User Manual v.2.0

Due+Lite

Portable bioelectrical signal amplifier

Read this manual carefully before using Due+Lite

1 GENERAL DESCRIPTION 6
2 DUE+LITE KIT CONTENT 7
3 END USER 7
3.1 Contraindications 8
3.2 Side effects 8
4 SAFETY PRECAUTIONS AND OTHER WARNINGS 8
5 SYMBOLS USED ON DUE+LITE AND IN THE USER MANUAL 10
6 TECHNICAL SPECIFICATIONS 12
7 DETAILED DESCRIPTION 13
7.1 Due+ probe - Controls, indicators, and connectors 13
7.1.1 Input connection port and charging 14
7.1.2 ON/OFF button 15
7.1.3 LED indicators 15
7.1.4 Patient Ref connector 17
8 USE OF DUE+LITE 18
8.1 Use of the Due+ probe 18
8.1.1 Due+ probe WiFi interface 18
8.1.2 Signals 19
8.1.3 Acquisition electrodes and patient connection 22
8.1.4 Recharge of the Due+ probes 23
8.1.5 Wireless data transfer 23
8.1.6 Due+ internal web page 24

9 TROUBLESHOOTING 27

10 DUE+LITE MAINTENANCE AND STORAGE 28

11 RISK ANALYSIS 30

11.1 General requirement for basic safety and essential performance CEI EN 60601-1-2 30

12 INTENDED USE 32

13 TECHNICAL CHARACTERISTICS 33

14 WARRANTY 34

14.1 Warranty conditions 34

1 GENERAL DESCRIPTION

The Due+Lite is a modular system for the acquisition of 2 bipolar signals. It is composed by one Due+ probe and a recharger called BipolarSC.

The Due+ probe is a wireless amplifier with 2 bipolar channels that is a miniaturized and wearable device. It is able to detect bipolar surface electromyographic signals (sEMG).

The probe performs amplification, filtering, digital conversion and then wireless transfer of the acquired signals to the PC, for real-time viewing and archiving.

The Due+ probe doesn't require adapters for the connection of the recording electrodes, the electrodes in fact are connected directly to the instrument.

On the website https://otbioelettronica.it/downloads, freeware software is available for viewing and archiving in real time of the bioelectrical signals, called OT BioLab+, designed by OT Bioelettronica.

The Due+Lite is a system designed for clinical research, carried out by qualified researchers and is completely safe for the patient. Safety is achieved by meeting the design requirements for devices with an electronic part applied to the patient.

Attention: The Due+ device should NOT be recharged while acquiring signals and while the electrodes are connected to the patient.

2 DUE+LITE KIT CONTENT

- 1 BipolarSC;
- 1 Due+ probe with 2 bipolar channels;
- 1 Reference bipolar electrode;
- 1 Due+Lite User Manual;
- Electrodes of different sizes, depending on the customer request.

3 END USER

Due+Lite allows non-invasive recording of biopotentials (sEMG) detected by superficial electrodes. The end user must be familiar with the technique and have received proper training in EMG detection and interpretation. Consequently, it is intended to be used primarily as a laboratory device, secondly it can be used in the physiotherapy outpatient setting to evaluate muscle activity in a qualitative and quantitative manner.

The user should be a specialised operator:

a) Minimum knowledge and basic notions of the human body
b) Understanding of the Italian and/or English language
c) Minimum training for the use of the device
d) Permissible impairments:
    - maximum hearing reduction of 40% with residual hearing at 60%
    - 40% vision reduction with 60% residual vision

The patient should be:

a) Age: >15 Years

b) Weight: not relevant

c) Health: free of cardiological problems and not a pacemaker wearer

d) Nationality: indifferent

3.1 Contraindications

Due+Lite 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 Due+Lite system is absolutely forbidden in the following conditions:

- While other monitoring devices are in use with the patient.
- While the device is charging.
- While electro surgery equipment, short wave or microwave therapy devices are being 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: Due+Lite 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 Due+Lite 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 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 Due+Lite and other electrical devices must be done in compliance with the European standard EN 60601-1-1 on medical devices.
- The use of the Due+Lite is restricted to skilled personnel.
- Incorrect measurements can arise when unskilled personnel use the device in presence of strong sources such as 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.

