

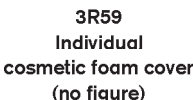
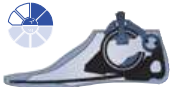


3C98-1/3C88-1

CE

(GB) C-Leg® Knee Joint System

Instructions for Use..... 2

 4R104=60 4R104=75  4R57 4R57=ST  4R41 4R43 4R89  4R111=N 4R111 4R116  4R40  4R118						 757L16-1  4E50-1	
with adjustment pyramid		with threaded connector		4X150			
				 (4X73) 			
3C98-1 C-Leg®		3C88-1 C-Leg®		 4X160=1.2  			
Tube adapter			Tube adapter with torsion unit				
							
2R80			2R81				
 3S26 Cosmetic foam cover (no figure)  3R59 Individual cosmetic foam cover (no figure)							
 4X180 C-Soft  60X3 BionicLink 60X4 BionicLink PC							
 1C40						 1E40	 1E56
 1E57		 1C30		 1D35			
 1A30			 1D10				
 4X78/ 4X79		 4X81		 4X77			
 4X83=430-USB							



These Instructions for Use were updated on June 1, 2006

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Explanation of symbols used in these Instructions for Use



Information:

Important information about the fitting, use, patient instructions and the product.



Attention/Caution:

Warning signal for possible technical damages / Warning signal for possible risk of accident or injury.



Note:

Reference to another instructions for use.

Recommended accessories for prosthetists:

710D4	Torque Wrench	
710Y2=5	Hex Bit	
743L100	LASAR Posture	(647H189 Instructions for Use)
743L200 / 743L300	LASAR Assembly	(647H193 Instructions for Use)
60X3	BionicLink	(647G192 Instructions for Use)
4X180	C-Soft	(647G268 Instructions for Use)

1 Important C-Leg® Information



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 Operational conditions, 1.5 Safety instructions, 2.4 Charging the C-Leg® knee joint system, 2.9 Remote control and switching into 2nd mode, 2.11 Important user instructions, 3.1 Service intervals, 3.3 Technical information, 3.6 Liability

1.1 Medical purpose

The C-Leg® knee joints 3C98-1 and 3C88-1 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 (3C88-1).

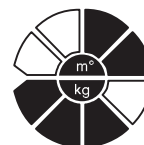
Field of application according to the **Otto Bock MOBIS® Mobility System**:

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

Approved for a **patient weight of up to 125 kg (275 lbs)**.

Exception:

The 2R80=110 Tube Adapter is approved for a patient weight of up to 100 kg (220 lbs).



1.3 Operational conditions



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 a further person 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 Safety instructions



Information:

Advise your patients of the information in this section.



Attention:

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 damages to the C-Leg®.

General Safety Instructions

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.

In the interest of the patient (operational safety and warranty), the C-Leg® should be sent in for maintenance at the specified service intervals.

Do not shorten the tubes as that may damage the integrated strain gauges.

During the data transfer (PC to C-Leg®), the patient must remain still and the BionicLink or the communication cable must not be removed.

Patients who have been using forearm crutches or a cane during the dynamic adjustment of the maximum load generally become more active within a very short time. For that reason it is indispensable to check and possibly readjust the settings. A readjustment of the C-Leg® settings is also required for patients who switch from forearm crutches to a cane or to no walking aid at all.

Any changes or modifications of the device can lead to restrictions of usage. Patients are to be advised about the charging procedure, the proper handling of the remote control as well as the switching into the 2nd mode. The following patient information (pages 6 f.) should be handed to the patient.

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 centers (exchanges are not permissible).

The C-Leg® may only be used with the specified prosthetic feet and must not be used with components from other manufacturers (warranty will become void). (Please see component overview on the folded front page).

Always use the shipping case for transport.

Patient Information

In the case that you commanded an unwanted action with the remote control by mistake (vibration or sound signal), relieve the C-Leg® of any load and rectify the command.

Avoid proximity to strong magnetic and electric interference sources (e.g. transformer stations, high-powered radio or television transmitters) as well as areas with extreme temperatures or humidity.

Do not subject the system components to intensive smoke, dust, or mechanical vibrations or jolts.

Neither solid particles nor liquids should penetrate the system components. Should the joint come into contact with liquid, remove the cosmetic cover and let the components dry. The joint should then be sent to an authorized Otto Bock service for inspection. Your prosthetist is the contact person.

Should the C-Leg® come into contact with salt water, clean it immediately with a cloth moistened with freshwater and let it dry. The joint should then be sent to an authorized Otto Bock service for inspection. Your prosthetist is the contact person.

The C-Leg® has been developed for everyday use 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 the patient's safety. Should the prosthesis be subjected to unusual stress (e.g. a fall), contact your prosthetist immediately and have the prosthesis inspected for any damage. If necessary, the responsible prosthetist will pass the prosthesis on to the Otto Bock Service.

The hydraulic unit may overheat during extended, continuous use (e.g. lengthy downhill walks). In that case, the alarm will repeatedly vibrate to alert you of the risk of overheating. As soon as these vibrations begin, stop all activities and allow the hydraulic unit to cool down. Avoid touching the hot parts! 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 be serviced following a case of overheating.

