computer

A1 Carrier



B System ON



C Computer Charger

C1 Isolation Transformer

C2 Power Cord



D Power Connector and Charging Port



E Wand Connection Port

Figure 1. Hardware Components and Connections

Callouts for Figure 2

- H** VESA System Mount Attaches to Variety of Mounting Accessories
- H1** Wand Holder

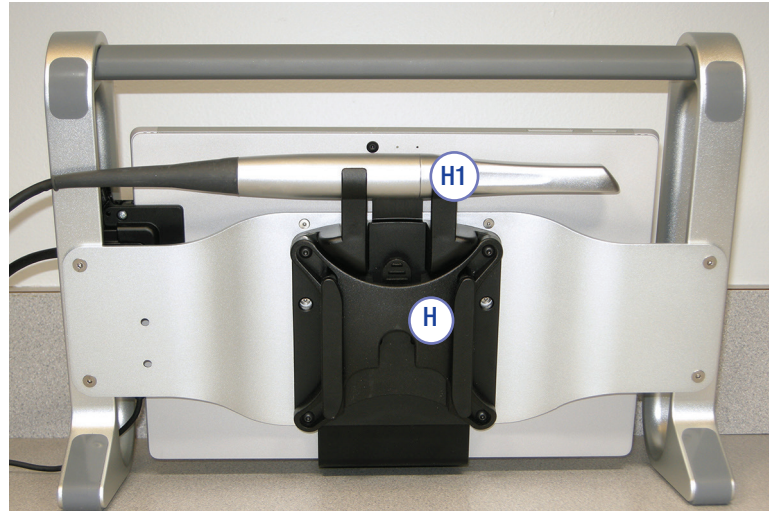


Figure 2. VESA System Mount and Wand Holder

Callouts for Figure 3

- I** System Alternate Working Position

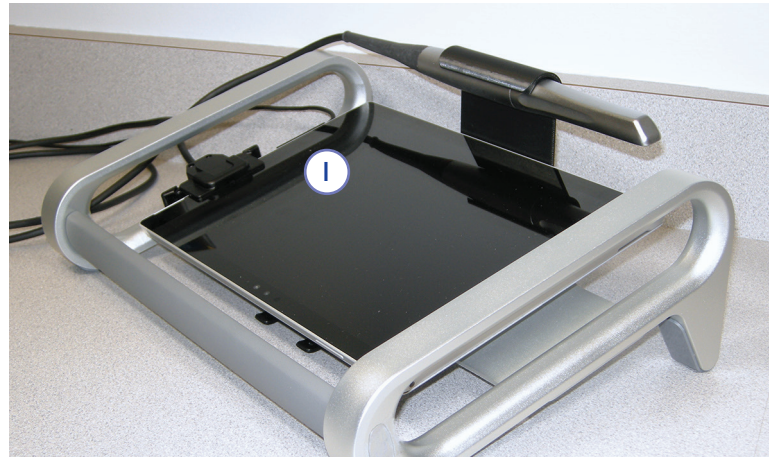


Figure 3. Alternate Working Position



Callouts for Figure 4

- J** Lens
- K** Sealed Seam
- L** Unsealed Seam
- M** Wand Cable Protector and Strain Relief



Figure 4. Scanning Wand

SAFETY INFORMATION

Signal Words	
 WARNING	Indicates a hazardous situation which, if not avoided, could result in death or serious injury.
 CAUTION	Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.
NOTICE	Indicates a situation, which, if not avoided, may result in property damage.

Warnings, Cautions and Notices

WARNINGS

To reduce the risks associated with hazardous voltage and fire:

- Use only the Midmark supplied power connection for this product and certified for the country of use.
- Use only properly grounded outlet; do not use extension cords or multiple portable socket outlets.
- Use only the Isolation Transformer, Power Cord, and USB cable provided by Midmark to power and recharge the computer.
- Do not open the computer casing.
- Do not use a power source adapter.
- Do not modify any part of the system.
- Do not position the equipment where unplugging is difficult. The plug serves as the disconnect device.
- Protect the power cords from being walked on.
- Do not jerk, knot, sharply bend or otherwise abuse the power cords.
- Do not allow electrical components or power cord to get wet.
- Do not attempt to service the system yourself; the system contains no user serviceable parts; contact Midmark for service.

To reduce the risks associated with hazardous voltage:

- Do not use the wand or any part of the system (computer, cables, etc.) if damaged.
- Do not plug the system into an uninterruptable power supply (UPS).
- The system contains single connection USB – Do not use USB hub.
- Do not attempt to plug or unplug the power cord from an electrical outlet with wet hands.
- Look for any loose parts, sharp edges or signs of wear or damage that could interfere with the scanner's proper use. Contact Technical Support if there is visible damage or if the device does not perform as expected.
- Disconnect the scanner from the AC power if the system falls or the cables are damaged.

To reduce the risks associated with fire:

- Do not use the scanner wand in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.
- Assure the system is completely dry after cleaning and disinfecting.
- The system is not intended or designed for use in wet or outdoor environments.



To reduce the risks associated with hazardous voltage and fire: Do not open the computer casing.

To reduce the risks associated with hazardous voltage: Do not service the scanner — use only Midmark authorized service personnel.



Examine the wand and the system (carrier, screen, etc.) for physical damage before each use. Look for any loose parts, sharp edges or signs of wear or damage that could interfere with its proper use. Contact Technical Support if there is visible damage or if the device does not perform as expected.

CAUTION

If gloves may have been soiled during the procedure, handle the device only on the top or side handles or on the touchscreen. Change soiled gloves before disconnecting cables or handling any other parts of the device.

To reduce the risks associated with cross-contamination:

- Read, understand, and follow the cleaning and disinfecting instructions. (See **Cleaning and Disinfection Tab**).
- Disinfect the wand before each use, including the first use. (See **Cleaning and Disinfection Tab**).
- Always store the wand in a barrier sheath or other suitable plastic bag and place in the wand holder.
- Clean the computer and computer carrier, the body of the wand and the wand cable after each patient.

To reduce the risks associated with bio-incompatibility:

- Use only Midmark High-Resolution Scanning Spray (see Midmark High-Resolution Sprayer User Guide and Midmark High-Resolution Scanning Spray Instructions for Use).

Warning: Battery Safety

This device contains a built-in battery, improper use of which may result in explosion. Do not heat, open, puncture, mutilate, or dispose of the product in fire. Do not leave the device in direct sunlight for an extended period of time, which could cause melting or battery damage. The battery in this device is not user replaceable and should only be replaced by Microsoft or a Microsoft Authorized Service Provider.

CAUTIONS

To reduce the risks associated with very strong electromagnetic fields:

- Avoid using any strong radio frequency signal or any portable or mobile communication devices near the scanner.
- Move the portable or mobile device away from the Scanner if the Midmark Scanner exhibits unexpected behavior.

To reduce the risks associated with impact or pinch:

- Always determine and use correct mounting hardware (e.g., size and grade) for your application.
- Do not mount the system so that the computer carrier is located above the patient.
- Position the power cord and wand cable to avoid a trip hazard.
- Avoid getting finger(s)/thumb caught between quick-release and mounting system.

To reduce the risks associated with environmental contamination:

- Follow applicable regulations when disposing of all electronic circuits and related replacement parts.
- Ensure the biocides used for cleaning and disinfection are disposed of according to local applicable government regulations. For disposal information refer to the respective product Material Safety Data Sheet (MSDS).



To reduce the risks associated with environmental contamination:
Follow applicable regulations when disposing of all electronic circuits and related replacement parts.

NOTICE

If multiple wands and/or systems are used, contact Midmark Technical Support and Service to ensure parts are interchangeable before switching and scanning.

NOTICE

It is possible to encounter a wand communication failure due to a transient power fluctuation or electrostatic charge. If such a failure occurs during scanning, navigate to the home screen and then return to the scan interface.

NOTICES

The wand temperature can increase to 41° C (106° F) which is not expected to cause any clinical effects for the intended patient population. The wand is in continuous movement and it is expected there will be less than 1 minute of uninterrupted contact with the oral soft tissues.

To reduce the risk of damaging the scanner, read, understand, and follow these notices.

To avoid damage to the system:

- Usage only by qualified operators, trained by Midmark or authorized Midmark trainers.
- Do not break or alter any existing connections on the Scanner.
- Do not press and hold the power button on the top of the computer.
- Do not use ammonia-based cleaners on the Touchscreen.
- Do not use an alcohol solution over 70% on the Touchscreen and system.
- Do not spray or pour liquids on the Touchscreen, carrier, wand body or wand cable.
- Do not leave the Scanner in direct sunlight for an extended amount of time. Ultraviolet light and excessive heat can damage the Touchscreen.
- Be sure the power cord is unplugged before moving the system.
- Plugging in and turning on the system are the only power- or service-related interactions a user should have with the scanner. If the system fails to function properly, call Technical Support.
- Install where the temperature range is 10°C to 32°C (50°F to 89.6°F).
- Store and use the scanner within prescribed temperature, humidity and altitude limits.

To avoid damage to the battery:

- To protect the tablet's rechargeable Lithium-ion battery, store the Scanner system in temperatures between 0°C to 35°C (32°F to 95°F)
- The battery does not need to be empty or low to recharge.

To avoid damage to the wand:

The scanning wand is a high-precision optical instrument. Improper handling of the wand, such as dropping, shaking or bumping, could cause the wand to malfunction or break.

Always follow these guidelines:

- Exercise caution when handling the scanning wand.
- Return the wand to its holder when not in use.
- Do not kink the wand cable that connects to the wand.
- See the Cleaning and Disinfection Tab in this manual.

EMC Statement

Information regarding potential EMC interference and advice for avoiding it.

	<p>Mobile RF communications equipment can affect the performance of medical electrical equipment. (The True Definition scanner is not considered life-supporting equipment.) Midmark advises against using the scanner adjacent to other devices. If it must be used near other devices, carefully adjust their configuration to ensure that electromagnetic interference (EMI) does not degrade performance. Test both devices for normal operation. See the Immunity Test and Emissions Test tables below for detailed information.</p>
	<p>Use the shielded signal cord supplied with the scanner. Using accessories, transducers, or cables other than those provided by or specified by Midmark can result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment. This can result in improper operation.</p>
⚠ WARNING	<p>Use portable RF (radio frequency) communications equipment, including peripherals such as antenna cables and external antennas (including cables specified by Midmark) no closer than 30 cm (12 in.) to any part of the scanner. Otherwise, performance of the equipment may be degraded.</p>
	<p>There is no guarantee that interference will not occur in a particular installation. If the scanner does cause harmful interference to radio or television reception, which can be determined by turning it off an on, try to correct the interference by one or more of these measures:</p> <ul style="list-style-type: none"> • Reorient or relocate the receiving antenna. • Increase the separation between the equipment and the receiver. • Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
	<p>Changes or modification to this scanner not expressly approved by the party responsible for compliance could void the user's authority to operate it.</p>

Immunity Test	Immunity Test Level
Electrostatic discharge	± 8 kV Contact, ±15 kV Air
Radiated RF EM fields	3V/m
	80MHz-2.7 GHz 80% AM at 1kHz
Rated power frequency magnetic fields	30 A/m
Electrical fast transients	±2 kV at 100kHz repetition frequency
Surges	Line to Line: ±1 kV
Conducted RF	6V: 0.15MHz -80MHz
	80% AM at 1kHz
Voltage dips	0 % UT; 0,5 cycle
	At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
	0 % UT; 1 cycle
	and
	70 % UT; 25/30 cycles
	Single phase: at 0°
Voltage interruptions	0 % UT; 250/300 cycle

Emissions Test	Emissions Test Level
Conducted and radiated RF emissions	CISPR 11 Group 1 Class B

Safety/Regulatory Symbols














Safety/Regulatory Symbols	
	Information useful to an operator, not related to safety.
	A hazardous situation which, if not avoided, could result in minor or moderate injury.
	A hazardous situation which, if not avoided, could result in serious injury or death.
	Consult instructions for use.
	Refer to instruction manual/booklet.
	The FCC (Federal Communications Commission) mark.
	For indoor use only.
	Type B applied part.
	Alternating current.

table continued...

Safety/Regulatory Symbols	
	<p>Model G7</p> <p>This product has been tested and certified in accordance with the following standards:</p> <ul style="list-style-type: none"> • AAMI ES60601-1 Issued: 2006/03/09 2005 version (R2012) Medical Electrical Equipment. Part 1: General requirements for Basic Safety and Essential Performance; with AMD C1; 2009, AMD 2; 2010, AMD 1; 2012 • CAN/CSA-C22.2 NO. 60601-1:14 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance • EN 60601-1:2006/A1: 2013 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance • IEC 60601-1-6:2010/AMD1:2013 Amendment 1 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability • IEC 62366:2007/AMD1:2014 Amendment 1 - Medical devices - Application of usability engineering to medical devices
	<p>Atmospheric pressure limitation.</p>
	<p>Temperature limit.</p>
	<p>Manufacturer.</p>

FCC Requirements

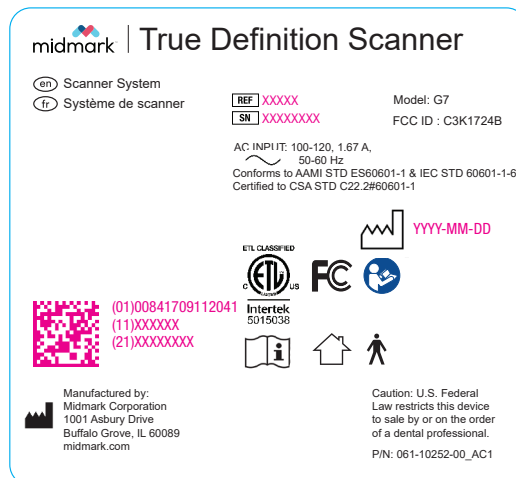
This device was tested and complies with the limits for a Class B digital device, pursuant to Part 15 of the Federal Communications Commission (FCC) Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radiofrequency energy, and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. There is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

To comply with the limits of an FCC Class B computing device, always use the shielded signal cord supplied with this unit. Changes or modification to this equipment not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Rating and ID Plate

The information on the rating plate describes the scanner and includes the registration number.



The rating plate is located on the rear frame of the scanner.

Technical and Regulatory Specifications

The Technical and Regulatory specifications of the scanner are summarized in the following pages. All specifications are subject to change. The Scanner has been evaluated using the processes described in these standards and was found to meet the relevant requirements.

Standards Compliance		
Standard	Title	Type of Standard
ISO/EN 10993-1: 2009(E)	Biological Evaluation of Medical Devices — Part 1: Evaluation and Testing with a Risk Management Process	Biocompatibility
IEC/EN62304: 2015	Medical Device Software — Software Life Cycle Processes	Quality Management
IEC 60601-1: 1988 +A1: 1991 +A2: 1995	Medical electrical equipment — Part 1: General Requirements for Safety	Product Safety
ANSI/AAMI ES60601-1: 2005 CAN/CSA C22.2 No. 60601-1: 08 IEC 60601-1: 2005 +CORR. 1 (2006) +CORR. 2 (2007) EN 60601-1: 2006/AC: 2010	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	Product Safety
IEC 60601-1-2: 2014	Medical electrical equipment — Part 1: General Requirements for Safety: Collateral Standard: Electromagnetic Compatibility Requirements and Tests	Electromagnetic Compatibility (EMC)
IEC 60601-1-6: Issue: 2010/01/27 Ed:3 CAN/CSA C22.2# 60601-1-6: 11	Medical electrical equipment — Part 1-6: General Requirements for Safety: Collateral Standard: Usability Medical electrical equipment — Part 1-6: General requirements for safety — Collateral Standard: Usability	Usability (Model G5 only)
IEC 62471: 2006 EN 62471: 2008	Photobiological safety of lamps and lamp systems	Safety
ISO/EN ISO 1041: 2008 + A1:2013	Information supplied by the manufacturer of medical devices	Labeling
ISO/EN 15223-1: 2016	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied	Labeling
IEC 62366-1: 2015	Medical devices — Part 1: Application of usability engineering to medical devices	Usability

Specifications

This device is an optical impression taking system.

General Specifications and Classifications	
Field of View	~10mm x 13.5mm at nominal depth
Working Depth	0mm to 17mm from Wand lens
Direction of View	90° from long axis of Wand
Illumination	Narrow-band blue light, 470 (+20 to -10nm)
Video Capture Rate/Flash Rate	20 Hz 20 Captures/second (60 Images/second)
Touchscreen Size	30.5cm (12 in.) diagonal
Dimensions of Tablet and Carrier	36.8cm W x 25.9cm H x 14.9cm D (14.5 in. W x 10.2 in. H x 5.9 in. D)
Power Input	100-120/220-240V ac, 50/60 Hz
Protection Against Electric Shock	Class II
Protection Against Harmful Ingress of Water or Particulate Matter	IPX0
Mode of operation	Continuous
Wireless LAN Adapter	IEEE 802.11 a/b/g/n/ac
Frequency Bands of Wireless Communications	2.4/5 GHz

Weights	
Total Shipping Weight	15.88kg (35 lbs)
Tablet with Carrier	2.75kg (6.06 lbs)
Wand	253g (8.9 oz)

Wand Dimensions	
Length	304.8mm (12 in.)
Wand Tip Width	15.6mm (0.61 in.)
Wand Tip Height	14.2mm (0.56 in.)
Maximum Diameter	24.4mm (0.96 in.)
Wand Cable Length	1.79m (5.9 ft.)
Calibration	No Field Calibration Required

Temperatures	
Operating	10°C to 32°C (50°F to 89.6°F), up to 1524m (5000 ft.) 10°C to 30°C (50°F to 86°F), 1525-3000m (5001-10,000 ft.)
Storage/Transport	-10°C to 50°C (14°F to 122°F)

Humidity	
Operating	30% to 85% RH, non-condensing
Non-operating	10% to 85% RH, non-condensing

Altitude	
Operating	Up to 3000m (10,000 ft.)
Storage/Transport	Up to 12.19km (40,000 ft.)

Atmospheric Pressure	
Operating	700 - 1060 hPa
Storage/Transport	700 - 1060 hPa

Scanner Cables				
Qty.	Type	Part Number	Exposed Length	Designation
1	Unshielded, Power Cable	78-8150-2344-1	0.61 m (2 ft.)	AC power to transformer
1	Unshielded, Power Cable		1.8 m (6 ft.)	Transformer to system power supply
1	Shielded USB Cable, Wand		1.98 m (6.5 ft.)	Digital video cable
1	Unshielded, Power Cable		1.7 m (5.6 ft.)	DC power to Tablet

The scanner complies with the safety standard for medical devices IEC 60601-1 and with the EMC standard for medical devices IEC 60601-1-2. The use of cables other than those supplied by Midmark with the system may result in increased EMISSION or decreased IMMUNITY. To avoid risk of electrical shock, do not connect the system to a power source using any other connection than the provided isolation transformer.

Problem Reporting and Suggestions

Your comments are important to us. You can influence the quality and future design of the system and its documentation. Submit problems, questions, enhancements, and recommendations to Midmark Technical Support by phone or mail.

Warranty

Midmark warrants this product will be free from defects in material and manufacture. Refer to your Purchase and Sales agreement for full warranty terms. Midmark MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the products for user's application. If this product is defective within the warranty period, your exclusive remedy and Midmark's sole obligation shall be repair or replacement of the Midmark product.

Attempting to open or service the unit yourself could damage it and void the warranty!

Limitation of Liability

Except where prohibited by law, Midmark will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Cleaning and Disinfection

Wand Cleaning and Disinfecting

Cleaning and high-level disinfecting are distinct procedures required to reprocess the scanner wand for reuse.



Step 1: Wand Cleaning¹

Use fresh gloves prior to unplugging and cleaning the wand.

1. Unplug the wand using the boot (textured portion) of the connector and loop the cord to make it portable.
2. Rinse the wand surface under running tap water (~22°C/72°F) for one minute without getting the cable strain relief or the USB connector wet.
3. Use a soft, non-abrasive cloth wetted with CaviCide AF to wipe the cable and connector. (In Canada, use Birex SE instead of CaviCide AF.) Do not immerse the cable or connector.
4. Wipe the wand surface for thirty seconds with a soft, non-abrasive wipe wetted with an enzymatic detergent solution.
5. Discard the wipe into a biohazard waste container.
6. Rinse the wand again under running tap water for one minute without getting the cable strain relief or the USB connector wet.
7. Dry the wand with a clean, non-abrasive, lint-free wipe and allow it to dry completely.
8. Inspect the wand for any visible contamination. If necessary, repeat the cleaning process.

Step 2: Wand Disinfecting¹

1. Use fresh gloves prior to disinfecting the wand.
2. Do Not Use CaviWipes™. Immerse the wand in an appropriate soaking container containing one of the high-level disinfectants listed in the table below. (The cable does not have to be disinfected.)
3. Follow the disinfectant manufacturer's instructions for use. Note the prescribed soak times.
4. After soaking, rinse the wand under running water for one minute.
5. Dry the wand with a clean, non-abrasive, lint-free wipe and allow it to dry completely.
6. Before use, reconnect the wand by plugging the connector into the USB port.
7. Use a barrier sheath to keep the wand clean prior to next use.

Step 3: Pre-use Checking

1. Before use, perform a visual check of the system.
2. Look for cracks in the wand or cable.
3. Check for severe kinks in the cable.
4. Look for metal discoloration, corrosion, or damage of any kind.
5. Make sure the wand and lens are clean.

¹ Meets regulatory agencies' requirements.

High-Level Disinfectants for the Wand (United States)			
Active Ingredient Minimum Concentration	Examples of Trade Names*	pH Range	Directions for Use
0.55% Ortho-phthaldahyde (OPA)	Cidex® OPA, Rapicide® OPA, Metricide™ OPA	7.2-7.8	Follow disinfectant label instructions for soak time and conditions
2% Glutaraldehyde	Dentasept® Ultra, Metricide™ Plus 30, ProCide-D® Plus, Aldahol® HLD	6.5-10	
<p>*High-level disinfection validations were conducted for the Midmark True Definition Scanner Wand using Cidex® OPA, Dentasept® Ultra and Metricide™ Plus 30. If these are not available, determine a compatible equivalent disinfectant based upon regulatory clearance (high-level disinfectant), equivalent or higher active ingredient concentration and listed pH range.</p> <p>Failure to adhere to the proper protocol listed in the previous steps may lead to improper disinfection and potential cross-contamination hazards.</p>			

High-Level Disinfectants for the Wand (Canada)				
Active Ingredient Minimum Concentration	Examples of Trade Names*	Drug Identification Number (DIN)	pH Range	Directions for Use
0.55% Ortho-phthaldahyde (OPA)	Cidex® OPA, Rapicide® OPA	02239732 02414333	7.2-7.8	Follow disinfectant label instructions for soak time and conditions
2% Glutaraldehyde	Metricide™ Plus 30	01964496	6.5-10	
<p>*High-level disinfection validations were conducted for the Midmark True Definition Scanner Wand using Cidex® OPA and Metricide™ Plus 30. If these are not available, determine a compatible equivalent disinfectant based upon regulatory clearance (high-level disinfectant), equivalent or higher active ingredient concentration and listed pH range.</p> <p>Failure to adhere to the proper protocol listed in the previous steps, may lead to improper disinfection and potential cross-contamination hazards.</p>				

Cleaning and Disinfecting the Scanner

Step 1: Cleaning¹

1. Use a soft cloth wet with warm water to remove visible debris immediately after use. (Midmark True Definition scanners do not need to be shut down for cleaning.)
2. Use fresh gloves before further cleaning.
3. Wipe surfaces with Birex SE[®] (using a soft cloth) or CaviWipes[™] (in the United States or Canada), CaviWipes[™] AF (in the United States only) or an equivalent detergent.

Step 2: Disinfecting¹

1. Use fresh gloves when disinfecting the scanner.
2. Thoroughly wipe surfaces with Birex SE[®] (using a soft cloth) or CaviWipes[™] or an equivalent intermediate-level disinfectant wipe. See the photograph and the table below for the appropriate solutions. (CaviWipes[™] AF can be used only in the United States.)
3. Follow the disinfectant manufacturer's instructions for application and wet contact time.
4. Dry surfaces with a soft, lint-free cloth.

Refer to the color-coding in this photograph when deciding which cleaning and disinfection products to use on the various areas of the scanner.



Do NOT apply liquids directly to any surface.
Only the wand allows for direct liquid contact per instructions.









- 1 Meets regulatory agencies' requirements.
- 2 CaviWipes[™] AF are an alcohol-free quaternary ammonium wipe. CaviWipes[™] can be used on the touchscreen. Do not use isopropyl alcohol, window cleaner, or other chemical cleaners on the touchscreen.
- 3 Birex SE[®] diluted according to the manufacturer's recommendations can be used to disinfect the touchscreen and bezel. Do NOT use Birex[®] Wipes as the ingredients are incompatible with the touchscreen.

