



**User Manual v1.4**

# DueLite

**The first, truly, smart EMG system**



Read carefully this manual before using the device.

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## 1 GENERAL DESCRIPTION

DueLite is a modular wireless system for the acquisition of up to 2 EMG signals. It is composed by one Due probe and a recharging station called DueCharger.

- **The Due** probe is used to acquire two bipolar surface electromyographic signals (sEMG).

The probe transmits wirelessly data to a PC, Tablet or Smartphone.

The Software is available to visualize, acquire or process signals: OT Biolab+ software for Windows PC or Due App for Android Tablet/Smartphone. The OT Biolab+ software can be downloaded for free from the website <https://otbioelettronica.it/downloads>.

Due App is available for free on [Google Play Store](#).

## 2 DUELITE KIT CONTENT

- 1 DueCharger
- 1 DueDongle;
- 1 Due probe
- 1 pack CDE-C (Adhesive bipolar electrode)
- 1 DueStrap - M
- 1 DueLite User Manual

### **3 END USER**

The DueLite system allows non-invasive recording of biopotentials (sEMG) detected by superficial electrodes. The end user should be familiar with this technique and should have received a proper training in sEMG detection and interpretation.

#### **3.1 Contraindications**

DueLite is a battery-powered device having parts in contact with the patient. It has no particular contraindications even if used jointly with personal computers, provided that all the electrical devices connected to it comply with safety rules and standards concerning grounding and leakage currents.

#### **3.2 Side effects**

No significant side effects are known. The materials used for manufacturing and all the parts in contact with the patient are biocompatible. Possible slight cutaneous allergic reactions (e.g. skin reddening) are reduced to a minimum during short duration of bioelectrical signal acquisitions.

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

The use of the DueLite is absolutely forbidden in the following conditions:

- While other monitoring devices are in use with the patient
- While electro-surgery equipment, short waves or microwave therapy devices are used
- By mentally impaired people
- Whenever the equipment is damaged
- In proximity of inflammable substances (especially inflammable liquids and gases) or in environments with a high concentration of oxygen

- On patients carrying life-supporting equipment that might be adversely affected by electromagnetic interferences, such as pacemakers, etc
- The operator must be sure that the battery of the device is completely charged following what is indicated in this User's Manual before giving the device to the patient
- The device must be kept out of reach of children



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

The following precautions should be observed:

- Only use electrodes supplied by the manufacturer: DueLite 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 impact (like a drop to the floor, etc.), verify that no crack or any other kind of damage is visible due to the impact. In case of doubt, please contact the manufacturer
- The DueLite 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 consider the presence of noise in your signal processing tasks and evaluations
- The connection between DueLite and other electrical devices must be done in compliance with the European standard EN 60601-1-1 on medical devices
- The use of the DueLite is restricted to skilled personnel
- Incorrect measurements can arise when unskilled personnel use the device in presence of strong electromagnetic interference (e.g. strong electromagnetic fields). The presence of interference in the signals is easily recognised by skilled personnel

## 5 SYMBOLS USED ON DUELITE AND IN THE USER MANUAL



Class BF for circuitry applied to patient



Serial number



Read carefully the instruction remarks before use



Manufacturer



Do not dispose of this product as non-differentiated waste.

Prepare the re-use or separate collection of the product in accordance with the provisions of Directive 2002/96 / EC of the European Parliament and of the Council of the European Union on the disposal of electrical and electronic equipment



CE Marking – Device in compliance with applicable Community directives



Read the instruction

## 6 TECHNICAL SPECIFICATIONS

DueLite 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 DueLite and the PC for real time data display and storage, is intrinsically achieved via the wireless data transfer and communication. The wireless battery charging of all the probes composing the DueLite device is achieved using the DueCharger. When the Due probe is charging, it is physically impossible to connect the electrodes, thus avoiding the chance to supply Due from an external source when it is connected to the patient.

