



User manual



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Legend of symbols used in this manual



Attention: important information.



Reference to a chapter, section, or document.

Information contained in this manual are subject to changes without notice and do not represent product specifications or any commitment of Teethan S.p.A.



BTS SpA
Via Capriccio, 3/A
Vigonza (PD)
I-35010 Italy

Safety Information

It is recommended that before undertaking any operation to observe the safety instructions contained in this manual. The safety of the instrument cannot be guaranteed if the following terms are not adhered to.

Intended use

Teethan is a surface electromyographic analysis instrument, classified as a medical device according to the European Directive 93/42/EC (and subsequent amendments, including Directive 2007/47/EC). EMG probes are classified as ETSI EN 330 440 “Receiver category 3” according to the R&TTE Directive 99/5/EEC.

Teethan must always be used solely for this purpose, by qualified personnel, in environments suitable for performing electromyographic analysis, and in compliance with the regulations in force in the countries where it is used. The use of the device for purposes and with methods different from those indicated in this manual are not to be considered congruent with the intended use of the device.

Acquisition results must be evaluated by persons legally authorized by national laws, with appropriate knowledge of muscle anatomy and function.

The instrument should be used in a medical environment, as it has a high level of sensitivity (voltage levels measured between 1 microvolt and 6 millivolts).

During patient preparation, take special care that the system components do not impede the subject’s normal movements in any way. Apply probes to undamaged skin only.

- Use only CE-marked electrodes and hypoallergenic double-sided tape compatible with use on undamaged skin for short periods of time.
- Periodically check the integrity of the system and its components.

- Do not wet or immerse system parts in water.
- No modification of the device is allowed.
- Only technicians authorized by Teethan S.p.A. may service the instrument.
- Teethan S.p.A. cannot be held responsible for the safety of the system if it has been opened, if repairs have been made, if third party software has been installed, or if the system components have been replaced by personnel not authorized by Teethan S.p.A.
- Users may not change the software configuration (including the operating system and burning software).
- In case the device is accidentally dropped, probes broken, or other incidents occur, always contact technical support.
- Use only the supplied power supply FW7363M/09 (FRIWO) or another power supply provided by Teethan S.p.A. If a different power supply is used, compliance with IEC 60601-1 is not guaranteed.
- Only original cables must be used, otherwise Teethan S.p.A. cannot guarantee the safety of the instrument. If it is necessary to replace any part of the system, use only original Teethan S.p.A. parts.

Other operating precautions

In addition to user instructions, accident prevention regulations and technical occupational safety regulations must also be observed. The relevant national regulations and the regulations of the country of use about accident prevention and the environment are to be regarded as an extension of the user instructions.

- Make sure the cables are connected properly. To disconnect the cables, grasp the connectors, but do not pull directly on the cable.
- The power plug of an external power supply is considered a disconnecting device.
- Avoid connecting probes to the charger with polarity reversed from that indicated

- on the cover of the charger – this could cause irreparable damage.
- For safe use and proper maintenance of rechargeable batteries, follow the instructions in this manual. If the rechargeable batteries are used in a manner different from that specified by Teethan S.p.A., their duration, functionality and integrity are not guaranteed

Teethan is designed for CONTINUOUS operation, whose limit of use is determined by the battery life and the memory available for storing acquisition data.

The device uses lithium-ion batteries to operate. Contact technical support for battery replacement or disposal. Under no circumstances should the integrity of



Disposal (RAEE)

When disposing of the device in an approved manner, please observe relative regulations. In accordance with the Directive 2002/96/EC (WEEE), all devices supplied after August 13th, 2005, may no longer be disposed of with household waste. This device belongs to category 8 (medical devices) and is classified as business-to-business. The crossed-out wheeled bin symbol indicated that the device must not be disposed of with household waste. Disposal regulation may differ in individual EU countries. If necessary, please contact your dealer.

Introduction

Teethan is the ideal solution for the functional analysis of dental occlusion. It provides information on neuromuscular alterations induced by occlusal contact. It is an innovative and technologically advanced instrument that offers a complete and immediate picture of the patient's occlusal balance. Teethan performs a surface electromyographic analysis of the main masticatory muscles, to quantify the influence of the occlusal state on the patient's neuromuscular balance.

The system consists of four electromyographic probes with active electrodes, unique in the world of lightness, small size, and accuracy of acquisition. These probes - in no way invasive for the patient – communicate via Wi-Fi with a USB receiver and the transmitted data are made available to the operator in real time, through the interface of the dedicated software.

Teethan's protocol is based on tests in maximum intercuspidation (maximum voluntary contraction) lasting five seconds each. The results obtained expresses the degree of balance of the muscular activity through percentage indices, recognized and validated by more than 20 years of international scientific publications.

Teethan software automatically processes the patient's occlusal balance, presenting real-time results in a graphic format that is immediately comprehensible to both the doctor and the patient.

A unique feature of Teethan™, which distinguishes it from traditional electromyography, is the normalization of the electromyographic signal given by the ration between two successive locking tests, performed with and without the interposition of cotton rolls between the dental arches. This method is registered under the name of Synchronomyography®. This guarantees the objectivity and repeatability of the measurement, eliminating all alterations that could affect the single measurement. In fact, the physiological and anatomical variability of the patient is eliminated, as well as the variability introduced by external factors such as incorrect positioning of the electrodes, skin conductivity, interference, etc.

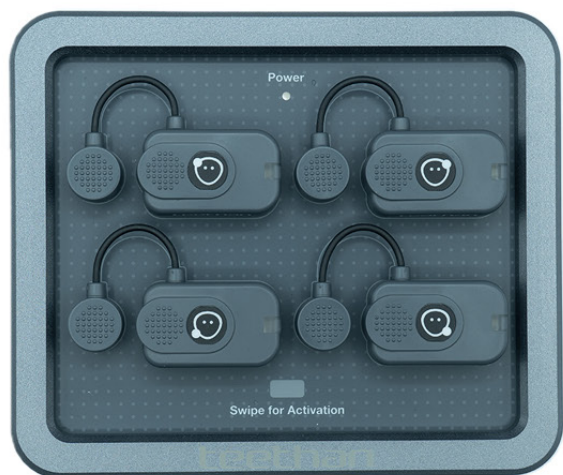
All acquired results are automatically archived and exportable in PDF format, which becomes an effective mean of communication with the patient, as well as

with other professionals and experts in the field of occlusal relations. The reports provide important information on prevalence of each muscle pair (POC), occlusal plane center of gravity (BAR), torsional attitude of the mandible on the horizontal plane (TORS), muscle work (IMPACT), and asymmetry between right and left side (ASIM).

2

INTRODUCTION

2.1 Package Content



Teethan's charging station with 4 EMG wireless probes



USB Receiver



Power cable



USB extension cable



USB power adaptor



Pre-gelled electrodes



Stainless steel plate

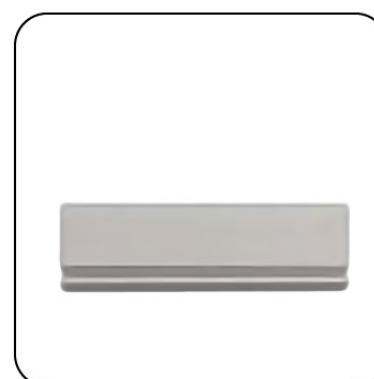


Plate support



If any parts are damaged or missing, contact Teethan Customer Service immediately at support@teethan.com

2.2 System Components

Wireless EMG Probes

Teethan acquires EMG signal through miniaturized wireless probes with active electrodes, weighing less than 14 grams. Their design ensures a minimum footprint and maximum comfort for the patient, without altering proprioception and muscle contraction.

Probes can be attached directly to the pre-gelled electrodes without further fixation. This, together with the total absence of cables, allows for a rapid preparation of the patient, drastically reducing the time of each work session.

Each probe consists of a mother electrode and a satellite electrode, which in turn are equipped with clips. The two parts, connected by a flexible cable, can be positioned at a variable distance according to the user's needs (variable geometry



- 1 Mother electrode
- 2 Satellite electrode
- 3 Status LED
- 4 Flexible cable
- 5 Snap connector

Buffer memory

All probes are equipped with a buffer memory, solid state, to avoid data loss due to Wi-Fi network problems or due to exceeding the useful operating range.

Power on

The supplied charging station has a magnetic zone indicated by the words “Swipe for activation”. To turn on the probes, which have a magnetic switch, simply swipe the probes at the indicated gray area.

Recharge

The probes are recharged by means of the charging station to which they are connected by means of the same clips. For more information on charging the probes, please refer to the “Charging Station” section of this chapter.

Status LED

The probe can be in one of the following states, indicated by the appropriate LED:

- Charging (blue LED): it indicated that the probes are connected to the Charger on, and the probe charge level is below 90%. Connecting the probe to the Charger, it enters in “Deep Sleep” mode, so it is completely passive and does not respond to any command.
- Search for receiver unit (white LED, flashing fast): The probe is searching for the receiver unit, performing 1-minute-long scans every few seconds.

- Probe connected (white LED, flashing slowly): The probe is waiting for commands. If the connection is broken, the probe returns to the search state and attempts to re-establish the connection with the receiving unit.
- Acquisition in progress (white LED, flashing at approximately 1-second intervals): If the connection to the receiving unit is lost during acquisition, the probe continues to acquire and store data locally for one minute, while simultaneously scanning to reconnect to the receiving unit. If, after one minute, the scan is not successful, the probe returns to the search state and stops storing data.
- Probes low on battery or “Deep Sleep” mode (LED off): The probe does not perform any scan cycle, but is turned off, thus ensuring power saving.

USB Receiver Unit

Connected to a USB port on your computer, it allows you to receive signals captured by wireless EMG probes. The illumination of a green status LED confirms that the device is properly powered.



Charging station (Charger)

Teethan's probes charging is done through the supplied charging station, which allows the simultaneous charging of all the EMG probes. These are hooked to the charger through the same clips used during the acquisition phase, taking care to respect the polarity, as indicated on the support plane of the charger. The probes will not be recharged if connected with inverse polarity.

Once the probes are hooked up, insert the USB cable into the wall power supply or plug the cable directly into a USB port that allows power to the Charger. When the Charger is properly connected, the "Power" status LED is lit with a steady green light. The charging status of the probes is indicated by the status LED on the probes.



3

INSTALLATION

3.1 Minimum Requirements

Operative Systems: Windows 10 o superiori

Processor: Intel i5 Dual Core (o equivalente)

RAM: 4 GB

Video Cards: risoluzione 1280x768 o superiore

Disk Space: 100 Mb

USB: 2.0 o superiore

Connections: Wi-Fi

3.2 Installation Procedure

This section describes the installation procedure of the Teethan software. To proceed with the installation of Teethan, follow this procedure:

- Connect to the site <http://sw.teethan.com>
The software download will start automatically.
- Double click on the installation file just downloaded to start the “Setup Wizard” installation procedure.
The installation window (3.1) will appear.
- Proceed with the various steps proposed, always leaving the default parameters. If Teethan has been successfully installed, a window indicating that the installation procedure is complete will be displayed (3.2).

3.3 First startup

Activate teethan® v.3.0.0.1
Confirm your data

Name* Surname*

Email*

Organization* Nation*

City* Address*

+39 - Mobile phone*

Teethan - S/N* ?

I read and accept Terms and Privacy Policy *
 Yes, I would like to receive marketing e-mails

CONFIRM

Workstations available 2/3

3.3

Activate teethan® v.3.0.0.1
Validate your email

An email was send at info@teethan.com.
If you haven't received any email, please:

REQUEST A NEW CODE

Validation code

VALIDATE EMAIL

3.4

Activate teethan® v.3.0.0.1

Press here to scan the QR code

Insert here your activation key

00000-00000-00000-00000-00000-0000000000

CHECK LICENSE

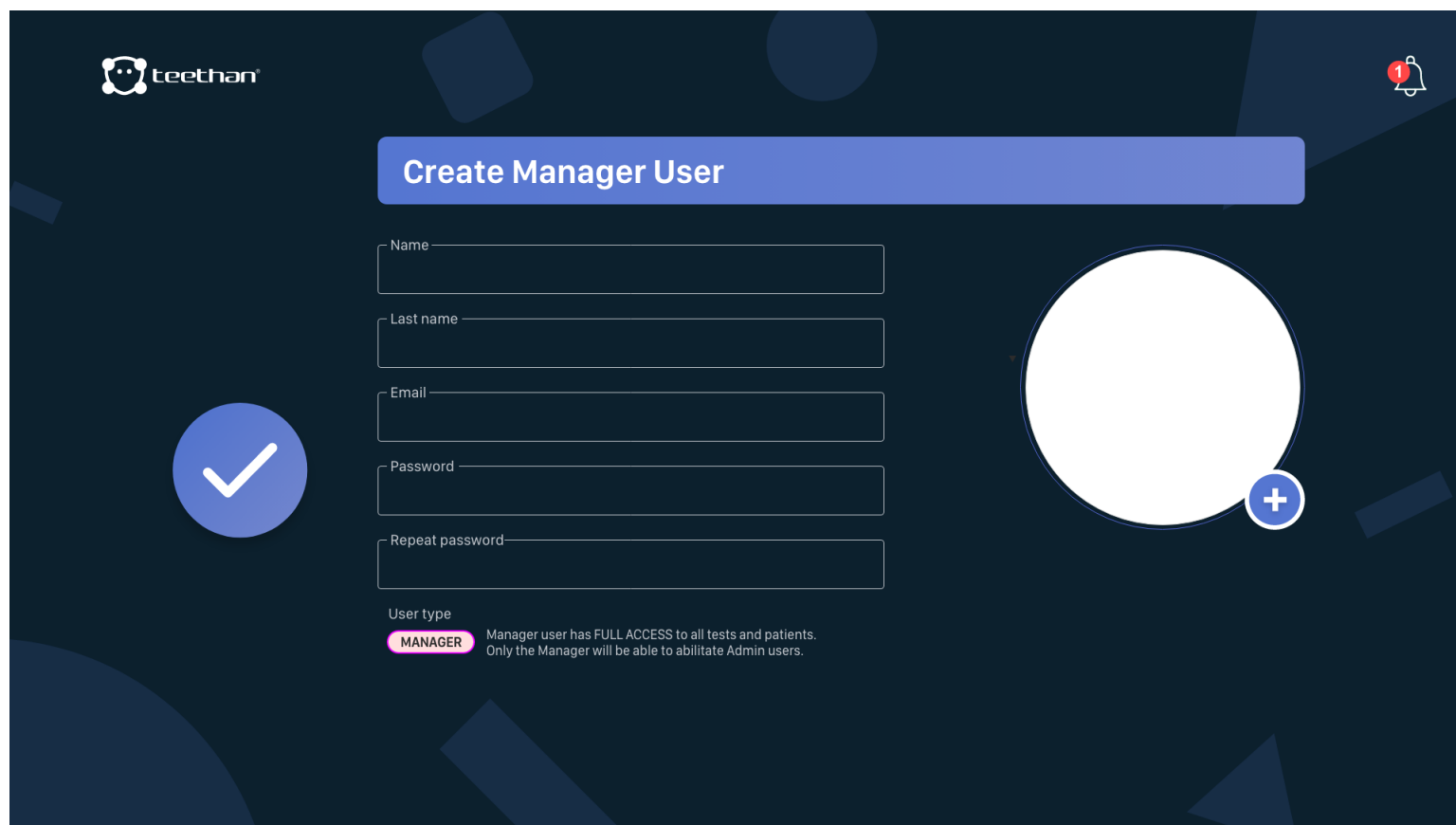
3.5

To complete the installation procedure, you must activate the software using the activation code inside the package. To do this:

- Launch the software by double-clicking on the desktop icon.
- Fill in all parts of the form that will be displayed by entering your personal data and your e-mail (3.3). In the case of subsequent installations, the fields will be pre-completed with the data of the licensee and cannot be modified.
- Click on “Next” to confirm the insertion. The software will automatically send an email to the previously entered mailbox containing the Validation Code.
- Enter the Validation Code and continue by clicking on the “Validate Email” button (3.4).

- Finally, insert the Activation Key. To do this, scan the QR Code that is on the last page of this guide, alternatively enter the activation code written under the QR Code manually (3.5).

Then, it is possible to proceed with the creation of the first user, the **MANAGER**, who can manage all the patients and their relative examiner.



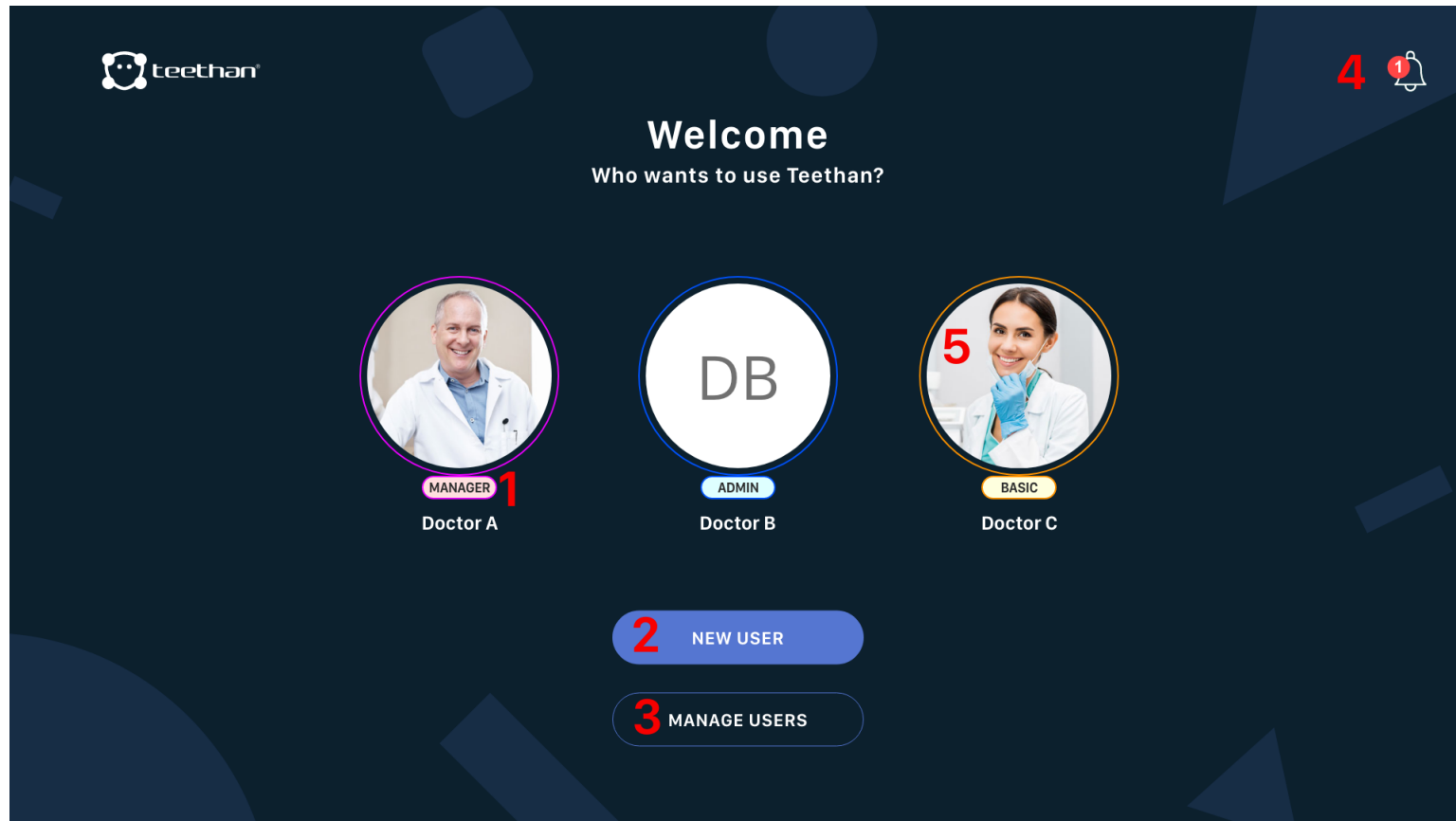
The screenshot shows the 'Create Manager User' form in the teethan application. The form is set against a dark blue background with the teethan logo in the top left and a notification bell in the top right. A large blue checkmark icon is on the left side of the form. The form fields include: Name, Last name, Email, Password, and Repeat password. To the right of the form is a large white circular placeholder for a profile picture with a blue plus sign. Below the form, the 'User type' is set to 'MANAGER', with a description: 'Manager user has FULL ACCESS to all tests and patients. Only the Manager will be able to abillitate Admin users.'

4

**SOFTWARE
DESCRIPTION**

4.1 Login Screen

The following screen will appear when the software starts:



In this screen, the following main areas can be identified:

1. “User Type” tag
2. “New User” button
3. “Manage Users” button
4. Notifications Area
5. User Icons

4.1.1 “User Type” tag




In Teethan, users can be of two types: **ADMIN** and **BASIC**. The first type manages all patients present in the Teethan database. A BASIC user, instead, manages only the patients he creates himself. It cannot create

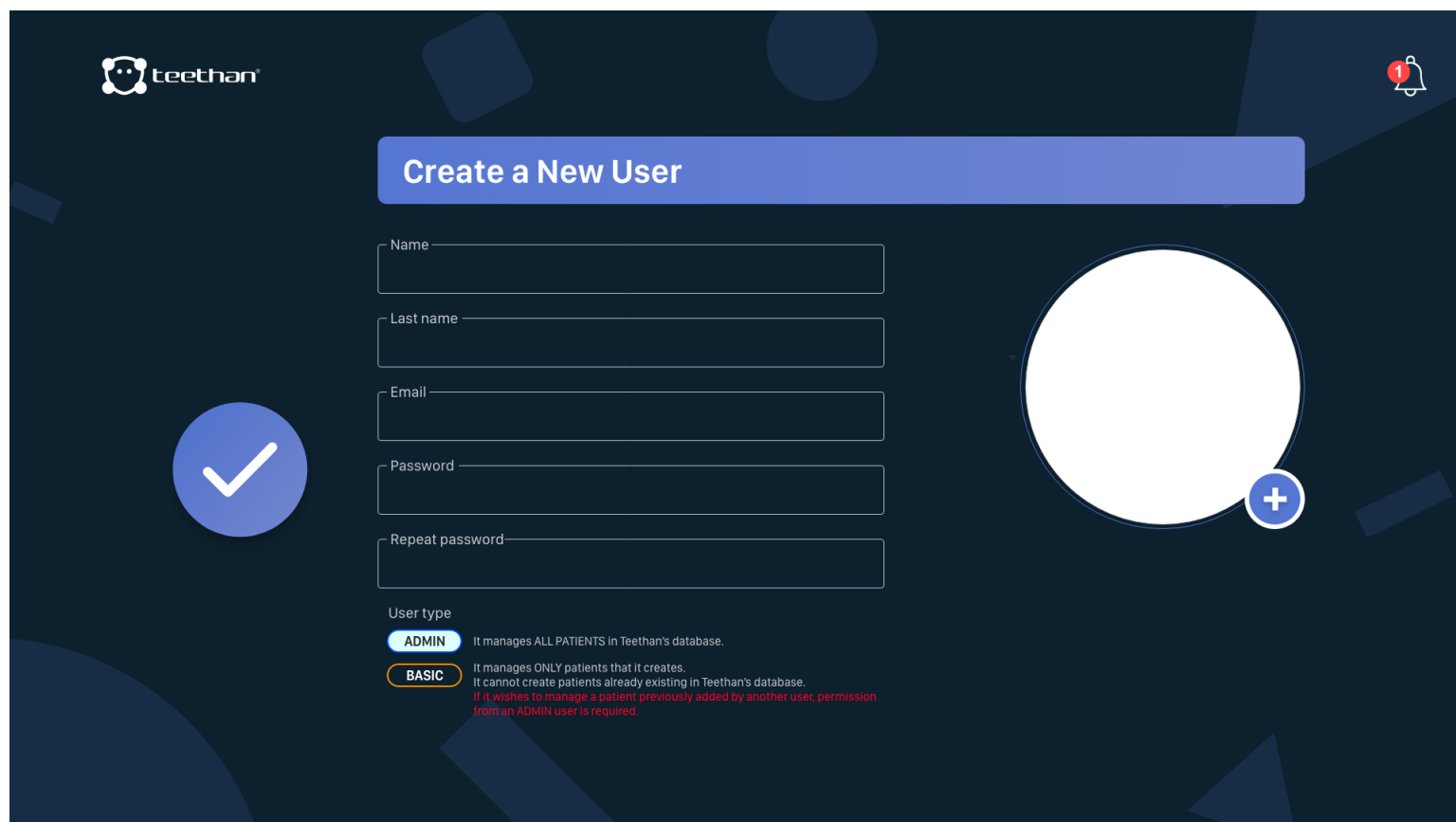
patients already existing in the Teethan database. If it wants to manage a patient already inserted by another user, it will have to be enabled by an ADMIN user.

