User Manual v1.3

NOD

Three functions, one device

⚠ Read this manual carefully before using NOD

1 GENERAL DESCRIPTION

The NOD device is a generic 1-channel amplifier. This system can amplify and filter any differential and single ended signal.

NOD is a multi-purpose tool that combines the functionality of three different tools:

1) **Biofeedback**, provides real-time feedback on the force exerted by the patient during an exercise to allow you to correctly perform rehabilitation protocols.

2) **Dynamometer**, can measure the traction and compression force produced by the patient during an exercise and allow comparisons in different measurement sessions.

3) **Algometer**, allows to mimic the acupressure action used to measure pain in a specific body district.

The information collected from the input is conditioned and transferred to a smartphone / tablet via wireless communication (Bluetooth®).

In Bluetooth® wireless mode, the NOD device can be used with an App, called Physio (available on Google Play Store) to view the detected data.

2 NOD KIT CONTENT

- 1 portable mono-channel amplifier NOD;
- 1 USB-C cable;
- 1 Algometer tip;
- 1 Pad;
- 1 Magnetic pad.

3 END USER

NOD is intended to be used in an outpatient physiotherapeutic or medical environment, so that the medical staff can use the information detected by the device to perform a diagnosis.

Type of users are specialized operators:

a) Background: Minimum. Basic physics

b) Language Understanding: Basic English

c) Experience: Minimum. Minimum training for the use of the device

d) Eligible impairments:

- 40% maximum hearing reduction with 60% residual hearing;
- 40% sight reduction with 60% residual sight

3.1 CONTRAINDICATIONS

NOD has no contraindications when used jointly with a smartphone or tablet, provided that all the electrical devices connected to it and the power line comply with safety rules and standards concerning grounding and leakage currents.

3.2 SIDE EFFECTS

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

4 SAFETY PRECAUTIONS AND WARNINGS

The use of the NOD 1-channel amplifier is absolutely forbidden in the following conditions:

- Simultaneous or near use of electrosurgery systems, a shortwave or microwave therapy device.
- From people unable to understand and / or will.
- When the system is visibly damaged.
- In the presence of flammable anaesthetics mixtures with air, oxygen or nitrous oxide.

The following precautions should be observed:

- Contact the manufacturer immediately if any material enters the device (liquids, etc.). In case of strong shocks impact (falling on the floor, etc.), check the integrity of the device after the impact. If in doubt, please contact the manufacturer.
- The NOD device may be sensitive to electro-magnetic interference from other devices that could alter the force measurements and, consequently, the variables calculated based on the data collected. Therefore, we recommend that you do not use the NOD device near devices that could cause the problems described above such as mobile phones, instrumentation with large transformers, etc. ...).
- The operator must ensure that the battery of the appliance has been fully recharged, as indicated in this user manual, before using the device.
- DO NOT leave the device within reach of children or incapable people without supervision.

- DO NOT clean the device using acetone, ether, freon, petroleum derivatives or other solvents.
- DO NOT use soap or water on the connector pins.
- DO NOT clean the NOD device or connect cables by immersion, autoclave or steam cleaning.

5 SYMBOLS USED ON NOD AND IN THE USER MANUAL

Serial number


Manufacturer


Do not dispose of this product as non-differentiated waste. Prepare the re-use or separate collection of the product according to the provisions of Directive 2002/96 / EC of the European Parliament and of the Council of the European


Attention read the attached documents before starting the device


CE marking - Device compliant with applicable Community directives


Read the instructions

USB Indicates the USB input

ON/OFF Power button

STATUS Indicates the device's status

The *NOD* device has been tested with reference to the EN 60601-1 and EN 60601-1-2 Standards. If the user connects to the *NOD* another instrumentation not previously validated for joint use according to the EN 60601-1 and EN 60601-1-2 Regulations, he must ensure that the coupling between the two devices meets the requirements of the Regulations mentioned above.
Otherwise OT Bioelettronica declines any responsibility. Regarding the functionality of the software, please refer to the specific manual provided.

6 TECHNICAL SPECIFICATIONS

The *NOD* system is a battery-powered device designed according to medical regulations to guarantee patient safety.
The signals picked up and amplified by the system are then transferred to a Smartphone / Tablet wirelessly (**Bluetooth®**). Table 6.1 shows the technical specifications of the *NOD* device.

