ottobock.

AxonArm Ergo 12K501=*

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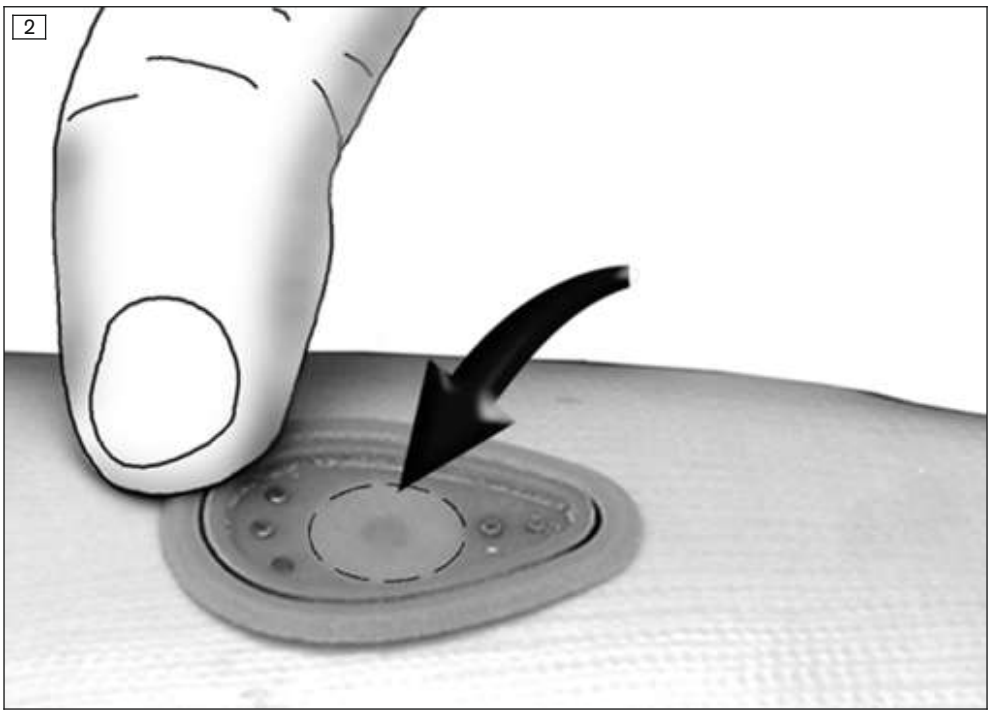

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EN

1 Foreword

INFORMATION

Date of last update: 2022-07-07

- ► 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 12K501 AxonArm Ergo is referred to simply as the AxonArm or the product 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.

2 Product description

2.1 Construction and Function

The 12K501 AxonArm Ergo is a myoelectrically locked elbow joint. Locking and unlocking is controlled myoelectrically by means of electrode signals or with a switch.

The AxonArm Ergo helps the patient perform everyday tasks in combination with other prosthetic components of the Axon-Bus prosthesis solution, such as the 8E500 Michelangelo hand.

A lithium-ion battery integrated into the product provides the required energy.

If the elbow joint is switched off or the battery is depleted, the pull cable can be used to lock and unlock the elbow joint in any position, even when loaded.

2.2 Definition of terms

AFB (Automatic Forearm Balance)

AFB is a flexion assist in the form of a mechanical gear mechanism in the forearm of the elbow joint. The Automatic Forearm Balance provides for harmonious movement control, free swing and reduction of energy consumption. It stores the energy that is released when the arm is extended and uses this to assist with flexion. The degree of flexion assistance can be adjusted to the individual weight of the prosthetic forearm and to different clothing by means of a dial.

The free swing of the forearm corresponds to the natural movement behaviour of the upper limb while walking. After extension of the forearm, the vario-gear automatically decouples the forearm from the drive unit so it can swing freely. The AFB slightly dampens the free swing, thereby making a close approximation of the forearm's physiological movement behaviour possible.