4.1.2 “New User” button

Click on the “New User” button to access the “Create New User” window, which allows the creation of a new user.

To create a new user:

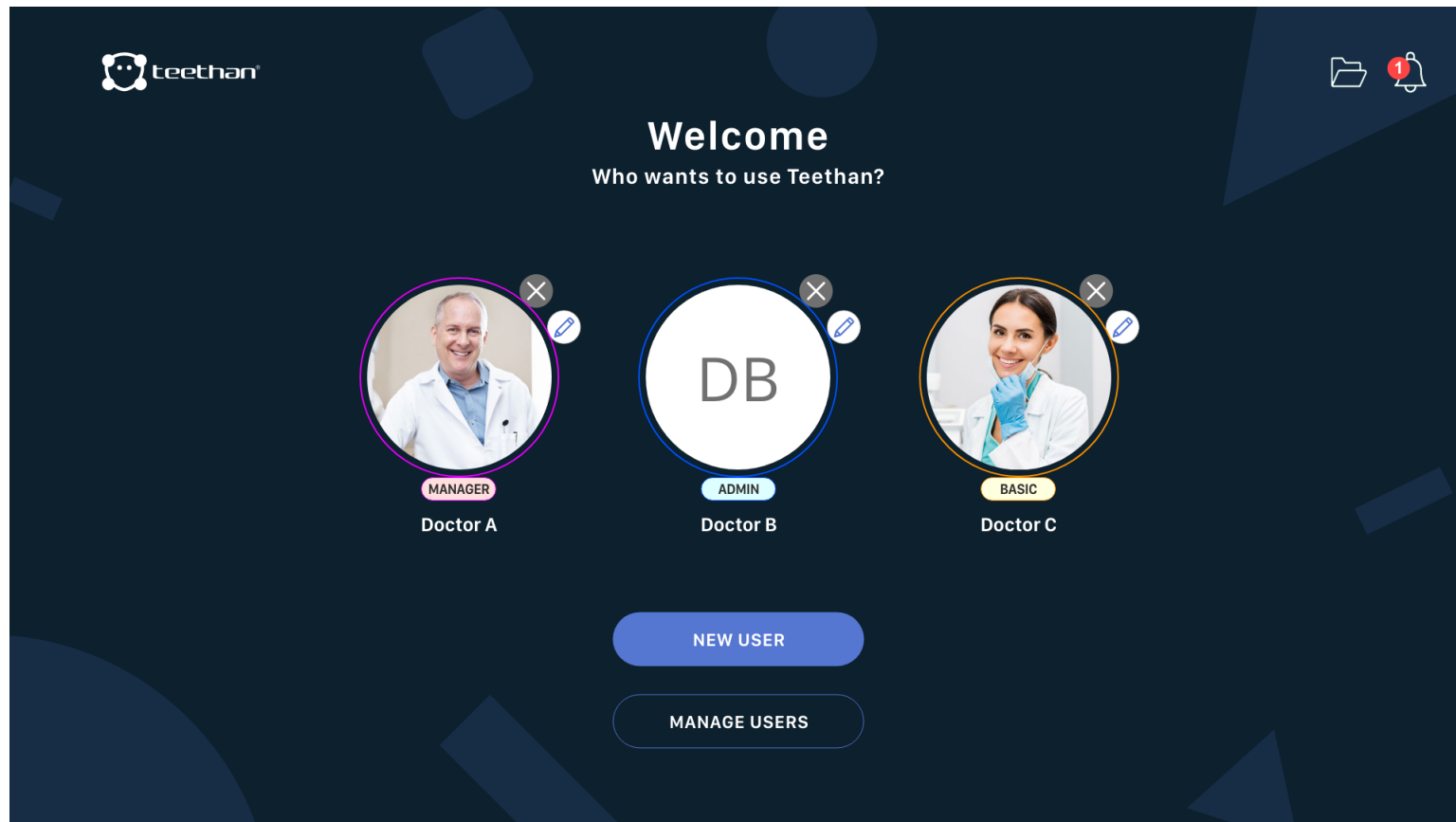
- Complete all required fields: Name, Surname, E-mail, Password and Repeat Password
- Clicking on the icon  - if one wishes to - a picture can be taken and used as profile pic. If you want to delete a previously inserted image, instead, click on the button  .
- To add and save the new user, click on  .





The screenshot shows the 'Create a New User' form in the Teethan application. The form is set against a dark blue background with the Teethan logo in the top left and a notification bell in the top right. The form title 'Create a New User' is displayed in a blue header bar. Below the title, there are five input fields: 'Name', 'Last name', 'Email', 'Password', and 'Repeat password'. To the right of these fields is a large white circular area for a profile picture, with a plus icon in the bottom right corner. Below the input fields, there is a 'User type' section with two radio buttons: 'ADMIN' (selected) and 'BASIC'. The 'ADMIN' option is described as 'It manages ALL PATIENTS in Teethan's database.' The 'BASIC' option is described as 'It manages ONLY patients that it creates. It cannot create patients already existing in Teethan's database. If it wishes to manage a patient previously added by another user, permission from an ADMIN user is required.' A large blue checkmark icon is positioned to the left of the form, and a blue plus icon is positioned to the right of the profile picture area.

4.1.3 “Manage Users” button

By clicking on the “Manage Users” button you can delete or modify the created users.



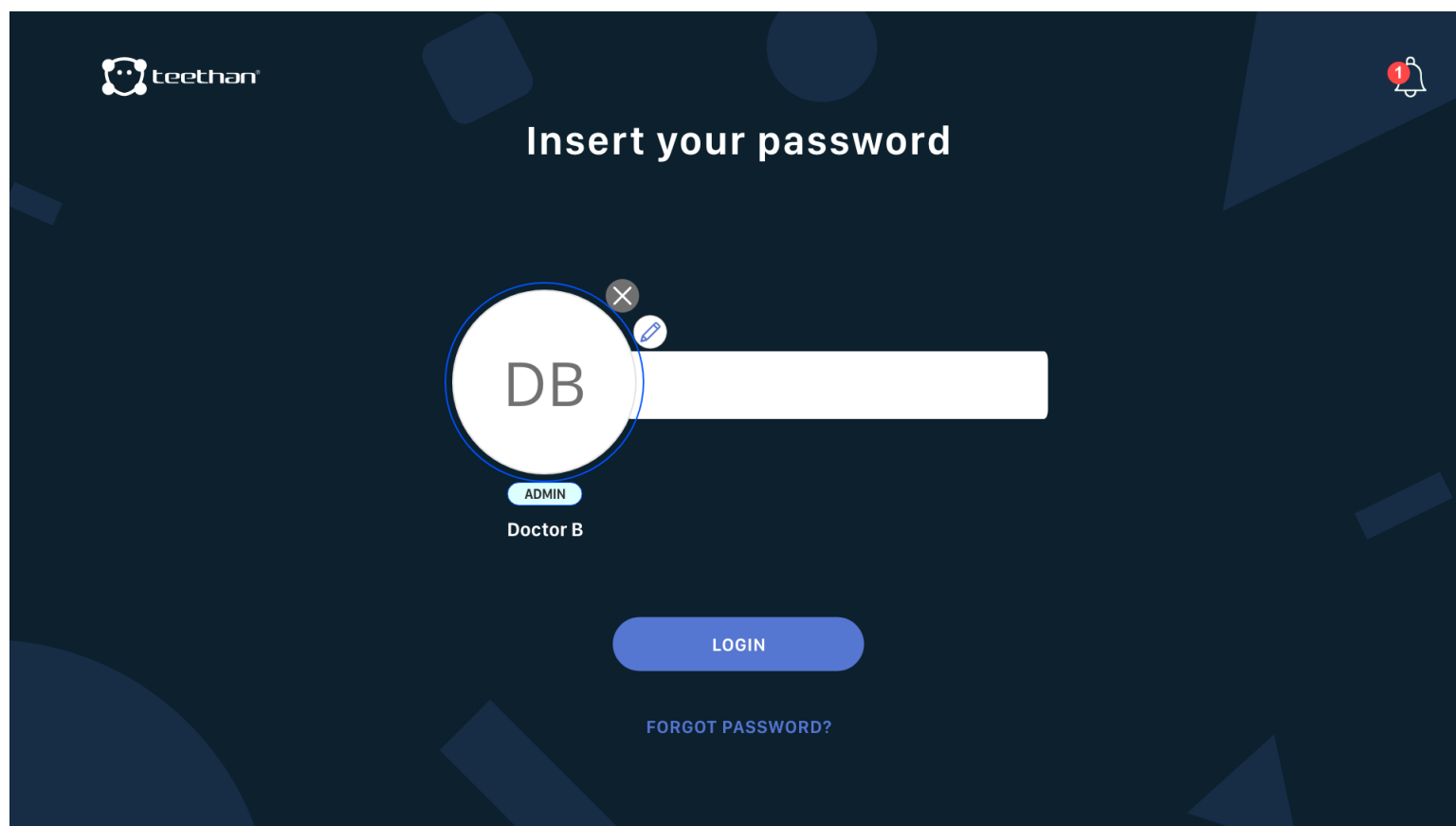
- To delete a user, click on  , confirm the operation, then enter the User Password and press “DELETE”.
- To modify a previously created User, click on  .

4.1.3 Notifications Area

Click on the “Notifications” icon to access the Notifications area. In the Notifications area it is possible to consult Teethan notifications received.

4.1.4 User Icons

By clicking on one of the User icons it is possible to access the software.



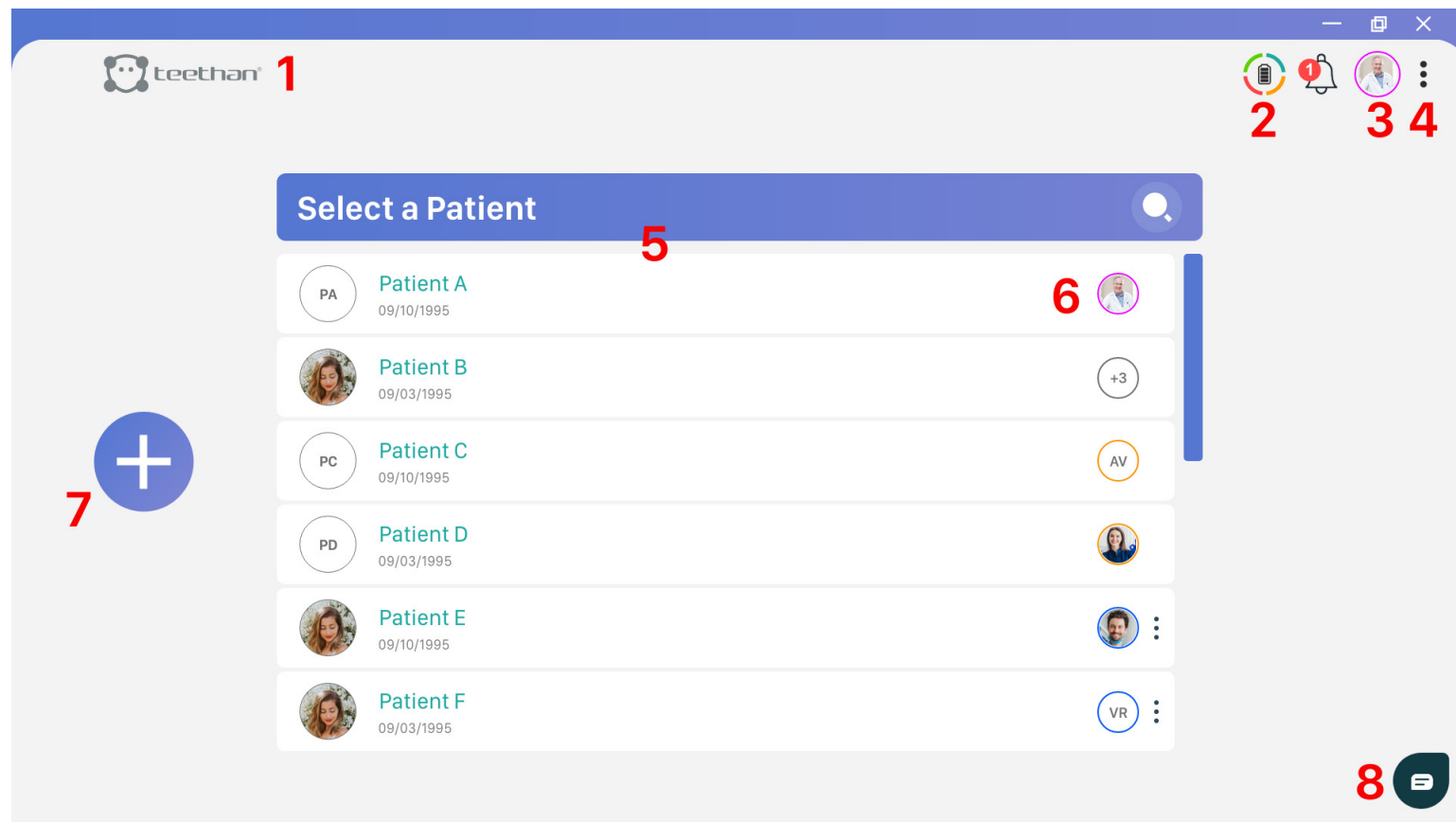
To access: click on the icon, enter the Password, then click on “LOGIN”. If you don’t remember your password, it is possible to recover it.

To recover the Password, click on the “Forgot Password?” button. Then, confirm the operation.

An e-mail with instructions for recovering the password will be sent to the e-mail address used during user registration.

4.2 Home Screen

After logging in, the following interface will appear:




In this screen you can identify the following main areas:


1. “Teethan” button
2. Hardware Control icon
3. Account menu
4. Options menu
5. Patient List and Search Bar
6. Sharing patients between Users
7. Add New Patient
8. Support Widget

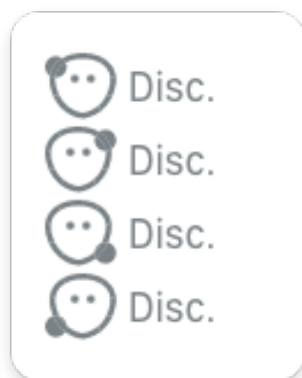
Areas 1-2-3-4 are in the upper right corner and are repeated in several screens of the software. In the following paragraphs will be given a detailed description of all these elements. In the remaining chapters of this manual, we will always refer to the information here described.


4.2.1 “Teethan” button

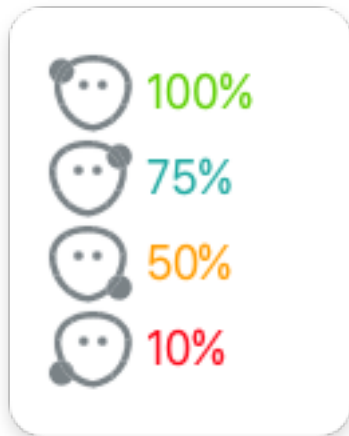
Teethan button  **teethan**® allows you to instantly return to the software’s Home screen at any time.


4.2.2 Hardware Control icon

This icon allows you to know, at any time, Teethan hardware’s – probes and USB receiver - status. In case the receiver is not connected, the icon  indicates the absence of connection.








If only the receiver is connected, without the probes being activated, the icon will look like this  and the pop-up menu will report them disconnected.



If only the receiver is connected, without the probes being activated, the icon will look like this  and the pop-up menu will report them disconnected.

4.2.3 Account menu

The icon  shows the Doctor's profile photo that has been set. If this has not been added, the icon displayed will be the default one that contains his/her initials . In both cases, the icon also suggests the type of user through the following color coding:

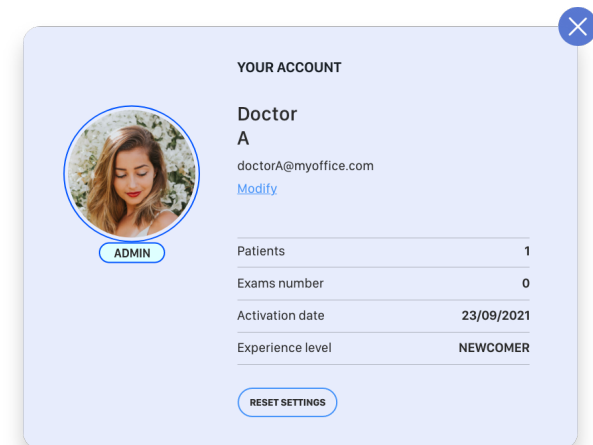
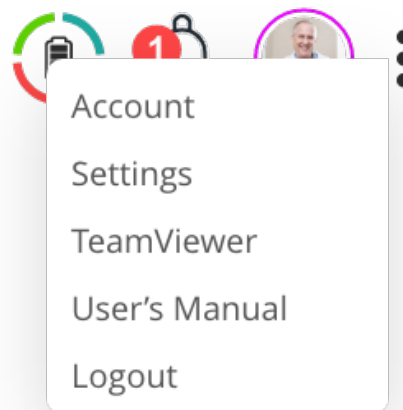
-  MANAGER User
-  ADMIN User
-  BASIC User

4.2.4 Options menu



Click on the icon  to access the Options menu, which allows you to activate the various functions available within the software. It is divided into five submenus:

- Account
- Settings
- TeamViewer
- User's Manual
- Logout



Account

The Account menu grants you access to the Account screen, in which the following info are reported:

- User type
- Number of patients
- Number of examinations performed
- Activation date
- Level of experience based on the use of Teethan

Settings

The Settings menu provides access to the menu for all system settings. The menu is described in detail in Section 4.6.

TeamViewer

Clicking on the “TeamViewer” menu starts the remote-control software of the same name.

User Manual

From this menu item, you can open the user manual in PDF format. The software will use the default PDF reader.




Logout

The Logout option allows you to exit the current doctor profile and then return to the Doctor Login page.

4.2.5 Patient List and Search Bar

Patient List

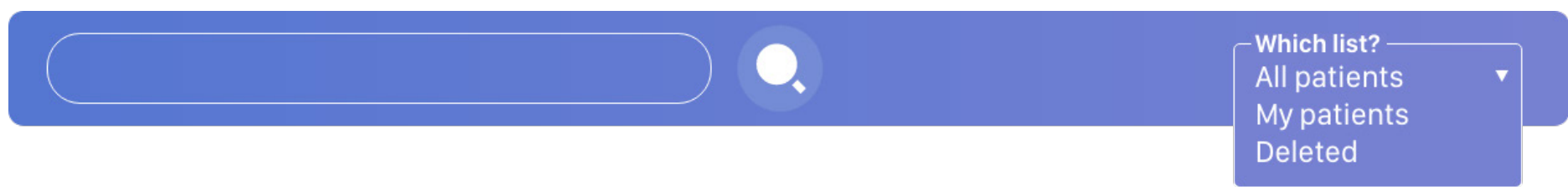
Within the patient list, all the patients inserted in the doctor’s current database are visible. Clicking on a patient will take you to the Patient Screen (described in Section 4.3) from which you can run a new test and view the results of those previously acquired.


PA	Patient A 09/10/1995	
	Patient B 09/03/1995	+3
PC	Patient C 09/10/1995	AV
PD	Patient D 09/03/1995	

By clicking on the icon  (or by right-clicking on a patient), the Patient menu is displayed.

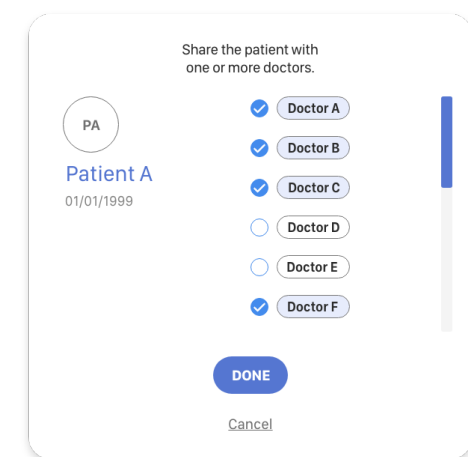
- **View:** this allows you to see the main data of the selected patient
- **Edit:** this allows you to modify the main data of the selected patient
- **Export:** it allows you to export the examination history and reports of that patient in a compressed folder.
- **Share:** this allows you to view which doctors the selected patient is currently shared with and – if necessary – to modify/add further shares.
- **Delete:** this allows that the selected patients be deleted.

