BTS FREEEMG 100 RT

user manual

english
version 2.0.3

BTS Bioengineering

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contents

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

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

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

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

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

the European Union (see Declaration of Conformity).

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

Symbol on the equipment and in the users' instructions:
Symbol for the separate disposal of electrical and electronic equipment, in accordance with Directive 2002/96/CE (WEEE).
The equipment belongs to Group 8 (medical equipment).
In force in the nations of the European Union, Norway and Switzerland.

Rx only

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

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

Symbol on the equipment:
Symbol located next to the series number on the equipment.

Acronyms used in this manual:

RU	Receiving Unit
EMG	Electromyography
WS	Workstation

radio regulation

Radio equipment identification:

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

- FSWEGN probes:
  FCC ID: YQH-BTSWAUX
  IC: 9188A-BTSWAUX

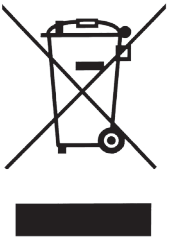
- Receiving Unit contains:
  FCC ID: TFB-MATRIXLP
  IC: 5969A-MATRIXLP

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

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

disposal (WEEE)

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



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

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

This is a battery-powered equipment.

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

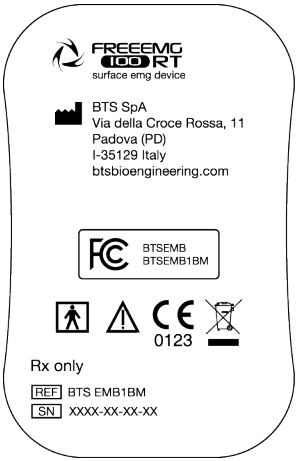
intended use

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).

BTS FREEEMG 100 RT 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.

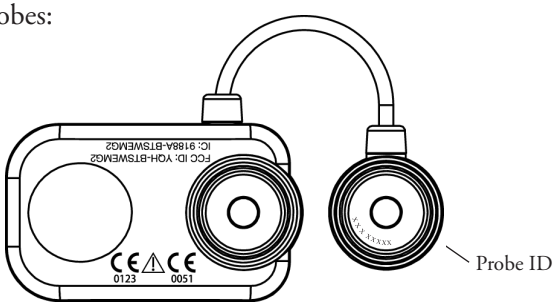
regulatory label

Receiving Unit Regulatory label

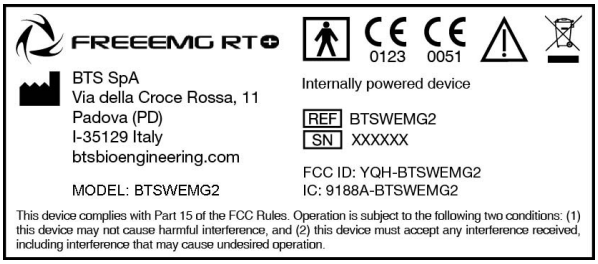


EMG Wireless Probes Regulatory label

Label on the probes:

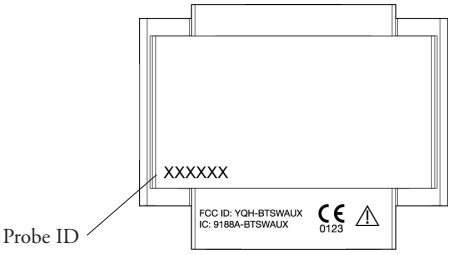


Label not on actual probes due to size constraints:

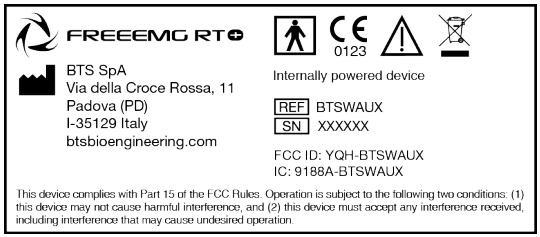


AUX Wireless Probes Regulatory label

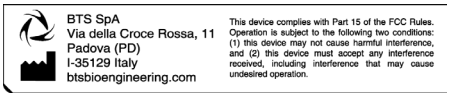
Label on the probes:

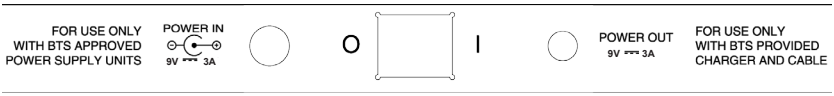


Label not on actual probes due to size constraints:



BTS Charger Regulatory label





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 100 RT 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 of 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 hypoallergenic double-sided tape, compatible with the usage on undamaged skin for brief periods of time
- Periodically verify the integrity of the system and of its components.
- To not wet or dip in water the parts which 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 the 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 100 RT 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.

