"WAVE PLUS" MULTICHANNEL ELECTROMYOGRAPH

USER MANUAL

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The system is classified according to 93/42/CEE regulation

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 such that may cause undesired operations.

Any change or modification not expressly approved by Cometa Srl for compliance could void the user's authority to operate the equipment.

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1. INTRODUCTION

Wave Plus system is an innovative multi-channel wireless surface electromyographic system with accelerometers.

The leading specifications of this new system are:

- Wireless and low-power electrodes for a quick patient set-up and for movements performed in total freedom;
- Acquisition of SEMG signal simultaneously with the accelerometer signal
- Digital transmission via RF;
- Receiver device equipped with analog and digital (USB port) data output for all channels;
- Developed with high integration "SMD" technology;
- Compatible with ISM standard – low power devices (ETSI, FCC, JAPAN);
- Designed to be integrated with lab equipment for multipurpose acquisition systems.

2. DESTINATION AND CLASSIFICATION

Wave Plus is a system for the data collection of biologic signals; the main system feature is the absence of cables between the transmitters on the patient and the data receiver/recording unit.

This allows the acquisition of EMG and accelerometer signal while patient is free to move.

This feature is very useful for clinical and scientific applications, for example in pathologic gait analysis or in rehabilitation.

Low invasivity and high safety allow to use Wave Plus system for patients who tolerate the adhesive electrodes and conductive gel for SEMG detection through medical electrodes.

Wave Plus system application areas are:

- Neurology;
- Physiatry and rehabilitation;
- Orthopedy;
- Ergonomics;
- Sport medicine;
- Veterinary.

Wave Plus system is classified according to CEI 60601-1:1998:

- The applied part is a **BF type** according to CEI EN 60601-2-40 regulation (icon):

- **Second class** device working with an external power supply providing power to internal peripheral units; lithium rechargeable battery (icon):

- **IPX0** protection degree of shells (NOT water proof);
- Functioning type: **continuous.**

Other graphic symbols on equipment:

-Ambient operating humidity range(graphic symbol):

-The device and its components must be disposed of according to regulations in the country of use(graphic symbol):

-Ambient temperature range of operation(graphic symbol):

-Consult the user manual for instructions on operating (graphic symbol):

2.1 How to use it

To use Wave Plus, two pre-gelled disposable electrodes for each channel have to be applied to the subject. The EMG acquisition module is applied on the surface electrodes using a snap connector.

If required by the exam, piezoelectric sensors are applied for the identification of plantar supports; the foot-switch acquisition module is applied to the sensor by the appropriate cables.

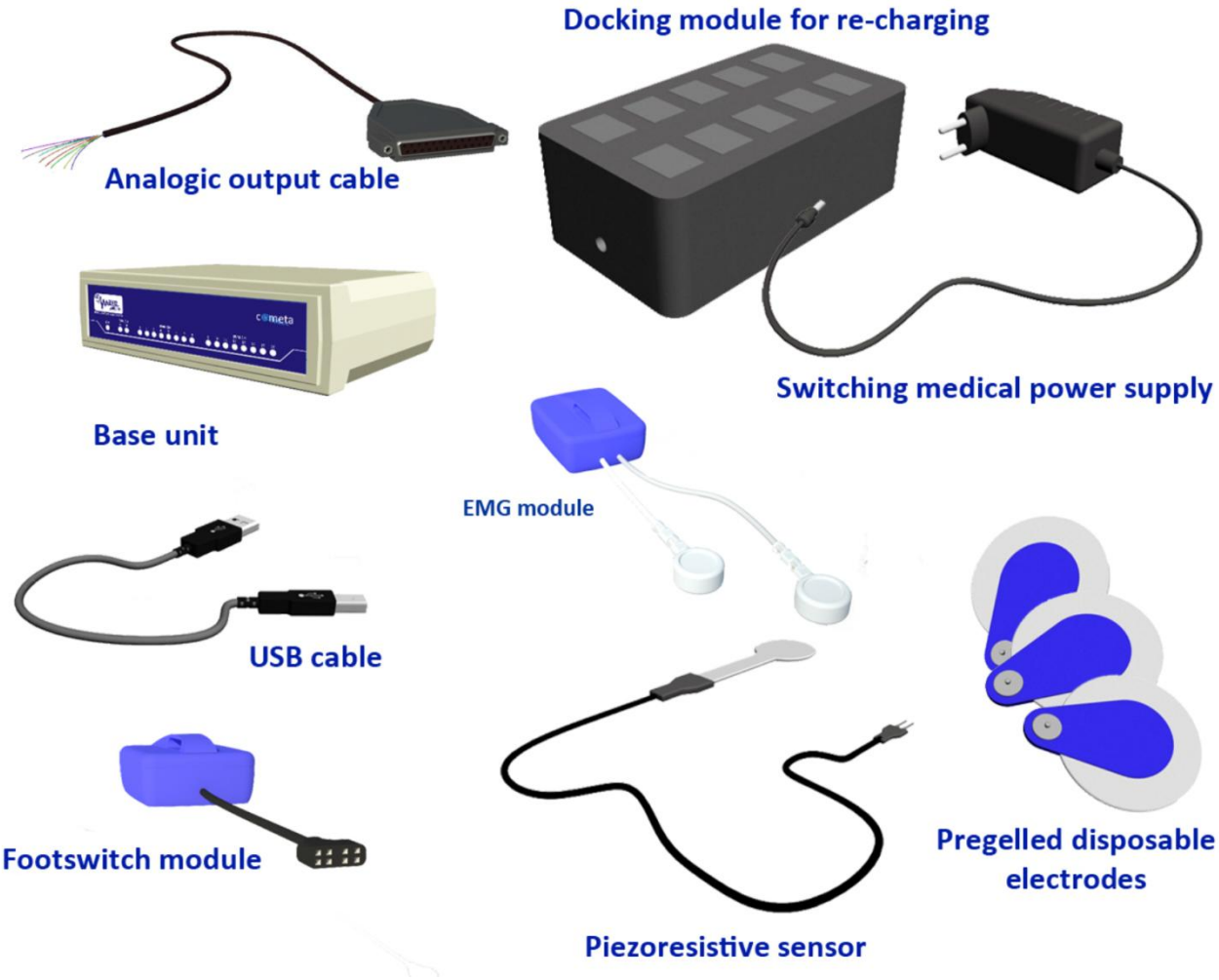
To use the Wave Plus system only as an inertial acquisition system, that is by using only the accelerometers included in the probes and not the EMG signal acquisition, it is sufficient to attach or strip the probes in the designated place, without any need for pre-gelled electrodes.

Wave Plus system can be used by doctors, paramedics and technicians.

To use Wave Plus system, please, read carefully the instructions in the relative chapter.

3. WAVE PLUS SYSTEM COMPONENTS

The following representation shows all Wave Plus components.



The standard configuration of the system is composed of:

- EMG / accelerometer wireless modules, whit snap connections to the electrodes;
- two wireless modules, to transmit gait cycle events (footswitches);
- a receiver unit;
- a docking box to recharge the wireless modules.

Wireless modules are equipped with an internal rechargeable battery. The modules communicate with the PC through the base unit thanks to a bi-directional link working at 2400 MHz.

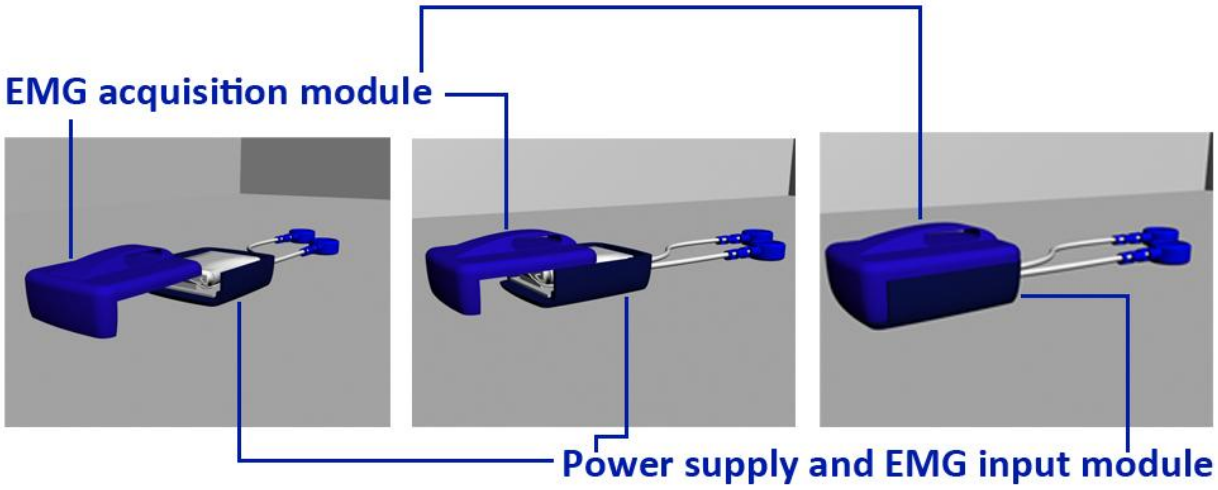
When not used, modules should be displaced in the dedicated areas of the docking box to receive energy for battery recharge.

