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

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.

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.

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

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

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

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

NO | 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 tarjoaa CD-levy käyttöohje myös lisää kieliä (katso kansilehden takapuoli). Painettu käyt- töohje kunkin maan omalla kielenä on pyynnöstä tilattavissa maksutta alla ilmoitetusta osoitteesta.

CZ | INFORMACE
Kromě této vytisknuté verze návodu k použití jsou na přiloženém CD k dispozici také další jazykové verze překladu (viz zadní stra- na obalu). V případě požadavku si můžete na níže uvedené adrese zdarma objednat vytisknutý návod k použití v příslušném jazy- ce.

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

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

HU | INFORMATION
A kinyomtatott használati utasítást kiegészítő és további nyelveket tartalmazó, mellékelt CD (ld. a hátlapon lévő borítékot). Az alábbi címen, kérésre költségmentesen megrendelhet az adott ország nyelvén kinyomtatott használati utasítást.

HR | INFORMACIJA
Dodatno uz tiskane upute za uporabu priloženi su i drugi jezici na CD-u (vidi poledinu). Na upit možete na dolje navedenoj adre- si besplatno naručiti tiskane upute za uporabu na dotičnom jeziku.
TR | INFORMATION
Basılmış olan kullanım kilavuzuna ilave olarak CD’de daha fazla alternatif diller bulunmaktadır (bakınız zarfın arkası yüzü). İstek üzerine ilgili dilde basılmış kullanım kilavuzunu aşağıda belirtilmiş olan adresten temin edebilirsiniz.

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

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

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

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<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Foreword</td>
</tr>
<tr>
<td>2</td>
<td>Product description</td>
</tr>
<tr>
<td>2.1</td>
<td>Design</td>
</tr>
<tr>
<td>2.2</td>
<td>Function</td>
</tr>
<tr>
<td>2.3</td>
<td>Combination possibilities</td>
</tr>
<tr>
<td>3</td>
<td>Application</td>
</tr>
<tr>
<td>3.1</td>
<td>Indications for use</td>
</tr>
<tr>
<td>3.2</td>
<td>Area of application</td>
</tr>
<tr>
<td>3.3</td>
<td>Conditions of use</td>
</tr>
<tr>
<td>3.4</td>
<td>Indications</td>
</tr>
<tr>
<td>3.5</td>
<td>Qualification</td>
</tr>
<tr>
<td>4</td>
<td>Safety</td>
</tr>
<tr>
<td>4.1</td>
<td>Explanation of warning symbols</td>
</tr>
<tr>
<td>4.2</td>
<td>Structure of the safety instructions</td>
</tr>
<tr>
<td>4.3</td>
<td>General safety instructions</td>
</tr>
<tr>
<td>4.4</td>
<td>Information on the Power Supply/Battery Charging</td>
</tr>
<tr>
<td>4.5</td>
<td>Battery charger information</td>
</tr>
<tr>
<td>4.6</td>
<td>Information on Alignment/Adjustment</td>
</tr>
<tr>
<td>4.7</td>
<td>Information on Proximity to Certain Areas</td>
</tr>
<tr>
<td>4.8</td>
<td>Information on Use</td>
</tr>
<tr>
<td>4.9</td>
<td>Notes on the safety modes</td>
</tr>
<tr>
<td>5</td>
<td>Scope of Delivery and Accessories</td>
</tr>
<tr>
<td>6</td>
<td>Charging the prosthesis battery</td>
</tr>
<tr>
<td>6.1</td>
<td>Connecting the power supply and battery charger</td>
</tr>
<tr>
<td>6.2</td>
<td>Connect battery charger to the product</td>
</tr>
<tr>
<td>6.3</td>
<td>Display of the current charge level</td>
</tr>
<tr>
<td>7</td>
<td>Preparation for use</td>
</tr>
<tr>
<td>7.1</td>
<td>Alignment</td>
</tr>
<tr>
<td>7.1.1</td>
<td>Shortening the Tube Adapter</td>
</tr>
<tr>
<td>7.1.2</td>
<td>Installing the Tube Adapter</td>
</tr>
<tr>
<td>7.1.3</td>
<td>Bench alignment in alignment apparatus</td>
</tr>
<tr>
<td>7.1.4</td>
<td>Static alignment optimisation</td>
</tr>
<tr>
<td>7.1.5</td>
<td>Dynamic alignment optimisation</td>
</tr>
<tr>
<td>7.1.6</td>
<td>Torque values of the screw connections</td>
</tr>
<tr>
<td>7.2</td>
<td>Completing the fitting</td>
</tr>
<tr>
<td>8</td>
<td>Use</td>
</tr>
<tr>
<td>8.1</td>
<td>Movement pattern in activity mode A (locked mode)</td>
</tr>
<tr>
<td>8.1.1</td>
<td>Standing</td>
</tr>
<tr>
<td>8.1.2</td>
<td>Walking</td>
</tr>
<tr>
<td>8.1.3</td>
<td>Sitting down</td>
</tr>
<tr>
<td>8.1.4</td>
<td>Sitting</td>
</tr>
<tr>
<td>8.1.5</td>
<td>Standing up</td>
</tr>
<tr>
<td>8.1.6</td>
<td>Walking down stairs</td>
</tr>
<tr>
<td>8.1.7</td>
<td>Walking up stairs</td>
</tr>
<tr>
<td>8.1.8</td>
<td>Walking backwards</td>
</tr>
<tr>
<td>8.2</td>
<td>Movement pattern in activity mode B (semi-locked mode)</td>
</tr>
<tr>
<td>8.2.1</td>
<td>Standing</td>
</tr>
<tr>
<td>8.2.2</td>
<td>Walking</td>
</tr>
<tr>
<td>8.2.3</td>
<td>Sitting down</td>
</tr>
<tr>
<td>8.2.4</td>
<td>Sitting</td>
</tr>
<tr>
<td>8.2.5</td>
<td>Standing up</td>
</tr>
<tr>
<td>8.2.6</td>
<td>Walking down stairs</td>
</tr>
<tr>
<td>Section</td>
<td>Title</td>
</tr>
<tr>
<td>---------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>8.2.7</td>
<td>Walking up stairs</td>
</tr>
<tr>
<td>8.2.8</td>
<td>Walking backwards</td>
</tr>
<tr>
<td>8.3</td>
<td>Movement pattern in activity mode C (yielding mode)</td>
</tr>
<tr>
<td>8.3.1</td>
<td>Standing</td>
</tr>
<tr>
<td>8.3.2</td>
<td>Walking</td>
</tr>
<tr>
<td>8.3.3</td>
<td>Sitting down</td>
</tr>
<tr>
<td>8.3.4</td>
<td>Sitting</td>
</tr>
<tr>
<td>8.3.5</td>
<td>Standing up</td>
</tr>
<tr>
<td>8.3.6</td>
<td>Walking down stairs</td>
</tr>
<tr>
<td>8.3.7</td>
<td>Walking up stairs</td>
</tr>
<tr>
<td>8.3.8</td>
<td>Walking down a ramp</td>
</tr>
<tr>
<td>8.3.9</td>
<td>Walking backwards</td>
</tr>
<tr>
<td>8.4</td>
<td>Using a wheelchair</td>
</tr>
<tr>
<td>8.5</td>
<td>Switching off the product</td>
</tr>
<tr>
<td>9</td>
<td>Additional operating states (modes)</td>
</tr>
<tr>
<td>9.1</td>
<td>Empty battery mode</td>
</tr>
<tr>
<td>9.2</td>
<td>Mode for charging the prosthesis</td>
</tr>
<tr>
<td>9.3</td>
<td>Safety mode</td>
</tr>
<tr>
<td>9.4</td>
<td>Overheating mode</td>
</tr>
<tr>
<td>10</td>
<td>Maintenance</td>
</tr>
<tr>
<td>10.1</td>
<td>Cleaning and Care</td>
</tr>
<tr>
<td>11</td>
<td>Disposal</td>
</tr>
<tr>
<td>12</td>
<td>Legal information</td>
</tr>
<tr>
<td>12.1</td>
<td>Liability</td>
</tr>
<tr>
<td>12.2</td>
<td>Trademarks</td>
</tr>
<tr>
<td>12.3</td>
<td>CE Conformity</td>
</tr>
<tr>
<td>12.4</td>
<td>Local Legal Information</td>
</tr>
<tr>
<td>13</td>
<td>Technical data</td>
</tr>
<tr>
<td>14</td>
<td>Appendices</td>
</tr>
<tr>
<td>14.1</td>
<td>Symbols Used</td>
</tr>
<tr>
<td>14.1.1</td>
<td>Symbols on the product</td>
</tr>
<tr>
<td>14.1.2</td>
<td>Symbols on the battery charger</td>
</tr>
<tr>
<td>14.2</td>
<td>Operating states/error signals</td>
</tr>
<tr>
<td>14.2.1</td>
<td>Signals for operating states</td>
</tr>
<tr>
<td>14.2.2</td>
<td>Warnings/error signals</td>
</tr>
<tr>
<td>14.2.3</td>
<td>Status signals</td>
</tr>
</tbody>
</table>
1 Foreword

