



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

Instructions for use (user)	5
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- JA** | 製品の安全な使用方法については、有資格担当者の指示に従ってください。
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- ZH** | 由专业人员就产品的安全使用提供指导。
使用说明书的其他语言版本可在线获取，也可免费订购印刷版（参见第 2 页）。

Basic UDI-DI:

C-Leg 3C88-3*: 4064411000000003C88-3NC

C-Leg 3C98-3*: 4064411000000003C98-3NK

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1 Foreword

INFORMATION

Date of last update: 2024-02-20

- ▶ Please read this document carefully before using the product and observe the safety notices.
- ▶ Obtain instruction from the qualified personnel in the safe use of the product.
- ▶ Please contact the qualified personnel 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 your needs.

For this purpose, the product is adjusted by qualified personnel using adjustment software.

The product features MyMode for special motion types (e.g. cross-country skiing...). These are pre-configured by the O&P professional using the adjustment software and can be activated with special movement patterns and the Cockpit app (see page 27).

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 29).

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 29).

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

3 Intended use

3.1 Indications for use

The product is to be used **solely** for lower limb exoprosthetic fittings.

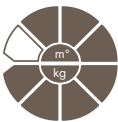
3.2 Conditions of use

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 31).

The product is intended **exclusively** for use on **one** user. 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 users 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 user must fulfil the physical and mental requirements for perceiving optical/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
Using the prosthesis while operating a vehicle
Accident due to unexpected behaviour of the prosthesis because of changed damping behaviour.
▶ All users are required to observe their country's national and state driving laws when operating vehicles with a prosthesis. For insurance purposes, drivers should have their driving ability examined and approved by an authorised test centre.
▶ Observe national legal regulations for retrofitting your vehicle in accordance with the type of fitting.
▶ The leg on which the prosthesis is worn may not be used to control the vehicle or its peripheral components (e.g. clutch pedal, brake pedal, gas pedal, etc.).

 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 35) 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

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 your own 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 16) and "Accessories" (see page 16).

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 product behaviour because of changed damping behaviour.

- ▶ For safety reasons, take the product off before charging the battery.

⚠ 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 31).

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 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.

- ▶ Avoid remaining in the vicinity of visible or concealed theft prevention systems at the entrance/exit of stores, metal detectors/body scanners for people (e.g. in airports) or other sources of strong magnetic and electrical interference (e.g. high-voltage lines, transmitters, transformer stations...).

If this cannot be avoided, make sure to at least have a safeguard when walking or standing (e.g. a handrail or the support of another person).

- ▶ When walking through theft prevention systems, body scanners or metal detectors, watch for unexpected changes in the damping behaviour of the product.
- ▶ 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.

- ▶ Take off the product before entering a room or area with strong magnetic fields and store 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.

- ▶ Avoid remaining in areas with temperatures outside of the permissible range (see page 31).

4.7 Information on Use

⚠ CAUTION

Walking up stairs

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

- ▶ Always use the handrail when walking up stairs and place most of the area of the sole of your foot on the stair surface.
- ▶ Particular caution is required when carrying children up stairs.

⚠ CAUTION

Walking down stairs

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

- ▶ Always use the handrail when walking down stairs and roll over the edge of the step with the middle of the shoe.
- ▶ Observe the warning/error signals (see page 35).
- ▶ Be aware that resistance in the flexion and extension direction can change in case of warning 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, you must reduce your level of activity 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 for damage by an O&P professional. If necessary, they will forward the product to an authorised Ottobock Service Center.

⚠ CAUTION

Overloading due to activities with unusual loads

- > Falling due to unexpected product behaviour as the result of a malfunction.
- > Falling due to breakage of load-bearing components.
- > Skin irritation due to defects on the hydraulic unit with leakage of liquid.
- ▶ The product was developed for everyday use and must not be used for activities with unusual loads. 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 your 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 by an O&P professional. If necessary, he or she will forward the product to an authorised Ottobock Service Center.

⚠ CAUTION

Improper mode switching

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

- ▶ Ensure that you stand securely during all switching processes.
- ▶ Verify the changed damping characteristics after switching and observe the feedback from the acoustic signal emitter.
- ▶ Switch back to basic mode once the activities in MyMode have been completed.
- ▶ Take the weight off the product and correct the switching, if required.

⚠ CAUTION

Improper use of the stance function

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

- ▶ Make sure that you are standing safely when using the stance function and check the lock of the knee joint before placing your full weight on the prosthesis.
- ▶ Make sure you have been instructed in the correct use of the stance function by the O&P professional and/or therapist. Information on the stance function see page 21.

