User Manual v1.2

Novecento+

Bioelectrical signal device

⚠ Read this manual carefully before using the Novecento+ device

1 GENERAL DESCRIPTION

Novecento+ device is a multichannel device for bioelectrical signals generated by the human body. It can detect surface electromyographic (sEMG) signals, intramuscular electromyographic (iEMG) signals and electroencephalographic (EEG) signals.
The signals acquired with Novecento+ are amplified, filtered, digitally converted and then transferred to a PC, via an ethernet interface, for real-time visualization and storage. A freeware software called OTBioLab, designed by OT Bioelettronica, and is available for download on the website https://www.otbioelettronica.it/software/.

Novecento+ is a research instrument designed for clinical research carried out by qualified researchers.

Novecento+ allows you to use different configurations and types of electrodes simultaneously. The different types of electrodes can be connected by means of active digital probes to the 10 input connectors on the front panel: connectors marked as IN1, IN2… IN10. There are probes that allow you to acquire signals from pairs of electrodes, from matrix electrodes, from EEG caps and from wire or needle electrodes for intramuscular sampling. Novecento+ allows you to acquire a maximum of 960 bioelectrical signals, when 10 probes with 96 channels are connected to the 10 inputs. In addition, it has 16 channels called AUX1, AUX2… AUX16 for the acquisition of auxiliary signals. These can, for example, receive signals generated by other amplifiers or transducers such as force, torque, angle, position or trigger signal amplifiers or transducers.

To ensure the electrical safety of the patient and prevent the risk of electric shock, Novecento+ is divided into different parts, isolated from each other, which allow it to process signals coming from electrodes applied to the patient, from sensors and transducers and to interface with the PC for data recording.

2 NOVECENTO+ KIT CONTENT

- 1 Multichannel device Novecento+
- Probes to connect electrodes to the device (depending on customer request)
- 1 Conductive cream package
- 3 Reference straps for the wrist
- 3 Reference straps for the ankle
- 3 Reference cables
- 1 Ethernet cable
- 1 USB-Ethernet adapter
- 1 USB cable type A-B
- 1 AC power adapter (36W 12V)
- Arrays and matrix of electrodes of different sizes, depending on the customer request
- 1 Novecento+ User Manual

3 END USER

Novecento+ multichannel device allows invasive and non-invasive recording of biopotentials (iEMG, sEMG, EEG) detected by superficial and intramuscular electrodes.
In case of sEMG and EEG recordings the end user must be familiar with the technique and received a proper training in EMG or EEG detection and interpretation. The detection of iEMG signals is subjected to the insertion of needles or wires into the muscle and must be supervised by trained medical staff.

3.1 Contraindications

Novecento+ has no particular contraindications when used jointly with personal computers, provided that all the electrical devices connected to it and the power line comply with safety rules and standards concerning grounding and leakage currents.

3.2 Side effects

In case of sEMG or EEG signal detection, no significant side effects are known. The materials used for manufacturing all the parts in contact with the patient are biocompatible. Possible slight cutaneous allergic reactions (e.g. skin reddening) are reduced to a minimum during short duration of bioelectrical signal acquisitions. In case of iEMG, the needles or wires used to detect the signals must be sterilized. No significant side effects are known.

4 SAFETY PRECAUTIONS AND OTHER WARNINGS

The use of the multichannel device Novecento+ is absolutely forbidden in the following conditions:

- While electro-surgery equipment, short waves or microwaves therapy devices are used.
- By mentally impaired people.
- Whenever the equipment is damaged.
- In proximity of inflammable substances (especially inflammable liquids and gases) or in environments with a high concentration of oxygen.
- On patients carrying life-supporting equipment that might be adversely affected by electromagnetic interferences, such as pacemakers, etc.

The following precautions should be observed:

- The detection of iEMG signals must be supervised by trained medical staff.
- Only use electrodes supplied by the manufacturer: Novecento+ is guaranteed to achieve tested performance only if used with electrodes supplied by the manufacturer.
- Contact the manufacturer immediately if extraneous materials permeate into the device (liquids, powders, etc.). In case of strong impacts (like a drop to the floor, etc.), verify that no crack or any other kind of damage is visible. If in doubt, please contact the manufacturer.
- The Novecento+ device is subject to electromagnetic interference that is not dangerous for the patient (such as electrostatic or electromagnetic interference generated by electrical motors and other sources). This interference may affect the measurements of the physiological variables derived from the EMG or EEG signals. These measurements are not meant to be used for diagnostic purposes, and thus these signal alterations cannot be dangerous for the patient, please always consider the presence of noise in your signal processing tasks and evaluations.
- Before making any measurement, it is mandatory to check the quality of the grounding of the power line to which the Novecento+ is connected. The use of electrical devices with grounding connections not compliant with safety standards represents a high risk for the patient and the operator.
- The connection between Novecento+ and other electrical devices (e.g. a PC) must be done in compliance with the European standard EN 60601-1-1 on medical devices.
- Always use the Novecento+ device with a PC manufactured in compliance with the European standards EN 60950 (safety standard for information technology devices), EN 55022 (EMC standard) and EN 55024 (immunity standard).
- The use of the Novecento+ is restricted to skilled personnel.
- Incorrect measurements can arise when unskilled personnel use the device in presence of strong sources electromagnetic interference (e.g. strong electromagnetic fields). The presence of interference in the signals is easily recognised by skilled personnel.
- Novecento+ is not designed to be portable. Should it be necessary to move the Novecento+, it must be properly packaged to avoid typical vibrations and shocks arising from transportation. Vibrations could cause the release of metallic particles inside the appliance, such as screws, nuts and bolts, that could compromise the safety of the patient and the integrity of the appliance.

5 SYMBOLS USED ON NOVECENTO+ AND IN THE USER MANUAL

SN	Serial number – Production year
REF	Device identification number in the catalogue
CE	CE marking - Device in compliance with applicable Community directives.
	Device with applied parts of type BF
	Read the instructions of use
	Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary following the 2002/96/EC Law of the European Parliament and Council of the European Union about the disposal of e-waste.
	Manufacturer
IP20	Degree of protection: Protected against solid bodies larger than 12 mm Unprotected against water
⎓ **12VDC – 36W**	Indicates that the equipment is suitable for direct current only; with indication of nominal voltage and power supply.
Model: Novecento+ OT0269	Model: 960 bioelectrical signals + 16 auxiliary channels (OT0269)
	Read the operating instructions carefully before putting the device into service.
	Dangerous voltage levels, mains voltage.
	Indicates a medical device that should not be used if the package has been damaged or opened
	Indicates the temperature limits to which the medical device can be safely exposed

Indicates the range of humidity to which the medical device can be safely exposed

Indicates the range of atmospheric pressure to which the medical device can be safely exposed

Indicates that natural rubber latex was not used in the manufacture of the product, its container or packaging

RoHS

Indicates that the electronic equipment is in compliance with the RoHS Directive on the restriction of the use of hazardous substances

6 TECHNICAL SPECIFICATIONS

Novecento+ is a device equipped with a double galvanic insultation barrier designed to ensure a high level of safety for the patient and the operator in all operating conditions. The double galvanic insulation separates the circuitry connected to the patient from the circuitry connected to external non-medical devices, such as the PC used for data acquisition or the external power supply.
The interface between Novecento+ and the bioelectrical signal collection electrodes occurs by means of active digital probes. Table 6.1 shows a list of the different probes available.

Probe	Available Connections
Bio96-HD	Digital probe for the amplification and A/D conversion of 96 bioelectrical inputs
Bio64-HD	Digital probe for the amplification and A/D conversion of 64 bioelectrical inputs
Bio32-HD	Digital probe for the amplification and A/D conversion of 32 bioelectrical inputs
Bio8-BP	Digital probe for the amplification and A/D conversion of 8 bipolar inputs
Bio40-IM	Digital probe for the amplification and A/D conversion of 40 intramuscular inputs

TAB. 6.1: *probes list available for Novecento+.*

It is possible to simultaneously acquire signals with different probes. This is useful when signals from different muscles need to be recorded at the same time or when EEG and EMG must be recorded together. In addition to the probes listed in table 6.1, additional probes can be made under customer request to interface other types of electrodes or sensors that can be designed on request.

Novecento+ technical specifications are shown in 6.2.

Amplification channels (IN1 to IN10)	
Preamplification gain	2, 4, 6, 8 V/V
Selectable bandwidth	**High pass filter:** it can be active or not, with a cutoff frequency equal to: F_{Samp}/190 Hz **Low pass filter:** set by the sampling rate and equal to: F_{Samp}/4 Hz
Maximum input range	$\pm 0.3V_{pp}$, $\pm 0.45V_{pp}$, $\pm 0.6V_{pp}$, $\pm 1.2V_{pp}$ depending on the used preamplifier gain
Noise level referred to input	$< 2\ \mu V_{RMS}$
Input resistance	$> 10^9\ \Omega$

CMRR	> 95 dB
Analog output range	0 ÷ 5 V
Insulation voltage	4.000 V_{DC}

Auxiliary and Extension channels (AUX1 to AUX4 and EXT1 to EXT10)	
Input range	± 5 V for AUX | 0 – 5 V for EXT
Bandwidth	DC – 3400 Hz
Gain	0.5 V/V
Input resistance	> 10^9 Ω
A/D converters input dynamic	0 ÷ 5 V

Auxiliary channels for load cells (LOAD CELL 1 and LOAD CELL 2)	
Input range	± 12.2 mV
Bandwidth	DC – 14.5 Hz
Gain	205 V/V
Input resistance	> 10^9 Ω
A/D converters input dynamic	0 ÷ 5 V

Data conversion	
A/D converter resolution	16 or 24 bits
Data transfer to PC	Ethernet interface
Selectable sample frequency	500, 2000, 4000, 8000 Hz can be set independently for each input and rear panel signals

TAB. 6.2: *Novecento+ Technical Specifications.*

7 DETAILED DESCRIPTION

7.1 Front panel

FIG. 7.1 shows controls, indicators and connectors present on the front panel of the Novecento+ and described in the following sections.