An automatic system for power saving optimise battery life during the phases in which the electrodes are not used.

3.1 Fundamental, optional and accessory components

SYSTEM ELEMENTS	Classification
Base Unit	Fundamental
Friwo power supply FW7555M/09	Fundamental
Docking base	Fundamental
EMG Electrodes	Optional
USB Cable	Optional
Analogue Cable	Accessory
Foot-switch Electrodes	Accessory

3.2 Wireless electrodes

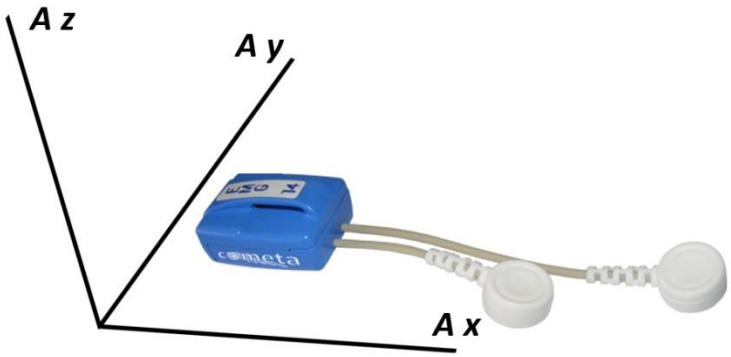


The Wave Plus system module is composed of two parts:

- The conditioning signal module, with active circuitry for signal radio-transmission;
- Power supply module and I/O interface including rechargeable battery, recharge coil, and the connections to the detection points.

The power supply module is connected to the acquisition unit through a sliding mechanism; the unit disassembly should be done only during maintenance (exhausted battery or electric wire deteriorated). In these cases follow the instructions in the chapter "Replacement of electrode battery".

Each EMG module (total of 16) is also equipped with a tri-axis accelerometer, able to capture the minimum movement of the body in space. The disposition of the accelerometer sensors is the following:



The electrodes are realized with fully bio-compatible plastic produced by Bayer. Below teh factsheet of the material used for the electrodes casings:

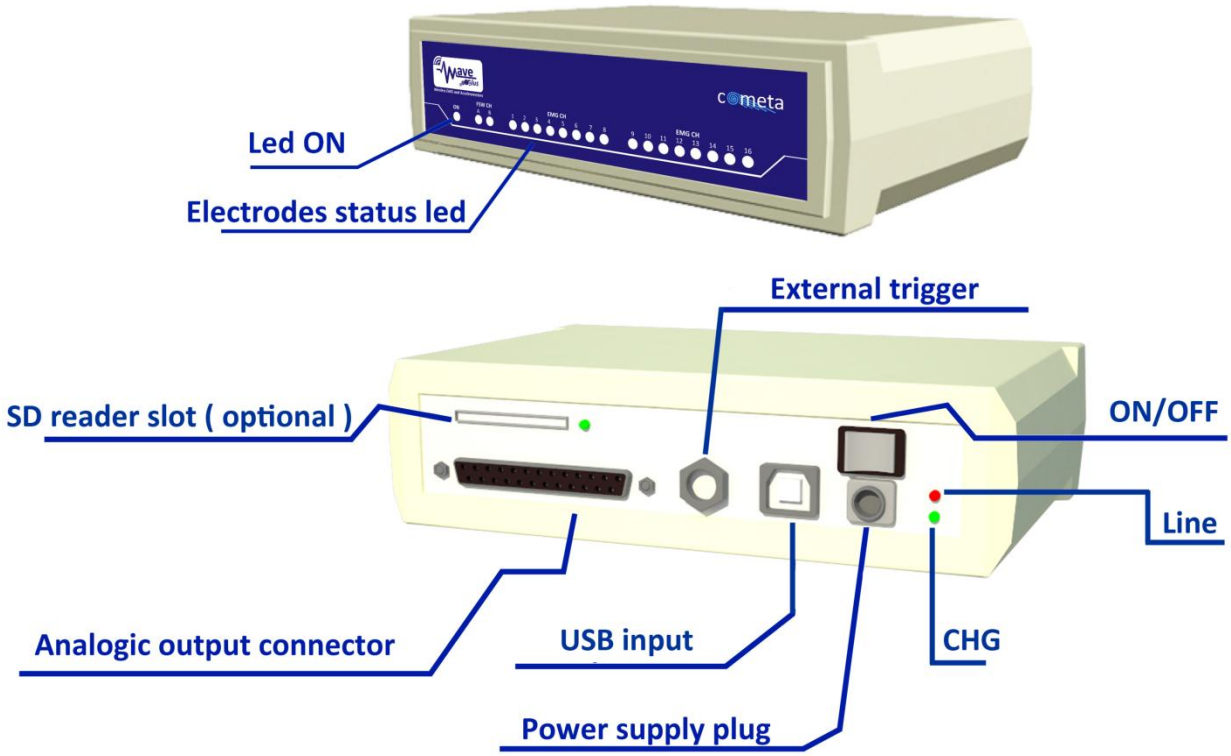
Makrolon Rx1805

Grades / Medical devices	Global grade; MVR (300 °C/1.2 kg) 6.0 cm³/10 min; medical devices; high lipid resistance; suitable for sterilization with high-energy radiation; biocompatible according to many ISO 10993-1 test requirements; high viscosity; injection molding - melt temperature 280 - 320 °C; available in color code 451118 only; transparent parts for medical devices
ISO Shortname	ISO 7391-PC,M,(,,)-09-9

Property	Test Condition	Unit	Standard	Value
Rheological properties				
Melt mass-flow rate	300 °C; 1.2 kg	g/10 min	ASTM D1238	6.5
Mold shrinkage, flow/cross to flow		in/in	ASTM D955	0.006-0.008
Mechanical properties (23 °C/50 % r. h.)				
Tensile modulus	1 mm/min	lb/in²	ASTM D638	350000
Tensile stress at yield	-	lb/in²	ASTM D638	9400
Tensile elongation at yield	-	%	ASTM D638	6.0
Tensile elongation at break	-	%	ASTM D638	120
Tensile stress at break	-	lb/in²	ASTM D638	10200
Izod notched impact strength	73 °F, 0.125 in	ft·lb/in	ASTM D256	18
Flexural modulus	-	lb/in²	ASTM D790	340000
Flexural stress at 5 % strain		lb/in²	ASTM D790	13000
Thermal properties				
Deflection temperature under load, Unannealed	264 psi; 0.250 in	°F	ASTM D648	259
Deflection temperature under load, Unannealed	66 psi; 0.250 in	°F	ASTM D648	273
Vicat softening temperature	50 N, 50 °C/h	°F	ASTM D1525	291
Coefficient of linear thermal expansion, flow/cross-flow		in/in/°F	ASTM D696	3.34E-05
Thermal conductivity		Btu·in/(h·ft²·°F)	ASTM C177	1.39
Specific heat		Btu/(lb·°F)	ASTM D2766	0.28

In order to apply the electrodes on the patient's skin it is necessary to use bi-adhesive tape suitable to be in contact with the skin and therefore certified to that use, such as the 3M 1522 Double Coated Medical Tape produced and certified by 3M.

3.3 Base unit



The base unit has a front panel with status LEDs.
The signals are:

- LED off: the electrode is non active;
- LED on: green light: the electrode is active.

The front panel has also a further green LED indicating the on/off status of the base unit.

