



Genium – Bionic Prosthetic System

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INFORMATION

This patient information was last updated on 04.05.2012.

Explanation of symbols

⚠ DANGER Warnings regarding directly impending risks of severe accident or injury.

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

⚠ CAUTION Warnings regarding possible risks of accident or injury.

NOTICE Warnings regarding possible technical damage.

Application

INFORMATION

Before using the 3B1/3B1=ST knee joint, please read these instructions for use thoroughly! Please follow your prosthetist's directions and observe the safety instructions carefully.

The 3B1 / 3B1=ST knee joint is intended **exclusively** for exoprosthetic fittings of the lower extremities.

Conditions of Use

The 3B1 / 3B1=ST knee joint was developed for activities of daily life but not for extreme sports such as free climbing, skydiving, paragliding, etc. Please see the *Technical Information* section for the permissible environmental conditions. The 3B1 / 3B1=ST knee joint is intended exclusively for fittings of amputees or dysmelia patients. Use of the product by other persons is not approved by the manufacturer.

Function

The 3B1 / 3B1=ST knee joint is an electronic knee joint system with hydraulic stance and swing phase control. It is controlled by a microprocessor-based hydraulic system that dynamically adapts the system in real time. The control mechanism works in conjunction with a sensor system. The sensors collect measurements every 0.01 seconds (corresponds to 100 Hz). Through the evaluation of the measurements, the 3B1 / 3B1=ST knee joint recognises which phase of gait the user is in.

Safety Instructions

⚠ CAUTION

Non-observance of safety instructions. Failure to follow the safety instructions below can lead to control errors or malfunction of the 3B1/3B1=ST knee joint and result in risk of injuries for the patient as well as damage to the knee joint.

⚠ CAUTION

Use of unsuitable prosthetic components. If unsuitable prosthetic components are installed in the prosthesis, malfunction of the knee joint and a loss of functionality due to structural failure may occur. This can cause you to fall.

The 3B1/3B1=ST knee joint may only be combined with adapters and feet approved by Ottobock.

Ottobock assumes no liability if the 3B1/3B1=ST knee joint is used with prosthetic feet other than those specified.

⚠ CAUTION

Manipulation of system components. Independent changes and/ or modifications of system components may lead to malfunction of the knee joint and a loss of functionality due to structural failure. This can cause you to fall.

- Any changes or modifications to the knee joint may limit its usability.
- Opening and repairing of the knee joint may only be performed by authorised Ottobock personnel and the handling of the battery may only be carried out by Ottobock Service Centres (independent replacement is not permitted). Please contact your prosthetist if you have any service questions.

⚠ CAUTION

Improper use of the Remote Control. Improper use may damage the Remote Control. This can lead to malfunction of the Remote Control and result in unexpected actions of the knee joint. This can cause you to fall.

Please observe the information on the proper use of the Remote Control in the Remote Control *section*.

⚠ CAUTION

Transport damage. Mechanical impacts or stress during transportation of the knee joint, such as shocks and vibrations, can lead to:

- Defects and resulting malfunctions of the knee joint.
- Battery and hydraulic unit damage resulting in leaks.
- Loss of functionality due to structural failure.

This can cause you to fall and/ or result in skin irritation.

For the purpose of transportation, use the packaging in which the knee joint was delivered.

⚠ CAUTION

Magnetic interference. The knee joint can malfunction when near high-tension power lines, transmitters, transformers, computer tomography equipment 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 sources of magnetic and electric interference (e.g. transformer stations, transmitters).

⚠ CAUTION

Thermal overloading. Extended exposure to high temperatures can lead to defects and result in malfunctions of the knee joint with a loss of functionality due to structural failure. This can cause you to fall.

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

⚠ CAUTION

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

- Short circuits in the electronics and battery, resulting in malfunction of the knee joint.
- Defects of the battery and the hydraulic unit, resulting in leaks.
- Loss of functionality due to structural failure.

This can cause you to fall and / or 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, resulting in malfunctions of the knee joint.
- Hydraulic unit defects with an associated leakage of fluid or a loss of functionality due to structural failure. This may cause the patient to fall and/or result in skin irritation.
- Ensure that neither solid particles nor liquids can penetrate the system components.
- The knee joint and the AXON tube adapter are protected against splashed water from all directions.
- The knee joint and the AXON tube adapter are not protected against submersion, jets of water and steam.
- If water has penetrated electronic system components, remove the cosmetic cover and allow the components to dry. The knee joint must then be sent to an authorised Ottobock Service Centre for inspection. Your prosthetist is the contact person.
- If the knee joint comes into contact with salt water, clean it immediately with a cloth moistened with freshwater and let it dry. The knee joint must then be sent to an authorised Ottobock Service Centre for inspection. Your prosthetist is the contact person.

⚠ CAUTION

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

- Defects and resulting malfunctions of the knee joint
- Loss of functionality due to structural failure
- Defects of the battery and the hydraulic unit, resulting in leaks

This can cause you to fall and / or result in skin irritation.

