ottobock.



Michelangelo Hand 8E500

EN Instructions for use (qualified personnel)	3
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1 Foreword

INFORMATION

Date of last update: 2022-02-14

- Please read this document carefully before using the product and observe the safety notices.
- Instruct the user in the safe use of the product.
- Please contact the manufacturer if you have questions about the product or in case of problems.
- Report each serious incident related to the product to the manufacturer and to the relevant authority in your country. This is particularly important when there is a decline in the health state.
- Please keep this document for your records.

The 8E500=R/L Michelangelo Hand is referred to as the product / Axon-Bus terminal device / Michelangelo Hand below.

These instructions for use provide you with important information on the use, adaptation and handling of the product.

According to the manufacturer (Otto Bock Healthcare Products GmbH), the patient is the operator of the product according to the IEC 60601-1:2005/A1:2012 standard.

Only put the product into use in accordance with the information contained in the accompanying documents supplied.

2 Product description

2.1 Function

The Michelangelo Hand is a myoelectrically controlled gripping component in the modular Ottobock Axon-Bus prosthetic system. The complex gripping kinematics combined with the anatomical appearance and low weight support the patient in his or her daily activities, thereby providing the highest rehabilitation value.

The Michelangelo Hand is equipped with two drives to achieve a natural motion pattern. The main drive is responsible for the gripping movements and gripping force. The thumb drive facilitates the two gripping modes 'Opposition Mode' and 'Lateral Mode'. Actively driven components are thus the thumb, index finger and middle finger. The ring finger and little finger passively follow the movements.

Gripping modes of the Michelangelo Hand

The following gripping options are possible:



Neutral Position

Natural, physiological appearance in the rest position.



Lateral Power Grip

The thumb moves laterally to the index finger; this laterally fixates mediumsized objects when the thumb is in the half-open position.



Lateral Pinch

The thumb moves laterally to the index finger; this laterally fixates flat objects when the thumb is in the closed position.



Open Palm

In the Open Palm position the thumb is positioned far to the outside; this achieves a flat hand position with a completely opened thumb position.



Opposition Power Grip

The opening width makes it possible to hold cylindrical objects with large diameters and with an open thumb position.



Tripod Pinch

Together with the index finger and the middle finger, the thumb forms a three-point support; small objects can then be securely fixated with the thumb in closed position.



Finger Abduction/Adduction

By spreading the fingers, a flat, thin object (< 3 mm / < 0.12 inch) can be held between the fingertips when closing the hand.

2.1.1 Wrist unit

Starting at the neutral position, the joint can be flexed by approximately 75° in 4 locking positions; extension is 45° with 3 locking positions. Flexion and extension are performed passively. A flexible and a rigid mode are available according to the application situation.

Flexible mode

Flexible mode simulates the natural movement characteristics of a relaxed wrist joint. This flexible condition closely approximates the physical movement characteristics of the hand and wrist joint. To select the flexible mode, push the unlock lever to the stop (see fig. 2) until it engages. The joint can be moved without engaging at the ratchet positions. Pushing the lever again terminates the flexible mode and the wrist unit engages at the next available position in the rigid mode.

Rigid mode

Various everyday conditions require an individually adjustable wrist unit of the gripping component in the rigid mode. When the unlock lever is only pushed lightly and not to the stop (see fig. 2), the wrist unit can be moved to the desired position. When the unlock lever is released, the wrist unit engages at the next available position.

2.2 Combination possibilities

This product is to be combined exclusively with components in the Axon-Bus prosthetic system. Components of the Ottobock MyoBock system or components from other manufacturers cannot be used with this product.

3 Intended use

3.1 Indications for Use

The Michelangelo Hand 8E500 is to be used **exclusively** for exoprosthetic fittings of the upper limbs.

3.2 Conditions of use

The product was developed for everyday use and must not be used for unusual activities. These unusual activities include, for example, sports which involve excessive strain and/or shocks to the wrist joint (pushups, downhill racing, mountain biking, ...) or extreme sports (free climbing, paragliding, etc.). Furthermore, the product should not be used to operate motor vehicles, heavy equipment (e.g. construction machines), industrial machines or motor-driven equipment.

