



BIONIT LABS[®]

EN

TURNING DISABILITIES INTO NEW POSSIBILITIES

AH **ADAM'S HAND[®]**
The First of its Kind



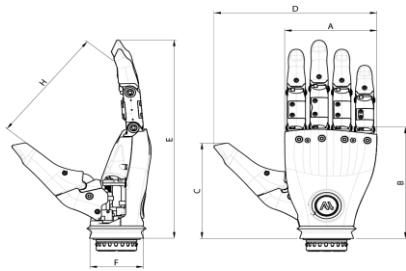
ADAM'S HAND

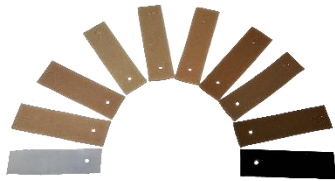
Mod. AH02-CDY-EE


DATASHEET



WARNING: the image shown on the cover contains the prosthetic hand without a glove, but for representative purposes only, to highlight the actual position of the button and the quick disconnect wrist. For the safety of the user and for the correct functionality of the "Adam's Hand®" prosthetic hand, this must ALWAYS be used with its own "Adam's Skin" glove mod. AS02-CDY-EE.

COMMERCIAL NAME	Adam's Hand®		
REF	AH02-CDY-EE, with C = side code, D = size code, Y = wrist code, EE = colour code		
INTENDED USE	The "Adam's Hand®" prosthetic hand is a non-invasive medical device intended to be used in myoelectric prostheses made for subjects with mono- or bi-lateral amputations, starting from a transradial amputation level.		
TECHNICAL FEATURES	COMPATIBILITY		
	Consult the chart on p. 4, containing the list of devices compatible with the Adam's Hand®.		
	PRODUCT DATA		
	Size	Medium (M)	
	Dimensions		
		A – Palm width: 82 mm	
		B – Palm length: 110 mm	
		C – Thumb height: 94 mm	
		D – Max. hand width: 146 mm	
		E – Hand length: 194 mm	
		F – Frame diameter at wrist: 50 mm	
		H – Max. opening width: 108 mm	
Side	Left (C=L) Right (C=R)		
N° actuators	2		
Wrist type	Quick Disconnect Wrist (Y=1)		
Weight	560 g		
Thumb adduction/abduction	Passive, 3 selectable positions: <ul style="list-style-type: none"> ● 0° (lateral), ● 45° (intermediate), ● 90° (opposition). 		
Expected lifetime	6 years		
Warranty	3 years (with possibility of extension up to 5 years)		

	<p>Available Glove Colours</p> 	<p>Black (EE=B1), White/Transparent (EE=W1) Skin tone 1 (EE=N1) Skin tone 2 (EE=N2) Skin tone 3 (EE=N3) Skin tone 4 (EE=N4) Skin tone 5 (EE=N5) Skin tone 6 (EE=N6) Skin tone 7 (EE=N7) Skin tone 8 (EE=N8)</p>
ELECTRICAL AND MECHANICAL FEATURES		
	Supply voltage	6 ÷ 8.4 V (DC)
	Supply current	6 A
	Degree of protection against liquid and solid particles penetration (IEC 60529)	IP67
	Max. grip strength	<ul style="list-style-type: none"> • Lateral grip: 65 N / 15 lbf • Tripod grip: 35 N / 8 lbf • Power grip: 70 N / 16 lbf
	Closing time	<ul style="list-style-type: none"> • Lateral grip: 1.0 s • Tripod grip: 0.7 s • Power grip: 1.2 s
	Vertical push-down load through knuckles	120 kg / 265 lb
	Max. load with closed hand (static, carrying a bag)	40 kg / 88 lb
	Static force on frame	75 kg / 165 lb
SOFTWARE		
	<p>The Adam's Hand® prosthetic hand integrates a Bluetooth® Low Energy (BLE) module, useful for connection to an external device hosting the “MyoLogic” (iOS® and Android® app) or “MyoLogic Pro” (iOS® app) Apps, respectively dedicated to Patient and Orthopedic Technician or authorized Distributor, through which it is possible to read the electromyographic signals detected by the electrodes, calibrate the operating parameters and calibrate the Adam's Hand® to adapt it to the individual's muscle tone. Once the Adam's Hand® has been installed and calibrated, the use of these apps for the use of the device by the Patient and the Orthopedic Technician or Authorized Distributor is recommended but not required.</p>	
	Minimum system requirements	<p>MyoLogic: iOS® 15 or next MyoLogic Pro: iPadOS® 13 or next</p>
OPERATING CONDITIONS		
	Use temperature	from 0 °C/+14 °F to + 40 °C/+104 °F
	Usage humidity	30% ÷ 85 %, non-condensing
	Storage and transport temperature	from -20 °C/-4 °F to +70 °C/+158 °F
	Relative humidity of storage and transport	≤ 85 %, non-condensing
FUNCTIONALITIES	MULTIFUNCTION BUTTON	
	<p>By activating the button on the back of the hand, the User can perform the following functions, which can be programmed via the App:</p> <ul style="list-style-type: none"> • activation/deactivation of the EMERGENCY mode • activation/deactivation of the STANDBY mode • activation/deactivation of the GLOVE mode 	

