User's Manual v 1.4
Trentadue

⚠ **Read this manual carefully before using Trentadue.**

SYMBOLS USED

The graphic symbols used on this device and on this manual refer to the UNI EN ISO 980 Law, CEI EN 60601-1, RAEE Law and 2002/96/ECC Directive.

SYMBOL	DESCRIPTION
SN	Serial Numb er
	Device with BF parts
	Class II device
	Warning, read the instructions before using the device. This symbol could also be used as a "Warning" symbol
	Read the instructions of use
	Manufacturer
	Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary following the 2002/96/EC Law of the European Parliament and Council of the European Union about the disposal of e-waste.

The Trentadue device has been tested in reference to the EN 60601-1 and the EN 60601-1-2 Law. If the user connects the Trentadue device to any other unauthorized device following the EN 606011 and EN 60601-1-2 Laws, he/she has to ensure that the combined use of the two devices follows the laws above mentioned.

Otherwise OT Bioelettronica shall not be held liable for accidents and/or injuries to persons or damage. For the features of the software, read the Software Manual.

1. INDEX

1. GENERAL DESCRIPTION

The Trentadue is a 32-channel surface electromyographic (EMG) device. This system has been designed to detect the surface electromyography signal (sEMG) from skeletal muscles trough the use of the surface electrodes.

The information detected from the electrodes is then transferred to a PC with a wireless connection WiFi. The Trentadue works with a software called OT BioLab in order to display and process the data. This software is part of the Trentadue system and it is also possible to download it free on the website www.otbioelettronica.it in the Downloads section.

Alternatively it is possible to acquire from Trentadue by directly reading data with a custom software o script, further details can be found in this manual.

2. INTENDED USE

Trentadue has been designed to be used as an electromyography device to detect the activity of skeletal muscles up to 16 muscles simultaneously.

⚠ **The device is not intended to be used near inflammable anaesthetics.**

3. PLACE OF USE

Trentadue is intended to be used primarily as a laboratory device and secondly as a hospital device: as a home device, the patient uses the device at home during the day, and as a hospital device, in this case the operator uses the information detected in order to make a diagnosis.

4. USER PROFILE

USER: Specialized operator

a) Knowledge: Minimum. Basic notions about the human body

b) Languages: Italian and/or English

c) Experience: Minimum training about the device use

d) Handicaps:

       - maximum reduction of the hearing of 40% with residual hearing at 60%;

       - maximum sight reduction of 40% with residual sight at 60%

KIND OF PATIENT:

a) Age: >= 15 years

b) Weight: Not Important

c) Health: No cardiovascular problems no pacemakers

d) Nationality: not relevant

5. SAFETY CAUTIONS AND WARNINGS

The use of Trentadue is forbidden in the following conditions:

• Simultaneous use of electro surgery systems, shortwave or microwave therapy or near these type of devices;

• Unsound mind patient;

• The device is damaged;

• Near inflammable anaesthetics with air, oxygen or nitrous oxide.

• To make an electrocardiographic exam

• Pacemaker users

These warnings must be followed:

• Contact immediately the manufacturer if foreign materials (liquids, etc.) come into contact with the device.

• If the device falls in to the ground or something similar happens, check that the device is undamaged. In case of doubt, contact the manufacturer.

The Trentadue could be sensitive to electromagnetic interferences of other devices that could alter its electromyography measurements and consequently the physiological variables calculated on the basis of the information detected. For this reason, do not use it near devices that could cause the problems described above, for example mobile phones, instruments with power transformer, 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 to give the device to the patient.

• The device must be kept out of reach of children or unsound mind patient

• Do not clean the device using acetone, ether, freon, oil products or any other solvent

• Do not use soap or water on the connector pin

• Do not clean Trentadue or connection cables with water, in autoclave or steam cleaning

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

6. TRENTADUE DEVICE ACCESSORIES

In Table 1 there details about adapters and cables usable with Trentadue device.

REF	Description	Image	Characteristics	
CUSB02	USB cable adapter for recharge and connection to PC		**NON STERILE**	**REUSABLE**
AD1x16TR	Adapter for 16 electrodes arrays		**NON STERILE**	**REUSABLE**
AD1x32TR	Adapter for 32 electrodes matrices		**NON STERILE**	**REUSABLE**
AD8x1TR	Adapter for 8 couples of bipolar electrodes		**NON STERILE**	**REUSABLE**
ADX1TR	Cable for connection of one bipolar electrode with connector jack-concentric		**NON STERILE**	**REUSABLE**
AD1x16TR	Adapter for connection to 16 electrodes armband		**NON STERILE**	**REUSABLE**
ADX2TR	Cable for connection of 2 bipolar electrodes with connector jack-concentric		**NON STERILE**	**REUSABLE**
Sync1TR	Synchronization system for Trentadue with BNC uotput		**NON STERILE**	**REUSABLE**
J-Sync TR	Adapter with jack connector for synchronization		**NON STERILE**	**REUSABLE**
J-BNC TR	Adapter with jack-BNC connector for Trentadue		**NON STERILE**	**REUSABLE**
CPAT1	Reference cable		**NON STERILE**	**REUSABLE**

Table 1 Adapters and cables for Trentadue

In Table 2 there are electrodes usable with Trentadue.

