EGI
dense array EEG

GES 400 Series

Geodesic EEG Systems

Clinical User Manual

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GES 400 Series

Geodesic EEG Systems

Clinical User Manual

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Contents

Preface

Welcome to the 400 series Geodesic EEG Systems™ (GES systems) from Electrical Geodesics, Inc. (EGI). GES systems use the Net Amps™ (NA) amplifiers to acquire electroencephalographic (EEG) data from HydroCel Geodesic Sensor Nets™ (HC GSNs, or Nets) and peripheral nervous system (PNS) data with the optional Physio16™ polygraphic data acquisition device.

GES systems can be used for low to high density EEG (32 to 256 channels) for routine (short term) and LTM (long-term monitoring) recording.

GES System Models

Table P-1. Current models of the GES system

System	Amplifier	Sampling Rate*	Nets
GES 400	Net Amps 400 (NA 400)	8 Ksps	all HC GSNs, except G Nets
GES 405	Net Amps 405 (NA 405)	8 Ksps	only HC GSN G Nets
GES 410	Net Amps 410 (NA 410)	20 Ksps	all HC GSNs, except G Nets

*Sampling rates are software dependent. Net Station allows 1 Ksps and Amp Server Pro SDK facilitates up to the full sampling rate capability of the amplifiers.

Table P-2. Parts list for typical GES systems

Part	Qty	Mfr	Mfr P/N	EGI P/N
Amplifier				
Net Amps 400 (NA 400)	1	EGI		4608880 (256 chs) 4606168 (128 chs) 4606358 (64 chs) 4603285 (32 chs)
Net Amps 405* (NA 405)				4603293 (32 chs)
Net Amps 410 (NA 410)				4608884 (256 chs) 4606172 (128 chs) 4606362 (64 chs) 4603289 (32 chs)
Other system components				
HC GSN*	1	EGI		Refer to the HC GSN manual
Net Station (NS) software	1	EGI		3104200
HASP key	1	Safenet	YWRGC	6158560
Ethernet switch	1	Black Box	LGB2008A-R2	6156363
Isolation transformer	1	Toroid	ISB-060M	6156331
GES external power supply	1	EGI		4603986
Documentation (Net placards differ per Net model—routine or LTM)				
GES manual	1	EGI		8100400
NS manual	1	EGI		version dependent
HC GSN manual	1	EGI		model dependent
Routine EEG placard	1	EGI		model dependent
LTM EEG placard	1	EGI		model dependent
Optional components				
Physio16	1 or 2	EGI		4609268

*Most Nets have a modular Hypertronics connector. HC GSN G Nets have a D-sub connector and connect only to the Net Amps 405 amplifier.

Typical GES System

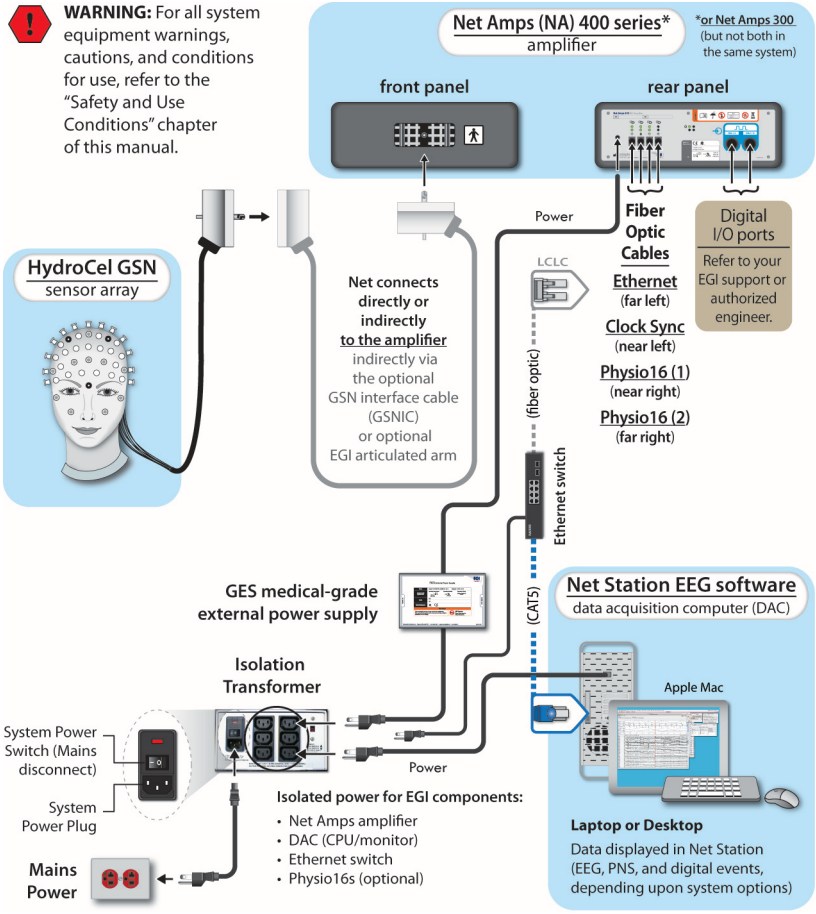


Figure P-1. Core components of a typical EEG-only GES system

About This Manual

This manual provides concise information for using the GES system to display and record EEG data. ***It assumes a working proficiency with EEG and computer systems.***

Note: The term *patient* is used to refer to subjects, participants, or patients.

An EGI support or authorized engineer will install and configure your EGI system, including all connections required for its operation. At the time of initial installation, the EGI support or authorized engineer will also train relevant staff in its operation. At any time you have additional questions or wish retraining, contact EGI Technical Support (Table P-3).

Typographic Conventions

- *Italics* are used for definitions or newly introduced terms.
- ***Boldface italics*** are used for important concepts or special emphasis.
- **Boldface** is used for command paths (for example, **File > Open**).

Warnings, Cautions, and Notes

The following are used to convey important information:

WARNING: Warnings provide important information that, if unheeded, could result in serious physical injury, death, or equipment damage.

CAUTION: Cautions provide important information that, if unheeded, could hinder the use of a product, feature, or procedure, or result in physical injury or equipment failure.

Note: Notes provide clarifying information about a product, feature, or procedure.

Support, Repairs, and Documentation

If you have a question, please:

- For *urgent issues during acquisition*, contact EGI immediately.
- For *nonurgent issues*, do the following before contacting EGI:
  - **Isolate the problem.** Try to repeat and define the problem.
  - **Document the problem.** Carefully record the sequential details of the problem.
  - **Report the defined problem.** Contact EGI.

Table P-3. EGI contact information

EGI Technical Support web page	www.egi.com/support
Email Technical Support	supportteam@egi.com
Email Sales	orderdesk@egi.com
Telephone	+1.541.687.7962
Fax	+1.541.687.7963
Address	Electrical Geodesics, Inc. (EGI) 500 E 4th Avenue, Suite 200 Eugene, OR 97401 USA

1. Safety and Use Conditions

WARNING: Never bring GES 400 components into the MR environment.

