

# Michelangelo and Axon-Bus® System Reimbursement Guide

January 1, 2021



Quality for life

# Michelangelo and Axon-Bus® system

## Product Information

### Adaptive eXchange of Neuroplacement Data (Axon)

Axon-Bus Prosthetic System (APS) is advanced technology, developed by Ottobock for prosthetics. Axon-bus is a self-contained data transmission system, that allows the componentry to communicate perfectly, eliminating losses in data transmission, speed, and functionality. The result is greater reliability and reduced sensitivity to external interference when compared to traditional myoelectric prostheses.

### Axon-Bus System Primary Components

**Michelangelo Hand** is an electronic hand with an oval (naturally shaped) integrated wrist joint, active thumb, and articulating fingers. It is used for transradial applications as well as transhumeral applications in combination with AxonArm Ergo.

**Michelangelo Transcarpal Hand** is an electronic hand with an active thumb and articulating fingers. It is used for transradial applications as well as transhumeral applications in combination with AxonArm Ergo.

**AxonHook** is a powerful and rugged electronic work-type terminal device, designed to meet the performance needs of the most demanding wearers by increasing the number of functional work tasks possible.

**AxonRotation** is an electronic wrist rotator that can be used with both the Michelangelo Hand and the AxonHook. AxonRotation benefits the user by allowing them to perform bimanual activities. It also helps reduce compensatory movements by avoiding awkward and painful angles to reach certain body positions. For example, pouring a glass of water by rotating the wrist versus bending laterally which puts unnecessary strain on the back and shoulders. It has proportional control and a return to neutral feature.

**AxonArm Ergo** is an electronic locking elbow with automatic forearm balance. The microprocessor controlled electronic feature allows unlocking and locking of the elbow joint. The microprocessor picks up the user's EMG signals that are captured by electrodes within the socket. Once programmed, these signals are then used to control the hand, hook, or wrist.

**AxonSkin** is the name for a variety of Michelangelo PVC gloves, including AxonSkin and Natural, Visual/Black.

### Who can provide Axon-Bus components?

APS components are prescribed by a physician and may only be provided by a qualified Prosthetist who has received specific product training. Ottobock employs a team of orthotists and prosthetists to educate practitioners on fabricating and fitting our products. This includes in-person and online training, webinars, and technical bulletins. We also provide Cooperative Care Services for the more challenging fittings, which includes on-site assistance with the fitting in conjunction with product qualification training for the practitioner.

### Warranty

Ottobock warrants all of its products, to the original purchaser, to be free from defects in materials and workmanship. Michelangelo Hand comes with a 2-year Limited Warranty, which includes a 12-month service inspection. Extended warranties are available for purchase which include service inspection by trained and qualified service technicians. AxonRotation, AxonHook, and AxonArm Ergo also come with 2-year Limited Warranties.

### Health Canada Compliance

This device meets the requirements of the Medical Device Regulations (SOR/98-282). It has been classified as a class I medical device according to the classification criteria outlined in schedule 1 of the Medical Device Regulations.

### FDA Classification

#### Axon-Bus Prosthetic System

510(k) Number	K123795
Device Class	2
Regulation Number	21 CFR 882.1320
Classification Product Code	GXY (Electrode, Cutaneous)
Subsequent Code	IQZ (Hand, External Limb Component, Powered)
Medical Specialty Review Panel	Neurology

## Michelangelo and Axon-Bus® System

### Coding and Manufacturer Suggested Retail Price (MSRP) – U.S. only

January 2021

Currently, there are no HCPCS codes to adequately describe the Michelangelo Hand, Michelangelo Transcarpal Hand, and the AxonHook. Therefore, a combination of existing and miscellaneous codes must be used to describe them.

#### <sup>1</sup>HCPCS CODES

##### Michelangelo Hand

- L7499 Michelangelo Hand +
  - L6882 Microprocessor Ctrl Terminal Device +
  - L6881 Autograsp Feature +
  - L6629 Quick Disconnect +
  - L6890 PVC Glove for Terminal Device +
- Add Michelangelo wrist option below*

##### Michelangelo Wrist Options

###### 9S501 Passive Wrist

- L6624 Flex/Ext Rotation Wrist

###### 9S503 Active Wrist

- L6624 Flex/Ext Rotation Wrist +
- L7259 Electronic Wrist Rotator +
- L6882 Microprocessor Ctrl