	<ul style="list-style-type: none"> • modification of the Mode of Use (ECO, NORMAL, BOOST) • activation/deactivation of the Bluetooth® Low Energy connection • activation/deactivation of the Proportional Control • new Calibration of the device. <p>VISUAL ALERTS</p> <p>Polychromatic LED integrated in the button on the back of the hand for signaling alarms, device status changes and confirmation of activations/deactivations implemented with the button or via the App.</p> <p>ACOUSTIC ALERTS</p> <p>4 kHz frequency buzzer for signalling alarms, device status changes and confirmation of activations/deactivations implemented with the multifunction button or via the App.</p> <p>HAPTIC ALERTS</p> <p>The vibration is proportional to the grip force exerted by the prosthetic hand. It is also used for signalling alarms, device status changes and confirmation of the activation/deactivation of the prosthetic hand functions (implemented with the multifunction button or via the App).</p> <p>SENSORS</p> <ul style="list-style-type: none"> • Internal temperature sensors • Automatic protection against: overtemperature, overcurrent and overvoltage • Sending data via Bluetooth® Low Energy • The inertial platform (IMU) integrated in the Adam's Hand® allows the device to have information on the spatial attitude (without measurement function) through acceleration and rotation sensors with 16-bit resolution.
TESTS	<p>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.</p>
TECHNICAL RULES	<p>IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, IEC 62304, IEC 62366 ISO 10993-10, ISO 22523 RED ETSI 300 328</p>
LABELLING	<p>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.</p>
DISPOSAL INSTRUCTIONS	<div style="display: flex; align-items: center;">  <p>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".</p> </div>

**Expected service life in the case of annual check-ups as detailed in the sales and warranty conditions.*

Chart 1: Devices compatible with the Adam's Hand® prosthetic hand.

Manufacturer	Product	Type	Model / Part Number
BionIT Labs® S.r.l.	ThunderCell Battery	External battery	EB01 / EB02-E
BionIT Labs® S.r.l.	Ricettacolo con Cavo per ThunderCell Battery	Receptacle for external battery	ER01-E-XX
BionIT Labs® S.r.l.	Wave Electrode	Analogic electrode	AE02-NN
Otto Bock HealthCare GmbH	Coupling piece	Wrist interface	10S4
Otto Bock HealthCare GmbH	Coaxial plug (4 bands)	Wrist interface	9E169
Otto Bock HealthCare GmbH	Lamination Ring	Wrist interface	10S1
Steeper Group	Quick Disconnect Wrist Unit	Wrist interface	QDAWA-40 / -45 / -50
Motion Control	Coaxial plug (4 band)	Wrist interface	1701009
Motion Control	Endcap	Wrist interface	3010758
Motion Control	Lamination Collar for MC Wrist	Wrist interface	1100288
Össur	Coupling piece	Wrist interface	PL091032
Össur	4-way coaxial plug	Wrist interface	PL091036
Össur	Lamination Ring	Wrist interface	091037
Otto Bock HealthCare GmbH	Energy Pack®	External battery	757B20
Otto Bock HealthCare GmbH	Energy Pack®	External battery	757B21
Otto Bock HealthCare GmbH	MyoEnergy Integral®	Internal battery	757B35=0 / =1 / =3 / =4 / =5
Otto Bock HealthCare GmbH	MyoBock® Electrode	Analogic electrode	13E200=50 / =60
Otto Bock HealthCare GmbH	Suction Socket Electrode	Analogic electrode	13E202=50 / =60
Össur	1300/2000 mAh Battery	Internal battery	PL000335/6
Össur	Rechargeable Li-Polymer Battery	Internal battery	000172B
Össur	Replaceable Battery	External battery	SA069313
Össur	Compact Electrode Kit	Analogic electrode	PL091-XXX
Steeper Group	Lithium Polymer Battery	External battery	BLPA72
Steeper Group	S-Charge System®	Internal battery	SC2200
Steeper Group	Electrode	Analogic electrode	ELEC50 / ELEC60
Steeper Group	Espire Elbow Pro	Myoelectric Elbow Prostheses	EEP-XXX
TASKA	TASKA® Battery system	Internal battery	-
COVVI Ltd.	Power Supply systems	Internal battery	COVSB-1600
COVVI Ltd.	Power Supply systems	Internal battery	COVSB-2600
COVVI Ltd.	Electrode	Analogic electrode	CEL-50 / CEL-60
IBT	FlexCell®	Internal battery	2017200
IBT	FlexCell Mini®	Internal battery	2037200
Vincent Systems GmbH	VINCENTaccu flex®	Internal battery	-
Motion Control	MC Standard Wrist Rotator	Active Wrist Rotator	5010045, 5010054, 5010055
Motion Control	MC Standard Wrist Rotator + Six bands coaxial plug	Active Wrist Rotator	5010045, 5010054, 5010055, 3010869
Otto Bock HealthCare GmbH	Electric Wrist Rotator	Active Wrist Rotator	10S17
Otto Bock HealthCare GmbH	MyoRotronic	Control System for Active Wrist Rotator	13E205
Otto Bock HealthCare GmbH	DynamicArm*	Elbow prosthesis	12K100N
COAPT LLD	Coapt Gen2® Complete Control®**	Control System for upper limb prosthesis	-

*Compatibility with this item is not fully covered: Adam's Hand proportional control is not available when used with this device.

**Compatibility with this item is not fully covered: at the moment only the analog communication between the two devices is guaranteed.

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





BIONIT LABS[®]
TURNING DISABILITIES INTO NEW POSSIBILITIES



+39 0836 1946903



www.bionitlabs.com



support@bionitlabs.com



Via Cracovia, 1
73010 Soleto (LE) - Italia