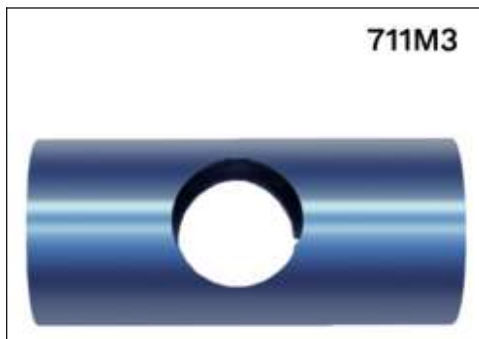
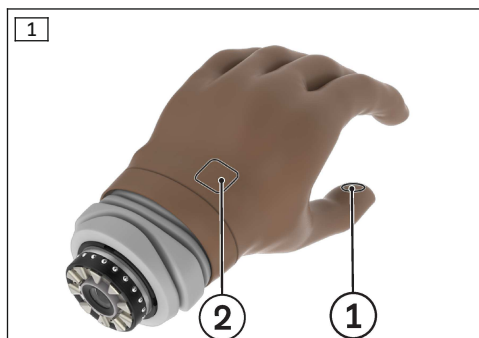




8E2=* speed.hand, 10V61=1 wrist.flex, 10V62=1 wrist.eqd, 10V63=1 wrist.short, 10V64=1 wrist.trans-carpal



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1 General

INFORMATION

Date of last update: 2025-02-06

- ▶ 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 “speed.hand 8E2=*” terminal device is referred to as the product/prosthesis/terminal device in the following document.

The “connect.grip.” app is referred to as the adjustment app in the following document.

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 Function

The terminal device is a myoelectrically controlled prosthetic hand and is a further development of the SensorHand Speed and VariPlus Speed. It features high gripping speed and gripping force combined with an innovative, sensitive control concept.

Proportional control device with DMC (dynamic mode control) allows the user to regulate the gripping speed and gripping force in proportion to the level of the muscle signal. When the strength of the muscle signal changes, the gripping speed and gripping force immediately adjust to the changed muscle signal.

The terminal device is supplied with a standard program for 2 electrodes.

The combination of a control unit (myosmart) and the adjustment app allows the control device to be optimally adapted to the individual needs and abilities of the user.

The terminal device is available in 2 variants, with a (8E2=*-1) and without a (8E2=*-0) thumb sensor.

Automatic gripping force readjustment (AutoGrasp), only for 8E2=*-1

The sensor (see fig. 1, (1)) integrated into the thumb recognises when a gripped object changes position and is therefore at risk of slipping out of the hand. In this case, the current gripping force is automatically increased until the object is in a stable position again.

The AutoGrasp function can be stopped at any time with a brief “OPEN” impulse.

FlexiGrip function, only for 8E2=*-1

The FlexiGrip function allows a grasped object to be turned or shifted in the hand without having to loosen the grip via electrode signals and subsequently re-grip the object.

The terminal device with thumb sensor follows the changes in the position of the grasped object in a similar way to a natural hand. This makes the grip flexible.

The FlexiGrip function can be stopped at any time with a brief “OPEN” impulse.

Essential performance of the product

- No essential performance according to IEC 60601-1

2.1.1 Wrist joint versions

The terminal device can be combined with 4 different wrists:



10V62=1 Wrist with EQD

The quick-disconnect wrist (EQD) makes it easy to disconnect the terminal device from the prosthetic socket. The terminal device can be quickly removed if necessary and replaced with another terminal device with the same closure. To change the terminal device, see the section "Changing the terminal device" (see page 26). Passive rotation of the terminal device is possible in 15° increments (maximum rotation range approx. 340°).



10V61=1 Wrist with EQD and flexion

The flexion joint with quick-disconnect wrist EQD not only allows easy change of the terminal device, but also allows positioning in the 20° or 40° flexion position, neutral position and 20° or 40° extension position (see section "Locking/unlocking the wrist" see page 27).

Passive rotation of the terminal device is possible in 15° increments (maximum rotation range approx. 340°).



10V63=1 Low-profile wrist with rotation

For users with a long transradial amputation/dysmelia.

The terminal device can be rotated in both directions (approx. 155 °) against a constant frictional resistance to the stop that is adjusted during treatment.

The terminal device can only be separated from the prosthetic socket by the O&P professional.

The 9S110=50 lamination ring is included in the scope of delivery.

The 9S110=54 lamination ring can be optionally ordered.



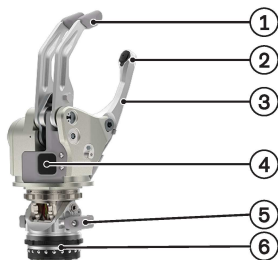
10V64=1 Fixed transcarpal wrist

For users with a transcarpal amputation.

The hand and wrist are permanently connected to the prosthetic socket, and do not permit rotation of the terminal device.

The position of the terminal device is set and cannot be changed afterwards, and the terminal device cannot be disconnected from the prosthetic socket.

2.2 Design



1. Fingers
2. Thumb sensor (for variant 8E2=*-1)
3. Thumb
4. ON/OFF button (switching on/off)
5. **For 10V61=***: Slider (locking/unlocking the wrist)
6. Wrist

Structure of the article numbers

Article number	Side	Size	Thumb sensor	Description
8E2=*				speed.hand
	L			Left hand
	R			Right hand
		-XS		Size extra small
		-S		Size small
		-M		Size medium
		-L		Size large
			-0	Without thumb sensor
			-1	With thumb sensor
8E2=L-L-1				Example: speed.hand, left hand, size large, with thumb sensor

2.3 Product combinations

This product can be combined with the following Ottobock components:

Control units

- myosmart 13E522=1

Electrodes

- Electrode 13E200=*, suction socket electrode 13E202=*
- Electrodes 13E400=*, 13E401=* (only in combination with a control unit)
- Electrode cable 13E129=* (only in combination with 13E200, 13E202)

Control elements

The control elements listed can be used with or without a control unit.

