



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

EN Instructions for use (qualified personnel)	5
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DE | INFORMATION

Zusätzlich zu der gedruckten Gebrauchsanweisung, sind auch weitere Sprachen auf CD beigelegt (siehe rückseitigen Umschlag). Auf Anfrage können Sie eine gedruckte Gebrauchsanweisung kostenlos in der jeweiligen Landessprache unter der unten angegebenen Anschrift bestellen.

EN | INFORMATION

In addition to the printed Instructions for Use, additional language versions are also included on CD (see back cover). You can order a printed version of the Instructions for Use at no charge in the respective national language at the address below.

FR | INFORMATION

Le mode d'emploi est disponible en d'autres langues sur CD en supplément de la version imprimée (voir au dos de la couverture). Vous pouvez commander gratuitement une version imprimée du mode d'emploi dans la langue de votre choix en envoyant votre demande à l'adresse indiquée ci-dessous.

ES | INFORMACIÓN

Aparte de las instrucciones de uso impresas, se incluye un CD con dichas instrucciones en otros idiomas (véase la solapa del dorso). Puede solicitar de forma gratuita unas instrucciones de uso impresas en el idioma de su país a la dirección que se indica más abajo.

IT | INFORMAZIONE

In aggiunta alle istruzioni per l'uso in formato cartaceo, il CD contiene le istruzioni anche in altre lingue (vedere il retro della copertina). Su richiesta, potete ordinare gratuitamente le istruzioni per l'uso in formato cartaceo nella relativa lingua del vostro Paese all'indirizzo di seguito riportato.

PT | INFORMAÇÃO

Adicionalmente ao manual de utilização impresso encontra-se incluído um CD com mais idiomas (consultar a contracapa). A pedido é possível encomendar gratuitamente um exemplar impresso do manual de utilização no respectivo idioma junto do endereço especificado.

NL | INFORMATIE

De gebruiksaanwijzing is behalve in gedrukte vorm ook in diverse andere talen bijgevoegd op cd (zie de achterzijde van de omslag). Een gedrukte gebruiksaanwijzing in de gewenste taal kunt u kosteloos bestellen op het hieronder vermelde adres.

SE | INFORMATION

Som komplement till den tryckta bruksanvisningen har dessutom ytterligare språk bifogats på CD (se baksidan av omslaget). Vid efterfrågan kan du utan kostnad beställa en tryckt bruksanvisning i det respektive språket under den angivna adressen.

DA | INFORMATION

Supplerende til brugsanvisningen på papir er der også vedlagt yderligere sprog på cd (se bagsiden af omslaget). På den oplyste adresse nedenfor kan du bestille en gratis brugsanvisning på papir på det pågældende sprog.

NO | INFORMASJOU

I tillegg til den trykte bruksanvisningen er flere språk vedlagt på CD (se på baksiden omslaget). Ved forespørsel kan du bestille en gratis trykt bruksanvisning i det gjeldende språket via adressen nedenfor.

FI | TIEDOT

Painetun käyttöohjeen lisäksi tarjoaa oheinen CD-levy käyttöön myös lisää kieliä (katso kansilehden takapuoli). Painettu käyttöohje kunkin maan omalla kielellä on pyynnöstä tilattavissa maksutta alla ilmoitetusta osoitteesta.

CZ | INFORMACE

Kromě této vytištěné verze návodu k použití jsou na přiloženém CD k dispozici také další jazykové verze překladu (viz zadní strana obalu). V případě požadavku si můžete na níže uvedené adrese zdarma objednat vytištěný návod k použití v příslušném jazyce.

PL | INFORMACJA

Dodatkowo do wydrukowanej instrukcji użytkownika dołączono na CD wersję w innych językach (patrz tył okładki). Na żądanie istnieje możliwość zamówienia bezpłatnie pod podanym poniżej adresem wydrukowanej instrukcji użytkownika w języku danego kraju.

SK | INFORMÁCIA

Dodatočne ku vytlačnému návodu na používanie sú na CD uložené aj ďalšie jazyky (pozri zadnú obálku). Na požiadanie si môžete bezplatne objednať vytlačený návod na používanie v príslušnom jazyku krajiny na dole uvedenej adrese.

HU | INFORMATION

A kinyomtatott használati utasítást kiegészíti a további nyelveket tartalmazó, mellékelt CD (ld. a hátlaapon lévő borítékot). Az alábbi címen, kérésre költségmentesen megrendelhet az adott ország nyelvén kinyomtatott használati utasítást.

HR | INFORMACIJA

Dodatno uz tiskane upute za uporabu priloženi su i drugi jezici na CD-u (vidi poledinu). Na upit možete na dolje navedenoj adresi besplatno naručiti tiskane upute za uporabu na dotičnom jeziku.

TR | INFORMATION

Basılmış olan kullanım kılavuzuna ilave olarak CD'de daha fazla alternatif diller bulunmaktadır (bakınız zarfın arka yüzü). İstek üzerine ilgili dilde basılmış kullanım kılavuzunu aşağıda belirtilmiş olan adresten temin edebilirsiniz.

RU | ИНФОРМАЦИЯ

Дополнительно к руководству по применению в печатном виде на приложенном диске представлены также руководства на других языках (смотри обратную сторону обложки). Вы можете бесплатно заказать печатную версию руководства по применению на соответствующем языке по указанному ниже адресу.

JA | 備考

冊子版取扱説明書とCDには他言語版もございます(裏表紙を参照)。
下記までご連絡いただければ、各国の言語による冊子版取扱説明書を無料で送付いたします。

ZH | 信息

除了该使用说明书印刷件之外，CD中还附有其它语言的版本（参见封底）。
如有需要，您可以按照下列地址免费索取您所在国家语言的印刷版使用说明书。

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Table of contents

EN

1	Foreword	7
2	Product description	7
2.1	Design	7
2.2	Function	7
2.3	Combination possibilities	8
2.3.1	Combination with an osseointegrated implant system	8
3	Application	9
3.1	Indications for use	9
3.2	Conditions of use	9
3.3	Indications	9
3.4	Qualification	9
4	Safety	10
4.1	Explanation of warning symbols	10
4.2	Structure of the safety instructions	10
4.3	General safety instructions	10
4.4	Information on the Power Supply/Battery Charging	12
4.5	Battery charger information	12
4.6	Information on Alignment/Adjustment	13
4.7	Information on Proximity to Certain Areas	14
4.8	Information on Use	15
4.9	Notes on the safety modes	16
4.10	Instructions for use with an osseointegrated implant system	17
4.11	Information on the use of a mobile device with the cockpit app	17
5	Scope of Delivery and Accessories	18
6	Charging the battery	18
6.1	Connecting the power supply and battery charger	19
6.2	Charging the prosthesis battery	19
6.3	Display of the current charge level	19
6.3.1	Display of battery charge level without additional devices	20
6.3.2	Display of the current charge level using the Cockpit app	20
7	Preparation for use	20
7.1	Alignment	20
7.1.1	Shortening the Tube Adapter	20
7.1.2	Installing the Tube Adapter	21
7.1.3	Bench alignment in alignment apparatus	21
7.1.4	Installing/removing the knee extender	22
7.1.5	Checking the socket after bench alignment	23
7.1.6	Static alignment optimisation	23
7.1.7	Dynamic alignment optimisation	24
7.1.8	Flexion stop	24
7.2	Optional: Installing the foam cover	25
8	Cockpit app	25
8.1	System Requirements	25
8.2	Initial connection between cockpit app and prosthesis	25
8.2.1	Starting the cockpit app for the first time	26
8.3	Control elements for cockpit app	26
8.3.1	Cockpit app navigation menu	27
8.4	Managing components	27
8.4.1	Adding component	27
8.4.2	Deleting a component	28
8.4.3	Connecting component with multiple devices	28

