ottobock.

CE

Kenevo 3C60*/3C60=ST*

1 Foreword

English

INFORMATION

Date of last update: 2024-03-12

- ► 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 "Kenevo 3C60*/3C60=ST*" is referred to as the product/prosthesis/knee 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.

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

2 Product description

2.1 Design

The product consists of the following components:

1. Proximal pyramid adapter
2. LED (blue) as indicator for the Bluetooth connection
3. 8° flexion stops (already installed on delivery)
4. Battery and cover caps
5. Hydraulic unit
6. Receiver of the inductive charging unit
7. Distal tube clamp screw
8. Connecting cable for tube adapter

2.2 Function

This product features a microprocessor-controlled switch between the stance phase and swing phase and a microprocessor-controlled stance phase.

The microprocessor uses the measurements of an integrated sensor system as a basis to control a hydraulic unit that influences the damping behaviour of the product.

These sensor data are updated and evaluated 100 times per second. As a result, the behaviour of the product is adapted to the current motion situation (gait phase) dynamically and in real time.

The product can be individually adapted to the needs of the patient with the K-soft adjustment software.

Through the adjustment software, it is possible to choose from three activity modes that make the various functions of the product available. This permits optimum adaptation of the product to the corresponding mobility grade of the patient. The configured activity mode cannot be changed by the patient.

The product features the "**Bicycle ergometer**" MyMode. It has default values configured using the adjustment software and can either be accessed automatically or via the Cockpit app.

In case of a product malfunction, safety mode makes restricted operation possible. Resistance parameters that are predefined by the product are configured for this purpose (see page 34).

The microprocessor-controlled hydraulic unit offers the following advantages

- Stability while standing and walking
- Smooth, harmonious, quiet initiation of the swing phase
- Automatic recognition of sitting down. Manual unlocking of the joint not required.
- Support while sitting down with individually adaptable resistance. This resistance remains constant during the entire process of sitting down.
- Support while standing up. The knee joint can be loaded even before reaching full extension.
- Approximation of the physiological gait pattern
- Adaptation of product characteristics to various surfaces, inclines, gait situations and walking speeds
- Manual locking of the knee joint for use of a wheelchair (see page 32). This function makes it possible to lock the knee joint in any extended position while sitting down. This is particularly useful in order to keep the foot from dragging on the ground when the patient is being transported in a wheelchair.

Essential performance of the product

- Stability in the stance phase
- Initiating the swing phase
- Adjustable swing phase extension resistance
- Adjustable swing phase flexion resistance

2.3 Combination possibilities

This product can be combined with the following Ottobock components:

Prosthetic hip joints

- Modular prosthetic hip joint: 7E7
- Monocentric prosthetic hip joint: 7E9
- Helix^{3D} prosthetic hip joint: 7E10

Adapters

- Double adapter: 4R72=32
- Double adapter: 4R72=45
- Double adapter: 4R72=60
- Double adapter: 4R72=75
- Double adapter: 4R76
- Double adapter: 4R78
- 4R104=60 double adapter, sliding
- 4R104=75 double adapter, sliding
- Rotation adapter: 4R57, 4R57=*
- 4R89 lamination anchor with pyramid adapter
- 4R116 lamination anchor with pyramid adapter
- 4R41 lamination anchor with pyramid receiver
- 4R111 lamination anchor with pyramid receiver
- Lamination anchor with pyramid receiver and angled arm: 4R119
- 4R43 lamination anchor with threaded connector
- 4R111=N lamination anchor with threaded connector
- 4R40 torsion adapter
- 4R118 adapter plate

AXON tube adapter

- AXON tube adapter: 2R17
- AXON tube adapter: 2R20
- AXON tube adapter with torsion unit: 2R21

Cosmetic cover

- Foam cover: 3S26

Prosthetic feet

The maximum allowable patient weight depends on the foot size.

- Cosmetic light foot: 1G6
- Pedilan single axis foot, light: 1G9
- Single axis foot without toes: 1H32 or 1H34 (depending on the heel height)
- Single axis foot with toes: 1H38 or 1H40 (depending on the heel height):
- SACH foot with toes: 1S49, 1S66, or 1S67 (depending on the heel height and foot shape):
- SACH Foot with toes and abducted big toe: 1S90
- SACH^{+}foot: 1S101, 1S102, 1S103
- 1C11 Terion K2
- 1D10 Dynamic foot
- Dynamic foot without adapter: 1D10
- 1D11 Dynamic foot (women)
- 1M10 Adjust
- 1A30 Greissinger plus
- Terion: 1C10
- 1C30 Trias
- Taleo: 1C50
- 1C51 Taleo Vertical Shock:
- Taleo Harmony: 1C52
- Taleo Low Profile: 1C53

- 1C56 Taleo Adjust
- 1C70 Evanto
- 1D35 Dynamic Motion

[1] Note the Ottobock system height

- Kintrol: VS4[1]
- Restore: VS5[1]
- Promenade: VS2[1]

2.3.1 Limits for combination options with prosthetic feet

⚠ CAUTION

Failure to observe the tables provided

Falling due to breakage of load-bearing components of the prosthetic knee joint.

► Depending on the patient's body weight, the listed prosthetic feet may only be combined in the respective described foot sizes [cm].

► Please contact Ottobock customer service if you would like a combination outside the approved ranges.

1C50 Taleo

Body weight	Approved foot size [cm]	Maximum stiffness
Up to 115 kg (253 lbs)	Up to 30	7
116 kg to 125 kg (255 lbs to 275 lbs)	Up to 28	9

2.3.2 Combination with an osseointegrated implant system

This product can be connected to a socket or to an osseointegrated, percutaneous implant system.

In case of connection to an implant system, verify that the manufacturer of the implant system and the manufacturers of the corresponding exoprosthetic components/adapters also permit this combination. It must be ensured that all indications/contraindications, the field of application, the conditions of use and all safety instructions are complied with for the implant system, corresponding exoprosthetic components, corresponding adapters and for the knee joint.

Among other things, this relates to the body weight, mobility grade, type of activity, load capacity of the implant and bone anchoring, freedom from pain under functional load and compliance with the permissible ambient conditions (see page 37).

Please ensure that the qualified personnel applying the product is not only authorised for fitting this knee joint, but also for the connection to the osseointegrated implant system.

3 Intended use

3.1 Indications for use

The product is intended exclusively for lower limb exoprosthetic fittings.

3.2 Conditions of use

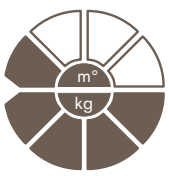
The product was developed for everyday use and should not be used for walking speeds over 3 km/h or unusual activities. These unusual activities include, for example, extreme sports (free climbing, parachuting, paragliding, etc.).

Permissible ambient conditions are described in the technical data (see page 37).

The prosthesis is intended for use **exclusively** on the patient for whom the adjustment was made. The manufacturer does not authorise use of the prosthesis on another person.

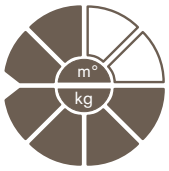
The MOBIS classification describes the mobility grade and body weight, and makes it easy to identify compatible components.

Activity mode A (locked mode)



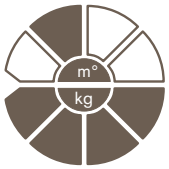
The product is recommended for mobility grade 1 (indoor walker). Approved for a body weight of **max. 150 kg**.

Activity mode B (semi-locked mode)



This product is recommended for mobility grade 1 (indoor walker) and mobility grade 2 (restricted outdoor walker). Approved for a body weight of **max. 150 kg**.

Activity mode C (yielding mode)



This product is recommended for mobility grade 2 (restricted outdoor walker). Approved for a body weight of **max. 150 kg**.

3.3 Indications

- For patients with knee disarticulation, transfemoral amputation or hip disarticulation.
- For unilateral or bilateral amputation
- Dysmelia patients with residual limb characteristics corresponding to knee disarticulation or a transfemoral amputation
- The patient must fulfil the physical and mental requirements for perceiving visual/acoustic signals and/or mechanical vibrations.

3.4 Contraindications

3.4.1 Absolute Contraindications

- Body weight over 150 kg

3.5 Qualification

The product may be fitted only by qualified personnel authorised by Ottobock after completing the corresponding training.

If the product is to be connected to an osseointegrated implant system, the qualified personnel must also be authorised for the connection to the osseointegrated implant system.

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

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

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

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

⚠ CAUTION

Failure to observe warning/error signals

Falling due to unexpected product behaviour because of changed damping behaviour.

- ► The warnings/error signals (see page 41) and corresponding change in damping settings must be observed.

⚠ CAUTION

Independent manipulation of the product and the components

Falling due to breakage of load-bearing components 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 authorised, qualified Ottobock personnel (no replacement by the user).
- ► The product and any damaged components may only be opened and repaired by authorised, qualified Ottobock personnel.

⚠ CAUTION

Mechanical stress on the product

- > Falling due to unexpected product behaviour as the result of a malfunction.
- > Falling due to breakage of load-bearing components.
- > Skin irritation due to defects on the hydraulic unit with leakage of liquid.
- ► Do not subject the product to mechanical vibrations or impacts.
- ► Check the product for visible damage before each use.

⚠ CAUTION

Use of the product when battery charge level is too low

Falling due to unexpected behaviour of the prosthesis because of changed damping behaviour.

- ► Check the current charge level before use and charge the prosthesis if required.
- ► Note that the operating time of the product may be reduced at low ambient temperatures or due to ageing of the battery.

⚠ CAUTION

Risk of pinching in the joint flexion area

Injuries due to pinching of body parts.

- ► Ensure that fingers/body parts or soft tissue of the residual limb are not in this area when bending the joint.

⚠ CAUTION

Penetration of dirt and humidity into the product

- > Falling due to unexpected product behaviour as the result of a malfunction.
- > Falling due to breakage of load-bearing components.
- ► Ensure that solid particles, foreign objects and liquids (such as body and/or wound fluids) are not allowed to penetrate into the product.
- ► Do not expose the product to splashed water.
- ► Thick clothing should be worn over the product as a minimum in rainy conditions.
- ► If water, salt water or body and/or wound fluid has penetrated the product and components, the Protective Cover (if any) must be removed immediately. Dry the knee joint and components with a lint-free cloth and allow the components to fully air dry. The prosthesis must be inspected by an authorised Ottobock Service Centre.

⚠ CAUTION

Mechanical stress during transport

> Falling due to unexpected product behaviour as a result of a malfunction.
> Falling due to breakage of load-bearing components.
> Skin irritation due to defects on the hydraulic unit with leakage of liquid.

► Only use the transport packaging for transportation.

⚠ CAUTION

Signs of wear and tear on the product components

Falling due to damage or malfunction of the product.

► Regular service inspections (maintenance) are mandatory in the interest of patient safety and in order to maintain operating reliability and protect the warranty.

⚠ CAUTION

Use of unapproved accessories

> Falling due to product malfunction as a result of reduced interference resistance.
> Interference of other electronic devices due to increased emissions.

► Use the product only in combination with the accessories, signal converters and cables listed in the sections "Scope of delivery" (see page 13) and "Accessories" (see page 13).

NOTICE

Improper product care

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

► Clean the product with a damp cloth only (fresh water).

4.4 Information on the Power Supply/Battery Charging

⚠ CAUTION

Charging the prosthesis without taking it off

Falling due to unexpected behaviour of the prosthesis because of changed damping behaviour.

► Inform the patient that wearing the prosthesis is not permitted during the entire charging process.