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. Additional adapter can be realized under user request to interface other type of electrodes or sensors. Table 6.1 shows the technical specifications of the DueLite system.

DueLite	
Number of Channels	2
Maximum number of Due probes	1



**TAB. 6.1:** *Technical specifications of the DueLite system and all its parts.*

Due	
Number of sEMG signals	2
Gain	200 V/V
Bandwidth	10 ÷ 500Hz
Input noise	< 2 $\mu$ V <sub>RMS</sub>
CMRR	>100 dB
Sampling frequency	2048 Hz
Input Range	±8mV (RTI – Referred To Input)
A/D converter resolution	16 bits
Receiver	PC (Windows), Smartphone or Tablet (Android)
Wireless transmission protocol	Bluetooth 4.0®
Power supply	3.7V LiPo battery
Charging mode	Inductive
Battery lifetime during continuous transmission	13 hours
Weight	12g
Size	21mm (Radius) x 11mm (thickness)

DueCharger	
Charging function	Inductively charges Due probe or (one DueBio optional probe).
Power supply	5V, DC Power supply provided by manufacturer

DueDongle	
Receiver function	Receives data from Due and communicates with a PC.
Data transmission protocol	USB 2.0 or higher

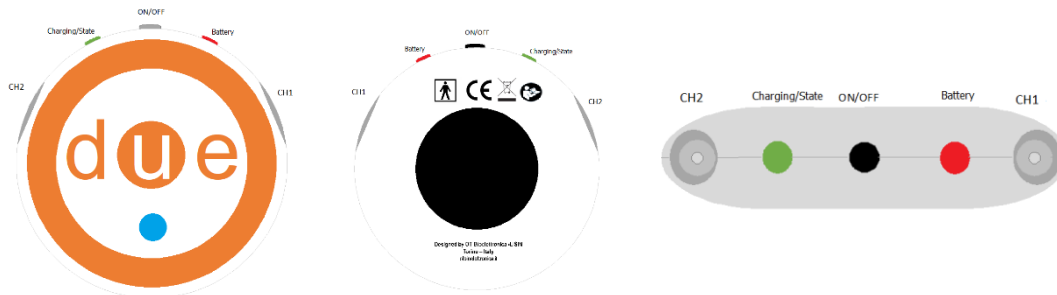
## 7 DETAILED DESCRIPTION

DueLite is a portable, battery powered device for the acquisition of surface EMG. Data can be acquired using Due probe. Signals are transferred to a PC, Smartphone or Tablet for real time display and recording. The device can connect directly to an Android Smartphone/Tablet or to a Personal Computer using the DueDongle device.

The communication protocol is available for custom development together with the demonstration Matlab code. See Section 8.6 – Design of Custom Software Applications and USB Communication - for further details. The following sections describe in detail the Due and DueDongle devices composing the DueLite system.

### 7.1 Due

The Due probe is a device designed to acquire up to two surface EMG signals through two pairs of bipolar electrodes (CDE - Bipolar electrodes diameter 15mm with concentric connector). Figure 7.1 shows the top, bottom and frontal view of the Due probe. Due probe has two indicators (green and red LEDs), a pushbutton and two concentric connectors (FIG: 7.1, frontal view). On the bottom view, it is possible to observe a Velcro pad used to secure the Due probe to the subject, through belts.



**FIG. 7.1:** From left to right. Top, bottom and frontal view of the Due probe for the acquisition of two sEMG signals.

### 7.1.1 Controls, indicators and connectors

- **Input connectors**

The Due probe has two concentric connectors used to connect two pairs of bipolar electrodes. If it is necessary to acquire only one sEMG signal, is highly recommended to use the connector next to the red LED (channel 1) to minimize input noise and reduce the power line interference.

- **On/Off Push button**

The probe turns on or off by pushing the ON/OFF push button. See the LEDs indicators section to understand the indicators associated with these states. When the system is On, pushing the ON/OFF button for 30 seconds or more resets the system's configuration to the default state (standard name and connection settings). It is not recommended to reset the system. Check the user manual of the [App DueProgrammer](#) to setup again the probe or see the youtube tutorial video at this [link](#).

