

# BTS TMJOINT



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## user manual

english  
version 3.0.0

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## icons, symbols and acronyms

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Symbol in the instructions for the function.  
The icon represents the information which requires special attention.



Symbol in the instructions for the function.  
This icon makes reference to a more detailed discussion of the subject in hand.



Symbol on the equipment:  
The data appearing next to the manufacturer's symbol refer to the place of manufacture of the equipment itself.



Symbol on the equipment:  
The "FCC" symbol refers to the Federal Communication Commission of the USA. The device complies with the relevant regulations put forth by the FCC as long as it is operated according to the instructions contained in this manual and to all national and local regulations.



Symbol on the equipment:

The figure in the square indicates the insulation class and the part types used. In accordance with Standard ISO 60601-1, the equipment has an internal power supply and the parts used are type BF.



Symbol on the equipment:

Attention, read the information in the users' manual carefully before using the equipment.



Symbol on the equipment:

The double square indicates that the product is a medical device of II Class (In accordance with the law EN 60601-1).



Symbol on the equipment:

CE mark with the code of the Notified Body. The CE mark certifies that the product conforms to the standards applicable in the member states of



the European Union (see Declaration of Conformity).



Symbol on the equipment:

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



Symbol on the equipment and in the users' instructions:

Symbol for the separate disposal of electrical and electronic equipment, in accordance with Directive 2002/96/CE (WEEE).

The equipment belongs to Group 8 (medical equipment).

In force in the nations of the European Union, Norway and Switzerland.

## **Rx only**

Symbol for prescription only. U.S. Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

**REF**

Symbol on the equipment:

Symbol located next to the model number (ref.to catalogue).

**SN**

Symbol on the equipment:

Symbol located next to the series number on the equipment.

Acronyms used in this manual:

RU Receiving Unit

EMG Electromyography

WS Workstation

DCA Dental Contact Analyzer

POC Percent Overlapping Coefficient

MVC Maximum Voluntary Contraction

### Radio equipment identification:

- EMG probes:  
FCC ID: YQH-BTSWEMG2  
IC: 9188A-BTSWEMG2
  
- receiving Unit contains:  
FCC ID: TFB-MATRIXLP  
IC: 5969A-MATRIXLP

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.



Modifications not expressly approved by BTS SpA could void the user's authority to operate the equipment under FCC rules.

## disposal (WEEE)

---

In disposing of the equipment observe the legal prescriptions.  
In accordance with Directive 2002/96/CE (WEEE) all equipment supplied after 13/08/2005 may not be disposed of in general domestic waste. This equipment belongs to Category 8 (medical equipment) and is classified in the Business-to-Business sector.



The symbol of the crossed out rubbish bin indicates that the equipment must not be disposed of in normal domestic waste.

The regulations for disposal may differ between individual countries in the EU. In cases of doubt, refer to the respective sales outlet.

This is a battery-powered equipment.



See Appendix D for information about the batteries used. Operate and dispose of this equipment according to the instructions set in the “warnings” section.

This equipment is an instrument for the EMG surface analysis, classified as medical equipment in accordance with European Directive 93/42/CE (and its amendments).

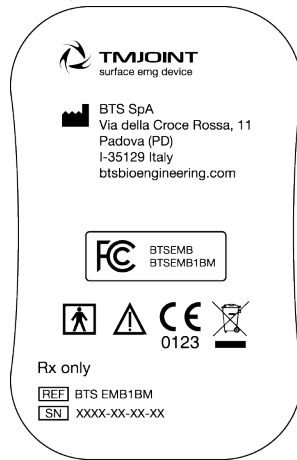
BTS TMJOINT must always be used only for this purpose, by qualified persons, in an environment suitable for the execution of EMG analyses and respecting the prevailing regulations in the countries in which it is being utilised.

# BTS TMJOINT

## regulatory label

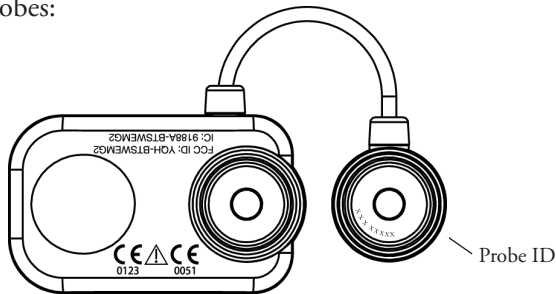
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### Receiving Unit Regulatory label









### EMG Wireless Probes Regulatory label


Label on the probes:



Label not on actual probes due to size constraints:

|   |   |
|---|---|
|  <b>TMJOINT</b>  |      |
|   |   |
| This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. |   |

### Charger Regulatory label

|   |   |
|---|---|
|  BTS SpA<br>Via della Croce Rossa, 11<br>Padova (PD)<br>I-35129 Italy<br>btsbioengineering.com | This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. |
|   | FOR USE ONLY WITH BTS APPROVED POWER SUPPLY UNITS   |

|   |   |   |   |   |   |   |                        |  |
|---|---|---|---|---|---|---|------------------------|--|
| FOR USE ONLY WITH BTS APPROVED POWER SUPPLY UNITS | POWER IN<br> 9V***1.5A |  |  |  | I |  | POWER OUT<br>9V***1.5A | FOR USE ONLY WITH BTS PROVIDED CHARGER AND CABLE |
|---|---|---|---|---|---|---|------------------------|--|

|   |
|---|
|      |
| REF: BTSFE3CHG<br>SN: XXXX-XXXX   |

## warnings

---



We recommend to carry out any kind of operation keeping strictly to the security regulations contained in this manual.

TMJOINT is a medical device (EU Directive 93/42/CE and its amendments, including Directive 2007/47/CE) which use must be at all times be supervised by qualified and authorized personnel, according to the laws in force in the nation it is in use. The EMG probes are classified as ETSI EN 300 440 “Receiver category 3” according to Directive R&TTE 99/5/EEC.

The results of the acquisitions must be assessed by people legally authorised by national law, who possess the suitable necessary knowledge of anatomy and muscular function.

The uses of the device for other purposes and with methodologies different from of those indicated in this manual are not to be considered congruent with the precise use of the device.

- Use the product according to the usage that it has been intended.
- Avoid connecting the probes to the charger with inverted polarity with respect to that shown on the cover of the recharger - this could cause irreparable damage to them.
- To not wet or dip in water the parts that make up the system.



- Apply the probes only on undamaged skin.
- Only use CE branded probes and hypoallergenic double-sided tape, compatible with the usage on undamaged skin for brief periods of time.
- Periodically verify the integrity of the system and of its components.
- In case the device accidentally falls, tear of the probes or other accidents always address authorized technical support.
- Do not undertake any kind of internal maintenance of the device: in case of need always address to authorized technical support.
- The use of any components different from the original ones declines the conformity of the device.
- The instrument must be used in a medical environment, since it has a high level of sensitivity (measured voltage levels of between 1 microvolt and 6 millivolt).
- In addition to the users' instructions, the prescriptions regarding accident prevention and technical regulations regarding occupational safety must also be complied with.  
The appertaining national regulations and standards of the country of use, with regards prevention of accidents and environment, are an extension of the users' instructions.
- TMJOINT is a device that is able to function CONTINUOUSLY,

this is of course limited by the battery duration and by the memory available for the acquisition data storing.

- the device uses lithium ion battery. For the battery replacement and disposal please contact the technical support. At any rate, ensure that device component (i.e. probes, receiving unit,...) integrity is never compromised.



The information contained in this manual is subject to change without notice and does not constitute product specifications or any obligation on the part of BTS S.p.A.

The software of the system described in this manual is supplied with the “licence to use” contract. The software may be used or copied only as stipulated under the terms of this contract.

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# BTS TMJOINT

## introduction

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### General description

BTS TMJOINT is the solution for the functional analysis of dental occlusion. Functional information is provided on the neuromuscular alterations induced by occlusal contact.

BTS TMJOINT integrates the latest wireless technology available today. Based on wireless technology, this solution includes a set of EMG probes with active electrodes, the only one of its kind in the world due to its light weight (weighing less than 9 grams), compact size and data capturing accuracy, a USB receiving unit and the dedicated software BTS Dental Contact Analyzer.

BTS TMJOINT uses surface electromyographic analysis to measure the differential influence of the occlusal function through indices validated and published in scientific literature.

Special feature of this system is the standardization of the electromyographic signal that is provided by the comparison between two test of clenching, done with and without the interposition of cotton rolls between the dental arches. This method allows the elimination of problems of the wrong positioning of the electrodes, of the difference of impedance of the patient's skin, of the differences of muscular tropism, etc. making it accurate and repeatable.

The results are shown via a special graphic interface that is easy to

understand for both the physician and patient.

The specialized software BTS Dental Contact Analyzer, provide, indeed, the automatic indices calculation, plotted in a table form, with pie charts and histograms.

BTS TMJOINT is a modular and scalable solution, structured on various levels of analysis.

The first level, called POC4, includes 4 capture probes and the analysis protocol. Through a quick 5 second clenching test, the activities of the masseter and anterior temporal muscles, right and left, provide, as an immediate result, a POC percentage overlapping coefficient (an index of the symmetric distribution of the muscular activity determined by the occlusion) and a TORS torque coefficient (to estimate the possible presence of mandibular torque), which makes it possible to establish the role of occlusion on muscular balance.

A third index, called IMPACT, allows to evaluate the muscular work, providing information about the occlusal vertical dimension.

The second level, called POC6, adds to the previous 2 capture probes for calculating the indices related to the sternocleidomastoid muscle, right and left. The effects of the teeth touching, on the neck muscles are evaluated.

The third level, called MASTICATION, analyses the neuromuscular coordination during mastication. The masticatory frequency, the Lissajous curve, and indices of muscle symmetry are calculated.

## Case contents

- Receiving Unit

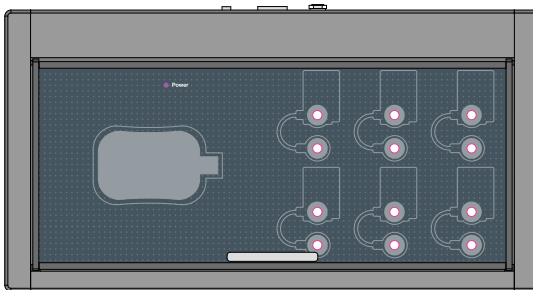


- Probes Kit available in 2 versions:
  - POC4: include 4 wireless probes\*
  - POC6: include 6 wireless probes\*



\*(identificative labels available in 4 different colors)

- Probes Charger (AC adapter included)



- Set of disposable electrodes
- USB extension cable
- User manual



You will receive the instructions for use for other possible optional components not mentioned in this manual.

# BTS TMJOINT

## system components

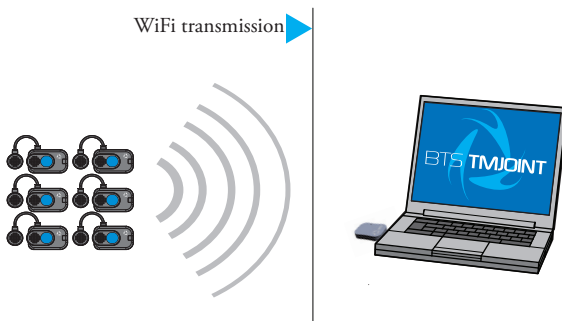
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BTS TMJOINT system consists of two parts: the receiving unit and the wireless EMG probes.

### Receiving unit



The receiving unit, connected to the PC through USB, allows the WiFi reception of the EMG signal acquired by the wireless probes





### Wireless EMG Probes

BTS FREEEMG 300 utilises miniaturized probes with active electrodes weighing less than 13 grams.

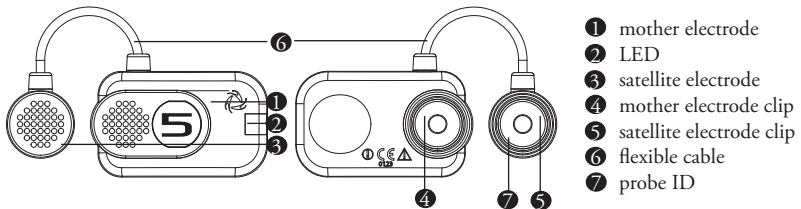
The special design ensures maximum space-saving and comfort for the patient who is free to move around without obstacles.

The probes can be hooked on directly to the pre-gelled electrodes without requiring additional fixing with plasters or double-sided tape.

This together with the total absence of cables enables a much faster patient preparation, drastically reducing the time of each session.

Each probe consists of a mother electrode and a satellite electrode, each fitted with a clip. The two parts, connected via a flexible cable, may be positioned as needed by the user at adjustable distance (electrodes with variable geometry).

All probes are also equipped with a solid state memory buffer, to prevent data loss for problems due to the WiFi network or due to exceeding the useful operating range.



Each probe is fitted with a LED indicating its state.

The probes can be in one of a number of different states:

- Charge: steady blue LED.

During the recharging phase the steady blue LED is on. This phase occurs when the probes are connected to the charger turned on, and the charge level is less than 90%.

When the charge level reaches 90% the led turns OFF.

Since, by connecting a probe to the charger on, it enters in “Deep Sleep” mode, even while charging the probe will be completely passive and does not respond to any commands.

- **Active-Scanning:** white LED which cyclically lights for a few seconds.

In this mode the probe is searching for the receiving unit.

At intervals of about 1 minutes it carries out a scan of the frequencies of few seconds. During the scan the white LED flashes quickly.

- **Active-Connected:** white LED which flashes slowly.

When the probe and the receiving unit establish a connection, the white LED begins to pulse slowly: the probe is waiting for commands.

If the connection is interrupted, the probe returns to “Active-Scanning” mode and attempts to re-establish the connection with the receiving unit.

