

WITHINGS

PRODUCT GUIDE

TABLE OF CONTENTS

Important Notice	5
Product Overview	5
Intended use	6
Warnings and safety notice	7
How to use the Withings Sleep RX and start tracking your nights	8
Taking medical measurements	8
Access to your medical measurements	9
What is the Withings index ?	10
Withings index outputs and interpretations	11
Troubleshooting - Withings Sleep RX	13
LED Colors Meaning	14
Technical Specifications	15
Wireless Information	15
Cleaning, Maintenance, Storage	16
Safety and Performance	17
Federal Communication Commission Interference Statement	19
Disposal	20
Warranty	20
Security	20
Equipement Symbol Description	22

USER GUIDE - EN - US Region

This guide explains how to use your Withings Sleep Rx.
It applies to users in the United States of America.
Disclaimer: Information in this guide may change without notice.

Rx ONLY Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Important Notice

Before using the Withings Sleep Rx, review the information in this guide. You may also find this guide online at:
<https://www.withings.com/us/en/guides>

Retain this documentation for future reference.

Installation instructions are available within the Quick Start Guide provided with this user guide.
Information regarding non medical functions can be found in the Companion App.

Please contact Withings when in need of assistance, setting up, using or maintaining the device or to report unexpected operations or events

- On the webpage: <https://support.withings.com/hc/>
- Via the Companion App

Any serious incident related to the Withings Sleep Rx should be reported to Withings and competent authorities in your country of residence.

Product Overview

The Withings Sleep Rx is a device intended for the pre-screening of obstructive sleep apnea (OSA) syndrome. The device is indicated for use in adults in a home environment during sleep and resting conditions. The device is placed under the mattress and is contactless with the user. It provides a Withings index based on breathing (sound, variations of pressure in the bladder) and heart rate measured in a contactless manner. The number of breathing events per hour is displayed to the user in the companion app. The results are used to assist the healthcare professional in determining the need for further diagnosis and evaluation.

Intended use

Withings Sleep Rx is indicated to record a patient's Withings index during sleep for the purpose of pre-screening patients for obstructive sleep apnea (OSA) syndrome.

The Withings Sleep Rx is intended to record heart rate and movement in an automatic contactless manner.

The device is designed for use in home-screening of adults with suspected possible sleep breathing disorders. Results are used to assist the healthcare professional in determining the need for further diagnosis and evaluation. The system is not intended as a substitute for full polysomnography when additional parameters such as sleep stages, limb movements, or EEG activity are required.

The operation of the Withings Sleep Rx has been studied in adults weighing ≤350 lbs.

The device is indicated for use in adults (18 years old and older) in a home environment during sleep and resting conditions.

This device is not indicated for active patient monitoring, as it does not provide alarms for timely response in life-threatening situations.



Warnings and safety notice

- The patient is not intended to interpret or take clinical action based on outputs without consultation of a qualified healthcare professional. Do not change your medication or treatment without talking to your doctor. You should talk to your doctor if you experience symptoms or concerns.
- The device is not intended to continuously monitor vital signs in critical conditions or where the nature of the variations is such that it could result in immediate danger to the user.
- The device does not provide alarms.
- If you believe you're having a medical emergency, call emergency services.
- The patient should not have direct contact with the Withings Sleep Rx. A mattress (other than water or air mattress) should always be placed between the Withings Sleep Rx and the patient.
- Do not use the device with waterbeds and air beds.
- Do not take into consideration results from data tracked when someone other than you lays on the top of the Withings Sleep Rx.
- Do not use the Withings Sleep Rx in close vicinity to strong electromagnetic fields. Portable RF 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 device. Otherwise, degradation of the performance of this equipment could result.
- Use of this equipment adjacent to or stacked with other equipment 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.
- Do not interconnect this device with other equipment not described in this product guide.
- Misuse of the device can cause injury.
- Keep away from children and pets. Power cord may injure children and cause strangulation or be damaged by pets.
- Do not use the device if it is damaged. Use of a damaged device could cause injury or device failure.
- The patient is an intended operator. Do not try to repair or modify this device yourself. No service or repairs should be performed on the device other than the Troubleshootings listed in this guide.
- Use of accessories other than those specified in this guide could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Follow operational and storage conditions described in the technical specifications section of this guide. Otherwise, measurements' accuracy may be impacted.
- Do not use the device if you have bradycardia (HR < 37bpm) or tachycardia (HR > 110 bpm).

