SonoChart

User & Installation Guide

Notice

The User & Installation Guide for SonoChart includes information on the installation of the handpiece as well as its usage. We recommend that you thoroughly familiarize yourself with this guide to make the most effective use of your system.

The SonoChart handpiece is an ultrasonic system intended for use by healthcare professionals to evaluate soft tissues (small oral cavity organs) using clinical applications as diagnostic support of adult patients.

The resulting imaging capabilities of the product could be used for dental professional to assess the periodontium context of a patient.

Important: We recommend that you consult the "Safety, Regulatory and the Technical Specification User Guide" before using the SonoChart product.

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This document is originally written in English.

The SonoChart product is intended for professional use only.

U.S. Federal law restricts this handpiece to sale by or on the order of a dentist.

If any serious incident occurs in relation to the handpiece, the user must report it to Carestream Dental and to the competent authority of its Member State in the European Union.

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The SonoChart product complies with Medical Device Regulation (EU) 2017/745 and the UK Medical Device Regulation 2002 (UK MDR 2002).

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1 Conventions in this Guide

Conventions in this Guide

The following special messages emphasize information or indicate potential risk to persons or equipment:

WARNING: Warns you to avoid injury to yourself or others by following the safety instructions precisely.

CAUTION: Alerts you to a condition that might cause serious damage.

Important: Alerts you to a condition that might cause problems.

Note: Emphasizes important information.

Tip: Provides extra information and hints.

2 SonoChart Product Packaging

Opening the box

To open the SonoChart packaging box, follow these steps:

1. Open the SonoChart packaging box.
2. Remove the protective covers of the individual components of the package.
3. Connect the AC adapter and the battery charge station to the mains power supply to charge the battery.
4. It is recommended that you recharge the battery before using it (solid blue indicator).

The SonoChart product packaging comprises:

- The handpiece
- A battery
- A battery charge station
- USB-A to USB-C wire
- Wrist strap

Overview

The front of the SonoChart product packaging box displays a few labels that will give you a better installation experience.

Link to the resource library	Product Serial Number	Link to the Application Store
Scan this QR code using the handpiece camera to display the resource library pages of the SonoChart product hosted on Carestream Dental website.	Scan this QR code using the handpiece camera to directly enter the product serial number in the corresponding application fields.	Scan this QR code using the handpiece camera to connect the user to the application store to download and install the SonoChart application.

3 Overview

SonoChart is an intraoral ultrasonic system intended for use by healthcare professionals to evaluate of oral cavity soft tissues of adult patients.

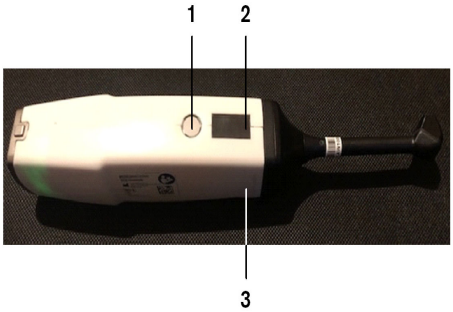
Main Components

The following are the main components of SonoChart.

Component	Description
	Handpiece, comprising a: • Removable head • Body (including the battery)
	Battery
	USB-A to USB-C wire (for battery charge station)
	Battery charge station (front view) • No battery detected - Off: • Charging - flashing blue: • Charged (charge station still connected) - solid blue:
	Battery charge station (side view):
	Wrist strap

Functional Components

The following are the functional components of SonoChart.

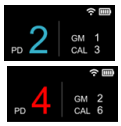
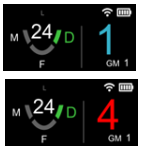


1 - ON / OFF button:

Description	Display
Switched off	
Switched on	

2 - Handpiece Display Screen

Description	Display
Battery is low, need charging	
Handpiece initialization in progress	
Handpiece initialized and needs configuration	
Link with a smartphone/tablet established. Configuration in progress.	
Configuration completed. Handpiece connected to the local Wi-Fi network.	
Homepage of the handpiece. Options: • Mobile terminal connection • Handpiece autonomous mode activation	
Homepage of the handpiece with no connection to the local Wi-Fi network. Limited number (30) of exams allowed. For more acquisitions, internet connection is needed.	
Handpiece autonomous mode activated. Handpiece waiting for periodontal measurements to be displayed.	

Description	Display
Handpiece autonomous mode activated. Blue: Periodontal measurements obtained and displayed. Red: Periodontal threshold exceeded.	
Mobile terminal guided mode activated. Handpiece connected to a mobile terminal. Positioning information provided by the mobile terminal. Handpiece waiting for periodontal measurements to be displayed.	
Mobile terminal guided mode activated. Handpiece connected to a mobile terminal. Blue: Periodontal measurements obtained and displayed. Red: Periodontal threshold exceeded.	
Mobile terminal guided mode activated. Guided mode delay screen activated. Delay screen between two successive periodontal measurements.	

3 - Status Indicator LED

Description	Display
Solid green Small size pocket depth detected for periodontal procedures	
Solid orange For either: • Medium size pocket depth detected for periodontal procedures, or • Warnings	
Solid red For either: • Large size pocket depth detected for periodontal procedures, or • Error notifications	

Important: The size of the pocket depth depends on the threshold parameters you set as handpiece configuration. See "Handpiece Configuration" , Step 12. and "Managing User Profile" , Step 6.

4- Active surface of the handpiece head

Consumables

Important: You MUST wear gloves (not provided) when you apply the intraoral ultrasound gel or the hydrogel.

Intraoral Ultrasound Gel and Hydrogel

Compatible gel	Suppliers	Commercial presentation
AEVO Oral Ultrasound Gel	SmileSonica Inc The Aevo Oral Ultrasound Gel is delivered under a 5g pouch packaging	
Hydrogel	Carestream Dental	

4 Mobile Application Interface

The SonoChart Mobile Application Interface is a user-friendly interface designed and developed specifically for the SonoChart product.

The SonoChart mobile application and the acquired images can be viewed on the following mobile terminals:

- Smart phones: iPhone
- Tablets: iPad

Minimum Mobile Terminal System Requirements

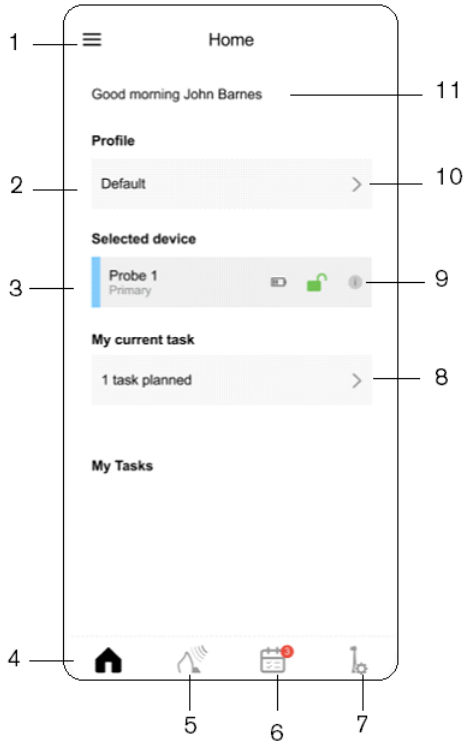
See the ***SonoChart Safety, Regulatory and Technical Specifications User Guide (SMA87) Ed01*** for the minimum mobile terminal system requirements for the SonoChart Mobile Application software.

If necessary you must update your mobile terminal system configuration.

The mobile terminal should ideally be situated in, or close, to the operating area, in the visual field of the practitioner when he is with the patient.

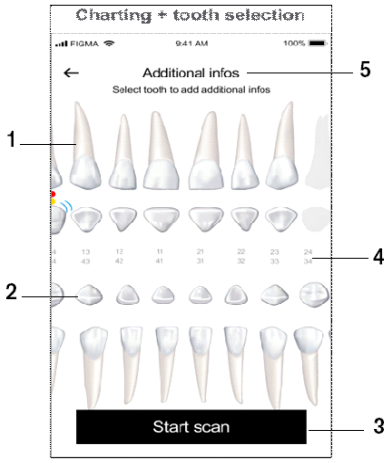
The visual access of the acquired data for the patient encourages communication.

SonoChart Mobile Application Homepage



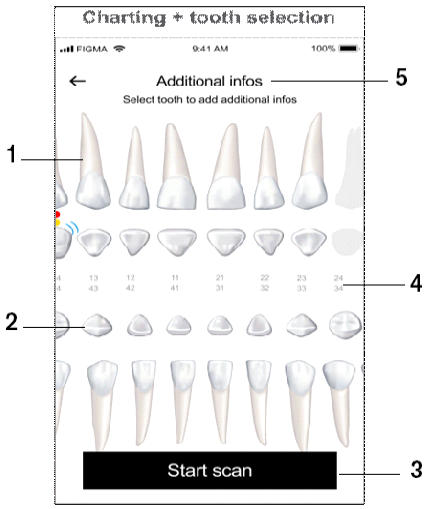
1	Application Preference: Displays the preference dialog box of the SonoChart Mobile Application
2	User Profile: Selected user profile
3	SonoChart Handpiece List: Lists the SonoChart handpiece discovered in the environment
4	Homepage Access: Directs to the Mobile Application homepage
5	Autonomous mode: Accesses the remote display of the autonomous mode
6	Working List: Accesses the patient working list
7	Add Handpiece Button: Accesses the SonoChart handpiece configuration page
8	Current Task: Shows the current task that is in operation
9	Handpiece Information: Accesses the handpiece information page
10	User Profile Selection: Lists user profiles
11	User Identifier: Practitioner first and last name

Scanning Modes



1	**Full mode**: Selects the full guided periodontal acquisition mode
2	**Video mode**: Selects the video acquisition mode
3	**Free mode**: Selects the free acquisition mode
4	**Custom mode**: Selects the customized periodontal acquisition mode

Periodontal Chart



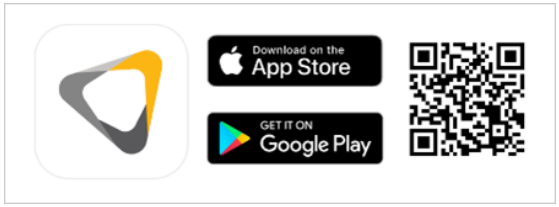
1	**Teeth Vestibular Surfaces**: Vestibular representation of the teeth
2	**Teeth Occlusal Surfaces**: Occlusal representation of the teeth
3	**Start scan**: Launches the selected acquisition procedure
4	**Teeth Numbers**: Teeth numbering in accordance with the user profile preferences (FDI, ADA)
5	**Additional Periodontal Information**: Tooth additional information in accordance with the user profile preferences (Mobility, Suppuration, Furcation, Bleeding, Plaque, Calculus)

5 Setting Up the Mobile Application

Installing the Application

To install the application, follow these steps:

1. Using the video camera of your mobile terminal, scan the installation QR Code of your product packaging.

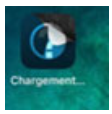


   A link to the application store will appear on your mobile terminal screen.

2. Tap the link to open the application store dedicated to your mobile terminal.
   The application store page displays on the mobile terminal screen inviting you to get the application.

3. Tap **Get** to download and install the product.

   During the download and installation, a progress animate will appear on the application icon.



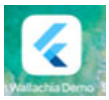
Once the application completes the installation, you will see the application icon on the mobile terminal desktop.

Application Signing Up / Signing In

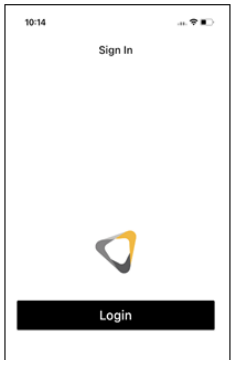
Signing Up

To sign up (creating an account), follow these steps:

1. Tap the application icon on the mobile terminal desktop.

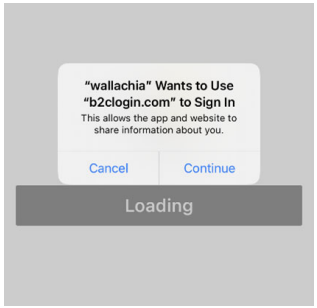
   

   The application launches the **Sign In** page.

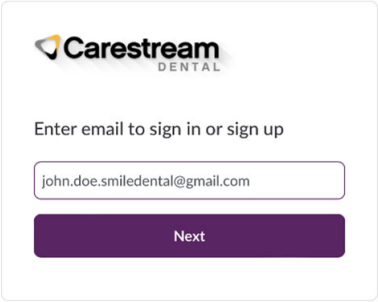
2. Tap **Login**.

The following page displays:



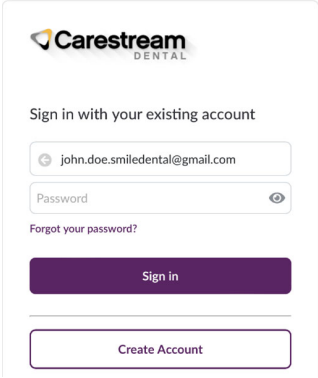
3. Tap **Continue**.

   The following page displays:



4. Fill in the information and tap **Next**.

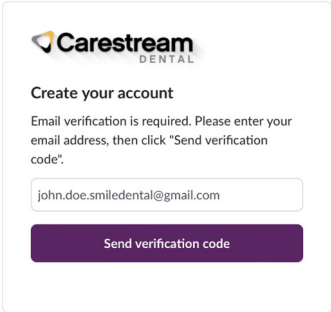
   The following page displays:



5. If you have a Carestream Dental Single Signed On account, enter your **Username** and **Password**, then tap **Sign in**.

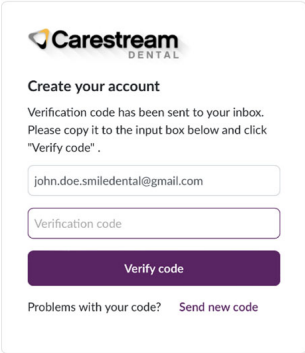
6. Tap **Create Account** if you do not have an account.

The following page displays:



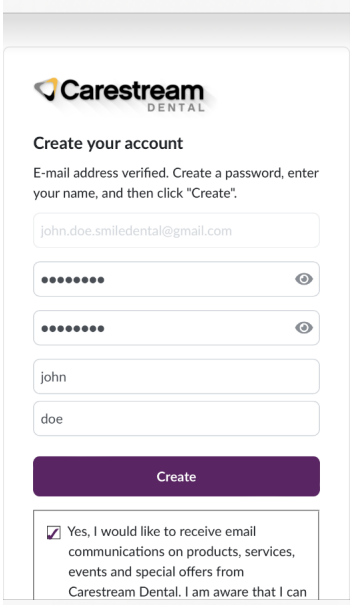
7. Tap **Send verification code**.

   The following page displays:



8. Enter the verification code that you received in your inbox, then tap **Verify code**.

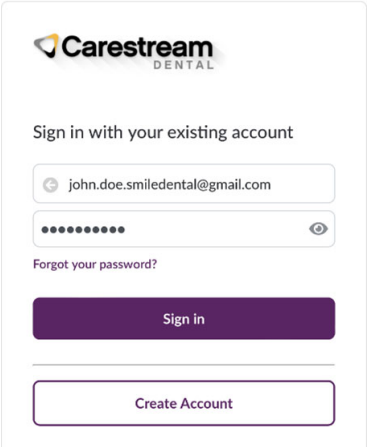
9. When the following page displays, fill in the information and tap **Create** to finalize the account creation.



