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ZEROWIRE MULTICHANNEL ELECTROMYOGRAPH


USER MANUAL

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

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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1. INTRODUCTION

ZeroWire system is an innovative multi-channel wireless surface electromyographic system.

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;
- Digital transmission of the EMG signal;
- Receiver device equipped with analog and digital (USB port) data output;
- 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

ZeroWire 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 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 ZeroWire system for patients who tolerate the adhesive electrodes and conductive gel for SEMG detection through medical electrodes.

ZeroWire system application areas are:

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

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ZeroWire 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**.


2.1 How to use it

To use ZeroWire, 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.

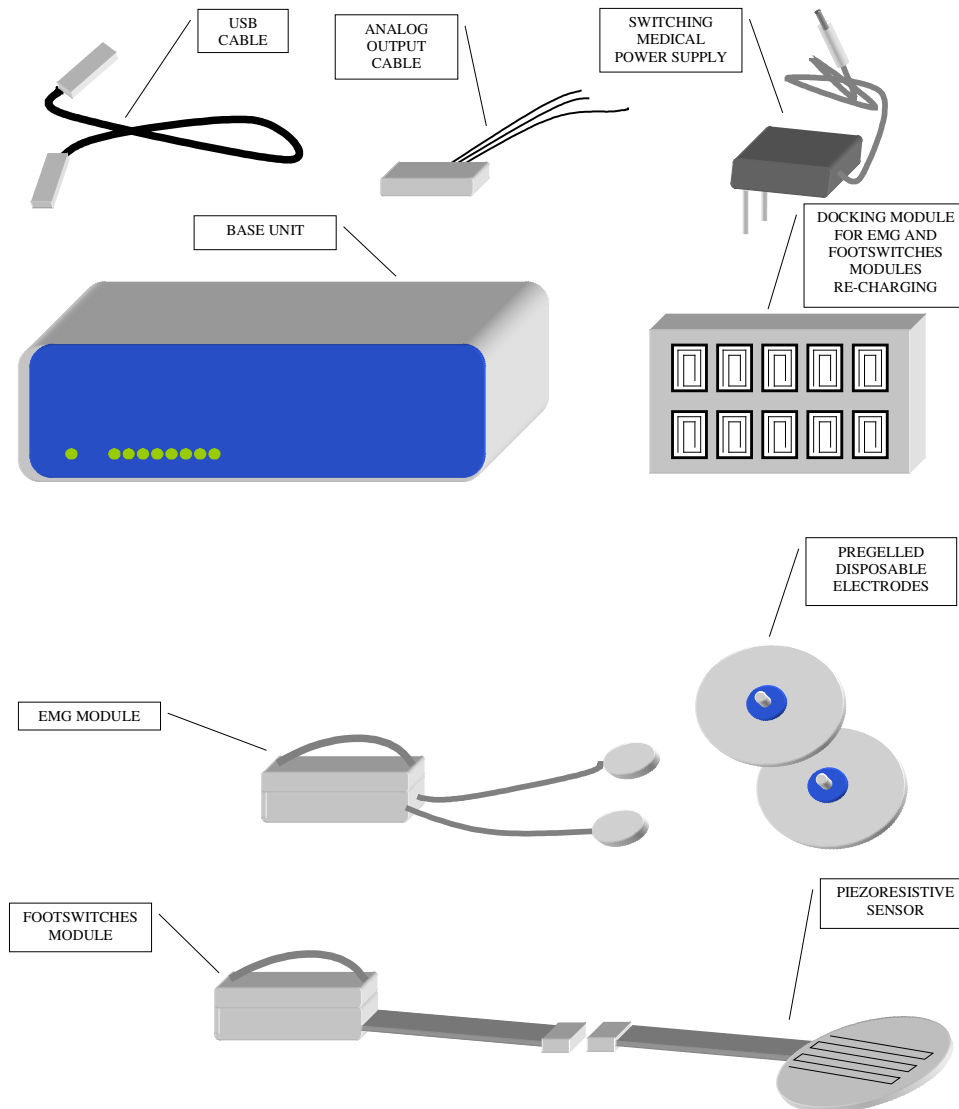
ZeroWire system can be used by doctors, paramedics and technicians.