The electrode cable 13E129=* is also required to connect the following control elements.

- Linear control element 9X50
- 4-stage control element 9X51
- Linear control element 9X52
- 4-stage control element 9X53

Switch

The switches listed can be used with or without a control unit.

The connection cable 13E99=* is also required to connect the following switches.

- Harness pull switch 9X14
- 9X25 Rocker switch
- Cable pull switch 9X18
- Pressure switch 9X37

Power supply (rechargeable battery)

- MyoEnergy Integral 757B35=3, 757B35=4, 757B35=5
- 757B20/757B21 EnergyPack

Lamination rings

- Lamination ring 10S1=* (for 10V61=1, 10V62=1)
- 9S110=50 Lamination ring (included in the scope of delivery for 10V63=1)
- 9S110=54 Lamination ring (can be optionally ordered)

Active rotation

- 10S17 Electric wrist rotator
- MyoRotronic 13E205 (for prostheses without control unit)

Passive rotation

- 9E169 coaxial plug
- 10S4 coupling piece

Elbow

- ErgoArm Hybrid plus: 12K44=*
- ErgoArm Electronic plus: 12K50=*
- DynamicArm: 12K100N=*

Battery chargers

The following battery chargers can be used depending on the rechargeable battery:

- 757L20 charger (including 757L16* power supply)
- 757L35 charger (including 757L16* power supply unit)

3 Intended use

3.1 Indications for use

The product is intended **exclusively** for upper 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, sports which involve excessive strain and/or shocks to the wrist joint (pushups, downhill racing, mountain biking, ...) or extreme sports (free climbing, paragliding, etc.). Furthermore, the product should not be used to operate motor vehicles, heavy equipment (e.g. construction machines), industrial machines or motor-driven equipment.

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

3.3 Environmental conditions

Storage (with and without packaging)	+5 °C to +40 °C Max. 90 % relative humidity, non-condensing
Transport (with and without packaging)	-20 °C to +60 °C Max. 90 % 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)

3.4 Indications

- For unilateral or bilateral amputation
- Transcarpal/carpal amputation
- Wrist disarticulation
- Transradial amputation (below-elbow amputation)
- Elbow disarticulation
- Transhumeral amputation (above-elbow amputation)
- Shoulder disarticulation

- Interthoracascapular amputation
- Dysmelia with characteristics similar to that of an amputation mentioned
- The user must be able to understand usage instructions and safety notices and put them into practice.
- The user must fulfil the physical and mental requirements for perceiving optical/acoustic signals and/or mechanical vibrations

3.5 Contraindications

- Finger/thumb amputation or equivalent dysmelia
- Partial hand amputation and equivalent dysmelia
- Diseased or unhealed condition of skin areas that come into contact with the system in the area of the socket while the prosthesis is being used.

3.6 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-related information

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.

WARNING!

Risk of injury due to improper use

- ▶ 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.
- ▶ Observe the operating conditions and safety notes stipulated by the manufacturer of the implant.
- ▶ The prosthesis and implant must not be electrically connected.
- ▶ Do not make any changes to the product that have not been approved by the manufacturer.

WARNING!

Risk of injury due to malfunction of the product or interference with other electronic devices

- ▶ Only combine the product with the accessories, signal converters and cables listed in the chapters "Product combinations", "Scope of delivery" and "Accessories".
This prevents a malfunction of the product (reduced electromagnetic interference immunity) or interference with other electronic devices (increased emissions).

WARNING!

Risk of injury due to skin contact with allergenic substances

- ▶ Wear suitable gloves during the work to avoid contact with lubricants, production-related residues and components containing nickel.

CAUTION!

Risk of injury due to product malfunction

- ▶ Adjust the prosthesis so that the patient can disengage from the socket in case of complete hand failure.
- ▶ The prosthetic glove must extend beyond the wrist to prevent the penetration of dirt and liquids.

- Avoid proximity to sources of strong magnetic or electrical interference (e.g. theft prevention systems, metal detectors).

CAUTION!

Risk of injury due to malfunction of the product or interference with other electronic devices

- 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 with other electronic devices cannot be avoided, monitor the product and verify its intended use in the existing setup.

CAUTION!

Risk of injury due to incorrect product alignment

- Do not use silicone spray when applying the glove to ensure a secure fit.

CAUTION!

Risk of injury due to electric shock

- Do not touch live electrical contacts. See the section Changing the terminal device.

5 Scope of delivery

- 1x speed.hand 8E2=*
 - 1 pc. Instructions for use (qualified personnel)
 - 1 pc. instructions for use (user)

6 Accessories

- 8S11* prosthetic glove
- 8S12* prosthetic glove
- 8S13* prosthetic glove
- Optional: connectgrip adjustment app (in combination with a control unit), see the corresponding instructions for use of the adjustment app.
- USB charging adapter: 757L43 (only in combination with MyoEnergy Integral)
To connect the 757L43 USB charging adapter to the respective charger, observe the information in the USB charging adapter instructions for use.

7 Preparing the product for use

Operation without control unit

Check the function of the prosthesis by touching the electrodes, or together with the user when using the prosthesis.

Operation with control unit

Check the function of the assembled prosthesis with the adjustment app, or together with the user after creating a control device (recording).

Ensure that the prosthesis fittings can move freely.

7.1 Wrist

The following tools must be ordered to prepare the product for use.