Intermediate-Level Disinfectants (United States)		
Active Ingredient	Trade Names*	Directions for Use**
0.28% Diisobutylphenoxyethyl dimethyl benzyl ammonium chloride, 17.2% Isopropanol	Cavicide™	Wet contact time: 3 minutes at 20°C
Diethylene Glycol Monobutyl Ether	Cavicide™ AF	Wet contact time: 3 minutes at 20°C
7.7% Phenylphenol, 7.6% p-tertiary-amylphenol	Birex SE®	Wet contact time: 10 minutes at room temperature
<p>* Listed disinfectants are not available in all geographic areas; consult a local supplier for products available in your area. Equivalent products will have the same active ingredients and be able to kill hepatitis and tuberculosis. Recommendations only. Midmark is not responsible for any damage to equipment from improper use of the product and/or not following instructions.</p> <p>** Follow disinfectant label instructions for wet contact time and conditions. Failure to adhere to the proper protocol listed in the previous steps may lead to improper disinfection and potential cross-contamination hazards.</p> <p>Metricide™ Plus 30, Metricide™ OPA, ProCide-D®Plus, CaviWipes™ and Cavicide™ are trademarks of Metrex Research. Cidex® OPA is a registered trademark of Advanced Sterilization Products, a Johnson & Johnson company. Rapicide® is a registered trademark of Medivators Inc. Dentasept® Ultra is a registered trademark of Unident SA. Birex SE® is a registered trademark of Biotrol. Aldahol® is a registered trademark of Healthpoint, Ltd.</p>		

Intermediate-Level Disinfectants (Canada)			
Active Ingredient	Trade Names*	Drug Identification Number (DIN)	Directions for Use**
0.28% Benzethonium chloride, 17.2% Isopropanol	CaviWipes™	02242209	Follow the disinfectant label instructions for soak time and conditions.
7.7% Phenylphenol, 7.6% p-tertiary-pentylphenol	Birex SE®	02168723	
<p>* Listed disinfectants are not available in all geographic areas; consult a local supplier for products available in your area. Equivalent products will have the same active ingredients and be able to kill hepatitis and tuberculosis. Recommendations only. Midmark is not responsible for any damage to equipment from improper use of the product and/or not following instructions.</p> <p>** Follow disinfectant label instructions for wet contact time and conditions. Failure to adhere to the proper protocol listed in the previous steps may lead to improper disinfection and potential cross-contamination hazards.</p> <p>Metricide™ Plus 30, Metricide™ OPA, ProCide-D®Plus and Cavicide™ are registered trademarks of Metrex Research. Cidex® OPA is a registered trademark of Advanced Sterilization Products, a Johnson & Johnson company. Rapicide® is a registered trademark of Medivators Inc. Dentasept® Ultra is a registered trademark of Unident SA. Birex SE® is a registered trademark of Biotrol. Aldahol® is a trademark of Healthpoint, Ltd.</p>			

Icons/Tools/Features/Status

Scanning/Interface Icons and Buttons

Icon	Purpose
	Upper/lower arches — Touch one of these buttons to select which arch to scan (after the arch has been scanned, the button displays in color).
	Mandible/Maxilla switch — Touch this button to switch the arch designation of a previously scanned arch from mandible to maxilla and vice versa.
	Right, anterior, left bites — Select which bite to scan to create a registration (after the bite has been scanned, the button displays in color).
	Additional scan — orders an additional study model. Only 1 additional scan may be ordered..
	Check preparation — This button becomes active after a scan is accepted. Touch it to display a dropdown box to add or remove preparations.
	Add preparation — Access the Preparation Selection screen, to identify a prepared tooth by number and preparation on the scene. This button is available in the preparation dropdown box and when reviewing a scan.
	Start/stop scan — Start and stop a scan by pressing these buttons on the screen (or by tapping the wand). (See NOTICE).
	Delete scan — Delete the last scan, or all scans, in the selected arch.

NOTICE

Turning the wand on and off:

- To start or stop the scan, you may use the buttons on the screen.
- Alternatively, you may double tap the wand to start it and likewise to stop it.
- Double-tap functionality is turned OFF by default. To turn it on: Go to Home > Management > Settings > Wand

Home Screen Features

Navigation: Back and Home Buttons

Touch a tab or button to navigate through the screens. Some screens have a **Back** button to return to the previous screen. The **Home** button returns to the main screen.

Message Line

The Home Screen has a message line that identifies the screen and provides visual cues to the user on the bottom left. Messages about the page are displayed as Page Titles. The Health icons (bottom right) provide visual cues about the wand, system messages, wireless, Connection Center and Battery life (Midmark True Definition Scanner).

Wand Health

The Wand Health icon is at the bottom right of the screen. The Wand Health icon indicates whether a wand is connected to the system and also if there are any problems with a connected wand (such as a missing camera file).

System Message Alert

The **System Message Alert** icon is next to the Wand Health icon at the bottom right of the screen. It indicates if there are any warnings or alerts that require your immediate attention. If there is a message, touch the button to display the Messages screen.

Wireless Connectivity Status Icon

The **Wireless Connectivity Status** icon is located next to the **System Message Alert** icon at the bottom right of the screen. The Wireless Status icon indicates if the system can properly communicate with the Wireless Access Point (WAP). Touch the icon to display more details.

Help Line Status Icon

The **Help Line** icon is on the bottom right hand corner of the device next to the battery icon. When touched, the status of the help line is displayed. Also, a help line can be established by selecting “Start Session” or disconnected by selecting “End Session.”

Battery Status Icon

The **Battery Status** icon is located in the bottom right corner of the screen. The battery status indicates if the tablet is plugged in and charging or operating on battery. When plugged in to power, a charging symbol is overlaid on the battery icon. Pressing the battery icon gives a battery percent. (See Battery Level Considerations for icons and explanations).

NOTICE

The scanner is intended to operate routinely while connected to power. It can be operated, for brief periods, from its internal battery.








NOTICE

The scanner **must** be connected to the power cable to upload cases. Uploading **will not** be initiated while the system is unplugged. Upon reconnecting to power, uploading will resume within 5 minutes.

NOTICE

If the battery drops below 5%, which is considered critically low, the device will not function until the power cable is reconnected.

Battery Level Considerations

Charge Levels	
	90 - 100%
	70 - 89%
	50 - 69%
	30 - 49%
	15 - 29%
	1 - 14%
	Plugged in, charging

Battery Level and Usability

With the device unplugged:

10-14% battery:

- Access available to the scanning interface, but will not be able to scan. A warning message will appear: **Insufficient Battery**. This action requires that the battery be at least 15% charged or that the power cable be reconnected.
- The user is able to fill out and sign a prescription.

<10% battery:

- No access to scanning interface. The warning message will appear: **Insufficient Battery**. This action requires that the battery be at least 10% charged or that the power cable be reconnected.

Scanning on battery


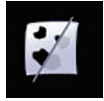



Level of battery is over 15%:

- Access available to the scanning interface and will be able to begin scan.
- If while scanning, the battery drops below 10%, the scan will be interrupted with the following message: Attention: This action requires that the battery be at least 10% charged or that the power cable be reconnected.
- After dismissing the message, the user can accept or reject the portion of scan that was obtained.

Scanning and Reviewing Tools and Features

This section describes the various tools and features found on the right side of the Scanning Interface screen.

Manipulation Icons and Buttons

Icon	Meaning
	Reset — Returns to the initial view of the scan.
	Presentation View — Temporarily fills in holes to present the image of a complete scan.
	Completion Arrows — Indicate areas where the scan has not been able to mesh properly. The arrows can be displayed or hidden.
	Facing Patient Orientation — Sets the scan orientation while facing the patient.
	Behind Patient Orientation — Sets the scan orientation while seated behind the patient.

NOTICE








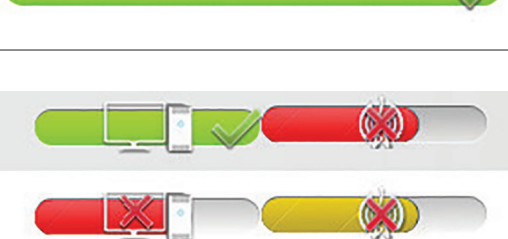
Hiding the completion arrows does **not** correct the scan.

Status Icons

The **Status** icons associated with a case are color coded.

Blue is the normal status, requiring no attention. Yellow means some user attention is required. Red means either a failure or a case has required attention for a long time. Technical Support should be contacted.

Touch the status icon and a message at the bottom of the Attention tab displays more details about the case including instructions on what, if anything, is required.

Status Icons and Buttons	Meaning
	Case in progress; still requires user action, e.g., a scan or a prescription
	Needs user's attention. Case was modified at least 2 days ago but has not yet been signed
	Case requires immediate attention or has required attention for some time
	Case's prescription has been signed and the scanner is processing/uploading
	Case was signed 2 or more days ago but the system has not yet started to upload the case
	Signed case has a critical issue that should be addressed
	The scanner has successfully processed and uploaded the case.
	Status Bars when sending a case using a Chairside Connection.

Scanning Positions and Protocol

Patient Wand Positioning

The Midmark True Definition wand design allows scanning from multiple patient and operator positions.

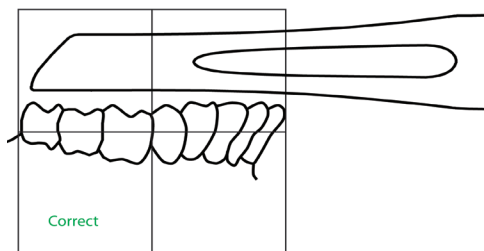
Seated Position

- Patient may be in an upright or reclined position
- Operator is seated on the side or behind the patient
- Wand is parallel to the occlusal plane in the starting position
- Wand can be held with one hand (Figures 1 and 2) or two hands (Figure 3)
- Use a fulcrum to steady the wand and ensure timely data capture

Standing Position

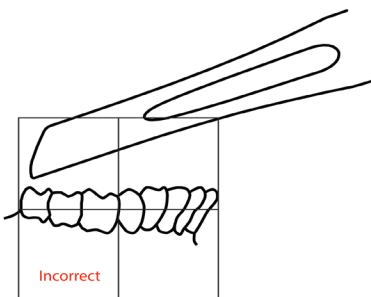
- Patient in an upright position with occlusal plane to be scanned parallel to the floor
- Operator standing next to patient at a 9 o'clock (right handed) or 3 o'clock (left handed) position
- Wand is parallel to the occlusal plane in the starting position
- Use a fulcrum on the outside of the patient's chin

Wand Orientation

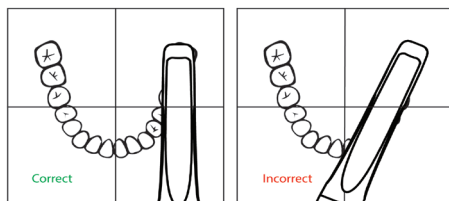


Above: When starting on the occlusal surface, the wand should be parallel to the mandibular arch.

Right: Improper starting orientation — the wand is not parallel to the mandibular arch.



Mandibular Orientations

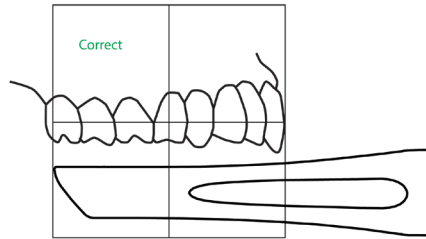


Top Left: When starting on the occlusal surface, the wand should be parallel to the midline of the arch, **NOT** parallel to the line of the teeth.

Top Right: Improper starting orientation — the wand is parallel to the line of the teeth instead of being parallel to the arch's midline.

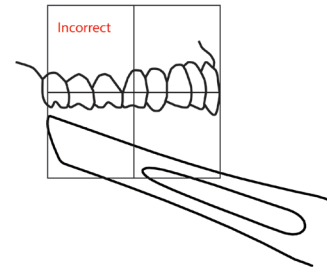
Figure 1. Mandibular Orientations

Maxillary Orientations



Above: When starting on the occlusal surface, the wand should be parallel to the maxillary arch.

Right: Improper starting orientation — the wand is not parallel to the maxillary arch.



Maxillary Orientations

Bottom Left: When starting on the occlusal surface, the wand should be parallel to the midline of the arch, **NOT** parallel to the line of the teeth.

Bottom Right: Improper starting orientation — the wand is parallel to the line of the teeth instead of being parallel to the arch's midline.

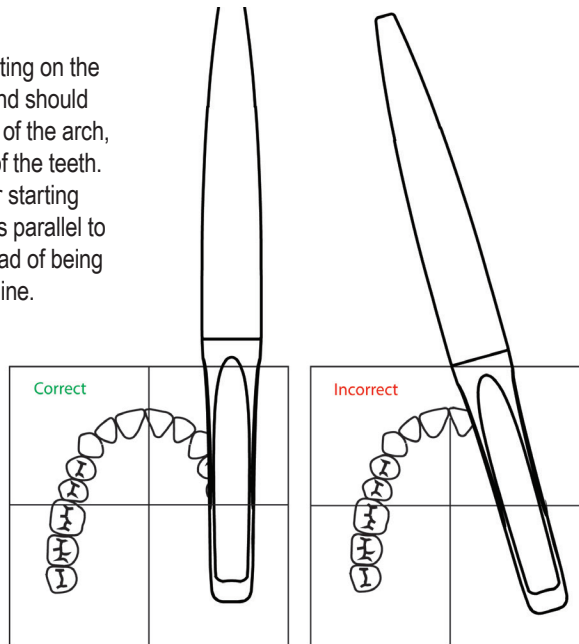
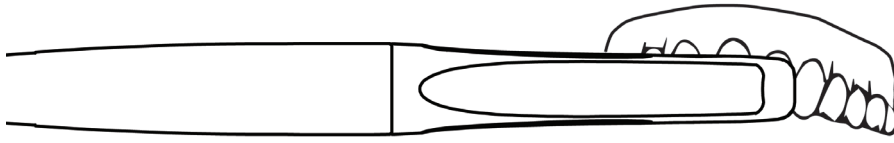
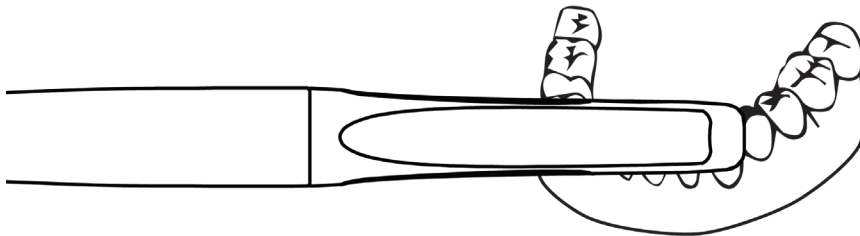


Figure 2. Maxillary Orientations



These are the proper positions for holding the wand toothbrush-style for the maxilla.



These are the proper positions for holding the wand toothbrush-style for the mandible.

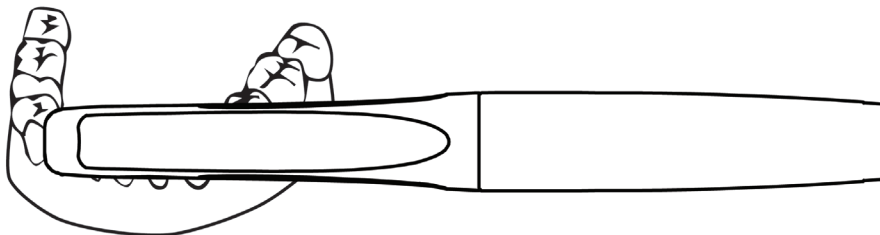


Figure 3. Toothbrush Style Orientations, Maxillary and Mandibular

NOTICE

Although the lollipop style orientation can be used, it is recommended to scan the anterior teeth using a toothbrush style orientation. (Fig. 6).

These are the proper positions for holding the wand lollipop-style for the mandible and maxilla.

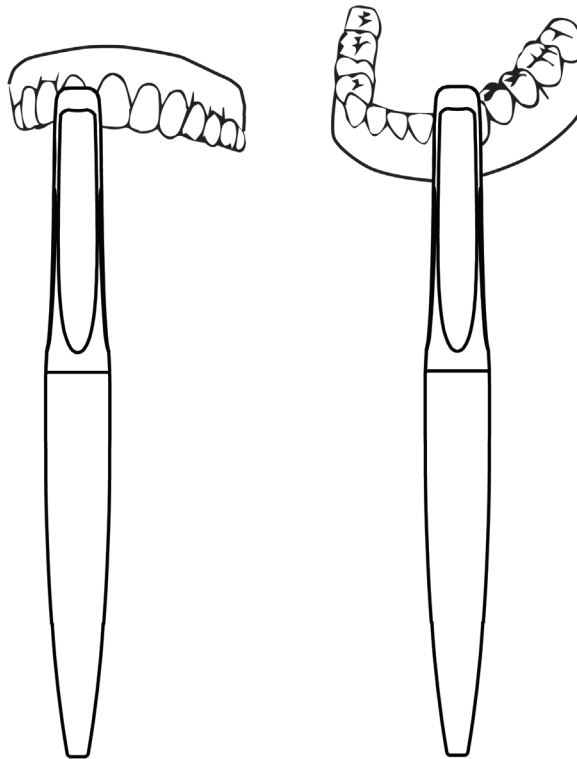


Figure 4. Lollipop Style Orientations, Maxillary and Mandibular

Scan Path Protocol

Begin each scan on the occlusal surface of the first molar area. To properly align the opposing scans to ensure a correct bite scan, always start the scan on the same tooth for both the maxillary and mandibular scans.

Quadrant Scan Path Protocol

- Begin the scan on the occlusal in the first molar area.
- Scan the entire occlusal surface to include the cuspid area.
- Rotate the wand to capture the lingual surface from the cuspid to the last molar.
- Rotate the wand over the occlusal surface to the buccal surface.
- Scan the buccal surface from the last molar to the cuspid area.
- Complete the quadrant scan by rotating the wand back to the occlusal surface.

Anterior Scan Protocol

- Begin the scan on the occlusal of the bicuspid.
- Scan the entire occlusal/incisal from one side of the arch to the opposite side.
- Rotate the wand to scan the lingual surface from one side of the arch to the opposite side.
- Rotate the wand over the occlusal of the bicuspid to the buccal surface.
- Scan the buccal and facial surfaces of the teeth, keeping the wand in a horizontal position across the anteriors.
- Complete the anterior scan by rotating the wand back to the occlusal surface on the bicuspid.

Full Arch Scan Protocol (pages 5-8)

- The full arch scan is a combination of two 2/3 arch scans which overlap across the anterior region.
- Begin the scan on the occlusal of the molars.
- Scan the entire occlusal surfaces across the arch to the bicuspid on the opposite side of the arch.
- Rotate the wand to the lingual surface and scan the lingual, back across the arch, to the last molar.
- Rotate the wand over the last molar to the buccal surface.
- Scan the buccal and facial surfaces across to the opposite side of the arch.
- Complete the first 2/3 arch scan by rotating the wand on to the occlusal of the bicuspid.
- Save the scan.
- Repeat the above steps, starting on the opposite side of the arch.
- Complete the full arch scan by rotating the wand on to the occlusal surface of the bicuspid.
- Save the scan to mesh the two scans together.



Figure 5. Lower Right Full Arch Scan



Figure 6. Lower Left Full Arch Scan

NOTICE

It is also possible to achieve an entire full arch scan without stopping. Retraction and isolation must be maintained to capture an entire arch with one scan.



Figure 7. Upper Right Full Arch Scnn



Figure 8. Upper Left Full Arch Scan

Bite Scans Protocol

Bite Scan Protocol for Quadrant Scans

- Insert the wand tip as far to the posterior as possible.
- Scan one (1) narrow vertical strip, taking care not to move the wand horizontally.
- The bite scan must include 2-3 mm of gingival tissue from both the maxillary and mandibular arches.

Bite Scan Protocol for Anterior Scans

When the Anterior Bite icon is chosen on the scan screen, a vertical wand position appears by default. Change the wand position to horizontal before proceeding with the bite scan.

- Position the wand horizontally between the Centrals.
- Scan one (1) narrow vertical strip, taking care not to move the wand horizontally.
- The bite scan must include 2-3 mm of gingival tissue from both the maxillary and mandibular arches.

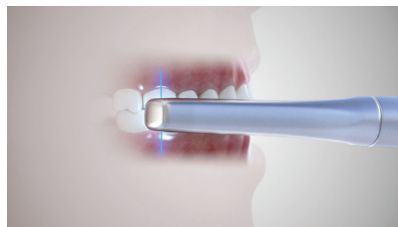


Figure 9. Right Bite Scan

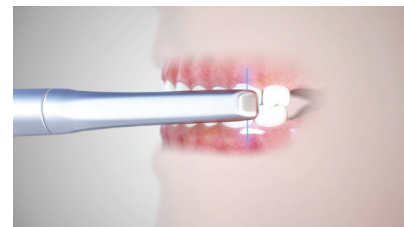


Figure 10. Left Bite Scan

When the Anterior Bite icon is chosen on the scan screen, a vertical wand position appears by default. Change the wand position to horizontal before proceeding with the bite scan.

- Position the wand horizontally between the Centrals.
- Scan one (1) narrow vertical strip, taking care not to move the wand horizontally.
- The bite scan must include 2-3 mm of gingival tissue from both the maxillary and mandibular arches.



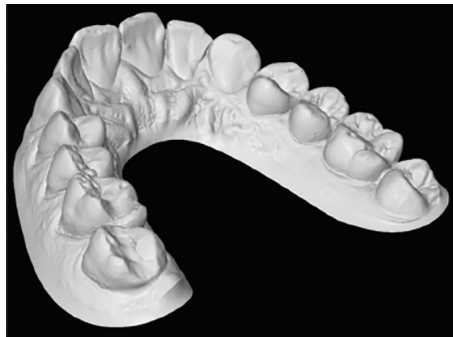
Figure 11. Anterior Bite Scan

Bite Scan Protocol for Full Arch Scans

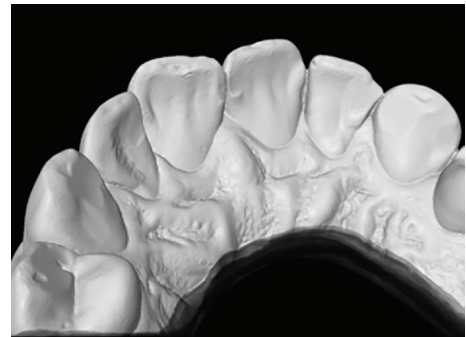
To maintain accuracy in the bite, three (3) bite scans must be used when submitting a full arch scan. (A posterior bite scan on either side of the arch and an anterior bite scan) The posterior scans should be positioned as far away from the anterior bite scan as possible.

Scan Requirements: Orthodontic Appliances

- Capture the entire arch including the terminal molars regardless orthodontic appliance.
- All incisal edges and marginal ridges should be clear and sharp.
- Occlusal surfaces need to be complete without voids.
- Interproximal embrasures and natural IP spaces need to be clean and well defined.
- 3-5mm of gingiva should be captured.
- Palatal rugae should be completely captured
- Three (3) bite registrations must be used when submitting a full arch scan. (A posterior bite scan on either side of the arch and an anterior bite scan) The posterior scans should be positioned as far away from the anterior bite scan as possible.



Capture the entire arch — full dentitions for Incognito.



Capture a minimum of 3-5mm of gingiva lingually.



Capture complete occlusal surfaces — no holes.



Capture a minimum of 3-5mm of gingiva labially.

Obtain patient's bite registration. Refer to **Bite Scans Protocol** in this tab. (Figures 9, 10, 11)

Scanning Tips

- Look at the Touchscreen — not in the patient's mouth — while scanning.
- Keep the lens of the wand parallel to the surface you are scanning.
- Working distance — the wand has a working distance of 0mm to 17mm from the lens located at the top of the wand. For best scan quality, keep the lens approximately 10mm above the surface being scanned, as shown by the depth indicator.

Scan Instructions

This quick reference section describes only the basic steps involved in using the Midmark True Definition Scanner. Additional detailed instructions are included in the following parts of this section.

Starting the System

1. Plug in the power cord and press **On** button.
2. When prompted, select user name.
3. Enter PIN and select **Log In**.

Enter New Patient and Prepare to Scan

1. On Home screen, touch **Patients** button to display Patients screen.
2. Touch **Add New** button.
3. Complete information in required fields. Selecting a field will generate an on-screen keyboard. Press **Enter** to complete each field.
4. Verify patient information, then select **Save**.
5. Touch **Scan Later** to place patient in Pending Patients list (on cases in Progress tab) or **Scan Now** to display scanning interface.

Basic Scanning Workflow (single preparation)

For details, see your Midmark True Definition Scanner User Manual, Midmark High Resolution Sprayer Guide and Midmark High Resolution Scanning Spray IFU.

1. On Scanning interface screen, select arch to be scanned.
 2. When ready to scan, press **Start** button on user interface or double tap wand (if activated).
 3. Scan prepared tooth and contact walls of adjacent teeth.
- IMPORTANT — Avoid respraying or change in field.**
4. Select **Check Mark** to accept scan.
 5. Select **Select/Check Preparation** button.
 6. Select **Add Preparation** button.
 7. Select preparation number of tooth, then touch preparation on model to highlight.
 8. Select **Check Mark** to review (or **X Mark** to delete). System displays still images for review.
 9. Tap screen to see close-up of still image. Review image(s) to make sure margin is clearly visible.
 10. Select **Check Mark** to approve preparation (or **X Mark** if not approved).
 11. Touch arch to scan remainder of operative arch. System will merge scan with preparation scan. Review and approve merged scan.
 12. Scan opposing arch, review and approve.
 13. Select **Bite**, then scan bite/s. System will register upper and lower arches.
 14. Accept or reject bite registration with **Check Mark** or **X Mark**.

Prescription

1. Select **Prescription** tab on Scan screen to display Prescription screen.
2. Follow on-screen instructions to request a delivery date, select a lab and enter specific information, e.g., type of crown, material, shade, etc.
3. The NOTES area may be used for additional information. Tap on NOTES section for on-screen keyboard.
4. Review information and select **Sign** button to display the Patient Data Submission screen.
5. Confirm to display the Prescription Digital Signature keypad.
6. Enter PIN to sign prescription.

Log Out/Shut Down

Select **Power** button from HOME screen, then select **Log Out** or **Shut Down**.

WARNING

To reduce the risks associated with hazardous voltage and fire: Do not plug the scanner into an Uninterruptible Power Supply (UPS). Do not attempt to open or service the unit yourself. Attempting to open or service the unit yourself could damage the unit and void the warranty.

To reduce the risks associated with hazardous voltage: Do not use a damaged power supply cord.

CAUTION

To reduce the risks associated with impact or pinch:

- Use the locking casters when the system is in use.
- Position the power cord and wand cable so they do not create a tripping hazard.
- To reduce the risks associated with **pinch**: Avoid getting finger(s)/thumb caught between quick-release and mounting system.

NOTICE

Plugging in and turning on the system are the only power- or service-related interactions a user should have with the scanner. If the system fails to function properly, call Technical Support.

Turning On and Logging Into the System

Powering On

1. Plug the power cord and isolation Transformer into a wall outlet.
2. Press the **Power On** button on the top left edge of the tablet. The system will turn on and display the login screen.

