



**User Manual v.2.0**

# Sessantaquattro+

**Portable bioelectrical signal amplifier**



Read this manual carefully before using Sessantaquattro+



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## 1 GENERAL DESCRIPTION

Sessantaquattro+ is a multichannel amplifier and datalogger for bioelectrical signals. The Sessantaquattro+ device allows the detection and recording of the electric signals generated by the human body. The signals acquired by the instrument are amplified, filtered, digitally converted and then transferred to a PC, through a WiFi connection, for real-time visualization and storage, or stored in a MicroSD card. A freeware software for real time display and storage, called OT BioLab+, has been designed by OT Bioelettronica and is available for download at this link: <https://otbioelettronica.it/downloads>. The Sessantaquattro+ device is a research instrument designed for clinical research carried out by qualified researchers. It is completely safe for the patient. The safety is achieved by satisfying the design requirements for devices with an electronic part applied to the patient. Sessantaquattro+ has different adapters to connect different electrode configurations. Each of them also has two inputs for auxiliary signals.

## 2 SESSANTAQUATTRO+ KIT CONTENT

- 1 Sessantaquattro+
- 1 Adapter for the battery charging (CUSB01SP)
- Cable adapters to connect electrodes to the amplifier, depending on the customer request
- 1 Conductive cream package
- 1 Reference strap for the wrist
- 1 Reference strap for the ankle
- 1 Reference cables
- 1 USB cable type A-C
- 1 MicroSD card
- Arrays and matrix of electrodes of different sizes, depending on the customer request
- 1 Sessantaquattro+ user manual

### **3 END USER**

Sessantaquattro+ multichannel amplifier allows non-invasive recording of biopotentials (sEMG, EEG) detected by superficial electrodes. The end user must be familiar with the technique and received proper training in EMG or EEG detection and interpretation.

#### **3.1 Contraindications**

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

#### **3.2 Side effects**

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 by reducing the duration of bioelectrical signal acquisitions.

### **4 SAFETY PRECAUTIONS AND OTHER WARNINGS**

The use of the multichannel amplifier Sessantaquattro+ is absolutely forbidden in the following conditions:

- While other monitoring devices are in use with the patient.
- 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 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:

- Only use electrodes supplied by the manufacturer: Sessantaquattro+ 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 dropping on the floor, etc.), verify that no crack or any other kind of damage is visible. If in doubt, please contact the manufacturer.
- The Sessantaquattro+ 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 take into account the presence of noise in your signal processing tasks and evaluations.
- The connection between Sessantaquattro+ and other electrical devices must be done in compliance with the European standard EN 60601-1-1 on medical devices.
- The use of the Sessantaquattro+ 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. Read carefully the instruction remarks before use.

## 5 SYMBOLS USED ON SESSANTAQUATTRO+ AND IN THE USER MANUAL



Serial number



Indicates the manufacturer's catalogue number so the medical device can be identified



Identifies a type BF applied part complying with IEC 60601-1



Manufacturer



Do not dispose of this product as non-differentiated waste. Prepare the re-use or separate collection of the product Union on the disposal of electrical and electronic equipment in compliance with the Directive 2002/96/CE.



CE marking indicates that product complies with applicable European Union regulations



Read the instruction manual



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

Degrees of protection:

### IP20

Protected against solid objects over 12.5 mm

No protection against liquid



Read carefully the instruction remarks before use

## 6 TECHNICAL SPECIFICATIONS

Sessantaquattro+ is a battery powered device designed to guarantee a high safety level for the patient and the operator in all operating conditions. The insulation between Sessantaquattro+ and the PC for real time data display and storage, is intrinsically achieved by the wireless data transfer and communication. The same connector is used for electrode interface and battery recharge avoiding the chance to power the Sessantaquattro+ device from an external source when it is connected to the patient.

The connector for the auxiliary inputs is intended for the interface with other floating devices (goniometers, accelerometers or amplifiers for other biological signals). The connection must be done in compliance with the European standard EN 60601-1-1 on medical devices. Table 6.1 shows the list of available adapters and their connections.

Adapter	Available connections
CUSB01SP	USB type C, for battery recharge
AD8x1SP	Eight four poles 3.5 mm jacks for connection of two bipolar electrode pairs (16 electrodes pairs in total). An additional four poles 3.5 mm jack for two auxiliary signals. 2 mm female banana for the patient reference connection.
AD1x16SP	16 pin connector for linear electrode arrays. An additional four poles 3.5 mm jack for two auxiliary signals. 2 mm female banana for the patient reference connection.
AD2x32SP	Two 32 pin connectors for 32 electrode matrices. An additional four poles 3.5 mm jack for two auxiliary signals. 2 mm female banana for the patient reference connection.
AD1x64SP	70 pin connectors for 64 electrode matrices or 64 electrode EEG caps. An additional four poles 3.5 mm jack for two auxiliary signals. 2 mm female banana for the patient reference connection.

**TAB. 6.1:** List of Sessantaquattro+ available adapters

Additional adapters can be made under user request to interface other types of electrodes or sensors. The Sessantaquattro+ technical specifications are shown in Table 6.2.

<b>EMG/EEG channels</b>	
Number of channels	64
Gain	1 V/V
Band pass filter EMG	10 - 500 Hz
Band pass filter EEG	DC coupled – 125 Hz
Noise level referred to input EMG	< 8 $\mu\text{V}_{\text{RMS}}$
Noise level referred to input EEG	< 6 $\mu\text{V}_{\text{RMS}}$
Input resistance	500 M $\Omega$
Input range	0 – 3.3 V
<b>Auxiliary channels</b>	
Number of channels	2
Gain	0.5 V/V
Low pass filter	$\sim F_{\text{SAMP}}/4$
High pass filter	DC coupled
Noise level referred to input	< 6.1 $\mu\text{V}_{\text{RMS}}$
Input resistance	500 M $\Omega$
Input range	$\pm 3.3$ V
<b>IMU – inertial sensor</b>	
Number and type	<ul style="list-style-type: none"> <li>- Triaxial Accelerometer (+/- 4g)</li> <li>- Triaxial Gyroscope (2000 °/s)</li> <li>- Triaxial Magnetometer</li> </ul>
<b>Data conversion and communication</b>	
A/D converter resolution	16, 24 bits (EEG, EMG)
A/D converter input dynamics	$\pm 2.4$ V
Selectable sample frequency	500 or 2000 Hz (EEG or EMG)
Data transfer to PC	WiFi through TCP socket
Data storage	MicroSD
<b>Battery</b>	
Battery life – Charging time	8 hours (full charge) – 7 hours

**TAB. 6.2:** Sessantaquattro+ technical specification

## 7 DETAILED DESCRIPTION

Sessantaquattro+ is a battery powered portable device for the acquisition of surface EMG and EEG. Signals can be transferred to a PC for real time display and recording or directly stored on a MicroSD card by the device. The device can act as a WiFi access point or connect to an existing network provided by an external access point. In both cases, Sessantaquattro+ has an IP address in which a web page can be reached using any browser, for configuration, control and firmware updates. Data transfer to a PC is obtained through a TCP socket opened by the PC. A configuration string sent to Sessantaquattro+ can set all the acquisition parameters and start the data transfer. The communication protocol is available for custom development together with a demonstration MatLab code.