Do not operate your GES system ***until you are fully trained and understand*** all warnings, cautions, and conditions for use provided in EGI's manuals for the components of your GES system. If you have any questions, contact EGI Technical Support (Table P-3).

WARNING: All EGI system components must be installed and configured by an EGI support or authorized engineer. Deviating from the supported configuration or running the system with non-EGI-approved components attached can cause hazards or unexpected performance.

Note that the information in this manual is subject to change, without notice. The manufacturer declines responsibility for the safety, reliability, and performance of EGI system components if not used in compliance with EGI documentation.

1.1 Intended Use

The Geodesic EEG System™ 400 Series (GES 400) is intended to measure and record the electrical activity of the patient's brain. It can be used on adults, children, and infants.

Rx only.

1.2 Features

- ADAPT™ technology for on-board computing and remote updates
- Fiber optic signal input and output for optimal digital bandwidth and safety isolation, including:
  - Ethernet data and control with Net Station
  - 32 bipolar channel inputs, including $Sp0_2$, with two Physio16 PNS devices
- Vertex referenced inputs
- 4 kV patient isolation to mains ground and 1.5 kV isolation mains to mains ground
- Choice of sampling rates (see Table P-1)
- Full range of channel counts (32 to 256)

1.3 Regulatory Compliance

1.3.1 European Union (EU) Authorized Representative

Contact
Gerhard Frömel

EC REP

Phone 011 49 6442 962073
Fax 011 49 6442 962074
Email g.froemel@mps-gmbh.eu

Mailing Address
MPS
Medical Product Service GmbH
Borngasse 20
35619 Braunfels
Germany

1.4 Conditions for Use

1.4.1 Environmental Conditions for Transport and Storage

Table 1-1. Environmental conditions for the transport and storage of GES components

Shipping temperature	0˚ to 47˚C (32˚ to 116˚F)
Storage temperature	-10˚ to 50˚C (14˚ to 122˚F)
Shipping humidity	5% to 95% noncondensing
Shipping altitude	11,500 m (37,700 ft) maximum

1.4.2 Environmental Conditions for Use

For EMC declarations, see Appendix A.

Table 1-2. Environmental conditions for the use of GES components

Operating temperature	10˚ to 35˚C (50˚ to 95˚F)
Relative operating humidity	5% to 95% noncondensing
Operating altitude	3,000 m (9,842 ft) maximum

1.4.3 Site Requirements for Location and Use

Table 1-3. Site requirements for the location and use of GES components

Location	For indoor use only
Surface Area	102 x 150 cm (40 x 59 in.)
Ventilation Clearance	7.62 cm (3 in.)

1.4.4 System Power

Table 1-4. Maximum power values for GES components

Device	Rated Power Dissipation (watts)
NA 400 series amplifier	30
Mac Pro desktop computer	1,150
Mac 27-inch display	250
Dell computer	500
Dell 17-inch display	200

1.4.5 System Contraindications

No contraindications for the use of GES systems are known to exist.

1.4.6 Certifications and Classifications

For all current EGI regulatory certifications, including CE declarations, go to www.egi.com or contact EGI Technical Support (Table P-3).

This medical equipment is certified to the following:

- CAN/CSA C22.2 No 601.1-M90 (Safety of Medical Electrical Equipment, Part I: General Requirements for Safety)
- CSA 601.1 Supplement 1:1994 (Requirements for Safety)
- CSA 601.1 Amendment 2:1998
- CAN/CSA C22.2 No 60601-2-26:04 (Particular Requirements for the Safety of Electroencephalograph)
- UL Standard No 60601-1 (1st Edition) (Safety of Medical Electrical Equipment, Part I: General Requirements for Safety)

- IEC 60601-2-26:2002 (Particular Requirements for the Safety of Electroencephalograph)
- The GES 400 series systems carry the European CE mark

This medical equipment is classified as follows:

- Applied part: Type BF
- System: MDD Class IIa Equipment, Electrical Class I Equipment
- Articulated arms for the GES: Electrical Class I Equipment

1.4.7 Ratings

Table 1-5. Input ratings for GES components

Part	Input Rating
GES External Power Supply	100-240 VAC, 50/60 Hz, 1.0 A
NA 400 series amplifier (from ext pwr sup)	12 VDC, 1.5 A

1.4.8 Interference

It is your responsibility to ensure that your GES system and its components are safe and operate properly before using them.

All GES components have been tested and found to comply with the electromagnetic compliance limits for the Medical Device Directive 93/42/EEC (EN 60601-1-2:2007 Class A and JIS T 0601-1-2:2002). See Appendix A.

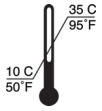
These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates radio-frequency energy and, if not installed and used in accordance with the instructions, may cause interference to other devices in the vicinity. If this equipment does interfere with other devices, which can be determined by turning the equipment off and on, try to correct the interference by one or more of the following measures:

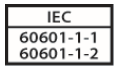
- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment to an outlet on a different circuit than the one used by the other devices.
- Consult EGI Technical Support (Table P-3).

1.4.9 Symbols

The following symbols are used on GES components and in this manual.

Table 1-6. Symbols used on GES components and in this manual

Symbol	Description	Symbol	Description
	MR unsafe	**Rx only**	Prescription medical device
	Imminent hazard		European conformity
	Potential hazard		Canadian Standards Association approval
	Electrical hazard		Manufacturer
	Type BF applied part (body protected, patient isolation)		EU authorized representative
	Interference hazard		Temperature limit 10˚C to 35˚C (50˚F to 95˚F)
	Functional earth terminal		Humidity limits

Symbol	Description	Symbol	Description
	Read product documentation (EGI and third-party mfr)		No unauthorized servicing
	Keep dry		Do not use in gas environment
	Always adhere to IEC 60601-1-1 and 60601-1-2		Do not dispose with other waste (comply with local regulations)
	Signal input		Digital inputs
	Linked		Part number
	Active		Serial number
	Locked		Power input
	Ethernet		Powered
	Clock sync		

1.5 Safety Warnings

1.5.1 General Safety Warnings

WARNING:

- ***Always connect all GES components to the isolation transformer.*** Never connect components directly to mains electricity supply, which may result in physical injury or equipment damage.
- ***Never deviate from supported configurations and never connect non-EGI components to the isolation transformer or to other EGI components.*** All EGI components must be installed and

configured by an EGI support or authorized engineer. Deviating from the supported configurations or running the system with non-EGI components attached may result in unexpected hazards or performance due to additional loading or leakage.