ELECTRODES USABLE WITH TRENTADUE				
REF	**Description**	**Image**	**STERILE**	**SINGLE USE**
CODE401500	Adesive concentric electrode		**NO**	**YES**
CODE501500	Adesive concentric electrode		**NO**	**YES**
CDE	Adesive bipolar electrode		**NO**	**YES**
SA16/2.5	Dry array 16 electrodes i.e.d. 2,5 mm		**NO**	**NO**
SA16/5	Dry array 16 electrodes i.e.d 5 mm		**NO**	**NO**
SA16/10	Dry array 16 electrodes con i.e.d 10mm		**NO**	**NO**
ELSCH016	Semi-reusable array 16 electrodes 10mm i.e.d.		**NO**	**NO**
ELSCH032	Matrix 32 electrodes 10mm i.e.d.		**NO**	**NO**
KITAD016	Foam for 16 electrodes array ELSCH016		**NO**	**YES**
KITAD032	Foam for 32 electrodes array ELSCH032		**NO**	**YES**

Table 2 Electrodes for Trentadue

7. DETAILED DESCRIPTION

Controls, indicators and connectors of the Trentadue are shown in Fig. 1 and described in the following sections.
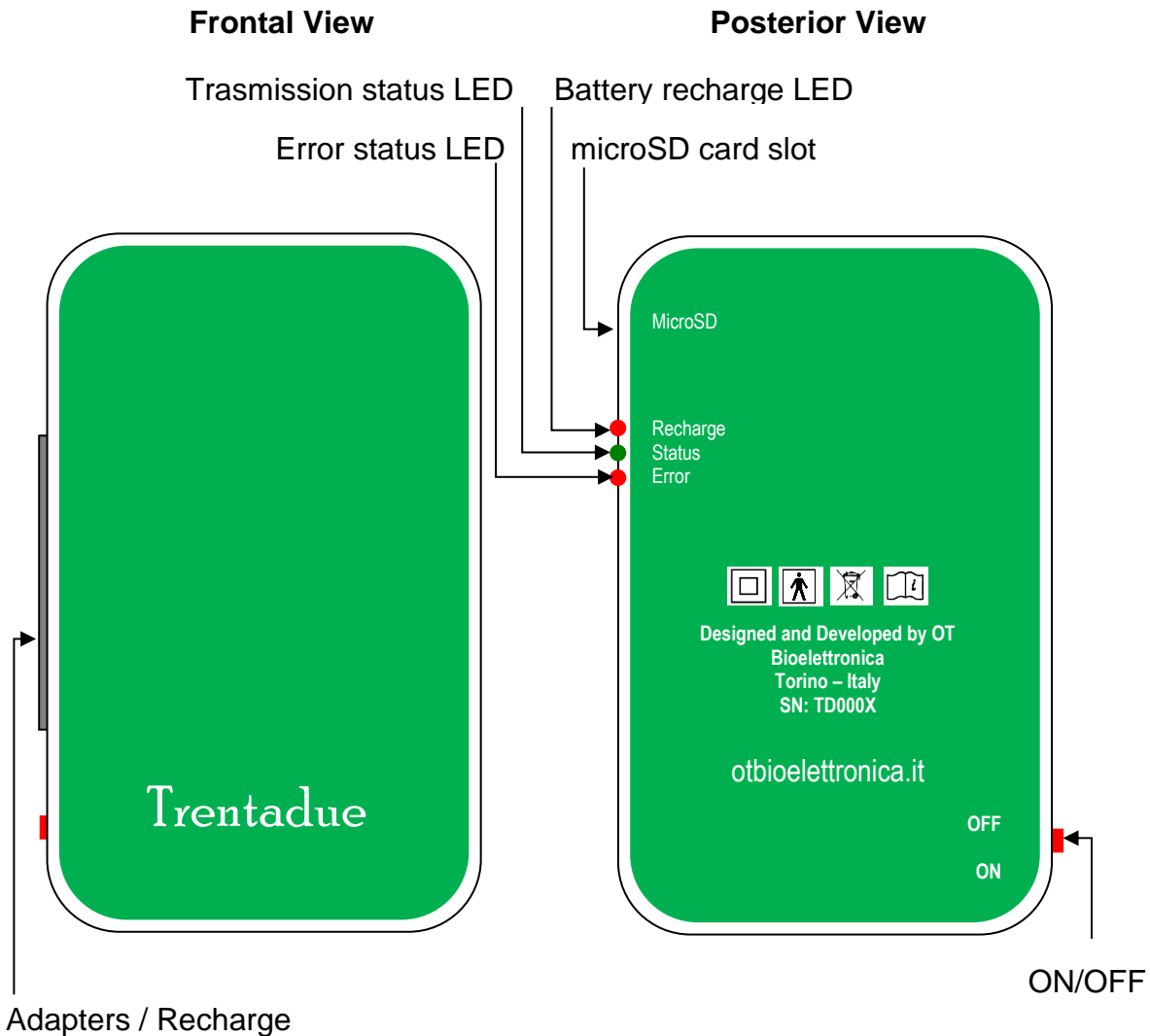
Fig. 1: Front view and Back view of the Trentadue

Description of controls, indicators and connectors shown in fig.1:

- **Adapters / Recharge Connector:** adapter connector to interface electrode and recharge the battery.

- **Battery recharge LED:** this red LED switches on when recharging the internal battery. It switch off when the battery is fully charged.

- **Status LED:** this green LED blink when Trentadue is creating the WiFi network, it is on when the network has been created.

