Instructions for use

EN  English (US)
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Introduction

Obstructive sleep apnea (OSA) is a potentially serious sleep disorder. It causes breathing to repeatedly stop and start during sleep. OSA occurs when the throat muscles relax and block the airway during sleep. A noticeable sign of OSA is snoring. When sleep apnea occurs mainly when people sleep on their back (supine position), it is called positional obstructive sleep apnea (POSA).

The Sensor Device is worn in a Chest Strap on your body. It monitors you while you are asleep and gently vibrates to remind you to not sleep on your back, while preserving your natural sleep. Several clinical studies have demonstrated its efficacy and positive impact on the quality of life.

Sleep well!
Intended use

Intended use
NightBalance is indicated for prescription use for the treatment of adult patients with positional obstructive sleep apnea with a non-supine apnea-hypopnea index < 20. It records position and movement, so that positional changes in sleep quality can be assessed.

Contraindications for use

• NightBalance should not be used by a patient using another medical aid that can be affected by mild vibrational stimuli - on the chest.
• NightBalance is not recommended for the treatment of patients who are supposed to sleep in a supine position because of a medical condition (e.g. because of shoulder of back surgery or osteoarthritis).
• NightBalance cannot be used by patients who sleep in an upright position or require more than 2 pillows during sleep.

⚠ Always inform your physician if you are using another electronic medical device (e.g. pacemaker) prior to using NightBalance.
⚠ Do not exchange NightBalance with someone else. Use NightBalance only for your own therapy.
Warnings & Precautions

Warnings
⚠️ NightBalance is only to be used for the purpose as specified in the ‘Intended Use’. Note all warnings and cautions throughout this user guide and on labels on the components.
⚠️ NEVER wear or use the Sensor Device or Docking Station in a wet environment such as the shower or bath. This may result in injury and may damage the device.
⚠️ NightBalance vibrations may interfere with the operation of another electronic medical device. Always CONSULT a physician when using NightBalance with another medical device.
⚠️ CHECK for any damage to the Sensor Device, Docking Station and Power Adapter when you receive the device, and whenever you charge the Sensor Device. DO NOT use the device if any part is damaged. Respironics cannot ensure continued safe use of a damaged device.
⚠️ DO NOT attempt to open or modify NightBalance components for any reason. The device does not contain any parts that you can service. Opening or modifying NightBalance components can affect your right on warranty and might result in short-circuiting and/or an electrical shock.
⚠️ DO NOT replace the lithium battery of the Sensor Device. Replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a hazard.
⚠️ DO NOT attach other pieces than specified in these instructions to NightBalance components. This may damage the device. Continued safe use cannot be ensured...
of a damaged device.

⚠ Only use accessories, detachable parts and materials described in the Instructions for Use. Only use the Power Adapter provided by NightBalance (100-240 V, 50-60 Hz) included in your NightBalance pack. Use of other parts and/or materials may damage the device. Respironics cannot ensure continued safe use of a damaged device.

⚠ DO NOT keep NightBalance near young children and pets. Strangulation by long parts and swallowing small parts are hazards.

⚠ DO NOT place the Chest Strap on damaged skin.

⚠ DO NOT touch the contact pins on the Docking Station. This may result in an electrical shock and may damage the device.
Precautions

⚠ CHARGE the Sensor Device at least once every other day for optimal performance. There is no harm in charging the Sensor Device every morning after use.

⚠ USE, and CHARGE NightBalance in temperatures between 50°F and 104°F (10°C and 40°C). STORE NightBalance in temperatures between -4°F and 113°F (-20°C and 45°C).

⚠ CHECK that the wall outlets you use to plug in the Power Adapter are providing the right voltage (100-240V). You may damage the device if these voltages do not match.

