ottobock.

CE

Genium X4 3B5-4=P, 3B5-4=ST

Table of contents

EN

1 Foreword

INFORMATION

Date of last update: 2024-05-15

- ► 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 any serious incident related to the product, in particular any deterioration of health, to the manufacturer and the competent authority in your country.

The product "Genium X4 3B5-4=*“ is called the product/prosthesis/knee joint/component in the following.

The product "USB charging adapter 757L47=1" is referred to as the charging adapter below.

These instructions for use provide you with important information on the use, adaptation and handling of the product.

Only put the product into use in accordance with the information contained in the accompanying documents supplied.

According to the manufacturer (Otto Bock Healthcare Products GmbH), the patient is the operator of the product according to the IEC 60601-1:2005/A2:2020 standard.

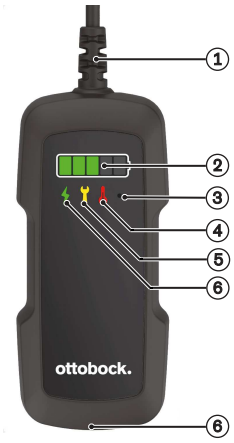
2 Product description

2.1 Design

The product consists of the following components:

1. Knee head with proximal connection (pyramid for 3B5-4=P or screw thread for 3B5-4=ST)
2. Flexion stop (15°, pre-installed)
3. Hydraulic unit
4. ⓘ Status indicator of the knee joint (see page 29)
5. ᛒ LED as indicator for the Bluetooth connection (see page 30)
6. Charging receptacle
7. Distal tube clamp screws

Charging adapter



1. Cable for connecting to the charging receptacle of the prosthetic knee joint
2. LED bar to indicate the charge level while charging (see page 33)
3. Light sensor for adjusting the LED brightness to the ambient light
4. Temperature warning for the battery in the prosthetic knee joint (see page 33)
5. Maintenance indicator (see page 33)
6. Status indicator of the charging adapter (see page 33)
7. USB-C bushing for connecting the power supply or a USB power source using the USB type C to USB type A connection cable (included in the scope of delivery)

2.2 Function

This product features microprocessor control of the stance and swing phase.

The microprocessor uses the measurements of an integrated sensor system as a basis to control a hydraulic unit that influences the damping behaviour of the product.

These sensor data are updated and evaluated 100 times per second. As a result, the behaviour of the product is adapted to the current motion situation (gait phase) dynamically and in real time.

The product can be individually adapted to the needs of the patient with the “560X29-*=* connectgo.pro” adjustment app.

The product features MyModes for special motion types (e.g. golf, table tennis, etc.). These are pre-configured using the adjustment app and can be activated with special movement patterns and the Cockpit app (see page 20).

In case of an error in the sensor system, hydraulic control or when the battery is empty, safety mode provides restricted function and makes safe walking possible. Resistances that are predefined by the product are configured for this purpose (see page 22).

The Cockpit app makes it possible to switch between preconfigured MyModes and to change the product behaviour to a certain extent (e.g. while becoming accustomed to the product). In addition, information about the product (step counter, charge level, etc.) can be retrieved.

With the USB charging adapter, it is possible to charge the knee joint using a mobile power source while out and about (see the section “Charging the battery” see page 10).

The microprocessor-controlled hydraulic unit offers the following advantages

- Approximation of the physiological gait pattern
- Stability while standing and walking
- Adaptation of product characteristics to various surfaces, inclines, gait situations and walking speeds
- Automatic detection of cycling without additional switching (see page 19)
- Walking backwards safely without switching to the swing phase

Essential performance of the product

- Stability in the stance phase
- Initiating the swing phase
- Extension and flexion resistances set automatically by swing phase control

2.3 Combination possibilities

This product can be combined with the following Ottobock components:

Prosthetic hip joints

- 7E9 Monocentric prosthetic hip joint
- 7E10 Helix^{3D} prosthetic hip joint

Adapters

- 4R104=60 double adapter, sliding
- 4R104=75 double adapter, sliding
- 4R57, 4R57=ST Rotation adapter (not waterproof, not corrosion-resistant)

- 4R57=WR, 4R57=WR-ST Rotation adapter (waterproof, corrosion-resistant)
- 4R41 lamination anchor with pyramid receiver
- 4R43 lamination anchor with threaded connector
- 4R47=* Refit adapter for lamination anchor
- 4R48=* Refit socket adapter
- 4R89 lamination anchor with pyramid adapter
- 4R111=N lamination anchor with threaded connector
- 4R111 lamination anchor with pyramid receiver
- 4R116 lamination anchor with pyramid adapter
- 4R119 Lamination anchor with pyramid receiver and angled arm
- 4R40 torsion adapter
- 4R118 adapter plate
- 4R10 Quickchange

Tube adapter

- 2R68=280 Axon tube adapter (waterproof, corrosion-resistant)
- 2R69=280 Axon tube adapter with torsion unit (not waterproof, not corrosion-resistant)

Prosthetic feet

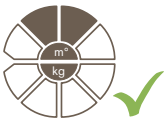
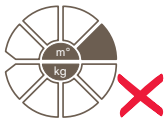
- 1C10 Terion
- 1C30-1 Trias
- 1C31 Trias
- 1C40 C-Walk
- 1C50 Taleo
- 1C51 Taleo Vertical Shock
- 1C52 Taleo Harmony
- 1C53 Taleo Low Profile
- 1C56 Taleo Adjust
- 1C58 Taleo Side Flex
- 1C60 Triton
- 1C61 Triton Vertical Shock
- 1C62 Triton Harmony
- 1C63 Triton Low Profile
- 1C64 Triton Heavy Duty
- 1C68 Triton side flex
- 1C70 Evanto
- 1D35 Dynamic Motion
- 1E56 Axtion
- 1E57 Lo Rider
- 1E95 Challenger
- 1B1 Meridium
- 1B1-2 Meridium
- 1A1-2 Empower
- F11 Maverick Xtreme
- F21 Maverick Xtreme AT
- F22 Maverick Comfort AT
- F23 Maverick Vertical Shock
- LP-W2 Freestyle Swim

2.3.1 Limits for combination options with prosthetic feet

1C63 Triton Low Profile

Body weight	Approved foot size [cm]
Up to 125 kg (up to 275 lbs)	21 to 30
126 kg to 150 kg (276 lbs to 330 lbs)	21 to 28

1C56 Taleo Adjust

	
Approved for mobility class 2 to 3	Not approved for mobility class 4

F21 Maverik Xtreme AT

Body weight	Approved foot size [cm]	Maximum stiffness
Up to 125 kg (275 lbs)	Up to 30	9
126 kg to 150 kg (277 lbs to 330 lbs)	Up to 27	9
	Up to 28	7

FS5 Thrive

Body weight	Approved foot size [cm]	Maximum stiffness
Up to 125 kg (275 lbs)	Up to 31	9
126 kg to 150 kg (277 lbs to 330 lbs)	Up to 26	9

LP2-W2 Freestyle Swim

Body weight	Approved foot size [cm]	Maximum stiffness
Up to 100 kg (220 lbs)	Up to 31	6
101 kg to 150 kg (222 lbs to 330 lbs)	Not approved	

2.3.2 Combination with an osseointegrated implant system

This product can be connected to a socket or to an osseointegrated, percutaneous implant system.

In case of connection to an implant system, verify that the manufacturer of the implant system and the manufacturers of the corresponding exoprosthetic components/adapters also permit this combination. It must be ensured that all indications/contraindications, the field of application, the conditions of use and all safety instructions are complied with for the implant system, corresponding exoprosthetic components, corresponding adapters and for the knee joint.

Among other things, this relates to the body weight, mobility grade, type of activity, load capacity of the implant and bone anchoring, freedom from pain under functional load and compliance with the permissible ambient conditions (see page 25).

Please ensure that the qualified personnel applying the product is not only authorised for fitting this knee joint, but also for the connection to the osseointegrated implant system.

3 Intended use

3.1 Indications for use

The product is to be used **solely** for lower limb exoprosthetic fittings.

3.2 Conditions of use

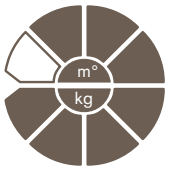
The product was developed for everyday use and must not be used for unusual activities. These unusual activities include, for example, extreme sports (free climbing, parachuting, paragliding, etc.).

Permissible ambient conditions are described in the technical data (see page 25).

The product is intended **exclusively** for use on **one** patient. Use of the product by another person is not approved by the manufacturer.

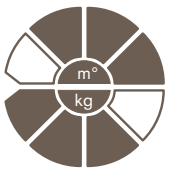
The MOBIS classification describes the mobility grade and body weight, and makes it easy to identify compatible components.

Knee joint with attached 2R68=280 Axon tube adapter



The product is recommended for mobility grade 2 (restricted outdoor walker), mobility grade 3 (unrestricted outdoor walker) and mobility grade 4 (unrestricted outdoor walker with particularly high demands). Approved for a body weight of up to **150 kg (330 lbs)**.

Knee joint with attached 2R69=280 Axon tube adapter with torsion



The product is recommended for mobility grade 2 (restricted outdoor walker), mobility grade 3 (unrestricted outdoor walker) and mobility grade 4 (unrestricted outdoor walker with particularly high demands). Approved for a body weight of up to **125 kg (275 lbs)**.

