




Kenevo 3C60/3C60=ST

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- NL** | Laat u door deskundig personeel uitleggen hoe u veilig met het product moet omgaan. Andere talen van deze gebruiksaanwijzing zijn online beschikbaar of kunnen gratis in gedrukte vorm worden besteld (zie pagina 2).
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- PL** | Personel fachowy powinien poinstruować użytkownika na temat bezpiecznego używania produktu.
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Bu kullanım kılavuzundaki diğer diller online olarak mevcuttur veya ücretsiz basılı kopya olarak sipariş verilebilir (bkz. sayfa 2).
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Текст настоящего руководства по применению на других языках доступен онлайн или может быть заказан бесплатно в печатном виде (см. стр. 2).
- JA** | 製品の安全な使用方法については、有資格担当者の指示に従ってください。
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Basic UDI-DI: 40644110000000003C60G3

INFORMATION

Date of last update: 2023-07-20

- ▶ Please read this document carefully before using the product and observe the safety notices.
- ▶ Obtain instruction from the qualified personnel in the safe use of the product.
- ▶ Please contact the qualified personnel if you have questions about the product or in case of problems.
- ▶ Report each serious incident related to the product to the manufacturer and to the relevant authority in your country. This is particularly important when there is a decline in the health state.
- ▶ Please keep this document for your records.

The product "Kenevo 3C60/3C60=ST" is referred to as the product/prosthesis/knee joint 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.

2 Product description

2.1 Design

The product consists of the following components:



1. Connection of the knee joint to a trans-femoral socket or other prosthesis component
2. Optional flexion stops
3. Battery and cover caps
4. Hydraulic unit
5. Receiver of the inductive charging unit

2.2 Function

This product features a microprocessor-controlled switch between the stance phase and swing phase and a microprocessor-controlled stance 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.

Thanks to the microprocessor-controlled stance phase, the knee joint can be individually adapted to your needs.

The product can be individually adapted to your needs with adjustment software.

Through the adjustment software, it is possible to choose from three activity modes that make the various functions of the product available. This permits optimum adaptation of the product to the

corresponding mobility grade of the patient. The configured activity mode can only be changed by qualified personnel.

The product features the “**Bicycle ergometer**” MyMode. It has default values configured using the adjustment software and can either be accessed automatically or via the Cockpit app (see page 18).

In case of a product malfunction, safety mode makes restricted operation possible. Resistance parameters that are predefined by the product are configured for this purpose (see page 32).

The microprocessor-controlled hydraulic unit offers the following advantages

- Stability while standing and walking
- Smooth, harmonious, quiet initiation of the swing phase
- Automatic recognition of sitting down. Manual unlocking of the joint not required.
- Support while sitting down with individually adaptable resistance. This resistance remains constant during the entire process of sitting down.
- Support while standing up. The knee joint can be loaded even before reaching full extension.
- Approximation of the physiological gait pattern
- Adaptation of product characteristics to various surfaces, inclines, gait situations and walking speeds
- Manual locking of the knee joint for use of a wheelchair (see page 29). This function makes it possible to lock the knee joint in any extended position while sitting down. This is particularly useful in order to keep the foot from dragging on the ground when the user is being transported in a wheelchair.

Essential performance of the product

- Stability in the stance phase
- Initiating the swing phase
- Adjustable swing phase extension resistance
- Adjustable swing phase flexion resistance

3 Intended use

3.1 Indications for use

The product is intended exclusively for lower limb exoprosthesis fittings.

3.2 Conditions of use

The product was developed for everyday use and should not be used for walking speeds over 3 km/h or 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 35).

The prosthesis is intended for use **exclusively** on the user for whom the adjustment was made.

The manufacturer does not authorise use of the prosthesis on another person.

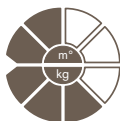
The MOBIS classification describes the mobility grade and body weight, and makes it easy to identify compatible components.

Activity mode A (locked mode)



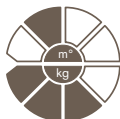
This product is recommended for mobility grade 1 (indoor walker). Approved for a body weight of **max. 125kg**.

Activity mode B (semi-locked mode)



This product is recommended for mobility grade 1 (indoor walker) and mobility grade 2 (restricted outdoor walker). Approved for a body weight of **max. 125 kg**.

Activity mode C (yielding mode)



This product is recommended for mobility grade 2 (restricted outdoor walker). Approved for a body weight of **max. 125 kg**.

3.3 Indications

- For users with knee disarticulation, transfemoral amputation or hip disarticulation.
- For unilateral or bilateral amputation
- Dysmelia patients with residual limb characteristics corresponding to knee disarticulation or a transfemoral amputation
- The user must fulfil the physical and mental requirements for perceiving optical/acoustic signals and/or mechanical vibrations

3.4 Contraindications

3.4.1 Absolute Contraindications

- Body weight over 125 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

4.1 Explanation of warning symbols

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

4.2 Structure of the safety instructions

 WARNING
The heading describes the source and/or the type of hazard
The introduction describes the consequences in case of failure to observe the safety instructions. Consequences are presented as follows if more than one consequence is possible:
> E.g.: Consequence 1 in the event of failure to observe the hazard
> E.g.: Consequence 2 in the event of failure to observe the hazard
▶ This symbol identifies activities/actions that must be observed/carried out in order to avert the hazard.

4.3 General safety instructions

WARNING

Using the prosthesis while operating a vehicle

Accident due to unexpected behaviour of the prosthesis because of changed damping behaviour.

- ▶ All users are required to observe their country's national and state driving laws when operating vehicles with a prosthesis. For insurance purposes, drivers should have their driving ability examined and approved by an authorised test centre.
- ▶ Observe national legal regulations for retrofitting your vehicle in accordance with the type of fitting.
- ▶ The leg on which the prosthesis is worn may not be used to control the vehicle or its peripheral components (e.g. clutch pedal, brake pedal, gas pedal, etc.).

WARNING

Use of damaged power supply unit, adapter plug or battery charger

Risk of electric shock due to contact with exposed, live components.

- ▶ Do not open the power supply unit, adapter plug or battery charger.
- ▶ Do not expose the power supply unit, adapter plug or battery charger to extreme loading conditions.
- ▶ Immediately replace damaged power supply units, adapter plugs or battery chargers.

CAUTION

Failure to observe warning/error signals

Falling due to unexpected product behaviour because of changed damping behaviour.

- ▶ The warnings/error signals (see page 39) and corresponding change in damping settings must be observed.

CAUTION

Independent manipulation of the product and the components

Falling due to breakage of load-bearing components or malfunction of the product.

- ▶ Manipulations to the product other than the tasks described in these instructions for use are not permitted.
- ▶ The battery may only be handled by authorised, qualified Ottobock personnel (no replacement by the user).
- ▶ The product and any damaged components may only be opened and repaired by authorised, qualified Ottobock personnel.

CAUTION

Mechanical stress on the product

- > Falling due to unexpected product behaviour as the result of a malfunction.
- > Falling due to breakage of load-bearing components.
- > Skin irritation due to defects on the hydraulic unit with leakage of liquid.
- ▶ Do not subject the product to mechanical vibrations or impacts.
- ▶ Check the product for visible damage before each use.

CAUTION

Use of the product when battery charge level is too low

Falling due to unexpected behaviour of the prosthesis because of changed damping behaviour.

- ▶ Check the current charge level before use and charge the prosthesis if required.
- ▶ Note that the operating time of the product may be reduced at low ambient temperatures or due to ageing of the battery.

⚠ CAUTION

Risk of pinching in the joint flexion area

Injuries due to pinching of body parts.

- ▶ Ensure that fingers/body parts or soft tissue of the residual limb are not in this area when bending the joint.

⚠ CAUTION

Penetration of dirt and moisture into the product

> Falling due to unexpected product behaviour as the result of a malfunction.

> Falling due to breakage of load-bearing components.

- ▶ Ensure that neither solid particles, foreign objects nor liquids (such as body and/or wound fluids) penetrate into the product.
- ▶ Do not expose the product to splashed water.
- ▶ In the rain, heavy clothing should be worn over the product as a minimum.
- ▶ If water, salt water or body and/or wound fluid has penetrated the product and its components, the Protective Cover (if any) must be removed immediately. Dry the knee joint and components with a lint-free cloth and allow the components to fully air dry. The prosthesis must be inspected by an authorised Ottobock Service Centre. The O&P professional is your contact person.

⚠ CAUTION

Signs of wear and tear on the product components

Falling due to damage or malfunction of the product.

