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g.Nautilus
WIRELESS BIOSIGNAL ACQUISITION

g.Nautilus Research

Instructions for use

V1.14.02

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1 Important Notes

"g.Nautilus Research" is not a medical device and is intended to be used for research purposes only. It is not intended for medical applications, such as diagnosis or treatment or disease.

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 Research or touching the electrodes. (see Chapter *Save operation of g.Nautilus Research*)
- the device must **not** be used in humans with pace-makers or electrical stimulators
- pay attention to the precautions regarding electromagnetic compatibility (see Chapter *Electromagnetic compatibility*)
- the operator has to be familiar with the operation of g.Nautilus Research and must operate the device according to the instructions for use manual
- each time you use g.Nautilus Research, 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!
- If g.Nautilus Research is used at the same time with other devices on subjects, the following leakage currents have to be checked:
 - Ground leakage current
 - Enclosure leakage current
 - Patient leakage current

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 Research.

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:

- a) changes to the device must be performed by the manufacturer only, and service and repair must be performed only by corresponding qualified personnel.
- b) the device must be used according to the instructions for use.

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

Electromagnetic compatibility

g.Nautilus Research and its components have been tested for EMC compatibility.

Warning: This device/system must be used by qualified personnel exclusively. This device/system may cause radio-interference or may interfere with other devices in the vicinity. If these problems occur, try one or more of the following measures:

- reorient or relocate the receiving device.
- increase the separation between the equipment.

If there are any questions, please contact technical service, the local specialist dealer or the manufacturer.

The intended use of the equipment

g.Nautilus Research is not a medical device and is intended to be used for research purposes only. The device is not intended to be used for other medical applications such as aiding in diagnosis or treatment or disease. The device is meant to measure and record electrical activity from the brain (electroencephalogram, or EEG) in research.

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 85 %. The device **must not** be used in combination with any other high-frequency device. Using a high frequency device with g.Nautilus Research can cause burning under the electrodes and could damage the device.

Recommended electrodes

The device is delivered with a fixed, non-exchangeable electrode configuration (maximum 32 electrodes in defined arrangement with reference- and ground-electrode). The electrode impedances should be below 30 kOhm.

Properties of PC or notebook

g.Nautilus Research requires a PC, notebook or embedded computer running a Microsoft Windows operating system (Windows 7 Professional English or higher).

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

2 g.Nautilus Research introduction

g.Nautilus Research is g.tec's biopotential amplifier with wireless data transmission technology and active wet or dry electrodes. The device can acquire EEG data with 24 Bit resolution and a sampling rate of 250 or 500 Hz.

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 sampling rate of 250 or 500 Hz. The user may choose this sampling rate. 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 Research is controlled via an Application Programming Interface (C-API).

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



g.Nautilus Research Headset device

Highlights

- EEG recordings without cable connection via radio signal
- active wet or dry electrodes
- 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 PC or notebook
- 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 ± 185 mV up to ± 2.25 V

3 g.Nautilus Research components

g.Nautilus Research consists of the following basic components

1 g.Nautilus Research Headset - wireless biopotential amplifier with prefixed electrode strands and a cap in size M (g.GAMMAcap² for g.Nautilus is a g.GAMMAcap² with a special Velcro pad to attach the g.Nautilus Headset device; please see the manual “gGAMMAcap_InstructionsForUse.pdf” for details about the cap).

1 g.Nautilus Research Base Station - stationary receiver unit with USB cable

1 Instructions for use manual

1 Qi-compatible charging device

Different versions of g.Nautilus

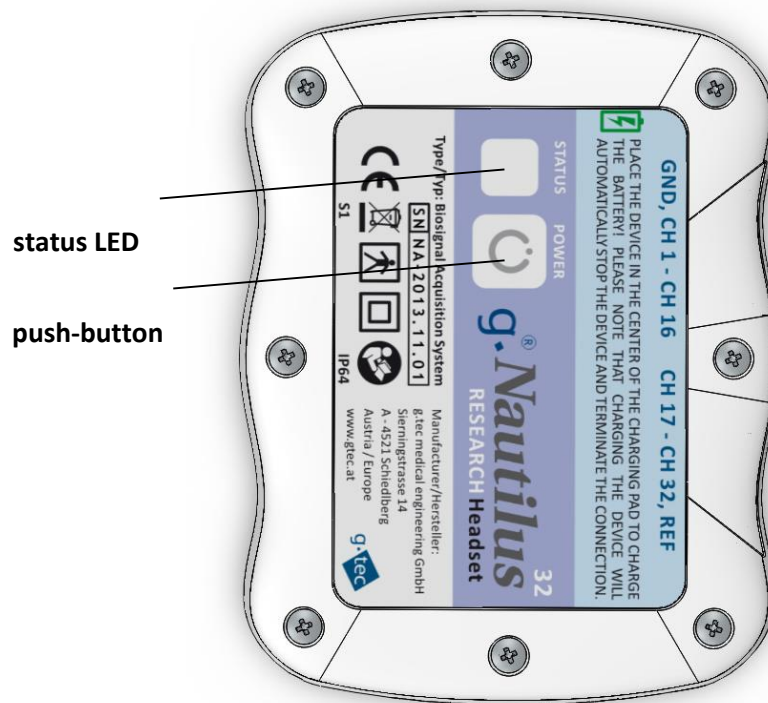
g.Nautilus Research is available with several different electrode layouts. The maximum number of channels is 32. Please contact g.tec for details about available electrode layouts for special applications.

