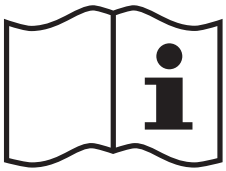
ottobock.

CE

Genium X3 3B5-3 / 3B5-3=ST



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Document: 647H47 Version: 08

https://product-documents.ottobock.com/IFU/INT/3B5-3/647H47/08/O/S/F

DE | Lassen Sie sich durch das Fachpersonal in den sicheren Gebrauch des Produkts einweisen. Weitere Sprachen dieser Gebrauchsanweisung sind online verfügbar oder können kostenlos als gedrucktes Exemplar bestellt werden (siehe Seite 2).

EN | Consult qualified personnel for instructions on how to use the product safely. These instructions for use are available in additional languages online or can be ordered as a printed copy free of charge (see page 2).

FR | Prière de demander au personnel spécialisé d'expliquer à l'utilisateur comment utiliser le produit en toute sécurité. D'autres langues de cette notice d'utilisation sont disponibles en ligne ou peuvent être commandées gratuitement en format papier (voir page 2).

IT | Richiedere al personale tecnico specializzato istruzioni sull'uso sicuro del prodotto. Altre lingue delle presenti istruzioni per l'uso sono disponibili online o possono essere ordinate gratuitamente su supporto cartaceo (vedere pagina 2).

ES | El personal técnico especializado le explicará cómo utilizar el producto de forma segura. Encontrará estas instrucciones de uso en otros idiomas en línea. También puede solicitarlo gratuitamente como ejemplar impreso (véase la página 2).

PT | Solicite ao pessoal técnico que o instrua no uso seguro do produto. Outros idiomas destas instruções de uso estão disponíveis online ou podem ser solicitados gratuitamente como um exemplar impresso (veja a página 2).

NL | Laat u door deskundig personeel uitleggen hoe u veilig met het product moet omgaan. Andere talen van deze gebruiksaanwijzing zijn online beschikbaar of kunnen gratis in gedrukte vorm worden besteld (zie pagina 2).

SV | Låt fackpersonal visa dig hur du använder produkten på ett säkert sätt. Den här bruksanvisningen finns tillgänglig på andra språk online och kan beställas kostnadsfritt i tryckt form (se sidan 2).

DA | Få faguddannet personale til at vise dig, hvordan du anvender produktet på sikker vis. Denne brugsanvisning er tilgængelig på yderligere sprog online eller kan bestilles gratis som et trykt eksemplar (se side 2).

NO | La fagpersonell instruerer deg i sikker bruk av produktet.
Flere språk for denne bruksanvisningen er tilgjengelige på nett, eller de kan bestilles som utskrevet eksemplar (se side 2).

FI | Anna ammattihenkilöstön perehdyttää itsesi tuotteen turvalliseen käyttöön.
Tämän käyttöohjeen muut kielet ovat saatavilla online tai niitä voi tilata maksutta painettuna versiona (katso sivu 2).

PL | Personel fachowy powinien poinstruować użytkownika na temat bezpiecznego używania produktu.
Niniejszą instrukcję używania w innych językach można przeczytać online lub zamówić bezpłatnie w wersji drukowanej (patrz strona 2).

HU | Kérje meg a szakszemélyzetet, hogy tanítsa meg Önt a termék biztonságos használatára.
A használati útmutató további nyelvi változatai az interneten elérhetők, vagy nyomtatott példányként ingyenesen megrendelhetők (lásd a 2. oldalt).

HR | Posavjetujte se sa stručnim osobljem o sigurnoj uporabi proizvoda.
Ostali jezici za ove upute za uporabu dostupni su na internetu ili se mogu besplatno naručiti u tiskanom obliku (vidi 2. stranicu).

CS | Nechte se poučit odborným personálem ohledně bezpečného použití produktu.
Další jazykové verze tohoto návodu k použití jsou k dispozici online nebo je lze zdarma objednat v tištěné podobě (viz str. 2).

SK | Nechajte sa odborným personálom zaučiť do bezpečného zaobchádzania s výrobkom.
Ďalšie jazykové mutácie tohto návodu na použitie sú dostupné online alebo si možno bezplatne objednať ich tlačenú verziu (pozri strana 2).

TR | Uzman personelin size ürünün güvenli kullanımı hakkında bilgi vermesini sağlayın.
Bu kullanım kılavuzundaki diğer diller online olarak mevcuttur veya ücretsiz basılı kopya olarak sipariş verilebilir (bkz. sayfa 2).

RU | Обратитесь к специалистам для получения инструктажа касательно безопасного и надежного применения изделия.
Текст настоящего руководства по применению на других языках доступен онлайн или может быть заказан бесплатно в печатном виде (см. стр. 2).

JA | 製品の安全な使用方法については、有資格担当者の指示に従ってください。
本取扱説明書のその他言語は、オンラインで入手可能ですが、印刷版も無料で注文できます（P2を参照）。

ZH | 由专业人员就产品的安全使用提供指导。
使用说明书的其他语言版本可在线获取，也可免费订购印刷版（参见第 2 页）。

Basic UDI-DI: 40644110000000003B5-3HG

1 Foreword

INFORMATION

Date of last update: 2024-01-03

- ► Please read this document carefully before using the product and observe the safety notices.
- ► Obtain instruction from the qualified personnel in the safe use of the product.
- ► Please contact the qualified personnel if you have questions about the product or in case of problems.
- ► Report each serious incident related to the product to the manufacturer and to the relevant authority in your country. This is particularly important when there is a decline in the health state.
- ► Please keep this document for your records.

The product “3B5-3, 3B5-3=ST Genium” 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. Optional flexion stops
3. Rechargeable battery
4. Hydraulic unit
5. LED (blue) as indicator for the Bluetooth connection
6. Receiver of the inductive charging unit

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.
The product can be individually adapted to your needs with adjustment software.
The product features MyModes for special motion types (e.g. cycling etc.). These are pre-configured by the orthotics and prosthetics professional (O&P professional) using the adjustment software and can be activated with special movement patterns and the Cockpit app (see page 32).
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 35).
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 35).

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

Essential performance of the product
- Stability in the stance phase
- Adjustable swing phase extension resistance

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 38).
The product is intended **exclusively** for use on **one** user. 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 3 (unrestricted outdoor walker) and mobility grade 4 (unrestricted outdoor walker with particularly high demands).
Approved for a max. body weight of **150 kg (330 lbs).**

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

3.4 Contraindications

3.4.1 Absolute Contraindications

- Body weight over 150 kg

3.5 Qualification

The product may be fitted only by qualified personnel authorised by Ottobock after completing the corresponding training.
If the product is to be connected to an osseointegrated implant system, the qualified personnel must also be authorised for the connection to the osseointegrated implant system.

4 Safety

4.1 Explanation of warning symbols

⚠ WARNING	Warning regarding possible serious risks of accident or injury.
⚠ CAUTION	Warning regarding possible risks of accident or injury.
NOTICE	Warning regarding possible technical damage.

4.2 Structure of the safety instructions

⚠ WARNING

The heading describes the source and/or the type of hazard
The introduction describes the consequences in case of failure to observe the safety instructions. Consequences are presented as follows if more than one consequence is possible:
> E.g.: Consequence 1 in the event of failure to observe the hazard
> E.g.: Consequence 2 in the event of failure to observe the hazard
► This symbol identifies activities/actions that must be observed/carried out in order to avert the hazard.

4.3 General safety instructions

⚠ WARNING

Non-observance of safety notices
Personal injury/damage to the product due to using the product in certain situations.
► Observe the safety notices and the stated precautions in this accompanying document.

⚠ WARNING

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

⚠ WARNING

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

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

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

⚠ CAUTION

Failure to observe warning/error signals

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

- ► The warnings/error signals (see page 43) and corresponding change in damping settings must be observed.