- ▶ Regular service inspections (maintenance) are mandatory in the interest of your own safety and in order to maintain operating reliability and protect the warranty.

NOTICE

Improper product care

Damage to the product due to the use of incorrect cleaning agents.

- ▶ Clean the product with a damp cloth only (fresh water).

4.4 Information on the Power Supply/Battery Charging

⚠ CAUTION

Charging the prosthesis without taking it off

Falling due to unexpected behaviour of the prosthesis because of changed damping behaviour.

- ▶ For safety reasons, wearing the prosthesis is not permitted during the entire charging process.

NOTICE

Use of incorrect power supply unit/battery charger

Damage to product due to incorrect voltage, current or polarity.

- ▶ Use only power supply units/battery chargers approved for this product by Ottobock (see instructions for use and catalogues).

⚠ CAUTION

Charging the product with damaged power supply unit/charger/charger cable

Falling due to unexpected behaviour of the product caused by insufficient charging.

- ▶ Check the power supply unit, charger and charger cable for damage before use.
- ▶ Replace any damaged power supply unit, charger or charger cable.

4.5 Battery charger information

⚠ WARNING

Storing/transporting the product near active implanted systems

Interference with active implantable systems (e.g. pacemaker, defibrillator, etc.) due to the product's magnetic field.

- ▶ When storing/transporting the product in the immediate vicinity of active implantable systems, ensure that the minimum distances stipulated by the manufacturer of the implant are observed.
- ▶ Make sure to observe any operating conditions and safety notices stipulated by the manufacturer of the implant.

NOTICE

Improper care of the housing

Damage to the casing through the use of acetone, white spirit or similar solvents.

- ▶ Only clean the housing with a damp cloth and mild soap (e.g. 453H10=1 Ottobock DermaClean).

NOTICE

Penetration of dirt and humidity into the product

Lack of proper charging functionality due to malfunction.

- ▶ Ensure that neither solid particles nor liquids can penetrate into the product.

NOTICE

Mechanical stress on the power supply/battery charger

Lack of proper charging functionality due to malfunction.

- ▶ Do not subject the power supply/battery charger to mechanical vibrations or impacts.
- ▶ Check the power supply/battery charger for visible damage before each use.

NOTICE

Operating the power supply unit/charger outside of the permissible temperature range

Lack of proper charging functionality due to malfunction.

- ▶ Only use the power supply unit/charger for charging within the allowable temperature range. The section "Technical data" contains information on the allowable temperature range (see page 35).

NOTICE

Independent changes or modifications carried out to the battery charger

Lack of proper charging functionality due to malfunction.

- ▶ Have any changes or modifications carried out only by Ottobock authorised, qualified personnel.

NOTICE**Contact of the battery charger with magnetic data storage devices**

Wiping of the data storage device.

- ▶ Do not place the battery charger on credit cards, diskettes, audio or video cassettes.

4.6 Information on Proximity to Certain Areas**⚠ CAUTION****Insufficient distance to HF communication devices (e.g. mobile phones, Bluetooth devices, WiFi devices)**

Falling due to unexpected behaviour of the product caused by interference with internal data communication.

- ▶ Therefore, keeping a minimum distance of 30 cm to HF communication devices is recommended.

⚠ CAUTION**Operating the product in very close proximity to other electronic devices**

Falling due to unexpected behaviour of the product caused by interference with internal data communication.

- ▶ Do not operate the product in the immediate vicinity of other electronic devices.
- ▶ Do not stack the product with other electronic devices during operation.
- ▶ If simultaneous operation cannot be avoided, monitor the product and verify proper use in the existing setup.

⚠ CAUTION**Proximity to sources of strong magnetic or electrical interference (e.g. theft prevention systems, metal detectors)**

Falling due to unexpected behaviour of the product caused by interference with internal data communication.

- ▶ Avoid remaining in the vicinity of visible or concealed theft prevention systems at the entrance/exit of stores, metal detectors/body scanners for people (e.g. in airports) or other sources of strong magnetic and electrical interference (e.g. high-voltage lines, transmitters, transformer stations...).
- ▶ If this cannot be avoided, make sure to at least have a safeguard when walking or standing (e.g. a handrail or the support of another person).
- ▶ When walking through theft prevention systems, body scanners or metal detectors, watch for unexpected changes in the damping behaviour of the product.
- ▶ In general, monitor the product for unexpected changes in the damping behaviour when electronic or magnetic devices are in the immediate vicinity.

⚠ CAUTION**Entering a room or area with strong magnetic fields (e.g. magnetic resonance tomographs, MRT (MRI) equipment...)**

- > Falling due to unexpected restriction of the product's range of motion caused by metallic objects adhering to the magnetised components.
- > Irreparable damage to the product due to the effect of a strong magnetic field.
- ▶ Take off the product before entering a room or area with strong magnetic fields and store the product outside this room or area.
- ▶ Damage to the product caused by exposure to a strong magnetic field cannot be repaired.

⚠ CAUTION

Remaining in areas outside the allowable temperature range

Falling due to malfunction or the breakage of load-bearing product components.

- ▶ Avoid remaining in areas with temperatures outside of the permissible range (see page 35).

4.7 Information on Use

⚠ CAUTION

Walking up stairs

Falling due to foot placed incorrectly on stair as a result of changed damping behaviour.

- ▶ Always use the handrail when walking up stairs and place most of the area of the sole of your foot on the stair surface.
- ▶ Particular caution is required when carrying children up stairs.

⚠ CAUTION

Walking down stairs

Falling due to foot being placed incorrectly on stair as a result of changed damping behaviour.

- ▶ Always use the handrail when walking down stairs and roll over the edge of the step with the middle of the shoe.
- ▶ Observe the warnings/error signals (see page 39).
- ▶ Be aware that resistance in the flexion and extension direction can change in case of warnings and error signals.
- ▶ Particular caution is required when carrying children down stairs.

⚠ CAUTION

Overheating of the hydraulic unit due to uninterrupted, increased activity (e.g. extended walking downhill)

- > Falling due to unexpected behaviour of the product because of switching into overheating mode.
- > Burns due to touching overheated components.
- ▶ Be sure to pay attention when pulsating vibration signals start. They indicate the risk of overheating.
- ▶ As soon as these pulsating vibration signals begin, you must reduce your level of activity so the hydraulic unit can cool down.
- ▶ Full activity may be resumed after the pulsating vibration signals stop.
- ▶ If the activity level is not reduced in spite of the pulsating vibration signals, this could lead to the hydraulic element overheating and, in extreme cases, cause damage to the product. In this case, the product should be inspected for damage by an O&P professional. If necessary, they will forward the product to an authorised Ottobock Service Center.

⚠ CAUTION

Overloading due to unusual activities

- > Falling due to unexpected product behaviour as the result of a malfunction.
- > Falling due to breakage of load-bearing components.
- > Skin irritation due to defects on the hydraulic unit with leakage of liquid.
- ▶ The product was developed for everyday use and should not be used for walking speeds over 3 km/h or unusual activities. These unusual activities include, for example, extreme sports (free climbing, parachuting, paragliding, etc.).

- ▶ Careful handling of the product and its components not only increases their service life but, above all, ensures your personal safety!
- ▶ If the product and its components have been subjected to extreme loads (e.g. due to a fall, etc.), then the product must be inspected for damage immediately by an O&P professional. If necessary, he or she will forward the product to an authorised Ottobock Service Centre.

CAUTION

Overloading due to changes in body weight when carrying heavy objects, backpacks or children

- > Falling due to unexpected behaviour of the product.
- > Falling due to breakage of load-bearing components.
- > Skin irritation due to defects on the hydraulic unit with leakage of liquid.
- ▶ Note that the behaviour of the product can change due to increased weight. It is possible that the swing phase may not be triggered, or triggered at the wrong time.
- ▶ Make sure that the permissible additional weight at the maximum body weight is not exceeded (see the section "Technical data", see page 35)

CAUTION

Incorrect switching between "Bicycle ergometer" MyMode/"Basic mode"

Falling due to unexpected product behaviour caused by changed damping behaviour.

- ▶ Ensure that you are sitting on the bicycle ergometer during all switching processes.
- ▶ Note the signals that indicate switching to the MyMode and to basic mode.
- ▶ Switch back to basic mode once the activities in MyMode have been completed.
- ▶ Correct the switching if necessary or use the Cockpit app.
- ▶ Always check whether the chosen mode corresponds to the desired movement type before taking the first step/making the first movement.

4.8 Notes on the safety modes

CAUTION

Using the product in safety mode

Falling due to unexpected product behaviour because of changed damping behaviour.