⚠ *The device must not be used in any other way than indicated in these instructions.*

5 SYMBOLS USED ON DUE+LITE AND IN THE USER MANUAL

Serial number

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

Identifies a type B 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

IP20

Degrees of protection:
Protected against solid objects over 12.5 mm
No protection against liquid

12VDC – 36W

Indicates that the equipment is suitable for direct current only, to identify relevant terminals with indication of nominal voltage and power supply.

Read carefully the instruction remarks before use

6 TECHNICAL SPECIFICATIONS

Due+Lite is a battery-operated device, designed to ensure a high level of safety for the patient and the operator in all conditions of use. Isolation between the Due+ device and the PC for displaying and recording real-time data is inherently achieved via wireless data transfer.

The central connector available on each Due+ probe is used for battery charging while the two lateral connectors are used for the interface with acquisition bipolar electrodes.

The connection must be done in compliance with the European standard EN 60601-1-1 on medical devices. The technical specifications of the Due+Lite are shown in Table 6.1.

Due+ probe	Functions	Acquisition of 2 sEMG bipolar signals
	Number of channels	2
	Low pass filter	~ $F_{SAMP}/4$
	High pass filter	DC coupling or 10 Hz digital filter
	Noise level referred to the input	< 4 μV_{RMS}
	Input resistance	500 MΩ
	Input range	0 – 3.3 V
	Battery	Battery LiPo 3,7V
	Battery life - Charging times	Turn on/Continuous Trasmitting - 6 hours/2.30 hours, complete charge - 2 hours and 30 minutes
	IMU	
	Number and type of signals	• Triaxial accelerometer (+/- 4g) • Triaxial gyroscope (2000 ° / s) • Triaxial magnetometer

	Data conversion and communication	
	Fixed Gain	202 V/V
	Resolution of the A/D converter	16 bit
	Input dynamic of the A/D converter	0 ÷ 3.3 V
	Data transfer to PC	WiFi through TCP socket

TAB. 6.1: *Technical specifications of the Due+ probe.*

7 DETAILED DESCRIPTION

The Due+Lite device is a system consisting of a battery powered portable probe that is used for the acquisition of surface EMG signals. The signals can be transferred to a PC for real-time data and recording.

The Due+ probe has a fixed IP address with which you can reach its web page, using any browser. Through the browser it is possible to configure, control and update the probe's firmware itself. The communication protocol is available for custom development with a Matlab demonstration code.

The following sections describe in detail the Due+ probe and the Due+Lite system.

7.1 Due+ probe - Controls, indicators, and connectors

The Due+ probe is a device designed to acquire 2 surface EMG signals through electrodes. In figure 7.1 you can see the probe with the different controls, indicators, and connectors on it.

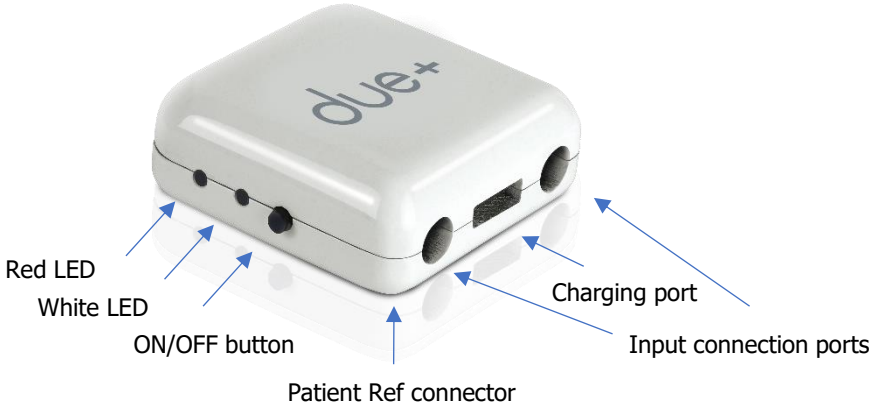

FIG. 7.1: *Due+ controls, connectors and indicators.*

The Due+ probe can be fully configured via its web page, while the ON/OFF button provides only quick access to basic functions, displayed by LEDs.

