



BIONIT LABS®

EN

TURNING DISABILITIES INTO NEW POSSIBILITIES

MYO UNIT



MYO UNIT

Mod. MU01

DATASHEET

| | | |
|--|---|--------------------|
| COMMERCIAL NAME | Myo Unit | |
| REF | MU01 | |
| INTENDED USE | Accessory of the Adam's Hand® medical device, intended for use by the Orthopedic Technician and used for: <ul style="list-style-type: none"> • the qualitative visualization of surface EMG signals, generated following the voluntary contraction of the forearm muscles and recorded via one or more electrodes. • evaluate the quality of the EMG signals and determine the optimal position of the EMG electrodes for the control of a myoelectric prosthesis under construction or modification. | |
| TECHNICAL FEATURES | COMPATIBILITY | |
| | Consult the chart on p. 3, containing the list of electrodes compatible with Myo Unit. | |
| | PRODUCT DATA | |
| | Dimensions | (88 x 82 x 112) mm |
| | Screen dimensions | 3.5" |
| | Weight | 170 g (6 oz) |
| | Expected lifetime | 5 years |
| | Warranty | 1 year |
| | ELECTRICAL AND MECHANICAL FEATURES | |
| | Supply voltage | 5 V |
| | Max. supply current | 2 A |
| | Electrode power supply | 7.4 V - 50 mA |
| | Battery technology | 1 li-ion cell |
| | Battery capacity | 2000 mAh |
| | Charging connector | USB Type-C |
| | Degree of protection against liquid and solid particles penetration (IEC 60529) | N/A |
| | OPERATING CONDITIONS | |
| Operating temperature (discharge phase) | from -10 °C/+14 °F to + 60 °C/+140 °F | |
| Operating temperature (charge phase) | from +5 °C/ +41 °F to + 45 °C/ +113 °F | |
| Storage and transport temperature | from -10 °C/+14 °F to + 35 °C/+95 °F | |
| Relative humidity of use/storage/transport | ≤ 60 % ± 25% | |

DETAIL OF CONNECTIONS AND BUTTONS

The Orthopedic Technician connects one or more electrodes to the "Myo Unit" device via the appropriate wiring and displays the EMG signal on the device screen and/or via "Myo Logic Pro", an app for iPad® with iOS® operating system dedicated to the Orthopedic Technician or to the Authorized Distributor. In fact, the "Myo Unit" device integrates a 3.5 " screen (320 x 480 Resolution, RGB 65K true to life colours, TFT Screened) and a Bluetooth Low Energy® transmission module, to allow short-range communication with devices on which the "MyoLogic Pro" app is installed.

The device has two buttons:

- on / off button
- background color selection button.

By rotating the device horizontally, you switch from the bar display of the EMG signal to that with a two-axis graph.




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| TESTS | Each medical device is tested before the shipment, in accordance with company procedures. The reference standards are affixed on the declaration of conformity attached to the device. |
| TECHNICAL REGULATIONS | IEC 60601-1, IEC 60601-1-2, IEC 62304, IEC 62366 IEC 62133-2:2017 ISO 22523 RED ETSI 300 328 |
| LABELLING | Labelling in accordance with UNI EN ISO 15223-1, IEC 60601-1; copy of the label is present in the Technical Manual and User Manual. |
| DISPOSAL INSTRUCTIONS |  This medical device must be managed in accordance with art. 13 - Legislative Decree 25 July 2005, n. 151 "Implementation of directives 2002/95/CE, 2002/96/CE and 2003/108/CE, relating to the reduction of the use of dangerous substances in electrical and electronic equipment, as well as waste disposal". |

Chart 1: Electrodes compatible with the Myo Unit device mod. MU01.

| Manufacturer | Product | Type | Model / Part Number |
|---------------------------|--------------------------|------------------|---------------------|
| BionIT Labs® S.r.l. | Wave Electrode | Analog electrode | AE02-50 / AE02-60 |
| Otto Bock HealthCare GmbH | MyoBock® Electrode | Analog electrode | 13E200=50 / =60 |
| Otto Bock HealthCare GmbH | Suction Socket Electrode | Analog electrode | 13E202=50 / =60 |
| Össur | Compact Electrode Kit | Analog electrode | PL091-XXX |
| Steeper Group | Electrode | Analog electrode | ELEC50 / ELEC60 |
| COVVI Ltd. | Electrode | Analog electrode | CEL-50 / CEL-60 |

Manufacturer's contacts

For any information, request or complaint, please contact:



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