INSTRUCTIONS FOR USE ENGLISH



SLEEPIZ ONE+



CE 0123

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1. **PRODUCT DESCRIPTION**

The Sleepiz One+ is a contactless medical device using radar technology to measure movement originating from breathing activity and heart contractions. The device is simply placed on a bedside table or a stand, mounted slightly higher than mattress level, from where it monitors a person at rest or during sleep. From that position, distance changes from the device to the person's body are captured by Doppler radar. Those distance changes are analyzed with signal processing algorithms to extract respiration rate, breathing pattern, and heart rate. The data recorded by Sleepiz One+ can be visualized and analyzed with a web application to which the data is transferred using Wi-Fi connectivity.

Sleepiz web application enables the healthcare professional to manage Sleepiz One+ devices, as well as to visualize and analyze the recorded data.

2. INTENDED USE

2.1. Intended Purpose

Sleepiz One+ hardware unit uses radar technology to allow contactless monitoring of breathing patterns, respiration rate and heart rate during sleep or at rest.

The hardware unit is intended to be used in combination with a web-based application displaying and analyzing signals analysis data sent by the hardware unit, and thus assists the software in achieving its medical purpose.

The hardware unit can be used by a healthcare professional, when the recordings are performed in a clinical setting, or by a patient or his/her carer when the recordings are performed in home environment.

2.2. Intended Population and Indications for Use

Adults (age >=18) diagnosed or suspected to suffer from sleep apnea or other conditions, where observation of breathing pattern or variations in vital parameters can provide additional information for diagnosis or clinical management. Sleepiz One+ is not intended to be used as vital signs monitor in situations when the variations of the measured parameters could result in immediate danger to the patient.

NOTE: The information provided by Sleepiz One+ are not intended to drive diagnosis, but to support clinical decision-making as an additional source of data. Sleepiz One+ should not be used with patients in critical conditions nor as a substitute of a standard of care in serious or



time-sensitive situations. Sleepiz One+ estimates respiration rate with accuracy of +/- 3 breaths per minute in more than 95% of cases, as evidenced by the results of clinical investigations. However, the risk of software error or failure cannot be completely excluded.

NOTE: Please contact your physician if you feel any discomfort while using the Sleepiz One+ device.

2.3. Intended Clinical Benefit

The Sleepiz One+ has the intended clinical benefit of improving patient quality of life by supporting unobtrusive and non-invasive management of sleep disorders and their comorbidities in the home setting and with remote physician monitoring.

The Sleepiz One+ has the intended clinical benefit of improving the diagnostic process for sleep disorders and their comorbidities by providing supporting information from patients recorded in their natural sleep environment.



3. CONTRAINDICATIONS

- Sleepiz One+ is not intended to be used for the direct diagnosis of sleep disorders.
- Sleepiz One+ is not meant for self-diagnosis or self-treatment.
- Sleepiz One+ is not intended to be used by pregnant women.
- Sleepiz One+ is not intended to be used by people with implanted electronic devices (active implants), such as pacemakers.
- Sleepiz One+ is not intended to be used as vital signs monitor in situations when the variations of the measured parameters could result in immediate danger to the patient.
- Sleepiz One+ is not intended to be used as apnea monitor.



4.

CAUTIONS

- The minimum operating distance between Sleepiz One+ and the human body while it is operating is 6.5 cm. Violation of this safety distance for a prolonged time can lead to overexposure to electromagnetic waves.
- Sleepiz One+ shall not be used for any purpose other than what the manufacturer has intended it for.
- Sleepiz One+ shall not be connected to any other devices.
- Sleepiz One+ shall not be used if it seems damaged or broken.
- Sleepiz One+ shall not be repaired by oneself.
- Sleepiz One+ shall not be opened at any time.
- Sleepiz One+ shall be powered only by the power supply specified by the manufacturer.
- In the event where multiple persons are sleeping on the bed, place the device closest to the person undergoing the measurement during whole course of night.
- Ensure that the device is operated, transported, and stored in the ambient conditions listed in section 17.1, or it can lead to degradation in performance of the device.
- The performance of the device can be degraded if over-exposed to dust and electrostatic discharge (ESD). Please follow maintenance procedures at regular intervals.
- Please don't play around with the power supply cable. Risk of strangulation due to excessive length of power supply cable
- Device is IP42 and is immune to common environmental Influences such as moisture, dust.
- The device enclosure is made of plastics and is immune to any user and environmental influences such as lint, light and sunlight. No light sensitive components are present in the device.
- The device shall not be placed near pets, or children. Risk of injury or misuse due to mishandling.