Different types of electrodes

g.Nautilus Research can be equipped with gel-based active electrodes (g.LADYbird technology) or with dry active electrodes (g.SAHARA technology). It is not possible to change between these two options in an existing device! For g.Nautilus Research, electrodes (g.LADYbird) or electrode clip connectors (g.SAHARA) are connected to the device with special flexible PCB strands instead of wires and cannot be disconnected from the Headset device. For details about the application of the electrodes, please see the manuals “gGAMMAcap_InstructionsForUse.pdf” (section 4) and “gSAHARAsys_InstructionsForUse.pdf” (section 7).

4 Explanation of switches and LEDs

Switches and LEDs on g.Nautilus Research headset



g.Nautilus Research Headset, switches and LED

g.Nautilus Research is equipped with 2 monopolar amplification-groups with separate electrode strands (each with 17 electrodes).

Group A:	Channels 01-16: 16 analog input-channels for EEG and GND channel
Group B:	Channels 17-32: 16 analog input-channels for EEG and REF channel
POWER:	Push-button for turning the device on and off
STATUS:	A multi-color LED indicates the status of the device

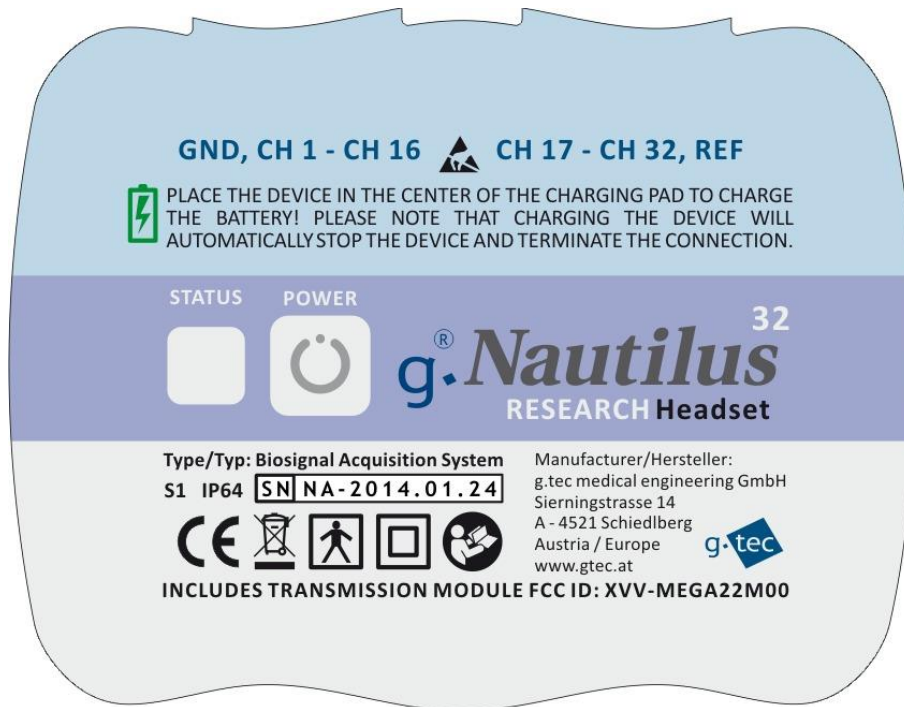
Indications of operation mode

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 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 headset



Label of Headset



CE mark



Do not dispose g.Nautilus Research 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



Standby for a part of the device

Manufacturer/Hersteller:
g.tec - medical engineering GmbH
Sierningstrasse 14
A - 4521 Schiedlberg
Austria / Europe
office@gtec.at
www.gtec.at

Manufacturer address

Type: Biosignal Acquisition System

Device type

IP 64

IP 64: No ingress of dust; complete protection against contact (dust tight).
Water splashing against the enclosure from any direction shall have no harmful effect.

S1

S1: permanent operation

SN NA-2013.04.01

Serial number in the format:
NA-YearOfProduction.Month.Number

XVV-MEGA22M00

FCC-ID of included transmission module

6 Base Station and USB-cable

The Base Station and the corresponding USB-cable, together with a connected PC and driver, allow the communication with the g.Nautilus Research Headset.



