

Adapter	 <p>4R104=60 4R104=75</p> <p>4R57 4R57=ST</p> <p>4R41 4R43 4R89</p> <p>4R111=N 4R111 4R116</p> <p>4R40</p> <p>4R118</p>	 <p>757L16-*</p> <p>4E50-*</p>	Charger/AC Adapter
C-Leg® Knee Joint	<p>with pyramid adapter</p>  <p>3C98-2</p> <p>with threaded connector</p>  <p>3C88-2</p> <hr/> <p>4X150-2</p>  <p>4X73</p>  <p>4X261</p> 	 <p>4X160=1.2</p>	Cosmetic Cover/Protector
Tube Adapter	<p>Tube adapter</p>  <p>2R80</p> <p>Tube adapter with torsion unit</p>  <p>2R81</p>	<p>3S26 Cosmetic foam cover (not illustrated)</p> <p>3R59 Individual cosmetic foam cover (not illustrated)</p>	Cosmetic Cover/Protector
Prosthetic Foot	 <p>1C40</p>  <p>1E56</p>  <p>1E57</p>  <p>1C30</p>  <p>1D35</p>  <p>1A30</p>  <p>1C60</p>	 <p>4X180=*</p> <p>C-Soft</p>  <p>60X3 BionicLink 60X5 BionicLink PC</p>	C-Soft (V2.4 and higher)/BionicLink
Accessories	 <p>4X78/ 4X79</p>  <p>4X74</p>  <p>4X77=GB</p>  <p>4X83=430-USB</p>		Accessories

INFORMATION

These Instructions for Use were updated on 31.5.2011.

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Explanation of Symbols used in these Instructions for Use

⚠ WARNING	Warnings regarding possible risks of severe accident or injury.
⚠ CAUTION	Warnings regarding possible risks of accident or injury.
I INFORMATION	Additional information on the fitting/use.

Recommended accessories for prosthetists

710D4	Torque Wrench	
710Y2=5	Hex Bit	
743L100	L.A.S.A.R Posture	(647H189 Instructions for Use)
743L200/743L300	L.A.S.A.R Assembly	(647H193 Instructions for Use)
60X3	BionicLink	(647G192 Instructions for Use)
4X180=* (V2.4 and higher)	C-Soft	(647G268 Instructions for Use)

1 Important C-Leg Information – Intended Use

I INFORMATION

Before using the C-Leg, please read these Instructions for Use thoroughly! Please pay special attention to the safety instructions!

The patient must be taught how to handle, care for and operate his/her prosthesis properly.

Please see the following Sections: 1.3 Conditions of Use; 1.8 Safety Instructions; 2.4 Charging the C-Leg Prosthesis System; 2.9 C-Leg Modes, 2.12 Important User Instructions; 3.1 Service Intervals; 3.3 Technical Information; 3.6 Liability.

1.1 Medical Purpose

The **3C98-2 and 3C88-2** C-Leg knee joints are to be used **exclusively** for the exoprosthetic fitting of the lower extremity.

1.2 Field of Application

The C-Leg was designed for a broad field of application and can be used by transfemoral amputees as well as by active hip disarticulation amputees. For knee disarticulation amputees, a version for long residual limbs is available (3C88-2).

Field of application according to the **Otto Bock MOBIS[®] Mobility System**:

Recommended for **Mobility Grades 3 and 4** (unrestricted outdoor walkers and unrestricted outdoor walkers with especially rigorous demands).

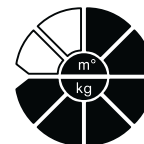
The patient must meet the following requirements:

- The patient must meet the physical and mental requirements with regard to the perception of acoustic signals and/or mechanical vibrations.
- The skin on the residual limb must be fully healed.

Approved for a **patient weight of up to 136 kg/300 lbs.**

Exception: The 2R82=110 Tube Adapter is approved for a patient weight of up to 100 kg/220 lbs.

The 2R81=* Tube Adapter is approved for a patient weight of up to 125 kg/275 lbs.



1.3 Conditions of Use

INFORMATION

Advise your patients of the information in this section.

The C-Leg was developed for everyday activities and not for extreme sports such as free climbing, parachuting or paragliding. For the necessary environmental conditions, please see Section 3.3 "Technical Information".

The C-Leg prosthesis system is designed **exclusively** for use on one patient. Use of the product by other persons is not approved by the manufacturer.

1.4 Qualification of the Prosthetist

The fitting of a patient with a C-Leg may only be carried out by prosthetists who have been authorized with the corresponding Otto Bock training.

1.5 Function

The product 3C98-2/3C88-2 C-Leg is a hydraulically damped, monocentric knee joint with microprocessor controlled swing phase control. The hydraulic damping is controlled with the aid of a microprocessor, which uses built-in sensors to determine the motion of and load on the prosthesis.

The 3C98-2/3C88-2 electronic knee joint offers the following benefits when compared to a knee joint without electronic swing phase control:

- physiological gait pattern
- stability when walking
- alternative modes can be activated for additional movement patterns which cannot be covered by the normal walking mode

1.6 Minimum scope of delivery

1 pc. 3C98-2/3C88-2 C-Leg Knee Joint

1 pc. 4X150-2 C-Leg Remote Control

1.7 Individual minimum system components (not included in the scope of delivery)

1 pc. 2R82=* C-Leg Tube Adapter

1 pc. 2R81=* C-Leg Tube Adapter with Torsion Unit

1.8 Safety Instructions

INFORMATION

Advise your patients of the information in this section.

⚠ CAUTION

Non-observance of safety instructions. Failure to follow the below-mentioned safety instructions can lead to a faulty control or malfunction of the C-Leg and result in risk of injuries for the patient as well as damage to the C-Leg.

General Safety Instructions

⚠ CAUTION

Alignment and adjustment error. During alignment and adjustment of the prosthesis, errors can occur resulting in malfunction of the joint up to loss of function due to structural failure. This can cause the patient to fall.

- Participation in an Otto Bock product training course for the C-Leg is obligatory before the first fitting. Additional product training courses may become necessary to qualify for fitting product updates.
- The tubes must not be shortened as that may damage the integrated strain gauges.
- During the data transfer (PC to C-Leg), the prosthesis wearer must remain standing or sitting still and the BionicLink or the communication cable must not be removed.
- If the prosthesis wearer uses crutches or walking canes during adjustment, readjustment is required as soon as he stops using these walking aids.

⚠ CAUTION

Use of inappropriate prosthetic components. If inappropriate prosthetic components are installed in the prosthesis, malfunction of the joints can occur up to loss of function due to structural failure. This can cause the patient to fall.

Combine the C-Leg only with adapters and feet approved by Otto Bock (see component overview on the folded front page).

⚠ CAUTION

Manipulations on system components. Any changes or modifications you make to system components on your own initiative can lead to malfunction of the joint up to loss of function due to structural failure. This can cause the patient to fall.

- Any changes or modifications to the device may limit its use.
- The opening and repairing of the joint may only be performed by authorized Otto Bock technicians, and the handling of the battery may only be carried out by Otto Bock Service Centres (exchanges are not permissible).

⚠ CAUTION

Incorrect battery charging. Charging the battery with battery chargers that have not been approved by Otto Bock can lead to defects and result in malfunction of the joint. This can cause the patient to fall.

Advise the patient about the charging procedure and refer to the Patient Information. Advise the patient of the following patient instructions.

⚠ CAUTION

Improper use of the joint. Any kind of overloading or excessive strain as well as improper use can lead to defects and result in malfunction of the joint up to loss of function due to structural failure. This can cause the patient to fall.

Advise the patient of the proper use of the C-Leg as well as of the following patient instructions.