<u>5.</u>

WARNINGS

- If any of the products get wet or start to heat up, immediately turn it off and disconnect it from the power supply, as it can degrade the performance of the device.
- Do not use Sleepiz One+, if you have a pacemaker or other active implants, as it can lead to electromagnetic interference with pacemaker and other active implants and result in improper operation.
- Do not use Sleepiz One+ in the presence of medical equipment such as magnetic resonance imaging (MRI) equipment, as it can lead to electromagnetic interference with MRI and result in improper operation.
- Do not immerse or autoclave the Sleepiz One+ or the power supply, as it can damage the device.
- Sleepiz One+ is not suitable for use in the presence of flammable substances, as it can damage the device.
- Sleepiz One+ shall be kept away from water, as contact with water can damage the device. No modification of this equipment is allowed, as it can degrade the performance of the device.
- Use of this equipment adjacent to or stacked with other equipment transmitting at 24GHz should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, power supply other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Sleepiz One+ as it can degrade the performance of the device.
- Replacement of battery by inadequately trained personnel could result in excessive temperatures.
- No parts of the devices should be serviced or maintained while in use.
- The Sleepiz One+ should be opened only by a Sleepiz-trained service personnel.
- Do not place any object on the top of the device during the recording as it can produce misleading values in the recording.
- Do not place any metal object in front of the device during recording as it can produce misleading results for the recording.
- Do not place any vibrating object in the vicinity of the device during recording, as it can lead to incorrect analysis results.

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- Do not use the device in an Intensive Care Unit (ICU) as it can result in electromagnetic interference with other devices.
- All power supply failures should be examined by a qualified technician. Risk of electrical shock and energy hazard.
- Please do not remove the case of the power supply by yourself! Risk of fire or electrical shock. The openings should be protected from foreign objects or dripping liquids.
- Power supply should be placed on a reliable surface. A drop or fall could cause damage.
- Please do not put power supply in places with high moisture, near the water, high ambient temperature or near fire source.

NOTE: Any serious incident that has occurred in relation to the Sleepiz One+ device needs to be reported to Sleepiz AG and to the competent authority of the member state in which the user and/or patient is established.



SYMBOLS USED IN THESE INSTRUCTIONS FOR USE AND DEVICE LABEL



If the instructions are not adhered to, the situation may lead to a death of serious personal injury (in these instructions for use). ATTENTION – consult accompanying documents.

C E 0123

CE symbol indicates conformity to the European Medical Device Regulation (MDR) 2017/745. Conformity assessment according to MDR has been performed by TÜV SÜD Product Service GmbH.



Indicates manufacturer's name and address.



Indicates the date when the medical device was manufactured.



Indicates Authorized Representative in the European Union.



Warning: device creates an electromagnetic field that can impair functioning of other devices.



Warning: the device shall not be used by patients with implanted electronic devices.



Indicates the need for the user to consult the instructions for use.



Indicates that the device intentionally applies radio frequency electromagnetic waves for diagnosis. Interface may occur in the vicinity of the equipment marked with this symbol.



Symbol of European Waste Electrical and Electronic Equipment Directive (WEEE Directive). Indicates a product should not be disposed of in a landfill; the black bar indicates that the equipment was manufactured after 2005.

Specification of the Ingress Protection rating (IP42) (4-Protection from entry by wires or solid foreign objects with a diameter or thickness of 1.0mm 2-Protection from vertically 15^o dripping water)



IP42

Indicates the manufacturers serial number so that a specific medical device can be identified.



Identifies the model number of a product.



Indicates Unique Device Identification; numbers following the numbers in brackets indicate the following information: (01) Basic UDI-DI, (11) Production date, (17) Expiration date, (10) Batch number, (21) Serial number.



Identifies equipment meeting the safety requirements specified for Class II equipment according to IEC 61140.



Indicates compliance with the rules of Federal Communications Commision



Indicates a medical device that needs to be protected from moisture.



Indicates that the contents of the package are fragile and the package shall be handled with care.



^{5°C} Indicates the temperature limits to the which the Sleepiz One+ can be safely operated (from 5°C. to +35°C).



Power button. Turns the device ON and OFF.

Indicates battery status.

NOTE: The code on Sleepiz One+ device is used for an additional safety layer with which the device can be identified by the user. Users might need this code to initialize the device on the Software from time to time.