3.3 Indications

- For patients with knee disarticulation, transfemoral amputation or hip disarticulation
- For unilateral or bilateral amputation
- Those affected by dysmelia, with the characteristics of the affected body part corresponding to a knee disarticulation, transfemoral amputation or hip disarticulation
- Osseointegration
- The patient must fulfil the physical and mental requirements for perceiving visual/acoustic signals and/or mechanical vibrations.
- The patient must be able to understand usage and safety messages and put them into practice.

3.4 Contraindications

3.4.1 Absolute Contraindications

- Body weight over 150 kg

3.4.2 Relative Contraindications

- Body weight less than 35 kg

3.5 Qualification

The product may be fitted only by qualified personnel authorised by Ottobock after completing the corresponding training.

If the product is to be connected to an osseointegrated implant system, the qualified personnel must also be authorised for the connection to the osseointegrated implant system.

4 Safety

Ottobock developed this product according to applicable standards and rules and tested it multiple times. In order for you to enjoy the product, we need your help. Only by complying with the following instructions can we guarantee safe treatment and operation.

4.1 Meaning of warning levels

WARNING! Failure to follow the instructions can lead to serious accidents and injuries.

CAUTION! Failure to follow the instructions can lead to accidents and injuries.

NOTICE! Failure to follow the instructions can result in technical damage.

4.2 Before treatment

WARNING! Possibility of influences on the human body

- ► Observe the areas of application and operating conditions of your product in combination with osseointegrated implant systems according to the information of the manufacturer.
- ► Note the instructions of the clinical personnel that indicated the use of the osseointegrated implant system.

NOTICE! Possibility of damage to the product

- ► Use the appropriate packaging for transportation.

NOTICE! Possibility of product malfunctions

- ► Only work (manipulations) described in this accompanying document may be performed on the product.

4.3 During treatment

CAUTION! Possibility of falling

- ► If the product is to be used in water, salt water or chlorinated water, the entire prosthesis has to be suitable for such use. Resistance to these liquids has to be checked for each prosthetic component.
- ► The listed prosthetic feet may only be combined with the respective foot sizes [cm] described, depending on the patient's body weight. Please contact Ottobock customer service if you would like a combination outside the approved ranges.
- ► Observe the alignment and assembly instructions.
- ► At maximum flexion under full load, it is essential to maintain a minimum distance of 3 mm (5 mm when using a functional cosmesis) between the frame of the knee joint and the socket.
- ► If the minimum distance of 3 mm (5 mm when using a functional cosmesis) is not met, a flexion stop has to be installed. If a flexion stop has already been installed, it has to be replaced with the next larger flexion stop. If the largest flexion stop is already installed, please contact Ottobock Customer Service.
- ► There should be no contact between the knee joint and the socket at maximum extension (obtained through manual extension).
- ► If there is contact, either install an additional, appropriate adapter between the knee joint and the socket, or change the socket position by optimising alignment.

5 Scope of Delivery and Accessories

5.1 Scope of delivery

- 1 pc. 3B5-4 Genium X4 (with pyramid) or 1 pc. 3B5-4=ST Genium X4 (with threaded connector)
- 1 pc. 2R68=280 Axon tube adapter (waterproof, corrosion-resistant) or
  1 pc. 2R69=280 Axon tube adapter with torsion (weatherproof, not corrosion-resistant)
- 1 pc. 757L48=1 Power supply unit with country adapter for US and EU
- 1 pc. 757L47=1 USB Adapter for charging (including USB cable)
- 1 pc. 4H109=7.5 Genium X4 Flexion stop 7.5°
- 1 pc. 4H109=15 Genium X4 15° flexion stop (already installed on delivery)
- 1 pc. 4H109=22.5 Genium X4 22.5° flexion stop
- 2 pc. high-strength hexagon socket head cap screws M3x5 (for assembly of the supplied flexion stop and as replacement for the already assembled screws)
- 1 pc. cosmetic case for USB Adapter for charging and power supply unit
- 1 pc. 646C107 Bluetooth PIN card
- 1 pc. prosthesis passport
- 1 pc. Instructions for use (qualified personnel)
- 1 pc. instructions for use (user)

5.2 Accessories

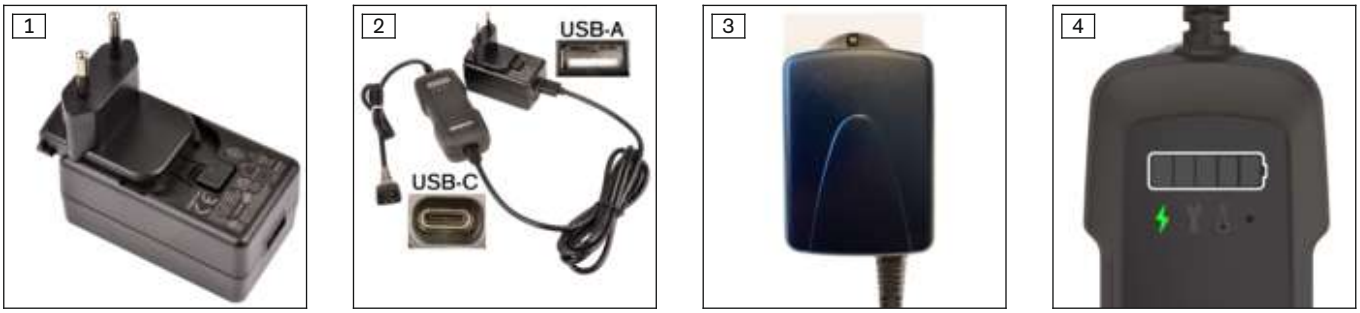
- 4P100=7 Genium X4 Protective cover, short
- 4P110=7 Genium X4 Protective cover, long
- 3F2=0 Functional cosmesis Genium X4
- 99B122=* Functional stocking
- 3D13=1 Tigh kit/Magnetic closure
- 4P112=1 Functional knee part
- 757L45 Charger Genium X4 (charging adapter with USB cable and power supply unit)
- 757S10=GB Country Adapter for power supply
- 757S10=AU Country Adapter for power supply
- "560X29-*=* connectgo.pro" adjustment app for download from the app stores (Apple App Store, Google Play, …). Enter the following search terms: Ottobock, connectgo.
  Further information about the app and how it works can be found either in the link in the description of the app stores or in the installed app.
- "Cockpit 4X441-*=*" app for download from the app stores (Apple App Store, Google Play, …). Enter the following search terms: Ottobock, Cockpit.
  Further information about the app and how it works can be found either in the link in the description of the app stores or in the installed app.

6 Charging the battery

The following points must be observed when charging the battery:

- For charging the battery, use the supplied power supply unit or a USB power source with an output current / power of at least 2.5 A (12.5 W).
  When a portable battery (power bank) is used, it must have a capacity of at least 10,000 mAh to ensure that the prosthetic knee joint will be fully charged.
- Ensure that the USB power source meets the EMC requirements according to EN 55032/EN 55035 at a minimum.
- Use the included charging adapter and included USB cable to charge the battery.
- With average use, the capacity of the fully charged battery is sufficient for about 5 days.
- We recommend charging the product once a day when used by the patient on a daily basis.
- The battery should be charged for at least 3 hours prior to initial use.
- Note the permissible temperature range for charging the battery (see page 25).
- The tube adapter has to be connected before disconnecting the charging adapter, otherwise an error message is generated (see page 29).

6.1 Connecting the power supply and charging adapter



1) Slide the country-specific plug adapter onto the power supply unit until it locks into place (see fig. 1).
2) Use the **provided** USB cable to connect the USB-A bushing on the power supply unit to the USB-C bushing on the charging adapter (see fig. 2).
3) Plug the power supply into the outlet (see fig. 3).
   → The status indicator on the charging adapter lights up green (see fig. 4).

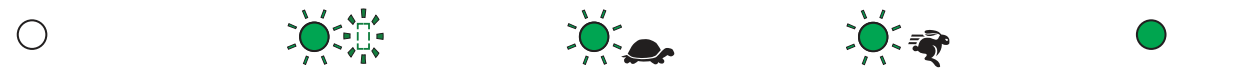
→ If the status indicator on the charging adapter does not light up, or lights up in a different colour, this indicates an error (see page 33).

6.2 Charging the prosthesis battery

1) Connect the charging plug to the charging receptacle of the product.
   INFORMATION: The charging plug is held by a magnet
   → A short vibration signal is generated and a short, soft sound (whee) is produced.
   → The status LED (ⓘ symbol) above the charging receptacle lights up yellow .
   → The charging process starts.
   → The status LED (ⓘ symbol) lights up during the charging process.
   → The charging progress is indicated on the charging adapter by five green LEDs (see page 11).
2) Disconnect the product after the charging process is complete.
   → The status LED (ⓘ symbol) lights up green and a short, soft sound (whee) is produced.

6.3 Display of the current charge level

Illustration of the LED symbols



LED is not lit	LED flashes	LED flashes slowly	LED flashes quickly	LED is lit

6.3.1 Display of the current charge level during the charging process

During the charging process, the current charge level is indicated by the number of LEDs lit on the charging adapter. If the LEDs do not light up or light up in a different colour, this indicates an error. For troubleshooting, see the section "LED symbols on the charging adapter" (see page 33).

0%–20%	20%–40%	40%–60%	60%–80%	80%–95%	>95%

The following charging times apply only when the provided power supply unit and the provided USB cable are used:

Charging time of the prosthesis battery	
Charge level after 1 hour charging time	35 %
Charge level after 2 hours charging time	70 %
Charge level after 3 hours charging time	90 %

Charging time of the prosthesis battery	
Charge level after 4 hours charging time	Fully charged

INFORMATION

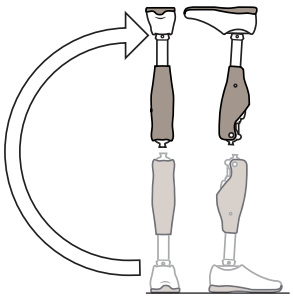
Note charging progress

► When a rechargeable battery has been deeply discharged, charging times may become longer. For this reason, check the charge level on the charging adapter display while charging.
If the first symbol does not light up continuously even after 8 hours , the component must be inspected by an authorised Ottobock Service Centre.