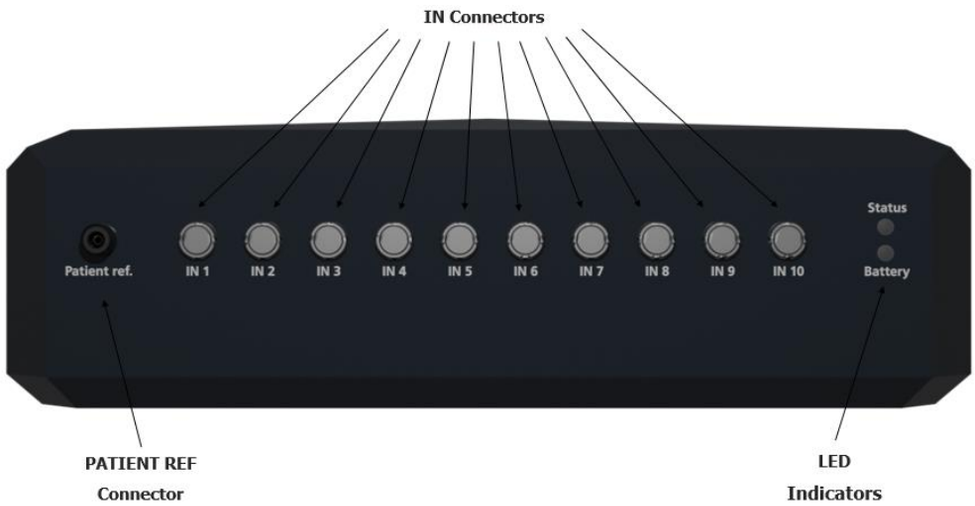

FIG. 7.1: *Novecento+ front panel view*

7.1.1 PATIENT REF connector

The *PATIENT REF* connector on the front panel is used to connect the device reference point to the patient. On the PATIENT REF connector there is a constant voltage generated inside the Novecento+ equidistant from the positive and negative voltages supplying the front-end for the bioelectric signals. The connection of *PATIENT REF* to the patient is essential to have a common voltage reference between patient and amplifier. In fact, the bioelectric signals generated, having the *PATIENT REF* voltage as reference, can have positive and negative excursions while remaining within the voltage range available to the instrument. Other *PATIENT REF* connectors are present on each probe and can be used in addition to or as an alternative to the one on the front panel. The reference point must be connected to a point on the patient's body without myoelectric activity (e.g. the ankle or the wrist) using the supplied ground strip. The strip must be wet with water to ensure a good electric contact with the patient.

⚠ *REMARK: failure in connecting this electrode prevents the correct acquisition of the EMG signal.*

7.1.2 Input connectors IN1 to IN10

Each *IN* connector allows the connection of a digital probe with a maximum number of 96 channels. These inputs accept different types of probes. The probes are active and allow the interfacing of electrode grids, EEG caps, or pairs of surface and intramuscular electrodes with Novecento+. For the collection of surface EMG signals (sEMG), different types of probes are available that allow the connection of a 96-electrode grid, a 64-electrode grid, a 32-electrode grid and/or 8 bipolar electrodes. For the collection of intramuscular EMG signals (iEMG), a probe is available that allows the connection of up to 40 intramuscular electrodes. For a complete consultation of the available probes, refer to section 8.9.

Communication between probes and Novecento+ occurs through a specific protocol that is initialized when the data visualization on the PC starts. In the initial phase, the probe provides its own characteristics and Novecento+ configures it by setting the sampling frequency and filter settings. Connecting a probe after communication with the PC has started does not allow data to be received correctly from the newly connected probe. Therefore, it is necessary to interrupt and restart communication with the PC every time a new probe is connected to one of the *IN* inputs.

7.1.3 LED Status and Battery indicators

The Status LED, green, lights up when the power switch is switched to the ON position. When the Status LED is on, the Ethernet interface is active and you can reach the Novecento+ configuration page by opening a browser, the default IP address of the device is: 169.254.1.10.

The Battery LED is on steady green when the battery is fully charged, it is on steady orange when the battery is charging, it blinks orange when the battery is below the 20% threshold. The Battery LED also lights up when the instrument is off, if the external power supply is connected to the Novecento+ to indicate its charge.

7.2 Rear panel

Figure 7.2 shows the connectors on the rear panel of Novecento+ described in the following sections.

FIG. 7.2: *Novecento+ rear panel view*

All signals supplied to the Novecento+ via the rear panel connectors are sampled at the same rate, which can be set to 500Hz, 2000Hz, 4000Hz or 8000Hz. In total, there are 16 signals with 16-bit resolution that work even if no input is connected to the front panel. In this mode, the Novecento+ can be compared to a 16-channel acquisition card. Table 7.1 shows the main information relating to the signals from the rear panel.

Channels ID	Channels Type	Input range	Gain (V/V)	Bandwidth
1 – 4	AUX1 – AUX4	±5 V	0.5	DC – 4300 Hz
5, 6	LOAD CELL 1 e 2	±12.2 mV	205	DC – 14.5 Hz
7 – 16	EXP1 – EXP10	0 – 5 V	1	DC – 4300 Hz

TAB. 7.1: *Main information relating to the signals from the rear panel*

7.2.1 Power supply socket

The Novecento+ device can be powered by connecting to the 12 V_{DC} voltage generated by its AC/DC power adapter or alternatively by the internal battery. The battery is automatically charged when Novecento+ is connected to the external power supply, when it is not transferring data to the PC and when the "Analog Supply Mode" setting is different from "Always from battery" (see section 8.3). A low battery level is indicated by the Battery LED blinking orange.

⚠ *WARNING: the use of different AC/DC power adapter other than the one provided by the seller can modify the performances of NOVECENTO+.*

7.2.2 Power switch

This switch turns the Novecento+ on and off. When in the OFF position, the battery is physically disconnected from the main circuit of Novecento+. Regardless of the position of the switch, the charging circuit is functional, and the Battery LED indicates whether charging is in progress or complete.

7.2.3 Load cells connectors

The two load cell connectors allow you to use two internal amplification circuits specifically designed for signals coming from Wheatstone bridge sensors. These connectors have 4 contacts and are able to provide a power supply between 0 and 5V and amplify a differential signal with a gain of 205 V/V. Figure 7.3 shows the details of the connector that must be used to pair with Novecento+ load cell connectors.

Four-pole male Binder connector
Part Number: 09-9767-70-04

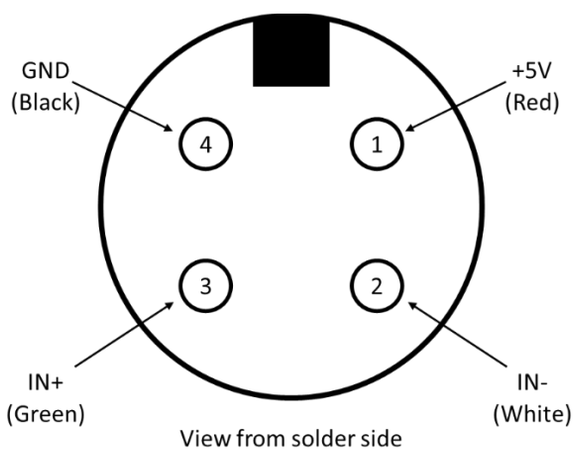

FIG. 7.3: *Load cells connector pinout*

The signals obtained from the load cells connected to the LOAD CELL 1 and 2 inputs are then amplified, lowpass filtered at 14.5 Hz, converted to digital on 16 bits and are available among the data acquired by the instrument after the 4 AUX channels. The input range of the A/D converter for these channels is 0 – 5V, which, considering the gain of 205 V/V, allows a range of the signal produced by the load cells of ±12.2 mV.

The data provided by Novecento+ can be converted into force or torque values transduced by the load cells using the following formula:

$$SENS = DIGVAL \frac{ADC_{RANGE} \cdot LC_{FS} \cdot 1000}{ADC_{RES} \cdot GAIN \cdot LC_{SENS} \cdot LC_{SUPV}}$$

where:

- SENS is the force or torque applied to the load cell that you want to calculate
- DIGVAL is the digital value converted by the A/D converter hat can be read from the data provided in output on the ethernet
- ADC_{RANGE} is the A/D converter input dynamic, equal to 5V
- LC_{FS} is the Load Cell full scale
- 1000 allows you to convert the Load Cell sensitivity expressed in mV into a value in V
- ADC_{RES} is the A/D converter resolution, equal to 2^{16}
- GAIN is the internal Gain of Novecento+ equal to 205
- LC_{SENS} is the Load Cell sensitivity, typical values are around 2mV/V
- LC_{SUPV} is the Load Cell supply voltage, equal to 5V

The resulting value is expressed in the same unit of measurement used for the full scale of the load cell or torque meter.