- ▶ The warnings/error signals (see page 39) have to be observed.

CAUTION

Safety mode cannot be activated due to malfunction caused by water penetration or mechanical damage

Falling due to unexpected behaviour of the product because of changed damping behaviour.

- ▶ Do not continue using the defective product.
- ▶ Consult the O&P professional promptly.

CAUTION

Safety mode cannot be deactivated

Falling due to unexpected behaviour of the product because of changed damping behaviour.

- ▶ If safety mode cannot be deactivated by recharging the battery, a permanent error has occurred.
- ▶ Do not continue using the defective product.
- ▶ The product must be inspected by an authorised Ottobock Service Center. The O&P professional is your contact.

⚠ CAUTION

Safety signal occurs (ongoing vibration)

Falling due to unexpected behaviour of the product because of changed damping behaviour.

- ▶ Observe the warnings/error signals (see page 39).
- ▶ Do not continue using the product after the safety signal has been emitted.
- ▶ The product must be inspected by an authorised Ottobock Service Center. The O&P professional is your contact.

4.9 Instructions for use with an osseointegrated implant system

⚠ WARNING

High mechanical loads due to normal or unusual situations, such as falling

- > Overloading of the bone, which can lead to pain, loosening of the implant, death of bone tissue or bone fracture, among other things.
- > Damage or breakage of the implant system or its components (safety components...).
- ▶ Verify compliance with the fields of application, conditions of use and indications according to the information of the manufacturers, both for the knee joint and for the implant system.
- ▶ Note the instructions of the clinical personnel that indicated the use of the osseointegrated implant system.
- ▶ Note changes in your state of health that result in restrictions or doubt regarding the use of the osseointegrated connection.

4.10 Information on the use of a mobile device with the cockpit app

⚠ CAUTION

Improper use of the mobile device

Falling due to changed damping behaviour as a result of unexpected switching to a MyMode.

- ▶ Make sure you have been instructed in the proper use of the mobile device with the Cockpit app.

⚠ CAUTION

Independently applied changes or modifications made to the mobile device

Falling due to altered damping behaviour as a result of unexpected switching to a MyMode.

- ▶ Do not make any independent changes to the hardware of the mobile device on which the app is installed.
- ▶ Do not make any independent changes to the software/firmware of the mobile device that are not included in the update function of the software/firmware.

⚠ CAUTION

Improper mode switching with the device

Falling due to unexpected product behaviour because of changed damping behaviour.

- ▶ Ensure that you stand securely during all switching processes.
- ▶ Verify the changed damping characteristics after switching and observe the feedback from the acoustic signal emitter (beeper) and the display on the device.
- ▶ Switch back to basic mode once the activities in MyMode have been completed.

5 Scope of Delivery and Accessories

5.1 Scope of delivery

- 1 pc. Kenevo 3C60=ST (with threaded connector) or
- 1 pc. Kenevo 3C60 (with pyramid connector)
- 1 pc. AXON 2R17 tube adapter or
- 1 pc. 2R20 AXON tube adapter or
- 1 pc. 2R21 AXON tube adapter with torsion
- "4X441-V2=* Cockpit" app for download from the website: <https://www.ottobock.com/cockpitapp>
- 1 pc. 757L16-4 power supply
- 1 pc. 4E70-1 inductive charger
- 1 pc. Instructions for use (user)
- 1 pc. prosthesis passport
- 1 pc. cosmetic case for battery charger and power supply

The Cockpit app has to be installed in version 2.5.0 or higher for use with this knee joint.

5.2 Accessories

The following components are not included in the scope of delivery and may be ordered separately:

- 3S26 cosmetic foam cover
- Kenevo Protective Cover 4X840

6 Charging the prosthesis battery

The following points must be observed when charging the battery:

- Use the 757L16-4 power supply and 4E70-1 battery charger to charge the battery.
- The full surface of the inductive charger must be in contact with the receiver of the charging unit. This must be verified, particularly when using a cosmetic foam cover. Prior to application, check the contact surfaces for dirt and ensure that no objects are adhering to them.
- The capacity of a fully charged battery is sufficient for one full day.
- We recommend charging the product every day when used on a daily basis.
- For the maximum operating time with one battery charge, disconnecting the battery charger from the product only immediately before using the product is recommended.
- 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 35).
- The battery may discharge while the product is not being used.

INFORMATION

Depending on the distance between the battery charger and the receiver on the knee joint, the battery charger can warm up considerably during the charging process. This is not a malfunction.

6.1 Connecting the power supply and battery charger



- 1) Slide the country-specific plug adapter onto the power supply until it locks into place (see fig. 1).
- 2) Connect the round, **three-pin** plug of the power supply to the receptacle on the inductive battery charger so that the plug locks into place. (see fig. 2)
INFORMATION: Ensure correct polarity (guide lug). Do not use force when connecting the cable plug to the battery charger.
- 3) Plug the power supply into the outlet (see fig. 3).
 → The green LED on the back of the power supply lights up.
 → If the green LED on the power supply does not light up, there is an error (see page 39).

6.2 Connect battery charger to the product

INFORMATION

Do not move the knee joint while it conducts the self-test immediately after disconnecting the charger. Otherwise, an error may occur; if this happens, the problem can be corrected by reconnecting and then disconnecting the charger.





- 1) Remove the prosthesis.
- 2) Connect the inductive charger to the receiver of the charging unit on the back of the product.
 Make sure the contact surfaces are clean, with no objects adhering to them.
 → The charger is held in place by a magnet.
 → A correct connection between the battery charger and the product is indicated by feedback (see page 41).
- 3) The charging process starts.
 → Once the product battery is fully charged, the LED on the battery charger lights up green.
- 4) After the charging process is complete, remove the inductive charger from the receiver and hold the product still.
 → A self-test is performed, and the product should not be moved while this is in progress. The joint is ready for operation only after corresponding feedback (see page 41).
- 5) Put the prosthesis on.

INFORMATION

To make the operating time of the prosthesis as long as possible, the charger should not be removed until immediately before the prosthesis is used.

Indication of the charging process:

Battery charger	
	Battery is charging. The on time of the LED indicates the current charge level. The on time of the LED gets longer as the charge level increases. It only flashes briefly at the start of the charging process and stays on continuously at the end of the charging process.
	Battery is fully charged, or the temperature has exceeded/fallen below the permissible range for the knee joint during charging. Check current charge level (see page 16).

6.3 Display of the current charge level

6.3.1 Display of battery charge level without additional devices

INFORMATION

The charge level cannot be displayed during the charging process, e.g. by turning the prosthesis over. The product is in charging mode.




- 1) Turn the prosthesis 180° (the sole of the foot has to face up).
- 2) Hold still for 2 seconds and wait for beeps.

Beep signal	Vibration signal	Battery charge level
5x short		more than 80%
4x short		65% to 80%
3x short		50% to 65%
2x short		35% to 50%
1x short	3x long	20% to 35%
1x short	5x long	less than 20%

6.3.2 Display of the current charge level using the Cockpit app

Once the Cockpit app has been started, the current charge level is displayed in the bottom line of the screen:



1.  38% – Charge level of battery for currently connected component

7 Cockpit app



The patient can change the behaviour of the product to a certain extent with the Cockpit app. In addition, information about the product (step counter, charge level, etc.) can be retrieved. The adjustment software can be used to trace the change at the patient's next appointment.

Information on the Cockpit app

- The Cockpit app can be downloaded free of charge from the respective online store. For more information, please visit the following website: <https://www.ottobock.com/cockpitapp>. To download the Cockpit app, the QR code on the supplied Bluetooth PIN card can also be read with the mobile device (requirement: QR code reader and camera).

- The language of the user interface in the Cockpit app can be changed using the adjustment software.
- Depending on the version of the Cockpit app being used, the language of the user interface in the Cockpit app corresponds to the language of the mobile device on which the Cockpit app is being used.
- The serial number of the component to be connected has to be registered with Ottobock the first time it is connected. If the registration is not accepted, use of the Cockpit app for this component will be limited.
- Bluetooth on the prosthesis must be turned on in order to use the Cockpit app. If Bluetooth is switched off, it can be turned on by turning the prosthesis upside-down (sole of the foot must point up) or by connecting/disconnecting the battery charger. Bluetooth is then turned on for approx. 2 minutes. During this time, the app must be started and used to establish a connection. If required, Bluetooth on the prosthesis can be switched on permanently afterwards (see page 31).
- Keep the mobile app up to date at all times.
- Please contact the manufacturer if you suspect cybersecurity problems.