9	Use	28
9.1	Movement patterns in basic mode (mode 1)	28
9.1.1	Standing	28
9.1.1.1	Stance function.....	28
9.1.2	Walking	29
9.1.3	Sitting down	29
9.1.4	Sitting.....	29
9.1.4.1	Sitting function	30
9.1.5	Standing up	30
9.1.6	Walking up stairs	30
9.1.7	Walking down stairs	30
9.1.8	Walking down a ramp.....	31
9.1.9	Walking down flat steps.....	31
9.1.10	Kneeling	31
9.2	Changing prosthesis settings	31
9.2.1	Changing the prosthesis setting using the cockpit app	32
9.2.2	Overview of adjustment parameters in basic mode	32
9.2.3	Overview of adjustment parameters in MyModes.....	32
9.3	Switching off the product	33
9.4	Turning Bluetooth on the prosthesis on/off	33
9.4.1	Switching Bluetooth off/on using the cockpit app.....	33
9.5	Querying the prosthesis status.....	34
9.5.1	Query status through cockpit app	34
9.5.2	Status display in the cockpit app.....	34
10	MyModes	34
10.1	Switching MyModes with the cockpit app	34
10.2	Switching MyModes using motion patterns	35
10.3	Switching from a MyMode back to basic mode	35
11	Additional operating states (modes)	36
11.1	Empty battery mode.....	36
11.2	Mode for charging the prosthesis.....	36
11.3	Safety mode	36
11.4	Overheating mode.....	36
12	Storage and bleeding	37
13	Cleaning	37
14	Maintenance	37
14.1	Identification of the product by the Service Center	37
15	Legal information	37
15.1	Liability	37
15.2	Trademarks	38
15.3	CE conformity.....	38
15.4	Local Legal Information	38
16	Technical data	39
17	Appendices	41
17.1	Symbols Used	41
17.2	Operating states/error signals	42
17.2.1	Signals for operating states	42
17.2.2	Warnings/error signals	42
17.2.3	Error messages while establishing a connection with the cockpit app.....	44
17.2.4	Status signals.....	44
17.3	Directives and manufacturer's declaration	45
17.3.1	Electromagnetic environment.....	45

1 Foreword

INFORMATION

Date of last update: 2018-03-19

- ▶ Please read this document carefully before using the product.
- ▶ Instruct the user in the proper and safe use of the product.
- ▶ Please contact the manufacturer if you have questions about the product (e.g. regarding the start-up, use, maintenance, unexpected operating behaviour or circumstances). Contact information can be found on the back page.
- ▶ Please keep this document in a safe place.

The product "C-Leg" is called the product/prosthesis/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. Proximal pyramid adapter
2. LED (blue) as indicator for the Bluetooth connection
3. Flexion stops 8° (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. cycling ...). These are pre-configured using the adjustment software and can be activated with special movement patterns and the Cockpit app (see Page 34).

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 36).

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 36).

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

2.3 Combination possibilities

This product can be combined with the following Ottobock components:

Adapters

- 4R104=60 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
- 4R104=75 double adapter, sliding
- 4R43 lamination anchor with threaded connector
- 4R111=N lamination anchor with threaded connector
- 4R40 torsion adapter
- 4R118 adapter plate

Tube adapter

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

Cosmetic cover/protector

- Foam cover: 3S26
- 4X860=* C-Leg Protective Cover (w/o shield)

Prosthetic feet

The maximum allowable patient weight depends on the foot size.

- 1D10 Dynamic foot
- 1D11 Dynamic foot (women)
- 1M10 Adjust
- 1C10 Terion
- Terion K2: 1C11
- 1A30 Greissinger plus
- 1C30 Trias
- 1D35 Dynamic Motion
- 1C40 C-Walk
- Meridium: 1B1-2
- 1C66 Triton smart ankle
- 1C60 Triton
- 1C61 Triton Vertical Shock
- 1C62 Triton Harmony
- 1C63 Triton Low Profile
- 1C64 Triton Heavy Duty
- 1E56 Axtion
- 1E57 Lo Rider
- 1B1 Meridium

Depending on the patient's weight, **this knee joint may be combined with the prosthetic feet from the Triton range (1C60 through 1C66) and the 1B1 Meridium and 1B1-2 Meridium prosthetic feet** in the following foot sizes only (see table).

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

Body weight	Approved foot size [cm]
up to 100 kg (up to 220 lbs)	21 to 30 (24 to 29 with 1B1, 1B1-2)
101 kg to 125 kg (221 lbs to 275 lbs) (not permitted for 1B1 and 1B1-2)	up to 28 (up to 26 for 1C63 and 1C66)
126 kg to 136 kg (276 lbs to 300 lbs) (not permitted for 1C63, 1C66)	up to 26

2.3.1 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 39).

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 Application

3.1 Indications for use

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

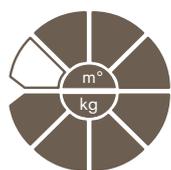
3.2 Conditions of use

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 39).

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

Our components perform optimally when paired with appropriate components based upon weight and mobility grades identifiable by our MOBIS classification information and which have appropriate modular connectors.



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 and 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.

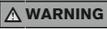
3.4 Qualification

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

 CAUTION
<p>The heading describes the source and/or the type of hazard</p> <p>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:</p> <ul style="list-style-type: none"> > E.g.: Consequence 1 in case of failure to observe the hazard > E.g.: Consequence 2 in case of failure to observe the hazard ▶ This symbol identifies activities/actions that must be observed/carried out in order to avert the hazard.

4.3 General safety instructions

 WARNING
<p>Non-observance of safety notices</p> <p>Personal injury/damage to the product due to using the product in certain situations.</p> <ul style="list-style-type: none"> ▶ Observe the safety notices and the stated precautions in this accompanying document.

 WARNING
<p>Use of damaged power supply unit, adapter plug or battery charger</p> <p>Risk of electric shock due to contact with exposed, live components.</p> <ul style="list-style-type: none"> ▶ 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
<p>Failure to observe warning/error signals</p> <p>Falling due to unexpected product behaviour because of changed damping behaviour.</p> <ul style="list-style-type: none"> ▶ The warnings/error signals (see Page 42) and corresponding change in damping settings must be observed.

 CAUTION
<p>Independent user manipulation of system components</p> <p>Falling due to breakage of load-bearing components or malfunction of the product.</p> <ul style="list-style-type: none"> ▶ Manipulations to the product other than the tasks described in these instructions for use are not permitted. ▶ The battery may only be handled by Ottobock authorised, qualified personnel (no replacement by the user). ▶ The product and any damaged components may only be opened and repaired by authorised, qualified Ottobock personnel.

 CAUTION
<p>Mechanical stress on the product</p> <ul style="list-style-type: none"> > Falling due to unexpected product behaviour as the result of a malfunction. > Falling due to breakage of load-bearing components. > Skin irritation due to defects on the hydraulic unit with leakage of liquid. ▶ Do not subject the product to mechanical vibrations or impacts. ▶ Check the product for visible damage before each use.

⚠ CAUTION**Use of the product when battery charge level is too low**

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

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

⚠ CAUTION**Risk of pinching in the joint flexion area**

Injuries due to pinching of body parts.

