

BTS FREEEMG 300



user manual

english
version 4.0.3

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icons, symbols and acronyms



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:

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



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.



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.

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.



0123

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).



0051

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:

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:

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.

Rx ONLY

Symbol on the equipment:

The symbol indicates that U.S. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Acronyms used in this manual:

AP	Access Point	PDA	Personal Digital Assistant
AU	Acquisition Unit	RU	Receiving Unit
EMG	Electromyography	SW	Workstation
FSW	Footswitch		

radio regulation

Radio equipment identification:

- EMG probes:

FCC ID: YQH-BTSWEMG2

IC: 9188A-BTSWEMG2

- FSWEGN probes:

FCC ID: YQH-BTSWAUX

IC: 9188A-BTSWAUX

- Acquisition 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.

intended use

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).

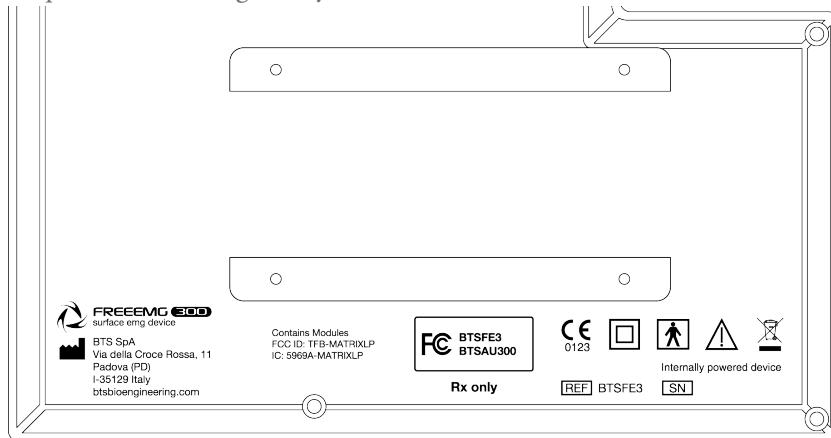
The BTS FREEEMG 300 must always be used only for this purpose, by qualified persons, in an environment suitable for the execution of EMG analyses and respecting the prevailing regulations in the countries in which it is being utilized.



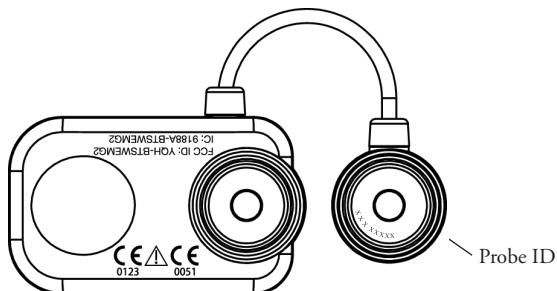
U.S. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

regulatory label

Acquisition Unit Regulatory label



EMG Wireless Probes Regulatory label
Label on the probes:



regulatory label

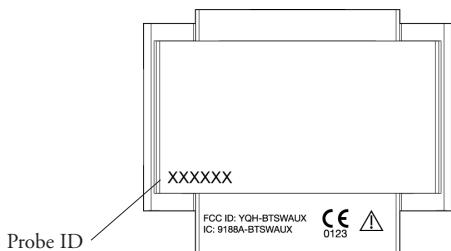
BTS FREEEMG 300

Label not on actual probes due to size constraints:

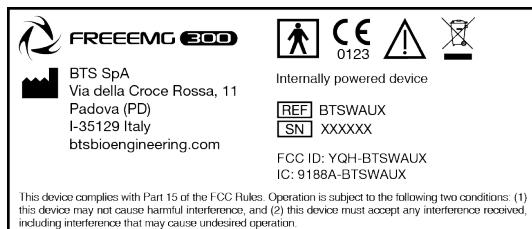


AUX Wireless Probes Regulatory label

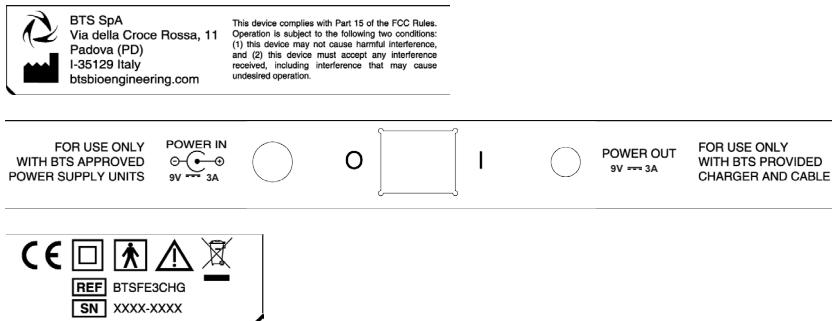
Label on the probes:



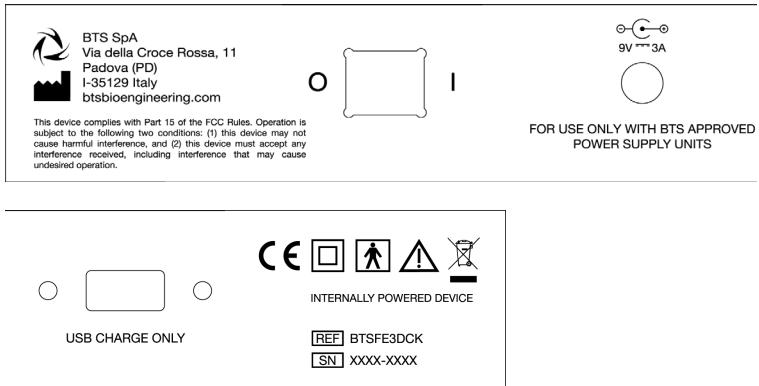
Label not on actual probes due to size constraints:



BTS Charger Regulatory label



BTS Docking Station Regulatory label



warnings

We recommend to carry out any kind of operation keeping strictly to the security regulations contained in this manual. The safety of the instrument cannot be guaranteed if these conditions are not respected.

BTS FreeEMG 300 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 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).



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

During the preparation of the patient, take particular care that the system's components do not impede in any way the normal movements of the subject. Apply the probes only on undamaged skin.

- Only use CE branded probes and hypoallergic 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.
- To not wet or dip in water the parts that make up the system.

No modification of this equipment is allowed.

- Only BTS S.p.A. authorized technicians may maintain and operate servicing to the instrument. BTS S.p.A. cannot be held responsible for system safety should the instrument be opened, repairs carried out, third parties software be installed, or system components be replaced by persons other than those authorized by BTS S.p.A.
- Users cannot change any software configuration (including O.S. and CD writer software).
- In case the device accidentally falls, tear of the probes or other accidents always address authorized technical support.
- Use only the provided power supply unit FW7363M/09 (FRIWO) or the one provided by BTS S.p.A. for supplying docking station and charger unit. If a different power supply unit is used, the compliance to IEC 60601-1 is not ensured.
- Only original cables must be used, otherwise BTS S.p.A. cannot assure the safety of the instrument. Should it be necessary to replace any part of the system, only original BTS S.p.A. parts may be used.



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.

- Make sure that the cables have been connected correctly. When disconnecting cables, use the connectors and not the cables themselves to unplug the connectors.
- Mains plug of external power supply unit is considered as disconnecting device.
- 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.
- For a safe use and adequate maintenance of rechargeable batteries strictly follow the instructions given in this manual. If rechargeable batteries are used in such a way that is not the one specified by BTS S.p.A. the shelf life, functionality and the integrity of the batteries is not ensured.
- ESD application to EGN probes, causes a loss of link to the device. Temporary loss of function or performance which is recoverable with operator action.



BTS FREEEMG 300 is a device that is able to function COUNTINUOUSLY, 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.



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introduction

General description

BTS FREEEMG 300 is an indispensable instrument for laboratories which are concerned with the study of muscular activity in the fields of rehabilitation, sports medicine, ergonomics, clinical research, and assessment of functional ability and muscular fatigue.

BTS FREEEMG 300 makes the selection of muscles, the setting of duration and frequency of acquisition, amplification gain and the correct positioning of electrodes, simple and rapid.

BTS FREEEMG 300 can be applied in research, sports, occupational medicine, gnatology, neurology, and orthopaedics.

With the software tools available, BTS FREEEMG 300 becomes an advanced diagnostic tool to evaluate neurological and orthopaedic disorders, pharmacological therapy, progression of motor deficits, use of orthoses, rehabilitative follow-up, and to optimize sports training programmes....

BTS FREEEMG 300 is applied with EMG-Analyzer the most complete software solution for analyzing electromyographic signals. It includes predefined templates for evaluations in the clinical, sports, and research field: Jump, plyometrics, walking, fatigue analysis, isokinetic, etc...

BTS EMG-Analyzer also has an editor for creating elaboration protocols:

thanks to an innovative object interface, that translates the biomechanical analysis language into graphical form, the user can develop quickly and effectively customized analysis protocols.

BTS FREEEMG 300 seamlessly integrates with BTS motion analysis systems, through the SMART (and ELITE) dedicated software.

Case contents

Standard components:

- Receiving Unit



- Acquisition Unit
- HP iPAQ hx4700 Pocket PC
- Belts for attachment to patient
- Stylus (located in the Pocket PC)

- Probes Kit

- up to 16 wireless probes (identificative labels available in 4 different colors)



- Probes Chargers:

- up to 2 “Charger” units:
each charger handles up
to 8 probes and 2 FSW/
EGN.



The second unit is included in the standard kit only for FREEEMG with at least 12 probes, or available as an option.

- The optional “Docking Station” version is also available



- Accessories

- USB-PDA cable

- AC adapter



- Access Point

- Set of disposable electrodes

- Manuals
 - BTS FREEEMG 300 user manual complete of CD



Optional components:

- Footswitch Kit

- 2 FSW/EGN Wireless Probes
- 2 Connectors of 4 Switches



- 10 single Switches

- Fine-Wire Adaptor

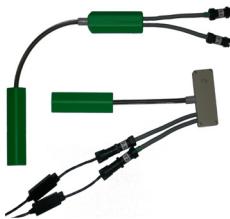
- Fine-Wire Kit
 - fixing set for Fine-Wire adaptor
 - set of disposal Fine-Wire electrodes with applicator

- Electrogoniometer Kit

- 1 FSW/EGN Wireless Probe
- 1 Connector



- 1 Electrogoniometer



- Supplementary Receiving Unit
- Secure Digital

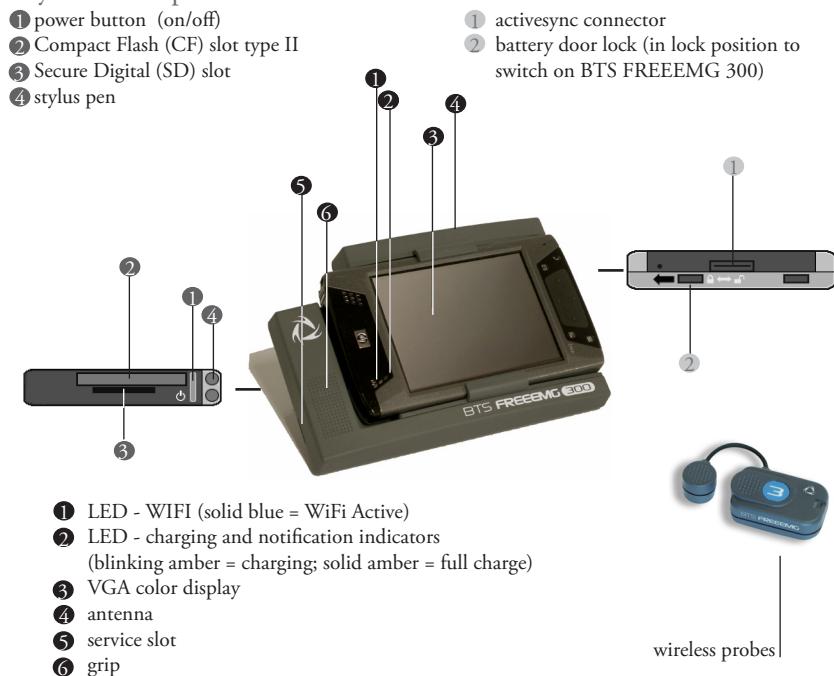


You will receive the instructions for use for other possible optional components not mentioned in this manual.

system components

BTS FREEEMG 300 electromyograph consists of a receiving unit which utilizes a PocketPC platform and wireless probes designed and developed by BTS SpA.

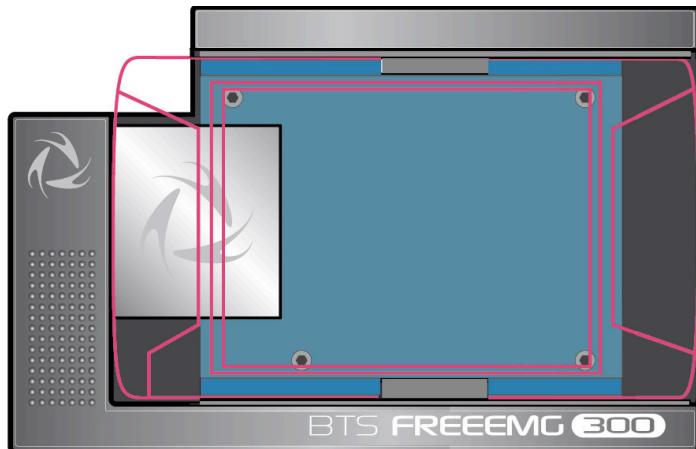
Physical description



Acquisition unit

The acquisition unit consists of:

- a digital card
- a receiver card
- a plastic casing
- a guide for the PDA insertion.