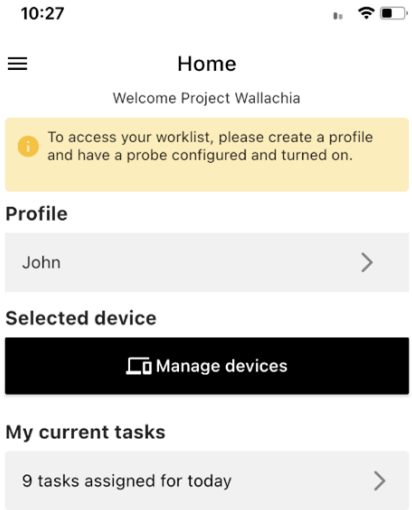
Signing In

To sign in (if you have a Carestream Dental Single Signed On account), follow these steps:

1. Enter the login and password, then tap **Sign in**.



You are now logged in the application. The homepage displays.



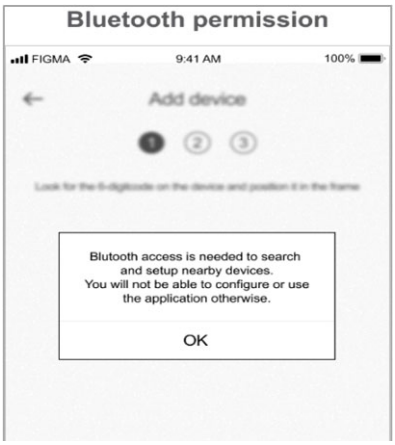
Setting Up the Wireless Communications

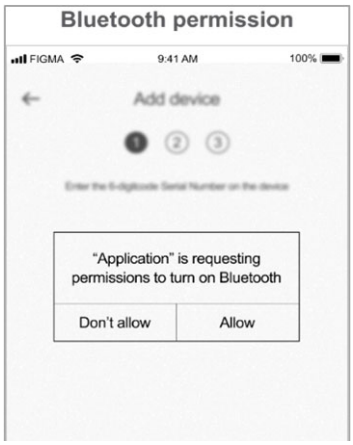
To use the SonoChart product, you must activate the Bluetooth and Wi-Fi wireless communications of the mobile terminal.

When you first connect to the application, you will be prompted to activate the wireless communications.

To set up the wireless communications, follow these steps:

1. Click **OK** and **Allow** on the **Bluetooth permission** pages.

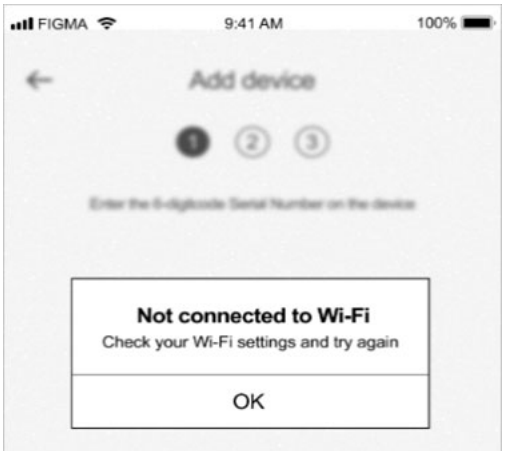




The Bluetooth wireless communication is now active on your mobile terminal.

If you already have Wi-Fi connectivity, go directly to the **Handpiece Configuration** section.

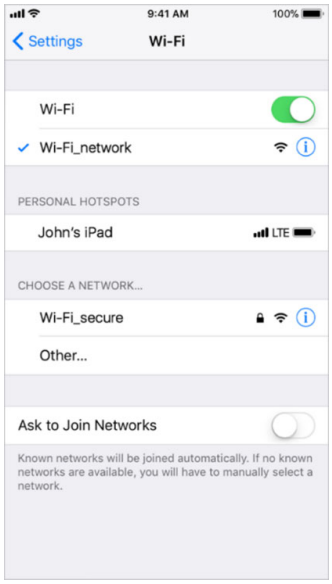
2. Click **OK** to enter the Wi-Fi mobile terminal system **Settings** page.

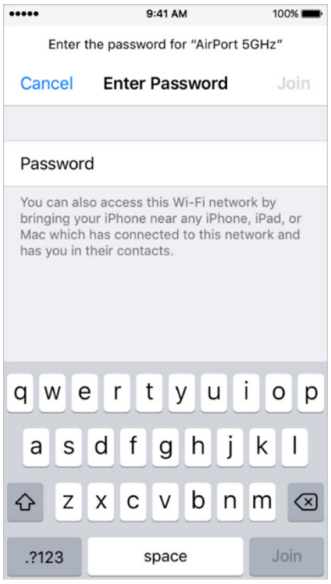


The Wi-Fi **Settings** page of the mobile terminal operating system displays.

3. Toggle and activate the **Wi-Fi** button, then select your Wi-Fi network from the list that your mobile terminal displays.

   If prompted, enter the password for the Wi-Fi network and tap **Join**.





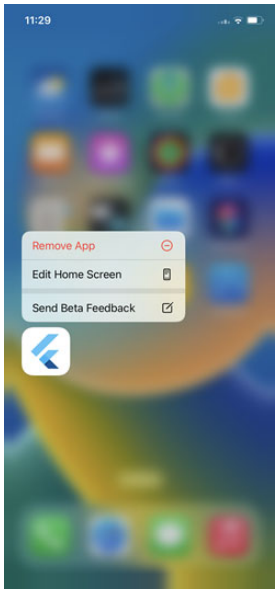
You are now connected to your Wi-Fi network.

Uninstalling/Deleting the Application

To uninstall or delete the application from your mobile terminal, follow these steps:

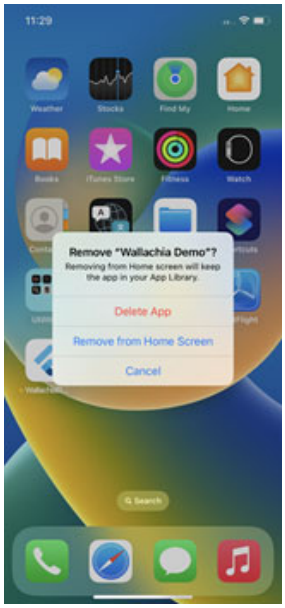
1. Press and hold the application icon on the mobile terminal desktop.

   The following screen displays:



2. Select **Remove app**.

   The following screen displays:



3. Select **Delete App** or **Remove from Home Screen**.

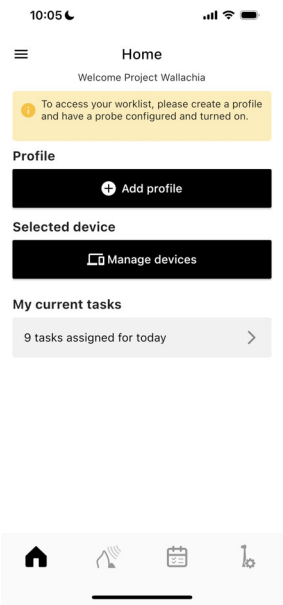
6 Configuring the Handpiece

Handpiece Configuration

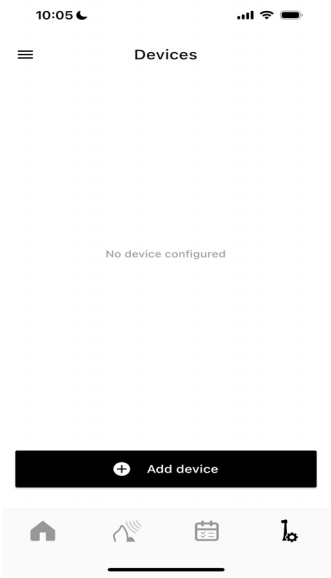
To configure the handpiece, follow these steps:

1. Check that the handpiece is switched on.

2. On the application homepage, tap **Manage devices**.

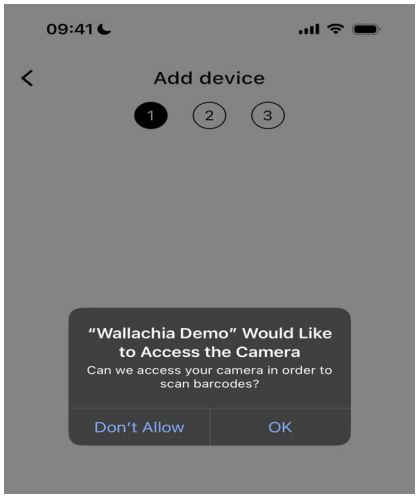


3. On the **Devices** window, tap **Add device** or .

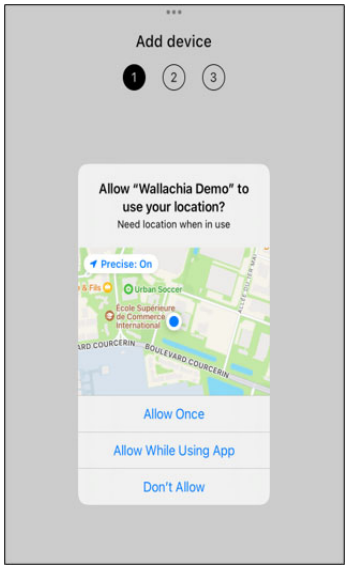


When you first log in the application, you will be requested to authorize the use of the mobile terminal video camera.

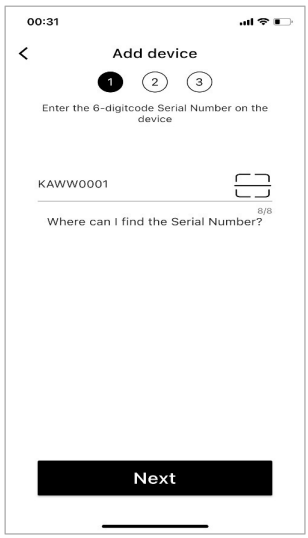
4. Tap **OK** to enable use of the mobile terminal video camera or tap **Don't Allow** to unable.



5. Tap **Allow Once** or **Allow While Using App** so you can continue using your handpiece after the configuration.

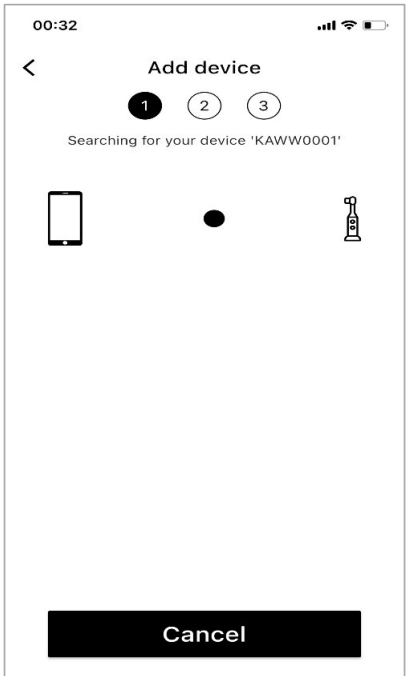


6. Scan the serial number QR Code on the handpiece or on the packaging (video camera activated) or manually enter the handpiece serial number.



Serial number of the handpiece is entered in the Serial Number field.

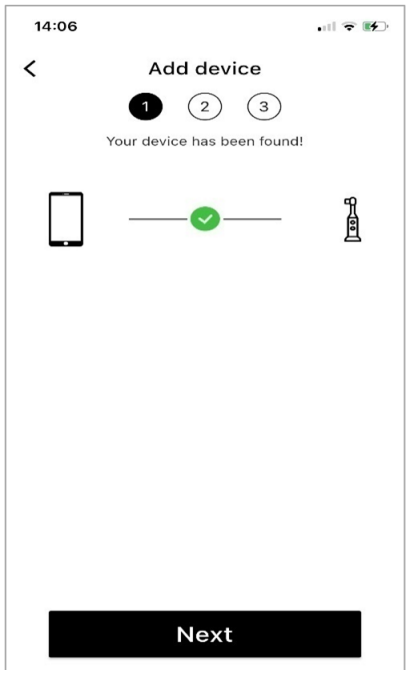
7. Tap **Next** to search for a handpiece.



If you did not find a handpiece:

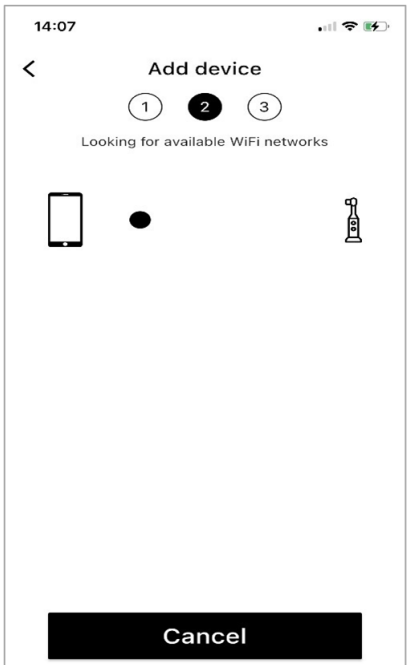
- Tap **Retry** to detect a handpiece.

- Tap **Cancel** to return to the Serial Number entry screen and check that the serial number you entered is correct.



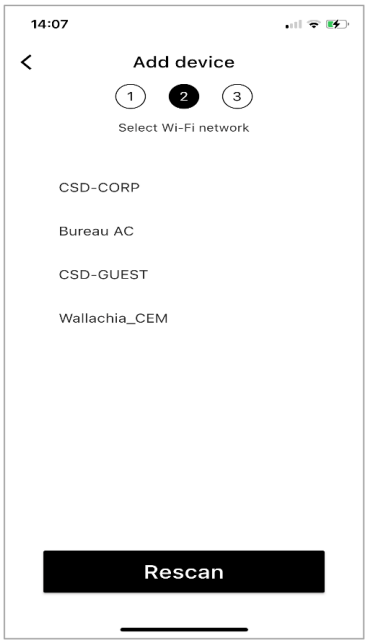
When the handpiece is detected, the application displays a green icon.

8. Tap **Next** to start searching for Wi-Fi networks for the handpiece.

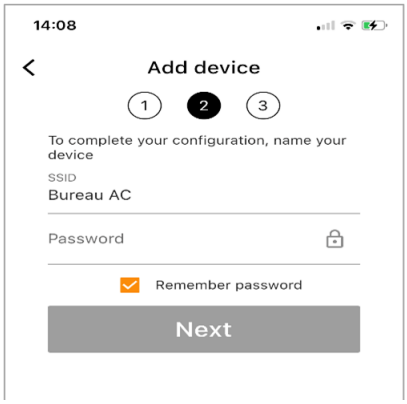


After few seconds, a list of available Wi-Fi networks display.

If a Wi-Fi network on the list is already connected to the mobile terminal, the mobile application will propose the same Wi-Fi network for the handpiece.

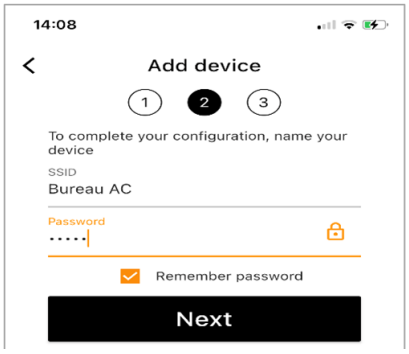


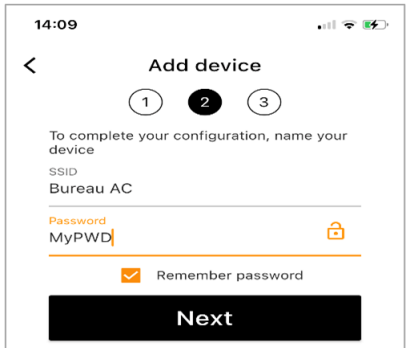
9. Select the Wi-Fi network for the handpiece.