When walking backwards, always put your heel down first. Putting down the toe first when walking backwards results in the risk of falling, because the C-Leg® can then switch from the high stance phase value to flexion.

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

Stop walking up or down the stairs immediately whenever the sound warning beeps. Make careful tests to verify if the stance phase stabilization is active (see Section "2.11 Important user instructions").

When the C-Leg® is not in use for an extended period of time, the battery may become discharged. We therefore recommend recharging prior to use.

Prior to using the C-Leg® in the 2nd 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 mode with insufficient power supply may cause the joint to switch into the safety mode (see Section "2.11 Important user instructions").

An incorrect switch from the 2nd mode into the 1st mode creates the risk of falling (see Section 2.9 "Remote control and switching into the 2nd mode")!

For your own safety, comply with the specified service and inspection intervals.

Driving a vehicle:

The ability of leg prosthesis users to drive a 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 vehicles. For insurance purposes, drivers should have their driving ability examined and approved by an authorized test center. Otto Bock recommends that the vehicle be professionally retrofitted to the user's individual needs (e.g. automatic shift). Risk-free driving must be ensured even when the prosthesis is not functioning.

Always use the protective plugs.

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

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 onto 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 / 165 lbs	75 kg - 100 kg / 165 lbs - 220 lbs	100 kg - 125 kg / 220 lbs - 275 lbs
		



Caution:

With the 3C98-1 and 3C88-1 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).

- 4 Turn the foot slightly outward (adjustment range $\pm 30^\circ$ to suit the needs of the patient) and pre-fasten the screws lightly at the clamp.

2.2 Bench alignment with the alignment tool (e.g. with LASAR Assembly)

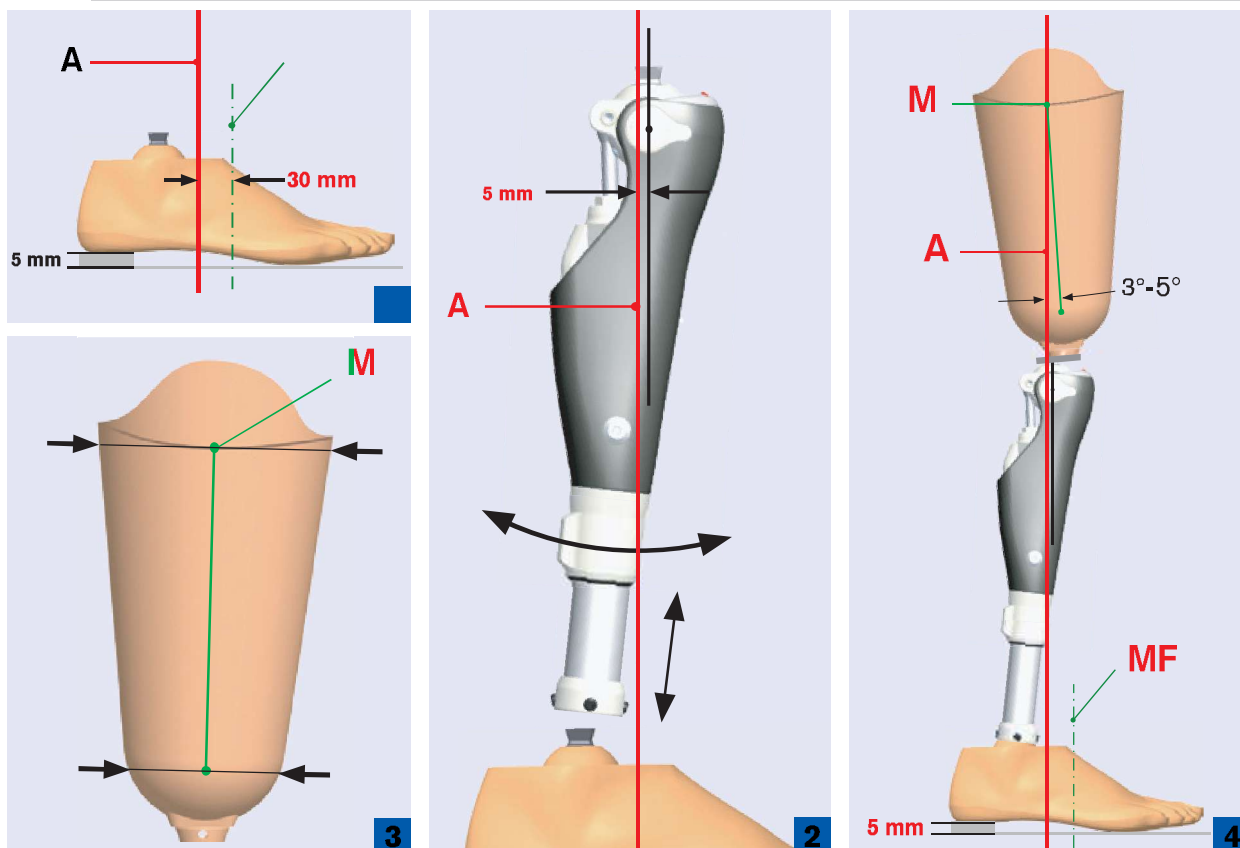


Information:

Proceed with the alignment in two steps:

The prosthesis is first aligned using the alignment tool (e.g. 743L200 LASAR Assembly).