- Torque wrench 710D4 (measuring range: 6 – 30 Nm)
- or
- Torque wrench 710D20 (measuring range: 2.5 – 25 Nm)
 - Hook wrench 709H11=1
 - Mounting plate 711M106=1
 - Vice

7.1.1 Assembling the wrist

7.1.1.1 Preparation



- 1) Clamp the mounting plate in the vice at the marked surface.



- 2) Push the system inner hand behind the base plate.

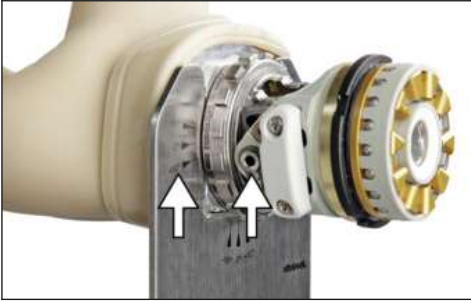


- 3) Slide the hand into the mounting plate with the square.



- 4) Set the hook wrench onto the torque wrench so the pin lies against the torque wrench.

7.1.1.2 Assembling the wrist flexion, EQD (10V61=1, 10V62=1)



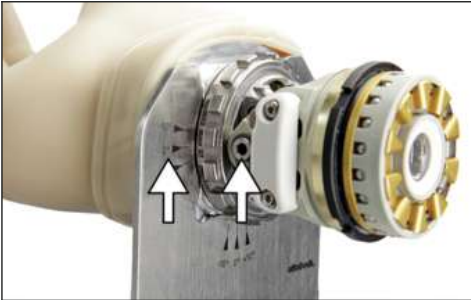
- 1) Set the wrist onto the hand. **For flexion:** Align the axis between **+10°** and **+20°**. Note the alignment of the slider depending on the desired actuating direction.

INFORMATION: The specified values are guidelines and do not have to be observed exactly. The wrist is twisted during tightening.

- 2) Manually tighten the wrist.



- 3) Tighten the wrist using the torque wrench. Tightening torque = **25 Nm**.



- 4) **For flexion:** Check that the axis is aligned **approximately** to the **+0°** marking.

INFORMATION: The specified values are guidelines and do not have to be observed exactly.



- 5) **For flexion:** Slide on the flexion guard with the hand symbol facing the hand.
- 6) Slide the flexion guard over the union nut up to the base plate.
- 7) Align the flexion guard with the knobs on the slider.



- 8) **For EQD, short:** Slide on the foam ring.
INFORMATION: The foam ring is included in the scope of delivery in 2 sizes (11S115=49, 11S115=54). It is used to create a harmonious transition between the socket and the hand.
For eqd: The size of the foam ring depends on the socket design and hand size.
For short: The size of the foam ring depends on the size of the lamination ring.

7.1.1.3 Assembling the wrist short (10V63=1)

The following description contains important information regarding assembly and alignment of the components relative to each other. Please read the following section prior to assembling the wrist.



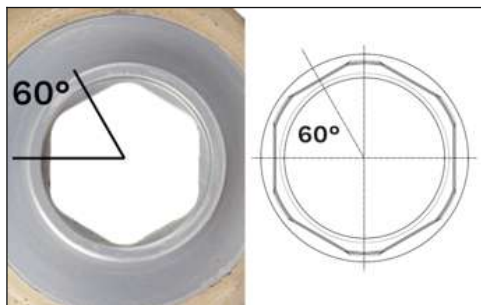
Marking

When inserting the disconnect piece, align the marking of the disconnect piece with the marking of the wrist.



Assembly note

The disconnect piece must be inserted into the lamination ring to the stop during assembly.

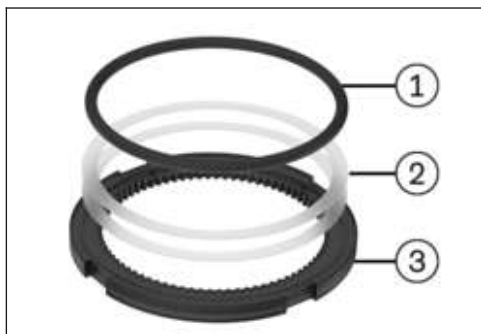


The disconnect piece can be rotated by 60° in either direction to insert it into the lamination ring.



Marking on the wrist wrist.short

When inserting the disconnect piece, align the marking of the disconnect piece with the marking of the wrist.



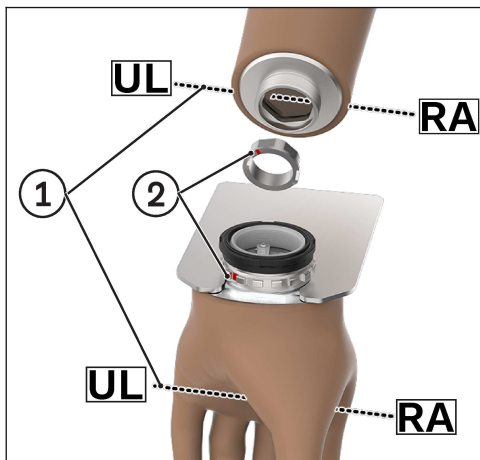
Arranging the O-ring, starting disc, sliding disc

- (1) O-ring
- (2) Starting disc

INFORMATION: The number of starting discs changes the sliding moment of the hand.

Recommendation: 2 starting discs.

- (3) Sliding disc



Overall orientation of the system

Align the ulna **UL**/radius **RA**/(1) axis with the plane of the palm. Align the radius with the thumb as you do so.

Align the mark on the disconnect piece (2) with the mark on the wrist (2).

