



# 17B203=\* E-MAG Active

**EN** Instructions for use (qualified personnel) ..... 3



# 1 Foreword

English

## INFORMATION

Date of last update: 2020-04-14

- ▶ Please read this document carefully before using the product and observe the safety notices.
- ▶ Instruct the user in the safe use of the product.
- ▶ Please contact the manufacturer if you have questions about the product or in case of problems.
- ▶ Report each serious incident in connection with the product, in particular a worsening of the state of health, to the manufacturer and to the relevant authority in your country.
- ▶ Please keep this document for your records.

These instructions for use provide important information on the processing of the 17B203 E-MAG Active orthotic knee joint.

A quick start guide is available for the user, providing an overview of the E-MAG Active functions.

Provide the user with the instructions for use and the quick start guide upon delivery of the orthosis, and point out the semiannual maintenance intervals.

## 2 Product description

### 2.1 Available sizes

The E-MAG Active orthotic knee joint is available in varying degrees of pre-flexion.

Article	Pre-flexion	17B206 Medial support	Max. body weight
17B203=L/R, 17B203=L/R-7.5	5° and 7.5°	Without medial support	Up to 85 kg
17B203=L/R, 17B203=L/R-7.5	5° and 7.5°	With medial support	Up to 100 kg

### 2.2 Function/design

#### Function

The E-MAG Active is an orthotic knee joint system with stance phase control which offers the user a free swing phase and locks the knee joint for a secure stance phase prior to heel strike.

The E-MAG Active features an electronic lock that is released during toe-off, allowing the user to swing the paralysed leg in a physiological manner. Prior to heel strike, the knee joint locks in the extended position, so the user can step down safely.

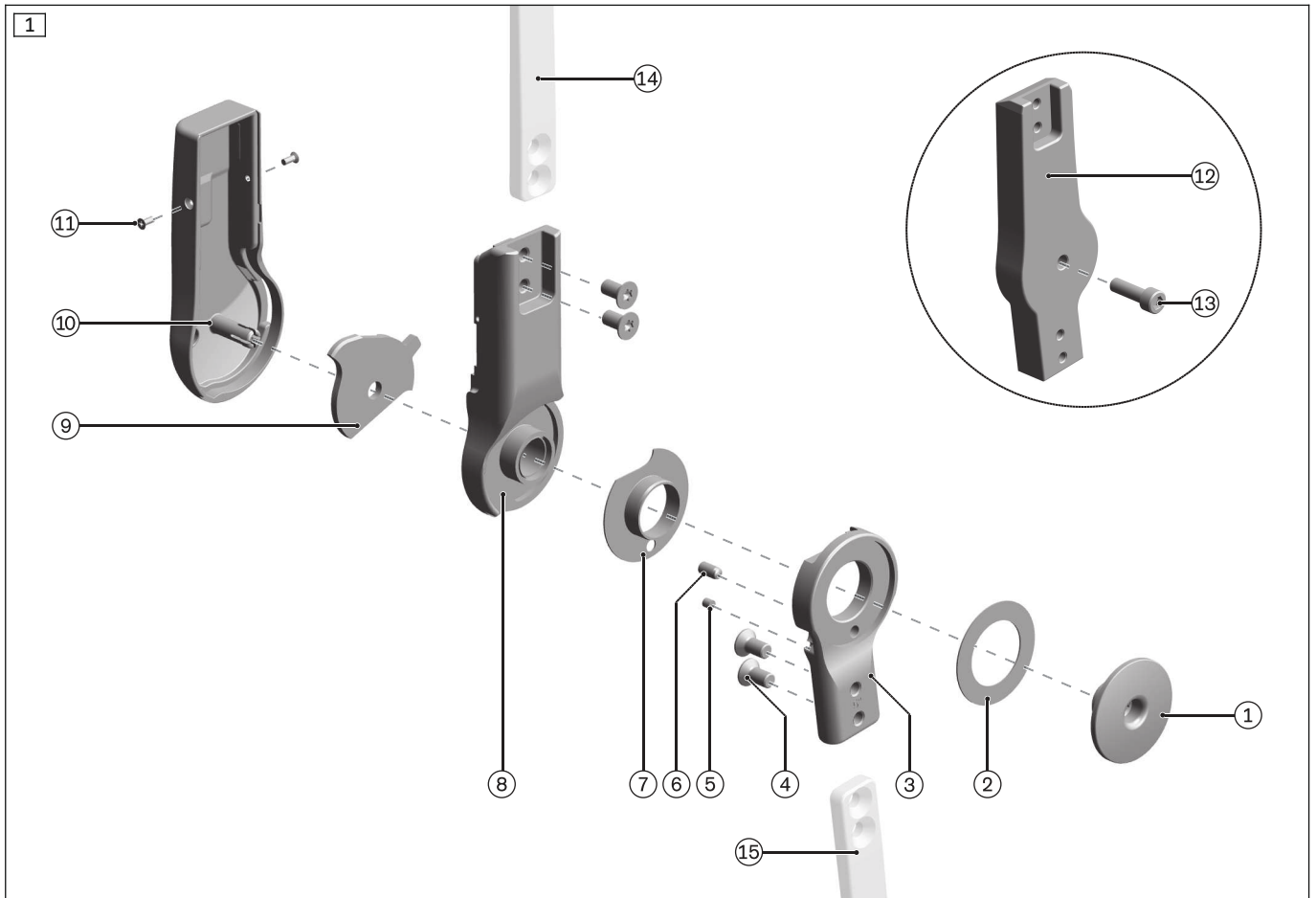
The E-MAG Active has an additional locking function (PreLock) that is activated at 15° of flexion. This secures the patient even before the swing phase as such ends. The orthotic knee joint is then fully locked when it reaches the extension stop.

#### Design

The bushing (radial bearing) and axial washer (axial bearing) are made of maintenance-free plastic. The wedge lock is connected to an electronically controlled spring, which secures it in the lower joint section. The electronic control unit consists of a gyroscope and 2D acceleration sensors to record the gait phase. It measures the position while the user is walking and releases the joint prior to toe-off before subsequently locking it again in the extended position prior to heel strike.

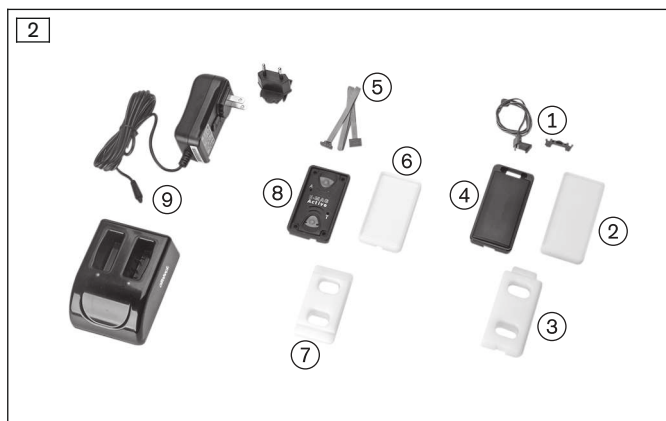
The open joint bar cases are used to attach the lamination bars. The electronic components are designed to be replaced by a technician. The battery can be removed from the battery receptacle on the orthosis and charged in the charger. The charger has two ports so two batteries can be charged simultaneously.

### 2.3 Components/design



Scope of delivery (see fig. 1)			
Item	Quantity	Description	Reference number
1	1	Joint screw	30Y112
2	1	Axial washer	17BS203
3	1	Lower joint section	
4	4	Countersunk head screws	501S137=M5x10
5	1	Stop bumper	617G28=3-9
6	1	Cylinder pin	506A8=4x8
7	1	Bushing with collar	30Y295=*
8	1	Upper joint section	
9	1	Unlocking mechanism	30Y353=*
10	1	Cover	30Y440=*
11	1	Countersunk Phillips head screws	501S21=M2x5
12	1	Lamination dummy	30Y297=*
13	1	Cap screw	501T28=M6x20
Not included in scope of delivery			
Item	Quantity	Description	Reference number
14	1	Lamination bar	17LS3=16, 17LS3=16-T
15	1	Lamination bar	17LS3=16, 17LS3=16-T

## 2.4 Electronic components

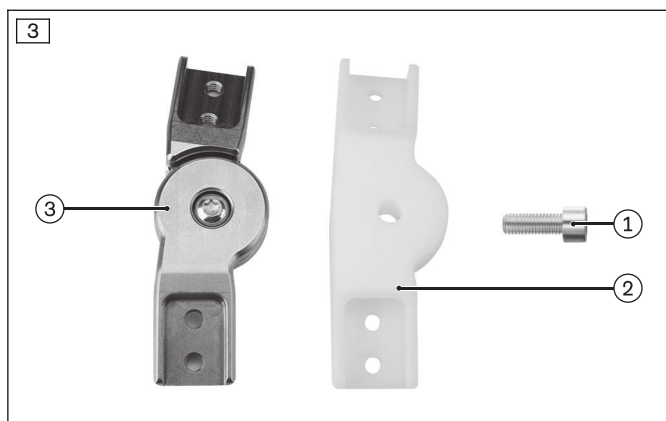


- 1 317E20 Battery cable and locking unit
- 2 30Y103 Battery dummy for battery receptacle
- 3 30Y124 Battery dummy
- 4 317B20, 317Z21 Battery/receptacle set
- 5 317E2 Electronics cable
- 6 30Y100 Dummy for electronics receptacle
- 7 30Y123 Dummy for electronics
- 8 317B3, 317Z13 Electronics/receptacle set
- 9 317L20 Battery charger

## 2.5 Options

### INFORMATION

The subsequent conversion of the E-MAG 5° flexion lower part to 7.5° may only be completed by an authorised Ottobock Service Centre.



