C-Brace

EN Instructions for use (qualified personnel) ........................................................................... 3
DE | INFORMATION
Zusätzlich zu der gedruckten Gebrauchsanweisung, sind auch weitere Sprachen auf CD beigelegt (siehe rückseitigen Um- schlag). Auf Anfrage können Sie eine gedruckte Gebrauchsanweisung kostenlos in der jeweiligen Landessprache unter der un- ten 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

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 co- pertina). Su richiesta, potete ordinare gratuitamente le istruzioni per l’uso in formato cartaceo nella relativa lingua del vostro Paese all’indirizzo di seguito riportato.

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 indi- ca más abajo.

PT | INFORMAÇÃO
Adicional 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 gebruiksvoorschrift is behalve in gedrukte vorm ook in diverse andere talen bijgevoegd op cd (zie de achterzijde van de oms- lag). Een gedrukte gebruiksvoorschrift 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 oplys- te adresse nedenfor kan du bestille en gratis brugsanvisning på papir på det pågældende sprog.

NO | INFORMASJON
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 tarjotaan CD-levyn tyyppiä myös lisää kieliä (katso kansilehden takapuoli). Painettu käyty- tööhe kunkin maan omalla kiellällä on pyynnöstä tilattavissa maksutta alla ilmoitetusta osoitteesta.

TR | INFORMATION
Basılmış olan kullanım kilavuzuna ilave olarak CD’de daha fazla alternatif diller bulunmaktadır (bakanız zarfin arka yüzü). İstek üzerine ilgili dilde basılmış kullanım kilavuzunu aşağıdaki belirtilmiş olan adressten temin edebilirsiniz.

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

INFORMATION
Last update: 2016-02-05
► Please read this document carefully before using the product.
► Follow the safety instructions to avoid injuries and damage to the product.
► Instruct the user in the proper and safe use of the product.
► Please contact the manufacturer if you have questions about the product (e.g. regarding the start-up, use, maintenance, unexpected operating behaviour or circumstances). Contact information can be found on the back page.
► Please keep this document in a safe place.

The product "17B300= C-Brace" is referred to simply as the product/joint unit below.
These instructions for use provide you with important information on the use, adaptation and handling of the product.
Instruct the patient in the proper use and care of the product. The product may not be transferred to the patient without prior instruction.
Only put the product into use in accordance with the information contained in the accompanying documents supplied.

2 Product description

2.1 Design
The C-Brace orthosis can be constructed using two different systems.

2.1.1 C-Brace orthosis with spring element
The product consists of the following components:

1. Thigh shell
2. Thigh closure straps
3. Medial joint support
4. Calf closure strap
5. Foot component (closure strap optional)
6. Lower clamp adapter (connection for the Spring Element)
7. Spring Element (17CF2=1, 17CF2=4, 17CF2=HD) for energy storage during the stance phase, with integrated sensor to detect control signals. The type of Spring Element that is used depends on the respective patient.
8. Upper clamp adapter (holder for the Spring Element)
9. Plug for Spring Element
10. Hydraulic unit (joint unit) to control the damping behaviour

2.1.2 C-Brace orthosis with Sensor Ankle
The product consists of the following components:
2.1.3 Hydraulics

**Buttons**
1. Top button, button 1 – switching from an additional mode back to basic mode (1st mode) (see Page 33)
4. Lower button, button 2 – switching to an additional mode or LOM (see Page 30)

**Plugs** (beneath plug cover)
2. Charging plug – connection for the battery charger to charge the product
3. Bionic Link plug – connection for the "60X7 BionicLink" Bluetooth adapter to configure the parameters of the product

2.2 Function
This product features microprocessor control of the stance and swing phase.
The microprocessor uses the measurements of an integrated sensor system as a basis to control a hydraulic unit that influences the damping behaviour of the product.
These sensor data are updated and evaluated 50 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 system can be individually adapted to the needs of the patient.

For this purpose, the product is configured with the C-Soft adjustment software.
The product has an additional mode for special motion patterns (e.g. riding a therapy bike ...). This is preconfigured using the adjustment software and can be activated using buttons on the hydraulic unit.
An additional mode "LOM" (lock orthosis mode) can also be selected. It results in strong damping (similar to the behaviour of a locked joint unit) in the stance phase, offering a certain level of security for beginners in particular.
The swing phase can be triggered notwithstanding high stance phase damping.
3 Application

3.1 Indications for use
The product is intended solely for orthotic fittings of the lower limbs.

3.2 Indications

3.2.1 Orthosis construction with spring element
- Unilateral or bilateral lower limb paresis or flaccid paralysis, e.g. due to polio, traumatic paresis including paraplegia.
- Physical prerequisites such as muscle status, mobility grade and axis deviations that guarantee proper control of the orthosis are crucial.
- The patient must fulfil the physical and mental requirements for the perception of audible signals. Indications must be determined by the physician.

3.2.2 Orthosis construction with Sensor Ankle
- Unilateral or bilateral lower limb paresis or flaccid paralysis, e.g. due to polio, traumatic paresis including paraplegia.
- Ankle arthrodesis
- Physical prerequisites such as muscle status, mobility grade and axis deviations that guarantee proper control of the orthosis are crucial.
- The patient must fulfil the physical and mental requirements for the perception of audible signals. Indications must be determined by the physician.

3.3 Contraindications

3.3.1 Orthosis construction with spring element
- Flexion contracture in the knee and hip joint in excess of 10°
- Varus malposition in excess of 10° or valgus malposition in excess of 10°
- Ankle arthrodesis: passive range of motion less than 2°
- Body weight over 125 kg/275 lbs with use of the Spring Element (17CF2=HD)
- Body weight over 110 kg/242 lbs with use of the carbon Spring Element (17CF2=1)
- Body weight over 100 kg / 220 lbs with use of the glass fibre spring element (17CF2=4)
- Body weight less than 45 kg/100 lbs
- Body height less than 150 cm/59.06 inch

3.3.2 Orthosis construction with Sensor Ankle
- Flexion contracture in the knee and hip joint in excess of 10°
- Varus malposition in excess of 10° or valgus malposition in excess of 10°
- Body weight over 85 kg/187 lbs with use of one ankle joint (lateral installation) (17LA3=16-T)
- Body weight over 120 kg/265 lbs with use of two ankle joints (lateral and medial installation) (17LA3=16-T)
- Body weight over 110 kg/242 lbs with use of one ankle joint (lateral installation) (17LA3=20-T)
- Body weight over 125 kg/275 lbs with use of two ankle joints (lateral and medial installation) (17LA3=20-T)
- Body height less than 150 cm/59.06 inch

3.4 Qualification

3.4.1 Qualification of the orthopaedic technician
Fitting a patient with the product may only be carried out by orthopaedic technicians who have been authorised by Ottobock after completion of a corresponding training course. The adjustment software may only be used by users who have participated in the relevant product training and have been certified for the application. Additional product training courses may become necessary to qualify for software updates.

3.4.2 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.
3.5 Use/Field of Application
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.

The orthopaedic technician and patient must discuss the daily duration of use and potential therapeutic measures (e.g. occupational therapy or physiotherapy) to improve performance. In general, major discomfort should not be experienced when wearing the product. The affected limb should be checked by patient or caregiver periodically for areas of excessive pressure. If excessive pressure is observed, the orthopaedic technician should be seen as soon as possible.

4 Safety

4.1 Explanation of warning symbols

<table>
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<th>Description</th>
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<td>![WARNING]</td>
<td>Warning regarding possible serious risks of accident or injury.</td>
</tr>
<tr>
<td>![CAUTION]</td>
<td>Warning regarding possible risks of accident or injury.</td>
</tr>
<tr>
<td>![NOTICE]</td>
<td>Warning regarding possible technical damage.</td>
</tr>
</tbody>
</table>

4.2 Structure of the safety instructions

**A CAUTION**

The heading describes the source and/or the type of hazard

The introduction describes the consequences in case of failure to observe the safety instructions. Consequences are presented as follows if more than one consequence is possible:

> E.g.: Consequence 1 in case of failure to observe the hazard
> E.g.: Consequence 2 in case of failure to observe the hazard

This symbol identifies activities/actions that must be observed/carried out in order to avert the hazard.

4.3 General safety instructions

**A CAUTION**

Independent manipulations of the leg orthosis

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

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

**A CAUTION**

Danger when empty battery mode is activated

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

- Inform the patient of the configured damping behaviour in empty battery mode ("high damping" = high safety/reduced comfort or "low damping" = less safety/higher activity).
- For the "low damping" setting in empty battery mode, the patient must have the necessary muscular and cognitive abilities to control a freely moving knee joint without stance phase stability.
- You can switch back to basic mode from empty battery mode by charging the product.
- Observe the error signals (see Page 38).

**A CAUTION**

Signs of wear on the product

Injury due to faulty control or malfunction of the product.

