

PHILIPS

NightBalance

Sleep position therapy



Instructions for use

EN English (EU)



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Read all instructions for use before using NightBalance. Contact your physician if you have any questions as to whether NightBalance is right for you. You may also contact customer service if you have any questions about NightBalance, see page 43.

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 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 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.

Indications for use

The following are the Indications for Use for NightBalance.

- You are at least 18 years of age.
- You have a supine AHI which is at least twice as high as the non-supine AHI.
- You have been diagnosed with mild or moderate OSAS ($5 \leq \text{AHI} \leq 30$).
- You have an AHI in non-supine position below 10.
- You sleep at between 10-90% in supine position.
- You should be able to switch sleeping positions independently.

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 or 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. NightBalance 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. NightBalance 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.

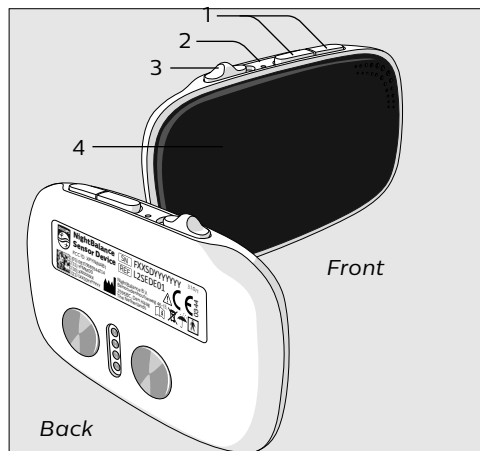
Precautions

- ⚠ 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 -5°C and 40°C (23°F and 104°F). STORE NightBalance in temperatures between -25°C and 70°C (-13°F and 158°F).
- ⚠ 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

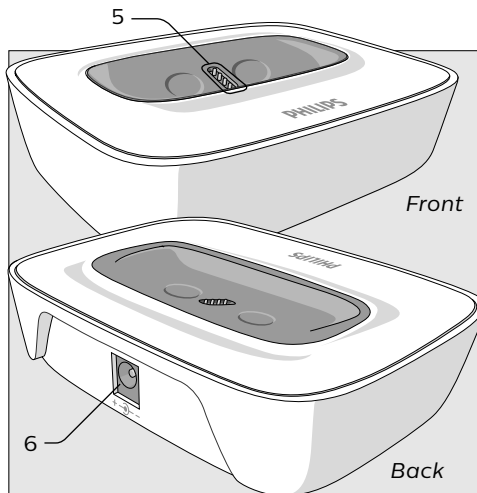
Sensor Device

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



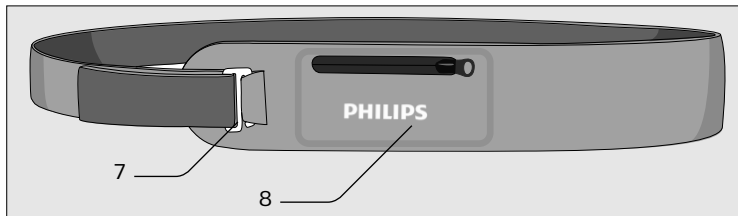
Docking Station

5. Contact pins
6. Power port



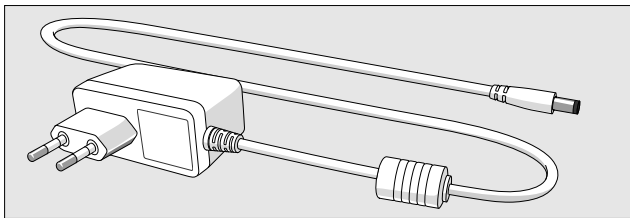
Chest Strap

- 7. Buckle
- 8. Device pocket



Power Adapter

Cable length: 1.5m (4'11")