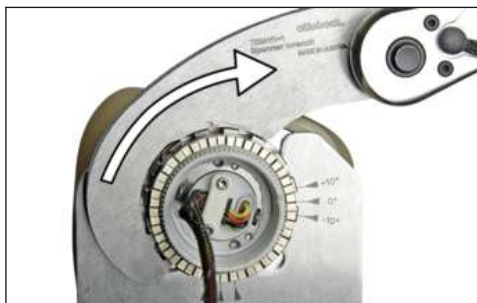
INFORMATION: The wrist itself has no specific alignment to other components

Required tools

- Pliers 706Z10

Required tools

- FSV 765 White special grease paste 633F100=*



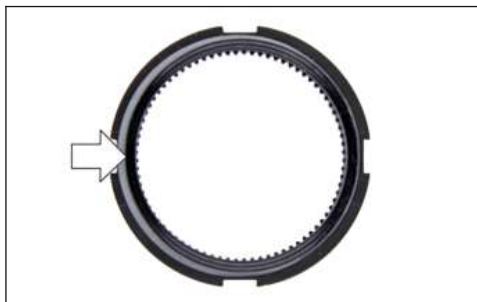
- 1) Set the wrist onto the hand and tighten it manually.
- 2) Tighten the wrist using the torque wrench. Tightening torque = **25 Nm**.



- 3) Clamp the mounting plate in the horizontal position by hand.



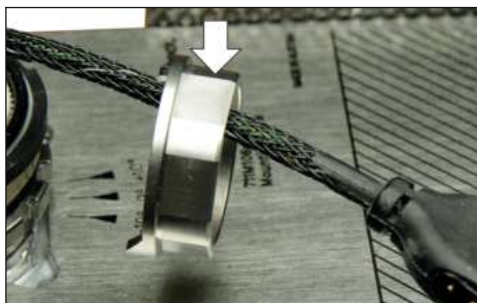
- 4) Apply special grease paste to the sliding disc.
- 5) Insert the washers into the black sliding washer and press them in.



- 6) Apply special grease paste to the O-ring.
- 7) Place the O-ring on the washers.



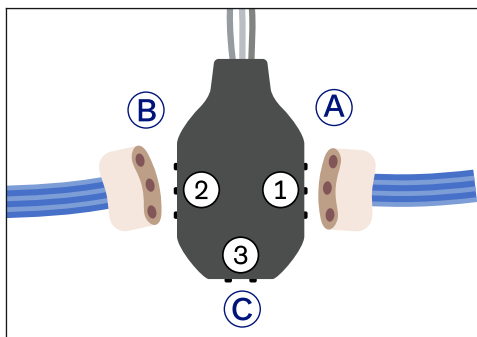
- 8) Slide the black sliding washer onto the wrist so the teeth interlock.



- 9) Thread the disconnect piece onto the hand cable so the hexagon faces in the direction of the plug.



10) Remove the plug cover.



11) **A**: Connect the cable from the opening contact to the hand cable (1).

12) **B**: Connect the cable from the closing contact to the hand cable (2).

INFORMATION: When using a control unit, the cable from the closing contact is marked with a blue dot.

13) **C**: Connect the battery cable to the hand cable (3).



14) Snap on the plug cover.



15) Thread the cables into the socket.

16) Align the ulna axis/radius of the socket to the hand.

17) Align the markings of the disconnect piece and wrist with each other

18) Slide the disconnect piece into the socket.



- 19) Hold the socket with your hand.
- 20) Manually tighten the black friction ring.
NOTICE! Damage to the cables and thread
 - Make sure you **do not twist the socket** during tightening.
 - When tightening by hand, ensure that the **threads interlock precisely**.
 - Make sure the **O-ring is not pinched**.



- 21) Set the pliers onto the black friction ring and tighten them gently.
- 22) Take the hand out of the mounting plate.
- 23) Secure the socket by hand.
- 24) Set the pliers onto the black friction ring and tighten them. Tightening torque: The guideline value is 3–4 times the sliding torque of the hand (corresponds to approx. **5–10 Nm**)

7.1.1.4 Assembling the transcarpal wrist (10V64=1)

Required tools

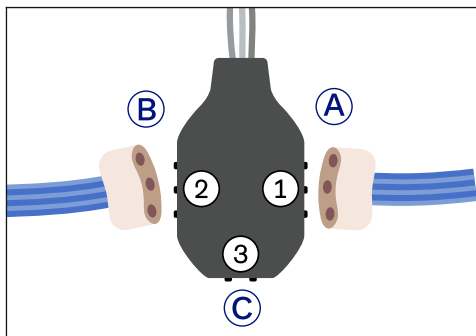
- Torque wrench, 40 cNm
- Torx bit T 6

Required tools

- 636W60 Adhesive (Loctite 243)



- 1) Remove the protective cap and plug cover.



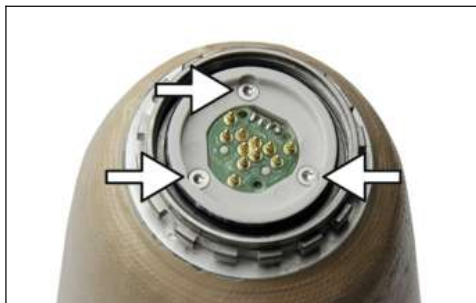
- 2) **A:** Connect the cable from the opening contact to the hand cable (1).
- 3) **B:** Connect the cable from the closing contact to the hand cable (2).

INFORMATION: When using a control unit, the cable from the closing contact is marked with a blue dot.

- 4) **C:** Connect the battery cable to the hand cable (3).



- 5) Snap on the plug cover.



- 6) Insert the cables into the socket.
- 7) Apply Loctite 243 to the countersunk screws.
- 8) Apply the connection plate and screw it in 3 times (Torx bit T 6).
Tightening torque = **35 cNm**.



- 9) Place the socket on the hand.
- 10) Manually tighten the union nut.
- 11) Tighten the union nut using the torque wrench.
Tightening torque = **25 Nm**.

