

Ninenovo Sleep System

User Manual

1. Introduction

1.1 Intended Use

The Ninenovo Sleep System is a wearable device intended to record, analyze, display, export, and store biophysical parameters to aid in evaluating moderate to severe sleep-related breathing disorders of adult patients suspected of sleep apnea. The device is intended for use in clinical and home settings under the direction of a Healthcare Professional (HCP).

Note:

The data and results provided by this device are for pre-check screening purpose only and cannot be directly used for diagnostic or treatment.

The data provided by the APP is not intended for diagnosis or treatment purpose, always consult your doctor for any health condition (Rx only) .

No known contraindications.

The patient is an intended operator.

The patient is an intended operator. At the end of the product's lifespan, please dispose of this product as medical waste.



Warnings and Cautionary Advices

- ◆ Before using this product, it should be ensured that it is in normal working condition and operating environment. For more accurate measurement, this product should be used in a quiet and comfortable environment.
- ◆ Do not use this product immediately when transitioning from a cold environment to a warm and humid location. If this product is splashed or has water condensation, stop the operation.
- ◆ Do not use sharp objects to operate this product.
- ◆ Do not use this device during MRI examination.
- ◆ Do not use the device in a combustible environment (i.e., oxygen-enriched environment).
- ◆ Never submerge the device in water or other liquids. Do not clean the device with acetone or other volatile solutions.
- ◆ This product is suitable for adults aged 18 and above.
- ◆ Do not place this device in pressure vessels or gas sterilization device.
- ◆ Do not place the device in contact with children or pets, to avoid children or pets using the device as a toy and accidentally swallowing dry batteries, resulting in suffocation and other dangerous situations.
- ◆ This product may not be suitable for everyone. If satisfactory measurements cannot be achieved, please give up using it.
- ◆ Data averaging and signal processing on SpO₂. Delay in displaying and transmitting data values. The measurement data update cycle is less than 30 seconds, and when signal attenuation, weak perfusion, or other interference occurs, it will lead to an increase in the time for taking the dynamic mean, which depends on the pulse rate value.
- ◆ The service life of this product is 5 years, and the production date can be found on the label.

- ◆ This product does not provide alarm functions for blood oxygen saturation and pulse rate exceeding limits, and is not suitable for places that require alarm functions for measuring value exceeding limits.
- ◆ Do not drop this device or subject it to strong impact, such as falling on the floor, to avoid damaging the sensor and affecting the performance of the device.
- ◆ Do not dismantle the device, as this could cause damage or malfunctions or impede the operation of the device.
- ◆ This device is not intended for use by people (including children) with restricted physical, sensory or mental skills or a lack of experience and/or a lack of knowledge, unless they are supervised by a person who has responsibility for their safety or they receive instructions from this person on how to use the device.
- ◆ The volume recording waveform has not been normalized and serves as an indicator of signal incompleteness. When the waveform does not tend to be smooth and stable, the accuracy of the measured value may decrease. When the waveform tends to be smooth and stable, the measured value read is the optimal value, and the waveform at this time is also the most standard. Our company can provide circuit diagrams, component lists, annotation and other information as required, so that qualified technical personnel of users can repair product components designated by our company that can be repaired.
- ◆ The test part should not have external colorants, such as nail polish, colorants or colored skin care products, otherwise the measurement will be affected.
- ◆ Fingers should be placed correctly (refer to 2.4 of this manual). Improper placement or contact with sensors can affect measurement.
- ◆ The light between the photoelectric receiving tube and the light emitting tube of this product must pass through the small arterial bed of the tested person; There should be no light barriers such as adhesive tape in the area where the light path passes through, otherwise it may cause inaccurate measurement values.
- ◆ Excessive ambient light can affect measurements, such as surgical lamps (especially aviation light sources), bilirubin lamps, fluorescent lamps, infrared heating lamps, and direct sunlight. To prevent interference from ambient light, it is essential to place the sensor properly and cover the sensor area with opaque materials.
- ◆ Excessive movement (active or passive) or intense activity of the subject can affect measurement accuracy.
- ◆ Do not place the sensor on limbs with blood pressure cuffs, arterial catheters, or intraluminal pipelines. This product does not have anti defibrillation function, and measurement values may be inaccurate during and shortly after defibrillation.
- ◆ This product undergoes pre factory calibration.
- ◆ This product has been calibrated to display functional blood oxygen saturation.
- ◆ Do not place the device in direct sunlight.
- ◆ Do not store the device in the following locations: locations in which the device is exposed to direct sunlight, high temperatures or levels of moisture, or heavy contamination; locations near to sources of water or fire; or locations that are subject to strong electromagnetic influences.
- ◆ Vital signs measurements, such as those taken with this device, cannot identify all diseases. Regardless of the measurement taken using this device, you should consult your doctor immediately if you experience symptoms that could indicate acute disease.
- ◆ Do not self-diagnose or self-medicate on the basis of this device without consulting your doctor. In particular, do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.