⚠ 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.
- ▶ Therefore, familiarise yourself with swing phase activation in such situations under secure conditions (e.g. while holding on to parallel bars) and with the instruction of trained, qualified personnel.
- ▶ For sports where this movement pattern may occur, use a corresponding pre-configured MyMode. For further information about the MyModes, see the section 'MyModes' (see page 27).

⚠ CAUTION

Overloading due to changed 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.
- ▶ Note that the behaviour of the product can change due to increased weight. The swing phase may not be triggered, or triggered at the wrong time.
- ▶ Make sure that the maximum permissible body weight is not exceeded due to the additional weight.

4.8 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 35) 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 behaviour of the product because of changed damping behaviour.

- ▶ Do not continue using the defective product.
- ▶ Consult the O&P professional promptly.

⚠ CAUTION

Safety mode cannot be deactivated

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

- ▶ If safety mode cannot be deactivated by recharging the battery, a permanent error has occurred.
- ▶ Do not continue using the defective product.
- ▶ The product must be inspected by an authorised Ottobock Service Center. The O&P professional is your contact.

⚠ CAUTION

Safety signal occurs (ongoing vibration)

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

- ▶ Observe the warnings/error signals (see page 35).
- ▶ Do not continue using the product after the safety signal has been emitted.
- ▶ The product must be inspected by an authorised Ottobock Service Center. The O&P professional is your contact.

4.9 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, death of bone tissue or bone 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.
- ▶ Note changes in your state of health that result in restrictions or doubt regarding the use of the osseointegrated connection.

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. cosmetic case for battery charger and power supply
- 1 pc. prosthesis passport
- 1 pc. 646C107 Bluetooth PIN card
- 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:

- 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

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 every day when used 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) 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 35).

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 35).
- 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 38).
 - 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 24).

7 Use

7.1 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) can be requested from the following email address, specifying the name of the app:

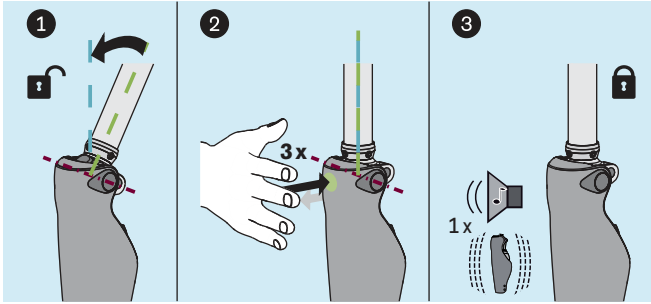
order-ifu@ottobock.com

7.2 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).

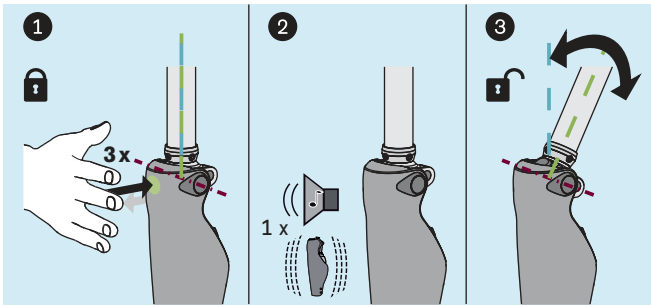
The manual locking function can be deactivated for the user in the app. Note that after deactivation in the app, the manual locking function no longer responds until the function is reactivated in the app. For more detailed information, see the app's instructions for use.

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.

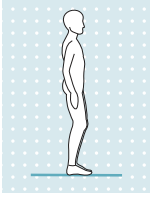
7.3 Movement patterns in basic mode (mode 1)

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.

7.3.1 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.

7.3.1.1 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 user 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°.

The type of joint locking (intuitive/deliberate) has to be established by the O&P professional. The locking type cannot be changed using the Cockpit app.

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).

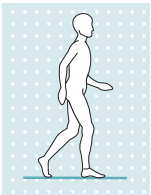
Deliberate locking of the joint

- 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).

7.3.2 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.

7.3.3 Sitting down



The resistance in the prosthetic knee joint while sitting down ensures even bending into the sitting position.

The O&P professional can use the adjustment software 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 24).

7.3.4 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.

7.3.4.1 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 24).

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.