7. CLEANING

CAUTION Do not spray, pour, or spill liquid onto the power supply, device, cables, or sensor. Disconnect the power supply unit from the AC power before cleaning.

The Sleepiz One+ may be surface cleaned using a soft cloth dampened with a commercial, nonabrasive cleaner with, i.e. 70% alcohol (e.g. Indicin Plus Aktiv).

The Sleepiz One+ packaging may be surface cleaned using a soft cloth. The product, accessories and the packaging shall be cleaned before the deployment to another patient.





8. PACKAGE CONTENTS

- 1. Sleepiz One+ device
- 2. Power supply*
- 3. Instructions for use
- 4. Support structure:
 - a. Baseplate
 - b. Monopod
- 5. Data Hub with power supply**
- 6. Optional: SpO2 Sensor***

Notes:

- * Depending on your location the model of the power supply may vary.
- ** Depending on your location the model of the Data Hub may vary. Please refer to the Quick Setup Guide and third party Instructions for use provided.
- *** Depending on your configuration an optional SpO2 sensor is provided. Please refer to the Quick Setup Guide and third party instructions for use provided.



9. MINIMUM REQUIREMENTS

- Electrical outlet (110-230 AC) for the included 5V power supply.
- Good cellular network coverage. When the cellular network coverage is not available, recorded data cannot be visualized and analyzed by Sleepiz web application as the device cannot send data to the server. This will led to repeated procedures or further diagnostic tests.
- There are no other additional minimum requirements related to IT networks characteristics and IT security measures as device transmission is secure, encrypted and is well protected against unauthorized access due to implemented protocols in the device.

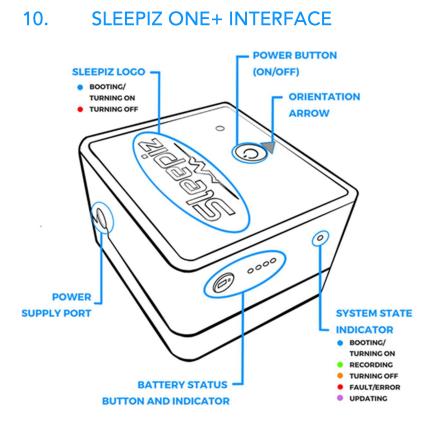


Figure 1. Sleepiz One+ interface



Figure 2. Sleepiz One+ real life interface

11. SETUP

NOTE: Prior to beginning the setup, please check that the monopod is working.

Sleepiz AG ensures that monopods can be exchanged within 72 hours after the notification from the handler.

11.1. Mounting and Positioning



Figure 3. 1) Screw monopod onto base 2) Extend the monopod 3) Screw the device on the monopod.

- 1. Screw the monopod onto the base plate.
- Place the support structure (monopod + base plate) on the floor. Extend the monopod by opening the flip-locks and pulling up until the monopod is around 5-10 cm above the surface of the mattress (see Figure 4, next page). Fix by closing the flip-locks of the monopod.
- 3. Mount the device on the support structure by screwing the stand screw clockwise into the device base.



4.

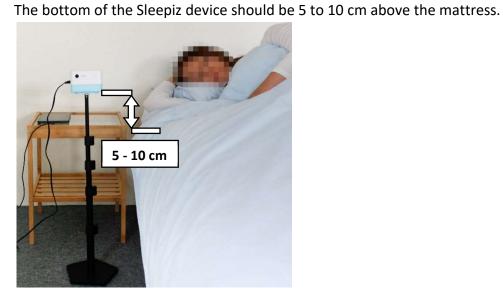


Figure 4. Positioning of Sleepiz One+ device

5. Position the Sleepiz device at the level of the lower part of your chest and upper part of your belly, 40- 50 cm away from the edge of your body (see Figure 5). If needed, you can find a ruler on the last page of this instruction for use.

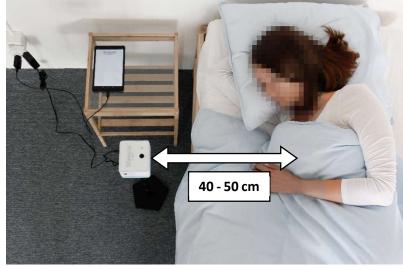


Figure 5. Positioning of Sleepiz One+ device

Note: If your doctor has prescribed you Sleepiz One+ for long-term use (more than 1 week), you can place the device on your bedside table (Figure 6A) or on the monopod (Figure 6B) Point the orientation arrow towards your chest area. You can also use other materials, like books or a chair, to adjust the device to the right height.

