

NeuroOrthopaedics – the latest generation of stance control orthosis systems

FreeWalk and E-MAG Active



Quality for life

Information for specialist dealers





Introduction

Stance control orthoses (SCO) make it possible to not only walk dynamically but also to stand securely in the stance phase. These special orthosis systems from Ottobock lock the knee joint in stance phase and release it for swing phase. As a result, the patient achieves a dynamic, almost physiological gait pattern requiring less energy, for example, than with a locked joint system.

At the same time, the E-MAG Active and FreeWalk take pressure off of the back as well as hip and knee joints. Both systems increase the patient's security, stability and, above all, mobility, in different ways.

The E-MAG Active and FreeWalk orthoses differ in terms of their functionality and their construction. Whereas the E-MAG Active has electronic components and functions independently from the ankle joint, the FreeWalk system is controlled purely mechanically, with the ankle joint connected to the knee joint.

Another major difference is their method of construction. The knee-ankle-foot orthosis (KAFO) the E-MAG Active is integrated into, is custom-made by the orthopaedic technician using a plaster cast.

This is not the case for the FreeWalk. This is a complete system fabricated by the manufacturer's service fabrication department from measurements supplied by the orthopaedic technician. Here, the orthopaedic technician is responsible for taking measurements and then fine-tuning the orthosis to the patient.

The different systems cater to different patient groups. In general, the knee-ankle-foot orthosis (KAFO), into which the E-MAG Active is integrated, is ideal for patients who:

- ▶ Have significant deviations in the frontal and sagittal planes (of the knee joint and ankle joint), and/or
- ▶ Have a highly atrophic, bony leg with little soft tissue coverage, and/or
- ▶ Have a considerably shortened leg (over 5 cm), and/or
- ▶ Require a dorsal stop in the ankle joint to achieve knee joint extension, and/or
- ▶ Have a stiff ankle, and/or
- ▶ Require a pronounced dorsiflexion function

The FreeWalk orthosis is suitable for patients who have lost control of their muscles due to trauma, but have not suffered any severe lesions on the limb (for example, a history of incomplete paraplegia). Thus it is ideal for patients who:

- ▶ Have no or only minor deviations in the leg axis, and
- ▶ Have an ankle joint that is stable yet flexible (range of motion of at least 10°), and
- ▶ Do not require the orthosis to feature large support surfaces.

The biomechanics of human gait

The gait cycle consists of a stance phase and a swing phase. The stance phase begins when the heel touches the ground and ends when the toe leaves the ground. The swing phase begins when the toe leaves the ground and ends at the next heel contact.

The **stance phase** begins when the heel touches the ground. As soon as the heel makes contact, the thigh and lower leg muscles take over control of the knee. As the leg starts to bear weight, the knee is stabilised by the thigh extensors. In the mid-stance phase, the thigh and lower leg muscles stabilise the leg up to the end of transition to the terminal stance phase, with the latter being accomplished by the lower leg muscles alone.

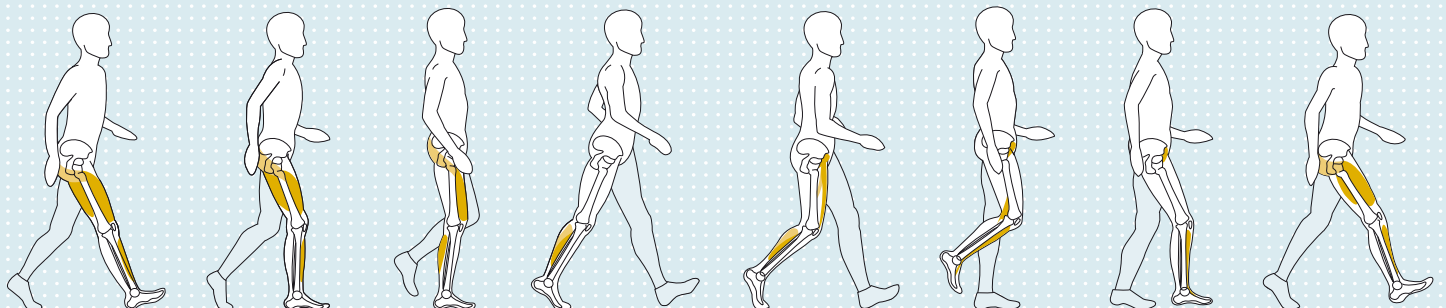
The thigh extensors provide significant support during the stance phase. If this supporting function is missing or significantly weakened, the normal stance phase cycle is disturbed.

