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InnerView® System

USER MANUAL

01-1008, Rev. A

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1. Overview

The InnerView® System is an electromagnetically driven percussion system designed for dental professionals to collect percussion data of intraoral sites, such as teeth and/or implants. The device utilizes non-destructive quantitative percussion diagnostics (QPD), a mechanics-based methodology that tests the damping capacity of the tooth or implant by gently percussing the buccal surface.

The InnerView® System consists of a handheld wireless handpiece, a base station and disposable tips. The base station connects to the user's PC via the USB connection. The system is software operated.

The handpiece transfers the collected percussion response data wirelessly to the base station, which forwards the data to the PC via USB. The handpiece and base station are automatically paired when the handpiece is placed int the base station. The base station also acts as the handpiece battery charger when the handpiece is docked. The system requires a fresh disposable tip to be attached to the handpiece prior to each new procedure.

The InnerView® software analyzes the percussion data collected by the handpiece and displays the results for each tested site as an energy return graph (ERG) and a mobility value through the User Interface. The ERG is a graphical representation of how the site responds to percussion and is used as raw data for calculations of mobility values. This data can aid clinicians in diagnosis and treatment planning and early preventive treatment.

The device is intended for professional use on dental patients. Procedures must be performed only by trained dental professionals.

No modification of this device is allowed.

2. Labels and Symbols

Symbols used in this User Manual, on the product labels and the packaging:

Symbol	Description	
	Manufacturer	
	Catalogue/Part Number	
	Unique Device Identifier (UDI)	
	Lot Number	
	Non-Sterile	
	WEEE Waste Electrical and Electronic Equipment. Do Not Throw In Trash. Dispose of as regulated.	
	Type B Applied Part	
	Non-ionizing electromagnetic radiation	
	Temperature Limitation	
	Single Use Only. Do not re-use.	
	Keep Dry	
	Humidity Limitation	
	Atmospheric Pressure Limitation	
	Caution	
	Refer to User Manual	
	Consult instructions for use	
Rx Only	Caution: US Federal Law restricts this device to sale by or on the order of a dentist or other licensed dental practitioner	
FCC ID	Base Station INV-2000 FCC ID: 2AXNK-INV2000 IC: 33686-INV2000	Handpiece INV-1000 FCC ID: 2AXNK-INV1000 IC: 33686-INV1000

3. General Safety Information

Carefully read these instructions before installing and operating the InnerView® System. Only licensed dental professionals that have received proper training for correct use should operate this device.

The device is intended for use by dental professionals, such as dentists, dental assistants, and dental hygienists to take mobility measurements. The interpretation of the output results, clinical diagnosis, treatment decisions, and the urgency of follow-up visits are the responsibility of the dentist only.

Prescription Statement:

Caution: US Federal Law restricts this device to sale by or on the order of a dentist or other licensed dental practitioner.

3.1. Indications for Use

The InnerView® System is intended to precisely measure the damping characteristics of the periodontium and its associated fixed structures (teeth and/or implants). It can provide data to quantify tooth and/or implant mobility.

3.2. Contraindications

Patient risk must always be considered before using the device. Clinicians must understand the patient's medical conditions, use clinical judgment, and exercise caution for medical conditions, which may contraindicate the use of the device.

The InnerView® System should not be used on patients with the following conditions:

- Acute periapical periodontitis
- Acute and chronic trauma
- Orthodontic patients with traditional braces

3.3. Adverse Events and Side Effects

There are no known adverse reactions or other side effects associated with the use of the device.

Caution: If any serious incident or patient injury has occurred in relation to this device, report immediately to Perimetrics' customer service at 1 (213) 712-5925.

3.4. Malfunction or Damage

If the device fails to turn on, pair with the base station, or start tapping, stop using it immediately. Refer to Troubleshooting Guide in Section 16 or contact Perimetrics' customer service.

Caution: No modification of this device is allowed.

- Do not use the device in any manner other than as described in this User Manual.
- Do not modify this device at any time.
- Do not use this device for any purpose other than its intended use and indications. If so, Perimetrics is not responsible for any injuries, incorrect diagnosis, or damage caused by this.
- Use of accessories not authorized for use in connection with this device may cause malfunction and compromise patient safety.
- Don't use the device if the USB cable is damaged, worn or loose.
- Never use this device in the presence of flammable anesthetic agents mixed with air or pure oxygen.
- Do not attempt to open the handpiece housing. Do not repair, modify, or disassemble the device as this may damage the system and make it inoperable.
- The device is not waterproof. Do not submerge in water or any other liquids. Do not spray the handpiece or base station with disinfectants or cleaning solutions. Fluid ingress will damage internal parts of the system and make it inoperable. For cleaning and disinfection, follow instructions provided in section 9 - Cleaning and Disinfection.
- The handpiece must be used with specifically designed disposable tips intended for one single patient only. Always inspect the tips prior to use to ensure that the film membrane at the tip opening is intact. Do not use if any tear, damage, deformation is observed as it may lead to contamination of the tapping mechanism. Replace with a new tip.
- The handpiece must be used with disposable protective sleeves to prevent handpiece contamination. Always inspect the sleeve prior to use. Replace any damaged or broken sleeve. See section 9 for details.
- Routinely inspect the device for any cracks or damage. Do not use the handpiece if any sign of damage or corrosion on the tapping rod is noticed as it may cause system malfunctioning and incorrect measurements.
- Take care when moving the InnerView® System between operatories. Do not throw or drop it. The device may break down and malfunction.

3.5. Operating Environment

The InnerView® System is suitable for use in its intended environment [professional healthcare (dental) facility] other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

4. Description of InnerView® System

4.1. System Components

4.1.1 InnerView® Handpiece

Figure 1: INV-1000 Handpiece

4.1.2 InnerView® Base Station

Figure 2: INV-2000 Base Station

4.1.3 InnerView® Disposable Tip

Figure 3: INV-3000 Disposable Tip

4.2. InnerView® Software

The InnerView® System is operated through a software application run on the user's PC. The application enables users to take measurements, which provides a user interface for the clinician to set up the device, collect and review the collected data. The software coordinates all system activities including storing and management of patient appointments and measurements, it allows for automatic software/firmware updates and other system data requirements.

4.2.1 Installing the InnerView® Software

Follow the link provided by Perimetrics to securely install the InnerView® software application on your PC. The software must be installed on the PC computer to which the base station is connected via USB. The computer must run Windows 10 or later version. The computer must have up-to-date anti-malware/anti-virus software already installed to minimize potential cybersecurity risks.
Refer to Section 11 for information on secure software updates.

4.3. Connected Components

The InnerView® handpiece may only be used with the InnerView® base station due to the unique communication protocol allowing the two components to link wirelessly during use. LED light indicators on the handpiece and base station serve as visual aids signaling the status of the wireless connection:

Base station - **blinking green**- pairing is established
Handpiece- **blinking red**- pairing not established

The handpiece and base station are reusable system components and must be cleaned and disinfected between patients. Refer to Section 9 for complete instructions on cleaning and disinfection.

Caution: The InnerView® handpiece must be used only with the InnerView® disposable tips supplied by Perimetrics. Using different tips will render the device inoperable.

4.4. Power Supply and Battery

The handpiece is equipped with an internal built-in battery which is charged when the handpiece is placed in the base station. The base station is powered via a USB cable connected to a PC.
The handpiece should always be stored in the base station when not in use to ensure proper charging.

Caution: Do not use any other power supply or charging equipment as they will damage the device. Never attempt to open the handpiece to remove the internal battery. Contact Perimetrics with any charging and/or assumed battery related issues.

4.5 Disposable Tips

The InnerView® disposable tips are exclusively designed for use with the InnerView® handpiece. Each tip contains an embedded security chip (Figure 5) that communicates with the handpiece once the tip is attached. The software verifies the tip's authenticity, registers it as new and valid, and assigns it to a specific patient for 1-hour of use. After 1-hour of use, the tip is automatically disabled and must be discarded. This feature prevents reuse and reduces the risk of cross- contamination between patients.

Figure 5: InnerView Disposable Tip

The tips are **non-sterile, single-use only** and **must** be discarded after completion of the measurements on one patient.

Caution: Always wipe the tip with alcohol prior to use. Discard the tip after use.

Caution: The tip opening is sealed with a film membrane. **Always inspect each tip prior to use to ensure the film membrane is intact**. DO NOT USE damaged tips.

The InnerView® software prompts the user to attach a new, unused tip to the handpiece prior to each new procedure as shown below (Figure 6).

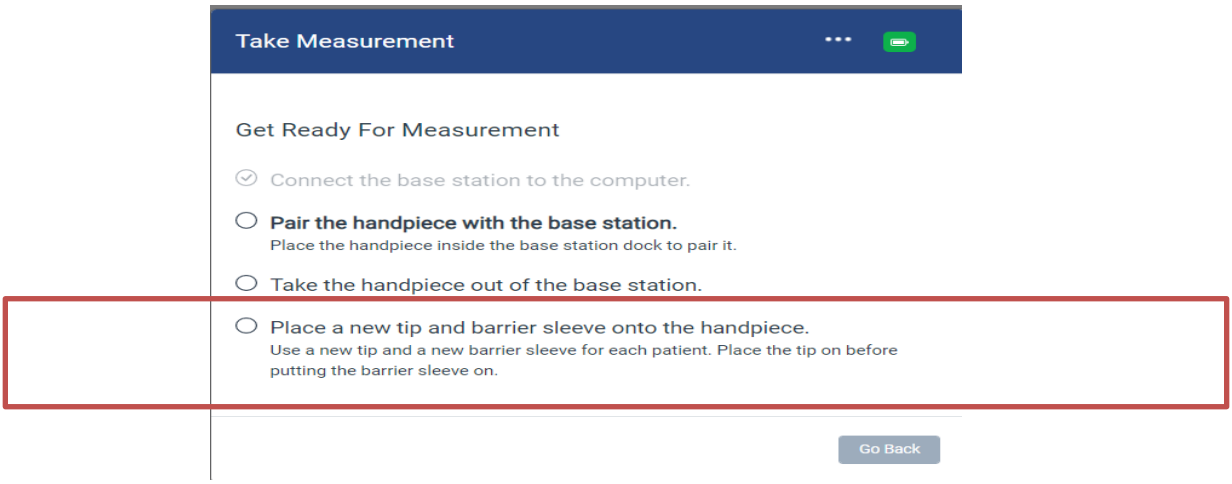


Figure 6: Attach Tip message

When a new, unused tip is attached, the handpiece will illuminate **green** to indicate it is ready for use (Figure 7a). If the handpiece illuminates **red**, it indicates that a used tip was attached, and the system will not function (Figure 7b).