⚠ REPLACE NightBalance components after their service life (equivalent to in-use life on page 34 and 35) has passed. After the service life has passed, performance of sensors and electronics can degrade.
NightBalance components

**Sensor Device**
1. Navigation buttons
2. LED light
3. ON/OFF switch
4. Display

**Docking Station**
5. Contact pins
6. Power port
**Chest Strap**
7. Buckle
8. Device pocket

**Power Adapter**
Cable length: 4’11” (1.5m)

*The Power Adapter and wall outlet as visualized in the instructions are an example only, they might look different.*
Getting started

Step 1: Check packaging contents
Upon receiving, make sure your packaging contains:

1. Travel case
2. Instructions for Use
3. Chest Strap
4. Docking Station
5. Sensor Device
6. Power Adapter

If any of these items are missing upon receiving, contact your distributor or customer service (see page 43).
Step 2: Install the app and register

Don’t have a smartphone? You can also create an account in the Portal to register your Sensor Device. Go to the online Portal at us.mynightbalance.com and follow the instructions on the Portal.

1. Download the Philips NightBalance App on your smartphone from the Play Store (for Android) or App Store (for iPhone).

2. Open the Philips NightBalance App. Select and confirm your region (United States).

3. Next, choose “Create new account” and follow the instructions in the app. Complete the registration process by activating your account with the link in your email.
Step 3: Login and pair your Sensor Device

1. Login to the Philips NightBalance app after activating your account. Follow the instructions in the app to complete your account.

2. Once indicated by the app, activate the pairing mode by switching the Sensor Device ON while pressing one of the navigation buttons.

*Pairing ensures a secure connection between your Sensor Device and your smartphone and is to be performed once.*

⚠ Only activate the pairing mode of the Sensor Device on first use. For daily synchronization of your therapy data, see page 26.
Step 4: Setting up the Docking Station

1. Insert the Power Adapter cable into the back of the Docking Station.

⚠ Only use the Power Adapter provided by NightBalance (100-240 V, 50-60 Hz) included in your NightBalance pack.

⚠ DO NOT position the Docking Station on such way that it is difficult to operate the Power Adapter.

2. Connect the Power Adapter into a standard wall outlet (100-240V AC).
3. Place the Sensor Device on the Docking Station with the buttons on top and display towards you.

On the Docking Station, the Sensor Device charges itself automatically.

4. The display and LED of the Sensor Device should become active. This indicates the right placement.

NightBalance is now ready for use.
Step 5: Understand the Adaptation Period
The adaptation program of NightBalance is designed to slowly train you to respond to the Sensor Device’s vibrations during sleep. You need to use NightBalance for nine nights before the device will provide full position therapy.

1) Analysis phase
No vibrations are given during the first two nights of the therapy. NightBalance gathers baseline data on your sleep patterns during night 1 and 2. This data is used to tailor the therapy to your individual sleeping behavior later on.

2) Build-up phase
NightBalance starts to deliver vibrations during night 3 to 9. The vibrations will build up gradually when laying on your back, allowing you to get used to therapy.

It is recommended to use NightBalance every night, or as agreed with your physician for best therapy results.
How to use NightBalance daily

**Step 1: Placing the Chest Strap**

1. Wrap the Chest Strap around your chest

   - *It is recommended to place the Chest Strap on bare skin.*

   - *In case the Chest Strap is too short, adjust the tightness (see next page).*

2. Hook the buckle through the opening
3. Adjust the tightness if needed by adjusting the velcro position of the Chest Strap. The Chest Strap should fit tight enough to stay in place and feel comfortable to wear at the same time.

4. Make sure the Device pocket is placed in the middle of your chest.
Step 2: Placing the Sensor Device

1. Power on the Sensor Device by sliding the ON/OFF switch to the ON position.

2. Confirm that the white LED light on the Sensor Device starts blinking. This indicates it is switched on.

温馨提醒：Sensor Device 使用前请确保充电。

Ensure the Sensor Device is charged before using it during sleep.
3. Place the Sensor Device inside the Device pocket of the Chest Strap. Check that the Device pocket is placed on the middle of your chest.