##### Michelangelo Transcarpal Hand

- L7499 Michelangelo Hand +
- L6882 Microprocessor Ctrl Terminal Device +
- L6881 Autograsp Feature +
- L6890 PVC Glove for Terminal Device

##### AxonHook

- L7499 AxonHook+
  - L6882 Microprocessor Ctrl Terminal Device +
  - L6881 Autograsp Feature +
  - L6629 Quick Disconnect +
- Add Michelangelo wrist option above*

##### AxonArm Ergo

- L6693 Forearm Counterbalance +
- L6638 Electric Lock

##### Microprocessor Control Feature

- L7499 Sequential MP Control electric lock & TD

#### <sup>1,2</sup> MISCELLANEOUS CODES AND MSRP

##### Michelangelo Hand

**Long Description:** L7499 Ottobock 8E500

Michelangelo Electric hand with oval integrated wrist joint, switch or myoelectric control; programmable for proportional /digital control; articulating fingers (MCP flexion / extension, adduction/abduction) and powered multi-positional thumb (oppositional, lateral, and neutral grip patterns); includes lithium ion power source and charger.

**Short Description:** L7499 Ottobock 8E500

Michelangelo elec hand w/integr wrist w/pow src & chgr

**MSRP** for Michelangelo's L7499 code is \$85,000

##### Michelangelo Transcarpal Hand

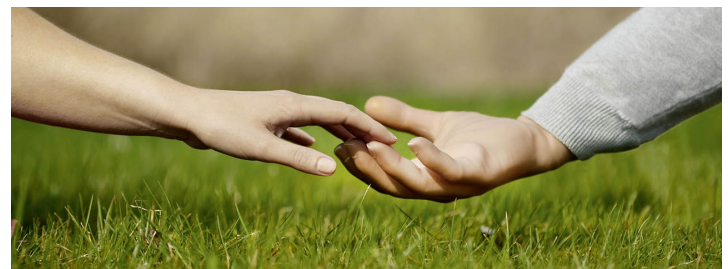
**Long Description:** L7499 Ottobock 8E550 APS

Michelangelo Transcarpal Hand, switch or myoelectric control; Programmable or Proportional/Digital control; articulating fingers (MCP flexion/extension, adduction/abduction) and powered multi-positional thumb (oppositional, lateral, and neutral grip patterns); includes lithium ion power source and charger.

**Short Description:** L7499 Ottobock 8E550

Michelangelo Transcarpal elec hand w/integr wrist w/pow src & chgr

**MSRP** for Michelangelo Transcarpal L7499 code is \$85,000



## Michelangelo and Axon-Bus® System

### Coding and Manufacturer Suggested Retail Price (MSRP) – U.S. only

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#### AxonHook

**Long Description:** L7499 Ottobock 8E600 Electric Hook with oval integrated wrist joint, switch or myoelectric control; Programmable for proportional/digital control; Polyurethane coated hook tips; Automatic return to neutral feature; Includes Lithium-ion power source and charger.

**Short Description:** L7499 Ottobock 8E600 AxonHook elec hook w/integr wrist w/pow src & chgr

**MSRP** for AxonHook's L7499 code is \$26,691

#### Microprocessor Control Feature

**Long Description:** Addition to upper extremity external powered prosthesis (Ottobock 12K501 AxonArm Ergo & 8E500 Michelangelo Hand); Sequential microprocessor control of electric locking feature and terminal device (similar to L7180 without elbow lift, which is instead provided by the forearm counterbalance feature).

**Short Description:** L7499 Sequential MP Control elbow lock & TD.

**MSRP:** for the MP control feature is \$30,000

#### Other items that might be coded on the claim

The Axon-Bus Prosthetic System is custom fabricated and other items that may be on a claim (separately coded) include the following (not all inclusive): Base external powered prosthesis, electrodes, battery, charger, socket styles & materials, test & replacement sockets, socket inserts (liners), locks, suspension, harnesses, switches, and transducers.



#### References

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<sup>2</sup>The manufacturer's suggested retail pricing (MSRP) is a suggested retail price only. Ottobock has provided the suggested MSRP in the event that third-party and/or federal healthcare payers request it for reimbursement purposes. The practitioner and/or patient care facility is neither obligated nor required to charge the MSRP when submitting billing claims for third-party reimbursement for the product(s).



# Michelangelo and Axon-Bus® system

## Features and Benefits

### Michelangelo Hand Articulating Fingers:

Michelangelo has four compliant fingers with anatomically correct alignment of the metacarpophalangeal joints (MCP) joints.