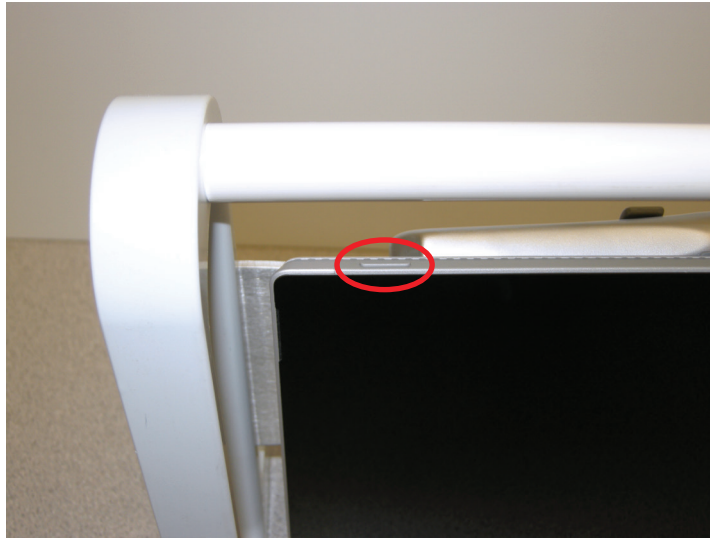


Figure 3. Power ON button

Logging In

To log in to the system:

1. Select user name.
2. Enter personal identification number.
3. Select the **Login** button.



Figure 4. Login Screen

Reset PIN

Failure to enter the proper PIN when signing in will display the **Forgot Pin?** Button. Re-enter the correct PIN on the Password screen.

To reset a PIN, touch the **Forgot Pin?** Button to display the PIN Recovery Screen. The Connection Center account number must be entered to change the PIN. Contact Midmark support and service for help.

Logging Out

To log out of the system:

1. Select the **Power** button in the upper right corner of the screen.
2. Select **Log Out**.

Note:

To log in as another user: Select the user and enter the PIN.

Shutting Down

To shut down the system:

1. Select the **Power** button in the upper right corner of the screen.
2. Select **Shut Down**.
3. When prompted, choose to **Shut Down Now** or **Shut Down After Processing**.
4. Choose **Do Not Shutdown** to return to the Home Screen.

NOTICE

If cases remain to be processed or uploaded, leave the system on or select **Shut Down After Processing**.

NOTICE

Do not unplug the scanner before shutting down the system. Unplugging without properly shutting down may corrupt the operating system.

NOTICE

Disconnect the power cord from the wall outlet before moving the system.

Figure 5 Callouts

- A** Patients Button
- B** Tutorials Button
- C** Management Button
- D** Cases in Progress Tab
- E** Signed Cases Tab
- F** !Attention Tab
- G** Wand Health Status Button
System Message Alerts
Wireless Connectivity Status
Help Line Status
- H** Battery Status
- I** Pending Patients Display
- J** Active Cases Display



Figure 5. The Home Screen

The Home Screen

After logging in, the **Home Screen** displays. From the **Home Screen** the user can:

Patients:

- Add new patients.
- Find existing patients.
- View patient history.

Tutorials:

- View Training videos for self-training or review.

IMPORTANT — A practice scan cannot be saved or sent to a lab. When you leave the Practice Scan screen, all practice scans are deleted. For more information see **SCANNING** section.

Management:

- Access the Managements screens (refer to **Management** Section of this manual).

There are three tabs on the **Home Screen**:

- Cases in Progress.
- Signed Cases.
- ! Attention.

On the lower right side of the **Home Screen** it is possible to:

- See the status of the Wand Health.
- Receive system message alerts.
- See the status of the Wireless Connectivity.
- See status, initiate or disconnect a Help Line.
- See the Battery Status of the scanner's computer.

Patient Information

Add a New Patient

To add a new patient or search for an existing patient touch the **Patients** button on the Home screen. The Patient Search screen appears. (Figure 7).

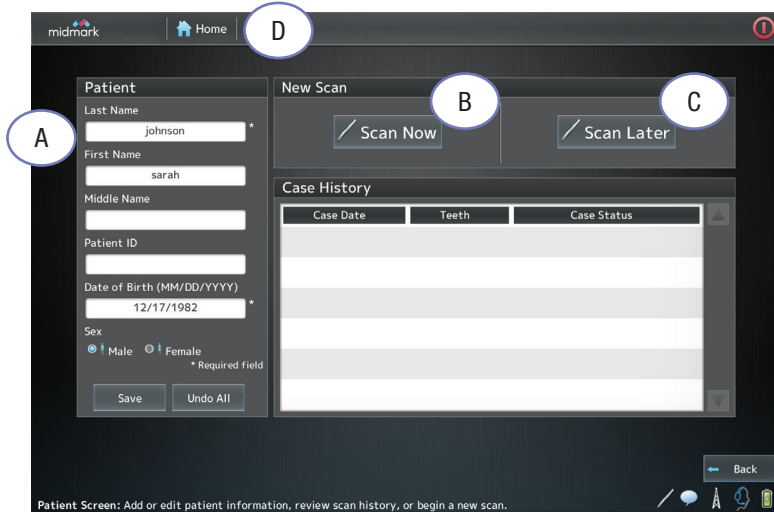


Figure 6. Patient screen

1. Touch the **Add New** button at the bottom of the Patients Search Screen (Figure 7). The Patient Screen is displayed. (Figure 6).
2. Touch an entry field.
3. The entry field and on-screen keyboard are displayed.
4. Use the on-screen keyboard to enter the patients information (Name, Patient ID, DOB, etc.) Required patient information fields are shown with an asterisk (*).
5. Press the **OK** button to store the information in each field. To complete the date of birth, touch the **Enter** button.
6. When the information is complete, touch the **Save** button in the Patient box.

NOTE: A new patient may also be added by typing a last or first name in the Search box of the Patient Search screen and then pressing the Add New button. When the Patient screen is displayed, the name you entered will be in the name field.

NOTE: The Patient ID is an optional, unique identifier created by the dental practice.

Figure 6 Callouts

- A** Patients box
- B** Scan Now button
- C** Scan Later button
- D** Home Screen button

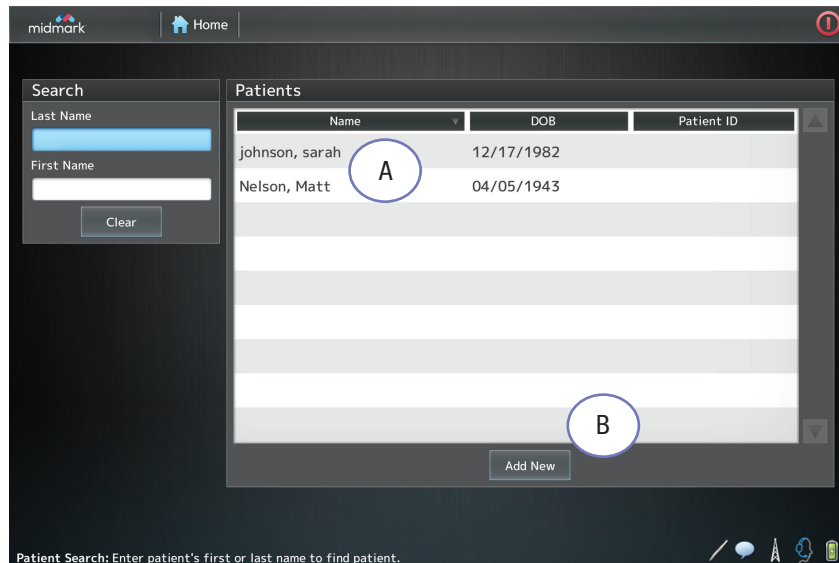
NOTICE

To return to the Home page at any time, press the **Home** button. (Figure 6-D)

Figure 7 Callouts

- A Patients list
- B Add New Button

Search for a Patient:



There are two options to find a patient on the Patient Search Screen (Figure 12):

- Scroll through the Patients list.
- Touch **Last Name** or **First Name** boxes to bring up the on-screen keyboard. Start to type the patient's name. Press the OK button. All matches will appear.

After finding a patient, select the name from the list to display the Patient's screen.

After finding or adding a patient, select either the **Scan Now** or **Scan Later** button on the Patient screen (Figure 6).

Scan Now

Takes you to the Scanning Screen, which is described in detail later in this manual.

Scan Later

The patient name is placed in the **Pending Patients** list on the **Cases in Progress** tab of the Home screen.

Tutorials

The Tutorials button contains short videos demonstrating basic and advanced scanning protocol (Figure 5, B). They can be used for self training, review after training or as an aid when training new personnel.

To access the Tutorials:

- From the Home Screen, select the **Tutorials** button. The tutorial videos window will display.
- Use the scroll bar along the right side to view all available videos.
- Select one of the video icons to open the content. The video playback begins immediately.
- To adjust the volume, use the slider on the bottom right corner of the video screen.
- To move the video forward or backward, use the slider on the bottom of the video screen.
- Select the **Pause** button to pause playback. Select **Play** to continue playback.
- To exit the video and return to the Tutorials window, select the **Back** button in the bottom right corner of the screen.

Management

The Management button displays the Management screen. There are three (3) tabs on this screen: Settings Systems, and Maintenance. Detailed information can be found in the **Management Tab** of this manual.

NOTICE

If a video is currently playing, you must first select the **Pause** button before selecting the **Back** button to return to the Tutorials window.

Cases in Progress Tab

This tab contains all pending patients (no data created) and all active cases (data created but case not signed). If patients have been previously entered into the system and the user has selected the **Scan Later** button, they are identified as **Pending Patients**.

Patients stay on the Pending Patients list until they are scanned. If a **Pending Patient** remains unscanned for 30 hours, the patient is deleted from the **Pending Patients** list.

The patient remains available in the patient records.

Active Cases are cases with at least some information associated with them, for example, a scan or some prescription information. Cases are considered active until their prescriptions have been signed.

The status bar associated with a case is color coded:



NOTE: If the progression tab is red it may be necessary to call Technical Support. The message line provides additional information and instructions, if needed.

Display an Active Case

To see the scan or prescription of an active case, touch the case in the **Active Cases** list. The case will open either to the **Scanning Screen** or the **Prescription Screen**. Choose either the **Scan** tab to display the case's scan or the **Prescription** tab to display its prescription. **Scanning** and **Prescriptions** are explained in detail later in this manual.

Delete an Active Case

To delete an active case, touch the **Manage Cases** button. The Manage Cases screen is displayed. Select the case to delete and then touch the **Delete Case** button.

A PIN must be entered before completing a deletion.

Signed Cases Tab

The **Signed Cases** tab lists the cases whose scans and prescriptions are complete.

Completed cases will remain on this list for 7 days after they have been uploaded. After a case has been completed and uploaded, you can access it in the patient records.

Hiding a Signed Case

To hide a signed case, touch the **Manage Cases** button. The Manage Cases Screen is displayed. Select the case to hide and touch the **Hide Case** button.

Un-signing Cases


Once a signed case receives a Case ID number, it is possible to un-sign it. The user will be directed to a screen to enter their password for confirmation.

Once a case is unsigned, the case moves back to the Cases in Progress tab where the user can modify the case. The Case progress bar will appear red in this tab. The case will also appear in the **!Attention Tab**.

To un-sign a case that is uploading:

- In the **Signed Cases** tab, press the **Manage Cases** button at the bottom of the screen. The Manage Cases screen will appear.
- Select the case to highlight it. This will activate the options at the bottom of the screen; **Unsign Case**, **Hide Case**, **Close**.
- While a case is uploading, the **Unsign Case** button will not be active until a Case Number ID has been assigned. The progression bar will be blue and the following message will appear:

Information



This dental prescription will be revoked. You will be free to modify this case. No further action will be needed to cancel since the case did not complete uploading to Connection Center.

Figure 8. Unsign Dialog that is Uploading

NOTICE

Hiding a case will remove it from the Signed Cases tab. To view a hidden case go to the patient screen, select the patient and select the case that was hidden. To place a case back in the Signed Cases tab, contact Midmark Support and Service.

NOTICE

After unsigning a case, it is placed in both the Cases in Progress and Attention! Tab. The Progress bar will be red. The user is free to modify and resign the case.

NOTICE

Failure to contact the lab could result in a fee for the unsigned case.

To unsign a case that has completed uploading:

- In the signed Cases tab, press the **Manage Cases** button at the bottom of the screen. The Manage Cases screen will appear.
- Select the case to highlight it. This will activate the options at the bottom of the screen; **Unsign Case, Hide Case, Close**.
- The progress bar will be green and the following message will appear:

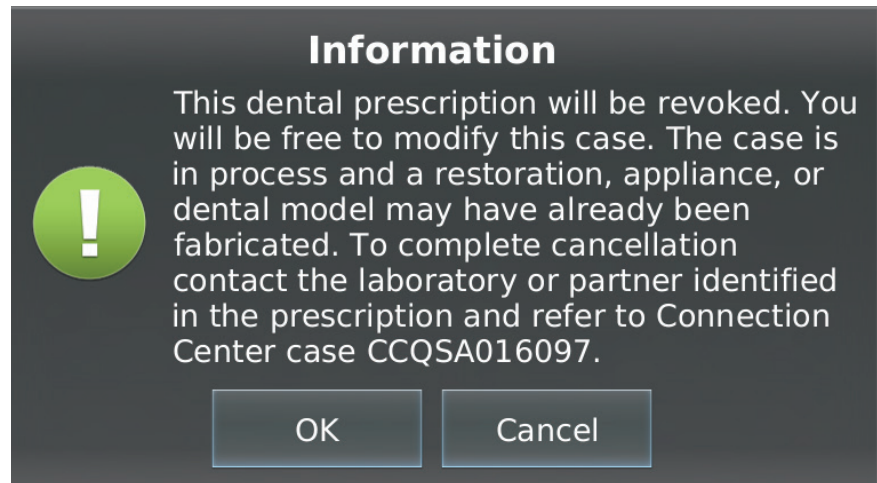


Figure 9. Unsign Dialog for Case that has Completed Uploading

To Unsign a Chairside Case:

- In the Signed Cases tab, press the **Manage Cases** button at the bottom of the screen. The Manage Cases screen will appear.
- Select the case to highlight it. This will activate the options at the bottom of the screen; **Unsign Case, Hide Case, Close**.
- When the **Unsign Case** button is selected for a Chairside Case, the progress bars will appear in some combination of green and blue and the following message will appear:

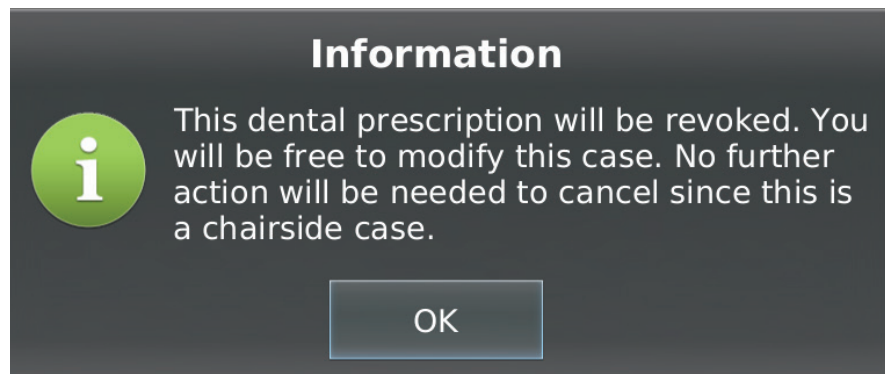


Figure 10. Unsign Dialog for Chairside Case

What Happens When a Case is Unsigned:

- **Case is Uploading;** Unsigned will cancel the upload to Connection Center and set the case in Connection Center to a Closed Status. The user does nothing else.
- **Case is Fully Uploaded;** Unsigned will do nothing in Connection Center. To close the case, the user must contact the lab where the case was sent. If the lab is not contacted, the case will continue through the requested workflow and will not be closed.

!Attention Tab

The **!Attention** tab displays cases that require attention for any reason. For example, if scans have been completed but failed to upload, or a case was unsigned. Those cases would be listed here.

When you turn on the scanner, the **!Attention** tab appears by default if something needs attention.

After clicking on a case, the message box will explain why the case needs attention.

NOTICE

When a case is resigned, it will receive a new Case Number ID.

Figure 11 Callouts

- A Arch Selection Button
- B Right, Anterior, Left Bite Buttons
- C Check Preparation Button
- D Inspection Scan Button
- E Additional Scan Button
- F Start/Stop Button
- G Delete Button
- H Screen Capture Button
- I Wand Orientation Button
- J 3D Image Tool
- K Margin Annotation Tools
- L Magnification Feature
- M Occlusal Clearance Tool

Scanning Screen



Figure 11. Scanning Interface

Inspection

The wand's camera can be used to examine the field closely by recording an inspection video. It's similar to using an intra-oral video camera (Figure 11, D).

1. Select the appropriate **Arch**. (Figure 11, A)
2. Select the **Inspection Scan** button on the Scanning interface toolbar. (Figure 11, D)
3. Double Tap the wand or press the **Start** button (Figure 11, F) to start the wand and inspect the area. Double tap the wand or press the **Stop** button (Figure 11, F) to review the video. The inspection allows you to view areas you intend to scan, i.e. preparation, retraction, etc..

NOTE: The video captured is for review only and cannot be saved.

4. The viewer may pause, run forward, backward or frame-by-frame to enhance the inspection. It may also be viewed in 3D mode. (Figure 11, J).

Turning Wand On and Off

- Start and stop a scan by pressing the button on the Scanning interface. (Figure 11, F)
- Alternatively, a double tap to the wand will also start and stop the scan, if the functionality has been turned on.
- By default the Double-tap functionality is turned OFF. To turn it on: Go to Home>Management>Settings>Wand.

NOTICE

This is an overview of the scanning process. For details on how to scan in a clinical setting, refer to your Midmark True Definition Scanner training materials.

NOTICE

The **3D Image** can be used in the **Inspection Mode** to review tooth preparations, tissue retraction, moisture control and spray levels.

Screen Capture

- Press the **Screen Capture** button to capture a screenshot. (Figure 11, H). The message in Figure 12 will appear.
- Select **Upload** or **Cancel** on the screen. The .png file will be uploaded to Midmark Connection Center.
- An email will be sent, with a link to the .png file, to the email address associated with the system.

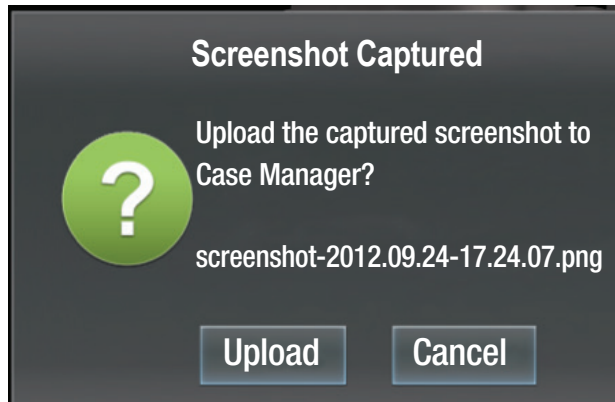


Figure 12. Screenshot Captured

Deleting Scans

If you need to delete a scan, select the **Delete** button (Figure 11, G). The system displays a message asking you to confirm the deletion. Select whether you want to delete the last scan or all scans of the current type (for example, all maxillary scans).

Alternate Starting Wand Orientation

When scanning an arch, the start position is not limited to an occlusal surface. If scanning anterior teeth, it may be easier to start the scan with the lens of the wand facing the facial surface. To change the default scanning orientation, touch the **Wand Orientation** button to display the menu. Select the preferred starting wand orientation by pressing the position to highlight. The current wand orientation is displayed until scanning begins.

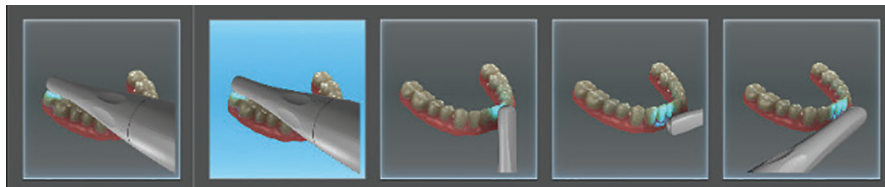


Figure 13. Alternate Wand Orientation Menu

Additional Scan

An additional scan may be desired to send to the dental laboratory. The scan will be printed and included in the model kit for the lab.

To make an additional scan:

1. Select the **Additional Scan** button on the Scanning Interface (Fig. 11, E) toolbar.
2. Choose either the maxillary or mandibular icon that appears.
3. Perform the scan.
4. When completed, approve the scan using the **Check Mark**. This scan is automatically added to the patient's case data to be uploaded to the lab.

NOTICE

Alternate starting wand orientations apply only to the beginning of each scan, not continued scans. If you are continuing a scan, resume scanning the area with the same wand orientation used when the scan was stopped.

NOTICE

It is not the purpose of the Additional Scan feature to add extra scans of the preparation. Labs are not able to use this additional scan to identify the margin. Only one additional scan per case can be created. (maxillary or mandibular). An Additional Scan can be created at any point in the scanning process. The scan time is limited to 4 minutes.

Basic Scan

1. Select an existing case (or touch the **Scan Now** button for a new case) to go to the Scanning screen.
2. On the scan screen select the arch to scan.
3. Tap the wand or press the **Start** button on the Scan Screen to start the scan.
4. When done, tap the wand or press the **Stop** button to stop scanning. The system displays the scan on the Scan Review screen.
5. The following options are now available:
 - Delete the scan by touching the **X Mark**.
 - Accept the scan by touching the **Check Mark**. This saves the scan.
 - Rewind the scan in ten-second segments or back to the last saved scan (see Scan Rewind).
 - Continue scanning to add coverage (see Continue Scanning and Merging Scans).
 - Remove completion arrows, if present (see Completion Arrows).
 - Add a preparation by touching the **Check Preparation** button (Figure 11, C) then the **Add Preparation** button. This displays the Preparation Selection screen (see Add, Review and Approve a Preparation).

Visual Cues While Scanning

The following visualization cues are available while you are in the act of scanning:

- **Video Frame Box:** This box is the active area of the scanner. Surfaces within the box are being captured. Try to keep the tooth centered in the box while scanning.
- **Surfaces:** Illustrates what tooth structure has been acquired. White indicates fully captured data. Red indicates data not fully captured.
- **Depth Indicator:** Helps determine correct depth to begin scanning. The Blue icon on the depth indicator moves to show the rotation of the wand on the surface of the tooth being scanned.
- **Timer:** Displays the time elapsed during a scan (see Maximum Scanning Times).

Figure 14 Callouts

- A Video Frame Box
- B Surfaces
- C Depth Indicator
- D Timer

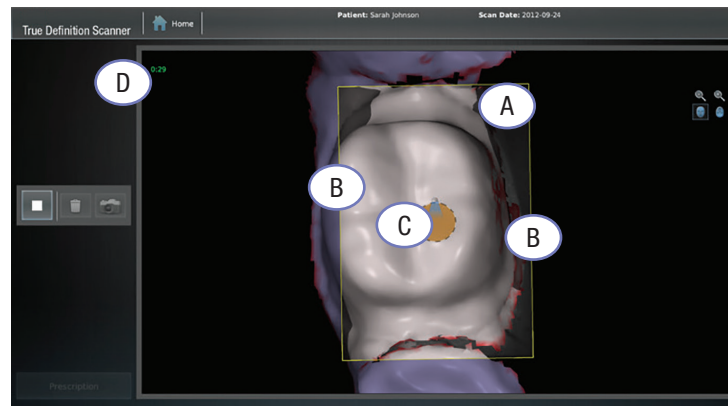


Figure 14. Visual Cues

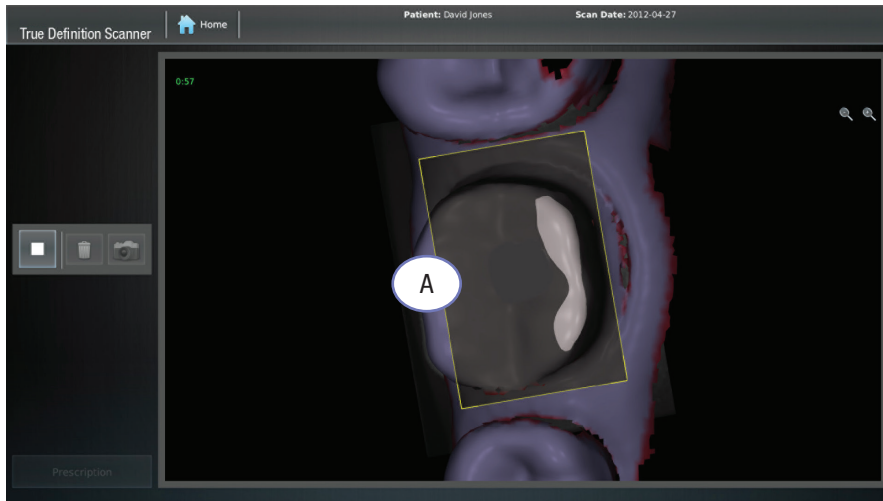


Figure 15. Depth Cues — Gray

While scanning, the scanner gives color cues to help judge the distance from the scanner's lens to the tooth.

In the example above, the areas of the tooth displayed in gray are too far away from the scanner's lens to be captured.

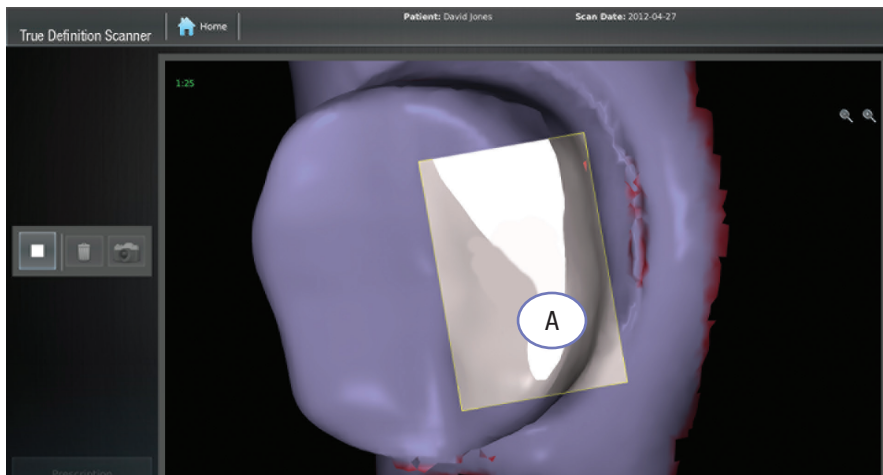


Figure 16. Depth Cues — Bright White

In this example, the area of the tooth displayed in bright white is too close to the lens to be captured.

