ottobock.

DynamicArm 12K100N

1 Foreword

English

INFORMATION

Date of last update: 2022-12-22

- ► 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 product “12K100N=* DynamicArm” is referred to as the product/elbow joint below.

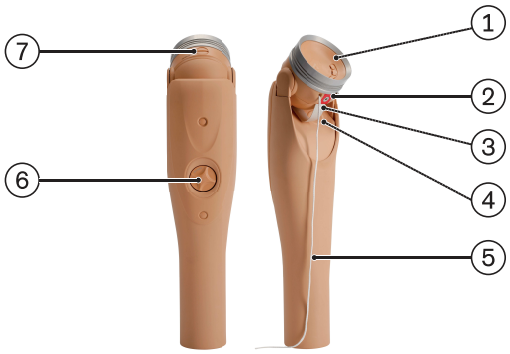
These instructions for use provide you with important information on the use, adaptation and handling of the product.

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

The product may not be transferred to the patient without prior instruction.

2 Product description

2.1 Design



1. Easy Plug
2. ON switch
3. Strap clamp
4. Charging receptacle
5. Pull cable (mechanical release)
6. AFB dial
7. Humeral rotation feature adjusting screw

2.2 Function

The product is a myoelectrically controlled elbow joint driven by an electric motor. It helps the wearer perform everyday tasks in combination with other prosthetic components (see page 5).

A Li-Ion battery integrated into the product provides the energy required. The “646C42=V* ElbowSoft” software is used for the patient-specific adjustment of the product.

If the elbow joint is off or the battery is depleted, the elbow joint can still be locked and unlocked in any position, even when loaded, by means of the pull cable.

In new condition, the product can lift a load of up to 5 kg. Once this load is exceeded, the joint will be locked. Flexion and extension are only possible again after the load is reduced.

2.2.1 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.

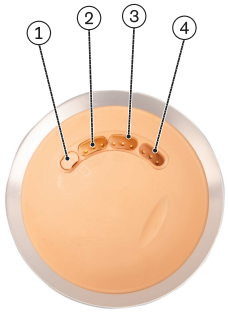
The free swing of the forearm corresponds to the natural movement behaviour of the upper limb while walking. After extension of the forearm, the vario-gear automatically decouples the forearm from the drive unit so it can swing freely. The AFB slightly dampens the free swing, thereby making a close approximation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

Humeral rotation feature

The humeral rotation feature is an upper arm rotation joint with bilateral stops. It is used for rotation of the forearm. The resistance of the humeral rotation feature can be changed using the adjusting screw.

Easy Plug

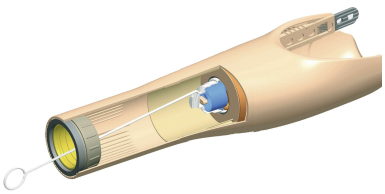


1. Optional switch
2. Electrode
3. Electrode
4. Optional switch

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

The connecting cables of the electrodes and an optional switch are connected to the Easy Plug. Its interior cable routing minimises the risk of cable breaks.

Forearm cable



The forearm cable establishes the electrical connection between the product, electric wrist rotator and System Electric Hand or System Electric Greifer.
On delivery the forearm cable is rolled up in the forearm of the elbow joint. After the forearm has been cut to its final length, the forearm cable can be pulled out.

INFORMATION

Do not pull out cables before cutting the forearm to length.

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.

On/off switch

Press the on/off switch to operate it (arrow).

A signal sounds and the product briefly vibrates once when it is turned on. It is recommended for the patient to turn the product off during longer passive breaks. This increases the period of use before charging the battery.

2.3 Combination possibilities

- 10S17 electric wrist rotator
- 13E200=* electrode
- 13E202=* suction socket electrode
- bebionic hand EQD: 8E70=*
- bebionic hand Flex: 8E72=*
- Cable pull switch: 9X18
- 9X25 Rocker switch
- Linear control element: 9X50
- 9X51 4-stage control element
- System Electric Greifer DMC VariPlus: 8E3*=9*
- 8E38=8, 8E39=8 Sensor Hand Speed
- MyoHand VariPlus Speed: 8E38=9, 8E39=9, 8E41=9
- Pressure switch: 9X37
- Linear control element: 9X52
- 9X53 4-stage control element

3 Intended use

3.1 Indications for use

The product is to be used **exclusively** for exoprosthetic fittings of the upper limbs and serves as an anatomical replacement for the elbow joint and forearm.

3.2 Conditions of use

The product is suitable for patients with unilateral or bilateral upper arm amputations.

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, sports which involve excessive strain and/or shocks to the wrist joint (pushups, downhill racing, mountain biking, ...) or extreme sports (free climbing, paragliding, etc.).

The product is intended **exclusively** for the fitting of a patient. Use of the product by a further person is prohibited by the manufacturer.

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

⚠ 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 product near active implanted systems

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

► When operating the product 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 the product while operating a vehicle or machinery

> Risk of accident due to unexpected behaviour of the product.