On the rear panel:

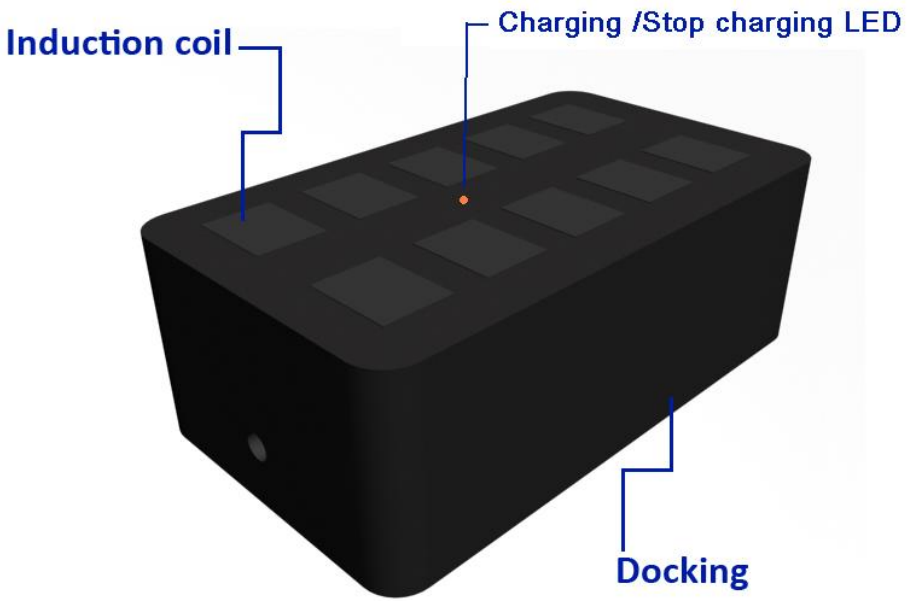
- on-off switch;
- jack for the external power supply
- female port SCSI 68 pin for analog outputs;
- jack for the connection of the external trigger;
- USB port to connect the host PC;
- LED showing presence of supply;
- LED for auxiliary functions (CHG) – not active

The base unit has a RF transceiver at 2,4 GHz, a microprocessor for data synchronisation and separation, D/A converter, a USB port to connect the host PC.

The base unit can be supplied with built–in antennas (as standard), or with external antennas. The application of the external antennas allows the extension of the useful working area of the system.

3.4 Docking module

When not in use, wireless electrodes should be in the docking module to recharge the batteries.



The recharge occurs by coils, attached to the electrodes support base and on the layer of the charger; the energy transfer occurs via induction.

Coils on the docking are excited to resonance by adequate impulses in frequency and amplitude; when the electrode is on the docking, there is an induced alternate current in the electrode coil that will be sent to the battery for its recharging.

The docking module has a LED status indicator of the charger; during charging the LED is orange, when charging is over, the LED turns to green, as described below.

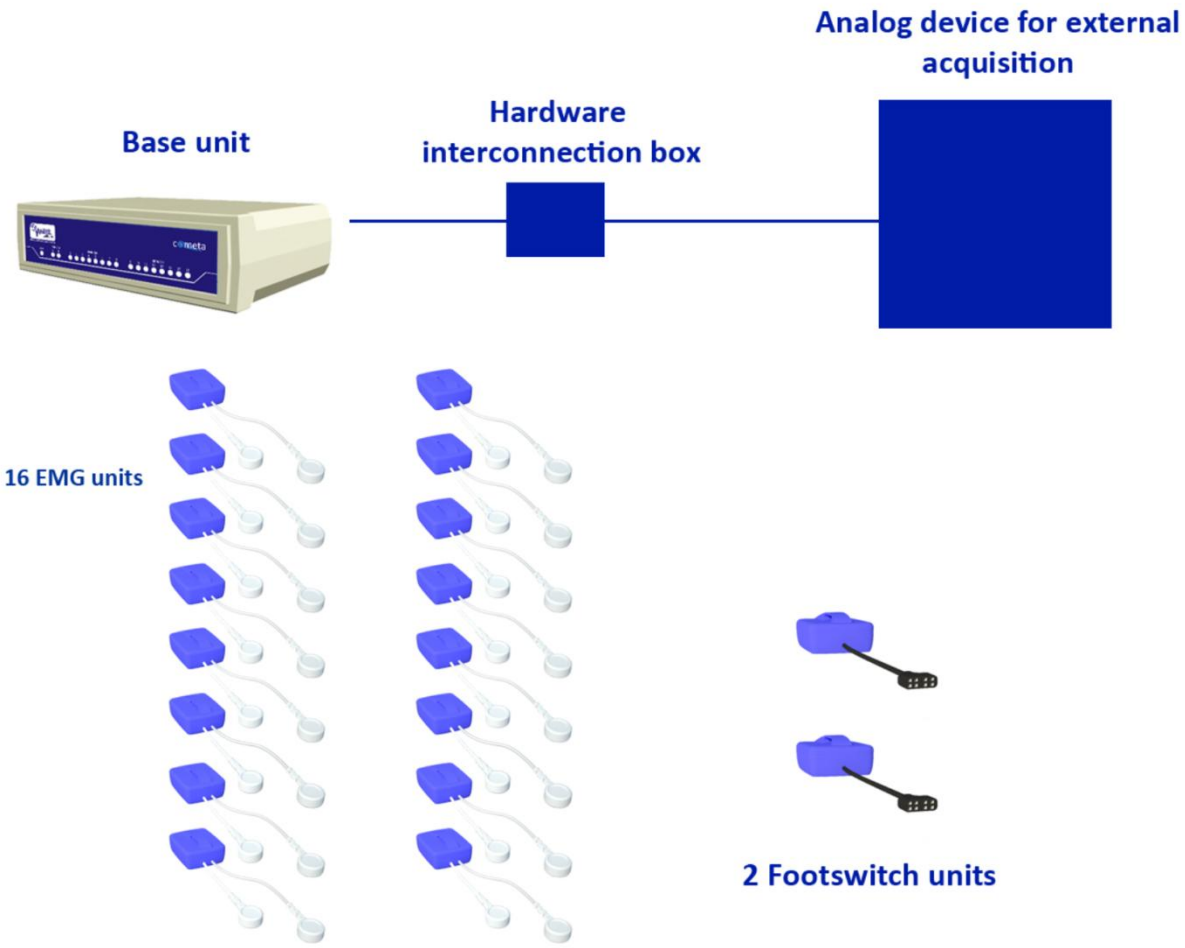
4. WAVE PLUS SYSTEM USE

Wave Plus system can be used in two different configurations:

- Linked to an A/D converter for visualisation and analog storage of EMG and basography data, adopting external devices;
- Linked to a PC through the USB port for visualisation, system control and digital data storage of EMG and basography (third party software not produced by Cometa srl).

The two configurations can be used simultaneously.

4.1 Analog mode



To operate the system:

1) Connect J26 connector of Wave Plus by cable (analog output) to the analog A/D interface of the external device;
2) If required, connect the trigger cable to the external device. Check trigger electric features (voltage and timing) adopted by the system (see "Technical specifications" chapter);
3) Connect Wave Plus power supply and switch on the system.

The system can be powered only with Friwo FW7555M/09 power supply provided by the producer; the use of other power supply units can cause electric shock and damage the system.

If used in analog mode, the system does not require a Personal Computer; after switching on the base unit, EMG and basographic signals are available in continuous on analog output connector J26.

4.1.1 Supported external devices

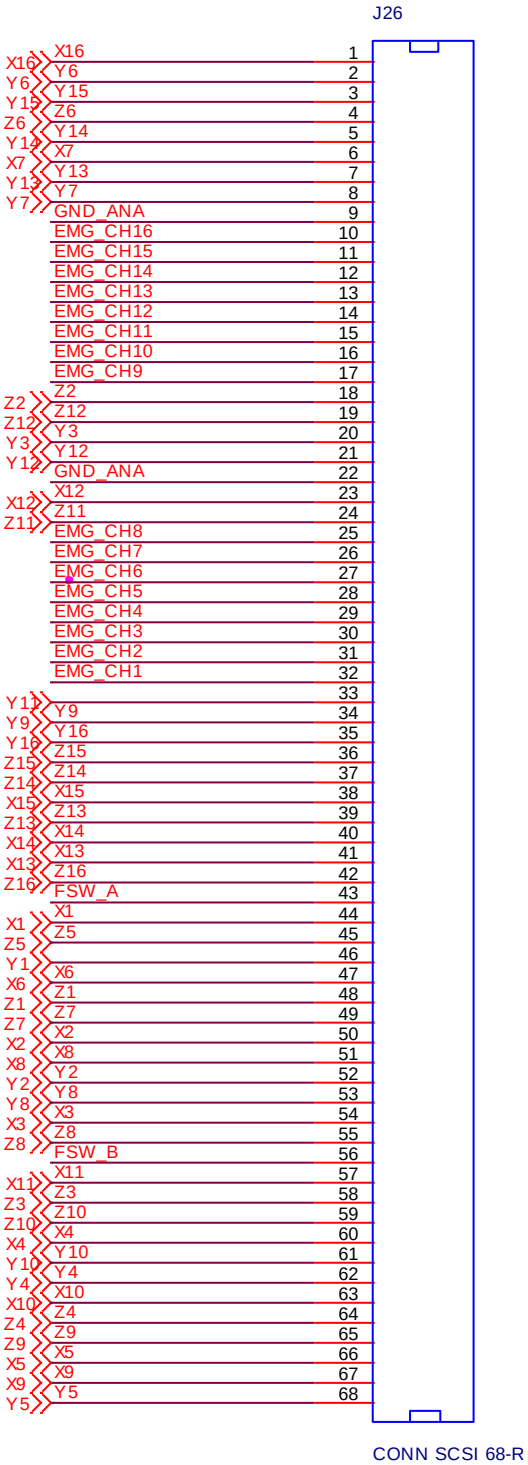
The Wave Plus system can be connected to analog devices commonly used in clinical and scientific environments; these are the features required by systems:

- At least 8 or 16 EMG data collection channels, configured for signals with Zout = 100 ohm and an amplitude of ± 2,5 V;
- At least two analog channels to acquire footswitches, configured for signals with Zout = 100 ohm and an amplitude of + 2,5 V;
- If also accelerometer signals has to be transmitted to the analog device, another24 or 48 data collection channels (3 for each tri-axis accelerometer) are needed;
- It complies with IEC 60950.

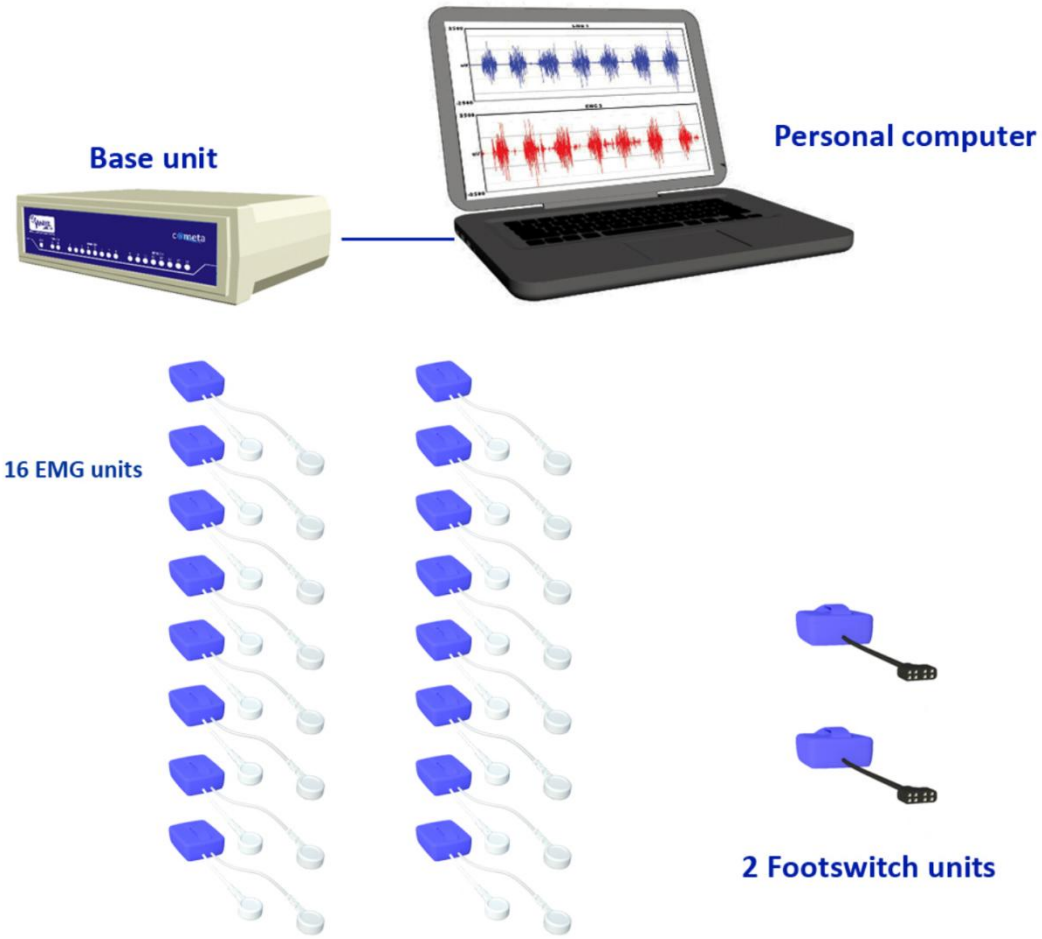
The use of external devices non-complying with IEC 60950 can cause electric shock and damage the system. The external devices connected to Wave Plus with an analog interface, do not have any control over the system acquisition or settings. Any third party system used with Wave Plus has to be placed out of the patient area, and must be powered via an isolation transformer or power supply conform to the IEC 60601-1.

4.1.2 Layout of cable connections

Pin out of the analog output connector.



4.2 Digital mode



To operate the system:

1. Connect Wave Plus USB cable to the PC USB port. The power is taken directly from the USB port;

The use of Personal Computer non-complying with IEC 60950 can cause electric shock and damage the system. The use of Personal Computer non-complying with IEC 60950 is allowed using a medical class insulation transformer to power the PC.

2. If required, connect the trigger cable to the external device, after checking trigger electric feature (voltage and timing) adopted by the system (read “Technical specifications” chapter);
3. Connect, if required, the Wave Plus power supply and switch on the system;

Use only the supplied power supply FRIWO FW7555M/09 . The use of other units could lead to electric shock or damage to the instrumentation.

4. open the control program and follow the third party software indication for data graphic rendering and digital data collection.

The operation of the system Wave Plus is now under the control of the Personal Computer. Refer to the User Manual supplied by the manufacturer of third party software for the description of the operational commands. The following table gives the references:

Software Code:	NA
Release:	NA
Manufactured by:	NA

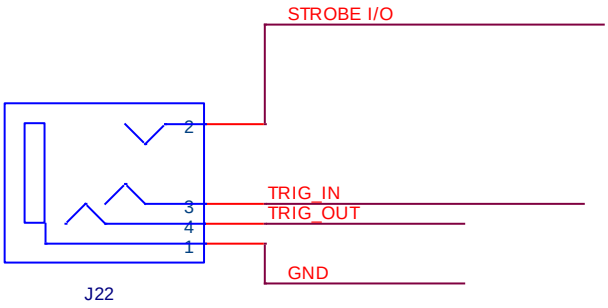
When operating in digital mode, the device is powered directly from the PC via the USB interface; for correct operation, the connection must provide the rated current provided by the USB II specification(500mA). In this case, the use of the external power supply is optional, and the computer must be powered via an isolation transformer or power supply according to IEC60601-1.
You can also use a personal computer equipped with USB ports with reduced current (100mA), in which case you must connect, in addition to the USB cable, the external power supply.

4.2.1 External trigger

Wave Plus has a connector for external trigger of data capture. External trigger lines are not insulated from the Wave Plus system ground.

The use of external devices not complying with IEC 60950 can cause electric shock and damage the system.

Pin out of the trigger jack:



4.2.1.1 Trig in

Data capture can be synchronised with an external trigger signal. If required, connect the trigger cable to the external device after checking that the trigger control complies with the electric features required by the system (see “Technical Specifications”).

Trigger logic:

1) Data acquisition if the “trigger in” signal is at “1” logic level
2) No data acquisition if the “trigger in” signal is at “0” logic level

The default condition of the line is “1”.

Storing data on the hard disk of your computer is managed by the acquisition and processing SW; for information about the data file format and processing, refer to the user manual of the SW.