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

⚠ CAUTION**Penetration of dirt and humidity into the product**

> Falling due to unexpected product behaviour as the result of a malfunction.

> Falling due to breakage of load-bearing components.

- ▶ Ensure that no solid particles or foreign objects can penetrate into the product.
- ▶ The knee joint is weather-proof but not resistant to corrosion. Therefore, the knee joint should not come into contact with salt water, chlorinated water or other solutions (such as soap or shower gel, and body and/or wound fluids). Do not use the knee joint under extreme conditions like diving or jumping into water. The knee joint is not designed for prolonged underwater use or prolonged submersion.
- ▶ After contact with 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 knee joint and tube adapter. Dry the knee joint and components with a lint-free cloth and allow the components to fully air dry.
- ▶ Should the knee joint or tube adapter come into contact with **salt water, chlorinated water or other solutions** (such as soap or shower gel, and body and/or wound fluids), **promptly** remove the Protective Cover (if installed) and clean the **knee joint**. In order to do so, rinse knee joint, tube adapter and Protective Cover with fresh water and let them dry.
- ▶ In case of a malfunction after drying, the knee joint and tube adapter must be inspected by an authorised Ottobock Service Center.
- ▶ The knee joint is not resistant to penetration from water jets 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 to the product components**

Falling due to damage or malfunction of the product.

- ▶ In the interest of the patient's safety and in order to maintain operating reliability, the product must be serviced at regular intervals.

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).

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.

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 damaged power supply unit/charger/charger cable

- Falling due to unexpected behaviour of the product caused by insufficient charging.
- ▶ Check the power supply unit, charger and charger cable for damage before use.
 - ▶ Replace any damaged power supply unit, charger or charger cable.

NOTICE

Use of incorrect power supply unit/battery charger

- Damage to product due to incorrect voltage, current or polarity.
- ▶ Use only power supply units/battery chargers approved for this product by Ottobock (see instructions for use and catalogues).

4.5 Battery charger information

NOTICE

Penetration of dirt and humidity into the product

- Lack of proper charging functionality due to malfunction.
- ▶ Ensure that neither solid particles nor liquids can penetrate into the product.

NOTICE

Mechanical stress on the power supply/battery charger

- Lack of proper charging functionality due to malfunction.
- ▶ Do not subject the power supply/battery charger to mechanical vibrations or impacts.
 - ▶ Check the power supply/battery charger for visible damage before each use.

NOTICE

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

- Lack of proper charging functionality due to malfunction.
- ▶ Only use the power supply unit/charger for charging within the allowable temperature range. The section "Technical data" contains information on the allowable temperature range (see Page 39).

NOTICE

Independent changes or modifications carried out to the battery charger

- Lack of proper charging functionality due to malfunction.
- ▶ Have any changes or modifications carried out only by Ottobock authorised, qualified personnel.

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 8).
- ▶ 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 39).
- ▶ 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 (1/5") between the electronics/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) still occurs, contact Ottobock Customer Service.

⚠ 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 during the adjustment process with the adjustment software

Falling due to unexpected prosthesis behaviour.

- ▶ Do not charge the prosthesis battery during the configuration process since the prosthesis is not functional while the battery is being charged.
- ▶ The prosthesis must not remain unattended during the configuration process while connected to the adjustment software and being worn by the patient.
- ▶ Observe the maximum range of the Bluetooth connection and take note that obstacles may limit this range.
- ▶ During the data transfer (PC to prosthesis) the prosthesis wearer should sit still or stand securely, and the BionicLink PC must not be removed from the computer.
- ▶ If only temporary changes to the settings are to be made while connected to the adjustment software, these changes must be reversed before the adjustment software is closed.
It must also be ensured that the patient does not leave the range of the Bluetooth connection with settings that have been changed temporarily.
- ▶ Inform the patient immediately if the data connection is accidentally interrupted during the configuration process.
- ▶ The connection to the prosthesis must always be disconnected after adjustments have been completed.
- ▶ Participation in an Ottobock product training course is mandatory prior to the initial use of the product. Additional product training courses may be required to qualify for software updates.
- ▶ Correctly entering the foot size, the prosthesis dimensions and the body weight are important criteria for the quality of the 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, readjustment is required as soon as the patient stops using these walking aids.
- ▶ Use the online help which is integrated into the software.
- ▶ Do not pass on 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

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).

⚠ 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 39) 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 42).
- ▶ 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 28.

⚠ 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 34).

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 42) 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 42) 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.

4.11 Information on the use of a mobile device with the cockpit app**⚠ CAUTION****Improper use of the device**

Falling due to altered damping behaviour as a result of unexpected switching into MyMode.

- ▶ Use the instructions for use (user) to instruct the patient on proper use of the device with the cockpit app.

⚠ CAUTION**Independently applied changes or modifications made to the device**

Falling due to altered damping behaviour as a result of unexpected switching into MyMode.

- ▶ Do not make any independent changes to the hardware of the device.
- ▶ Do not make any independent changes to the software/firmware of the device which are not included in the update function of the software/firmware.

⚠ CAUTION**Improper mode switching with the device**

Falling due to unexpected product behaviour 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 and the device display must be observed.
- ▶ Switching back to basic mode is mandatory once the activities in MyMode have been completed.

NOTICE**Destruction of the device due to falling or penetration of water**

Malfunction of the device.

- ▶ Note the instructions for use for the device.
- ▶ If it should no longer be possible to switch back from a MyMode to basic mode, the component can only be switched back to basic mode by using a movement pattern (see Page 35) or by connecting/disconnecting the inductive battery charger.

NOTICE

Failure to observe the system requirements for the installation of the cockpit app

Malfunction of the device.

- ▶ Install the cockpit app only on the operating systems listed in the section "System requirements" (see Page 25).

INFORMATION

The illustrations in these instructions for use are only examples and may deviate from the respective mobile device being used and the version.

5 Scope of Delivery and Accessories

Scope of Delivery

- 1 pc. 3C88-3 C-Leg knee joint (with threaded connector) or
- 1 pc. 3C98-3 C-Leg (with pyramid adapter)
- 1 pc. 2R57 titanium tube adapter short, Ø 34 mm, or
- 1 pc. 2R67 tube adapter with torsion unit, Ø 34 mm
- 1 pc. 757L16* 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. card holder for prosthesis passport
- 1 pc. 647F542 prosthesis passport
- 1 pc. 647G1375 Instructions for use (qualified personnel)
- 1 pc. 647H569, 647H569=1 instructions for use (user)

Cockpit app for download from the website: <http://www.ottobock.com/cockpitapp>

- iOS app "Cockpit 4X441- IOS=V*"
- Android app "Cockpit 4X441-Andr=V*"

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 21)
- 4H106 16° C-Leg flexion stop
- 3S26 cosmetic foam cover
- 4P862 C-Leg guard
- 4X860=* C-Leg Protective Cover (w/o shield)
- 4P863* Shield Insert
- 4X156 Charger Extension Cable – Ankle
- 4X158 charger extension cable – ankle, long
- 4X157 Charger Extension Cable – Knee
- "4X440=* C-Soft Plus" adjustment software

6 Charging the battery

The following points must be observed when charging 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.
- When used daily, the complete charging unit (power supply – battery charger) may remain plugged into the wall socket.
- 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.
- Use the 757L16* power supply and 4E50* battery charger to charge the battery.
- 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 42).