The digital card is connected to the palmtop, via the Compact Flash port, when this is made to slide in the proper guide.

When the acquisition unit is connected to the palmtop, the card communicates, “describing” itself to the driver in operation and thereby allowing the system to self-configure and to carry out a self-diagnosis.

In addition to serving as a Compact Flash interface the card allows control

of the receiver card and handles acquisition of data coming from the probes.

The receiver card is comprised of 4 elements that act as coordinators of the wireless connection network with the probes, thus managing communications with the probes, both for activation and data acquisition.

The acquisition unit is able to handle:

- up to 16 probes, used for acquisition of the activity of the same number of electromyographic signals
- up to 2 probes of 4 auxiliary channels for switch connection, used for the basographic acquisition
- as an alternative to the EMG channels it is possible to acquire up to 8 electrogoniometers (each EGN occupies 2 analogue channels).

In particular, the following probe combinations are possible:

EGN	EMG	FSW
0	up to 16 probes	2 probes of 4 switches
1-2	up to 12 probes	2 probes of 4 switches
3-4	up to 8 probes	2 probes of 4 switches
5-6	up to 4 probes	1 probe of 4 switches
7-8	0	0

PDA (Personal Digital Assistant)

HP iPAQ hx4700 Pocket PC is based on Microsoft® Windows®.

It uses the Intel® PXA270 processor and the new transreflective display VGATFT, 4" with 64k colors, to provide exceptional graphics power and performance to display large dimension images at highest quality resolution.



HP hx4700 is fitted with excellent expansion capacity (Compact Flash Type II and SD slot) to provide more storage space and greater function range.

64 MB of SDRAM and 128 MB of ROM memory allow a greater number of programmes and files to be stored, while the 1800 mAh lithium ion battery ensures longer uninterrupted use of the Pocket PC.

Processor, Operating System and Memory	
Operating system installed	Microsoft Windows Mobile 2003 Second Edition Software
Processor	Processor based on Intel® PXA270 technology
Processor speed	624 MHz
Standard memory	64 MB SDRAM
Max. memory	Up to 135 MB of memory available to user, which includes 80 MB of iPAQ File Store
Memory slot	SD slot: supports standard memory type SDSDIO/MMC of 1 and 4 bit; CF slot: 1 Type II, expandable CF card
Memory upgrades	Up to 1 GB with optional SD card; up to 4 GB with optional CF card
Internal ROM	128 MB of Strata Flash ROM

System Specifications

Dimensions (l x h x w)	77 x 14.9 x 131 mm
Weight	186.7 g
Display type	TFT
Dimensions of display	4" (diagonal)
Pixel pitch	0.126 mm
Video resolution	480 x 640 (L x W), 64k colours (65,536 colours), 16 bit
Wireless technology	Bluetooth® 1.2, Wi-Fi and IrDA (FIR) integrated
Expansion slot	SD slot: supports standard memory type SDSDIO/MMC, 1 and 4 bit; CF slot: 1 Type II
Power supply	Battery: removable/rechargeable lithium ion battery, 1800 mAh, exchangeable by user; optional lithium ion battery extension removable/rechargeable, 3600 mAh, available for purchase; (Note: the autonomy of the battery varies depending on the type of use and the configuration of the palmtop. The use of some internal wireless functions and rear illumination can greatly reduce the battery autonomy).
Power supply requirements	AC power supply: AC input: 100~240 Vac, 50/60 Hz, AC input current: 0.3 A max; Output potential: 5VDC (normal), Output current: 2A (normal)
Description of mouse/selection device	Touchpad for navigation with cursor, with operation similar to that of a mouse
Keyboard	4 programmable buttons
External I/O ports	Cradle/battery recharger USB from table
Audio	Microphone, loudspeaker, 3.5 mm headphone input jack, stereo MP3 (via audio and loudspeaker input)
Alarms	Actuation switch: charging and notification indicators; green flashing light - notification; amber flashing light - charging; constant amber - charging complete; LED - Bluetooth/WLAN: constant blue LED - wireless operation ACTIVE
Operating temperature	from 0 to 40 °C
Storage temperature	from -20 to 60 °C
Operative humidity	90% relative humidity



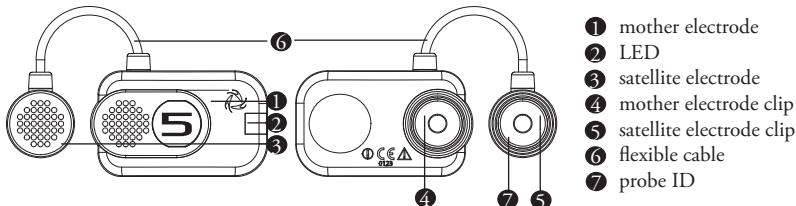
For further details please refer to the HP iPAQ hx4700 Pocket PC Manual included.

Wireless EMG Probes

BTS FREEEMG 300 utilizes 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 receiving unit can control up to 16 probes, for a total therefore of 16 analysable muscles in a single exam (standard configuration with one receiving unit).



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).

In the mother electrode there are the A/D converter, the antenna and the battery. In the satellite electrode there is the Signal Conditioning (preamplifier and filter) and is reported the probe ID.

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

Each probe is fitted with an 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.

- Inactive: white LED which cyclically lights with a steady light for a few seconds every 3 minutes.

In the “Inactive” mode the probes cannot be used directly by the patient unit but are in constant standby to be activated by the activation software. When the probe is inactive, it carries out a scan of the radio frequencies: during the scan the white LED is lit continuously.

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

In this mode the probe is searching for the receiving unit on the channel assigned during the activation phase. 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.

- 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. 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. After this operation they will pass to “Inactive” mode.

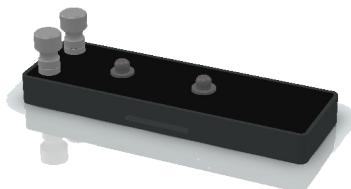
The probes are charged by a dedicated charger to which the probes are connected via their respective clips.



When the probes are in charge and the charger is turned on, they are in “Deep Sleep” mode and all the LEDs are off. it is necessary to reactivate the probes, prior to use them, using a magnet.

The EMG probes can be used also to acquire the EMG signal by means of Fine-Wire electrodes.

With this aim, there are available, in option, adaptors allowing for the connection with Fine-Wire electrodes. The EMG probes can be connected to them using the clips. Each adaptor can be fixed to the subject by means of proper elastics.



For these applications the acquisition frequency must be set on 4 KHz (the guidelines recommend for Fine-Wire electrodes an acquisition frequency major or equal to 2 KHz).

Wireless FSW/EGN Probes (optional)

For collecting the on-off analysis signals coming from the Footswitch or for collecting data from the Electrogoniometers (optional system components) BTS FREEEMG 300 uses wireless probes which must be connected to the FSW or EGN probes using a special connector.



The probe will work differently if used with one or the other probe and will receive from the same receiving unit information on its work modality during activation.

The probe consists of a single parallelepiped-shaped block.

The upper face has an ID tag characterized by a color (Green, Red, Yellow, Blue) and a letter (A, B, C, D, E or F) and a status LED which operates similar to that described for the EMG probes (see previous paragraph).

The two lateral faces have two connectors; the one on the ID tag side serves to charge the probe, and a cable will be connected to this to enable connection to the charger (Charger or Docking Station).

The one on the other side is for the probe connections (FSW or EGN).

Finally, the ID identifier of the probe is on the bottom left corner of the back side.

On-off analysis (optional)

The footswitches are useful in defining the contact points during the contact phases of deambulation.



The footswitches consist of a resistive membrane, (FSR technology), of diameter 18 mm and thickness less than 0.5 mm, expressly designed for applications in the analysis of movement.

The compact size of the instrument permits a maximum of flexibility in positioning on the patient's foot.

For applications other than gait analysis, there are available on request smaller diameter (8 mm) switch probes (appliable, for example, to the finger), and square (useful for tapping tests), 44 mm x 44 mm.

BTS FREEEMG 300 permits up to 8 basographic zones to be measured, through 2 connectors from 4 single switches (usually right and left side) that are connected to the two FSW/EGN wireless probes.



The footswitch channels are supplementary to the 16 electromyographic channels.



Refer to § "Acquisition unit" for the list of probe combinations possible in case of acquisition also with EGN.

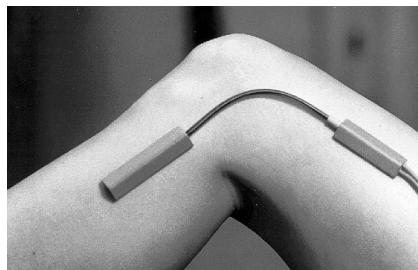
Electrogoniometers (optional)

The electrogoniometer is an easy to use device that allows the measurement of joint angle progress over time.

There are primarily two types of electrogoniometers: the potentiometer and the strain gauge. BTS FREEEMG 300 uses the strain gauge electrogoniometer of Biometrics LTD.

There are single-axle models for the neck (axial rotation) and the forearm (prone-supination) and biaxial models for other main joints: wrist, elbow, knee, ankle, hip and back.

The strain gauge electrogoniometers are made up of two sensors, connected to each other, that are fixed to the bone segments involved in the joint to value.



The measure of the angle is provided by the relative angle between the axes of the two sensors and, unlike the potentiometric electrogoniometers, it doesn't depend on the linear slidings in which the two extremities can incur.

Each electrogoniometer is connected to a FSW/EGN wireless probe using the appropriate connector. Each receiving unit can handle up to 8 electrogoniometers.



The electrogoniometer channels are not supplementary to the 16 electromyographic channels, but each electrogoniometer used engages 2 EMG channels. Refer to § “Acquisition unit” for the detailed list of probe combinations possible.

Charger

The Charger, included with the product, charges the FREEEMG probes.



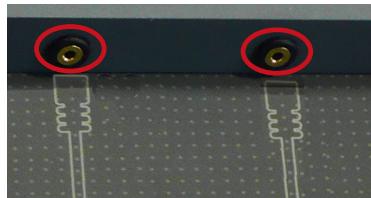
The Charger can simultaneously charge 8 EMG probes and 2 FSW/EGN probes.

Two units are provided for systems with more than 12 probes.

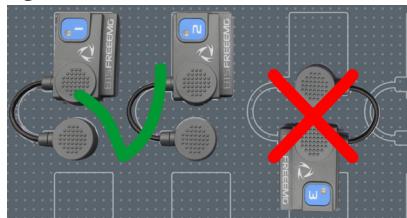


More units can be connected in series for simultaneous power supply through the same AC adapter, using the cable included.

The EMG probes are connected to the charger using the same clips that normally collect the EMG signal, while the FSW/EGN probes connect to the charger using the special connector as shown in the figure below:



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



The Charger comes with an output short circuit protection system also in case of reversed recharging poles. At any rate, poles connected incorrectly will not recharge.

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 EMG probes and of the FSW/EGN probes is indicated by the respective status LED (see § "Wireless EMG Probes" and "Wireless FSW/EGN 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 these probes, prior to use them, using a magnet. After this operation they will pass to “Inactive” mode. While, connecting the FSW/EGN probes to the Charger (connected to the mains and turned on) if they are charged less than 90% they will be automatically reset and will pass to the “Inactive” mode. To proceed with another acquisitions it is necessary to repeat the activation procedure.

Docking Station (optional)

As an alternative to the Charger an optional Docking Station is available.



This unit has additional features that are described below.

Each Docking Station can simultaneously charge 8 EMG probes and 2 FSW/EGN probes.



Unlike the standard Charger, each Docking Station will have to be powered separately; therefore two units cannot be connected in series for contemporary power supply.

The EMG probes are connected to the charger using the clips for collecting the electromyographic signal, while the FSW/EGN probes connect to the charger using the special connector.

For correct positioning simply follow the outline shown on the base of the Docking Station as shown in the following figure:



The Docking Station comes with an output short circuit protection system also in case of reversed recharging poles.

At any rate, poles connected incorrectly will not recharge.

The Docking Station also allows for recharging the receiving unit by connecting it with the relevant cable (USB/PDA cable) in the USB port located on the rear panel.



It should be noted that you can use the Docking Station to recharge the PDA only when by pressing the power button the palmtop turns on.

Otherwise you will need to recharge the PDA with the supplied HP by connecting it to the network. In order to go back and recharge using the Docking Station, simply charge with the power supply unit for about one minute, and then check that it is

sufficiently charged by unplugging it from the power supply unit and turning it off and then back on.

There are two ways to recharge the probes:

- using the medical power supply unit from the network
- using the internal battery

The first method involves the connection of the Docking Station by means of the AC/DC adaptor to the mains. In this case not only the connected probes will be charged but also the internal battery of the unit itself.

The second method lets you recharge the probes and/or the receiving unit when you are not at the laboratory and a mains power network is unavailable. In particular with the battery fully charged you can fully recharge all the probes and receiving unit or fully charge the probes only twice.

