

ottobock.

Myo Plus.
Reimbursement Guide.
January 2024.



Myo Plus pattern recognition.

Product Information.

Myo Plus is currently available for transradial (TR) applications and is compatible with Ottobock's bebionic Hand, SensorHand Speed, MyoHand VariPlus Speed, and the System Electric Greifer DMC VariPlus.

Myo Plus Primary Components.

13E520 Myo Plus TR

757B35=5 Myo Energy Integral

13E400 /401 Remote Electrodes

13Z161 /162 /163 Electrode Domes

560X18 Myo Plus App (android/IOS)

Who can provide the Myo Plus?

Myo Plus must be 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. Myo Plus comes with a Limited 12-month Warranty.



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.

510(k) Number	K191179
Device Class	2
Regulation No.	21 CFR 882.1320
Classification	GXY (Electrode,
Product Code	Cutaneous)
Subsequent Code	IQZ (Hand, External Limb Component, Powered)
Medical Specialty	Neurology
Review Panel	Neurology

Myo Plus pattern recognition. Coding and MSRP (US only).

¹HCPCS Coding.

At this time, there is not an existing Healthcare Common Procedure Coding System (HCPCS) code to completely describe Myo Plus pattern recognition, and miscellaneous code L7499 is available to use. We do not recommend billing the Myo Plus to Medicare until specific coding is secured.

Short Description:

L7499 Addition to UL prosthesis, Ottobock 13E520 Myo Plus Pattern Recognition System

Long Description:

L7499 Addition to upper extremity external powered myoelectric prostheses; Ottobock 13E520 Myo Plus TR pattern recognition system; Multi-factor, layered processing of the user's amplified natural EMG signal patterns captured by a multiple electrode array to produce patient-specific rule set algorithms, allowing Myo Plus to recognize individual patient muscle signal patterns which are translated to intuitively control several prosthetic hand functions/grip types and/or several prosthetic devices (e.g. prosthetic hand, wrist rotator, wrist flexion/extension) instantaneously. The microprocessor integrates system calibration, signal quality evaluation, filtering, conditioning, processing, recognition of multiple muscle activation patterns, and transmission of complex functional controls.

²Manufacturer Suggested Retail Price (MSRP).

2024 MSRP for Myo Plus: \$44,200

References

¹ The 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 do not replace the Supplier's judgment. These recommendations may be subject to revision based on additional information or alpha-numeric system changes.

² 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).

Myo Plus Justification.

Intuitive and Individualized Control.

Myo Plus pattern recognition provides intuitive and individualized control by mapping a user's unique muscle patterns and translating them directly into various movements of the prosthesis. For example, if the user thinks of opening his/her hand and activates the physiologic muscles used for that task, the system immediately translates these signals to open the prosthetic hand or terminal device. This innovative control is considerably easier to master, which may increase adoption rate, may reduce duration of training, and accelerate a return to typical daily activities.

Reduced Complexity.

Clinicians no longer have to identify and place electrodes on specific anatomical targets to isolate strong signals. Weak signals are equally important because with pattern recognition, multiple myo-sites are working together. This enables the system to recognize and utilize the contraction of multiple muscles that are then recognized as patterns. Plus, the system can be recalibrated any time desired. This creates additional layers of data to further support accuracy of pattern recognition and system efficiency.

Additionally, if the relationship between limb and electrodes happens to change within the socket, the system can still function once it is recalibrated because the interpretation of the signals is not fixed to a specific location. The system adapts to the patient rather than the patient having to adapt to the system. This flexibility saves time and reduces overall complexity for both the Clinician and the user.



Elimination of Switching Events.

Mode switching with traditional myo-electric control such as a hand and a powered wrist requires the user to either activate a physical switch (button, prosthesis digit manipulation), co-contract muscles to change grip patterns in the hand, or allow multiple components to be activated. Mode switching can be difficult and requires both training time and concentration. In some cases, the user cannot co-contract their muscles at all which inhibits prosthesis functionality and may lead to rejection or abandonment of the device. With Myo Plus pattern recognition, the user has direct mode selection and access to prosthetic movements without requiring cumbersome switching events or “mode switching”. It provides *direct and fast control* and decreases the cognitive and physical burden. This may increase utilization of certain movements such as wrist rotation. For example, the user may tie their shoelaces or button a shirt more easily and with less frustration. Increasing the ease and utility of the prosthesis may help increase overall acceptance rate and user satisfaction.

Improved Functionality and Ease of Use.