1.2 Model

| | |
|-------|--------------------------------------|
| Model | Size: Inner diameter × Width (in mm) |
|-------|--------------------------------------|

| | |
|--------------------------------------------------------------------------------------------------------------|----------|
| OSRMB-01-6 | 16.5×7.8 |
| OSRMB-01-7 | 17.4×7.8 |
| OSRMB-01-8 | 18.2×7.8 |
| OSRMB-01-9 | 19.0×7.8 |
| OSRMB-01-10 | 19.9×7.8 |
| OSRMB-01-11 | 20.7×7.8 |
| OSRMB-01-12 | 21.5×7.8 |
| OSRMB-01-13 | 22.3×7.8 |
| OSRMB-01-14 | 23.1×7.8 |
| Remark: Besides of the inner diameter is different as the above, all other factor of the device is the same. | |

1.3 Unpacking

Ninenovo Sleep System(Main Unit) × 1

Smart Charging Case × 1

Charging cable × 1

User Manual × 1

1.4 App version

V1.0.0

2 Using the Device

2.1 Download App

App name: Ninenovo Health

iOS: App Store

Android: Google Play



Download the app from App Store or Google Play by searching “Ninenovo Health”!

Install the Ninenovo Health App on your mobile device and set up/register an account.

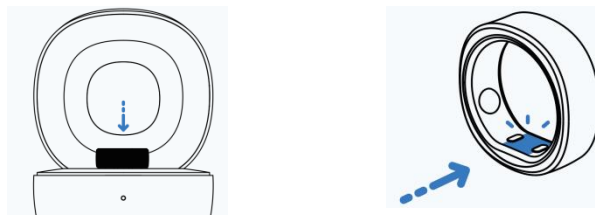
Please follow the prompts to complete your account registration.

Only complete your account registration, the Smart Ring could be started to use.

2.2 Charge your ring to activate it before your first use

We recommend that charge your ring for 60 minutes or until the power level is greater than 80% for the first use.

Remove the ring from the box and place it in the charging case. The blue light will begin flashing within 5 seconds and will automatically activate the ring and enter the waiting binding state.



Note:

The ring must be activated before it can be used properly. The ring must be positioned properly on the charging case for the contacts to line up. It will only fit in one position. See figure 1

Do NOT force it into the case in a different position.

When charging, do not place the product in a place where it is difficult to disconnect the adapter

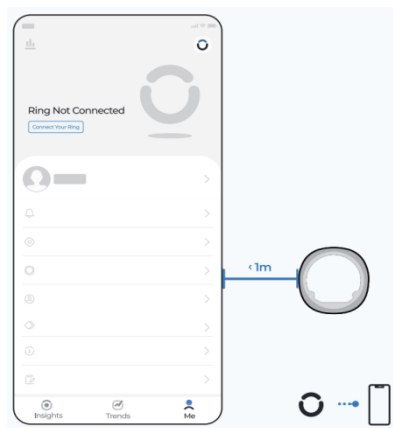
Requirements for charging adapter: comply with the requirements of IEC 60601-1 standard, with output parameters of 5.0V dc, 0.5A.