- **Active-Capturing:** white LED which lights and goes out at regular intervals.

During acquisition the white LED flashes at regular intervals of approximately one second. At the conclusion of the acquisition, the probe returns to the “Active-Connected” condition.

If during the acquisition, connection to the receiver unit is lost,

the probe continues to acquire, storing the data locally for one minute and at the same time scans the assigned channel trying to reconnect to the receiving unit.

If after one minute the scan is unsuccessful, the probe returns to the “Active-Scanning” condition interrupting the storage of data.

- Completely discharged or in “Deep Sleep” mode: LED is off. If the probe is completely discharged the LED does not display any flashing cycle and is off. The same happens when it is in “Deep Sleep” mode (except during the recharging phase in which the led is steady blue).



The probes in “Deep Sleep” mode do not perform any scan cycle, but are turned off. It is therefore guaranteed energy savings.

To put the probe in “Deep Sleep” mode it is necessary to connect them to the Charger switched on, or to put them in contact with a magnet for half a second.



Before the next use is necessary to reactivate the probes, putting them in contact with a magnet.

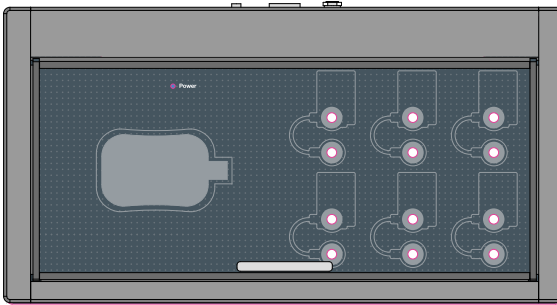
The probes are charged by a dedicated charger to which the probes are connected via their respective clips.



For more info about the probes charge see the paragraph “Charger” of this chapter.

## Charger

The Charger, included with the product, charges the BTS TMJOINT probes.



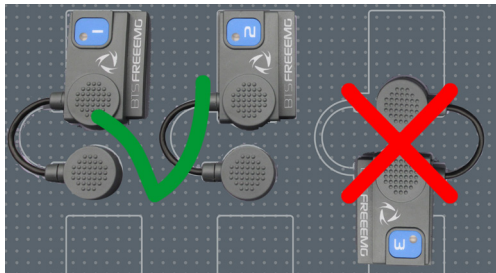
The Charger can simultaneously charge all the EMG probes of the system (6 maximum) and includes a lodging to store the receiver when not in use for acquisition.

The EMG probes are connected to the charger using the same clips that normally collect the EMG signal.



For correct connection simply follow the outline of the probes shown on the base of the Charger.

At any rate, poles connected incorrectly will not recharge.





In any case, the Charger comes with an output short circuit protection system also in case of reversed recharging poles.

To recharge connect all the probes that you would like to charge to the Charger (follow the instructions described above) and connect the AC/DC adaptor to the mains and turn on the switch located on the rear panel.

When the Charger is properly connected to the mains and has been turned on, the status LED “Power” will show a steady GREEN light.

The charging status of the probes is indicated by the status LED of the probes (see § “Wireless Probes”).



Note that inserting the EMG probes into the Charger when it is on, these come in “Deep Sleep” mode.

It is necessary to reactivate the probes, prior to use them, using a magnet.

## installation

---

### User PC minimum configuration

|                  |  |
|------------------|--|
| Operating system | Windows 7  |
| Processor        | Intel Dual Core  |
| RAM              | 2 GB   |
| Video resolution | 1280x800   |
| Disk space       | 100 MB for the application,<br>not including storage for acquired data |
| USB              | 2.0  |

### Connections

The wireless probes transmit in real-time the acquired data to the receiver connected via USB to the Workstation.

Connect the receiver to the WS using the USB connector.



If the morphology of the WS does not allow direct connection of the receiver, use the USB extension cable.

Also verify that the probes are fully charged and ready for use.



It is required that the probes are disconnected from the charger to be recognized and activated by the system.

Description of the software on the user PC

BTS TMJOINT is provided with BTS DENTAL CONTACT ANALYZER - DCA, the specialized software for the automatic calculation of indices correlated to the occlusal contact and to the possible neuromuscular alterations induced by it.

The software allows managing the patient database, organized with a tree root with sessions, trials and subject data, explorable through different database queries.

The provided data are translated in graphical form for an easier interpretation and plotted in a table form, with pie charts and histograms.

It is possible to create report of single trial or to compare two trials such as a pre and a post treatment.

All the reports, once created, can be saved and reloaded in a second time.

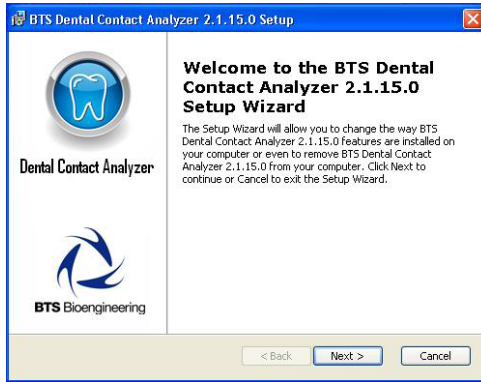
Software installation

BTS DENTAL CONTACT ANALYZER software is usually pre-installed and configured.

However, if it is necessary to perform again the installation just follow the instructions below.

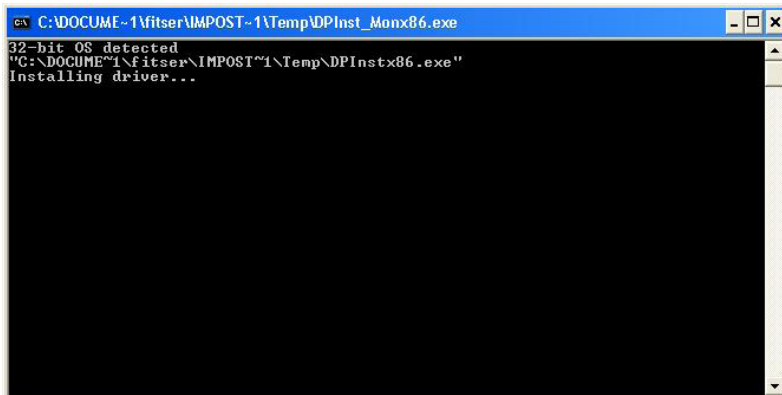
Once entered in the CD player of the computer dedicated, the BTS CD software containing the installation files, launch the .exe file "POCAnalyzer-X.X.XX.X.msi" and follow the instructions provided by the application.

It will appear the following screen:



After have accepted the installation terms and chosen the Typical installation, click always on “Next” key, until the procedure end.

Then perform a double click on the “CDM20814\_Setup.exe” file and wait for the window that has just opened, to close.







- Check that on the PC are installed the following two elements:
- “Microsoft.NET Framework 3.5” (for Windows XP) or “Microsoft.NET Framework 4” (for the next versions);
  - “PDF Creator 1.2.1” (disable the research for possible updates)



In case they are not already on your PC please download them from the Internet (they are free) and install them.

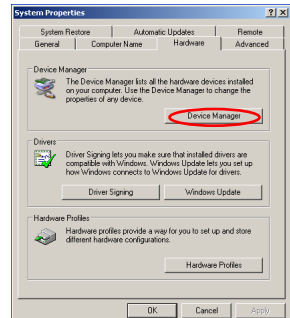
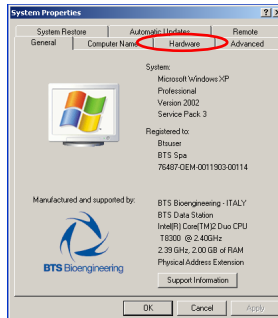
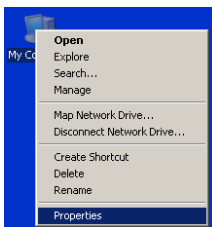
### Hardware installation

After have performed all the steps above, it will be necessary to configure the port for the USB receiver.

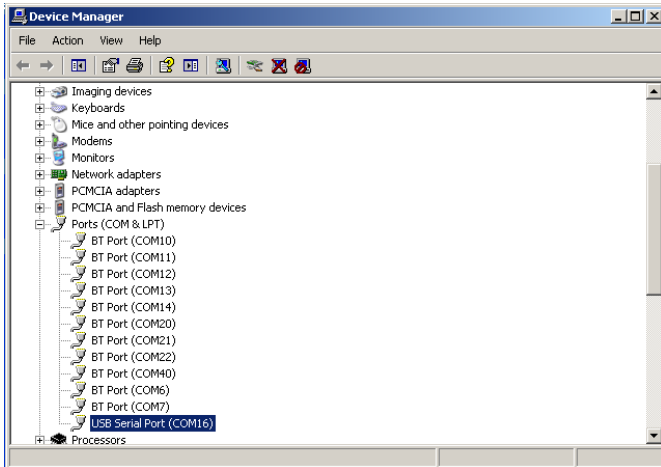


To set the characteristics of the receiver the system requires the receiver to be connected to the PC via a USB port.

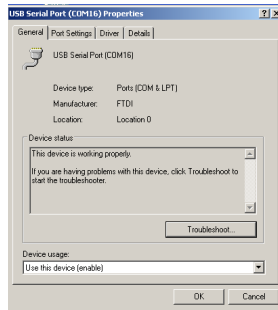
Then, clicking the mouse right button on “My Computer”, select “Properties”, choose “Hardware” and then enter the “Device Manager”:



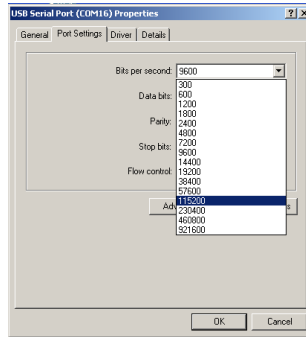
Once inside the Device Manager menu, select “Ports (COM & LPT)” and click the right button on the item below “USB Serial Port (COMx)” and select “Properties”.



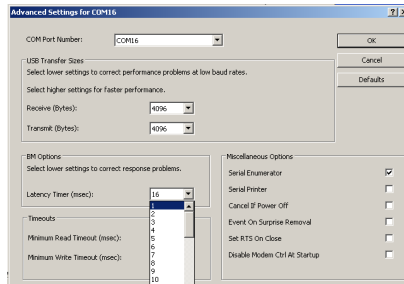
Entering the port properties window it will be displayed the following:



In which you must select “Port Settings”.



Set in the drop box menu related to the “Bits per second”, the value 115200 and then click “Advanced”.



In the window that opens, you must set the value of “Latency Timer (msec)” equal to 1msec, and then click “OK”, returning to the previous screen. Also in the “Port Settings” window click on “OK” then close the windows remained still open.



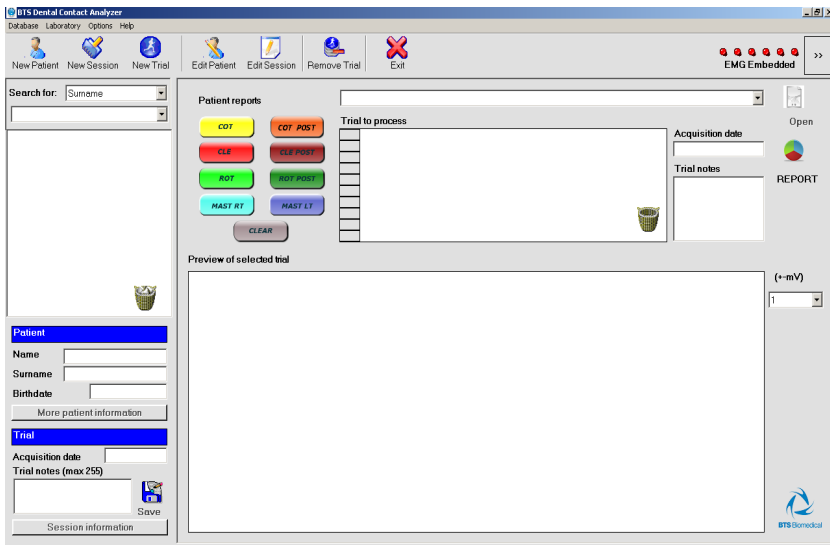
During the setting operations of the COM port, take note of the port number that the PC automatically associates to the device, because you will need it at the software first start..

## First software use

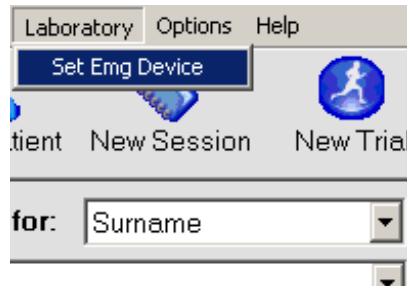
Continuing to keep the USB receiver into the USB input, double-click the icon on your desktop “Dental Contact Analyzer” to run the software.

On the first start it will be asked to choose the preferred language for the interface software; once selected you must click on OK.

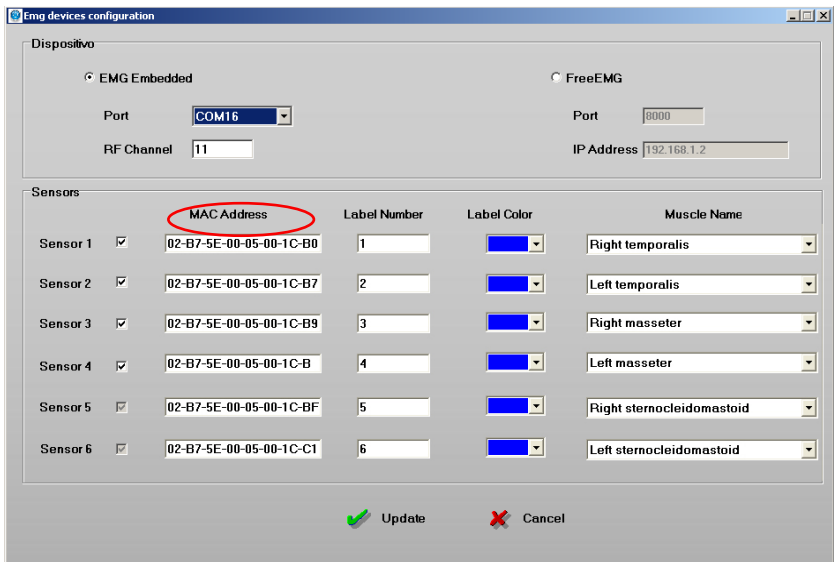
When the procedure will be completed, the software will start showing the following window:



On the first start you should check that the correct COM port is set by selecting the “Laboratory” voice from the tool bar and click “ Set EMG Device”.