### 7.1 Controls, indicators and connector

Sessantaquattro+ can be fully configured by means of its internal web page, while the LEDs and button just provide a quick access to basic functions.



**FIG. 7.1:** Sessantaquattro+ controls, connectors and indicators

### 7.1.1 Input and recharge connector

The 80 pins connector is the interface between Sessantaquattro+ and its adapters. The different adapters allow to connect the device with different types of electrodes and sensors or to recharge the battery.

The pinout of the connector is available on request for custom projects. Refer to section 8.3 for additional details about the available adapters.

### 7.1.2 OFF/ON switch

This switch turns on and off the Sessantaquattro+ device by completely removing the battery supply from all its parts. You should move the switch to the OFF position when the device is not used to avoid battery discharge.

### 7.1.3 MicroSD card slot

This socket accepts MicroSD card formatted as FAT16 or FAT32 to use the Sessantaquattro+ device as a data logger. The acquisition can be started with the Start/Stop REC pushbutton if enabled or through commands on the WiFi. Refer to section 8.5 for additional details about the data recording on the MicroSD card.

### 7.1.4 LEDs indicators

Three LEDs are used to identify the state of Sessantaquattro+. Each of them reflects the state of a different device activity:

- 1) the red LED highlights errors or problems
- 2) the blue LED indicates the state of the data logging
- 3) the white LED is related to the wireless data transfer

The three LEDs are independent, and the information provided from each one is displayed cyclically by a given number of blinks. In Table 7.1 the different states and related number of LEDs blinks are highlighted.

N. of blinks	1	2	3	4
<b>White LED</b>	WiFi active	Connected to a network	Connected to a TCP socket	Transferring data
<b>Blue LED</b>	Waiting for a trigger	Recording data on SD	-	-
<b>Red LED</b>	Data lost during Wifi transfer	MicroSD card error	Low battery	-

**TAB. 7.1:** Relation between the number of blinks of each LED and Sessantaquattro+ states.

## White LED

This LED indicates the state of the WiFi and data transfer through a TCP socket.

Slightly different information is provided depending on the role of Sessantaquattro+.

When acting as an access point:

- a) one blink of the white LED indicates that the network has been generated and is available to connect to another device;
- b) two blinks indicate that a device is connected to the network generated by Sessantaquattro+.

When configured to connect to an external WiFi network:

- a) one blink indicates that Sessantaquattro+ is active and is searching for one network
- b) two blinks indicate that Sessantaquattro+ has successfully connected to an external network

Regardless of the Sessantaquattro+ role, three blinks indicate that Sessantaquattro+ is connected as a client to a TCP socket generated by a server device (usually the PC used for real time data display and recording); four blinks indicate that Sessantaquattro+ is transferring data through the TCP socket to a server. Using OT BioLab+ software the three blinks condition is never visible because the TCP socket is opened when pressing the button of data transfer and, as soon as Sessantaquattro+ is connected to the socket, the data transfer begins. The three blinks condition can be useful for custom development in the debugging phase to understand when the TCP socket is correctly created and Sessantaquattro+ is connected to it.

### **Blue LED**

The blue LED reflects the state of the data logging on the MicroSD card. All the settings for the data logging can be provided to Sessantaquattro+ using the internal web page, including how to control the start and stop recording. One blink of the LED indicates that the recording on MicroSD card is ready and Sessantaquattro+ is waiting for the triggering event to start the recording. The typical trigger event to start a recording is pressing the button, but more options are available using the configuration string sent to Sessantaquattro+ through the TCP socket. When starting an acquisition directly from the internal web page or with the configuration string, the 1 blink state does not occur, and the recording starts instantly. Two blinks of the blue LED reflect that data storing on the MicroSD card is in progress.

### **Red LED**

The red LED is used to alert the user of an error or a critical condition. One blink indicates that samples has been lost in the wireless data transfer. This happen when the Sessantaquattro+ device internal data buffers are full, and the transmission of data packets is not possible. The acquisition of the next signal sample will create a reset of the internal data buffer with the loss of an amount of data equal to the

data buffers size (refer to section 8.2 for additional details). If this condition is temporary (e.g., Sessantaquattro+ for a limited time is too far from the PC for the acquisition), and the data transfer restarts properly, the red LED will stop to blink.

The data loss in recorded data can in any case be verified offline by checking one of the accessory channels (see section 8.2 for additional details).

Two blinks of the red LED indicate an error in the process of the MicroSD data recording. Typical conditions that generate this error are: MicroSD not inserted, MicroSD not formatted as FAT16 or FAT32, maximum file size larger than the maximum contiguous space on the MicroSD. This error condition persists until another data recording on MicroSD card starts successfully or until another type of error occur.

Three blinks of the red LED correspond to a battery level lower than the 20%. Please note that there is no priority in the error reporting and always the last error detected generates the number of blinks of the red LED. For example, if a data recording on the MicroSD produce an error and then an error on data transfer happens, the LED will indicate the error related to the data transfer until it persists (because it happens later). As soon as the wireless communication restarts properly, the LED will indicate no error.

In general, the low battery level will prevail on the other error conditions, simply because the battery level is monitored quite frequently and continuously.

### **7.1.5 Start/Stop REC button**

The Sessantaquattro+ pushbutton has the main function to start and stop the data recording on the MicroSD. It can be activated/deactivated from the internal web page or by means of the commands sent through the TCP socket. The option to deactivate the pushbutton has been introduced to avoid the possibility to accidentally press the button during a long-time data recording and stop involuntarily the



data logging. A second function of the pushbutton is obtained if it is pressed for about 5 seconds while the device is on. In this condition, all the three LEDs start flashing simultaneously for four times and the Sessantaquattro+ role is forced to be “access point”. This feature can be helpful if Sessantaquattro+ has been configured as a station connecting to an external WiFi network, but none of the networks in the Sessantaquattro+ list is available. In this condition, the device cannot be reached for any type of communication and the only way to access it again is the use of this secondary function of the pushbutton.

## 8 USE OF SESSANTAQUATTRO+

The Sessantaquattro+ device can be interfaced to any computer with a network interface and running any kind of operative system. This manual refers to the use of Sessantaquattro+ together with PC with Windows and the freeware software OT BioLab+. 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 Sessantaquattro+ is available as Matlab examples. Please contact OT Bioelettronica to receive the additional manual and examples.

### 8.1 Sessantaquattro+ WiFi interface

The WiFi interface available for Sessantaquattro+ is similar to the interface available for other devices like printers, routers or access points. As any other device connected to a network, Sessantaquattro+ has its own IP address. When Sessantaquattro+ is connected to a network (with the same IP range of the PC) it is accessible for data transfer, ping or configuration through its web configuration page. It can act as an access point or can connect to a WiFi network generated from other access points. In the default factory settings, Sessantaquattro+ generates an open WiFi network (with no password) with the name "Sessantaquattro+" and acts as a DHCP server providing the settings to the devices that are connected to the network. The Sessantaquattro+ default IP address, when it acts as access point, is 192.168.1.1, with subnet mask 255.255.255.0. When successfully connected to the network generated by Sessantaquattro+, typing the IP address on any browser the internal configuration page will be displayed (refer to section 8.6). The configuration page allows you to check the current settings and to change all the parameters.