6.2 Charging the prosthesis battery



- 1) Open the charging receptacle cover.
- 2) Connect the charging plug to the charging receptacle of the product.
INFORMATION: Take note of the plug direction!
→ The correct connection of the battery charger to the product is indicated by feedback (see Page 42).
- 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.
→ A self-test is performed. The product is operational only after corresponding feedback (see Page 44).
- 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
 If the **Volume** parameter is set to '0' in the Cockpit app, there are no beep signals (see Page 31).

6.3.2 Display of the current charge level using the Cockpit app

Once the Cockpit app has been started, the current charge level is displayed in the bottom line of the screen:



1. 38% – Charge level of battery for currently connected component

7 Preparation 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 21).

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 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 cutting surface with a deburring knife (e.g. 718S2) and sandpaper.
NOTICE! In case of raised material at the outer edge due to shortening the tube adapter, smoothing this by machine is mandatory. Carefully deburr the inside.

7.1.2 Installing the Tube Adapter

⚠ CAUTION

Improper assembly of the screw connections

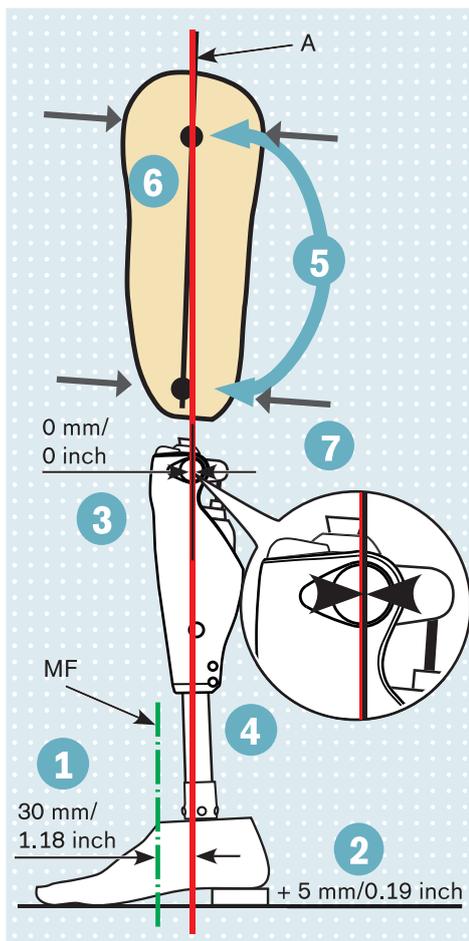
Falling due to breakage or loosening of the screw connections.

- ▶ Clean the threads before every installation.
- ▶ Apply the specified tightening torque values for installation (see the section "Technical data" see Page 39).
- ▶ 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 adapter to a torque of 15 Nm**.
INFORMATION: Replace any set screws that are protruding or recessed too much with suitable ones. For approved set screws, see the section "Technical data" (see Page 39).
- 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 slightly tighten the two **distal tube clamp screws (approx. 4 Nm)**.
INFORMATION: After the fitting, all screws have to be tightened alternately in several steps, increasing the tightening torque slowly until the prescribed tightening torque is reached; see the section "Technical data" (see Page 39).

7.1.3 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 Place the alignment reference point (=knee axis) approx. 0-5 mm/0-0.19 inch anterior to the alignment reference line. Take into account the knee-ground distance and outward rotation of the knee (the adapter insert provides for a rotation of approx. 5°). Recommended sagittal positioning of the alignment reference point: 20 mm/0.79 inch above the medial tibial plateau.
- 4 Connect the foot and knee joint using a tube adapter. To do so, tilt the joint in the correct position and set the required tube length.
- 5 Mark the lateral centre of the socket with a centred, proximal dot and a centred, distal dot. Mark a line through both dots from the socket brim to the end of the socket. Use the 4H105 knee extender (see Page 22).
- 6 Now position the socket such that the alignment reference line passes through the proximal centre 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.

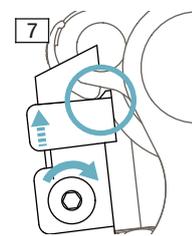
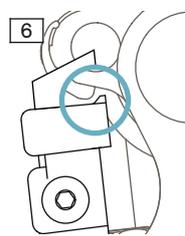
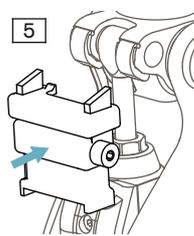
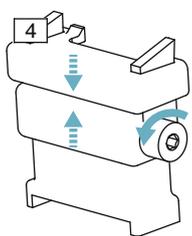
7.1.4 Installing/removing the knee extender

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.



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 24).
- 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.

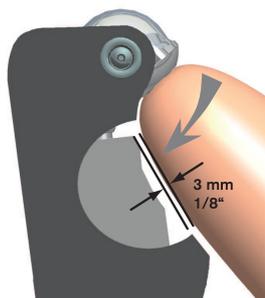
7.1.5 Checking the socket after bench alignment

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

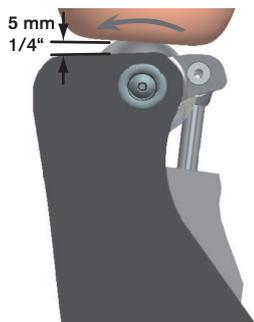


If the distance between the socket and hydraulics is not sufficient, the hydraulics may be damaged. Check the distance as follows:

- 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.

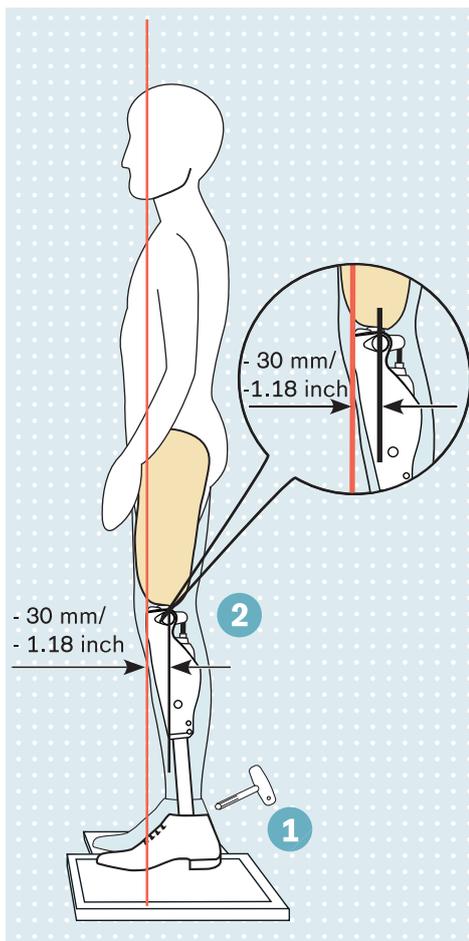
INFORMATION: If the knee extender is used to verify the distance, note that this is only permissible if the 8° flexion stops are installed.

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.

7.1.6 Static alignment optimisation

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



- 1 To determine the load line, have the patient (with shoes) stand on the force measurement plate with the prosthesis side and on the height compensation plate with the other leg. The prosthesis side must be sufficiently loaded (> 35% body weight). Note the weight display on the L.A.S.A.R. Posture.
- 2 Optimise the alignment solely by changing the plantar flexion. Only make adjustments to the distal and proximal set screws of the socket adapter on the prosthetic foot, so that the load line (laser line) runs approx. 30 mm/1.18 inch in front of the alignment reference point (= knee axis) of the knee joint.

7.1.7 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.

7.1.8 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 23).