⚠ CAUTION

Improper use of the remote control. The remote control can get damaged by improper use. This can lead to malfunction of the remote control and result in unexpected actions of the joint. This can cause the patient to fall.

Advise the patient about the proper use of the remote control and refer to the Patient Information. Advise the patient of the following patient instructions.

⚠ CAUTION

Switching between modes with the remote control. When switching between modes with the remote control, the damping behaviour of the joint changes. In certain situations, this can cause the patient to fall.

Advise the patients about the switching into the 2nd mode and refer to the Patient Information. Advise the patient of the following patient instructions.

⚠ CAUTION

Transport damage. Mechanical impact or stress during transportation of the joint such as shocks and vibrations can lead to

- defects and result in malfunction of the joint;
- defects on the battery and hydraulic damper resulting in leakage of liquid; or
- loss of function due to structural failure.

This can cause the patient to fall as well as result in skin irritation.

Always use the transport packaging for transport.

⚠ CAUTION

Results of product deterioration. Wear and tear on system components can lead to malfunction of the joint. This can cause the patient to fall.

In the interest of the prosthesis wearer (maintenance of operational safety and guaranty), the specified service intervals must be complied with.

Patient Instructions

⚠ CAUTION

Magnetic interferences. The joint can malfunction when near high-tension power lines, transmitters, transformers, CT scanners, or other sources of strong electromagnetic radiation (such as security systems for goods in department stores). This can cause the patient to fall.

Avoid proximity to strong magnetic and electric interference sources (e.g. transformer stations, high-powered radio or television transmitters).

⚠ CAUTION

Thermal overloading. Extended exposure to high temperatures can lead to defects and result in malfunction of the joint up to loss of function due to structural failure. This can cause the patient to fall.

Avoid areas with extreme temperatures (see Section 3.3 "Technical Information").

⚠ CAUTION

Mechanical overloading. Exterior mechanical impact or stress such as shocks and vibrations can lead to

- short circuits in the electronics and battery and result in malfunction of the joint;
- defects on the battery and hydraulic damper resulting in leakage of liquid; or
- loss of function due to structural failure.

This can cause the patient to fall as well as result in skin irritation.

Do not expose system components to mechanical vibrations or shocks.

⚠ CAUTION

Penetration of dirt and humidity. Penetration of dirt and humidity into the system components can lead to

- short circuits in the electronics and battery and result in malfunction of the joint;
- defects on the hydraulic damper resulting in leakage of liquid; or
- loss of function due to structural failure.

This can cause the patient to fall as well as result in skin irritation.

- Do not let foreign particles or liquids enter the system components. Should the joint come into contact with liquid, remove the cosmetic cover and let the components dry. The joint must then be sent to an authorized Otto Bock Service for inspection. Your prosthetist is the contact person.
- Always use the plug protectors / plug covers.
- If the C-Leg comes into contact with salt water, immediately clean it with a cloth moistened with freshwater and let it dry. The joint must then be sent to an authorized Otto Bock Service for inspection. Your prosthetist is the contact person.

⚠ CAUTION

Improper use of the joint. Any kind of overloading or excessive strain as well as improper use can lead to

- defects and result in malfunction of the joint;
- loss of function due to structural failure; or
- defects on the battery and hydraulic damper resulting in leakage of liquid.

This can cause the patient to fall as well as result in skin irritation.

- The C-Leg was designed for everyday activities and must not be used for unusual activities such as extreme sports (i.e. free climbing, paragliding, etc.).
- Careful handling of the prosthesis and its components not only increases their service life but, above all, ensures your personal safety. Should the prosthesis be subjected to unusual stresses (such as a fall), immediately contact your prosthetist and have the prosthesis inspected for any damage. If necessary, the responsible prosthetist will pass the prosthesis on to the Otto Bock Service Centre.

⚠ CAUTION

Overheating of the hydraulic unit. Extended, continuous use (e.g. lengthy downhill walks) can lead to

- overheating of the hydraulic unit and result in malfunction of the joint; or
- defects on the hydraulic damper resulting in leakage of liquid.

This can cause the patient to fall as well as result in skin irritation. Touching overheated components can cause burns.

- Pay attention to the vibration signals that will occur in such cases to alert you that there is a risk of overheating. As soon as these vibrations begin, all activities must be stopped and the hydraulic unit be allowed to cool down. You may resume your activities once the vibration signals stop.
- If activities are continued despite the vibration signals, the hydraulic element may overheat and, in extreme cases, lead to a damage to the C-Leg. The joint should then be sent to an authorized Otto Bock Service for inspection.

⚠ CAUTION

Risk of falling when walking backwards. When putting down the toe first when walking backwards, the C-Leg® can switch from the high stance phase resistance to swing phase resistance. When the patient actively flexes the hip joint at this point in time, this can cause the patient to fall. When walking backwards, secure the joint actively with the residual limb muscles.

⚠ CAUTION

Risk of falling when going downstairs. When walking downstairs, the banister or handrail should always be used and the prosthetic foot should be placed on the step so that the heel (max. centre of the foot) is close to the edge of the step to facilitate rollover.

- Stop walking downstairs immediately whenever the sound warning beeps. Make careful tests to verify if the stance phase stabilization is active (see Section 2.12 "Important User Instructions").
- Pay attention to the vibration and sound warnings (beeps) of the C-Leg.
- Special caution is required when walking downstairs while carrying children.

⚠ CAUTION

Non-active safety mode. If the safety mode can no longer be activated, there is the risk that the patient will fall. If the C-Leg does not switch to the safety mode (e.g. due to short-circuit due to water penetration), the amputee must actively stabilize the C-Leg at heel strike with his/her residual limb muscles until a prosthetist can be reached or a prosthesis replacement be accomplished.

⚠ CAUTION

Self-discharge of the battery. When the joint is not in use for an extended period of time, self-discharge of the battery will result. This can lead to insufficient power supply to the electronics of the joint and result in undefined conditions. This can cause the patient to fall.

- We therefore recommend recharging prior to every use.
- Prior to using the C-Leg in the 2nd/3rd mode (e.g. bike riding), check the battery status. To do so, attach the charger to the C-Leg. The yellow LED should flash (battery is charged more than a half) or should not be lit (battery is fully charged). Using the C-Leg in the 2nd/3rd mode with insufficient battery capacity may cause the C-Leg to switch into the safety mode (see Section “2.12 Important User Instructions”).

⚠ CAUTION

Improper switching between modes. An incorrect switch from the 2nd/3rd mode into the 1st mode creates the risk of falling (see Section 2.9 “C-Leg Modes”)!

⚠ CAUTION

Switching between modes with the remote control. The patient can use the remote control to initiate different actions. As a result the damping behaviour of the joint will change. In certain situations, this can cause the patient to fall.

In the case that you have mistakenly selected an unwanted action with the remote control (vibration or sound signal), unweight the C-Leg and select a new command.

⚠ WARNING

Risk of accident when driving a motor vehicle. The ability of leg prosthesis users to drive a motor vehicle is determined on a case-by-case basis. Criteria include the type of fitting (amputation level, unilateral or bilateral, residual limb conditions, design of the prosthesis) and the amputee’s individual abilities. All persons are required to observe their country’s national and state driving laws when operating motor vehicles. For insurance purposes, drivers should have their driving ability examined and approved by an authorized test centre. Otto Bock recommends that the motor vehicle be professionally retrofitted to the user’s individual needs (e.g. automatic shift). Risk-free driving must be ensured even when the leg prosthesis is not functioning.

Before operating a motor vehicle, make sure to turn off the standing mode feature using the remote control unit.

⚠ CAUTION

Malfunction of the joint. Malfunctions of the joint can cause the prosthesis wearer to fall.