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

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3. ZEROWIRE SYSTEM COMPONENTS


The following representation shows all ZeroWire components.



The standard configuration of the system is composed of:

- EMG wireless modules, with 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.

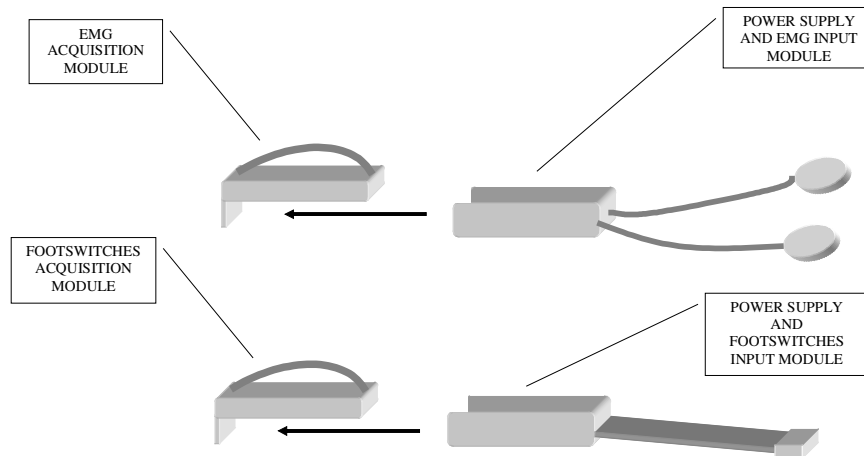
Wireless modules are equipped with an internal rechargeable battery. The modules communicate with PC through the base unit thanks to a bi-directional link working at 2400 MHz.

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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 those phases in which the electrodes are not used.


3.1 Wireless electrodes



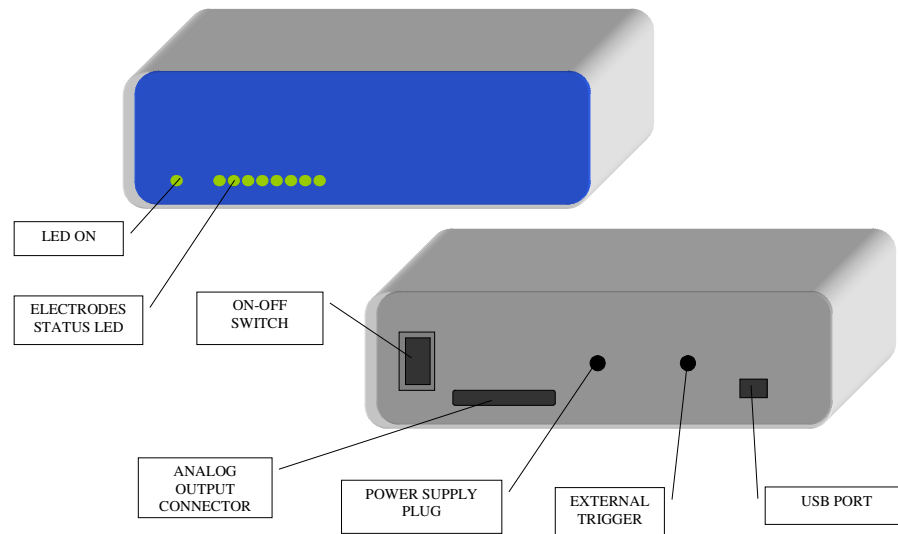
The ZeroWire system module is composed of two parts:

- 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 wear). In these cases follow the instructions in chapter “Replacement of electrode battery”.

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3.2 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:

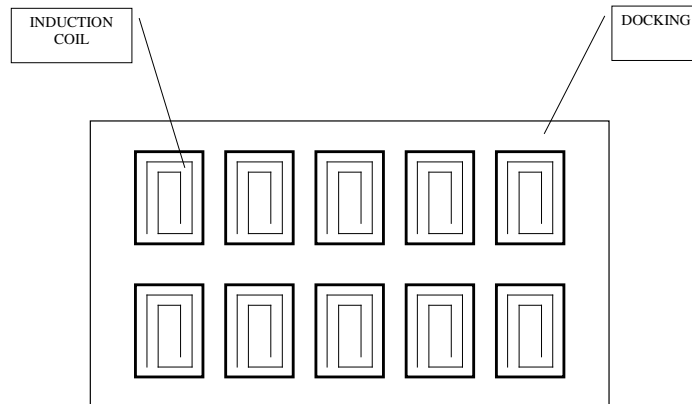
- on-off switch;
- female port DB25 for analog EMG output and for foot switches signals;
- jack for the connection of the external trigger;
- USB port to connect the host PC.

