



C-Leg 3C98-2/3C88-2


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INFORMATION

This patient information was last updated on 04/12/2012.

Explanation of Symbols

English

 **WARNING** Warnings regarding possible risks of severe accident or injury.

 **CAUTION** Warnings regarding possible risks of accident or injury.

C-Leg – The Microprocessor-Controlled Knee Joint System from Otto Bock

Dear C-Leg User!

Your lower limb prosthesis includes a high-quality knee joint system that offers you new functional possibilities and increases wearing comfort. To help you get the most from your system, we would like to introduce you to some of its technical features.

INFORMATION

Please follow your prosthetist's directions and read the safety instructions carefully.

The C-Leg is to be used exclusively for the exoprosthetic fitting of amputations of the lower limb.

Safety Instructions

CAUTION

Non-observance of safety instructions. Failure to follow the safety instructions can lead to faulty control or malfunction of the C-Leg and result in risk of injuries.

CAUTION

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

CAUTION

Risk of falling when climbing stairs. On stairs, always use the banister or handrail. When walking down stairs, the prosthetic foot should always be placed on the step so that the heel and posterior half of the foot contact the tread surface; the forefoot may extend beyond the riser to make knee flexion easier.

Stop walking on stairs immediately whenever the sound warning beeps. Make careful tests to verify if the stance phase stabilisation is active (see Section "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

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 you 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).

Your prosthetist is the contact person.

⚠ 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 you to fall.

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

⚠ 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, to loss of function due to structural failure, or to battery or hydraulic damper defects what may result in liquid leakage.

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

The C-Leg has been developed for everyday use and must not be used for unusual activities such as extreme sports (free climbing, paragliding, etc.).

Careful handling of the prosthesis and its components not only increases their service life but, above all, ensures your 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.

⚠ 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 authorised test centre.

Otto Bock recommend 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

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 you 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 damage to the C-Leg. The joint should then be sent to an authorised Otto Bock Service for inspection. Your prosthetist is the contact person.

⚠ 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 you to fall. When walking backwards, secure the joint actively with the residual limb muscles.

⚠ 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 you 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

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 you to fall.

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

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 you 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 joint to switch into the empty battery mode (see Section "Important User Instructions").

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.

CAUTION

Improper switching between modes. An incorrect switch from the 2nd/3rd mode into the 1st mode creates the risk of falling (see Section "Switching between 1st, 2nd and 3rd modes")!

When switching between modes, concentrate on the switching procedure and on the subsequent beep and vibration signals, which confirm that the correct change has been made.

INFORMATION

If you have been using forearm crutches or a cane during the C-Leg fitting, you will generally become more active within a short time. For that reason it is important that the settings are checked and possibly readjusted. A readjustment of the C-Leg settings by your prosthetist is also required if you switch from forearm crutches to a cane or to no walking aid at all.

CAUTION

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

For your own safety, comply with the specified service and inspection intervals (maintenance of operational safety and guaranty). Your prosthetist is the contact person.

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 you to fall.

Only use battery chargers approved by Otto Bock for charging the battery of the C-Leg (also refer to Section "Charging the C-Leg Knee Joint System").

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 you to fall. For information regarding the proper use of the remote control refer to Section "Switching between 1st and 2nd/3rd Mode".

CAUTION

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

CAUTION

Risk of pinching where the joint bends. Ensure that fingers and other body parts are not in this area when bending the joint.

Function

Stance Phase and Swing Phase

The C-Leg is an electronic knee joint system with hydraulic stance and swing phase control.

Biomechanical analyses have led to the creation of an electronically-controlled knee joint which closely matches the swing characteristics of the prosthetic limb to those of the sound limb. The C-Leg immediately adapts to different walking speeds and provides knee stability the moment it is needed. At heel contact you may notice the added hydraulic stance stability. Any unintentional bending of the knee that might occur when walking on uneven terrain, etc. will be prevented. This knee joint makes it easy to comfortably walk downhill or go downstairs with a natural gait, but for your own safety, always use a handrail when walking on stairs.

During every phase of walking, the C-Leg offers you safety, comfort and dynamic response, regardless of your walking style, so you can think about where you're going – instead of thinking about how you'll take the next step. In addition, you can switch the C-Leg to a 2nd/3rd mode, which allows for such activities as cycling (in 2nd mode only), ice skating or inline skating. You'll need to discuss the use of the 2nd and 3rd modes as well as the required settings with your prosthetist.