7.2.4 AUX Extension connector

The extension connector allows for ten additional inputs that are acquired with the probe signals, load cell signals and AUX signals. The extension connector is a 20-pin D-type connector on which are available the Novecento+ internal power supplies, an internal voltage reference and accepts 10 single-ended signals with an input range of 0 - 5V.

The connector pinout is shown in figure 7.4.

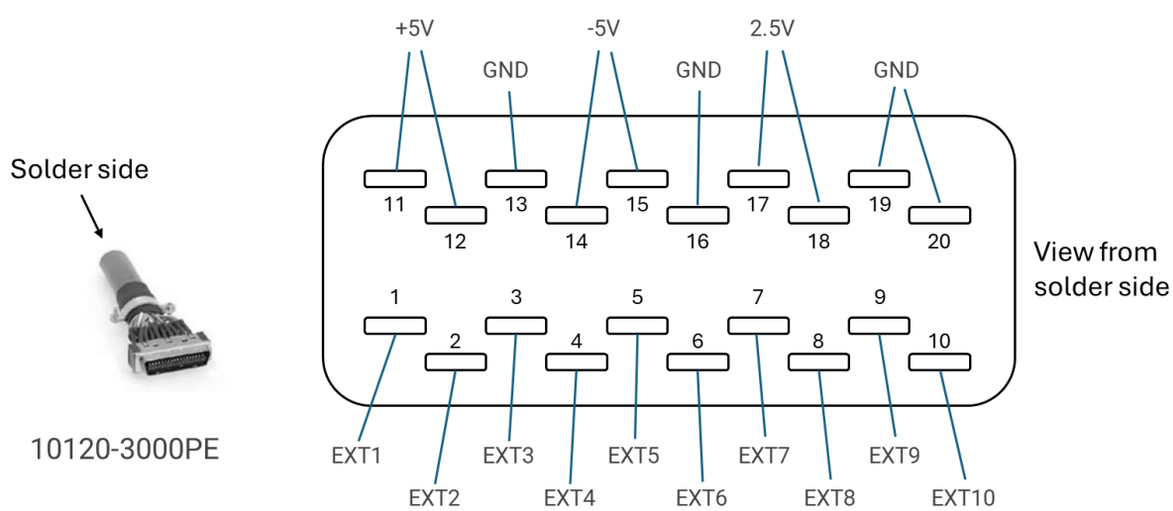

FIG. 7.4: *AUX extension connector pinout*

7.2.5 Auxiliary IN connectors

These BNC connectors can be used to acquire external amplified signals in the range of ±5V along with the acquisition of bioelectrical signals and other signals from the rear panel. Filtering of these signals is a simple first order anti-aliasing low pass filter at 3400 Hz. There is no high pass filter.

7.2.6 Trigger connector

This BNC type connector can be used as a digital input or output. When used as an input, logic 0 level corresponds to voltages lower than 0.8V, logic 1 level to voltages higher than 2V. Do not exceed 5.5V. The digital signal connected to this BNC can control the start and stop recording on the OTBioLab software.

When the trigger is used as an output, the level of the signal present on it indicates the recording status of the OTBioLab SW: 0V indicates that the data recording is not in progress, 5V indicates that the data recording is in progress.

The signal on this connector is sampled/generated synchronously with the sampling of the accessory signals at a frequency of 8000 Hz. The misalignment between the transition on the trigger signal and the first or last sample recorded by OTBioLab software is lower than 2ms. A post-processing analysis of the accessory signals allows a resolution of up to 125 µs.

7.2.7 Analog Out connector

This BNC type connector outputs one of the channels acquired by Novecento+, selectable via the OT BioLab software. The samples of the selected signal are intercepted from the data flow to the PC for acquisition and sent to a D/A converter to obtain an analog signal. The output range is 0 ÷ 5V (with 2.5V intended as a reference level) and the bandwidth range from DC to 4100 Hz with a first-order filter that acts as a low-pass filter that intervenes after the conversion of the D/A converter. The signals on this output are available at the same rate used to sample the input signals but have a delay of 3 samples which translates into a time delay of about 6, 1.5, 0.75 and 0.38ms for the sampling rates of 500, 2000, 4000 and 8000 Hz respectively. This delay is due to the settling time of the A/D converters present in the digital probes which, being of the Sigma-Delta type, introduce a delay between the sampling of the signals and the moment in which the digital code in output reflects a variation on the analog signals in input.

Given the low gain used in input (2, 4, 6 or 8), for the analog output a digital amplification can be introduced from the OTBioLab settings, this amplification can be selected between 256, 512, 1024 or 2048 V/V.

A possible use of this output could be to send the signal to an audio amplifier to listen to the EMG signal. The signal can also be shared with other instruments to have a common signal useful for synchronization.

⚠ *WARNING: the analog signals at the Analog Out are delayed of 3 samples.*

⚠ *WARNING: the analog signals are available on the Analog Out only after Novecento+ has been connected to the PC by means of an ethernet cable and the signal visualization has been started on OTBioLab.*

7.2.8 Ethernet connector

The Ethernet port of Novecento+ can be connected directly to the PC or to a switch/router via an Ethernet cable. The default IP address of Novecento+ is 169.254.1.10 with Subnet Mask 255.255.0.0. This address falls within the range of addresses called Auto IP that Novecento+ assigns itself when DHCP mode is not active or when there is no DHCP server capable of providing the address to the device. A PC with a Windows operating system connected directly to Novecento+ will fall within the same range of addresses 169.254.X.Y and the same Subnet Mask 255.255.0.0, which makes communication between the two devices possible. Communication between PC and Novecento+ occurs via a TCP socket in which Novecento+ implements the server side on port 54321. Once the connection to the socket is established, it is possible to send commands to Novecento+ to obtain information on the current configuration, to set the parameters for the acquisition or to start/stop the data acquisition. All these operations are managed by the OTBioLab software, but in case you want to control the instrument directly with your own script or software, all the necessary information relating to the configuration and communication protocol are available for download on the website otbioelettronica.it.

8 USE OF NOVECENTO+

Novecento+ device can be connected to any computer with a network interface and running any kind of operative system. This manual refers to the use of Novecento+ together with a PC with Windows and the freeware OTBioLab software. In case a different type of operative system is used, or if the user interface needs to be customized, the configuration and communication protocol of Novecento+ is available as well as Matlab and Python examples. Please refer to the download section on otbioelettronica.it website.

8.1 Novecento+ network interface

The network interface available for Novecento+ is similar to the interface available for other devices like printers, routers or access points. As any other device connected to a network, Novecento+ has its own IP address that is shown on the display. When Novecento+ is connected to a network with the same IP range, it is accessible for data transfer, ping or configuration through its web configuration page.

Configuration of Novecento+ can be changed connecting to the IP address (shown on the display) using a web browser (refer to section 8.9). Warning: the PC must be connected to the same network and with the same IP address range.

The IP address can be fixed by the user or can be assigned automatically from a DHCP server on the network.

When the DHCP option is enabled, Novecento+ waits for 20 seconds after power to receive a configuration from a DHCP server. If no configuration is received, then the default IP, subnet mask and gateway set by the user are applied.

A service called *Auto IP* is available on windows computers. When the computer does not have any fixed IP and no DHCP server is present on the network, the *Auto IP* service automatically assign an IP address in the range 169.254.X.Y (with subnet mask 255.255.0.0). For this reason, Novecento+ has, by factory default, the IP address set in the same range, in particular 169.254.1.10. Thus, connecting directly the Novecento+ to a Windows computer, without a fixed IP, they will have the same IP address range and will be able to communicate. When changed are matched to the network interface (disconnecting the Novecento+ from a network and connect it to another) it is necessary to turn off the device and then turn on it again in order to receive new settings for the DHCP protocol and reconfigure the network board.

8.2 Web page setup

Using a web browser and connecting to the IP address 169.254.1.10, the webpage of the Novecento+ device will be shown (see Fig. 8.1).

FIG. 8.1: *Embedded web page of Novecento+*

This webpage lets you configure parameters like default IP address, TCP post or Analog Supply mode. To submit and save changes, you must press the button "Apply and Restart".
When DHCP is enabled, Novecento+ takes 20 seconds to connect to the server and the IP address. If it does not receive any IP address, it sets the default one as the IP address (see section 8.1)

Analog Supply mode can be set in this way:

- Battery when acquiring
- Always from battery
- Always from external supply

This setting specifies how to power the isolated part of Novecento+, where the probes for collecting bioelectrical signals are located, when using the AC power supply. By default, the power mode is *"Battery when acquiring".* This means that the power supply changes automatically when you start acquiring data from the PC. During data transfer, the internal battery is used, while when the display is interrupted, the isolated part of the instrument is powered by the AC power supply.
When Novecento+ is not powered, regardless of the settings, the isolated part is powered by the battery (see section 8.3 for details).

Firmware upgrades require a file .bin provided by OT Bioelettronica. Do not start any firmware upgrade procedure if you have not been instructed on how to do it and without the proper file.

8.3 Power Supply

Novecento+ has an insulation barrier that divides the part applied to the patient (isolated part) to the part that provides the connections to other instruments or PC (non-isolated part).

The isolated part can be supplied by an internal battery or, through an insulated DC-DC converter, by the main 12V from the back panel of Novecento+.