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

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introduction

General description

BTS FREEEMG 100 RT allows for a functional evaluation and a real-time visualization of the acquired signals for biofeedback and monitoring applications.
That makes it an indispensable instrument in the fields of sport, rehabilitation, ergonomics, neurology and orthopaedics.

With BTS FREEEMG 100 RT the patient set up in very quick: the lightweight probes are attached directly to the pre-gelled electrodes and do not require any additional fixing such as adhesive tape. Thanks to the total absence of cables the patient can move around freely.

BTS FREEEMG 100 RT is supplied with EMG-Analyzer the most complete software solution for analyzing electromyographic signals and with BTS MIOFEED, an easy-to-use therapeutic solution, studied also for home applications.

BTS EMG-Analyzer software 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 MIOFEED software allows a real-time monitoring of muscular activations during rehabilitative or sports tests execution.
The EMG signal acquired with BTS FREEEMG 100 RT are transmitted in real-time directly at the receiving unit connected to the PC and transformed in graphic form and sounds to provide a prompt audio-visual feedback to the subject. This increase of audio and visual afferences is fundamental in order to improve the contractile capacities of the muscles., also of the paretic ones.

BTS FREEEMG 100 RT seamlessly integrates with BTS motion analysis systems, through the SMART (and ELITE) dedicated software.

Case contents

Standard components:

- Receiving Unit

- Up to 6 wireless EMG probes (identificative labels available in 4 different colors)

- Magnet for EMG probes activations

• Probes Charger (AC adapter included)

• Set of disposable electrodes

• USB extension cable

• User manual

Optional components:

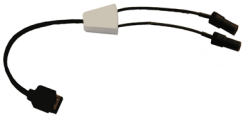
• Footswitch Kit

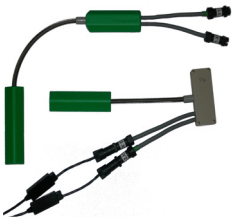
• 2 FSW/EGN Wireless Probes

• 2 Connectors of 4 Switches

• 10 single Switches

- Electrogoniometer Kit
  - 1 FSW/EGN Wireless Probe
  - 1 Electrogoniometer
  - 1 Connector





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

system components

BTS FREEEMG 100 RT system consists of two parts: the receiving unit and the wireless probes.

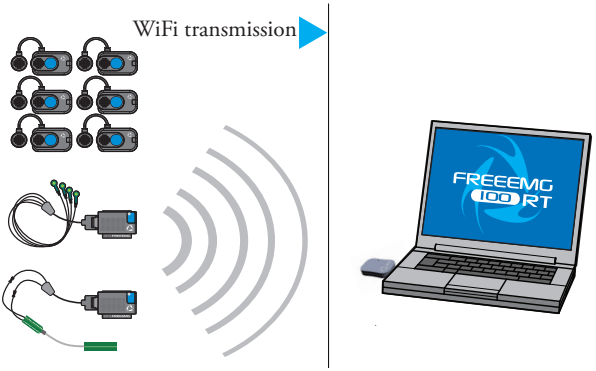
Receiving unit

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

The receiving unit is able to handle simultaneously 6 wireless probes with the following limitations:

- up to 6 EMG probes, used for acquisition of the same number of electromyographic signals;
- up to 2 probes for the connection of 4 switches each, used for the basographic acquisition;
- up to 6 probes for electrogoniometers connection, used for acquisition of up to 2 angle components each;
- it is not possible to acquire simultaneously FSW and EGN probes.

All the probe combinations that respect what indicated above are possible.



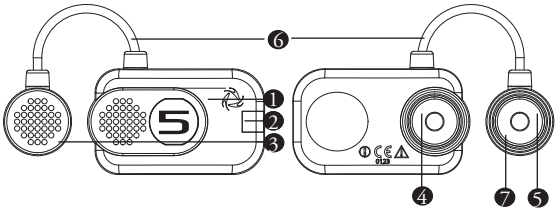
Wireless EMG Probes

BTS FREEEMG 100 RT 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 probe consists of a mother electrode and a satellite electrode, each fitted with a clip. The two parts, connected via a flexible cable, may be positioned as needed by the user at adjustable distance (electrodes with variable geometry).

