

C-Brace joint unit 17K01=*^{*}

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

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

EN | INFORMATION

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

FR | INFORMATION

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

ES | INFORMACIÓN

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

IT | INFORMAZIONE

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

PT | INFORMAÇÃO

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

NL | INFORMATIE

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

SE | INFORMATION

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

DA | INFORMATION

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

NO | INFORMASJOU

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

FI | TIEDOT

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

CZ | INFORMACE

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

PL | INFORMACJA

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

TR | INFORMATION

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

RU | ИНФОРМАЦИЯ

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

JA | 備考

冊子版取扱説明書とCDには他言語版もございます(裏表紙を参照)。

下記までご連絡いただければ、各国の言語による冊子版取扱説明書を無料で送付いたします。

ZH | 信息

除了该使用说明书印刷件之外，CD中还附有其它语言的版本（参见封底）。

如有需要，您可以按照下列地址免费索取您所在国家语言的印刷版使用说明书。

Ottobock Healthcare Products GmbH

Brehmstraße 16 | 1110 Wien | Austria

Service-admin.vienna@ottobock.com | Fax (+43-1) 526 79 85

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1 Foreword

INFORMATION

Date of last update: 2020-05-19

- ▶ Please read this document carefully before using the product and observe the safety notices.
- ▶ Instruct the user in the safe use of the product.
- ▶ Please contact the manufacturer if you have questions about the product or in case of problems.
- ▶ Report each serious incident in connection with the product, in particular a worsening of the state of health, to the manufacturer and to the relevant authority in your country.
- ▶ Please keep this document for your records.

The product "C-Brace joint unit 17KO1=*" is referred to as the product/component/orthosis/joint unit below.

These instructions for use provide you with important information on the use, adjustment and handling of the product "17KO1=* C-Brace joint unit".

More details about installing the joint unit are found in the section "Preparation for use" (see Page 23).

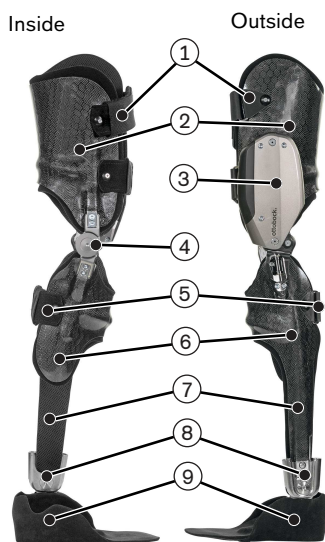
Only put the product into use in accordance with the information contained in the accompanying documents supplied.

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

2 Product description

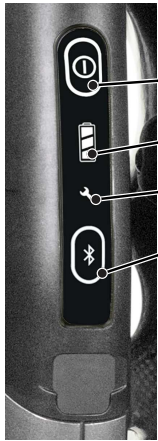
2.1 Design

The fabricated orthosis and the course of the orthosis shell edges can be individually designed. For this reason, the following illustration and the illustration on the cover page of these instructions for use only show one possible version:



1. Thigh closure straps
2. Thigh shell
3. 17KO1=* C-Brace joint unit with control panel
4. Medial joint support
5. Lower leg closure straps
6. Lower leg shell
7. Connecting element to ankle joint.
The connection can also be established with a dorsal spring element.
8. Ankle joint
9. Foot component

2.1.1 Control panel on the joint unit



1. Long button press: turns the component on/off (see Page 41)
Short button press: queries the status (see Page 51)
2. Displays the charge level of the integrated battery (see Page 22)
3. Maintenance required (see Page 51)
4. Long button press: turns the Bluetooth function on/off (see Page 42).
Short button press: if the Bluetooth function is on, the component becomes "visible" for about 2 minutes so it can be detected by another device such as a smartphone.



Under the cover at the end of the control panel: Charging receptacle to connect the battery charger (see Page 20)

2.2 Function

The product is an orthopaedic device that makes everyday activities such as standing and walking possible or easier for the patient. If the patient's activity level increases in the course of use, adjustments may be required. Changes will also have to be made if the patient's physical condition worsens and more support from the product is needed.

This product features microprocessor control of the stance and swing phase (SSCO).

The microprocessor uses the measurements of an integrated sensor system as a basis to control a hydraulic unit that influences the extension and flexion resistance of the product.

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

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

For this purpose, the product is configured with the "C-Brace Setup" adjustment app using a tablet.

The product features MyModes for special motion types (e.g. cycling ...). These are pre-configured using the adjustment app and can be activated using the Cockpit app (see Page 44).

In case of an error in the sensor system, hydraulic control or when the battery is empty, safety mode makes restricted operation possible. Resistance parameters that are predefined by the product are configured for this purpose (see Page 46).

The microprocessor-controlled hydraulic unit offers the following advantages

- Approximation of the physiological gait pattern
- Stability while standing and walking
- Adaptation of product characteristics to various surfaces, inclines, gait situations and walking speeds

Essential performance of the product

- Stability in the stance phase

2.3 Combination possibilities

- 17KF100=16* C-Brace medial support
- 17LA3N=* Ankle joint
- 17AO100=* ankle joint
- 17AD100=* Ankle joint
- Individually fabricated spring element, at the discretion of the O&P professional, as connection to the foot component

- Prosthetic components
Ottobock has to be contacted prior to combination with prosthetic components.

Weight restriction for the use of ankle joints

Combination with the 17LA3N=*, 17AO100=* and 17AD100=* ankle joints is permitted only in the ranges listed below (see table).

	< 85 kg	85–110 kg	110–125 kg
Unilateral ankle joint	17AO100=22-T		–
Bilateral ankle joint	17LA3N=16-T	–	
	17AD100=16-T		
	17LA3N=20-T		–
	17AD100=20-T		
	17AO100=22-T		

3 Application

3.1 Indications for use

The product is intended **solely** for orthotic fittings of the lower limbs.

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.), sports activities that involve jumping, sudden movements or fast sequences of steps (e.g. basketball, badminton, sporty riding).

Permissible ambient conditions are described in the technical data (see Page 49).

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

3.3 Indications

- Unilateral or bilateral lower limb paresis or flaccid paralysis, e.g. due to post-polio syndrome, traumatic paresis, incomplete paraplegia.
- Physical prerequisites such as muscle status, joint mobility and possible axis deviations are crucial and proper control of the orthosis must be guaranteed.
- The user must fulfil the physical and mental requirements for perceiving optical/acoustic signals and/or mechanical vibrations
- The existing muscle strength of the hip extensors and flexors must permit the controlled swing-through of the limb (compensation using the hip is possible).

3.4 Contraindications

3.4.1 Absolute Contraindications

- Flexion contracture in the knee and/or hip joint in excess of 10°
- Knee varus/valgus malposition in excess of 10°
- Severe spasticity
- Body weight over 125 kg / 275 lbs

3.4.2 Relative Contraindications

- Moderate spasticity

3.5 Qualification

3.5.1 Qualification of the O&P professional




The fitting of a patient with the product may only be carried out by O&P professionals who have been authorised with the corresponding Ottobock training.

3.5.2 Qualifications of the therapist or nursing staff


The therapists or nursing staff must be trained in handling the product. Training must be carried out by the authorised orthopaedic technician.

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


<p> WARNING</p> <p>The heading describes the source and/or the type of hazard</p> <p>The introduction describes the consequences in case of failure to observe the safety instructions. Consequences are presented as follows if more than one consequence is possible:</p> <ul style="list-style-type: none"> > E.g.: Consequence 1 in 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

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

<p> WARNING</p> <p>Use of damaged power supply unit, adapter plug or battery charger</p> <p>Risk of electric shock due to contact with exposed, live components.</p> <ul style="list-style-type: none"> ▶ Do not open the power supply unit, adapter plug or battery charger. ▶ Do not expose the power supply unit, adapter plug or battery charger to extreme loading conditions. ▶ Immediately replace damaged power supply units, adapter plugs or battery chargers.

<p> CAUTION</p> <p>Failure to observe warning/error signals</p> <p>Falling due to unexpected product behaviour because of changed damping behaviour.</p> <ul style="list-style-type: none"> ▶ The warnings/error signals (see Page 51) and corresponding change in damping settings must be observed.

<p> CAUTION</p> <p>Penetration of dirt and moisture into components of the orthosis</p> <ul style="list-style-type: none"> > Falling due to unexpected behaviour of the orthosis as a result of malfunction. > Falling due to breakage of load-bearing components. ▶ Ensure that neither solid particles, foreign bodies nor liquids penetrate the orthosis components. ▶ The orthosis components are protected against splashed water from all directions. ▶ However, the orthosis components are not protected against submersion, jets of water and steam. ▶ If water has penetrated the components of the orthosis, remove the straps and pads if possible and allow the components to dry. ▶ In case of a malfunction after drying, the orthosis must be inspected by an authorised Ottobock Service Centre. ▶ Always close the charging receptacle with the protective cap after disconnecting the charging cable.

⚠ CAUTION

Independent manipulations on the joint unit and orthosis components

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

- ▶ Manipulations on the joint unit and orthosis components other than the tasks described in these instructions for use are not permitted.
- ▶ The battery may only be handled by Ottobock authorised, qualified personnel (no replacement by the user).
- ▶ The joint unit and orthosis components may only be opened and repaired by authorised, qualified Ottobock personnel.

⚠ CAUTION

Use of the product when battery charge level is too low

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

- ▶ Check the current charge level before use and charge the product 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

Mechanical stress during transport

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

⚠ CAUTION

Signs of wear and tear on the product components

Falling due to damage or malfunction of the product.

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

⚠ CAUTION

Use of unapproved accessories

- > Falling due to product malfunction as a result of reduced interference resistance.
- > Interference of other electronic devices due to increased emissions.
- ▶ Use the product only in combination with the accessories, signal converters and cables listed in the sections "Scope of delivery" (see Page 20) and "Accessories" (see Page 20).

NOTICE

Improper product care

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

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

INFORMATION

Movement noises of the joint unit

When using orthotic 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 noises increase noticeably during the lifecycle of the orthosis, the orthosis should be inspected promptly by an authorised Ottobock Service Centre.

4.4 Information on the Power Supply/Battery Charging

⚠ 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.

⚠ CAUTION

Charging while wearing the product

- > Falling due to walking and getting caught on the connected battery charger.
- > Falling due to unexpected product behaviour because of changed damping behaviour.
- ▶ Inform the patient that the product may only be charged while sitting down.

NOTICE

Use of incorrect power supply unit/battery charger

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

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

4.5 Battery charger information

NOTICE

Penetration of dirt and humidity into the product

Lack of proper charging functionality due to malfunction.

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

NOTICE

Mechanical stress on the power supply/battery charger

Lack of proper charging functionality due to malfunction.

- ▶ Do not subject the power supply/battery charger to mechanical vibrations or impacts.
- ▶ Check the power supply/battery charger for visible damage before each use.

NOTICE

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

Lack of proper charging functionality due to malfunction.

- ▶ Only use the power supply unit/charger for charging within the allowable temperature range. The section "Technical data" contains information on the allowable temperature range (see Page 49).

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.

INFORMATION

Depending on the battery charge level, the battery charger can warm up considerably during the charging process. This is not a malfunction.

4.6 Information on Alignment/Adjustment

⚠ CAUTION

Improper assembly of the screw connections

Falling due to breakage or loosening of the screw connections.

