



Bagnoli-2 EMG System

User's Guide



Bagnoli™ 2-Channel Handheld EMG System

User's Guide

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Important Information

Intended Use

The Bagnoli™ 2-Channel EMG System is designed for research, investigational and scholarship purposes only. Delsys® products are not intended for measurement purposes or for use in the treatment and diagnosis of humans.

Rx ONLY

Contraindications



DO NOT USE on Patients with implanted electronic devices of any kind, including cardiac pace-makers or similar assistive devices, electronic infusion pumps, and implanted stimulators.



DO NOT USE on irritated skin or open wounds.



DO NOT USE on Patients with allergies to Silver.

Technical Service and Support

For information and assistance visit our web site at:
www.delsys.com

Contact us at:
E-mail: support@delsys.com
tel: (617) 236 0599

Warnings and Precautions



Consult all accompanying documents for precautionary statements and other important information.



Consult accompanying user's guide for detailed instructions.



Keep the device dry. The presence of liquids may compromise the safety features of the device.



Handle with care.



Sensitive electronic device. Avoid static discharges. Do not operate or store near strong electrostatic, electromagnetic, magnetic or radioactive fields. Interference from external sources may decrease the signal-to-noise ratio or result in corrupted data.



This device may cause electrical disturbances in sensitive equipment within its operating environment.



Connect only to Delsys-approved devices.



Connecting a patient to high-frequency surgical equipment while using Delsys EMG systems may result in burns at the site of the EMG sensor contacts.



Immediately discontinue device use if skin irritation or discomfort occurs.



Immediately discontinue device use if a change in the device's performance is noted. Contact Delsys technical support for assistance.



Delsys Inc. guarantees the safety, reliability, and performance of the equipment only if assembly, modifications and repairs are carried out by authorized technicians; the electrical installation complies with the appropriate requirements; and the equipment is used in accordance with the instructions for use.

Device Information



Complies with Requirements put forth by the Medical Device Directive 93/42/EEC. Class I device, Annex VII.



Type BF device (IEC 60601-1).



Isolated device, (Class II, IEC 60601-1)



Do not dispose this product with house waste. Contact Delsys Inc. for instructions on responsibly disposing this device. This product should not be mixed with other commercial wastes.



Date of Manufacturing (appears on device)



Serial Number (appears on device)



EMERGO EUROPE
Molenstraat 15
2513 BH, The Hague
The Netherlands

Authorized Representative



DELSYS INC.
650 Beacon St.
Boston MA 02215
USA

Manufacturer

Disclaimer

DELSYS INC. makes no warranties, express or implied, as to the quality and performance of this product including but not limited to, any implied warranty of applicability for other than research uses by qualified individuals. DELSYS INC. shall not be liable to any person for any medical expenses or any direct or consequential damages resulting from any defect, failure or malfunction, whether a claim for such damages is based upon theory of warranty, contract, tort or otherwise. No representative, agent, or licensed practitioner is authorized to waive this disclaimer. DELSYS INC. makes no diagnosis or prescription by virtue of anything about this product.

Limited Warranty

The Bagnoli™ 2-Channel EMG Systems are warranted against failure of materials and workmanship for a period of 1 year from the date of delivery, provided that the product is given proper care and has not been subject to abuse during this period. This warranty is in lieu of all other warranties expressed or implied. Operation of this device outside specifications determined by DELSYS INC. or use with any other input devices other than DELSYS INC. sensors constitute an invalidation of this limited warranty. This warranty is not transferable.

Bagnoli 2-Channel Handheld EMG System

The Bagnoli 2-Channel EMG System is designed to make the acquisition of EMG signals hassle-free and reliable. The active sensors are specifically designed to optimally detect EMG signals at the skin surface while rejecting common noise signals such as motion and cable artifacts, yielding an excellent signal-to-noise ratio. Gains of 100, 1000 or 10000 can be selected for the ideal acquisition of signals of various amplitudes. The unit is powered from a standard 9-Volt battery and is equipped with a low voltage battery indicator. Each channel output is isolated to 3750 Volts (RMS) and meets medical standards for CE marking and 510K Pre-approval. The integration of all these features in a lightweight portable unit lends the Bagnoli-2 practical in classroom, lab and field environments.