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



❶ mother electrode
❷ LED
❸ satellite electrode
❹ mother electrode clip
❺ satellite electrode clip
❻ flexible cable
❼ probe ID

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.

- Active-Scanning: white LED which cyclically lights for a few seconds.
  In this mode the probe is searching for the receiving unit.
  At intervals of about 1 minutes it carries out a scan of the frequencies of few seconds. During the scan the white LED flashes quickly.

- Active-Connected: white LED which flashes slowly.
  When the probe and the receiving unit establish a connection, the white LED begins to pulse slowly: the probe is waiting for commands.
  If the connection is interrupted, the probe returns to "Active-Scanning" mode and attempts to re-establish the connection with the receiving unit.

- Active-Capturing: white LED which lights and goes out at regular intervals.
  During acquisition the white LED flashes at regular intervals of approximately one second. At the conclusion of the acquisition, the probe returns to the "Active-Connected" condition.
  If during the acquisition, connection to the receiver unit is lost, the probe continues to acquire, storing the data locally for one minute and at the same time scans the assigned channel trying to reconnect to the receiving unit. If after one minute the scan is unsuccessful, the probe returns to the "Active-Scanning" condition interrupting the storage of data.

- Completely discharged or in "Deep Sleep" mode: LED is off.
  If the probe is completely discharged the LED does not display any flashing cycle and is off.
  The same happens when it is in "Deep Sleep" mode (except during the recharging phase in witch 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.

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

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

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 100 RT 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.

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

- Charge: steady red LED.
  During recharging the red LED is on, the probe is completely passive and does not respond to any command.
  When the battery is fully recharged or when the probe is removed from the charger, if sufficiently recharged it passes to the "Active-Scanning" mode.

- Active-Scanning: green LED which cyclically lights for a few seconds.
  In this mode the probe is searching for a receiving unit.
  At intervals of about 3 minutes for 3 seconds its carries out a scan of the frequencies.
  During the scan the green LED flashes quickly.

- Active-Connected: Green LED which flashes slowly.
  When the probe and the receiving unit establish a connection, the green 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: Green LED which lights and goes out at regular intervals.

During acquisition the green 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.

- Probe discharged: LED is off.
  If the probe is completely discharged the LED does not display any flashing cycle and is off.

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.

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 (applicable, for example, to the finger), and square (useful for tapping tests), 44 mm x 44 mm.

BTS FREEEMG 100 RT 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.

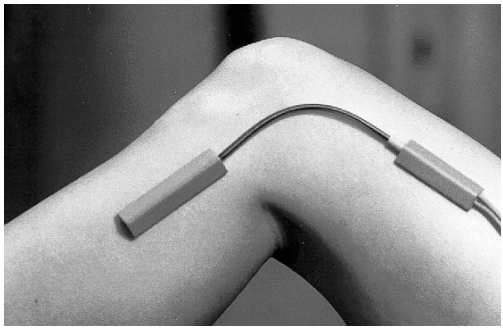
The footswitch channels are not supplementary to the 6 electromyographic channels. Moreover it is not possible to acquire simultaneously FSW and EGN.

Refer to § "receiving unit" for the possible probes combination.

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 100 RT 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 6 electrogoniometers.

The EGN channels are not supplementary to the electromyographic ones, each EGN probe replace a EMG probe. Each EGN probe allows acquiring up to two angular components. Moreover it is not possible to acquire simultaneously FSW and EGN.

Refer to § "receiving unit" for the possible probes combinations.

Charger

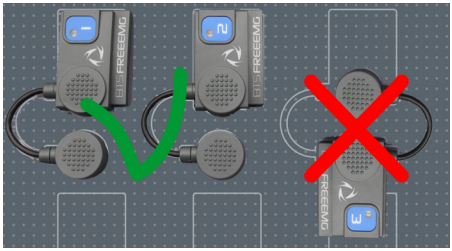
The Charger, included with the product, charges the BTS FREEEMG 100 RT probes.

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

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

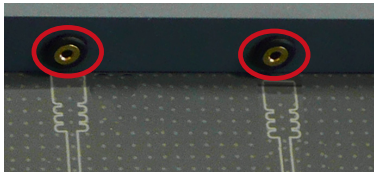
The EMG probes are connected to the charger using the same clips that normally collect the EMG signal.