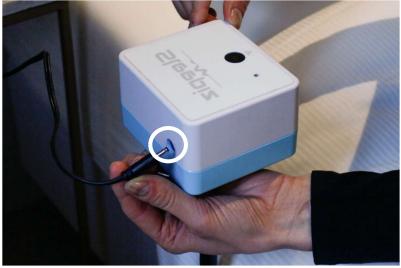


Figure 6. Alternative position of Sleepiz One+. A - on a bedside table, turned towards the chest; B - on the monopod

11.2. Charging

NOTE: The handler or physician is instructed to fully charge the device before giving it to the user.

- To charge the Sleepiz One+ device, connect the provided power supply to the device (see Figure 7) and plug it into the power source. The battery status indicator shows the charging state for four seconds when power supply is plugged in.
- 2. If the battery status indicator indicates that the device is charging, proceed to step 11.3.





3. If the battery status indicator shows 100% upon pressing the battery status button, switch off the AC mains connected to the power supply. Then, plug-out the DC jack from the device.

11.3. Recording

- 1. Press the power button on the Sleepiz One+ device (see Figure 8).
 - Sleepiz One+ might take up to 20s to turn on, during which time, the system indicator light (see Figure 9) will be blue.



Figure 8. The power button is circled



Figure 9. The system state indicator is circled

- 2. Check the battery level by pressing the button on the left side of the Sleepiz One+ device (see Figure 8).
 - If at least 2 out of 4 battery status indicators turn on, proceed to the next step. The device has enough power for the whole night of recording.
 - If the battery is not sufficiently charged, please proceed to step 11.2.





Figure 10. The battery status button is circled. Next to the button, there are 4 battery status indicators. When the battery is sufficiently charged to record for 8h, at least two battery status indicators turn on after the button press

- 3. When the Sleepiz One+ starts recording, the blue light swipes through the logo and the operation indicator turns green.
- 4. To turn off the Sleepiz One+ device, press the button (see Figure 10).
 - The orange light will swipe briefly through the logo and the operation indicator will turn off.

CAUTION Turn on the light if you get out of bed at night to avoid tripping over the device.

11.4. Connectivity

The Sleepiz One+ requires to be connected to the Sleepiz Data Hub (Tablet) to connect and upload the raw data of the recordings to the Sleepiz Cloud for processing and analysis. The model of the Data Hub may differ depending on the hardware configuration of your Sleepiz system. Please refer to the Quick Installation Guide provided in the package to setup the Sleepiz Data Hub.

11.5. Shutdown

1. Soft shutdown

• When the device is in ON mode, press the ON/OFF (power) button on the device for less than six seconds to soft shutdown the device. It takes less than 20 seconds for the device to switch off.

2. Hard shutdown

 When the device is in ON mode, press the ON/OFF (power) button on the device for more than six seconds to hard shutdown the device. It takes less than 20 seconds for the device to switch off.



12. MEANING OF THE LIGHTS

12.1. System state indicator

The system state indicator depicted in Figure 7 indicates the status of the Sleepiz One+ device. Table 1 below explains which color indicates which device status.

Table 1. Meaning of the system state indicator.

SLEEPIZ ONE+ STATE	LIGHT COLOR
Booting / turning on	BLUE
Recording	GREEN
Turning off	ORANGE
Fault / error	RED
Firmware update in progress	PURPLE

12.2. Battery status indicator

When the device is not charging, the battery status indicator display the below patterns upon pressing the battery status button. This pattern is displayed only for four seconds. The user has to press the battery status button again if the battery state needs to be checked after 4 seconds.

Table 2. Meaning of the battery status indicator lights.
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DESCRIPTION	BATTERY STATE
First LED blinks 4 times	0-10%
First LED is lit	10-25%
First two LEDs are lit	25-50%
First three LEDs are lit	50-75%
All four LEDs are lit	75-100%



12.3. Battery status indicator while charging

When power supply is charging, the battery status indicator display the below patterns upon pressing the battery status button. This pattern is displayed only for four seconds. The user has to press the battery status button again if the charging state needs to be checked after 4 seconds.

Table 3. Meaning of the battery status indicator lights, while the device is charging.