7.1.1 Input connection port and charging

The two input connection ports are the interface between Due+ and the electrodes and the central connector is used for charging the internal battery.

Attention: It is recommended to NOT recharge the battery while the device is used.

Refer to section 8.1.3 for more details on electrodes available.

7.1.2 ON/OFF button

This button turns the Due+ probe on and off by completely removing battery power from all of its parts.

7.1.3 LED indicators

Two LEDs have been installed to identify the status of the Due+. Each one reflects the status of a different device activity:

1) the white LED is related to wireless data transfer

2) the red LED highlights errors or problems

The two LEDs are independent and the information, provided by each of them, is displayed cyclically for a given number of flashes. Table 7.1 shows the different states and the relative number of LED flashes.

N. flashes	1	2	3	4
White LED	WiFi active	Connected to network	Connected to TCP socket	Data transfer
Red LED	Loss of data during WiFi transfer	-	Low battery level	-

TAB. 7.1: *Relationship between number of LED flashes and Due+ probe status*

White LED

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

The white LED provides different information depending on the state of Due+.

When Due+ is acting as an access point:

(a) one flash of the white LED indicates that the network has been generated and is available for connection from another device.
(b) two flashes indicate that a device is connected to the network generated by Due+.

If Due+ is configured to be connected to the SyncStationBipolar network:
(a) one flash indicates that Due+ is active and searching for a network;
(b) two flashes indicate that Due+ has successfully connected to the external network.

Regardless of the role of the Due+ probe, three flashes of the white LED indicate that the probe is connected as a client to a TCP generated by a server device (usually the PC used for viewing and recording real-time data); four flashes of the white LED indicate that the probe is transferring data, via the TCP socket, to a server. When communicating via the SyncStationBipolar, the two flashes don't occur, this is because the connection to the TCP socket takes place while the probe connects to the network generated by the SyncStationBipolar. If, on the other hand, the probe is connected directly to the PC and the OT BioLab+ software is used, the connection to the socket takes place at the same time as the start of the data transfer, so the white LED switches directly from two flashes to four flashes.

Red LED

The red LED is used to alert the user of an error or critical condition. A single blink of the red LED indicates that samples have been lost during the wireless data transfer, this situation occurs when the internal data buffer of the Due+ is full and data transmission is not possible, acquisition of the next signal sample will create a reset of the internal data buffer with the loss of data, equal to the buffer size.

The red LED will stop blinking, if the above condition is temporary (e.g., the Due+ probe remains too far from the acquisition PC for a limited time) and then the data transfer restarts correctly.
Loss of recorded data can still be verified offline by checking one of the accessory channels.
Three flashes of the red LED correspond to a battery level below 20%. Note that there is no priority in error reporting and the last error detected is always displayed, with the corresponding number of red LED flashes.
In general, the low battery level will take priority over the other error conditions, simply because the battery level is monitored more frequently than the other parameters.

7.1.4 Patient Ref connector

The clip for Patient Ref is on the probe's back. It is the patient reference and should be positioned using a pre-gelled electrode, placed on the patient's body at a point without electromyographic activity (e.g., wrist or ankle). All EMG signals are acquired as the difference between the potential taken from the two electrodes of each channel, thus generating bipolar signals.

8 USE OF DUE+LITE

This manual refers to the use of the Due+Lite system together with the PC running Windows and the free OT BioLab+ software. In case the user wants to use an operating system different from Windows, or if the user wants to customise the interface, documents describing the communication protocol of the Due+Lite system and some samples of MatLab codes are available in the download section of the otbioelettronica.it web site.