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

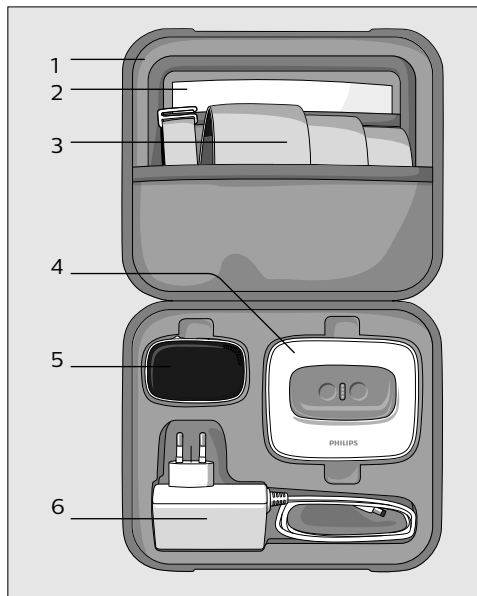
Getting started

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

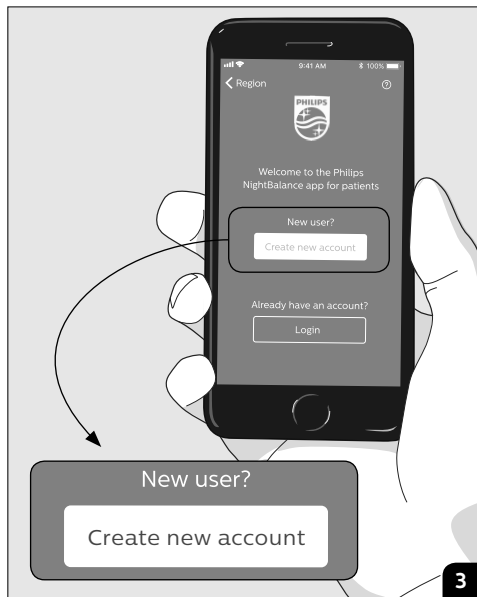
i *If any of these items are missing upon receiving, contact your distributor or customer service (see page 43).*



Step 2: Install the app and register

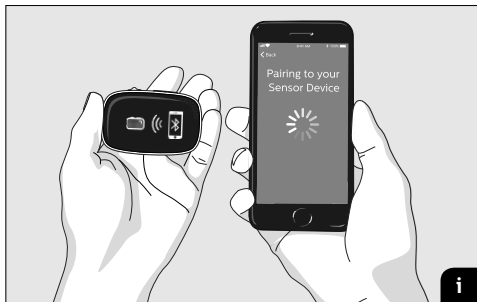
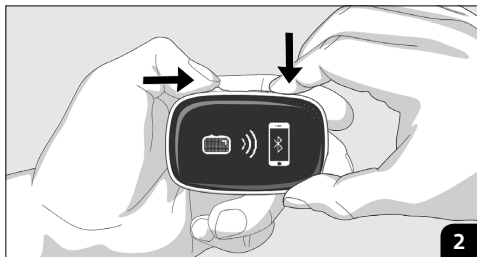
i *Don't have a smartphone? You can also create an account in the Portal to register your Sensor Device. Go to the online Portal at **eu.mynightbalance.com** and follow the instructions on the Portal.*

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 (Europe).
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.



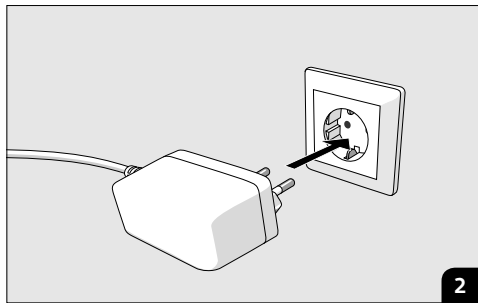
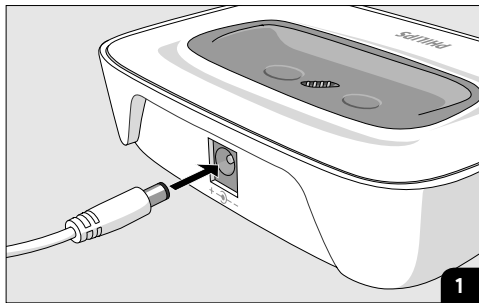
Step 3: Login and pair your Sensor Device

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.
- i** *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.
2. Connect the Power Adapter into a standard wall outlet (100-240V AC).