⚠ CAUTION

Failure to observe activated mute mode (silent mode)

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

The following feedback signals are deactivated when mute mode is activated:

- > Long vibration signal if the hydraulic unit overheats.
- > Beep and vibration signal to confirm that the movement pattern has been recognised (switching to a MyMode/basic mode with movement pattern).
- > Beep and vibration signal to indicate successful switching to a MyMode/basic mode.
- > Beep and vibration signal upon successfully switching to deep sleep mode.
- ► Before activating mute mode, note that these feedback signals will be deactivated. For more information about mute mode, see the section "Mute mode" (see page 30).
- ► After switching to a MyMode/basic mode, verify the changed damping settings.
- ► Ensure that you stand securely during all switching processes.
- ► To deactivate mute mode, connect and then disconnect the battery charger.

⚠ CAUTION

Independent manipulation of the product and the components

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

- ► Manipulations to the product other than the tasks described in these instructions for use are not permitted.
- ► The battery may only be handled by authorised, qualified Ottobock personnel (no replacement by the user).
- ► The product and any damaged components may only be opened and repaired by authorised, qualified Ottobock personnel.

⚠ CAUTION

Mechanical stress on the product

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

⚠ CAUTION

Use of the product when battery charge level is too low

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

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

⚠ CAUTION

Risk of pinching in the joint flexion area

Injuries due to pinching of body parts.

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

⚠ CAUTION

Penetration of dirt and humidity into the product

- > Falling due to unexpected product behaviour as the result of a malfunction.
- > Falling due to breakage of load-bearing components.
- ► Ensure that no solid particles or foreign objects can penetrate into the product.
- ► The knee joint and the AXON tube adapter are waterproof, corrosion-resistant and protected against the penetration of jets of water. The knee joint and AXON tube adapter can be operated in fresh and salt water. Do not use the knee joint under extreme conditions like diving or jumping into water. The knee joint and AXON tube adapter are designed for underwater use (for the maximum duration and water depth, see the section "Technical data" (see page 38).
- ► After contact with water, hold the prosthesis with the sole of the foot facing up until the water has drained from the knee joint and AXON tube adapter.
- ► After using the knee joint in a salt water environment, remove the Protective Cover and rinse knee joint, AXON tube adapter and Protective Cover with fresh water. Dry the knee joint and components with a lint-free cloth and allow the components to fully air dry.
- ► Should the knee joint or AXON tube adapter come into contact with **solutions other than fresh or salt water**, **promptly** remove the Protective Cover and clean the **knee joint**. In order to do so, rinse knee joint, AXON tube adapter and Protective Cover with fresh water and let them dry.
- ► In case of a malfunction after drying, the knee joint and AXON tube adapter must be inspected by an authorised Ottobock Service Center.
- ► The knee joint and the AXON tube adapter are not protected against the penetration of steam.

⚠ CAUTION

Use of the product without protector or with damaged protector

- > Falling due to unexpected product behaviour as the result of malfunction.
- > Falling due to breakage of load-bearing components.
- ► If the protector has been removed, ensure prior to the next use of the product that the protector has been properly installed.
- ► Using the product with a damaged protector or without the protector is not permitted.
- ► Using the product with a foam cover is not possible, since the protector would have to be removed for this purpose.

⚠ CAUTION

Signs of wear and tear on the product components

Falling due to damage or malfunction of the product.

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

⚠ CAUTION

Use of unapproved accessories

> Falling due to product malfunction as a result of reduced interference resistance.

> Interference of other electronic devices due to increased emissions.

► Use the product only in combination with the accessories, signal converters and cables listed in the sections "Scope of delivery" (see page 15) and "Accessories" (see page 15).

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).

► Only use fresh water with a temperature of no more than 65 °C for cleaning.

► If dirt cannot be removed, the product must be sent to an authorised Ottobock Service Center. Your contact is the O&P professional.

INFORMATION

Knee joint movement noise

When using exoprosthetic knee joints, servomotor, hydraulic, pneumatic or brake load dependent control functions can cause movement noises. 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 the O&P professional immediately.

4.4 Information on the Power Supply/Battery Charging

⚠ CAUTION

Charging the product without taking it off

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

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

⚠ CAUTION

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

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

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

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

NOTICE

Use of incorrect power supply unit/battery charger

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

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

4.5 Battery charger information

⚠ WARNING

Storing/transporting the product near active implanted systems
Interference with active implantable systems (e.g. pacemaker, defibrillator, etc.) due to the product's magnetic field.
- ► When storing/transporting the product in the immediate vicinity of active implantable systems, ensure that the minimum distances stipulated by the manufacturer of the implant are observed.
- ► Make sure to observe any operating conditions and safety notices stipulated by the manufacturer of the implant.

NOTICE

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 38).

NOTICE

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

NOTICE

Contact of the battery charger with magnetic data storage devices
Wiping of the data storage device.
- ► Do not place the battery charger on credit cards, diskettes, audio or video cassettes.

NOTICE

Improper care of the housing
Damage to the casing through the use of acetone, white spirit or similar solvents.
- ► Only clean the housing with a damp cloth and mild soap (e.g. 453H10=1 Ottobock DermaClean).

4.6 Information on Proximity to Certain Areas

⚠ CAUTION

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

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

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

⚠ CAUTION

Operating the product in very close proximity to other electronic devices

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

► Do not operate the product in the immediate vicinity of other electronic devices.
► Do not stack the product with other electronic devices during operation.
► If simultaneous operation cannot be avoided, monitor the product and verify proper use in the existing setup.

⚠ CAUTION

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

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

► Avoid remaining in the vicinity of visible or concealed theft prevention systems at the entrance/exit of stores, metal detectors/body scanners for people (e.g. in airports) or other sources of strong magnetic and electrical interference (e.g. high-voltage lines, transmitters, transformer stations...).
If this cannot be avoided, make sure to at least have a safeguard when walking or standing (e.g. a handrail or the support of another person).
► When walking through theft prevention systems, body scanners or metal detectors, watch for unexpected changes in the damping behaviour of the product.
► In general, monitor the product for unexpected changes in the damping behaviour when electronic or magnetic devices are in the immediate vicinity.

⚠ CAUTION

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

> Falling due to unexpected restriction of the product's range of motion caused by metallic objects adhering to the magnetised components.
> Irreparable damage to the product due to the effect of strong magnetic fields.
► Take off the product before entering a room or area with strong magnetic fields and store the product outside this room or area.
► Damage to the product caused by exposure to strong magnetic fields cannot be repaired.

⚠ CAUTION

Remaining in areas outside the allowable temperature range

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

► Avoid remaining in areas with temperatures outside of the permissible range (see page 38).

4.7 Information on Use

⚠ CAUTION

Walking up stairs

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

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

⚠ CAUTION

Walking down stairs

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

- ► Always use the handrail when walking down stairs and roll over the edge of the step with the middle of the shoe.
- ► Observe the warning/error signals (see page 43).
- ► Be aware that resistance in the flexion and extension direction can change in case of warning and error signals.
- ► Particular caution is required when carrying children down the stairs.

⚠ CAUTION

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

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

⚠ CAUTION

Overloading due to 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 your personal safety!
- ► If the product and its components have been subjected to extreme loads (e.g. due to a fall, etc.), then the product must be inspected for damage immediately by a prosthetist. If necessary, the prosthetist will 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 you stand securely during all switching processes.
- ► Verify the changed damping characteristics after switching and observe the feedback from the acoustic signal emitter.
- ► Switch back to basic mode once the activities in MyMode have been completed.
- ► Take the weight off the product and correct the switching, if required.

⚠ CAUTION

Improper use of the stance function

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

- ► Make sure that you are standing safely when using the stance function and check the lock of the knee joint before placing your full weight on the prosthesis.
- ► Make sure you have been instructed in the correct use of the stance function by the O&P professional and/or therapist. Information on the stance function see page 22.

⚠ CAUTION

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

> Falling due to unexpected activation of the swing phase.

- ► Note that the knee joint may flex unexpectedly when the hip is pushed forward quickly while the prosthesis is extended.
- ► Therefore, familiarise yourself with swing phase activation in such situations under secure conditions (e.g. while holding on to parallel bars) and with the instruction of trained, qualified personnel.
- ► For sports where this movement pattern may occur, use a corresponding pre-configured MyMode. For further information about the MyModes, see the section 'MyModes' (see page 32).

