cometa

“WAVE PLUS”
MULTICHANNEL
ELECTROMYOGRAPH

USER MANUAL

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Revision:

Revision:	Approval Date:	Changes Description:
01	24/02/2012	Revision post IMQ review
02	30/12/2013	Added new Mini Wave sensor
03	12/05/2014	Change of symbol
04	11/04/2019	Added new sensors

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 S.r.l for compliance could void the user's authority to operate the equipment.

Table of Contents

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 sensors for a quick patient set-up and for movements performed in total freedom;
- Acquisition of SEMG signal simultaneously with the accelerometer signal;
- Acquisition of data from accelerometers, gyroscopes and magnetometers using inertial sensors (IMU);
- 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.

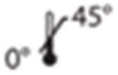
This allows the acquisition of EMG, accelerometer signal and inertial data while patient is free to move.

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.
	**Second class** device working with an external power supply providing power to internal peripheral units; lithium rechargeable battery.
IPX0 protection degree of shells (NOT water proof).	
Functioning type: **continuous.**	
Other graphic symbols on equipment:	
	Ambient operating humidity range.
	The device and its components must be disposed of according to regulations in the country of use.
	Ambient temperature range of operation.
	Consult the user manual for instructions on operating.

2.1 How to use it

The Wave Plus system can be used with:

- EMG sensors;
- Inertial sensors;
- Footswitch sensors.

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

If required by the exam, piezoelectric sensors are applied for the identification of plantar supports; the Footswitch 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 sensors and not the EMG signal acquisition, it is sufficient to attach or strap the sensors in the designated place, without any need for pre-gelled electrodes.

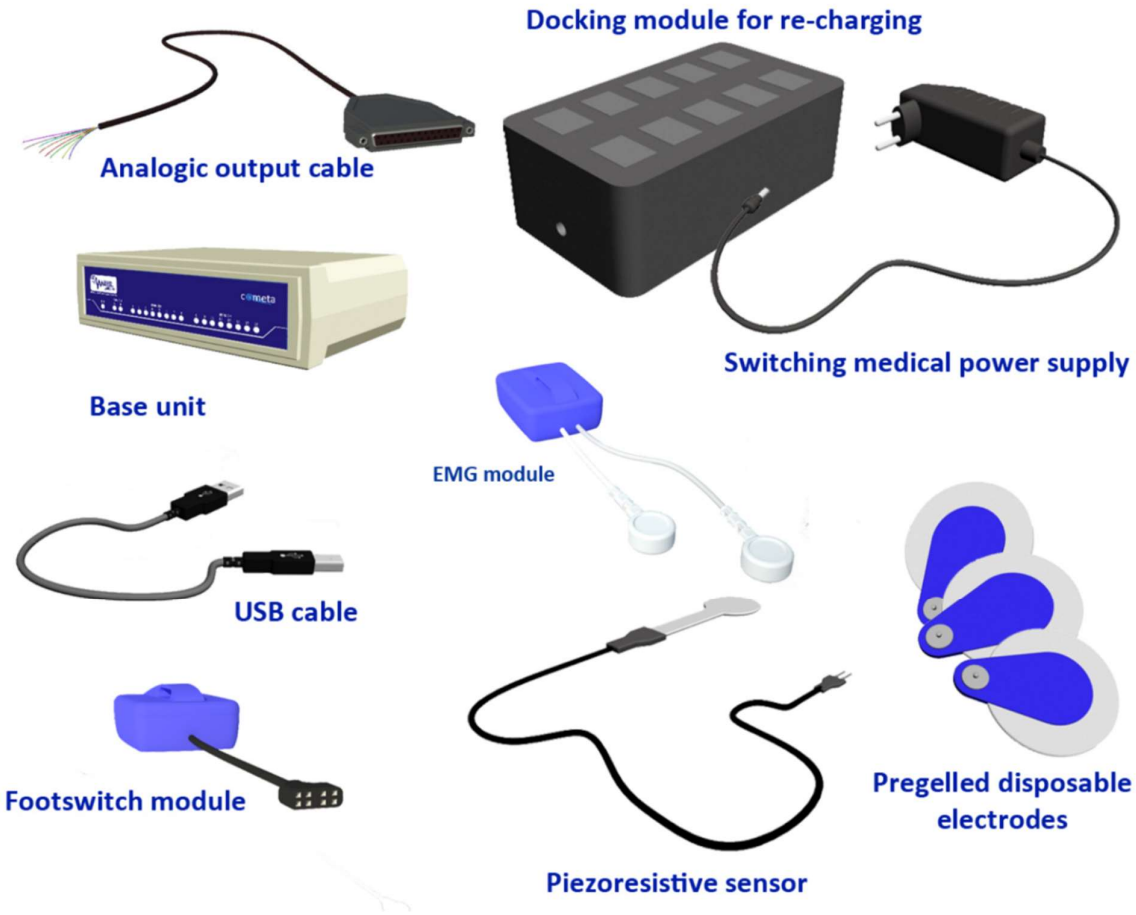
To use the inertial sensors (IMUs), sensors must be attached to the subject's skin using bio-compatible double-sided tape. Positioning and fixing of the sensors on the body should be done in a way to minimize the movement of the sensors with respect to the body segments.

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

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

3. WAVE PLUS SYSTEM COMPONENTS

The following representation shows typical Wave Plus components.



The standard configuration of the system is composed of:

- EMG / accelerometer wireless sensors, whit snap connections to the electrodes;
- Inertial wireless sensors (WAVETRACK IMU);
- two wireless sensors, to transmit gait cycle events (Footswitches);
- a receiver unit;
- a docking box to recharge the wireless sensors.

Wireless sensors are equipped with an internal rechargeable battery. The sensors communicate with the PC through the base unit thanks to a bi-directional link working at 2400 MHz.
When not used, sensors 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 sensors 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 Sensors	Optional
IMU Sensors	Optional
USB Cable	Optional
Analogue Cable	Accessory
Footswitch Sensors	Accessory
Remote controller	Accessory
BNC patch panel	Accessory
Passive Spring Adaptors	Accessory
Trigger box with BNC connector	Accessory
WaveTrack elastic bands	Accessory
Micro golden electrodes	Accessory
Medical grade stickers	Accessory

3.2 Sensors

The Wave Plus systems can be used with this type of sensors:

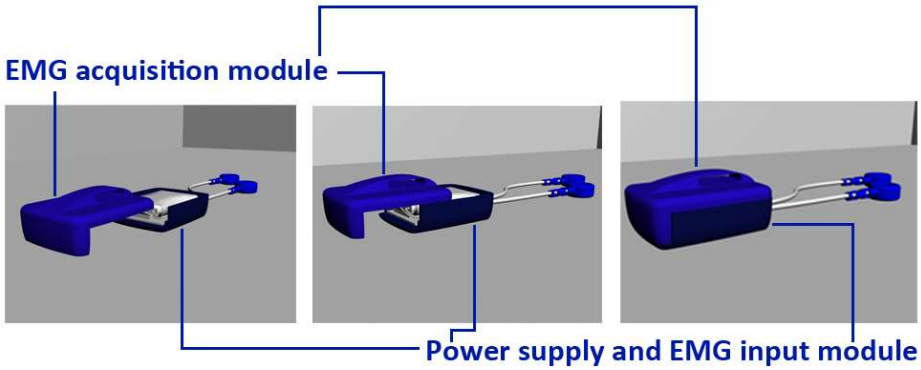
- EMG wireless sensors:

  - WAVE PLUS EMG STANDARD;
  - MINI WAVE;
  - MINI WAVE INFINITY;
  - MINI WAVE INFINITY WATERPROOF;
  - PICOEMG;

- Inertial wireless sensors:

  -WAVETRACK IMU.