10. Enter the password and tap **Next** to start the Wi-Fi network configuration.

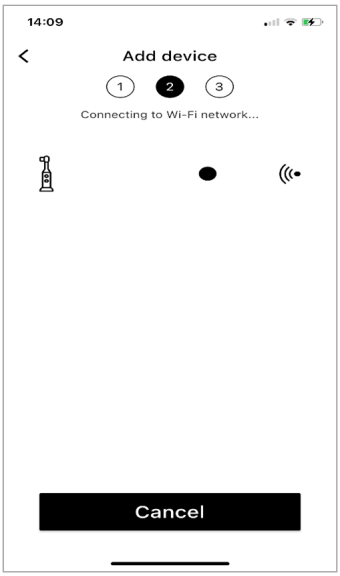
Tap to hide or show the password.

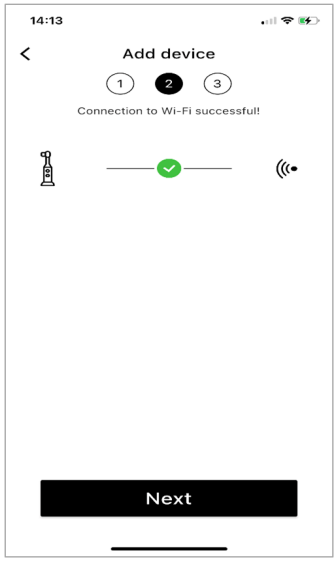




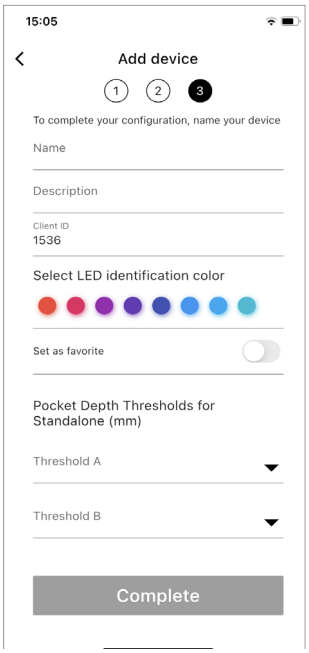
A configuration progress animation appears.

When the handpiece is configured, the application displays a green icon.





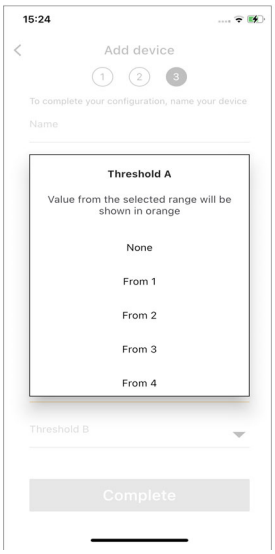
11. Tap **Next**. The following screen displays:

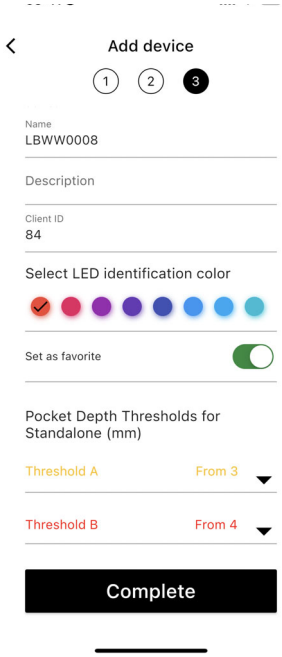


12. Enter all the additional information:

- Name: A nickname to easily identify your handpiece in the mobile application
- Description: Personal information (location)
- Client ID: To filter the handpieces in your establishment
- Select LED identification color: Select the color that you want for your handpiece
- Set as favorite: To specify the handpiece as your favorite
- Pocket Depth Thresholds for Standalone (mm): The visual indicator for **Pocket Depth Threshold A** and **B** for the Standalone mode. The selection that you make will set the visual threshold indicator on the handpiece.

  Click ▼ to set and select the value of the threshold for the pocket depth.

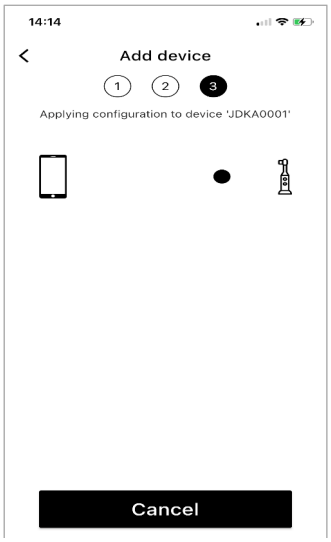


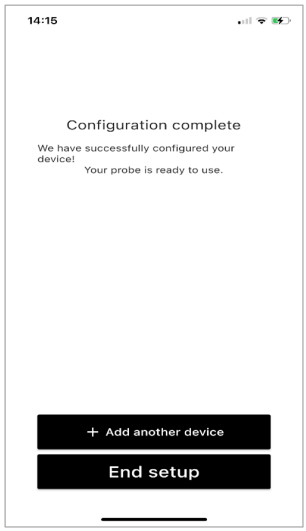


13. Tap **Complete**.

    A progress animation appears for the handpiece configuration.

    A notification is displayed when the handpiece configuration is completed.





14. Tap **End setup** to return to the homepage or tap **Add another device** to start configuring another handpiece.

Managing User Profile

To be able to perform an exam, you must generate a user profile.

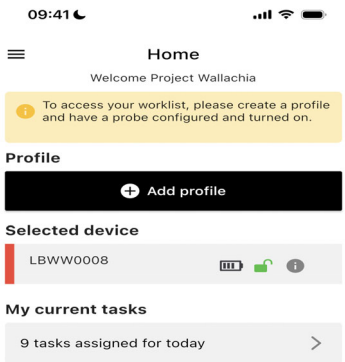
A user profile is linked to a mobile terminal. You must not use the same user profile for different mobile terminals.

You must create a new user profile to use another mobile terminal.

Creating a User Profile

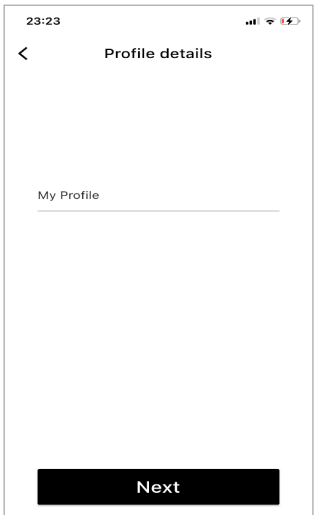
To create a user profile, follow these steps:

1. Tap **Add profile** on the homepage screen.



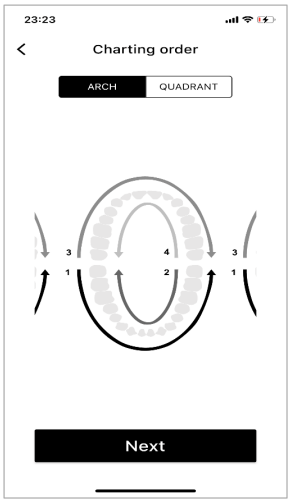
A new page displays asking you to specify a profile name.

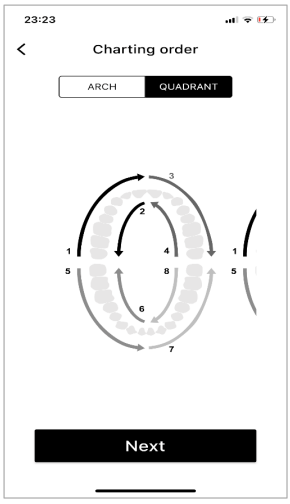
2. Enter a profile name and tap **Next**.



3. Select a charting order of your preference and tap **Next**.

   The application will propose four **Arch** investigation options and two **Quadrant** investigation options.

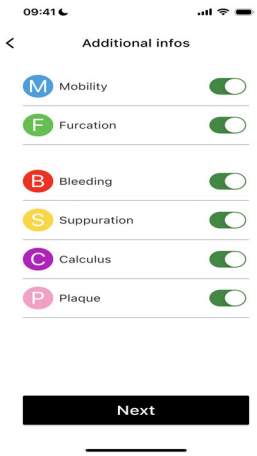




4. **Enable** or **Disable** periodontal charting additional options according to your preference and tap **Next** to continue.

   The mobile application allows you to toggle six additional periodontal information:

   - Mobility: Tooth displacement beyond normal physiological boundaries
   - Furcation: Bone loss at the branching point of a tooth root
   - Bleeding: Sign of periodontal inflammation
   - Suppuration: Local accumulation of pus in the tissues
   - Calculus: Hardened dental plaque
   - Plaque: Localized bacterial biofilm

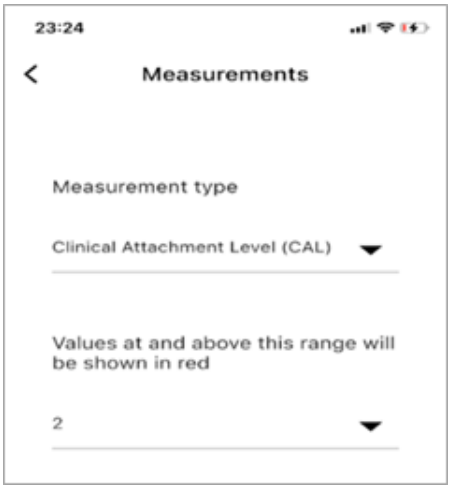


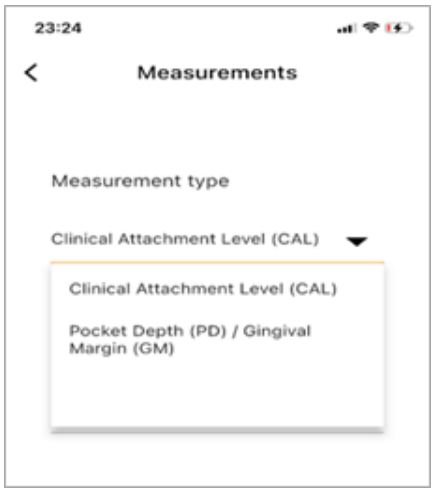
5. Select a measurement type.

   The mobile application enables you to record two types of periodontal measurements:

   - Clinical Attachment Level (CAL)
   - Couple Pocket Depth (PD) and Gingival Marin (GM)

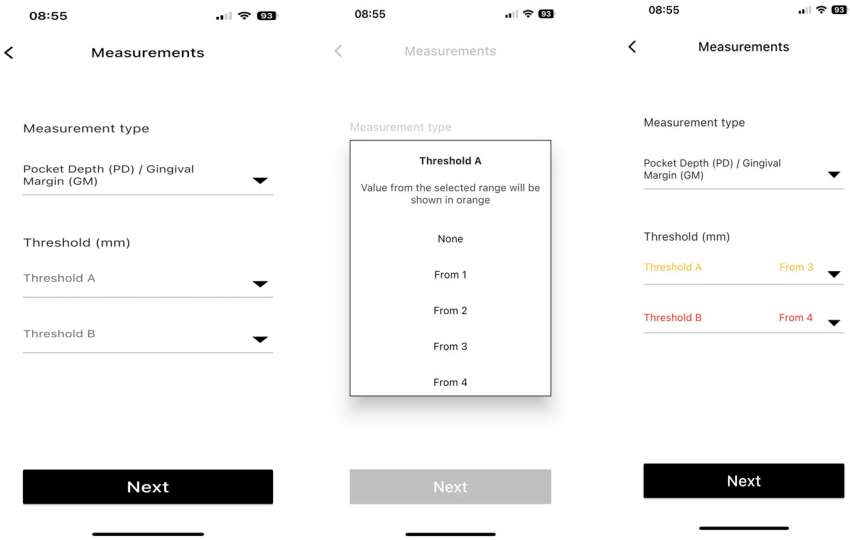
   The type of measurement that you select will impact the measurement information that displays during the periodontal exam.





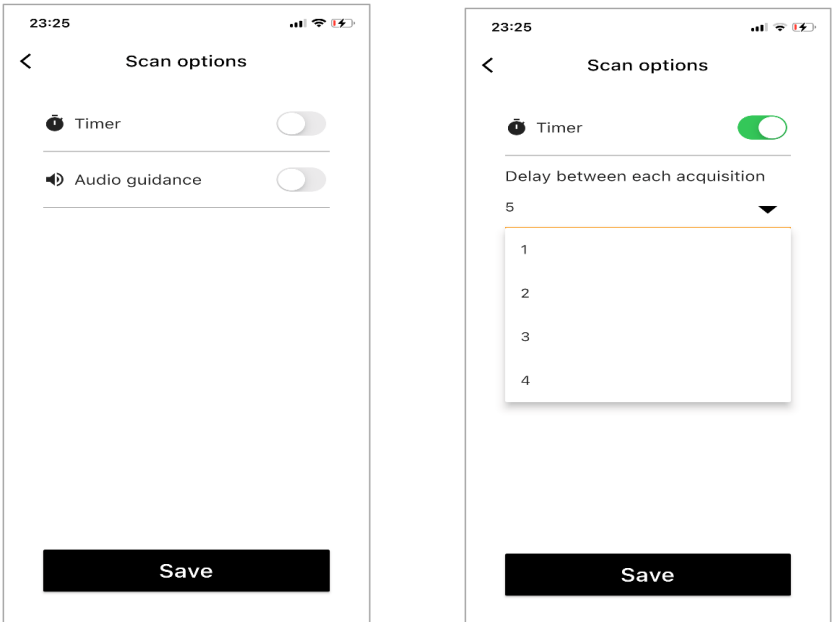
6. Select the thresholds for anomaly notification and tap **Next**. Specify your periodontal thresholds for your guided procedures (paired to your mobile terminal)

   The mobile application will use visual effects to notify the presence of an anomaly according to the threshold value that you select.



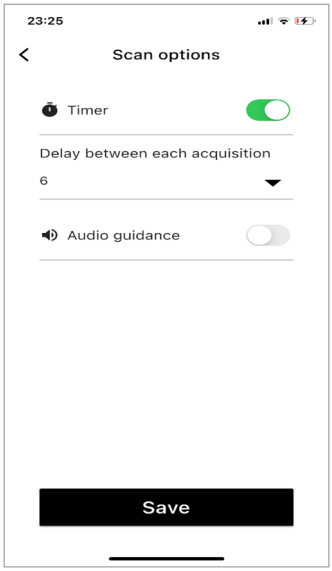
7. Toggle to enable or disable the **Timer** delay option and specify a delay value.

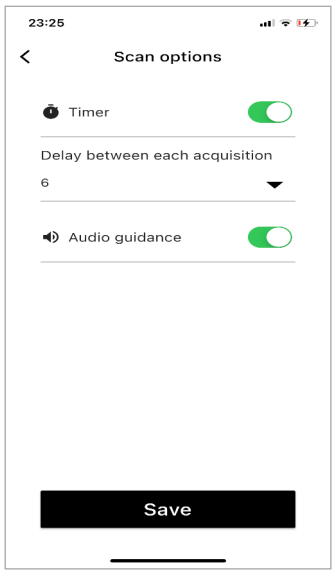
   The timer automatically launches the next measurement if there is a delay during the periodontal exam.



