teethan®

User Manual

Document Number: ERTHN-01376-00
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Symbols used in this manual


Attention: important information follows


See image

The 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.

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Safety Information

It is recommended undertaking any operation observing 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 an instrument for the EMG surface analysis, classified as medical equipment in accordance with European Directive 93/42/EC (and its amendments). Teethan® shall always be used only for this purpose, by qualified staff, in an environment suitable for the execution of EMG analyses, and in compliance with the prevailing regulations of the country in which it is used.

Teethan® is a medical device (European Directive 93/42/EC and its amendments, including Directive 2007/47/EC) whose use should always be conducted under the supervision of skilled and authorized staff, in accordance with current regulations of the country in which it is used.
The EMG probes are classified as ETSI EN 300 440 "Receiver category 3" in accordance with Directive R&TTE 99/5/EEC.
Acquisition results must be assessed by individuals legally authorized by local laws, with appropriate knowledge of anatomy and muscular functionality.

Since it has a high level of sensitivity (voltage levels ranging from 1 microvolt to 6 millivolt), the equipment must be used in a medical environment. The use of the device for purposes and methods different from the ones mentioned in this manual are not to be regarded as consistent with the intended use of the device.
During the patient preparation, we recommend paying particular attention to the components of the system that should not impede in any way the subject's natural movement. Apply the probes only to undamaged skin.

- Use only electrodes with CE mark and hypoallergenic double sided tape, compatible with the use on undamaged skin for short periods of time.
- Regularly check the integrity of the system and its components.
- Do not let the system components get wet or immerse them in water.
- Any modification to the device is not allowed.

- Maintenance of the device should be performed only by technicians authorized by Teethan S.p.A. Teethan S.p.A shall not be held responsible for the safety of the system if it has been opened or repaired, a software has been installed by third parties, or the components of the system have been replaced by staff unauthorized by Teethan S.p.A.
- The user cannot modify the software configuration (including the operating system and the burning software).
- If the device is dropped, probes are broken or other accidents occur, always contact the technical assistance.
- Use only the supplied FW7363M/09 (FRIWO) power supply or another one provided by Teethan S.p.A. If another power supply is used, the conformity to IEC 60601-1 cannot be guaranteed.
- It is recommended using only original cables, otherwise Teethan S.p.A. cannot guarantee the safety of the equipment. If it is necessary to replace any part of the system, use only Teethan S.p.A. original parts.

Further precautions of use

In addition to the user instructions, requirements on accident prevention and technical regulations on safety at work must be adhered to. As for environment and accident prevention, local regulations and those of the country where the product is used must be considered as an extension of the user instructions.

- Make sure that all cables have been properly connected. To disconnect them, grab the connectors refraining from yanking the cable.
- The power plug of an external power supply is considered as a disconnection device.
- Avoid connecting the probes to the charger with reverse polarity ignoring the indications specified on the charger shell - This could cause irreparable damage.
- For a safe use and an appropriate maintenance of rechargeable batteries please carefully comply with the instructions given in this manual. If rechargeable batteries are used in a manner different from the one specified by Teethan S.p.A. their duration, functionality and integrity cannot be guaranteed.

Teethan® is able to work CONTINUOUSLY. The duration of the acquisitions are only limited by battery duration and data storage availability. For its operation, the device uses lithium-ion batteries. For battery substitution or disposal please contact the technical support. In no circumstances should the integrity of the components be compromised.

Disposal (WEEE)

In disposing of the equipment observe the legal prescriptions.
In accordance with Directive 2002/96/EC (WEEE) all equipment supplied after 13/08/2005 may not be disposed of in general domestic waste. This equipment belongs to Category 8 (medical equipment) and is classified in the B2B sector.
The symbol of the crossed out rubbish bin indicates that the equipment must not be disposed of in normal domestic waste.

The regulations concerning disposal may differ according to each EU country.
In case needed please refer to the respective sales outlet.

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Introduction

Teethan® is the solution for the functional analysis of dental occlusion. It provides information on neuromuscular alterations induced by the occlusal contact. It is an innovative solution that integrates the latest technology available today and provides an immediate and comprehensive evaluation of patient's occlusal balance.

Teethan® is made up of four EMG probes with active electrodes, the only one of its kind in the world due to its light weight, compact size and data capturing accuracy. The probes, which are absolutely non invasive for the patient, communicate through Wi-Fi with a USB receiver and data are transmitted to the user in real time, through the interface of the dedicated software. Teethan® performs a surface EMG analysis of the main muscles of mastication, in order to quantify the influence of the occlusal condition on patient's neuromuscular balance.

The protocol has been validated in the International Scientific Literature by approximately 20 years of publications and it is based on maximum clenching tests (maximum voluntary contraction) each lasting 5 seconds. The obtained result shows the balance level of muscular activity through validated and approved percentage indexes.

The special feature of Teethan®, that sets it apart from traditional electromyography, is the standardization of the electromyographic signal resulting from the comparison between the two clenching tests, performed with and without the interposition of cotton rolls between the dental arches. This method is registered under the name Syncromyography®. This ensures objectivity and repeatability of measurements, allowing the elimination of all alterations that could influence every single measurement.
Problems related to physiological and anatomical variability of the patient, but also the variability of external factors such as wrong positioning of the electrodes, impedance of patient's skin and interferences are eliminated.

The software automatically elaborates the occlusal balance of the patient, providing real time results with a graphic layout easy to understand both for the clinician and the patient.

The result of the functional analysis is displayed in three different forms (mandibular plane, histogram, pie chart) with related numerical indexes and normality bands.

All the acquired results are automatically stored and can be exported in PDF format as a medical report, that becomes an effective means of communication with the patient and a common language that allows the user to talk with other professionals and experts in the occlusal field.

Teethan provides the acquisition of the electrical activity of the main muscles of mastication (Anterior temporalis muscles and Masseter muscles).
By performing two clenching tests, each lasting 5 seconds, it is possible to obtain the main evaluation indexes of the occlusal condition:

- POC
  Assessment of the symmetry of contraction standardized within the same muscle pair;
- BAR
  Assessment of the position of the occlusal barycenter;
- TORS
  Assessment of the torsion attitude of the mandible in the horizontal plane;
- IMPACT
  Assessment of muscle activity (strictly related to the bite force, therefore in the vertical dimension of the subject, the potential presence of nociceptive reflex, etc.).
- ASIM
  Assessment of the asymmetry between the left and right sides.


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Contents

Teethan® charging station
complete with 4 wireless EMG probes

USB receiver

USB memory key with
with self-installing
software and manual

USB power cable

USB extension cable

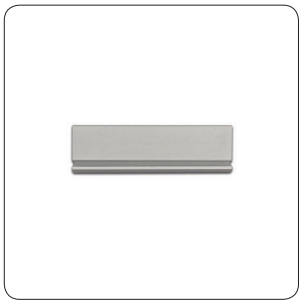
USB power adapter

13

Pre-gelled electrodes

Stainless steel plate

Plate support



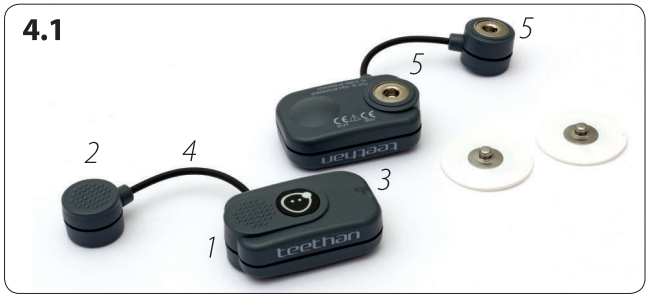
4

System components

EMG wireless probes

Teethan® is able to acquire the EMG signal using small wireless probes with active electrodes, weighing less than 14 grams. The probes have been designed to be light weight and compact in size to ensure maximum comfort for the patient, without altering natural muscle contraction. Probes can be directly attached to the pre-gelled electrodes and do not require any additional fastening such as plasters or double-sided tape. This, together with the total absence of cables, enables a much faster patient preparation, drastically reducing the time of each session.