6.3.2 Display of battery charge level without additional devices

INFORMATION

The charge level cannot be queried during the charging process or when MyMode is activated, e.g. by turning the prosthesis over. The product is in charging mode.



1) Turn the prosthesis by 180° (the sole of the foot must face up).
INFORMATION: It must be a complete 180° rotation as shown in the picture. A rotation from a horizontal to a vertical position (90° rotation) is not enough.
2) Hold still for 2 seconds and wait for feedback signals.

Melody/sound	Repeat	LED ⓘ	Charge level	Operating time with new rechargeable battery at room temperature
 (booey)	5x		>80 %	>4 days
	4x		60 % - 80 %	>3 days
	3x		40 % - 60 %	>2 days
	2x		20 % - 40 %	One more day, if the query takes place in the morning
 (wheeoo wop wop)	–	 2x, 4x repeated	<20 %,	Less than one day if the query takes place in the morning

7 Preparing the product for use

7.1 Alignment

INFORMATION:

- **Do not clamp the tube adapter in a vice.**
- **Only shorten the tube adapter with a tube cutter.**
- **When shortening the tube adapter, make sure the cable does not get damaged.**

7.1.1 Shortening the Tube Adapter

1) Screw the tube adapter (maximum length) together with the prosthetic foot.
2) Insert the tube adapter approximately 60 mm into the prosthetic knee joint.
For use, the tube adapter must be inserted at least 40 mm into the prosthetic knee joint. Since the maximum insertion depth is 70 mm, there is 10 mm to slide the tube adapter further in, and 20 mm to pull the tube adapter further out.
3) Measure the overall size.
4) Determine the knee pivot point to ground measurement on the patient.

5) Determine the required length of the tube adapter based on the difference between the overall size and the knee pivot point to ground measurement.
6) Shorten the tube adapter by the determined value with the 719R5 tube cutter.
7) Store the tube adapter cable in the tube adapter. If this is not possible, the cable must be protected against damage.
8) Use a file (cut 2 (medium), e.g. 715H1=2 recommended) to file the cut edge smooth. Be careful of the tube adapter cable.
   NOTICE! When filing or deburring, make sure that no metal shavings can get into the plug of the tube adapter cable.
9) Bevel the outer side with a file.
10) Smooth the inside and outside of the cut edge with sandpaper (recommended grit 120).

7.1.2 Installing the Tube Adapter

1) Install the prosthetic foot on the tube adapter and tighten the **set screws on the tube adapter to 15 Nm**.
   INFORMATION: The printed scale on the tube adapter must face in the anterior direction.
2) Connect the cable of the tube adapter to the cable of the prosthetic knee joint.
   INFORMATION: With the 2R68=280, 2R69=280 tube adapters, the cable of the tube adapter can be shortened by disconnecting the intermediate piece (extension).
3) Push the protruding cable loop back into the tube adapter. If the tube adapter has been shortened to the minimum length, the plug must be inserted into the cavity. The cable loop must then be stored carefully.
4) Insert the tube adapter approximately 60 mm into the prosthetic knee joint.
   INFORMATION: The tube adapter must be inserted at least 40 mm into the prosthetic knee joint. The maximum insertion depth is 70 mm.
5) Tighten the two **distal tube clamp screws to 7 Nm**.

7.1.3 Adjusting the torsion moment on the 2R69=280 Axon tube adapter

INFORMATION:

- **The marking on the hexagon socket screw must not be turned as far as the red area or beyond the red area.**

The torsion moment can be adjusted with the Allen head screw in the centre of the adapter.

Increasing the torsion moment:

► Turn the mark in the centre of the torsion unit clockwise.

Decreasing the torsion moment:

► Turn the mark in the centre of the torsion unit counterclockwise.

INFORMATION

If the patient notices a sudden change in the torsion moment, check whether the mark of the Allen head screw is still within the setting range. Correct the setting if this is not the case.

7.1.4 Disconnecting the tube adapter without a warning message

When the tube adapter is disconnected while the joint is switched on, a sound sequence and vibration signal are emitted. The yellow LED on the back of the knee joint flashes at the same time. In order to prevent this, either switch the joint off (Switching off the product) or perform the following steps before disconnecting the charging adapter:

1) Connect the charging plug to the charging receptacle of the product.
2) Wait 16 seconds.
3) The tube adapter can be disconnected without generating a warning signal.
4) Connect the tube adapter before disconnecting the charging plug.

7.1.5 Bench Alignment

With correct bench alignment, e.g. in the PROS.A. assembly alignment apparatus (743A200), the benefits of the product are realised to best advantage. If the L.A.S.A.R. assembly alignment apparatus (743L200) is available, it can be used as well.
Alignment can also be carried out using LaserLine/plumb line.

INFORMATION

Changed position of the pyramid/threaded connector (0°)

If the fitting was modified from a previous knee joint generation such as the 3B1-2, 3B1-3, 3B5-2, 3B5-3; 3C98-*, 3C88-* to this knee joint (3B5-4=P/3B5-4=ST) without fabricating a new socket, the changed position of the pyramid/threaded connector has to be taken into account since the pyramid/threaded connector is no longer angled (0°). Use intermediate adapters (e.g. 4R47=*, 4R48=*) to adjust the position if necessary.

A calibrated alignment recommendation for bench alignment of the prosthesis is provided in the adjustment app for the individual conditions of the prosthesis and patient. The adjustment app must therefore be consulted for the alignment data.

The following points must be observed during alignment:

- If the static alignment is being carried out with the **Ottobock PROS.A. Assembly or L.A.S.A.R. Assembly alignment apparatus**, this must always be done **without footwear**, otherwise correct adjustment will not be possible.
- Static alignment with a **laser line/plumb line** must be carried out **with footwear** (except 1B1* Meridium), otherwise correct adjustment will not be possible.
- Ensure the knee joint is in full extension during bench alignment. To do so, briefly push the socket once into the fully extended position.

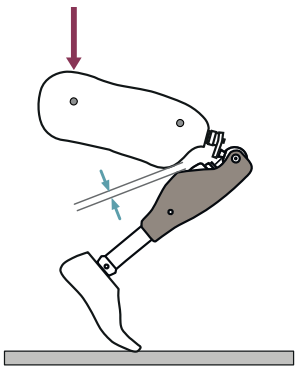
7.1.6 Checking the clearance between the prosthetic socket and knee joint

After bench alignment or changes to the prosthesis, verify that the distance from the socket to the prosthetic knee joint is not less than the minimum under load at maximum flexion and extension. Damage to the hydraulics, frame, electronics housing etc. may occur if the distance is insufficient (flexion) or in case of contact (extension) between the socket and the prosthetic knee joint.

Verification at maximum flexion

The distances and prerequisites for the measurement differ depending on the components that are subsequently combined:

Component	Reference number	Protective component installed/not installed	Distance from socket – prosthetic knee joint under load
Prosthetic knee joint without Protective Cover, without functional cosmesis	3B5-4=*	–	3 mm (**distance to prosthetic knee joint**)
Prosthetic knee joint with Protective Cover, short	3B5-4=* and 4P100=7	Protective Cover **installed**	3 mm (**distance to Protective Cover**)
Prosthetic knee joint with Protective Cover, long	3B5-4=* and 4P110=7	Not relevant	3 mm (**distance to prosthetic knee joint**)
Prosthetic knee joint with functional cosmesis	3B5-4=* and 3F2=0	Functional cosmesis **not installed**	5 mm (**distance to prosthetic knee joint**)



1) Flex the knee joint of the prosthesis and measure the available distance (see table).
2) Then place the prosthesis on the workbench with both hands, grasp the upper area of the socket at the front and place a substantial load on the socket in the flexion direction.
3) Check the available distance between the prosthetic knee joint and socket (see table).
   INFORMATION: If the value falls short of this distance, a flexion stop has to be installed or an existing flexion stop has to be replaced with a larger flexion stop. If the largest flexion stop is already installed, please contact Ottobock Customer Service. For information on the flexion stop, see the next section.

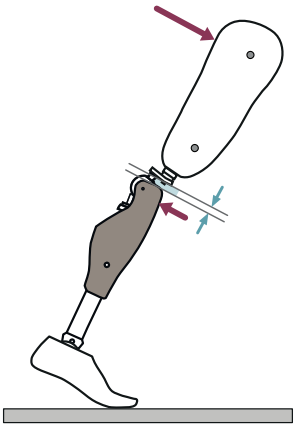
During the fitting, verify that the distance under the user's weight (e.g. kneeling) is not less than the minimum. If the minimum distance is not reached (see table), the next larger flexion stop has to be used.

INFORMATION

Padding material to check the distance

Instead of using a measuring tool, a large piece of padding material (e.g. 617S3 Pedilin from Ottobock) with a thickness of 3 mm or 5 mm can be used as a distance gauge between the socket and knee joint during the test.

Verification at maximum extension



If the distance between the socket and prosthetic knee joint is not sufficient, the joint may be damaged. Check the distance as follows:

1) Position the prosthesis as illustrated.
2) Grasp the prosthetic knee joint from the front with one hand below the pivot point.
3) Then use the other hand to pull the socket from the upper rear to the lower front.
4) There should be no contact between the prosthetic knee joint and the socket.
   INFORMATION: If there is contact, an additional appropriate adapter has to be installed between the prosthetic knee joint and the socket or the socket position has to be changed by optimising the alignment.