Refer to the cover of the charger to identify the correct polarity. The probes cannot be recharged if the polarities are inverted.



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.

While the FSW/EGN probes connect to the charger using the special connector as shown in the figure below:



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 the probes, prior to use them, using a magnet.

User PC minimum configuration

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

Connections

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

Connect the receiver to the WS using the USB connector.

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

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

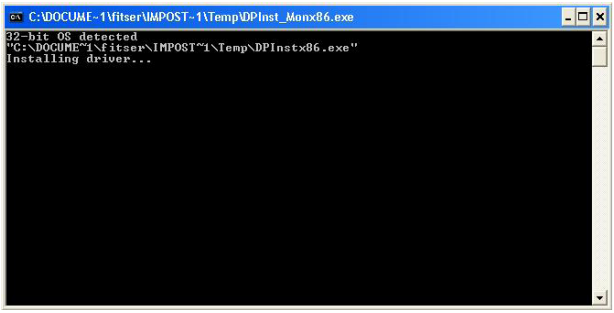
Note that to be recognized and activated by the system it is necessary that all the probes have been disconnected from the Charger (if switched-on) and that the EMG probes have been also reactivated using a magnet.

Hardware installation

The first step of the hardware installation procedure consist in the USB receiver driver installation.

To do that enter in the CD player of the workstation, the BTS CD software containing the installation files that contains the “EmbEMG-X.X.XX.X.zip” file.

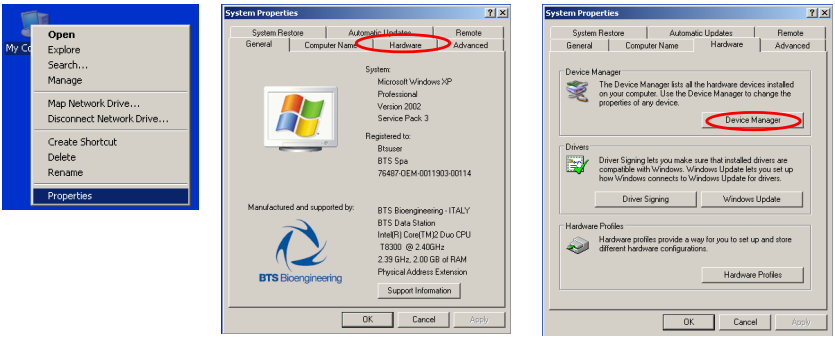
Extract the .zip file in the local disk C and then perform a double click on the file “CDM20814_Setup.exe” and wait for the window that has just opened, to close.



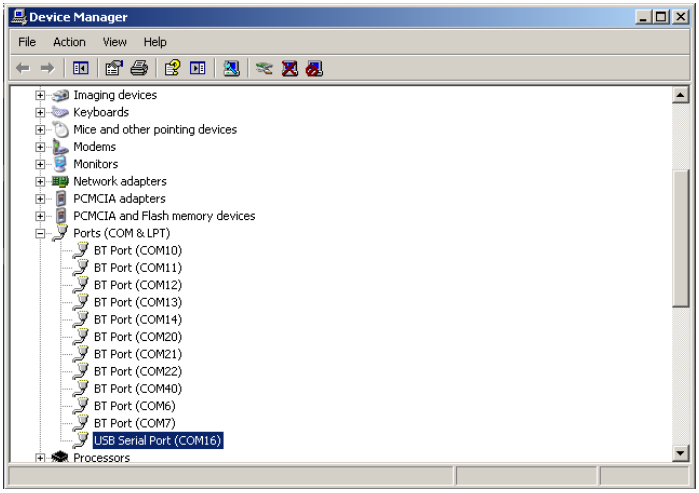
After have performed all the steps above, it will be necessary to configure the port for the USB receiver.