4.1



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

Each probe consists of a mother electrode and a satellite electrode, each fitted with a snap connector. The two parts, connected via a flexible cable, can be placed at a variable distance according to the user's needs (probes with variable geometry). **4.1**

Solid-state memory buffer

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

Start-up

The probes are equipped with a magnetic switch. Note that the supplied charging station has a magnetic area specified by the text "Swipe for Activation". To switch on the probes simply bring them into contact with the specified grey area.

Charging

The probes are charged by a dedicated charger to which they are connected via specific snap connectors. For more information on how to charge the probes see the section "Charging station" of this chapter.

Status LED

Each probe is equipped with a status LED. The possible probe statuses are:

- **Charging**: steady blue LED.
  When the probes are charging, the steady blue LED is on. This status indicates that the probes are connected to the charger and the charger power is on, while the charging level of the probe is less than 90%. By connecting a probe to the charger, it enters in "Deep Sleep" mode; it is therefore completely inactive and it does not respond to any command.

- **Scanning**: white LED blinks at high speed for a few seconds.
  The probe is trying to establish a connection with a receiving unit. The probe performs a scan of the frequencies at intervals of about 1 minute for a few seconds.

- **Connected (waiting)**: white LED blinks slowly.
  When the probe and the receiving unit establish a connection, the white LED starts blinking slowly: the probe is waiting for commands. If the connection with the receiver is interrupted, the probe enters the Scanning mode in an attempt to restore the connection with the receiving unit.

- **Capturing:** white LED blinks at regular intervals of approximately one second.
  At the end of the acquisition, the probe returns into the Connected status. If during the acquisition the connection with the receiving unit is lost, the probe continues to acquire data, storing it locally for 1 minute and, at the same time, scans the assigned channel trying to restore the connection with the receiving unit. If after one minute the scan is unsuccessful, the probe returns into the Scanning status interrupting data storage.

- **Discharged or in "Deep Sleep" mode**: LED light is off.
  If the probe is completely discharged, the LED does not perform any blinking cycle and is off. The same applies if the probe is in "Deep Sleep" mode (except for the charging phase where the LED is on with a steady blue light). The probe in "Deep Sleep" mode does not perform any scan cycle. Since it is turned off, it ensures energy saving.

USB receiver

4.2

The receiving unit, connected to the computer through USB, allows the Wi-Fi reception of EMG signals acquired by the wireless probes. If the status LED displays a green light, the device is correctly powered. **4.2**

Charging station (Charger)

Teethan probes can be charged using the dedicated charging station.
The charger provided with the system can simultaneously charge all the EMG probes.
The probes can be connected to the snap fasteners of the charger through their respective snap connectors used for the acquisition of the EMG signal. To connect the probes to the charger with the correct polarity, place the probes as specified on the support plane of the charger. If the probes are connected with reverse polarity, they will not be recharged. **4.3**

4.3

To recharge the probes, connect them to the charger (following the instructions described above) and insert the USB cable into the power supply or directly into a USB port through which the charger can be powered.
When the charger is correctly connected, the status LED "Power" displays a steady green light. The status LED of the probes indicates their charging status.

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Installation

Software installation

Minimum requirements

The software installation requires a computer with Windows 7 operating system or above, equipped with the following minimum requirements:

- Intel i5 Dual Core Processor (or equivalent AMD). RAM 4GB
- 100 Mb free disk space
- 1 free USB 2.0 port
- 1280x768 screen resolution or above
- Internet connection

Installation

Insert the USB memory key included in the packaging to install Teethan® software. **5.1**
Select the folder "Teethan installer" and double click on the file setup.exe; the installation wizard will begin.

5.1

License activation

During the installation wizard you will be asked to enter the activation code issued upon confirmation of the contract. You will also have to connect to the Internet to allow the automatic activation of the license for use and the regular updates.

Connection and Start-up

If for space reasons, it is not possible to connect the receiver directly to the computer, use the USB exten sion cable provided with the system.

Connection of the receiving unit

The wireless probes transmit the data in real-time to the receiver, connected via USB to the computer. **5.2**
Before starting the test, connect the receiver to the computer through the dedicated USB connector. If the computer morphology does not allow direct connection of the receiver, use the USB extension cable provided with the system. To connect to the receiver, the software automatically scans the COM ports. If the computer does not detect the USB receiver, click on the button to force the unit search.

Connection of the charging station

Connect the charging station to a power source (computer or socket) through the USB cable and/or the external power supply. The green LED "Power" will turn on. **5.3**

Charging of the EMG probes

Each probe has a status LED, a steady blue light indicates that the probe is charging.
When the probes are fully recharged the LED turns off.

5.2

Probes Activation

Remove the probes from the charging station by disconnecting the mother electrode and the satellite, being careful not to pull the cable that connects them. **5.4**
Activate the probes by swiping on the "Swipe for activation" area. **5.5**
The fast blinking of the LED indicates that the probe is on and it is searching for the receiver to which it can connect.

5.3

5.4

5.5

Extract the probe and its satellite by disconnecting them from the snap connectors: be careful not to pull the cable that connects them.

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Software

Teethan® includes the specialized software for the automatic measurement of the indexes related to the occlusal contact and the possible neuromuscular alterations. The indexes are generally represented by a numerical value, but they can also be displayed in three different forms: mandibular plane, histograms and pie charts. The software allows the management of patient's database, presenting a tree structure for patients and trials, that can be exported by name or surname. It is possible to create a report for each trial or to compare two trials (pre and post treatment). Once created, all the reports can be saved and reviewed at a later stage.

Software Start-Up

Once the receiver is inserted into a USB port and the probes are on, double-click on the Teethan® icon to launch the software.

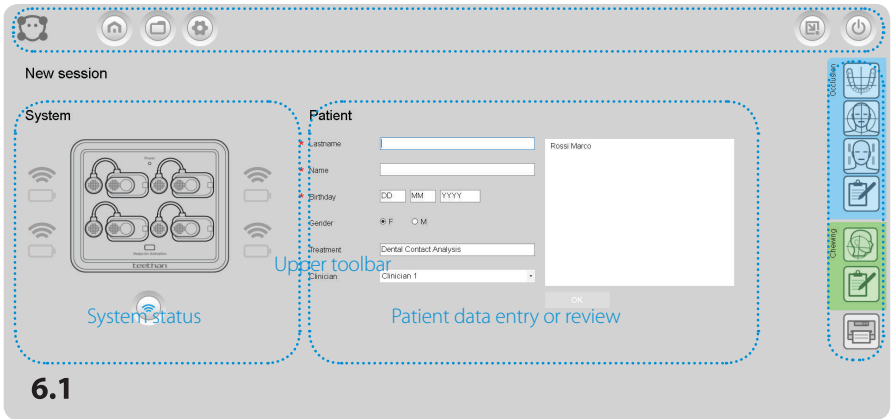
At the first start-up, you will be asked to enter the license activation code provided to the user.

