



HydroCel Geodesic Sensor Net™

Sponged (routine), Spongeless (LTM), and Magnetic resonance (MR) Nets

Size Chart

8403488-58 (20181210)

How to Use the Size Chart

Always base your Net size selection on the circumference of your patient's head, not on your patient's age.

Stage	Head Circum. and Net Size	General Age or Head Size		Channel Counts				Monitoring Type		
		Males	Females	32	64	128	256	Routine	LTM	MR
Preterm infant	28 – 30 cm	Preterm Small		✓	✓	✓		✓		
	30 – 32 cm	Preterm Medium		✓	✓	✓		✓		
	32 – 34 cm	Preterm Large		✓	✓	✓		✓		
Infant	34 – 36 cm	Neonate	Neonate	✓	✓	✓		✓		✓
	36 – 37 cm	Birth – 2 weeks	Birth – 1 month	✓	✓	✓		✓		✓
	37 – 38 cm	2 weeks – 1 month	1 – 2 months	✓	✓	✓		✓		✓
	38 – 40 cm	1 – 2 months	2 – 3 months	✓	✓	✓		✓		✓
	40 – 42 cm	2 – 3 months	3 – 6 months	✓	✓	✓		✓		✓
	42 – 43 cm	3 – 5 months	6 – 7 months	✓	✓	✓		✓		✓
	43 – 44 cm	5 – 7 months	7 – 9 months	✓	✓	✓		✓		✓
	44 – 47 cm	7 – 15 months	9 – 21 months	✓	✓	✓		✓		✓
Pediatric	47 – 51 cm	Pediatric Small		✓	✓	✓		✓	✓	✓
	51 – 54 cm	Pediatric Large		✓	✓	✓	✓	✓	✓	✓
Adult	54 – 56 cm	Adult Small		✓	✓	✓	✓	✓	✓	✓
	56 – 58 cm	Adult Medium		✓	✓	✓	✓	✓	✓	✓
	58 – 61 cm	Adult Large		✓	✓	✓	✓	✓	✓	✓
	61 – 64 cm	Adult Extra Large		✓	✓	✓	✓	✓	✓	✓

For questions or additional assistance, please contact us at:



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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Microbiologics, Inc.
200 Cooper Avenue North
St. Cloud
Minnesota
56303
USA

Holds Certificate No:

FM 595607

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, Development, Production and Distribution of Microorganism and Molecular Controls.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2013-06-13

Latest Revision Date: 2020-07-20

Effective Date: 2020-07-20

Expiry Date: 2023-06-12

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The optional Physio16 input box is a polygraphic data acquisition device used within EGI's Geodesic EEG System™ (GES) 400 series systems, along with the Net Station™ 5.1 (or later) software, to acquire peripheral nervous system (PNS) data simultaneously with EEG data.

For all safety and use conditions for using your EGI system, refer to the manuals and instructions that shipped with your GES system configuration.

Overview

Two Physio16 input boxes can be connected to the Net Amps™ amplifier to collect up to 32 bipolar channels of PNS activity simultaneously with up to 256 channels of EEG.

Features of each Physio16 input box:

- 16 analog bipolar inputs
- 1 digital SpO₂ input
- Usable with most standard PNS sensors (see tested compatible sensors in Table 1)
- 15 meters (50 ft) fiber optic cable distance between the Physio16 input box and the amplifier
- Selectable gain values within the Net Station software
- Operates with mains (AC) power or with battery power
- Maintains PNS isolation from EEG

Battery Power

When not operating with mains power (via the provided medical-grade AC adapter plugged into the isolation transformer), the Physio16 input box can operate with battery power.

When operating the Physio16 input box via its internal lithium-ion polymer (LiPo) battery:

- It can operate for up to 16 hours on a full charge.
- You need to recharge the battery when the power LED is flashing **yellow** (showing that the battery charge is low).
- You should recharge the battery after two months of nonuse.
- The battery can be fully recharged within 20 hours.



CAUTION: Be aware of the following when recharging the internal LiPo battery of the Physio16 input box. If you have any questions, contact EGI Technical Support at supportteam@egi.com.

- Only use the provided medical-grade AC adapter with the Physio16 input box.
- Do not expose the Physio16 input box (with its internal LiPo battery) to prolonged direct sunlight or excessive heat.
- Store the Physio16 input box (with its internal LiPo battery) at ambient room temperature.



