ottobock.

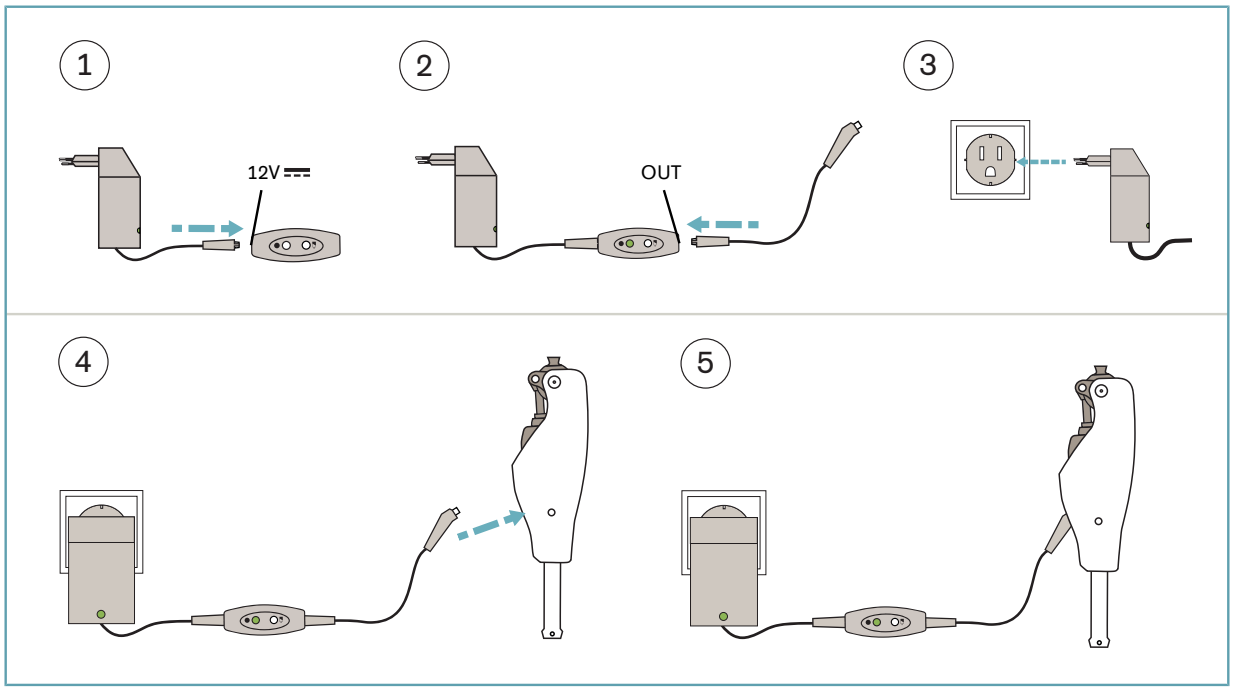
CE

C-Leg 3C98-3/3C88-3

Quick Reference Guide

This "Quick Reference Guide" does not replace the instructions for use

6



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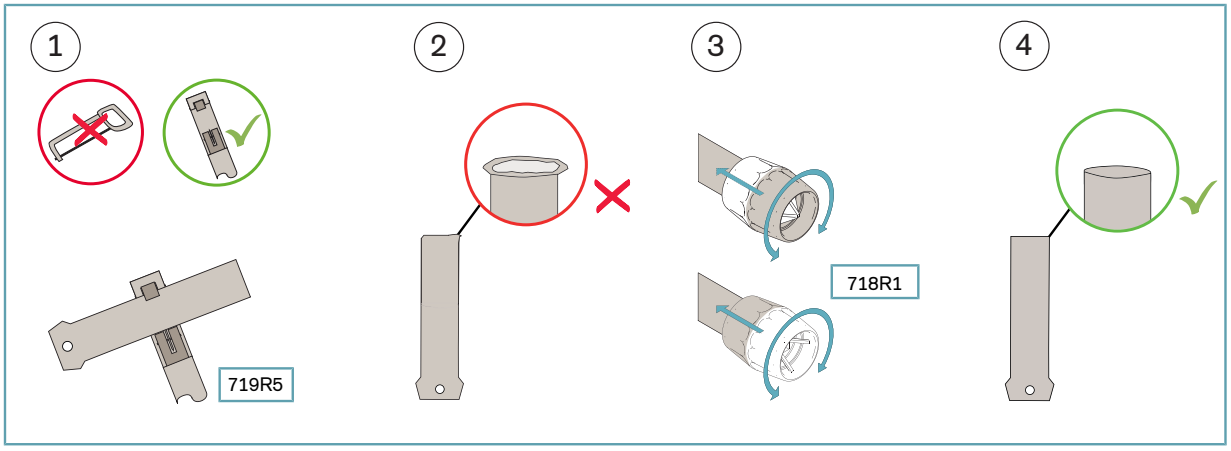

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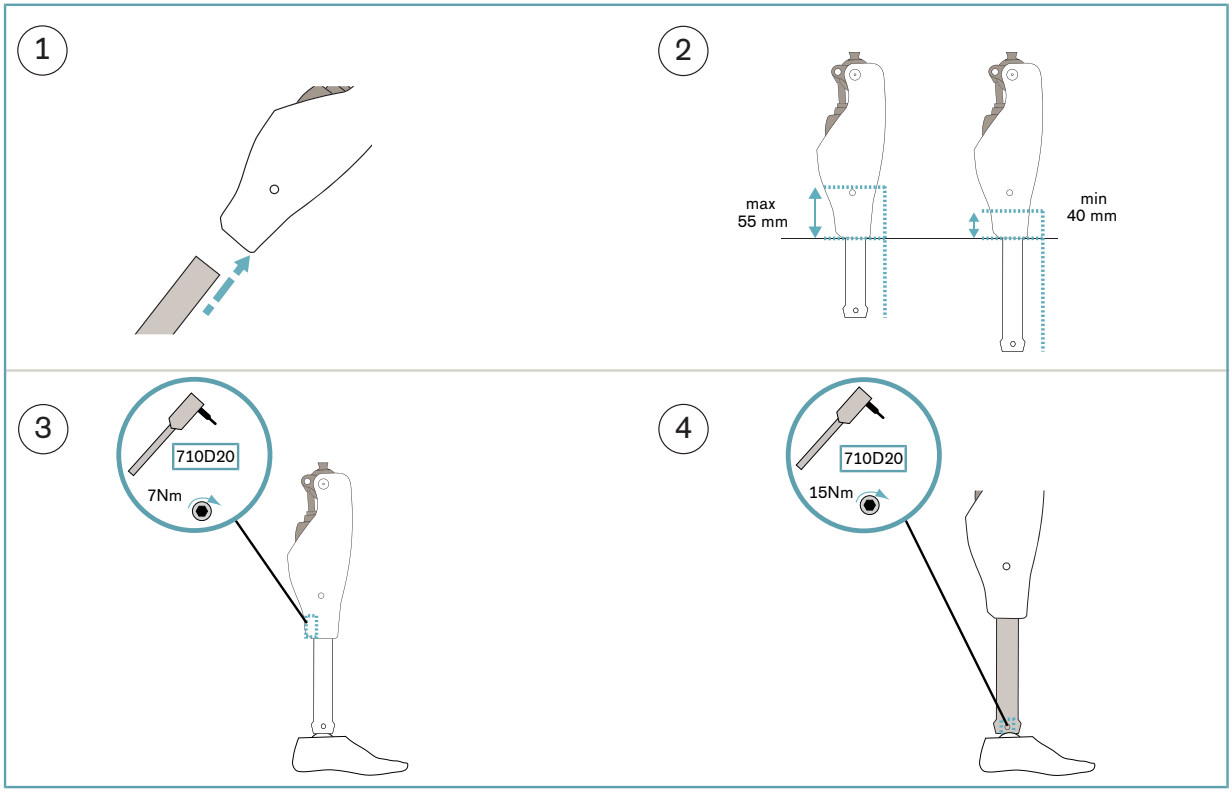
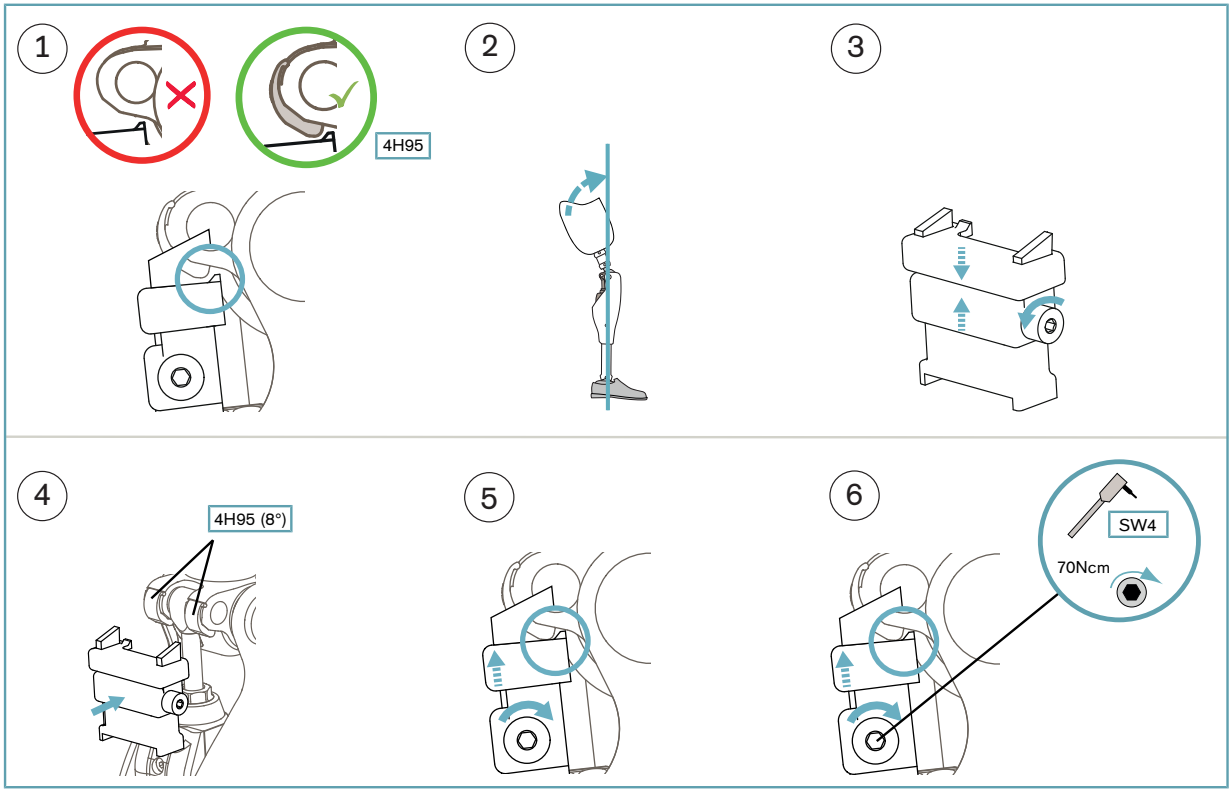