8.1 Use of the Due+ probe

8.1.1 Due+ probe WiFi interface

Due+ probe can be used individually, with a direct connection to the PC: this mode allows you to acquire only the signals coming from a Due+ probe without the possibility of synchronisation with other probes or other devices.

If you want to use a Due+ probe directly connected to the PC, you need to start the probe by holding down the power button for 5 seconds. The probe LEDs will start flashing 5 times at the same time and, once the button is released, the probe will generate an open WiFi network, without password, to which you can connect. The name of the generated WiFi network will be "DPXXX-ID", where XXX is the serial number of the Due+ probe and ID is the identification number of the Due+ probe. In this mode the Due+ probe acts as a DHCP server providing settings to devices connected to its network, but only one device at a time can connect to the network generated by the Due+ probe. This mode can be configured as the default power mode via the Due+ probe's internal web page.

Regardless of the mode of operation used, the IP address of the Due+ probe is 192.168.14.ID, where ID represents the probe's identification number. The subnet mask is fixed and equal to 255.255.255.0.

Typing the IP address on any browser will display the internal configuration page (refer to section 8.1.5). The configuration page allows you to check the current settings of the device, the battery level and to change some settings that will be maintained even after turning off the probe.
In addition, the OT BioLab+ software provides a button in the configuration window to directly open the Due+ web page.

8.1.2 Signals

For EMG data collection, a firmware high-pass filter is implemented (only on the bioelectrical signals, thus not on the IMU) that removes the DC component and moves the baseline of the signals to the center of the dynamic. This condition makes it possible to acquire EMG signals with a reduced resolution of 16 bits. The data format is big endian.
The filter is implemented by subtracting the exponential moving average from the signals, obtained from:

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

Where α is equal to $1/2^5$. The result is a high-pass filter with a cutoff frequency of 10.5 Hz, when sampling signals at 2000 Hz. More generally, the high-pass cut off frequency is $F_{samp}/190$.
The sampling rate is 2000 Hz. It automatically sets the high-pass filter and the 16-bit resolution. This mode is designed for EMG signal acquisition.
The A/D converters have differential inputs that allow the inputs to theoretically range between 0 and 3.3 V. In the case of the Due+, the limit is imposed by the supply voltage, which is 3.3 V. The positive input is fed with signals from the electrodes, the negative signals are connected to the patient reference (center point of the power supply). The least significant bit (LSB) of the signals is obtained from:

$$\mathbf{LSB = ADC_{RANGE}/2^{24} = 286.1\ nV}$$

When the 16-bit resolution is set, only the 16 least significant bits are transferred for bioelectric signals, and this introduces a limitation in the signal range to 18,75 mV_{PP}.
Table 8.1 summarises the different input ranges, LSB, RMS, and peak-to-peak noise values with the different acquisition settings for bioelectric signals.

Resolution	Input Range	LSB	RMS R.T.I. Noise	P-P R.T.I. Noise
16 bits	18,75 mV	286.1 nV	0.6 – 1.2 µV	3.6 – 7.8 µV

TAB. 8.1. *Characteristics of the signals acquired.*

In addition to the biological signals, there are 4 channels from an inertial sensor and 2 accessory channels. All 6 channels are represented on 16 bits consistent with the resolution of the bioelectrical signals. In other words, the acquired bioelectric signals have a resolution of 16 bit and also the 6 additional channels are represented on 16 bit.
The first four additional channels (channels 3, 4, 5 and 6) are the data related to the IMU (Inertial Measurement Unit) present in each Due+ probe, 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 actual resolution of the quaternion data is 14 bits, extended with sign to 16 bits. The quaternions are the result of an internal calculation within the inertial sensor and are updated at a frequency of 100 Hz, so in the case of sampling at 2000 Hz, there would be 20 samples with the same quaternion values before a new set of values is obtained for the quaternions. In figure 8.1 is shown the IMU sensor placement in the Due+ probe with axis orientation.