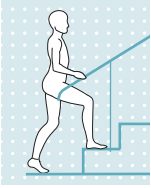
7.3.5 Standing up

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.

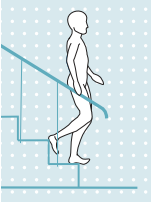
7.3.6 Walking up stairs



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.

7.3.7 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

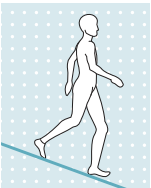
Walking down stairs step-over-step must be practised and executed consciously. The knee joint can switch correctly and permit a controlled rollover only by stepping down properly with the sole of the foot. The motion must be carried out in a continuous pattern in order to allow the motion sequence to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

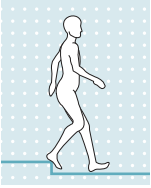
7.3.8 Walking down a ramp



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.

7.3.9 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.

7.3.10 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.

7.4 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.
- 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 everyday behaviour of the prosthesis can be changed to a certain extent using the app (e.g. while becoming accustomed to the prosthesis). The O&P professional can use the adjustment software to track these changes at the next appointment.
- If the settings of a MyMode are to be modified, one must first switch to this MyMode.

7.4.1 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 21). Further information on the sitting function (see page 22).

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 21)
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.

7.4.2 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.

Parameter	Adjustment software range	Setting range, app	Meaning
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.

7.5 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.

7.6 Deep sleep mode

INFORMATION

If the **Volume** parameter is set to '0' in the Cockpit app, there are no beep signals (see page 24).

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.

7.6.1 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.

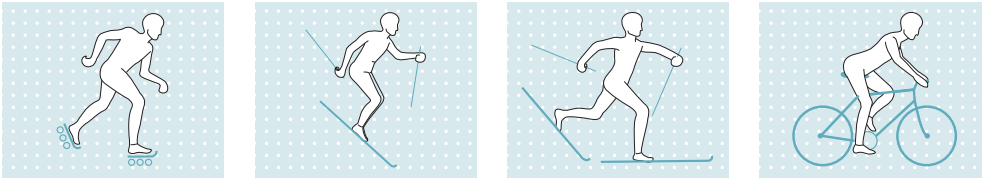
A short beep signal and a short vibration signal indicate that deep sleep mode has been activated.

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.

8 MyModes

With the help of adjustment software, the O&P professional can activate and configure MyModes in addition to the basic mode. These can be selected by using the Cockpit app or movement patterns. Switching by using movement patterns has to be activated in the adjustment software by the O&P professional.



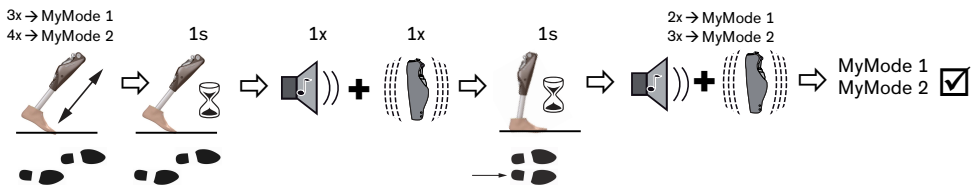
These modes are intended for specific motion patterns or postures (e.g. inline skating...). Settings can be adjusted using the Cockpit app (see page 25).

8.1 Switching MyModes using motion patterns

Information on switching

- Switching and the number of movement patterns must be activated by the O&P professional 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 24).

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).

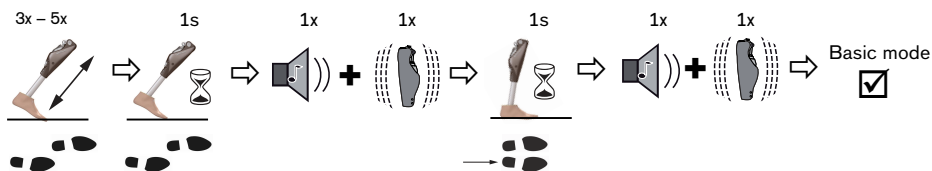
INFORMATION: If this confirmation signal does not sound, the leg with the prosthesis was not correctly repositioned and kept still. Repeat the process to correctly switch to the required mode.

8.2 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 24).

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.

9 Additional operating states (modes)

9.1 Empty battery mode

Beeps and vibration signals are emitted if the available battery charge level is 4% (see page 35). 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.

9.2 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.

9.3 Safety mode

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

Default resistance 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 35).

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.

9.4 Overheating mode

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

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

10 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).