Model	NOD
Classification	Battery powered system
Classification code	IP20
Housing	Painted Plexiglas case
Power Supply	3,7V rechargeable battery
Battery life	8 hours (full charge)
Charging time	2 hours
Number of channels	1
Dynamic	0 ÷ 50 mV_{PP}
Band	0 ÷ 34Hz
Input noise	< 20 μV_{RMS}
Amplification (digital)	942 V/V
Output range	0 ÷ 5 V
Resolution of the A/D converter	16 bit
Wireless transmission model	**Bluetooth®**
Sampling rate	100 Hz
Dimensions	79 x 194 x 17 mm
Weight	300g

Tab. 6.1: *Technical specifications of the NOD system*

7 DETAILED DESCRIPTION

Figure 7.1 shows the controls, indicators and connectors on the NOD system and described in the following section.

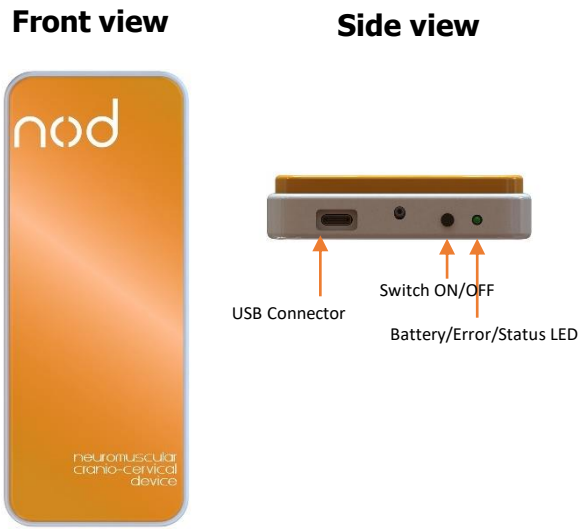


Fig. 7.1: *Front panel and side view of the NOD system.*

7.1 CONTROLS, INDICATORS AND ADAPTERS

Description of controls, indicators and connectors shown in figure 7.1:

7.1.1 LED INDICATORS

Battery/Error/Status LED: This two-colour LED (Red or Green) performs multiple functions:

- **Status:**
    1. **flashes Green** when the system is running and is waiting for a connection;
    2. it **remains lit Green** when the system is running and is connected to a smartphone / tablet via the app.

- **Battery:**
    1. **blinks between Green and Red** when it is not connected and discharged;
    2. it **remains lit Green** with a **Red LED flashing intermittently** when the system is connected to a smartphone / tablet and is also discharged;
    3. **blinks between Green and Red** also when it is charging;
    4. **flashes Green** when the charge is complete.
- **Errors:**
    1. **blinks between Green and Red** when there is a communication problem via the smartphone / tablet (try restarting the NOD);
    2. **flashes Red** when the connection with the smartphone or tablet has been lost.

7.1.2 ON/OFF SWITCH

The NOD system turns on and off using the ON/OFF button.

7.1.3 CONNECTORS AND ADAPTERS

USB connector: this connector is used to recharge the battery.

USB cable for battery charging: The NOD device is equipped with a USB adapter called CUSB03 (USB C). This cable has the function to recharge the battery of the device once connected to a PC or a power supply with a USB output.

Note. If the NOD device is charged while turned off, the LED will not light up, but the device will anyway be charging.

7.2 System requirements for smartphones/ Tablets

1. Minimum Android version 4.4 (KitKat)
2. **Bluetooth®** from 2.1

7.3 Charging the NOD

Behaviour of the device during charging

During the charging phase, the red "Recharge" LED located on the right side of the NOD device (posterior view) flashes red until it is recharged, then the LED turns off.

Charge the device for at least 2 hours before using it.

7.4 Use of NOD

Application and data acquisition with the NOD System

To correctly apply the NOD system, proceed as follows:

Smartphone / Tablet

- pair the NOD device to the Smartphone or Tablet via **Bluetooth®**;
- launch the Physio application;
- select from the device list the name of the NOD device (only the first time);
- select the desired functionality;
- if necessary, reset the offset via the App and proceed with signal acquisition.

8 USE OF NOD

NOD is intended to be used as a force detection system generated by load cells or transducers with differential output and single ended.

PRINCIPLE OF OPERATION

The device, called NOD, is a dynamometer capable of detecting force when it is applied perpendicular to its front surface. The detected force is transmitted via **Bluetooth®** connection to a smartphone / tablet where a dedicated application will allow the display and recording of the force. Force display and recording modes depend on clinical applications. The device has been developed to be hand-held by an operator.