A list of networks, and relative passwords to access them, can be saved in the internal flash memory of Sessantaquattro+ (refer to section 8.6). When the Sessantaquattro+ is configured to connect to an

external WiFi network, at start-up, it tries to connect to one of the networks in its list and, when successfully connected, the white led blinks twice. In this condition, a service called mDNS running on Sessantaquattro+ can be used to find its IP address. OT BioLab+ software provides a button in the configuration window to directly open the Sessantaquattro+ web page.

## 8.2 Signals

The native resolution of Sessantaquattro+ is 24 bits obtained by sampling the signals with a sigma-delta A/D converter. The signals are acquired DC coupled and the only hardware filtering is a simple antialiasing filter at 154 kHz. The low pass filter is imposed by the sampling frequency and is about  $\frac{1}{4}$  of the sampling frequency. The acquisition with all the 24 bits is intended for EEG signals DC coupled to a maximum sampling frequency of 1 kHz. For the EMG data collection, a firmware high pass filter is implemented (only on the bioelectrical signals, not on the auxiliary) removing the DC component and moving the signals baseline to the middle scale of the dynamic. This condition makes possible the acquisition of the EMG signals with a reduced 16 bits resolution. The data format in both cases, 24 bits and 16 bits, is big endian.

The filter is obtained by subtracting to the signals the exponential moving average, obtained by:

$$\text{Mean\_ChX}[t] = (1-\alpha) \text{Mean\_ChX}[t-1] + \alpha \text{ChX}[t]$$

Where  $\alpha$  is equal to  $1/2^5$ . This result in a high pass filter with a cut-off frequency of 10.5 Hz, when sampling the signals at 2000 Hz. More in general the High-pass cut-off frequency is  $F_{\text{samp}}/190$ .

The A/D converters have differential inputs that allow the positive and negative inputs to swing theoretically between  $\pm 2.4$  V. In the case of Sessantaquattro+, the limit is imposed by the voltage supply that is 3.3V. The positive input is feed with the signals from the electrodes, the negative signals

are connected to the patient reference (midpoint of the power supply). The least significant bit (LSB) of the signals is obtained by:

$$\text{LSB} = \text{ADC}_{\text{RANGE}}/2^{24} = 286.1 \text{ nV}$$

On the standard adapters, that have the jack connector for the collection of the two auxiliary signals, a simple circuit allows you to extend the input range to  $\pm 3.3 \text{ V}$  by increasing the LSB value to  $572.2 \text{ nV}$ . An additional extension factor on the bioelectrical analog signals can be added (only in custom development, not using OT BioLab+) to increase the input range when the 16 bits resolution is used, with values of 2, 4, 8. When the 16 bits resolution is set, only the 16 less significant bits are transferred for the bioelectrical signals and only the 16 most significant bits are transferred for the AUX signals.

This introduces a limitation in the signal range for the bioelectrical signals to  $18,75 \text{ mV}_{\text{PP}}$  and a limitation in the resolution for the auxiliary signals with an LSB of  $146,48 \mu\text{V}$ .

Table 8.1 summarize the different input ranges, LSB values, RMS and peak to peak noise with the different acquisition settings for bioelectrical and auxiliary signals.

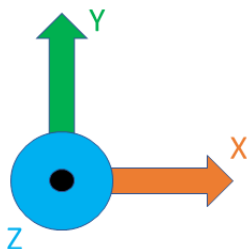
Resolution	Input Range	LSB	Noise RMS R.T.I.	Noise P-P R.T.I.
16 bits, BioSig	18,75 mV	286.1 nV	0.6 – 1.2 $\mu\text{V}$	3.6 – 7.8 $\mu\text{V}$
16 bits, Ext = 2, BioSig	37.5 mV	572.2 nV	0.9 – 1.8 $\mu\text{V}$	5.7 – 12.1 $\mu\text{V}$
16 bits, Ext = 4, BioSig	75 mV	1.144 $\mu\text{V}$	1.6 – 3.2 $\mu\text{V}$	9.8 – 22.2 $\mu\text{V}$
16 bits, Ext = 8, BioSig	150 mV	2.289 $\mu\text{V}$	3 – 6.1 $\mu\text{V}$	17.9 – 41.8 $\mu\text{V}$
24 bits, BioSig	3,3 V	286.1 nV	0.6 – 1.2 $\mu\text{V}$	3.6 – 7.8 $\mu\text{V}$
16 bits, AuxSig	6,6 V	146,48 mV	3 – 6.1 $\mu\text{V}$	17.9 – 41.8 $\mu\text{V}$
24 bits, AuxSig	6,6 V	572.2 nV	3 – 6.1 $\mu\text{V}$	17.9 – 41.8 $\mu\text{V}$

**TAB. 8.1.** Characteristics of acquired signals with different settings. The noise range is related to different sampling frequencies.

Additionally, to the biological and auxiliary signals, 4 channels from an inertial sensor and 2 accessory channels have been added to the set signals, both when data is transferred via WiFi and when signals are recorded on the MicroSD card. All 6 channels are represented on 16 or 24 bits consistent with the resolution of the bioelectric signals. In other words, if the acquired bioelectrical signals are EMG and the resolution is 16 bits, the 6 additional channels are also represented on 16 bits. Conversely, if the acquired signals are EEG, all channels will be represented at 24 bits, but without altering the information contained, only by extending the numbers with a representation on 24 bits.

The first four additional channels (channels 65, 66, 67 and 68) are the data relating to the IMU (Inertial Measurement Unit) and corresponding 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, extended with sign to 16 or 24 bits depending on the acquisition mode of the Sessantaquattro+. The quaternions are the result of an internal calculation of 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 values of the quaternions before obtaining a new set of values for the quaternions.

Figure 8.1 shows the positioning of the IMU sensor inside the Sessantaquattro+ with indication of the orientation of the axes.



**FIG. 8.1:** Positioning and positioning of the IMU inertial sensor.

The two accessory channels contain information about the RF synchronization signal sent by the SyncStation, the use of the Sessantaquattro+ internal memory buffer and a sample counter. In particular, the first channel provides information about the internal buffer usage and the trigger state. The buffer usage is represented on the 15 less significant bits and indicates how many bytes (the value has to be multiplied by 4) are currently in the internal buffer waiting to be written on the MicroSD card or sent through the WiFi network. The remaining bit is used to represent the binary state of the trigger.

The second accessory channel is a sample counter. This is incremented with each new sample acquired and can be used to check if one or more samples have been lost. The difference between two successive values in fact indicates how many samples have elapsed since the previous sampling and if some data have been lost, it is possible to identify how many samples have been lost. Once the counter reaches the largest possible value with the corresponding resolution, it restarts with the count.