- **Battery/Error LED:** this red LED indicates battery low or wireless communication samples loss.

- **ON/OFF switch:** With this switch it is possible to turn on and off Trentadue.

Electrode adapters connector: to detect the electromyographic signals produced by muscles Trentadue needs one of the following adapters: AD8x1TR, AD16x1TR, AD1x16TR or AD1x32TR. Some of them are directly connected to electrodes, others need further adapter as shown in the next section.

Electrodes connection:

AD8x1TR: AD8x1TR adapter can be combined with 8 couples of bipolar electrodes or with 8 concentric electrodes. Both kinds have concentric connector (CDE – CoDe401500 – CoDe501500). Between adapter and electrodes there must be connection cable ADx1TR. Figure 2 shows an example of connection AD8x1TR with concentric electrodes.

Fig.2 Detailed connection between AD8x1TR and concentric electrodes.

Attention: adapter AD8x1TR has 10 connectors: 8 of them are reserved to sEMG signals, one is reserved to auxiliary input and the last one is reserved for reference cable REF. In Figure 3 there are shown AD8x1TR input details. AUX1 channel automatically replace channel 8 and the selection has been done by set up of Software OT Biolab.
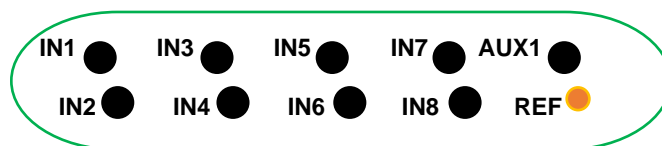
Fig.3 Input details of AD8x1TR adapter.

AD16x1TR: AD16x1TR adapter can be combined with 16 couples of bipolar electrodes or with 16 concentric electrodes. Both kinds have concentric connector (CDE – CoDe401500 – CoDe501500). Between adapter and electrodes there must be connection cable ADx2TR. Figure 4 shows an example of connection between AD16x1TR and concentric electrodes.
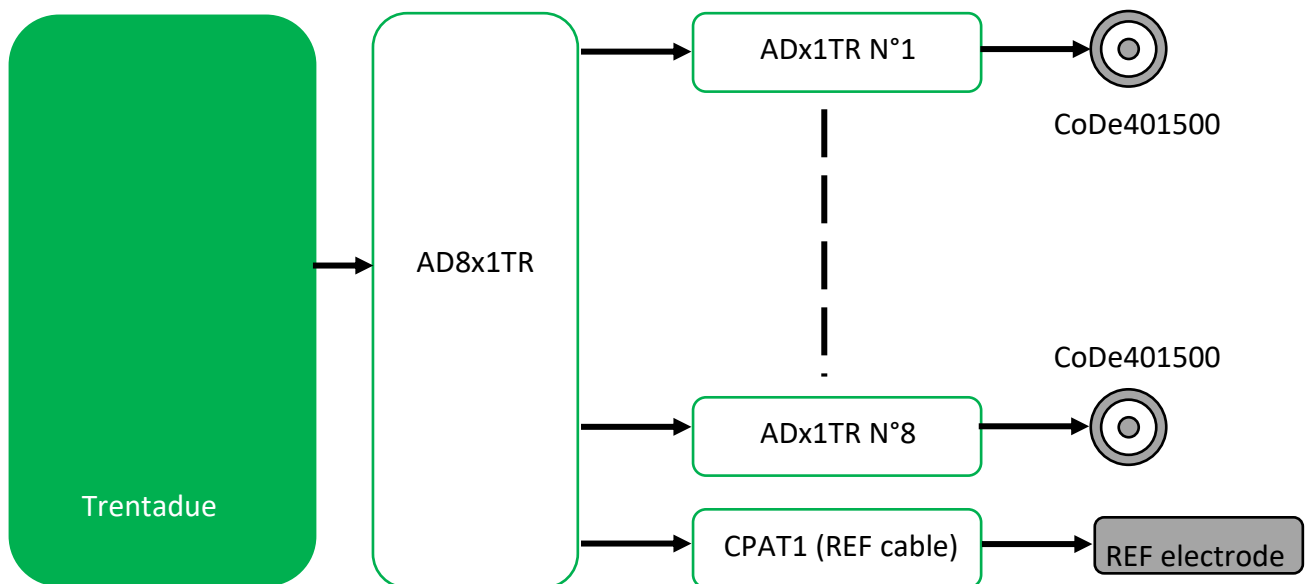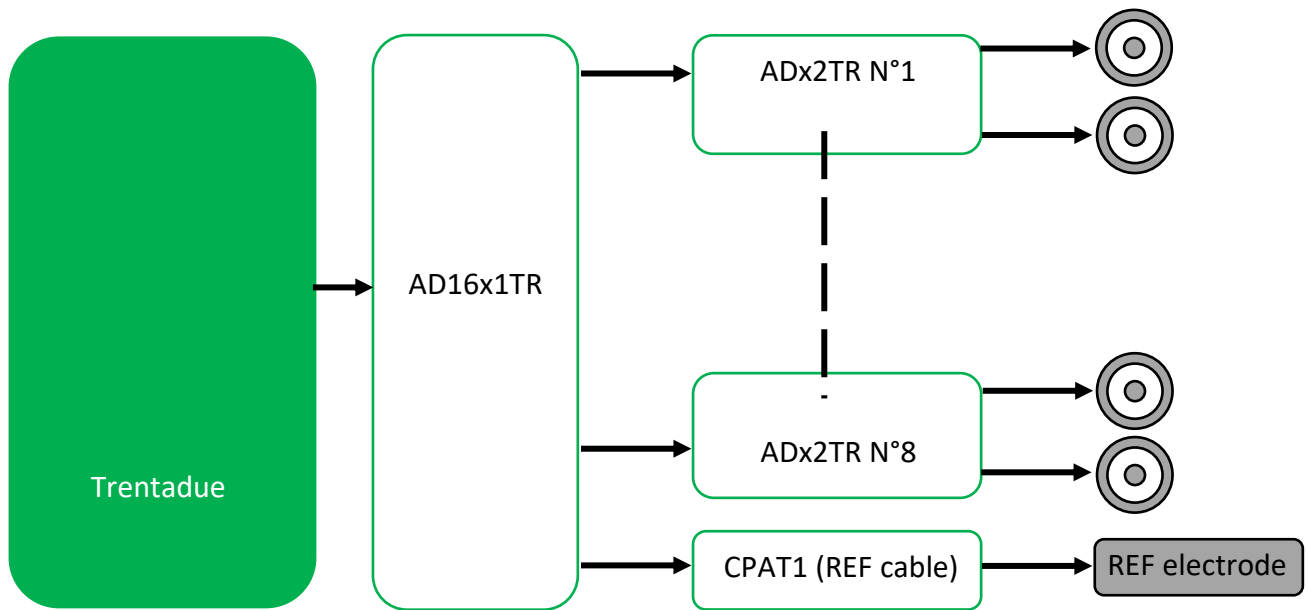