- **LEDs indicators**

Two LEDs are used to identify the state of the Due probe. Each of them reflects a different state of the device:

- **Running state:** The Green LED blinks every 2 seconds when the system is working properly. The device automatically tries to make a connection with a PC with DueDongle connected or a paired Smartphone or Tablet with the Due app running. When a connection is established, the device starts to send data automatically
- **Battery alarm:** The Red LED blinks every two seconds when the battery level is lower than 10% and it turns off when the battery level is lower than 5%
- **System configuration reset:** When the device configuration has been reset the green LED, blinks alternate with the red LED

## 7.2 DueDongle

DueDongle (FIG. 7.2) is a device that can be used as a Bluetooth receiver. It is a plug & play device needed to transfer real time data from up to seven Due probe to a Windows PC.



**FIG. 7.2:** *DueDongle*

### 7.3 DueStrap

Due probe can be worn using different wearable straps (not included):

- DueStrap-S (Support strap size Small);
- DueStrap-M (Support strap size Medium);
- DueStrap-L (Support strap size Large);
- DueStrap-B (Support strap for chest - Body).

## 8 USE OF DUELITE

The probe that makes up the DueLite system can be connected to a Windows Personal Computer (PC) or an Android Smartphone/Tablet.

Software is available to visualize, acquire and record the received signals:

- 1) The OT BioLab+ software has to be used to acquire data with Windows PC
- 2) The Due App has to be used to acquire data with an Android Smartphone or Tablet.

Either in case of using the DueLite system with Windows PC or Android Smartphone/Tablet, a first-time start-up procedure is needed.

The OT BioLab+ software can be downloaded for free from the website <https://otbioelettronica.it/downloads> whereas Due App is available for free on [Google Play Store](#).

### 8.1 Using DueLite with Windows PC

DueLite can be interfaced to any computer with a USB 2.0 (or higher) interface and running Windows Operating System (Windows 7 or later is recommended). This section refers to the use of DueLite together with a PC with Windows and the software OT BioLab+. If a different Operative System is used, or if the user interface needs to be customized, several Matlab/Octave examples are available. Please contact OT Bioelettronica to receive additional manuals and examples.

In order to use the DueLite system with a Windows PC it is necessary to use DueDongle acting as a Bluetooth Receiver.

### 8.1.1 First-time start-up procedure

The following procedure must be carried out at the first use of the DueLite system:

1. Install the OT BioLab+ software on your PC (See OT Biolab+ Manual)
2. Install the Due Drivers (See OT Biolab+ Manual)
3. Follow the 8.1.2 Section ([Standard start-up procedure](#))

### 8.1.2 Standard start-up procedure

In case of standard start-up procedure make sure that OT Biolab+ software and Due drivers are correctly installed on the PC Windows which you want to start the acquisition.

1. Connect the DueDongle to a free USB 2.0 port of a Windows PC. It is highly recommended to avoid the connection of the DueDongle devices to a USB Hub. In this case, depending on the USB Hub used, some data loss can occur. It is forbidden to connect multiple DueDongle devices simultaneously. In this case, unpredictable behaviour of the OT BioLab+ software can happen
2. Run OT BioLab+
3. Create Acquisition Setup (See OT Biolab+ Manual)
4. Start the Visualization
5. Turn on the Due probe configured in your setup
6. Connect the bipolar electrodes to the Due probe
7. Apply the electrodes onto the skin. Clean skin before applying the electrodes (to avoid artifacts and noises on signals)
8. Use DueStrap to secure the probes to the body
9. Record the acquired signals as described in the OT BioLab+ User Manual