The 3B1/3B1=ST knee joint was 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 personal safety. Should the prosthesis be subjected to extreme strain (e.g. by falling or similar), it must be inspected for possible damage by a prosthetist immediately. If necessary, the responsible prosthetist will pass the prosthesis on to Ottobock Service.

⚠ CAUTION

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

- Overheating of the hydraulic unit resulting in malfunction of the knee joint
- Defects of the hydraulic unit resulting in leakage of liquid

This can cause you to fall and / or result in skin irritation. Touching overheated components can also cause burns.

Please take note of pulsating vibration signals. They indicate the risk of overheating. As soon as these pulsating vibrations begin, stop all activities and allow the hydraulic unit to cool down. You may resume your activities once the pulsating vibration signals stop.

If activities are continued despite the pulsating vibration signals, there is the risk of overheating the hydraulic element and, in extreme cases, of damage to the 3B1/3B1=ST knee joint. The knee joint should then be sent to an authorised Ottobock Service Centre for inspection. Please contact your prosthetist with any service questions.

⚠ CAUTION

Risk of falling when walking down stairs.

- When walking down stairs, 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.
- If the audible signal sounds, stop descending immediately and check whether stance phase control is active (see Section „Important Information for Users“).
- Observe the vibration signals and audible warning signals (beeps) of the 3B1/3B1=ST knee joint.
- Special caution is required when walking down stairs while carrying children.

⚠ CAUTION

Improper switching between MyModes. Incorrectly switching from MyModes into basic mode or vice versa results in a risk of falling (see the section *MyModeSwitching with the Remote Control*)!

- After switching to one of the MyModes, check the functions since you may have accidentally activated a different MyMode than you intended (see the section „MyMode Switching without the Remote Control“ and the section „MyMode Switching with the Remote Control“)
- Ensure that you switch back to basic mode once your activities in the MyMode have ended.

⚠ CAUTION

MyMode Switching with the Remote Control. You can use the Remote Control to initiate various actions which cause the damping behaviour of the knee joint to change. In certain situations, this can cause you to fall.

If an unintended action was accidentally initiated using the Remote Control (feedback in the form of a vibration or audible signal), take your weight off the 3B1/3B1=ST knee joint and switch back to the intended mode.

⚠ CAUTION

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

For your own safety, comply with the specified service and inspection intervals (maintaining operational safety and protecting the warranty). Please contact your prosthetist with any service questions.

⚠ WARNING

Risk of accidents when operating a motor vehicle. The ability of leg prosthesis wearers to operate a motor vehicle is determined on a case-by-case basis. Criteria include the type of fitting (amputation height, unilateral or bilateral, residual limb conditions, design of the prosthesis) and the individual abilities of the leg prosthesis wearer. Ensure you observe the applicable national laws for the operation of motor vehicles and have your driving ability examined and certified by an authorised agency for insurance purposes. In general, Ottobock recommends that vehicles should be professionally retrofitted to meet each user's individual needs (e. g. automatic transmission).

Risk-free driving must be ensured even when the leg prosthesis is not functioning.

⚠ CAUTION

Malfunction of the knee joint. Malfunctions of the knee joint can cause you to fall.

Observe the vibration signals and audible warnings (beeps) of the 3B1/3B1=ST knee joint.

⚠ CAUTION

Non-active safety mode. If safety mode can no longer be activated, there is a risk of falling. If the 3B1/3B1=ST knee joint is no longer able to select safety mode (e.g. in case of short circuit caused by water penetration), the knee joint may have to be actively secured upon heel impact using the residual limb musculature until reaching a prosthetist or replacing the prosthesis. In this case, the prosthetist must be contacted promptly.

⚠ CAUTION

Risk of pinching in the flexion range area of the joint. Keep fingers / body parts away from this area when flexing the joint.

INFORMATION



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.

Charging the 3B1/3B1=ST Knee Joint

INFORMATION

Charging the battery is only possible at temperatures over 0 °C.

Fully charging the battery in the knee joint takes approx. 6 - 8 hours. The better the connection between the charger and receiver on the knee joint (not interrupted e.g. by a sock), the shorter the charging time.



1. Connect the power cord to the charger with the correct polarity (Figure 1).

2. Start the inductive charging process by connecting the charger to the receiver on the back of the knee joint. The charger is held in place by a magnet (Figure 2a/2b). Verify the battery capacity using the LEDs on the side (Figure 3) and the charging process based on the colour of the illuminated ring (Figure 2b) (see tables below).



3. End the inductive charging process by disconnecting the charger from the receiver. The 3B1/3B1=ST knee joint performs a self-test and is then ready for operation, provided it is connected to the AXON Tube Adapter. This is indicated by a single vibration signal and beep. If this is not the case, an error has occurred. In that case please send the knee joint to your prosthetist or an authorised Ottobock Service Centre.