Interface

Initial screen 6.1

Once the program is launched, the initial screen of the application opens.
The screen is divided into the following main areas:

1. System Status
2. Patient Data Entry
3. Report Sidebar
4. Upper Toolbar

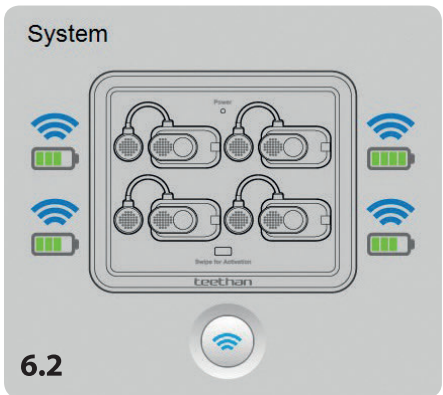


1. System Status

The diagram shows the charging station with the connected probes.

The level of battery charge appears alongside each probe, together with the probe/receiver wireless connection status **6.2**. The blue icon indicates that the probe is connected to the receiver. .

If one or more probes are not connected (grey icon) press the search key to make a new connection. If the problem persists, it may be necessary to change the transmission channel frequency (See the "Troubleshooting" section of this manual).



2. Patient data entry or review

Before performing a new test you have to enter patient data.

Data can be entered manually (new patient) or automatically from the data-base by entering the initial characters in the "Surname" field and selecting the name from the Suggestion box.

3. Report Sidebar

It contains commands to display the trial outcomes. These commands, are enabled once the acquisition is completed and are still available during the trials consultation in Archive section.

4. Upper Toolbar

The toolbar consists of 5 icons, each having different functions.
From the top left, the bar displays in sequence:

System information: to see the version of the software in use

New exam: to perform a new trial;

Archive: to search for patients and trials already present in the database;

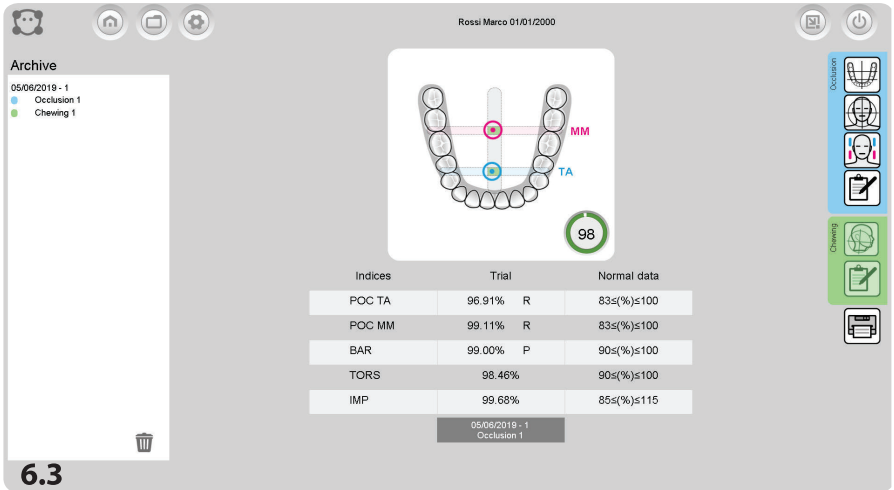
Settings: to manage the system setup;

Off: software shutdown button.

Minimize: button for minimizing the software

New trial

This is the screen that appears when you open the program, containing information on system status and fields for patient data entry, type of treatment and operator.
At the end of a session, the command allows the user to start a new session.



Archive

To display the trials of a previously added patient, just click on the "Archive" icon and fill in the search field with the patient's surname.
In the suggestion box below, a list of names compatible with the inserted characters appears.

Trials Display Area

Once the patient is selected, the list of all performed trials divided by date will appear. By double-clicking on the trial, you will display the report outcome in the display box.
By dragging another trial in the display box (Drag&Drop), the pre&post comparison will be performed. **6.3**

Settings

By clicking on the Settings icon, all Teethan® settings will be displayed. **6.4**
The screen is divided into 3 areas:

1. System
2. Software
3. Report

1. System

In the "System" section you can see the connection status, the charging status, the serial number (engraved on the snap connector of the satellite electrode) and the radio-frequency channel of each probe. In case of interference, it is possible to select another channel.

2. Software

In the "Software" section you can:

- Check the license status (Active/Expired).
- ect the language (Italian/English).
- Change the database: you can upload a database which is different from the selected one or create a new one.
- Customize the name of the operators (if multiple specialists are using Teethan in the same studio).

To activate the changes made to the "Software" section click on the "Save" button.

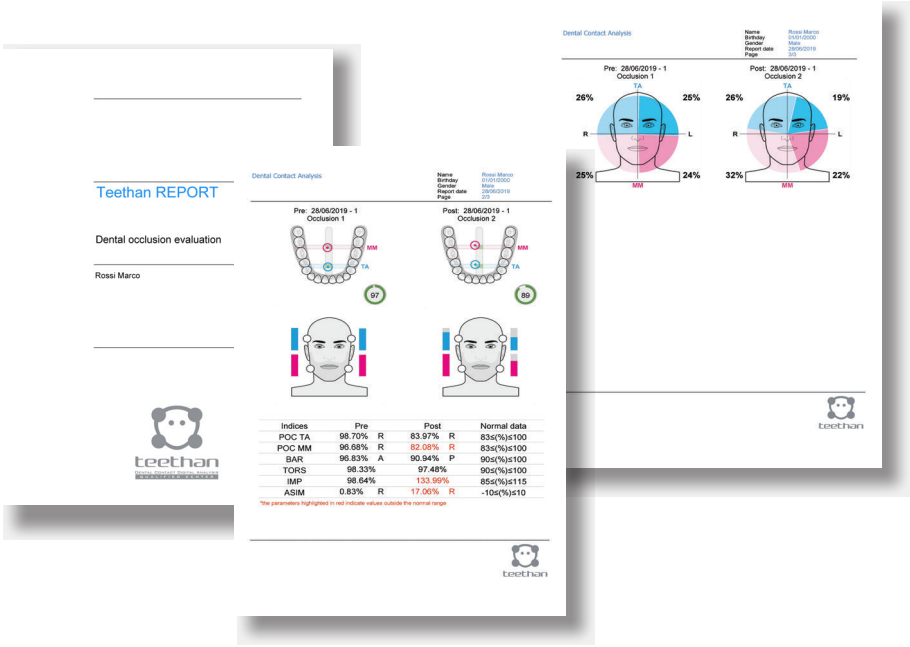
3. Report

In the "Report" section, it is possible to customize the report display settings such as:

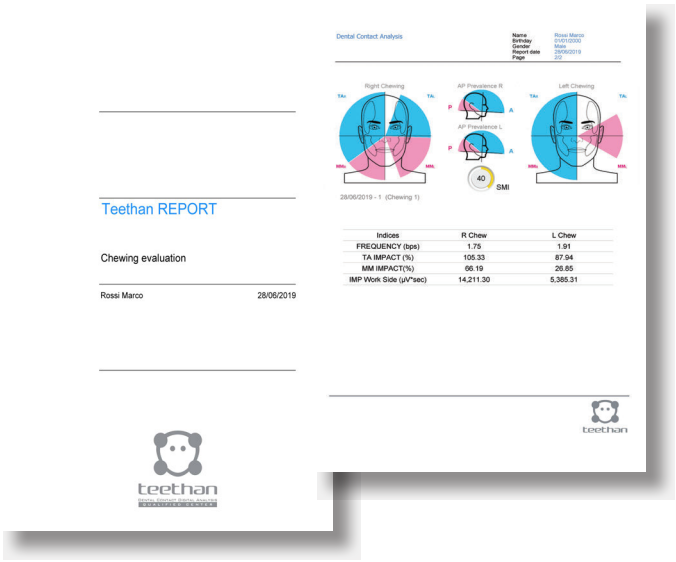
- Show Balance:
  If there is a checkmark, the Global Index of Neuromuscular Balance is displayed. By removing the checkmark, it will be hidden.
- Highlight out-of-range values:
  If there is a checkmark, all the indexes having out of normality bands values are highlighted in red. By removing the checkmark all the out-of-range values will be displayed in black.
- Show Operator:
  If there is a checkmark, the name of the operator who performed the test appears in the report; you can specify up to 5 different operators.
- Print:
  This allows the customization of the report printout, the checkmark specifies what forms must be included in the printed report.
- Include Header:
  This allows you to enter data for the report customization and to upload your logo. To do this, complete the fields of interest and click on the icon (magnifying glass) to select the image of your logo directly from the computer.