Fig.4 Detailed connection between AD16x1TR and concentric electrodes.

Attention: adapter AD16x1TR has 10 connectors: 8 of them are reserved to sEMG signals, one is reserved to auxiliary input and the last one is reserved for reference cable REF. In Figure 5 there are shown AD16x1TR input details. AUX1 channel automatically replace channel 16 and the selection has been done by set up of Software OT Biolab.
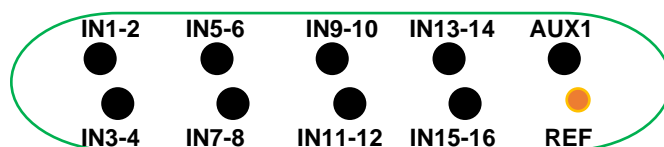
Fig.5 Input details of AD16x1TR adapter.

AD1x16TR: AD1x16TR adapter can be combined with semi-reusable array of 16 electrodes ELSCH016 or with all dry OT array: SA16/10 – sa16/5 AND sa16/2.5.
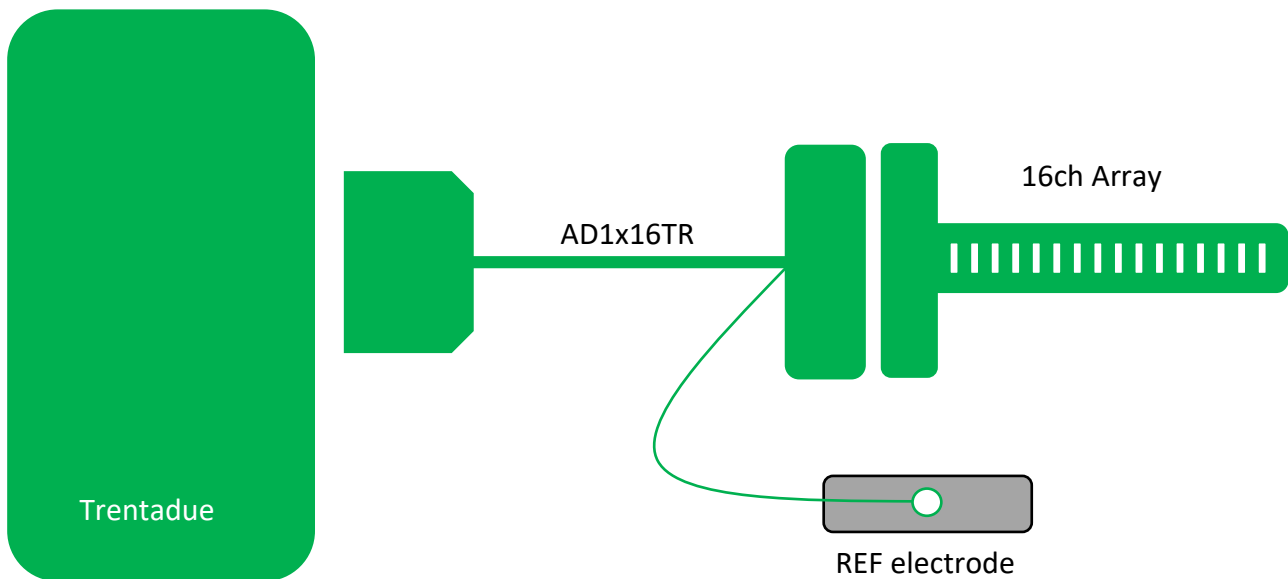
Fig.6 Connection details between adapter AD1x16TR and array.

In Fig.6 AD1x16TR adapter is shown. There is a wire with clip connector for reference electrode. Reference electrode must be placed on a zone without EMG activity.