Base Station



USB connection cable

7 Safe operation of g.Nautilus Research

Setting up the device

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 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 Research:

Step 1: Place the Headset on the head of the subject and position the electrodes according to the international 10/20 electrode system¹. Fill all electrodes with conductive gel. You must coat at least 1 cm² of skin under electrode with, gel and the electrode must be filled completely. The electrode impedance should be below 30 kOhm.

Step 2: 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 switched on even after the accumulator has been fully charged.

Step 3: Connect the Base Station, using the USB cable, to a free USB port on your PC. 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.

Step 4: 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 Research 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.

Measuring biosignal data

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 the PC.

¹Webster, J.G., (Ed.): Medical Instrumentation: Application and Design, p.194-216. Houghton Mifflin: Boston 1992.

Impedance measurement

An internally generated square wave (+/- 7.5 mV) is supplied to the ground electrode. The transmitted signals can be evaluated to calculate the electrode impedance at 10 Hz.

Switching off and storage of g.Nautilus Research Headset

To switch off and store g.Nautilus Research 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.

Step 3: Disconnect the USB-cable of the Base Station.

Charging of g.Nautilus Research Headset

The g.Nautilus Research Headset is charged via an inductive charging technology according to the Qi standard of the Wireless Power Consortium². Position the Headset (switched on or off) onto a Qi compatible charging pad. Charging starts automatically and is indicated via the permanently blue glowing status-LED (see **Error! Reference source not found.**). 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.

Details for the correct maintenance of the accumulator:

The g.Nautilus Research 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, or every 8 weeks at most, until the status-LED blinks slowly.

In case the device is not switched off after use, it will run until the voltage of the accumulator falls to a critical value and will switch off automatically. In this case, the device should be charged as soon as possible to prevent deeper discharge and damage of 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 % happens 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 shows flashes quickly.

²<http://www.wirelesspowerconsortium.com/>



Charging of g.Nautilus Research Headset via a Qi-compatible charging pad. The design of the charging device may vary.

Cleaning of headset and electrodes

After usage, the Headset must be cleaned immediately to prevent the desiccation of gel. Use a flat bowl (about 10 cm deep) filled with warm water. A small amount of soap or shampoo may be used. Detach the device carefully from the cap, but leave the electrodes in the cap. Soak the cap with the electrodes for about 2 minutes in warm water. The device itself is splash water protected, but must not submerged into water! Clean all electrodes inside and outside with a soft toothbrush, ideally under water, until all gel is removed. Take care that the electrode leads are not damaged during cleaning! Do not use excessive force while cleaning. Finally, rinse the cap and all electrodes with clean, lukewarm water. Again, do not submerge the device in water, and do not expose it powerful streams of water such as some cleaning jets.

Put one towel inside the cap and one towel outside to remove the water. Then, put the cap in an appropriate place for drying. Avoid stretching the cap's fabric during the process of drying. 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. Careful treatment prolongs life time. Take care that all components are fully dry before storing or packing g.Nautilus Research!

After drying, the cap and the electrodes may be disinfected by submerging them into 70 % Isopropanol for 2 minutes. The device itself must be prevented from germicide.

8 General notes

Classification

Safety Class	II
Type of applied part	BF
Protection against mechanical distortion and liquids	IP64
Operation mode	S1 (Permanent operation)
Conformity class	Ila

Transportation and storage conditions

The device can be stored at temperatures between –20 to +45 degrees Celsius. The relative humidity must be between 25 % and 65 %. 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 +45° Celsius.

Waste disposal details

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

9 Declaration of Conformity

Product name

Product: g.Nautilus Research Headset

Manufacturer

g.tec medical engineering GmbH, Sierningstrasse 14, 4521 Schiedlberg, Austria

Classification

Safety class	II
Type of applied part	BF
Protection against mechanical distortion and liquids	IP64
Operation Mode	S1 (Permanent operation)

CE mark



CE mark

g.Nautilus Research is NOT a medical product and has not been designed to serve as a medical product according to 93/42/EWG. Electrical safety and EMC has been followed for:

EN Standards:

EN 60601-1/1990 +A1/93 +A2/95
EN 60601-1-2: 2007
EN 60601-2-26: 2004

IEC Standards:

IEC 60601-1: 1988+A1/91 +A2/95
IEC 60601-1-2: 2007
IEC 60601-2-26: 2004

Dr. Christoph Guger
Chief Executive Officer

Dr. Günter Edlinger
Chief Executive Officer

Schiedlberg, January 2014

10 Technical specifications

g.Nautilus Research

Model	g.Nautilus Research Headset
Type	wireless biosignal acquisition system
Accumulator	LIP 523450 AJL, 1100 mAh
Rated power consumption	0.5 W
Rated DC voltage	3.7 V
Rated current of fuse	Little fuse 0467.500NR (0.5 A)
Rated voltage of the fuse	32 V
Produced	see serial number of g.Nautilus Research 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	$\pm 185 \text{ mV to } \pm 2.25 \text{ V}$
Highpass:	0 Hz
Lowpass:	10.23 kHz
Input impedance:	$>100 \text{ M}\Omega$

