Axon-Bus Prosthetic System

Instructions for use (user)
1 Foreword

<table>
<thead>
<tr>
<th>INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last update: 2014-06-30</td>
</tr>
<tr>
<td>► Please read this document carefully.</td>
</tr>
<tr>
<td>► Follow the safety instructions and the precautions specified in this accompanying document.</td>
</tr>
<tr>
<td>► Please contact the responsible prosthetist if assistance is required during the start-up, use or maintenance of the product, or in the event of unexpected operating behaviour or circumstances.</td>
</tr>
</tbody>
</table>

Have your prosthetist instruct you in the use of the prosthesis.
Only put the prosthesis into use according to the information contained in the accompanying documents supplied.

2 Product Description
The Axon-Bus prosthetic system comprises the following components:

2.1 Battery Charger (757L500 AxonCharge Integral)
The battery charger is used to charge the battery. LEDs on the charger provide information about the following:
- Operating states of the battery charger
- Operating states of the Axon-Bus prosthetic system
- Battery charge level.

2.2 Battery (AxonEnergy Integral 757B500 or 757B501)
Power is supplied to the Axon-Bus prosthetic system by the battery integrated in the socket.
The charging receptacle on the socket provides the following functions:
- Contacts for charging the battery
- LEDs to indicate the operating state and battery charge level
- Button to switch the Axon-Bus prosthetic system on and off
- Beeper for audible feedback on operating states.

2.3 Wrist Unit
The wrist unit consists of the following components:
- 9S500=* AxonFlexion Adapter (mechanical flexion unit)
- AxonRotation Adapter 9S501 (mechanical rotation unit).

2.3.1 AxonFlexion Adapter 9S500=* 
Starting at the neutral position, the joint can be flexed by approx. 75° in 4 ratchet positions; extension is approximately 45° with 3 ratchet positions.

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 Flexible Mode, push the unlock lever to the stop (see Fig. 8) until it engages. The joint can be moved without engaging at the ratchet positions. Pushing the lever again terminates Flexible Mode and the wrist unit engages at the next available position in Rigid Mode.

Rigid Mode
Various everyday conditions require an individually adjustable wrist unit of the gripping component in Rigid Mode. When the unlock lever is only pushed lightly and not to the stop (see Fig. 8), 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.
2.3.2 AxonRotation Adapter 9S501
The gripping component can be manually rotated continuously through 360°. There are 24 ratchet positions for this purpose, one at every 15°.

2.4 Elbow Joint
12K501 AxonArm Ergo (myoelectrically locked elbow joint)
Locking and unlocking is controlled myoelectrically by means of electrode signals or with a switch.

12K500 AxonArm Hybrid (mechanically locked elbow joint)
Locking and unlocking is carried out mechanically, e.g. by means of body harnesses.

2.5 Axon-Bus Gripping Component (Michelangelo Hand 8E500)
The Michelangelo Hand is a myoelectrically controlled gripping component in the modular Axon-Bus prosthetic system. Complex gripping kinematics combined with the anatomical appearance and low weight support everyday activities for maximum rehabilitation value. It features the following possible gripping options:

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 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
If the fingers are spread several flat, thin objects can be held between the finger-tips when the hand is closed.

3 Application
3.1 Indications for Use
The Axon-Bus prosthetic system is to be used exclusively for exoprosthesis fittings of the upper limbs.

3.2 Use/Field of Application
The Axon-Bus prosthetic system is suitable for unilateral or bilateral amputations starting with the transradial/transhumeral amputation level or, in case of dysmelia, for forearm or upper arm fittings.

3.3 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 wrist unit (pushups, downhill, 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 prosthesis 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 22).

3.4 Qualification
Fitting a patient with the Axon-Bus prosthetic system may only be carried out by a prosthetist who has been authorised by Ottobock after completion of a corresponding training course.

4 Safety
4.1 Explanation of Warning Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![WARNING]</td>
<td>Warning regarding possible serious risks of accident or injury.</td>
</tr>
<tr>
<td>![CAUTION]</td>
<td>Warning regarding possible risks of accident or injury.</td>
</tr>
<tr>
<td>![NOTICE]</td>
<td>Warning regarding possible technical damage.</td>
</tr>
</tbody>
</table>

4.2 Structure of the safety instructions

![CAUTION]
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 case of failure to observe the hazard
> E.g.: Consequence 2 in case 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

⚠️ CAUTION
Non-observance of safety instructions
> Injury due to faulty control or malfunction of the Axon-Bus prosthetic system.
> Destruction of Axon-Bus components.
► Follow the safety instructions in this accompanying document.

