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PRO
g.Nautilus
Wireless Biosignal Acquisition

Instruction for use

V1.16.06

g.Nautilus PRO

UDI Sticker

SN: NP-

printed October 9, 2017

How to contact g.tec:

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Content

1 Important Notes

In the following document, the term g.Nautilus refers to both g.Nautilus PRO wet and dry systems. Depending upon your purchased device, the specific paragraphs for the wet or dry system apply. Please check your purchasing documentation or the device label to identify your device type.

Attention

- conductible parts of all electrodes **must not** have contact with the earth or other conductible parts
- avoid electrostatic discharge impulses when handling g.Nautilus or touching the electrodes
- the device must **not** be used in humans with pace-makers or electrical stimulators
- pay attention to the precautions regarding electromagnetic compatibility
- the operation of the device can be compromised within shielded rooms. In case of problems, relocate the receiving device or consult g.tec Technical Support (see page 2, How to contact g.tec).
- the operator has to be familiar with the operation of g.Nautilus and must operate the device according to the instructions for use
- the device and its accessories must not be exposed to increased mechanical stress
- each time you use g.Nautilus, you must first check the device and its accessories for possible damage to connectors, sockets and cables. Check the electrode cable connections with special care and ensure that the electrode lines have no breaks or cracks. Any cables, connectors, accessories, or other parts of the equipment must be replaced immediately if damaged or not working correctly.
- the device is not protected against electrical defibrillation - before defibrillation, the electrodes must be removed from the subject!
- only use accessories identified for use with this device
- If g.Nautilus is used at the same time as other devices on subjects, the following leakage currents have to be checked:
    - Ground leakage current
    - Enclosure leakage current
    - Patient leakage current

Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible for ensuring the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, consult the technical service department or your local representative.

Warning and safety notice

The device is powered internally via a Lithium-Ion accumulator. The accumulator must only be replaced by the manufacturer.

Opening the device destroys the housing. Hence, the device must be sent back to the manufacturer for any visual inspection of the inside of g.Nautilus.

Special treatment of electrodes and cables

g.tec uses special lightweight, thin and highly flexible cables for active electrodes to provide high comfort and easy cap mounting, especially for multi-channel recording. These cables are sensitive and need to be treated with special care. Following some basic guidelines will prolong the lifetime of electrodes and cables:

- never pull on electrode cables
- avoid knots in cables
- do not soak cables and electrodes for more than 30 minutes
- avoid exposure to direct sunlight or chemical agents
- do not autoclave electrodes
- make sure that no gel remains on electrodes or cables after cleaning
- protect from contamination with gel, water or disinfectant
- always make sure that electrodes, cables and caps are completely dry before storing
- don’t cut or pinch electrode cables; light bending is safe

Warranty/replacement of electrodes

Electrode and cable lifetime depends on proper usage, careful treatment and cleaning, and appropriate storage. g.tec will provide warranty replacement only if there is no visible physical damage to the parts, such as: damaged, broken or pinched cables; isolated, eroded contact pellets; or damaged housings or connectors.

Limitations of Reprocessing

- do not use any other detergent as mentioned in this policy!
- Do not perform automated reprocessing in Washer Disinfectors (WD) or Endoscope Washer Disinfectors (EWD)!
- do not machine-wash!
- do not use a laundry dryer or other hot air devices!
- do not put into an ultrasonic bath!
- do not autoclave caps or electrodes!

For disinfection (if required) use 'Sekusept plus' or Metricide® cold sterilizing solution or disinfection alcohol like isopropyl alcohol (70%, 5 minutes) only. Do not exceed the treatment time indicated in the Sekusept or Metricide manuals. 'Sekusept plus' is a product of ECOLAB (www.ecolab.com) and is available from most local healthcare providers.

Inspection

The manufacturer is responsible for the safety, performance and reliability of the device as supplied to the customer at the time of delivery. This responsibility expires if the device is changed. Please note the following:

- changes to the device must be performed by the manufacturer only, and service and repair is performed by corresponding qualified personnel only
- the device must be used according to the instruction for use

According to EN 62353:2008, the device and its accessories must be checked once every two years (minimum).

Interference

g.Nautilus and its components have been tested and comply with the electromagnetic compliance limits for the Medical Device Directive 93/42/EWG (EN 60601-1-2:2007 Class B). See the chapter on Electromagnetic compatibility. The equipment, if not installed and used in accordance with the instructions, may cause interference with 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 through one or more of the following measures:

- reorient or relocate the receiving device.
- increase the separation between the equipment.
- consult g.tec Technical Support (see page 2, How to contact g.tec).

Intended use

The g.Nautilus PRO is intended to be used to acquire the electroencephalogram (EEG) and transmit it wirelessly to a computer.

Limitation

The device **must not** be used for patient monitoring. The device **must not** be used for the determination of brain death. Additional examinations are needed for diagnosis, and no diagnosis may be done based only on using this device.

The device is not suitable for high density recordings for source localization, diagnostic investigations related to brain diseases as in routine clinical settings, combined EEG with FMRI[1], invasive recordings, recordings on non-intact skin and EEG recordings where very high sample rates are necessary (BAEPs[2]).

As g.Nautilus PRO provides 8 independent digital inputs, for event related experiments the number of events, which could happen at the same time, is limited to 8.

Limitation regarding the electrode grid layouts is addressed in section “Grid limitation” of “

[1]Functional magnetic resonance imaging
[2] brainstem auditory evoked potentials

Different versions of g.Nautilus PRO".

Intended user
Researcher or medical doctor with experience in EEG measurements.

The intended environment of use
The device **must not** be used in dangerous conditions such as wet rooms or explosive environments. The relative humidity must be between 25 % and 80 %. The device **must not** be used in combination with any other high-frequency device. Using a high frequency device with g.Nautilus can cause burning under the electrodes and could damage the device.

Recommended electrodes and electrode gel
g,Nautilus PRO (wet system) is delivered with a fixed, non-exchangeable electrode configuration pre-mounted in an electrode cap (maximum 32 electrodes in defined arrangement with reference- and ground-electrode). For this system, use electrode gel (model: E9) from Electro-cap Intl., Inc. (K111717).

g.Nautilus PRO (dry system) does not require electrode gel. It is delivered with a fixed, non-exchangeable electrode configuration pre-mounted in an electrode cap (maximum 32 electrodes in defined arrangement with reference- and ground- clip). For the ground and reference electrodes, use adhesive disposable Ag/AgCl electrodes (recommended: Kendall H135SG from Tyco Healthcare, K953649). For the EEG channels, use only the gold coated dry electrodes included in delivery for connection to the electrode clips.

Properties of PC or notebook
g.Nautilus requires a PC, notebook or embedded computer with UPS[3] (according to IEC/EN60950) running a Microsoft Windows operating system (Windows 10

Professional English with 64 Bit). The following table shows the minimum requirements:

Hardware	Minimum Requirements
CPU	Pentium working at 2000 MHz or faster
Harddisk	20-30 Gigabyte
RAM	4 Gigabyte or higher
USB 2.0 port **(EHCI – enhanced host controller interface)**	1 free USB Port for each Base Station
Uninterruptible power supply (UPS)	

Prescription device
Caution: US federal law restricts the devices described herein to sale by or on the order of a physician.

[3] uninterruptible power supply

2.4 GHz transmission

g.Nautilus uses the 2.4 GHz band for wireless transmission. Ensure that enough transmission bandwidth is available in your environment, since other devices might also use the same band (e.g. WiFi or Bluetooth devices). Use wireless screening tools to ensure the availability of the necessary transmission channel.

2 g.Nautilus PRO Introduction

g.Nautilus PRO is g.tec's biopotential amplifier with wireless data transmission technology with active wet or dry electrodes (8-32 channels). The device can acquire EEG data with 24 Bit resolution and a sampling rate of 250 or 500 Hz. It also has a 3-axis acceleration sensor that can sense ±6 g.

Up to 32 analog to digital converters perform the simultaneous sampling. Each analog to digital converter operates at 1.024 MHz. A corresponding down-sampling then yields a user-selectable sampling rate of 250 or 500 Hz. A sampling rate of 250 Hz means an oversampling of 4096, yielding a high signal to noise ratio.

The device is equipped with an internal impedance check to determine the electrode-skin-impedance. g.Nautilus is controlled via an Application Programming Interface (C-API).

A Base Station receives the digitized EEG data and can be connected to any free USB port of the PC or notebook.

g.Nautilus PRO
with 32 active wet electrodes

g.Nautilus PRO
with 32 active dry electrodes

The Headset of the biosignal amplifier g.Nautilus with wireless transmission is attached to the back side of the cap.

g.Nautilus PRO is equipped with gel-based active electrodes (LADYbird technology), or with dry active electrodes (SAHARA technology). The electrodes (LADYbird) or electrode clip connectors (SAHARA) are connected to the g.Nautilus Headset with special flexible PCB strands instead of wires and cannot be disconnected from the device Headset. Thus, the electrode system can be mounted very quickly, and this approach avoids mistakes caused when connecting the electrodes' wires to each electrode.

Highlights

- wireless EEG recordings with high signal quality
- very lightweight to minimize artifacts
- active wet or active dry electrodes for fast mounting without using abrasive gel
- up to 32 analog input channels with 24 Bit resolution
- sampling rate of 250 or 500 Hz per channel
- digital filtering
- oversampling to achieve a high signal to noise ratio
- g.Nautilus Base Station can be connected to a computer
- simultaneous sample and hold for all channels
- easy and fast application of electrodes via prefixed positions
- wireless charging of the accumulator
- adjustable input sensitivity of ± 187.5 mV up to ± 2.25 V
- three axis acceleration sensor

The following table shows the available input ranges and the corresponding voltage resolution:

Input range	**Voltage resolution**
mV	***nV***
± 187.5	22.05
± 375	44.70
± 562.5	67.06
± 750	89.41
± 1125	134.11
± 2250	268.22

Top view of g.Nautilus PRO Headsets with 8 (red color), 16 (purple color), 32 (blue color), CSP32 (orange color), CSP16mB (black color) and CSP16rX (black color) channels. The different Headset colors indicate the different electrode configurations, which are identical for wet and dry systems.

Different versions of g.Nautilus PRO

g.Nautilus PRO is available with several different electrode layouts, ranging from 8 to 32 channels with one ground and one reference channel. The additional reference channel allows the input stage to work in fully-differential mode. This brings the advantage of maximum noise rejection, an increased dynamic range and increased SNR. The appendix shows the different electrode configurations in detail. The following electrode layouts are available:

32 electrodes distributed according to the extended 10/20 electrode system

Covered regions: frontal, central, temporal, parietal

- Advanced BCI experiments (P300, motor imagery, Visual evoked potential (VEP), Steady state visually evoked potential (SSVEP), etc)
- Advanced psycho-physiological experiments (Event-related potential (ERP))

16 electrodes distributed according to the extended 10/20 electrode system

Covered regions: frontal, central, temporal, parietal

- BCI experiments
- Simple psycho-physiological experiments (event related potentials)

8 electrodes distributed for performing P300 experiments

Covered regions: parietal

- BCI experiments (P300 spelling)

32 electrodes with CSP layout distributed for performing motor imagery based brain-computer interface experiments

Covered regions: frontal, central, temporal

- Advanced BCI experiments (motor imagery with common spatial patterns, source derivations over the sensory motor cortex)
- Advanced psycho-physiological experiments focused on sensory motor cortex activation

16 electrodes with CSP16mB layout on selected positions on the motor cortex of the extended 10-20 system

Covered regions: central

- BCI experiments (motor imagery with common spatial patterns, auditory evoked potentials, vibrotactile evoked potentials)
- Simple psycho-physiological experiments focused on sensory motor cortex activation

16 electrodes with CSP16rX layout on selected positions on the motor cortex of the extended 10-20 system

Covered regions: frontal, central

- BCI experiments (motor imagery with common spatial patterns)
- Simple psycho-physiological experiments focused on sensory motor cortex activation

Grid limitation

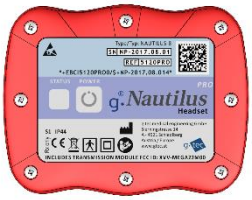
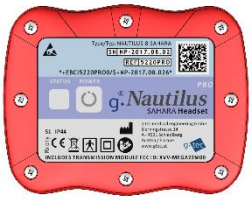
32 channels or less are not suitable for high density recordings for source localization. Furthermore g.Nautilus PRO is not intended for EEG recording in clinical use (clinical EEG).