**If the probe does not connect to DueDongle, retry switching it on again.**



**Electrodes are disposable (single use). Do not re-use them.**

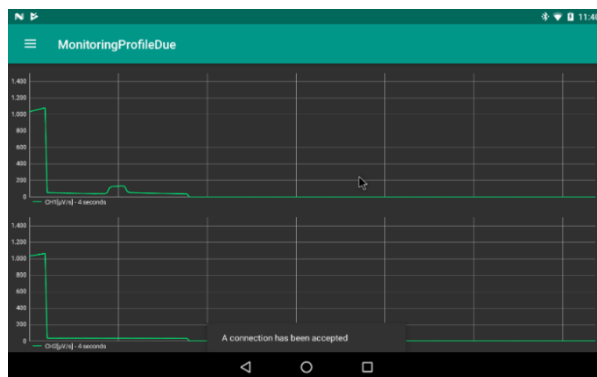
## 8.2 Using DueLite with mobile devices

It is possible to receive the signals acquired with DueLite by means of a mobile device (i.e. smartphone or tablet) with Android Operating System and Bluetooth 4.0 SmartReady interface. A first-time start-up procedure (pairing) is not needed to enable the communication with the Due probe. Using Due App with mobile devices does not need either DueDongle.

### 8.2.1 Standard start-up procedure

Follow the steps below to acquire signals from Due probes using a mobile device. The mobile device must have the Due application installed. It is possible to download the Due App using the [Google Play Store](https://play.google.com/store/apps/details?id=com.bioelettronica.due).

1. Run the Due App and allow pop-up windows
2. Turn on the Due probe
3. Due probe automatically connects to the mobile device (Figure 8.1)
4. Use the Due App to follow profiles



**FIG. 8.1:** Screenshot indicating that the Due was connected

### 8.3 Charging Due

Due probe can be inductively charged by using DueCharger.

Follow these instructions to charge the probes that make up the DueLite system:

1. Power the DueCharger connecting the available micro-USB power supply
2. Insert the probe into a slot to charge a Due probe. The associated charge status LED is green and blinks with a period of one second. This indicates that the Due probe is charging (if the probe is not at the best distance of the coil the green led will blinks faster then one second, it will only make more time to recharge)
3. When the charging process is finished, the charge status LED (green) stops blinking and stays on
4. If an error occurs with the charging process, the associated status LED becomes red and the charging process stops



## 8.4 Design of custom software applications and USB communication

With DueLite, it is possible to develop custom software compatible with a PC or Tablet. The following sections describe the USB setup needed to connect DueDongle with custom software and the communication protocol needed to correctly interpret data-packets coming from Due.

### 8.4.1 USB Setup

DueDongle creates a virtual COM port to communicate with a Personal Computer. The Virtual COM port has the following settings:

- Baud Rate            921600 bps
- Data Length        8 bit
- Parity                None
- Stop Bit             1 bit
- Flow Control        None

The PC starts the communication with DueDongle opening a virtual COM port and sending the 0x80 character.

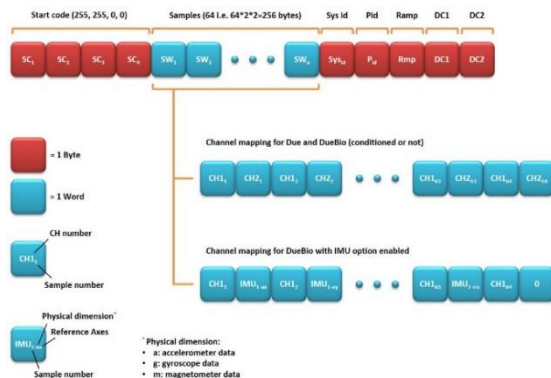
### 8.4.2 Data packet composition

Due probe transmits a data packet organized as showed in Figure 8.2. Each Data packet is composed of a 4 bytes long header, 128 bytes long data and 5 termination bytes. The header is composed of a constant, four bytes long sequence (255, 255, 0, 0) and it is used to identify the start of a new data packet.

