BIONIT LABS

ENGINEERING HUMAN POTENTIAL

EN

ADAM'S HAND

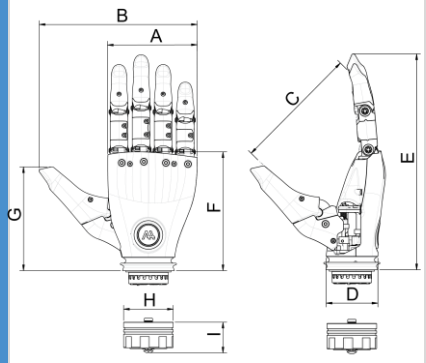
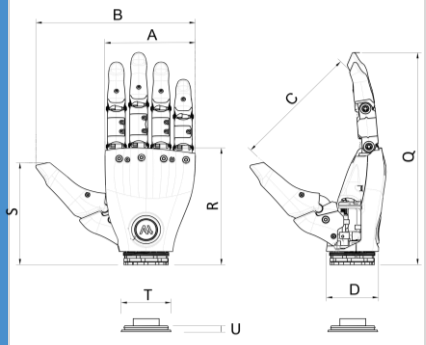
The First of its Kind

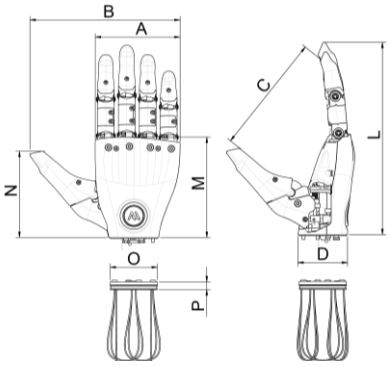
Mod. AH02-CDY-EE

ADAM'S HAND

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 wrist disarticulation level.					
TECHNICAL FEATURES	COMPATIBILITY					
	Consult the chart on p. 4, containing the list of devices compatible with the Adam's Hand.					
	PRODUCT DATA					
	Side		Left (C = L) Right (C = R)			
	SIZE		Small 7-¼" (D=S)		Medium 7-¾" (D=M)	
	Dimensions (including the glove)	A – Palm width	72 mm 2.83"		82 mm 3.23"	
		B – Max. hand width	129 mm 5.08"		146 mm 5.75"	
		C – Max. opening width	97 mm 3.82"		110 mm 4.33"	
		D – Frame diameter at wrist	46 mm 1.81"		50 mm 1.97"	
		DIMENSIONS	QDW without Flexion Module (Y = 1, D = S)	QDW with Flexion Module (Y = 4, D = S)	QDW without Flexion Module (Y = 1, D = M)	QDW with Flexion Module (Y = 4, D = M)
		E – Hand length	172 mm 6.77"	194 mm 7.64"	196 mm 7.72"	218 mm 8.58"
		F – Palm length	94 mm 3.70"	116 mm 4.57"	108 mm 4.25"	130 mm 5.12"
		G – Thumb height	82 mm 3.23"	104 mm 4.09"	94 mm 3.70"	116 mm 4.57"
		H – Lamination ring diameter	45 mm – 1.77" 50 mm – 1.97"			
		I – Lamination ring height	27 mm 1.06"			
		DIMENSIONS	Friction Wrist without Flexion Module (Y = 2, D = S)	Friction Wrist with Flexion Module (Y = 5, D = S)	Friction Wrist without Flexion Module (Y = 2, D = M)	Friction Wrist with Flexion Module (Y = 5, D = M)
		Q – Hand length	172 mm 6.77"	194 mm 7.64"	196 mm 7.72"	218 mm 8.58"
		R – Palm length	94 mm 3.70"	116 mm 4.57"	108 mm 4.25"	130 mm 5.12"
		S – Thumb height	82 mm 3.23"	104 mm 4.09"	94 mm 3.70"	116 mm 4.57"
		T – Lamination ring diameter	45 mm – 1.77"			
		U – Lamination ring height	12 mm – 0.47"			