CLINICAL APPLICATIONS

NOD is a non-invasive clinical device for the evaluation and treatment of patients with neuromuscular problems characterized by muscular hyposthenia and / or musculoskeletal pain. The device is intended to come into contact with the patient only temporarily and at an epidermal level on intact and healthy skin. Three different clinical applications of the device are possible. Patients should be properly informed about the purposes and modalities of clinical applications and these should be conducted under the supervision of a physiotherapist or a physician.

8.1 BIOFEEDBACK (ISOMETRIC MUSCLE TESTING)

This function provides real-time feedback of the force produced during a muscle contraction. This function can be used to train muscles in all regions of the body including the cranio-cervical flexor muscles. The operator before performing the test,

instructs the patient to assume a standardized position that will allow the selective activation of a muscle group. The operator will place the NOD on the patient's body (at a specific point) and the latter will have to progressively push against the front surface of the NOD until reaching his/her maximum strength. The operator must ensure that no joint movements occur.

8.2 Dynamometer (Cranio Cervical Flexion Test)

Cranio Cervical Flexion Test (CCFT) is a clinical examination for the evaluation of neuromotor control of the deep flexors of the cervical area. The test is indicated in patients with cervicalgia (subacute and chronic), whiplash and cervicogenic headache. The patient should be lying on a medical bed in a supine position. The cervical district must be in a neutral position, the chin and the forehead must be aligned on a horizontal (imaginary) plane parallel to the couch.

The operator positions the NOD, with the appropriate support, behind the neck so that it adheres to the occiput. The patient is instructed to increase pressure on the NOD progressively by moving his/her head vertically, as if nodding.

8.3 Algometer (Pain Test)

The algometer provides a clinical and research tool for the assessment of pain perception. Digital algometry provides a reliable and objective quantification of the pressure pain threshold.

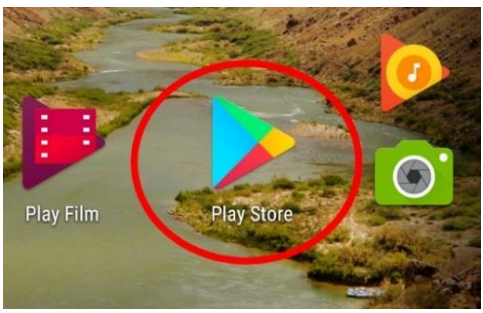
After positioning the adapter on the front of the NOD device, the operator will position the adapter

tip (1 cm^2) perpendicularly on the anatomical structure to be evaluated. Then the pressure will gradually increase until it causes pain. The patient should be instructed to stop the operator as soon as the pressure causes the appearance of the pain. The pain threshold, defined as the minimum pressure needed to evoke pain, will be measured in Kg/cm^2.

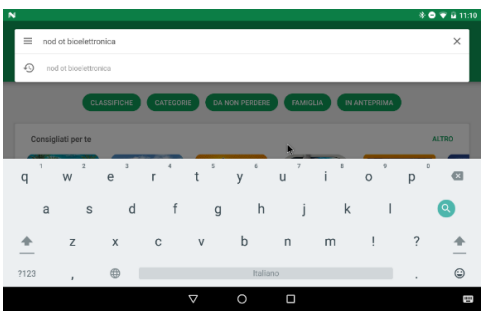
8.4 METHODS OF USE

8.4.1 DOWNLOAD THE NOD APP

- Click on the Google Play Store icon



- Write the word "nod ot bioelettronica" in the search bar

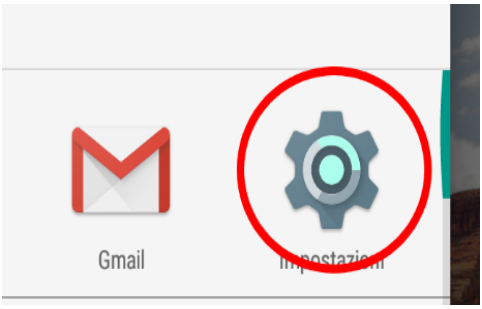


- Click on the NOD App icon (OT Bioelettronica)
- Click on "install" icon and wait for the end of the process

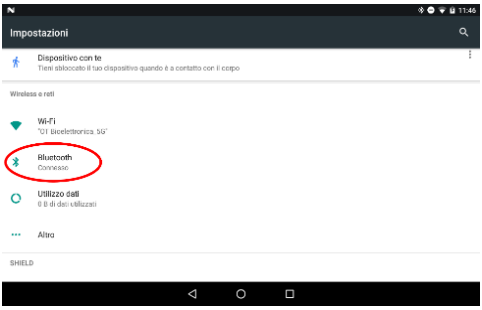
- Exit Google Play Store and proceed with the next step