A new standing mode, which locks the knee in a desired flexion angle, can also be selected with the remote. Switching between 1st and 2nd mode can be accomplished either by using the included remote control or by bouncing on the toe. By quickly bouncing three times on the toe, the leg will change modes and then confirm the change with a beep and vibration signal. You must confirm this immediately by lifting the extended prosthesis. The knee joint will now switch over and signal this through another beep and vibration signal. For your security, the load shift resulting from rocking on the toes, required to initiate the mode switch, must precisely match given guidelines, both in terms of load and time.

You can switch from 1st mode to 3rd mode and vice-versa by bouncing three times **on the heel** in a precisely defined rhythm and with exactly the right amount of pressure. The C-Leg indicates that it has changed mode by beeping and vibrating. You must confirm this immediately by taking the pressure off the prosthesis. The knee joint will now switch to 3rd mode and signal this through another beep and vibration signal.

The load shifts resulting from bouncing on the toes or heel that are required for switching must precisely match given guidelines, both in terms of load and time.

Note: After changing the joint, the C-Leg will always start in the 1st mode, regardless of the last active mode. The remote control cannot be used to switch the C-Leg into 3rd mode.

CAUTION

Risk of falling if mode switching has not been performed. To avoid falling, do not forget to switch back to the 1st mode as soon as you have finished your activities in the 2nd/3rd mode.

Application

Charging the C-Leg Knee Joint System

⚠ CAUTION

Incorrect behaviour while charging the joint. If you walk while the battery charger is connected to the prosthesis, you 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 you to fall.

During charging, keep the C-Leg fully flexed.

INFORMATION

Before using your 4E50-* Battery Charger, make sure your prosthetist has instructed you in its correct use.

INFORMATION

The capacity of a fully charged battery is sufficient for one full day. We recommend charging the battery over night when using the prosthesis on a daily basis.

Charging is only possible at temperatures above 0 °C.



- 1 Bend the C-Leg until it hits the stop.
- 2 Remove the red Protective Plug.
- 3 Connect the 4E50-* Battery Charger and verify the charging status (see following figures).



Both LEDs are off.

No power supply
(or defective charger)



Both LEDs are lit.

Battery is being charged.
Battery capacity is
lower than 50%.



Yellow LED flashes.
Green LED is lit.

Battery is being charged.
Battery capacity is
above 50%.



Yellow LED is off.
Green LED is lit.

Battery is fully charged
(or connection with C-Leg
is interrupted).

Once the joint has been charged successfully, remove the 4E50-* charger.

4 Close plug cover.

Switching between 1st, 2nd and 3rd 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.

Switching between modes can be done with the remote control or through specific movement patterns in the joint. The 2nd and 3rd modes can also be defined and modified by your prosthetist using 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.

CAUTION

Improper use of the remote control. When using the remote control, the functionality of the joint changes. In certain situations, this can cause you to fall.

When using the remote control, you must always stand securely. Then carefully try, whether the desired function has been activated.

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 you to fall.

Any changes or modifications to the device may limit its use.

⚠ 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 you 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. Your prosthetist is the contact person

INFORMATION

Important user information for switching modes and configurations with the remote control!

Deliberately keep the joint and the residual limb still (do not bend or extend!).

The remote control must be activated before switching modes or changing 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/3rd mode, configuration of the standing mode functionality, etc.).

For safety purposes, the working range of the remote control is limited to approximately 70 cm (28 in.). However, the remote control will only function properly if held at least 30 cm (12 in.) away from the joint. If a mode switch was not performed, place the remote between 30 cm and 70 cm (12 in. to 28 in.) of the C-Leg and repeat the command.

Activating 1st Mode



Activation of the remote control:

Press key 3 and keep it pressed (Fig. 1) until the joint confirms the activation with a vibration signal



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, this is the way to switch to the 1st mode.

If the C-Leg is in the 3rd mode, this is the way to switch to the 1st mode.

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

The 1st mode remains turned on until you actively switch to the 2nd or 3rd mode.

Activating 2nd Mode



Activation of the remote control:

Press key 3 and keep it pressed (Fig. 1) until the joint confirms the activation with a vibration signal.



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, this is the way to switch to the 2nd mode

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

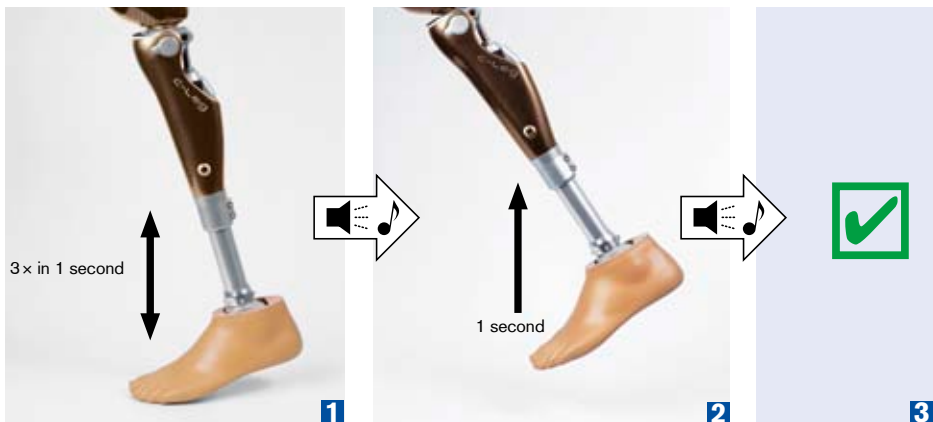
The 2nd mode remains turned on until you actively switch to the 1st mode.