⚠ CAUTION

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

Falling 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.

NOTICE

Use of incorrect power supply unit/battery charger

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

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

4.5 Battery charger information

⚠ WARNING

Storing/transporting the product near active implanted systems

Interference with active implantable systems (e.g. pacemaker, defibrillator, etc.) due to the product's magnetic field.

► When storing/transporting 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 notices stipulated by the manufacturer of the implant.

NOTICE

Improper care of the housing

Damage to the casing through the use of acetone, white spirit or similar solvents.

► Only clean the housing with a damp cloth and mild soap (e.g. 453H10=1 Ottobock DermaClean).

NOTICE

Penetration of dirt and humidity into the product

Lack of proper charging functionality due to malfunction.

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

NOTICE

Mechanical stress on the power supply/battery charger

Lack of proper charging functionality due to malfunction.

► Do not subject the power supply/battery charger to mechanical vibrations or impacts.

► Check the power supply/battery charger for visible damage before each use.

NOTICE

Operating the power supply unit/charger outside of the permissible temperature range

Lack of proper charging functionality due to malfunction.

► Only use the power supply unit/charger for charging within the allowable temperature range. The section "Technical data" contains information on the allowable temperature range (see page 37).

NOTICE

Independent changes or modifications carried out to the battery charger

Lack of proper charging functionality due to malfunction.

► Have any changes or modifications carried out only by Ottobock authorised, qualified personnel.

NOTICE

Contact of the battery charger with magnetic data storage devices

Wiping of the data storage device.

► Do not place the battery charger on credit cards, diskettes, audio or video cassettes.

4.6 Information on Alignment/Adjustment

⚠ CAUTION

Use of unsuitable prosthetic components

Falling due to unexpected behaviour of the knee joint or breakage of load-bearing components.

► Use the product only in combination with the components listed in the section “Combination possibilities” (see page 4).

⚠ CAUTION

Improper assembly of the screw connections

Falling due to breakage or loosening of the screw connections.

► Clean the threads before every installation.

► Apply the specified tightening torque values for installation (see the section "Technical data" see page 37).

► Observe the instructions for securing the screw connections and the use of the correct length.

⚠ CAUTION

Incorrectly secured screws

Falling due to breakage of load-bearing components caused by screw connections coming loose.

► After completing all settings, the set screws in the tube adapter must be secured before they are tightened to the specified torque.

► The screws in the clamp bracket must not be secured but only tightened to the specified torque.

⚠ CAUTION

Incorrect alignment or assembly

Falling due to damage to the prosthesis components.

- ► Observe the alignment and assembly instructions.

⚠ CAUTION

Errors during prosthesis alignment

Falling due to breakage of load-bearing components.

- ► At maximum flexion (reached under full load!), it is essential to maintain a minimum distance of 3 mm (1/8") between the hydraulic unit and the socket.
- ► At maximum flexion and insofar as contact with the frame of the knee joint cannot be avoided (in case of voluminous residual limbs), the socket must lie flat against the frame. Soft cushioning on the socket will assist in keeping the socket flat.

⚠ CAUTION

Insufficient insertion depth of the tube adapter

Falling due to breakage of load-bearing components.

- ► Insert the tube adapter at least 40mm to ensure operational safety.
- ► The patient must be seated for length adjustments.

⚠ CAUTION

Operator errors when adjusting settings using the adjustment software

Falling due to unexpected prosthesis behaviour.

- ► Do not charge the prosthesis battery during the adjustment process since the prosthesis is not functional while the battery is being charged.
- ► During the adjustment process, the prosthesis must not remain unattended when connected to the adjustment software while being worn by the patient.
- ► Observe the maximum range of the Bluetooth connection and note that obstacles may limit this range.
- ► During the data transfer (PC to prosthesis), the prosthesis wearer should sit or stand still, and the BionicLink PC must not be removed from the computer.
- ► If you want to make only temporary changes to the settings while connected to the adjustment software, you must reverse these changes before disconnecting the adjustment software.
  You must also ensure the patient does not leave the range of the Bluetooth connection if settings have been changed temporarily.
- ► Inform the patient immediately if the data connection is accidentally interrupted during the adjustment process.
- ► The connection to the prosthesis must always be disconnected after adjustments have been completed.
- ► Successful participation in an Ottobock product training course is mandatory prior to initial use. Additional product training courses may be required to qualify for software updates.
- ► The correct input of the foot size, prosthesis dimensions, body weight and calibration are important criteria for achieving a quality fitting. If the values are too high, the prosthesis may not switch to the swing phase. If the values are too low, the prosthesis may trigger the swing phase at the wrong time.
- ► If the patient uses walking aids (e.g., crutches or walking canes) during the adjustment process, you will need to readjust the settings when the patient no longer requires these aids.
- ► Use the online help function integrated into the software.
- ► Do not disclose your personal access data.

⚠ CAUTION

Error during optimisation of damping behaviour

Falling due to unexpected behaviour of the product.

- ► Note that the patient must stand very securely during this procedure to ensure safety.

4.7 Information on Proximity to Certain Areas

⚠ CAUTION

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

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

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

⚠ CAUTION

Operating the product in very close proximity to other electronic devices

Falling 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

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

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

► Ensure that the patient is not in the vicinity of sources of strong magnetic and electrical interference during trial fitting (such as theft prevention systems, metal detectors...).
If this cannot be avoided, ensure at least that the patient has a safeguard when walking or standing (e.g. a handrail or the support of another person).

► In general, monitor the product for unexpected changes in the damping behaviour when electronic or magnetic devices are in the immediate vicinity.

⚠ CAUTION

Entering a room or area with strong magnetic fields (e.g. magnetic resonance tomographs, MRT (MRI) equipment...)

> Falling due to unexpected restriction of the product's range of motion caused by metallic objects adhering to the magnetised components.

> Irreparable damage to the product due to the effect of strong magnetic fields.

► Make sure that the patient takes off the product before entering the room or area and stores the product outside this room or area.

► Damage to the product caused by exposure to strong magnetic fields cannot be repaired.

⚠ CAUTION

Remaining in areas outside the allowable temperature range

Falling due to malfunction or the breakage of load-bearing product components.

► Ensure that the patient is not in areas outside the permissible temperature range (see page 37) during trial fitting.

4.8 Information on Use

⚠ CAUTION

Walking up stairs

Falling due to foot being placed incorrectly on stair as a result of changed damping behaviour.

► Inform the patient that the handrail always has to be used when walking up stairs, and that most of the sole of the foot has to be set onto the stair surface.

► Particular caution is required when carrying children up the stairs.

⚠ CAUTION

Walking down stairs

Falling due to foot being placed incorrectly on stair as a result of changed damping behaviour.

- ► Inform the patient that the handrail always has to be used when walking down stairs, and that the patient has to roll over the edge of the step with the middle of the shoe.
- ► The warnings and error signals have to be observed (see page 41).
- ► Notify the patient that resistance in the flexion and extension direction can change in case of warnings and error signals.
- ► Particular caution is required when carrying children down the stairs.

⚠ CAUTION

Overheating of the hydraulic unit due to uninterrupted, increased activity (e.g. extended walking downhill)

- > Falling due to unexpected behaviour of the product because of switching into overheating mode.
- > Burns due to touching overheated components.
- ► Be sure to pay attention when pulsating vibration signals start. They indicate the risk of overheating.
- ► As soon as these pulsating vibration signals begin, the activity level has to be reduced so the hydraulic unit can cool down.
- ► Full activity may be resumed after the pulsating vibration signals stop.
- ► If the activity level is not reduced in spite of the pulsating vibration signals, this could lead to the hydraulic element overheating and, in extreme cases, cause damage to the product. In this case, the product should be inspected by an authorised Ottobock Service Centre.

⚠ CAUTION

Overloading due to unusual activities

- > Falling due to unexpected product behaviour as the result of a malfunction.
- > Falling due to breakage of load-bearing components.
- > Skin irritation due to defects on the hydraulic unit with leakage of liquid.
- ► The product was developed for everyday use and should not be used for walking speeds over 3 km/h or unusual activities. These unusual activities include, for example, extreme sports (free climbing, parachuting, 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

Incorrect switching between “Bicycle ergometer” MyMode/“Basic mode”

Falling due to unexpected product behaviour because of changed damping behaviour.

- ► Ensure that the patient is sitting on the bicycle ergometer during all switching processes.
- ► Inform the patient that the signals that indicate switching to the MyMode and to basic mode have to be observed.
- ► Switching back to basic mode is mandatory once the activities in the MyMode have been completed.
- ► Correct the switching or use the Cockpit app if necessary.
- ► Inform the patient that verifying whether the chosen mode corresponds to the desired movement type is always required before taking the first step/making the first movement.

4.9 Notes on the safety modes

⚠ CAUTION

Using the product in safety mode

Falling due to unexpected product behaviour because of changed damping behaviour.

- ► The warnings/error signals (see page 41) have to be observed.

⚠ CAUTION

Safety mode cannot be activated due to malfunction caused by water penetration or mechanical damage

Falling due to unexpected product behaviour because of changed damping behaviour.

► Using the product when it is defective is prohibited.

► The product must be inspected by an authorised Ottobock Service Centre.

⚠ CAUTION

Safety mode cannot be deactivated

Falling due to unexpected product behaviour because of changed damping behaviour.

► If safety mode cannot be deactivated by recharging the battery, a permanent error has occurred.

► Using the product when it is defective is prohibited.

► The product must be inspected by an authorised Ottobock Service Centre.

⚠ CAUTION

Safety signal occurs (ongoing vibration)

Falling due to unexpected product behaviour because of changed damping behaviour.

► The warnings/error signals (see page 41) have to be observed.

► After the safety signal has been emitted, further use of the product is prohibited.

► The product must be inspected by an authorised Ottobock Service Centre.

4.10 Instructions for use with an osseointegrated implant system

⚠ WARNING

High mechanical loads due to normal or unusual situations, such as falling

> Overloading of the bone, which can lead to pain, loosening of the implant, necrosis or fracture among other things.

> Damage or breakage of the implant system or its components (safety components...).

► Verify compliance with the fields of application, conditions of use and indications according to the information of the manufacturers, both for the knee joint and for the implant system.

► Note the instructions of the clinical personnel that indicated the use of the osseointegrated implant system.

5 Scope of Delivery and Accessories

5.1 Scope of delivery

- 1 pc. Kenevo 3C60=ST* (with threaded connector) or
- 1 pc. Kenevo 3C60* (with pyramid connector)
- 1 pc. AXON 2R17 tube adapter or
- 1 pc. 2R20 AXON tube adapter or
  1 pc. 2R21 AXON tube adapter with torsion
- 1 pc. 757L16-4 power supply
- 1 pc. 4E70-1 inductive charger
- 1 pc. Instructions for use (qualified personnel)
- 1 pc. Instructions for use (user)
- 1 pc. prosthesis passport
- 2 pc. 4H107 8° flexion stop (already installed on delivery)
- 2 pc. 4H108 16° flexion stop
- 1 pc. cosmetic case for battery charger and power supply
- "Cockpit" app and corresponding instructions for use for download from the corresponding app stores

5.2 Accessories

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

- Kenevo Protective Cover 4X840
- "4X445=V1.6 K-Soft" or higher adjustment software, update by Internet download.
  Note the system requirements!
- 3S26 cosmetic foam cover
- 4X633 Kenevo foam cover toolset
- 4X634 Kenevo foam cover charging set

6 Charging the prosthesis battery

The following points must be observed when charging the battery:

- Use the 757L16-4 power supply and 4E70-1 battery charger to charge the battery.
- The full surface of the inductive charger must be in contact with the receiver of the charging unit. This must be verified, particularly when fabricating a cosmetic foam cover. Prior to application, check the contact surfaces for dirt and ensure that no objects are adhering to them.
- The capacity of a fully charged battery is sufficient for one full day.
- We recommend charging the product once a day when used by the patient on a daily basis.
- For the maximum operating time with one battery charge, disconnecting the battery charger from the product only immediately before using the product is recommended.
- 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 37).
- The battery may discharge while the product is not being used.
- The tube adapter must be connected before disconnecting the battery charger, otherwise an error message will result (see page 41).