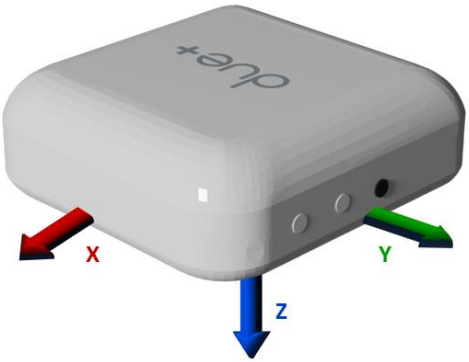

FIG. 8.1: *IMU sensor placement and axis orientation.*

The two accessory channels contain information related to the RF synchronisation signal sent by the SyncStationBipolar, the use of the internal memory buffer of the Due+ probe, and a sample counter. In particular, channel 7 provides information about the internal buffer usage and the trigger state.

The second accessory channel (channel 8) is a sample counter. This one 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 passed since the previous sampling and, if some data has been lost, it is possible to identify how many samples have been lost. Once the counter has arrived at the largest possible value with the corresponding resolution, it starts over with the counting.

8.1.3 Acquisition electrodes and patient connection

The Due+ probe connects directly to the acquisition electrodes, so no additional adapters or cables are required. In the case of sEMG signal acquisition, two types of electrodes are available that can be connected to the Due+ probes:

- CDE-C: bipolar electrodes 24mm with concentric connector.

- CDE-S: bipolar electrode 24mm with snap on connector used with adapter C-2S

The acquisition electrodes are defined as semi-reusable because, for their use on a patient, they are adhesive, and they can be reused.

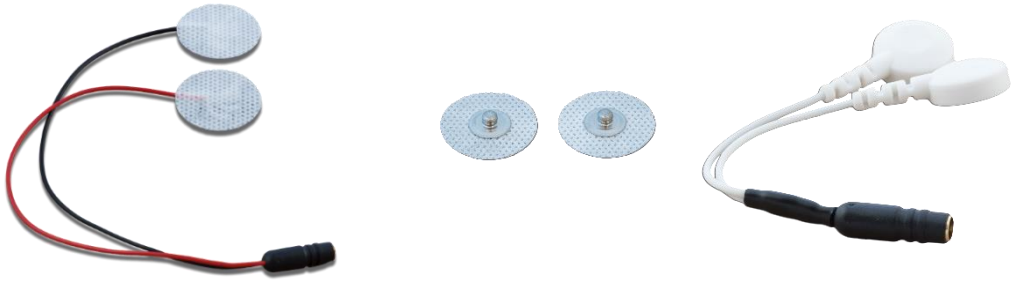

FIG. 8.2: *Semi-disposable adhesive electrodes CDE-C and CDE-S with adapter C-2S*

Regardless of the electrode used, the Due+ probe can be connected to the patient with a reference electrode, this operation is useful to fix the potential of the patient's body, to the internal reference potential of the Due+ probe, for this purpose, a clip connector is available on the probe’s back.

All the signals recorded by the Due+ probe are acquired in bipolar mode, with the difference between the two electrodes. The Due+ probe is designed as a mobile device.

8.1.4 Recharge of the Due+ probes

Due+ probes can be recharged using their own recharge connector. Due+ probes automatically turn off when they are put on charge.

Attention: The Due+ device should NOT be recharged while acquiring signals and while it is connected to the patient.

8.1.5 Wireless data transfer

The communication between the Due+ probe and PC is direct so the network is generated by the Due+ probe (refer to paragraph 8.1.1) but it is the PC (or tablet, smartphone) that has to open a TCP socket with the role of server to which the Due+ probe will try to connect. The probe, in fact, knows the IP address of the PC as it has been assigned by the probe itself with the DHCP protocol. Once the TCP connection is established, it is possible to send the control byte to the probe to configure the acquisition and start the data transfer.

