ottobock.

757M20=*

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.

1 Foreword

INFORMATION

Date of last update: 2022-03-29

- ► Please read this document carefully before using the product and observe the safety notices.
- ► Instruct the user in the safe use of the product.
- ► Please contact the manufacturer if you have questions about the product or in case of problems.
- ► Report each serious incident 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 "757M20=* Myo cuff" is referred to as the product/cuff below.
These instructions for use provide you with important information on the use, adaptation and handling of the product.
The product may not be transferred to the patient without prior instruction.
Only put the product into use in accordance with the information contained in the accompanying documents supplied.
According to the manufacturer (Otto Bock Healthcare Products GmbH), the patient is the operator of the product according to the IEC 60601-1:2005/A1:2012 standard.

2 Product description

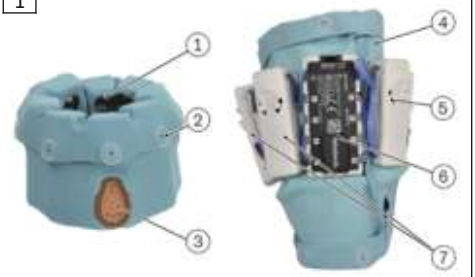
2.1 Function

The product is intended to determine the suitability of a patient for using Myo Plus control. The product is a flexible armband that is temporarily applied to the patient's forearm. This makes it possible to evaluate the patient's signal patterns using the Myo Plus app, without fabricating a check socket. In case of problems with separation of the signal patterns, the patient can use the product to practise at the facilities of the O&P professional or in the rehabilitation centre.
The product is a flexible armband that is applied to the end user's sound limbs.
The product measures the patient's control signals and assigns them to the prosthesis movements.

2.2 Design

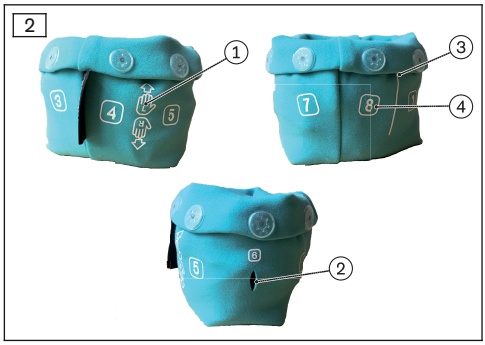
The product consists of the following components:

1



1. Remote electrode dome
2. Textile cuff snap fasteners
3. Charging receptacle and battery
4. Textile cuff
5. Housing for remote electrodes and battery
6. Housing and MyoPlus TR
7. Nameplate

Explanation of symbols



1. Donning direction (left/right)
   The arrow has to point towards the hand.
2. Charging receptacle
3. Alignment for the patient's ulna

4. Electrode position (1–8)

3 Intended use

3.1 Indications for use
The product is to be used exclusively for exoprosthetic fittings of the upper limbs.

3.2 Conditions of use
The product is to be used **exclusively** for the period of end user evaluation and training.

3.3 Indications
- For patients with unilateral and bilateral amputations.
- For patients with transcarpal and transradial amputation.

3.4 Contraindications
- For patients with transhumeral amputation.
- For patients with partial hand amputation.
- For patients with shoulder disarticulation.

3.5 Qualification
Fitting a patient with the product may only be carried out by O&P professionals, therapists or nursing staff who have been authorised by Ottobock upon completion of a corresponding training course. Furthermore, the O&P professional must have the technical qualifications required for the alignment of a prosthesis together with all necessary settings and adjustments.
The "O&P professional mode" of the adjustment app may only be used by qualified personnel, therapists and nursing staff after participating in the relevant product training and obtaining certification for the application. Additional product training courses may become necessary to qualify for app updates.

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

Non-observance of safety notices
Injury due to faulty control or malfunction of the product.
Destruction of the product.
► Observe the safety notices and the stated precautions in this accompanying document.

⚠ WARNING

Operating the product near medical devices critical for safety
Interference with life-sustaining medical devices (e.g., pacemaker, defibrillator, heart-lung machine, etc.) due to electromagnetic interference of the product.
► When operating the product in the immediate vicinity of life-sustaining medical devices, ensure that the minimum distances stipulated by the manufacturer are observed.
► Make sure to observe the operating conditions stipulated by the manufacturer and the safety notices.

⚠ WARNING

Use of inappropriate components
Injury due to malfunction of the product.
► Operate the product only with components prescribed by the manufacturer. You can find the list of components in the section "Combination possibilities".
► Operate the product only with accessories recommended by the manufacturer. You can find the list of components in the section "Scope of delivery and accessories".