⚠ CAUTION

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

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

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

4.8 Notes on the safety modes

⚠ CAUTION

Using the product in safety mode

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

- ► The warnings/error signals (see page 43) have to be observed.
- ► Particular caution is necessary when using a bicycle without a freewheel (with a fixed gear).

⚠ CAUTION

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

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

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

⚠ CAUTION

Safety mode cannot be deactivated

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

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

⚠ CAUTION

Safety signal occurs (ongoing vibration)

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

- ► Observe the warnings/error signals (see page 43).
- ► Do not continue using the product after the safety signal has been emitted.
- ► The product must be inspected by an authorised Ottobock Service Center. The O&P professional is your contact.

4.9 Instructions for use with an osseointegrated implant system

⚠ WARNING

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

- > Overloading of the bone, which can lead to pain, loosening of the implant, death of bone tissue or bone fracture, among other things.
- > Damage or breakage of the implant system or its components (safety components…).
- ► Verify compliance with the fields of application, conditions of use and indications according to the information of the manufacturers, both for the knee joint and for the implant system.
- ► Note the instructions of the clinical personnel that indicated the use of the osseointegrated implant system.
- ► Note changes in your state of health that result in restrictions or doubt regarding the use of the osseointegrated connection.

4.10 Information on the use of a mobile device with the cockpit app

⚠ CAUTION

Improper use of the mobile device

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

- ► Make sure you have been instructed in the proper use of the mobile device with the Cockpit app.

⚠ CAUTION

Improper use of the setting parameters in the MyModes

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

► Ask the O&P professional and/or therapist to instruct you regarding the functionality and adjustment options for **all parameters** of the MyModes.

⚠ CAUTION

Independently applied changes or modifications made to the mobile device
Falling due to altered damping behaviour as a result of unexpected switching to a MyMode.
► Do not make any independent changes to the hardware of the mobile device on which the app is installed.
► Do not make any independent changes to the software/firmware of the mobile device that 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 you stand securely during all switching processes.
► Verify the changed damping characteristics after switching and observe the feedback from the acoustic signal emitter (beeper) and the display on the device.
► Switch back to basic mode once the activities in MyMode have been completed.

NOTICE

Failure to observe the system requirements for the installation of the Cockpit app
Mobile device malfunction.
► The Cockpit App should only be installed on mobile devices and versions which comply with the specifications in the respective online stores (e.g. Apple App Store, Google Play Store, ...)

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

5.1 Scope of delivery

- 1 pc. 3B5-3=ST Genium X3 (with threaded connector) or
  1 pc. 3B5-3 Genium X3 (with pyramid)
  each with preinstalled 4X900 or 4X193-1 Genium X3 Protective Cover
- 1 pc. 2R19 AXON tube adapter
- 1 pc. 757L16-4 power supply
- 1 pc. 4E60* inductive charger
- 1 pc. cosmetic case for battery charger and power supply
- 1 pc. 646C107 Bluetooth PIN card
- 1 pc. 647F542 prosthesis passport
- 1 pc. Instructions for use (user)

Cockpit app for download from the website: https://www.ottobock.com/cockpitapp
- "4X441-V2=IOS Cockpit" iOS app
- "4X441-V2=ANDR Cockpit" Android app

5.2 Accessories

The following components are not included in the scope of delivery and may be ordered separately:
- Genium X3 Protective Cover: 4X900
- 757L43 USB charging adapter
- Genium X3 Protective Cover: 4X193-1

6 Charging the battery

The following points must be observed when charging the battery:

- Use the 757L16-4 power supply unit and 4E60* battery charger to charge the battery.
- With average use, the capacity of the fully charged battery is sufficient for about 5 days.
- We recommend charging the product every day when used on a daily basis.
- The battery should be charged for at least 3 hours prior to initial use.
- Note the permissible temperature range for charging the battery (see page 38).
- The distance between the battery charger and the receiver on the product must not exceed 2 mm.

6.1 Connecting the power supply and battery charger

1

2

3

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

→ If the green LED on the power supply and the LED ring on the battery charger do not light up, there is an error (see page 43).

6.2 Charging the prosthesis battery

INFORMATION

When the Protective Cover is installed, the battery charger cable has to point to the upper closure. A correct knee joint charging process is only ensured with this alignment.

1) Connect the inductive charger to the receiver of the charging unit on the rear of the product. The charger is held in place by a magnet.
   → The LED ring on the rear of the charger pulsates purple (4-second cycle).
   → If the LED ring lights up in a different colour, this indicates an error (see page 43).
2) The charging process starts.
   → Once the product battery is fully charged, all LEDs on the side of the battery charger light up.
3) After the charging process is complete, hold the prosthesis still and remove the inductive charger from the receiver.
   → A self-test is performed. The joint is operational only after corresponding feedback (see page 46).

6.3 Display of the current charge level

6.3.1 Display of battery charge level without additional devices

INFORMATION

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

1) Turn the prosthesis by 180° (the sole of the foot must face up).
2) Hold still for 2 seconds and wait for beep signals.

Beep signal	Battery charge level
5x short	more than 80%
4x short	60% to 80%
3x short	40% to 60%
2x short	20% to 40%
1x short	less than 20%

INFORMATION

If the **Volume** parameter is set to '0' in the Cockpit app (see page 26) or if mute mode (silent mode) is activated, there are no beep signals.

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

6.3.3 Display of the current charge level during the charging process

During the charging process, the current battery charge level is indicated by the number of LEDs lit on the side of the charger.

Quantity	Battery charge level
0	0%-10%
1	10%-30%
2	30%-50%
3	50%-70%
4	70%-90%
5	> 90%

7 Cockpit app

The Cockpit app enables switching from basic mode to the pre-configured MyModes. In addition, information about the product (step counter, battery charge level, etc.) can be retrieved.
The everyday behaviour of the product can be changed to a certain extent using the app (e.g. while becoming accustomed to the product). The O&P professional can use the adjustment software to track these changes at the next appointment.

Information on the Cockpit app

- The Cockpit app can be downloaded free of charge from the respective online store. For more information, please visit the following website: https://www.ottobock.com/cockpitapp. To download the Cockpit app, the QR code on the supplied Bluetooth PIN card can also be read with the mobile device (requirement: QR code reader and camera).
- The language of the user interface in the Cockpit app can be changed using the adjustment software.
- Depending on the version of the Cockpit app being used, the language of the user interface in the Cockpit app corresponds to the language of the mobile device on which the Cockpit app is being used.
- 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.
- 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 29).
- Keep the mobile app up to date at all times.
- Please contact the manufacturer if you suspect cybersecurity problems.

7.1 System Requirements

See the information in the Apple App Store or Google Play Store regarding compatibility with mobile devices and versions.

7.2 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 29).
- Bluetooth on the mobile device must be switched on.
- The mobile device must not be in "flight mode" (offline mode), otherwise all wireless connections are turned off.
- **The mobile 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, contact your O&P professional.

7.2.1 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.

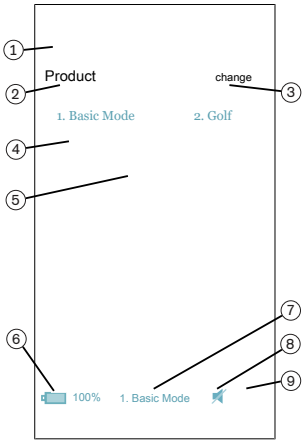
INFORMATION

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

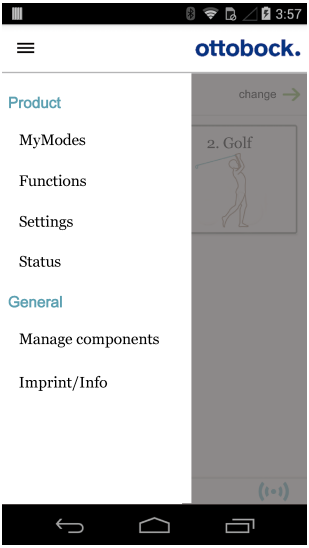
After activating the "visibility" of the component (holding the component with the sole of the foot facing up, or connecting and then disconnecting the battery charger), the component can be recognised by another device (e.g. smartphone) within 2 minutes. If registration or establishing the connection 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.