7.1.2 Disassembling the wrist (all variants)



- 1) Clamp the mounting plate in the vice at the marked surface.



- 2) **For wrist 10V61=1:** Pull off the flexion guard.



- 3) **For wrist 10V62=1, 10V63=1:** Pull off the foam ring.



- 4) Pull off the prosthetic glove.
- 5) Slide the hand into the mounting plate with the square.



- 6) Set the hook wrench onto the torque wrench so the pin lies against the torque wrench.



- 7) Loosen the union nut using the torque wrench.

7.2 Assembling the coaxial plug



Insert the coaxial plug 9E176 into the coupling crown with the lug facing the recess.



Secure the coaxial plug with the lock ring 9E170. Install the lock ring with the bevel facing upwards.

Article number	Designation	Contains the following parts
9E169	Coaxial plug	- Coaxial plug piece 9E176 - Lock ring 9E170 - Cup screw 501Z49=M4x6
10S4	Coupling piece	- Clutch crown - Lock ring 9E170

7.3 Positioning the electrodes

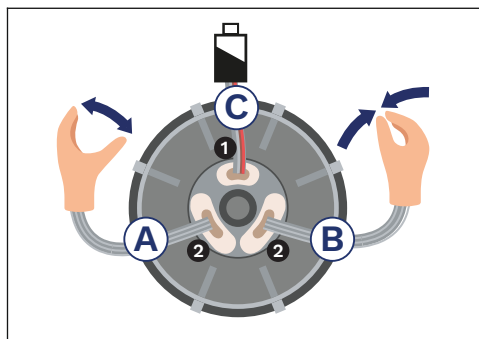
The ideal position of the electrodes is determined with the adjustment app and the 757M20-2=* cuff; see the instructions for use of the adjustment app and cuff.

Alternatively, the electrodes can be positioned with the MyoBoy 757M11=X-CHANGE; see the corresponding instructions for use.

7.4 Operation without control unit

7.4.1 Connecting the coaxial plug

7.4.1.1 Forearm prosthesis, ErgoArm



Ⓐ Connect the cable from the opening contact to the left contact no. 2.

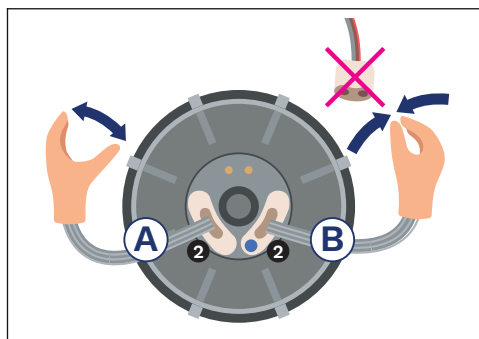
Ⓑ Connect the cable from the closing contact to the right contact no. 2.

INFORMATION: For the ErgoArm, the cable from the closing contact is marked with a blue dot

Ⓒ Connect the battery cable to contact no. 1. Secure the cables on the coaxial plug with the cup screw 501Z49=M4x6.

Push the coaxial plug into the lamination ring. Secure the coaxial plug with the lock ring 11S4.

7.4.1.2 DynamicArm



Ⓐ Connect the cable from the opening contact to the left contact no. 2.

Ⓑ Connect the cable from the closing contact to the right contact no. 2.

The 2-pin cable must not be connected.

Secure the cables on the coaxial plug with the cup screw 501Z49=M4x6.

Insert the coaxial plug into the socket.

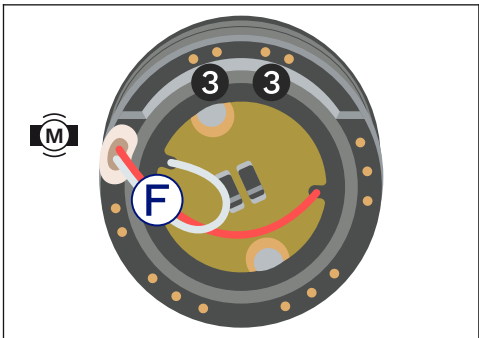
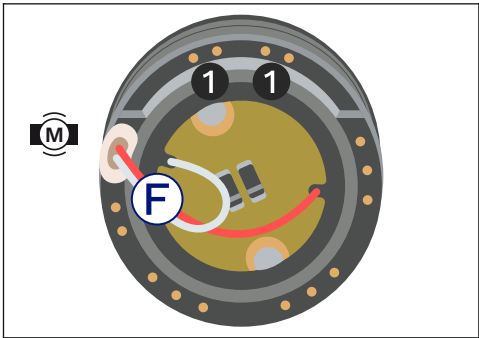
Secure the coaxial plug with the lock ring 11S4.

7.4.2 Connecting the electric wrist rotator

7.4.2.1 Forearm prosthesis, ErgoArm

If a forearm prosthesis or ErgoArm is combined with an electric wrist rotator, a MyoRotronic must also be used.

Attaching the MyoRotronic



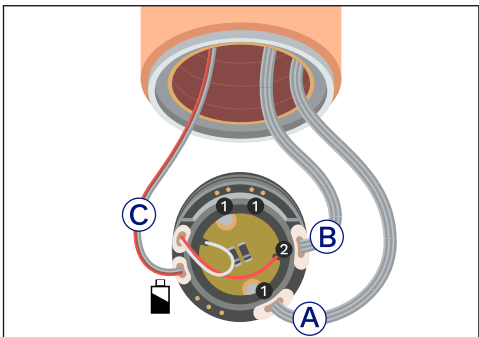
Left hand

Disconnect the motor cable from the electric wrist rotator.
Attach the MyoRotronic to the electric wrist rotator so that the no. 1 contacts remain free.
(F) Connect the motor cable to the MyoRotronic.