2.3 Connect the ring with app

Open the Ninenovo Health APP, click the "Me" page and select "Bind the device".

Note:

Bluetooth must be enabled on your device. Please keep the ring within one meter/yard of your mobile device for them to bind.



2.4 Wear the ring correctly

Position the ring so that the sensors fit snugly on the base of your finger.

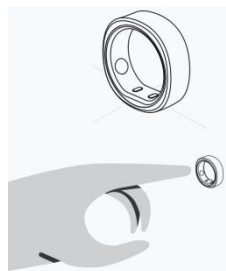
It must remain in this position to optimize data collection although you can switch it between different fingers if needed.

Note:

We recommend that you wear the ring on your index finger.

If that is not the best fit for you, wear it on the finger you selected the size for.

If the ring shifts during wear, please adjust it back into position.



2.5 OSAHS monitoring

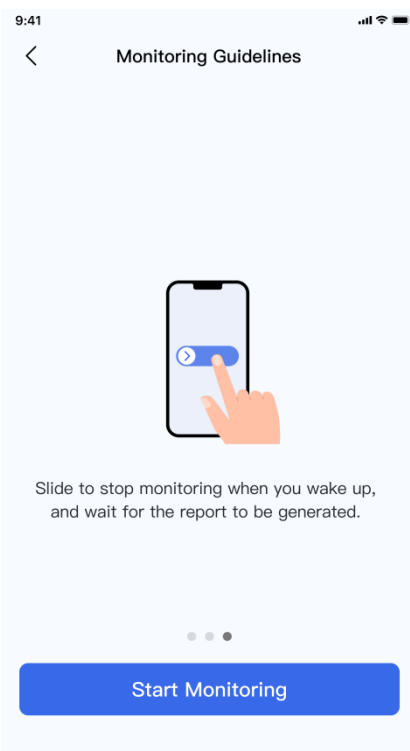
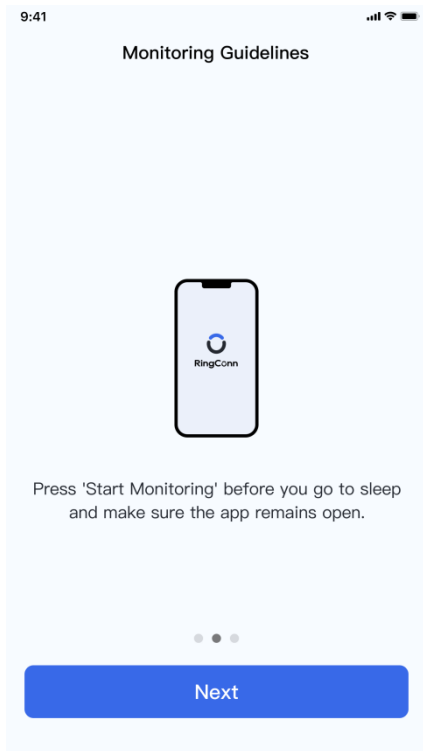
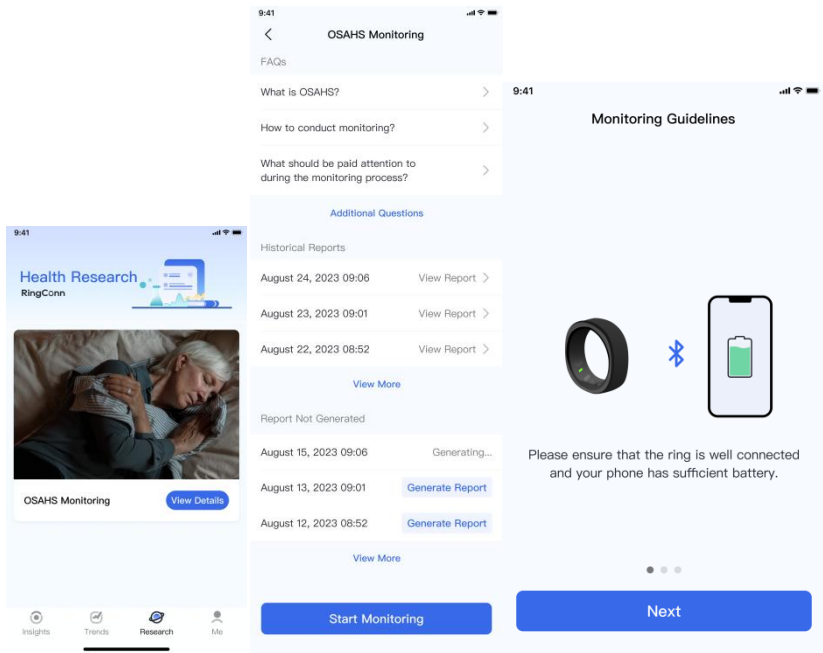
Click the "Research" page on the bottom of the app, at the next page Click "Strat Monitoring",