Following completion of the terminal stance phase, the **swing phase** begins with the pre-swing phase, with toe-off initiating the actual swing phase. In the pre-swing phase, the pretibial muscles and the hip flexors are primarily employed.

The initial swing phase is controlled by the hip flexors, the knee extensors and the anterior lower leg muscles. During transition to the mid-swing phase, knee flexion is no longer needed to bring the leg with its pendulum mass into the terminal swing phase. The terminal swing phase ends directly upon initial heel contact, where the entire chain of muscles is needed to stabilise the knee joint.

The swing phase itself is not greatly affected by knee extensor deficits. This demonstrates that conventional locked orthoses that promote stance phase stabilisation are, in fact, too immobilising during the swing phase.

Human gait phases



Initial contact

- Beginning of the stance phase with heel contact
- 0 % of the gait cycle

Load transfer

- Weight transfer, shock absorption through knee flexion, maintenance of forward motion
- 0-12% of the gait cycle

Mid-stance phase

- Forward motion of the body over the stationary foot, start of knee extension
- 12-31% of the gait cycle

End of stance phase

- Forward motion of the body over the forefoot
- 31-50% of the gait cycle

Pre-swing

- Preparation of the swing phase, knee flexion has been initiated
- 50-60% of the gait cycle

Beginning of the swing phase

- Toe-off and forward swing of the leg, achieving maximum knee flexion
- 60-75% of the gait cycle

Mid-swing phase

- Continued forward swing of the leg, knee extension
- 75-87% of the gait cycle

End of swing phase

- Braking the forward swing, preparation for the next step
- 87-100% of the gait cycle

Gait cycle with stance control knee joint systems

Compared to a healthy person with a normal gait cycle, a patient with non-functional knee-stabilising muscles requires an orthosis that stabilises the knee joint.

Ottobock's stance control knee joint systems (SCOs) provide stability only in the phase where it is needed.

The swing phase is not compromised.

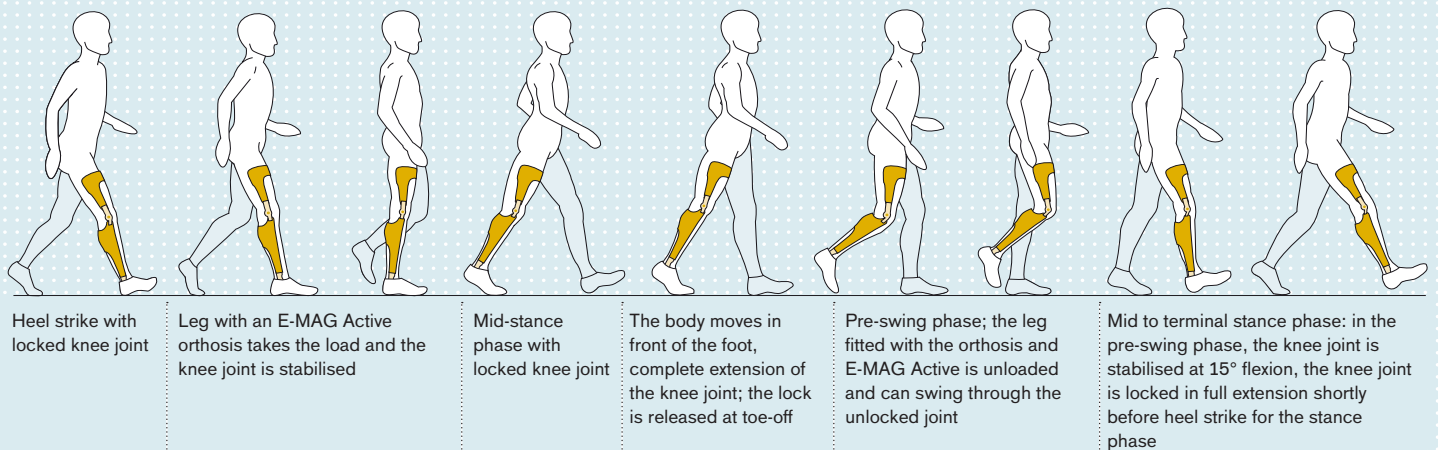
Between heel contact and toe-off – in other words, for as long as the foot is bearing weight on the ground – the orthosis secures the knee joint and supports the knee-stabilising muscles.