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

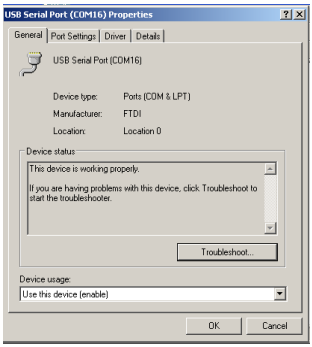
Then, clicking the mouse right button on “My Computer”, select “Properties”, choose “Hardware” and then enter the “Device Manager”:



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

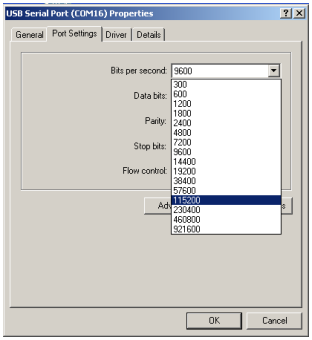


Entering the port properties window it will be displayed the following:

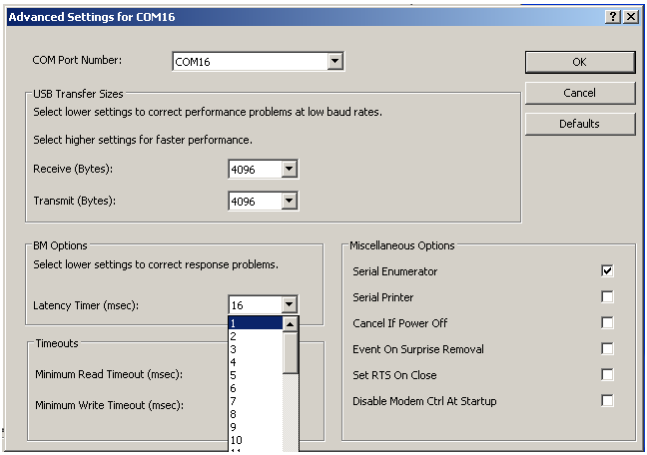


In which you must select the TAB “Port Settings”.

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



In the window that opens, you must set the value of “Latency Timer (msec)” equal to 1msec, and then click “OK”, returning to the previous screen.



Also in the “Port Settings” window click on “OK” then close the windows remained still open.

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

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.

In the following paragraph we will refer to this software, however BTS FREEEMG 100 RT is manageable also by BTS MIOFEED software and all BTS applications of SMART family dedicated to the motion analysis.

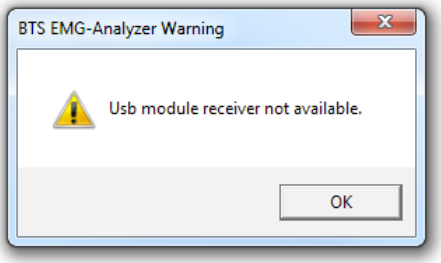
For more details concerning the use of BTS FREEEMG 100 RT with other software, please refer to its specific manual.

Before to proceed verify that the software BTS EMG-Analyzer has been properly installed on the user PC (please refer to its manual for the installation procedure).

BTS EMG-Analyzer configuration check

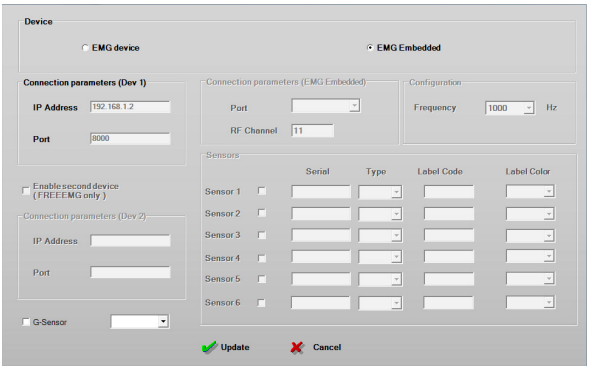
Keeping the receiver still inserted in the USB port, launch BTS EMG-Analyzer double-clicking on the relative icon.

If the following windows appears:

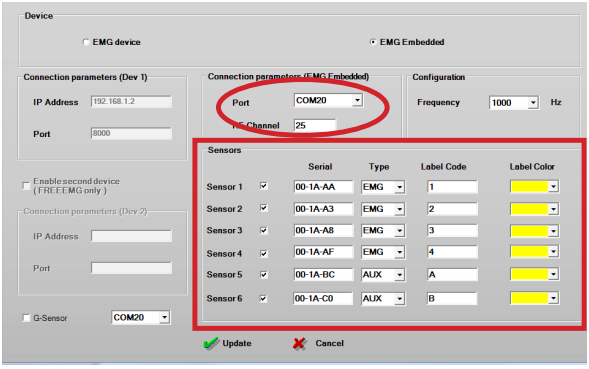


Click on “OK” to reach the software main screen.