How to use the Withings Sleep RX and start tracking your nights

Follow the information in the Quick Start Guide and in the Companion App to set-up your device.

- Place the device under the mattress, at chest level, with the power cord facing the nearest outer edge of the bed. The maximal contact surface between the Withings Sleep Rx and the bed is important. A cardboard sheet should be used to maximize contact when put over a slatted frame.
- To wake up your device for the first time, position your device and plug it to a power source with the furnished power supply unit. Ensure that the power cord is not stretched too tight or is not trailing on the floor to avoid someone tripping over it.
- Once your product is paired, it will appear in your Devices list on the Companion App.
- After pairing, calibration will start, during this time do not stay on your bed, nor leave a heavy object on the bed. You will receive a notification when calibration is over.
- To take the first measurement, sleep as usual on your bed. The Withings Sleep Rx will synchronize the data to your Companion App account once you get out of bed.
- The Withings Index is available when the total sleep time is at least 5 hours.

Taking medical measurements

How to get your medical measures:

- Make sure that the Withings Sleep Rx is plugged with the furnished power supply unit.
- Make sure that the Withings Sleep Rx is correctly positioned, centered on the sleep position at chest level.
- Sleep on top of your sleep mat.
- The Withings Sleep Rx displays your medical measures at the end of each sleep and results are visible on the Companion App and made available to your Healthcare Professional.

Access to your medical measurements

On your Companion App, you will be able to find your medical measurements. From your Home Page, click on *Sleep Medical Data*.



You will find your medical measurements captured by your Withings Sleep Rx :

- **Heart Rate** (number of times the heart beats per minute)
- **Movement** (duration of moving time during the night)
- **Withings Index** (index that corresponds to the average number of breathing events per hour)

What is the Withings index ?

Your Withings Sleep Rx allows you to estimate gaps in breathing sounds and to generate an index. This index corresponds to the number of breathing events per hour.

Withings Index is calculated based on the inputs generated by the sensors located in the device. The sound and pressure sensors capture data and calculate the heart rate and movement and display them on the Companion App. Those medical measures allow the device to generate the Withings Index.

Four different Withings Index outputs can be obtained¹ :

- **No/Mild** (between 0 and 15 events per hour on average)
- **Moderate** (between 15 and 30 events per hour on average)
- **Severe** (more than 30 events per hour on average)

Note: 5 hours of sleep are required in order to calculate the Withings Index. If the Withings Sleep Rx detects less than 5 hours of sleep, the output will be **inconclusive**.

¹ The International Classification of Sleep Disorders , third edition. American Academy of Sleep Medicine

Withings index outputs and interpretations

Category	Results on the Companion App	Meaning
No/Mild	Withings Index Withings Index No/Mild Events 6 events/h No / MildModerateHigh Your Withings Index is No/Mild. This suggests you experience less than 15 breathing events per hour during your sleep. You should talk to your doctor if you experience symptoms or concerns.	Your Withings Index is No/Mild. This suggests you experience less than 15 breathing events per hour during your sleep. You should talk to your doctor if you experience symptoms or concerns.
Moderate	Withings Index Withings Index Moderate Events 16 events/h No / MildModerateHigh Your Withings Index is Moderate. This suggests you experience between 15 and 30 breathing events per hour during your sleep and are at a moderate risk of obstructive sleep apnea. You should talk to your doctor if you experience symptoms or concerns.	Your Withings Index is Moderate. This suggests you experience between 15 and 30 breathing events per hour during your sleep and are at a moderate risk of obstructive sleep apnea. You should talk to your doctor if you experience symptoms or concerns.

Withings index outputs and interpretations

Category	Results on the Companion App	Meaning
Severe	Withings Index Withings Index ● Severe Events 32 events/h No / MidModerateHigh Your Withings Index is Severe. This suggests you experience more than 30 breathing events per hour during your sleep and are at a high risk of obstructive sleep apnea. You should talk with a doctor. Always consult your doctor before making any medical decisions.	Your Withings Index is Severe. This suggests you experience more than 30 breathing events per hour during your sleep and are at a high risk of obstructive sleep apnea. You should talk with a doctor. Always consult your doctor before making any medical decisions.
Inconclusive	Withings Index Withings Index ● Inconclusive Events -- No / MidModerateHigh There isn't enough data to determine the Withings Index. To collect enough data, make sure your Withings Sleep Rx is well positioned and that you sleep for more than 5 hours.	There isn't enough data to determine the Withings Index. To collect enough data, make sure your Withings Sleep Rx is well positioned and that you sleep for more than 5 hours.