> Risk of injury due to faulty control or malfunction of the product.

► Applicable national legal regulations must be complied with when operating vehicles of any kind or when operating machinery with the product.

► Have your driving ability examined and verified by an authorised test centre.

► Switch off the product before driving.

⚠ 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

Overloading due to unusual activities

Injury due to unexpected product behaviour as a result of a malfunction.

► The product 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 joint (pushups, downhill mountain biking, ...) or extreme sports (free climbing, paragliding, etc.).

► Careful handling of the product and its components not only increases their service life but, above all, ensures the patient's personal safety!

► If the product and its components have been subjected to extreme loads (e.g. due to a fall, etc.), then the product must be inspected for damage immediately. If necessary, forward the product to an authorised Ottobock Service Centre.

⚠ CAUTION

Overheating of drive unit due to continuous activity

Injury due to touching the overheated drive unit.

► Avoid touching the housing of the drive unit in case of overheating.

⚠ CAUTION

Independent user manipulation of system components

Injury due to faulty control or malfunction of the product.

► Manipulations to the product other than the tasks described in these instructions for use are not permitted.

► The battery may only be handled by Ottobock authorised, qualified personnel (no replacement by the user).

► The product and any damaged components may only be opened and repaired by authorised, qualified Ottobock personnel.

⚠ CAUTION

Use of unsuitable prosthetic components

Injury due to unexpected product behaviour.

► Use the product only in combination with components listed in the section "Combination Possibilities" (see page 5).

⚠ CAUTION

Improper use

Injury due to loss of product functionality.

► Instruct the patient in the proper use of the product.

⚠ 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

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

Mechanical stress on the prosthesis

Injury due to faulty control or malfunction of the prosthesis.

► Do not subject the prosthesis to mechanical vibrations or impacts.

► Check the prosthesis for visible damage before each use.

⚠ CAUTION

Penetration of dirt and humidity into the product

Risk of injury due to unexpected product behaviour or malfunction.

► Ensure that neither solid particles nor liquids can penetrate into the product.

► Do not expose the product, and especially the elbow joint, to dripping or splashing water.

► Wear the product, and especially the elbow joint, under suitably resistant clothing in the rain.

⚠ CAUTION

Changing prosthetic components when switched on

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

► Before changing prosthetic components (e.g. terminal device) switch the product off.

⚠ CAUTION

Signs of wear and tear on the product components

Injury due to faulty control or malfunction of the product

► In the interest of patient safety and in order to maintain operating reliability and protect the warranty, the specified service intervals must be observed (see the section "Maintenance").

⚠ CAUTION

Injury due to incorrect adjustment of the product.

Loosening of the components.

► In case of a product with a quick-disconnect wrist, position the terminal device before use so that a slight turn cannot disconnect the terminal device from the prosthesis.

⚠ CAUTION

Incorrect donning and doffing of the prosthesis

Risk of injury due to sudden flexion of the prosthesis.

► Switch off the prosthesis before donning or doffing.

► The prosthesis must always be flexed for donning and doffing.

⚠ CAUTION

Unintentional unlocking of the terminal device

Risk of injury due to releasing the terminal device from the forearm (e.g. while carrying objects).

► When using a quick-disconnect wrist unit, position the terminal device so that slight twisting does not release the terminal device from the forearm.

⚠ CAUTION

Charging the product with damaged power supply unit/charger/charger cable

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

► Check the power supply unit, charger and charger cable for damage before use.

► Replace any damaged power supply unit, charger or charger cable.

⚠ CAUTION

Risk of pinching in the joint flexion area

Injuries due to pinching of body parts.

► Ensure that fingers and other body parts are not in this area when bending the joint.

NOTICE

Coating, gluing or painting the prosthesis

Damage or fracture due to chemical processes.

► The prosthesis must not be coated, glued or painted.

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).

INFORMATION

► The electrodes are to be placed on intact skin only and with as much electrode-skin contact as possible.
► In case of strong interference from electronic devices, the position of the electrodes should be checked and changed if necessary.
► If interference cannot be eliminated, please contact the Ottobock branch responsible for your country.
► Allow the patient to rest during the adjustment of the electrodes. Muscle fatigue leads to inconsistent results, and therefore the therapist will tend to establish electrode settings that are excessively sensitive.

5 Scope of delivery

- 1 pc. 12K100N=* DynamicArm
- 1 pc. cable lock
- 1 pc. cable guide
- 4 pcs. oval head self-tapping screw
- 1 pc. electric wrist rotator dummy
- 1 pc. 757L24 charger
- 1 pc. 10S1=40 lamination ring
- 1 pc. Instructions for use (qualified personnel)
- 1 pc. Instructions for use (user)
- 1 pc. Technical information (qualified personnel)
- 1 pc. Service pass
- 1 pc. hook
- 1 pc. Lamination protection cover (hollow ball)
- 1 pc. Lamination protection cover (disc with arrow)
- 1 pc. O-ring
- 1 pc. clamp ring
- 4 pcs. mounting brackets
- 1 pc. foam cover

6 Preparing the product for use

6.1 Shortening the forearm

INFORMATION

Wrap the elbow area with plastic wrap to prevent swarf from entering it during cutting.