The product is intended **exclusively** for use on **one** patient. Use of the product by another person is not approved by the manufacturer.

Permissible ambient conditions are described in the technical data (see page 14).

3.3 Indications

- · Amputation level transradial and transhumeral
- For unilateral or bilateral amputation
- Dysmelia of the forearm or upper arm
- The user must be able to understand usage instructions and safety notices and put them into practice.
- The patient must fulfil the physical and mental requirements for perceiving visual/acoustic signals and/or mechanical vibrations.

3.4 Contraindications

 All conditions which contradict or go beyond the specifications listed in the section on "Safety" and "Indications for use".

3.5 Qualification

The fitting of a patient with the product may only be carried out by O&P professionals who have been authorised with the corresponding Ottobock training.

4 Safety

4.1 Explanation of warning symbols

	Warning regarding possible serious risks of accident or injury.
	Warning regarding possible risks of accident or injury.
NOTICE	Warning regarding possible technical damage.

4.2 Structure of the safety instructions

The heading describes the source and/or the type of hazard

The introduction describes the consequences in case of failure to observe the safety instructions. Consequences are presented as follows if more than one consequence is possible:

• E.g.: Consequence 1 in the event of failure to observe the hazard

- > E.g.: Consequence 2 in the event of failure to observe the hazard
- This symbol identifies activities/actions that must be observed/carried out in order to avert the hazard.

4.3 General safety instructions

Non-observance of safety notices

Personal injury/damage to the product due to using the product in certain situations.

• Observe the safety notices and the stated precautions in this accompanying document.

Use of damaged power supply unit, adapter plug or battery charger

Risk of electric shock due to contact with exposed, live components.

- Do not open the power supply unit, adapter plug or battery charger.
- Do not expose the power supply unit, adapter plug or battery charger to extreme loading conditions.
- Immediately replace damaged power supply units, adapter plugs or battery chargers.

Operating the prosthetic system near active implanted systems

Interference with active implantable systems (e.g., pacemaker, defibrillator, etc.) due to electromagnetic interference of the prosthetic system.

- When operating the prosthetic system in the immediate vicinity of active implantable systems, ensure that the minimum distances stipulated by the manufacturer of the implant are observed.
- Make sure to observe any operating conditions and safety instructions stipulated by the manufacturer of the implant.

▲ CAUTION

Independent manipulation of the product

Injury due to malfunction and resulting unexpected prosthesis actions.

- Manipulations to the product other than the tasks described in these instructions for use are not permitted.
- The product and any damaged components may only be opened and repaired by authorised, qualified Ottobock personnel.

Signs of wear on the product

Injury due to faulty control or malfunction of the product.

In the interest of the patient's safety and in order to maintain operating reliability, the product should be serviced at regular intervals.

4.4 Information on Proximity to Certain Areas

Proximity to sources of strong magnetic or electrical interference (e.g. theft prevention systems, metal detectors)

Injury due to unexpected behaviour of the prosthesis system caused by interference with internal data communication.

- Avoid remaining in the vicinity of visible or concealed theft prevention systems at the entrance/exit of stores, metal detectors/body scanners for persons (e.g. in airports) or other sources of strong magnetic and electrical interference (e.g. high-voltage lines, transmitters, transformer stations, computer tomographs, magnetic resonance tomographs, etc.).
- When walking through theft prevention systems, body scanners or metal detectors, watch for unexpected behaviour of the prosthetic system.

Insufficient distance to HF communication devices (e.g. mobile phones, Bluetooth devices, WiFi devices)

Injury due to unexpected behaviour of the product caused by interference with internal data communication.

Therefore, keeping a minimum distance of 30 cm from HF communication devices is recommended.

4.5 Information on Alignment/Adjustment

▲ CAUTION

Operator errors during the adjustment process with the adjustment software

Injury due to unexpected product behaviour.

- Participation in an Ottobock product training course is mandatory prior to using the product. During this product training course you will receive a password giving you access to the adjustment software. Additional product training courses may become necessary to qualify for software updates.
- ► Do not share your unlock PIN.
- ▶ Use the online help which is integrated into the software.