INFORMATION

Depending on the distance between the battery charger and the receiver on the knee joint, the battery charger can warm up considerably during the charging process. This is not a malfunction.

6.1 Connecting the power supply and battery charger

1) Slide the country-specific plug adapter onto the power supply until it locks into place (see fig. 1).
2) Connect the round, **three-pin** plug of the power supply to the receptacle on the inductive battery charger so that the plug locks into place. (see fig. 2)
   INFORMATION: Ensure correct polarity (guide lug). Do not use force when connecting the cable plug to the battery charger.
3) Plug the power supply into the outlet (see fig. 3).
   → The green LED on the back of the power supply lights up.

→ If the green LED on the power supply does not light up, there is an error (see page 41).

6.2 Connect battery charger to the product

INFORMATION

Do not move the knee joint while it conducts the self-test immediately after disconnecting the charger. Otherwise, an error may occur; if this happens, the problem can be corrected by reconnecting and then disconnecting the charger.

1) Remove the prosthesis.
2) Connect the inductive charger to the receiver of the charging unit on the back of the product.
   Make sure the contact surfaces are clean, with no objects adhering to them.
   → The charger is held in place by a magnet.
   → A correct connection between the battery charger and the product is indicated by feedback (see page 43).
3) The charging process starts.
   → Once the product battery is fully charged, the LED on the battery charger lights up green.
4) After the charging process is complete, remove the inductive charger from the receiver and hold the product still.
   → A self-test is performed, and the product should not be moved while this is in progress. The joint is ready for operation only after corresponding feedback (see page 43).
5) Put the prosthesis on.

INFORMATION

To make the operating time of the prosthesis as long as possible, the charger should not be removed until immediately before the prosthesis is used.

Indication of the charging process:

Battery charger	
	Battery is charging. The on time of the LED indicates the current charge level. The on time of the LED gets longer as the charge level increases. It only flashes briefly at the start of the charging process and stays on continuously at the end of the charging process.
	Battery is fully charged, or the temperature has exceeded/fallen below the permissible range for the knee joint during charging. Check current charge level (see page 15).

6.3 Display of the current charge level

6.3.1 Display of battery charge level without additional devices

INFORMATION

The charge level cannot be displayed during the charging process, e.g. by turning the prosthesis over. The product is in charging mode.

1) Turn the prosthesis 180° (the sole of the foot has to face up).
2) Hold still for 2 seconds and wait for beeps.

Beep signal	Vibration signal	Battery charge level
5x short		more than 80%
4x short		65% to 80%
3x short		50% to 65%
2x short		35% to 50%

Beep signal	Vibration signal	Battery charge level
1x short	3x long	20% to 35%
1x short	5x long	less than 20%

7 Preparing the product for use

7.1 Alignment

The following alignment guidelines contain descriptions for connecting the knee joint to a prosthetic socket. In principle, the alignment of the prosthesis is independent of the type of connection for the knee joint. In case of a connection to an osseointegrated, percutaneous implant system, a socket is not used during bench alignment in the alignment apparatus. In this case, the central proximal point on the prosthetic socket corresponds to the trochanter of the thigh bone (see illustration in the section "Bench alignment in the alignment apparatus" see page 18).

Ensure that possible flexion or adduction of the transfemoral residual limb can be compensated to a permissible extent by an adapter approved by the implant manufacturer in the course of static alignment optimisation. Safe functioning of the knee joint is only guaranteed with biomechanically correct alignment.

7.1.1 Settings with the "K-Soft" adjustment software

7.1.1.1 Introduction

The "K-Soft" adjustment software makes it possible to optimise the product settings for a patient. The adjustment software provides step-by-step guidance through the adjustment process. After the settings are configured, the data for them can be saved and printed for documentation. These data can be retrieved if required and imported into the product.

Please consult the integrated online help in the adjustment software for further information.

INFORMATION

The **4X445 K-Soft adjustment software, version 1.6 or higher, is required** for correct alignment. If K-Soft is on hand in version 1.0 or higher, it can be updated.
Note the system requirements!

Updating the K-Soft adjustment software

1) Click "**Help > About**" in the menu bar of the Data Station when you are connected to the Internet.
   → The window opens with the versions of the previously installed programs and the manufacturer's address.
2) Click the "**Check for updates**" button in this window.
   → A search for updates of previously installed software products and components is performed via the Internet.
3) If updates are available, click "**Download**" in the column on the right in order to download and save the update.
4) Extract the "ZIP file" and execute it.

INFORMATION

Cybersecurity

- ► Keep your operating system up to date and always install any available security updates.
- ► Protect your computer from unauthorised access (e.g., by using virus scans, password protection etc.).
- ► Do not use unsecured networks.
- ► Please contact the manufacturer if you suspect cybersecurity problems.

7.1.1.2 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 included with the adapter.

7.1.1.3 Preparing the product to connect to the adjustment software

If the product does not emit any signals when querying the charge level (see page 15), the battery is drained or the product is switched off.

Switching on the product

1) Connect the power supply with battery charger to the wall socket.
2) Connect the battery charger to the product.
3) Wait for feedback signals.
4) Disconnect the battery charger from the product.

→ After feedback signals are emitted (self test), the product is switched on.

Switching on Bluetooth

Upon delivery, the Bluetooth function of the prosthesis is switched off.

When the Bluetooth function is switched off, it is only turned on for 2 minutes after connecting/disconnecting the battery charger and is then turned off again automatically. When a connection with the PC is active (the symbol is lit up), the Bluetooth function is not switched off automatically.

7.1.2 Shortening the Tube Adapter

⚠ CAUTION

Incorrect processing of tube

Falling due to damage to the tube.

- ► Do not clamp the tube into a vice.
- ► For shortening the tube, use only a tube cutter.

⚠ CAUTION

Damage to the cable while shortening the tube adapter

Falling due to unexpected product behaviour as the result of switching into safety mode.

- ► When shortening the tube adapter, make sure the cable does not get damaged.

1) Determine the required length of the tube adapter using the configuration assistant in the adjustment software.
2) Shorten the tube adapter to the determined value with the 719R3 tube cutter.
3) Store the tube adapter cable in the tube adapter. If this is not possible, the cable must be protected against damage.
4) Use a file (cut 2 (medium), e.g. 715H1=2 recommended) to file the cut edge smooth. Be careful of the tube adapter cable.
   NOTICE! When filing or deburring, make sure that no metal shavings can get into the plug of the tube adapter cable.
5) Chamfer the outside with a file.
6) Smooth the inside and outside of the cut edge with sandpaper (recommended grit 120).

7.1.3 Installing the Tube Adapter

⚠ CAUTION

Improper assembly of the screw connections

Falling due to breakage or loosening of the screw connections.

- ► Clean the threads before every installation.
- ► Apply the specified tightening torque values for installation (see the section "Technical data" see page 37).
- ► Observe the instructions for securing the screw connections and the use of the correct length.

1) Install the prosthetic foot on the tube adapter and tighten the **set screws on the tube adapterto a torque of 15 Nm**.
   INFORMATION: Replace any set screws that are protruding or recessed too much with suitable ones. For approved set screws, see the section "Technical data" (see page 37).
   INFORMATION: The printed scale on the tube adapter must face forward.
2) Connect the cable of the tube adapter to the cable of the knee joint.
3) Push the protruding cable loop back into the tube adapter. If the tube adapter has been shortened to the minimum length, the plug must be inserted in the cavity. The cable loop must then be stored carefully.
4) Insert the tube adapter about 60 mm into the knee joint (for the exact value, consult the configuration assistant in the adjustment software).
   INFORMATION: Corrections in the insertion depth between 40 mm and 73 mm are permissible (slide in 13 mm and pull out 20 mm).

5) Turn the foot outwards slightly and slightly tighten the **distal tube clamp screw(approx. 4 Nm)**.
INFORMATION: After alignment optimisation, this screw must be tightened to a torque of 7 Nm.

INFORMATION

A calibration procedure must be performed after each change to the tube adapter, prosthetic foot or knee joint using the adjustment software.

INFORMATION

Disconnect tube adapter without error message

If the tube adapter is disconnected while the knee joint is operational, an error message is output. To prevent this error message, the knee joint must be switched off before the tube adapter is disconnected (see page 34).

7.1.4 Adjusting the torsion moment on the 2R21 AXON tube adapter

⚠ CAUTION

Incorrect setting of the torsion moment in the torsion unit

Falling due to unexpected behaviour of the product.

► The marking on the Allen head screw may not be turned as far as the red area or beyond the red area.

The torsion moment can be adjusted with the Allen head screw in the centre of the adapter.

Increasing the torsion moment:

► Turn the mark in the centre of the torsion unit clockwise.

Decreasing the torsion moment:

► Turn the mark in the centre of the torsion unit counterclockwise.

INFORMATION

If the patient notices a sudden change in the torsion moment, check whether the mark of the Allen head screw is still within the setting range. Correct the setting if this is not the case.

7.1.5 Bench alignment in alignment apparatus

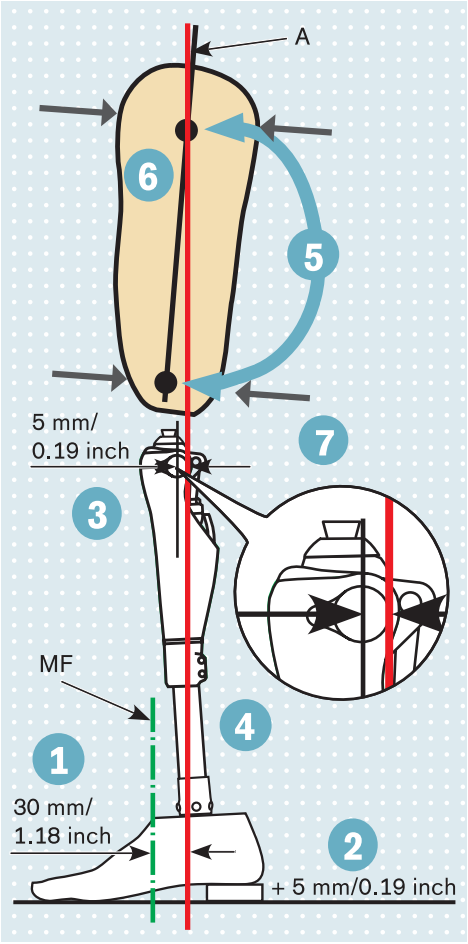
INFORMATION

The alignment recommendations must be observed in order for the prosthesis to function correctly.

INFORMATION

The patient's gait pattern shall change as he/she becomes accustomed to the prosthesis.
Therefore it is recommended to complete the entire adjustment procedure again about two weeks after the initial fitting.