The orthoses remain locked during the entire stance phase. They only release the knee joint for the swing phase between the terminal stance phase and the pre-swing phase. This provides users with a high level of mobility, comparable to that of a healthy person during a normal gait cycle.

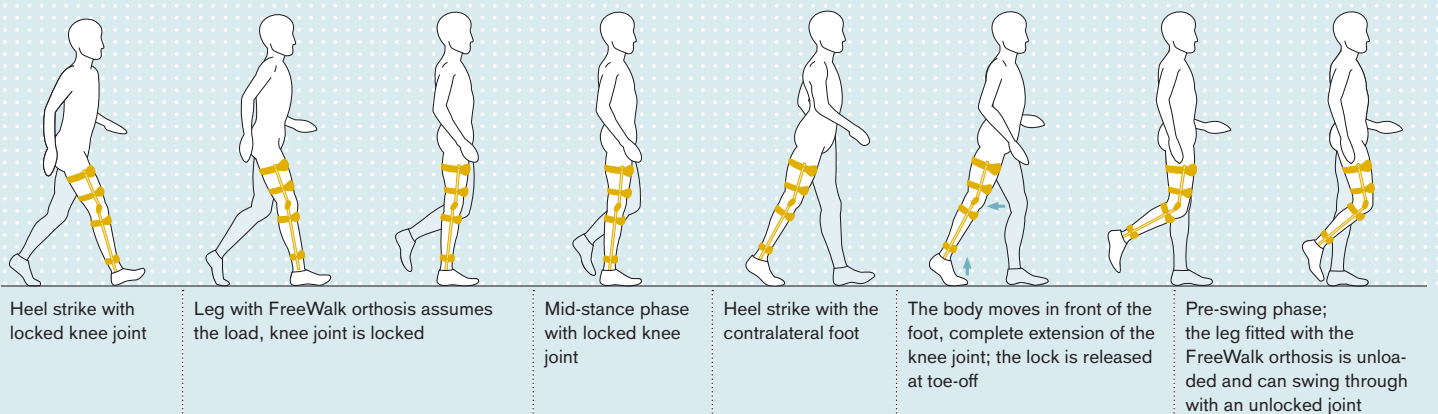
Studies have shown that, compared with a locked orthosis, stance control orthoses offer considerable advantages with regard to energy expenditure, walking speed and reduction of the strain on the contralateral side.

- Literature review by B. Zacharias and A. Kannenberg 'Zum klinischen Nutzen standphasenkontrollierter Orthesen-systeme – Eine Analyse der wissenschaftlichen Literatur' ('On the clinical uses of stance control orthosis systems - an analysis of the scientific literature'), published in Orthopädie Technik 6/2011.