When the AC power adapter is connected to the Novecento+, the internal battery starts recharging. This is identified as stand-by mode. By switching ON the button on the rear panel, Novecento+ is activated and the data acquisition can be started.

The battery is charged also if Novecento+ o is active, but data transfer is not in progress and the supply mode is "*Battery when acquiring"* or "*Always from external supply"* (see section 8.2).

In figure 8.2 three schematic representations show the different possible supply modes. When the supply mode selected on the embedded web page is set to "*Battery when acquiring",* Novecento+ automatically switch between configuration (a) and (b). Configuration (c) allows to have a completely floating setup if the computer used for the acquisition is a laptop running with battery.

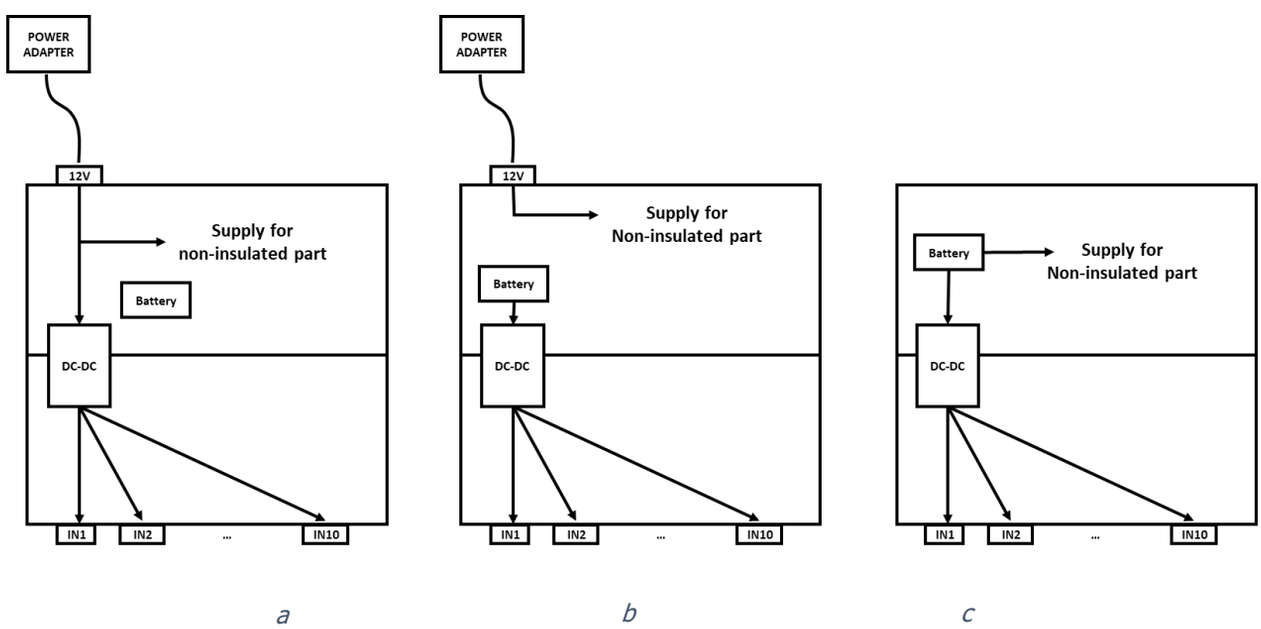

FIG. 8.2: *Supply scheme available for Novecento+:*

a) The supply for both insulated (probes) and non-insulated parts are provided by the external power adapter. b) Power for the non-insulated part is provided by the AC power adapter and the insulated part is supplied by the internal battery.

c) Power for the insulated and non-insulated part is provided by the battery.

8.4 Quick setup

Follow these steps for connection and a quick setup of the device:

1. Connect the ethernet port of Novecento+ (see section 7.2.8) to the ethernet port of a PC.
2. Supply Novecento+ with the AC power adapter provided (see section 7.2.1) or with battery.
3. Switch the button on the rear panel to ON to activate Novecento+.
4. Connect the desired probes to any input on the Novecento+ and apply the electrodes to the patient (refer to section 8.10 of this manual).
5. Open a browser and insert the address 169.254.1.10 to verify that the webpage is reachable and that communication between the PC and Novecento+ is working.
6. Run OTBioLab.
7. On the OTBioLab main menu press the "Open Setup window". Set Novecento+ as the device, choose the desired acquisition frequency and number of channels and create an acquisition configuration (refer to the OTBioLab User Manual for details).
8. Start the signals visualization with Start Visualization button.
9. Acquire the signals using the Record Acquisition and Stop Acquisition buttons (refer to the OTBioLab User Manual for details).
10. Stop the data transfer and signals visualization by going back to the review mode in OTBioLab.
11. Disconnect the AC power adapter and switch the button to OFF to completely turn off Novecento+.

FIG. 8.3: *Standard connection setup for Novecento+*

8.5 Detection mode

Novecento+ can be used with different types of probes that allow different acquisition modes. Most probes allow monopolar signals to be acquired and have a specific 2 mm bushing for the connection of the reference electrode for monopolar signals. This means that each acquired channel is obtained as the difference between an electrode of a grid or EEG cap and the reference electrode for the monopolar.

There are also probes that allow bipolar sampling for the traditional acquisition of bipolar EMG signals. These probes have two electrodes for each channel and the acquired signal is the difference between the signals taken from the two electrodes.

The OTBioLab software allows you to obtain, using real-time or offline processing, differential signals useful for example to evaluate the propagation of muscle action potentials along the fibers. Differential signals are obtained from the difference between the signals obtained from two adjacent electrodes of a matrix or an array of electrodes.

8.6 Probes amplification

The digital active probes integrate a front-end for the acquisition of bioelectric signals, a 24-bit analog/digital converter and a microcontroller capable of performing simple operations on the converted values. The data can be read without removing the continuous component by using all 24 bits of resolution or, by introducing a high-pass filter, with a resolution of 16 bits. The probes have a preamplification factor that can be set via the OTBioLab software and can have values of 2, 4, 6 or 8. The input dynamics of the A/D converter is ±2.4V. A higher preamplification factor allows to obtain a lower noise, but at the same time limits the input range of the signals.

⚠ *WARNING: the term noise refers only to random noise generated mainly by electronic circuits and electrode-skin contact. Interferences due to parasitic coupling of cables, circuits or patient with sources of disturbance such as the electrical network, motors or antennas are a different matter. Changing the preamplification factor has no effect on reducing interference.*

The gain introduced by the preamplifier is always taken into account by the OTBioLab software that correctly calculates the amplitude of the signals on the skin. In case the data is read with a Matlab or Python script written by the user, a different conversion factor must be considered to obtain the amplitude of the input signals, when the preamplification factor is changed. To better understand the conversion factor to be used to convert the raw value received via Ethernet, consider the following formula:

$$LSB_{RTI} = \frac{ADC_{RANGE} \cdot COMP}{GAIN_{PREAMP} \cdot ADC_{RES}}$$

Where:

- LSB_{RTI} is the amplitude in Volts of the Least Significant Bit obtained from the analog/digital converter. Multiplying this value by the raw data received from Novecento+ Ethernet interface, we obtain the amplitude of the RTI (Referred to Input) signals, i.e. the amplitude recorded by the electrodes
- ADC_{RANGE} is the input range of the A/C converter equal to 4.8V
- $GAIN_{PREAMP}$ is the preamplification factor that can be set equal to 2, 4, 6 or 8
- ADC_{RES} is the resolution of the A/D converter equal to 2^{24}
- COMP is a compensation factor introduced in the probes' firmware to obtain an appropriate range when the data is requested on 16 bits. COMP is 8 in case of data acquisition at 16 bits and is 2 in case of data acquisition at 24 bits

Table 8.1 shows the conversion factors, i.e. the LSB_{RTI} values for each preamplification and resolution value used.

Preamplification	Resolution	Conversion factor LSB_{RTI}
2	24 bits	0.286 µV
4	16 bits	0.572 µV
6		0.429 µV
8		0.286 µV

TAB. 8.1: *Bioelectrical signals' conversion factors depending on the used preamplification and resolution*

8.7 Probes High pass and Low pass filters

The high pass filter can be active or not depending on the configuration of the used probes, the chosen settings are applied to all channels of the probe. The high pass filter is obtained digitally with a filter implemented in real time in the firmware of the microcontroller present in the probes. The microcontroller calculates an exponential moving average that is updated at each sample and then subtracted from the value just converted.

$$EXP_{AVE}\_ChX[t] = (1-\alpha)\ Average\_ChX[t-1] + \alpha\ ChX[t]$$

Where:

- EXP_{AVE}_ChX[t] is the exponential moving average è la media mobile for channel X at time t
- α is equal to $1/2^5$

The obtained result is a high pass filtering which, in the case of a sampling frequency of 2000 Hz, has a 3 dB cut-off frequency equal to 10.5 Hz.

The low-pass filter is intrinsic into the signal sampling introduced by Sigma-Delta converters. The cutoff frequency corresponds to approximately ¼ of the sampling frequency with an attenuation of up to 140 dB at frequencies multiples of the sampling frequency. Figure 8.4 shows the graphs obtained from the A/D converter datasheet relating to the attenuation introduced at the various frequencies.