DESCRIPTION	BATTERY STATE
First LED blinks 4 times	0-10%
First LED is lit and second LED blinks 2 times	10-25%
First two LEDs are lit and third LED blinks 2 times	25-50%
First three LEDs are lit and fourth LED blinks 2 times	50-75%
All four LEDs are lit	75-100%

This pattern is also displayed for 4 seconds by battery status indicator when the power supply is plugged in.

13. TROUBLESHOOTING PROCEDURES

Follow the procedures listed below if unexpected device behavior is seen:

Table 4. Troubleshooting procedures.

ERROR	TROUBLESHOOTING	COURSE OF ACTION
Device doesn't switch ON	Plug in power supply cable	Call Sleepiz service is the device doesn't switch on
Device doesn't switch OFF	Perform a hard shutdown (see 11.6.2.)	Call Sleepiz service if the device doesn't switch off
Operation indicator is red for more than 10 seconds	 Switch off the device Wait for 15 minutes Switch on the device 	Call Sleepiz service if this scenario is seen again
Device switches OFF by itself	Plug in the power supply cable	Call Sleepiz service if the device switches OFF by its own again
Unexpected indicator behavior	N/A	Call Sleepiz service



14. DEVICE MAINTENANCE

14.1. Monthly maintenance procedure

- a. Perform a hard shutdown of the device (see 11.5.2.)
- b. Clean all the device surfaces as specified in section 7

14.2. Half-yearly maintenance procedure

Perform full discharge/charge cycle of the device:

- a. Switch off the device
- b. Plug-in the power supply
- c. Leave the device for charging till its fully charged
- d. Detach the power supply
- e. Switch on the device
- f. Wait until the device switches off on its own, i.e. it enters low-power mode
- g. Plug-in the power supply
- h. Leave the device for charging until it is fully charged



CAUTION Contact Sleepiz Service to replace the device battery every 4 years.

NOTE: The device maintenance is essential to preserve the life expectancy of the device.

15. SERVICE

The user should contact the Sleepiz Service for assistance, if needed, in setting up, using or maintaining the device or to report unexpected operation or events.

16. DISPOSAL OF THE DEVICE

The Sleepiz One+ device will be decommissioned and disposed by the manufacturer.



17. TECHNICAL DESCRIPTION

17.1. Technical Specifications

Table 5. Technical Specification of Sleepiz One+

TECHNICAL SPECIFICATIONS OF SLEEPIZ ONE+ AND ACCESSORIES				
	Model / Type Reference	v1.0		
	Dimensions	107 x 95 x 67.5 mm		
	Operational ambient temperature	5 °C to +40 °C		
	Operational ambient atmosphere pressure	700 hPa to 1060 hPa		
	Operational ambient humidity	15 % to 90 %, non- condensing		
Sleepiz Device	Transportation and storage ambient environmental conditions	 25 °C to + 5 °C; + 5 °C to + 35 °C at a relative humidity up to 90 %, non-condensing; > 35 °C to 70 °C at a water vapour pressure up to 50 hPa 		
	Life expectancy	11 years*		
	Shelf life	12 months		
	IP rating	IP42		
	Time output noise	± 1 ms		
Battery	Battery life expectancy	4 years		
,	Battery shelf life	12 months		



	Battery performance	14 hours
	Device charge time	6 hours
Wi-Fi Module	RF Band	2.4 GHz (Antenna gain: 2.5 dBi)
	RF Type	Transceiver
	Operating frequency change	24.05-24.25 GHz
	Number of channels	2 (I, Q)
	Output power	< 18 dBm
Radar	Bandwidth	200 MHz
	Type of transmission	CW
	Modulation	Unmodulated
	Type of antenna	Integrated patch antenna
	Antenna gain	8.6 dBi
	I/Q phase shift	90° ±10°
	Manufacturer	Eljintek Inc., Taiwan
	Input Voltage	100 to 240 VAC
	Output Voltage	+5VDC
Main Power Supply	Storage temperature	- 40 °C to + 85 °C
	Relative humidity	5% to 95% non-condensing
	IP rating	IP22
	Operating temperature	-20°C to + 40 °C

*On the condition that the battery is replaced every 4 years



17.2. Device Classification

Degree of protection against electrical shock

Class II i.e. device is equipped with double insulation for protection against electrical shock

Powering of the device

- Internally powered (battery)
- Device has means for connection to supply mains. It is intended to be connected to a mains power grid of at-most overvoltage category II i.e. hospital/household mains

Degree of protection against ingress of liquids

IP42 i.e. device is protected against ingress of liquid that is dripping at an angle less than 15 degrees vertically.