The product does not consume electrical energy during the free swing. A short muscle signal to flex the product ends the free swing.

Easy Plug

The Easy Plug is a through-connection for myoelectrically controlled prostheses that is integrated in the elbow joint.

The connecting cables of the electrodes, switches and batteries are connected to the Easy Plug. Its interior cable routing minimises the risk of cable breaks.

With the AxonArm, only the 13E500 AxonMaster is connected in the area of the elbow ball. All other plug connections have no function and are therefore closed with cover caps.

Forearm cable

The forearm cable establishes the electrical connection between the product and the terminal device. The cable is rolled up in the forearm of the elbow joint on delivery and can be replaced in case of damage.

Lock

Releasing and locking the elbow joint is automated according to operating situations, the applied load and the control signal generated by the patient by means of the electronically controlled locking drive.

The product has a load capacity of up to 230 N in the locked state with a forearm lever length of 305 mm. The lock will slip under higher loads.

Mechanical release
With the product switched off or when the battery is drained, the elbow can be manually unlocked and locked again with a slight pull on the unlock cable. In this way, the forearm can be brought into the desired position. Mechanical release can also take place under load.

Electronic release
Locking and unlocking is controlled by myoelectric electrode signals or a switch. These control devices have to be connected to the 13E500 AxonMaster. See the corresponding instructions for use for further information on control devices and control programs.

Control of the electronic lock
Myoelectric control of the electronic lock can be realised in the following ways:
- One long co-contraction on channel 1 and 2 of the AxonMaster releases or engages the lock.
- A short co-contraction switches the grip of the terminal device.
- An impulse on channel 3 of the AxonMaster releases or engages the lock.

3 Intended use

3.1 Indications for use
The product is intended **exclusively** for upper limb exoprosthetic fittings.

3.2 Conditions of use
The product is designed for use by unilateral or bilateral amputees.

The product is intended **exclusively** for use on adults.

The product was developed for everyday use and must not be used for unusual activities. These unusual activities include, for example, extreme sports (free climbing, parachuting, paragliding, etc.).

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

3.4 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

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

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

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

- ► Observe the safety instructions and the stated precautions in this accompanying document.

⚠ CAUTION

Signs of wear and tear on the product components

Injury due to faulty control or malfunction of the product

- ► In the interest of preventing patient injuries and to maintain product quality, we recommend performing regular service.
- ► Please see the service pass for more information about the service intervals. This is included in the purchased extended warranty packages.

⚠ CAUTION

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.

⚠ CAUTION

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

Injury due to unexpected behaviour of the product 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 product.

⚠ CAUTION

Operating the product in very close proximity to other electronic devices

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

- ► Do not operate the product in the immediate vicinity of other electronic devices.
- ► Do not stack the product with other electronic devices during operation.
- ► If simultaneous operation cannot be avoided, monitor the product and verify proper use in the existing setup.

⚠ CAUTION

Operator errors during the adjustment procedure

Injury due to faulty control of the Axon-Bus prosthesis system.

- ► Participation in an Ottobock product training course is mandatory prior to using the product. During product training, you will receive a password which provides you with authorisation to access the 560X500=* AxonSoft software. To qualify for software updates, additional product training courses may be necessary.
- ► Do not share your unlock PIN.
- ► Use the online help which is integrated into the software.

⚠ CAUTION

Independent 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.
- ► Do not damage the battery or separate the connection cables between the battery packs.
- ► The Axon-Bus prosthetic system and any damaged Axon-Bus components may only be opened and/or repaired by certified Ottobock Myo-Service technicians.

⚠ CAUTION

Incorrect electrode settings

Injury due to faulty control or malfunction of the product.