In a second step, the static alignment is optimized with the 743L100 LASAR Posture (see Section 2.5 "Static alignment optimization").



A correct bench alignment (e.g. using the 743L200 LASAR Assembly) ensures that the user can benefit from all the advantages of the C-Leg®. The residual limb position must be considered when positioning the socket connector. Plumb lines in the frontal and sagittal planes (drawn from the hip joint's center of rotation and marked during plaster cast taking and trial fitting of the test socket) will facilitate the correct positioning of the lamination anchor or socket adapter.

- Position the middle of the foot (MF) approx. 30 mm in front of the alignment reference line (A). This applies to all feet that are recommended for the C-Leg®, independently of former specifications in instruction manuals of those feet! (Exception: LuxonMax, anterior placement = 15 mm).
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 alignment reference point (=knee axis) approx. 0-5 mm in front of 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 LASAR Assembly). Recommended positioning of the alignment reference point: 20 mm above the MTP (Fig. 2).
- Connect the foot to the modular knee joint via the tube adapter. To do so, tilt the joint in the correct position and set the required tube length (Fig. 2).
- Mark the center of the socket proximally (M) and distally on the lateral side. Connect both points to a line from the socket brim to the socket end (Fig. 3).
Position the socket so that the alignment reference line (A) meets the central proximal point (M). Set the socket flexion to 3°– 5°, all the while considering the individual situation (e.g. hip joint contractures) and the ischial tuberosity-to-floor distance (Fig. 4).



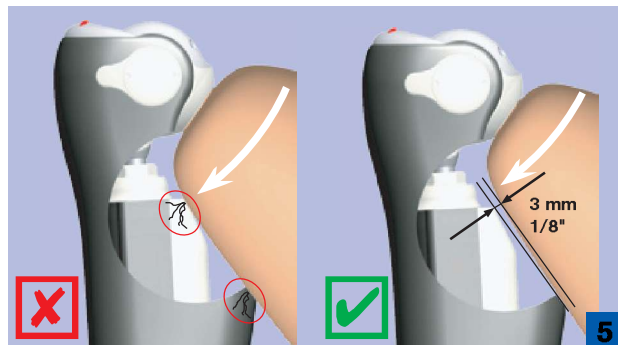
Attention!

If the residual limb flexion is not taken into account, the joint will be positioned too far to the front. That leads to malfunctions and insufficient fitting results.

Connect the socket and modular knee joint via the corresponding adapter (e.g. 4R111, 4R41 Socket Adapter). For alignment correction, use the 4R112 Sliding Adapter (**Attention:** 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.

- Control of the bench alignment and all measurements.

2.2.1 Checking the socket after bench alignment

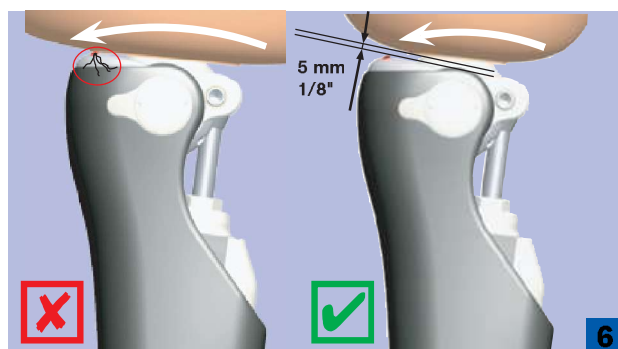


Attention:

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 (for voluminous residual limbs), there must be a flat contact surface between the socket and the C-Leg® frame. Soft cushioning at the socket will assist in getting a flat contact surface.

- 5 At maximum flexion, it is essential that the minimum distance of 3 mm (1/8") is maintained between the hydraulic unit and the socket.



Attention:

The electronic unit may become damaged by contact with the socket!

- 6 At maximum extension (is 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.



Information:

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").

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

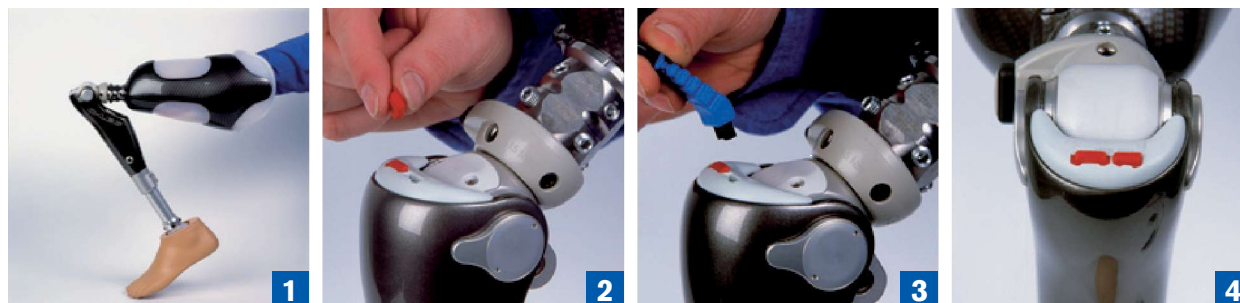
- 4 Lamination anchor with threaded connector: 10 Nm

2.4 Charging the C-Leg® knee joint system



Information:

Advise your patients of the information in this section.