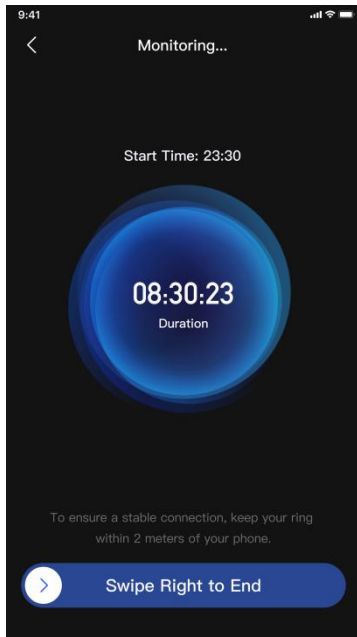
Please ensure that the ring is well connected and your phone has sufficient battery, Click "Next";

Please start monitoring before you go to sleep and make sure the app remains open, Click "Next";

Slide to stop Monitoring when you wake up, and wait for the report to be generated; Click "Start Monitoring";

When monitoring time is up, swipe right to end.





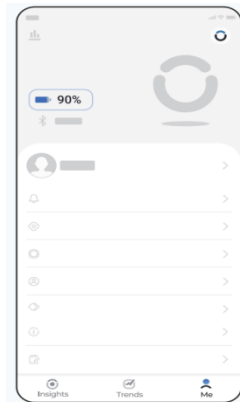
2.6 Check health data & battery information

You can sync your data from your ring to the Ninenovo Health App at any time to check your health data and your battery status. Your ring will retain data for 5 to 7 days if it is not synced.

It will automatically sync when you hold your mobile device while the app is open as long as your Bluetooth is enabled.

Note:

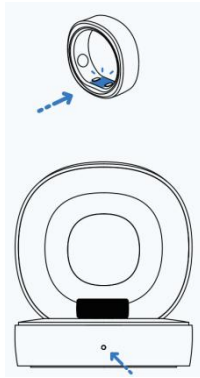
You can check the charging status of the ring on your phone. Click the "Me" page on the bottom right of the app, you can see the remaining percentage of power and a battery icon next to it on the top left of the page.



When the ring is charging, you will see a blue bolt blinking inside the battery icon.



2.7 LED color reference



Smart Ring



Blinking blue:

The ring is activated and enters pairing mode.

Solid blue for 3 sec: The ring is out of airplane mode.



Charging Case

Blinking white: The charging case is charging. Once the charging case stops charging, the light will stop blinking and turn solid white.

○ Solid white: Charging case power is above 40%.

● Solid orange: Charging case power is lower than 40%.

● Solid blue:

When the ring is correctly placed on the charging case and it connects, the ring will begin to charge. After 5 seconds, the light on the case will go out.