Troubleshooting - Withings Sleep Rx

If you cannot fix the problem using the following troubleshooting instructions, please contact Withings.

Companion App can't find your Withings Sleep Rx via Bluetooth

- Turn off the Bluetooth of your mobile device then turn it back on.
- Unplug your Withings Sleep Rx and plug it back in.
- Uninstall the Companion App and then reinstall it.
- If the issue persists, press the reset button.

You have no sleep data in the Companion App

- Make sure that your Withings Sleep Rx is plugged in.
 - Make sure that your Withings Sleep Rx appears in Devices in the Companion App. If not, you need to install it.
 - Make sure that your Withings Sleep Rx has been assigned to the correct user when installing your device. You can check in the Devices tab which profile the device is assigned to by checking the user name directly under the device name.
 - Make sure your Wi-Fi network works properly. If it doesn't, your Withings Sleep Rx won't be able to communicate with the Companion App.
 - Log in to the web dashboard to see if your sleep data is there. If it is, simply log out from the Companion App and then log back in.
- If that still doesn't fix the issue, try uninstalling the Companion App and installing it again.
- Make sure the sensor is properly positioned.
 - It should be below your mattress, at chest level.
 - If you're sleeping alone in a double bed, make sure the sensor is centered below the mattress.
 - If the bed has a slatted frame, you may need to place a thin flat object (such as a piece of cardboard, for example) between the frame and the sensor.

Your data seems inaccurate

- Make sure that your Withings Sleep Rx is assigned to the correct user in the Devices tab under the device name.
- Make sure the sensor is properly positioned. It should be below your mattress, at chest level.
- If you're sleeping alone in a double bed, make sure the sensor is centered below the mattress.
- If your bed has a slatted frame, you may need to place a thin, flat object (such as a piece of cardboard, for example) between the frame and the sensor.

LED Colors Meaning

The LED display on the Withings Sleep Rx can be:

Flashing blue: If the Withings Sleep Rx hasn't been installed or paired with a mobile device.

Solid blue: If the Withings Sleep Rx has been paired with a mobile device and is in setup mode.

Flashing red: If the inflation process has been stopped or if the air bladder has a potential leak. The LED can also flash red if you press and hold the reset button.

Solid red: If the Withings Sleep Rx can't connect to the Internet.

Solid green: If the factory reset has been completed. The LED can also be green when the Withings Sleep Rx is ready for Wi-Fi configuration or when you try to set up a device already installed.

Flashing purple: The installation has timed out. The Withings Sleep Rx is no longer discoverable via Bluetooth. Restart the installation process. Note that the Withings Sleep Rx can be installed during the first 30 minutes that it is plugged in. After that, the LED blinks purple which means that the setup time is over. In this case, you'll need to unplug, then replug the Withings Sleep Rx using the provided adapter. You'll then be able to install it.

Flashing yellow: If the device has been dissociated from the user (no user associated).

Solid white: If the deflation process is ongoing.

Technical Specifications

Product Name: Withings Sleep Rx
Model Name: wsm02_Rx
Product Description: Air inflated pad equipped with a pressure sensor and a sound sensor
Pad inflation: Automatic inflation with air pump of the pad at 100 mmHg (13 333 Pascal)
Pressure sensor (type, range, accuracy): Digital air pressure sensor - Pressure Range: 0 à 200 mmHg - Accuracy: +/- 0,01 mmHg
Heart Rate (range, accuracy): Measuring range: 37 to 110 bpm - Accuracy: +/- 5 bpm
Sound sensor (type, tolerance, range): Micro-electromechanical systems microphone - Frequency Range: from 60 Hz to 20 kHz - Tolerance: 1dB
Power source: Withings Sleep Rx has no battery and should be plugged into a power socket, using the provided adapter.
100-240Vac - 50/60Hz - 0.5A Max
Weight: 350 grams
Mode of operation: Continuous Operation
Expected product life: 2 years

Transport and storage conditions: -20°C (-4°F) 65°C (150°F) 20% 90% 50kPa 106kPa

Operation conditions: 10°C (50°F) 35°C (95°F) 20% 90% 70kPa 106kPa

Wireless Information

Wireless Specifications:

Mode	Frequency Band (MHz)	Maximum Output Power (dBm)
802.11 b/g/n	2400-2483.5	24.38
BT-LE	2402-2480	7.99
BT EDR	2402-2480	-6.47

The wireless communication of the Withings Sleep Rx is supported by BLE and WiFi communication. This communication is established between the Withings Sleep Rx and the Companion App. The communication between the Withings Sleep Rx and the Companion App is encrypted through an exchange of a paired key.