Figure 15 Callouts

A Depth Cue Gray

Figure 16 Callouts

A Bright White

Maximum Scanning Times

There are limits to the scanning times for a case. The scanner will stop a scan for these reasons:

- Current continuous scan exceeds 7 minutes.
- Current continuous bite scan exceeds 2 minutes.
- Total of the current case's maxillary scans exceeds 7 minutes.
- Total of the current case's mandibular scans exceeds 7 minutes.
- Total of the current case's bite scans exceeds 6 minutes.
- Total of the current case's additional scan exceeds 4 minutes.
- Total of all scans (not including bite scans) exceeds 15 minutes.

To avoid reaching these maximums, it is good practice to delete any unnecessary scans for a case.

Pause Mode

Some scanning practices, (e.g., moving the wand too fast, being too close to or too far away from the teeth) can generate insufficient or inaccurate data. To safeguard against acquiring such data, the scanner enters Pause Mode.

Pause Mode can be used to take a break from scanning. For example; if the patient needs to cough, sneeze, swallow, etc.

There are several ways to resume from Pause Mode:

- Return to any scanned area with the wand in approximately the same orientation it was in when the area was originally scanned.
- Return to a previously scanned occlusal surface.
- Backtrack and align the live video (in white) with the static yellow image (which represents the last image of the scan captured). Find the correct depth by aligning the Depth Indicator circles. When the system matches the live video to the captured video image, the scan will continue.

Figure 17 Callouts

- A Yellow = already captured video
- B White = currently active video

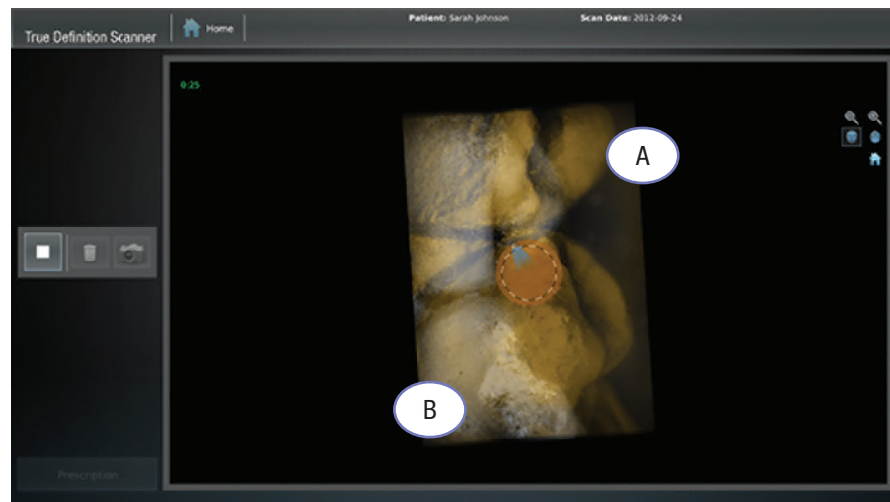


Figure 17. Pause Mode

Smart Scan

Smart Scan helps remove scanning artifacts created by moving objects and other objects of the field that have been scanned inadvertently.

FOR EXAMPLE: When scan data is captured that is unusable, Smart Scan can erase the undesirable data while capturing the correct data underneath.

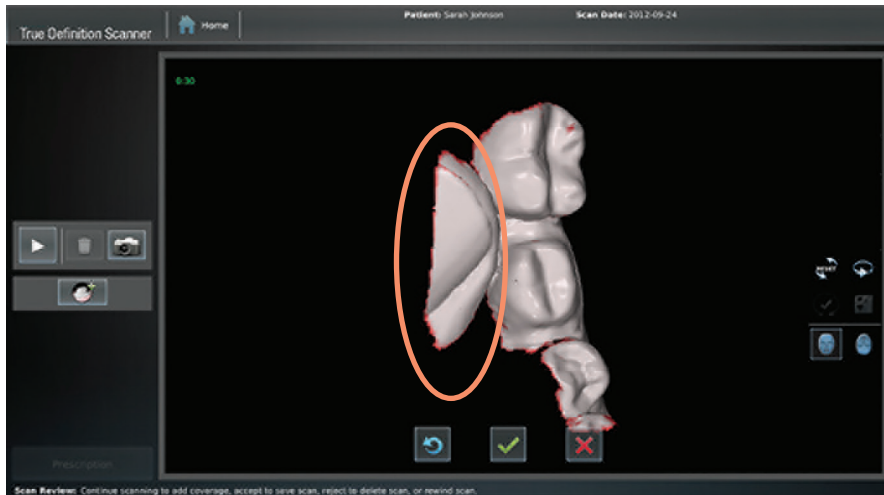


Figure 18. Movable Object Scanned

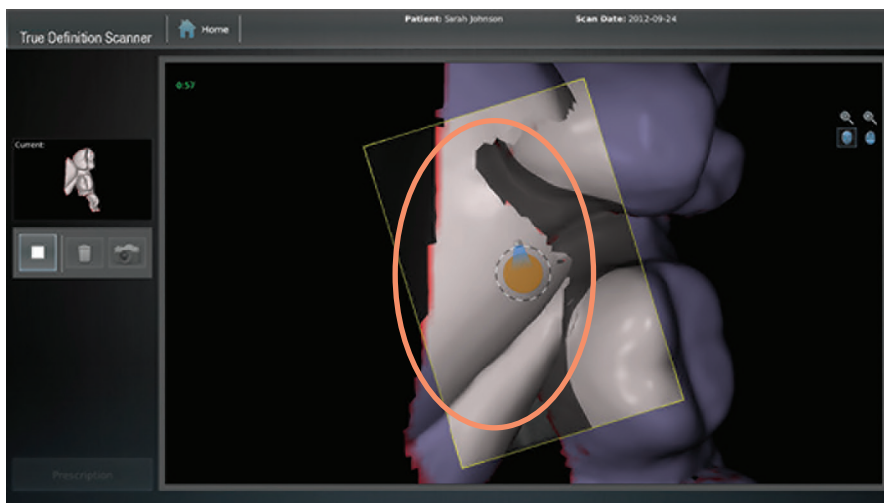


Figure 19. Movable Object Erased During Scan

A scan pixelating (sparkling) inside the yellow box indicates Smart Scan is erasing either a previously scanned, unwanted object or a new object that has moved into an already scanned area.

NOTE: When pixelation occurs, Midmark recommends stopping the scan and either rewinding in 10 second sections until the area is gone, or delete the scan and rescan.

Scan Review

The Scan Review screen is displayed when you stop a scan. As the optimization of the scan occurs a progression bar is displayed in the lower right side of the screen. (Figure 20).

The scan review allows the user to visually inspect the 3D model prior to saving it. Touch gestures allow the user to rotate, zoom in/out and move the model on the screen.

The user has the option to continue the scan, rewind the scan, accept and save the scan or reject the scan. It is not required to save the existing scan before adding additional data. The newly scanned data is automatically appended to the existing model and allows capture of more coverage. (Fill in missing data, etc.)

NOTICE

It is not necessary to wait for the optimization bar to complete before accepting or rejecting a scan. As soon as the Check Mark and X Mark buttons become active, accept or reject the scan.



Figure 20. Optimizing Screen



Scan Review Features

On-screen tools and touch gestures are provided to manipulate the model during scan review.

Touchscreen Gestures

Touch gestures include 3D zoom control, 3D rotation control, 3D position control (panning), and automatic rotation.

- **3D zoom** (Available in scan review as well as during scanning) is changed via a two finger pinch-and-open gesture.
- **3D rotation** is done by dragging one finger on the screen.
- **3D panning** is done via a two finger gesture in which the fingers remain at a constant distance from each other.
- **Automatic rotation** is initiated by quickly swiping a finger across the screen in the direction the model is to be rotated. (throw gesture)

On Screen Tools

- **Reset** button (Figure 21, A) resets the model to the default 3D view.
- **Correction Arrow Viewing** button (Figure 21, B) allows the user to show or hide the correction arrows. Hiding the arrows will not correct the scan.
- **Hole-fill** button (Figure 21, C) artificially fills holes in the mesh.
- **Scan Display Orientation** buttons (Figures 21, D,E) control the display screen allowing the user to either face the object being scanned or sit behind the object being scanned. This affects only the on-screen display while scanning is being performed.

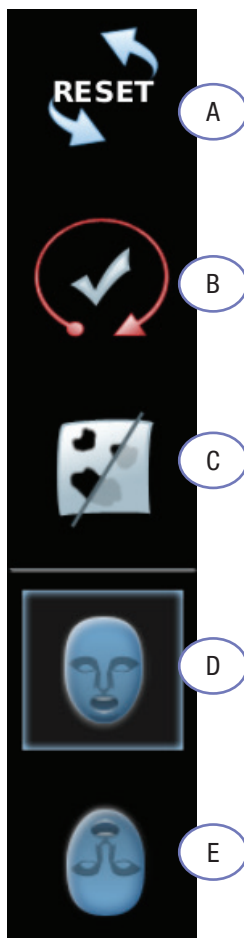


Figure 21. On Screen Viewing Tools

NOTICE

The **Hole Fill** button is for cosmetic viewing only. This action will not add data to the scan file. Only rescanning the area will add additional information.

Figure 21 Callouts

- A Reset Button
- B Correction Arrows Viewing Button
- C Hole Fill Button
- D Scan Display Orientation (Facing the Patient)
- E Scan Display Orientation (Behind the Patient)

Scan Rewind

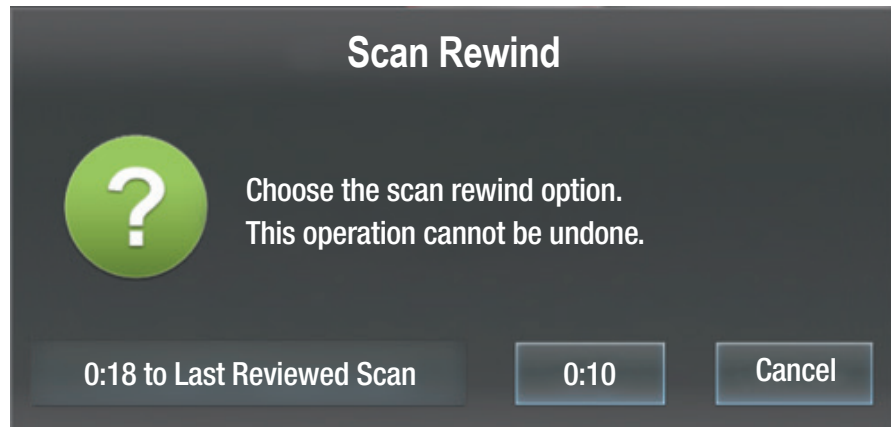


Figure 22. Scan Rewind

IMPORTANT

Do not change the field or re-spray when in Scan Review mode. Changing the field will distort the current scan. If changes to the field are required, accept or delete the current scan before changing the field and then continue scanning.

The Scan Rewind feature has two options:

1. Rewind the scan in ten-second increments, by selecting the **Scan Rewind** dialog box and then pressing the **0:10** button.
2. Rewind back to the last saved scan, i.e., the last time the green check mark was pressed by selecting **Last Reviewed** scan button.

Continue Scanning

In this example, after an initial scan is stopped, a hole becomes apparent when the scan is rotated.

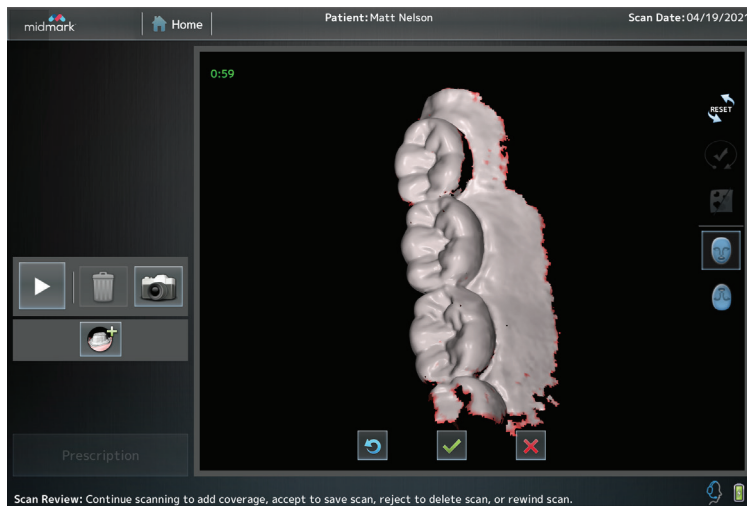


Figure 23. First Scan Showing Hole

To complete the scan data, DO NOT press the **ACCEPT** check mark button or the **DELETE X** button. Continue the scan by double tapping the wand or pressing the **Start** button, focusing on the area not previously captured.

While scanning, the screen will display a thumbnail on the upper left side of the screen. The thumbnail is labeled, **Current**. It is a useful guide to compare the two scans and ensure complete data capture.

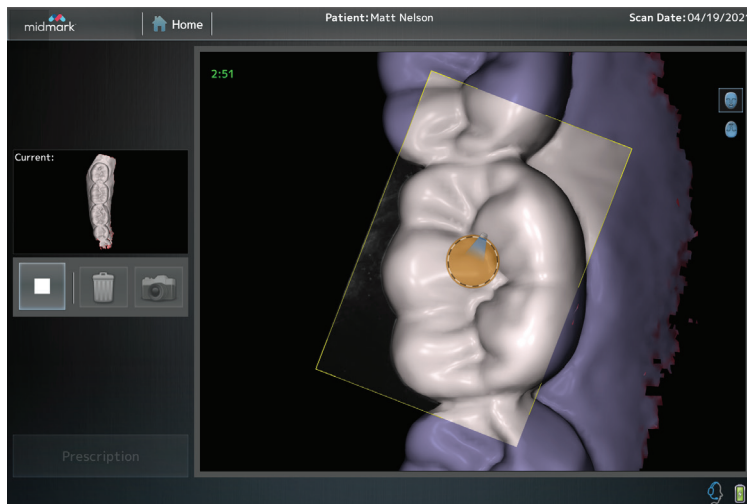


Figure 24. Continue Scanning

When the scan is stopped, the scanner adds the new scan data to the previous scan. The data will combine each time you continue/add a scan. The additional data is now captured. Note that each continued scan in this process took place without leaving the Scan Review interface. If the scan is acceptable, press the **Check Mark** button to save. Press the **X Mark** button to delete the added scan or press the **Rewind** button to rewind the scan in 10 second increments.

NOTICE

To achieve a successful merge of scans, overlap the continuing scan with the data captured from the previous scan.

Figure 25 Callouts

- A** Older Scan
- B** Newer Scan

Merging

Merged scans are the combination of two or more separate scans that mesh together automatically. A scan will merge whether or not it is a saved scan.

By saving a scan, (pressing the **Check Mark** button) it becomes a separate scan. At this point, it cannot be changed. It can be deleted.

The color for the older scan is gray; and the color for the newer scan is white. This pattern continues for each successive scan.

Press the **Check Mark** button to save, if the merged scan is acceptable. Press the **Reject** button to delete and rescan. Press **Rewind** button to delete the scan in ten-second increments.

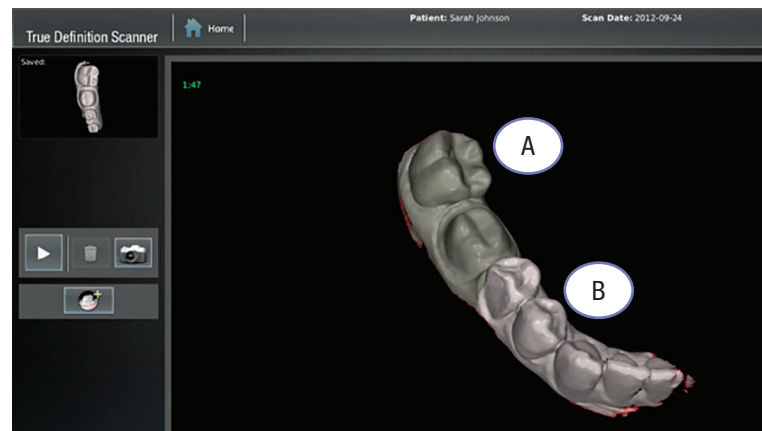


Figure 25. Merged Scans

NOTICE

The scan can be sent to the lab, even with the red completion arrows. However, this may result in an inaccurate model and restoration.

Figure 26 Callouts

- A** Completion Arrows Viewing button

NOTICE

Hiding the completion arrows will not correct the scan.

Completion Arrows

The scanner has a tool to help evaluate scan quality. The Completion Arrows feature indicates whether the scan path captured enough accuracy to proceed. If the scan path needs correction, the tool identifies where to correct it.



Figure 26. Completion Arrows

To correct the scan and remove the completion arrows, resume scanning in the direction of the arrow from the starting dot to the arrow.

If a scan has multiple arrows, start the scan in the center of the cluster.

If a scan has arrows that cannot be corrected, or additional arrows appear after a correction scan, Midmark recommends deleting the scan and rescanning.

The **Display Arrows** button toggles the display of completion arrows on or off. (Figure 26, A). This button is available only when the arrows are present.

Add, Review and Approve a Preparation

When a case is sent to a lab, the data includes high contrast black-and-white images of the scan, including the preparation. A review of the preparation images must be done to ensure there is a clear, unobstructed view of the margin.

To review the scanned preparation:

This can be done any time after scanning the preparation but before completing the prescription.

1. Select the **Check Preparation** (Fig. 11, C) button on the left side of the Scan Review screen. Selecting it shows the Preparation Panel.
2. Select the **Add Preparation** button which will take you directly to the Preparation Selection screen.
3. Select the number of the prepared tooth and then touch the prepared tooth on the scan. The system highlights the preparation and the area around it (Figure 27).
4. Press the **Check Mark** button (Figure 27, C) to move to the preparation review screen. This screen will allow you to review the still image of the preparation.

OR

5. To cancel the selection and return to the previous screen, press the **X Mark** button (Figure 27, D).

NOTICE

This is a required step in the scanning process for restorative work. It must be completed before the prescription can be signed. It is not a requirement if selecting — Models and Appliances.

NOTICE

For multiple preparation cases, repeat these steps for each preparation.

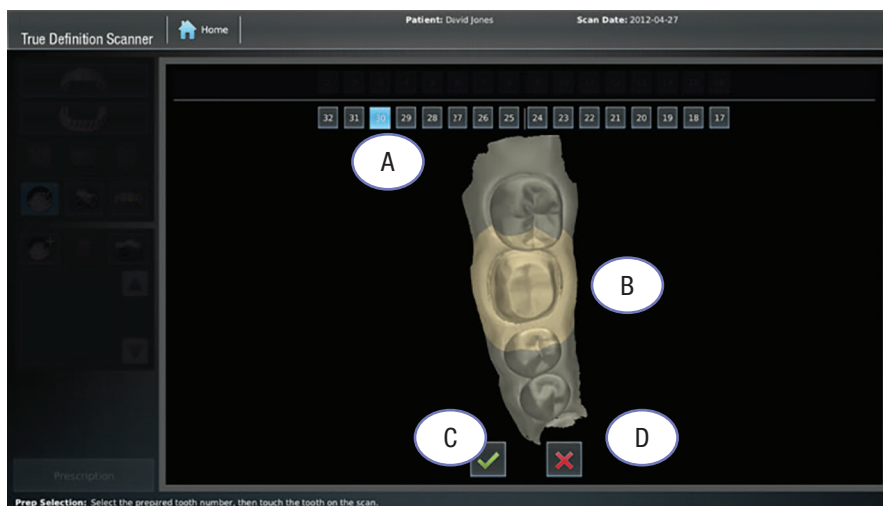


Figure 27. Select Preparation Number: Touch Preparation on Scan

Figure 27 Callouts

- A** Select number on prepped tooth
- B** Touch prepared tooth on scan
- C** Check Mark
- D** X Mark

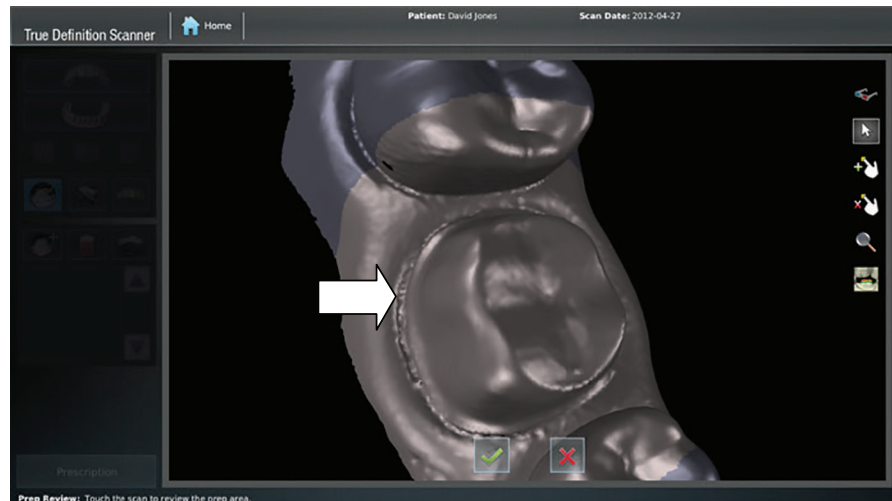


Figure 28. Preparation Review Screen

To view alternate areas of the preparation, tap the location on the preparation to be viewed and the image will zoom for inspection. To rotate the scan, drag the image to the desired location and tap the preparation to view the close-up image. For example, tapping a spot inside the highlighted area on the scan, (as shown by the arrow in Figure 28), will zoom in to a close-up still image of the area (Figure 29).

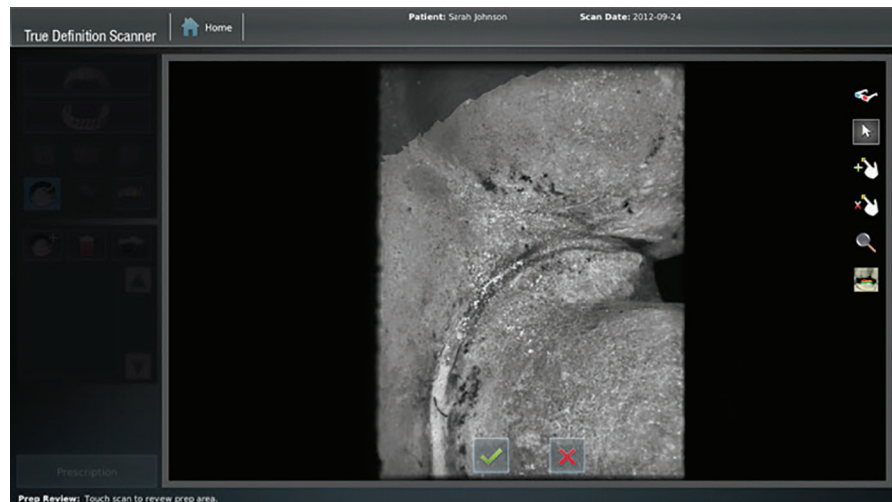


Figure 29. Close-up of Preparation — Still Image View

For a three-dimensional look at the still image of the preparation, select the **3D Glasses** button (Figure 20, A). The system switches to stereo mode. Red-blue stereo glasses are needed to perceive the 3D image.

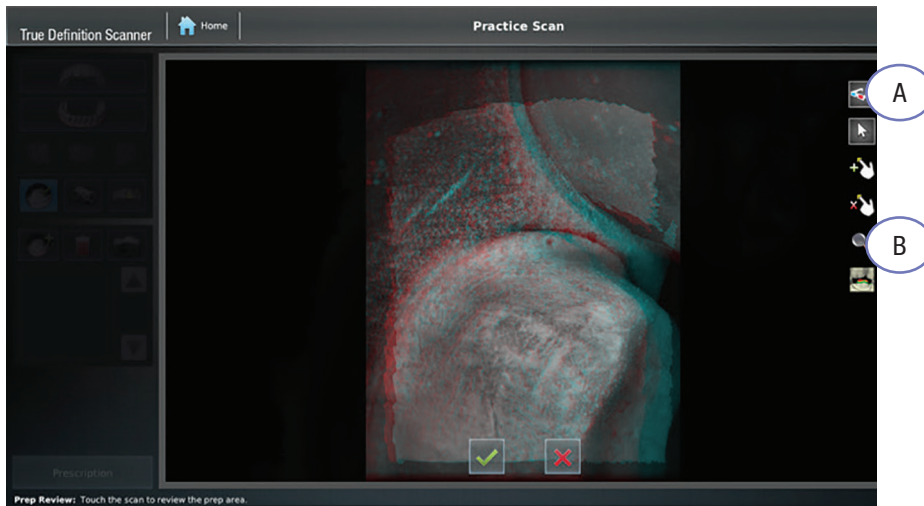


Figure 30. 3D View of the Preparation

NOTICE

The three-dimensional image can be magnified by selecting the **magnification glass** (Figure 30, B) and placing a finger on the desired area to be enlarged.

Figure 30 Callouts

- A 3D Glasses
- B Magnification Glass

Margin Annotation Feature

This feature allows the user to add or remove points on the margin.

1. On the Preparation Review screen, press the **Add Margin Annotation** button (Fig. 31, A), then touch and hold finger on the margin in the area of ambiguity. A square window opens magnifying the area under your finger. The crosshair (+) in the magnifying window indicates the location where the annotation will be placed (Fig. 31, C).
2. Roll the finger on the screen to move the crosshair over the magnified edge of the margin.