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

⚠ CAUTION

Incorrectly secured screws

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

- ▶ Before installing the joint unit and joint mechanism, the screws must be secured before they are tightened to the specified tightening torque (see the section "Technical data" see Page 49).

⚠ CAUTION

Operator errors during the adjustment process with the adjustment app

Falling due to unexpected orthosis behaviour.

- ▶ Do not charge the orthosis battery during the adjustment process since the orthosis is not functional while the battery is being charged.
- ▶ The orthosis must not remain unattended during the adjustment process while connected to the adjustment software and being worn by the patient.
- ▶ Observe the maximum range of the Bluetooth connection and note that obstacles may limit this range.
- ▶ During the data transfer (tablet to orthosis), the user should sit still or stand with support.
- ▶ If only temporary changes to the settings are to be made while connected to the adjustment app, these changes must be reversed before the adjustment app is closed.
It must also be ensured that the patient does not leave the range of the Bluetooth connection with settings that have been changed temporarily.
- ▶ Inform the patient immediately if the data connection is accidentally interrupted during the adjustment process.
- ▶ The connection to the orthosis must always be disconnected after adjustments have been completed.
- ▶ Participation in an Ottobock product training course is mandatory prior to the initial use of the product. Additional product training courses may be required to qualify for software updates.
- ▶ Correctly entering the patient data and especially the body weight is an important criterion for the quality of the fitting. If the values are too high, the orthosis may not switch to the swing phase. If the values are too low, the orthosis may trigger the swing phase at the wrong time.
- ▶ When entering the weight and dimensions, note the settings for the units. To change the units, see the section "Changing the units for weight and length" (see Page 26).
- ▶ If the patient uses walking aids (e.g. crutches or walking canes) during the adjustment process, readjustment is required as soon as the patient stops using these walking aids.
- ▶ Do not pass on your personal access data.

⚠ CAUTION

Use of unsuitable orthosis components

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

- ▶ Use the product only in combination with components listed in the section "Combination possibilities" (see Page 9).

⚠ CAUTION

Disassembling the joint unit on a standing patient

- > Risk of falls due to lack of support from the product.
- > Damage to the medial support.
- ▶ Disassemble the joint unit only on a sitting patient or with the orthosis taken off.

4.7 Notes on applying the product

⚠ CAUTION

Foreign objects between the leg and orthosis shells

Pressure points on the leg due to foreign objects at the contact points between the leg and orthosis shells.

- ▶ Smooth out wrinkles in the padding material and clothing.
- ▶ Check the leg for pressure points.

⚠ CAUTION

Improper fit of the orthosis

Falling/skin irritation due to insufficient support/hold by the orthosis shells.

- ▶ Take the orthosis off immediately and put it back on.
- ▶ Observe the instructions for applying and removing.

⚠ CAUTION

Pinching skin in the area of the closures

Injuries and swelling due to disruption of blood circulation to the skin in the area of the closures.

- ▶ Do not over-tighten the closures when applying the product.

⚠ CAUTION

Volume fluctuations of the leg or problems with the fit of the orthosis

Injuries, friction and local pressure caused by improper fit of the orthosis shells (too firm/too loose).

- ▶ Sensitivity problems and skin damage require special attention with regard to the fit. Instruct the patient to inspect the skin areas daily.
- ▶ The patient should consult a doctor or O&P professional if there are any signs of skin damage, even if they are only minor.
- ▶ If the improper fit is the result of weight gain or loss, new thigh shells and lower leg shells have to be fabricated based on a new plaster cast.
- ▶ Check the leg for pressure points.

4.8 Information on Proximity to Certain Areas

⚠ CAUTION

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

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

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

⚠ CAUTION

Operating the product in very close proximity to other electronic devices

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

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

⚠ CAUTION

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

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

- ▶ Ensure that the patient is not in the vicinity of sources of strong magnetic and electrical interference during trial fitting (such as theft prevention systems, metal detectors...).
If this cannot be avoided, ensure at least that the patient has a safeguard when walking or standing (e.g. a handrail or the support of another person).
- ▶ In general, monitor the product for unexpected changes in the damping behaviour when electronic or magnetic devices are in the immediate vicinity.

⚠ CAUTION

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

- > Falling due to unexpected restriction of the product's range of motion caused by metallic objects adhering to the magnetised components.
- > Irreparable damage to the product due to the effect of strong magnetic fields.
- ▶ Make sure that the patient takes off the product before entering the room or area and stores the product outside this room or area.
- ▶ Damage to the product caused by exposure to strong magnetic fields cannot be repaired.

⚠ CAUTION

Remaining in areas outside the allowable temperature range

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

- ▶ Ensure that the patient is not in areas outside the permissible temperature range (see Page 49) during trial fitting.

4.9 Information on Use

⚠ CAUTION

Improper mode switching

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

- ▶ Ensure that the patient stands securely during all switching processes.
- ▶ Inform the patient that the changed damping characteristics have to be verified after switching and feedback from the acoustic signal emitter must be observed.
- ▶ Switching back to basic mode is mandatory once the activities in MyMode have been completed.
- ▶ If required, take the weight off the product and correct the switching.

⚠ CAUTION

Risk of pinching in the joint flexion area

- > Injury due to pinching of body parts.
- > Damage to garments due to pinching in the mechanism of the joint unit or medial support.
- ▶ Ensure that no body parts or garments are in this area when flexing the product.

⚠ 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.
- ▶ Inform the patient that they must pay attention when pulsating vibration signals start. They indicate the risk of overheating.
- ▶ Inform the patient that the activity level has to be reduced immediately when these pulsating vibration signals begin, so the hydraulic unit can cool down.
- ▶ Inform the patient that full activity may be resumed after these 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 has to be inspected by an authorised Ottobock Service Centre.

⚠ CAUTION**Overloading due to unusual activities**

- > Falling due to unexpected product behaviour as the result of a malfunction.
- > Falling due to breakage of load-bearing components.
- > Skin irritation due to defects on the hydraulic unit with leakage of liquid.
- ▶ The product was developed for everyday use and must not be used for unusual activities. These unusual activities include, for example, extreme sports (free climbing, parachuting, paragliding, etc.), sports activities that involve jumping, sudden movements or fast sequences of steps (e.g. basketball, badminton, sporty riding).
- ▶ 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. If necessary, forward the product to an authorised Ottobock Service Centre.

4.10 Notes on the movement patterns**⚠ CAUTION****Improper use of the stance function**

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

- ▶ Make sure that the patient is standing safely when using the stance function and checks the lock of the knee joint before placing their full weight on the orthosis.
- ▶ Instruct the patient in the correct use of the stance function. Information on the stance function see Page 28.

⚠ CAUTION**Walking up stairs**

- > Falling due to foot being placed incorrectly on stair as a result of changed damping behaviour.
- > Falling due to breakage of load-bearing components.
- ▶ Ensure that the patient uses the handrail when walking up stairs and places most of the sole of the foot on the stair surface.
- ▶ Always step up with the less affected leg, followed by the leg with the product.
- ▶ If there is a connection to a foot component, support by bouncing with the product extended while walking up stairs is not allowable and therefore has to be avoided.
- ▶ Particular caution is required when carrying children up the stairs.

⚠ CAUTION**Walking down stairs with moveable orthosis foot component**

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

- ▶ Inform the patient that the handrail always has to be used when walking down stairs, and that most of the sole of the foot has to be set onto the stair surface.
- ▶ The warnings and error signals have to be observed (see Page 51).
- ▶ Notify the patient that resistance in the flexion and extension direction can change in case of warnings and error signals.
- ▶ Particular caution is required when carrying children down the stairs.

⚠ CAUTION**Walking down stairs with rigid orthosis foot component**

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

- ▶ Inform the patient that the handrail always has to be used when walking down stairs, and that the patient has to roll over the edge of the step with the middle of the shoe.
- ▶ The warnings and error signals have to be observed (see Page 51).
- ▶ Notify the patient that resistance in the flexion and extension direction can change in case of warnings and error signals.
- ▶ Particular caution is required when carrying children down the stairs.

⚠ CAUTION

Walking down stairs and ramps

Falling due to unexpected, increased stance phase damping during the transition from walking on the level to stairs or ramps, for example when the orthosis is in a MyMode.

- ▶ Inform the patient of the changed product behaviour, especially in the MyModes.
- ▶ Inform the patient that changed stance phase damping has to be verified before walking on stairs or ramps.

⚠ CAUTION

Lack of support from the product when walking down stairs

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

- ▶ Inform the patient that it is essential to check whether corresponding flexion of the joint is possible before walking down stairs. If this is not possible, either the Cockpit app or turning the product off/on must be used to switch back to basic mode.

⚠ CAUTION

Improper use of the MyMode "Training mode"

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

- ▶ Make sure that the patient is standing safely when using this MyMode and checks the lock of the knee joint before placing their full weight on the orthosis.
- ▶ Inform the patient that the knee joint is locked in the flexion direction in this MyMode. For information about this mode, see Page .
- ▶ Switching back to basic mode is mandatory once the activities in this MyMode have been completed.

⚠ CAUTION

Improper use of the MyMode "Freeze position"

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

- ▶ Make sure that the patient is standing safely when using this MyMode and checks the lock of the knee joint before placing their full weight on the orthosis.
- ▶ Inform the patient that the knee joint is locked in the both the flexion and extension direction in this MyMode. For information about this mode, see Page .
- ▶ Switching back to basic mode is mandatory once the activities in this MyMode have been completed.

⚠ CAUTION

Lack of support from the product while sitting down

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

- ▶ Inform the patient that it is essential to check whether corresponding flexion of the joint is possible before sitting down. If this is not possible, either the Cockpit app or turning the product off/on must be used to switch back to basic mode.

⚠ CAUTION

Quickly pushing the hip forward with the orthosis extended

> Falling due to unexpected activation of the swing phase.

- ▶ Note that the joint may flex unexpectedly when the hip is pushed forward quickly while the orthosis is extended.
- ▶ With the patient, practice movement patterns where this behaviour can occur. If the patient participates in sports where this movement pattern can occur, configure a corresponding "user-defined MyMode" using the adjustment app.

⚠ CAUTION

Changing the gait pattern influences activation of the swing phase

> Falling due to unexpected activation of the swing phase.

- ▶ Inform the patient that changing the gait pattern influences activation of the swing phase. Adjustment by the O&P professional has to be repeated in this case.

4.11 Notes on the safety modes

⚠ CAUTION

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

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

- ▶ Using the product when it is defective is prohibited.
- ▶ The product must be inspected by an authorised Ottobock Service Centre.

⚠ CAUTION

Safety mode cannot be deactivated

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

- ▶ If safety mode cannot be deactivated by recharging the battery, a permanent error has occurred.
- ▶ Using the product when it is defective is prohibited.
- ▶ The product must be inspected by an authorised Ottobock Service Centre.

⚠ CAUTION

Safety signal occurs (ongoing vibration)

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

- ▶ The warnings/error signals (see Page 51) have to be observed.
- ▶ After the safety signal has been emitted, further use of the product is prohibited.
- ▶ The product must be inspected by an authorised Ottobock Service Centre.

⚠ CAUTION

Using the product in safety mode

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

- ▶ The warnings/error signals (see Page 51) have to be observed.
- ▶ Particular caution is necessary when using a bicycle without a freewheel (with a fixed gear).

