Instructions for Use

CE
0297

Foot control

S-NW, S-N2, S-N1

Contents

Symbols in the Instructions for Use

WARNING!
(if persons could be injured)

ATTENTION!
(if property could be damaged)

General explanations,
without risk to persons or property

Foot control

Symbols

on the foot control S-NW

CE marking
with identification number
of the Notified Body

Do not dispose of with
domestic waste

DataMatrix code
for product information
including UDI (Unique Device
Identification)

Manufacturer

UL Component Recognition
Mark indicates compliance
with Canadian and U.S.
requirements

Non-ionizing electromagnetic
radiation

Battery compartment closed

Battery compartment open

Category AP equipment

Catalogue number

Serial number

Date of manufacture

Medical Device

Symbols

radio symbols on the foot control S-NW

GITEKI (MIC) – Japan

01237-16-03402

ANATEL – Brazil

Contains FCC ID: QOQBLE113
Contains IC: 5123A-BGTBLE113

FCC / IC – USA / Canada

Complies with
IMDA Standards
DA103787

IMDA – Singapur*

*Symbol only in IFU

NCC – Taiwan

S-NW: CCAH19LP2780T2
CAN dongle: CCAH19LP2790T5
SPI dongle: CCAH19LP2800T8

RCM – Australian / New Zealand

IC – South Korea

KCC-CRM-BGT-BLE113

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.

Symbols

on the foot control S-N2 / S-N1

CE XXXX
CE marking
with identification number
of the Notified Body

Do not dispose of with
domestic waste

DataMatrix code
for product information
including UDI (Unique Device
Identification)

c UL us
UL Component Recognition
Mark indicates compliance
with Canadian and U.S.
requirements

REF
Catalogue number

SN
Serial number

Date of manufacture

AP
Category AP equipment

Manufacturer

MD
Medical Device

Symbols

on the packaging

CE XXXX — CE marking with identification number of the Notified Body

 This way up

 Fragile, handle with care

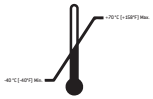
 Keep dry

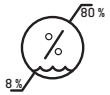
 "Der Grüne Punkt" (The Green Dot) trademark of Duales System Deutschland GmbH

 Trademark of RESY OfW GmbH for identification of recyclable transport and outer packaging of paper and cardboard

 DataMatrix code for product information including UDI (Unique Device Identification)

 Data structure in accordance with Health Industry Bar Code

 Temperature limitation

 Humidity limitation

℞ only — Caution! According to Federal law restricts this device to sale by or on the order of a physician, dentist, veterinarian or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device.

1. Introduction

For your safety and the safety of your patients
These Instructions for use explain how to use your medical device. However, we must also warn against possible hazardous situations. Your safety, the safety of your team and, of course, the safety of your patients, are of paramount importance to us.

Observe the safety notes.

Intended use
Foot control for operation of medical electrical equipment.

Misuse may damage the foot control and hence cause risks and hazards for patients, users and third parties.

Qualifications of the user
We have based our development and design of the foot control for the physician, dental hygienists, dental employees (prophylaxis) and dental assistants target group.

Introduction

Hereby, W&H declares that the medical product is in compliance with Directive 2014/53/EU (RED).
The full text of the EU declaration of conformity is available at the following internet address https://wh.com

Responsibility of the manufacturer
The manufacturer can only accept responsibility for the safety, reliability and performance of the foot control when it is used in compliance with the following directions:

> The foot control must be used in accordance with these Instructions for Use and with the Instructions for Use of the drive unit.
> The foot control has no components that can be repaired by the user.
> Modifications or repairs must only be undertaken by an authorized W&H service partner (see page 31).
> Unauthorized opening of the foot control invalidates all claims under warranty and any other claims.

The respective foot control may only be used with the control unit listed in the scope of delivery.

Improper use, unauthorized assembly, modification or repair to the medical device, non-compliance with our instructions or the use of accessories and spare parts which are not approved by W&H, invalidates all claims under warranty and any other claims.

Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority!