WARNING: The internal lithium-ion polymer (LiPo) battery of the Physio16 input box is not replaceable by users. When you need a battery replaced, contact EGI Technical Support at supportteam@egi.com.



WARNING: Faulty batteries are rare. If the Power LED ever flashes **red**, however, discontinue use and contact EGI Technical Support at supportteam@egi.com.

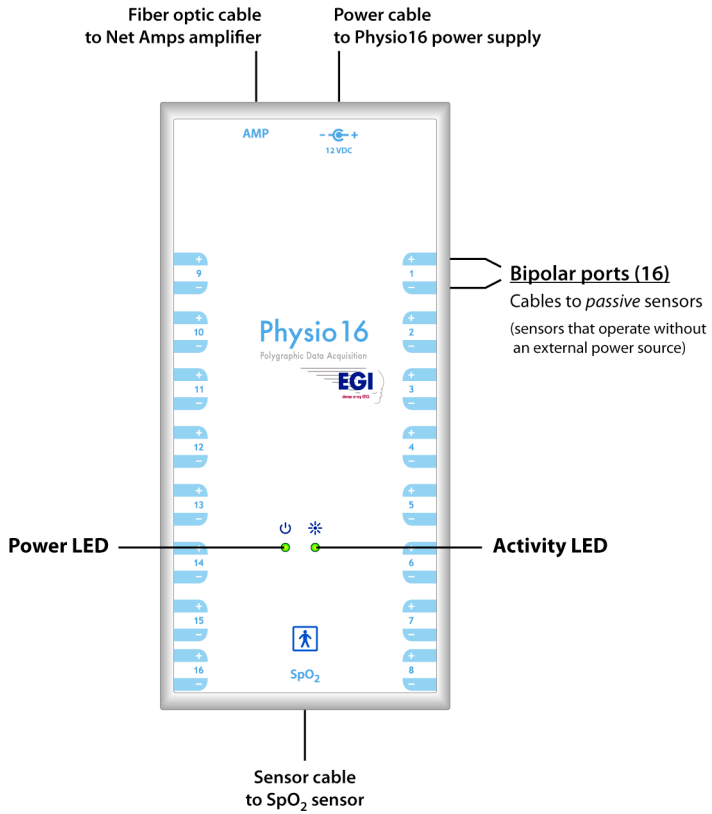


Figure 1. Connections and LEDs of the Physio16 input box

Compatible Sensors

Table 1 provides a list of PNS sensors that have tested compatible with the Physio16 input box. For a list of the latest sensors that have tested compatible with the Physio16 input box, contact EGI Technical Support at supportteam@egi.com or EGI Sales at orderdesk@egi.com.



WARNING: To ensure safe and effective performance, only sensors supplied by and approved by EGI should be used with the Physio16 input box.

If other sensors are used, the user bears sole responsibility for ensuring that the resulting system is safe and effective for the intended use. In particular, the use of mains-powered sensors requires a patient-isolated medical grade power supply, and may introduce issues related to signal quality and the accumulation of individually safe leakage currents.

For recommendations, contact EGI Technical Support at supportteam@egi.com.

Table 1. Sensors tested compatible with the Physio16 input box 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)	3	Vital	SA1454-120-05	6156163
120" EMG leads (blue, button snap, 1.5 mm safety connector)	3	Vital	SA1454-120-27	6156162
Meditrace 230 general monitoring sensors (pk of 30)	1 pk	MVAP	31078135	6156165
Ambu Blue Sensor (pk of 25)	1 pk	MVAP	BS004	6156167
Adult SpO2 pulse oximeter	1	Nonin for EGI	6156168	6156168