4. Make sure the Sensor Device buttons are on the top and the display is facing away from your body. Close the zipper of the pocket of the Chest Strap.

Now you can go to sleep.
Step 3: Sleeping with the Sensor Device

1. Fall asleep in any position you desire.

   *NightBalance allows you to fall asleep in any position. 15 minutes after switching the Sensor Device ON, the therapy starts.*

2. Once the Sensor Device vibrates, turn to your side.

   *NightBalance regulates the intensity of the vibrations based on your sleeping behavior.*

   *The Sensor Device will not vibrate during the first two nights of therapy. See page 15.*
**Tip: Activating Pause Mode**

In pause mode, the Sensor Device will not give vibrations for 5 minutes. Pause mode can be activated if you get up during the night, or if you turn the Device pocket of the Chest Strap vertical for a second.
Step 4: Removing the Sensor Device

1. Use the buckle to remove the Chest Strap.

2. Take the Sensor Device out of the Chest Strap.

3. View last night’s sleep data on the Sensor Device’s display if desired.

ℹ️ *Sleep data from short naps (<2 hours) is excluded from any data calculations.*
How to use NightBalance daily

- Percentage of time you slept on your back last night: 13%
- Total time you used the Sensor Device the night before: 07:42
- Your daily response to the vibrations of the Sensor Device: 86%
- Battery level

**Tip:** Press the navigation buttons on top of the Sensor Device to switch from one screen to the next.
4. Power off the Sensor Device by sliding the ON/OFF switch to the OFF position.

5. Confirm that the white LED light on the Sensor Device stops blinking. This indicates it is switched OFF.

ℹ️ *It might take some time before the LED is switched OFF in case the Sensor Device is transmitting data.*
Step 5: Charging the Sensor Device

1. Place the Sensor Device on the powered Docking Station with the buttons on top and display towards you.

   *In order to stop charging the Sensor Device, it can be removed from the Docking Station to disconnect the power supply.*

2. Upon correct placement onto the Docking Station, the Sensor Device display will become active and the LED will start to blink.

   *The display of the Sensor Device shows a battery icon when charging takes place.*
View therapy data

Background information on Bluetooth use
The Sensor Device uses a Bluetooth connection with your smartphone to establish a connection. Via this connection, therapy data can be sent to the Philips NightBalance App.

Synchronization with the smartphone on a daily basis ensures your therapy data is up to date.

Synchronization of therapy data with your smartphone takes place automatically directly after turning the Sensor Device ON or OFF during daily use when the Philips NightBalance app has been downloaded to your smartphone. For synchronization progress and information, see the Philips NightBalance app.

- The Sensor Device is designed to be used with Bluetooth version 4.2 or 5.0. Compatibility with other Bluetooth versions cannot be guaranteed.

- The Bluetooth connection takes place over an encrypted channel.
Step 1: Manually synchronizing the Sensor Device with your smartphone

1. Ensure the app is available:
   • Bluetooth is enabled on your smartphone
   • You are logged into the Philips NightBalance app and your Sensor Device is paired to your smartphone
   • The app is opened or running in the background of your smartphone
   • Sensor Device and smartphone are within reach (max. 5m/16ft) of each other

2. Turn the Sensor Device ON, wait a few seconds, and turn the Sensor Device OFF again. Synchronizing should start automatically.

   The Philips NightBalance app indicates when the last successful data transfer took place. Go to ‘Profile’, and click ‘Sensor Device’.
Step 2: View therapy data in the app and Portal

Information: Viewing therapy data is possible on the Sensor Device, smartphone (Philips NightBalance app) and the online Portal. The following data views are available:
- **Sensor Device:** Last night
- **Smartphone:** Last night and last 7 days
- **Online Portal:** Last 30 days

Information: Sleep data from short naps (<2 hours) is excluded from any data calculations in the app and Portal.