Gait cycle with E-MAG Active

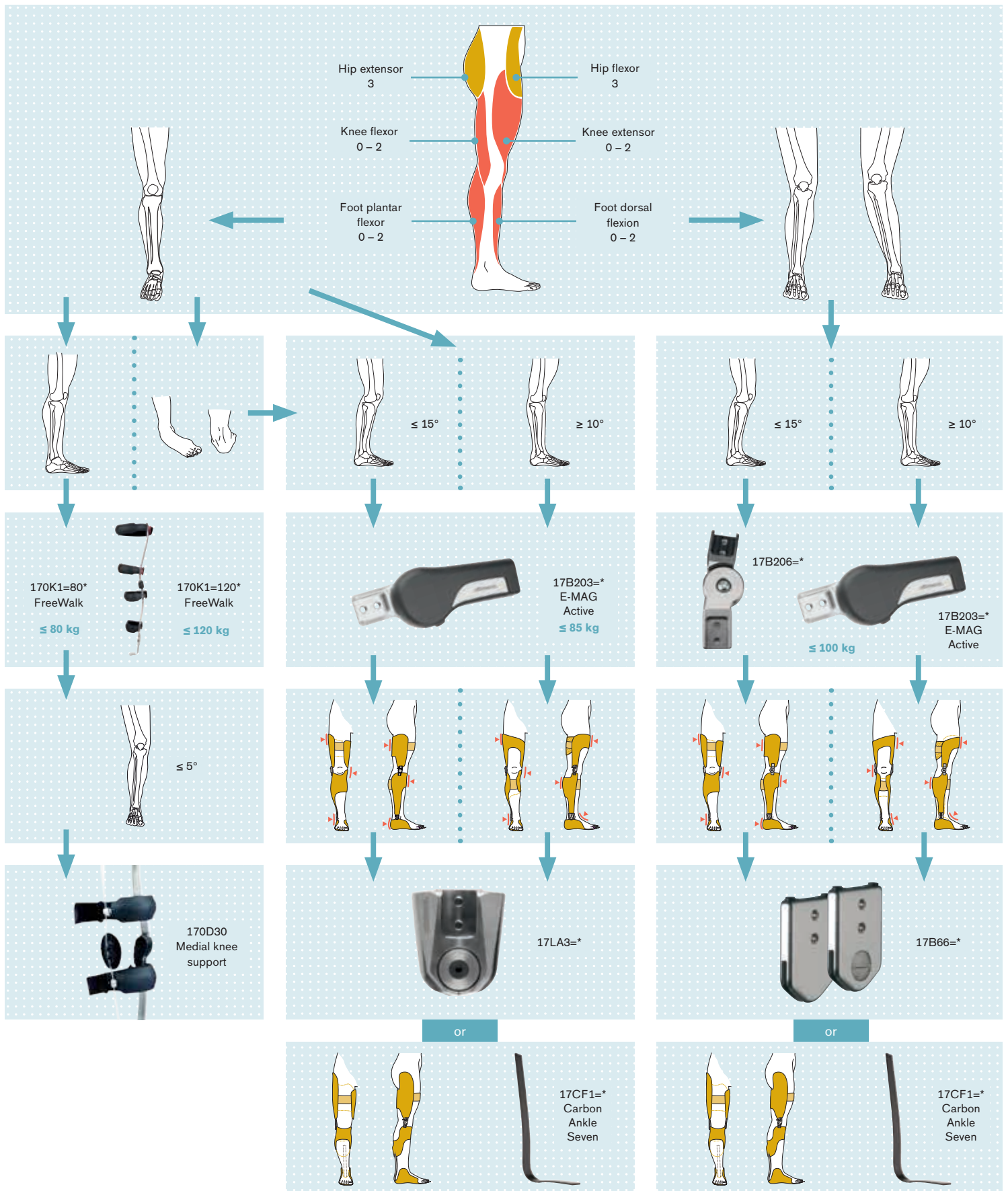


Gait cycle with FreeWalk



Selection guide SCO*

*Stance phase controlled orthosis systems



Prerequisites for use and the differences between knee-ankle-foot orthoses fitted with the E-MAG Active joint system and the FreeWalk orthosis

Indications for fitting with an SCO

Treatment with stance control orthosis systems is indicated for paresis or paralysis of muscles and muscle groups of the lower limbs. These conditions can be triggered by various underlying diseases such as poliomyelitis/post-polio syndrome or traumatic paraplegia.

