

Michelangelo and Axon-Bus[®] System Reimbursement Guide

September 2022



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

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

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At this time, there are not existing Healthcare Common Procedure Coding System (HCPCS) codes to completely describe the Michelangelo Hands, Axon-Hook and Microprocessor Control for the above elbow configuration. Miscellaneous code L7499 is available to use. We do not recommend billing these products to Medicare until specific coding is secured.

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 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 for Above Elbow

- 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

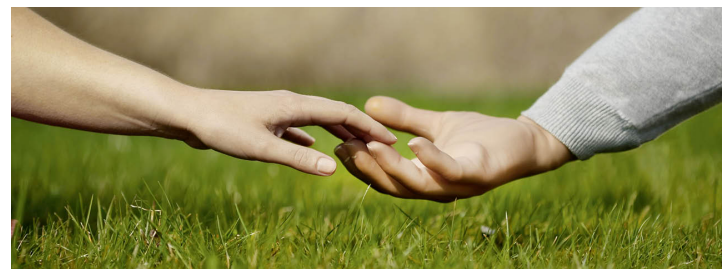
MSRP for Michelangelo’s L7499 code is \$85,000

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



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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 \$29,948

Microprocessor Control Feature

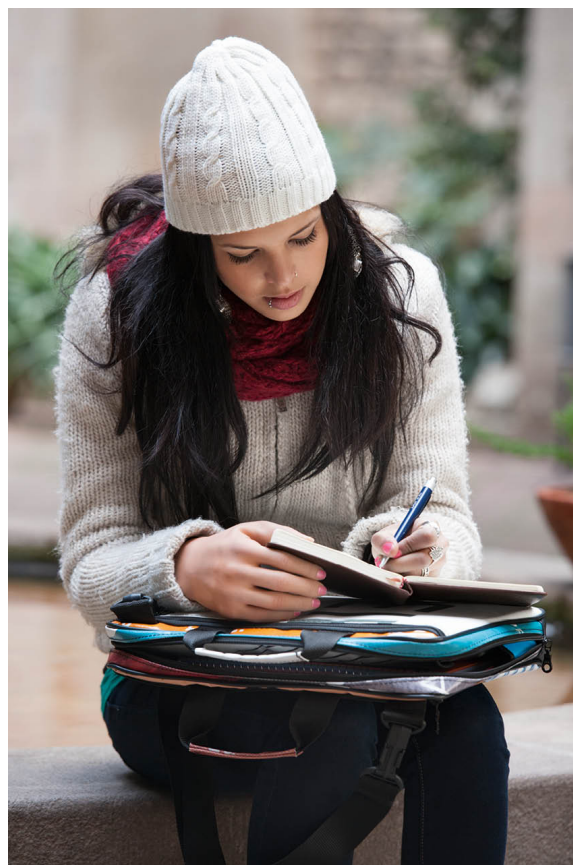
Long Description: Addition to upper extremity external powered prosthesis (Ottobock 12K501 AxonArm Ergo & 8E500 Michelangelo Hand); Sequential microprocessor control of electric locking feature and terminal device (similar to L7180 without elbow lift, which is instead provided by the forearm counterbalance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

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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.

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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.

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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.

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 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](#)

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