- 1 501T28=M6x16 Cap screw for lamination dummy
- 2 317X206, 317X206=7.5 Lamination dummy for medial support in 5 or 7.5° (not illustrated)
- 3 17B206, 17B206=7.5 Medial support

## 3 Intended use

### 3.1 Indications for use

The product is intended **exclusively** for orthotic devices for the lower limbs, for dynamic knee-ankle-foot orthoses and knee orthoses with a free swing phase and locked stance phase. The manufacturer recommends that the orthotic knee joint be processed using lamination technology or carbon prepreg technology when used on one side of the body and in pairs.

### 3.2 Indications

#### INFORMATION

To ensure optimal functionality of the orthosis, the patient must generate a knee extension moment before heel lift-off and also at heel impact.

Partial or total paralysis of the leg muscles.

Indications must be determined by the physician.

Ottobock recommends the 646A214 "Therapeutic Application and Gait Training" brochure.

### 3.3 Contraindications

**Contraindications:**

- Contractions in the knee joint that prevent the knee joint lock from being relieved
- Uncontrollable spasticity
- Tuberosity supports

**Additional contraindications when used without a medial support:**

- Non-physiological deviations in the frontal plane
- Non-physiological deviations in the sagittal plane
- Instabilities of the capsular/ligamentous apparatus

**Additional contraindications when used with a medial support:**



- Flexion contractures in excess of 15°

**3.4 Support**


Your national Ottobock team will be happy to answer any technical questions. Contact addresses and telephone numbers are listed on the last page of this manual.

**4 Safety**

**4.1 Explanation of warning symbols**


 CAUTION	Warning regarding possible risks of accident or injury.
 NOTICE	Warning regarding possible technical damage.

**4.2 Safety instructions**

 **CAUTION**

**Risk of falling due to improper use**


Provide your patient with precise instructions on the operation and use of the E-MAG Active. Be sure to inform your patient that, in case of improper use, the joint cannot release prior to toe-off or the swing phase, or cannot lock prior to heel strike. Also inform your patient of the PreLock function.

 **CAUTION**

**Mechanical damage to the product**


Injuries due to changes in or loss of functionality

- ▶ Use caution when working with the product.
- ▶ Check the product for proper function and readiness for use.
- ▶ In case of changes in or loss of functionality, discontinue use of the product and have it checked by authorised, qualified personnel.

 **CAUTION**


**Risk of injury due to the use of unapproved components or spare parts**

Components and spare parts that have not been authorised by the manufacturer may break. Only use components and spare parts approved by the manufacturer for installation and service.

 **CAUTION**

**Explosion hazard**

Do not throw the battery into fire. Never expose it to heat. Avoid direct sunlight. Please pass this information on to your patient.

 **CAUTION**

**Excessive strain on load-bearing components**

Injuries due to changes in or loss of functionality

- ▶ Only use the product for the defined area of application.
- ▶ If the product has been exposed to extreme strain (e.g. due to falling), take any necessary measures (e.g. repair, replacement, inspection by the manufacturer's customer service etc.).

**⚠ CAUTION****Risk of injury due to system joint bars coming loose**

Secure the countersunk head screws for attaching the 17LS3=16, 17LS3=16-T lamination bars with a tightening torque of 7 Nm using 646K13 Loctite 241.

**⚠ CAUTION****Risk of pinching**

Ensure freedom of movement during flexion. Do not allow sockets to overlap. The knee joint has a maximum flexion angle of **140°**.

**⚠ CAUTION****Risk of falling due to incorrect calibration**

During auto-calibration, proceed according to the prescribed steps in order to avoid accidentally triggering the joint.

**⚠ CAUTION****Risk of falling due to improper operation of the service buttons**

You must inform the patient that the service buttons must not be activated or manipulated.

**⚠ CAUTION****Risk of injury during fitting**

We recommend fabricating a trial orthosis in order to verify the functionality and fit before the final orthosis is constructed. Patient suitability can also be verified by following this process. Ensure that the patient is standing securely during this process in order to eliminate the risk of falling. Carry out the fittings between parallel bars.

**⚠ CAUTION****Risk of injury due to incorrect patient selection**

In the selection of patients, ensure that the patient can fully extend the knee during heel lift-off and heel strike.

**⚠ CAUTION****Incorrect alignment, assembly or adjustment**

Risk of injury due to change in or loss of functionality

- ▶ Assembly, adjustment and maintenance operations may only be completed by qualified personnel.
- ▶ Observe the alignment, assembly and adjustment instructions.

**⚠ CAUTION****Exposure of the product to unsuitable environmental conditions**

Patient injury, damage, brittleness or destruction due to improper handling

- ▶ Do not expose the product to condensing ambient humidity or liquids.
- ▶ Do not expose the product to abrasive substances (e.g. sand, dust).
- ▶ Do not expose the product to temperatures below -10 °C (14 °F) or above +60 °C (140 °F) (e.g. sauna, excessive sunlight, drying on a radiator).

**⚠ CAUTION****Improper handling**

Risk of falling due to accidentally opening or engaging the lock

- ▶ Before placing weight on the orthosis, verify that the lock is in the desired position.
- ▶ Avoid accidentally opening or engaging the lock.
- ▶ Instruct the patient in the correct handling of the orthotic joints.

**NOTICE**

**Thermal overloading of the orthosis joint**

Damage to the bearing washers due to improper thermal treatment, loss of orthosis joint movement

- ▶ Do not carry out any heat treatment.
- ▶ Check the function of the orthosis joint.
- ▶ Replace damaged bearing washers.

**CAUTION**

**Knee not fully extended at heel strike**

Risk of injury due to unlocked orthosis joint

- ▶ Fully extend the knee prior to heel strike.

**NOTICE**

**Risk of damage to electronic components due to installation errors or improper use**

Incorrect handling of the electronics can cause malfunctions and/or damage to the electronics. Please observe the following safety instructions:

- ▶ Please read the information regarding the operation of the electronics thoroughly and instruct the patient in the use of the electronics (see the information on the functionality of electronic components).
- ▶ Only install electronic components in the thigh area.
- ▶ All electronic connections should be protected against oxidisation with silicone grease.
- ▶ Only use the M5 x 10 screws included in the scope of delivery.
- ▶ If electronic components are defective, always replace the entire component with a spare part.

**NOTICE**

**Contact with salt water or water containing chlorine/soap as well as abrasive substances (e. g. sand)**

Damage and premature product wear

- ▶ Following any contact with the substances identified above, promptly clean the product in accordance with the section "Cleaning and care".

**INFORMATION**

When using the system in a knee orthosis, take care to ensure that the orthosis is permanently positioned on the leg.

**INFORMATION**

Maintenance and repairs to the orthotic knee joint in the area of the bearing are permitted. Repairs to the locking mechanism may only be performed by an Ottobock Service Centre.

## 5 Preparation for use

### 5.1 Processing

**Installation in the orthosis:**

This section describes the steps required to install the E-MAG knee joint system in an orthosis. It also includes instructions for fabricating a casing which is attached to the outer socket and protects the electronics, cables and battery housing from outside influences. The 17B203=\* knee joint system is supplied to you as a complete package. All required functional components (such as the lamination dummy) are included, except for the medial support and lamination bars.

**NOTICE**

**Damage to the control electronics**

Use the dummies included in the scope of delivery for all process steps until the orthosis is completed. Only replace the dummies with the electronic components directly before the fitting or upon completion of fabrication. The upper joint section of the E-MAG knee joint has threaded blind holes to attach the lamination bars. To avoid damaging the control electronics in the upper joint section of the E-MAG knee joint, only use the supplied M5 x 10 screws.

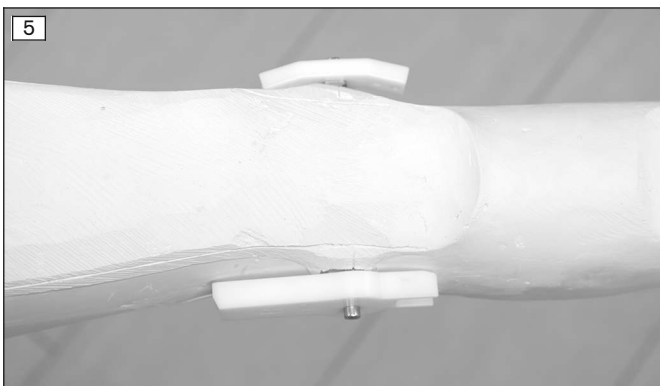


**INFORMATION**

We recommend fabricating a trial orthosis prior to the definitive orthosis. This helps prevent alignment errors and incorrect positioning of the E-MAG knee joint and lets you check that the knee joint is opening and closing reliably.

**5.2 Fabricating the E-MAG orthosis****Installing the E-MAG orthotic knee joint**

Model the patient-specific plaster positive. Position the 30Y297=\* lamination dummy for the orthotic knee joint directly onto the compromise pivot point according to Nietert with the help of the 743R6 joint alignment fixture.



Arrange the 30Y297=\* and 317X206=\* lamination dummies for the orthotic knee joints parallel to each other.

**Positioning of the electronic components**

The electronic components are positioned laterally on the thigh. This prevents a collision with the contralateral side in bilateral fittings. The optimal position for the electronics is proximal and in the vertical course of the load line. If the electronics and battery are located on one side of the thigh, the cable between the electronics and battery is not subjected to unnecessary strain. **Optional:** The battery can also be positioned on the medial side of the thigh.



