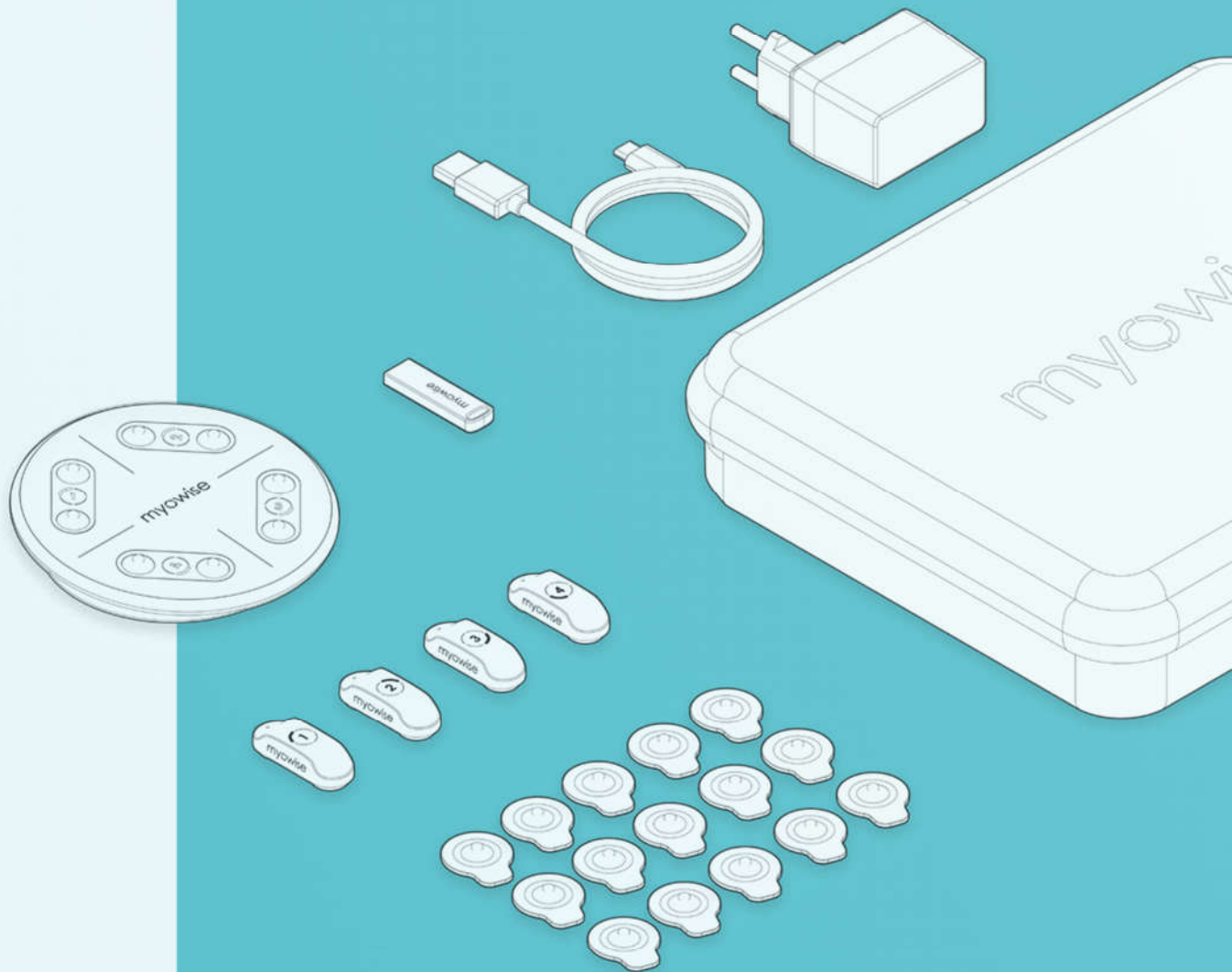


myowise
bite improvement technology

User Manual



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1 General informations

1.1 Instructions for use in electronic form

These instructions for use are also available in electronic form (PDF) by accessing the manufacturer's website: www.myowise.com. In order to download the instructions for use from the site, it is necessary to register in the appropriate section using email and password.

Registration will be successful when the manufacturer accepts the user's registration. After logging in, the link to the Dropbox folder containing the manuals will be available in the appropriate section.

1.2 General description

This user manual contains all the information relating to the safety, use and operation of the Myowise medical device and the Myowise software medical device. Below, we describe the intended use for each of the 2 medical devices and the regulatory framework applied.

1.3 Intended use – Myowise

Medical device for the acquisition of electromyographic (EMG) signals of the temporal and masseter muscles (right and left) in order to provide information relating to the patient's occlusal condition.

1.4 Intended use – Myowise software

Stand-alone software medical device for the analysis of the EMG signals of the temporal and masseter muscles (right and left) in order to provide information relating to the condition of the patient's dental occlusion.

1.5 Expected clinical benefit

The expected clinical benefit resulting from the use of the two medical devices mentioned consists in providing medical personnel with useful information relating to the patient's occlusal condition, in order to identify any disturbances and plan the most appropriate treatment. The devices are not intended to provide a direct diagnosis of a patient's pathological condition.

1.6 Classification – Myowise

Classification according to Regulation (EU) 2017/745 Article 51 – Annex VIII rule 13 class I.

1.7 Classification – Myowise software

Classification according to Directive 93/42/EEC – Annex XI rule 12 class I.

1.8 Users

The devices are intended to be used by doctors and medical personnel specially trained in dentistry.

1.9 Patients

Considering the characteristics of the device and its intended use, there is no specific range of gender or ethnicity of the patients. As far as age is concerned, considering the small size of the Myowise device and the potential danger of ingestion, a minimum age of 3 years is considered and its use on non-cooperative patients is considered inappropriate.

1.10 Contraindications and side effects

There are no particular contraindications or side effects.

1.11 Preliminary warnings and safety information

Failure to observe the following warnings as well as the rules and precautions described in this user manual will result in the immediate invalidation of any warranty on the Myowise device. Cometa Srl is not responsible for any damage to people or things following failure to observe the rules or precautions listed below and reported in general in this user manual.



FAILURE OR NEGLIGENCE IN FULFILLMENT OF THE FOLLOWING INDICATIONS MAY CAUSE MALFUNCTIONING OF THE DEVICE, DAMAGE AND INJURY TO THE USER



DO NOT USE THE DEVICE UNTIL YOU HAVE READ AND UNDERSTAND THIS USER MANUAL IN ITS ENTIRETY



NO MODIFICATION OF THE DEVICE AND/OR ITS PARTS IS PERMITTED



THE USE OF THE DEVICE FOR PURPOSES DIFFERENT FROM THOSE INDICATED IN THIS USER MANUAL COULD EXPOSE THE PATIENT AND THE OPERATOR TO DANGERS



ASK THE PATIENT ABOUT PADS GEL SENSITIVITY



DO NOT USE IN THE PRESENCE OF LIFE SUPPORT EQUIPMENT OR IN THE VICINITY OF SHORTWAVE OR MICROWAVE THERAPEUTIC DEVICES, POTENTIAL CAUSE OF INSTABILITY OF APPLIED PARTS



AVOID ACCIDENTAL CONTACT BETWEEN THE APPLIED PARTS AND OTHER CONDUCTIVE PARTS.



DUE TO THE SMALL SIZE OF SOME COMPONENTS, IT IS NOT ADVISABLE TO USE THE DEVICE ON PERSONS UNDER THE AGE OF 3 YEARS OR ON NON-COLLABORATING PERSONS. IN THESE CASES, MAKE A DIRECT AND CONTINUOUS VISUAL CHECK ON THE SUBJECT.



SIMULTANEOUS CONNECTION OF A PATIENT TO A HIGH FREQUENCY SURGICAL EQUIPMENT AND AN EKG MYOGRAPH MAY CAUSE BURNS AT THE POINT OF CONTACT WITH THE ELECTRODES OF THE STIMULATOR OR BIOPOTENTIAL INPUT PART AND POSSIBLE DAMAGE TO THE STIMULATOR OR BIOLOGICAL AMPLIFIERS



REPORT ANY SERIOUS INCIDENT WITH THE DEVICE TO THE MANUFACTURER AND THE COMPETENT AUTHORITY OF THE MEMBER STATE WHERE THE USER AND/OR THE PATIENT IS ESTABLISHED

2 Maintenance



ALWAYS CHECK THAT THE SENSORS AND THE CHARGING STATION ARE DISCONNECTED FROM THE ELECTRIC MAINS BEFORE CARRYING OUT ANY OPERATION DESCRIBED BELOW



The useful life of the Myowise device if properly maintained and used is 10 years.



For the Myowise software, it is not possible to accurately determine its useful life. Therefore, this value is traced back to the introduction of new requirements or new technologies that make the use of the SW itself complex or inefficient. Considering the hypothetical technological development, a useful life time of 8 years is estimated.

2.1 Cleaning

To clean the system components, use a soft cloth slightly moistened with a mild disinfectant for the skin which is a medical surgical device.

The penetration of liquids inside the transmitters can cause the reduction of the amplitude of the detected EMG signal. If this disturbance is detected, leave the transmitters to dry. If the fault persists, finish the test by replacing the faulty transmitter and then contact the manufacturer.

3 Disposal



Do not dispose of the Myowise device as general waste. Prepare the product for recycling or separate collection pursuant to Legislative Decree of 14 March 2014, n. 49 "Implementation of Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)".

In case of use in hospitals, follow the internal rules for the disposal of electrical and electronic waste.

4 Technical features

The technical characteristics of the Myowise system components, 4 EMG sensors, the recharging station and the power supply are listed below.

4.1 Sensors

Nordic nRF52832	
Transmit/receive frequency	2.4 GHz
Modulation	FSK
Data Rate	1 Mbps
Sensitivity	- 96 dBm
Antenna	Flex PCB antenna
Output Power	4 dBm
general informations	
Supply voltage	3.3 V
Absorbed power	10.5 mW
Autonomy of use (100% charged battery)	18 h
Autonomia in stand by	> 80 days
EMG inputs	
Bandwidth	10-500 Hz
Sampling	1000 Hz
Input impedance	20 M Ω
CMRR	> 100 dB (real differential)
SNR	> 50 dB
Hardware filters: LP e HP	1st order
Slope	-20 dB / dec
Firmware version	
Applied parts	Type BF

4.2 Charger

Charging capability	4 sensors
Supply voltage	5V
Power consumption max.	2,25W
Charging time	3:50 h

4.3 Power supply

Template	AC/DC Adapter 1899497
Supply voltage	100–240VAC
Output voltage	5VDC
Insulation class	II

4.4 Environmental conditions

Temperature	Usage	10 / 40°C
	Storage/transport	-25 / 70°C
Moisture	Usage	20 / 80% Ur non-condensing
	Storage/transport	5 / 95% Ur non-condensing
Atmospheric pressure	Usage	700 at 1020 hPa
	Storage/transport	500 a 1060 hPa (375 – 795 mm Hg)
Maximum altitude	Usage	2000 m
	Storage/transport	2000

4.5 Labeling

Label on **charging station** with all the system identification information reported.



Label on **packaging** of the system



4.6 Symbology used

System identification information



Manufacturer identification



Product identification code



Serial number identifying the production number



AAAA/MM

Country of manufacture and date of manufacture



Medical device

Electromedical symbols



Insulation class II



Type BF applied part



Disposal according to WEEE regulation

Security information



Consult the user manual



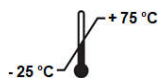
Complies with Regulation (EU) 2017/745



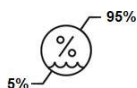
Website from which it is possible to download the instructions for use in electronic form

www.myowise.com

Environmental conditions



Storage ambient temperature



Storage ambient humidity



Do not expose to direct heat sources



Do not expose to rain and keep dry

5 Electromagnetic compatibility

5.1 EMC warnings

The appliance complies with the collateral standard CEI EN 60601-1-2 Standard applicable to the product and relating to electromagnetic compatibility.



THE EQUIPMENT SHOULD BE INSTALLED AND PUT INTO SERVICE ACCORDING TO THE EMC INFORMATION PROVIDED IN THIS SECTION.



USE OF THIS DEVICE NEAR OR TOP-ON OTHER DEVICES SHOULD BE AVOIDED AS THIS MAY LEAD TO INCORRECT OPERATION. IN THESE CASES THE APPLIANCE AND OTHER EQUIPMENT SHOULD BE OBSERVED TO VERIFY THEIR NORMAL OPERATION.



THE USE OF ACCESSORIES, TRANSDUCERS, AND CABLES OTHER THAN THOSE SPECIFIED OR PROVIDED BY THE MANUFACTURER OF THIS EQUIPMENT COULD LEAD TO INCREASED ELECTROMAGNETIC EMISSIONS OR A DECREASE IN THE LEVEL OF ELECTROMAGNETIC IMMUNITY OF THIS EQUIPMENT, RESULTING IN INCORRECT OPERATION.



TRANSPORTABLE RF COMMUNICATION EQUIPMENT (INCLUDING PERIPHERALS SUCH AS ANTENNA CABLES AND EXTERNAL ANTENNAS) SHOULD BE OPERATED NO closer than 30 CM (12 INCHES) FROM ANY PART OF THE EM EQUIPMENT, INCLUDING SPECIFIED CABLES FROM THE MANUFACTURER. OTHERWISE, THE PERFORMANCE DEGRADE OF THIS EQUIPMENT MAY RESULT.



THE DEVICE MAY ONLY BE USED IN PROFESSIONAL CARE ENVIRONMENTS (FOR EXAMPLE, DENTAL PRACTICES, CLINICS, HOSPITALS...)

For class A equipment only

NOTE The EMISSION characteristics of this device make it suitable for use in industrial and hospital environments (class A of CISPR 11). When used in residential environments (for which class B of CISPR 11 is normally required) this equipment may not offer adequate protection for radio frequency communications services. The user may need to implement mitigation measures, such as relocating or reorienting the equipment

5.2 Evaluation tables 60601-1-2

The device is intended for use only in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

The device is intended for use only in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment
RF emissions CISPR 11	Group 1	I: This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in any nearby electronic equipment. A: This device is suitable for use in all buildings except those used for domestic purposes and those connected directly to the public distribution network which supplies power to buildings used for domestic purposes.
RF emissions CISPR 11	Class A	
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions EN 61000-3-3	According	
CISPR 14	Not applicable	
CISPR 15	Not applicable	

The device is intended for use only in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	EN 60601-1-2 Test level	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) EN 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV in Aria	IN 60601-1-2 Test level	Professional care environment
Electrical fast transient/burst EN 61000-4-4	± 2 kV Repetition frequency 100kHz	IN 60601-1-2 Test level	Professional care environment
Surge EN 61000-4-5	± 0.5 kV, ± 1 kV between phases ± 0.5 kV, ± 1 kV, ± 2 kV between phase and earth	IN 60601-1-2 Test level	Professional care environment
Voltage dips, short interruptions and voltage variations on power supply input lines IN 61000-4-11	0 % UT; 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70% UT; 25/30 single-phase cycles: at 0° Voltage interruption 0 % UT; 250/300 cycles	IN 60601-1-2 Test level	Professional care environment
Power frequency (50/60 Hz) magnetic field IN 61000-4-8	30 A/m 50 Hz o 60 Hz	IN 60601-1-2 Test level	Professional care environment

The device is intended for use only in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	EN 60601-1-2 Test level	Compliance level	Electromagnetic environment
Radiated RF EN 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	IN 60601-1-2 Test level	Professional care environment
Conducted RF EN 61000-4-6	3 V 0,15 MHz – 80 MHz 6V in the ISM band between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 V IN 60601-1-2 Test level	Professional care environment

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Fields from fixed transmitters, such as base stations for radio telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be estimated accurately by calculation. To assess the electromagnetic environment due to fixed RF transmitters, the need to take a survey of the application should be considered. If the measured field strength in the location where the device is used exceeds the strength of V/m field established, observe the device to verify that normal operation is maintained. In the event of abnormal operation, additional protective measures must be taken, such as moving the device away from the emitting element or using a place of use more shielded from RF radiation and/or using a more effective filter

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Recommended separation distance for non-life support devices and intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications devices (transmitters) and the device as recommended below, according to the maximum output power of the equipment. communication.

Maximum output power of the transmitter (IN)	Separation distance according to the transmitter (m)	
	80MHz to 800MHz $d = 1.2 \times \sqrt{P}$	800MHz to 2.5GHz $d = 2.3 \times \sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23

For transmitters rated at maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated from the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Use:

(1) 800 MHz, the separation distance for the higher frequency range

(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

NB The system has not been tested for electromagnetic immunity to radiated RF over the entire frequency range 80 MHz to 2.5 GHz



6 Introduction

From the awareness that every man is morphologically and functionally different from the other arises the need to measure the effects that certain treatments can produce on his physiological state. Nowadays, the study of the stomatognathic system from a morphological point of view alone is no longer sufficient.

A study of this type should therefore also be accompanied by a functional analysis, which can only really be carried out through an objective quantification of the quantities involved and through tests and measurement tools developed ad hoc.

The introduction of electromyography in the daily clinical setting has therefore made it possible to reliably measure what was previously hidden and perceivable only qualitatively by palpation.

The purpose of the examination is to quantify the influence of dento-periodontal proprioception on the recruitment of masticatory muscles in order to better manage the modalities and timing of the patient's functional rehabilitation.

The goal of a rehabilitation is to re-establish correct anatomy that can promote adequate function. From this point of view, a verification of the functional adaptation to the new anatomical situation can be a useful aid for the dentist. An electromyographic analysis with appropriate standardization procedures is able, in a scientifically reliable way, to measure the changes to the muscular motor pattern due to teeth.

6.1 The Myowise system

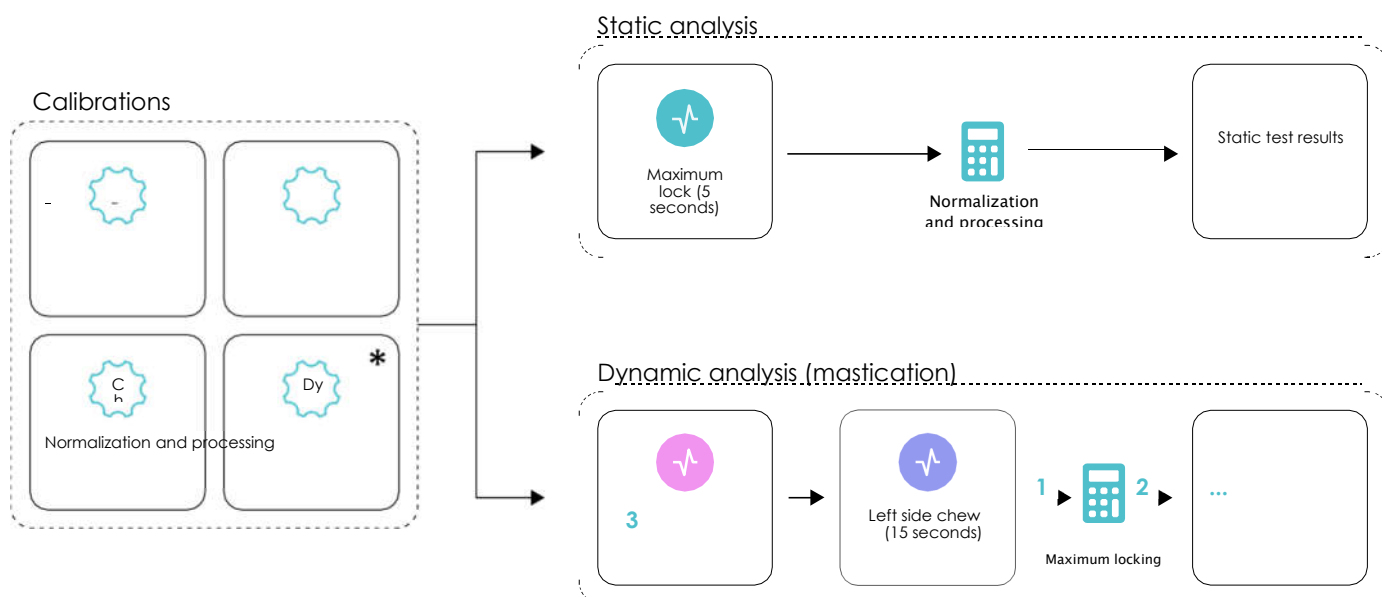
Myowise has been designed to help the user in the analysis and identification of occlusal morphologies causing muscle alterations. The software provides the user with useful information for treatment planning.

6.2 Calibrations and tests

Myowise provides two different types of acquisition, calibration and examination. Calibration is performed at the beginning of each new session and serves both to validate the correct positioning of the sensors on the patient and for the subsequent reprocessing of the test data.

Given the importance of this step, it is recommended to carry out multiple calibrations. The second type of acquisition is the actual exam. The exam can be static or dynamic.

The static test consists of the maximum lock lasting 5 seconds. The dynamic test consists of chewing on each side of the mouth for 15 seconds.



* E' consigliato eseguire almeno tre calibrazioni, il numero massimo è 6.

6.1

6.3 Output in Myowise

In this manual we will go into detail about all the information and indexes returned by the system.

Myowise allows both the export of raw EMG data relating to an examination and the creation of a comprehensive report.

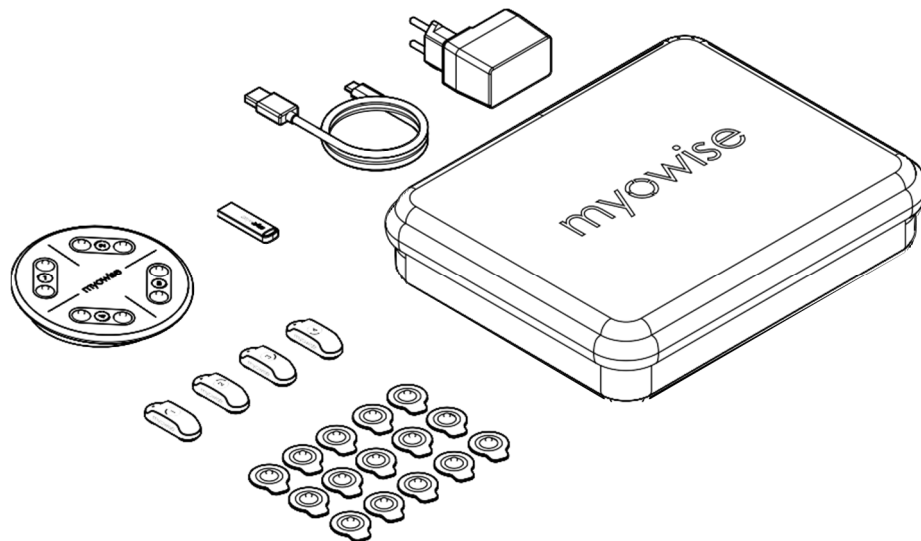


7 System overview

Myowise is a complete and ready to use system, the package contains everything needed to perform high precision electromyographic examinations.

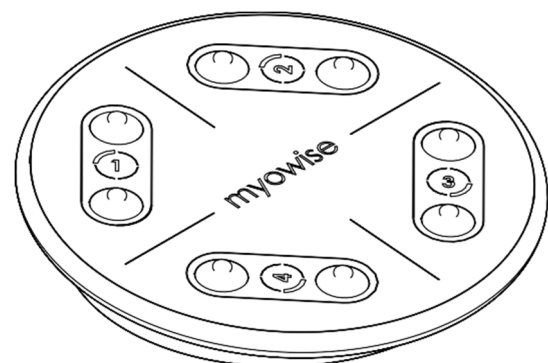
7.1 Box contents

The package contains the following components:



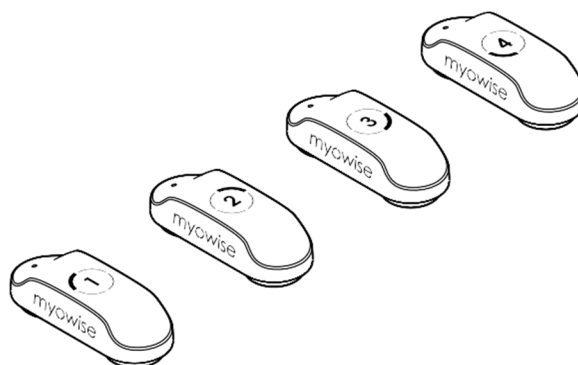
Charging station

Charging station for the 4 EMG sensors. Equipped with LED signals indicating the charging stage of each sensor.



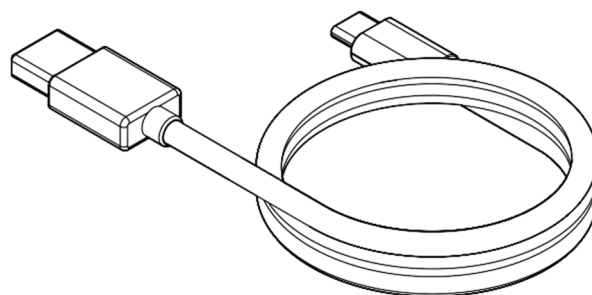
4 EMG sensors

The smallest and lightest sensors in the world, excellent for application on the face. Battery autonomy in recording up to 18 hours.

**7.2**

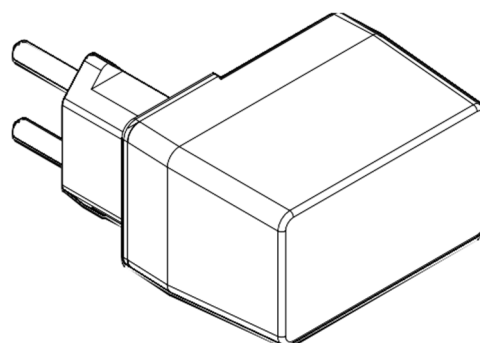
USB-C cable

For powering the charging station via the computer's USB port.

**7.3**

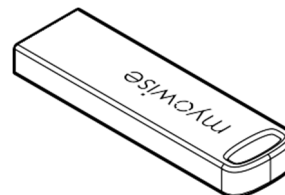
USB adapter

For powering the charging station via wall socket.

**7.4**

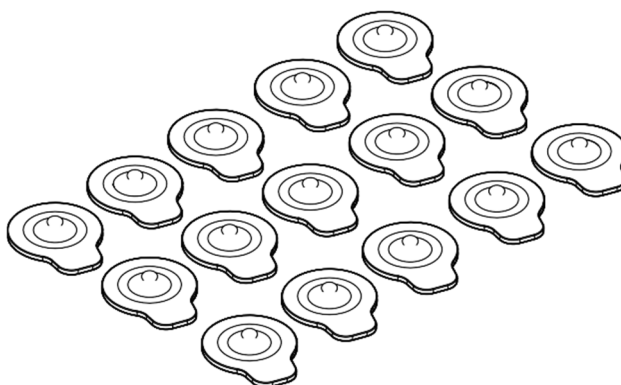
USB software key

The USB stick contains the Myowise software and the patient database.

**7.5**

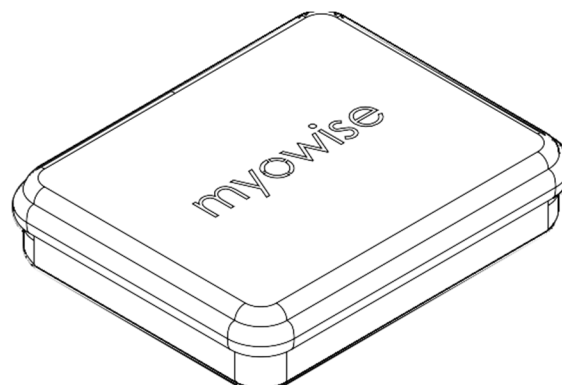
Pre-gelled electrodes

Bag with disposable Kendall electrodes. Once they run out, they can be purchased on the main sites of medical consumables.