To recharge a probe simply connect it as described in the method above.

 Connection to the Docking Station resets the probe if charged less than 90%, to use it again for acquisitions you must repeat the activation procedure.

The Docking System is equipped with an “Activate” button and 3 status LEDs: “Charge”, “Battery” and “Power”.



The “Activate” button allows immediate activation of the FSW/EGN probes connected to the Docking Station and selected to activate in the receiving unit (see § “Active” Button); you do not need to wait for the software cycle of the “inactive” state probe to be complete. By pressing the button the FSW/EGN probe will immediately scan the radio frequencies and enter immediately in communication with the receiving unit.

The “Charge” LED gives information on the probes charging and consists of a BLUE light which signals the following:

- BLUE LED “breathing”: indicates that the probes are charging.
Two situations can be verified in this case:
 - Status LED of the probe on: The probe is charged less than 90%
 - Status LED of the probe off: The probe is more than 90% charged but still not complete.



It is important to remember that the LED of the probe stays on until it is 90% charged. This function allows you to have an indication on the full charge of the probe, therefore increasing the autonomy of the probe by about 10%.

- BLUE LED off: indicates that all probes are fully recharged.
- BLUE LED fix on: indicates that the “activate” button has been pressed. In this case the probes are not powered by the Docking Station but by the probe’s battery.

The “Battery” LED is an indicator of the state of the auxiliary battery and consists of a two-tone RED- GREEN LED, whose signals have the

following significance:

- LED off (both the RED light and the GREEN light are off): in this case the battery is in sleep mode or has been removed from the Docking Station
- GREEN light of LED on: the auxiliary battery is charging.
- Steady RED light of LED on: the auxiliary battery is fully charged.
- Blinking RED light of LED on: indicates battery malfunction or a battery charging problem.

The “Power” LED is on (GREEN light) when the switch located on the rear panel of the Docking Station is ON and it is connected to the mains or, if this is not the case, the auxiliary battery is sufficiently charged.

The Docking Station has a lid, which opens automatically by means of a spring- brake mechanism, which works by pressing close to the word “Push”, located on the left shoulder of the unit.



The probes should be put back in the Docking Station when not in use for acquisition sessions. Moreover, if left for a long period, we recommend turning of the unit by moving the switch located on the rear panel of the Docking Station to OFF. Close the lid for better protection of the probes.

installation

User PC minimum configuration

Operating system	Windows XP Microsoft.NET framework 1.1
Processor	P IV 1600 MHz
RAM	256 MB
Video card	32 MB, Open GL
Disk space	100 MB for the application, not including storage for acquired data
USB	2.0

Installation of the Wi-Fi Interface

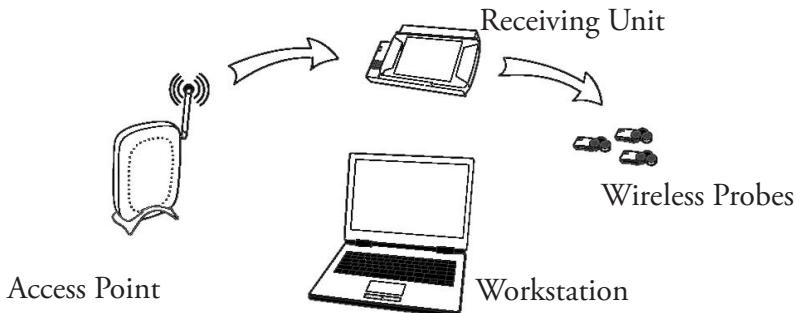
The real time data transmission between the BTS FREEEMG 300 and the Workstation occurs thanks to the Wi-Fi network. This type of connection is permitted using an Access Point supplied with the system.

An AP is an Ethernet device which works with devices present in a small area.

The AP, starting point of the service, operates from bridges between the wireless devices and the systems physically connected to the network with an RJ45 connector.

The AP transmits the signals to the surrounding area via radio waves. All the wireless devices within the area can receive signals and communicate with the AP, and through them, with all the other devices, creating a network without cables.

Connecting a Workstation (PC laptop or desktop), not provided with a Wi-Fi interface, to Access Point with a normal network cable is created through the wireless connection with BTS FREEEMG 300.



The access point included in the system is already configured with the network name (SSID) "BTSTFREEEMG300" with transmission on channel 6. The base configuration prepared in BTS (factory settings) uses the following IP addresses:

Access Point	192.168.1.1
BTS FREEEMG 300	192.168.1.2
Workstation	assigned automatically by the Access Point



You should always use the AP included even if the Workstation is equipped with a Wi-Fi interface.

Description of the software on the user PC

BTS EMG-Analyzer is the complete and highly flexible solution for making advanced elaborations of electromyographic signals and angular measurements of body segments.

Includes predefined templates for evaluations in clinics, sports, and research and an editor to develop customized elaboration protocols.



For more details concerning the use of this software, please refer to its specific manual.

However BTS FREEEMG 300 is manageable by all BTS applications of SMART family dedicated to the motion analysis with which is possible to acquire and process the electromyography signals in a integrate and synchronous way with the other devices connected.

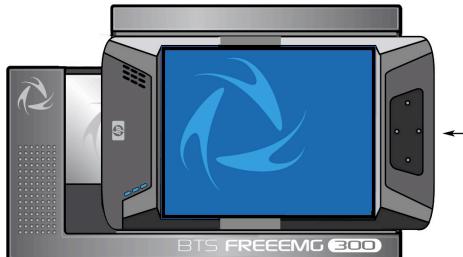
The SMART-Analyzer software allows to perform advanced elaborations of the EMG signals, integrating the electromyography information with the cinematic and kinetic data.

It is possible to construct customized analysis protocols complete of advanced multimedial report.

Switching on BTS FREEEMG 300

The patients unit consists of two main components: the PDA and the Acquisition Unit and is usually given with the two parts already connected. Anyway, to connect the Acquisition Unit to the palmtop, run the PDA along the AU guides, being particularly careful that the CF enters the

appropriate slot without being forced or receives any sudden impact, and avoid any excessive pressure on the palmtop screen.



To avoid damaging the Compact Flash we suggest only to remove the PDA from the AU only if necessary and in any case, even if expressly requested, it is suggested not to move it completely from its place, but to let it slip just enough to disconnect it from the digital card (more or less 1 cm) event that will be signalled by an audio beep.

The recharge of the battery and the transfer of data with the USB can also be done through the specific cable, without disconnecting the AU or the PDA.



It is also advisable to perform a connecting/separating operation of these parts only when the device is turned off.

Check the connection between PDA and AU.

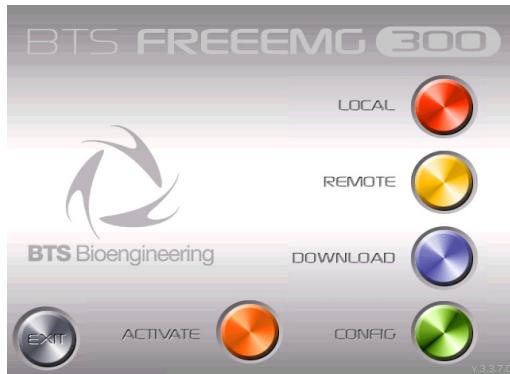
Switch on the BTS FREEEMG 300: check that the slot switch, located on the side of the BTS FREEEMG 300 shown in the diagram, is in the position closest to the closed lock symbol. If not, move it to this position.



Switch on by actuating the button on the opposite side of the BTS FREEEMG 300, as shown here:



At this point wait until the application BTS FREEEMG 300 is completely charged. On the BTS FREEEMG 300 display the following screen will be visualized:



First Connection

The BTS FREEEMG 300 is supplied with the onboard PDA software preinstalled and configured. In any case for the first connection we suggest to perform some verifications.

Connection check

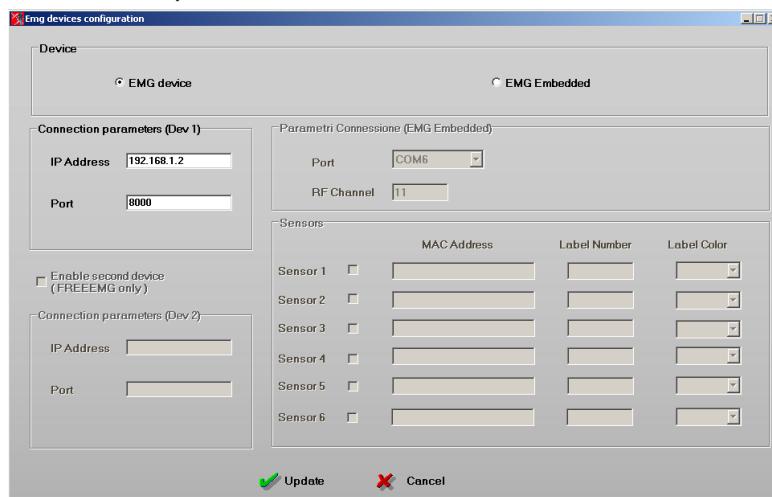
The user PC communicates with the BTS FREEEMG 300 by means of Wi-Fi protocol through the Access Point (see § “Installation of the Wi-Fi Interface”).

Verify that the local net resources are laid out, like assumed in the configuration of default according to BTS, the PC user IP address must be assigned automatically by the Access Point.

Verify the software configuration installed on the PC.

To do so, launch the program that you want to configure, i.e. EMG-Analyzer, and on the menu bar at the voice “Laboratory” select “Select Emg Device” and verify that the check is on the voice “FREEEMG”.

Then, again from the menu bar at the voice “Laboratory”, select “Set Emg Device” and verify that the check is on “EMG device”:



Verify that the IP address and the port are set with the following connection parameters:

IP Address: 192.168.1.2
Port: 8000

Moreover, if there is a second BTS FREEEMG 300 receiving unit available (mind that in this case it is possible to manage up to 8 channels with each unit), select the option “Activate Second Unit (only for BTS FREEEMG)” and check that the IP address and the port for the second device are set up with the following connection parameters:

IP Address: 192.168.1.3
Port: 9000

If the values do not correspond change them and click on “Update” before closing the window.

Switch-on the BTS FREEEMG 300 (see § “switching on BTS FREEEMG 300”), wait until the application of the acquisition management is completely loaded and select the remote application clicking on “Remote”. If the Wi-Fi connection between the Receiving Unit and the Workstation is assigned in the correct way, after clicking on the “Remote” button, the connection led of the Wi-Fi net, that you can find on the front of the BTS FREEEMG 300 and that presents the Wi-Fi logo (), will result on (solid blue).





During the start-up of the Remote mode different wireless nets can be found present in the working area.

Always use the “BTSTFREEEMG 300” net ignoring the other nets.

From the Workstation launch the BTS EMG-Analyzer application.

Wait until, in the application being used, the respective LED indicating the state of the Wi-Fi connection between the receiving unit and the workstation changes from red to flashing green.

Correct data visualization check

During the initial connection, check the correct operation of the probes in use, and the correct display of data on the BTS FREEEMG 300.

To do this, activate all the EMG probes and, if the system is also provided with footswitches, two FSW/EGN probes, enabled as FSW, to be tested all previously charged, as indicated in § “Active” Button”. When all the probes are shown to be active on the display, select the Remote mode by clicking on the “Remote” button. Select the default protocol and then “Setup Probes” from the menu and wait for all the activated probes to be acknowledged (the respective box must be green).

To verify the correct functioning of the EMG probes, position a pair of electrodes (see § “Fitting the Patient”) and connect Probe 1. Next, select “Gains” from the menu and check the progress of the EMG1 signal.

Repeat the procedure connecting the other probes one at a time.

After checking the electromyograph channels, if the system is also

provided with footswitches, attach the connectors with the 4 switches already inserted to the 2 corresponding FSW/EGN probes. After selecting from the menu the item “Footswitch” (as shown later in § “Guide to using the software on the BTS FREEEMG 300”), check each contact is functioning correctly by pressing firmly each switch and observing the corresponding red LED light on the display of the BTS FREEEMG 300 (see § “Footswitch”).

If your system has one or more electrogoniometers, repeat the probe activation procedures deactivating all the EMG probes and enabling as EGN a number of FSW/EGN probes equal to the number of electrogoniometers included (maximum 8), refer to § “Active” Button”. When all the probes required are active go back to Remote mode by clicking on the “Remote” button. From the Workstation prepare an acquisition protocol that entails the use of a number of EGN equal to those provided with your system and transfer it on the receiving unit (see § “Create a new protocol”). Selection the newly transferred protocol, select “Probes setup” on the menu and assign each channel to an EGN probe, checking that they are all recognized (the respective box must be green) (see § “Probes Setup”).

Finally, connect each electrogoniometer to a connector and then to a FSW/EGN probe. Select “Gains” from the menu and check the related signal to the EGN channel that is testing. Repeat the procedure for each electrogoniometer provided.

acquisition protocol

Now we will describe a basic procedure about how to create a new protocol using BTS EMG-Analyzer software.

 Refer to the EMG-Analyzer manual for further details about the “Protocol Builder” function.

 The procedure may be different if performed with other applications. In this case, refer to the specific manual of the software you are using.