3 g.Nautilus PRO components

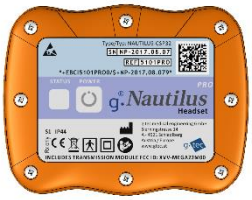
g.Nautilus PRO consists of the following basic components	**WET system**	**DRY system**
1 g.Nautilus PRO Headset - wireless bio potential amplifier with prefixed electrode strands mounted inside a small, medium or large cap	**X**	**X**
1 g.Nautilus PRO Base Station - stationary receiver unit	**X**	**X**
1 set of dry electrodes (8, 16 or 32)		**X**
1 USB cable (2 m)	**X**	**X**
1 power supply for US or 1 power supply for UK or 1 power supply for EU or 1 power supply for CH (China)	**X**	**X**
1 QI-compatible charging device	**X**	**X**
1 USB cable for the charging device (1.5 m)	**X**	**X**
1 USB cable for the charging device (0.3 m)	**X**	**X**
1 g.Nautilus PRO Instruction for use	**X**	**X**
1 CD with driver software (g.NEEDaccess SERVER software and CLIENT API)	**X**	**X**

4 Explanation of switches and LEDs on the Headset

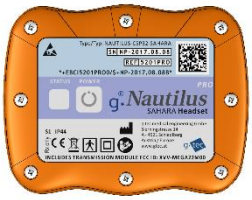
g.Nautilus Headset (32 channel gel version shown here)

Type/Typ:		Number of channels
NAUTILUS-32	**NAUTILUS-32-SAHARA**	
		**32 channels**
NAUTILUS-16	**NAUTILUS-16-SAHARA**	
		**16 channels**
NAUTILUS-8	**NAUTILUS-8-SAHARA**	
		**8 channels**

NAUTILUS-CSP32



NAUTILUS-CSP32-SAHARA



32 CSP channels

NAUTILUS-CSP16mB

NAUTILUS-CSP16mB-SAHARA

16 CSPmB channels

NAUTILUS-CSP16rX

NAUTILUS-CSP16rX-SAHARA

16 CSPrX channels

POWER:	Push-button for turning the device on and off
STATUS:	A multi-color LED indicates the status of the device

Indications of operation mode

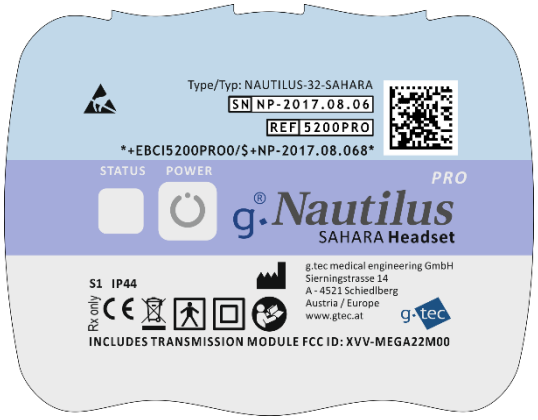
STATUS LED	device operating mode
Short turquoise flashing (20 ms, every second)	Sender/Receiver standby state (not yet connected to Base Station)
Slow turquoise blinking (1000 ms, every 2 seconds)	Ready for transmission (connected to Base Station)
Steadily turquoise	Data transmission
Short orange flashing (20 ms, every second)	Sender/Receiver standby state (not yet connected to Base Station) capacity of accumulator < 30 %.
Slow orange blinking (1000 ms, every 2 seconds)	Ready for transmission (connected to Base Station) capacity of accumulator < 30 %.
Steadily orange	Data transmission capacity of accumulator < 30 %.
Fast orange blinking	capacity of accumulator < 10 %.

Indications of charging mode

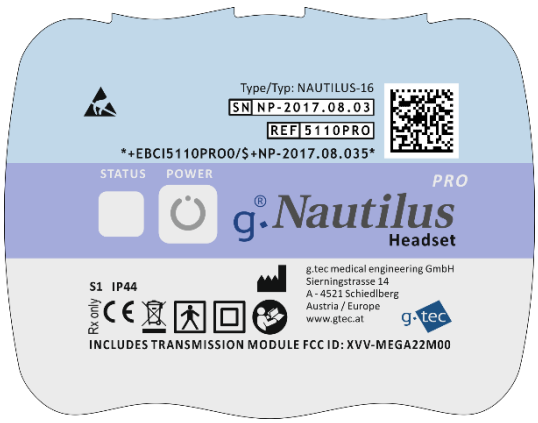
STATUS LED	device charging mode
Steadily blue	Charging of Headset
Slow blue blinking	The capacity has reached 70 % of maximum
Short blue flashing (20 ms, every second)	The Headset is fully charged.

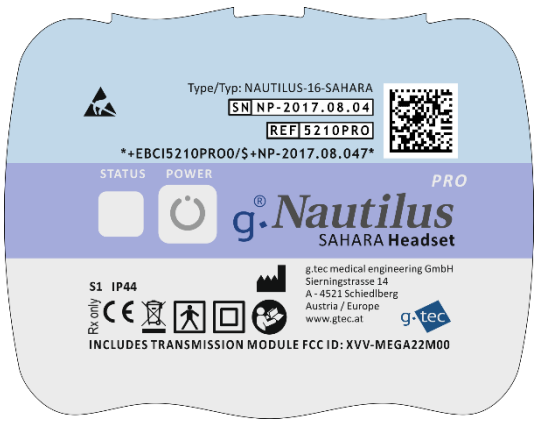
5 Marking on the top side of the g.Nautilus Headset

g.Nautilus 32-channel setup (wet and dry versions)



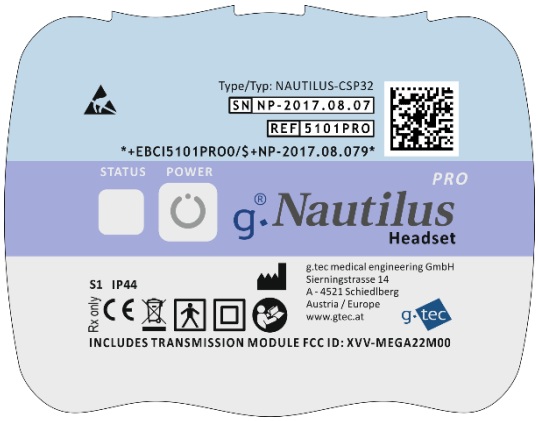
g.Nautilus 16-channel setup (wet and dry versions)

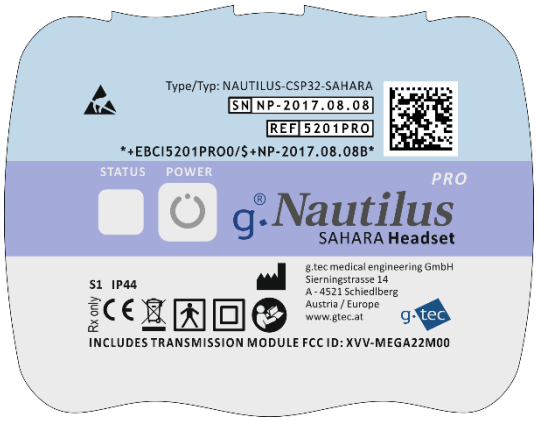




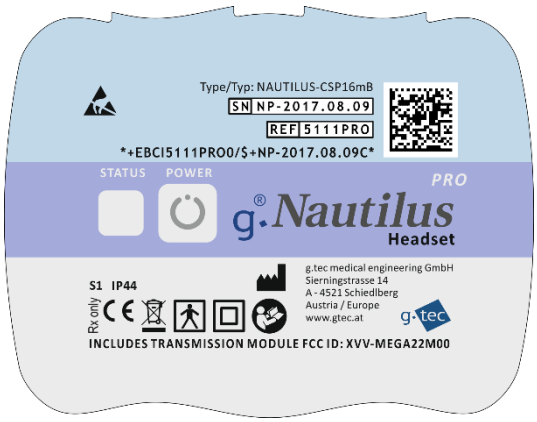
g.Nautilus 8-channel setup (wet and dry versions)

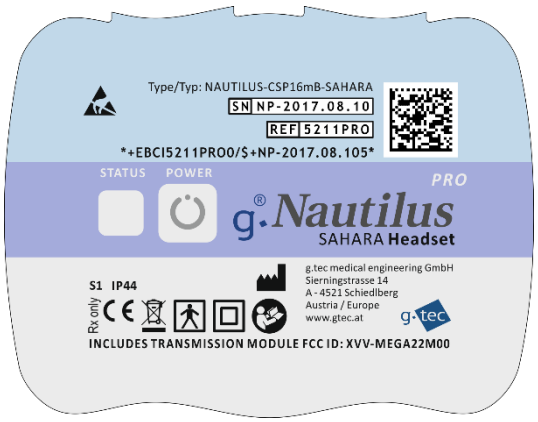
g.Nautilus 32-channel setup CSP system (wet and dry versions)



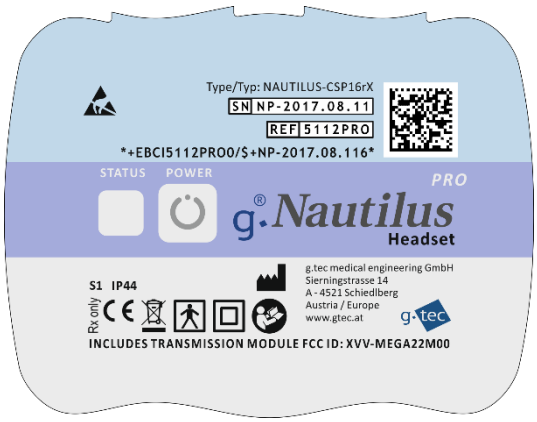


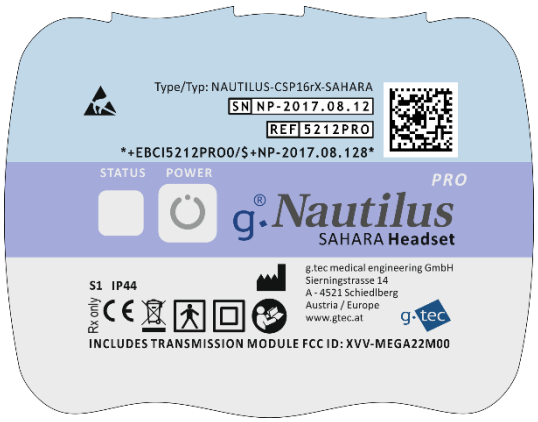
g.Nautilus 16-channel setup CSPmB system (wet and dry version)





g.Nautilus PRO 16-channel setup CSPrX system (wet and dry version)





Type/Typ: NAUTILUS-32	g.Nautilus PRO 32-channel setup, gel version
or Type/Typ: NAUTILUS-16	g.Nautilus PRO 16-channel setup, gel version
or Type/Typ: NAUTILUS-8	g.Nautilus PRO 8-channel setup, gel version
or Type/Typ: NAUTILUS-CSP32	g.Nautilus PRO 32-channel setup CSP system, gel version
or Type/Typ: NAUTILUS-CSP16mB	g.Nautilus PRO 16-channel setup CSPmB system, gel version
or Type/Typ: NAUTILUS-CSP16rX	g.Nautilus PRO 16-channel setup CSPrx system, gel version
or Type/Typ: NAUTILUS-32-SAHARA	g.Nautilus PRO 32-channel setup, dry version
or Type/Typ: NAUTILUS-16-SAHARA	g.Nautilus PRO 16-channel setup, dry version
or Type/Typ: NAUTILUS-8-SAHARA	g.Nautilus PRO 8-channel setup, dry version
or Type/Typ: NAUTILUS-CSP32-SAHARA	g.Nautilus PRO 32-channel setup CSP system, dry version
or Type/Typ: NAUTILUS-CSP16mB-SAHARA	g.Nautilus PRO 16-channel setup CSPmB system, dry version
or Type/Typ: NAUTILUS-CSP16rX-SAHARA	g.Nautilus PRO 16-channel setup CSPrx system, dry version

CE mark

Do not dispose g.Nautilus with domestic waste. Dispose it via the separate collection system for electrical and electronic equipment.