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.

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3.3 Docking module

When not in use, wireless electrodes should be in the docking; it recharges 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.

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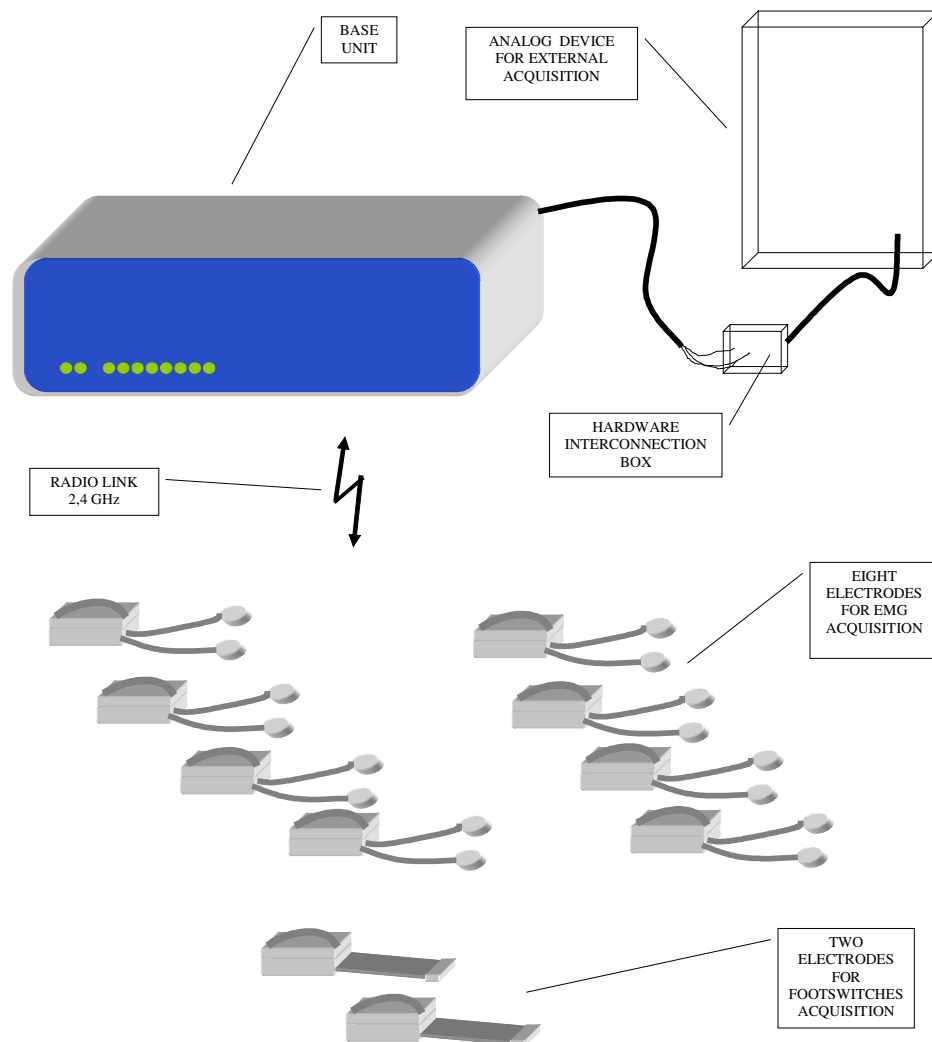
4. ZEROWIRE SYSTEM USE


ZeroWire 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.

The two configurations can be used simultaneously.

4.1 Analog mode



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To operate the system:

- 1) connect ZeroWire Y1 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 ZeroWire 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 doesn't require a Personal Computer; switching on the base unit EMG and basographic signals are available in continuous on analog output connector J13.