**7.6**

Travel case

Compact and safe carrying case for the Myowise system.

**7.7**



8 Set up and use

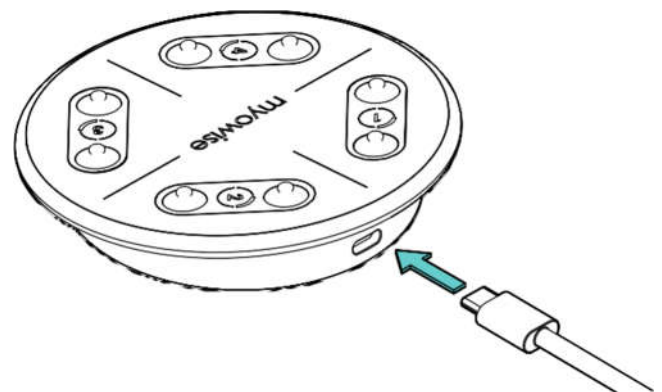
The procedure for setting up the hardware and recharging the sensor batteries is described below.

8.1 Set up hardware

To charge the Myowise sensors follow the procedure below.

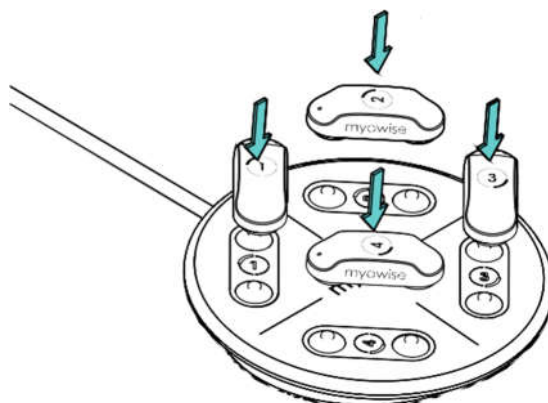
Power up the charging station

Connect the charging station to the power supply via the USB-C socket located on the back of the station itself. The four sectors of the light ring light up green.

**8.1**

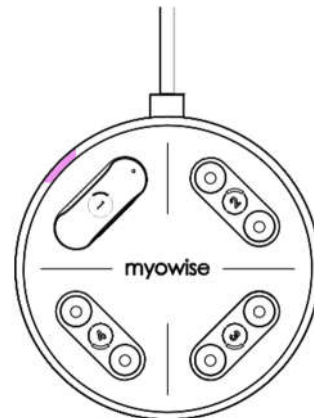
Sensor placement

Place the sensors on the charger as shown.

**8.2**

Charging sensor

The sensor is correctly positioned on the magazine when both clips have clicked. The sensor is now charging or trickle charging.



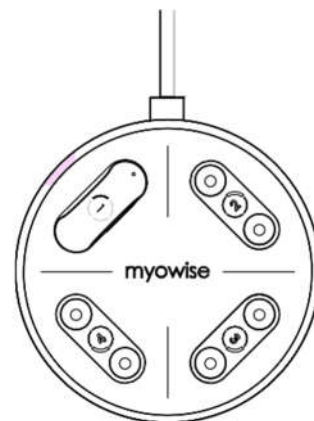
8.3

Charging phase

During the charging phase the luminous sector corresponding comes with pulsating light



button



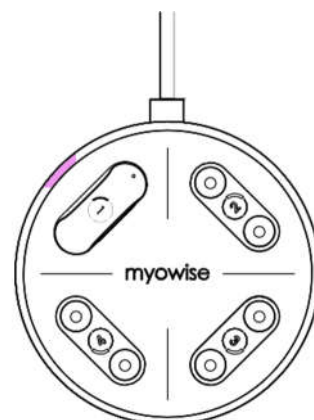
8.4

Charge completion

When the charge phase is completed the sector corresponding light shows up with steady light.



fixed



8.5

Charging time

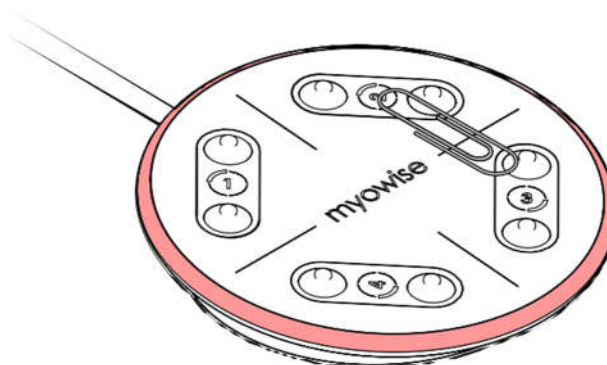
A complete charge cycle takes 3 hours.



8.6

Abnormal contact

If there is abnormal contact between the charging clips, the light ring flashes orange. Remove the cause of the contact and disconnect the power supply.



8.7

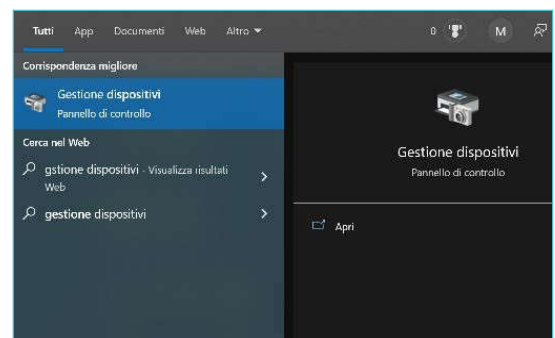
8.2 Software setup and minimum requirements

Myowise is supplied with software for calculating indices related to occlusal contact and neuromuscular alterations. The Bluetooth compatibility check, startup and usage procedures are described below. To guarantee the correct functioning of the software it is necessary to have the operating system installed on the PC **Windows 10** or later. During use it is not recommended to use the energy saving mode of the PC and if you are using a laptop it is recommended that it be connected to the power supply.

To allow data transmission, the computer must have connectivity **Bluetooth 4.2**.

Here are the steps to view the Bluetooth version on your computer:

- In the search box on the taskbar, type **device management**.
- Log in **Device management**.
Expand the menu **Bluetooth** to view the list of devices on the PC

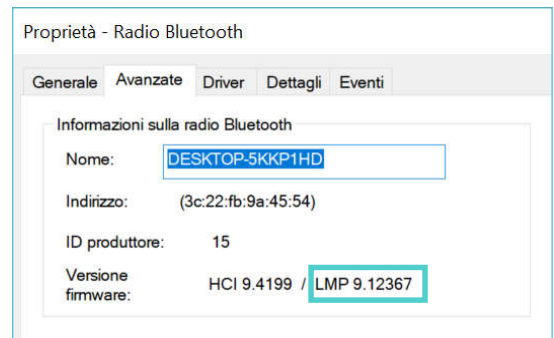


Bluetooth device (RFCOMM Protocol TDI) Enumerator Bluetooth
Enumerator LE Bluetooth
Commercial name of the Bluetooth board (If the Bluetooth item is not displayed, the computer does not have one, see page 10)

- Double click on **marketing name of the Bluetooth card**, the window will open **Property**.
(Or right click – properties)



- Open the tab **Advance** and check the LMP number under Firmware Version.
- The minimum Bluetooth requirement is **LMP 8** which corresponds to **Bluetooth 4.2**.



8.11

8.3 Bluetooth compatibility

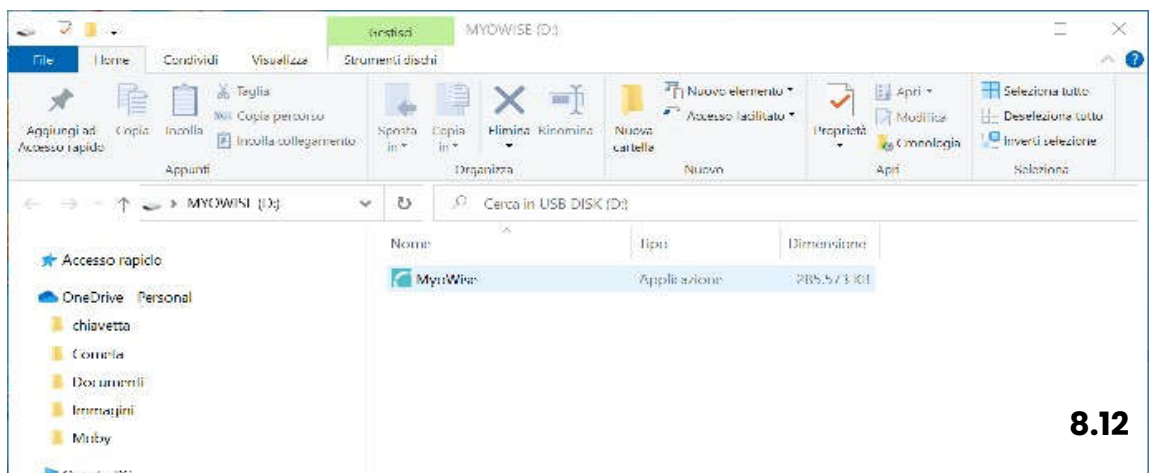
The Myowise system is designed for plug and play use however if your computer does not meet the minimum Bluetooth connectivity requirements an intermediate step is required. In this case, a Bluetooth USB key is supplied with the system which allows data transmission.

The three main cases and the actions to be taken to guarantee the correct connection of the system are described below.

The computer has Bluetooth 4.2:

(or later)

- It does not need any kind of installation or integration. (do not use the USB Bluetooth stick even if supplied)
- Make sure Bluetooth is turned on (Start - Settings - Bluetooth - ON)
- Insert the Myowise USB stick, a window opens showing its contents.
- Double click the software icon to launch it.

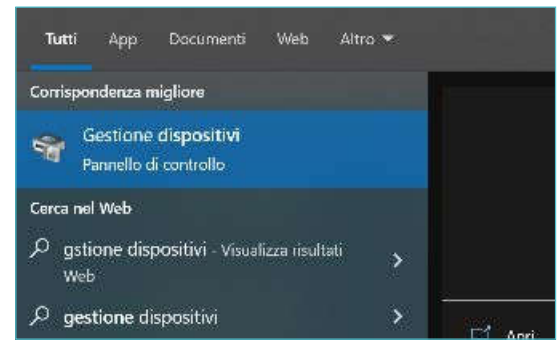


8.12

The computer has Bluetooth 4.1:

(or earlier versions)

- Sign in **Device management**.
- Expand the menu **Bluetooth** to view the list of devices on the PC.
- Disable commercial Bluetooth card only (Right click - disable device)
- Insert the Bluetooth USB stick into your computer. (And leave it inserted)
- Drivers install automatically. (Otherwise see the instructions on the packaging)
- **Restart your computer.**
- After restarting the computer make sure that Bluetooth is turned on (Start - Settings - Bluetooth - ON)
- Insert the Myowise stick, a window opens showing its contents.
- Double click the software icon to launch it.



8.13



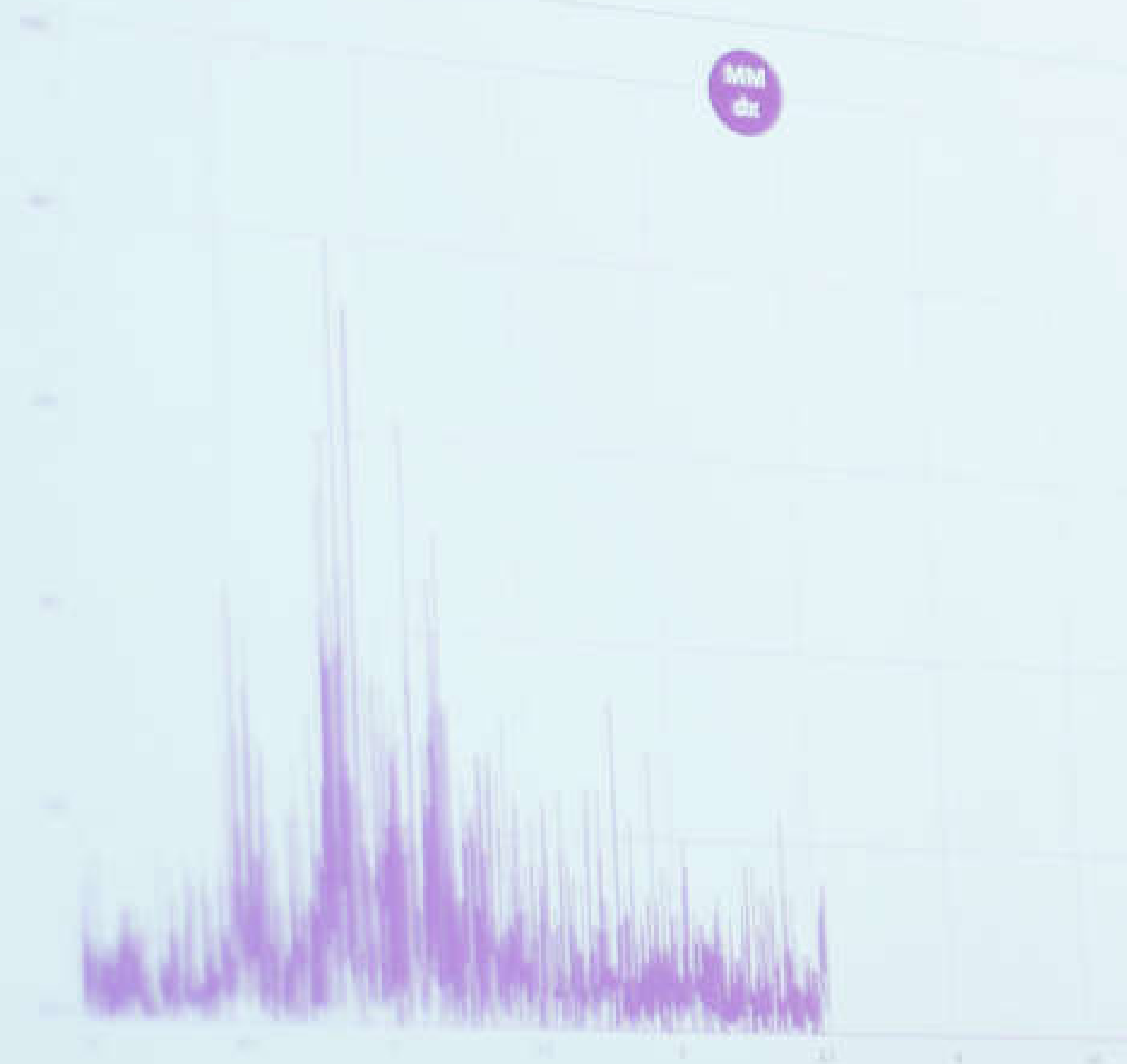
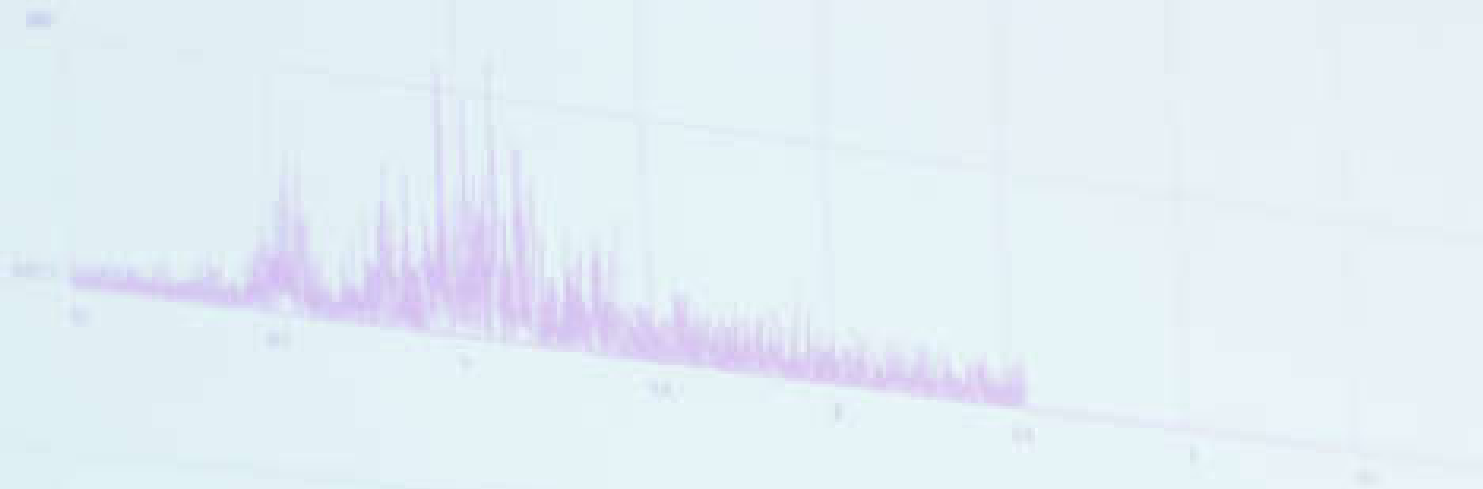
8.14



8.15

The computer does not have Bluetooth:

- Insert the Bluetooth USB stick into your computer. (And leave it inserted)
- The drivers install automatically. (Otherwise see the instructions on the packaging)
- **Restart your computer.**
- After restarting the computer make sure that Bluetooth is turned on (Start - Settings - Bluetooth - ON)
- Insert the Myowise stick, a window opens showing its contents.
- Double click the software icon to launch it.



9 Software Myowise

Myowise is supplied with software for calculating indices related to occlusal contact and neuromuscular alterations.

These indices, in addition to numerical values, are represented in three different forms: mandibular plane, bar graph and pie graph.

9.1 Starting the software

The Myowise software does not need to be installed on the computer, it only needs the Myowise USB stick.

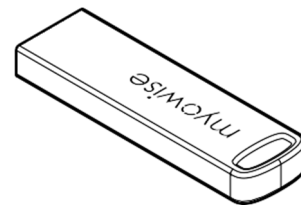
The key contains the software, the database, the configuration file (where all the settings are saved) and the license.

The Myowise software license is linked to the specific USB key.

The procedure for launching the Myowise software is shown below.

USB pendrive

Insert the Myowise USB stick into the PC, a window automatically opens showing the contents of the stick.



9.1

Start Myowise

Double click the Myowise icon to launch the software.



9.2

Startup screen



9.3

System serial

When starting the Myowise software for the first time, you need to enter the **serial number** of the system which is indicated on the label on the base of the charging station.

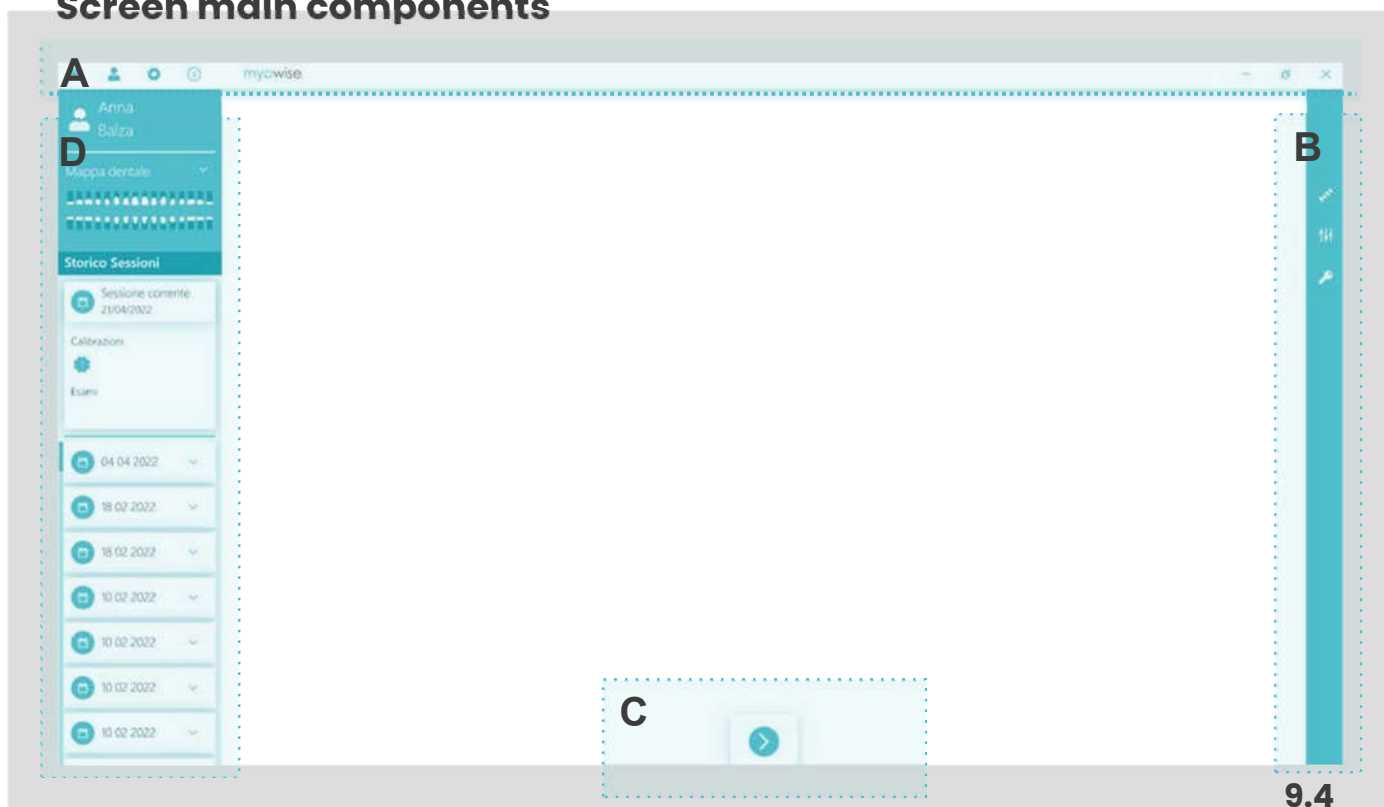
Language selection

In the start screen of the software you can select the language. The user can make this change later from the panel **Tongue** of the settings.

Added operator

In the start screen of the software it is necessary to enter the name of the first operator. The user can edit or add more contacts in the panel **Operators** of the settings.

Screen main components



A – Top bar

This bar is present in all the software screens and allows you to go back to the following screens with a click:

- | | | | |
|---|-----------------------|---|-------------------|
|  | Home (startup screen) |  | Full screen |
|  | Patient search screen |  | Minimize the icon |
|  | Settings |  | close |
|  | Software information | | |

B – Right sidebar

This bar is present in all the software screens and gives access to the sensor status summary panel. At any time it is possible to view the connection and battery status of each sensor.

C – Central command bar

This bar houses all the main commands of the software and is configured according to the current screen.

D – Side panel

This panel features the **basic information** of the patient and **session history**. Each session panel includes all calibrations and exams performed. The notes of each session and the tooth map relating to that specific session can also be consulted. The side panel allows you to view or hide each exam to compare the results even between different sessions.

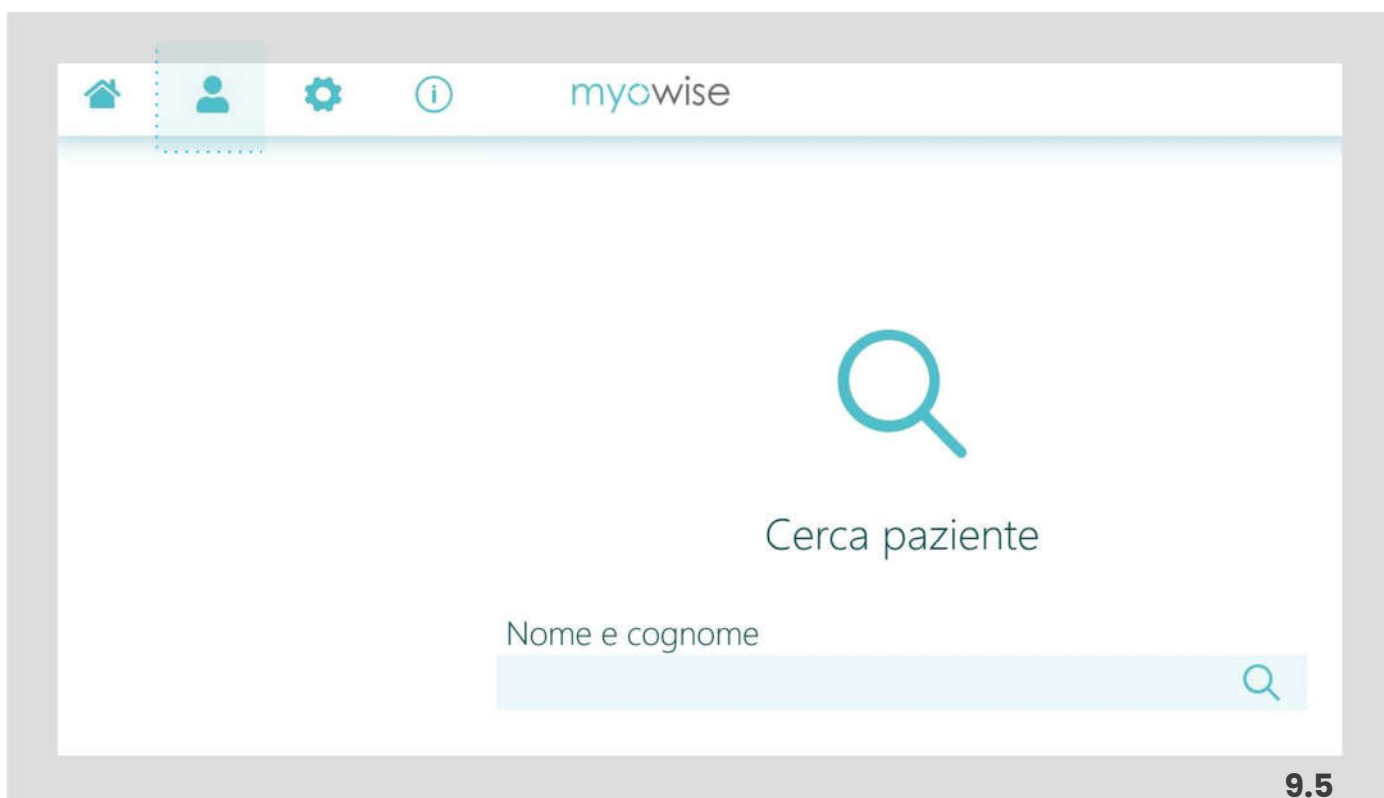
9.2 Patient databases

Patient management is divided into folders. To insert a new Patient in the database it is necessary to create a new folder and fill in the Patient's personal data. The Patient folder will contain all the sessions with the respective exams relating to that Patient.