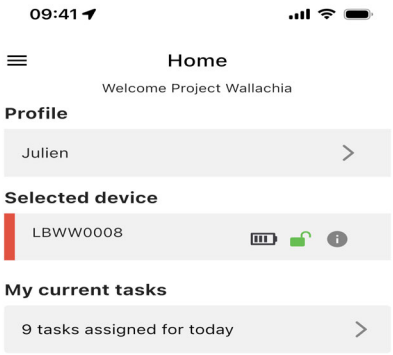
8. Toggle to enable or disable the **Audio guidance** mode, then tap **Save** to complete the user profile creation.

   The audio guidance mode enables the voice guidance function during the periodontal exam.





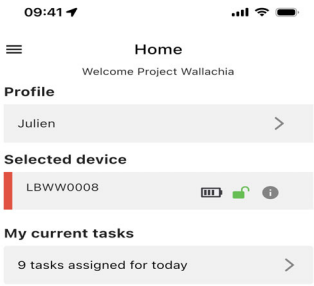
The homepage displays the current selected user profile in the **Profiles** section.



Editing / Deleting an existing User Profile

To edit or delete an existing user profile, follow these steps:

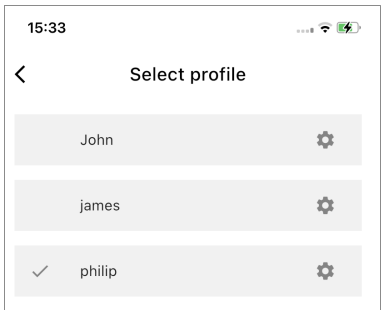
1. Go to the homepage.



2. Tap if you want to edit the current profile. The **Edit profile** page displays. See Step 5.

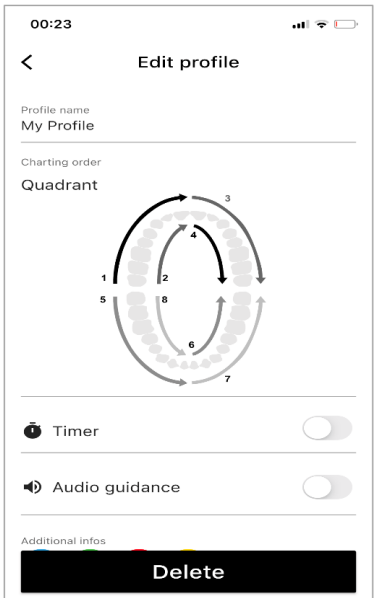
3. Tap on the profile field if you want to see a list of available profiles.

A list of available profiles displays with a check sign beside the active profile:

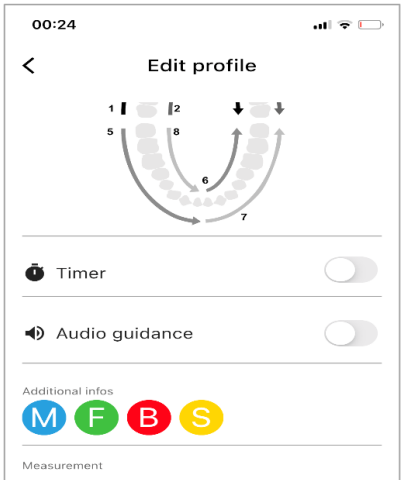


4. Select the profile that you want to edit and tap . The edit profile page displays.

5. Edit the user profile parameters.



6. Tap **Delete** if you want to delete the user profile definitively.



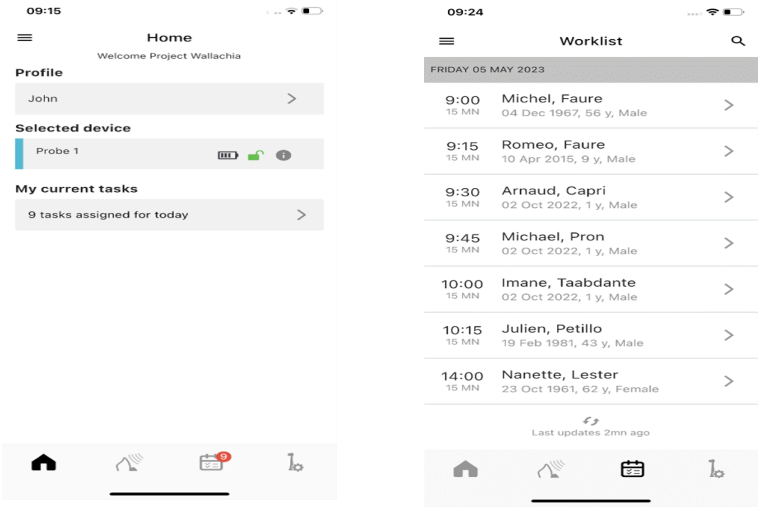
7. Tap to save the modification and to return to the user profile selection list.

7 Managing the Working/Appointment List

Appointment List

To manage the appointment list, follow these steps:

1. From the homepage, tap **Worklist** to display the appointments list.

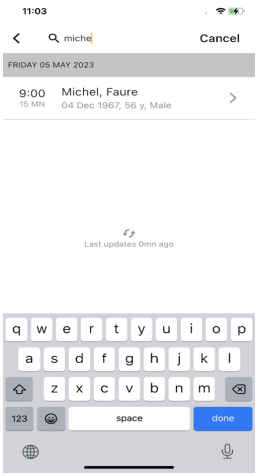


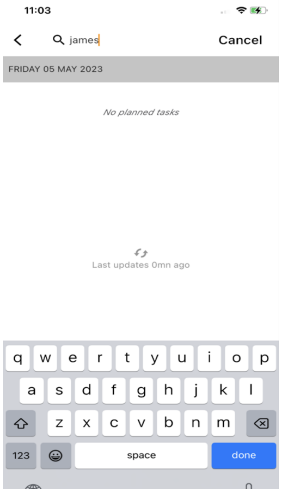
The patient appointment list displays, including the following information:

Patient's personal information:	Appointment details:
- Last name - First name - ID - Age - Gender	Date Time Duration

You can filter the working list using the search engine.

To proceed, tap 🔍 and enter the filtering characters.

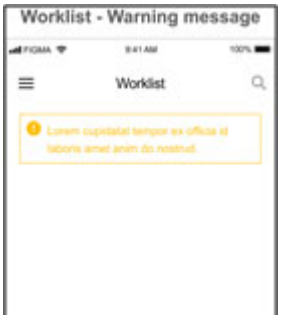


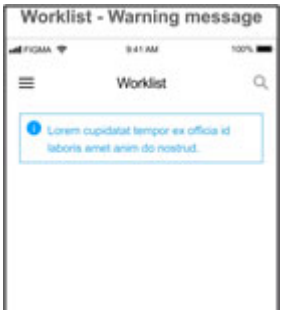


The patient appointment appears together with details of the task.

If the name you entered is not in the database, no results will appear.

If there are errors that need to be shared with the operator, the application displays text messages that describe the error.

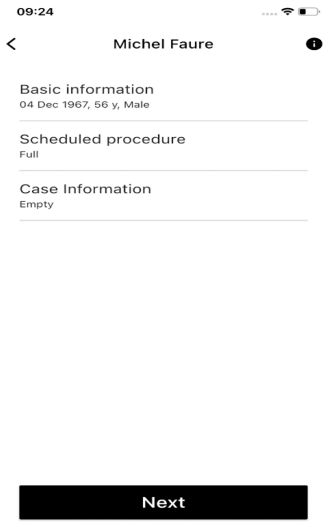




Patient Selection

To select a patient, follow these steps:

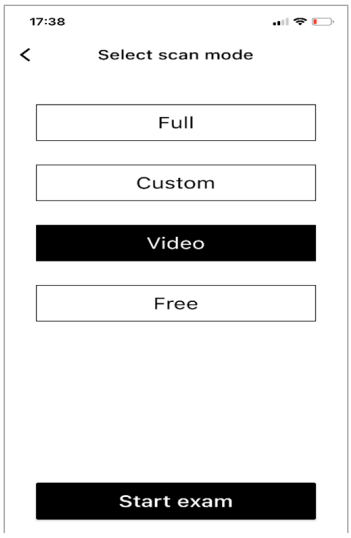
1. Tap to select a patient appointment.



Details on patient appointment information displays:

- Patient personal information
- Scheduled scan procedure
- Case information

2. Tap **Next** to display the scan mode selection page.



8 Setting Up the Handpiece

To set up the handpiece for a periodontal measurement acquisition, you must apply the:

- Intraoral ultrasound gel, or
- Hydrogel

Important: You MUST wear gloves (not provided).

Using the Intraoral Ultrasound Gel

Important: You must:
- **Use consumables according to the manufacturer instructions for use.**
- **Handle the consumables according to standard operating procedures.**

To use the ultrasound gel, follow these steps:

1. Open the packet.

2. Apply an adequate quantity of the gel on the active surface of the SonoChart handpiece head.

   The SonoChart handpiece is now ready for use.

Note: You can, if needed, add more gel during the acquisition.

Using the Hydrogel

To use the hydrogel, follow these steps:

1. Open the gel packet and take out the hydrogel.

2. Press and push the hydrogel gently over to completely cover the handpiece head.

The SonoChart handpiece is now ready for use.

9 Acquiring Periodontal Measurements

The mobile application panel provides access to the following acquisition protocol modes:

- **Full scan mode**: This procedure enables you to scan the teeth according to the user's profile preferences. Additional information for each tooth can be made following an ultrasonic acquisition.
- **Video scan mode**: This procedure is a conventional ultrasonic acquisition that allows you to view the ultrasonic video flow on the mobile terminal.

In addition, the Wallachia portable handpiece can also be used while disconnected from any portable handpiece:

- **Autonomous mode**: This procedure enables you to perform periodontal measurements without being connected to a mobile terminal. Measurements are displayed live on the handpiece display screen.

  Autonomous mode with remote display: The handpiece display screen can also be optionally displayed on a paired mobile terminal (remote display).

Preparing for Acquisition

To prepare the handpiece and the patient for acquisition, follow these steps:

1. Disinfect the handpiece head.

   See the ***SonoChart Safety, Regulatory and Technical Specifications User Guide (SMA87) Ed01*** for more information on disinfection.

2. Fit the wrist strap to the handpiece.
3. Switch on, configure and connect the handpiece to the Wi-Fi. See "Handpiece Configuration" .
4. Wait for the handpiece to calibrate. It will vibrate when ready.
5. Set up the handpiece. See "Setting Up the Handpiece" .
6. Go to the mobile application interface.
7. Login in to your account. See "Managing User Profile" .
8. Tap on the Working List icon to find the existing patient.
9. Select the patient.
10. Ask the patient to lie down on the dental chair.

Full Scan Mode

The full scan periodontal checkup procedure can be implemented in two phases:

- Phase I: Allows you to specify additional information for each tooth (mobility, bleeding, suppuration, calculus, plaque, furcation).
- Phase II: Allows for the periodontium measurement of the ultrasonic acquisition.

Acquiring a Full Scan Mode Periodontal Measurement

Before you acquire a full scan mode periodontal measurement, you must first prepare for acquisition. See “Preparing for Acquisition” .

Selecting the Full Scan Mode

To select the Full Scan mode, follow these steps:

1. On your mobile terminal screen, select **Full**, then tap **Next**:

The charting panel displays.

2. Ask the patient to open the mouth.
3. Position the handpiece in the patient mouth at the area of interest.

4. Tap **Start scan**.

Modifying the Full Scan Mode Settings

The settings follow the user profile parameters by default.

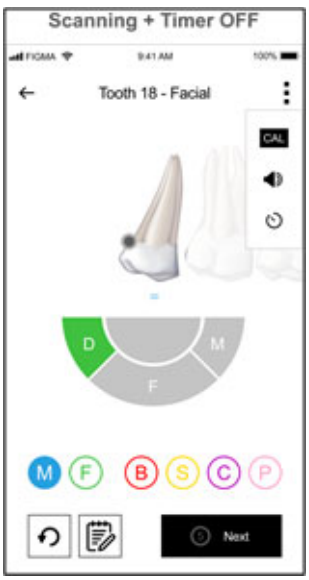
To modify the full scan mode settings, follow these steps:

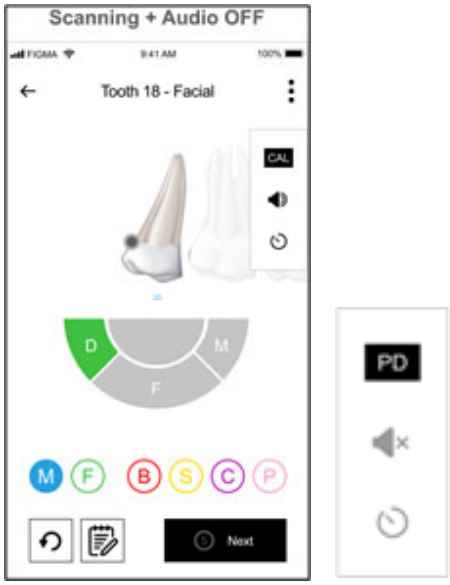
1. From the charting panel, tap **Start scan**.

   The scanning panel displays. You can edit the settings if needed.

2. Tap .

The settings menu displays.





- Tap to enable the audio guidance mode or to disable it.
- Tap to enable the timer delay or to disable it.
- Tap **CAL** to acquire clinical attachment loss.
- Tap **PD** to acquire Periodontal Depth measurement.

Adding Periodontal Additional Information

After you chose the full scan mode, the **Charting** menu displays.

To add periodontal additional information, follow these steps:

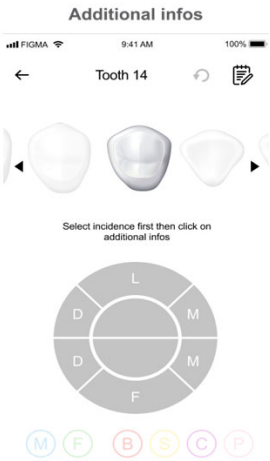
1. Tap **Start Scan** to start the acquisition.

When entering the **Full mode exam**, the additional information window displays. You can add, for each tooth, information on mobility, bleeding, suppuration, calculus, plaque or furcation.

2. Tap **Yes** if you want to add information or tap **Skip** to open the scanning panel.

The periodontal charting panel displays.

3. Select the tooth for which you want to add information.

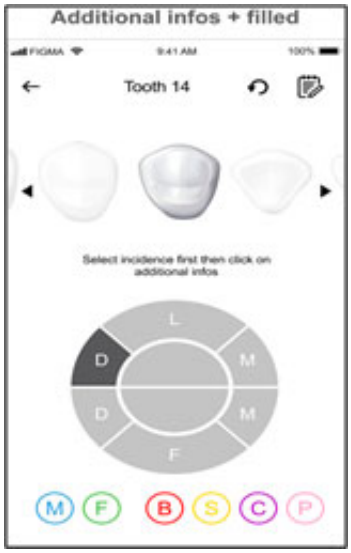


For each tooth, the software can manage up to six different incidences:

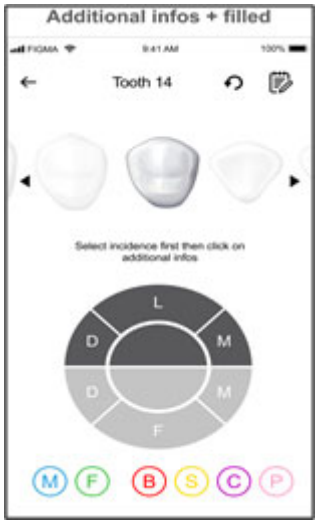
- Vestibular: Medial measurement
- Vestibular: Central measurement

- Vestibular: Distal measurement
- Lingual: Mesial measurement
- Lingual: Central measurement
- Lingual: Distal measurement

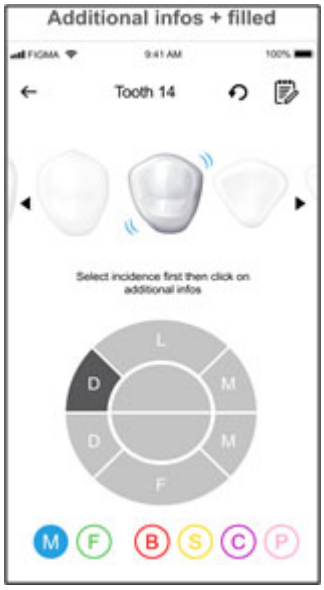
4. Select an incidence, then click on the information you want to add.