Right hand

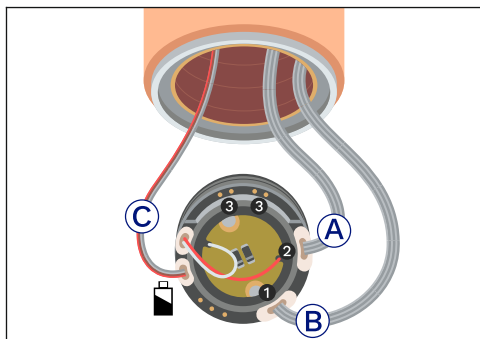
Disconnect the motor cable from the electric wrist rotator.
Attach the MyoRotronic to the electric wrist rotator so that the no. 3 contacts remain free.
(F) Connect the motor cable to the MyoRotronic.

Connecting the MyoRotronic



Left hand

(A) Connect the 3-pin cable from the opening contact to the right contact no. 1.
(B) Connect the 3-pin cable from the closing contact to the right contact no. 2.
INFORMATION: For the ErgoArm, the cable from the closing contact is marked with a blue dot.
(C) Connect the 2-pin battery cable to the contact with the battery symbol.



Right hand

(A) Connect the 3-pin cable from the opening contact to the right contact no. 2.

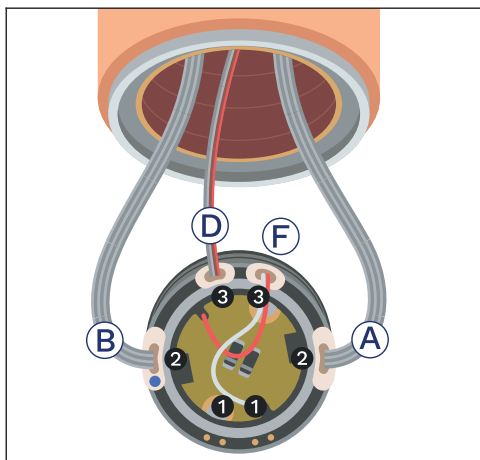
(B) Connect the 3-pin cable from the closing contact to the right contact no. 1.

INFORMATION: For the ErgoArm, the cable from the closing contact is marked with a blue dot.

(C) Connect the 2-pin battery cable to the contact with the battery symbol.

7.4.2.2 DynamicArm

The MyoRotronic is not required for the DynamicArm.



(A) Connect the 3-pin cable without the blue dot to the right contact no. 2.

(B) Connect the 3-pin cable with the blue dot to the left contact no. 2.

(D) Connect the 2-pin cable to left contact no. 3.

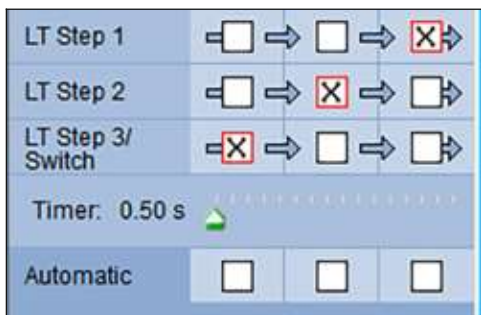
(F) Connect the motor cable of the electric wrist rotator to the right contact no. 3.

No cable may be connected to the two no. 1 contacts.

7.4.2.3 Adjusting the elbow joint with ElbowSoft

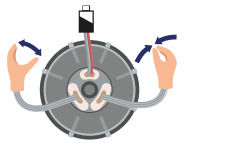
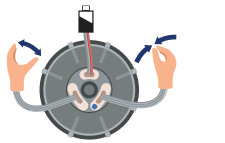
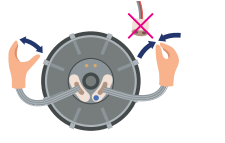
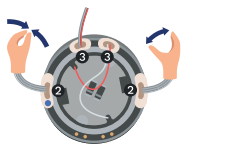
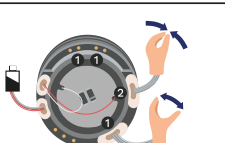
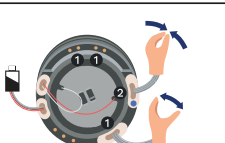
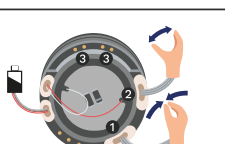
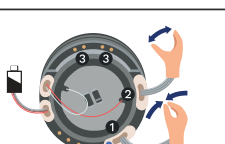
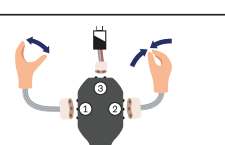
The following adjustments must be made in ElbowSoft to ensure correct prosthesis control functionality.

See the ElbowSoft instructions for use and the corresponding training documentation from the Ottobock Academy.



- 1) Calibrating the elbow joint.
- 2) Set control program 5.
- 3) Set the speed to 100 %.
- 4) Clear all check boxes next to "Automatic".
- 5) Activate the checkbox Manual for "LT Step 1."
- 6) Select the checkbox Wrist for "LT Step 2."
- 7) Select the checkbox Elbow joint for "LT Step 3."
- 8) Set "LT Timer" to 0.5 seconds.
- 9) Deactivate feedback signals.

7.4.3 Overview of connections without control unit

	Transradial	Transhumeral	
		ErgoArm	DynamicArm
Coaxial plug			
Electric wrist rotator without MyoRotronic	–	–	
Left hand Electric wrist rotator with MyoRotronic			
Right hand Electric wrist rotator with MyoRotronic			
Hand cable (for wrist 10V63=1, 10V64=1)			

7.5 Operation with control unit

The optional control device with a control unit (e.g. myosmart) in combination with the "connectgrip." app allows the individual adaptation of the prosthesis control to the needs of the user, as well as settings for other prosthesis components. To do this, install the "connectgrip." app, which is available for free from the various app stores on your mobile device or tablet. After configuration by qualified personnel, it is possible to adjust the control device according to your own needs by adding further transaction data and activating/deactivating functions.