Muscle strength requirements

The hip or the knee extensors must be strong enough to extend the knee in order to release the orthosis in the terminal stance phase and lead it into the pre-swing phase. When this is not the case, passive hyperextension of the knee joint can also be sufficient.

At the end of the stance phase, an active hip or knee flexor function is also required to launch the swing phase. Before initial heel contact, the knee joint must be actively extended in order for the orthotic knee joint to lock automatically. If this is not possible, a compensatory hip movement can make up for this. The pendulum effect caused by the hip movement may suffice to fully extend the knee joint. To assess the patient's suitability and decide which of the two joint systems may be appropriate, muscle strength and mobility of movement must be assessed.

Prerequisites for mobility

For optimal use of the E-MAG Active or FreeWalk orthoses, certain mobility criteria must also be met. Should a patient not meet these criteria, the therapist or physician can assess whether the patient could meet them upon the completion of therapy.

E-MAG Active

- Knee joint extension, no flexion contracture above 15° in ankle joint (can possibly be influenced by dorsal stop)
- No hip flexion contracture
- No uncontrollable spasms

In addition, for unilateral use:

- Only slight non-physiological deviations in the frontal and sagittal planes
- Slight capsular and / or ligament instabilities

FreeWalk

- Mobility of the ankle joint of at least 10°
- Knee joint extension, no flexion contracture in excess of 10°
- Valgus/varus deviations in the ankle joint, to a maximum of 10° (not shown)
- Valgus/varus deviations in the knee joint, to a maximum 10°
- No hip flexion contracture
- Sufficient contralateral leg support
- Leg length discrepancy not exceeding 7 cm (with a stable ankle joint only)
- No uncontrollable spasms

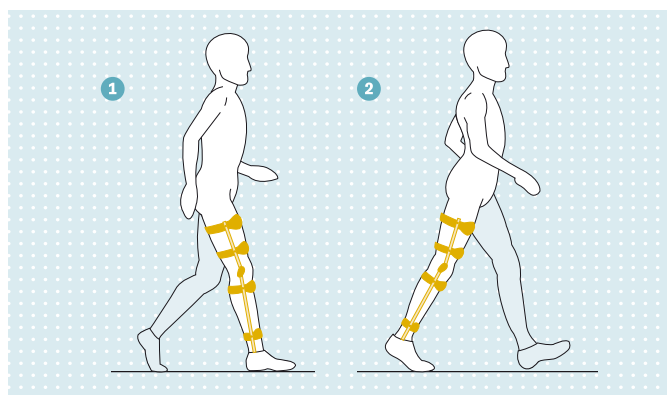
Functional principle and advantages over conventional orthoses

In contrast to the gait cycle of a healthy person, patients whose knee stabilising muscles do not function adequately require an orthosis to stabilise their knee joints. SCO orthoses provide stability only in the phase where it is needed. The swing phase is not compromised.

Between heel contact and toe-off, i.e. when the foot bears weight on the ground, the SCO orthoses secure the knee joint and support the knee stabilising muscles. During the entire stance phase, the orthosis remains locked. The orthotic joint is then released between the terminal stance phase and the pre-swing phase, allowing the patient's knee joint to move freely during the swing phase.

Due to the low weight and the functionality of the SCO orthoses, significantly less torque affects the knee joints of both legs. As a result, the mechanical stress is lower and the risk of arthrosis reduced.

Gait analyses have shown that users with SCO orthoses need less oxygen and thus expend less energy. This creates cardiovascular reserves for greater physical performance.



1 Stability in the stance phase

The orthotic knee joint locks automatically when the knee is extended prior to heel strike. The patient can then stand securely and put weight on the leg during the stance phase. The FreeWalk thus fulfills the function of a locked orthosis.

2 Disengagement in the swing phase

The patient releases the orthotic knee joint by extending his or her knee prior to toe-off and allowing dorsiflexion of the upper ankle joint. This allows the patient to flex the leg and let it swing through freely.