1
2
max
55 mm
min
40 mm
3
710D20
7Nm
4
710D20
15Nm

7.1.5


1
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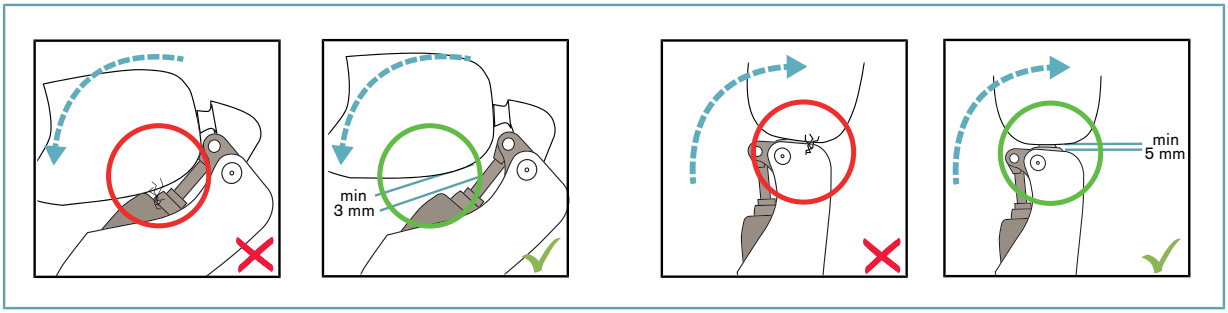
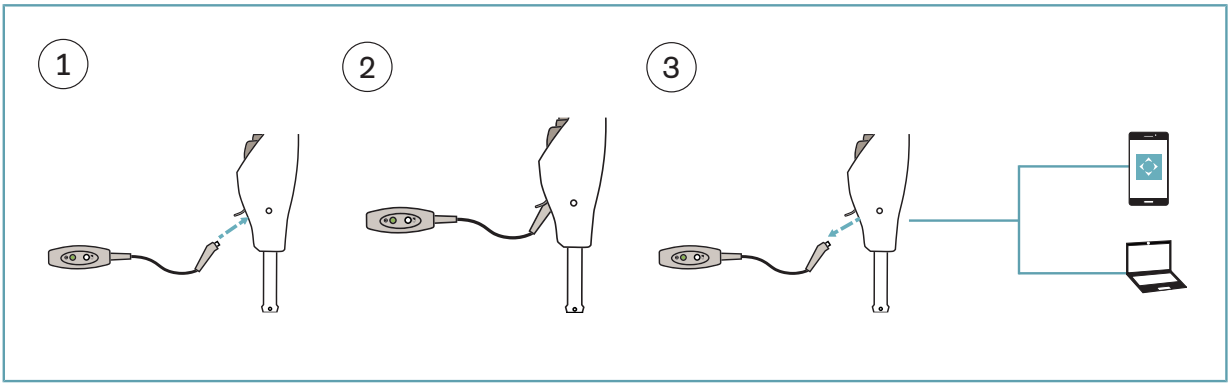
2
3
4
4H95 (8°)
5
6
SW4
70Ncm

7.1.6


min
3 mm
min
5 mm

8.6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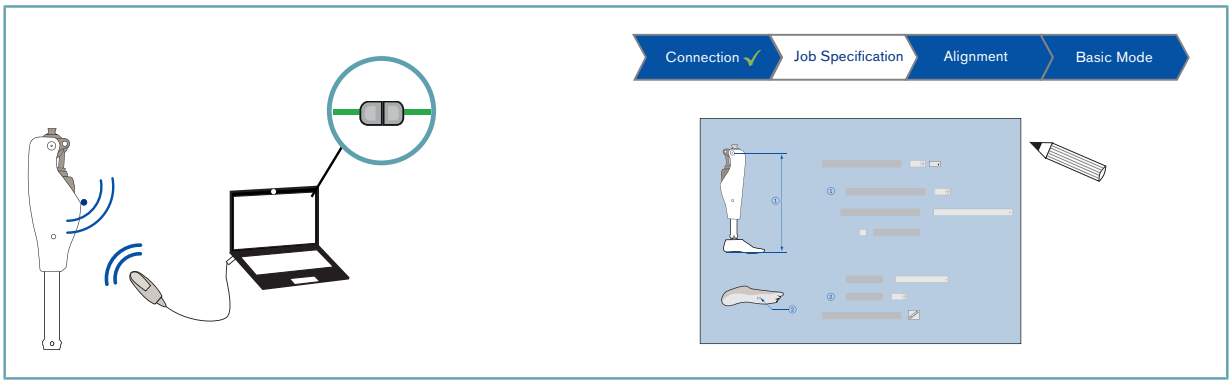
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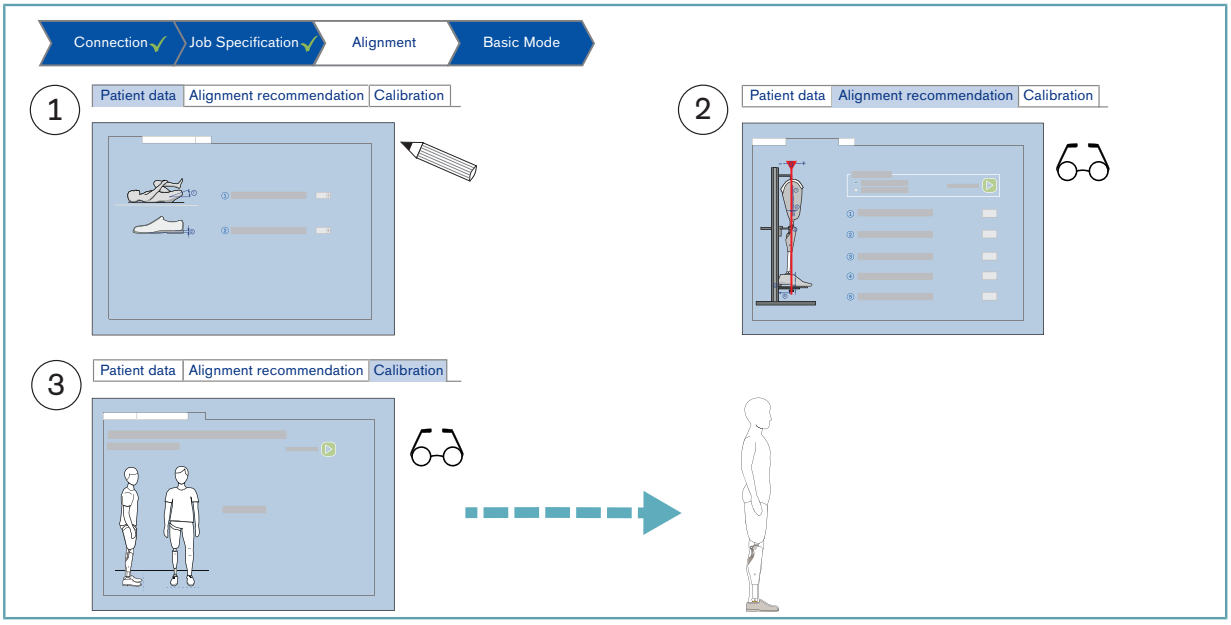
7.1.4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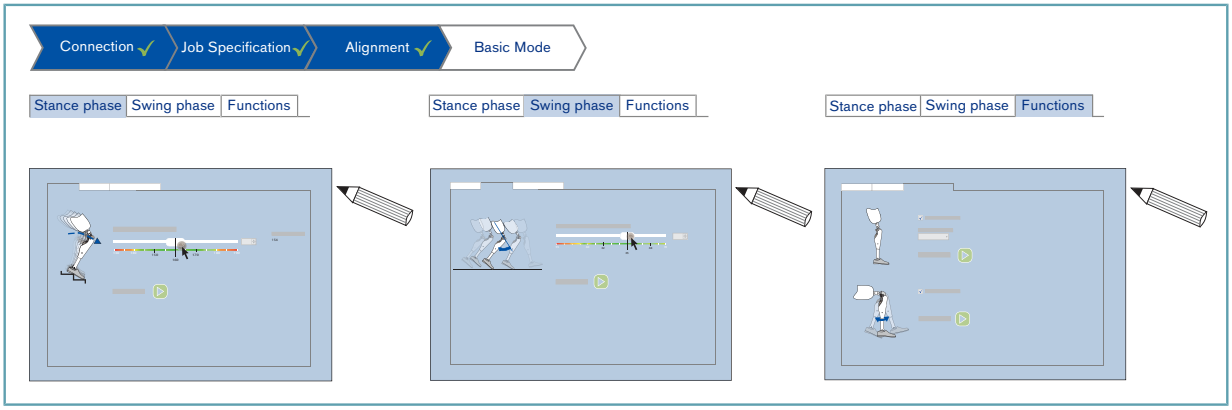
7.1.8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Swing phase
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Stance phase
Swing phase
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Swing phase
Functions

Symbols Used

Read the section in the instructions for use

x-Nm

Tightening torque in the direction of rotation and screw geometry

Use a torque wrench

de | Gleichspannung
en | Direct-current voltage

Wrong

Right

Cockpit App

Use the adjustment software

A successful connection between the product and the adjustment software is established

Fill in the fields in the adjustment software

Check the values

Table of contents

EN

1 Foreword

INFORMATION

Date of last update: 2024-02-20

- ► 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 "3C98-3*, 3C88-3* C-Leg" is called the product/prosthesis/prosthetic knee joint/component in the following.