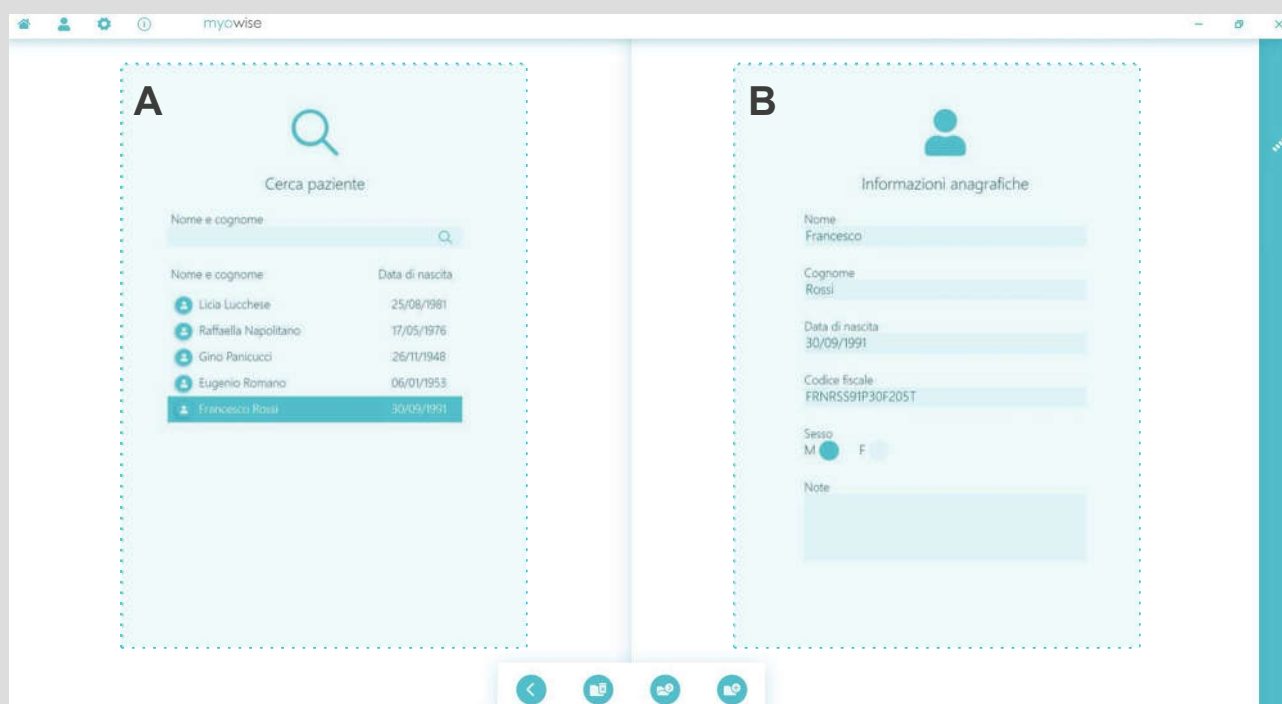
Patients already entered in the database can be selected from the list or via the search text field. Once a Patient has been selected, a preview of the personal data is displayed. By clicking on **Open Patient Folder** the Patient folder is accessed.

The database is saved on the Myowise USB stick. For backup procedures, see paragraph **11.4** of this manual.

The Patient search screen is accessed via the hot key in the top bar.



Patient Search



The screenshot displays the myowise web application interface for patient search. It is divided into two main panels, A and B, within a window titled 'myowise'.

Panel A: Cerca paziente

Panel A features a search bar labeled 'Cerca paziente' with a magnifying glass icon. Below the search bar, there is a table listing patients. The table has two columns: 'Nome e cognome' and 'Data di nascita'.

Nome e cognome	Data di nascita
Licia Lucchese	25/08/1981
Raffaella Napolitano	17/05/1976
Gino Panicucci	26/11/1948
Eugenio Romano	06/01/1953
Francesco Rossi	30/09/1991

Panel B: Informazioni anagrafiche

Panel B displays the demographic information for the selected patient, Francesco Rossi. It includes fields for Name, Surname, Date of Birth, Fiscal Code, Sex, and a Note field.

Nome: Francesco
Cognome: Rossi
Data di nascita: 30/09/1991
Codice fiscale: FRNRSS91P30F205T
Sesso: M (selected) F
Note:

9.6

A – Search Patient

The Patient can be selected from a list or by entering the name or surname in the search field.

B – Patient information preview

The preview of the demographic information of the selected patient is displayed.

Command bar

Allows you to create a new Patient folder to enter a name not yet present in the database or to open the folder of an existing Patient.

9.3 Patient Folder

The Patient folder contains all the information relating to the Patient. The part of **personal information** presents the main information of the patient.

There **dental map** is a tool designed to keep track of the patient's dental situation. An updated and correctly compiled dental map is required for the correct functioning of the Myowise index calculation engine. The warnings and diagnostic suggestions are in fact also based on the analysis of the patient's dental situation as well as on muscle performance.

The **session history** collects all the sessions performed on the patient with the respective calibrations and analyses. At any time it is possible to open a previously performed session and view the summary of the individual tests.

It is not possible to add exams to a previously closed session as it cannot be guaranteed that the patient's conditions and the positioning of the sensors have remained unchanged.

As illustrated in the paragraph **6.3 Performing calibration** each new session requires a new set of calibrations which are used to normalize the analyzes of that same session. It is not possible to use a calibration in conjunction with analyzes from different runs.

Patient Folder

The screenshot displays the 'myowise' Patient Folder interface, which is divided into three main panels labeled A, B, and C.

- Panel A: Informazioni anagrafiche** (Personal data). It contains fields for:
 - Nome: Francesco
 - Cognome: Rossi
 - Data di nascita: 30/09/1991
 - Codice fiscale: FRNRSS91P30F205T
 - Sesso: M (selected) / F
 - Note: A text area for additional information.
- Panel B: Mappa dentale** (Dental map). It shows a diagram of upper and lower dental arches with icons representing teeth. Below the arches are checkboxes for:
 - Rapporti mascellari sagittali alterati orizzontalmente
 - Rapporti mascellari sagittali alterati verticalmente
 - Salute tessuti duri e molli orali
- Panel C: Storico Sessioni** (Session history). It displays a list of sessions with details such as date and time (e.g., 13/06/2022 15:04), calibration status, and exam types (e.g., Clenching 1, Clenching 2, Clenching 3, Clenching 4, Masticazione).

A command bar at the bottom of the interface contains icons for navigation and actions.

9.10

A – Personal data

The main personal data of the patient. Allows the insertion of textual notes.

B – Map of the situation

The patient's dental situation with indication of missing teeth, prostheses or other specific situations. This step is essential to give the software the information useful for the formulation of some warnings.

C – Session history

The list of all sessions supported by the Patient. The panel of each session shows the calibrations and exams performed during the session.

Command bar

It allows the modification of the patient data, the opening or creation of a session and the creation of the report. By opening a new session, you continue to **connection guide**.

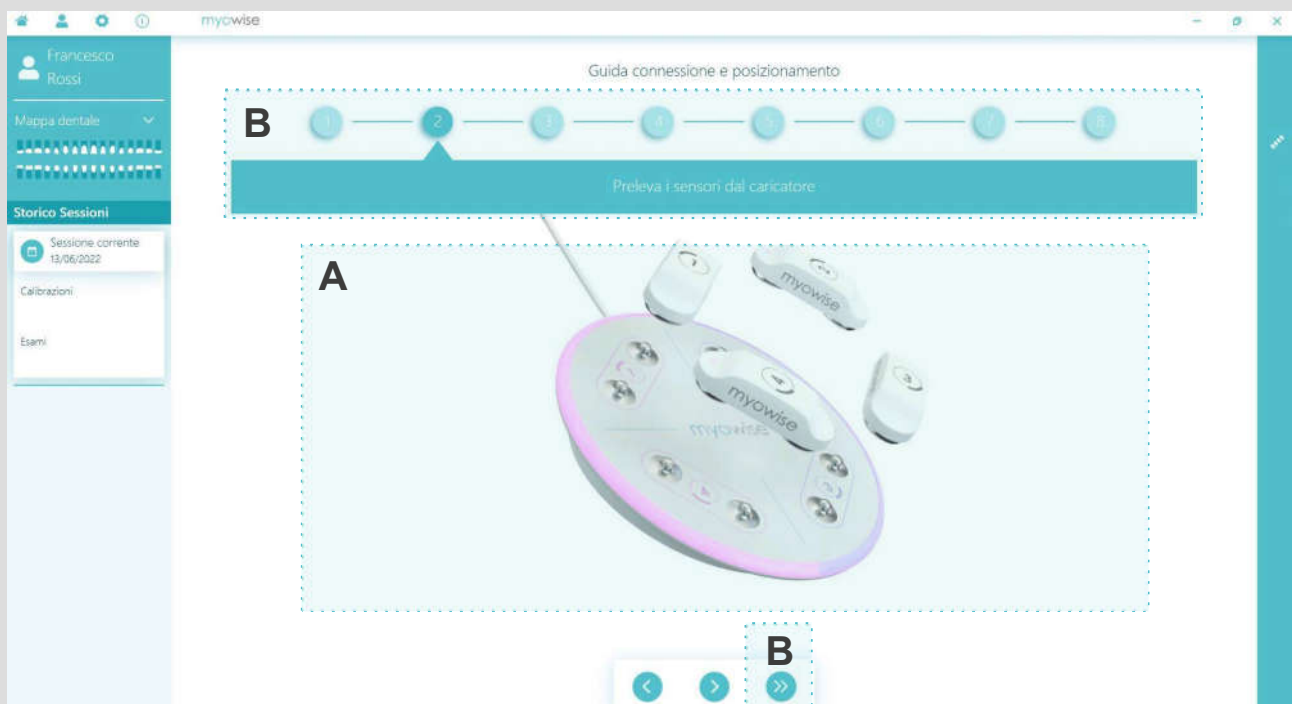
9.4 Sensor connection to PC

Once a new Patient has been entered or a Patient already present in the database has been selected and the information present in the Patient folder has been verified, it is possible to add a new session of exams.

Once selected **Open new session** a new session panel is inserted into the **Session history** and it is possible to insert textual notes.

By clicking on **Forward** is displayed **connection and positioning guide** which describes the procedures for connecting to the PC via bluetooth and positioning the sensors on the face of the Patient. Experienced users can skip the placement guide and go straight to **summary connection and placement**.

Connection and positioning guide



9.11

A – Guided operation illustration

The steps necessary for the connection of the sensors and their correct application on the patient are described.

B – Dynamic index

Tells the user where they are in the guide.

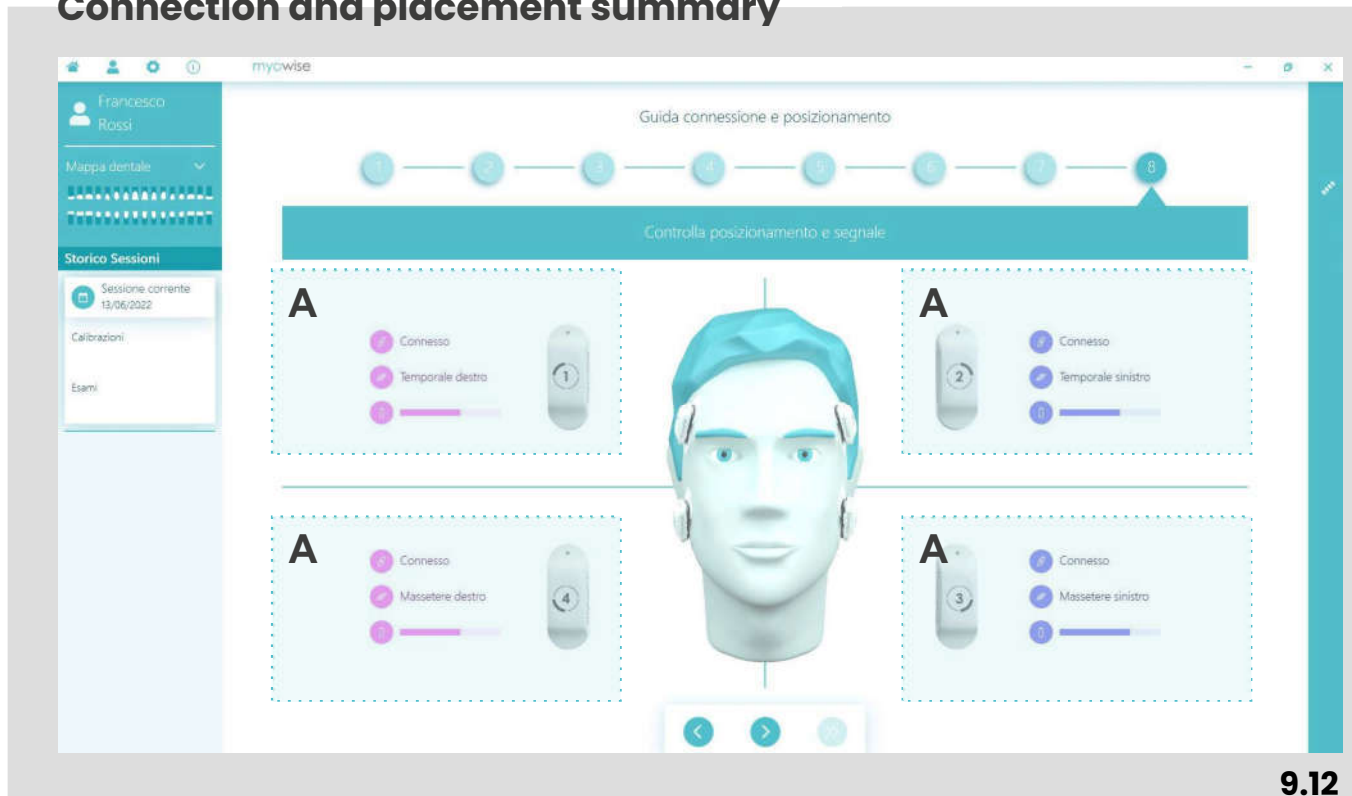
C – Skip the guide

Experienced users can skip the sensor placement guide and go straight to the **summary connection and placement**

Command bar

In all the screens of the connection and positioning guide, the command bar allows the user to go back to the previous step or to continue up to the **summary connection and placemen**

Connection and placement summary



9.12

A – State of the sensors

This screen shows the status of the sensors and allows you to check the correct positioning. There is also information on the battery status of each individual sensor. The autonomy of the sensors in recording is approx **18 hours**, it is recommended to reposition the sensors on the charger at the end of the working day.

The LED on the sensor indicates its status:

- **Light off** = sensor **in charge** on the charger or in mode **sleep**
- **Slow pulsating light** = sensor in **advertising** (The sensor is available for connection for 1 hour then goes back to sleep mode, to go back to advertising mode connect the sensor to the switched on charging station and disconnect it)
- **Flashing light** = sensor **connected** at the PC
- **Steady light** = sensor in **registration**

Command bar

It allows the user to go back or to validate the positioning of the sensors and continue to the screen **calibration**

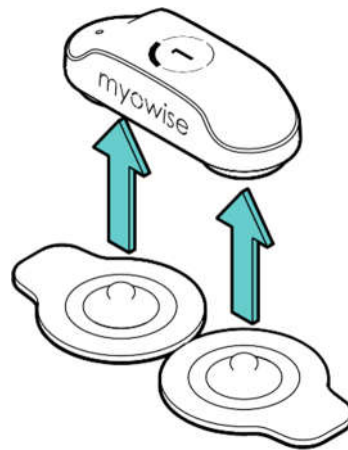
9.5 Sensor placement

The 4 Myowise sensors have a **unique placement on the face** of the patient. Within the software there is a step-by-step guide for their correct positioning. We report below a summary scheme.

Attention! An incorrect positioning of the sensors compromises the correctness of the data.

Electrode application

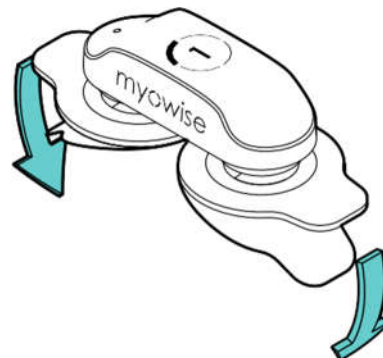
Remove the sensors from the charging station and apply the pre-gelled electrodes.



9.13

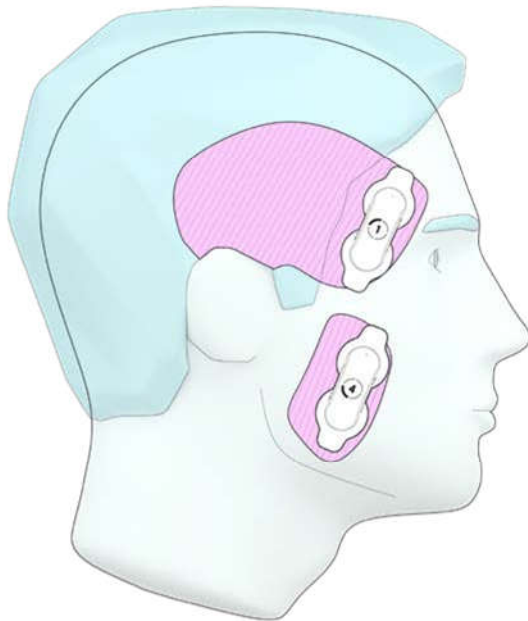
Remove the film

Pre-gelled electrodes have a film that must be removed before application on the patient. Clean the skin in the application area and position the sensors as shown in the figure 9.15



9.14

Right side



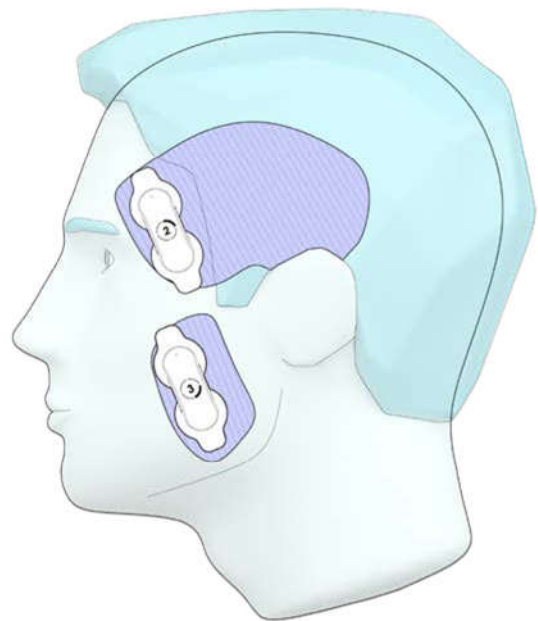
Sensor number 1
**Right
 thunderstorm**



Sensor number 4
Right masseter



Left side



Sensor number 2
Sinister storm



Sensor number 3
Left masseter



9.15

9.6 Performing calibration

Once the correct positioning of the sensors on the patient's face has been checked, we move on to the calibration phase. Calibration is critical for subsequent data normalization.

Standardized surface electromyography differs from traditional electromyography in the normalization of the electromyographic signal.

Normalizing means expressing a value as a percentage of another value considered to be a reference. This procedure greatly improves the objectivity and repeatability of the measurement, eliminating the majority of alterations that could influence a single measurement of this entity, subject to numerous variables such as inter- and intra-Patient physiological and anatomical variability, the different positioning of the electrodes, skin conductivity, external electrostatic interference, etc.

As described in the paragraph **6.3 Patient Record** for each new session it is necessary to create a new group of calibrations. To give Myowise the amount of data necessary for correct normalization, it is recommended to perform a minimum of 3 calibrations.

Calibration is carried out with the aid of two dental rolls. Place the two dental rolls between the arches on the 5th and 6th teeth (second premolars and molars).

Ask the patient to arrange the rollers in order to perceive a symmetrical and comfortable support and to clench the teeth as tightly as possible, then click on the button **Start recording**.

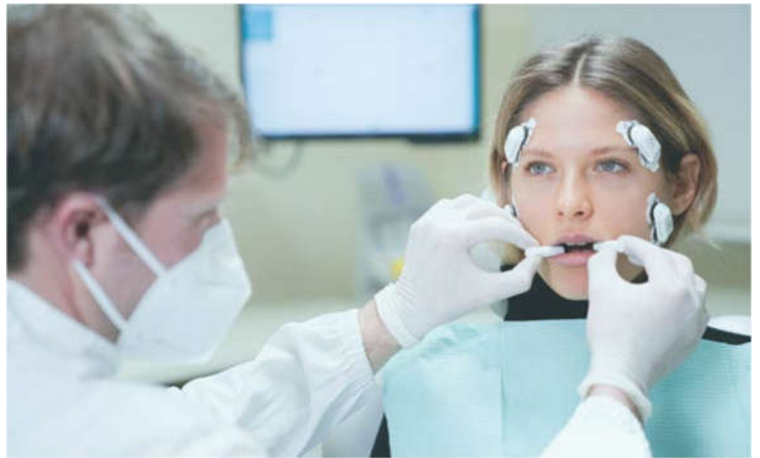
The recording has a duration of 5 seconds during which the patient must maintain the maximum clench.

Recording stops automatically and the **calibration result** which summarizes the graph of muscle coordination, an assessment on the quality of

The three basic steps of the calibration procedure are illustrated below.

Cotton placement

Place the two dental rolls between the arches between the 5th and 6th teeth (second premolars and molars).



9.16

Accommodation

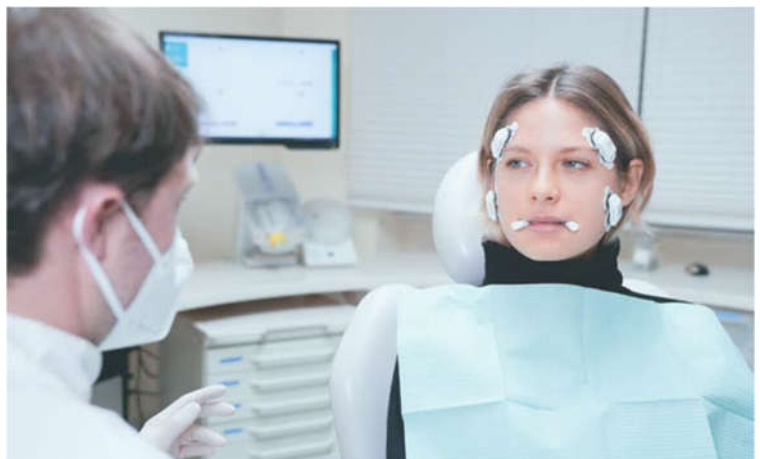
Ask the patient to arrange the rollers to obtain a sensation of symmetry. Make sure it does not move them beyond the 5th and 6th teeth.



9.17

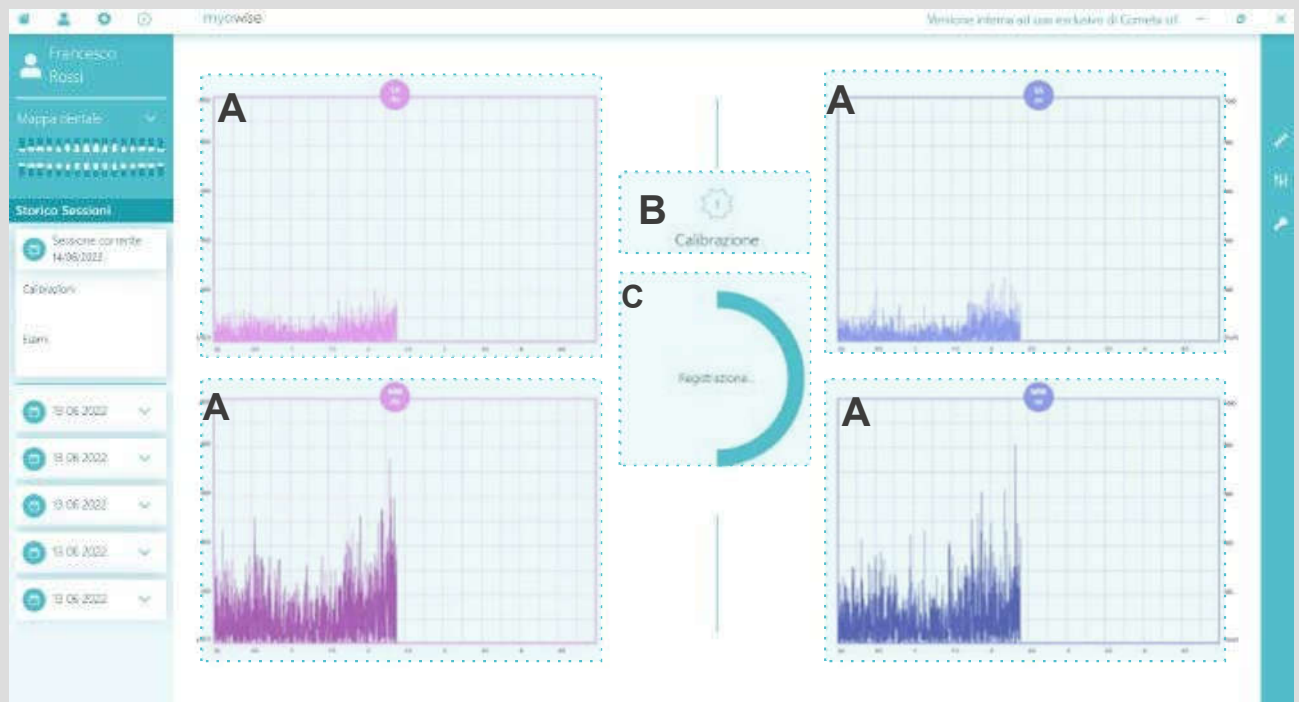
Maximum lock

Ask the patient to clench their teeth as hard as possible then click on the button **Calibration begins**. The recording lasts 5 seconds.



9.18

Calibration record



9.19

A – Preview EMG signals

The calibration screen presents previews of the signals from the four sensors. Calibration starts when you click on **Start calibration**.

B – Calibration label

Identifies the name under which the calibration is saved in the system.

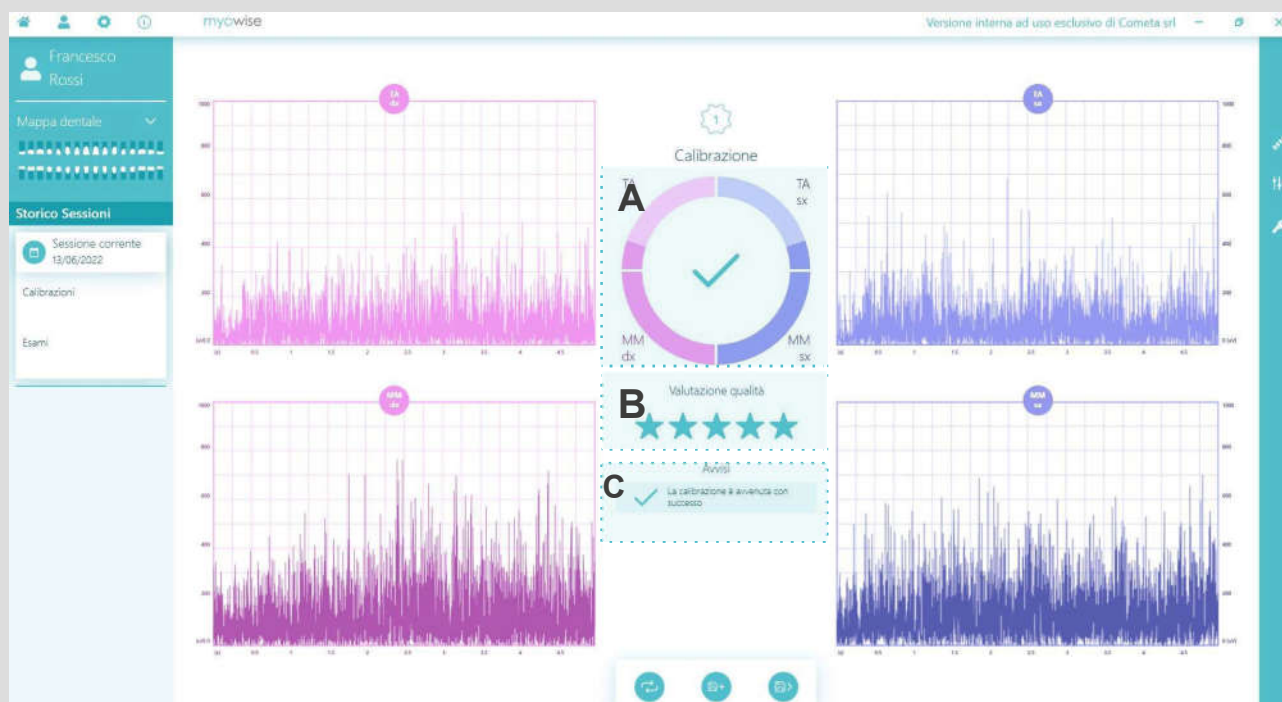
C – Advancement

The duration of each calibration is 5 seconds.