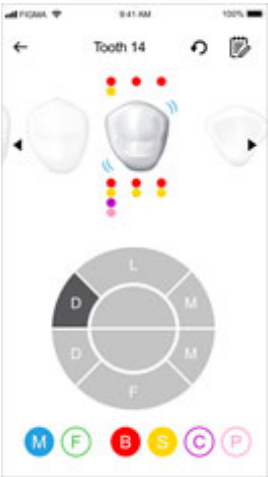
Tip: Click on the middle button to select all incidences at once.



5. Tap on the **Add information** icons to add the information.



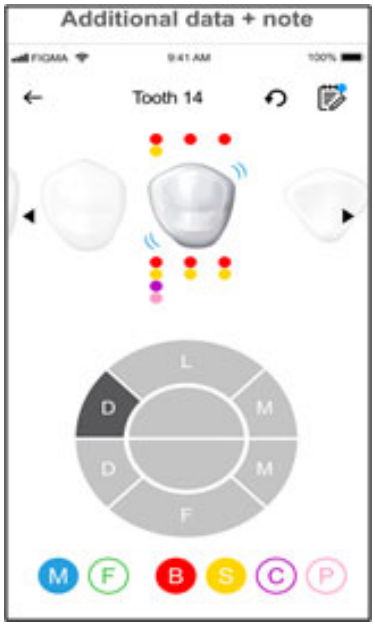
Tap to add, edit, or delete a note.



You can:

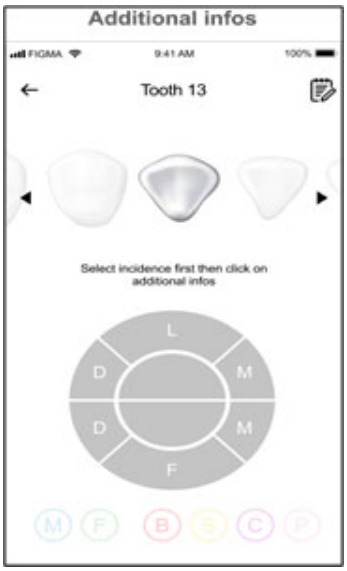
- Write a note.
- Tap **Save** to record the note.
- Tap **Cancel** to leave the note unchanged.
- Tap **Delete** to delete the note.

A notification appears on when a note is saved.

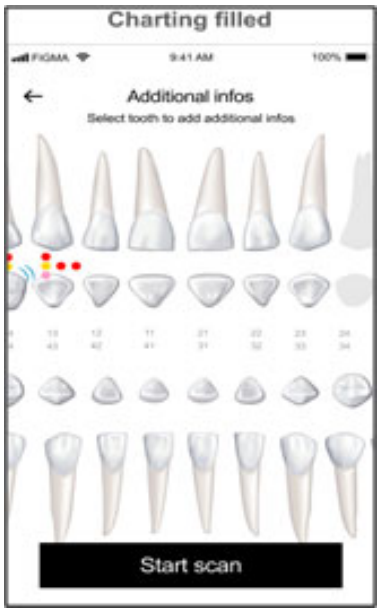


6. Tap to move to the next tooth.

The additional information for the next tooth displays:

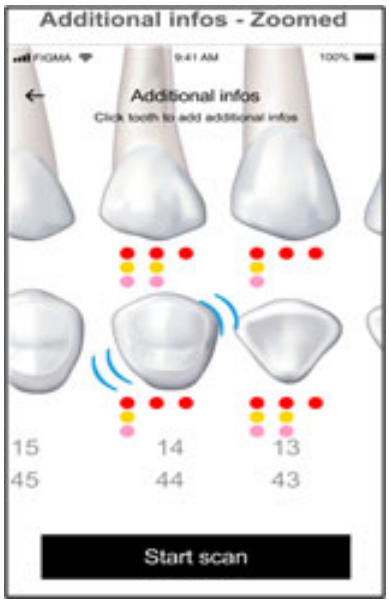


7. Tap ← to open the scanning panel.



The completed charting panel displays.

You can zoom in for more clarity.



Full Scan Acquisition

To carry out a full scan acquisition, follow these steps:

1. Tap **Start scan** to start the acquisition.

For each tooth, the software can manage up to six different incidences:

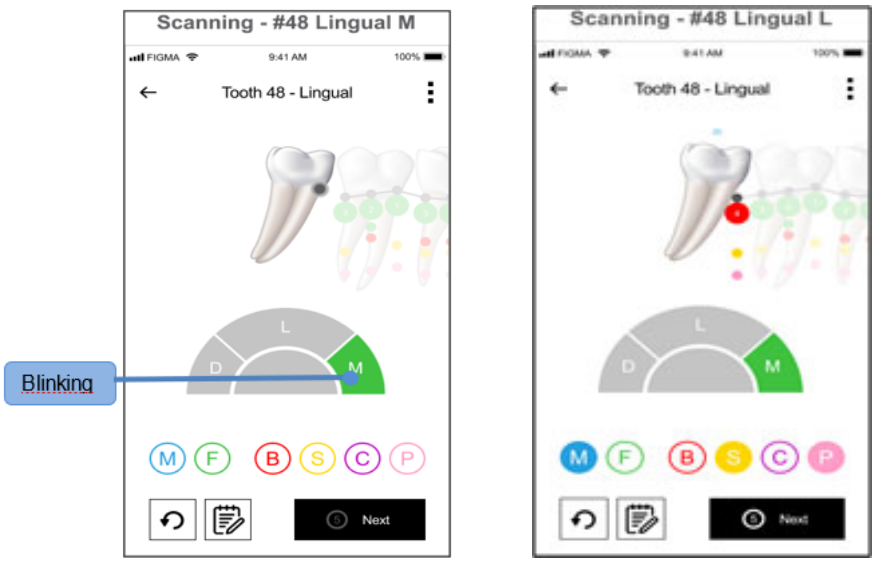
- Vestibular: Medial measurement
- Vestibular: Central measurement
- Vestibular: Distal measurement
- Lingual: Mesial measurement
- Lingual: Central measurement
- Lingual: Distal measurement

According to your user profile, the periodontal procedure will guide you through the tooth per tooth approach. See Creating a User Profile.

The mobile terminal will display the current tooth incidence: the tooth number and the expected incidence (Mesial, Central or Distal).

Vestibular Distal Measurement:

Lingual Mesial Measurement:



Current incidence blinks during acquisition.

Values will appear in red when it exceeds the settled threshold.

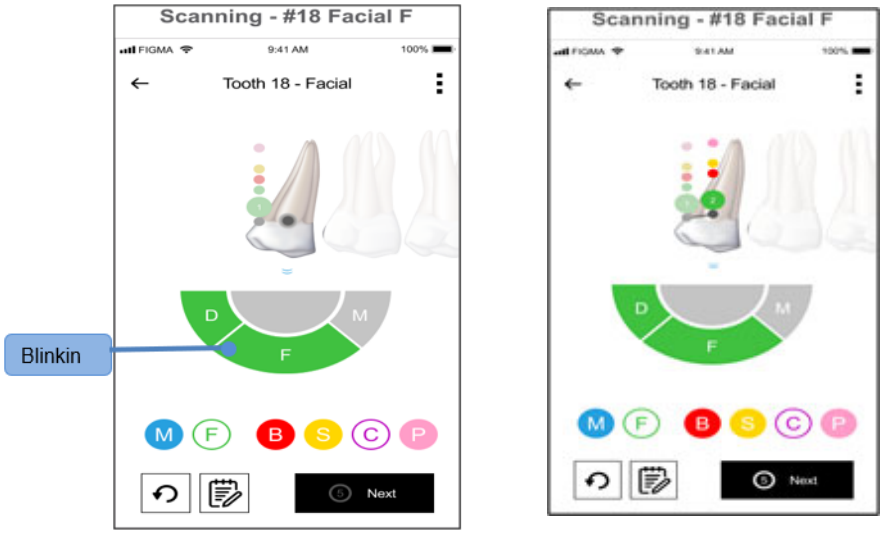
> **Tip:** You can select directly, without waiting, the incidence you want to measure by tapping the corresponding letter.

2. Tap **Next** to go to the next measurement.

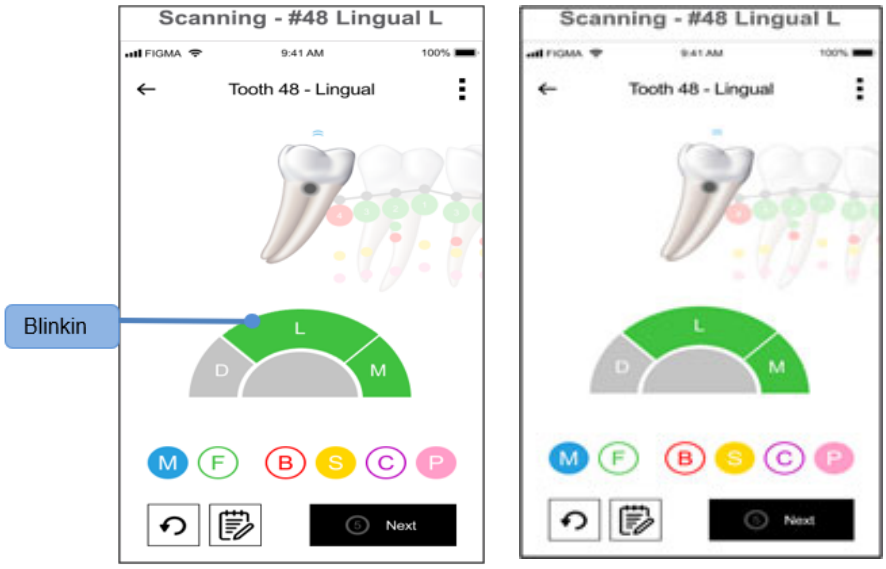
   You can set your timer to automatically go to the next measurement during the periodontal exam.

   The current incidence blinks during acquisition.

   Vestibular Facial Measurement:



Lingual Facial Measurement:



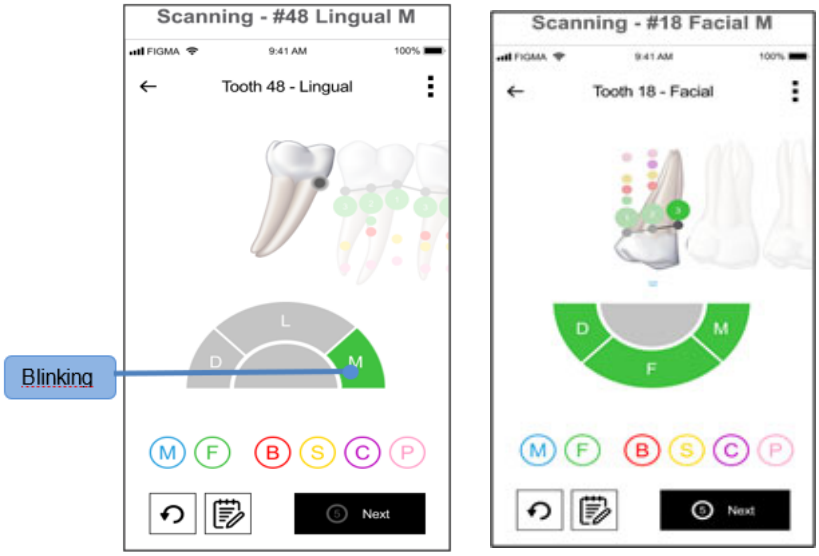
3. Tap **Next** for the next measurement.

According to your Timer settings, you can automatically go to the next measurement after a pause during the periodontal exam.

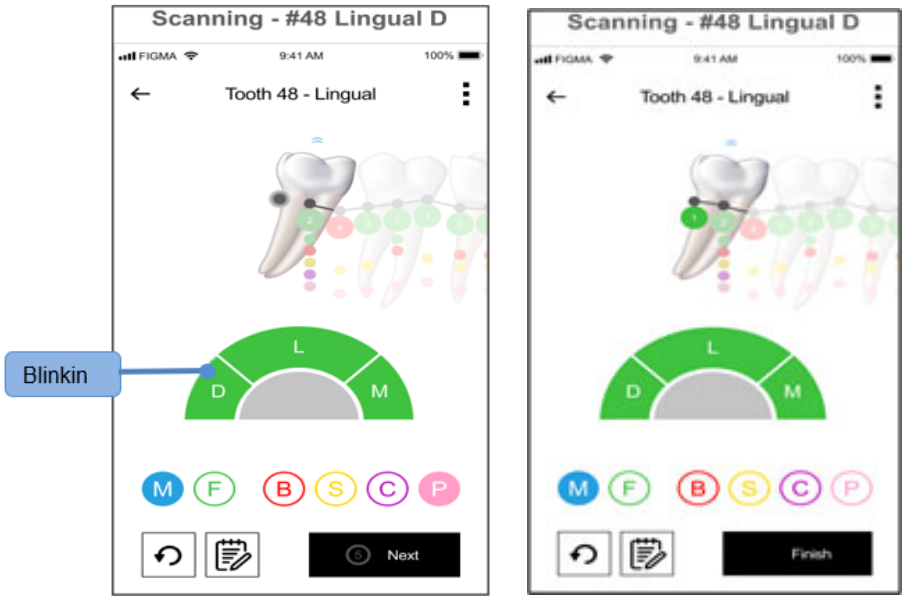
For example, you can skip a given incidence (without taking a measurement) by tapping **Next**.

The current incidence blinks during acquisition.