System Diagram

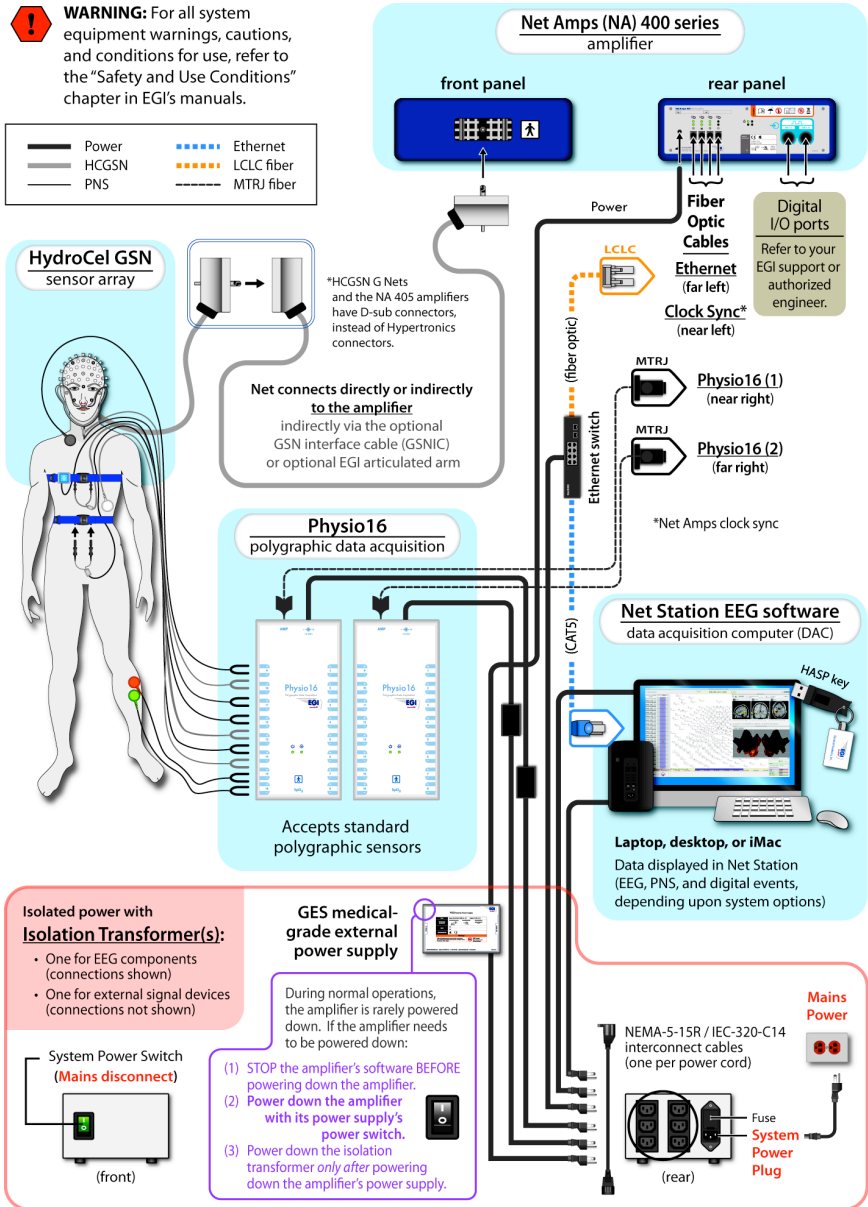


Figure 2. Core components of a typical EEG-PNS GES 400 series system showing the connections of the Physio16 input box

Using the Physio16 Input Box

You can use one or two Physio16 input boxes to record from 16 to 32 bipolar channels of PNS data.



WARNING: Do not get the Physio16 input box wet to avoid the risk of electrical shock or equipment damage.

Before you begin, decide how you will power the input box(es):

- **Battery power:** If operating with battery power, ensure that the needed batteries are charged.
- **Mains (AC) power:** If operating with mains (AC) power, ensure that the provided AC adapters are readily available.

For the step-by-step instructions for using the various components of your EGI system, refer to the manuals and instructions that shipped with your GES system configuration.

Applying the Net

Generally, you will apply the Geodesic Sensor Net™ (GSN) before applying the PNS sensors, but follow your facility's protocols for the correct sequence of application of EEG and other sensors.

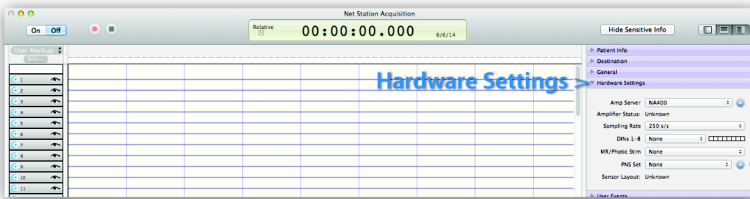
To apply the Net, follow the instructions for your Net model.