Applied part BF

Safety class II

Avoid electrostatic discharge

Follow instruction for use

Standby for a part of the device

Manufacturer address

IP44

IP 44: Protected against objects >1 mm.
Water splashing against the enclosure from any direction shall have no harmful effect.

S1

S1: permanent operation

XVV-MEGA22M00	FCC-ID of included transmission module
Rx only	Prescription device in the USA
SN NP-2017.08.01	Serial number in the format: NP-YearOfProduction.Month.Number Must be the same as on Base Station.
REF 5120PRO	Catalog Reference
+EBCI5120PRO0/$+NP-2017.08.014	UDI Human readable
	UDI code in automatic identification and data capture (AIDC) format

6 g.Nautilus PRO Base Station, LED and USB cable

The Base Station and the corresponding USB-cable, together with a connected PC (according IEC/EN60950) and driver, allow communication with the g.Nautilus Headset.

g.Nautilus Base Station (for the 32 channel gel version is shown)

USB cable

Type/Typ:		Number of channels
NAUTILUS-32 	NAUTILUS-32-SAHARA 	32 channels
NAUTILUS-16 	NAUTILUS-16-SAHARA 	16 channels
NAUTILUS-8 	NAUTILUS-8-SAHARA 	8 channels

NAUTILUS-CSP32	**NAUTILUS-CSP32-SAHARA**	
		**32 CSP channels**
NAUTILUS-CSP16mB	**NAUTILUS-CSP16mB-SAHARA**	
		**16 CSPmB channels**
NAUTILUS-CSP16rX	**NAUTILUS-CSP16rX-SAHARA**	
		**16 CSPrX channels**

STATUS:	A blue LED indicates the status of the device

Indications of operation mode

STATUS LED	device operating mode
Short blue flashing (20 ms, every second)	Sender/Receiver standby state (not yet connected to Headset)
Slow blue blinking (1000 ms, every 2 seconds)	Ready for transmission (connected to Headset)
Steadily blue	Data transmission

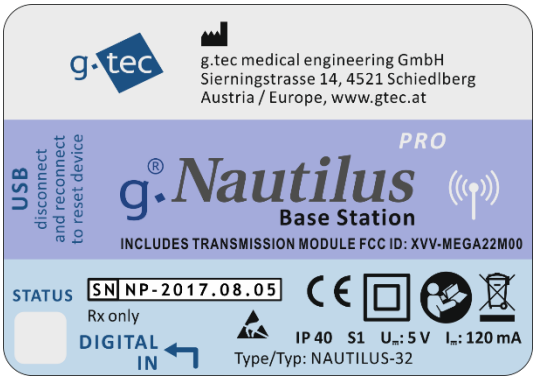
Part of the g.Nautilus medical equipment is the USB cable (2 m). It is a 4 pin cable used to connect the Base Station to a PC. One side has a standard USB connector the other side a Mini-USB connector.

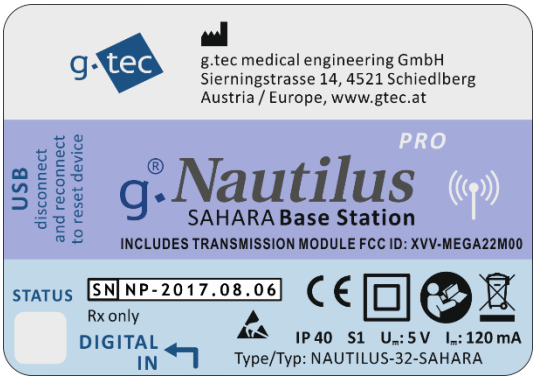
Labels on the cable

USB - PC	USB connector to PC
g.Nautilus PRO Base Station	USB connector to Base Station

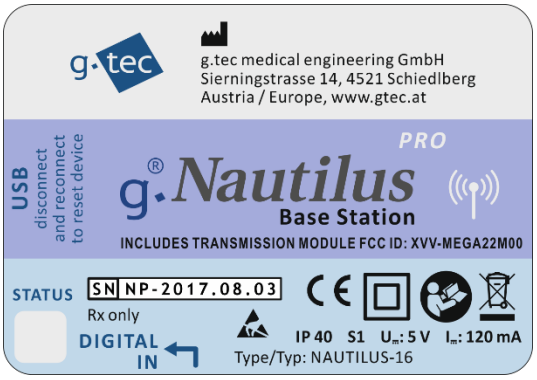
7 Marking on the top side of the Base Station

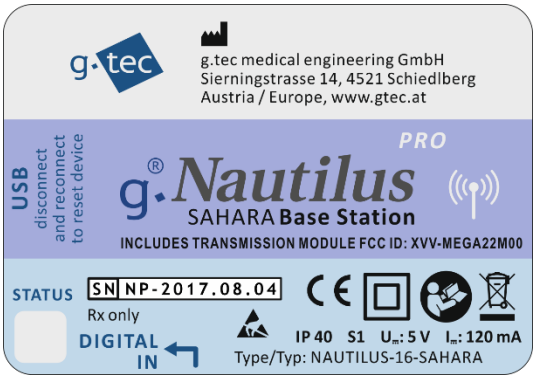
g.Nautilus PRO 32-channel setup (wet and dry versions)



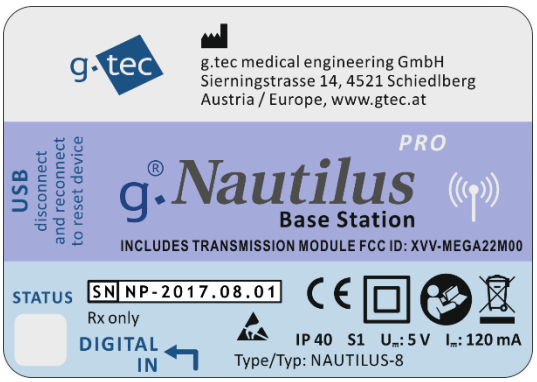


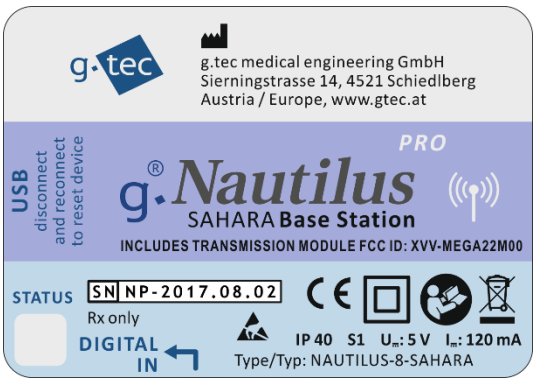
g.Nautilus PRO 16-channel setup (wet and dry versions)



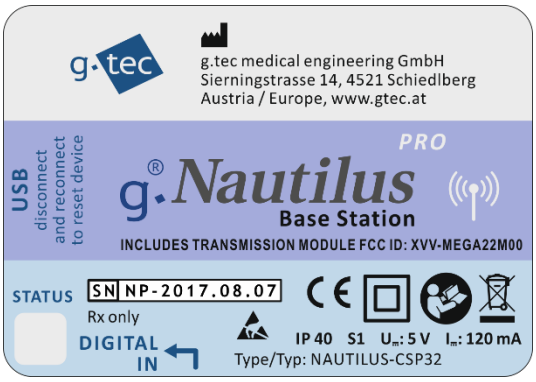


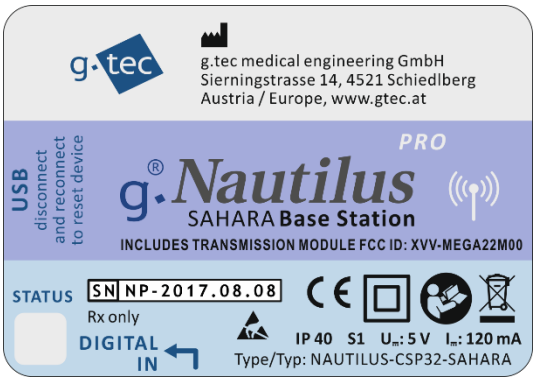
g.Nautilus PRO 8-channel setup (wet and dry versions)



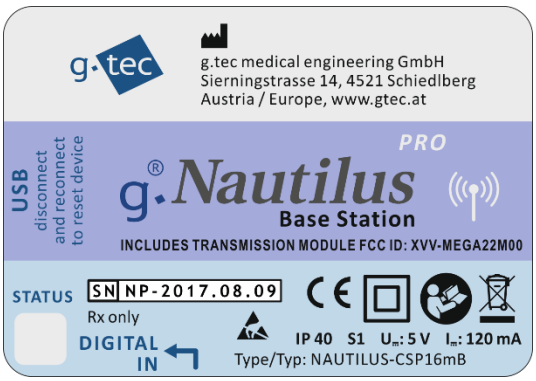


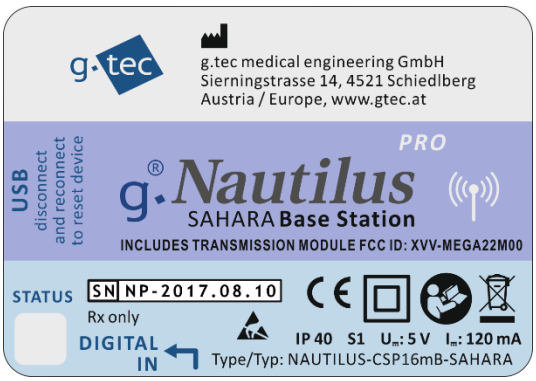
g.Nautilus PRO 32-channel setup CSP system (wet and dry versions)



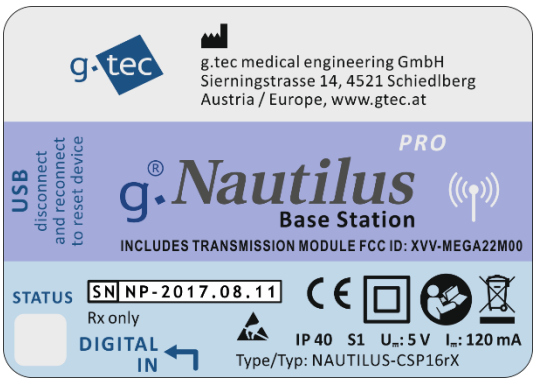


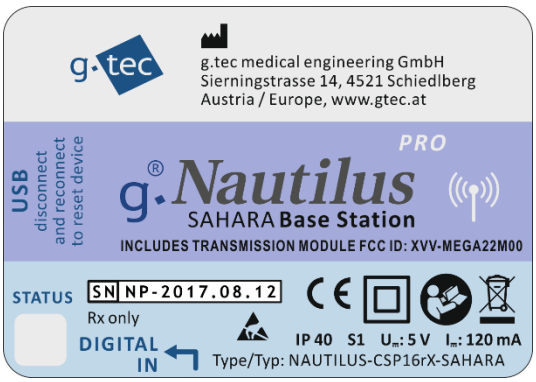
g.Nautilus PRO 16-channel setup CSPmB system (wet and dry version)





g.Nautilus PRO 16-channel setup CSPrX system (wet and dry version)





Type/Typ: NAUTILUS-32	g.Nautilus PRO 32-channel setup, gel version
or Type/Typ: NAUTILUS-16	g.Nautilus PRO 16-channel setup, gel version
or Type/Typ: NAUTILUS-8	g.Nautilus PRO 8-channel setup, gel version
or Type/Typ: NAUTILUS-CSP32	g.Nautilus PRO 32-channel setup CSP system, gel version
or Type/Typ: NAUTILUS-CSP16mB	g.Nautilus PRO 16-channel setup CSPmB system, gel version
or Type/Typ: NAUTILUS-CSP16rX	g.Nautilus PRO 16-channel setup CSPrx system, gel version
or Type/Typ: NAUTILUS-32-SAHARA	g.Nautilus PRO 32-channel setup, dry version
or Type/Typ: NAUTILUS-16-SAHARA	g.Nautilus PRO 16-channel setup, dry version
or Type/Typ: NAUTILUS-8-SAHARA	g.Nautilus PRO 8-channel setup, dry version
or Type/Typ: NAUTILUS-CSP32-SAHARA	g.Nautilus PRO 32-channel setup CSP system, dry version
or Type/Typ: NAUTILUS-CSP16mB-SAHARA	g.Nautilus PRO 16-channel setup CSPmB system, dry version
or Type/Typ: NAUTILUS-CSP16rX-SAHARA	g.Nautilus PRO 16-channel setup CSPrx system, dry version

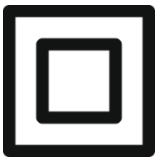
CE mark

Do not dispose g.Nautilus with domestic waste.
Dispose it via the separate collection system for electrical and electronic equipment.