3.2.1 Wave Plus EMG Standard

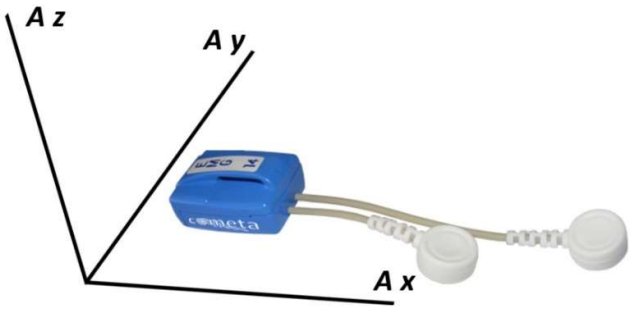


The Wave Plus EMG Standard is composed of two parts:

- The conditioning signal module, with active circuitry for signal radio-transmission;
- The 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 sensor wires deteriorated). In these cases, follow the instructions in paragraph 5.2: "Replacement of sensor 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 sensors are manufactured with fully bio-compatible plastic produced by Bayer. Below the factsheet of the material used for the sensor's casings:

Makrolon Rx1805

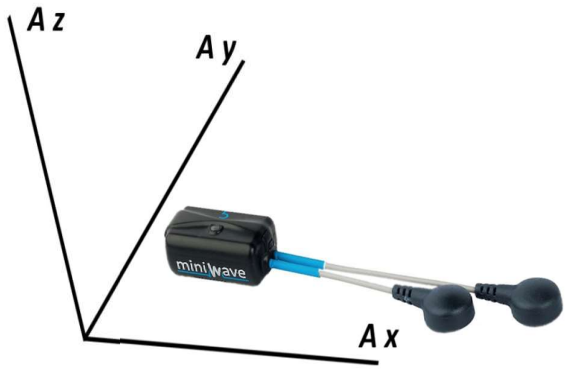
Grades / Medical devices	Global grade; MVR (300 °C/1.2 kg) 6.0 cm³/10 min; medical devices; high lipid resistance; suitable for sterilization with high-energy radiation; biocompatible according to many ISO 10993-1 test requirements; high viscosity; injection molding - melt temperature 280 - 320 °C; available 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

To apply the sensors on the patient's skin, 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. Pre-cut adhesive stickers are available from Cometa (see paragraph 4.4).

3.2.2 Mini Wave, Mini Wave Infinity and Mini Wave Infinity Waterproof

The Mini Wave is composed in the same way of the Wave Plus EMG Standard, but with different technical specifications, optimizing size and weight (see chapter 7).
As the previous sensor, 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:



Mini Wave Infinity is equipped with a memory for 8 hours of acquisition (max 256 segments for each session).

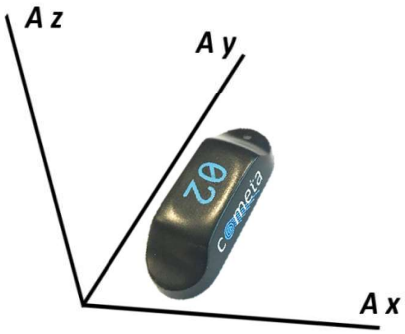
Mini Wave Infinity Waterproof is a special version of Mini Wave Infinity equipped with a fully waterproof coating.

All these sensors are manufactured with fully bio-compatible plastic produced by Bayer (for the factsheet of the material see paragraph 3.3)

3.2.3 PicoEMG

The PicoEMG is composed like Mini Wave but without the cable clips. This feature reduces the antenna effect and its symmetrical construction reduces motion artefacts. PicoEMG is applied directly on the muscle and supported by the pre-gelled sensors themselves, without additional stickers.

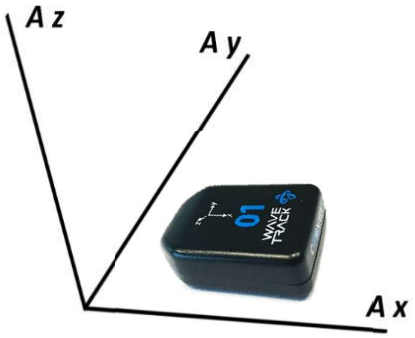
Also, this sensor is equipped with a tri-axis accelerometer, able to capture the minimum movement of the body in space. The disposition of the accelerometer sensors is the following:



The picoEMG are manufactured with fully bio-compatible plastic produced by Bayer (for the factsheet of the material see paragraph 3.3).

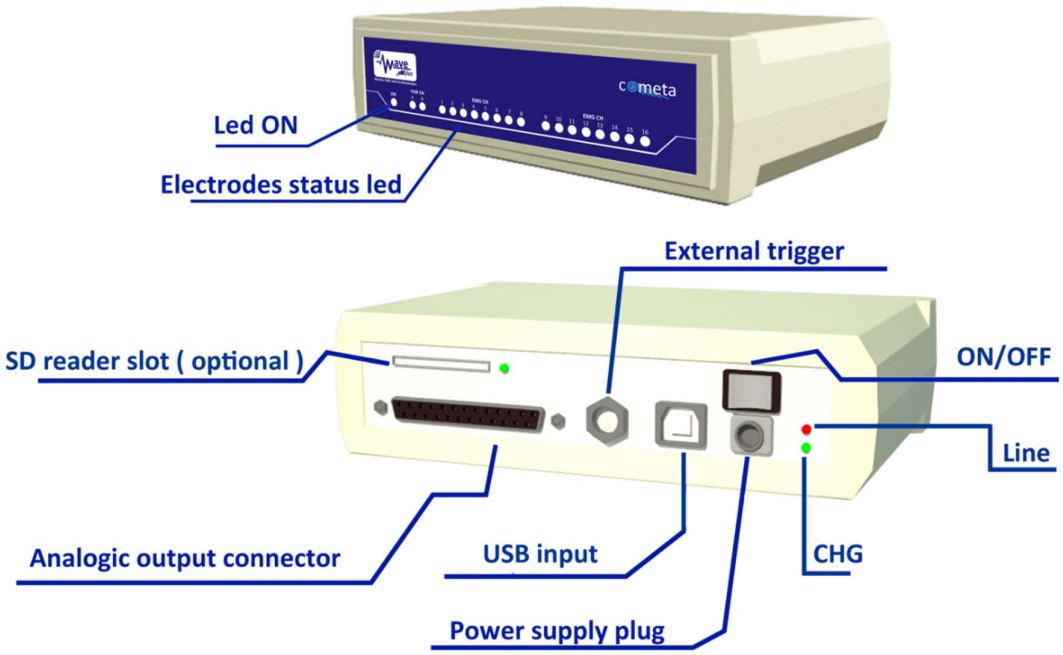
3.2.4 WaveTrack IMU

WaveTrack IMU is a wireless inertial measurement unit (IMU) system with built-in accelerometers, gyroscopes and magnetometer that allow the simultaneous acquisition of either the raw signals or the 6- or 9-axis fused data (quaternions).



The WaveTrack IMU are manufactured with fully bio-compatible plastic produced by Bayer (for the factsheet of the material see paragraph 3.3).

3.3 Base unit



The base unit has a front panel with status LEDs.

The signals are:

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

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

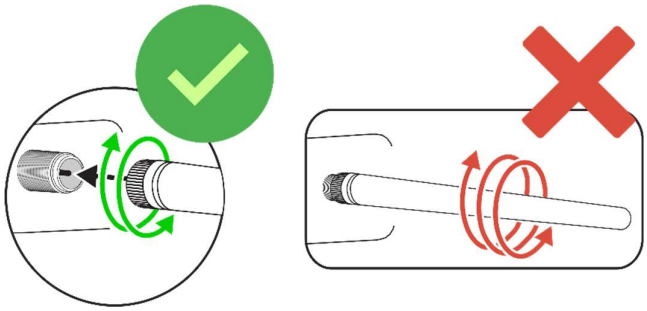
On the rear panel:

- 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.