2. Electromagnetic compatibility (EMC)

Medical electrical equipment is subject to particular precautions in regard to EMC and must be installed and put into operation in accordance with the EMC notes included.

W&H guarantees the compliance of the device with the EMC requirements only when used with original W&H accessories and spare parts. The use of accessories and spare parts not approved by W&H can lead to an increased emission of electromagnetic interference or to a reduced resistance against electromagnetic interference.

HF communication equipment
Portable HF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to the medical device. Otherwise, degradation of the performance of this medical device could result.

The medical device may be interfered by other equipment, even if these other devices comply with CISPR (International special committee on radio interference) emission requirements.

Use of this medical device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this medical device and the other equipment should be observed to verify that they are operating normally.

The medical device is not intended for use in the vicinity of HF surgical devices.

3. Scope of delivery

Foot control	Incl. dongle	Compatible with control unit*
S-NW, REF 30264000 S-NW, REF 30264003	REF 07759700	SI-1010/SI-1015/SI-1023, M-UK1010/ M-UK1015/M-UK1023, SA-430 M/SA-435 M Built-In Solution (to be agreed with the system assembler)
S-NW, REF 30264001	REF 07795800	SA-320, SA-310, SI-915/SI-923 (REF 16929000/16929001)
S-N2, REF 30285000 S-N2, REF 30285002		SI-1010/SI-1015/SI-1023, SI-915/SI-923 (REF 30286xxx, 30287xxx) M-UK1010/M-UK1015/M-UK1023, SA-430 M/SA-435 M Built-In Solution (to be agreed with the system assembler)
S-N1, REF 05046200		SI-915/SI-923 (REF 009001xx)
S-N1, REF 06202400		SA-310 SI-915/SI-923 (REF 16929000/16929001)
S-N1, REF 07004400		SA-320
S-N1, REF 06382200		PA-123, PA-115
Locator, REF 04653500		For all listed foot controls

Foot control S-NW
3 disposable batteries AA / Mignon / LR6 / 1.5V

* Not included

> Before using the foot control for the first time, store it at room temperature for 24 hours.
> Check the foot control for damage and loose parts each time before using.
> Do not operate the foot control if it is damaged.
> Replace the foot control as soon as the resistance is noticeably reduced.
> Never touch the patient and the electrical contacts on the medical device simultaneously.

> The ESD spring contact on the bottom of the foot control must be in contact with the ground during operation.

ESD is the abbreviation for “electrostatic discharge”.

The foot control is approved for use in explosive areas (AP).

Risks due to electromagnetic fields
The functionality of implantable systems, such as cardiac pacemakers and implantable cardioverter defibrillator (ICD) can be affected by electric, magnetic and electromagnetic fields.

> Find out if patient or user have implanted systems before using the medical device and consider the application.
> Weigh the risks and benefits.
> Keep the medical device away from implanted systems.
> Make appropriate emergency precautions and take immediate action on any signs of ill-health.
> Symptoms such as raised heartbeat, irregular pulse and dizziness can be signs of a problem with a cardiac pacemaker or ICD.

Keep the orange/middle button pressed and switch between the control units/applications.

Disposable batteries

> Replace the disposable batteries at the first prompt (battery icon on display or LED on dongle).
> Replace batteries outside explosive atmospheres only.
> Pay attention to the battery icon on the display before and after each treatment.

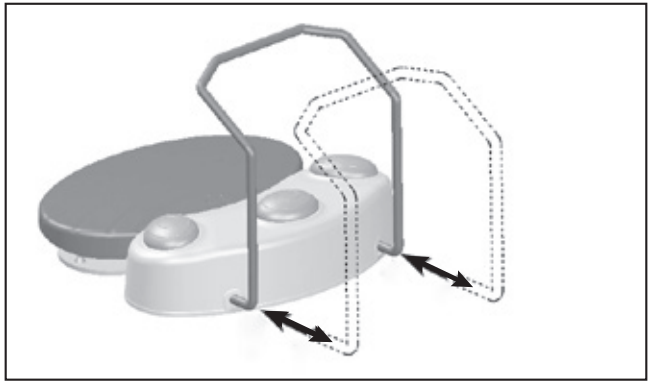
> Dispose faulty or flat batteries immediately and correctly via recycling systems. Do not dispose batteries in domestic waste.