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

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

2 Product description

2.1 Design

The product consists of the following components:

1. Knee head with proximal connection (pyramid or thread)
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. Charging receptacle cover
7. Charging receptacle
8. Distal tube clamp screws

2.2 Function

This product features microprocessor control of the stance and swing 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.

Thanks to the microprocessor-controlled stance and swing phase, the product can be individually adapted to the needs of the patient.

In order to do so, the product is configured with the "4X440=* C-Soft-Plus" adjustment software.

The product features MyModes for special motion types (e.g. cross-country skiing, etc.). These are pre-configured using the adjustment software and can be activated with special movement patterns and the Cockpit app (see page 37).

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 38).

Empty battery mode permits safe walking when the battery is drained. Resistance parameters that are predefined by the product are configured for this purpose (see page 38).

The microprocessor-controlled hydraulic unit offers the following advantages
- Approximation of the physiological gait pattern
- Stability while standing and walking
- Adaptation of product characteristics to various surfaces, inclines, gait situations and walking speeds

Essential performance of the product
- Stability in the stance phase

2.3 Combination possibilities

This product can be combined with the following Ottobock components:

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

Adapters
- 4R104=60 double adapter, sliding
- 4R104=75 double adapter, sliding
- Rotation adapter: 4R57, 4R57=*
- 4R41 lamination anchor with pyramid receiver
- 4R111 lamination anchor with pyramid receiver
- 4R89 lamination anchor with pyramid adapter
- 4R116 lamination anchor with pyramid adapter
- 4R43 lamination anchor with threaded connector
- 4R111=N lamination anchor with threaded connector
- 4R40 torsion adapter
- 4R118 adapter plate
- 4R11=* Quickchange

Tube adapter
- 2R57 tube adapter
- 2R67 tube adapter with torsion unit

Cosmetic cover/protector
- Foam cover: 3S26
- 3F1=1 Functional cosmesis C-Leg
- 99B120=* Functional stocking
- 4X860=* C-Leg Protective Cover (w/o shield)
- 4P862 C-Leg guard
- 4P863* Shield Insert

Prosthetic feet

The maximum allowable patient weight depends on the foot size.
- 1D10 Dynamic foot
- 1D11 Dynamic foot (women)
- 1M10 Adjust
- 1C10 Terion
- 1C11 Terion K2
- 1A30 Greissinger plus
- 1C30 Trias
- 1C30-1 Trias
- 1D35 Dynamic Motion
- 1C40 C-Walk
- 1C50 Taleo
- 1C51 Taleo Vertical Shock
- 1C52 Taleo Harmony
- 1C53 Taleo Low Profile
- 1C56 Taleo Adjust
- 1C58 Taleo Side Flex
- 1C60 Triton
- 1C61 Triton Vertical Shock
- 1C62 Triton Harmony
- 1C63 Triton Low Profile
- 1C64 Triton Heavy Duty
- 1C70 Evanto
- 1C68 Triton side flex
- 1E56 Axtion
- 1E57 Lo Rider
- 1B1 Meridium
- 1B1-2 Meridium
- 1A1-2 Empower
- Maverick Comfort AT: F22[1]
- Promenade: VS2[1]
- Thrive: FS5[1]

[1] Note the Ottobock system height

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 knee joint.

- ► Depending on the patient's body weight, the listed prosthetic feet may only be combined in the respective foot sizes [cm] described.
- ► Inform the patient that the body weights changes when carrying heavy objects, backpacks or children.
- ► 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 25	8
	Up to 28	7
	Up to 30	6

1C51 Taleo Vertical Shock, 1C52 Taleo Harmony

Body weight	Approved foot size [cm]	Maximum stiffness
Up to 115 kg (255 lbs)	Up to 30	7

1C53 Taleo Low Profile

Body weight	Approved foot size [cm]	Maximum stiffness
Up to 100 kg (221 lbs)	Up to 30	6
101 kg to 115 kg (222 lbs to 253 lbs)	Up to 28	7

1C58 Taleo Side Flex

Body weight	Approved foot size [cm]	Maximum stiffness
Up to 136 kg (299 lbs)	Up to 28	7
	Up to 30	6

1C60 through 1C64 Triton

Body weight	Approved foot size [cm]
Up to 125 kg (up to 275 lbs)	Up to 28
126 kg to 136 kg (277 lbs to 299 lbs)	Up to 26

1C66 Triton

Body weight	Approved foot size [cm]
Up to 100 kg (up to 220 lbs)	Up to 30
101 kg to 125 kg (221 lbs to 275 lbs)	Up to 26

1C68 Triton Side Flex

Body weight	Approved foot size [cm]
Up to 100 kg (220 lbs)	No restriction
101 kg to 125 kg (221 lbs to 275 lbs)	Up to 26

1A1-2 Empower

Body weight	Approved foot size [cm]	Maximum stiffness
Up to 115 kg (253 lbs)	Up to 30	7
116 kg to 136 kg (255 lbs to 299 lbs)	Up to 27	8

1B1, 1B1-2 Meridium

Body weight	Approved foot size [cm]
Up to 100 kg (up to 220 lbs)	Up to 29
101 kg to 136 kg (221 lbs to 299 lbs)	Up to 26

Promenade VS2

Body weight	Approved foot size [cm]	Maximum stiffness
Up to 100 kg (220 lbs)	Up to 31	3
101 kg to 115 kg (222 lbs to 253 lbs)	Up to 28	4

Maverik Comfort AT F22

Body weight	Approved foot size [cm]	Maximum stiffness
Up to 100 kg (220 lbs)	Up to 28	7

FS5 Thrive

Body weight	Approved foot size [cm]	Maximum stiffness
Up to 100 kg (220 lbs)	Up to 26	7

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 42).

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 to be used **solely** for lower limb exoprosthetic fittings.

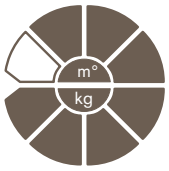
3.2 Conditions of use

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

Permissible ambient conditions are described in the technical data (see page 42).

The product is intended **exclusively** for use on **one** patient. Use of the product by another person is not approved by the manufacturer.

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



The product is recommended for mobility grade 2 (restricted outdoor walker), mobility grade 3 (unrestricted outdoor walker) and mobility grade 4 (unrestricted outdoor walker with particularly high demands). Approved for a body weight of **136 kg max.**

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, transfemoral amputation or hip disarticulation
- 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 136 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 45) 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 moisture 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 no solid particles or foreign objects can penetrate into the product.

► Do not use the prosthetic knee joint under extreme conditions like jet skiing or deep jumps into water.

► The C-Leg is safe for occasional use in fresh water. The electronic components of the C-Leg are protected from fresh water exposure up to 3 m for 1 hour (IP 68). Please note that the mechanical components may corrode.

► After contact with fresh water, remove the Protective Cover (if installed) and hold the prosthesis with the sole of the foot facing up until the water has drained from the prosthetic knee joint and tube adapter. Dry the prosthetic knee joint and components with a lint-free cloth.

► The prosthetic knee joint should not come into contact with salt water, chlorinated water or other solutions (such as soap or shower gel, and body and wound fluids). If it comes into contact, remove the Protective Cover (if installed) and rinse the prosthetic knee joint with fresh water. Dry the prosthetic knee joint and components with a lint-free cloth.

► In case of a malfunction after drying, the prosthetic knee joint and tube adapter must be inspected by an authorised Ottobock Service Centre. The O&P professional is your contact.

► The prosthetic knee joint is not protected against penetration of jets of water or steam.

⚠ 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 21) and "Accessories" (see page 22).

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 product without taking it off

> Falling due to walking and getting caught on a connected battery charger.

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

► Instruct the patient that the product must be taken off before it is charged.

⚠ CAUTION

Charging the product with a damaged power supply / battery charger / charging cable / charging adapter

Falling due to unexpected product behaviour caused by insufficient charging.

► Check the power supply / battery charger / charging cable / charging adapter for damage before use.

► Replace any damaged power supply / battery charger / charging cable / charging adapter.

NOTICE

Use of incorrect power supply / battery charger / charging adapter

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

► Only use power supplies / battery chargers / charging adapters approved for this product by Ottobock (see instructions for use and catalogues).

NOTICE

Mechanical stress on the power supply / battery charger / charging adapter

Lack of proper charging functionality due to malfunction.

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

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

NOTICE

Operation of the power supply / battery charger / charging adapter outside the allowable temperature range

Lack of proper charging functionality due to malfunction.

► Only use the power supply / battery charger / charging adapter for charging within the allowable temperature range. For the allowable temperature range, see the section “Technical data” (see page 42).

4.5 Notices regarding the battery charger / charging adapter

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

Independent changes or modifications to the battery charger / charging adapter

Lack of proper charging functionality due to malfunction.

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

4.6 Information on Alignment/Adjustment

⚠ CAUTION

Use of unsuitable prosthetic components

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

► Use the product only in combination with components listed in the section "Combination possibilities" (see page 10).

► If the product is to be used in water, verify that each prosthetic component is waterproof.