A correct bench alignment (e.g. using the 743A200 PROS.A. Assembly alignment apparatus) ensures that the user can benefit from all the advantages of the product. If the L.A.S.A.R. Assembly alignment apparatus (743L200) is available, it can be used as well. The position of the residual limb must be taken into account when positioning the socket connector. Plumb lines in the frontal and sagittal planes (drawn from the hip joint's centre of rotation and marked during plaster cast taking and trial fitting of the check socket) will facilitate correct positioning of the lamination anchor or socket adapter.

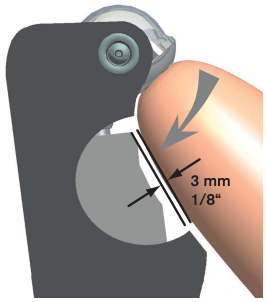


1. Position the middle of the foot (MF) approx. 30 mm/1.18 inch anterior to the alignment reference line (A). This applies to all foot components that are recommended for use with the product, independently of the previous alignment specifications in the instructions for use of those feet!
2. Noting the alignment recommendation of the foot component, add 5 mm to the effective heel height (shoe heel height – sole thickness in the forefoot area) and set the outward rotation of the foot.
3. Place the alignment reference point (=knee axis) approx. 0-5 mm/0-0.19 inch anterior to the alignment reference line.
   Take into account the knee-ground distance and outward rotation of the knee (the adapter insert provides for a rotation of approx. 5°). Recommended sagittal positioning of the alignment reference point: 20 mm/0.79 inch above the medial tibial plateau.
4. Connect the foot and knee joint using a tube adapter. To do so, tilt the joint in the correct position and set the required tube length.
5. Mark the lateral centre of the socket with a centred, proximal dot and a distal dot. Mark a line through both points from the edge to the end of the socket.
6. Now position the socket such that the alignment reference line passes through the proximal centre mark.
   Adjust the socket flexion to 3° – 5°, but take the individual situation (e.g. hip joint contractures) and the ischial tuberosity-to-ground distance into account.
7. Connect the socket and modular knee using adapters.

7.1.6 Checking the socket after bench alignment

After bench alignment, verify that at maximum extension and maximum flexion the distance from the socket to the knee joint is not less than the minimum. A collision of the socket with the hydraulics or frame can cause damage to the knee joint.

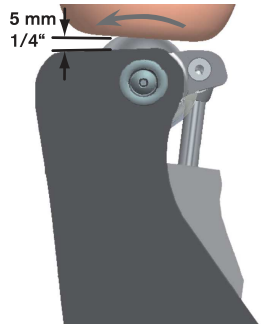
Verification at maximum flexion



If the distance between the socket and hydraulics is not sufficient, the hydraulics may be damaged. Check the distance as follows:

1) Bring the knee joint with socket to maximum flexion.
2) Check the available distance between the hydraulics and socket. It must be at least 3 mm.
   INFORMATION: If the distance is less, a flexion stop has to be installed or an existing flexion stop replaced with a larger one. For information on the flexion stop, see the next section.

Verification at maximum extension



If the distance between the socket or system components such as a rotation adapter and the electronics is not sufficient, these may be damaged. Be sure to follow the system component instructions for use.
Check the distance as follows:

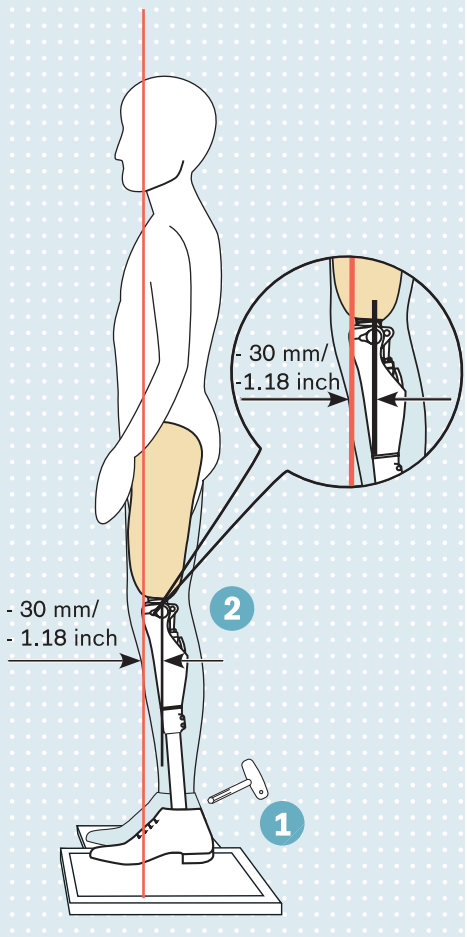
1) Bring the knee joint and socket to maximum extension.
2) Check the available distance between the electronics/top edge of the installed Protective Cover and the socket or system components such as a rotation adapter. It must be at least 5 mm.

INFORMATION

If a protective cover is subsequently installed, the available distance between the electronics and socket without the protective cover has to be at least 10 mm. Installing the protective cover reduces this distance by 5 mm.

7.1.7 Static alignment optimisation

Static alignment can be substantially improved using the L.A.S.A.R. Posture (743L100=*). In order to achieve adequate safety while simultaneously providing easy swing phase initiation, please proceed with alignment as follows:



1. To determine the load line, have the patient (with shoes) stand on the force measuring plate with the prosthetic side and on the height compensation plate with the other leg.
The prosthesis side must be sufficiently loaded (>35% body weight). Note the weight display on the L.A.S.A.R. Posture.

2. Optimise the alignment solely by changing the plantar flexion. Only make adjustments to the distal and proximal setscrews of the socket adapter on the prosthetic foot, so that the load line (laser line) runs approx. 30 mm/1.18 inch in front of the alignment reference point (= knee axis) for the knee joint.

7.1.8 Dynamic alignment optimisation

After adjusting the product with the adjustment software, perform dynamic optimisation during trial walking. Often, the following aspects have to be observed and adapted, if necessary:

- Socket flexion position by verifying step length symmetry (sagittal plane)
- Adduction position of the socket and M-L positioning of the socket adapter (frontal plane)
- Rotation position of the knee joint axis and outward rotation of the prosthetic foot (transversal plane)

7.1.9 Flexion stop

The knee joint comes fitted with a flexion stop upon delivery. This reduces the maximum flexion angle by 8°, thus preventing the socket from coming into contact with the hydraulic unit.

To limit the flexion angle, the knee joint can be equipped with the following flexion stops:

- 4H107 flexion stop (already installed): reduction of the maximum flexion angle by 8°
- 4H108 flexion stop (in scope of delivery): reduction of the maximum flexion angle by 16°

The flexion stop can be removed to increase the flexion angle. In this case, it must be ensured that the socket and the hydraulic unit do not collide (see page 19).

Removing the flexion stop

1) Use an appropriate screwdriver to loosen the screws on both flexion stops (to the left and right of the piston rod).
2) Remove both flexion stops from the joint together with the screws.
   INFORMATION: Do not insert screws without flexion stops!

Inserting the flexion stop

1) Insert both flexion stops (to the left and right of the piston rod).
2) Secure the screws with 636K13 thread lock.
3) Insert the screws.
4) Tighten the screws to 0.6 Nm with the 710D1 torque wrench.

7.2 Optional: Installing the foam cover

If a foam cover is used with the knee joint, a charging shaft has to be mounted so the charger can be applied.

Preparing the foam cover

> **The required tools and components are included in the 4X633 Kenevo foam cover toolset:** centring plate, centring rod, hole cutter, 65X3 O-ring

1) Attach the centring plate to the knee joint over the receiver of the charging unit using the O-ring. (see fig. 4)
2) Pull on the foam cover.
3) Feel the area of the centring bore through the foam and mark the area.
4) Make an opening for the threaded rod in the marked area.
5) Insert the centring rod through the opening and screw it into the centring plate to the stop. (see fig. 5)
   NOTICE! The two nuts are used to limit the screw-in depth and protect the charging receiver and must not be removed.
6) Apply the hole cutter and rotate it clockwise to cut a hole. (see fig. 6)
7) Unscrew the centring rod.
8) Remove the foam cover.

9) Take the centring plate off the knee joint.

Installing the charging shaft

> **The required tools and components are included in the 4X634 Kenevo foam cover charging set:** charging shaft receiver, charging shaft, cover for charging shaft, 65X3 O-ring

1) Attach the charging shaft receiver to the knee joint using the O-ring. (see fig. 7)
2) Shorten the charging shaft using a suitable tool (see fig. 8) so the length corresponds to the thickness of the foam cover material.
3) Deburr the cut edge.
4) Clip the charging shaft cover to the charging shaft.
5) Pull on the foam cover.
6) Insert the charging shaft and push it in until it engages in the charging shaft receiver. (see fig. 9)

7.3 Completing the alignment

Upon finalising all settings, all screw connections must be tightened to the proper tightening torque (see page 37).

INFORMATION

A calibration procedure must be performed after each change to the tube adapter, prosthetic foot or knee joint using the adjustment software.

⚠ CAUTION

Incorrectly secured screws

Falling due to breakage of load-bearing components caused by screw connections coming loose.

- ► After completing all settings, the set screws in the tube adapter must be secured before they are tightened to the specified torque.
- ► The screws in the clamp bracket must not be secured but only tightened to the specified torque.

8 Use

INFORMATION

Knee joint movement noise

When using exoprosthetic knee joints, servomotor, hydraulic, pneumatic or brake load dependent control functions can cause movement noise. This kind of noise is normal and unavoidable. It generally does not indicate any problems. If movement noise increases noticeably during the lifecycle of the knee joint, the knee joint should be inspected by an authorised Ottobock Service Centre immediately.

8.1 Recommended apps

The following table gives an overview of the recommended apps that will help you configure and use the product in the best possible way.

App name	App manufacturer	Operating systems	Target user group
Cockpit	Ottobock SE & Co. KGaA	Android, iOS	User (patient)
Kenevo A-B-C (available in selected regions)	Ottobock SE & Co. KGaA	Android, iOS	Qualified personnel (therapist)

INFORMATION

The app is downloaded from the app store of the device to be used and kept up to date.

If the app does not appear in the app store, it means it is unavailable for the version of the device's operating system. An operating system update or the use of another device may help.

For the safe use of the app, its instructions for use must also be observed.

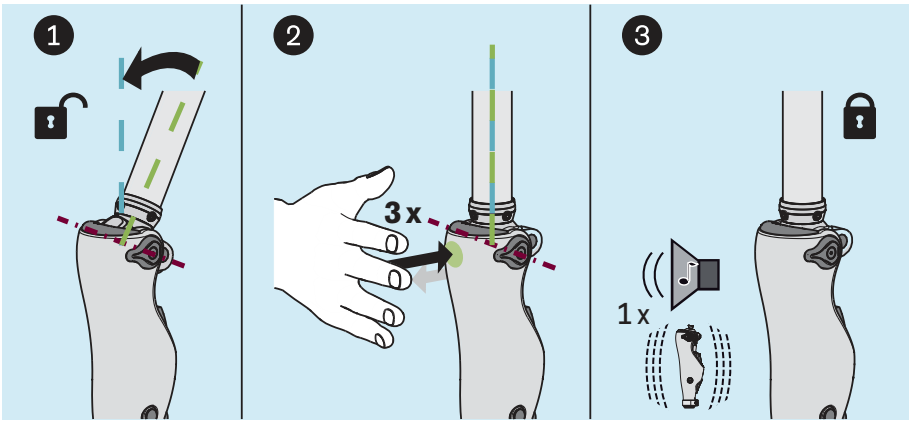
In the app store, there is a download link for the instructions for use for the app on the description page of the app. When you update the respective app, the latest instructions for use should also be downloaded.

