Kenevo 3C60/3C60=ST

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1 Foreword

INFORMATION

Last update: 2015-06-19
► Please read this document carefully before using the product.
► Follow the safety instructions to avoid injuries and damage to the product.
► Receive instruction in the correct and safe use of the product by qualified personnel.
► Please contact the qualified personnel 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 "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 screws
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 your needs.
For this purpose, the product is adjusted by qualified personnel using 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 can only be changed by qualified personnel.
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 22).

**The microprocessor-controlled hydraulic unit offers the following advantages**
- Stability while standing and walking
- Smooth, harmonious, quiet initiation of the swing phase
- Support while sitting down with individually adaptable resistance
- 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

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:

![Recommended for mobility grades 1 and 2 (indoor walkers and restricted outdoor walkers). Approved for a body weight of up to 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 28).

The prosthesis is intended for use **exclusively** on the user for whom the adjustment was made. The manufacturer does not authorise use of the prosthesis on another person.

3.4 Indications
- For users with knee disarticulation and transfemoral amputation
- For unilateral amputation
- Dysmelia patients with residual limb characteristics corresponding to knee disarticulation or a transfemoral amputation
- The user must fulfil the physical and mental requirements for perceiving optical/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>
</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/carried out in order to avert the hazard.

4.3 General Safety Instructions

⚠️ WARNING
Using the prosthesis while operating a vehicle
Accidents due to unexpected behaviour of the prosthesis because of changed damping behaviour.
► All users are required to observe their country’s national and state driving laws when operating vehicles. 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.

⚠️ 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 26) 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 and other body parts 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. The prosthetist is your contact person.
> If salt water has penetrated the prosthesis, the protector must be removed immediately. The prosthesis must be inspected by an authorised Ottobock Service Centre. The prosthetist is your contact person.

**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 on system components**
Falling due to damage or malfunction of the product.
> In the interest of the user’s own safety and in order to maintain the operational reliability and the validity of the warranty, the specified service intervals must be observed.
### 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

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 cause any problems. If movement noise increases noticeably during the lifecycle of the knee joint, the knee joint should be inspected by a prosthetist 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.
- For safety reasons, take the prosthesis off before charging the battery.

#### 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).

#### 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

#### 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 28).

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 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.
► Avoid remaining in the vicinity of visible or concealed theft prevention systems at the entrance/exit of stores, metal detectors/body scanners for persons (e.g. in airports) or other sources of strong magnetic and electrical interference (e.g. high-voltage lines, transmitters, transformer stations, computer tomographs, magnetic resonance tomographs, etc.). If this cannot be avoided, ensure at least that you are able to walk or stand steadily (e.g. by using a handrail or the support of another person).
► When walking through theft prevention systems, body scanners or metal detectors, watch for unexpected changes in the damping behaviour of the product.

CAUTION
Remaining in areas outside the allowable temperature range
Falling due to malfunction or the breakage of load-bearing product components.
► Avoid remaining in areas with temperatures outside of the permissible range (see Page 28).
4.7 Information on Use

**CAUTION**

**Walking up stairs**
Falling due to foot placed incorrectly on stair as a result of changed damping behaviour.
- Always use the handrail when walking up stairs and place most of the area of the sole of your foot on the stair surface.
- Particular caution is required when carrying children up stairs.

**CAUTION**

**Walking down stairs**
Falling due to foot being placed incorrectly on stair as a result of changed damping behaviour.
- Always use the handrail when walking down stairs and roll over the edge of the step with the middle of the shoe.
- Observe the warnings/error signals (see Page 26).
- Be aware 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 stairs.

**CAUTION**

**Overheating of the hydraulic unit due to uninterrupted, increased activity (e.g. extended walking downhill)**
> Falling due to unexpected behaviour of the product because of switching into overheating mode.
> Burns due to touching overheated components.
- Be sure to pay attention when pulsating vibration signals start. They indicate the risk of overheating.
- As soon as these pulsating vibration signals begin, you have to reduce the activity level 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 checked for damage by a prosthetist. If necessary, the prosthetist will forward the product to an authorised Ottobock Service Centre.

**CAUTION**

**Overloading due to unusual activities**
> Falling due to unexpected product behaviour as the result of a malfunction.
> Falling due to breakage of load-bearing components.
> Skin irritation due to defects on the hydraulic unit with leakage of liquid.
- The product was developed for everyday use and must not be used for unusual activities. These unusual activities include, for example, sports that require continuous high walking speeds (running ...) or extreme sports (free climbing, parachuting, paragliding, etc.).
- Careful handling of the product and its components not only increases their service life but, above all, ensures your personal safety!
- If the product and its components have been subjected to extreme loads (e.g. due to a fall, etc.), then the product must be inspected for damage immediately by a prosthetist. If necessary, the prosthetist will forward the product to an authorised Ottobock Service Centre.
4.8 Notes on the safety modes

**CAUTION**

**Using the product in safety mode**
Falling due to unexpected product behaviour because of changed damping behaviour.
► The warnings/error signals (see Page 26) have to be observed.