DIMENSIONS	Short Wrist without Flexion Module (Y = 3, D = S)	Short Wrist with Flexion Module (Y = 6, D = S)	Short Wrist without Flexion Module (Y = 3, D = M)	Short Wrist with Flexion Module (Y = 6, D = M)
L – Hand length	161 mm 6.34"	183 mm 7.20"	185 mm 7.28"	207 mm 8.15"
M – Palm length	83 mm 3.27"	105 mm 4.13"	97 mm 3.82"	119 mm 4.69"
N – Thumb height	71 mm 2.80"	93 mm 3.66"	83 mm 3.27"	105 mm 4.13"
O – Lamination ring diameter	45 mm 1.77"			
P – Lamination ring height	9 mm 0.35"			

Weight	WRIST TYPE	Without Flexion Module (D = S)	With Flexion Module (D = S)	Without Flexion Module (D = M)	With Flexion Module (D = M)
	Quick Disconnect Wrist	485 g 17.1 oz	535 g 18.9 oz	570 g 20.1 oz	620 g 21.9 oz
	Friction Wrist	455 g 16.1 oz	505 g 17.8 oz	540 g 19.1 oz	590 g 20.8 oz
	Short Wrist	445 g 15.7 oz	495 g 17.5 oz	530 g 18.7 oz	580 g 20.5 oz

Lamination Ring weight		
	Quick Disconnect Wrist	44 g – 1.55 oz (Ø 45 mm – 1.77") 64 g – 2.26 oz (Ø 50 mm – 1.97")
	Friction Wrist	23 g 0.81 oz
	Short Wrist	16 g 0.56 oz

N° actuators	2
Thumb adduction/abduction	Passive, 3 selectable positions: • 0° (lateral), • 45° (intermediate), • 90° (opposition).
Expected lifetime*	6 years
Warranty	Up to 5 years

Available color swatches

Basic Color Swatch (CS01)

Complete Color Swatch (CS02)

AVAILABLE GLOVE COLOURS				
	Basic (1 colour) With CS01		Advanced (3 colours) with CS02	Individual (5 colours) with CS02
Black		EE = B1	EE = A0	EE = I0
White		EE = W1		
Natural skin tone		EE = N1		
Natural skin tone 2		EE = N2		
Natural skin tone 3		EE = N3		
Natural skin tone 4		EE = N4		
Natural skin tone 5		EE = N5		
Natural skin tone 6		EE = N6		
Natural skin tone 7		EE = N7		
Natural skin tone 8		EE = N8		

	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	• Lateral grip: 45 N – 10 lbf • Tripod grip: 30 N – 7 lbf • Power grip: 70 N – 16 lbf
	Closing time	• Lateral grip: 0.90 s • Tripod grip: 0.65 s • Power grip: 1.0 s
	Vertical push-down load through knuckles	120 kg – 265 lbs
	Max. load with closed hand (static, carrying a bag)	45 kg – 100 lbs
	Static force on frame	75 kg – 165 lbs
	Max flexion load (at 75 mm – 3" from the wrist)	32 kg – 70 lbs
	Max torsional load (in case of Short Wrist)	38 kg – 84 lbs
	SOFTWARE	
	The Adam's Hand integrates a Bluetooth® Low Energy (BLE) module, useful for connection to the "MyoLogic" (available for iOS® and Android®) or "MyoLogic Pro" (available for iPadOS®) software, respectively dedicated to the Patient and to the Clinician or the authorized Distributor. Through these software, it is possible to read the electromyographic signals detected by the analog electrodes, perform the calibration procedure of the Adam's Hand, in order to adapt the AI algorithm to patients' muscle capacities. Once the Adam's Hand has been installed and calibrated, the use of these apps, both for the Patient and the Clinician or Authorized Distributor, is recommended but not strictly required.	
	Minimum system requirements	MyoLogic: iOS® 16.6 or next and Android® 10 or next MyoLogic Pro: iPadOS® 16.6 or next
	OPERATING CONDITIONS	
	Use temperature	from 0 °C/+32 °F to + 40 °C/+104 °F
	Usage humidity	30% ÷ 85 %, non-condensing
	Storage and transport temperature	from -25 °C/-13 °F to +70 °C/+158 °F
	Relative humidity of storage and transport	≤ 85 %, non-condensing
FUNCTIONALITIES	**MULTIFUNCTION BUTTON**	
	By activating the button on the back of the hand, the User can perform the following functions, which can be programmed via the App: • activation/deactivation of the EMERGENCY mode • activation/deactivation of the STANDBY mode • activation/deactivation of the GLOVE mode • activation/deactivation of the Bluetooth® Low Energy connection • activation/deactivation of the Proportional Control • calibration of the device.	
	VISUAL ALERTS	
	Polychromatic LED integrated in the button on the back of the hand for signalling alarms, device status changes and confirmation of activations/deactivations executed via the button or via the App.	
	ACOUSTIC ALERTS	
	4 kHz frequency buzzer for signalling alarms, device status changes and confirmation of activations/deactivations executed via the multifunction button or via the App.	
	HAPTIC ALERTS	
	Adam's Hand provides a haptic feedback by vibrating twice when the maximum closing force is reached. It is also used for signalling alarms, device status changes and confirmation of the activation/deactivation of the prosthetic hand functions, executed via the multifunction button or via the App.	