Select the soft tissue regions and adapt the fibre mesh to the shape of the lamination dummies. Adapt the plaster positive in the selected regions so the lamination dummies lie flat.

Note the length of the cables when positioning the components:

- Battery – electronics: **500 mm**, variable length
- Electronics – knee joint: **300 mm**, fixed length



Mark the final position of the lamination dummies onto the region of the thigh:

- 30Y103 lamination dummy **3** for battery **2** with receptacle **1**.



- 30Y100 lamination dummy **3** for electronics **2** with receptacle **1**.

**CAUTION**

**Risk of injury due to joint bars breaking**

A broken joint bar can result in injury to the patient. Carefully sand down and smooth fissures and ridges on the lamination bars before laminating the orthosis.

**NOTICE**

**Risk of damage due to improper installation**

When setting up the orthosis, ensure that the bending radius is not less than **15 mm** to avoid the risk of breaking. Grind away surface imperfections such as grooves and burrs caused during shaping. The joint bars must not be subjected to heat treatment.

**INFORMATION**

The sole function of the casing is to protect and secure the battery, electronics and cable connections. The casing only has to be large enough to enclose these components.

Remove all lamination dummies except for the E-MAG knee joint dummy and set up the lamination bars. The drilled holes in the insertion area of the knee joint are used to temporarily fasten the lamination bars with a screw during the alignment of the orthosis until the fitting.



Reinforce the orthosis according to the requirements of the patient profile.



Lateral view.

**INFORMATION:**

The 646T5441 technical information for orthosis fabrication titled “Fabricating a definitive knee-ankle-foot orthosis” can be optionally used. Available in German and English. Other languages available on request.

### Fabricating the casing

**CAUTION**

**Risk of damage due to improper installation**

Ensure that no notches are made in the joint bar material during milling since this creates predetermined breaking points.

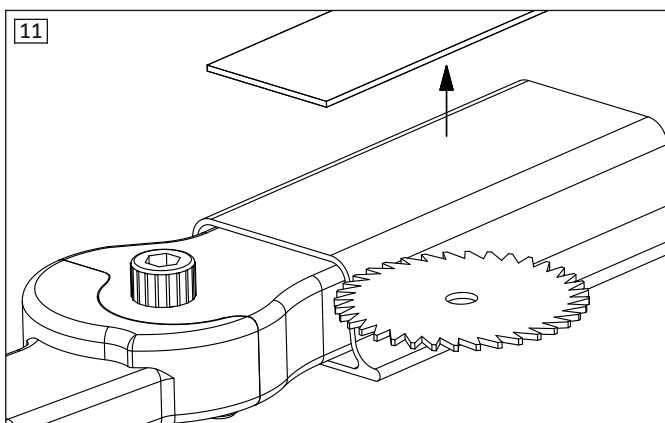
**NOTICE**

**Risk of damage due to improper installation**

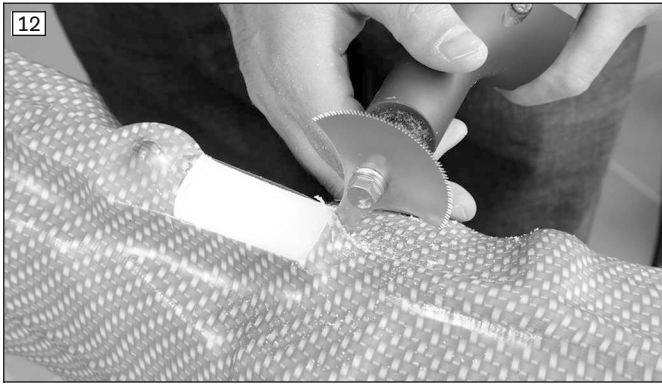
Incorrect installation can cause malfunctions and/or damage to the orthotic knee joint. Please observe the following safety instructions:

- ▶ Follow the instructions for use provided for the charger and battery.
- ▶ Use the supplied dummies. Do not process joint or electronic components directly.
- ▶ Follow the installation instructions and the sequence of the individual steps (see Section 3.1).

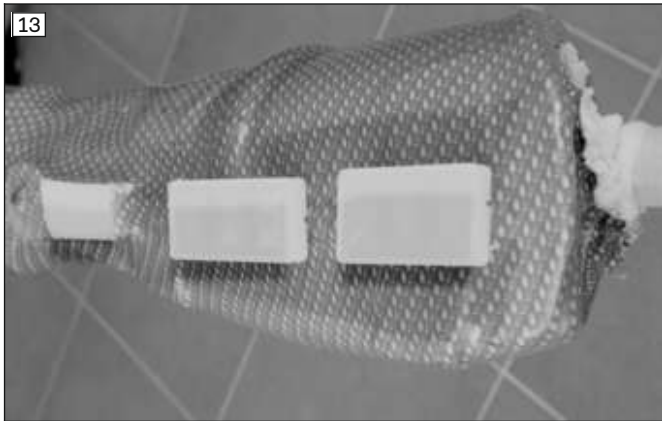
This section describes how to fabricate a casing for protecting and retaining cables and electronic components.



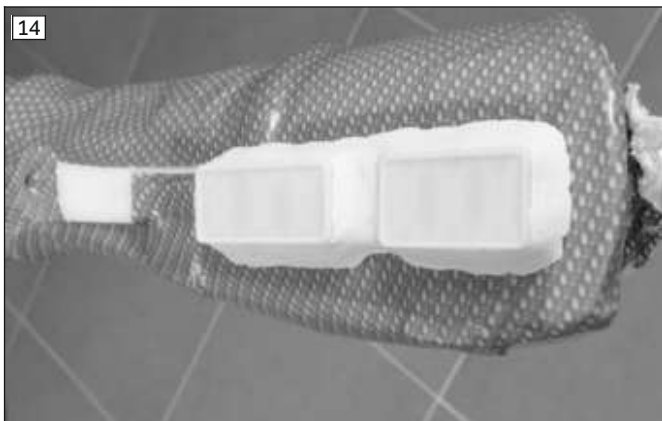
Cut the lamination dummy free.



Mill the cable groove into the lamination dummy.

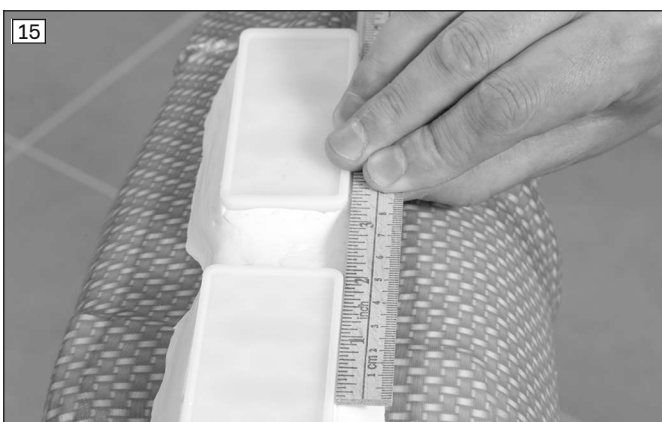


Position the lamination dummies for the electronic components on the model.



Measure the length of the supplied cable dummies:

- For the lamination dummy, **7 mm** between the knee joint and electronics.
- Perlon wire for the cable connecting the electronics to the battery.



Secure the lamination dummies for the electronic components on the model with a strip of double-sided adhesive tape. Fill the edges between the dummies and the socket with plasticine in order to achieve a smooth transition.

Push down the protruding edges with a spatula so there is a distance of **2 mm** between the dummies and plasticine.

Fasten the cable dummies in the designated recesses of the electronics and battery dummies:

- From the orthotic knee joint to the electronics.
- From the electronics to the battery.



Apply the reinforcement for the casing:

- Pull one layer of 99B25 nylon stockinette over the finished orthosis.
- Pull over one PVA bag.
- Pull two layers of Perlon stockinette over the model.
- Secure two layers of carbon fibre mesh on the dummies.
- Pull two layers of Perlon stockinette over the model.
- Pull over one PVA bag.

Fabricate the casing with an appropriate amount of lamination resin.



Demould the casing after it cures. Carefully sand down the lamination dummies of the battery and its receptacle as well as the electronics and their receptacle to the edges.



Fully demould the orthosis from the model and remove all dummies and the plasticine. Sand down the edges of the orthosis and the casing.

Insert the dummy **1** for the electronics into the corresponding receptacle **2**. Position the receptacle in the casing from the outside.

Repeat the steps for the battery receptacle.



**INFORMATION: Ensure that the cable connection goes from the orthotic knee joint cable to the electronics and from the electronics cable to the battery.**

Secure the receptacles and dummies with PVC adhesive tape from the outside. Pull the adhesive tape tight to prevent the sealing resin from penetrating during gluing.





Turn the casing so the receptacles are visible from the inside. Mix a small amount of sealing resin with a sufficient amount of hardener. Do not use too much hardener, since this could cause bubbles to form in the resin during hardening and make the connection brittle. Glue the receptacle to the casing. Carefully let the sealing resin flow in a thin stream around the receptacle into the recess.

### Finishing the orthosis

- 1) Connect the orthotic knee joints to the lamination bars using the screws. Secure the screws in the lamination bars using Loctite 241, and observe the tightening torque of **7 Nm**.
- 2) Connect the orthotic ankle joint to the lamination bar using the screws.
- 3) Fabricate the paddings and hook-and-loop closures.

### Installing the electrical components

#### NOTICE

#### Risk of cable damage

Shortening, extending and frequent bending can destroy the cables between the joint and electronics, and between the battery and electronics. If possible, do not bend or crease the electronics cables until they are ready to be fastened into their final positions.

#### NOTICE

#### Risk of short circuit

Do not insert the battery until the entire system has been assembled.