If there are difficulties with the download, the instructions for use (PDF file: 647G1566) can be requested from the following email address, specifying the name of the app:
order-ifu@ottobock.com

8.2 Manual locking function

If necessary, the user can use the manual locking function to manually lock and also unlock the prosthetic knee joint without an app. This function can be used in situations where an enhanced feeling of safety from the manual lock is required while walking (e.g. on damp or slippery surfaces).

The manual locking function can be deactivated for the user in the app. Note that after deactivation in the app, the manual locking function no longer responds until the function is reactivated in the app. For more detailed information, see the app's instructions for use.

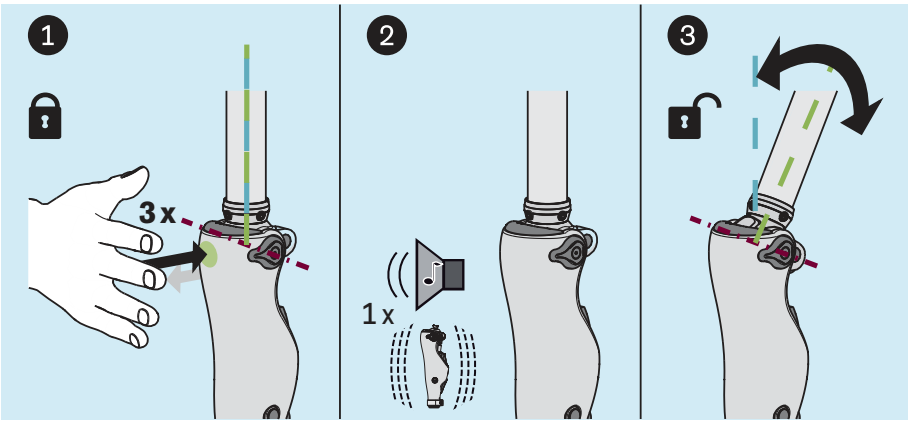


Activating lock using the manual locking function

1) Extend the prosthetic knee joint to maximum full extension.
2) Tap the marked area with the palm of the hand **3x**.
3) The control device of the prosthetic knee joint emits **1x** acoustic signal and **1x** vibration signal when the lock is activated.

→ The prosthetic knee joint is locked and can only be flexed again after the lock is deactivated using the manual locking function.

Deactivating lock using the manual locking function



1) Tap the marked area with the palm of the hand **3x**.
2) The control device of the prosthetic knee joint emits **1x** acoustic signal and **1x** vibration signal when the manual locking function is deactivated.
3) The prosthetic knee joint is unlocked.

→ The prosthetic knee joint can be used again in basic mode.

8.3 Training feedback signals

In relation to training for everyday life – whether initially with qualified personnel (therapists) or later by the user alone – acoustic training feedback signals can be activated via an app.

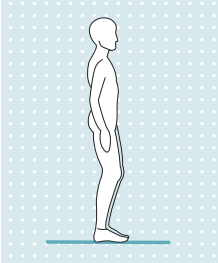
After training, the feedback signals must be turned off to avoid confusion with other warning signals that may occur during daily use. This is particularly important for qualified personnel (therapists), since there are special training feedback signals that **cannot** be activated and deactivated in the user app.

The following table gives an overview of the available training feedback signals, as well as which app and which mode types they can be used in. Further information on the training feedback signals can be found in the app instructions for use as well as the training documentation for qualified personnel via the Ottobock Academy Portal.

Overview of training feedback signals				
Feedback Function	**Availability**			**Description**
	Cockpit (app for users)	**Kenevo A-B-C** (app for therapists - available in selected regions)	**Mode type**	
Sitting down movement detected	No	Yes	A/B/B+	Training feedback signal when the triggering criteria for the sitting down movement are reached
Supported sitting down/standing up	No	Yes	A/B/B+	Training feedback signal when the “pre-lock” is activated during sitting down and standing up processes, see the section “Standing up” (see page 25)
Stance phase flexion	Yes	Yes	B+/C	Training feedback signal after performing a stance phase flexion shortly after heel contact
Stance release	Yes	Yes	B/B+/C	Training feedback signal when swing phase triggering criteria are reached
Swing phase angle too high	No	Yes	B/B+/C	Training feedback signal (3 x fast beep) when reaching an excessively high swing phase angle
Load on prosthesis	Yes	Yes	A/B/B+/C	Training feedback signal if the prosthesis load is too low or too high
Load on prosthesis forefoot – heel	Yes	Yes	A/B/B+/C	Training feedback signal for forefoot or heel load on the prosthesis side

8.4 Movement pattern in activity mode A (locked mode)

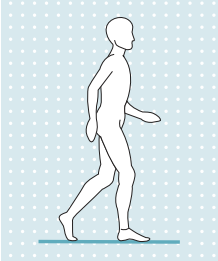
8.4.1 Standing



The knee joint is locked in the flexion direction. Therefore, proceed as you would with a rigid knee joint.

INFORMATION: In response to a sitting movement, the joint switches to high flexion resistance.

8.4.2 Walking



Initial attempts at walking with the prosthesis always require the instruction of trained, qualified personnel.

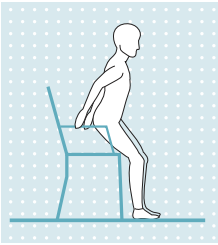
The knee joint is locked in the flexion direction. Therefore, proceed as you would with a rigid knee joint.

8.4.3 Sitting down

The prosthesis makes it possible to sit down without unlocking it manually. The adjustable flexion resistance of the hydraulic unit provides support while sitting down.

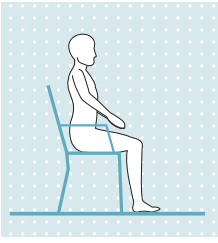
We recommend that the user supports themselves with their hands while sitting down, e.g.:

- Support on the armrests of the chair
- Support on the handles of a walker
- Use of forearm crutches
- Use of a cane



1) Stand 5 to 10 cm in front of the edge of the chair.
   While standing up, the edge of the chair should not yet touch the hollow of the knee nor press against the lower leg.
2) Place both feet side by side at the same level.
3) While sitting down, distribute weight evenly on both legs and push the pelvis in the direction of the backrest.
   This causes the weight to shift to the heel and the prosthesis to tilt backward, which makes the knee joint switch to the "sitting resistance". Support is therefore provided while sitting down.

8.4.4 Sitting



If the user is in a sitting position, i.e. the thigh is close to horizontal and there is no load on the leg, the knee joint switches to a low resistance in both the flexion and extension direction.

If the load on the prosthesis was not sufficient while sitting down, the leg is extended during this process. Due to the nearly horizontal position of the lower leg, the flexion resistance is reduced automatically and the lower leg lowers on its own.

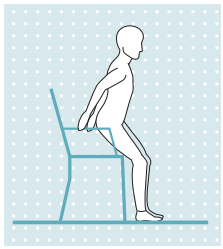
If the sitting function is enabled in the adjustment software and activated via the Cockpit app (Changing the prosthesis setting using the cockpit app), the resistance in the flexion direction is reduced as well.

8.4.5 Standing up

Notwithstanding low damping while sitting, the prosthesis supports standing up.

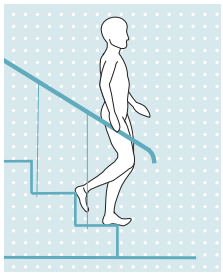
Damping is increased after rising from the seat. From an angle of approx. 45°, the knee joint identifies a "standing up process" which results in what is called "pre-locking" in the flexion direction. This function makes it possible to stand up with pauses in between. The joint fully supports weight during these pauses. If standing up is aborted,

the "sitting down" function is activated again.
The joint is locked after fully standing up.



1) Place the feet at the same level.
2) Lean the upper body forward.
3) Put the hands on armrests, if available.
4) Stand up with support from the hands, while keeping weight evenly distributed over feet.

8.4.6 Walking down stairs

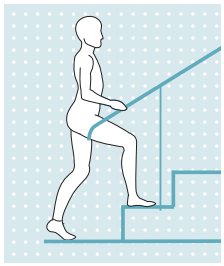


The knee joint is locked in the flexion direction.

1) Hold the handrail with one hand.
2) Place the foot of the prosthetic leg on the first step.
3) Pull up the other leg.

INFORMATION: Walking down stairs step-over-step is not possible in this activity mode.

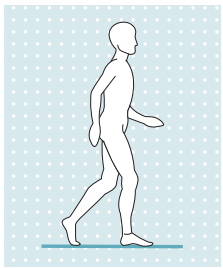
8.4.7 Walking up stairs



Walking up stairs step-over-step is not possible.

1) Hold the handrail with one hand.
2) Place the foot of the less affected leg onto the first step.
3) Pull up the other leg.

8.4.8 Walking backwards

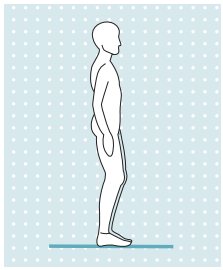


The knee joint is locked in the flexion direction. Proceed as you would with a rigid knee joint.

8.5 Movement pattern in activity mode B (semi-locked mode) / B+ (semi-locked mode with stance phase flexion)

8.5.1 Standing

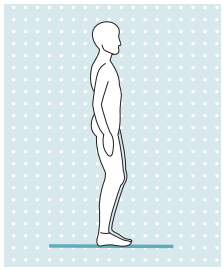
Activity mode B (semi-locked mode)



The knee joint is locked in the flexion direction.

INFORMATION:The joint responds to a sitting movement by switching to high flexion resistance.

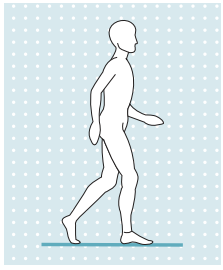
Activity mode B+ (semi-locked mode with stance phase flexion)



The knee joint is locked starting at stance phase flexion of up to 10°.

INFORMATION:The joint responds to a sitting movement by switching to high flexion resistance.

8.5.2 Walking



Initial attempts at walking with the prosthesis always require the instruction of trained, qualified personnel.

The hydraulics stabilise the knee joint in the stance phase and release the knee joint in the swing phase so that the leg can swing forward freely.

In order to safely switch to the swing phase, the prosthesis has to be partially unloaded from the lunge position with a simultaneous forward movement.

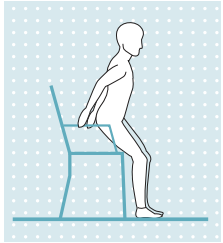
If desired, stance phase flexion of up to 10° can be permitted for this mode in the adjustment software (setting only available in activity mode B).

8.5.3 Sitting down

The prosthesis makes it possible to sit down without unlocking it manually. The adjustable flexion resistance of the hydraulic unit provides support while sitting down.

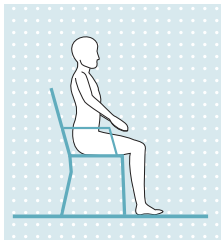
We recommend that the user supports themselves with their hands while sitting down, e.g.:

- Support on the armrests of the chair
- Support on the handles of a walker
- Use of forearm crutches
- Use of a cane



1) Stand 5 to 10 cm in front of the edge of the chair.
   While standing up, the edge of the chair should not yet touch the hollow of the knee nor press against the lower leg.
2) Place both feet side by side at the same level.
3) While sitting down, distribute weight evenly on both legs and push the pelvis in the direction of the backrest.
   This causes the weight to shift to the heel and the prosthesis to tilt backward, which makes the knee joint switch to the "sitting resistance". Support is therefore provided while sitting down.