The combination of the control unit and adjustment app allows the following:

- Visualisation of myosignals for evaluation and training
- Using different types of electrodes, numbers of electrodes and external control elements
- Recording and training of user-specific myosignals for prosthesis movements and switching between the prosthesis components
- Fitting by the user in everyday life by adding additional movement recordings
- Fine adjustment of the prosthesis control (reaction time, on threshold, speed adjustment, ...)
- Manual control and activation/deactivation of prosthesis movements
- Feedback via optional signal emitter
- Setting specific prosthesis functions (opening width of the neutral position, thumb sensor, ...)
- Preparation of documentation for reimbursement by the paying party

- Access to further product information

7.5.1 Adjustment app



The qualified personnel can carry out the basic product settings using the adjustment app after a successful login in “qualified personnel mode”. These basic settings are part of treatment and can only be adjusted or deleted by qualified personnel.

INFORMATION

The adjustment app can be downloaded free of charge from the respective online store. Enter the search terms “ottobock” or “connectgrip”.

The instructions for use of the adjustment app can be opened as a PDF file in the adjustment app via **Menu > Instructions for use**.

7.6 Charging the battery

The following information is found in the instructions for use of the respective batteries or elbow components:

- Handling the battery
- Querying the charge level
- Feedback (beeps and vibration signals)

8 Use

8.1 Terminal device on/off

The terminal device can be switched off when a grip is to be maintained for a longer period of time, while holding cutlery, writing or during longer passive pauses, for example, while travelling by rail or air. This prevents unintentional opening of the hand caused by inadvertent tensing of the muscles or extreme electrical interference. The operating time of the prosthesis battery is also extended.

The terminal device is switched on or off by pressing the button on the back of the hand for about 2 seconds, see fig. 1 (2).

INFORMATION

Only for battery 757B20, 757B21

The terminal device is activated when the battery is inserted.

Duration of operation	Function	Vibration signal
approx. 2 seconds	Switching the hand on	2x short
approx. 2 seconds	Switching the hand off	1x long
Longer than 4 seconds	Open hand, then switch off	-

8.2 Changing the terminal device

INFORMATION

Changing the terminal device only works in combination with the 10V61=1 (wrist.flex) or 10V62=1 (wrist.eqd) wrist variants.

Separating the terminal device from the socket

- 1) Turn the prosthesis off with the button in the charging receptacle (prosthetic socket) or the switch on the elbow joint.

- 2) For an interchangeable battery system (757B20, 757B21): Remove the battery.
- 3) Rotate the terminal device once or twice around its own axis until a slight resistance is felt.
- 4) Overcome this resistance and pull the terminal device off the socket.

Attaching the terminal device to the socket

- 1) Insert the quick-disconnect wrist unit into the lamination ring and press it in firmly.
- 2) Turn the terminal device slightly to the left or right.
- 3) Verify proper attachment by pulling on the terminal device.

8.3 Locking/unlocking the wrist (10V61=1)

A slider underneath the wrist cover can be used to switch the wrist lock on or off in 20° increments.

The locking/unlocking direction of the slider is determined by the O&P professional when the wrist is assembled onto to the terminal device.



Unlocking the wrist

- Push the slider in the direction of the arrow ①.
→ The wrist lock is unlocked. The wrist can be moved freely.

Locking the wrist

- 1) Push the slider in the direction of the arrow ① to unlock the wrist lock.
- 2) When the desired position is reached, push the slider in the direction of the arrow ②.
→ The wrist engages at the next available position.

8.4 Opening the terminal device manually

In addition to the muscle signals, other options are available for opening the terminal device.

Slip clutch

The integrated slip clutch allows the terminal device to be opened regardless of the active control signals.

A noise is audible when the slip clutch is released. Then the hand engages again and another noise is audible.

- Manually pull the fingers and thumb of the terminal device apart.

Opening and switching off

This safety function allows the terminal device to be opened regardless of the active control signals.

- 1) With the product switched on, press the On/Off button of the terminal device for more than 4 seconds until the terminal device starts to open, see fig. 1 (2).
- 2) After the terminal device has opened, it is switched off.

8.5 Relaxed hand position

The terminal device has a neutral position in combination with the control unit that can be activated in the adjustment app. After the terminal device is fully opened and the muscles are relaxed, the terminal device automatically returns to a slightly open position (neutral position) after a specified time.

8.6 Activating/deactivating the thumb sensor (AutoGrasp, FlexiGrip)

The thumb sensor can be deactivated (AutoGrasp and FlexiGrip are deactivated) for gripping very soft and pliable objects, such as very soft foams or tweezers.

Note that the gripping force is not readjusted automatically if the thumb sensor is deactivated, and gripped objects may slip.

8.6.1 Operation without control unit

Complete the following steps to deactivate/activate the thumb sensor.

- 1) Open the hand to the stop and keep it open with a muscle signal of any strength.

- 2) At the same time, apply some pressure to the thumb sensor (see fig. 1, (1)), e.g. by pressing on the edge of a table.
 - **2 vibration signals:** thumb sensor activated
 - **1 vibration signal:** thumb sensor deactivated

8.6.2 Operation with control unit

The thumb sensor can only be activated/deactivated with the adjustment app.

9 Storage

Observe the following instructions for storage or transportation of the terminal device.