Avoid electrostatic discharge

Applied part BF

Follow instruction for use



Safety class II

g.tec medical engineering GmbH
Sierningstrasse 14, 4521 Schiedlberg
Austria / Europe, www.gtec.at

Manufacturer address

IP 40

IP 40: Protected against objects >1 mm.
Not protected against water.

S1

S1: permanent operation

SN NP-2017.08.01

Serial number in the format:
NP-YearOfProduction.Month.Number
Must be the same as on Headset.

XVV-MEGA22M00

FCC-ID of included transmission module

DIGITAL IN	D-SUB connector to connect digital input signals
USB disconnect and reconnect to reset device	Mini-USB connector to connect computer
	Radio transceiver inside
Rx only	Prescription device in the USA
$U_{\overline{\overline{\cdots}}}$: 5 V	Rated voltage
$I_{\overline{\overline{\cdots}}}$: 120 mA	Rated current

8 Charging device

The g.Nautilus medical equipment includes the T-200 wireless charger charging pad and the DCH5 power supply that are connected via a USB cable. The power supply delivers 5 V DC to the charging pad that wirelessly charges the g.Nautilus. The USB cable has one standard USB connector and one micro-USB port.

Charging device

Labels on the charging pad

Wireless Charging Pad	Type
Input: DC 5V, 1500 mA	Voltage and current on input
Made in China	Origin
	interface standard developed by the Wireless Power Consortium
	CE mark
	FCC mark
	Recycle mark
	Do not dispose with domestic waste. Dispose it via the separate collection system for electrical and electronic equipment

DA5-050EU

DA5-050US

DA5-050UK

DA5-050CH

Power supply for charger

Labels on the power supply

Artesyn	Manufacturer
Model: DA5-050EU, DA5-050US, DA5-050UK, DA5-050CH	Model code for EU, US, UK and CH (China)
Input: 100-240V~, 0.2A, 50/60Hz	Input voltage, current and frequency
Output: 5V⎓ 1A	Output voltage and current
	Do not dispose with domestic waste. Dispose it via the separate collection system for electrical and electronic equipment
	CE mark
Made in China	Origin
L620QT00UBAPL	Serial number
	Safety class II
	Energy efficiency level 6
	For indoor use only

USB cable

Labels on the cable

Wall adapter	USB connector to power supply
Charging Pad	Micro USB connector to charging pad

9 Packaging

The figures below show the packaging of the device and the labelling of the box.

UDI label:

10 Safe operation of g.Nautilus

Set up and measurement with the device

Use on healthy, intact skin only.

Do not use on or near open wounds, bruised or weakened skin, whether due to injury and/or other medical conditions of the patient.

Do not use on patients with a history of skin allergies or sensitivity to cosmetics and lotions.

If rash, redness, itching, swelling, or abnormality appears on skin, remove the cap and wash any residual gel off immediately.

Instruct patients to communicate any persistent redness, soreness or swelling at the electrode sites.

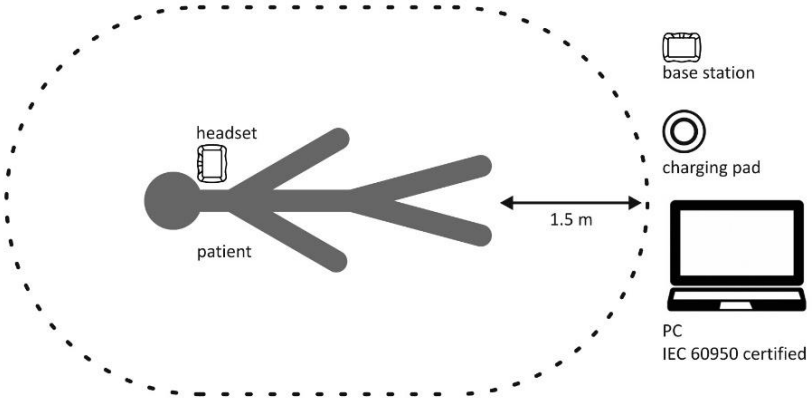
It is not recommended that the cap be left in place for longer than eight hours for any single recording session.

Avoid eye contact with gel as it may cause mild transient irritation. Wash eyes with appropriate 0.9% saline solution, commercial eye wash solution or water to flush out residual particles. Avoid rubbing eyes.

Electro-Gel is essentially non-toxic, however ingestion could result in nausea, vomiting and/ or diarrhea. Drink 1 to 2 glasses of water if ingested.

Patient environment

- The Base Station MUST be placed outside the patient environment.
- The PC or notebook and UPS[4] (according to IEC/EN60950) MUST be placed outside the patient environment.
- The charging pad MUST be placed outside the patient environment, even the device is not charging.



Avoiding electrostatic discharge

Electrostatic discharge (ESD) events can harm electronic components inside your device. Under certain conditions, electric charge may build up on your body or an object, such as a peripheral, and then

[4] uninterruptible power supply

discharge into another object, such as your device. To prevent ESD damage, you should discharge static electricity from your body before you interact with any of your devices.
You can protect against ESD and discharge static electricity from your body by touching a metal grounded object.

Please perform the following steps to record data with g.Nautilus:

Step 1: Place the g.Nautilus Headset on the head of the subject to position the electrodes according to the international 10/20 electrode system[5].

In order to properly mount the electrode cap, measure the distance between the Nasion and Inion and the distance between the left and right preauricular points of the subject. The position at the middle of these two locations is the vertex position, Cz. Put on the electrode cap and align this measured position with the position Cz of the electrode cap. Now, the electrode cap is in the correct position.

Fix the cap with the chin strap to keep the cap in place.

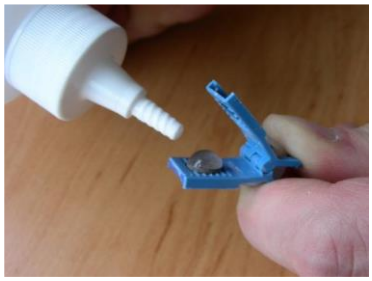
Step 2: Mount EEG electrodes

g.Nautilus PRO: Gel electrodes
Fill all electrodes with conductive gel. You must coat at least 1 cm² of skin under the electrode with gel and the electrode must be filled completely. The electrode impedance should be below 100 kOhm. The gel is best applied with a syringe. Insert the tip of the syringe into the ready-mounted electrode and make sure to reach the skin. Press the syringe and move it around a bit with the tip on the skin, with slight pressure to make sure that gel is distributed on the skin. Then carefully fill the electrode with gel. It is essential that gel completely fills the gap between the skin and the electrode surface! However, using too much gel may cause shortcuts between electrodes.

[5]Webster, J.G., (Ed.): Medical Instrumentation: Application and Design, p.194-216. Houghton Mifflin: Boston 1992.

g.Nautilus PRO: Inject electrode gel into the active, gel electrodes.

The ear-clip electrode is attached with gel as well. Just put a small amount of gel onto the electrode surface (Ag/AgCl disk) and put the earclip on the earlobe, with the electrode outside.



Reference electrode

If a signal shows high noise, drift or other disturbance, check the proper filling of the electrode ring and assure that the gel touches the skin. Note that the ground electrode (yellow) is a passive electrode, and therefore it is the only electrode that needs to be mounted with special care. Very high impedance at

the ground electrode may reduce the signal quality. One can use abrasive gel to prepare the skin at the ground electrode if necessary.

g.Nautilus PRO: Dry electrodes

The dry electrodes (g.tec medical engineering GmbH, Austria) have 8 golden pins with 7 mm (standard configuration) or 19 mm length.

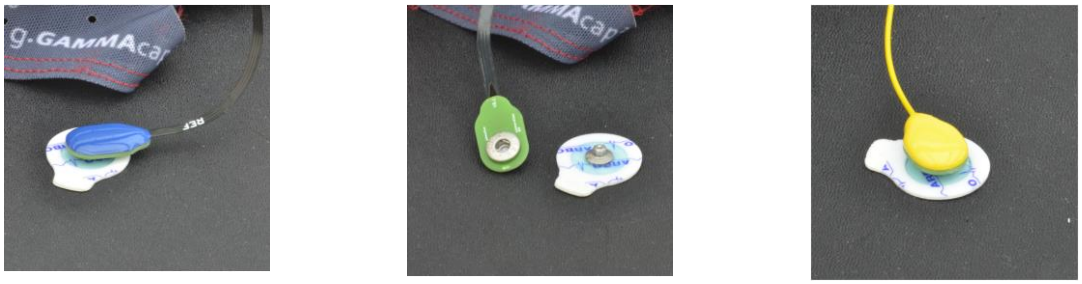
Dry electrode versions

The electrodes can be clipped into the g.Nautilus PRO dry active electrode system.

Electrode cap with inserted dry electrodes

For short and normal hair, use the standard version. For long and dense hair, use the long-pin version. Use a cap size (S, M or L) that provides gentle pressure to all electrodes on the skin without causing pain to the subject. Rotate each electrode back and forth a few times at an angle of 10° – 20° to remove hair between the electrodes and the skin, and to ensure a proper galvanic contact between the electrode pins and the skin.

Mount the blue reference electrode on the right mastoid with disposable Ag/AgCl electrodes. Mount the ground electrode on the left mastoid, also with disposable electrodes.



Left: reference electrode; Middle: Ag/AgCl snap-able electrode; Right: ground electrode

Note: After 4-5 minutes at most, all signals should be visible and show a stable baseline. In case of high drifts or noisy signals on a certain channel, the corresponding electrode needs to be checked for good contact with the skin. Place gentle pressure on the electrode and move it a little bit on the skin, then wait again for 1 minute and check the signal again.