Figure 7a: Green Color – new tip attached

Figure 7b: Red Color - tip is not new

Once the tip is attached, the "Place a new tip onto the handpiece" message will disappear, and the device is ready for use on the patient, as shown in Figure 8.

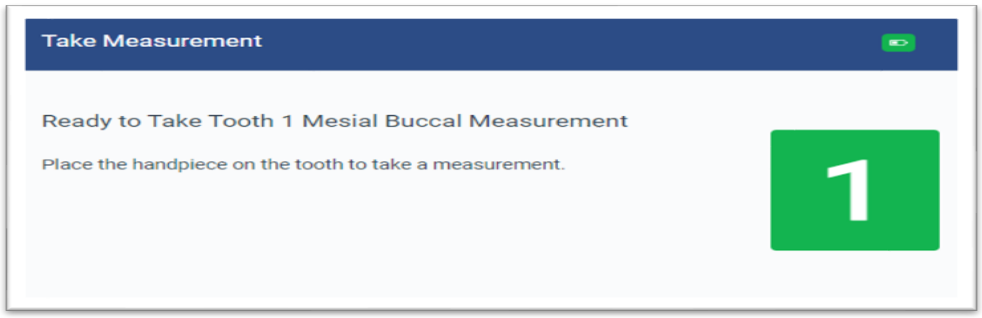
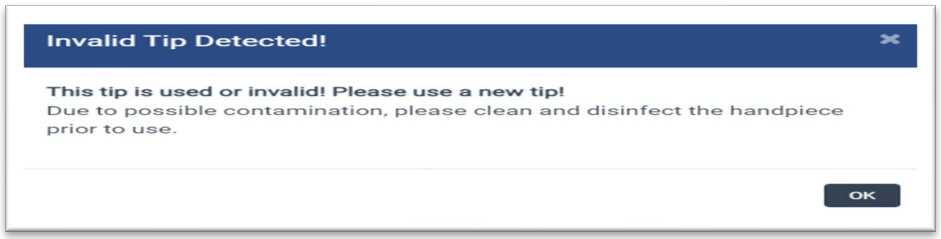


Figure 8: Begin measurements on the patient.

Once the tip has been used, it must be removed for disposal and cannot be used on another patient. When the system detects that a "used" tip is inadvertently installed, a message will appear indicating the tip was previously used and the handpiece will not function until a new, unused tip is installed. (Figure 9).

Figure 9: Indication of previously used tip



Caution: If a used tip is inadvertently placed on the handpiece, immediately clean and disinfect the handpiece before inserting a new tip. Refer to Section 9 for cleaning and disinfection steps.

5. Handpiece Battery Charge

The InnerView® handpiece is powered by a rechargeable lithium polymer battery. To charge the handpiece, insert it into the base station.

> **Caution:** Always remove both the barrier sleeve and the tip before inserting the handpiece into the base station.

The base station **bright blue** light ring indicates the handpiece is charging (Figure 10).

Figure 10- Handpiece Charging

It takes up to 4 hours to charge the battery from completely discharged to fully charged. When the handpiece is fully charged, a **green** indicator is displayed on the screen (Figure 11c).

Keep the handpiece stored in the base station to ensure a consistent charge and to protect the longevity of the battery. If a **yellow** low charge (Figure 11b) or **red** insufficiently charged **(**Figure 11a**)** indicator is displayed on the screen, place the handpiece in the base station as soon as possible.

Contact Perimetrics' customer service for any charging problems.

Only connect the base station to a computer complying with international standards (i.e., IEC 60950-1 or IEC 62368-1) and with the USB connection requirement for the standard, 5VDC ES1 (Class 1 electrical energy source) or SELV (Safety Extra Low Voltage). The power equipment shall not exceed PS2 (Class 2 power source) or LPS (Limited Power Source).

6. Battery Charge Indicators

The battery charge status is displayed at the top of the InnerView® application screen, indicated by red, yellow, or green icons (Figures 11a,b,c):

Red - insufficiently charged

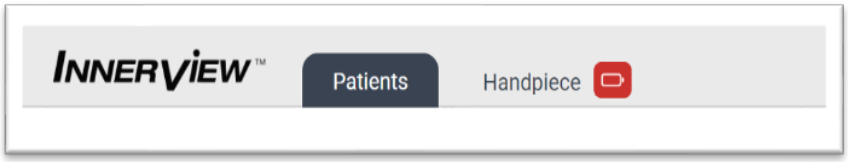


Figure 11a: Red indicates that the handpiece is insufficiently charged

Yellow- low charge

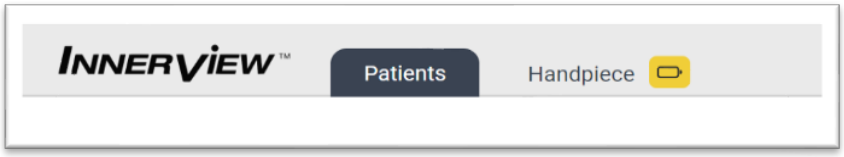


Figure 11b: Yellow indicates partial, weakening charge

Green – fully charged

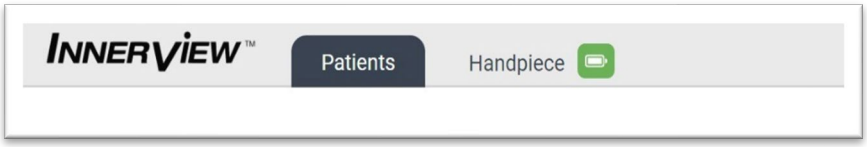


Figure 11c: Green indicates full charge

Caution: Always keep the handpiece docked in the base station to ensure a consistent charge and protect the longevity of the battery. When the yellow light indicator is on, indicating low charge, place the handpiece into the base station as soon as possible.

7. System Light Indicators

The InnerView® System is equipped with LED light indicators to signal the status of the device, its readiness for use, use errors, or lost communication. For troubleshooting refer to Section 16.

7.1. InnerView® Handpiece Light Indicators

Color				Meaning
Red	Green	Amber	State	
OFF	Blinking	OFF	Tip attached	Handpiece paired and new unused tip attached, ready to use
Blinking	OFF	OFF	Tip attached	System detected that used tip was attached to handpiece
Solid	OFF	OFF	Patient test, no pressure applied	Inclination beyond usable range/ level out handpiece
Solid	OFF	OFF	Patient test, pressure applied	Too much pressure applied, decrease pressure to take measurement
OFF	OFF	Solid	Patient test, pressure applied	High, but acceptable pressure applied, taking measurement
OFF	Solid	OFF	Patient test, pressure applied	Low but acceptable pressure applied, taking measurement
OFF	OFF	OFF	Patient test, pressure applied	Not enough pressure applied, increase pressure to take measurement
OFF	Blinking	OFF	Docked	Handpiece OTA update in process

7.2. InnerView® Base Station Light Indicators

Color			Meaning
Red	Green	Blue	
Blinking	OFF	OFF	Cleaning button pressed while handpiece is docked
OFF	Blinking	OFF	Handpiece successfully paired with base station
OFF	OFF	Solid - Dim	No handpiece docked
OFF	OFF	Solid -Bright	Handpiece docked and charging
OFF	OFF	Blinking	Base Station OTA firmware updated in progress

8. Technical Specifications

8.1. InnerView Handpiece

Specification	Description
Tapping force	Less than 36 Newtons
Handpiece taps	4 times per measurement at 3.3 µs increments
Weight of tapping rod assembly	Approximately 9 g
Weight of handpiece	100 g
Weight of base station	430 g
Housing IP class	IPX0
Unit of measure	Mobility
Scale	0- 100

8.2. InnerView Base Station

Specification	Description
Input Voltage	5V
Housing IP class	IPX0
Protection class	II

9. Cleaning and Disinfection

The handpiece and base station are non-sterile and reusable components. During clinical use, the handpiece, although not in direct contact with the patient, may be exposed to contamination from contact with soiled hands of the clinician or accidental splatter of body fluids because of proximity to the patient. Therefore, **the handpiece and base station must be cleaned and disinfected following each patient use, and before placing the handpiece back in the base station to avoid cross-contamination**. **They cannot be autoclaved**; doing so will make them unusable. Do not immerse any components of this product in any liquids and/or cleaning /disinfecting solutions. Do not spray the device with any liquids.

Caution: The handpiece **must** be used with a commercially available, FDA-cleared protective sleeve to provide extra protection against contamination. Perimetrics recommends the use of FDA-cleared **Dentsply Sirona Disposa-Shield®** (Reorder number: A88007). For details on how to prepare and apply the barrier sleeve refer to Section 9.1, below. Make sure the barrier sleeve is trimmed and placed on the handpiece according to instructions to ensure proper coverage.