7.1.7 Flexion stop

The knee joint comes fitted with a flexion stop upon delivery. This reduces the maximum flexion angle by 15°, thereby preventing the socket from coming into contact with the hydraulics, frame, electronics housing, etc.

To limit the flexion angle, the knee joint can be equipped with the following flexion stops:

- 7.5° flexion stop (optional accessory): Maximum flexion angle 127.5°
- 15° flexion stop (already installed on delivery): Maximum flexion angle 120°
- 22.5° flexion stop (included in scope of delivery): Maximum flexion angle 112.5°

To reach the maximum possible flexion angle of 135°, the flexion stop can be removed. Ensure that the minimum distance of 3 mm or 5 mm between the socket and the joint is maintained (see table in previous section see page 14).

Removing the flexion stop

1) Use an appropriate screwdriver to loosen the screws on the flexion stop (left and right of the piston rod).
2) Remove the flexion stop and screws from the joint.
   INFORMATION: Do not insert the screws without the flexion stop!

Insert the flexion stop

1) Insert the flexion stop.
2) Secure the screws with 636K13 thread lock.
3) Insert the screws.
4) Tighten the screws to 0.6 Nm with the 710D21 torque wrench.

7.1.8 Static alignment optimisation

The adjustment app specifies concrete reference values based on measurement data to help optimise the alignment.

Consideration of the alignment recommendations for bench alignment of the prosthesis is a prerequisite. Minimising the compensation via the residual limb and/or the contralateral side is the goal of optimal alignment.
The patient's required energy expenditure can be reduced by optimising the arrangement of the prosthetic components.

INFORMATION

Common causes of errors during alignment

- ► Foot position with excessive plantar flexion or dorsiflexion.
- ► Insufficient socket flexion. This has to be set according to the measured hip flexion contracture.

INFORMATION

During static alignment optimisation, the knee joint is automatically locked in the flexion direction. This should enable the patient to stand in a stable stance that is unaffected by the alignment. Patients can only walk with the prosthetic leg fully extended in this situation!

7.1.9 Dynamic alignment optimisation

After configuring the product with the adjustment app, dynamic optimisation during trial walking must be carried out. In doing so, the following aspects frequently have to be observed, with adjustments as needed:

- Socket flexion position by verifying step length symmetry (sagittal plane)
- Adduction position of the socket and M-L positioning of the socket adapter (frontal plane)
- Rotation position of the knee joint axis and outward rotation of the prosthetic foot (transversal plane)

8 Use

INFORMATION

Knee joint movement noise

When using exoprosthetic knee joints, servomotor, hydraulic, pneumatic or brake load dependent control functions can cause movement noise. This kind of noise is normal and unavoidable. It generally does not indicate any problems. If movement noise increases noticeably during the lifecycle of the knee joint, the knee joint should be inspected by an authorised Ottobock Service Centre immediately.

8.1 Standing

Knee control through high hydraulic resistance and correct static alignment.

A stance function can be activated using the adjustment app. Please see the following section for further information on the stance function.

8.1.1 Stance function

The stance function (standing mode) is a functional supplement to the basic mode (mode 1). This function makes it easier, for example, to stand on an inclined surface for a longer time. Depending on the situation, the joint is automatically fixed in the flexion direction.

8.2 Walking

Initial attempts at walking with the prosthesis always require the instruction of trained, qualified personnel.

The hydraulics stabilise the knee joint in the stance phase and release the knee joint in the swing phase so that the prosthesis can swing forward freely.

Switching to the swing phase requires a rollover to the front over the prosthesis out of the stride position.

"Start-to-walk" function

With this function, the knee joint can be flexed more easily when starting to take a step without initiating a swing phase. This also makes walking in confined spaces easier since initial flexion is possible not only from the step position via stance release/swing phase initiation but also from the standing position.

Optimised slope ascent

This function makes it easier to walk up ramps by automatically increasing the Preflex value depending on the angle of the ramp, making an easier rollover possible by shortening the stride and leg length. Adapted stance phase control occurs during forward movement to enable a physiological movement pattern.

PreFlex

This function ensures that the knee is at 4° of flexion at the end of the swing phase and in preparation for the heel strike. This makes initiating stance phase flexion easier, improves shock absorption and facilitates forward movement.

8.3 Running short distances ("walk-to-run" function)

For covering short distances quickly, the knee joint detects a transition from walking to running in basic mode and automatically changes the following settings according to the higher dynamics required while running:

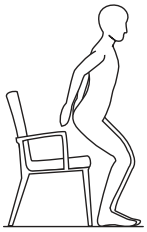
- The swing phase angle is increased
- Preflexion of 4° at heel strike (PreFlex) is reduced to 0°

The requirements to automatically switch to the running motion are fast forward movement of the prosthetic leg and high dynamic load on the knee joint. When stopping from the running motion, the changed settings are set back to the standard values.

INFORMATION

For running long distances, a "Running" MyMode can be configured via the adjustment app (see page 20).

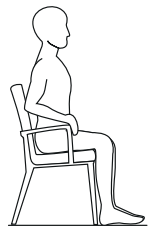
8.4 Sitting down



The resistance in the prosthetic knee joint while sitting down ensures the body is lowered evenly into the sitting position.

1) Place both feet side by side at the same level.
2) While sitting down, weight should be distributed evenly between both legs and the arm supports used if available.
3) Move the buttocks in the direction of the back support and lean the upper body forward.

8.5 Sitting/standing up

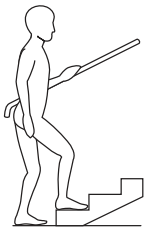


If the patient is in a sitting position for more than two seconds, i.e. the thigh is close to horizontal and there is no load on the leg, the knee joint switches the resistance to a minimum in the extension direction.

Getting up is recognised automatically and the resistance is switched back to the normal stance phase resistance.

8.6 Walking up stairs step-over-step/crossing obstacles

"Stairs and obstacles" function



Although the knee joint is passive, which means it cannot execute any active movements on its own, climbing stairs step-over-step or crossing obstacles is possible.

This function must be consciously practised and executed.

1) Lift the extended prosthesis off the floor.
2) Immediately after lifting the extended leg off the floor, extend the hip briefly and then abruptly flex it. This requires adequate suspension in the prosthetic socket and sufficient residual limb strength.
   → This “whip motion” flexes the knee, because the knee joint automatically recognises the movement and reduces the flexion resistance to minimum.
   INFORMATION: To avoid injuries caused by the prosthesis swinging back and up, take note of people behind you before executing the “whip motion”.

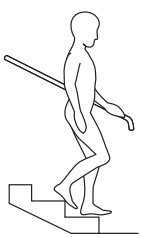
Climbing stairs

1) When sufficient knee flexion has been achieved, the 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.
2) Set the foot onto the next step or across the obstacle.
   At this time, the knee joint is blocked in the flexion direction and therefore provides support for climbing stairs. The foot has to have a sufficient support area on the step so the heel does not project too far over the edge of the step. If the support area is insufficient, the lower leg would extend too early and the function would be deactivated (deactivation of the flexion block, switching to the normal stance phase flexion resistance). In this phase, the knee joint has already set the flexion resistance to maximum (blocked). The knee joint cannot be flexed further, but only extended. This ensures that the leg does not buckle if the hip strength is not sufficient for the extending motion.
3) The user should use their hand for support on the contralateral side. A flat wall is also sufficient for this purpose. This lateral support is intended to prevent twisting of the residual limb in the prosthetic socket, which can cause unpleasant surface tension between the skin and socket. Support also makes it easier to maintain balance.
4) Extend the knee. When the knee joint is fully extended, the initial position has been reached.
5) You can climb the next step or continue walking normally.

Crossing obstacles

► With the knee flexed, step over the obstacle. If there is sufficient knee flexion, the extension resistance is increased to allow enough time for crossing the obstacle.

8.7 Walking down stairs



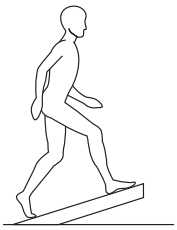
This function must be consciously practised and executed. Only when the sole is properly positioned can the knee joint react correctly and permit controlled flexion.

1) Hold the handrail with one hand.
2) Position the leg with the prosthesis on the step so that the foot projects halfway over the edge of the step.
3) Roll the foot over the edge of the step.
4) Place the foot of the other leg onto the next step.
5) Place the leg with the prosthesis on the next step after that.

8.8 Walking down a ramp

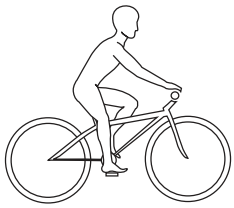
Under increased flexion resistance, permit controlled flexion of the knee joint which lowers the body's centre of gravity.

8.9 Walking up a ramp



Activating the "**Optimised slope ascent**" function makes it easier to walk up ramps.

8.10 Cycling



When the "**Intuitive cycling**" function is activated, cycling is detected due to the characteristic cyclical motion of the prosthesis and the resistance in the prosthetic knee joint is reduced. Upon dismounting from the bicycle, the joint switches back to the resistances for walking and standing.

INFORMATION

The user must wear a bicycle helmet to ensure their safety while cycling.

In addition, the bicycle must have a freewheel function, and the shoes may not be secured on the pedals (with clips, click mountings or the like).