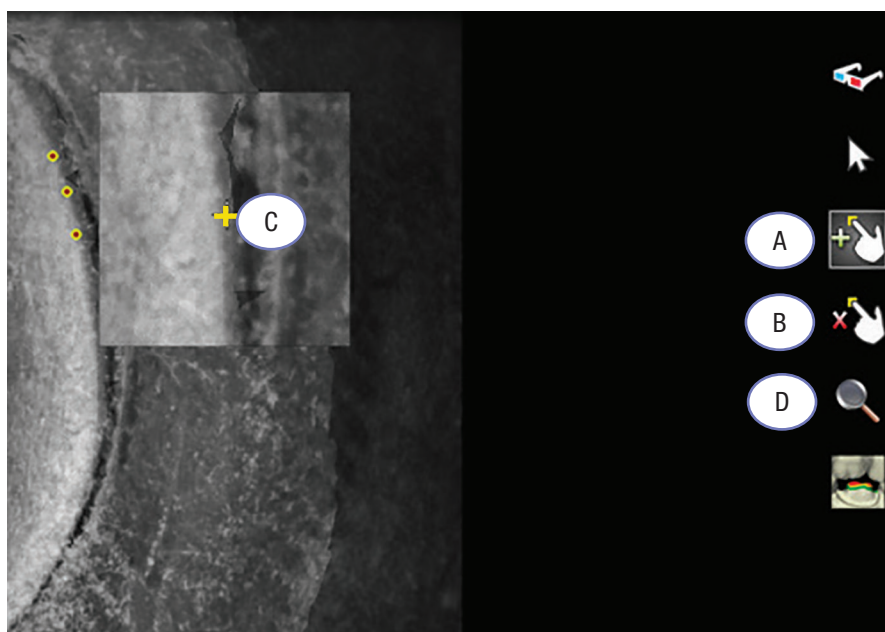


Figure 31. Magnification Window with Annotation Crosshair

Figure 31 Callouts

- A Add Margin Annotation
- B Delete Margin Annotation
- C Crosshair
- D Magnification

3. Remove finger to place an annotation dot at the crosshair.
4. Add more margin-marking annotations as necessary.
5. When done, touch the **Check Mark** button on the bottom of the screen.

The annotations are included in the case information uploaded to the lab.

- To remove margin-marking annotations, touch the **Remove Annotation** button (Figure 31, B), then touch the yellow dot to remove.
- To review the area under magnification and not place dots on the image, touch the **Magnification** button (Figure 31, D).

After verifying the scan offers a clear, unobstructed view of the margin, press the **Check Mark** button to save the preparation.

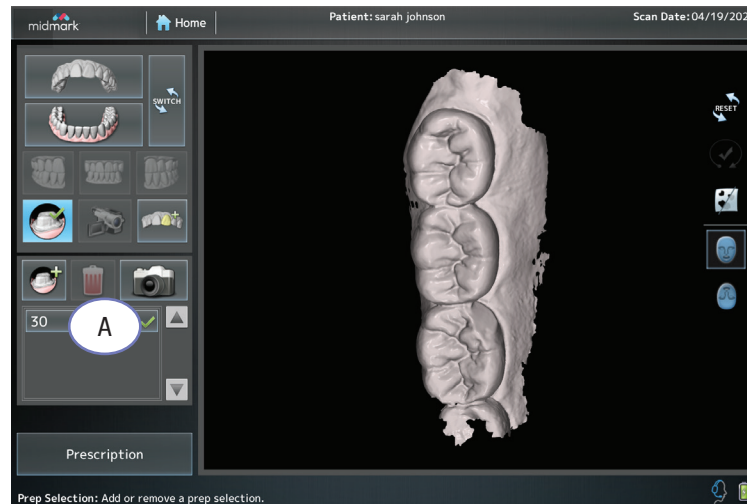


Figure 32. Approved and Saved Preparation

The prepared tooth is added to a dropdown box and marked with a green check mark (Figure 32, A). In order to return to the preparation review, press the **Check Preparation** button followed by the approved preparation number on the drop down panel.

Multiple Preparations

To add, review and approve multiple preparations, follow steps 1–5 above.

Opposing Scans

The opposing arch is scanned in the same manner as the operative arch. This must be completed before a bite registration scan can be produced.

Figure 32 Callout

A Approved Prep

NOTICE

Each preparation is required to be added, reviewed and approved before the prescription can be signed and submitted.

Bite Scan

The bite is scanned last.

1. Select one of the bite buttons, right, anterior or left from the upper toolbar (Figure 19, B).
The system will display the two arches already scanned.

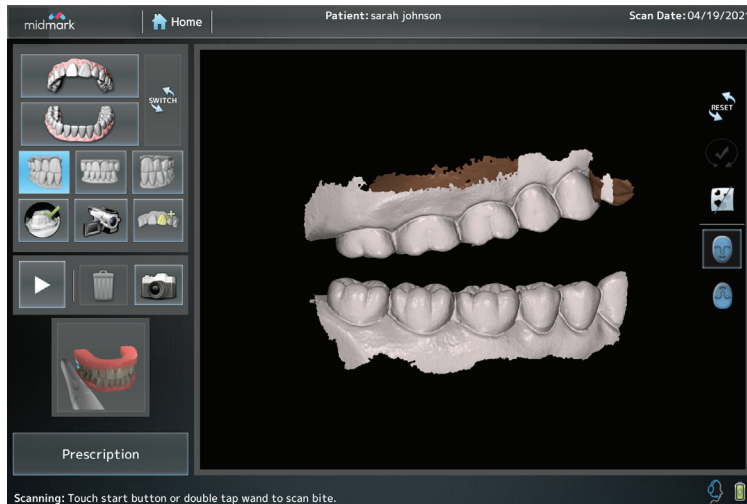


Figure 33. Scanned Arches

2. With the patient in centric occlusion, scan the bite. When done, the system will merge the upper, lower and bite scans into proper registration.



Figure 34. Generated Bite Registration

Accept or reject the registration by selecting the **Accept** Check Mark or **Delete X** button.

IMPORTANT

A quadrant bite scan should be taken as far to the posterior as possible. Use only a narrow vertical strip incorporating as much tissue apically as possible.

IMPORTANT

To maintain accuracy in the bite, three bite scans must be used when submitting a full arch scan. (A posterior bite scan on either side of the arch and an anterior bite scan) The posterior scans should be positioned as far away from the anterior bite scan as possible.

3. If the bite registration fails, you can still choose to accept the bite scan. In such a case, the unregistered bite is sent to the lab with a warning tag and the lab will need to articulate the bite manually.

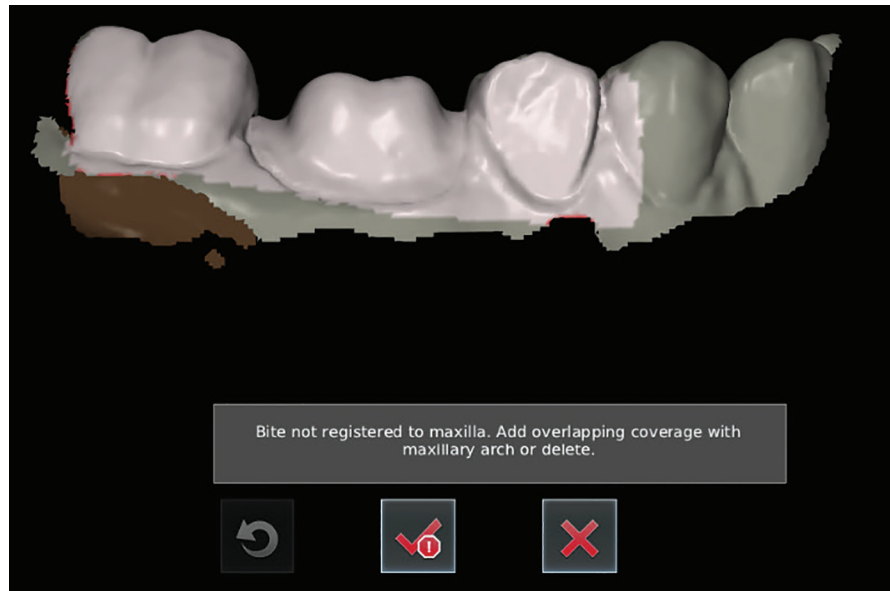


Figure 35. Unregistered Bite Warning

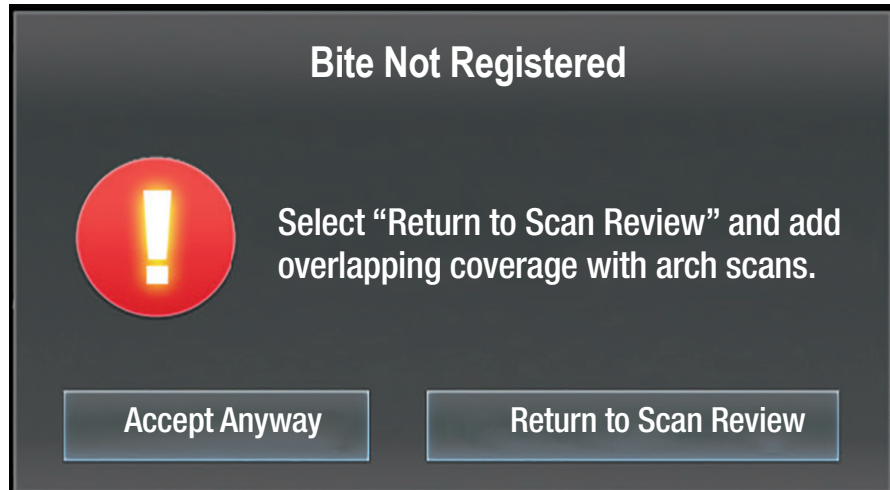


Figure 36. Bite Not Registered Warning

When scanning is completed, proceed to the Prescription screen for this case by pressing the **Prescription** button on the lower left side of the screen.

Occlusal Clearance Tool

After completion of the operative, opposing and bite scans, the **Occlusal Clearance Tool** (Figure 37, B) verifies adequate reduction of the preparation. The tool color codes the distances between surfaces. This tool is only available after the bite scan has been completed and accepted. To access this tool, press the **Select Preparation** button (Figure 37, A) and select the preparation to view in the preparation panel.

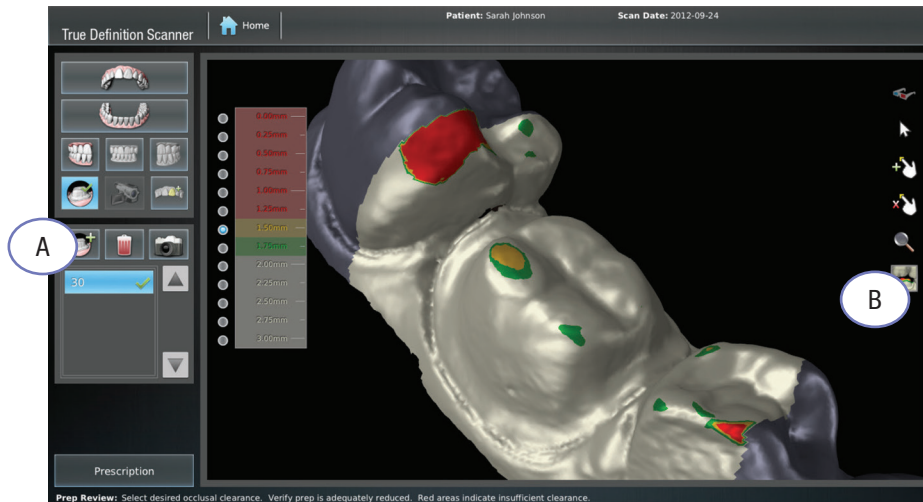


Figure 37. Occlusal Clearance Tool

In this example, areas at 1.50mm or greater are green. Areas at 1.50mm distance are in yellow and all areas with 1.25mm clearance or less are highlighted in red. The preparation may require additional reduction in its red area to achieve acceptable occlusal clearance.

NOTICE

The selected range is between 0 and 3.0 millimeters for the system to measure and identify adequate clearance. The range can be selected by the user.

Figure 37 Callouts

- A** Select Preparation
- B** Occlusal Clearance

Maxillary Flip Feature

The Maxillary Flip Feature ensures the motion of the wand is congruent with what is seen on the screen. Moving the wand left to right, the image on the screen also moves left to right. This feature is designed to make scanning the maxillary, specifically the upper anterior, easier and more intuitive.

When scanning the anterior and the wand severely rotates from its original starting position, the scanner software detects a mismatch in the orientation of the wand and the displayed image. The on-screen image will automatically flip its screen orientation. The direction of the wand and the direction of the on-screen image will be consistent.

Midmark True Definition Data Plans

The data plan defines the indications and connections available to the user. The practice chooses a data plan based on the clinical workflows they anticipate needing most often; such as unlimited usage for the standard indirect restorations. They can also select the Advanced data plan that includes Midmark Trusted Connections.

Filling Out the Electronic Prescription

To fill out an electronic prescription:

1. Touch the **Prescription** button on the lower left side of the Scanning screen.
2. A blank Prescription Screen for the patient is displayed.

Figure 38. Prescription Screen

3. Touch the Date Requested field to display the calendar. Select the requested date on the calendar.

Figure 39. Calendar

4. Touch the Lab field to display the Lab selection list box. Select the desired lab.
5. Check the Dentist field to ensure the correct name is selected. To change the Dentist's name, touch the Dentist field to display the selection list box. Select the name of the dentist who will sign the prescription.
6. Enter the information required, including:
 - Restoration type
 - Selected and missing teeth
NOTE: To chart missing teeth, touch the tooth two (2) times. A red X will appear over the selected tooth.
 - Options for restoration materials
 - Shade selections, etc.
 - Notes for the restoration

NOTICE

A prescription can be filled out at any time, but before signing a prescription, all three (3) scans for a case (operative, opposing and bite) are required. At least one (1) preparation must be selected and reviewed for restorative cases. This is not required when completing a prescription for Models and Appliances.

Figure 40 Callouts

- A Sign
- B Add Indication
- C Delete Indication
- D Save as Defaults

midmark Home Patient: John Doe Scan Date: 02/14/2020
Status: Scanned awaiting Signature ID:

Prescription

Date Requested: 02/15/2020

Destination: Workshop NoPrint

Doctor: George Jones

Shipping Address: 5252 North Lake Dr, Lakeland MI 49454, United States

Billing Address: 5252 North Lake Dr, Lakeland MI 49454, United States

Indication 1 of 1

Indication	Inlay
Selected Teeth	30
Material	All Ceramic
Brand	Lava™ Zirconia
Limited Occlusal Clearance	Call Office
Finishing Opacity	Translucent
Finishing Occlusal Staining	
Finishing Surface Glaze	

Notes

Return to Scan Sign

Sign: When all selections are made, touch Sign button to sign prescription.

Figure 40. Prescription Screen in Progress

When a line is touched, the appropriate selection box will pop up.

- Verify Rx for accuracy, then press the **Sign** button (Figure 40, A). The Patient Data Submission will display.

NOTICE

Each field does not need to be filled out. If it is not relevant or required for the case, these fields may remain empty.

- I acknowledge that this patient's data is being transmitted to Midmark Connection Center and that this data will be accessible to the model maker, the lab and/or third party I have selected as part of this patient's treatment.

- I further acknowledge that I have the ability to select services from third parties who will receive this data and reside outside of my country or region. I agree that is my responsibility to maintain the appropriate agreements with those third parties according to applicable law.

Confirm Cancel

Figure 41. Patient Data Submission

In order to comply with various national and international data privacy regulations, doctors must acknowledge the transmission of patient data for each case by acknowledging language similar to the text in Figure 41. Actual text may be slightly modified to account for regional variations and changes in various regulatory policies.

- After confirmation of the Patient Data Submission, the Prescription Digital Signature keypad will appear. Enter the PIN to sign the Prescription. The system automatically schedules the case to be sent for processing.

Additional Restoration

To add another restoration, before signing the prescription, touch the **Add Restoration** button (Figure 40, B) and continue through the process again.

Delete Restoration

To delete a restoration, touch the **Delete** button (Figure 40, C). The system will ask for confirmation to delete.

Save as Defaults

The **Save as Defaults** option (Figure 40, D) on the prescription screen can be used to save the current restoration selections as defaults. This way restoration details need not be re-entered for each prescription.

After filling out a prescription, select the **Save as Defaults** button.

When a subsequent prescription is being filled out, select the **Save as Defaults** button from the restoration type pop-up. The field(s) will automatically be filled in.

NOTICE

Cases do not get uploaded or processed when the device is shut down. If Shut Down Immediately is chosen, it is recommended the device be plugged in and powered up as soon as feasible to continue the uploading and processing of cases.

NOTICE

The scanner system must be plugged into the power source to upload cases.

Uploading Cases

Once the prescription has been signed, the system handles the uploading of cases (scan, video and prescription data) automatically. If the operator tries to shut down the system while cases are being processed, it displays this warning message:

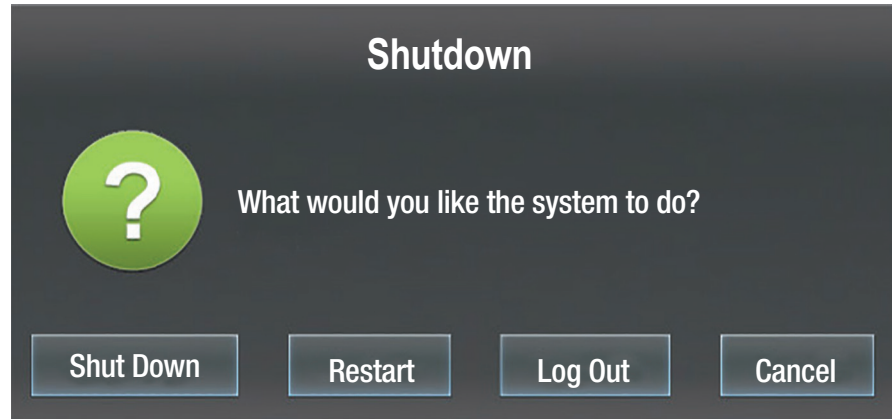


Figure 42. System is Processing Cases

The operator can choose to Shutdown, Restart, Log Out or Cancel the shutdown request. After choosing Shut Down, a dialog box will appear (Figure 43).

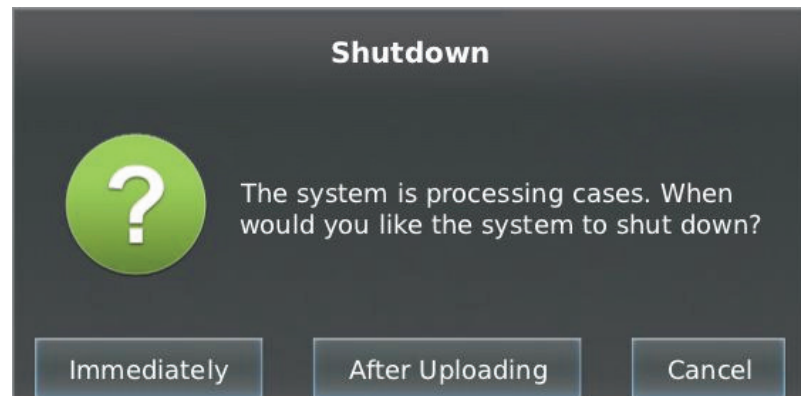


Figure 43. Processing Image

- **Immediately:** Any processing will stop. Processing will start automatically the next time the system is powered up and a wireless connection has been established.
- **After Uploading:** The system will remain on until the scan files have been uploaded. The system will then automatically shut down.

Rx/Trusted Connections/File Transfer

NOTICE

You can fill out a prescription at any time, but before you can sign a prescription, you must complete all three required scans for a case (operative, opposing and bite) and select at least one preparation for restorative cases. This is not needed when filling out a prescription for Models and Appliances.

Filling Out the Electronic Prescription

To fill out an electronic prescription:

1. Select the case for which you want to fill out a prescription (if the system displays the Scanning Screen instead of the Prescription Screen, touch the **Prescription** button).
2. A blank Prescription Screen for the patient is displayed.

The screenshot shows the 'Prescription' screen for Patient: John Doe. The status is 'Scanned awaiting Signature' and the scan date is 02/14/2020. The screen is divided into two main sections. On the left, there are several input fields: 'Date Requested' (02/15/2020), 'Destination', 'Doctor', 'Shipping Address', and 'Billing Address' (5252 North Lake Dr, Lakeland MI 49454, United States). A 'Notes' field is also present. On the right, there is a large empty area labeled 'Indication 1 of 1'.

Figure 1. Prescription Screen

3. Touch the Date Requested field to display a calendar. Then touch the requested date on the calendar.

The screenshot shows the 'Prescription' screen for Patient: Sarah Johnson. The status is 'Scanned awaiting Signature' and the scan date is 2012-09-24. A 'Select Date' calendar overlay is displayed, showing the month of September 2012. The date 29 is selected. The Prescription screen fields include 'Date Requested', 'Lab', 'Dentist' (Mandy Anderson), 'Shipping Address', and 'Billing Address' (12345 Happy Path, St Paul MN 55144, United States). A 'Return to Scan' button is visible at the bottom. A note at the bottom of the screen reads: 'Date: Touch Date to request delivery date.'

4. Touch the Lab field to display the Lab selection list box, then touch a specific lab to select it.
5. Touch the Dentist field to display the Dentist selection list box. Then touch the name of the dentist who will sign the Prescription.

6. Enter the information required, including:

- Restoration type
- Selected and missing teeth
- Options for restoration materials
- Shade selections, etc.
- Notes for the restoration

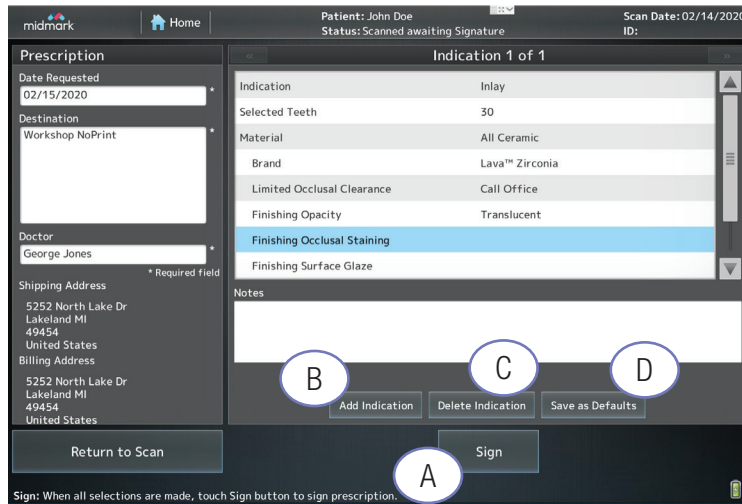


Figure 3. Prescription Screen in Progress

When you touch a line, the appropriate selection box will pop up.

7. Verify Rx for accuracy, then press the **Sign** button. The Patient Data Submission will display.

Figure 3 Callouts

- A** Sign
- B** Add Indication
- C** Delete Indication
- D** Save as Defaults

NOTICE

You do not have to fill out each field if it's not relevant or required for the case. Instead, you can leave these fields empty.

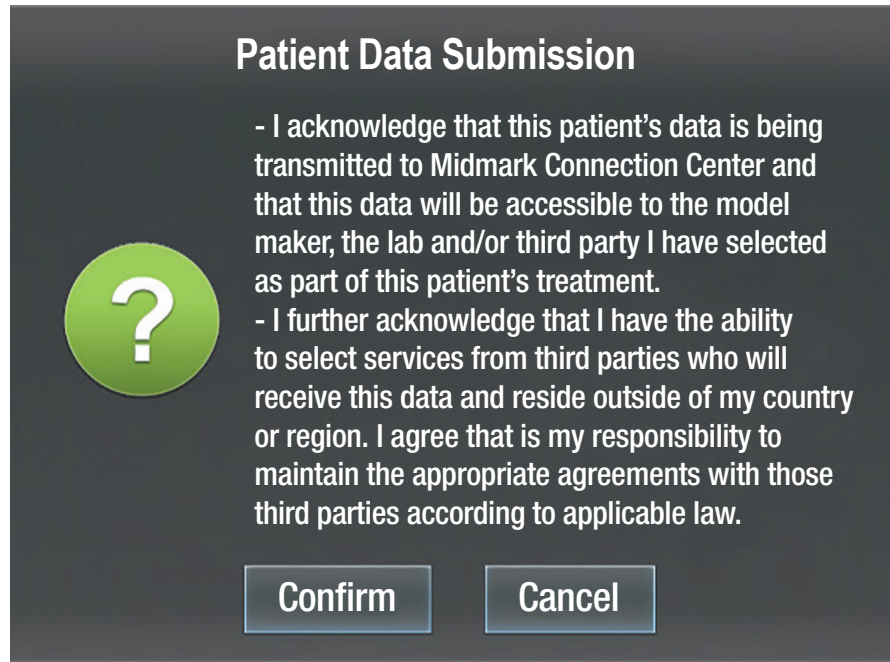


Figure 4. Patient Data Submission

In order to comply with various national and international data privacy regulations, doctors must now acknowledge the transmission of patient data for each case by acknowledging language similar to the text in Figure 4. Actual text may be slightly modified to account for regional variations and changes in various regulatory policies.

8. After confirmation of the Patient Data Submission, the Prescription Digital Signature keypad will appear. Enter your PIN to sign the Prescription. The system automatically schedules the case to be sent for processing.

Additional Restoration

To add another restoration, before you sign the prescription, touch the **Add Restoration** button and continue through the process again.

Delete Restoration

To delete a restoration, touch the **Delete** button. The system will ask you to confirm.

Save as Defaults

You can use the **Save as Defaults** option on the prescription screen to save the current lab and restoration selections as your defaults. In this way you don't have to re-enter the same restoration details for each prescription to the lab.

After you fill out a prescription, select the **Save as Defaults** button.

When you fill out a subsequent prescription, select the saved default from the restoration type pop-up.