Caution:

Take off the prosthesis prior to charging.

Attention:

During charging, keep the C-Leg® fully flexed.



Note:

Prior to charging with 4E50-1 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 Remove the 4X73 Protective Plug for the C-Leg®.
- 3 Connect the 4E50-1 Charger and verify the charging status (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).

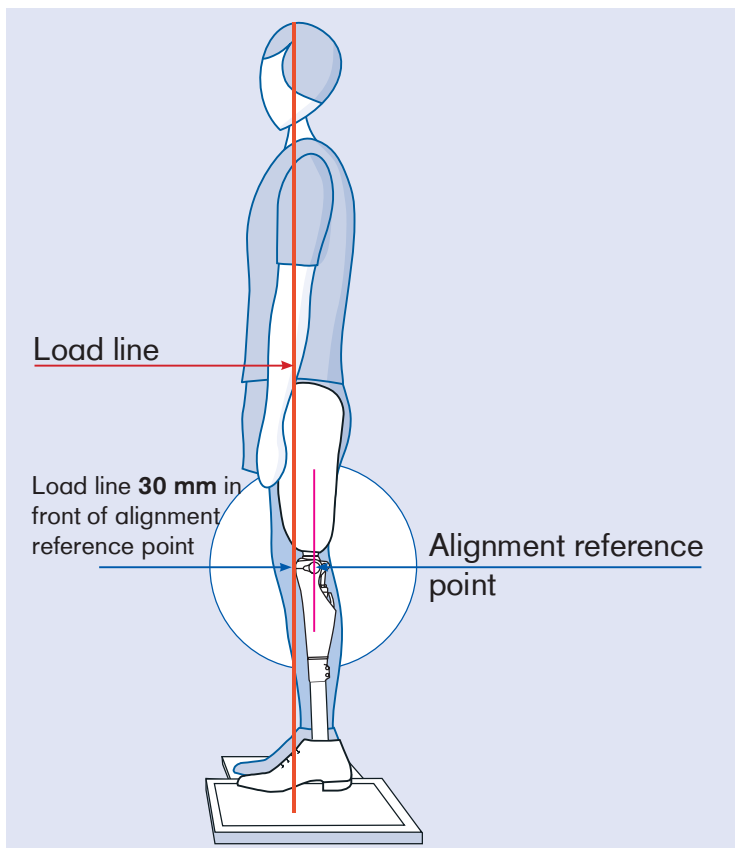
- 4 After charging, remove the charging plug (C-Leg® performs self-test and activates 1st mode) and reattach the protective plug.



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.

2.5 Static alignment optimization (with LASAR Posture)



Static alignment optimization with LASAR Posture (743L100)

The static alignment can be considerably optimized with the help of the LASAR Posture. In order to ensure an appropriate stability and at the same time an easy swing phase initiation, proceed as follows:

- 1 After the self-calibration of the LASAR device, the load line can be measured. For that, the transfemoral amputee steps onto the force sensing plate with the C-Leg® and onto the height compensation plate with the other leg. The prosthesis side must be sufficiently loaded (>35% of body weight).
- 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® (see Section 2.7 "C-Soft") perform dynamic optimizations during trial walking.

2.6 BionicLink/optional: Serial data cable



Note:

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



1



2

- 1 Connect the wireless adapter cable (BionicLink) (optional: connect serial data cable).
- 2 Engage the BionicLink into the C-Leg® and attach it medially (for left fittings) or laterally (for right fittings) at the C-Leg®.

2.7 C-Soft



Note:

- Prior to the parameter adjustment with 4X180=V1.0 C-Soft, read the corresponding 647G268 Instructions for Use.
- Prior to the parameter adjustment with the old Sliders adjustment software, download and read the corresponding instructions for use at www.ottobock.com/en/sliders. The remainder of this section can then be skipped.



Information:

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

2.7.1 C-Soft in the Otto Bock Data Station (back folded page)

Changing the language in the software (optional):

In the menu, select **"Edit - Options"** with the left mouse key. In the next window, select the tab **"language"**. Select the desired language (by selecting the field in front of the language) and confirm with **"OK"**.

I Otto Bock Data Station

1 Selecting or creating a patient file:

- Select the symbol or text for "Company" (Marking 1).

Selecting a patient:

- See point 3

Creating a new patient file:

- In the menu **"File"** select the sub-category **"New patient"**.