Vestibular Mesial Measurement:



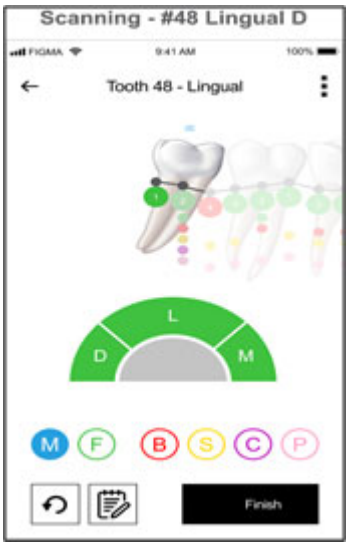
Lingual Distal Measurement:



Full Scan Charting

Charting Display

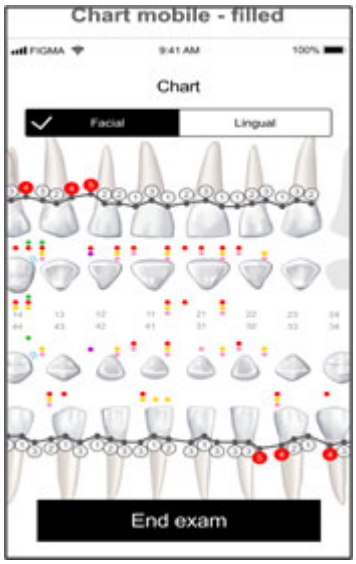
At the end of the acquisition and at end of the quadrant you will reach the Finish button:



To display a chart, follow these steps:

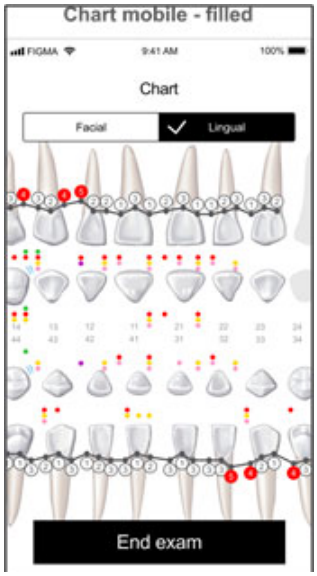
1. Tap **Finish** to go to the chart that you filled.

   The facial view chart of the periodontal charting displays:

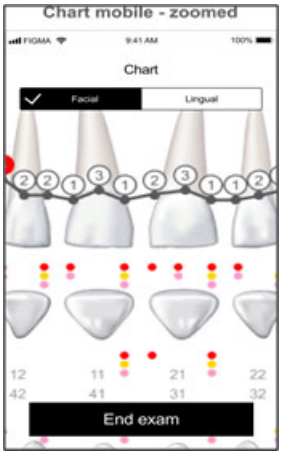


2. Tap **Lingual** to go to the lingual view chart.

   The lingual view chart displays:



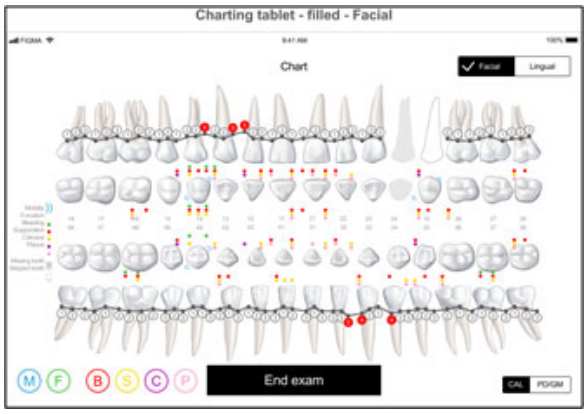
   You can zoom in to the chart:



For each incidence on a tooth, you can acquire:

- A Periodontal Depth (PD) measurement.
- A Gingiva Margin (GM) measurement.
- The Clinical Attachment Level (CAL) of the gingiva.

A facial chart on a tablet screen that is filled:



A lingual chart on a tablet screen that is filled:

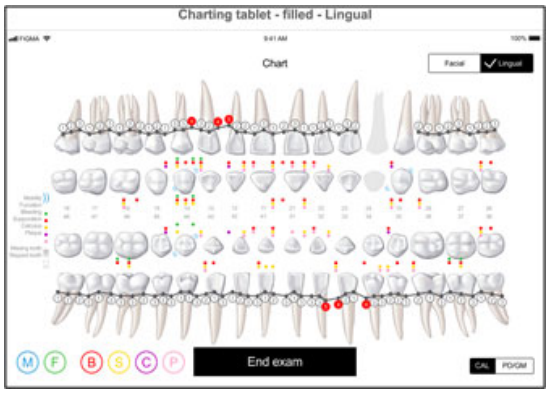
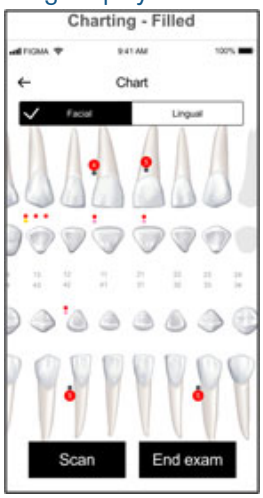


Chart Editing

To edit charting, follow these steps:

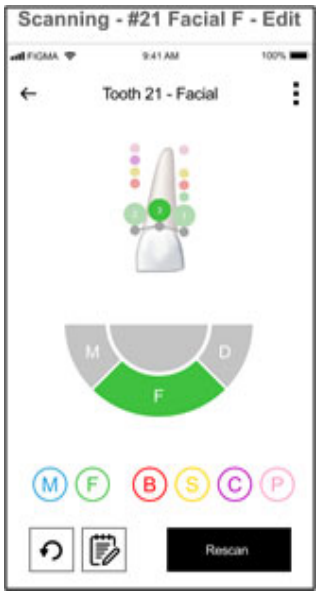
1. Go to Charting Panel. See "Charting Display" .



2. Click on the tooth you want to edit from the Charting panel.

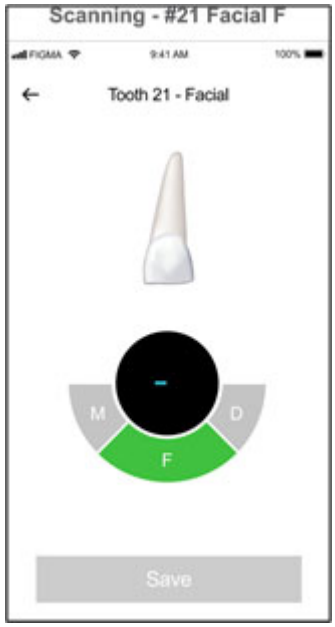
   The selected tooth panel displays:

3. Select the incidence that you want to edit or tap to select all incidences at once.



4. Tap **Rescan** to do a new measurement.

   The Rescan panel displays:



The new detected value displays:

5. Tap **Save** to register the new value.

   The recorded value displays:

Tap to add a note if needed.

A notification appears on when a note is saved.

6. Tap .

The **Reset confirmation** panel displays. You can:

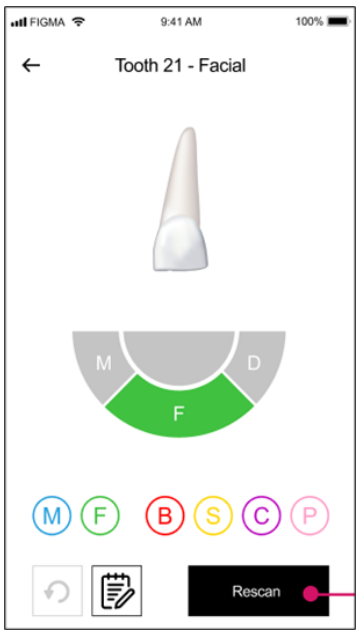
- Reset measurement
- Reset additional information
- Reset both
- Cancel reset

7. If you want to reset both, tap **Reset both**.

   The **New measurement** panel displays:

8. Select an incidence.

   The additional information icons are highlighted. Tap on the icons that you want to add.



9. To do a new measurement click **Rescan** and follow **Step 4** above.

   Tap ← to go to **Edited charting**.

   The edited charting panel displays:

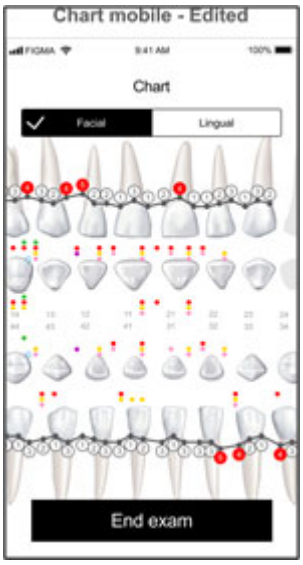


Chart mobile - Edited
FIGMA
9:41 AM
100%
Chart
Facial
Lingual
End exam

Video mode

Acquiring a Video Mode Periodontal Measurement

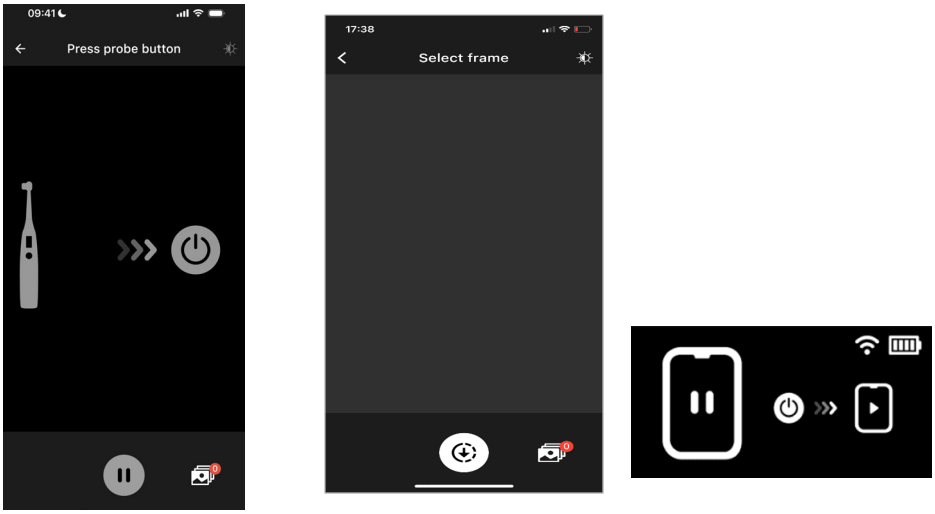
Before you acquire a full scan mode periodontal measurement, you must first prepare for acquisition. See “Preparing for Acquisition” .

Acquiring a Video

To acquire a video flow, follow these steps:

1. On your mobile terminal screen, select **Video** and tap **Next**.

The video mode frame displays on the mobile terminal screen. The handpiece screen positions to video mode:

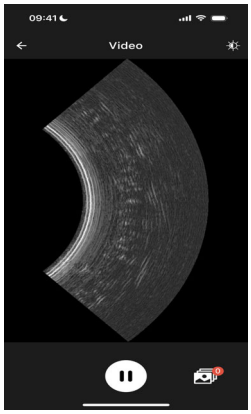


2. Ask the patient to open the mouth.
3. Position the handpiece in the patient mouth at the area of interest.

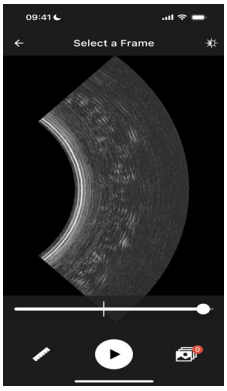
4. Tap or click the handpiece ON/OFF button to activate the video.

   On the mobile terminal screen: the ultrasonic video displays.

   On the handpiece: triggers a sound and vibrates to indicate that acquisition is in progress. An animate on the handpiece screen indicates that the handpiece is acquiring ultrasonic video frames.



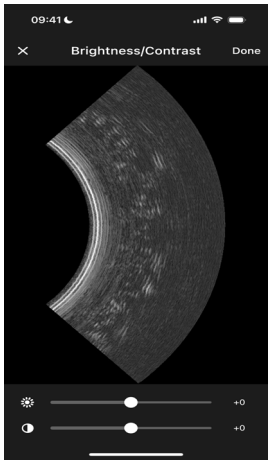
5. Tap or click the handpiece ON/OFF button to pause the video flow.



After you pause the video flow, you can review any part of the last 15 seconds by moving the timeline cursor.

6. Using the timeline cursor, select the relevant frame of interest.

7. Tap to adjust the brightness and the contrast of the frame.



Periodontal Measurement Tool

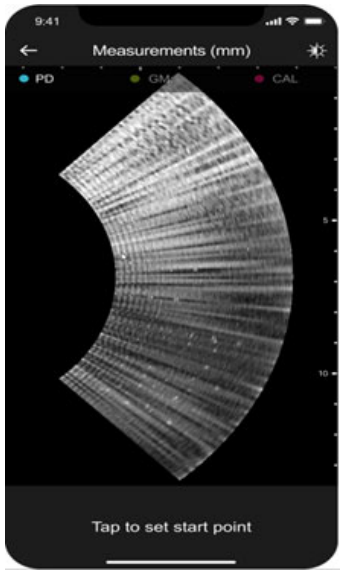
To carry out a periodontal measurement, follow these steps:

1. Tap on the selected frame.

   The measurement tools opens on the selected frame.

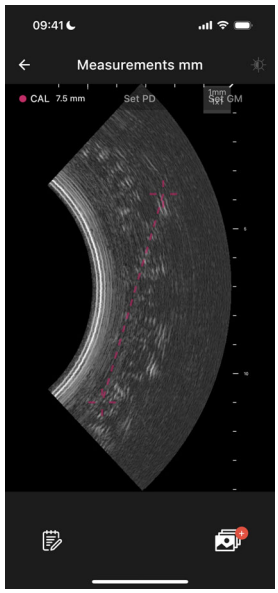
   The Pocket Depth (PD) measurement is selected by default.

   If needed, you can select another periodontal measurement type by tapping on the abbreviation: Pocket Depth (PD), Gingival Margin (GM) or Clinical Attachment Level (CAL).



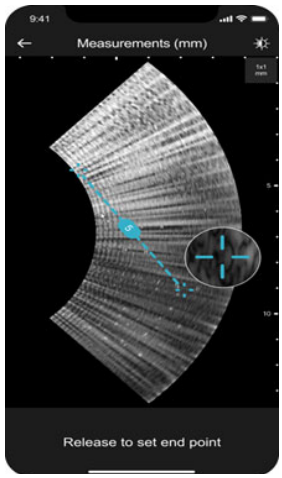
2. Press and on the image to set the starting point of the segment that you want to measure.

   A highlight mechanism with zoom in effect will help you to better position the starting point.

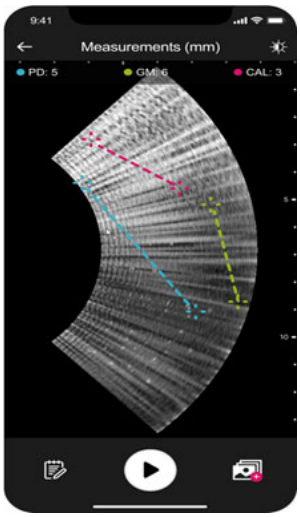


3. From that point, drag and drop the cursor to the ending point of the segment that you want to measure.

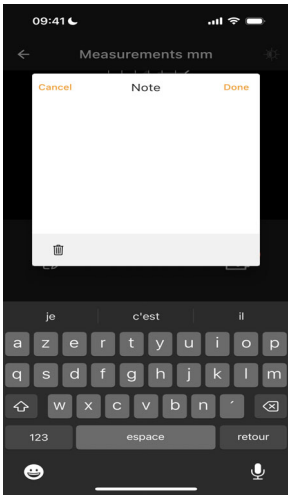
   The segment and the measurement are displayed on the ultrasonic image:



4. Redo steps **1, 2** and **3** of this section to record multiple periodontal measurements.



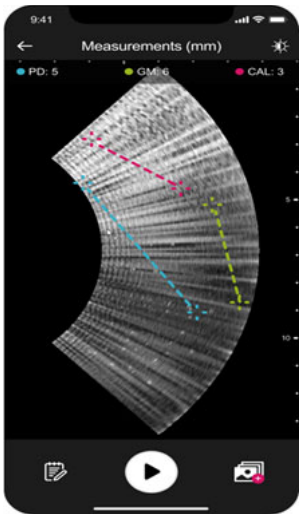
5. If needed, tap to add a note for that frame.