- ► 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 Ottobock Myo-Service.
- ► Set the electrode gains as low as possible to reduce the risk of malfunctioning due to strong electromagnetic radiation (e.g. 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 electromagnetic interference (e.g. high-voltage lines, transmitters, transformer stations, computer tomographs, magnetic resonance tomographs, etc.).
- ► Allow the patient to rest during the adjustment of the electrodes; otherwise, muscle fatigue will lead to inconsistent results. As a result, the therapist will tend to set the electrode gains too high.

⚠ 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 Scope of Delivery and Accessories

5.1 Scope of delivery

- 1 pc. 12K501 AxonArm Ergo
- 1 pc. Lamination protection cover (disc with arrow)
- 1 pc. Lamination protection cover (hollow ball)
- 1 pc. Cable lock

- 2 pc. bracket cover
- 1 pc. lamination ring
- 1 pc. 13Z146 lamination ring (for Axon-Bus terminal device)
- 1 pc. clamp ring
- 4 pcs. mounting brackets
- 1 pc. spherical cord lock
- 4 pc. Cable ties
- 4 pcs. oval head self-tapping screw
- 1 pc. Instructions for use (qualified personnel)
- 1 pc. Technical information (qualified personnel)

5.2 Accessories

- 757L500 AxonCharge Integral
- 13E500 AxonMaster
- 9S501 AxonRotation Adapter (passive rotation unit)
- 13E200=* or 13E202=* electrode
- "560X500=* AxonSoft" adjustment software
- Axon-Bus terminal device (e.g. 8E500 Michelangelo hand)
- 9X18 Cable pull switch
- Prosthetic glove (e.g. 8S500=R/L AxonSkin Natural when 8E500 Michelangelo hand is used)

Additional MyoBock components such as suction socket electrode, electrode cable, pull-in tube and tube valve for suction socket as needed.

6 Preparing the product for use

6.1 Installing the AxonRotation Adapter

1) Use silicone grease to seal the plug connection.

2) Connect the AxonRotation Adapter with the connecting cable.

3) Position the AxonRotation Adapter such that the **middle screw holes on the lamination ring** can be used.
   INFORMATION: The other screw positions can be used for correcting the alignment of the AxonRotation Adapter after the lamination ring has been glued in.
4) Screw the AxonRotation Adapter to the lamination ring.

6.2 AxonMaster

Various control programmes and switching methods as well as the option of making refined patient-specific settings are available for optimum adaptation to the patient. The standard programmes can be selected using the 560X500=* AxonSoft adjustment software and include predefined control options and switching methods.

Two MyoBock electrodes, e.g., 13E200/202=*, or if necessary a pull switch, e.g., 9X18, can be connected to the 13E500 AxonMaster. For information please refer to the 647G590 instructions for use for the 13E500 AxonMaster

Input on AxonMaster	Electrode
Input 1	Closing the hand
Input 2	Opening the hand
Input 3	Pull switch (optional)

► Remove the cover caps from the required inputs. The remaining inputs cannot be used at this time and therefore remain covered by the caps.

6.2.1 Controlling the Electronic Lock

The electronic lock can be controlled myoelectrically by the following means configured at the factory:

- A long co-contraction on channels 1 and 2 of the AxonMaster releases or locks the lock.
- A short co-contraction switches the gripping mode of the gripper.
- A pulse on channel 3 of the AxonMaster releases or locks the lock.

6.2.2 Connecting the Electrodes

1) Remove the cover caps from the required inputs.
2) Seal the slots on the AxonMaster with silicone grease.

3) Connect the electrode cables to the AxonMaster. Observe the slot assignments:
   Slot 1: close
   Slot 2: open
   Slot 3: pull switch (optional)

6.2.3 Installing the AxonMaster in the Upper Arm Socket

The AxonMaster can be secured with adhesive tape or a hook-and-loop fastening strap. The AxonMaster can be covered with film to provide additional protection against moisture ingress.

Should the available space in the upper arm socket be too small an area for the AxonMaster (lamination dummy) must be reserved during lamination of the inner socket.