Figure 1. Bagnoli 2-Channel EMG System with Analog Output Cable.



Figure 2. Bagnoli 2-Channel EMG System with EMGworks Package.

Bagnoli-2 EMG System Components

Main Amplifier Unit

This portable unit supplies power to the EMG Sensors and receives and conditions the signals detected by the EMG Sensors.

Each channel has a selectable gain which can be set to a factor of 100, 1000 or 10000. EMG signals are filtered to a bandwidth of 20 to 450 Hz.

The 2 analog outputs are supplied to a modular style output connector. Several cables are available to interface with the output connector.

The power switch is located on the side of the unit along with an LED indicator that illuminates when the unit is turned on. The belt-clip provides a secure mounting option.



Figure 3. Bagnoli-2 Main Amplifier Unit

DE-2.1 Single Differential Surface EMG Sensor

The DE-2.1 EMG Sensor subtracts EMG potentials detected at two distinct locations on the surface of the skin directly above an active muscle. The EMG potentials are always measured with respect to the electric potential of a neutral site located away from the EMG muscle source. This potential is detected by the Reference Electrode.

The sensor is designed using a parallel-bar contact geometry for ensuring signal stability, repeatability between recordings and optimal frequency content representation. This versatile sensor is well-suited for most EMG applications and ideal for both large and small muscles.

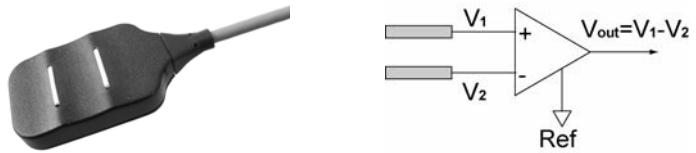


Figure 4. DE-2.1 Single Differential Surface EMG Sensor. The surface EMG signal is the result of the potential difference between V_1 and V_2 on the skin surface.

The sensor housing is constructed from durable polycarbonate and completely sealed. It is also internally shielded to reject ambient electrical noise. The sensor contacts are made from 99.9% pure silver bars measuring 10mm in length, 1mm in diameter and spaced 10mm apart for optimal signal detection and consistency. The curved enclosure geometry is designed to maximize skin contact and adhesion while minimizing the negative effects of sweat during vigorous activities.

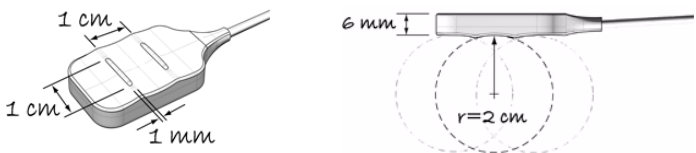


Figure 5. DE-2.1 EMG Sensor Geometry.

DE-3.1 Double Differential Surface EMG Sensor (Optional)

The DE-3.1 EMG Sensor is not included in the standard Bagnoli-2 EMG system and must be purchased separately. It is specifically designed to reduce the presence of EMG crosstalk emanating from muscles underneath and adjacent to the muscle of interest. The external dimensions of the sensor are identical to the standard DE-2.1 Sensors. This sensor uses 3 bars instead of 2, however. It works on the principle that a signal originating from a source further away (some other muscle) will arrive at adjacent detection surfaces with less relative latency than a signal which originates from the muscle beneath the sensor. By performing two subtractions, the signals with short relative latency (those originating from distant sources) will cancel out.

Visit our web site at www.delsys.com for more information on the use of the DE-3.1 Double Differential Surface EMG Sensors.

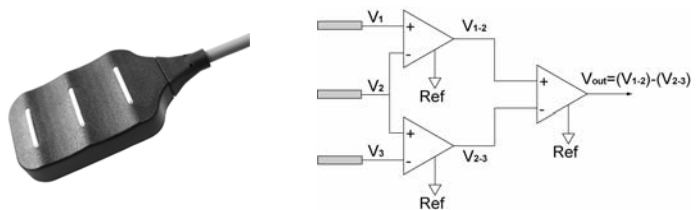


Figure 6. DE-3.1 Double Differential Surface EMG Sensor. The sensor performs a 2-stage subtraction: the first stage establishes the difference between contact V_1 and contact V_2 as well as between contact V_2 and contact V_3 . The second stage then performs a subtraction between these differences.