On the menu bar at the voice “Laboratory” select “Set Emg Device”.
The following windows will open:



Verify that the check is on “EMG embedded”.
Select the correct Port number acting on the drop box menu, according with the port number that the PC has automatically associated to the device during the COM port setting operations (see §”Hardware installation”).
If the port number selected is the correct one the software will activate the Sensors area of the windows and all the info about the sensors associated with the USB receiver connected to the workstation will be visualized.



Verify that all the parameters values coincide with those reported on the supplied sensors that you want to use (see § “Wireless EMG probes” and “Wireless EGN/FSW probes”).

During the acquisition the system will acquire always all the sensors enable in this windows. Is possible to disable the sensors that you don’t need for the acquisition. Click on “Update” before closing the window to save the new configuration.

To enable a sensor click on the white square correspondent, the check mark will appear and then fill the fields “Serial”, “Label Code” and “Label Color”, according with the value reported on the probes (see § “Wireless EMG probes” and “Wireless EGN/FSW probes”), and select a “Type” between “EMG” and “AUX”.

Click on “Update” before closing the window to save the new configuration.

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 100 RT it is possible to acquire up to 6 probes.

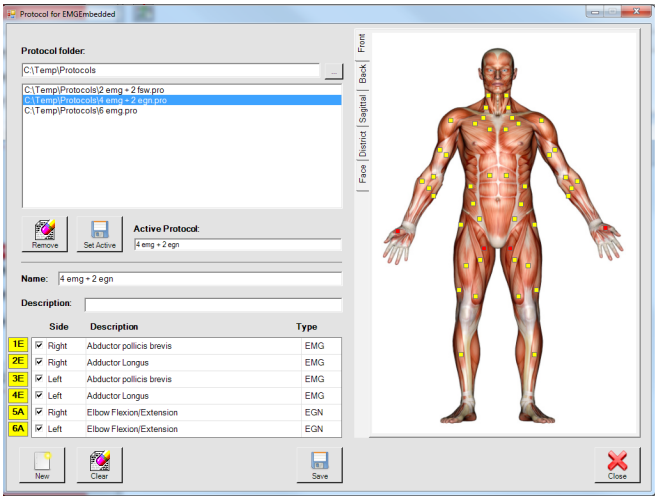
Refer to § “Receiving unit” for the details about possible probe combinations.

Launch the software EMG-Analyzer.

Before to proceed we suggest you to make the procedure described in the § “Software configuration check” to be sure to have selected the EMG embedded device and to have enabled all the probes required for the acquisition.

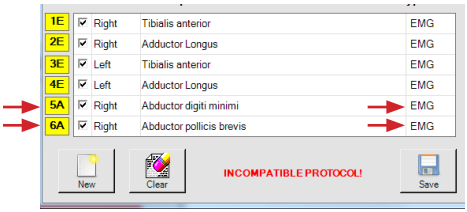
To create a new protocol, from the menu voice “Laboratory” of BTS EMG-Analyzer, select “Create Emg Protocol” .

The window for the creation or modification of protocols will open.



If the receiver is connected to the PC and correctly set, in the first column of the protocol table there will be reported the labels of the probes connected to the receiver, and the active protocol will be displayed.

If the active protocol is not consistent with the set of probes connected to the receiver the following warning message will be displayed on the bottom part of the windows:



To proceed with the acquisitions it is necessary to have the probes set and the selected protocol compatible.

To reach this condition it is possible:

- to select a line of the protocol and modify any fields to make it consistent with the probes set,
- to select an other protocol compatible with the probes set among the ones saved in the database and displayed in the "Protocol folder" area of this windows, and set it as "Active protocol" clicking on "Set Active",
- coming back to the "Set Emg Device" windows and modify the probes set.

To create a new protocol follow this procedure:

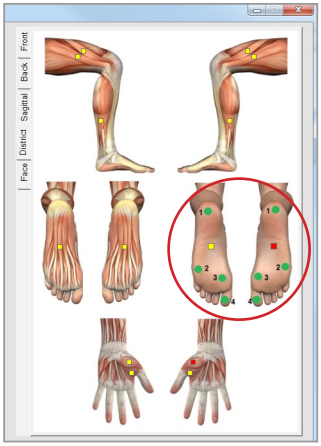
- click on "New". The fields to be filled for the protocol creation will be enabled.