The disposable tips are for **single use** only and must be discarded after one use. **The tips are non-sterile** when sold and should be thoroughly wiped with alcohol prior to use to reduce the risk of becoming contaminated through routine handling. **The tips are not autoclavable and should never be reused.**

Caution: Visually inspect each tip prior to use for any damage to the film membrane. **DO NOT USE** if the tip or film membrane appears to be damaged/torn. Broken film membrane may lead to contamination of the tapping mechanism. **If breakage is noticed during use, stop the procedure, immediately clean, and disinfect the handpiece and use a new tip.**

The cleaning and disinfection steps outlined below were created following US FDA recommendations and CDC guidelines. These methods have been validated to ensure that soil and contaminants are effectively removed, and the device is free of viable microorganisms. Adherence to the recommended steps is essential for maintaining patient safety and preventing transmission of infectious agents during use. Do not use other alternative methods and/or cleaning solutions as they may not provide inadequate cleaning and disinfection and present a risk to the health of the next patient.

Cleaning:

The cleaning process is intended to physically remove soil and other contaminates from the surface of the handpiece and base station.

Caution: Use only the MANUAL cleaning process described below. Other cleaning methods should be avoided since they may damage the components inside the handpiece. Cleaning should be performed **immediately after each patient use**, and **prior to disinfection** to prevent drying of the soil and contaminants on the device. Any delays may create conditions favorable to microbial growth which may be challenging to subsequent cleaning and disinfection steps.

Wear protective gloves when handling the contaminated system components. Follow standard practices and precautions for personal protection.

1. After use, carefully remove the barrier sleeve, and disposable tip and dispose of in a biohazard medical waste sharp container.
2. Promptly perform the cleaning of the handpiece and base station wearing new/clean gloves. Follow the steps outlined the table below:

Component	Step	Cleaning Instructions
Handpiece	1	Orient the handpiece with the tapping rod pointing down.  Depress the button on base station to partially extend the tapping rod out from the handpiece.
	2	Use CaviWipes to remove gross soil from the handpiece and the tapping rod. Use fresh CaviWipes to wipe the metal parts of the handpiece for 2 minutes. Use additional CaviWipes as needed to maintain the 2-minute contact time. Wipe the remaining portion of the handpiece for an extra 1 minute. Make sure that CaviWipe solution comes into contact with all seams and recessed areas.
	3	**Visually inspect the handpiece for any residual soil. If any residual soil is still present, repeat step 2 above until all residual soil is removed**.
	4	Allow the handpiece to air dry prior to proceeding to disinfection.
Base Station	5	Using a fresh CaviWipe, wipe all external surfaces of the base station for 1 minute to remove any visible debris. Pay particular attention to the “Cleaning Button”, contact pins, and the docking recess.
	6	Saturate a cotton-tipped swab (or equivalent) with CaviCide and scrub the contact pins and handpiece docking recess for a total of 3 minutes. Rotate the swab and repeat with fresh swabs as necessary.
	7	Using a fresh dry wipe (lint-free), remove the CaviWipes residue. For the handpiece docking recess, use a dry cotton-tipped swab. Additional dry wipes and swabs may be used to ensure the residue has been removed**.**
	8	**Visually inspect the base station for any residual soil to ensure all surfaces are clean and free of any debris.** Pay particular attention to the “Cleaning Button”, contact pins, and handpiece docking recess. **If any residual soil is present, repeat the cleaning steps beginning with step 5 until all residual soil is removed.**

Disinfection:

The disinfection procedure is intended to destroy any present microorganisms. **Always perform this procedure immediately after cleaning and prior to docking the handpiece in the base station.**

Component	Step	Disinfection Instruction
Handpiece	1	Orient the handpiece with the tapping rod pointing down.  Depress the button on base station to extend the tapping rod out from handpiece.
	2	Using a fresh CaviWipe, thoroughly wipe the rod and surrounding area including contact pins and light pipes using an aggressive rotating wipe technique and continue down the length of the handpiece, ensuring the disinfectant reaches all seams, recesses, and articulating areas. Allow disinfected surfaces to remain visibly wet for **a minimum of 3 minutes**, per manufacturer's instructions. Additional CaviWipes may be used to ensure a minimum 3-minute contact time.
	3	Using a fresh dry wipe (lint-free), remove the CaviWipes residue. Additional dry wipes may be used to ensure the residue has been removed.
Base Station	4	Using a fresh CaviWipe, wipe all external surfaces ensuring the disinfectant reaches recessed areas. Allow disinfected surfaces to remain visibly wet for a minimum of 3 minutes, per manufacturer's recommendation. Pay particular attention to the "Cleaning Button", contact pins, and handpiece docking recess.
	5	Saturate a cotton-tipped swab (or equivalent) with CaviCide and scrub the contact pins and handpiece docking recess. Rotate the swab and repeat with fresh swabs as necessary. Allow disinfected surface to remain visibly wet for a minimum of 3 minutes, per manufacturer's recommendation. Additional fresh swabs may be used to ensure a minimum 3-minute contact time.
	6	Using a fresh dry wipe (lint-free), remove the CaviWipes residue. For the handpiece docking recess, use a dry cotton-tipped swab. Additional dry wipes and swabs may be used to ensure the residue has been removed.

Caution: Always inspect the handpiece prior to use. Discontinue use of the handpiece if any of the following is noticed:

- Corrosion of the metal pins or tapping rod
- Presence of cracks or chips on the handpiece or any other signs of wear
- Colored light indicators do not work as designed.

Use of a damaged or worn-out device may compromise its clinical performance and result in false reading.

9.1 Barrier Sleeve

Caution: The InnerView® handpiece **must be used** with commercially available FDA-cleared barrier sleeves, such as Dentsply Sirona Disposa-Shield® (Reorder# A88007). Always inspect the sleeve prior to use. **DO NOT USE if any damage or loss of coverage integrity is noticed**. Replace it with a new sleeve.

Follow the instructions and illustrations below to prepare the barrier sleeve and place it on the handpiece.

Step1:

Trim a new barrier sleeve to allow the tip to extend through the barrier sleeve (Figure 12).

Step 2:

Place the trimmed barrier sleeve over the handpiece with attached tip. Ensure the sleeve **does not cover the tip opening** / film membrane. (Figure 12).

Figure 4: Placement of Barrier Sleeve over Handpiece with attached Tip

Step 3:

After each use, carefully remove the barrier sleeve and dispose of it in a biohazard medical waste sharp container. Proceed to cleaning and disinfection per Section 9, above.

10. Patient Set Up and Data Management

10.1. Practice Configuration

The first time the InnerView® software is run, a "Practice Configuration" dialog box will appear. Enter the Practice ID assigned to your practice by Perimetrics and then click "Save" (Figure 13).

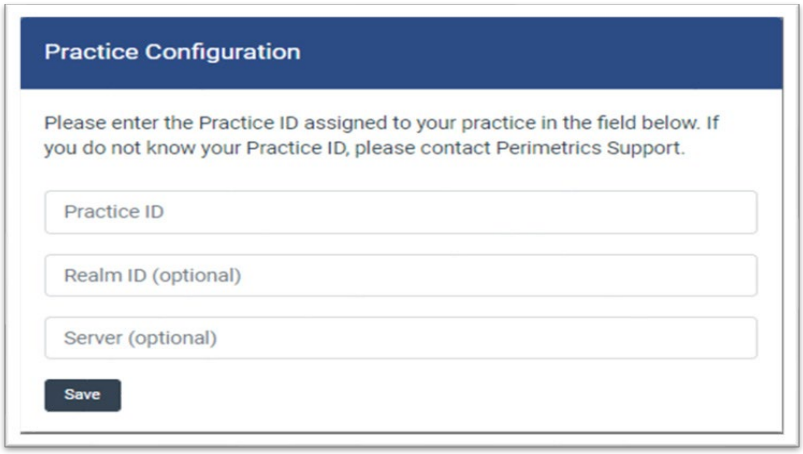


Figure 13. "Practice Configuration" dialog box

10.2. Logging In

Once the Practice ID has been set, all subsequent launches of the InnerView® software will result in a dialog box prompting you to log in (Figure 14).

If the Practice ID needs to be changed, click the "**X**" in the top right corner of the "**Login**" dialog box. You will automatically be taken back to "**Practice Configuration**" dialog box to update your Practice ID.

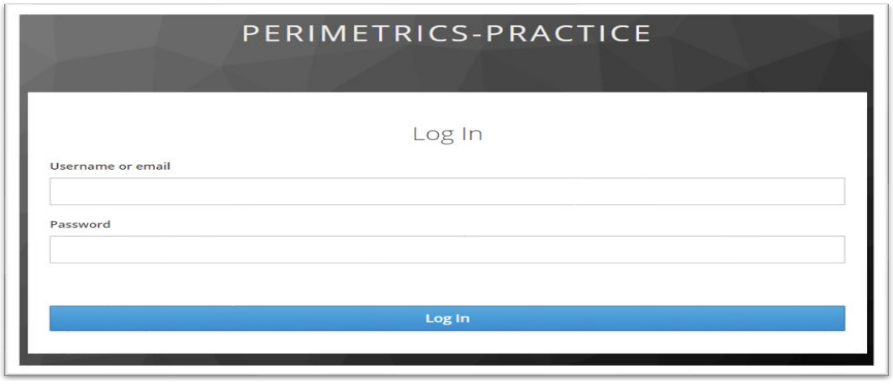


*Figure 5: **"Log In"** dialog box.*

Each user in your practice is required to have a unique username and password. To log in, enter your username and password and click "**Log In**".

10.3 Working with Patient Records

Data captured by the InnerView® System is organized by patients. After logging in the "**Patients**" tab will appear which provides access to patient records (Figure 15).