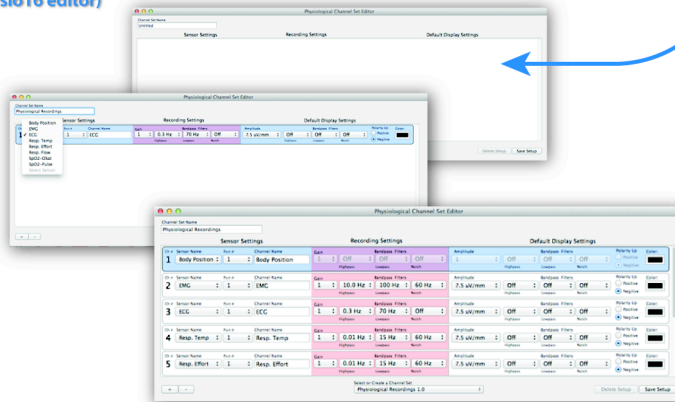
Selecting a PNS Setup

- 1) If necessary, create a new or modify an existing PNS setup using the Physio16 editor, which is available from the Hardware Settings control panel on the Net Station 5 Acquisition interface.

Net Station Acquisition

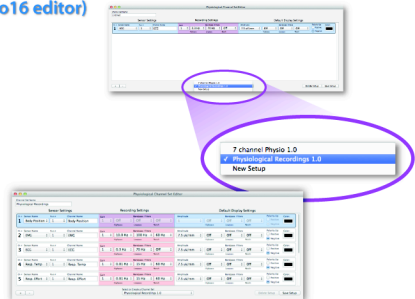


Physiological Channel Set Editor dialog (Physio16 editor)

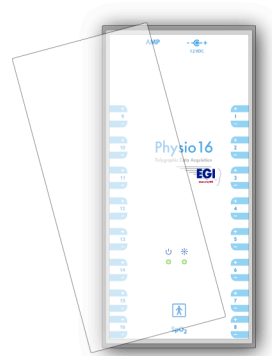


- 2) Select a PNS setup.

Physiological Channel Set Editor (Physio16 editor)



- 3) If you will be using a removable, writable clear film, use a grease pencil to identify the PNS setup and what PNS sensors will be plugged into which ports on the Physio16 input box.

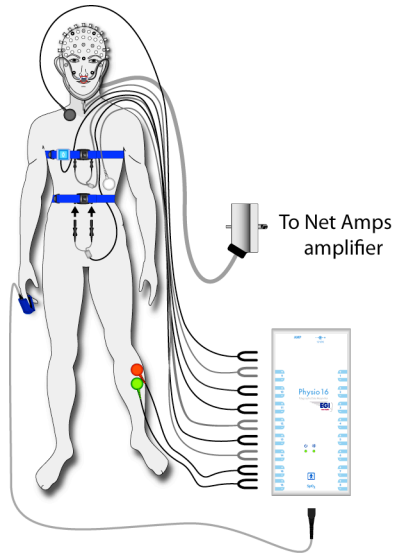


This is especially helpful if the PNS port numbers in a PNS setup are not in sequence with the channel numbers.

Note: Each Physio16 input box comes with several removable, writable clear films. For additional films or replacements, contact orderdesk@egi.com.

Applying the PNS Sensors

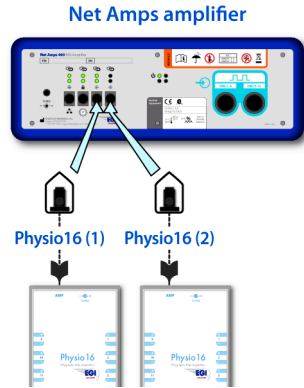
- 1) Apply the PNS sensors to the patient according to your facility's protocols.
- 2) Connect the PNS sensors to the Physio16 input box.
- 3) Verify that the sensors are plugged into the correct ports, according to the selected PNS setup.



Connecting the Physio16 Input Box to the Amplifier and to Power

- 1) Connect the fiber optic cable between the Physio16 input box and the amplifier.

Note: Each Physio16 input box must be within 15 meters (50 ft) of the amplifier, which is the length of the connecting fiber optic cable.