7.1 Initial connection between cockpit app and component




The following points need to be observed before establishing the connection:

- Bluetooth of the component must be switched on (see page 31).
- Bluetooth on the mobile device must be switched on.
- The mobile device must not be in "flight mode" (offline mode), otherwise all wireless connections are turned off.
- **The mobile device must be connected to the Internet.**
- The serial number and Bluetooth PIN of the component being connected must be known. They are found on the enclosed Bluetooth PIN card. The serial number begins with the letters "SN".

INFORMATION

If the Bluetooth PIN card with the Bluetooth PIN and serial number of the component is lost, the Bluetooth PIN can be determined using the adjustment software.

7.1.1 Starting the cockpit app for the first time

- 1) Tap the symbol of the Cockpit app ().
 - The end user license agreement (EULA) is displayed.
 - 2) Accept the end user license agreement (EULA) by tapping the **Accept** button. If the end user license agreement (EULA) is not accepted, the Cockpit app cannot be used.
 - The welcome screen appears.
 - 3) Hold the prosthesis with the sole of the foot facing up, or connect and then disconnect the battery charger, in order to activate recognition (visibility) of the Bluetooth connection for 2 minutes.
 - 4) Tap the **Add component** button.
 - The Connection Wizard opens and guides you through the process of establishing a connection.
 - 5) Follow the subsequent instructions on the screen.
 - 6) After the Bluetooth PIN is entered, a connection to the component is established.
 - While the connection is being established, 3 beep signals sound and the  symbol appears.
 - The  symbol is displayed when the connection has been established.
- Once the connection has been established, the data are read from the component. This process may take up to a minute.
Then the main menu appears with the name of the connected component.

INFORMATION

After the initial connection to the component has been established successfully, the app will connect automatically each time it is started. No further steps are required.

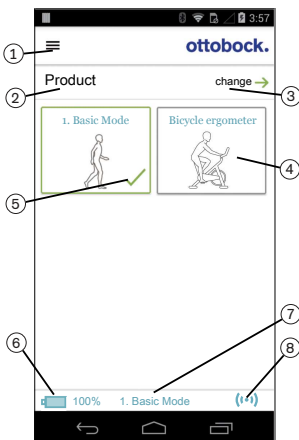
INFORMATION

After activating the "visibility" of the component (holding the component with the sole of the foot facing up, or connecting and then disconnecting the battery charger), the component can be recognised by another device (e.g. smartphone) within 2 minutes. If registration or establishing the connection takes too long, the process of establishing a connection is cancelled. In this case, hold the component with the sole of the foot facing up again, or connect and then disconnect the battery charger.

7.2 Control elements for cockpit app

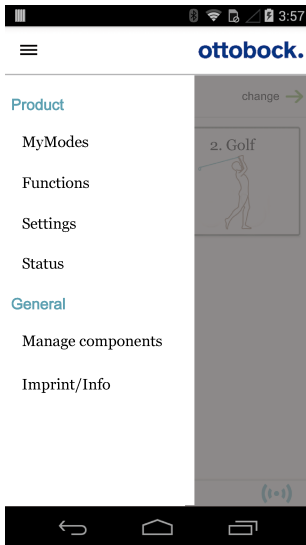
INFORMATION

The illustrations in these instructions for use are only examples and may deviate from the respective mobile device being used and the version.



1. ☰ Access the navigation menu (see page 19)
2. **Product**
The component name can only be changed with the adjustment software.
3. If connections to more than one component have been saved, you can switch between the saved components by tapping the **change** option (see page 19).
4. If the "**Intuitive bicycle ergometer function**" function has been enabled in the adjustment software and in the Cockpit app, this function can be activated manually by tapping the "**Bicycle ergometer**" MyMode and confirming with "**OK**". See the section "Using a bicycle ergometer" (see page 28) for further information.
5. Currently selected mode
6. Charge level of the component.
 - 🔋 Component battery fully charged
 - 🔌 Component battery empty
 - 🔌🔋 Component battery chargingThe current charge level is also displayed in %.
7. Display of and designation for the currently selected mode (e.g. **1. Basic Mode**)
8. (🔌🔋) Connection to component has been established
(🔌🔌) Connection to component has been interrupted. The app is attempting to re-establish the connection automatically.
(🔌) No existing connection to the component.

7.2.1 Cockpit app navigation menu



Tap the ☰ symbol in the menus to display the navigation menu. Additional settings for the connected component can be configured in this menu.

Product

Name of the connected component

MyModes

Return to the main menu to switch MyModes

Functions

Call up additional functions of the component (e.g. turn off Bluetooth) (see page 31)

Settings

Change settings of the currently selected mode (see page 29)

Status

Query status of the connected component (Querying the prosthesis status)

Manage components

Add or delete components (see page 19)

Imprint/Info

Display information/legal notices for the cockpit app

7.3 Managing components

Connections with up to four different components can be stored in the app. However, a component can only be connected to one mobile device at a time.

INFORMATION

Before establishing the connection, observe the points in the section "Initial connection between Cockpit app and component" (see page 17).

7.3.1 Adding component

- 1) Tap the ☰ symbol in the main menu.
→ The navigation menu opens.
- 2) In the navigation menu, tap the "**Manage components**" item.
- 3) Hold the prosthesis with the sole of the foot facing up, or connect and then disconnect the battery charger, in order to activate recognition (visibility) of the Bluetooth connection for 2 minutes.
- 4) Tap the "+" button.
→ The Connection Wizard opens and guides you through the process of establishing a connection.
- 5) Follow the subsequent instructions on the screen.
- 6) After the Bluetooth PIN is entered, a connection to the component is established.
→ While the connection is being established, three beep signals sound and the (📶) symbol appears.
The (📶) symbol is displayed when the connection has been established.

- Once the connection has been established, the data are read from the component. This process may take up to a minute.

The main menu will then appear with the name of the connected component.

INFORMATION

If establishing a connection to a component is not possible, perform the following steps:

- ▶ Delete the component from the Cockpit app if applicable (see the section "Deleting a component")
- ▶ Add the component again in the Cockpit app (see the section "Adding a component")

INFORMATION

After activating the "visibility" of the component (holding the component with the sole of the foot facing up, or connecting and then disconnecting the battery charger), the component can be recognised by another device (e.g. smartphone) within 2 minutes. If registration or establishing the connection takes too long, the process of establishing a connection is cancelled. In this case, hold the component with the sole of the foot facing up again, or connect and then disconnect the battery charger.

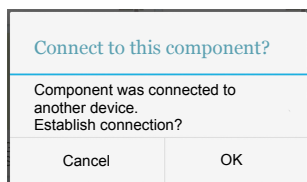
7.3.2 Deleting a component

- 1) Tap the ☰ symbol in the main menu.
 - The navigation menu opens.
- 2) In the navigation menu, tap the entry "**Manage components**".
- 3) Tap the "**Edit**" button.
- 4) Tap the 🗑 symbol under the component you want to delete.
 - The component is deleted.

7.3.3 Connecting component with multiple mobile devices

The connection for a component can be stored on more than one mobile device. However, only one mobile device can be connected to the component at one time.

If there is an existing connection between the component and a different mobile device, the following information appears while the connection is being established with the current mobile device:



- ▶ Tap the "**OK**" button.
- The connection to the last connected mobile device is broken off and established with the current mobile device.

8 Use

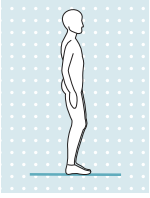
INFORMATION

Knee joint movement noise

When using exoprosthetic knee joints, servomotor, hydraulic, pneumatic or brake load dependent control functions can cause movement noises. 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 the O&P professional immediately.

8.1 Movement pattern in activity mode A (locked mode)

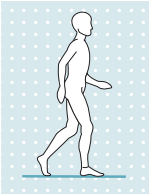
8.1.1 Standing



The knee joint is locked in the flexion direction. Therefore, proceed as you would with a rigid knee joint.

INFORMATION: In response to a sitting movement, the joint switches to high flexion resistance.

8.1.2 Walking



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

The knee joint is locked in the flexion direction. Therefore, proceed as you would with a rigid knee joint.

8.1.3 Sitting down

The prosthesis makes it possible to sit down without unlocking it manually. The adjustable flexion resistance of the hydraulic unit provides support while sitting down.

We recommend that the user supports themselves with their hands while sitting down, e.g.:

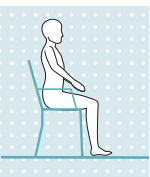
- Support on the armrests of the chair
- Support on the handles of a walker
- Use of forearm crutches
- Use of a cane



- 1) Stand 5 to 10 cm in front of the edge of the chair.
While standing up, the edge of the chair should not yet touch the hollow of the knee nor press against the lower leg.
- 2) Place both feet side by side at the same level.
- 3) While sitting down, distribute weight evenly on both legs and push the pelvis in the direction of the backrest.