1. After synchronizing your therapy data with your smartphone, you can view your therapy data in the ‘Night view’ and ‘Week view’ tabs.
2. If you synchronize your therapy data with the app, you can also view your therapy data in the online Portal. Go to us.mynightbalance.com and login.

Tip: discuss therapy progress with your physician if desired. Note that your physician can only review your sleep data on their online Portal once you grant them access. See the ‘Profile’ section in the Philips NightBalance app or Portal.

Logout from the online Portal after use.
Care and maintenance

**Charging the Sensor Device**
It is recommended that you charge the Sensor Device every morning after use. Getting in the habit of charging the Sensor Device every day will ensure that the Sensor Device has enough battery level for next use. See page 25 on instructions for charging.

**Cleaning your Chest Strap, Sensor Device and Docking Station**
- The Chest Strap can be washed in a washing machine on a regular basis (e.g. once every week or when visibly soiled) with a mild detergent not containing chlorine (bleach) or fabric softener. After washing, let the strap dry by air. DO NOT place the Sensor Device in a wet Chest Strap. DO NOT dry the strap in a dryer. DO NOT iron the Chest Strap.
- It is the user’s responsibility to keep NightBalance equipment dust free. Before cleaning, turn the Sensor Device OFF and unplug the Power Adapter from the Docking Station and the wall outlet. Clean the Sensor Device and Docking Station with a dampened cloth with water or mild cleaning solution (e.g. standard detergent) if they are visibly dirty. DO NOT use bleach or other aggressive cleaning solutions. Ensure that moisture does not penetrate the openings.

**Traveling with NightBalance**
- Use the Travel case to store, and transport your NightBalance components.
- Check if the Power Adapter is compatible with the foreign power systems. A voltage converter may be needed.
• When travelling by airplane, check with the carrier to confirm that (the battery of) the device can be carried and/or used on the airplane.

**Disposal**
• DISPOSE of the Sensor Device and Docking Station according to local regulations for the disposal of electronic waste. Please note that the Sensor Device can contain data that has not been transferred by synchronizing with your smartphone. This data is encrypted.
• DISPOSE of the Chest Strap, packaging and Instructions for Use in a regular waste system.

**Maintenance**
• The Sensor Device and Docking Station do not contain any parts that can be serviced.
• After the service life (equivalent to in-use life on page 34 and 35) of NightBalance components has expired, replace the component with a new one.
# Troubleshooting

<table>
<thead>
<tr>
<th>Problem</th>
<th>Why it happened</th>
<th>What to do</th>
</tr>
</thead>
<tbody>
<tr>
<td>I cannot pair the Sensor Device with the Philips NightBalance app and the Sensor Device shows the following screen:</td>
<td>Bluetooth on your smartphone is switched OFF</td>
<td>Enable Bluetooth on your smartphone.</td>
</tr>
<tr>
<td>The Philips NightBalance app is not ready to pair.</td>
<td></td>
<td>Follow the instructions in the app. Initiate pairing on the Sensor Device only if the app indicates to do so. See page 12.</td>
</tr>
<tr>
<td>The smartphone and Sensor Device are not within reach.</td>
<td></td>
<td>Keep the smartphone and Sensor Device within reach (1m) of each other</td>
</tr>
<tr>
<td>The Sensor Device is not turning ON, or shows the following screen:</td>
<td>The battery is empty.</td>
<td>Place the Sensor Device on the powered Docking Station. After a few hours, the Sensor Device should be fully charged. See page 13, 14, and 25.</td>
</tr>
<tr>
<td>Problem</td>
<td>Why it happened</td>
<td>What to do</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>The Sensor Device shows the following screen:</td>
<td>An error occurred in the Sensor Device.</td>
<td>Do not use NightBalance. Contact your distributor, or customer service (see page 43), and mention the error number that your Sensor Device shows.</td>
</tr>
<tr>
<td>My sleep data is not visible in the Philips NightBalance app or Portal.</td>
<td>The Sensor Device has not yet synchronized with the Philips NightBalance app.</td>
<td>Synchronize the Sensor Device with your smartphone. Follow the instructions on page 26.</td>
</tr>
<tr>
<td></td>
<td>The Portal does not show data from the Analysis Phase (day 1-2 of therapy).</td>
<td>Sleep for a few days with the Sensor Device, synchronize the sleep data (see pages 26-27) and come back to the Portal.</td>
</tr>
<tr>
<td></td>
<td>Short naps (&lt;2 hours) are excluded from any data calculations</td>
<td>Sleep for a full night (&gt;2 hours) with the Sensor Device and synchronize the Sensor Device with your smartphone.</td>
</tr>
</tbody>
</table>
## Technical specifications