- In the interest of the patient’s safety and in order to maintain operating reliability, the product should be serviced at regular intervals.
4.4 Notes on transportation

**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.

4.5 Information on the Power Supply/Battery Charging

**WARNING**

**Use of damaged power supply unit, adapter plug or battery charger**
Risk of electric shock due to contact with exposed, live components.
- Do not open the power supply unit, adapter plug or battery charger.
- Do not expose the power supply unit, adapter plug or battery charger to extreme loading conditions.
- Immediately replace damaged power supply units, adapter plugs or battery chargers.

**CAUTION**

**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**

**Charging the product without taking it off**
- Falling due to walking and getting caught on a connected battery charger.
- Falling due to unexpected behaviour of the product because of changed damping behaviour.
- Instruct the patient that the product must be taken off before it is charged.

**CAUTION**

**Danger when empty battery mode is activated**
Falling due to unexpected behaviour of the product because of changed damping behaviour.
- Inform the patient of the configured damping behaviour in empty battery mode (*high damping* = high safety/reduced comfort or *low damping* = less safety/higher activity).
- For the *low damping* setting in empty battery mode, the patient must have the necessary muscular and cognitive abilities to control a freely moving knee joint without stance phase stability.
- You can switch back to basic mode from empty battery mode by charging the product.
- Observe the error signals (see Page 38).

**CAUTION**

**Air in the hydraulics**
Falling due to unexpected product behaviour because of changed damping behaviour.
- Flex the joint to the stop several times until the play is largely eliminated.
- If the feeling of improper stance phase control remains after several attempts to bleed the air, the product must be inspected by an authorised Ottobock Service Centre.
Safety

⚠️ CAUTION

**Product not set upright for storage/charging**
Falling due to unexpected behaviour of the product as a result of changed damping behaviour caused by air in the hydraulic unit.
- Always keep the product upright for charging and storage.
- Before using the product, verify that the damping behaviour corresponds to the chosen mode.
- Take note of noises or inconsistent damping behaviour.
- Walk 10 to 20 steps in order to activate the automatic bleeding process.

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).

### 4.6 Information on Alignment/Adjustment

⚠️ CAUTION

**Disconnecting/establishing the connection during the adjustment process with the adjustment software**
Falling due to unexpected behaviour of the product.
- When wearing the product, the patient must not remain unattended during the configuration process while connected to the adjustment software.
- Observe the maximum range of the Bluetooth connection.
- During the data transfer (PC to product), the patient must remain standing or sitting still and the BionicLink or the communication cable must not be removed.
- If the connection fails while making adjustments, the orthotist must immediately warn and secure the patient.
- The connection to the product must always be disconnected after adjustments have been completed.

⚠️ CAUTION

**Operator errors during the adjustment process with the adjustment software**
Falling due to unexpected behaviour of the product.
- Participation in an Ottobock product training course is mandatory prior to using the product. Additional product training courses may become necessary to qualify for software updates.
- 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.

⚠️ CAUTION

**Damage to the plug contacts of the BionicLink connection**
Falling due to unexpected behaviour of the product.
- After completing the adjustments, ensure that the plug cover on the hydraulic unit is completely closed.

⚠️ CAUTION

**Error during adaptation to the patient**
- Falling due to unexpected behaviour of the product
- Chafing during relative flexion between product and leg
- During adaptation to the patient, note the correct position of the product knee rotation point (height and A-P alignment).
- Note that the product is a monocentric knee joint so that slight movements between the frame structure and leg can occur.
- Avoid wearing the product directly on the skin.
### Safety

#### CAUTION
Incorrect alignment, assembly or adjustment
Risk of injury due to change in or loss of functionality
- Assembly, adjustment and maintenance operations may only be completed by qualified personnel.
- Observe the alignment, assembly and adjustment instructions.

#### CAUTION
Maximum load not checked
- Falling due to unexpected product behaviour because of changed damping behaviour.
- The Maximum Toe Load parameter must be checked after each adjustment or change to the dorsal stop.

#### NOTICE
Thermal overloading of the product
Damage due to improper thermal treatment
- Do not carry out any heat treatment at a temperature above 300 °C (570 °F).

#### INFORMATION
The value selected for elevated flexion resistance (STP Flexion Damping Plus) cannot be lower than the value selected for stance phase damping (STP Flexion Damping). Upon attempting to enter a lower value, this value is automatically set to the value of the parameter STP Flexion Damping.

### 4.7 Notes on applying the product

#### CAUTION
Foreign objects between the leg and frame structure
Pressure points on the leg due to foreign objects at the contact points between the leg and frame structure.
- Smooth out wrinkles in the padding material and clothing.
- Check the leg for pressure points.

#### CAUTION
Using the product without shoes
- Falling due to altered swing phase triggering behaviour caused by incorrect heel height.
- Falling due to slipping when walking on smooth floor surfaces caused by the lack of a shoe profile on the foot component.
- Only use the product with suitable shoes and with shoes that have the heel height established at the initial fitting.

#### CAUTION
Tying tall footwear (above the ankle)
Falling due to unexpected product behaviour caused by transmission of incorrect forefoot load data to the electronics.
- By tying footwear too tight above the ankle, the spring element is bent even while it is not under load, which can distort important sensor signals for the control unit.
- In case of footwear that extends above the ankle, ensure the laces are not tied to tight.

#### CAUTION
Incorrect fit of the frame structure
Falling/skin irritation due to insufficient support/hold by the frame structure.
- Take the frame structure off immediately and put it back on.
- Observe the instructions for applying and removing.
4.8 Information on Proximity to Certain Areas

**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 (e.g. computer tomographs, magnetic resonance tomographs …). If this cannot be avoided, ensure at least that the patient is able to walk or stand securely (e.g. by using a handrail or the support of another person).

**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 41) during trial fitting.

**CAUTION**

Distance to HF communication devices is too small (e.g. mobile phones, Bluetooth devices, WiFi devices)

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

- Therefore, keeping the following minimum distances to these HF communication devices is recommended:
  - Mobile phone GSM 850/GSM 900: 0.99 m
  - Mobile phone GSM 1800/GSM 1900/UMTS: 0.7 m
  - DECT cordless phones incl. base station: 0.35 m
  - WiFi (routers, access points,…): 0.22 m
  - Bluetooth devices (third-party products not approved by Ottobock): 0.22 m

**CAUTION**

Excessive strain on load-bearing components

Injuries due to changes in or loss of functionality

- Only use the product for the defined area of application.
- If the product has been exposed to extreme strain (e.g. due to falling), take any necessary measures (e.g. repair, replacement, inspection by the manufacturer’s customer service etc.).
4.9 Information on Use

**WARNING**

Use of the product while operating a vehicle

Accident due to unexpected behaviour of the product.

- All users are required to observe their country's national and state driving laws when operating vehicles with the product. For insurance purposes, drivers should have their driving ability examined and approved by an authorised test centre.
- Observe national legal regulations for retrofitting your vehicle in accordance with the type of fitting.

**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 (beeper) must be observed.
- Switching back to basic mode is mandatory once the activities in the additional mode have ended.
- Take weight off the product and correct the switching if required.

**CAUTION**

Risk of pinching in the joint flexion area

Injury due to pinching of body parts.

- Ensure that body parts are not in this area when flexing the product.

**CAUTION**

Penetration of dirt and humidity into the product

- Falling due to unexpected product behaviour as the result of malfunction.
- Falling due to breakage of load-bearing components.
- Ensure that neither solid particles, foreign objects nor liquids penetrate into the product.
- Should the product come into contact with liquids, allow the product to dry. The product must be inspected by an authorised Ottobock Service Centre.
- Should the product come into contact with salt water, immediately clean it with a cloth moistened with fresh water and let it dry. The product must be inspected by an authorised Ottobock Service Centre.

**CAUTION**

Mechanical stress on the product

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

**NOTICE**

**Exposure of the product to unsuitable environmental conditions**

Damage, brittleness or destruction due to improper handling

- Avoid storage in condensing ambient humidity.
- Avoid contact with abrasive substances (e.g. sand, dust).
- Do not expose the product to temperatures below -10 °C (14 °F) or above +60 °C (140 °F) (e.g. sauna, excessive sunlight, drying on a radiator).

**NOTICE**

**Thermal overloading of product components**

Loss of function due to improper thermal treatment

- Prior to the thermal treatment of the product, remove all temperature-critical components (e.g. plastic parts).
### CAUTION

#### Mechanical damage to the product
Injuries due to changes in or loss of functionality
- Use caution when working with the product.
- Check the product for proper function and readiness for use.
- In case of changes in or loss of functionality, discontinue use of the product and have it checked by authorised, qualified personnel.

### CAUTION

#### Excessive strain due to use on more than one patient
Risk of injury and loss of functionality as well as damage to the product
- Use the product on only one patient.
- Observe the maintenance recommendations.

### INFORMATION

#### The product may be exposed to increased loads by the patient.
Shorten the maintenance intervals according to the expected loads, in particular for especially heavy and/or highly active patients.

### 4.10 Notes on the movement patterns

#### CAUTION

##### First step from a standing position with the leg wearing the product set back
Falling due to unexpected product behaviour because of changed damping behaviour.
- Extending the knee joint and placing load on the toes may cause the product to switch to the swing phase (no damping).
- Always take the first step from a standing position, starting with the contralateral leg.