EMG Accessory Kit

All Delsys Systems include the essential accessories to get started with hassle-free EMG detection, including:

- Adhesive EMG Sensor Interfaces
- Reference Electrodes
- Reference Electrode Cable



Figure 7. EMG Accessory Kit including Adhesive Sensor Interfaces and Reference Electrodes.

Analog Output Package (Option 1)

The Analog Output Package includes a BNC Output Cable, which connects to the Bagnoli-2 Main Amplifier Unit via a convenient modular plug and jack. The cable terminates into two BNC connectors for reliable connections to an oscilloscope or other data acquisition system. The cable is 25 feet long, which allows for a large usage area.



Figure 8. Analog Output Cable terminates in 2 BNC cables.

EMGworks Package (Option 2)

The EMGworks Package includes all of the components necessary to control data acquisition using a Bagnoli-2 EMG System and EMGworks on a PC or laptop:

- EMGworks® Data Acquisition and Analysis Software
- National Instruments USB-6009 DAQ Device
- Bagnoli-2 Output Cable for USB-6009



Figure 9. National Instruments USB-6009 Data Acquisition (DAQ) Device. This device interfaces with a USB port on a PC or laptop to enable data acquisition using EMGworks Software.



Figure 10. Bagnoli-2 Output Cable for USB-6009. This cable connects to the Bagnoli-2 Main Amplifier Unit to the NI USB-6009 Data Acquisition (DAQ) Device. The cable is 25 feet long, which allows for a large usage area.

Getting Started with the Bagnoli-2 System

Installing the 9V Battery

Open the battery door on the underside of the Bagnoli-2 Main Amplifier and carefully install a 9V battery. Close the door when the battery is secure.

Connecting the Analog Output Signals

If you are using the Analog Output Cable, the Bagnoli-2 can easily be connected to an oscilloscope or a data acquisition system via the convenient BNC connectors.



The input of any device connected to the Bagnoli-2 EMG System with the BNC Output Cable should be appropriately buffered. The output impedance of each Bagnoli-2 channel is approximately 15 K Ω .

Installing the USB-6009 and EMGworks

The National Instruments (NI) drivers, USB-6009 device, and EMGworks must be installed on the computer that will be used for data acquisition.

1. Insert the Delsys Software CD into the computer and proceed to install the NI drivers. The computer will need to be restarted in order to complete the installation.
Note: If the Delsys Software CD is not available to provide the NI drivers, use the National Instruments CDs provided with the USB-6009 or download the drivers from the EMGworks page on the Delsys web site (www.delsys.com).
2. Connect the USB-6009 device to an available USB port on the computer and allow Windows to find and install the necessary drivers.
3. Install EMGworks after the NI drivers and the USB-6009 have installed properly



Refer to the “EMGworks Installation Guide” for detailed installation instructions.



Consult the National Instruments documentation provided with the USB-6009 for detailed hardware information.

Connecting the Bagnoli-2 to the USB-6009

The Output Cable then connects the Main Amplifier Unit to the USB-6009 device.



Figure 11. Connecting the Output Cable to the USB-6009.



Ensure the Bagnoli-2 Output Cable is connected to the “Analog” input side of the USB-6009 device. Connecting to the “Digital” output side of the USB-6009 may cause damage to the Bagnoli-2 Main Amplifier and USB-6009 device.



Figure 12. Ensure the Cable is connected to the “Analog” input side of the USB-6009 device.

Connecting the EMG Sensors

The Bagnoli-2 EMG System is supplied with DE-2.1 Single Differential Surface EMG Sensors. These plug into the receptacles on the Main Amplifier that are labeled with channel numbers. The connectors have a key so that they can only be inserted with a specific orientation. The order of the sensors can be interchanged with no consequences to the performance of the EMG System. The sensor cables are five feet in length so that they can be placed on any part of a user's body when the Main Amplifier is mounted at waist level.



Only use sensors that have been approved by Delsys. Connecting unapproved sensors to the Bagnoli-2 System constitutes an invalidation of the Delsys Warranty and may result in personal injury and/or permanent damage to the system or the sensors.

