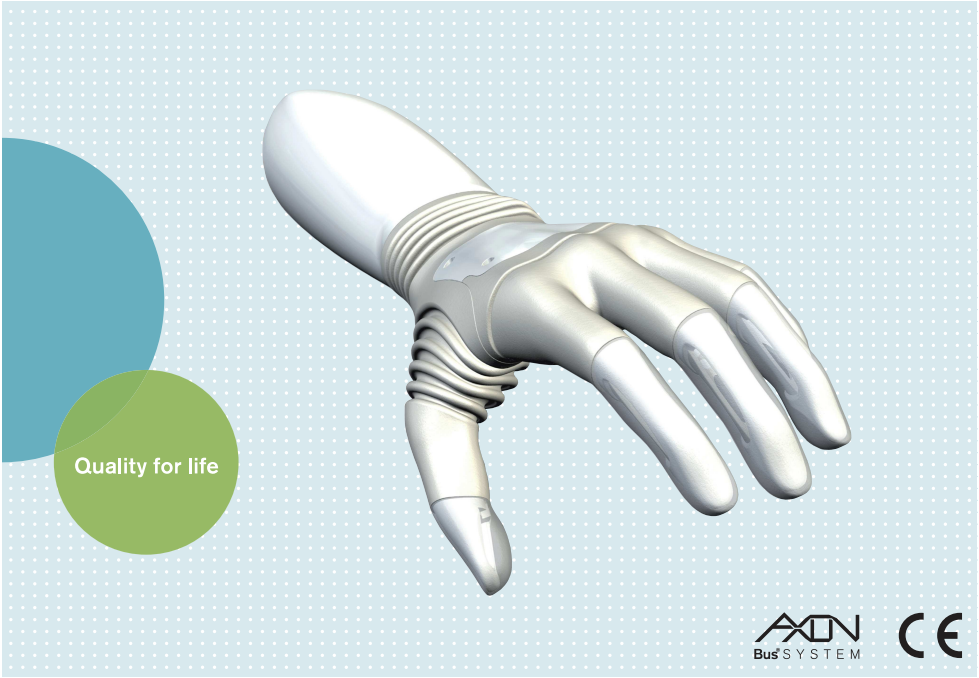
ottobock.



Michelangelo Hand Transcarpal 8E550

1 Foreword

INFORMATION

Date of last update: 2022-02-07

- ► 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.

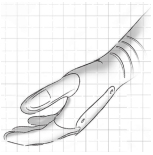
The 8E550=R/L Michelangelo Hand Transcarpal is referred to as the product / Axon-Bus terminal device / Michelangelo Hand below.
These instructions for use provide you with important information on the use, adaptation and handling of the product.
Only put the product into use in accordance with the information contained in the accompanying documents supplied.
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.

2 Product description

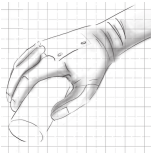
2.1 Function

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.

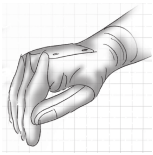
Gripping modes of the Michelangelo Hand
The following gripping options are possible:



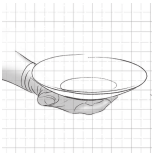
Neutral Position
Natural, physiological appearance in the rest position.



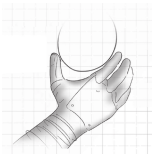
Lateral Power Grip
The thumb moves laterally to the index finger; this laterally fixates medium-sized objects when the thumb is in the half-open position.



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

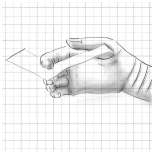


Open Palm
In the open palm position, the thumb is positioned all the way out; this allows for a flat hand position with a completely opened thumb position. The degree of mobility for internal and external rotation of the forearm depends on the length of the residual limb. A compensatory movement from the upper arm may be required in order to hold a flat object in a horizontal position.
INFORMATION: The starting position of the rotation setting can be adjusted within a range of ± 15 ° (see page 11, see fig. 8).



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.

2.2 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 8E550 Michelangelo Hand Transcarpal is to be used **exclusively** for upper limb exoprosthetic fittings.

3.2 Conditions of use

The Axon-Bus prosthetic system was developed for everyday use and must not be used for unusual activities. These unusual activities include, for example, sports with excessive strain and/or shocks to the socket connection (pushups, downhill racing, mountain biking, ...) or extreme sports (free climbing, paragliding, etc.). Furthermore, the Axon-Bus prosthetic system should not be used for the operation of 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 13).