#### CAUTION

##### Risk of falling when walking backwards
Falling due to unexpected product behaviour because of changed damping behaviour.
- Extending the knee joint and placing load on the toes may cause the product to switch to the swing phase (no damping).
- When walking backwards, take smaller steps and put a consistent load on the foot in order to prevent unintentional buckling due to switching to the swing phase.

#### CAUTION

##### Walking up stairs
Falling due to foot being placed incorrectly on stair as a result of changed damping behaviour.
- Inform the patient that the handrail always has to be used when walking up stairs, and that most of the sole of the foot has to be set onto the stair surface.
- Particular caution is required when carrying children up the stairs.

#### CAUTION

##### Walking down stairs with use of the Spring Element
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 38).
- 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.
4.11 Notes on the safety modes

**CAUTION**

**Safety mode cannot be deactivated**
Falling due to unexpected product behaviour because of changed damping behaviour.
- If you cannot deactivate safety mode by recharging the battery, a permanent malfunction has occurred.
- Do not continue using the defective product.
- The product must be inspected by an authorised Ottobock Service Centre.

**CAUTION**

**Safety signal occurs (ongoing beep signal)**
Falling due to unexpected product behaviour because of changed damping behaviour.
- Observe the warning/error signals (see Page 38).
- 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 safety mode behaviour because of changed damping behaviour.
- The warnings/error signals (see Page 38) have to be observed.
5 Scope of Delivery and Accessories

Scope of Delivery
• 1 pc. 757L16* power supply
• 1 pc. 4E50 Battery Charger for C-Leg
• 1 pc. leg orthosis (aligned) with 17B300=* C-Brace joint unit
• 1 pc. 647G631 instructions for use (qualified personnel)
• 1 pc. 646D458 instructions for use (user)
• 1 pc. 647F449 orthotic passport
• 1 pc. cosmetic case for XEKT2337 battery charger

Accessories
• "C-Soft 4X180=V2.8" or higher adjustment software
  Update from 4X180=V2.0, 4X180=V2.2, 4X180=V2.4, 4X180=V2.6 to 4X180=V2.8 by internet download
• 60X7 BionicLink
• 60X5 BionicLink PC

INFORMATION
The adjustment software only works correctly with the "60X5 BionicLink PC" Bluetooth adapter. All other Bluetooth adapters, including those integrated into the computer, are not supported.

6 Charging the battery
The following points must be observed when charging the battery:
• The capacity of a fully charged battery is sufficient for one full day.
• We recommend charging the product overnight when used by the patient on a daily basis.
• When used daily, the complete charging unit (power supply – battery charger) may remain plugged into the wall socket.
• The battery should be charged for at least 3 hours prior to initial use.

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.
2) Connect the round, three-pin plug of the power supply to the 12V receptacle on the battery charger so that the plug locks into place.
   INFORMATION: Ensure correct polarity (guide lug). Do not use force when connecting the cable plug to the battery charger.
3) 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.
   INFORMATION: Ensure correct polarity (guide lug). Do not use force when connecting the cable plug to the battery charger.
4) Plug the power supply unit into the wall socket.
   → The green LED on the back of the power supply and the green LED on the battery charger light up.
   → 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 38).
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!
   → The correct connection of the battery charger to the product is indicated by feedback (Status signals).
3) The charging process starts.
   → After approx. 6 hours, the product battery is fully charged and the yellow LED on the battery charger turns off.
4) Disconnect the product after the charging process is complete.
   → This is followed by an electronics self-test which is confirmed by feedback (Status signals).
5) Close the charging receptacle cover.

6.3 Display of the current charge level

The current battery charge level can only be displayed by connecting the battery charger and power supply to the product.

<table>
<thead>
<tr>
<th>Battery charger</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] [ ] [ ]</td>
<td>Battery charge level less than 50%</td>
</tr>
<tr>
<td>[ ] [ ] [ ]</td>
<td>Battery charge level over 50%</td>
</tr>
<tr>
<td>[ ] [ ] [ ]</td>
<td>Battery is fully charged</td>
</tr>
</tbody>
</table>

7 Preparation for use

7.1 C-Brace orthosis with spring element

The following steps need to be carried out the first time the product is put on and adjusted:
1) Apply the product to the seated patient (see Page 26).
2) Establish the connection between the product and the software (see Page 20).
3) Bring the product to full extension and do not put a load on it.
4) Click the “Calibrate” button in the software.
   → Several beeps indicate successful calibration.
5) In the software, set the controls for stance phase flexion and maximum load to maximum.
6) Have the patient stand up.
7) The patient has to walk a few steps between parallel bars.
8) Adapt the values in the software depending on the patient (see Page 22).
9) Save the configured values and disconnect the product from the software.

7.2 C-Brace orthosis with Sensor Ankle

CAUTION

Maximum load not checked
> Falling due to unexpected product behaviour because of changed damping behaviour.
► The Maximum Toe Load parameter must be checked after each adjustment or change to the dorsal stop.

The following steps need to be carried out the first time the product is put on and adjusted:
1) Establish the connection between the product and the software (see Page 20).
2) Bring the product to full extension and do not put a load on it.
3) Bring the foot shell to plantar flexion.
4) Click the “Calibrate” button in the software (see Page 21).
   → Several beeps indicate successful calibration.
5) Apply the product to the seated patient (see Page 26).
6) In the software, set the controls for stance phase flexion and maximum load to maximum.
7) Pull the cable head off the sensor screw.
   → Long beeps are emitted.
   → The product switches to safety mode.
8) Push and hold the top button on the joint unit until a long beep is emitted (see fig. 1).
   → The beeps stop.
   → The product remains in safety mode.
9) Have the patient stand up.
10) Put the supplied counter nut onto the sensor screw.
11) The sensor screw must be turned in at least 5 mm (max. 18 mm of the screw can still be seen).

   INFORMATION: The dorsal stop can be adjusted by turning the sensor screw.

12) The patient has to walk a few steps between parallel bars.
13) Put the cable head onto the sensor screw.

   INFORMATION: Make sure that the marking on the cable head and the marking on the sensor screw line up (see fig. 2).
14) Restart the product by connecting the charging cable.
   → The product switches to 1st mode.
15) Calibrate the product again (see points 2 - 4).
16) Adapt the values in the software depending on the patient (see Page 22).
17) Secure the sensor screw with the supplied counter nut (see fig. 3).
18) Save the configured values and disconnect the product from the software.

8 Adjustment with C-Soft

8.1 Introduction
The “C-Soft” adjustment software makes it possible to optimise the product settings for a patient. The adjustment software provides step-by-step guidance through the adjustment process. After the settings are configured, the data for them can be saved and printed for documentation. If needed, these data can be loaded and fed into the product.

8.2 Indications for use
The “C-Soft” adjustment software is intended for the patient-specific adjustment of the following products:
• Leg orthosis with 17B300=* C-Brace joint module
• Electronic knee joint systems with the article numbers: 3C95/3C85, 3C96/3C86, 3C96-1/3C86-1, 3C98/3C88, 3C98-1/3C88-1, 3C98-2/3C88-2.

8.3 Installation
For the installation/removal of C-Soft, please read the 647G268 instructions for use.
8.4 Data transfer between the product and the PC
Product settings using the adjustment software can only be made via Bluetooth data transfer. For this, a Bluetooth wireless connection must be established between the product and the PC with the help of the 60X5 BionicLink PC. To install the 60X5 BionicLink PC for the first time, follow the procedure described in the instructions for use supplied with this adapter.

INFORMATION
Do not disconnect the 60X5 BionicLink PC from the PC when there is an active Bluetooth connection.

INFORMATION
Secure data transfer is only assured up to a distance of 10 m between the BionicLink PC and the product.

8.4.1 BionicLink

INFORMATION
Prior to connecting the 60X7 BionicLink, read the corresponding instructions for use.

1) Open the plug cover.
2) Connect the cable of the BionicLink to the lower receptacle.
   → The blue LED on the BionicLink has to light up. If it does not, charge the product battery or check the connecting cable.
3) Attach the BionicLink to the joint module using the hook-and-loop closure.

8.5 Using the Ottobock DataStation
For the use of the Ottobock DataStation, please read the adjustment software instructions for use. You can also consult the integrated online help of the adjustment software for further information.

8.6 C-Soft application

CAUTION
Disconnecting/establishing the connection during the adjustment process with the adjustment software
Falling due to unexpected behaviour of the product.
► When wearing the product, the patient must not remain unattended during the configuration process while connected to the adjustment software.
► Observe the maximum range of the Bluetooth connection.
► During the data transfer (PC to product), the patient must remain standing or sitting still and the BionicLink or the communication cable must not be removed.
► If the connection fails while making adjustments, the orthotist must immediately warn and secure the patient.
► The connection to the product must always be disconnected after adjustments have been completed.