AD1x32TR: Adapter AD1x32TR can be combined with semi-reusable matrices with 32 channels ELSCH032.
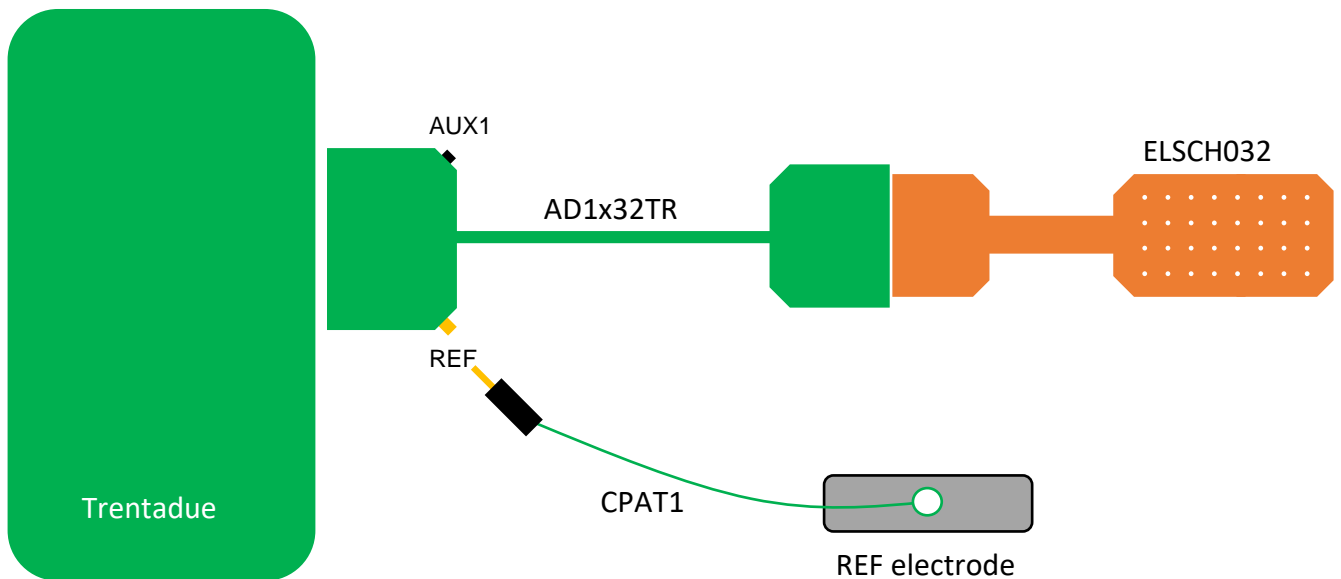
Fig.7 Connection details between adapter AD1x32TR and matrix.

As shown in Fig.7, adapter AD1x32TR (Trentadue side) has a 2.5 mm female banana connector for reference cable CPAT1. Adapter AD1x32TR (Trentadue side) has a female jack for AUX input. AUX input automatically replace 32nd channel. Selection can be performed using Software OT Biolab.

USB cable: charge battery cable

The Trentadue device has as accessory a USB cable as shown in fig. 2 called CUSB02. This cable allows to charge Trentadue by its connection to a USB PC port or to a power supplier that incorporates an USB output.

Fig. 2: *Cable for Trentadue battery charge*

System Requirements for PC connection

1. Windows Operating system for PC (Windows XP, Vista, Windows 7, Windows 8, Windows 8.1, Windows 10)

2. USB port to recharge Trentadue equipment

3. One WiFi board installed in the PC to allow Trentadue wireless connection.

Behaviour of the device during battery charge process

During the battery charge process the red Recharge LED located on the Trentadue right side (frontal view) becomes red till the end of the recharge process, when the battery is fully charged the red LED switches off.

⚠ **Charge the device for at least 2 hours before to use it.**

Application and acquisition with Trentadue

To use Trentadue system properly follow these instructions:

- connect the selected electrode adapter to the Trentadue device;
- take the electrodes/matrices/armband and apply them in direct contact with the investigated muscles;
- take the snap-on connector of the reference cable and connect it to the reference electrode displaced on a point without EMG activity.
- connect the electrode adapter to the interested electrodes;
- switch on the Trentadue device using the ON/OFF switch;
- wait fot the Trentadue net creation;

- connect the pc to the ad hoc net created by Trentadue (see Chapter 8).

- run the OT BioLab software and proceed with the signal acquisition (see OT BioLab SW manual)

- at the end of the measurement session remove the electrodes and disconnect them. Disconnect the electrode adapter from the Trentadue device, and then put the device and its accessories back in its packaging. Discard the single-use electrodes.

⚠ **The single-use electrodes cannot be reused.**

AUX connection to Trentadue

AUX input can be connected to adapters AD8x1TR, AD16x1TR and AD1x32TR. AUX channel must be configured in the Set-up of SW OT BioLab. Depending on the adapter, AUX channel replace the last channel of the used adapter, hence:

- if adapter is AD8x1TR, AUX channel replaces the 8th channel

- if adapter is AD16x1TR, AUX channel replaces the 16th channel

- if adapter is AD32x1TR, AUX channel replaces the 32nd channel.

External AUX channel must be connected to Trentadue by adapter Jack – BNC named J-BNC TR

⚠ **AUX channel accepts floating signal in the range +/- 1,2 V**

Synchronization of Trentadue with external devices

Trentadue can be synchronized with external devices using AUX input of adapters AD8x1TR, AD16x1TR or AD1x32TR.