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 Charger Extension Cable – Ankle
- 4X158 charger extension cable – ankle, long
- 4X157 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 Cockpit app



The cockpit app enables switching from basic mode into the pre-configured MyModes. In addition, information about the product (step counter, battery charge level, etc.) can be called up.

The behaviour of the product can be changed to a certain extent on a day-to-day basis using the app (e.g. while becoming accustomed to the product). The adjustment software can be used to trace the change at the patient's next appointment.

INFORMATION

The Cockpit app can be downloaded free of charge from the respective online store. For more information, please visit the website: <http://www.ottobock.com/cockpitapp>. To download the Cockpit app, the QR code on the supplied Bluetooth PIN card can be read with the mobile device (requirement: QR code reader and camera).

INFORMATION

The language of the Cockpit app user interface can only be changed using the adjustment software.

INFORMATION

The serial number of the component to be connected has to be registered with Ottobock the first time it is connected. If the registration is not accepted, use of the Cockpit app for this component will be limited.

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 (sole of the foot must point up) or by connecting/disconnecting the battery charger. Bluetooth is then turned on for approx. 2 minutes. During this time, the app must be started and used to establish a connection. If required, Bluetooth on the prosthesis can be switched on permanently afterwards (see Page 33).

8.1 System Requirements

The functioning of the Cockpit app is assured on devices that support the following operating systems:

- **iOS (for iPhone, iPad, iPod):** version 9.3 or higher. The mobile device has to support Bluetooth 4.0 (BT LE).
- **Android:** version 4.0.3 or higher

8.2 Initial connection between cockpit app and prosthesis

The following points should be observed before the initial connection:

- Bluetooth of the component must be switched on (see Page 33).
- Bluetooth of the device must be switched on.
- The device must not be in "flight mode" (offline mode), otherwise all wireless connections are turned off.
- **The device must be connected to the internet.**
- The serial number and Bluetooth PIN of the component being connected must be known. They are found on the enclosed Bluetooth PIN card. The serial number begins with the letters "SN".

INFORMATION

If the Bluetooth PIN card with the Bluetooth PIN and serial number of the component is lost, the Bluetooth PIN can be determined using the adjustment software.

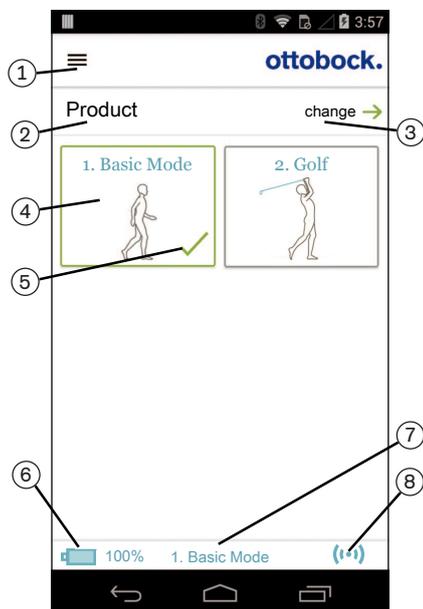
8.2.1 Starting the cockpit app for the first time

- 1) Tap the symbol of the Cockpit app ().
 - The end user license agreement (EULA) is displayed.
 - 2) Accept the end user license agreement (EULA) by tapping the **Accept** button. If the end user license agreement (EULA) is not accepted, the Cockpit app cannot be used.
 - The welcome screen appears.
 - 3) Hold the prosthesis with the sole of the foot facing up, or connect and then disconnect the battery charger, in order to activate recognition (visibility) of the Bluetooth connection for 2 minutes.
 - 4) Tap the **Add component** button.
 - The Connection Wizard opens and guides you through the process of establishing a connection.
 - 5) Follow the subsequent instructions on the screen.
 - 6) After the Bluetooth PIN is entered, a connection to the component is established.
 - While the connection is being established, 3 beep signals sound and the  symbol appears.
 - The  symbol is displayed when the connection has been established.
- Once the connection has been established, the data are read from the component. This process may take up to a minute.
Then the main menu appears with the name of the connected component.

INFORMATION
After the initial connection to the component has been established successfully, the app will connect automatically each time it is started. No further steps are required.

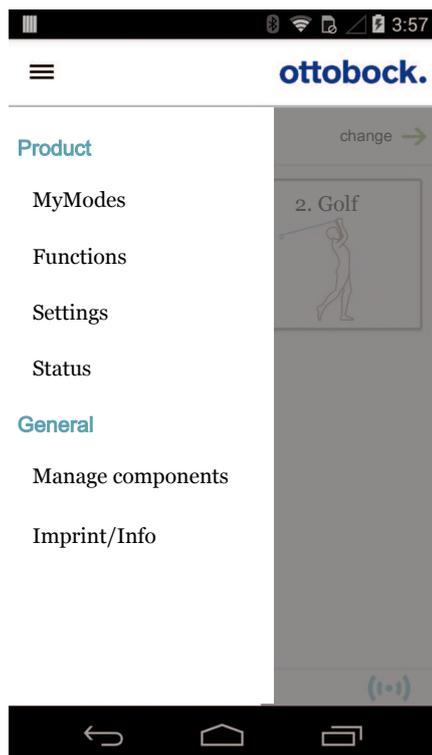
INFORMATION
After activating the "visibility" of the component (holding the component with the sole of the foot facing up, or connecting and then disconnecting the battery charger), the component can be recognised by another device (e.g. smartphone) within 2 minutes. If registration or establishing the connection takes too long, the process of establishing a connection is cancelled. In this case, hold the component with the sole of the foot facing up again, or connect and then disconnect the battery charger.

8.3 Control elements for cockpit app



1.  Call up the navigation menu (see Page 27)
2. Product
The component name can only be changed with the adjustment software.
3. If connections to more than one component have been saved, you can switch between the saved components by tapping the entry **change** (see Page 27).
4. MyModes configured with the adjustment software.
Switching the mode by tapping the corresponding symbol and confirming by tapping "**OK**".
5. Currently selected mode
6. Charge level of the component.
 -  Component battery fully charged
 -  Component battery empty
 -  Component battery is being charged
 The current charge level is also displayed in %.
7. Display and name of the currently selected mode (e.g. **1. Basic Mode**)
8.  Connection to component has been established
 Connection to component has been interrupted. The app is attempting to re-establish the connection automatically.

8.3.1 Cockpit app navigation menu



Tap the ☰ symbol in the menus to display the navigation menu. Additional settings for the connected component can be configured in this menu.

Product

Name of the connected component

MyModes

Return to the main menu to switch MyModes

Functions

Call up additional functions of the component (e.g. turn off Bluetooth) (see Page 33)

Settings

Change settings of the currently selected mode (see Page 31)

Status

Query status of the connected component (see Page 34)

Manage components

Add or delete components (see Page 27)

Imprint/Info

Display information/legal notices for the cockpit app

8.4 Managing components

Connections with up to four different components can be stored in the app. However, a component can only be connected to one device at a time.

The following points need to be observed before establishing the connection:

- Bluetooth of the component must be switched on (see Page 33).
- Bluetooth of the device must be switched on.
- The device must not be in "flight mode" (offline mode), otherwise all wireless connections are turned off.
- **The device must be connected to the internet.**
- The serial number and Bluetooth PIN of the component being connected must be known. They are found on the enclosed Bluetooth PIN card. The serial number begins with the letters "SN".

INFORMATION

If the Bluetooth PIN card with the Bluetooth PIN and serial number of the component is lost, the Bluetooth PIN can be determined using the adjustment software.