⚠️ WARNING
Operating a vehicle with the prosthesis
Accidents due to unexpected actions of the prosthesis.
► The prosthesis should not be used for the operation of motor vehicles and heavy equipment (e.g. construction machines).

⚠️ WARNING
Operating machines with the prosthesis
Injury due to unexpected actions of the prosthesis.
► The prosthesis should not be used for the operation of industrial machines or motor-driven equipment.

⚠️ WARNING
Simultaneous use of the product with active, implanted systems
Injuries due to temporary influences of active implantable systems (e.g. pacemakers, defibrillators etc.) due to electromagnetic interference of the product.
► Do not bring the product into the immediate proximity of active, implantable systems.

⚠️ 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.

⚠️ WARNING
Charging the prosthesis without taking it off
Risk of electric shock due to defects in the power supply unit or in the battery charger.
► For safety reasons, remove the prosthesis prior to charging it.

⚠️ CAUTION
Unauthorised manipulation of Axon-Bus components
Injury due to faulty control or malfunction of the Axon-Bus prosthetic system.
► Manipulations to the Axon-Bus prosthetic system other than the tasks described in these instructions for use are not permitted.
► The Axon-Bus prosthetic system and any damaged Axon-Bus components may only be opened and/or repaired by certified Ottobock Myo-Service technicians.
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 faulty control or malfunction of the Axon-Bus prosthetic system.

- 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 functions of the Axon-Bus prosthetic system.

**CAUTION**

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

Injury due to faulty control or malfunction of the prosthesis system.

- 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, etc.): 0.11 m
  - Bluetooth devices (third-party products not approved by Ottobock): 0.11 m

**CAUTION**

Wearing in extreme ambient temperatures

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

- Avoid wearing the prosthesis in areas with temperatures outside of the permissible range. See the section “Technical Data”.

4.5 Information on Use

**CAUTION**

Using the prosthesis with pointed or sharp objects (e.g. knives in the kitchen)

Injury due to unintentional movements.

- Use extra caution when using the prosthesis for handling pointed or sharp objects.

**CAUTION**

Excessive strain or overloading due to unusual activities

Injury due to faulty control or malfunction of the Axon-Bus prosthetic system.
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 wrist unit (pushups, downhill, mountain biking) or extreme sports (free climbing, paragliding, etc.).

- Careful handling of the Axon-Bus prosthetic system and the Axon-Bus components not only increases their service life, but is primarily in the interest of your own safety.
- If the Axon-Bus prosthetic system and the Axon-Bus components have been subjected to extreme loads (e.g. through a fall or similar occurrence) the Axon-Bus prosthetic system must be inspected by a prosthetist immediately for possible damage. The contact person for this is the responsible prosthetist, who will send the Axon-Bus prosthetic system to Ottobock Service if necessary.

**CAUTION**

Mechanical overload caused by mechanical influences or external loads

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

- Do not subject the Axon-Bus components to mechanical vibrations or impacts.
- Check the Axon-Bus components for any visible damage before each use.

**CAUTION**

Penetration of dirt and moisture

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**

Unintentional unlocking of the Axon-Bus gripping component

Injuries 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 care

Damage or fracture due to embrittlement of the plastic through the use of acetone, petrol or similar solvents.

- Clean the Axon-Bus prosthetic system with a damp cloth and mild soap only.
- Use only the following products for cleaning/disinfecting the inner socket:
  
  **Cleaning:** 453H10=1 Ottobock DermaClean
  
  **Disinfection:** 453H16 Ottobock DermaDesinfect

**4.6 Information on the Power Supply/Battery Charging**

**CAUTION**

Dirtying of the electrical contacts

Injuries due to faulty control or malfunction of the Axon-Bus prosthetic system caused by an insufficient supply of power to the Axon-Bus components.

- Ensure that the contacts of the charging receptacle are always clean and free of grease.
- Clean the electrical contacts of the battery charger and charging receptacle regularly using cotton swabs and a mild soap solution.
Avoid damaging the contact surface coating with pointed or sharp objects.