⚠ WARNING

Changes or modifications to the product made independently
Injury due to faulty operation or malfunction of the product.
► Have any changes or modifications to the product carried out only by authorised, qualified Ottobock personnel.
► The battery may only be handled by authorised, qualified Ottobock personnel (replacement by the user is not permitted).
► The product and any damaged components may only be opened and repaired by authorised, qualified Ottobock personnel.

⚠ CAUTION

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

Injury 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 persons (e.g. in airports) or other sources of strong magnetic and electrical interference (e.g. high-voltage lines, transmitters, transformer stations, computer tomographs, magnetic resonance tomographs, etc.).
- ► When walking through theft prevention systems, body scanners or metal detectors, watch for unexpected behaviour of the product.

⚠ CAUTION

Skin irritation due to inadequate cleaning of the product

Skin irritation due to contact with soiled electrode domes.

- ► Clean the product only as described in the section "Cleaning and care" (Cleaning and care).

⚠ CAUTION

Reuse on another user without corresponding cleaning of the product

Skin irritation due to soiling of the product by a previous user.

- ► Only use the product on one user for the duration of a fitting.
- ► Between two fittings, send the product to the Ottobock Service Centre for cleaning.

⚠ CAUTION

Insufficient distance to HF communication devices (e.g. mobile phones, Bluetooth devices, WiFi devices)

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

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

⚠ CAUTION

Operating the product in very close proximity to other electronic devices

Injury 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

Use of a damaged product

Injury due to material damage of the product.

- ► Inspect the product each time for sharp-edged and pointy parts before putting it on.
- ► Have the product repaired by an authorised Ottobock Service Centre in case of damage.

NOTICE

Insufficient skin contact of the electrodes

Insufficient information about the suitability of the muscle signals to use MyoPlus

► Makes sure that the contact surfaces of the electrode domes are placed on intact skin only and have full-surface contact during a test.

NOTICE

Shifting of the electrodes

Insufficient information about the suitability of the muscle signals to use MyoPlus

► Make sure that the electrodes do not shift during a test, or restart the test.

NOTICE

Incorrect electrode settings due to muscle fatigue

Insufficient information about the suitability of the muscle signals to use MyoPlus

► Make sure that breaks are taken during calibration.

NOTICE

Penetration of dirt and humidity into the product

Reduction of the informative value of the muscle signal due to product malfunction.

Skin irritation due to dirt or chemical reactions in combination with perspiration.

► Make sure that neither solid particles nor liquids can penetrate into the product.

NOTICE

Improper product disposal

Environmental damage due to improper disposal.

► After the end of the service life or in case of total loss of the product, dispose of the product according to the applicable national legal regulations.

5 Scope of Delivery and Accessories

Scope of Delivery

Items in the scope of delivery or accessories marked with ■ are application parts according to the IEC 60601-1:2005/A1:2012 standard.

- 1 pc. 646C107 Bluetooth PIN card
- 1 pc. 757M20=* Myo gaiter
  includes: 13Z161 electrode dome, flat ■ or 13Z162 electrode dome, medium ■ or 13Z163 electrode dome, high ■
- 1 pc. battery charger 757L35 MyoCharge Integral
- 1 pc. Instructions for use (qualified personnel)

Accessories

- Myo Plus app
- 1 pc. 757P41-1 Y-cable

6 Charging the battery

We recommend charging on a daily basis. If the device is not used for an extended period, the battery charge level should be checked regularly and the battery recharged.

1) Connect the charging plug to the charging receptacle of the product.
   → A correct connection between the battery charger and the product is indicated by feedback (see page 14).

→ The product is switched off automatically.
→ The charging process starts.

2) Disconnect the battery charger from the product after the charging process is complete.

7 Preparing the product for use

7.1 Determine electrode position

1) Pull the product over the end user's forearm.
2) Position the product 6 to 7 cm distal of the olecranon.
3) Position the charging pill laterally.

INFORMATION

Make sure that the electrode domes are in contact with the end user's skin.

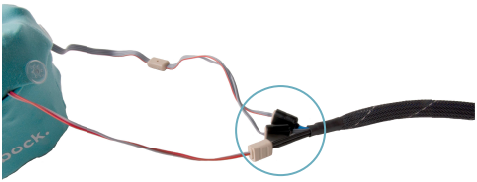
7.2 Establishing a connection to a demo prosthesis

Prerequisite for intended use

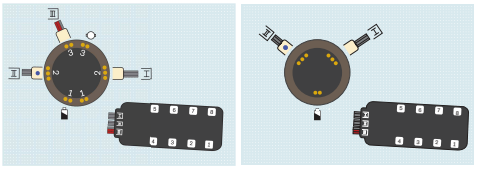
- Base
- 10S17 Active rotation unit
- Compatible hand prosthesis
- Compatible battery

Note the following steps for establishing a connection:

1) Open the product's fabric far enough so the cables (two-pin cable and 757P41-1 Y-cable) can be brought to the outside.
2) Refasten the product's snap fasteners.