#### NOTICE

#### Risk of damage to electronic components

Dust, moisture and heat may destroy the electronics.

- ▶ Always seal the electronics on the E-MAG knee joint before sanding or performing other work on the orthosis.
- ▶ Loosen bonded components mechanically. Do not use a hot air gun.

#### INFORMATION

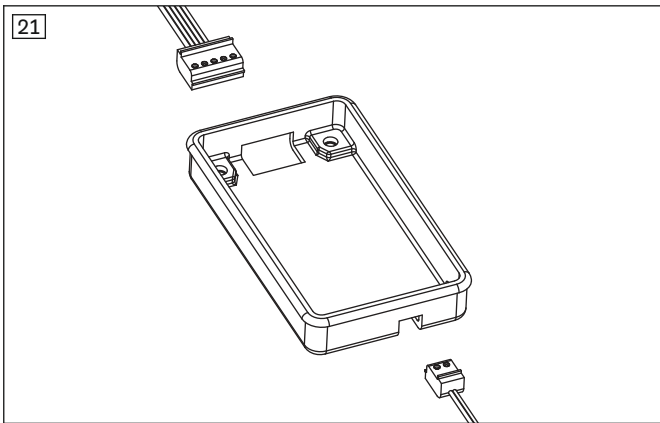
The E-MAG knee joint is equipped with polarity protection: If the polarity is incorrect, the electronics are turned off to prevent a short circuit. If the E-MAG knee joint system fails to indicate operational readiness for no apparent reason after the cables are connected, please check the polarity.

#### INFORMATION

Please ensure that the full cable cross-section is maintained after shortening.

#### INFORMATION

The casing and the electronics cable should be removed when working on the orthosis. To do so, disconnect the cable directly on the E-MAG knee joint.

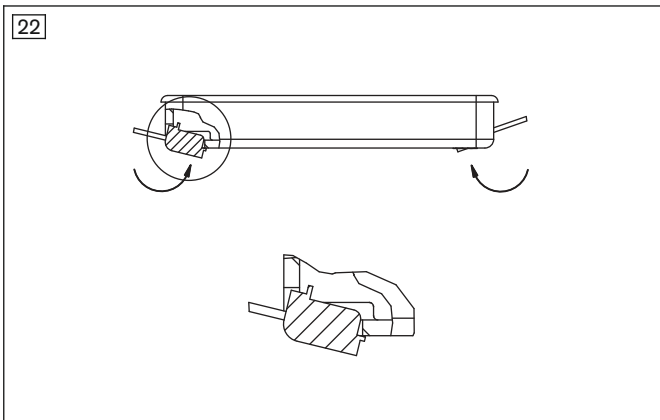
**NOTICE:**

The cable between the orthotic knee joint and electronics may not be shortened or extended.

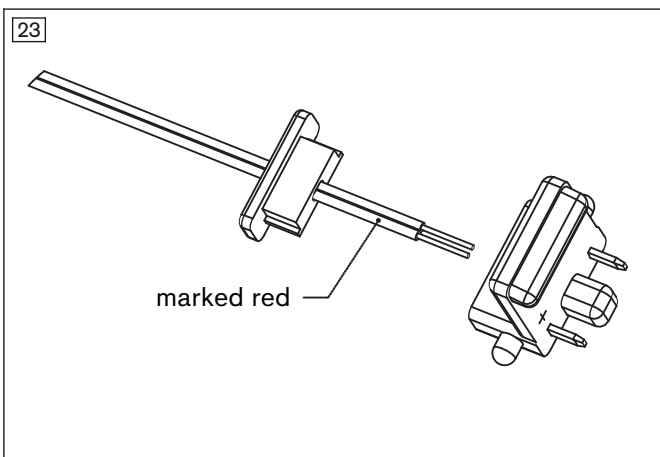
**INFORMATION:** If there is excess cable length, lay the cable in flat loops and secure it in the casing with double-sided adhesive tape.

To install the electrical components, remove the dummies for the electronics and battery from the receptacles.

Connect the two cables to the electronics receptacle.

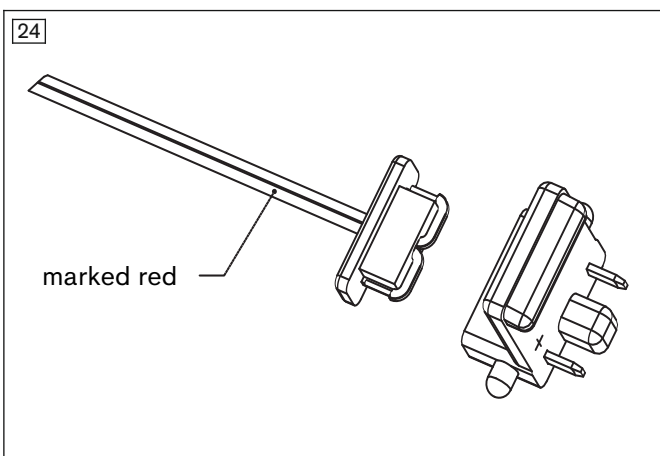


Ensure the cable clips engage properly.



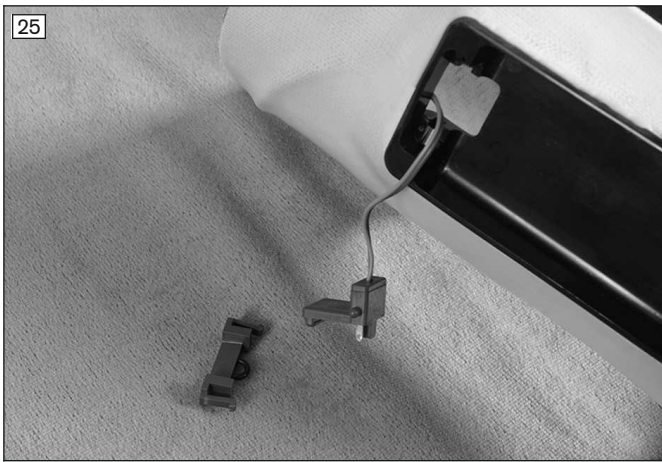
**INFORMATION:** Leave approximately 5 cm of additional cable length to allow for installation of the locking unit.

Optionally, you may shorten the battery cable in the battery plug section. Ensure that the cable cross-section is maintained.

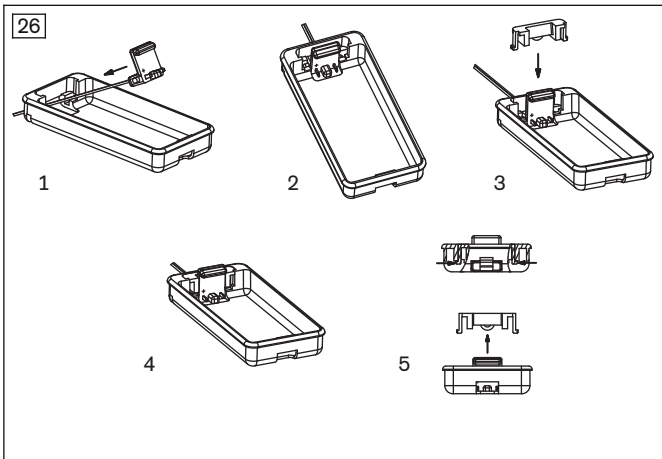


**INFORMATION:** Ensure the correct polarity is maintained after shortening: plus cable (red) to plus connection (+ symbol on locking unit), minus cable (grey) to minus (no symbol).

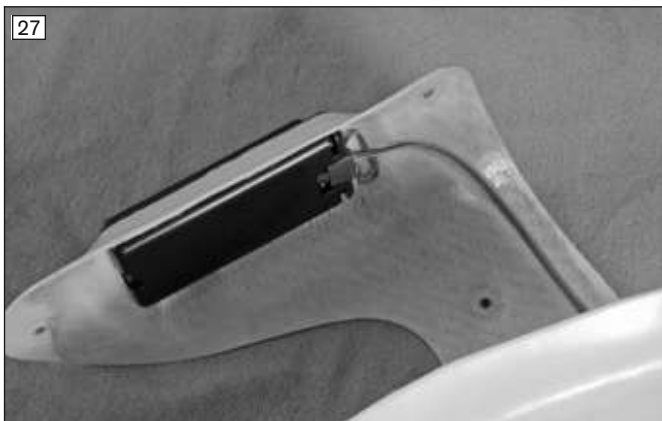
Connect the battery plug to the locking unit.



Thread the battery cable through the receptacle.



Assemble the locking unit of the battery cable. Perform steps 1 through 5 to do so.

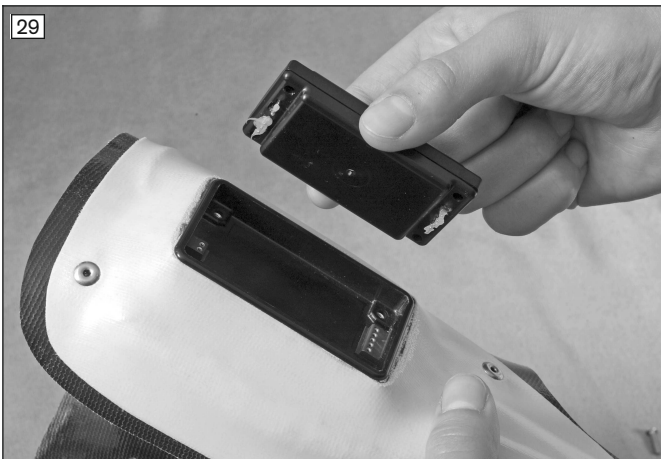


Install the cable from the electronics to the battery. Secure the cable in the cable channel of the casing using double-sided adhesive tape.