This causes the weight to shift to the heel and the prosthesis to tilt backward, which makes the knee joint switch to the "sitting resistance". Support is therefore provided while sitting down.

8.1.4 Sitting



If the user is in a sitting position, i.e. the thigh is close to horizontal and there is no load on the leg, the knee joint switches to a low resistance in both the flexion and extension direction.

If the load on the prosthesis was not sufficient while sitting down, the leg is extended during this process. Due to the nearly horizontal position of the lower leg, the flexion resistance is reduced automatically and the lower leg lowers on its own.

If the sitting function is enabled in the adjustment software and activated via the Cockpit app (see page 30), the resistance in the flexion direction is reduced as well.

8.1.5 Standing up

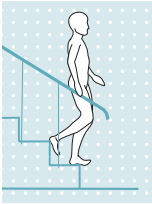
Notwithstanding low damping while sitting, the prosthesis supports standing up. Damping is increased after rising from the seat. From an angle of approx. 45°, the knee joint identifies a "standing up process" which results in what is called "pre-locking" in the flexion direction. This function makes it possible to stand up with pauses in between. The joint fully supports weight during these pauses. If standing up is aborted, the "sitting down" function is activated again.

The joint is locked after fully standing up.



- 1) Place the feet at the same level.
- 2) Lean the upper body forward.
- 3) Put the hands on armrests, if available.
- 4) Stand up with support from the hands, while keeping weight evenly distributed over feet.

8.1.6 Walking down stairs

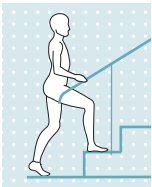


The knee joint is locked in the flexion direction.

- 1) Hold the handrail with one hand.
- 2) Place the foot of the prosthetic leg on the first step.
- 3) Pull up the other leg.

INFORMATION: Walking down stairs step-over-step is not possible in this activity mode.

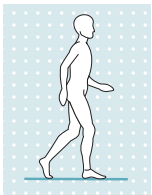
8.1.7 Walking up stairs



Walking up stairs step-over-step is not possible.

- 1) Hold the handrail with one hand.
- 2) Place the foot of the less affected leg onto the first step.
- 3) Pull up the other leg.

8.1.8 Walking backwards

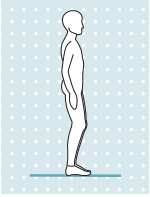


The knee joint is locked in the flexion direction. Proceed as you would with a rigid knee joint.

8.2 Movement pattern in activity mode B (semi-locked mode) / B+ (semi-locked mode with stance phase flexion)

8.2.1 Standing

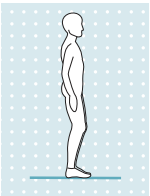
Activity mode B (semi-locked mode)



The knee joint is locked in the flexion direction.

INFORMATION:The joint responds to a sitting movement by switching to high flexion resistance.

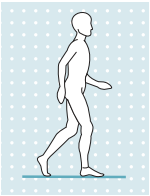
Activity mode B+ (semi-locked mode with stance phase flexion)



The knee joint is locked starting at stance phase flexion of up to 10°.

INFORMATION:The joint responds to a sitting movement by switching to high flexion resistance.

8.2.2 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 leg can swing forward freely.

In order to safely switch to the swing phase, the prosthesis has to be partially unloaded from the lunge position with a simultaneous forward movement.

If desired, stance phase flexion of up to 10° can be permitted for this mode in the adjustment software (setting only available in activity mode B).

8.2.3 Sitting down

The prosthesis makes it possible to sit down without unlocking it manually. The adjustable flexion resistance of the hydraulic unit provides support while sitting down.

We recommend that the user supports themselves with their hands while sitting down, e.g.:

- Support on the armrests of the chair
- Support on the handles of a walker
- Use of forearm crutches
- Use of a cane



- 1) Stand 5 to 10 cm in front of the edge of the chair.
While standing up, the edge of the chair should not yet touch the hollow of the knee nor press against the lower leg.
- 2) Place both feet side by side at the same level.
- 3) While sitting down, distribute weight evenly on both legs and push the pelvis in the direction of the backrest.

This causes the weight to shift to the heel and the prosthesis to tilt backward, which makes the knee joint switch to the "sitting resistance". Support is therefore provided while sitting down.

8.2.4 Sitting



If the user is in a sitting position, i.e. the thigh is close to horizontal and there is no load on the leg, the knee joint switches to a low resistance in both the flexion and extension direction.

If the load on the prosthesis was not sufficient while sitting down, the leg is extended during this process. Due to the nearly horizontal position of the lower leg, the flexion resistance is reduced automatically and the lower leg lowers on its own.

If the sitting function is enabled in the adjustment software and activated via the Cockpit app (see page 30), the resistance in the flexion direction is reduced as well.

8.2.5 Standing up

The prosthesis supports standing up despite the low flexion resistance while sitting.

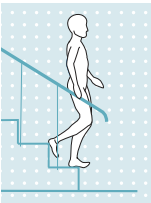
The resistance is increased after rising from the seat. From an angle of approx. 45°, the knee joint identifies a "standing up process" which results in what is called "pre-locking" in the flexion direction. This function makes it possible to stand up with pauses in between. The joint fully supports weight during these pauses. If the process of standing up is discontinued, the "sitting down" function is activated again.

The joint is locked after fully standing up.



- 1) Place the feet at the same level.
- 2) Lean the upper body forward.
- 3) Place the hands on arm supports, if available.
- 4) Stand up with support from the hands while distributing weight evenly between the feet.

8.2.6 Walking down stairs

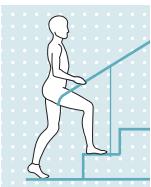


The knee joint is locked in the flexion direction.

- 1) Hold the handrail with one hand.
- 2) Place the foot of the prosthetic leg on the first step.
- 3) Pull up the other leg.

INFORMATION: Walking down stairs step-over-step is not possible in this activity mode.

8.2.7 Walking up stairs

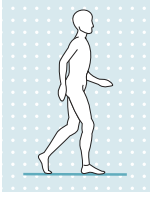


Walking up stairs step-over-step is not possible.

- 1) Hold the handrail with one hand.
- 2) Place the foot of the less affected leg onto the first step.
- 3) Pull up the other leg.

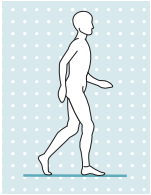
8.2.8 Walking backwards

Activity mode B (semi-locked mode)



The knee joint is locked in the flexion direction. Proceed as you would with a rigid knee joint.

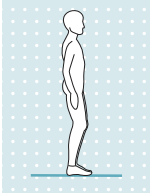
Activity mode B+ (semi-locked mode with stance phase flexion)



The knee joint is locked starting at stance phase flexion of up to 10°. Proceed as you would with a rigid knee joint.

8.3 Movement pattern in activity mode C (yielding mode)

8.3.1 Standing



Knee control through high hydraulic resistance and correct static alignment. A stance function can be enabled using the adjustment software. Please see the following section for further information on the stance function.

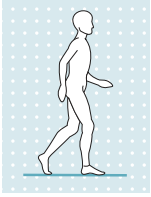
8.3.1.1 Stance function

INFORMATION

To use this function, it needs to be enabled in the adjustment app. It also has to be activated using the Cockpit app (see page 30).

The intuitive stance automatically recognises any situation that puts strain on the prosthesis in the flexion direction but where flexion is not permitted. Examples of this include standing on uneven or sloping surfaces. The knee joint is always locked in the flexion direction when the prosthetic leg is not fully extended, is under some amount of load and is at rest. When the load is taken off the leg or forward or backward rollover occurs, the level of resistance is immediately reduced to stance phase resistance again.

8.3.2 Walking



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

The hydraulics stabilise the knee joint with high flexion resistance in the stance phase and release the knee joint in the swing phase so that the leg can swing forward freely.

In order to safely switch to the swing phase, the prosthesis has to be partially unloaded from the lunge position with a simultaneous forward movement.

8.3.3 Sitting down

The prosthesis provides high flexion resistance while sitting down. This ensures that the knees bend evenly, thereby supporting the contralateral side.

We recommend that the user supports themselves with their hands while sitting down, e.g.:

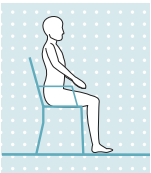
- Support on the armrests of the chair
- Support on the handles of a walker
- Use of forearm crutches
- Use of a cane



- 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 where applicable.
- 3) Move the buttocks in the direction of the back support and lean the upper body forward.