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

⚠ CAUTION

Improper use of the mobile device

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

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

⚠ 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 mobile device

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

- ▶ Ensure that the patient stands securely during all switching processes.
- ▶ Inform the patient that the changed damping characteristics have to be verified after switching, and feedback from the acoustic signal emitter and the mobile device display must be observed.
- ▶ Switching back to basic mode is mandatory once the activities in the MyMode have been completed.

NOTICE

Destruction of the mobile device due to falling or penetration of water

Malfunction of the mobile device.

- ▶ If necessary, let the mobile device dry at room temperature (at least 1 day).
- ▶ Should it no longer be possible to switch back from a MyMode to basic mode, the component can only be switched back to basic mode by turning it off/on (see Page 41).

NOTICE

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

Malfunction of the mobile device.

- ▶ Install the Cockpit app only on the operating systems listed in the section "System requirements" (see Page 32).

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. 757L16-4 power supply
- 1 pc. 4E50-2 C-Leg battery charger
- 1 pc. cosmetic case for battery charger and power supply
- 2 pc. 646C107 Bluetooth PIN card
- 1 pc. Orthotic passport
- 1 pc. 17KO1=L C-Brace joint unit left, or 17KO1=R C-Brace joint unit right
- 1 pc. Instructions for use (qualified personnel)
- 1 pc. Instructions for use (user)

5.2 Accessories

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

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

The "C-Brace Setup" adjustment app is available for download from the Apple App Store or Google Play. Enter the following search terms: Ottobock, C-Brace, C-Brace Setup

- iOS app "560X17-IOS=V* C-Brace Setup"
- Android app "560X17-ANDR=V* C-Brace Setup"

The following additional padding materials are recommended:

- 623P3 terry cloth padding fabric
- 623F62 SpaceTex padding fabric

6 Charging the battery

The following points must be observed when charging the battery:

- Use the 757L16-4 power supply and 4E50-2 battery charger to charge the battery.
- With uninterrupted walking, the capacity of the fully charged battery is sufficient for at least 18 hours. It lasts about 2 days with average use.
- We recommend charging the product once a day when used by the patient on a daily basis.
- The battery should be charged for at least 3 hours prior to initial use.
- For the maximum operating time with one battery charge, turning the product off when it is not being used is recommended.

- Switching the MyModes and changing setting parameters using the Cockpit app is not possible during the charging process.
- After disconnecting the battery charger, the orthosis is in the same state it was in before connecting the battery charger. For example, if the orthosis was switched off before connecting the battery charger, it will also be switched off after disconnecting the battery charger.

6.1 Connecting the power supply and battery charger




- 1) Slide the country-specific plug adapter onto the power supply until it locks into place (see fig. 1).
 - 2) Connect the round, **four-pin** plug of the charging cable to the **OUT** receptacle on the battery charger so that the plug locks into place (see fig. 2).
INFORMATION: Ensure correct polarity (guide lug). Do not use force when connecting the cable plug to the battery charger.
 - 3) Connect the round, **three-pin** plug of the power supply to the **12 V** receptacle on the battery charger so that the plug locks into place (see fig. 2).
INFORMATION: Ensure correct polarity (guide lug). Do not use force when connecting the cable plug to the battery charger.
 - 4) Plug the power supply unit into the wall socket.
→ The green LED on the back of the power supply (see fig. 3) and the green LED on the battery charger light up.
- If the green LED on the power supply and the green LED on the battery charger do not light up, there is an error (see Page 55).

6.2 Connect battery charger to the product



- 1) Open the charging receptacle cover.
- 2) Connect the charging plug to the charging receptacle of the product.
INFORMATION: Take note of the plug direction!
→ After the displays are tested, a short beep is emitted followed by three short vibration signals.
→ If the **!** symbol lights up, this means an error was identified during the self-test (see Page 51).
- 3) The charging process starts.
→ To check the charge level while the battery charger is connected, briefly press the **!** button on the control panel.
- 4) Disconnect the product after the charging process is complete.
→ After disconnecting the battery charger, a vibration signal is emitted followed by a short beep, and the current status is displayed for approx. 5 seconds (see Page 51).
→ When the symbol in the **!** button is lit up green **!**, the product is switched on and ready for operation.
- 5) Close the charging receptacle cover.

INFORMATION

After disconnecting the battery charger, the orthosis is in the same state it was in before connecting the battery charger. For example, if the orthosis was switched off before connecting the battery charger, it will also be switched off after disconnecting the battery charger. A descending sequence of beeps is emitted when the battery charger is disconnected while the orthosis is switched off .

INFORMATION
No display after connecting the battery charger
If no symbols light up on the control panel after connecting the battery charger, the battery may be deep discharged. Leave the battery charger connected for at least 15 minutes and check the charge level while charging by disconnecting/connecting the battery charger.

6.3 Display of the current charge level

6.3.1 Display of battery charge level without additional devices

The current charge level of the installed battery can be displayed by briefly pressing the ⓘ button:

Symbol	Battery charge level
	Charge level 67% to 100%
	Charge level 34% to 67%
	Charge level 10% to 34%
	Charge level 5% to 10%
	Charge level 1% to 5%
	Battery empty

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:



- 38% – Charge level of battery for currently connected component

6.3.3 Display of the current charge level using the adjustment app

Once the adjustment app has been started and connected to the component, the current charge level is displayed in the bottom line of the screen:



- 98% – Charge level of battery for currently connected component

6.3.4 Display of the current charge level during the charging process

After connecting the battery charger or pressing the ⓘ button while the battery charger is connected, the current charge level is shown by an animated symbol on the control panel in addition to the display on the battery charger (, ,).

Control panel	Battery charger	
	● ● ⓘ	Battery is being charged, battery charge level is less than 34%
		Battery is being charged, battery charge level is 34% to 50%
	● ● ⓘ	Battery is being charged, battery charge level is 50% to 67%
	The on time of the yellow LED gets shorter as the charge level increases. It only flashes briefly at the end of the charging process.	Battery is being charged, battery charge level is 67% to 99%
		Battery is fully charged

7 Preparing the product for use

7.1 Assembling/disassembling the joint unit on the orthosis



Assembling the joint unit on the orthosis (see fig. 9)

CAUTION

Reusing the screws to assemble the joint unit on the frame after maintenance

Falling due to breakage of screws that are reused to assemble the joint unit.

- ▶ The mounting screws of the joint unit have to be replaced each time after maintenance. This is required at least every 24 months or after reaching one million steps.
- ▶ To assemble the loaner unit and subsequently the joint unit after maintenance, use the screw set that is included with the loaner unit or can be ordered under article number 17KO1A=SET-1.

INFORMATION

Use thread lock

During assembly of the joint unit, the screws must be secured with Loctite 241 (636K13).

- 1) Ensure that the anchor nuts protruding from the carbon are clean.
- 2) Place the adapter plate onto the lower leg shell, secure it with the 2 screws (M6) and tighten with a torque wrench to 7 Nm.
- 3) Place the joint unit onto the thigh shell of the orthosis and secure it with the 3 long screws (M5x40).
- 4) Place the joint unit onto the adapter plate on the lower leg shell and secure it with the 3 short screws (M5x8).
- 5) Tighten all screws to 7 Nm using the torque wrench.
- 6) Calibrate the joint unit on the patient and configure additional settings using the "C-Brace Setup" adjustment app.

Disassembling the joint unit from the orthosis (screw position see fig. 8)

CAUTION

Disassembling the joint unit on a standing patient

- > Risk of falls due to lack of support from the product.
- > Damage to the medial support.
- ▶ Disassemble the joint unit only on a sitting patient or with the orthosis taken off.

- 1) Read out the joint unit data with the adjustment app ("**Data overview**" (see Page 31)).
- 2) Loosen and remove the 3 screws (1) of the joint unit (lower leg shell).
- 3) Loosen and remove the 3 screws (2) of the joint unit (thigh shell).
- 4) Remove the joint unit.
- 5) Loosen and remove the 2 adapter plate screws.
- 6) Remove the adapter plate from the lower leg shell.
- 7) Clean the threads of the anchor nuts, anchor plate and adapter plate.
Before reassembling the joint unit, all residues of the thread lock must be removed from the threads.

8 "C-Brace Setup" adjustment app



The "C-Brace Setup" adjustment app makes it possible to optimise the product settings for a patient. The adjustment app provides step-by-step guidance through the adjustment process. After the settings are configured, the settings data can be exported in PDF format. The adjustment app is also used for configuration of the Cockpit app.

INFORMATION

Demo mode of the adjustment app

A demo mode can be started by tapping the "**Start demo mode**" button in the bottom right corner of the screen. This mode makes it possible to demonstrate the functionality of the adjustment app without a connection to a component. The information "**Demo mode active**" is displayed in the status bar at the bottom while the demo mode is active.

Tap the "**End demo mode**" button to exit demo mode.

INFORMATION

Text cut off on the screen

Large font sizes in combination with small screens can cause text on the screen to be cut off or illegible. Information about the functions of the controls and adjustment parameters in the adjustment app is provided in these instructions for use.

- Keep the mobile app up to date at all times.
- Please contact the manufacturer if you suspect cybersecurity problems.

8.1 System requirements

The functioning of the "C-Brace Setup" adjustment app was tested on a Samsung Galaxy Tab A SM-T58x with Android 7.0.

The following mobile devices and operating systems are supported:

iOS (Apple)

- iPad (4th generation or later)/iPad mini (2nd generation or later)/iPad Air (all versions)/iPad Pro (all versions)
- From iOS 10.3.4 to iOS13.x/iPad OS 13.x

Android

- Android 5.1 to 10.x
- **Screen sizes:** 7" to 13.3"

8.2 Starting the adjustment app

Initial login

- 1) Tap the "C-Brace Setup" (🔧) symbol.
→ The end user licence agreement (EULA) is displayed.
- 2) Accept the end user licence agreement (EULA) by tapping the "**Accept**" button. If the end user licence agreement (EULA) is not accepted, the adjustment app cannot be used.
→ The login screen is displayed.
- 3) Enter the relevant information that was provided during the Ottobock product training course for the adjustment app in the "**User name**" and "**Unlock-PIN**" fields.
INFORMATION: The use of uppercase and lowercase letters must be observed for the input.
- 4) Tap the "**Log in**" button.
→ The screen to enter the password is displayed.
- 5) Enter and confirm a password of your choice. This password replaces the unlock PIN at the next login. Entering the password is required for the login.
INFORMATION: This password entry window only appears after entering the unlock PIN. When a password has already been entered during the login, the password entry screen will not appear.

- 6) Tap the **"OK"** button to assign the password to the user and save it. The last 5 users who have logged in are saved on the tablet with their username and the corresponding password. When logging in again, these users can be chosen from a list during input of the username.
 - The "App settings" screen is displayed.
- 7) Tap the desired units for weight and length.
- 8) Tap the **"OK"** button to assign the selected units to the user and save the setting. The next time this user logs in, the saved setting for the units is applied. To subsequently change the units, see the section "Changing the units for weight and length" (see Page 26).
 - The screen for establishing the connection to the component appears.
- 9) See the next section for establishing a connection to the component.

Logging in with a previously saved password

- 1) Tap the "C-Brace Setup" (🔗) symbol.
 - The login screen is displayed.
- 2) Enter the username and password in the **"User name"** and **"Password"** fields. The last 5 users who logged in on this tablet can also be chosen from the list that is displayed during input.
- 3) Tap the **"Log in"** button.
 - After logging in, the length and weight units configured and saved during the user's initial login are used. To subsequently change the units, see the section "Changing the units for weight and length" (see Page 26).
 - The screen for establishing the connection to the component appears.
- 4) See the next section for establishing a connection to the component.