Command bar

No operations are possible while the calibration is being recorded.

Calibration result



9.20

A – Muscle coordination

Non-normalized muscle coordination is reported. An alert is displayed if the calibration does not meet the minimum signal quality requirements.

B – Quality assessment

The calibration is subjected to an analysis which determines its quality. Calibrations with at least three stars are to be considered usable. (see section **Calibration summary** for more details)

C – Alerts

Any warnings regarding individual muscles are displayed.

Command bar

The user can repeat the calibration without saving it, save it and add a new one or save it and proceed directly to **calibration summary**.

9.7 Calibration summary

Once you have done at least 3 good quality calibrations (recommended) by clicking **save and continue** you go to the screen of **calibration summary** where all the calibrations performed during the current session are displayed.

Myowise automatically selects the calibrations that meet the minimum quality requirements but the user can change the selection at any time. Only the selected calibrations are used by Myowise to normalize the exam results.

The scale of **quality rating** it's the following:

-  Calibration of **poor quality**, check the good adherence of the electrodes and the positioning of the sensors.
 Not recommended for normalization.
-  Calibration of **insufficient quality**, verify the constancy of the clevis throughout the examination.
 Not recommended for normalization.
-  Calibration of **good quality**, produces reliable results during the normalization phase.
-  Calibration of **best quality**, make the most of the potential of the instrument, the normalization of the examination data will be excellent.

The user has the possibility to go back to the calibration summary and to change the selection of calibrations even if he has already done some exams. By clicking on **Recalculate indices** the exam results for that session will be recalculated using the new calibration set.

The user can add a calibration at any time if they are in the current session. It is not possible to add calibrations to past sessions or change their selection.

The calibration summary panel shows the non-normalized muscle coordination graph obtained with cotton rolls placed between the two arches (with reduced dento-periodontal proprioception).

Calibration summary



9.21

A – Calibration panels

A summary panel is displayed for each calibration.

B – Information and notices

Information on non-normalized muscle coordination, quality and warnings are reported to give the user the possibility to evaluate the goodness of the individual calibrations.

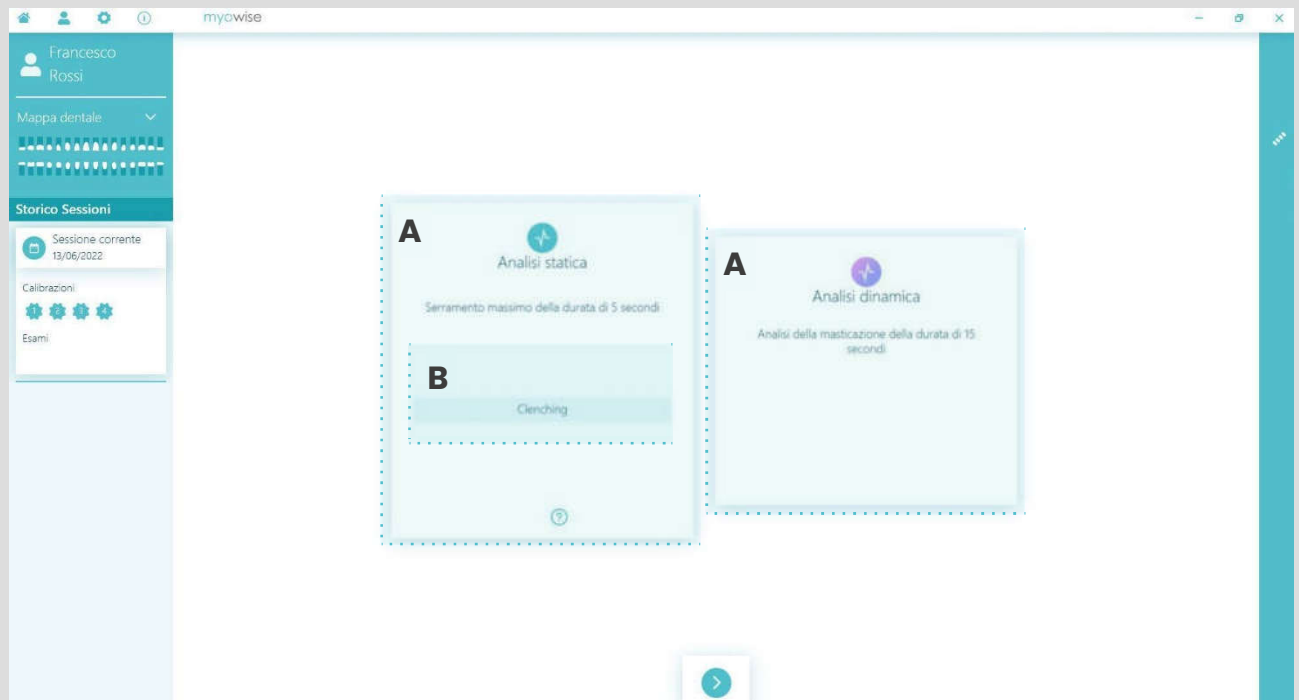
C – Selection key

Myowise automatically selects the calibrations with at least 3 stars, this button allows the user to change the selection of which calibrations will be used for the normalization of the exam data.

Command bar

The user can add a new calibration or continue to the screen **exam type selection**.

Exam type selection



9.22

A – Selection of type of exam

The screen shows all the types of exams that can be performed with Myowise. The selection takes place by clicking on the corresponding panel.

B – Examination label entry

The user chooses a label to give to the exam, this is the name with which the exam is saved in the database.

Command bar

The possibility of continuing is subject to the choice or insertion of a label for the examination.



10 Static exam

After having carried out the calibrations and having chosen the type of test to be carried out, the test is carried out.

The measurement protocol has been validated in international scientific literature for almost 30 years of publications. The results obtained express the degree of balance of muscle activity during the masticatory act through recognized and validated percentage indices.

10.1 Exam execution

The screen of **exam acquisition** and shows previews of EMG signals from 4 sensors.

To proceed to the static examination **remove the dental rolls** in order to allow natural dental intercuspitation.

Ask the Patient again to clench their teeth fully, then click on **start analysis**.

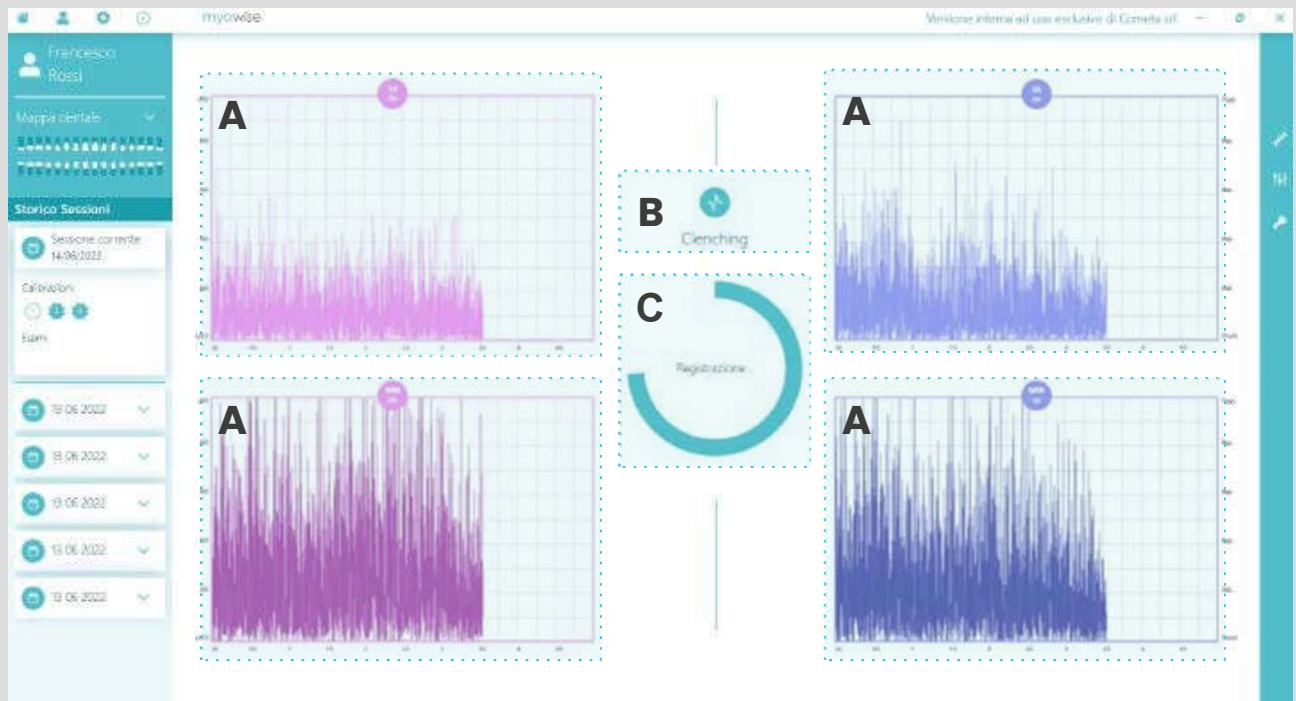
The recording has a duration of 5 seconds during which the patient must maintain the maximum clench.

Recording stops automatically and the **result of the static test** which summarizes the graph muscle coordination and any alerts. In this phase it is possible to enter notes.

By clicking on **Save and process** Myowise normalizes all results using the previously selected calibrations and returns the **exam summary** full screen.

The next click on **forward** takes you to the summary screen of all the exams of the current session.

Static exam registration



10.1

A – Preview EMG signals

The exam recording screen presents previews of the signals of the four sensors in real time.

B – Exam label

Identifies the name under which the exam is saved in the database.

C – Advancement

The duration of each static exam is 5 seconds.

Command bar

Registration begins after clicking on **forward**. (play)

Static test result



10.2

A – Muscle coordination

Non-normalized muscle coordination is reported.

B – Alerts

Any warnings regarding individual muscles are displayed.

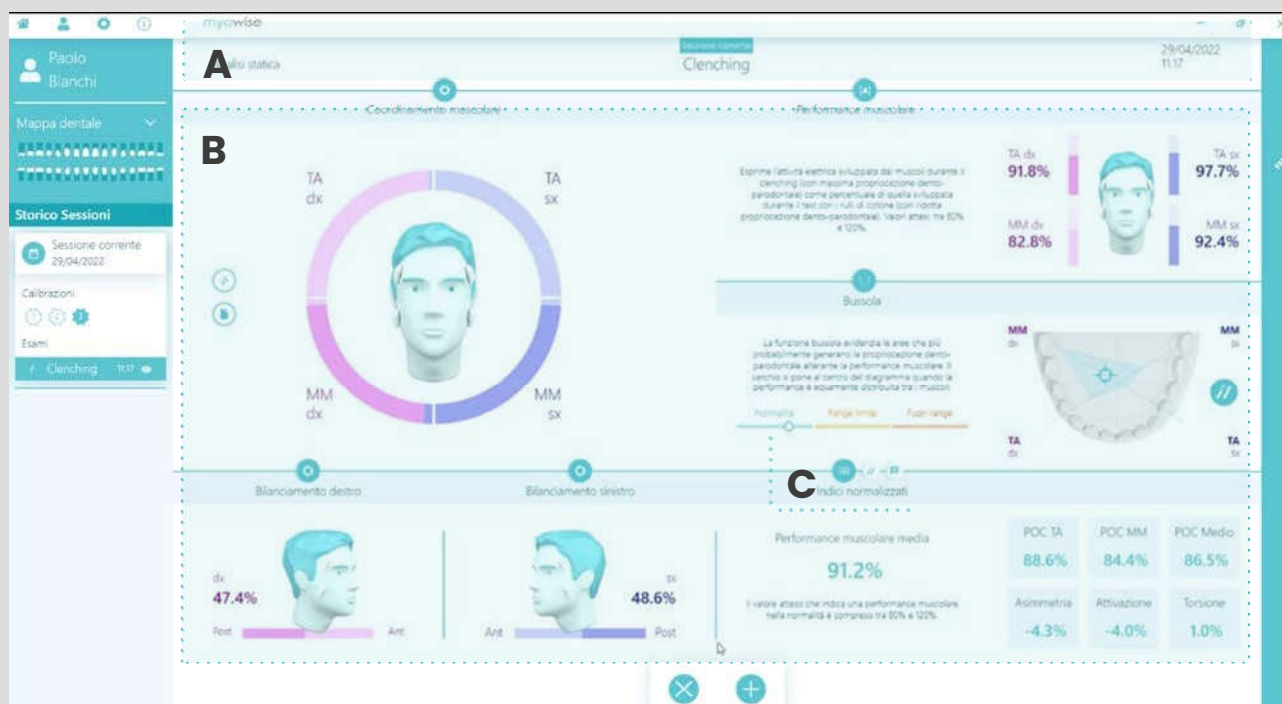
C – Note

The user can enter notes.

Command bar

The user can repeat the registration without saving it or continue with processing and al **static exam summary**.

Full screen static exam summary



10.3

A - Exam header

This section shows the type of exam, the label with which it was saved in the database, the time and date. If you are in the current session, another label is displayed **Current session**.

B - Static exam summary

The normalized information and graphs related to the exam are displayed, which are detailed in the section **Static exam graphs**. (page 52)

C - Grouping graphs

To allow a good display size of the graphs, some information has been grouped in tabs. In full screen mode, the normalized indexes, warnings and notes are grouped together.

Command bar

The user can add a new exam (directed to the **exam type selection**) or it can close the current session (it is returned to the **Patient folder**)

Multiple panel static exam summary



10.4

A - Exam summary panels

A summary panel is displayed for each exam. The information is grouped according to the available space.

B - View/hide exams

Thanks to the sidebar, it is possible to display or hide individual exams, even from previous sessions. The exams belonging to the current session show the additional label at the top **Current session**.

C - Panel scrolling

If more than 4 exams are displayed at the same time it is necessary to use the left and right arrows to navigate between the panels.

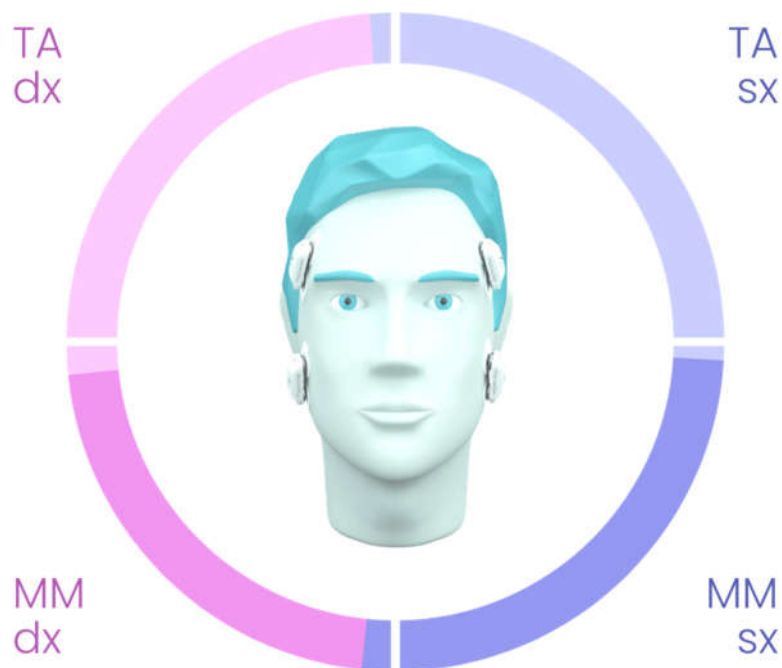
Command bar

The user can add a new exam (directed to the **exam type selection**) or it can close the current session (it is returned to the **Patient folder**)

10.2 Static exam graphs

Static examination with Myowise returns a series of graphs which are described and explained in this section of the manual.

Normalized muscle coordination

**10.5**

Graphic description

It expresses the standardized differential activity, attributable to dental proprioception; a subject in whom all four muscles are affected equally by dental proprioception will have this pie with four equal slices.

The two different shades of pink indicate the muscles of the right side while the two shades of purple show those of the left side.

Interpretation tips

This graph (Figure 4.a and 4.b) shows the result of superimposing the Cotton Rolls and μV pie graphs. It expresses the standardized differential activity, attributable to dental contact.

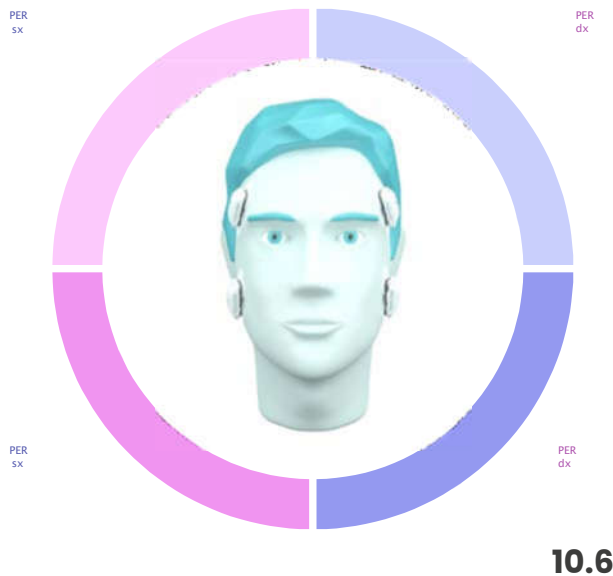


Figure 10.6 Example of graph in the case of Maximum frame protocol: Masseters vs Anterior Temporals. Muscular balance not affected by dental contact

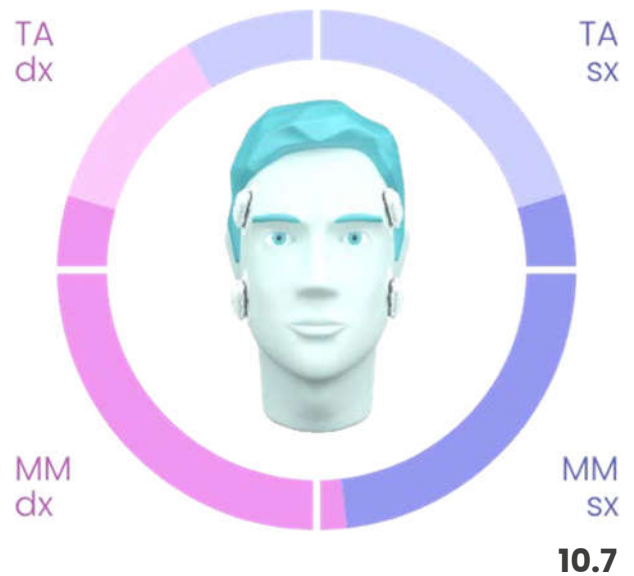


Figure 10.7 Example of graph in the case of Maximum frame protocol: Masseters vs Anterior Temporals. Muscular balance altered by dental contact

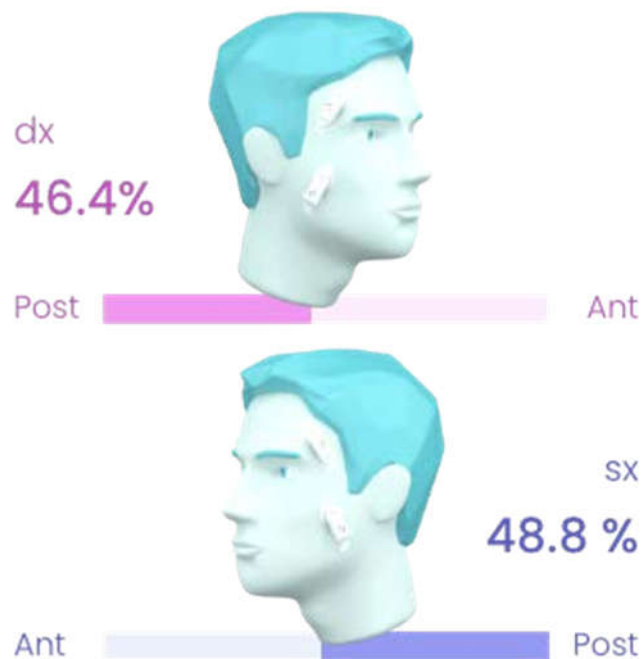
Scientific studies have shown that young healthy subjects, without functional and morphological alterations, exert similar muscle performances by clenching their teeth in maximum intercuspitation or with cotton rolls between the arches. In this condition the pie chart will represent 4 very similar slices Like

In figure 10.6, when this does not happen, as in the example in Figure 10.7, it means that in maximum intercuspitation the subject has established a different muscle recruitment from that performed with the cotton rolls and it is advisable to investigate the possible causes.

The normalized quantification of the dento-periodontal proprioceptive component thus extrapolated has two main advantages:

- Reduces the variability of the electromyographic examination by increasing its repeatability in subsequent sessions, significantly improving its usability in a clinical context
- It allows to isolate a single factor (dento-periodontal proprioception) allowing to understand the consequences in the coordination of masticatory muscles and neck.

Left and right balance



10.8

Graphic description

This graph represents the distribution of muscular performance related to dental occlusion between the masseter and temporal muscles of the right and left sides.

The right balance graph indicates the relationship between the performance of right temporalis and right masseter muscles in anterior-posterior direction

The left balance graph indicates the relationship between the performance of the left temporal and left masseter muscles in the anterior-posterior direction

The displayed percentage values indicate the share of performance linked to the dental proprioception of the masseter muscle compared to the global masseter and temporal proprioception of the side analysed.

Interpretation tips

The expected values, in a situation of sagittal morphological normality, are around 50% or a similar performance distribution between the masseter and the temporal. A value significantly greater than 50% on one side and significantly less on the opposite side will generate torsional effects during mandibular clenching.

Impact

**10.9**

Graphic description

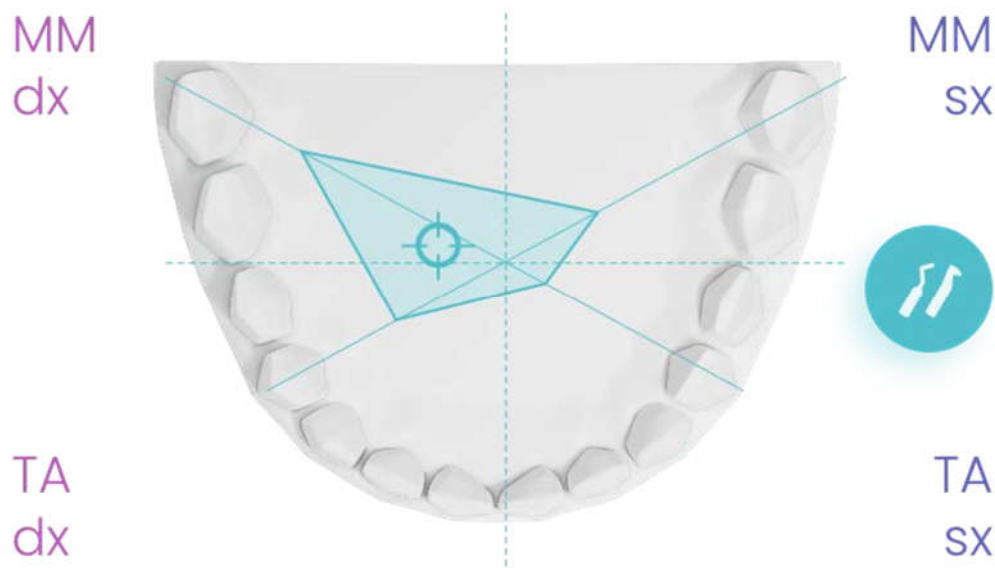
The impact represents the ratio of the intensity of the muscular work performed during a test versus that done during calibration on cotton rolls. It is a fundamental index as it represents the muscular performance which, in case of significant occlusal proprioceptive alteration, will be reduced.

The values represent the work expressed by the muscle; a value of 100% indicates that the muscle analyzed expressed the same electromyographic values when tightening in maximum intercuspitation as those expressed during the reference test on cotton rolls.

Interpretation tips

The subjects in which the dental occlusion does not require significant muscular adaptations are able to express from 80 to 120% of the activity performed on the cottons. Lower values indicate a proprioceptive inhibition attributable to dental contact.

Compass



10.10

Graphic description

It indicates in which occlusal areas the activities of the most unbalanced muscles are carried out.

When the graph is green the normality discrepancy is slight, yellow for values very distant from the norm but with possible occlusal origin. In the case of an orange graph, the values are extremely distant from the normal values, suggesting a possible technical error and/or problems not of occlusal origin. The legend shown below is always visible together with the compass.



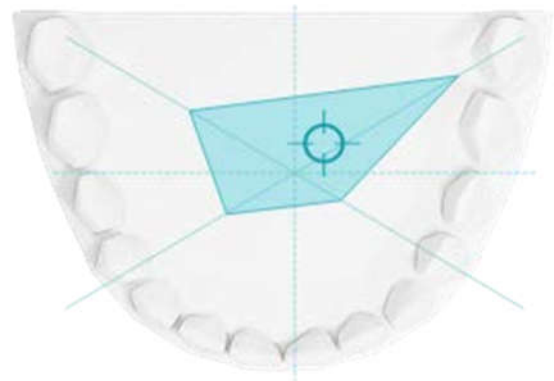
This panel contains the key to access the **Virtual assistant** which is described in detail in the section **10.5** of this manual.

Interpretation tips

This visualization is rather intuitive but below we report some indications and examples to help in understanding the possible clinical pictures.

Clinical situation 1

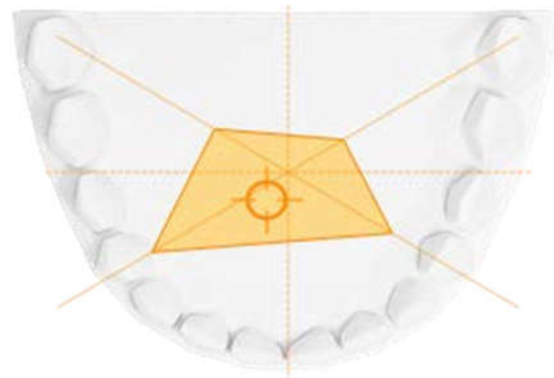
The performance of the muscles analyzed does not deviate much from the ideal values (the graph is green). The muscle whose performance is furthest from the ideal values, stresses the left molar functional area from which more likely- the altering proprioceptive input arises.



10.11

Clinical situation 2

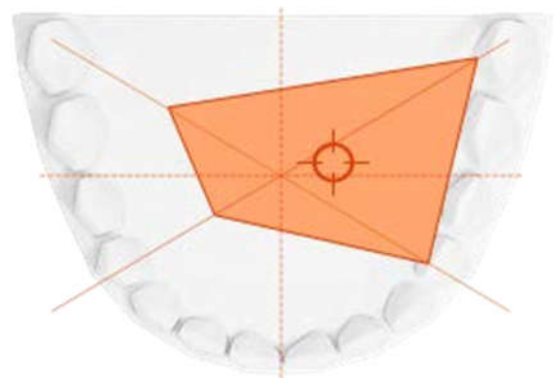
The Performance Values are at the limit of the normal range, indicating a plausible verticality alteration beyond that what a fine occlusal proprioception. The muscles with the most impaired performance stress the right and left premolar areas. The origin of the altering proprioceptive input, in the absence of significant morphological alterations, is to be found primarily in these dental areas.