To activate the changes, click on the "Save" button. It is possible to make other changes to the saved settings.

Example of a printed report
Occlusion Protocol



Example of a printed report
Chewing Protocol



7

Test execution

System Start-up

Probes Activation

Remove the probes from the charging station by disconnecting the mother and satellite probes. Be careful not to pull the cable that connects them.
Activate the probes by swiping on the "Swipe for activation" area; the fast blinking LED indicates that the probe is searching for the receiver to which it can connect.

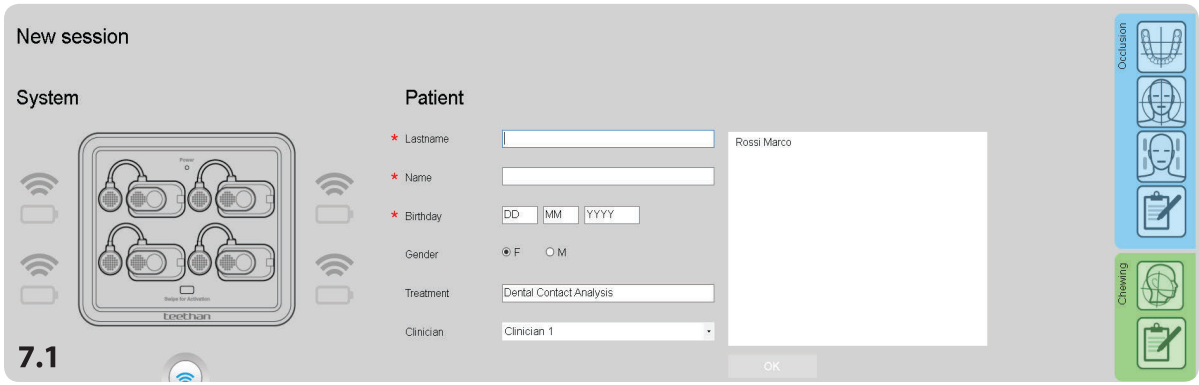
System Check

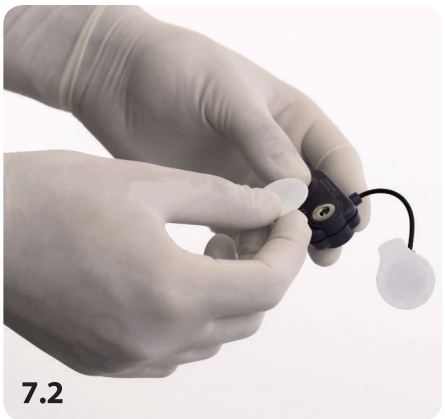
Launch the software. The initial screen **7.1** allows the system status check.
The level of battery charge appears alongside each probe, together with the probe/receiver connection status. The blue icon indicates that the probe is connected to the receiver. If one or more probes are not connected (grey icon) press the search key to establish a new connection. If the problem persists, it may be necessary to change the transmission channel frequency (See the "Troubleshooting" section of this manual).

If all probes are connected and patient data has been entered, the "OK" button is activated.

Start-up

When all probes are connected, the test can start. Enter the patient's details in the appropriate fields and click OK: the calibration screen appears.

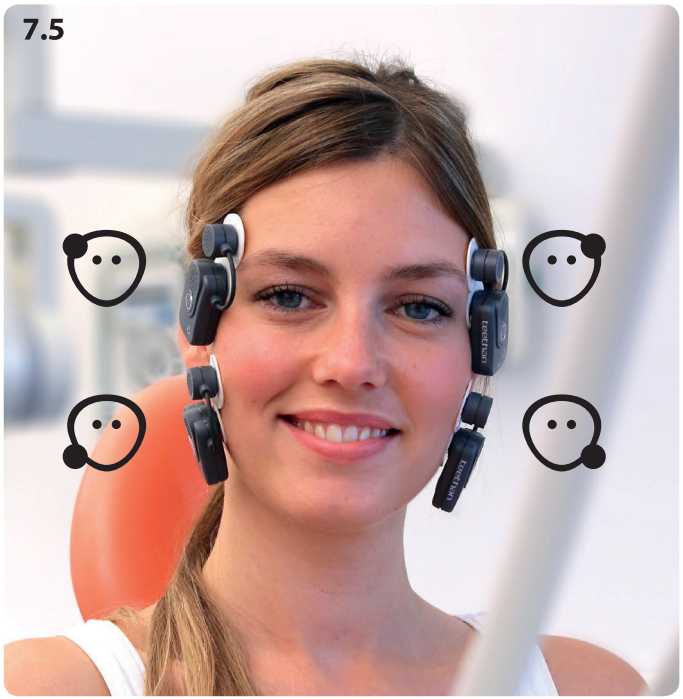




7.2

7.3

7.4



7.5

Patient Preparation

The POC4 protocol provides the acquisition of 4 muscles: masseter and temporalis muscles.

Attaching Electrodes

Apply the pre-gelled electrodes to the probe using the provided snap connector and remove the protective film **7.2**

Probes Positioning

Place the probes on the patient's face in line with the masseter and temporalis muscles **7.5**.
Each probe is dedicated to the acquisition of a specific muscle, identified on the label:

 Right Temporalis

 Left Temporalis

 Right Masseter

 Left Masseter

Errors reported between the probe and the selected muscle provide inaccurate results.

Application of probes to Temporalis muscles

In order 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). **7.3**

Application of probes to the Masseter muscles

In order to identify the masseter, 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). **7.4**

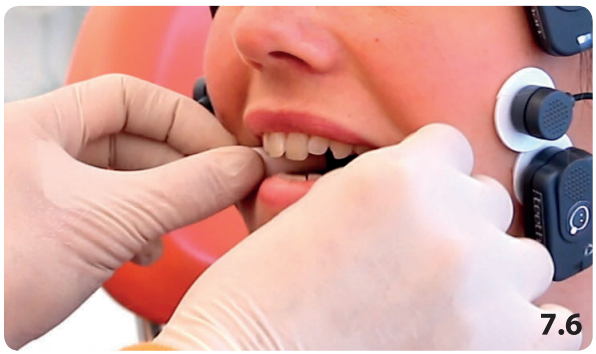
Symmetry and Posture

Symmetry of positioning 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.

Calibration with cotton rolls

When the patient begins clenching his teeth, the recording can start.

Once the patient has been created (or selected a previously acquired one from the list on the right), by clicking on the "OK" button you will directly access the trials acquisition screen.
The first trial is "Calibration".