Search Bar



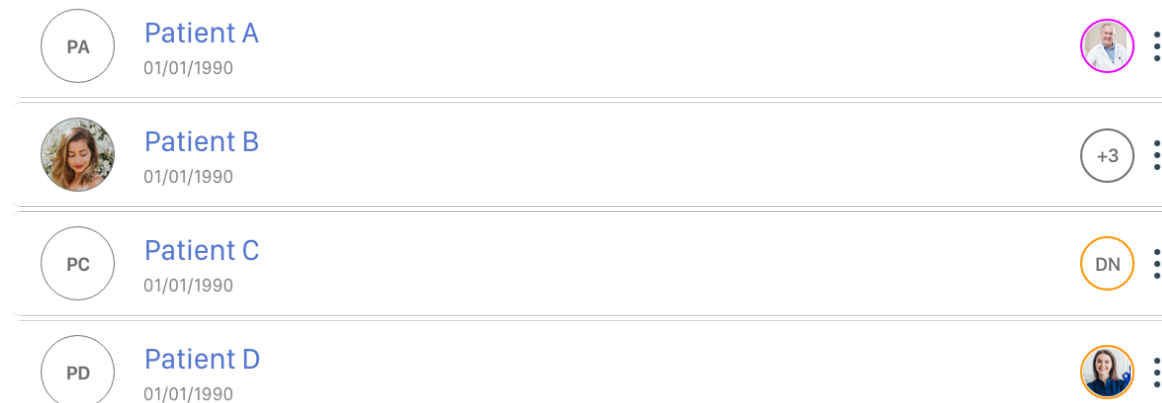
Clicking on  on the “Select Patient” bar icon displays the search bar that allows you to search for a patient within the doctor’s patient list.



The drop-down menu to the right, on the other hand, allows you to view patients belonging to the user (“My Patients”), recently deleted patients (“Deleted”) and all patients in the Teethan database (“All Patients”).



The “All patients” entry will only be available to ADMIN users. BASIC users, in fact, by definition, do not have access to it. Therefore, they will only be able to view their own patients and their recently deleted patients.

4.2.6 Sharing Patients between Users

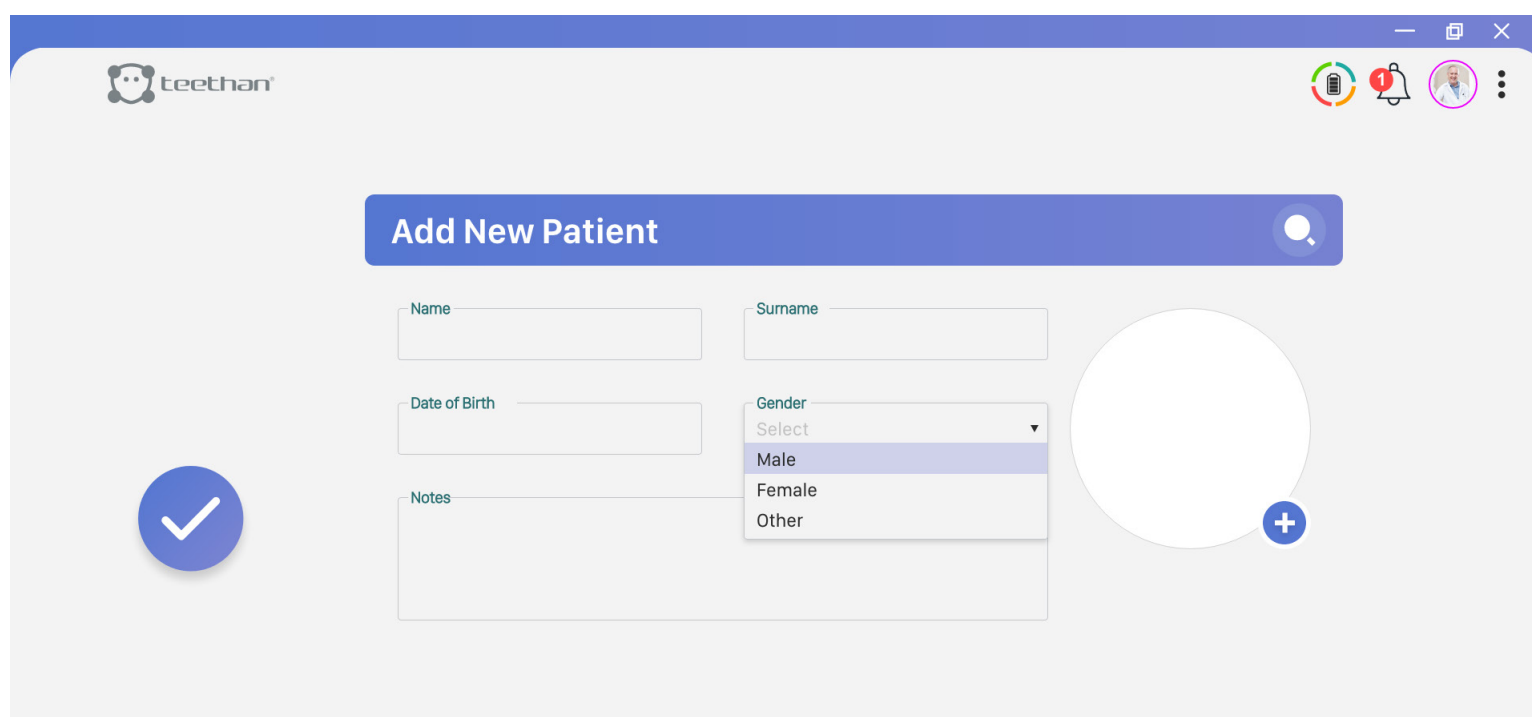


For each patient, the icon  of the user who has access to it is shown. If the patient is shared with more than one user, you can view the names of those users by placing the cursor over the icon .

4.2.7 Add New Patient

 The Add New Patient button allows you to add a new patient to the doctor's patient list.

Clicking the add new patient button takes you to the “New Patient” screen.




A screenshot of the 'Add New Patient' form in the teethan application. The form is titled 'Add New Patient' and includes a search icon. It contains several input fields: 'Name', 'Surname', 'Date of Birth', and 'Notes'. A 'Gender' dropdown menu is open, showing options: 'Select', 'Male', 'Female', and 'Other'. A large circular profile picture placeholder with a '+' icon is on the right. A blue checkmark icon is on the left. The teethan logo is in the top left, and navigation icons are in the top right.

To add a new patient, you must enter all required fields:

- Name
- Surname
- Date of Birth
- Gender

If desired, one can also enter:

- Patient photo: to insert the photo of the patient, click on the icon .
- Notes: any notes regarding the patient can be inserted in the appropriate box.

Once all the patient's data has been entered, click on the button  to save the patient and insert it in the patient list.

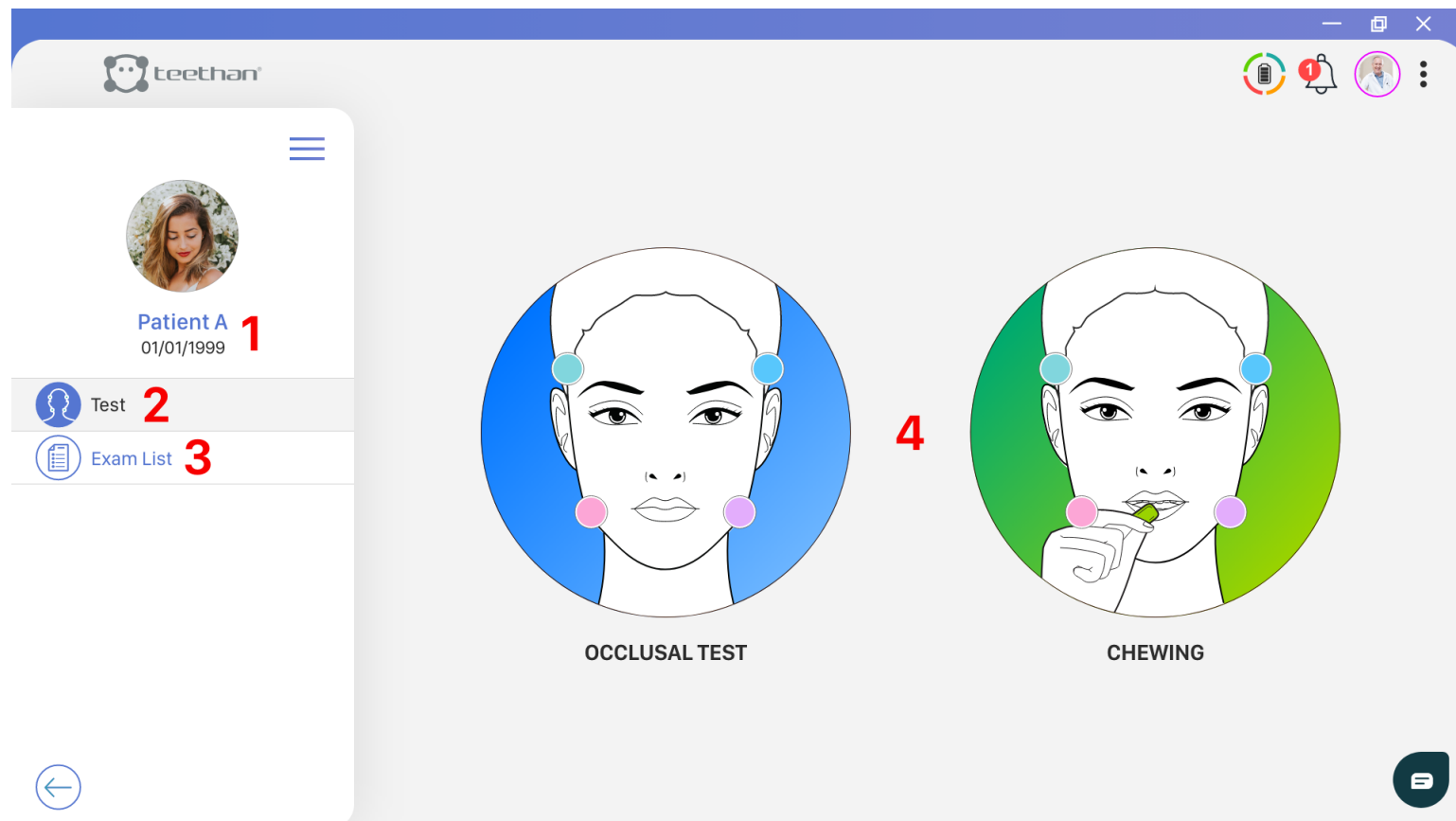
4.2.8 Support Widget

Clicking on the icon  will open the pop-up menu that contains fill-out form to contact Teethan Customer Support. After adding all the necessary information, click  for the request to be successfully submitted.

4.3 Patient Screen

After clicking on a patient from the patient list on the “Home” screen, you will access the patient page from which you can run a new test, perform a new exercise, and view the results of previously acquired tests and exercises. In this screen you can identify the following main areas:

1. Patient’s personal details
2. “Test” button
3. “Exam List” button
4. Selection area



4.3.1 Patient's personal details

This section displays the following patient's biographical information:

- Name
- Surname
- Date of Birth

4.3.2 "Test" button


Clicking on the "Test" button, you can get access to the list of available tests in the selection area:

- Occlusal Test
- Chewing

Click on the icon of the test you want to run to access the relative acquisition screen (Section 4.4).

4.3.3 “Exam List” button

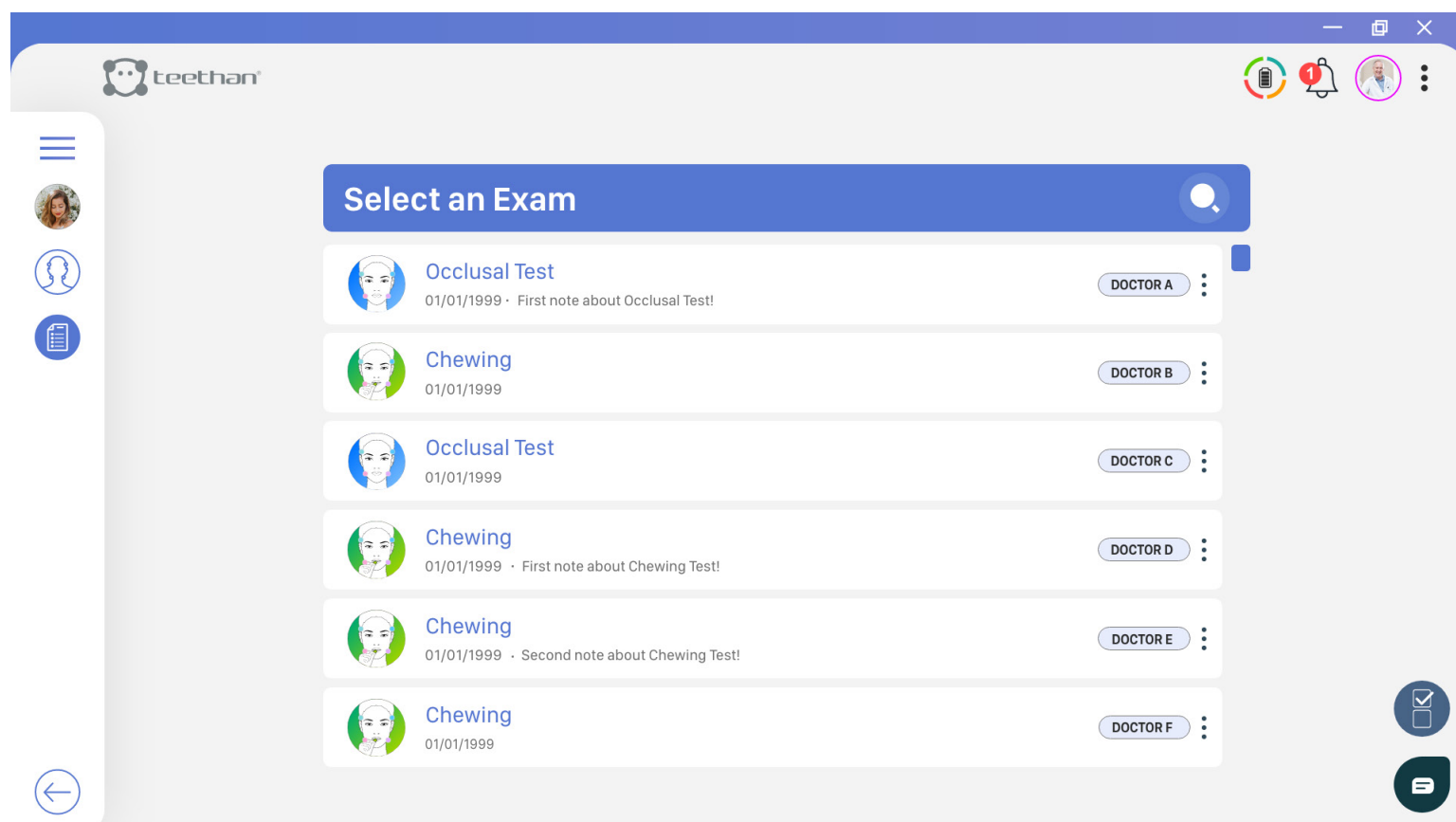
By clicking the “Exam List” button in the selection area, the list of previously acquired Tests is displayed.

By clicking  on the “Select an exam” bar icon, it is possible to search within the exam list, by name and/or date of execution.

The  tag indicates which doctor did the test.

Clicking on the icon  (or by right-clicking on a test) the Analysis menu is displayed:

- Export .bin: allows you to export raw data of the analysis in .bin format
- Export .tdf: allows you to export raw data of the analysis in .tdf format.
- Delete: allows you to delete the selected test. Before proceeding, Teethan software asks for confirmation.



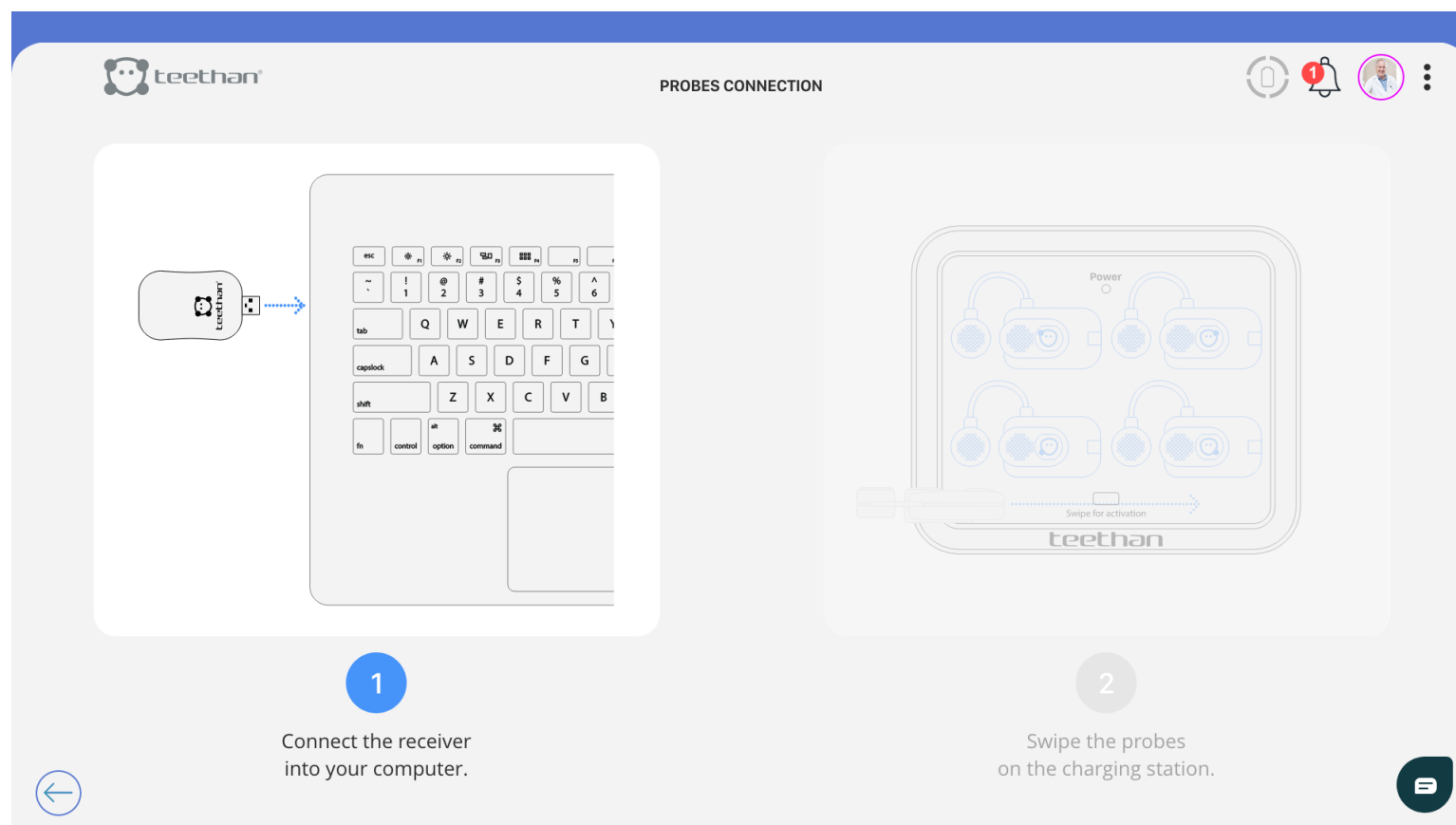
4.4 Test Acquisition Screen

Clicking on the “Test” icons on the “Patient Screen” will take you to the test acquisition test.

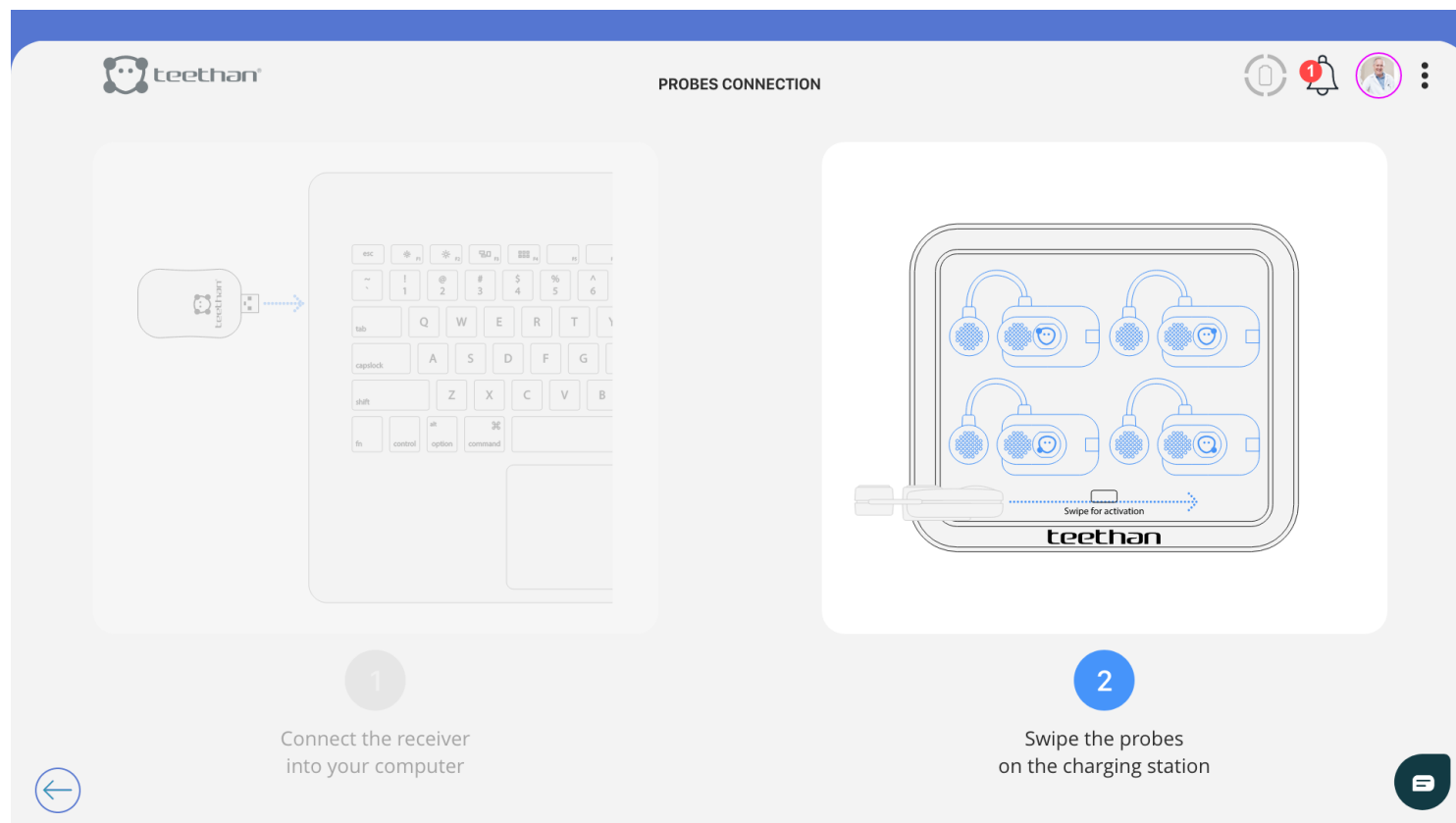
4.4.1 Probe Search Screen

You can access the acquisition screen only if the USB receiver is correctly connected and if the probes have been correctly activated.