- ***Use only approved equipment.*** Do not connect the GES to unauthorized equipment, as physical injury or equipment damage may result. The user is responsible for ensuring that a reconfigured GES meets all applicable local and national regulations for safety and performance. See IEC 60601-1.
- ***Only connect GES components to a mains electricity supply with protective earth to avoid the risk of electrical shock or electrocution.***
- ***Do not obstruct access to any GES component, including the isolation transformer, such that it is difficult to access, difficult to operate, or results in entanglements.*** The mains disconnect (the isolation transformer's mains disconnect switch) must remain accessible.
- ***Certify all accessory equipment according to the relevant IEC standards.*** Accessory equipment connected to the digital or clock sync ports of the amplifier must be certified according to the respective IEC standards (e.g., IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Any person who connects additional equipment to the signal input port or signal output port configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, consult EGI Technical Support (Table P-3).
- ***Ensure that the environment is safe.*** The room where GES components are used must comply with all applicable local and national safety requirements.
- ***Position the patient and operate the GES only as described in this manual.***
- ***Do not use in flammable gas environments.***
- ***Do not use in oxygen rich environments.***

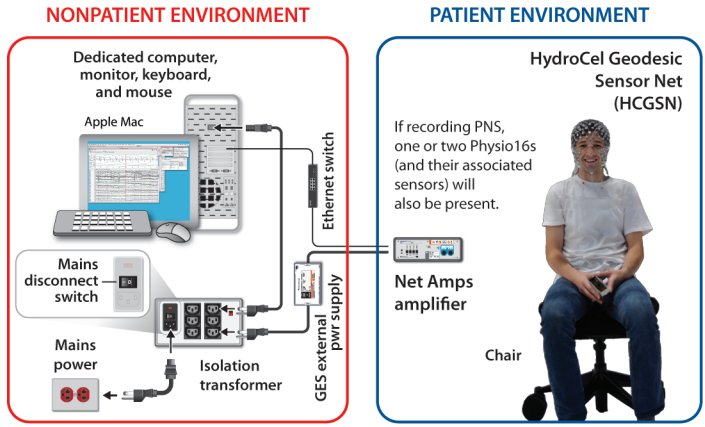
- ***Do not immerse or splash electrical equipment.*** Physical injury or equipment damage may result. If liquids are spilled on any GES electronic component, immediately disconnect it from its power source. Do not use a GES component that has suffered exposure to liquids until EGI or other qualified personnel certifies that the liquid or liquid residue has not affected device operation or patient safety.
- ***Do not use the system if it has been damaged, until it has been verified to be working correctly.***
- ***Only EGI support or authorized engineers may service this equipment.*** Hazardous mains voltage inside. Refer all servicing to EGI Technical Support (Table P-3).
- ***Do not remove any parts, while the GES is powered.*** The GES uses potentially dangerous line voltages, which are present within some subsystem devices.

1.5.2 Patient Isolation

WARNING:

- ***Connect all GES components only to the power mains cord supplied with the protective ground terminal.*** The presence of ground protection preserves the patient's safety, as well as your own. Check that your local electrical plant can guarantee an efficient grounding. The grounding reliability of a GES can be ensured only when used with a hospital-grade plug.
- ***Connect all GES components to the isolation transformer's outlets.*** Never connect the computer or other system components directly to a wall power socket, because the leakage currents in the computer can present an electrical hazard to you and the patient.
- ***Ensure electrode isolation.*** Prevent contact between the conductive part of the electrodes and other conductive parts, including the ground.

- ***Maintain patient isolation within patient environment.*** Never simultaneously touch the patient and any component outside of the patient area and never let patients touch any component, other than the Net that is being worn, inside or outside of the patient area.



WARNING: For all system equipment warnings, cautions, and conditions for use, refer to the "Safety and Use Conditions" chapter of this manual.

1.5.3 Ground Warnings

WARNING:

- ***Disconnect power before servicing to prevent physical injury or equipment damage.***
- ***Ensure grounding reliability.*** Achieved only when equipment is connected to an equivalent receptacle marked "Hospital Only" or "Hospital Grade."
- ***Use a properly grounded outlet.*** Otherwise, physical injury or equipment damage may result.

1.5.4 Cords, Connectors, and Cables

WARNING:

- ***Use only approved power connections and never connect a non-GES power cord or multiple socket outlet (i.e., power strip or extension cord) to the GES.*** Use only the EGI-approved power cords, connectors, cables, adapters, and multiple socket outlet that came with the GES.
- ***Inspect your connectors and cables.*** To reduce the risk of electrical shock, discontinue the use of worn or damaged electrical connectors and cables. Contact EGI Technical Support (Table P-3) for approved replacement parts for the country where the system is being used.
- ***Never repair nondetachable cords.*** Contact EGI Technical Support (Table P-3) for cord repair or replacement.
- ***Do not position any cable such that it is subject to abuse.***

1.5.5 Disassembly

WARNING: *Do not open or disassemble the amplifier*. The interior of the amplifier contains no user-serviceable parts. In the event that the amplifier requires servicing, contact EGI Technical Support (Table P-3) for instructions on how to safely pack and return it to EGI for evaluation and servicing.

1.5.6 Lightning

WARNING: System isolation is designed to protect the patient even if a high-voltage source is accidentally applied to either the patient or GES components. However, because of the large, unpredictable electrical charges involved in a lightning strike, disconnect the patient and discontinue the data acquisition session during a thunderstorm.

1.5.7 Other Devices, System Accessories, and Peripherals

WARNING:

- ***Evaluate leakage risk.*** If the GES is used in conjunction with electric stimulation devices, ask qualified personnel to evaluate any possible risk resulting from the sum of the leakage currents or connections within the GES, in compliance with IEC 60601-1.
- ***GESs are not protected from defibrillation potentials.*** Do not use GES components simultaneously with a defibrillator. If you must use a defibrillator, disconnect the HC GSN from the amplifier and move the amplifier away from the patient.
- ***Certify all accessory equipment according to the relevant IEC standards.*** Accessory equipment connected to the digital or clock sync ports of the amplifier must be certified according to the respective IEC standards (e.g., IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Any person who connects additional equipment to the signal input port or signal output port configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, consult EGI Technical Support (Table P-3).
- ***Use only accessories, cables, and replacement parts sold by EGI.*** The use of accessories and cables other than those that ship with the GES, with the exception of those sold by EGI as replacement parts for internal components, may result in increased emissions or decreased immunity of the GES.
- ***Avoid stacking or adjoining EGI equipment with other equipment.*** EGI equipment should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, EGI equipment should be observed to verify normal operation in the configuration in which it will be used.
- ***If using EGI's optional rolling cart, never place non-GES components on it to avoid the risk of tipping.***

1.5.8 Isolation Transformer

No maintenance instructions apply to isolation transformers other than fuse replacement. For fuse replacement instructions, refer to third-party manufacturer documentation.