<table>
<thead>
<tr>
<th>Sensor Device</th>
<th>Docking Station</th>
<th>Travel Case</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dimensions:</strong> 2.7 x 1.8 x 0.6 inch (6.9 x 4.5 x 1.4 cm)</td>
<td><strong>Dimensions:</strong> 4.0 x 3.3 x 1.3 inch (10.2 x 8.3 x 3.2 cm)</td>
<td><strong>Dimensions:</strong> 7.9 x 6.7 x 2.7 inch (20.0 x 17.0 x 6.8 cm)</td>
</tr>
<tr>
<td><strong>Weight:</strong> 1.1 oz (30 gr)</td>
<td><strong>Weight:</strong> 3.0 oz (85 gr)</td>
<td><strong>Weight:</strong> 8.8 oz (250 gr)</td>
</tr>
<tr>
<td><strong>Power Source:</strong> Lithium polymer, 3.7V, 165mA</td>
<td><strong>Material:</strong> ABS, PC</td>
<td><strong>Material:</strong> Nylon, Polyester, EVA</td>
</tr>
<tr>
<td><strong>Material:</strong> ABS, PMMA</td>
<td><strong>In-use life:</strong> 3 years</td>
<td><strong>In-use life:</strong> 3 years</td>
</tr>
<tr>
<td><strong>Internal clock battery:</strong> MS621FE (lifetime: 3 years)</td>
<td><strong>Power Adapter:</strong> Input: 100-240V AC, 50-60 Hz, 0.27-0.15A Output: 5.0V DC, 2.0A, 10W MAX</td>
<td><strong>Travel Case:</strong> Accessory of NightBalance</td>
</tr>
<tr>
<td><strong>Frequency characteristics:</strong> Bluetooth: version 4.2, 5.0 Band support: 2.4GHz Effective radiated power: +6 dBm</td>
<td><strong>In-use life:</strong> 3 years</td>
<td></td>
</tr>
<tr>
<td><strong>Bluetooth encryption:</strong> AES-CCM encrypted channel</td>
<td><strong>Travel Case:</strong> Accessory of NightBalance</td>
<td><strong>Travel Case:</strong> Accessory of NightBalance</td>
</tr>
</tbody>
</table>

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34 Technical specifications
Chest Strap
Dimensions: 58.7 x 2.8 x 0.1 inch (149.0 x 7.0 x 0.3 cm)
Weight: 2.2 oz (62 gr)
Materials: Polyamide, Polyester, Lycra, Polyurethane, Silicone
In-use life: 1 year

Model references
<table>
<thead>
<tr>
<th>System</th>
<th>Model</th>
<th>Device Identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>L2US01US</td>
<td></td>
</tr>
<tr>
<td>NL</td>
<td>L2EU01NL</td>
<td></td>
</tr>
<tr>
<td>FR</td>
<td>L2EU01FR</td>
<td></td>
</tr>
<tr>
<td>DE</td>
<td>L2EU01DE</td>
<td></td>
</tr>
<tr>
<td>UK</td>
<td>L2EU01UK</td>
<td></td>
</tr>
</tbody>
</table>

IEC 60601-1 Classifications: This device is Class II Equipment. The Sensor Device used in combination with the Chest Strap is Applied Part Type BF, Continuous Operation. The device meets the requirements of IEC-EN 60601-1, IEC-EN 60601-1-2, IEC-EN 60601-1-11.