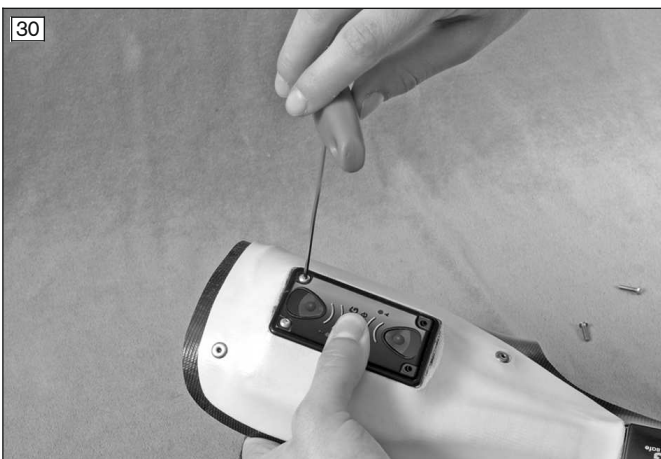


**INFORMATION: Apply 633F11 silicone grease to protect the contacts and cable connections against oxidation.**

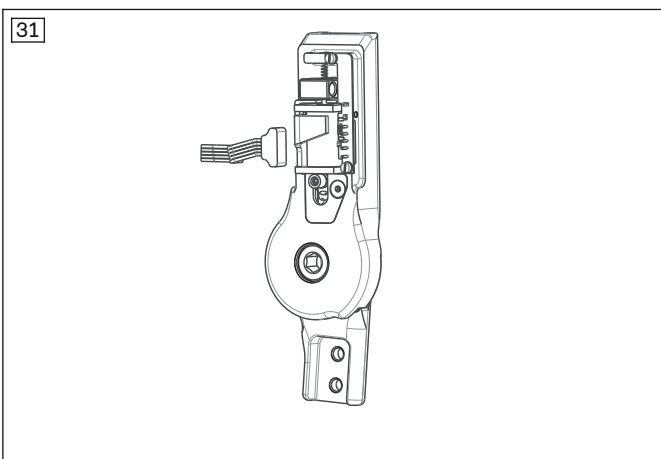




Insert the electronics into the receptacle.

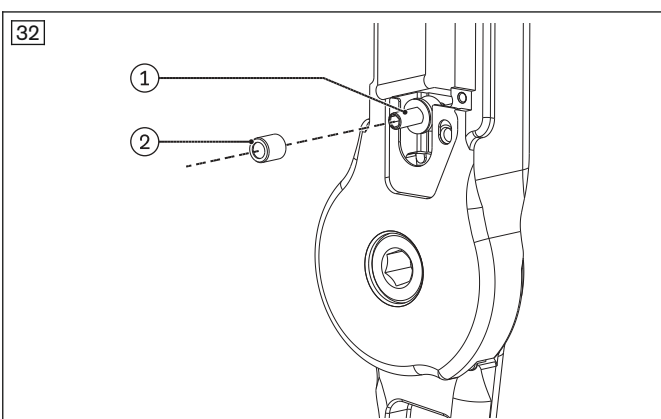


Fasten the electronics using the supplied screws at a maximum torque of **1 Nm**.

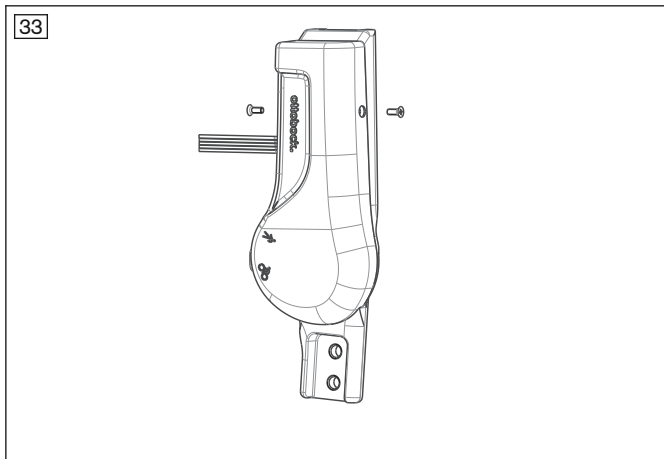


Connect the electronics cable to the orthotic joint:

- Loosen the screws of the cover on the E-MAG orthotic joint.
- Remove the cover.
- Apply silicone grease to the contacts of the electronics cable.
- Connect the electronics cable to the plug contacts.



**INFORMATION:** When removing the joint cover of the E-MAG, ensure that the roller (item 2) stays positioned on the actuating bolt (item 1) to enable secure temporary unlocking.



Secure the cover on the E-MAG orthotic joint using the screws.

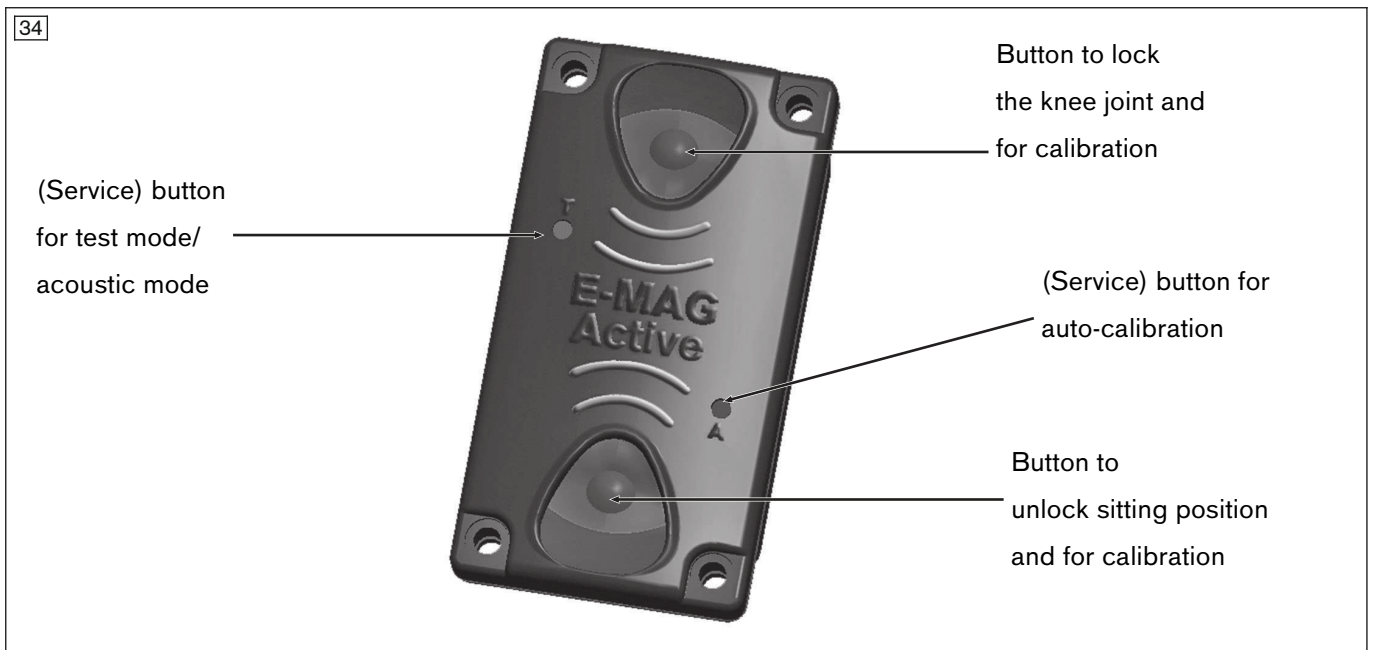
Secure the casing on the upper part of the orthosis. The E-MAG orthotic joint is ready for operation after fully charging and inserting the battery.

### 5.3 Working instructions for electronic components

#### 5.3.1 Control electronics

The electronic control unit measures the position of the orthosis during the gait cycle and unlocks the orthotic joint prior to toe-off. Prior to heel strike at the end of the swing phase, the orthotic knee joint is locked in the extended position so the patient can step down safely. In order to determine the optimum activation point of the orthotic knee joint for the patient, the electronics are equipped with an auto-calibration feature. This must be activated by the O&P professional during the initial patient fitting. A further helpful feature is the test mode, which provides acoustic feedback on joint activity during walking so the O&P professional can determine the settings.

Two switching options are available to the patient. The patient activates/deactivates the sitting and locking function with two separate buttons.



##### 5.3.1.1 Power-on self test – initial battery installation

After all cables are connected, the battery can be inserted. The contacts have to face up and in. In order to do so, insert the battery into the receptacle at an angle and press it against the orthosis. One can hear the battery lock into place when it is properly inserted.