Incorrect electrode settings

Injury due to unexpected product behaviour.

- The electrodes are to be placed on intact skin only and with as much electrode-skin contact as possible. In the case of strong interference from electronic devices, the position of the electrodes should be checked and changed if necessary. If the interference cannot be eliminated or if you do not achieve the expected results by adjustment or selection of the appropriate control programme, please contact the Ottobock branch responsible for your country.
- Set the electrode gain as low as possible in order to reduce interference from powerful electromagnetic radiation (e.g. visible or or concealed theft prevention systems at the entrance/exit of stores), metal detectors/body scanners for persons (e.g. in airports) or other sources of strong electromagnetic interference (e.g. high-voltage lines, transmitters, transformer stations, computer tomographs, magnetic resonance tomographs, etc.).

4.6 Information on Use

▲ CAUTION

Improper use

Injury due to malfunction and resulting unexpected prosthesis actions.

Instruct the patient in the proper use of the product.

Mechanical stress on the product

Injury due to faulty control or malfunction of the product.

- Do not subject the product to mechanical vibrations or impacts.
- Check the product for visible damage before each use.

▲ CAUTION

Operation outside of the permissible temperature range

Injury due to faulty control or malfunction of the product.

Avoid operation in areas outside the permissible temperature range (see page 14).

▲ CAUTION

Penetration of dirt and humidity into the prosthetic components

Injury due to faulty control or malfunction of the prosthetic components.

Ensure that neither solid particles nor liquids can penetrate into the product or prosthetic components (e.g. the terminal device).

Changing Axon-Bus gripping components when switched on

Injury due to faulty control or malfunction of the Axon-Bus prosthetic system.

Power down the Axon-Bus prosthetic system by pressing the button in the charging receptacle before changing any Axon-Bus components (e.g. Axon-Bus gripping component).

Unintentional unlocking of the Axon-Bus gripping component

Injury due to releasing the Axon-Bus gripping component from the forearm (e.g. while carrying objects).

The two release buttons should only be activated in order to change the Axon-Bus gripping component, deliberately and with due consideration of the respective situation.

NOTICE

Improper product care

Damage to the product due to the use of incorrect cleaning agents.

- Only clean the product with a damp cloth and mild soap (e.g. 453H10=1-N Ottobock DermaClean).
- Use only the following products for cleaning/disinfecting the inner socket: Cleaning: 453H10=1-N Ottobock DermaClean Disinfection: Colourless, conventional medical disinfectants

4.7 Information on the Power Supply/Battery Charging

Charging the product with soiled or damaged contacts

Injury due to unexpected behaviour of the product caused by insufficient charging.

- Make sure that the contacts are always clean and free of grease.
- Clean the electrical contacts of the charging plug and charging receptacle regularly using cotton swabs and a mild soap solution.
- Take care to avoid damaging the contacts with pointed or sharp objects.

NOTICE

Use of incorrect power supply unit/battery charger

Damage to product due to incorrect voltage, current or polarity.

Use only power supply units/battery chargers approved for this product by Ottobock (see instructions for use and catalogues).

NOTICE

Contact of the charging plug with magnetic data carriers

Wiping of the data carrier.

▶ Do not place the charging plug on credit cards, diskettes, audio or video cassettes.

5 Scope of Delivery and Accessories

5.1 Scope of delivery

- 1 pc. 8E500 Michelangelo hand
- 1 pc. Instructions for use (qualified personnel)
- 1 pc. Instructions for use (user)

5.2 Accessories

The following components are not included in the scope of delivery and must be ordered separately:

- "560X500=* AxonSoft" adjustment software
- 757L500 AxonCharge Integral
- 757B501 AxonEnergy Integral
- 13E500 AxonMaster
- 9S503 AxonRotation (active rotation unit)

or

- 9S501 AxonRotation Adapter (passive rotation unit)
- 13E200=* electrode
- 13E202=* suction socket electrode
- 13E129=* electrode cable
- 8S501=* AxonSkin Natural for men (different skin colours)
- 8S502=* AxonSkin Natural for women (different skin colours)
- 8S500=* AxonSkin Visual (sheer, translucent)
- 8S511=* AxonSkin Silicone for men (different skin colours)
- 8S512=* AxonSkin Silicone for women (different skin colours)

6 Preparing the product for use

6.1 Donning the prosthetic glove

INFORMATION

Do not use silicone spray when putting on the prosthetic glove. This impairs the secure fit of the glove and can limit the functionality of the product (hand).