10.12

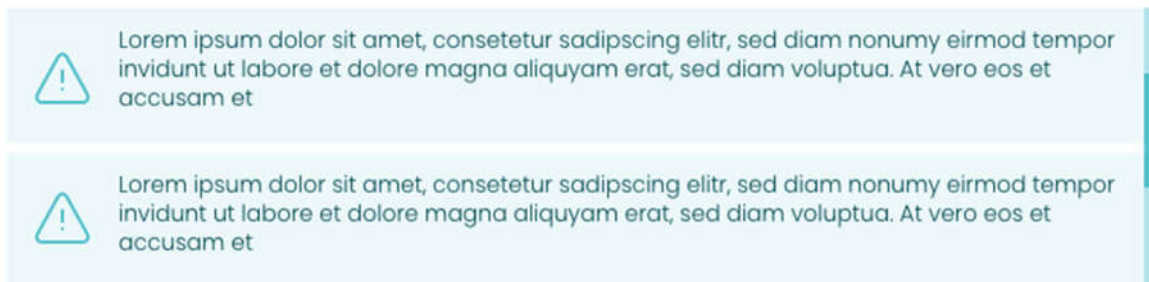
Clinical situation 3

In this example, the performance values are significantly distant from the normal ones (orange graph). Hence the suggestion to repeat the exam, evaluating the entire left masticatory area more carefully.



10.13

Alerts

**10.14**

Graphic description

This section shows all the messages and warnings regarding the test, in this way the user has a clear view of whether particular or anomalous conditions have occurred during the recording of the EMG signals and can keep them in mind when processing the diagnosis.

Note

**10.15**

Graphic description

This panel shows the notes entered by the user immediately after acquiring the exam.

This can be useful for keeping track of observations and feedback received from the patient immediately after performing the exam. The notes can be modified by clicking on the button on the right of the panel itself.

10.3 Static exam indices

In addition to the graphs, the static examination with Myowise returns a series of indices which are described and explained in detail in this section of the manual.

All the main useful indexes are grouped in a single panel. The box of each index is green if the value falls within the normal range and orange if it goes outside the normal range. The indices are as follows:

- **LITTLE TA**
- **POC MM**
- **medium POC**
- **Asymmetry**
- **Activities**
- **Twist**

POC TA 88.6%	POC MM 84.4%	POC medio 86.5%
Asimmetria -4.3%	Attività -4.0%	Torsione 1.0%

Hint POC

The POC (Percentage Overlapping Coefficient) indicates, as a percentage, how similar is the influence of dental contact on the muscles in the left antimerre compared to the right antimerre, not only in terms of contraction intensity but also in terms of time (superimposability of the activation areas).

Temporary POC

Indicates, as a percentage, how similar the influence of dental contact is in the left Temporal compared to the right one.

POC Masseteri

Indicates, in percentage terms, how similar is the influence of dental contact in the left Masseter compared to the right one.

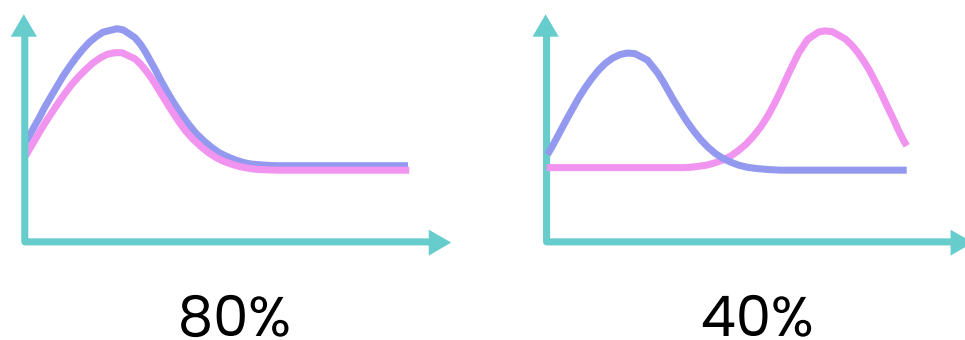
POC Medium

The expected value that indicates a normal muscle performance is between 80% and 100%.

Interpretation tips

A hypothetical POC of 100% identifies that the pair of muscles analyzed is affected in the same amount by dental contact. This implies that the areas of activation will be very similar in intensity and duration of activation, as in the left graph of Figure 10.7. This does not exclude that the electrical activity that the muscles have generated may be higher or lower than in the calibration test.

95% of asymptomatic subjects have POC values greater than 80%. In case of lower values, instead, a situation similar to the one shown in the right graph in Figure 10.17 could occur in which the activation areas, although presenting a similar activity in terms of intensity, show a low overlap due to different timings. It is the most refined index because it combines a quantitative evaluation of the contraction with a temporal evaluation of the gesture.



10.17

Figure 10.17 Overlapping of the temporal contraction activation areas

Activity Index

Compare the influence of dental contact on the activity of the temporalis versus that of the masseters. The Activity index evaluates the prevalence of muscle activity on a sagittal plane projection, of the relative position of the occlusal center of gravity and of the mandibular lever arm, when the dental arches are in contact. It is in the range from -100% to 100%. A negative index implies a greater differential recruitment of the temporal muscles (anterior centroid) or a relative inhibition of the masseter muscles. In Figure 10.8 a biomechanical hypothesis whereby, in the absence of one or more molars for example, the masseters could be inhibited in their maximal performance to avoid overloading the temporomandibular joint structures.

Interpretation tips

A positive index indicates a prevalence of the masseter muscles (rear center of gravity). 95% of healthy subjects have activation values between 10% and -10% (Figure 10).

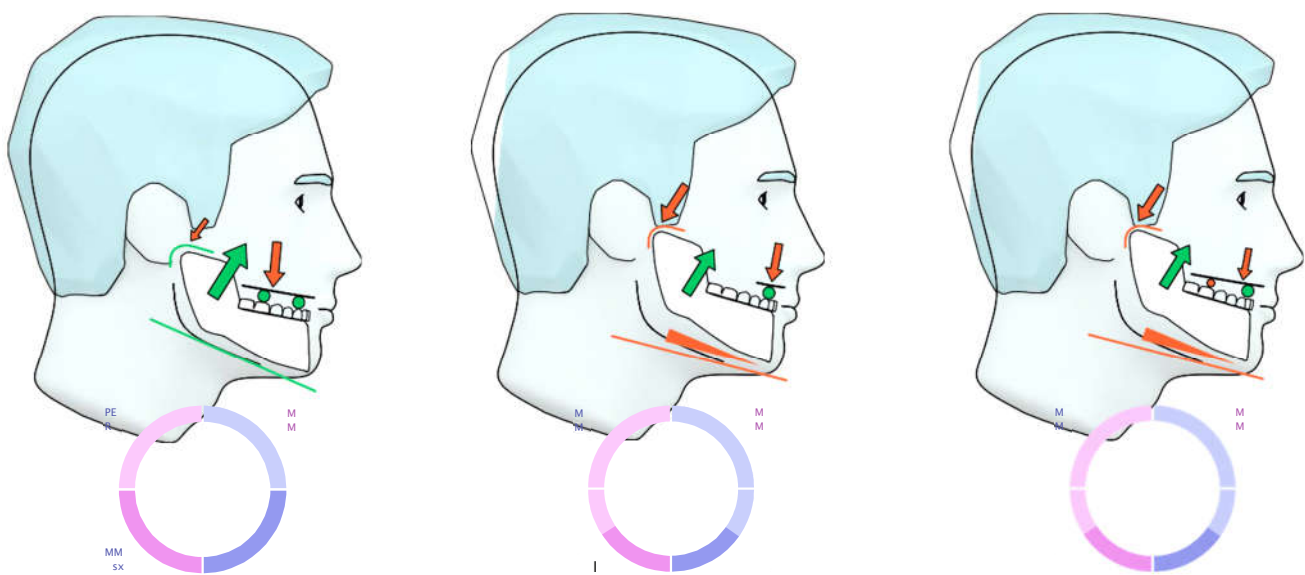
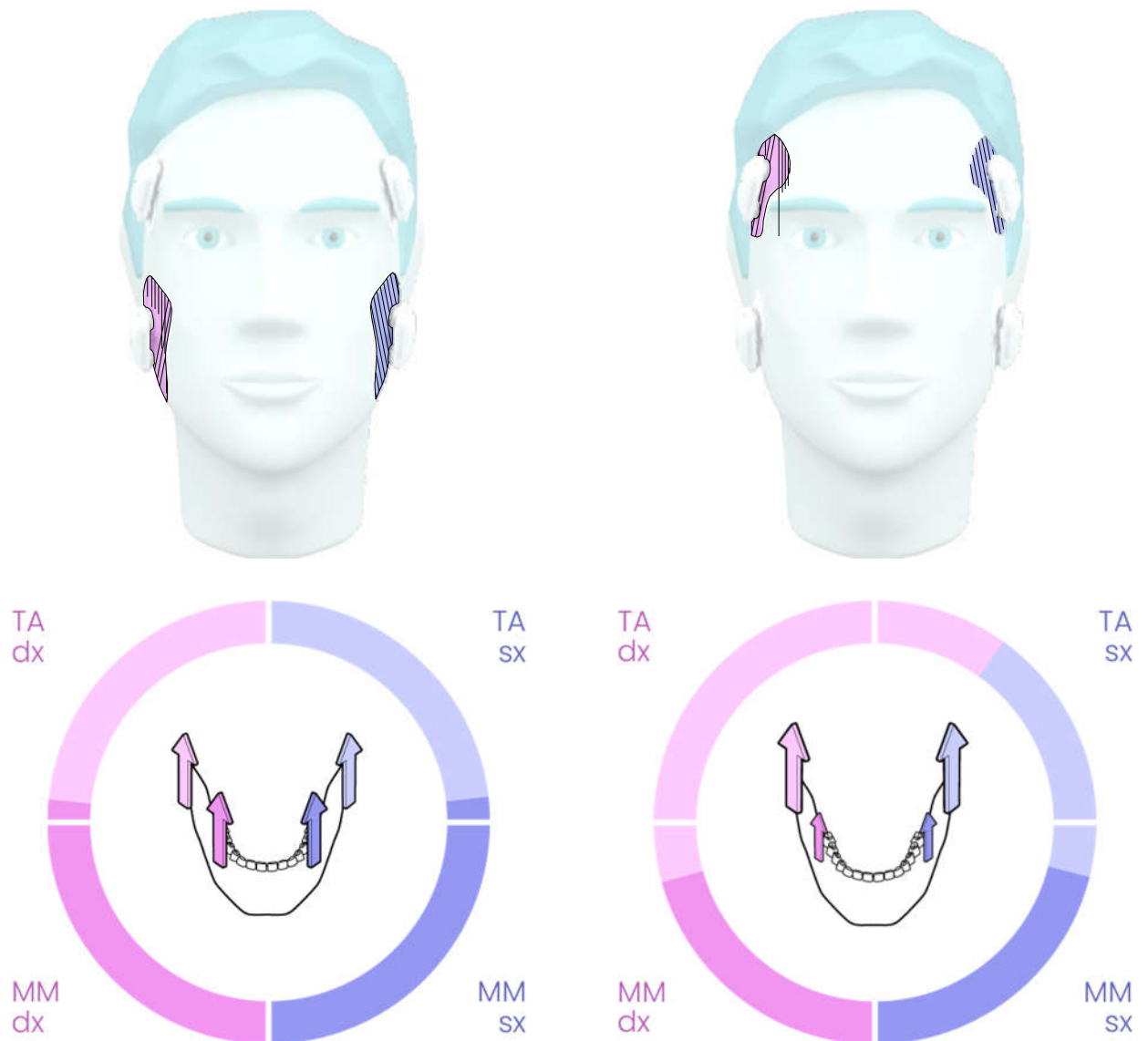


Figure 10.18 biomechanical hypothesis according to which the masseters could be inhibited in their maximal performance to avoid overloading the structures

10.18

Positive Activity Index ()
Rear center of gravity

Negative Activity Index (-)
Front center of gravity



10.19

Figure 10.19 Muscles most activated in the presence of a positive or negative Activity index

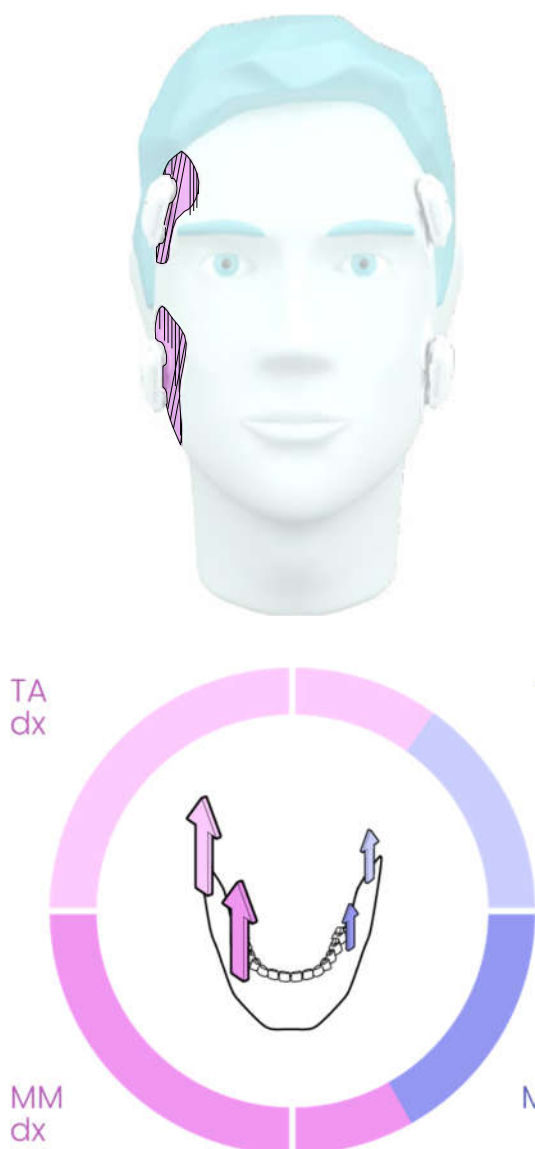
Asymmetry index

Compare the influence of dental contact on the total activity of the right versus the left antimeres. This value essentially indicates how much the right muscles are influenced by the dental contact compared to those on the left (Figure 10.20) and it helps to identify if there is any asymmetry in the distribution of the occlusal contacts.

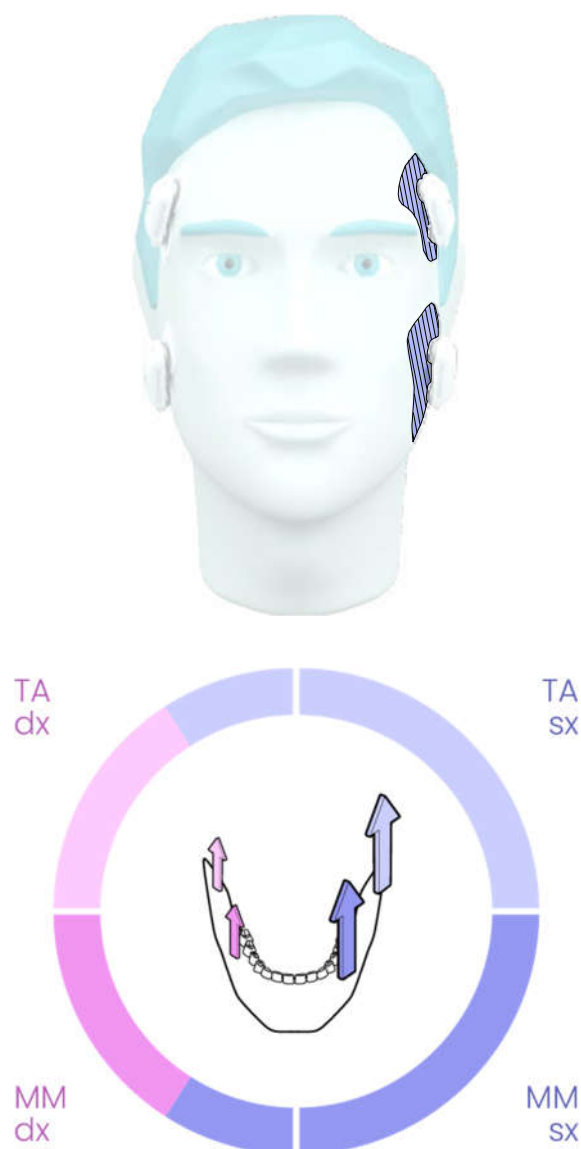
Interpretation tips

A positive index shows a prevalence of right muscle activity. A negative index, on the other hand, indicates a greater differential activity of the left antimeres. 95% of healthy subjects have asymmetry values between 10% and -10% (0% no asymmetry).

Positive asymmetry index (+)



Negative asymmetry index (-)



10.20

Figure 10.20 Most activated muscles with positive or negative Asymmetry index

Torque index

The TORQUE index measures the differential activity of the right temporal and left masseter in relation to the opposing pair.

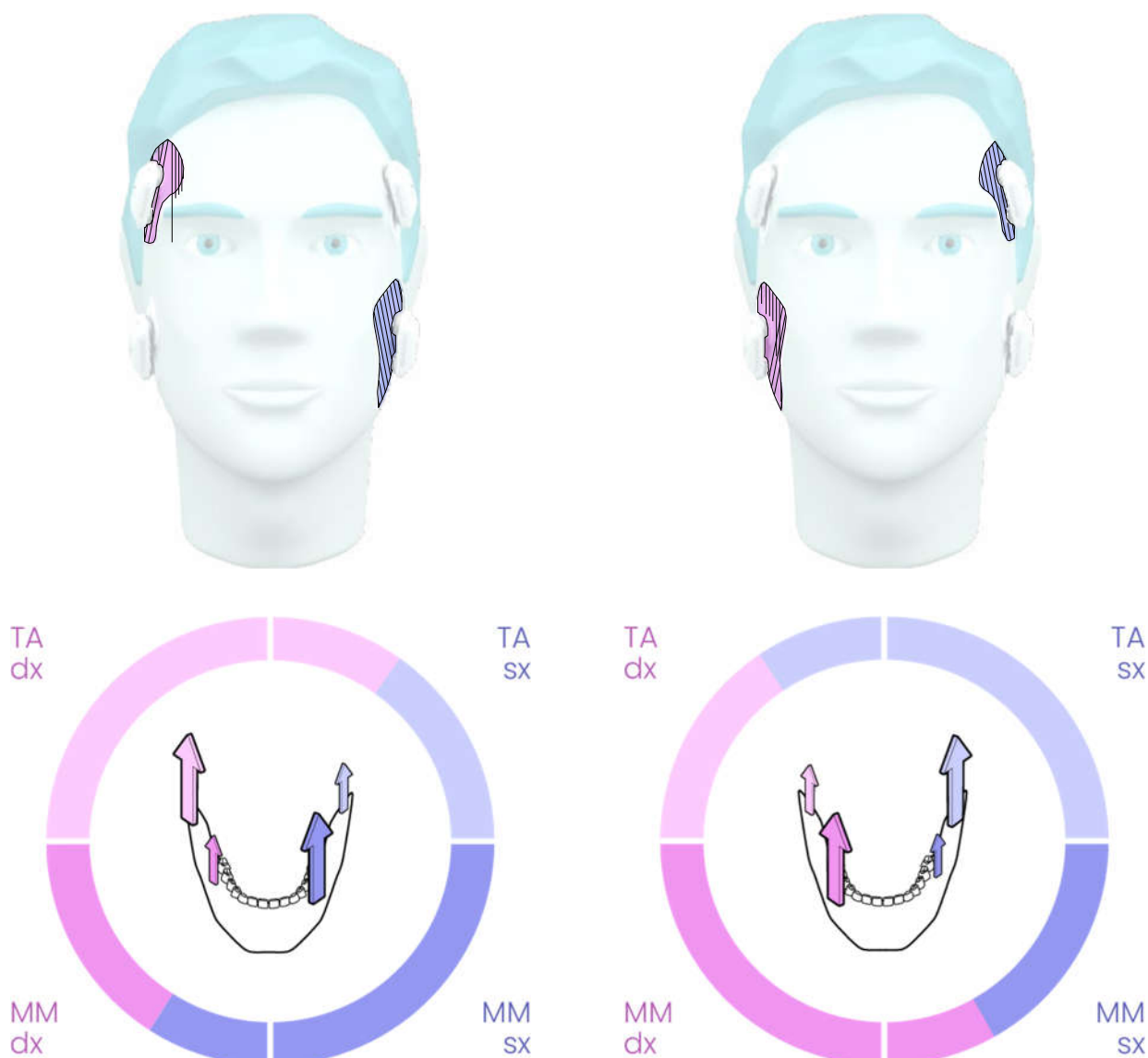
A prevalence of the right temporal and left masseter muscles can result in torsional forces on the mandible with latero-deviation to the right; in this case the torsion index will be positive (Figure 12).

Interpretation tips

A predominance of the left temporalis and right masseter muscles will be displayed as a negative TORQUE index, indicating leftward twisting forces. 95% of healthy subjects have TORQUE values between 10% and -10%.

Positive asymmetry index (+)

Negative asymmetry index (-)



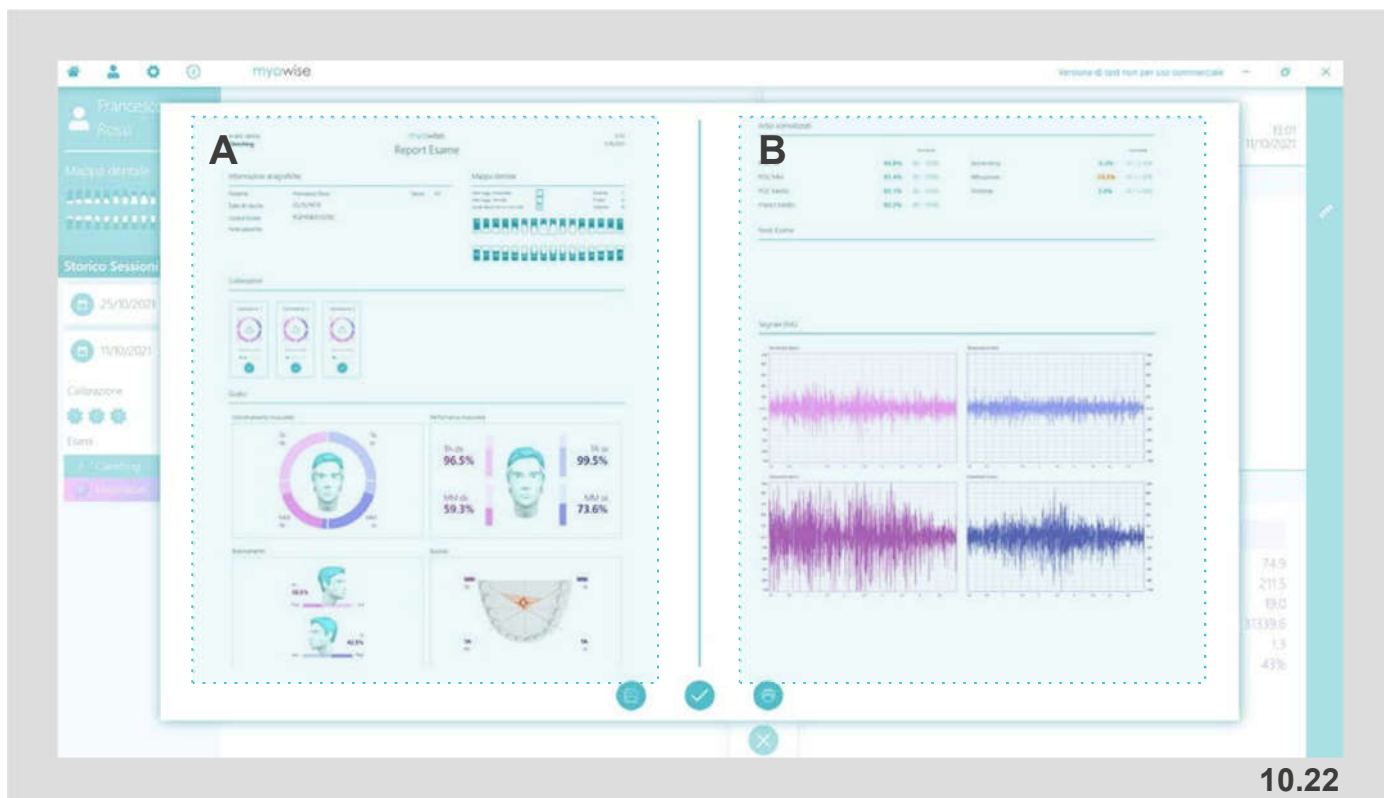
10.21

Figure 10.21 Muscles most activated in the presence of a positive or negative Torsion index

10.4 Static exam report

The user can save a report for each exam performed with Myowise. The software allows you to directly print the report in A4 format or save it in pdf format in a folder of your choice on the PC.

The button  **view exam report** is visible in the exam summary to the left of the muscle coordination graph.



10.22

A – Information and graphics

The information of the patient, the operator and the date and time of the exam are reported, as well as calibrations and graphs of the static analysis.

B – Indices and raw signal

All the indices calculated by Myowise are reported together with the 4 raw signals and the notes entered by the user during the exam.

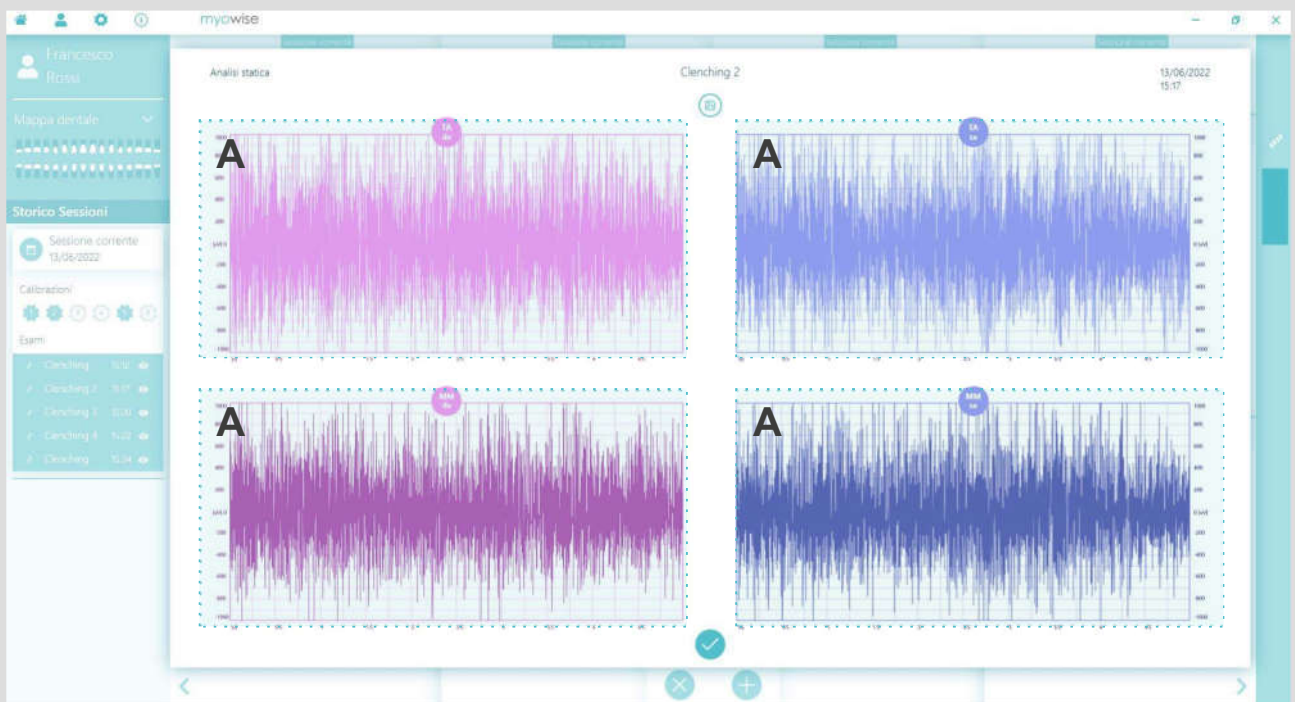
Command bar

The user can print the report directly from Myowise or save it in pdf format.