If the first condition is not met, Teethan invites you to correctly connect the USB receiver in one of the PC ports through the following screen:

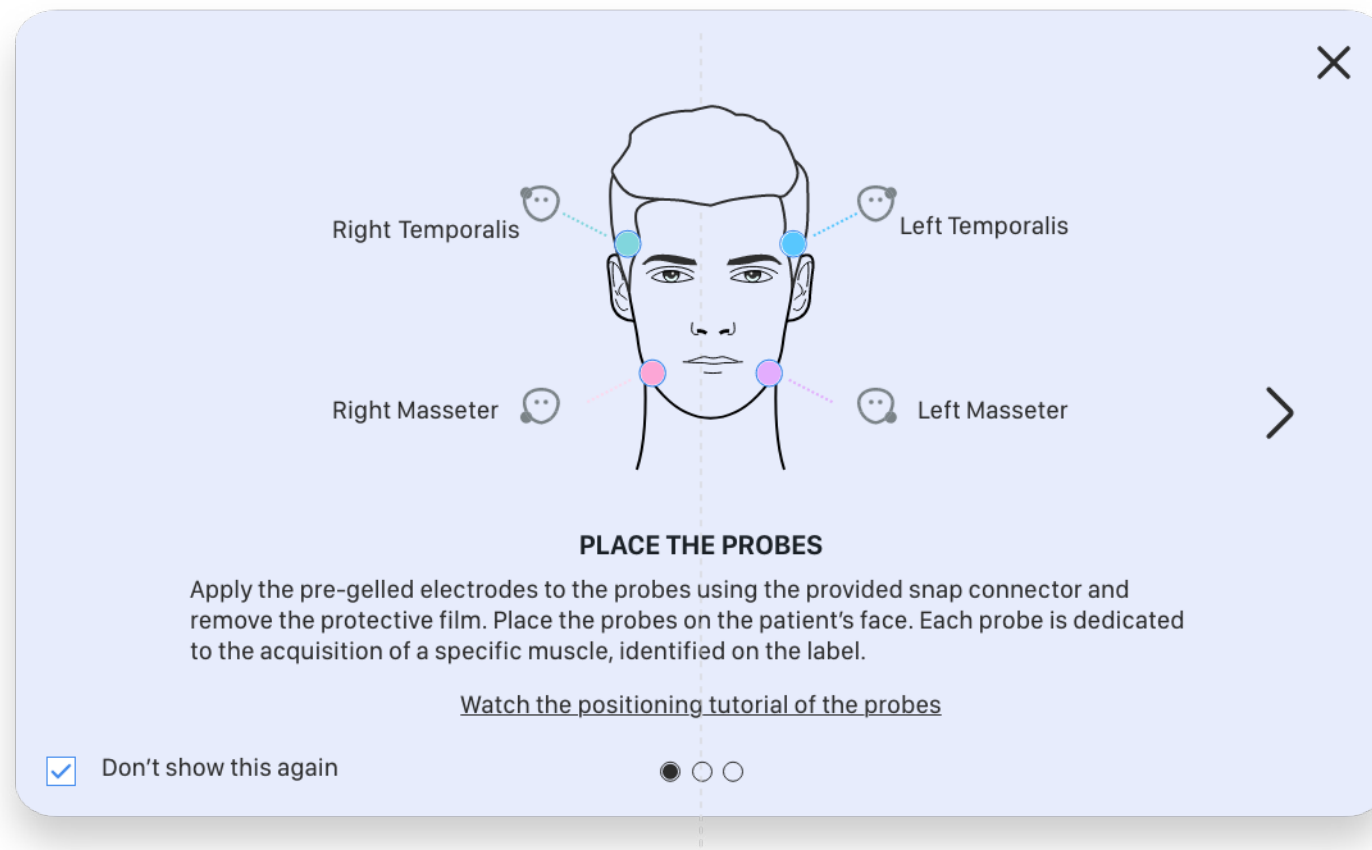


Similarly, if the probes have not been activated, a warning screen will be displayed, showing the activation process required for the system to function properly. In addition, as the probes are connected, an animation alerts the user that the connection is proceeding.



4.4.2 Explanation Pop-Up

If enabled, pop-ups explaining the test will be displayed before accessing the acquisition screen. They show how to perform the acquisition of selected test step-by-step.



If you wish, you can stop displaying the Explanation Pop-Ups by selecting the “Don’t show anymore” option. In any case, you can reactivate the display of the explanation pop-ups from the Settings screen – “Analysis Options” button (see Section 4.6.5).

4.4.3 Acquisition screen

By clicking on the “Test” icons, after connecting the probes (if not already connected), and displaying the explanation Pop-Up (if active), the acquisition screen will appear.

In this screen you can identify the following main areas:

1. Biofeedback ring
2. Test footer bar
3. Audio On/Off button
4. Rec&Stop button



Biofeedback ring

During acquisition, the biofeedback ring allows you to view the current acquisition in real-time Biofeedback.

Test footer bar

The test footer bar is present because more than one acquisition is required to generate the report. Therefore, it allows you to select the sub-test to be acquired.

Audio On/Off button

By clicking on the following button, you can enable  and disable  sounds during acquisitions.

Rec&Stop button

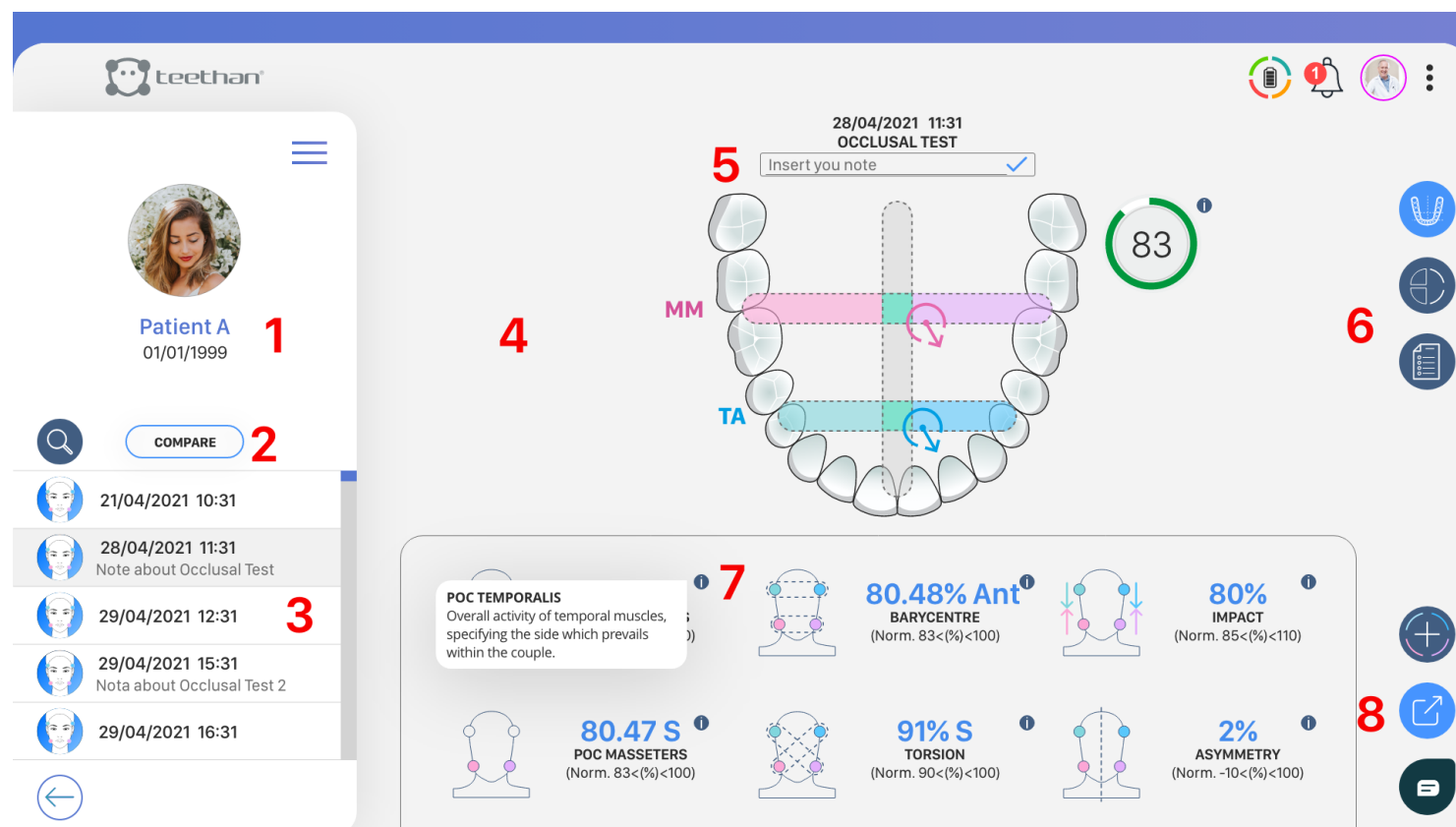
Click on the Record button to start the recording. Clicking on the Stop button will stop the recording in progress.

4.5 Test Report screen

At the end of the acquisition procedure, or by clicking on a test previously saved in the database and visible in the “Examination List” (Section 4.3.3), the software will automatically show the Test Report window.

In this screen, you can identify the following main areas:

1. Patient’s personal data
2. “Compare” button
3. Exam List
4. Report Area
5. Title’s Notes
6. “Report Navigation” buttons
7. Index’s Guide
8. “Export” button



Patient's personal data

This section displays the following patient biographical information:

- Name
- Surname
- Date of Birth

Compare button

Clicking on the “Compare” button, displays the exam comparison screen (Section 4.5.2).

Exam List

The Exam List contains the list of tests previously acquired and saved in the database.

Report Area


The Report Area contains the report of the displayed exam.

Title's Notes


The Title's notes bar allows to you to log any information regarding the test. To insert a Note, click on . When finished, to save the note, click on .

“Navigation Report” buttons

“Navigation Report” buttons allow you to navigate between the different pages of the report, according to the test performed.

The  “Notes” button – common to all test reports, allows access to the “Notes” page (see Section 4.5.1).

Index's Guide

To learn more about what each index stands for, click on  to visualize a brief explanation of the parameter you're interested in.

POC TEMPORALIS

Overall activity of temporal muscles, specifying the side which prevails within the couple.

4.5.1 Notes Page

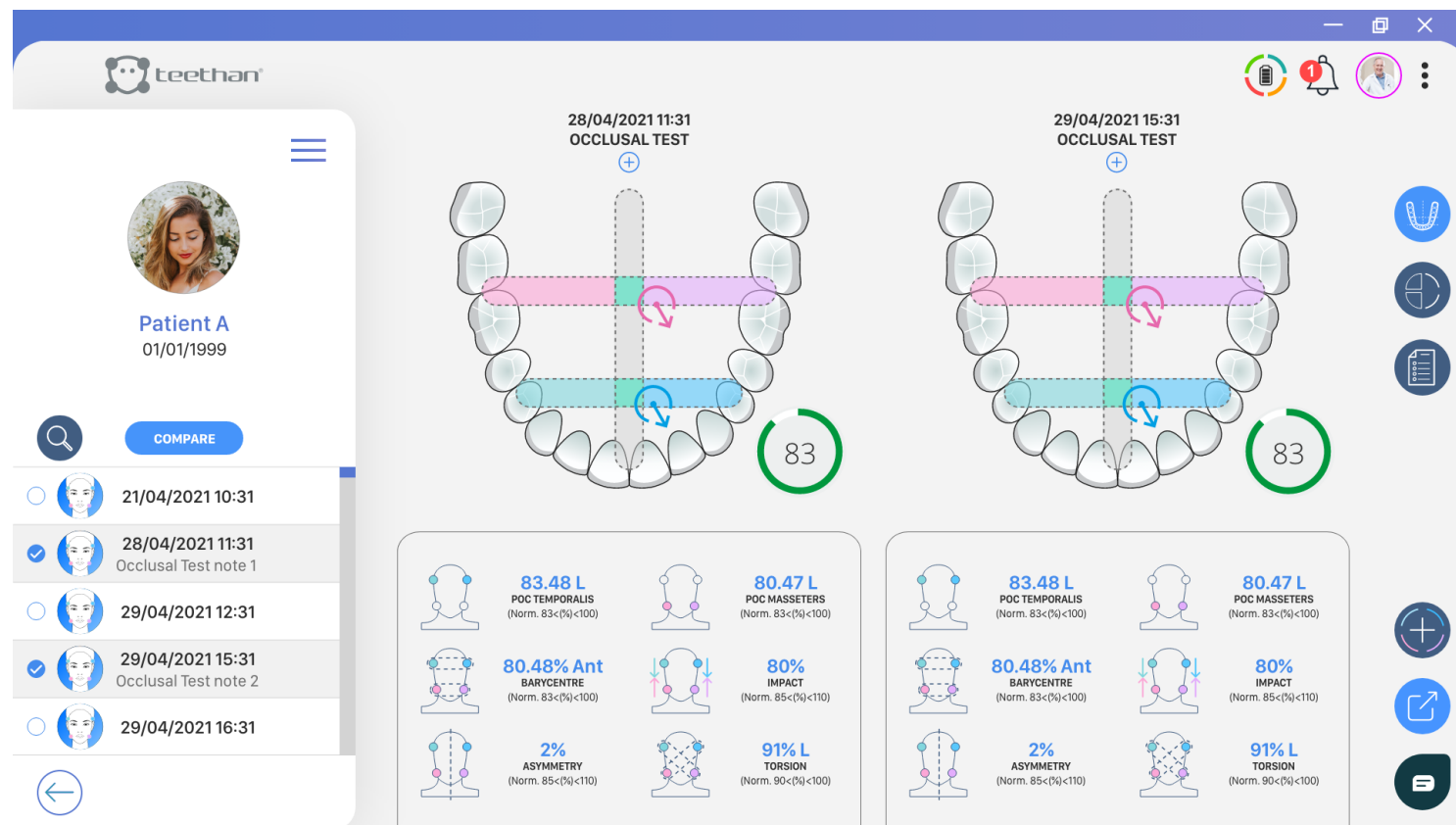
Click on the “Notes” button to access the page of the same name where it is possible to:

- Briefly verify the normality of the values assumed by the indices extracted on the basis of literature data for the Occlusal Test.
- Write notes on the test carried out for both the Occlusal Test and the Chewing Test.

4.5.2 Comparison Report Screen

The screenshot displays the teethan mobile application interface. At the top left, the teethan logo is visible. The main header shows the date and time: 28/04/2021 11:31, and the test type: OCCLUSAL TEST. Below this, there is a section for patient information, including a profile picture of Patient A and their birth date, 01/01/1999. A 'COMPARE' button is located below the patient information. A list of recent tests is shown, with the current test highlighted: 28/04/2021 11:31, Occlusal Test note 1. The main content area features a list of test parameters with radio button options for 'R' (Right) and 'L' (Left), and 'Ant' (Anterior) and 'Post' (Posterior). The parameters are: TEMPORALIS PREVALENCE (R checked), MASSETER PREVALENCE (L checked), BARYCENTRE (Ant checked), TORSION (R checked), MUSCULAR WORK (Low checked), and ASYMMETRY (R checked). To the right of these options is a circular diagram of a human face, divided into four quadrants: TA (Top Anterior, blue), TL (Top Left, light blue), BL (Bottom Left, pink), and MM (Bottom Middle, purple). Below the diagram is a 'Note' section with a text input field labeled 'Insert notes...' and a 'Modify' button. The bottom right corner contains several navigation icons: a hand, a circular arrow, a document, a plus sign, a share icon, and a message icon.

Clicking on the Report screen button **COMPARE** (see Section 4.5) will take you to the Comparison Report screen.






The Comparison Report screen allows you to compare two or more tests of the same type to verify the difference in the values assumed by the test parameters.

To select the tests to be compared click on the button next to the tests. Immediately, the test will be selected and it will be added to the list of tests displayed.



You can only compare tests of the same type. If you want to change the type of test to be compared, click on the “Finish” button, select the desired test type, then click again on the “Compare” button.

By default, Teethan will side-by-side reports of the tests selected to be compared. To navigate between selected tests, simply use the arrows  to see the next one and  to see the previous one.


If you want to view the time trend of the test parameters over time, click on the button  to access the Time Evolution screen:



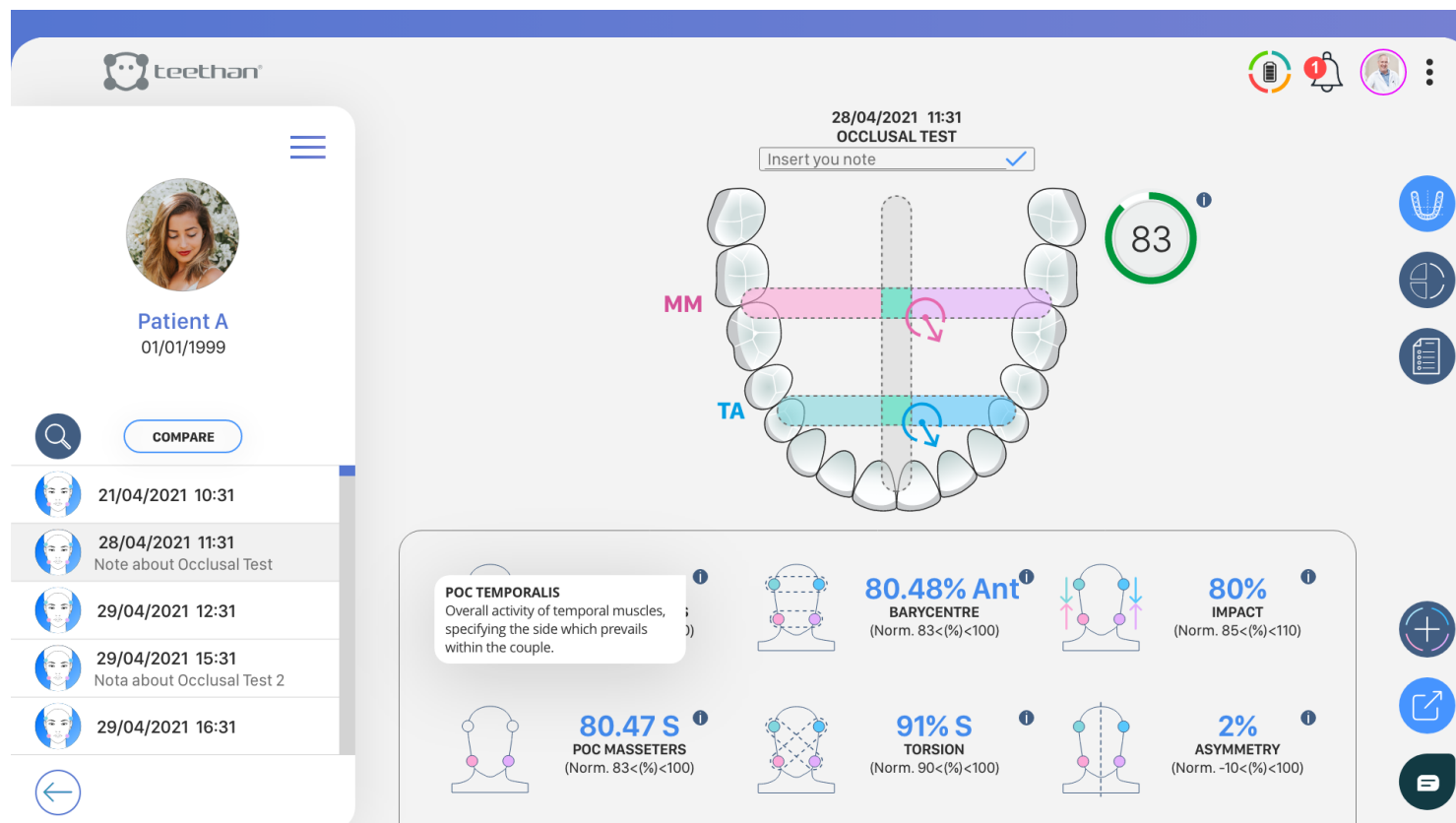
The Time Evolution screen allows you to judge how the acquired test parameters have changed over time, through graphical display and a measure of percentage increase (or decrease).

To exit the Comparison Report page, click again on the  of the Comparison screen.



4.5.3 Export Screen

It is possible to export the report of the test or the comparison of several tests - both in terms of Report and Time Evolution - as a .pdf print or by email. To export the Report, click on the button  in the Report screen (Paragraph 4.5) or in the Comparison screen (Paragraph 4.5.2).



The report preview page will appear immediately:



If desired, one can add or remove tests from the report.

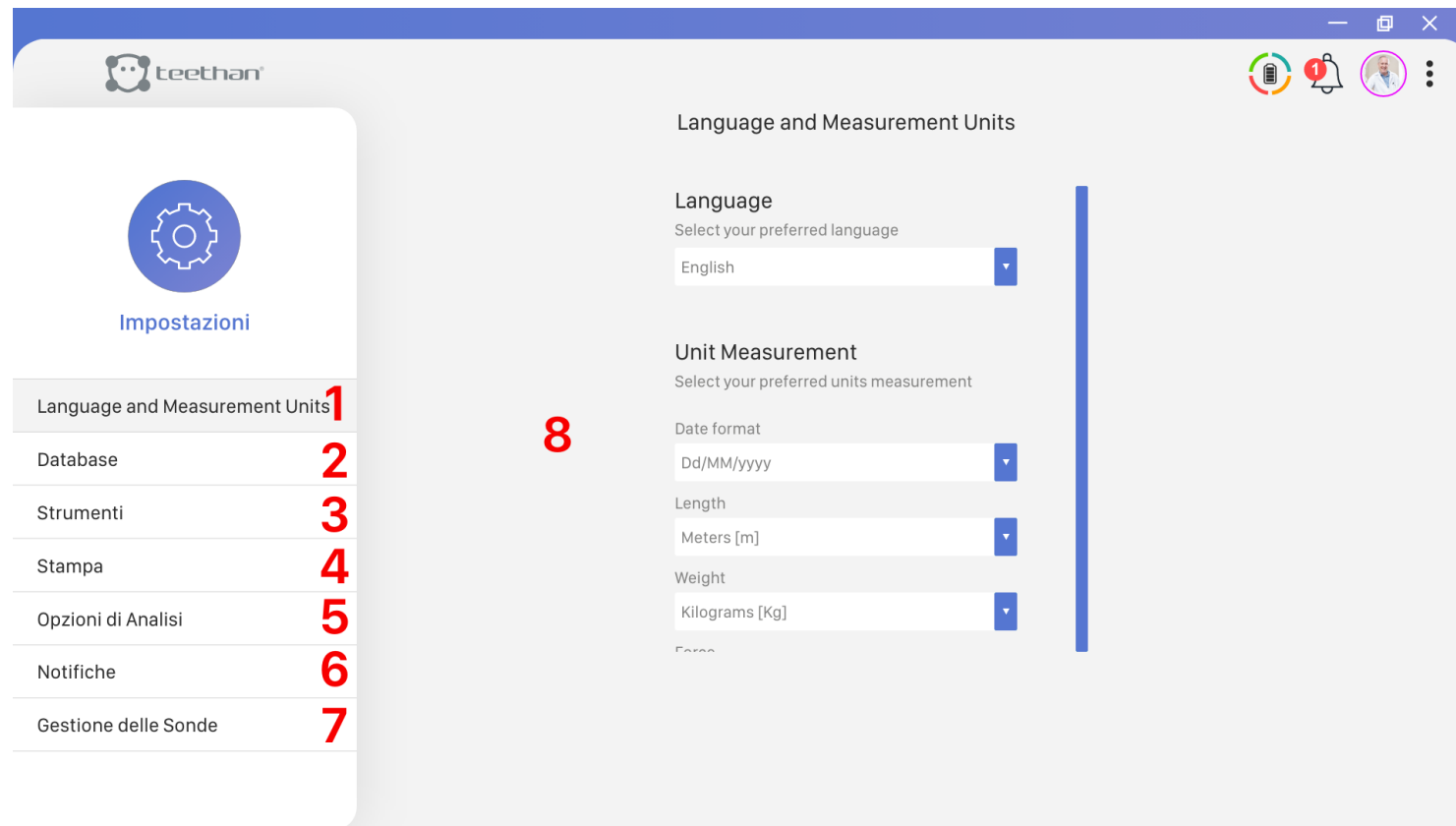
- To add a test to the current report, click on the button  of the test icon to add.
- To remove a test, click on the button  of the test to remove.