4.2.1.2 Trig out

A “trigger out” channel shows the system status:

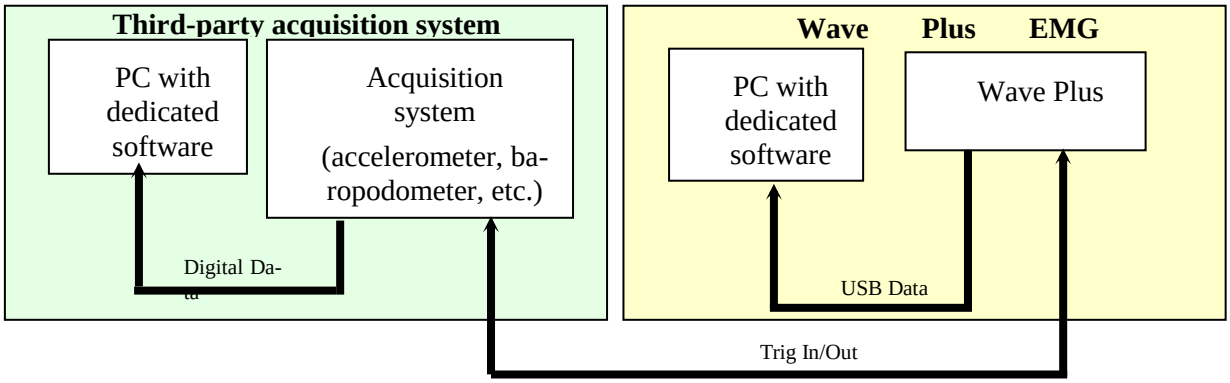
1) “Trig out” signal at “1” logic level when the system is acquiring
2) “Trig out” signal at “0” logic level when the system is not acquiring

4.2.1.3 Strobe IO

The line "Strobe IO" is used for synchronization of a second Wave Plus receiver for the expansion to 32channelsof the system. This line is used by the system and should only be connected to another Wave Plus unit, according to information provided by Cometa.

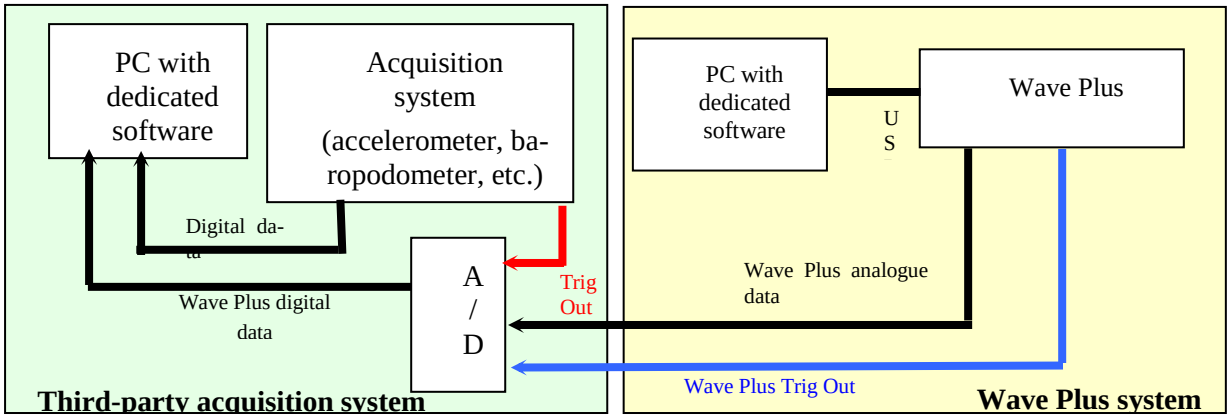
4.2.1.4 How to use the Trigger port

Usually, the Triggers (Input and Output) are used when the Wave Plus system is interfaced with third-party devices by digital port (USB). Here below, you can see the typical configuration in order to obtain the synchronisation between the Wave Plus EMG system and a third-party device by using the Trig In/Out port.



For further details on how to use the Trigger option, please refer to the third party software manual provided by the producer of the software used.

However, it is some way possible to synchronize the Wave Plus EMG system and a third-party device also using the analog EMG signals. Here below, there is a simple scheme which describes how to implement this type of synchronism.



We can consider two possible modes for synchronous recording. In the first case, we assume that the third-party device is able to control the synchronous acquisition by using its own "internal synchronisms" mechanism; in this case the synchronisms will be totally handled by software/firmware of the third-party device self. In the second case, we assume the third-party acquisition device must "read" a trigger signal or record a "*start*" event into the acquisition data streaming (e.g. the event related to the TMS stimulation).

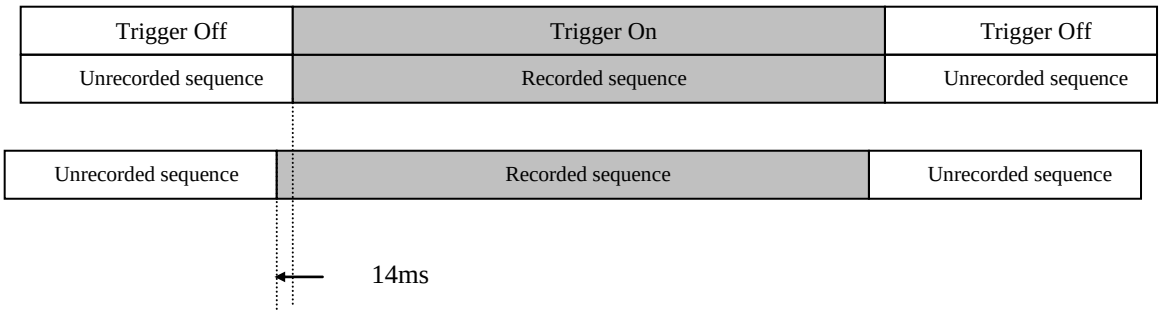
In this latter case, we suggest to record both, the signals coming from the Wave Plus analog output and the trigger signal, using the same A/D converter. In that way, not only the Wave Plus data, but also the

event of the beginning and the end of the data acquisition or, in general, a temporal reference event (e.g. the timing of the TMS stimulation) can be directly saved into the same data streaming.

The scheme above shows the required connections to realise this type of synchronism in case:

1. The third-party device is working as *master*: red connection;
2. The Wave Plus system is working as *master*: blue connection[1].

NOTE THAT if you want synchronize the Wave Plus system with third-party devices collecting the EMG signals from the Wave Plus analogue port, you should also consider the 13 ms delay related to the Wave Plus analogue output. In this case you should correct the recorded data in order to remove the 13 ms delay. NOTE THAT the 14 ms delay is constant and it can be easily removed by shifting the temporal sequence in the following way:



NOTE THAT the delay does not produce a loss of acquired data at all.

Please, for further details contact Cometa.

4.2.2 Supported external devices

Wave Plus system can be connected to any PC with USB interface; these are the features required by systems:

- Type 2 USB interface
- Windows 2000 or XP
- VGA graphic card with a resolution of at least 1024 x 768
- Minimum ram memory, 512 MB
- Minimum processor frequency, 800 MHz
- Minimum hard disk, 20 GB

[1] In this case, it's necessary to use also the dedicated software in order to produce the trigger signal.

The Personal Computer linked with the Wave Plus system has to comply with IEC 60950 regulation and has to be placed outside the patient's area. The use of Personal Computer non-complying with IEC 60950 is allowed using a medical class insulation transformer to power the PC. The software (produced and commercialized by third parties) has to comply with the CE93/42 regulations for medical devices.

4.3 LED signalling during operation

4.3.1 Base unit LEDs:

During Wave Plus functioning, LEDs are used to indicate the functioning status of the system.

On the base unit front panel there are eighteen bicolour LEDs:

- LED off: the correspondent electrode is in stand–by (non active);
- LED on, green light: the electrode is on;
- LED on, orange light: the electrode is on and the battery is low.

4.3.2 Electrode unit LED:

On the EMG unit there is one LED:

- LED off: the electrode is in stand–by condition (not active);
- LED on, green light: the electrode is on and recognised by the receiver unit;
- LED blinking green light: the electrode is on and the battery is low.

The LED of the transmitting module, when the electrode is placed on the charging cradle, also carries an indicator function of the charging phases. In this case the color of the LED is orange. For more information, refer to the battery charger chapter.

4.4 Pre-gelled electrodes

The Wave Plus system can be used with single-use pre-gelled electrodes equipped with snaps. Pre-gelled electrodes are available in different dimensions, and may be purchased through local distributors of consumable medical accessories.

To apply electrodes see the information provided by the manufacturer.

Warning: the quality of the EMG signal acquired by the Wave Plus system is linked to the quality of the contact between electrode and skin; to obtain best results:

1. Use pre-gelled electrodes certified for a medical use and complying with the 93/42/CEE regulation;
2. Do not use pre-gelled electrodes beyond the expiration date or with dry conductive gel;
3. Do not re-use the same electrode;
4. Do not use the electrode after having already applied it;
5. For long data acquisition periods, check the electrodes adhesive;
6. Apply electrodes only on undamaged skin and verify that their removal does not cause any damage.