> Use only high-quality disposable alkaline AA / Mignon / LR6 / 1.5 V batteries. Risk of explosion if the wrong type of battery is used.
> Do not mix new, old or different types of disposable batteries.
> Do not use rechargeable batteries.
> When inserting disposable batteries make sure that they are correctly oriented.
> Check the O-ring of the battery cover for damage. Replace a faulty or leaking O-ring immediately.
> Always keep spare batteries on hand.

Disposable batteries may cause damage due to leakage or corrosion.

> Remove the disposable batteries if you are not going to use the foot control for a longer period.
> See the safety notes of the battery manufacturer.

5. Attaching - detaching the locator

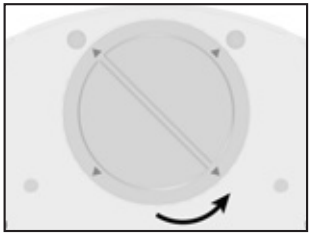


Attaching and detaching the locator

> Push it right in until the locator reaches the stop.
> Pull the locator out.

Inserting and replacing batteries

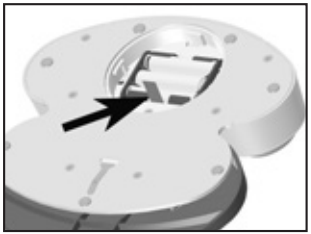
Open battery compartment



❶ Open the battery compartment.

Note the symbols!

Remove batteries



❷ Pull the red thread to remove the batteries.

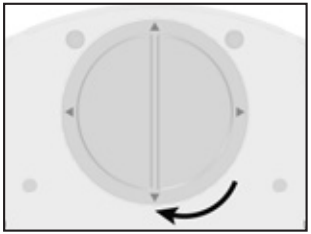
Insert batteries

Reposition the red thread before inserting batteries.

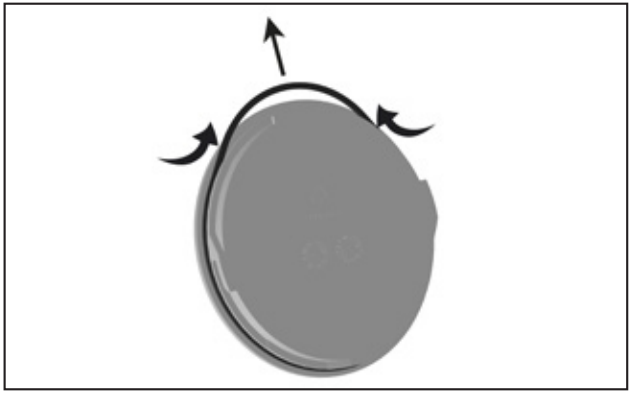
❸ Insert the batteries.

Pay attention to the positioning!

Lock battery compartment



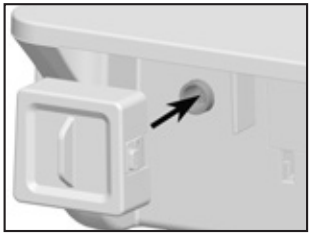
❹ Lock the battery compartment.



Do not use sharp tools!

1. Firmly squeeze the O-ring between your thumb and index finger so that it forms a loop.
2. Pull off the O-ring.
3. Push the new O-ring on in its place.

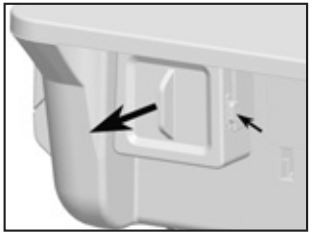
Connecting CAN dongle



❶ Plug in the CAN dongle.

Pay attention to the positioning!

Removing CAN dongle



❷ Press the side lock and remove the CAN dongle.