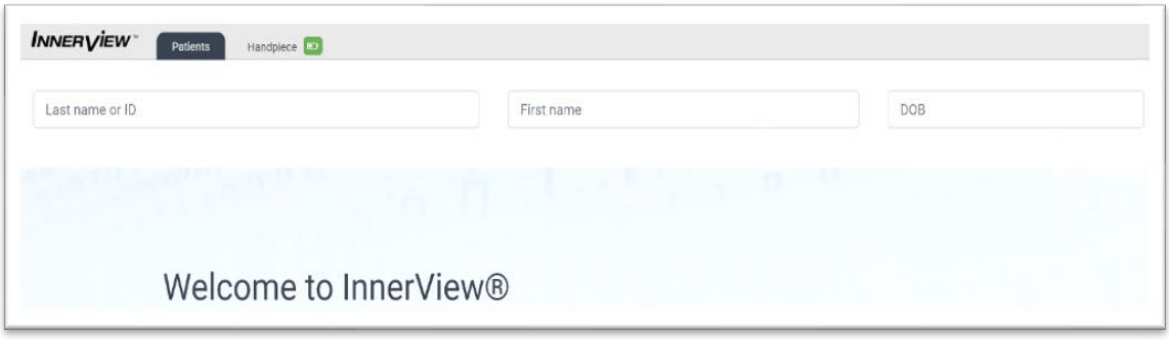


*Figure 6: **"Patients"** tab*

From this screen either a new patient record can be created, or an existing patient record can be opened. Enter the patient's last name, first name, and date of birth in the fields provided. If one or more matching patients are found, click the "Select This Patient" button next to the matching patient (Figure 16).

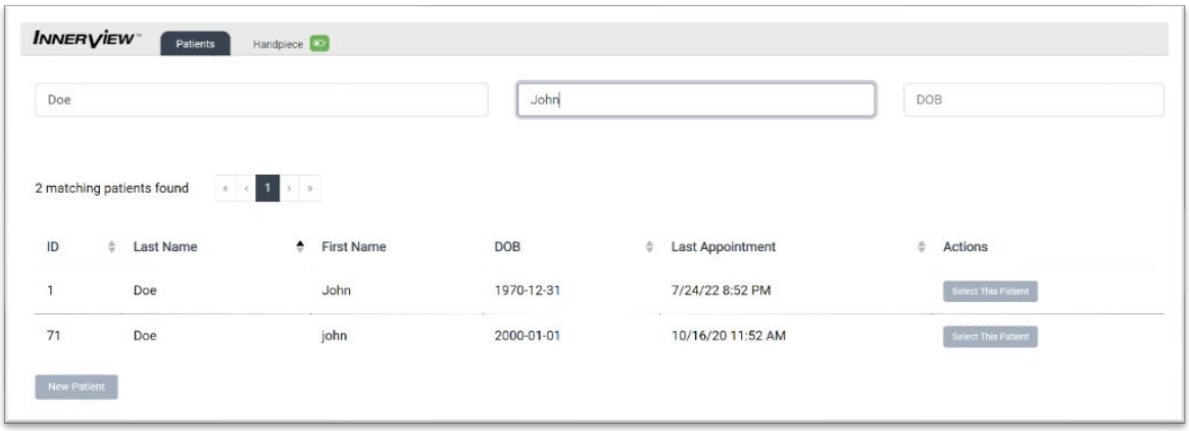


*Figure 7: **"Select This Patient"** button*

If no matching patient is found, click "**New Patient**" button at the bottom of the window.

10.4 Measuring Protocol

After a patient record is opened, the "**Measure**" tab will appear (Figure 17).

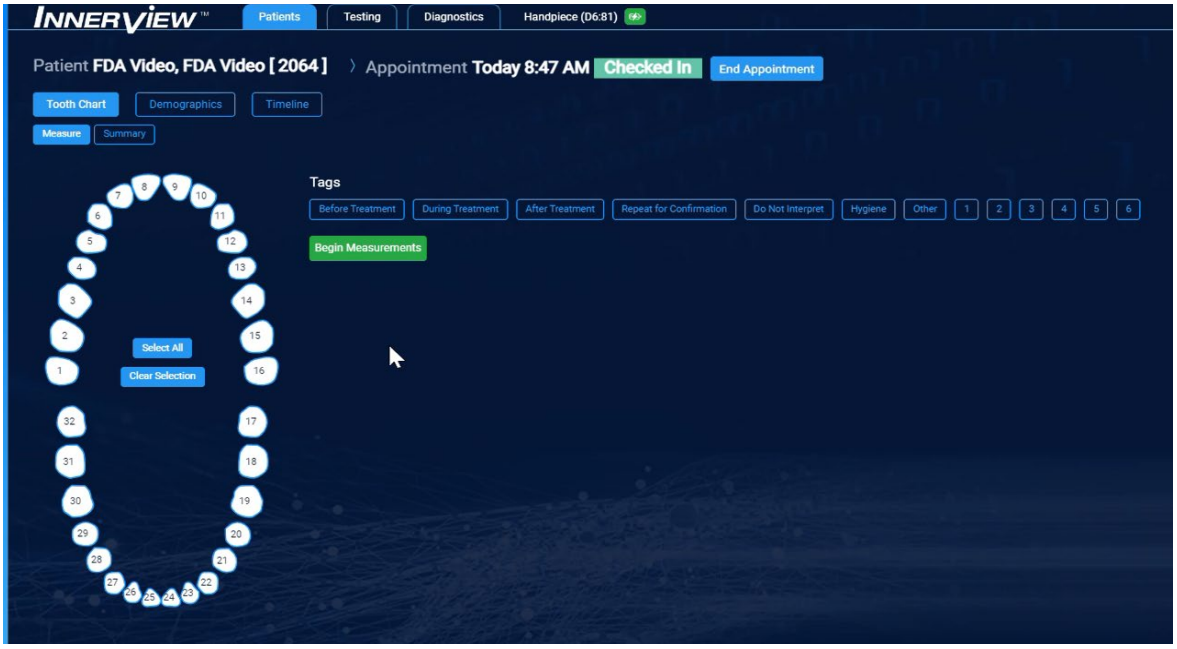


*Figure 8: **"Measure"** tab*

Prior to taking an InnerView measurement, remove the clean and disinfected handpiece from the base station. Place a new disposable tip and a new trimmed barrier sleeve onto the handpiece.

Measurements taken on teeth and implants follow the same protocol outlined below:

1. Select the teeth or implants to measure on the diagram located on the left side of the screen (Figure 17). You have the option of selecting all or individual sites.
2. (Optional) Select one or more of the tag buttons (see "**Tags**" section in the middle of Figure 17) to identify the reason for taking the measurement). The tag buttons are provided as a convenience only and do not impact the measurement itself.
3. Click on "**Begin Measurements**". (If there is not yet an active appointment for this patient, the button will be labeled "**Check in and Begin Measurements**".)
4. Position the tip against the buccal or labial edge of the tooth/implant to be measured. The occlusal tab at the end of the tip will stabilize the position of the handpiece against the labial surface of the site to ensure consistent positioning. For molars/implants, position the handpiece so that the site is tapped on the mesial buccal cusp. For bicuspids and anterior teeth/implants, position the tip to tap the center of the labial surface. Refer to Section 8 for tip placement guidance.

5. Follow the prompts to complete the measurement of all selected teeth/implants. The system will auto-advance from one measurement to the next by site number, with both audio and visual prompts. If poor reading is noted, retake the measurement on that tooth/implant, until an accurate reading is determined.
6. At the end of the measurement, the "Summary" tab will appear (Figure 18) displaying the following information for each measured site:
    - **Energy Return Graph (ERG)**- a line graph representing percussion data generated by the handpiece during measurements. This graph is utilized for calculating mobility values and is displayed for illustration purposes only.
    - **Mobility** – a numerical value that represents tooth/implant mobility

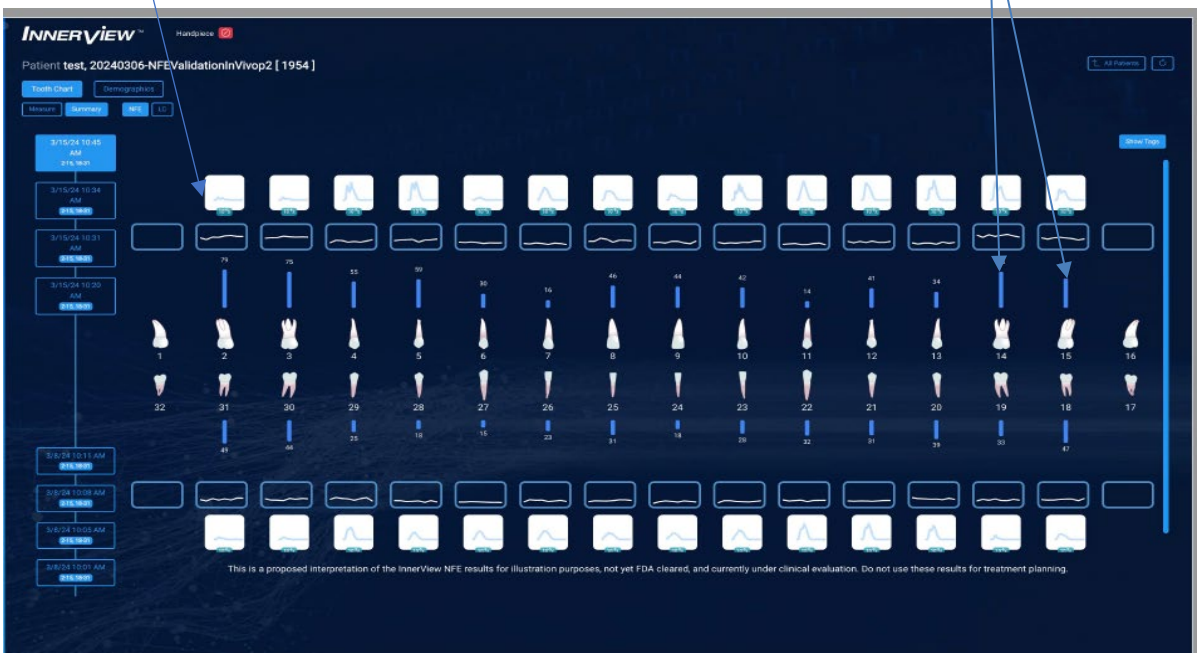


*Figure 9: **"Summary"** tab showing loss coefficient and normal fit error values from measurement.*

If multiple measurements are taken during one appointment, for example before and after treatment, use the "Measure" tab and repeat steps 1-5 as described above.