7.6

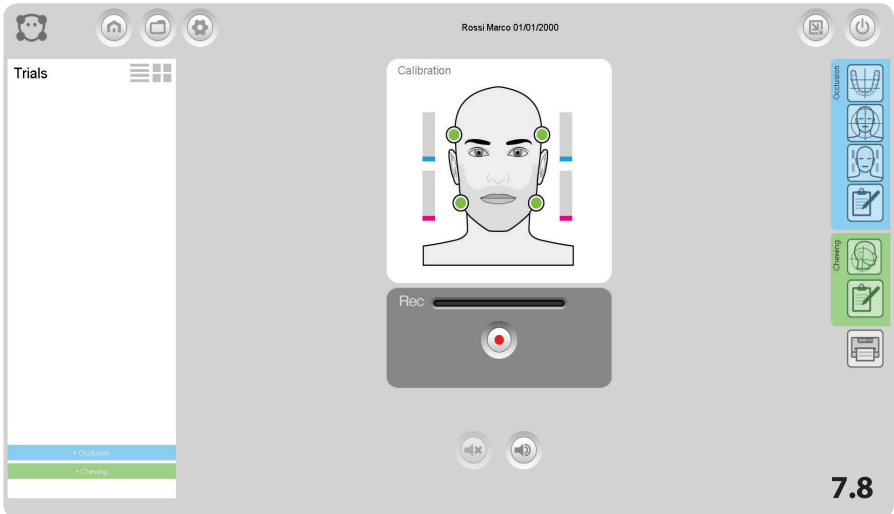

7.7

Calibration Test

Insert the cotton rolls between the arches on the 5th and 6th tooth (second premolars and molars) **7.6** Ask the patient to clench their teeth as hard as possible **7.7** and click on the "Rec" button to start the calibration **7.8**, the recording stops automatically after 5 seconds.

The bars on both sides corresponding to the face indicate the electrical activities of the analyzed muscles. At the end of each calibration test a preview of the pie chart showing the RMS value of the acquired data will be displayed on the left panel. It is possible to perform and compare a number of calibration tests to check data repeatability, before moving to the acquisition stage.

At the end of the calibration test, select the most suitable trial (by entering a checkmark) **7.9** and proceed with acquisitions in natural intercuspidation.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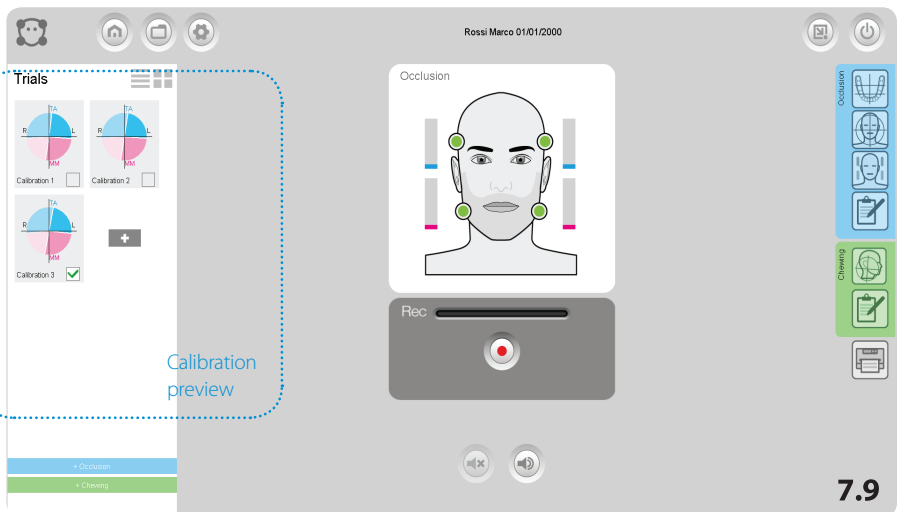
Trials
Calibration
Rec
Occlusion
Chewing
+ Occlusion
+ Chewing
7.8


Rossi Marco 01/01/2000
Trials
Calibration 1
Calibration 2
Calibration 3
Calibration preview
Occlusion
Rec
Occlusion
Chewing
+ Occlusion
+ Chewing
7.9

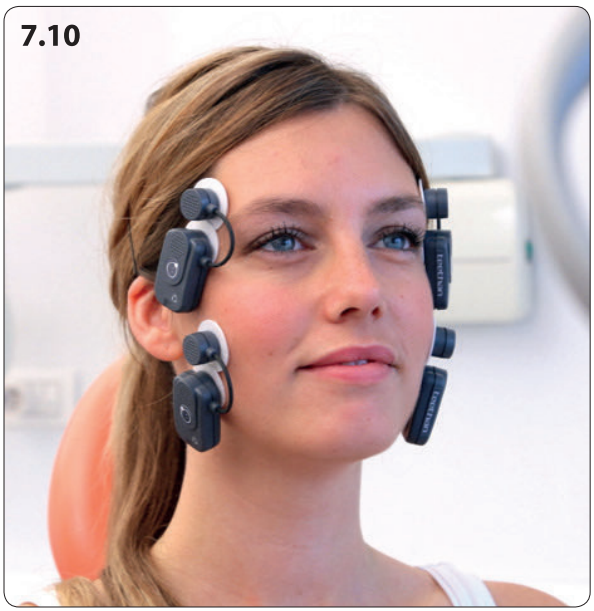
Acquisition

Remove the cotton rolls.
Ask the patient to clench their teeth again as hard as possible (allowing the natural dental intercuspidation) **7.10** and start the acquisition by clicking on the recording button.

It is possible to perform a number of consecutive acquisitions. At the end of each session, you will be asked to select the trials you want to save. They are all selected by default.

Saving
Save the acquisitions. The files are automatically recorded in the archive with the patient's name, date of implementation and sequential acquisition number.

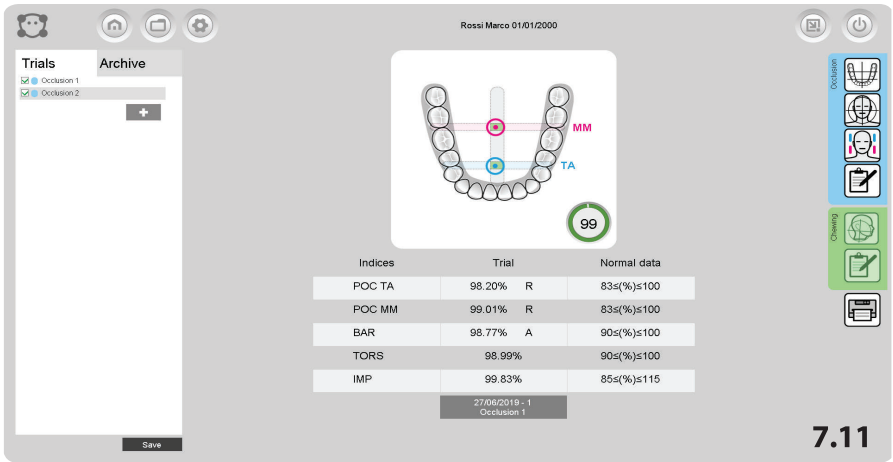
7.10

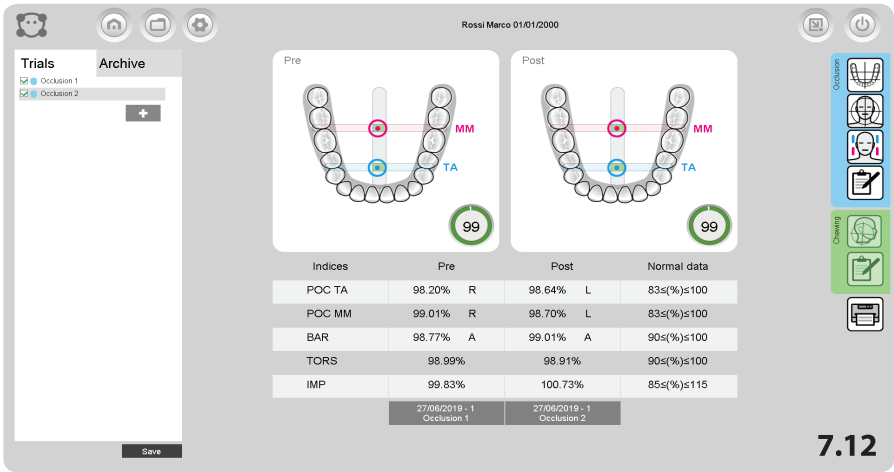


Report generation and comparison

At the end of the acquisition, the report is automatically generated **7.11**. By clicking on the "Save" button the test is saved and displayed in the patient's archive.
If you add other acquisitions, the report will display the comparison between the various tests, assigning the label "PRE" to the tests performed before a treatment and "POST" to the tests performed after a treatment.