7.3 Control elements for cockpit app



1. ☰ Access the navigation menu (see page 20)
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**.
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. Mute mode is activated
9. Connection to component has been established
   Connection to component has been interrupted. The app is attempting to re-establish the connection automatically.
   No existing connection to the component.

7.3.1 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 29)

Settings
Change settings of the currently selected mode (see page 26)

Status
Query status of the connected component (see page 30)

Manage components
Add or delete components (see page 21)

Imprint/Info
Display information/legal notices for the cockpit app

7.4 Managing components

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

INFORMATION

Before establishing the connection, observe the points in the section "Initial connection between Cockpit app and component" (see page 19).

7.4.1 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 "**+**" 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.

7.4.2 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.

7.4.3 Connecting component with multiple mobile devices

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

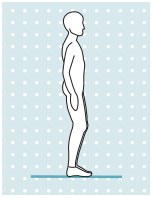
If there is an existing connection between the component and a different mobile device, the following information appears while the connection is being established with the current mobile device:

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

8 Use

8.1 Movement patterns in basic mode (mode 1)

8.1.1 Standing



Knee control through high hydraulic resistance and static alignment.
A stance function can be enabled by the O&P professional. Please see the following section for further information on the stance function.

8.1.1.1 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 27).

The stance function (standing mode) is a functional supplement to the basic mode (mode 1). This function makes it easier, for example, to stand on an inclined surface for a longer time. The joint is fixed in the flexion direction.
The stance function must be enabled by the O&P professional. In addition, the type of joint locking (conscious/intuitive) has to be established by the O&P professional. Changing the locking type using the Cockpit app is not possible.

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

Deliberate locking of the joint
1) Assume the desired knee angle.
2) Do not remove the entire load from the prosthesis.
3) Do not change the knee angle for a brief period (1/8 second). This time period prevents unintentional activation of the stance function while walking.

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

Deliberate unlocking of the joint

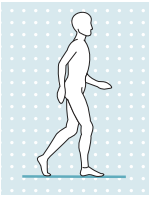
► By deliberately extending or unloading the knee joint, is it unlocked again.

INFORMATION

Stance function with hip disarticulation amputation level

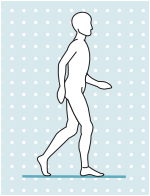
Due to personal abilities and experiences with prostheses, these users may encounter difficulties with activating/deactivating the stance function. If these users want to stand with a flexed and locked knee joint for extended periods of time, the O&P professional can configure a MyMode that can be activated/deactivated using the Cockpit app.

8.1.2 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.

8.1.3 Running short distances ("walk-to-run" function)



For covering short distances quickly, the knee joint detects a transition from walking to running in basic mode and automatically changes the following settings:

- The swing phase angle is increased
- Preflexion of 4° at heel strike (PreFlex) is reduced to 0°

The requirements to automatically switch to the running motion are fast forward movement of the prosthetic leg and high dynamic load on the knee joint.
When stopping from the running motion, the changed settings are set back to the standard values.

INFORMATION

For covering longer distances, the prosthetist can configure a "Running" MyMode (see page 32).

8.1.4 Sitting down

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

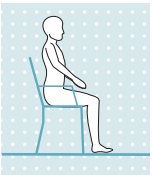
1) Place both feet side by side at the same level.
2) While sitting down, weight should be distributed evenly between both legs and the arm supports used where applicable.
3) Move the buttocks in the direction of the back support and lean the upper body forward.

INFORMATION: Resistance while sitting down can be changed with the Cockpit app via the parameter “Resistance” (see page 27).

8.1.5 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 by the O&P professional. For more information about the sitting function, see the following section.

8.1.5.1 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 27).

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

8.1.6 Standing up

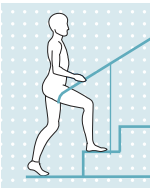
Flexion resistance is increased steadily while standing up.

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

8.1.7 Walking up stairs step-over-step

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 27).



Although the knee joint is passive, which means it cannot actively initiate movements, negotiating stairs step-over-step is possible.
This function must be practised and executed consciously.

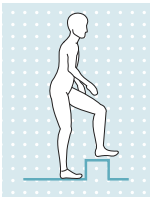
1) Lift the extended prosthesis off the floor.
2) Immediately after lifting the extended leg off the floor, extend the hip briefly and then abruptly flex it. This requires a sufficiently secure hold in the socket and a certain level of residual limb strength.
   → This whip motion flexes the knee, because the knee joint automatically recognises the movement and sets the flexion resistance to minimum.

   INFORMATION: Take note of people behind you before executing the whip motion.
3) When sufficient knee flexion has been achieved, the knee joint increases extension resistance so that there is enough time to position the foot on the next step before the knee joint is extended again.
4) Set the foot onto the next step.
   The support area for the foot on the step must be large enough that the heel does not extend back too far over the edge. With too little support area, the lower leg would extend too early and position the leg too far backwards. In this phase, the knee joint has already set the flexion resistance to maximum (blocked). The knee joint can no longer be flexed but only extended. This ensures that the leg does not buckle if the hip strength is not sufficient for the extending motion.
5) Support yourself with your hand on the contralateral side. A smooth wall will also work. This lateral support is intended to prevent the residual limb from twisting in the socket. Twisting can lead to unpleasant surface tension between the skin and the socket. Lateral support also improves balance.
6) Bring the knee into extended position. When the knee joint is fully extended, the initial position has been reached.
7) You can climb the next step or continue walking normally.

8.1.8 Overcoming obstacles

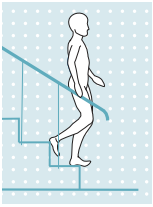
INFORMATION

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 27).



The stair function can also be used to cross obstacles:
1) Lift the extended prosthesis off the floor.
2) Briefly extend the hip.
3) Quickly flex the hip. This causes the knee to flex.
4) With the knee flexed, step over the obstacle.
   With sufficient knee flexion, the extension resistance is increased to allow enough time for crossing the obstacle.

8.1.9 Walking down stairs

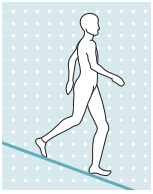


This function must be practised and executed consciously. Only when the sole is properly positioned can the knee joint react correctly and permit controlled flexion.

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 ensure 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.

INFORMATION: The flexion speed of the knee joint can be changed using the Cockpit app via the parameter "Resistance" (see page 27).

8.1.10 Walking down a ramp



Under increased flexion resistance, permit controlled flexion of the knee joint which lowers the body's centre of gravity.

INFORMATION: The flexion resistance at which the knee bends can be changed using the Cockpit app via the parameter "Resistance" (see page 27).

8.2 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.

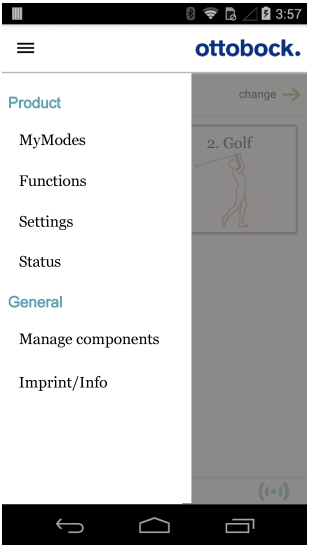
INFORMATION

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

8.2.1 Changing the prosthesis setting using the cockpit app



1) Once the component is connected and in the desired mode, tap the ☰ icon in the main menu.
   → The navigation menu opens.
2) Tap the "**Settings**" menu option.
   → A list appears with the parameters for the currently selected mode.
3) Change the setting of the desired parameter by tapping the "**<**", "**>**" icons.
   INFORMATION: The O&P professional's setting is marked and, after the setting has been changed, can be restored by tapping the "Standard" button.

8.2.1.1 Overview of adjustment parameters in basic mode

INFORMATION

When mute mode (silent mode) is activated, no beep and vibration signals are generated.

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, sitting function and/or stairs and obstacles function can also be activated/deactivated. Further information on the stance function (see page 22), sitting function (see page 24), stairs and obstacles function (see page 24).