NOTE: Special requirements for high quality EEG recording with dry electrodes

EEG recordings in general are quite sensitive to a number of disturbing influences such as movements of the subject, the cables and the electrodes, or coupling of electromagnetic and electrostatic fields near the recording environment. For dry electrodes especially, movements of the electrodes and electrostatic charges can cause significant artefacts in the signals. Consider the following actions to avoid artefacts:

Avoiding electrode and cable movements

- ensure the subject is in a comfortable and relaxed position during recording
- instruct the subject to stay in a relaxed position and to avoid movements
- place electrode wires to avoid tension and direct contact with moving parts of the body
- if the subject needs to speak during the recordings, use the chest belt rather than the chin strap to fixate the cap

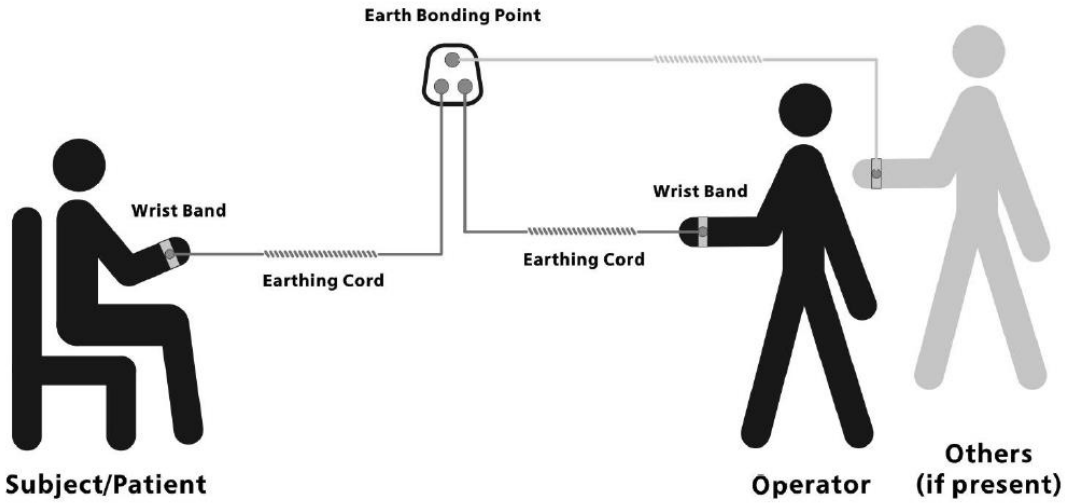
Avoiding electrostatic charges

- choose an antistatic environment/lab for high quality recordings
- use a room with antistatic carpet or floor covering or wooden/stone floor instead of normal carpets or artificial parquet floors
- furniture made of wood, metal and leather is preferable to any plastic materials and synthetic textiles
- cotton clothing is preferred to wool and synthetics

- avoid shoes with synthetic soles

Grounding

- grounding of any additional equipment (using a potential equalization conductor) and metal-made furniture to a central earth/ground contact (lab ground) is recommended
- the subject as well as the operator(s) may be grounded to avoid electrostatic charges (e.g. using an antistatic wrist band connected to the lab ground)



Example of recommended connection, including antistatic wrist bands from the subject and the operator(s) to one common earth bonding point.

Step 3: Press the power button on the Headset for at least 3 seconds to switch on the device. During the button press, the **STATUS** LED must be solid turquoise. After switching on the device, the **STATUS** LED must flash quickly in turquoise. The Headset is not yet connected to the Base Station.

Contact the manufacturer if the LED is not on, even after the accumulator has been fully charged.

Step 4: Connect the Base Station to a free USB 2.0 port on your computer (according to IEC/EN60950) using the USB cable. After a short time period (around 3 seconds), the **STATUS** LED of the Headset should blink slowly. The Headset has automatically connected to the Base Station.

The **STATUS** LED of the Headset should slowly blink in turquoise. If the **STATUS** LED is orange, the Headset must be charged.

The **STATUS** LED indicates that g.Nautilus PRO is operating correctly. If the **STATUS** LED is not on, please check the charge of the accumulator by pressing the power button, or contact the manufacturer.

ATTENTION: The Base Station MUST be placed outside the patient environment. The PC or notebook and UPS (according to IEC/EN60950) MUST be placed outside the patient environment.

Step 5: Connect digital inputs to the Base Station if synchronization of the EEG data with external

devices is required.

Step 6: Check the impedance of the electrodes to ensure a proper contact between the electrodes and the skin. An internally generated square wave (+15 mV) is supplied to the ground electrode to measure the impedance at 10 Hz.

Step 7: Adjust the bandpass filters and Notch filters for the recording channels, specify any bipolar or common average reference (CAR) derivations, and select the sampling frequency, noise reduction and digital inputs. For gel electrodes, use a sensitivity setting of 187.5 mV (highest resolution). For dry electrodes, due to polarization effects causing DC offsets, use 562.5 mV.

Step 8: Perform the EEG measurement with the g.Nautilus according to your experimental procedure. In measuring mode, the **STATUS** LED indicates the data transfer with a permanent turquoise color. All input channels (referred to the REF channel) are amplified, sampled at 250 Hz or 500 Hz, and converted with a 24 bit analog to digital converter. The digitized data are sent via the wireless data link to the Base Station and via USB to the computer.

Switch off and store the device

To switch off and store g.Nautilus Headset correctly, please perform the following steps:

Step 1: Switch off the Headset by pressing the push-button for at least 3 seconds. The **STATUS** LED will be on steadily during the button press, and will turn off after about 3 seconds.

Step 2: Carefully remove the Headset with the cap and the electrodes from the subject's head and clean the electrodes immediately. The gel electrodes can be cleaned under warm water. The dry electrodes can be cleaned with cleaning alcohol (do not use water for the dry electrodes).

Step 3: Disconnect the USB-cable of the Base Station and any trigger cables.

Step 4: Put the device and all the accessory into the corresponding slot in the case (see **Figure 1**). Pay attention that the device and the cap are not wet when they are stored. Also the wires mustn't be buckled and wedged-in when the case is closed.

Figure 1: device and accessory in the case

Charging of g.Nautilus

The g.Nautilus Headset is charged via an inductive charging technology according to the QI standard of the wireless power consortium[6]. Position the Headset (switched on or off) on a QI compatible charging pad. Connect the charging pad with the delivered power supply and USB cable to a mains receptacle. Charging starts automatically and is indicated via the permanently blue glowing **STATUS** LED. A blue blinking **STATUS** LED indicates that the capacity has reached 70 % of its maximum. If the **STATUS** LED is flashing very quickly, the accumulator is fully charged. The accumulator cannot be overcharged, so the Headset can stay on the charging pad without being damaged.

ATTENTION

! The charging pad is able to detect whether a device is close that can be charged. Therefore, it is important to put the g.Nautilus with label facing up onto the charging pad.

! The charging pad MUST be placed outside the patient environment, even the device is not charging.

Details for the correct maintenance of the accumulator

The g.Nautilus Headset has a built-in Lithium-Ion accumulator. When the device is delivered, the accumulator is partly charged. Before first use, fully charge the device until the **STATUS** LED starts flashing. If the device is not used for more than 2 weeks, take care that the accumulator is always charged between 50 and 90 %. This will maximize the accumulator's lifetime. So, before longer storage, the device should be charged until the **STATUS** LED blinks slowly. If the device is stored for more than 8 weeks, a risk of deep discharge of the accumulator exists, which could lead to damage! For this reason, the device must be charged every 4 weeks until the **STATUS** LED blinks slowly.

If the device is not switched off after use, it will run until the voltage of the accumulator drops to a certain value and will be switched off automatically. In this case, the device should be charged as soon as possible to prevent deeper discharge and damage to the accumulator.

The longest possible lifetime of a Lithium-Ion accumulator is achieved if it is charged to 100 % and then discharged to less than 20-30 % as rarely as possible. If feasible under the operational conditions, the accumulator should be charged if the **STATUS** LED color changes from turquoise to orange, and charging should be stopped when the **STATUS** LED starts to blink slowly. If the maximum operation time is required, continue charging till the **STATUS** LED flashes quickly.

[6]http://www.wirelesspowerconsortium.com/

Charging of g.Nautilus Headset via a QI-compatible charging pad.

Cleaning and Disinfection of Headset, cap and electrodes

Notes

- The electrode caps do not have an expiration date. Elasticity of the material dictates the life of the cap. When a cap becomes stretched, it loses its elasticity. It must then be discarded and replaced, as the electrode placements will be inaccurate and artifacts may occur more often.
- Do not submerge the device in water, and do not expose it to powerful streams of water such as some cleaning jets.
- Please note that devices that blow warm or hot air, such as devices to dry hands or hair, must not be used to dry electrode caps, because it weakens the elastic material; the cap lifetime will be greatly shortened. Hanging the cap in front of a fan will accelerate drying.
- The g.Nautilus PRO is a noncritical patient contact device.
- Take care that the electrode leads are not damaged during cleaning!
- Do not use excessive force while cleaning.
- The device itself must not come in contact with germicide.
- It is the user's responsibility to qualify any deviations from the recommended method of processing. Users should note appropriate disclaimers if there are deviations. g.tec medical engineering GmbH assumes no responsibility for damage to its products caused by the use of products or processes not recommended in this policy.
- If questions arise, or more information is needed, please call g.tec medical engineering GmbH for assistance:
    a. phone: +43 7251 22240-0
    b. fax: +43 7251 22240-39
    c. mail: office@gtec.at

Initial instructions on how to make the device patient ready

Clean the g.Nautilus PRO before using it for the first time, as described below for gel electrodes or dry electrodes. Check before use that no electrode leads or housing are damaged!

Removing gel:

1. When the EEG recording is finished, remove the cap and ear electrodes.
2. Wipe the patient's forehead and ears with a tissue or cloth towel, and lightly wipe the hair. Brushing or combing the hair will remove all visual evidence of the gel. The patient's next shampoo will easily and completely eliminate any remaining gel.

Containment and Transport

Prior to disinfection (when required), transport the cap and equipment safely (such as in a closed box) and wear appropriate gloves for safety (see Figure 3).

Attention

! Ag/AgCl electrodes and dry electrodes do not have an expiration date, but careful treatment prolongs life time! When an electrode becomes noisier and artifacts occur more often, it must be replaced by the manufacturer only.

Cleaning g.Nautilus PRO: Gel electrodes and cap

After usage, the Headset must be cleaned immediately to prevent the desiccation of gel. All steps must be performed thoroughly.

Equipment: Detergent: multistage enzymatic cleaner (e.g. Sekusept® MultiEnzyme P #3046670 from ECOLAB (www.ecolab.com) or your facility may have a similar product), lukewarm water (20°C to 25°C) of at least drinking water quality, soft brush (e.g. Interlock #09068, #09084), detergent tank.

1. The cleaner should be prepared in accordance to the manufacturer's instructions with a concentration of 2%.
2. Detach the device carefully from the cap, but leave the electrodes in the cap.
3. The device is protected against water splashes, but must not be submerged in water or any fluid!
4. Immerse the submergible part of the device into the detergent (see Figure 2).
5. Soak for at least 30 minutes.
6. Clean all electrodes inside and outside with the brush until all gel is removed (see Figure 3).

Figure 2: bowl with cap and electrodes inside

Attention: Do not submerge the device!

Figure 3: cleaning of the electrodes with the toothbrush

7. Remove the device from the detergent.
8. Immerse the submergible part of the device into a tank with tap water and rinse the cap and the electrodes thoroughly.
9. Visually inspect the cap and each electrode and repeat the preceding steps if necessary.

Disinfection of g.Nautilus PRO: Gel electrodes and cap

Equipment: Low Level disinfectant based on Glucoprotamin (e.g. Sekusept® PLUS #3011100 from ECOLAB (www.ecolab.com) or your facility may have a similar product), lukewarm water (20°C to 25°C) of at least drinking water quality, disinfectant tank.

1. The disinfectant should be prepared in accordance to the manufacturer's instructions.
2. Immerse the submergible part of the device into the detergent (see Figure 2).
3. Continue soaking as long as recommended in the manufacturer's instructions.
4. Remove the device from the disinfectant bath.
5. Rinse the device under tap water for at least 30 seconds (at least 1 liter).
6. Put one towel inside the cap and one towel outside to remove the water.
7. Put the cap in an appropriate place for drying (see Figure 4). The cap will dry in about one hour.
8. Avoid stretching the cap's fabric during the process of drying.
9. Take care that all components are completely dry before storing or packing g.Nautilus PRO.

Figure 4: one example of a way to dry the wet electrode system

Cleaning g.Nautilus PRO: Dry electrodes and cap
All steps must be performed thoroughly.

Equipment: Detergent: multistage enzymatic cleaner (e.g. Sekusept® MultiEnzyme P #3046670 from ECOLAB (www.ecolab.com) or your facility may have a similar product), lukewarm water (20°C to 25°C) of at least drinking water quality, detergent tank.

1. The cleaner should be prepared in accordance to the manufacturer's instructions.
2. Detach the dry electrodes and the device with the wires from the cap (see Figure 5).
3. The device is protected against water splashes, but must not be submerged in water or any other fluid!
4. Immerse the submergible part of the cap into the detergent (see Figure 6).
5. Soak for at least 30 minutes.

Figure 5: assembly and disassembly of the wires from the dry electrodes

Attention: Do not submerge the device!

