# Philips NightBalance FAQ's

## Patient Device Questions & Answers

*(Please refer to the Instructions for Use for information that is more detailed)*

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| **Q:** What is the intended use of the product? | **A:** NightBalance is intended as a therapy for mild to moderate Positional Obstructive Sleep Apnea (POSA) in adults with a non-supine AHI<10. NightBalance is intended to be used by patients during sleep in their home environment without the need for instructions from a physician. |
| **Q:** I have a pacemaker/ICD (Implantable Cardioverter Defibrillator) can I use NightBalance? | **A:** If a patient wishes to use the NightBalance device with another medical device or therapy, he or she should consult a medical specialist. |
| **Q:** I sleep in an upright position or propped up on more than two pillows.  Can I use NightBalance  ? | **A:** The NightBalance cannot be used by patients that sleep in the upright position or require more than two pillows during sleep. |
| Q: What if I am required to sleep in supine position? | A:  The NightBalance is not recommended for the treatment of patients who are supposed to sleep in the supine position because of a medical condition (back/shoulder surgery or osteoarthritis). |
| **Q:** Do I need a prescription to get a NightBalance? | **A:** Yes, the NightBalance is prescription use only. |
| **Q:** Can I get out of bed at night? | **A:** Yes, if you need to get out of bed during the night, you can pause the device.  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. In pause mode, the Sensor Device will not give vibrations for 5 minutes. |
| **Q:** Can I still sleep on my stomach? | **A:** Yes, the device functions in any sleeping position. |
| **Q:** What is in the package? | **A:** The packaging contains a user manual, chest strap, charging base, charging cable, travel case and the NightBalance sensor device. |
| **Q:** How big is the NightBalance device and its accessories? | **A:**<br>**Sensor Device:**<br>&bull; Dimensions: 6.9 x 4.5 x 1.4 cm (2.7 x 1.8 x 0.6 inch)<br>&bull; Weight:  30 gr (1.1 oz)<br>&bull; Power Source: Lithium polymer, 3.7V, 165Ma<br>&bull; Material: ABS, PMMA<br>&bull; In-use life: 3 years<br>&bull; Internal clock battery: MS621FE (lifetime 3 years)<br>&bull; Frequency characteristics:<br>    o Bluetooth: version 4.2, 5.0<br>    o Band support: 2.4GHz<br>    o Effective radiated power: +6 dBm<br>**Docking Station:**<br>&bull; Dimensions: 10.2x8.3x3.2cm (4.0x3.3x1.3 inch)<br>&bull; Weight: 85 gr (3.0 oz)<br>&bull; Material: ABS, PC<br>&bull; In-use life: 3 years<br>&bull; Power Adapter:<br>    o Power source: 100-240V AC, 50/60 Hz<br>    o Output: 5V, 200 Ma, 10W<br>**Travel Case – Accessory of NightBalance:**<br>&bull; Dimensions: 20.0x17.0x6.8cm |

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| | • Weight: 250 gr (8.8oz)<br>• Material: Nylon, Polyester, EVA<br>• In-use life: 3 years<br>**Chest Strap:**<br>• Dimensions: 149.0x7.0x0.3cm (58.7x2.8x0.1 inch)<br>• Weight: 62 gr (2.2 oz)<br>• Materials: Polyamide, Polyester, Lycra, Polyurethane, Silicone<br>• In-use life: 1 year |
| **Q:** What is the warranty for the NightBalance? | **A:**<br>NightBalance B.V. provides a two-year warranty on the Sensor Device and Docking Station. NightBalance 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.<br><br>**This warranty will not cover:**<br>• Any components that are subject to normal wear and tear. This includes the Chest Strap and Sensor Device batteries.<br>• Any damage or malfunction due to incorrect use, unauthorized alterations or repairs to the device, or not storing he device as outlined in the Instructions for Use |
| **Q:** How long can I expect to be able to use my NightBalance device and accessories before I need to replace them? | **A:** Each accessory along with your device has an "In-Use life" this is the amount of time that each individual item can be used before needing to be replaced (this is sometimes referred to as the "service life").<br><br>    a. Sensor device – 3 years<br>    b. Docking station – 3 years<br>    c. Chest strap – 1 year<br>    d. Travel case – 3 years |
| **Q:** Is there any maintenance that needs to be done to my device? | **A:** a. The sensor device and docking station do not contain any parts that can be serviced<br>    b. After the in-use life of NightBalance components has expired, replace the component with a new one. |