⚠ 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").
- ► 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 (see the section "Technical data" see page 42).
- ► The tube clamp screws 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 unexpected product behaviour as the result of a malfunction.
- > Falling due to breakage of load-bearing components.
- ► At maximum flexion, it is essential to maintain a minimum distance of 3 mm (1/8") between the hydraulic unit and the socket.
- ► At maximum extension (reached under full load), it is essential to maintain a minimum distance of 5 mm (1/4") between the sealing sleeve/top edge of the installed Protective Cover and the socket.
- ► If there is contact between the socket and the joint (hydraulic unit, frame) at maximum flexion, then the joint must be fitted with a flexion stop (e.g. in the case of voluminous residual limbs).
  If contact between the socket and joint (hydraulic unit, frame) occurs anyway at maximum flexion, the socket has to lie flat on the frame (with the help of soft padding on the socket).

⚠ 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

Safety mode flexion resistance set too low

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

- ► Safety mode flexion resistance should be configured so that it is possible to stand safely without the knee joint buckling.

⚠ CAUTION

Using the product without calibration

Falling due to unexpected product behaviour as the result of the swing phase being initiated too early/too late.

- ► Use the adjustment software to carry out calibration at the beginning of static alignment optimisation and at the end of dynamic alignment optimisation.

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 42) 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 45).
- ► 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 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 must not be used for unusual activities. These unusual activities include, for example, extreme sports (free climbing, paragliding, etc.).

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

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

⚠ CAUTION

Improper mode switching

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

► Ensure that the patient stands securely during all switching processes.

► Inform the patient that the changed damping characteristics have to be verified after switching and feedback from the acoustic signal emitter must be observed.

► Switching back to basic mode is mandatory once the activities in MyMode have been completed.

► If required, take the weight off the product and correct the switching.

⚠ CAUTION

Improper use of the stance function

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

► Make sure that the patient is standing safely when using the stance function and checks the lock of the knee joint before placing his/her full weight on the prosthesis.

► Inform the patient whether and in what way the stance function was configured in the adjustment software. Information on the stance function see page 31.

⚠ CAUTION

Quickly pushing the hip forward with the prosthesis extended (e.g. serve while playing tennis)

> Falling due to unexpected activation of the swing phase.

► Note that the knee joint may flex unexpectedly when the hip is pushed forward quickly while the prosthesis is extended.

► If the patient participates in sports where this movement pattern can occur, configure corresponding MyModes using the adjustment software. For further information about the MyModes, see the section 'MyModes' (see page 37).

⚠ CAUTION

Overloading due to changes in body weight when carrying heavy objects, backpacks or children

> Falling due to unexpected behaviour of the product.

> Falling due to breakage of load-bearing components.

> Skin irritation due to defects on the hydraulic unit with leakage of liquid.

► Inform the patient that the behaviour of the product can change due to increased weight. It is possible that the swing phase may not be triggered, or triggered at the wrong time.

► Inform the patient that the maximum permissible body weight must not be exceeded due to the additional weight.

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 45) have to be observed.

► Particular caution is necessary when using a bicycle without a freewheel (with a fixed gear).

⚠ 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 45) 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. 3C88-3 C-Leg (with threaded connector) or 3C98-3 C-Leg (with pyramid)
- 1 pc. 757L16-4 power supply
- 1 pc. 4E50 Battery Charger for C-Leg

- 1 pc. 4H95 8° C-Leg flexion stop (already installed on delivery)
- 1 pc. cosmetic case for battery charger and power supply
- 1 pc. 646C107 Bluetooth PIN card
- 1 pc. prosthesis passport
- 1 pc. Instructions for use (qualified personnel)
- 1 pc. Instructions for use (user)
- “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:

- 4H105 knee extender for bench alignment (see page 26)
- 4H106 16° C-Leg flexion stop
- 3S26 cosmetic foam cover
- 3F1=1 Functional cosmesis C-Leg
- 99B120=* Functional stocking
- 4X860=* C-Leg Protective Cover (w/o shield)
- 4P862 C-Leg guard
- 4P863* Shield Insert
- 4X156-1 Charger Extension Cable – Ankle
- 4X158-1 charger extension cable – ankle, long
- 4X157-1 Charger Extension Cable – Knee
- 757L43 USB charging adapter
- "4X440=* C-Soft Plus" adjustment software
- 560X29* ”connectgo.pro” adjustment app

6 Charging the battery

The following points must be observed when charging the battery:

- Use the 757L16-4 power supply / 757L43 charging adapter and 4E50* battery charger to charge the battery.
- With uninterrupted walking, the capacity of the fully charged battery is sufficient for at least 16 hours. It lasts about 2 days with average use.
- 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 until the yellow LED on the battery charger turns off prior to initial use, and for at least 4 hours. This calibrates the charge level indicator via the Cockpit app and by turning over the prosthesis.
  If the battery charger is disconnected from the prosthesis too soon, the charge level indicator via the Cockpit app and by turning over the prosthesis may not correspond to the actual charge level.
- The battery may discharge while the product is not being used.

6.1 Connecting the power supply and battery charger

1

2

3

1) Slide the country-specific plug adapter onto the power supply until it locks into place (see fig. 1).
2) Connect the round, **four-pin** plug of the charging cable to the **OUT** receptacle on the 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) Connect the round, **three-pin** plug of the power supply to the **12 V** receptacle on the 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.
4) Plug the power supply unit into the wall socket.
   → The green LED on the back of the power supply and the green LED on the battery charger light up (see fig. 3).

→ If the green LED on the power supply and the green LED on the battery charger do not light up, there is an error (see page 45).

6.2 Charging the prosthesis battery

1) Open the charging receptacle cover (open up the flap or push the slider up).
2) Connect the charging plug to the charging receptacle of the product.
   INFORMATION: Make sure to insert it in the right direction!
   A low insertion force has to be overcome during connection so the charging plug remains reliably connected to the charging receptacle.
   → A correct connection between the battery charger and the product is indicated by feedback (see page 45).
3) The charging process starts.
   → Once the product battery is fully charged, the yellow LED on the battery charger turns off.
4) Disconnect the product after the charging process is complete.
   INFORMATION: A low separating force between the charging plug and charging receptacle has to be overcome to disconnect the plug.
   → A self-test is performed. The product is ready for operation only after corresponding feedback (see page 47).
5) Close the charging receptacle cover.

6.3 Display of the current charge level

INFORMATION

The charge level cannot be displayed during the charging process.

6.3.1 Display of battery charge level without additional devices

1) Rotate the prosthesis 180° (the sole of the foot must 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%
1x short	3x long	20% to 35%
1x short	5x long	less than 20%

INFORMATION

A familiar tune sounds instead of the beeps

If this tune sounds, this indicates that the rules for controlling the prosthesis were loaded correctly and the prosthesis is ready for operation.

INFORMATION

If the **Volume** parameter is set to '0' in the Cockpit app, there are no beep signals (see page 34).

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 26).

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 "C-Soft Plus" adjustment software

INFORMATION

The “connectgo.pro” adjustment app is available as an alternative to the adjustment software described in these instructions for use.

The app is available for the following operating systems:

Android, iOS

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 a different device (tablet/smartphone) can 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) can be requested from the following email address, specifying the name of the app:

order-ifu@ottobock.com

7.1.1.1 Introduction

The "C-Soft Plus" 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 **4X440 C-Soft Plus adjustment software, version 1.10 or higher, is required for correct alignment**. If C-Soft Plus version 1.0 or higher is available, it can be updated.

⚠ CAUTION

Using the prosthesis in the delivery state (factory settings)

Falling due to unexpected behaviour of the prosthesis because the knee joint locks in the flexion direction

- ► After receiving the knee joint, it needs to be adjusted with the C-Soft Plus adjustment software, version 1.10 or higher.
- ► Using the knee joint on the patient without prior adjustment with the adjustment software is not permitted.

Updating the C-Soft Plus adjustment software

1) Make sure you are connected to the internet and go to the "http://ottobock.com/en/datastation/" website.
   → The webpage for the "Data Station" software will open.
2) Search for the description of the software that is to be updated under "Application/Patch".
3) Search for the applicable version.
4) Click "Download" in the column on the right in order to download the update.
5) 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 23), 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 on.

The Bluetooth function can be switched off using the Cockpit app or the adjustment software. When the Bluetooth function is switched off, it is only turned on temporarily 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.

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) Smooth the cut surface with a deburring knife (e.g. 718S2) and sandpaper.

NOTICE

Inserting the tube adapter without deburring the cut edge

Damage to the tube stop while inserting the tube adapter.

- ► If shortening the tube adapter resulted in raised material on the outside, a machine must be used to sand the material flat. Carefully deburr the inside.

7.1.3 Installing the Tube Adapter

⚠ CAUTION

Improper assembly of the screw connections

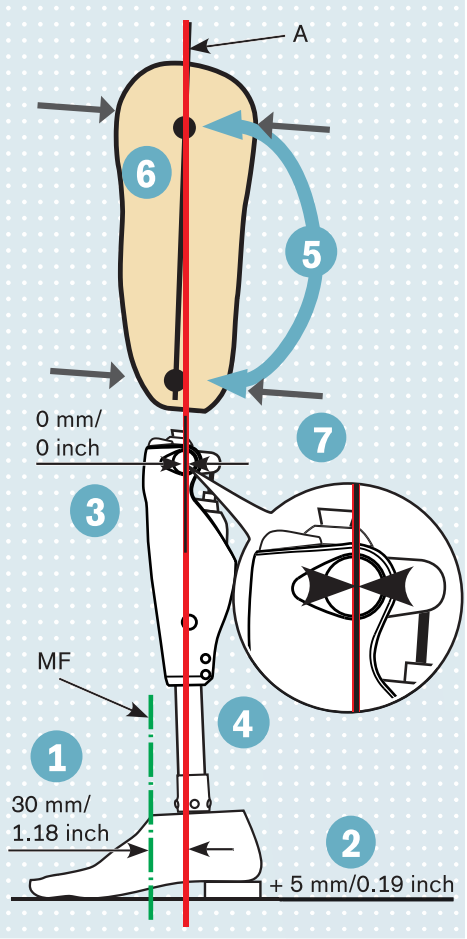
Falling due to breakage or loosening of the screw connections.