● Blinking orange: Abnormal charging (input or output).

3 Clearing and Maintenance

3.1 Clearing and disinfecting

For clearing and disinfecting the Smart Ring, the following procedures are recommended.

Keep this device away from dust, lint, vibration, corrosive substances, explosive materials, high temperature and moisture.

Clean and disinfect the device whenever you see any type of contamination.

Clean and disinfect the device prior to giving to a new user.

Before cleaning and disinfecting, take away the Ring from the charging case.

Clean the Ring and charging case once per week or more frequently if need.

The performance will be affected if there is any obstacle such as dust, lint, or stain on the sensor area, when necessary, clean the sensor area by following the direction in this manual.

The surface of the Smart Ring can be gently wiped with an industrial nonabrasive cleaner or a soft cloth or sponge soaked in a solution with an alcohol content of 70%.

The most commonly used hospital cleaning liquids and noncorrosive detergents can be used to clean the Smart Ring, but note that many of these cleaning agents must be diluted before use. Please follow the instructions of the cleaning agent manufacturer for use.

Avoid using ethanol based, amino based, or acetone based cleaning agents.

The outer shell of the Smart Ring should be kept free from dust contamination and can be wiped with a lint free soft cloth or a sponge soaked in a cleaning agent. Be careful not to pour liquid onto the instrument during cleaning,

and ensure that no liquid enters the interior of the instrument. Be particularly careful when wiping to ensure that no water enters.

It is prohibited to use abrasive materials such as wire brushes or metal polishing agents, as these materials may cause damage to the surface of the Ring.

3.2 Maintenance

This device is a precision electronic device and necessary maintenance must be performed by ShenZhen Ninenove Technology Limited service ONLY, except charging the battery.

No modification to this device is allowed, as it may affect the device performance.

Do not break the surface of the smart ring, as it may damage the sensor, which may lead to the malfunction and /or inaccurate measurement.

Check the device and other parts at least once a week to ensure there is no visible damage that may affect safety and performance of this device, when obvious damage is observed, stop using the device.

Do not service or maintain any part of this device while it is being used with a patient.

A functional tester cannot be used to assess the accuracy of this device.

The ring can be charged by placed onto the charging case.

The device should be recharged every 3months when it is not regularly used. If the battery is depleted, it may take longer charging time- 10mintus before it returns to normal function.

3.3 Battery

To keep the battery in good condition, charge the battery every 6 months when the device is not in use. Please keep in remind to recycle the battery to name place while the device reach to the life of using.

4 Trouble shooting

| Problem | Possible Solution |
|--------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The ring does not work properly | Please put it into the charging case to activate it before the first use. |
| | Please put it into the charging case, and check if the ring has a blue light flashing. |
| | Please open the app and check whether the ring can be connected to it normally. |
| Unable to connect the ring to the app (The ring and the app are not connected) | Please ensure your device's Bluetooth is enabled and check if it is connected to the network properly. |
| | Please put the ring into the charging case and check whether it has insufficient power. |
| | Please keep the ring and the device within a range of1 meter/yard for binding. |
| Manual detection failure | The ring should fit securely and comfortably around the base of your finger. The sensor inside the ring should be on the palm side of your finger. |
| | Please keep your body still during the manual detection. |
| | Please make sure the ring is well connected to your device when testing. |
| Data missing | Make sure your ring is connected and bound to the app. You can verify this from any page by tapping on the small Ninenovo logo in the upper right hand corner of your screen and then tapping on Ring Settings. If you are properly bound, it will only offer you the option to unbind. |

If none of the above measures can solve the problem, please contact Shenzhen Ninenovo Technology Limited.