8.3 Establishing the connection between the adjustment app and component

The following points should be observed before the initial connection:

- The component must be switched on (see Page 41).
- Bluetooth of the component must be switched on (see Page 42).
- Bluetooth of the tablet must be switched on.
- The serial number and Bluetooth PIN of the component being connected must be known. They are found on the enclosed Bluetooth PIN card. The serial number begins with the letters "SN".

INFORMATION

If the Bluetooth PIN card with the Bluetooth PIN and serial number of the component is lost, the Bluetooth PIN for an already connected component can be determined using the adjustment app. If the Bluetooth PIN is needed even to start the adjustment app, please contact an authorised Ottobock service centre. The serial number must be provided so a new card can be issued.

8.3.1 Connecting to the component



- 1) Briefly press the ⌘ button on the control panel of the component to activate recognition (visibility) of the Bluetooth connection for 2 minutes.
- 2) From the components in range that are shown, select the desired component based on the serial number.
- 3) Tap the serial number to establish a connection.
- 4) Follow the subsequent instructions on the screen.
- 5) After the Bluetooth PIN is entered, a connection to the component is established.

INFORMATION: If an incorrect Bluetooth PIN has been entered 3 times, it is necessary to wait about 2 minutes before making a 4th attempt.

- While the connection is being established, 3 beep signals sound and the (🔗) symbol appears in the bottom right corner of the screen. 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 screen for entering the patient data appears.

Section "Connect to already saved component:"



This section shows the last two connected components. A connection to these components can be established more quickly by tapping these serial numbers.

8.4 Changing the units for weight and length

To enter the "Height", "Knee Center to floor" and "Weight", the units can be changed between "kg" and "lbs" or "cm" and "ft / in".

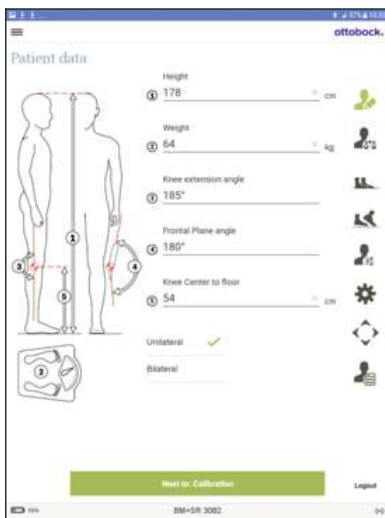


- 1) Tap the ☰ symbol in the top left corner to open the navigation menu.
- 2) Tap the "App settings" menu item.
→ The unit settings menu is displayed.
- 3) Tap the setting in question.
- 4) Tap the "OK" button to save the setting and close the navigation menu.



8.5 Entering patient data

After each input, a confirmation signal is emitted by the component to confirm the successful transfer of the values.



Height

Body height of the patient.
Changing the units (see Page 26).

Weight

Body weight of the patient with or without orthosis.
Changing the units (see Page 26)

Knee extension angle

Knee angle of the extension position for which the orthosis was aligned. Slight hyperextension of the knee joint must be possible starting from this angle.

Frontal Plane angle

Input of the varus/valgus angle for the component. It has to be measured with a goniometer.

Knee Center to floor

Distance from the knee rotation point to the floor.
Changing the units (see Page 26)

Unilateral

If the orthosis is part of a unilateral fitting, this parameter has to be selected.

Bilateral

If the orthosis is part of a bilateral fitting, this parameter has to be selected.

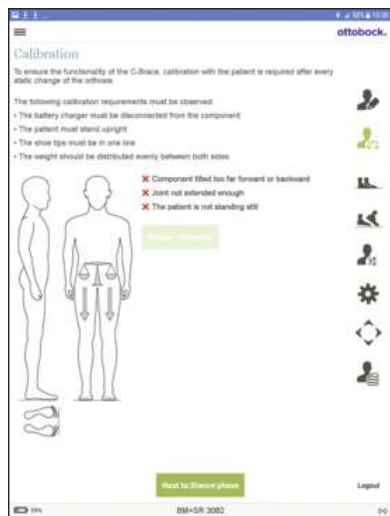
8.6 Calibration (zero setting)

The individual position of the joint unit has to be calibrated on the patient. If calibration on the patient is omitted, the swing phase is initiated too early or too late due to incorrect data.

The calibration process must be repeated after every static change on the orthosis (e.g. after adjusting the ankle joint).

The adjustment process can only be continued after completing the calibration.

INFORMATION
Do not use the hands to help extend the leg.



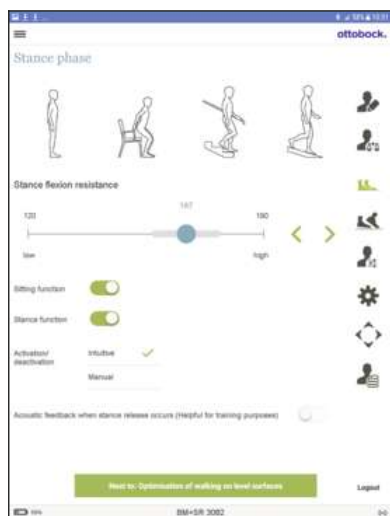
If the prerequisites listed in the adjustment app are not met, the corresponding deviations are displayed. Only after the deviations are corrected can the calibration be started.

- **The patient is not standing still**
The patient should be standing as still as possible. The support of parallel bars may help.
- **Joint not extended enough**
The patient should independently bring the orthosis to full extension. If this is not possible, the static alignment has to be corrected (for example by adjusting the ankle joint).
- **Component tilted too far forward or backward**
Check the static orthosis alignment. Make sure the patient is standing upright and the feet are aligned.

Calibration procedure

- 1) Tap the **"Calibrate"** button.
- 2) Successful calibration is confirmed with the message **"Calibration complete"**.
→ If required (e.g. after changing the static alignment), the calibration can be repeated by clicking the **"Repeat calibration"** button again.

8.7 Stance phase



Parameter "Stance flexion resistance"

This parameter is the resistance against flexion of the knee, which is required for descending stairs or ramps or for supported sitting motions.

The value configured on delivery has to be adapted to the patient.

Preliminary adjustment: For verification, the patient sits down on a chair while supporting themselves with the hands on the arm supports. The patient lets themselves sink into the product and feels the supporting effect of the flexion resistance.

Fine tuning: Have the patient walk down a ramp and then stairs, keeping one hand on the handrail for safety. If the resistance is subjectively too low or too high, it can be adjusted accordingly.

The goal is to find a good compromise setting that permits sitting down in comfort and also walking on ramps and stairs safely. If the setting of the parameter **"Stance flexion resistance"** is changed from the factory setting, the parameter **"Stance flexion resistance when walking on level surfaces"** is not reduced automatically. The flexion resistance may therefore be higher in the stance phase while walking on the level.

Setting "Acoustic feedback when stance release occurs"

To check whether the patient is able to initiate the swing phase correctly and reliably, a beep signal upon stance release can be activated.

8.7.1 Sitting function


When the function is activated, the resistance in the flexion direction while sitting is reduced in addition to the reduction of resistance in the extension direction. Enable the function by dragging the switch to the right . When the function is activated, it can be turned on/off using the Cockpit app.

If this function has been deactivated by the patient, the information "(deactivated by patient)" appears next to the switch .

8.7.2 Stance function

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

Enable the function by dragging the switch to the right . When the function is activated, it can be turned on/off using the Cockpit app.

Once the function is enabled (switch  dragged to the right), it is also possible to choose between an intuitive and a manual lock. Subsequently changing the type of lock using the Cockpit app is not possible.

Intuitive locking of the joint

The intuitive stance function recognises any situation that puts strain on the orthosis in the flexion direction but where flexion is not permitted. Examples of this include standing on uneven or sloping surfaces. The joint is always locked in the flexion direction when the leg with the orthosis is not fully extended and is kept still for a brief moment.

The joint is not locked when the above conditions are met and a sitting position is assumed.

Intuitive unlocking of the joint


- ▶ Upon forward or backward rollover or extension, the flexion resistance is immediately switched from high to stance phase resistance again.

Manual joint lock

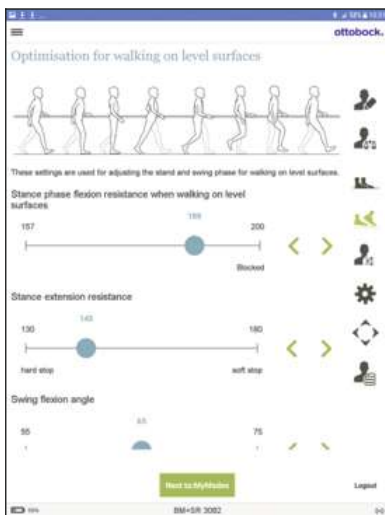
- ▶ Flex the joint between 5° and 60°.
- Now the blocked joint can be loaded in the flexion direction.

Releasing the manual joint lock

- ▶ The Manual Stance function is automatically deactivated again by extending the knee or by repositioning the leg (e.g. taking a step).

If this function has been deactivated by the patient, the information "(deactivated by patient)" appears next to the switch .

8.8 Optimisation while walking on the level



Parameter "Stance flexion resistance when walking on level surfaces"

If the parameter "Stance flexion resistance" for sitting down and negotiating stairs and ramps is set correctly, but the patient sinks down in the stance phase while walking on the level, the parameter "Stance flexion resistance when walking on level surfaces" should be adjusted for the patient.

If elevated stance phase flexion resistance for walking on the level is not wanted, the value of the parameter "Stance flexion resistance when walking on level surfaces" has to be set equal to the value of the parameter "Stance flexion resistance".

Parameter "Stance extension resistance"

This parameter can decide how quickly the knee joint returns to an extended position again after stance phase flexion. The hardness of the stop can be influenced with this parameter.

Parameter "Swing flexion angle"

This parameter determines the target angle that represents the maximum flexion of the knee in the swing phase. The angle is approximately 65° for a physiological gait, regardless of the walking speed.

8.9 MyModes

8.9.1 Basic mode



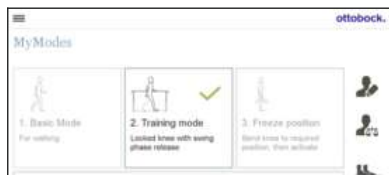
This mode is intended for daily use. The parameters configured in the previous screens describe the dynamic behaviour of the orthosis in the gait cycle. These parameters act as basic settings for automatically adjusting the damping behaviour to the current motion situation (e.g. ramps, slow walking speed, etc.).

8.9.2 MyMode "Training mode"

(if the knee joint is locked during the stance phase and swing phase release is possible)

The knee joint is locked in the stance phase. Swing phase initiation is possible as in basic mode. In this mode, walking down stairs or a ramp is only possible one step at a time.

Switching process



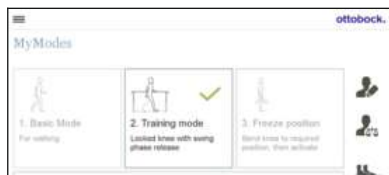
- 1) On the screen of the tablet, tap the symbol to activate training mode. → A confirmation signal sounds to indicate the switch to training mode.
- 2) The hydraulics stabilise the joint with high flexion resistance in the stance phase and release the joint in the swing phase so that the leg can swing forward freely.