6.2.4 Sealing the prosthesis

1) After laminating the lamination ring, remove the grease and any dirt.
2) Lubricate the groove, inner edge and thread of the lamination ring with 633F30 Special Grease.

6.2.5 Connecting the AxonMaster to the EasyPlug

1) Grease the plug of the AxonMaster cable with 633F11 silicone grease.
2) Connect the cable.
3) Apply 633F11 silicone grease around the plug and blanking covers to seal.

6.3 Installing the EasyPlug

1) Lubricate the groove, inner edge and thread of the lamination ring with 633F30 special grease.
2) Push the EasyPlug with the attached cable into the lubricated lamination ring and press in firmly. The EasyPlug enclosure must engage completely.
   → **You must be able to hear a loud click!**

⚠ CAUTION

Misalignment of the EasyPlug during installation

> Injury due to faulty control or malfunction of the product.

> Reduction in mechanical strength due to thread misalignment.

► The circuit board and the edge of the lamination ring must be parallel to each other.

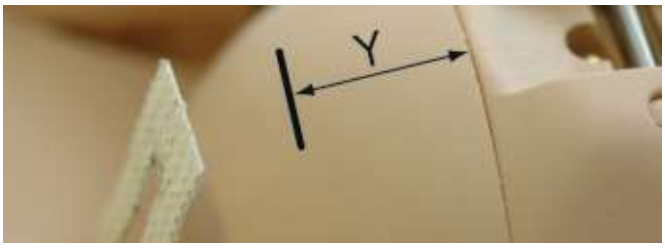
► **Left picture:**
The EasyPlug has been snapped in properly. The circuit board and the edge of the lamination ring are parallel to each other.

Right picture:
The EasyPlug has not been snapped in properly; it is crooked. If the EasyPlug is extremely crooked (as shown in the picture), you need to remove it and insert it again because otherwise it may become damaged.

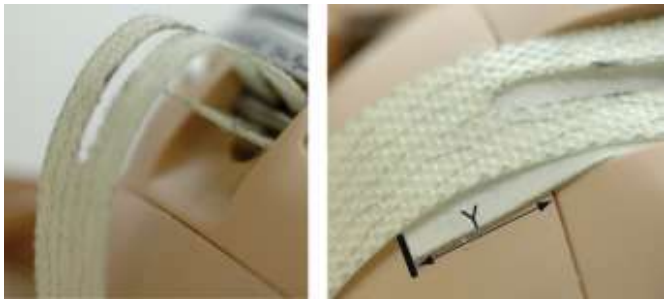
6.4 Connecting the Elbow Joint to the Upper Arm

1) Unscrew the frictional clamp until the top thread is lined up with the fixed thread (right picture).

2) Position the lamination ring on the upper arm socket such that the notch in the lamination ring is across from the start of the thread.



3) Mark the base position for the flexion angle (preflexion) on the joint ball. Dimension Y = 1.5 cm.



4) Thread the belt under the axis.
5) Pull the belt up to the marking (dimension Y) with tweezers.

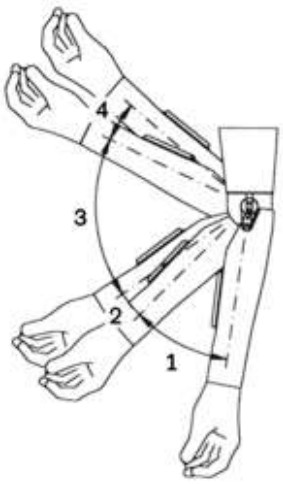
6) Twist the forearm to the upper arm socket until the notch on the lamination ring is visible above the guide of the strap clamp (left picture). Otherwise the strap clamp will not be able to be inserted (right picture).
INFORMATION: Ensure the strap is straight and not twisted.

7) Slide the strap clamp under the lamination ring.

8) Screw the strap clamp in.