In Fig.9 it is shown the scheme for synchronization of Trentadue with external devices.

Pressing P1 button on the device Sync1TR the led turns on and its light is converted by the phototransistor of adapter J-Sync TR. In the mmeanwhile a square wave is generated and available on BNC of SYNC1TR (squared wave +5V).
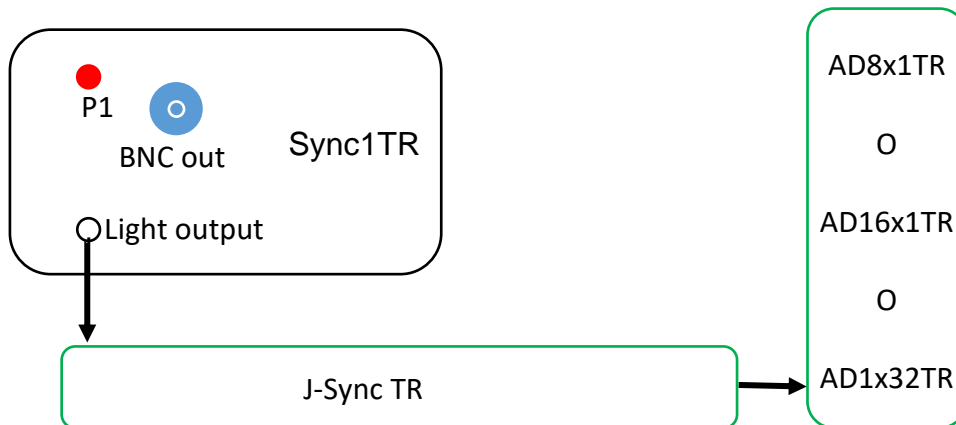
Fig.9: System for synchronization between Trentadue and external devices

Bandwidth of Trentadue device

Trentadue has low cutoff frequency 10Hz while high cutoff frequency depends on sample frequency.

Cutoff frequency is higher than 1/4 of sample frequency except for 32 channels 1 kHz acquisition, when cutoff frequency is half sample frequency.

8. HOW TO CONNECT TRENTADUE TO PC

How to connect to Windows 7 PC.

1. Turn on Trentadue.

2. Wait the green light stop blinking.

3. When the green light is steady, check in the WiFi Networks. An "Ad Hoc" Wi-Fi Network named TrentadueXYZ will be available, where XYZ are replaced by the device serial number.

4. Connect to the Trentadue's network.

How to connect to Windows 8 and Windows 10 PC.

1. Turn on Trentadue.

2. Wait the green light to stop blinking.

3. When the green light is steady, right click on the Network icon of the Taskbar
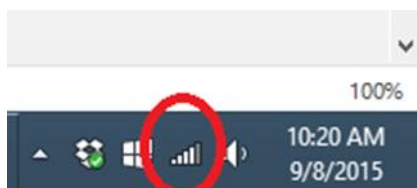
4. Choose Open Network and Sharing Center
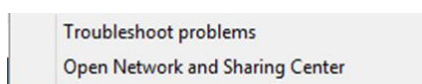
5. Set up a new connection or network.

6. Manually connect to a wireless network.

7. Fill the form as follows (using the name of your own Trentadue)

8. Open the command line: press Win button ( ) and then digit "cmd". Run "cmd.exe".

9. In the command window type the following line (where XYZ has to be replaced with the serial number of your Trentadue):

netsh wlan set profileparameter TrentadueXYZ ConnectionType=ibss

10. As result you should read "Profile "TrentadueXYZ" on interface "Wi-Fi" updated succesfully".

11. Close command window.
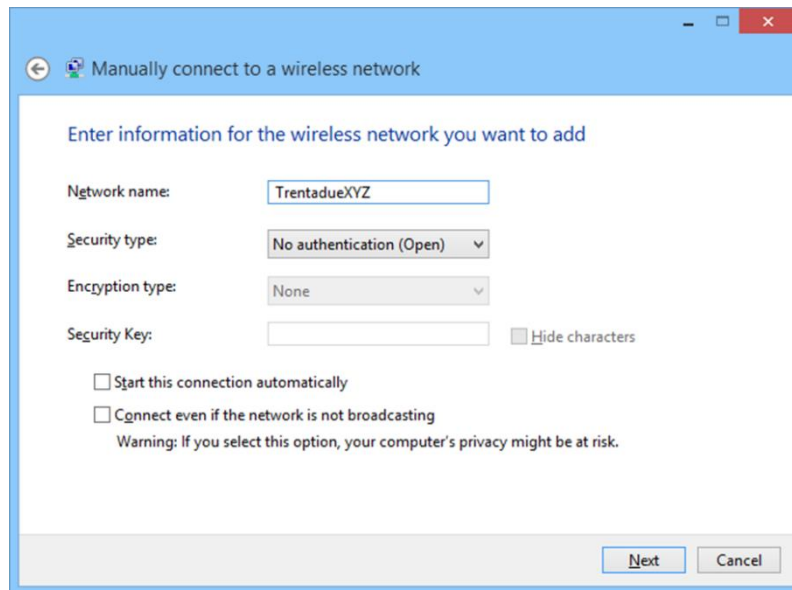
To connect the operator has to create two .bat files (respectively for connection/disconnection). It can be done with a txt editor (or can be provided by OT Bioelettronica):

1. Open a new .txt file
2. Paste the string:

netsh wlan connect TrentadueXYX

3. Save the file as "ConnectTrentadueXYZ.bat".
4. Repeat the same procedure in a second txt file with the string:

netsh wlan disconnect

5. Save the file as "DisconnectTrentadue.bat".

From now on just double click on the file " ConnectTrentadueXYZ.bat " when you need to connect to Trentadue or double click on "DisconnectTrentadue.bat" to disconnect from Trentadue.
When test are over, remember to double click on "DisconnectTrentadue.bat" in order to free the device.