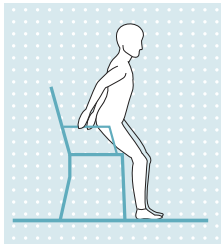
8.5.4 Sitting



If the user is in a sitting position, i.e. the thigh is close to horizontal and there is no load on the leg, the knee joint switches to a low resistance in both the flexion and extension direction.
If the load on the prosthesis was not sufficient while sitting down, the leg is extended during this process. Due to the nearly horizontal position of the lower leg, the flexion resistance is reduced automatically and the lower leg lowers on its own.
If the sitting function is enabled in the adjustment software and activated via the Cockpit app (Changing the prosthesis setting using the cockpit app), the resistance in the flexion direction is reduced as well.

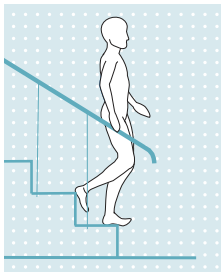
8.5.5 Standing up

The prosthesis supports standing up despite the low flexion resistance while sitting.
The resistance is increased after rising from the seat. From an angle of approx. 45°, the knee joint identifies a "standing up process" which results in what is called "pre-locking" in the flexion direction. This function makes it possible to stand up with pauses in between. The joint fully supports weight during these pauses. If the process of standing up is discontinued, the "sitting down" function is activated again.
The joint is locked after fully standing up.



1) Place the feet at the same level.
2) Lean the upper body forward.
3) Place the hands on arm supports, if available.
4) Stand up with support from the hands while distributing weight evenly between the feet.

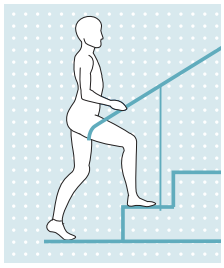
8.5.6 Walking down stairs



The knee joint is locked in the flexion direction.
1) Hold the handrail with one hand.
2) Place the foot of the prosthetic leg on the first step.
3) Pull up the other leg.

INFORMATION: Walking down stairs step-over-step is not possible in this activity mode.

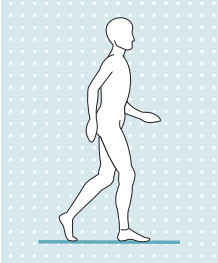
8.5.7 Walking up stairs



Walking up stairs step-over-step is not possible.
1) Hold the handrail with one hand.
2) Place the foot of the less affected leg onto the first step.
3) Pull up the other leg.

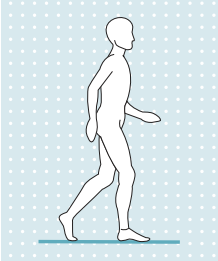
8.5.8 Walking backwards

Activity mode B (semi-locked mode)



The knee joint is locked in the flexion direction. Proceed as you would with a rigid knee joint.

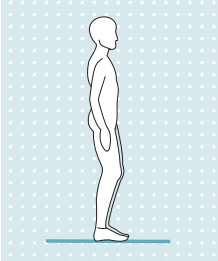
Activity mode B+ (semi-locked mode with stance phase flexion)



The knee joint is locked starting at stance phase flexion of up to 10°. Proceed as you would with a rigid knee joint.

8.6 Movement pattern in activity mode C (yielding mode)

8.6.1 Standing



Knee control through high hydraulic resistance and static alignment.

A stance function can be enabled using the adjustment software. Please see the following section for further information on the stance function.

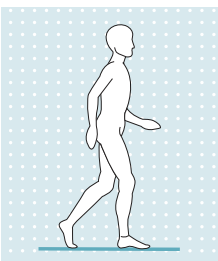
8.6.1.1 Stance function

INFORMATION

To use this function, it needs to be enabled in the adjustment app. It also has to be activated using the Cockpit app (Changing the prosthesis setting using the cockpit app).

The intuitive stance automatically recognises any situation that puts strain on the prosthesis in the flexion direction but where flexion is not permitted. Examples of this include standing on uneven or sloping surfaces. The knee joint is always locked in the flexion direction when the prosthetic leg is not fully extended, is under some amount of load and is at rest. When the load is taken off the leg or forward or backward rollover occurs, the level of resistance is immediately reduced to stance phase resistance again.

8.6.2 Walking



Initial attempts at walking with the prosthesis always require the instruction of trained, qualified personnel.

The hydraulics stabilise the knee joint with high flexion resistance in the stance phase and release the knee joint in the swing phase so that the leg can swing forward freely.

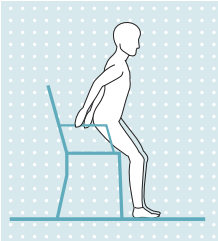
In order to safely switch to the swing phase, the prosthesis has to be partially unloaded from the lunge position with a simultaneous forward movement.

8.6.3 Sitting down

The prosthesis provides high flexion resistance while sitting down. This ensures that the knees bend evenly, thereby supporting the contralateral side.

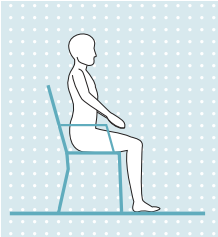
We recommend that the user supports themselves with their hands while sitting down, e.g.:

- Support on the armrests of the chair
- Support on the handles of a walker
- Use of forearm crutches
- Use of a cane



1) Place both feet side by side at the same level.
2) While sitting down, weight should be distributed evenly between both legs and the arm supports used where applicable.
3) Move the buttocks in the direction of the back support and lean the upper body forward. This causes the weight to shift to the heel, making the knee joint switch to the "sitting resistance". Support is therefore provided while sitting down.

8.6.4 Sitting



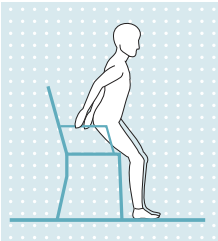
If the user is in a sitting position, i.e. the thigh is close to horizontal and there is no load on the leg, the knee joint switches to a low resistance in both the flexion and extension direction.
If the load on the prosthesis was not sufficient while sitting down, the leg is extended during this process. Due to the nearly horizontal position of the lower leg, the flexion resistance is reduced automatically and the lower leg lowers on its own.
If the sitting function is enabled in the adjustment software and activated via the Cockpit app (Changing the prosthesis setting using the cockpit app), the resistance in the flexion direction is reduced as well.

8.6.5 Standing up

Notwithstanding low damping while sitting, the prosthesis supports standing up.
Damping is increased after rising from the seat.
After standing up entirely, high damping (corresponding to the value of the "stance phase damping" parameter) is set automatically.

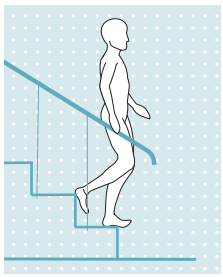
INFORMATION

If the intuitive stance function was deactivated in the adjustment software, there is no support while standing up.



1) Place the feet at the same level.
2) Lean the upper body forward.
3) Put the hands on armrests, if available.
4) Stand up with support from the hands. while keeping weight evenly distributed on the feet.

8.6.6 Walking down stairs



The joint makes it possible to walk down stairs step-over-step or one at a time.

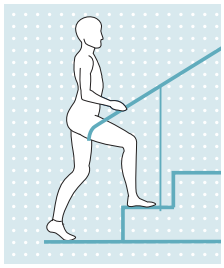
Walking down stairs step-over-step
Walking down stairs step-over-step must be practised and executed consciously. The knee joint can switch correctly and permit a controlled rollover only by stepping down properly with the sole of the foot. The motion must be carried out in a continuous pattern in order to allow the motion sequence to proceed in a fluid manner.

1) Hold the handrail with one hand.
2) Position the leg with the prosthesis on the step so that the foot projects halfway over the edge of the step.
   → This is the only way to ensure a secure rollover.
3) Roll the foot over the edge of the step.
   → This flexes the prosthesis slowly and evenly under high flexion resistance.
4) Place the foot of the other leg onto the next step.

Walking down stairs one step at a time (step by step)

1) Hold the handrail with one hand.
2) Place the foot of the prosthetic leg on the first step.
3) Pull up the other leg.

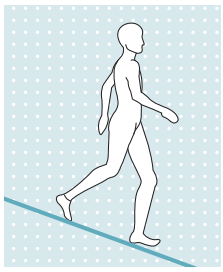
8.6.7 Walking up stairs



Walking up stairs step-over-step is not possible.

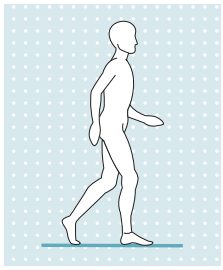
1) Hold the handrail with one hand.
2) Place the foot of the less affected leg onto the first step.
3) Pull up the other leg.

8.6.8 Walking down a ramp



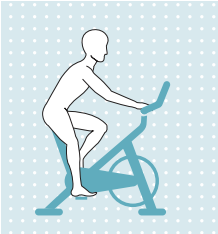
Under increased flexion resistance, permit controlled flexion of the knee joint which lowers the body's centre of gravity.
The swing phase is not triggered even though the knee joint is flexed.

8.6.9 Walking backwards



While walking backwards, the hydraulics keep the knee joint stable with high flexion resistance.

8.7 Using a bicycle ergometer



The "**Bicycle ergometer**" MyMode allows a bicycle ergometer to be used without exiting the currently selected activity mode.
Note the prerequisites for switching and the differences for activation in the respective activity modes.

Prerequisites for activating the "Bicycle ergometer" MyMode

- A bicycle ergometer is required. Switching is not possible for recumbent bicycles or so-called pedal trainers.
- The bicycle ergometer must have a freewheel.
- The user must be in the sitting position.
- The sitting position must not be too high, otherwise the knee is extended during the pedaling movement, ending the MyMode.
- The sitting position must not be too low. Note the permissible flexion range of the knee joint.
- The feet have to be positioned on the pedals.
- Pedaling movements must be possible.

Activating the "Bicycle ergometer" MyMode (activity mode A, B, B+)

1) Sit on the bicycle ergometer with the leg extended.
2) Hold the leg horizontally until the knee joint flexes on its own due to gravity.
3) Put the feet on the pedals and perform pedaling movements within one minute, or activate the "**2.Bicycle ergometer**" MyMode using the Cockpit app.
   → After a few pedaling movements, these are recognised by the knee joint and a short beep and vibration signal is produced. If this signal is not produced, the time limit for positioning the feet on the pedals (one minute) was exceeded or the prerequisites for activating this MyMode are not met.
   → The short beep and vibration signal is produced periodically at intervals during the pedaling movement until the resistances in the flexion and extension direction have been reduced to the extent that the knee joint moves freely.
   → This MyMode (**2. Bicycle ergometer**)is shown in the overview in the Cockpit app.

Activating the "Bicycle ergometer" MyMode (activity mode C)

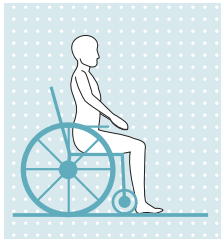
1) Sit on the bicycle ergometer.
2) Put the feet on the pedals.
3) Perform pedaling movements or activate the "**2.Bicycle ergometer**" MyMode using the Cockpit app.
   → After a few pedaling movements, these are recognised by the knee joint and a short beep and vibration signal is produced. If this signal is not produced, the prerequisites for activating this MyMode were not met.
   → The short beep and vibration signal is produced periodically at intervals during the pedaling movement until the resistances in the flexion and extension direction have been reduced to the extent that the knee joint moves freely.
   → This MyMode (**2. Bicycle ergometer**) is shown in the overview in the Cockpit app.