2 Entering the patient's name and personal data:

- In the window **"Patient data"** enter all personal data of the patient.
When selecting the field **"Address"**, further patient data appears. All fields marked with an asterisk "*" must be filled out.
Confirm the entry by clicking **"OK"**.

3 Starting C-Soft:

- Select the patient file (patient) with the left mouse button (Marking 2). With **right** mouse button, click on the selected patient, and in the following window, click on **"Start C-Soft"** with the left mouse button.

4 Establishing the connection:

- By clicking on the corresponding tab, select the type of connection (**Bluetooth** or **RS232/ USB**). Then establish the connection by selecting **"Autoconnect"** (Automatic Establishment of Connection).

2.7.2 Otto Bock C-Soft (back folded page)



Information:

The program does not effect any automatic changes to the settings. The adjustment begins following the successful connection establishment with Step 1. The individual steps are explained with text and images.

II Otto Bock C-Soft

A Navigation section:

- All adjustments can be performed in steps (1, 2, etc.). Adjustment steps that are not feasible are highlighted in gray.



Note:

Read the additional information for every new adjustment!

The information can be viewed by clicking on the **"Information"** field (Marking 3).

- Very experienced users can also use the expert mode by clicking on the **"Expert mode"** button.

B Adjustment section:

- All adjustment steps (1, 2, etc.) are explained with text and images. Follow the instructions to adjust the joint.
- You can navigate back and forth between the individual adjustment steps (1, 2, etc.) with the **"Next"** and **"Back"** buttons.

C Status section:

- The status of the connection, battery, as well as knee angle, maximum load, toe load and heel load are dynamically visualized in real time.

2.8 Optional: Parameter settings with foam cover and C-Soft

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

For that purpose, a 4X78 Charger Extension Cable can be integrated in the C-Leg® fitting. If the charger extension cable is not used, a connection cap made of 2 mm Pedilin® allows 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 behavior. With the 60X3 BionicLink (wireless programming interface), which is attached below the pre-shaped foam block, the damping behavior can be completely taken into account by adapting the parameter settings.

That process furthermore requires the 60X4 BionicLink PC for the data transfer and the 4X180 C-Soft for the parameter adjustment (see Section "2.7 C-Soft").

2.9 Remote control and switching into 2nd mode



Information:

Advise your patients of the information in this section.

For normal operation, the C-Leg® can be used in the 1st mode (optional with standing mode) and in the 2nd mode. The 1st mode is for daily use while the 2nd mode allows to individually pre-program a specific type of movement or position (e.g. cycling, inline skating, or jogging). The 2nd mode can be set and adapted with the 4X180=V1.0 C-Soft adjustment software (or the Slider adjustment software).



Attention:

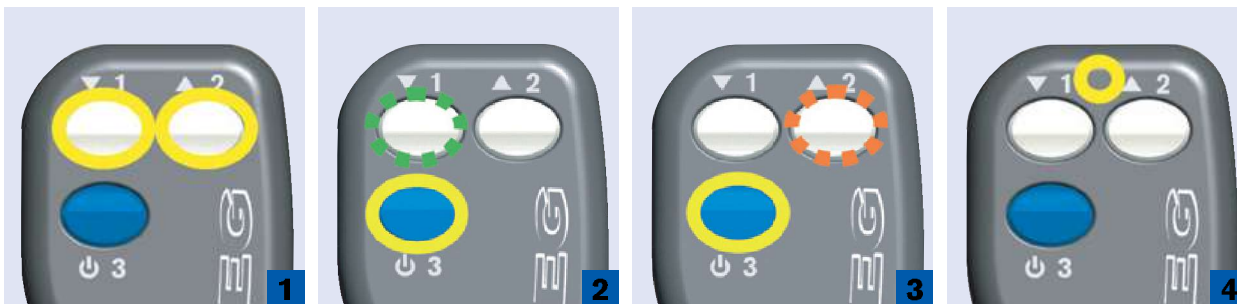
- The patient must stand securely when performing any switch and must test with caution whether the desired function was successfully set by the C-Leg®.
- The remote control is not waterproof. If water penetrates the remote control, the device may become damaged (warranty will become void). The device should then be dried at room temperature for at least 1 day. If defective, the remote control should be sent to an authorized Otto Bock Service.



Important user information for switches and configurations:

- Deliberately maintain the joint and the residual limb still (no bending or extending!).
- The remote control must be activated prior to any switches or configurations.
- The remote control turns off automatically after prolonged non-use. For safety purposes, the switch will only be possible a few seconds following the activation.
- For safety purposes, the working range of the remote control is limited to approximately 100 cm. However, the remote control will only function properly if held at least 30 cm away from the joint. If the switch was not performed, ensure that the remote control is placed within the right distance range of the C-Leg® and repeat the command.

2.9.1 Switching modes with the remote control



Information:

The configuration is only possible with an active 1st mode.

1 Configuration of the standing mode:



Attention:

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.