8.6.1 Starting the Program
C-Soft can be started in the following ways:

New job
1) Click the Add Job button.
Adjustment with C-Soft

→ The tab opens.
2) Click the C-Soft button.
   If a lower limb application has already been installed, the button is on the Prosthetic Lower Extremity tab.

Existing job
The job must have been created previously using C-Soft 2.6 or higher.
▷ Double-click the existing job.

Entering the password
The password input screen is displayed after starting the Ottobock DataStation > C-Soft.

- Before the first use, the Username and Unlock-PIN fields must be filled in with the relevant information that was given to you during the Ottobock product training course for the adjustment software.
  Information: make sure to use correct spelling (upper/lower case) when entering the information.
- Click the Log On button.
  
- After entering the unlock PIN and clicking the Log On button you will be asked to enter and confirm a password of your own choice.
  Information: the password entry window only appears after you have entered the unlock PIN. If you have already entered a password in the previous step, the password entry screen will not appear.
- Click the OK button.

INFORMATION
Unlock PIN: This code is valid on any computer.
Personal password: This code is only valid on the computer on which it was entered/changed.

INFORMATION
If certification for the C-Leg has been obtained, the user name is not valid for the fitting with this product. Only by entering the user name for the fitting with this product will the C-Soft version for this product be available.
Certification for the C-Leg cannot be used for this product. An error message is therefore displayed when establishing a connection.

INFORMATION
To switch from a C-Leg fitting to a fitting with this product, close the Ottobock DataStation, restart it and enter the user name for the fitting with this product.

8.6.2 Establishing a connection between the product and C-Soft
The following points need to be observed for establishing the connection:
- The 60X5 BionicLink PC is connected to the PC being used and the corresponding drivers are installed.
- The 60X7 BionicLink is connected to the product.
- The product battery is charged (the blue LED on the 60X7 BionicLink is lit up or flashing).
- The battery charger is disconnected from the product.
- The product is within the range of the Bluetooth connection.
  The range is around 10 m but can vary depending on local conditions.

After entering the password, the Establish connection tab is displayed automatically.

1) Click the Connect via Bluetooth button to establish a Bluetooth connection between C-Soft and the product.
  INFORMATION: When several products are present, select the desired BionicLink device according to the information on the reverse side of the device. If only one BionicLink device is available, the selection will be skipped automatically.
2) Read the security notice on the screen and click the OK button.
   → A connection is established to the product.
The product emits beep signals in order to indicate to the patient and orthotist that the connection has been established. The blue LED on the BionicLink flashes as well.

**INFORMATION**

If the connection is disrupted during operation, see the section "Troubleshooting" (see Page 40).

Once the connection has been established, the data are read from the product.

**Disconnecting from the product**

1) Click the Establish connection tab.
2) Click the Disconnect button.
   → The connection to the product is disconnected.
3) Disconnect the BionicLink from the product.
4) Close the plug cover.

**Reconnecting to the product**

1) Connect the BionicLink to the product.
2) Click the Establish connection tab.
3) Click the Reconnect button.
4) Read the security notice on the screen and click the OK button.
   → A connection is established to the product.

### 8.6.3 Calibration (zero setting)

**INFORMATION**

Calibration is required for all products adjustable with C-Soft. Adjustments are not possible without prior calibration! Instruct the patient in accordance with the explanations in the software’s adjustment section.

**INFORMATION**

Calibration is required each time a connection has been established.

**Calibration while standing**

Once the connection has been established, the Calibration tab is displayed automatically.

1) The patient must stand between parallel bars or with crutches.
2) Extend the leg with the product to the rear with no movement in the knee joint and no load.
3) Click the Calibration button.
   → The product is calibrated.

The symbol is displayed after calibration is successfully completed.
If the symbol is displayed, calibration could not be performed. To correct errors, read the section "Troubleshooting" (see Page 40). Perform calibration again after correcting errors.

**Calibration while sitting**

Once the connection has been established, the Calibration tab is displayed automatically.

1) The patient has to sit in a chair of suitable height.
2) Extend the leg with the product, the edge of the heel touches the floor.
   **INFORMATION:** Neither a heel nor a toe load should be shown on the screen in this position.
3) Click the Calibration button.
   → The product is calibrated.

The symbol is displayed after calibration is successfully completed.
If the symbol is displayed, calibration could not be performed. To correct errors, read the section "Troubleshooting" (see Page 40). Perform calibration again after correcting errors.
8.6.4 Adjustment procedure on product

**INFORMATION**
The program does not perform any automatic changes of the adjustments! Each change must be made or confirmed by the orthotist!

The adjustment software describes the procedure for each adjustment step in the adjustment section.

► After successful calibration, click the Settings tab.
→ The product adjustments are displayed.

**8.6.5 Overview of adjustment parameters**
The adjustment parameters of the adjustment software are described in more detail in the section that follows. In this overview, the sequence of the parameters is based on the movement pattern or the gait phases when walking on level ground that are relevant for the parameters. The sequence in the description therefore deviates from the listing in the C-Soft adjustment software.

The denotation of the parameters differentiates between the stance phase (STP = Stance Phase) and the swing phase (SWP = Swing Phase).

**STP Flexion Damping**

The parameter **‘STP Flexion Damping’** 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 should sit down on a chair while supporting him or herself with the hands on the armrests. The patient lets him or herself sink into the product and feels the supporting effect of stance phase damping (STP Flexion Damping).

**Fine adjustment:**
Have the patient walk down a ramp and then stairs, keeping one hand on the handrail for safety. If the resistance is 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.

**STP Flexion Damping Plus (only in expert mode)**

**CAUTION**

**Walking down stairs and ramps**

Falling due to unexpected, increased stance phase damping during the transition from a level surface to stairs or ramps.

► Inform the patient of the changed product behaviour.
► Inform the patient that changed stance phase damping has to be verified before walking on stairs or ramps.
The value selected for elevated flexion resistance (STP Flexion Damping Plus) cannot be lower than the value selected for stance phase damping (STP Flexion Damping). Upon attempting to enter a lower value, this value is automatically set to the value of the parameter STP Flexion Damping.

For some patients, the optimum stance phase flexion damping setting (STP Flexion Damping) may be too low for walking on level ground. This is why the parameter 'STP Flexion Damping Plus' is available in expert mode. During physiological walking, slight flexion in the knee joint follows shortly after heel strike with the knee extended. This movement pattern is called "stance phase flexion". Due to muscular deficits and/or contractures in the knee or hip joint, some patients flex the knee excessively in this gait phase. As a result, more energy needs to be expended for the renewed extension of the knee joint with simultaneous forefoot load.

With the parameter 'STP Flexion Damping Plus', increased stance phase damping can be configured which is only active following a swing phase while walking on level ground and only for a short, adjustable period of time. (Parameter 'STP flexion plus time [“20ms”]')

It is activated at the time of swing phase extension, shortly before the leg is fully extended. After the time 'STP flexion plus time [“20ms”]' has elapsed, the system switches back to normal stance phase damping.

**Adjustment:**
Have the patient walk on level ground and observe the stance phase flexion. If the patient flexes the knee very far, the parameter 'STP Flexion Damping Plus' should be set to a higher value.

**STP flexion plus time [“20ms”] (only in expert mode)**

The parameter 'STP flexion plus time [“20ms”]' determines the length of time for which damping 'STP Flexion Damping Plus' is active. After this time has elapsed, the system switches back to regular stance phase damping (STP Flexion Damping).

To avoid limiting comfort and safety on ramps and stairs, this parameter should be set to the shortest possible time. Ideally this parameter reflects the duration of the stance phase while walking on level ground.

This setting is only available in expert mode. In the delivery condition, the parameter is set to 0. This means the function is deactivated.

**Adjustment:**
Have the patient walk on level ground and continue reducing the time until bending during stance phase flexion can be clearly observed. Take note of feedback from the patient.

**Adjustment error:**
If the configured time is too long, flexion when stepping onto ramps or stairs may be delayed; this can cause the patient to fall. If the configured time is too short, this results in a loss of comfort when walking on level ground.
STP Extension Damping

During physiological gait, stance phase flexion is followed by renewed extension of the knee joint while shifting weight to the forefoot (triggering the swing phase).

The parameter ‘STP Extension Damping’ influences this harmonious and natural gait pattern, which results in a movement pattern that protects the remainder of the locomotor system.

The adjustment of the parameter ‘STP Extension Damping’ determines how smoothly the leg returns to an extended position after stance phase flexion. This influences the abruptness of the stop when the knee is stopped prior to full extension after stance phase flexion. The extension movement of the leg can be controlled with this adjustment.

Adjustment:
Have the patient walk at several different walking speeds and adjust the parameter ‘STP Extension Damping’ using the slider control. The goal is to avoid an abrupt extension stop, while also avoiding the feeling that the knee joint is stuck in a flexed position at different walking speeds. The amount of force required by the patient to extend the knee joint must not be excessive.

Maximum Toe Load

⚠️ CAUTION
Maximum load not checked
> Falling due to unexpected product behaviour because of changed damping behaviour.
▶ The Maximum Toe Load parameter must be checked after each adjustment or change to the dorsal stop.