Deactivating the "Bicycle ergometer" MyMode (activity mode A, B, B+, C)

► From the sitting position, either extend the knee or take the foot off the pedal and put it on the floor. The foot has to be ahead of the knee joint when it is set on the floor.
   → This is recognised by the knee joint and a long beep and vibration signal is produced. If this signal is not produced, either repeat the process or switch to the "**1. Basic Mode**" MyMode using the Cockpit app.
   → This MyMode is shown in the overview in the Cockpit app.

8.8 Using a wheelchair

When sitting in a wheelchair, the joint can be locked in the flexed position for short distances. The lock can be engaged in any position from an angle of 45°. This prevents the foot from dragging on the floor. To use this function, it must be enabled in the adjustment software.



Locking the joint

► Raise the foot and hold it still in the desired position.
The lock engages automatically.
INFORMATION: At full extension, the lock engages in a slightly flexed position so the foot can be lifted in order to release the lock.

Disengaging the lock

The lock can be disengaged in the following ways:

- Extended pressure on the ball of the foot.
- Extended pressure on the toes (from the top of the foot).
- Lift the foot (extend the knee) and allow the foot to lower again.

INFORMATION

Turning the "Wheelchair function" function off/on using the Cockpit app

If the "**Locking function for wheelchair**" function was turned on in the adjustment software, the "**Wheelchair function**" function can be turned off and back on again using the Cockpit app.

8.9 Changing prosthesis settings

Once an active connection to a component has been established, the settings **of the respective active mode** can be changed using the Cockpit app.

INFORMATION

Bluetooth on the prosthesis has to be switched on to change the prosthesis settings (see page 33).

Information for changing the prosthesis settings

- Before changing settings, always check the main menu of the Cockpit app to make sure the correct component has been selected. Otherwise parameters could be changed for the wrong component.
- It is not possible to change prosthesis settings nor to switch to a different mode while the prosthesis battery is being charged. Only the status of the prosthesis can be called up. Instead of the symbol, the symbol appears in the bottom row of the screen in the cockpit app.
- The O&P professional's setting is in the middle of the scale. After making adjustments, this setting can be restored by tapping the "**Standard**" button in the Cockpit app.
- Prosthesis settings should be optimised using the adjustment software. The Cockpit app is not intended for use by the O&P professional to set up the prosthesis. The patient can use the app to change the behaviour of the prosthesis to a certain extent during everyday use (e.g. while becoming accustomed to the prosthesis). The O&P professional can use the adjustment software to track these changes at the patient's next appointment.

8.10 Turning Bluetooth on the prosthesis on/off

INFORMATION

Bluetooth on the prosthesis must be turned on in order to use the Cockpit app.
If Bluetooth is switched off, it can be turned on by turning the prosthesis upside-down (function only available in basic mode) or by connecting/disconnecting the battery charger. Bluetooth is then turned on for approx. 2 minutes. During this time, the app must be started and used to establish a connection. If required, Bluetooth on the prosthesis can be switched on permanently afterwards (see page 33).

Switching off Bluetooth

1) With the component connected, tap the ☰ icon in the main menu of the Cockpit app.
   → The navigation menu opens.
2) Tap the "**Functions**" option in the navigation menu.
3) Tap the "**Deactivate Bluetooth**" option.
4) Follow the on-screen instructions.

Switching on Bluetooth

1) Turn the component over or connect/disconnect the battery charger.
   → Bluetooth is switched on for approx. 2 minutes. The Cockpit app must be started within this time to establish a connection to the component.

2) Follow the on-screen instructions.

→ If Bluetooth is switched on, the icon appears on the screen.

8.11 Querying the prosthesis status

1) With the component connected, tap the ☰ icon in the main menu of the Cockpit app.
2) Tap the "**Status**" option in the navigation menu.

Menu option	Description	Possible actions
Trip: 1747	Daily step counter	Reset the counter by tapping the "**Reset**" button.
Step: 1747	Total step counter	Information only
Batt.: 68	Current prosthesis charge level, as a percentage	Information only

8.12 Switching off the product

⚠ CAUTION

Using the product while switched off

Falling due to unexpected behaviour of the product because of changed damping behaviour.

► Before using the product, switch it on by connecting the power supply and battery charger.

In certain cases, e.g. for storage or transportation, the prosthesis can be purposely switched off. It can only be switched on by connecting to a live outlet, a power supply and a battery charger.

Switching off

The product can be switched off by briefly connecting/disconnecting the battery charger 3 times.

1) Connect the battery charger to the product and wait for the beep signal.
2) Disconnect the battery charger immediately after the beep signal sounds.
3) Reconnect the battery charger immediately after another beep signal sounds.
4) Carry out this process (steps 2 and 3) a total of three times.

→ After the charger has been disconnected for the third time, a descending sequence of five beeps is emitted and the product is then switched off.

INFORMATION

If too much time passes between connecting and disconnecting (e.g. a vibration signal is already emitted), the process of connecting and disconnecting 3 times has to be repeated.

Switching on

1) Connect the power supply with battery charger to the outlet.
2) Connect the battery charger to the product.
   → The correct connection of the battery charger to the product is indicated by feedback (see page 43).

9 Additional operating states (modes)

The product automatically switches to special operating states (modes) when an error occurs, in case of an empty battery or while charging. Functioning of the prosthesis is limited due to its altered damping behaviour.

9.1 Empty battery mode

The joint emits beeps and vibration signals when the charge level is 15% or less (see page 41). Then the damping settings are set to high flexion resistance and low extension resistance, and the product is switched off. Before switching to empty battery mode, warning signals are emitted at a battery charge level below 35% (see page 41). You can switch back to basic mode from empty battery mode by charging the product.

9.2 Mode for charging the prosthesis

The product is non-functional during charging.
To switch to basic mode, the battery charger for the product must be disconnected after the battery is charged.

9.3 Safety mode

The product automatically switches to safety mode if a critical fault occurs (e.g. failure of a sensor signal). Safety mode remains in effect until the error has been rectified.

A setting for high flexion resistance and low extension resistance is applied in safety mode. This makes limited walking possible for the user even though the product is not active.

The switch to safety mode is indicated by beeps and vibration signals immediately prior to switching (see page 41).

Safety mode can be disabled by connecting and disconnecting the battery charger. If the product switches into safety mode again, this means a permanent error exists. The product must be inspected by an authorised Ottobock Service Centre.

9.4 Overheating mode

When the hydraulic unit overheats due to uninterrupted, increased activity (e.g. extended walking downhill), the flexion resistance is increased along with the rising temperature in order to counteract the overheating. When the hydraulic unit cools down, the product switches back to the settings that existed prior to overheating mode.

The hydraulic unit cannot overheat in activity mode A or B. Therefore, no overheating mode is triggered in these two activity modes.

Overheating mode is indicated by a long vibration every 5 seconds.

The following functions are deactivated in overheating mode in activity mode C:

- Joint lock for use of a wheelchair (see page 32)
- Battery level indication (see page 15)

10 Cleaning

1) Clean the product with a damp cloth (fresh water) when needed.
2) Dry the product with a lint-free cloth and allow it to air dry fully.

11 Maintenance

Regular maintenance (service inspections) is mandatory in the interest of patient safety and in order to maintain operating reliability and protect the warranty, maintain basic safety and the essential performance characteristics, and ensure safety in regards to EMC.

When maintenance is due, this is indicated by feedback after disconnecting the battery charger (see the section "Operating states/error signals", see page 41).

The following maintenance intervals must be observed depending on the country/region:

Country/region	Maintenance interval
All countries/regions except: USA, CAN, RUS	24 months
USA, CAN, RUS	As needed*, No later than every 36 months

*As needed: the maintenance interval depends on the patient's activity level. For patients with a normal to low activity level who take up to 1,800 steps per day, the expected maintenance interval is 3 years. For highly active patients who take more than 1,800 steps per day, the expected maintenance interval is 2 years.

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

11.1 Identification of the product by the Service Center

The product may have been identified by an authorised Ottobock Service Center:

Factory setting
The patient-specific product settings have been reset to the state at delivery (factory setting).

User setting
The settings already configured using the adjustment software were not changed.

⚠ CAUTION

Use of the prosthesis with incorrect setting data

Falling due to unexpected prosthesis behaviour caused by triggering the swing phase at the wrong time.

► The prosthesis settings (parameters) have to be checked using the corresponding adjustment software and changed as needed.

12 Legal information

12.1 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.

12.2 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.

12.3 CE conformity

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

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

The product meets the requirements of the RoHS Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic devices.

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

12.4 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.

13 Technical data

Ambient conditions	
Transport in original packaging	-25 °C/-13 °F to +70 °C/+158 °F
Storage in the original packaging (≤3 months)	-20 °C/-4 °F to +40 °C/+104 °F Max. 93% relative humidity, non-condensing
Long-term storage in the original packaging (>3 months)	-20 °C/-4 °F to +20 °C/+68 °F Max. 93% relative humidity, non-condensing
Transport and storage between applications (without packaging)	-25 °C/-13 °F to +70 °C/+158 °F Max. 93% relative humidity, non-condensing
Operation	-10 °C/+14 °F to +40 °C/+104 °F Max. 93% relative humidity, non-condensing
Time for warming to the operating temperature after storage between applications, from -25 °C/-13 °F at an ambient temperature of +20 °C/+68 °F	30 minutes
Time for cooling to the operating temperature after storage between applications, from +70 °C/+158 °F at an ambient temperature of +20 °C/+68 °F	30 minutes
Charging the battery	+5 °C/+41 °F to +40 °C/+104 °F

Product	
Reference number	3C60*/3C60=ST*
Mobility grade according to MOBIS (activity mode A)	1
Mobility grade according to MOBIS (activity mode B)	1 and 2
Mobility grade according to MOBIS (activity mode C)	2
Maximum body weight	150 kg
Protection rating	IP22
Water resistance	Not waterproof and not corrosion-resistant Protect the product with clothing in rainy conditions
Proximal system height up to alignment reference point 3C60* (pyramid connector)	5 mm
Proximal system height up to alignment reference point 3C60=ST (threaded connector)	23 mm
Minimum distal system height with tube adapter	270 mm
Maximum distal system height with tube adapter	490 mm
Range of Bluetooth connection to PC	Max. 10 m
Maximum possible flexion angle	124°
Maximum insertion depth of the tube adapter in the knee joint	73 mm

Product	
Weight of the prosthesis without tube adapter and Protective Cover	Approx. 910 g
Frequency range of the receiver of the inductive charging unit	110 kHz to 205 kHz
Information on the product's ruleset and firmware version	Accessible via the Cockpit app navigation menu and the menu item "**Imprint/Info**"
Expected lifetime given compliance with prescribed maintenance intervals	6 years
Test procedure	ISO 10328-P6-150 kg / 3 million load cycles

Data communication	
Wireless technology	Bluetooth 5.0 (Bluetooth Low Energy)
Distance range	Approx. 10 m / 32.8 ft
Frequency range	2,402 MHz to 2,480 MHz
Modulation	GFSK
Data rate (over the air)	Up to 2 Mbps
Maximum output power (EIRP):	+4 dBm (~2.5 mW)