4.5 Electrodes battery recharge

To recharge the electrode batteries, put the electrode in the appropriate slot in the recharging module; then power on the recharging module and wait for the signal that indicates the end of the recharging period.

The jack socket for the power supply is accessible on the left side of the briefcase.

The charging module is equipped with an eight hours timer, after which the charge is automatically stopped. This allows the unlimited permanence of electrodes into their respective housings, without the risk of overload the batteries.
To reset the timer and start a new charge cycle, you must disconnect the power jack and then reconnect it.

4.5.1 LED indicator of the charging module

The operation of the charging module is indicated by a bicolor LED placed in the center of the unit; alerts are:

1)Led Orange: the charger is on and the electrodes placed in the charging slots are subject to charge;
2)LED green: the unit has completed the eight-hour charge cycle.

It is recommended to leave the case open during the recharge of the electrodes units.

If the batteries are deeply discharged, it may be necessary to perform two or more charge cycles, to restore its original capacity.
The electrode, when not in use, has a very low power consumption and maintains the charge for a long time, but to maximize the life of the battery, in case of non-use, we suggest to perform at least one charge cycle every three months.

4.5.2 LED indicator of the electrodes

When the probes are charging, the green LED light provides an indication about the level of charge. Particularly, three states are available:

1) LED orange flashing at one flash/sec.: probe on pre-charge (when battery is entirely un-charged);
2) LED orange flashing at five flash/sec.: probe on normal charging phase;
3) LED orange off: full charge

The transmitter units can be charged by placing on the charger the only lower part of the electrode. The feedback on the state of charge takes place through a second green LED placed within that module. Charging is complete when the LED is off.

IMPORTANTNOTE. The unit placed in the docking box, during the charging process, do not transmit. This is valid only during the charging process (charging module active -Orange LED). At the end of the charging cycle, the transmitting units resume its normal functionality.

4.6 Warnings

Extended non-use of the device

If the device has not been used for a long time, we suggest to:

- Recharge the electrodes battery every six months, or,
- Unlink/Disconnect the EMG acquisition module from the battery module and keep the elements in a dry and clean environment.

How to use the device in an environment in which a wireless LAN is working

If the Wave Plus receiving unit is close to an active WLAN unit, some interference could occur causing a loss of EMG data. Moving away the two units, the system would work properly, at least one or two meters. Data loss is shown by the corresponding "CH#" led that temporary switches off. Data loss is always recognizable. In case of continuous loss of data and/or problems of acquisition, it

will be necessary to move the frequency of the device responsible for the interference to the highest available, and move the source of the wireless signal away from Wave Plus of at least 3 meters.

How to use the device with disturbing electromagnetic fields

If strong electromagnetic fields are in the environment where Wave Plus works, some interference could occur during the data transfer via USB, causing a loss of EMG data. To make the system work properly, the USB cable has to be moved away from the source of noise.

Use of the transportation Case

If the system is provided with a transportation case (blue flight case), it is recommended to always keep it with the downside facing downwards. The case can protect the system only from very light shocks, so it is NOT to be considered as an absolute way of protecting it. Be sure to keep the key to the lock of the case in a safe place and away from children.

How to remove the EMG probes positioned on the patient.

The cables with clip connections used by standard wireless units for EMG (see paragraphs 3 and 3.1) are delicate and breakable elements of the system, not to be submitted to continuous strains and tractions which could partially or totally damage them, with negative effects on the reliability of the EMG signal acquired. For this reason, we suggest, during detachment of the probes, to uncouple the clips from the pre-gelled electrodes, directly handling the clips and without stretching the cables, before proceeding to the complete removal of the EMG probe.

Safety risk:

The simultaneous connection of a patient to both a high frequency chirurgical device and an EMG system can cause burns where the electrical stimulation or biopotential input takes place, and can possibly cause damages to the pre-amplifiers.

More warnings:

Do not use Wave Plus system in an environment with inflammable anaesthetic mixture with air or oxygen or nitrogen protoxide.

Ask the patient if he/she is sensitive to electrode gel and to polycarbonate of the external shell.

Do not use in presence of devices essentials to life support.

Due to the small dimension of some components, we suggest not to use the system in children of less than 3 years of age or in non co-operative subjects. In these cases use the system watching carefully and continuously the subject.

The main unit is supplied with three rubber antennas that have been selected and certified by the producer to get the best result in every application; the use of different antennas could cause malfunctions or could lead to exceed the specifications of the FCC and CE certification of the device.

4.7 Piezoresistive sensors

Piezoresistive sensors for the gait cycles events detection are placed under the foot surface, in a position that allows a precise measurement of support and toe off. Up to four sensors for foot are available, and these are displaced in the typical positions:

- Toe sensor n. 1
- First metatarsus, sensor n. 2
- Fifth metatarsus, sensor n. 3
- Heel, sensor n. 4

Sensors are not different from each other and they are numbered from 1 to 4 only to identify the application area.

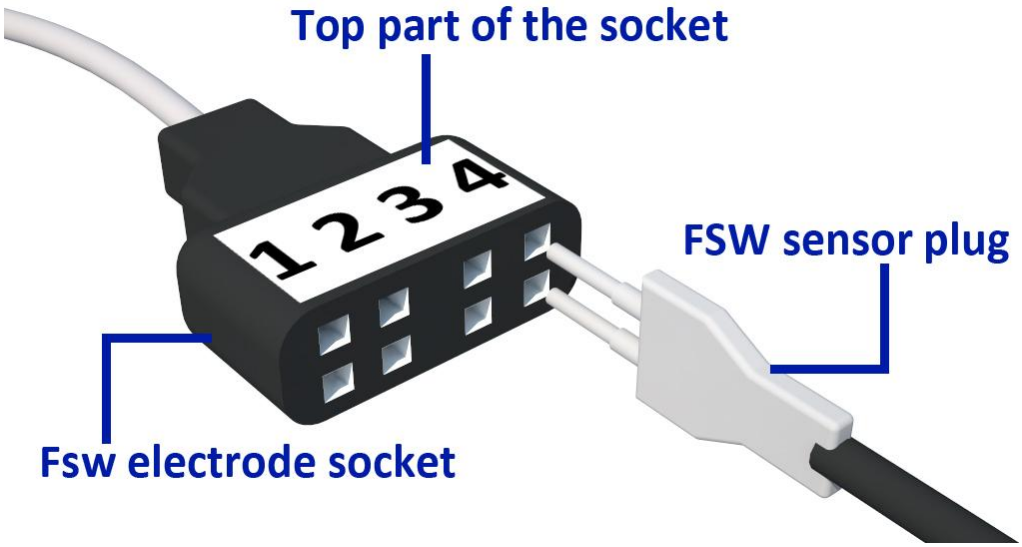
The location and the positioning techniques can change according to operator's preferences.

The connection to Footswitch electrode has to be done according to the following representation:

Proceed according to the following instructions:

1. Apply the sensor on the patient;
2. Identify the orientation of the FSW electrode socket;
3. Put the FSW sensor plug into the FSW electrode socket according to the number.

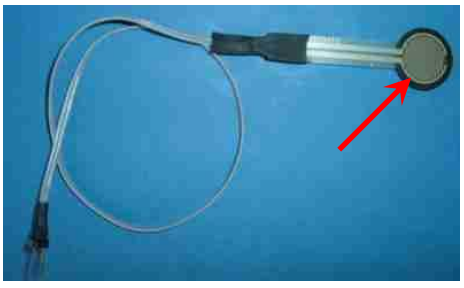
The four inputs are electrically and mechanically identical; to have correct data identification, inputs are:



The FSW sensor plug isn't polarised and can be connected in both ways; the FSW electrode socket has a white coloured label to make easier the numeric assignment of sensors.

If FSW has been wrongly connected, sensors will not work properly, but the system will not be damaged.

To avoid any damage of the sensors, we suggest sticking the dedicated circular stickers on the grey side of footswitches (i.e., on the side with pressure sensors), as in the picture below. The stickers application on the black side can damage footswitches themselves.