Clicking on the device settings, a new window will open.



Select the correct COM port number among the voices in the drop box menu "Port".

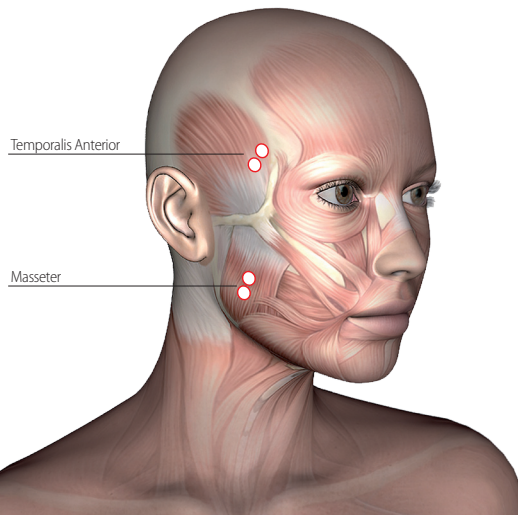


If the chosen port is the one corresponding to the USB receiver and if it is set correctly, the fields below will activate showing the “MAC Address” of the probes associated with the receiver you are using.

If all of these operations are successful, clicking on “Update” the window will close and you can start using the software.

### POC4 Protocol

The POC 4 protocol provides the acquisition of 4 muscles: the masseter and the temporalis anterior bundle for both face sides.



Each probe is numbered and for this protocol we will use the probes from 1 to 4.

It is mandatory to follow this sequence:

- probe n. 1 – right anterior temporalis;
- probe n. 2 – left anterior temporalis;
- probe n. 3 – right masseter;
- probe n. 4 – left masseter.

For the RIGHT temporalis anterior bundle, touch the muscle during the maximum clenching and find the major axis of the zygomatic process of the frontal bone; the electrode should be applied along a line parallel to this axis that runs through a couple of centimeters posterior to the process and above the temporal process of the zygomatic bone.

Repeat the procedure also with the LEFT temporalis anterior bundle, trying to maintain a symmetry of positioning.

For the RIGHT masseter, position yourself behind the patient when possible and touch the muscle during the maximum clenching, finding its venter.

The electrode should be applied along the line that connects the external canthus of the eye with the mandibular angle.

Repeat the procedure also with the LEFT masseter, trying to maintain a symmetry of positioning.



It is recommended to apply in advance the probes on the pre-gelled through the special clips, in order to avoid exerting pressure directly on the subject face.

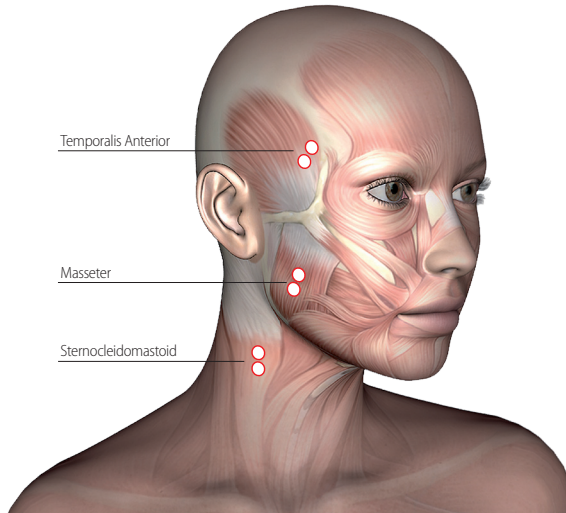


Before proceeding with the acquisition, verify that the chair's back is in vertical position. We ask to the subject to stay relaxed with your legs uncrossed, hands resting on his knees and looking forward.



### POC6 Protocol

The POC 4 protocol provides the acquisition of 6 muscles: will be acquired also the sternocleidomastoid muscles, in addition to the masseters and the temporalis anterior bundles analyzed in the POC 4 protocol.



We will use the probes from 1 to 6 following this sequence:

- probe n. 1 – right anterior temporalis;
- probe n. 2 – left anterior temporalis;
- probe n. 3 – right masseter;
- probe n. 4 – left masseter.
- probe n. 5 - right sternocleidomastoid;
- probe n. 6 - left sternocleidomastoid.

For the probes positioning on the masseters and temporal muscles, refers

to the instructions in the previous paragraph.

To find the RIGHT sternocleidomastoid, asks the subject to rotate, as much as possible, the head to the left; the electrodes will be positioned on the muscle so identified.

Repeat the procedure also with the LEFT sternocleidomastoid, trying to maintain a symmetry of positioning.

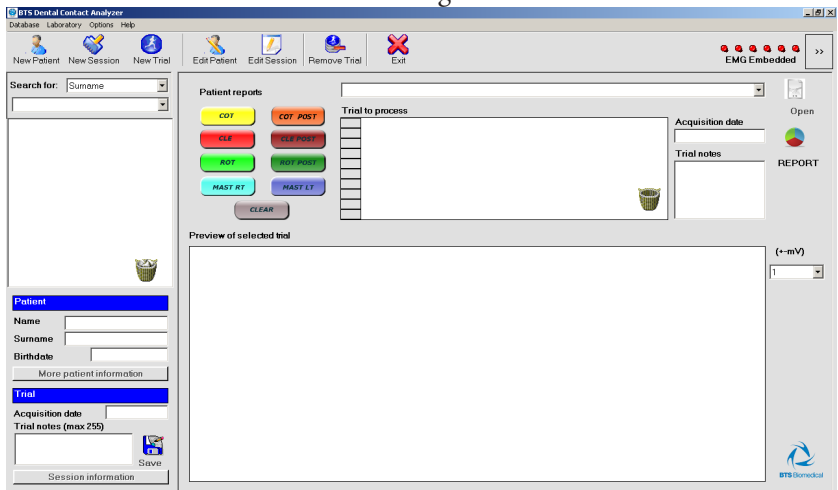
## guide to the use of BTS DCA

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### Initial screen

To launch the software DCA doubleclicking on the relative icon.

Once loaded the software the following windows will be loaded:



The windows includes the following main areas:

- the menu bar
- the tool bar
- the probe status bar
- the list of patients in the database provided with a search filter
- the information related to the patient, session or trial selected from the list
- the area which manages the trial viewing and the report generation.

## Menu bar

The menu bar contains:

- The “Database” menu which manages all the operations associated with the patient database;
- The “Laboratory” menu from which to configure the EMG devices to use;
- The “Options” menu which allows setting the software languages and the chart property;
- The “Help” menu which supplies the software version number.

The following functions can be accessed from the “Database” pop-down menu:

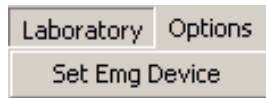


- “New Patient” to add a new patient to the Database.
- “New Session” to add a session to the patient already inserted in the Database.
- “New Trial” to capture or import trials to an existing session.

- “Edit Patient” to modify the information about a patient.
- “Edit Session” to modify the information associated with a session.
- “Remove Patient” to eliminate the selected from the database. A confirmation is requested.
- “Remove Session” to eliminate the selected session. A confirmation is requested;
- “Remove Trial” to eliminate the selected trial. A confirmation is requested.

From the database menu by selecting the voice “Database & Data folder” it is also possible to select another Database or create a new one, modify the data folder path and select an application to read reports in PDF format.

The second menu of the menu bar is the “Laboratory” menu:



From this menu the voice “Set Emg Device” may be accessed:

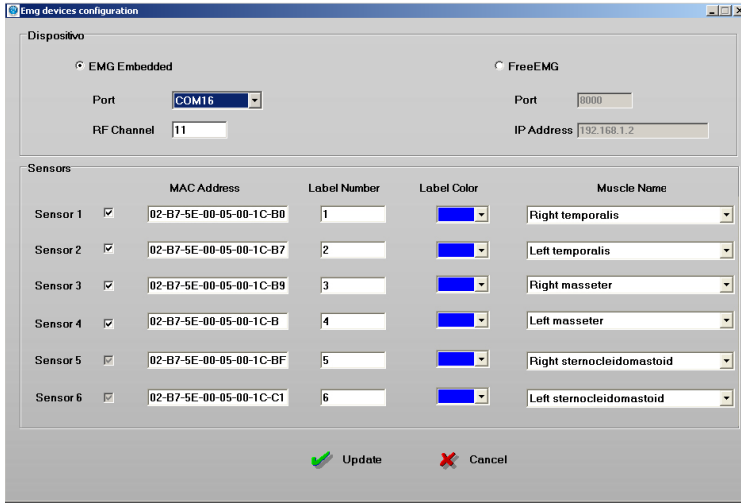


BTS TMJOINT use an Embedded EMG device, for this reason be sure that this option is selected.



The BTS Dental Contact Analyzer software can interface itself also with the BTS FREEEMG systems for the data acquisition. Anyway the procedure of use of DCA with these other devices is not described in this manual.

The following windows will be displayed:



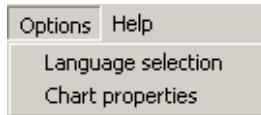
This window is divided in two areas:

- the “Device” area containing the information related to the Port and to the RF Channel for the data transmission;
- the “Sensors” area containing the information related to the 4 or 6 probes (depending on the version installed) and in particular for each probes is indicated:
  - the MAC Address containing the probe identificative code printed on the clip of the same probe.
  - the number indicated on the probe label
  - the identificative color of the probe label
  - the name of the muscle associated to that probe.

All these value can be modified by the user.

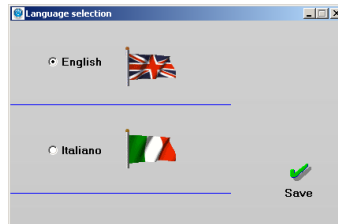
If any change has been done, click on “Update” to make the changes effective, while clicking on “Cancel” the values previously saved won’t be changed.

The next menu is the “Options” one:



From this menu the following functions may be accessed:

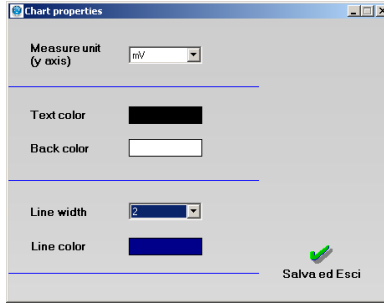
- “Language selection” to choose between Italian and English.  
Select this command to call up the window in the figure:



Click on “Save” and restart the programme to make the changes effective, or close this windows to come back to the previous screen.

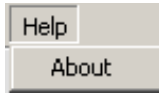
- “Chart properties” to set the visualization parameters of the graphs of the acquired EMG signals and in particular the abscissa unit of measure and the text, background and line color and the line tight.

From this menu voice the following windows may be accessed:

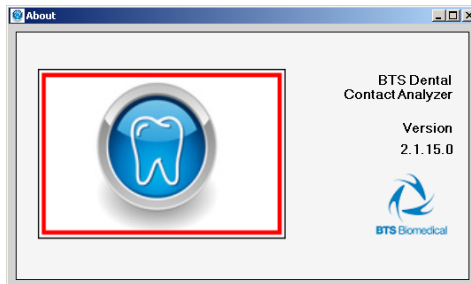


Click on “Save and Exit” to make the changes effective, or close this windows to come back to the previous screen.

The last voice is the “Help” menu:



From this menu may be selected the voice “About” that supplies the software version number:





To close this windows and come back to the previous screen, just click on the top right hand corner cross.

### Tool bar



The tool bar provides rapid access to the most used functions:

- “New Patient” to insert a new patient in the Database.
- “New Session” to add a session to a patient already in the Database.
- “New Trial” to manage the acquisition or import of a trial in an existing session.
- “Edit Patient” to correct details about a patient.
- “Edit Session” to modify the information associated with a session.
- “Remove Trial” to eliminate the selected trial. A confirmation is required before proceeding with the operation.



The deleted trial is moved to the recycle bin.

- “Exit” to leave the programme.

### Probes status bar

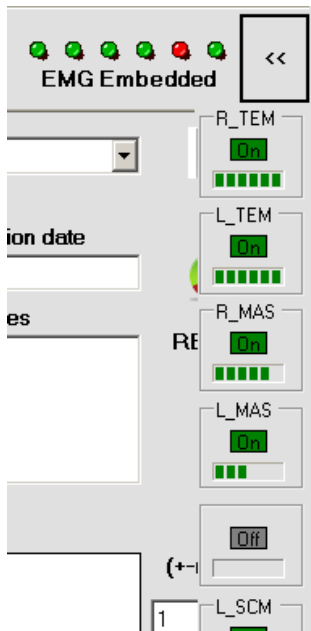
The probes status bar, located in the top right hand area of the main screen, allows knowing immediately at any time the connection status of the 4 or 6 supplied probes.



The LED can appear:

- blinking GREEN if the probe is active;
- blinking RED if the probe is not active;
- GRAY if the probe is not enabled.

It is also possible to know the active probes battery status by clicking on the button marked by the symbol ">>":



### Patient list and research filter

On the left side of the screen there is the area to manage the patients inserted in the database.