3) Connect the projecting cables to the supplied extension cables.
   Make sure the cables are respectively connected with the same marking.



4) Connect the other ends of the extension cable to the demo prosthesis.
   See the information for connecting the rotation unit in the Myo Plus TR instructions for use.
5) Switch on the product and connect to the app.
6) In the menu of the Myo cuff, press the “Connect demo prosthesis” button.
7) Switch the prosthesis on within ten seconds.

INFORMATION

Only use the 757P41-1 Y-cable for the connection.

8 Myo Plus app

With the Myo Plus app, the user can view and evaluate their signals and the frequently used functions together with the O&P professional. The repeatability of movements can be trained with the app. When combined with the product, the app permits the simulation of bebionic hands or MyoBock hands.

INFORMATION

The Myo Plus app can be downloaded free of charge from the respective online store. To download the Myo Plus app, the QR code on the supplied Bluetooth PIN card can be read with the mobile device (requirement: QR code reader and camera).

8.1 System Requirements

See the information in the Apple App Store or Google Play Store regarding compatibility with mobile devices and versions.

8.2 Initial connection between MyoPlus app and product

The following points should be observed before the initial connection:

- Bluetooth on the mobile device must be switched on.
- The Bluetooth ID and Bluetooth PIN of the product being connected must be known.
  The Bluetooth PIN and Bluetooth ID are found on the enclosed Bluetooth PIN card.
  The Bluetooth ID is found on the Myo Plus TR (see fig. 1, item 6) and starts with the letters "BT ID".

8.3 Starting the Myo Plus app for the first time

INFORMATION

Keep mobile app up to date.

- Please contact the manufacturer if you suspect cybersecurity problems.

INFORMATION

Bluetooth on the prosthesis must be turned on in order to use the MyoPlus app.
After turning on Bluetooth, it remains active for approx. 5 minutes. The app must be started and the connection established during this time.

1) Tap the icon for the Myo Plus app .
   → The end user licence agreement (EULA) is displayed.
2) If rights are requested the first time the app is started, these have to be granted. Otherwise, the app cannot be started.
3) Accept the end user licence agreement (EULA). If the end user license agreement (EULA) is not accepted, the Myo Plus app cannot be used.
4) The "Bluetooth connection" menu item is opened.
5) Tap + to establish a connection.
6) Select the desired component from the list.
7) Enter the Bluetooth PIN code and tap "Connect".
   → The (•ı) icon is displayed when the connection has been established.

→ Once the connection has been established, the data are read from the component. Then the radar chart is displayed.

9 Use

9.1 Evaluating muscle signals in the MyoPlus app

To perform an evaluation of the muscle signals or for training, the following steps have to be completed:

1) Press the charging receptacle button and hold for one second.
   → The product is switched on.
   → Two short beeps are emitted.
2) In the app, tap the "Myo Cuff" menu.
3) Select the desired hand that was chosen in the planned fitting.

→ Now the muscle signals can be evaluated and trained.

Connecting to the demo prosthesis

1) Press the Myo cuff button and hold for one second.
   → The product is switched on.
   → Two short beeps are emitted.
2) Establish a connection between Myo Plus and the Myo cuff.
3) In the app, tap the “Myo cuff” menu.
4) Press the button to establish a connection to the demo prosthesis.
5) Switch on the demo prosthesis within 10 seconds.

→ Now the muscle signals can be evaluated and trained.

9.2 Display of the current charge level

The battery charge level can be queried at any time.

1) With the product switched on, press the button on the charging receptacle and hold for less than one second.
2) The LED display on the charging receptacle provides information on the current battery charge level (see page 14).

9.3 Safety Shutoff

The purpose of the safety shutoff is to protect the battery; it is triggered in case of:

- Excessively high or low temperature during the charging process
- Short circuit
- Overvoltage or undervoltage

INFORMATION

After a safety shutdown, the battery charger must be connected to reactivate the electronics.

10 Cleaning and Care

⚠ CAUTION

Reuse on another user without corresponding cleaning of the product

Skin irritation due to soiling of the product by a previous user.

► Only use the product on one user for the duration of a fitting.
► Between two fittings, send the product to the Ottobock Service Centre for cleaning.

Cleaning the electrode domes

1) Clean the electrode domes with a cleaning cloth and 634A58 isopropyl alcohol after each application.
2) Dry the electrode domes with a cloth.

11 Legal information

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

11.1 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.

11.2 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.