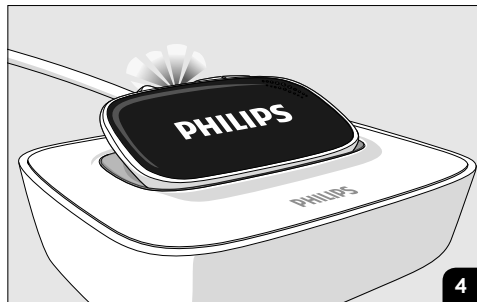
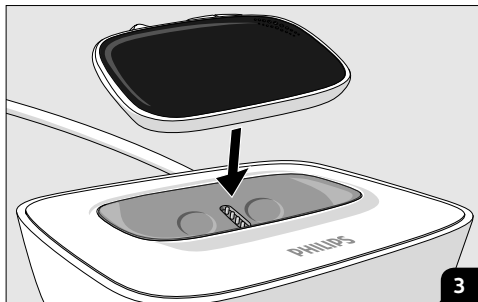


3. Place the Sensor Device on the Docking Station with the buttons on top and display towards you.

i *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

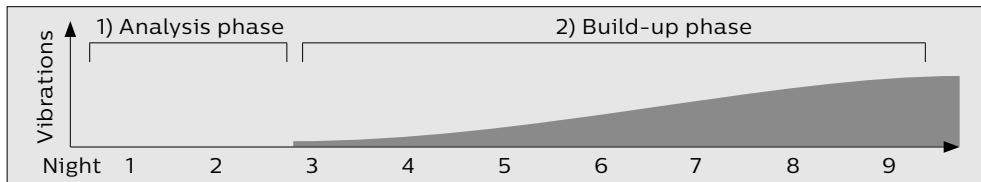
No vibrations are given during the first two nights of the therapy. NightBalance gathers baseline data on your sleep patterns during night 1 and 2. This data is used to tailor the therapy to your

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.

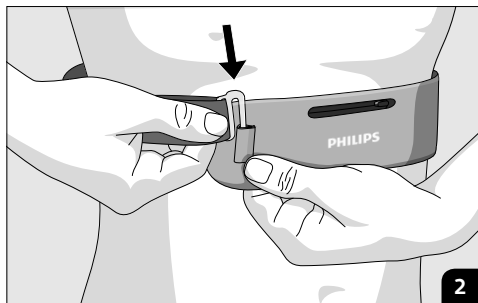
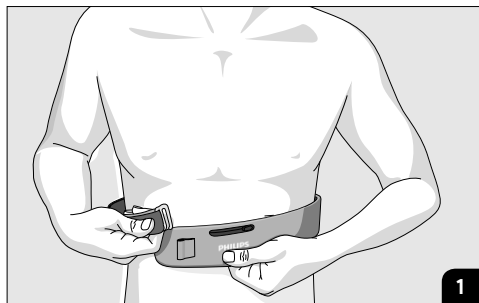


How to use NightBalance daily

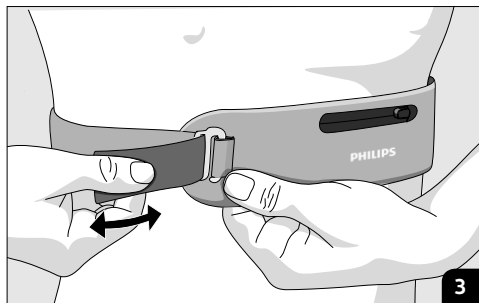
Step 1: Placing the Chest Strap

1. Wrap the Chest Strap around your chest
2. Hook the buckle through the opening

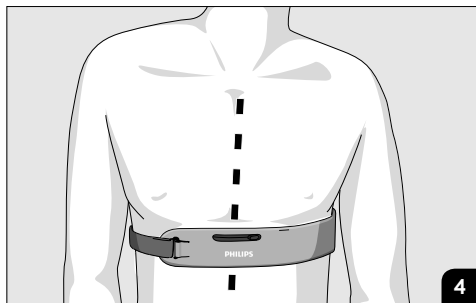
i In case the Chest Strap is too short, adjust the tightness (see next page).