Observe the instructions for use provided for the prosthetic glove and the process for putting it on and taking it off described in the same.

For daily use, the Michelangelo Hand must be worn with the AxonSkin prosthetic glove. The glove protects the mechanism against environmental influences such as moisture, dirt and dust.

For information about the use (putting on and taking off) and care of the prosthetic glove, please refer to the instructions for use included with the prosthetic glove.

6.2 Settings

Adjustments to the product can be made via Bluetooth data transmission using the 560X500=* AxonSoft software. For this purpose, a wireless connection must be established between the 13E500 AxonMaster and the PC with the help of the 60X5 BionicLink PC.

For further information, see the instructions for use provided with the 13E500 AxonMaster and the 560X500=* AxonSoft software.

7 Use

7.1 Changing the Axon-Bus gripping component

Attaching the Axon-Bus gripping component to the socket

- 1) Slide the terminal device on to the socket (rotation anchored in the socket) until it locks in place audibly.
- 2) Verify proper attachment by pulling on the terminal device.

Separating the Axon-Bus gripping component from the socket



- To switch off the Axon-Bus prosthetic system, press the charging receptacle button and hold for more than one second.
- 2) Press both unlock buttons on the flexion wrist unit.
 - **INFORMATION:** For safety reasons the Axon-Bus gripping component cannot be removed if only one unlock button is pressed.
- 3) Separate the Axon-Bus gripping component from the socket.

7.2 Switching the product on and off

INFORMATION

Switching off the Axon-Bus prosthetic system during extended passive pauses (e.g. air or rail travel, visit to a theatre or cinema, etc.) will make the battery last longer before requiring a recharge. Only the entire Axon-Bus prosthetic system with all connected components can be switched off. Individual Axon-Bus components cannot be switched off separately.

Storage of the product in the closed state

Injury due to faulty control or malfunction of the product as a result of damage to the sensors and mechanism.

Store the product only in the neutral position or in the open state.



▶ 1) Push and hold the charging receptacle button until a confirmation sound is heard (at least 1 second).

 $\rightarrow\,$ The prosthesis and prosthetic components are switched on. Repeat this process to switch the prosthesis and prosthetic components off.

INFORMATION

The Axon-Bus prosthetic system cannot be used as long as the charging plug is connected to the charging receptacle. The Axon-Bus prosthetic system is deactivated for the duration of charging.

7.3 Opening the Axon-Bus gripping component in an emergency



This safety function allows the Axon-Bus gripping component to be opened regardless of the control signals present.

- With the Axon-Bus prosthetic system switched on, press the charging receptacle button and hold for approximately three seconds until the Axon-Bus gripping component begins to open.
 → A pulsating beep sounds as it opens.
- Releasing the button immediately stops the process of opening the Axon-Bus gripping component and turns the entire Axon-Bus prosthetic system off.

8 Maintenance

Performing regular maintenance (service inspections) every 24 months is recommended to prevent injuries and maintain the quality of the product.

In general, all products are subject to compliance with the maintenance intervals during the warranty period. This is the only way to maintain full warranty cover.

Additional services such as repairs may be provided in the course of maintenance. These additional services may be provided free of charge or can be billable according to an advance cost estimate, depending on the extent and validity of the warranty.

The following components must always be sent in for maintenance and repairs:

The product, battery charger and power supply. The shipping container for the loaner unit you receive must be reused for sending back the components requiring inspection.

9 Legal information

9.1 Liability

The manufacturer will only assume liability if the product is used in accordance with the descriptions and instructions provided in this document. The manufacturer will not assume liability for damage caused by disregarding the information in this document, particularly due to improper use or unauthorised modification of the product.