The parameter ‘Maximum Toe Load’ is essential for triggering the swing phase. As soon as the forefoot load with the leg extended exceeds 70% of the value configured for this parameter, the knee joint is released. This permits unimpeded flexion in the swing phase.

Adjustment:
The patient walks a few steps (between parallel bars). Observe the course of the toe load in the bar diagram at the bottom right while the patient is walking. Adjust the ‘Maximum Toe Load’ slider control so that the maximum value of the trailing pointer clearly exceeds the grey mark (70% of the parameter ‘Maximum Toe Load’) and reaches the orange mark of the bar diagram. The numeric display of the slider control is for information only. The patient should be able to reliably trigger the swing phase while walking on level ground.

Also verify the adjustment while standing: the swing phase must not be triggered unintentionally while standing. If this is the case, the setting for the parameter ‘Maximum Toe Load’ is too low.
**SWP initial flex. damping**

This damping value is active immediately after triggering swing phase flexion.

**Adjustment:**
This parameter is set to a minimum value at the factory. Readjustment is only required for highly active patients. In most cases, readjustment is not required and should therefore not be done.

**SWP Dynamic Factor**

This value in relation to the walking speed determines how far the lower leg with the product swings through in the dorsal direction. This damping begins with the configured value of the parameter ‘SWP Knee Angle Threshold’. This value can also be configured in conjunction with the adjustment ‘SWP Knee Angle Threshold’. For a large knee angle, the value ‘SWP Dynamic Factor’ must be higher than for a small knee angle. This also influences the stride length since it determines the flexion time.

**Adjustment:**
Use the slider control ‘SWP Dynamic Factor’ to find a setting that is comfortable for the patient.

**SWP Knee Angle Threshold**

In addition to the adjustment 'SWP Dynamic Factor', a knee angle from which dorsal swing-through is dampened can also be configured.

At the factory, the parameter is set so that switching from stance phase damping to elevated damping (SWP Dynamic Factor) takes place from a knee angle of approx. 35°.

**Adjustment:**
Have the patient walk on level ground at normal walking speed and check the ground clearance. If the ground clearance is insufficient or the patient tends to stumble, the value of the parameter 'SWP Dynamic Factor' should be reduced.

After adjusting ‘SWP Dynamic Factor’, a harmonious gait pattern can also be achieved by adjusting ‘SWP Knee Angle Threshold’.
SWP Extension Damping

This is the resistance against the extension of the leg at the end of the swing phase. It affects the abruptness with which the leg is stopped at full extension. However, the value also influences the duration of the swing phase. The higher the value of ‘SWP Extension Damping’, the later the leg reaches full extension. This damping becomes active at an angle of approx. 20° and continues until full extension.

**Adjustment:**
Adjust the parameter ‘SWP Extension Damping’ so that there is no uncomfortably hard end stop, but not so much that the patient feels the need to wait for the extension of the leg. During the adjustment process, have the patient walk at several noticeably different speeds.

**Stance function timer [*20ms] (only in expert mode)**

At the end of this time in a standing position with the knee joint slightly flexed (knee angle approx. 5° to approx. 20°), high stance phase damping (STP Flexion Damping) is automatically selected (STA mode). This makes it possible, for example, to stand on uneven surfaces or slopes. When the leg is extended, this mode is deactivated. This parameter is entered in the unit [20ms]. If the value "3" is entered for this parameter, this means a time of 3*20 ms = 60 ms.

**Adjustment:**
Consult the patient to determine the time period before standing mode is activated. This mode is turned off when "0" is entered as the time.

### 9 Use

**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.

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

**CAUTION**

**Foreign objects between the leg and frame structure**
Pressure points on the leg due to foreign objects at the contact points between the leg and frame structure.
- Smooth out wrinkles in the padding material and clothing.
- Check the leg for pressure points.

For a first-time fitting, the patient needs to learn how to handle and use the product. Donning and doffing, sitting, standing, walking and especially walking backwards require practice.

**9.1 Application**
For donning and doffing the product, we recommend:
• Have the patient sit on a chair.
• Unfasten all closures.
1) Remove the shoe.
2) Flex the joint of the product by manually applying a load to the forefoot.
3) Insert the foot into the foot component and position the heel and lower leg in the shell.
4) Slightly extend the foot and apply the thigh shell of the product to the thigh from below.
5) Fasten the top closure.
   → This serves to keep the product in place temporarily.
6) Fasten the closure below the knee.
7) Fasten the ankle closure if applicable.
8) Fasten the closure above the knee.
9) Retighten the top closure.
10) Put on the shoe.

INFORMATION: Ensure that the shoe is open wide enough to slip in with the product.
11) Stand up and retighten all closures.
12) Verify the correct fit of the product.
13) After approx. 15 minutes of active movement, slightly retighten all straps.

9.2 Removal

INFORMATION
If a mode with a high setting for the parameters ‘Base Resistance’ and/or ‘Resistance Gain’ such as ‘Extended standing’ is configured as the additional mode (2nd mode), switching back to basic mode (1st mode) must be performed before sitting down (see Page 33). Otherwise it is not possible to flex the knee joint.

1) Sit on a chair.
2) Remove the shoe.
3) Open the upper closures.
4) Open the closure below the knee.
5) Open the closure below the ankle if applicable.
6) Pull the thigh shell down and off.
7) Step out of the product.
8) Set the product upright and fasten the closures.
9) Store the product upright and charge the battery if necessary.

9.2.1 Storage and bleeding

CAUTION
Air in the hydraulics
Falling due to unexpected product behaviour because of changed damping behaviour.
► Flex the joint to the stop several times until the play is largely eliminated.
► If the feeling of improper stance phase control remains after several attempts to bleed the air, the product must be inspected by an authorised Ottobock Service Centre.

The product has an automatic venting mechanism that vents the hydraulics while walking.
In general, the product is vented automatically by movement during regular use.
Air may accumulate in the product if it is not used for an extended period of time. This is indicated by play (dead travel) in the extension stop.
The following points need to be observed in order to vent the product:
► Flex the joint to the stop against the damping resistance several times until the play is largely eliminated.

To avoid accumulation of air in the product, the following points have to be observed:
► Store the product properly (fully flexed, thigh shell vertical).
► Avoid extended disuse of the product (use the product regularly).

INFORMATION
Minimal play is system-specific and impairs neither the function nor the safety of the product.
9.3 Movement patterns

9.3.1 Standing

Knee control through high hydraulic resistance and static alignment.

The knee joint of the product has no locking function, so that slow bending is possible under flexion load. To restore the stable standing position, place the leg back under the body and put weight on the heel.

Manually switch to LOM (see Page 32) for extended standing.

INFORMATION: By adjusting the parameter 'Stance function timer [*20ms]' via the adjustment software, high stance phase damping is activated after the knee joint remains slightly flexed (5° to 20°) for a period of time (STA mode (see Page 30)). This mode is deactivated by extending the knee joint.

9.3.2 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.

To safely switch to the swing phase, the system requires special measurements and prerequisites. The fundamental prerequisite is a sufficient forefoot load with simultaneous extension of the product’s knee joint. If this is not achieved, the leg cannot swing through.

INFORMATION: When walking on soft surfaces (forest floor), more force may be required to trigger the swing phase.

9.3.3 Sitting down

INFORMATION

If a mode with a high setting for the parameters 'Base Resistance' and/or 'Resistance Gain' such as 'Extended standing' is configured as the additional mode (2nd mode), switching back to basic mode (1st mode) must be performed before sitting down (see Page 33). Otherwise it is not possible to flex the knee joint.

The damping of the product while sitting down ensures that the knees bend evenly, thereby supporting the less affected side.

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

9.3.4 Standing up

INFORMATION

If the product was switched to the additional mode 'Cycling' for sitting, it must be switched back to the basic mode (1st mode) before standing up. Otherwise secure standing with the product is not assured.
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.

9.3.5 Walking down stairs
Depending on the construction of the orthosis (spring element or Sensor Ankle), the movement pattern is carried out as follows.

9.3.5.1 Orthosis construction with spring element

⚠️ CAUTION
Walking down stairs
Falling due to foot being placed incorrectly on stair as a result of changed damping behaviour.

- Inform the patient that the handrail always has to be used when walking down stairs, and that the patient has to roll over the edge of the step with the middle of the shoe.
- The warnings and error signals have to be observed (see Page 38).
- 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.

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 assure 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.
5) Place the foot of the leg with the product on the next step after that.

9.3.5.2 Orthosis construction with Sensor Ankle

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.
4) Place the foot of the leg with the product on the next step after that.

9.3.6 Walking up stairs

⚠️ CAUTION
Walking up stairs
Falling due to foot being placed incorrectly on stair as a result of changed damping behaviour.

- Inform the patient that the handrail always has to be used when walking up stairs, and that most of the sole of the foot has to be set onto the stair surface.
- Particular caution is required when carrying children up the stairs.
The product does not have an active drive system to support this movement pattern. This means walking up stairs step-over-step is only possible if certain physical conditions are met.