**CAUTION**

**Safety mode cannot be activated due to malfunction caused by water penetration or mechanical damage**
Falling due to unexpected behaviour of the product because of changed damping behaviour.
► Do not continue using the defective product.
► Contact your prosthetist immediately.

**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. The prosthetist is your contact person.

**CAUTION**

**Safety signal occurs (ongoing vibration)**
Falling due to unexpected behaviour of the product because of changed damping behaviour.
► Observe the warnings/error signals (see Page 26).
► Do not continue using the product after the safety signal has been emitted.
► The product must be inspected by an authorised Ottobock Service Centre. In this case, the contact person is your prosthetist.

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 tube adapter 2R17
- 1 pc. 757L16* power supply
- 1 pc. 4E70* inductive charger
- 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:
- 3S26 cosmetic foam cover
- Kenevo Protector 4X840
6 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 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 28).
- Use the 757L16* power supply and 4E70* battery charger to charge the battery.

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 26).

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 28).

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 28).

**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>
</table>
| ![LED](image) | 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. |
| ![Battery](image) | Battery is fully charged, or the temperature fell above/below the permissible range during charging. Check current charge level (see Page 14). |

**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></td>
<td>36% to 50%</td>
</tr>
<tr>
<td>1x short</td>
<td>3x long</td>
<td>20% to 35%</td>
</tr>
<tr>
<td>1x short</td>
<td>5x long</td>
<td>less than 20%</td>
</tr>
</tbody>
</table>
7 Use

7.1 Movement pattern in activity mode A
(if the knee joint is permanently locked)

7.1.1 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.

7.1.2 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.

7.1.3 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.
7.1.4 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.

7.1.5 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.

7.1.6 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 prosthesis leg on the first step.
3) Bring up the contralateral leg.

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

7.1.7 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 contralateral leg on the first step.
3) Bring up the leg with the prosthesis.
7.1.8 Walking backwards

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.

7.2 Movement pattern in activity mode B
(if the knee joint is locked during the stance phase and swing phase release is possible)

7.2.1 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.

7.2.2 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).

7.2.3 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.

### 7.2.4 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.

### 7.2.5 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.

### 7.2.6 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 prosthesis leg on the first step.
3) Bring up the contralateral leg.

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

### 7.2.7 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 contralateral leg on the first step.
3) Bring up the leg with the prosthesis.
7.2.8 Walking backwards

The knee joint is locked in the flexion direction. Therefore, 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).

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

7.3 Movement pattern in activity mode C

(if the knee joint provides high resistance during the stance phase and swing phase release is possible)

7.3.1 Standing

Flexion resistance is generally high while standing. In addition, the standing function automatically recognises any situation that puts strain on the knee joint in the flexion direction but where flexion is not permitted. The knee joint is always locked in the flexion direction when the prosthetic leg is not fully extended, under some amount of load and at rest. 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.

7.3.2 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.

7.3.3 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.
7.3.4 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.

7.3.5 Standing up
Notwithstanding low damping while sitting, the prosthesis supports standing up. Damping is increased after rising from the seat. After standing up entirely, high damping is set automatically.

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.

7.3.6 Walking down stairs
With the joint, it is possible to walk down stairs step-over-step or not step-over-step.

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

**Walking down stairs not step-over-step**
1) Hold the handrail with one hand.
2) Place the foot of the prosthesis leg on the first step.
3) Bring up the contralateral leg.
7.3.7 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 contralateral leg on the first step.
3) Bring up the leg with the prosthesis.

7.3.8 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.

7.3.9 Walking backwards

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

7.4 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 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 plantar tip of the foot (from the sole of the foot).
• Extended pressure on the dorsal tip of the foot (from the top of the foot).
• Briefly lifting the leg and allowing it to drop.
8 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.

8.1 Empty battery mode
The joint emits beeps and vibration signals when the charge level is 15% or less (see Page 26). 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 26). You can switch back to basic mode from empty battery mode by charging the product.

8.2 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.

8.3 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 26).
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.

8.4 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 or B. 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:
• Joint lock for use of a wheelchair (see Page 21)
• Battery level indication (see Page 14)

9 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 user’s own safety, and in order to maintain operating reliability and protect the warranty. These service inspections include an inspection of the 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.
9.1 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.

10 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.

11 Legal Information

11.1 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.

11.2 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.

11.3 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.

11.4 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 interference radioélectrique reçu, même si celle-ci est susceptible de compromettre le fonctionnement du dispositif.