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| **Q:** How do I charge my Sensor device? | **A: Charging the Sensor Device**:<br>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. |
| **Q:** How do I clean my device and accessories? | **A:**<br>• **Cleaning your Chest Strap, Sensor Device, and Docking Station**:<br>    ○ 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.<br>    ○ 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. |
| **Q:** Can I travel with NightBalance? | **A: Traveling with NightBalance**<br>    ○ Use the Travel case to store, and transport your NightBalance components<br>    ○ Check if the power adapter is compatible with the foreign power systems. A voltage converter may be needed<br>    ○ 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 |
| **Q:** What if I need to dispose of NightBalance? | **A: Disposal:**<br>    ○ 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<br>    ○ DISPOSE of the Chest Strap, packaging and instruction for use in a regular waste system |
| **Q:** How do I know that I am placing the Sensor Device in the chest strap correctly? | **A:** a. Place the Sensor Device inside the Device pocket of the Chest Strap.<br>   b. Check that the Device Pocket is placed in the middle of your chest. |

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| | c. Make sure the Sensor Device's buttons are on the top and the display is facing away from your body. |
| **Q:** How do I know that the NightBalance is turned on? | **A:** a. Power on the Sensor Device by sliding the ON/OFF switch to the ON position.<br>   b. Confirm that the white LED light on the Sensor Device starts blinking.  This indicates that it is switched on. |
| **Q:** How often should I charge my NightBalance device? | **A:** a. Charge the Sensor Device at least once every other day for optimal performance.<br>   b. There is no harm in charging the Sensor Device every morning after use (recommended). |
| **Q:** Does my therapy begin as soon as I switch the device on? | **A:** No, the NightBalance allows you 15 minutes to fall asleep once the device is switched on. |
| **Q:**  Do I have to fall asleep on my side? | **A:** No.  You may fall asleep in any position that you desire.  Once the sensor vibrates turn to your side. |
| **Q:** Can I get a new or extra Chest Strap and Extension piece? | **A:** Yes, you can order an additional or replacement chest strap. |
| **Q:** What is the adaptation program? | **A:** 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.<br>*1) Analysis phase*<br>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.<br>*2) Build-up phase*<br>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. |
| **Q:** Does the device clear itself of data after data upload? | **A:** Data transferred to the mobile app and portal is (automatically) removed from the Sensor Device memory. |
| **Q:** Does the device retain data after the data has been transferred to the cloud? | **A:** a. The Sensor Device will retain data up to the point it has been successfully transferred to mobile app. |
| **Q:** How much data can the sensor device store? | **A:** The Sensor Device can store (at least) one year of data.<br>*Whenever the Sensor Device is full it will overwrite the oldest data first.* |
| **Q:** Can I use the NightBalance device with Home Sleep Test (HST) devices? | **A:** If a patient wishes to use the NightBalance device with another medical device or therapy, they should consult their medical specialist. |
| **Q:** Would there be any sort of interference with CPAP/BiPAP units using Bluetooth to communicate? | **A:** The product complies with the standards applicable for the intended use. If a patient wishes to use the NightBalance device with another medical device or therapy, they should consult their medical specialist. |
| **Q:** If a replacement device is sent out will the new device pick up where the old one left off, treatment-wise, or will it need to reanalyze and start over? | **A:** Replacement device will start over. Data from old device to new device can be merged via the portal. |
| **Q:** What type of memory is in the device?  Flash? | **A:** The Sensor Device has Flash Memory. |
| **Q:** Is there a capacitor that stores energy when the battery is fully discharged for memory purposes? | **A:** The Sensor Device does not lose the recorded sleep data when the battery is fully discharged (non-volatile memory). |
| **Q:** How many battery charging cycles are available with this device? | **A:** > 1000 cycles. |
| **Q:** What is the average amount of data collected per night (file size)? | **A:** 8-50 kB per day depending on the user (duration, number of vibrations, events….). |