The product "Kenevo 3C60/3C60=ST" is referred to as the product/prosthesis/knee joint below.

These instructions for use provide you with important information on the use, adaptation and handling of the product.

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

2 Product description

2.1 Design

The product consists of the following components:

1. Proximal pyramid adapter
2. LED (blue) as indicator for the Bluetooth connection
3. Battery and cover caps
4. Hydraulic unit
5. Receiver of the inductive charging unit
6. Distal tube clamp screw
7. Connecting cable for tube adapter

2.2 Function

This product features a microprocessor-controlled switch between the stance phase and swing phase and a microprocessor-controlled stance phase.

The microprocessor uses the measurements of an integrated sensor system as a basis to control a hydraulic unit that influences the damping behaviour of the product.

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

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

For this purpose, the product is configured with the "K-Soft" adjustment software.

Through the adjustment software, it is possible to choose from three activity modes that make the various functions of the product available. This permits optimum adaptation of the product to the corresponding mobility grade of the patient. The configured activity mode cannot be changed by the patient.

In case of a system malfunction, safety mode makes restricted operation possible. Predefined resistance parameters are configured in the product for this purpose (see Page 29).
The microprocessor-controlled hydraulic unit offers the following advantages
• Stability while standing and walking
• Smooth, harmonious, quiet initiation of the swing phase
• Automatic recognition of sitting down. Manual unlocking of the joint not required.
• Support while sitting down with individually adaptable resistance. This resistance remains constant during the entire process of sitting down.
• Support while standing up. The knee joint can be loaded even before reaching full extension.
• Approximation of the physiological gait pattern
• Adaptation of product characteristics to various surfaces, inclines, gait situations and walking speeds
• Manual locking of the knee joint for use of a wheelchair (see Page 28).

2.3 Combination possibilities
This product can be combined with the following Ottobock components:

Adapters
• Double adapter: 4R72=32
• Double adapter: 4R72=45
• Double adapter: 4R72=60
• Double adapter: 4R72=75
• Double adapter: 4R76
• 4R104=60 double adapter, sliding
• 4R104=75 double adapter, sliding

AXON tube adapter
• AXON tube adapter: 2R17
• AXON tube adapter: 2R20

Cosmetic cover
• Foam cover: 3S26

Prosthetic feet
The maximum allowable patient weight depends on the foot size.
• Cosmetic light foot: 1G6
• Pedial single axis foot, light: 1G9
• Single axis foot without toes: 1H32 or 1H34 (depending on the heel height)
• Single axis foot with toes: 1H38 or 1H40 (depending on the heel height):
• SACH foot with toes: 1S49, 1S66, or 1S67 (depending on the heel height and foot shape):
• SACH Foot with toes and abducted big toe: 1S90
• SACH+foot: 1S101, 1S102, 1S103

• 4R57, 4R57=ST rotation adapter
• 4R89 lamination anchor with pyramid adapter
• 4R41 lamination anchor with pyramid receiver
• Lamination anchor with pyramid receiver and angled arm: 4R119
• 4R43 lamination anchor with threaded connector
• 4R40 torsion adapter
• 4R118 adapter plate

• AXON tube adapter with torsion unit: 2R21

3 Application
3.1 Indications for use
The product is to be used solely for lower limb prosthetic fittings.

3.2 Area of application
Area of application according to the MOBIS mobility system:
Activity mode A (locked mode)

This product is recommended for mobility grade 1 (indoor walker). Approved for a body weight of max. 125 kg.

Activity mode B (semi-locked mode)

This product is recommended for mobility grade 1 (indoor walker) and mobility grade 2 (restricted outdoor walker). Approved for a body weight of max. 125 kg.

Activity mode C (yielding mode)

This product is recommended for mobility grade 2 (restricted outdoor walker). Approved for a body weight of max. 125 kg.

3.3 Conditions of use
The product was developed for everyday use and should not be used for walking speeds over 3 km/h or unusual activities. These unusual activities include, for example, extreme sports (free climbing, parachuting, paragliding, etc.).
Permissible ambient conditions are described in the technical data (see Page 32). The prosthesis is intended for use exclusively on the patient for whom the adjustment was made. The manufacturer does not authorise use of the prosthesis on another person.

3.4 Indications
• For patients with knee disarticulation and transfemoral amputation
• For unilateral or bilateral amputation
• Dysmelia patients with residual limb characteristics corresponding to knee disarticulation or a transfemoral amputation
• The patient must fulfil the physical and mental requirements for perceiving visual/acoustic signals and/or mechanical vibrations.

3.5 Qualification
The product may be fitted only by qualified personnel authorised by Ottobock after completing the corresponding training.

4 Safety
4.1 Explanation of warning symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<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

**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/carry out in order to avert the hazard.

### 4.3 General safety instructions

**WARNING**
**Use of damaged power supply unit, adapter plug or battery charger**
Risk of electric shock due to contact with exposed, live components.

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

**CAUTION**
**Failure to observe warning/error signals**
Falling due to unexpected product behaviour because of changed damping behaviour.
- The warnings/error signals (see Page 35) and corresponding change in damping settings must be observed.

**CAUTION**
**Independent user manipulation of system components**
Falling due to breakage of load-bearing components or malfunction of the product.

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

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

**CAUTION**
**Use of the product when battery charge level is too low**
Falling due to unexpected behaviour of the prosthesis because of changed damping behaviour.