10.5 EMG signal display

The user can view the raw EMG signal for each exam performed with Myowise.

The  button **displays EMG signal** is visible in the exam summary to the left of the muscle coordination graph



10.23

A - Right side raw EMG signal

The raw signal of the 4 sensors is displayed.

For a more in-depth analysis it is possible to change the scale of both axes of the graphs in the following ways:

Mouse wheel = y-axis scale

Mouse wheel right click = x-axis scale

Left mouse button drag = scroll on x axis

Command bar

The user can save the raw data in txt format for any subsequent processing.

10.6 Virtual assistant

This feature, exclusive to Myowise, supports the user in making the diagnosis and planning the treatment.

Thanks to its powerful calculation engine Myowise crosses and analyzes the data resulting from the static examination and the morphological data and returns feedback on the occlusal areas which could be the cause of any problematic situations.

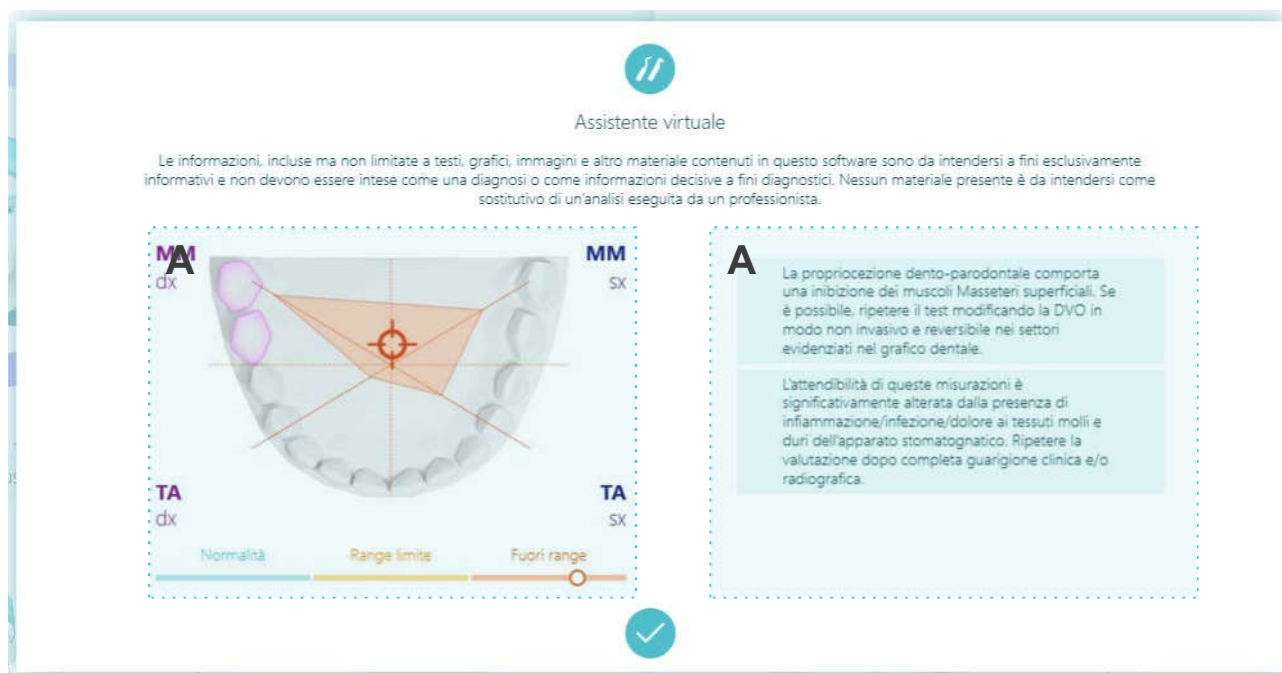
To ensure that the virtual assistant works properly, the **dental map** of the patient is updated and corresponds to the real clinical situation, in fact the alerts created by the virtual assistant take into account any missing teeth, prostheses or implants.

Please note:

The information, including but not limited to text, graphics, images and other materials contained in this software are intended for informational purposes only and should not be construed as a diagnosis or as decisive information for diagnostic purposes. No material present is intended as a substitute for an analysis performed by a professional.

Any intervention of a reversible or irreversible nature performed on the patient is entirely the responsibility of the operator.

Virtual assistant



10.24

A – Problem areas

Dental map of the Patient on which the areas that possibly create an imbalance or alter the function are highlighted.

B – Diagnostic Alerts

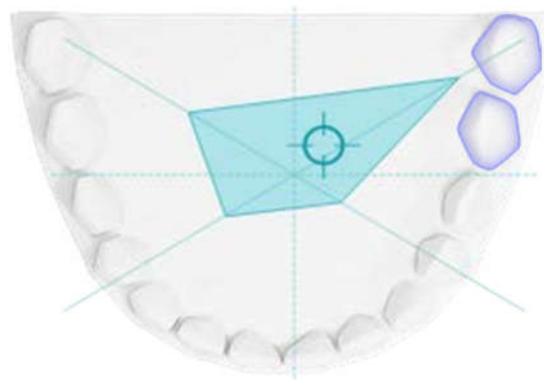
To complete the graph, textual diagnostic advice is given which seeks the origin of the proprioception which alters the muscular balance.

Interpretation tips

This visualization is rather intuitive but below we report some indications and examples to help in understanding the possible clinical pictures.

Clinical situation 1

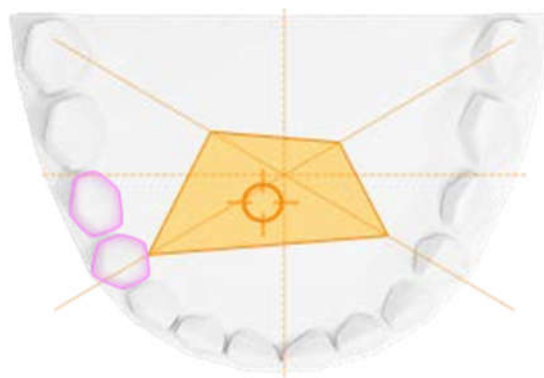
The performance of the muscles analyzed does not deviate much from the ideal values (the graph is green). The muscle whose performance is furthest from the ideal values, stresses the left molar functional area from which more likely- the altering proprioceptive input arises.



10.25

Clinical situation 2

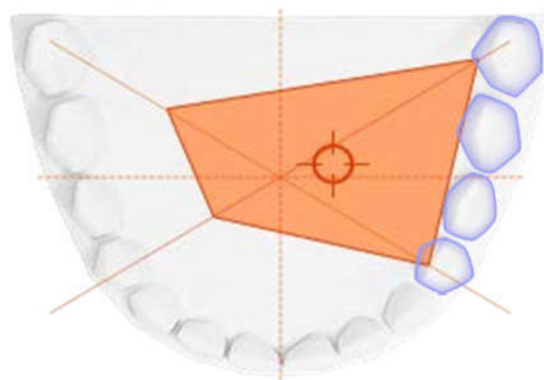
The Performance Values are at the limit of the normal range, indicating a plausible verticality alteration beyond that what a fine occlusal proprioception. The muscles with the most impaired performance stress the right and left premolar areas. The origin of the altering proprioceptive input, in the absence of significant morphological alterations, is to be found primarily in these dental areas.



10.26

Clinical situation 3

In this example, the performance values are significantly distant from the normal ones (orange graph). Hence the suggestion to repeat the exam, evaluating the entire left masticatory area more carefully.



10.27



11 Chewing test

The second type of examination possible with Myowise is the dynamic examination of mastication.

The exam consists of two consecutive recordings, one chewing of 15 seconds from the right side and one from the left side.

11.1 Dynamic exam execution

The screen of **exam acquisition** and shows previews of EMG signals from 4 sensors.

To proceed with the dynamic exam, make sure you have completed the calibration procedure properly.

Before starting the test, give the patient a sugar-free chewing gum asking him to chew it liberally until it is soft. Ask the Patient to chew using the right side of the mouth, then click **start analysis**.

The recording lasts 15 seconds during which the patient must chew continuously.

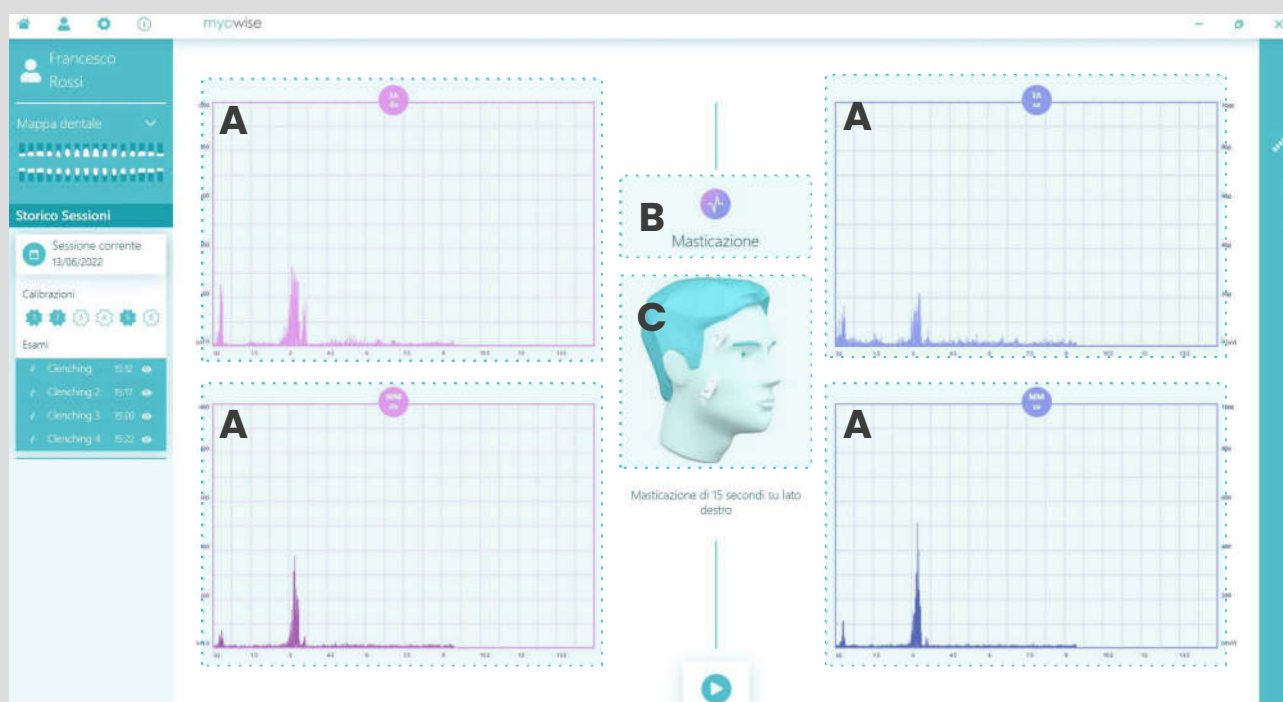
Recording stops automatically and the **outcome of chewing on the right side**.

Now ask the Patient to chew using the left side of the mouth, then click on **continues**.

By clicking on **Save and process** Myowise normalizes all results using the previously selected calibrations and returns the **exam summary** full screen.

The next click on **forward** takes you to the summary screen of all the exams of the current session.

Right side chewing recording



11.1

A – Preview EMG signals

The exam recording screen presents previews of the signals of the four sensors in real time.

B – Exam label

Identifies the name under which the exam is saved in the database.

C – Advancement

The duration of chewing on the right side is 15 seconds.

Command bar

Registration begins after clicking on **forward**. (play)

Right side chewing result



11.2

A – Superimposed normalized signals

The normalized signals of the two Thunderstorms are displayed.

B – Superimposed normalized signals

The normalized signals of the two Masseters are displayed

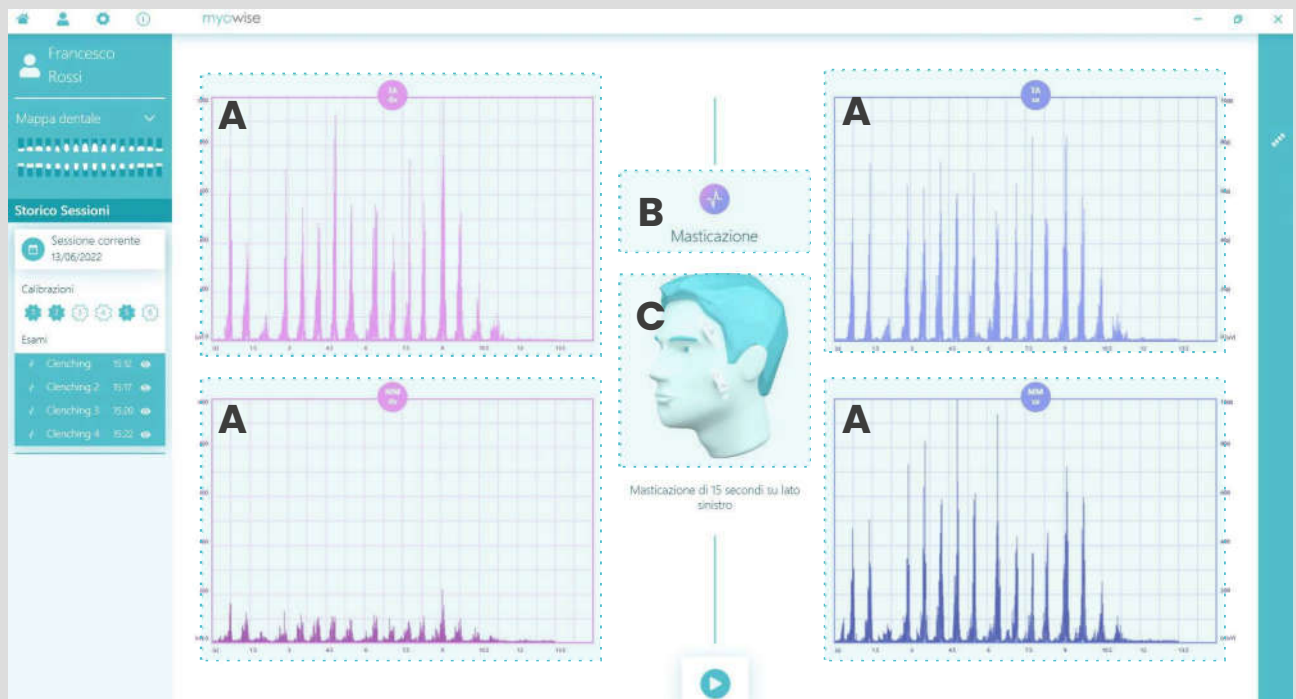
C – Alerts

Warnings are displayed regarding possible signal quality or transmission problems.

Command bar

The user can repeat the recording of the chewing from the right side or continue with the one on the left side.

Left side chewing registration



11.3

A – Preview EMG signals

The exam recording screen presents previews of the signals of the four sensors in real time.

B – Exam label

Identifies the name under which the exam is saved in the database.

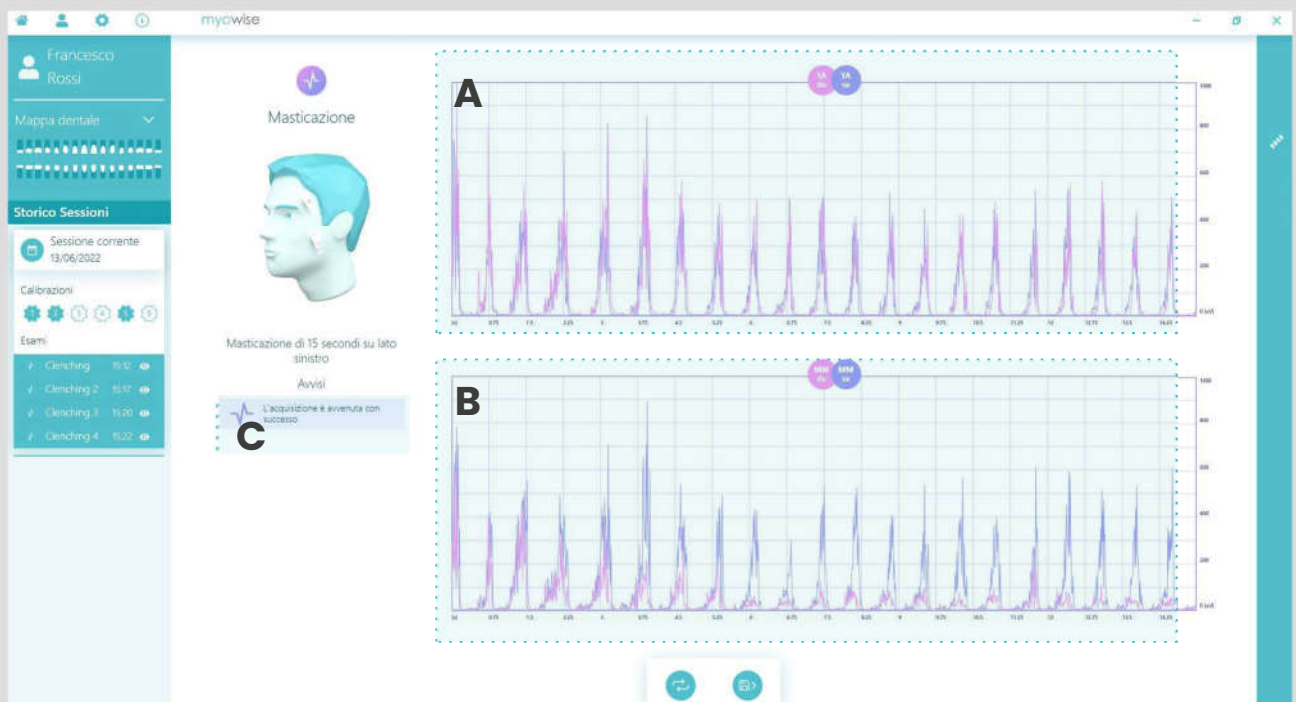
C – Advancement

The duration of chewing on the left side is 15 seconds.

Command bar

Registration begins after clicking on **forward**. (play)

Left side chewing result



11.4

A – Superimposed normalized signals

The normalized signals of the two Thunderstorms are displayed.

B – Superimposed normalized signals

The normalized signals of the two Masseters are displayed.

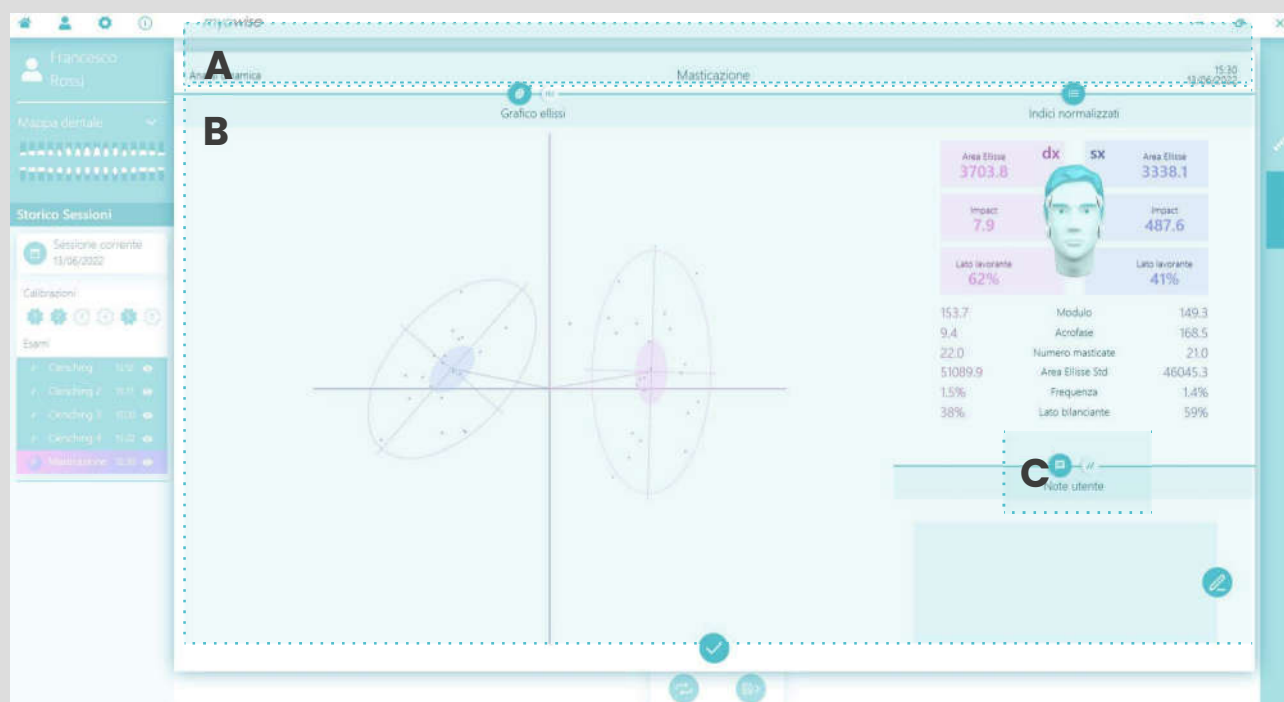
C – Alerts

Warnings are displayed regarding possible signal quality or transmission problems.

Command bar

The user can repeat the registration without saving it or continue with processing and a **dynamic exam summary**.

Full screen dynamic exam summary



11.5

A - Exam header

This section shows the type of exam, the label with which it was saved in the database, the time and date. If you are in the current session, another label is displayed **Current session**.

B - Dynamic exam summary

The normalized information and graphs related to the exam are displayed, which are detailed in the section **Dynamic exam graphs**. (page 78)

C - Grouping graphs

To allow a good display size of the graphs, some information has been grouped in tabs. In full screen mode, the normalized indexes, warnings and notes are grouped together.

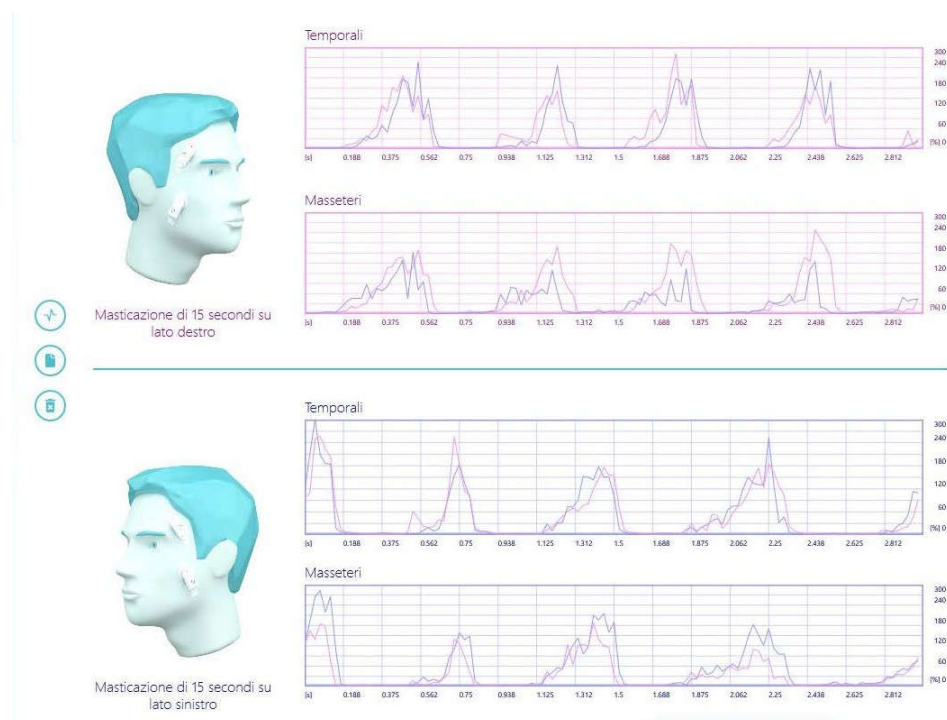
Command bar

The user can add a new exam (directed to the **exam type selection**) or it can close the current session (it is returned to the **Patient folder**)

11.2 Dynamic exam graphs

The dynamic chewing test with Myowise returns a series of graphs and indices which are described and explained in this section of the manual.

Superimposed normalized signal

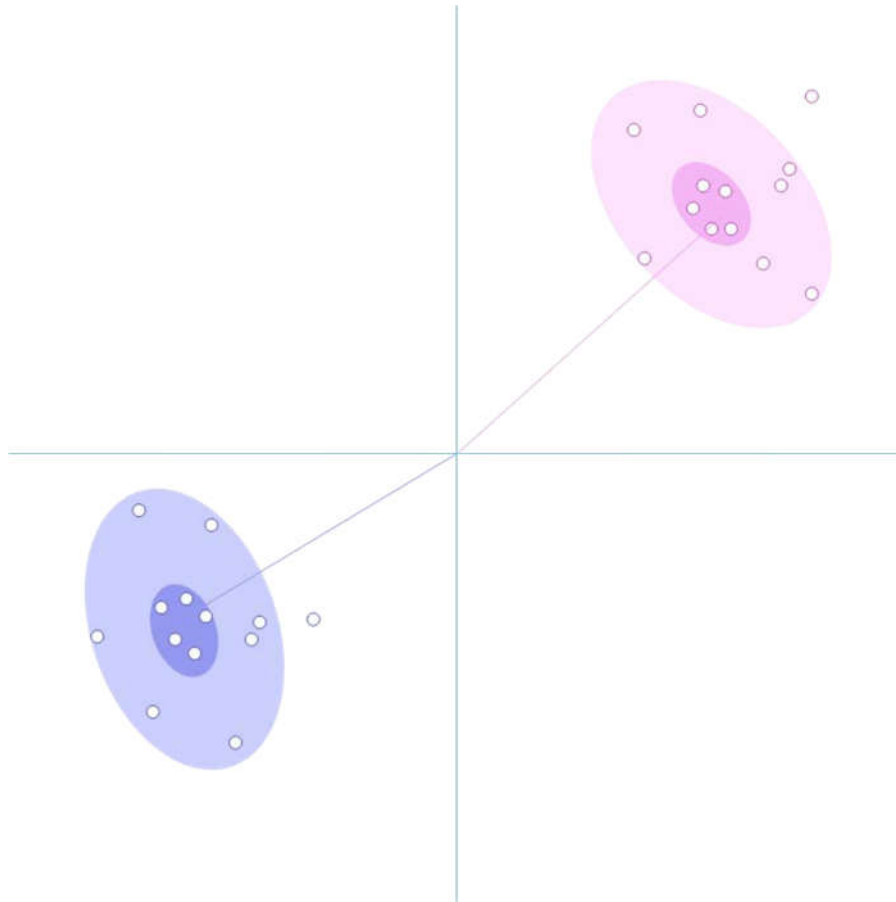


11.6

Graphic description

It reports, for both mastications, the normalized signals of the Temporals and of the Masseters superimposed on each other. This makes it possible to highlight the relationship between the various muscles for each chewing stroke.

Ellipse chart



11.7

Graphic description

The algorithm that interprets the acquisitions concerning the mastication processes gives rise to an elliptical Lissajous figure which is represented on a Cartesian graph.

In this graph, the X-axis represents the differential activity of the masseters (right masseter minus left masseter) while the Y-axis represents the differential activity of the anterior temporals (right anterior temporal minus left anterior temporal). Therefore, during a single masticatory act a single point is generated whose spatial coordinates X and Y will depend on the differential temporo-masticatory values specific for that act. This operation is repeated for each chewing act thus obtaining a cloud of identification points of the patient's chewing dynamics. Two representative ellipses of the populations of points obtained from the acquisitions of the chewing acts are then generated. Chewing therefore finds its natural representation in ellipse graphs on the Cartesian plane.