Tap **Cancel** to return to the previous screen without saving the note for the frame.

Tap **Save** to return to the previous screen and to save the note for the frame.

A blue mark appears on when a note is saved.

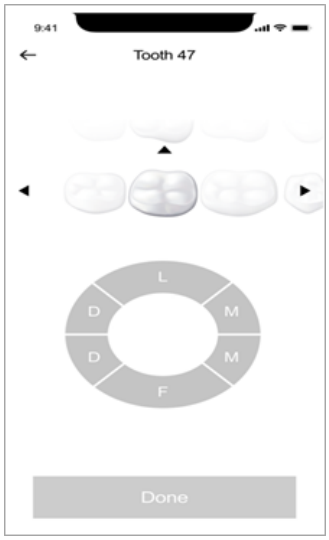


Saving a Frame Context in the Mobile Application Gallery

To save a frame context in the mobile application gallery, follow these steps:

1. Tap to save the contexts (images, notes and measurements) of the frame to the mobile application gallery.

   A tooth selector tool displays:



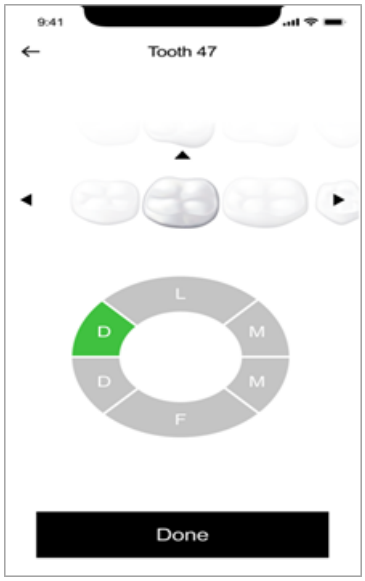
2. Toggle right, left, up or down to select the tooth of interest for which you want to save the current context (image, note and measurements) to the mobile application gallery.

   The selected tooth of interest and number is displayed on the top of the frame.

3. Select the incidence for which you want to save the current context (image, note and measurements) to the mobile application gallery.

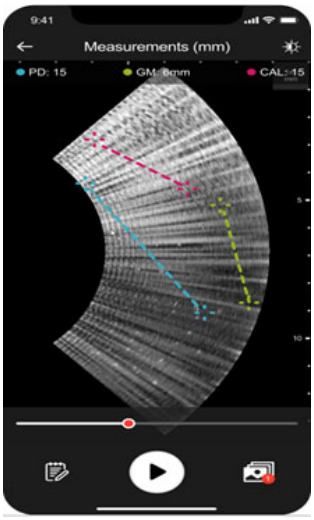
You can select up to six incidences:

- Vestibular: Mesial (M) measurement
- Vestibular: Central (F) measurement
- Vestibular: Distal (D) measurement
- Lingual: Mesial (M) measurement
- Lingual: Central (L) measurement
- Lingual: Distal (D) measurement



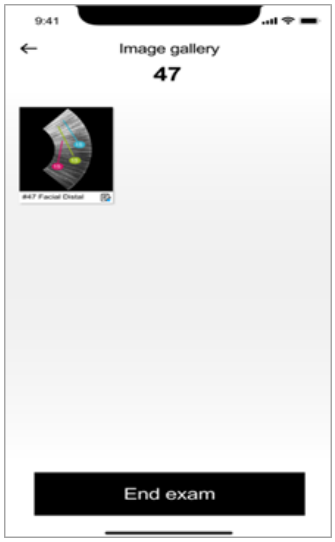
4. Tap **Done** to save current context.

   The application redirects to the video frame selection page and the gallery notification number increases by one (+1).



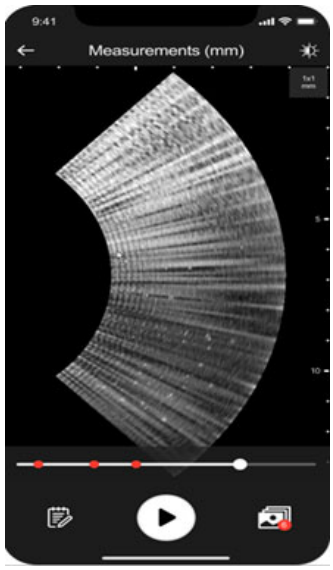
5. Tap to access the mobile application gallery to review the saved contexts.

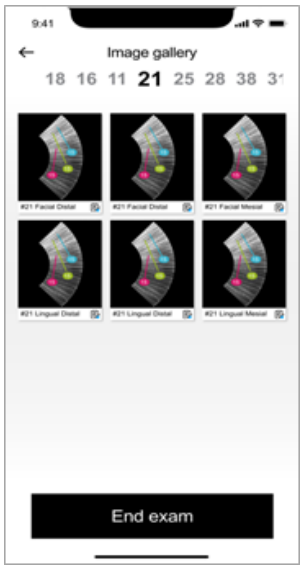
The image gallery displays:



For multiple saved contexts:

- Individual frames of interest are highlighted in red on the video frame selection page.
- Contexts saved in the mobile application gallery are grouped by tooth numbers.
- You can toggle to the right or left to swap the tooth number in the mobile application gallery.

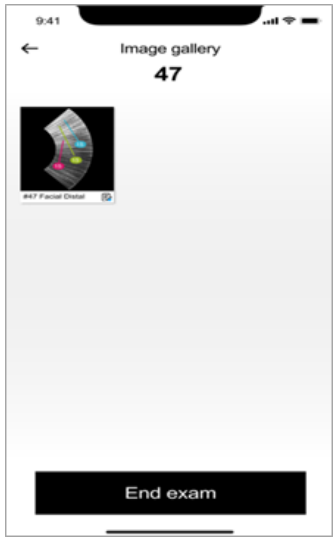




Exporting results outside the mobile application

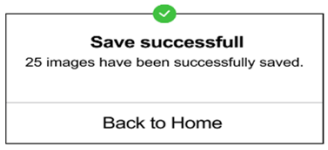
To export results outside the mobile application, follow these steps:

1. Tap **End exam** in the image gallery.



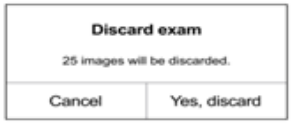
The gallery End exam panel displays with two choices: **Save all images** and **Discard exam**.

2. You can either select **Save all images** to save the contexts. The following page displays:



Tap **Back to Home** to display the homepage.

3. Or you can select **Discard exam** to delete them. The **Discard exam** panel displays:



Tap **Cancel** to cancel the discard operation or tap **Yes, discard** to proceed.

Autonomous mode

Acquiring a Autonomous Mode Periodontal Measurement

Before you acquire a full scan mode periodontal measurement, you must first prepare for acquisition. See "Preparing for Acquisition" .

Acquiring periodontal data

To acquire periodontal data without being connected to a mobile terminal, follow these steps:

1. On your mobile terminal screen, press the ON/OFF button to switch on the handpiece.

   The homepage of the handpiece appears on the display screen:

2. Ask the patient to open the mouth.
3. Position the handpiece in the patient mouth at the area of interest.
4. Pres the ON/OFF button again to start the autonomous mode.

   The autonomous page appears on the display screen:

After few seconds of initialization the handpiece will be ready for periodontal measurements.

5. Position the handpiece on soft tissue of the patient.

   The computed measurement for every valid acquisition will be displayed on the on the display screen:

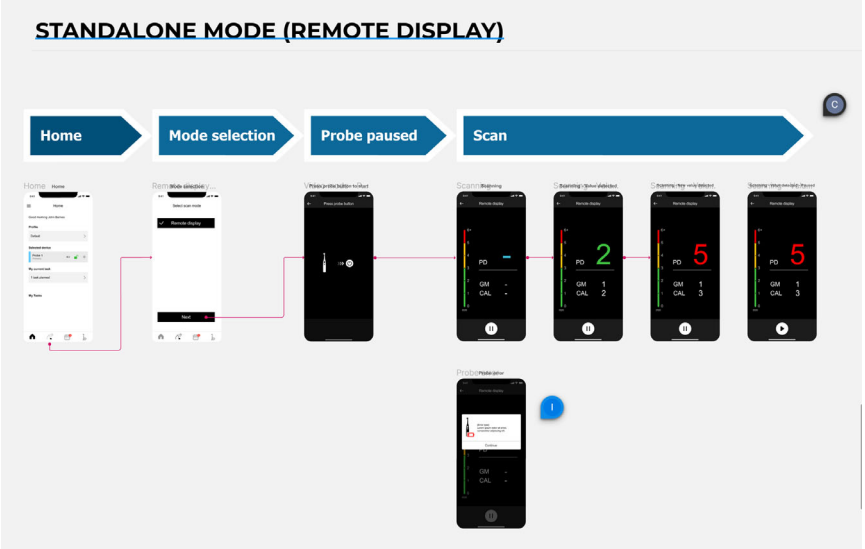
6. Press the ON/OFF button again to pause the autonomous mode.

   The autonomous acquisition process stops:

Note: If you press the ON:OFF button before the 15 seconds of inactivity, it will return to the acquisition mode. To make another acquisition, see **Step 3**.

After 15 seconds of inactivity, the homepage of the handpiece displays and you must go to **Step 2** to start the autonomous mode again:

Autonomous mode with remote display



To acquire periodontal data on a paired remote mobile terminal, follow these steps:

1. Press the ON/OFF button to switch on the handpiece.

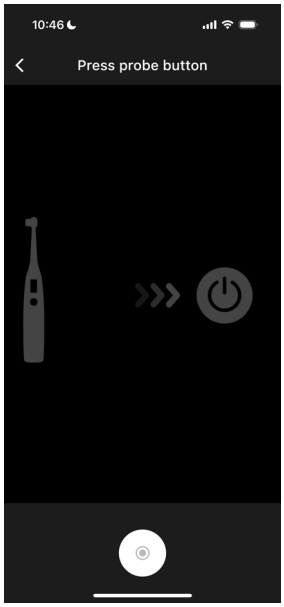
   The homepage of the handpiece appears on the display screen:

2. On your mobile terminal screen, select

   The remote display screen displays:

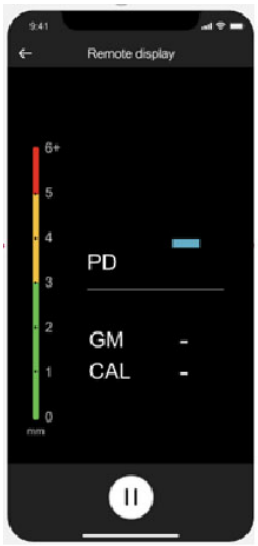
3. Tap **Remote display.**

The **Press probe button** screen appears:



4. Ask the patient to open the mouth.
5. Position the handpiece in the patient mouth at the area of interest.
6. On your handpiece, pres the ON/OFF button again to start the remote acquisition.

The remote acquisition displays on the mobile terminal screen:



10 Maintenance

We recommend a general inspection of SonoChart by an authorized service technician.

During the entire clinical investigation period, the maintenance routine will be managed by Carestream Dental or its subsidiary, Trophy SAS.

No periodic maintenance is required. The system comprises a built-in check-up that will monitor the product performance before each exam.

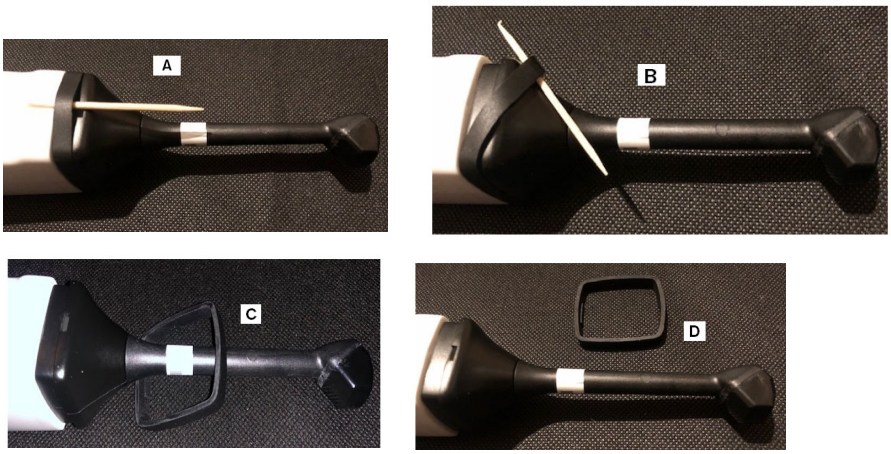
Replacing the Handpiece Head

To replace a defective handpiece head, follow these steps:

1. From the application interface on your mobile terminal, position the handpiece head in the parking position.

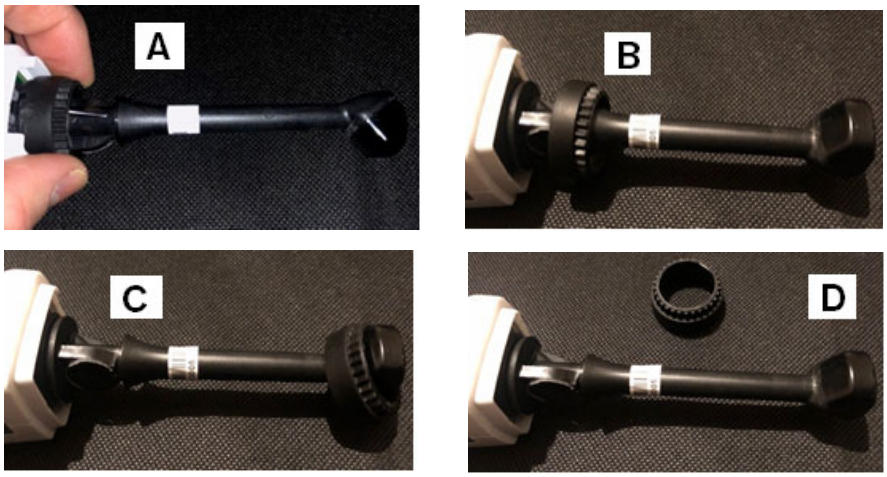
2. On your handpiece, press and hold on the ON/OFF button to switch it off.

3. Remove the seal for the handpiece head using a toothpick.



4. Unclip the intermediate covers and remove them from the base of the handpiece head.

5. Unscrew and remove the handpiece head tightening ring from the base.

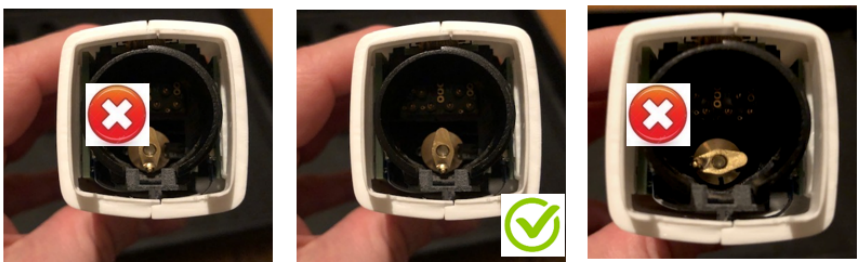


6. Remove the handpiece head from the main handpiece body.

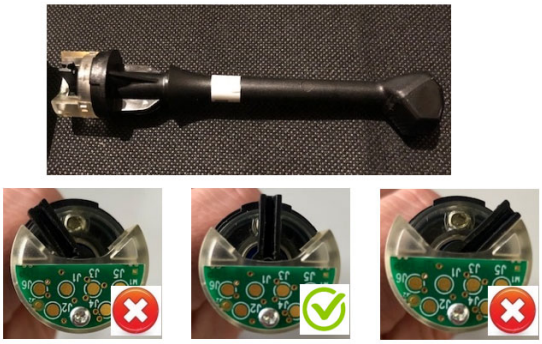
7. Before inserting the new handpiece head, check that the positioner is in the correct position.