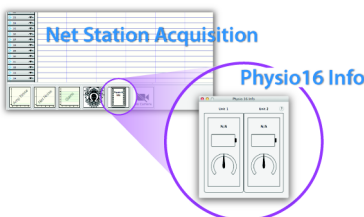
- 2) Provide power to the Physio16 input box:

If using battery power:

Check the battery level via the Physio16 Info dialog.

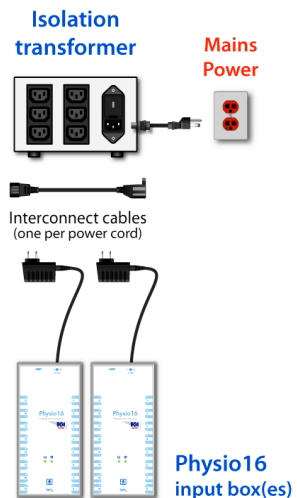
Note: After the device is connected to the amplifier and **Stream On** is clicked in Net Station Acquisition, you can check the following :

- Battery level
- Current temperature
- Firmware version



If using mains power:

Connect the provided power cable to the isolation transformer.



Verifying Data

While verifying the quality of the data (as per the instructions for the Net Station 5 software), also verify that the PNS channels are displaying the expected data from each PNS sensor. (This will confirm the PNS sensor connections against the channel ports of the PNS setup.)

If any channels are displaying data from the wrong sensors, then move those sensor's plugs to the correct ports on the Physio16 input box to match the port assignments of the selected PNS setup in the Physio16 editor.

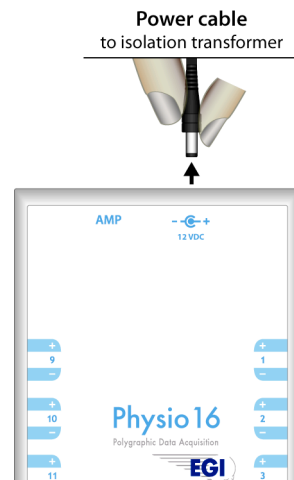
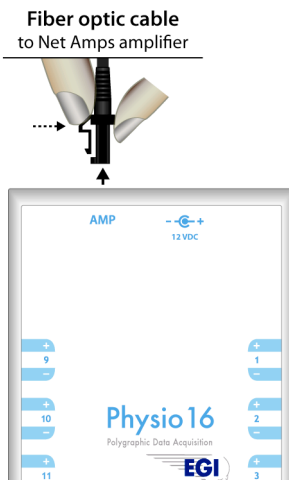
If Needed, Disconnect the Physio16 Input Box

When an interruption to a recording session is needed, as for restroom breaks, simply:

1. Unplug the fiber optic cable from the top of the Physio16 input box.
2. *If operating with mains (AC) power* unplug the power cable from the top of the Physio16 input box.

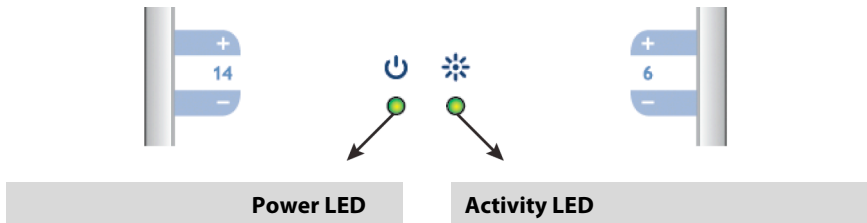
Replug the cable, when ready.

Replug the cable, when ready.



During a Recording Session

During operation, watch the LEDs on the Physio16 input box for its operating status.



When mains (AC) powered:

- Solid **green**: charging complete
- Solid **yellow**: battery charging
- Flashing **red**: battery fault

Solid **green**: connected to amplifier

Flashing **green**: communicating with amplifier

Discontinue use, then contact EGI Technical Support.

When battery powered:

- Solid **green**: battery full
- Solid **yellow**: battery good
- Flashing **yellow**: battery low
- Flashing **red**: battery fault

Discontinue use, then contact EGI Technical Support.

When not mains (AC) powered and not connected to the amplifier:

- Blinks **green**: checking for connection to amplifier
(once every 20 sec.)

After a Recording Session

Follow your facility's protocols to remove the PNS sensors and care for the patient.

For questions or additional assistance, please contact us at:



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