The following parameters can be modified:

Parameter	Adjustment software range	Setting range, app	Meaning
Resistance	120 – 180	+/- 10	Resistance against flexion motion e.g. when walking down stairs or when sitting down
Angle	55° – 70°	+/- 3°	Maximum flexion angle in the swing phase
Stance function	Deactivated Activated	0 - deactivated 1 - activated	Activation/deactivation of the stance function. For switching with the Cockpit app, this function has to be activated in the adjustment software. Further information (see page 22).

Parameter	Adjustment software range	Setting range, app	Meaning
Sitting function	Deactivated Activated	0 - deactivated 1 - activated	Activation/deactivation of the sitting function. For switching with the Cockpit app, this function has to be activated in the adjustment software. Further information (see page 24).
Stair Function	Deactivated Activated	0 - deactivated 1 - activated	Activating/deactivating the stair and obstacle function. For switching with the Cockpit app, this function has to be activated in the adjustment software. Further information (see page 24).
Pitch	1000 Hz – 4000 Hz	1000 Hz – 4000 Hz	Pitch of beep signal for confirmation tones
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 in case of errors are still generated.

8.2.1.2 Overview of adjustment parameters in MyModes

⚠ CAUTION

Improper use of the setting parameters in the MyModes

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

► Ask the O&P professional and/or therapist to instruct you regarding the functionality and adjustment options for **all parameters** of the MyModes.

INFORMATION

When mute mode (silent mode) is activated, no beep and vibration signals are generated.

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.

Parameter	Adjustment software range	Setting range, app	Meaning
Basic flex.	0–200	+/- 20	Level of flexion resistance at the start of flexing the knee joint
Gain	0–100	+/- 10	Increase in flexion resistance (starting with the parameter "**Basic flex.**") when flexing the knee joint. The knee joint locks at a certain flexion angle, which depends on the setting of the parameters "**Basic flex.**" and "**Gain**".
Basic ext.	0–60	+/- 20	Level of extension resistance

Parameter	Adjustment software range	Setting range, app	Meaning
Locking angle	0–90	+/- 10	Angle up to which the knee joint can be extended. **Information:** If this parameter is >0, the knee joint is locked in a flexed position in the extension direction. To unlock it, unload the prosthesis and tilt it back for at least 1.5 seconds. This makes extension of the joint possible independently of the settings for the parameters "**Basic ext.**" and "**Locking angle**". This may be necessary to switch to basic mode using a movement pattern.
Pitch	1000 Hz–4000 Hz	1000 Hz–4000 Hz	Pitch of beep signal for confirmation tones
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 in case of errors are still generated.

8.3 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 29).

INFORMATION

Basic mode (mode 1) has to be active to turn off Bluetooth. If a MyMode is activated, one has to switch to basic mode to turn off Bluetooth.

8.3.1 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) Turn the component over 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.

8.4 Querying the prosthesis status

8.4.1 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**".

8.4.2 Status display in the cockpit app

Menu option	Description	Possible actions
Trip	Daily step counter (steps with the prosthesis side)	Reset the counter by tapping the "**Reset**" button.
Step	Total step counter (steps with the prosthesis side)	For informational purposes only
Service	Display of the next maintenance date	For informational purposes only
Batt.	Current prosthesis charge level, as a percentage	For informational purposes only
Stb/Act: 58/29	Estimated remaining operating time of prosthesis in hours. Rest mode (Stb) e.g. 58 hours, active use (Act) e.g. 29 hours	For informational purposes only

8.5 Mute mode (silent mode)

Activating mute mode (silent mode) turns off the audible feedback signals and the vibration signals. However, warnings in case of component errors are still generated (see page 43).
Mute mode can be activated/deactivated using the Cockpit app.

INFORMATION

Connecting the battery charger automatically deactivates mute mode again.

8.5.1 Turning mute mode on/off using the Cockpit app

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 "**Mute mode**".
4) Follow the on-screen instructions.

8.6 Deep sleep mode

INFORMATION

When mute mode (silent mode) is activated, no beep and vibration signals are generated.

INFORMATION

If the **Volume** parameter is set to '0' in the Cockpit app, there are no beep signals (see page 26).

The Cockpit app can be used to place the knee joint into a deep sleep mode, in which power consumption is minimised. The knee joint offers no functionality in this mode. The safety mode damping values are activated.

It can be awakened from deep sleep mode with the Cockpit app or by connecting the battery charger. Waking from deep sleep mode using the Cockpit app can take up to 30 seconds.
After ending deep sleep mode, the knee joint is in basic mode again.

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

Activating deep sleep mode

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 "**Activate deep sleep mode**".
4) Follow the on-screen instructions.

→ The activation of deep sleep mode is indicated by a short beep signal and a short vibration signal, assuming that mute mode (silent mode) is not active.

Deactivating deep sleep mode

1) When deep sleep mode is active for the currently connected prosthesis, the **Exit deep sleep mode** button automatically appears when the Cockpit app is started.
2) Tapping this button establishes a connection to the prosthesis and deactivates deep sleep mode.
   INFORMATION: Establishing a connection in deep sleep mode can take up to 30 seconds.

If a prosthesis is in deep sleep mode but not connected to the Cockpit app, a connection to the prosthesis has to be established (see page 21).

8.7 OPG function (Optimised Physiological Gait)

INFORMATION

The O&P professional can turn the "PreFlex" function on or off using the adjustment software. All other parameters of the OPG function are always active and cannot be influenced.

The OPG function minimises the prosthesis wearer's prosthetic deviations from a harmonious gait pattern and promotes more biomechanically correct walking. This function enables the following features:

PreFlex
PreFlex ensures the knee is in 4° of flexion at the end of swing phase in preparation for loading response. This makes initiating stance phase flexion easier and forward movement is less restricted.

Adaptive yielding control
The knee joint has auto-adaptive stance and swing extension resistance. The stance flexion resistance experienced by the user is dependent on the slope or incline when walking downhill. When walking on a ramp, adaptive yielding control manages flexion depending on the angle of the ramp. The knee joint flexes slowly if the ramp is flat, and flexes quickly if the ramp is steep.

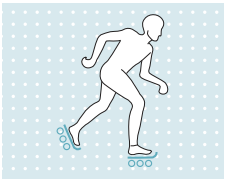
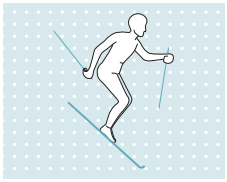
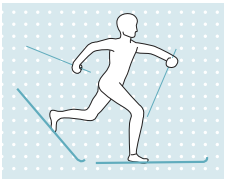
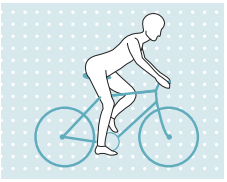
Dynamic stability control (DSC)
DSC ensures the knee will not release stance resistance during biomechanically unstable static and dynamic conditions. Constantly checking multiple parameters, DSC ensures the optimally timed decision for the knee to safely switch from stance to swing. Because DSC is always monitoring knee function, multi-directional movement and walking backward are also possible without risk of stance resistance releasing.

Adaptive swing phase control
Instantaneous adaptation to varied walking cadences and to changes of the pendular mass (e.g. varying footgear) ensures the knee always achieves the swing flexion target angle within (+/-) one degree. The swing phase extension and flexion resistance experienced by the user are auto-adaptive.

The flexed and partially loaded knee will also disable the stance phase on slopes and ramps to allow for greater knee flexion and more ground clearance in the swing phase.

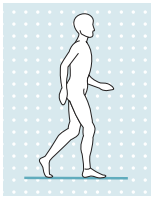
9 MyModes

The O&P professional can activate and configure up to five MyModes in addition to basic mode using adjustment software. These can be selected by using the Cockpit app. Only the first three MyModes can be selected using movement patterns. Switching by using movement patterns has to be activated in the adjustment software by the O&P professional.

These modes are intended for specific motion patterns or postures (e.g. inline skating, running (jogging) ...). Settings can be adjusted using the Cockpit app (see page 28).