At the software startup, it appears empty:



By opening the drop box menu marked with the red ellipse, a list of all the patients inserted in the Database will appear.

Each patient is identified by a surname, first name and if available among the patient data, by his or her internal code.

The patients are ordered, according to the alphanumeric characters, respect the field indicated in the drop box menu “Search for”, in the

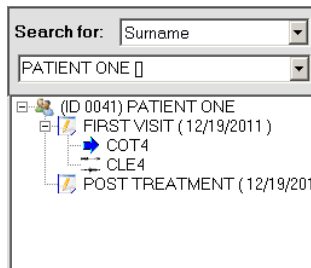
example “Surname”.

It is possible to search for the patient via “Surname” or “Internal Code”.

When the number of patient included in the database is high, it is possible to use a search filter to restrict the number of patients displayed in the drop box menu.

To do that, select the search criteria to be used between the two voice of the drop box menu “Search for” (“Surname” and “Internal Code”) and type in the underlying white box the letters or the numbers to be used as filter (i.e. if you are looking for the patient “JOHN SMITH” you have to select the “Surname” search criteria and type the letters “S”, “M”...).

Once selected a patient from the list, it will be loaded in the underlying area, and all his sessions and trials will be available for the elaboration organized in tree structure.



Click the “+” symbol to expand the patient node and access the list of the sessions for that patient. Expanding the session node obtains the list of the trials for that session.

If a patient or a session doesn't have the “+” symbol it doesn't contain any

data.

To compact the list and hide the trials or the sessions click the “-” symbol.

When the node is selected, the node icon is substituted by an azure arrow. In this way the patient, the session, or the selected trial, can always be identified..

Besides the name of the patient there is an ID number that is a code assigned automatically by the software to the patient and cannot be changed. It identify all the data related to this patient saved in the PC.

If the file is not physically present in the current data folder, the icon alongside the node is cancelled with a cross



The information continues to be present in the database, but it is not possible to use them.

When a node is selected to which data is no longer associated, the arrow appears within a prohibited symbol.

The icon of a full recycle bin at the bottom on the right indicates that there are data (patients, sessions or trials) which have been deleted but can be recovered.

To recover them double click the full recycle bin symbol to access the deleted files.

The empty recycle bin symbol indicates that there are no files which can be recovered.

## Patient, session and trial information

In the bottom left hand corner area of the main screen there are the information of the selected patient, session and trial.

There are two main panels:

- the first one contains the information related to the patient that are:

- “Name”
- “Surname”
- “Birthdate”

Click the “More patient information” button to open a table which records all the information related to that patient: :

| Patient                          |            | Patient information |         |
|----------------------------------|------------|---------------------|---------|
| <b>Name</b>                      | ONE        | Tex ID              |         |
| <b>Surname</b>                   | PATIENT    | Internal code       |         |
| <b>Birthdate</b>                 | 12/19/1977 | Clinician           |         |
| <b>Close patient information</b> |            | Age                 | 34      |
|                                  |            | Sex                 | M       |
|                                  |            | Patient note        | MYNOTES |
|                                  |            | Address             |         |
|                                  |            | Town                |         |
|                                  |            | ZIP Code            |         |
|                                  |            | Country             |         |
|                                  |            | Telephone number    |         |

To close the table click the “Close patient information” button.

- The second one contains information related to the trial and in particular:

- “Acquisition date”;
- “Trial notes (max 255)”.

This last field can be updated by editing the notes field and clicking the “Save” icon.

It is also possible to visualize the information of the session that contains the selected trial by clicking on “Session information”.

| Trial  |            | Session information  |         |
|--|------------|----------------------|---------|
| Acquisition date   | 12/19/2011 | Pathology            | HEALTHY |
| Trial notes (max 255)  |            | Session notes        |         |
| <div style="border: 1px solid gray; height: 20px; width: 100%;"></div> <div style="text-align: right; margin-top: 5px;">  Save                 </div> |            | Previous treatments: |         |
|  |            |                      |         |
| Close session information  |            |                      |         |

“Close session information” close the panel.

#### Trial viewing and report generation area

The trial viewing and report generation area is made of the following panels:

- “Patient reports”: consists of a drop box menu containing all the saved report of the selected patient.

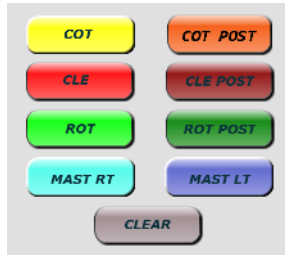
After selecting a report from the drop box menu the “Open” button became active.

By clicking the “Open” button the application for the PDF reading will be loaded and the selected report will be visualized.

- “Trial to process”: this panel contains all the trials among whom selected the trials for the report generation.

To insert a trial in the “Trial to process” panel is enough a double-click on the trial from the tree of the selected patient and it will be added immediately to the trial list.

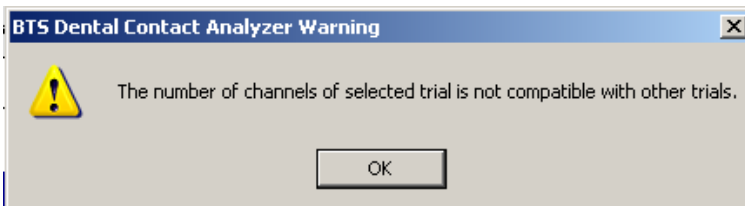
To proceed with the report generation, it is necessary to identify the type of trial by using the 8 button at the left of the panel:



The software will automatically assign a typology among “COT”, “CLE”, “ROT”, “MASTDx”, “MASTSx”, to each trial loaded. The “POST” label will be assigned to the second trial of the same type loaded, while all other trials of this typology loaded after won't be labeled.

If the type that you are trying to assign to a trial is not compatible with it a warning message will be displayed.

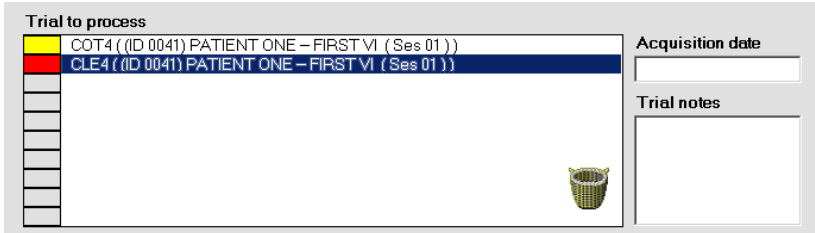
For example:



! Before to proceed with the report generation verify that the type assigned to each trial is correct, otherwise modify it by selecting the trial from the list and clicking on the right button.



To facilitate the procedure of classification, when one trial is selected the “Acquisition date” and any “Trial notes” are displayed on the right side of the panel:



To remove a label from a trial in the list, select it and click on “CLEAR”.

To remove all the trial from the panel “Trial to process” is enough to click on the recycled bin icon.

Once the trial labeling procedure has been properly executed it is possible to create the report by clicking the “REPORT” button:

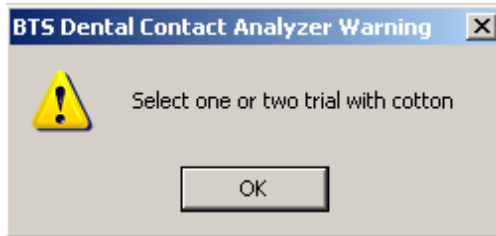


The report could be created only if:

- at least one “COT” type trial and one “CLE” trial have been loaded;
- a “MASTDx” and/or “MASTsX” type trial have been loaded.

If at least one of these two condition is not verified a warning

message will be displayed. For example:

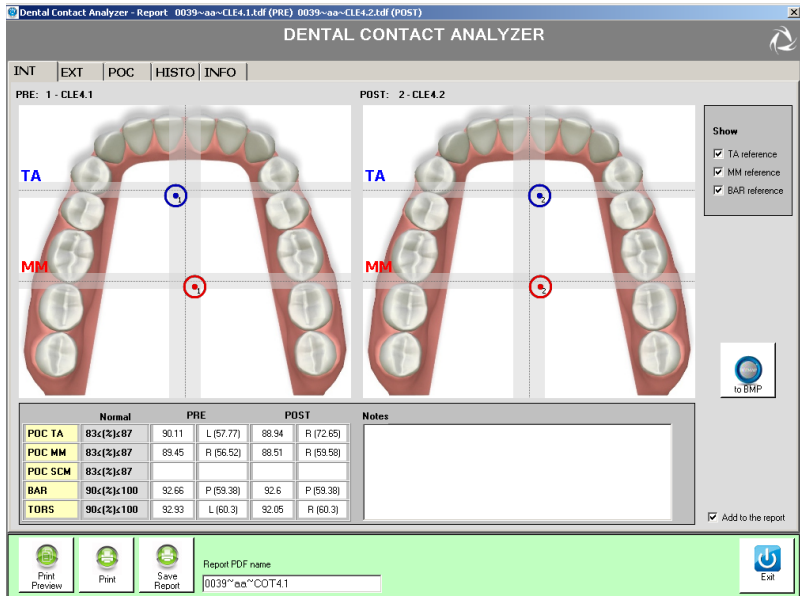


! When a PRE-POST report must be created it is possible to use two different trials of cotton type labeled as “COT” and “COT POST”(typically when we need to compare trials acquired in different days), or to use just on “COT” type trial that will be used to normalize both the “CLE” trial and the “CLE POST” trial (typically when we need to compare trials acquired the same day, without modify the position of the electrodes, such as clench test executed with and without bite).

! Only the trials witch have been marked with a color correspondent to one of the 8 trial typologies, among all the trial present in the list “Trial to processed” will be used to construct the report.

If all the operation have been executed correctly the window for the report management will be displayed. From that window it is possible to select all the element to be inserted in the report. There will be also the button to open the print preview, to launch the print or to save the report in the database to recall it in a second time.

The windows is divided in two area:



- the main area shows, organized in TABS, the graphs, the tables and the info that can be inserted in the report.
  - the button bar contains the “Print preview”, “Print” and “Save Report” buttons, the field “report PDF name” in witch is visualized the report name automatically assigned by the software (this name can be modified by the user before to click on “Save Report”), finally there is the “Exit” button to come back to the main screen of the software.
- “Preview of selected trial”: in this panel in shown a preview of the Trial selected in the panel “Trial to process”.

The screenshot displays the software interface for patient reports and trial selection. At the top left, under "Patient reports", there are buttons for COT, COT POST, CLE, CLE POST, ROT, ROT POST, MAST RT, and MAST LT, along with a CLEAR button. The "Trial to process" section shows a list of trials: COT4 ((ID 0041) PATIENT ONE - FIRST VI ( Ses 01 )) and CLE4 ((ID 0041) PATIENT ONE - FIRST VI ( Ses 01 )). To the right, there are fields for "Acquisition date" and "Trial notes", and a REPORT button. Below this is a "Preview of selected trial" section with four sub-plots: "Right Temporalis", "Left Temporalis", "Right Masseter", and "Left Masseter". Each plot shows a blue waveform over a 5-second period with a y-axis ranging from -1.00 to 1.00. To the right of the plots is a dropdown menu labeled "(+mV)" with the value "1" selected. The BTS Biomedical logo is in the bottom right corner.

The scale of the y-axis can be modified selecting the maximum value to be visualized among the value of the drop box menu “(+mV)” placed at the right of the panel.

## main features of the BTS DCA software

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### New patient

Select “New Patient” from the menu and tool bar to open the window below:



The screenshot shows a 'New Patient' dialog box with the following fields and controls:

- Name \***: Text input field.
- Surname \***: Text input field.
- Birth date \***: Date picker showing 12/19/2011.
- Sex \***: Radio buttons for Male and Female.
- Tax ID**: Text input field.
- Clinicia**: Text input field.
- Internal code**: Text input field.
- Address (Street, Room...)**: Text input field.
- Town**: Text input field.
- ZIP Code**: Text input field.
- Country**: Text input field.
- Telephone number**: Text input field.
- Notes (max 255)**: Text area.
- Import patient**: Button with a green checkmark and a person icon.
- Add patient**: Button with a green checkmark and a pencil icon.
- Cancel**: Button with a red X icon.

To insert a new patient simply fill in the fields and click “Add Patient”.



The fields marked with an \* are mandatory.

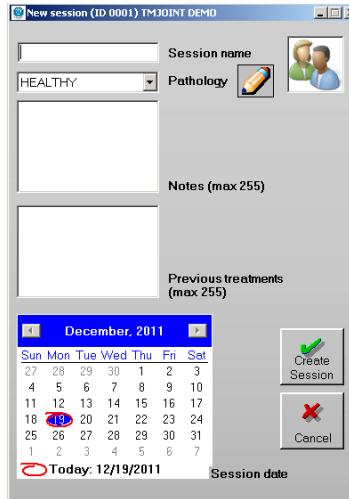
Click on “Cancel” to come back to the previous screen.



Any inserted data will be lost.

## New session

Select “New Session” from the menu and tool bar to open the window below:



Session name

HEALTHY Pathology

Notes (max 255)

Previous treatments (max 255)

December, 2011

| Sun | Mon | Tue | Wed | Thu | Fri | Sat |
|-----|-----|-----|-----|-----|-----|-----|
| 27  | 28  | 29  | 30  | 1   | 2   | 3   |
| 4   | 5   | 6   | 7   | 8   | 9   | 10  |
| 11  | 12  | 13  | 14  | 15  | 16  | 17  |
| 18  | 19  | 20  | 21  | 22  | 23  | 24  |
| 25  | 26  | 27  | 28  | 29  | 30  | 31  |
| 1   | 2   | 3   | 4   | 5   | 6   | 7   |

Today: 12/19/2011 Session date

Create Session

Cancel

To create a new session simply fill in the fields and click “Create Session”.