6.5 Setting the Preflexion

- The level of AFB compensation (flexion assistance) can be adjusted and adapted to the weight of different clothing with the dial. Adjustments are easier to make when the forearm is flexed.
- The adjustment mechanism is protected by a slip coupling.
- The hydrodynamic damper of the flexion aid mechanism is designed to counterbalance the weight of the forearm plus Axon-Bus gripping component. Please be sure to stabilise the upper arm component of the AxonArm Ergo while testing the joint functions.



Region 1
Minimal compensation that allows natural free swing of the arm while walking.

Region 2
Compensation increases progressively with flexion of the arm and decreases during extension.

Region 3
Compensation remains constant. If set correctly, the weight of the forearm is balanced by the compensation and the elbow remains flexed.

Region 4
Reduced compensation until flexion stop.

⚠ CAUTION

Lock released during donning, doffing or storing of the extended arm

Injury due to sudden bending of the forearm or the upper arm socket due to released lock.

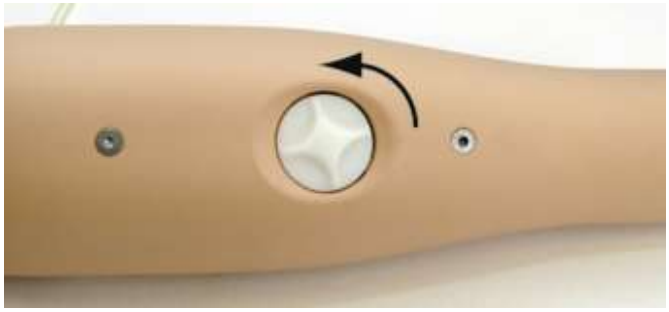
- ► The Axon-Bus prosthethic system must always be flexed for donning and doffing.
- ► The Axon-Bus prosthethic system must be stored in flexed condition.

⚠ CAUTION

Release of lock when arm horizontal or raised vertically

- ► Injury due to sudden bending of the arm due to released lock and lack of a load, especially with a high compensation force setting.

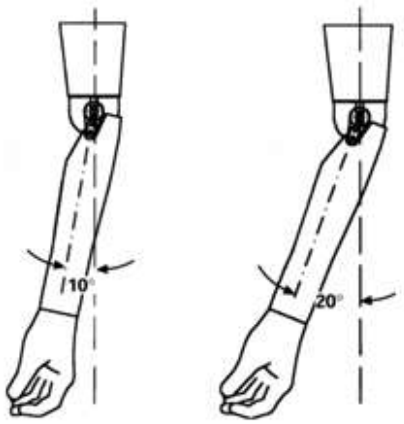
→ Inform the patient of this danger.



1) Flex the AxonArm Ergo and minimise the compensation force using the dial.

2) Flex the AxonArm Ergo until a loop can be made in the strap using your finger (approx. 45°) and lock the joint using the pull cable.

3) Secure the strap (e.g. using an artery clamp).
INFORMATION: When using an artery clamp, verify that the jaws of the artery clamp have no sharp edges. Otherwise, tape over the jaws to protect the strap.
4) Loosen the screw on the strap clamp, but do not remove the strap clamp.
5) Shorten or lengthen the strap.
Lengthening the strap: preflexion is decreased.
Shortening the strap: preflexion is increased.
6) Tighten the screw on the strap clamp.
7) Remove the strap securing device (artery clamp).



A 3 mm change in the strap length results in an approx. 5° change in the flexion angle (preflexion).

The free swing range is changed by the same amount as the flexion angle. The start of the adjacent compensation region changes accordingly.

The factory-set preflexion is approx. 10°.

6.6 Adjusting the Humeral Rotation Feature

► The humeral rotation turntable has integral stops (+/- 80 degrees) to block extreme movements. Turntable friction is easily adjusted by turning of the external adjustment screw, using a coin or similar object.

6.7 Installing the Pull Cable

⚠ CAUTION

Removing the pull cable

Injury due to malfunction of the product.