8.4.1 Adding component

- 1) Tap the ☰ symbol in the main menu.
→ The navigation menu opens.
- 2) In the navigation menu, tap the entry "**Manage components**".
- 3) Hold the prosthesis with the sole of the foot facing up, or connect and then disconnect the battery charger, in order to activate recognition (visibility) of the Bluetooth connection for 2 minutes.
- 4) Tap the **Add component** button.
→ The Connection Wizard opens and guides you through the process of establishing a connection.
- 5) Follow the subsequent instructions on the screen.
- 6) After the Bluetooth PIN is entered, a connection to the component is established.
→ While the connection is being established, 3 beep signals sound and the (📶) symbol appears.
The (📶) symbol is displayed when the connection has been established.
→ Once the connection has been established, the data are read from the component. This process may take up to a minute.
Then the main menu appears with the name of the connected component.

INFORMATION

If establishing a connection to a component is not possible, perform the following steps:

- ▶ Delete the component from the Cockpit app if applicable (see the section "Deleting a component")
- ▶ Add the component again in the Cockpit app (see the section "Adding a component")

INFORMATION

After activating the "visibility" of the component (holding the component with the sole of the foot facing up, or connecting and then disconnecting the battery charger), the component can be recognised by another device (e.g. smartphone) within 2 minutes. If registration or establishing the connection takes too long, the process of establishing a connection is cancelled. In this case, hold the component with the sole of the foot facing up again, or connect and then disconnect the battery charger.

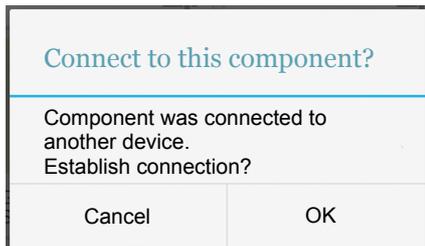
8.4.2 Deleting a component

- 1) Tap the ☰ symbol in the main menu.
→ The navigation menu opens.
- 2) In the navigation menu, tap the entry "**Manage components**".
- 3) Tap the "**Edit**" button.
- 4) Tap the 🗑️ symbol under the component you want to delete.
→ The component is deleted.

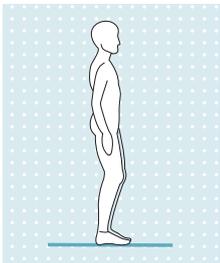
8.4.3 Connecting component with multiple devices

The connection for a component can be stored on more than one device. However, only one device can be connected to the component at one time.

If there is an existing connection between the component and a different device, the following information appears while the connection is being established with the current device:



- ▶ Tap the **OK** button.
→ The connection to the last connected device is broken off and established with the current device.

9 Use**9.1 Movement patterns in basic mode (mode 1)****9.1.1 Standing**

Knee control through high hydraulic resistance and static alignment.

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

9.1.1.1 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 (see Page 32).

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, it is also possible to choose between an intuitive and a manual 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).

The stance function can also be set manually to any flexion angle between 5° und 65° (see the next section).

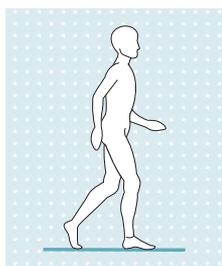
Manual joint lock

- 1) Flex the joint between 5° and 65° and keep it still for one second.
 - 2) Slowly extend the joint up to the desired standing angle.
 - 3) In this position, keep the joint still for one second until it vibrates.
- The blocked joint can now be fully loaded in the flexion direction.

Releasing the manual joint lock

- ▶ Quickly extend the joint or tilt the thigh slightly forward or more than 50° back.

9.1.2 Walking

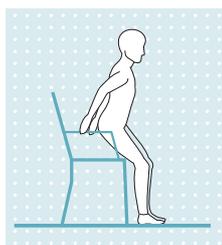


Initial attempts at walking with the prosthesis always require the instruction of trained, qualified personnel.

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.

9.1.3 Sitting down



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

- 1) Place both feet side by side at the same level.
- 2) While sitting down, distribute weight evenly between both legs and use armrests, if available.
- 3) Move the buttocks in the direction of the backrest and lean the upper body forward.

9.1.4 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.

9.1.4.1 Sitting function

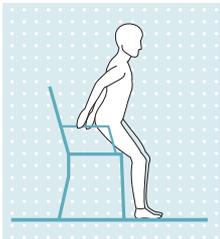
INFORMATION

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 32).

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.

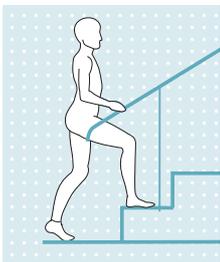
9.1.5 Standing up

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.

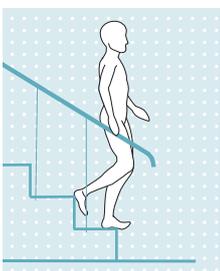
9.1.6 Walking up stairs



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.

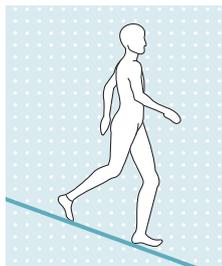
9.1.7 Walking down stairs



This function must be practised and executed consciously. Only when the sole is properly positioned can the system react correctly and permit controlled flexion.

- 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 assure a secure rollover.
- 3) Roll the foot over the edge of the step.
→ This flexes the prosthesis slowly and evenly in the knee joint.
- 4) Place the foot of the other leg onto the next step.
- 5) Place the foot of the prosthetic leg on the next step after that.

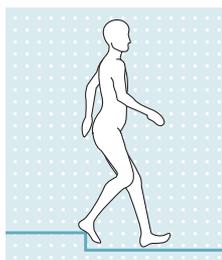
9.1.8 Walking down a ramp



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.

9.1.9 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.

9.1.10 Kneeling



Under increased flexion resistance, permit controlled flexion of the 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 protector is recommended for kneeling frequently.

9.2 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

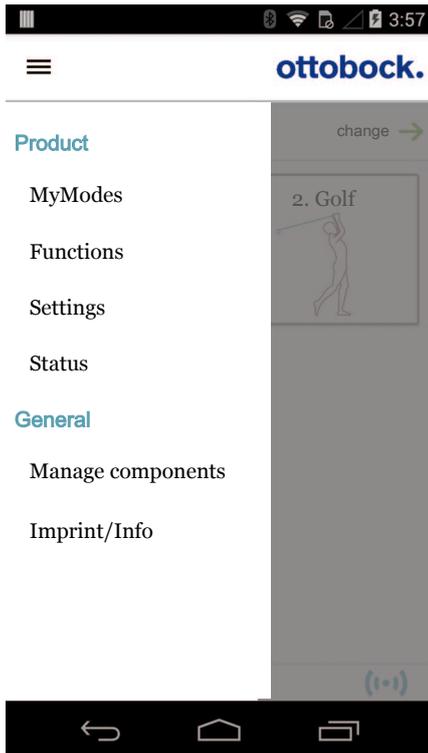
Bluetooth on the prosthesis must be switched on to change the prosthesis settings.

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 located 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 trace 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.

9.2.1 Changing the prosthesis setting using the cockpit app



- 1) Once the component is connected and in the desired mode, tap the ☰ symbol in the main menu.
→ The navigation menu opens.
- 2) Tap the menu entry "**Settings**".
→ A list appears with the parameters for the currently selected mode.
- 3) Change the setting of the desired parameter by tapping the "<", ">" symbols.