4.1.1 Supported external devices

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

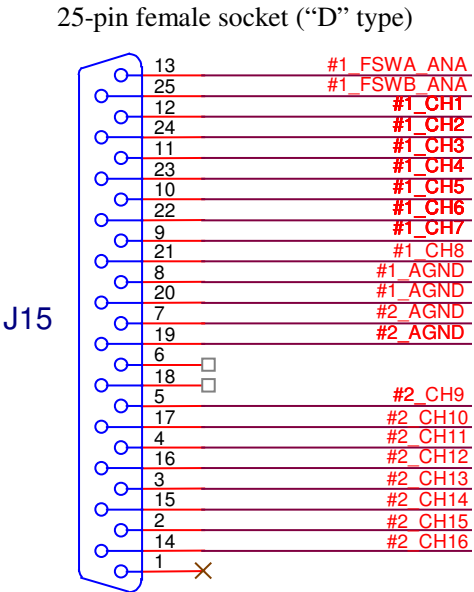
- at least eight EMG data collection channels, with $Z_{out} = 100 \text{ ohm}$ and an amplitude of $\pm 2,5 \text{ V}$
- at least two analog channels to acquire footswitches, configured for signals with $Z_{out} = 100 \text{ ohm}$ and an amplitude of $+ 4 \text{ V}$.
- it complies with IEC 60950




The use of external devices non complying with IEC 60950 can cause electric shock and damage the system.

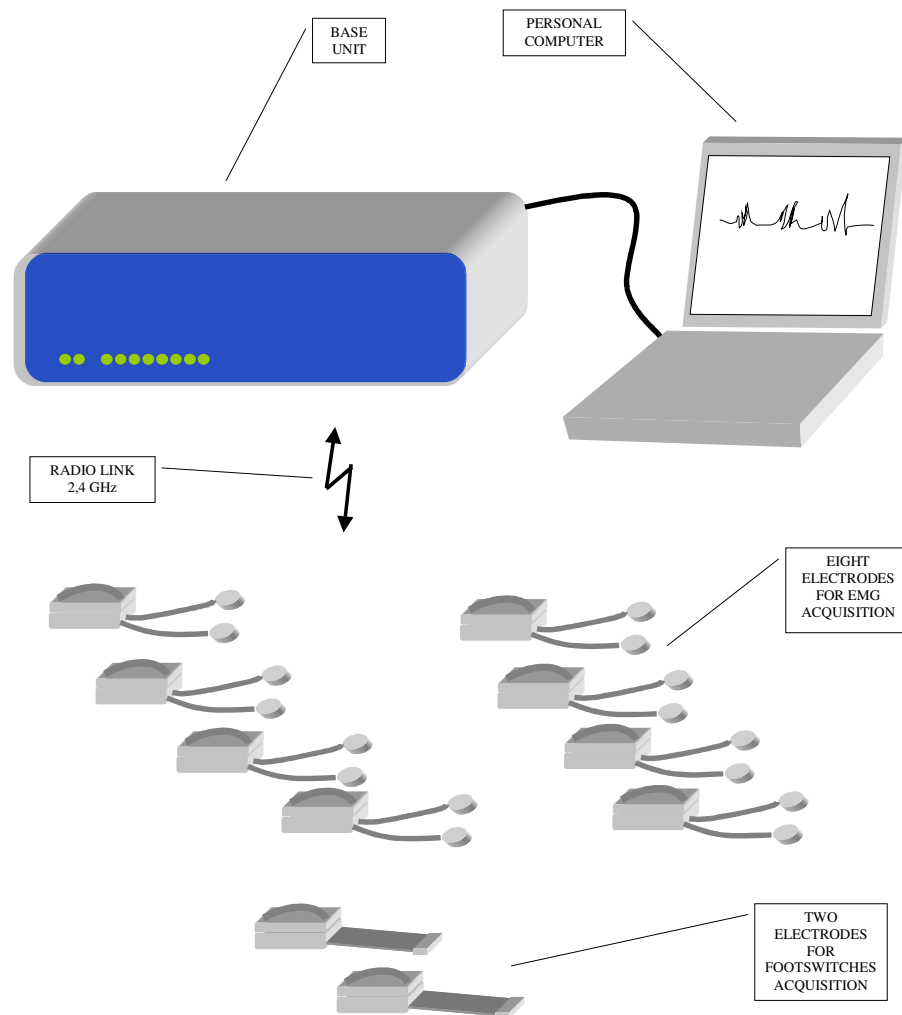
4.1.2 Layout of cable connections

Pin out of the analog output connector.



