



BIONIT LABS[®]

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TURNING DISABILITIES INTO NEW POSSIBILITIES

MYO UNIT



MYO UNIT

Mod. MU01

DATASHEET

COMMERCIAL NAME	Myo Unit	
REF	MU01	
INTENDED USE	<p>Accessory of the Adam's Hand medical device, intended for use by the Clinicians and designed for carry out:</p> <ul style="list-style-type: none"> • the visualization of EMG signals, via the onboard display or via the MyoLogic Pro software (available for iPad®), generated by the voluntary contraction of the forearm muscles and recorded via one or more analog electrodes. • the qualitative evaluation of the EMG signals and determine the optimal position of the analog electrodes, via the onboard display or via the MyoLogic Pro software (available for iPad®), in order to control a myoelectric prosthesis under construction or modification. • the analysis of the patient capability to use and control the Adam's Hand, simulating the driving, the calibration procedure and its settings thanks to dedicated section into the MyoLogic Pro software (available for iPad®) 	
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 / (3.5 x 3.5 x 4.5) inches
	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 time (fast-charge)	180 minutes
	Battery Life	6 hours
	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 +0 °C/ +32 °F to + 45 °C/ +113 °F	
Storage and transport temperature	from -10 °C/+14 °F to + 35 °C/+95 °F	
Relative humidity of use	35 % ± 80 %	
Relative humidity of storage/transport	≤ 45 % ± 75%	

DETAIL OF CONNECTIONS AND BUTTONS

The Clinician 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 Clinician 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.




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 available in the Installation, Maintenance and Operation 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
COVI Ltd.	Electrode	Analog electrode	CEL-50 / CEL-60

Manufacturer's contacts

For any information, request or complaint, please contact:



BionIT Labs S.r.l.
Via Cracovia, 1
73010 – Soleto (LE) – ITALY
+39 0836 1946903
support@bionitlabs.com

Certified Company





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+39 0836 1946903



www.bionitlabs.com



support@bionitlabs.com



Via Cracovia, 1
73010 Soleto (LE) - Italia