SCO orthoses:

- Are secure in the stance phases, like locked orthoses
- Are flexible during the swing phases, due to the disengaging of the orthotic knee joint (thus making the user's gait pattern very similar to a physiological gait pattern)
- Reduce the formation of pressure spots as a result of less skin contact and/or fewer rubbing points
- Offer quick exchange of worn parts
- Are fabricated individually
- Have no medial joint interference when sitting or walking (up to 85 kg for E-MAG Active)
- Allows users to sit comfortably, thanks to flexible straps

Fitting with SCO orthoses - FreeWalk and E-MAG Active test orthoses

The fitting process

The process of fitting patients differs fundamentally for the FreeWalk and the E-MAG Active.

The FreeWalk orthosis is a complete system that is made to measure for the patient, by order of the orthopaedic technician, using a particular manufacturing technique which requires special tools. With the new FreeWalk, the clamps are adjustable and the ankle joint is freely adjustable in terms of height and angle, which makes the system flexible and also means it can be adjusted at a later time if the patient's needs change.

With the E-MAG Active, the process is comparable to that of a classic fitting with knee-ankle-foot orthoses (KAFO). The orthopaedic technician undertakes the entire fitting process, from the plaster cast through to manufacturing the sockets, alignment, etc.

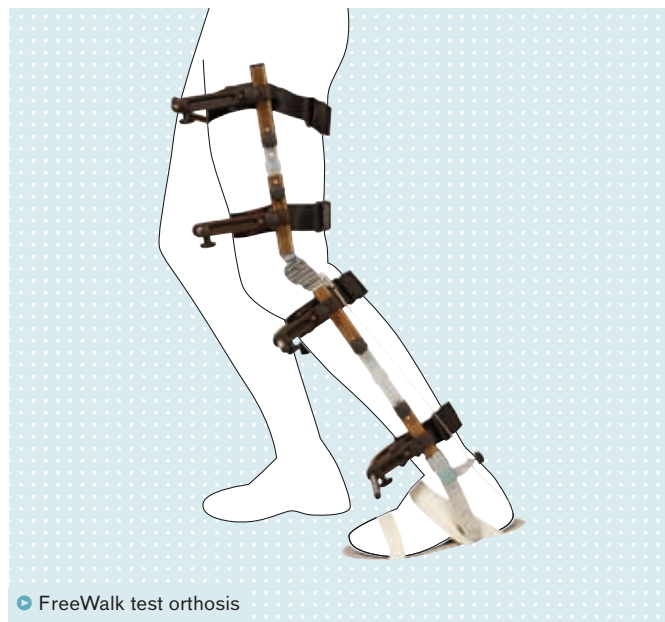
For both SCO fittings, it is possible during the first trial fitting and/or the first functional test to adjust the settings or functions of the orthosis and perform any necessary fitting alterations. In general, the orthopaedic technician takes measurements and makes drawings of the patient. On the basis of this data, the FreeWalk orthosis is then prepared for the patient. During the first trial fitting, the orthopaedic technician adjusts the foot piece with the foot clamp and the insole. He or she checks the length measurements, such as the knee and base measurements and the breadth measurements.

When checking the functions, it is possible to change the orthosis's settings. The orthopaedic technician explains to the patient how it operates and gives him or her a gait training session. Additional exercises follow while the orthopaedic

technician checks the functioning of the orthosis and makes any necessary adjustments. Only when the patient feels comfortable with the SCO orthosis is it completed and handed over. To ensure that the SCO functions perfectly for a long time, Ottobock recommends that it be checked by an orthopaedic technician every six months.

Test orthoses

Test orthoses are available for both the FreeWalk and E-MAG Active as a practical aid for specialist dealers. These can be used – in rehabilitation facilities, for example – to quickly and easily determine whether the FreeWalk or the E-MAG Active orthosis is better suited to the patient's condition. Available in one universal size, they are applied over the patient's clothing and footwear.



Important

The FreeWalk and E-MAG Active test orthoses are only available on loan from your authorised Ottobock branch.