INFORMATION: The prosthetist's setting is marked and, after the setting has been changed, can be restored by tapping the "Standard" button.

9.2.2 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 28). Further information on the sitting function (see Page 29).

The following parameters can be modified:

Parameter	Adjustment software range	Setting range, app	Meaning
Resistance	120 to 180	+/- 10 of the configured value	Resistance against flexion e.g. when walking down stairs or when sitting down
Stance function		0/Off - deactivated 1/On - activated	Activation/deactivation of the stance function. This function needs to be enabled in the adjustment software.
Sitting function		0/Off - deactivated 1/On - activated	Activation/deactivation of the sitting function. This function needs to be enabled in the adjustment software.
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.

9.2.3 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
Gain	0 to 100	+/- 10	Value for speed at which flexion resistance increases as the knee angle increases
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.

9.3 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 42 and see Page 44).

9.4 Turning Bluetooth on the prosthesis on/off

INFORMATION

Bluetooth on the prosthesis must be turned on in order to use the Cockpit app.

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

9.4.1 Switching Bluetooth off/on using the cockpit app

Switching off Bluetooth

- 1) When the component is connected, tap the ☰ symbol in the main menu.
 - The navigation menu opens.
- 2) In the navigation menu, tap the entry "**Functions**".
- 3) Tap the entry "**Deactivate Bluetooth**".
- 4) Follow the on-screen instructions.

Switching on Bluetooth

- 1) Rotate the component or connect/disconnect the battery charger.
 - Bluetooth is switched on for approx. 2 minutes. During this time, the app must be started in order to establish a connection to the component.
- 2) Follow the on-screen instructions.
 - If Bluetooth is switched on, the  symbol appears on the screen.

9.5 Querying the prosthesis status

9.5.1 Query status through cockpit app

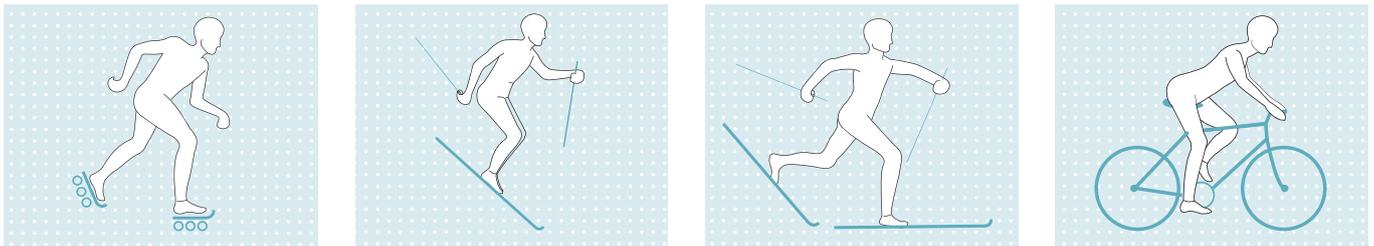
- 1) When the component is connected, tap the  symbol in the main menu.
- 2) In the navigation menu, tap the entry "**Status**".

9.5.2 Status display in the cockpit app

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

10 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 32).

10.1 Switching MyModes with the cockpit app

INFORMATION

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

INFORMATION

If the **Volume** parameter is set to '0' in the Cockpit app, there are no beep signals (see Page 31).

Once a connection to a prosthesis has been established, the cockpit app can be used to switch between the MyModes.



- 1) Tap the symbol of the MyMode (1) you want in the main menu of the app.
 - A security question for changing the MyMode appears.
- 2) If you want to change the mode, tap the "OK" button.
 - A beep signal sounds to confirm the switch.
- 3) After switching, a symbol (2) is displayed to identify the active mode.
 - The current mode is also indicated by the name on the lower edge of the screen (3).

10.2 Switching MyModes using motion patterns

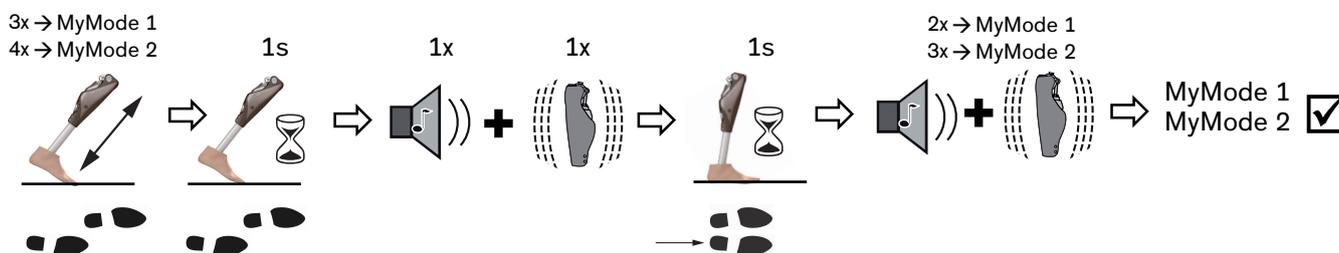
INFORMATION

If the **Volume** parameter is set to '0' in the Cockpit app, there are no beep signals (see Page 31).

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.

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.

10.3 Switching from a MyMode back to basic mode

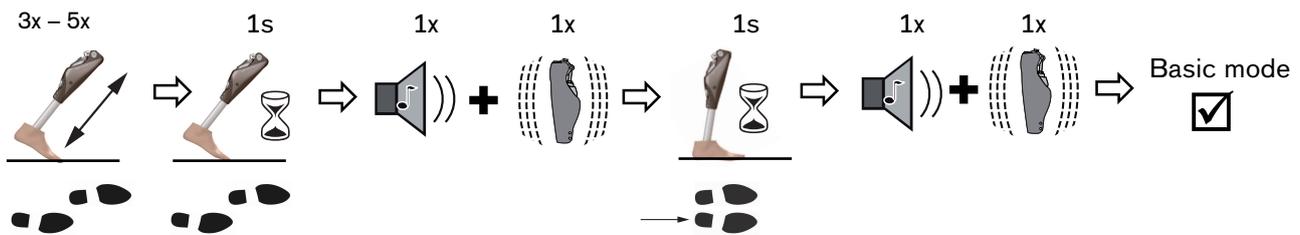
Information on switching

- 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.

Switching process

INFORMATION

If the **Volume** parameter is set to '0' in the Cockpit app, there are no beep signals (see Page 31).



- 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.**

11 Additional operating states (modes)

11.1 Empty battery mode

Beeps and vibration signals are emitted if the available battery charge level is 0% (see Page 42). 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.

11.2 Mode for charging the prosthesis

The product is non-functional during charging.

The product is set to safety mode damping. This may be low or high depending on the setting in the adjustment software.

11.3 Safety mode

The product automatically switches to safety mode if a critical system 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 system is not active.

The switch to safety mode is indicated by beeps and vibration signals immediately prior to switching (see Page 42).

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.

11.4 Overheating mode

When the hydraulic unit overheats due to uninterrupted, increased activity (e.g. extended walking downhill), damping 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 damping settings that existed before the 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

12 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

- When storing the knee joint, press the top of the knee to the flexion stop.
- Avoid extended disuse of the product (use the product regularly).

13 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.

14 Maintenance

INFORMATION

This component was tested for three million load cycles in accordance with ISO 10328.

Depending on the activity level, this corresponds to a service life of three to five years.

The duration of use can be individually extended depending on the intensity of use by performing regular service inspections.