5 Specifications

| Power Supply | |
|--------------|-----------------------------------------------------|
| Battery type | 3.7 V Lithium Battery for charge case, Rechargeable |
| | 3.8 V Lithium Battery for smart ring, Rechargeable |

| | |
|--------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| Charge input: | Charge case DC 5V \pm 10% \leq 500mA Smart Ring DC 5V \pm 10% \leq 23mA |
| SpO2 parameter | |
| SpO2 range | 70% to 100% |
| SpO2 Accuracy (Arms) | 90%-100%: \pm 2%, 80%-89%: \pm 2%, 70%-79%: \pm 3%, 0%-69%: not defined |
| PR range | 30bpm to 240 bpm |
| PR accuracy | \pm 2 bpm or \pm 2%, whichever is greater |
| Wave length | 640nm-940nm Red light: 640nm \pm 20nm,Maximum optical output power:2mW Infrared light: 940nm \pm 20nm,Maximum optical output power: 1.2mW |
| Weight | 3g-5g |
| Dimension | As model list named |
| Operate environment | 5 $^{\circ}$ C – 40 $^{\circ}$ C |
| Transportation and Storage Condition | Temperature: -20 $^{\circ}$ C to 60 $^{\circ}$ C Humidity: 10% to 95% RH Atmospheric: 700hPa to 1060hPa |
| Mobile APP | |
| Wireless | Bluetooth 5.2 BLE |
| IOS | IOS 14.0 or above |
| Android | Android 8.0 or above, with Bluetooth 5.2 BLE |
| Normal Service Life | 5 years |
| Safety type | |
| Classification | Class II |
| Power source | Internally powered |
| Degree protection against electrical shock | Type BF |
| Degree of dust & water resistance | Charge case IP22 Smart Ring IP68 |

6 Electromagnetic Compatibility

The device meets the requirements of IEC60601-1-2:2014+A1:2020.



Warnings and Cautions:

- Using accessories other than those specified in this manual may result in increased electromagnetic emission or decreased electromagnetic immunity of the equipment.
- The device or its components should not be used adjacent to or stacked with other equipment.
- The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Other devices may interfere with this device even though they meet the requirements of CISPR.
- When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.

- Portable and mobile communication equipment may affect the performance of this device.
- Other devices that have RF transmitter or source may affect this device (e.g. cell phones, PDAs, and PCs with wireless function).

Essential performance:

- 1) SpO2 range: 70%~100%; SpO2 Accuracy (Arms): 80%-100%: $\pm 2\%$, 70% -79%: $\pm 3\%$, 0%-69%: not defined.
- 2) PR range: 30 to 240bpm; PR accuracy: bpm ± 2 bpm or $\pm 2\%$, whichever is greater.

Guidance and manufacturer's declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS


| Guidance and manufacturer's declaration – electromagnetic emission | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Nineno Sleep System is intended for use in the electromagnetic environment specified below. The customer or the user of Nineno Sleep System should assure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment - guidance |
| RF emissions CISPR 11 | Group 1 | The Nineno Sleep System uses RF energy only for its internal function. There for, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The Nineno Sleep System 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. |
| Harmonic emissions IEC 61000-3-2 | Class B | |
| Voltage fluctuations flicker emissions IEC 61000-3-3 | Complies | |

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

| Guidance and manufacturer's declaration – electromagnetic immunity |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Nineno Sleep System is intended for use in the electromagnetic environment specified below. The customer or the user of the Nineno Sleep System should assure that it is used in such an environment. |

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
|--------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air | ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrostatic transient / burst IEC 61000-4-4 | ± 2 kV for power supply lines ± 1 kV for input/output lines | ± 2 kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV differential mode ± 2 kV common mode | ± 1 kV differential mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | 0% U_T ; 0.5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T ; 1 cycle and 70% U_T ; 25/30 cycles Single phase: at 0° 0% U_T ; 250/300 cycle | 0% U_T ; 0.5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T ; 1 cycle and 70% U_T ; 25/30 cycles Single phase: at 0° 0% U_T ; 250/300 cycle | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Nineno Sleep System requires continued operation during power mains interruptions, it is recommended that the Nineno Sleep System be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | 30 A/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 a. c. mains voltage prior to application of the test level. | | |

Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEM

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Nineno Sleep System is intended for use in the electromagnetic environment specified below. The customer or the user of the Nineno Sleep System should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
| <p>Conducted RF</p> <p>IEC 61000-4-6</p> | <p>3 Vrms</p> <p>150 kHz to 80 MHz</p> <p>6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz</p> | <p>3V</p> <p>150 kHz to 80 MHz</p> <p>6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz</p> | <p>Portable and mobile RF communications equipment should be used no closer to any part of the Nineno Sleep System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{12}{V_2} \right] \sqrt{P}$ |
| <p>Radiated RF</p> <p>IEC 61000-4-3</p> | <p>10 V/m</p> <p>80 MHz to 2.7 GHz</p> <p>385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)</p> | <p>10 V/m</p> <p>80 MHz to 2.7 GHz</p> <p>385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)</p> | $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.7 \text{ GHz}$ <p>where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).^b</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div> |
| <p>NOTE 1:At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2:These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.</p> | | | |
| <p>a.The ISM (industrial, scientific and medical) bands between 150 kHz 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.</p> <p>b.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 Nineno Sleep System is used exceeds the applicable RF compliance level above, the Nineno Sleep System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Nineno Sleep System.</p> <p>c. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.</p> | | | |

**Recommended separation distances between portable and mobile
RF communications equipment and the EQUIPMENT or SYSTEM -
for EQUIPMENT and SYSTEMS**

| Recommended separation distances between portable and mobile RF communications equipment and the Nineno Sleep System | | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|--------------------------------------------------------|--------------------------------------------|------------------------------------------|
| The Nineno Sleep System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Nineno Sleep System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Nineno Sleep System as recommended below, according to the maximum output power of the communications equipment. | | | | |
| Rated maximum output of transmitter W | Separation distance according to frequency of transmitter m | | | |
| | 150 kHz to 80 MHz outside ISM and amateur radio bands | 150 kHz to 80 MHz in ISM and amateur radio bands | 80 MHz to 800 MHz | 800 MHz to 2.7 GHz |
| | $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ | $d = \left[\frac{12}{V_2}\right]\sqrt{P}$ | $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ | $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ |
| 0.01 | 0.12 | 0.20 | 0.035 | 0.07 |
| 0.1 | 0.38 | 0.63 | 0.11 | 0.22 |
| 1 | 1.2 | 2.00 | 0.35 | 0.70 |
| 10 | 3.8 | 6.32 | 1.10 | 2.21 |
| 100 | 12 | 20.00 | 35 | 70 |
| For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (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. NOTE1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | | |

Smart Health Monitor Ring is compliance with the following international Standard

IEC 60601-1:2005+AMD1:2012+AMD2:2020

IEC60601-1-2:2014+A1:2020




















IEC60601-1-11:2015+AMD1:2020

ISO 80601-2-61:2017

ANSI C63.27:2017/AAMI TIR69:2017

FCC Part2.1093 IEEE Std1528:2013

7. Guide to Symbols

| | |
|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
|  | Type BF-Applied Part |
|  | Manufacturer |
|  | MRI unsafe Presents hazards in all MR environments as device contains strongly ferromagnetic materials. |
|  | Indicate separate collection for electrical and electronic equipment (WEEE) |
| IP68 | Protected against spraying water and against access to hazardous parts with a tool, per IEC 60529 |
|  | Follow Instructions for Use |
|  | Warning and Caution |
|  | Serial number |
|  | No alarm system |
|  | Recycled Material |
|  | Radiated Interference |
|  | General warning sign |
|  | Direct current |
|  | Useful life |
|  | Temperature limits |
|  | Humidity limits |
|  | Atmospheric limits |
|  | This way up |
|  | Fragile, handle with care |
|  | Keep away from rain |

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FCC Caution:

Part 15.21

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

Part 15.19

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 RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.
3. The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

Part 15.105

Note: 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.