The Sensor Device is IP22 rated for normal use (when placed in the Chest Strap). This means that the device is protected against solid foreign objects of 12,5 mm diameter and greater, and against vertically falling water drops when enclosure tilted up to 15°.

The Docking Station is IP21 rated for normal use. This means that the device is protected against solid foreign objects of 12,5 mm diameter and greater, and against vertically falling water drops.
## Symbols

<table>
<thead>
<tr>
<th>Symbols</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>CE</td>
<td>CE mark</td>
</tr>
<tr>
<td>🚨</td>
<td>Type BF medical equipment</td>
</tr>
<tr>
<td>!</td>
<td>Caution</td>
</tr>
<tr>
<td>⚠️</td>
<td>General warning sign</td>
</tr>
<tr>
<td>IP22</td>
<td>Ingress protection</td>
</tr>
<tr>
<td>+ −</td>
<td>Polarity</td>
</tr>
<tr>
<td>⦿</td>
<td>Direct Current</td>
</tr>
<tr>
<td>📖</td>
<td>Consult Instructions for Use</td>
</tr>
<tr>
<td>📜</td>
<td>Refer to instruction manual/booklet</td>
</tr>
<tr>
<td>🗑️</td>
<td>Waste Electrical and Electronical Equipment</td>
</tr>
<tr>
<td>✖️</td>
<td>Do not bleach</td>
</tr>
<tr>
<td>✖️</td>
<td>Do not iron</td>
</tr>
<tr>
<td>✖️</td>
<td>Do not dry clean</td>
</tr>
<tr>
<td>✖️</td>
<td>Do not tumble dry</td>
</tr>
<tr>
<td>🛠️</td>
<td>Machine wash, 86°F (30°C)</td>
</tr>
<tr>
<td>🚫</td>
<td>Prescription</td>
</tr>
<tr>
<td>🏧</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>☑️</td>
<td>Serial Number</td>
</tr>
<tr>
<td>🔐</td>
<td>Batch code</td>
</tr>
<tr>
<td>📜</td>
<td>Reference code</td>
</tr>
<tr>
<td>☂️</td>
<td>Keep dry</td>
</tr>
<tr>
<td>📡</td>
<td>Non-ionizing electromagnetic radiation</td>
</tr>
<tr>
<td>☑️</td>
<td>Class II equipment</td>
</tr>
</tbody>
</table>
## Environmental conditions

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<th>Storage conditions</th>
<th>Operating conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Temperature icon" /> 45°C</td>
<td><img src="image" alt="Temperature icon" /> 40°C</td>
</tr>
<tr>
<td><img src="image" alt="Humidity icon" /> 90%</td>
<td><img src="image" alt="Humidity icon" /> 90%</td>
</tr>
<tr>
<td><img src="image" alt="Pressure icon" /> 1060 hPa</td>
<td><img src="image" alt="Pressure icon" /> 1060 hPa</td>
</tr>
<tr>
<td><img src="image" alt="Pressure icon" /> 700 hPa</td>
<td><img src="image" alt="Pressure icon" /> 700 hPa</td>
</tr>
</tbody>
</table>

NightBalance components can be safely stored at temperatures between -4°F (-20°C) and 113°F (45°C), a relative humidity between 10% and 90%, and an atmospheric pressure between 700 and 1060 hPa.

NightBalance components can be safely used at temperatures between 50°F (10°C) and 104°F (40°C), a relative humidity between 15% and 90%, and an atmospheric pressure between 700 and 1060 hPa.