After the activation of the remote control, operate the keys "1" and "2" simultaneously until the joint confirms

- the activation of the functionality with three short beeps
- the deactivation of the functionality with one short beep

2, 3 Optimization of the damping behavior:



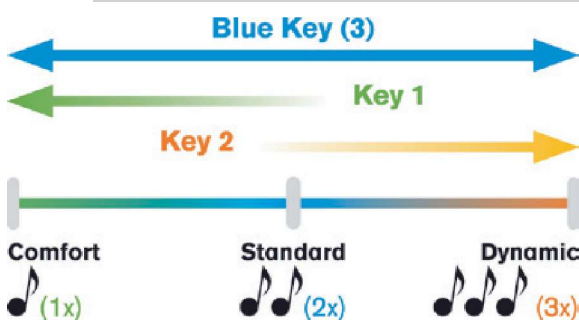
Information:

This functionality is not intended for joint adjustment by the prosthetist, who should adjust the joint by means of the C-Soft (Slider) adjustment software. Rather, this functionality is designed so that the patient can adapt the damping behavior slightly during everyday use (e.g. when getting used to the prosthesis or for a changed gait pattern). For safety purposes, the damping behavior can only be slightly changed with the remote control. Changes to the damping behavior which were effected with the remote control are not displayed by the C-Soft (Slider).



Attention:

The patient must stand very securely during this procedure.



After activation of the remote control, the selection steps Comfort - Standard - Dynamic must be set by pressing key 3 in combination with keys 1 or 2.

The successful setting of the damping parameters is confirmed acoustically with the following beep signals:

Comfort = 1x beep signal

Standard = 2x beep signals

Dynamic = 3x beep signals

4 Pairing (Connecting the C-Leg® to the remote control):

Pairing does not have to be performed upon delivery. Pairing must be 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 a fully charged battery of both the joint and the remote control within the working range of the remote control (1 m).

Execution:



Attention:

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.

Briefly press the start button by reaching with a thin object (e.g. a paper clip) through the small hole of the remote control. The joint will confirm the successful pairing with 5 short beep signals.

2.9.3 Changing the battery of the remote control

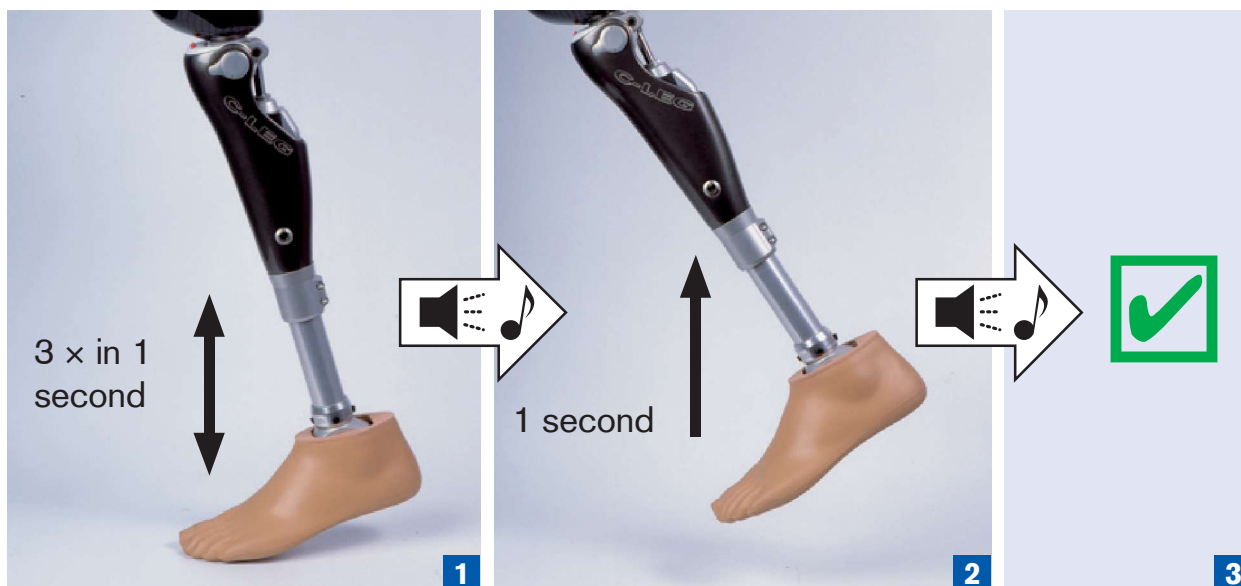


Attention:

The battery of the remote control may only be changed by an authorized Otto Bock Service. The battery is automatically replaced at the biennial service intervals (see 646A140 C-Leg® Warranty Concept).

To change a battery outside of the biennial service intervals, send the remote control to an authorized 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 2.9.2).

2.9.4 Optional: Switching between 1st mode and 2nd mode without the remote control



- 1 Rock up and down on the forefoot while maintaining continuous ground contact and a speed of at least 3 rocking movements per second (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).
- 2 Once the acoustic signal beeps, lift the prosthesis for at least one second (no ground contact).
- 3 With further sound signals, the prosthesis acknowledges receipt of the switch command and switches to the other mode (1st mode = 1 beep signal or 2nd mode = 2 beep signals).