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| **Q:** Can the data acquired be exported to CSV? | **A:** No. |
| **Q:** How many options for strength and pattern of vibration are available, since the device tailors itself to each patient? | **A:** There are 10 Levels of Vibration and 5 Vibration Patterns. These are built into the device and cannot be changed by the patient. |
| **Q:** Is there an FAA letter for this device to carry on an airplane? | **A:** No, not at this time. |
| **Q:** If a patient were to bring this in a sleep lab, will this interfere sleep recording system and or study while patient is wearing this? | **A:** The product complies with the standards applicable for the intended use. If a patient wishes to use the NightBalance device with another medical device or therapy, they should consult their medical specialist. |
| **Q:** How long does the device need to be in the up positon to put it into the pause mode? | **A:** +/- 5 seconds. |

## Mobile Application/Web Portal Questions & Answers

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| **Q:** What are the steps to install the mobile app and register? | **A:** Download the Philips NightBalance App on your smartphone from the Play Store (for Android) or App Store (for iPhone).<br>2. Open the Philips NightBalance App. Select and confirm your region (Europe).<br>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. |
| **Q:** How do I pair my sensor device? | **A:** 1. Login to the Philips NightBalance app after activating your account. Follow the instructions in the app to complete your account.<br>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.<br>⚠⚠ Only activate the pairing mode of the Sensor Device on first use. |
| **Q:** How do I synchronize the sensor device to the smartphone**?** | **A:** 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.<br>1. Ensure the app is available:<br>• Bluetooth is enabled on your smartphone<br>• You are logged into the Philips NightBalance app and your Sensor Device is paired to your smartphone<br>• The app is opened or running in the background of your smartphone<br>• Sensor Device and smartphone are within reach (max. 5m/16ft) of each other<br>2. Turn the Sensor Device ON, wait a few seconds, and turn the Sensor Device OFF again. Synchronizing should start automatically.<br><br>Synchronization with the smartphone on a daily basis ensures your therapy data is up to date. |
| **Q:** What data can I see in the mobile application? | **A:** Sensor Device: Last night<br>Smartphone: Last night and last 7 days<br>Online Portal: Last 30 days |

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| | Sleep data from short naps (<2 hours) is excluded from any data calculations in the app and Portal. |
| Q: How does the online portal work? | **A:** Data is pushed to the online portal via the mobile application. If you synchronize your therapy data with the app, you can also view your therapy data in the online portal. |
| **Q:** Can a profile have the email changed to a new/different address? | **A:** Yes in the patient portal menu. |
| **Q:** If I chose the wrong Physician at first then I switch to the correct Physician, will the first Physician (incorrect chosen) be able to see the patient data? | **A:** Up to the point where you switch the Physician; Yes. After the point where you switch the Physician; No. |
| **Q:** How fast does the data upload from the sensor device (while in dock) to the portal? How long does it take to get the data to the portal? | **A:** Depends on the number of days of data that have not been uploaded. For 1 day of data; a couple of seconds. |
| **Q:** How do we handle cloud maintenance scheduling/outages? | **A:** The Docking Station will retry upload at later time after the maintenance period is complete. |
| **Q:** If I do not make the 15-minute window for activation, can I use the same user name and password be used to start the registration process over? | **A:** Yes. |
| **Q:** If a patient gets a replacement device will the physician that they have chosen see both old and new data? | **A:** Yes. |
| **Q:** Where can I find the serial number that I need for registration in the NightBalance Portal? | **A:** The serial number is located on the back of the Sensor Device. |