8.4.2 PAIRING SMARTPHONE / TABLET AND NOD DEVICE

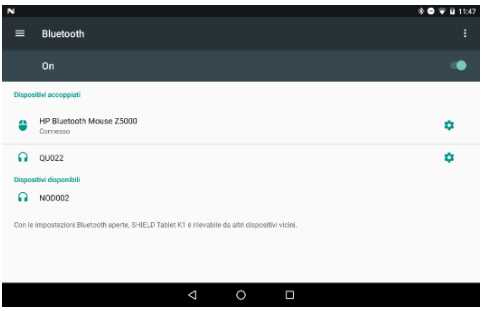
- Turn on the NOD device
- Click on the settings icon of your Android device



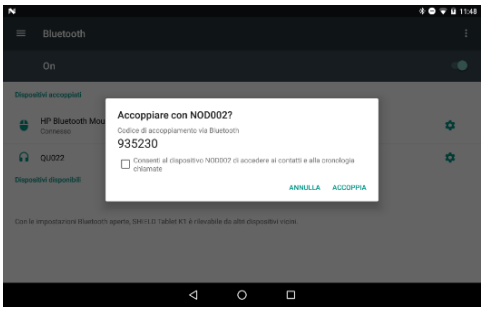
- Press the "**Bluetooth®**" button



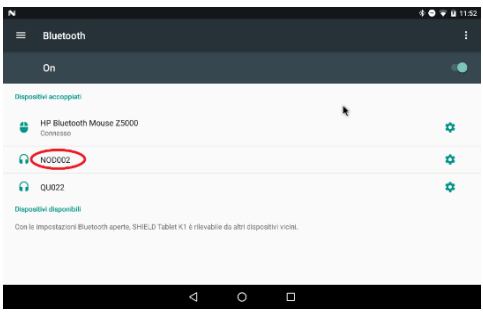
- Search for the NODxxx device and then click on it



- Click on “pair”



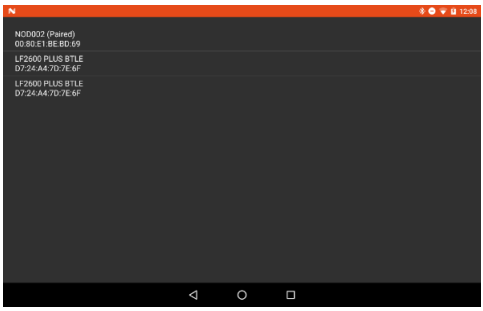
- Check that the NODxxx device is present among the paired devices and NOT on the available devices



- Return to the main screen and proceed to the next step.

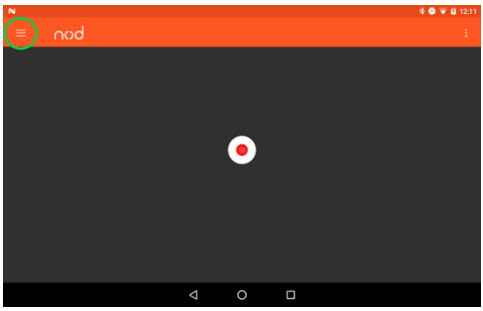
8.4.3 FIRST USE

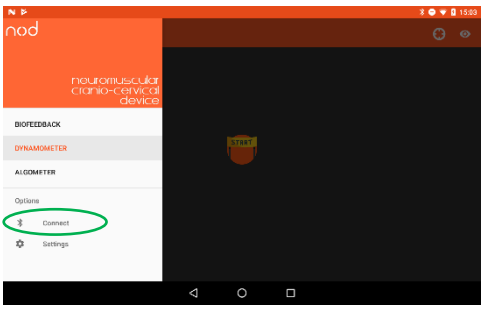
- Turn on the NOD device
- Launch the NOD App
- Allow all the required permissions
- Click on NODxxx (Paired) and wait for the connection



- Select the required function

If **it is not visible** NODxxx (Paired) click on the Android button (◁ ←), select the required function, open the side menu bar and then press "Connect". Then click on NODxxx.