9. FIRMWARE UPGRADE

This section describes the upgrade of firmware that can be done by the user.

Proceed as follows:

- Turn off the Trentadue.

- Upload on a empty micro SD card the hex and cfg files provided by OT Bioelettronica.

- Pay attention to upload the files in the main folder and not in any subfolder.

- Plug the micro SD card in the Trentadue.

- Turn on the Trentadue.

- Trentadue's LEDs will start blinking in random order.

- Wait until they stop blinking.

- When they stop blinking, turn off the Trentadue.

- Remove the micro SD card.

- Upgrade has been successfully completed.

10. MATLAB CONNECTION

This section shows the Matlab connection code to connect to Trentadue. In order to connect to Trentadue, you must use the code provided by OT Bioelettronica, that can be found in the installation folder of OT Biolab.

% Routine for the direct communication with Trentadue.

```
% This Matlab scripts doesn't need OT BioLab to communicate with trentadue.
% It opens a TCP socket, set the configuration of trentadue and reads back
% data at the desired sampling frequency.
%
% OT Bioelettronica
% August 11th 2015
% v 1.2
%

close all
clear all

path = cd;
javaaddpath(path);
addpath(path);
warning off

NumCycles = 20; % How many times matlab reads data from trentadue

GainFactor = 4.8/2^16/256*1000;      % Provide amplitude in mV
                                     % 4.8 is the ADC input swing
                                     % 2^16 is the resolution
                                     % 256 is the gain
                                     % 1000 to get the mV

AuxGainFactor = 4.8/2^16;            % Gain factor to convert Aux Channels in V

device = OTClient('192.168.1.1', 9760);

% The SET command is used to configure the instrument:
%
% - The first number indicates the number of transmitted channels:
% Can be 0 = 8 channels, 1 = 16 channels, 2 = 32 channels;
%
% - The second number set the sampling frequency:
% Can be 0 = 250 Hz, 1=500 Hz, 2=1000 Hz, 3= 2000 Hz
% Note: when the samplig frequency is set to 2000 Hz and the number of channels
is equal to 32,
% the internal sampling frequency is 2000 but only one sample out of two is
transmitted to fit the
% datarate of the WiFi module.
% The -3dB corner of the internal low pass filter is equal to 1/4 fsamp.
%
% - The third number set the resolution:
% Only 1 is valid and is 16 bits
%
% - The fourth number indicates the type of adapter connected:
% Can be: 0: AD8x1TR, 2: AD16x1TR, 3: Generic monopolar acquisition
```

```
% This overwrite the number of channels when is < 3
% In particular, the AD8x1TR and the AD16x1TR are used to set the
% difference directly into the trentadue.
%
% - The fifth number indicates whitch AUX channel has to be acquired. If
% the number is set to 0, no AUX channel will be acquired.
% For AD8x1TR the AUX has to be set = 3
% For AD16x1TR the AUX has to be set = 4
% For AD1x32TR the AUX has to be set = 4
%
% - The sixth number indicates witch channel is replaced by the AUX channel
% For AD8x1TR the channel has to be set = 8
% For AD16x1TR the channel has to be set = 16
% For AD1x32TR the channel has to be set = 32
%
% device.control('SET:0 3 1 0 3 8');    % 8 channels, 2000 Hz, 2 bytes,
Differential
device.control  ('SET:1 3 1 1 4 16');   % 16 channels, 2000 Hz, 2 bytes,
Differential
% device.control('SET:2 2 1 3 4 32');   % 32 channels, 1000 Hz, 2 bytes,
Monopolar

% Read back the configuration
device.getConfig();

low_pass_filter = device.channelConfig (3,:);
high_pass_filter = device.channelConfig (2,:);
gain = device.channelConfig (1,:);
nEMG = device.nEMG;
nAux = device.nAux;
Samplerate = device.Samplerate;

% Start data transef
device.control('start');

for i = 1 : NumCycles

    % Wait for 1 second to have some data
    pause(1);

    % Read data
    Data{i} = double(device.readData)';

    % Plot the signals
    hold off
    for ch = 1 : nEMG
        plot(Data{i}(:,ch)*GainFactor + double(ch*5))
        hold on
    end

    % Display the number fo samples and channels received
    size(Data{i})
end

% Stop data transfer.
% !!! Important !!!
% During debug always stop data transfer before start a new
% session otherwise the sinchronization with trentadue is lost.
device.control('stop');

% Close the communication
device.delete;
```

11. TROUBLESHOOTING

Table 3 describes the most common problems that may be found by Trentadue users.

Problem Description	How to deal with it
After the Trentadue switch-on the Trentadue net has not been created	Check the Battery charge
The red LED Error is switched-on	Battery empty, recharge it Or Data transmission error, please move near to the PC with Trentadue device

Table 3 Common problems found by Trrentadue users.