CAN dongle activated

Icon visible on display

> CAN dongle inserted
> Control unit switched on
> Foot control actuated

Pairing

> The foot control S-NW and the CAN dongle are paired by default.
> If pairing is inactive, you can activate pairing on the control unit (see Instructions for Use Implantmed/system assembler) and follow the directions.
> Press and hold the green/left and orange/middle buttons simultaneously on the S-NW foot control for at least 3 seconds.

Disable pairing

Press and hold all three buttons simultaneously on the foot control S-NW for at least three seconds.

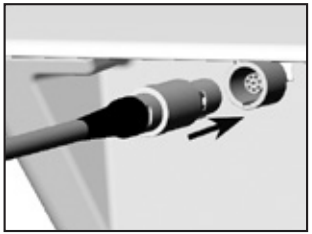
Switching between multiple control units

Press the orange/middle button for 3 seconds.

Change application

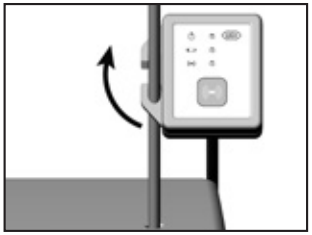
Press the orange/middle button for 3 seconds until an acoustic signal sounds.

Connecting and disconnecting the SPI dongle



Pay attention to the positioning!

❶ Plug in the SPI dongle or disconnect the SPI dongle from the control unit.



❷ Attach the SPI dongle to the irrigant support or remove the SPI dongle from the irrigant support.

Green – SPI dongle activated
LED on if the SPI dongle is connected and the control unit is switched on.

Orange – battery
LED flashes if the batteries on the foot control need to be replaced.

Blue – pairing

The foot control S-NW and the SPI dongle are paired in default status.
If pairing is active: LED indicator flashes
If pairing is inactive:

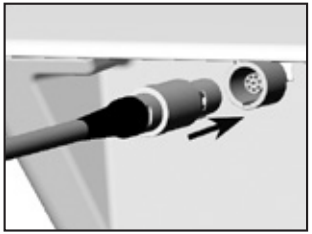
1. Press and hold the button on the SPI dongle for 4 seconds.
2. LED indicator flashes. SPI dongle is in pairing mode for 30 seconds.
3. Press and hold the green and orange buttons simultaneously on the S-NW foot control.
4. LED flashes three times when pairing is successful.

Disable pairing
Press and hold the green, orange and yellow buttons simultaneously on the foot control S-NW for at least three seconds.

Switching between multiple control units
Press the orange/middle button for 3 seconds.

> Check the plug-in connection of the dongle.
> Remove metallic objects between foot control, control unit and dongle.
> Change the position of the foot control.
> Eliminate any sources of interference (e.g. brush motors, mobile telephones, radios, WLAN, ...).
> Replace the pairing and repeat the pairing process.
> Remove and replace the batteries.

If the pairing problem cannot be remedied using the steps described above, the unit will need to be inspected by an authorized W&H service partner.



Pay attention to the positioning!

❶ Plug in the foot control S-N2 / S-N1 or disconnect the foot control from the control unit.

8. Hygiene and maintenance

General notes

Follow your local and national laws, directives, standards and guidelines for cleaning.

> Wear protective clothing, safety glasses, face mask and gloves.

> The foot control is sealed and may be wiped clean.
> The foot control is not approved for automated processing in a washer-disinfector and sterilization.

> The ESD spring contact on the bottom of the foot control must be cleaned regularly.

9. Servicing

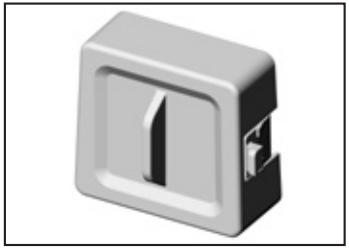
Regular checks
Regular periodic inspection of the function and safety of the medical device is necessary and should be carried out at least once every three years, unless shorter intervals are prescribed by law.
The periodic inspection covers the complete medical device and must only be performed by an authorized service partner.