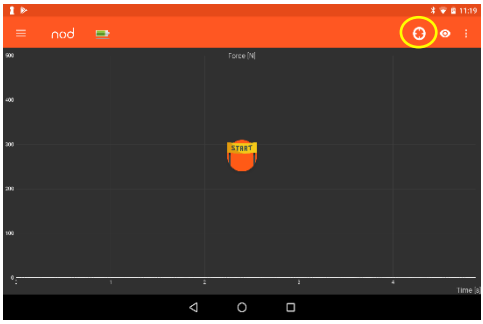


8.4.4 USAGE FUNCTIONS

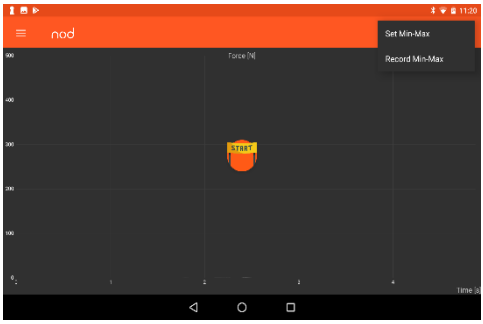
In the NOD App you can use three different modes: Dynamometer, Force Biofeedback and Algometer.

- **Biofeedback (IST)**

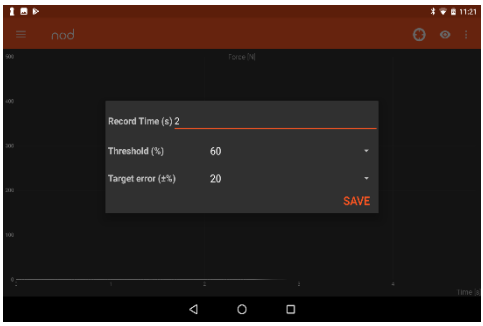
- Place the magnetized Magnetic pad over the NOD device and then press the Calibration button, if there is an offset it will be reset. The yellow circle in the figure below shows the Calibration button.



- You can set manually the Maximum Voluntary Contraction value (MVC) o record it. To record the MVC value click on the "Rec" button when you are ready.



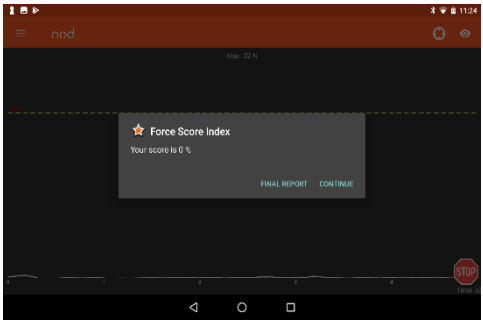
- You can change the options for using the function by pressing the "Settings" button in the side menu. Click "Save".



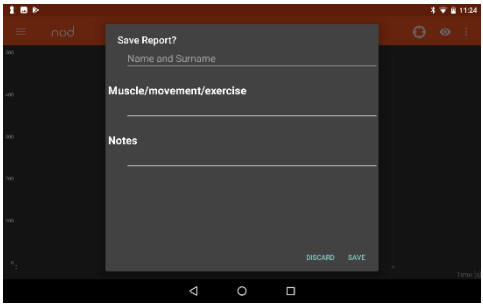
- The new graph is the relative mode which shows the level of contraction expressed as a percentage of the previously recorded MVC. When you are ready press on "Start" button.

- The figure below shows the recording window. To stop the acquisition press on "Stop" button.

- Choose whether to continue with another recording or end the session.

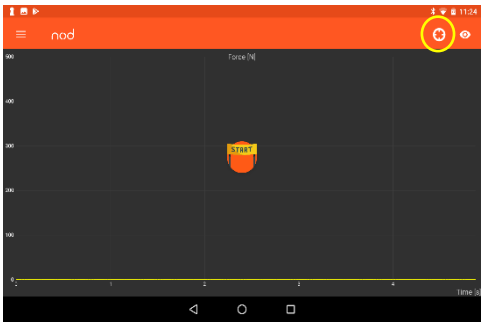


- If you want to proceed with the final report, the results will be shown. In the window shown below you can choose the PDF report name and add notes.

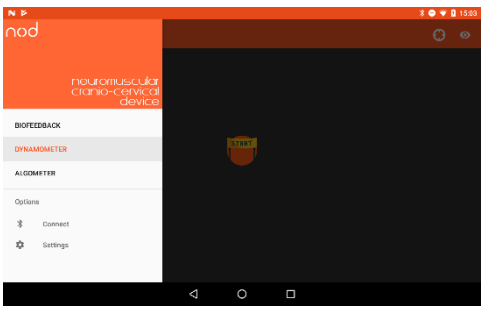


- **Dynamometer (CCFT)**

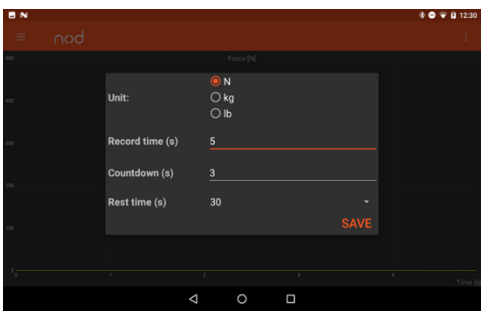
- Place the magnetized Magnetic pad over the NOD device and then press the Calibration button, if there is an offset it will be reset.