6.1.1 Forearm length and intended use of the 10S17 electric wrist rotator

INFORMATION

Please note that the minimum forearm length is 213 mm when using an electric wrist rotator and 187 mm without an electric wrist rotator.
The forearm length is measured from the distal end of the lamination ring to the middle of the elbow axle.

DynamicArm forearm length	10S17 Electric wrist rotator
305–213 mm	possible
212–187 mm	not possible

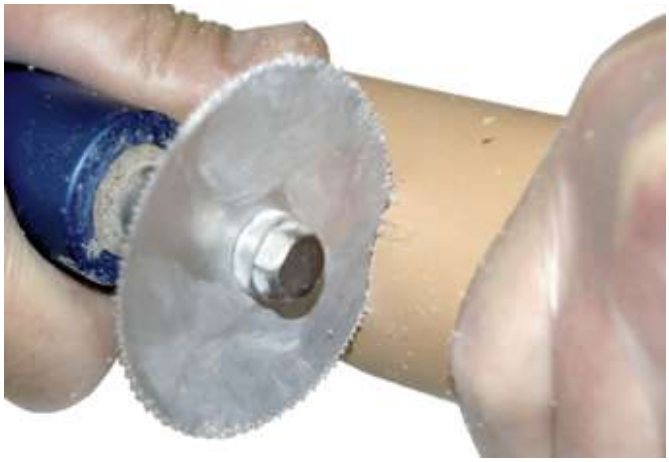
6.1.2 Cutting to length

NOTICE

Do not pull the foam or cable protection sleeve out of the forearm under any circumstances before the forearm is cut to length and before the lamination ring is glued in! Doing so will reduce the useable portion of the forearm!

If the cables were pulled out anyway, they have to be pushed back into the forearm and secured with the foam disc before performing further work. The cables take up more space in the forearm as a result.

1) Mark the length to be cut off plus 1 cm on the forearm. Reason: The prosthesis should be approx. 1 cm shorter than the sound arm.



2) Cut the forearm using a vibrating saw.

3) Sand all sides of the cut edge at a right angle. Deburr inner and outer sanded edges. Round the inside edge slightly.

4) Use the hook to remove the foam cover.

6.2 Gluing in the lamination ring with quick-disconnect wrist unit

1. Lamination cover
2. Lamination ring
3. Socket head screw
4. Dummy for electric wrist rotator

The lamination ring with quick-disconnect wrist unit has to be glued in after the forearm has been cut to length. Before starting to glue it in, please read these instructions very carefully and proceed exactly in the order described.

INFORMATION

Read the relevant material safety data sheets before processing the 636K18 Orthocryl sealing resin compact adhesive and the 617H14 hardener paste.

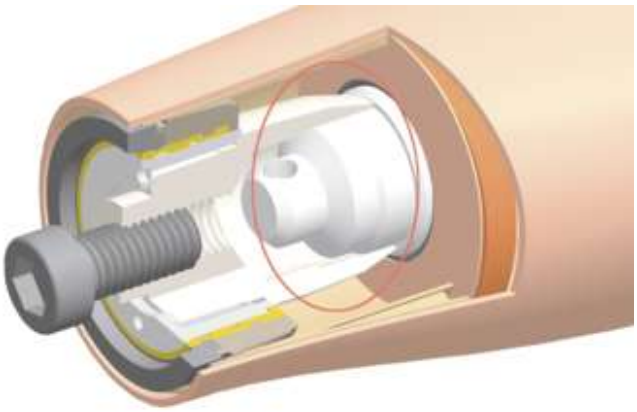
1) Determine the height of the lamination ring.

2) Mark this measurement on the inside of the forearm.
3) Mix 636K18=1 Orthocryl sealing resin compact adhesive and 2% 617H14 hardener paste.
4) Cover the outside of the forearm with 627B4 polyethylene adhesive tape to avoid soiling it while gluing.

5) Using a paintbrush, apply the resin in a wedge shape to the marked area of the inside forearm and the outside of the lamination ring.

6) Insert the lamination ring and lamination ring cover. The lamination ring must be flush with the socket! Let the adhesive joint harden.
INFORMATION: Measure the forearm length.