This initiates the system self-test, which runs each time the battery is inserted. Three different audible signals may be emitted:

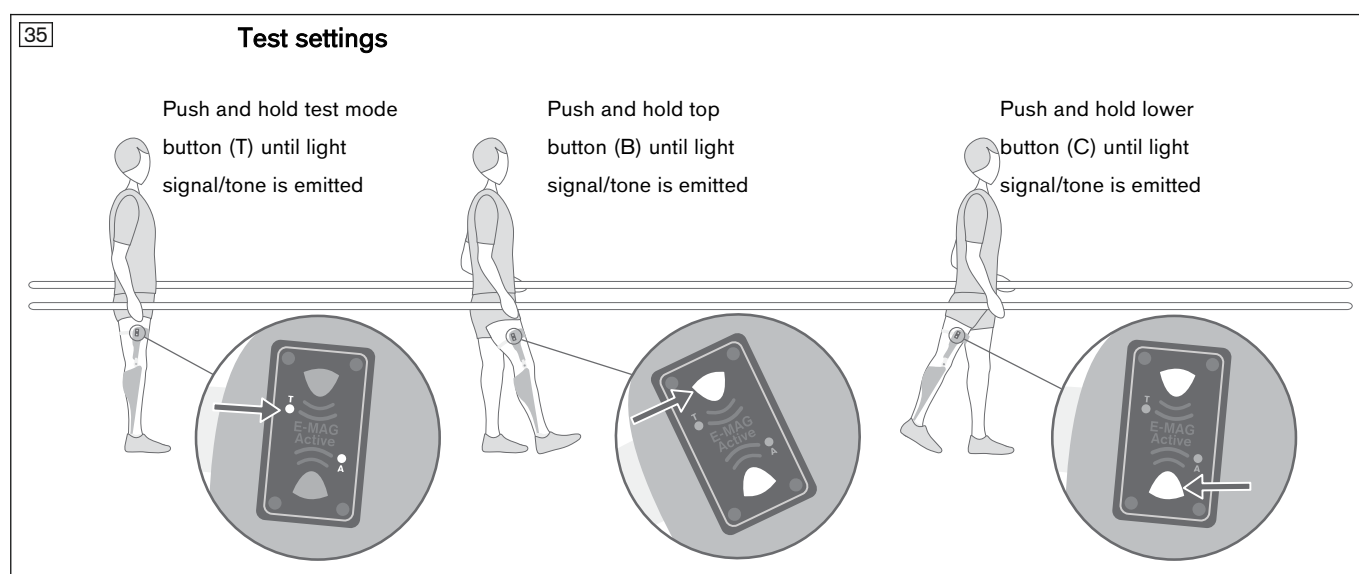
- 1) If the joint is locked when the battery is inserted, the system reports “OK” by briefly illuminating the LEDs and with a short rising tone.

- 2) If the joint is open, the green and white LEDs flash accompanied by a continuous alternating tone sequence (tone, pause, tone). Once the joint is extended, the system reports "OK" as described under 1.
- 3) Sensor error. Continuously illuminated (red) and continuous sound. Remove and then reinsert the battery.

### 5.3.1.2 Initial walking in test mode

Initial walking attempts (see fig. 35) should definitely be made between parallel bars or at least with the help of crutches. In order to make the joint easy to unlock, test mode can be activated so that the system does not look for an optimised setting but opens the joint in a defined toe-off position (provided the patient's knee joint is extended).

- 1) Press the T button for at least **5 seconds** until the system reports that it is ready.
- 2) The patient takes a step forward to simulate heel strike. The technician pushes the top button B. Confirmation is indicated by a white light and low-high tone.
- 3) The patient takes a step back to simulate the end of the stance phase, i.e. shortly before toe-off. The technician confirms by pushing the bottom button C. Once again, confirmation is indicated by a white light and low-high tone. Switching processes of the electronics are also confirmed by an audible tone in parallel to controlling the joint. **INFORMATION: These settings are not saved and are intended for test purposes only!**
- 4) Test mode is deactivated by removing the battery.



### 5.3.1.3 Auto-calibration

#### INFORMATION

Auto-calibration requires the battery to be removed and reinserted after the test mode.

The purpose of auto-calibration is to adjust the electronics to the respective gait pattern of the patient. The settings are independent from the position of the electronics on the orthosis, the design of the orthosis and the fitting side of the patient. We recommend installing the electronics in the vicinity of the hip and the load line (i.e. vertical to the load) in all cases. This allows the patient to easily switch the orthosis functions from the inside of the trouser pocket.

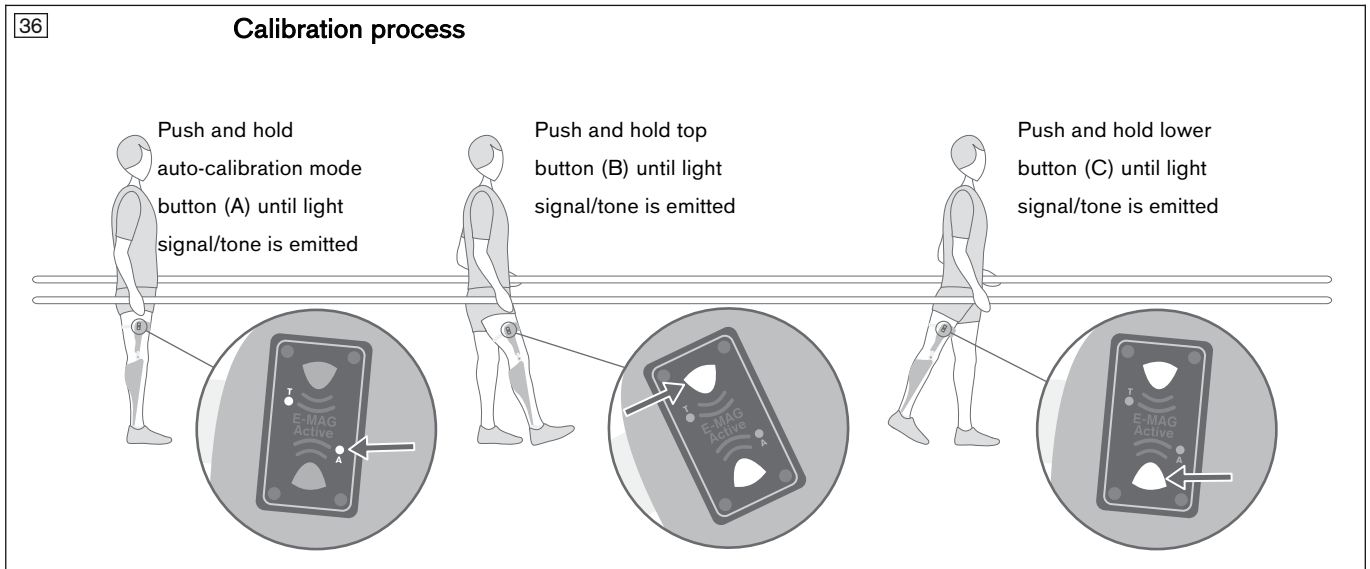
### 5.3.1.4 Auto-calibration adjustment

The electronics need to be calibrated prior to initial use on the patient. Once the settings have been successfully established for the patient, the calibration process does not have to be repeated. However, calibration may be repeated at any time if the patient's gait pattern changes (see fig. 36).

Calibration process:

- 1) During initial use, the patient should stand between parallel bars to ensure their safety at all times.
- 2) The O&P professional removes the battery and reinserts it. The technician then activates calibration mode by pushing and holding the auto-calibrate button (see page ) until an audible tone and light signal are emitted.
- 3) The patient is asked to start taking a step forwards with the leg that is fitted with the orthosis (position similar to heel strike). The patient briefly remains in this position until the technician confirms the position by pressing the top button B (see page ). A brief audible tone combined with a white light indicates confirmation.
- 4) The patient is then asked to simulate toe-off by positioning the leg behind the body's centre of gravity. Once again, the position is confirmed by pressing the lower button C. An audible tone and light signal follow.

- 5) The software now reports that the joint is in calibration mode. The patient can then walk in the locked state until the software uses a different audible tone to warn the patient that the joint is about to automatically unlock at the end of the stance phase in order to facilitate an unobstructed swing-through. The system tries to find the optimal switching point.
- 6) The calibration process is complete when the system indicates the knee joint is ready by means of an audible tone (long, low tone, followed by long, high tone) and a light signal (continuous green-white light). These settings are then saved by the software. If the technician or patient is not satisfied with the settings, steps 1–5 can be repeated as often as desired.



**5.3.1.5 Function and activation of acoustic mode after successful calibration**

Acoustic mode is used to verify whether the switching points were correctly adjusted during calibration. Due to an incorrect patient movement or if the orthosis alignment is not yet optimised, the switching points may deviate. In acoustic mode, an audible tone is emitted in parallel to joint operation during switching processes of the electronics. The audible signal confirms releasing and locking of the joint.

Acoustic mode is activated by pressing the button **T**.

**5.3.1.6 Electronic unlocking (once)**

The patient can use the lower button **C** to unlock the joint once (for instance in order to sit down). They can do this by briefly pressing button **C** twice in quick succession (like double-clicking a computer mouse). This function is not confirmed by an audible signal.

**5.3.1.7 Electronic locking (permanent)**

If the patient feels unsafe, he can lock the joint using the top button **B**. This may be the case when walking on a slope or if the patient wants to stand up for an extended period of time without focusing on the electronic control unit. In order to do so, he briefly presses button **B** twice in quick succession (like double-clicking a computer mouse). This function is confirmed by an audible signal.

The locking function is deactivated by pressing the upper button **B** twice in quick succession until you hear an audible signal.

**5.3.1.8 Mechanical unlocking (temporary)**

**CAUTION**

**Risk of injury due to unlocking of the knee joint**

After activating the release mechanism / unlocking feature (switch to " ⚙️ "), the knee joint is not secured by the E-MAG Active system. In order to use the system for walking (switch to " 🚶 "), it must first be secured by reactivating the release mechanism.



For certain activities (such as cycling), it may be beneficial to temporarily unlock the E-MAG Active joint. Mechanical unlocking of the system is done directly on the knee joint (switch to " ⚙️ ").

The unlocking feature needs to be cancelled in order to restore the functionality of the E-MAG Active joint. The switch is pushed in the opposite direction to secure the system again. The normal state of the joint is indicated by the symbol of a walking person (switch to " 🚶 ").