Regardless of the type of acquisition (direct or via the SyncStationBipolar), the data is buffered inside the probe and is sent in packets of about 1400 bytes as soon as possible. If the PC is not able to receive data or if the WiFi connection does not allow it, the data will start to accumulate inside the buffers until the buffer is full. If this condition occurs the data will be lost until the PC and the WiFi connection are available for transfer again.

8.1.6 Due+ internal web page

The Due+ probe has an internal web page that allows you to view and change certain settings. To reach the web page, you must be connected to the Due+. The PC's IP address and subnet mask must be in the same range as those of the Due+ probe. The internal web page can be opened by typing the IP address of the Due+ probe in the address bar of any browser.

The IP address is composed of a first fixed part which is the same for all the Due+ probes: 192.168.14.X, while the X reflects the probe ID.

When the Due+ probe is connected directly to the PC the access to the web page is direct. When the probes are connected to the SyncStationBipolar and the PC is connected through an ethernet cable, the SyncStationBipolar acts as a bridge between the network to which the PC is connected and the network to which the probes are connected. However, it is necessary to inform the PC on which you are trying to open the web page that the address you are looking for must be reached via a bridge. This can be done by modifying the routing table of the PC and informing the operating system that the address range 192.168.14.X can be reached through the address 192.168.76.1.

The page has different sections, and each section has an information area in the lower right corner. Moving the mouse cursor over this area will display an explanation of the corresponding section. A description of each section of the web page follows. Figure 8.3 shows an example of a Due+ web page.

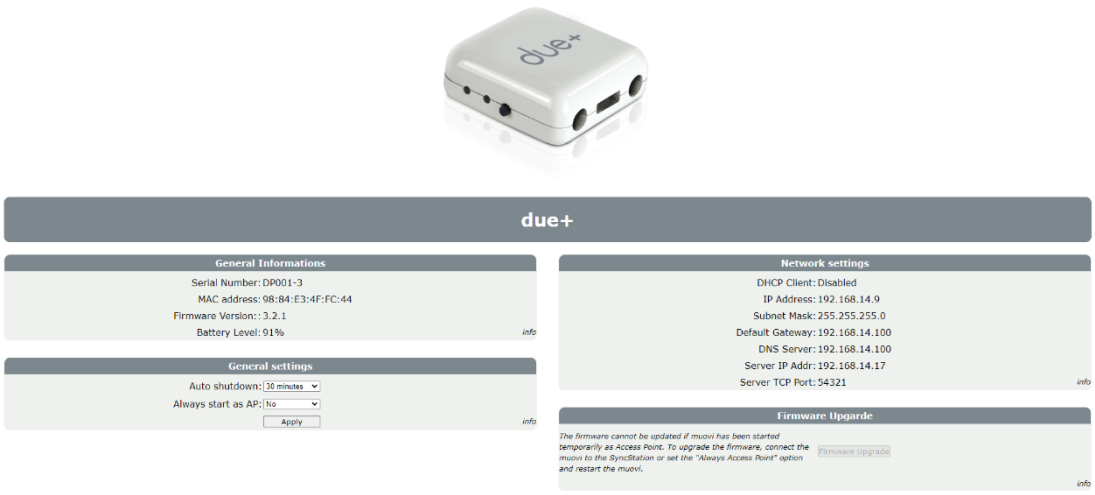

FIG. 8.3: *Due+ internal web page.*

General Information

This section provides information that cannot be changed: serial number, MAC address, firmware version and battery level. To update the battery indicator you need to refresh the web page.

General Settings

It allows you to select the auto power off of the probe between: never, 15 minutes, 30 minutes or 1 hour.

It allows you to set as default the access point mode for the direct connection of the Due+ probe with the PC. Normally the Due+ probes try to connect to the SyncStationBipolar, but if the button is pressed for more than 5 seconds (see paragraph 8.1.1) the probe creates its own WiFi network. It is possible to make this mode the default one so that the probe will always start in this mode regardless of how long the button is pressed.

Network information

This section shows information about the Due+'s network that cannot be changed.