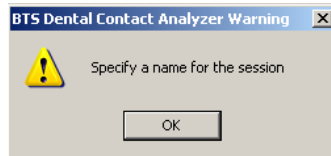
In particular it is required to:

- give a name to the session to be created.




This field is mandatory.

To proceed with the creation of the session the session name must be inserted otherwise the following warning message will be displayed:



- select the pathology among the voices available in the drop box menu (automatically the first voice of the list respect the alphabetic order will be proposed).



the list of pathologies is completed entirely by the user. To add, eliminate or modify a pathology from the list click the  icon, to access the “Edit pathology” window.



At the first use of the software the pathology list will be empty. It is necessary to insert at least one pathology to proceed with the session creation.

- insert any Note about the session (field not mandatory).
- indicate any previous treatment of the patient.




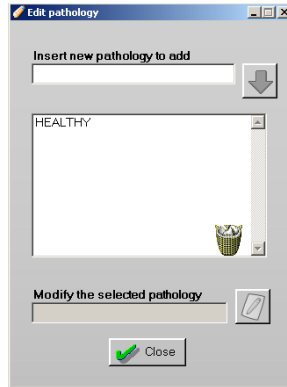
For both these fields there are 255 characters available.

- modify the session date (if different from the date of the actual day proposed as default).

To delete the session creation and come back to the previous screen click on the button “Cancel”.

## Edit Pathology

From the “New Session” window, click the  symbol to open the pathology list.



In the central panel all the pathology already inserted in the database are listed in alphabetic order.

To add a new pathology write the name of the pathology in the field “Insert new pathology to add” and click the blue arrow to add the pathology to the list.

To change a pathology:

- Select the pathology from the list. The name is shown in the field “Modify the selected pathology”.
- Modify the name of the pathology
- Click the icon alongside to apply the change to the list.

To delete a pathology:

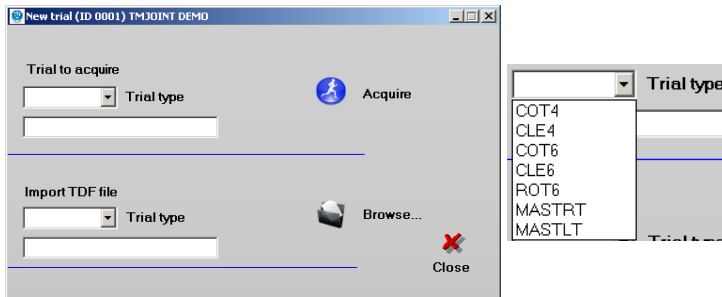


- Select the pathology to be deleted
- Click on the recycle bin icon
- Confirm the deletion of the trial by clicking “Yes”.

To exit from the window “Edit pathology” click on “Close”.

### New Trial

Select “New Trial” from the menu and tool bar to open the following window:



To create a new trial it is possible to make an acquisition or to import a trial acquired in the past.

In any case it is necessary to select a “Type” among the voices proposed in the drop box menu for the trial to be created.

Fill the fields relative to “Trial to acquire” if you want to proceed with an acquisition, or fill the fields relative to “Import TDF file” if instead you want to import a trial acquired in the past.

7 typologies of test are allowed:

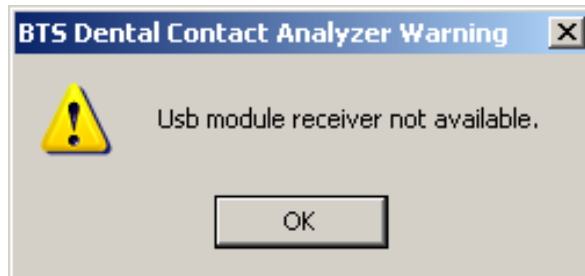
- **COT4**: requires the use of 4 probes placed on the temporal and masseter muscles. To the subject it is required to perform a clenching of 5 seconds with two cotton roll interplaced between the two arches, one for each side.
- **CLE4**: requires the use of 4 probes placed on the temporal and masseter muscles. To the subject it is required to perform a clenching of 5 seconds.
- **COT6**: requires the use of 6 probes placed on the temporal, masseter and sternocleidomastoid muscles. To the subject it is required to perform a clenching of 5 seconds with two cotton roll interplaced between the two arches, one for each side.
- **CLE6**: requires the use of 6 probes placed on the temporal, masseter and sternocleidomastoid muscles. To the subject it is required to perform a clenching of 5 seconds.
- **ROT6**: requires the use of 6 probes placed on the temporal, masseter and sternocleidomastoid muscles. To the subject it is required to perform a series of head rotations.
- **MASTRT**: requires the use of 4 probes placed on the temporal and masseter muscles. To the subject it is required to chew for 15 seconds on the right side.
- **MASTLT**: requires the use of 4 probes placed on the temporal and masseter muscles. To the subject it is required to chew for 15 seconds on the left side.

Once all the fields have been filled in, click respectively on “Acquire” to start the process of acquisition (see next chapter), or on “Browse...” to select the trial to be imported directly from Windows Explorer on your PC.



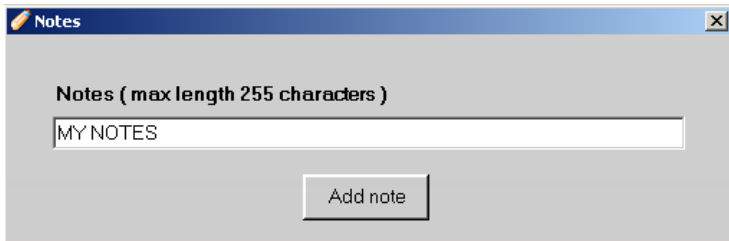
Before clicking on “Acquire”, ensure that the receiving unit is connected to the PC via USB and check the status of the probes from the probes status bar of the probes.

If an acquisition is launched when the receiver is not connected to the PC, the following warning message will be displayed:



When a trial is imported the user can enter some notes that will be saved in the database.

After selecting the test to be imported the following window will appear:



Edit the notes and click “Add note” or, if you don’t want to enter any notes

simply close the window.

The procedure for trial acquisition or import can be repeated several times to add more trials to the same session.

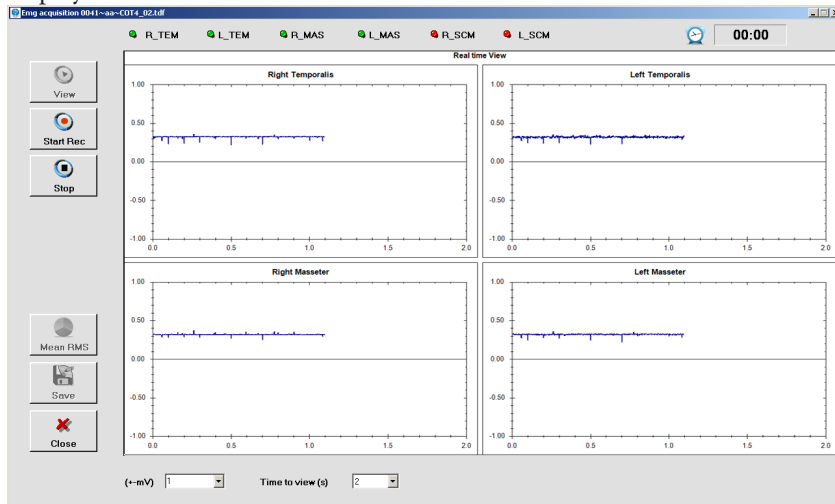


Note that the system doesn't allow for two tests with the same name under the same session.

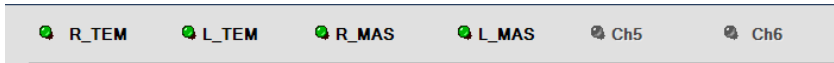
Once all the required trial were acquired or imported, click “Close” to return to the main screen.

## Data acquisition

By clicking on “Acquire” from “New Trial” the following screen will be displayed:



On the top bar is shown the six probes status:



Information displayed are referred in sequence to probes number 1, 2, 3, 4, 5, and 6 starting from left going to right.

For each probe there are a status LED and an identification label.

The status LED beside each channel can be:

- GREEN: if the probe is active;
- RED: if the probe is not active;
- GREY: if the probe is not allowed for the system.

The identification label is linked to the muscle is acquired with that specific probe:

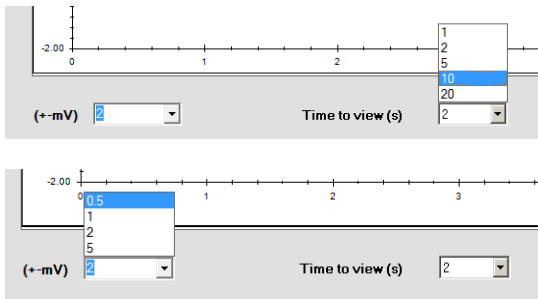
- R\_TEM for the right temporal muscle,
- L\_TEM for the left temporal muscle,
- R\_MAS for the right masseter muscle,
- L\_MAS for the left masseter muscle,
- R\_SCMCL for the right sternocleidomastoid long head muscle,
- L\_SCMCL for the left sternocleidomastoid long head muscle.

In case of inactive probes, the label is usually Ch1, Ch2, Ch3, Ch4, Ch5, Ch6.

On the central area of the screen the real-time oscilloscope will show the signals coming from the probes. There will be displayed 4 or 6 channels depending on the protocol chosen:

The oscilloscope allows to verify the correct probes positioning before starting the real acquisition and to verify the proper movement execution required to the patient.

For a better signals visualization it is possible to modify the axis scales clicking on the drop down menu on the bottom:



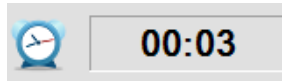
To start the acquisition all probes required in the selected trial's protocol have to be active. Before proceeding with the next steps verify that all the LED corresponding to the probes required by the Protocol are green.

When everything is ready, click on "Record" to start recording the trial.



In clenching trials, with or without cotton rolls, and in chewing tests it is better to start the acquisition just after the patient has already start to perform the movement required from the protocol.

When the acquisition starts, the "Timer" on the right top of the screen starts.



The clenching trials CLE4, COT4, CLE6 and COT6 stop automatically after 5 seconds, while chewing trials MASTRT and MASTLT stop after 15 seconds.

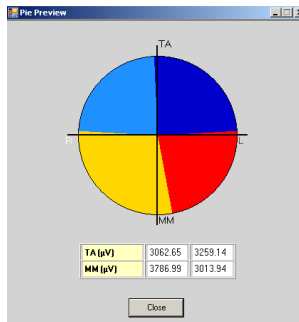
By the way it is possible to interrupt before the record clicking on “Stop”.

The acquisition of the rotation trial ROT6 has to be interrupted manually clicking on “Stop” when the subject executed all the movements required.

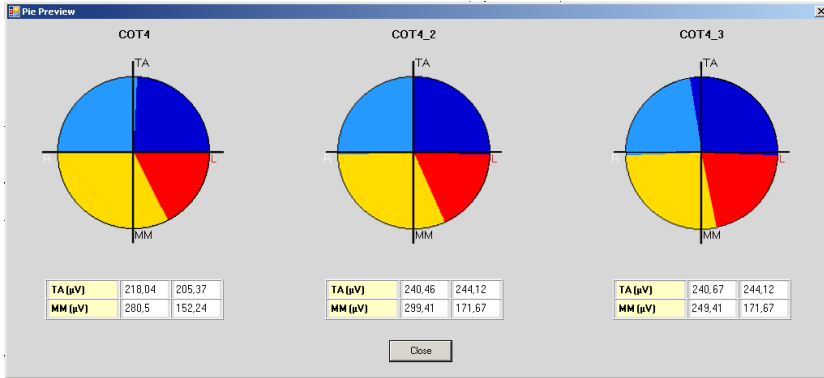
At the end of the trial data will be automatically downloaded, when this will be complete a signals acquired preview will be shown.

It is possible to modify the visualization range to zoom in the signal to evaluate that the trial has been performed properly before save it.

For clenching trials, (COT and CLE) at the end of each acquisition, it is possible to visualize a preview of the pie chart related to the RMS mean value clicking on the correct button:

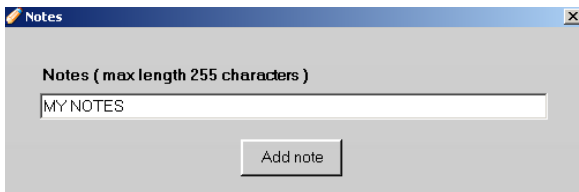


If more than one acquisition of clenching trials has been performed, besides the pie chart of the current trial, there will be also displayed pie charts of the previous ones (up to two) to allow the verification of the data repeatability:



If the acquisition is good it is possible to save the trial clicking on “Save”.

A window will appear to add, if necessary, notes related to the trial:



After edited the notes, click on “Add note” while if notes are not required just close the window.

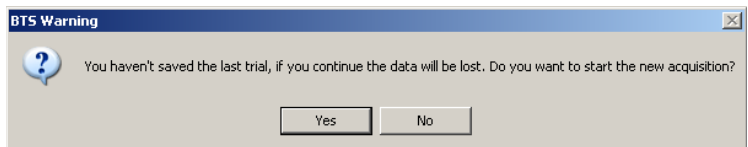
Once this operation is done the “New Trial” window will appear again.



If the trial just acquired is not good enough to be saved, it is possible to proceed with a new acquisition. To do that click on “View” to restart the real-time oscilloscope and repeat the recording procedure.