Analog-Digital-Converter (ADC)

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

RF module

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

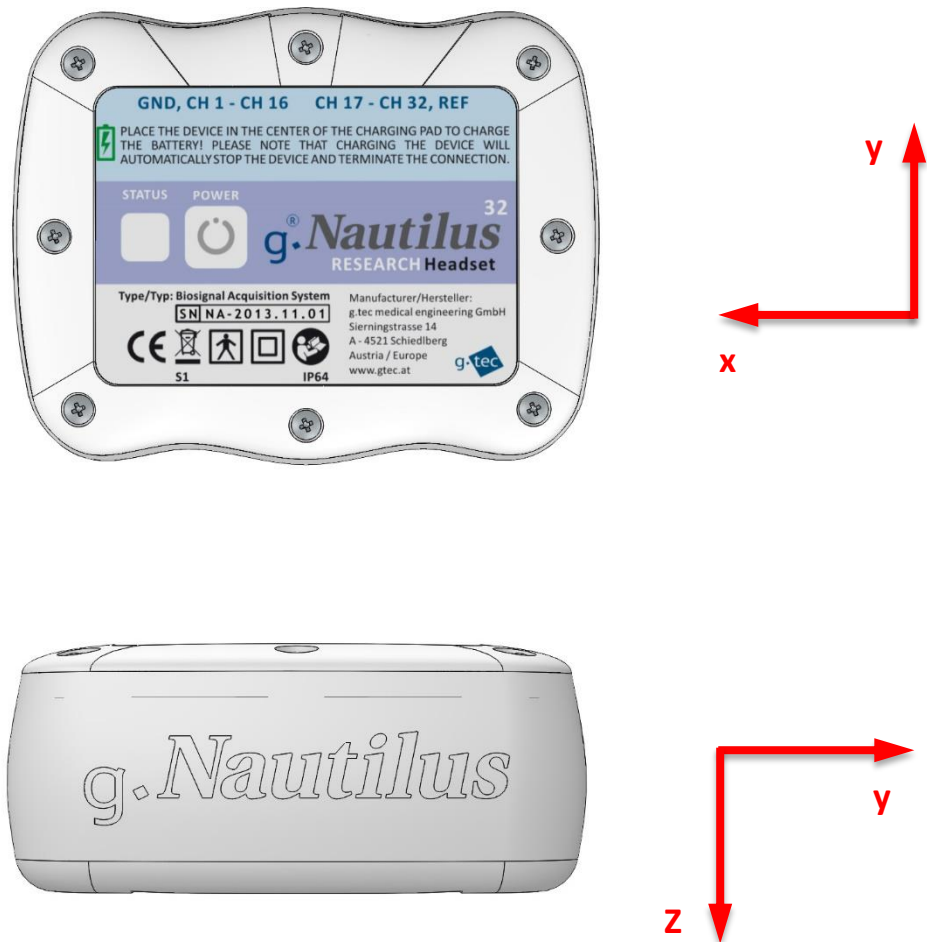
11 Electromagnetic compatibility

Please keep in mind the precautions in this instruction for use manual before installing and operating g.Nautilus Research. Pay attention to the fact that HF-communication devices (e.g. mobile phones, routers etc.) may interfere with electric devices. g.Nautilus Research must not be used near, or stockpiled with, other devices. Only the original components for g.Nautilus Research (see Chapter “g.Nautilus basic components”) 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 Research, and/or other problems. As electric and magnetic fields may interfere with the functional reliability of the device, avoid using g.Nautilus Research close to devices emitting electro-magnetic fields.

12 Appendix

g.Nautilus Research Headset

Acceleration Sensor



g.Nautilus Base Station

Maximum voltages at the following sockets

USB 5 V DC

DIGITAL IN 5 V DC

Digital inputs

Inputs Sensitivity: 3.3 V / 5 V

Logic Low: ≤ 0.66 V

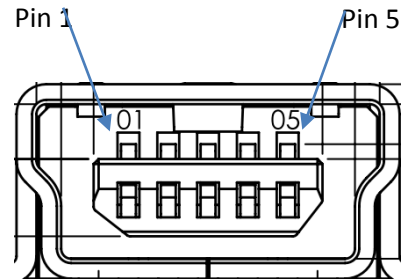
Logic High: ≥ 2.31 V

PIN assignment

USB socket

Pin-assignment for the 5 pin Mini-USB

Pin 1	+Vbus
Pin 2	D -
Pin 3	D +
Pin 4	ID
Pin 5	GND



Digital Ins

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