The communication latency between the Withings Sleep Rx and the Companion App takes less than 10 seconds when the Withings Sleep Rx and the smartphone are less than 16 feet (5 meters) apart. The communication between the Withings Sleep Rx and the Companion App is not modified with sources of interference located within 5 meters. Wireless coexistence has been tested in accordance with the following standards:

- ANSI C63.27:2017 and,
- AAMI TIR69:2017/(R2020)

Electromagnetic disturbances have been tested in accordance with the standard IEC 60601-1-2.

Cleaning, Maintenance, Storage

Cleaning and maintenance of the Withings Sleep Rx: To clean the textile cover of the sensor, gently remove the cover first. The cover can be machine washed, but do not tumble dry or iron it. Wait until the cover is completely dry before replacing it on the sensor. **Storage:** Store the device and the components in a clean and safe location. If storage conditions are different from the operation conditions indicated in this document, please wait 30 minutes before installing the device.

Safety and Performance

Radio frequency (RF) Statement

Medical electrical equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the following tables. Portable and mobile RF communications equipment can affect medical electrical equipment.

Guidance and manufacturer's declaration-electromagnetic emissions

Withings Sleep Rx is intended for use in the electromagnetic environment specified below. The customer or the user of the Withings Sleep Rx should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment — guidance
CE emissions CISPR11	Group 1	Withings Sleep Rx uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	Withings Sleep Rx 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 purposes.
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable	

Safety and Performance

Declaration: electromagnetic emissions and immunity for equipment and systems that are not life-supporting and are specified for use only in a shielded location.

Electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions

The Withings Sleep Rx is intended for use in the electromagnetic environment specified below. The customer or the user of the Withings Sleep Rx should ensure that it is used in such an environment.

Emissions Test	Test Items	Measured	Result
CISPR 11:2010 (Group 1), Class B	Conducted Emissions	-19.39dB QP @ 0.377MHz	Pass
CISPR 11:2010 (Group 1), Class B	Radiated Emissions	-3,53dB QP@ 43.45MHz	Pass
IEC 61000-3-2:2014, Class A	Harmonic Current Emissions	Note 1	Pass
IEC 61000-3-3:2013	Voltage Fluctuations and Flicker	Meet the requirement of limit.	Pass

Note 1 : The EUT is not required to meet the limits as its power consumption is less than 75W.

Safety and Performance

Electromagnetic immunity

Withings Sleep Rx is intended for use in the electromagnetic environment specified below. The customer or the user of the Withings Sleep Rx should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Result
IEC 61000-4-2:2008 ED 2.0	Contact Discharge: ± 2 / ± 4 / ± 6 kV / ± 8 kV Air Discharge: ± 2 / ± 4 / ± 8 / ± 15 kV	Pass
IEC 61000-4-3:2010 ED 3.2	Radio Frequency Electromagnetic Field (RS)	Pass
IEC 61000-4-3:2010 ED 3.2	Proximity fields from RF wireless communications equipment	Pass
IEC 61000-4-4:2012 ED 3.0	Electrical Fast Transient/Burst (EFT)	Pass
IEC 61000-4-5:2017 ED 3.1	Surge	Pass
IEC 61000-4-6:2013 ED 4.0	Conducted Disturbances (CS)	Pass
IEC 61000-4-8:2009 ED 2.0	Power Frequency Magnetic Field (PFMF)	Pass
IEC 61000-4-11:2004 ED 2.0	Voltage Dips/Interruption	Pass

Clinical Benefit / Performance

The Withings Sleep Rx enables the pre-screening of obstructive sleep apnea (OSA) syndrome in a home environment. To validate the performance of the Withings Sleep Rx for the screening of obstructive sleep apnea (OSA), a clinical study was performed and tested against polysomnography (PSG).