11 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.

12 Maintenance

Regular maintenance (service inspections) is mandatory in the interest of your own 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 user's activity level. For users with a normal to low activity level, with up to 1,800 steps per day, the expected maintenance interval is 3 years. For highly active users with 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 34).

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 always have to be submitted to the O&P professional for maintenance and repairs:

The prosthesis, battery charger, charging adapter (if used as an accessory) and power supply.

13 Legal information

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

13.1 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.

13.2 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.

13.3 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>

13.4 Local Legal Information

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

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

- 1) This device may not cause harmful interference, and
- 2) This device must accept any interference received, including interference that may cause undesired operation.

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

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/ TV technician for help.

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

Caution: Exposure to Radio Frequency Radiation.

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

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.

14 Technical data

Environmental conditions	
Transportation in original packaging	-25°C/-13°F to +70°C/+158°F

Environmental conditions	
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 users below this body weight is also possible, provided a trial fitting by a certified O&P professional confirms that these users are able to fully utilise the prosthesis.
Protection rating	IP68
Water resistance	Water-resistant, not corrosion-resistant
Maximum possible flexion angle	130°
Maximum possible flexion angle with pre-installed flexion stops	122°
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
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 %

Prosthesis battery	
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

15 Appendices

15.1 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



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



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



Article number



Medical device



Caution, hot surface

15.2 Operating states/error signals

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

15.2.1 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 24).

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.

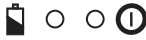
15.2.2 Warnings/error signals

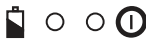

Error during use

Beep signal	Vibration signal	Event	Required action
–	1 x long at interval of approx. 5 seconds	Overheated hydraulic unit	Reduce activity.
–	3 x long	Battery 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.

Beep signal	Vibration signal	Event	Required action
10 x long	10 x long	Charge level 4% After the beep and vibration signals, the product switches to empty battery mode and then switches off.	Charge the battery.
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 immediately by an O&P professional.
-	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 immediately by an O&P professional.

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.

LED on power supply	LED on battery charger	Error	Resolution
●		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).	<p>Take note of the confirmation signal for differentiation.</p> <p>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.</p> <p>If no signal is emitted, the connection to the product is interrupted.</p> <p>If the connection to the product is interrupted, an authorised Ottobock Service Centre must inspect the product, battery charger and power supply.</p>

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 31).






15.2.3 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 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.

Error message	Cause	Correction
	A current connection to the component was interrupted	<p>Check the following points:</p> <ul style="list-style-type: none"> • Distance from the component to the device • Charge level of the component's battery • Bluetooth of the component switched on? (Switching Bluetooth of the component on/off) • Hold the component with the sole of the foot facing up to make the component "visible" for 2 minutes. • If multiple components were stored, was the correct component selected?

15.2.4 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	Event
1 x short	1 x short	Self-test completed successfully. Product is operational.
3 x short	–	<p>Maintenance note</p> <p>Conduct the self-test again by connecting/disconnecting the battery charger. If the beep signal sounds again, visit your O&P professional soon. If necessary, he or she will forward the product to an authorised Ottobock Service Center.</p> <p>The product can be used without restrictions. However, vibration signals may not be generated.</p>
–	–	Conduct the self-test again by connecting/disconnecting the battery charger. If no beep and/or vibration signal is emitted after connecting/disconnecting the battery charger again, the product must be inspected by the O&P professional.

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

15.3 Directives and manufacturer's declaration

15.3.1 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 12).

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

Phenomenon	EMC basic standard or test procedure	Interference immunity test level
Conducted interference induced by high-frequency fields	IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur frequency bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage drops	IEC 61000-4-11	0% U _T ; 1/2 period At 0, 45, 90, 135, 180, 225, 270 and 315 degrees
		0% U _T ; 1 period and 70% U _T ; 25/30 periods Single phase: at 0 degrees
Voltage interruptions	IEC 61000-4-11	0% U _T ; 250/300 periods

Interference resistance against wireless communication devices

Test frequency [MHz]	Frequency band [MHz]	Radio service	Modulation	Maximum power [W]	Distance [m]	Interference immunity test level [V/m]
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	1.8	0.3	28
710	704 to 787	LTE band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/90-0, TETRA 800, iDEN 820, CDMA 850, GSM 800/90-0, 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						

Test frequency [MHz]	Frequency band [MHz]	Radio service	Modulation	Maximum power [W]	Distance [m]	Interference immunity test level [V/m]
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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