ℹ️ *The device is ready for use when within the operating conditions.*
Regulatory information

Data privacy & security
Respironics offers its patients the use of a secure web-based application (Portal) and smartphone application which provides you with secure electronic access to your recorded data only you can access and, with your permission, your physician.

Respironics seeks to use reasonable organizational, technical and administrative measures to protect Personal Data within our organization. Unfortunately, no data transmission or storage system can be guaranteed to be 100% secure. The best technical security can be defeated, particularly if you do not protect your user ID and password to access the portal. If you have reason to believe that your interaction with us is no longer secure, please immediately notify us.

We are compliant with the following laws and regulations:
• GDPR (2018)
• HIPAA (1996)

Electromagnetic compatibility (EMC)
NightBalance is intended for use in the electromagnetic environment specified in the coming sections. The customer or the user of NightBalance should assure that it is used in such an environment. NightBalance needs special precautions regarding EMC according to the EMC information provided in this chapter.
Representative to the function of the device EMC testing has been performed per 60601-1-2 and 60601-1-11.

⚠ WARNING: Portable and mobile RF communications equipment including antennas can affect NightBalance’s operations. DO NOT use portable and mobile RF communications equipment closer than 12 inches (30 cm) to any part of NightBalance, including cables specified by the manufacturer. Other equipment, even if that other equipment complies with CISPR emission requirements, may interfere with NightBalance.

⚠ WARNING: the use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by NightBalance as replacement parts for internal components, may result in increased emissions or decreased immunity of NightBalance.

⚠ WARNING: NightBalance should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, NightBalance should be observed to verify normal operation in the configuration in which it will be used.

NightBalance does not have essential performance.
### Electromagnetic emissions

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions (CISPR 11)</td>
<td>Group 1</td>
<td>The NightBalance 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.</td>
</tr>
<tr>
<td>RF Emissions (CISPR 11)</td>
<td>Class B</td>
<td>The NightBalance 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.</td>
</tr>
<tr>
<td>Harmonic Emissions (IEC 61000-3-2)</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions (IEC61000-3-3)</td>
<td>Complies</td>
<td></td>
</tr>
<tr>
<td>Immunity test</td>
<td>IEC 60601 Test Level</td>
<td>Compliance Level</td>
</tr>
<tr>
<td>--------------------------------------------------------</td>
<td>------------------------------------</td>
<td>--------------------------------</td>
</tr>
<tr>
<td>Electrostatic discharge (ESD) (IEC 61000-4-2)</td>
<td>±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air</td>
<td>±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air</td>
</tr>
<tr>
<td><strong>Electromagnetic Environment - Guidance</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiated RF Electromagnetic Field (IEC 61000-4-3)</td>
<td>10 V/m 80 MHz to 2.7GHz</td>
<td>10 V/m</td>
</tr>
<tr>
<td>Proximity fields from RF wireless communication systems (IEC 61000-4-3)</td>
<td>Refer to page 42</td>
<td>Refer to page 42</td>
</tr>
<tr>
<td>Electrical fast transient/burst (IEC 61000-4-4)</td>
<td>±2 kV for power supply lines</td>
<td>±2 kV for power supply lines</td>
</tr>
<tr>
<td>Surge (IEC 61000-4-5)</td>
<td>±0.5 kV, ±1 kV line(s) to line(s)</td>
<td>±0.5 kV, ±1 kV line(s) to line(s)</td>
</tr>
<tr>
<td>RF Common mode/Conducted susceptibility (IEC 61000-4-6)</td>
<td>3 Vrms, 6V in amateur radio bands. 150 kHz to 80 MHz</td>
<td>3 Vrms, 6V in amateur radio bands.</td>
</tr>
<tr>
<td>Power frequency (50–60 Hz) magnetic field (IEC 61000-4-8)</td>
<td>30 A/m</td>
<td>30 A/m</td>
</tr>
<tr>
<td>Voltage dips (IEC 61000-4-11)</td>
<td>0% U&lt;sub&gt;T&lt;/sub&gt;; 1 cycle and 70% U&lt;sub&gt;T&lt;/sub&gt;; 25/30 cycles. Single phase: at 0°, 0% U&lt;sub&gt;T&lt;/sub&gt;; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</td>
<td>0% U&lt;sub&gt;T&lt;/sub&gt;; 1 cycle and 70% U&lt;sub&gt;T&lt;/sub&gt;; 25/30 cycles. Single phase: at 0°, 0% U&lt;sub&gt;T&lt;/sub&gt;; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</td>
</tr>
<tr>
<td>Voltage interruptions (IEC 61000-4-11)</td>
<td>0% U&lt;sub&gt;T&lt;/sub&gt;; 250/300 cycle</td>
<td>0% U&lt;sub&gt;T&lt;/sub&gt;; 250/300 cycle</td>
</tr>
</tbody>
</table>