► The pull cable on the 12K501 AxonArm Ergo is to be used for emergency operation only. For safety reasons, it must not be removed. When the Axon-Bus prosthethic system is switched off or defective and when the battery is empty, the AxonArm cannot be locked or unlocked without the pull cable.

1) Bring the forearm into neutral position (no outward or inward rotation).
2) Affix the cable guide to the socket with cap screws (centred in relation to the strap clamp and approx. 30 mm away from the lamination ring).
3) Test inward and outward rotation of the socket up to the stop. Ensure that the pull cable cannot be tensioned (loop).

6.8 Checking the Symmetry

1) Connect the Axon-Bus gripping component (e.g. Michelangelo Hand) to the AxonArm.
2) Check the symmetry with respect to the other hand (e.g. using the 743L20=230 Ottobock Laser-Line).

7 Handling

7.1 Charging the Battery

The 757B501 AxonEnergy Integral must be charged prior to initial use. The 757B501 AxonEnergy Integral may **only** be charged with the 757L500 AxonCharge Integral. The charging process can only be performed with the 13E500 AxonMaster connected.

1) Connect the charging plug of the 757L500 AxonCharge Integral to the charging receptacle.
   → The beeper sounds briefly 2x.
   → The Axon-Bus prosthethic system is deactivated and the charging process starts automatically.
2) To activate the Axon-Bus prosthethic system, disconnect the charging plug and switch on the Axon-Bus prosthethic system.
   INFORMATION: The prosthesis cannot be used during the charging process.

The product is powered by an integrated high-quality Li-Ion battery with sufficient capacity to operate for one full day of usual everyday activities. Turning the product off during longer periods of passive use (e.g. air or rail travel, visit to a theatre or cinema, etc.) will make the battery last longer. We recommend charging the product once a day when used by the patient on a daily basis. Electronic battery management provides the patient with information about the battery charge level (battery management).

The charging unit consists of the charging plug and the power cord. The battery charger has an input voltage range of 100–240 V and may be operated in a mains frequency range of 50–60 Hz.

7.2 Charging Receptacle

The charging receptacle (Fig. 1, item 2) has the following functions:

- Contacts for charging the battery
- LED display to indicate the current battery charge level
- LED display for providing feedback on operating states
- Button to turn the Axon-Bus prosthetic system on and off, display the battery charge level and open the Axon-Bus gripping component in an emergency
- Beeper for providing feedback on operating states
- Button for activating the Bluetooth function.

7.3 Determining the Battery Charge Level

The battery charge level can be queried at any time.

1. With the Axon-Bus prosthetic system switched on, press the charging receptacle button (Fig. 2, arrow) and hold for less than one second.
2. The LED is illuminated. The colour of the LED indicates the current battery charge level.

Battery empty	Orange LED is illuminated
Battery 50% charged	Yellow LED is illuminated
Battery fully charged	Green LED is illuminated

7.4 Switching On the Axon-Bus Prosthetic System

► Press the charging receptacle button and hold for one second (Fig. 2, arrow).
→ The beeper emits two short signals.

7.5 Switching Off the Axon-Bus Prosthetic System

► Press the charging receptacle button and hold for more than one second (Fig. 2, arrow).
→ The beeper emits one long signal.

7.6 Safety Shutoff

The purpose of the 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 battery charger must be connected and then disconnected in order for the electronics to be activated.

7.7 Open 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 until the Axon-Bus gripping component begins to open. A pulsating beep sounds as it opens.
2) Releasing the button immediately stops the process of opening the Axon-Bus gripping component and turns the entire Axon-Bus prosthetic system off.

7.8 Bluetooth Function

Pressing the button in the charging receptacle and holding for more than four seconds with the Axon-Bus prosthetic system turned off activates the Bluetooth function of the connected AxonMaster 13E500. The blue LED lights up. Once a connection to the PC has been successfully established, the LED flashes blue.