This causes the weight to shift to the heel, making the knee joint switch to the "sitting resistance". Support is therefore provided while sitting down.

8.3.4 Sitting



If the user is in a sitting position, i.e. the thigh is close to horizontal and there is no load on the leg, the knee joint switches to a low resistance in both the flexion and extension direction.

If the load on the prosthesis was not sufficient while sitting down, the leg is extended during this process. Due to the nearly horizontal position of the lower leg, the flexion resistance is reduced automatically and the lower leg lowers on its own.

If the sitting function is enabled in the adjustment software and activated via the Cockpit app (see page 30), the resistance in the flexion direction is reduced as well.

8.3.5 Standing up

Notwithstanding low damping while sitting, the prosthesis supports standing up.

Damping is increased after rising from the seat.

After standing up entirely, high damping (corresponding to the value of the "stance phase damping" parameter) is set automatically.

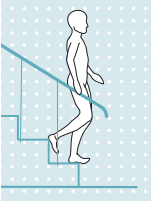
INFORMATION

If the intuitive stance function was deactivated in the adjustment software, there is no support while standing up.



- 1) Place the feet at the same level.
- 2) Lean the upper body forward.
- 3) Put the hands on armrests, if available.
- 4) Stand up with support from the hands. while keeping weight evenly distributed on the feet.

8.3.6 Walking down stairs



The joint makes it possible to walk down stairs step-over-step or one at a time.

Walking down stairs step-over-step

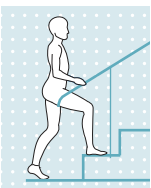
Walking down stairs step-over-step must be practised and executed consciously. The knee joint can switch correctly and permit a controlled rollover only by stepping down properly with the sole of the foot. The motion must be carried out in a continuous pattern in order to allow the motion sequence to proceed in a fluid manner.

- 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.
→ This is the only way to ensure a secure rollover.
- 3) Roll the foot over the edge of the step.
→ This flexes the prosthesis slowly and evenly under high flexion resistance.
- 4) Place the foot of the other leg onto the next step.

Walking down stairs one step at a time (step by step)

- 1) Hold the handrail with one hand.
- 2) Place the foot of the prosthetic leg on the first step.
- 3) Pull up the other leg.

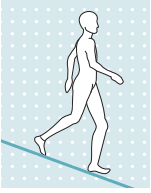
8.3.7 Walking up stairs



Walking up stairs step-over-step is not possible.

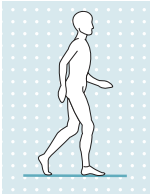
- 1) Hold the handrail with one hand.
- 2) Place the foot of the less affected leg onto the first step.
- 3) Pull up the other leg.

8.3.8 Walking down a ramp



Under increased flexion resistance, permit controlled flexion of the knee joint which lowers the body's centre of gravity.
The swing phase is not triggered even though the knee joint is flexed.

8.3.9 Walking backwards



While walking backwards, the hydraulics keep the knee joint stable with high flexion resistance.

8.4 Using a bicycle ergometer



The **"Bicycle ergometer"** MyMode allows a bicycle ergometer to be used without exiting the currently selected activity mode.
Note the prerequisites for switching and the differences for activation in the respective activity modes.

Prerequisites for activating the "Bicycle ergometer" MyMode

- A bicycle ergometer is required. Switching is not possible for recumbent bicycles or so-called pedal trainers.
- The bicycle ergometer must have a freewheel.
- The user must be in the sitting position.
- The sitting position must not be too high, otherwise the knee is extended during the pedaling movement, ending the MyMode.
- The sitting position must not be too low. Note the permissible flexion range of the knee joint.
- The feet have to be positioned on the pedals.
- Pedaling movements must be possible.

Activating the "Bicycle ergometer" MyMode (activity mode A, B, B+)

- 1) Sit on the bicycle ergometer with the leg extended.
- 2) Hold the leg horizontally until the knee joint flexes on its own due to gravity.
- 3) Put the feet on the pedals and perform pedaling movements within one minute, or activate the **"2.Bicycle ergometer"** MyMode using the Cockpit app.
 - After a few pedaling movements, these are recognised by the knee joint and a short beep and vibration signal is produced. If this signal is not produced, the time limit for positioning the feet on the pedals (one minute) was exceeded or the prerequisites for activating this MyMode are not met.
 - The short beep and vibration signal is produced periodically at intervals during the pedaling movement until the resistances in the flexion and extension direction have been reduced to the extent that the knee joint moves freely.

→ This MyMode (**2. Bicycle ergometer**) is shown in the overview in the Cockpit app.

Activating the “Bicycle ergometer” MyMode (activity mode C)

- 1) Sit on the bicycle ergometer.
- 2) Put the feet on the pedals.
- 3) Perform pedaling movements or activate the “**2. Bicycle ergometer**” MyMode using the Cockpit app.
 - After a few pedaling movements, these are recognised by the knee joint and a short beep and vibration signal is produced. If this signal is not produced, the prerequisites for activating this MyMode were not met.
 - The short beep and vibration signal is produced periodically at intervals during the pedaling movement until the resistances in the flexion and extension direction have been reduced to the extent that the knee joint moves freely.
 - This MyMode (**2. Bicycle ergometer**) is shown in the overview in the Cockpit app.

Deactivating the “Bicycle ergometer” MyMode (activity mode A, B, B+, C)

- ▶ From the sitting position, either extend the knee or take the foot off the pedal and put it on the floor. The foot has to be ahead of the knee joint when it is set on the floor.
 - This is recognised by the knee joint and a long beep and vibration signal is produced. If this signal is not produced, either repeat the process or switch to the “**1. Basic Mode**” MyMode using the Cockpit app.
 - This MyMode is shown in the overview in the Cockpit app.

8.5 Using a wheelchair

When sitting in a wheelchair, the joint can be locked in the flexed position for short distances. The lock can be engaged in any position from an angle of 45°. This prevents the foot from dragging on the floor. To use this function, it must be enabled in the adjustment software.



Locking the joint

- ▶ Raise the foot and hold it still in the desired position.
The lock engages automatically.

INFORMATION: At full extension, the lock engages in a slightly flexed position so the foot can be lifted in order to release the lock.

Disengaging the lock

The lock can be disengaged in the following ways:

- Extended pressure on the ball of the foot.
- Extended pressure on the toes (from the top of the foot).
- Lift the foot (extend the knee) and allow the foot to lower again.

INFORMATION

Turning the “Wheelchair function” function off/on using the Cockpit app

If the “**Locking function for wheelchair**” function was turned on in the adjustment software, the “**Wheelchair function**” function can be turned off and back on again using the Cockpit app.



8.6 Changing prosthesis settings

Once an active connection to a component has been established, the settings **of the respective active mode** can be changed using the Cockpit app.

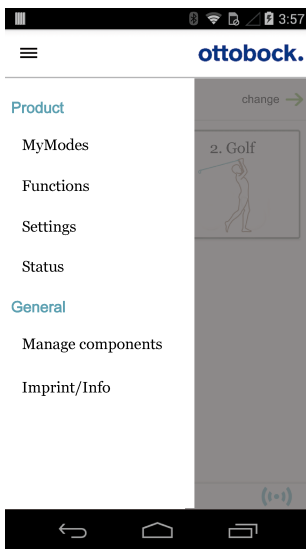
INFORMATION


Bluetooth on the prosthesis has to be switched on to change the prosthesis settings (see page 31).

Information for changing the prosthesis settings

- Before changing settings, always check the main menu of the Cockpit app to make sure the correct component has been selected. Otherwise parameters could be changed for the wrong component.
- It is not possible to change prosthesis settings nor to switch to a different mode while the prosthesis battery is being charged. Only the status of the prosthesis can be called up. Instead of the  symbol, the  symbol appears in the bottom row of the screen in the cockpit app.
- The O&P professional's setting is in the middle of the scale. After making adjustments, this setting can be restored by tapping the **“Standard”** button in the Cockpit app.
- Prosthesis settings should be optimised using the adjustment software. The Cockpit app is not intended for use by the O&P professional to set up the prosthesis. The everyday behaviour of the prosthesis can be changed to a certain extent using the app (e.g. while becoming accustomed to the prosthesis). The O&P professional can use the adjustment software to track these changes at the next appointment.