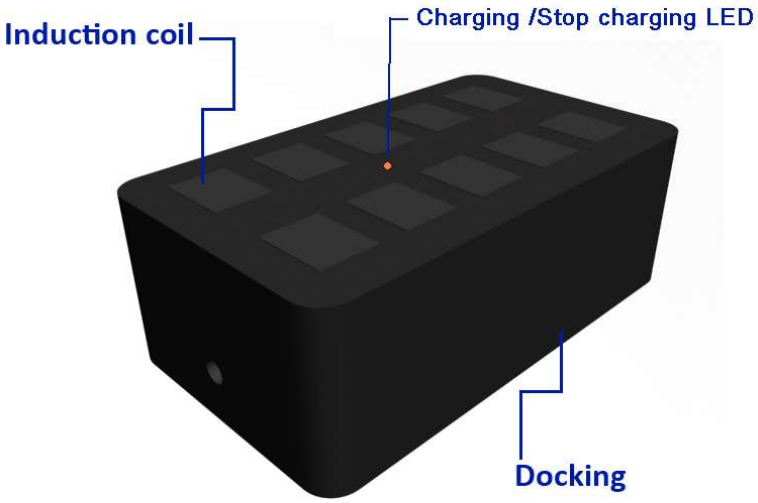
The base unit can be supplied with built–in antennas (as standard), or with external antennas. The application of the external antennas allows the extension of the useful working area of the system.

PLEASE NOTE: Please note: Never fasten or unfasten the receiver's antennas by turning them using the plastic parts to avoid breaking their internal connections. Always use each antenna's metal ring near its receiver connection.



3.4 Docking module

When not in use, wireless sensors should be stored on the docking module embedded into the carrying case. This is required for sensors recharging. For more information about recharging, refer to the "Sensors battery recharge" chapter (see paragraph 4.5).



The recharge occurs by coils, attached to the sensors support base and on the upper 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 sensor is on the docking, there is an induced alternate current in the sensor coil that is sent to the battery for its recharging.

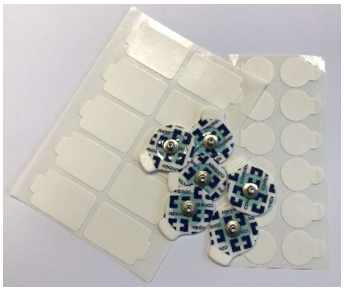
The docking module has a LED status indicator of the charger; during charging the LED is orange, when charging is over, the LED turns to green, as described at the "Sensors battery recharge" chapter (see paragraph 4.5).

With this type of docking module is possible to charge 10 sensors. The charging module is equipped with an eight hours timer, after which the charge is automatically stopped. This allows the unlimited permanence of sensors into their respective place, without the risk of overloading the batteries.
To reset the timer and start a new charge cycle, you must disconnect the power jack and then reconnect it.
The last versions of the Wave Plus System presents also a new type of docking module (see the following picture).
With this type of docking module, it is possible recharge 16 sensors. If it remains connected, it charges the sensors for 8 hours, after this time the charge is automatically stopped but after 24 hours it switched on and it charges for 15 minutes, then it is stopped and continue to charge for 15 minutes every 24 hours. This is a form of cycle that can be used when the sensors (that are always in deep sleep mode) are not going to be used for a long period of time. To reset the timer and start a new charge cycle, you must disconnect the power jack and then reconnect it.
Also this docking module has a LED status indicator of the charger; during charging the LED blinking orange, when charging is over, the LED turns to green, as described at the "Sensors battery recharge" chapter (see paragraph 4.5).

Note that in the carrying case the first type of charger is shown.

3.5 Accessories

Accessory	Short description
Remote Controller 	It can be used to start/stop a remote acquisition whenever using a PC is not feasible or not possible. Note that this accessory can be used only with PicoEMG, Mini Wave Infinity and Mini Wave Infinity Waterproof and WaveTrackIMU. (see paragraph 4.7 for more details).
BCN patch panel 	BCN patch panel allows the connection between the analog output of Wave Plus systems to any acquisition board using BNC connection. This interface can be provided with 66 outputs.
Finewire probe 	This probe can be used to interface with any certified electrodes that accept a free wire connection. In most cases this is used with finewire needles for intramuscular EMG acquisitions.
Trigger box 	It allows to: - Synchronize two Wave Plus system to obtain a total number of channels up to 32; - Synchronize with virtually all systems accepting a TL trigger with a BNC cable; - Synchronized with a GaitRite or Zero mat simply using the 3.5 mm jack connector provided.
SDK	Free of charge with a complete set APIs that allow the experienced user to integrate the USB acquisition in virtually any software on windows platform, giving full control of the hardware.
Footswitches	See paragraph 4.6

Micro golden electrodes 	These electrodes are made for small muscles acquisitions, upper limbs. Coated with a layer of gold, they must higher level of detail, with an acquisition area only 5 mm in diameter.
WaveTrack Elastic bands 	These elastic Velcro bands have a small pocket that fits and keep fixed a WaveTrack transmitter, allowing the use of the sensors in the most dynamic applications, including swimming, running, jumping etc.
Medical grade stickers 	They are made with 3M medical grade 1522 double sided tape, that allows you to attach to the subject's skin all our accessories: - Rectangular stickers for EMG trasmitters and IMU sensors; - Roud stickers for FSW sensors; - Round stickers with hole for Micro Golden electrodes.

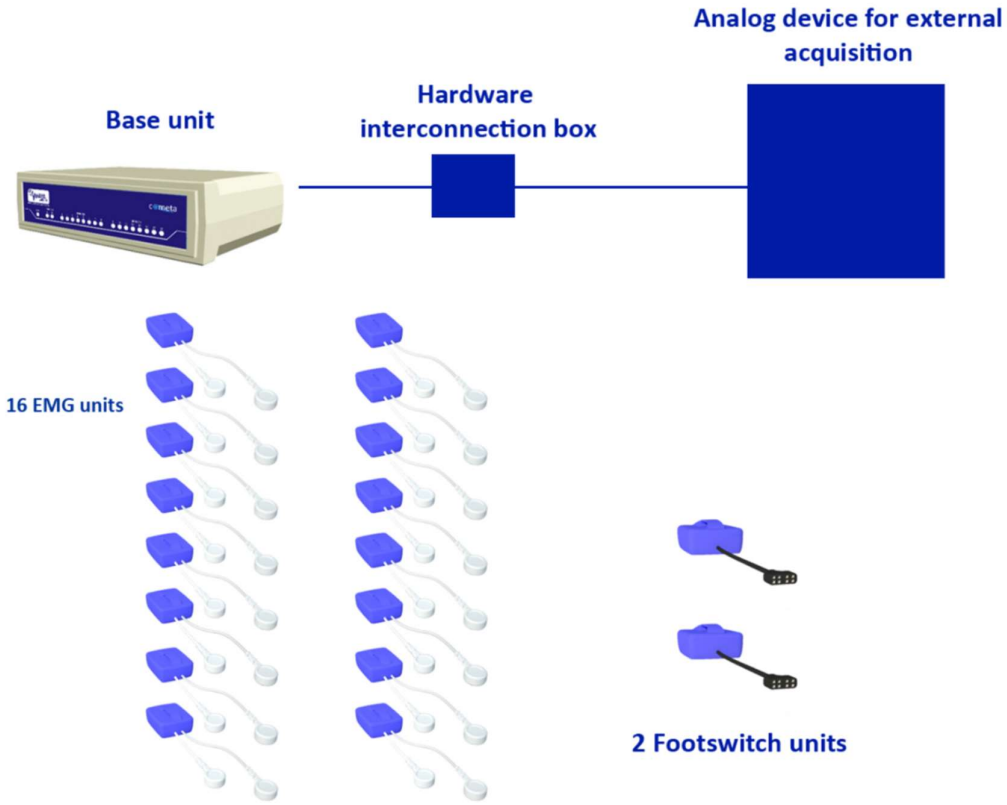
4. WAVE PLUS SYSTEM USE

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 chapter 7: "Technical specifications");
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.