7.9 Beep Function

Action	Beep 1x long	Beep 2x short	Beep 3x short	Beep 1x short, 1x long	Beep Pulsating
Turn the Axon-Bus prosthesis solution on Push the button for one to four seconds.		♪♪			
Turn the Axon-Bus prosthesis solution off Push the button for more than one second.	♪				
Charge the Axon-Bus prosthesis solution Connect the charging plug, charging begins.		♪♪			
Stop charging Disconnect the charging plug. Charging ends and the Axon-Bus prosthesis solution is switched off.	♪				
Empty battery indicator			♪♪♪		
Turn Bluetooth function on (if the Axon-Bus prosthesis solution was previously switched off) Push the button for more than four seconds.				♪ ♪	
Emergency opening of the Axon-Bus terminal device Push and hold the button for about three seconds until the Axon-Bus terminal device opens.					~

7.10 Data transfer between the product and the PC

Product settings using the adjustment software can only be made via Bluetooth data transfer. For this purpose, a Bluetooth wireless connection must be established between the product and the PC using the “60X5=* BionicLink PC” Bluetooth adapter. The installation and use of the “60X5=* BionicLink PC” adapter are described in the instructions for use included with the adapter.

8 Legal information

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

8.1 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.

8.2 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.

8.3 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.

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

8.4 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.

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s)..

Operation is subject to the following two conditions:

(1) This device may not cause interference.

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

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

(1) L'appareil ne doit pas produire de brouillage;

(2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

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.

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.

9 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	**AxonArm Ergo**
Reference number	12K501=*
Dimensions [mm]	Approx. 345 mm x d55 mm to d80 mm (arm extended)
Weight without Axon-Bus terminal device [g]	Approx. 840
Forearm length as delivered [mm]	305
Minimum adjustable forearm length [mm]	187
Flexion angle	15 °–145°
Maximum vertical load with locked elbow joint and a forearm length of 305 mm [kg]	23
Expected lifetime given compliance with service intervals [years]	5
Operating time with full charge	Approx. 2500 gripping and locking cycles or approx. 8 hours
Rechargeable battery lifetime [years]	2
Charging time [h]	3.5

10 Appendices

10.1 Symbols Used

CE — Declaration of conformity according to the applicable European directives

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.

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

MD — Medical device

Manufacturer

10.2 Fault Display and Fault Elimination

10.2.1 LED flashes red and beeper sounds for 3 seconds

Probable cause: Error in the Axon-Bus prosthetic system.

Remedy:
1. Switch the Axon-Bus prosthetic system off and back on.
2. Check the plug connections in the socket.
3. Connect the charger. If the charger displays the service symbol (yellow spanner) or the system error symbol (red spanner) send the Axon-Bus prosthetic system to Ottobock Myo-Service.

10.2.2 The LED flashes three times after pressing the button in the colour of the current battery capacity

Probable cause: The connection from the AxonEnergy Integral to the Axon-Master has been interrupted.

Remedy:
1. Check the connection (e.g. plug connections, flex cable, EasyPlug etc.).
2. If no fault can be found, send the Axon-Bus prosthetic system to Ottobock Myo-Service.

10.2.3 LED alternately flashes yellow/red and beeper sounds for 3 seconds

Probable cause: The Axon-Bus prosthetic system is overheated.

Remedy:
1. Allow the Axon-Bus prosthetic system to cool for a few minutes.
2. Do not use the Axon-Bus prosthetic system at high ambient temperatures.

10.2.4 The movements of the Axon-Bus gripping component are becoming increasingly slower

The patient is alerted to the diminishing battery charge level as the Axon-Bus gripping component increasingly slows down and the gripping force decreases. Finally, when there is very little battery capacity remaining, the Axon-Bus prosthetic system switches off automatically to protect the battery against harmful deep discharge.

10.3 Axon

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.

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