Regular service inspections (maintenance) are mandatory in the interest of the patient's safety and in order to maintain operating reliability and protect the warranty. These service inspections include an inspection of the sensors and replacement of wear and tear parts.

If maintenance is due, this is indicated after the service interval has expired by three brief beep signals after disconnecting the battery charger. Further information is available upon request by contacting the authorised Ottobock Service Center responsible for your country.

To have a service inspection carried out, please send the product as well as the battery charger and power supply unit to an authorised Ottobock Service Centre.

The knee joint should be flexed before sending.

14.1 Identification of the product by the Service Center

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



Factory setting

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



User setting

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

CAUTION

Use of the prosthesis with incorrect setting data

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

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

15 Legal information

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

15.1 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.

15.2 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.

15.3 CE conformity

This product meets the requirements of the European Directive 93/42/EEC for medical devices. This product has been classified as a class I device according to the classification criteria outlined in Annex IX of the directive. The declaration of conformity was therefore created by the manufacturer with sole responsibility according to Annex VII of the directive.

Hereby, Ottobock Healthcare Products GmbH declares that the product is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: www.ottobock.com/conformity

The product meets the requirements under the RoHS Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

15.4 Local Legal Information

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



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

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

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

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

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

Caution: Exposure to Radio Frequency Radiation.

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

Responsible party:

Otto Bock Health Care, LP
3820 West Great Lakes Drive
Salt Lake City, Utah 84120-7205 USA
Phone + 1-801-956-2400
Fax + 1-801-956-2401

This device complies with RSS 210 of Industry Canada.

Operation is subject to the following two conditions:

- (1) this device may not cause interference, and
- (2) this device must accept any interference, including interference that may cause undesired operation of this device.

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

- (1) il ne doit pas produire d'interference et
- (2) l' utilisateur du dispositif doit être prêt à accepter toute interference radioélectrique reçu, même si celle-ci est susceptible de compromettre le fonctionnement du dispositif.

Caution: Exposure to Radio Frequency Radiation.

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

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

Responsible party:

Otto Bock Healthcare Canada Ltd.

5470 Harvester Road

L7L 5N5 Burlington, Ontario

Canada

Phone + 1-800-665-3327

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

16 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	136 kg/300 lb
Prox. system height up to alignment reference point 3C98-3 (pyramid connector)	5 mm
Prox. 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 class	IP67
Water resistance	Weatherproof but not corrosion-resistant Not designed for prolonged underwater use or prolonged submersion
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°

Product	
Maximum insertion depth of the tube adapter in the knee joint	55 mm/2.17 inch
Weight of the prosthesis without Protective Cover	approx. 1,250 g ±25 g/ 44.09 oz ±0.88 oz
Data transfer	
Wireless technology	Bluetooth Smart Ready
Range	approx. 10 m / 32.8 ft
Frequency range	2402 MHz to 2480 MHz
Modulation	GFSK, $\pi/4$ DQPSK, 8DPSK
Data rate (over the air)	2178 kbps (asymmetrical)
Maximum output power (EIRP):	+8.5 dBm
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 %
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	
Reference number	757L16*
Storage and transport in original packaging	-40 °C/-40 °F to +70 °C/+158 °F
Storage and transport without packaging	-40 °C/-40 °F to +70 °C/+158 °F 10 % to 93 % relative humidity, non-condensing
Operation	0 °C/+32 °F to +40 °C/+104 °F max. 90 % relative humidity, non-condensing
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 ==
Cockpit app	
Reference number	Cockpit 4X441-IOS=* / 4X441-Andr=V*
Supported operating system	iOS 9.3 / Android 4.0.3 or higher
Website for download	http://www.ottobock.com/cockpitapp

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.

Screw connection	Tightening torque
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.

17 Appendices

17.1 Symbols Used



Legal 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

IP67

Dustproof, protection against temporary submersion

DUAL

The product's Bluetooth wireless module can establish a connection to 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|YYYY WW NNN

Serial number

LOT|PPPP YYYY WW

Lot number



Caution, hot surface



Please note the instructions for use



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

17.2 Operating states/error signals

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

17.2.1 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 connection of 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 31).

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.

17.2.2 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 39).

17.2.3 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.
	A current connection to the prosthesis was interrupted	Check the following points: <ul style="list-style-type: none"> • Distance from the prosthesis to the device • Charge level of the prosthesis • Bluetooth on the prosthesis switched on? (see Page 33) • Hold the component with the sole of the foot facing up to make the component "visible" for 2 minutes. • Prosthesis switched on? (see Page 33) • If multiple prostheses were stored, was the correct prosthesis selected?

17.2.4 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	
   	<p>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.</p>

17.3 Directives and manufacturer’s declaration

17.3.1 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)

The customer or user of the product must ensure that it is operated in such an environment.

Observe the safety notices in the section "Information on proximity to certain areas" (see Page 14).

The following tables outline the test levels of the tests to be carried out. The higher value applies if there is a difference between the operating environments listed in the tables below.

Table 4 - casing

Phenomenon	EMC basic standard or test procedure	Interference immunity test level	
		Professional healthcare facility	Environments in areas of home healthcare
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	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz
High frequency electromagnetic fields in the immediate vicinity of wireless communication devices	IEC 61000-4-3	See Table 9	
Magnetic fields with rated power frequencies	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	

Table 5 - alternate current gate for the supply input

Phenomenon	EMC basic standard or test procedure	Interference immunity test level	
		Professional healthcare facility	Environments in areas of home healthcare
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	
Surges Line against ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV	
Conducted interference induced by high frequency fields	IEC 61000-4-6	3 V/ 0.15 MHz to 80 MHz 6 V in ISM frequency bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	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

Table 8 – gates of signal input/signal output parts (SIP/SOP)

Phenomenon	EMV basic standard	Interference immunity test level	
		Professional healthcare facility	Environments in areas of home healthcare
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Electrical fast transients/bursts	IEC 61000-4-4	± 1 kV 100 kHz repetition rate	
Surges Line against ground	IEC 61000-4-5	± 2 kV	
Conducted interference induced by high frequency fields	IEC 61000-4-6	3 V/ 0.15 MHz to 80 MHz 6 V in ISM frequency bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	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

Table 9 – Test specifications for the interference resistance of casings against high frequency 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						
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						

Test frequency [MHz]	Frequency band [MHz]	Radio service	Modulation	Maximum power [W]	Distance [m]	Interference immunity test level [V/m]
2450	2400 to 2570	Bluetooth WLAN 802.11- b/g/n, RFID 2450 LTE band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11- a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

The product 3C98-3/3C88-3 is covered by the following patents:

Canada	CA 2 780 511
China:	CN 102 711 672; CN 102 647 963; CN 102 724 936; CN 102 762 171; CN 105 517 511
Finland:	FI 110 159
Germany:	DE 10 2013 013 810
Japan:	JP 5 394 579; JP 5 619 910
Russia:	RU 2 508 078; RU 2 533 967
Taiwan:	R.O.C. Invention Patent No. I551278; I551277; I530278; I542335; I563994
USA:	US 6 908 488; US 8 876 912; US 9 278 013; US 9 572 690
European Patent	EP 1237513 in DE, FR, GB EP 2498724 in DE, FR, GB, IT, IS, NL, SE, TR EP 2498725 in DE, FR, GB EP 2498726 in DE, FR, GB, IT, IS, NL, SE, TR EP 2498730 in DE, FR, GB

Patents pending in Australia, Brazil, Canada, EPA, Japan, Russia and USA.



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