12. MAINTENANCE AND STORAGE

Trentadue has to be used, transported and stored in the following conditions:

Temperature: **from 10°C to +40°C**

Maximum relative humidity: **from 30% to 75%**

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

It is recommended to turn off the Trentadue at the end of every session.

Trentadue should be stored with all the enclosed accessories on a safe place far from all the conditions described in the section Warnings of this manual. Trentadue does not need any particular maintenance procedure to work. To maintain the battery efficiency, recharge the device before every use and check regularly the efficiency status of the battery.

⚠ If during the use and after the battery charging the battery lasts less than 1 hour, contact the manufacturer to check the controls of the electrical source itself.

Cleaning the device: At the end of every use clean the Trentadue with a clean cloth.

- ⚠ Do not clean Trentadue using acetone, ether, freon, oil products or any other solvent;

- ⚠ Do not use soap or water on the connectors pin contacts.

- ⚠ Do not clean Trentadue or its cables with water, in autoclave or with steam cleaning.

⚠ **WARNING: clean the electrodes adapter cable only with hospital disinfectants before every use to avoid microbial contamination between patients and healthcare professionals.**

Product Disposal

The Trentadue 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 in order to ensure the correct disposal of the Trentadue and its accessories. For further information about the disposal of this device, contact the Environment Department and local authority.
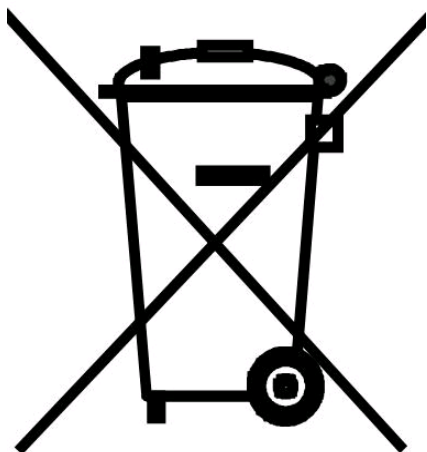
⚠ **Warning**: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment of necessary, following the 2002/96/EC of the European Parliament and European Council on waste electrical and electronic equipment. (WEEE). The regulation is not valid in case of corrupted product.

Life span of the device

The Trentadue system is produced in order to last, if the use and maintenance conditions indicated in this User's manual are followed, but 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.

13. TECHNICAL SPECIFICATIONS

The Trentadue device is a battery system designed following the medical regulations in order to ensure the patient safety.

The signal amplified by the system is transferred to a PC ina wireless mode.

In table 1 there are the technical specifications of the Trentadue device.

Model	Trentadue
Classification	Battery system
Degree of Protection	IP32
Case	Plastic case
Power Supply	3,7V Battery, rechargeable
Battery time	4 hours (full charge)
Charging time	3 hours
Class	II
Numbers of Channels	32
Dynamics	3,3 V_{PP}
High Pass Filter	10Hz
Low Pass Filter	Fsample / 4 **
Input Noise	< 2 μV_{RMS}
Amplification	1 V/V
Input impedance	> 90 MΩ on the entire bandwidth
CMRR	>96 dB
Output Dynamics	0 ÷ 3.3 V
A/D converter resolution	24 bits
Wireless transmission modality	WiFi
Selectable sampling rate	250 - 500 -1.000 - 2.000 Hz
Dimensions	59 x 95 x 20 mm
Weight	110g

*** For 32 channels Sample frequency = 1 kHz Low Pass Filter become = Fsample/2;*

TAB.4: Technical Specifications of the Trentadue

⚠️ **CUSTOMER SERVICE**

Trentadue has no parts that can be replaced or repaired by the user; contact the distributor for assistance so that he/she can repair or replace the products under warranty.

Maintenance and replacement of parts, modifications and/or reparations made by unauthorized Companies and/or operators by OT Bioelettronica will forfeit entitlement to warranty.

OT Bioelettronica denies any and all responsibility for damages caused directly or indirectly as a result of maintenance, replacement of parts, modifications and/or reparations made by Companies and/or operator that are not authorized by the OT Bioelettronica

Trentadue does not need any prior maintenance.

⚠️ **WARRANTY**

OT Bioelettronica ensures that every new product has no defects due to materials and labour and will repair and/or replace in warranty products used following the intended use and used in the use conditions described in this manual.

Warranty lasts **2 years** only after filling and signature of the warranty application form that you find below.

Warranty conditions: the obligations of OT Bioelettronica following the warranty are limited exclusively to what follows:

- reparation will be made by and no later than 30 work days after the receipt of the product and only after the verification that the malfunctioning is not due to inadequate or inaccurate use, maintenance and /or reparation.

If OT Bioelettronica verifies that the malfunctioning is not due to inadequate or inaccurate use or unauthorized maintenance/reparation, the reparation costs (materials and labour) will be invoiced only after acceptation of the budget of reparation by the owner

These warranty conditions substitute all the other warranty conditions, explicit or implicit, included, but not within limits of the general conditions specified in the international sale regulations.

OT Bioelettronica reserves the right to refuse the reparation of any products sent by the user for reparation; this refusal will be conveniently explained. The only obligation of OT Bioelettronica is that of returning the product to the user at its own expenses.

Manufactured by:

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