Once you have selected all the tests you want to export, you can:

- Print the test by clicking on the button 
- Export the test in .pdf format by clicking on the button 

- Send the test by e-mail by clicking on the button 

4.6 Setting Screen



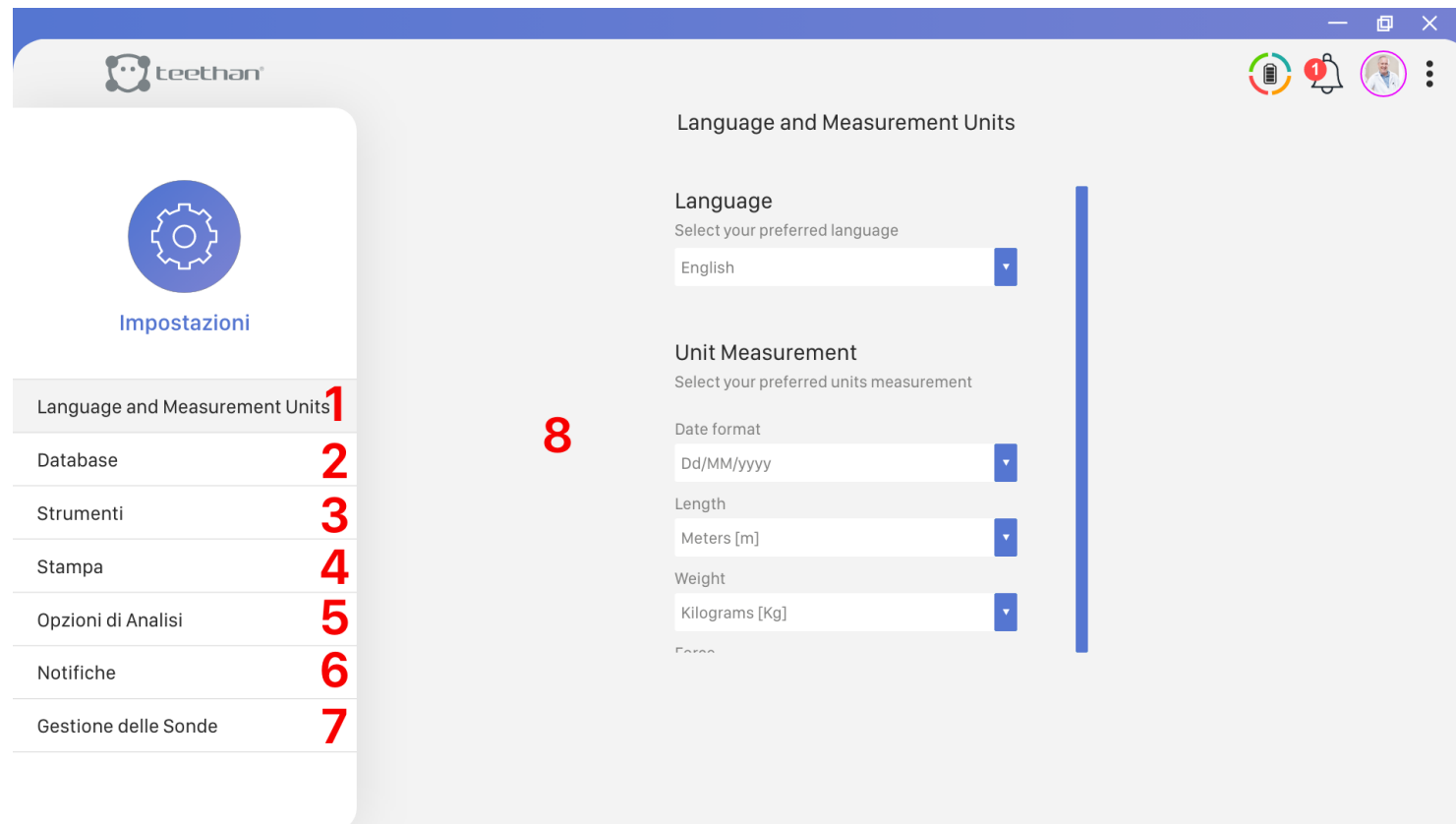
Clicking on the icon  in the upper right corner takes you to the Options menu. This allows you to activate the various functions available within the software. By clicking on “Settings”, you can access the Settings screen.

In this screen you can distinguish the following main areas:

1. “Language and Units of Measurement” button
2. “Database” button
3. “Tools” button
4. “Print” button
5. “Analysis Options” button
6. “Notifications” button
7. “Probes Management” button
8. Settings area

4.6.1 Language and Units of Measurement button

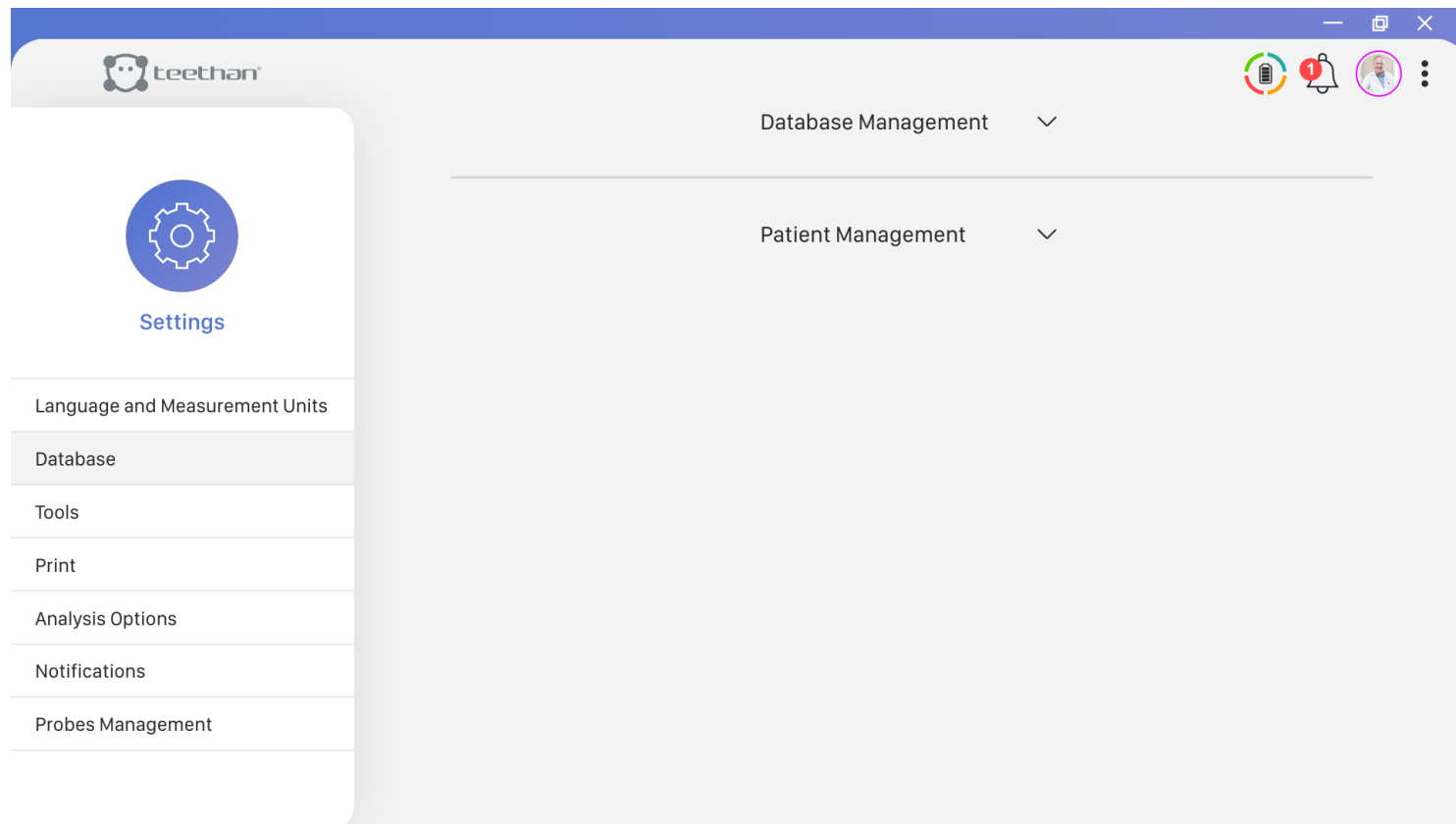
By clicking on the Language and Units of Measurement button, you can access the Language and Units of Measurement screen.



From this screen, you can set the language of the software and the units of measurement. To change the settings, select the desired language and/or unit of measure from the drop-down menu.

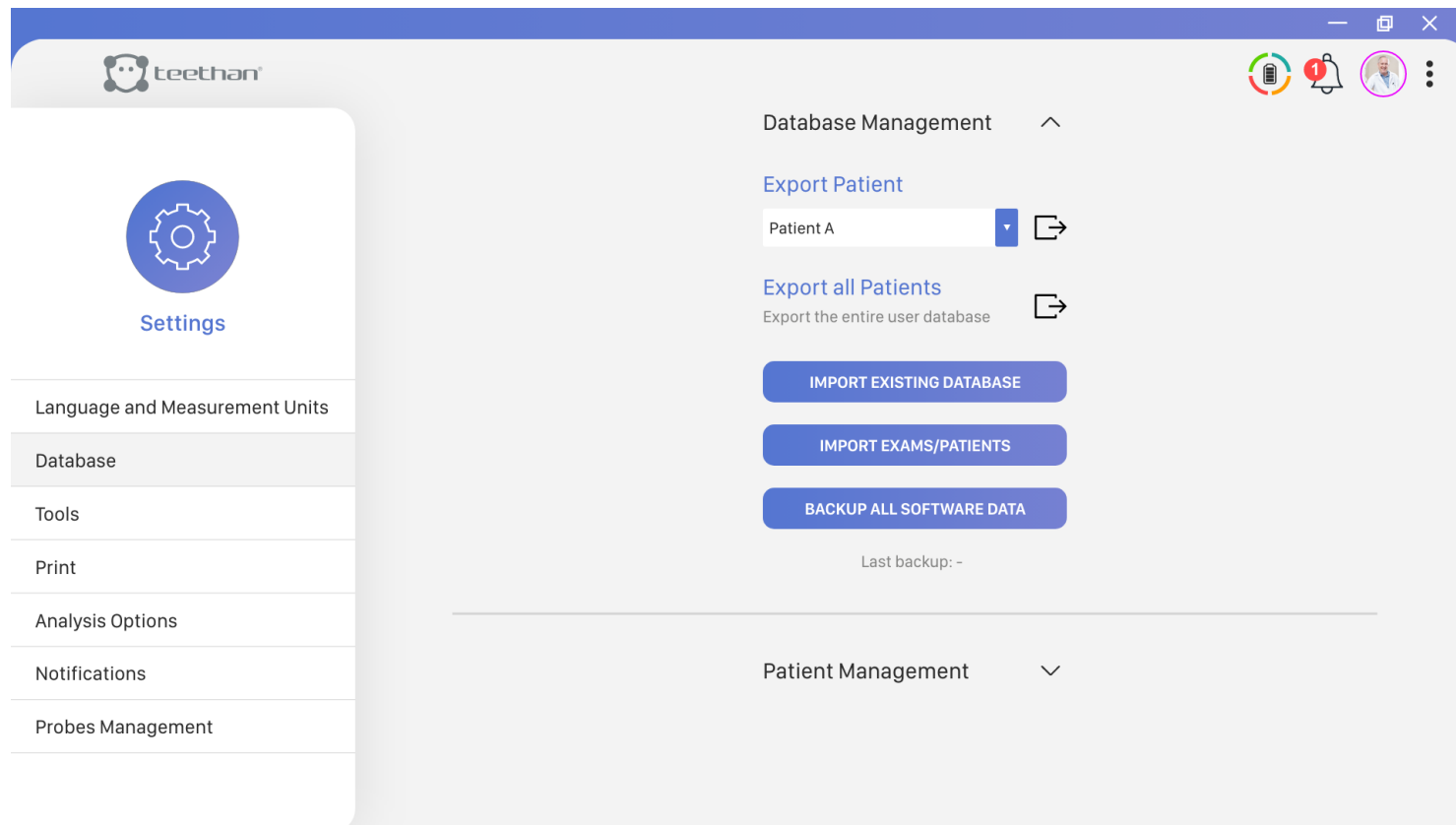
4.6.2 Database button



Clicking on the Database button takes you to the Database screen. Clicking on the icon opens the pull-down menus.

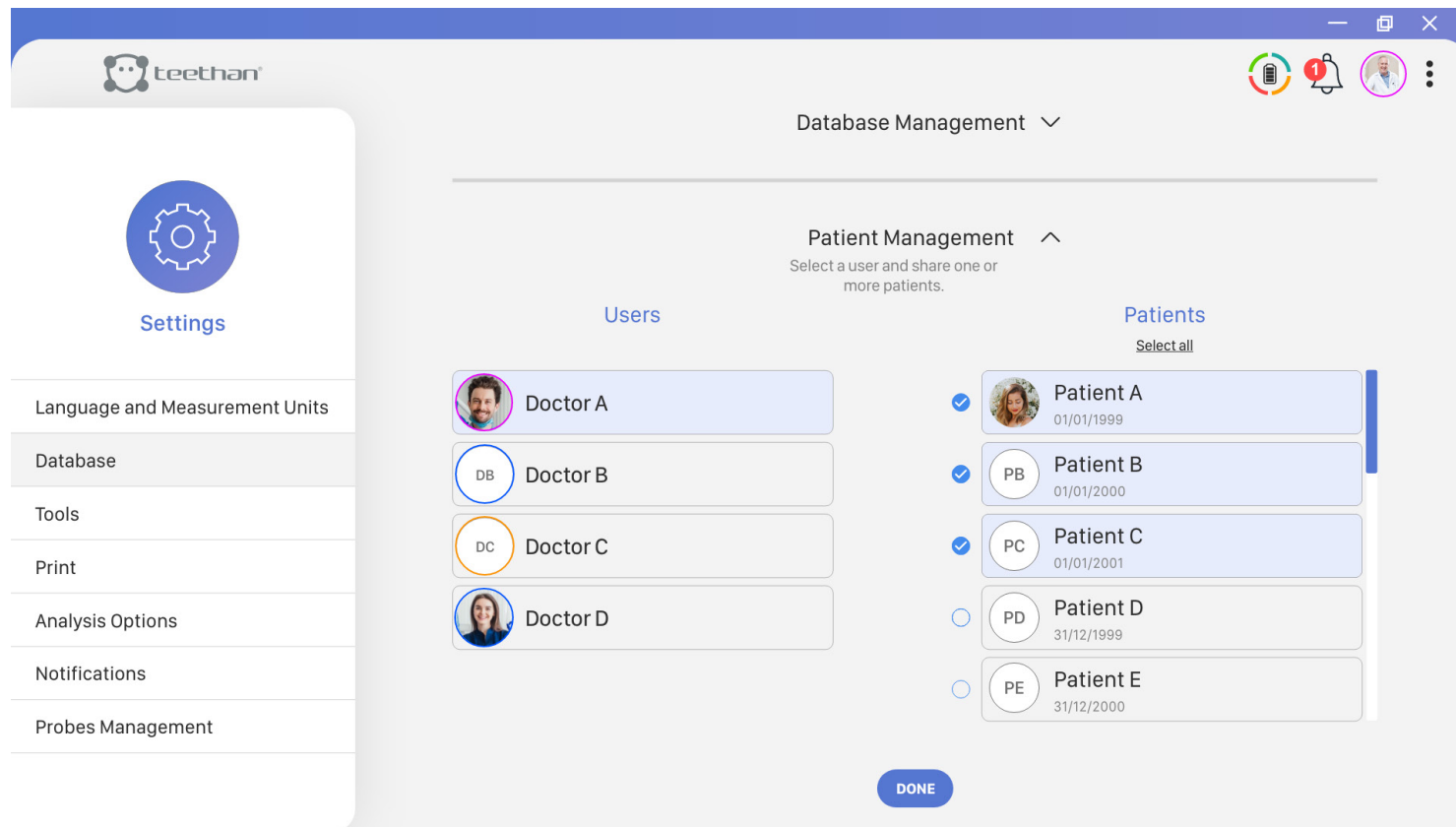



The Database Management menu allows you to:

- Export all exams for a patient. Select the patient from the drop-down menu, click the Export button and save the file.
- Export the exams of all the user's patients. From the "Export all patients" item, click the Export button and save the file.
- Import Teethan exams. Click on the appropriate button and follow the on-screen instructions by selecting the desired file for import.
- Perform a complete back up of all exams performed with Teethan.




In the Patient Management menu, on the other hand, once a user has been selected, it is possible to view the patients currently shared with that specific user and – if desired – to add further shared patients. To select patients to be shared, click on the button  situated on the left of the Patient List. Immediately, the icon will become .



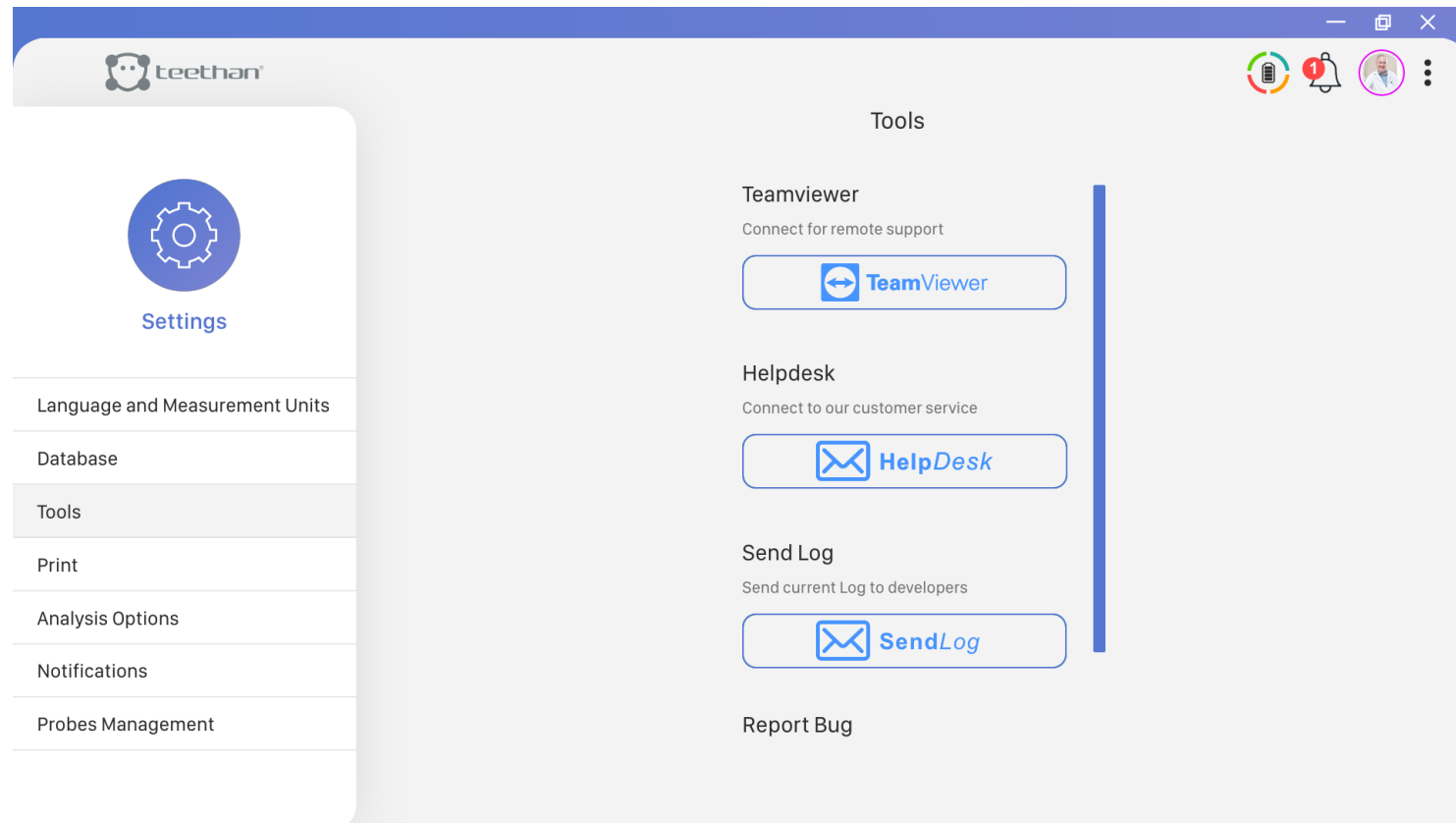
For the sharing to become effective, press **DONE** and confirm through the appropriate icon  in the banner that appears:

Do you confirm the sharing of patients of the selected user?  

If, on the other hand, you want to undo the changes you just made, click on the icon .