- 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, first of all verify that there were no EGN already selected in the protocols, otherwise the protocol won't be valid and the software won't allow saving it.
  Select the "District" anatomical map and proceed click on the right and then on the left foot by selecting the corresponding square in the

anatomical map:



- If you want to acquire Electrogoniometers, first of all verify that there were no FSW already selected in the protocols, otherwise the protocol won't be valid and the software won't allow saving it.
  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 angles 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.

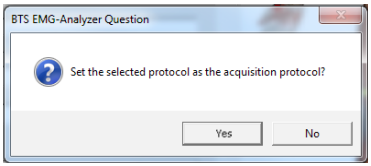
-it is possible to insert also a short description of the protocol using the appropriate box "Description".

When every signal of the protocol has been inserted, proceed saving the

protocol, clicking on “Save”.

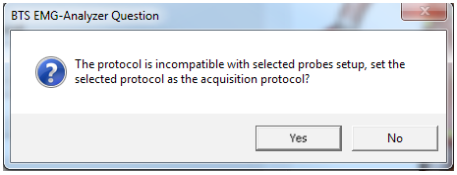
If the protocol is compatible with the probes combination allowed by the system the protocol could be saved.

If the Probes setup is compatible with the protocol the following windows will be displayed:



Clicking on “Yes” it will be set as “Active protocol” and will be used in the next acquisition session.

Instead if the Probes setup is not compatible with the protocol the message displayed will be:



To proceed with the acquisition it is necessary make the probes set and “Active protocol” consistent.

In both cases clicking on “NO” the protocol will be saved in the “Protocol Folder” and will be available in the future, but the “Active protocol” won’t be modified.

appendix A
technical specifications

Wireless Probes

Geometry:	variable
Electrodes:	standard with clip connection
Separation:	min: 16mm - max: 66mm
Autonomy:	8h of use some days stand-by some months deep sleep
Battery:	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:	1KHz
Sensitivity:	1µV
Accuratezza di misura*:	± 2%

Receiving Unit

Connection:	USB
Dimensions:	82x44x22,5mm
Weight:	80 gr

Frequency used:	ISM band 2.4GHz (standard IEEE802.15.4)

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

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 100 RT USB receiving unit EMG wireless probes	FREEEMG 100 RT
FSW/EGN 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
EMG-Analyzer: software application for EMG signal analysis	SMAN0901
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 receiving unit is powered by the USB port.

To switch off the system the following operation must be done:
- Exit from the application software
- Unplug the receiving unit from the USB port.
- Put the probes in “Deep Sleep Mode” placing them on the “Charger”.

appendix D
battery

BTS FREEEMG 100 RT probes are internally powered.

The Probe battery replacement can be done only by BTS qualified personnel.
The probes are sealed to avoid the access to the internal circuit components.

Batteries are equipped with battery protection circuit to:
- -over-voltage, threshold 4.3V
- -under-voltage, threshold 2.8V
- - short-circuits

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

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

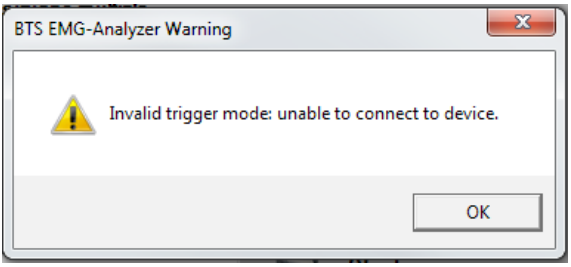
appendix E
troubleshooting guide

Warning – Invalid trigger mode

During the hardware installation, the USB port dedicated to the receiver, is configured. May happen that these port settings went lost.

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

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



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

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

appendix E
declartion of conformity

BTS Bioengineering

CE

DECLARATION OF CONFORMITY

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

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

name / description: Electromyographic system / device for recording myoelectrical activity.
model: **FreeEMG 100 RT**
S/N: SN

satisfies the essential requirements of the **Medical Devices Directive 93/42/EC** (and its amendments inluding 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
EN 62304	Medical device software - Software life-cycle processes
ETSI EN 301 489-3	Electromagnetic compatibility and Radio spectrum Matters (ERM) – Electromagnetic Compatibility (EMC) – standard for radio equipment and services – Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 KHz and 40 GHz.
ETSI EN 301 440-2	Electromagnetic compatibility and Radio spectrum Matters (ERM) – Short Range Devices (SRD) – Radio equipment to be used in the 1 GHz to 40 GHz frequency range – Part 2: Harmonized EN covering essential requirements of Article 3(2) of the R&TTE Directive.