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

**CAUTION**
**Risk of pinching in the joint flexion area**
Injuries due to pinching of body parts.

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

Penetration of dirt and humidity into the product

- Falling due to unexpected product behaviour as the result of malfunction.
- Falling due to breakage of load-bearing components.
- Ensure that neither solid particles, foreign objects nor liquids penetrate into the product.
- Do not expose the product to splashed water.
- In the rain, thick clothing should be worn over the product as a minimum.
- If water has penetrated system components, remove the protector and allow the components to dry. The prosthesis must be inspected by an authorised Ottobock Service Centre.
- If salt water has penetrated the prosthesis, the protector must be removed immediately. The prosthesis must be inspected by an authorised Ottobock Service Centre.

**CAUTION**

Mechanical stress during transport

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

**CAUTION**

Signs of wear to system components

Falling due to damage or malfunction of the product.

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

**NOTICE**

Improper product care

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

- Only clean the product with a damp cloth and mild soap (e.g. 453H10=1 Ottobock DermaClean).

**INFORMATION**

Knee joint movement noise

When using exoprosthesis knee joints, servomotor, hydraulic, pneumatic or brake load dependent control functions can cause movement noise. This kind of noise is normal and unavoidable. It generally does not indicate any problems. If movement noise increases noticeably during the lifecycle of the knee joint, the knee joint should be inspected by an authorised Ottobock Service Centre immediately.

4.4 Information on the Power Supply/Battery Charging

**CAUTION**

Charging the prosthesis without taking it off

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

- Instruct the patient that the prosthesis must be taken off before it is charged.

**CAUTION**

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

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

- Check the power supply unit, charger and charger cable for damage before use.
- Replace any damaged power supply unit, charger or charger cable.
4.5 Battery charger information

**WARNING**

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

**NOTICE**

**Penetration of dirt and humidity into the product**
Lack of proper charging functionality due to malfunction.
- Ensure that neither solid particles nor liquids can penetrate into the product.

**NOTICE**

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

**NOTICE**

**Operating the power supply unit/charger outside of the permissible temperature range**
Lack of proper charging functionality due to malfunction.
- Only use the power supply unit/charger for charging within the allowable temperature range. The section "Technical data" contains information on the allowable temperature range (see Page 32).

**NOTICE**

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

**NOTICE**

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

4.6 Information on Alignment/Adjustment

**CAUTION**

**Use of unsuitable prosthesis components**
Falling due to unexpected behaviour of the product or breakage of load-bearing components.
- Use the product only in combination with components listed in the section "Combination possibilities" (see Page 8).
**CAUTION**

**Improper assembly of the screw connections**
Falling due to breakage or loosening of the screw connections.
► Clean the threads before every installation.
► Apply the specified installation torque values.
► Observe the instructions for securing the screw connections and the use of the correct length.

**CAUTION**

**Incorrect alignment or assembly**
Falling due to damage to the prosthesis components.
► Observe the alignment and assembly instructions.

**CAUTION**

**Errors during prosthesis alignment**
Falling due to breakage of load-bearing components.
► At maximum flexion (reached under full load!), it is essential to maintain a minimum distance of 3 mm (1/8") between the hydraulic unit and the socket.
► At maximum flexion and insofar as contact with the frame of the knee joint cannot be avoided (in case of voluminous residual limbs), the socket must lie flat against the frame. Soft cushioning on the socket will assist in keeping the socket flat.

**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 stand or sit without moving.
► If the connection fails while making adjustments, the prosthetist must immediately warn and secure the patient.
► The connection to the product must always be disconnected after adjustments have been completed.

**CAUTION**

**Insufficient insertion depth of the tube adapter**
Falling due to breakage of load-bearing components.
► Insert the tube adapter at least 40mm to ensure operational safety.
► The patient must be seated for length adjustments.
Safety

**CAUTION**

Operator errors during the adjustment process with the adjustment software

Falling due to unexpected prosthesis behaviour.

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

**CAUTION**

Error during optimisation of damping behaviour

Falling due to unexpected behaviour of the product.

- Note that the patient must stand very securely during this procedure to ensure safety.

4.7 Information on Proximity to Certain Areas

**CAUTION**

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

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

- Therefore, keeping the following minimum distances to these HF communication devices is recommended:
  - Mobile phone GSM 850/GSM 900: 0.50 m
  - Mobile phone GSM 1800/GSM 1900/UMTS: 0.35 m
  - DECT cordless phones incl. base station: 0.18 m
  - WiFi (routers, access points, …): 0.11 m
  - Bluetooth devices (third-party products not approved by Ottobock): 0.11 m

**CAUTION**

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

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

- Ensure that the patient is not in the vicinity of sources of strong magnetic and electrical interference during trial fitting (such as theft prevention systems, metal detectors...). If this cannot be avoided, ensure at least that the patient has a safeguard when walking or standing (e.g. a handrail or the support of another person).
Entering a room or area with strong magnetic fields (e.g. magnetic resonance tomographs, MRT (MRI) equipment...)
> Falling due to unexpected restriction of the product’s range of motion caused by metallic objects adhering to the magnetised components.
> Irreparable damage to the product due to the effect of strong magnetic fields.
> Make sure that the patient takes off the product before entering the room or area and stores the product outside this room or area.
> Damage to the product caused by exposure to strong magnetic fields cannot be repaired.

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 32) during trial fitting.

4.8 Information on Use

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.

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 35).
> 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.

Overheating of the hydraulic unit due to uninterrupted, increased activity (e.g. extended walking downhill)
> Falling due to unexpected behaviour of the product because of switching into overheating mode.
> Burns due to touching overheated components.
> Be sure to pay attention when pulsating vibration signals start. They indicate the risk of overheating.
> As soon as these pulsating vibration signals begin, the activity level has to be reduced so the hydraulic unit can cool down.
> Full activity may be resumed after the pulsating vibration signals stop.
> If the activity level is not reduced in spite of the pulsating vibration signals, this could lead to the hydraulic element overheating and, in extreme cases, cause damage to the product. In this case, the product should be inspected by an authorised Ottobock Service Centre.
4.9 Notes on the safety modes

**CAUTION**

*Using the product in safety mode*

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

- The warnings/error signals (see Page 35) have to be observed.

**CAUTION**

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

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

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

**CAUTION**

*Safety mode cannot be deactivated*

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

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

**CAUTION**

*Safety signal occurs (ongoing vibration)*

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

- The warnings/error signals (see Page 35) have to be observed.
- After the safety signal has been emitted, further use of the product is prohibited.
- The product must be inspected by an authorised Ottobock Service Centre.

5 Scope of Delivery and Accessories

**Scope of Delivery**

- 1 pc. Kenevo 3C60=ST (with threaded connector) or
- 1 pc. Kenevo 3C60 (with pyramid connector)
- 1 pc. AXON 2R17 tube adapter or
- 1 pc. 2R20 AXON tube adapter or
  1 pc. 2R21 AXON tube adapter with torsion
- 1 pc. 757L16* power supply
- 1 pc. 4E70* inductive charger
- 1 pc. 647G947 instructions for use (qualified personnel)
- 1 pc. 646D700, 646D700=1 instructions for use (user)
- 1 pc. cosmetic case for battery charger and power supply
- 1 pc. 647F507 prosthesis passport
- 1 pc. card holder for prosthesis passport

**Accessories**

The following components are not included in the scope of delivery and may be ordered separately:
Charging the prosthesis 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.
- Note the permissible temperature range for charging the battery (see Page 32).
- Use the 757L16* power supply and 4E70* battery charger to charge the battery.
- The tube adapter must be connected before disconnecting the battery charger, otherwise an error message will result (see Page 35).