1.5.9 Cleaning GES Components

To clean GES components (other than HC GSNs), do the following:

- Turn off and unplug GES components before cleaning.
- Prevent any liquid or sterilizing agent from entering any GES component.
- Do not use abrasive products.
- Clean the different surfaces as follows:
  - *To clean cracks and near connectors*: Use a soft brush to remove dust.
  - *To clean camera lenses and monitor screens*: Use a lint-free, antiscratch brush or cloth.
  - *To clean external surfaces (except camera lenses and monitor screens)*: Use a cloth dampened with mild soapy water or isopropyl alcohol, taking care not to wet any electrical contacts.
- Dry with a clean, dry, lint-free cloth.

1.5.10 Component Recycling and Disposal

WARNING: Hazardous Material Disposal—
Replace internal batteries only with exactly matching batteries, which are available from EGI. For replacement and disposal instructions, contact EGI Technical Support (Table P-3).

CAUTION: Comply with local regulations when recycling or disposing of GES components, consumables, and accessories.

You may return components to EGI for recycling or disposal, if desired. Contact EGI Technical Support (Table P-3) to arrange for this service.

2. Net Amps Amplifiers

Each channel of the Net Amps amplifier continuously detects the voltage being acquired at the corresponding sensor of the HydroCel GSN. This voltage is amplified, filtered, sampled, and digitized.

2.1 Overview and Specifications

Table 2-1. Dimensions and weight of the Net Amps amplifier

Height	10.77 cm (4.24 in.)	**Depth**	30.18 cm (11.88 in.)
Width	28.98 cm (11.41 in.)	**Weight**	6.8 kg (15 lb)

Table 2-2. Performance specifications of the Net Amps amplifier

Sampling frequencies Software dependent. See Table P-1.	Sampling rates (per model): • Up to 8 Ksps for the NA 400 • Up to 8 Ksps for the NA 405 • Up to 20 Ksps for the NA 410
Conversion	24-bit A/D
Noise	0.9 µV RMS (1.4 µV pp)
Dynamic range	± 200 mV
Precision	0.024 µV/bit
Common-mode rejection	≥ 90 dB
Isolation-mode rejection	≥ 120 dB
Filters	4 KHz antialiasing filter
Input impedance	≥ 1.0 GΩ
Patient isolation	4 kV

2.2 Anti-aliasing Filter Effects on EEG Timing

The anti-aliasing filters of the Net Amps amplifiers introduce a temporal delay in the EEG. Whether EEG is steaming, displaying, or recording, there is a temporal delay from *real time* and any event aligned with real time.

Without adjustment, this delay affects the alignment of EEG with the real-time events (as from digital inputs or TCP/IP connection) recorded during EEG acquisition.

This delay does not affect the alignment of events manually entered during EEG acquisition. It also does not affect the alignment of events entered during review or from the operation of tools after data acquisition.

Note: Net Station 5.1.1 and later provide options for automatic adjustment of this delay.

If you are segmenting data, you can adjust the delay between EEG and real-time events by adding a positive value in the Offset Segment field of the Segmentation tool, in addition to adjusting for external event or digital input (DIN) offsets. For details, refer to the Net Station 5 manual (8100050) or contact EGI Technical Support (Table P-3).

CAUTION: The anti-aliasing filters of the Net Amps amplifiers introduce a temporal delay in the EEG. To adjust for the delay between recorded EEG and the real-time events recorded during EEG acquisition, use the following known delays for each sampling rate and amplifier model:

Sampling Rate	NA 300	NA 400	NA 405	NA 410
1,000 s/s	8 ms	36 ms	36 ms	13 ms
500 s/s	18 ms	66 ms	66 ms	34 ms
250 s/s	36 ms	112 ms	112 ms	76 ms
125 s/s	72 ms			

2.3 Physical Connections

2.3.1 Front Connections

All HydroCel GSNs, except for the HydroCel GSN G Nets, connect to most Net Amps amplifiers directly or indirectly as follows. See Figure 4-2 for the HC GSN G Net's connection to the Net Amps 405 amplifier.

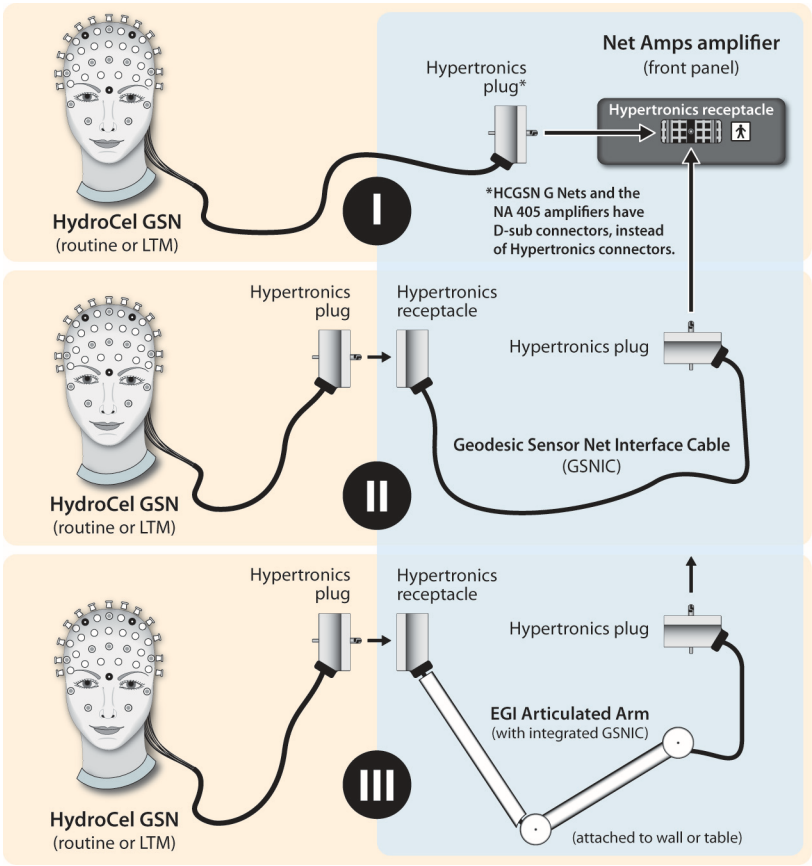


Figure 2-1. Three ways an HC GSN connects to most Net Amps amplifiers

2.3.2 Rear Connections

The Net Amps amplifier connects to other system components with the connections and indicators shown in Figure 2-2 and described in Table 2-3.