- Each finger has its own axis (MCP flexion/extension). Due to the mechanical design of the finger axes, the fingers abduct, spreading apart when the hand opens, and they move together (adduct) as the hand closes.
- Using nature as a model, the fingers were replicated in great detail to achieve an unparalleled physiological appearance functional design.

### Michelangelo Hand Active Thumb:

Michelangelo has a fully electronic multi-positional thumb.

- The sweeping motion of the thumb drive allows Opposition and Lateral grip patterns.
- Rotating the thumb outward creates a palm so that additional movement options are possible.

### Michelangelo Hand Functions:

Michelangelo® has complex gripping kinematics with 7 functional grip types:

- Lateral Power Grip allows for secure grasping and handling of objects
- Lateral Pinch allows one to easily hold thin objects such as credit cards.
- Open Palm allows a flat hand position for holding items such as plates and bowls.
- Tripod Pinch allows precise grasping of small objects.
- Power Grip is for grasping large objects
- Neutral Position allows a natural position at rest. The hand will not open while walking and the thumb is tucked in safely like a natural hand. The Michelangelo hand automatically relaxes into neutral position, which reduces the physical and mental burden of the user.
- Finger Adduction and Abduction allows fingers to spread out as the hand opens.

### AxonWrist: Oval Integrated Wrist Joint on the Michelangelo Hand and AxonHook

- AxonWrist is comprised of two components: the AxonFlexion adapter and the AxonRotation adapter. These components permit greater freedom of movement for the user.
- The AxonFlexion adapter is integrated into the hand and it provides flexion (75°) and extension (45°); movement is progressively dampened with 8 ratchet positions.
- The AxonRotation adapter provides unlimited pronation and supination (360°) with 24 ratchet positions.
- The flexion and rotation adaptors include a quick disconnect mechanism for the hand and socket. Together they provide a multi-axial movement pattern which helps avoid unnatural compensatory movements and thereby promotes a healthy, natural body posture.

## Michelangelo and Axon-Bus® system

### Features and Benefits

#### AxonHook

- Slim compact design allows user greater visibility of the handled object
- High degree of fine proportional control
- AxonWrist functionality is included, which allows for reduced compensatory movements.
- Durable polyurethane (rubber like) coating supports user in grasping small and complex shaped objects.
- Automatically returns to Neutral Position when signal is relaxed. This function can also be used for soft gentle grasping of fragile objects.
- Hook tips can be replaced by the practitioner if broken
- Fully digital communication with prosthesis

#### AxonRotation

- Automatic Neutral Positioning – hand starts from same position and doesn't have to remember in which position the hand was in. This reduces the cognitive burden on the user.
- Faster Rotation Speed allowing for smooth, precise and delicate motions
- Proportional Control

#### AxonArm Ergo and Hybrid:

- **Automatic Forearm Balance (AFB)** assists elbow flexion and extension. The AFB is an internal mechanism built into both the AxonArm Ergo and AxonArm Hybrid that provides a spring assist to lifting the elbow. When the arm is extended (hanging down) the user can use shoulder motion to swing the elbow forward, which will then initiate the AFB, raising the elbow to a level position. AFB also compensates for weight of the forearm. It is easily adjusted by the user.
- **Electronic Ratchetless lock (AxonArm Ergo only):** Locking and unlocking the elbow joint is realized with myoelectric signals picked up by the electrodes. The electronic lock is programmable and controlled by a microprocessor.
- **Internal and External Humeral Rotation:** AxonArm Ergo has a feature that allows the wearer to manually rotate the arm. The friction rotation can be easily adjusted.
- **Forearm** can be shortened

#### Microprocessor Communication System:

- The Axon-Bus system microprocessor evaluates muscle signals and optimum electrode adjustment and documents all recorded user data.
- The AxonMaster is mounted inside the socket and it contains the main microprocessor control feature. It controls the Axon-Bus communication process. This includes receiving and processing myoelectric signals from the electrodes and managing communication between the components.
- There are 5 microprocessors in addition to the AxonMaster Microprocessor Control, including two in the Michelangelo hand, one in the AxonArm Ergo, and one each in the AxonMaster and AxonEnergy Integral. The Axon-Bus system is programmed via integrated Bluetooth Module.