Tube adapter				
Reference number	2R17			
Weight	190 g–300 g / 0.42–0.66 lbs			
Material	Aluminium			
Max. body weight	150 kg			
Protection rating	IP22			
Water resistance	Not waterproof and not corrosion-resistant Protect the product with clothing in rainy conditions			
Lifetime	6 years			
Approved set screws				
Length	10 mm	12 mm	14 mm	16 mm
Reference number	506G3= M8x10	506G3= M8x12V	506G3= M8x14	506G3= M8x16
Maximum tightening torque	15 Nm			

Tube adapter				
Reference number	2R20		2R21 (with torsion unit)	
Weight	190–300 g/0.42–0.66 lbs		435–545 g/0.96–1.20 lbs	
Material	Aluminium			
Max. body weight	150 kg		125 kg	
Protection rating	IP67		IP54	
Water resistance	Weatherproof but not corrosion-resistant Not designed for prolonged underwater use or prolonged submersion		Weatherproof but not corrosion-resistant Protected against splashed water from all directions, but not designed for underwater use	
Lifetime	6 years		6 years	
Approved set screws				
Length	10 mm	12 mm	14 mm	16 mm
Reference number	506G3= M8x10	506G3= M8x12	506G3= M8x14	506G3= M8x16

Prosthesis battery	
Battery type	Li-Ion

Prosthesis battery	
Charging cycles (charging and discharging cycles) after which at least 80% of the original battery capacity remains available	300
Charging time until battery is fully charged	6–8 hours
Product behaviour during the charging process	The product is non-functional
Operating time of prosthesis with fully charged battery	1 day with average use

Power supply unit	
Reference number	757L16-4
Type	FW8001M/12
Storage and transport in original packaging	-40 °C/-40 °F to +70 °C/+158 °F 10% to 95% relative humidity, non-condensing
Storage and transport without packaging	-40 °C/-40 °F to +70 °C/+158 °F 10% to 95% relative humidity, non-condensing
Operation	0 °C/+32 °F to +50 °C/+122 °F Max. 95% relative humidity Air pressure: 70–106 kPa (up to 3,000 m without pressure equalisation)
Input voltage	100 V~ to 240 V~
Mains frequency	50 Hz to 60 Hz
Output voltage	12 V ⎓

Battery charger	
Reference number	4E70-1
Storage and transport in original packaging	-25 °C/-13 °F to +70 °C/+158 °F
Storage and transport without packaging	-25 °C/-13 °F to +70 °C/+158 °F Max. 93% relative humidity, non-condensing
Operation	0 °C/+32 °F to +40 °C/+104 °F Max. 93% relative humidity, non-condensing
Protection rating	IP40
Input voltage	12 V ⎓
Lifetime	6 years
Wireless technology	Qi
Frequency range	110 kHz to 205 kHz
Modulation	ASK, load modulation
Maximum output power (EIRP)	-18.00 dBµA/m @ 10 m

Torque values of the screw connections

Using a torque wrench, tighten the corresponding screws alternately in several cycles until the specified tightening torque is reached.

Screw connection	Tightening torque
Tube adapter on prosthetic foot	15 Nm/133 lbf. In.
Clamp bracket on knee joint	7 Nm/62 lbf. In.
Proximal prosthesis components with pyramid receiver	15 Nm/133 lbf. In.
Proximal prosthesis components with threaded connector	10 Nm/89 lbf. In.
Flexion stop	0.6 Nm/5 lbf. In.

14 Appendices

14.1 Symbols Used

Manufacturer

Type BF applied part

Please note the instructions for use

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

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

Non-ionising radiation

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.

LE
DUAL

The product's Bluetooth wireless module can establish a connection to mobile devices with the following operating systems: iOS (iPhone, iPad, iPod...) and Android

Declaration of conformity according to the applicable European directives

SN

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

LOT

Lot number (PPPP YYYY WW)
PPPP – plant
YYYY – year of manufacture
WW – week of manufacture

MD

Medical device

REF

Article number

Protect from moisture

IP40

Protection against penetration of solid foreign objects with a diameter greater than 1 mm, no protection against water

IP22

Protection against penetration of solid foreign objects with a diameter greater than 12.5 mm, protection against water dripping diagonally up to 15°.

Caution, hot surface

14.2 Operating states/error signals

The prosthesis indicates operating states and error messages through beeps and vibration signals.

14.2.1 Signals for operating states

Battery charger connected/disconnected

Beep signal	Vibration signal	Event
1 x short	–	Battery charger connected or Battery charger already disconnected prior to start of charging mode
–	3 x short	Charging mode started (3 sec. after connecting the battery charger)
1 x short	1 x before beep signal	Battery charger disconnected after start of charging mode

Mode switching

Beep signal	Vibration signal	Additional action performed	Event
1x short	1x short	Mode switching using the Cockpit app	Mode switching is performed using the Cockpit app.
1x short	1x short	User has sat on the bicycle ergometer and commenced pedaling movement	After a few pedaling movements, this was recognised and switching to the "**2.Bicycle ergometer**" MyMode took place.
Short at periodic intervals	Short at periodic intervals	The pedaling movements were continued.	The flexion and extension resistances are reduced to the extent that the knee joint moves freely.
1x long	1x long	The prosthetic leg was extended or the foot was placed on the floor.	Placing the foot on the floor was recognised and switching back to the "**1. Basic Mode**" MyMode took place.

14.2.2 Warnings/error signals

Error during use

Beep signal	Vibration signal	Event	Required action
–	1x long at interval of approx. 5 seconds	Hydraulics overheated	Reduce activity.
–	3x long	Charge level under 25%	Charge battery soon.
–	5x long	Charge level under 15%	Charge battery immediately; the product will be switched off after the next warning signal.
10x long	10x long	Charge level 0% After the beep and vibration signals, the product switches to empty battery mode and then switches off.	Charge the battery.

Beep signal	Vibration signal	Event	Required action
30x long	1x long, 1x short repeated every 3 seconds	**Severe error/indication of safety mode activation** For example, a sensor is not ready for operation, AXON tube adapter not connected or valve drive failure Possibly no switching into safety mode.	Walking possible with restrictions. Please note the possible change in flexion/extension resistance. Attempt to reset this error by connecting/disconnecting the battery charger. The battery charger must remain connected for at least 5 seconds before it is disconnected. If the error persists, use of the product is prohibited. The product must be inspected by an authorised Ottobock Service Center.
–	Continuous	**Total failure** Electronic control no longer possible. Safety mode active or undetermined valve state. Unknown product behaviour.	Attempt to reset this error by connecting/disconnecting the battery charger. If the error persists, use of the product is prohibited. The product must be inspected by an authorised Ottobock Service Center.

Error while charging the product

LED on power supply	LED on battery charger	Battery charger connected to product	Error	Resolution
○	○	No	Country-specific plug adapter not fully engaged on power supply	Check whether the country-specific plug adapter is fully engaged on the power supply.
			Outlet not functioning	Check outlet with another electrical device.
			Defective power supply	The battery charger and power supply must be inspected by an authorised Ottobock Service Centre.
●	○	Yes	Distance between battery charger and receiver on knee joint too great	The distance between the battery charger and the receiver on the knee joint must not exceed 1 mm
			No connection between battery charger and power supply	Check whether the charging cable plug is fully engaged on the battery charger.
			Defective battery charger	The battery charger and power supply must be inspected by an authorised Ottobock Service Centre.

LED on power supply	LED on battery charger	Battery charger connected to product	Error	Resolution
●	The LED turns off or changes colour at irregular intervals	Yes	Temperature of the battery charger too high	The distance between the battery charger and the receiver on the knee joint must not exceed 1 mm. If this distance is too great during the charging process, the magnetic surface of the battery charger can heat up and interrupt the charging process.
				Take the battery charger off the knee joint, disconnect it from the power supply and let it cool down. If the error recurs, the battery charger must be inspected by an authorised Ottobock Service Centre.

Beep signal	Error	Resolution
4 x short at intervals of approx. 20 sec. (continuously)	Charging the battery outside the allowable temperature range	Check whether the specified ambient conditions for charging the battery are met (see page 37).

14.2.3 Status signals

Battery charger connected

LED on power supply	LED on battery charger	Event
●	☀	Power supply and battery charger operational

Battery charger disconnected

Beep signal	Vibration signal	Event
1 x short	1 x short	Self-test completed successfully. Product is operational.
3 x short	–	Maintenance note Conduct the self-test again by connecting/disconnecting the battery charger. If the beep signal is repeated, maintenance of the product should be carried out by an authorised Ottobock Service Centre. The product can be used without restrictions. However, vibration signals may not be generated.

Battery charge level

Battery charger	
☀	Battery is charging. The on time of the LED indicates the current charge level. The on time of the LED gets longer as the charge level increases. It only flashes briefly at the start of the charging process and stays on continuously at the end of the charging process.
●	Battery is fully charged, or the temperature has exceeded/fallen below the permissible range for the knee joint during charging. Check current charge level (see page 15).

14.3 Directives and manufacturer's declaration

14.3.1 Electromagnetic environment

This product is designed for operation in the following electromagnetic environments:

- Operation in a professional healthcare facility (e.g. hospital, etc.)
- Operation in areas of home healthcare (e.g. use at home, use outdoors)

Observe the safety notices in the section "Information on proximity to certain areas" (see page 11).

Electromagnetic emissions

Interference measurements	Compliance	Electromagnetic environment directive
HF emissions according to CISPR 11	Group 1/class B	The product uses HF energy exclusively for its internal functioning. Its HF emissions are therefore very low, and interference with neighbouring electronic devices is unlikely.
Harmonics according to IEC 61000-3-2	Not applicable – power below 75 W	–
Voltage fluctuations/flicker according to IEC 61000-3-3	Product meets the requirements of the standard.	–

Electromagnetic interference immunity

Phenomenon	EMC basic standard or test procedure	Interference immunity test level
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air,
High-frequency electromagnetic fields	IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz
Magnetic fields with rated power frequencies	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Electrical fast transients/bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition rate
Surges Line against line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Conducted interference induced by high-frequency fields	IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur frequency bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage drops	IEC 61000-4-11	0% U_T; 1/2 period At 0, 45, 90, 135, 180, 225, 270 and 315 degrees
		0% U_T; 1 period and 70% U_T; 25/30 periods Single phase: at 0 degrees
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 periods

Interference resistance against wireless communication devices

Test frequency [MHz]	Frequency band [MHz]	Radio service	Modulation	Maximum power [W]	Distance [m]	Interference immunity test level [V/m]
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	1.8	0.3	28

Test frequency [MHz]	Frequency band [MHz]	Radio service	Modulation	Maximum power [W]	Distance [m]	Interference immunity test level [V/m]
710	704 to 787	LTE band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, GSM 800/900, LTE band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1,720	1,700 to 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1,845						
1,970						
2,450	2,400 to 2,570	Bluetooth WLAN 802.11-b/g/n, RFID 2450 LTE band 7	Pulse modulation 217 Hz	2	0.3	28
5,240	5,100 to 5,800	WLAN 802.11-a/n	Pulse modulation 217 Hz	0.2	0.3	9
5,500						
5,785						

Immunity to magnetic fields in close range

Test frequency	Modulation	Interference immunity test level [A/m]
30 kHz	CW	8
134.2 kHz	Pulse modulation 2.1 kHz	65
13.56 MHz	Pulse modulation 50 kHz	7.5

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