Caution: Disposable tips and barrier sleeves are designed for **single patient use only**. After all measurements have been taken, carefully remove the tip and barrier sleeve from the handpiece and discard in a biohazard waste container. Proceed with the cleaning and disinfection protocols per Section 9 prior to placing the handpiece into the base station.

Caution: A disposable tip can be used for up to one hour on the same patient. If additional time is required for measurements, the software will prompt a tip replacement, and the system will not operate until a new tip is installed.

10.5 Interpreting Results

Use the initial measurements as a baseline. Monitor changes in the mobility values between the measurements. Sequential readings over time and changes in the measurements may indicate changes in tooth or implant mobility. If changes greater than 20% are noticed, use traditional examination methods, such as x-rays, to determine the appropriate treatment. The final treatment decisions are the responsibility of the clinician.

The following should be used as a guidance only:

- A low mobility reading for a tooth is an indication of low tooth mobility
- A high mobility reading for a tooth is an indication of high tooth mobility.
- A low mobility reading for an implant is an indication of low implant mobility.
- A high mobility reading for an implant is an indication of high implant mobility

Note: Provisional restorations will exhibit higher readings due to the damping capacity of the acrylic resin.

10.6 Comparison of Results

To compare mobility results from previous measurements, navigate to the “Trendline” tab and select a tooth or implant. This option Is available for convenient review and comparison of historical data.

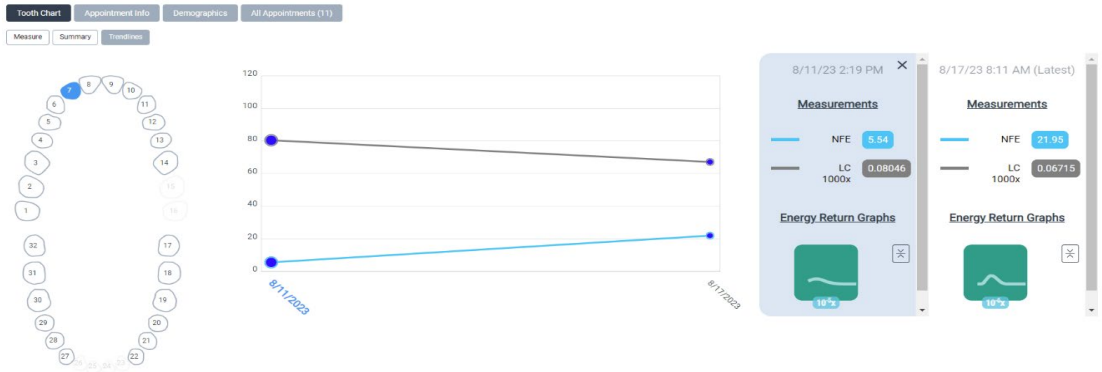


Figure 19 – comparing results tab

10.7 Ending Appointment

All measurements taken during an appointment are grouped together, placed in the patient’s record, and automatically saved. If a patient has two or more appointments within a 24-hour period that need to have multiple measurements tracked separately, click the **“Appointment Info”** tab and **“End Appointment”** to finalize the patient record for the first appointment (Figure 20).

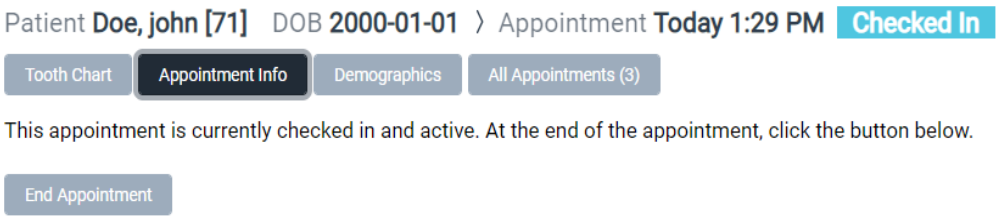


*Figure 10: **"Appointment Info"** tab*

A new appointment can then be started by clicking the "**Check In and Begin Measurements**" button.

To return to the main patient search screen, click on the "**All Patients**" button at the top right of the window (Figure 21).

*Figure 11: **"All Patients"** button*

10.7 Reviewing Past Measurements

Open the patient record as described earlier to see data from a prior appointment. Measurements from the patient's last appointment will be shown under the "Tooth Chart" tab.
Click on the **"Tooth Chart"** tab and choose between the **"Summary"** tab, which shows all the teeth tested, and the "**Trendlines**" tab, to review all measurements. To see measurements from another appointment, click on the **"All Appointments"** tab, and then click the **"Open This Appointment"** button for the appointment of interest (Figure 22).

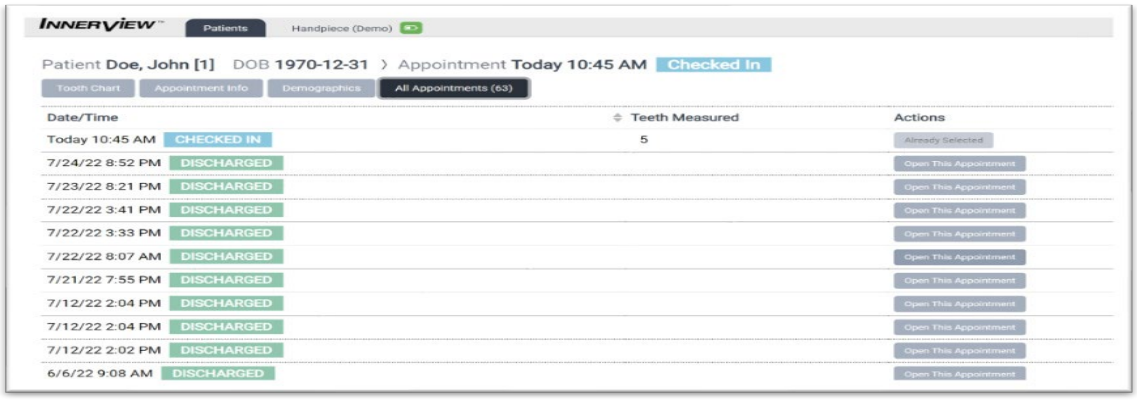
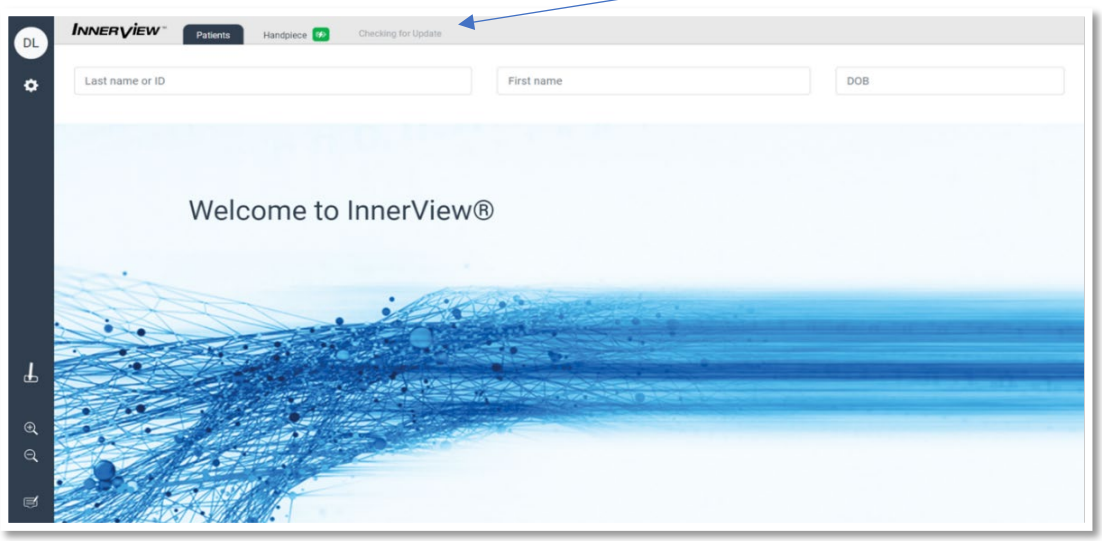


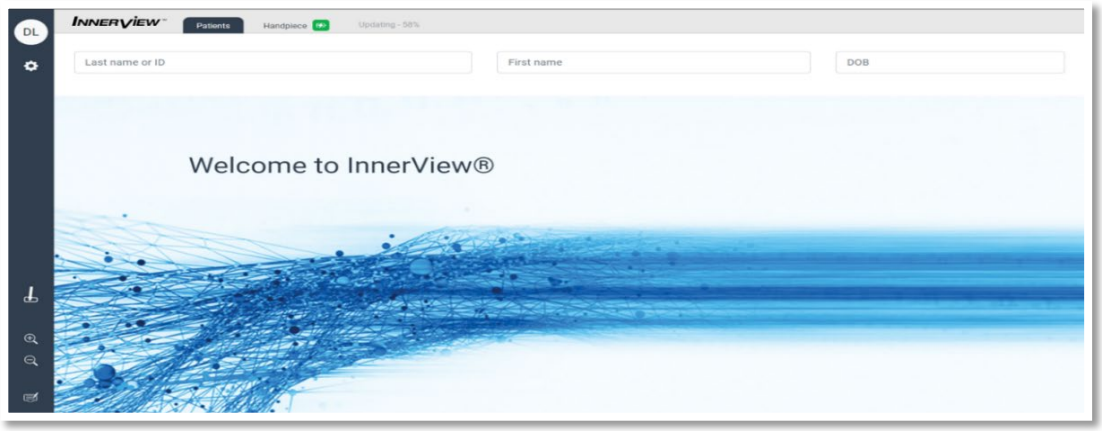
*Figure 12: **"All Appointments"** tab*

11. Software Updates

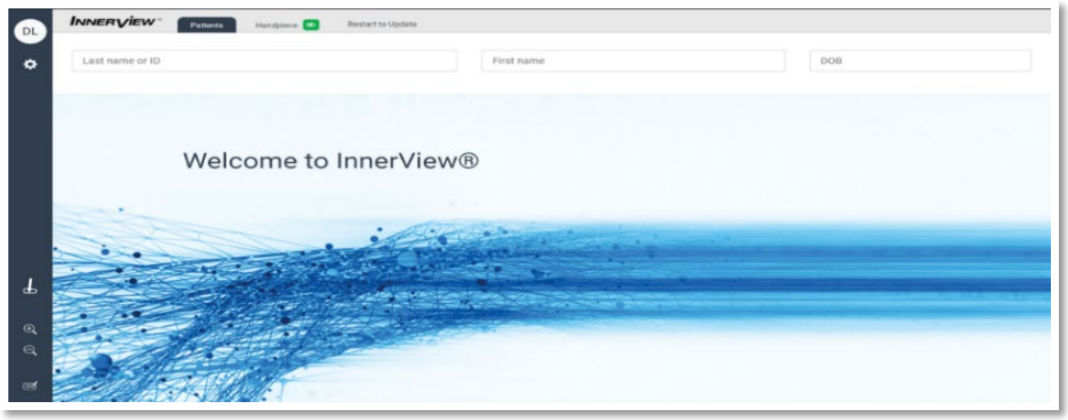
At each startup, the InnerView® app will automatically check for new available software updates which have been released. This process is indicated by a "**Checking for Update**" indicator message at the top of the app screen.