Repairs and returns
In the event of operating malfunctions immediately contact an authorized W&H service partner.
Repairs and maintenance work must only be undertaken by an authorized W&H service partner.

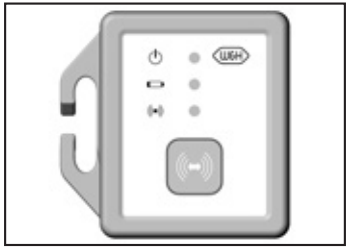
> Always return equipment in the original packaging
> Foot control S-NW: Remove the batteries.

10. W&H accessories and spare parts

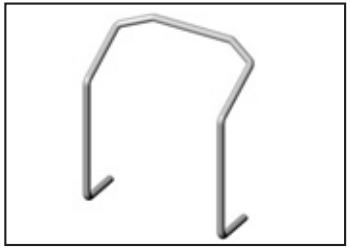
Use only original W&H accessories and spare parts or accessories approved by W&H.
Suppliers: W&H partners (Link: https://www.wh.com)



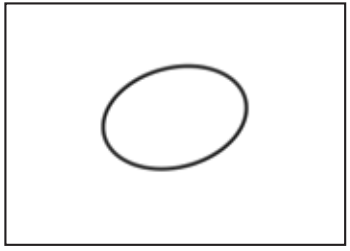
07759700
CAN dongle



07795800
SPI dongle



04653500
Locator for foot control



07823400
O-ring

11. Technical data

Foot control	**S-NW**	**S-N2 / S-N1**
Power supply:	3 disposable batteries AA / Mignon / LR6 / 1,5V	–
Dimensions in mm (height x width x depth):	154 x 202 x 210	156 x 207 x 206
Weight in kg:	1.2	1.3

Freuquency band:	2.4 GHz ISM band (2.402 – 2.480 GHz)
Transmitting power:	Class 3:1 mW (0 dBm)
Modulation:	GFSK
Channels:	40 channels with 2 MHz spacing

Ambient conditions	
Temperature during storage and transport:	-40 °C to +70 °C (-40°F to +158°F)
Humidity during storage and transport:	8 % to 80 % (relative), non-condensing
Temperature during operation:	+10 °C to +40 °C (+50°F to +104°F)
Humidity during operation:	15 % to 80 % (relative), non-condensing

Technical data

Classification according to Paragraph 6 of the General Specifications for the Safety of Medical Electrical Device according to IEC 60601-1/ANSI/AAMI ES 60601-1

S-NW / S-N2 / S-N1 are approved for operation in potentially explosive atmospheres.

S-NW / S-N2 / S-N1 are waterproof according to IPX8, 1 m depth of immersion, 1 hour (water-tight in accordance with IEC 60529)

Pollution level:	2
Altitude:	up to 3,000 m above sea level

12. Disposal

Ensure that the parts are not contaminated on disposal.

Follow your local and national, directives, standards and guidelines for disposal.

> Medical device
> Waste electrical equipment
> Packaging

Explanation of warranty terms

This W&H product has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantees faultless operation. Please note that claims under warranty can only be validated when all the directions in the Instructions for Use have been followed.

As the manufacturer, W&H is liable for material or manufacturing defects within a warranty period of twenty-four months from the date of purchase. Accessories and consumables (batteries, O-ring, locator for foot control) are not covered by the warranty.

We accept no responsibility for damage caused by incorrect handling or by repairs carried out by third parties not authorized to do so by W&H!

Claims under warranty – accompanied by proof of purchase – must be sent to the vendor or to an authorized W&H service partner. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

24 months warranty

Authorized W&H service partners

Find your nearest authorized W&H service partner at http://wh.com
Simply go to the menu option “Service” for full details.

Or simply scan the QR code.