The Withings Sleep Rx device has a performance for the estimation of heart rate with accuracies equal to 95.97%. The Withings Sleep Rx sensitivity and specificity for the movement (binary activity assessment) of a patient on a bed are 92% for both values.

The Withings Sleep Rx Withings' Index performance for the detection of breathing events as compared to the polysomnography Apnea Hypopnea Index threshold values. Withings Index ≥ 15 events/hour with sensitivities and specificities equal to 88.0% and 88.0%. And for Withings Index ≥ 30/hour with sensitivities and specificities equal to 86% and 91.2%.

Federal Communication Commission Interference Statement

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.

FCC Caution: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment

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.

IMPORTANT NOTE:

Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 cm between the radiator & your body.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Country Code selection feature to be disabled for products marketed to the US/CANADA

FCC ID: XNAWSM02

Disposal



Dispose of the device, components and accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution. Follow your city or state laws for recycling electronic waste.

Warranty

Withings™ Two (2) Years Limited Warranty - Withings Sleep Rx

Withings, 2 rue Maurice Hartmann, 92130 Issy-les-Moulineaux, ("Withings") warrants the Withings-branded hardware product («Withings Product») against defects in materials and workmanship when used normally in accordance with Withings' published guidelines for a period of TWO (2) YEARS from the date of original retail purchase by the end-user purchaser ("Warranty Period"). Withings' published guidelines include but are not limited to information contained in technical specifications, safety instructions or the quick start guide. Withings does not warrant that the operation of the Withings Product will be uninterrupted or error-free. Withings is not responsible for damage arising from failure to follow instructions relating to the Withings Product's use.

Security

Withings recommends that you add a passcode (personal identification number [PIN]), Face ID or Touch ID (fingerprint) to your phone to add a layer of security. It is important to secure your phone since you will be storing personal health information. Users will also receive additional update notifications on the device via the Companion App, and updates are delivered wirelessly, encouraging rapid adoption of the latest security fixes.

Do not install the device on a smartphone that you do not own.

Do not use a public Wi-Fi network you don't know. Use a trusted Wi-Fi network with your device.

The Companion App is not intended to be used on a computer. No indication of anti-virus software is needed.

Only use official app stores to download the Companion App. In case of doubt, use the link go.withings.com.

Security

Device configuration:

If needed, users can restore device configurations by following the factory reset procedure which is available through the Withings' Help Center. The device installation will set secured parameters by design. If you notice any cybersecurity vulnerability or incident, do not hesitate to reach the customer support.

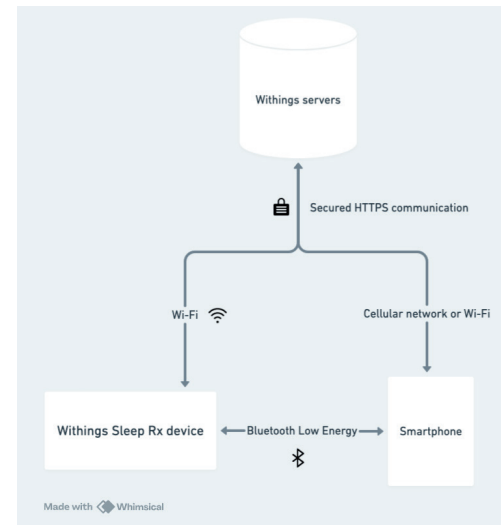
Security notifications:

You will receive emails when sensitive actions are performed by yourself such as password update. Moreover, you can subscribe to our status webpage (status.withings.io) in order to be notified if there is an incident or maintenance ongoing.

More information about how Withings protects your data can be found through the Withings' security web page (withings.com/us/en/data-security).

Decommissioning:

If you no longer use the device, we recommend you to perform a factory reset of your device in order to remove the personal data stored within the device.



Equipment Symbol Description

Rx only	US Federal Law restricts this Device to sale by or on the order of a physician.
	Read the Instruction Manual before use
	Read the Instruction Manual before use
	Direct Current
	Medical device
	Medical device manufacturer
	Temperature range
	Upper and lower limits of pressure
	Upper and lower limits of relative humidity
IP22	Ingress of water or particulate matter
	Do not dispose of this product as unsorted municipal waste, take it to electronic recycling.
	Do not use if package is damaged and consult instructions for use
	Caution
	Complies with FCC regulations
	Unique device identifier
	Serial number

WITHINGS

Withings Sleep Rx | Proactive Health Tracking
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