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.

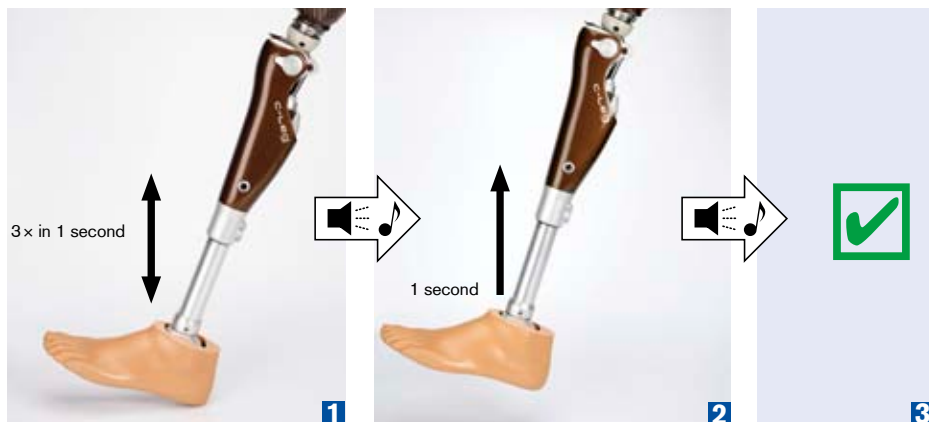
Switching between 1st and 2nd modes without the remote control:



- 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)

Standing Mode Function in the 1st Mode

⚠ CAUTION

Improper configuration of the standing mode functionality. When trying to configure the standing mode while the you are standing, unwanted switching can cause you to fall. Turning the standing mode function on requires that the 1st mode has been activated. For safety purposes, you 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 you 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:

Turning the standing mode function on

Requirement: The knee joint is fully bent.



Activation of the remote control:

Press key 3 and keep it pressed (Fig. 1) until the joint confirms the activation with a vibration signal.

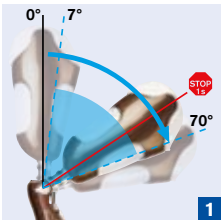


Turning the standing mode function on:

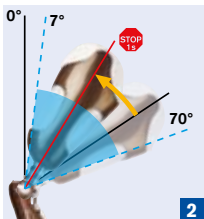
Within 3 seconds after activation of the remote control simultaneously press the keys 1 and 2 (Fig. 2) until the joint confirms turning on of the standing mode with three short beep signals.

Using the standing mode

Adjusting the standing angle



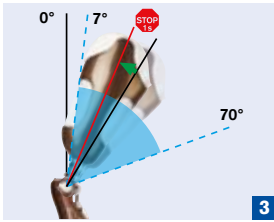
- 1 Flex the joint between 7 – 70° and keep it still for one second (Fig. 1).
- 2 **Slowly extend** the joint up to the desired angle (70 – 7°; Fig. 2).
- 3 In this position, keep the joint still for one second until the C-Leg shortly vibrates.
- 4 The blocked joint can now be fully loaded in the flexion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



INFORMATION

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

Fine tuning of the standing angle (if required)

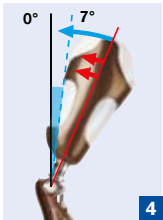


1. To optimize the angle, **very slowly continue to extend** the joint (70 – 7°; Fig. 3).
2. The blocked joint can be fully loaded in the flexion direction.

INFORMATION

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

Unblocking the standing angle







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 “Adjusting the standing angle“ / “Fine tuning of the standing angle“. 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.



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 "Switching Between 1st, 2nd and 3rd Mode").