**NOTICE**

**Use of incorrect power supply unit**

Destruction of Axon-Bus prosthetic system due to incorrect voltage, current or polarity.

- To charge the Axon-Bus prosthetic system use only the 757L500 AxonCharge Integral power supply unit.

**NOTICE**

**Contact of the charging plug with magnetic data carriers**

Loss of data or wiping of the data carrier.

- Do not place the magnetic charging plug on data carriers such as credit cards, diskettes, audio and video cassettes or the like.

**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.

4.7 Notes on Using an Elbow Joint (e.g. 12K501 AxonArm Ergo, 12K500 AxonArm Hybrid)

**CAUTION**

**Risk of pinching in elbow joint flexion region**

- Injuries due to pinching of body parts.
  - Ensure that fingers and other body parts are not in this area when bending the elbow joint.

**CAUTION**

**Manual unlocking of elbow lock under load**

Injury by release of elbow lock under load.

- Particular caution should be exercised when unlocking the elbow lock while lifting heavy loads.
- Be careful when unlocking the lock under such conditions due to the possibility of injury.

**CAUTION**

**Penetration of dirt and moisture**

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

- Do not let foreign particles or liquids get into the prosthetic arm.
- Do not expose the prosthetic arm, especially the elbow joint, to dripping or splashing water.
- Wear the prosthetic arm and especially the elbow joint under suitably resistant clothing in the rain.

**NOTICE**

**Coating, gluing or painting the product**

Damage or fracture due to chemical processes.

- The product must not be coated, glued or painted.
5 Preparation for Use
The Axon-Bus prosthetic system must be charged before it can be used the first time.

5.1 Charge the Battery
By attaching the adapter, the power supply can be adapted to national plug standards.
1) Move the button in the direction of the arrow and remove the cover (see Fig. 1).
2) Allow the adapter to lock into the power supply (see Fig. 2).

5.2 Starting the Charging Process
1) Connect the power supply unit or the optionally available car power supply unit to the battery charger. Ensure correct polarity (see Fig. 3).
   INFORMATION: If LED 6 on the battery charger flashes red the charger or the power supply unit is defective.
2) Plug the power supply unit into the socket-outlet.
   → LED 6 (see Fig. 6, item 6) lights up green. If this is not the case, please see the section ‘Troubleshooting’ (see Page 18).
3) Connect the charging plug to the charging receptacle and allow it to snap into place (see Fig. 5).
   The charging process starts:
   • The beeper sounds briefly twice.
   • LED 6 flashes green.
   • LEDs 2 through 5 flash or light up according to the battery charge level.
   • The Axon-Bus prosthetic system is switched off automatically.

5.3 Displaying Battery Charge Level
During the charging process the current battery charge level is indicated by the LEDs lighting up in sequence (see Fig. 6, items 2–5).

<table>
<thead>
<tr>
<th>Action/Event</th>
<th>Battery charger</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Charging in progress</td>
<td>✚❚❚❚❚❚ 1</td>
<td>Battery empty</td>
</tr>
<tr>
<td>Charging in progress</td>
<td>✚❚❚❚❚ 1</td>
<td>Battery 25% charged</td>
</tr>
<tr>
<td>Charging in progress</td>
<td>✚❚❚❚ 1</td>
<td>Battery 50% charged</td>
</tr>
<tr>
<td>Charging in progress</td>
<td>✚❚❚ 1</td>
<td>Battery 75% charged</td>
</tr>
<tr>
<td>Charging in progress</td>
<td>✚❚ 1</td>
<td>Battery 100% charged</td>
</tr>
</tbody>
</table>

5.4 Finishing the Charging Process
The charging plug may be disconnected at any time. Partially charging the battery does not shorten its lifespan (no memory effect).
1) Disconnect the charging plug from the Axon-Bus prosthetic system.
2) Unplug the power supply unit from the socket-outlet.
3) To switch on the Axon-Bus prosthetic system press the charging receptacle button and hold for one second.

5.5 Query Battery Charge Level
The battery charge level can be queried at any time.
► With the Axon-Bus prosthetic system switched on, press the charging receptacle button (see Fig. 4, arrow) and hold for less than one second.