4.6.3 Tools button

Clicking on the Tools button takes you to the Tools screen:

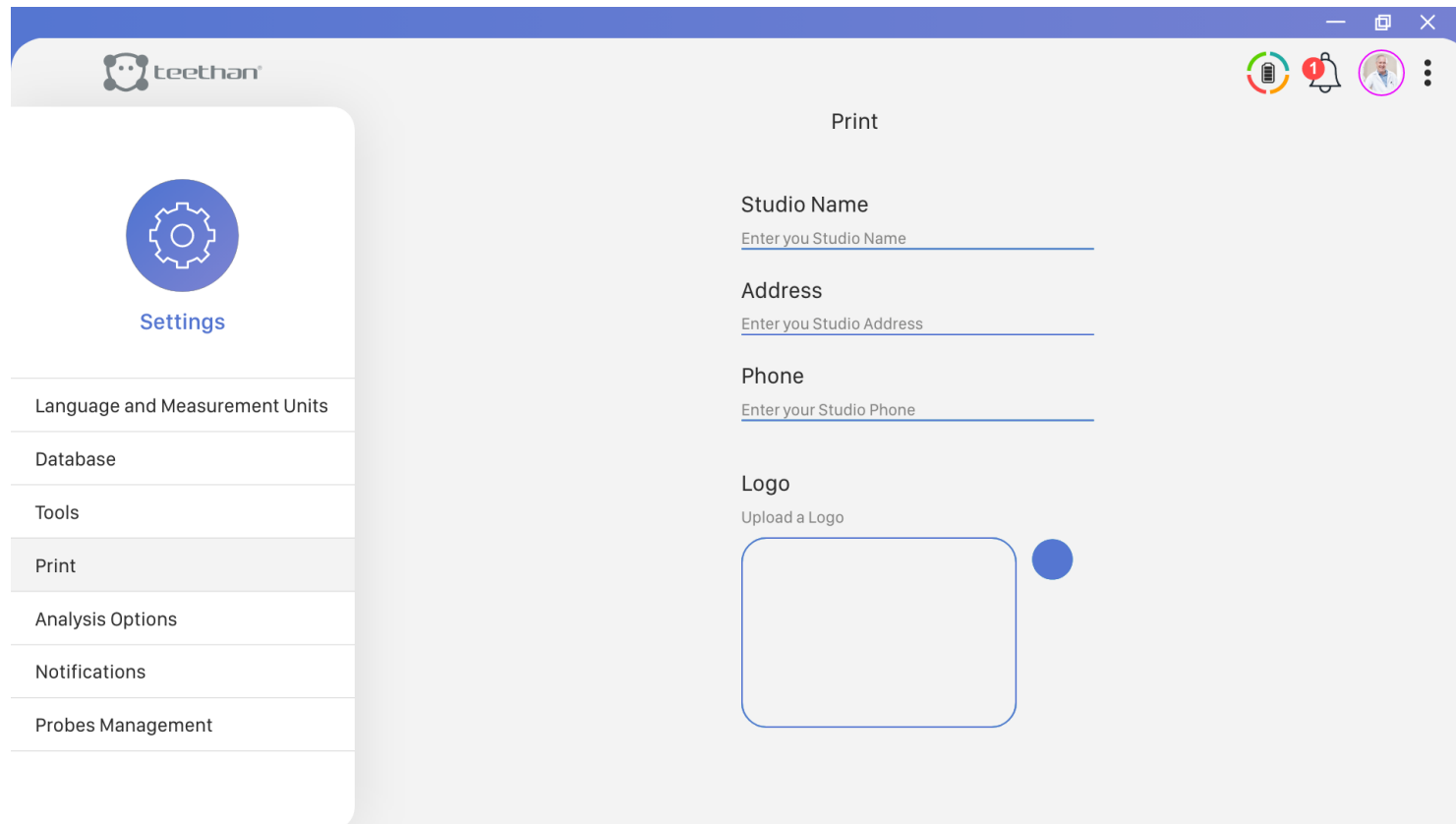


From this screen you can:

- Activate the Teamviewer Software: clicking on the “Team Viewer” button will activate the software that allows customer support to remotely control the machine.
- Contact the Customer Assistance Service: clicking on the “Help Desk” button will open a new e-mail message addressed to the Teethan assistance service
- Send Log: in case of unexpected errors, by clicking on the “Send Log” button it is possible to send the error the Teethan Development Team.

4.6.4 Print button

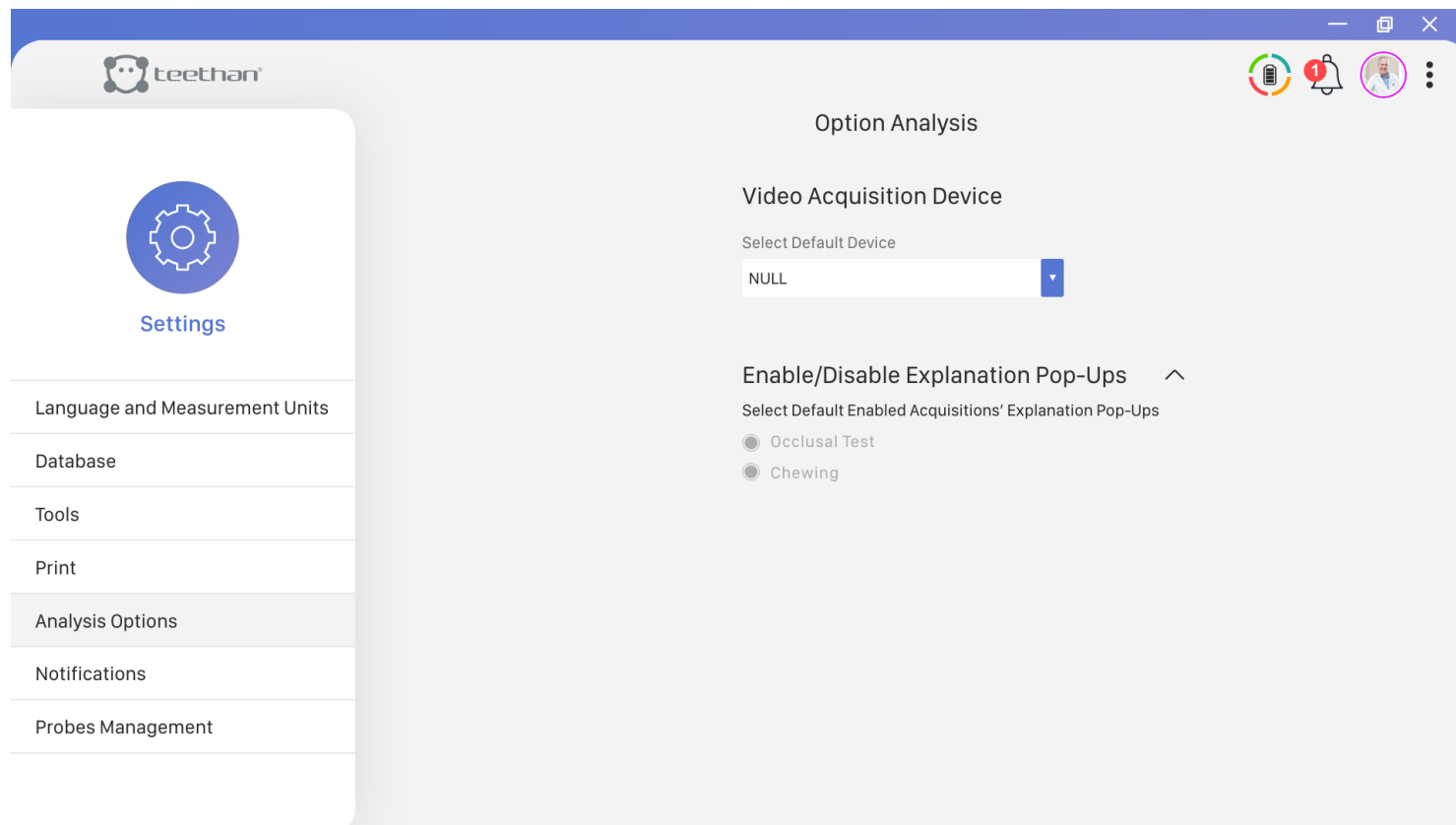
Clicking on the Print button will take you to the Print screen:



From the Print screen, you can enter the header displayed in the print file or .pdf Export.

4.6.5 Analysis Options button

Clicking on the Analysis Options button will take you to the Analysis Options screen:

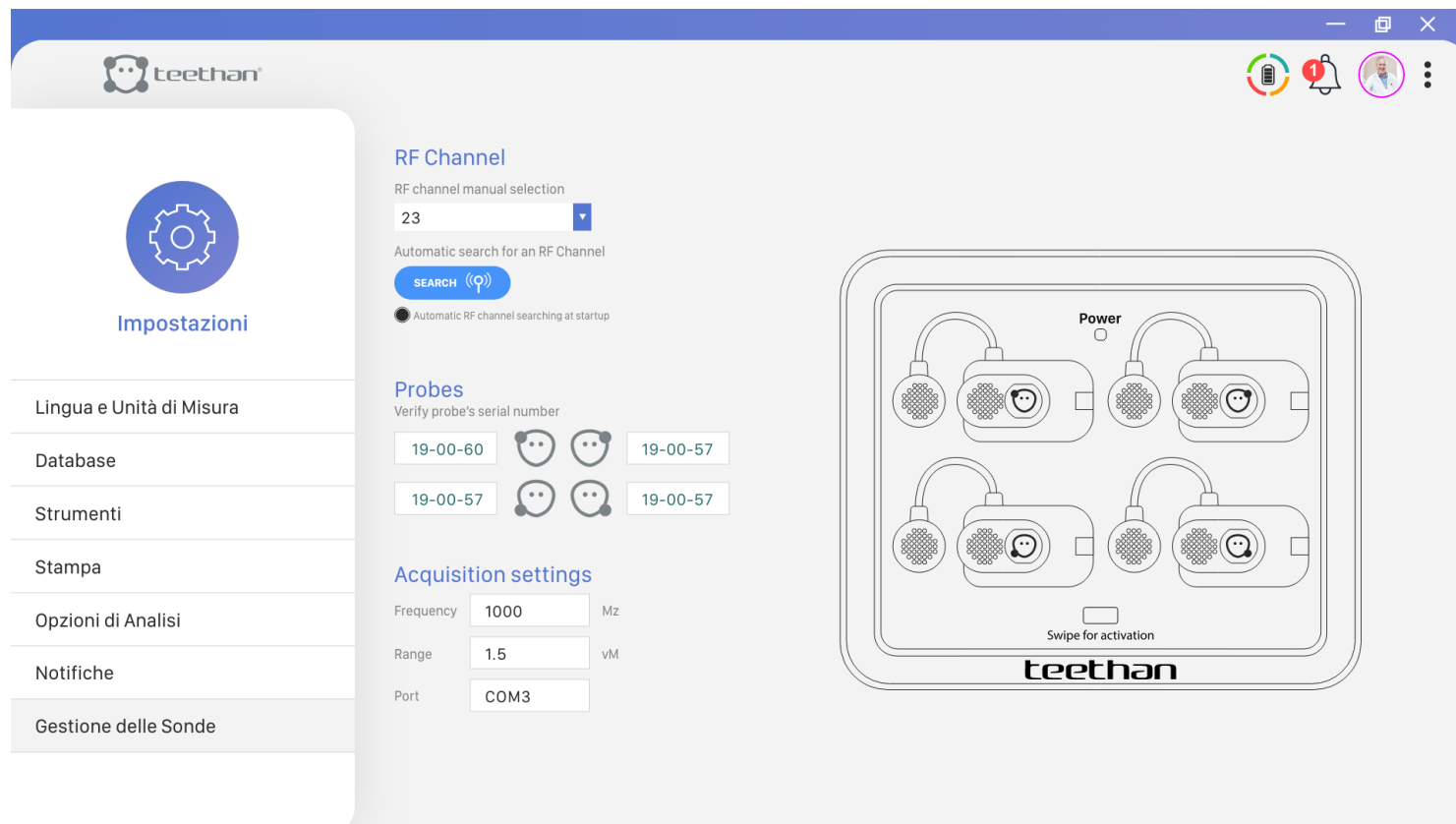


Here you can:

- Enable or disable the Explanation Pop-Ups. Select the desired test to enable them. Uncheck the desired test to disable them.
- Choose the video device with which to capture patient and user profile photos.

4.6.7 Probes Management button

Click on the “Probes Management” button to access the screen of the same name.




In this screen you can:

- Display the currently active RF channel
- Check the serial number of each probe
- Read the acquisition settings

Display the currently active RF channel

When the automatic channel search at startup is active , the software selects the best available RF channel.

If you are experiencing interference and/or want to scan the available RF channels, simply click on the icon  .

To manually change the RF channel, click on the appropriate arrow  to open the selection menu.

Check each probe's serial number

With reference to the legend represented by the graphic representation of the charging station and the electromyographic probes, for each of these it is possible to display the serial number.

Acquisition settings

In this portion of the screen, Teethan software shows you the value of the sampling frequency, the acquisition range, and the COM port to which the USB receiver is connected.

5

TEST

Teethan system includes the following tests:

1. Occlusal Test – Static: protocol for measuring dental occlusion’s balance.
2. Chewing Test – Dynamic: protocol for evaluating neuromuscular coordination during the masticatory act.

In this chapter, for each test, we’ll illustrate:

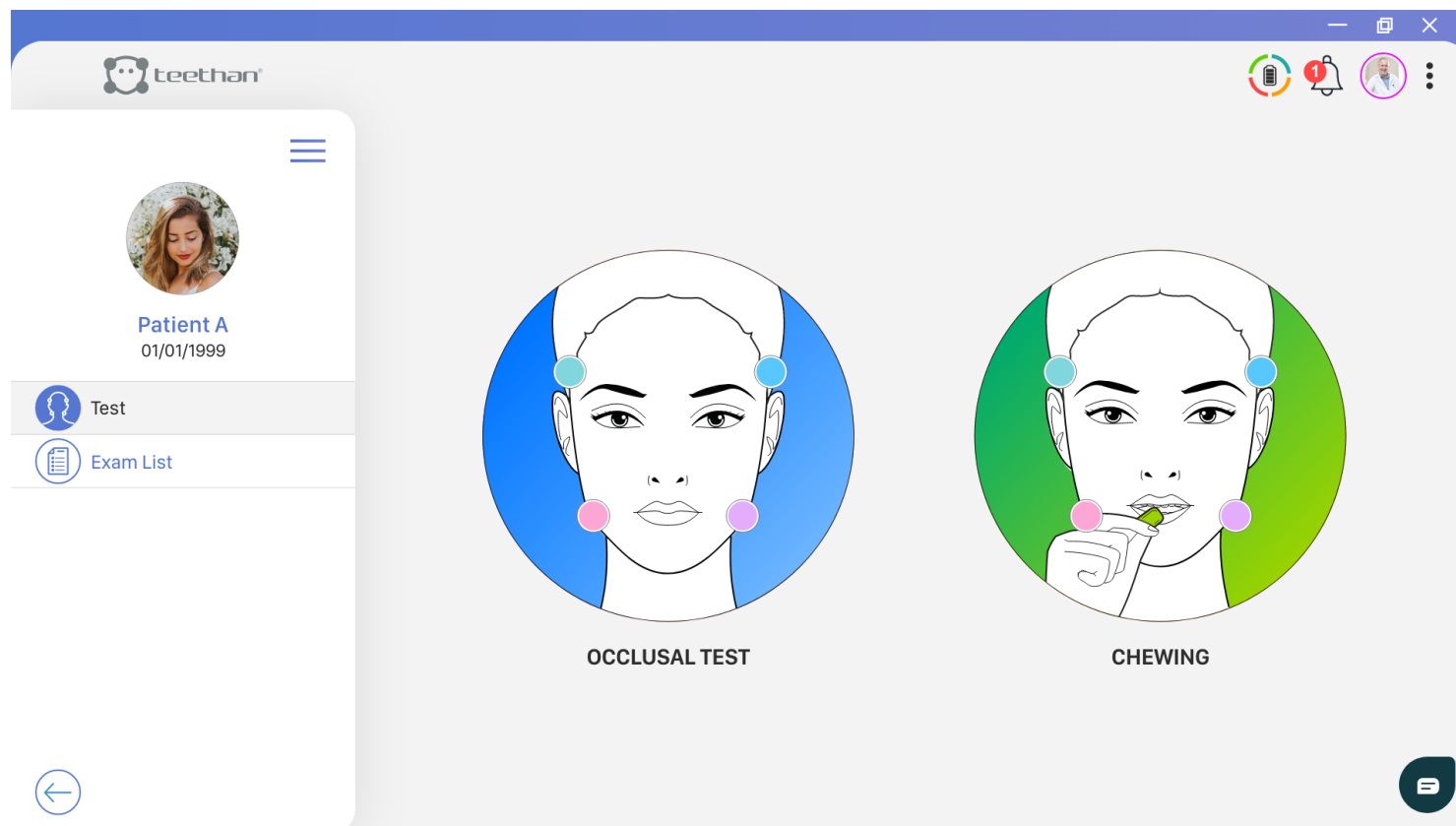
- How to start the test protocol
- Probes’ placing
- Test acquisition
- Report

5.1 Occlusal Test

To measure the balance of the dental occlusion, the patient must perform two clenching tests of five seconds each - the first with cotton rolls, the second one without. Once these trials are done, the report is automatically generated.

5.1.1 Test Start-Up

To proceed with a new acquisition, from the Home screen of the software, select the desired patient. From the Patient screen, in the Test section, click on Occlusal Test.



5.1.2 Probes' placing

To obtain reliable and repeatable data during the tests, it is necessary to correctly place the probes on the subject to be evaluated.

Before proceeding with the actual placing, apply the pre-gelled electrodes using the provided snap connector and remove the protective film (5.1).

Then, activate the probes and place them on the patient's face in line with masseter and temporalis muscles (5.2).



Each probe is dedicated to the acquisition of a specific muscle, identified on the label:



Right Masseter



Left Masseter



Right Temporalis



Left Temporalis

Application of probes to Temporalis muscles

To identify the anterior bundle of the temporalis, palpate the muscle by asking the patient to perform a full clench. Identify the major axis of the zygomatic process of the frontal bone and apply the probe along with the muscle anterior margin - close to the coronal suture and keeping 2 centimeters from the zygomatic process (5.3).



Application of probes to the Masseter muscles

To identify the masseter muscle, palpate the clenched muscle by identifying its belly. Apply the probe in a direction parallel to the course of the muscle fibers and in the central portion of the muscle - along the line joining the outside edge of the eye with the angle of the jaw (5.3).



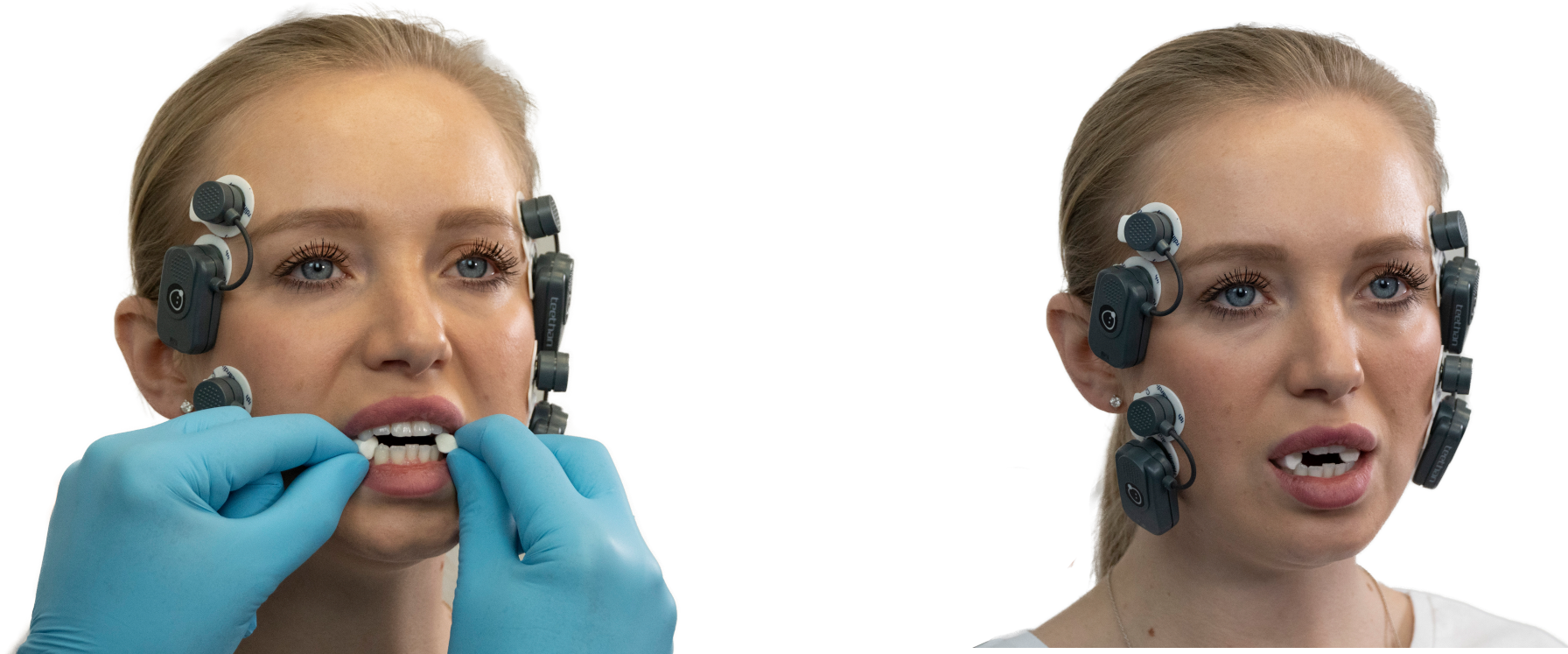
Symmetry and Posture

Symmetry of placing between right and left should be maintained. To minimize any interference due to the patient's posture, ensure that the chair back is upright, and the patient is in a relaxed position with uncrossed legs, hands resting on the knees and looking straight forward.

5.1.3 Test Acquisition

Calibration test with cotton rolls

Insert the cotton rolls between the arches on the 5th and 6th tooth - second premolars and molars (5.4). Ask the patient to clench their teeth as hard as possible (5.5).



To start the calibration, press the “Rec” button.