Orienting the EMG Sensors on the Skin

The DE-2.1 EMG Sensor is fitted with two silver bar contacts for detecting the EMG signal at the skin surface. It is crucial that the orientation of these bars be perpendicular to the muscle fibers for maximum signal detection. The top of the sensor is stamped with an arrow to aid in the determination of this orientation. The arrow should be placed parallel to the muscle fibers underneath the sensor. The sensor should also be placed in the center of the muscle belly away from tendons and the edge of the muscle. The sensor is easily attached to the skin using the Delsys Adhesive Sensor Interface.

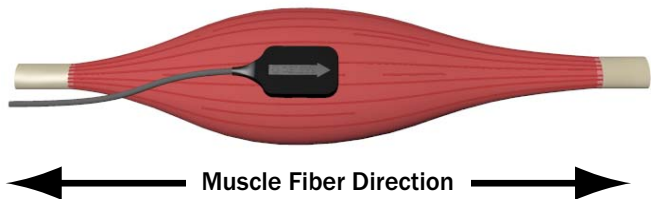


Figure 13. Sensor orientation with respect to the muscle fibers. It is important that the orientation of the arrow on the sensor be parallel to the underlying muscle fibers.

Using the Delsys Adhesive Sensor Interface

The Adhesive Sensor Interfaces use medical-grade adhesive specifically designed for dermatological applications. Usage of the interface promotes a high quality electrical connection between the sensor bars and the skin, minimizing motion artifacts and the ill-effects of line interference. To ensure a strong bond with the skin, it is advised to remove excessive hair and wipe the skin area and the EMG Sensor with isopropyl alcohol to remove oils and surface residues. Allow the skin to dry completely before applying the interfaces.

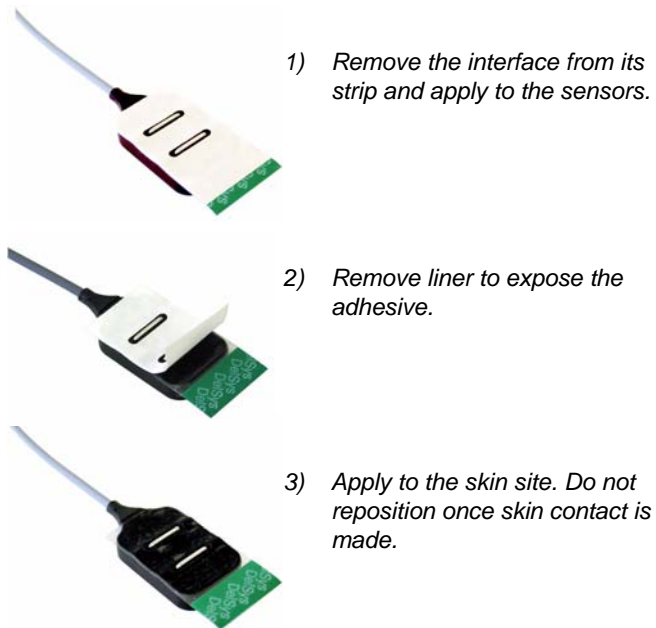


Figure 14. Application of the Adhesive Sensor Interface.



Adhesive Sensor Interfaces are for single use only.



Immediately discontinue use if skin irritation or discomfort occurs. All Adhesive Sensor Interfaces and Reference Electrodes are for single use only. Discard after using. Reseal storage bag to maintain freshness.

Connecting the Reference Electrodes



Connect the Reference Electrode Cable to the Main Amplifier Unit using the “banana” jack.

Apply the Reference Electrode to the skin considering the points below:

- A high quality electrical connection between the Reference Electrode and the skin is critical for obtaining reliable EMG signals. Be sure to clean and, if necessary, shave the skin prior to affixing the Reference.
- Only one Reference Electrode is required when collecting EMG signals. The site should be an electrically inactive area on the skin surface.
- The Sensor Accessory Kit includes disposable disc Reference Electrodes that provide a robust connection and superior conductance. These electrodes are lined with a conductive medical grade adhesive. Conductive electrodes other than the ones supplied may be used as substitutes, but note that performance may vary significantly between manufacturers.



Consult the labeling of the supplied Reference Electrodes for details on their proper use.



Immediately discontinue use if skin irritation or discomfort occurs. All Adhesive Sensor Interfaces and Reference Electrodes are for single use only. Discard after using. Reseal storage bag to maintain freshness.