Pay attention to the vibration and sound warnings (beeps) of the C-Leg.

INFORMATION

When using exoprosthetic knee joints, servomotoric, hydraulic, pneumatic or brake load dependent control functions can cause movement noise. This kind of noise is normal and unavoidable. Usually, it does not cause any problems.

If the movement noise noticeably increases in the knee joint’s life cycle, the joint should be inspected immediately by a prosthetist.

2 Alignment and Adjustment

2.1 Connecting the Tube Adapter



- 1 Mount the foot to the tube adapter (lightly tighten the screws).
- 2 Plug the tube adapter plug into the knee joint (only one polarity possible).
- 3 Push the protruding cable into the tube and push the tube adapter into the C-Leg. In doing so, take care to achieve the minimum insertion depth (see following table).

max. 75 kg	75 kg - 100 kg	100 kg - 136 kg
<p>50 mm max. adjust- ment range</p>	<p>45 mm max. adjust- ment range</p>	<p>40 mm max. adjust- ment range</p>

CAUTION **Error during alignment of the prosthesis.** Errors during the alignment of the prosthesis can lead to malfunction of the joint up to loss of function due to structural failure. This can cause the patient to fall. With the 3C98-2 and 3C88-2 models, the scaling must be positioned in front of the tube (With the former models 3C98 and 3C88, the scaling had to be on the back of the tube). The 2R82=110 Tube Adapter is approved for a maximum weight of 100 kg/220 lbs, the 2R81=* Tube Adapter is approved for a maximum weight of 125 kg/275 lbs.

- 4 Turn the foot slightly outward (adjustment range +/-30° to suit the needs of the patient) and pre-fasten the screws lightly at the clamp.

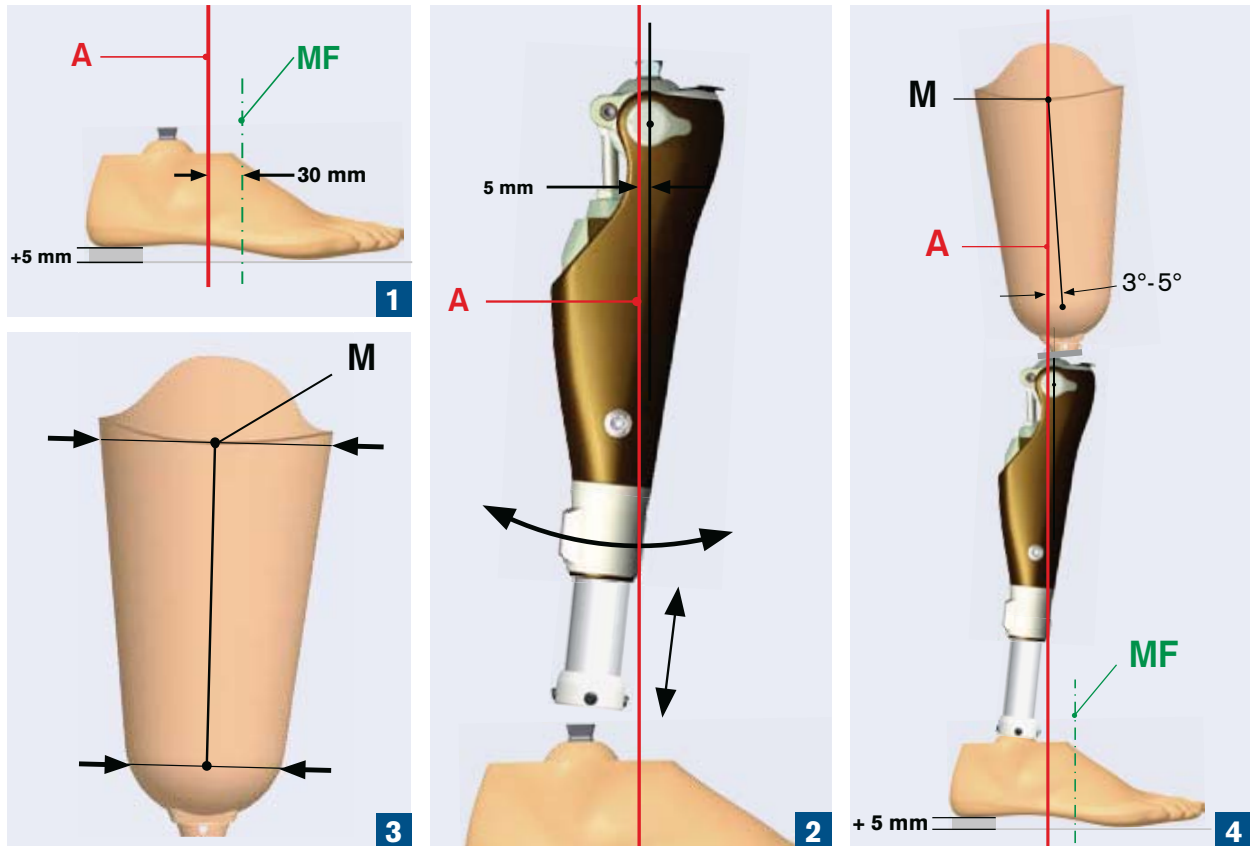
2.2 Bench Alignment Using an Alignment Tool such as L.A.S.A.R. / PRO.S.A. Assembly

INFORMATION

To align the prosthesis please proceed in two steps:

First make the bench alignment using an alignment tool such as 743L200 L.A.S.A.R. Assembly / 743A200 PRO.S.A. Assembly.

In a second step, the static alignment is optimized with the 743L100 L.A.S.A.R. Posture (see Section 2.5 "Static Alignment Optimization").



A correct bench alignment (e.g. using the 743L200 L.A.S.A.R. Assembly / 743A200 PRO.S.A. Assembly.) ensures that the user can benefit from all the advantages of the C-Leg. The optimal residual limb position must be anticipated 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 test socket) will facilitate correct positioning of the lamination anchor or socket adapter.

- Position the middle of the foot (MF) approx. 30 mm anterior to the alignment reference line (A). This applies to all feet that are recommended for use with the C-Leg, independently of the specifications in the instruction manuals of those feet!

Add 5 mm to the required heel height. Set correct outward rotation of the foot (Fig. 1).

- Clamp the knee joint with the mounted tube adapter into the alignment tool. Place the alignment reference point (=knee axis) approx. 0-5 mm anterior to the alignment reference line. Consider the knee-floor distance and outward rotation of the knee (approx. 5° are provided for by the adapter insert in the L.A.S.A.R. Assembly / PRO.S.A. Assembly.). Recommended positioning of the alignment reference point: 20 mm above the medial tibial plateau (Fig. 2).
- Connect the foot to the modular knee joint using a tube adapter. To do so, tilt the joint in the correct position and set the required tube length (Fig. 2).
- Mark the centre of the socket proximally (M) and distally on the lateral side. Draw a line through both marks from the socket brim to the distal end of the socket (Fig. 3).

Now position the socket such that the alignment reference line (A) passes through the proximal centre mark (M). Set the socket flexion to somewhere between 3° and 5°; however, the individual situation (e.g. hip joint contrac-

tures) must be taken into account and, if necessary, more flexion should be provided. Also pay attention to the ischial tuberosity to ground distance (Fig. 4).

CAUTION Error during alignment of the prosthesis. Errors during the alignment of the prosthesis can lead to malfunction and insufficient fitting results of the joint up to loss of function due to structural failure. This can cause the patient to fall.