INFORMATION
 After disconnecting the charger the knee joint will conduct a self test. Be sure not to move the knee joint during this brief self test, since it can cause an error. If you encounter this error, the problem can be corrected by reconnecting and then disconnecting the charger.



INFORMATION
 Charging is not possible if the distance between the transmitter and receiver is greater than 1.5 mm. However, charging should proceed normally if, for example, a sock or Superskin is between the transmitter and receiver of the charger (also see the Charging Process table).

Battery capacity indicator on the battery charger (Figure. 3):

LEDs	0	1	2	3	4	5
Battery capacity	0 – 10 %	10 – 30 %	30 – 50 %	50 – 70 %	70 – 90 %	> 90 %

Charging Process Table

Status	Status LED	Battery capacity indicator
The power supply is connected, but the charger is not attached to the knee joint	 Continuous green	All five LEDs off
Charger connected to knee joint, good connection	 Purple pulsing (4-second cycle) *	Display of the battery capacity (green) according to the number of illuminated LEDs
Charger connected to knee joint, bad connection	 Weak purple *	Display of the battery capacity (green) according to the number of illuminated LEDs

<p>a) Charger excess temperature b) Joint excess / insufficient temperature c) Connection may be improved by reducing the distance between the charger and receiver</p>	 <p>Continuous yellow. The joint is not charged.</p>	<p>a) 2nd and 4th LED illuminated a) 1st, 3rd and 5th LED illuminated c) 3rd LED illuminated (see the section <i>Charging the 3B1/3B1=ST Knee Joint</i>, Figure 3)</p>
<p>Charger fault (error correction by disconnecting and reconnecting the power supply may be possible)</p>	 <p>Flashing red. The joint is not charged.</p>	<p>LEDs indicate an error code.</p>

* This display turns off automatically after approx. one minute to avoid bothersome light at night. The charging process is not affected.

The charging status of the knee joint is also shown on the display of the remote control.

In addition, the remaining operating time is indicated to the user by knee joint vibration signals once the remaining battery capacity reaches approx. 25% (see table below).

Knee Joint Vibration Signal	Battery Capacity	Remaining Operating Time
3x vibration	25 %	approx. 24 hours
5x vibration	10 %	approx. 6 hours
10x vibration and beeping	5 %	0 hours

INFORMATION

When the knee joint is fully charged (all 5 LEDs at the side light up (Fig. 3)), the maximum period of use for the knee joint before the next charging process is up to 5 days, depending on patient activity. However, we recommend charging the knee joint every night.

Sitting function

When a sitting position is maintained for more than two seconds (i.e. the thigh is close to horizontal and there is no load on the leg), the 3B1/3B1=ST Knee Joint switches the resistance to a minimum in both the flexion and extension directions. The sitting function can be activated by the prosthetist by using the X-Soft adjustment software.

INFORMATION

While sitting, the knee joint switches to an energy-saving mode. This energy-saving mode is activated regardless of whether the Sitting function has been enabled or not.

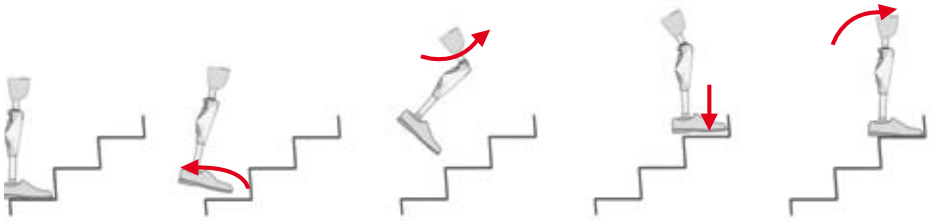
Intuitive Stance function

The Intuitive Stance function automatically recognises any situation that puts strain on the prosthesis in the flexion direction but where flexion is not permitted. Examples where this is the case include standing on uneven or sloping surfaces. The joint is always locked in the flexion direction when the prosthetic leg is not fully extended, under some amount of load and at rest.

When the load is taken off the leg or upon forward or backward rollover, the level of resistance is immediately reduced to stance phase resistance again. The knee joint is not locked when the above conditions are met and a sitting position is assumed (for example while driving). The Intuitive Stance function can be activated by the prosthetist by using the X-Soft configuration software.

Stairs and Obstacles function

Negotiating stairs step-over-step:



Although the 3B1/3B1=ST is a passive knee joint, which means it cannot actively initiate movements, negotiating stairs step-over-step is possible.

In order to do so, the prosthetic foot has to be placed on the next higher step first with the knee flexed. Then the hip is extended, which also extends the knee. This requires a sufficiently secure hold in the socket and a certain level of residual limb strength. During physiological stair climbing, knee flexion is accomplished by actively raising the lower part of the leg. With 3B1/3B1=ST knee joint, knee flexion can be achieved via the mass inertia of the lower part of the leg. Immediately after lifting the extended leg off the floor, simultaneously extend the hip briefly and then abruptly flex it. This whip action flexes the knee. The 3B1/3B1=ST knee joint recognises this movement sequence and sets flexion resistance to minimum. Without activation of this mode - i.e. with stance phase resistance - knee flexion would be limited and unpleasant pressure would be felt on the residual limb. The movement pattern is very similar to the physiological process if the toes extend below the next higher step at the beginning of the cycle. Here, too, the heel has to be pulled back first. Practice the “toes under the step” movement pattern with the sound side and with the prosthesis; then the complete movement pattern is intuitive and easy to learn.