For forearm lengths from 225 mm to 213 mm with 10S17 electric wrist rotator

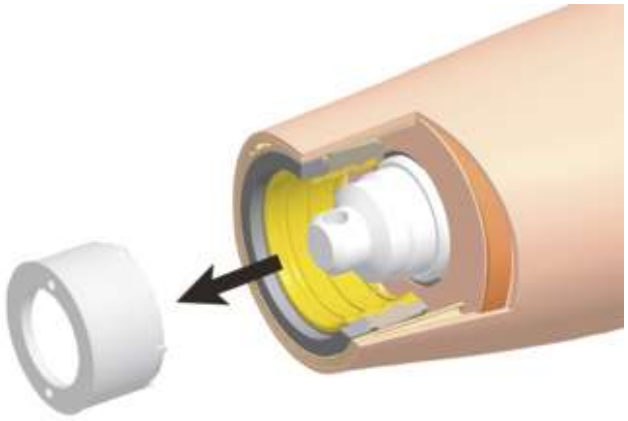


► Make sure the 10S17 electric wrist rotator dummy is pushed over the cable protector cap. This ensures correct axial alignment of the lamination ring.

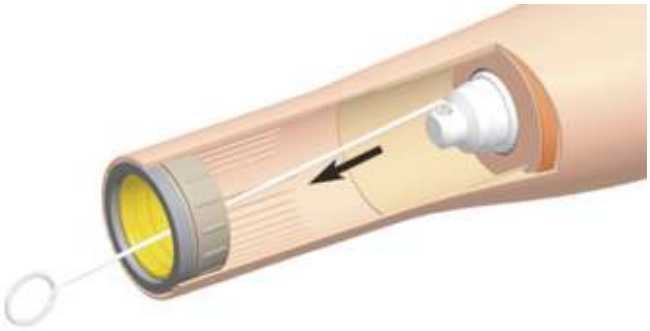
For forearm lengths from 225 mm to 187 mm without 10S17 electric wrist rotator

1) Pull the 10S17 electric wrist rotator dummy back and out of the lamination ring. The lamination ring cover has to remain in the lamination ring.

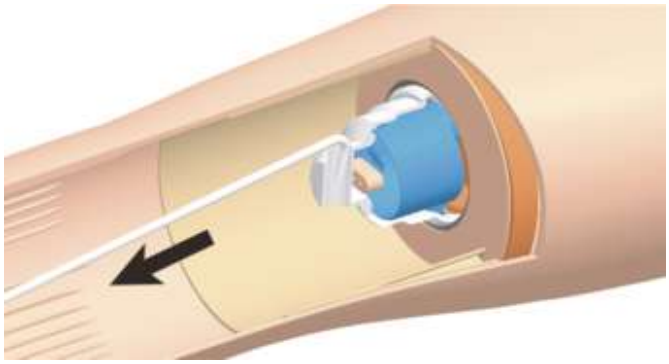
2) Pull out the 10S17 electric wrist rotator dummy with the lamination ring cover by the socket head screw.



3) Or, pull out the lamination ring cover on its own.



4) Remove the cable protector cap using the hook.



5) The cables are rolled up inside the cable protector cap. When removing the cable protector cap, the cables are pulled out of the forearm.

INFORMATION

Cables pulled out before cutting to length

If the cables were pulled out before the forearm has been cut to length and the lamination ring has not been glued in yet (for example after a trial fitting), the cables have to be pushed back into the forearm and secured with the foam disc before performing further work on the forearm.
As a result, the cables take up more space in the forearm compared to the delivery condition from the factory. The usable length of the forearm will be reduced.

Then the forearm can only be shortened to the following lengths:

- To a minimum of 230 mm when using the 10S17 electric wrist rotator.
- To a minimum of 207 mm when not using the 10S17 electric wrist rotator.

Proceed as described above to cut to length and glue in the lamination ring

INFORMATION

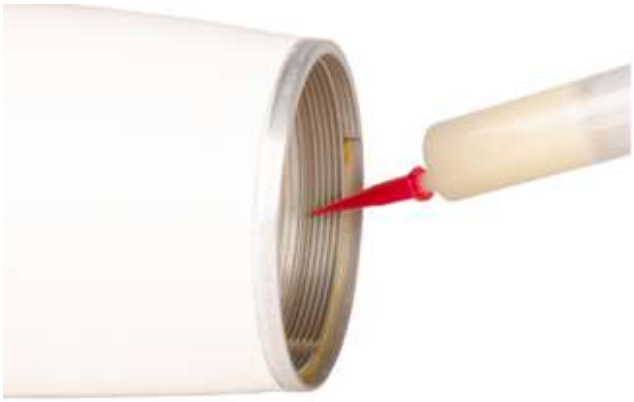
If the foam disc has been glued into place, the cables can be pulled out carefully through the slotted foam disc using the hook.

6.3 Checking the symmetry

1) Connect prosthetic components to the forearm.
2) Check the symmetry using the 743L20=230 Ottobock LaserLine.

6.4 Sealing the prosthesis

Consult the enclosed technical information for the fabrication of the patient's socket and cutting the forearm socket to length.



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

6.5 Assembling the housing

1) Slide the electrode housing with the connected cables into the greased lamination ring. It has to engage completely!
2) The circuit board and the edge of the lamination ring must be parallel to each other.

3) The electrode housing has engaged properly. The circuit board and the edge of the lamination ring are parallel to each other.