8.11 Walking backwards

It is possible to walk backwards safely and quickly without initiating a swing phase and without excessive flexion.
An increased flexion resistance and situation-specific locking angle make it possible to pull a load backwards, for example.

9 Switching the product on/off

In certain cases, e.g. for storage or transportation, the product can be switched off.
It can be switched on only by connecting to the charging adapter and a USB power source.

Switching off

1) Connect the charging adapter to the prosthetic knee joint with a USB power source.
2) Hold the prosthetic knee joint vertical with the charging adapter connected.
3) Tilt the prosthetic knee joint forwards by 90° and back to the vertical position twice within 10 seconds.
4) Then disconnect the charging adapter within 5 seconds.

→ A falling tone sequence (dee doo day dah) and a vibration signal are generated. The prosthetic knee joint is then switched off.

INFORMATION

Actual deactivation only some time after playing the melody

When there is a Bluetooth connection to a mobile device (LED on the back of the joint shows continuous blue light ●), deactivation occurs only some time after the deactivation melody plays.

Switching on

1) Connect the USB power source to the charging adapter.
2) Connect the charging adapter to the knee joint.
   → You can tell whether the USB power source is properly connected to the knee joint via the charging adapter based on feedback (see page 30 and see page 32).

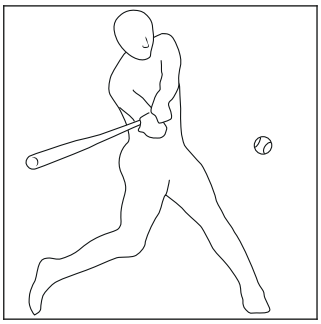
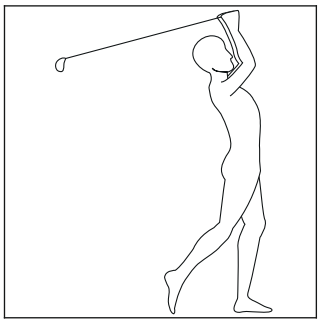
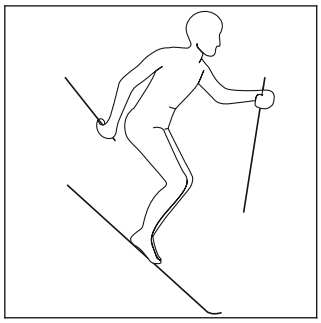
10 Bluetooth

10.1 Establishing the Bluetooth connection

The Bluetooth function provides a wireless connection between the component and various devices. Bluetooth must be switched on at the component in order to establish a connection.

► Rotate the prosthesis by 180° (sole of the foot bottom – sole of the foot top) or connect and then disconnect the charging adapter, in order to make the Bluetooth connection recognizable (visible) for 2 minutes.
   → The LED ✱ on the back of the prosthetic knee joint flashes blue during this time ☼.
   → As long as this LED flashes blue, a Bluetooth connection to a terminal device is possible.

11 MyModes


These MyModes are intended for specific types of movement or posture (e.g. golf, basketball, etc.). They can be activated and configured with the adjustment app in addition to basic mode (mode 1). The patient can switch the MyModes using the Cockpit app or movement patterns. Switching by using movement patterns has to be activated in the adjustment app.

Settings can also be adjusted using the Cockpit app.

11.1 Running function as configured MyMode

For running over longer periods of time, a "**Running**" MyMode can be configured using the adjustment app. This mode can be activated using the Cockpit app or a movement pattern. In this mode, every step will be performed as a running step with a larger swing phase angle and no pre-flexion at heel strike (Preflex).

INFORMATION

The running function will work with specialised running feet such as the 1E95 Challenger as well as with prosthetic feet with axial compression such as the 1C61 Triton Vertical Shock. For details on assembly and alignment please refer to the instructions for use of the foot.

Feet without axial compression are generally not suited for running.

11.2 Switching MyModes using motion patterns

Information on switching

- Before the first step, always check whether the selected mode corresponds to the required motion type.

Requirements for successful switching using motion patterns

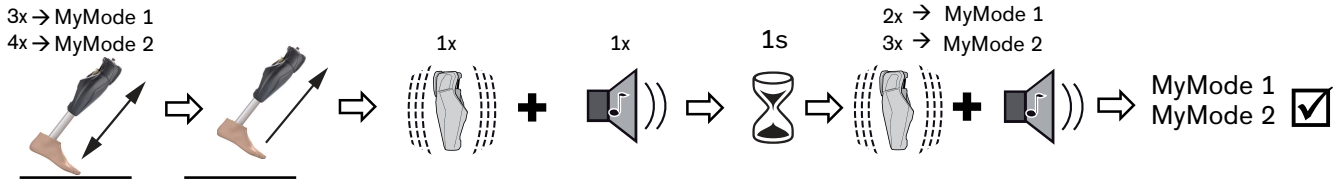
The following points must be observed to carry out switching successfully:

- Switching using movement patterns has to be enabled in the adjustment app.
- Position the prosthetic leg back slightly and bounce on the forefoot with the leg extended while maintaining constant contact with the floor.
- Weight must be placed on the forefoot while bouncing.
- Do not take the weight off fully during unloading while bouncing.

Switching process

INFORMATION

If the **Volume** parameter is set to "0" in the Cockpit app, there are no acoustic signals. Observe the vibration signal in this case.



1) Position the prosthetic leg slightly to the rear (step position).
2) While maintaining constant contact with the floor, bounce on the forefoot with the leg extended according to the desired MyMode (MyMode 1 = three times, MyMode 2 = four times).
3) Keep the prosthetic leg still in this position (step position) without placing weight on it.
   → A vibration signal and acoustic signal will be emitted to confirm that the movement pattern has been recognised (see page 29).
   INFORMATION: If this vibration signal and acoustic signal are not emitted, the requirements were not met while bouncing the forefoot.
4) After the vibration signal and acoustic signal are emitted, keep the prosthetic leg extended with no load for 1 second.

→ A vibration signal and acoustic signal (two times = MyMode 1, three times = MyMode 2) are emitted to indicate successful switching to the respective MyMode.
INFORMATION: If this vibration signal and the corresponding acoustic signal are not emitted, the leg with the prosthesis was not held still correctly. Repeat the process to switch MyModes correctly.

11.3 Switching from a MyMode back to basic mode

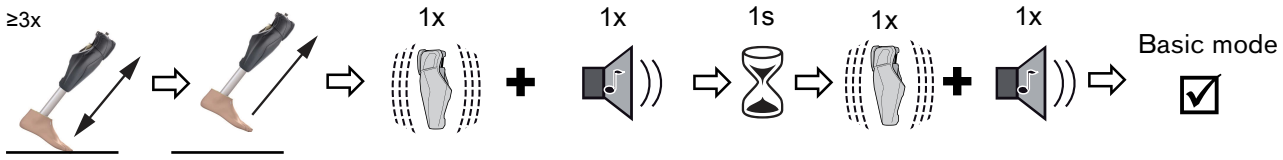
Information on switching

- Regardless of the configuration of the MyModes in the adjustment app, it is always possible to switch back to basic mode (mode 1) using a movement pattern.
- It is always possible to switch back to basic mode (mode 1) by connecting/disconnecting the charging adapter.
- Note the prerequisites for successfully switching using movement patterns at the start of the previous section.
- Before the first step, always check whether the selected mode corresponds to the required motion type.

Switching process

INFORMATION

If the **Volume** parameter is set to "0" in the Cockpit app, there are no acoustic signals. Observe the vibration signal in this case.



1) Position the prosthetic leg slightly to the rear (step position).
2) While maintaining constant contact with the floor, and with the leg extended, bounce on the forefoot three or more times.
3) Keep the prosthetic leg still in this position (step position) without placing weight on it.
   → A single vibration signal and acoustic signal will be emitted to confirm that the movement pattern has been recognised (see page 29).
   INFORMATION: If this vibration signal and acoustic signal are not emitted, the requirements were not met while bouncing the forefoot.
4) After the vibration signal and acoustic signal are emitted, keep the prosthetic leg extended with no load.

→ A single vibration signal and acoustic signal will be emitted to indicate successful switching to basic mode.
INFORMATION: If this vibration signal and acoustic signal are not emitted, the leg with the prosthesis was not held still correctly. Repeat the process to switch MyModes correctly.

12 Additional operating states (modes)

12.1 Empty battery mode

Acoustic signals sound if the available battery charge level is less than 1 per cent (see page 29). Following the acoustic signals, the flexion resistance is set to the safety mode values. This flexion resistance may be low or high depending on the setting in the adjustment app. Then the product is switched off.
After the charging process has been completed (disconnection of the charging adapter from the product), basic mode (mode 1) is activated again.

12.2 Mode for charging the prosthesis

The product is non-functional during charging.
The flexion resistance is set to the safety mode values. This can be low or high depending on the setting in the adjustment app.

12.3 Safety mode

The product automatically switches to safety mode if a critical error occurs (e.g. failure of a sensor signal) or if the battery is drained. Safety mode remains in effect until the error has been rectified.

A flexion resistance (**Safety mode flexion resistance**) configured in the adjustment app is activated in safety mode. This resistance can be set to low or high. If the resistance is set to low, note that the heel strike has to be actively secured through hip extension to prevent falling or unintentional flexing/buckling. The extension resistance is low and cannot be changed. Stance release is not possible. This makes limited walking possible for the patient and allows the patient to sit down, even though the sensor system is not active.

The switch to safety mode is indicated directly beforehand by an acoustic and vibration signal (see page 29).