### 8.3 Electrode and recharge adapters

The different adapters essentially provide access to input connector. Each adapter is intended for the connection to particular electrodes type or for the battery recharge. A predefined detection mode is associated to each adapter. Detailed description of each adapter is highlighted in the following section.

#### CUSB01SP

It is the battery charger adapter for the Sessantaquattro+. The supply can be provided with a USB type C cable connected to a PC or to a wall DC adapter, like the ones used for any smartphone.

When connected to a PC, please check the PC power supply settings to ensure that it won't enter standby mode during the recharge and interrupt it.

The red LED on the top of the CUSB01SE indicates, when it is on, that the battery recharge is in progress and, when it turns off, that the recharge is completed (Fig. 8.2).



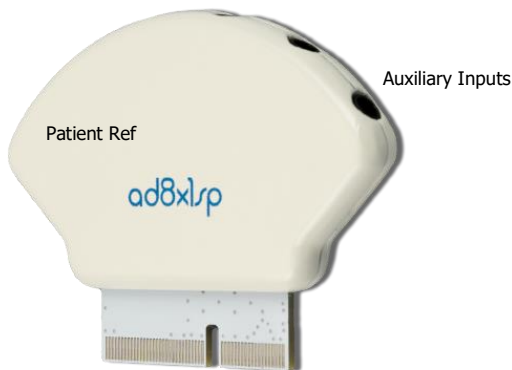
**FIG. 8.2:** The CUSB01SP adapter

The integrated circuit that controls the battery recharge is in the adapter itself that implements different recharge techniques depending on the battery level: battery conditioning, constant current and constant voltage. The constant current phase is the one that lasts longer and produces a more efficient battery recharge. The recharge current is internally set to about 300 mA.

Avoid patient connection while the device is also connected to an external power supply source.

### AD8x1SP

This adapter allows the connection of up to 8 electrode pairs through four four-poles 3.5 mm jacks (see Fig. 8.3). The signal detected from the 16 electrodes feed the positive inputs of the first 16 channels. The patient reference, available on the adapter as a 2 mm female banana connector, has to be placed using a reference strap or a large electrode to the patient body on a place without bioelectrical activity.

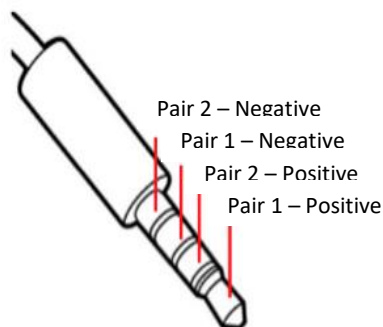


**FIG. 8.3:** *The AD8x1SE adapter*

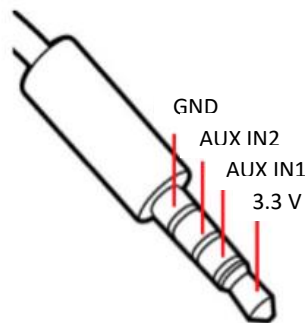


At the same time, this electrode fixes the standard patient body potential mode to the midpoint of the power supply of Sessantaquattro+ and feed the negative inputs of all the channels.

This adapter is intended for the detection of 8 bipolar signals obtained as a difference between each electrode pair. The differences are estimated from the microcontroller by subtracting, sample by sample, the A/D conversions generated from the channels corresponding to each electrodes pair. Figure 8.4 shows the 3.5 mm jack pinout to interface the two electrode pairs to the Sessantaquattro+.



**FIG. 8.4:** Four poles 3.5 mm jack connector pinout for the connection of two electrode pairs to the



**FIG. 8.5:** Four poles 3.5 mm jack connector pinout for the connection of two auxiliary signals to the

Additionally, to the EMG signals, the AD8x1SP allows the connection of two auxiliary signals through a fifth jack connector. This connector can also provide a 3.3 V output voltage to eventually supply external circuits.

There is not a limit for the current supplied by this output voltage, but it is intended for small loads, in the order of few tens of milliamps. This voltage is also the voltage used for the internal analog circuits

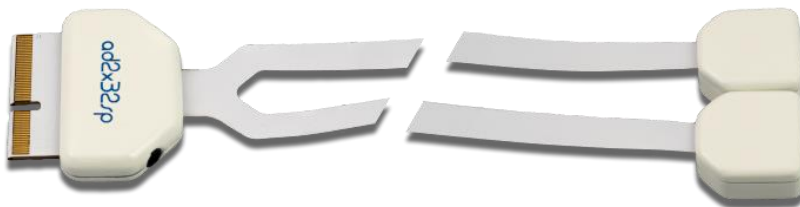
supply; thus, unregulated absorption can generate noise on the biopotential signals. Figure 8.5 shows the pinout of the auxiliary input connector.

The input swing for the AUX IN signals is  $\pm 3.3$  V. Refer to section 8.2 for further details about the AUX IN signals conversion.

### AD2x32SP

The AD2x32SP provides two connections towards 32 electrode matrices. A single model of 4 rows and 8 columns is available as a standard electrode grid, but additional shapes and sizes can be designed on request. The two adapter branches are labelled with 1 and 2 indicating which matrix will be connected to the first 32 channels and which to channels 33 to 64.

The patient reference connection is available as a 2 mm banana connector as well as two additional auxiliary inputs. Refer to previous described adapters for further details about patient reference connection and auxiliary inputs.

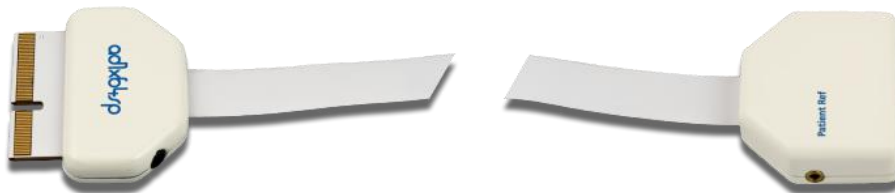


**FIG. 8.7:** *The AD2x32SP adapter*

### AD1x64SP

The AD1x64SP make available a connection for 64 electrode matrices. Different electrode matrix types, sizes and shapes are available, refer to our website for a complete list.

The patient reference connection is available as a 2 mm banana connector and as well as two additional auxiliary inputs. Refer to previous described adapters for further details about patient reference connection and auxiliary inputs.