Traditional myo-electric control is limited by the number of isolated, strong EMG signals and associated electrode sites (only 1 or 2). Some users have weak signals that fatigue quickly, neuropathy, or scarring that make electrode placement challenging. This inhibits prosthetic candidacy, acceptance rates and functionality. Alternatively, Myo Plus pattern recognition uses up to 8 myosite pairs which provide significantly more information as to the nature of the contraction rather than just amplitude to control the prosthesis. Any signal, even those considered “weak” by conventional myoelectric systems, can be as equally useful if they are present during specific activities. Thus, pattern recognition has the potential to allow patients who were previously unable to use myoelectrics to do so. In addition, accessing the multitude of grip types available in multigrip and multiarticulating prosthetic hands by switching through them may be too cumbersome for many patients. That’s why most patients use only 2-3 of the available up to 18 grip types of these hands. This becomes even more of a problem if the patient uses additional myoelectric devices, such as an electric wrist. In these cases, pattern recognition has the potential to access a much greater number of grip types and additional devices easily and intuitively without having to switch through the available functions.¹

Improved Speed and Proportional Control

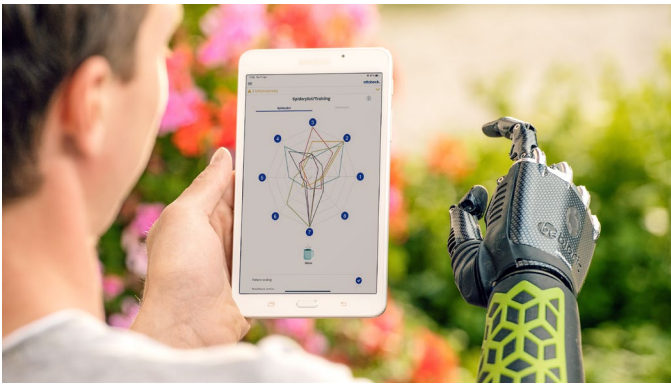
Like traditional control, pattern recognition allows users to temper their muscle contractions to modulate the speed of the prosthesis. With traditional control, EMG signals are isolated and have to meet strict measurements to initiate a movement in the prosthesis. Weaker signals and other

extraneous “noise” are intentionally filtered out. Myo Plus pattern recognition maps and utilizes multiple sets of data that are also used to enhance and provide proportional control. For example, the user can generate a “weak” signal and the hand will close more slowly around a glass. Multiple sets of data improve the efficiency of proportional control and provide greater utility of the device in everyday activities.



Reduced Cognitive Burden

Pattern recognition reduces the cognitive burden associated with traditional Myo electric control. Standard Myo users are required to concentrate deeply on difficult and unnatural myo signal patterns to fit the strict control method of 1 or 2 site control. They must adapt to the device. For example, many users struggle with the cumbersome nature of signal isolation to switch into rotation or different grip patterns. This results in a delay and interruption of movement, leading to low motivation while training and insufficient use. Due to this lack of practice, the user may lack confidence with the device control during everyday life and often abandon the prosthesis. Since Myo Plus pattern recognition only requires the user to think of and utilize innate and natural movements to operate their prosthesis, users are able to more easily and quickly control their device. Myo Plus unlocks the full potential of the user and their prosthesis because the device now adapts to the user instead of the other way around.



Real-time App Feedback and Adjustment

With traditional myo electric control, the prosthesis can be like a black box. There is no interface, visibility, or feedback on the status of the system or the quality of control signals. With the *Myo Plus app* and patented Spider Plot EMG signal graphical interface, both users and clinicians are provided with real time feedback and the ability to make immediate adjustments. Once the muscles are mapped, the user can adjust the speed or sensitivity of the prosthesis or even activate or deactivate certain movements to suit a specific situation. Additionally, the user can now remotely troubleshoot their own control map. If there is interference suppression, such as electrode failure, the malfunction is displayed via the app. This allows the user and Clinician to quickly identify potential solutions. The Myo Plus app also includes some important safety features. To secure certain settings, the Myo Plus app has a Clinician Mode which requires a pin-code. Any adjustments to the Basic control set can only be adjusted by the Clinician.

Less Compensatory Movements

Users who use a body-powered or traditional myo electric prosthesis tend to over utilize their contralateral arm musculature to compensate for lack of flexibility and function with their device. For example, they may elevate their shoulder awkwardly when pouring water into a glass to avoid the strain and delay of using a wrist rotation device. Consistent and long-term compensatory movements can lead to long term health complications. With the intuitive control of the Myo Plus pattern recognition system, users can increase the functionality, efficiency and speed of their prosthesis and potentially avoid the strain of unnatural compensatory movements. This in turn can promote increased use of their prosthesis in daily activities such as work and social activities.



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