9.2 Trademarks

All product names mentioned in this document are subject without restriction to the respective applicable trademark laws and are the property of the respective owners.

All brands, trade names or company names may be registered trademarks and are the property of the respective owners.

Should trademarks used in this document fail to be explicitly identified as such, this does not justify the conclusion that the denotation in question is free of third-party rights.

9.3 CE conformity

Otto Bock Healthcare Products GmbH hereby declares that the product is in compliance with applicable European requirements for medical devices.

This product meets the requirements of the 2014/53/EU directive.

The full text of the regulations and requirements is available at the following Internet address: http://www.ottobock.com/conformity

9.4 Local Legal Information

Legal information that applies **exclusively** to specific countries is written in the official language of the respective country of use in this chapter.



This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1) This device may not cause harmful interference, and

2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/ TV technician for help.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Caution: Exposure to Radio Frequency Radiation.

This device must not be co-located or operating in conjunction with any other antenna or transmitter.

Responsible party: Otto Bock Health Care, LP 3820 West Great Lakes Drive Salt Lake City, Utah 84120-7205 USA Phone + 1-801-956-2400 Fax + 1-801-956-2401

This device complies with RSS 210 of Industry Canada.

Operation is subject to the following two conditions:

(1) this device may not cause interference, and

(2) this device must accept any interference, including interference that may cause undesired operation of this device.

L' utilisation de ce dispositif est autorisée seulement aux conditions suivantes:

(1) il ne doit pas produire d'interference et

(2) l' utilisateur du dispositif doit étre prêt à accepter toute interference radioélectrique reçu, même si celle-ci est susceptible de compromettre le fonctionnement du dispositif.

Caution: Exposure to Radio Frequency Radiation.

The installer of this radio equipment must ensure that the antenna is located or pointed such that it does not emit RF field in excess of Health Canada limits for the general population; consult Safety Code 6, obtainable from Health Canada's website

http://www.hc-sc.gc.ca/rpb. Responsible party: Otto Bock Healthcare Canada Ltd. 5470 Harvester Road L7L 5N5 Burlington, Ontario Canada Phone + 1-800-665-3327

Caution: Federal law (USA) restricts this device to sale by or on the order of a practitioner licensed by law of the State in which he/she practices to use or order the use of the device.

10 Appendices

11 Appendices

11.1 Symbols Used



Manufacturer



In some jurisdictions it is not permissible to dispose of these products with unsorted household waste. Disposal that is not in accordance with the regulations of your country may have a detrimental impact on health and the environment. Please observe the instructions of your national authority pertaining to return and collection.

CE

Declaration of conformity according to the applicable European directives

SN

Serial number (YYYY WW NNN) YYYY – year of manufacture WW – week of manufacture NNN – sequential number

11.2 Technical data

Ambient conditions	
Storage (with and without packaging)	+5 °C/+41 °F to +40 °C/+104 °F
	Max. 85% relative humidity, non-condensing
Transport (with and without packaging)	-20 °C/-4 °F to +60 °C/+140 °F
	Max. 90% relative humidity, non-condensing
Operation	-5 °C/+23 °F to +45 °C/+113 °F
	Max. 95% relative humidity, non-condensing

General information	
Reference number	8E500
Opening width	120 mm/4.72 inch
Weight of Michelangelo hand alone, without the AxonRotation Adapter and without a pros- thetic glove	approx. 510 g/18 oz
Flexion of the wrist	75°/four locking positions
Extension of the wrist	45°/three locking positions
Expected lifetime given compliance with the recommended maintenance intervals	5 years

The following gripping forces and load limits apply only when the battery of the Axon-Bus prosthetic system is fully charged and at room temperature.