When sufficient knee flexion has been achieved, the 3B1/3B1=ST Knee Joint increases extension resistance so that there is enough time to position the foot on the next step before the knee joint is extended again. The supporting area for the foot on the step has to be sufficient so that the heel does not extend back too far over the edge. With too little support area, the lower leg would extend too early and position the leg too far backwards. In this phase, the 3B1/3B1=ST Knee Joint has already maximised the flexion resistance (that is, further flexion is blocked). The knee joint can no longer be flexed but only extended. This ensures that the leg does not buckle if the hip strength is not sufficient for the extending motion.

Support yourself with your hand on the contralateral side. A smooth wall is also sufficient for this purpose. This lateral support is intended to prevent the residual limb from twisting in the socket. Twisting can lead to unpleasant surface tension between the skin and the socket. Lateral support also improves your balance.

When the knee joint is fully extended, the initial position has been reached. You can climb the next step or continue walking normally.

Crossing obstacles:

The stairs and obstacles function can be used to cross obstacles. Instead of achieving the required ground clearance of the prosthetic foot through lateral abduction of the extended leg, the whip action described above can be used. This is also possible from the walking motion.

Take the weight off the prosthetic leg when the knee joint is extended and then perform the whip motion, which switches the 3B1/3B1=ST Knee Joint to the stair and obstacle function. This delays the extension movement, giving enough time and ground clearance to step over an obstacle.

The prosthetic leg will not be fully extended upon heel impact. An active knee joint would be required to achieve this. Since the knee joint is locked in the flexion direction during this phase, putting weight on it does not pose a hazard. You can then resume walking normally. The stairs and obstacles function can be activated by the prosthetist using the X-Soft configuration software.

Optimized Physiological Gait (OPG) function

OPG minimizes the Genium user's prosthetic deviations and promotes a more biomechanically correct gait pattern. There are no initiation or exit strategies that apply to OPG - it simply happens during the course of normal walking. Selection of this function enables the following features: (1) PreFlex (2) Adaptive Yielding Control (3) Dynamic Stability Control (DSC) (4) Stance Release on Ramps, and (5) Adaptive Swing Phase Control. Adaptive Swing Phase Control and DSC are enabled even if OPG is not selected on the functions tab.

OPG FEATURES

(1) PreFlex

PreFlex ensures the knee is in four degrees of flexion at the end of swing phase in preparation for loading response. PreFlex allows users to walk with natural stance flexion independent of gait speed. The prosthetic foot will also reach foot flat more quickly to promote stability especially on uneven surfaces when PreFlex is present. PreFlex also allows users to ascend ramps in a more anatomically correct way by reducing the need for users to vault over a fully extended knee.

(2) Adaptive Yielding Control

The knee has an intelligent, auto adaptive control of stance flexion (max 17°) and extension movements, depending on the forces affecting the knee system. The varying stance flexion resistance experienced by the user is e.g. dependent on the behavior of the user, the surface condition and the angle of a slope or incline.

(3) Dynamic Stability Control (DSC)

DSC ensures the knee will not release stance resistance during biomechanically unstable static and dynamic conditions. Constantly checking multiple parameters, DSC ensures the optimally timed decision for the knee to safely switch from stance to swing. Because DSC is always monitoring knee function, multidirectional movement and walking backward are also possible without risk of stance resistance releasing.

(4) Stance Release on Ramps

Although flexed and partially loaded - the knee will release stance on hills and ramps to allow for greater knee flexion, improved swing phase clearance, and less hip flexion force needed to bring the shank into extension.

(5) Adaptive Swing Phase Control

Instantaneous adaptation to varied walking cadences and to changes of the pendular mass (i.g. varying footgear) ensures the knee always achieves the swing flexion target angle within (+/-) one degree. The swing extension and flexion resistance experienced by the user is autoadaptive.

Enabling the OPG function:

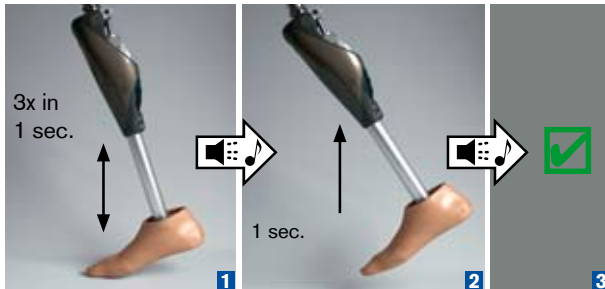
Enable the OPG function by selecting the corresponding checkbox. When this function is activated, both stance phase extension and swing phase extension are adjusted automatically. This means that the configurations in these areas are not necessary and the corresponding slider bars in the Swing phase and Stance phase tabs of the adjustment software are deactivated.