6.1 Connecting the power supply and battery charger

1) Slide the country-specific plug adapter onto the power supply until it locks into place (see fig. 1).
2) Connect the round, three-pin plug of the power supply to the receptacle on the inductive charger so that the plug locks into place. (see fig. 2)

INFORMATION: Ensure correct polarity (guide lug). Do not use force when connecting the cable plug to the battery charger.

3) Plug the power supply unit into the outlet (see fig. 3).
   → The green LED on the back of the power supply lights up.
   → The yellow LED on the inductive charger lights up briefly to indicate the correct connection to the power supply.
   → If the green LED on the power supply does not light up and the yellow LED on the inductive charger does not light up briefly while connecting the cable, there is an error (see Page 35).

6.2 Connect battery charger to the product

INFORMATION
Do not move the knee joint while it conducts the self-test immediately after disconnecting the charger. Otherwise, an error may occur; if this happens, the problem can be corrected by reconnecting and then disconnecting the charger.

1) Connect the inductive charger to the receiver of the charging unit on the rear of the product. The charger is held in place by a magnet.
   → The correct connection of the battery charger to the product is indicated by feedback (see Page 36).
2) The charging process starts.
   → Once the product battery is fully charged, the LED on the battery charger lights up green.
3) After the charging process is complete, hold the product still and remove the inductive charger from the receiver.
   → A self-test is performed. The joint is operational only after corresponding feedback (see Page 36).
**INFORMATION**
To make the operating time of the prosthesis as long as possible, the charger should not be removed until immediately before the prosthesis is used.

**Indication of the charging process:**

<table>
<thead>
<tr>
<th>Charger</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Sun]</td>
<td>Battery is charging. The on time of the LED indicates the current battery charge level. The on time of the LED gets longer as the charge level increases. It only flashes briefly at the start of the charging process and stays on continuously at the end of the charging process.</td>
</tr>
<tr>
<td>![Green Circle]</td>
<td>Battery is fully charged, or the temperature fell above/below the permissible range during charging. Check current charge level (see Page 18).</td>
</tr>
</tbody>
</table>

**6.3 Display of the current charge level**

1) Turn the prosthesis 180° (the sole of the foot has to face up).
2) Hold still for 2 seconds and wait for beeps.

<table>
<thead>
<tr>
<th>Beep signal</th>
<th>Vibration signal</th>
<th>Battery charge level</th>
</tr>
</thead>
<tbody>
<tr>
<td>5x short</td>
<td></td>
<td>more than 80%</td>
</tr>
<tr>
<td>4x short</td>
<td></td>
<td>66% to 80%</td>
</tr>
<tr>
<td>3x short</td>
<td></td>
<td>51% to 65%</td>
</tr>
<tr>
<td>2x short</td>
<td>3x long</td>
<td>36% to 50%</td>
</tr>
<tr>
<td>1x short</td>
<td>5x long</td>
<td>20% to 35%</td>
</tr>
<tr>
<td>1x short</td>
<td></td>
<td>less than 20%</td>
</tr>
</tbody>
</table>

**7 Preparation for use**

**7.1 Alignment**

**7.1.1 Shortening the Tube Adapter**

**CAUTION**

Incorrect processing of tube
Falling due to damage to the tube.
► Do not clamp the tube into a vice.
► For shortening the tube, use only a tube cutter.

**CAUTION**

Damage to the cable while shortening the tube adapter
Falling due to unexpected product behaviour as the result of switching into safety mode.
► When shortening the tube adapter, make sure the cable does not get damaged.

1) Determine the required length of the tube adapter using the configuration assistant in the adjustment software.
2) Shorten the tube adapter to the determined value with the 719R3 tube cutter.
3) Smooth the cutting surface with a deburring knife (e.g. 718S2) and sandpaper.

**NOTICE!** In case of raised material at the outer edge due to shortening the tube adapter, smoothing this by machine is mandatory. Carefully deburr the inside to prevent damage to the tube adapter cable.

### 7.1.2 Installing the Tube Adapter

<table>
<thead>
<tr>
<th>CAUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Improper assembly of the screw connections</strong></td>
</tr>
<tr>
<td>Falling due to breakage or loosening of the screw connections.</td>
</tr>
<tr>
<td>➤ Clean the threads before every installation.</td>
</tr>
<tr>
<td>➤ Apply the specified installation torque values.</td>
</tr>
<tr>
<td>➤ Observe the instructions for securing the screw connections and the use of the correct length.</td>
</tr>
</tbody>
</table>

1) Install the prosthetic foot on the tube adapter and tighten the set screws on the tube adapter to a torque of 15 Nm.

**INFORMATION:** Replace any set screws that are protruding or recessed too much with suitable ones.

For approved set screws, see the section "Technical data" (see Page 32).

**INFORMATION:** The printed scale on the tube adapter must face forward.

2) Connect the cable of the tube adapter to the cable of the knee joint.

3) Push the protruding cable loop back into the tube adapter. If the tube adapter has been shortened to the minimum length, the plug must be inserted in the cavity. The cable loop must then be stored carefully.

4) Insert the tube adapter about 60 mm into the knee joint (for the exact value, consult the configuration assistant in the adjustment software).

**INFORMATION:** Corrections in the insertion depth between 40 mm and 73 mm are permissible (slide in 13 mm and pull out 20 mm).

5) Turn the foot outwards slightly and slightly tighten the distal tube clamp screw (approx. 4 Nm).

**INFORMATION:** After alignment optimisation, this screw must be tightened to a torque of 7 Nm.

<table>
<thead>
<tr>
<th>INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>A calibration procedure must be performed after each change to the tube adapter, prosthetic foot or knee joint using the adjustment software.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>If the tube adapter is disconnected while the knee joint is operational, an error message is output. To prevent this error message, the knee joint must be switched off before the tube adapter is disconnected (see Page 28).</td>
</tr>
</tbody>
</table>

### 7.1.3 Bench alignment in alignment apparatus

<table>
<thead>
<tr>
<th>INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>The alignment recommendations must be observed in order for the prosthesis to function correctly.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>The patient’s gait pattern shall change as he/she becomes accustomed to the prosthesis. Therefore it is recommended to complete the entire adjustment procedure again about two weeks after the initial fitting.</td>
</tr>
</tbody>
</table>

A correct bench alignment (e.g. using the 743A200 PROS.A. Assembly alignment apparatus) ensures that the user can benefit from all the advantages of the product. If the L.A.S.A.R. Assembly alignment apparatus (743L200) is available, it can be used as well. The position of the residual limb must be taken into account when positioning the socket connector. Plumb lines in the frontal and sagittal planes (drawn from the hip joint’s centre of rotation and marked during plaster cast taking and trial fitting of the check socket) will facilitate correct positioning of the lamin-ation anchor or socket adapter.
Position the middle of the foot (MF) approx. 30 mm/1.18 inch anterior to the alignment reference line (A). This applies to all foot components that are recommended for use with the product, independently of the previous alignment specifications in the instructions for use of those feet!

Noting the alignment recommendation of the foot component, add 5 mm to the effective heel height (shoe heel height – sole thickness in the forefoot area) and set the outward rotation of the foot.