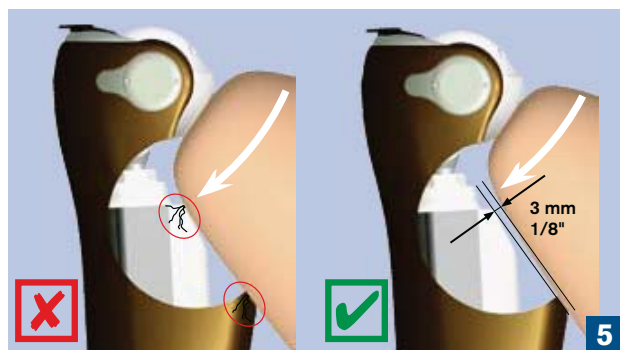
If the residual limb flexion is not taken into account, the joint will be positioned too far to the front.

- Connect the socket and modular knee joint using a corresponding adapter (e.g. 4R111, 4R41 Socket Adapter, etc.). For alignment correction, use the 4R112 Sliding Adapter (only for temporary use!). When using socket adapters with a 4-hole connection (e.g. 5R1=*, 5R6=*), the 4R118 Sliding Adapter can be used for a permanent, additional posterior placement of 10 – 25 mm.

CAUTION Error during alignment of the prosthesis. If incorrectly positioned, the support for the lamination anchor is not provided. This puts too much strain on the screwed connection adapter and may cause damage and subsequently cause the patient to fall. The rotation adjustment must **not** be used for length adjustment. Screw in the thread adapter as far as possible and clamp with the cap screw. In case of the **4R43** Lamination Anchor with threaded connector, position the **clamp laterally or medially**. In case of the **4R111=N** Lamination Anchor with threaded connector, the **anchor arms** must be positioned in the **anterior/posterior and medial/lateral directions**. Here, the clamp must be positioned to show in the anterior/medial or anterior/lateral direction.

- Confirm the bench alignment and all measurements.

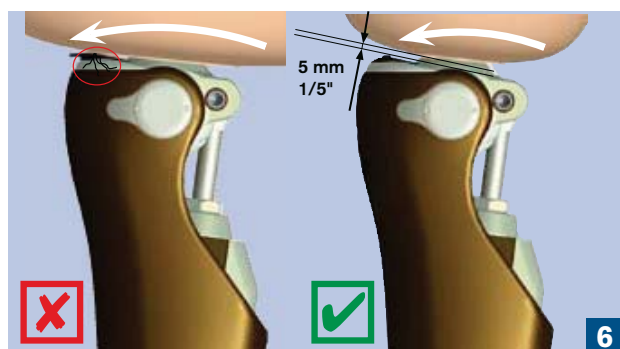
2.2.1 Checking the Socket after Bench Alignment



CAUTION Error during alignment of the prosthesis.

Errors during the alignment of the prosthesis can damage the hydraulic unit of the joint. A defective hydraulic unit can lead to malfunction of the joint up to loss of function due to structural failure. This can cause the patient to fall.

The hydraulic unit may become damaged by contact with the socket! At maximum flexion and insofar as contact with the frame of the C-Leg cannot be avoided (in case of voluminous residual limbs), the socket must lie flat on the frame. Soft cushioning at the socket will assist in maintaining the socket flat. At maximum flexion, it is essential that the minimum distance of 3 mm (1/8") is maintained between the hydraulic unit and the socket.



CAUTION Error during alignment of the prosthesis.

Errors during the alignment of the prosthesis can damage the electronics of the joint. Defective electronics can lead to malfunction of the joint. This can cause the patient to fall.

The electronic unit may become damaged by contact with the socket! At maximum extension (reached under full capacity load!) the minimum distance of 5 mm (1/5") must be maintained between the electronic unit and the socket at the beginning of the dampening phase.

For fittings with the 4X160=* C-Leg Protector, the minimum distance between the electronic unit and the socket must be at least 10 mm (3/8").

CAUTION

Error during alignment of the prosthesis. If the socket drain or air expulsion hole is incorrectly positioned, the draining sweat may drop into the electric connector and lead to short-circuits in the electronics and malfunction of the knee joint which may subsequently cause the patient to fall.

Make sure the socket drain or air expulsion hole is not positioned frontally above the electric connector. Position the hole on the side or back of the socket.

2.3 Torque Values of the Screw Connections

INFORMATION

The torque values for additional as well as optional system components (in item 3 below) are indicated in the Instructions for Use of those products.



Using the 710D4 Torque Wrench with the 710Y2=5 Hex Bit, turn the screws alternatively to the prescribed torque so that the torque is gradually increased:

- 1 Tube adapter: 15 Nm
- 2 Clamp: 7 Nm

Fitting for short residual limb

- 3 Rotation adapter or sliding adapter: 15 Nm

Fitting for long residual limb

- 4 Lamination anchor with threaded connector: 10 Nm

2.4 Charging the C-Leg Prosthesis System

INFORMATION

Advise your patients of the information in this section.



⚠ CAUTION

Incorrect behaviour while charging the joint. If the patient walks while the battery charger is connected to the prosthesis, he can get caught on the cable and fall.

Take off the prosthesis prior to charging.

⚠ CAUTION

Incorrect handling while charging the joint. If the joint is not flexed completely during charging, the charging plug can get damaged and the joint can no longer be charged. This can lead to insufficient power supply to the electronics of the joint and result in undefined conditions. This can cause the patient to fall.





During charging, keep the C-Leg fully flexed.

INFORMATION

Prior to charging with the 4E50-* Charger, read the corresponding 647G262 Instructions for Use.

The battery is empty upon delivery. The battery of the C-Leg must therefore be charged prior to the first fitting of the patient.

- 1 Bend the C-Leg until it hits the stop.
- 2 Open plug cover.
- 3 Connect the 4E50-* Charger and verify the charging process (see following figures).

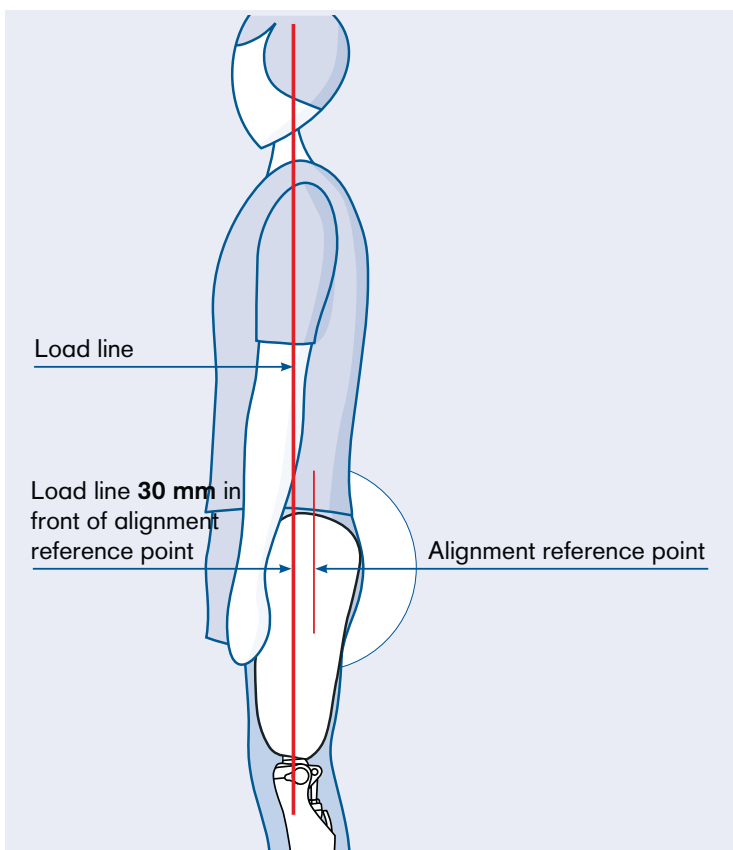
			
Both LEDs are off.	Both LEDs are lit.	Yellow LED flashes; green LED is lit.	Yellow LED is off; green LED is lit.
No power supply (or defective charger)	Battery is being charged. Battery capacity is lower than 50%.	Battery is being charged. Battery capacity is above 50%.	Battery is fully charged (or connection with C-Leg is interrupted).