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.

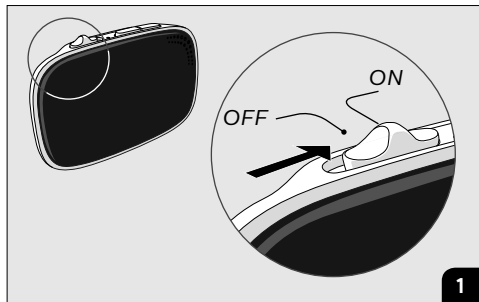


4. Make sure the Device pocket is placed in the middle of your chest.



Step 2: Placing the Sensor Device

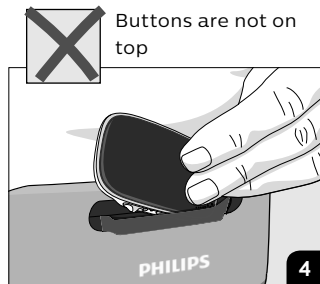
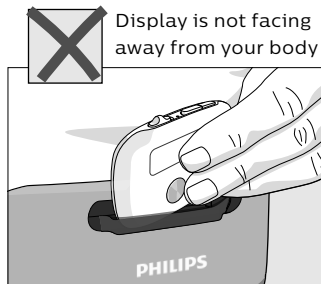
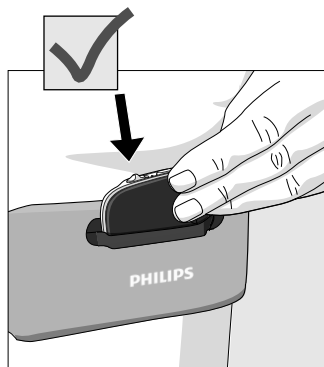
1. Power on the Sensor Device by sliding the ON/OFF switch to the ON position.
2. Confirm that the white LED light on the Sensor Device starts blinking. This indicates it is switched on.



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.

Now you can go to sleep.



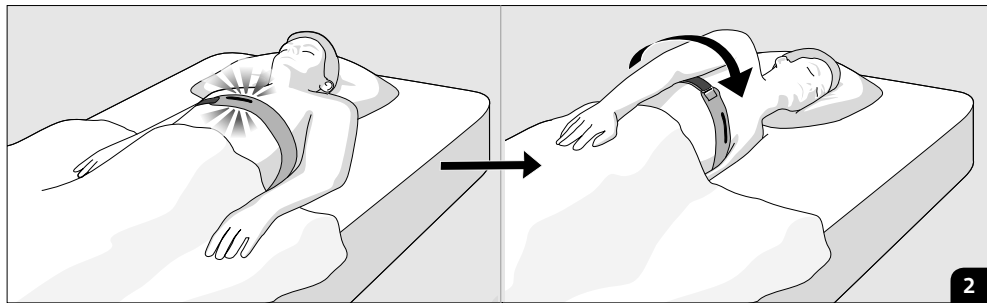
Step 3: Sleeping with the Sensor Device

1. Fall asleep in any position you desire.

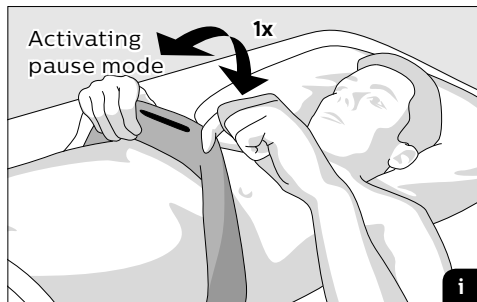
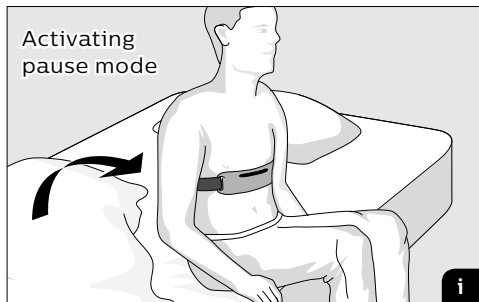
i *NightBalance allows you to fall asleep in any position. 15 minutes after switching the Sensor Device ON, the therapy starts.*