9.1 Running function as configured MyMode



For running over longer periods of time, the O&P professional can configure a "Running" MyMode which can be activated using the cockpit app or a movement pattern.
In this mode, every step will be performed as a running step with larger swing phase angle and no preflexion at heel strike (PreFlex) (see page 31).

INFORMATION

The running function will work with specialised running feet such as the 1E95 Challenger as well as with prosthetic feet with axial compression such as the 1C61 Triton Vertical Shock. For details on assembly and alignment please refer to the instructions for use of the foot.
Feet without axial compression are generally not suited for running.

9.2 Switching MyModes with the cockpit app

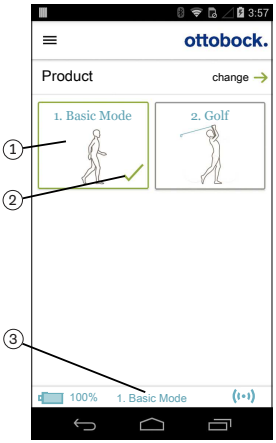
INFORMATION

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 29).

INFORMATION

If the **Volume** parameter is set to '0' in the Cockpit app (see page 26) or if mute mode (silent mode) is activated, there are no beep signals.

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).

9.3 Switching MyModes using motion patterns

INFORMATION

When mute mode (silent mode) is activated, no beep and vibration signals are generated.

INFORMATION

If the **Volume** parameter is set to '0' in the Cockpit app (see page 26) or if mute mode (silent mode) is activated, there are no beep signals.

Information on switching

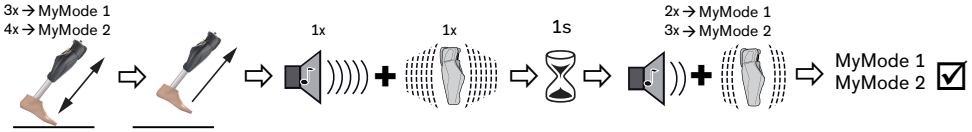
- Switching and the number of movement patterns must be activated by the O&P professional in the adjustment software.
- Before the first step, always check whether the selected mode corresponds to the required motion type.

Requirements for successful switching using motion patterns

The following points must be observed to carry out switching successfully:

- Switching using movement patterns has to be enabled by the O&P professional.
- Position the prosthetic leg back slightly and bounce on the forefoot with the leg extended while maintaining constant contact with the floor.
- Weight must be placed on the forefoot while bouncing.
- Do not take the weight off fully during unloading while bouncing.

Switching process



1) Position the prosthetic leg slightly to the rear (step position).
2) While maintaining constant contact with the floor, bounce on the forefoot with the leg extended a number of times in one second depending on the desired MyMode (MyMode 1 = 3 times, MyMode 2 = 4 times).
3) Fully unload and keep the prosthetic leg still in this position (step position).

→ A beep and vibration signal will sound to confirm that the movement pattern has been recognised.

INFORMATION: If this beep and vibration signal does not sound, the requirements were not observed when bouncing the foot or mute mode (silent mode) is activated. For more information about mute mode, see the section "Mute mode" (see page 30).

4) After the beep and vibration signal sounds, keep the prosthetic leg extended and still for 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 kept still or mute mode (silent mode) is activated. Repeat the process for correct switching. For more information about mute mode, see the section "Mute mode" (see page 30).

9.4 Switching from a MyMode back to basic mode

Information on switching

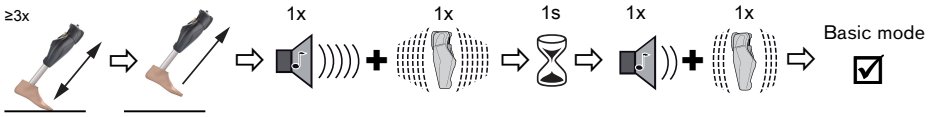
- Regardless of the configuration of additional MyModes in the adjustment software, it is always possible to switch back to basic mode (mode 1) with a motion pattern.
- It is always possible to switch back to basic mode (mode 1) by connecting/disconnecting the battery charger.
- Before the first step, always check whether the selected mode corresponds to the required motion type.

Requirements for successful switching using motion patterns

The following points must be observed to carry out switching successfully:

- Position the prosthetic leg back slightly and bounce on the forefoot with the leg extended while maintaining constant contact with the floor.
- Weight must be placed on the forefoot while bouncing.
- Do not take the weight off fully during unloading while bouncing.

Switching process



1) Position the prosthetic leg slightly to the rear (step position).
2) While maintaining constant contact with the floor, and with the leg extended, bounce on the forefoot three or more times.
3) Fully unload and keep the prosthetic leg still in this position (step position).

→ A beep and vibration signal will sound to confirm that the movement pattern has been recognised.

INFORMATION: If this beep and vibration signal does not sound, the requirements were not observed when bouncing the foot or mute mode (silent mode) is activated. For more information about mute mode, see the section "Mute mode" (see page 30).

4) After the beep and vibration signal sounds, keep the prosthetic leg extended and still for 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 kept still or mute mode (silent mode) is activated. Repeat the process for correct switching. For more information about mute mode, see the section "Mute mode" (see page 30).

10 Additional operating states (modes)

10.1 Empty battery mode

Beeps and vibration signals are emitted if the available battery charge level is 5% (see page 43). During this time, damping settings are set to their safety mode values. This may be low or high depending on the setting in the adjustment software. The prosthesis is then switched off. You can switch back to basic mode (mode 1) from empty battery mode by charging the product.

10.2 Mode for charging the prosthesis

The product is non-functional during charging.
The product is set to the flexion resistance of safety mode. This may be low or high depending on the setting configured by the O&P professional.

10.3 Safety mode

The product automatically switches to safety mode if a critical fault occurs (e.g. failure of a sensor signal). Safety mode remains in effect until the error has been rectified.
The switch to safety mode is indicated by beeps and vibration signals immediately prior to switching (see page 43).
Safety mode can be disabled by connecting and disconnecting the battery charger. If the product switches into safety mode again, this means a permanent error exists. The product must be inspected by an authorised Ottobock Service Centre.
Depending on the type and severity of the error, different remaining functionality is offered in safety mode. This makes limited walking possible for the user depending on the type of error.

The following remaining functionality is available:

- **Minor error:** Continuous stance phase flexion resistance is set, with the ability to initiate the swing phase.
- **Moderate error**: Continuous stance phase flexion resistance is set, with the ability to initiate the swing phase. The swing phase control and stance phase extension resistance may be available or not depending on the type of error.
- Safety mode flexion resistance is configured. This may be low or high depending on the setting configured by the O&P professional.

The following functions are deactivated in safety mode:

- OPG function
- Stairs and obstacles function
- Stance function
- Sitting function

10.4 Overheating mode

INFORMATION

When mute mode (silent mode) is activated, no beep and vibration signals are generated.

When the hydraulic unit overheats due to uninterrupted, increased activity (e.g. extended walking downhill), the flexion resistance is increased along with the rising temperature in order to counteract the overheating. When the hydraulic unit cools down, the product switches back to the settings that existed prior to overheating mode.
Overheating mode is not activated in the MyModes.

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

The following functions are deactivated in overheating mode:
- Sitting function
- Display of the battery charge level without additional equipment
- Switching to a MyMode

11 Storage and bleeding

Air may accumulate in the hydraulic unit if the product is stored for longer periods and not in an upright position. This is noticeable through sounds and irregular damping behaviour.
The automatic bleeding mechanism ensures that all functions of the product are again intact after approximately 10 - 20 steps.

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

12 Cleaning

1) Rinse the product with clear fresh water.
2) Dry the product with a soft cloth.
3) Allow to air dry in order to remove residual moisture.

INFORMATION

Please note that the weight of dirt adhering to the prosthesis can affect the gait pattern.

13 Maintenance

Regular maintenance (service inspections) at 12-monthly intervals is mandatory in the interest of your own safety and in order to maintain operating reliability and protect the warranty, to maintain basic safety and the essential performance characteristics, and to ensure safety in regards to EMC.
When maintenance is due, this is indicated by feedback after disconnecting the battery charger (see the section “Operating states/error signals”, see page 42). The manufacturer grants a grace period of no more than two months before, or three months after, the due date.
Additional services such as repairs may be provided in the course of maintenance. These additional services may be provided free of charge or can be billable according to an advance cost estimate, depending on the extent and validity of the warranty.
The following components always have be submitted to the O&P professional for maintenance and repairs:
The prosthesis, battery charger and power supply unit.