## Michelangelo and Axon-Bus® system

### Features and Benefits

#### Programming:

Adjustments to the prosthesis components can be performed through Bluetooth® data transfer using the AxonSoft program. The Bluetooth® module is in the control unit. Four control options and five switching modes are offered. This allows for multiple fitting options, such as:

- Proportional control (opening and closing speed as well as grip force is proportional to the muscle contraction)
- Digital control (constant speed, gripping force is proportional to the duration of the signal)
- One or two electrodes or three switch options (short and long co-contraction, impulse switching, and long open signal)

#### Battery

- The 757B501 AxonEnergy Integral serves exclusively to provide power to the Axon-Bus system. The battery consists of 3 Li-Ion cells. The integrated electronics protect the battery against short circuits, overvoltage, undervoltage and charging outside the allowable temperature range.
- The Axon-Bus cable with the three-pin receptacle is used to exchange data and connects the respective prosthesis components to the battery.
- These components are fabricated into the socket and permanently connected to each other.

#### Charger

- The AxonCharge Integral magnetically connects to the charging port which is integrated into the socket.

#### Michelangelo PVC Glove

- The AxonSkin gloves come in six different color variations. In addition to a physiological appearance, the new gloves feature excellent durability.

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**Specialized User Training** is recommended for this product. See Ottobock Brochure “Using the Michelangelo Hand in Practice Therapy and Rehabilitation: Using Therapy May be Beneficial” at:

<https://professionals.ottobockus.com/media/pdf/646D593-EN-03-1503-k.pdf>

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## Michelangelo and Axon-Bus® System

### Clinical Studies

Cutti AG, Kannenberg A. Review of the current literature on the clinical benefits of multiarticulating prosthetic hands. MyoElectric Controls Symposium, Fredericton, New Brunswick. 2017 (August). [download](#)

Luchetti M, Cutti AG, Verni G, Sacchetti R, Rossi N. Impact of Michelangelo prosthetic hand: Findings from a crossover longitudinal study. *J Rehabil Res Dev*. 2015;52(5):605-18. [download](#)

Pröbsting E, Kannenberg A, Conyers DW, Cutti AC, Miguelez JM, Shonhowd TP, Ryan TA. Ease of activities of daily living with conventional and multigrip myoelectric hands. *J Prosthet Orthot*. 2015;27(2):46-52. [download](#)

Belter JT, Segil JL, Dollar AM, Weir RF. Mechanical design and performance specifications of anthropomorphic prosthetic hands: A review. *J Rehabil Res Dev*. 2013;50(5):599–618. [download](#)

Cutti AG, Parel I, Luchetti M, Gruppioni E, Rossi NC, Verni G. The Psychosocial and Biomechanical Assessment of Amputees Fitted with Commercial Multi grip Prosthetic Hands – Case Study: Michelangelo Hand. *Grasping the Future: Advances in Powered Upper Limb Prosthetics*. 2012;59-77. [download](#)

Ottobock  
Reimbursement, North America  
P 800 328 4058 F 800 230 3962  
professionals.ottobockus.com/Reimbursement  
professionals.ottobock.ca/Reimbursement  
[reimbursement911@ottobock.com](mailto:reimbursement911@ottobock.com)



## Michelangelo/Axon-Bus®

### Suggested Coding Options<sup>1</sup>

January 2021

The Michelangelo Hand is used on a custom fabricated prosthesis. Due to customization, additional coding may apply.

#### Base Code Options (includes Socket, Forearm, Humeral Section, Shoulder Bulkhead, Cables, Batteries, Charger, and Switch/Myoelectric Control)

Transcarpal switch/myo	L6026
Wrist Disarticulation switch/myo	L6920/L6925
Below Elbow switch/myo	L6930/L6935
Elbow Disarticulation switch/myo	L6940/L6945
Above Elbow switch/myo	L6950/L6955
Shoulder Disarticulation switch/myo	L6960/L6965
Interscapular-Thoracic switch/myo	L6970/L6975

#### Socket Options (add as appropriate, not all inclusive)

Test Sockets	L6680 (WD/BE), L6682 (ED/AE), L6684 (SD/IT)
Suction Socket	L6686
*Removable Insert (e.g. Thermolyn/ Bocklite)	L6691
*Silicone Insert (e.g. Proflex with Silicone)	L6692
Frame Socket	L6687 (WD/BE), L6688 (ED/AE), L6689 (SD), L6690 (IT)
Ultralight Material	L7400 (WD/BE), L7401 (ED/AE), L7402 (SD/IT)
Acrylic	L7403 (WD/BE), L7404 (ED/AE), L7405 (SD/IT)

#### Replacement Socket Base Code

Replacement Socket	L6883 (BE/WD), L6884 (ED/AE), L6885 (SD/IT)
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#### Harness (if used)

##### Above Elbow Harness, Triple Control, Steel

21A35=1	L6677 (harness triple) + L6655 (standard ctrl cable, extra)
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##### Active TH Harness

21A47	L6672 harness chest or shoulder, saddle type
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##### Armloop for 21A47

included in L6672

\*Medicare allows the patient to have a total of 2 inserts (which includes liners) at any given time.