If you want to compare the results of the acquired trials with those obtained from previous trials, select the trial to be compared from the patient historical list on the left, then open the trial with a double click or drag it (Drag&drop) to the center of the screen to simultaneously display the comparison between the two acquisitions. **7.12**


Rossi Marco 01/01/2000
Trials
Archive
Occlusion 1
Occlusion 2
Save
MM
TA
99
Occlusion
Chewing
Indices
Trial
Normal data
POC TA
98.20% R
83≤(%)≤100
POC MM
99.01% R
83≤(%)≤100
BAR
98.77% A
90≤(%)≤100
TORS
98.99%
90≤(%)≤100
IMP
99.83%
85≤(%)≤115
27/06/2019 - 1
Occlusion 1
7.11


Rossi Marco 01/01/2000
Trials
Archive
Occlusion 1
Occlusion 2
Save
Pre
Post
MM
TA
99
Occlusion
Chewing
Indices
Pre
Post
Normal data
POC TA
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98.64% L
83≤(%)≤100
POC MM
99.01% R
98.70% L
83≤(%)≤100
BAR
98.77% A
99.01% A
90≤(%)≤100
TORS
98.99%
98.91%
90≤(%)≤100
IMP
99.83%
100.73%
85≤(%)≤115
27/06/2019 - 1
Occlusion 1
27/06/2019 - 1
Occlusion 2
7.12

8

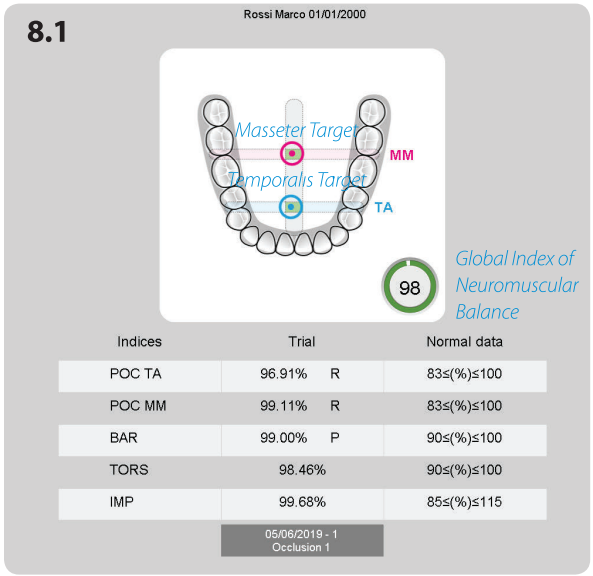
Report: data reading

The results of the functional analysis of dental occlusion are given in a report divided into 4 panels.

PRE & POST Comparison
In each panel it is possible to compare two trials for PRE and POST treatment assessments. It is possible to compare trials of the same session or different sessions to check the effectiveness of the treatment used.

Panel 1: evaluation indexes of the occlusal condition

The representation of the dental arch **8.1** 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 position of both targets includes the occlusal condition, according to the calculated indexes listed below.

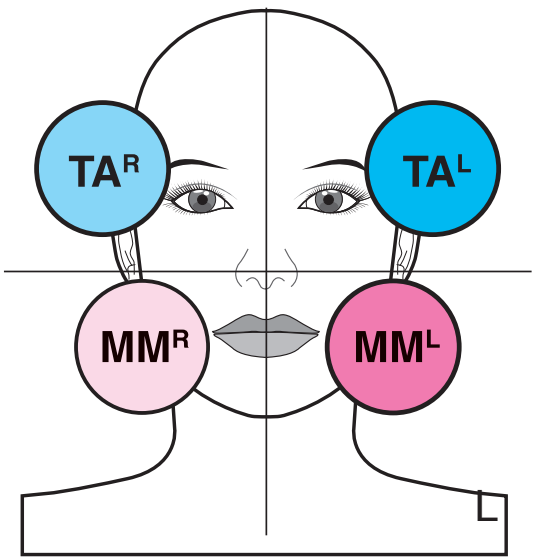
The dashed bars represent the normality bands of benchmark indexes.

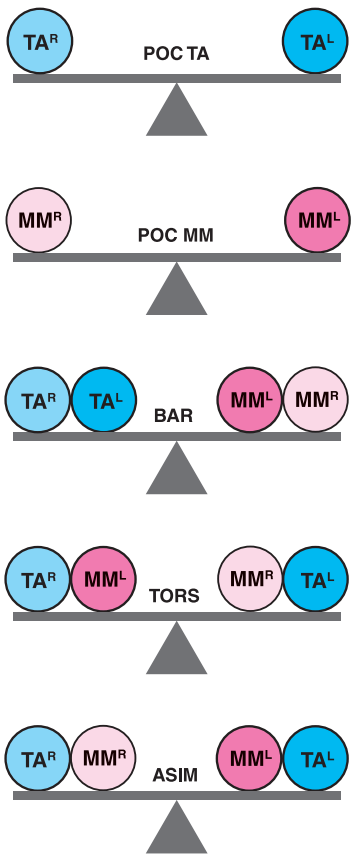
The intersection is the area where both targets appear in case of balanced occlusion.

Immediately beside the image of the arch **the Global Index of Neuromuscular Balance** is displayed.
This index includes the values of the indexes below. It is represented with a green ring if the overall balance is higher than 83%, yellow if it is between 82-75%, red if it is less than 74%.

The chart shows the evaluation indexes of the occlusal condition **8.2**:

- POC assessment of the symmetry prevalence within the same muscle pair
- BAR assessment of the position of the occlusal barycenter
- TORS assessment of the torsion attitude of the mandible in the horizontal plane
- IMPACT assessment of muscle activity
- ASIM assessment of the right/left asymmetry



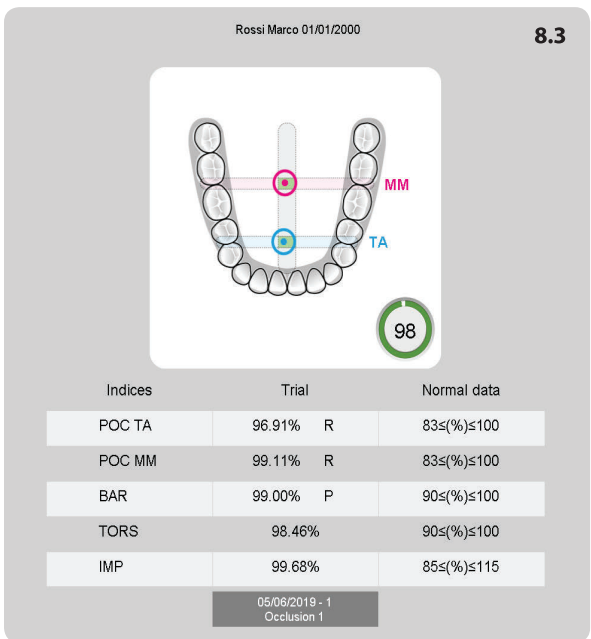


8.2

POC: Percent Overlapping Coefficent

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 temporal in the front quadrants, and that of the right or left masseter muscle, in the rear quadrants.