Maximum gripping forces	
Gripping force "Opposition Mode"	Approx. 70 N
Gripping force "Lateral Mode"	Approx. 60 N
Gripping force "Neutral Mode"	Approx. 15 N

Load limits	
Maximum vertical load on the palm with locked wrist joint (e.g. when holding a sphere)	10 kg / 22.1 lbs
Maximum load on the actively driven fingers (index finger, middle finger) in the fully open hand position (e.g. holding a plate)	10 kg / 22.1 lbs
Maximum load on the actively driven fingers (index finger, middle finger) in the closed hand position (e.g. carrying bags)	20 kg / 44.1 lbs
Maximum vertical load on the knuckles (e.g. bracing oneself on the fist)	60 kg / 132 lbs
Weight of objects (typical diameter 19 mm/0.75 inch) before they slide out of the hand ("Power Grip" grip type)	18 kg / 39.6 lbs

11.3 Glossary

The term "Axon" stands for **A**daptive exchange of **n**europlacement data. The Axon-Bus is an Ottobock innovation for the field of exoprosthetics: a data transmission system, derived from safety-related bus systems in the aviation and automobile industries. For the user this means enhanced safety and reliability because of a considerably reduced sensitivity to electromagnetic interference in comparison with conventional systems.

The 8E500 Michelangelo is covered by the following patents:

Australia:	AU 2006 332 253; AU 2006 332 292; AU 2006 332 315; AU 2006 332 317; AU 2006 332 318; AU 2006 332 316;
Canada:	CA 2 631 970; CA 2 631 982; CA 2 632 241; CA 2 632 551; CA 2 632 240; CA 2 676 196; CA 2 678 987; CA 2 631 966
China:	CN 101 340 864; CN 101 340 865; CN 101 340 866; CN 101 340 867, CN 101 346 107; CN 101 346 109; CN 101 681 704
Japan:	JP 4 843 055; JP 5 242 409; JP 5 123 206; JP 5 074 414; JP 5 155 183; JP 5 389 667; JP 5 074 415
Mexico	MX 285 670; MX 286 932; MX 291 871; MX 291 872; MX 292 784
Russia:	RU 2 387 412; RU 2 414 871; RU 2 416 379; RU 2 423 952; RU 2 427 348; RU 2 429 803; RU 2 469 429
South Korea	KR 101 131 692; KR 101 169 834; KR 101 178 679; KR 101 178 646; KR 101 509 265; KR 101 509 264; KR 101 353 867; KR 101 265 934
Taiwan:	R.O.C. Invention Patent No. I421884
USA:	US 7 867 287; US 8 016 969; US 8 257 446; US 8 188 835; US 8 579 991; US 8 663 339; US 8 690 963
European Patent	EP 1962732 in AT, DE, FR, GB, IT, NL, SE, TR; EP 1962734 in AT, DE, FR, GB, IT, NL, SE, TR; EP 1962737 in AT, DE, FR, GB, IT, NL, SE, TR; EP 1962738 in DE, FR, GB, TR; EP 1971297 in AT, DE, FR, GB, IT, NL, SE, TR; EP 2129340 in DE, FR, GB, IS, IT, NL, SE, TR; EP 2115752 in AT, CH, DE, ES, FR, GB, IT, NL, SE, TR; EP 2528549 in DE, FR, GB, IS, PL, TR

Patents pending in Brazil, EPA, Germany, India, Mexico and USA.

The 8E500 Michelangelo or parts thereof are covered by the following registered designs and design patents:

Australia:	317212; 317213; 317214; 317789; 317790; 317791; 317792; 317866; 317867; 317868; 317869; 317870; 317871
Canada:	@Ottobock No. 122162; 122163
China:	ZL 200730154423.X; ZL 200730154429.7; ZL 201130050582.1; ZL 201130050654.2; ZL 200730154424.4; ZL 200730154425.9
European Design:	No.000786421; No.000786694; No.001824004
Germany:	40701345.8; 40701357.1
India:	212295; 212296; 212297; 212298; 212299; 212300; 212301; 212302; 212303
Japan:	Registered Design No. 1 365 277; 1 365 278
Russia:	69 071; 70 542
Taiwan:	R.O.C. Design Patent D 128 170; D 128 171
USA:	Patent US D 595,854; D 597,672; D 694,189; D697 030

Michelangelo is a tradename of Otto Bock Healthcare GmbH.

Michelangelo is a registered trademark in many countries of the world, beside others registered at the US Patent and Trademark Office, Reg.-No. 4008171.

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