6.6 Installing the elbow joint

1) Do not remove the two joint covers!
2) Screw the elbow joint into the upper arm socket. Make sure the friction adjustment screw and lamination ring thread recess are applied opposite to each other.

3) Set the AFB dial to minimum compensation force.

4) Extend the elbow and lock it with the pull cable. Switch off the product.

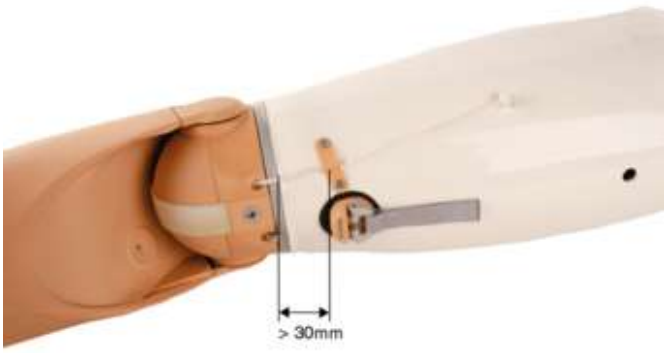
5) Remove the Allen head screw.

6) Lift and remove the red assembly clamp.
7) The lifter strap must not be removed from the elbow ball. Fixing the lifter strap in place (e.g. with a haemostat) is no longer necessary.

8) Slide the strap clamp under the lamination ring.

9) Install the Allen head screw.

6.7 The pull cable



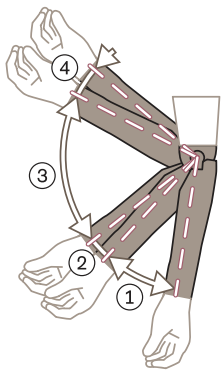
1) Bring the forearm into neutral position (no outward or inward rotation).
2) Affix the cable guide to the socket with cap screws (centred in relation to the strap clamp and approx. 30 mm away from the lamination ring).
   CAUTION! The pull cable is to be used for emergency operation only. For safety reasons, it must not be removed!
3) Rotate the socket in and out up to the stop. Ensure that the pull cable does not tighten.

Complete the following additional steps to finish the switch cable:

1) Thread the switch cable through the cable lock.
2) Secure the end of the switch cable with a knot.
3) Tighten the switch cable and make a loop.

6.8 Adjusting the product

1) The level of compensation (flexion assistance) can be adjusted and adapted to the weight of different clothing with the AFB dial. Adjustments are easier to make when the forearm is not flexed.
2) The adjustment mechanism is protected by a slip coupling.
3) Hydrodynamic damping of the AFB mechanism is designed to counterbalance the weight of the forearm and terminal device. Therefore hold the upper arm section of the prosthesis while testing the joint function.



4) **Position 1**
   Low compensation that allows natural free swing of the arm while walking.
   Position 2
   Compensation increases progressively with flexion of the arm and decreases automatically during extension.
   Position 3
   Compensation remains constant. If set correctly, the weight of the forearm is balanced by the compensation and the forearm “floats”.
   Position 4
   Low compensation until flexion stop.

6.9 Adjusting the humeral rotation feature

► The upper arm rotation joint has bilateral stops (± 80 degrees) to block extreme movements. The friction of the humeral rotation feature at the upper arm connection is easily adjusted by turning the external adjustment screw.

6.10 Wiring the product with the electric wrist rotator

1) The MyoRotronic cannot be combined with the elbow joint. The MyoRotronic would be destroyed when operating the elbow joint.
2) There are numbers for the plug contacts on the plastic housing of the electric wrist rotator. These numbers serve as orientation for connecting the cables.
3) Attach the motor cable to one of the two contacts. Connect two-pole receptacle to contact no. 3.
4) Connect three-pole receptacle to contact no. 2. One of the three-pole connectors is marked with a coloured dot.
5) If the two three-pole connectors are interchanged when connecting them to the two contacts, no function of the System Electric Hand or System Electric Greifer is possible.

6) To secure the coaxial plug, insert the retaining ring into the groove of the lamination ring using tweezers.
7) Then install the electric wrist rotator in the lamination ring.

6.11 Wiring without electric wrist rotator

1) One of the two three-pole connectors is marked with a coloured dot (arrow). The two receptacles must not be interchanged!
   INFORMATION: The two-pole motor cable must not be attached to the coaxial plug.

2) Install the plastic screw to secure the two connectors.
3) Push the coaxial plug in to the stop and rotate it until the stop noticeably engages.
4) Install the coaxial plug in the lamination ring.

7 Handling

7.1 Charging the battery

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.

INFORMATION

Please note the corresponding instructions for use of the battery charger.

7.1.1 Charging process

⚠ 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.

1. Extend and switch off the product.
2. Lock the product with the pull cable.
3. Take off the elbow joint.
4. Connect the power cord to the battery charger.
5. Insert the charging plug into the charging receptacle (see figure).
   Do not force it in!
6. Plug the power cord into a wall socket. If the LED shows an orange light, the battery is charging.
   If the LED shows a green light but the battery is drained, the charging plug was not inserted correctly.
7. If the LED shows a green light after charging, this indicates that the battery is fully charged.
8. Disconnect the power cord of the battery charger from the wall socket.