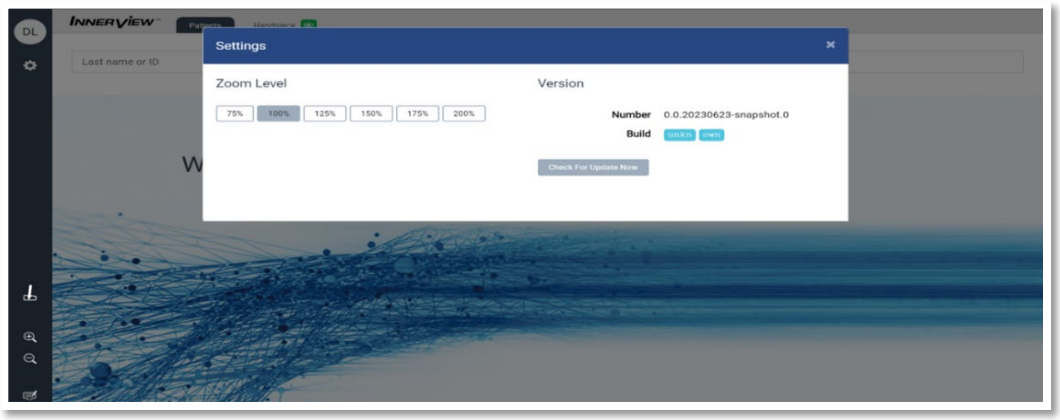
If an update is found, the app will automatically begin downloading the new software. This is indicated by an "**Updating**" indicator message and an associated progress percentage.



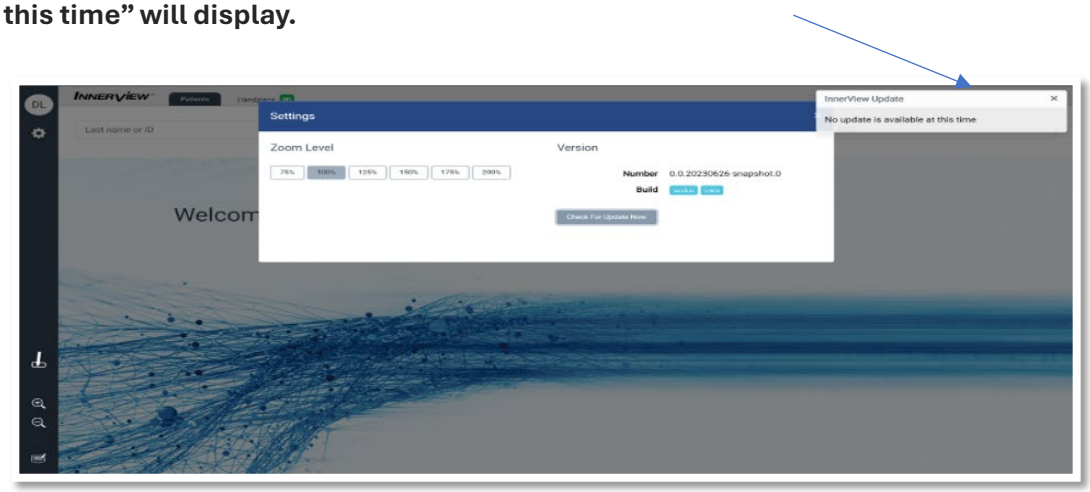
When the installation is complete, the indicator message will be replaced by a "**Restart to Update**" prompt. Clicking this prompt will install the upgrade and open the app with the new software version. This prompt can also be deferred, and the software upgrade will be installed the next time the app is opened.



Alternatively, the process to check for an update can be triggered manually by opening the settings button from the app side toolbar and clicking the "**Check For Update Now**" button.

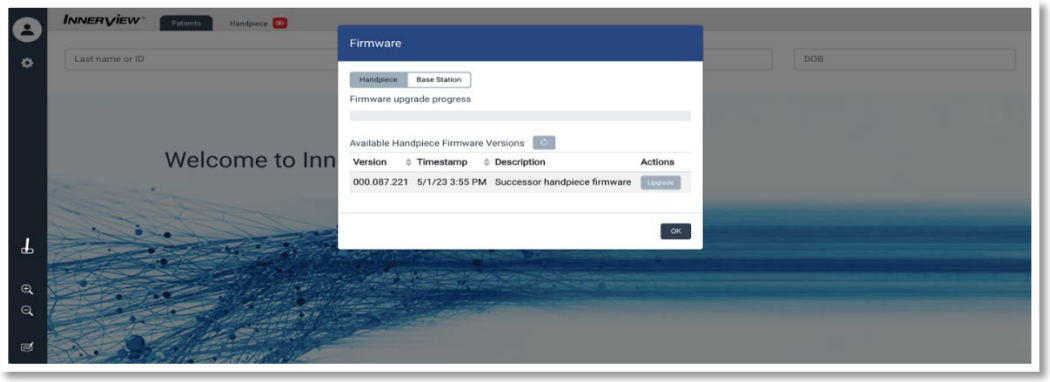


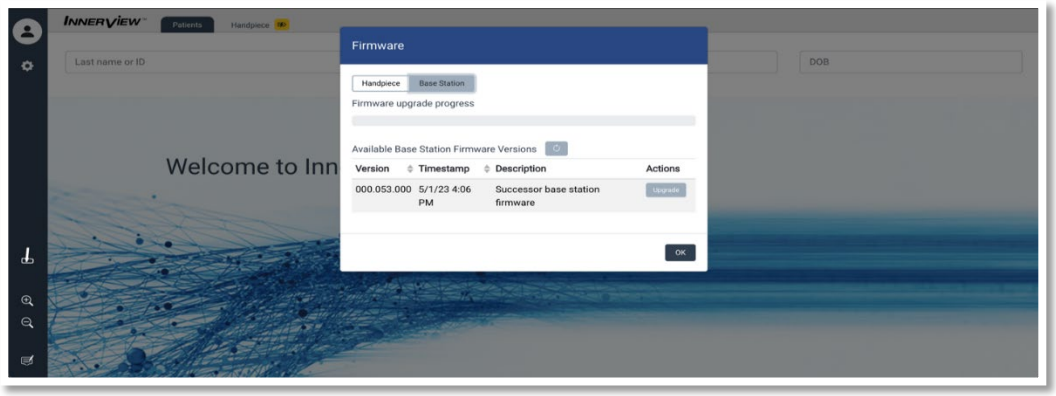
If the software does not have an available upgrade, then the message "**No update is available at this time" will display.**



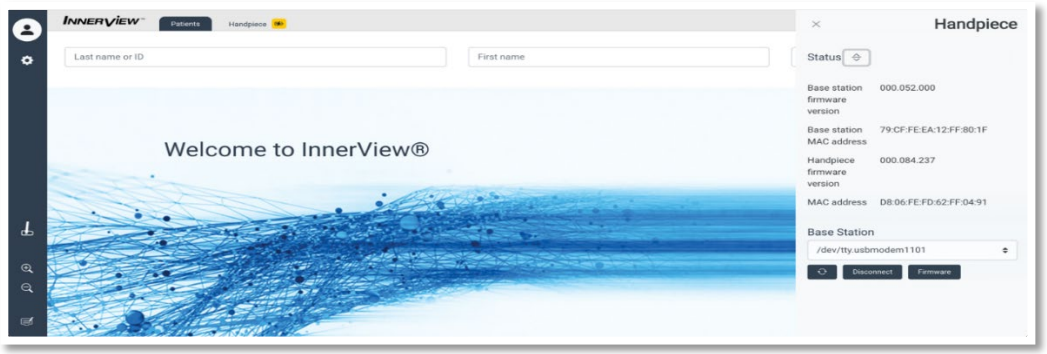
12. Handpiece and Base Station Firmware Upgrades

When a base station is first connected to the user's PC and the InnerView® application is displayed, or when the app is started up and a base station is connected, the app automatically checks for any available firmware upgrades for the base station or handpiece firmware. If updates are available for either, the app will automatically display a "Firmware" window, where either handpiece firmware or base station firmware can be viewed. Clicking the "Upgrade" button next to an available firmware version will initiate a firmware upgrade to that version, after which the "Firmware upgrade progress" bar will display the progress of the update.





This same "Firmware" window can be accessed manually by navigating to the handpiece panel and clicking the "Firmware" button at the bottom of the screen.



13. Handpiece Positioning

The measurements should be taken with the patient sitting upright.