Firmware upgrade

A firmware update of Due+ is possible by uploading a compressed file containing the firmware itself. Pressing the button will open a new page with instructions on how to proceed and will show the progress of the process. In a first step the file will be loaded into the flash memory of the Due+ and the files will be extracted from the compressed file. Afterwards, the Due+ will automatically reboot trying to start with the new firmware and connect back to the PC. If this does not happen the loaded file will be discarded, and the firmware will revert to the previous one. It is important that the battery level of the device is not too low during the firmware update and that it allows you to finish the procedure.

9 TROUBLESHOOTING

This section describes the most common problems that may be found by Due+Lite 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 Due+ does not turn on	The battery level is too low.	Leave the device charging for at least one hour.
	If a firmware update had just been performed, something wrong might have happened.	Contact OT Bioelettronica.
The embedded web page is not displayed at the expected IP address	The PC is not connected to the same network as the Due+ or they are not in the same address range.	Check that the connection is on the same network and check the network card settings on the PC.
	The expected IP address may be wrong.	Use OT BioLab+ to reach the Due+ web page

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

10 DUE+LITE MAINTENANCE AND STORAGE

Due+Lite 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 Due+ probe at the end of each measurement session, and to remove all connections. The Due+Lite system should be stored with all the enclosed accessories on a safe desk far from all the situations listed in the section *Warnings.*

Due+Lite 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 Due+Lite system should be repaired by the manufacturer only. Every repair executed by unauthorised personnel will be considered as a device violation that voids the manufacturer's warranty.

Disposal

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

The Due+Lite device contains electronic components that must be disposed of as electronic waste. Dispose of the device and accessories according to local regulations. Follow the regulations regarding the disposal of your country to ensure the correct disposal of Due+Lite and its accessories. For more information on disposal of this device, contact the Environment Department and local authorities.

Warning: Do not dispose of this product as unsorted municipal waste. Collection of such waste separately for special treatment of the necessary, following Directive 2002/96/EC of the European Parliament and of the European Council on waste Electrical and Electronic Equipment (WEEE). The regulation is not valid in case of damaged product.

Lifespan of the device

The Due+Lite system is manufactured to last if the use and maintenance conditions indicated in this User Manual are followed. The lifespan of the device is determined by the battery life (5 years). After this period, it is advisable to bring the device to the manufacturer every two years.

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
- ETSI EN 301 489-1 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services - Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility

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

Manufacturer's declaration and guidelines – electromagnetic emissions	
EN 60601-1-2 and ETSI EN 301 489-1	
Phenomenon	**Professional healthcare environment**
RF conducted and radiated emissions	EN 55011:2009 + A1:2010
	EN 55032:2015
RF conducted and radiated emissions	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
EN 60601-1-2, EN 60601-2-40 and ETSI EN 301 489-1		
Electrostatic discharges	IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV in air
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

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

12 INTENDED USE

Due+Lite 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 you to obtain 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 you 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

Model:	Due+Lite
Risk Class:	I in compliance with the Regulation MDR 2017/745.
Insulation Class:	BF type with applied parts, in compliance with the European standard EN 60601-1
Basic UDI:	805697785PORTABLEEMG002SF
Classification:	IP20, based on liquids' and dust's penetration; unprotected device.
Case:	*Painted ABS*
Power supply:	Internal Rechargeable Li-Po battery 3.7 V
Consumption:	0.6 W
Limitations:	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.
Working conditions:	Device suitable for continuative work.
Input channels:	8 independents: 2 biopotential signals, 4 quaternions, 2 control channels.
Input range:	0 – 3.3 V for biopotential signals.
Noise Referred to the Input:	$< 6\ \mu V_{RMS}$
Bandwidth:	DC ÷ 500 Hz
Signal gain:	202 V/V for biopotential signals.
Resolution:	16 bits
Input resistance:	500 MΩ
Commands:	1 pushbutton x Device
Dimensions:	Probe: 45 x 45 x 20 mm
Weight:	Probe: 42 g

14 WARRANTY

Due+Lite 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 unauthorised 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, unauthorised 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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