Type	Notice
Terminal device with thumb sensor	Storage, transport in open state: the thumb and fingers must not touch
Terminal device with Flex wrist	Storage and transport in flexible mode of the wrist

10 Cleaning

- 1) Switch off the product before cleaning.
- 2) Clean the product with a damp cloth and mild soap when needed.
Make sure that no liquids get into the product and product components.
- 3) Dry the product with a lint-free cloth and allow it to air dry fully.

INFORMATION

For the prosthetic glove, note the cleaning instructions in the instructions for use of the prosthetic glove.

11 Maintenance and repair

To prevent injuries and maintain the quality of the product, it is recommended that regular maintenance (service inspection) is performed every 24 months by an authorised Ottobock service centre.

In general, all products are subject to compliance with the maintenance intervals during the warranty period. This is the only way to maintain full warranty cover.

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.

11.1 Replacing the system inner hand

Required tools

- 711M1 Mounting tool
- 711M2 Mounting plate
- 711M3 Mounting tool

Required tools

- FSV 765 White special grease paste 633F100=*

Spare parts

- 8X12=* Inner hand



1) Mount the hand on the assembly tool.



2) Pull off the system inner hand and remove it.



3) Apply and distribute special grease paste on the inner diameter of the new system inner hand.



4) Pull on the system inner hand.
5) Engage the groove of the system inner hand in the base plate.



- 6) Secure the system inner hand with string.

11.2 Replacing the ball bearing retainer

Required tools

- FSV 765 White special grease paste 633F100=*

Spare parts

- 509Y1=3 Bearing ball
- 11S9 Ball bearing retainer



- 1) Pry off and remove the ball bearing retainer.
- 2) Remove the balls.



- 3) Clean the ball track.
- 4) Apply special grease paste to the ball track.



- 5) Snap on the new ball bearing retainer.



- 6) Use a flat object to press the balls into the ball bearing retainer.



- 7) Twist the ball bearing retainer several times to distribute the special grease paste.

11.3 For short, transcarpal: Replacing the electronics with cable

Required tools

- 710D21 Torque screwdriver
- Torx bit T 6

Required tools

- 636W60 Adhesive (Loctite 243)

Spare parts

- 11S117=1 Electronics with cable



- 1) Loosen and remove the 3 screws (Torx bit T 6).
- 2) Remove the electronics with cable.
- 3) Insert the new electronics with cable into the wrist.
- 4) Apply Loctite 243 to the countersunk screws.
- 5) Screw on the electronics with 3 countersunk screws 501S137=M2X3 (Torx bit T 6). **Tightening torque = 35 cNm.**

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.

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>

13 Technical data

Designation	
Opening width (depending on the size of the hand)	80 up to 100 mm
Proportional speed	15–300 mm/s
Proportional gripping force	105 ± 15 N
AutoGrasp (8E2=*-1)	Proportional: Up to max. 1.5 times the current gripping force
FlexiGrip (8E2=*-1)	Depending on the current gripping force, takes effect slightly above the maximum gripping force readjustment in each case Min. from 20 N to max. from 130 N
Nominal voltage range (hand and wrist)	Approx. 6.5 V to approx. 8.2 V
Lifetime	6 years

Hand size	Weight (with system inner hand)	Length to base plate	Length to under- side of thread
XS	368 g	103 mm	111 mm
S	376 g	107 mm	115 mm
M	392 g	107 mm	115 mm
L	425 g	109 mm	117 mm

Maximum load on the hand (with wrist)	Strength
When carrying objects protruding from the hand (e.g. tray: size 100 x 100 mm)	120 N
On the fingers from the outside with the hand closed (e.g. sup- porting the hand)	450 N
On the fingers from the inside with the hand closed (e.g. when carrying a bag)	250 N

Recharge- able bat- tery refer- ence num- ber	757B20	757B21	757B35 =1	757B35 =3	757B35=4	757B35 =5
Temperat- ure range for charging [°C]	+5 to +40					
Capacity [mAh]	900 ¹ / 950 ¹	680 ¹ / 800 ¹	600	1150	2350	3450
Rechargea- ble battery lifetime [years]	2					
Product behaviour during the charging process	The product is non-functional					
Charging times (rechargea- ble battery fully dis- charged) [hours]	Approx. 3.5	Approx. 3	Approx. 2.5		Approx. 3	Approx. 3
Nominal voltage [V]	Approx. 7.4					
Battery technology	Li-ion		Li-poly	Li-ion		

Recharge- able bat- tery refer- ence num- ber	757B20	757B21	757B35 =1	757B35 =3	757B35=4	757B35 =5
Approved battery chargers	757L20		757L35			

¹ See labeling on battery

Wrists	10V61=1 wrist.flex	10V62=1 wrist.eqd	10V63=1 wrist.short	10V64=1 wrist.transcarpal
				
Weight	115 g	60 g	50 g	40 g
Overall installation length with lamination ring (from the cover plate for the inner hand)	61 mm	39 mm	24 mm	17 mm
Length of the wrist	48 mm	26 mm	21 mm	14 mm
Maximum rotation	340°		Both directions 155° each	–
Lamination ring scope of delivery	–		9S110=50	
Lamination ring can be optionally ordered			9S110=54	
Rotation stages	15°		–	
Removable terminal device	Yes			
Combination with active rotation possible?				
Flexion possible	Yes (in 20° increments)	No		

14 Appendices

14.1 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
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	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.
	Declaration of conformity according to the applicable European directives
	Serial number (21)YYYYWWNNNN YYYY – year of manufacture

	WW – week of manufacture NNN – sequential number
	Medical device
	UDI number (Unique Device Identifier)
	Article number
	Global Trade Item Number
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°

14.2 Directives and manufacturer's declaration

14.2.1 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 "Safety" (Safety).

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

Phenomenon	EMC basic standard or test procedure	Interference immunity test level
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
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						

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



A series of horizontal lines for writing, spanning the width of the page.

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

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.



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