2.10 Finalizing 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 need be).
- 2 Secure all screws required for the prosthesis alignment (see Section 2.3) with 636K13 Loctite.
- 3 Fasten all screws to the right torque (see Section 2.3) with the 710D4 Torque Wrench.
- 4 Optional: Apply the cosmetic foam cover or the 4X160 C-Leg® Protector.

2.11 Important user instructions



Information:

Advise your patients of the information in this section.

Safety mode

Aside from the operation modes (1st and 2nd mode), the C-Leg® has a safety mode. As soon as a critical error occurs in the system or when the battery is almost empty, the C-Leg® automatically switches to the safety mode. In that mode, the prosthesis activates a high flexion damping (high safety/reduced comfort), which enables the patient to walk safely despite a non-active system.

The switch to the safety mode is announced immediately prior to the switch with sound and vibration signals. If the safety mode was prompted by an empty battery, recharge the battery. The joint will then switch back automatically to the operation mode (1st mode).



Caution:

Non-active safety mode!

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.

Safety mode is activated!

As soon as the sound and vibration signals go off simultaneously, the patient must stop all activities with the leg prosthesis. After approximately 10 seconds, the patient must check if the safety mode is activated with the high flexion damping in a safe standing position with repeated slight bending of the C-Leg® and under controlled weight bearing.

Safety mode cannot be deactivated!

If the safety mode could not be deactivated by recharging the battery, an error has occurred. Contact your prosthetist for troubleshooting.

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

Safety signal for incorrect connection to the tube adapter

As soon as the tube adapter has no connection when the C-Leg® is in operation (i.e. 1st, 2nd 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® activates the stance phase damping, which it maintains until the connection of the tube adapter is properly reset (provided the battery capacity remains sufficient).



Caution:

In the case of such a safety warning, stop any operation of the C-Leg® and resolve the error by properly connecting the tube adapter (by the prosthetist or 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.

Ventilation

After extended non-vertical storage of the C-Leg®, air may accumulate in the hydraulic unit. This is noticeable through sounds and irregular damping behavior.

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

To ensure proper function and the safety of the patients, a maintenance service is required every two years. This service includes the inspection of the sensors and the replacement of worn parts.

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

Operating and storage temperature range	0 °C to + 60 °C
Weight of the joint	1145 g
Weight of the 2R80 Tube Adapter	178 g - 256 g
Weight of the 2R81 Tube Adapter	438 g - 482 g
Max. flexion angle	125°
Operating voltage of the battery charger:	90 V - 264 V AC
Operating frequency of the battery charger:	47 Hz - 63 Hz

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.

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).



Type BF Applied Part

3.4 Transport

Always use the **X-3C100 Shipping Case** when transporting your electronic joint system and the 3C88=S/3C98=S Service Joint.

3.5 Warranty

Otto Bock offers an extensive warranty service on the basis of the current C-Leg[®] warranty concept (see 646D130). 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 Declaration of Conformity

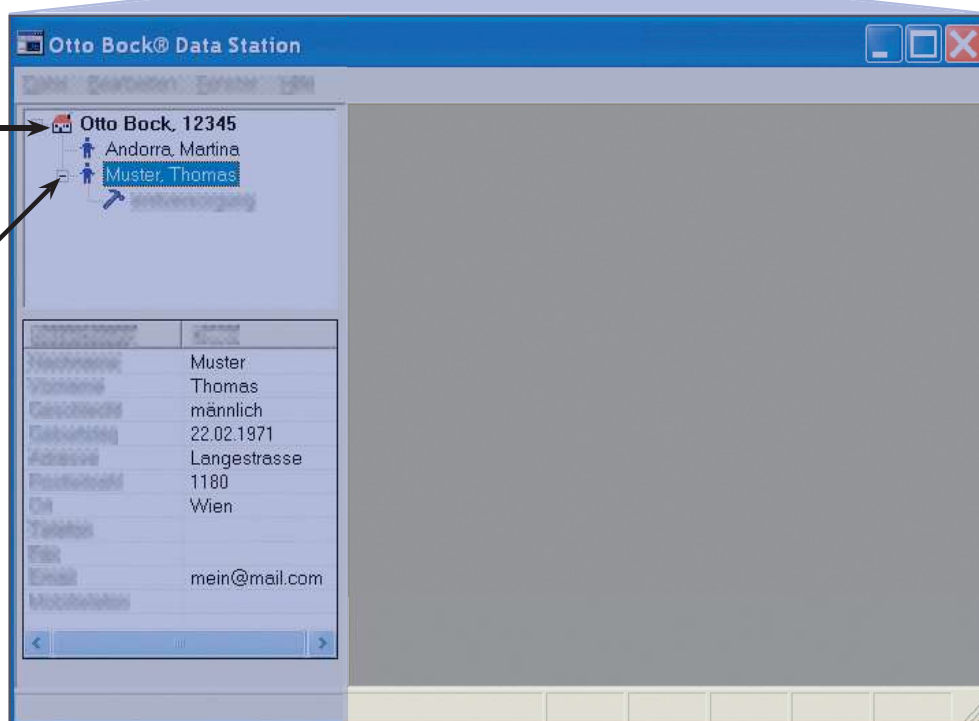
Otto Bock Healthcare Products GmbH herewith declares that the electronic 3C88-1/ 3C98-1 C-Leg® Knee Joint System complies with the basic requirements and the respective provisions of the directives 1999/5/EC and 93/42/EEC. A copy of the declaration of conformity can be requested from the manufacturer (see back side of the Instructions for Use).