Place the alignment reference point (=knee axis) approx. 0-5 mm/0-0.19 inch anterior to the alignment reference line.
Take into account the knee-ground distance and outward rotation of the knee (the adapter insert provides for a rotation of approx. 5°). Recommended sagittal positioning of the alignment reference point: 20 mm/0.79 inch above the medial tibial plateau.

Connect the foot and knee joint using a tube adapter. To do so, tilt the joint in the correct position and set the required tube length.

Mark the lateral centre of the socket with a centred, proximal dot and a distal dot. Mark a line through both points from the edge to the end of the socket.

Now position the socket such that the alignment reference line passes through the proximal centre mark.
Adjust the socket flexion to 3° – 5°, but take the individual situation (e.g. hip joint contractures) and the ischial tuberosity-ground distance into account.

Connect the socket and modular knee using adapters.

### 7.1.4 Static alignment optimisation

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

1. Prepare for use Kenevo 3C60/3C60=ST
To determine the load line, have the patient (with shoes) stand on the force measuring plate with the prosthetic side and on the height compensation plate with the other leg. The prosthesis side must be sufficiently loaded (>35% body weight). Note the weight display on the L.A.S.A.R. Posture.

Optimise the alignment solely by changing the plantar flexion. Only make adjustments to the distal and proximal setscrews of the socket adapter on the prosthetic foot, so that the load line (laser line) runs approx. 30 mm/1.18 inch in front of the alignment reference point (= knee axis) for the knee joint.

7.1.5 Dynamic alignment optimisation
After adjusting the product with the adjustment software, perform dynamic optimisation during trial walking. Often, the following aspects have to be observed and adapted, if necessary:

- Socket flexion position by verifying step length symmetry (sagittal plane)
- Adduction position of the socket and M-L positioning of the socket adapter (frontal plane)
- Rotation position of the knee joint axis and outward rotation of the prosthetic foot (transversal plane)

7.1.6 Torque values of the screw connections

<table>
<thead>
<tr>
<th>Screw connection</th>
<th>Torque</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tube adapter on prosthetic foot</td>
<td>15 Nm/133 lbf. In.</td>
</tr>
<tr>
<td>Clamp bracket on knee joint</td>
<td>7 Nm/62 lbf. In.</td>
</tr>
<tr>
<td><strong>Fitting for short residual limb</strong></td>
<td></td>
</tr>
<tr>
<td>Rotation adapter or sliding adapter</td>
<td>15 Nm/133 lbf. In.</td>
</tr>
<tr>
<td><strong>Fitting for long residual limb</strong></td>
<td></td>
</tr>
<tr>
<td>Lamination anchor with threaded connector</td>
<td>10 Nm/89 lbf. In.</td>
</tr>
</tbody>
</table>
A calibration procedure must be performed after each change to the tube adapter, prosthetic foot or knee joint using the adjustment software.

7.2 Completing the fitting
Upon finalising all settings, all screw connections must be tightened to the proper torque.

8 Use

8.1 Movement pattern in activity mode A (locked mode)

8.1.1 Standing
The knee joint is locked in the flexion direction. Therefore, proceed as you would with a rigid knee joint.

INFORMATION: In response to a sitting movement, the joint switches to high flexion resistance.

8.1.2 Walking
Initial attempts at walking with the prosthesis always require the instruction of trained, qualified personnel.
The knee joint is locked in the flexion direction. Therefore, proceed as you would with a rigid knee joint.

8.1.3 Sitting down
The prosthesis makes it possible to sit down without manual unlocking. Here the adjustable flexion resistance of the hydraulic unit provides support while sitting down.
Hand support is recommended while sitting down, e.g.:
• Support on the armrests of the chair
• Support on the handles of a wheeled walking frame
• Use of forearm crutches
• Use of a cane

Sitting down
1) Stand 5 to 10 cm in front of the edge of the chair.
   While standing up, the edge of the chair should not yet touch the hollow of the knee nor press on the lower leg.
2) Place both feet side by side at the same level.
3) While sitting down, put even weight on both legs and push the pelvis in the direction of the backrest.
   This causes the weight to shift to the heel and the prosthesis to tilt backward, which makes the knee joint switch to “sitting damping”. Support is therefore provided while sitting down.
8.1.4 Sitting

In a sitting position, i.e. when the thigh is close to horizontal and there is no load on the leg, the knee joint switches to low resistance in both the flexion and extension directions. If the load on the prosthesis is not adequate, the leg remains extended while sitting down. Due to the nearly horizontal position of the lower leg, damping is reduced automatically and the lower leg drops down on its own.

8.1.5 Standing up

Notwithstanding low damping while sitting, the prosthesis supports standing up. Damping is increased after rising from the seat. From an angle of approx. 45°, the knee joint identifies a "standing up process" which results in what is called "pre-locking" in the flexion direction. This function makes it possible to stand up with pauses in between. The joint fully supports weight during these pauses. If standing up is aborted, the "sitting down" function is activated again. The joint is locked after fully standing up.

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

8.1.6 Walking down stairs

The knee joint is locked in the flexion direction.

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

**INFORMATION:** Walking down stairs step-over-step is not possible in this activity mode.

8.1.7 Walking up stairs

Walking up stairs step-over-step is not possible.

1) Hold the handrail with one hand.
2) Place the foot of the less affected leg onto the first step.
3) Pull up the other leg.
8.1.8 Walking backwards
The knee joint is locked in the flexion direction. Proceed as you would with a rigid knee joint.

8.2 Movement pattern in activity mode B (semi-locked mode)
8.2.1 Standing
The knee joint is locked in the flexion direction.
If desired, stance phase flexion of up to 10° can be permitted for this mode in the adjustment software (setting only available in activity mode B).
INFORMATION: In response to a sitting movement, the joint switches to high flexion resistance.

8.2.2 Walking
Initial attempts at walking with the prosthesis always require the instruction of trained, qualified personnel.
The hydraulics stabilise the knee joint in the stance phase and release the knee joint in the swing phase so that the leg can swing forward freely.
In order to safely switch to the swing phase, the prosthesis has to be partially unloaded from the lunge position with a simultaneous forward movement.
If desired, stance phase flexion of up to 10° can be permitted for this mode in the adjustment software (setting only available in activity mode B).

8.2.3 Sitting down
The prosthesis makes it possible to sit down without manual unlocking. Here the adjustable flexion resistance of the hydraulic unit provides support while sitting down.
Hand support is recommended while sitting down, e.g.:
• Support on the armrests of the chair
• Support on the handles of a wheeled walking frame
• Use of forearm crutches
• Use of a cane

Sitting down
1) Stand 5 to 10 cm in front of the edge of the chair.
   While standing up, the edge of the chair should not yet touch the hollow of the knee nor press on the lower leg.
2) Place both feet side by side at the same level.
3) While sitting down, put even weight on both legs and push the pelvis in the direction of the backrest.
   This causes the weight to shift to the heel and the prosthesis to tilt backward, which makes the knee joint switch to "sitting damping". Support is therefore provided while sitting down.
8.2.4 Sitting

In a sitting position, i.e. when the thigh is close to horizontal and there is no load on the leg, the knee joint switches to low resistance in both the flexion and extension directions. If the load on the prosthesis is not adequate, the leg remains extended while sitting down. Due to the nearly horizontal position of the lower leg, damping is reduced automatically and the lower leg drops down on its own.