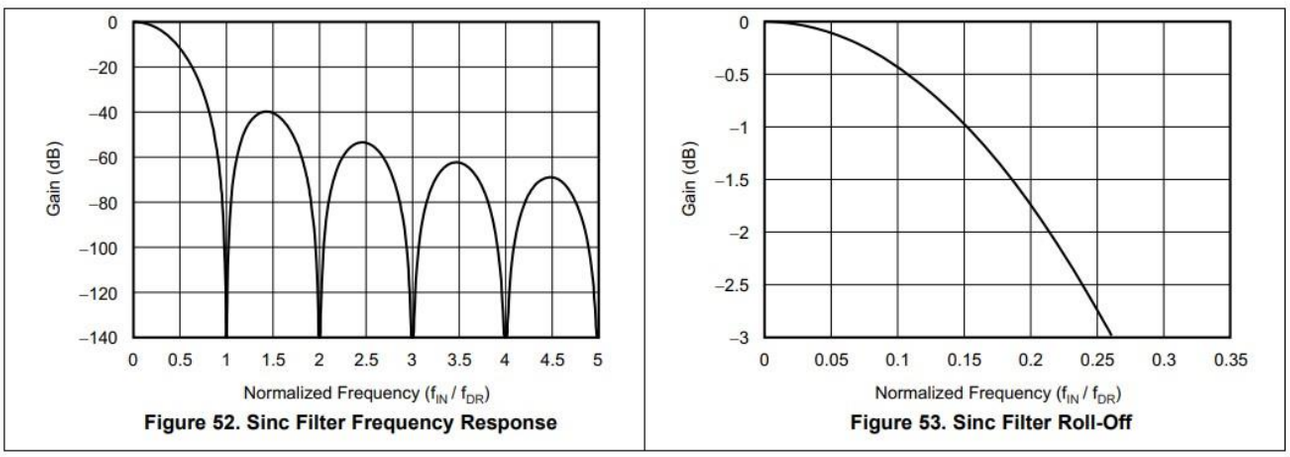

FIG. 8.4: *Attenuation introduced by the Sigma-Delta A/D converter depending on the used sampling frequency*

By setting a sampling frequency of 2000 Hz, typical for surface EMG channels, the introduced filter has a 3 dB cut-off frequency equal to 500 Hz.

8.8 Analog Out setting

Novecento+ device features an analog out BNC connector (refer to the details in the rear panel section of the system) where one of the signals filtered and amplified by the available channels can be output. The bioelectric signals acquired inside the instrument are converted in digital form at the desired frequency, cross the insulation barrier as digital signals and are re-converted to analog. After the digital-to-analog conversion, a "post DAC" low-pass filter with a cutoff frequency of 4400 Hz is used to eliminate the transitions introduced by the digital-to-analog converter.

The delay between the sampling of the channel used to feed the analog output and the generation of the same sample on the digital-to-analog converter output is less than the sampling time:

$$DEL_{AN\_OUT} < 1/Fsamp$$

The settling time of the A/D converters must be taken into account, which is equal to about 3 samples and is reflected on the analog output. The settling time is linked to the Sigma-Delta conversion which introduces a delay between the variations of the sampled analog signals and the moment in which the same variations appear on the digital output data.
The user can choose the input signals to feed the analog output by acting on the Analog Out parameter shown in the OTBioLab acquisition interface. To change this parameter, click on the Set Analog OUT button in the OTBioLab setup.
It is also possible to introduce an additional gain on the analog output from OTBioLab. The gain can be 1, 2, 4 or 16 V/V. Please consider that this gain is obtained digitally by shifting the bits position of the samples.

⚠ *REMARK: even if any of the bioelectrical signals can be selected, only the signals sent to PC through the ETHERNET interface (refer to the OTBioLab manual) are useful signals. A flat line is generated by the analog output when a channel not sent to the PC is selected.*

8.9 Data format, Auxiliary and Accessories channels

Novecento+ is able to sample signals from different probes, from the rear panel inputs and adds to these signals a series of additional information for sampling control or reporting some states of internal variables.

Since different sampling frequencies and resolutions can be used on different probes, it is not possible to transfer the multiplexed data to the PC with a fixed sequence of values for the various channels repeated at each sample. A minimum interval of 2 ms has therefore been set, which is equivalent to the sampling time of the 500 Hz frequency. Each probe, the rear panel channels and the accessory channels therefore provide packets containing the data relating to 2 ms of sampling. These packets are sent in sequence on the Ethernet port to the PC and each packet can have different dimensions that can be calculated based on the system settings. In particular, each packet has a size that depends on the number of channels, the sampling frequency and the resolution. As regards the probes, refer to paragraph 8.10 and to the description of the different probes available. Below, instead, there is table 8.2 which indicates the dimensions of the 2 ms packets generated by the channels coming from the rear panel here collectively called auxiliary channels. For the auxiliary channels it is possible to choose the sampling frequency, but the number of channels is fixed at 16 (4 AUX, 2 LOAD CELL IN and 10 EXP) and the resolution is also fixed at 16 bits.

Sampling Freq.	Num AUX CH	Resolution	Data Packet
500 Hz	16	16 bits	32 bytes
2000 Hz			128 bytes
4000 Hz			256 bytes
8000 Hz			512 bytes

TAB. 8.2: *Size of a 2 ms data packet from AUX inputs depending on the used sampling rate*

The accessory channels are always sampled at 8000 Hz, they can be considered as 4 channels with 32 bits and therefore the packet size for the accessory channels has a fixed size of 256 bytes.

Sampling Freq.	Num AUX CH	Resolution	Data Packet
8000 Hz	4	32 bits	256 bytes

TAB. 8.3: *Size of a 2 ms data packet from Accessory channels*

The first accessory channel ACC1 contains the sampling of an internal counter in Novecento+. It is a 32-bit value that, reset at power-on, is incremented by a 100 kHz clock.
The second accessory channel ACC2 contains different information, including the status of different digital signals on single bits and some more complex information on groups of bits. Not all bits are used, considering the 32 bits contained in the ACC2 channel numbered from 0 to 31, only the bits used are reported:

- Bit0: reflects the status of the TRIGGER signal when used as an input
- Bit2: reflects the status of the $VACQ_{EN}$ signal that controls the activation of the power supply to the probes
- Bit3-4: two-bit code that indicates the initial configuration phases of the probes
- Bit6: reflects the status of the TRIGGER signal when configured as an output
- Bit7: reflects the status of the green component of the Status LED
- Bit8: reflects the status of the yellow component of the Status LED
- Bit9: indicates the presence of the external 12 V power supply
- Bit10: reflects the status of the green component of the Battery LED
- Bit11: reflects the status of the yellow component of the Battery LED
- Bit12: indicates that the power supply to the internal probes comes from the external 12V socket
- Bit13: indicates whether the buzzer is ringing
- Bit16-31: contains the 16-bit sample that is about to be generated as Analog Out

The third accessory channel ACC3 contains the sampling of the 32-bit internal counter used to trigger the start of a new 2 ms packet, it is incremented by an internal clock at 50 Mhz and can assume values between 0 and 99999.
The fourth accessory channel ACC4 contains the sampling of the 32-bit internal counter used to trigger writing to the Analog OUT output, it is incremented by an internal clock at 50 Mhz and can assume values between 0 and 99999.

8.10 Detection probes

The IN connectors (IN1 to IN10) can accept different types of probes. The probes are active with analogue to digital conversion and allow the interfacing of electrode matrices, intramuscular electrodes or EEG caps with Novecento+, up to a maximum of 96 channels for each probe.
The probes are powered by 5V via the IN connectors and exchange information with Novecento+ via a synchronous digital serial bus. The probes have a purely digital part where a microcontroller receives the settings from Novecento+ and configures the various parameters, such as sampling frequency, resolution, filters, preamplification etc... The microcontroller supervises the sampling, receives the sampled data of all the channels, it packs them and transfers them in 2 ms blocks. In addition to the digital part, there is an analogue part with the acquisition front-end for the bioelectric signals and the analogue/digital converters.
The probes are therefore independent acquisition systems with serial bus output and have been designed to also have a USB interface and be able to be used individually as a stand-alone device. However, an interface is required that allows the probes to be electrically isolated and provides a standard USB connector. The same interface can be used to update the probe firmware if a new firmware version is available.
In the first phase of communication between the probes and Novecento+, an exchange of information takes place in which the probe indicates its own identification code, the firmware version and the last configuration command received. Novecento+ instead provides the new configuration for the probe. This happens in the first phase of communication, when communication between the PC and Novecento+ is started. For this reason, connecting a probe while communication is in progress does not allow a correct configuration and the data sent by the probe does not correspond to the expected ones. To add a probe, it is therefore necessary to interrupt the display and then restart it.
In case the probe resolution is set to 16 bits, all channels are transferred providing 2 bytes for each sample. If the resolution is 24 bit the channels are transferred providing 4 bytes for each sample. The fourth byte is therefore devoid of useful information and only reports the extension of the 2's complement sign. Transferring 4 bytes instead of 3 simplifies reading by the data acquisition software which can read the samples as DWORD.

In addition to the bioelectric channels, the number of which varies with the type of probe, 4 signals are available obtained from an IMU present in the probe and 2 accessory channels. These channels are also expressed on 2 or 4 bytes consistently with the bioelectric channels. The 4 IMU channels are the so-called quaternions, and the 2 accessory channels report useful information for the system, such as a sample counter which allows you to verify that there is no data lost in the various steps between probe and saving to file.