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

I

1

2



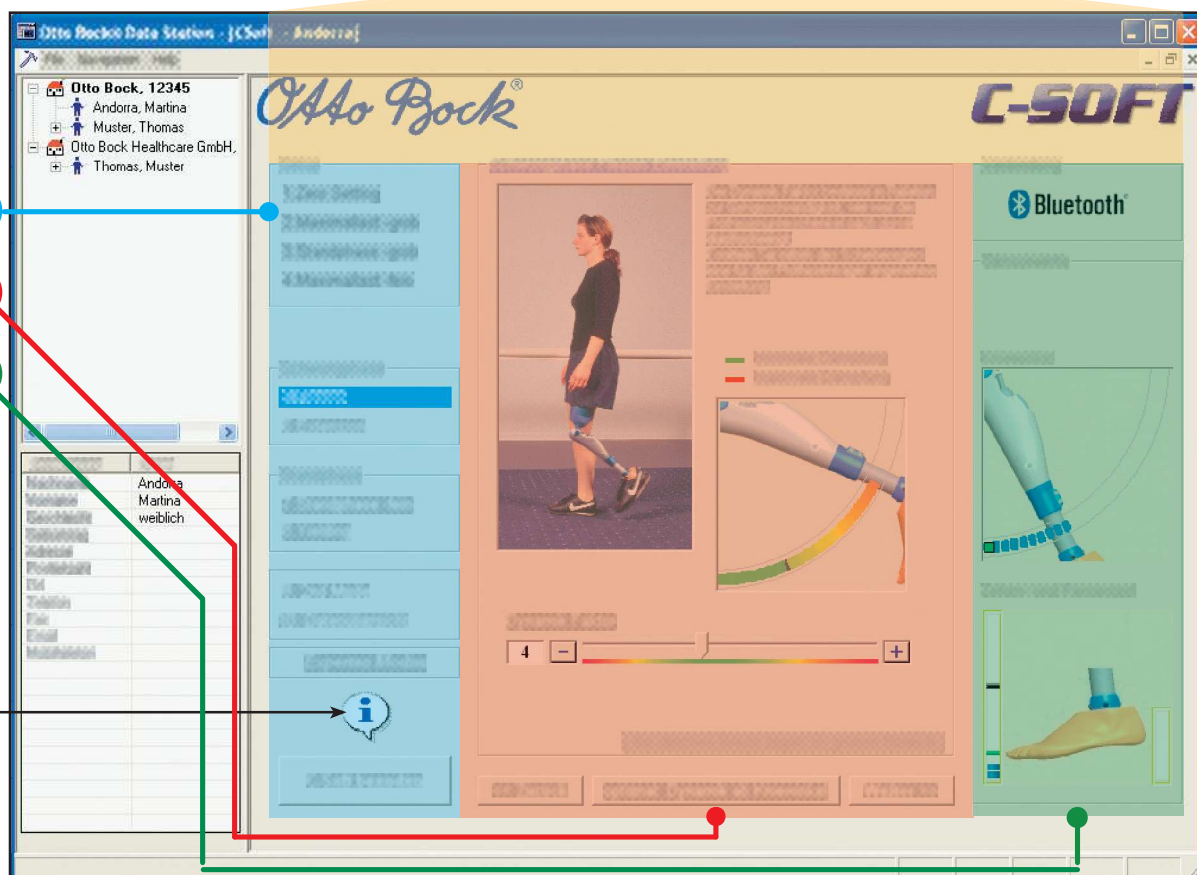
II

A

B

C

3





FCC-Statement:

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- 1) This device may not cause harmful interference, and
- 2) this device must accept any interference received, including interference that may cause undesired operation. This device and its antenna must not be co-located or operating in conjunction with any other antenna or transmitter. Modifications not expressly approved by Otto Bock could void the user's authority to operate the equipment.

Note:

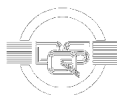
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/ TV technician for help.

Patents:

European Patent No. 0 549 855 (B, D, GB, F, I, L, NL, A, P, S, CH, E),
patented in Canada 1991 No. 2 057 108, patented in Russia No. 2 089 138, R.O.C.
Invention Patent No. 076 088,
patented in Japan No. 3 131 933, patented in Korea No. 176 977

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Otto Bock has been certified by the German Society for the Certification of Quality Assurance Systems (DQS) in accordance with DIN EN ISO 9001, Reg. No. 779 (Management System).