8.2.5 Standing up

Notwithstanding low damping while sitting, the prosthesis supports standing up. Damping is increased after rising from the seat. From an angle of approx. 45°, the knee joint identifies a "standing up process" which results in what is called "pre-locking" in the flexion direction. This function makes it possible to stand up with pauses in between. The joint fully supports weight during these pauses. If standing up is aborted, the "sitting down" function is activated again. The joint is locked after fully standing up.

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

8.2.6 Walking down stairs

The knee joint is locked in the flexion direction.

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

INFORMATION: Walking down stairs step-over-step is not possible in this activity mode.

8.2.7 Walking up stairs

Walking up stairs step-over-step is not possible.

1) Hold the handrail with one hand.
2) Place the foot of the less affected leg onto the first step.
3) Pull up the other leg.
8.2.8 **Walking backwards**

The knee joint is locked in the flexion direction. Proceed as you would with a rigid knee joint. If desired, knee flexion of up to 10° can be permitted in the adjustment software (setting only available in activity mode B).

8.3 **Movement pattern in activity mode C (yielding mode)**

8.3.1 **Standing**

Flexion resistance is generally high while standing. The intuitive stance function automatically recognises any situation that puts strain on the prosthesis in the flexion direction but where flexion is not permitted. Examples of this include standing on uneven or sloping surfaces.

The knee joint is always locked in the flexion direction when the prosthetic leg is not fully extended, is under some amount of load and is at rest. When the load is taken off the leg or upon forward or backward rollover, the level of resistance is immediately reduced to stance phase resistance again.

**INFORMATION**

The intuitive stance function can be deactivated in the adjustment software for training purposes (e.g. walking down stairs). The stance function should be reactivated once therapy exercises have been completed. The patient must be able to master the stairs with the stance function switched on as well.

8.3.2 **Walking**

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

The hydraulics stabilise the knee joint with high flexion resistance in the stance phase and release the knee joint in the swing phase so that the leg can swing forward freely.

In order to safely switch to the swing phase, the prosthesis has to be partially unloaded from the lunge position with a simultaneous forward movement.

8.3.3 **Sitting down**

The prosthesis provides high flexion resistance while sitting down. This ensures that the knees bend evenly, thereby supporting the contralateral side.

Hand support is recommended while sitting down, e.g.:

- Support on the armrests of the chair
- Support on the handles of a wheeled walking frame
- Use of forearm crutches
- Use of a cane

**Sitting down**

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.

This causes the weight to shift to the heel, making the knee joint switch to "sitting damping". Support is therefore provided while sitting down.
8.3.4 Sitting
In a sitting position, i.e. when the thigh is close to horizontal and there is no load on the leg, the knee joint switches to low resistance in both the flexion and extension directions. If the load on the prosthesis is not adequate, the leg remains extended while sitting down. Due to the nearly horizontal position of the lower leg, damping is reduced automatically and the lower leg drops down on its own.

8.3.5 Standing up
Notwithstanding low damping while sitting, the prosthesis supports standing up. After rising from the seat. After standing up entirely, high damping (corresponding to the value of the "stance phase damping" parameter) is set automatically.

INFORMATION
If the intuitive stance function was deactivated in the adjustment software, there is no support while standing up.

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

8.3.6 Walking down stairs
The joint makes it possible to walk down stairs step-over-step or one at a time.

Walking down stairs step-over-step
Walking down stairs step-over-step must be practised and executed consciously. Only by properly stepping down with the sole can the system switch correctly and permit controlled rollover. The motion must be carried out in a continuous pattern in order to allow the motion sequence to proceed in a fluid manner.

1) Hold the handrail with one hand.
2) Position the leg with the prosthesis on the step so that the foot projects halfway over the edge of the step.
   → This is the only way to ensure a secure rollover.
3) Roll the foot over the edge of the step.
   → This flexes the prosthesis slowly and evenly under high flexion resistance.
4) Place the foot of the other leg onto the next step.

Walking down stairs one step at a time (step by step)
1) Hold the handrail with one hand.
2) Place the foot of the prosthetic leg on the first step.
3) Pull up the other leg.
8.3.7 Walking up stairs

Walking up stairs step-over-step is not possible.
1) Hold the handrail with one hand.
2) Place the foot of the less affected leg onto the first step.
3) Pull up the other leg.

8.3.8 Walking down a ramp

Under increased flexion resistance, permit controlled flexion of the knee joint which lowers the body’s centre of gravity.
The swing phase is not triggered even though the knee joint is flexed.

8.3.9 Walking backwards

While walking backwards, the hydraulics keep the knee joint stable with high flexion resistance.

8.4 Using a wheelchair

When sitting in a wheelchair, the joint can be locked in the flexed position for short distances. The lock can be engaged in any position from an angle of 45°. This prevents the foot from dragging on the floor. This function needs to be enabled in the adjustment software.

Locking the joint

► Lift the foot and keep it still in the desired position.
The lock engages automatically.

INFORMATION: At full extension, the lock engages with slight flexion so that the foot can be lifted in order to disengage the lock.

Disengaging the lock

The lock can be disengaged in the following ways:
• Extended pressure on the ball of the foot.
• Extended pressure on the toes (from the top of the foot).
• Briefly lifting the leg and allowing it to drop.

8.5 Switching off the product

⚠️ CAUTION

Using the product while switched off
Falling due to unexpected behaviour of the product because of changed damping behaviour.
► Before using the product, switch it on by connecting the power supply and battery charger.
In certain cases, e.g. for storage or transportation, the prosthesis can be purposely switched off. It can only be switched on by connecting to a live outlet, a power supply and a battery charger.

**Switching off**

The product can be switched off by briefly connecting/disconnecting the battery charger 3 times.
1) Connect the battery charger to the product and wait for the beep signal.
2) Disconnect the battery charger immediately after the beep signal sounds.
3) Immediately after another beep signal sounds, reconnect the battery charger.
4) Repeat this process (steps 2 and 3) three times.
→ After the third time, a descending sequence of 5 beeps is emitted and the product is then switched off.

**INFORMATION**
If too much time passes between connecting and disconnecting (e.g. a vibration signal is already emitted), the process of connecting and disconnecting 3 times has to be repeated.

**Switching on**
1) Connect the power supply with battery charger to the outlet.
2) Connect the battery charger to the product.
→ The correct connection of the battery charger to the product is indicated by feedback (see Page 36).

**9 Additional operating states (modes)**

The product automatically switches to special operating states (modes) when an error occurs, in case of an empty battery or while charging. Functioning of the prosthesis is limited due to its altered damping behaviour.

**9.1 Empty battery mode**

The joint emits beeps and vibration signals when the charge level is 15% or less (see Page 35). Then the damping settings are set to high flexion resistance and low extension resistance, and the product is switched off. Before switching to empty battery mode, warning signals are emitted at a battery charge level below 35% (see Page 35).

You can switch back to basic mode from empty battery mode by charging the product.

**9.2 Mode for charging the prosthesis**

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.

**9.3 Safety mode**

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

A setting for high flexion resistance and low extension resistance is applied in safety mode. This makes limited walking possible for the user even though the system is not active.

The switch to safety mode is indicated by beeps and vibration signals immediately prior to switching (see Page 35). Safety mode can be disabled by connecting and disconnecting the battery charger. If the product switches into safety mode again, this means a permanent error exists. The product must be inspected by an authorised Ottobock Service Centre.