The four IMU (Inertial Measurement Unit) channels correspond respectively to the W, X, Y and Z quaternions derived from the 3 integrated sensors: accelerometer, gyroscope and magnetometer. The inertial sensor used is the Bosch BNO055 configured in "Fusion Mode - NDOF" with the default measurement ranges and absolute orientation with respect to the gravity vector and magnetic north. The real resolution of the quaternion data is 14 bits, signed to 16 or 24 bits depending on the acquisition mode. The quaternions are the result of an internal calculation in the inertial sensor and are updated at a frequency of 100 Hz, therefore, in the case of sampling at 2000 Hz, there will be 20 samples with the same quaternion values before obtaining a new set of values for the quaternions.

All monopolar type probes have two 2mm banana bushings called PAT REF and MON REF. The first is the replica of the Patient Reference connector on the front panel of Novecento+ and can be used as an alternative to the connector on the front panel. PAT REF, in other devices is also referred to as GND, this is a constant voltage in the middle of the front-end power range. The second bushing, MON REF, allows the connection of a common reference electrode for monopolar sampling which is essential to be able to acquire signals with the probe. In other devices for sampling bioelectrical signals, it is sometimes referred to generically as REF.

If multiple probes are used at the same time, especially if the electrode matrices are applied on adjacent muscles or in any case on the same limb or district, a single electrode can be used for the monopolar reference and "bridge" cables to make bridges between a probe and the another and share the monopolar reference electrode between multiple probes. The limit in using a monopolar reference electrode that is too far from the electrode matrix is that the monopolar signal will be affected by more crosstalk, i.e. a common mode signal generated by muscles far from the one of interest. A typical case is the presence of an ECG signal superimposed on the EMG signal if the reference electrode is located on one limb and the matrix on another.

All probes also have a status LED which indicates when the probe is powered and active and the connector for the connection cable to the IN inputs of Novecento+ or to the USB interface.

A detailed description of each available probe is provided in the following section.

Bio96-HD

This is a monopolar probe that allows you to connect a 96-channels electrode matrix to one of the inputs IN1, IN2… IN10. The probe has an input with a multipolar connector that accepts the matrices produced and sold by OT Bioelettronica with 96 electrodes with code HDXXMMYYZZ (where XX indicates the interelectrode distance in mm, YY the number of rows and ZZ the number of columns of the electrode grid).

FIG.8.4: *Bio96-HD probe for electrode grids with 96 channels*

The size of the 2 ms packets for this probe is reported, as a function of sampling rate and resolution, in Table 8.4.

Signals	Number of Channels	Resolution	Sampling Freq.	Data Packet
EMG	96 BIO + 4 IMU + 2 ACC	2 bytes	2000 Hz	816 bytes
EEG		4 bytes	500 Hz	408 bytes

TAB. 8.4: *Size of a 2 ms data packet from Bio96-HD probe depending on the used sampling rate and resolution*

Bio64-HD

This is a monopolar probe that allows you to connect a 64-channels electrode matrix to one of the inputs IN1, IN2… IN10. The probe has an input with a multipolar connector that accepts the matrices produced and sold by OT Bioelettronica with 64 electrodes with code HDXXMMYYZZ (where XX indicates the interelectrode distance in mm, YY the number of rows and ZZ the number of columns of the electrode grid).

FIG. 8.5: *Bio64-HD probe for electrode grids with 64 channels*

The size of the 2 ms packets for this probe is reported, as a function of sampling rate and resolution, in Table 8.5.

Signals	Number of Channels	Resolution	Sampling Freq.	Data Packet
EMG	64 BIO + 4 IMU + 2 ACC	2 bytes	2000 Hz	560 bytes
EEG		4 bytes	500 Hz	280 bytes

TAB. 8.5: *Size of a 2 ms data packet from Bio64-HD probe depending on the used sampling rate and resolution*

Bio32-HD

This is a monopolar probe that allows you to connect a 32-channels electrode matrix to one of the inputs IN1, IN2… IN10. The probe has an input with a multipolar connector that accepts the matrices produced and sold by OT Bioelettronica with 32 electrodes with code HDXXMMYYZZ (where XX indicates the interelectrode distance in mm, YY the number of rows and ZZ the number of columns of the electrode grid).

FIG. 8.6: *Bio32-HD probe for electrode grids with 32 channels*

The size of the 2 ms packets for this probe is reported, as a function of sampling rate and resolution, in Table 8.6.

Signals	Number of Channels	Resolution	Sampling Freq.	Data Packet
EMG	32 BIO + 4 IMU + 2 ACC	2 bytes	2000 Hz	280 bytes
EEG		4 bytes	500 Hz	140 bytes

TAB. 8.6: *Size of a 2 ms data packet from Bio32-HD probe depending on the used sampling rate and resolution*

Bio8-BP

Allows to connect up to 8 bipolar signals to one of the IN1, IN2… IN10 inputs.

FIG. 8.7: *Bio8-BP probe for 8 bipolar channels*

The size of the 2 ms packets for this probe is reported, as a function of sampling rate and resolution, in Table 8.7.

Signals	Number of Channels	Resolution	Sampling Freq.	Data Packet
EMG	8 BIO + 4 IMU + 2 ACC	2 bytes	2000 Hz	56 bytes
iEMG			4000 Hz	112 bytes
			8000 Hz	224 bytes

TAB. 8.7: *Size of a 2 ms data packet from Bio8-BP probe depending on the used sampling rate and resolution*

Bio40-IM

Allows to connect up to 40 intramuscular signals to one of the IN1, IN2… IN10 inputs.

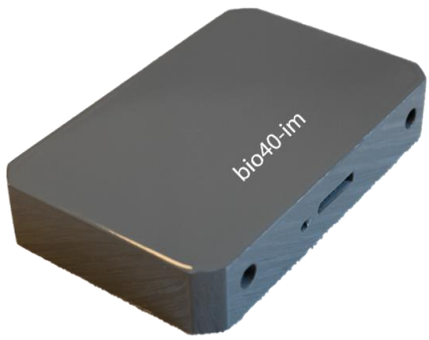

FIG. 8.8: *Bio40-IM probe for 40 intramuscular signals*

The size of the 2 ms packets for this probe is reported, as a function of sampling rate and resolution, in Table 8.8.

Signals	Number of Channels	Resolution	Sampling Freq.	Data Packet
iEMG	40 BIO + 4 IMU + 2 ACC	4 bytes	4000 Hz	368 bytes
		4 bytes	8000 Hz	736 bytes

TAB. 8.8: *Size of a 2 ms data packet from Bio40-IM probe depending on the used sampling rate and resolution*

Acquisition electrodes

Bipolar acquisition electrodes

FIG. 8.9: *Bipolar electrodes: CDE-C, CoDe 1.0 C and CoDe 2.0 C.*

Electrode matrices

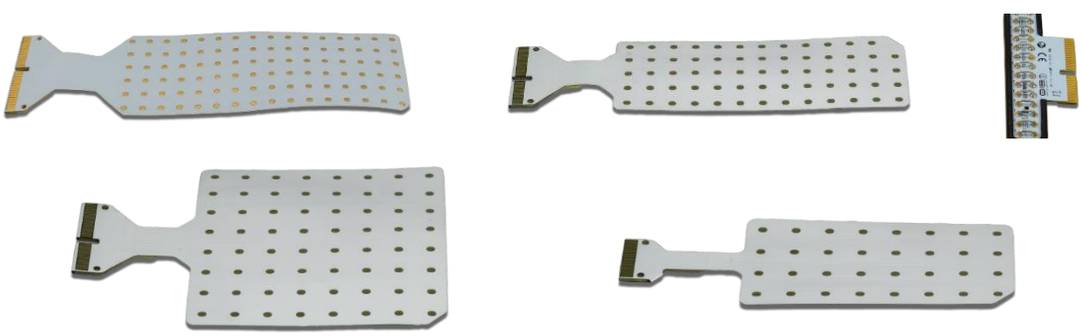

FIG. 8.10: *Electrode grids: wet and dry*

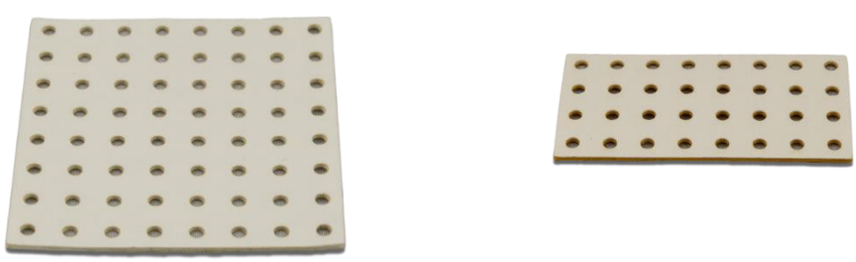

FIG. 8.11: *Double adhesive foam for wet electrode grids application*

To use the double adhesive foams for electrode matrices, refer to the instructions of use in figure 8.12.