**CAUTION****Risk of falling due to unlocking / locking**

Both permanent and one-time unlocking as well as permanent locking of the system can result in an elevated risk of falling. The patient should not use these functions whilst walking.

**5.3.1.9 Alarm configuration**

Signal	Visual feedback (LEDs)	Acoustic feedback	Tone/length
Battery low	Alternate flashing (white and red)		High-low series/individual signals
Battery empty			Falling/long

The “Low battery” warning indicates that the battery charge level is low. If the battery is not replaced, the warning is repeated after each status signal. The electronics will turn off if the battery power is insufficient. In this case, the knee joint can also be released manually.

**5.3.1.10 Rechargeable battery****INFORMATION**

Please read the instructions for use of the battery and charger carefully before using the battery for the first time. In particular, please be sure to take note of the safety information provided.

**INFORMATION**

The battery should always be removed when the orthosis is not in use.

**INFORMATION**

Failure to unlock the orthotic knee joint for more than one hour automatically causes the control electronics to switch to standby mode. To reactivate the system, simply push the top button.

The 17B203=\* system is to be used only with the appropriate 317B20 battery (see fig. 37). Prior to initial use, the battery should be charged using the 317L20 battery charger. Insert the battery into the receptacle and make sure it engages. The electrical contact will be made when the mechanical locking mechanism is engaged.

**5.3.1.11 Battery charger****INFORMATION**

Read the instructions for use for the charger thoroughly before using the charger. In particular, be sure to take note of the safety information provided.

**INFORMATION**

The LEDs on the charger must not be illuminated prior to inserting the battery. If they are illuminated, please submit the charger to an authorised Ottobock Service Centre.

The Ottobock 317L20 charger is intended exclusively for charging the 317B20 battery.

37



38



## 6 Cleaning

After contact with water containing salt, chlorine or soap, or if they get dirty, the orthotic joints must be promptly cleaned.

- 1) Clean the joint with a damp cloth when needed.
- 2) Dry it with a lint-free cloth and allow it to air dry fully. Do not expose to direct heat sources (e.g. sunlight, stove or radiator).

## 7 Maintenance instructions

### ⚠ CAUTION

#### Unallowable use of lubricants

Risk of injury and loss of functionality as well as damage to the product

- ▶ The product is designed to be free of lubricants. Avoid contact with lubricants (e.g. grease, oil).
- ▶ After contact with lubricants, promptly clean the product or parts of the product with a degreasing cleaning agent (e.g. acetone or isopropyl alcohol).

### NOTICE

Do not make any structural changes to mechanical or electronic system components.

Please note that the orthosis must be inspected for functionality and signs of wear and tear every six months, that the axial washer and bushing may need to be replaced and that the effectiveness of the locking function and electronics must be verified (for example: visual inspection of cable routing).

The joint connection (bushing and pin) is lubricant-free. The joint mechanism may be optionally protected against dirt with suitable protective devices (such as joint protectors) in order to ensure proper joint functionality.

The joint and electronic components are designed to be resistant against splashed water but are not waterproof!

Use the maintenance schedule (see page 24) as a template for making copies. Retain completed maintenance schedules as part of your documentation and advise the customer of the need for regular maintenance.

### INFORMATION

There is a serial number on the E-MAG case. Take note of it. It serves as proof of the guarantee and is used to identify the corresponding electronic components.

### 7.1 Verification of functionality and inspection for wear

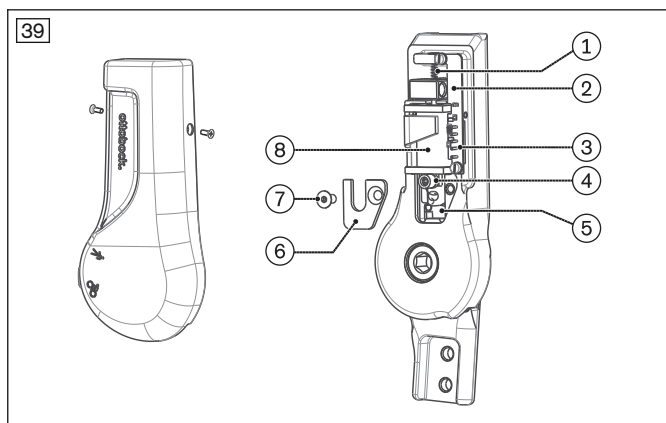
### ⚠ CAUTION

#### Risk of malfunction due to disassembly

The magnet (see fig. 39, item 8), electronics (see fig. 39, item 2) and actuating bolt (see fig. 39, item 4) must not be loosened or removed, since this can affect the functionality of the orthotic knee joint.

### INFORMATION

Document your maintenance work and intervals. The maintenance schedule at the end of this document serves as a template for making copies. We recommend including a copy in your documentation after each maintenance order is completed. Also be sure to inform your customer about the required maintenance intervals.



**INFORMATION:** If the magnet, electronics or actuating bolt malfunction, contact **Ottobock Support**.

Check the components for soiling:

- Remove the joint cover.
- To check the lock, remove the countersunk head screw (item 7) and the lock cover (item 6).
- **Optional:** Remove dirt from the spring (item 1) and lock (item 5) using a brush.
- **Optional:** Clean the plug contacts (item 3) with a brush and then grease them with silicone.

### Replacing joint components

Replace the components if there is wear and tear to the axial washer (see fig. 1, item 2), bearing bushing (item 7) or ELADUR bumper (item 5):

- Remove the joint screw (item 1).
- Disassemble the upper joint section (item 8) from the lower joint section (item 3).
- **Optional:** Replace the axial washer (item 2).

**INFORMATION:** Only use a washer of the same colour when replacing the axial washer contained in the 17BS203 maintenance set.

- **Optional:** Replace the bearing bushing (item 7) (included in the 17BS203 maintenance set).
- In case of wear and tear, replace the ELADUR bumper (item 5) (included in the 17BS203 maintenance set).
- Assemble the orthotic knee joint, and secure the joint screw with a tightening torque of **35 Nm**.

## 7.2 Faults or defects of electronic components

### NOTICE

#### Risk of short circuit

Never open electronic components. If there is a defect, send all electronic components to Ottobock. **Optional:** Replace the 317E2 electronics cable and the 317E20 battery connection cable.

### INFORMATION

The orthotic joint remains locked when the electronic components fail.

- ▶ Remove and then reinsert the battery in order to restart the electronics.

Defects of electronic components are indicated by a continuous light or tone.

The **17B203=L-S**, **17B203=R-S** service set is available for repairs.

The service set is subject to a rental fee outside the warranty period. When sending the E-MAG Active in for service, please be sure to include all of the following components: orthotic knee joint, electronics, battery, battery charger, case with serial number.

### 7.2.1 System does not start

If the system does not start, remove the battery and reinsert it. Should the system still fail to start, there is a defect in the electronics. Check the cable system and contacts. Reinsert the battery. If the system still does not start, replace the electronics.

### 7.2.2 Lock does not close

If the lock of the E-MAG Active does not engage, check the following in sequence:

- 1) Alignment of the orthosis, and if the orthosis wearer reaches the required extension
- 2) The axial washer and the bushing with collar for wear and tear or dust particles inside the joint. If both checks do not resolve the failure, replace the orthotic knee joint.



### 7.3 Maintenance schedule

Maintenance schedule for regular service		E-MAG Active		Patient:
First used on:	Serial number:	Left <input type="checkbox"/>	Right <input type="checkbox"/>	Patient weight [kg]: .....
				User height [cm]: .....
Medial support serial number:		<b>Inspection (checklist for ticking off)</b>		
Item	Department	Yes	No	Measure
<b>1</b>	<b>Orthotic knee joint</b>			
	Dirt/wear and tear?			
	Play in the joint when locked (ML)?			
	Play in the joint when unlocked (ML)?			
	Problem-free unlocking/locking function?			
	Noise?			
	Knee electronics cable connection?			
	Tight connection between bars/joints?			
<b>2</b>	<b>Medial support</b>			
	Play in the joint when unlocked?			
	Noise?			
	Tight connection between bars/joints?			
<b>3</b>	<b>Electronics</b>			
	Cable connections tight and undamaged?			
	Plug connections clean and free of oxidation?			
	Control electronics – correct settings?			
	Blue buttons ok?			
	Tone and light signals ok?			
	Correct activation of stance and swing phase?			
<b>4</b>	<b>Battery and battery charger</b>			
	Battery ok, no damage?			
	Battery connections clean and free of oxidation?			
	Battery lock operates easily and contacts are clean?			
	Function of battery charger ok?			
<b>Notes</b>				
	Do the settings meet the patient's requirements?			
	The maintenance was carried out	by:	.....	
		on:	.....	



## 8 Technical data

<b>Storage temperature range</b>	-20 °C to +70 °C (-4 °F to 176 °F)
<b>Operating temperature range</b>	-15 °C to +50 °C (-5 °F to 122 °F)
<b>Relative humidity for both ranges</b>	15% to 93%
<b>Power supply for joint</b>	NiMh battery, 4.8 V nominal voltage
<b>Range of a battery pack</b>	Approx. 5,000 steps, corresponds to about 5 km

## 9 Disposal

Dispose of the product in accordance with national regulations.

## 10 Legal information

All legal conditions are subject to the respective national laws of the country of use and may vary accordingly.

### 10.1 Liability

The manufacturer will only assume liability if the product is used in accordance with the descriptions and instructions provided in this document. The manufacturer will not assume liability for damage caused by disregarding the information in this document, particularly due to improper use or unauthorised modification of the product.

### 10.2 CE conformity

The product meets the requirements of Regulation (EU) 2017/745 on medical devices. The CE declaration of conformity can be downloaded from the manufacturer's website.