Trusted Connection: TS150 In-Office Milling Solution For the Midmark True Definition Scanner

(See Management Tab/Chairside Connection)

Complete a Prescription and Sign a Case

Scan Screen

1. Complete a digital impression.
2. Select the Prescription button.

Prescription Screen

1. Select **Date Requested**.
2. Select **Lab**: TS150* Chairside Mill.
3. Select **Dentist**.
4. Press **Touch to Select Restoration** and select the restoration type.
5. Indicate a prepared tooth by touching and highlighting in green.
6. Select **Brand**.
7. Select **Block Size**.
8. Select **Shade**.
9. Select the **Sign** button.
10. **Confirm** the Patient Data Submission. A key pad will appear to sign the case.
11. The case will automatically arrive in the “Cases” tab of FastDesign™ CAD/CAM Design Software.*

Trusted Connection: Planmeca® PlanMill™ 40 Chairside Mill For the Midmark True Definition Scanner

Complete a Prescription and Sign a Case

Scan

1. Complete a digital impression.
2. Select the Prescription button.

Complete the Prescription Screen

1. Select **Date Requested**.
2. Select **Lab**: Chairside Mill Lab.
3. Select **Dentist**.
4. Select **Restoration** type.
5. Select each prepped tooth by touching the tooth once.
6. Select **Material**, **Shade Guide** and **Shade**.
7. To add another restoration, select the **Add Restoration** button and repeat steps 4-6.
8. Verify Rx for accuracy, Select the **Sign** button.
9. **Confirm** the Patient Data Submission screen. A key pad will appear to enter your PIN.
10. Verify the file transferred to Planmeca® PlanCD™ by checking the message alert icon on the bottom right corner of the scan screen.

Importing Midmark True Definition Scanner Data

Planmeca and E4D systems that have the Midmark collaboration software can import scans from the scanner.

1. Once the prescription is signed on the scanner, the file is transferred to Planmeca PlanCAD's design hard drive.

NOTICE

The license for importing Midmark files is sold separately. When the license is active, the button for importing is on the Home Screen next to **Start a New Restoration**.

NOTICE

It is important to follow the Scanning Protocol, Implant Work Flow Procedure and Prescription Instructions from the Midmark True Definition User Guide. Deviation from these instructions will result in delays.

NOTICE

- Encode® Patient Specific Dental Abutments made from oral scans provided from Midmark True Definition Scanner and the True Definition software are intended for use as an accessory to endosseous dental implants.
- This workflow feature supports a prosthetic device in a partially or edentulous patient.
- Encode Patient Specific Dental Abutments are intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prostheses can be screw or cement retained to the abutment.

Trusted Connection: BIOMET 3i Bellatek™ Encode® Implant System For the Midmark True Definition Scanner

Overview

This project expands the capability for the scanner by adding an option to connect with the BIOMET 3i/Bellatek™ Encode® implant system. The Midmark Scanner is used to scan an Encode® healing abutment which also functions as a scan locator. The scan locator contains precise markings which cipher the precise implant system being used and indicates its exact orientation. The electronic scan is transmitted to BIOMET 3i where an abutment is designed and digitally inserted in the scan file, replacing the locator. The digital file is sent to the dental laboratory to craft the final restoration at the same time as the abutment.

Instructions for Use

Preparation Prior to Scanning BellaTek™ Encode® Healing Abutments

1. Call your Midmark Service Center to request the Trusted Connection to BIOMET 3i™ indication for the scanner.
2. Verify the Restoration Lab is listed as “active” on the Midmark True Definition screen. Select **Home** screen, **Management, Settings, Labs**. Highlight the laboratory to be activated. Select the **De/Activate** button. If the desired laboratory is not on the scanner’s laboratory list, contact Midmark Service Center to request the laboratory.

Scanning BellaTek™ Encode®

Preview the powdered BellaTek™ Encode® using the Inspection Feature

- Scan the BellaTek™ Encode® and contacts.
- Multiple BellaTek™ Encode® Healing Abutments or restorative preparations can be included in the scan.
- Review implant images in high resolution. Select the correlating tooth number to the position of the BellaTek™ Encode® placement.
- Save successfully scanned implants.
- Scan the opposing arch and save.
- Scan the bite, including the Implant Healing Abutment and analyze the occlusion.

Filling Out the Electronic Prescription

To fill out an electronic prescription:

1. Select the **Prescription (Rx)** tab.
2. Select **Date Requested**.
3. Select Lab: Choose the **Restorative Lab**.
4. Select the **Dentist Name**.
5. **Touch to select Restoration Type**.
6. Select: BIOMET Implant Abutment.
7. Identify the tooth number of the BellaTek™ Encode(s).

Selecting Implant Abutment Design

Complete abutment design steps **00** to **013**.

The design of the custom abutment is now complete. You **MUST** now complete the steps to design the restoration that will be placed on the abutment. Failure to follow these steps will result in a manufacturing delay for the case.

NOTICE

Make sure you can clearly see the entire diameter and top including the notches of the Healing Abutment. Too much powder will make it hard to read exact placement of the BellaTek™ Encode® and make it difficult for BIOMET *3i* to design the custom abutment.

NOTICE

Each scanned implant must be reviewed and saved in high resolution. Scan the operative arch and save to combine with the Implant Healing Abutment Scan.

NOTICE

A prescription can be filled out at anytime, however, all three required scans must be completed (operative, opposing and bite) and at least one prep selected.

NOTICE

Failure to fill out the abutment design portion of the prescription will result in BIOMET 3i using default settings to design the abutment.

If step 013 **Design File Check and Approval** is left blank, the abutment will be designed and processed without approval.

NOTICE

If a screw is not requested in the **Notes** section, the abutment will be sent without a screw.

NOTICE

When scanning multiple implants, selecting Implant Abutment Design and selecting Restoration design must be repeated for each implant.

Selecting Restoration Design

1. Select **Add Restoration** and continue to design the restoration for placement on the abutment.
2. Use the **Notes** section to request a screw be included with the abutment and restoration. Other notes pertaining to the case may also be written here.

Sign Case and Submit

- Upon completion of the prescription, select the **Sign** icon.
- **Confirm** the Patient Data Submission screen.
- A key pad will appear to sign the case using the PIN number.

Scanning Suggestions for Implants

- The BellaTek™ Encode® must be placed so that it is 1mm supragingival.
- When scanning around the Encode or edentulous areas, slightly point the camera toward the soft tissue to prevent going into pause mode.
- If the LED ring of lights or sparkling on the scanning surface is visible, not enough powder or too much moisture is in an area. It will be difficult to scan. Re-powder dry the area with a gentle stream of air.
- If voids appear in a critical area, the scan must be deleted and rescanned.
- It is critical to scan the soft tissue around the BellaTek™ Encode® and adjacent teeth.
- Edentulous areas can be scanned and included in the model. Capture as much soft tissue as possible on the buccal and lingual surfaces of the ridge.
- For a bridge over implants, enter the abutments information on the prescription first. Then add the bridge prescription under **New Restoration**.

BIOMET 3i LLC:
1-888-800-8045

for BIOMET 3i abutment design, manufacturing and technical support.

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Palm Beach Garden, FL 33410
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Fax: +1-561-776-1272
.biomet3i.com

BellaTek is a trademark of BIOMET 3i
and BIOMET 3i is a trademark of
BIOMET Inc.

Trusted Connection: Straumann® Dental Implant System For the Midmark True Definition Scanner

Overview

This project expands the capability for the scanner by creating a Trusted Connection to the Straumann® Dental Implant System. The True Definition Scanner is used to scan a Straumann® CARES® Mono Scanbody. The Mono Scanbody identifies the precise implant type and size being used and indicates its exact orientation. The digital scan and prescription are transmitted to the CARES® laboratory where an abutment is designed and digitally inserted in the scan file, replacing the locator. The CARES® laboratory can also design the restoration at the same time the custom abutment is designed. The design files are sent to Straumann® for manufacture of the custom abutment and restoration.

Instructions for Use

Tooth Borne Restoration from Straumann®

1. Determine individual tooth shade and surface structure.
2. Prepare tooth.
3. Scan prepped tooth utilizing the scanner procedure.

To fill out an electronic prescription:

1. Select the **Prescription (Rx)** tab.
2. Select **Date Requested**.
3. Select **Lab**: Choose the appropriate CARES® Lab.
4. **Touch to Select Restoration**: Crown or bridge.
5. Identify the tooth number.
6. Select **Material** (All Ceramic, Cobalt Chrome, Titanium or Polymers).
7. Choose **Other Brand** to view and select Straumann® materials.
8. Complete Prescription as prompted, including **Shade Guide** and **Shade**.
9. Finalize order on the scanner by signing the Prescription.

NOTICE

There are currently three possible workflows with the True Definition Scanner/Straumann® connection: Tooth Borne Restoration, Custom Implant Abutment Only and Custom Implant Abutment and Implant Borne Restoration.

NOTICE

Only 3M Lava™ Ultimate CAD/CAM Restorative and Straumann® materials can be used with the Straumann Trusted Connection.

NOTICE

Refer to the True Definition Scanner/
Straumann® Trusted Connection
Quick Start Guide for scan protocol.

NOTICE

WN Individual Abutment is only
available with Straumann®
CARES® Titanium.

Custom Implant Abutment Only from Straumann®

1. Place corresponding Straumann® Bone Level or Tissue Level Mono Scanbody.
2. Scan Mono Scanbody utilizing Midmark True Definition Scanner procedure protocol.

To fill out an electronic prescription:

1. Select the **Prescription (Rx)** tab.
2. Select **Date Requested**.
3. Select **Lab**: Choose the appropriate CARES® Lab.
4. **Touch to Select Restoration**: Straumann Implant Abutment.
5. Identify the tooth number.
6. Select **Material** (Straumann CARES® Titanium or Straumann CARES® ZrO2)
7. Select **Implant Platform**.
 - NC Individual Abutment.
 - NN Individual Abutment.
 - RC Individual Abutment.
 - RN Individual Abutment.
 - WN Individual Abutment (See Notice).
8. **Add restoration to abutment?** Select: **No**.
9. Finalize order on the True Definition Scanner by signing the prescription.

Custom Implant Abutment and Implant Borne Restoration from Straumann®

1. Place corresponding Straumann® Bone Level or Tissue Level Mono Scanbody.
2. Scan Mono Scanbody utilizing True Definition Scanner procedure protocol.

To fill out an electronic prescription:

Follow previous Steps 1-7 for Abutment design.

8. **Add restoration to abutment**: Select: **Yes**.
9. Select **Add Restoration**. (Bottom right of Prescription Form).
10. **Touch to Select Restoration**: Crown or Only Single Units for the first stage.
11. Identify the tooth number.
12. Select **Material** (All Ceramic, Cobalt Chrome, Titanium or Polymers).
13. Choose **Other Brand** to view and select Straumann® materials.
14. Complete Prescription as prompted, including **Shade Guide** and **Shade**.
15. Finalize order on the scanner by signing the prescription.

Straumann® products are registered trademarks of Straumann Corporation.

Trusted Connection: Invisalign® for the Midmark True Definition Scanner

Complete a Prescription and Sign a Case Scan

1. Complete Full Arch Scans and Bite Registration. (See the Notice.)
2. Select the Prescription button.

Complete the Prescription Screen

1. Select **Date Requested**.
2. Select lab: Align Technology, Inc.
3. Select: **Dentist Name**.
4. Select: **Touch to Select Restoration**.
5. Select: **Models and Appliances**.
6. Select: **Select Type**.
7. Select: ***Invisalign® or *Realine™**.
8. Sign and enter PIN to complete and send the case.

Log In to Align Websites

Allow up to 75 minutes for digital impression files to be available on the Invisalign Doctor's Site and the Realine Doctor's Site.

NOTICE

Refer to Align Technology, Inc. data capture requirements and Midmark True Definition Scanner User Guide or Midmark True Definition Scanner–Scan Path tutorial.

NOTICE

Refer to Unitek™ data capture requirements and Midmark True Definition scanner User Guide or Midmark True Definition Scanner–Scan Path Tutorial.

Trusted Connection: Unitek™ Treatment Management Portal/ TMP for Unitek™ Digital Models and Incognito™ Appliances for the Midmark True Definition Scanner

Place customized orders for digital model storage and the Incognito™ Appliance System through a secure Unitek-supported process. Digital Model storage provides digitally prepared models with added ABO bases and a multitude of treatment planning tools. This connection is available to Certified Incognito™ Orthodontists only.

Complete a Prescription and Sign a Case

Scan

1. Complete Full Arch Scans and Bite Registration. (See *Notice)
2. Select the Prescription button.

Complete the Prescription Screen

1. From the **Date Requested** field, choose the current date. Note that this date does not affect the delivery promise dates for products produced by Unitek from the scan.
2. Select **Lab: Unitek TMP Lab**
3. Choose: **Dentist**
4. Select **Restoration**
5. Choose: **Models and Appliances**
6. Choose: **Select Type**
7. Select: **Unitek™ Treatment Management Portal**
8. Enter **Notes** if desired
9. Verify Rx for accuracy. Select the **Sign** button.
10. **Confirm** the Patient Data Submission screen. A key pad will appear to enter your PIN.

Upload of Digital Impressions to Treatment Management Portal (TMP)

Allow up to 90 minutes for digital impression files to be available at the Unitek Lab. Ensure that the patient name used to create the scan matches the name used on your Treatment Management Portal.

Trusted Connection: Open STL File Access for the Midmark True Definition Scanner

This Trusted Connection allows access to download open STL files from the Midmark True Definition Scanner.

Complete a Prescription and Sign a Case

Scan

1. Complete a digital impression.
2. Select the **Prescription** button.

Complete the Prescription Screen

1. Select: **Date Requested**.
2. Select: **Lab**: Midmark-Doctor STL Only (No Models).
3. Select: **Dentist Name**.
4. Select **Restoration**: Models and Appliances.
5. Verify Rx for accuracy. Select the **Sign** button.
6. **Confirm** the Patient Data Submission screen. A key pad will appear to enter your PIN.

Access to Scan Files

To access the open STL files, follow these instructions:

1. Log into Connection Center at: <https://connectioncenter.3m.com>
2. Enter Username and Password. (See NOTICE).
3. Under the **Cases** tab, select the specific case by clicking on the case number.
4. Select the **Files** tab and download the **Open STL Only** to obtain the STL files of the individual scans that can include the mandible, maxilla and bite.

NOTICE

Access to STL files requires an Advanced Data Plan. Contact Technical Support to register for the Advanced Data Plan and obtain a Username and Password for Connection Center. Access to Connection Center, where the STL files are stored, requires a Username and Password.

NOTICE

Before starting an implant restoration with a scan body, verify with the implant supplier and restorative lab that an abutment can be created using a STL file.

NOTICE

For the open connection implant workflow, the prescription should be completed as a restorative case by entering the implant(s) as a crown (or bridge if appropriate). Do Not enter the case as an implant. Information regarding the implant should be placed in the notes section of the prescription.

Implant Restorations with Scan Bodies in an Open Connection Workflow for the Midmark True Definition Scanner

Step by Step Guide

Dental Office:

1. Verify with implant supplier or restorative lab that an abutment can be designed from a digital STL file.
2. The doctor places the scan body on the implant.
3. Scan as for a restorative case, (scan body, adjacent teeth, opposing and bite registration). Verify the scan body is completed captured, including the base of the scan body.
4. To complete the prescription, enter the implant scan body as a crown (or bridge, if appropriate). **Do not** enter it as an implant. Information regarding the implant should be placed in the notes section of the prescription.
5. Sign and submit the prescription.

Dental Laboratory:

6. The lab receives the scanned case in Midmark Connection Center and Margin Marking software. There are several options to the lab at this point:
 - Option A:** The lab has a lab cad software capable of designing abutments:
 - Download the STL file from Connection Center and import into CAD software.
 - Design the abutment and restoration.
 - Option B:** The lab has 3Shape CAD software capable of designing abutments:
 - The lab marks the margins in the Margin Marking software. A lab CAD 3Shape file (30XZ) will be generated in Connection Center.
 - Import the file into the 3Shape lab CAD software.
 - Design the abutment and restoration.
 - Option C:** The lab has no CAD software:
 - The lab downloads the STL file from Connection Center and sends the file to a design/milling center.
 - The abutment is designed and milled. A model with a replica of the abutment is provided to the outsourcing lab to produce the restoration on, along with the milled abutment.

3i™ Biomet and Straumann® Implant Cases

(Trusted Connections with the Midmark True Definition Scanner)

Refer to the Quick Start Guides for Biomet 3i™ BellaTek™ Encode® Impression System and Straumann® CARES® Workflow.

BioHorizons abutments can be designed only the 3Shape lab CAD software.

(In Canada, BioHorizons® implants are distributed by Core3dcentres®) For information contact BioHorizons® at 1-866-468-8338.

Implant Direct Implant Cases

For Implant Direct implant cases, contact Implant Direct at 1-888-649-6425.

Management Screens

The Management screens are generally for the use of Midmark Oral Care Technical Support. There are some management features the user will access. For example; adding a new user, adjusting the Tap On/Off feature or adjusting LED light brightness.

Select the **Management** button on the Home screen to display the Management screen. There are three tabs in this section: Settings, System, and Maintenance.

Settings

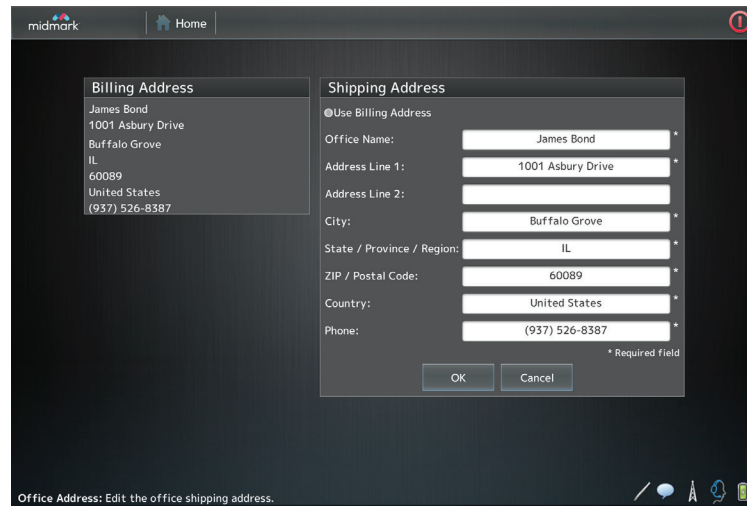


Figure 1. Setting — Office

To edit the information on the Office screen, press the **Edit** button and then use the on-screen keyboard to type in the information that has changed. Required fields are marked with an asterisk. Press **OK** when you have completed the changes.

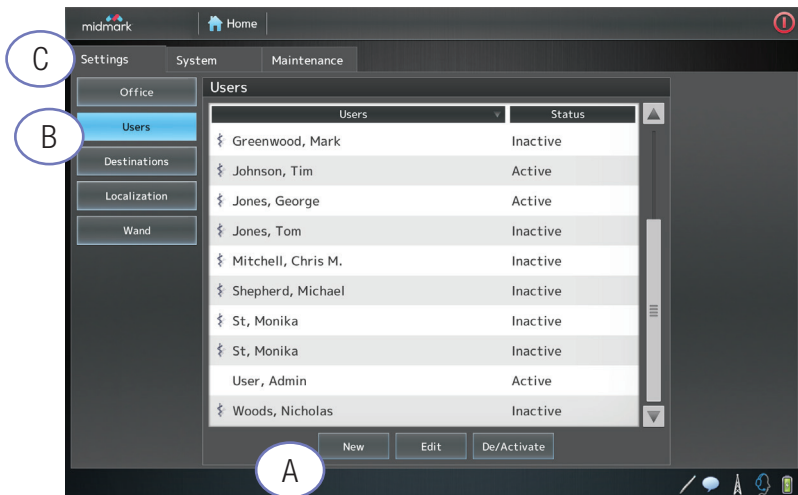


Figure 2. Settings — User

The **User** screen lists the system's users and their status (i.e., active or inactive). To add a user to this system, select the **New** button and use the on-screen keyboard to type in the relevant information. Select **OK** when completed.

User Information

User Type: Doctor

First Name: *

Middle Name: *

Last Name: *

PIN: *

Repeat PIN: *

License: *

License Type: *

Email: *

* Required field

OK Cancel

User Information: Add or edit information about this user.

To edit the information for a user, select the user name from the user list. Select the **Edit** button and type in the new information.

To make a user active or inactive, select the user name from the user list. It will be displayed in blue. Then press the **Deactivate/Activate** button, as appropriate.

Figure 2 Callouts

- A New
- B User
- C Settings

IMPORTANT NOTICE

Adding a new doctor will require the doctor's license number, which is added to the License field. This is required for signing electronic prescriptions.

Figure 4 Callouts

- A** Destinations
- B** De/Activate
- C** Sync All

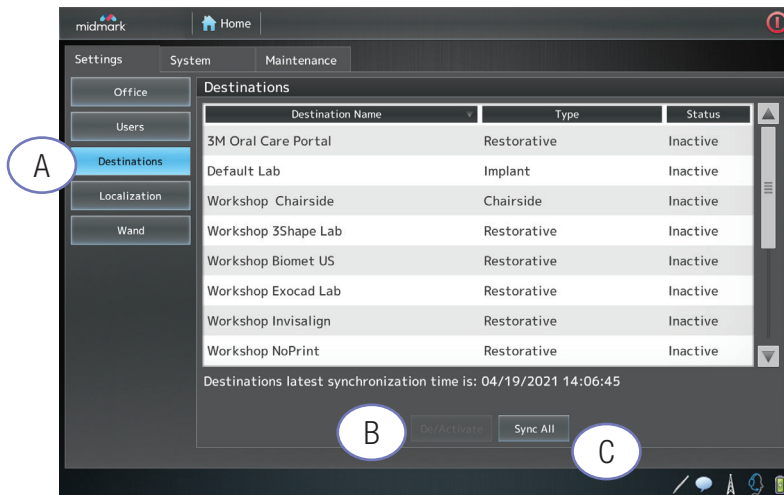


Figure 4. Settings — Labs

The **Destinations** screen displays the list of labs Midmark has entered into the system. To make a lab inactive (i.e., your dental practice does not use the lab), select the lab's name and press the **De/Activate** button. Contact Midmark Technical Support to add a lab not listed. Midmark updates the lab list on the scanner as needed. To synchronize the data on your system, press the **Sync All** button.

Figure 5 Callouts

- A** Localization

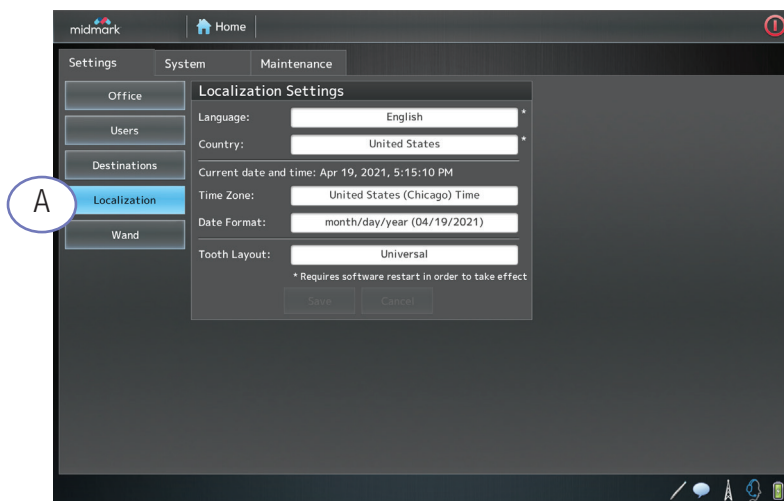


Figure 5. Settings — Localization

The **Localization** screen is used to select local information for the system, including time zone and tooth layout.

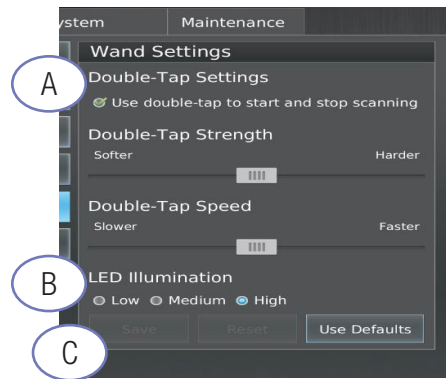


Figure 6. Settings — Wand

By default, the double tap functionality will be turned off.

To turn the functionality on:

- Press the **Double Tap Activation** button (Figure 6-A) at the top of the wand settings screen
- Press the **Save** button (Figure 6-C) to enable

To adjust the double tap strength or speed:

- Drag the slider tabs as desired
- Press the **Save** button to enable

The user can configure the LED light setting for the wand. By default, the LED lights are set at **High** (Figure 6-B.)

- Press **Low** or **Medium** to change the brightness for the LED for scanning.
- Press the **Save** button to enable.

Figure 6 Callouts

- A** Double-Tap Activation Button
- B** LED Illumination Buttons
- C** Save, Reset, Use Defaults Buttons

NOTICE

These settings will be saved for the signed-in user only. All users can have their own preferred wand settings by enabling the wand settings while logged in under their own name.