Please note that with BTS FREEEMG 300 it is possible to acquire:

- up to 16 analog channels: electromyographic signals - EMG (each EMG employs 1 analog channel), up to 16 electrogoniometer signals - EGN (each EGN employs 2 analog channels)
- 8 on-off analysis areas - FSW.

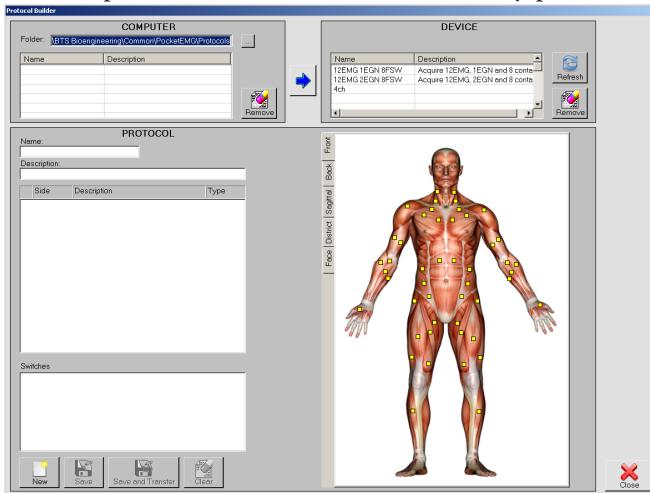
 Refer to § “Acquisition unit” for the detailed list of possible probe combinations.

Launch the software EMG-Analyzer and wait for the led of communication with the receiving unit to be green.

Put BTS FREEEMG 300 in Lab Modality by clicking from the main page on the “Remote” button; if two receiving units are being used, make sure that both of them have the Remove Mode activated.

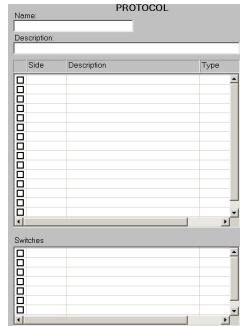
To create a new protocol, from the menu voice “Laboratory” of EMG-Analyzer, select “Create Emg Protocol” .

A window will open, which allows to create or modify protocols.



To create a new protocol follow this procedure:

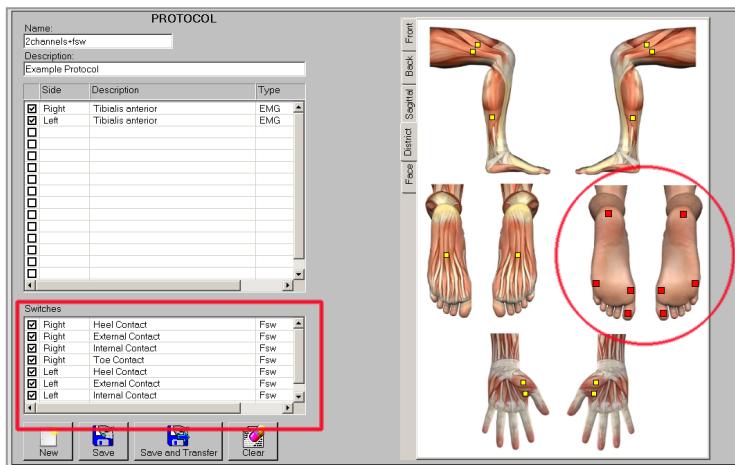
- Click on “New”. The fields to be filled for the protocol creation will be enabled:



-select the anatomical map containing the muscle you want to add to the protocol and click on the little yellow square that identified it; immediately the first free row available in the protocol table will be filled with the info related to the selected muscle.

- repeat this operation for all the muscles to be acquired.

-If you want to acquire Footswitches, select the “District” anatomical map and proceed insert the 8 contact point in the protocol by selecting the corresponding square in the anatomical map:



-Finally, if you want to acquire electrogoniometers check the first free line in the protocol table, click on the “Type” field and select EGN among the voices available in the drop box menu:

In the same way, click on the “Description” field and select among the drop box menu voices the angle you want to acquire with the EGN, then on the “Side” field to select the body side to which the data refers.

- indicate a name for the protocol specifying it on the “Name” box
 - it is possible to insert also a short description of the protocol using the appropriate box “Description”

When every signal of the protocol is inserted, proceed saving the protocol, following these instructions:

- make sure that the BTS FREEEMG 300 is in the Lab Modality
 - click on “Save and Transfer”: the protocol will be both saved on the PC and transferred on to the BTS FREEEMG 300.

If two receiving units are being used, it is necessary to wait for the protocol to be transferred to both units. At the end of the transfer, the protocol will be visible in both, but in each unit will be displayed only the respective signals from the channels they are

connected to.



Note that If you are working with two receiving units the first 8 channels and the FSW will always be assigned to the first unit, while the other, starting from the 9th to the 16th, will be loaded on the second unit.

For example, if a protocol with 10 EMG channels and the footswitches has been created, the protocol on the first unit will register 8 EMG channels and the FSWs, while the protocol on the second unit will register only 2 EMG channels.

fitting the patient

Here some guidelines to follow for a correct application of the probes.

Carefully prepare the skin of the subject in the area of the muscle in which the pre-gelled electrodes will be positioned.



Note that the condition of the skin where the electrodes are applied influences the quality of the acquired signal.
Therefore you should pay careful attention to this phase in preparing the subject.

Attach the probes, previously activated (see § ““Active” Button), to the electrodes using the appropriate clips.

Find the position in which to place the electrode on each muscle that you want to analyze and apply the probe in the direction of muscle fibers through the pre-gelled already applied to the probe, trying to keep the two electrodes as close as possible (tangent to each other).



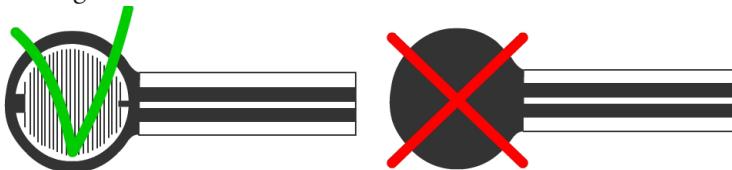
Thanks to the special hardware architecture of the probes and the much reduced weight, normally no extra fixing is required.

If the analysis protocol being used requires it, proceed to the positioning of the footswitches to the respective contact areas.

When FSWs are used, these are fixed to the skin of the subject used tape

or hyper-allergenic bi-adhesive tape.

 Never apply the tape on the black membrane of the sensor, removing the tape could cause the detachment of the membrane making the switch unusable.



After positioning the sensors, connect them by means of the appropriate connector to the corresponding preactivated probe.

Finally, attach the probe and the switch box with the hypo-allergenic adhesive tape close to the same switches (i.e. close to the ankle when the sensor have been placed on the foot sole) at all times taking care to leave the patient the greatest degree of freedom of movement.

Finally, If the analysis protocol being used requires it, proceed to the positioning of the Electrogoniometers.

Each EGN should be positioned straddling the joint with the two stiff ends positioned on the sagittal plane, parallel to the axes of the two body segments that make up the joint under investigation, securing them to the patient's skin using the plaster or hypoallergenic double-sided tape.

After positioning the sensors, connect them by means of the appropriate connector to the corresponding preactivated probe.

Finally, attach the probe and the switch box with the hypo-allergenic adhesive tape close to the sensor on the side where the connection cable comes out.

Throughout the dressing procedure of the patient or at the end of it you can use the receiving unit to check, using the oscilloscope of the “Gains” function of the RU, the correct placement of the electrodes and control that the acquisition gain of the EMG channels is properly set.

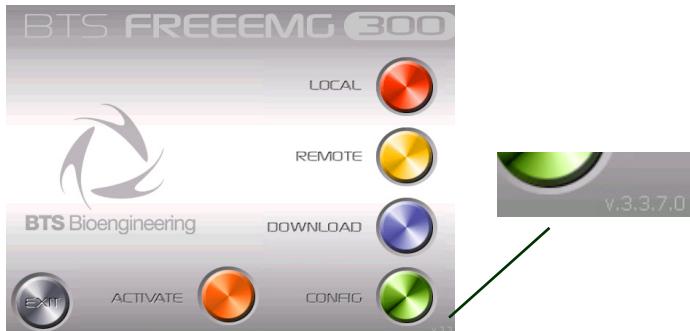
It's possible also to compare two channels at a time using the “Cross check” function (see § “Guide to the use of the onboard software”).

After making all the checks, it is possible to proceed with the acquisition session.

guide to the use of onboard software

Initial screen

At the start-up of the BTS FREEEMG 300 you see the initial screen comprised of six buttons: “Local”, “Remote”, “Download”, “Config”, “Activate” and “Exit”.

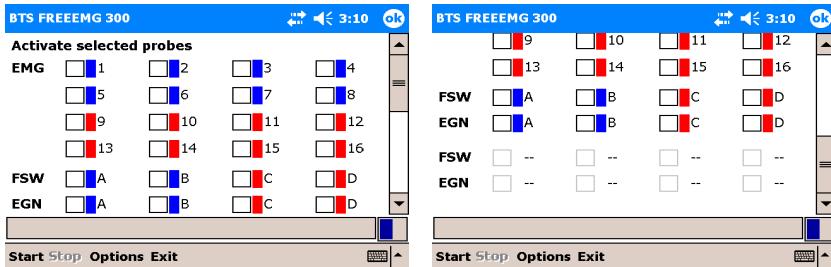


In the lower right hand corner of the main screen there is the version number of the software installed on board.

“Active” button

The “Active” button allows only those probes to be activated which are to be used during the acquisition and to assign each of these to a specific channel.

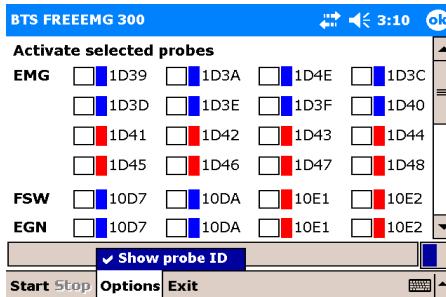
Click on this button to call up the following display:



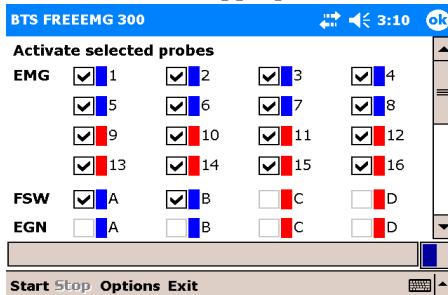
The probes are divided by type: EMG, up to 16 probes for collecting electromyographic signals, FSW, up to 8 probes for collecting basographic signals (up to 2 can be selected at the same time), and EGN, up to 8 probes for collecting signals from the electrogoniometers.

A number (or letter) and the color corresponding to the ID tag of the probe is shown next to each probe.

By clicking on Options and then "Show probe ID" you can pass from viewing by label to that for viewing by "ProbeID" identification code, the code shown on the clip of each probe and vice versa:

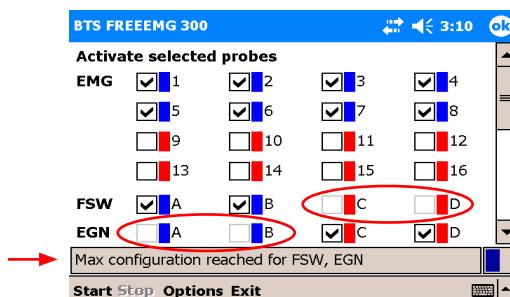


To activate, select the probe that you would like to use for the acquisition by enabling the check mark in the appropriate box:



It is important to remember that only certain probe configurations can be activated (for the detailed list of possible configurations, see § “acquisition unit”).

This procedure will be guided by the software disabling, upon reaching a configuration limit, all the checkboxes that can no longer be selected, furthermore, in the notification area at the bottom, any time the maximum configuration for a type of probe (EMG, EGN, or FSW) is reached, a warning message will appear as shown in the following figure:



Before proceeding to activation, connect the probes to the Charger (or to the Docking Station) included, use two units if required.

This operation resets the probes, deactivating any probes already active, except for those probes that are more than 90% charged (in case of Charger to reset these probes you must wait for the battery level to below the threshold of 90%).



It is advisable to connect all the probes and not just those used during acquisition to ensure that you reset any previously activated probes, which will not be used.



An already active probe can be reused and does not require reactivation. In this case it must be selected in the activation program, but do not connect it to the Charger or Docking Station so it doesn't reset.



It is in any case necessary that the probes are sufficiently charged for the activation to succeed.

Click Start to initiate the probe activation procedure.

Now we would like to distinguish between operations to perform based on if you use the Charger or Docking Station:

- Charger procedures:

The probes will be activated only when removed from the Charger.

Remove the probes, therefore, from the charger, and wait for the BTS FREEEMG 300 to activate all the selected probes.



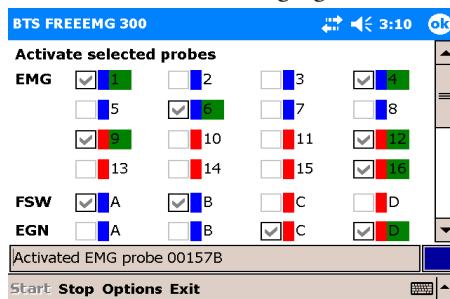
To facilitate the activation and to verify that all the required probes are active, we suggest detaching the probes from the charger one at a time.