INFORMATION

Your prosthetist can activate these MyModes using the X-Soft configuration software.

MyMode Switching without the Remote Control

If switching by bouncing was activated in the X-Soft configuration software, switching into the first MyMode without the Remote Control is accomplished by bouncing on the forefoot at least three times within one second while maintaining ground contact and keeping the prosthetic leg extended. In doing so, the forefoot has to bear approx. 40 % of the total body weight at peak load and less than approx. 25 % of the body weight at the lowest load. However, the load may not be taken off the foot fully.



After the audible signal is emitted (one long beep), your weight needs to be taken off the prosthesis entirely for at least one second with the knee extended (no ground contact). The 3B1/3B1=ST knee joint then switches to the first MyMode and emits two short beeps.

The procedure for switching to the second MyMode is similar, but by bouncing four times. In this case, the switch is indicated by three short beeps.

Returning to basic mode from any MyMode is accomplished by bouncing at least three times. The switch is confirmed by a short beep.

If bouncing three times is activated but bouncing four times is not, any number of bounces greater than or equal to 3 switches to the first MyMode.

CAUTION

Improper MyMode switching. Incorrectly switching from MyModes into basic mode results in a risk of falling (see the section *MyMode Switching with the Remote Control*)!

- After switching to one of the MyModes, check the functions since you may have accidentally activated a different MyMode than you intended (see the sections *MyMode Switching without the Remote Control* and *MyMode Switching with the Remote Control*).
- Ensure that you switch back to basic mode once your activities in the MyMode have ended.

INFORMATION

Switching back to basic mode by bouncing three or more times cannot be deactivated. This means basic mode will be selected even if switching by bouncing was not activated in the X-Soft configuration software.

Remote Control

During normal operation, the 3B1/3B1=ST knee joint can be used in basic mode (including optional Intuitive Stance function, Sitting function, Stairs and Obstacles function, and OPG function) and in up to five different MyModes. The MyModes can be activated using the Remote Control.

Basic mode is used on a day-to-day basis, while the MyModes are pre-programmed for specific movements and / or postures such as standing at a workbench, cycling, inline skating or cross-country skiing.

X-Soft is used to configure which MyModes are used as well as their settings. However, some parameters can also be adjusted with the remote control.

⚠ CAUTION

Improper MyMode switching using the Remote Control. MyMode switching using the Remote Control changes the cushioning properties of the knee joint. In certain situations, this can cause you to fall. You must stand securely when switching between modes and must carefully confirm whether the desired function was successfully set by the 3B1/3B1=ST knee joint.

⚠ CAUTION

Penetration of water into the Remote Control. The Remote Control is not waterproof. If water penetrates the Remote Control, the device may be damaged (warranty will become void). This can lead to malfunction of the Remote Control, result in unexpected actions of the knee joint and cause you to fall. If penetrated by water, the Remote Control should be dried at room temperature for at least 1 day. Before using the Remote Control again, send it to an authorised Ottobock Service Centre. Please contact your prosthetist with any service questions.

⚠ CAUTION

Manipulation of 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 knee joint. This can cause you to fall. Any changes or modifications to the device may limit its usability.

⚠ CAUTION

Unauthorised connection. If an unauthorised connection between a Remote Control and a knee joint is established, the knee can react unexpectedly. This can lead to the patient falling. Pairing between the knee and the Remote Control does not require any password or acknowledgment from the knee. It is therefore theoretically possible (with known serial number of the knee or if only one knee is within range of the Remote Control), that a third party performs pairing with the knee joint and changes settings or switches MyModes.

INFORMATION

The knee joint should be consciously kept motionless during the switching process.

INFORMATION

For safety reasons, the Remote Control automatically turns off after two minutes. After the Remote Control is turned on, approx. three seconds may elapse before it is ready for mode switching processes.

INFORMATION

The range of the Remote Control is max. 5 m.

Control Elements of the Remote Control



1. LCD screen
2. Input key
3. Navigation keys: Left ◀, right ▶, up ▲, down ▼
4. Charging receptacle

Initial Connection Between the Remote Control and the 3B1/3B1=ST Knee Joint (Pairing)



1. Turn on the Remote Control by pressing the input key. The start-up screen with the date, time and battery capacity of the Remote Control is displayed. Without additional input, the Remote Control turns off automatically after 5 seconds.
2. Attempt to establish a connection by pressing ▼. The Remote Control searches for active prostheses.
3. When a knee joint is found (serial number is displayed), confirm by pressing the input key. If several knee joints are found, the serial number of the desired knee joint has to be selected using the navigation keys (display: serial number). Then the configuration data are downloaded from the knee joint.

INFORMATION

This process can take a few minutes.