**FIG. 8.8:** *The AD1x64SP adapter*

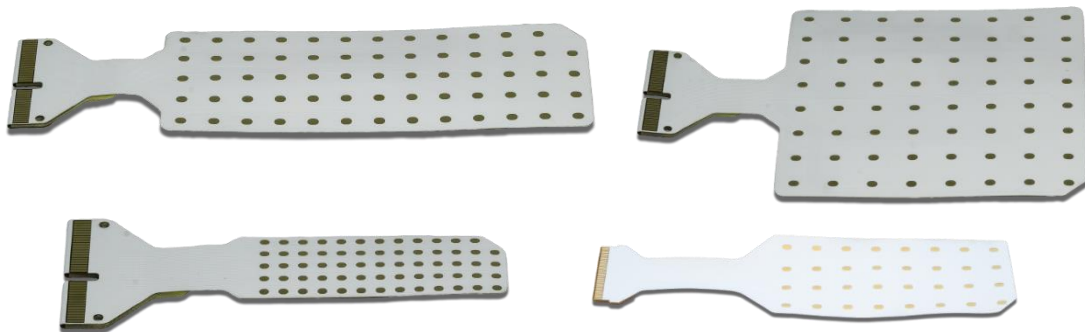
## Acquisition electrodes

- Bipolar acquisition electrodes

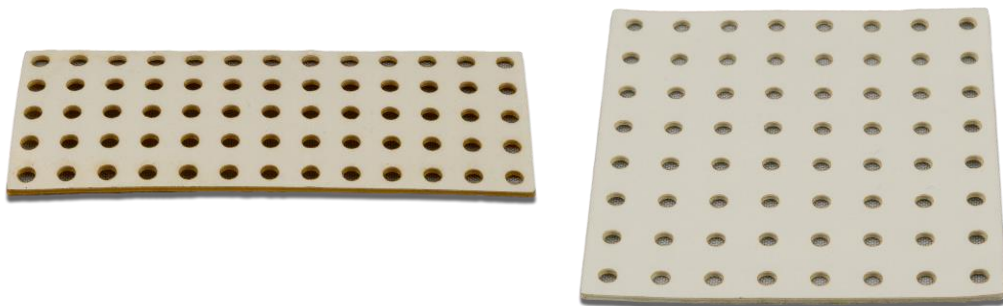


**FIG. 8.9:** *Bipolar electrodes: CDE-C.*

- Electrode matrices



*FIG. 8.11: Electrode matrices: wet.*



*FIG. 8.12: Double adhesive foam for wet electrode matrices application.*

## 8.4 Wireless data transfer

Signals acquired with Sessantaquattro+ can be read with a WiFi interface using a TCP connection. A TCP socket has to be opened by the computer (or tablet, smartphone) running OT BioLab+ or other custom applications. The default port is 45454 but can be changed in custom applications by the user. When Sessantaquattro+ is connected to a WiFi network, it continuously searches for a TCP socket opened on the IP address provided through the internal web page and connected as a client to the socket as soon as it is found.

When the connection through the socket is established, the communication can be started by sending a configuration command that sets the number of channels, the sampling frequency, the detection mode etc...

The server-client role has been chosen to allow the connection of more than one Sessantaquattro+ to the same PC. Options for the synchronization are available for future implementations.

The signals acquired are internally double buffered from the first microcontroller that manage the signals sampling and from the second that manage the WiFi network and data transfer. The space available on the first microcontroller is 90 kBytes while on the second microcontroller it is about 74 kBytes. Data is transferred between the two microcontrollers in blocks of about 0.5 kBytes (depending on channels settings) and firstly placed in the buffer of the second microcontroller. When this buffer is full, due to impossibility to transfer data to the PC, the data is accumulated also in the first microcontroller buffer. The accessory channel that reports the buffer usage only reports the buffer usage of the first microcontroller.

## 8.5 MicroSD data logging

Sessantaquattro+ can work as a data logger by recording the data onto a MicroSD card. The MicroSD card has to be formatted as FAT16 or FAT32. Acquisition parameters: sampling frequency, number of channels to be acquired, resolution, high pass filter and detection mode, can be set through the embedded webpage (refer to section 8.6), with OT BioLab+ software or with custom software using the communication protocol available on request.

The Start/Stop REC button can be used to manually start and stop an acquisition with data storing on the MicroSD card, when the button is enabled. The button can be disabled by the web page or with OT BioLab+, to avoid undesired clicks on it.

Due to the large amount of data flow to be written on the MicroSD card, Sessantaquattro+ needs to optimize the writing process and for this reason it needs to know a maximum file size (from the web page or OT BioLab+) when starting a new recording. This information will be used by the device for searching an available contiguous space on the MicroSD card and lock that space for data writing. At any time, it will be possible to stop the data recording and the Sessantaquattro+ will free the unused space. If no stop commands are issued before to reach the maximum data acquisition time, Sessantaquattro+ will automatically stop the acquisition and close the file. The time limit for data acquisition is 4 hours and 30 minutes, the file size associated to this maximum acquisition time depends on the sampling frequency, number of channels and resolution.

A prefix code of 5 characters can be set for the filenames, additional 3 numbers will be added from Sessantaquattro+ to sequentially enumerate the files related to each acquisition. At any start of an acquisition, the device will search for available filenames starting from the provided prefix followed by "000" and then incrementing the 3 digits until an unused filename is found.

Since the ON/OFF switch completely disconnects the battery from the circuit, the internal real time clock loses time and date. The correct time and date can be easily passed to Sessantaquattro+ from a computer automatically when opening the Sessantaquattro+ embedded web page or connecting to it with OT BioLab+. In case, after turning on the device, one of this two actions are performed, the file created on the MicroSD will have the proper time and date. If instead, the start/stop REC button is active, and it is pressed after turning on the Sessantaquattro+, a file with the last settings will be created and the time and date will be calculated starting from 23:00 of December 31<sup>ST</sup>, 2012.

Especially when working with all 64 channels and 2000 Hz of sampling frequency, the MicroSD have to be chosen with care. More than the MicroSD class, that represent how fast is the data writing on the card, it is important how long the card takes to provide the address of a new sector or cluster. The buffer usage can provide feedback of the goodness of a particular MicroSD card.

## 8.6 Webpage setup

Sessantaquattro+ has an internal web page that allows to see the current configuration and to change it. To reach this page it is necessary to be connected to the same network of Sessantaquattro+, it could be the network generated by the device itself or the network generated from another access point. The IP address and the subnet mask must be in the same range. Refer to section 8.1 for additional details about the Sessantaquattro+ IP address.

The internal web page can be opened typing the IP address of Sessantaquattro+ with any browser, but Mozilla or Chrome are suggested due to few features that other browsers do not have. Alternatively, in OT BioLab+, the button *WebPage* is available under Tools->Option when Sessantaquattro+ is set as Device.

Two different views are available depending on the network role of Sessantaquattro+. Few options are common between the two views and others are specifically related to the network role. Figures 8.14 and 8.15 show an example of the two views.

When loading the web page automatically the time and date of the device used to access the page are transferred to the Sessantaquattro+ device to update its internal real-time clock. The page has different sections, each section has an *info* area on the right bottom corner. Moving the mouse cursor over this area will pop-up an explanation of that section. Few settings need the restart of Sessantaquattro+ to take effect. A description of each section of the web page follows.

### **General Information**

This section only provide information that cannot be changed: serial number, MAC address, firmware version and the battery level. To update the battery level it is necessary to refresh the web page.

### **Data Logger**

The parameters in this section reflect the current configuration of Sessantaquattro+ and can be changed to set an acquisition on the MicroSD card. Refer to section 8.5 for details about the parameters. The recording can be started directly when pressing the *Apply* button of this section if the option *Start/Stop Recording* is set to *When submitting the settings*.