- 4 Close plug cover.

INFORMATION

- The capacity of a fully charged battery is sufficient for one full day. We recommend charging the battery overnight when using the prosthesis on a daily basis.
- Charging is only possible at temperatures above 0 °C.

2.5 Static Alignment Optimization (with L.A.S.A.R. Posture)



Static alignment optimization with LASAR Posture (743L100)

The static alignment can be substantially improved using L.A.S.A.R. Posture. In order to ensure appropriate stability combined with easy swing phase initiation, please proceed as follows:

- 1 After the self-calibration of the L.A.S.A.R. device, the load line can be measured. To do this, have the transfemoral amputee step onto the force sensing plate with the C-Leg and onto the height compensation plate with the other leg. Approximately the same amount of weight should be applied to both feet (monitor weight display on the L.A.S.A.R. Posture).
- 2 The alignment is adapted exclusively by modifying the plantar flexion so that the load line/laser line runs approximately 30 mm in front of the alignment reference point (=knee axis) of the C-Leg.
- 3 After adjusting the C-Leg with C-Soft (V2.4 and higher) (see Section 2.7 "C-Soft") perform dynamic optimizations during trial walking.

2.6 BionicLink/Optional: Serial Data Cable

INFORMATION

Prior to connecting the 60X3 BionicLink, read the corresponding 647G192 Instructions for Use.



- 1 Open plug cover.
- 2 Snap the BionicLink into place and attach it medially (for left-side fittings) or laterally (for right-side fittings) to the C-Leg.

2.7 C-Soft

INFORMATION

Prior to the parameter adjustment with 4X180=* C-Soft (V2.4 and higher), read the corresponding 647G268 Instructions for Use.

INFORMATION

Otto Bock Data Station is the platform for Otto Bock applications such as C-Soft and others.

Otto Bock C-Soft (V2.4 and higher) cannot be used without the Otto Bock Data Station. The Otto Bock Data Station is a standard component of C-Soft and is automatically installed when installing C-Soft.

2.8 Optional: Parameter Settings with Foam Cover and C-Soft

The 3S26 or 3R59 Foam Covers can be used for the cosmetic enhancement of the leg prosthesis.

For that purpose, a 4X78 Charger Extension Cable can be integrated into the C-Leg fitting. If the charger extension cable is not used, a connection cap made of 2 mm Pedilin® makes it possible to pull down the foam cover in order to reach the charging receptacle at the C-Leg.

Allow a 60 mm "compression allowance" to minimize the effect of the protective foam cover on the knee function. When determining the proper cover length, increase the thigh dimension by 30 mm and the shin dimension by the same amount.

The mounted foam cover changes the damping behaviour. With the 60X3 BionicLink, which is attached below the pre-shaped foam block, the damping behaviour can be taken into account by changing the parameter settings.

That process also requires the 60X5 (60X4) BionicLink PC for the data transfer and the 4X180=* C-Soft (V2.4 and higher) for the parameter adjustment (see Section "2.7 C-Soft").

2.9 C-Leg Modes

2.9.1 1st Mode, 2nd Mode and 3rd Mode

INFORMATION

Advise your patients of the information in this section.

Upon delivery to the user, the C-Leg must always be in the 1st mode.

The C-Leg features a 1st, 2nd and 3rd mode: The 1st mode (optionally with standing mode) is for everyday use, the 2nd and 3rd modes can be used to preprogram specific movement patterns or postures individually, such as riding a bicycle (only available in the 2nd mode), inline skating, or cross-country skiing. The 2nd and 3rd modes can also be defined and modified with the 4X180=* C-Soft Adjustment Software (V2.4 and higher).

Switching between modes can be done with the remote control or through specific movement patterns in the joint. For changing between the 1st and 2nd mode using the remote control, the following prerequisites have been determined:

⚠ CAUTION

Improper switching between modes with the remote control. When switching between modes with the remote control, the damping behaviour of the joint changes. In certain situations, this can cause the patient to fall. The patient must stand securely when switching between modes and must carefully confirm whether the desired function was successfully set by the C-Leg.

⚠ CAUTION

Penetration of water in the remote control. The remote control is not waterproof. If water penetrates the remote control, the device may become damaged (guaranty will become void). This can lead to malfunction of the remote control, result in unexpected actions of the joint, and cause the patient to fall. Should water have penetrated the remote control, the device should be dried at room temperature for at least one day. Before starting to reuse the remote control, return it to an authorized Otto Bock Service for inspection.

⚠ CAUTION

Manipulation on the remote control. Any changes or modifications you make to the remote control on your own initiative can lead to malfunction and result in unexpected actions of the joint. This can cause the patient to fall. Any changes or modifications to the device may limit its use.

INFORMATION

Patient instructions for switching and configuring with the remote control!

Keep the joint and the residual limb still (no bending or extending!).

The remote control must be activated prior to switching between modes or configurations.

The remote automatically deactivates itself, if no action is performed within three seconds after activation of the remote control (e.g. switching between 1st mode and 2nd mode, configuration of the standing mode functionality, etc.).

For safety purposes, the working range of the remote control is limited to approximately 70 cm. However, the remote control will only function properly if held at least 30 cm away from the joint. If the mode switch was not performed, ensure that the remote control is placed between 30 and 70 cm of the C-Leg and repeat the command.

Activating the 1st mode:



- 1 **Activation of the remote control:** Press key 3 and keep it pressed (Fig. 1) until the joint confirms the activation with a vibration signal.
- 2 **Activation of the 1st mode:** Within 3 seconds after activation of the remote control press key 1 and keep it pressed (Fig. 2). You will hear a short beep signal, and the joint switches to the 1st mode.

INFORMATION

If the C-Leg is in the 2nd mode, then the 1st mode is selected.

If the C-Leg is in the 3rd mode, then the 1st mode is selected.

If the C-Leg is already in the 1st mode, then this mode is reconfirmed.

The 1st mode remains active until the patient actively switches to the 2nd or 3rd mode.

Activating the 2nd mode:



- 1 **Activation of the remote control:** Press key 3 and keep it pressed (Fig. 1) until the joint confirms the activation with a vibration signal.
- 2 **Activation of the 2nd mode:** Within 3 seconds after activation of the remote control press key 2 and keep it pressed (Fig. 2). You will hear two short beep signals, and the joint switches to the 2nd mode.

INFORMATION

If the C-Leg is in the 1st mode, this is the way to switch to the 2nd mode.

If the C-Leg is in the 3rd mode, then the 2nd mode is selected.

If the C-Leg already is in the 2nd mode, this mode will be reconfirmed.