E-MAG Active 17B203: the 3rd generation with PreLock function



Launched in 2008, the E-MAG Active has shown itself to be a groundbreaking innovation in the development of orthosis knee joint systems. It has defined new standards in dynamics and mobility.

The concept:

The E-MAG Active is as innovative as it is reliable: an intelligent sensor system measures the position of the leg while walking and controls the orthosis joint accordingly.

The key advantage

The user can benefit from the functionality of the orthosis joint even if they have no function in their ankle, as the joint is activated independently of the ankle and the sole of the foot. The E-MAG Active offers users a significant increase in mobility and safety and facilitates a smoother, more natural gait pattern, thus enhancing their quality of life.

Suitable for

Users with greater mobility requirements who up to now have not been able to be satisfactorily fitted with an orthosis, or who have, for other anatomical reasons, rejected this particular orthotic solution.

Use of the E-MAG Active can prevent contractures and joint damage caused by immobilisation, reduce muscular atrophy and build up existing muscles. It provides relief for the contralateral side and helps the user avoid making compensatory movements. Less energy is required for walking and users benefit from increased mobility.

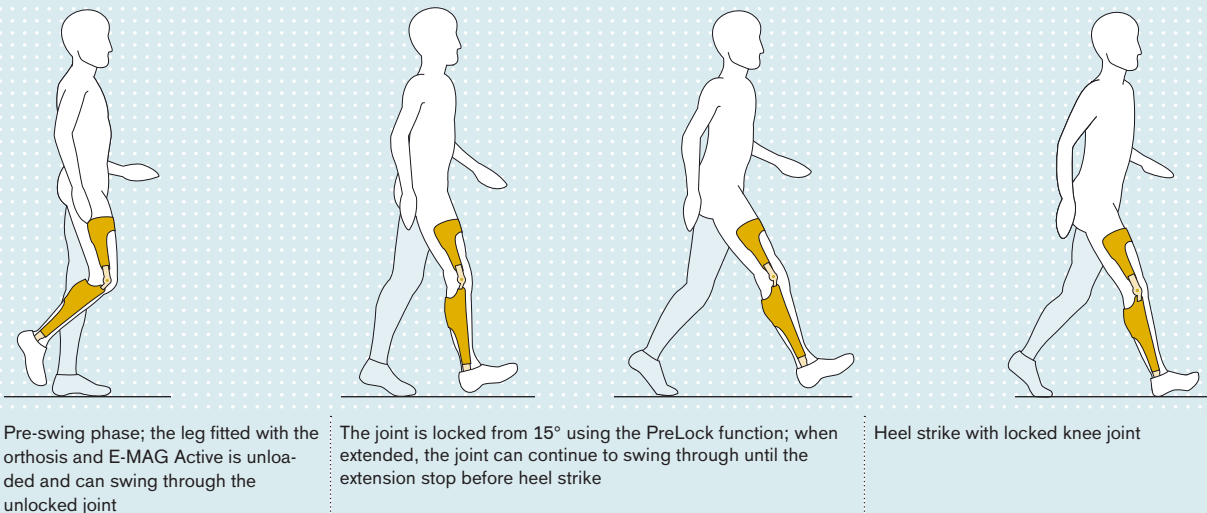


Secured stance phase – free swing phase

PreLock – dual security

Up to now, the joint was designed to lock once the knee joint orthosis was fully extended, before heel strike. To give patients an additional feeling of security, the joint is now locked earlier – at 15° flexion before complete knee extension is

achieved. This means that the joint will already be stabilised at 15°, providing greater security even in cases where the patient does not perform the swing completely.