Data is arranged in a Round-Robin fashion (i.e. the sampled signals are multiplexed). Each sample is composed by a word (2 bytes). The packet's tail is composed by 5 different bytes listed in the following:

- **SysID** represents the probe type (Due);
- **PID** represents the probe identifier code (this value ranges from 1 to 7);
- **Ramp** is an incremental counter used to know if lost packets occur during transmission;

- **DC1** is a byte reserved for future use and set to 0 at the moment;
- **DC2** is a byte reserved for future use and set to 0 at the moment.



**FIG. 8.2:** *USB and Bluetooth packet data composition.*

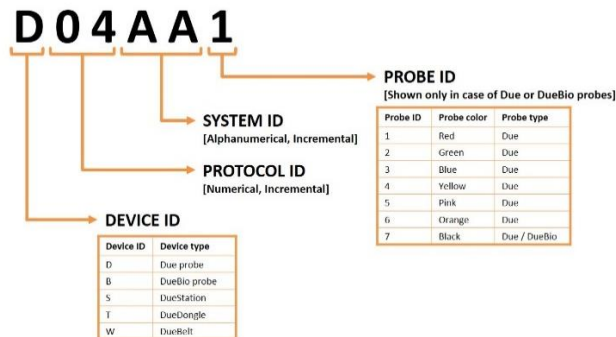
## 8.5 Signals

The resolution of Due probe is 16 bits obtained by sampling the signals with a SAR A/D converter. The other stages into the Due probe allow you to amplify and filter the EMG signals with a fixed gain of 200 V/V and bandwidth between 10 Hz and 500 Hz.

Two separate, single channel A/D converters are used for all 2 channels composing the Due probe. The A/D converter input dynamic is  $0 \div +3.3$  V, considering the amplification gain this reflects a resolution referred to the input equal to:  $LSBRTI = ADCRANGE/Gain/2^{16} = 244$  nV That is lower than the intrinsic noise generated by the electrode-skin contact, allowing the detection of the smallest possible EMG activity.

## 8.6 DueLite naming convention

All the devices composing the DueLite system can be recognized by means of a specific identification code. FIG. 8.3 illustrates the naming convention for the Due probe (red) related to the “AA” DueLite system updated to the protocol number “04”. Due probe composing the DueLite system is identified by a 6-characters alphanumeric code. The first character identifies the Device name (D stands for Due, see FIG. 8.3 for details). The Protocol ID field is composed by two digits representing the system version. The System ID field is a two-characters alphanumeric code representing the DueLite system identifier. It ranges from AA to ZZ. The latest field is a number indicating the probe number and colour (see Figure 8.3 for details). Only Due probes have this field.



**FIG. 8.3:** *DueLite identification code.*

## 8.7 Electrodes



CDE-C

Bipolar electrodes 15x15mm with concentric connector, 5pcs kit.

## 9 TROUBLESHOOTING

This section describes the most common problems that may be found by DueLite users, with some suggestions to solve them. For problems not described in this section contact the technical support team of OT Bioelettronica.

**TAB. 9.1:** *Troubleshooting of the general problem that can occur using the DueLite.*

Problem Description	Solving
Bluetooth connection does not work	Control Battery level looking at the probe LED. If Battery level is higher than 10% reboot the probe.
Due probe does not turn on	Charge the probe for at least 20 minutes.

## 10 MAINTENANCE AND STORAGE

DueLite must be used in the following ambient conditions:

**Temperature:** from 0°C to +40°C

**Maximum relative humidity:** 75%

**Atmospheric pressure:** 700hPa to 1060hPa

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

DueLite and its accessories must be stored in a safe zone and in conditions listed in Warning section of this manual.

DueLite does not need specific maintenance procedures to maintain its performance. To maintain battery performance recharge the batteries before each use.

Check regularly battery performance.



*If during use and after recharge battery life is lower than 1 hour contact the manufacturer to perform a battery health check.*

### 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 DueLite 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.



DO NOT clean DueLite using acetone, ether, freon, oil products or any other solvent.