14 Legal information

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

14.1 Liability

The manufacturer will only assume liability if the product is used in accordance with the descriptions and instructions provided in this document. The manufacturer will not assume liability for damage caused by disregarding the information in this document, particularly due to improper use or unauthorised modification of the product.

14.2 Trademarks

All product names mentioned in this document are subject without restriction to the respective applicable trademark laws and are the property of the respective owners.
All brands, trade names or company names may be registered trademarks and are the property of the respective owners.
Should trademarks used in this document fail to be explicitly identified as such, this does not justify the conclusion that the denotation in question is free of third-party rights.

14.3 CE conformity

Otto Bock Healthcare Products GmbH hereby declares that the product is in compliance with applicable European requirements for medical devices.
The product meets the requirements of the RoHS Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic devices.
This product meets the requirements of the 2014/53/EU directive.
The full text of the regulations and requirements is available at the following Internet address: http://www.ottobock.com/conformity

14.4 Local Legal Information

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

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
1) This device may not cause harmful interference, and
2) This device must accept any interference received, including interference that may cause undesired operation.
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
—Reorient or relocate the receiving antenna.
—Increase the separation between the equipment and receiver.
—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
—Consult the dealer or an experienced radio/ TV technician for help.
Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
Caution: Exposure to Radio Frequency Radiation.
This device must not be co-located or operating in conjunction with any other antenna or transmitter.
Responsible party:
Otto Bock Health Care, LP
3820 West Great Lakes Drive
Salt Lake City, Utah 84120-7205 USA
Phone + 1-801-956-2400

Fax + 1-801-956-2401

This device complies with RSS 210 of Industry Canada.
Operation is subject to the following two conditions:
(1) this device may not cause interference, and
(2) this device must accept any interference, including interference that may cause undesired operation of this device.

L' utilisation de ce dispositif est autorisée seulement aux conditions suivantes:
(1) il ne doit pas produire d'interference et
(2) l' utilisateur du dispositif doit étre prêt à accepter toute interference radioélectrique reçu, même si celle-ci est susceptible de compromettre le fonctionnement du dispositif.

Caution: Exposure to Radio Frequency Radiation.
The installer of this radio equipment must ensure that the antenna is located or pointed such that it does not emit RF field in excess of Health Canada limits for the general population; consult Safety Code 6, obtainable from Health Canada's website
http://www.hc-sc.gc.ca/rpb.
Responsible party:
Otto Bock Healthcare Canada Ltd.
5470 Harvester Road
L7L 5N5 Burlington, Ontario
Canada
Phone + 1-800-665-3327

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

15 Technical data

Ambient conditions	
Transport in original packaging	-25 °C/-13 °F to +70 °C/+158 °F
Storage in the original packaging (≤3 months)	-20 °C/-4 °F to +40 °C/+104 °F Max. 93% relative humidity, non-condensing
Long-term storage in the original packaging (>3 months)	-20 °C/-4 °F to +20 °C/+68 °F Max. 93% relative humidity, non-condensing
Transport and storage between applications (without packaging)	-25 °C/-13 °F to +70 °C/158 °F Max. 93% relative humidity, non-condensing
Operation	-10 °C/+14 °F to +60 °C/+140 °F Max. 93% relative humidity, non-condensing
Time for warming to the operating temperature after storage between applications, from -25 °C/-13 °F at an ambient temperature of +20 °C/+68 °F	30 minutes
Time for cooling to the operating temperature after storage between applications, from +70 °C/+158 °F at an ambient temperature of +20 °C/+68 °F	30 minutes
Charging the battery	+10 °C/+50 °F to +45 °C/+113 °F

Product	
Reference number	3B5-3* / 3B5-3=ST*

Product	
Mobility grade (MOBIS)	3 and 4
Maximum body weight including additional weight	150 kg
Protection rating	IP66 / IP68 Maximum water depth: 3 m Maximum time: 1 hour
Water resistance	Waterproof, corrosion-resistant, resistant to penetration from jets of water
Range of Bluetooth connection to mobile device	Max. 10 m
Weight of the prosthesis without tube adapter, with Protective Cover	Approx. 1700 g
Information on the product's ruleset and firmware version	Accessible via the Cockpit app navigation menu and the menu item "**Imprint/Info**"
Expected lifetime if prescribed maintenance intervals are complied with	6 years
Test procedure	ISO 10328-P6-150 kg / 3 million load cycles

Data transfer	
Wireless technology	Bluetooth Smart Ready
Range	approx. 10 m / 32.8 ft
Frequency range	2402 MHz to 2480 MHz
Modulation	GFSK, π/4 DQPSK, 8DPSK
Data rate (over the air)	2178 kbps (asymmetrical)
Maximum output power (EIRP):	+8.5 dBm

Tube adapter	
Reference number	2R19
Weight	190 g–300 g
Material	Aluminium
Max. body weight	150 kg
Protection rating	IP66/IP68 Maximum water depth: 3 m Maximum time: 1 hour
Water resistance	Waterproof, corrosion-resistant, resistant to penetration from jets of water
Lifetime	6 years

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 %

Prosthesis battery	
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	Approx. 5 days with average use

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

Battery charger	
Reference number	4E60*
Storage and transport in original packaging	-25 °C to 70 °C/-13 °F to 158 °F
Storage and transport without packaging	-25 °C to 70 °C/-13 °F to 158 °F Max. 93% relative humidity, non-condensing
Operation	5 °C to 40 °C/41 °F to 104 °F Max. 93% relative humidity, non-condensing
Protection rating	IP40
Input voltage	12 V ⎓
Wireless technology	Proprietary protocol
Frequency range	270 kHz to 450 kHz
Modulation	ASK, load modulation
Maximum output power (EIRP)	-12.7 dBµA/m @ 10 m

Cockpit app	
Reference number	4X441-V2=IOS Cockpit/4X441-V2=ANDR Cockpit
Version	Version 2.5.0 or higher
Supported operating system	See the information in the respective online store (e.g. Apple App Store, Google Play Store, etc.) regarding compatibility with mobile devices and versions.
Website for download	https://www.ottobock.com/cockpitapp

16 Appendices

16.1 Symbols Used

Manufacturer

Type BF applied part

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

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

Non-ionising radiation

IP40 Protection against penetration of solid foreign objects with a diameter greater than 1 mm, no protection against water

IP66 Dust-proof, protected against strong jets of water

IP68 Dustproof, protection against permanent submersion.
Maximum depth: 3 m
Maximum time: 1 hour

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.

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

CE Declaration of conformity according to the applicable European directives

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

LOT

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

REF

Article number

MD

Medical device

Caution, hot surface

Protect from moisture

16.2 Operating states/error signals

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

16.2.1 Signals for operating states

Battery charger connected/disconnected

Beep signal	Vibration signal	Event
–	3x long	Charging mode started (3 sec. after connecting the battery charger)
1x short	1x short	Self-test completed successfully, product is operational

Mode switching

INFORMATION

When mute mode (silent mode) is activated, no beep and vibration signals are generated.

INFORMATION

If the **Volume** parameter is set to '0' in the Cockpit app, there are no beep signals (see page 26).

Beep signal	Vibration signal	Additional action performed	Event
1x short	1x short	Mode switching using the Cockpit app	Mode switching is performed using the Cockpit app.
1x long	1x long	Bouncing on the forefoot followed by unloading the prosthetic leg	Bouncing pattern recognised.
1x short	1x short	Weight taken off prosthetic leg and leg kept still for 1 second	Switching to basic mode (mode 1) carried out.

Beep signal	Vibration signal	Additional action performed	Event
2x short	2x short	Weight taken off prosthetic leg and leg kept still for 1 second	Switching to MyMode 1 (mode 2) carried out.
3x short	3x short	Weight taken off prosthetic leg and leg kept still for 1 second	Switching to MyMode 2 (mode 3) carried out.