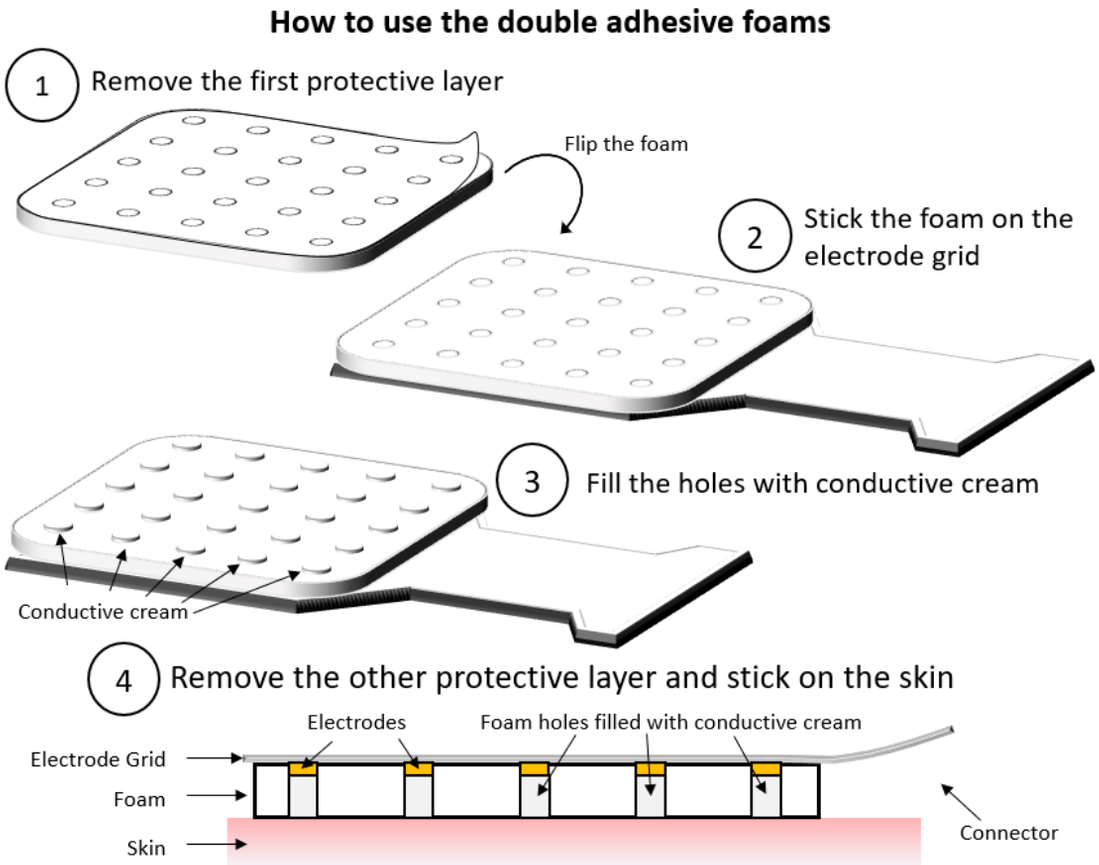

FIG. 8.12: *Double adhesive foams instructions of use for electrode grids*

8.11 Patient connections

To perform a biopotential recording, follow the instructions listed below:

- For each input, select the suitable adapter for the measurement to perform and plug it into one of the IN.
- Connect to the probes the electrode arrays or grids, the wires or needles suitable for the desired application.
- Connect a patient ground strip to PATIENT REF plug with the enclosed cable. The strap must be wet with water to assure a good electric contact with the patient and has to be connected on a point without bioelectrical activity (e.g. the ankle or the wrist, see fig. 8.13).

⚠ *REMARK: the lack of this connection prevents the correct acquisition of the bioelectrical signals.*

Figures 8.13 e 8.14, show some connection examples to acquire bioelectrical signals in different modalities available using Novecento+.

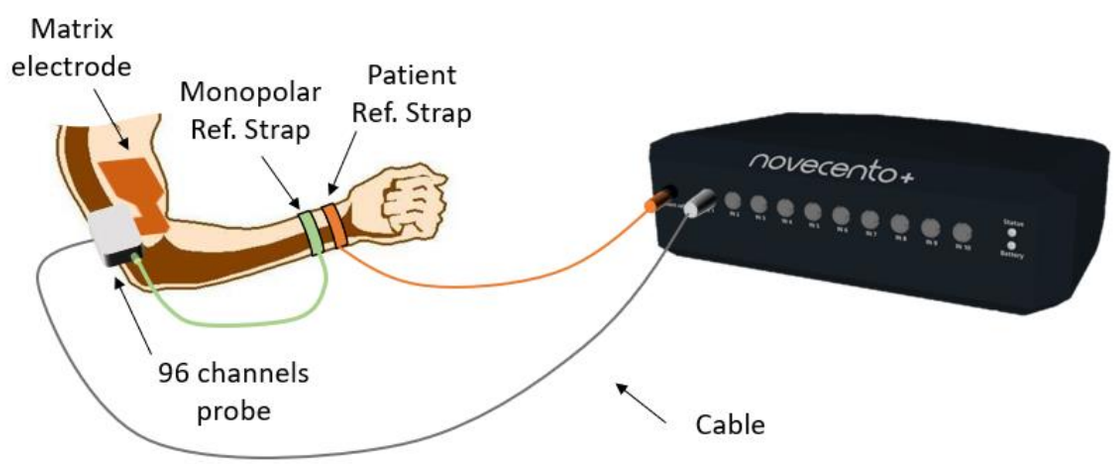

FIG. 8.13: *Patient standard connection diagram for signal acquisition in monopolar mode. The 96, 64, 32 channel probes provide an additional connection for a reference. A strap or a standard adhesive electrode can be used. This connection is used as the negative input for all the preamplifiers of the 96, 64, 32 channel probes, while the positive inputs are fed with the signals from the electrode grid. It is really important that the monopolar reference is on a point without EMG activity, close to the electrode matrix and not in contact with the patient reference*

⚠ *REMARK: patient reference strap and monopolar reference strap must not be in contact with each other*

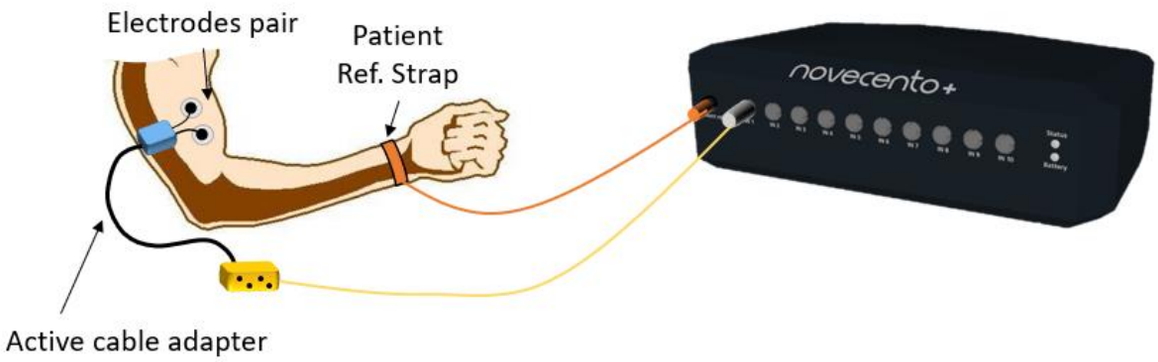

FIG. 8.14 *Patient connection diagram for signals acquired in bipolar mode. Up to 8 pairs of electrodes can be connected to each IN connector. In the figure, a passive adapter divides IN1 into 8 jack connectors*

8.12 Script development for reading data

As an alternative to using the OTBioLab software, it is possible to acquire data from the Novecento+ by communicating directly with the instrument. As an example, some Matlab and Python scripts are provided that can be downloaded from GitHub or from the OT Bioelettronica website.

The logic that the code must follow, summarized in steps, is the following:

- Connect to the TCP socket created at port 54321 by Novecento+
- Send a command to read the current configuration and the type of probes connected to Novecento+ (refer to the configuration and communication protocol available for download from the otbioelettronica.it website)
- Create the configuration command and calculate the size of data packets (refer to tables 8.2, 8.3… 8.8 of this manual for size calculation) coming from different data sources:
    - Each probe (SizeP1 for the probe 1, SizeP2 for the probe 2 ecc...)
    - from the inputs on the rear panel (SizeAUX)
    - from the accessory channels (SizeACC)
- Calculate the sum of the packet sizes from the previous point. The result is the size of a 2ms block from all active channels (Size2msBlock = SizeP1 + SizeP2 + SizeAUX + SizeACC, in case there are two active probes)
- Send the configuration command through the TCP socket to Novecento+
- Read block data of multiple size of Size2msBlock
- Extract from each block of size Size2msBlock the sub-blocks and concatenate these into new arrays, one for each data source (see figure 8.14)
- The new arrays obtained can be considered as data streams to be inserted into a matrix where the rows represent the channels and the columns the samples. This can be done in Matlab, for example, with the "reshape" command. Note that the new arrays can have different sampling frequencies and, if you want to plot them, they will have to have different time vectors.