3.3 Indications

The 8E550 Michelangelo Hand Transcarpal can be used for unilateral or bilateral amputees from a transradial to transcarpal amputation level or in the case of dysmelia of the forearm.

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

4.2 Structure of the safety instructions

⚠ WARNING

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

⚠ WARNING

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.

⚠ WARNING

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.

⚠ WARNING

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.

⚠ 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.

⚠ CAUTION

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

⚠ CAUTION

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.

⚠ CAUTION

Distance to HF communication devices is too small (e.g. mobile phones, Bluetooth devices, WiFi devices)

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

- ► Therefore, keeping the following minimum distances to these HF communication devices is recommended:
  - • Mobile phone GSM 850/GSM 900: 0.50 m
  - • Mobile phone GSM 1800/GSM 1900/UMTS: 0.35 m
  - • DECT cordless phones incl. base station: 0.18 m
  - • WiFi (routers, access points,…): 0.11 m
  - • Bluetooth devices (third-party products not approved by Ottobock): 0.11 m

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.

⚠ CAUTION

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.

⚠ CAUTION

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

Risk of pinching between the fingertips
Injury due to pinching of body parts.
► Ensure that no body parts are between the fingertips when using the product.

⚠ 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 13).

⚠ CAUTION

Penetration of dirt and moisture in the Axon-Bus components
Injury due to faulty control or malfunction of the Axon-Bus prosthetic system.
► Ensure that neither solid particles nor liquids can penetrate into the Axon-Bus prosthetic system or Axon-Bus components (e.g. the Axon-Bus gripping component).

⚠ CAUTION

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.

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

⚠ CAUTION

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

Charging the Axon-Bus prosthetic system with an incorrect power supply/battery charger
Damage to the Axon-Bus prosthetic system due to incorrect voltage, current or polarity.
- ► Use only power supply units/battery chargers approved for the Axon-Bus prosthetic system 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. 8E550=L/R-M Michelangelo Hand Transcarpal
- 1 pc. 10S550=M lamination ring
  Includes the lamination dummies for the upper and lower side in addition to the lamination ring.
- 8 pc. 501S101=M4x12 countersunk head screws
- 8 pc. 501S84=M4x14 countersunk head screws
- 1 pc. Instructions for use (qualified personnel)
- 1 pc. Instructions for use (user)
- 1 pc. prosthesis passport
- 1 pc. cosmetic case for battery charger and power supply

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
- 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

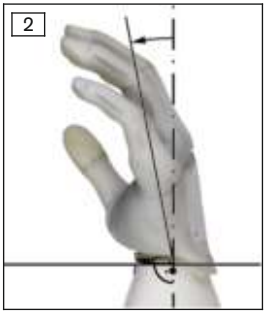
6.1 Alignment

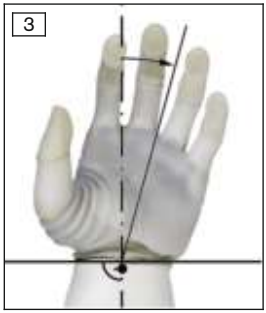
INFORMATION

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.

Please observe the following points during alignment of the Michelangelo Hand Transcarpal:

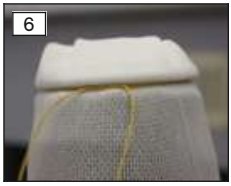
Flexion and ulnar deviation





The Michelangelo Hand Transcarpal is designed in such a way that the hand is positioned in a slightly flexed (**see fig. 2**), ulnar deviation (**see fig. 3**) position when the lamination ring is mounted at a 90° angle to the socket axis (**see fig. 1**).
This design is based on the relaxed position of the physiological hand and gives the Transcarpal prosthesis a natural appearance.
The recommended alignment is to be used as a guideline for the prosthetic alignment. Before the lamination ring is laminated, the position of the lamination ring must be adapted to the patient's requirements. This cannot be changed later on.

6.1.1 Fabricating the forearm socket



Prerequisites for lamination

- Foaming of the socket and sanding of the inner socket model have been completed.
- The PVA bag has been soaked, pulled over the foam core and knotted at the distal end.
- The lamination ring has been completely assembled with the lamination cover and affixed in the proper position to the PVA bag using double-sided adhesive tape.

Preparation for lamination

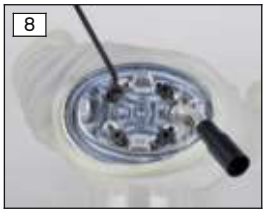
1) Cut off 2 double-length layers of Perlon stockinette.
2) (**see fig. 4**) Pull 1 layer of Perlon stockinette over the socket and tie it off in the proximal groove.