Degree of protection against ingress of solid particles

IP42 i.e. device is protected from entry by wires or solid foreign objects with a diameter or thickness greater than or equal to 1.0 mm.

IP22 i.e. power supply is protected from entry by wires or solid foreign objects with a diameter or thickness greater than or equal to 12.5 mm.

Mode of operation

Continuous operation

Flammability

Device is not intended for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.

17.3. Electromagnetic Compatibility - Emissions

The device emissions comply to below limits specified in IEC 60601-1-2:

Table 6. Meaning of the system state indicator.

TEST	STANDARD	COMPLIANCE LEVEL
Conducted Emissions	CISPR 11	Class B Group 1
Radiated Emissions	CISPR 11	Class B Group 1
Voltage Fluctuations	IEC 61000-3-3	IEC 61000-3-3

Note: Harmonic distortion test IEC 61000-3-2 is applicable for Sleepiz One+ as the typical power consumed by the Sleepiz device is around 3.3 W.

17.4. Electromagnetic Compatibility - Immunity

Table 7. Electromagnetic Compatibility - Immunity tested for IEC 60601-1-2 Levels.

TEST	STANDARD	COMPLIANCE LEVEL
Electrostatic Discharge Immunity	IEC 61000-4-2	± 8 kV contact ± 2kV, ± 4 kV, ± 8 kV, ± 15 kV air
Surge immunity Line-to-Line	IEC 61000-4-5	± 1 kV
Electrical fast transients/bursts immunity	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Immunity from voltage dips	IEC 61000-4-11	0% UT; 0.5 cycle 0°, 45°, 90° 135°, 180° 225°, 270°, 315° 0% UT; 1 cycle 70% UT; 25 cycles; 0° 70% UT; 30 cycles; 0°
Immunity from voltage interruptions	IEC 61000-4-6	0% UT; 250 cycles 0% UT, 300 cycles



Conducted immunity due to disturbances induced by RF fields	IEC 61000-4-6	3 V 6V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% at 1 kHz
Radiated RF electromagnetic immunity	IEC 61000-4-3	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz
Immunity to proximity fields from RF wireless equipment	IEC 61000-4-3	380-390 MHz, 18 Hz pulse 430-470 MHz, 1 kHz sine FM; 430-470 MHz, 5 kHz FM; 704-787 MHz, 217 Hz pulse; 800-960 MHz, 18 HZ pulse; 1.7-1.9 GHz, 217 Hz pulse; 2.4-2.57 GHz, 217 Hz pulse; 5.1-5.8 GHz, 217 Hz pulse;

17.5. Wi-Fi Module Specifications

Table 8. Wi-Fi Module Specifications.

RF BAND	CHANNEL BW	STANDARD	OUTPUT POWER (OBM)
	20 MHz	802.11b	18 (1Mpbs) - 18 (11Mbps)
2.4 GHz	20 MHz	802.11g	18 (6Mpbs) - 14 (54Mbps)
	40 MHz	802.11n/ac	17 (MCS0) - 13 (MCS7)
	40 MHz	802.11n/ac	15 (MCS0) - 13 (MCS7)

NOTE: Nominal powers are subject to regulatory domain regulations. Due to manufacturing tolerance, these nominal output powers may be reduced up to 3 dB.

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17.6. Restrictions of Use in the Member States

2.4 GHz

Table 9. Restrictions of Use in the Member States, 2 GHz.

2.4 GHZ BAND CHANNEL #	CENTER FREQUENCY (MHZ)
1	2412
2	2417
3	2422
4	2427
5	2432
6	2437
7	2442
8	2447
9	2452
10	2457
11	2462
12	2467
13	2472



17.7. Performance of the Hardware Unit

Measurement of movement frequency with an error equal or less than 10%, where the moving object:

- Has a radar cross-section equivalent or greater than a human torso
- Is at a distance of 100 cm or less
- Has a movement frequency between 0.2 Hz and 5 Hz

Performance Limits of the Sleepiz Hardware

Performance limits between fully functional device and total loss of identified performance in normal condition:

• Measurement of movement frequency of above specified objects has an error less than 10%

Performance limits between fully functional device and total loss of identified performance in fault condition:

 Measurement of movement frequency of above specified objects has an error less than 10%

18. CONTACT INFORMATION

Legal Manufacturer



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