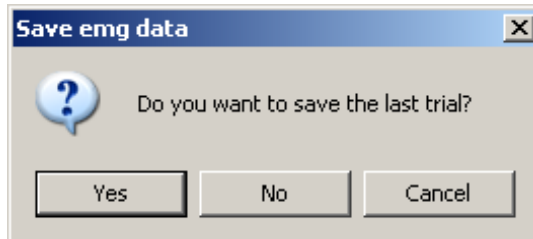


Data just acquired are not going to be recovered, for that reason a window will ask a confirmation about choosing not to save the last acquisition:



Finally, to exit from the acquisition and go back to the “New Trial” section, click on “Exit”.

If the last trial has not been saved, the following screen will appear:



Clicking on “Yes” data will be stored, clicking on “No” the acquisition window will be closed and last trial data will be canceled, finally clicking on “Cancel” you go back to the acquisition screen.

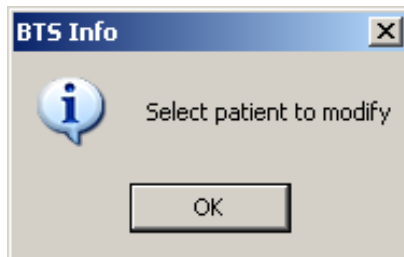
## Edit patient

Select “Edit patient” from the menu and tool bar to open the following window:

The 'Edit patient' window is a standard Windows-style dialog box. It features a title bar with the text 'Edit patient' and a close button. The main area is divided into two columns. The left column contains a dropdown menu with 'ONE' selected, a text field with 'PATIENT', a date field with '12/19/1977', radio buttons for 'Male' and 'Female', several empty text fields, and a 'MY NOTES' text area. The right column contains labels for 'Name \*', 'Surname \*', 'Birth date \*', 'Sex \*', 'Tax ID', 'Clinica', 'Internal code', 'Address (Street, Room.)', 'Town', 'ZIP Code', 'Country', and 'Telephone number'. Below these fields are two buttons: 'Update patient' with a green checkmark icon and 'Cancel' with a red X icon. A 'Notes (max 255)' label is at the bottom right.



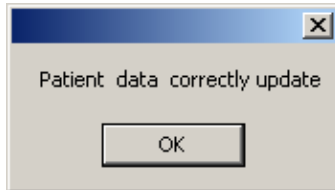
Note that to do this a patient must be selected in the database, otherwise the following warning message will appear:



The “Edit patient” window will show all the selected patient data previously entered. It is possible to modify them or add new ones.

When all changes have been made click on “Update patient” to save the new data in the database.

Se l'operazione è andata a buon fine comparirà la seguente finestra:



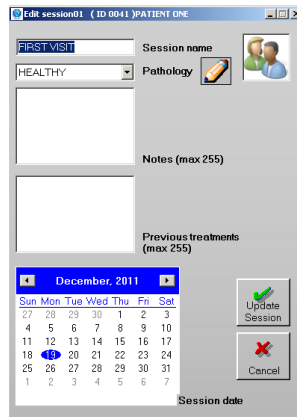
Finally, to exit without making any changes to the data click on “Cancel”.



Any change made will be lost.

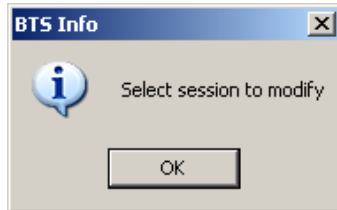
### Edit session

Select “Edit Session” from the menu and tool bar to open the following window:





Note that to do this a patient must be selected in the database, otherwise the following warning message will appear:



The “Edit Session” window will show all the selected patient data previously entered.

It is possible to modify them or add new ones.

When all changes have been made click on “Update Session” to save the new data in the database.

To exit without making any changes to the data click on “Cancel”.



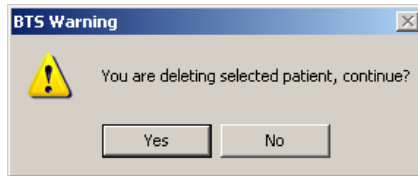
Any change made will be lost.

## Delete patient

To remove a patient from the database, select it and choose “Delete Patient” from the menu bar.

This operation will move the selected patient in the recycled bin together with all sessions and trials related to him.

A conform to the cancellation will be asked:



Note that to do this operation a patient must be selected in the database, otherwise the following warning message will appear:

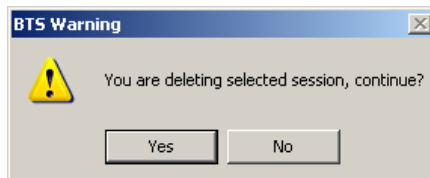


### Delete session

To remove a session from the database, select it and choose “Delete Session” from the menu bar.

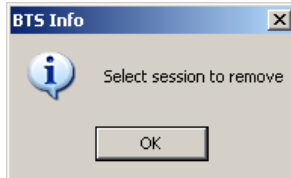
This operation will move the selected session in the recycled bin together with all the trials related to him.

A conform to the cancellation will be asked:





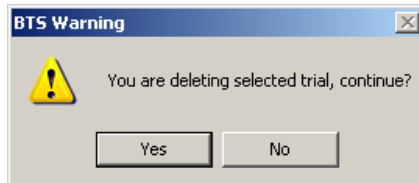
Note that to do this operation a session must be selected in the database, otherwise the following warning message will appear:



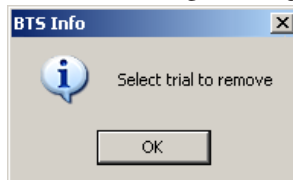
## Delete trial

To remove a trial from the database, select it and choose “Delete Trial” from the menu bar.

This operation will move the selected trial in the recycled bin.  
A conform to the cancellation will be asked:



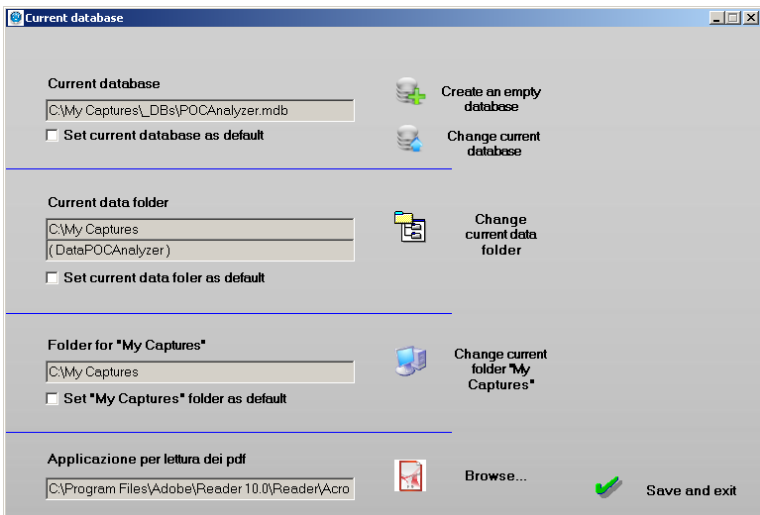
Note that to do this operation a trial must be selected in the database, otherwise the following warning message will appear:



more features of the BTS DCA software

Database and data folder

From the menu bar select the “Database” option, and then the “Database & Data folder” function to open the window below:



The field “Current database” shows the path of the database actually selected. It is possible to load another database or to create a new empty one.

To create an empty database, click the icon “Create an empty database”: a new window in which enter the name of the new database will appear. Click “Save” to create a new database. The “Current Database” field will

be updated accordingly.

To work with a different database to the default one:

- Click the icon “Change current database”
- Browse the folders and select the database desired.
- Click “open” to change the database. The “Database” field will be updated.

If you wish to use the new database as a reference, tick the option “Set current database as default”.



If this is not done, the setting will be lost when the BTS Dental Contact Analyzer is closed, and the default database will be loaded at the next launch of the program.

To change the data folder:

- Click the “Change current data folder” icon.
- Select or create the new folder.

A sub-folder will be created automatically in which the files will be saved.

The name of the subfolder is shown in brackets under “Current data folder”.

In the figure the subfolder is “DataPOCAnalyzer”.

This folder is changed automatically when the current database is changed.

Also in this case to set the new folder as the default data folder put a check in the “Set current data folder as default”.





If this is not done, the setting will be lost when the BTS Dental Contact Analyzer is closed, and the data will be saved in the default folder at the next launch of the program.

The reference My Captures folder is that which contains all the file required by the software to work properly.



It is therefore recommended to choose a new folder only with the consent of the technical staff of BTS.

To change this folder:

- Click the icon “Change current folder “My Captures””.
- Select the new reference folder (which will contain all the file required by the software to work properly)

Also in this case to set the new folder as the default data folder put a check in the “Set “My Captures” folder as default”.



If this is not done, the setting will be lost when the BTS Dental Contact Analyzer is closed, and the old “My Captures” folder will be used at the next launch of the program.

From this screen you can then select the application used to read the report in PDF format.

To select the application click on “Browse...” and select the exe file you want to use.



Please note that if no application is selected you can not see the reports.

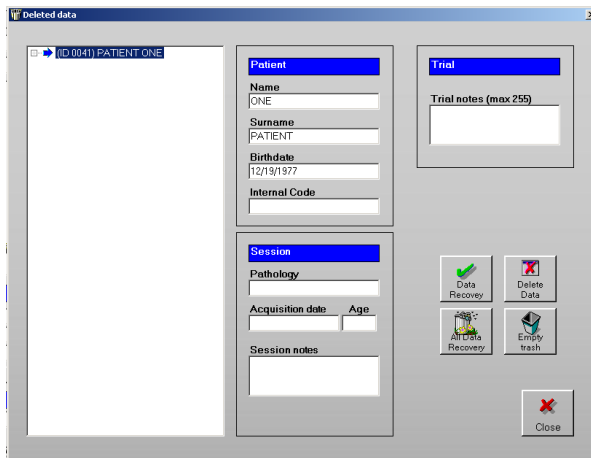
To apply the changes click “Save and exit”.

## Managing files in the recycle bin

If you wish to remove a patient, session or trial, the file is moved to the recycle bin.

To access the files held in the recycle bin, double click the icon representing the recycled bin which appears in the patient list.


The following windows will appear:



In the left side of the panel there are all the data contained in the recycled bin organized per patient with a tree structure.

By expanding the nodes it is possible to access to sessions and trials.

In the file tree the node labels may have three different colors:

- The black label indicates that the file (patient, session or trial) has been removed from the database together with all the files associated with it.
- The dark grey label and  icon indicate that the file is present in the database, but some elements associated with it have been removed (e.g. a session of a patient has been removed, or a trial from a session).
- The light grey label indicates that the file has been deleted along with the root file (e.g. a patient main file has been deleted. As a result all of the related sessions and trials have also been removed).

Selecting a node which has been removed updates the patient, session and trial information.

From the “Deleted data” window it is possible to carry out four different operations:



This button recovers the selected file.

When a session is selected all the associated trials will also be recovered. When a patient is selected all the associated sessions and trials will also be recovered.




This button eliminates the selected file permanently.

Before eliminating the file, a confirmation will be requested.

If you eliminate a file, it cannot be recovered. Eliminating a session also eliminates all the associated trials. Eliminating a patient also eliminates the associated sessions and trials.



If the button is deactivated, it means that the file is not present in the recycle bin (the  icon alongside dark grey text), or it may not be recovered individually. In this case it is necessary to select the root file.



This button recovers all the files in the recycle bin. All patients, sessions and trials will be available again in the database and the recycle bin will be empty.



This button permanently eliminates all the files in the recycle bin. A confirmation must be given for this operation.



Confirming the elimination means that the files will no longer be recoverable. At the end of this operation the recycle bin will be empty.

## guide to the report data reading

The data report is automatically generated by the software DCA. The results of the data elaborations are organized in tabs: INT, EXT, POC, ISTO and MAST.

Moreover there is an INFO tab for the customization of the printed report.

### INT tab

**DENTAL CONTACT ANALYZER**

INT | EXT | POC | HISTO | INFO

PRE: 1 - CLE4      POST: 2 - CLE4

TA      TA

MM      MM

to BMP

**Show**

- TA reference
- MM reference
- BAR reference

Add to the report

|         | Normal     | PRE                | POST               | Notes |
|---------|------------|--------------------|--------------------|-------|
| POC TA  | 83:(%)<100 | 47,16    R (76,25) | 88,95    L (66,95) |       |
| POC MM  | 83:(%)<100 | 76,71    R (53,87) | 86,76    L (60,37) |       |
| POC SCM | 83:(%)<100 |                    |                    |       |
| BAR     | 90:(%)<100 | 70,07    A (55,24) | 91,79    A (63,09) |       |
| TORS    | 90:(%)<100 | 67,55    R (70,69) | 92,28    L (53,69) |       |

Print Preview    Print    Save Report    Report PDF name: 0002~aa~COT4    Exit

The elaborated data are divided into PRE and POST sections, for the comparison of two tests of the same acquisition session, or of tests made in different temporal session. This is helpful in evaluating the treatment efficacy and for the patient follow up.

The graphic shows a dental arch, which works as a 2D morphological map, on which are superimposed icons “target” style (they will be so called in the rest of the document), positioned in order to summarize the occlusal condition, according to the calculated indices, whose values are given in the table below.

- **POC: percentage overlapping coefficient**

It is an index of the standardized contraction symmetry within the same muscular couple. It expresses, in percentage terms, the difference in electrical signal generated by a muscle couple during a maximum voluntary contraction (MVC) compared to its homologous standardized value.

If the two homologous muscles of each pair are contracted in perfect symmetry, thanks to a functionally balanced dental occlusion, the POC result is expected close to 100%.

While if muscle couples show standardized values in percentage terms different from each other, the POC turns out to be considerably less than 100%.

When the POC exceeds 83%, there is a normal muscular symmetry, induced by the contact of the teeth, otherwise, the dental contact is influencing the neuromuscular equilibrium of the patient.