### **Wireless**

The network role of Sessantaquattro+ can be selected between:

- 1) Sessantaquattro+ is the access point
- 2) Use an external access point, choose if connect it to SyncStation or not:
  - a) No
  - b) Yes, with ID=1
  - c) Yes, with ID=2



Changing the selection in the drop-down list will change the view in the web page, in particular, the right column. Until the *Apply* button is not pressed the new settings are not sent to Sessantaquattro+. After the settings are changed by pressing the *Apply* button, it is in any case necessary to turn off the Sessantaquattro+ device to let it restart in the new configuration mode.

## Firmware Update

The upgrade of Sessantaquattro+ happens through a folder on dropbox. Thus, it is necessary that the Sessantaquattro+ device is connected to an external access point providing internet access. When pressing the *Check for firmware upgrade button*, in fact, the Sessantaquattro+ device searches for the upgrade files in a specific folder in the OT Bioelettronica drop box account and, if a new file is found, it automatically downloads the file and updates itself. The firmware upgrade will open a new page and display the progress in the process. The firmware of two microcontrollers has to be updated. The main processor is updated simply by replacing a file into the internal flash memory, the secondary microcontroller, by entering the boot mode and transferring the new firmware from the main processor. It is important that the battery level of the device is not too low and can complete the firmware upgrade. If not, then the device may enter an unknown state that will require it to be opened and reprogrammed using a specific hardware interface.

## Access Point

This section is available when the Sessantaquattro+ acts as an access point. It is possible to set the WiFi channel, the serving set identifier (SSID, the name of the network) and assign a protection with a password. In case the password is applied and then lost, by pressing the push button of Sessantaquattro+ while turning on the device and the keeping the button pressed for five seconds, it will be possible to force the default settings with no password.

### **IP Settings** (Access Point mode)

When Sessantaquattro+ is the access point, it can also provide the IP settings to the devices connected to its network. The parameters of this section let the user set the IP address of Sessantaquattro+ and the range of available addresses for providing the IP to other connected devices.

### **IP Settings** (Using external Access Point)

When an external access point is used, the IP settings of Sessantaquattro+ can be assigned from the access point (if the DHCP option is enabled) or fixed by the user. The field *Server IP Address* is automatically filled and transferred to the Sessantaquattro+ device when the web page is loaded. It is the IP address of the PC that is displaying the web page and it should also communicate with Sessantaquattro+ for the data transfer. The Sessantaquattro+ device will use this particular address for searching the TCP socket for data transfer. The automatic detection of the IP address of the PC connected to the web page is only available when using Mozilla and Chrome browsers.

### **Add Network**

Up to seven networks with associated passwords and priorities can be stored in the internal flash memory of Sessantaquattro+. This section allows you to add networks to the existing list. At start-up Sessantaquattro+ will try to connect to the network in its list starting from the one with the lower number in the priority field.

### **Networks List**

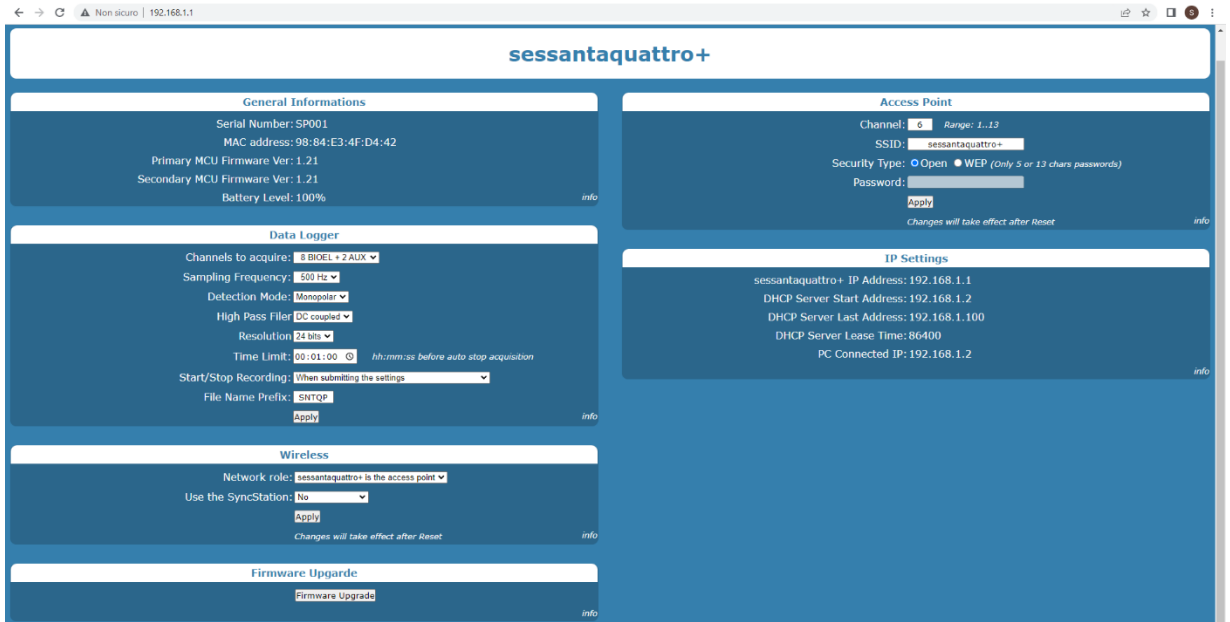
In this section, the list of networks previously added can be checked and deleted, if necessary. The sequential order of the network is not relevant, while the priority that fixes the order used from Sessantaquattro+ when trying to connect to them is.

### **SyncStation Settings** (Using SyncStation as external Access point)

When using the SyncStation, the IP settings of the Sessantaquattro+ are assigned by the SyncStation itself and are fixed, they depend only on the selection of the device ID (ID = 1 or 2). Sessantaquattro+ connects to the SyncStation as device number 5 or 6 depending on the ID selection.