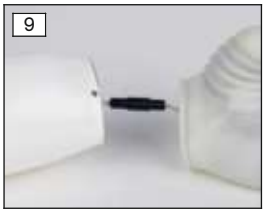
3) (**see fig. 5**) If extra reinforcement is required, use double-sided adhesive tape to affix carbon fibre cloth to the first layer of the Perlon stockinette as a frame structure.
4) Pull the second layer of Perlon stockinette downwards over the carbon fibre cloth.
   → Check whether the Perlon stockinette is still in the proximal groove.
5) Cut off 2 double-length layers of Perlon stockinette once more.
6) Turn the Perlon stockinette inside out.
7) (**see fig. 6**) Pull 1 layer of Perlon stockinette over the socket and tie it off in the distal groove.
8) Pull down the second layer of the Perlon stockinette.
   → Check whether the Perlon stockinette is still in the distal groove.
9) Laminate the socket.

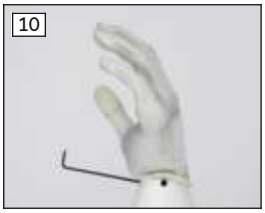
Finishing the socket

1) (**see fig. 7**) Once lamination has been completed, melt the screw holes for the lamination ring through the socket from the inside.
2) Drill the screw holes from the outside using a 4 mm drill bit and then countersink the screw holes on the outside.
3) Insert the supplied screws in the holes and check whether the screws protrude at least 4.5 mm into the interior.
   → If the screw length is too short, use longer screws. Please see the section "Technical data" for approved screws (see page 13).

6.1.2 Connecting the Michelangelo Hand with the socket







Once the socket has been completed, the rotational position of the Michelangelo Hand needs to be checked.

1) (**see fig. 8**) Loosen the 5 screws in the connection plate slightly and twist the hand. A correction of ± 15 ° is possible.
2) Then tighten the screws to a torque of 1.5 Nm.
3) (**see fig. 9**) Apply silicone grease to the connector plugs and connect them.
   → Position the cables and plugs such that they will not be damaged when putting on the Michelangelo Hand.
4) Place the hand on the socket.
5) (**see fig. 10**) Insert the provided screws into the bore holes on the sides and tighten them to 1.5 Nm.

6.2 Donning the prosthetic glove

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.

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.

6.3 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 Cleaning

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).

1) Clean the product with a damp cloth and mild soap (e.g. Ottobock 453H10=1-N Derma Clean) when needed.
   Ensure that no liquid penetrates into the system component(s).
2) Dry the product with a lint-free cloth and allow it to air dry fully.

8 Maintenance

Performing regular maintenance (service inspections) every 24 months is recommended to prevent injuries and maintain the quality of the product.
The grace period is no more than one month before or three months after maintenance is due.
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

All legal conditions are subject to the respective national laws of the country of use and may vary accordingly.

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.
The product meets the requirements of the RoHS Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic devices.
The full text of the regulations and requirements is available at the following Internet address: http://www.ottobock.com/conformity

10 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
Charging the battery	+5 °C/+41 °F to +40 °C/+104 °F Max. 85% relative humidity, non-condensing

General information		
Reference number	8E550=L-M or 8E550=R-M	
Opening width	120 mm/4.72 inch	
Weight of Michelangelo Hand without prosthetic glove	approx. 460 g/16 oz	
Approved screws for connecting Michelangelo Hand with socket	Length: 12 mm (in scope of delivery)	Length: 14 mm (in scope of delivery)
	501S101=M4X12	501S84=M4X14
Product service life	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 (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

Load limits	
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 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

MD

Medical device

11.2 Glossary

The term "Axon" stands for **A**daptive e**x**change **o**f **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 8E550 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
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
USA:	US 7 867 287; US 8 016 969; US 8 257 446; US 8 188 835; US 8 579 991

Patents pending in Australia, Brazil, Canada, China, EPA, Germany, India, Japan, Mexico, South Korea, Russia, Taiwan and USA.

The 8E550 Michelangelo or parts thereof are covered by the following registered designs and design patents:

Australia:	317214; 317789
Canada:	ⒹOttobock No. 122162; 122163
China:	ZL 200730154423.X; ZL 200730154429.7; ZL 201130050582.1; ZL 201130050654.2
European Design:	No.000786421; No.000786694; No.001824004
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