Optimisation of the Damping Behaviour in the 1st Mode

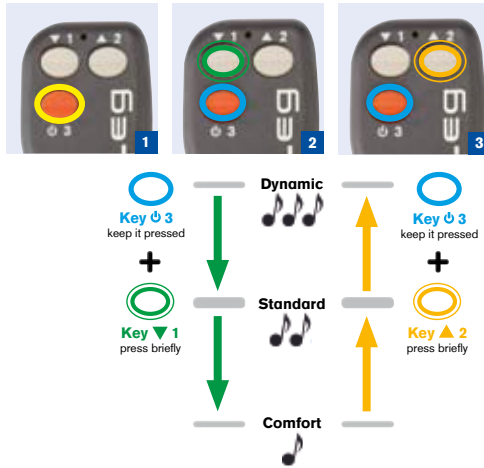
⚠ CAUTION

Risk of falling during optimisation of the damping behaviour. This adaptation changes the damping behaviour of the joint. In certain situations, this can cause you to fall.

You must be standing in a secure position during this procedure.

This functionality enables you to adapt the damping behaviour of the 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 changed slightly 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

Pairing (Connecting the C-Leg to the Remote Control)

⚠ 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 you to fall.

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

ℹ INFORMATION

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

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 / 28 in.).

Performing the Pairing



1. **Distance between the remote control and C-Leg:** Hold the remote control at a distance of 30 to 70 cm (12 in. to 28 in.) 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.

Changing the Battery of the Remote Control

⚠ CAUTION

Impermissible battery replacement 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 you to fall.

The battery of the remote control may only be changed by an authorised Otto Bock Service Centre.

To change a battery outside of the service intervals, send the remote control to an authorised Otto Bock Service. Upon receipt of the remote control with control with a new battery, the remote control must be paired with the C-Leg. Your prosthetist is the contact person.

Important user instructions

Safety Mode

Besides the operation modes (1st, 2nd and 3rd mode) and the standing mode, the C-Leg also has a safety mode. If a critical error occurs in the system, the C-Leg will immediately switch to the safety mode. In that mode, the prosthesis will not easily flex (high safety/reduced comfort). This allows you to walk even though the system is not active.

The switch to the safety mode will be 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 you will fall.

If the C-Leg does not switch to the safety mode (e.g. due to short-circuit due to water penetration), you must actively stabilise the C-Leg at heel strike with your residual limb muscles until a prosthetist can be reached or a prosthesis replacement be accomplished. Immediately contact your prosthetist.

⚠ 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 you to fall.

As soon as the sound and vibration signals go off simultaneously, you 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 you 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.

Safety signal for incorrect connection to the tube adapter

If the tube adapter is somehow disconnected from the C-Leg joint while in operation (i.e. 1st, 2nd/3rd or standing mode with sufficient battery capacity), the C-Leg will emit short beeps and, for approximately five minutes, vibrate with slow, pulsing 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). Safety signal occurs. The safety signal indicates an error of the joint. When in this condition, malfunctions can occur. This can cause you to fall.

⚠ CAUTION

Safety signal occurs. The safety signal indicates an error of the joint. When in this condition, malfunctions can occur. This can cause you to fall. In the event such a safety signal occurs, stop all activities with the C-Leg and have the error resolved by your prosthetist.

Battery capacity

During normal operation in the 1st, 2nd and 3rd modes, the battery capacity is indicated with different vibration signals:

Battery capacity	Vibration impulse
Approx. 1 hour of operation remains	3 ×
Approx. 30 minutes of operation remains	5 ×
Immediately prior to switching into the safety mode	10 ×

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 you 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 you can safely use the "low damping" setting when the empty battery mode is active.

⚠ 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 to fall.

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

You can switch from empty battery mode to operating mode (1st mode) again by charging the knee joint.

Ventilation

Air may accumulate in the hydraulic unit if the C-Leg is not stored in an upright position. If this is the case, the C-Leg may make unusual sounds and offer irregular resistance. An automatic ventilator will void the air and make sure your C-Leg returns to normal after 10 to 20 steps.

Additional Information

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=*).

To ensure proper function and for your own safety, a maintenance service is required every two years. This service includes the inspection 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 observe the service requirements, send in the C-Leg knee joint complete with mounted tube adapter, the remote control, and the complete charging unit including the AC adapter.

Please contact your prosthetist well before the service inspection is due.

Warranty

Otto Bock offers an extensive warranty service on the basis of the C-Leg service and warranty concept. Your prosthetist is the contact person.

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 – 260 V AC
- Operating frequency of the battery charger: 50 Hz – 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 (14 °F to 140 °F)

INFORMATION



This product may not be disposed of with regular domestic 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 information provided by the responsible authorities in your country regarding return and collection processes.

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.

The C-Leg prosthesis system is designed exclusively for use on one patient. Use of the product by a further person is not approved by the manufacturer.

Trademarks

All denotations within this accompanying document are subject to the provisions of the respective applicable trademark laws and the rights of the respective owners, with no restrictions.

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

Should trademarks in this accompanying 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.

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).

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