- ► Clean the threads before every installation.
- ► Apply the specified tightening torque values for installation (see the section "Technical data" see page 42).
- ► 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 15 Nm**.
   INFORMATION: Replace any set screws that are protruding or recessed too much with compatible ones. For approved set screws, see the section “Technical data” (see page 42).
2) Insert the tube adapter about 50 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 55 mm are permissible (slide in 5 mm and pull out 10 mm).
3) Turn the foot outwards slightly and tighten the two **distal tube clamp screwsto 7 Nm**.

7.1.4 Bench alignment in alignment apparatus

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, regardless 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. 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 to the correct position and set the required tube length.
5. Mark the lateral centre of the socket with a centred proximal and distal dot. Mark a line through both dots from the socket brim to the end of the socket. Insert the 4H105 knee extender (see page 26).
6. Position the socket so the alignment reference line passes through the centred, proximal dot.
   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.
   The adjustment software helps to determine the socket flexion precisely.
7. Connect the socket and modular knee joint using an adapter.

7.1.5 Installing/removing the knee extender

⚠ CAUTION

Using the prosthesis on the patient with the knee extender installed

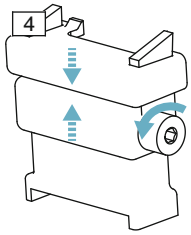
Falling due to unexpected prosthesis behaviour.

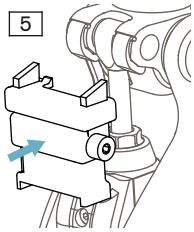
- ► Before trial fitting the prosthesis on the patient, remove the knee extender.
- ► Do not use the knee joint with the knee extender inserted under any circumstances during dynamic alignment optimisation.

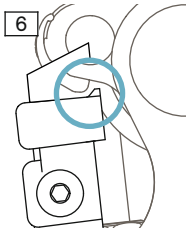
INFORMATION

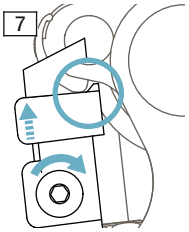
Support for using of the knee extender via the adjustment software

When the knee joint is connected to the C-Soft Plus adjustment software, version 1.10 or higher, correct extension of the knee joint with the help of the knee extender is shown in real time.









Mounting the knee extender

The knee extender has to be used for bench alignment of the prosthesis. This ensures the recommended sagittal positioning of the prosthetic components – the foot, socket and knee joint – relative to each other and therefore offers the full functionality of the knee joint.

1) Check whether both 8° flexion stops are mounted on the knee joint (see page 29).
2) Turn the knee extender adjustment screw counter-clockwise, setting the knee extender to the minimum height (see fig. 4).
3) Extend the knee joint.
4) Set the knee extender onto the hydraulics housing and slide it in to the stop (see fig. 5).
   INFORMATION: Check whether the two positioning lugs on the upper section of the knee extender are behind the flexion stops (see fig. 6).
5) Turn the adjustment screw clockwise, extending the knee extender until it touches the flexion stops (see fig. 7).
6) Insert an Allen key (size 4) into the adjustment screw and continue turning the adjustment screw clockwise 70 Ncm/10 full turns.

→ Now the knee joint is in the correct position for bench alignment.

Removing the knee extender

1) Insert an Allen key (size 4) in the adjustment screw and turn it counter-clockwise, setting the knee extender to the minimum height.
2) Remove the knee extender.

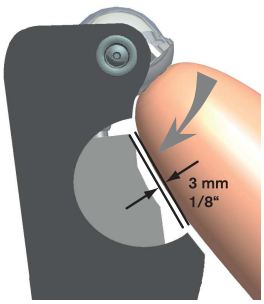
7.1.6 Checking the socket after bench alignment

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.

INFORMATION

If the fitting with a knee joint of a previous generation such as the 3C100; 3C105; 3C98-1/3C88-1; 3C98-2/3C88-2; 3C95/3C85; 3C96/3C86; 3C98-2/3C88-2 was modified to use this knee joint (3C98-3/3C88-3) without fabricating a new socket, this verification is mandatory. The available space is reduced by approx. 2 mm when the 3C88-3 or 3C98-3 knee joints are used compared to knee joints of previous generations.

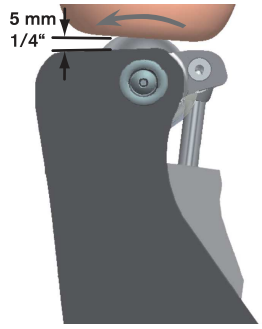
Verification at maximum flexion



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 (4R57) and electronics is not sufficient, the electronics may be damaged. Be sure to follow the system component instructions for use.
Check the distance as follows:

1) Bring the knee joint with 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 the knee extender is used to verify the distance, note that this is only permissible if the 8° flexion stops are installed.

INFORMATION

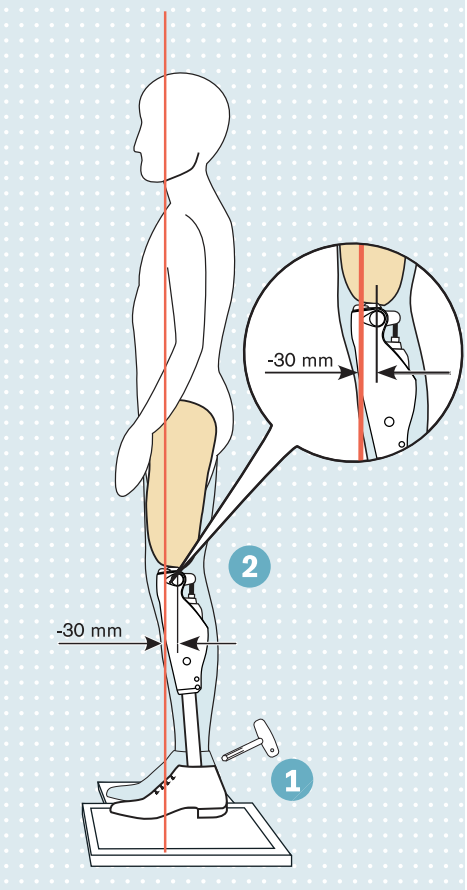
If a protective cover is subsequently installed, the available distance between the electronics and socket without the protective cover has to be at least 10 mm. Installing the protective cover reduces this distance by 5 mm.

7.1.7 Static alignment optimisation

The static alignment can be considerably improved with the help of the L.A.S.A.R. Posture (743L100=*) or 3D L.A.S.A.R. Posture (743L500). In order to achieve adequate safety while also making it easy to initiate the swing phase, please proceed with the alignment as described in the following sections.
Note the different distances from the load line to the alignment reference point (= knee axis)

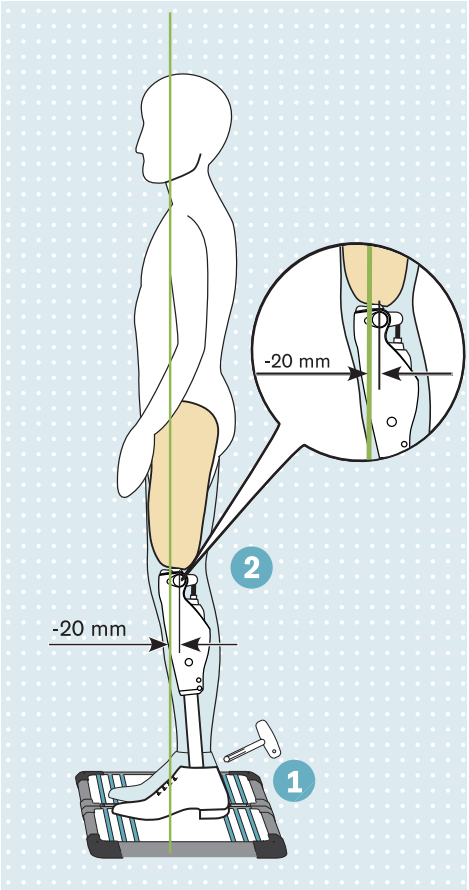
Alignment apparatus	Distance from load line to alignment reference point
743L100=* L.A.S.A.R Posture	30 mm
743L500 3D L.A.S.A.R. Posture (3D mode)	20 mm

743L100 L.A.S.A.R. Posture



1. To determine the load line, have the patient wear footwear (1B1-2 Meridium prosthetic foot without footwear) while standing on the force measurement plate with the side being treated with the prosthesis and on the height compensation plate with the other leg.
   Sufficient weight should be placed on the prosthesis side (> 35 per cent of the body weight). Note the weight display on the L.A.S.A.R. Posture.
2. Optimise the alignment by changing the plantar flexion. Only make adjustments to the distal and proximal set screws of the socket adapter on the prosthetic foot so that the **load line (laser line) runs approx. 30 mm in front of the alignment reference point** (= knee axis) of the knee joint.

743L500 3D L.A.S.A.R. Posture (3D mode)



1. To determine the load line, have the patient wear footwear (1B1-2 Meridium prosthetic foot without footwear) while standing on the force measurement plate with both legs.
   Sufficient weight should be placed on the prosthesis side (> 35 per cent of the body weight). Note the weight display on the L.A.S.A.R. Posture.
2. Optimise the alignment by changing the plantar flexion. Only make adjustments to the distal and proximal set screws of the socket adapter on the prosthetic foot so that the **load line runs approx. 20 mm in front of the alignment reference point** (= knee axis) of 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)

At the end of the dynamic alignment optimisation, calibration must be performed using the adjustment software.

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:

- 4H95 flexion stop (already installed): reduction of the maximum flexion angle by 8°
- 4H106 flexion stop (optional accessory): 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 27).

Removing the flexion stop

1) Use an appropriate screwdriver to loosen the screws on both flexion stops (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 1 Nm with the 710D1 torque wrench.

7.2 Optional: Installing the foam cover

If a cosmetic foam cover is installed on the knee joint, the charging receptacle has to be moved with the following charging cable extensions:

- 4X156-1 Charger Extension Cable – Ankle
- 4X158-1 charger extension cable – ankle, long
- 4X157-1 Charger Extension Cable – Knee

Further information on the installation and use of the charging cable extensions is found in the instructions for use included with the charging cable extensions.