Supported external devices

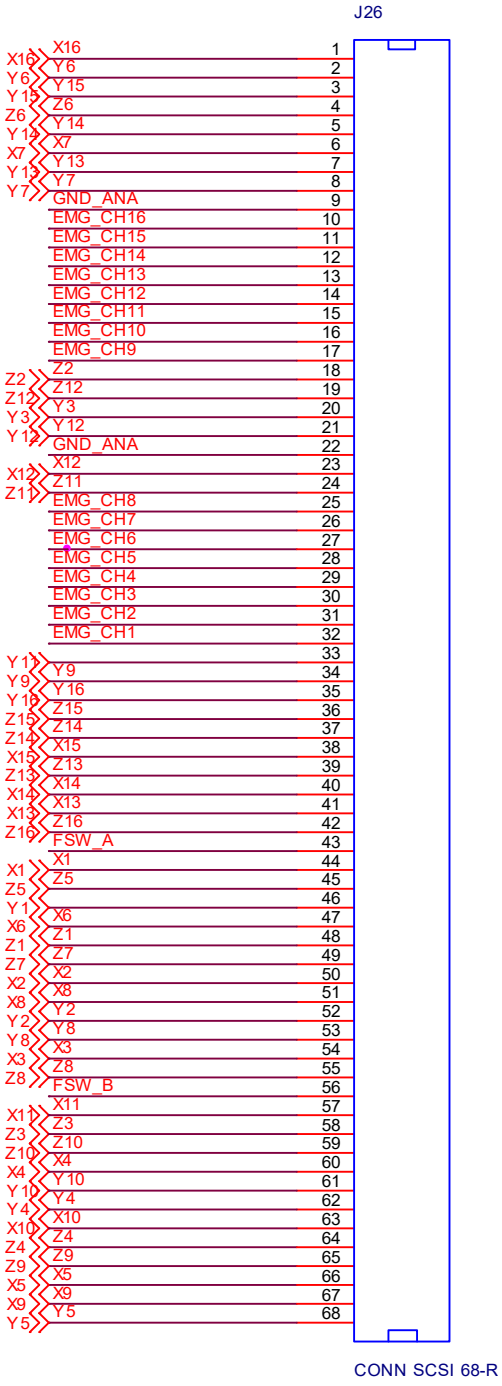
The Wave Plus system can be connected to analog devices commonly used in clinical and scientific environments; these are the features required by systems:

- 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, another 24 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.

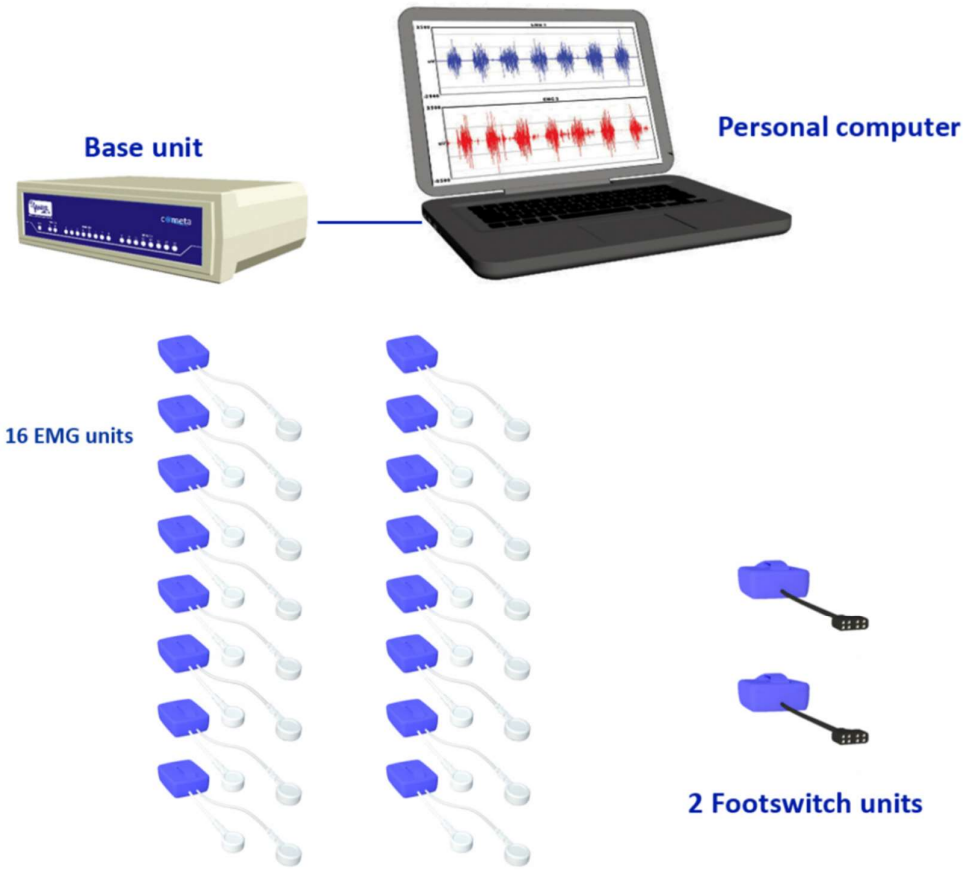
Layout of cable connections

Pin out of the analog output connector.



4.2 Digital mode

With the last version of the Wave Plus System it is possible to use all sensorss (Wave Plus EMG Standard, Mini Wave, Mini Wave Infinity, Mini Wave Infinity Waterproof, WaveTrack IMU, Footswitches) in 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

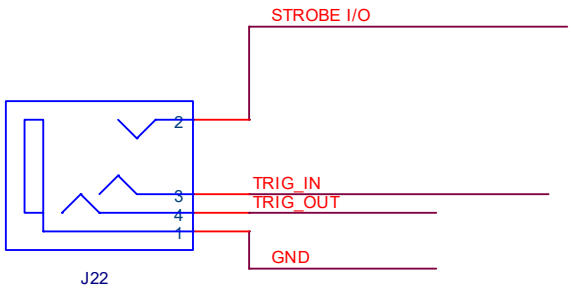
	When operating in digital mode, the device is powered directly from the PC via the USB interface; for correct operation, the connection must provide the rated current provided by the USB II specification (500mA). In this case, the use of the external power supply is optional, and the computer must be 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 addiction to the USB cable, the external power supply.

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 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 values required by the system (see chapter 7: "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.

4.2.2 Trig out

A "trigger out" channel shows the system status:

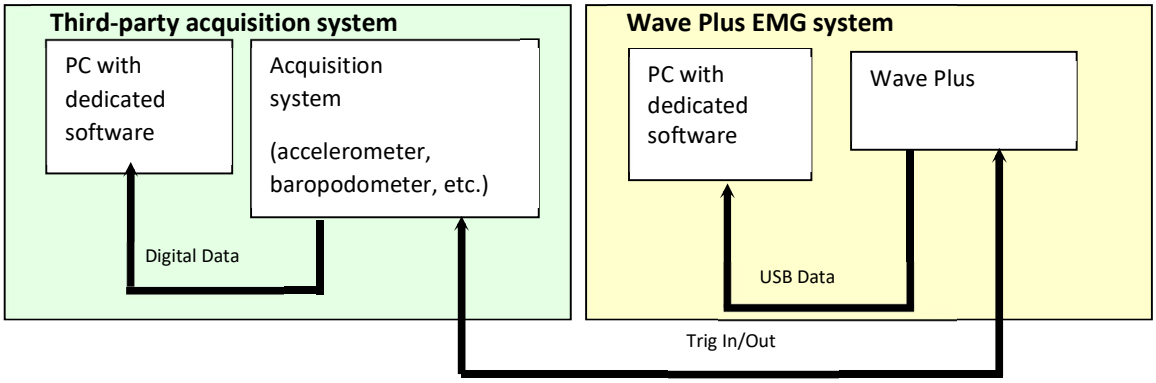
1) "Trig out" signal at "1" logic level when the system is acquiring;
2) "Trig out" signal at "0" logic level when the system is not acquiring.

4.2.3 Strobe IO

The line "Strobe IO" is used for synchronization of a second Wave Plus receiver for the expansion to 32channels of 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.