Chairside Connection

Activating a Chairside Connection

1. From the Home Screen press **Management**.
2. Select the **Settings** tab.

Figure 7 Callouts

A Settings

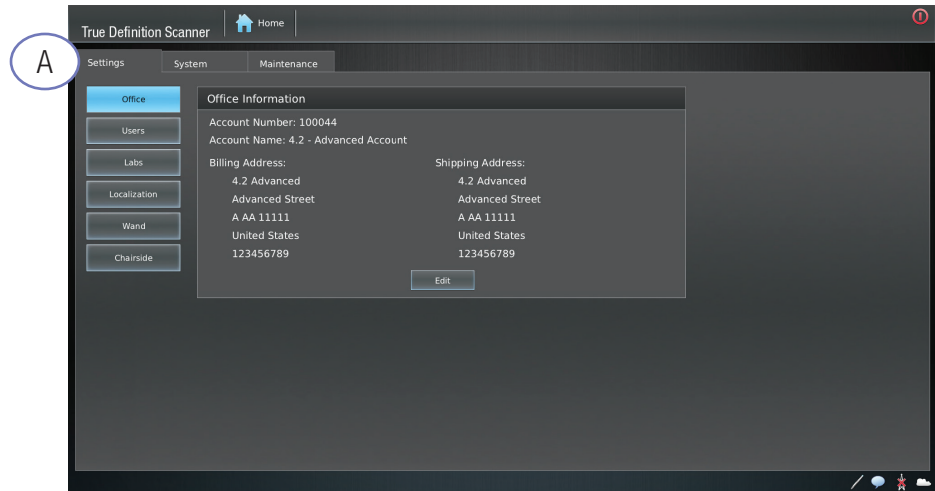


Figure 7. Settings Screen

3. Select the **Labs** button.
4. Select the **Sync All** button on the bottom of the screen (Figure 8-B).

Figure 8 Callouts

A Labs Button

B Sync All Button

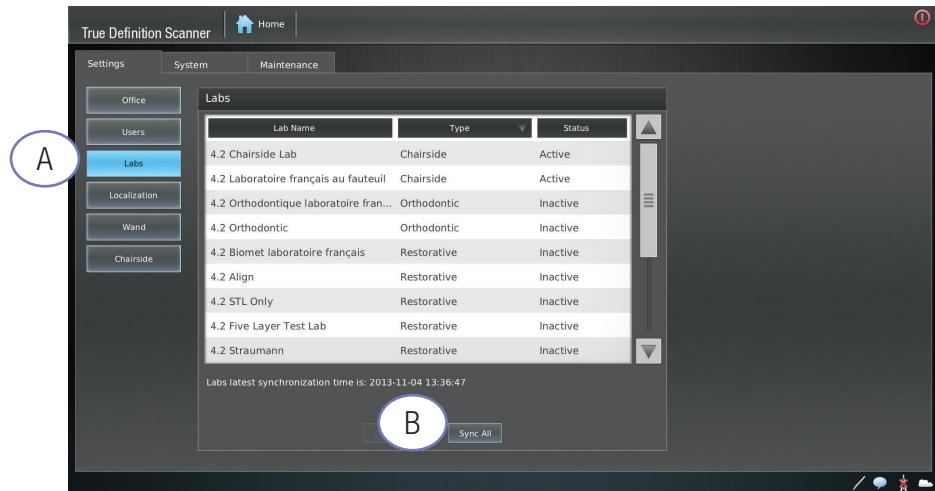


Figure 8. Settings — Labs Screen

5. In your **Settings** tab, press the **Chairside** button.

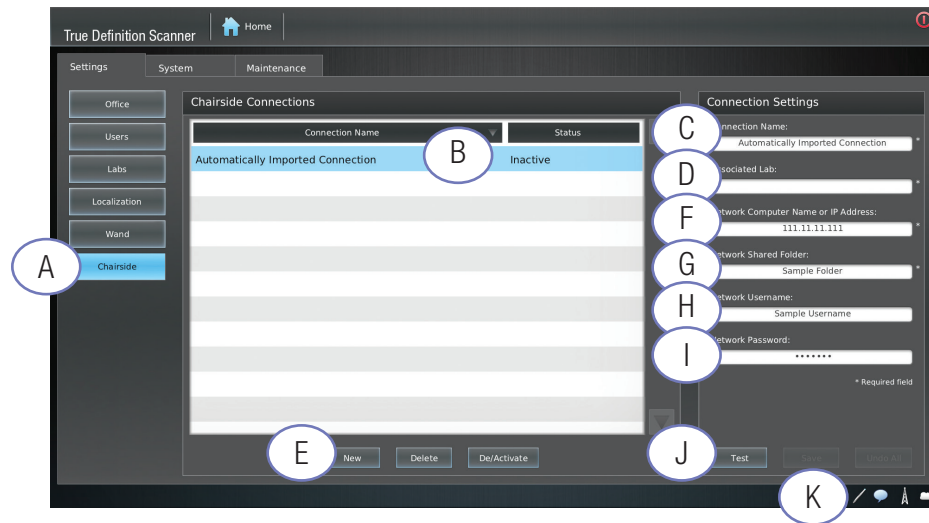


Figure 9. Settings — Chairside Screen — Existing Chairside Connection

Instructions for Existing Chairside Connections

1. The **Connection Name** is labeled as “Automatically Imported Connection.”(refer to Figure 9) (Callout B).
2. Select Automatically Imported Connection.
 - The Connection Name appears on the prescription. Edit the name by selecting the **Connection Name** field.
3. Press **Associated Lab** field and select the previous chairside lab used. (If you have not synced labs in step 4 under Activating a Chairside Connection, the chairside lab will not appear).
4. Select your chairside lab.
5. Select **SAVE**. (Callout K)
6. Proceed to **Test Connection**. (Callout J)

Instructions for New Chairside Connections

1. Press **New** on the bottom of the screen. (Callout E)
2. Enter a **Connection Name**. (This Connection Name will appear on the Prescription). (Callout C)
3. Press **Associated Lab** field and select the chairside lab. (Callout D)
4. Enter the **Network Computer Name or IP Address**. (Callout F)
5. Enter the **Network Shared Folder**. (Callout G)
6. Enter the **Network Username** (if applicable). (Callout H)
7. Enter the **Network Password** (if applicable). (Callout I)
8. Select **SAVE**. (Callout K)
9. Proceed to **Test Connection**. (Callout J)

Figure 9 Callouts

- A Chairside
- B Connection Name
- C Connection Name
- D Associated Lab
- E New
- F Network Computer Name or IP Address
- G Network Shared Folder
- H Network Username
- I Network Password
- J Test Button
- K Save

NOTICE

The **Associated Lab** field is the only field that users must fill out for an Existing Chairside Connection (step 3). All other fields are automatically populated.

NOTICE

The default status of an existing Chairside Connection is “inactive”. (See **Changing Lab Status** for instructions).

NOTICE

The default status of a new Chairside Connection is “active.”

Figure 10 Callouts

- A** Test Button
- B** Chairside Connection
- C** De/Activate

NOTICE

Cases will not successfully send to a Chairside Design Center if the test fails.

NOTICE

The default status of a new Chairside Connection is “active.”

Testing Connection

1. Press the **Test** (Callout **A**) button to verify the connection.

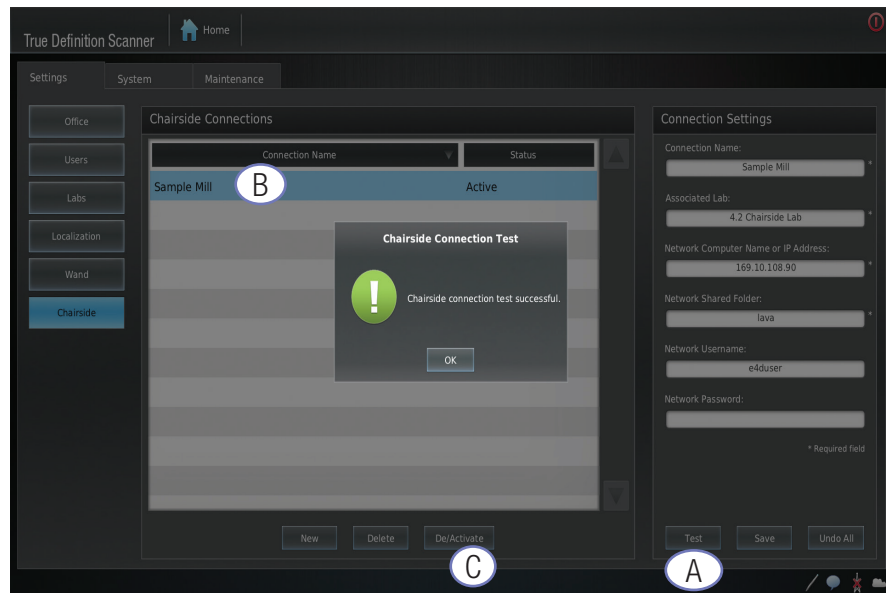


Figure 10. Chairside Connection Test Results

2. If the Chairside Connection Test failed, verify the information entered and perform the test again.
3. After verifying the connection information, if the test is still unsuccessful, call Midmark Technical Support.

Changing Lab Status

1. Highlight the **Chairside Connection** (Callout **B**) in the Chairside Connections window.
2. Press the **De/Activate** (Callout **C**) button to change the status.

Sending Chairside Cases

When sending a case using a Chairside Connection, an additional status bar is displayed.

After sending a case using a Chairside Connection, two status bars will appear.

1. The first status bar represents the progress of sending the patient case to a chairside design station.
2. The second status bar represents the progress of sending the patient case to be stored in Connection Center.

Complete upload of a case will result in two green status bars.

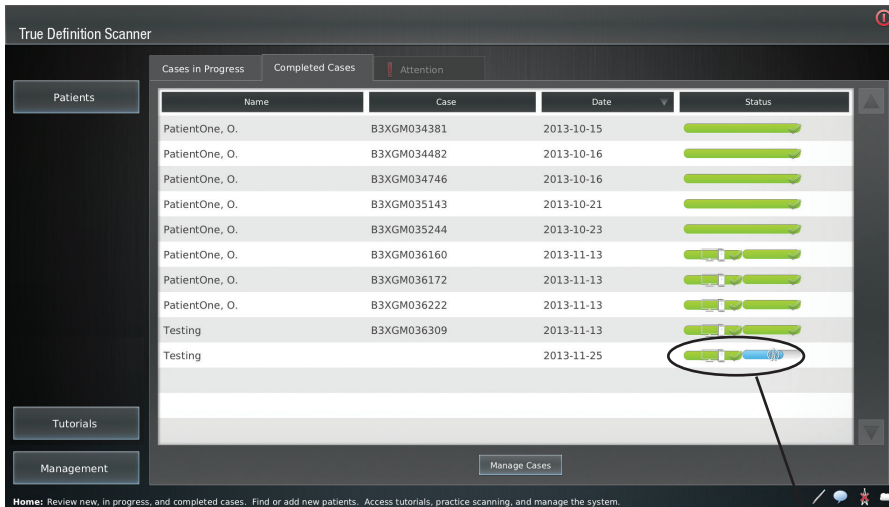


Figure 11. Status Bars

Status Bars

If a case fails to upload, contact Midmark Technical Support.

NOTICE

The status bar for cases sent to a dental laboratory will display a single status bar. This status bar represents the upload progress to Connection Center.

System

Figure 12 Callouts

- A Messages
- B System

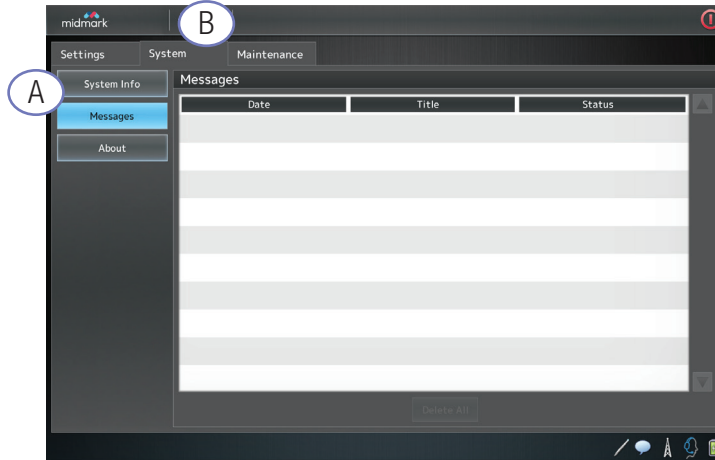


Figure 12. System — Messages

System messages are displayed on the **Messages** screen.

Figure 13 Callouts

- A System Info

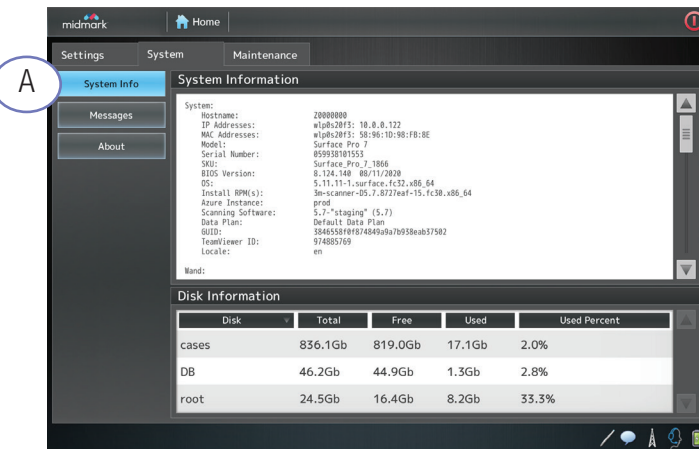


Figure 13. System — System Information

Figure 14 Callouts

- A About

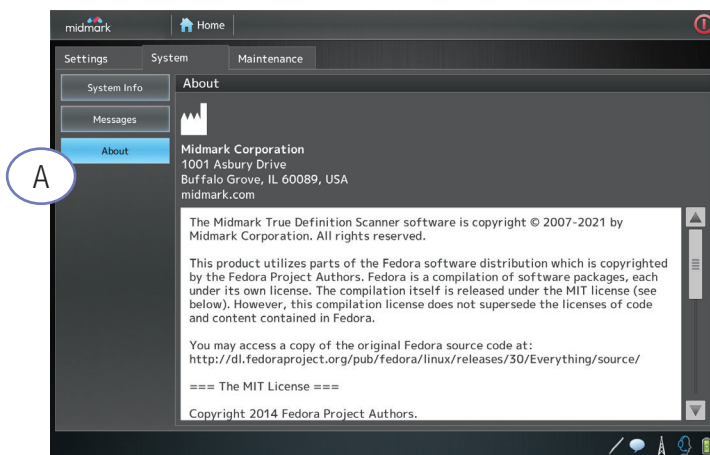


Figure 14. System — About

The **System** screen displays copyright and software information.

Maintenance

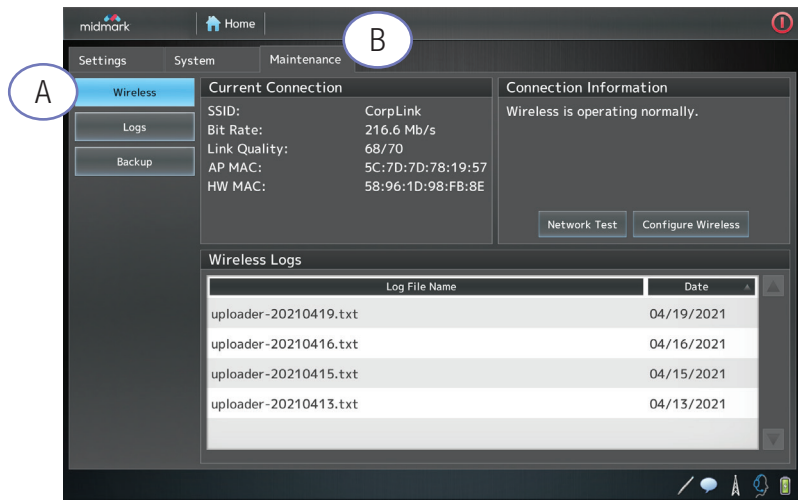


Figure 15. Maintenance — Wireless

The **Wireless** screen displays information about the system's wireless connection.

Figure 15 Callouts

A Wireless

B Maintenance

Back Up and Transfer Data

NOTICE

Backup commands are controlled and initiated by Midmark.

NOTICE

Note that this data is encrypted and will not transfer to other operating systems or programs.

NOTICE

Any cases other than ones marked complete (ie. Active, Pending, Failed etc.) will prevent the backup process.

NOTICE

The Logs screen is used by Technical Support Only.

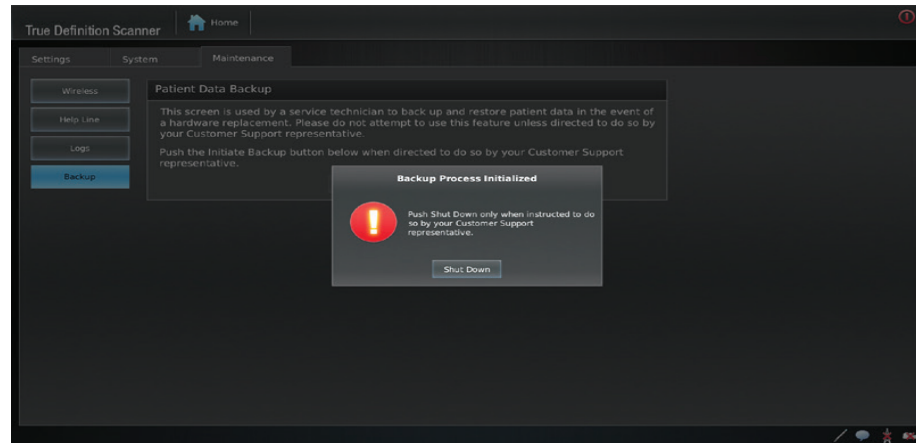


Figure 17: Backup Process Initialized Message

In the case of a system replacement, the data backup and transfer feature will allow an owner of a True Definition Scanner to back up and transfer data to another True Definition Scanner.

Instructions

1. Before initiating the backup process, verify that there are no Pending, Active or Failed cases.
2. Attach backup device into the wand USB port located on the monitor or tablet.
3. From the **Home** screen, press the **Management** button.
4. Select the **Maintenance** tab.
5. Press the **Help Line** button.
6. Open a Help Line.

- Call Midmark Technical Support and request assistance with backup and data transfer.
- Midmark will initiate Backup.
- When the user presses the **Initiate Backup** button, the pop-up shown in Figure 18 will continue to display regardless of the backup status. The completion status is **only** viewable by the Technical Support representative. Do not shut down the system until directed to do so by the Technical Support representative.

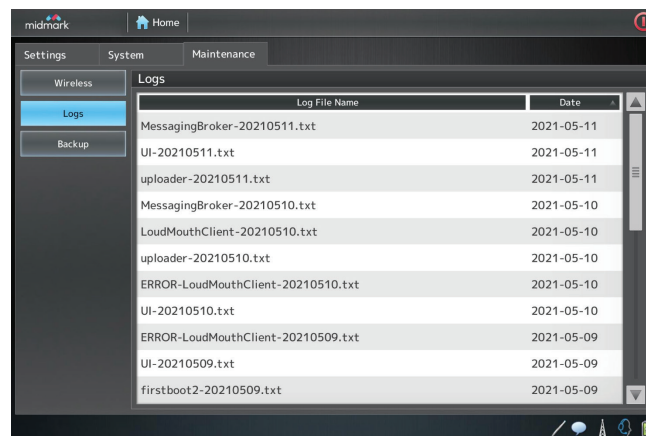


Figure 18. Maintenance — Logs

Technical Support uses the **Logs** screen to display system logs.

Setup Guide

CAUTION

Read and understand all instructions before carrying out any work.

Introduction

This section describes only the procedures and information required for setting up the scanner and connecting it to a wireless network.

Every effort has been made to verify this guide's completeness and accuracy. Midmark makes no warranty or guarantee as to its accuracy or applicability for use. Information in this guide is subject to change without notice.

Intended User Profile

Trained professionals (Dentists, Orthodontists, Dental Assistants and Dental Hygienists) in a dental office are the primary users.

The sales force and trainers are secondary users. It is expected that any secondary users using the product in-vivo will have had appropriate training for such (e.g., they were previously dental assistants). They are expected to have training in prevention of cross-contamination and disinfection procedures.

Other users may include individuals in dental training (dental school or dental assistance training) working under the supervision of dental professionals.

Limitation of Liability

Except where prohibited by law, Midmark will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Safety

Read all Safety Warnings, Cautions and Notices Information.

Network Communication

The scanner is a wireless medical device. The customer must have a wireless network, a wireless router, and a wireless access point (WAP) available before installing the scanner.

The internet connection's upload speed must be at least 256 Kbps.

Customer's router may use Dynamic Host Configuration Protocol (DHCP) or Static IP addressing, and must have available IP addresses for the scanner.

Lead lined operatories, operatories which limit positioning of the scanner, and operatories over 15 meters (49 feet) from the wireless access point may reduce wireless connectivity.

Quick Start Guide

The quick start guide is included in the main scanner box. It visually describes how to connect the isolation transformer and power adapter to the scanner.

Power On

1. Move the scanner near the Wireless Access Point that will be used.
2. Connect the power cord to the scanner and plug it into a properly grounded wall outlet.
3. Press the Power On button on the top left edge of the tablet for one second to turn it on.



Log In

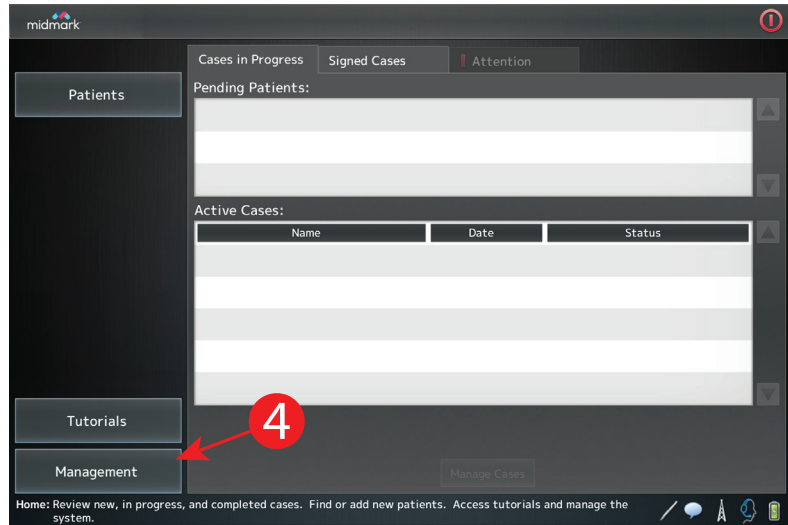
1. Using the Touchscreen Display, press to highlight User, Admin
2. Enter the PIN: **629407**; for older systems use **1111** (see notice).
3. Press **Login**.



NOTICE

Due to California's IoT law requiring manufacturers of connected devices to equip each device with unique initial administration passwords, newly manufactured devices will come with the admin password set to the numeric portion of the Device Name. The Device Name can be found in the bottom left corner of the login screen..

- When the **Home** screen is displayed, press **Management** button.



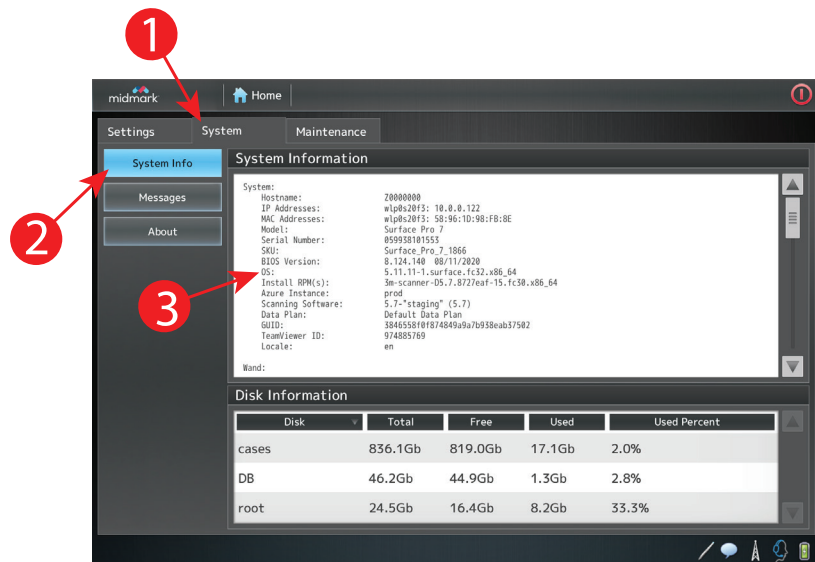
System Information

- Press **System** tab
- Press **System Info** button
- Midmark Technical Support may ask for the OS and Scanning Software versions.

Examples from image below:

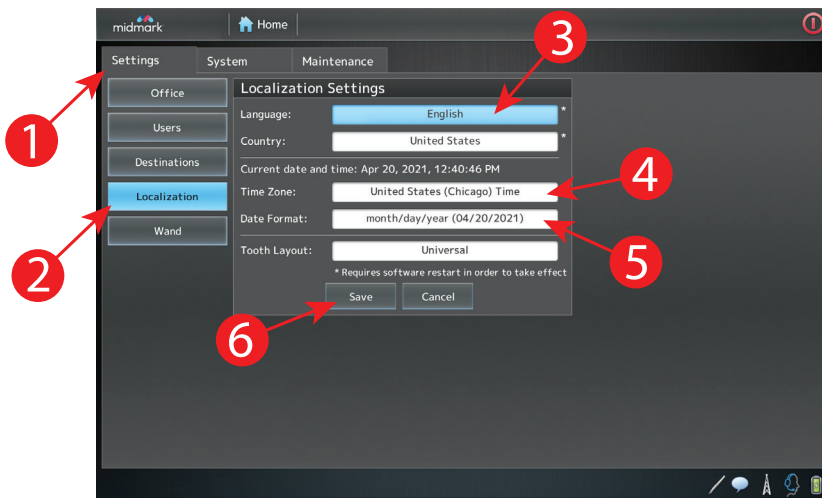
OS: 3.15.10-201.fc20.x86_64

Scanning Software: 5.0



Time Zone and Date Format

1. Press **Settings** tab.
2. Press **Localization** button.
3. Verify **Language** and **Country** (these changes require a reboot).
4. Select appropriate **Time Zone**.
5. Select appropriate **Date Format** for your region (for the USA, use month/day/year, not month-day-year).
6. Press **Save** button.



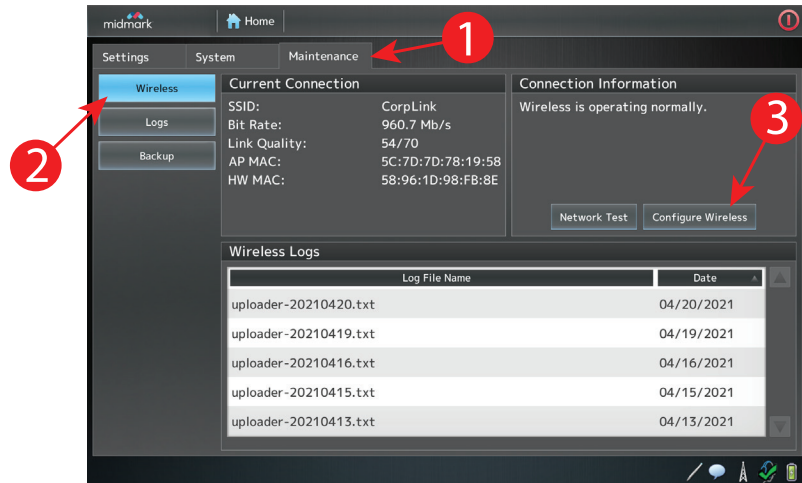
Configure Wireless Network

Although not required (there is an onscreen keyboard) you may find that attaching an external USB keyboard will facilitate the entry of the wireless password (security key). To use an external keyboard, unplug the Midmark™ True Definition Scanning Wand from the USB port on the right edge of the display, and plug in the keyboard.