Exit training mode by selecting a different MyMode or by turning the component off and then on again.

8.9.3 MyMode "Freeze position"

(if the knee joint is permanently locked)

Switching process

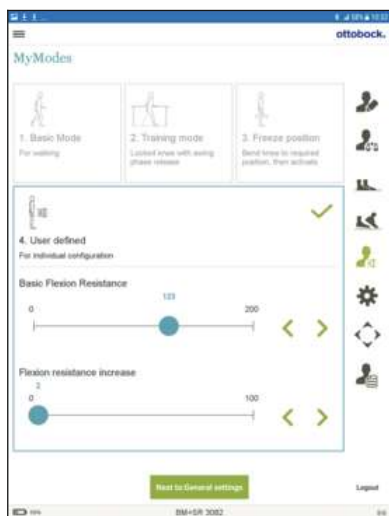


In this MyMode, the joint is locked in its current position and cannot be moved in the flexion nor the extension direction.

- 1) Flex or extend the knee joint to the angle where it should be locked.
- 2) On the screen of the tablet, tap the symbol to activate the lock. → A confirmation signal sounds to indicate activation of the lock.
- 3) The orthosis is locked in the flexion and extension directions.

Deactivate the lock by selecting a different MyMode/basic mode or by turning the component off and then on again.

8.9.4 MyMode "User defined"



This MyMode is individually configurable. Tap this MyMode to configure the settings.

Parameter "Basic Flexion Resistance"

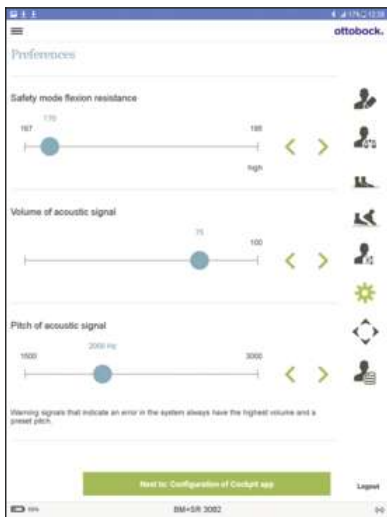
This parameter is used to set the initial resistance at the start of flexing the knee joint. The higher the value, the greater the resistance against flexing the joint.

Parameter "Flexion resistance increase"

This parameter is used to set the increase in the flexion resistance (starting from the parameter "Basic Flexion Resistance") while flexing the knee joint. The flexion resistance increases continuously along with the flexion angle until the knee joint locks at a certain flexion angle. Thus the flexion angle at which the knee joint locks depends on the settings for the parameters "Basic Flexion Resistance" and "Flexion resistance increase".

8.10 Preferences

When switching to this settings screen, the flexion resistance is set to the value of the parameter "Safety mode flexion resistance". When leaving this screen, the flexion resistance is set back to the value of the parameter "Stance flexion resistance".



Parameter "Safety mode flexion resistance"

When a critical error occurs or if the battery is drained, the component switches to safety mode and triggering a swing phase is no longer possible. Further information about safety mode (see Page 46).

The flexion resistance is set to constant with the value of the parameter "**Safety mode flexion resistance**" in the following cases:

- The component is in safety mode
- The component has been switched off
- The component battery is empty
- The component is being charged (battery charger is connected to the component)

Parameter "Volume of acoustic signal"

Setting for the volume of the acoustic signal generator for the confirmation signals. Warning signals that indicate an error in the system always have the highest volume.

Parameter "Pitch of acoustic signal"

Setting for the pitch of the acoustic signal for the confirmation signals.

8.11 Configuration of the Cockpit app



Button "Show Bluetooth PIN"

A Bluetooth PIN is required to establish a connection with the Cockpit app. This PIN is provided on a card included in the scope of delivery. If this card is no longer available, the Bluetooth PIN can be displayed by tapping this button. The Bluetooth PIN is only valid for the currently connected component.

Menu language of Cockpit app

Select the user interface language of the Cockpit app. Only the languages that can be selected here are available for the Cockpit app. Subsequently changing the language via the mobile device is not possible.

Name of the component

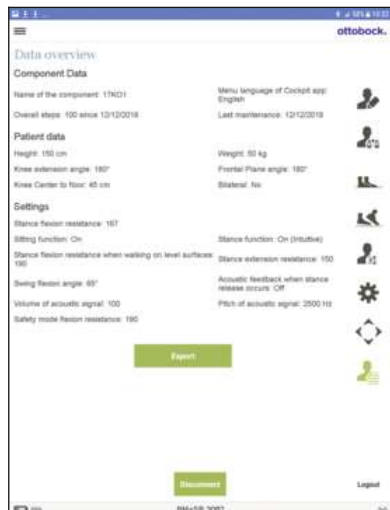
Enter an individual name of the component for identification in the Cockpit app.

Button "Transfer configuration of Cockpit app"

The changes (**Menu language of Cockpit app**, **Name of the component**) are not saved in the component until this button is tapped.

The patient has to sit or stand with support during the data transfer.

8.12 Data overview



All data previously entered and saved in the component are shown here. These data can be exported in PDF format by tapping the "**Export**" button. Subsequently this file can be saved, printed or sent. Directly changing the data in this overview is not possible.

8.13 Navigation menu of the adjustment app



Tap the ☰ symbol in the top left corner of the menus to display the navigation menu. The following functions are available in this menu:

Establishing a connection

Establish a connection to a component (see Page 25)

Imprint/Manufacturer

Display information, legal notice for the adjustment app. If a connection to a component has been established, additional information for the component is displayed.

App settings

Configure additional app settings (such as changing units (see Page 26))

If no user is logged in, the entry **Login** is displayed in addition

9 Cockpit app



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

The behaviour of the product can be changed to a certain extent on a day-to-day basis using the app (e.g. while becoming accustomed to the product).

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: <http://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 Cockpit app user interface can only be changed using the adjustment software.
- 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 ().
- Keep the mobile app up to date at all times.
- Please contact the manufacturer if you suspect cybersecurity problems.

9.1 System Requirements

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

- **iOS (for iPhone, iPad, iPod):** version 10.0 or higher
- **Android:** version 5.0 or higher

9.2 Initial connection between cockpit app and prosthesis



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

- Bluetooth of the component must be switched on (see Page 42).
- 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, the Bluetooth PIN for an already connected component can be determined using the adjustment app. If the Bluetooth PIN is needed even to start the adjustment app, please contact an authorised Ottobock service centre. The serial number must be provided so a new card can be issued.

9.2.1 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) Briefly press the  button on the control panel of the component 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 in the bottom right corner of the screen.
 - 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

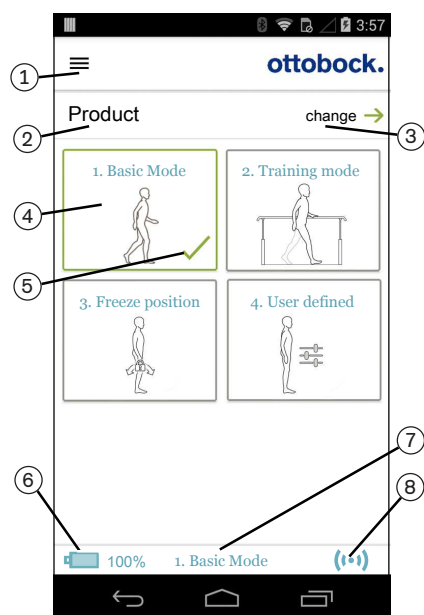
After the initial connection to the component has been established successfully and when the Bluetooth function is activated, the app will connect automatically each time it is started. No further steps are required.

INFORMATION

After activating the "visibility" of the component (briefly pressing the button), 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 the button on the control panel must be briefly pressed again.

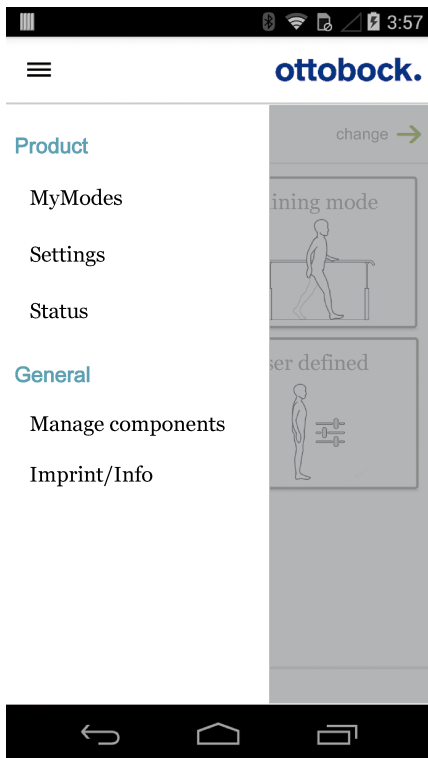
INFORMATION

If the connection to the component could not be established or the connection process is terminated, reset the component by connecting and disconnecting the battery charger.

9.3 Control elements for cockpit app

1. Access the navigation menu (see Page 34)
2. Name of the component. This name can only be changed using the adjustment app.
3. If connections to more than one component have been saved, you can switch between the saved components by tapping the **change** item (see Page 34).
4. MyModes configured with the adjustment app. Switching the mode by tapping the corresponding symbol and confirming by tapping "**OK**".
5. Currently selected mode
6. Charge level of the component.
 - Component battery fully charged
 - Component battery empty
 - Component battery is being charged
 The current charge level is also displayed in %.
7. Display and name of the currently selected mode (e.g. **1. Basic Mode**)
8. Connection to component has been established
 Connection to component has been interrupted. The app is attempting to re-establish the connection automatically.
 No existing connection to the component.

9.3.1 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

Settings

Change settings of the currently selected mode (see Page 39)

Status

Query status of the connected component (see Page 42)

Manage components

Add or delete components (see Page 34)

Imprint/Info

Display information/legal notice for the Cockpit app and the connected component

9.4 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 32).

9.4.1 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) Briefly press the ✂ button on the control panel of the joint unit 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").
- ▶ If present, delete the component from the Bluetooth settings on the device (unpair).
- ▶ Rest the component by connecting and disconnecting the battery charger.
- ▶ Add the component again in the Cockpit app (see the section "Adding a component").

INFORMATION

After activating the "visibility" of the component (briefly pressing the ✂ button), 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 the ✂ button on the control panel must be briefly pressed again.

9.4.2 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.

10 Use

INFORMATION

Before each use, check the product for functional reliability and for possible wear or damage.

Handling and use of the product must be learned before using it for the first time.

Applying and removing, sitting down and standing up as well as walking must be practised.

In general, major discomfort should not be experienced when wearing the product. The affected limb should be checked by the patient or caregiver periodically for areas of excessive pressure. If pressure points are observed, stop using the product and consult the O&P professional as soon as possible.

10.1 Application

INFORMATION

The individual approach to put on and take off the product should be developed in cooperation with the orthopaedic technician and/or therapist.

- 1) Open all orthosis shell closures.
- 2) Remove the shoe.
- 3) Sit on the front edge of a chair.
- 4) Flex the orthotic joint.
- 5) Insert the foot into the foot component. While doing so, position the heel and lower leg in the shell.
- 6) Slightly extend the leg and apply the orthosis to the thigh and lower leg.
- 7) Fasten the ankle closure if applicable.
- 8) Fasten the lower leg shell closure.
- 9) Fasten the thigh shell closure.
- 10) Retighten the top closure.
- 11) Put on the shoe.
- 12) Stand up from the chair and retighten all closures.
- 13) Check the correct fit of the orthosis.

