

Michelangelo/Axon-Bus[®] Prosthetic System (APS) Reimbursement Guide



Quality for life

Michelangelo/Axon-Bus® Prosthetic System (APS)

Product Information

Adaptive eXchange of Neuroplacement Data (Axon)

Axon-Bus Prosthetic System (APS) is new 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.

APS Primary Components

Michelangelo Hand is an electronic hand with an oval 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 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 available.

AxonRotation is an electronic wrist rotator that can be used with both the Michelangelo Hand and the AxonHook. AxonRotation allows the user benefit from bimanual activities. It has proportional control and a return to neutral feature.

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

AxonArm Ergo is a passive elbow component with an electronic locking elbow and automatic forearm balance. The microprocessor controlled electronic feature allows unlocking and locking of the elbow joint, realized with myoelectric signals picked up by the electrodes and may be programmed to control the hand, hook or wrist.

Who can provide APS 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

Otto Bock HealthCare (Otto Bock) 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. An extended 1-year warranty is available for purchase and includes a 24-month service inspection. AxonRotation, AxonHook, and AxonArm Ergo 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/Axon-Bus® Prosthetic System (APS)

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

January 2020

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

¹HCPCS 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

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

AxonArm Ergo

- L6693 Forearm Counterbalance +
- L6638 Electric Lock

AxonArm Hybrid

- L6693 Forearm Counterbalance

Microprocessor Control Feature

- L7499 Sequential MP Control electric lock &
TD

^{1,2} 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

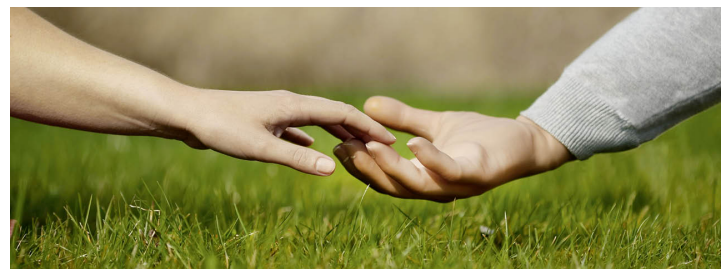
MSRP for Michelangelo's L7499 code is \$75,000

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 \$75,000



Michelangelo/Axon-Bus® Prosthetic System (APS)

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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, Light weight, heavy duty titanium 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 \$15,000

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

¹The product/device “Supplier” (defined as an O&P practitioner, O&P patient care facility, or DME supplier) assumes full responsibility for accurate billing of Ottobock products. It is the Supplier’s responsibility to determine medical necessity; ensure coverage criteria is met; and submit appropriate HCPCS codes, modifiers, and charges for services/products delivered. It is also recommended that Supplier’s contact insurance payer(s) for coding and coverage guidance prior to submitting claims. Ottobock Coding Suggestions and Reimbursement Guides are based on reasonable judgment and are not recommended to replace the Supplier’s judgment. These recommendations may be subject to revision based on additional information or alpha-numeric system changes.

²The 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/Axon-Bus[®] Prosthetic System (APS) 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.

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 is achieved for holding plates and bowls.
- Tripod Pinch allows precise grasping of small objects.
- Power Grip for grasping large objects
- Neutral Position allows a natural position at rest. Hand will not open while walking and the thumb is tucked in like a natural hand. The hand automatically positions itself in neutral. The user does not need to think about the hand position.
- Finger Adduction and Abduction allows fingers to spread out as hand opens.

AxonWrist: Oval Integrated Wrist Joint on the Michelangelo Hand and Axon Hook

- AxonWrist is comprised of two components; the AxonFlexion adapter and the AxonRotation adapter.
- 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/Axon-Bus[®] Prosthetic System (APS) 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.
- Light weight with heavy duty titanium fingers
- 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 also can 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.
- 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

APS Microprocessor Communication System:

- APS 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 APS is programmed via integrated Bluetooth Module.

Michelangelo/Axon-Bus® Prosthetic System (APS) Features and Benefits

APS 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).

APS Battery

- Two AxonEnergy Integral (battery) options are available; an 11.1 Volt, 1500 mAh system and a smaller 11.1 Volt, 1150 mAh system. Both systems consist of a charging receptacle, Li-Ion battery, and the Axon-Bus® cable. The components are fabricated into the socket and permanently connected to each other.

APS 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.

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>

Michelangelo/Axon-Bus® Prosthetic System (APS) 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](#)

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