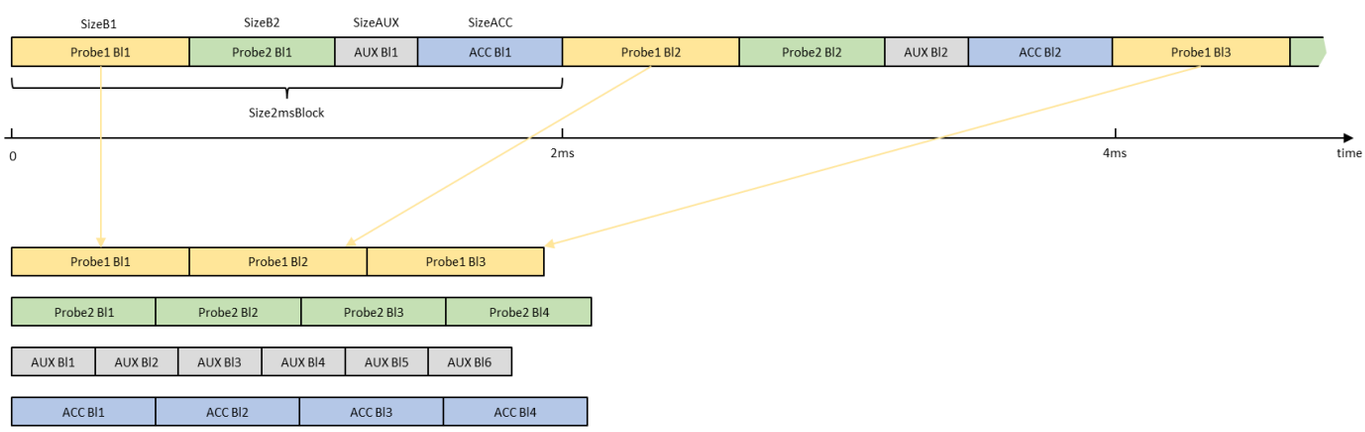

FIG. 8.15 *Schematic example of reading data from Novecento+. In the example, 2 probes are active, whose packets related to 2 ms are added to those of the AUX and Accessory channels. The code to read the data must create new arrays in which packets from the same source are concatenated.*

TROUBLESHOOTING

This section describes the most common problems that may be found by Novecento+ users, with some suggestions to solve them.

For problems not described in this section contact the technical support team of OT Bioelettronica.

GENERAL PROBLEMS		
Problem	**Possible causes**	**Solution**
The Novecento+ device does not turn on	Power supply cable is not inserted properly in the device or into the wall socket and the battery is fully discharged.	Check the power supply cable and the socket connection.
	The supply is provided only through the battery and Novecento+ does not automatically turn on	The button has to be switched in ON position to turn on Novecento+.
The embedded webpage is not displayed at the device IP address	The PC is not connected to the same network as Novecento+ or they are not in the same address range.	Check the connection on the same network and verify the network adapter settings on the PC.
	If Novecento+ is connected directly to the PC maybe some initialization of the ethernet board failed	Turn off the device and then turn it on again to re-initialize the ethernet board.
Connecting Novecento+ to a different network, therefore it does not have the new OP address assigned correctly	The assignment of the IP address with Novecento+ is only managed in the initialization phase.	Restart Novecento+ turning the switch off and on again.
Signals are not displayed on OTBioLab	The IP address set in OTBioLab is not correct.	Set the correct IP address under Open Setup window -> Parameters

	The network interface has not completed the initialization. If the DHCP mode is active, wait 20s before returning to the default settings.	Wait until the IP address is reachable through the IP address.
	Problems with the ethernet connection or the address range.	Try to open the Novecento+ webpage in your browser and refer to "The embedded webpage is not displayed at the device IP address" problem on this table.
Signals are saturating	Monopolar reference strap is disconnected	Pay attention to the cable or strap clip
	Signals are present but saturated for a higher DC component.	In the "Pre-Amp Gain" section of the Setup (OTBioLab software) select the value 4. In this way the signals will be within the dynamic range, but the noise will increase slightly. Attention: in this way the LSB is also modified.
All channels present large noise	Patient reference strap is disconnected	Pay attention to the cable or strap clip
All channels present interference	Patient reference strap and monopolar reference strap are in contact with each other	Pay attention to the reference straps
	The subject is coupled with interference source	

TAB. 9.1: *Troubleshooting of the general problems that can occur using the Novecento+*

9 NOVECENTO+ MAINTENANCE AND STORAGE

Novecento+ must be used in the following ambient conditions:

Temperature:	from 0°C to +40°C
Maximum relative humidity:	75%
Atmospheric pressure:	from 700 hPa to 1060 hPa

It is recommended to turn off the Novecento+ device at the end of each measurement session, and to remove all the cables and connections. The Novecento+ device should be stored with all the enclosed accessories on a safe desk far from all the situations listed in the section *Warnings.*

Novecento+ should be stored in the following ambient conditions:

Temperature:	from -20°C to +40°C
Maximum relative humidity:	75%
Atmospheric pressure:	from 700 hPa to 1060 hPa

Cleaning: use only a dry cloth to clean the device.

It is recommended to plan a device check every 24 months with the manufacturer. The Novecento+ device should be repaired by the manufacturer only. Every repair executed by unauthorized staff will be considered as a device violation voids the manufacturer's warranty.

Disposal

The device and the accessories should be disposed in compliance with the relative standards in special equipped areas or with special waste.

10 RISK ANALYSIS

10.1 General requirement for basic safety and essential performance CEI EN 60601-1-2

- EN 60601-1 Medical electrical equipment - Part 1: General safety requirement
- EN 60601-1-2 Medical electrical equipment - Part 1: General requirement for basic safety and essential performance

Novecento+ is designed to be used in an electromagnetic environment with the characteristics specified below. The purchaser or user of Novecento+ is obliged to ensure that the device is used in an environment conforming to these specifications.

Manufacturer's declaration and guidelines - electromagnetic emissions	
Phenomenon	Professional healthcare environment
RF conducted and radiated emissions	EN 55011:2009 + A1:2010
Voltage fluctuations and flicker	IEC 61000-3-3

TAB. 11.1: *Tests carried out and passed for compliance with current regulations on electromagnetic emissions.*

Manufacturer's declaration and guidelines - electromagnetic immunity - casing door		
Phenomenon	**EMC reference standard or test method**	**Immunity test levels – Professional healthcare environment**
Electrostatic Discharges	IEC 61000-4-2	+/- 8 kV at contact +/- 2 kV, +/- 4 kV, +/- 8 kV e +/- 15 kV[a)] in air
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz
Radiated RF EM fields and proximity wireless fields	IEC 61000-4-3	28 V/m 450 MHz, 810 MHz - 2.45 GHz at 18/217 Hz 27 V/m 385 MHz at 18 Hz 9 V/m 710 MHz – 780 MHz, 5.24 GHz – 5.785 GHz at 217 Hz
Electrical fast transient and bursts	IEC 61000-4-4	+/- 2 kV direct injection +/- 1 kV capacitive clamp
Surges	IEC 61000-4-5	1 kV line to line 2 kV line to earth
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V RMS outside ISM band 80% AM at 1 kHz 6 V RMS in ISM band 80% AM at 1 kHz
Voltage dips and interruptions	IEC 61000-4-11	50 Hz and 60 Hz
Rated power-frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz and 60 Hz
[a)] The tests at 15 kV were exceeded by the casing and button, while this test was not exceeded by the display.		

TAB. 11.2: Tests carried out and passed for compliance with current regulations on electromagnetic immunity.

11 INTENDED USE

The device allows you to acquire bioelectric signals generated by the human body, save them in a file and be able to review them on a PC thanks to the use of the OTBioLab software. The system therefore allows you to evaluate physiological parameters in the context of clinical or applied research, but it was not designed to make diagnoses of any kind or even to monitor vital parameters.

The electroencephalogram section has been designed for machine learning and not for diagnostic purposes of any kind.

Typical applications are in the field of bioengineering and the interface between man and machine, in sport and motor science, in basic research in medicine.

12 TECHNICAL CHARACTERISTICS

Model:	Novecento+
Risk classification:	I, in compliance with Regulation 745/2017.
Insulation class:	BF type applied part, in compliance with the European standard EN 60601-1
Classification:	IP20, about the penetration of fluids and dust; device not protected.
Case:	*painted Plexiglas case.*
Power supply:	12 V_{DC}
Consumption:	50 W
Limitations:	Device not suitable for use in environments with high oxygen concentration and/or flammable fluids and/or gases; do not use with electro-surgery or short wave/microwave therapy equipment.
Working conditions:	device suitable for continuative work.
Input channels:	up to 960 independents
Amplification:	Maximum input range 2.4 V_{PP}
Bandwidth:	10 ÷ 2000 Hz
Total noise (RTI)	< 2μV_{RMS} (monopolar) < 1μV_{RMS} (differential)
Bioelectrical signal gain:	2, 4, 6, 8 V/V
Auxiliary signal gain:	0.5 V/V
Resolution:	16 or 24 bits
Input resistance	> $10^9\Omega$ on the entire bandwidth
CMRR	> 95 dB
Commands:	1 button
Dimensions:	310 x 225 x 100 mm
Weight:	3 Kg

13 WARRANTY

Novecento+ electrical parts are covered by a 24-month warranty starting from the purchasing date.
Connection cables are covered by a 24-month warranty.
The warranty is void in case of device violation or in case of intervention from unauthorized staff.
Warranty conditions are reported hereinafter.

13.1 Warranty conditions

- The electronic parts warranty lasts 24 months. Warranty is provided by the manufacturer.
- The warranty covers only device damage that causes malfunctioning. The product must have the same serial number indicated on this certificate, or the warranty is released.
- The warranty covers only the cost of repair or substitutions of defective components, including the costs of labour.
- The warranty is void in case of damage caused by negligence, use not compliant with the instructions supplied, unauthorized repairs and accidental circumstances, especially for the external part.
- The warranty is void if damage is caused by incorrect power supply.
- The warranty is not applied on all the parts subject to wear and tear.
- The warranty does not include the shipment costs.
- After 24 months, the warranty is released. All the substituted parts, the labour costs and the shipment costs will be charged to the purchaser according to the rates in force.

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