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

### 9.3.7 Walking backwards

**Risk of falling when walking backwards**
Falling due to unexpected product behaviour because of changed damping behaviour.

- When walking backwards with toe contact, active flexion in the hip could cause the product to switch to the swing phase (no damping).
- The patient has to actively secure the product with the residual musculature while walking backwards.

Walking backwards with the knee joint extended and the toes on the floor results in a forefoot load. This may cause the product to switch to the swing phase. This means there is a risk of falling.

In order to avoid this risk, practice walking backwards under the instruction of trained, qualified personnel.

### 9.3.8 Walking up a ramp

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

### 9.3.9 Walking down a ramp

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

### 9.4 Basic mode and additional modes

A further mode (2nd mode) can be activated and configured in addition to basic mode (1st mode) using the adjustment software. It can be accessed by the patient using the buttons on the hydraulic unit (see Page 32). A LOM can also be accessed (see Page 32); it provides the patient with a certain feeling of safety during initial use, since the knee joint is locked in the stance phase. Nevertheless, the swing phase is triggered when walking.

**Basic mode (1st mode)**
This mode is intended for daily use.
**Additional mode (2nd mode)**

This mode is intended for specific motion patterns or postures (e.g. cycling ...). Default settings for the motion pattern and posture can be accessed and individually adapted using the adjustment software.

**LOM**

This special mode has the characteristics of the basic mode with blocked knee joint. With this mode, the patient is provided with a certain feeling of safety after the initial fitting since the knee joint cannot be flexed but can be extended. The knee joint is blocked in the stance phase since stance phase damping is set to maximum. Nevertheless, the swing phase is triggered when walking. To allow the user to sit down with the knee joint flexed, it is necessary to manually switch to basic mode (1st mode) before sitting down (see Page 33). In this mode it is not possible to descend stairs and ramps step over step.

**STA mode (Stance function timer [*20ms]*)**

High stance phase damping (STP Flexion Damping) is automatically activated during an extended stance phase with the knee slightly flexed (knee angle approx. 5° to approx. 20°). This occurs after the time ‘Stance function timer [*20ms]’ has elapsed.

**INFORMATION:** If this mode is not desired, it can be deactivated by adjusting the parameter 'Stance function timer [*20ms]' in the adjustment software.

**9.4.1 Switching modes with the buttons on the hydraulic unit**

Upper button (⁻) – return to basic mode (1st mode)
Lower button (⁺) – switching to the additional mode (2nd mode) and LOM

**INFORMATION:** With the exception of the basic mode (1st mode), some movement patterns are limited or not possible in all other modes.
Use

<table>
<thead>
<tr>
<th>Symbol guide</th>
<th>Overview – mode switching</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Press bottom button 1x long</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Press top button 1x long</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Press bottom button 2x short</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Short beep signal</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Long beep signal</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Relieve load on leg</td>
</tr>
</tbody>
</table>

### Table – mode switching

<table>
<thead>
<tr>
<th>from</th>
<th>to</th>
<th>Press top button</th>
<th>Press bottom button</th>
<th>Beep signal</th>
<th>Additional action</th>
<th>Beep signal</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st</td>
<td>2nd</td>
<td></td>
<td>1 x long</td>
<td>1 x long</td>
<td>Relieve load on leg</td>
<td>2 x short</td>
</tr>
<tr>
<td>1st</td>
<td>LOM</td>
<td></td>
<td>2 x short</td>
<td>1 x long</td>
<td>Relieve load on leg</td>
<td>1 x short</td>
</tr>
<tr>
<td>2nd</td>
<td>1st</td>
<td>1 x long</td>
<td>2 x short</td>
<td>1 x long</td>
<td>Relieve load on leg</td>
<td>3 x short</td>
</tr>
<tr>
<td>2nd</td>
<td>LOM</td>
<td></td>
<td>2 x short</td>
<td>1 x long</td>
<td>Relieve load on leg</td>
<td>1 x short</td>
</tr>
<tr>
<td>LOM</td>
<td>1st</td>
<td>1 x long</td>
<td></td>
<td>1 x long</td>
<td>Relieve load on leg</td>
<td>1 x short</td>
</tr>
<tr>
<td>LOM</td>
<td>2nd</td>
<td></td>
<td>1 x long</td>
<td></td>
<td>Relieve load on leg</td>
<td>2 x short</td>
</tr>
</tbody>
</table>

**INFORMATION**

If 4 short beep signals are emitted, this means switching could not be completed. The most frequent cause of this is that the weight was not taken off the leg after the first beep signal.

### 9.4.2 Activating the additional mode (2nd mode)

**INFORMATION**

Before the first step, always check whether the selected mode corresponds to the desired motion type.

1) Press and hold the lower button (\( \textcircled{b} \)).
   → A long beep signal is emitted.

2) Take weight off the leg \( \textcircled{f} \) and keep it still for approx. 1 second.
   → Two short beep signals sound to indicate successful switching to the additional mode (2nd mode).
   **INFORMATION:** If four beep signals sound, the weight was not taken off the leg correctly or for long enough. Repeat the process to correctly switch to the desired mode.

### 9.4.3 Activating LOM

**From basic mode (1st mode) to LOM:**

- Briefly press the lower button (\( \textcircled{b} \)) twice.
  → Three short beep signals are emitted.
  → The product has successfully switched to LOM.

**From additional mode (2nd mode) to LOM:**

1) Briefly press the lower button (\( \textcircled{b} \)) twice.
   → A long beep signal is emitted.

2) Take weight off the leg \( \textcircled{f} \).
   → Three short beep signals are emitted.
   → The product has successfully switched to LOM.
9.4.4 Switching from an additional mode back to basic mode
1) Press and hold the upper button ( ).
   → A long beep signal is emitted.
2) Take weight off the leg and keep it still for approx. 1 second.
   → A short beep signal sounds to indicate successful switching to basic mode (1st mode).
   INFORMATION: If four beep signals sound, the weight was not taken off the leg correctly or for long enough. Repeat the process to correctly switch to the desired mode.

10 Additional operating states (modes)

10.1 Empty battery mode

CAUTION
Danger when empty battery mode is activated
Falling due to unexpected behaviour of the product because of changed damping behaviour.
► Inform the patient of the configured damping behaviour in empty battery mode ("high damping" = high safety/reduced comfort or "low damping" = less safety/higher activity).
► For the "low damping" setting in empty battery mode, the patient must have the necessary muscular and cognitive abilities to control a freely moving knee joint without stance phase stability.
► You can switch back to basic mode from empty battery mode by charging the product.
► Observe the error signals (see Page 38).

Beep signals sound if the available battery charge level is less than 1% (see Page 38). Then damping is set to the value that was configured in the parameter ‘Damping in empty battery mode’ of the adjustment software. This parameter should be chosen with the setting ‘high’ (stance phase damping value) in order to ensure a secure stance when the battery is drained. You can switch back to basic mode (1st mode) from empty battery mode by charging the product.

10.2 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.

10.3 Safety mode
The product automatically switches to safety mode if a critical fault occurs (e.g. failure of a sensor signal). Safety mode remains in effect until the error has been rectified.
In this mode, the product sets the stance phase damping value (parameter ‘STP Flexion Damping’) but does not trigger a swing phase. This ensures the safety of the patient even if the product is not active.
Default damping values are activated in safety mode. This makes limited walking possible for the user even though the product is not active.
The switch to safety mode is announced by beep signals immediately prior to the switch (see Page 38).
The beep signals can be muted by pressing the top button (5 seconds) on the joint unit. The product remains in safety mode.
Pressing the top button on the joint unit for 5 seconds again starts a check of the sensor. If there is a sensor signal (e.g. contact with the spring was established, or the connection with the sensor screw was established), the product switches back to 1st mode and can be used.

11 Cleaning
1) Clean the product with a damp cloth and mild soap (e.g. Ottobock 453H10=1 Derma Clean) when needed.
   Ensure that no liquid penetrates into the leg orthosis.
2) Dry the product with a lint-free cloth and allow it to air dry fully.

Textile component:
1) Remove the textile component from the product.
2) Fasten all hook-and-loop closures.
3) Hand wash the textile component in warm water at 30 °C/86 °F with a standard mild detergent. Rinse thoroughly.
4) Allow to air dry. Do not expose to direct heat sources (e.g. sunlight, stove or radiator).

**Sensor Ankle**
1) Clean the product with a damp, soft cloth.
2) Dry the product with a soft cloth.
3) Allow to air dry in order to remove residual moisture.

### 12 Maintenance

The manufacturer requires at least an annual inspection of the orthosis to verify functionality and check for wear.

**INFORMATION**

Each time the Spring Element/Sensor Ankle is replaced, the settings of the joint unit have to be checked (see Page 18).

### 12.1 Replacing the spring element

**INFORMATION**

Configuring an improper spring stiffness increases the amount of energy expended by the patient while walking.

The Spring Element is available with various levels of bending strength depending on patient requirements. The Spring Elements can be trimmed to the corresponding length.