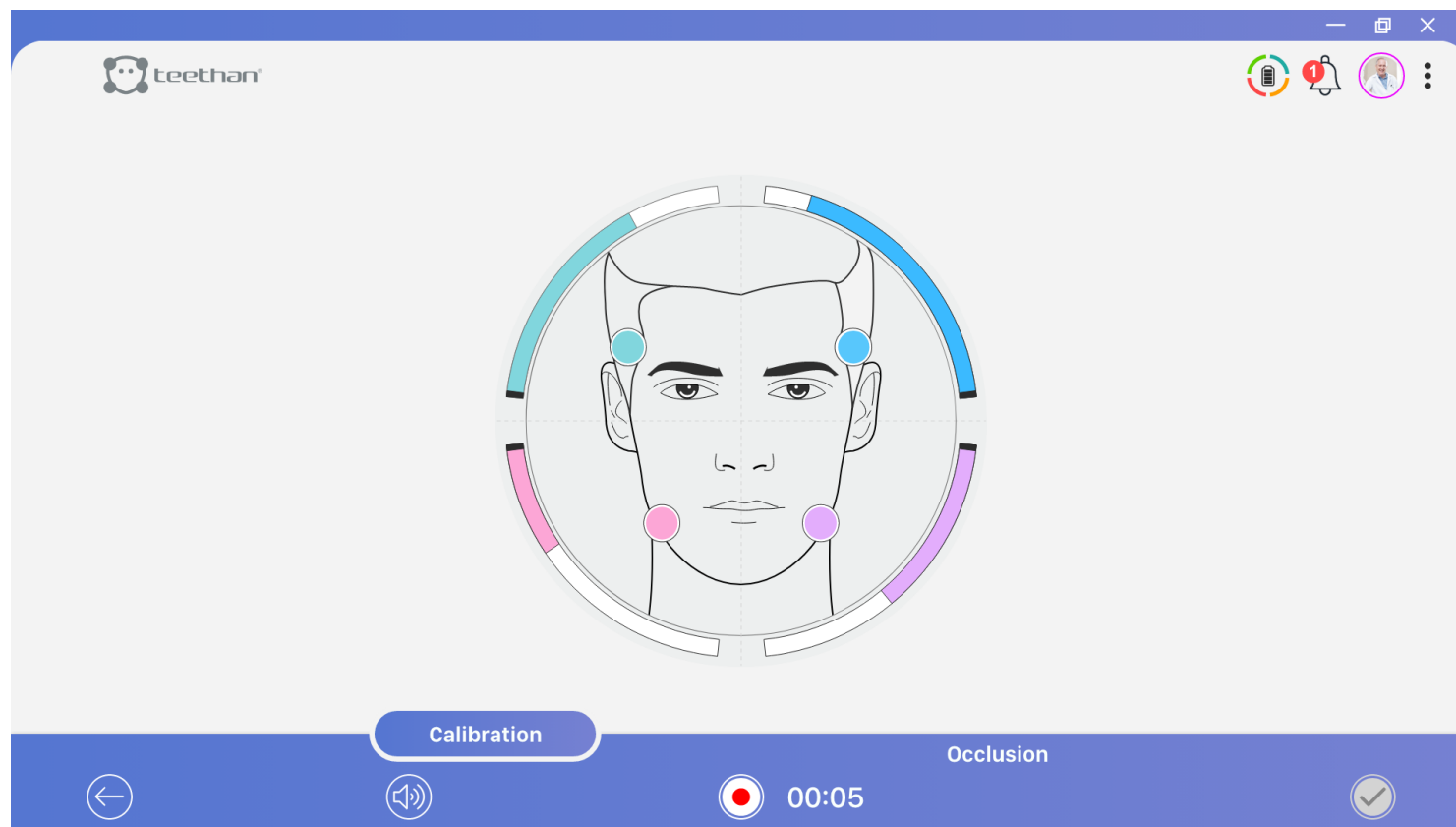


During the test execution, the electrical activity of the analyzed muscles is displayed in real-time, using bars that get filled with color proportionally to the degree of muscular activation. Each of the four muscles is identified by a characteristic color:



The recording stops automatically after five seconds and goes directly to the next acquisition step by activating the “Occlusion” button.

It is possible, however, to carry out and compare several calibration tests to select the one you consider best and test data repeatability. To do this, click on the “Calibration” button on the lower bar and start the acquisition using the Record button. On the left, you will see previews of the pie charts for each of the calibration tests performed.



Natural intercuspation test

Once you have acquired the occlusal calibration test (or selected the one that you think is best among those performed), the software is ready to perform the actual Occlusal Test. So, after removing the cotton rolls, ask the patient to clench as hard as possible to allow natural dental intercuspation.





5.1.4 Report


At the end of the acquisition process, the report is automatically generated. Teethan's Occlusal Test clinical report is composed by three main sections:

- Occlusal Plane's Parameters and Indexes
- Muscular Activity and Intensity of Muscular Contraction
- Normality Values and Notes

Occlusal Plane's Parameters and Indexes

The representation of the dental arch includes two targets:

- The blue target  refers to the activity of temporalis muscles (that govern the front of the mouth)
- The pink target  refers to the activity of masseter muscles (that govern the back of the mouth)

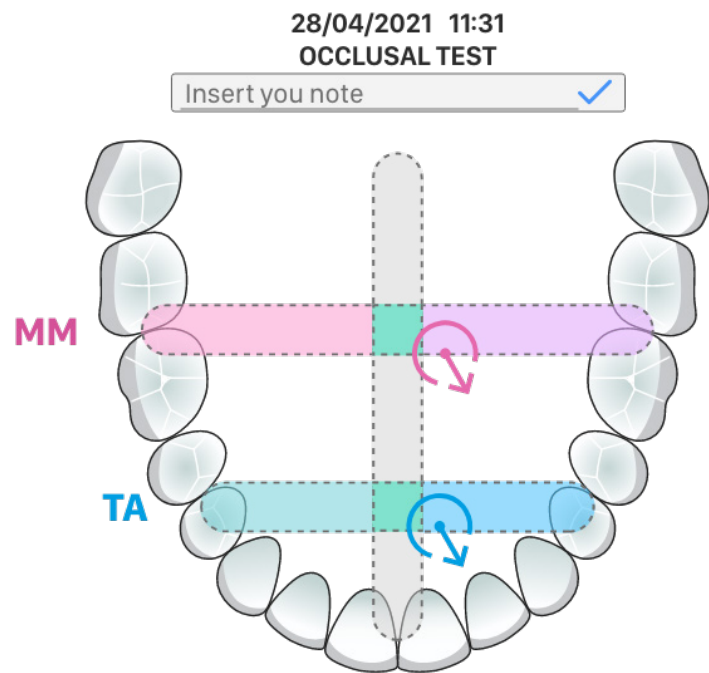
The dashed bars represent the normality bands of benchmark indexes. The intersections  are areas where both targets appear in case of balanced occlusion.

Immediately beside the image of the arch, the Global Index of Neuromuscular Balance is displayed. It is represented with a color-coded biofeedback ring:

Green: when the global balance is greater than 83%.

Yellow: when the global balance is between 82% and 75%

Red: when the global balance is less than 74%.



Immediately beside the image of the arch, the Global Index of Neuromuscular Balance is displayed. It is represented with a color-coded biofeedback ring:



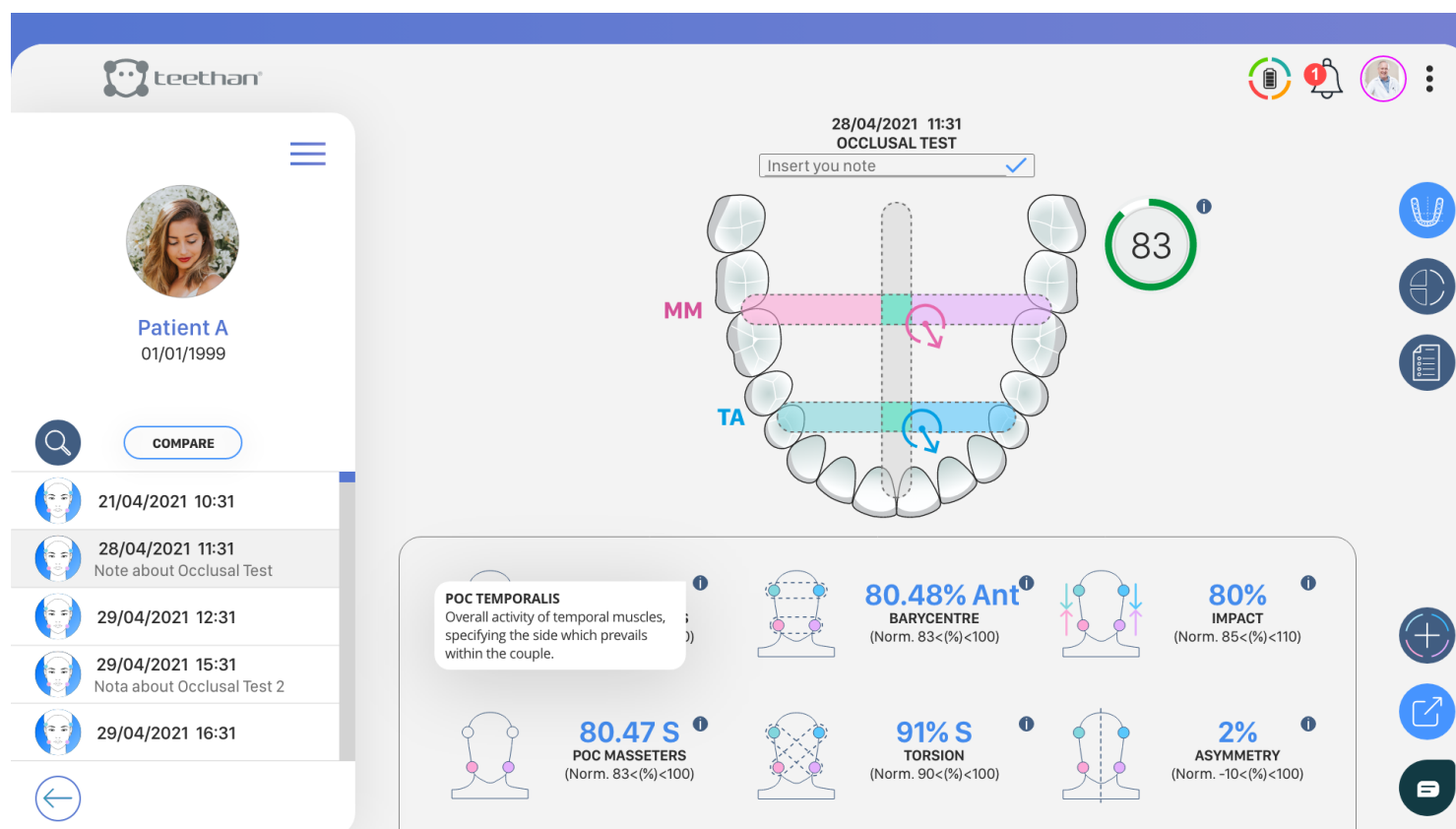
Green: when the global balance is greater than 83%.



Yellow: when the global balance is between 82% and 75%



Red: when the global balance is less than 74%.



Parameters and indexes for the evaluation of the Occlusal Plane are:

- **Percent Overlapping Coefficient (POC):** it is an index used to assess the symmetry of contraction standardized within the same muscle pair. It indicates the imbalance (right/left) within the examined muscle pair: in particular, the POC calculates the predominance of the right or left temporalis in the front quadrants, and that of the right or left masseter muscle, in the rear quadrants.

POC index states, as a percentage value, the difference in electrical signal generated by a muscle pair in maximum voluntary contraction (MVC), compared to the analogous standardized value. If the two muscles of the same muscle pair contract symmetrically, the expected theoretical result of POC is close to 100%; instead, if the two muscles have standardized values with a different percentage, the POC is considerably less than 100%. If POC exceeds 83%, there is a normal muscular symmetry induced by teeth contact. Otherwise, dental contact is affecting the neuromuscular balance of the patient. Out-of-range POC values indicate prevalent or insufficient quality of the contact of one side than the other.

The vertical dashed central line, with a light grey color, indicates the normal range, up to 83% value, to the left and the right of the central line, to represent the predominance of the right or left muscle activity.

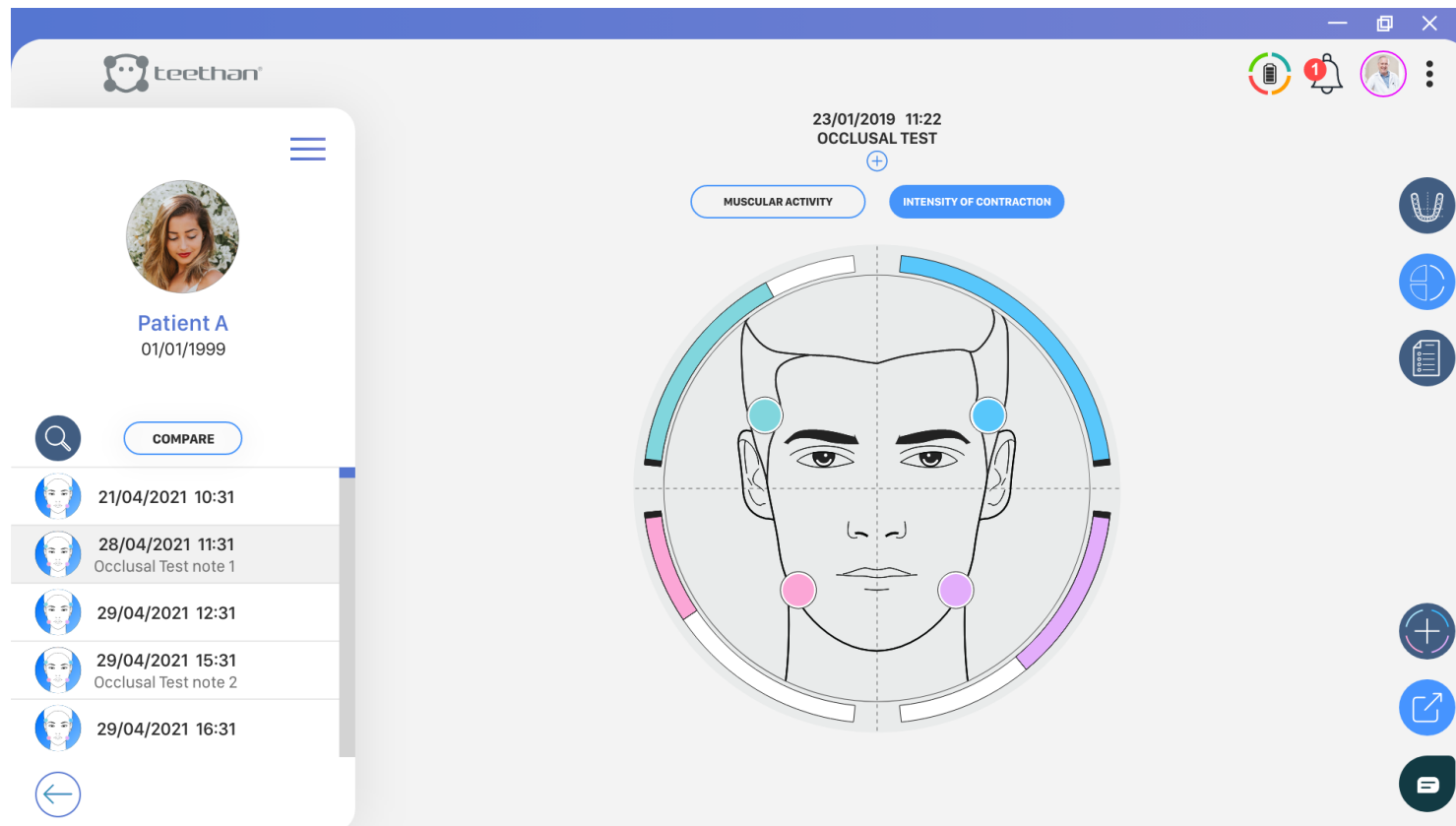
- **Barycentre (BAR):** it assesses the position of the occlusal barycentre. It is obtained by calculating the percentage of overlapping coefficient between the activities of the two temporals and the activities of the two masseters (unlike the POC index that compares individual analogous muscles). When the contact points tend to concentrate on molars, the masseters record a greater contraction than the corresponding temporal muscles (rear barycentre). Conversely, in the occlusal condition where the barycentre moves to the antero-lateral sectors (i.e. up to the first-second premolar), the temporal muscles state greater contractile forces (front barycentre). In this case, there is an overload of bilateral joints that, over time, can lead to pathological conditions. As for BAR index, if the barycentre position is mainly anterior, the expression “Ant” is entered. Conversely, if the barycentre position is mainly posterior, the expression “Post” is entered.

The normality value of the BAR index is greater than 90%.

• **Torsion (TORS)**: this assesses the torsion attitude of the mandible in the horizontal plane when it is in occlusion with the upper jaw. It is the result of the comparison of the force couple of crossed muscle pairs: comparison between the right temporal and left masseter pair and between the left temporal and the right masseter pair. When this index is $> 90\%$, there are no force couples on the jaw. On the contrary, if this index is outside normal values, that is less than 90% , muscles tend to make the lateral displacement of the jaw to the right or left depending on whether the one of the other muscle pair prevails, due to the presence of occlusal fulcrums. The letter “R” is entered when there is mainly torsion to the right, “L” when there is mainly torsion to the left. The result of the action of the temporal muscle added to the result of the strength of the contralateral masseter muscle, generates a pair of forces with a moment that tends to latero-deviate the mandible towards the result of the temporalis anterior: if the one on the right is greater, the target is not only circular, but displays an arrow to the right. Similarly, the arrow is to the left if it is greater than the coefficient calculated for the left temporalis anterior-right masseter muscle.

• **Impact (IMP)**: it indicates the muscular activity of masticatory muscles and is proportional to the bite force. The normality values of the index are over the range of 100% - 115% . Values above the standard suggest the formulation of a diagnosis of the clenching patient. Sub-standard values can state a condition of acute proprioceptive inhibition and thus pain in MVC or reaching chronic levels due to the presence of a protective nociceptive reflex. If POC, TORS and BAR indexes are normal, the IMP index is related to the vertical dimension. The user is provided with indications of the possibility of raising (index higher than normal) or reducing (index lower than normal) the vertical dimension compatibly with the aesthetic condition of the patient.

• **Asymmetry (ASIM)**: this index allows you to compare the activity of the right muscles with that of the left ones. A positive value indicates a greater activation of the right-hand side, while a negative value indicates a greater activation of the left-hand side. Normality ranges from -10 to 10 .



Muscular Activity & Intensity of Muscular Contraction

In this page, it is possible to visualize the distribution of the average and normalize muscular activity by clicking on **MUSCULAR ACTIVITY** or the intensity of contraction of each investigated muscle by clicking on **INTENSITY OF CONTRACTION**.

In the first case, each sector of the pie chart is more colored the more dominant the activation of that muscle was. With a good neuromuscular balance, corresponding to the absence of malocclusion, the colors will be evenly distributed in the four quadrants and each sector will occupy a portion equal to 25%.

In the second, on the other hand, the muscle that expresses the greatest amplitude value is represented with a full bar, while the remaining bars are represented proportionally to it.

Normality Values and Notes

In this page it is possible to visualize the self-reading of the out-of-norm data and

add clinical notes for the personalization of the report. In the upper area, the out-of-norm values are highlighted with a check. This section is filled in automatically and it is not possible to make any changes.

The lower area is dedicated to the addition of notes and any information related to the Occlusal Test performed by clicking on the Modify button and save with the Save button.

The screenshot displays the teethan mobile application interface. At the top, the teethan logo is on the left, and system icons (battery, notifications, profile) are on the right. The main header shows the date and time: 28/04/2021 11:31, with 'OCCLUSAL TEST' below it. A central diagram of a human face is divided into four quadrants: TA (top), MM (bottom), R (left), and L (right). To the left of the diagram is a list of test parameters with radio button options:

- TEMPORALIS PREVALENCE: R, L
- MASSETER PREVALENCE: R, L
- BARYCENTRE: Ant, Post
- TORSION: R, L
- MUSCULAR WORK: High, Low
- ASYMMETRY: R, L

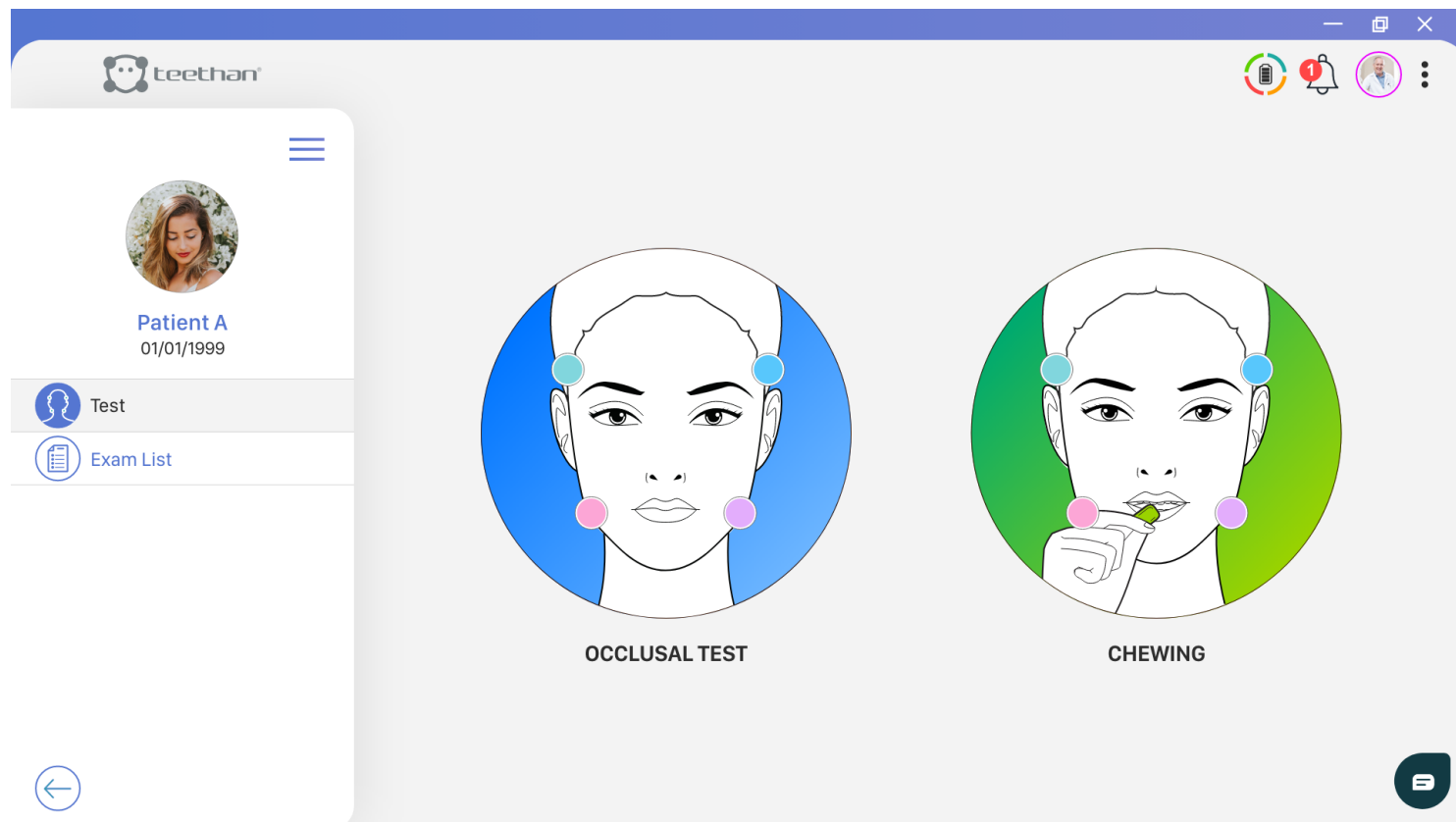
Below the diagram is a 'Note' section with a text input field labeled 'Insert notes...' and a 'Modify' button. On the left side, there is a patient profile for 'Patient A' (01/01/1999) and a list of previous occlusal test notes with dates and times. A 'COMPARE' button is located above the list. On the right side, there are several circular icons for navigation and actions.