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4.2 Digital mode




To operate the system:

1. connect ZeroWire USB cable to the PC 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)

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3. connect ZeroWire 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.

4. open ZeroWire control program and follow the SW indication for data graphic rendering and digital data collection.

The PC controls ZeroWire system. See SW User Manual for the description of operating controls.

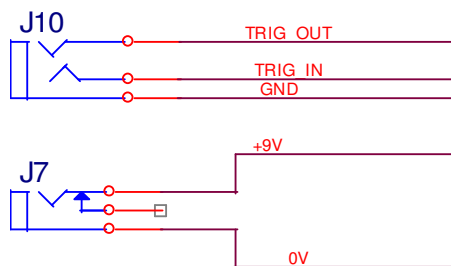
4.2.1 External trigger


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



The use of external devices non complying with IEC 60950 can cause electric shock and damage the system.

Pin out of connections to trigger and power supply:



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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”.

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


4.2.2 Supported external devices

ZeroWire 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 1024 x 768 at least
- minimum ram memory, 512 MB
- minimum processor frequency, 800 MHz
- minimum hard disk, 20 GB

The Personal Computer linked with the ZeroWire system has to comply with IEC 60950 regulation.

ZeroWire system has a software for data collection and system set-up; for additional details see the user manual provided with the SW.

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4.3 LED status indicators

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

On the base unit there are ten LEDs:

- LED off: the correspondent electrode is in stand-by (non active);
- LED on, green light: the electrode is on

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 on, blinking green light: the electrode is on and has a low battery level.

4.4 Pregelled electrodes

The ZeroWire 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 Noraxon USA or a local distributor of consumable items.


To apply electrodes see the information provided by the manufacture.

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

1. Use pregelled 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 doesn't 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 recharge lasts about eight hours; when charged, remove electrodes from the apposite unit or switch off the unit. During charging the green LED is on, when the probe is fully charged the green LED turns off.

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The system is designed for a long lasting recharging time; although, to maximise battery life, we suggest not to exceed 24 hours of recharging.



If the ZeroWire system is supplied with the suitcase, it is recommended to leave the case opened during the recharge of the electrodes units.

4.6 LED indicator during charging

When the probes are charging, the green LED light provide an indication about the level of charge. Particularly, two state are available:

- LED on: probe on charge;
- LED off: probe fully charged.

The probes may be charged simply place the only power supply module on the charging slots. A second green LED mounted in the power supply unit provides the feedback about the level of charging, with the same logic of what described above.

NOTE THAT. During charging the probes do not transmit data.

4.7 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 ZeroWire receiving unit is close to an active LAN 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.



How to use the device with a disturbing electromagnetic fields

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If strong electromagnetic fields are in the environment where ZeroWire 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.



Do not use ZeroWire 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 polycarbon of the external shell.



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



For 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.