The product meets the requirements of the RoHS Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic devices.



# Kundenservice/Customer Service

## Europe

Otto Bock HealthCare Deutschland GmbH  
Max-Näder-Str. 15 · 37115 Duderstadt · Germany  
T +49 5527 848-3411 · F +49 5527 848-1414  
healthcare@ottobock.de · www.ottobock.de

Otto Bock HealthCare Deutschland GmbH  
Max-Näder-Str. 15 · 37115 Duderstadt · Germany  
T +49 5527 848-3411 · F +49 5527 848-1414  
healthcare@ottobock.de · www.ottobock.de

Otto Bock HealthCare Deutschland GmbH  
Max-Näder-Str. 15 · 37115 Duderstadt · Germany  
T +49 5527 848-3455 · F +49 5527 848-1510  
healthcare@ottobock.de · www.ottobock.de

Otto Bock HealthCare Deutschland GmbH  
Max-Näder-Str. 15 · 37115 Duderstadt · Germany  
T +49 5527 848-3433 · F +49 5527 848-1460  
healthcare@ottobock.de · www.ottobock.de

Otto Bock HealthCare  
Deutschland GmbH  
37115 Duderstadt · Germany  
T +49 5527 848-3433  
F +49 5527 848-1460  
healthcare@ottobock.de

Otto Bock Healthcare Products GmbH  
Brehmstraße 16 · 1110 Wien · Austria  
F +43 1 5267985  
service-admin.vienna@ottobock.com · www.ottobock.at

Otto Bock Healthcare  
Products GmbH  
1110 Wien · Austria  
F +43 1 5267985  
service-admin.vienna@ottobock.com

Otto Bock Adria d.o.o. Sarajevo  
Ramiza Salčina 85  
71000 Sarajevo · Bosnia-Herzegovina  
T +387 33 255-405 · F +387 33 255-401  
obadria@bih.net.ba · www.ottobockadria.com.ba

Otto Bock Adria d.o.o. Sarajevo  
71000 Sarajevo  
Bosnia-Herzegovina  
T +387 33 255-405  
F +387 33 255-401  
obadria@bih.net.ba

Otto Bock Bulgaria Ltd.  
41 Tzar Boris III Blvd. · 1612 Sofia · Bulgaria  
T +359 2 80 57 980 · F +359 2 80 57 982  
info@ottobock.bg · www.ottobock.bg

Otto Bock Bulgaria Ltd.  
1612 Sofia · Bulgaria  
T +359 2 80 57 980  
F +359 2 80 57 982  
info@ottobock.bg

Otto Bock Suisse AG  
Luzerner Kantonsspital 10 · 6000 Luzern 16 · Suisse  
T +41 41 455 61 71 · F +41 41 455 61 70  
suisse@ottobock.com · www.ottobock.ch

Otto Bock Suisse AG  
6000 Luzern 16 · Suisse  
T +41 41 455 61 71  
F +41 41 455 61 70  
suisse@ottobock.com

Otto Bock ČR s.r.o.  
Protetická 460 · 33008 Zruč-Senec · Czech Republic  
T +420 377825044 · F +420 377825036  
email@ottobock.cz · www.ottobock.cz

Otto Bock ČR s.r.o.  
33008 Zruč-Senec  
Czech Republic  
T +420 377825044  
F +420 377825036  
email@ottobock.cz

Otto Bock Iberica S.A.  
C/Majada, 1 · 28760 Tres Cantos (Madrid) · Spain  
T +34 91 8063000 · F +34 91 8060415  
info@ottobock.es · www.ottobock.es

Otto Bock Iberica S.A.  
28760 Tres Cantos (Madrid)  
Spain  
T +34 91 8063000  
F +34 91 8060415  
info@ottobock.es

Otto Bock France SNC  
4 rue de la Réunion · CS 90011  
91978 Courtaboeuf Cedex · France  
T +33 1 69188830 · F +33 1 69071802  
information@ottobock.fr · www.ottobock.fr

Otto Bock France SNC  
91978 Courtaboeuf Cedex  
France  
T +33 1 69188830  
F +33 1 69071802  
information@ottobock.fr

Otto Bock Healthcare plc  
32, Parsonage Road · Englefield Green  
Egham, Surrey TW20 0LD · United Kingdom  
T +44 1784 744900 · F +44 1784 744901  
bockuk@ottobock.com · www.ottobock.co.uk

Otto Bock Healthcare plc  
Egham, Surrey TW20 0LD  
United Kingdom  
T +44 1784 744900  
F +44 1784 744901  
bockuk@ottobock.com

Otto Bock Hungária Kft.  
Tatai út 74. · 1135 Budapest · Hungary  
T +36 1 4511020 · F +36 1 4511021  
info@ottobock.hu · www.ottobock.hu

Otto Bock Hungária Kft.  
1135 Budapest · Hungary  
T +36 1 4511020  
F +36 1 4511021  
info@ottobock.hu

Otto Bock Adria d.o.o.  
Dr. Franje Tuđmana 14 · 10431 Sveta Nedelja · Croatia  
T +385 1 3361 544 · F +385 1 3365 986  
ottobockadria@ottobock.hr · www.ottobock.hr

Otto Bock Adria d.o.o.  
10431 Sveta Nedelja · Croatia  
T +385 1 3361 544  
F +385 1 3365 986  
ottobockadria@ottobock.hr

Otto Bock Italia Srl Us  
Via Filippo Turati 5/7 · 40054 Budrio (BO) · Italy  
T +39 051 692-4711 · F +39 051 692-4710  
info.italia@ottobock.com · www.ottobock.it

Otto Bock Italia Srl Us  
Via Filippo Turati 5/7 · 40054 Budrio (BO) · Italy  
T +39 051 692-4711 · F +39 051 692-4710  
info.italia@ottobock.com · www.ottobock.it

Otto Bock Italia Srl Us  
Via Filippo Turati 5/7 · 40054 Budrio (BO) · Italy  
T +39 051 692-4711 · F +39 051 692-4720  
info.italia@ottobock.com · www.ottobock.it

Otto Bock Italia Srl Us  
Via Filippo Turati 5/7 · 40054 Budrio (BO) · Italy  
T +39 051 692-4711 · F +39 051 692-4720  
info.italia@ottobock.com · www.ottobock.it

Otto Bock Italia Srl Us  
40054 Budrio (BO) · Italy  
T +39 051 692-4711  
F +39 051 692-4720  
info.italia@ottobock.com

Otto Bock Benelux B.V.  
Mandenmaker 14 · 5253 RC  
Nieuwkuijk · The Netherlands  
T +31 73 5186488 · F +31 73 5114960  
info.benelux@ottobock.com · www.ottobock.nl

Otto Bock Benelux B.V.  
5253 RC Nieuwkuijk  
The Netherlands  
T +31 73 5186488  
F +31 73 5114960  
info.benelux@ottobock.com

Industria Ortopédica Otto Bock Unip. Lda.  
Av. Miguel Bombarda, 21 - 2º Esq.  
1050-161 Lisboa · Portugal  
T +351 21 3535587 · F +351 21 3535590  
ottobockportugal@mail.telepac.pt

Industria Ortopédica  
Otto Bock Unip. Lda.  
1050-161 Lisboa · Portugal  
T +351 21 3535587  
F +351 21 3535590  
ottobockportugal@mail.telepac.pt

Otto Bock Polska Sp. z o. o.  
Ulica Korolowa 3 · 61-029 Poznań · Poland  
T +48 61 6538250 · F +48 61 6538031  
ottobock@ottobock.pl · www.ottobock.pl

Otto Bock Polska Sp. z o. o.  
61-029 Poznań · Poland  
T +48 61 6538250  
F +48 61 6538031  
ottobock@ottobock.pl

Otto Bock Romania srl  
Șos de Centura Chitila · Mogoșoaia Nr. 3  
077405 Chitila, Jud. Ilfov · Romania  
T +40 21 4363110 · F +40 21 4363023  
info@ottobock.ro · www.ottobock.ro

Otto Bock Romania srl  
077405 Chitila, Jud. Ilfov  
Romania  
T +40 21 4363110  
F +40 21 4363023  
info@ottobock.ro

OOO Otto Bock Service  
p/o Pultikovo, Business Park „Greenwood”,  
Building 7, 69 km MKAD  
143441 Moscow Region/Krasnogorskiy Rayon  
Russian Federation  
T +7 495 564 8360 · F +7 495 564 8363  
info@ottobock.ru · www.ottobock.ru

OOO Otto Bock Service  
143441 Moscow  
Region/Krasnogorskiy Rayon  
Russian Federation  
T +7 495 564 8360  
F +7 495 564 8363  
info@ottobock.ru

Otto Bock Scandinavia AB  
Postal: Box 4041 · 169 04 Solna · Sweden  
Visiting: Barks Väg 7, Solna, Sweden  
SE: T +46 11 28 06 89 · NO: T +47 23142600  
FI: T +35 8 10 400 6940 · DK: T +45 70 22 32 74  
To order: order@ottobock.se  
Inquiries: info@ottobock.se  
professionals.ottobock.se

Otto Bock Scandinavia AB  
169 04 Solna · Sweden  
SE: T +46 11 28 06 89  
NO: T +47 23142600  
FI: T +35 8 10 400 6940  
DK: T +45 70 22 32 74  
info@ottobock.se



Ottobock SE & Co. KGaA  
Max-Näder-Straße 15 · 37115 Duderstadt · Germany  
T +49 5527 848-0 · F +49 5527 848-3360  
healthcare@ottobock.de · www.ottobock.com