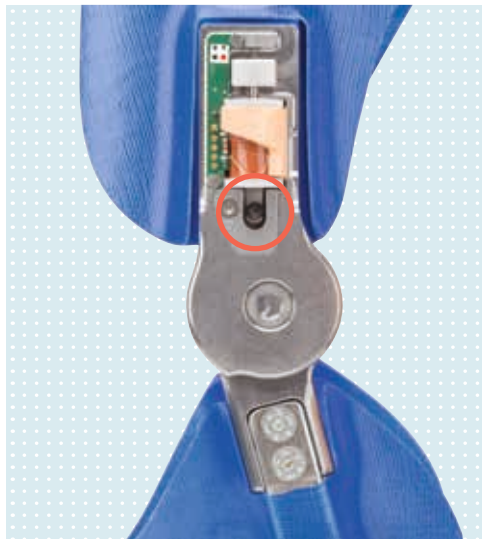


Benefits at a glance:

- E-MAG Active is a joint system for custom-made orthoses
- Free choice of the orthosis design in the lower leg and foot
- Greater safety as a result of the coordination of angle and acceleration sensors
- The system operates autonomously, regardless of terrain and surroundings
- It works independently of the ankle joint
- No troublesome electronic components in the lower leg and foot area
- Even greater security is provided with the PreLock function, which locks the knee joint 15° prior to full extension
- The scope of delivery includes two batteries (about 5,000 steps each)
- Self-adjusting software provides straightforward calibration
- The first functional test can be made with the E-MAG Active test orthosis
- In addition to the preset 5° flexion angle, a flexion angle of 7.5° is available
- The mechanical (temporary) unlocking function allows additional uses, e.g. cycling
- The noiseless system allows for discreet use



▶ Unlocked during flexion



▶ First stage of locking at 15° prior to full extension



▶ Second stage of locking at full extension

Scope of delivery

The 17B203=R/L E-MAG Active joint system is supplied in a case with all necessary components. This contains:

1	Electromagnetic knee joint
1	Electronic unit with receptacle
2	Battery units with receptacle
4	Resin lamination dummies
2	Cables (one for the electronics, one for the battery)
1	Battery charger
1	Operating instructions
1	Mounting and service manual
1	Quick Start

In addition, you will need two 17LS3=16(-T) casting bars. If the orthosis is to be fitted with an ankle joint, we recommend using the 17LA3=16(-T) unilateral or bilateral ankle joint. For each ankle joint, you will also need a 17LS3=16(-T) casting bar and a 17LF3=16 foot clamp.

Spare parts for the E-MAG Active as well as service sets for maintenance of the joint bearings are available.

▶ Notice

Online training is available for patient fitting with the E-MAG Active. We recommend acquiring this certificate of competence. Please see our 646K4=GB catalogue for further product information.

FreeWalk 170K1: the next generation – product highlights



1 Closures

As a new, attractive colour option, red closures are now also available (Art. no.: 170D20=2).

2 Clamp adapters

The new FreeWalk features sliding and rotating clamp adapters. In contrast to the previous model, where the clamp adapters were firmly attached, the screws on the new Free Walk can be loosened. This allows the straps to be better adjusted to users and their individual requirements.

3 Three-way switch

A three-way switch now comes as standard on the FreeWalk (Art. no: 170D71). This allows the user to choose between the settings: “free-moving”, “locked” and “FreeWalk mode”. Older FreeWalk orthoses can be retro-fitted with the new three-way switch.

4 Specially designed slim-line padding

Attractive new padding design ensures that the orthosis has an optimal, slim-line fit to the contours of the leg.

5 Ankle joint

The ankle joint has been optimised to allow it to be easily fine-tuned to user. The freely-adjustable angle between the ankle joint and foot clamp allows for straightforward optimisation of the FreeWalk's functionality. A graduated measuring scale allows settings to be easily reproduced. In addition, the foot clamp is height-adjustable, with a greater number of setting options on the foot section. This means it is possible to select a lower construction height, thus allowing the orthosis to be adapted to fit shorter users. The top bolt is now made of a non-corrosive material.

Photo measurement

A new photo measuring process makes it easier to take the user's measurements.





Please contact us if you have any further questions or would like more information.



Otto Bock HealthCare GmbH
Max-Näder-Str. 15 · 37115 Duderstadt/Germany
T +49 5527 848-1706 · F +49 5527 848-72330
export@ottobock.de · www.ottobock.com