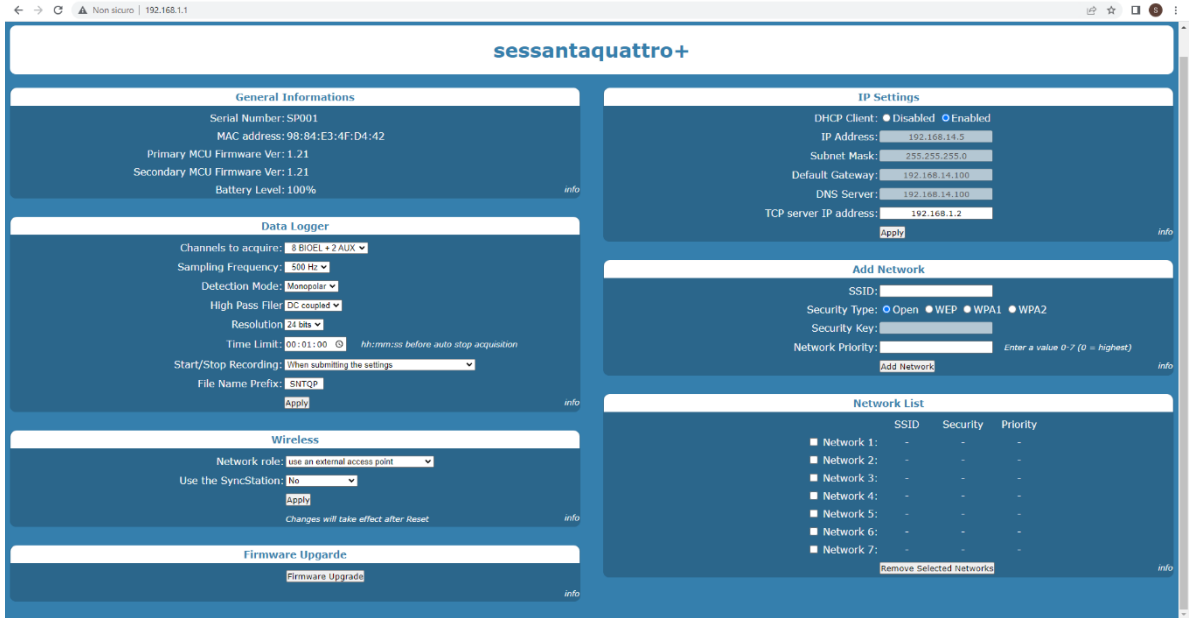
*Refer to the MuoviPro user manual and the SyncStation communication protocol for further information.*



The screenshot displays the embedded web interface for the Sessantaquattro+ device, accessed via a browser at 192.168.1.1. The interface is titled "sessantaquattro+" and is organized into several configuration panels:

- General Informations:** Displays device details such as Serial Number (SP001), MAC address (98:84:E3:4F:D4:42), Primary MCU Firmware Ver (1.21), Secondary MCU Firmware Ver (1.21), and Battery Level (100%).
- Data Logger:** Configures data acquisition parameters including Channels to acquire (8 BIOEL + 2 AUX), Sampling Frequency (500 Hz), Detection Mode (Monopolar), High Pass Filter (DC coupled), Resolution (24 bits), Time Limit (00:01:00), Start/Stop Recording (When submitting the settings), and File Name Prefix (SNTQP).
- Wireless:** Sets the Network role (sessantaquattro+ is the access point) and Use the SyncStation (No).
- Access Point:** Configures network settings including Channel (6), SSID (sessantaquattro+), Security Type (WEP), and Password.
- IP Settings:** Shows the device's IP Address (192.168.1.1) and DHCP server settings for Start Address (192.168.1.2), Last Address (192.168.1.100), Lease Time (86400), and PC Connected IP (192.168.1.2).
- Firmware Upgrade:** Provides a button to initiate the Firmware Upgrade process.

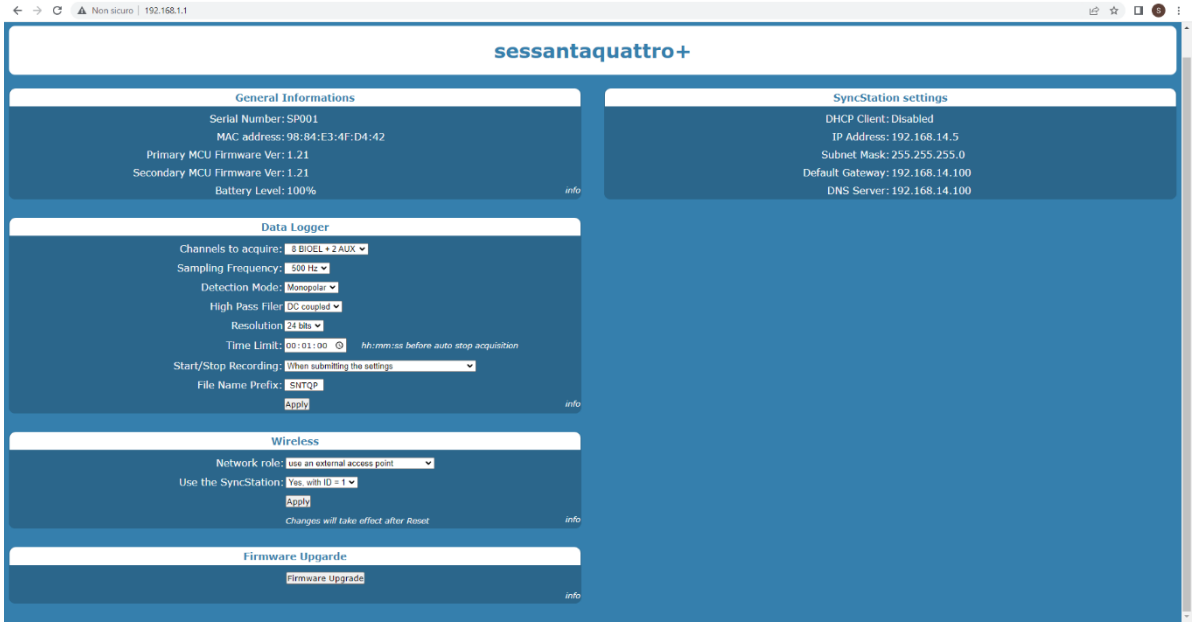
*FIG. 8.14: Embedded web page of Sessantaquattro+ when it acts as access point*



The screenshot displays the configuration interface for the Sessantaquattro+ device. The browser address bar shows the URL 192.168.1.1. The page is divided into several sections:

- General Informations:** Serial Number: SP001, MAC address: 98:84:E3:4F:D4:42, Primary MCU Firmware Ver: 1.21, Secondary MCU Firmware Ver: 1.21, Battery Level: 100%.
- Data Logger:** Channels to acquire: 8 BIODEL + 2 AUX, Sampling Frequency: 500 Hz, Detection Mode: Monopolar, High Pass Filter: DC coupled, Resolution: 21 bits, Time Limit: 00:01:00, Start/Stop Recording: When submitting the settings, File Name Prefix: SNTQP.
- Wireless:** Network role: use an external access point, Use the SyncStation: No.
- Firmware Upgrade:** Firmware Upgrade button.
- IP Settings:** DHCP Client: Disabled, IP Address: 192.168.14.5, Subnet Mask: 255.255.255.0, Default Gateway: 192.168.14.100, DNS Server: 192.168.14.100, TCP server IP address: 192.168.1.2.
- Add Network:** SSID, Security Type (Open, WEP, WPA1, WPA2), Security Key, Network Priority.
- Network List:** A table listing 7 networks with columns for SSID, Security, and Priority.

**FIG. 8.15:** Embedded web page of Sessantaquattro+ when an external access point is used



**FIG. 8.16:** Embedded web page of Sessantaquattro+ when is used with SyncStation

## 8.7 Patient connection

Regardless of the adapter used and the detection mode, Sessantaquattro+ needs to be connected to the patient with a reference strap or electrode. This is necessary to fix the standard body potential mode of the patient to the midpoint of the Sessantaquattro+ power supply. All the adapters provide a 2 mm female banana connector for this purpose.