NOTE:

You will need to work with your **Network Administrator** to properly configure the wireless network and assure the proper network ports are open.

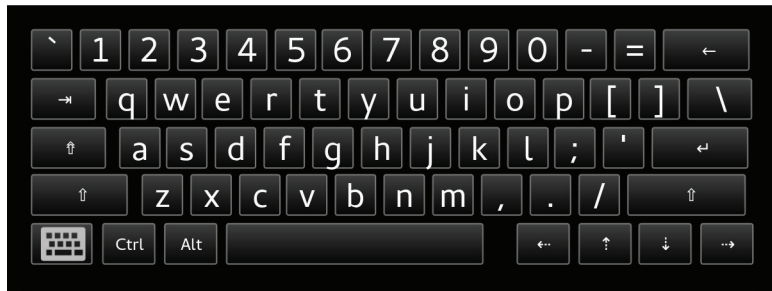
1. Press **Maintenance** Tab
2. Press **Wireless** Button



3. Press **Configure Wireless** button. A **Wireless Network Connections** window and onscreen keyboard opens.

NOTE:

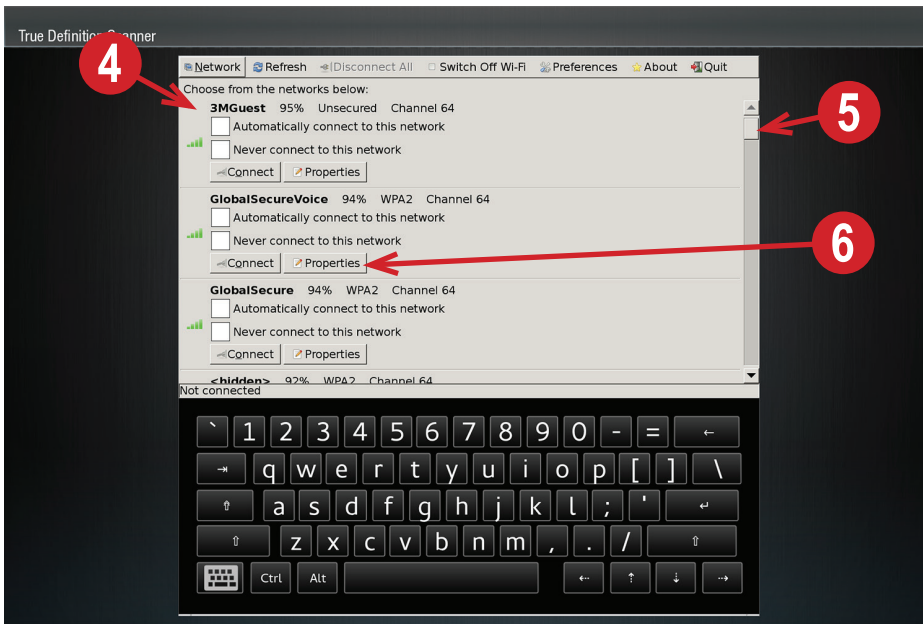
Although this **onscreen keyboard** can be used to enter most data, an external USB keyboard may still be needed in some instances. To use an external USB keyboard, unplug the wand and plug in the USB keyboard.



4. A list of wireless networks discovered will be displayed.
5. Use the scroll **bar** on the right side of the list to view additional entries.

NOTE:

If the required wireless network is not listed, search for it with the tool described in step 11.

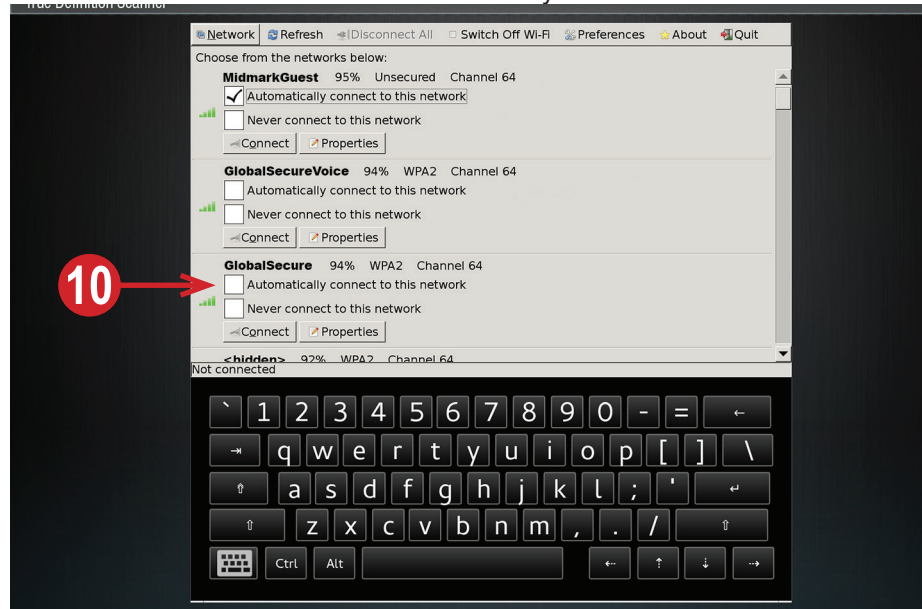


- From the list of discovered wireless networks, find the one **your Network Administrator** wants the scanner connected to, and select the **Properties** button. The following window will appear.

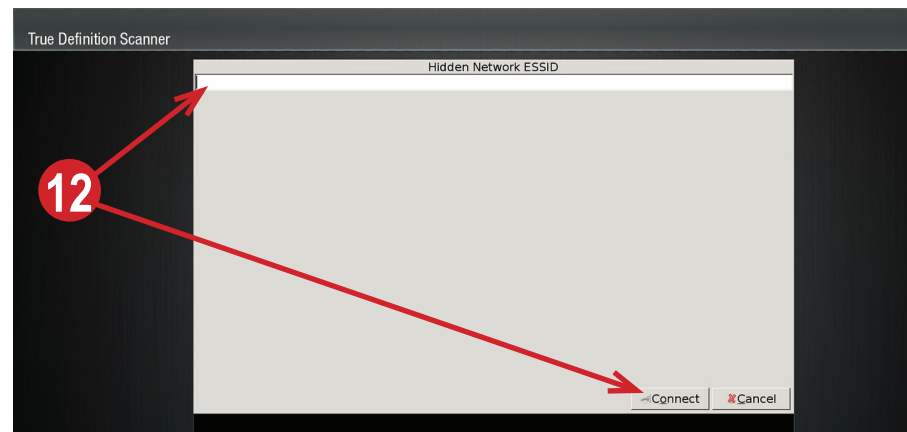
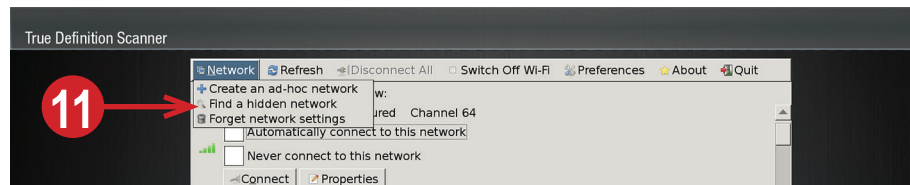


- Check the Use Encryption checkbox as shown above. WPA Personal is the default security protocol. Select the drop down menu to display the list of available network security protocols. Select the protocol that your Network Administrator tells you to use.
- If desired, check the Show checkbox to display the password as it is entered.
- When settings are complete, scroll down until the **OK** button is displayed. Select **OK** to save the set up and return to the main wireless network list.

10. Once configured, **check** the box labeled **Automatically connect to this network** on the wireless network to be used by the scanner. Make sure this box is **unchecked** on any other networks listed.

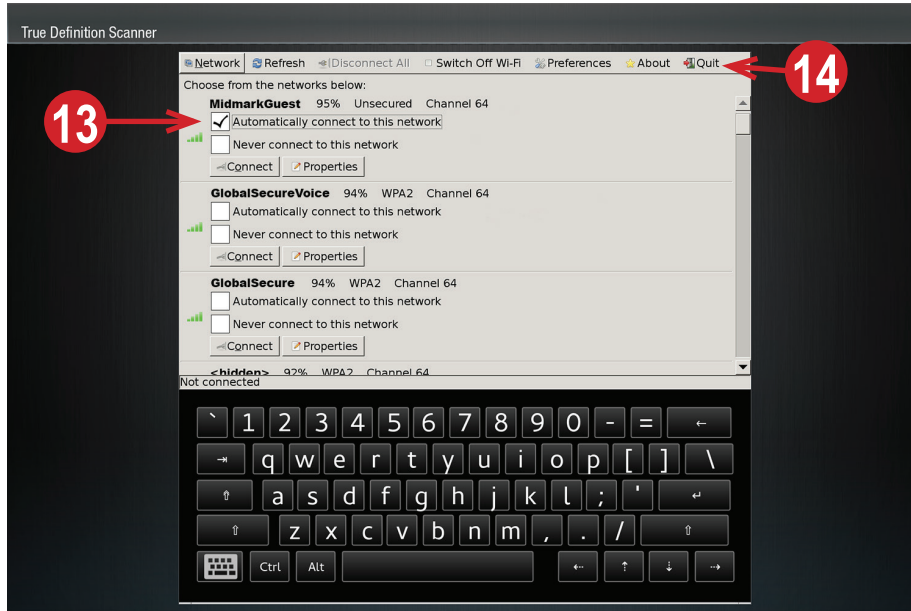


11. If the desired wireless network is not in the list, search for it with the **Find a hidden network** tool. Select the **Network** button in the top left corner and select **Find a hidden network**.



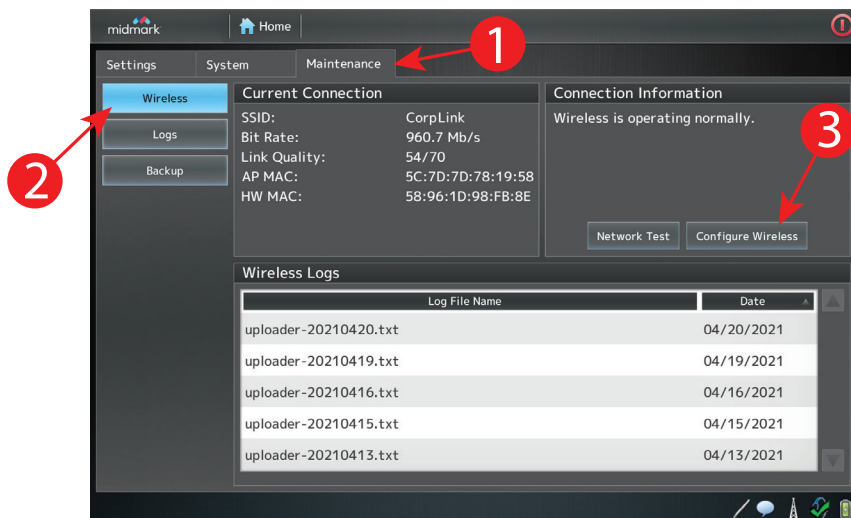
12. Enter the **Hidden Network ESSID** exactly as specified by the **Network Administrator** and then select **Connect** button.
13. Check the **Automatically connect to this network** box under your network. Make sure this box is unchecked under any other network.

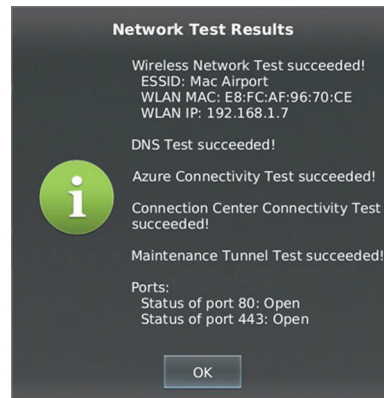
14. Close the wireless network connections window by selecting **Quit** from the menu at the top right.
15. If you attached an external USB keyboard to facilitate typing the password (security key), you can unplug it now, and plug the scanner wand back into the USB port on the right side of the display.



Network Test

1. Press **Maintenance** tab
2. Press **Wireless** button
3. Press **Network Test** button and record any failures to report to Midmark Technical Support.
4. If any failures are reported, contact Midmark Technical Support, and your **Network Administrator**, for assistance.



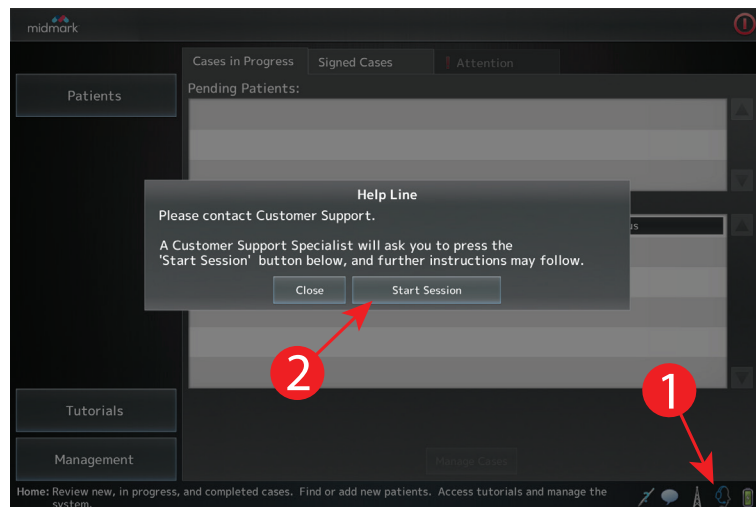


5. Press **OK** button to close the Network Test Results window, then press **Home** button at the top of the screen to return to the main window.

Set Up and Test Remote Access

Contact **Midmark Technical Support** to help set up **TeamViewer** remote access, to test the remote service access via TeamViewer, and with standard Tunnel Commands. The Help Line can be accessed from any view on the device using the Help Line Icon in the bottom right side of the display.

1. Press **Start Session** button.



2. If remote access is established, the window will report **Maintenance Connection Established**. If an error message is displayed, report it to **Midmark Technical Support**.

Install the Wand

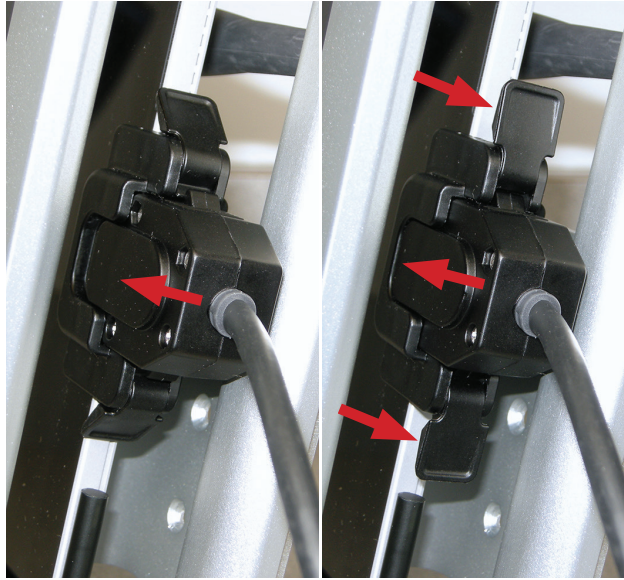
1. Unpack the wand from its box, being careful not to kink the wand cable.
2. Record the serial number for future reference. The Serial Number is located on a label attached to the wand cable



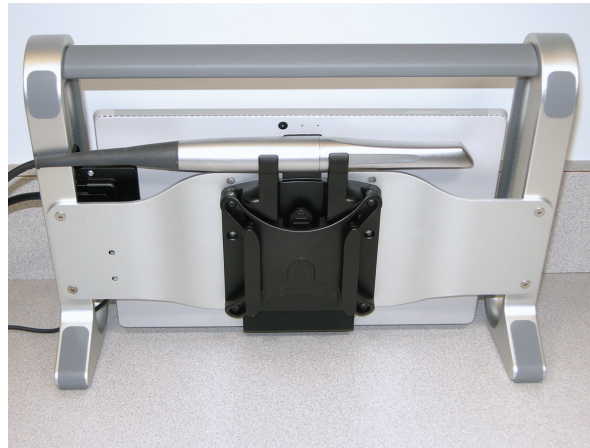
3. Plug the wand's USB 3 cable into the USB 3 port on the right edge of the tablet. Note that the USB3 port **Open Slot** is toward the **Rear** of the tablet.
4. Look at the end of the Wand USB3 cable connector (inset). Orient the **blue** solid tab toward the rear of the tablet; the open slot toward the front.



5. Insert the wand's cable connector into the USB3 port until the locking tabs click together. Do not force the connectors. They should fit easily together until the last few millimeters when the locking tabs are ready to engage. To disconnect the wand, reverse the above steps.



Wand Holders



There are two wand holders: The rear wand holder is intended to be used for storage of the wand when not in use.



The front wand holder is intended to be used for storage of the wand when it is in use.

Chairside Mill Setup Overview

The scanner can be set up to pass scanned data directly to a **qualified** Chairside Mill. A “**connection**” must be made between the scanner, and the workstation running the design software for the chairside mill.

Every chairside mill, receiving scanned data, will require a different set up connection.

The chairside connections window is accessed from the **Management > Settings** tab.

Chairside Connections Requirements

- The scanner must be attached to an **Account in Connection Center**.
- The **Account** must have a **Data Plan** assigned.
- The scanner must be rebooted in order for the **Chairside** button to appear, and the **Chairside Labs** to load.
- **Sync All** button (under Labs) has completed successfully.
- At least one of the **Chairside Labs** has been activated (**Management > Settings > Labs**).

For more information, refer to Management Screens > Chairside Connections.


Work with the Midmark Technical Support to Complete the Installation

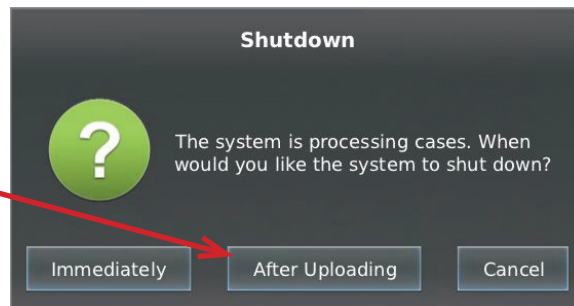
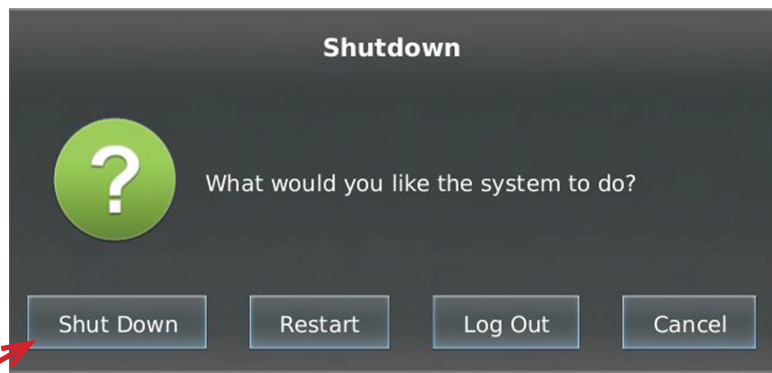
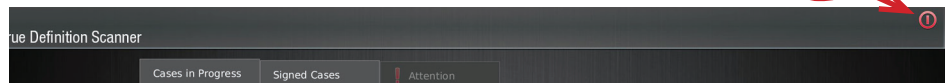
Once the network is set up and remote access is working, Midmark Technical Support will work with you to:

- Verify the wand functionality by performing some scanning with a dental model from your office.
- Update scanner software if needed.
- Verify scanner and wand serial numbers.

Shut Down

Once the **Midmark Technical Support** person has completed their required tests and given you the OK to finalize the install, you may shut down the system.

1. Press the **RED** Shutdown/Logout button  in the upper right corner of the screen.
2. Select **Shutdown**.
3. Select **After Uploading**, and leave the system plugged in.
The system will upload and download information, and turn off when completed.

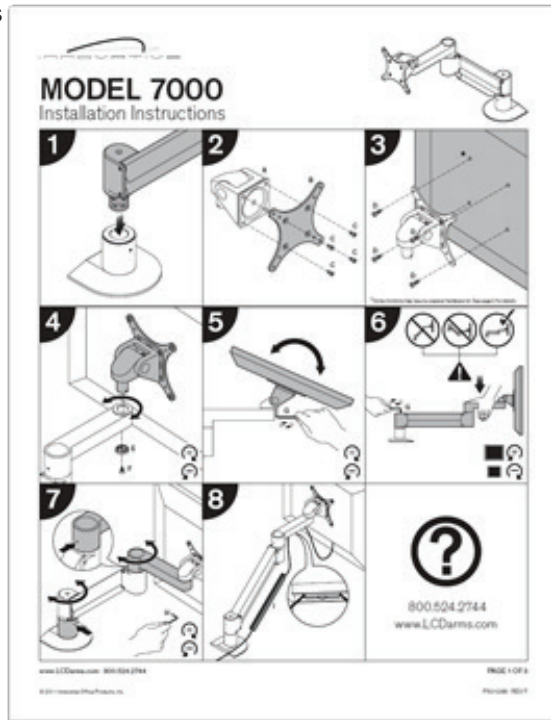


4. Refer to Chapter 1 for more information on navigating the software.

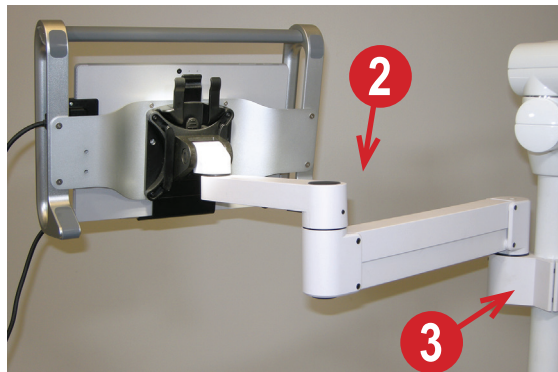
Optional Mounting Accessories

The following optional mounting accessories are available.
Refer to the installation instructions for any optional accessories used.

1. The Model 7000 Series Adjustable Arm and mounting hardware.



2. Model 7000 Adjustable Arm shown mounted to a pole.
3. Also pictured: Model 9170 Vertical Pole Mount.



WARNING

Verify location of electrical conductors and utility pipes (e.g., gas or water pipes) in supporting wall structure before making wall surface penetrations during installation of wall mount systems.

CAUTION

To reduce the risks associated with impact from heavy objects which, if not avoided, could result in minor or moderate injury:

Verify load capacity of supporting structure before installation.

Use the correct mounting hardware (e.g., size and grade) for your application.

CAUTION

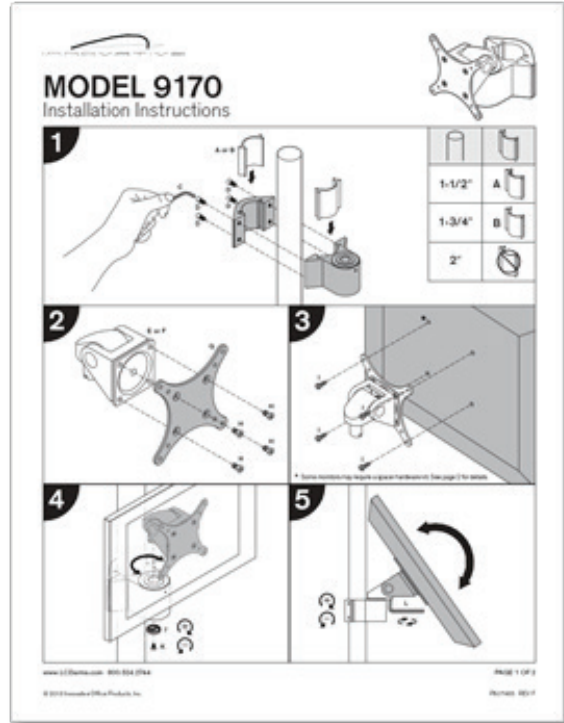
To reduce the risks associated with impact from heavy objects which, if not avoided, could result in minor or moderate injury:

Do not mount the system so the computer carrier is located above the patient

- 4. Model 9170 Vertical Pole Mount instructions for mounting to an existing pole - Adjusts to 3 pole diameters:

1½ inch
1¾ inch
2 inch.

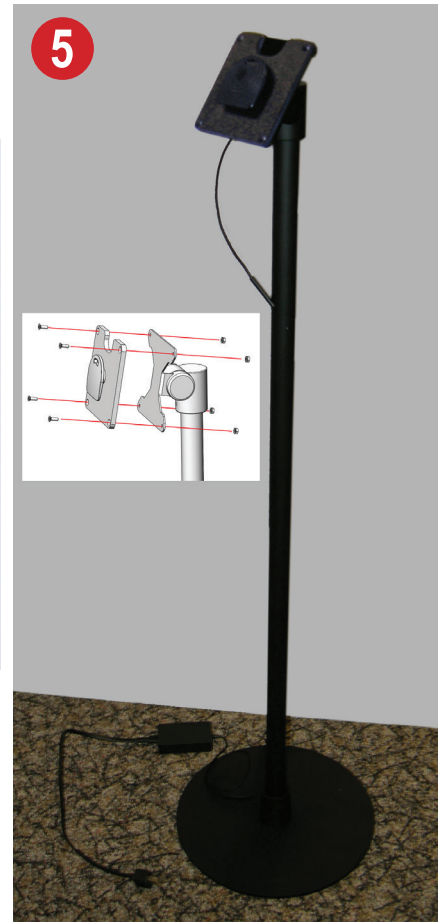
Can be used with the Model 7000 Adjustable Arm.



- 5. The Model 9231 Floor Stand requires the Midmark custom VESA Mounting Quick Release Plate be attached first (see inset image).

The power cable can be run through the stand as shown in image 5.

- 6. Closeup view of attached plate.



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