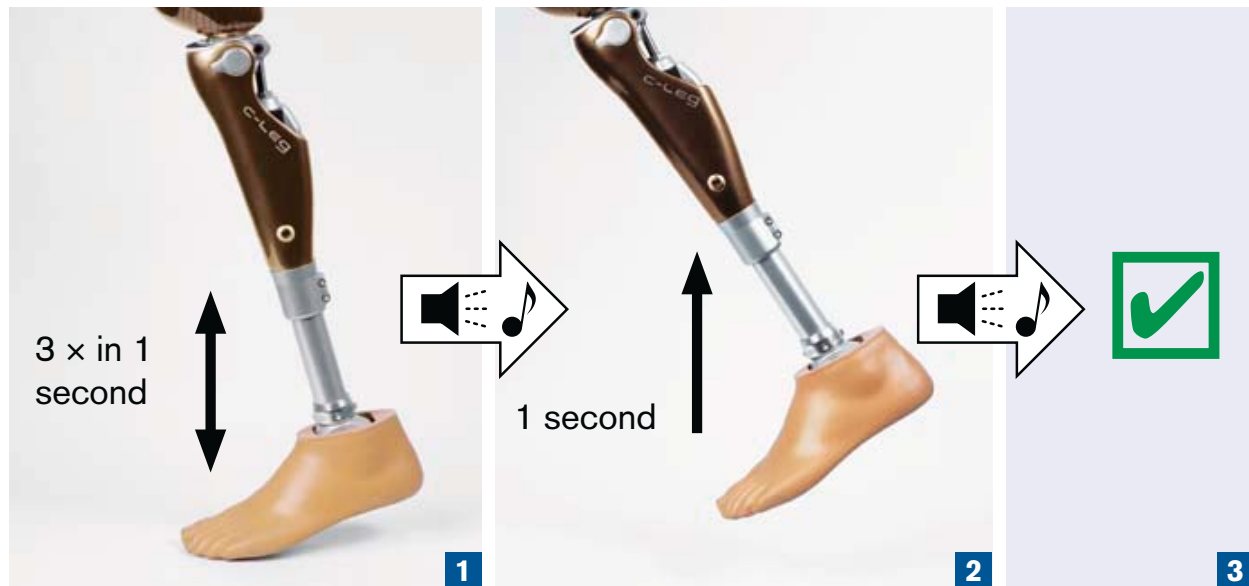
The 2nd mode remains turned on until the patient actively switches to the 1st mode or the charging process is started.

INFORMATION

No provisions are made for using the remote control to switch to the 3rd mode. Switching to the 3rd mode is only possible through specific movement patterns in the joint.

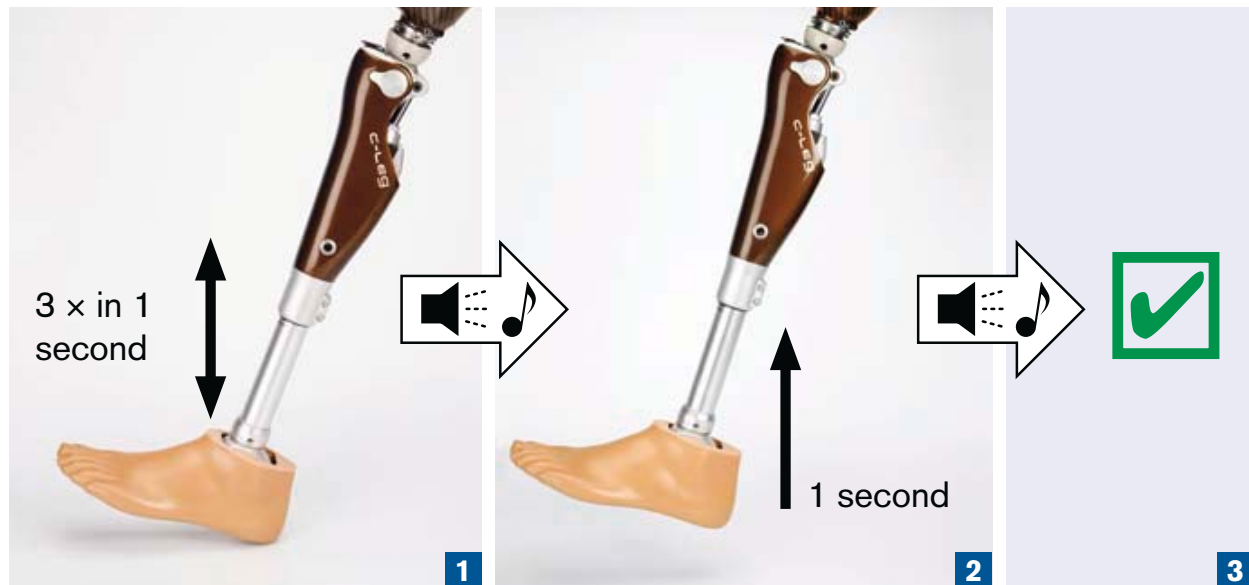
However, it is possible to switch from the 3rd mode to the 1st or 2nd mode with the remote control.

Switching between 1st and 2nd modes without the remote control:



- 1 Bounce up and down on the forefoot at least 3 times in one second while maintaining continuous ground contact. The foot must bear at least 70% of the maximum load. When relieving the foot, the foot must bear at least 15% of the maximum load. You will hear a beep signal.
- 2 Lift the leg for at least one second and extend it to the rear (no ground contact).
- 3 The C-Leg confirms the switching and changes to the respective other mode:
 - Activation of the 2nd mode = 2 short beep signals (joint changes from 1st mode to 2nd mode)
 - Activation of the 1st mode = 1 short beep signal (joint changes from 2nd mode to 1st mode)

Switching between 1st and 3rd modes without the remote control:



- 1 While maintaining contact with the ground, bounce on the heel at least 3 x within a second. During this process, at least 70% of the maximum heel load must be placed on the foot. When the load is reduced, the minimum value must not be less than 15% of the maximum heel load. A beep signal sounds.
- 2 Take weight off the leg for at least one second.
- 3 The C-Leg confirms the switching process and switches to the other mode:
 - Activating 3rd mode = 3 short beeps (joint switches from 1st mode into 3rd mode)
 - Activating 1st mode = 1 short beep (joint switches from 3rd mode into 1st mode)

2.9.2 Standing Mode Function in the 1st Mode

INFORMATION

Advise your patients of the information in this section.

Turning the standing mode function on requires that the 1st mode has been activated (see Section 2.9.1).

CAUTION

Improper configuration of the standing mode functionality. When trying to configure the standing mode while the patient is standing, unwanted switching can cause the patient to fall. For safety purposes, the patient must sit with a fully flexed joint for this configuration. After the beeps, check whether the joint is still in the 1st mode.

WARNING

Risk of accident when driving a motor vehicle. The ability of leg prosthesis users to drive a motor vehicle is determined on a case-by-case basis. Criteria include the type of fitting (amputation level, unilateral or bilateral, residual limb conditions, design of the prosthesis) and the amputee's individual abilities. All persons are required to observe their country's national and state driving laws when operating motor vehicles. For insurance purposes, drivers of motor vehicles should have their driving ability examined and approved by an authorized test centre. Otto Bock recommends that the motor vehicle be professionally retrofitted to the user's individual needs (e.g. automatic shift). Risk-free driving must be ensured even when the leg prosthesis is not functioning. Before operating a motor vehicle, make sure to turn off the standing mode feature using the remote control unit.

The standing mode is an additional functional feature of the 1st mode. It makes it easier for the patient to stand on an inclined surface for a longer time. The C-Leg is fixed in the flexion direction at a flexion angle between 7° and 70°.

For individual use of the standing mode function, please proceed as follows:

1. Turning the standing mode function on:

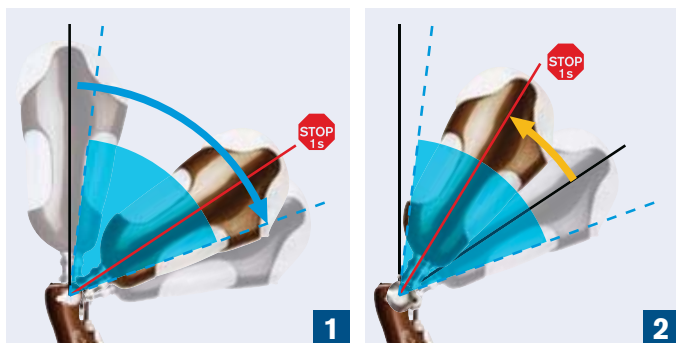
Requirement: The knee joint is fully bent (the patient is seated).