With the 4-channel protocol, are calculated the POC of the anterior temporal and masseter muscles, which are respectively indicated by POC TA and POC MM, indicators of the influence of tooth contact on the

neuromuscular balance of the stomatognathic system; with 6-channel protocol, is calculated in addition the coefficient of overlapping percentage of the sternocleidomastoid muscles POC SCM, indicator of the influence of tooth contact on the cranio-cervical neuromuscular balance.

For each POC is also indicated which is the predominant muscle and in what percentage it contributes to the total level of asymmetry. In particular, the letter “R” indicates that there is a prevalence of the right muscle while the letters “L” that there is prevalence of the left one.

- POC: graphical representation

The central vertical line, dark gray, dotted, corresponds to the 100% value and the light-gray vertical band indicates the range of normality, up to the value 83%, both right and left of central line, in order to represent the prevalence of right or left muscle activity.

The blue target refers to the POC index of the anterior temporal (POC TA), while the red refers to the POC index of the masseters (POC MM).



The POC TA index corresponds to the influence of dental contacts of the incisors, canines and first premolars.

The index POC MM corresponds to the influence of dental contacts of the premolar and molar teeth.

Values of POC out of the norms indicates a quality of contact prevalent or lack of one side respect the controlateral.

The target is represented at a distance from the central vertical line corresponding to the calculated value.

If the POC value is more than 83%, the target is represented within the gray central band, while if it is lower it is represented outside the normal

range.

So it is easy to observe the predominance of the right or left temporal in the anterior quadrants, and the masseter, left or right, in the posterior quadrants.

The value of the POC SCM does not affect the targets position, but only the percentage of co-contraction of neck muscles during MVC.

- **BAR: Barycenter**

It provides an estimate of the occlusal barycenter position. It is obtained by calculating the percentage overlapping coefficient between the activities of the couple of temporal and the activities of the couple of masseter (while the POC index compares single homologous muscle).

When the contact points tend to focus on the molars, the masseters record a major contraction respect to the correspondent temporalis (Posterior barycenter).

Instead, in the occlusal condition in which the barycenter moves in the anterior-lateral areas, that means until the first-second premolar, the temporalis express major contraction forces (Anterior barycenter). In this case there is a bilateral overload of the joints that, with the passing of time, can lead to pathological conditions.

For the BAR index if the position of the barycenter is mainly anterior, there will be the letter "A", will also be indicated in what percentage the anterior temporal muscles contribute to move the barycenter upwards. Vice versa there will be the letter "P" and will also be indicated in what percentage the masseter muscles contribute to move backwards the barycenter.

- **BAR: graphical representation**

The normal value of the BAR index is  $> 90\%$ .



The two horizontal dark gray lines with dots, superimposed to dental arch, represent the BAR value equal to 100%, while the gray bands represent the normal range up to 90%.

The two targets will be translated at a distance from the relative horizontal line of a value corresponding to the BAR index calculated, upwards or downwards following the prevalence of the BAR index (anterior or posterior), according to the occlusal condition.

The value and the direction of the vertical displacement of the two target points are then exactly the same.



The BAR value in the normal population always expresses a prevalence of differential activities of the couple of masseter muscles compared to that of temporal.

This condition is reversed in the second skeletal class in which the temporal muscles always express a differential electrical activity greater than the masseter's one.

- TORS: torsion

It provides an estimate of the rotation attitude of the mandible in the horizontal plane when it is in occlusion with the superior maxilla. Is obtained from the comparison of the torque moment of the right temporal and the left masseter couple (by convention rightward torque) with the torque moment of the left temporal with the right masseter couple (by convention leftward torque).

When this index is >90%, torque moments do not occur on the mandible. On the contrary, if this index is outside of the normal ranges that means below 90%, the muscles tend to twist the lower jaw to the right or left depending on whether one or the other muscular couple prevalence, due to the presence of occlusal fulcrums.

There will be the letter “R” when there is mainly a torsion to the right, while the letters “L” when the torsion is mainly to the left. It will be also reported in what percentage the dominant couple contributes to the creation of torque.

- **TORS:** graphical representation

The resulting action of the temporalis muscle, added to the resulting strength of the contralateral masseter, generates a pair of forces with a moment which tends to laterodeviate the jaw in the direction of the resultant of the anterior temporal.

If the right is greater, the target will be not only circular, but it will report an arrow to the right.

Similarly, the arrow will be leftward if the coefficient calculated for the couple anterior temporal-right masseter is greater.



We must not think that there is a real torsion of the mandible because we are under static conditions. Any clinical condition, which can be likened to pre-contact and then to tooth contact sliding, is therefore already occurred. The TORS index expresses a condition clinically worse because detectable only using instruments, that is the presence of fulcrums.

The muscles continue to activate and inhibited themselves in the pursuit of stability. Clinically this corresponds to a contact mainly in the antero lateral area of the dental arch or to a contact qualitatively insufficient in the latero posterior sectors. It is generally associated also with temporomandibular joint problems. If associated with values of IMPACT lower than normal, it may indicate the presence of both, pain and protective mechanism to nociceptive stimulus.

• NOTE

In the “Notes” field it is possible to add a text description that the clinicians want to include in the printable report as a comment of the represented data in the INT tab.

• “Add to report” checkbox

If the check is in the box, the INT tab content will be included in the printed report, otherwise it will be ignored.

“EXT” tab

DENTAL CONTACT ANALYZER

INT EXT POC HISTO INFO

**CLE4**

|         | Value  | Normal   |
|---------|--------|----------|
| POC TA  | 47.16  | 83(2)100 |
| POC MM  | 76.71  | 83(2)100 |
| POC SCM |        | 83(2)100 |
| TORS    | 67.55  | 90(2)100 |
| ATTV    | -3.14  | -10(2)10 |
| TORQUE  | -13.43 | -10(2)10 |
| POCm    | 61.94  | 83(2)100 |
| ASIM    | 15.18  | -10(2)10 |
| CL      |        | (2)15    |
| IMP     | 268    | 85(2)115 |

| R      | TA%  | L      |
|--------|------|--------|
| 365.28 |      | 206.65 |
| 273.4  | MM%  | 263.72 |
|        | SCM% |        |

**CLE4**

|         | Value | Normal   |
|---------|-------|----------|
| POC TA  | 88.95 | 83(2)100 |
| POC MM  | 86.76 | 83(2)100 |
| POC SCM |       | 83(2)100 |
| TORS    | 92.28 | 90(2)100 |
| ATTV    | -2.15 | -10(2)10 |
| TORQUE  | 0.57  | -10(2)10 |
| POCm    | 87.86 | 83(2)100 |
| ASIM    | -3.26 | -10(2)10 |
| CL      |       | (2)15    |
| IMP     | 112   | 85(2)115 |

| R      | TA%  | L      |
|--------|------|--------|
| 110.28 |      | 118.86 |
| 106.74 | MM%  | 112.77 |
|        | SCM% |        |

Text results

Add to the report

Print Preview Print Save Report

Report PDF name  
0002~aa~COT4

Exit

In this tab are represented the ulterior calculated indices, reporting for an easier reading also the values of the coefficients already seen in the previous tab.

The referring indices are TA%, MM%, SCM%, ATTIV, TORQUE, POCm, ASIM, CL and IMP.

- TA%, MM%, SCM%

These indexes represent in percentage the standardized average value of the activity respectively of the anterior temporal muscles, masseters and sternocleidomastoids left and right.

The graphical representation includes a 3D model, for a male or female, according to the patient for whom the report relates.

The status bars represent the level of electrical intensity, measured in the muscle near which are represented.

Depending on the protocol used (4 or 6 channels), 4 or 6 bars are displayed corresponding to the anterior temporal muscles, masseters and sternocleidomastoids.

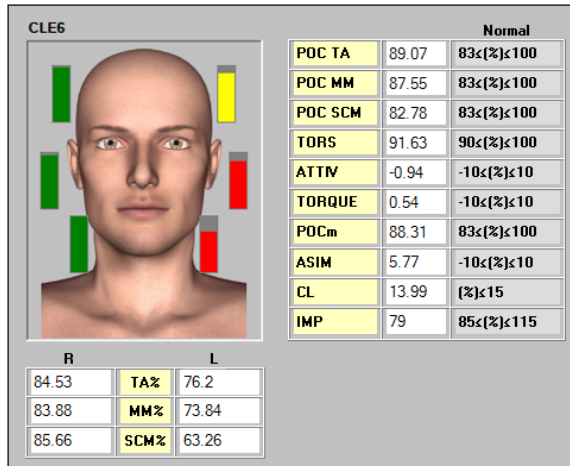
The muscle that expresses the greater amplitude value of the electric potential, percentualized, is represented with a full bar and becomes the reference scale for the bars graphical representation of the other muscles, which will be compared to.

In the example shown in the figure the right TA% is 83.57% and is the highest value of the 4. Then the bar will be represented “full” and the others will be represented in proportion according to the calculated

values: left TA% = 57.92%, right MM = 45.62%, left MM = 38.67%.

The bars can be green if the width value is greater than 83%, yellow if the amplitude is less than 83%, but above 75%, red if the width value is less than 75%.

Similar interpretation for the SCM muscle, shown in the figure below as an example.



The SCM POC is calculated only when using the POC6 protocol.

- **ATTIV:** activation

It's a parameter similar to the BAR, but computed on the average value of maximum contraction and compared to zero, instead of 100%.

Provides an estimate of the occlusal barycenter position.

It is very useful for an immediate interpretation of the biomechanics levers induced by the contact of the teeth.

When the contact points tend to focus on the molars, the masseters record a greater contraction than the corresponding temporalis and so the index takes a positive value.

In the occlusal condition in which the barycenter moves in the anterior-lateral areas, that means until the first-second premolar, the temporalis express greater contraction forces and the index becomes negative.



Normally this index is always positive except in the second skeletal class in which the index is usually negative.

For the resolution of TMJ (temporomandibular joint) acute pain problems it must be find a condition biomechanically favorable to the discharge of the forces burden on the TMJ that leads to a positivization of this index.

- **TORQUE:** mandibular torque

It's a parameter similar to the TORS, but compared to zero, instead of 100%.

The resultant force of the action of the temporalis muscle, added to the resultant force of the controlateral masseter, generates a force couple. The moment of this couple tends to laterodeviate the jaw in the direction of the resultant of the anterior temporal: if the right is greater, the torque values will be negative; while it will be positive if the left TA is predominant.

- **POCm :** medium percentage overlapping coefficient

It is simply the medium between the TA POC and the MM POC. It

represents the global POC. Also in this case the normality range is on  $\geq 83\%$  values.

- ASIM: asymmetry

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

A positive value indicates a greater activation of the right side, while a negative value indicates a greater activation of the left side. The normal range is between -10 and 10.

- CL: Cervical Load



This index is calculated only when using the protocol POC6, which includes the performance of a test of maximum rotation of the head to the right and left, in addition to the trials of clenching with and without cotton roll (thus with maximum intercuspation).

Gives the percentage of co-contraction of SCM muscle during clenching: a cervical load of 0% indicates an absence of recruitment, while a value of 100% indicates that the recruitment is maximum.

The normal values occurs at  $CL \leq 15\%$ .



Excessive values of CL indicate an excessive recruitment of neck muscles during the MVC, which may favor the persistence of clinical conditions for neck ache, especially in clencher patients.

- IMP: Impact

this index indicates the muscle work, represented geometrically by the

area under the curve of the electrical activity of muscles examined in the time.

The normal range of the index are in the range  $100\% \pm 15\%$ .



Higher values indicated that the subject should be considered a strong clencher.

Values lower than normal may express a condition of proprioceptive inhibition acute with presence of pain during MVC, or chronic with presence of a nociceptive protective reflex.

If the POC, TORS and BAR indexes are normal the IMP index is related to the vertical dimension.

In this case there are indications on the possibility of raising (index higher than normal) or reducing (index lower than normal) the vertical dimension, compatibly with the aesthetic condition of the patient.

- Outcome

It is possible to add some notes to the report. Write them in this box to put them in the printed report.

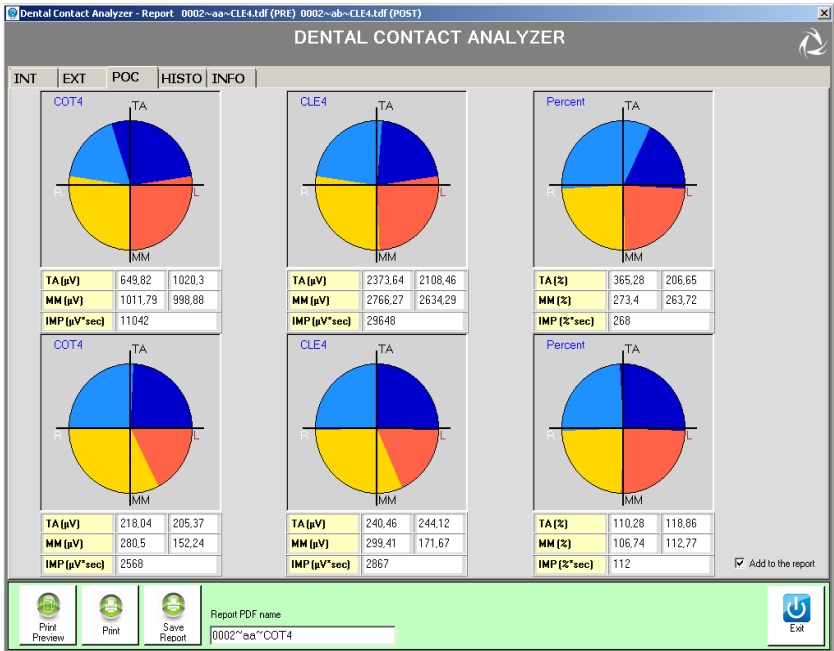
- “Add to report” Checkbox

If the check is in the box, the contents of the EXT tab will be included in the printed report, otherwise it will be ignored.