6. Remove the cap from the detergent.
7. Immerse the submergible part of the cap into a tank with tap water and rinse the cap thoroughly.
8. Visually inspect the cap and each electrode and repeat the preceding steps if necessary.

Figure 6: submergible part

Disinfection g.Nautilus PRO: Dry electrodes and cap
Equpiment: cleaning and disinfection wipes (e.g. Mikrozid® sensitive wipes #70000807, Mikrozid® AF wipes #109203 from Schülke & Mayr GmbH (www.schuelke.com), or your facility may have a similar product).

1. Clean the pins of the dry electrodes with the cleaning wipe (see Figure 7).
2. Be sure to wipe all surfaces thoroughly.
3. Take a disinfection wipe and repeat step 1 and 2.
4. Don't use water.
5. When the cap is dry, reassemble the device and the electrodes on the cap.
6. Take care that all components are completely dry before storing or packing g.Nautilus PRO.

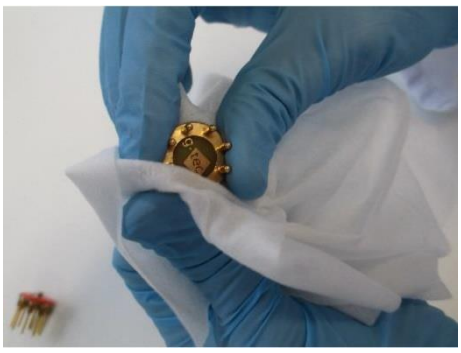


Figure 7: cleaning of the pins

Equipment: Low Level disinfectant based on Glucoprotamin (e.g. Sekusept® PLUS #3011100 from ECOLAB (www.ecolab.com) or your facility may have a similar product), lukewarm water (20°C to 25°C) of at least drinking water quality, disinfectant tank.

7. The disinfectant should be prepared in accordance to the manufacturer's instructions.
8. Immerse the submergible part of the device into the detergent (see Figure 6).
9. Continue soaking as long as recommended in the manufacturer's instructions.
10. Remove the device from the disinfectant bath.
11. Rinse the device under tap water for at least 30 seconds (at least 1 liter).
12. Put one towel inside the cap and one towel outside to remove the water.
13. Put the cap in an appropriate place for drying (see Figure 4). The cap will dry in about one hour.
14. Avoid stretching the cap's fabric during the drying process.
15. Take care that all components are completely dry before storing or packing g.Nautilus PRO.

Cleaning and Disinfection of enclosure parts of Headset, Base Station and charging pad

Equpiment: cleaning and disinfection wipes (e.g. Mikrozid® sensitive wipes #70000807, Mikrozid® AF wipes #109203 from Schülke & Mayr GmbH (www.schuelke.com), or your facility may have a similar product).

1. Clean the device enclosure with the cleaning wipes.
2. Be sure to wipe all surfaces thoroughly and keep them wet for the whole exposure time.
3. Take a disinfection wipe and repeat steps 1 and 2.
4. Ensure that all components are completely dry before storing or packing.

Attention

! During cleaning and disinfection, the Base Station must be disconnected from the PC.
! During cleaning and disinfection, the charging pad must be disconnected from the main voltage supply.
! Do not spill fluids on the Headset, Base Station, or charging pad.

11 General notes

Classification

Safety Class	II
Type of applied part	BF
Protection against mechanical distortion and liquids (Headset)	IP44
Protection against mechanical distortion and liquids (Headset)	IP40
Operation mode	S1 (Permanent operation)
Conformity class	IIa

Transportation and storage conditions

The device can be stored at temperatures between –20° to +45° Celsius. The relative humidity must be between 25 % and 80 %. If there is any condensed water, wait until it disappears before use (wait at least 1h in a heated room).

Location details

Do not use the device near a heating system or directly in the sun. During operation, the outside temperature should be between +5° Celsius and +35° Celsius and the air pressure between 700 and 1060 hPa.

Waste disposal details

Bring the device to a recycling center or sent it back to the manufacturer.

Warranty

One-year warranty

12 Declaration of conformity

The declaration of conformity is available on request.

13 Technical specifications

Model	g.Nautilus PRO
Type	NAUTILUS-32 or NAUTILUS-32-SAHARA or NAUTILUS-16 or NAUTILUS-16-SAHARA or NAUTILUS-8 or NAUTILUS-8-SAHARA or NAUTILUS-CSP32 NAUTILUS-CSP32-SAHARA NAUTILUS-CSP16mB NAUTILUS-CSP16mB-SAHARA NAUTILUS-CSP16rX NAUTILUS-CSP16rX-SAHARA
Accumulator	PA-L36.K06.R001, 1300 mAh, IEC 62133(ed.2)
Rated power consumption	0.5 W
Rated DC voltage	3.7 V
Rated current of fuse	Little fuse 0467001.NR (1.0 A)
Rated voltage of fuse	32 V
Produced	see serial number of g.Nautilus Headset
Manufacturer	g.tec medical engineering GmbH Sierningstrasse 14 4521 Schiedlberg Austria http://www.gtec.at

Amplifier Settings

Channels 1 to 32 and REF channel

Sensitivity	± 187.5 mV to ± 2.25 V
Highpass:	0 Hz
Lowpass:	10.23 kHz
Input impedance:	>100 MΩ

Acceleration sensor

x-, y- and z-axis	±6 g (bias of 0 – 0.4 g)

Analog-Digital-Converter (ADC)

Resolution	24 Bit
Sampling frequency	250 / 500 Hz
Number of ADCs	32

Analog signal processing time and digital inputs

Sampling frequency	ASD AI/DI *)
Hz	Samples
250	2 to 3 + 0 to 11
500	2 to 3 + 0 to 11

*) Analog Signal line Delay between the Analog Input of the Headset and the Digital Input of the Base Station due to the Analog to Digital converter in the Headset and the wireless transmission between Headset and Base Station.

Due to the intrinsic filtering and down sampling of the ADC for analog channels, there is a delay between the analog biosignal input and digital trigger input lines (2 to 3 samples). For the electrode input signal a 70 % threshold was used for specify logic HIGH level.

Due to an internal ring buffer in the Headset, that is able to buffer 11 frames to minimize data loss, an additional delay (up to 11 samples) may be added, depending on the quality of the connection.

RF module

Frequency band	2.4 GHz
Transmission power	+3 dBm
IEEE standard	802.15.4
Marking	CE, ETSI, FCC
FCC ID:	XVV-MEGA22M00

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.

Maximum voltages at the following sockets on Base Station:

USB	5 V DC
DIGITAL IN	5 V DC

Digital inputs

Sensitivity:	3.3 V / 5 V
Logic Low:	≤ 0.66 V
Logic High:	≥ 2.31 V

14 Electromagnetic compatibility

Please keep in mind the precautions in this **Instruction for Use** manual before installing and operating g.Nautilus. Note that HF-communication devices (e.g. mobile phones, routers etc.) may interfere with electric devices. g.Nautilus must not be used near, or stockpiled with, other devices. Only the original components for g.Nautilus from g.tec medical engineering GmbH are to be used for this device. Using third party manufacturer accessories may result in increased emission or decreased functional immunity of g.Nautilus, and/or other problems. As electric and magnetic fields may interfere with the functional reliability of the device, avoid using g.Nautilus close to devices emitting electro-magnetic fields.

The following values are the values given by EN 60601-1-2 for electromagnetic immunity testing:

Immunity test	**IEC 60601 test level**	**Compliance level**
Conducted RF IEC 61000-4-6	3 Veff 150 kHz to 80 MHz	1 → $V1$ in V [7]
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	1 → $E1$ in V/m [3]

During all tests, g.Nautilus PRO was in acquisition mode, which is the most significant operating mode for the wireless transmission.

[7] The lower compliance levels are allowed (according to normative EN60601-1-2, top 36.202.1 A) as g.Nautilus must be able to accurately measure biosignals with very low amplitudes. Using electromagnetic interference suppression would yield an inappropriately low signal to noise ratio for g.Nautilus.

Table 1

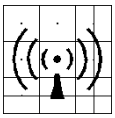
Guidance and manufacturer´s declaration – electromagnetic emission		
The g.Nautilus is intended for use in the electromagnetic environment specified below. The customer or the user of the g.Nautilus should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The g.Nautilus uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The g.Nautilus is suitable for use in all establishments, including domestic establishments 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	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Table 2

Guidance and manufacturer´s declaration – electromagnetic immunity The g.Nautilus is intended for use in the electromagnetic enviroment specified below. The customer or the user of the g.Nautilus should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge 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	Not applicable as all cables have a maximum length of 3 meters.	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	Not applicable as all cables have a maximum length of 3 meters.	Mains power quality should be that of a typical commercial or hospital environment.
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 ½ 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 s	Not applicable as no mains supply port available.	Mains power quality should be that of a typical commercial or hospital environment. If the use of the g.Nautilus PRO requires continued operation during power mains interrupts, it is recommended that the g.Nautilus PRO be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz/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 a.c. mains voltage prior to application of the test level.			

Table 4

Guidance and manufacturer´s declaration – electromagnetic immunity The g.Nautilus is intended for use in the electromagnetic enviroment specified below. The customer or the user of the g.Nautilus should assure 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 g.Nautilus PRO , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter: **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 → $V1$ in V *)	$d = \left(\frac{3,5}{V1}\right) * \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 → $E1$ in V/m *)	$d = \left(\frac{3,5}{E1}\right) * \sqrt{P}$ 80 MHz to 800 MHz
		*) In the frequency range 20 MHz up to 400 MHz, the compliance level is only 1 V_{eff} or 1 V/m, respectively.	$d = \left(\frac{7}{E1}\right) * \sqrt{P}$ 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 metres (m).[b] Field strengths from fixed RF transmitters, as determined by an 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, an electromagnetic site survey should be considered. If the measured field strength in the location in which the g.Nautilus PRO is used exceeds the applicable RF compliance level above, the g.Nautilus PRO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the g.Nautilus PRO.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Table 6

Recommended separation distances between portable and mobile RF communications equipment and the g.Nautilus PRO

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

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**				
	150 kHz to 20 MHz $d = \left(\frac{3,5}{V1}\right) * \sqrt{P}$	**20 MHz to 80 MHz** $d = \left(\frac{3,5}{V1}\right) * \sqrt{P}$	**80 MHz to 400 MHz** $d = \left(\frac{3,5}{E1}\right) * \sqrt{P}$	**400 MHz to 800 MHz** $d = \left(\frac{3,5}{E1}\right) * \sqrt{P}$	**800 MHz to 2,5 GHz** $d = \left(\frac{7}{E1}\right) * \sqrt{P}$
0,01	0,12	0,35	0,35	0,12	0,23
0,1	0,37	1,11	1,11	0,37	0,74
1	1,17	3,50	3,50	1,17	2,33
10	3,69	11,07	11,07	3,69	7,38
100	11,67	35,00	35,00	11,67	23,33

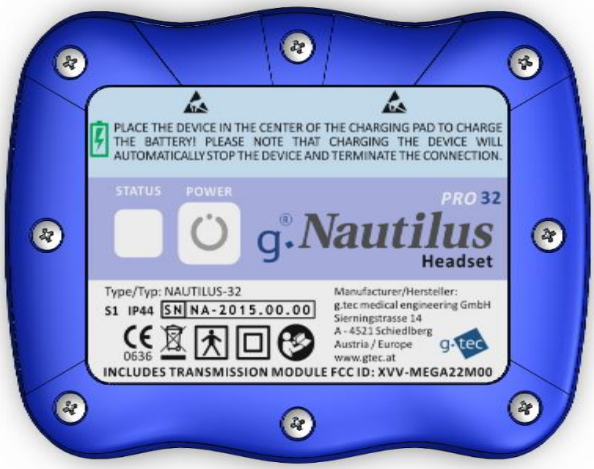
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter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

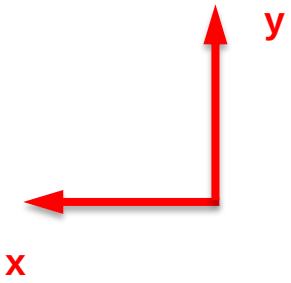
NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