⚠ CAUTION

Pinching skin in the area of the closures

Injuries and swelling due to disruption of blood circulation to the skin in the area of the closures.

- ▶ Do not over-tighten the closures when applying the product.

10.2 Removal

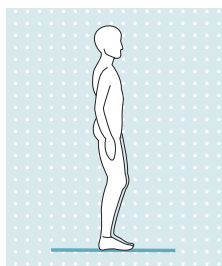
INFORMATION

Before sitting down, check whether adequate resistance is provided for support while sitting down. If a MyMode with very high or very low stance phase flexion resistance is activated, the Cockpit app must be used to switch back to basic mode before sitting down. Basic mode can also be activated by switching the product off and back on again.

- 1) Sit on a chair.
- 2) Open the orthosis shell closures.
- 3) Take off the orthosis.
- 4) Fasten the orthosis shell closures.
- 5) Store the orthosis and charge the battery if possible.

10.3 Movement patterns in basic mode (mode 1)

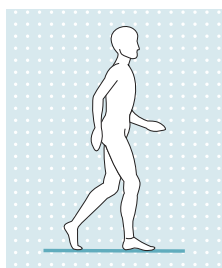
10.3.1 Standing



A stable stance must be assured by the static alignment of the orthosis.

A stance function can be enabled using the adjustment app. Please see the section "Stance function" (see Page 28) for further information on the stance function.

10.3.2 Walking



Initial attempts at walking with the product always require instruction from 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 rolling the product over to the front out of the stride position.

An acoustic feedback signal when initiating the swing phase can be activated via the adjustment app (see Page 28).

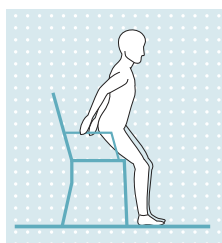
INFORMATION

Inform the patient that changing the gait pattern influences activation of the swing phase and an adjustment by the O&P professional is therefore required.

10.3.3 Sitting down

INFORMATION

Before sitting down, check whether adequate resistance is provided for support while sitting down. If a MyMode with very high or very low stance phase flexion resistance is activated, the Cockpit app must be used to switch back to basic mode before sitting down. Basic mode can also be activated by switching the product off and back on again.



The resistance in the product's knee joint while sitting down ensures even lowering into the sitting position.

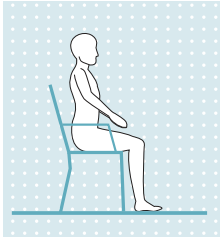
- 1) Position both feet side by side at the same level.
- 2) While sitting down, distribute your weight evenly between both legs and use the arm supports where applicable.
- 3) Move the buttocks in the direction of the back support and lean the upper body forward.

INFORMATION: Resistance while sitting down can be changed with the Cockpit app via the parameter "Stance flexion resistance" (see Page 40).

10.3.4 Sitting

INFORMATION

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



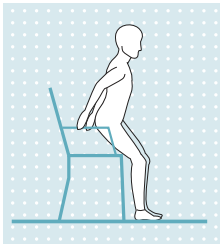
When a sitting position is maintained for more than two seconds (i.e. the thigh is close to horizontal and there is no load on the leg), the product switches the resistance in the extension direction to a minimum.

If the sitting function is activated in the adjustment app and switched on via the Cockpit app (see Page 40), the resistance in the flexion direction is also reduced.

10.3.5 Standing up

INFORMATION

If a MyMode with a very high extension resistance (component remains flexed while standing up) or very low flexion resistance (no support as expected) is activated, it is necessary to switch back to basic mode. Basic mode can also be activated by switching the product off and back on again.



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

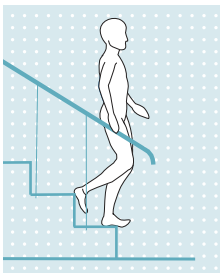
10.3.6 Walking down stairs

INFORMATION

Before walking down stairs, check whether adequate resistance is provided for walking down stairs. If a MyMode with very high or very low stance phase flexion resistance is activated, the Cockpit app must be used to switch back to basic mode before walking down stairs. Basic mode can also be activated by switching the product off and back on again.

Depending on the construction of the orthosis (rigid or with movement in the ankle joint possible), the movement pattern is carried out as follows.

10.3.6.1 Orthosis construction with rigid ankle joint or dorsal spring element



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

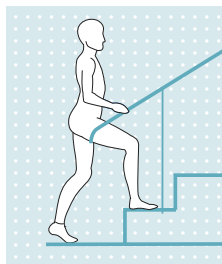
- 1) Hold the handrail with one hand.
- 2) Position the leg with the product on the step so that the foot projects halfway over the edge of the step.
 - This is the only way to ensure a secure rollover.
- 3) Roll the foot over the edge of the step.
 - This flexes the product slowly and evenly at the knee joint.
- 4) Place the foot of the less affected leg onto the next step.

10.3.6.2 Orthosis construction with movement in the ankle joint

This function must be practised and executed consciously. Only by properly stepping down with the sole can the product respond correctly and permit controlled flexion.

- 1) Hold the handrail with one hand.
- 2) Position the leg with the product on the step so that as much of the sole of the foot as possible is on the step.
- 3) Place the foot of the less affected leg onto the next step.

10.3.7 Walking up stairs



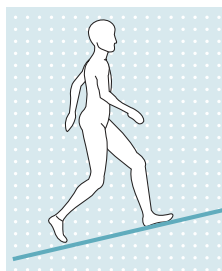
Walking up stairs one step at a time

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

Walking up stairs step-over-step

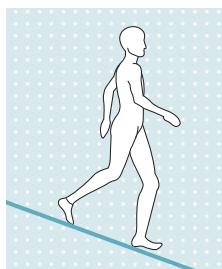
The product does not have an active drive system to support walking up stairs step-over-step. This is possible given certain physical prerequisites (residual muscular function present in the affected leg) and with corresponding training.

10.3.8 Walking up a ramp



- 1) Hold the handrail with one hand.
- 2) Place the foot of the less affected leg onto the ramp.
- 3) Move the leg with the product forward.

10.3.9 Walking down a ramp



Use the handrail if possible.

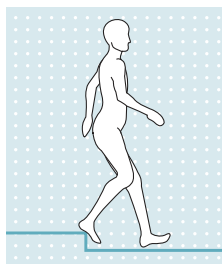
Slight slope (< 5-10%)

The sequence of movements is equivalent to walking on the level. Swing phase initiation is possible.

Moderate/steep slope (> 5-10%)

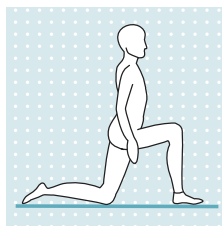
The sequence of movements is similar to walking down stairs. Place a load on the orthosis, permit knee flexion against the flexion resistance and roll over the forefoot.

10.3.10 Walking down flat steps



A (possibly surprising) swing phase may be triggered when walking down a flat step (such as a curb). The user can either use the stance phase flexion resistance or initiate a swing phase.

10.3.11 Kneeling



The individual approach to kneeling down and getting up again should be developed in cooperation with the O&P professional and/or therapist.

Kneeling down is supported by increased flexion resistance, which permits controlled flexion of the knee joint.

10.4 Changing orthosis 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

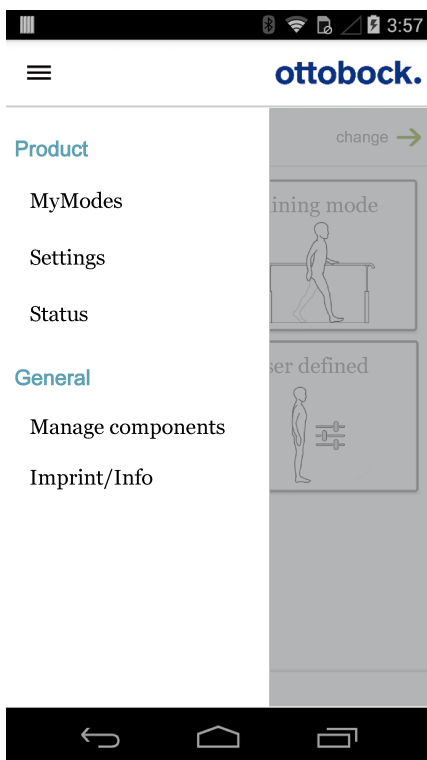
Bluetooth of the component must be switched on to change the orthosis settings. Briefly press the **ⓘ** button on the control panel to check.

If the **📶** symbol is not lit up, Bluetooth has to be activated by a long press of the **📶** button on the control panel.

Information for changing the orthosis 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 orthosis settings nor to switch to a different MyMode while the orthosis battery is being charged. Only the status of the orthosis can be called up. Instead of the **🔋** symbol, the **🔌** symbol appears in the bottom row of the screen in the Cockpit app.
- If the settings of a MyMode are to be modified, one must first switch to this MyMode.

10.4.1 Changing the orthosis settings using the Cockpit app



- 1) Once the component is connected and in the desired mode, tap the **☰** symbol in the main menu.
→ The navigation menu opens.
- 2) Tap the **"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 **"<"**, **">"** symbols.

INFORMATION: The setting configured using the adjustment app is marked and, after the setting has been changed, can be restored by tapping the "Standard" button.

10.4.2 Overview of adjustment parameters in basic mode

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

The stance function and/or the sitting function can also be activated/deactivated. Further information on the stance function (see Page 28). Further information on the sitting function (see Page 37).

The following parameters can be modified:

Parameter	Adjustment range of the O&P professional via the adjustment app	Cockpit app adjustment range	Meaning
Stance flexion resistance	120 to 190	+/- 10 of the configured value	Resistance against flexion motion e.g. when walking down stairs or while sitting down
Stance function		0/Off - deactivated 1/On - activated	Activation/deactivation of the stance function. This function needs to be enabled in the adjustment app.

Parameter	Adjustment range of the O&P professional via the adjustment app	Cockpit app adjustment range	Meaning
Sitting function		0/Off - deactivated 1/On - activated	Activation/deactivation of the sitting function. This function needs to be enabled in the adjustment app.
Volume of acoustic signal	0 to 100	0 to 100	Volume of beep signal for confirmation tones (e.g. when switching MyModes). The "0" setting deactivates the audible feedback signals. However, warning signals are still generated if errors occur.
Pitch of acoustic signal	1500 Hz 3000 Hz	1500 Hz 3000 Hz	Pitch of beep signal for confirmation tones

INFORMATION

Confirmation of the successful transfer of the parameters

A beep and vibration signal is emitted by the orthosis while changing the parameters using the Cockpit app. If the parameter "**Volume of acoustic signal**" is set to "0", only a vibration signal is emitted.

10.4.3 Overview of adjustment parameters in MyModes

The parameters in the MyMode "**User defined**" describe the static behaviour of the orthosis for a specific movement pattern such as cycling. There is no automatically controlled adjustment of the extension and flexion resistance.

The parameters of the MyModes "**Training mode**" and "**Freeze position**" are preconfigured and cannot be changed.