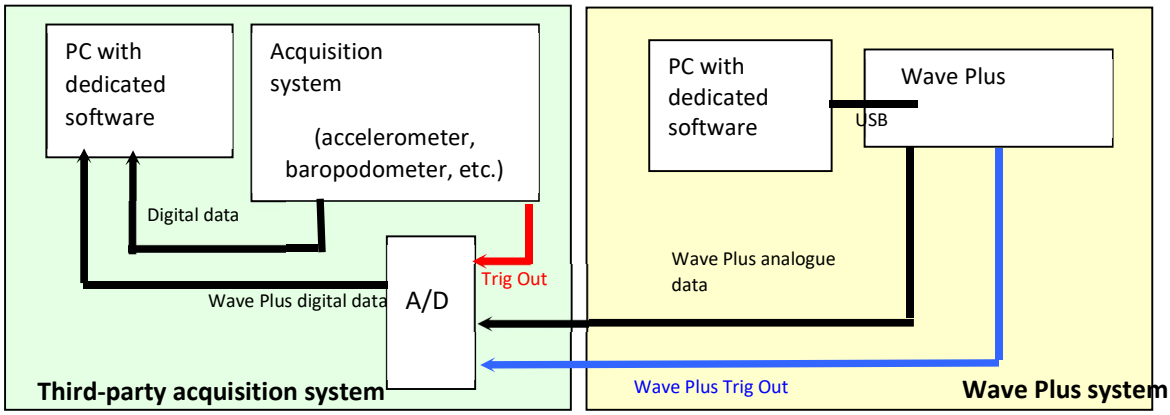
4.2.4 How to use the trigger port

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

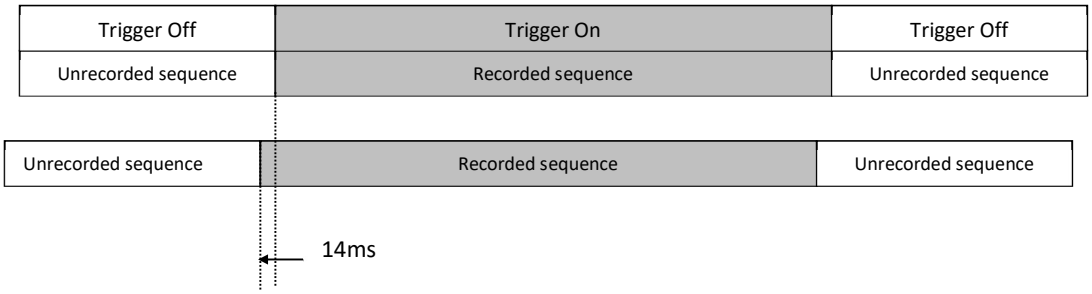
acquisition device must "read" a trigger signal or record a "*start*" event into the acquisition data streaming (e.g. the event related to the TMS stimulation).

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 to synchronize the Wave Plus system with third-party devices collecting the EMG signals from the Wave Plus analogue port, you should also consider the 14 ms delay related to the Wave Plus analogue output. In this case you should correct the recorded data in order to remove the 14 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.

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

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

Sensor unit LED

On the EMG unit (Wave Plus EMG Standard, Mini Wave and PicoEMG) there is one LED:

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

On the inertial IMU unit there is one LED:

- LED off: the sensor is stand-by condition (not active);
- LED on, blinking green light: the sensor is on and recognized by the receiver unit.

The LED of the transmitting module, when the sensor 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 Sensors battery recharge

To recharge the sensors, put the sensor 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.

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.

For the first charging module (10 sensors integrated in the transport case), the LED meanings are:

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

For the last charging module, the alerts are:

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

Note that the carrying case integrates the first type of charger.

It is mandatory to leave the carrying case open during the recharge of the sensors.

If the batteries are deeply discharged, it may be necessary to perform two or more charge cycles, to restore their original capacity.

The sensor, when not in use, has 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.

LED indicator of the sensors

When the sensors are charging, the orange LED provides an indication about the level of charge. Particularly, three states are available:

1) LED orange flashing at one flash/sec.: sensor on pre-charge (when battery is completely empty. This phase lasts only a few minutes);
2) LED flashing quickly: sensor on normal charging phase;
3) LED orange off: full charge.

NOTE ON WAVE PLUS EMG STANDARD SENSORS:

The transmitter units of the sensors can be charged by placing on the charger just the lower part of the sensor (this should be done only when the sensors are completely discharged). The feedback on the state of charge takes place through a second green LED placed within that module (beneath the battery itself). Charging is complete when the internal LED is off.

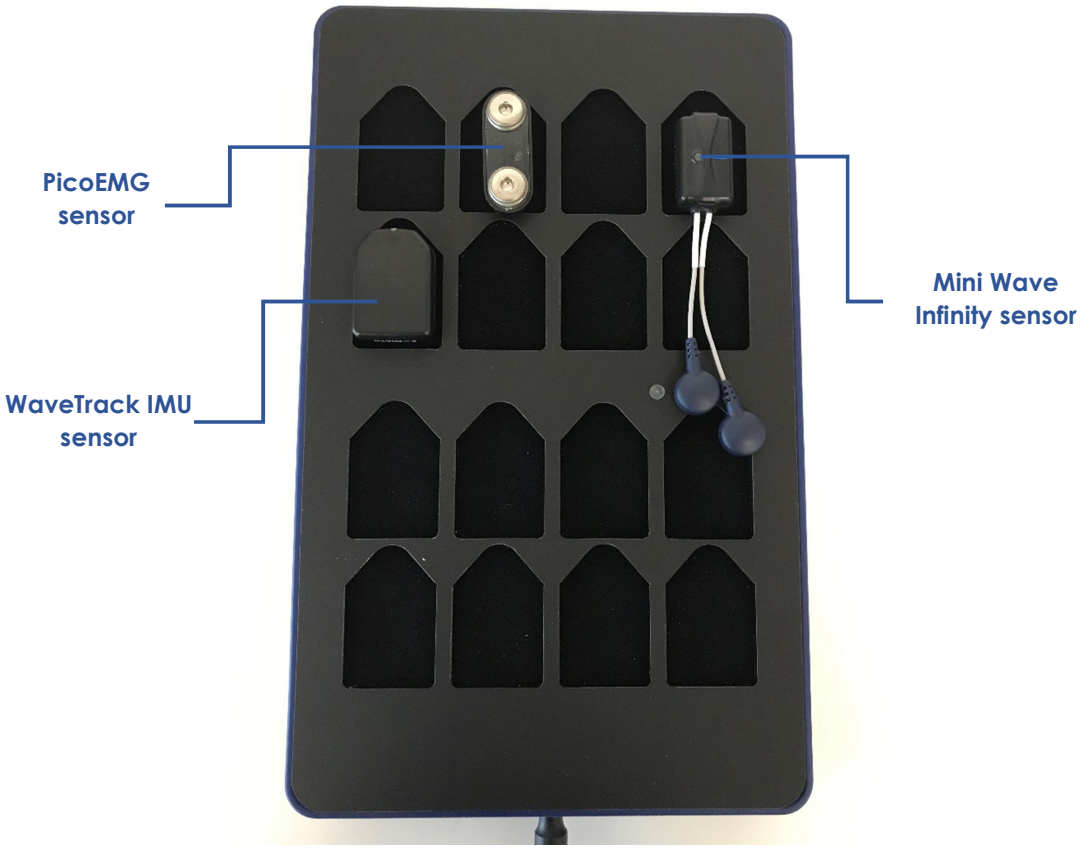
NOTE: The sensors can be recharged only when closed (upper part mounted on the lower one). No charging takes place if the only lower part is placed on the charger.

IMPORTANT NOTE. During the charging process, the sensor placed in the docking box *does not transmit* (unless the memory is being downloaded). This is valid only during the charging process (charging module active - LED light orange). At the end of the charging cycle (charging module off – LED light green), the transmitting unit resumes its normal functionality.

Position of sensors during the recharge

The position of the sensor on charging module:

- For standard and mini wireless sensors (Wave Plus EMG Standard, Mini Wave, Mini Wave Infinity and Mini Wave Infinity Waterproof): put the sensor in the appropriate slot in the recharging module with the number of sensors upward;
- For Pico wireless sensors (PicoEMG): put the sensor in the appropriate slot in the recharging module with the number of sensors downward;
- For inertial wireless sensors (WaveTrack IMU): put the sensor in the appropriate slot in the recharging module with the number of sensors downward.