- 1 **Activation of the remote control:** Press key 3 and keep it pressed (Fig. 1) until the joint confirms the activation with a vibration signal.
- 2 **Turning the standing mode function on:** Within 3 seconds after activation of the remote control simultaneously press the keys 1 and 2 (Fig. 2) until the joint confirms turning on of the standing mode with three short beep signals.

2. Using the standing mode

2a. Adjusting the standing angle

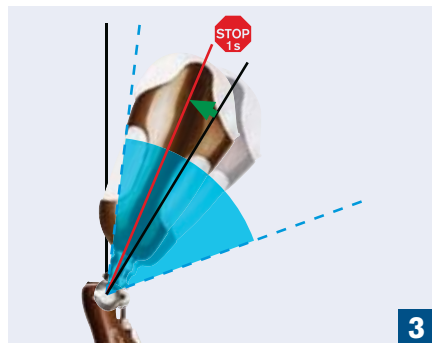


- 1 Flex the joint between 7 – 70° and keep it still for one second (Fig. 1).
- 2 **Slowly extend** the joint up to the desired angle (70 – 7°; Fig. 2).
- 3 In this position, keep the joint still for one second until the C-Leg shortly vibrates.
- 4 The blocked joint can now be fully loaded in the flexion direction.

INFORMATION

Slow extension (fig. 2.): Actively standing up from sitting at this speed would take about 2 – 5 seconds.

2b. Fine tuning of the standing angle (if required)



- 1 To optimize the angle, **very slowly continue to extend** the joint (70 – 7°; Fig. 3).
- 2 The blocked joint can be fully loaded in the flexion direction.

INFORMATION

Very slow extension (fig. 3): Actively standing up from sitting at this speed would take more than 5 seconds.

2c. Unblocking the standing angle



- 1 The standing angle can be unblocked at any time by either a quick extension movement **or complete extension** (7 – 0°, Fig. 4).

INFORMATION

Quick extension (fig. 4): Actively standing up from sitting at this speed would take less than 2 seconds. The standing mode function remains turned on. A new standing angle can be selected at any time by repeating steps 2a./2b. 1st mode remains active.

Explanation of arrow symbols:

Flexion/Extension
 Very slow extension
 Slow extension
 Quick extension

Turning the standing mode function off:

Requirement: The knee joint is fully bent (the patient is seated).



- 1 **Activation of the remote control:** Press key 3 and keep it pressed (Fig. 1) until the joint confirms the activation with a vibration signal.
- 2 **Turning the standing mode function off:** Within 3 seconds after activation of the remote control simultaneously press the keys 1 and 2 (Fig. 2) until the joint confirms turning off of the standing mode with one short beep signal.

INFORMATION

After the joint's confirmation with the beep signal, check whether the joint is still in the 1st mode (see Section 2.9.1).

2.9.3 Optimization of the Damping Behaviour in the 1st Mode

INFORMATION

Advise your patients of the information in this section.

This functionality is not intended for joint adjustment by the prosthetist, who should adjust the joint by means of the C-Soft adjustment software.

Changes to the damping behaviour which were effected with the remote control are not displayed by the C-Soft.

CAUTION

Incorrect behaviour during optimization of the damping behaviour. The patient can adapt the damping behaviour slightly during everyday use to meet his or her requirements. In certain situations, this can cause the patient to fall.

The patient must stand very securely during this procedure.

This functionality enables the patient to adapt the damping behaviour of his or her C-Leg slightly during everyday use (e.g. when getting used to the prosthesis or for a changed gait pattern). For safety purposes, the damping behaviour can only be slightly changed with the remote control.

Optimization of the damping behaviour



- 1 Activation of the remote control:** Press key 3 and keep it pressed (Fig. 1) until the joint confirms the activation with a vibration signal.

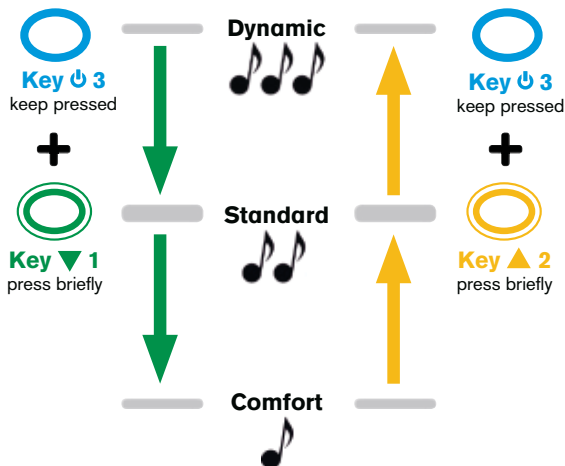


- 2 Configuration of the damping behaviour:** Within 3 seconds after activation, push and hold button 3 on the remote control again. Additionally, press key 1 or 2 briefly:

- Key 1 – change from standard to comfort or from dynamic to standard respectively (Fig. 2).
- Key 2 – change from standard to dynamic or from comfort to standard respectively (Fig. 3).

- 3 Signals:** The successful setting of the damping parameters is confirmed acoustically with the following beep signals:

- Comfort = 1 × beep signal
- Standard = 2 × beep signals
- Dynamic = 3 × beep signals



2.10 Pairing of the Remote Control and Battery Change

INFORMATION

Advise your patients of the information in this section.

2.10.1 Pairing

CAUTION

Fault while connecting the C-Leg and remote control (pairing). If several joints are present in close proximity, this can result in unwanted connection of the remote control with another joint (pairing). This can cause the patient to fall.

Given that only one joint may be paired with a remote control, it must be ensured that no other joint is in the circumference of 3 m during the pairing.

INFORMATION

If the C-Leg still is in the delivery state, pairing is not required.

Pairing serves to permanently connect a C-Leg to a remote control. Pairing is done

- as soon as a new remote control (replacement) is used with the C-Leg.
- if a configuration or mode switch cannot be effected with fully charged batteries of the joint and the remote control within the working range of the remote control (70 cm).

For pairing, the following switching procedures with the remote control have been determined:

Performing the pairing (matching the C-Leg to the remote control)



- 1 Distance between the remote control and C-Leg:** Hold the remote control at a distance of 30 to 70 cm to the joint.
- 2 Pairing between the remote control and C-Leg:** Briefly press the start button by poking a thin object (e.g. a paper clip) through the small hole of the remote control (Fig. 1).
- 3 Signals:** The joint will confirm the successful pairing with 5 short beep signals.

2.10.2 Battery Change

CAUTION

Impermissible replacement of the battery of the remote control. Replacing the battery on your own initiative can result in defects of the remote control. Malfunction and subsequent unexpected actions of the joint are then possible. This can cause the patient to fall.

- The battery of the remote control may only be changed by an authorized Otto Bock Service Centre.
- To replace the batteries outside of the prescribed service intervals, send the remote control to the authorised Otto Bock Service. Upon receipt of the remote control with a new battery, the remote control must be paired with the C-Leg (see Section 2.10.1).

2.11 Finishing the Prosthesis

Upon finalizing all settings, all screws must be fastened and tightened to the proper torque.

- 1 Optional: Remove the cosmetic foam cover (and also the BionicLink, if present).
- 2 Secure all screws required for the prosthesis alignment (see Section 2.3) with 636K13 Loctite.
- 3 Tighten all screws to the proper torque (see Section 2.3) with the 710D4 Torque Wrench.
- 4 Optional: Apply the cosmetic foam cover or the 4X160=* C-Leg Protector.

2.12 Important User Instructions

INFORMATION

Advise your patients of the information in this section.