The following parameters can be modified in MyModes:

Parameter	Adjustment app setting range	Cockpit app adjustment range	Meaning
Flexion resistance increase	0 to 100	+/- 10 of the configured value	Value for speed at which flexion resistance increases as the knee angle increases This parameter can only be changed in the MyMode " User defined ".
Volume of acoustic signal	0 to 100	0 to 100	Volume of beep signal for confirmation tones (e.g. when switching MyModes). The "0" setting deactivates the audible feedback signals. However, warning signals are still generated if errors occur.
Pitch of acoustic signal	1500 Hz 3000 Hz	1500 Hz 3000 Hz	Pitch of beep signal for confirmation tones

INFORMATION

Confirmation of the successful transfer of the parameters

A beep and vibration signal is emitted by the orthosis while changing the parameters using the Cockpit app. If the parameter "**Volume of acoustic signal**" is set to "0", only a vibration signal is emitted.



10.5 Switching the product on/off

In certain cases, e.g. for storage or transportation, the product can be purposely switched off.





CAUTION

Using the product while switched off




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

- Prior to using the product, briefly press the  button on the control panel to check whether it is switched on. The button symbol lights up green  when the product is switched on.

Switching off



- 1) Briefly press the  button on the control panel to check whether the product is switched on. The symbol in the button lights up green  and the current charge level is displayed (see Page 51).
- 2) With the product switched on, press and hold the  button on the control panel until the symbol in the button turns off and a descending series of beeps (shut-down melody)  is emitted.

Switching on

- ▶ Press the  button on the control panel to switch the product on.
- A long vibration signal followed by a short beep is emitted, and the current status is displayed for about 5 seconds (see Page 51).
- When the symbol in the  button is lit up green , the product is switched on and operational.
- Basic mode is activated after switching on.




INFORMATION


No display after switching on

If the  symbol does not light up after a long press of the  button, the battery may be deep discharged. Charging for at least 15 minutes is required in this case.



10.6 Switching Bluetooth of the component on/off

INFORMATION




Bluetooth on the component must be turned on in order to use the Cockpit app. Briefly press the  button on the control panel to check. In the  button, the symbol must be lit up blue .

If the symbol in the button is not lit up, Bluetooth has to be switched by a long press of the  button.

10.6.1 Switching off Bluetooth


- ▶ With the Bluetooth function activated, press and hold the  button on the control panel until a vibration signal is emitted and the symbol in the button turns off.
- Bluetooth is switched off.
- To check whether the Bluetooth function was deactivated correctly, query the status by pressing the  button (see Page 51).

10.6.2 Switching on Bluetooth

- ▶ With the Bluetooth function deactivated, press and hold the  button on the control panel until a short vibration signal is emitted and the symbol in the button lights up blue .
- Bluetooth is switched on.
- To check whether the Bluetooth function was activated correctly, query the status by pressing the  button (see Page 51).

10.7 Querying the status of the component

10.7.1 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".

10.7.2 Status display in the cockpit app

Menu option	Description	Possible actions
Steps per day: 25	Daily step counter	Reset the counter by tapping the "Reset" button.
Overall steps: 1745	Total steps since most recent maintenance	For informational purposes only
Batt.: 68	Current charge level of the component in percent	For informational purposes only

10.8 Recommendations for air travel

Observing the following points is recommended prior to air travel or on board the airplane:

- Take along the 647F558 orthotic passport so you can show it on request or in case of questions.
- Turn off the component's Bluetooth function on board the aircraft if required (see Page 42).

-
- Take along the corresponding power supply adapter according to your destination. The power supply is suitable for connecting to alternating voltages from 100 V to 240 V at a network frequency of 50 Hz to 60 Hz.

11 MyModes

For further information about the MyModes and their configuration, see the section "C-Brace Setup adjustment app" (see Page 24).

The parameters of the MyModes "**Training mode**" and "**Freeze position**" are preconfigured and cannot be changed.

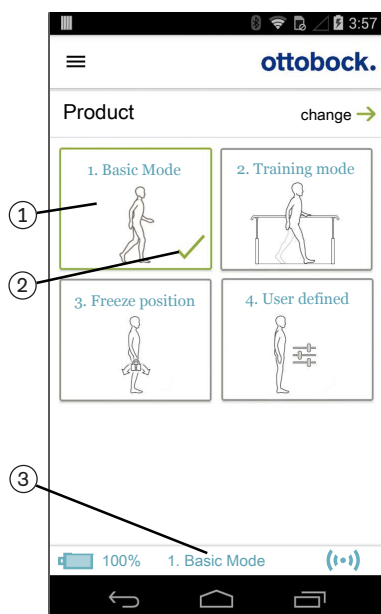
11.1 Switching MyModes with the cockpit app

Once a connection to an orthosis has been established, the Cockpit app can be used to switch between the MyModes.

Information on switching

- It is always possible to switch back to basic mode by turning the product off and back on (see Page 41) and by connecting/disconnecting the battery charger.
- Before the first step, always check whether the selected mode corresponds to the required motion type.
- Check whether the battery charger is connected. Changing the mode is not possible when the battery charger is connected, even though the (••) symbol is lit up.
- On the device, check whether a connection to the component has been established. The (••) symbol must be lit up.
- On the device, check whether the correct component has been selected.

Switching process



- 1) Tap the symbol of the desired MyMode (1) in the main menu of the Cockpit 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).

11.2 Basic mode

This mode is intended for daily use.

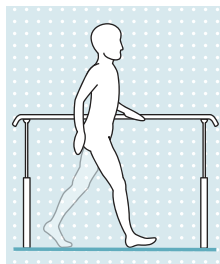
11.3 MyMode "Training mode"

(if the knee joint is locked during the stance phase and swing phase release is possible)

The knee joint is locked in the stance phase. Swing phase initiation is possible as in basic mode.

In this mode, walking down stairs or a ramp is only possible one step at a time.

Switching process

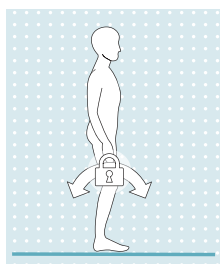


- 1) On the screen of the device, tap the corresponding symbol to activate training mode.
→ A confirmation signal sounds to indicate the switch to training mode.
 - 2) The hydraulics stabilise the joint with high flexion resistance in the stance phase and release the joint in the swing phase so that the leg can swing forward freely.
- Exit training mode by selecting a different MyMode or by turning the component off and then on again.

11.4 MyMode "Freeze position"

(if the knee joint is permanently locked)

Switching process

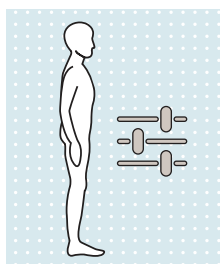


In this MyMode, the joint is locked in its current position and cannot be moved in the flexion nor the extension direction.

- 1) Flex or extend the knee joint to the angle where it should be locked.
- 2) On the screen of the device, tap the corresponding symbol to activate the lock.
→ A confirmation signal sounds to indicate activation of the lock.
- 3) The orthosis is locked in the flexion and extension directions.

Deactivate the lock by selecting a different MyMode/basic mode or by turning the component off and then on again.

11.5 MyMode "User defined"



The MyMode "**User defined**" is intended for specific motion patterns or postures (e.g. cycling ...). This MyMode can be configured individually using the adjustment app.


Settings can also be adjusted by the patient using the Cockpit app (see Page 41).

12 Additional operating states (modes)

12.1 Empty battery mode

Beeps and vibration signals are emitted if the available battery charge level drops to 5% (see Page 51). The settings are changed to the safety mode parameters during this time. Then the product is switched off.

INFORMATION

After disconnecting the battery charger, the orthosis is in the same state it was in before connecting the battery charger. For example, if the orthosis was switched off before connecting the battery charger, it will also be switched off after disconnecting the battery charger. A descending sequence of beeps is emitted when the battery charger is disconnected while the orthosis is switched off .

12.2 Mode for charging the product


The product is non-functional during charging.

To switch to basic mode, the battery charger for the product must be disconnected after the battery is charged.

12.3 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.

Flexion resistance configured in the adjustment app is activated in safety mode (**Safety mode flexion resistance**), corresponding at least to the stance phase resistance. The extension resistance is low and cannot be changed. Swing phase release is not possible. This makes limited walking possible for the user and allows the user to sit down, even though the sensor system is not active.


The switch to safety mode is indicated by the red  symbol on the control panel and by beeps and vibration signals immediately prior to switching (see Page 51).

The current safety mode can be reset by switching the product off/on (see Page 41), or by connecting and then disconnecting the battery charger. If the product switches into safety mode again or at a later time, this means a permanent error exists. The product must be inspected by an authorised Ottobock Service Centre.

12.4 Overheating mode

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

Overheating mode is not activated in the MyMode "User defined".

Overheating mode is indicated by a long vibration every 5 seconds and additionally by the orange  symbol lighting up.

The following functions are deactivated in overheating mode:

- Sitting function
- Switching to a MyMode
- Changing the orthosis settings

13 Cleaning

1) Clean the product with a damp cloth and mild soap when needed.

2) Dry the product with a lint-free cloth and allow it to air dry fully.

Orthosis shell padding

1) Remove the padding materials from the orthosis shells.

2) Fasten all hook-and-loop closures, if any.

3) If the padding materials "623P3 terry cloth padding fabric" or "623F62 SpaceTex padding fabric" are used, hand wash these in warm water at 30 °C/86 °F with a standard mild detergent.

If other padding materials are used, observe the care symbols and cleaning instructions for those materials.

4) Rinse out detergent residues thoroughly.

5) Allow to air dry. Do not expose to sources of direct heat (e.g. sunlight, stove or radiator).

6) After the padding material is completely dry, reattach it to the orthosis shells on the correct sides.

14 Maintenance

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

When maintenance is due, this is indicated by feedback after connecting the battery charger (see the section "Operating states/error signals", see Page 51). The manufacturer grants a grace period of no more than one month before, or two 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 must always be sent in for maintenance and repairs:

The joint unit, battery charger and power supply unit. For disassembling/assembling the joint unit, see the section "Assembling/disassembling the joint unit on the orthosis" (see Page 23). The shipping container for the loaner unit you receive must be reused for sending back the components requiring inspection.

17KO1=* C-Brace joint unit

Regular maintenance (service inspections) must be carried out at intervals of 2 years or 2 million steps, whichever comes first.

Additional orthosis components used, e.g. joints

Observe the service intervals and maintenance instructions for all orthosis components used.

15 Legal information

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

15.1 Liability

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

15.2 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'interférence et
- (2) l' utilisateur du dispositif doit être prêt à accepter toute interférence radioélectrique reçue, 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.

15.3 CE conformity

Only applicable for "17KO1=L C-Brace joint unit"/"17KO1=R C-Brace joint unit"

Ottobock Healthcare Products GmbH hereby declares that the product is in compliance with 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>

Valid only for the 560X17-ANDR=V* and 560X17-IOS=V* C-Brace Setup adjustment app

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

The full text of the regulations and requirements is available at the following Internet address:

<http://www.ottobock.com/conformity>

15.4 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.