<table>
<thead>
<tr>
<th>Event</th>
<th>Charging receptacle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery almost empty</td>
<td>●</td>
</tr>
<tr>
<td>Battery 50% charged</td>
<td>○</td>
</tr>
<tr>
<td>Battery 100% charged</td>
<td>● and ○</td>
</tr>
</tbody>
</table>
5.6 Safety Shutoff
The purpose of the Axon-Bus prosthetic system safety shutoff is to protect the battery; it is triggered in case of:
• Excessively high or low temperature
• Overvoltage or undervoltage
• Short circuit.
After a short circuit the charging plug must be plugged into the charging receptacle and then unplugged in order for the electronics to be activated.

6 Use
6.1 Separating the Axon-Bus Gripping Component from the Socket

⚠️ CAUTION
Changing Axon-Bus gripping components when turned on
Injury due to faulty control or malfunction of the Axon-Bus prosthesis system.
 ► Power down the Axon-Bus prosthesis system by pressing the button in the charging receptacle before changing any Axon-Bus components (e.g. Axon-Bus gripping component).

1) To switch off the Axon-Bus prosthetic system, press the charging receptacle button and hold for more than one second (see Fig. 4, arrow).
2) Press both unlock buttons on the wrist unit (see Fig. 7).
 INFORMATION: For safety reasons the Axon-Bus gripping component cannot be removed if only one unlock button is pressed.
3) Pull off the Axon-Bus gripping component.

6.2 Attaching the Axon-Bus Gripping Component to the Socket
1) To switch off the Axon-Bus prosthetic system, press the charging receptacle button and hold for more than one second (see Fig. 4, arrow).
2) Slide the Axon-Bus gripping component on to the socket until it locks in place audibly.
3) Verify proper attachment by pulling on the Axon-Bus gripping component.

7 Initial Operation

 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.

7.1 Switching On the Axon-Bus Prosthetic System
 ► Press the charging receptacle button and hold for one second (see Fig. 4, arrow).
  → The beeper emits two short signals.

7.2 Switching Off the Axon-Bus Prosthetic System
 ► Press the charging receptacle button and hold for more than one second (see Fig. 4, arrow).
  → The beeper emits one long signal.

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.
1) With the Axon-Bus prosthetic system switched on, press the charging receptacle button and hold for approximately three seconds (see Fig. 4), until the Axon-Bus gripping component begins to open.
   → A pulsating beep will sound as it opens.
2) Releasing the button immediately stops the process of opening the Axon-Bus gripping component and turns the Axon-Bus prosthetic system off.

8 User Instructions

8.1 Storing the 8E500 Michelangelo Hand

⚠️ CAUTION

Storing the 8E500 Michelangelo Hand in the closed position
Injury due to faulty control or malfunction of the 8E500 Michelangelo Hand because of damage to the sensors and mechanism.
▶ Store the 8E500 Michelangelo Hand in the open state (neutral position) only.

8.2 Putting On the Axon-Bus Prosthetic System with the Donning Assist
8.3 Switching the Axon-Bus Prosthetic System On/Off

8.4 Hand Flexion, Hand Extension

8.5 Utilising Hand Flexion
8.6 Hand Rotation

8.7 Supporting the Michelangelo Hand 8E500
9 Application Examples

9.1 Using Finger Adduction/Abduction, e.g. when Carrying a Bag

9.2 Using the Fixed Wrist Unit

9.3 Avoiding Compensating Movements
9.4 Interaction with Other People

9.5 Grasping Objects on the Floor

9.6 Grasping Cutlery

10 Operating States
There are 3 ways for the Axon-Bus prosthetic system to give feedback about the operating states. Signals are output individually or in combined form. The following components are equipped with a means for providing feedback:
• Charging receptacle (visual) and beeper (acoustic)
• Battery charger (visual).
10.1 Charging Receptacle and Beeper