8.6.1 Changing the prosthesis setting using the cockpit app



- 1) Once the component is connected and in the desired mode, tap the  icon in the main menu.
→ The navigation menu opens.
- 2) Tap the **“Settings”** menu option.
→ A list appears with the parameters for the currently selected mode.
- 3) Change the setting of the desired parameter by tapping the **“<”**, **“>”** icons.

INFORMATION: The O&P professional’s setting is marked and, after the setting has been changed, can be restored by tapping the “Standard” button.

The following parameters can be modified:

INFORMATION

Number of parameters depending on selected activity mode

Some parameters are not available depending on the currently selected activity mode.

Parameter	Adjustment software range	Cockpit app adjustment range	Meaning
Resistance	120 to 180	+/- 10 of the configured value	Flexion resistance while sitting down, in the stance phase, while walking on ramps and stairs.

Parameter	Adjustment software range	Cockpit app adjustment range	Meaning
Intuitive stance function¹	0/Off – deactivated 1/On – activated	0/Off – deactivated 1/On – activated	Information about this function is provided in the section “ Stance function ” (see see page 25)
Intuitive bicycle ergometer function¹	0/Off – deactivated 1/On – activated	0/Off – deactivated 1/On – activated	Information about this function is provided in the section “ Using a bicycle ergometer ” (see see page 28)
Wheelchair function¹	0/Off – deactivated 1/On – activated	0/Off – deactivated 1/On – activated	Information about this function is provided in the section “ Using a wheelchair ” (see see page 29)
Sitting function¹	0/Off – deactivated 1/On – activated	0/Off – deactivated 1/On – activated	When the function is activated, the resistance in the flexion direction while sitting is reduced in addition to the reduction of resistance in the extension direction.
Donning function	0/Off – deactivated 1/On – activated	0/Off – deactivated 1/On – activated	If the knee joint is not loaded for a few seconds after disconnecting the charger, the prosthesis can be flexed. Flexion makes putting on the prosthesis easier. Ending knee flexion or loading the prosthesis immediately reactivates the configured operating state. This function can be activated in mode A, B or B+.

¹ To use these functions in the Cockpit app, they need to be enabled or turned on in the adjustment app.

8.7 Turning Bluetooth on the prosthesis on/off

INFORMATION

Bluetooth on the prosthesis must be turned on in order to use the Cockpit app. If Bluetooth is switched off, it can be turned on by turning the prosthesis upside-down (function only available in basic mode) or by connecting/disconnecting the battery charger. Bluetooth is then turned on for approx. 2 minutes. During this time, the app must be started and used to establish a connection. If required, Bluetooth on the prosthesis can be switched on permanently afterwards (see page 31).

Switching off Bluetooth

- 1) With the component connected, tap the ☰ icon in the main menu of the Cockpit app.
→ The navigation menu opens.
- 2) Tap the “**Functions**” option in the navigation menu.
- 3) Tap the “**Deactivate Bluetooth**” option.
- 4) Follow the on-screen instructions.

Switching on Bluetooth

- 1) Turn the component over or connect/disconnect the battery charger.

- Bluetooth is switched on for approx. 2 minutes. The Cockpit app must be started within this time to establish a connection to the component.
- 2) Follow the on-screen instructions.
- If Bluetooth is switched on, the (↔) icon appears on the screen.

8.8 Querying the prosthesis status

- 1) With the component connected, tap the ☰ icon in the main menu of the Cockpit app.
- 2) Tap the “**Status**” option in the navigation menu.

Menu option	Description	Possible actions
Trip: 1747	Daily step counter	Reset the counter by tapping the “ Reset ” button.
Step: 1747	Total step counter	Information only
Batt.: 68	Current prosthesis charge level, as a percentage	Information only

9 Additional operating states (modes)

The product automatically switches to special operating states (modes) when an error occurs, in case of an empty battery or while charging. Functioning of the prosthesis is limited due to its altered damping behaviour.

9.1 Empty battery mode

The joint emits beeps and vibration signals when the charge level is 15% or less (see page 39). Then the damping settings are set to high flexion resistance and low extension resistance, and the product is switched off. Before switching to empty battery mode, warning signals are emitted at a battery charge level below 35% (see page 39).

You can switch back to basic mode from empty battery mode by charging the product.

9.2 Mode for charging the prosthesis

The product is non-functional during charging.

To switch to basic mode, the battery charger for the product must be disconnected after the battery is charged.

9.3 Safety mode

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

A setting for high flexion resistance and low extension resistance is applied in safety mode. This makes limited walking possible for the user even though the product is not active.

The switch to safety mode is indicated by beeps and vibration signals immediately prior to switching (see page 39).

Safety mode can be disabled by connecting and disconnecting the battery charger. If the product switches into safety mode again, this means a permanent error exists. The product must be inspected by an authorised Ottobock Service Centre.

9.4 Overheating mode

When the hydraulic unit overheats due to uninterrupted, increased activity (e.g. extended walking downhill), the flexion resistance is increased along with the rising temperature in order to counteract the overheating. When the hydraulic unit cools down, the product switches back to the settings that existed prior to overheating mode.

The hydraulic unit cannot overheat in activity mode A or B. Therefore, no overheating mode is triggered in these two activity modes.

Overheating mode is indicated by a long vibration every 5 seconds.

The following functions are deactivated in overheating mode in activity mode C:

- Joint lock for use of a wheelchair (see page 29)
- Battery level indication (see page 16)

10 Cleaning

- 1) Clean the product with a damp cloth (fresh water) when needed.
- 2) Dry the product with a lint-free cloth and allow it to air dry fully.

11 Maintenance

Regular maintenance (service inspections) is mandatory in the interest of your own safety and in order to maintain operating reliability and protect the warranty, maintain basic safety and the essential performance characteristics, and ensure safety in regards to EMC.

When maintenance is due, this is indicated by feedback after disconnecting the battery charger (see the section "Operating states/error signals", see page 38).

The following maintenance intervals must be observed depending on the country/region:

Country/region	Maintenance interval
All countries/regions except: USA, CAN, RUS	24 months
USA, CAN, RUS	As needed*, No later than every 36 months

*As needed: the maintenance interval depends on the user's activity level. For users with a normal to low activity level, with up to 1,800 steps per day, the expected maintenance interval is 3 years. For highly active users with more than 1,800 steps per day, the expected maintenance interval is 2 years.

Additional services such as repairs may be provided in the course of maintenance. These additional services may be provided free of charge or can be billable according to an advance cost estimate, depending on the extent and validity of the warranty.

The following components always have to be submitted to the O&P professional for maintenance and repairs:

The prosthesis, battery charger and power supply unit.

12 Legal information

12.1 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.

12.2 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.

12.3 CE conformity

Otto Bock Healthcare Products GmbH hereby declares that the product is in compliance with applicable European requirements for medical devices.

This product meets the requirements of the 2014/53/EU directive.

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.

The full text of the regulations and requirements is available at the following Internet address: <http://www.ottobock.com/conformity>

12.4 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.

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s)..

Operation is subject to the following two conditions:

- (1) This device may not cause interference.
- (2) This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

- (1) L'appareil ne doit pas produire de brouillage;
- (2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Caution: Exposure to Radio Frequency Radiation.

The installer of this radio equipment must ensure that the antenna is located or pointed such that it does not emit RF field in excess of Health Canada limits for the general population.

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.

13 Technical data

Environmental conditions	
Transportation in original packaging	-25°C/-13°F to +70°C/+158°F
Transportation without packaging	-25°C/-13°F to +70°C/+158°F Max. 93% relative humidity, non-condensing
Storage (≤3 months)	-20°C/-4°F to +40°C/+104°F Max. 93% relative humidity, non-condensing
Long-term storage (>3 months)	-20°C/-4°F to +20°C/+68°F Max. 93% relative humidity, non-condensing
Operation	-10°C/+14°F to +40°C/+104°F Max. 93% relative humidity, non-condensing
Charging the battery	+5 °C/+41 °F to +40 °C/+104 °F

Product	
Reference number	3C60*/3C60=ST*
Mobility grade (MOBIS)	1 and 2
Maximum body weight	125 kg
Protection rating	IP22
Water resistance	Not waterproof and not corrosion-resistant Protect the product with clothing in rainy conditions
Weight of the prosthesis without tube adapter and Protective Cover	Approx. 910 g
Frequency range of the receiver of the inductive charging unit	110 kHz to 205 kHz
Information on the product's ruleset and firmware version	Accessible via the Cockpit app navigation menu and the menu item "Imprint/Info"
Expected lifetime given compliance with the prescribed maintenance intervals	6 years
Test procedure	ISO10328-P6-125 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)