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

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

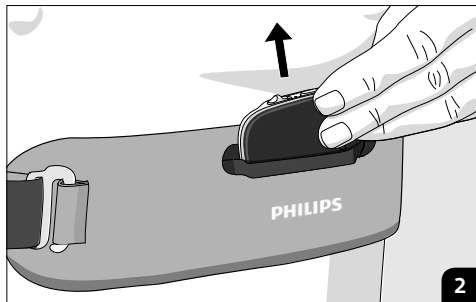
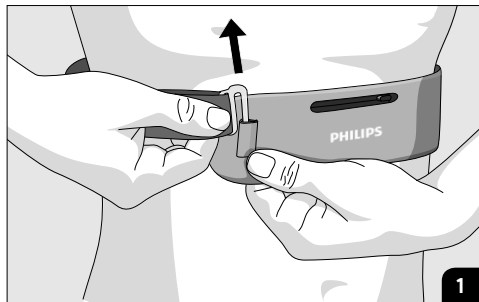


- i** **Tip: Activating Pause Mode**
Pause mode can be activated if you get up during the night, or if you turn the Device pocket of the Chest Strap vertical for a second. In pause mode, the Sensor Device will not give vibrations for 5 minutes.

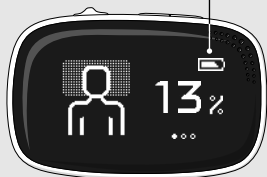


Step 4: Removing the Sensor Device

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.
- i** Sleep data from short naps (<2 hours) is excluded from any data calculations.



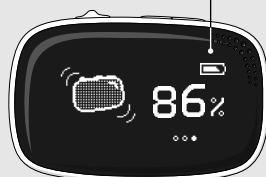
Battery level



Percentage of time
you slept on your back
last night

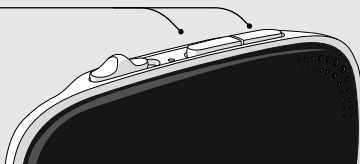


Total time you used the
Sensor Device the night
before



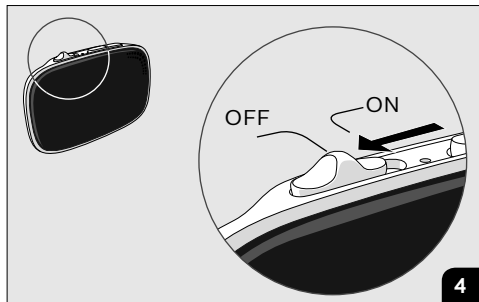
Your daily response to
the vibrations of the
Sensor Device

i *Press the navigation buttons on top
of the Sensor Device to switch from
one screen to the next.*

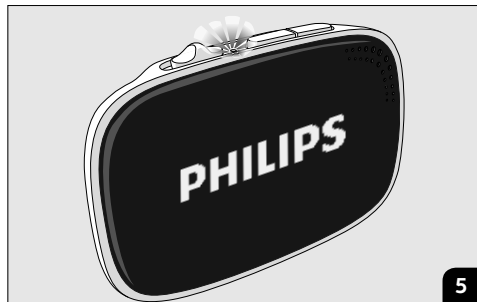


3

4. Power off the Sensor Device by sliding the ON/OFF switch to the OFF position.

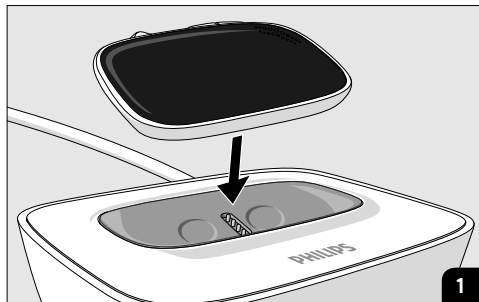


5. Confirm that the white LED light on the Sensor Device stops blinking. This indicates it is switched OFF.



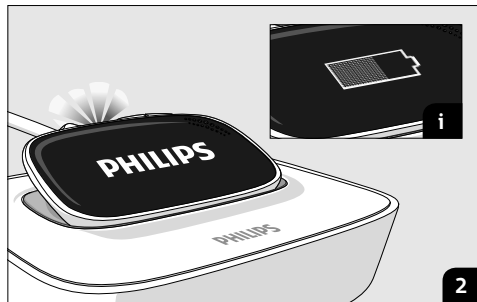
Step 5: Charging the Sensor Device

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



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

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



View therapy data

Step 1: Manually synchronizing the Sensor Device with your smartphone

- i** *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.*
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.