<table>
<thead>
<tr>
<th>Action/Event</th>
<th>Charging receptacle</th>
<th>Beeper</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Query battery charge level</td>
<td></td>
<td></td>
<td>Battery fully charged</td>
</tr>
<tr>
<td>Query battery charge level</td>
<td></td>
<td></td>
<td>Battery 50% charged</td>
</tr>
<tr>
<td>Query battery charge level</td>
<td></td>
<td></td>
<td>Battery almost empty</td>
</tr>
<tr>
<td>Warning</td>
<td></td>
<td>3 x short</td>
<td>Battery empty, the Axon-Bus prosthetic system switches itself off</td>
</tr>
<tr>
<td>Switch on the Axon-Bus</td>
<td></td>
<td>2x short</td>
<td>Confirmation</td>
</tr>
<tr>
<td>Switch off the Axon-Bus</td>
<td></td>
<td>1x long</td>
<td>Confirmation</td>
</tr>
<tr>
<td>System</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Connect charging plug</td>
<td></td>
<td>2x short</td>
<td>Charging begins</td>
</tr>
<tr>
<td>Disconnect charging plug</td>
<td></td>
<td>1x long</td>
<td>Charging is finished</td>
</tr>
<tr>
<td>Emergency</td>
<td></td>
<td>Pulsating</td>
<td>Emergency opening of the Axon-Bus gripping component</td>
</tr>
</tbody>
</table>

10.2 Battery Charger and Beeper

The battery charger outputs operating states when connected to the power supply unit and the Axon-Bus prosthetic system.

(LED flashing)

- LED flashing
- LED illuminated
- LED not illuminated

<table>
<thead>
<tr>
<th>Action/Event</th>
<th>Battery charger</th>
<th>Beeper</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power supply unit connected to</td>
<td></td>
<td></td>
<td>Power supply unit ready</td>
</tr>
<tr>
<td>battery charger</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Charging cable connected to the</td>
<td></td>
<td>1x short</td>
<td>Initialising charging process</td>
</tr>
<tr>
<td>charging receptacle</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Charging in progress</td>
<td></td>
<td></td>
<td>Battery empty</td>
</tr>
<tr>
<td>Charging in progress</td>
<td></td>
<td></td>
<td>Battery 25% charged</td>
</tr>
<tr>
<td>Charging in progress</td>
<td></td>
<td></td>
<td>Battery 50% charged</td>
</tr>
<tr>
<td>Charging in progress</td>
<td></td>
<td></td>
<td>Battery 75% charged</td>
</tr>
<tr>
<td>Charging in progress</td>
<td></td>
<td></td>
<td>Battery 100% charged</td>
</tr>
</tbody>
</table>

11 Repair

11.1 Maintenance

Since all moving mechanical components are subject to wear and tear, regular service is required within the guarantee period. The entire Axon-Bus prosthetic system is inspected by Ottobock Service (Ottobock Myo-Service). Wear parts are replaced as required. Omitting a scheduled service inspection voids the guarantee.

11.2 Troubleshooting

The Axon-Bus prosthetic system indicates operating states audibly and visually.
### Action/Event

<table>
<thead>
<tr>
<th>Action/Event</th>
<th>Charging receptacle</th>
<th>Beeper</th>
<th>Remedy</th>
</tr>
</thead>
</table>
| Error in the Axon-Bus prosthetic system | ![charging symbol]  | 1x long | Switch the Axon-Bus prosthetic system off/on  
Open/close the Axon-Bus gripping component  
In case of a persistent error, contact your prosthetist. |
| Outside operating temperature range   | ![charging symbol]  |        | Allow the Axon-Bus prosthetic system to warm up or cool down; see the section ‘Technical Data’ (see Page 22). |

### Action/Event

<table>
<thead>
<tr>
<th>Action/Event</th>
<th>Battery charger</th>
<th>Probable cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery not charging</td>
<td>![charging symbol]</td>
<td>The charging plug is not properly connected to the charging receptacle.</td>
<td>Disconnect and then reconnect the charging plug.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The charging plug or charging receptacle contacts are dirty.</td>
<td>Use a cotton swab and a mild soap solution to clean the contacts of both components.</td>
</tr>
<tr>
<td>Battery not charging</td>
<td>![charging symbol]</td>
<td>The battery or battery charger temperature is outside the permissible range.</td>
<td>Disconnect the charging plug and allow the battery or the charger to warm up or cool down.</td>
</tr>
<tr>
<td>Error message</td>
<td>![charging symbol]</td>
<td>There is an error in the Axon-Bus prosthetic system.</td>
<td>Contact your prosthetist.</td>
</tr>
<tr>
<td>Service message</td>
<td>![charging symbol]</td>
<td>Service required.</td>
<td>Contact your prosthetist.</td>
</tr>
<tr>
<td>Error message</td>
<td>![charging symbol]</td>
<td>The battery charger or the power supply unit is defective.</td>
<td>Contact your prosthetist.</td>
</tr>
</tbody>
</table>