**9.4 Overheating mode**

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

The hydraulic unit cannot overheat in activity mode A (locked mode) or B (semi-locked mode). Therefore, no overheating mode is triggered in these two activity modes.

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

**The following functions are deactivated in overheating mode in activity mode C (yielding mode):**
- Joint lock for use of a wheelchair (see Page 28)
- Battery level indication (see Page 18)
10 Maintenance

INFORMATION
This component was tested for three million load cycles in accordance with ISO 10328. Depending on the patient's activity level, this corresponds to a service life of three to five years. The duration of use can be individually extended depending on the intensity of use by making use of regular service inspections.

Regular service inspections are recommended in the interest of the patient's safety and in order to maintain operating reliability and protect the warranty. These service inspections include an inspection of sensors and replacement of worn parts.

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

- Following an individual period for the patient to get accustomed to the product, check the settings of the prosthesis and, if necessary, adapt them.
- Arrange regular maintenance intervals with the patient depending on the level of use.

10.1 Cleaning and Care
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 system component(s).
2) Dry the product with a lint-free cloth and allow it to air dry fully.

11 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.

12 Legal information

12.1 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.

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

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

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

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

This product meets the requirements of the European Directive 1999/5/EC for radio equipment and telecommunications terminal equipment. The conformity assessment was drawn up by the manufacturer in accordance with Annex IV of the directive.


12.4 Local Legal Information
Legal information that applies exclusively to specific countries is written in the official language of the respective country of use in this chapter.
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
1) This device may not cause harmful interference, and
2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
— Reorient or relocate the receiving antenna.
— Increase the separation between the equipment and receiver.
— Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
— Consult the dealer or an experienced radio/TV technician for help.

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

**Caution: Exposure to Radio Frequency Radiation.**
This device must not be co-located or operating in conjunction with any other antenna or transmitter.

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

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

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

**Caution: Exposure to Radio Frequency Radiation.**
The installer of this radio equipment must ensure that the antenna is located or pointed such that it does not emit RF field in excess of Health Canada limits for the general population; consult Safety Code 6, obtainable from Health Canada’s website

Responsible party:
Otto Bock Healthcare Canada Ltd.
5470 Harvester Road
L7L 5N5 Burlington, Ontario
Canada
Phone + 1-800-665-3327

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

### Environmental conditions

<table>
<thead>
<tr>
<th>Condition</th>
<th>Temperature Range</th>
<th>Humidity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transportation in original packaging</td>
<td>-25°C/-13°F to +70°C/+158°F</td>
<td>Max. 93% relative humidity, non-condensing</td>
</tr>
<tr>
<td>Transportation without packaging</td>
<td>-25°C/-13°F to +70°C/+158°F</td>
<td>Max. 93% relative humidity, non-condensing</td>
</tr>
<tr>
<td>Storage (≤3 months)</td>
<td>-20°C/-4°F to +40°C/+104°F</td>
<td>Max. 93% relative humidity, non-condensing</td>
</tr>
<tr>
<td>Long-term storage (&gt;3 months)</td>
<td>-20°C/-4°F to +20°C/+68°F</td>
<td>Max. 93% relative humidity, non-condensing</td>
</tr>
<tr>
<td>Operation</td>
<td>-10°C/+14°F to +40°C/+104°F</td>
<td>Max. 93% relative humidity, non-condensing</td>
</tr>
<tr>
<td>Charging the battery</td>
<td>+5°C/+41°F to +40°C/+104°F</td>
<td></td>
</tr>
</tbody>
</table>

### Product

<table>
<thead>
<tr>
<th>Reference number</th>
<th>Mobility grade according to MOBIS (activity mode A)</th>
<th>Mobility grade according to MOBIS (activity mode B)</th>
<th>Mobility grade according to MOBIS (activity mode C)</th>
<th>Maximum body weight</th>
<th>Protection rating</th>
<th>Prox. system height up to alignment reference point 3C60* (pyramid connector)</th>
<th>Prox. system height up to alignment reference point 3C60=ST (threaded connector)</th>
<th>Minimum distal system height with tube adapter</th>
<th>Maximum distal system height with tube adapter</th>
<th>Range of Bluetooth connection to PC</th>
<th>Maximum possible flexion angle</th>
<th>Weight of the prosthesis without tube adapter and protective cover</th>
</tr>
</thead>
<tbody>
<tr>
<td>3C60*/3C60=ST</td>
<td>1</td>
<td>1 and 2</td>
<td>2</td>
<td>125 kg</td>
<td>IP22</td>
<td>5 mm</td>
<td>23 mm</td>
<td>270 mm</td>
<td>490 mm</td>
<td>max. 10 m</td>
<td>124°</td>
<td>approx. 910 g</td>
</tr>
</tbody>
</table>

### Tube adapter

<table>
<thead>
<tr>
<th>Reference number</th>
<th>Weight</th>
<th>Material</th>
<th>Max. body weight</th>
<th>Protection rating</th>
<th>Prox. system height up to alignment reference point 3C60* (threaded connector)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2R17</td>
<td>190 g -300 g / 0.42-0.66 lbs</td>
<td>Aluminium</td>
<td>125 kg</td>
<td>IP22</td>
<td>23 mm</td>
</tr>
<tr>
<td>2R20</td>
<td>190-300 g / 0.42-0.66 lbs</td>
<td>Aluminium</td>
<td>150 kg (330 lbs)</td>
<td>IP54</td>
<td>16 mm</td>
</tr>
</tbody>
</table>

### Approved set screws

<table>
<thead>
<tr>
<th>Length</th>
<th>Reference number</th>
<th>Material</th>
<th>Max. body weight</th>
<th>Protection rating</th>
<th>Maximum torque</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mm</td>
<td>506G3= M8x10</td>
<td></td>
<td></td>
<td></td>
<td>15 Nm</td>
</tr>
<tr>
<td>12 mm</td>
<td>506G3= M8x12V</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14 mm</td>
<td>506G3= M8x14</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16 mm</td>
<td>506G3= M8x16</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Material

<table>
<thead>
<tr>
<th>Tube adapter</th>
<th>Weight</th>
<th>Material</th>
<th>Max. body weight</th>
<th>Protection rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>2R21 (with torsion unit)</td>
<td>435-545 g / 0.96-1.20 lbs</td>
<td>Aluminium</td>
<td>125 kg (275 lbs)</td>
<td>IP54</td>
</tr>
</tbody>
</table>
**14 Appendices**

**14.1 Symbols Used**

**14.1.1 Symbols on the product**

In some jurisdictions it is not permissible to dispose of these products with unsorted household waste. Disposal that is not in accordance with the regulations of your country may have a detrimental impact on health and the environment. Please observe the instructions of your national authority pertaining to return and collection.