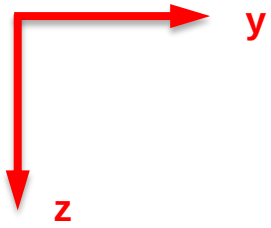
15 Appendix

g.Nautilus PRO Headset

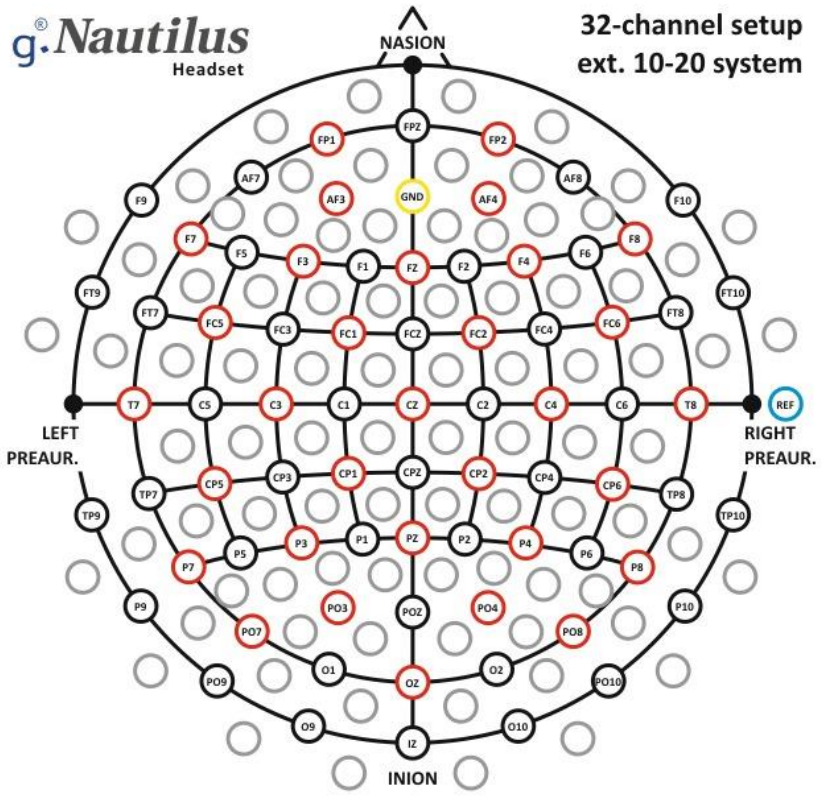
Acceleration sensor





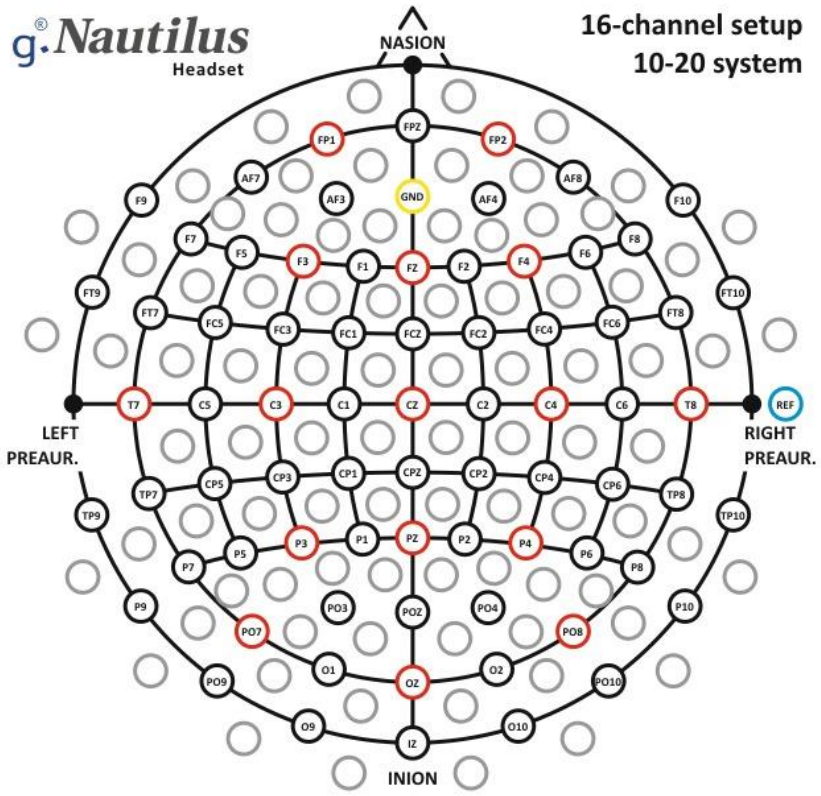


g.Nautilus PRO (32-channel setup)



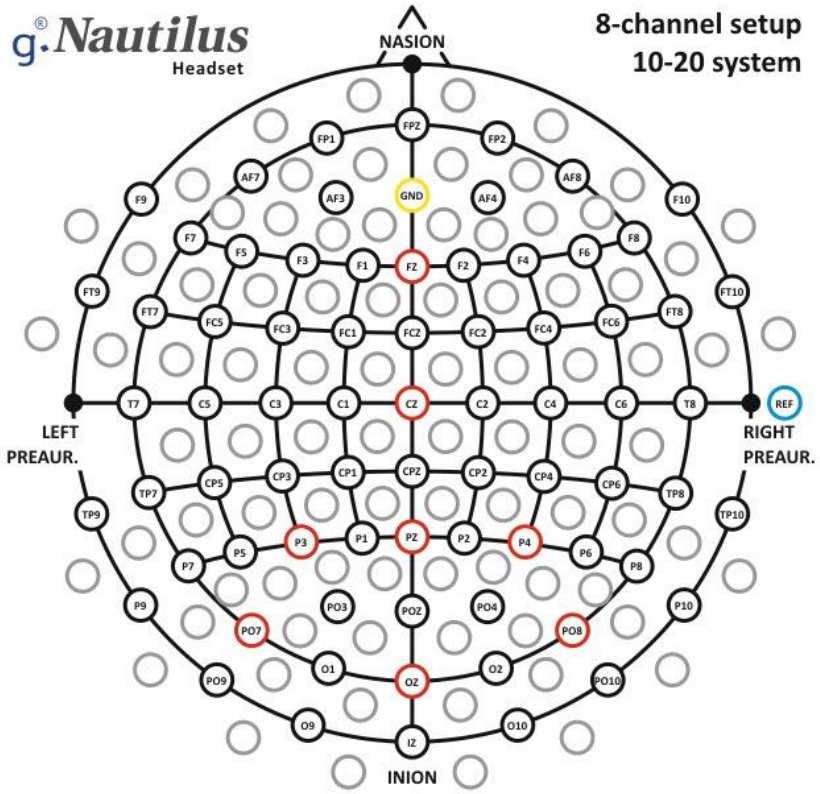
Electrode	Logical Channel
FP1	1
FP2	2
AF3	3
AF4	4
F7	5
F3	6
FZ	7
F4	8
F8	9
FC5	10
FC1	11
FC2	12
FC6	13
T7	14
C3	15
CZ	16
C4	17
T8	18
CP5	19
CP1	20
CP2	21
CP6	22
P7	23
P3	24
PZ	25
P4	26
P8	27
PO7	28
PO3	29
PO4	30
PO8	31
OZ	32

g.Nautilus PRO (16-channel setup)



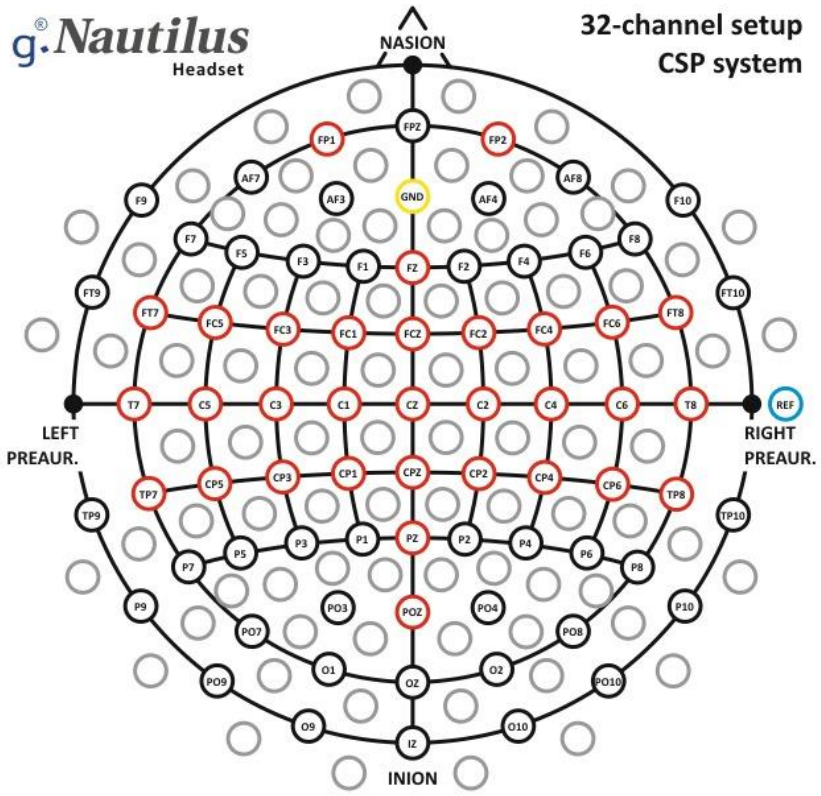
Electrode	Logical Channel
FP1	1
FP2	2
F3	3
FZ	4
F4	5
T7	6
C3	7
CZ	8
C4	9
T8	10
P3	11
PZ	12
P4	13
PO7	14
PO8	15
OZ	16

g.Nautilus PRO (8-channel setup)



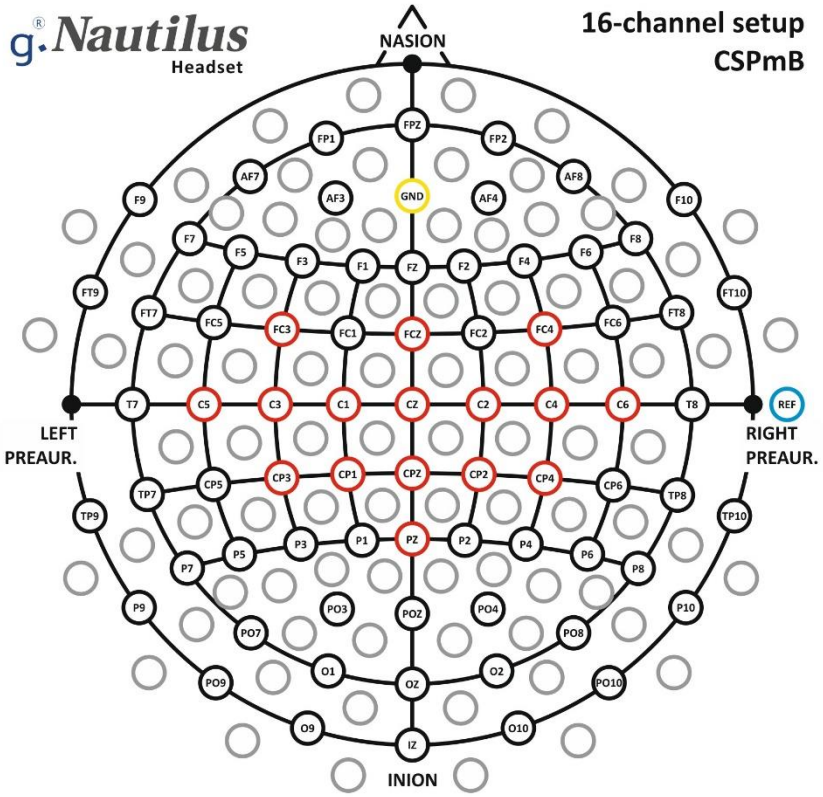
Electrode	Logical Channel
FZ	1
CZ	2
P3	3
PZ	4
P4	5
PO7	6
PO8	7
OZ	8

g.Nautilus PRO (32-channel setup CSP system)