Safety mode can be disabled by connecting and then disconnecting the charging adapter from the knee joint. The charging adapter has to stay connected until the status LED on the knee joint lights up yellow before it is disconnected. If the knee joint switches into safety mode again, this means there is a permanent error. The knee joint must be inspected by an authorised Ottobock Service Center.

If the temperature continues to increase in overheating mode and the critical temperature of the hydraulics is reached (see the section "Reaching the critical temperature of the hydraulics"), the product first switches to safety mode and then turns off. It automatically switches on again after cooling down.

12.4 Overheating mode

When the knee joint gets very hot due to uninterrupted, increased activity (e.g. extended walking downhill) or external heat sources (sunlight), the flexion resistance is increased along with the rising temperature in order to counteract the overheating. After the knee joint cools down, it switches back to the settings that existed prior to overheating mode.

In the MyModes, the overheating mode signal is generated but there is no increase in the flexion resistance.

Overheating mode is indicated by 4 high sounds (deen deen deen deen) that are repeated every 5 seconds. In addition, the **status LED** on the back of the knee joint **slowly flashes yellow**.

The following functions are deactivated in overheating mode:

- Switching to a MyMode
- Changes to the prosthesis setting

12.4.1 Reaching the critical temperature of the hydraulics

If activity continues despite switching to overheating mode, safety mode is activated once the critical temperature of the hydraulics is reached and the knee joint is then turned off. The **status LED lights up red** to indicate switching to this mode.

The knee joint is automatically switched on again after it cools.

13 Storage

- Before storing the knee joint, the knee head has to be extended. The knee head must not be flexed!
- Avoid extended disuse of the product (use the product regularly).
- Avoid prolonged storage and/or transportation of the product at high temperatures.

14 Cleaning

14.1 Cleaning the knee joint

14.1.1 Cleaning the knee joint with 2R68=280 Axon tube adapter

1) In case of soiling, clean the product with clear fresh water and pH-neutral soap (e.g. Ottobock Derma Clean 453H10=1-N) at a water temperature between 10°C (50°F) and 40°C (104°F).
2) Rinse the soap away with clear fresh water (e.g. under a shower).
   If dirt cannot be removed, even with a jet of water from a garden hose, the product must be sent to an authorised Ottobock Service Center.
3) Dry the product with a lint-free cloth and allow it to air dry fully.
4) If necessary, disinfect the surface by wiping with a surface disinfectant (e.g. Descosept Pur) and drying.

INFORMATION

Please note that the weight of dirt adhering to the prosthesis can affect the gait pattern.

Cleaning after contact with salt water

1) Remove all covers installed on the knee joint (Protective Cover short, Protective Cover long, functional cosmesis).
2) Rinse the knee joint and AXON tube adapter with clear fresh water.
   For the cleaning instructions for the other components, see the instructions for use included with these components.
3) Dry the components with a soft cloth.
4) Allow them to fully air dry in order to remove all residual moisture.
   In case of a malfunction after drying, the knee joint and AXON tube adapter must be inspected by an authorised Ottobock Service Center.

Cleaning after contact with solutions other than fresh or salt water

1) **Promptly** remove all covers installed on the knee joint (Protective Cover short, Protective Cover long, functional cosmesis).
2) **Promptly** rinse the knee joint and AXON tube adapter with clear fresh water. For the cleaning instructions for the other components, see the instructions for use included with these components.
3) Dry the components with a soft cloth.
4) Allow them to fully air dry in order to remove all residual moisture.
   In case of a malfunction after drying, the knee joint and AXON tube adapter must be inspected by an authorised Ottobock Service Center.

14.1.2 Cleaning the knee joint with 2R69=280 Axon tube adapter with torsion

1) Clean the product with a damp cloth and mild soap (e.g. 453H10=1-N Ottobock Derma Clean) when needed. Ensure that no liquid penetrates into the tube adapter.
2) Dry the product with a lint-free cloth and allow it to air dry fully.
3) If necessary, disinfect the surface by wiping with a surface disinfectant (e.g. Descosept Pur) and drying.

14.2 Cleaning the charging adapter

1) Clean the product with a damp cloth and mild soap (e.g. 453H10=1-N Ottobock Derma Clean) when needed. Make sure that no liquid penetrates into the product.
2) Dry the product with a lint-free cloth and allow it to air dry fully.
3) If necessary, disinfect the surface by wiping with a surface disinfectant (e.g. Descosept Pur) and drying.

14.3 Cleaning the contacts of the charging receptacle and charging plug

► Clean the electrical contacts of the charging plug and charging receptacle regularly using a cotton swab and mild soap solution.
NOTICE! Take care to avoid damaging the coating of the contact surfaces with pointed or sharp objects.

15 Maintenance

Regular maintenance (service inspections) at 24-month intervals or every 2.8 million steps, whichever comes first, is mandatory in the interest of patient safety and in order to maintain operating reliability and protect the warranty, maintain basic safety and the essential performance characteristics, and ensure safety with regard to EMC.

The maintenance interval may be reduced by unusual strain.

When maintenance is due, this is indicated by feedback (see the section “Operating states/error signals”, see page 29).

The following components must always be sent in for maintenance and repairs:

The product with installed tube adapter, with installed flexion stops, charging adapter, USB cable and power supply unit used. The packaging material for the loaner unit you previously received must be reused for sending back the components requiring inspection.

Before shipping, the knee head of the prosthetic knee joint has to be extended. The knee head must not be flexed!

16 Legal information

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

16.1 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.

16.2 Trademarks

All product names mentioned in this document are subject without restriction to the respective applicable trademark laws and are the property of the respective owners.

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

Should trademarks used in this document fail to be explicitly identified as such, this does not justify the conclusion that the denotation in question is free of third-party rights.

Bluetooth is a registered trademark of Bluetooth SIG, Inc.

16.3 CE conformity

The following products meet the requirements of the listed European standards. The CE declarations of conformity can be downloaded from the respective manufacturer's website.

Product	Reference number	Specifications
Genium X4	3B5-4=*	Regulation (EU) 2017/745, Directive 2011/65/EU, Directive 2014/53/EU
		Ottobock Healthcare Products GmbH hereby declares that the radio equipment [3B5-4=* Genium X4] complies with Directive 2014/53/EU. The full text of the EU declaration of conformity is available under the following Internet address: https://www.ottobock.com/conformity
AXON tube adapter	2R68=280, 2R69=280	Regulation (EU) 2017/745, Directive 2011/65/EU

Product	Reference number	Specifications
Power supply unit	757L48=1	Directive 2014/35/EU, Directive 2014/30/EU, Directive 2011/65/EU, Directive 2009/125/EG, Regulation (EU) 2019/1782
USB charging adapter	757L47=1	Regulation (EU) 2017/745, Directive 2011/65/EU

16.4 Local Legal Information

Legal information that applies **exclusively** to specific countries is written in the official language of the respective country of use in this chapter.

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

1) This device may not cause harmful interference, and

2) This device must accept any interference received, including interference that may cause undesired operation.

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

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver.

—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

—Consult the dealer or an experienced radio/ TV technician for help.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Caution: Exposure to Radio Frequency Radiation.

This device must not be co-located or operating in conjunction with any other antenna or transmitter.

Caution: Federal law (USA) restricts this device to sale by or on the order of a practitioner licensed by law of the State in which he/she practices to use or order the use of the device.

17 Technical data

Environmental conditions	
Transport in original packaging	-20 °C/-4 °F to +60 °C/+140 °F 15% to 90% relative humidity, non-condensing
Transport and storage between applications (without packaging)	-20 °C/-4 °F to +60 °C/+140 °F 15% to 90% relative humidity, non-condensing Air pressure: 70 kPa to 106 kPa (- 425 m to 3000 m without pressure equalisation)
Storage in the original packaging (≤3 months)	+5 °C/+41 °F to +30 °C/+86 °F 15% to 85% relative humidity, non-condensing
Storage and transport in original packaging (>3 months)	+5 °C/+41 °F to +20 °C/+68 °F 15% to 85% relative humidity, non-condensing
Operation	-5 °C/+23 °F to +45 °C/+113 °F 15% to 90% relative humidity, non-condensing Air pressure: 70 kPa to 106 kPa (- 425 m to 3000 m without pressure equalisation)
Maximum temperature that can be reached at the connection piece between the knee joint and the prosthetic socket before switching to overheating mode	40 °C / 104 °F
Time for warming to the operating temperature after storage between applications, from -20 °C/-4 °F at an ambient temperature of +20 °C/+68 °F	30 minutes

Environmental conditions	
Time for cooling to the operating temperature after storage between applications, from +60 °C/+140 °F at an ambient temperature of +20 °C/+68 °F	30 minutes
Charging the battery	+5 °C/+41 °F to +40 °C/+104 °F 15% to 90% relative humidity, non-condensing Air pressure: 70 kPa to 106 kPa (- 425 m to 3000 m without pressure equalisation)

Knee joint	
Reference number	3B5-4=P / 3B5-4=ST
Mobility grade according to MOBIS	2, 3 and 4
Maximum body weight	150 kg
Permissible additional weight at max. body weight	15 kg
Protection rating	IP66/IP68 Maximum water depth: 3 m Maximum time: 1 hour
Waterproofness	Waterproof, corrosion-resistant, protected against the penetration of jets of water
Proximal system height up to alignment reference point 3B5-4=P (with pyramid) / 3B5-4=ST (with threaded connector)	0 mm / 26 mm
Minimum knee pivot point to ground measurement when using 2R68=280/2R69=280 and 1C63	359 mm
Minimum distal system height with 2R68=280/2R69=280 tube adapter	299 mm / 330 mm
Maximum distal system height with 2R68=280/2R69=280 tube adapter	514 mm / 545 mm
Maximum possible flexion angle	135°
Maximum possible flexion angle with preinstalled 22.5° flexion stop	112.5°
Maximum possible flexion angle with 15° flexion stop	120°
Maximum possible flexion angle with 7.5° flexion stop	127.5°
Maximum insertion depth of the tube adapter in the knee joint	70 mm
Weight of the prosthesis without tube adapter	Approx. 1600 g
Information on the version of the software package	Accessible using the adjustment app
Expected lifetime given compliance with prescribed maintenance intervals	6 years
Test procedure	ISO 10328-P7-150 kg/3 million load cycles