- You can change the options for using the function by pressing the Settings button in the side menu.



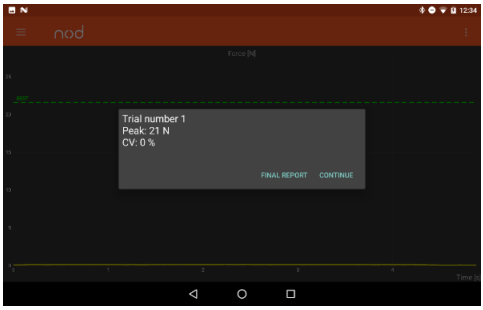
The image below shows the available settings.



- Click on the "Record" button when you are ready to record the MVC.

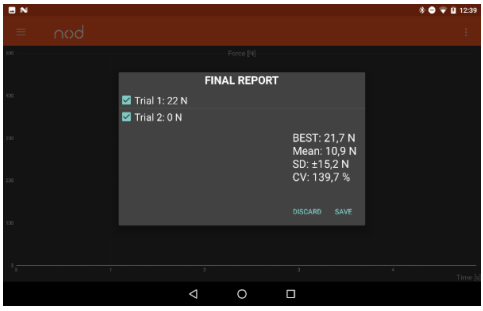
- Save or discard the recording.

- Choose whether to continue with another recording or end the session.

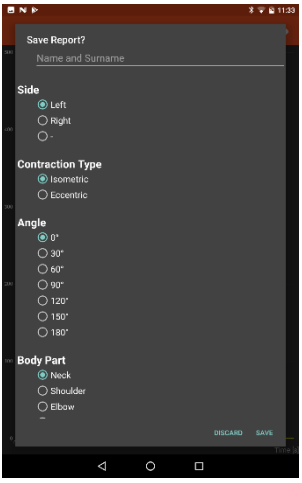


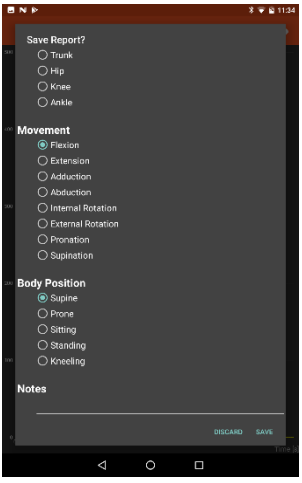
- If you want to continue, there is a waiting time that you can also skip by pressing the "Skip" button. Return to step 3 with a green line representing the best MVC performed.

- If you want to proceed with the final report, the results will be shown. In the window shown below you can choose which tests to include in the PDF report.



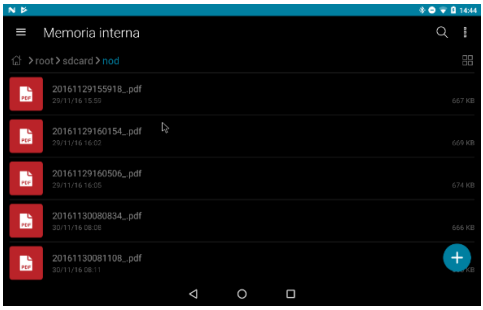
- Then you can select the Setup using in the test.





- The PDF can be shared via e-mail, Whatsapp, etc

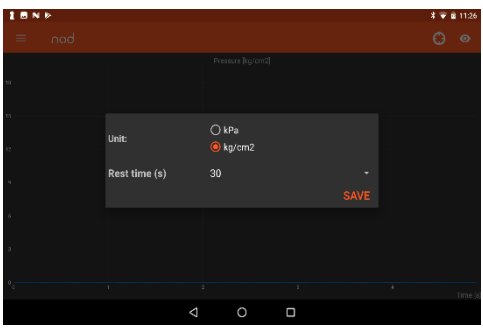
- All PDFs are stored in the internal memory → nod



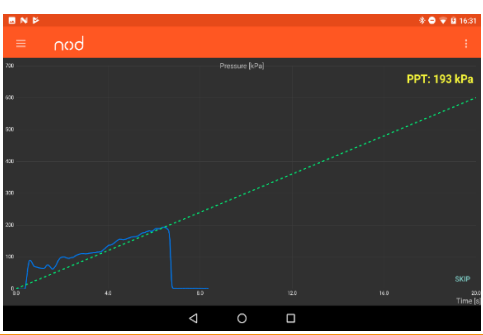
- **Algometer (PT)**

- Place the magnetized awl above the NOD and then press the Calibration button, if there is an offset it will be reset.