- Docking Station procedures:

Click on the Docking Station “Activate” button.

Immediately all the probes selected in the activation probe will be automatically activated and all the other probes will be reset, regardless of the charge level.

When a probe has been recognized and activated, it will be highlighted by a green rectangle, as shown in the following figure:



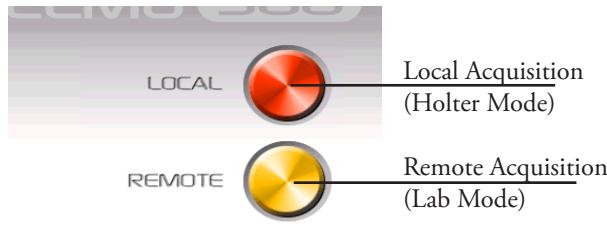
When all the selected EMG, EGN and FSW probes are indicated as activated, click “Stop” to terminate the activation procedure.

Finally, click “Exit” to return to the initial screen.

Selecting the work mode

The first two buttons (Red and Yellow) allows the user to select the desired

working mode: button “Local” Holter mode, button “Remote” Lab mode.



Clicking on the button for the desired mode, you can enter the software of relative management.

In particular by clicking on the “Local” and “Remote” buttons you will see the following screens:



Description of the main bars and menu

All of the BTS FREEEMG 300 pages have a button bar on the right and a status bar at the top.

Button Bar



The side arrows (Toggles) can be used to change the active field.

The up and down buttons make it possible to:

- change the value in the active field
- navigate around the main menu

The menu button opens the main menu

Status Bar



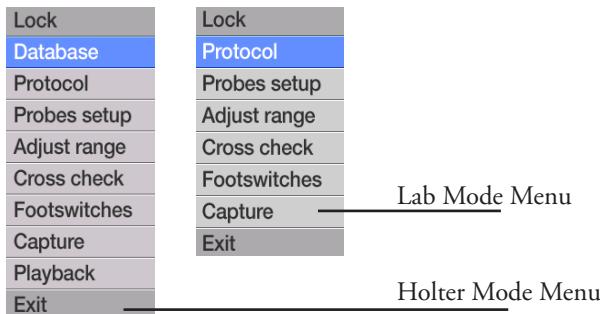
The status bar displays:

- active page
- the condition of the 4 transmitters indicated with A, B, C, D. One transmitter can serve more than one probe. When a probe is transmitting the LED of its corresponding transmitter turns steady green
- The status of the FSWs (steady green LED if at least 1 FSW probe is active and recognized by the system)
- battery level

Main Menu

Clicking on the “menu” button of the buttons bar you enter the main menu.

There are two menus: one for the Holter mode and one for the Lab mode. The two are different for the items: “Database” and “PlayBack” which exist only in the Holter mode.

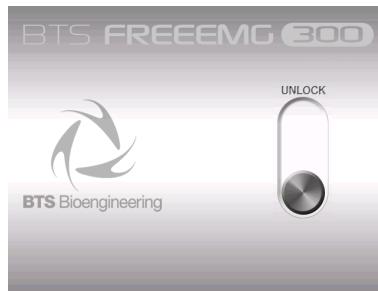


The main menu allows you to:

- explore the functions of the BTS FREEEMG 300.

To enter a page select the corresponding icon by clicking with the stylus on the desired function or by using the Up and Down Buttons.

- lock up the palm by clicking with the stylus on the icon “Lock”. Accomplishing this function will result in the following screen:



To unlock the palm, click on the “Unlock” button, this will

immediately move to another position.

To complete this procedure it is necessary to press it again before it goes back to the original position.

- close the application by clicking on the “Exit” button.

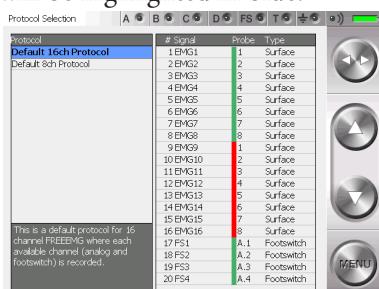
The following describes the menu functions starting from the ones that you can find both in the Holter Mode and in the Lab Mode that have the same characteristics.

Protocol

This item allows the user to select a protocol from the ones previously created by the user (see § “Acquisition protocol”).

In any case if a protocol hasn't yet been created it is possible to use the default protocol.

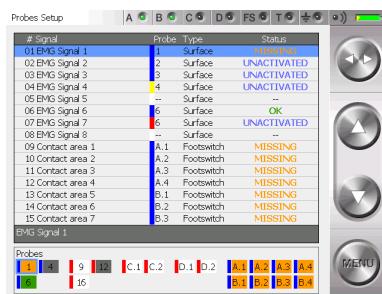
Selecting a protocol is achieved by scrolling through the list on the left panel by clicking on the Up and Down buttons of the buttons bar. The protocol you select will be highlighted in blue.



Probes Setup

When a new protocol is defined, the user needs to associate with the items of the protocol (muscles, joints and foot areas) the channel that physically acquires the data.

By clicking “Probes setup” from the menu you will see the following screens:



In particular we can identify two zones:

- the probe-protocol association table
- The “Probes” area

The table, for each signal of the acquisition protocol, previously selected in the “protocol” section shows:

- the identifier of the assigned probe (comprised of the color and number/letter of the label), if no probe has been assigned the field is set on “--”
- the type of probe: Surface, Footswitch, Electrogoniometer,...
- the state of the probe:
 - OK: Signal/probe properly assigned, the probe has been

selected in the activator and is connected to the RU.

- NOT CONNECTED: Signal/probe properly assigned, the probe has been selected in the activator, but does not appear to be connected to the RU.
- “--” : no assigned probe.
- NOT ACTIVATED: the probe is assigned to the protocol signal, but has not been selected in the activator.
- ERROR: the signal/probe has not been properly assigned as the type of probe expected by the protocol does not match the actual probe

In the “Probes” area (rectangle at the bottom) where the selected probes in the activator are listed and the state is described.

In particular, the boxes associated to channels can have different colors:

- Green:
the selected probe in the activator is connected to the RU and is assigned to a protocol signal (the “Status” field of the protocol is “OK”)
- Grey:
the selected probe in the activator is connected to the RU but is not assigned to any protocol signal
- Orange:
the selected probe in the activator is not connected to the RU but is assigned to a protocol signal (the “Status” field of the protocol is “NOT CONNECTED”)
- White:
the selected probe in the activator is not connected to the RU and has not been assigned to any protocol signal

- Red:

the selected probe in the activator is connected to the RU and assigned to a protocol signal, but the type of probe expected by the protocol does not match the actual probe (the “Status” field of the protocol is “ERROR”).

To make the association probe-signal:

1. use Up and Down buttons to select a signal
2. use toggle to select the “Probe” field
3. choose among the available ones (all the probes present in the probe area will be proposed), the probe to pair to the highlighted signal
4. use toggle to select the description (the whole row)
5. move on the next description with the arrow Down and restart from point 2 to assign the channel to the next item.

Active fields (Toggle)	Value range (Select)
Description Probe	Signals List 1, 2, ..., 15, 16, for EMG channels A.1, A.2, A.3, A.4, B.1, B.2, B.3, B.4, C.1, C.2, C.3, C.4, D.1, D.2, D.3, D.4, E.1, E.2, E.3, E.4, F.1, F.2, F.3, F.4, for EGN and FSW

all available in 4 colors:
Green, Red, Blue, Yellow



Each Electrogoniometer generates two signals, it is important that you assign two channels of the same probe to the signals generated by the same EGN, e.g. C.1, C.2



To properly assign the basographic signals to the FSW probe channels please remember to match the 4 signals related to one probe to the protocol signals related to the physically close contact area, e.g. A.1, A.2, A.3, A.4 for the Right foot and B.1, B.2, B.3, B.4 for the Left foot.



Before starting acquisition, the user needs to confirm that the “Status” of each protocol voice is OK.

Digital Oscilloscope (gain)

With BTS FREEEMG 300 the user can set up to 3 different ranges of values to see the muscular contractions better.



To setting this value see § “Config” Button”.

The selectable values are:

- S1: 6mV;
- S2: 3mV;
- S3: 1,5mV.

By accessing the gains page it is possible to verify that electrodes have been well positioned (no noise or motion artefacts) and that the signals are properly displayed and if they are not you can change the range of value

set in the configuration section.

To do this, simply view via the oscilloscope the real-time muscular activity of each muscle you would like to analyze for a few seconds, asking the patient to perform several contractions.

If the intensity of the muscle is very low, so that it is difficult to distinguish between when the muscle is in contraction from when it is at rest, the range needs to be reduced (the system will increase the gain correspondingly).

If, on the other hand, the signal in the current amplitude tends to saturate (meaning during the contraction there are peaks in the orange zone or beyond), it is necessary to increase the range (the system will reduce the signal gain accordingly).



Keep in mind that the base range value will be the same for all signals acquired.

Therefore select the value that lets you best see the channels simultaneously without saturation.

If the selected range is insufficient to contain the entire signal dynamic, the acquisition data will tend to saturate during the contraction, which will appear as unnatural plateaus in measurement values at the limits of the selected range.

On the other hand, if the signal is very weak, maintaining a high range is not a mistake. It is recommended, however, that the range be reduced whenever possible, in order to make better use of the digitalization of the acquisition card.



The gain used in the acquisition of the EMG signals is managed by the application on the basis of the range selected, the choice of range should be done with great care since it affects not only the display but also the acquisition signal (it is not just a simple zoom!).

By clicking the voice “Gain” from the menu you will see the following screens:



To scroll the different signals, click on the Toggle to activate the “Signal” active field and select the protocol item desired by actuating the Up and Down buttons.

To make the signal visualization easier it is possible to use the “Time” active field (by selecting it with the Toggle) this allows to adjust the speed at which the signals run on the screen (this is only for display purposes, and will have no effect on the capture).

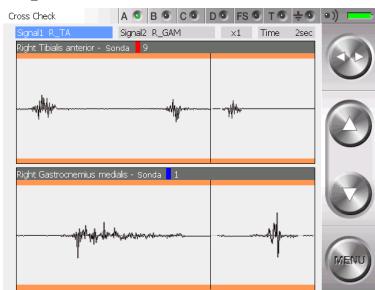
It is possible to set the time value interval shown on the axes of the oscilloscope abscissas, selecting from a range of values from 1 to 10 seconds, that can be selected with the Up and Down buttons.

Active fields (Toggle)	Value range (Select)
Signal	Protocol signals
Time	1 sec - 10 sec

Digital Oscilloscope (cross check)

The Cross Check is very useful during the patient setup phase, allows the operator to verify, prior to the actual acquisition of the signals, that the electrodes have been positioned correctly.

The possibility of displaying two traces simultaneously prevents the problem of cross-talk: this phenomenon occurs as a detection of electrical activity on the trace of a muscle during a movement which should not involve the muscle in question.



Cross-talk is occurring if, for example, during the movement of extension of the wrist, one observes the activity of the ulnar carpus flexor.

This is due to an incorrect positioning of the electrodes, as a consequence of which the channel dedicated to a certain muscle is in reality measuring the activity of another muscle.

In the above example, the activity measured on the trace of the ulnar carpus flexor is not in reality being produced by that muscle, but by one deeper down or by its antagonist.

To appoint the signals to visualize select the “Signal 1” and then “Signal 2” field with the Toggle and scroll the signal list included in the protocol using the Up and Down buttons.

The current display can be enlarged or reduced via the zoom function: this does not affect in any way the data being read.

The “Time” field can be used to vary the speed at which the signal runs on the screen (again, this has no effect on the reading, but only on the display).

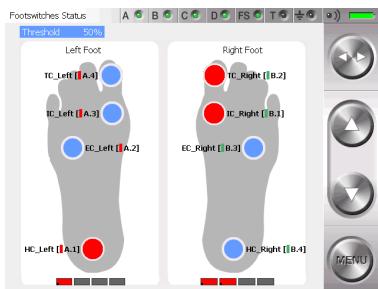
It is possible to fix the time intervals represented on the axis of the abscissas of the oscilloscope, choosing from a range of values from 1 to 10 seconds.

Active fields (Toggle)	Value range (Select)
Signal 1	Protocol signals
Signal 2	Protocol signals
Zoom	From 1/10 to x10
Time	From 1 sec to 10 sec

Footswitches

The Footswitches page shows in real time the activation of the contact zone during the deambulation contact phase.

When a zone is active, the foot is resting on it - the corresponding circle colors is red.



If there isn't correspondence between the contact points indicated on the display and the movements done by the subject (for example if with the right foot in stance the areas under the left foot of the display became red) we suggest you to review the FSW channels setup selecting the menu voice "Probes Setup".

Usually the Footswitches are used for studying the sole of the foot during deambulation.

Four points have been identified for this purpose in order to be able to distinguish the foot tread while walking.

These 4 areas are:

- Internal Contact,
- External Contact,
- Heel Contact,
- Toe Contact.

However, while preparing the protocol you can indicate the general contact areas:

- “Contact area 1”,
- “Contact area 2”,
- “Contact area 3”,
- ...