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4.8 Piezoresistive sensors

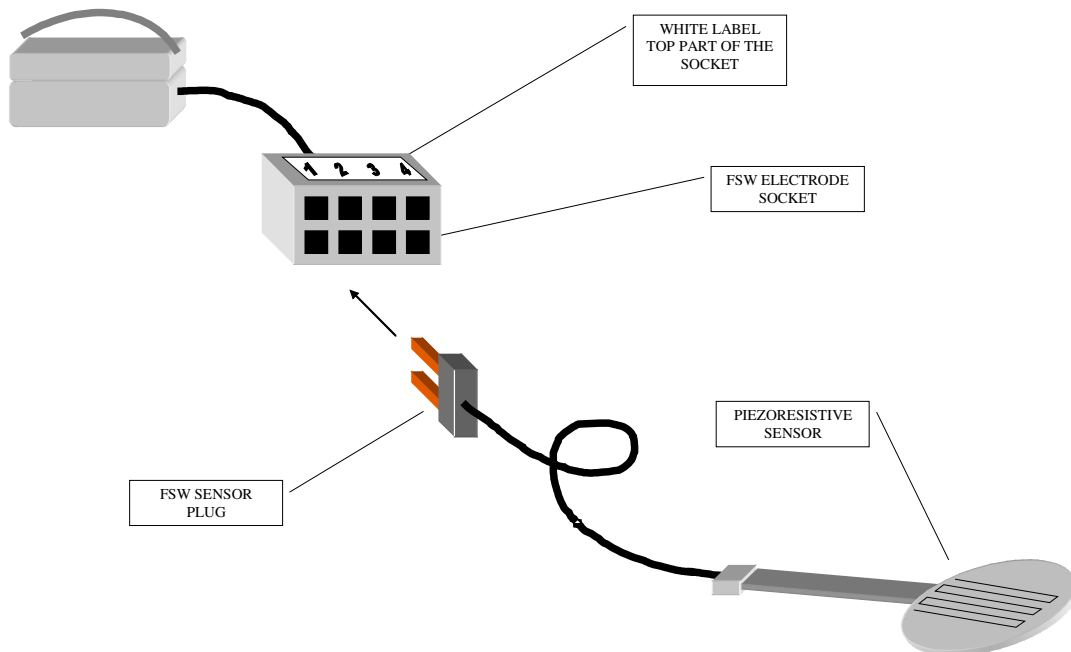
Piezoresistive sensors for the gait cycles events detection are placed under the foot surface, in a position that allows a precise measurement of support and toe off. Up to four sensors for foot are available, and these are displaced in the typical positions:


- 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 preferences.

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

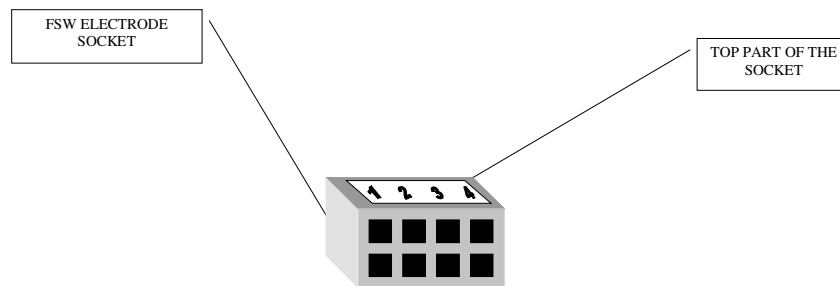


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Procede according to the following instructions:

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 a 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.

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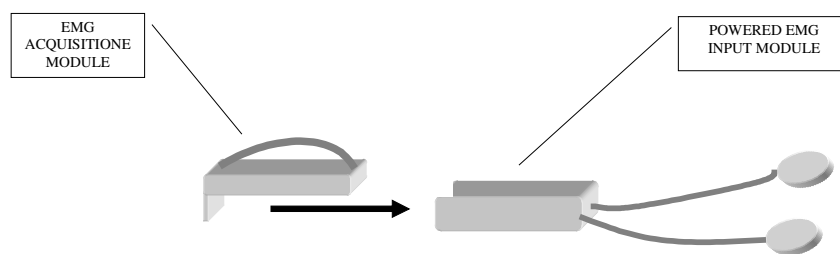
5. SYSTEM MAINTENANCE

5.1 Repairable parts

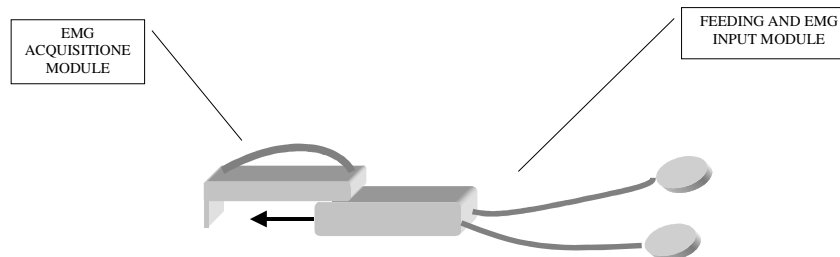
ZeroWire system doesn't contain parts repairable by the user; for standard maintenance see the following chapters.

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:



Take off the battery module from the acquisition module applying a small force in the direction of the arrow.