8 Use

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)

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.

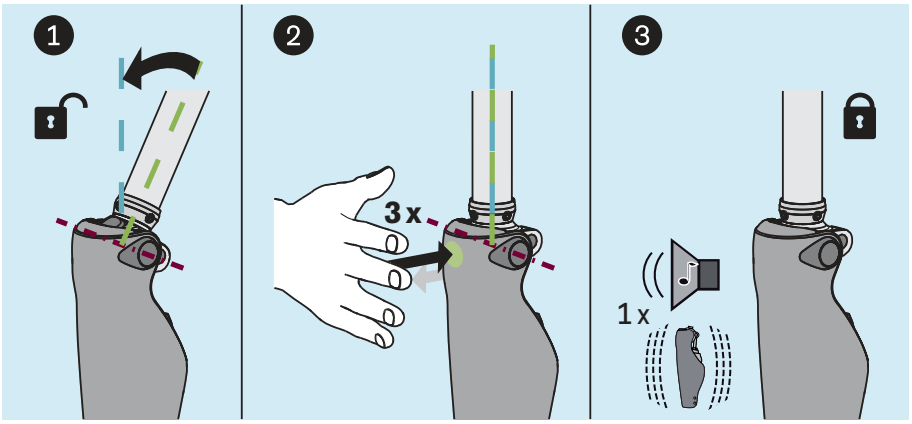
If there are difficulties with the download, the instructions for use (PDF file: 647G1566) can be requested from the following email address, specifying the name of the app:
order-ifu@ottobock.com

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.

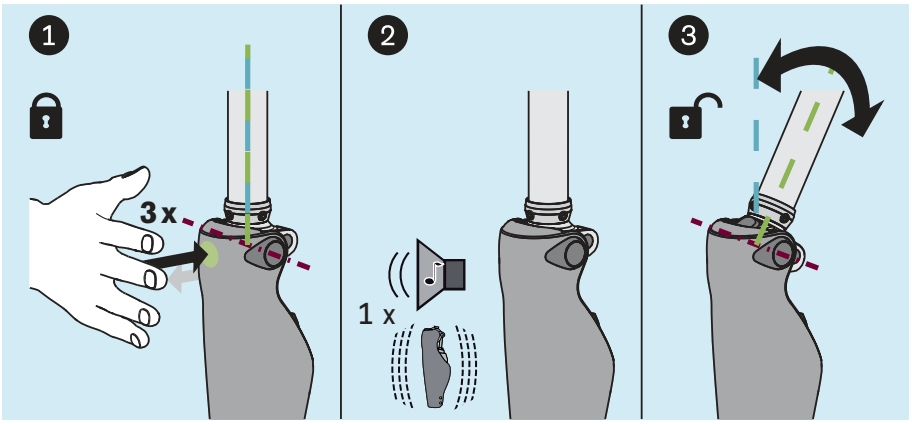
Activating lock using the manual locking function



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.

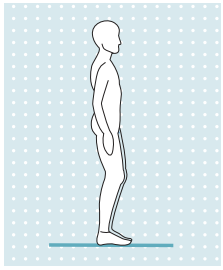
8.3 Movement patterns in basic mode (mode 1)

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.

8.3.1 Standing



Knee control through high hydraulic resistance and correct static alignment.

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

8.3.1.1 Stance function

INFORMATION

To use this function, it needs to be enabled in the adjustment software. It also has to be activated using the Cockpit app.

The stance function is a functional supplement to the basic mode. This function makes it easier for the patient to stand on an inclined surface for a longer time. The joint is fixed in the flexion direction at a flexion angle between 5° and 65°.

This function must be enabled in the adjustment software. Once the function is enabled, you can also choose between an intuitive and a conscious lock.

Intuitive locking of the joint

The intuitive stance function 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 and is kept still for a brief

moment. Upon forward or backward rollover or extension, the level of resistance is immediately reduced to stance phase resistance again.
The knee joint is not locked when the above conditions are met and a sitting position is assumed (for example while driving).

Deliberate locking of the joint

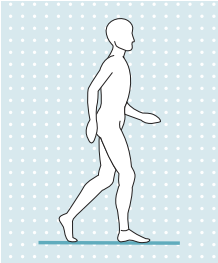
1) Assume the desired knee angle.
2) Do not change the knee angle for a brief period.

→ The blocked joint can now be loaded in the flexion direction.

Deliberate unlocking of the joint

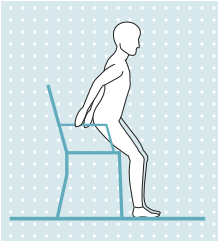
► The deliberate stance function is automatically deactivated again by extending the knee or by repositioning the leg (e.g. taking a step).

8.3.2 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.
Switching to the swing phase requires that the prosthesis roll over to the front out of the stride position.

8.3.3 Sitting down



The resistance in the prosthetic knee joint while sitting down ensures even bending into the sitting position.
The adjustment software can be used to configure whether the sitting process is to be supported or not.

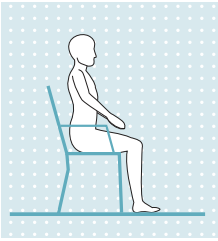
1) Place both feet side by side at the same level.
2) While sitting down, weight should be distributed evenly between both legs and the arm supports used where applicable.
3) Move the buttocks in the direction of the back support and lean the upper body forward.

INFORMATION: Resistance while sitting down can be changed with the Cockpit app via the parameter “Resistance” (see page 34).

8.3.4 Sitting

INFORMATION

While sitting, the knee joint also switches to energy saving mode. This energy saving mode is activated regardless of whether the sitting function is activated or not.



If the patient is in a sitting position for more than two seconds (i.e. the thigh is close to horizontal and there is no load on the leg), the knee joint switches the resistance to a minimum in the extension direction.
A sitting function can be enabled using the adjustment software. For more information about the sitting function, see the following section.

8.3.4.1 Sitting function

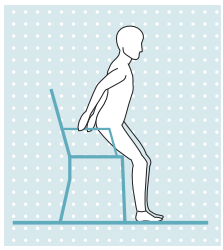
INFORMATION

To use this function, it needs to be enabled in the adjustment software. It also has to be activated using the Cockpit app (see page 34).

In the sitting position, the resistance in the flexion direction is reduced in addition to the reduction of resistance in the extension direction. This makes it possible to swing the prosthetic leg freely.

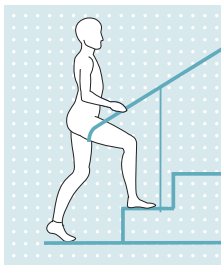
8.3.5 Standing up

Flexion resistance is increased steadily 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 feet.

8.3.6 Walking up stairs

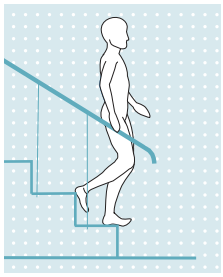


Walking up stairs step-over-step is not possible.

1) Hold the handrail with one hand.
2) Place the foot of the sound leg on the first step.

Bring up the leg with the prosthesis.

8.3.7 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

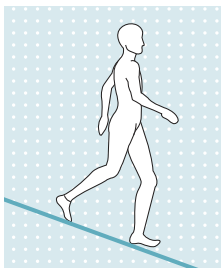
Walking down stairs step-over-step must be practised and executed consciously. The knee joint can switch correctly and permit a controlled rollover only by stepping down properly with the sole of the foot. The motion must be carried out in a continuous pattern in order to allow the motion sequence to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

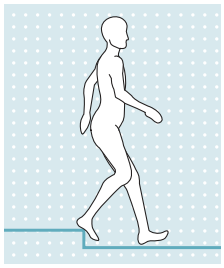
8.3.8 Walking down a ramp



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.

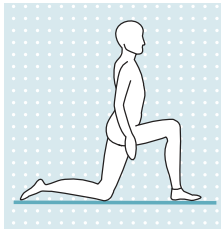
8.3.9 Walking down flat steps



To walk down ramps, flat steps or curbs, walking step-over-step with knee flexion under load is recommended for the best possible relief of the contralateral side upon the subsequent ground contact. This knee flexion should be initiated immediately upon heel strike, or as long as the prosthetic leg is still in front of the body.

For skilled users the prosthesis offers the option of initiating a swing phase while walking down ramps and crossing flat steps (such as curbs). In order to do so, the body's centre of gravity has to be far enough in front of the supporting leg and the swing phase has to be initiated with the leg extended. If the foot is positioned so that it projects far beyond the edge of the step in this situation, swing phase initiation may be surprising. However, the contralateral leg is ready to hold the weight in this situation.

8.3.10 Kneeling



Under increased flexion resistance, permit controlled flexion of the prosthetic knee joint to gradually reach the kneeling position. A hard impact of the knee joint on the ground should be avoided so the electronics are not damaged.

Using the 4X860=* C-Leg Protective Cover or the 4P862 guard is recommended for kneeling frequently.

8.4 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 must be switched on to change the prosthesis settings.
If Bluetooth is switched off, it can be turned on by turning the prosthesis upside-down or by connecting/disconnecting the battery charger. Bluetooth is then turned on for approx. 2 minutes. The connection must be established during this period.

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.
- If the settings of a MyMode are to be modified, one must first switch to this MyMode.

8.4.1 Overview of adjustment parameters in basic mode

The parameters in basic mode describe the dynamic behaviour of the prosthesis in a normal gait cycle. These parameters act as basic settings for automatically adjusting the damping behaviour to the current motion situation (e.g. ramps, slow walking speed, etc.).

The stance function and/or the sitting function can also be activated/deactivated. Further information on the stance function (see page 31). Further information on the sitting function (see page 32).