 The Footswitch probes can also be used for other applications and placed on other parts of the body where you would like to record the moment of contact (for example on a finger during pointing exercises).

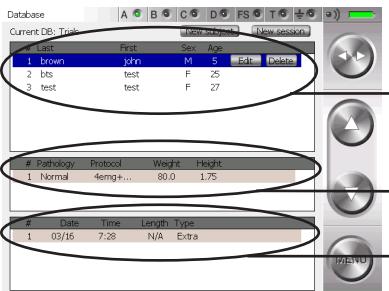
In this case you should use a general “Contact Area 1”, “Contact Area 2” in the protocol, and in the FSW page refer to the rectangles located under the figure showing the foot to check that the probes are properly activated.

“Local” button: Holter Mode

In this mode the RU is completely independent and it's possible to acquire the data independently of the WS.

Session preparation:

selecting “Local” you can enter the patient's database on the palm.



List of patients already included in the database of the BTS FREEEMG 300

List of sessions for the highlighted patient

List of the tests of the highlighted session

To add a new patient click with the stylus on “New subject” button.

A window will open which allows you to insert general information about the patient.

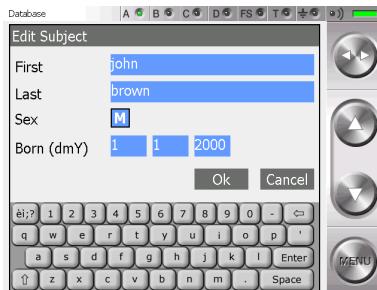


To insert the patient data:

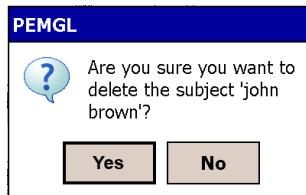
- move up to the field to insert
- insert the value with the keypad, (each tap on the gender field will change from F to M and viceversa)
- press OK to insert the patient into the database

It is possible to modify or to delete the data of a patient already inserted. By clicking on the line of that patient, it will be underlined in light blue and the “Delete” and “Modify” buttons will appear.

Clicking on “Modify” a window will open that allows to modify the general information of this patient.



Click on “Delete” and immediately a window with the request to confirm the deletion will appear:

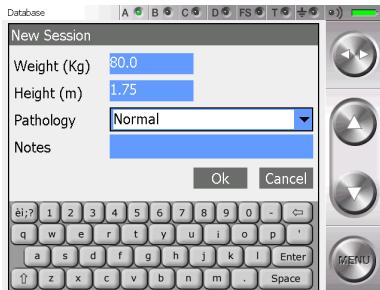


Clicking on “Yes” the trial will be removed from the database, with all the related sessions and trials, while if you choose “No” the deletion will be aborted.

To create a new test session click on “New Session”.

A window will open that allows to the user to insert data linked to the session:

- patient weight
- patient height
- pathology
- possible notes of the session



Press “OK” to add the session of the selected patient.



The default protocol is linked to the session; to change the protocol click on the Menu button and enter the “Protocol” item (see § “Protocol”).

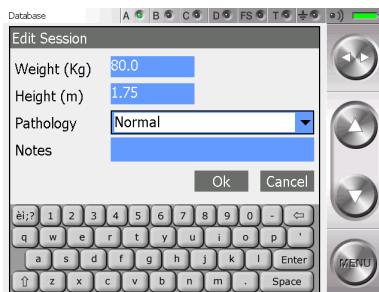


Cautious that it is not possible, rather than, to change protocol of a session when this has already got some acquisitions.

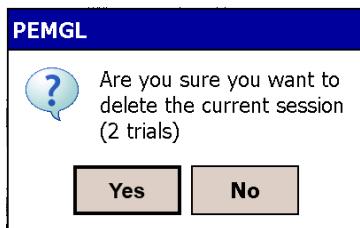
To continue working with the same patient but with a different protocol it is necessary to create a new acquisition session for that patient.

To modify or to delete the data of a session created previously click on the correspondent line, it will be underlined in light blue and the “Delete” and “Modify” buttons will appear.

Clicking on “Modify” a window will open that allows to modify the data related to this session:



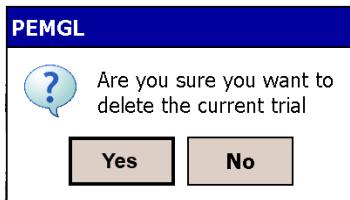
Click on “Delete” and immediately a window with the request to confirm the deletion of the session and the relate trials will appear:



Clicking on “Yes” the session and the trials will be removed from the database, with all the related sessions and trials, while if you choose “No” the deletion will be aborted.

Latter it is possible to delete single trials. To do that click on the correspondent line, it will be underlined in light blue and the “Delete” buttons will appear.

Click on “Delete” and immediately a window with the request to confirm the deletion of the trial will appear:



Clicking on “Yes” the selected trial will be removed from the database, with all the related sessions and trials, while if you choose “No” the deletion will be aborted.

Acquisition:

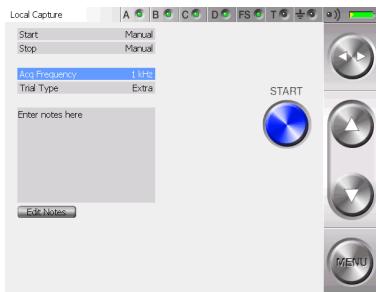
to proceed with the acquisition in “Local” mode it is necessary to have created a new session and to have selected an analysis protocol or to have selected a session already in the database.

Proceed then with the operations described in the previous paragraphs: “Probes Setup”, “Range”, “Digital Oscilloscope”, “Footswitches”.

Once finished all the preliminary operations and the necessary checking it is possible to proceed with the acquisitions.

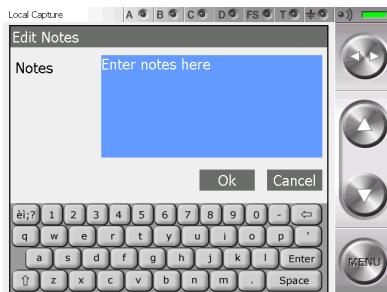
To do that, select the item “Capture” from the Menu.

A screen will appear, which gives the setup for that acquisition:



For every test it's possible to indicate the Start and Stop mode, the acquisition frequency and the type and notes of the test.

To edit the notes click on "Edit Notes", a window will open which allows you to edit the notes.



Introduce the note using the keyboard and then click on "OK" to confirm or on "Cancel" to come back to the previous screen without saving the text just typed.

To modify the other acquisition parameters select the relative field with the Toggle and then use the Up and Down buttons.

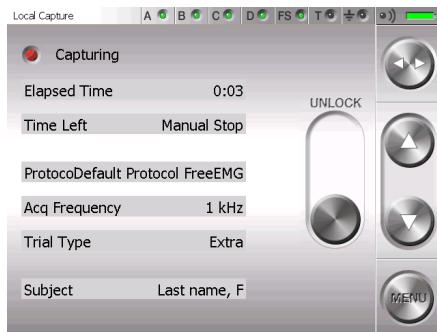
Active fields (Toggle)	Value range (Select)
Acq. Frequency	1KHz, 2KHz, 3KHz, 4KHz
Flag	MMT, Resting, Walking, Undefined, Extra



If the acquisition frequency selected is 3 or 4KHz, the system can acquire 8 EMG channels maximum.

If the selected protocol requires a higher number of probes a warning message will appear and the acquisition won't be allowed.

By clicking on the “Start” button, the acquisition starts and the system automatically goes into Lock mode, showing the following:



To unlock the palm click on the “Unlock” button, this will immediately

move to another position.

To complete this procedure it is necessary to press it again before it goes back to the original position.

Before quitting this mode the screen with the acquiring setup reappears but the “Start” (or “Arm”) button is substituted with the “Unlock” and “Stop” buttons.



The “Unlock” button allows to come back to the previous screen. Clicking on “Stop”, instead, will end the acquisition.

At this point the following screen will be visualized:



To save data on BTS FREEEMG 300 select “Store” whereas to cancel the data just acquired click on “Delete”.

In this case a confirmation for the cancellation will be asked of the user, select “Yes” if you want to delete the new acquired data.

Click “No” button and then “Store” to save the test.

After the storing or the cancellation of the last acquired test you are redirected to the screen containing the “Start” button.

To continue with another acquisition click on “Start” and repeat the operations just described. If any other acquisition won’t be executed, select “Exit” from the menu.

Playback

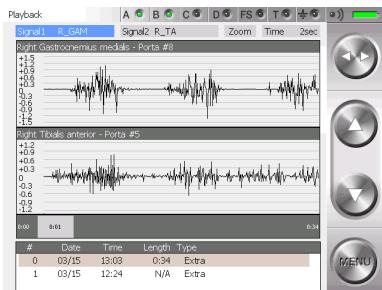
In the Holter mode it is possible to visualize a preview of the data acquired and saved in the database.

To do that, from the menu select the voice “Database” and select the patient, the session and the trial that you want to visualize clicking with the stylus on the correspondent line, that will be underlined in light blue.

Once the trial is selected, from the menu select the voice “Playback”.

At the end of an acquisition session it is possible to go directly to the “Playback” page, without passing from the “database”: in this circumstance all the trials saved in the last session acquired will be loaded.

In both these circumstances the following screen will appear:



From the lower panel select the trial to visualize by tapping on the correspondent line.

It is possible to visualize two signals at the same time.

To do that select the field “Signal 1” and than “Signal 2” using the Toggle and scroll the list of the available signals operating on the Up and Down buttons.

After that to improve the signal visualization, adjust the active fields “Zoom” and “Time” selecting them with the Toggle and changing their value with the Up and Down buttons.

In particular the “Zoom” field allows increasing or reducing the current view area (it acts on the axis of ordinates), while the “Time” field allows changing the temporal value range showed on the axis of the abscissas, choosing among a range of value in between 1 and 10 seconds.

This means that the selected trial will not be entirely visualized, but only bits of the length of 1, 2, 5 or 10 seconds according with the “Time” field.

Active fields (Toggle)	Value range (Select)
Signal 1	Protocol signals
Signal 2	Protocol signals
Zoom	
Time	From 1 sec to 10 sec
# Trial	Trials of the selected session

However it is possible to scroll the whole trial changing time after time the frame from where the visualization starts.

To do that click with the stylus on the grey band that represents the whole trial in the point correspondent to the first frame to visualize.

On the grey band at the two extremities, are indicated the beginning of the trial (that is 0:00) and the total length of it (like in the example in the figure 0:34, that means 0 minutes and 34 seconds).

In the spot in which you tap, a grey rectangle will appear in which will be indicated the correspondent time of the selected first frame (like in the example in the figure 0:21).

Therefore, if the “Time” field is set, for example, on “5sec”, we are visualizing 5 seconds of trial starting from the 21st second.

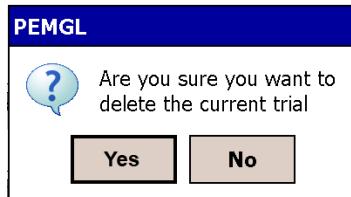


It is possible, if you regard it relevant, delete some trials.

Click on the trial, choosing it in the lower panel, that you want to delete. It will be underlined in light blue and the “Delete” button will appear.

#	Data	Data	Durata	Tipo	
0	03/15	13:03	0:34	Extra	Cancella
1	03/15	12:24	N/D	Extra	

Click on “Delete” and immediately a window with the request to confirm the deletion will appear:



Clicking on “Yes” the trial will be removed from the database, while if you choose “No” the deletion will be aborted.

Importing data to EMG-Analyzer

The data acquired in Holter mode is saved in a local database in the BTS FREEEMG 300. To execute the elaboration and the analysis of the data, you need to import the test using the software EMG-Analyzer.

To do this, proceed as described further in § “Download button”.

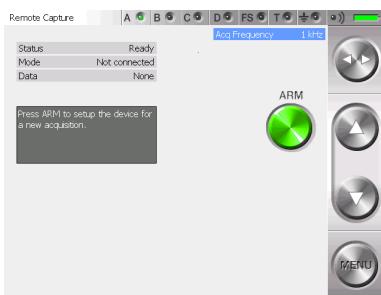
“Remote” button: Lab mode

In this mode the connection between RU and WS is always available.

The specific characteristics are:

- sending data boxes to the WS for the visualization in the remote oscilloscope, available in the applicative software.
- data transfer at the end of acquisition.
- the duration of acquisition and the Start/Stop are controlled by the PC.

Selecting “Capture” from the main menu the following screen appears:



This screen displays some information concerning the system:

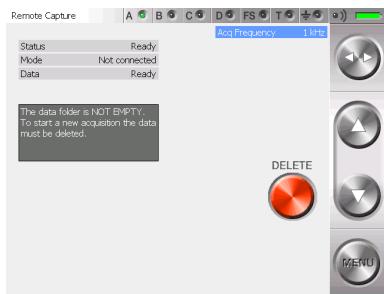
- Status: Ready mode
- Mode: Stand Alone
- Data: None



To make an acquisition in Lab mode, there must be no data saved on the BTS FREEEMG 300.

This possibility can happen only with a loss of WiFi connection between BTS FREEEMG 300 and Workstation during the last acquisition, or if the data transfer has not gone well.