1. Position the handpiece with the attached tip horizontally to the center of the facial surface of the tooth or restored implant (Figure 25a). The handpiece LED light will illuminate green when the correct position is achieved, indicating that the handpiece is ready to use.
2. The tab of the disposable tip should rest on the occlusal surface of the tooth or implant (Figure 25a).
3. Press the disposable tip against the buccal surface of the test site. The handpiece will continually beep if too much pressure is applied. Once the pressure is released, the beep will stop.
4. There is no on/off button on the handpiece. The handpiece will automatically trigger tapping when light pressure is applied against the tooth or implant.
5. During the measurement, there should be no contact between the maxillary and mandibular teeth. Instruct the patient to open their mouth to facilitate measurements.

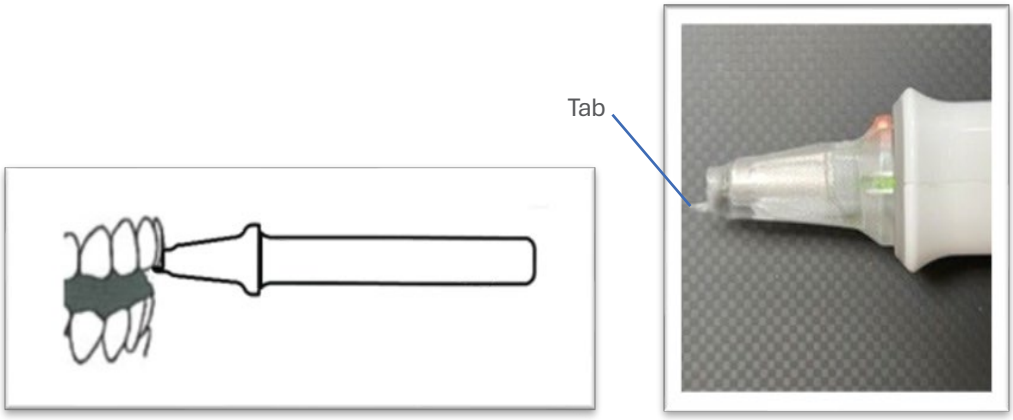


Figure 13a: ***Correct*** *inclination of the Handpiece and Tip tab*

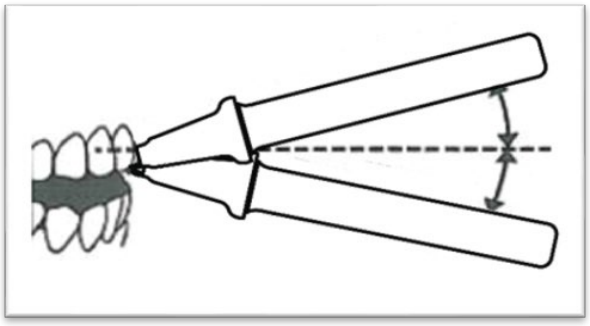


Figure 14a: ***Incorrect*** *positioning of the Handpiece*

14. Taking Measurements

14.1 Upper (Maxillary) Posterior Area

To access the buccal of the left maxillary posterior teeth/implants, tilt the patient's head towards the patient's right shoulder. Reverse the process for the right side.

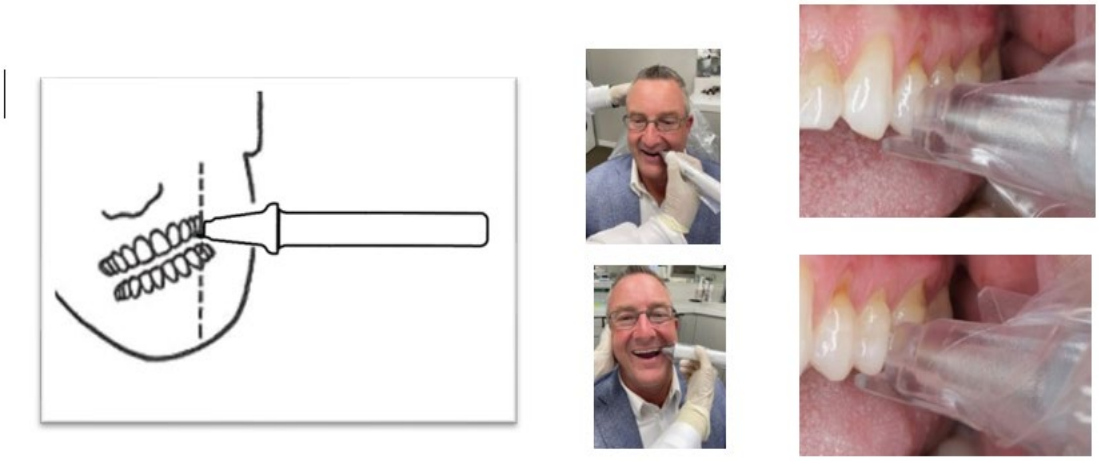


*Figure 26: **Maxillary Posterior** area*

14.2 Upper (Maxillary) Anterior Area

Instruct the patient to tilt their head slightly towards their chest to achieve a buccal surface perpendicular to the handpiece position (Figure 27).

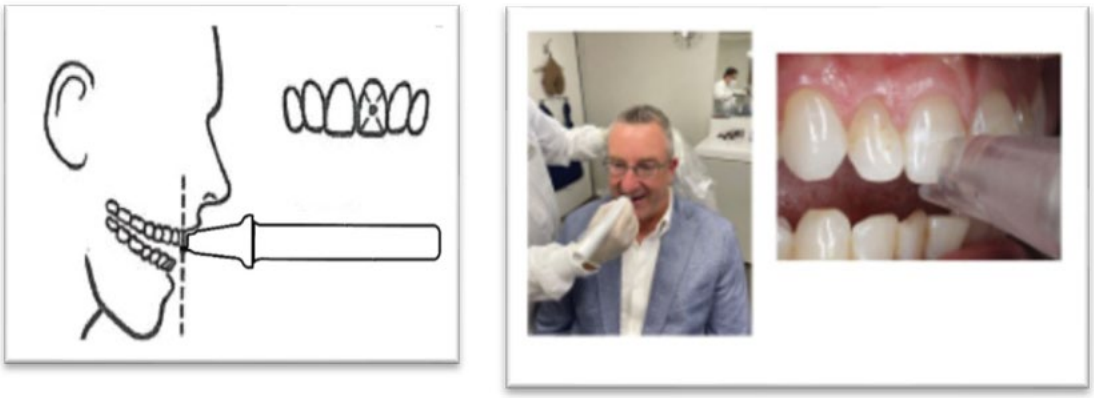


*Figure 27: **Maxillary Anterior** area*

14.3 Lower (Mandibular) Posterior Area

To access the buccal of left mandibular posterior teeth/implants, tilt the patient's head towards their left shoulder. Reverse this process for the right side (Figure 28).

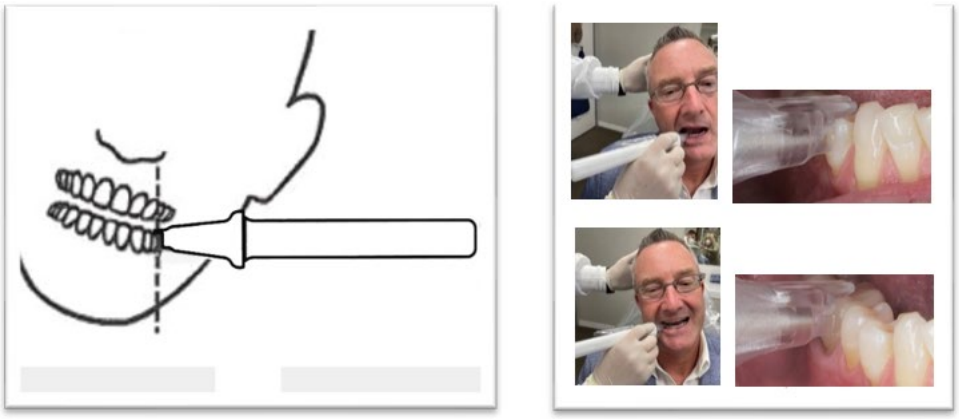


Figure 28: ***Mandibular Posterior*** *area*

14.4 Lower (Mandibular) Anterior Area

Instruct the patient to tilt their head backwards to help align the labial surface of their lower teeth/implants perpendicular to the level of the handpiece position. Rotate the handpiece clockwise by 180° to seat the tab of the tip and activate the handpiece when moving from the upper to the lower jaw (Figure 29)

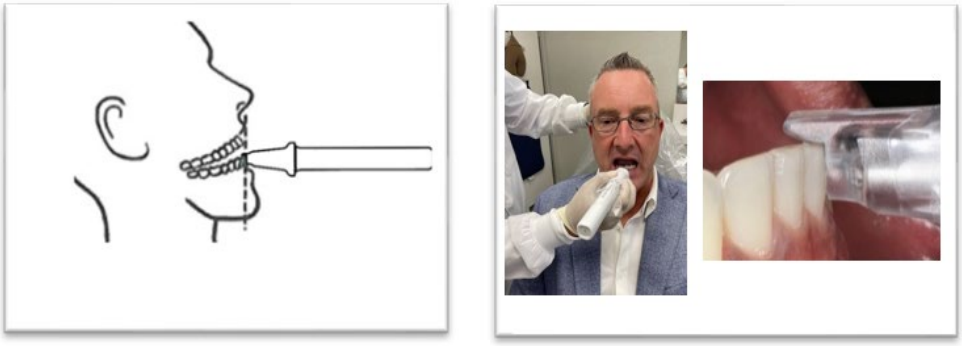


Figure 29: ***Mandibular Anterior*** *area*

14.5 Unrestored Implants

Testing of newly placed or uncovered but not yet restored implant.

Note: No additional attachments are required to test an unrestored implant using the InnerView® System.

1. Choose a healing cap, an impression abutment, or custom /solid standard abutment of the implant with a flat surface that provides enough height for the tip to be securely placed.