NOTE: U<sub>T</sub> is the a.c. mains voltage prior to application of the test level.
## Electromagnetic immunity

<table>
<thead>
<tr>
<th>Test frequency (MHz)</th>
<th>Band (MHz)</th>
<th>Service</th>
<th>Modulation</th>
<th>Maximum power (W)</th>
<th>Distance (m)</th>
<th>Immunity test level (V/m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>385</td>
<td>380-390</td>
<td>TETRA 400</td>
<td>Pulse modulation 18 Hz</td>
<td>1.8</td>
<td>0.3</td>
<td>27</td>
</tr>
<tr>
<td>450</td>
<td>430-470</td>
<td>GMRS 460, FRS 460</td>
<td>FM ± 5 kHz deviation 1kHz sine</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>710 745 780</td>
<td>704-787</td>
<td>LTE Band 13, 17</td>
<td>Pulse modulation 217 Hz</td>
<td>0.2</td>
<td>0.3</td>
<td>9</td>
</tr>
<tr>
<td>810 870 930</td>
<td>800-960</td>
<td>GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5</td>
<td>Pulse modulation 18 Hz</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>1720 1845 1970</td>
<td>1700-1900</td>
<td>GSM 1800, CDMA 1900, GSM 1900, DECT; LTE Band 1, 3, 4, 25; UMTS</td>
<td>Pulse modulation 217 Hz</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>2450</td>
<td>2400-2570</td>
<td>Bluetooth, WLAN, 80211 b/g/n, RFID 2450, LTE Band 7</td>
<td>Pulse modulation 217 Hz</td>
<td>2</td>
<td>0.3</td>
<td>28</td>
</tr>
<tr>
<td>5240 5500 5785</td>
<td>5100-5800</td>
<td>WLAN 802.11 a/n</td>
<td>Pulse modulation 217 Hz</td>
<td>0.2</td>
<td>0.3</td>
<td>9</td>
</tr>
</tbody>
</table>
Warranty

Respironics provides a two-year warranty on the Sensor Device and Docking Station. Respironics or the reseller will repair or replace the device(s) due to faulty materials or operation during the warranty period. Proof of damage must be provided along with the original purchase receipt must be provided to begin any repairs or replacement. This warranty will take precedence over any other local warranties that may apply, as permitted under applicable law.

This warranty will not cover:

• Any components that are subject to normal wear and tear. This includes the Chest Strap and Sensor Device batteries.
• Any damage or malfunction due to incorrect use, unauthorized alterations or repairs to the device, or not storing the device as outlined in the Instructions for Use.

Contact

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Murrysville, PA 15668-8550  
USA

Deutschland  
Gewerbestrasse 17  
82211 Herrsching  
Germany

Contact your local distributor for assistance and support or contact NightBalance’s customer service at support.nightbalance@philips.com


ℹ️ Store NightBalance components inside the Travel Case when sending it for repairs or returns.