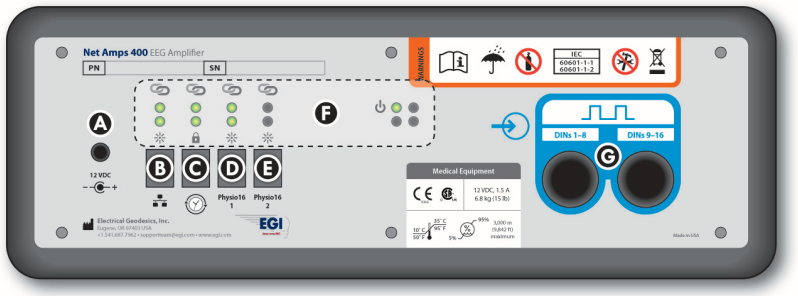


Figure 2-2. Net Amps amplifier rear panel connections and indicators

Table 2-3. Net Amps amplifier rear panel connections and indicators

Callout	Connection/ Indicator	Description
A	**Power**	Power cable connects to the isolation transformer through the GES External Power Supply.
B	**Ethernet**	Fiber optic cable connects to an Ethernet switch, which then connects to the DAC (via CAT5 cable) for Ethernet bidirectional communication.
C	**Clock Sync**	Not applicable.
D	**Physio16 (1)**	Fiber optic cable connects to one optional Physio16 for PNS measures.
E	**Physio16 (2)**	Fiber optic cable connects to a second optional Physio16 for additional PNS measures.

Callout	Connection/ Indicator	Description		
Ⓕ	**LEDs** Connection indicators	**Linked**		When illuminated, communication between devices is linked.
		Active		When illuminated, the connection between devices is active.
		Locked		When illuminated, the connection between devices is locked.
	LEDs Status indicators	**Power**		When illuminated, the amplifier is powered, turned on, and ready to collect data.
		blanks		For manufacturer's use only.
Ⓖ	**Digital**	Not applicable.		

2.4 Mounting Options

The Net Amps amplifier can be placed on a table, placed on EGI's optional rolling cart, or attached to a wall with EGI's amplifier wall mount bracket.

WARNING: To prevent injury and equipment damage when mounting the wall bracket to a wall: use a qualified service technician; adhere to all local codes; and ensure that the wall structure is solid and capable of supporting the weight of the amplifier, mounting hardware, and any attached components. Because wall construction varies widely, if necessary, reinforce the wall.

WARNING: If using EGI's optional rolling cart, never place non-GES components on it to avoid the risk of tipping.

Figure 2-3. Amplifier mounting options

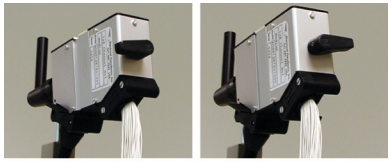
3. Other GES Components

3.1 HydroCel GSNs

The net-like elastomer structure of EGI's HydroCel GSNs conforms to a patient's head and gently holds each sensor (containing an electrode) in place without scalp abrasion or glues to collect EEG signals from the scalp. Routine HC GSNs are used with a mild saline solution and LTM HC GSNs are used with water-soluble EEG paste. HC GSNs are applied in minutes and removed in seconds. See Figure 2-1 for the three ways an HC GSN connects to the Net Amps amplifier.

Most HC GSNs* use half-turn, quick disconnect Hypertronics connectors. Whether you are plugging the HC GSN's Hypertronics plug into the amplifier's, GSNIC's, or arm's Hypertronics receptacle:

- **Lock** the connection by twisting the Net connector's lever 180° clockwise.
- **Unlock** the connection by twisting the Net connector's lever 180° counterclockwise



Unlocked (lever left) **Locked** (lever right)

**HC GSN G Nets and the NA 405 amplifiers connect with D-sub connectors, which are pushed in to seat and released by pressing the side latches.*

For the step-by-step instructions for using your HC GSNs, refer to the training materials, sizing chart, sensor layouts, and instructions shipped with your Nets.

Net Support Kits

The parts and consumables you receive in your Net support kit(s) will depend upon the models and quantities of Nets purchased.

Refer to the instructions shipped with your Net models for the list the kit supplies needed for the proper use of your Nets.

Typical routine Net support kit

Typical LTM Net support kit

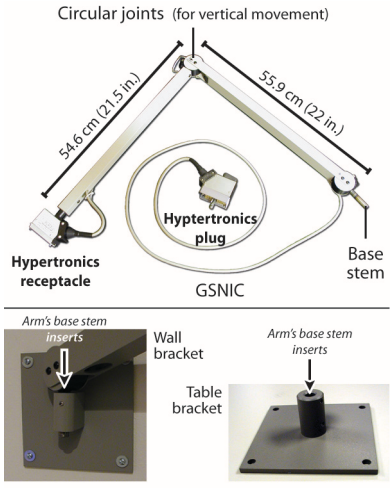
3.1.1 **GSNIC** (optional)

The optional Geodesic Sensor Net Interface Cable (GSNIC) connects between the HC GSN and the Net Amps amplifier to allow you to position the patient farther from the amplifier. The standard length is 58 cm (23 in.). For connectivity, see Figure 2-1.

3.1.2 **Articulated Arm** (optional)

The optional articulated arm (with an integrated GSNIC) connects between the HC GSN and the Net Amps amplifier to allow you to position the patient farther from the amplifier, to protect the GSNIC, or to hold cables out of the way. For connectivity, see Figure 2-1.

It can be mounted to a wall or table with different brackets.

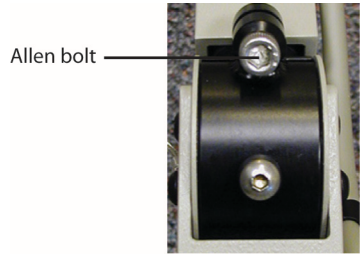


WARNING:

- Do not adjust the tension of a circular joint while a patient is present. Injury could result.
- Always support the arm before loosening any joints.
- Do not connect the arm to unauthorized equipment. Injury or equipment damage could result.

Use arms as follows:

- Extend or compress an arm by pulling or pushing one or both of its sections in a controlled manner.
- *With no patient present*, adjust the tension of circular joints using the provided Allen wrench to loosen or tighten the Allen bolt on that joint.



3.2 Net Station, DAC, and HASP

The Net Station EEG software resides on a GES-compatible data acquisition computer (DAC). The Net Amps amplifier sends packets of data containing digitized EEG samples to the DAC so that the Net Station EEG software can acquire, display, review, and store them. Your system may have one or more laptop or desktop DACs that are compatible with the amplifier(s) of your GES system.

EGI protects its software from unauthorized use by encoding the licensing data in a HASP key, which is similar to a USB flash drive. All authorized EGI software users have a HASP key that plugs into one of the USB ports of any EGI Mac OS system computer to allow access to the purchased applications licensed to that HASP key.

5.1 cm x 1.6 cm (2 in. x 0.625 in.)

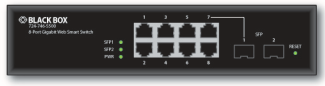
CAUTION: Before upgrading your EGI system (computer, operating system, or EGI software), confirm compatibility with EGI Technical Support (Table P-3).

