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TECHNICAL SHEET
Biothesiometer Plus

CLASS.CND: V030207 – INDEX N. 1721530

1. DESCRIPTION

Biothesiometer Plus is a portable, hand-held electro-medical device. It is self-calibrated and its vibrating amplitude is preset in micron, regardless of the pressure exerted by the operator on the patient's skin while performing the test. The vibration amplitude may be either set by the operator, or automatically increased/decreased in microns in order to assess the patient's sensitivity to vibration produced by a vibrating tactor.
It is an effective method to look for early signs of neuropathy by assessing the response to vibration of the peripheral nervous fibers responsible for tactile sensitivity.

1.1 TECHNICAL SPECIFICATIONS

The device is a compact unit comprising a user's interface with two buttons and a high visibility display.
The Teflon (PTFE) or polyzene tactor on the rear of the device, which is the only part which comes into contact with the patient's skin, vibrates at a frequency of 100Hz for the length of the test, i.e. only few minutes.

1.1.1 Battery

Biothesiometer Plus is powered by rechargeable Lithium-ion batteries Model GSP053759*3P; 3.7V 1250mAh 37.5*59.5mm (ØxH)

- Charge: 0~45℃
- Discharge: 20~60℃
- Extended time storage: -20~25℃

To recharge the device make sure it is switched off, then plug the micro USB cable of the charger (supplied with your Biothesiometer plus) into a standard power outlet.

Do not use in re-charge mode. The device is designed not to work while recharging.

The % battery charge level will be shown on the display both in on and off modes.

1.1.2 Battery Charger

The device comes with a micro USB cable battery charger: Input: 100-240 Vac, 50/60 Hz, Output: 5 Vdc, 1000 mA.

1.1.3 Optimal operating conditions

- Operating temperature 16°C to 40°C
- Operating relative humidity 30 to 70%
- Operating atmospheric pressure from 700 ÷ 1060 hpa

- Maximum operating altitude 2000 mt

1.1.4 Optimal storage and handling conditions

- Storage temperature -20°C to 60°C
- Storage and handling relative humidity 5% to 85% non condensing
- Storage and handling atmospheric pressure from 700 ÷ 1060 hpa
- Maximum altitude 2000 mt

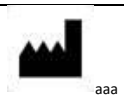
1.1.5 Operating life

Biothesiometer Plus is designed to work as intended for 5 years. METEDA guarantees the supply of spare parts throughout such period. Any failures and related risks are analyzed and included in the risk analysis document.

1.1.6 Installation

Bothesiometer Plus is ready for use and does not require any installation process.

1.1.7 Symbols

	Manufacturer's name and address, year of production
	This product complies with the provisions of the European Directive 93/42 / CEE on medical devices: Class I
	Type B applied part
	IMPORTANT! Consult the internal documents
	Operating instructions
	Polarity
	This product complies with the EU Directive 2012/19/EC. The crossed out wheeled-bin symbol on the device or its packaging indicates that at the end of its working life the product should not be treated as general household waste, but taken to one of the recycling centers for electrical and electronic equipment run by local authorities, or returned to the seller upon purchasing a similar device. The user is responsible for delivering the equipment to appropriate collection facilities at the end of its working life. By disposing of this product correctly you will help ensure that the waste undergoes the necessary treatment, recovery and recycling and thus prevent potential adverse effects on the environment and human health which could otherwise arise due to inappropriate waste handling. For more detailed information on the available waste collection systems, contact your local waste disposal service.

⎓	Direct Current
S/N xxxxxxx	Serial Number

2 CLASSIFICATION

Below is the device classification process according to which Biothesiometer plus is positioned within the risk class as specified in the Declaration of Conformity (section02_Declaration of Conformity).

The applied rules are those provided for in EU Directive 93/42/EEC (and its relative Italian transposition - Legislative Decree 37/2010).

As specified in Annex IX - Rule 12 of EU Directive 93/42/EEC, the product

- is normally intended for continuous use for less than 60 minutes.
- is non-invasive;
- is an active medical device;
- is non-therapeutic;
- does not emit energy which may be absorbed by the patient;
- does not allow direct diagnosis, as test results are obtained also through the patient's personal perception of the technical stimulus produced by the device. The system is intended to provide screening data for following objective medical tests;
- is not intended to administer and/or remove medicines to/from the patient's body.

and therefore belongs to CLASS I

As regards electric safety, in accordance with CEI EN 60601-1 and CEI EN 60601-1-2 regulations, this electrical medical device is classified as follows:

- with reference to protection against electric shock:
  -**Class II**; the protection against direct and indirect contact does not only consist in basic insulation precautions. The device is provided with double, reinforced insulation;
- the **Applied Part** "tactor" is type **B**;
- based on its dust protection and waterproof rating, the device is classified as a Standard Device **IPX0**;
- the EM device is not sterile;
- the EM device is not designed to work in environments where flammable gases may be present;
- .the EM device is intended for continuous operation.

3 PRECAUTIONS

i. Biothesiometer Plus does not cause any electromagnetic interference, nor does it have any adverse effects on the patient or the operator.

ii. Biothesiometer Plus may not be modified or tampered with in any way.

iii. The routine maintenance and cleaning of the device shall be seen to by the user and carried out by the operator prior to every test session (please see the related paragraph 'Routine maintenance and cleaning').

iv. The wearing parts of Biothesiometer Plus require extraordinary maintenance (please see the related paragraph 'Extraordinary maintenance' in this User's Guide).

v. In case of malfunction, or should any extraordinary maintenance be required, please refer to METEDA Technical Assistance service.

vi. As extraordinary maintenance is to be carried out exclusively by the manufacturer, as specified below, no circuit diagrams, list of components, repair instructions or any other information of the kind are included or provided to the final user.

vii. Do not attempt to use the device while the battery is being charged as Biothesiometer Plus is designed not to work while recharging.

viii. To avoid the risk of damage, do not use the device while it is being calibrated.

ix. Do not use power supply units other than the one provided with the device.

x. Do not immerse in water or other liquids;

xi. Do not sterilize, do not autoclave

4 DISPOSAL

At the end of its service life Biothesiometer Plus must be disposed of as special waste in accordance with national regulations, as it has built-in batteries.