16 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 +25 °C/+77 °F Max. 93% relative humidity, non-condensing
Transport and storage between applications (without packaging)	-25 °C/-13 °F to +35 °C/95 °F Max. 93% relative humidity, non-condensing +35 °C/95 °F to +70 °C/158 °F Water vapour pressure up to 50 hPa
Operation	-10 °C/+14 °F to +40 °C/+104 °F Relative humidity 15% to 93%, non-condensing, at a water vapour pressure up to 50 hPa Air pressure: 606.3 hPa (up to 4000 m without pressure equalisation)
Maximum temperature that can be reached on the surfaces of the orthosis during operation	+44 °C/+111 °F
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 +40 °C/+104 °F
General information	
Reference number	17KO1=L C-Brace joint unit left/17KO1=R C-Brace joint unit right
Joint unit weight [g/oz]	Approx. 1000 / 35
Maximum user body weight [kg/lbs]	125 / 276
Product service life [years]	6
Information on the product's ruleset and firmware version	Accessible via the Cockpit app navigation menu and the menu item "Imprint/Info"
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
Battery charger	
Reference number	4E50-2
Storage and transport in original packaging	-25 °C/-13 °F to +70 °C/+158 °F
Storage and transport without packaging	-25 °C/-13 °F to +70 °C/+158 °F Max. 93% relative humidity, non-condensing
Operation	0 °C/+32 °F to +40 °C/+104 °F Max. 93% relative humidity, non-condensing
Input voltage	12 V $\overline{=}$
Lifetime	8 years
Power supply unit	
Reference number	757L16-4
Type	FW8001M/12

Power supply unit	
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 ==

Orthosis battery	
Battery type	Li-Ion
Charging cycles (charging and discharging cycles) after which at least 80% of the original battery capacity remains available	500
Charge level after 1 hour charging time	30 %
Charge level after 2 hours charging time	50 %
Charge level after 4 hours charging time	80 %
Charge level after 8 hours charging time	Fully charged
Behaviour of the orthosis while being charged	The orthosis has no function
Operating time of the orthosis with new, fully charged battery at room temperature	At least 18 hours of uninterrupted walking Approx. 2 days with average use

Cockpit app	
Reference number	4X441-IOS=*/4X441-Andr=V* Cockpit
Supported operating system	iOS 10.0/Android 5.0 or higher
Website for download	http://www.ottobock.com/cockpitapp

“C-Brace Setup” adjustment app	
Reference number	iOS: 560X17-IOS=V*/Android: 560X17-ANDR=V*
Supported operating systems	From iOS 10.3.4 to iOS13.x/iPad OS 13.x Android 5.1 to 10.x
Supported tablets	iOS devices: iPad (4th generation or later)/iPad mini (2nd generation or later)/iPad Air (all versions)/iPad Pro (all versions) Android: Screen size 7" to 13.3"
Website for download	App Store (https://www.apple.com/de/ios/app-store/)/Google Play (https://play.google.com/store)

Torque values of the screw connections

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

Screw connection	Tightening torque
Joint unit to the thigh shell	7 Nm/62 lbf. In.
Joint to the lower leg shell	7 Nm/62 lbf. In.

17 Appendices

17.1 Symbols Used



Please note the instructions for use



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.



Type BF applied part



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



Non-ionising radiation



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



Declaration of conformity according to the applicable European directives



Manufacturer

IP54

Protected against dust, protected against splashing water



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



Article number





Medical device

17.2 Operating states/error signals

The orthosis indicates operating states and error messages with symbols on the control panel and through beeps and vibration signals.

17.2.1 Status display on the control panel








The current status of the component is displayed on the control panel for 5 seconds in the following cases:

- The  button on the control panel was pressed briefly.
- The component was switched on by pressing the  button.
- The battery charger was disconnected from the component.
- Battery charger was connected to the component.
- An error was identified during use.






INFORMATION

No status display due to battery deep discharge



If the status of the component is not displayed on the control panel, the battery may be deep discharged. In this case it must be charged for at least 15 minutes before the status can be queried again.

Symbols on the control panel	Beep signal	Vibration signal	Event	Required action
All symbols on the control panel light up alternately	—	—	Test of the indicators (LEDs) after connecting the battery charger	Check whether all symbols (LEDs) light up alternately and in the corresponding colours. If a symbol (LED) does not light up in a colour, the product should be inspected by an authorised Ottobock Service Center. If no symbols (LEDs) light up, the battery may be deep discharged. Leave the battery charger connected for at least 15 minutes and then repeat this test by disconnecting/connecting the battery charger.
	—	—	The product is switched on and ready for operation	
	1 x short	1 x long and 1 x short	The product was switched on by pressing the  button on the control panel.	
	—	1 x long at interval of approx. 5 seconds	Overheated hydraulics	Reduce activity.
	—	—	A self-test error was detected when connecting the battery charger.	<ul style="list-style-type: none"> Conduct the self-test again by connecting/disconnecting the battery charger. If the  symbol lights up again, the product must be inspected by an authorised Ottobock Service Center. For disassembly of the joint unit, see the section “Assembling/disassembling the joint unit on the orthosis” (see Page 23).
	30 x long	30 x long	Severe error/indication of safety mode activation (see Page 46) Switch to safety mode if possible.	<p>Walking possible with restrictions. Please note the possible change in flexion/extension resistance.</p> <ol style="list-style-type: none"> Attempt to reset this error by switching the product off/on (see Page 41). If the beep/vibration signal recurs, attempt to reset this error by connecting/disconnecting the battery charger. If the beep/vibration signal recurs, use of the product is prohibited. The product must be inspected by an authorised Ottobock Service Center. For disassembly of the joint unit, see the section “Assembling/disassembling the joint unit on the orthosis” (see Page 23)

Symbols on the control panel	Beep signal	Vibration signal	Event	Required action
	—	—	Charge level 10% to 34%	
	—	—	Charge level 34% to 67%	
	—	—	Charge level 67% to 100% Indicates that the battery is fully charged during the charging process.	
	—	—	Battery is being charged, charge level is less than 34%	
	—	—	Battery is being charged, charge level is 34% to 67%	
	—	—	Battery is being charged, charge level is 67% to 99%	
	3 x long	3 x long	Charge level between 5% and 10%	Charge battery soon. Remaining operating time approx. 1 hour.
	5 x long	5 x long	Charge level between 0% and 5%	Charge battery immediately; the product will be switched off after the next warning signal.
	10 x long	10 x long	Charge level 0% After the beep and vibration signals, the product switches to empty battery mode and then switches off.	Charge the battery.
	4 x short at intervals of approx. 65 sec. (continuously)	—	Charging the battery outside the allowable temperature range	Check whether the specified ambient conditions for charging the battery were met (see Page 49).
	—	—	Maintenance required because the maintenance date has already been reached or exceeded	The product must be inspected by an authorised Ottobock Service Center. For disassembly of the joint unit, see the section “Assembling/disassembling the joint unit on the orthosis” (see Page 23)
	—	—	Bluetooth activated	
—	1 x long	—	Battery charger is connected	
—	—	3 x short	Charging mode started (3 sec. after connecting battery charger)	
—	1 x short	1 x short	Mode switching or changing adjustment parameters is performed using the Cockpit app. If the parameter “ Volume of acoustic signal ” is set to “0” in the Cockpit app, only a vibration signal is emitted.	

Symbols on the control panel	Beep signal	Vibration signal	Event	Required action
—		—	<p>The product switches itself off. This occurs automatically in the following cases:</p> <ul style="list-style-type: none"> The  button on the control panel was pressed and held for longer than approx. 3 seconds while product was switched on. After the  symbol lights up. After disconnecting the battery charger, if the product was already switched off before connecting the battery charger. 	<ul style="list-style-type: none"> Charge the battery. If desired, switch on the product with the  button.
—	—	Ongoing	<p>Total failure Electronic control no longer possible. Safety mode active or undetermined valve state. Undetermined product behaviour.</p>	<ol style="list-style-type: none"> Press and hold the  button on the control panel until the vibration signal stops (approx. 10 seconds), completely switching off the product. If the vibration signal recurs after switching on, attempt to reset this error by connecting/disconnecting the battery charger. If the vibration signal recurs, use of the product is prohibited. The product must be inspected by an authorised Ottobock Service Center. For disassembly of the joint unit, see the section "Assembling/disassembling the joint unit on the orthosis" (see Page 23)

17.2.2 Error messages while establishing a connection with the cockpit app

Error message	Cause	Correction
Component was connected to another device. Establish connection?	The component was connected to another device	To disconnect the original connection, tap the " OK " button. If the original connection is not to be disconnected, tap the " Cancel " button.
Mode change failed	An attempt was made to switch to a different MyMode while the component was in motion (e. g. while walking)	For safety reasons, switching MyModes is only permitted when components are at rest, e.g. while standing or sitting.
	A current connection to the component was interrupted	<p>Check the following points:</p> <ul style="list-style-type: none"> Distance from the component to the device Charge level of the component's battery Bluetooth of the component switched on? (see Page 42) Briefly press the  button on the control panel to make the component "visible" for 2 minutes. Component switched on? (see Page 41) If multiple components were stored, was the correct component selected? Is the component still connected to another device, and is this connection still active?

17.2.3 Error while charging the product

LED on power supply	LED on battery charger	Error	Resolution
○	🔌 ○ ○ ⓘ	Country-specific plug adapter not fully engaged on power supply	Check whether the country-specific plug adapter is fully engaged on the power supply.
		Non-functional socket	Check socket with another electric device.
		Defective power supply	The battery charger and power supply must be inspected by an authorised Ottobock Service Centre.
●	🔌 ○ ○ ⓘ	No connection between battery charger and power supply	Check whether the charging cable plug is fully engaged on the battery charger.
		Defective battery charger	The battery charger and power supply must be inspected by an authorised Ottobock Service Centre.
●	🔌 ○ ● ⓘ	Battery is fully charged (or connection with product is interrupted).	Take note of the confirmation signal for differentiation. When the battery charger is connected, a self-test is conducted and confirmed by beeps/vibration signals. When these signals are emitted, the battery is fully charged. If no signals are emitted, the connection to the product is interrupted.
			If the connection to the product is interrupted, an authorised Ottobock Service Centre must inspect the product, battery charger and power supply.

17.3 Directives and manufacturer's declaration

17.3.1 Electromagnetic environment

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

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

Observe the safety notices in the section "Information on proximity to certain areas" (see Page 15).

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						



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Legal Manufacturer of Custom Made Device



The product "C-Brace joint unit 17KO1=" is covered by the following patents:

USA: US 9 022 965
European Patent: EP 2276433 in CH, DE, FR, IT, NL, SE
Patents pending in Germany.

The product "C-Brace joint unit 17KO1=" is covered by the following registered designs and design patents:

Australia: 201717600; 201810549
China: ZL 201730629343.9
European Design: No.004043412
Russia: 111643
Switzerland DM/098883
Turkey: DM/098883
USA: Reg.No :3,073,834
Brasilien Reg.No.: 827015380, 827015453, 827015461, 827015470
Canada Reg. No.: TMA796,976
Germany Reg. No.. 304 22 972.5/10
Taiwan Reg. No.: 01165470

Design and Design Patents pending in Germany, Hong Kong, India, USA and as international design application

C-Brace is a tradename of Ottobock SE & Co. KGaA.
C-Brace is a registered trademark in many countries of the world, beside others registered at the
US Patent and Trademark Office, Reg.No: 3.073.834
Brasilien Reg.No.: 827015380; 827015453; 827015461; 827015470
Canada Reg. No.: TMA796.976
Germany Reg. No.: 304 22 972.5/10
Taiwan Reg. No.: 01165470.



Legal Manufacturer of C-Brace joint unit 17KO1=* and C-Brace Setup 560X17-
Otto Bock Healthcare Products GmbH
Brehmstraße 16 · 1110 Wien · Austria
T +43-1 523 37 86 · F +43-1 523 22 64
info.austria@ottobock.com · www.ottobock.com