For computer specifications and operation instructions, refer to third-party manufacturer documentation.

For details about the Net Station software, refer to the Net Station manual(s) that shipped with your system.

3.3 Ethernet Switch

All EGI systems include an Ethernet switch (Black Box LGB2008A-R2) that links the system's Ethernet devices, such as the Net Amps amplifier and the DAC.

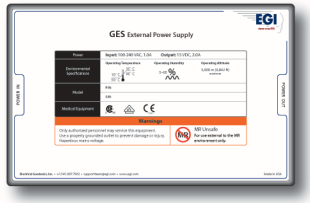


21.9 cm x 13.0 cm x 4.4 cm
(8.625 in. x 5.125 in. x 1.750 in.)

CAUTION: If needed, replace the Ethernet switch only with an exactly matching replacement, or contact EGI Technical Support (Table P-3) for an equivalent substitute.

3.4 GES External Power Supply

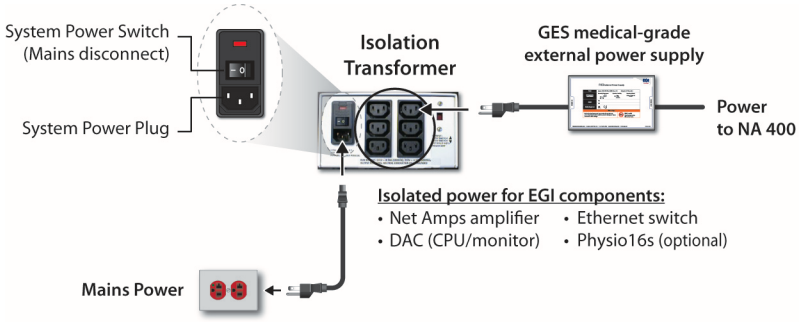
All Net Amps amplifiers are powered by the GES External Power Supply, which is medical grade. See section 1.4.7, “Ratings,” for input ratings.



18.4 cm x 10.5 cm x 8.3 cm
(7.250 in. x 4.125 in. x 3.250 in.)

3.5 Isolation Transformer

All EGI systems include one or more isolation transformers (medical grade Toroid W Series), and all EGI components must plug into an isolation transformer to provide the attached components with isolation from mains power for patient safety.



WARNING: For all system equipment warnings, cautions, and conditions for use, refer to the "Safety and Use Conditions" chapter of this manual.

Figure 3-1. Isolation transformer connections for GES systems

Table 3-1. General specifications for the Toroid W Series isolation transformers

Width x Depth x Height	16.8 x 26.7 x 10.2 cm (6.625 x 10.500 x 4.000 in.)
Compliance	UL2601.1, CSA C22.2 No. 601.1, EN60601-1, EN60742, IEC601-1, CE Mark
Power	Selectable, 115 or 230 V 50-60 Hz, input/output
Leakage current	< 100 µA
Outlets	Appliance type (IEC 60320)
Miscellaneous	Low weight, low magnetic strayfield, low mechanical noise, low losses, and high efficiency

Table 3-2. ISB-030M specifications and peak power values within laptop GES systems

Fuse rating	3.15 AT (120 V in.) or 1.6 AT (240 V in.)
Capacity	300 VA max.
Amplifier power dissipation	15 VA
DAC and amplifier load	55 VA

Table 3-3. ISB-060M specifications and peak power values within desktop GES systems

Fuse rating	6.0 AT (120 V in.) or 3.15 AT (240 V in.)
Capacity	600 VA max.
Amplifier power dissipation	15 VA
DAC, monitor, and amplifier load	245 VA

3.6 **Physio16** (optional)

Two Physio16 polygraphic data acquisition devices can collect up to 32 bipolar channels of peripheral nervous system (PNS) activity simultaneously with the EEG, when connected to the Net Amps amplifier.

WARNING: If active sensors (other than an SpO_2) are used, then they need to be connected to a second Physio16 and separated from the passive sensors to maintain patient isolation.

Features:

- 32 analog bipolar inputs (16 each)
- 2 digital SpO_2 input (1 each)
- Usable with most standard PNS sensors (see Table 3-6 or contact EGI Technical Support (Table P-3) for additional recommended sensors)
- Fiber optic cable distance from amplifier up to 30 meters (98 ft)
- Selectable gain values within the Net Station software
- Runs on wall power (via a medical-grade AC adapter plugged into the isolation transformer) or on battery power
- Maintains PNS isolation from EEG

3.6.1 Battery Power

The Physio16 operates on wall power (via a medical-grade AC adapter plugged into the isolation transformer) or on battery power. It can operate on battery power for up to 16 hours on a full charge.

Recharge the battery when the power LED is flashing **red** (showing that the battery charge is low) or after six months of nonuse.

The battery can be fully recharged within 20 hours.

WARNING: Use special caution with lithium-ion polymer (LiPo) batteries—they may explode or burn if mishandled. LiPo batteries are volatile and burn hotter than ordinary batteries; therefore, they CANNOT be handled or charged casually as other batteries can be. **Failure to comply with these precautions may result in physical injury, death, or equipment damage.** For all questions and assistance, contact EGI Technical Support (Table P-3).

- Before charging, using, or shipping, *inspect LiPo batteries for damage*, such as swelling, punctured protective cover, or broken wiring or plug.
- NEVER charge, use, or ship any damaged LiPo battery.
- NEVER leave charging LiPo batteries unattended.
- ALWAYS charge LiPo batteries:
  - on a fireproof surface
  - away from combustibles
  - in a ventilated area
  - with an ABC fire extinguisher present
  - with correct polarity connection ensured
- NEVER modify LiPo batteries or LiPo battery chargers.
- NEVER use non-EGI LiPo batteries or non-EGI chargers.
- ALWAYS store LiPo batteries in fireproof containers.
- NEVER store LiPo batteries near other batteries, including other LiPos.

WARNING: Hazardous Material Disposal—When needed, **replace the Physio16's internal lithium-ion polymer (LiPo) battery only with an exactly matching battery**, which is available from EGI. For replacement batteries and disposal instructions, contact EGI Technical Support (Table P-3).