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

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

Padova, Date

Bruno Ros
CEO
BTS S.p.A.

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appendix G
regulatory notice

FDA Medical Device Reporting System—Reportable Events

Notice to Agents: for inclusion in all BTS systems supplied to the United States of America, the master Medical Device Reporting (MDR) file is located at BTS S.p.A. Should an adverse event occur, the following form is to be completed and forwarded within one working day to BTS S.p.A.

Department of Health & Human Services,
US Food and Drug Administration
Medical Device Reporting System—Reportable Events
Code of Federal Regulations
Title 21, Volume 8
Revised as of April 1, 2006
Cite: 21CFG803.32

Under 803.1(a) device user facilities and manufacturers must report deaths and serious injuries to which a device has or may have caused or contributed. Should such an event occur, please complete the following details and forward the document in accordance with the applicable regulations and time limits to one of the following addresses:

BTS S.p.A.
via della Croce Rossa 11
35129 Padova PD - Italy
tel +39 049 981 5500
fax +39 049 792 9260

Adverse Event Report (21 CFR 803.32)

Use blank pages if required.

Section A. Patient Information

Patient confidentiality to be maintained unless authorized otherwise in writing by User Facility.

Patient name or other identifier		
Age at the time of the event (Years, Months), or Date of birth (MM/DD/YYYY)		
Gender	○ Female	○ Male
Weight	_____	○ lb ○ kg

Section B. Adverse Event or Product Problem

Identification of adverse event or product problem	
(check all that apply)	○ Adverse Event
	○ Product Use Error
	○ Product Problem (e.g. defects/malfunctions)
	○ Problem with Different Manufacturer of Same System

Outcomes attributed to the adverse event	
(check all that apply)	○ Death: _____ (MM/DD/YYYY)
	○ Life-threatening injury or illness
	○ Hospitalization—initial or prolonged
	○ Required intervention to prevent permanent impairment/ damage (Devices)
	○ Disability or permanent damage:
	○ Congenital Anomaly/Birth Defect
	○ Other Serious (Important Medical Events)
Date of Event	_____ (MM/DD/YYYY)
Date of this report	_____ (MM/DD/YYYY)
Describe event, problem or product use error (include a discussion of how the device was involved, nature of the problem, patient follow-up or required treatment, and any environmental conditions that may have influenced the event)	

Relevant tests/laboratory data, including dates

Other relevant history, including preexisting medical conditions
(e.g. allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

Section C. Device Information

Brand Name	
Type of Device	
Manufacturer name and address	

Model #		Lot #	
Catalog #		Expiration Date	(MM/DD/YYYY)
Serial #		Other #	

Operator of the device (delete not applicable)	○ health professional ○ patient ○ lay user ○ other: _____ (specify)
Date of system installation	_____ (MM/DD/YYYY)
Device available for evaluation? (Do not send to FDA)	○ yes ○ no ○ Returned to BTS S.p.A. or its agents on: _____ (MM/DD/YYYY)
Concomitant medical products and therapy dates (do not report products that were used to treat the event)	

Section D. Initial Reporter Information

For the reporter who initially provided information to you, or to the manufacturer or distributor:

Name		
Address		
Telephone Number		
E-mail Address		
Health Professional?	○	Yes
	○	No
Occupation (include speciality if appropriate)		
Initial reporter also sent a copy of report to FDA?	○	Yes
	○	No

Section E. User Facility Information

Health Professional?	○	User Facility
	○	Importer
User Facility Number		
User Facility Name		
User Facility Address		
Contact Person		
Phone Number		
Date User Facility became aware of event		_____ (MM/DD/YYYY)
Type of Report	○	Initial
	○	Follow-up # _____
Date of this Report		_____ (MM/DD/YYYY)
Approximate age of system		
Event problem Codes (refer to "MED-WATCH Medical Device Reporting Code Instructions")		
Report sent to FDA?	○	Yes _____ (MM/DD/YYYY)
	○	No
Report sent to manufacturer?	○	Yes _____ (MM/DD/YYYY)
	○	No

Location where event occurred	○	Hospital
	○	Home
	○	Nursing Home
	○	Outpatient Treatment Facility
	○	Outpatient Diagnostic Facility
	○	Ambulatory Surgical Facility
	○	other: _____ (specify)
Manufacturer Name/Address		

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