Manufacturer's declaration

Electromagnetic compatibility (EMC)
WARNING: The use of cables, power supplies, accessories other than those specified by the manufacturer may result in increased emission and/or decreased immunity. Only use original W&H accessories.

cables and accessories	length	refeeence
foot controller S-N2	2.85 m	Manufacturer: W&H REF 30285xxx
foot controller S-N1	2.85 m	Manufacturer: W&H REF 05083300
foot controller S-N1	2.85 m	Manufacturer: W&H REF 05046200
foot controller S-N1	2.85 m	Manufacturer: W&H REF 06202400
foot controller S-N1	2.85 m	Manufacturer: W&H REF 06382200
foot controller S-N1	2.85 m	Manufacturer: W&H REF 07004400
foot controller S-NW	---	Manufacturer: W&H REF 30264xxx
SPI Dongle	0.5 m	Manufacturer: W&H REF 07795800
CAN Dongle	---	Manufacturer: W&H REF 07759700

Operate the product in a place with a maximum distance to electrical and magnetic interfering transmitters. If operation of the product close to other devices or together in a stack is necessary, observe the correct function of the system.

Electromagnetic Immunity I (Table 2, IEC 60601-1-2:2007)
The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-Level (3rd Ed.)	IEC 60601-Level (4th Ed.)	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical fast transient/bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines 5kHz repetition rate	± 2 kV for power supply lines ± 1 kV for input/output lines 100kHz repetition rate	± 2 kV for power supply lines ± 1 kV for input/output lines Both repetition rates	Mains power quality should be that of a typical commercial and/or hospital environment
Surge IEC61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial and/or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	0% U_T 0.5 cycle @ 0°,45°,90°,135°,180°,225°,270° & 315° 0% U_T 1 cycle And 70% U_T 25/30* cycles @ 0° 0% U_T 250/300* cycle	Complies to both editions requirements	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the mains (AC) voltage before apply test levels
* 25/30 (250/300) means cycles at 50/60Hz

Electromagnetic Immunity II (Table 4, IEC 60601-1-2:2007)

The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-Level (3rd Ed.)	IEC 60601-Level (4th Ed.)	Compliance Level	Electromagnetic Environment Guidance
				Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms} 150 kHz to 80 MHz 6 V_{rms} in ISM and amateur radio bands* between 0,15 MHz and 80 MHz	6 V_{rms}	Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in Watt (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level [b] in each frequency range Interference may occur in the vicinity of equipment marked with the symbol described lateral.

Note 1: At 80 MHz and 800MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, people and animals.

* The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered, if the measured field strength in the location in which the product is used exceeds the applicable RF compliance level above, the product should be observed, additional measures may be necessary, such as reorienting or relocating the product.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Manufacturer's declaration

Immuity level of RF fields from wireless communication devices (Table 9, IEC 60601-1-2:2014)

Test frequency	Band[a]	Service[a]	Modulation[b]	Maximum power	Distance	IMMUNITY TEST LEVEL
(MHz)	(MHz)			(W)	(m)	(V/m)
385	380 – 390	TETRA 400	Pulse modulation[c] 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM[c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710						
745	704 – 787	LTE Band 13, 17	Pulse modulation[c] 217 Hz	0.2	0.3	9
780						
810						
870	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[c] 18 Hz	2	0.3	28
930						
1720						
1845	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[c] 217 Hz	2	0.3	28
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[c] 217 Hz	2	0.3	28
5240						
5500	5100 – 5800	WLAN 802.11 a/n	Pulse modulation[c] 217 Hz	0.2	0.3	9
5785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the product may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.
[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.
[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Recommended Separation Distances between portable and mobile HF- communications equipment and the product (Table 6, IEC 60601-1-2:2007)

The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product – according on output power and frequency of the communications equipment – as recommended in the following table.

Rated maximum output power of transmitter in watts (W)	Separation distance according to the frequency of transmitter in meter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, people and animals.

Electromagnetic Emission (Table 1, IEC 60601-1-2:2007)

The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Emission Test	Compliance	Electromagnetic Environment Guidance
RF-emission CISPR 11	Group 1	The product use RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment. However, a separation distance of 30 cm shall be maintained.
RF-emission CISPR 11	Class B	The product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.
Harmonic emissions IEC 61000-3-2 (1)	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3 (1)	complies	

(1) Remark: for devices with power consumption of 75 W to 1000 W only

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