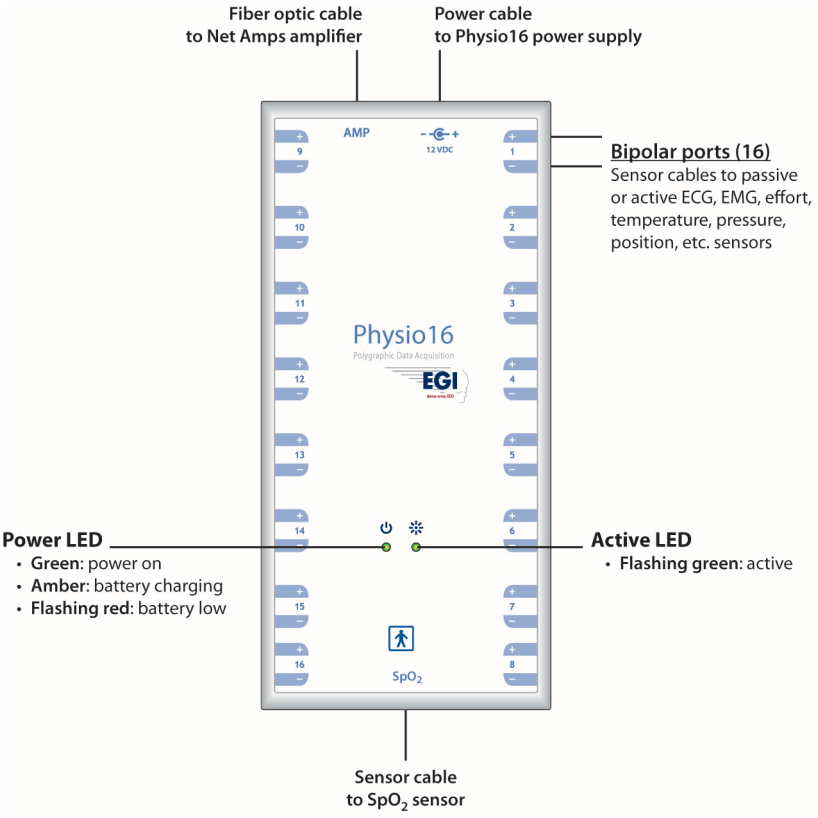


Figure 3-2. Physio16 connections and indicators

3.6.2 Compatible Sensors

Table 3-4. Sensors tested compatible with the Physio16 and available from EGI

Part	Qty	Mfr	Mfr P/N	EGI P/N
zRIP Kit (adult)	1	Pro-Tech	1076329	6156125
Thermistor-cannula	1	MVAP/Braebon	0510	6156131
PTAF Lite Pressure Transducer Start-up Kit	1	Pro-Tech	P1289	6156141
Body position sensor (SPI sensor DC)	1	Pro-Tech	P1664-WS2074	6156145
120" EMG leads (white, button snap, 1.5 mm safety connector)	2	Vital/MVAP	SA1454-120-05	6156163
120" EMG leads (blue, button snap, 1.5 mm safety connector)	2	Vital/MVAP	SA1454-120-27	6156162
Meditrace 230 general monitoring sensors	1	MVAP	31078135	6156165
Ambu Blue Sensor N-EMG chin (1-1/4", foam, snap connector, silver/silver chloride, wet gel)	1	MVAP	BS003	6156167
Biopotential Skin EEG electrodes	6	BioMed	BME 300 LP	6156166

4. System Configurations

All connections that are required for the operation of your EGI system are made by an EGI support or authorized engineer during installation. After the EGI support or authorized engineer has installed and trained you on the use of your EGI system, including the Net Station software, it is ready to use with minimum set up.

This chapter illustrates the typical EGI system configurations for:

- EEG-only data (with most NA 400 amplifiers) (see 4.1)
- EEG-only data (with the NA 405 amplifier) (see 4.2)
- EEG/PNS data (see 4.3)

For the step-by-step instructions for using your GES system, refer to the training materials and HC GSN instructions shipped with your system configuration.

For the use instructions of stimulus control devices, refer to third-party manufacturer documentation.

For additional details, contact EGI Technical Support (Table P-3).