Warnings

Extended non-use of the device	
	If the device should be left unused for a long time, we suggest to: -Wave Plus EMG Standard: unlink/Disconnect the EMG acquisition module from the battery module and keep the elements in a dry and clean environment; -All other sensors: 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 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.

How to remove the EMG sensors positioned on the patient.	
	The cables with clip connections used by wireless units for EMG (see paragraphs 3.3, 3.4 and 3.5) 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 sensors, 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 sensor.
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.
Additional 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 on children of less than 3 years of age or on 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.

4.6 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.

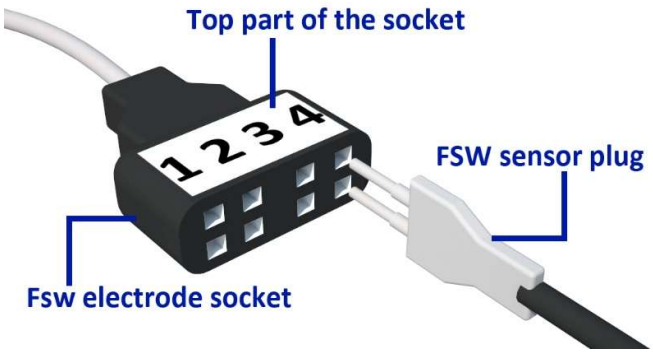
The connection to Footswitch sensor has to be done according to the following representation:

Proceed according to the following instructions:

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

The four inputs are electrically and mechanically identical.

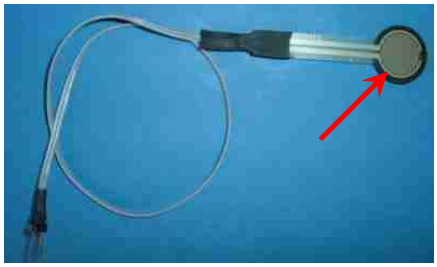
To have correct data identification, inputs are:



The FSW sensor plug isn't polarised and can be connected in both ways; the FSW sensor 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.

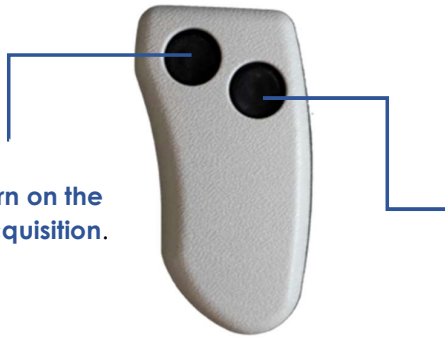


4.7 Remote Controller

The controller is used to turn on and off the sensors and start/stop the acquisitions. The remote can also be used to import a specific configuration into the transmitter's memory (such as accelerometer's gain and number of channels involved). It is recommended when the communication between the master transmitter (number 1) and the other transmitters can be difficult (outdoor) or impossible (underwater). The synchronization drift has been quantified in a few milliseconds per hour, so it does not affect the validity of the acquisition. The GRAY controller is used for synchronous acquisition, when transmitter #1 is keeping all the others perfectly synched. This is recommended for indoor acquisition (for example, gym, long hallway, etc.). The functioning of the two receivers is slightly different.

Before starting to use the remote, make sure that:

- All sensors are within the range of the remote controller (2-3 meters);
- **The USB receiver is turned off (if the receiver is left on, the remote will give an error beep sound and the acquisition will not start).**



Left button is used to turn on the sensors and start the acquisition.

Right button is used to turn off the sensors and stop the acquisition

Remote functioning:

Act on the buttons to send commands to the sensors, in particular:

- Short push (just press and release immediately the key);
- Long push (press the key and hold it down for at least 4 second, or until you hear a single short beep, then release);
- Double push (press both keys at the same time to program the remote).

The buttons:

- Both buttons pressed together: import of the configuration on the remote controller;
- Left button: keep pressed until the sensors turn on;
- Left button: press once to start the acquisition;
- Right button: keep pressed until the sensors turn off.

An acoustic feedback will show you if the command has been received or not, in particular:

- Single short "beep", when the input from one key is recognizes as valid;
- Three single short "beeps", when the command sent by the remote has been received by the #1 sensor;

- Single long "beep", when the command sent by the remote has ***not*** been received by the #1 sensor. It shows that the remote stops the command transmission and goes in a standby state, get closer or check the configuration and try again;

- Cricket "beep", when you are using the remote when a receiver, working on the same frequency, is on in the working field (this operation is NOT possible).

Once you have started the acquisition, the remote will not interact with the transmitters anymore, so distance will not be a problem.

Please note: single action on the stop button of the remote will NOT stop the acquisition: end of sensors acquisition needs to be forced by keeping the stop/off button pressed until they all turn off. This is necessary because every time you restart the sensors, synchronization will be reset. The STOP REG command (right key, long act) cannot have feedback from the sensors, so the single long beep that ends the transmission does not mean that the sensors did not receive the command, but only that the transmission from the remote has ended. The STOP REG command must be repeated if some sensors do no switch off. For stopping the acquisition, the sensors must be near the remote (within 1-2 meters).

The Remote control is powered by a rechargeable LI-ION battery that allows long usage of the unit; to recharge the battery, put the Remote Unit in the inductive recharger (as for recharging the sensors) until you hear a three "beep-beep-beep" sound or leave it until the charger switches off (led green). The unit has to be placed vertically, as shown in the picture:

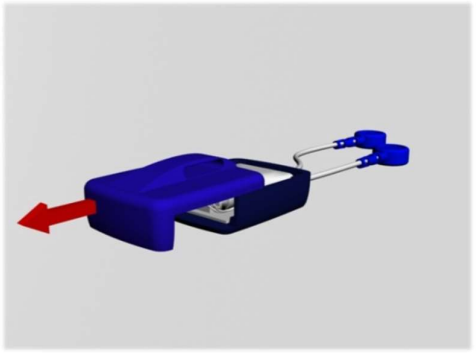
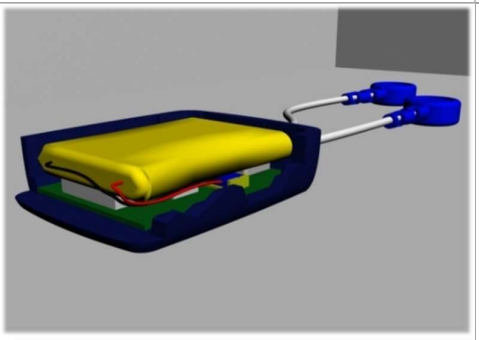
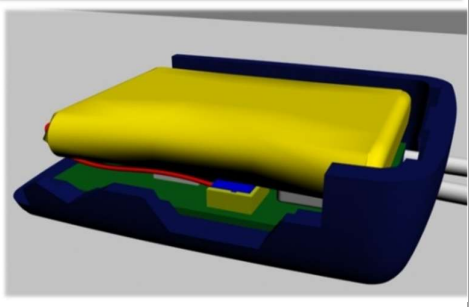
5. SYSTEM MAINTENANCE