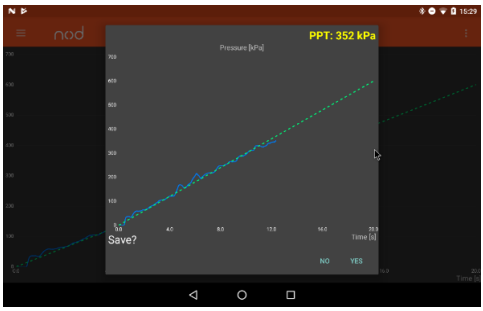
- You can change the options for using the function by pressing the Settings button in the side menu.



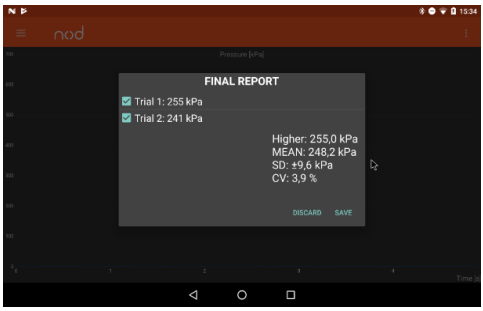
- Click on the Rec button when you are ready and follow the dashed line with the pressure



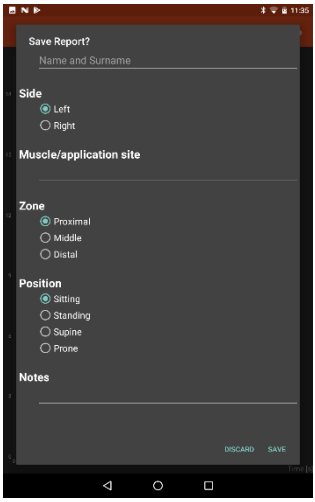
- Save or discard the trial



- Decide whether to continue or not:
- If you want to continue, there is a waiting time that you can also skip by pressing the "Skip" button. Return to step 3.
- If you want to proceed with the final report, the results will be shown. From this window you can choose which tests to include in the PDF report.



- Then you can select the Setup using in the test.



- PDF files can be shared via e-mail, Whatsapp, etc…
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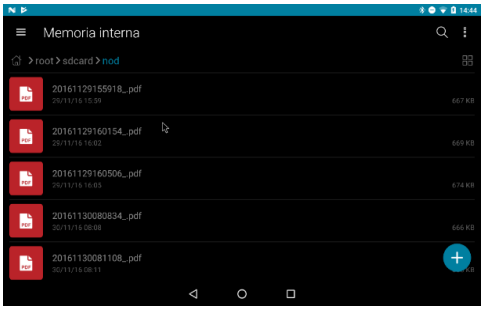

9 TROUBLESHOOTING

This section describes the most common problems encountered during the use of the NOD system.

Description of the problem	Intervention
After turning on the NOD device, the **Bluetooth®** connection does not work	Check the battery charge
The error LED is on	Low battery: recharge or Error in data transmission, approach with the NOD system to the Smartphone / tablet receiving device

10 NOD MAINTENANCE AND STORAGE

The NOD device must be used, stored and transported under the following conditions:

Temperature: from 10°C to +40°C
Maximum relative humidity level: from 30% to 75%
Atmospheric pressure: from 700 hPa to 1060 hPa

We recommend turning off the *NOD* device at the end of each session. *NOD* must be stored with all the accessories it is equipped with in a safe area and under conditions other than those listed in the Warnings section of this manual. *NOD* does not require special maintenance procedures to guarantee perfect operation. To keep the battery in perfect working order, recharge the device before each use; in any case it is advisable to regularly check the efficiency of the battery.

⚠ If, during use and after the battery has been recharged, it lasts a short time (less than 1 hour) is observed, contact the manufacturer to submit the device to checks regarding the efficiency of the internal source.