11.3 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.
This product meets the requirements of the 2014/53/EU directive.
The full text of the regulations and requirements is available at the following Internet address: http://www.ottobock.com/conformity

11.4 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.
Responsible party:
Otto Bock Health Care, LP
3820 West Great Lakes Drive
Salt Lake City, Utah 84120-7205 USA
Phone + 1-801-956-2400
Fax + 1-801-956-2401

This device complies with RSS 210 of Industry Canada.
Operation is subject to the following two conditions:
(1) this device may not cause interference, and
(2) this device must accept any interference, including interference that may cause undesired operation of this device.

L' utilisation de ce dispositif est autorisée seulement aux conditions suivantes:
(1) il ne doit pas produire d'interference et
(2) l' utilisateur du dispositif doit étre prêt à accepter toute interference radioélectrique reçu, même si celle-ci est susceptible de compromettre le fonctionnement du dispositif.
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; consult Safety Code 6, obtainable from Health Canada's website
http://www.hc-sc.gc.ca/rpb.
Responsible party:
Otto Bock Healthcare Canada Ltd.
5470 Harvester Road
L7L 5N5 Burlington, Ontario
Canada
Phone + 1-800-665-3327

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.

12 Technical data

Ambient conditions	
Storage in original packaging	+5 °C/41 °F to +40 °C/104 °F Max. 85% relative humidity, non-condensing
Transport in original packaging	-25 °C/-13 °F to +35 °C/95 °F 15% to 90% relative humidity, non-condensing +35 °C/95 °F to +70 °C/158 °F Water vapour pressure up to 50 hPa

Ambient conditions	
Storage between subsequent applications	-25 °C/-13 °F to +35 °C/95 °F 15% to 90% relative humidity, non-condensing +35 °C/95 °F to +70 °C/158 °F Water vapour pressure up to 50 hPa
Operation	+5 °C/41 °F to +40 °C/104 °F 15% to 90% relative humidity, non-condens-ing; air pressure 533 hPa to 1060 hPa
Charging the battery	0°C/+32°F to +45°C/+113°F

General	
Reference number	757M20=*
Inner diameter	45 mm
Exterior diameter	110 mm
Weight	210 g
Textiles used	80% polyamide (PA) 20% elastane (EL)
Service life	5 years

Battery of the product	757B35=0
Battery type	Li-Po
Output voltage	Approx. 7.4 V DC
Charging voltage	Approx. 8.2 V DC
Capacity	300 mAh
Dimensions of battery cells	35 x 20 x 6.5 mm per cell
Dimensions of protection electronics	22 x 17 x 5 mm
Weight	25 g (battery without accessories)
Operating time	7.5 h
Charging time until battery is fully charged	2.0 h
Product behaviour during the charging process	The product is non-functional

Data transfer	
Wireless technology	Bluetooth Smart Ready
Range	min. 3 m/9.84 ft
Frequency range	2402 MHz to 2480 MHz
Modulation	GFSK, π/4 DQPSK, 8DPSK
Data rate (over the air)	2178 kbps (asymmetrical)
Maximum output power (EIRP):	+8.5 dBm

13 Appendices

13.1 Symbols Used

Type BF applied part

Declaration of conformity according to the applicable European directives

Manufacturer

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.

SN

Serial number (YYYY WW NNN)
YYYY – year of manufacture
WW – week of manufacture
NNN – sequential number

REF

Article number

13.2 Operating States

13.2.1 Status signals

Charging receptacle	Event
LED shows green light	Battery fully charged
LED shows yellow light	Battery 50% charged
LED shows orange light	Battery empty

13.2.2 Beep signals

The following beep signals are set by default:

Beep signal	Additional display	Event
1 x long	-	• Turn off product on charging receptacle • Charging begins (charging plug connected to charging receptacle) • Charging ends (charging plug disconnected from charging receptacle)
2 x short	LED on charging receptacle lights up briefly	Switching on the product
3 x short	-	Battery voltage too low, product shuts off automatically

13.3 Troubleshooting

Event	Cause	Required action
Unexpected display of the recognised movement in various arm positions, e.g. during overhead use	Use in this arm position was not taken into account during calibration, or was incor-	• Note arm position during calibration • Take the weight into account during calibration • Adjust the values in the app under "Settings > Advanced Settings"

Event	Cause	Required action
	rectly configured in the app.	
-	General fault	• Turn the Myo gaiter off and back on again
Unexpected display of the recognised movement in case of unfavourable residual limb conditions	No contact between the electrodes and skin	• The Myo gaiter has to fully contact the residual limb
	Myo gaiter slipping out of place	

13.4 Directives and manufacturer's declaration

13.4.1 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" (Information on Proximity to Certain Areas).

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	± 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						
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						

The product is covered by the following patents:

USA: US 9,566,016 B2

Patents pending in: Germany

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