   The positioner must be aligned to the insertion guide.

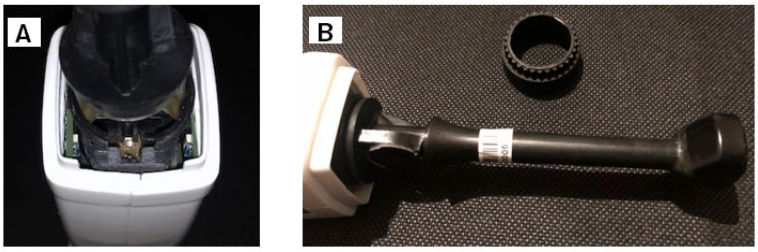
   If it is not, align the positioner and the insertion guide with your finger.



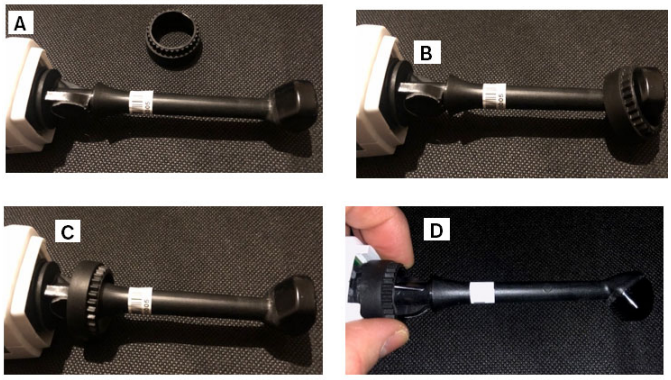
8. Hold the new handpiece head and position the mechanical groove to the center position.



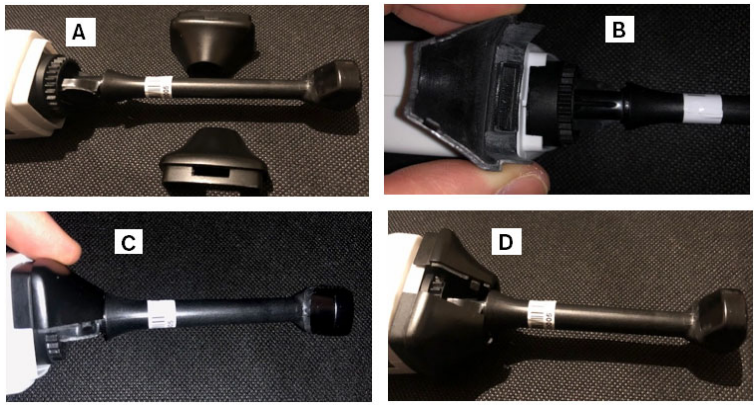
9. Insert the handpiece head into the handpiece body following the mechanical foolproof.



10. Place and screw the handpiece head tightening ring to mechanically block the handpiece head to the handpiece body.



11. Place and clip the intermediate covers to the handpiece head base.



12. Replace the seal for the handpiece head.

The new handpiece head is now replaced and the handpiece is ready for use.

Controlling the Image Quality

SonoChart has an integrally embedded image quality check-up tool.

At each boot-up of the handpiece, the system will control the image quality.

11 Troubleshooting

Incorrect use of SonoChart may result in malfunctions.

The General and Safety recommendations will guide you through the actions that you must take to correct the malfunction.

Important: If the malfunction persists or more serious conditions occur, contact your representative.

When you call your representative, have the following information ready:

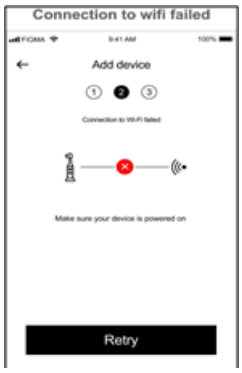
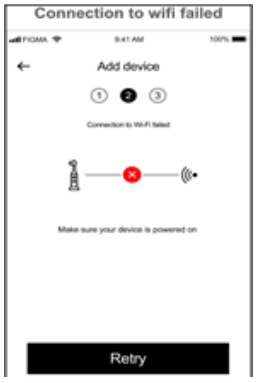
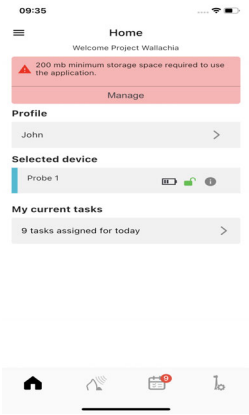
- Model Number: SonoChart
- Error Code Number:
- Message displayed on the popup of the mobile application.
- Handpiece serial number: KAWW0001

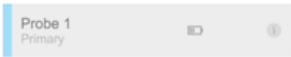
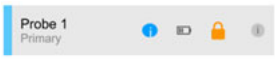
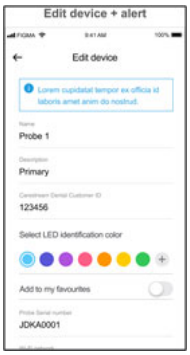
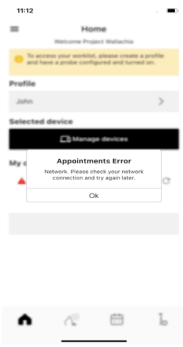
Error List

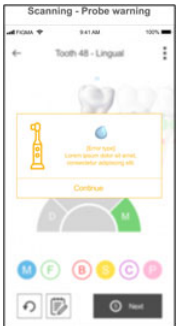
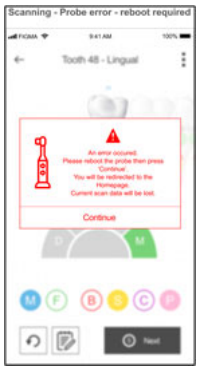
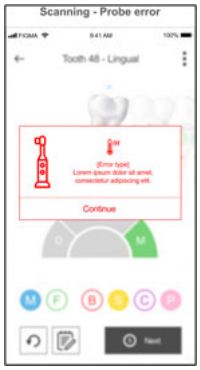
Malfunction	Screen	Possible cause	Action
Handpiece system error		Error occurred during execution	Short press the ON/OFF button to come back to the home screen
Loss of connection		Loss of connection between the mobile terminal and handpiece	Once the re-connection is established, the active screen displays
Missing couplant		Lack of ultrasonic couplant detected	Refill/Change the ultrasonic couplant
Overheating error		Safety temperature reached. System cool down in progress	System will recover once acceptable temperature conditions established
Lost frames		The images are lost.	Call your CSD technician.
Connection error		WCP client is disconnected	Make sure that your handpiece and mobile application are connected to the same Wi-Fi network. Do not leave the video mode panel while scanning.
Reached maximum number of acquisitions		The number of acquisitions has exceeded the limit for unit head replacements (10 000 exams)	What must the user do?
Configuration error		Data have been corrupted on the handpiece	Call your CSD technician.

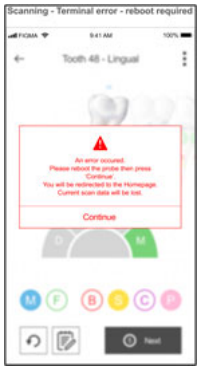
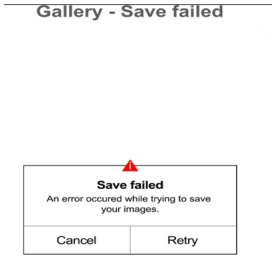
Mobile Application

Handpiece network configuration: Handpiece pairing

Malfunction	Screen	Possible cause	Action
Handpiece network configuration: Handpiece pairing			
Pairing failed		Handpiece not found	Make sure your handpiece is powered on and is nearby. For more information, see **Need help**.
Handpiece network configuration: Handpiece configuration			
Connection to Wi-Fi failed		Handpiece not powered on or is at a distance	Make sure your handpiece is powered on and is nearby. For more information, see **Need help**.
Homepage settings error			
Home storage alert		Insufficient storage space	Manage your mobile application space through your operating system settings.
Handpiece status errors			

Malfunction	Screen	Possible cause	Action
Favourite handpiece is not ready for use		Favourite handpiece is powered off	Power on the handpiece.
Additional handpiece is not ready for use		Additional handpiece is powered off	Power on the additional handpiece.
Handpiece is not configured		Handpiece requires Wi-Fi configuration	Make sure that the handpiece and the mobile terminal are connected to the same Wi-Fi network.
Handpiece is locked		Another user is using the handpiece	• Wait for the handpiece to be free. • Add another handpiece.
?		?	Edit handpiece???
?		?	?
Task selection errors			
No display of scheduled appointments		Working list is not updated	• Update the working list. • Check if there were any patients scheduled for the entire day.
Scanning/Handpiece errors			

Malfunction	Screen	Possible cause	Action
Missing ultrasonic couplant		Ultrasonic couplant not detected	Refill or change the ultrasonic couplant
Handpiece system error		Handpiece system error that occurred during acquisition	Reboot the handpiece, then tap **Continue** to be directed to the Homepage. The current scan data will be lost.
Overheating errors			
Overheating error	 	Reached safety temperature. The system is cooling down.	The system will recover once acceptable temperature conditions are established.
Scanning/Terminal errors			

Malfunction	Screen	Possible cause	Action
Terminal system error		Terminal system error that occurred during acquisition	Reboot the handpiece, then tap **Continue** to be directed to the Homepage. The current scan data will be lost.
Battery errors			
Discharged battery		The battery is empty	Charge the battery.
Exporting errors			
Exporting image errors		An error occurred when saving data	Make sure that you correctly saved the data in your operating system.

Safety recommendations

CAUTION: DANGER OF ELECTRIC SHOCK

This is an electrical unit. Do NOT expose it to water spray. Such action can cause an electric shock or a malfunction of the unit.

Important: **All known residual risks, contra indications, or undesirable side effects are listed in this guide. If any serious incident happens to the handpiece, you must report it to Carestream Dental and to the competent authority of your member state in the European Union.**

1. All other equipment not complying with IEC 60601 must be kept at least 1.83 meters away from the patient.

2. Medical checks must be done on operators who carry out operations where toxic chemical substances are used and are done under aspiration.

3. DO NOT maintain or service an equipment while it is in use on a patient.

4. The SonoChart handpiece head that comes into contact with a patient and operator must be cleaned and disinfected between every patient.

   See the ***SonoChart Safety, Regulatory and Technical Specifications User Guide (SMA87) Ed01*** for more information on disinfection.

5. DO NOT let the SonoChart handpiece cover be in direct contact within the patient mucosa.

6. You MUST get training on risk relating to electric shock.

7. If there is leaked cell, do not allow the liquid to come in contact with skin or eyes.

   If contact has been made, wash the affected area with copious amount of water and seek medical advice.

8. The product and packaging must be stored in the following conditions:

   - Temperature: -10°C to +60°C for storage
   - Relative humidity: 10 - 90%
   - Atmospheric pressure: 700 to 1060 hPa
   - Altitude up to 3000 m

9. The unit must operate in the following environment:

   - Temperature: 10°C to 30°C
   - Relative humidity: 30 - 80%
   - Atmospheric pressure 700 to 1060 hPa
   - Altitude up to 3000 m

10. We highly recommend that all users be trained on ultrasonic imaging technology.

11. All users must be trained to use the system.

12. You MUST maintain the handpiece in an optimum position during the entire procedure.

13. You must use consumables according to the manufacturer instructions for use.

14. You must handle the consumables according to standard operating procedures set out for the disposal of contaminated medical waste.

15. The SonoChart application uses the millimeter metric measurement.

General recommendations

1. You MUST read and understand this safety information before using the SonoChart product.

2. SonoChart MUST:

   - Only be used inside hospitals and other professional healthcare facilities.
   - NOT be used near high frequency surgical equipment.
   - NOT be used near a RF shielded room of an ME System for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.

3. You are responsible for the operation and maintenance of SonoChart. You must follow a self-training course to use SonoChart. When necessary, have a trained authorized service technician to carry out inspection and maintenance operations.

4. Before use, check the outer surfaces of the handpiece and accessories to ensure that there are no rough surfaces, sharp edges, or protrusions which may cause safety hazards.

5. DO NOT place objects within the field of operation of the handpiece.

6. When the handpiece is not in use, ensure that the product is switched OFF.

7. DO NOT pull or twist the charging cable.

8. DO NOT drop SonoChart or the accessories.

9. DO NOT replace the power adapter provided with SonoChart with any other power adapter. Substitutes may not provide the required protection against electric shocks and other safety hazards.

10. If the equipment is faulty, turn it OFF. Display an Out of Service notice and contact a qualified Carestream Dental service technician.

11. Using components, accessories, cables, and spare parts other than those specified or provided by the manufacturer of SonoChart may:

    - Decrease the safety protection.
    - Result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation.

12. No modification of SonoChart is allowed.

13. The maximum temperature of the applied part may reach 43 °C. To avoid overheating, do not use for extended periods.

14. To power off the handpiece, press and hold the power button for 6 seconds.

15. DO NOT maintain or service this equipment while in use on a patient

16. Connection of the PEMS (Programmable Electrical Medical System) to an IT network that includes other equipment could result in risks to patients, operators, or third parties. Your organization must identify, analyze, evaluate, and control these risks.

17. DO NOT operate the handpiece if there is a threat of an earthquake. Following an earthquake, ensure that the handpiece is operating satisfactorily before using it again. Failure to observe this precaution may expose patients to hazards.

18. Contact a service technician to dispose of the handpiece or its components.

19. DO NOT use SonoChart in conjunction with oxygen-rich environments. This handpiece is not intended for use with flammable anesthetics or flammable agents.

20. If you find that the SonoChart is too hot, switch it OFF and contact an authorized service technician.

12 Contact Information

Manufacturer's Address

Carestream Dental LLC
3625 Cumberland Boulevard, Suite 700,
Atlanta, GA USA 30339

Factory

Trophy

4, Rue F. Pelloutier, Croissy-Beaubourg

77435 Marne la Vallée Cedex 2, France

Authorized Representatives

Authorized Representative in the European Union

Trophy

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77435 Marne-la-Vallée Cedex 2, France

Responsible Person in the United Kingdom

Carestream Dental Ltd
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SG1 2EF,
England, United Kingdom

Authorized Representative in Brazil

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Cep (Zip Code): 12238-577

List of Importers for European Union according to MDR 2017/745

Carestream Dental France SAS
4 rue F. Pelloutier, Croissy-Beaubourg, 77435 Marne-la-Vallée Cedex 2, France

Carestream Dental Germany GmbH
Hedelfinger Str. 60, 70327 Stuttgart, Germany

Carestream Dental Spain
S.L.U. Paseo de la Castellana, 79, Madrid 28046, España

Carestream Dental Italy S.r.l.
Via Mario Idiojmi 3/3, Assago 20090 (MI), Italia

List of Importers for Switzerland

CURADEN AG
Riedstrasse 12
CH-8953 Dietikon
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Dema dent AG
Furtbachstrasse 16
CH-8107 Buchs
Switzerland

Jordi Röntgentechnik AG
Dammstrasse 70
CH-4142 Münchenstein
Switzerland

E. Schweizer AG
Bernerstrasse Nord 182
CH-8064 Zürich
Switzerland