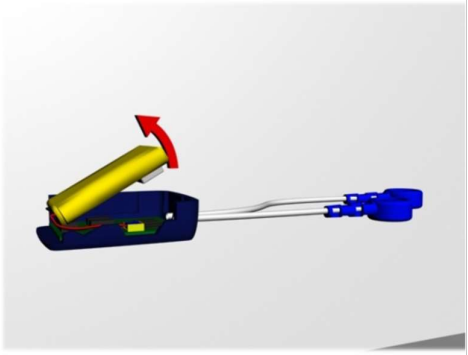
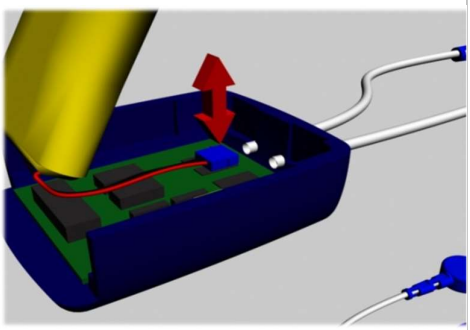
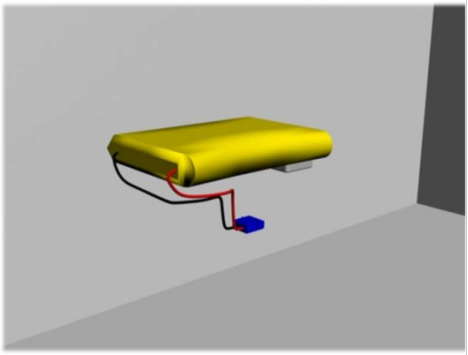
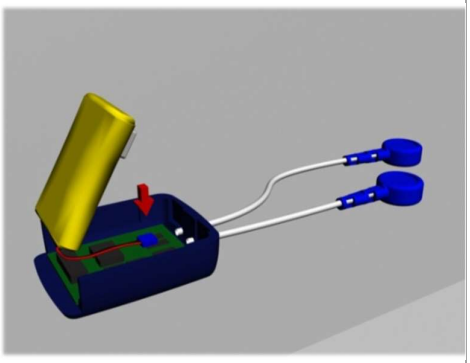
5.1 Repairable parts

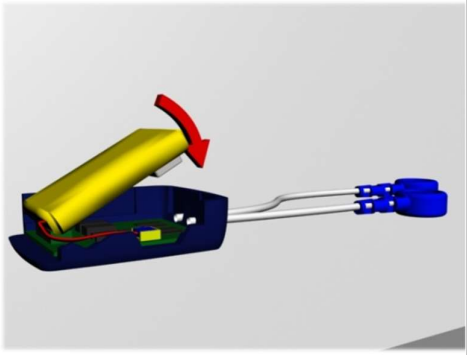
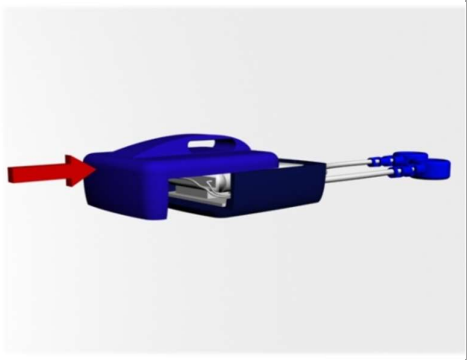
Wave Plus system does not contain parts repairable by the user with the exception of the batteries; for standard maintenance see the following chapters.

5.2 Replacement of sensor battery – Wave Plus EMG Standard

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

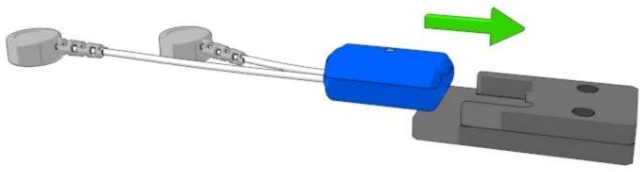
	1. Open the sensor by gently pushing as shown in the picture. The sensor will slide open separating in two parts (lower and upper).
 	2. Take the lower part of the sensor, the one containing the battery. As shown in the picture, the battery is linked to the sensor with a small connector.

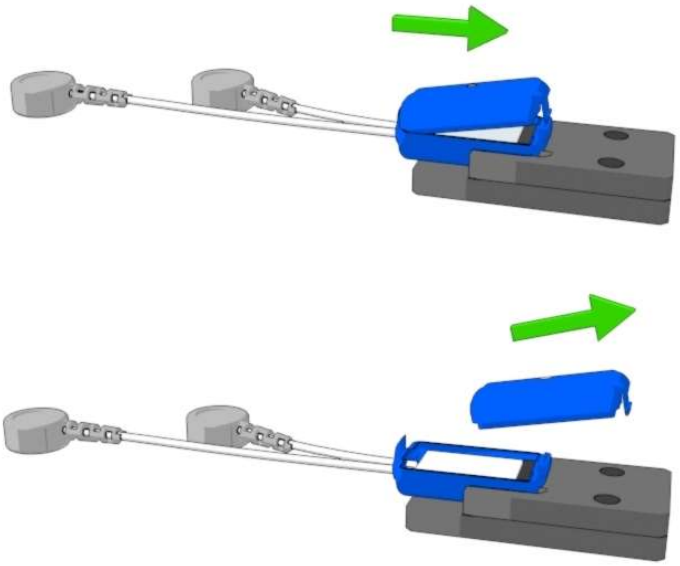
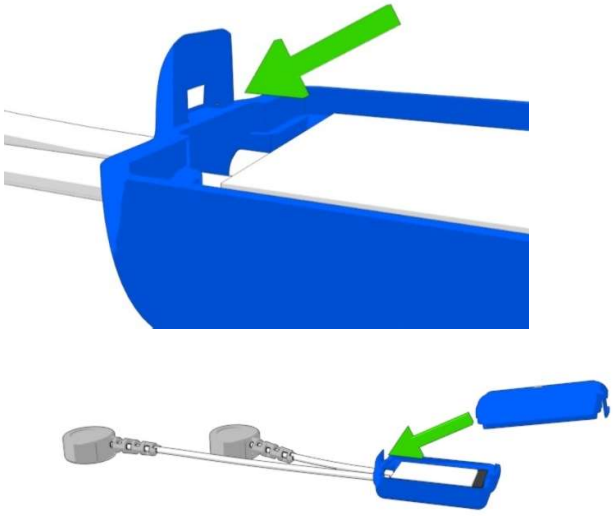
	3. Extract the battery after gently prying it out of the housing as shown in the picture.
	4. After having removed the battery, pull the connection cable VERTICALLY in order to detach the connector from the sensor.
	5. The exhausted Li-ion battery will have to be disposed of according to your country's regulations.
	6. Take the new battery and follow the same steps backwards to install it inside the sensor.

	7. Carefully insert the new battery, making sure it is positioned as shown in the picture.
	8. Put the sensor back together by sliding the upper part back into the lower one, as shown in the picture, until you hear a click.

5.3 Replacement of sensor battery - Mini Wave and Mini Wave Infinity

After about 300 charging/discharging cycles, the battery could reduce its electric capacity that leads to a shorter time of use of the sensors. To re-enable the normal efficiency, you should replace the battery module. Please note that you cannot change only the battery, but the whole lower part of the sensor, comprising the plastic shell and the sensor leads and clips. To do this, do as follow:

	1. Open the sensor by gently pushing it into the opening tool supplied with the new battery module. The retain hook will open.

	2. Pull up the hook side of the upper part and slip it out.
	3. To install a new battery module, first push the nose of the upper shell (it is on the opposite side of the retaining tab) into the correspondent hole of the battery module.

	4. Check that the retaining tab is positioned inward as shown and push gently until you hear a “click”.
	5. During the handling and assembling, be care not to stress the retaining tab of the upper module by bending it more than necessary, or permanent damage to the shell will occur. The exhausted module contains a Li-ion battery that will have to be disposed of according to your country’s regulations.

5.4 Sensor battery characteristics

Voltage: 4V

Capacity: IMU E FSW150 mA/h (60 mA/h for miniaturized sensors)

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 S.r.l

Via Giovanni Falcone 43

20010 Bareggio MI

Tel. +39 02 91410582

sales@cometasystems.com

The replacement of the battery of the Footswitch sensor is performed in the same way.

5.5 Warnings about sensors battery

	**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 sensors with battery that is losing electrolyte, or smells of electrolyte, or has the container blown up.
Warning:	Sensors 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".

Warnings for battery disposal

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

Warnings for device disposal

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

5.6 Replacement of worn parts

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

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

5.7 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. Sensors: every 50 hour or more often if required

Warning

For Wave Plus EMG standard, Mini Wave, Mini Wave Infinity:

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

- Take off the acquisition module (upper part) from the battery module, as described in "Replacement of sensor battery" chapter (see chapter 5);
- 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 sensor.

5.8 References

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

Cometa S.r.l.