The following parameters can be modified:

Parameter	Adjustment software range	Setting range, app	Meaning
Resistance	120 to 190	+/- 10 of the configured value	Flexion resistance while sitting down, in the stance phase, while walking on ramps and stairs.
Stance function[1]		0/Off – deactivated 1/On – activated	Information about this function is provided in the section "**Stance function**" (see page 31)
Sitting function[1]		0/Off – deactivated 1/On – activated	When the function is activated, the resistance in the flexion direction while sitting is reduced in addition to the reduction of resistance in the extension direction.
Acoustic feedback signal		On/Off	Acoustic feedback for switching between the stance and swing phase.
Volume	0 to 4	0 to 4	Volume of beep signal for confirmation tones (e.g. when checking the charge level, switching MyModes). The "0" setting deactivates the audible feedback signals. However, warning signals are still generated if errors occur.

[1] To use these functions in the Cockpit app, they need to be enabled in the adjustment software.

8.4.2 Overview of adjustment parameters in MyModes

The parameters in the MyModes describe the static behaviour of the prosthesis for a specific motion pattern such as cross-country skiing. Damping behaviour is not automatically controlled and adjusted in MyModes.

The following parameters can be modified in MyModes:

Parameter	Adjustment software range	Setting range, app	Meaning
Basic flex.	0–200	+/- 20 of the configured value	Level of flexion resistance when the knee joint begins to flex
Gain	0–100	+/- 10 of the configured value	Increase in flexion resistance (starting with the "**Basic flex.**" parameter) when flexing the knee joint. The knee joint locks at a certain flexion angle, which depends on the settings for the "**Basic flex.**" and "**Gain**" parameters.
Basic ext.	0–60	+/- 20 of the configured value	Level of extension resistance
Locking angle	0–90	+/- 10 of the configured value	Angle up to which the knee joint can be extended. **Information:** If this parameter is >0, the knee joint is locked in a flexed position in the extension direction. To unlock it, take all weight off the prosthesis and tilt it back for at least 2 seconds. This enables extension of the joint independently of the settings for the "**Basic ext.**" and "**Locking angle**" parameters. This may be necessary to switch to basic mode using a movement pattern.
Volume	0–4	0–4	Volume of beep signal for confirmation tones (e.g. when checking the charge level, switching MyModes). The "0" setting deactivates the audible feedback signals. However, warning signals are still generated if errors occur.

8.5 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 charging plug immediately after the beep signal sounds.
3) Immediately after another beep signal sounds, reconnect the charging plug.
4) Carry out this process (steps 2 and 3) a total of three times.

→ After the charging plug has been disconnected for the third time, a descending sequence of 5 beeps is emitted and the product is then switched off.

INFORMATION

After waiting too long between connecting/disconnecting (e.g. until a vibration signal is emitted), the process of connecting/disconnecting 3 times has to be repeated.

Switching on

1) Connect the power supply with battery charger to the socket.
2) Connect the battery charger to the product.
   → The correct connection of the battery charger to the product is indicated by feedback (see page 45 and see page 47).

8.6 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.

8.7 Deep sleep mode

INFORMATION

If the **Volume** parameter is set to '0' in the Cockpit app, there are no beep signals (see page 34).

The Cockpit app can be used to place the knee joint into a deep sleep mode, in which power consumption is minimised. The knee joint offers no functionality in this mode. The safety mode resistance values are activated.
It can be awakened from deep sleep mode with the Cockpit app or by connecting the battery charger.
Deep sleep mode can also be deactivated by activating another MyMode.

8.7.1 Turning deep sleep mode on/off using the Cockpit app

Activating deep sleep mode

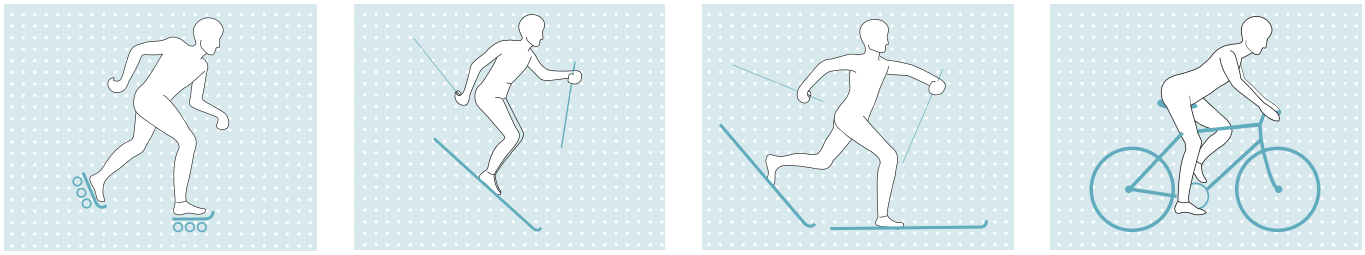
Deep sleep mode is displayed like a MyMode and can be activated via the Cockpit app like a MyMode.
Follow the steps in the section “Switching MyModes with the Cockpit app” (Switching MyModes with the cockpit app) for switching.
A short beep signal and a short vibration signal indicate that deep sleep mode has been activated.

Deactivating deep sleep mode

To deactivate deep sleep mode, select and activate basic mode or a MyMode in the Cockpit app. Deep sleep mode ends automatically.

9 MyModes

In addition to basic mode (mode 1), MyModes can be activated and configured with the adjustment software. They can be called up by the patient using the Cockpit app or movement patterns. Switching by using movement patterns has to be activated in the adjustment software.



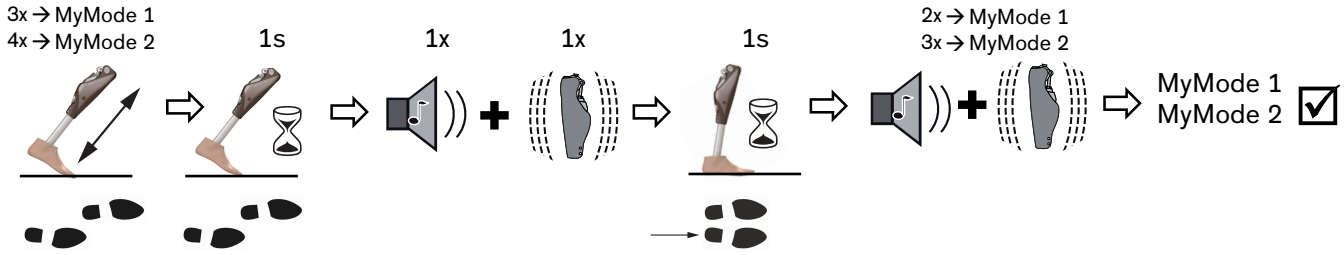
These modes are intended for specific movement patterns or postures (e.g. inline skating, ...). Default settings for these movement patterns and postures can be called up and individually adapted using the adjustment software. Settings can also be adjusted by the patient using the Cockpit app (see page 35).

9.1 Switching MyModes using motion patterns

Information on switching

- Switching and the number of motion patterns must be activated in the adjustment software.
- Before the first step, always check whether the selected mode corresponds to the required motion type.
- If the **Volume** parameter is set to "0" in the Cockpit app, there are no beep signals (see page 34).

Switching process



1) Position the prosthetic leg back slightly.
2) While maintaining constant contact with the floor, bounce on the forefoot a number of times in one second depending on the desired MyMode (MyMode 1 = 3 times, MyMode 2 = 4 times).
3) Keep the prosthetic leg still in this position (lunge position) for about 1 second without lifting the leg. Taking the weight off is no longer necessary.
   → A beep and vibration signal will occur to confirm that the movement pattern has been recognised.
   INFORMATION: If this beep and vibration signal is not emitted, the requirements were not met while bouncing.
4) Following the beep and vibration signal, move the prosthetic leg next to the contralateral leg, set it down and keep still for about 1 second.

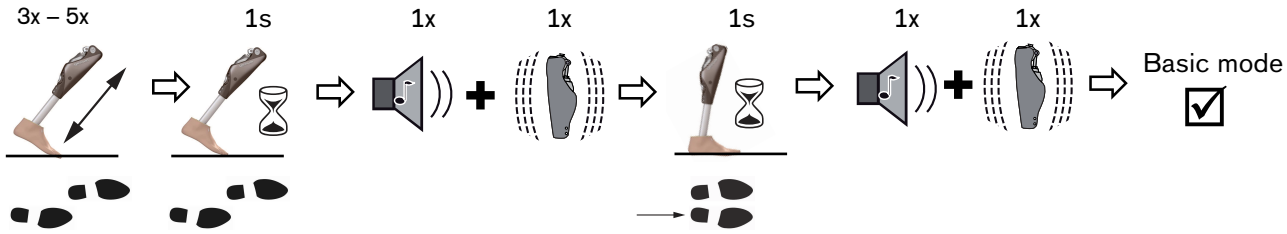
→ A confirmation signal will sound to indicate that the prosthesis has successfully switched to the corresponding MyMode (2 times = MyMode 1, 3 times = MyMode 2).
INFORMATION: If this confirmation signal does not sound, the leg with the prosthesis was not correctly repositioned and kept still. Repeat the process to correctly switch to the required mode.

9.2 Switching from a MyMode back to basic mode

Information on switching

- Regardless of the configuration of additional MyModes in the adjustment software, it is always possible to switch back to basic mode (mode 1) with a motion pattern.
- It is always possible to switch back to basic mode (mode 1) by connecting/disconnecting the battery charger.
- Before the first step, always check whether the selected mode corresponds to the required motion type.
- If the **Volume** parameter is set to "0" in the Cockpit app, there are no beep signals (see page 34).

Switching process



1) Position the prosthetic leg back slightly.
2) While maintaining constant contact with the floor, bounce on the forefoot at least 3 times but not more than 5 times.
3) Keep the prosthetic leg still in this position (lunge position) for about 1 second without lifting the leg. Taking the weight off is no longer necessary.
   → A beep and vibration signal will occur to confirm that the movement pattern has been recognised.
   INFORMATION: If this beep and vibration signal is not emitted, the requirements were not met while bouncing.
4) Move the prosthetic leg in next to the contralateral leg, set it down and keep it still for approx. 1 second.