DO NOT use soap or water on the connectors pin contacts.



DO NOT clean DueLite or its cables with water, in autoclave or with steam cleaning.

## Disposal

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

The DueLite device contains electronic parts that must be disposed of as e-waste. Dispose the device and the accessories following local regulations. Follow the disposal regulations of your country to ensure the correct disposal of the DueLite device and its accessories. For further information about the disposal of this device, contact the Environment Department and local authority.



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

## Life span of the device

The DueLite system is produced to last if the use and maintenance conditions indicated in this User's manual are followed. The life span of the device is determined by the life span of the battery (5 years). After this period, it is recommended to take 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

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

**TAB. 11.1:** Tests carried out and passed by the Due probe for compliance with the regulations on electromagnetic emissions

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

**TAB. 11.2:** Tests carried out and passed by the Due probe for compliance with the regulations in force on electromagnetic immunity

Manufacturer's declaration and guidelines - electromagnetic immunity – Due probe		
Phenomenon	EMC reference standard or test method	Immunity test levels - Professional healthcare environment
Electrostatic Discharges	IEC 61000-4-2	+/- 8 kV at contact +/- 8 kV e +/- 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 27 V/m 385 MHz 9 V/m 710 MHz – 780 MHz, 5.24 GHz – 5.785 GHz



**TAB. 11.3:** Tests carried out and passed by the DueCharger probe for compliance with the regulations on electromagnetic emissions

Manufacturer's declaration and guidelines - electromagnetic emissions – DueCharger	
Phenomenon	Professional healthcare environment
RF radiated emissions	EN 55011:2009 + A1:2010

**TAB. 11.4:** Tests carried out and passed by the DueCharger probe for compliance with current regulations on electromagnetic immunity

Manufacturer's declaration and guidelines - electromagnetic immunity – DueCharger		
Phenomenon	EMC reference standard or test method	Immunity test levels - Professional healthcare environment
Electrostatic Discharges	IEC 61000-4-2	+/- 8 kV at contact +/- 8 kV e +/- 15 kV in air
Radiated RF EM fields	IEC 61000-4-3	10 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 27 V/m 385 MHz 9 V/m 710 MHz – 780 MHz, 5.24 GHz – 5.785 GHz

## 12 INTENDED USE

Due probe allows you to acquire bioelectrical signals generated by the human body and save them in a file to be able to review them on a PC, thanks to the use of the OT BioLab+ software. The system allows you to evaluate physiological parameters in the context of clinical or applied research, but it was not designed to make diagnoses of any kind, or to monitor vital parameters. The applications of greatest use of the system are in the field of bioengineering, of the human-machine interface, in sport and motor science, as well as in basic research in medicine.

## 13 NORMATIVE REFERENCES AND ADDITIONAL SPECIFICATIONS

Signals acquired by Due probes are sent to the DueDongle and then to a PC or directly to a PC, Tablet or Smartphone. In Tab.4 there are technical specifications of the complete DueLite system.

Model:	<b>Due</b>
<i>Risk class:</i>	<b>Class I</b> in compliance with Regulations MDR 2017/745
<i>Insulation class:</i>	<b>BF</b> type applied part, in compliance with the European standard EN 60601-1
<i>Classification:</i>	<b>Class II</b> , about the protection from indirect contact <b>IP20</b> , about the penetration of fluids and dust; device not protected
<i>Case:</i>	Painted rigid polyurethane foam case.
<i>Limitations:</i>	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.
<i>Working conditions:</i>	Device suitable for continuative work.
<i>Box Dimensions:</i>	96 x 60 x 20 mm
Total Weight:	110 g

## **14 WARRANTY**

DueLite is covered by a 24 months warranty starting from the purchasing date of the electronic parts. Connection cables are covered by a 24 months 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 warranty lasts 24 months for the electronic parts. The 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 the certificate, or the warranty is released
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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