Put on the new battery module in the acquisition module until they are aligned and you hear a click.

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You can find the battery module at:

Aurion S.r.l.
Viale Certosa, 191
20151 Milano

Tel. +39 02 87.387.000
Fax +39 02 33.499.083
e-mail: aurion@aurion.it

The replacement of the powersupply module of the foot-switch electrode is the same.

5.2.1 Module identification

Modules are identified by a label inside of the electrode; to access to labels see the indication in the previous paragraph.

5.3 Warnings about electrodes battery

Lithium rechargeable battery is inside the power supply module; the replacement made by the user is not allowed; only the producer can replaces it.



Lithium battery of the power supply module


Warning: DON'T disassemble the battery.

Warning: DON'T short-circuit the battery terminals.

Warning: DON'T 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: DON'T burn down or put the battery in the fire.

Warning: DON'T use electrodes with battery that is losing electrolyte, or smells of electrolyte, or has the container blown up.

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Warning: Electrodes that are loosing 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 Warnings for battery disposal



Disposal of the power supply module

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

5.5 Warnings for device disposal




Disposal of the ZeroWire system

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

5.6 Replacement of worn parts

Parts up for wear in ZeroWire system 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.

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5.7 ZeroWire cleaning

To clean ZeroWire 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 of the acquisition module (upper part) from the battery module, as described in “Replacement of electrode battery” chapter;
- remove the liquid with a dry cloth;
- make the modules drying using a low temperature source (thermosiphon or oven at maximum 30°C);

If the problem holds over, change the electrode.


5.8 References

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

Aurion S.r.l.
Viale Certosa, 191
20151 Milano

Tel. +39 02 87.387.000
Fax +39 02 33.499.083
e-mail: aurion@aurion.it

or the authorised service:

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6. TECHNICAL SPECIFICATIONS

Base unit

Transmission / Reception frequency	2400 – 2524 MHz
Transmission power (ARP)	0,45 mW
Number of channels	125
Power supply voltage	9 Vcc +- 10%
Absorbed power	2 W
Operating temperature range	0 + 50 °C
Input:	
Start trigger	TTL, max ± 10 V
Trigger out	TTL
Output:	
EMG Output	$\pm 2,5$ V, Zout = 100 ohm
FSW Output	16 levels, max 4 V
USB	USB 2.0
Gain	1.000 (1V/mV)
Dimension	200 x 140 x 50 mm
Weight	800 gr.

EMG Module

Transmission / Reception frequency	2400 – 2524 MHz
Transmission power (ARP)	0,45 mW
Number of channels	125
Power supply voltage	4 Vcc
Absorbed power	50 uW
Operating temperature range	0 + 50 °C
Using range (charged battery 100%)	> 8 h
Stand by range	> 180 gg.
EMG input	+ - 2,5 mV
Filtering High-pass	10 Hz
Low-pass	1 KHz
Sampling rate	16 bit – 2 Ks/sec.
Dimensions	33 x 23 x 19 mm.
Weight	35 gr.

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FOOTSWITCHES Module

Transmission / Reception frequency	2400 – 2524 MHz
Transmission power (ARP)	0,45 mW
Number of channels	125
Power supply voltage	4 Vcc
Absorbed power	50 uW
Operating temperature range	0 + 50 °C
Using range (charged battery 100%)	> 8 h
Stand by - range	> 180 gg.
FSW input	for piezoresistive sensors
Dimensions	33 x 23 x 19 mm.
Weight	35 gr.

Docking Module


Recharging capacity	10 modules
Power supply voltage	9 V +- 10%
Maximum absorbed power	7 W
Recharging time	8 h (max. 24h)
Dimension	190 x 110 x 55 mm.
Weight	500 gr.

Net feeding

Power supply voltage	100 – 240 V 50/60 Hz
Output voltage	9 V cc, 1,5 A
Power supply cable	2,1 X 5,5 S 11,5 coax (+ central)

Environmental conditions

Operating temperature	0°C /+45 °C
Electrodes recharging temperature	0°C /+45 °C
Working damp	65 +- 20 % RH
Storing temperature	-20°C/ 35°C

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6.1 Suitability

For a correct functioning of the radio link between electrodes and base unit, the relative distance has not to be bigger than ten meters.