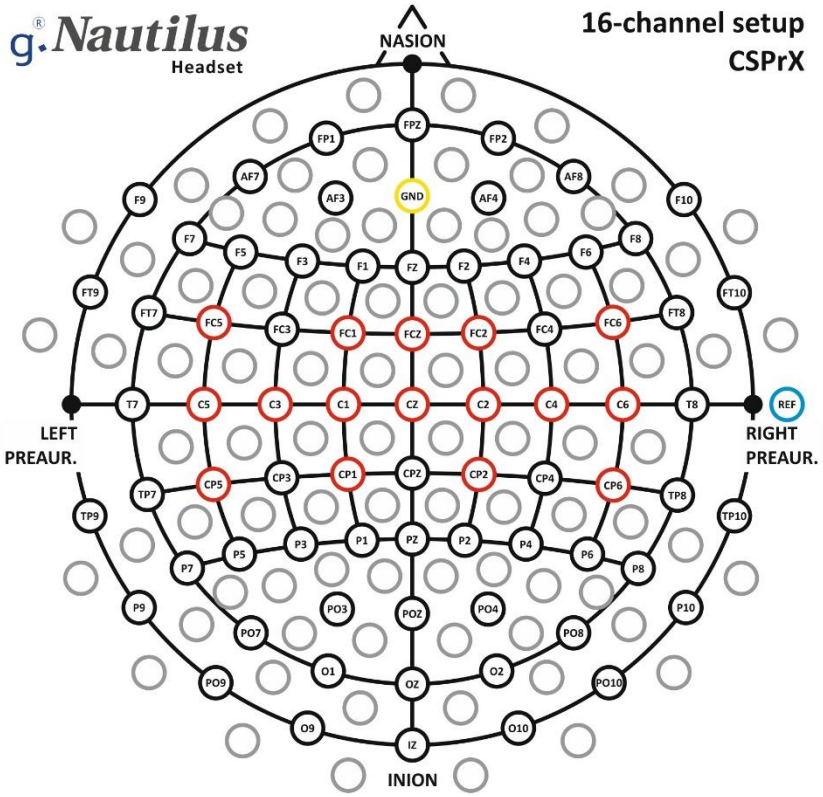
Electrode	Logical Channel
FP1	1
FP2	2
FZ	3
FT7	4
FC5	5
FC3	6
FC1	7
FCZ	8
FC2	9
FC4	10
FC6	11
FT8	12
T7	13
C5	14
C3	15
C1	16
CZ	17
C2	18
C4	19
C6	20
T8	21
TP7	22
CP5	23
CP3	24
CP1	25
CPZ	26
CP2	27
CP4	28
CP6	29
TP8	30
PZ	31
POZ	32

g.Nautilus PRO (16-channel setup CSPmB system)



Electrode	Logical Channel
FC3	1
FCz	2
FC4	3
C5	4
C3	5
C1	6
Cz	7
C2	8
C4	9
C6	10
CP3	11
CP1	12
CPz	13
CP2	14
CP4	15
Pz	16

g.Nautilus PRO (16-channel setup CSPrX system)

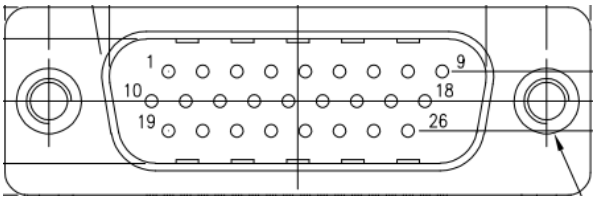


Electrode	Logical Channel
FC5	1
FC1	2
FCz	3
FC2	4
FC6	5
C5	6
C3	7
C1	8
Cz	9
C2	10
C4	11
C6	12
CP5	13
CP1	14
CP2	15
CP6	16

g.Nautilus PRO Base Station PIN assignment

Digital Inputs

Pin-assignment for the 26 pin Sub-D plug INPUTS



Pin 1 digital input 1 (3.3 V tolerant)
Pin 2 digital input 2 (3.3 V tolerant)
Pin 3 digital input 3 (3.3 V tolerant)
Pin 4 digital input 4 (3.3 V tolerant)
Pin 5 digital input 5 (5 V tolerant)
Pin 6 digital input 6 (5 V tolerant)
Pin 7 digital input 7 (5 V tolerant)
Pin 8 digital input 8 (5 V tolerant)
Pin 9 NC
Pin 10 NC
Pin 11 NC
Pin 12 NC
Pin 13 NC
Pin 14 NC
Pin 15 NC
Pin 16 NC
Pin 17 + 3.3 V dc
Pin 18 + 3.3 V dc
Pin 19 GND
Pin 20 GND
Pin 21 NC
Pin 22 NC
Pin 23 NC
Pin 24 NC
Pin 25 NC
Pin 26 NC

Information to aid in the detection of failures

Item	Issue	Reason	Solution
1	Data loss during acquisition (indicated by Validation Indicator)	The chosen network channel is occupied or disturbed by another wireless device (WIFI, Bluetooth, ZigBee or another device using the 2.4GHz ISM band)	• Choose another channel via end user software, or power cycle Headset and Base Station to initiate a new automatic channel selection • Eliminate interference sources such as wireless routers, mobile phones or Bluetooth devices
2	Data loss during acquisition (indicated by Validation Indicator)	Headset and its Base Station are out of range	Reposition Headset to be in wireless range of its Base Station (use Link Quality Indicator as measure).
3	No data is received (indicated by Validation Indicator)	Loss of battery power on Headset	Place Headset on charging pad
4	Error during configuration process	The chosen network channel is occupied by another wireless device (WIFI, Bluetooth, ZigBee or another device using the 2.4GHz ISM band)	Power cycle Headset and Base Station to initiate new automatic channel selection
5	Headset and/or Base Station indicated loss of pairing and do not automatically re-pair	The chosen network channel is occupied by another wireless device (WIFI, Bluetooth, ZigBee or another device using the 2.4GHz ISM band)	Power cycle Headset and Base Station to initiate automatic pairing mechanism
6	Bad signal quality indicated in end user software	• Distance between Headset and its Base Station is too great • Adverse arrangement of Headset and its Base Station (dependent on spatial conditions)	• Reduce distance between Headset and its Base Station • Change spatial arrangement of Headset and its Base Station
7	Headset is in acquisition mode but Base Station is not	• Acquisition has been stopped while Headset was out of range, or wireless channel encountered heavy interference while acquisition was stopped • USB cable has been removed from Base Station while acquisition was running	1. Turn off Headset 2. Wait until Base Station indicates non-paired state 3. Turn on Headset
8	Base Station is in acquisition mode but Headset is not	• Headset has been turned off while acquisition was running. • Headset has been placed on charging pad while acquisition was running. • Headset ran out of battery power • Wireless channel encountered heavy interference while acquisition was stopped	1. Disconnect and reconnect USB cable from Base Station to initiate automatic pairing sequence. 2. Turn on Headset • Charge Headset
9	Headset is not being charged, although it has been placed on charging pad.	• Headset is not centered on charging pad. • Headset has no direct contact with the charging pad (something is placed between charging pad and Headset, e.g. electrode cap). • Headset is not placed on the correct side of the charging pad. • Charging pad is not correctly powered.	• Check positioning of Headset on charging pad. • Make sure that nothing is positioned between Headset and charging pad. • Place the Headset on the side with no labeling. • Check if USB cable of the charging pad is correctly connected with the charging pad, and the light turns green on the power adapter and the charging pad.

10	One or more electrodes do not provide a correct signal	• Bad electrode/skin contact
		• When using wet electrodes:
		  ○ No gel in electrode
		  ○ Gel has no contact with skin
		• When using dry electrodes:
		  ○ Too much offset voltage
			• Check electrode/skin contact
			• Apply gel to wet electrodes
			• Check condition of the electrodes' connection cables (look for damage)
			• Reduce input sensitivity with dry electrodes

11	Headset cannot be turned on or signaling LED is blinking quickly in orange	• Battery is too low for correct operation	• Place Headset on charging pad to start charging cycle
12	Impedance measurement is not working properly	• Distance between Headset and its Base Station is too high • The used wireless channel is highly disturbed	• Minimize distance between Headset and its Base Station • Change wireless channel
13	• Base Station is not able to pair with its Headset • Headset is not able to pair with its Base Station	• Headset or Base Station is not powered on • Wrong combination of Headset and Base Station is used.	• Power on Headset and Base Station • Confirm that the serial numbers of Headset and Base Station are equal

Manual Best Channel Selection

g.Nautilus PRO includes an automatic channel selection algorithm to determine and select the best possible wireless channel for wireless data transmission. The channel selection algorithm is executed as soon as the g.Nautilus PRO Base Station is powered on. The measurements executed by this algorithm are always only a snapshot of the actual situation within the transmission band. Hence, future data acquisition may be affected by changes in the situation within the transmission frequency band (e.g. interferers appear after channel selection algorithm is executed). If problems related to the wireless connection between g.Nautilus PRO Headset and Base Station occur, we recommend performing the following steps to manually select the optimal g.Nautilus PRO network channel and achieve optimal performance for measurement with g.Nautilus PRO.

Step 1: Eliminate all possible sources of interference.
Since g.Nautilus operates within the worldwide free usable 2.4 GHz ISM band, it is essential for optimal device operation that there are no possible interferers enabled that are operating within this frequency band. Therefore, please make sure that:

- If applicable, please make sure that all existing g.Nautilus PRO devices in the vicinity use their own channel separated by at least one channel, e.g. 11, 13, 15 etc., or are switched off when not used (Headsets and Base Stations)
- If applicable, please make sure that all Bluetooth devices (e.g. Smartphones) within the operating range of g.Nautilus PRO are disabled.
- If applicable, please make sure that all ZigBee devices within the operating range of g.Nautilus PRO are disabled.
- If applicable, please make sure that all wireless LAN devices within the operating range of g.Nautilus PRO are disabled.
- If applicable, please make sure that all other devices that are operating within the 2.4GHz ISM band are disabled.

Step 2: Check for existing wireless LAN networks.
Use a Wi-Fi scanning software to examine wireless LAN situation in vicinity of your g.Nautilus PRO device. Check the signal strength of all wireless LAN channels. Identify which Wi-Fi channels are used by the existing wireless LAN networks, and which networks have the lowest signal strengths.

Step 3: Connect the g.Nautilus PRO Base Station to your PC via the provided USB cable to initiate the automatic channel selection and the pairing process between g.Nautilus PRO Headset and Base Station.

Step 4: Turn on the g.Nautilus PRO Headset by pressing the power on button for approximately 3 seconds.

Step 5: As soon as g.Nautilus PRO Headset and Base Station have successfully paired (indicated by LED), check the chosen network channel.

Step 6: Use the following table to determine whether the channel actually used by g.Nautilus PRO overlaps with an occupied Wi-Fi channel examined in step 2.

g.Nautilus PRO Channel	Overlap with Wi-Fi Channel
11	1, 2
12	1, 2, 3
13	1, 2, 3, 4
14	1, 2, 3, 4, 5
15	2, 3, 4, 5, 6
16	3, 4, 5, 6, 7
17	4, 5, 6, 7, 8
18	5, 6, 7, 8, 9
19	6, 7, 8, 9, 10
20	7, 8, 9, 10, 11
21	8, 9, 10, 11, 12
22	9, 10, 11, 12, 13
23	10, 11, 12, 13
24	11, 12, 13
25	12, 13, 14

Step 7: Via g.Nautilus PRO end user software, manually select a network channel. Apply the following rules to select the channel:

- If more than one g.Nautilus PRO channel exists that does not overlap with an existing Wi-Fi channel, choose the one furthest away from this Wi-Fi channel.
- If only one g.Nautilus PRO channel exists that does not overlap with an existing Wi-Fi channel, choose this one.
- If no g.Nautilus PRO channel exists that does not overlap with an existing Wi-Fi channel, choose one that overlaps with the Wi-Fi channel with the lowest signal strength.

Step 8: Verify performance of the wireless transmission by starting data acquisition and monitoring the validation indicator and the link quality indicator of the acquired data.