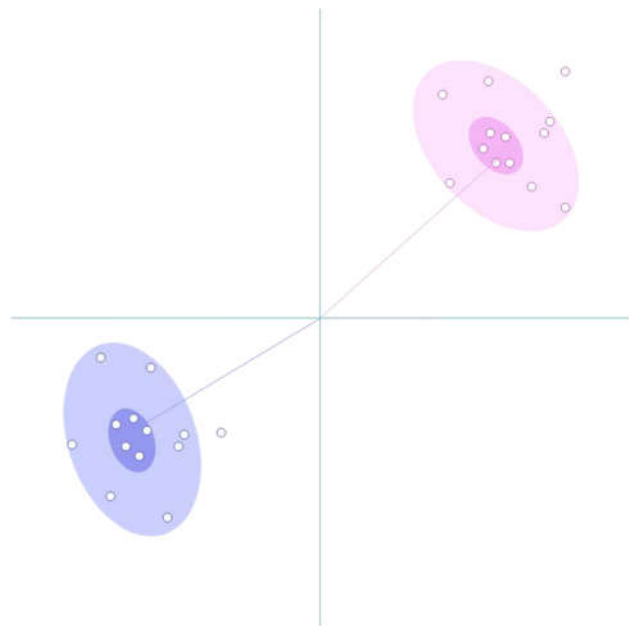
Interpretation tips

This graph is not easy to interpret, below are some indications and examples to help in understanding the possible clinical pictures.

Attention! In this Cartesian graph, the position of the ellipses in the various quadrants does not find an anatomical counterpart in the Patient. As one might erroneously think, the various quadrants do not in fact represent the various muscle districts (masseteria at the bottom and temporal at the top) but are the regions of space in which the various points will be positioned.

Balanced situation

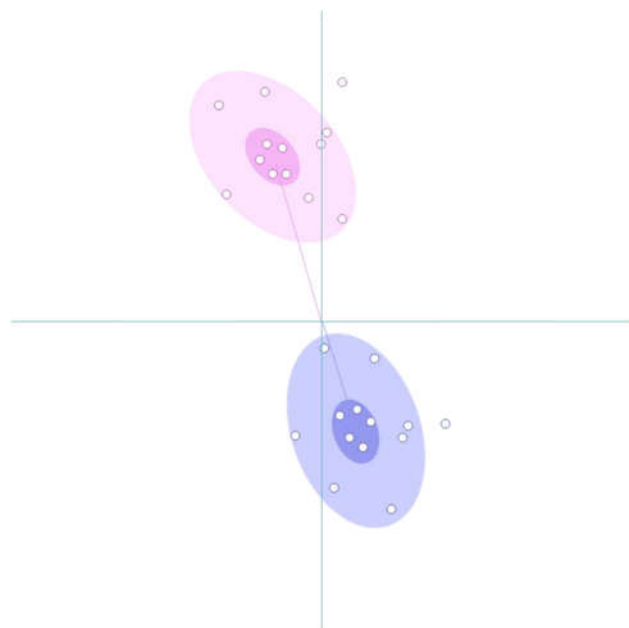
A graph in which the right and left ellipses are entirely in the first and third quadrants of the Cartesian plane, respectively, indicates a balanced clinical situation.



11.8

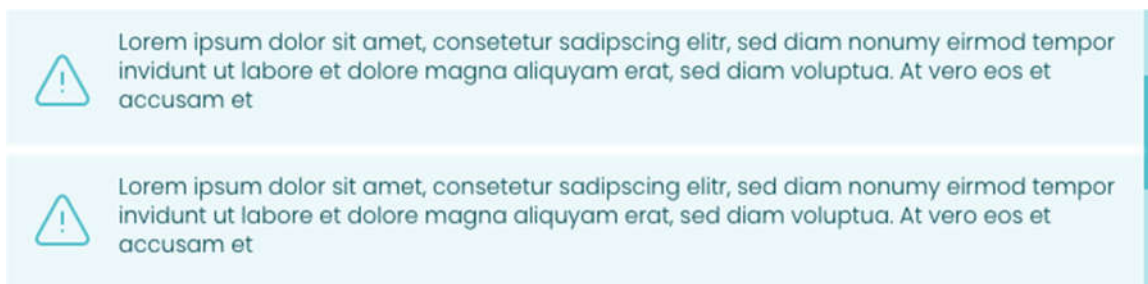
Unbalanced situation

A graph in which the right and left ellipses are not entirely in the first and third quadrants of the Cartesian plane, respectively, indicates an unbalanced clinical situation.



11.9

Alerts

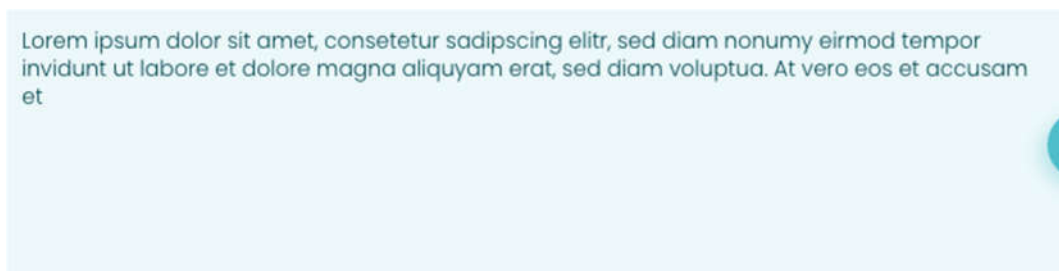


11.10

Graphic description

This section shows all the messages and warnings regarding the test, in this way the user has a clear view of whether particular or anomalous conditions have occurred during the recording of the EMG signals and can keep them in mind when processing the diagnosis.

Note



11.11

Graphic description

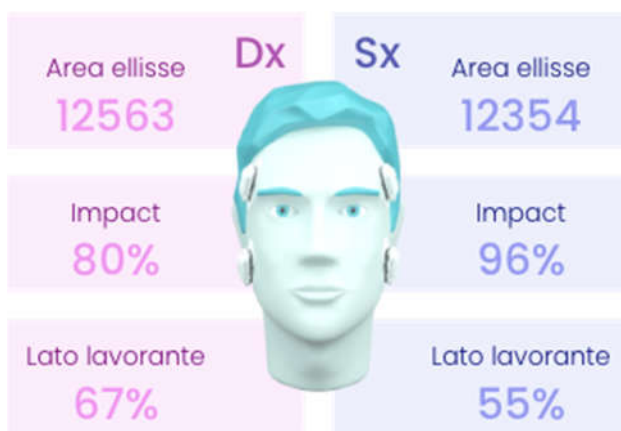
This panel shows the notes entered by the user immediately after acquiring the exam.

This can be useful for keeping track of observations and feedback received from the patient immediately after performing the exam. The notes can be modified by clicking on the button on the right of the panel itself.

11.3 Dynamic exam indices

The dynamic chewing test with Myowise returns a series of indices which are described and explained in this section of the manual. Grouped in a two panels are the following:

- **Ellipse area**
 - **Impact**
 - **working side**
-
- **Module**
 - **Acrofase**
 - **Balancing side**
 - **Number of chews**
 - **Frequency**
 - **Standard ellipse area**



Dx	Sx	
100.2%	Modulo	100.2%
100.2%	Acrofase	100.2%
100.2%	Numero masticate	100.2%
100.2%	Area ellisse std	100.2%
100.2%	Frequenza	100.2%
100.2%	Lato bilanciante	100.2%

Indices Area Ellipse and Area Ellipse Standard

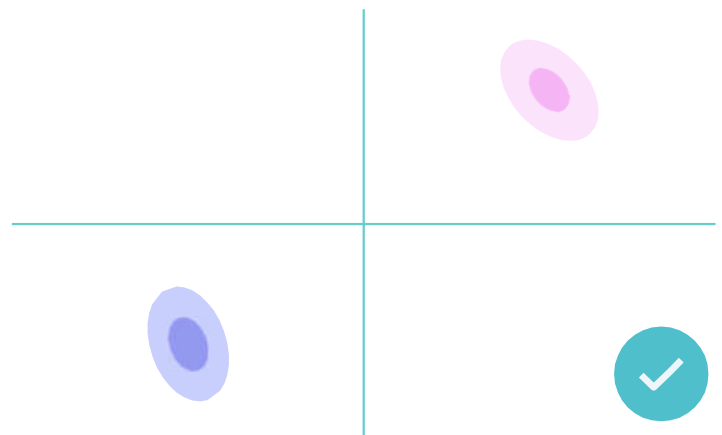
The area of the ellipse indicates the area within which the center of gravity of all chews is located. The smaller the area, the more repetitive are the masticatory muscle balances identified during the execution of the test. The Standard ellipse represents the area of the graph that encompasses 95% of all chews. The greater this area, the greater the variability of the chewing gesture.

Interpretation tips

It helps to understand if the patient has more or less high variability of contraction patterns during chewing and therefore if the patient always recruits the masticatory muscles in the same way during chewing. It is surrounded by a larger ellipse within which 90% of the chews are found.

Clinical situation 1

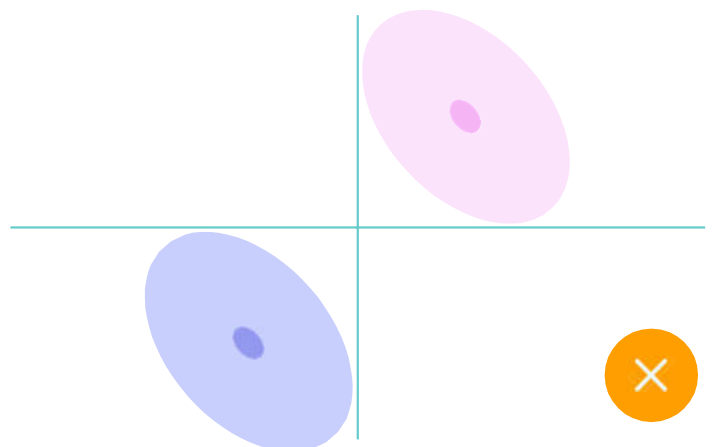
In this condition, the area of the right and left ellipse is less than the normal limit of about 1200 and indicates a repeatable chewing gesture with a defined and identifiable muscle pattern.



11.13

Clinical situation 2

In this condition, for both right and left chewing the area of the ellipse is significantly greater than 1200 indicating muscle patterns of chewing very variable. The patient chews by establishing different coordinations during the various chewing strokes.



11.14

Impact index

The Impact index, as for the homonymous index of the clenching test, quantifies the muscular work performed during chewing acts compared to that performed during the calibration test.

Interpretation tips

Low masticatory impact values indicate a patient with excellent biomechanical efficiency who requires minimal effort to chew.

Indices Working side and Balancing side

They quantify the percentage of muscular work done during chewing on the working side and on the balancing side. During right chewing, the working side is the right and the balancing side is the left and vice versa.

Interpretation tips

The higher the value of the working side, the lower the corresponding work of the balancing side (the sum of the two must be 100).

The greater the work of the working side, the greater the efficiency of the system as it requires a low effort of the balancing side.

Module index

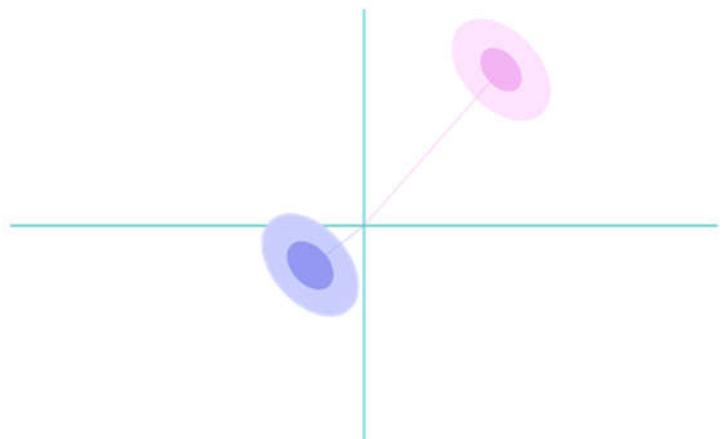
The module is graphically represented by the distance of the center of the ellipse from the center of the Cartesian axes. This means that the greater this value (and therefore the further away from the center the ellipse is located) the greater the differential between right and left antimere during a chewing test on one side. It helps to understand if chewing involves the working antimere more than the balancing one.

Interpretation tips

The module has normal values around 90. When the modulus value is low, below 50, it means that both the working and balancing sides have similar recruitment.

Clinical situation 1

In this example, during right chewing, the working side is significantly more recruited than the balancing side (minimum need for contralateral balancing). During left chewing instead the modulus is low (ellipse close to the center of the graph) indicating chewing with significant involvement of the balancing side.

**11.15**

Acrophase index

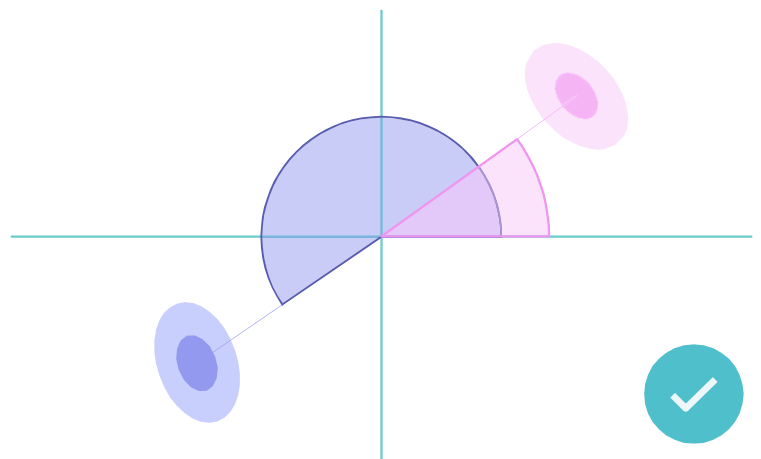
The acrophase is the angle between the straight line joining the center of the ellipse with the center of the axes and the X axis. The inclination of this straight line relates the differential activity of the masseters with respect to that of the anterior temporals during chewing on one side. It helps to understand which balance of muscle activation is established during chewing and how much this differs from the reference one.

Interpretation tips

Ellipses close to the X axis represent masticatory gestures during which the temporal muscles perform very similar performances, without major differences between the working and balancing sides. Ellipses close to the Y axis indicate exercises during which the masseters perform similarly.

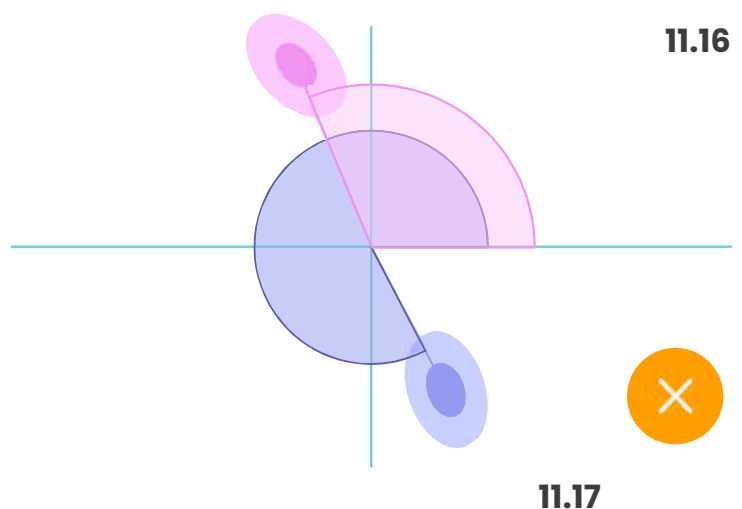
Clinical situation 1

In this example, right (about 45°) and left (about 225°) acrophase indicate a similar differential relationship between the masseters and temporals during both right and left mastication. Both of them the muscles, in both chews, have similar relationships between working-balancing and temporal masseters.



Clinical situation 2

in this example both for right and left chewing, the acrophase is greater than the normal values by inverting the ratio between the masseters. It means that, both during right and left chewing, the balancing masseter is more recruited than the balancing one.



Indices Number chewed and Frequency

They indicate the number of chews performed during the test and their frequency. Normal values are considered between 12 and 20.

Interpretation tips

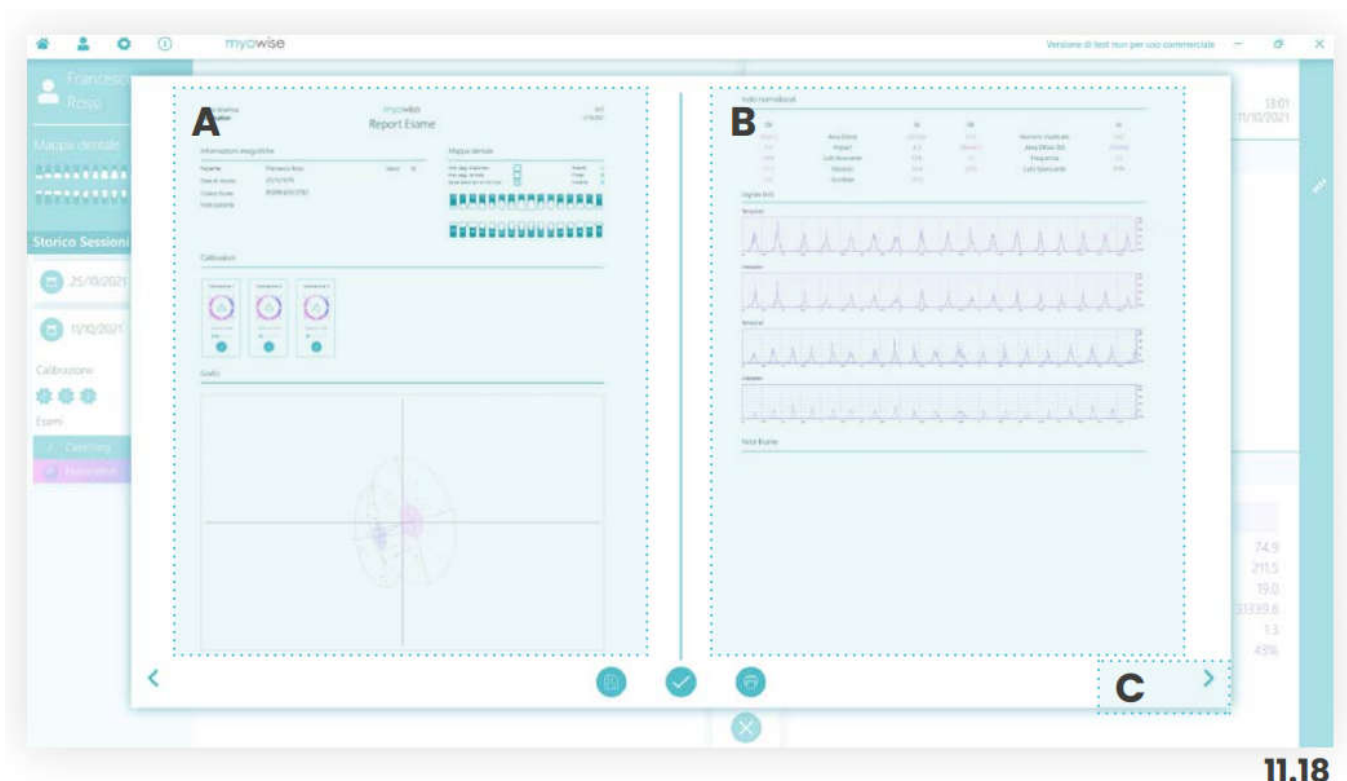
Variations of this number over time may indicate alterations in masticatory efficiency.



11.4 Chewing report

The user can save a report for each exam performed with Myowise. The software allows you to directly print the report in A4 format or save it in pdf format in a folder of your choice on the PC.

The  button **view exam report** is visible in the exam summary to the left of the muscle coordination graph



11.18

A – Information and graphics

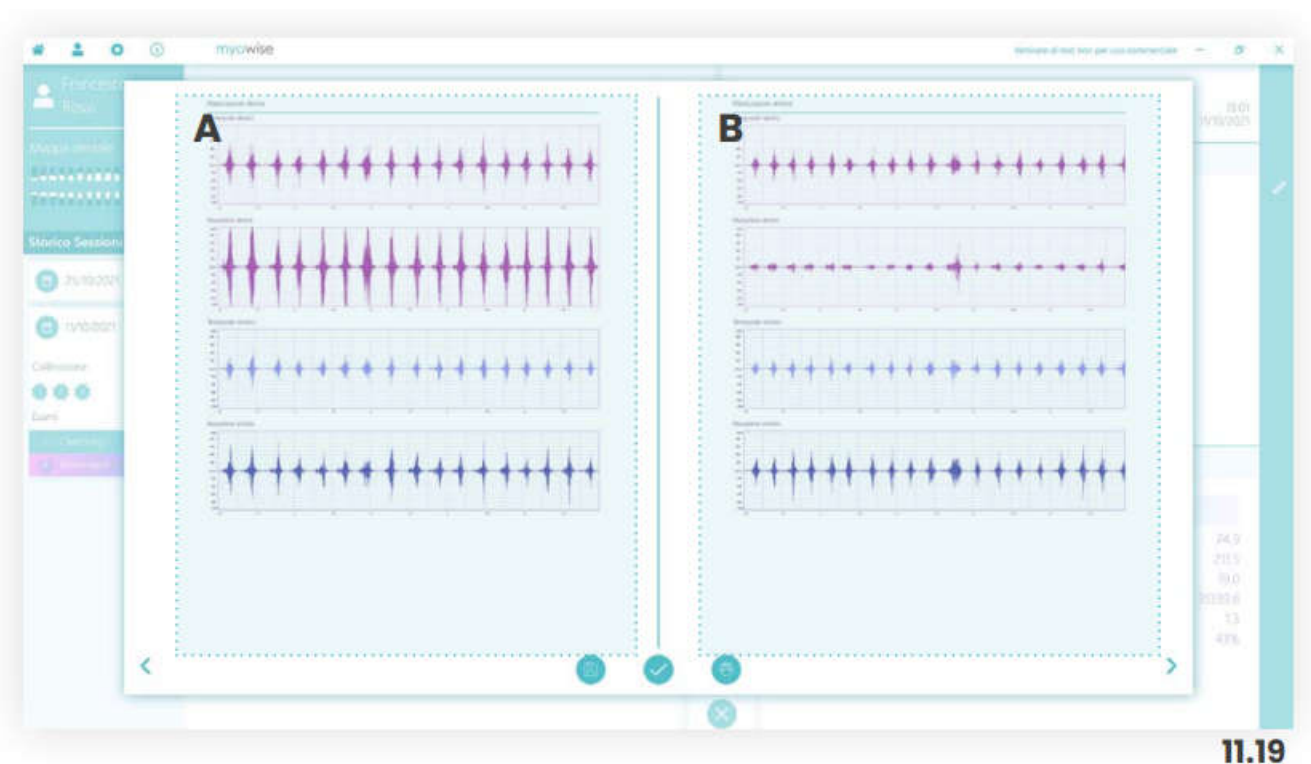
The information of the patient, the operator and the date and time of the exam are reported, as well as calibrations and graphs of the dynamic analysis.

B – Indices and normalized signal

All indices calculated by Myowise are reported together with superimposed normalized signals and notes entered by the user during the exam.

C – Following pages

The report is completed by pages with raw EMG signals.



11.19

A – Raw right chew signal

The 4 raw EMG signals recorded during chewing on the right side of the mouth are shown.

B – Raw left mastication signal

The 4 raw EMG signals recorded during chewing on the left side of the mouth are shown.

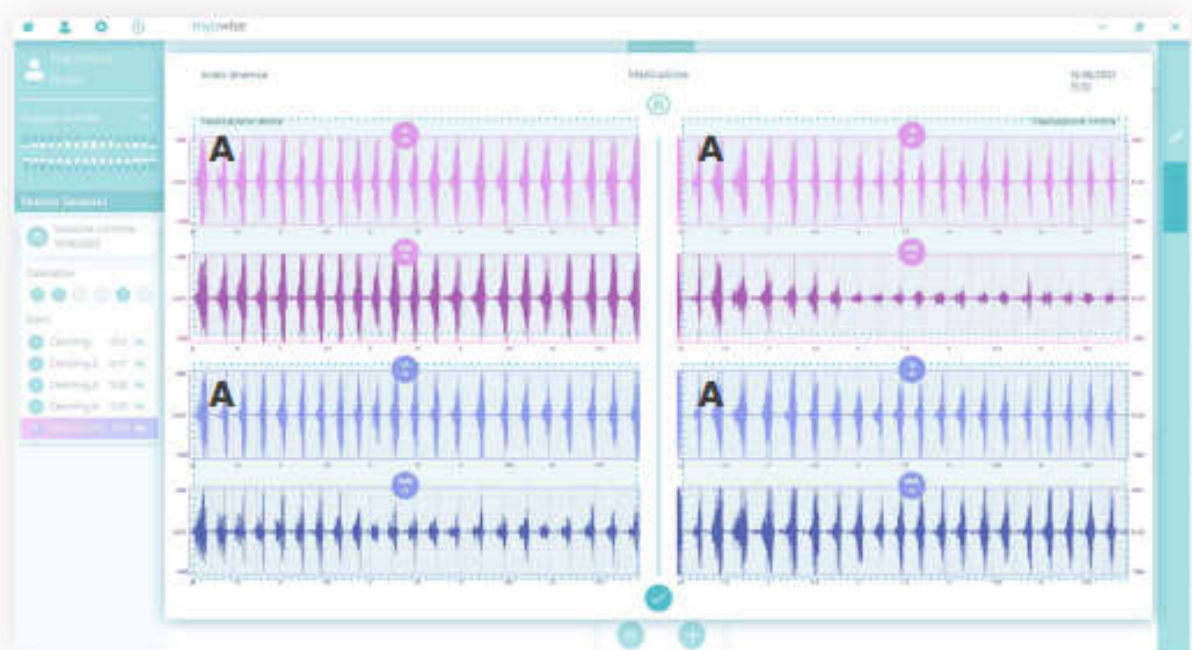
Command bar

The user can print the report directly from Myowise or save it in pdf format.

11.5 EMG signal display

The user can view the raw EMG signal for each exam performed with Myowise.

The  button **displays EMG signal** is visible in the exam summary to the left of the muscle coordination graph



A – Raw EMG signal

The raw signal of the 4 sensors is displayed.

For a more in-depth analysis it is possible to change the scale of both axes of the graphs in the following ways:

Mouse wheel = y-axis scale

Mouse wheel right click = x-axis scale

Left mouse button drag = scroll on x axis

Command bar

The user can save the raw data in txt format for any subsequent processing.