All the signals are recorded from Sessantaquattro+ as monopolar signals with respect to the patient reference. For this reason, it is important that the patient reference strap or electrode is placed on a point without activity and possibly close to the electrode for the detection on the biopotential signals. The bipolar or differential modes are obtained by subtracting the samples, digitalized by the A/D converter, in the microcontroller firmware.

Sessantaquattro+ has been designed as a floating device. For this reason, the battery recharge occurs through the same connector of the electrodes, avoiding the simultaneous connection of the patient and an external power source.

The same concept has to be respected when connecting external signals to the auxiliary input, both, for the patient safety and to avoid interferences on the biological signals.

### Impedance measurement

Sessantaquattro+ allows you to measure the skin-electrode contact impedance, for each electrode connected, at a frequency equal to  $\frac{1}{4}$  of the sampling frequency. This is obtained by pulling individually each electrode line to the positive and negative supply alternatively through a pull up and pull-down resistors, by generating an AC signal, which amplitude is inversely proportional to the skin-electrode impedance. The signal acquired, when the impedance check is activated, is the summation of the

biological signals from the electrodes and the AC signal. They can be separated by appropriate digital filters.

The value of the impedance can be obtained by considering that the standard patient mode voltage is fixed through the patient reference to the middle supply. The power supply is 3.3 V and the pull up and pull-down resistors are a 100 k $\Omega$ .

## **8.8 Other acquisition method**

As an alternative to the use of the OT Biolab+ software and to the acquisition on a microSD card it is possible to acquire data from Sessantaquattro+ by communicating directly with the instrument, an example is via MatLab script which provides information on the communication mode and the settings that must be provided to the device. The MatLab script can be found in the OT BioLab+ folder, which is installed together with the software.



## 9 TROUBLESHOOTING

This section describes the most common problems that may be found by Sessantaquattro+ 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 cause	Solution
The Sessantaquattro+ device does not turn on	The battery level is too low.	charge the device for at least one hour.
	If a firmware upgrade has just been performed something could have gone wrong.	Contact OT Bioelettronica.
The embedded webpage is not displayed at the expected IP address	The PC is not connected on the same network of Sessantaquattro+ or they are not in the same address range.	Check the connection is on the same network and verify the network adapter settings on the PC.
	The expected IP address could be wrong.	Use OT BioLab+ to reach the Web page.
Signals are not displayed on OT BioLab+	Sessantaquattro+ can't find the TCP socket opened on the PC.	Open the Sessantaquattro+ internal Web Page and check that the <i>Server IP Address</i> is the same of the computer.
The acquisition with microSD does not work	MicroSD format is not supported, e.g. model/constructor or dimension.	Try to re-insert the microSD card.
The red LED flashes during acquisition with microSD	The microSD may not be inserted correctly.	Try to remove and re-insert the microSD in the appropriate housing.
	The device cannot communicate with the microSD.	Contact OT Bioelettronica.

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

## 10 SESSANTAQUATTRO+ MAINTENANCE AND STORAGE

Sessantaquattro+ has to be used in the following 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 Sessantaquattro+ device at the end of each measurement session, and to remove all the connections. The Sessantaquattro+ device should be stored with all the enclosed accessories on a safe desk far from all the situations listed in the section *Warnings*.

Sessantaquattro+ should be stored in the following 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 Sessantaquattro+ device should be repaired by the manufacturer only. Every repair executed by unauthorized personnel will be considered as a device violation that 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.

## 11 RISK ANALYSIS

### 11.1 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

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

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

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

<b>Manufacturer's declaration and guidelines – electromagnetic immunity – casing door</b>		
<b>Phenomenon</b>	<b>EMC reference standard or test method</b>	<b>Immunity test levels - Professional healthcare environment</b>
Electrostatic discharges	IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV in air <sup>a)</sup>
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM a 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 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 at 100 kHz on power supply +/- 1 kV at 5 kHz on power supply
Surges	IEC 61000-4-5	500 V and 1 kV line to line 500 V, 1 kV and 2 kV line to ground
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 variation and dips	IEC 61000-4-11	V supply: 100 V AC, 240 V AC and 230 V AC with DIP pattern: 0V – 10ms; 0V – 20ms; 0.7 Un – 500ms; 0V – 5s Testing on power supply
Rated power-frequency magnetic fields	IEC 61000-4-8	30 A/m - 50 Hz

<sup>a)</sup> The tests at 15 kV weren't exceeded, the device stops functioning and enters an unknown state.

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

## 12 INTENDED USE

The Sessantaquattro+ is a medical device intended for the study of the biomechanics of movement and the acquisition of bioelectrical signals from the neuromuscular system.

The clinical applications of the system are in the context of:

- neurological rehabilitation
- prosthetic

### Neurological rehabilitation

- The device allows obtaining the so-called Bio-feedback, or visual or auditory feedback, which helps the physiotherapist in teaching the patient to contract or relax the target muscles. Condition that is necessary following lesions of the central nervous system or to counteract the difficulty in recruiting certain muscle groups due to prolonged immobility.

### Prosthetics

- The device allows to identify the areas in which the electromyographic signal is most intense, in order to determine the positioning of the electrodes of the active prostheses.

## 13 TECHNICAL CHARACTERISTICS

<b>Model:</b>	Sessantaquattro+
<b>Risk class:</b>	I in compliance with Regulation 745/2017.
<b>Insulation class:</b>	BF type applied part, in compliance with the European standard EN 60601-1.
<b>Classification:</b>	IP20, about the penetration of fluids and dust; device not protected.
<b>Basic UDI</b>	805697785PORTABLEEMG002SF
<b>Case:</b>	painted ABS
<b>Power supply:</b>	Internal Rechargeable Li-Po battery 3.7 V
<b>Consumption:</b>	0.6 W
<b>Limitations:</b>	the device is 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.
<b>Working conditions:</b>	device suitable for continuative work.
<b>Input channels:</b>	70 independents
<b>Input range:</b>	0 – 3.3 V for biopotential signals, $\pm 3.3$ V for auxiliary signals
<b>Bandwidth:</b>	DC ÷ 500 Hz
<b>Total noise (RTI):</b>	< 8 $\mu\text{V}_{\text{RMS}}$ (EMG) or < 6 $\mu\text{V}_{\text{RMS}}$ (EEG) for biopotential signals, < 6.1 $\mu\text{V}_{\text{RMS}}$ for auxiliary signals
<b>Signal gain:</b>	1 V/V for biopotential signals, 0.5 V/V for auxiliary signals
<b>Resolution:</b>	16/24 bits
<b>Input resistance:</b>	500 M $\Omega$
<b>Commands:</b>	1 pushbutton
<b>Dimensions:</b>	73 x 105 x 12 mm

## 14 WARRANTY

Sessantaquattro+ electronic 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.

### 14.1 Warranty conditions

1. The electronic parts warranty lasts 24 months. Warranty is provided by the manufacturer.
2. 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 invalid.
3. The warranty covers only the cost of repair or substitutions of defective components, including the costs of labour.
4. 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.
5. The warranty is void if damage is caused by incorrect power supply.
6. The warranty is not applied on all the parts subject to wear and tear.
7. The warranty does not include the shipment costs.
8. 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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