4.1 EEG-only (WITH MOST AMPLIFIERS)

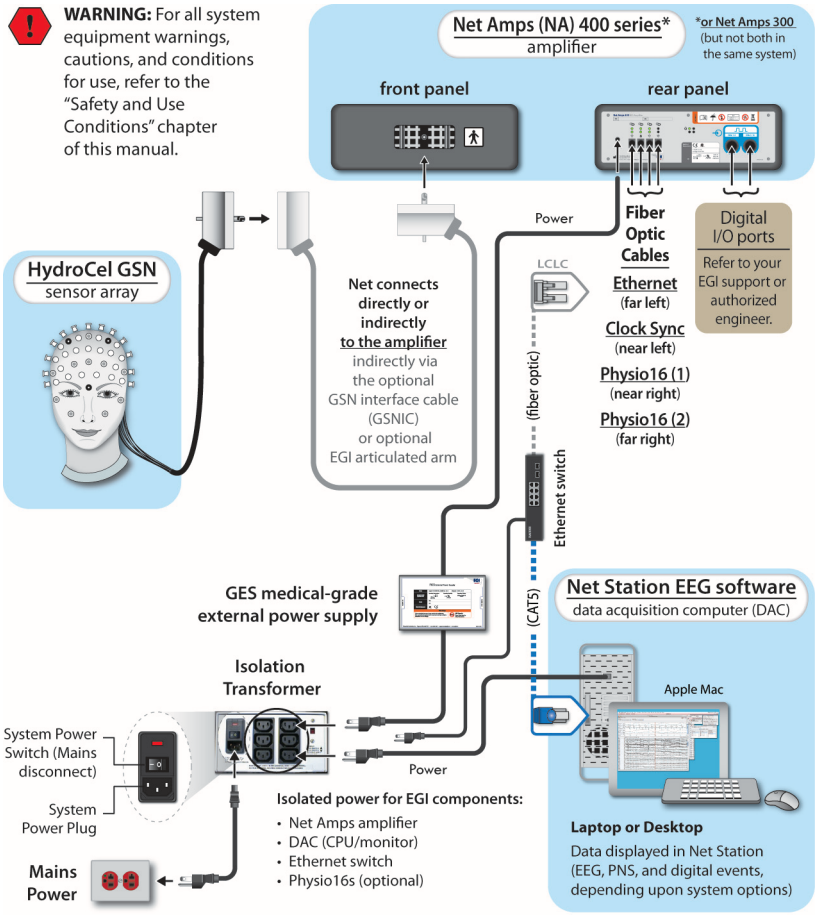


Figure 4-1. Typical EEG-only (with most amplifiers) configuration

4.2 EEG-only (WITH THE NA 405 AMPLIFIER)

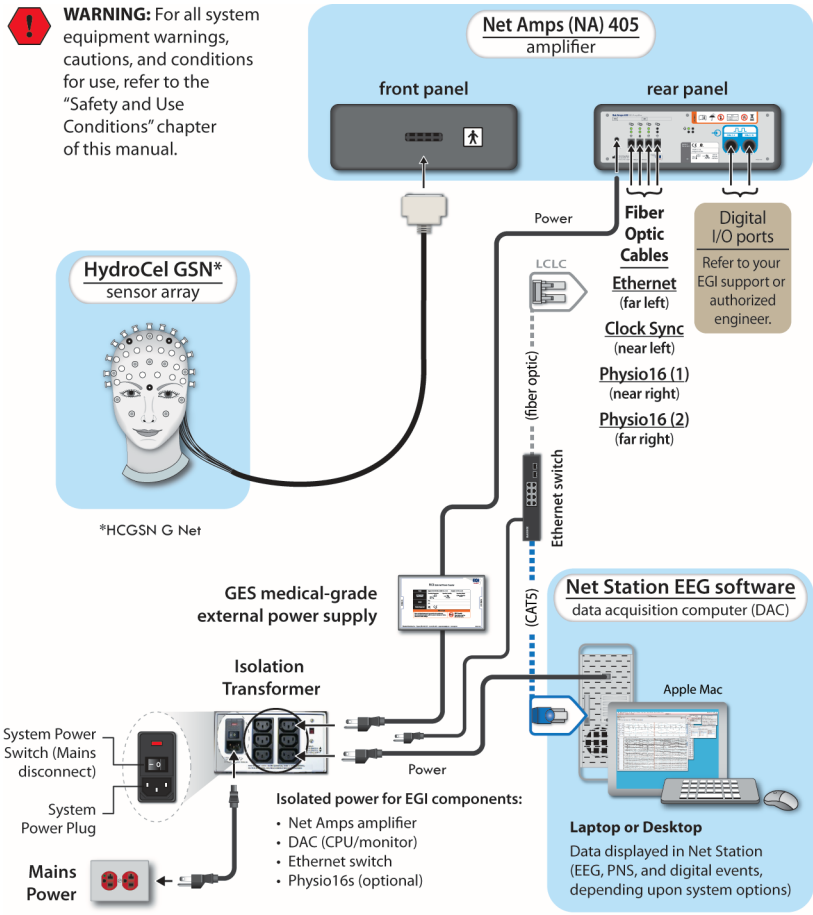


Figure 4-2. Typical EEG-only (with the NA 405) configuration

4.3 EEG/PNS

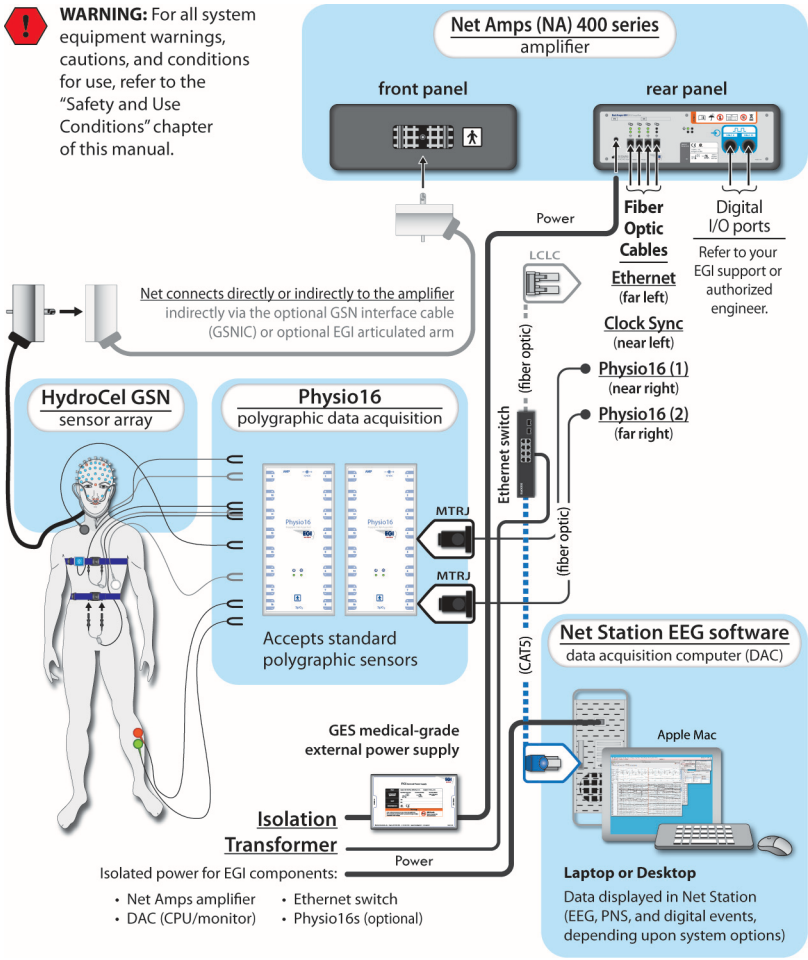


Figure 4-3. Typical EEG/PNS configuration

Appendix A: EMC Declarations

Geodesic EEG Systems (GESs) must be installed and put into service according to the electromagnetic compliance (EMC) guidelines and declarations provided here.

- Electromagnetic emissions (see Table A-1)
- Electromagnetic immunity (see Table A-2)
- Electromagnetic immunity for non-life-supporting equipment, such as GES components (see Table A-3)
- Recommended separation distances between radio-frequency (RF) communications equipment and the GES (see Table A-4)

Note: Portable and mobile RF communications equipment can affect GESs.

WARNING: The use of accessories and cables other than those sold by EGI may result in increased emissions or decreased immunity of the GES.

WARNING: EGI equipment should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, EGI equipment should be observed to verify normal operation in the configuration in which it will be used.

Electromagnetic Emissions

Table A-1. Electromagnetic compatibility (EMC) emissions guidelines and declarations for GESs

GESs are intended for use in the electromagnetic environment specified below. The customer or user of a GES should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment—Guidance**
RF emissions CISPR 11	Group 1	The GES uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The GES is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power-supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

Table A-2. Electromagnetic compatibility (EMC) immunity guidelines and declarations for GESs

GESs are intended for use in the electromagnetic environment specified below. The customer or user of a GES should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power-supply lines ± 1 kV for input/output lines	± 2 kV for power-supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Voltage dips, short interruptions, and voltage variations on power-supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec.	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the GES requires continued operation during power mains interruptions, it is recommended that the GES be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage before application of the test level.			

Electromagnetic Immunity for Non-life-supporting Equipment

Table A-3. Electromagnetic compatibility (EMC) immunity guidelines and declarations for non-life-supporting equipment (such as GES components)

GESs are intended for use in the electromagnetic environment specified below. The customer or user of a GES should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the GES, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation:**
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz	3 V rms	$d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
			meters (m). Field strengths from fixed RF transmitters, as determined by the electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the GES is used exceeds the applicable RF compliance level above, the GES should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocation the GES.

[b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Radio-frequency (RF) Communications Equipment

Table A-4. Recommended separation distances between RF communications equipment (portable and mobile) and GES components

GESs are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of a GES can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and GES components as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (in watts)	**Separation Distance According to Frequency of Transmitter** (in meters)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Electrical Geodesics, Inc.
500 E 4th Avenue, Suite 200
Eugene, OR 97401
USA

www.egi.com