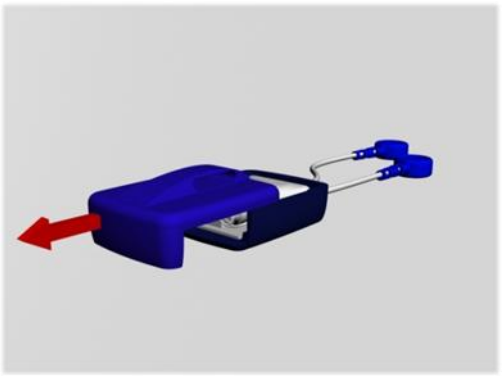
5. SYSTEM MAINTENANCE

5.1 Repairable parts

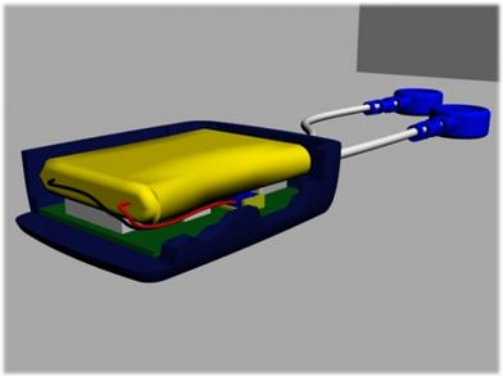
Wave Plus system does not contain parts repairable by the user with the exception of the batteries; for standard maintenance see the following chapters.

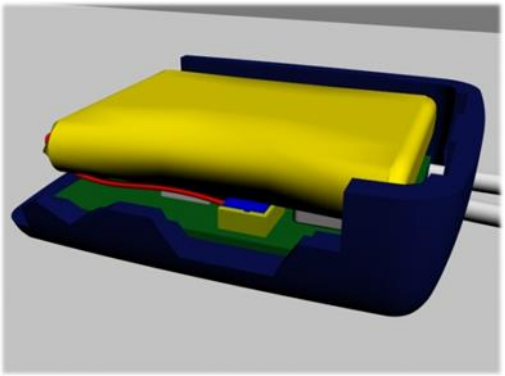
5.2 Replacement of electrode battery

After about 300 charging/discharging cycles, the battery could reduce its electric capacity that leads to a shorter time of use of the electrodes. To re-enable the normal efficiency, replace the battery module as follow:

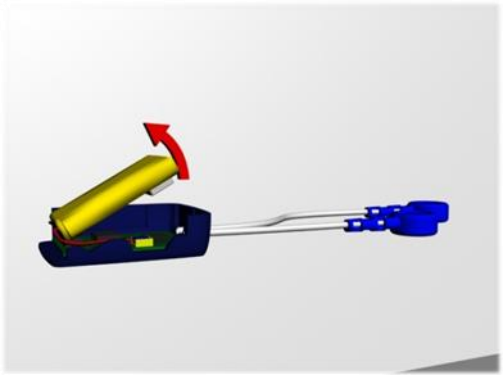


1. Open the probe by gently pushing as shown in the picture. The probe will slide open separating in two parts (lower and upper).

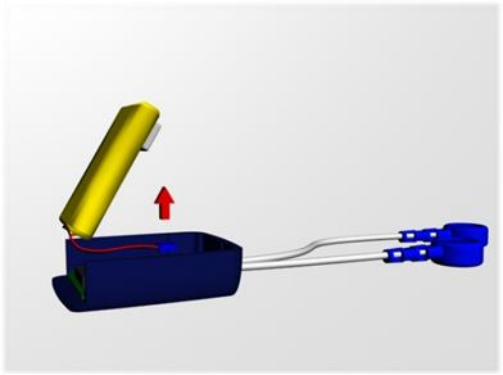


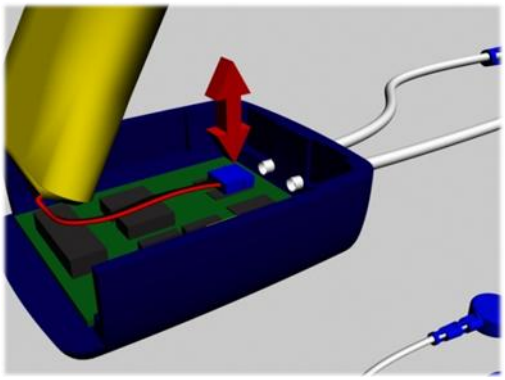


2. Take the lower part of the probe, the one containing the battery. As shown in the picture, the battery is linked to the probe with a small connector.

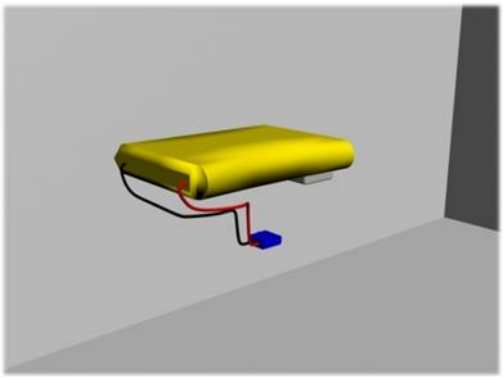


3. Extract the battery after gently prying it out of the housing as shown in the picture.

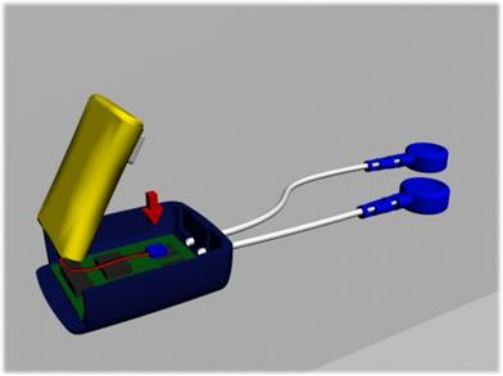
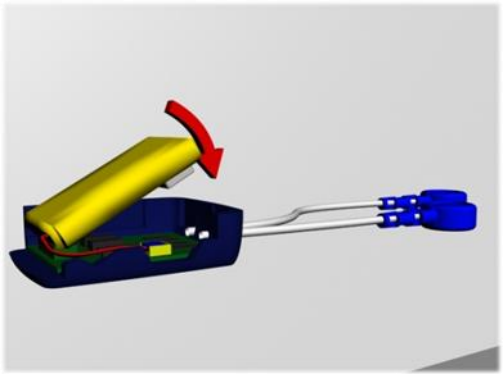
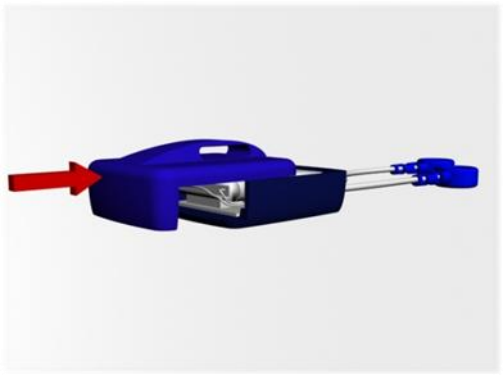




4. After having removed the battery, pull the connection cable VERTICALLY in order to detach the connector from the probe.



5. The exhausted Li-ion battery will have to be disposed of according to your country's regulations

	6. Take the new battery and follow the same steps backwards to install it inside the probe.
	7. Carefully insert the new battery, making sure it is positioned as shown in the picture.
	8. Put the probe back together by sliding the upper part back into the lower one, as shown in the picture, until you hear a click.

5.3 Electrode battery characteristics

Voltage:	4V
Capacity:	150 mA/h
Type:	LI – ION rechargeable battery
Max. Recharging cycles:	300 (80% residual capacity)

The battery has a label as follow:

REF.: WBAT (component code)

Lot.: AANN-N, where AA is the production year, NN is the production lot, -N is the traceability code.

Use of non original batteries

Change the exhaust batteries with original ones supplied by Cometa. Use of non original batteries could cause damage to the unit and safety risks for patient and operators; use of non original batteries will make the warranty void.

You can find the battery at:

Cometa srl
Via Verdi 24
20080 Cisliano MI
Tel. +39 2 90388119
Cometa.sas@tiscali.it

The replacement of the battery of the foot-switch electrode is performed in the same way.

5.4 Warnings about electrodes battery

5.4.1 General warnings

Warning: **DO NOT disassemble the battery.**

Warning: **DO NOT short-circuit the battery terminals.**

Warning: **DO NOT cut or drill the battery container; the electrolyte is dangerous for human body. If you touch the electrolyte, immediately wash the part with water and call a doctor.**

Warning: **DO NOT burn down or put the battery in the fire.**

Warning: **DO NOT use electrodes with battery that is losing electrolyte, or smells of electrolyte, or has the container blown up.**

Warning: **Electrodes that are losing electrolyte or smells of electrolyte have to be kept away from fire.**

Warning: **Check the storing modalities, working and recharging temperature in chapter "Technical Specifications"**

5.4.2 Warnings for battery disposal

The power supply module contains a rechargeable battery; for its disposal observe local and national limitation for lithium battery.