7.1.2 Charging times

Charging time	Capacity	Operating time
3 hours	100%	approx. 18 hours
1.5 hours	80%	approx. 14 hours
20 minutes	40%	approx. 4 hours

7.1.3 Display of the current charge level during the charging process

The battery charger has a battery capacity indicator LED:

LED shows orange light	Battery is charging.
LED shows green light	Charging process is finished and the battery is fully charged.

7.1.4 Battery management

Electronic battery management helps the patient maintain the function of individual prosthetic components as long as possible as the battery charge level drops.

Level 1	The product and the connected prosthetic components move with maximum speed and power.
Level 2	The flexion force becomes weaker, the product “fatigues”. The functions of the connected prosthetic components remain intact.
Level 3	The patient is informed of the low battery charge level by a vibration signal and a sound sequence. The product stops functioning. The elbow lock can be released and locked manually. The functions of the connected prosthetic components remain intact.
Level 4	A sound sequence informs the patient that the battery is empty. Now all other prosthetic components also cease to function.

7.1.5 Charging plug

The charging plug is suitable for bilateral amputees. It is designed so it can be inserted into the charging receptacle with a prosthetic hand or by mouth.

The following points must be observed when charging the battery:

- We recommend charging the product once a day when used by the patient on a daily basis.
- The battery should be charged for at least 3 hours prior to initial use.
- Note the permissible temperature range for charging the battery (see page 26).

7.2 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 supplied with the adapter.

7.3 “646C42=V1.6 ElbowSoft” software

INFORMATION

Observe the corresponding instructions for use for the installation/removal of “646C42=V1.6 ElbowSoft”.

7.3.1 Calibration

The flexion angle of the product is approx. 15°–145°. The effective flexion angle is determined on the user by the shape and size of the prosthetic socket and by clothing. The flexion angle has to be determined through the calibration process and stored in the product.

INFORMATION

Calibration takes place in the course of the initial fitting, after adapting a new or modified socket, after each repair and after every service.
The elbow joint cannot be adjusted if the calibration process has not been completed yet.

1) Mount the product on the socket.
2) Switch on the product.
3) Start the “646C42=V1.6 ElbowSoft” software.
   For the subsequent steps, see the corresponding instructions for use.

7.3.2 Programming

The programmes of the product serve to individually adapt it to the requirements of the respective user. Programming has to be carried out after calibration.

“646C42=V1.6 ElbowSoft” is used to select a programme and to program the product as well as the optional electric wrist rotator. A MyoRotronic is not needed since the electronics of the product control the electric wrist rotator. In addition, the VariPlus System Electric Greifer and the SensorHand Speed can be configured using the software after the black coding plug is inserted into the electronics.

The control of other System Electric Greifers or System Electric Hands is established according to type using MyoSelect or by connecting or disconnecting the function plug.

⚠ CAUTION

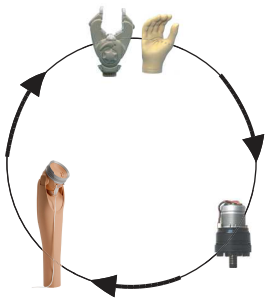
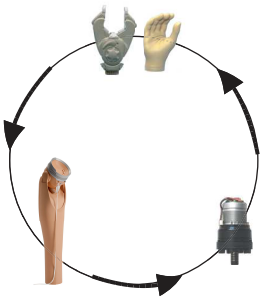
Incorrect donning and doffing of the prosthesis

Risk of injury due to sudden flexion of the prosthesis.

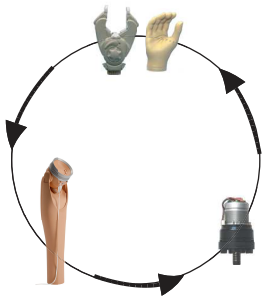
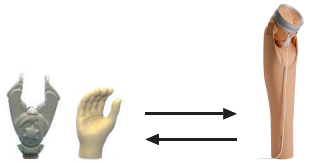
- ► Switch off the prosthesis before donning or doffing.
- ► The prosthesis must always be flexed for donning and doffing.

7.4 Switching modes

7.4.1 Switching version with co-contraction using electrode signals

Long co-contraction	Short co-contraction
	

7.4.2 Switching version with 4-stage control element or switch

Sequential switching	Switching back and forth	4-stage control element
		

7.5 Control Options

7.5.1 Programmes with use of electric wrist rotator

	DynamicArm	Electric wrist rotator	System Electric Hand and System Electric Greifer
Control	Two electrodes		
Indication	For patients with two strong muscle signals		
Control type	Proportional		
Switching using long co-contraction	Switching to the hand	Switching to the elbow joint	Switching to the electric wrist rotator
Switching using short co-contraction	Switching to the electric wrist rotator	Switching to the hand	Switching to the elbow joint
Switching back	Automatically switching back to the hand component takes place five seconds after relaxing the muscles.		