### POC tab

In this tab the average activity of the four muscles Masseter right and left and Temporal right and left, are represented by pie charts.





The first and second columns show the average activity of 4 muscles in microvolts, relative to clenching trials performed respectively with and without cottons. The third column, instead, shows the percentage value of the average activity of the 4 muscles as the ratio between the values obtained from the clenching trial without cotton and those with cotton.



In order to evaluate the occlusal state you must refer to this third column.

The dark blue sector represents the left temporal muscle activity while the

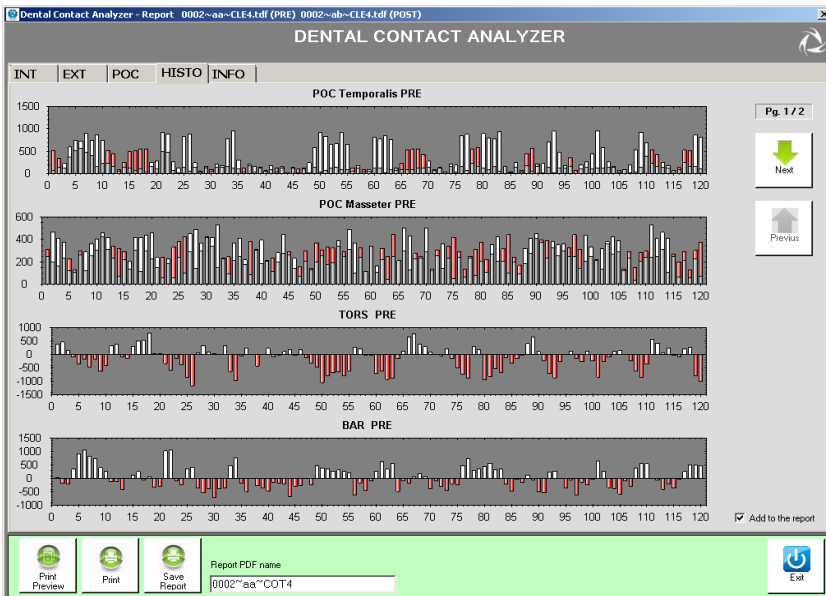
light blue sector the one of the right, the red sector represents the activity of the left masseter muscle, while the yellow of the one of right.



With a good neuromuscular balance, corresponding to the absence of malocclusion, the colors will be equally distributed in the 4 quadrants.

If you are analyzing two sessions (PRE, POST), the graphs for the second session can be visualized on a second row.

## ISTO tab



The tab “ISTO” provides an alternate view of the main indices calculated: Masseter POC, Temporal POC, Sternocleidomastoid POC (where provided 6 channels), TORS and BAR.

In the graphs of the POC the activities associated to homologous muscles are represented as histograms.

The activity of the right side (identified by white color) is compared with the activity of the left side (identified by red color): for each bar will be colored the data of the dominant muscle activity, while the contralateral muscle will be represented in gray.

The values for each bar are calculated considering the average value of muscle activity of the clenching trial normalized with respect to the clenching trial execute with cottons in an interval of 25 ms.

When the white is prevalent there is an activity of the muscle of the right side more pronounced, while when is the red to prevail, the left side is dominant.

Is then given information on a possible asymmetry of muscle.

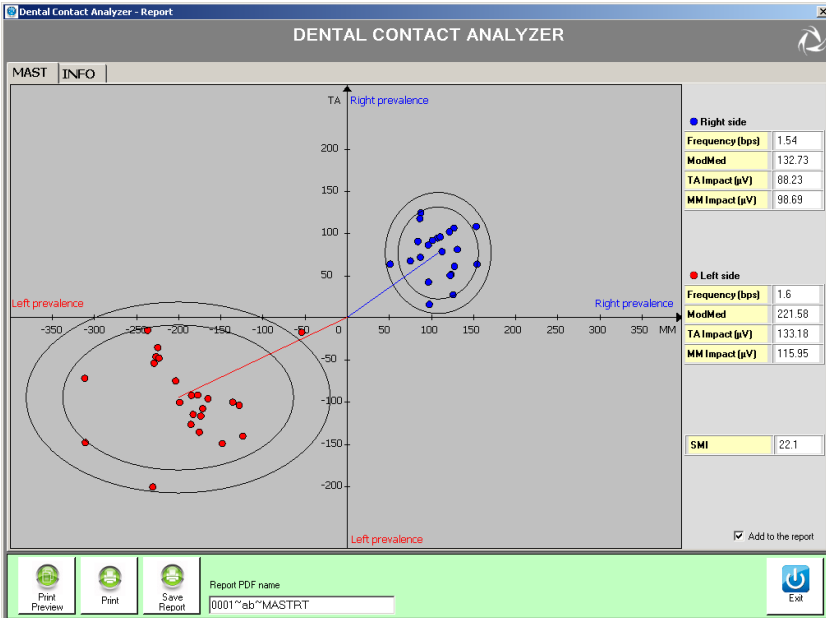
Regarding the TORS index any torsion attitudes rightward are represented with the color white, while those leftward with the color red.

Finally regarding the BAR index the white color indicates that the barycenter is moved anteriorly, while the red color, posteriorly.

If you are analyzing two sessions (PRE, POST), the graphs for the second session can be viewed by clicking on “Next”.

The “Previous” button allows returning to the charts of the first session.

MAST tab



The chewing protocol is composed of two separate trials, of 15 seconds each, in which the patient must chew a chewing gum holding it, for the entire duration of the test, on one side only.

Produces, as a result, a graph about the coordination of masticatory muscles TA and MM: while, therefore, with the POC and the evaluation of the clenching, we evaluate the neuromuscular balance (Static condition), with the mastication protocol we evaluate the neuromuscular coordination (Dynamic condition), by analyzing the repeatability of the muscular patterns.

The ideal situation, corresponding to a good level of chewing coordination, is when the two ellipses of confidence are equidistant from the origin and present reduced dimensions.

In addition to the graphical representation, some numerical indexes are calculated, for left and right side of chewing:

- Frequency (bps)

It is the number of masticatory acts per second.

- ModMed

It is the distance from the center of the graph and the center of the ellipse of representation.

- TA Impact (uV)

It is an index of the work done by the anterior temporal muscles during the test.

- MM Impact (uV)

It is an index of the work done by the masseter muscles during the test.

- SMI: Index of chewing symmetry.

It is a unique index, not differentiated by side. The ideal is a value of about 50%.

Dental contact analyzer allows processing also a single test: in this case will be represented a single ellipse for the side “measured”. The index SMI, in this case, will not be calculated.

## INFO tab

Dental Contact Analyzer - Report: 0039-aa~CLE4.1.tdf (PRE) 0039-aa~CLE4.2.tdf (POST)

DENTAL CONTACT ANALYZER

INT | EXT | POC | HISTO | INFO

Company Name:

Address:

Phone:

Website:

Logo:  None

Load info Update info

Ver. 2.1.15.0

Print Preview Print Save Report Report PDF name:  Exit

This tab allows you to enter data to customize the report and upload your own logo if desired.

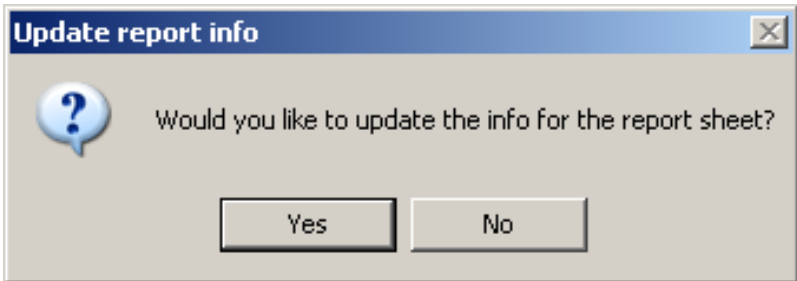
To do this, complete the fields of interest and click on “Browse” to select the image of your logo directly from your PC or put a check next to “None” if you do not want to use this option.

Once you have completed entering the info you need to click on “Modify Info” to ensure that data is stored and included in the report. At first use, the fields are empty.

Saving the data they will be automatically loaded at the next opening.

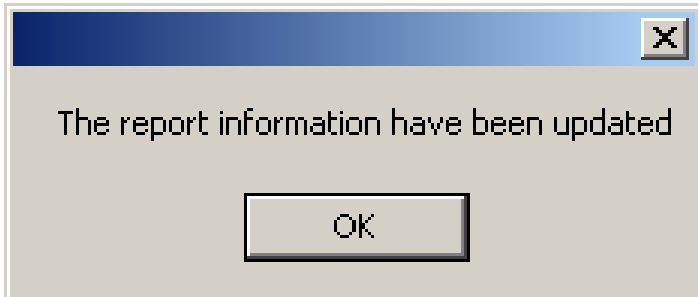
It is possible to make further changes to the saved data.

To save these changes it is necessary to click on “Modify info”. The following windows will appear:



Clicking on “Yes” to report information will be updated and will no longer be possible to recover previous data.

If the operation has been successful you will see the following screen:



If you do not want to save the changes click on “Upload Info” to reload the last save.





## appendix A

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### technical specifications

#### Wireless Probes

|                        |   |
|------------------------|---|
| Geometry:              | variable  |
| Electrodes:            | standard with clip connection                                       |
| Separation:            | min: 16mm - max: 66mm   |
| Autonomy:              | 5h of use<br>some days stand-by                                     |
| Battery:               | rechargeable, lithium ion   |
| Dimensions:            | 17x36x8mm mother electrode<br>diameter 17 x 8mm satellite electrode |
| Weight:                | <9g battery included  |
| Frequency used:        | ISM band<br>2.4GHz (standard IEEE802.15.4)                          |
| Input impedance:       | >10 GOhm  |
| CMMR:                  | >110 dB @ 50-60Hz   |
| Resolution:            | 16bit   |
| Acquisition frequency: | up to 4KHz  |
| Sensitivity:           | 1 $\mu$ V   |
| Measure accuracy*:     | $\pm$ 2%  |

#### Receiving Unit

|                 |              |
|-----------------|--------------|
| Connection:     | USB          |
| Dimensions:     | 82x44x22,5mm |
| Weight:         | 80 gr        |
| Frequency used: | ISM band     |

2.4GHz (standard IEEE802.15.4)

\* The system is calibrated at the factory. No further calibration is required

## appendix B environmental specifications

|                                   | <b>Min</b> | <b>Max</b> | <b>Note</b>                 |
|-----------------------------------|------------|------------|-----------------------------|
| Operating Temperature             | -20°       | +45°       |                             |
| Operating Humidity                | 50%        | 80%        | Relative,<br>non-condensing |
| Storage and Transport Temperature | 0°         | +40°       |                             |
| Storage and Transport Humidity    | 50%        | 80%        | Relative,<br>non-condensing |
| Altitude                          | 0m         | 2000m      |                             |

Degrees of protection provided by the dangerous enclosures of water and dust (IEC 60529): IPX0.

## appendix C

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### power supply and switch off

The receiving unit is powered by the USB port.

To switch off the system the following operation must be done:

- Exit from the DCA application
- Unplug the receiving unit from the USB port.
- Put the probes in Stand-By placing them on the “Charger”.

BTS TMJOINT probes are internally powered.



The Probe battery replacement can be done only by BTS qualified personnel.

The probes are sealed to avoid the access to the internal circuit components.

Batteries are equipped with battery protection circuit to:

- over-voltage, threshold 4.3V
- under-voltage, threshold 2.8V
- short-circuits

The specific characteristic of the Wireless probes equipped with the battery are:

|             |                                       |
|-------------|---------------------------------------|
| Quantity:   | 1 per each EMG probe                  |
| Technology: | lithium polymer (Li-Poly)             |
| Removable:  | NO, BTS technical service is required |

## appendix E

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### troubleshooting guide

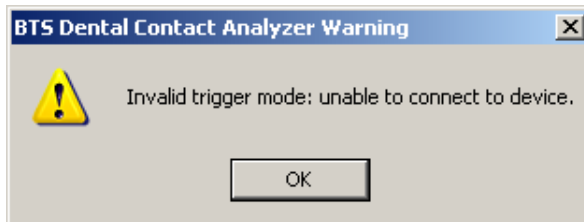
#### Warning – Invalid trigger mode

During the hardware installation, the USB port dedicated to the receiver, is configured.

May happen that these port settings went lost.

This event may occur for example when another USB device is connected to the PC and the PC assigns to it the same port previously assigned to the receiver, returning the port setting to the default configuration.

In these cases it may occur that by launching an acquisition the following warning message may appear:



In this case to proceed immediately with the acquisition, it is necessary to restart the application, however the same problem will recur in later acquisitions.

To resolve this problem you must repeat the USB port configuration procedure described in the “Hardware Installation” paragraph of the “Installation” chapter.

## appendix F declaration of conformity



**BTS Bioengineering**



DECLARATION OF CONFORMITY

**BTS SpA**  
Via della Croce Rossa 11, 35129 Padova (PD) - Italy  
Tel. +39 049 981 5500 Fax +39 049 792 9260

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

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

satisfies the essential requirements of the **Medical Devices Directive 93/42/EC** (and its amendments including 2007/47/CE), and therefore carries the CE marking of the European Union. The conformity assessment procedure is according to the article 11 of the directive (Annex 11.3 full quality assurance) and the article 12 it is not applicable.

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

In accordance with IEC 60601-1 is also classified as follows:  
Class: **internally powered device** Applied part type: **BF**

The product conforms to the following standards:

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

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

Notified Body : **TÜV Product Service GmbH, Zertifizierstelle, Ridlerstrasse 65, 80339 München – Germany**, Identification N. 0123.  
EC certificate N. **G1 12 10 65301 003** valid until January, 16 2018.

Padova, Date

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CEO  
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## appendix G

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