The POC 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 simmetrically, 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.



With the 4-channel protocol, it is possible to calculate the POC values of anterior temporalis and masseter muscles, designated POC TA and POC MM respectively, indicating the influence of the tooth contact on the neuromuscular balance of the stomatognathic apparatus.
For each POC the predominant muscle is also indicated (R= right and L = left).

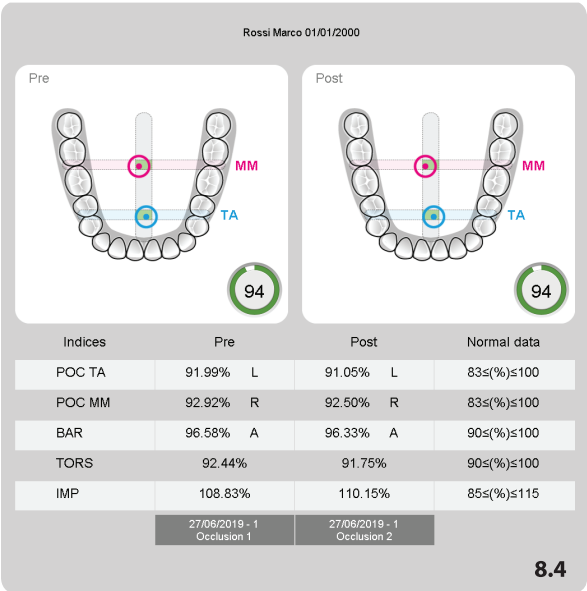
POC: graphical representation 8.3

The vertical dashed central line, with a light grey colour, indicates the normal range, up to 83% value, to the left and the right of the central line, in order to represent the predominance of the right or left muscle activity. The blue target refers to the POC index of the temporalis anterior muscles (POC TA), while the red one refers to the POC index of the masseters (POC MM). The POC TA index refers to the influence of dental contacts corresponding to the incisors, canines, and first premolars

The POC MM index refers to the influence of dental contacts corresponding to the premolars and molars.
The target is represented at a distance from the central vertical line corresponding to the calculated value. If the POC value is higher than 83%, the target is represented within the central grey band, while if it is lower, it is placed on the outside of the normality range.
At this stage, you can immediately observe the predominance of the right/left temporal muscle in the front quadrants, and the right/left masseter muscle, in the rear quadrants.

BAR: Barycenter
It assesses the position of the occlusal barycenter. 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 barycenter).
Conversely, in the occlusal condition where the barycenter moves to the antero-lateral sectors (i.e. up to the first-second premolar), the temporal muscles state greater contractile forces (front barycenter). In this case there is an overload of bilateral joints that, over time, can lead to pathological conditions.
As for BAR index, if the barycenter position is mainly anterior, the letter "A" is entered. Conversely, if the barycenter position is mainly posterior, the letter "P" is entered.

BAR: graphical representation **8.4**
The normality value of the BAR index is >90%.
The two dashed dark grey horizontal lines, represent the normality up to 90%.
The two targets are simultaneously shifted into a value corresponding to the calculated BAR index, at the bottom or top depending on whether there is rear or front prevalence, according to the occlusal condition.
The value and the direction of the vertical displacement of the two targets are exactly the same (both the targets in anterior or posterior position).
The BAR value in the normal population states a prevalence of a differential activity between the pair of masseter and the pair of temporal muscles (rear barycenter). This condition is reversed in the second skeletal classes where the temporal muscles always state an higher differential electrical activity than the masseter muscles.



TORS: torsion

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 pair and the left master and between the left temporal pair and the right masseter.
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%, the muscles tend to make the lateral displacement of the jaw to the right or left depending on whether the one or 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.

TORS: graphical representation 8.4

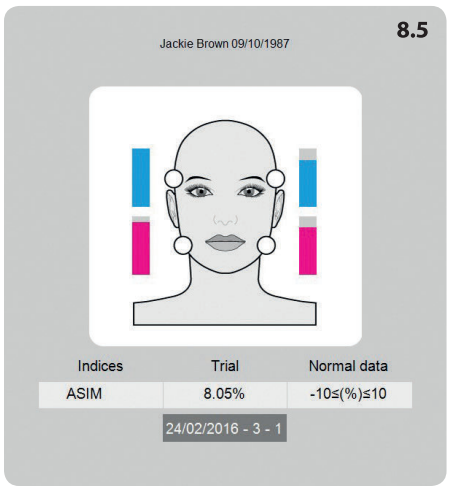
The result of the action of the temporal muscle added to the result of the strength of the contralateral masseter muscle, generates a pair of forces with a moment that tends to latero-deviate the mandible towards the result of the temporalis anterior: if the one on the right is greater, the target is 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. Note that there will be no actual twist of the lower jaw because of the static conditions. Any clinical condition that can be related to pre-contacts, and thus slippage of the contact between teeth, has already taken place.
The index states a clinically worse condition because it is only detectable instrumentally, which is the fulcrum one. The muscles continue to activate and inhibit in search of stability.
This clinically corresponds to prevalent contact in antero-lateral sectors of the dental arch or a qualitatively insufficient contact in latero-posterior sectors.
It is generally related to problems with the temporal-mandibular joint.
If it is associated with low IMPACT values compared to the standard, it may indicate the presence of both pain and protective mechanism in nociceptive stimulus (nociceptive reflex).

IMP: Impact

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 the 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.

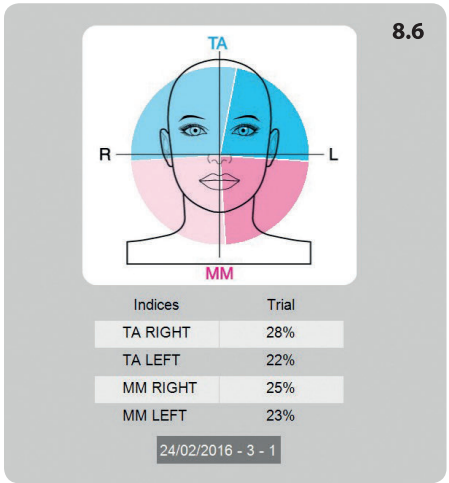
Panel 2: strength of muscular contraction

This form displays the ASIM index. In picture **8.5** the strength of contraction of each examined muscle is represented.
The muscle stating the greatest value of normalized electric potential range is represented with a full bar, while the remaining bars are represented in proportion to it.



ASIM: asymmetry

This index allows you to compare the activity of the right muscles with that of the left muscles. 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.



8.6

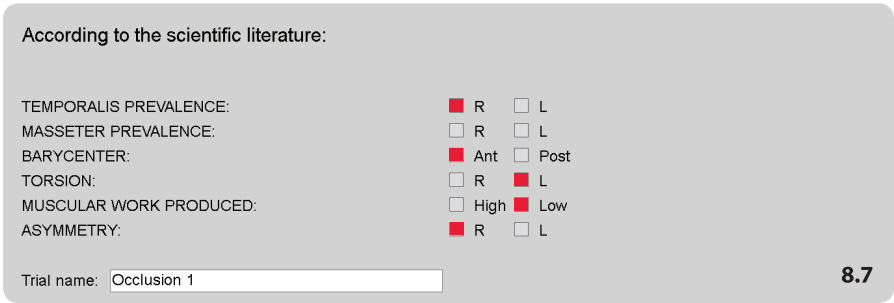
Panel 3: muscular activity in the quadrants

This panel displays the distribution of average muscle activities in four quadrants using pie charts. **8.6**.
The diagram refers to normalized activities.
The light blue sector represents the activity of the right temporal while the dark blue sector represents that of the left temporal. The light red sector represents the activity of the right masseter muscle, while the dark red one the activity of the left masseter muscle.