In this case the screen displayed after having selected “Capture” from the main menu will contain instead of the “Arm” button, the “Delete” button and the “Data” field will be “Ready”.



If you want, it is possible to recover the lost data saved in the RU before proceeding with the new acquisitions downloading them on the Workstation using the EMG-Analyzer software.



To know the download procedure consult the manual of EMG-Analyzer.

Otherwise the data will have to be deleted and cannot be retrieved in the future.

To delete the data, click on the “Delete” button; by doing this the system will ask you a confirmation for the deletion, select “Yes” if you really want to delete the data in a permanent way, otherwise click on “No” to come back to the previous screen.

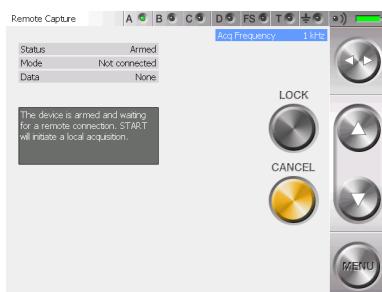
Once deleted the file, the “Arm” button appears again and the “Data” field will again become “None”; so it’s possible to proceed with the acquisition. Before arming the system it is possible to set the acquisition frequency using the Up and Down button of the button bar.

Active fields (Toggle)	Value range (Select)
Acq. Frequency	1KHz, 2KHz, 3KHz, 4KHz

! If the acquisition frequency selected is 3 or 4KHz, the system can acquire 8 EMG channels maximum. If the selected protocol requires a higher number of probes a warning message will appear and the acquisition won’t be allowed.

To prepare the system for capture it is necessary to “arm” it by simply tapping the “Arm” button that will be replaced by the “Lock” and the “Cancel” buttons.

Now it is possible to make the acquisition via remote control.

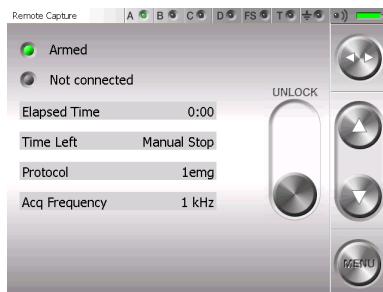


At this level it is not possible to change the acquisition frequency.

Tapping on the “Cancel” button the previous screen appears, returns control to the RU.

To proceed with the next acquisition, the system needs to be armed again.

It is possible to lock the system by clicking on “Lock” directly by this window, therefore at the beginning of the acquisition the BTS FREEEMG 300 locks automatically displaying:



The acquisition starts-up through the remote control, directly by the Workstation.

This display will remain on the BTS FREEEMG 300 until the acquiring session is over.

It's possible to interrupt the acquisition remotely and proceed with the next ones.

At the end of every acquisition an automatic data download will be executed. Only at the end of the download is it possible to launch another remote acquisition.

Once the acquisition session is over, unlock the BTS FREEEMG 300. In order to do so, press the “Unlock” button, this will immediately move to another position. To complete this procedure it is necessary to press it again before it goes back to the original position.

Finally to quit from the “Armed” status click on the “Cancel” button.



For the details of the remote management of the acquisition from the WS refer to the specific manual of the software meant to be used.

Download Button

If the Holter mode is chosen (local acquisition), the acquisitions are saved in a local database to BTS FREEEMG 300.

To elaborate the acquired data with the dedicate softwares installed on the Workstation, the user needs to download them with EMG-Analyzer following these instructions:

- Select from the main page the download mode clicking on the “Download” button
- BTS FREEEMG 300 keeps waiting, showing the following screen:



- From EMG-Analyzer, select the “View Local Database” item from the “Laboratory” menu.
- A window will appear that will allow you to explore and modify the active database on the BTS FREEEMG 300, and download all the files that you are interested in.



For further details concerning the data download refer to the user manuals of EMG-Analyzer software.



The data import takes place with a wireless connection; if the import operation fails, you need to verify that the RU and WS are connected (see § “Appendix C – troubleshooting guide”).

- When the download is finished on the BTS FREEEMG 300 keep pressing the “Exit” button to go back to the main screen.

“Config” button

The “Config” button launches an application that allows the modification of some system settings.

It uses five tabs to reach the different information and features:

- Info:
Main screen that contains information of the installed versions.
- General:
General settings (i.e. language, audio settings...).
- Radio:
Associates the ID identifier of each EMG and FSW/EGN probe to its label identified by color and number/letter;
setting of the signal range;
setting the radio channels utilizing the probes.
- Database:
Database management.
- Maintenance:
session permitted only to BTS Technician staff, for assistance.
For this reason to access this area a Password is required.

To execute any changes of the parts that can type on it is possible to use the touch-screen features of the display and where necessary, activate the keyboard, clicking on the low right corner icon represented by a little keyboard.

To exit this application and come back to the main screen, you must tap on the “Ok” button, placed in the top right corner.

One tap on this button will confirm all the changes made.

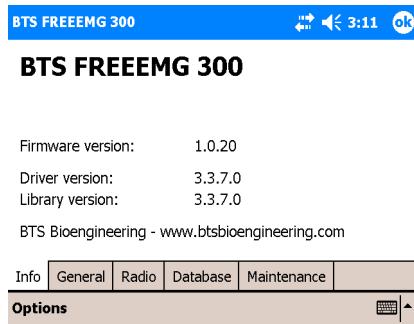
! It won't be possible to undo the changes made, apart setting again, manually the previous values.

All the changes made are immediately activated, therefore, in some circumstance, it will be necessary to restart the BTSEEEEMG300 application to see these changes applied (for example when you change the language).

Let's analyze now, more in depth, the four tabs that the user can modify.

Info

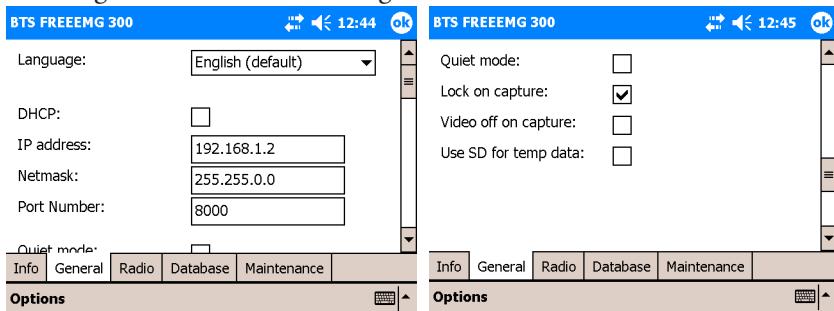
Clicking on the “Config” button on the main screen, it automatically selects the application screen in which the tab Info is selected:



On this page it is possible to read all the information about the versions of each installed component, hardware or software.

General

Selecting “General”, the following screen will be visualized:



It is possible to set:

- The language
- “DHCP”, for automatic host configuration, the “IP address” and “Netmask”, available only with the “DHCP” not checked, to manually assign the connection parameters and the “Port Number”.
- “Quite mode”: Checking this voice, the program will play without any noise (instead of what normally happens when for example you Tap on a button or activate an acquisition...)
- “Lock on Capture”: Checking this voice when an acquisition starts the BTS FREEEMG 300 will be automatically locked showing the “Unlock” button
- “Video off on Capture”: if checked, the display automatically will switch-off at the acquisition beginning. To activate the screen again a click on one of the PocketPC button is enough
- The use of a Secure Digital memory card to store the temp file generated during the acquisition (check this voice only if there is a Secure Digital board in the related port).

Radio

When “Radio” is selected the following page is displayed:

EMG probes:	Labels:
001D39	1
001D4E	3
001D3D	5
001D3F	7
001D41	9
001D43	11
001D3A	2
001D3C	4
001D3E	6
001D40	8
001D42	10
001D44	12

FSW/EGN probes:	Labels:
001D47	A
001D48	B
0010D7	C
0010E1	D
0	--
0	--
0	--

The “EMG probes” and “FSW/EGN probes” sections allow to associate the ID that uniquely identifies each probe manufactured by BTS S.p.A. with the probe’s label.

The ID is shown on the clip of every EMG probe and on the back of every FSW/EGN probe.

Up to 16 EMG probes and up to 8 FSW/ EGN probes can be registered.

 Probes that are not registered in this section will not be recognized by the Receiving Unit and therefore may not be used for acquisitions.

Generally, the system is distributed to the customer with this association already made.

However it could be useful if new probes are purchased or if probes are replaced due to a malfunction.



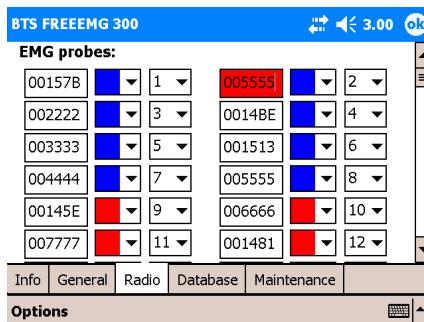
However when you receive the system it is advisable to check that the association has been made correctly. If a probe has been incorrectly associated to a label or the ID number does not match that on the clip the probe may not work. Instead, changing two IDs compared to the label could cause an exchange of acquisition signals as well and therefore cause false results in the Electromyographic examination.

Follow the procedure below, to register a probe that has not been introduced:

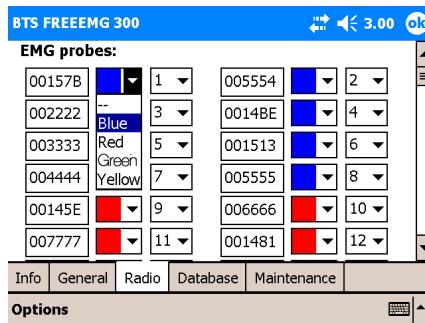
- Enter the ID of the probe using the keypad that can be activated on the bottom right-hand side of the page.



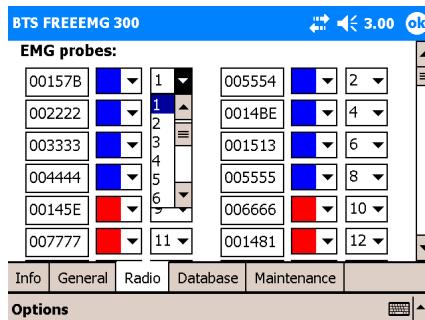
If the string entered is not admissible or has already been entered the software will highlight it in red.



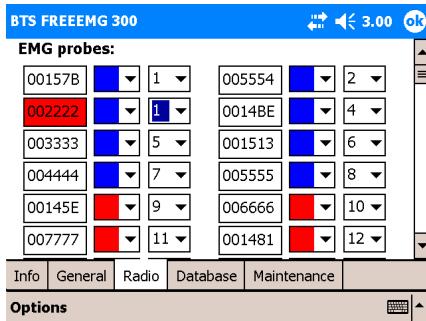
- Select the color of the probe's label (the colors can be Red, Green, Blue, and Yellow) using the drop down menu.



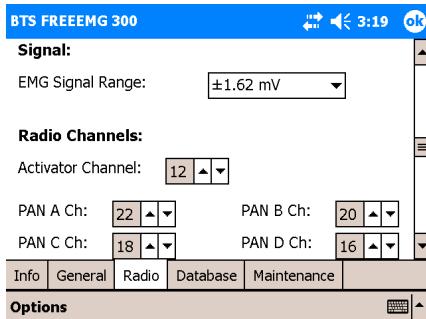
- Finally, select the number or letter shown on the probe's label (number selection from 1- 16, letter selection from A-F).



If the label (identified by the color/ number or letter combination) has already been used the software will highlight the ID string in red.



From the Radio page two other sections may be accessed.



The “Signal” section allows to select the Range for electromyographic signals. 3 different value are available:

- 6,34mV;
- 3,17mV;
- 1,62mV

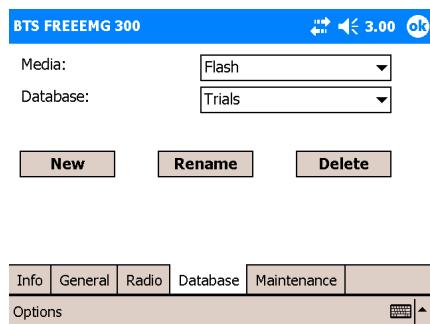
From the “Radio Channels” section the ZigBee channel with which to work can be assigned to the activator and the four transmitters.



It is recommended to modify this section only if absolutely necessary and eventually with referral to BTS technical support.

Database

Selecting “Database” the following screen will be visualized:



In this section it is possible to select the current database, to create new databases, to delete and rename existent databases.

There are two list-boxes, the first one, “Media”, allows the selection of the box in which the database can be found or to insert a new one.

In particular there are two possible medias: the flash memory, internal to the Pocket PC and the Secure Digital card.

If the latter is not present, a message will be visualized indicating that the card is not inserted.

Instead the error message:

“ERROR: media not initialized”

will be visualized if the card has been inserted but hasn't still been initialized.

In this circumstance a button will appear allowing the initialization.

Once selected the “Media” it is possible operating on the second list-box to select the database to use.



Mind that if the selected Media is empty, it is necessary to create a new one.

To create a new database click on “New”.

The new database will be created with the default name “TrialsDB”.

To change the name select it and click on “Rename”.

To delete a database select it and click on “Delete”.