→ A confirmation signal will sound to indicate that the prosthesis has successfully switched over to basic mode.
INFORMATION: If this confirmation signal does not sound, the leg with the prosthesis was not correctly repositioned and kept still. Repeat the process to correctly switch to the required mode.

10 Additional operating states (modes)

10.1 Empty battery mode

Beeps and vibration signals are emitted if the available battery charge level is 4% (see page 45). During this time, damping settings are set to their safety mode values. The prosthesis is then switched off. You can switch back to basic mode (mode 1) from empty battery mode by charging the product.

10.2 Mode for charging the prosthesis

The product is non-functional during charging.
The product is set to the safety mode resistance values. These may be low or high depending on the setting in the adjustment software.

10.3 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.

Default damping values are activated 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 45).

Safety mode can be disabled by connecting then 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.

10.4 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.

Overheating mode is not activated in the MyModes.

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

The following functions are deactivated in overheating mode:

- Sitting function
- Display of the battery charge level without additional equipment
- Switching to a MyMode
- Changes to the prosthesis setting

11 Storage and bleeding

Air may accumulate in the hydraulic unit if the product is stored for longer periods and not in an upright position. This is noticeable through sounds and irregular damping behaviour.

The automatic bleeding mechanism ensures that all functions of the product are again intact after approximately 10 - 20 steps.

Storage

- Before storing the knee joint, the knee head has to be extended. The knee head must not be flexed!
- Avoid extended disuse of the product (use the product regularly).

12 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.

13 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.

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.

When maintenance is due, this is indicated by feedback after disconnecting the battery charger (see the section "Operating states/error signals", see page 45).

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, charging adapter (if used as an accessory) and power supply. The packaging material for the loaner unit you previously received must be reused for sending back the components requiring inspection.

Before shipping, the knee head of the prosthetic knee joint has to be extended. The knee head must not be flexed!

13.1 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

Using the prosthesis in the delivery state (factory settings)

Falling due to unexpected behaviour of the prosthesis because the knee joint locks in the flexion direction

- ► After receiving the knee joint, it needs to be adjusted with the C-Soft Plus adjustment software, version 1.10 or higher.
- ► Using the knee joint on the patient without prior adjustment with the adjustment software is not permitted.

⚠ 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.

14 Legal information

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

14.1 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.

14.2 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.

Bluetooth is a registered trademark of Bluetooth SIG, Inc.

14.3 CE conformity

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

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

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

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

14.4 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.

15 Technical data

Environmental conditions	
Transportation in original packaging	-25°C/-13°F to +70°C/+158°F
Transportation without packaging	-25°C/-13°F to +70°C/+158°F Max. 93% relative humidity, non-condensing
Storage (≤3 months)	-20°C/-4°F to +40°C/+104°F Max. 93% relative humidity, non-condensing
Long-term storage (>3 months)	-20°C/-4°F to +20°C/+68°F Max. 93% relative humidity, non-condensing
Operation	-10°C/+14°F to +60°C/+140°F Max. 93% relative humidity, non-condensing
Charging the battery	+10°C/+50°F to +45°C/+113°F

Product	
Reference number	3C98-3*/3C88-3*
Mobility grade according to MOBIS	2 to 4
Maximum body weight including additional weight	136 kg/300 lb
Minimum body weight	45 kg/100 lb The treatment of patients below this body weight is also possible, provided a trial fitting confirms that these patients are able to fully utilise the prosthesis.
Proximal system height up to alignment reference point 3C98-3 (pyramid connector)	5 mm
Proximal system height up to alignment reference point 3C88-3 (threaded connector)	25.6 mm
Minimum distal system height with 2R57 tube adapter	289 mm
Minimum distal system height with 2R67 tube adapter	329 mm
Maximum distal system height with 2R57 tube adapter	494 mm
Maximum distal system height with 2R67 tube adapter	534 mm
Protection rating	IP68
Water resistance	Water-resistant, not corrosion-resistant
Range of Bluetooth connection to PC	Max. 10 m/32 ft
Range of Bluetooth connection to mobile device	Max. 10 m/32 ft
Maximum possible flexion angle	130°
Maximum possible flexion angle with preinstalled flexion stops	122°
Maximum insertion depth of the tube adapter in the knee joint	55 mm/2.17 inches
Weight of the prosthesis without Protective Cover	approx. 1250 g ±25 g/ 44.09 oz ±0.88 oz
Expected lifetime if prescribed maintenance intervals are complied with	6 years
Test procedure	ISO 10328-P6-136 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)

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	500
Charge level after 1 hour charging time	30 %
Charge level after 2 hours charging time	50 %
Charge level after 4 hours charging time	80 %
Charge level after 8 hours charging time	Fully charged
Product behaviour during the charging process	The product is non-functional
Operating time of the prosthesis with new, fully charged battery at room temperature	At least 16 hours of uninterrupted walking Approx. 2 days 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	4E50*
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
Input voltage	12 V ⎓
Service life	8 years

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.
Tube clamp of the 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	1 Nm / 5 lbf. In.

16 Appendices

16.1 Symbols Used

Manufacturer

Type BF applied part

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

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

Non-ionising radiation

IP68

The protection rating IP or “Ingress Protection” indicates how well electrical housing is sealed against the penetration of foreign objects (e.g. solids, dust, dirt) and moisture. The “IP” rating consists of two digits: the first digit indicates the protection of the housing against foreign objects, the second digit the protection against liquids. The higher the number, the greater the protection.

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

In some jurisdictions it is not permissible to dispose of these products with unsorted household waste. Disposal that is not in accordance with the regulations of your country may have a detrimental impact on health and the environment. Please observe the instructions of your national authority pertaining to return and collection.

Declaration of conformity according to the applicable European directives

SN

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

REF

Article number

MD

Medical device

Caution, hot surface

Please note the instructions for use

Check the product settings using the corresponding adjustment software of the Ottobock Data Station.

16.2 Operating states/error signals

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

16.2.1 Signals for operating states

Battery charger connected/disconnected

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

Mode switching

INFORMATION

If the **Volume** parameter is set to '0' in the Cockpit app, there are no beep signals (see page 34).

Beep signal	Vibration signal	Additional action performed	Result
1 x short	1 x short	Mode switching using the Cockpit app	Mode switching is performed using the Cockpit app.
1 x short	1 x short	Bouncing on the forefoot followed by holding still for 1 second in the walking position	Bouncing pattern recognised.
1 x short	1 x short	Prosthetic leg moved next to contralateral leg, set down and kept still for 1 second	Switching to basic mode (mode 1) carried out.
2 x short	2 x short	Prosthetic leg moved next to contralateral leg, set down and kept still for 1 second	Switching to MyMode 1 (mode 2) carried out.
3 x short	3 x short	Prosthetic leg moved next to contralateral leg, set down and kept still for 1 second	Switching to MyMode 2 (mode 3) carried out.

16.2.2 Warnings/error signals

Error during use

Beep signal	Vibration signal	Result	Required action
–	1 x long at interval of approx. 5 seconds	Overheated hydraulic unit	Reduce activity.
–	3 x long	Charge level under 25%	Charge battery soon.
–	5 x long	Charge level under 15%	Charge battery immediately; the product will be switched off after the next warning signal.
10 x long	10 x 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	Result	Required action
30 x long	1 x long, 1 x short repeated every 3 seconds	**Severe error/indication of safety mode activation** e.g. one or more sensors are not operational.	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 be 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. Undetermined 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	Error	Resolution
○		Country-specific plug adapter not fully engaged on power supply	Check whether the country-specific plug adapter is fully engaged on the power supply.
		Non-functional socket	Check socket with another electric device.
		Defective power supply	The battery charger and power supply must be inspected by an authorised Ottobock Service Centre.
●		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.
●		Battery is fully charged (or connection with product is interrupted).	Take note of the confirmation signal for differentiation. When the battery charger is connected or disconnected, a self-test is conducted and confirmed by a beep and vibration signal. The battery is fully charged if this signal is heard. If no signal is emitted, the connection to the product is interrupted.
			If the connection to the product is interrupted, an authorised Ottobock Service Centre must inspect the product, battery charger and power supply.

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 42).

16.2.3 Error messages while establishing a connection with the cockpit app

Error message	Cause	Correction
Component was connected to another device. Establish connection?	The component was connected to another mobile device	To disconnect the original connection, tap the "**OK**" button. If the original connection is not to be disconnected, tap the "**Cancel**" button.
Mode change failed	An attempt was made to switch to a different MyMode while the component was in motion (e.g. while walking)	For safety reasons, switching MyModes is only permitted when components are at rest, e.g. while standing or sitting.
	A current connection to the prosthesis was interrupted	Check the following points: • Distance from the prosthesis to the mobile device • Charge level of the prosthesis • Bluetooth on the prosthesis switched on? (see page 36) • Hold the component with the sole of the foot facing up to make the component "visible" for 2 minutes. • Prosthesis switched on? (see page 36) • If multiple prostheses were stored, was the correct prosthesis selected?

16.2.4 Status signals

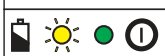
Battery charger is connected

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

Battery charger disconnected

Beep signal	Vibration signal	Result
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 sounds again, product maintenance should be carried out by an authorised Ottobock Service Center. The product can be used without restrictions. However, vibration signals may not be generated.
–	–	Conduct the self-test again by connecting/disconnecting the battery charger. If no beep/vibration signal is emitted after connecting/disconnecting the battery charger again, the product must be inspected by an authorised Ottobock Service Center.

Battery charge level

Battery charger	
	Battery is being charged, battery charge level is less than 50%
	Battery is being charged, battery charge level is over 50%

Battery charger	
	Battery is fully charged (or connection with product is interrupted). Take note of the confirmation signal for differentiation. When the battery charger is connected or disconnected, a self-test is conducted and confirmed by a beep and vibration signal. The battery is fully charged if this signal is heard. If no signal is emitted, the connection to the product is interrupted.

16.3 Directives and manufacturer's declaration

16.3.1 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 18).

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

Phenomenon	EMC basic standard or test procedure	Interference immunity test level
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
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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