With a good neuromuscular balance, corresponding to the absence of malocclusion, the colours will be equally spread over 4 quadrants (each sector will cover a portion equal to 25%).

Panel 4: out-of-range values and notes

This panel displays the automatic reading of out- of -range data and it is possible to add clinical notes to customize the PDF report **8.7**.
In the upper section out-of-range values are marked with a checkmark.
This section is automatically filled in and it is not possible to make changes.
In the lower section there is a Note field where you can add a textual description that the physician wishes to include in the PDF report, as comments for the represented data.



8.7

9

Chewing protocol

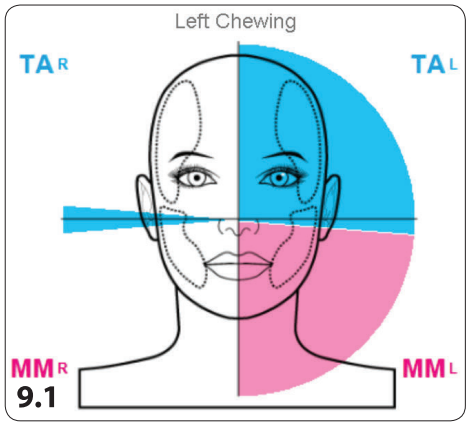
The Chewing test measures the neuromuscular coordination during the masticatory activity: while the occlusal protocol evaluates the neuromuscular balance in a “static” condition, thanks to the analysis of muscular patterns repeatability, this test evaluates the neuromuscular coordination in a “dynamic” condition.
It evaluates the global symmetry index, the masticatory frequency and the work produced during a dunamic task.

Test execution

A calibration test and two chewing tests (right and left side) are carried out.
During these tests the subject should chewing-gum for 15 seconds, separately on the right and left side.

The ideal scenario occurs when the TA and MM activation of the working side are in their own reference areas, while the activation of the non-working side is limited and balanced. 9.1

During the protocol validation researchers chose to make the subject chew a chewing-gum because the bolus keeps its volume during the test execution.



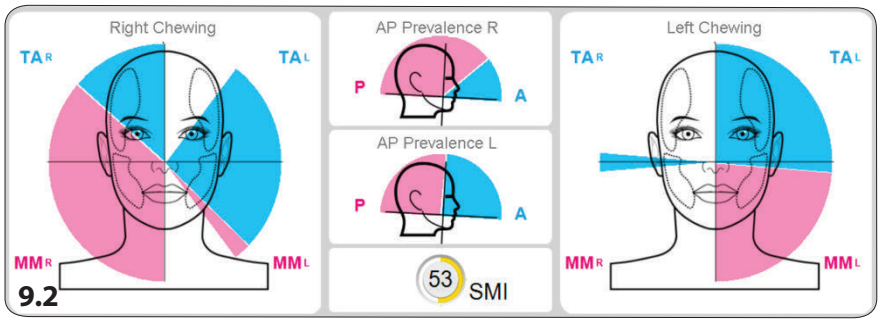
9.1

The graph represents the neuromuscular coordination of the patient’s left side: the patient shows a well-balanced activity between temporalis and masseters of the working side and a low activation level (negligible) of right side temporalis – non working side). The patient is well coordinated when chewing on the left side.

This protocol evaluates the SMI index (masticatory symmetry index), which is a globl index of neuromuscular coordination. The SMI is a unique index, that evaluates both sides together. It’s ideal value is 100%. The further we move from the ideal value, the greater the masticatory incoordination is.

The report

Below (9.2) is shown a mastication protocol report:



In sequence, from left to right:
- The right side chewing test;
- The antero-posterior prevalence of the right and left side during the dynamic task;
- The symmetry index;
- The left side chewing test.

The antero-posterior prevalence indicates whether the temporal or the masseter of the working side was more activated in the chewing test (therefore, if chewing occurred mainly 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 (bps)**: number of chewing acts per second.
- **TA Impact (%)**: index of muscular work performed by the anterior temporalis during the test.
- **MM 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.

Report printing

To print the chewing test report, simply click on the print icon and the XPS report (native Windows format equivalent to pdf) will be automatically generated.

Pre&Post

Different chewing tests can be compared by simply dragging them to the center of the screen, up to a maximum of 2 tests (Drag&Drop).

10

System management

Shutdown and 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). **9.1**

Battery Duration

Teethan® probes use Li-Poly batteries for their operation. The batteries provide a range of about 7 hours in continuous acquisition. For a 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 Teethan® personnel.

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.

9.1

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 into direct contact with the patient (thanks to the interposition of the pre-gelled electrodes), sterilization processes are not required.

11

Troubleshooting

1. Warning: "Insert the receiver"
If at the software start-up this message appears, the receiver is not correctly detected by the system.

Verify that the receiver has been correctly inserted into the USB port:
1) Close the software
2) Remove the receiver
3) Insert again the receiver
4) Open the software

If the problem persists, you need to run the installation of the software again (installation folder in the USB memory key provided with the system).

2. Irregular visualization of acquisition bars
If during the acquisition, the bars of contraction strength are irregularly displayed (click-stops), you are using a communication channel where there are interferences (other Wi-Fi networks). This is not an acquisition problem but a display problem (signals are correctly recorded).
To solve this problem, change the communication channel:
- In the Toolbar, click on Settings
- In the System section, select another channel (between 11 and 26)
- To activate the changes, click on the "Save" button.

3. Disconnected probes
Before performing every acquisition, check that all probes are connected (blue icon alongside each probe). If one or more probes are not connected (grey icon) press the search key to establish a new connection.

12

Technical Information

Specifications

Wireless probes

Geometry:	variable
Electrodes:	standard with clip connection
Separation:	min: 16mm - max: 66mm
Autonomy:	8h of use, some days in stand-by mode
Batteriy:	rechargeable lithium ion
Dimensions:	14x41,5x24,8mm mother electrode 16x12mm satellite electrode diameter
Weight:	13g battery included
Frequency used:	ISM - 2.4GHz band (IEEE802.15.4 standard)
Imput impedance::	100 MOhm
CMRR:	>110 dB @ 50-60Hz
Resolution:	16bit
Acquisition frequency:	1KHz
Sensitivity:	1µV
Measure accuracy*:	± 2%

Receiving unit

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

Charging station

Connection:	USB
Dimensions:	160x135x20mm
Wheight:	431,7 g
Power supply:	AC/DC adapter - type: FW7721M Input: 100-240 v 50-60 Hz/ 200-100 mA Output: 5V/1500 mA For Medical Equipment ta40 IP40 - USB

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

Environmental Conditions

Use	Min	Max
Operating 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.	

Radio regulation

Radio equipment identification:

EMG probes	FCC ID: YQH-BTSWEMG2 - IC: 9188A-BTSWEMG2
Receiver	FCC ID: TFB-MATRIXLP - IC: 5969A-MATRIXLP

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

1. This device should not cause harmful interference
2. 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.

Symbols and regulatory labels

Receiver ID label

Charging station ID label

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.

Rx only 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.

REF Model Number (ref. catalogue).

SN Serial Number.

Declaration of Conformity

CE

DECLARATION OF CONFORMITY

BTS SpA
via Risorgimento 9
35027 Noventa Padovana PD - Italy
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 17 11 65300 004** valid until January 16, 2023.

Padua, January 17, 2018

Bruno Ros
President
BTS S.p.A.

13

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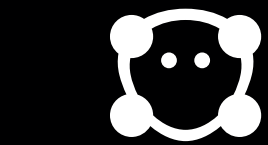

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