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

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

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

12.1 Symbols Used

12.1.1 Symbols on the product

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

\[ \text{Declaration of conformity according to the applicable European directives} \]

\[ \text{Serial number} \]

\[ \text{Lot number} \]

\[ \text{Legal manufacturer} \]

\[ \text{Compliance with the requirements according to "FCC Part 15" (USA)} \]

\[ \text{Non-ionising radiation} \]

\[ \text{Compliance with the requirements according to the "Radiocommunications Act" (AUS)} \]

\[ \text{Protection against penetration of solid foreign objects with a diameter greater than 12.5 mm, protection against water dripping diagonally up to 15°.} \]

\[ \text{Caution, hot surface} \]

12.1.2 Symbols on the battery charger

\[ \text{In some jurisdictions it is not permissible to dispose of these products with unsorted household waste. Disposal that is not in accordance with the regulations of your country may have a detrimental impact on health and the environment. Please observe the instructions of your national authority pertaining to return and collection.} \]
Declaration of conformity according to the applicable European directives

Lot number

Protect from moisture

IP20

Protection against penetration of solid foreign objects with a diameter greater than 12.5 mm, no protection against water

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

12.2.1 Signals for operating states
Battery charger connected/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>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>

12.2.2 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>Overheated hydraulic unit</td>
<td>Reduce activity.</td>
<td></td>
</tr>
<tr>
<td>3 x long</td>
<td>Battery charge level under 35%</td>
<td>Charge battery soon.</td>
<td></td>
</tr>
<tr>
<td>5 x long</td>
<td>Battery charge level under 20%</td>
<td>Charge battery immediately, since the product will be switched off after the next warning signal.</td>
<td></td>
</tr>
<tr>
<td>10 x long</td>
<td>Battery charge level under 15% After the beep and vibration signal, the product switches to empty battery mode and then switches off.</td>
<td>Charge the battery.</td>
<td></td>
</tr>
<tr>
<td>Beep signal</td>
<td>Vibration signal</td>
<td>Event</td>
<td>Required action</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------</td>
<td>--------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| 30 x long  | 1x long, 1x short repeated every 3 seconds | **Severe error**  
For example sensor not operational or valve drive failure  
Possibly no switching into safety mode (see Page 22). | Restricted walking possible. The possible change in flexion/extension resistance must be observed.  
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, it is no longer permissible to use the product. The product must be inspected immediately by a prosthetist. |

**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>No</td>
<td>Non-functional socket</td>
<td>Check socket with another electric device.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yes</td>
<td>Defective power supply</td>
<td>The charger and the power supply must be inspected by a prosthetist.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yes</td>
<td>Distance between battery charger and receiver of the charging unit too big</td>
<td>The distance between the battery charger and the receiver on the product must not exceed 1 mm / 0.04 inch</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yes</td>
<td>No connection between battery charger and power supply</td>
<td>Check whether the charging cable plug is fully engaged on the battery charger.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yes</td>
<td>Defective battery charger</td>
<td>The charger and the power supply must be inspected by a prosthetist.</td>
</tr>
</tbody>
</table>
12.2.3 Status signals

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, you should visit your prosthetist soon. If necessary, the prosthetist will forward the product to 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></th>
</tr>
</thead>
<tbody>
<tr>
<td></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></td>
<td>Battery is fully charged, or the temperature fell above/below the permissible range during charging. Check current charge level (see Page 14).</td>
</tr>
</tbody>
</table>

12.3 Technical data

<table>
<thead>
<tr>
<th>Environmental conditions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Transportation in original packaging</td>
<td>-25°C/-13°F to +70°C/+158°F</td>
</tr>
<tr>
<td>Transportation without packaging</td>
<td>-25°C/-13°F to +70°C/+158°F Max. 93% relative humidity, non-condensing</td>
</tr>
<tr>
<td>Storage (≤3 months)</td>
<td>-20°C/-4°F to +40°C/+104°F 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 Max. 93% relative humidity, non-condensing</td>
</tr>
<tr>
<td>Operation</td>
<td>-10°C/+14°F to +40°C/+104°F 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>
</tr>
<tr>
<td><strong>Product</strong></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Reference number</td>
<td>3C60*/3C60=ST*</td>
</tr>
<tr>
<td>Mobility grade according to MOBIS</td>
<td>1 and 2</td>
</tr>
<tr>
<td>Maximum body weight</td>
<td>125 kg</td>
</tr>
<tr>
<td>Protection rating</td>
<td>IP22</td>
</tr>
<tr>
<td>Weight of the prosthesis without protector and tube adapter</td>
<td>approx. 910 g</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Prosthesis battery</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Battery type</td>
<td>Li-Ion</td>
</tr>
<tr>
<td>Charging cycles (charging and discharging cycles) after which at least 80% of the original battery capacity remains available</td>
<td>300</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>

<table>
<thead>
<tr>
<th><strong>Power supply</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference number</td>
<td>757L16*</td>
</tr>
<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 10 % to 93 % relative humidity, non-condensing</td>
</tr>
<tr>
<td>Operation</td>
<td>0 °C/+32 °F to +40 °C/+104 °F max. 90 % relative humidity, non-condensing</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>

<table>
<thead>
<tr>
<th><strong>Battery charger</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference number</td>
<td>4E70*</td>
</tr>
<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>
<tr>
<td>Operation</td>
<td>0 °C/+32 °F to +40 °C/+104 °F Max. 93% relative humidity, non-condensing</td>
</tr>
<tr>
<td>Protection rating</td>
<td>IP20</td>
</tr>
<tr>
<td>Input voltage</td>
<td>12 V~</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 6 908 488; US 8 474 329; 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.