	DynamicArm	Electric wrist rotator	System Electric Hand and System Electric Greifer
Control	Two electrodes and one switch		
Indication	For patients with two strong muscle signals		
Control type	Proportional		
Switching by switch activation	Switching to the electric wrist rotator	Switching to the hand	Switching to the elbow joint
Switching back	Automatically switching back to the hand component takes place five seconds after relaxing the muscles.		

	DynamicArm	Electric wrist rotator	System Electric Hand and System Electric Greifer
Control	Switch		
Indication	For patients with weak or no muscle signals		
Control type	Digital		
Switching by switch activation	Switching to the electric wrist rotator	Switching to the hand	Switching to the elbow joint
Switching back	Automatically switching back to the hand component takes place five seconds after relaxing the muscles.		

	DynamicArm	Electric wrist rotator	System Electric Hand and System Electric Greifer
Control	Two electrodes and 4-stage control element		
Indication	For patients with two strong muscle signals		
Control type	Proportional		

	DynamicArm	Electric wrist rotator	System Electric Hand and System Electric Greifer
Switching by switch activation	Switching between the components takes place using a 4-stage control element. A prosthetic component can be assigned to each locking position.		
	Locking position 4	Locking position 3	Locking position 2
Switching back	Automatically switching back to the hand component takes place five seconds after relaxing the muscles.		

	DynamicArm	Electric wrist rotator	System Electric Hand and System Electric Greifer
Control	Switch and 4-stage control element		
Indication	For patients with weak or no muscle signals		
Control type	Digital		
Switching by switch activation	Switching between the components takes place using a 4-stage control element. A prosthetic component can be assigned to each locking position.		
	Locking position 4	Locking position 3	Locking position 2
Switching back	Automatically switching back to the hand component takes place five seconds after relaxing the muscles.		

	DynamicArm	Electric wrist rotator	System Electric Hand and System Electric Greifer
Control	Linear control element	Two electrodes	
Indication	For patients with two strong muscle signals		
Control type	Position control	Digital	
Switching with four-channel control	Not applicable The elbow joint is controlled using a linear control element.	Switching with fast and high electrode signals.	Switching with slow and low electrode signals.

	DynamicArm	Electric wrist rotator	System Electric Hand and System Electric Greifer
Control	Linear control element	Two electrodes	
Indication	For patients with two strong muscle signals		
Control type	Position control	Proportional	
Switching with co-contraction	Not applicable The elbow joint is controlled by the linear control element.	Switching to the terminal device	Switching to the electric wrist rotator
Switching back	Automatically switching back to the hand component takes place five seconds after relaxing the muscles.		

7.5.2 Programmes without use of an electric wrist rotator

	DynamicArm	System Electric Hand and System Electric Greifer
Control	Two electrodes and linear control element	
Indication	For patients with two strong muscle signals	
Control type	Proportional	
Switching with co-contraction	Switching to the hand	Switching to the elbow joint
Switching back	Automatically switching back to the hand component takes place five seconds after relaxing the muscles.	

	DynamicArm	System Electric Hand and System Electric Greifer
Control	Two electrodes and switch	

	DynamicArm	System Electric Hand and System Electric Greifer
Indication	For patients with two strong muscle signals	
Control type	Proportional	
Switching by switch activation	Switching to the hand	Switching to the elbow joint
Switching back	Automatically switching back to the hand component takes place five seconds after relaxing the muscles.	

	DynamicArm	System Electric Hand and System Electric Greifer
Control	Two switches	
Indication	For patients with weak or no muscle signals	
Control type	Digital	
Switching by switch activation	Switching to the hand	Switching to the elbow joint
Switching back	Automatically switching back to the hand component takes place five seconds after relaxing the muscles.	

	DynamicArm	System Electric Hand and System Electric Greifer
Control	Linear control element	Two electrodes
Indication	• For patients with two muscle signals of any strength • Possibility for simultaneous control of elbow joint and terminal device	
Control type	Position control	Proportional
Switching	Not applicable The elbow joint is controlled by the linear control element.	Switching to the elbow joint
Flexion	Pull on the linear control element	-
Extension	Release of the linear control element	-

	DynamicArm	System Electric Hand and System Electric Greifer
Control	Linear control element	Switch
Indication	For patients with weak or no muscle signals	
Control type	Position control	Digital
Switching	Not applicable The elbow joint is controlled by the linear control element.	Switching to the elbow joint
Flexion	Pull on the linear control element	-
Extension	Release of the linear control element	-

	DynamicArm	System Electric Hand and System Electric Greifer
Control	Linear control element	One electrode
Indication	• For patients with one strong muscle signal • Possibility for simultaneous control of the elbow joint and the terminal device	
Control type	Position control	Proportional
Switching	Not applicable The elbow joint is controlled by the linear control element.	Switching to the elbow joint
Flexion	Pull on the linear control element	-
Extension	Release of the linear control element	-

8 Cleaning and Care

1) Clean the product with a damp cloth and mild soap (e.g. 453H10=1-N Ottobock Derma Clean) when needed. Make sure that no liquids get into the product and product components.