Declaration of conformity according to the applicable European directives

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**Appendices**

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**Tube adapter**

<table>
<thead>
<tr>
<th>Length</th>
<th>10 mm</th>
<th>12 mm</th>
<th>14 mm</th>
<th>16 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference number</td>
<td>506G3=M8x10</td>
<td>506G3=M8x12</td>
<td>506G3=M8x14</td>
<td>506G3=M8x16</td>
</tr>
<tr>
<td>Maximum torque</td>
<td>15 Nm</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Prosthesis battery**

<table>
<thead>
<tr>
<th>Battery type</th>
<th>Li-Ion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Charging cycles (charging and discharging cycles)</td>
<td>300</td>
</tr>
<tr>
<td>after which at least 80% of the original battery capacity remains available</td>
<td></td>
</tr>
<tr>
<td>Charging time until battery is fully charged</td>
<td>6–8 hours</td>
</tr>
<tr>
<td>Product behaviour during the charging process</td>
<td>The product is non-functional</td>
</tr>
<tr>
<td>Operating time of prosthesis with fully charged battery</td>
<td>1 day with average use</td>
</tr>
</tbody>
</table>

**Power supply**

<table>
<thead>
<tr>
<th>Reference number</th>
<th>757L16*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage and transport in original packaging</td>
<td>-40 °C/-40 °F to +70 °C/+158 °F</td>
</tr>
<tr>
<td>Storage and transport without packaging</td>
<td>-40 °C/-40 °F to +70 °C/+158 °F</td>
</tr>
<tr>
<td>10 % to 93 % relative humidity, non-condensing</td>
<td></td>
</tr>
<tr>
<td>Operation</td>
<td>0 °C/+32 °F to +40 °C/+104 °F</td>
</tr>
<tr>
<td>max. 90 % relative humidity, non-condensing</td>
<td></td>
</tr>
<tr>
<td>Input voltage</td>
<td>100 V~ to 240 V~</td>
</tr>
<tr>
<td>Mains frequency</td>
<td>50 Hz to 60 Hz</td>
</tr>
<tr>
<td>Output voltage</td>
<td>12 V ===</td>
</tr>
</tbody>
</table>

**Battery charger**

<table>
<thead>
<tr>
<th>Reference number</th>
<th>4E70*</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</td>
</tr>
<tr>
<td>Max. 93% relative humidity, non-condensing</td>
<td></td>
</tr>
<tr>
<td>Operation</td>
<td>0 °C/+32 °F to +40 °C/+104 °F</td>
</tr>
<tr>
<td>Max. 93% relative humidity, non-condensing</td>
<td></td>
</tr>
<tr>
<td>Protection rating</td>
<td>IP20</td>
</tr>
<tr>
<td>Input voltage</td>
<td>12 V ==</td>
</tr>
</tbody>
</table>

---

**Declaration of conformity according to the applicable European directives**

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**Serial number**

SN YYYY WW NNN

YYYY – year of manufacture
WW – week of manufacture

**Lot number**

LOT PPPP YYYY WW
14.1.2 Symbols on the battery charger

In some jurisdictions it is not permissible to dispose of these products with unsorted household waste. Disposal that is not in accordance with the regulations of your country may have a detrimental impact on health and the environment. Please observe the instructions of your national authority pertaining to return and collection.

Declaration of conformity according to the applicable European directives

14.2 Operating states/error signals

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

14.2.1 Signals for operating states

<table>
<thead>
<tr>
<th>Beep signal</th>
<th>Vibration signal</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 x short</td>
<td>None</td>
<td>Battery charger connected or battery charger already disconnected prior to start of charging mode</td>
</tr>
<tr>
<td>3 x short</td>
<td>Charging mode started (3 sec. after connecting the battery charger)</td>
<td></td>
</tr>
<tr>
<td>1 x short</td>
<td>1x before beep signal</td>
<td>Battery charger disconnected after start of charging mode</td>
</tr>
</tbody>
</table>
### 14.2.2 Warnings/error signals

#### Error during use

<table>
<thead>
<tr>
<th>Beep signal</th>
<th>Vibration signal</th>
<th>Event</th>
<th>Required action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1x long at interval of approx. 5 seconds</td>
<td></td>
<td>Overheated hydraulic unit</td>
<td>Reduce activity.</td>
</tr>
<tr>
<td>3 x long</td>
<td></td>
<td>Battery charge level under 35%</td>
<td>Charge battery soon.</td>
</tr>
<tr>
<td>5 x long</td>
<td></td>
<td>Battery charge level under 20%</td>
<td>Charge battery immediately; the product will be switched off after the next warning signal.</td>
</tr>
<tr>
<td>10 x long</td>
<td>10 x long</td>
<td>Battery charge level under 15% After the beep and vibration signals, the product switches to empty battery mode and then switches off.</td>
<td>Charge the battery.</td>
</tr>
<tr>
<td>30 x long</td>
<td>1x long, 1x short repeated every 3 seconds</td>
<td>Severe error/indication of safety mode activation For example, a sensor is not operational, AXON tube adapter not connected or valve drive failure Possibly no switching into safety mode (see Page 29).</td>
<td>Restricted walking possible. Please note the possible change in flexion/extension resistance. Attempt to reset this error by connecting/disconnecting the battery charger. The battery charger must remain connected for at least 5 seconds before it is disconnected. If the error persists, use of the product is prohibited. The product must be inspected by an authorised Ottobock Service Centre.</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>Battery charger connected to product</th>
<th>Error</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>No</td>
<td>Country-specific plug adapter not fully engaged on power supply</td>
<td>Check whether the country-specific plug adapter is fully engaged on the power supply.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Non-functional socket</td>
<td>Non-functional socket</td>
<td>Check socket with another electric appliance.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Defective power supply</td>
<td>Defective power supply</td>
<td>The battery charger and power supply must be inspected by an authorised Ottobock Service Centre.</td>
</tr>
</tbody>
</table>
### Battery charger 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>When connecting the power supply to the outlet, the LED on the battery charger lights up briefly</td>
</tr>
<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>Vibration signal</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 x short</td>
<td>1 x short</td>
<td>Self-test completed successfully. Product is operational.</td>
</tr>
<tr>
<td>3 x short</td>
<td></td>
<td>Maintenance note Conduct the self-test again by connecting/disconnecting the battery charger. If the beep signal sounds again, product maintenance should be carried out by an authorised Ottobock Service Centre. The product can be used without restrictions. However, vibration signals may not be generated.</td>
</tr>
</tbody>
</table>

### Battery charge level

<table>
<thead>
<tr>
<th>Charger</th>
<th>Battery is charging. The on time of the LED indicates the current battery charge level. The on time of the LED gets longer as the charge level increases. It only flashes briefly at the start of the charging process and stays on continuously at the end of the charging process.</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓</td>
<td>Battery is fully charged, or the temperature fell above/below the permissible range during charging. Check current charge level (see Page 18).</td>
</tr>
</tbody>
</table>
The product 3C60/3C60-ST is covered by the following patents:

Canada: CA 2 678 987

China: CN 102 711 672; CN 102 647 963; CN 102 076 284

Finland: FI 110 159

Germany: DE 10 2008 010 281

Japan: JP 5 394 579; JP 5 619 910

Russia: RU 2 508 078; RU 2 533 967

USA: US 6 906 488; US 6 474 329; US 8 876 912

European Patent

EP 1237513 in DE, FR, GB
EP 2129340 in DE, FR, GB, IT, IS, NL, SE, TR
EP 2498724 in DE, FR, GB, IT, IS, NL, SE, TR
EP 2498725 in DE, FR, GB
EP 2498726 in DE, FR, GB, IT, IS, NL, SE, TR
EP 2498727 in DE, FR, GB, IT, IS, NL, SE, TR
EP 2498728 in DE, FR, GB
EP 2498730 in DE, FR, GB

Patents pending in Brazil, Canada, China, EPA, Germany, Japan, Russia, Taiwan and USA.