5.4.3 Warnings for device disposal

Base unit, electrodes and optional of the Wave Plus system have to be disposed off complying with national and local limitation for electronic devices and with European Directive 2002/95/CE, 2002/96/CE, 2003/108/CE.

5.5 Replacement of worn parts

In Wave Plus system, the parts that could result worn after usage are:

1. Terminals and clips of EMG electrodes; check monthly clips and wires; if the wire is worn, replace the lower EMG module;
2. Terminals and clips of foot-switch electrodes; check monthly the connector of piezoresistive sensors and wires; if the wire is worn, replace the FSW lower module.

5.6 Wave Plus cleaning

To clean Wave Plus system components use a soft cloth damped with neutral soap. System components are NOT protected by liquid infiltration.

The cleaning of the system elements has to be done:

1. Base unit: every six months or more often if required
2. Electrodes: every 50 hour or more often if required

Warning:

Liquid infiltration can cause the EMG signal amplitude reduction, or the interruption of the electrode functioning. In these cases, proceed as follow:

- Take off the acquisition module (upper part) from the battery module, as described in "Replacement of electrode battery" chapter;
- Remove the liquid with a dry cloth;
- Dry out the modules using a low temperature source (radiator or oven at maximum 30°C);

If the problem persists, replace the electrode.

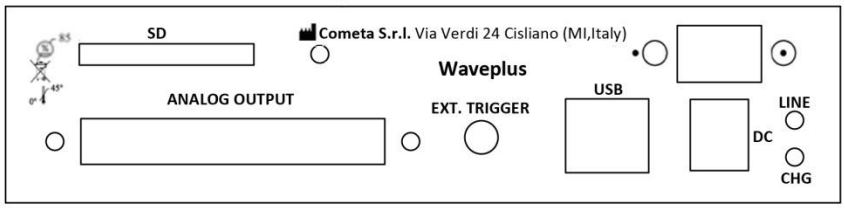
5.7 References

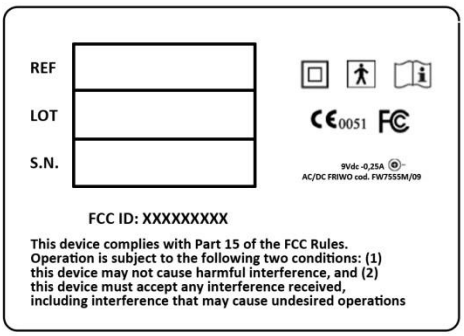
In the event of non-functioning, breakdown or other problems dealing with Wave Plus system, please contact:

Cometa srl
Via Verdi 24
20080 Cisliano MI
Tel. +39 2 90388119
Cometa.sas@tiscali.it

6. LABELS

6.1 Base Unit:



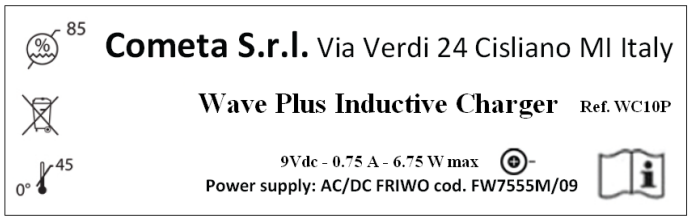


Label composition:

REF.: REFERENCE NUMBER
LOT.: PRODUCTION LOT IDENTIFIER
S.N.: PRODUCT SERIAL NUMBER

6.2 Brief case with charger:

6.3 Inductive charger (inside the brief case, up to two units):



6.4 Elettrodi:

The electrodes are made of two parts; the upper part is permanently pad printed with the brand “Wave Plus” on the top. The lowe part is permanently pad printed with the brand “Cometa” on one side and “Wave Plus” on the other side.

To the upper part is applied an adhesive label as follow:

<EMG CH#> or <FSW #>

with the number assigned to the electrode (from 1 to 16), or to the FSW (“A” or “B”).

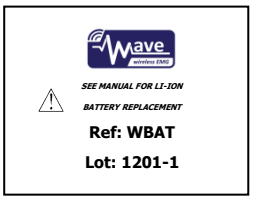
The labels of the two parts of the electrodes are visible after having taken apart the probe by separating the upper and the lower part

To the upper part is applied a label with these informations:

REF XXX
LOT XXXX

where REF. (three to six characters) is the Product Code and LOT. (four characters) is the production lot, for example 1201 = year 2012, lot nr. 1.

On the battery there is the following label:



where REF. is the Product Code (WBAT) of the battery, and LOT. (six characters) is the production lot, for example 1201-1 = year 2012, lot nr. 1, traceability code nr. 1

The lower part of the probe (PSC power supply module), once removed the battery, shows the code:

XXXXXX XXXX

Where the first field (from three to six characters) is the code of the item (for example, WPPSC: power supply of Wave Plus) and the last 4 elements is the year and the lot of production (for example, 1101 = year 2011, lot nr. 1).

7. TECHNICAL SPECIFICATIONS (WAVE PLUS 16 CH)

Base unit

Transmission / Reception frequency	2402 – 2480 MHz
Transmission power (ARP)	0,45 mW
Number of channels (16 EMG + 48 ACC + 2 FSW)	66
Power supply (stand alone, external wall plug medical grade SMPS)	9 Vcc +- 10%
Power supply (PC connected)	via USB
Absorbed power	2 W
Operating temperature range	0 + 50 °C
Input:	
Start trigger	TTL, max ±10 V
Trigger out	TTL, max ±10 V
Output:	
EMG Output	± 2,5 V, Zout = 100 ohm
ACC Output	± 2,5 V, Zout = 100 ohm
FSW Output	16 levels, max 3 V
Host USB link:	USB 2.0
Gain (EMG channels)	1.000 (1V/mV)
Dimension	155 x 105 x 50 mm
Weight	300 gr.

EMG Module

Transmission / Reception frequency	2402 – 2480 MHz
Transmission power (ARP)	0,45 mW
Power supply voltage	4 Vcc
Absorbed power	40 mW
Operating temperature range	0 + 50 °C
Full charge operation time (100% charged battery)	>12 h

Stand by time (100% charged battery)	> 180 gg.
EMG input	+- 2.5 mV
bandwidth	10 Hz – 500 Hz (or 1 KHz)
sampling	16 bit – 2 Ks/sec.
ACC sensitivity (SW selectable, full scale)	±2 g, ±4 g, ±8 g, or ±16 g.
bandwidth	DC – 70 Hz
sampling	10 bit – 142.8 s/sec.
Max. allowed acceleration	10,000g
Dimensions	33 x 23 x 19 mm.
Weight	12 gr.

FOOTSWITCHES Module

Transmission / Reception frequency	2402 – 2480 MHz
Transmission power (ARP)	0,45 mW
Number of FSR sensors	4
Power supply voltage	4 Vcc
Absorbed power	40 mW
Operating temperature range	0 + 50 °C
Full charge operation time (100% charged battery)	> 12 h
Stand by time (100% charged battery)	> 180 gg.
FSW input	for piezoresistive sensors
Dimensions	33 x 23 x 19 mm.
Weight	12 gr.

Docking Module

Recharging capacity	20 modules
Power supply voltage	9 V +- 10%
Maximum absorbed power	13.5 W
Recharging time	7.5 h (auto shut off)
Dimension	embedded into the Wave Plus briefcase

Net feeding

Power supply voltage	100 – 240 V 50/60 Hz
Output voltage	9 V cc, 1,5 A

Power supply cable	2,1x5,5 S 11,5 coax (+central)

Additional specifications

- Input impedance: 20MOhm
- CMRR: >120dB (true differential electrodes without reference elec trode);
- SNR: >50dB;
- Hardware filtering (LP and HP): 1st order, 6 dB/octave

Environmental conditions:

Ambient temperature when charging:	0°C /+40 °C
Relative damp when operating:	< 85 % RH
Storage relative damp	< 85 % RH
Storage temperature	-20°C/ +35°C
Storage pressure	500/1060 hPa

7.1 Suitability

For a correct functioning of the radio link between the electrodes and the base unit, the relative distance has to be less than 20 meters.