Cleaning the device: At the end of each operation clean the *NOD* device with a soft cleaning cloth.

The *NOD* device must **NOT** be cleaned as described below:

- ⚠ DO NOT clean the NOD device using acetone, ether, freon, petroleum derivatives or other solvents;
- ⚠ DO NOT use soap or water on the connector pin contacts;
- ⚠ DO NOT clean the *NOD* device or cables by immersion, autoclave or steam cleaning.

Product disposal

The *NOD* system contains electronic elements that must be treated as electronic waste. Dispose of the *NOD* system and accessories in accordance with local regulations.

Comply with the national recycling laws or the recycling strategy in force in your facility to ensure proper disposal of the *NOD* device and accessories.

For more information on recycling, contact the Ministry of Environment or local authorities.

Warning: Do not dispose of this product as non-differentiated waste. Prepare the re-use or separate collection of the product according to 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 (WEEE). The directive does not apply in the case of a contaminated product.

Lifespan of the Instrument

The *NOD* system is built to last over time if you comply with the conditions of use and maintenance indicated in this User Manual. However, it is believed that the lifespan of the device is determined by the battery life, presumably 5 years. After this period, it is suggested to subject the device to periodic checks at the manufacturer with a 2-year period.

11 RISK ANALYSIS

11.1 General rules for fundamental safety and essential performances CEI EN 60601-1-2

Manufacturer's declaration and guidelines - electromagnetic emissions – NOD	
Phenomenon	**Professional healthcare environment**
RF radiated emissions	EN 55011:2009 + EN 55032

Manufacturer's declaration and guidelines - electromagnetic immunity – NOD		
Phenomenon	**EMC reference standard or test method**	**Immunity test levels - Professional healthcare environment**
Electrostatic Discharges	IEC 61000-4-2 ETSI EN 301 489-1	+/- 8 kV at contact +/- 2 kV, +/- 4 kV, +/- 8 kV e +/- 15 kV in air
Radiated RF EM fields	IEC 61000-4-3 ETSI EN 301 489-1	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz 3 V/m 80 MHz – 6 GHz 80% AM at 1 kHz

12 TECHNICAL CHARACTERISTICS

Model: NOD

Risk class: I in compliance with the standard 93/42/CEE.

Classification: IP20, protected against solid objects over 12 mm - unprotected against falling drops of water.

Case: Painted Plexiglas case

Power supply: Internal Rechargeable Li-Po battery 3.7 V

Consumption: 0.04 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: 1 independent

Output range: 0 – 5 V

Bandwidth: 0 ÷ 34 Hz

Total noise (RTI): < 20 µVRMS (in standard mode)

Signal gain: 940 V/V for biopotential signals

Resolution: 16 bits

Commands: 1 pushbutton

Dimensions: 79 x 194 x 17 mm

Weight: 300 g

13 WARRANTY

ASSISTANCE

The *NOD* device has no parts that can be replaced and/or repaired by the user; contact the distributor for any assistance requests, which will repair or replace all the products covered by the warranty. Maintenance, replacement of parts, modifications and/or repairs made by companies and/or personnel not expressly authorized by OT Bioelettronica will immediately void the warranty.

OT Bioelettronica declines any responsibility for damage to people or things that derive from maintenance, replacement of parts, modifications and/or repairs carried out by companies and/or personnel not expressly authorized by OT Bioelettronica.

The *NOD* device does not require any preventive maintenance.

WARRANTY

OT Bioelettronica guarantees that every new product supplied is free from defects due to materials and labour and will repair and / or replace in warranty any product used for the intended use and used in normal conditions of use as specified in this Manual.

The warranty applies for the period of **2 years** and in any case, only after completing and signing the form attached below.

With regard to the service and repair services, the obligations of OT Bioelettronica under the terms of

the guarantee are limited exclusively to the following:

- the repair will be carried out no later than a period of 30 working days after the date of receipt of the product and only after verifying that the malfunction is not due to improper or inadequate use, maintenance and / or repair.

In case OT Bioelettronica verify that the malfunction is due to improper or inadequate use or unauthorized maintenance / repair, the costs of repair (materials plus labour) will be invoiced only after acceptance by the owner of the repair estimate.

These warranty conditions supersede all other express or implied warranty conditions, including but not limited to the general conditions specified in international sales regulations. OT Bioelettronica has the right to refuse the repair of any product sent by the customer for repair, this refusal will be appropriately detailed. The only obligation for OT Bioelettronica will be to return the product to the customer at his own expense.

Designed and produced by:

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