	SENSORS • 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 regarding its orientation in space (without measurement function) through acceleration and rotation sensors with 16-bit resolution.
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 RULES	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, IEC 62304, IEC 62366 ISO 10993-10, 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 both the Installation, Maintenance and Operation Manual for Clinician and for Patient.
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".

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

Table 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
Cogent Mechatronic Ltd	Internal Battery	Internal Battery	IB01
BionIT Labs S.r.l.	Receptacle with cable for ThunderCell Battery	External battery receptacle	ER01-E-YY
BionIT Labs S.r.l.	Wave Electrode	Analog electrode	AE02-NN
BionIT Labs S.r.l.	Remote Wave Electrode	Analog remote electrode	AE03-NN
Fillauer	Triad Preamps	Analog electrode	3010754
Fillauer	MC Standard Wrist Rotator	Electric Wrist Rotator with switch	5010045, 5010054, 5010055
Fillauer	MC Standard Wrist Rotator & Six Band Coaxial Plug	Electric Wrist Rotator with switch	5010045, 5010054, 5010055, 3010869
Fillauer	Utah Arm 3+	Electric Elbow Prosthesis	5010039
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
Otto Bock HealthCare GmbH	Electric Wrist Rotator	Electric wrist rotator unit	10S17
Otto Bock HealthCare GmbH	MyoRotronic	Control system for electric wrist rotator unit	13E205
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	Analog electrode	13E200=50 / =60
Otto Bock HealthCare GmbH	Suction Socket Electrode	Analog 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	Analog electrode	PL091-XXX
Steeper Group	Lithium Polymer Battery	External Battery	BLPA72
Steeper Group	S-Charge System®	Internal Battery	SC2200
Steeper Group	Electrode	Analog electrode	ELEC50 / ELEC60
Steeper Group	Espire Elbow Pro	Electric Elbow Prosthesis	EEP-XXX
TASKA	TASKA® Battery system	Internal Battery	TASKA-BIG1-1

COVVI Ltd.	Power Supply systems	Internal Battery	COVSB-1600
COVVI Ltd.	Power Supply systems	Internal Battery	COVSB-2600
COVVI Ltd.	Electrode	Analog electrode	CEL-50 / CEL-60
Infinite Biomedical Technologies, LLC.	FlexCell®*******	Internal Battery	2017200
Infinite Biomedical Technologies, LLC.	FlexCell Mini®*******	Internal Battery	2037200
Infinite Biomedical Technologies, LLC.	Glide	Control system for upper limb prosthesis	91000-GL
Vincent Systems GmbH	VINCENTbattery flex®	Internal Battery	-
Otto Bock HealthCare GmbH	DynamicArm*****	Myoelectric elbow prosthesis	12K100N
COAPT LLD	Coapt Gen2® Complete Control®******	Control system for upper limb prostheses	-

*** The operation of third-party devices, used in conjunction with the "Adam's Hand" mod. AH02-CDY-EE, may be affected by their default settings or any changes they may undergo.*

**** In cases of use of the Adam's Hand with wrist lamination kits not produced by BionIT Labs S.r.l, the IP67 degree of protection beyond the wrist is not ensured. However, the IP67 degree of protection of Adam's Hand (wrist excluded) remains assured thanks to the use of Adam's Skin.*

***** Adam' Hand is not compatible with the Energy Pack® mod. 757B21 with 680 mAh capacity.*

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

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

********Please, use the IBT FlexCell battery with at least two cells to ensure compatibility with the Adam's Hand.*

NOTE: the Adam's Hand full performances are guaranteed only with the accessories manufactured by BionIT Labs S.r.l.

Manufacturer's contacts

For any information, request or complaint, please contact:

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