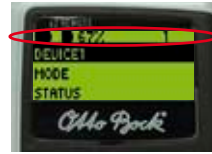
4. The main menu is displayed.

After the initial connection to the knee joint has been established successfully, the Remote Control will connect automatically each time it is turned on (input key followed by ▼). No further steps are required.

Status Bar

The status bar shows:

1. Battery capacity of the Remote Control
2. Charging state of the knee joint with percentage indicator
3. Current MyMode
4. In case of a deviation from normal knee joint functionality (e.g. when the charger is connected), an exclamation mark is shown in the status bar at the top right. The current MyMode is not displayed in some of these situations.



MyMode Switching with the Remote Control

Once an active connection to the prosthesis has been established, the Remote Control can be used to switch between MyModes.



1. Select "MyMode" in the main menu and confirm with the input key.
2. A list of the available MyModes is displayed. Use ∇ Δ to select the desired MyMode and confirm with the input key. If the list of MyModes was called up accidentally, the active MyMode can be selected again.
3. The Remote Control can be turned off by selecting and confirming "Power off".

Changing Prosthesis Settings

Once an active connection to the prosthesis has been established, the settings of the respective MyMode can be changed using the Remote Control.



1. Select "Device settings" from the main menu and confirm with the input key.
2. A list of available parameters for the current MyMode is displayed. Select the desired parameter and confirm with the input key.
3. A screen with a scale, the current parameter value and the limit values is displayed. Use \triangleleft \triangleright to change the setting as desired and confirm with the input key.



4. The list of parameters can be closed without making changes by selecting and confirming the arrow symbol. To select the arrow symbol, use the input key ∇ .

5. The Remote Control can be turned off by selecting and confirming "Power off".

In order to change the settings of another MyMode, you first have to switch to that MyMode (see the section *MyMode Switching with the Remote Control*).

INFORMATION
 The prosthetist's setting is usually found in the middle of the scale. After adjustment, you can reset the prosthetist's setting by moving the slider control into the middle.

INFORMATION
 The knee joint settings should be optimised by the prosthetist with the help of the X-Soft configuration software. The Remote Control is not intended for use by the prosthetist in order to set up the knee joint. The behaviour of the prosthesis can be changed to a certain extent on a day-to-day basis using the Remote Control (e.g. while becoming accustomed to the prosthesis). At the next appointment, the prosthetist can track the changes in the X-Soft configuration software.

The table below shows the adjustment parameters for the individual MyModes along with a brief description, the adjustment range of the Remote Control around the value selected by the prosthetist and the absolute value range.

Basic mode

Slider name in X-Soft	Absolute Range	Remote Control Adjustment Range	Description
Stance Phase Flexion Resistance (Resistance)	120 – 180	±10	Resistance to flexion movements, e.g. while walking downstairs or sitting down in a chair.
Swing phase - flexion angle	55° – 70°	±3°	Maximum flexion angle in the swing phase.
Pitch	1000 Hz – 4000 Hz	1000 Hz – 4000 Hz	Frequency (pitch) of the beeper for confirmation signals.
Volume	0 – 4	0 – 4	Volume of the beeper for confirmation signals.

MyModes except friction brake mode

Slider name in X-Soft	Absolute Range	Remote Control Adjustment Range	Description
Ascent	0 – 100	±10	Value for speed at which flexion resistance increases as the knee angle increases.
Pitch	1000 Hz – 4000 Hz	1000 Hz – 4000 Hz	Frequency (pitch) of the beeper for confirmation signals.
Volume	0 – 4	0 – 4	Volume of the beeper for confirmation signals.

Friction brake mode


Slider name in X-Soft	Absolute Range	Remote Control Adjustment Range	Description
Base	0–180	±20	Base resistance with no load on the knee joint
Pitch	1000 Hz–4000 Hz	1000 Hz–4000 Hz	Frequency (pitch) of the beeper for confirmation signals.
Volume	0–4	0–4	Volume of the beeper for confirmation signals.


Deep sleep mode

The remote control can be used to place the knee joint in a deep sleep mode, in which power consumption is minimised. The knee joint offers no functionality in this mode.

It can be awakened from deep sleep mode with the remote control or by connecting the charger.


Proceed as follows to activate deep sleep mode:

1.  Select „Device stgs.“ in the main menu and confirm the selection.

2.  A list of the parameters available for the current MyMode is displayed. The entry „Deep sleep“ is at the end of this list; select it and press the enter key.

3. A confirmation prompt is displayed. Press the enter key again.

Proceed as follows to wake the knee using the Remote Control:

1. Activate the Remote Control by pressing the enter button  and.
2. Select the “Wake device” menu entry and press the enter button to confirm.
3. The knee joint is reactivated after no more than 20 seconds, which is confirmed by a single beep and vibration signal. It will then be in basic mode.



Alternatively, the knee joint can be woken by connecting the charger.