2. Position the tip tab on the occlusal surface of the abutment and the face of the tip against the buccal surface of the abutment (Figure 30). The handpiece will automatically trigger tapping when lightly pressed against the abutment.

Figure 30: Examples of Abutments/Healing Cap Testing

15. Transport and Storage

The InnerView® System should be stored in a cool and dry place when not in use.

Recommended environmental conditions for storage and transportation are as follows:

Temperature	15 to 30 ˚C (59 to 86 ˚F)
Relative Humidity	20 to 90 %
Atmospheric pressure	50 to 100kPa (500 – 1000hPa)

16. Maintenance

After using the device, make sure to keep it clean for the next use. A standard disinfectant such as Cavicide or CaviWipes can be used to wipe down the device when not in use for an extended period. **Always follow the cleaning and disinfection protocols outlined in Section 9 prior to each clinical use.**

The device should be inspected daily for any signs of damage. Do not use the handpiece if any sign of damage or corrosion on the tapping rod is noticed as it may cause system malfunctioning and result in incorrect measurements.

Contact customer service for any maintenance or repair needs.

17. Warranty

Perimetrics warrants the device to be free from defects in materials and workmanship for a period of 1 year from the date of purchase.

Perimetrics assumes no liability whatsoever when:

- Work or repairs of the device are performed by unauthorized personnel.
- The InnerView® System is used for applications and not in accordance with the procedures described in this manual.

18. Troubleshooting

If a problem occurs with your InnerView® System, please refer to the guide below. If the problem persists, contact Perimetrics' customer service at **1(888) 325-7218.**

Problem	Cause	Solution
Base Station		
Base LED's do not light up	No power to base	Ensure USB is plugged into the computer and the computer is on
Base LED's turned off while plugged into computer	Computer went to sleep or is turned off	Check to see if computer is plugged into a working outlet and turned on
Cleaning button does not activate handpiece rod	Handpiece is not paired	Place handpiece back into the base and wait for the green LED's to flash. Remove handpiece and push the clean button
Handpiece does not charge	Handpiece is not seated properly	Visually inspect the pins on the handpiece to ensure no debris is present. Remove handpiece and replace it back in the base.
		If the LED are still light blue, check to see that pins in handpiece are extruding from handpiece.
		Clean both the handpiece pins and the base pin pad with an alcohol swab.
Base LED's stay light blue	Handpiece does not have a good connection with the base	Visually inspect the pins on the handpiece to ensure no debris is present. Remove handpiece and replace it back in the base.
		If the LEDs are still light blue, check to see that pins in handpiece are extruding from handpiece.
		Clean both the handpiece pins and the base pin pad with an alcohol swab.
Base LED's do not blink green when placing handpiece in the base	Handpiece is not pairing to the base	Cycle the handpiece by pressing the button on the handpiece until you hear a beep. Replace handpiece in base.
		If the handpiece still does not pair, follow steps above.
Base LED's are not dark blue when a handpiece is sitting in the base	Handpiece is not charging	Pull the handpiece and replace it in the base and make sure the LED's blink green then turn dark blue.
		If that does not work, follow steps for handpiece not pairing.
Handpiece		
No LED when placing a tip on the handpiece	Tip is not recognized by the handpiece as a valid tip.	Cycle the handpiece, place in base to pair until green LED's flash and then re-apply tip.

Handpiece does not tap	Handpiece lost connection	Wait for the system to re-connect. If it does not re-connect, cycle handpiece remove tip, place handpiece back in the base to pair, wait for green LED's on base to flash, remove handpiece and replace tip.
Battery becomes exhausted quickly	Handpiece may not have been charging or battery near end-of-life	Charge handpiece up to 4 hours; if the battery indicator is green and still gets exhausted quickly, contact customer service.
Software		
App can't be found on the computer	Software may have been removed from computer	Type "InnerView" in the computer search bar. If still not available, contact customer service for a link to download the app.
App does not open	Old App	Contact customer service to have the latest link sent to you to download a new version of the app
App won't accept my tenant ID	Wrong Tenant ID or value	Identify the correct tenant ID and insert the tenant ID followed by -practice. For example: smith-practice
My ID and Password don't work	Incorrect ID or password entered	Double check ID and password. If it still does not work, contact customer service to have password re-set
Unable to find a patient in the patient search	Patient search information does not match original information	Ensure patient name is entered correctly. If it is still not available search by last name only. Still not available search by first name only. Still not available search by DOB.
Unable to see results from a previous test	Appointment is not open	Go to "All Appointments" and click on "Open This Appointment" corresponding to the appointment date you want.
Unable to get the testing screen to appear	In an ended appointment	If you are in the patient account, click "All Patients" and then "Tooth Chart" and then "Measure" to set up test.
The system is stuck on "Remove handpiece from base" in the main screen	System is not paired	Place handpiece back into base until the green LED's on the base blink.
Can't get the testing screen to work	In an ended appointment	Click on "Back to patients" to set up a new appointment.
System stops working during testing	System lost connection	Cycle the handpiece, remove the tip and barrier sleeve and place it in the base station until the green base LED's blink.

19. Returns

Prior to return the InnerView® System must always be disinfected. Please contact your Perimetrics Sales Representative to obtain a Returned Goods Authorization and specific details for return shipment of the device at:

Perimetrics, Inc.
2942 Century Place
Costa Mesa, CA 92626
Tel. 1 (888) 325-7218

20. Disposal

The InnerView® handpiece is equipped with a Lithium-polymer battery and must be properly disposed of. Any disposal of this product must comply with the relevant local and national regulations.

21. Accessories/Spare Parts

Part Number	Description
INV-1000	InnerView® Handpiece
INV-2000	InnerView® Base Sation with UBS cable
INV-3000	InnerView® Disposable Tips, 24 pk
N/A	A88007- Dentsply Sirona Disposa-Shield® Order directly from the manufacturer or distributor

22. Electromagnetic Emission

IEC60601-1-2 Ed.4 testing has verified that electromagnetic interference stimulus has no effect to both safety critical functionality and essential performance of the InnerView® System. This includes the energy return graphs (ERGs) that it generates.

InnerView® System essential performance consists of a graph of energy return curves displayed for each series of percussions per site that indicates the damping effect of mobility for determining the oral health of the patient.

If abnormal performance is observed, such as degradation of essential performance in the form of perturbation of ERGs, additional measures may be necessary, such as re-orienting or relocating the device. Suggested actions according to Table 3: RF immunity of non-life-support equipment or system IEC 60601-1-2 Ed.4.

The InnerView® System is suitable for use in the electromagnetic environment specified below in Table 1, Table 2, and Table 3. The customer or user of the InnerView® System should ensure that the device is used in such an environment.

Emission Measurement	Conformity	Electromagnetic Environment Guidelines
RF emissions according to CISPR 11	Group 1	InnerView® System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions according to CISPR 11	Class A	InnerView® System is suitable for use in its intended environment [professional healthcare (dental) facility] other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics according to IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker according to IEC 61000-3-3	Complies	

Table 1: Electromagnetic emissions IEC 60601-1-2 Ed.4

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 2, 4, 8, 15 kV air	Professional healthcare (dental) facility
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m 60 Hz	Professional healthcare (dental) facility
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 2: Electromagnetic immunity IEC 60601-1-2 Ed.4

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 0.15 – 80 MHz 6 V m in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	Professional healthcare (dental) facility
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz Immunity to proximity fields from RF wireless communication equipment, levels according to 60601-1-2 Ed.4 Table 9.	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	Professional healthcare (dental) facility

Table 3: RF immunity of non-life-support equipment or system IEC 60601-1-2 Ed.4

23. Working Clearances

The InnerView® System is intended for operation in an electromagnetic environment where radiated RF disturbances are uncontrolled. The device only uses a BLE radio where the typical values of the equivalent radiated power are less than 10dBm and the use environment is specified as a professional healthcare (dental) facility.

The user can help prevent electromagnetic interference by duly observing a minimum distance of 30 cm (12”) between portable and/or mobile RF communication devices (transmitters). Otherwise, degradation of the performance of this equipment could occur.

Note: These guidelines may not be applicable in all cases. The propagation of the electromagnetic waves is influenced by their absorption and reflection by buildings, objects, and persons.

Interference may occur in the vicinity of equipment marked with the following symbol: 

WARNING! The use of other cables and accessories, other than those specified and provided by Perimetrics may negatively affect EMC performance of the InnerView® System.

WARNING! The InnerView® System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation.

The InnerView® System utilizes MiWi wireless technology based on IEEE 802.15.4 standard on the 2.4 GHz ISM band. The wireless function is secured by application-level encryption.

24. Wireless Equipment Statement

This statement applies to the wireless portion of the device.

FCC Compliance Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, 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 receiver.
- Connect the equipment into 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.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) this device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation. Please note that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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

FCC SAR Statement

This device has been evaluated for radiofrequency (RF) electromagnetic exposure requirements. The device can be used in portable exposure conditions without distance restriction and complies with applicable safety standards for radiofrequency radiation.

ISED non-interference disclaimer

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

(1) This device may not cause interference.

(2) This device must accept any interference, including interference that may cause undesired operation of the device.

This device complies with the Canadian ICES-003 Class B specifications. CAN ICES-003(B)/NMB-003 (B).

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempt de licence. L'exploitation est autorisée aux deux conditions suivantes :

(1) L'appareil ne doit pas produire de brouillage;

(2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.

ISED SAR compliance statement

This device has been evaluated for radiofrequency (RF) electromagnetic exposure requirements. The device can be used in portable exposure conditions without distance restriction and complies with applicable safety standards for radiofrequency radiation.

Cet appareil a été évalué selon les exigences relatives à l'exposition aux rayonnements électromagnétiques radioélectriques. L'appareil peut être utilisé dans des conditions d'exposition portables sans restriction de distance et est conforme aux normes de sécurité applicables en matière de rayonnement radioélectrique.

No modification to this device is allowed.