Via Giovanni Falcone 43

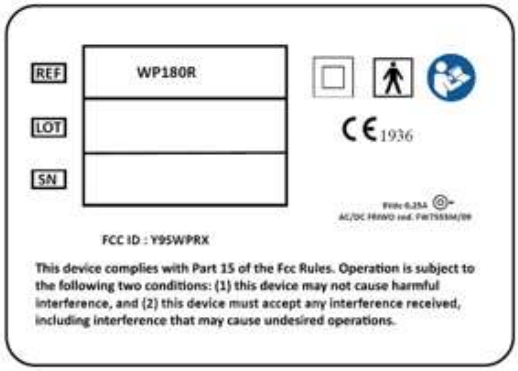
20010 Bareggio MI

Tel. +39 02 91410582

sales@cometasystems.com

6. LABELS

6.1 Base Unit



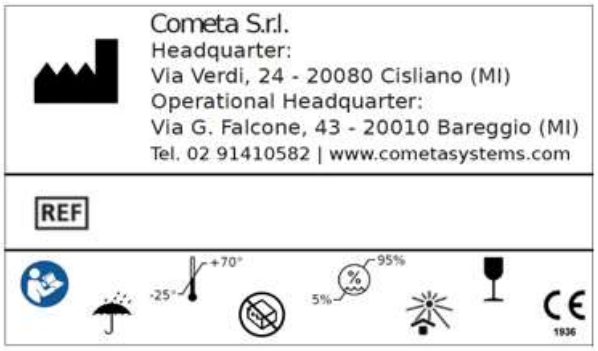
Label composition:

REF.: REFERENCE NUMBER

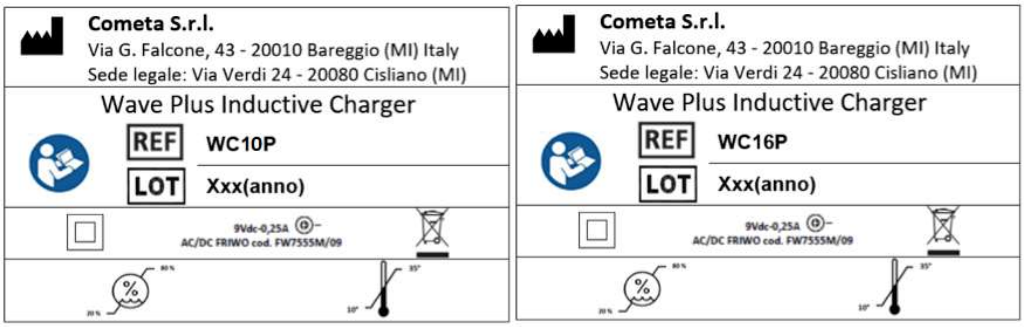
LOT.: PRODUCTION LOT IDENTIFIER

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 Wave Plus EMG Standard and Footswitch sensors

The sensors are made of two parts; the upper part is permanently printed with the brand "Wave Plus" on the top.

For **Wave Plus EMG Standard and Footswitch**: the lower part is permanently 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 sensor (from 1 to 16), or to the FSW ("A" or "B").

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

On the PC board of the upper part is printed the item code "MEMG V05".

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 sensor (PSC power supply module), once removed the battery, shows the code:

XXXXXXXXXX

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).

6.5 Mini Wave, Mini Wave Infinity and Mini Wave Infinity waterproof

The sensors are made of two parts; the upper part is permanently printed with the number assigned to the sensor (from 1 to 16) on the top. The lateral part is permanently pad printed with the brand "Cometa" on one side and "Miniwave" on the other side.

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

On the PC board of the upper part is printed the item code "MEMG V07".

On the battery there is the following label:

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

6.6 PicoEMG

The sensors are made of two parts; the upper part is permanently printed with the number assigned to the sensor (from 1 to 16) on the top. The lateral part is permanently pad printed with the brand "Cometa" on one side and "picoemg" on the other side.

The labels of the two parts of the sensors are visible after having taken apart the sensor by separating the upper and the lower part.

On the PC board of the upper part is printed the item code "PICOEMG V01".

On the battery there is the following label:

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

6.7 WaveTrack IMU

The sensors are made of two parts; the upper part is permanently printed with the number assigned to the sensor (from 1 to 16) on the top. The lateral part is permanently pad printed with the brand "Cometa" on one side and "WAVETRACK" on the other side.

The labels of the two parts of the sensors are visible after having taken apart the sensor by separating the upper and the lower part.

On the PC board of the upper part is printed the item code "MTRACKV02".

On the battery there is the following label:

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

7 TECHNICAL SPECIFICATIONS (WAVE PLUS 16 CH)

Base unit

Transmission/Reception frequency	2402-2484 MHz
Transmission power (ARP)	0.45 mW
Number of channels (16 EMG+48 ACC+2FSW)	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 Trigger out	 TTL, max ±10V TTL, max ±10 V
Output EMG Output ACC Output FSW Output	 ±2,5 V, Zout =100 ohm ±2,5 V, Zout =100 ohm ±16 levels, max 3V
Host USB link	USB 2.0
Gain (EMG channels)	1.000 (1V/mV)
Dimension	155 x 105 x 50 mm
Weight	300 gr.

Footswitches Module

Transmission/Reception frequency	2402-2484 MHz
Transmission power (ARP)	0.45 mW
Number of FSR sensor	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	14 gr

Wave Plus EMG Standard

Transmission/Reception frequency	2402-2484 MHz
Operating temperature range	0+50°C
Full charge operation time (100% charged battery)	>12 h
Stand by time (100% charged battery)	>180gg
EMG input	+-2.5Mv
Bandwidth	10Hz-500 Hz (or 1 KHz)
Sampling	16 bit- 2 Ks/sec
ACC sensitivity (SW selectable, full scale)	± 2 g, ±4 g ± 8, or ±16g
Sampling	10 bit – 142.8 s/sec
Max. allowed acceleration	10,000 g
Dimensions	33x23x19 mm
Weight	14 gr

Mini Wave, Mini Wave Infinity, Mini Wave Infinity Waterproof

Transmission/Reception frequency	2402-2484 MHz
Operating temperature range	0+50°C
Full charge operation time	> 12 h
Stand by time (100% charged battery)	>180 gg
EMG input	+- 2.5 mV
Bandwidth	10Hz-500Hz (or 1KHz)
Sampling	16 bit-2Ks/sec
Acc sensitivity (SW selectable, full scale)	± 2 g, ±4 g ± 8, or ±16g
Sampling	10 bit – 142.8 s/sec
Max. allowed acceleration	10,000g
Dimension	32x17x12 mm
Weight	10-14 gr

PicoEMG

Transmission/Reception frequency	2402-2484 MHz
Operating temperature range	0+50°C
Full charge operation time	> 12 h
Stand by time (100% charged battery)	> 180 gg
EMG input	+- 2.5 mV
Bandwidth	10Hz-500Hz (or 1KHz)
Sampling	16 bit- 2Ks/sec
Acc sensitivity (SW selectable, full scale)	± 2 g, ±4 g ± 8, or ±16g
Sampling	10 bit – 142.8 s/sec
Max. allowed acceleration	10,000g
Dimension	41x16x8.5 mm
Weight	7.6 gr

WaveTrack IMU

Transmission/Reception frequency	2402-2484 MHz
Operating temperature range	0+50°C
Full charge operation time	>8h
Stand by time (100% charged battery)	>180 gg
Avquisition Type	RawData Fused9xData_142Hz Fused6xData_ 284Hz Fused9xData_ 71Hz Fused 6xData_142 Hz Mixed 6x Data_142Hz
ACC sensitivity (Full scale)	2g, 4g, 8g, 16g
Gyroscope sensitivity (Full scale)	250dps, 500dps, 1000dps, 2000dps
Max. allowed acceleration	10,000 g
Dimension	36x25x10 mm
Weight	9.4 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 Vcc, 1.5 A
Power supply cable	2.1 x 5.5 S 11.5 coax (+central)

Additional specifications

Input impedance	20 MOhm
CMRR	>120 dB (true differential sensors without reference sensor)
SNR	> 50dB
Hardware filtering (LP and HP)	1st order, 6dB/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