Prosthesis battery	
Battery type	Li-Ion
Charging cycles (charging and discharging cycles) after which at least 80% of the original battery capacity remains available	300
Charging time until battery is fully charged	6–8 hours
Product behaviour during the charging process	The product is non-functional

Prosthesis battery	
Operating time of prosthesis with fully charged battery	1 day with average use

Power supply unit	
Reference number	757L16-4
Type	FW8001M/12
Storage and transport in original packaging	-40 °C/-40 °F to +70 °C/+158 °F 10% to 95% relative humidity, non-condensing
Storage and transport without packaging	-40 °C/-40 °F to +70 °C/+158 °F 10% to 95% relative humidity, non-condensing
Operation	0 °C/+32 °F to +50 °C/+122 °F Max. 95% relative humidity Air pressure: 70–106 kPa (up to 3,000 m without pressure equalisation)
Input voltage	100 V~ to 240 V~
Mains frequency	50 Hz to 60 Hz
Output voltage	12 V ===

Battery charger	
Reference number	4E70-1
Storage and transport in original packaging	-25 °C/-13 °F to +70 °C/+158 °F
Storage and transport without packaging	-25 °C/-13 °F to +70 °C/+158 °F Max. 93% relative humidity, non-condensing
Operation	0 °C/+32 °F to +40 °C/+104 °F Max. 93% relative humidity, non-condensing
Protection rating	IP40
Input voltage	12 V ===
Lifetime	6 years
Wireless technology	Qi
Frequency range	110 kHz to 205 kHz
Modulation	ASK, load modulation
Maximum output power (EIRP)	-18.00 dBµA/m @ 10 m

Cockpit app	
Reference number	4X441-V2=* Cockpit
Version	Version 2.5.0 or higher
Supported operating system	See the information in the respective online store (e.g. Apple App Store, Google Play Store, etc.) regarding compatibility with mobile devices and versions.
Website for download	https://www.ottobock.com/cockpitapp

14 Appendices

14.1 Symbols Used



Manufacturer



Type BF applied part



Please note the instructions for use



Compliance with the requirements according to "FCC Part 15" (USA)



Compliance with the requirements under the "Radiocommunications Act" (AUS)



Non-ionising radiation



In some jurisdictions it is not permissible to dispose of these products with unsorted household waste. Disposal that is not in accordance with the regulations of your country may have a detrimental impact on health and the environment. Please observe the instructions of your national authority pertaining to return and collection.

DUAL

The product's Bluetooth wireless module can establish a connection to mobile devices with the following operating systems: iOS (iPhone, iPad, iPod...) and Android



Declaration of conformity according to the applicable European directives



Serial number (YYYY WW NNN)

YYYY – year of manufacture

WW – week of manufacture

NNN – sequential number



Lot number (PPPP YYYY WW)

PPPP – plant

YYYY – year of manufacture

WW – week of manufacture



Medical device



Article number



Protect from moisture

IP40

Protection against penetration of solid foreign objects with a diameter greater than 1 mm, no protection against water

IP22

Protection against penetration of solid foreign objects with a diameter greater than 12.5 mm, protection against water dripping diagonally up to 15°.



Caution, hot surface

14.2 Operating states/error signals

The prosthesis indicates operating states and error messages through beeps and vibration signals.

14.2.1 Signals for operating states

Battery charger connected/disconnected

Beep signal	Vibration signal	Event
1 x short	–	Battery charger connected or Battery charger already disconnected prior to start of charging mode
–	3 x short	Charging mode started (3 sec. after connecting the battery charger)
1 x short	1 x before beep signal	Battery charger disconnected after start of charging mode

Mode switching

Beep signal	Vibration signal	Additional action performed	Event
1x short	1x short	Mode switching using the Cockpit app	Mode switching is performed using the Cockpit app.
1x short	1x short	User has sat on the bicycle ergometer and commenced pedaling movement	After a few pedaling movements, this was recognised and switching to the "2.Bicycle ergometer" MyMode took place.
Short at periodic intervals	Short at periodic intervals	The pedaling movements were continued.	The flexion and extension resistances are reduced to the extent that the knee joint moves freely.

Beep signal	Vibration signal	Additional action performed	Event
1x long	1x long	The prosthetic leg was extended or the foot was placed on the floor.	Placing the foot on the floor was recognised and switching back to the “ 1. Basic Mode ” MyMode took place.

14.2.2 Warnings/error signals


Error during use

Beep signal	Vibration signal	Event	Required action
–	1x long at interval of approx. 5 seconds	Hydraulics overheated	Reduce activity.
–	3x long	Charge level under 25%	Charge battery soon.
–	5x long	Charge level under 15%	Charge battery immediately; the product will be switched off after the next warning signal.
10x long	10x long	Charge level 0% After the beep and vibration signals, the product switches to empty battery mode and then switches off.	Charge the battery.
30x long	1x long, 1x short repeated every 3 seconds	Severe error/indication of safety mode activation For example, sensor not ready for operation or valve drive failure Possibly no switching into safety mode.	Walking possible with restrictions. Please note the possible change in flexion/extension resistance. Attempt to reset this error by connecting/disconnecting the battery charger. The battery charger must remain connected for at least 5 seconds before it is disconnected. If the error persists, use of the product is prohibited. The product must be inspected by an O&P professional immediately.

Beep signal	Vibration signal	Event	Required action
-	Continuous	Total failure Electronic control no longer possible. Safety mode active or undetermined valve state. Unknown product behaviour.	Attempt to reset this error by connecting/disconnecting the battery charger. If the error persists, use of the product is prohibited. The product must be inspected by an O&P professional immediately.

Error while charging the product



LED on power supply	LED on battery charger	Battery charger connected to product	Error	Resolution
○	○	No	Country-specific plug adapter not fully engaged on power supply	Check whether the country-specific plug adapter is fully engaged on the power supply.
			Outlet not functioning	Check outlet with another electrical device.
			Defective power supply	The battery charger and power supply must be inspected by an O&P professional.
●	○	Yes	Distance between battery charger and receiver on knee joint too great	The distance between the battery charger and the receiver on the knee joint must not exceed 1 mm
			No connection between battery charger and power supply	Check whether the charging cable plug is fully engaged on the battery charger.
			Defective battery charger	The battery charger and power supply must be inspected by an O&P professional.

LED on power supply	LED on battery charger	Battery charger connected to product	Error	Resolution
	The LED turns off or changes colour at irregular intervals	Yes	Temperature of the battery charger too high	<p>The distance between the battery charger and the receiver on the knee joint must not exceed 1 mm. If this distance is too great during the charging process, the magnetic surface of the battery charger can heat up and interrupt the charging process.</p> <p>Take the battery charger off the knee joint, disconnect it from the power supply and let it cool down. If the error recurs, the battery charger must be inspected by an O&P professional.</p>

Beep signal	Error	Resolution
4 x short at intervals of approx. 20 sec. (continuously)	Charging the battery outside the allowable temperature range	Check whether the specified ambient conditions for charging the battery are met (see page 35).

14.2.3 Status signals



Battery charger connected

LED on power supply	LED on battery charger	Event
		Power supply and battery charger operational

Battery charger disconnected

Beep signal	Vibration signal	Event
1 x short	1 x short	Self-test completed successfully. Product is operational.
3 x short	–	<p>Maintenance note</p> <p>Conduct the self-test again by connecting/disconnecting the battery charger. If the beep signal is emitted again, you should visit the O&P professional soon. If necessary, they will forward the product to an authorised Ottobock Service Center.</p> <p>The product can be used without restrictions. However, vibration signals may not be generated.</p>

Battery charge level

Battery charger	
	Battery is charging. The on time of the LED indicates the current charge level. The on time of the LED gets longer as the charge level increases. It only flashes briefly at the start of the charging process and stays on continuously at the end of the charging process.
	Battery is fully charged, or the temperature has exceeded/fallen below the permissible range for the knee joint during charging. Check current charge level (see page 16).

14.3 Directives and manufacturer's declaration

14.3.1 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)

Observe the safety notices in the section "Information on proximity to certain areas" (see page 10).

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,
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

Phenomenon	EMC basic standard or test procedure	Interference immunity test level
Surges Line against line	IEC 61000-4-5	$\pm 0.5 \text{ kV}, \pm 1 \text{ kV}$
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 $\pm 5 \text{ kHz}$ 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 800/90-0, TETRA 800, iDEN 820, CDMA 850, GSM 800/90-0, 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						

Test frequency [MHz]	Frequency band [MHz]	Radio service	Modulation	Maximum power [W]	Distance [m]	Interference immunity test level [V/m]
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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