Prosthesis Status Inquiry



1. Selecting and confirming "Status" displays the following:
 - The total pedometer value ("Total")
 - The daily pedometer value ("Day")
 - The battery capacity of the prosthesis in percent ("Battery").
 - The estimated remaining operating time of the prosthesis in hours during active use and at rest (e.g. sitting function) („Stb/Act“ for Standby/Active)
 - The next service due date
2. Selecting "Day" and pressing the selection key resets the day step counter.

Remote Control Settings



1. Select "Settings" in the main menu and confirm using the input key.
2. Adjust the date and time by selecting the corresponding line. Change settings using the navigation keys.



3. Additional connections can be set up ("Pairing") and connections can be deleted ("Delete connection") (see the section *Prosthesis Administration*).
4. The font size in the menu bar can be changed by selecting "Zoom".
- 5.–6. On the screen, use $\triangleleft \triangleright$
 - to select the normal (1, \triangleleft) or large font size (2, \triangleright) and confirm using the input key.



7. Information about the firmware version of the knee joint and signal strength is accessible under „Info“. Select the arrow symbol to return to the main menu on the display.

Prosthesis Administration

Connections with up to four different prostheses can be stored in a single Remote Control. Conversely, a prosthesis can only be connected to a single Remote Control. Complete the following steps to add additional connections:



1. Use Δ ∇ to select "Settings" from the main menu and confirm using the input key.
2. Select "Pairing" from the menu that appears.
3. The Remote Control searches for additional prostheses within range.
4. Use the input key to confirm once another prosthesis has been found. If several additional prostheses are found, the serial number of the desired prosthesis has to be selected using the navigation keys (display: serial number). Use Δ ∇ to select one of the four positions and confirm with the input key. One of the existing connections can also be overwritten. The configuration files are loaded from the prosthesis and the main menu is displayed.

To delete an existing connection, please follow the steps below:



1. Use Δ ∇ to select "Settings" from the main menu and confirm using the input key.
2. In the menu that appears, select "Delete connection" and confirm using the input key.
3. Select the connection you wish to delete using Δ ∇ and confirm with the input key.

Connecting to the Prosthesis during Normal Operation

INFORMATION

Advise your patients of the information in this section.

If more than one connection has been saved, a selection menu for the saved connections appears after powering up; the most recently active connection is pre-selected here.



1. To change the active connection, select the name of the current connection in the main menu and press enter to confirm.
2. In the list of saved connections which is then displayed, select the required connection and press enter to confirm.
3. If the chosen connection cannot be re-established, a reduced main menu appears. Choose „Select device“ to activate another selected connection.

In some cases following service, the connection cannot be restored even though the joint is within range of the remote control. In this case, the existing connection must be erased and the pairing process has to be completed again.

Charging the Remote Control

Disconnect the charging cable from the charger of the 3B1/3B1=ST knee joint and connect it to the charging receptacle on the Remote Control. Regardless of how often the Remote Control is used, it should last two months on a single charge. The battery capacity of the Remote Control is shown at the top left of the display (see Figure 1 in the section *Initial Connection between the Remote Control and 3B1/3B1=ST Knee Joint (Pairing)*). Fully charging the remote control battery takes a maximum of 3-4 hours.

Safety Messages and Safety Mode

Event	Vibration Signal	Beep Signal	Required Action
Overheated hydraulics	Every 5 sec. short	-	Reduce activity
Minor error: e.g. temporary disruption of a sensor signal	After charging, 3x short	After charging, 3x short	Walking possible without restrictions, consult prosthetist soon
Moderate error: e.g. a sensor is not operational	Every minute, 5x long	5 long beeps when stepping down	Walking possible with restrictions, consult prosthetist immediately
Severe error: e.g. failure of the valve drive	Intermittent continuous vibration	30 long beeps when stepping down	High flexion resistance, swing phase no longer possible, consult prosthetist immediately
Total failure: No electronic functionality	Continuous vibration	-	Safety mode or undefined condition, swing phase no longer possible, consult prosthetist immediately

As soon as the 3B1/3B1=ST knee joint identifies an error in the knee joint, at least 5 beeps and 5 slow pulsating vibration signals are emitted. The 3B1/3B1=ST knee joint activates a safety mode and remains in this state until the error is corrected (as long as the battery capacity is sufficient).

In addition to basic mode and the MyModes, the 3B1/3B1=ST knee joint has various safety modes that offer different levels of residual functionality depending on the type and severity of the error.

The OPG function, stairs and obstacles function, Intuitive Stance function and Sitting function are deactivated when the joint is in safety mode. Beyond that, the following levels of residual functionality are possible:

- Continuous high flexion resistance
- Continuous stance phase flexion resistance with the ability to initiate the swing phase

Depending on the type of error, protection against swing phase initiation while walking backwards may or may not be active. You must therefore exercise caution when walking backwards after an error.

In addition, swing phase control and stance phase extension resistance may or may not be available depending on the type of error.

If safety mode was triggered due to a flat battery (see Section "Charging Status"), charging the prosthesis resets it to basic mode. In this case, the resistance value configured in the X-Soft adjustment software is activated.