### 12 Disposal

This product may not be disposed of with regular domestic waste in all jurisdictions. Disposal that does not comply with the regulations of your country may have a detrimental impact on health and the environment. Please observe the information provided by the responsible authorities in your country regarding return and collection processes.
13 Legal Information

13.1 Liability
Otto Bock Healthcare Products GmbH, hereafter referred to as manufacturer, assumes liability only if the user complies with the processing, operating and maintenance instructions as well as the service intervals. The manufacturer explicitly states that this device may only be used in combination with components that were authorised by the manufacturer (see instructions for use and catalogues). The manufacturer does not assume liability for damage caused by component combinations which it did not authorise.
The device may only be opened and repaired by authorised Ottobock technicians.

13.2 Trademarks
All denotations within this accompanying document are subject to the provisions of the respective applicable trademark laws and the rights of the respective owners, with no restrictions.
All brands, trade names or company names may be registered trademarks and are subject to the rights of the respective owners.
Should trademarks in this accompanying 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.

13.3 CE Conformity
The Axon-Bus components meet the requirements of directive 93/42/EEC for medical devices. The Axon-Bus components have been classified as class I devices according to the classification criteria for medical devices outlined in annex IX of the directive. The manufacturer therefore drew up the declaration of conformity under its own responsibility according to annex VII of the directive.
The AxonMaster also meets the requirements of directive 1999/5/EC for radio equipment and telecommunications terminal equipment. The declaration of conformity was created by the manufacturer according to annex IV of the directive. A copy of the declaration of conformity can be requested from the manufacturer (see last page).

13.4 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’interférence et
(2) l’utilisateur du dispositif doit être prêt à accepter toute interférence radioélectrique reçue, 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 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.**

14 Appendices
14.1 Symbols Used

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.
Declaration of conformity according to the applicable European directives

SN YYYY WNN Serial number

14.2 Technical data

<table>
<thead>
<tr>
<th>Environmental conditions</th>
<th>-20 °C/-4 °F to +40 °C/+104 °F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage and transport in original packaging</td>
<td>-20 °C/-4 °F to +40 °C/+104 °F</td>
</tr>
<tr>
<td>Storage and transport without packaging</td>
<td>max. 80% relative humidity, non-condensing</td>
</tr>
<tr>
<td>Operation</td>
<td>-10 °C/+14 °F to +60 °C/+140 °F</td>
</tr>
<tr>
<td>Charging the battery</td>
<td>+5 °C/+41 °F to +40 °C/+104 °F</td>
</tr>
</tbody>
</table>

General Information

<table>
<thead>
<tr>
<th>Reference number</th>
<th>8E500</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opening width</td>
<td>120 mm/4.72 inch</td>
</tr>
<tr>
<td>Weight of the Michelangelo Hand alone without AxonRotation Adapter, AxonFlexion Adapter and prosthetic glove</td>
<td>approx. 420 g/14.82 oz</td>
</tr>
<tr>
<td>Product service life</td>
<td>5 years</td>
</tr>
</tbody>
</table>

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

<p>| 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 (&quot;Power Grip&quot; grip type) | 18 kg / 39.6 lbs |</p>
<table>
<thead>
<tr>
<th><strong>Load limits when using an elbow joint</strong> (e.g.12K501 AxonArm Ergo, 12K500 Axon-Arm Hybrid)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum vertical load with locked elbow joint and a forearm length of 305 mm / 12 inch</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Prosthesis battery</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Battery type</strong></td>
</tr>
<tr>
<td><strong>Battery service life</strong></td>
</tr>
<tr>
<td><strong>Charging time until battery is fully charged</strong></td>
</tr>
<tr>
<td><strong>Behaviour of the product during the charging process</strong></td>
</tr>
<tr>
<td><strong>Operating time of the product with fully charged battery</strong></td>
</tr>
</tbody>
</table>

**14.3 Accessories**

| 4X500 AxonCharge Mobile                                                                                                                                        | Car power supply |
| 757S500=AUS AxonCharge adapter                                                                                                                                  | AUS power supply adapter |
| 757S500=GB AxonCharge adapter                                                                                                                                    | GB power supply adapter |

**14.4 Glossary**

**14.4.1 Axon**

The term "Axon" stands for *Adaptive eXchange Of Neuroplacement* 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.
Ottobock has a certified Quality Management System in accordance with ISO 13485.