1. The spring material is carbon (hard) – 17CF2=1
2. The spring material is glass-fibre reinforced plastic (soft) – 12CF2=4, 12CF2=HD

**NOTICE**

Damage to the spring element

Damage to the electronics in the spring element or the contacts due to careless handling.

► Great care is required when replacing the spring element.

**INFORMATION**

Use the supplied screws to attach the clamp adapter when using the 12CF2=HD Spring Element.

### 12.1.1 Removing the spring element

1) Loosen all four screws on the lower clamp adapter of the spring element (see fig. 4). Do not remove the screws.
2) Remove the foot component.
3) Loosen all four screws on the upper clamp adapter of the spring element (see fig. 5). Do not remove the screws.
4) Pull the spring element out of the upper clamp adapter of the spring element.
   **INFORMATION:** Do not twist the spring element, since the contacts are also disconnected as it is pulled out.
5) Remove the spring element entirely (see fig. 6).

### 12.1.2 Inserting the spring element

<table>
<thead>
<tr>
<th>CAUTION</th>
</tr>
</thead>
</table>
| **Damage to the connection cable**  
Falling due to product malfunction. |

1) ▶ Replace the damaged connecting cable of the spring element immediately.

1) Remove the set screws of the plug on the upper clamp adapter.
2) Remove the plug from the upper clamp adapter.
3) Insert the Spring Element into the upper clamp adapter with the lettering facing the leg (anterior).
   **INFORMATION:** Observe the correct alignment of the plug.
4) Slide the Spring Element into the clamp adapter until the leading edge of the spring element is flush with the edge of the clamp adapter (see fig. 7).
5) Coat the threads of the screws for the upper clamp adapter with thread lock (Loctite® 243).
6) Tighten the screws of the clamp adapter to a torque of 4 Nm.
   **INFORMATION:** Always tighten the diagonally opposite screws in sequence. Tighten all screws using the torque wrench.
7) Carefully connect the plug to the upper clamp adapter.
   **INFORMATION:** Do not bend the pins in the plug.
8) Coat the threads of the screws for the plug with thread lock (Loctite® 243).
9) Tighten the screws for the plug to a torque of 0.1 Nm (see fig. 8).
10) Set the foot component onto the Spring Element and slide it on up to the marking.
   **INFORMATION:** The Spring Element must project from the clamp adapter in order to ensure correct data transmission.
11) Coat the threads of the screws for the lower clamp adapter with thread lock (Loctite® 243).
12) Tighten the screws for the lower clamp adapter to a torque of 4 Nm.
   **INFORMATION:** Always tighten the diagonally opposite screws in sequence. Tighten all screws using the torque wrench.

### 12.2 Replacing the Sensor Ankle

<table>
<thead>
<tr>
<th>INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The product may be exposed to increased loads by the patient.</strong></td>
</tr>
</tbody>
</table>

Shorten the maintenance intervals according to the expected loads, in particular for especially heavy and/or highly active patients.

The manufacturer requires at least a semi-annual inspection of the product to verify functionality and check for wear.
13 Disposal

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.

14 Legal information

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

14.1 Liability

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

14.2 CE Conformity

Only applies to joint module "17B300=L C-Brace"/"17B300=R C-Brace"

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

Applies only to "O17CF2=1"/"17CF2=4"/"17CF2=HD" Spring Element

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

Applies only for 17LA3=* Sensor Ankle

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

14.3 Trademarks

All product names mentioned in this document are subject without restriction to the respective applicable trademark laws and are the property of the respective owners.

All brands, trade names or company names may be registered trademarks and are the property of the respective owners.

Should trademarks used in this document fail to be explicitly identified as such, this does not justify the conclusion that the denotation in question is free of third-party rights.

15 Appendices

15.1 Symbols Used

15.1.1 Symbols on the joint module

Declaration of conformity according to the applicable European directives

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 detri-
mental impact on health and the environment. Please observe the instructions of your national authority pertaining to return and collection.

SN YYYY WW NNN Serial number

15.1.2 Symbols on the battery charger

Declaration of conformity according to the applicable European directives

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.

15.1.3 Symbols on the spring element

Declaration of conformity according to the applicable European directives

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.

Legal manufacturer

SN YYYY WW NNN Serial number

15.1.4 Symbols on the Sensor Ankle

Declaration of conformity according to the applicable European directives

LOT:PPPP YYYY WW Lot number

15.1.5 Symbols on the sensor screw

SN YYYY WW NNN Serial number

15.2 Operating states/error signals
The product indicates operating states and error messages with beep signals.

15.2.1 Signals for operating states

Mode switching

<table>
<thead>
<tr>
<th>Beep signal</th>
<th>Additional action performed</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1x short</td>
<td>Take weight off leg</td>
<td>Switching to basic mode performed successfully</td>
</tr>
<tr>
<td>1x long</td>
<td>Button 1 or 2 was pressed long or Button 2 was pressed 2x short</td>
<td>When the beep signal sounds, weight must be taken off the leg to switch to the corresponding mode.</td>
</tr>
<tr>
<td>2x short</td>
<td>Take weight off leg</td>
<td>Switching to the additional mode (2nd mode) performed successfully</td>
</tr>
</tbody>
</table>
### 15.2.2 Warnings/error signals

**Error during use**

<table>
<thead>
<tr>
<th>Beep signal</th>
<th>Event</th>
<th>Required action</th>
</tr>
</thead>
<tbody>
<tr>
<td>3x short</td>
<td>Take weight off leg</td>
<td>Switching to LOM performed successfully</td>
</tr>
<tr>
<td>3x short</td>
<td>Button 2 was pressed 2x short</td>
<td>Switching to LOM performed successfully</td>
</tr>
<tr>
<td>4x short</td>
<td>Take weight off leg</td>
<td>No switching performed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Check the following points:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Was weight put on the leg with the product or was there movement in the knee joint?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Is the spring element in the foot region bent and therefore defective?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Was calibration performed?</td>
</tr>
<tr>
<td>3x long</td>
<td>Battery charge level under 10 %</td>
<td></td>
</tr>
<tr>
<td>5x long</td>
<td>Battery charge level under 5 %</td>
<td></td>
</tr>
<tr>
<td>10x long, then switching to empty battery mode</td>
<td>Battery charge level approx. 1 %</td>
<td></td>
</tr>
<tr>
<td>Ongoing short beep signal</td>
<td>Overheated hydraulic unit</td>
<td>Reduce activity</td>
</tr>
<tr>
<td><strong>Error of moderate severity:</strong></td>
<td></td>
<td>Attempt to reset this error by connecting the battery charger. If this error persists, the product must be inspected by an authorised Ottobock Service Centre.</td>
</tr>
<tr>
<td>Loss of spring contact/loss of sensor screw contact</td>
<td></td>
<td>The beep signal can be muted by pressing the top button on the joint unit (5 seconds). Restore contact with the spring or sensor screw. By pressing the top button on the joint unit (5 seconds), check the sensor contact. The check is confirmed by a long beep signal. If this error persists, the product must be inspected by an authorised Ottobock Service Centre.</td>
</tr>
<tr>
<td>Ongoing short beep signal</td>
<td>Active safety mode</td>
<td>The product must be inspected by an authorised Ottobock Service Centre</td>
</tr>
<tr>
<td>Walking possible with restrictions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuous beep signal</td>
<td><strong>Severe error:</strong></td>
<td>The product must be inspected by an authorised Ottobock Service Centre</td>
</tr>
<tr>
<td>e.g. failure of valve drives</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Possibly no switching into safety mode</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undetermined product behaviour</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total failure:</strong></td>
<td></td>
<td>The product must be inspected by an authorised Ottobock Service Centre</td>
</tr>
<tr>
<td>Electronic control no longer possible</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safety mode active or undetermined valve state</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undetermined product behaviour</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Error while charging the product

<table>
<thead>
<tr>
<th>LED on power supply</th>
<th>LED on battery charger</th>
<th>Error</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>○</td>
<td>○ ○ ○</td>
<td>Country-specific plug adapter not fully engaged on power supply</td>
<td></td>
</tr>
</tbody>
</table>
### LED on power supply
<table>
<thead>
<tr>
<th>LED on battery charger</th>
<th>Error</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Check whether the country-specific plug adapter is fully engaged on the power supply.</td>
</tr>
</tbody>
</table>

- **Non-functional wall socket**
  - Check wall socket with another electric appliance.

- **Defective power supply**
  - The battery charger and power supply must be inspected by an authorised Ottobock Service Centre.