There is also an overheating mode to protect the knee joint against excessive temperatures. In this safety mode, stance phase resistance increases as the temperature rises – especially in order to slow down walking downhill so that overheating is not allowed to worsen. Swing phase control is also progressively reduced. Overheating mode is indicated by brief vibration every 5s.

Basic mode is reactivated once the temperature has fallen sufficiently.

⚠ 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 3B1/3B1=ST knee joint can no longer be set to safety mode (e.g. in the event of a short circuit due to water damage), the patient must actively secure the knee joint with the residual limb musculature upon heel strike and visit a prosthetist as soon as possible.

⚠ CAUTION

Danger when activating safety mode. The damping characteristics of the knee joint change when a safety mode is activated. In certain situations, this can cause you to fall.

As soon as the sound and vibration signals are emitted simultaneously, stop all activities involving the leg prosthesis. After approx. 10 seconds in a secure standing position, determine whether stance phase resistance is active by repeatedly flexing the 3B1/3B1=ST knee joint slightly under controlled load.

⚠ CAUTION

Safety mode cannot be deactivated. When the knee joint is in safety mode, this most likely indicates a knee joint defect. Malfunctions may occur in this state. This can cause you to fall.

If the safety mode could not be deactivated by recharging the battery, an error has occurred. Contact the prosthetist to have the error corrected.

Battery Capacity

During normal operation, the battery charge level is indicated via vibration signals (in addition to the display on the remote control) (see Section "Charging the 3B1 / 3B1=ST Knee Joint").

Storage and Bleeding Air

To store the knee joint, push the knee head to the flexion stop. Upon putting the knee joint back into use, hold it vertically with the knee head up and push the knee head to full extension.

During extended non-vertical storage of the 3B1/3B1=ST knee joint, air may accumulate in the hydraulics. This is noticeable through sounds and irregular damping behaviour.

The automatic ventilation mechanism ensures that all functions of the 3B1/3B1=ST knee joint are once again available after approx. 10 - 20 steps.

Service

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 (see Genium Service Pass 646D534=*).

In the interest of your own safety and in order to maintain operating safety and warranty, a service inspection is required after 24 months.

This service inspection includes a verification of the sensors and the replacement of worn parts.

For the service inspection, the 3B1/3B1=ST knee joint with installed AXON tube adapter (2R20/2R21), remote control (4X350) and complete charger (4E60) including power supply (757L16-3) and Genium Service Card (646D534) must be sent to the authorised Ottobock Service Centre.

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

Warranty

Ottobock offers an extensive warranty service on the basis of the Genium service and warranty concept. Your prosthetist is the contact person.

Technical Information

Operating, storage and transport temperature:	-10 °C to +60 °C (14 °F to 140 °F)
Battery charging temperature:	0 °C to +45 °C (32 °F to 113 °F)
Relative humidity range:	up to 80 %
Operating voltage of the battery charger:	100 V to 240 V AC
Operating frequency of the battery charger:	50 Hz to 60 Hz

Knee Joints



Description	3B1	3B1=ST
Proximal connection	Pyramid adapter	Threaded adapter
Distal connection	Tube clamp	
Weight without tube adapter	1400 g / 3.09 lbs	
Prox. system height to alignment reference point	0 mm	26 mm
Minimum distal system height With 2R20/2R21 AXON tube adapter	298 mm / 330 mm	
Maximum distal system height With 2R20/2R21 AXON tube adapter	514 mm / 546 mm	
Knee flexion angle	135 °	
Frame material	Carbon fibre	
Mobility grade	2, 3, 4	
Body weight max.	150 kg (330 lbs.)	
Water resistance of the knee joint	IPX4, protected against splashed water from any direction, but not against submersion, jets of water or steam.	

AXON Tube Adapter



Description	2R20	2R21 (torsion unit)
Weight	190-300 g / 0.42-0.66 lbs	435-545 g / 0.96-1.20 lbs
Material	Aluminium	
Body weight max.	150 kg (330 lbs.)	125 kg (275 lbs.)
Water-resistance of the AXON tube adapter	IPX4, protected against splashed water from any direction, but not against submersion, jets of water or steam.	

Liability

The product may only be used under the specified conditions and for the intended purpose, and in conjunction with the modular component combinations tested for the prosthesis, in accordance with the Ottobock MOBIS® mobility system, and in accordance with the instructions. The manufacturer is not liable for damage caused by component combinations that were not authorised by the manufacturer.

CE Conformity

The 3B1/3B1=ST knee joint meets the requirements of the 93/42/EEC guidelines for medical devices. This device 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 Ottobock with sole responsibility according to Appendix VII of the guidelines.

The 3B1/3B1=ST knee joint also meets the requirements of Directive 1999/5/EC for radio equipment and telecommunications terminal equipment. The conformity assessment was carried out by Ottobock according to Appendix I of the directive. A copy of the declaration of conformity can be requested from the manufacturer (see reverse).