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## Michelangelo/Axon-Bus®

### Suggested Coding Options<sup>1</sup>

January 2021

Elbow Options <i>*see Michelangelo Billing Tips</i>	
<b>AxonArm Ergo</b> 12K501=M /M1 /M2	Base code + L6693 (forearm counterbalance) + L6638 (elec.lock) + L7499* (MP Control of the APS System)
<b>AxonArm Hybrid</b> 12K500=M /M1 /M2	Base code + L6693 (forearm counterbalance)
Additional Switches (if used)	
9X14 Harness Pull Switch 9X18 Cable Pull Switch 9X25 Rocker Switch 9X37 Pressure Switch 9X50 & 9X52 Linear Transducer	L6611 (additional switch)
Hand, Hook Options <i>*See Michelangelo Billing Tips</i>	
<b>Michelangelo Hand</b> 8E500	L7499* (Michelangelo Hand) + L6882 (MP control) + L6881 (Autograsp) + L6629 (QD) + L6890 (glove) + Wrist Option (below)
<b>Michelangelo Wrist Options</b> 9S501 Passive Rotation <b>OR</b> 9S503 Active Rotation	L6624 (flex/ext rot wrist) <b>OR</b> L6624 (flex/ext wrist) + L7259 (rotator) + L6882 (MP Control)
<b>Michelangelo Transcarpal Hand</b> 8E550=*	L7499* (Michelangelo hand) + L6882 (MP control) + L6881 (Autograsp) + L6890 (glove)
<b>AxonHook</b> 8E600=*	L7499* (AxonHook) + L6882 (MP control) + L6881 (Autograsp) + L6629 (QD) + Michelangelo Wrist Option (above)
Donning Sheath (if used)	
<b>Donning Sheath EasyFit Arm</b> OC1560-*	L7600 prosthetic donning sleeve
Glove (prefabricated)	
<b>AxonSkin Gloves</b> 8S500 /01 / 02 / 11/	L6890 (glove any material)

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## Michelangelo/Axon-Bus®

### Suggested Coding Options<sup>1</sup>

January 2021

Liner options	
*14Y1 Silicone Arm Liner	L6694 (locking liner)
*14Y5 Silicone Arm Liner with CVD coating	L6694 (locking liner)
14A1 Lock Set	L6698 (lock)
*6Y416 Custom Shape Plus UE Urethane Liner (model made by hand)	<b>For Initial Liner use:</b> L6696 (custom liner congenital/atypical traumatic) <b>or</b> L6697 (custom liner not congenital/atypical traumatic)
*6Y417 Custom Shape Plus Urethane UE Replacement Liner (same mold)	<b>For Replacement Liner use:</b> L6694 (locking liner) <b>or</b> L6695 (liner not for lock)
*88L1=* Custom Silicone TR Liner	Send your Ottobock quote to <a href="mailto:reimbursement911@ottobock.com">reimbursement911@ottobock.com</a> for help with coding and MSRP
Replacement Electrodes (initial electrodes & cables included in base code)	
13E202=60 Suction Socket Electrode (60hz)	Included in base code, use L7510 for replacement
13E129 Electrode Cable	Included in base code, use L7510 for replacement
Replacement Battery/Charger (initial battery and charger are included in the base code)	
757B501 AxonEnergy Integral	L7367 lithium-ion battery replacement (check with payer, may require modifiers)
757L500 AxonCharge Integral	L7368 lithium-ion battery charger, replacement (check with payer, may require modifiers)

\*Medicare allows the patient to have a total of 2 inserts (which includes liners) at any given time.

Ottobock North America, Reimbursement  
P 800 328 4058  
[professionals.ottobockus.com/Reimbursement](https://professionals.ottobockus.com/Reimbursement)  
[reimbursement911@ottobock.com](mailto:reimbursement911@ottobock.com)

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