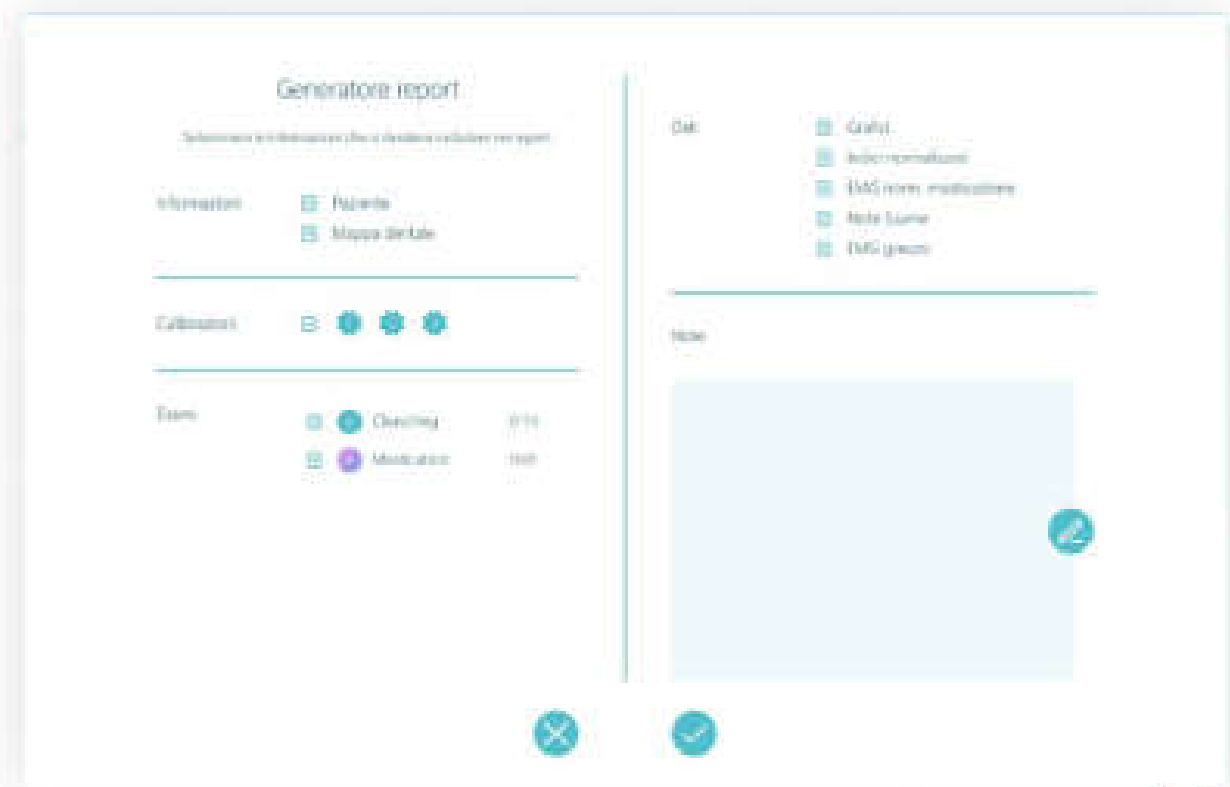
12 Session reports

With myowise it is possible to create a report for the entire session by selecting which information to include thanks to the **Report builders**. Once the session is closed, it can be accessed by clicking on the button **Create session reports**.

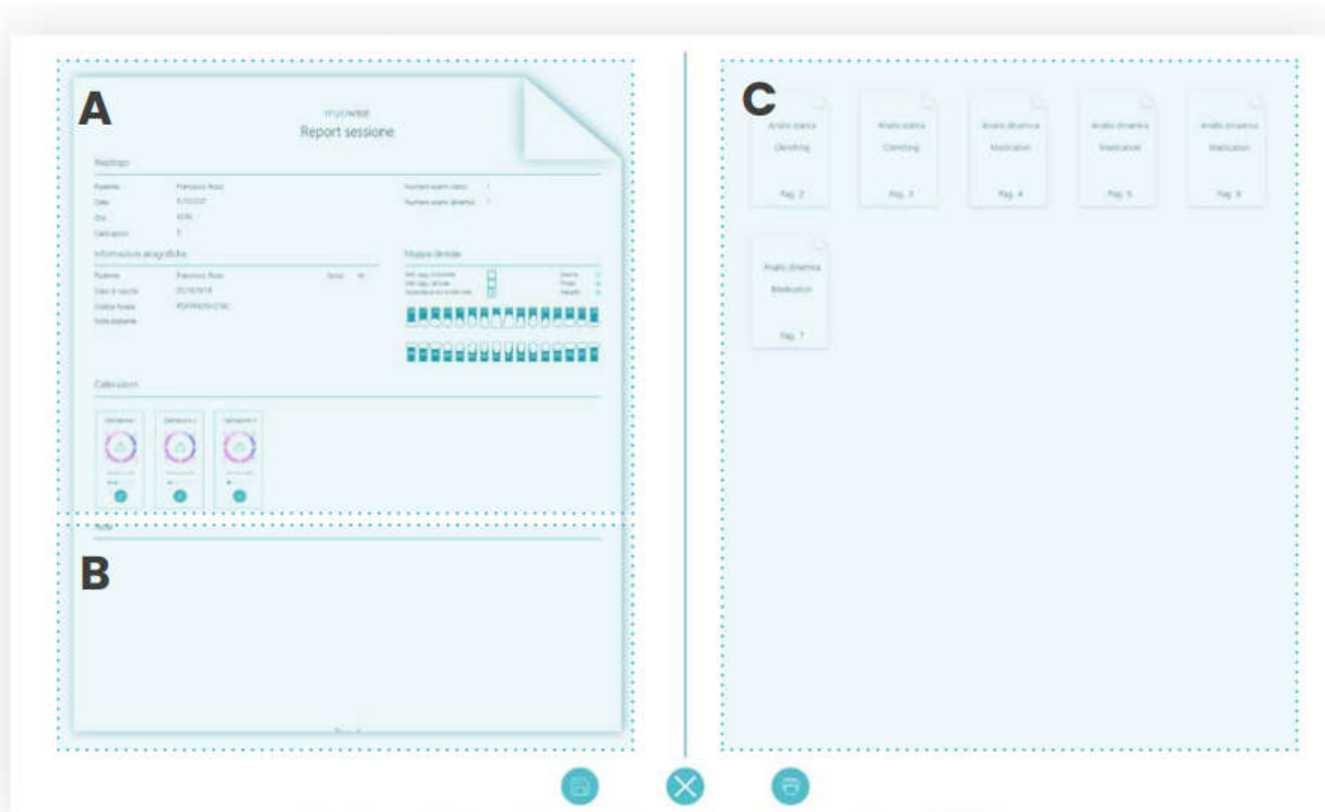
12.1 Report builder

This tool allows you to select which exams and which information to include in the session report, thus optimizing communication with the patient and collaborators.

At this stage it is also possible to insert the **Session report** which will be automatically saved in the report.

**12.1**

Once the exams and information to be included in the session report have been selected, the **preview**.



12.2

A – Summary

Shows summary of patient information, operator information, and selected calibrations.

B – Session report

Returns the text session report entered when creating the report.

C – Preview pages

Briefly summarizes the rest of the report.

Command bar

The user can print the report directly from Myowise or save it in pdf format.

13 Settings

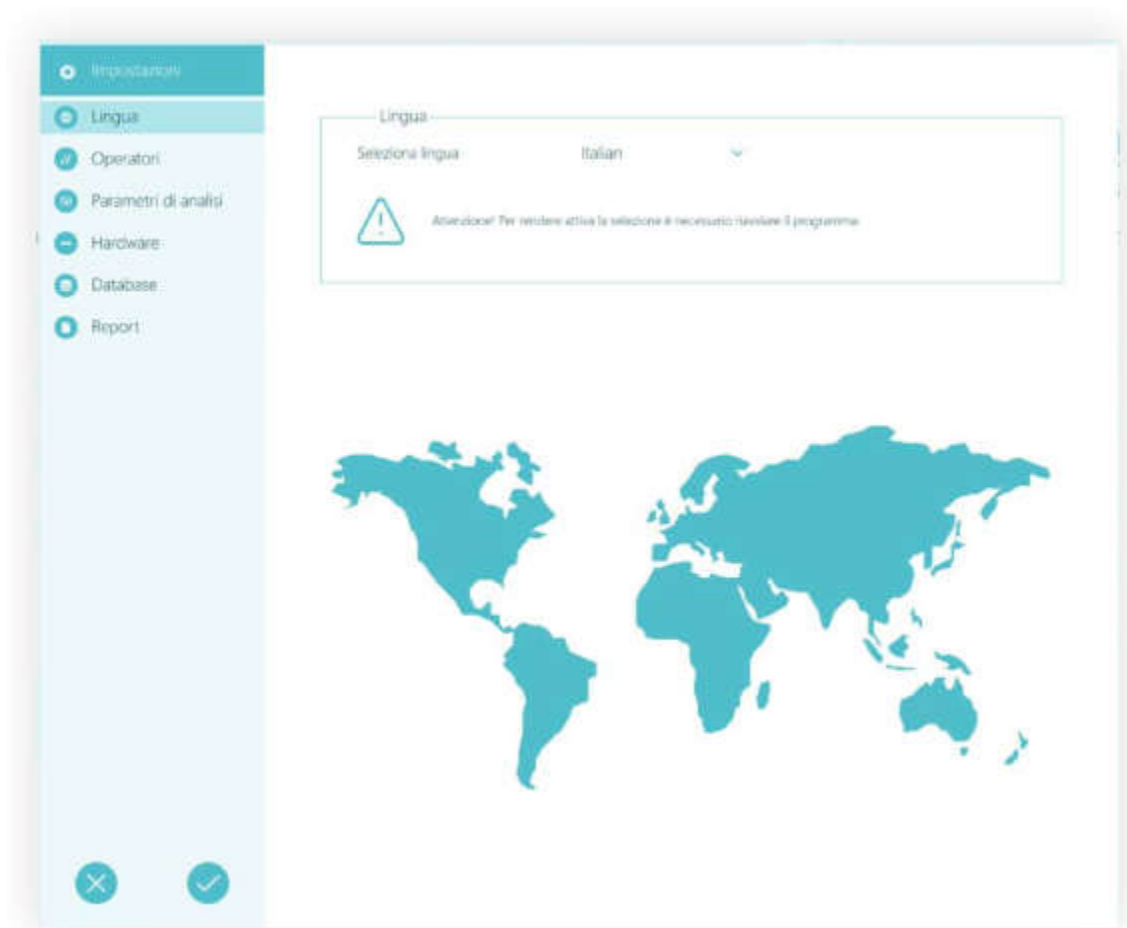
This section of the manual describes all the settings that can be modified by the user.

The settings are accessible via hot key in the top bar of Myowise



13.1 Language

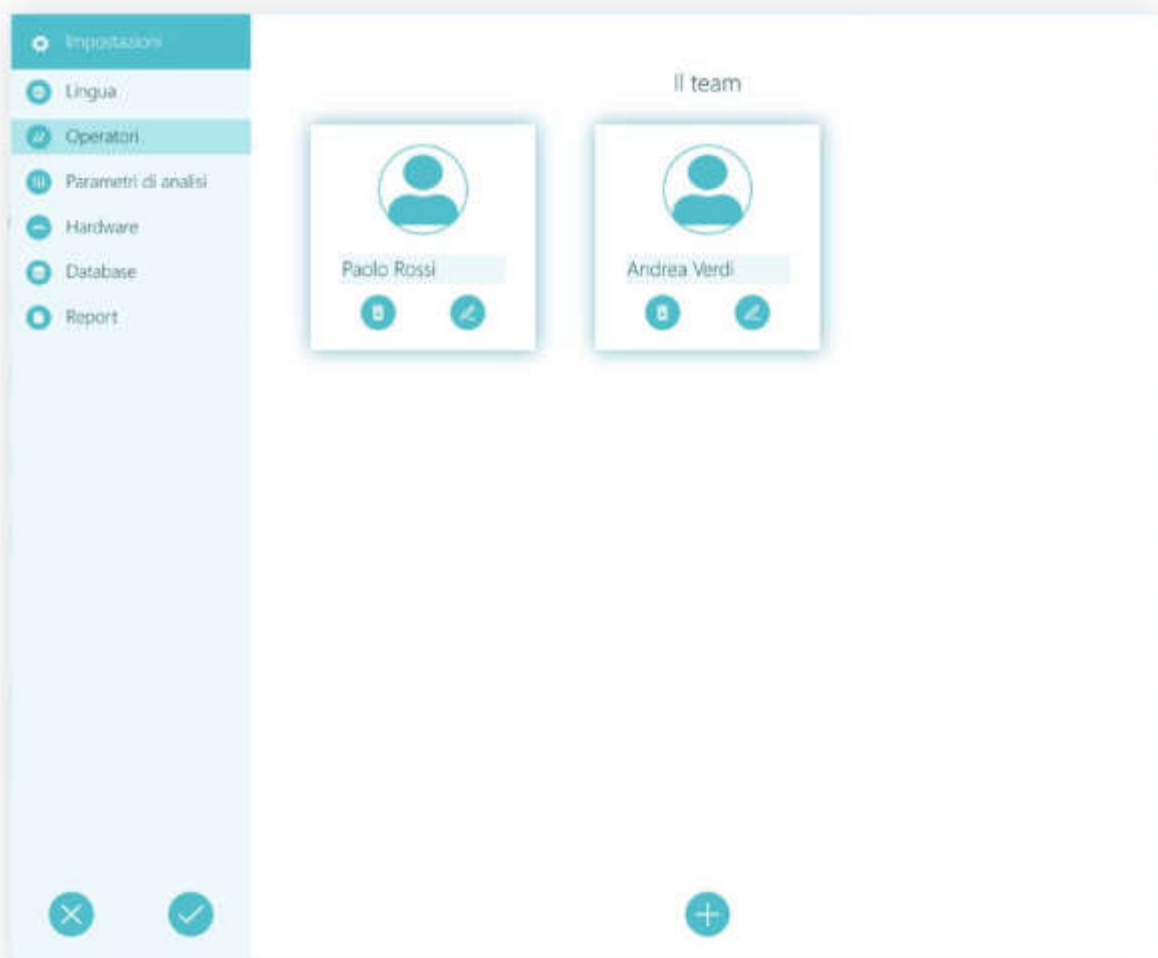
The first panel you can select the interface language of Myowise. This change is active from the next start of the software.

**13.1**

13.2 Operators

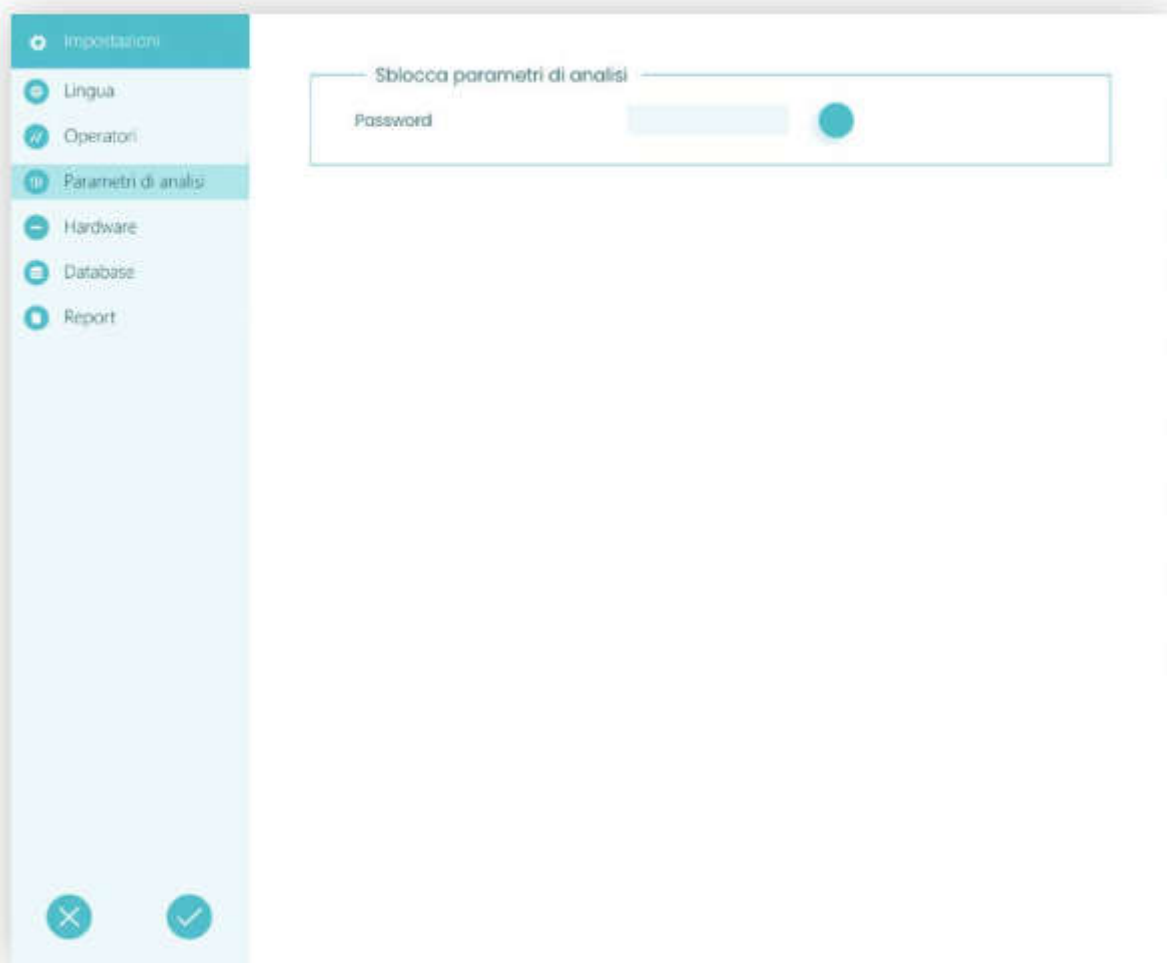
In this panel it is possible to add or delete an operator. When a session is saved, the operator who created it is tracked.
If an operator is canceled his exams still keep track of his name.

It is not possible to delete all the operators, there must always be at least one operator.

**13.2**

13.3 Analysis parameters

This panel is password protected and includes advanced analysis parameters which are the responsibility of the Myowise assistance service.

**13.3**

13.4 Hardware and system requirements

This panel contains all the information relating to the system hardware and the minimum requirements necessary for the correct functioning of the software.

The **serial number** it must be entered when the software is started and is shown on the label on the bottom of the charging station.

Impostazioni

- Lingua
- Operatori
- Parametri di analisi
- Hardware**
- Database
- Report

Sistema

Serial number sistema

Versione hardware 1.0

Dove si trova il numero di serie del mio sistema?

Requisiti di sistema

Sistema operativo Windows 10

Versione bluetooth Bluetooth 4.2

Posizionamento sensori

Sensore 1 temporale destro

Sensore 2 Temporale sinistro

Sensore 3 Massetere sinistro

Sensore 4 Massetere destro

Verificare sempre il corretto posizionamento dei sensori. Un posizionamento errato compromette la correttezza dei risultati.

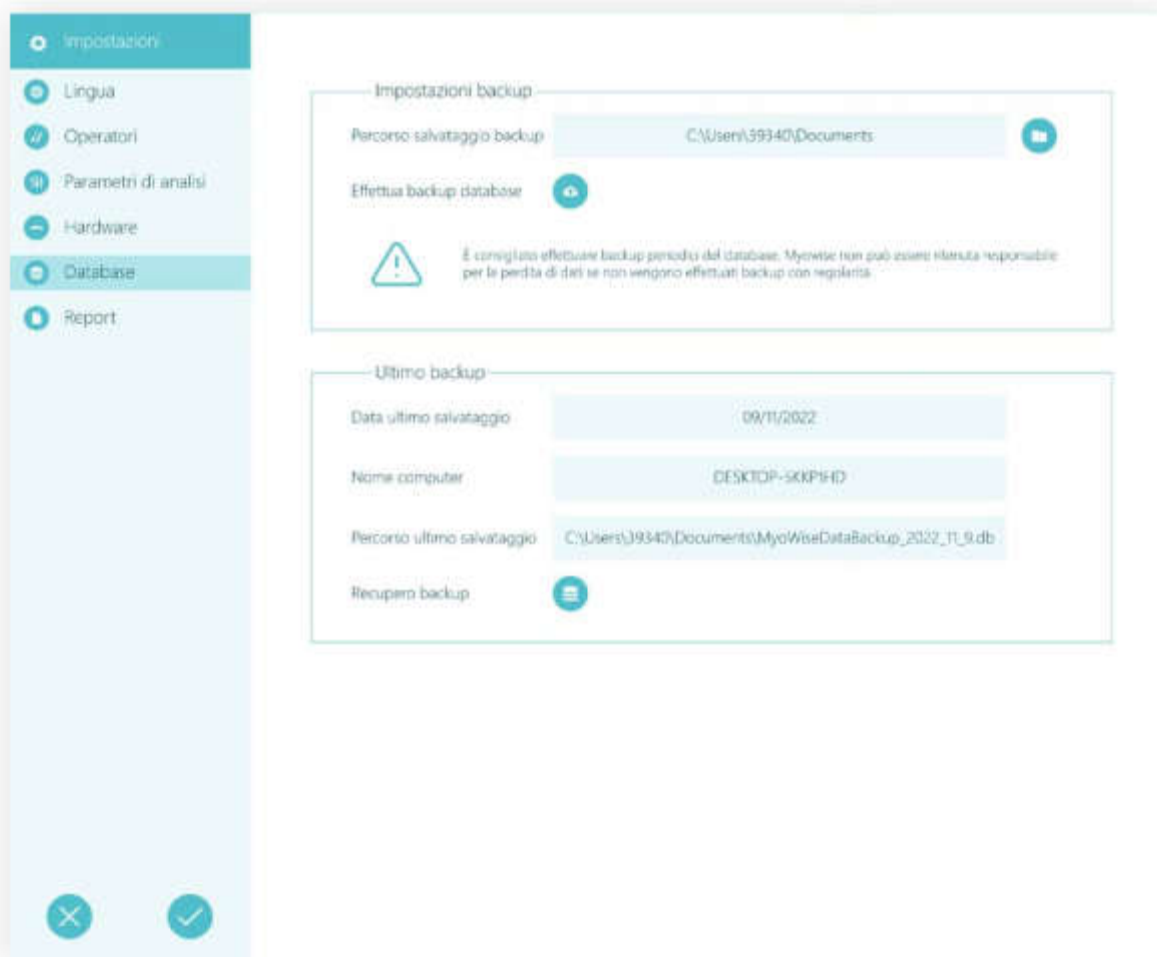
13.4

13.5 Database

This panel contains all the information relating to the Myowise database.

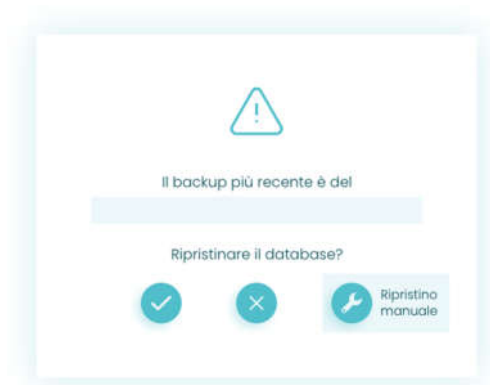
The user can indicate a folder on the PC in which to save the database backup and, if necessary, use the **recovery last backup**.

It is recommended to make periodic backups of the database. Myowise cannot be held responsible for data loss if backups are not performed regularly.

**13.5**

Most recent backup

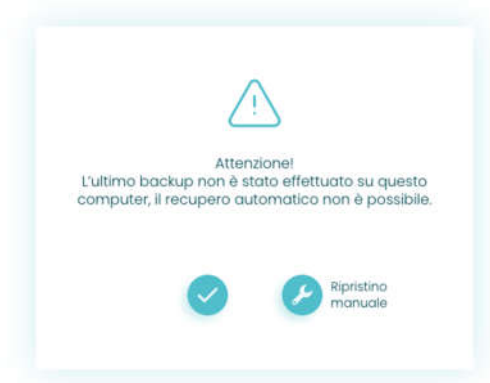
With the restore database backup function Myowise searches for the most recent backup and notifies the user of its date.



13.6

Local search

A safety feature alerts you if the last backup you made is not available on your current computer.



13.7

Manual reset

The user has the ability to restore a backup manually selecting the file. If the selected backup is not the most up-to-date, manual recovery leads to the loss of the most recent data.



13.8

13.6 Report

This panel allows you to select the information to include in exam and session reports.

Impostazioni

- Lingua
- Operatori
- Parametri di analisi
- Hardware
- Database
- Report**

Informazioni studio

Nome

Indirizzo

Numero di telefono

Logo

Contenuto report

Selezionare le informazioni che si desidera includere nel report

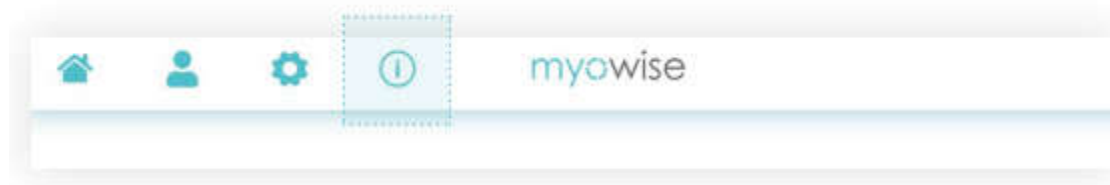
- ☒ Informazioni anagrafiche
- ☒ Mappa dentale
- ☒ Calibratori
- ☒ Grafici
- ☒ Indici normalizzati
- ☒ EMG norm. medicazione
- ☒ Note Esame
- ☒ EMG grezzo

X ✓

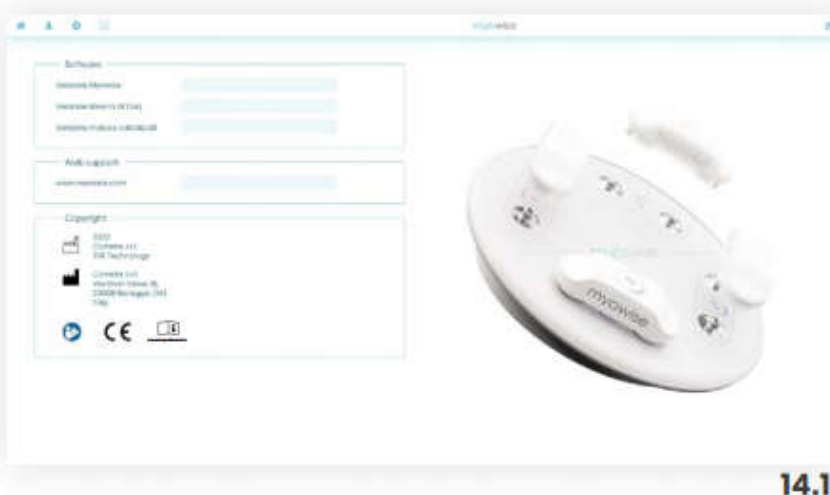
13.9

14 Copyright and information

The copyright and software information section is accessible via a hotkey in the top bar of Myowise.



This section contains information about the software including the installed version and markings.



14.1

Identification of the symbols used



Manufacturer identification



Consult the user manual



SW release year



Complies with Council Directive 93/42/EEC and subsequent amendments, DM Class I



Website from which it is possible to download the instructions for use in electronic form

15 Software updates

Myowise is constantly working to guarantee that the software is up to date and that is well maintained with updates, new functions and improvements.

The procedure to update your Myowise software is shown below:

- Before upgrading it is recommended to create a backup of the database following the procedure described at paragraph **13.5** of this manual.
- Obtain the new and latest version of Myowise (you will receive a single .exe file).
- Insert your Myowise USB key and a window will open showing its contents (or double click on it).
- If the **Program files** folder is visible do not alter the files it contains in any way, this will result in issues with your licence and database.
- Drag the new .exe file into the Myowise USB key selecting the **paste and replace** option.
- At the end of this procedure you should have a single Myowise.exe file in the USB key. (corresponding to the updated version)
- Enjoy the latest version of Myowise.

16 Bibliography

The measurement protocol has been validated in international scientific literature for almost 30 years of publications. The results obtained express the degree of balance of muscle activity during the masticatory act through recognized and validated percentage indices. Here is a brief bibliographical selection:

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