5.2 Chewing Test

The Chewing test measures the neuromuscular coordination during the masticatory activity. Thanks to the analysis of muscular patterns repeatability, while the occlusal protocol evaluates the neuromuscular balance in a “static” condition, this test evaluates the neuromuscular coordination in a “dynamic” condition.

5.2.1 Test Start-Up

To proceed with a new acquisition, from the Home screen of the software, select the desired patient. From the Patient screen, in the Test section, click on Occlusal Test.



5.2.2 Probes placing

To obtain reliable and repeatable data during the tests, it is necessary to correctly place the probes on the subject to be evaluated.

Before proceeding with the actual placing, apply the pre-gelled electrodes using the provided snap connector and remove the protective film (5.1).

Then, activate the probes and place them on the patient's face in line with masseter and temporalis muscles (5.2).

Each probe is dedicated to the acquisition of a specific muscle, identified on the label:

-  Right Masseter
-  Left Masseter
-  Right Temporalis
-  Left Temporalis



Application of probes to Temporalis muscles

To identify the anterior bundle of the temporalis, palpate the muscle by asking the patient to perform a full clench. Identify the major axis of the zygomatic process of the frontal bone and apply the probe along with the muscle anterior margin - close to the coronal suture and keeping 2 centimeters from the zygomatic process (5.3).



Application of probes to the Masseter muscles

To identify the masseter muscle, palpate the clenched muscle by identifying its belly. Apply the probe in a direction parallel to the course of the muscle fibers and in the central portion of the muscle - along the line joining the outside edge of the eye with the angle of the jaw (5.3).



Symmetry and Posture

Symmetry of placing between right and left should be maintained. To minimize any interference due to the patient's posture, ensure that the chair back is upright, and the patient is in a relaxed position with uncrossed legs, hands resting on the knees and looking straight forward.

5.2.3 Test Acquisition

Calibration test with cotton rolls

Insert the cotton rolls between the arches on the 5th and 6th tooth - second premolars and molars (5.4). Ask the patient to clench their teeth as hard as possible (5.5).



To start the calibration, press the “Rec” button.

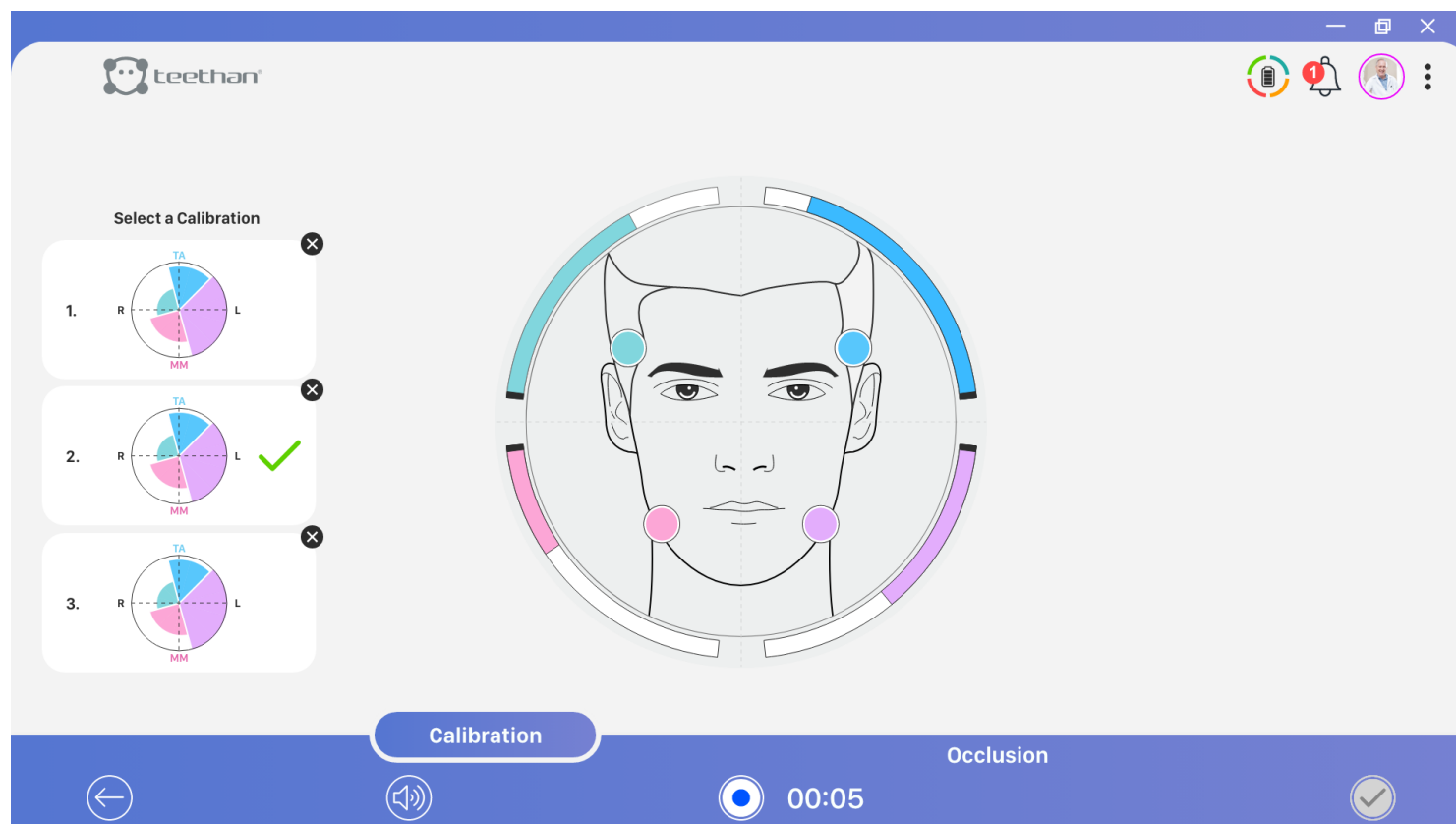


During the test execution, the electrical activity of the analyzed muscles is displayed in real-time, using bars that get filled with color proportionally to the degree of muscular activation. Each of the four muscles is identified by a characteristic color:



The recording stops automatically after five seconds and goes directly to the next acquisition step.

It is possible, however, to carry out and compare several calibration tests to select the one you consider best and test data repeatability. To do this, click on the “Calibration” button on the lower bar and start the acquisition using the Record button. On the left, you will see previews of the pie charts for each of the calibration tests performed.



Right chewing test

Once you have acquired the occlusal calibration test (or selected the one you think is best among the ones performed), the software is ready for the next step of acquiring the Chewing Test. Then, after removing the salivary rollers, provide the patient with chewing gum and ask him to chew on the right side only. To start the test, click on the Record button, which stops automatically after 15 seconds.

Left chewing test

Ask the patient to move the chewing gum to the left side and chew on the left side only. To start the test click on the Record button, which will automatically stop after 15 seconds.



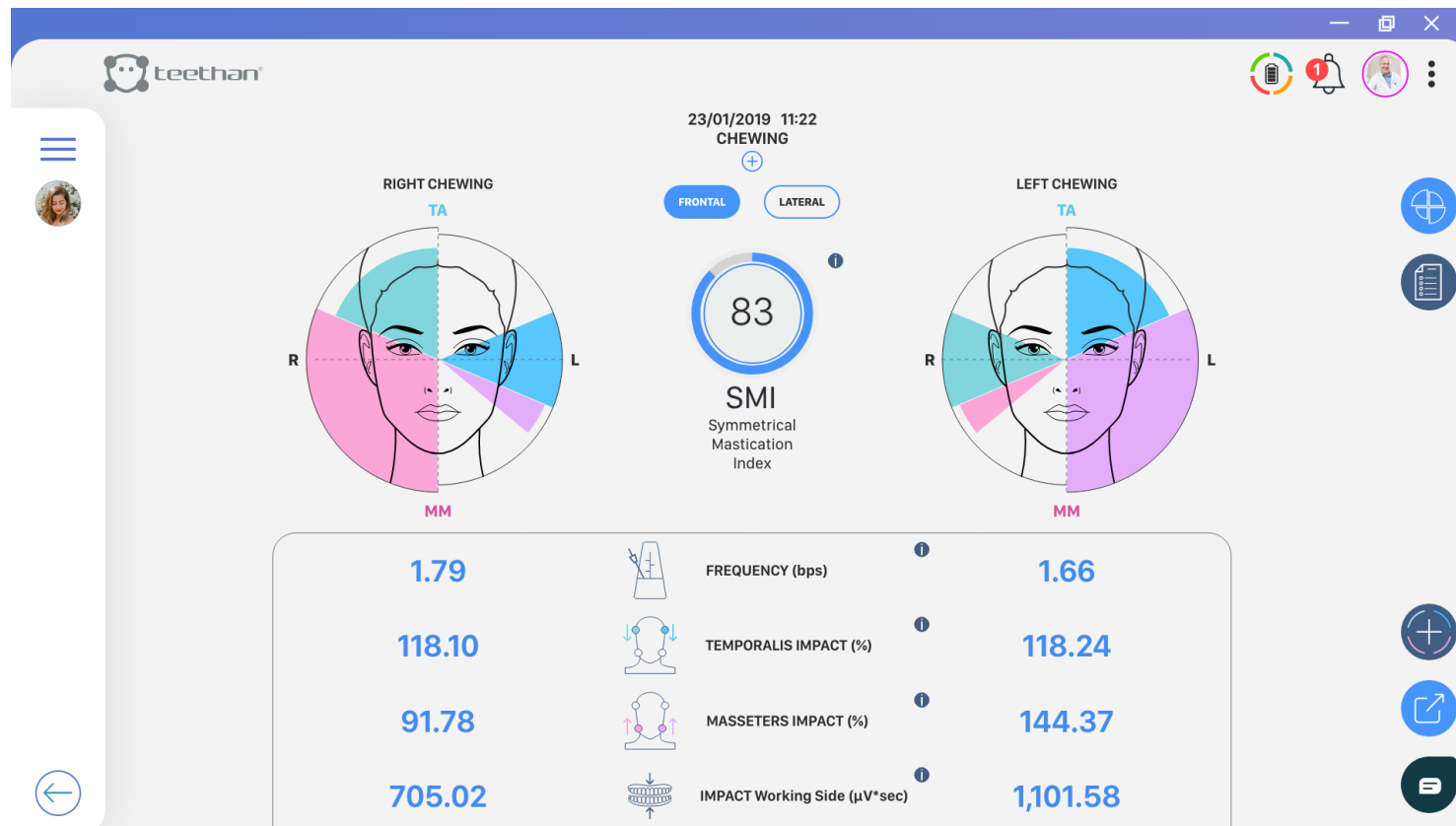
5.2.4 Report

At the end of the acquisition process, the report is automatically generated. Teethan's Chewing Test clinical report is composed by two main sections:

- Chewing Report
- Notes Page

Chewing Report

In the Chewing Report screen you can view the results of the test in two modalities: frontal and lateral. The first one, by default, shows the right and left side chewing test with the relative activities of the masticatory muscles that have contributed to the masticatory act.



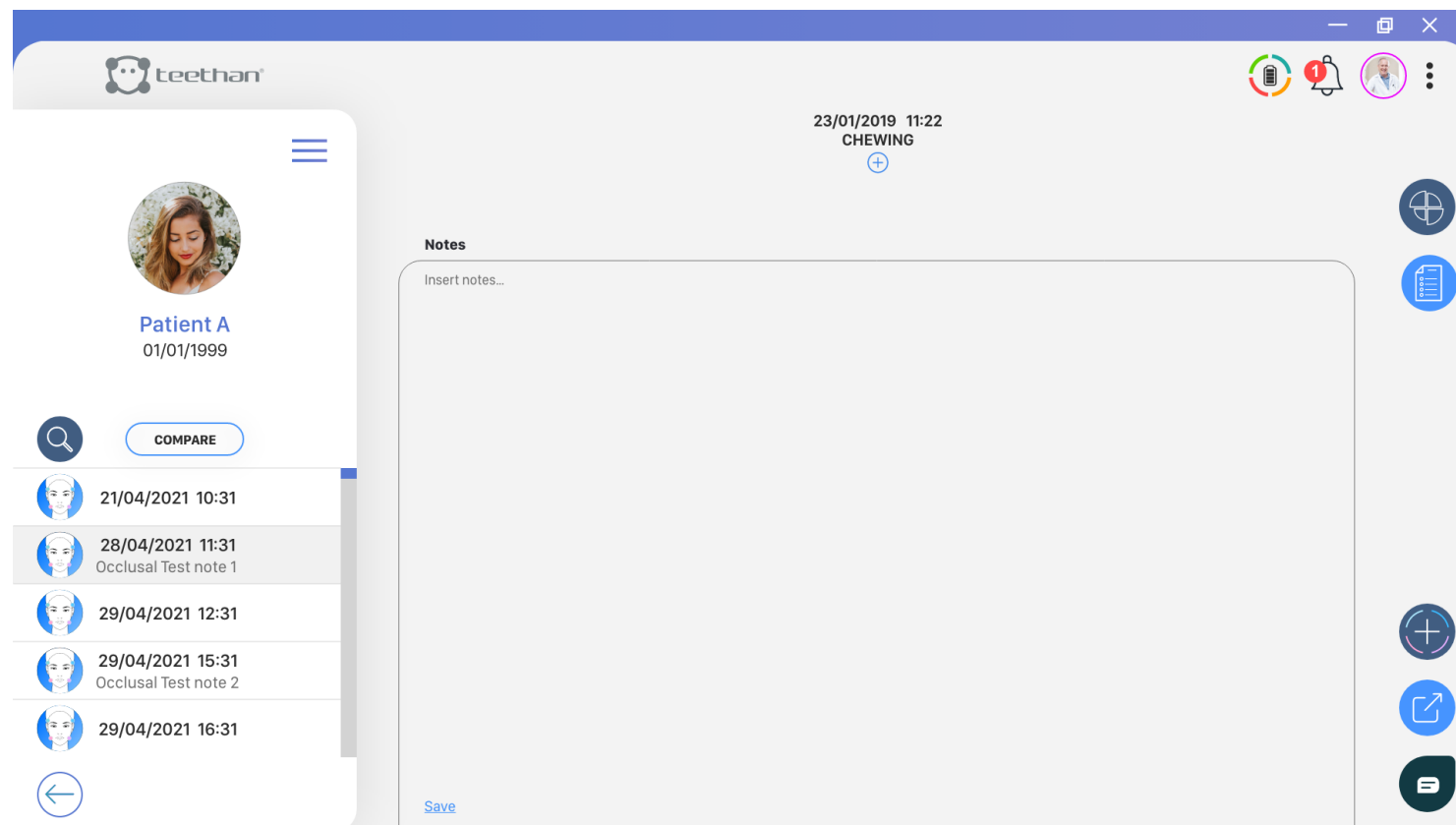
To switch to the lateral mode, click on **LATERAL**. Here, the antero-posterior prevalence of right and left chewing is shown – indicating a greater activation of the temporal muscles or masseters on the working side, i.e., whether chewing took place predominantly in the frontal or posterior group. In addition to the graphic representation, some numerical indices are calculated for the right and left chewing side:

- **Frequency:** number of chewing acts per second.
- **Temporalis Impact (%):** index of muscular work performed by the anterior temporalis during the test.
- **Masseters Impact (%):** index of muscular work performed by the masseter muscles during the test.
- **Working Side Impact:** muscular work of the right side (right temporal and right masseter) and of the left side (left temporal and left masseter) not normalized.

- **Symmetrical Mastication Index (SMI):** global index of neuromuscular coordination. It is a single index, not differentiated by side and its ideal value is 100%. The further from this value, the greater the masticatory incoordination.

Note Page

In this page, you can add any notes you wish to add to the Chewing Test.



6

**SYSTEM
MANAGEMENT**

6.1 Shutdown /Stand-by

At the end of the acquisition, reconnect the probes to the charging station. When the charging is finished, the system enters the stand-by mode and can stay permanently connected to the power supply. It is possible to switch off the probes individually by resting them for a moment on the activation surface (the white LED stops blinking).



6.2 Battery duration

TeethanÆ probes use Li-Poly batteries for their operation. The batteries provide a range of about 7 hours in continuous acquisition. For better performance, the probes should be replaced into the charging station at the end of every acquisition. The batteries are equipped with a protection circuit for overvoltage, undervoltage

and short circuits. They may only be replaced by TeethanÆ personnel.

6.3 Updates and License for Use

The use of Teethan® is regulated by the signed license for use. To keep the system updated and operating, the computer must be connected to the Internet at least once a month. The software automatically connects to Teethan server verifying the license status and the availability of any updates. If, by the tenth of each month, Teethan® is unable to establish a connection with the update center, a warning will appear to remind you to activate the internet connection.

6.4 Cleaning

For the cleaning of the probes charging station and the receiver, use a dry cloth or one dampened with a mild detergent. The devices must be kept dry. To avoid damage to the materials used, do not use alcohol, degreasers, or chemical solvents. Since the parts do not enter in direct contact with the patient (thanks to the interposition of the pre-gelled electrodes), sterilization processes are not required.

7

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8

**TECHNICAL
INFORMATION**

8.1 Specifications

Wireless probes

Geometry:	variable
Electrodes:	standard with clip connection
Separation:	min: 16mm – max: 66 m
Autonomy:	8h of use, some days in stand-by mode
Battery:	rechargeable lithium ion
Dimensions:	14x41, 5x24, 8mm mother electrode 16x12 mm satellite electrode diameter
Weight:	13g battery included
Frequency used:	ISM – 2.4 GHz band (IEEE802.15.4 standard)
Input impedance:	100 MOhm
CMRR:	> 110 dB @ 50-60 Hz
Resolution:	16bit
Acquisition frequency:	1kHz
Sensitivity:	1 μ V
Measure accuracy*:	\pm 2%

* The system is factory calibrated when production takes place. No further calibration is required.

Receiving unit

Connection:	USB
Dimensions:	82x44x22,5 mm
Weight:	80 grams
Frequency used:	ISM – 2.4 GHz band (standard IEEE802.15.4)

Charging station

Connection:	USB
Dimensions:	160x135x20 mm
Weight:	431,7 grams
Power supply:	AC/DC adapter – type: FW7721M Input: 100-240 v 50-60 Hz/ 200-100 mA Output: 5V/1500mA For Medical Equipment ta40IP40 - USB

8.2 Environmental Conditions

Use	Min	Max
Operative Temperature	-20°	+45°
Relative Non-condensing Operating Humidity	50%	80%
Altitude	0 m	2000 m
Storage and Transport Operating Temperature	0°	+40°
Relative Non-condensing Operating Humidity	50%	80%
Protection degree provided by the dangerous enclosures of water and dust	(IEC 60529): IPX0.	

8.3 Radio regulation

Radio equipment identification:

EMG probes FCC ID: YQH-BTSWEMG2 – IC: 9188A-BTSEMG2

Receiver FCC ID: TFB-MATRIXLP – IC: 5969°-MATRIXLP

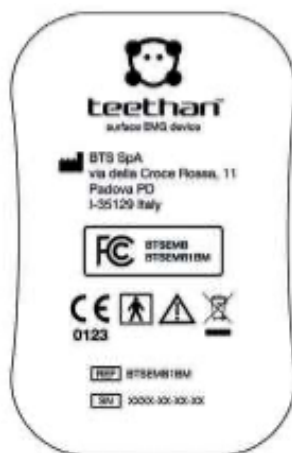
This device complies with part 15 of FCC Regulations. Operation is subject to the following conditions:

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

Modifications not expressly approved by Teethan S.p.A. could void the user's authority to use the equipment under FCC regulations.

8.4 Symbols and regulatory labels

Receiver ID label



Charging station ID label



8.5 Symbols on the equipment

Place of manufacture of the equipment.

The device complies with the relevant regulations put forth by the FCC, as long as it is used according to the instructions contained in this manual and to all national and local regulations.

It indicates the insulation class and the kind of the applied parts. In accordance with ISO 60601-1 Standard, the equipment has an internal power supply and the parts used are BF type.

It indicates that the product is a medical device of “II Class”, in some EU Member States restrictions may be applied.

Attention, read the information in this manual carefully before using the device.

It indicates that the product shows CE mark. The CE mark certifies that the product complies with the applicable standards for safe use (see the Declaration of Conformity).

CE mark with the code of the Notified Body. CE mark certifies that the product complies with the Directive 99/05/EEC - R & TTE and obtained the Expert Opinion by IMQ.

Symbol of the separate disposal of electrical and electronic equipment, in accordance with the Directive (WEEE/RAEE). The equipment belongs to Group 8 (medical equipment). In force in the nations of the European Union, Norway and Switzerland. Symbol for prescription only. U.S. Federal Law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

8.6 Declaration of Conformity



0123



Rx only





BTS Bioengineering



DECLARATION OF CONFORMITY

BTS SpA

via Risorgimento 9
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Tel +39 02 366 49000
Fax +39 049 792 9260

declare under our sole responsibility that the product(s):

name / description: Electromyographic system / device for the functional analysis of dental occlusion
model: **TEETHAN**
S/N: SN

satisfies the essential requirements of the **Medical Devices Directive 93/42/EC** (and its amendments including 2007/47/CE), and therefore carries the CE marking of the European Union. The conformity assessment procedure is according to the article 11 of the directive (Annex II.3 full quality assurance) and the article 12 it is not applicable.

In accordance with Annex IX of the 93/42/EC directive it is classified as follow:
CLASS **"IIa"** (rule 10)

In accordance with IEC 60601-1 is also classified as follow:
Class: **internally powered device**

Applied part type: **BF**

The product conforms to the following standards*:

EN ISO 14971	Medical Devices - Application of risk management to medical devices
IEC 60601-1	Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance
IEC 60601-1-6	Medical Electrical Equipment - Part 1-6: General Requirements for basic safety and essential performance - collateral Standard: Usability
IEC 60601-1-2	Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: electromagnetic compatibility - Requirements and tests.
IEC 60601-2-40	Medical Electrical Equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment
EN 62304	Medical device software - Software life-cycle processes
EN 62366	Medical devices - Application of usability engineering to medical devices
ETSI EN 301 489-3	Electromagnetic compatibility and Radio spectrum Matters (ERM) – Electromagnetic Compatibility (EMC) – standard for radio equipment and services – Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 KHz and 40 GHz.
ETSI EN 301 440-2	Electromagnetic compatibility and Radio spectrum Matters (ERM) – Short Range Devices (SRD) – Radio equipment to be used in the 1 GHz to 40 GHz frequency range – Part 2: Harmonized EN covering essential requirements of Article 3(2) of the R&TTE Directive

**The last revision of each standard needs to be considered.*

This compliance is valid ONLY for the equipment identified when used in a manner consistent with the intent of the referenced documents and according to the product's usage manual.

Notified Body : **TÜV SÜD Product Service GmbH, Zertifizierstelle, Ridlerstraße 65, 80339 München – Germany**, Identification N. 0123.

EC certificate N. **G1 15 03 65300 001** valid until January, 16 2018

Padua, February 24, 2017

Bruno Ros

President

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