2) Dry the product with a lint-free cloth and allow it to air dry fully.

9 Maintenance

Regular maintenance (service inspections) every 24 months is mandatory in the interest of patient safety, in order to maintain operating reliability, to protect the extended warranty and to maintain basic safety.

The grace period is no more than one month before or three months after maintenance is due.

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.

10 Legal information

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

10.1 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.

10.2 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.

10.3 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

10.4 Local Legal Information

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

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

1) This device may not cause harmful interference, and

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

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

— Reorient or relocate the receiving antenna.

— Increase the separation between the equipment and receiver.

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

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

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

Caution: Exposure to Radio Frequency Radiation.

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

Responsible party:

Otto Bock Health Care, LP

3820 West Great Lakes Drive

Salt Lake City, Utah 84120-7205 USA

Phone + 1-801-956-2400

Fax + 1-801-956-2401

This device complies with RSS 210 of Industry Canada.

Operation is subject to the following two conditions:

(1) this device may not cause interference, and

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

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

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

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

Caution: Exposure to Radio Frequency Radiation.

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

http://www.hc-sc.gc.ca/rpb.

Responsible party:

Otto Bock Healthcare Canada Ltd.

5470 Harvester Road

L7L 5N5 Burlington, Ontario

Canada

Phone + 1-800-665-3327

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

11 Technical data

Ambient conditions	
Storage (with and without packaging)	+5 °C/+41 °F to +40 °C/+104 °F Max. 93% relative humidity, non-condensing
Transport (with and without packaging)	-20 °C/-4 °F to +60 °C/+140 °F Max. 93% relative humidity, non-condensing
Charging temperature	+5 °C/+41 °F to +40 °C/+104 °F
Operation	+5 °C/+41 °F to +45 °C/+113 °F Max. 93% relative humidity, non-condensing

General information	
Reference number	12K100N=*
Weight (dependent on forearm length)	Approx. 1,000 g
Max. lifting force	50 N
Flexion angle	Approx. 15°–145°

General information	
Expected lifetime given compliance with the recommended maintenance intervals	5 years

Battery of the product	
Battery type	Li-Ion
Output voltage	approx. 3.7 V
Charging voltage	approx. 4.2 V
Capacity	1,880 mAh
Dimensions of battery cells	33.8 x 48.8 x 10.5 mm
Charging cycles (charging and discharging cycles) after which at least 80% of the original battery capacity remains available	500
Weight	38.5 g (battery without options)
Charging time until battery is fully charged	4.0 h

Power supply	
Reference number	757L24
Storage (with and without packaging)	-25 °C/-13 °F to +70 °C/+158 °F 10% to 95% relative humidity
Transport (with and without packaging)	-25 °C/-13 °F to +70 °C/+158 °F 10% to 95% relative humidity
Operation	-25 °C/-13 °F to +40 °C/+104 °F Max. 95% relative humidity, non-condensing
Input voltage	90 V~ to 264 V~
Mains frequency	47 Hz to 63 Hz

12 Appendices

12.1 Symbols Used

CE — Declaration of conformity according to the applicable European directives

Manufacturer

Compliance with the requirements according to "FCC Part 15" (USA)

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.

Compliance with the requirements under the "Radiocommunications Act" (AUS)

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

Non-ionising radiation

MD Medical device

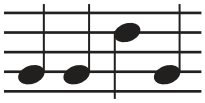
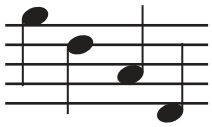
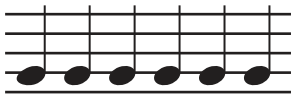
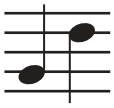
REF Article number

12.2 Operating states/error signals

12.2.1 Warnings/error signals

Beep signal	Vibration signal	Error	Required action
1 x long	1 x	Critical error (e.g. a sensor is not operational)	Turn the product off and on again or, with the product turned on, connect the battery charger. Contact Ottobock Service if the error has not been resolved.
1 x long	5 x	Severe error (e.g. temperature of the lifting motor too high)	
2 x	1 x	Malfunction (e.g. incompatible component connected)	

12.2.2 Signals for operating states

Sound sequence		Event	Elbow joint	Electric wrist rotator	Hand/Greifer
	Low, low, high, low	The product has been switched on.	Function is present	Function is present	Function is present
	Very high, high, low, very low	Decreasing battery charge level.	No function	Function is present	Function is present
	6 x low	Battery charger was connected during operation.	No function	No function	No function
	Low, high	Prosthetic component is being controlled.	Function of the prosthetic component in question is not possible.		

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