This operation removes completely the database and all its content (patients, sessions and trials).

For this reason the system will ask a confirmation before proceeding with the deletion.

“Exit” button

The “Exit” button allows the closing of the application and the visualization

of the operative system installed on the PDA.

To do that it is enough to press and hold the “Exit” button for few seconds.

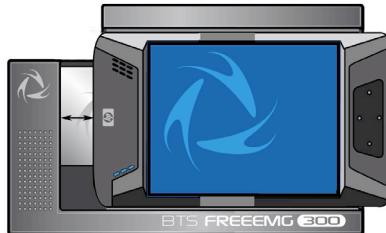
BTS FREEEMG 300 updating

Updating the onboard software

To update the BTS FREEEMG 300, exit the application by selecting the entry of the Exit menu and holding down the “Exit” button for some seconds.

Before carrying out the upgrade of the software it is recommended a backup be made of the software version currently installed.

Slide the PDA out of the methacrylate guide enough to disconnect the Compact Flash. Connect the PDA via the dedicated cable to the USB port of the WS.



On the WS, from Windows, run the update program, launching the “BTSFREEEMG300Setup.exe” file, and follow the video instructions till the update is complete.

Reinsert the PDA in the AU.

Restart the “BTSFREEEMG300” application on the BTS FREEEMG 300: from the Start menu, click on “Programs”, search for the “BTSFREEEMG300” icon and single click it. The main screen will appear.

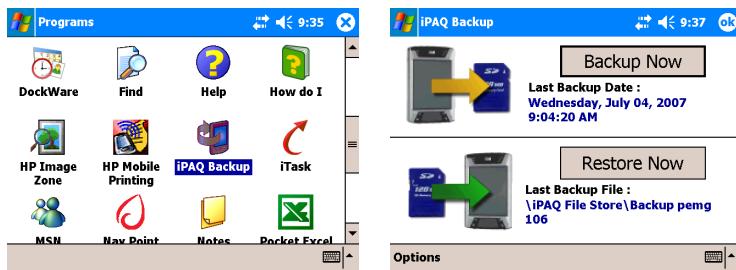
Creating a backup image

At the end of each software upgrading, it is important to remember to create a backup image.

 It can happen that the Pocket PC battery goes completely dead. When this happens all the BTS settings as also the BTSTFREEEMG300 software will be lost. To restore the software and bring the BTS FREEEMG 300 to the standard configuration it will be enough to proceed with the restore of the last backup done (see Appendix D – Troubleshooting guide).

To do the backup proceed as follow:

- exit from the BTSTFREEEMG300 application holding the button “Exit” for some seconds
- select “Start” and then “Programs”
- among the installed programs, choose “iPAQ Backup”:



- with the stylus tap on “Restore Now” and wait the end of the backup procedure.

The Pocket PC will restart and then the BTSTFREEEMG300 software will be automatically reloaded.

The backup procedure is now finished, therefore we suggest to rename the backup file created giving it a more meaningful name, in particular we recommend to indicate the version number of the software.

To do that proceed in this way:

- exit from the application
- select “Start” and then “Programs”
- among the installed programs, choose “File Explorer” click on the arrow that appears on the grey bar, under the title “File Explorer” and choose “Device”
- open the folder “iPAQ File Store”
- look for the backup file just created that will have a name like: Backup_2007-07-15, where the date is the one during the backup time
- with the stylus, tap and hold for few seconds on the backup file icon till when the menu appears
- choose rename and type the new name (i.e. Backup_v107 supposing you have updated the software with the version 1.2.107.0).

maintenance and cleaning

Periodically inspect the PDA and the slide of the receiving unit for any signs of detachment, cracks or other damage.

Clean the external parts periodically with cleaning liquid approved for computers. On the PDA monitor use a microfibre cloth only, and do not use liquid detergents or solvents.

Contact with the skin of the patients is achieved via the pre-gelled Ag/AgCl electrodes, which, being single-use disposable, intrinsically guarantee a sufficiently high level of hygiene.

Generally you use hypoallergenic band-aid or hypoallergenic double-sided tape to apply the Footswitches in correspondence of the foot contact points.

At the end of each work session, it is important to carefully remove every glue or gel residual from these parts and from the probes.

After each use we suggest to clean the switches using a soft cloth moist with a disinfectant solution, being careful removing any glue residual left.

The BTS FREEEMG 300 cannot be sterilised.

appendix A
technical specifications

Wireless Probes

Geometry:	variable
Electrodes:	standard with clip connection
Separation:	min: 16mm - max: 66mm
Autonomy:	8h of use
Battery:	some days stand-by some months deep sleep rechargeable, lithium ion
Dimensions:	14x41,5x24,8mm mother electrode diameter 16x12mm satellite electrode
Weight:	13g battery included
Frequency used:	ISM band 2.4GHz (standard IEEE802.15.4)
Input impedance:	>10 GOhm
CMMR:	>110 dB @ 50-60Hz
Resolution:	16bit
Acquisition frequency:	up to 4KHz
Sensitivity:	1µV
Accuracy of measurement*:	± 2%

Receiving Unit

Autonomy:	up to 24h with rechargeable battery up to 9h with single battery
Battery:	rechargeable, lithium ion

Dimensions:	155x106x35mm
Weight:	360 grams
Frequency used:	ISM band 2.4GHz (standard IEEE802.15.4 and IEEE802.11b)
Display:	4" VGA color touch-screen

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

BTS internal coding

Name of device, components, parts and/or accessories as per product label	Identifier for device (bar code, catalogue, model or part number)
FREEEMG 300 Pocket PC with Stylus Acquisition unit Belts and armbands for attachment to patient • 16 EMG probes	FREEEMG 300
FootSwitch/Electrogoniometer Wireless Probe Foot switches: Insole individual foot switches for the automatic identification of the gait events. Electrogoniometers: Sensors for the measurement of joint angles progress over the time.	FRESPU12

Name of device, components, parts and/or accessories as per product label	Identifier for device (bar code, catalogue, model or part number)
Fine-Wire adapter : Adapter for the Fine-Wire electrodes.	FRESPU23
O-Port expander : Digital to Analogue EMG data converter.	FREALG16
EMGenius : software application to acquire, elaborate and report electromyography and footswitch signals	EMGE0901
EMG-Analyzer : software application for EMG signal analysis	SMAN0901
Docking station	FRESPU05
Charger	FRESPU06

appendix B

environmental specifications

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

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

appendix C
power supply and switch off

The medical power supplier TR30RAM050 provided with the system has the following functionality:

- Provide power to the Receiving Unit and recharge its battery.
- Guarantee the galvanic insulation of the Receiving Unit from the power.

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

- Stand-By of the Receiving Unit:
 - 1) push the graphical button “MENU” and then select “Exit” to quit the application.
 - 2) set the Receiving Unit state on “stand-by” by clicking on the switch -on/off button of the PDA.
- Stand-By of the Probes:
place the probes on the “Charger” or “Docking Station”.

appendix D

battery

BTS FREEEMG 300 is an internally powered device: several of its components use batteries as indicated below.



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 different components of the system equipped with the battery are:

- Receiving Unit

Quantity:	1 per each unit
Technology:	lithium ion (Li-Ion)
Removable:	yes, by removing the PDA from the acquisition unit

- Wireless Probes

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

- Docking Station (optional)

Quantity: 1 for each unit
Technology: lithium polymer (Li-Poly)
Removable: NO, BTS technical service is required

appendix E

declaration of conformity

<p>BTS SpA Via della Croce Rossa 11, 35129 Padova (PD) – Italy Tel. +39 049 981 5500 Fax +39 049 792 9260</p> <p>R&D Office Corso Cap. 222/223/200 35129 Padova (PD) Italy Reg. Min. Court 123/14/30/58 R.E.A. 158871</p> <p>Head and Administrative Office Via della Croce Rossa 11, 35129 Padova (PD) Italy Reg. Min. Court 123/14/30/58 R.E.A. 158871</p> <p>www.btsbioengineering.com info@bts.it</p>	 BTS Bioengineering		DECLARATION OF CONFORMITY	
declare under our sole responsibility that the product(s):				
name / description: Electromyographic system / device for recording myoelectrical activity. model: FreeEMG300 S/N: SN				
satisfies the essential requirements of the Medical Devices Directive 93/42/EC (and its amendments including 2007/47/CE), and therefore carries the CE marking of the European Union. The conformity assessment procedure is according to the article 11 of the directive (Annex II.3 full quality assurance) and the article 12 it is not applicable.				
In accordance with Annex IX of the 93/42/EC directive it is classified as follow: CLASS "IIa" (rule 10)				
In accordance with IEC 60601-1 is also classified as follow: Class: internally powered device Applied part type: BF				
The product conforms to the following standards:				
EN ISO 14971 Medical Devices - Application of risk management to medical devices.				
IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance.				
IEC 60601-1-2 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 - Medical device software - Software life-cycle processes				
EN 62304 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, Ridderstrasse 65, 80339 München – Germany , Identification N. 0123, EC certificate N. G 12 10 65301 003 valid until January, 16 2018.				
Padova, Date				
Bruno Ros CEO BTS S.p.A.				

appendix F

troubleshooting guide

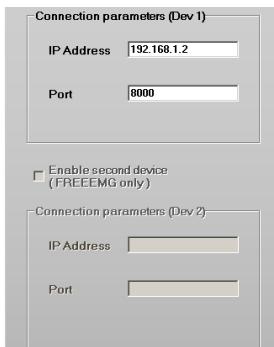
1708 Error – Incorrect IP address or port set up

The software uses IP address parameters and communication ports to create network connections between the Workstation and the PDA.

In the case of incorrect configuration, the correct parameter values need to be re-input.

To do this, launch the software that you are going to use and then, by the menu voice “Laboratory” select “Set Emg Device”.

Verify that the IP address and the port setting are correct.



The values to specify are the following:

IP Address: 192.168.1.2
Port: 8000

and if a second receiving unit is available:

IP Address: 192.168.1.3
Port: 9000

If necessary, correct the values and click on “Upgrade” before closing the windows.

1709 Error – Impossibility to connect to the unit

One or more Wi-Fi network resources (Access Point, Workstation, PDA) are not available.

In general, we recommend some simple checks as follows:

- Access Point

Check they are correctly connected to the power supply and switched on.

Try switching the AP off and then back on. Since some models are not fitted with an On/Off switch, it may be necessary to remove and reinsert the power cable.

If on the rear of the model there is a selection button, verify it is on position AP

- Workstation

If the Workstation is fitted with a Wi-Fi interface, check it is active and connected to “BTSFREEEMG300”.

As the connection is through the AP, check that the LAN (local area network) is active.

- BTS FREEEMG 300

The Wi-Fi connection is active only when the BTS FREEEMG 300 is in Remote Mode or in Download Mode.

From the main screen choose one of these two mode.

 If the connection is still not activated, also with all these settings, please contact the BTS Customer Care.

Backup restoring

The backup restoring procedure allows the reloading of the

“BTSFREEEMG300” software and the restoring of the standard configuration of the Pocket PC. This is very useful, for example, when the PDA battery goes completely dead. If this happens, when the PDA is switched on, the software “BTSFREEEMG300” won’t be loaded and, instead of it, a screen will appear in which the system will ask the user to execute some start-up operations.



In this circumstance, before proceeding with the restoring procedure, it is necessary to complete the start-up operations required by the system that consists in the execution of some simple exercises like the stylus pointing, to execute a copy and paste, etc... (for further details refer to the PDA manual).

When all these operation are finished, the windows main screen will be visualized and it will be possible to proceed with the restoring of the last backup.

To restore the backup follow these instructions:

- select “Start” and then “Programs”
- among the installed programs, choose “iPAQ Backup”;
- click on “Restore Now” to restore the last backup, the PDA will restart and then the “BTSFREEEMG300” software will be reloaded
- at this point, exit from the application to set the date and the time, to do that select the date under the voice “Start”.



For further details about the time and date setting refer to the PDA manual.

Receiving unit hardware reset

In case the PDA blocks during use and does not respond to any commands, you must perform an hardware reset operation.

To do that follow these instructions:

- place the receiver on a plane;
- grip with your right hand the PDA stylus;
- using index and middle finger of your left hand push the two buttons (marked by the icons keypad and arrow) positioned at the right of the PDA display and simultaneously, with your right hand, insert the stylus in the hole on the right side of the PDA, as shown in the figure below:



Immediately the system will be rebooted;

- when the PDA will switch on again the software “BTSFREEMG300” won’t be loaded and, instead of it, a screen will appear in which the system will ask the user to execute some start-up operations; complete the operations required that consists in the execution of some simple exercises like the stylus

pointing, to execute a copy and paste, etc... (for further details refer to the PDA manual).

- when all these operation are finished, wait for the windows main screen to be visualized;
- finally proceed with the restoring of the last backup procedure described in the previous paragraph.



BTS Bioengineering

BTS Bioengineering Corp.
147 Prince Street - Suite 11
11201 Brooklyn NY
USA
info: +1 347 204 7027
helpdesk: +1 646 575 0426

www.btsbioengineering.com
info@btsbioengineering.com

BTS S.p.A.
viale Forlanini 40
20024 Garbagnate M.se MI
Italy
tel +39 02 366 490 00
fax +39 02 366 490 24