Safety mode

Aside from the operation modes (1st, 2nd and 3rd mode), the CLeg® has a safety mode. The C-leg automatically switches to safe mode if a critical system fault occurs. In this mode, the prosthesis sets a high level of flexion damping (high safety/reduced comfort). This allows the patient to walk even though the system is not active.

The switch to the safety mode is announced immediately prior to the switch with sound and vibration signals.

⚠ CAUTION

Non-active safety mode. If the safety mode can no longer be activated, there is the risk that the patient will fall. If the C-Leg does not switch to the safety mode (e.g. because of a short-circuit due to water penetration), the amputee must actively stabilize the C-Leg at heel strike with his/her residual limb muscles until a prosthetist can be reached or a prosthesis replacement be accomplished.

⚠ CAUTION

Danger when activating the safety mode. Upon activation of the safety mode, the damping behaviour of the joint changes. In certain situations, this can cause the patient to fall.

As soon as the sound and vibration signals go off simultaneously, the prosthesis wearer must stop all activities with the leg prosthesis. After approximately 10 seconds, and from a secure standing position, check to see if the safety mode with the high flexion damping has been activated by slightly bending the C-Leg repeatedly under controlled weight bearing.

⚠ CAUTION

Safety mode cannot be deactivated. If the joint is exclusively in the safety mode, the joint has a defect. When in this condition, malfunctions can occur. This can cause the patient to fall.

If the safety mode is not deactivated by connecting and removing the battery charger, then a fault condition exists. Contact a prosthetist to correct the problem.

Battery capacity

During normal operation in the 1st and 2nd modes, the battery capacity is indicated with different vibration signals:

Battery capacity	Vibration impulse
Approx. 1 hour of operation remains	3 ×
Approx. 30 min. of operation remains	5 ×
When turning off	10 ×, then turns off

Empty battery mode

The C-Leg automatically switches to empty battery mode when the battery is almost empty. In this mode, the prosthesis either sets "high flexion damping" (high safety/reduced comfort) or "low damping" (less safety/higher activity). This allows the patient to walk even though the system is not active.

The standard factory setting for the knee joint is "high flexion damping". The prosthetist is responsible for deciding whether the patient can safely use the "low damping" setting when the empty battery mode is active. This setting can only be changed through the C-Soft adjusting software, V2.4 or higher.

CAUTION

Danger when empty battery mode is activated. Depending on the setting (made by the prosthetist using C-Soft V2.4 or higher), the prosthesis sets either "high flexion damping" (high safety/reduced comfort) or "low damping" (less safety/higher activity) when empty battery mode is activated. In certain situations, this can cause the patient to fall.

During the fitting process, the prosthetist must inform the patient of the selected damping behaviour during empty battery mode.

For the "low damping" setting in empty battery mode, the patient must have the necessary muscular and cognitive abilities to control a freely moving knee joint without stance phase locking.

If an empty battery was the reason for entering the empty battery mode, then the operating mode (1st mode) can be selected again by charging the joint.

Safety signal for incorrect connection to the tube adapter

CAUTION

Safety signal occurs. The safety signal indicates an error of the joint. When in this condition, malfunctions can occur. This can cause the patient to fall.

In the event such a safety warning occurs, stop all activities with the C-Leg and resolve the error by properly connecting the tube adapter (to be performed by your prosthetist or a service technician). Insofar as a contact failure has occurred between the plug of the tube adapter and the C-Leg (e.g. following the fitting by the prosthetist), send the knee joint (incl. tube adapter) to an authorized Otto Bock Service Centre.

As soon as the tube adapter has no connection when the C-Leg is in operation (i.e. 1st, 2nd, 3rd or standing mode with sufficient battery capacity), the C-Leg emits short beeps and, for the duration of approximately five minutes, slowly pulsing vibration signals. The C-Leg will activate the stance phase damping and maintain it until the tube adapter cable is correctly attached (provided the battery capacity remains sufficient).

Ventilation

Air may accumulate in the hydraulic unit if the C-Leg is not stored in an upright position. This is noticeable through sounds and irregular damping behaviour.

The automatic ventilation mechanism ensures that all functions of the C-Leg are again intact after approximately 10 – 20 steps.

3 Additional Information

3.1 Service Intervals

INFORMATION

This component has been tested according to ISO 10328 standard for three million load cycles. Depending on the amputee's activity this corresponds to a duration of use of three to five years.

The service life can be individually extended in dependence of the intensity of use by making use of regular service inspections (respectively after 24 months) (see C-Leg Service Pass 646D241=*).

In the interest of patient safety and in order to maintain operating safety and warranty, a service inspection is required after 24 months (see 646D241=* C-Leg Service Pass). This service inspection includes a verification of the sensors and the replacement of worn parts. It is essential that the tube adapter is replaced after a service life of 72 months at the latest.

To obtain the service, send in the knee joint with mounted C-Leg tube adapter and remote control as well as the complete charger unit including the AC adapter.

3.2 Damage Event

To simplify problem resolution, describe damage events in detail and document patient statements.

Unless the cause of a damage is very apparent, send in all accessories.

3.3 Technical Information

Weight of the joint:	approx. 1145 g
Weight of the 2R82 Tube Adapters	approx. 178 g to 256 g
Weight of the 2R81 Tube Adapters	approx. 438 g to 482 g
Max. flexion angle	approx. 125°
Operating voltage of the battery charger:	100 V to 260 V AC
Operating frequency of the battery charger:	50 Hz to 60 Hz
Battery charging temperature:	> 0 °C
Relative humidity range:	up to 80 %, non-condensing
Operating, storage, and transport temperature:	-10 °C to +60 °C

3.3.1 Symbols on the Joint



Declaration of conformity according to the European Directive for Medical Devices 93/42/EEC and 1999/5/ EU.



These products may not be disposed of with household waste in some jurisdictions. 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 information provided by the responsible authorities in your country regarding return and collection processes.

3.3.2 Symbols on the Remote Control



Declaration of conformity according to the European Directive for Medical Devices 93/42/EEC and 1999/5/ EC with the number of the specified authority (0681).



These products may not be disposed of with household waste in some jurisdictions. 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 information provided by the responsible authorities in your country regarding return and collection processes.

3.4 Transportation

Always use the **X-3C100 Shipping Case** when transporting your electronic joint system and the Service Joint.

3.5 Guaranty

Otto Bock offers an extensive guaranty service on the basis of the current C-Leg guaranty concept (see 646D241=* C-Leg Service Card). Please comply with the prescribed service intervals (see Section 3.1 "Service Intervals"). For your own interest, we also recommend obtaining a confirmation from your patients for the provision of instructions and the handing over of the device.

3.6 Liability

The device is only to be used under the specified conditions and for the intended purposes. The device must be maintained according to the Instructions for Use. The device must only be operated with tested modular components in accordance with the Otto Bock Mobility System. The manufacturer is not liable for damage caused by component combinations that were not authorized by the manufacturer.

3.7 CE Conformity

The electronic 3C88-2/3C98-2 C-Leg Prosthesis System meets the requirements of the 93/42/EEC guidelines for medical devices. This product has been classified as a class I device according to the classification criteria outlined in appendix IX of the guidelines. The declaration of conformity was therefore created by Otto Bock with sole responsibility according to appendix VII of the guidelines.

The electronic 3C88-2/3C98-2 C-Leg Prosthesis System also meets the requirements of the 1999/5/EC guidelines for radio equipment and telecommunications terminal equipment. Conformity assessment was carried out by Otto Bock according to appendix IV of the guidelines. A copy of the declaration of conformity can be requested from the manufacturer (see back side).

C-Leg Service

USA:	800-328-4058
Canada:	800-665-3327
Great Britain:	1784 744 900