Data communication	
Wireless technology	Bluetooth 5.0 (Bluetooth Low Energy)
Distance range	Approx. 10 m / 32.8 ft
Frequency range	2,402 MHz to 2,480 MHz
Modulation	GFSK
Data rate (over the air)	Up to 2 Mbps
Maximum output power (EIRP):	+4 dBm (~2.5 mW)

Axon tube adapter	
Reference number	2R68=280
Weight	190 g -300 g
Material	Aluminium
Max. body weight	150 kg

Axon tube adapter	
Protection rating	IP66 / IP68 Maximum water depth: 3 m Maximum time: 1 hour
Water resistance	Waterproof and corrosion-resistant
Expected lifetime	6 years
Approved set screws	
Length	16 mm
Reference number	506G3=M8x16 ZN
Maximum tightening torque	15 Nm

Axon tube adapter with torsion				
Reference number	2R69=280			
Weight	190 g–300 g			
Material	Aluminium			
Max. body weight	125 kg			
Protection rating	IP54			
Waterproofness	Not waterproof and not corrosion-resistant			
Expected lifetime	6 years			
Approved set screws				
Length	10 mm	12 mm	14 mm	16 mm
Reference number	506G3=M8x-10	506G3=M8x-12	506G3=M8x-14	506G3=M8x-16
Maximum tightening torque	15 Nm			

Prosthesis battery	
Battery type	Li-ion
Charging cycles (charging and discharging cycles) after which at least 80% of the original battery capacity remains available	500
Behaviour of the product during the charging process	The product is non-functional.
Operating time of the prosthesis with new, fully charged battery at room temperature	Approx. 5 days with average use

The following charging times apply only when the provided power supply unit and the provided USB cable are used:

Charging time of the prosthesis battery	
Charge level after 1 hour charging time	35 %
Charge level after 2 hours charging time	70 %
Charge level after 3 hours charging time	90 %
Charge level after 4 hours charging time	Fully charged

The specified period of use depends on the ambient temperature, the use and the age of the battery.

Charge level	**Walking**	**Sitting**
20 %	3.5 - 6.5 hours	32 - 54 hours
15 %	2.5 - 4.5 hours	35 - 39.5 hours
10 %	1.5 - 3 hours	15 - 25.5 hours
5 %	0.5 - 1 hour	6.5 – 11 hours

Power supply unit	
Reference number	757L48=1
Type	BI18-050300-IU

Power supply unit	
Mains plug	NEMA-1 (type A) e.g.: North America Euro plug (type C) e.g.: Europe The following country adapters are available as accessories: G-Type, BS1363 for UK and I-Type for Australia
Storage and transport with/without packaging	-20 °C/-4 °F to +60 °C/+140 °F 5 % to 95 % relative humidity, non-condensing
Operation	0 °C/+32 °F to +40 °C/+104 °F max. 90 % relative humidity Air pressure: 70 kPa to 106 kPa (-425 m to 3000 m without pressure equalisation)
Input voltage	100 V~ to 240 V~
Mains frequency	50 Hz to 60 Hz
Output voltage	5 V ⎓
Output current	3 A
Lifetime	8 years

Charging adapter	
Reference number	757L47=1
Storage in original packaging	5 °C/+41 °F to +40 °C/+104 °F 15% to 90% relative humidity
Transport in original packaging	-25 °C/-13 °F to +70 °C/+158 °F 15% to 90% relative humidity, non-condensing
Transport and storage between applications (without packaging)	-25 °C/-13 °F to +70 °C/+158 °F 15% to 90% relative humidity, non-condensing Air pressure: 70 kPa to 106 kPa (-425 m to 3000 m without pressure equalisation)
Operation	5 °C/+41 °F to +40 °C/+104 °F 15% to 90% relative humidity Air pressure: 70 kPa to 106 kPa (-425 m to 3000 m without pressure equalisation)
Input jack	USB-C
Input voltage	5 V ⎓
Minimum input current	2.5 A
Output voltage	12 V ⎓
Output current	0.96 A
Weight	90 g
Lifetime	8 years

Torque values of the screw connections

Using a torque wrench, tighten the corresponding screws alternately in several cycles until the specified tightening torque is reached.

Screw connection	**Tightening torque**
Tube adapter on prosthetic foot	15 Nm / 133 lbf. In.
Tube clamp of the knee joint	7 Nm / 62 lbf. In.
Proximal prosthesis components with pyramid receiver	15 Nm / 133 lbf. In.
Proximal prosthesis components with threaded connector	10 Nm / 89 lbf. In.
Flexion stop	0.6 Nm / 5 lbf. In.

18 Appendices

18.1 Symbols Used

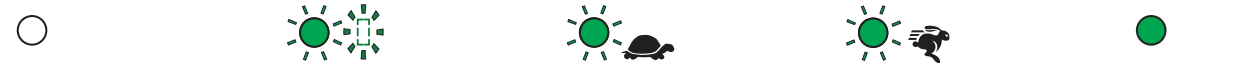
	In some jurisdictions it is not permissible to dispose of these products with unsorted household waste. Disposal that is not in accordance with regulations in your country can be harmful to health and the environment. Please observe the instructions of your national authority pertaining to return and collection procedures.
	Manufacturer
	Type BF applied part The product is classified as a type BF applied part from an electrical point of view only. There is no direct connection between the product and the user's body.
	Complies with the requirements of the Radiocommunications Act (AUS)
	Electrical device, protection class II
IP22	Protection against penetration of solid foreign objects with a diameter greater than 12.5 mm, protection against dripping water when tilted at up to 15°
IP54	Protected against dust, protected against splashed water
IP66	Dust-tight, protected against strong jets of water
IP68	Dust-tight, protection against continuous submersion. Maximum depth: 3 m Maximum time: 1 hour

CE	Declaration of conformity according to the applicable European directives
SN	Serial number (21)YYYYWWNNNN YYYY – year of manufacture WW – week of manufacture NNN – sequential number
MD	Medical device
LOT	Lot number (10)PPPPYYYYWW PPPP – plant YYYY – year of manufacture WW – week of manufacture
UDI	UDI number (Unique Device Identifier)
REF	Article number
	Data matrix code
GTIN	Global Trade Item Number
	Caution, hot surface
	Please note the instructions for use
	Limits for temperature
	Limits for atmospheric pressure
	Limits for relative humidity

18.2 Operating states/error signals

The prosthesis indicates operating states and error messages with vibration and acoustic signals, and by the illumination of the status LED ⓘ and the Bluetooth LED ᛒ above the charging receptacle.

Illustration of the LED symbols

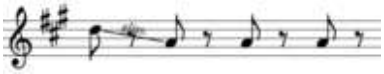
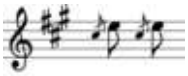
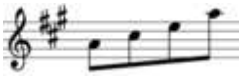


LED is not lit | LED flashes | LED flashes slowly | LED flashes quickly | LED is lit

Brief description of the acoustic signals

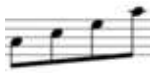
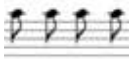
The description of the signal only serves as a rough overview. More detailed information is found in the sections that follow.

Acoustic signals	Text description	Time of occurrence/meaning
 (dee doo day dee doo day)	Double tone sequence with a high tone followed by a medium and a low tone	Maintenance date exceeded, critical temperature of the hydraulics reached, error (active safety mode, tube adapter not connected)

Acoustic signals	Text description	Time of occurrence/meaning
 (toot toot toot toot)	4 high tones	Maintenance is due soon, overheating of the knee joint
 (wheeoo wop wop)	Falling tone, followed by 2 short tones	Display of the charge level <20 %, <15 %, <10 %, <5 %, <2 % during operation
 (booey)	Rising and held tone	Displays charge level between 20% and 99% after querying by “turning over” the prosthesis
 (dee doo day dah)	Falling tones	Knee joint turns off. By switching off manually, if the battery is drained or by activating deep sleep mode
 (whee) Volume can be changed in the app	Short, soft sound	Confirmation of change made to the parameters/functions using the app, execution of mode switching by bouncing, feedback for correctly initiating the swing phase (corresponding parameter must be activated in the app).
 (whooey whooey) Volume can be changed in the app	Two short tones in sequence	Bouncing pattern for switching the MyModes recognised
 (dah day doo dee)	Rising tones	Operational readiness after disconnecting the charging adapter

18.2.1 Signals for operating states

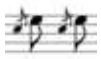
Charging adapter connected/disconnected

Melody/sound	LED ⓘ	Vibration signal	Event
 (whee)	 Illuminated during the charging process	1x	Charging adapter connected, battery is charging.
 (dah day doo dee)	 After the charging adapter is disconnected, this indicator turns off after about 30 seconds.	1x	Charging adapter disconnected from knee joint, joint is ready for operation.
 (deen, deen, deen, deen) 4x repeated	 4x, 4x repeated	1x	**Maintenance is due within 1 month** Use the Cockpit app to check the next maintenance date.