Turning the System “On”

The power switch is located on the side of the Main Amplifier Unit. The switch is labeled with an “I” to indicate the “on” position and with an “O” to indicate the “off” position. The switch is purposefully recessed to minimize its obtrusiveness and the possibility for accidental “power off” during EMG acquisition. The LED located next to the power switch illuminates when a charged battery is correctly installed and the unit is in use. This LED will flash when the battery needs to be replaced.



Never use an AC adapter to substitute power for the 9-volt battery. This will negate the safety features of the system and may place the user at risk.

Selecting Appropriate Amplifier Gains

There are two slide-switches located on the Main Amplifier Unit, each controlling the gain of a channel. Gains can be set to one of the following options:

100: This position sets the channel gain to 100. Gains of 100 should be used when recording abnormally large EMG signal amplitudes. Surface potentials ranging from ± 10 mV to ± 50 mV will result in output signal voltages of ± 1 to ± 5 Volts. Using this gain on EMG signals lower than ± 10 mV will result in recorded signals of poor resolution.

1k: This position sets the channel gain to 1000. This is the nominal gain for typical surface EMG signals ranging from $\pm 100\mu\text{V}$ to ± 5 mV, resulting in output voltage signals of $\pm 100\text{mV}$ to ± 5 Volts. This setting provides the ideal resolution when sampling with 16-bit A/D acquisition systems.

10k: This position sets the channel gain to 10000. This extremely sensitive gain should only be selected when attempting to record particularly faint EMG signals, in the range of $\pm 100\mu\text{V}$ to $\pm 500\mu\text{V}$. The output yielded in this case is ± 1 V to ± 5 V, but the resolution is not optimized.

Beginning Data Acquisition

EMGworks Package

Data acquisition with the USB-6009 is controlled by EMGworks Acquisition.



Refer to the “EMGworks User’s Guide” for detailed data acquisition instructions.

Analog Output Package

Data acquisition with the BNC Package requires an oscilloscope or other data acquisition system.



Consult the documentation for the oscilloscope or data acquisition system being used for instructions.

Maintenance and Care of the Bagnoli-2 System

Main Amplifier Unit and Input Modules

The Bagnoli-2 System is designed to provide years of reliable service when proper care is followed. A one-time calibration is performed at the time of manufacturing. No further calibration is needed. While the Main Amplifier Unit case is made of durable plastic, the following points should be kept in mind when using and handling the Bagnoli-2 EMG system:

- The device and its accessories should be visually inspected before every use to ensure that no mechanical deterioration has occurred.
- The Bagnoli-2 Main Amplifier Unit can be easily cleaned with a damp cloth and mild detergent.
- The unit is not shockproof and should not be dropped or be subjected to excessive forces or accelerations.
- Provide ample strain relief for the interconnecting cables so that none of them are under excessive tension. Do not pull on any of the interconnecting cables.
- Remove the 9V battery from the Main Amplifier Unit if the device will not be used for an extended period of time.



Only use sensors that have been approved by Delsys. Connecting unapproved sensors to the Bagnoli-2 System constitutes an invalidation of the Delsys Warranty and may result in personal injury and/or permanent damage to the system or the sensors.



The Main Unit and the Input Modules are not water-resistant. Under no circumstance should the units be exposed to water or any other type of liquids. Caution: The risk of electric shock exists if the Main Unit is operated while in contact with liquids.

DE Series Surface EMG Sensors

The DE Series Surface EMG Sensors are encased in a sealed polycarbonate case. The following points should be kept in mind when handling the sensors.

- All sensors should be visually inspected before each use to ensure that no mechanical deterioration has occurred
- The sensors can be cleaned and sterilized with a damp cloth and mild detergent, with isopropyl alcohol swabs, or with a 70% isopropyl alcohol solution. It is crucial that the sensor contacts remain clean at all times.
- The sensors are completely sealed and are water-resistant. These can be used on damp skin surfaces and in the presence of sweat without compromise to safety, sensor integrity or operation. The sensors should never be completely submerged in any liquid.
- The sensors contacts are made of pure silver and are quite soft. Care should be taken to preserve the integrity of these contacts. Do not scrape or dent these contacts.
- Do not pull on the sensor cable. Avoid kinks in the cable, as these will result in damage to the internal cable wires and intermittent connections.
- Handle the sensors with care: do not drop them on the ground or step on them.