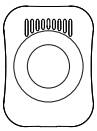
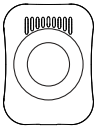
16.2.2 Warnings/error signals

Error during use

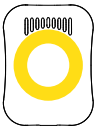
Beep signal	Vibration signal	Event	Required action
–	1x long at intervals of approx. 5 seconds (if mute mode (silent mode) is activated, this signal is not generated)	Overheated hydraulics	Reduce activity.
–	3x long	Battery charge level under 25%	Charge battery soon. Remaining operating time approx. 24 hours
–	5x long	Battery charge level under 10%	Charge battery soon Remaining operating time approx. 6 hours
5x long	5x long repeated every 60 seconds	**Error of moderate severity (see page 35)** e.g. a sensor is not operational	Walking possible with restrictions. Note the change in flexion resistance. The product must be inspected by an O&P professional immediately.
10x long	10x long	Charge level 5% After the beep and vibration signals, the product switches to empty battery mode and then switches off.	Charge the battery.
30x long	1x long, 1x short repeated every 3 seconds	**Severe error/indication of safety mode activation (see page 35)** e.g. one or more sensors are not operational	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 O&P professional immediately.

Beep signal	Vibration signal	Event	Required action
–	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 O&P professional immediately.

Error while charging the product

LED on power supply	Status 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 appliance.
		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.

	Status LED	Charging status indicator (5 LEDs)	Error	Resolution
	The LED ring is lit in weak purple	No LED is lit	Distance between battery charger and receiver of the charging unit on the prosthesis too great. If the distance is more than 2 mm, the prosthesis cannot be charged.	Reduce distance between battery charger and receiver of the charging unit.

	Status LED	Charging status indicator (5 LEDs)	Error	Resolution
	The LED ring is lit up yellow	LED 2 and 4 are lit up	Charger excess temperature	Check whether the specified ambient conditions for charging the battery are met (see page 38).
		LED 1, 3 and 5 are lit up	Excessively high or low temperature of the prosthesis	
		LED 3 is lit up	The prosthesis is not being charged Distance between battery charger and receiver of the charging unit too great.	Connection may be improved by reducing the distance between the charger and receiver of the charging unit.
	The LED ring is lit up green		The battery charger is functional but not connected to the receiver, or the distance between the battery charger and receiver of the charging unit is too great.	Connect the battery charger or reduce the distance between the charger and the receiver of the charging unit on the prosthesis.
	The LED ring is flashing red		The prosthesis is not being charged Defective battery charger.	Reset the error by disconnecting and connecting the power supply. If the error persists, the battery charger and power supply must be inspected by an authorised Ottobock Service Center.

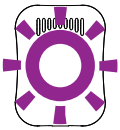
16.2.3 Error messages while establishing a connection with the cockpit app

Error message	Cause	Correction
Component was connected to another device. Establish connection?	The component was connected to another device	To disconnect the original connection, tap the "**OK**" button. If the original connection is not to be disconnected, tap the "**Cancel**" button.
Mode change failed	An attempt was made to switch to a different MyMode while the component was in motion (e. g. while walking)	For safety reasons, switching MyModes is only permitted when components are at rest, e. g. while standing or sitting.

Error message	Cause	Correction
	A current connection to the component was interrupted	Check the following points: • Distance from the component to the device • Charge level of the component's battery • Bluetooth of the component switched on? (Switching Bluetooth of the component on/off) • Hold the component with the sole of the foot facing up to make the component "visible" for 2 minutes. • If multiple components were stored, was the correct component selected?

16.2.4 Status signals

Battery charger connected

LED on power supply	Status LED on battery charger	Event
		Power supply and battery charger operational. Battery charger not yet connected to receiver.
		Battery charger connected to receiver, good connection. This display turns off automatically after approximately one minute to avoid bothersome light at night. The charging process is not affected.

Battery charger disconnected

Beep signal	Vibration signal	Event	Resolution
1x short	1x short	Self-test completed successfully. Product is operational.	

Beep signal	Vibration signal	Event	Resolution
3x short	3x short	Maintenance note: E.g.: Maintenance interval has been exceeded, temporary disruption of a sensor signal	• Use the Cockpit app to check the next maintenance date for the prosthesis (see page 30). If the date is within the next month, make a maintenance appointment with the O&P professional. For this appointment, the O&P professional has to be provided with the battery charger and power supply in addition to the prosthesis and tube adapter. • Conduct the self-test again by connecting/disconnecting the battery charger. • If the beep is emitted again and the maintenance date has not been reached or exceeded, you should visit the O&P professional soon. If necessary, the O&P professional will forward the prosthesis to an authorised Ottobock Service Center. • The product can be used without restrictions. However, vibration signals may not be generated.

Battery charge level
During the charging process, the current battery charge level is indicated by the number of LEDs lit on the side of the charger.

LEDs	0	1	2	3	4	5
Battery charge level	0%-10%	10%-30%	30%-50%	50%-70%	70%-90%	>90%

16.3 Directives and manufacturer's declaration

16.3.1 Electromagnetic environment

This product is designed for operation in the following electromagnetic environments:
- Operation in a professional healthcare facility (e.g. hospital, etc.)
- Operation in areas of home healthcare (e.g. use at home, use outdoors)

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

Electromagnetic emissions

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

Electromagnetic interference immunity

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

Interference resistance against wireless communication devices

Test frequency [MHz]	Frequency band [MHz]	Radio service	Modulation	Maximum power [W]	Distance [m]	Interference immunity test level [V/m]
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	1.8	0.3	28
710	704 to 787	LTE band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, GSM 800/900, LTE band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1,720	1,700 to 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1,845						
1,970						
2,450	2,400 to 2,570	Bluetooth WLAN 802.11 b/g/n, RFID 2450 LTE band 7	Pulse modulation 217 Hz	2	0.3	28
5,240	5,100 to 5,800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5,500						
5,785						

Immunity to magnetic fields in close range

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

The product 3B5-3/3B5-3=ST is covered by the following patents:

Canada:	CA 2 651 124; CA 2 714 469; CA 2 780 511; CA 2 704 792; CA 2 626 738;CA 2 780 192; CA 2 779 784
China:	CN 101 453 963; CN 101 909 553; CN 101 938 958; CN 102 711 672; CN 102 647 963; CN 101 346 110; CN 102 740 804; CN 102 762 171; CN 102 724 936; CN 102 740 803; CN 104 856 787
Finland:	FI 110 159
Germany:	DE 10 2008 010 281: DE 10 2009 052 887
Japan:	JP 4 718 635; JP 5 619 910; JP 5 547 091; JP 5 394 579;JP 5 968 591; JP 5 678 079; JP 6 109 793;
Russia:	RU 2 404 730; RU 2 484 789; RU 2 533 967; RU 2 488 367; RU 2 508 078; RU2 572 741
Taiwan:	R.O.C. Invention Patent No. I386194; I459936; I442912; I494095; I551277; I551278; 530278; I542335; I519292; I517845
USA:	US 7 731 759; US 6 908 488; US 8 083 807, US 8 474 329; US 8 876 912; US 8 814 948; US 9 066 818; US 9 278 013; US 9 248 031; US 9 572 690
European Patent	EP 1237513 in DE, FR, GB EP 2015712 in DE, ES, FR, GB, IT, NL, SE, TR EP 2240124 in DE, FR, GB, IT, NL, SE, TR EP 2498724 in DE, FR, GB, IS, IT, NL, SE, TR EP 2498725 in DE, FR, GB EP 2498726 in DE, FR, GB, IS, IT, NL, SE, TR EP 2498727 in DE, FR, GB, IS, IT, NL, SE, TR EP 2498729 in DE, FR, GB EP 2498730 in DE, FR, GB EP 2498728 in DE, FR, GB EP 2254525 in DE, FR, GB, IS, IT, NL, TR EP 2222253 in DE, FR, GB, IS, IT, NL, SE, TR EP 1940327 in DE, FR, GB, IS, IT, NL, SE, TR EP 2772232 in DE, GB, FR, IT, NL, SE, TR, IS

Patents pending in Brazil, Germany and USA

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