Melody/sound	LED ⓘ	Vibration signal	Event
 (dee doo day dee doo day) 4x repeated	 4x, 4x repeated	1x	**Maintenance date exceeded or unplanned maintenance** due to mechanical or thermal overloading of the knee joint • Use the Cockpit app to check the next maintenance date. • If the maintenance date has not yet been reached or has passed, the product may no longer be used. The product must be inspected by an authorised Ottobock Service Center.

Switching modes/changing settings

The volume of the listed signals can be changed in the Cockpit app.

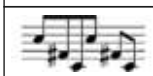
Melody/-sound	Repeat	LED ⓘ	Vibration	Additional action performed	Event
 (whee)	–	 3x	1x	Changing settings using the adjustment app or Cockpit app	New setting was saved in the prosthetic knee joint.
				Mode switching using the adjustment app or Cockpit app	Mode switching is performed using the Cockpit app.
				Swing phase initiated correctly while walking	Corresponding parameter must be switched on in the app.
 (whooey whooey)	–	 3x	1x	Bouncing on the forefoot followed by weight taken off the prosthetic leg	Bouncing pattern recognised.
 (whee)	1x	 3x	1x	Weight taken off prosthetic leg and leg kept still for 1 second	Switching to basic mode (mode 1) carried out.
	2x		2x	Weight taken off prosthetic leg and leg kept still for 1 second	Switching to MyMode 1 (mode 2) carried out.
	3x		3x	Weight taken off prosthetic leg and leg kept still for 1 second	Switching to MyMode 2 (mode 3) carried out.

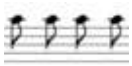
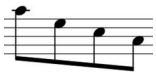
Bluetooth connection

LED ᛒ	Event
	The Bluetooth function is activated. The knee joint is in connection mode for 2 minutes. During this time, the knee joint can be recognised by a mobile device and the connection can be established.
	Bluetooth connection established between the mobile device and the knee joint.

18.2.2 Warnings/error signals

Error during use

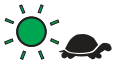
Melody/sound	Repeat	Vibration	LED ⓘ	Event/required action
–	–	Continuous	–	**Total failure** Attempt to reset this error by connecting/disconnecting the charging adapter. If the error persists, use of the product is prohibited. The product must be inspected promptly by an authorised Ottobock Service Centre.
 (dee doo day dee doo day)	8x	8x		**Critical temperature of the hydraulics reached** (see page 23) The prosthetic knee joint is shut down after the signals are generated. Stop activity and wait for the hydraulics to cool down. Automatic restart takes place as soon as the temperature drops sufficiently.

Melody/sound	Repeat	Vibration	LED ⓘ	Event/required action
 (dee doo day dee doo day)	8x	8x	 Continuous	**Indicates safety mode activation** (see page 22) Attempt to reset this error by connecting/disconnecting the charging adapter. If the error persists, use of the product is prohibited. The product must be inspected by an authorised Ottobock Service Center.
 (toot toot toot toot)	Every 5 seconds	–		**Knee joint in overheating mode** (see page 22) • Reduce activity • Note ambient temperatures
 (wheeoo wop wop)	4x	1x	 2x continuous	**Empty battery mode** (see page 22) Charge the battery soon, since the knee joint will be switched off after the signal with the falling sound sequence (dee doo day dah) is generated.
 (wheeoo wop wop)	1x	1x	–	**Charge level below 20 %, 15 %, 10 %, 5 %, 2 %** Charge battery soon
 (dih duh deh dah)	–	–		**Joint is switched off.** This occurs by manually turning off, when the battery is drained, or by activating deep sleep mode.

18.2.3 Status signals

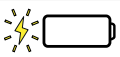
Battery charge level

Feedback after rotating the prosthesis by 180° (sole of the foot down – sole of the foot up).

Melody/sound	Repeat	LED ⓘ	Charge level	Operating time with new rechargeable battery at room temperature
 (booey)	5x		>80 %	>4 days
	4x		60 % - 80 %	>3 days
	3x		40 % - 60 %	>2 days
	2x		20 % - 40 %	One more day, if the query takes place in the morning
 (wheeoo wop wop)	–	 2x, 4x repeated	<20 %,	Less than one day if the query takes place in the morning

18.2.4 LED symbols on the charging adapter

Status LED and battery symbol

LED	Event	Required action
	Charging adapter is not supplied with power!	Check whether the charging adapter is correctly connected to the power supply unit or USB power source. Then check/complete the following items: • Check the outlet with another electrical device. • Check the power supply unit with a different USB device. • Plug in another power supply unit with an output current of at least 2.5 A or a power output of at least 12.5 W. • Check the USB connection cable with another USB device with a USB-C connection. • If a USB power source is being used, check it with a different USB device. • If the USB power source is operated with a rechargeable battery, check the charge level. If the icon does not light up after checking the specified items, the power supply unit, connection cable and charging adapter must be inspected by an authorised Ottobock Service Centre. The O&P professional is your contact.
	Charging adapter ready for operation, but not yet connected to the prosthetic knee joint	If the charging adapter is already connected to the prosthetic knee joint, check the following items: • Foreign object on the charging plug or the charging receptacle • Charging plug or charging receptacle dirty. For cleaning, see the chapter "Cleaning contacts of the charging receptacle and the charging plug" (see page 24). If the icon does not light up despite checking the specified items, the power supply unit, connection cable, charging adapter and prosthetic knee joint must be inspected by an authorised Ottobock Service Centre. The O&P professional is your contact.
	Prosthetic knee joint is charging	–
	Charging in progress with insufficient current!	It will take longer to fully charge the prosthetic knee joint's rechargeable battery. • Check the output current (power) of the USB power source. This has to be at least 2.5 A (12.5 W). • Check the connection cable between the USB power source and the charging adapter. Not all cables are designed to carry a current of 2.5 A or a power of 12.5 W. • Observe the permissible ambient temperatures in the technical data (see page 25).
	The temperature of the rechargeable battery is too high. The joint is not charging!	Observe the permissible ambient temperatures in the technical data (see page 25). Unplug the charging adapter from the prosthetic knee joint and wait a few minutes.

Temperature LED

LED	Event	Required action
	The temperature of the rechargeable battery is more than 52 °C	• Note ambient temperatures during charging (heat sources, radiator, etc.) • Increase the distance from any heat sources
	The temperature of the rechargeable battery is more than 57 °C	• Note ambient temperatures during charging (heat sources, radiator, etc.) • Pause the charging process and allow the knee joint to cool down

Maintenance LED

LED	Event	Required action
	No maintenance required in the near future.	The maintenance date can be seen using the adjustment app or Cockpit app.
	Maintenance is due within 4 weeks	The maintenance date can be seen using the adjustment app or Cockpit app.
	The maintenance date has been exceeded Unplanned maintenance due to mechanical or thermal overloading of the knee joint	• Use the Cockpit app to check the next maintenance date for the prosthesis. • If the maintenance date has not yet been reached or has been exceeded, the product may no longer be used. The product must be inspected by an authorised Ottobock Service Center.

18.3 Directives and manufacturer's declaration

18.3.1 Electromagnetic environment

This product is designed for operation in the following electromagnetic environments:

- Operation in a professional healthcare facility (e.g. hospital, etc.)
- Operation in areas of home healthcare (e.g. use at home, use outdoors)

The customer or user of the product must ensure that it is operated in such an environment.

Observe the safety notices in the section "Safety" (see page 9).

Electromagnetic emissions

Interference measurements	Compliance	Electromagnetic environment directive
HF emissions according to CISPR 11	Group 1/class B	The product uses HF energy exclusively for its internal functioning. Its HF emissions are therefore very low, and interference with neighbouring electronic devices is unlikely.
Harmonics according to IEC 61000-3-2	Not applicable – power below 75 W	–
Voltage fluctuations/flicker according to IEC 61000-3-3	Product meets the requirements of the standard.	–

Electromagnetic interference immunity

Phenomenon	EMC basic standard or Test procedure	Interference immunity test level
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air (except included power supply unit)
High-frequency electromagnetic fields	IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz
Magnetic fields with rated power frequencies	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Electrical fast transients/bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition rate
Surges Line against line	IEC 61000-4-5	± 0.5 kV, ± 1 kV

Phenomenon	EMC basic standard or Test procedure	Interference immunity test level
Conducted interference induced by high-frequency fields	IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur frequency bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage drops	IEC 61000-4-11	0% U_T; 1/2 period At 0, 45, 90, 135, 180, 225, 270 and 315 degrees
		0% U_T; 1 period and 70% U_T; 25/30 periods Single phase: at 0 degrees
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 periods

Interference resistance against wireless communication devices

Test frequency [MHz]	Frequency band [MHz]	Radio service	Modulation	Maximum power [W]	Distance [m]	Interference immunity test level [V/m]
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	1.8	0.3	28
710	704 to 787	LTE band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, GSM 800/900, LTE band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1,720	1,700 to 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1,845						
1,970						
2,450	2,400 to 2,570	Bluetooth WLAN 802.11-b/g/n, RFID 2450 LTE band 7	Pulse modulation 217 Hz	2	0.3	28
5,240	5,100 to 5,800	WLAN 802.11-a/n	Pulse modulation 217 Hz	0.2	0.3	9
5,500						
5,785						

Immunity to magnetic fields in close range

Test frequency	Modulation	Interference immunity test level [A/m]
30 kHz	CW	8
134.2 kHz	Pulse modulation 2.1 kHz	65
13.56 MHz	Pulse modulation 50 kHz	7.5

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