The sensors must only be used with Delsys EMG Systems. The DE-2.1 and the DE-3.1 EMG Sensors are specifically designed for the Bagnoli series EMG Systems. Using these sensors as inputs to any other EMG system constitutes an invalidation of the Delsys Warranty and may result in personal injury and/or permanent damage to the sensors or the system.



Do not submerge the sensors in any liquid under any circumstance.



The sensors contain sensitive electronic circuitry. Static discharges and intense magnetic fields should be avoided to prevent possible irreparable damage to the sensors.

Specifications

Main Amplifier Unit

Number of Channels	2 Analog EMG
Overall Amplification per Channel	100, 1000, 10000
Max. Output Voltage Range	± 5 Volts
Channel Frequency Response	20 \pm 5 Hz to 450 \pm 50 Hz, 80 dB/decade
EMG Sensors	DE-2.1 (single differential) or DE-3.1 (double differential)
System Noise (R.T.I.)	<1.2 μ V(rms) for the specified bandwidth
Power Requirements	9 VDC, 10mA (quiescent)
Channel Output Isolation	3750 V(rms) @ 60 Hz for 60 sec.
Operating Temperature	15°C to 40°C
Case Dimensions	114 mm x 71 mm x 33 mm
Weight	0.2 kg

BNC Output Cable

Output Connector	Male BNC (2)
Length	7.62 m
Cable	Shielded, 4-Conductor flat

Output Cable for USB-6009

Output Connector	USB DAQ connector, 16 position
Length	7.62 m
Cable	Shielded, 4-Conductor flat

EMGworks and National Instruments USB-6009

Sampling Rate	48 kS/s Aggregate
Resolution	14 bit
PC Interface	USB 2.0

DE-2.1 Single Differential Surface EMG Sensor

Output Connector	USB DAQ connector, 16 position
Length	7.62 m
Cable	Shielded, 4-Conductor flat
Sensor Contacts	2 silver bars 10 mm x 1 mm diameter
Contact Spacing	10 mm
Sensor Dimensions	19.8 mm x 5.4 x 35 mm
Preamplification	10 V/V
CMRR	92 dB (typical) 84 dB (minimum)
Power	± 18 mW (quiescent)
Cable Length	1.67 m
Number of Conductors	4 (shielded)
Case Material	Polycarbonate plastic

DE-3.1 Double Differential Surface EMG Sensor (Optional)

Sensor Contacts	3 silver bars 10 mm x 1 mm diameter
Contact Spacing	10 mm double differential configuration
Sensor Dimensions	19.8 mm x 5.4 x 35 mm
Preamplification	10 V/V (per differentiator)
CMRR	92 dB (typical) 84 dB (minimum)
Power	± 41 mW (quiescent)
Cable Length	1.67 m
Number of Conductors	4 (shielded)
Case Material	Polycarbonate plastic

Reference Electrode Cable

Connector	“Banana” & 2mm Tip plug
Conductor	Single
Length	1.67m

Component References

Part Description	Part Number
Bagnoli-2 EMG System with Analog Output Package	DS-B01
Bagnoli-2 EMG System with EMGworks Package	DS-B05
Bagnoli-2 Main Amplifier Unit	SP-B02
DE 2.1 EMG Sensor	SP-E04 or SP-E09
DE 3.1 EMG Sensor	SP-E06 or SP-E11
Bagnoli-2 BNC Output Cable, 25ft	DC-T03
Bagnoli-2 USB DAQ Output Cable, 25ft	DC-T06
DAQ Module for USB (NI USB-6009)	SC-A10
EMG Accessory Kit	SC-K05
Adhesive Sensor Interfaces DE 2.1 DE 3.1	SC-F01 SC-F02
Reference Electrode Cable	DC-R02
9V Battery	SC-T01
Carrying Case	SC-C07
Bagnoli-2 EMG System User's Guide	PM-B06
EMGworks Signal Acquisition and Analysis Software	SC-S04

*** N.B. Medical Device regulations prohibit the individual resale of the components listed above. These can only be obtained through the purchase of a complete Bagnoli-2 System since the Intended Use, the Safety and the Performance of these components can only be guaranteed when they are connected and used in accordance with the Bagnoli-2 Design Specifications.**