### Error after disconnecting the battery charger (error on self-test)

<table>
<thead>
<tr>
<th>Beep signal</th>
<th>Error</th>
<th>Resolution</th>
</tr>
</thead>
</table>
| 5 x long    | Self-test error | • Restart the product by connecting and disconnecting the battery charger (up to three times)  
• If the error persists, the product must be inspected by an authorised Ottobock Service Centre |

### 15.2.3 Status signals

#### Battery charger is connected

<table>
<thead>
<tr>
<th>LED on power supply</th>
<th>LED on battery charger</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Power supply and battery charger operational</td>
</tr>
</tbody>
</table>

#### Battery charger disconnected

<table>
<thead>
<tr>
<th>Beep signal</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 x short</td>
<td>Self-test completed successfully.</td>
</tr>
</tbody>
</table>

#### Battery charge level

The current battery charge level can only be displayed by connecting the battery charger and power supply to the product.
### Battery charger

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>🔄</td>
<td>Battery charge level less than 50%</td>
</tr>
<tr>
<td>🔄 🔄</td>
<td>Battery charge level over 50%</td>
</tr>
<tr>
<td>🔄 🔄 🔄</td>
<td>Battery is fully charged</td>
</tr>
</tbody>
</table>

### Battery charger connected/disconnected

<table>
<thead>
<tr>
<th>Beep signal</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1x short, pause, 2x short</td>
<td>Battery charger connected</td>
</tr>
<tr>
<td>1x short, 2x long</td>
<td>Charging mode started (3 sec. after connection of battery charger)</td>
</tr>
<tr>
<td>1x short</td>
<td>Battery charger disconnected after charging mode, self-test OK.</td>
</tr>
</tbody>
</table>

#### 15.3 Troubleshooting

**Troubleshooting disconnection of the adjustment software from the product ( – symbol is displayed)**

If the – symbol in the top right corner is replaced by the – symbol, the connection to the prosthesis was severed.

Verify operational readiness of the 60X5 BionicLink PC and the product using the table below. Eliminate any causes that apply.

<table>
<thead>
<tr>
<th>Event</th>
<th>Cause/required action</th>
</tr>
</thead>
</table>
| The blue LED on the 60X7 BionicLink is not lit up | The 60X7 BionicLink is not connected to the product.  
  • Connect the 60X7 BionicLink to the product.  
  The product battery is drained.  
  • Charge the product battery.  
  The connecting cable between the 60X7 BionicLink and the product is defective.  
  • Replace the connecting cable.  
  The battery charger is connected to the product.  
  • Disconnect the battery charger from the product.  
  The product does not function when the battery charger is connected. This means a connection to the computer cannot be established during the charging process.  
  The BionicLink plug on the product is defective.  
  • Check the BionicLink plug on the product.  
  If the contacts are damaged, the product must be inspected by an authorised Ottobock Service Centre. |
| The blue LED on the 60X7 BionicLink is lit up continuously | Connection to the PC disrupted because the distance to the product is too large  
  • Reduce the distance of the product to the 60X5 BionicLink PC. |
| The green LED on the 60X5 BionicLink PC is not lit up | The 60X5 BionicLink PC is not operational  
  • Check the connection of the BionicLink on the PC  
  • Connect the 60X5 BionicLink PC to a different USB port on the PC  
  • If a USB hub is being used, connect the 60X5 BionicLink PC directly to the USB port on the PC |
| The blue LED on the 60X5 BionicLink PC is not lit up | The connection to the PC is disrupted because the distance to the product is too large  
  • Reduce the distance of the product to the 60X5 BionicLink PC. |

Once the blue LED on the 60X7 BionicLink and the green LED on the 60X5 BionicLink PC light up after eliminating the cause of the problem, start another connection attempt. If a connection still cannot be established, contact the Ottobock branch responsible for your country.
Calibration error

<table>
<thead>
<tr>
<th>Symbol in status area</th>
<th>Error (zero setting not OK)</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Knee angle</strong></td>
<td>Check the following points:</td>
</tr>
<tr>
<td></td>
<td>The knee angle has not reached its zero value.</td>
<td>• Was the patient properly positioned?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Is there a mechanical blockage, e.g. due to caught fabric?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Is there an extreme flexion contracture on the knee joint?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Calibration is not possible at a flexion contracture of more than 10°.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The patient cannot use the product.</td>
</tr>
<tr>
<td></td>
<td><strong>Toe and heel load</strong></td>
<td>Check the following points:</td>
</tr>
<tr>
<td></td>
<td>The spring element could not be calibrated.</td>
<td>• Was weight put on the leg with the product or was there movement in the knee joint?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Is high footwear laced too tight in the ankle region, putting a load on the spring element?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Is the connecting cable to the plug of the spring element damaged?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Is the foot component/thigh component correctly screwed to the spring element?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Is the spring element bent in the foot region?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The connection between the two halves of the spring element may have loosened. To check, loosen the 4 screws on the clamp adapter of the foot component and tighten them again. If the spring element is straight and aligned again, the connection between the two halves of the spring element has loosened. The spring element must be replaced promptly.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Is the spring element properly connected?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Are the contacts of the spring element in good condition?</td>
</tr>
</tbody>
</table>

15.4 Technical data

**General information**

<table>
<thead>
<tr>
<th>Reference number</th>
<th>17B300=L C-Brace (left)/17B300=R C-Brace (right)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joint module weight</td>
<td>approx. 1400 g/49.4 oz</td>
</tr>
<tr>
<td>Maximum flexion angle [°]</td>
<td>120 (depending on the design)</td>
</tr>
<tr>
<td>Minimum patient weight</td>
<td>approx. 45 kg/100 lbs</td>
</tr>
<tr>
<td>Service life of the aligned leg prosthesis</td>
<td>5 years</td>
</tr>
</tbody>
</table>

**Environmental conditions**

<table>
<thead>
<tr>
<th>Storage and transport in original packaging</th>
<th>-10°C/+14°F to +60°C/+140°F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage and transport without packaging</td>
<td>-10°C/+14°F to +60°C/+140°F max. 80% relative humidity, non-condensing</td>
</tr>
<tr>
<td>Operation</td>
<td>-10°C/+14°F to +60°C/+140°F max. 80% relative humidity, non-condensing</td>
</tr>
<tr>
<td>Charging the battery</td>
<td>0°C/+32°F to +50°C/+122°F</td>
</tr>
</tbody>
</table>

**Battery charger**

<table>
<thead>
<tr>
<th>Reference number</th>
<th>4E50*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage and transport in original packaging</td>
<td>-25 °C/-13 °F to +70 °C/+158 °F</td>
</tr>
<tr>
<td>Storage and transport without packaging</td>
<td>-25 °C/-13 °F to +70 °C/+158 °F max. 93 % relative humidity, non-condensing</td>
</tr>
</tbody>
</table>
### Battery charger

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operation</strong></td>
<td>0 °C/+32 °F to +40 °C/+104 °F max. 93 % relative humidity, non-condensing</td>
</tr>
<tr>
<td><strong>Input voltage</strong></td>
<td>12 V ===</td>
</tr>
</tbody>
</table>

### Battery of the product

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Battery type</strong></td>
<td>Li-Ion</td>
</tr>
<tr>
<td><strong>Battery service life</strong></td>
<td>2 years</td>
</tr>
<tr>
<td><strong>Charging time until battery is fully charged</strong></td>
<td>6 to 8 hours</td>
</tr>
<tr>
<td><strong>Behaviour of the product during the charging process</strong></td>
<td>The product is non-functional</td>
</tr>
<tr>
<td><strong>Operating time of the product with fully charged battery</strong></td>
<td>1 day with average use</td>
</tr>
</tbody>
</table>

### Spring Element

<table>
<thead>
<tr>
<th>Reference number of the Spring Element</th>
<th>17CF2=1</th>
<th>17CF2=4</th>
<th>17CF2=HD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max. weight</strong></td>
<td>CFK</td>
<td>GFK</td>
<td>CFK</td>
</tr>
<tr>
<td><strong>Service life of the Spring Element</strong></td>
<td>5 years</td>
<td>5 years</td>
<td>5 years</td>
</tr>
<tr>
<td><strong>Weight of the Spring Element</strong></td>
<td>Approx. 115 g/4.06 oz</td>
<td>Approx. 145 g/5.11 oz</td>
<td>Approx. 155 g/5.47 oz</td>
</tr>
</tbody>
</table>

### Sensor Ankle

<table>
<thead>
<tr>
<th></th>
<th>17LA3=16-T</th>
<th>17LA3=20-T</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max. patient weight</strong></td>
<td>85 / 120 kg</td>
<td>110 / 160 kg</td>
</tr>
<tr>
<td><strong>Service life</strong></td>
<td>3 years</td>
<td>3 years</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>122 g</td>
<td>171 g</td>
</tr>
<tr>
<td><strong>Material</strong></td>
<td>Titanium</td>
<td>Titanium</td>
</tr>
</tbody>
</table>
The C-Brace is covered by the following patents:

**China**
- CN 101 404 959
- CN 102 036 628

**Japan**
- JP 4 819 914

**Russia**
- RU 2 406 467
- RU 2 464 956

**Taiwan**
- TW 1317 633

**USA**
- US 7 935 153
- US 90 22 965

**European Patent**
- EP 2276433 in AT, CH, DE, FR, IT, NL, SE
- EP 2276432 in CH, DE, FR, GB, IT, NL, PL, SE
- EP 1996120 in CH, DE, FR, GB, IT, NL, TR

Patents pending in Brazil, Germany and USA.

Ottobock has a certified Quality Management System in accordance with ISO 13485.