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



Step 2: View therapy data in the app and Portal

① 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

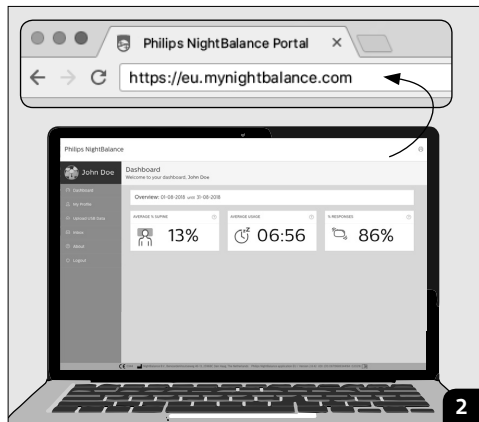
Online Portal: Last 30 days

① 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 **eu.mynightbalance.com** and login.



i *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.*

i *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.

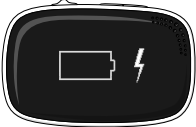

Disposal


- 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

Problem	Why it happened	What to do
<p>The Sensor Device is not turning ON, or shows the following screen:</p> 	<p>The battery is empty.</p>	<p>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.</p>
<p>The Sensor Device shows the following screen:</p> 	<p>An error occurred in the Sensor Device</p>	<p>Do not use NightBalance. Contact your distributor, or customer service (see page 43), and mention the error number that your Sensor Device shows.</p>

Problem	Why it happened	What to do
<p>I cannot pair the Sensor Device with the Philips NightBalance app and the Sensor Device shows the following screen:</p> 	<p>Bluetooth on your smartphone is switched OFF</p>	<p>Enable Bluetooth on your smartphone.</p>
	<p>The Philips NightBalance app is not ready to pair.</p>	<p>Follow the instructions in the app. Initiate pairing on the Sensor Device only if the app indicates to do so. See page 12.</p>
	<p>The smartphone and Sensor Device are not within reach.</p>	<p>Keep the smartphone and Sensor Device within reach (1m) of each other</p>

Problem	Why it happened	What to do
My sleep data is not visible in the Philips NightBalance app or Portal.	The Sensor Device has not yet synchronized with the Philips NightBalance app.	Synchronize the Sensor Device with your smartphone. Follow the instructions on page 26.
	The Portal does not show data from the Analysis Phase (day 1-2 of therapy).	Sleep for a few days with the Sensor Device, synchronize the sleep data (see pages 26-27) and come back to the Portal.
	Short naps (<2 hours) are excluded from any data calculations	Sleep for a full night (>2 hours) with the Sensor Device and synchronize the Sensor Device with your smartphone.

Technical specifications

Sensor Device	
Dimensions:	6.9 x 4.5 x 1.4 cm (2.7 x 1.8 x 0.6 inch)
Weight:	30 gr (1.1 oz)
Power Source:	Lithium polymer, 3.7V, 165mA
Material:	ABS, PMMA
In-use life:	3 years
Internal clock battery:	MS621FE (lifetime: 3 years)
Frequency characteristics:	Bluetooth: version 4.2, 5.0 Band support: 2.4GHz Effective radiated power: +6 dBm

Docking Station	
Dimensions:	10.2 x 8.3 x 3.2 cm (4.0 x 3.3 x 1.3 inch)
Weight:	85 gr (3.0 oz)
Material:	ABS, PC
In-use life:	3 years
Power Adapter:	Power Source: 100-240V AC, 50/60 Hz Output: 5V, 2000 mA, 10W








Travel Case	
Accessory of NightBalance	
Dimensions:	20.0 x 17.0 x 6.8 cm (7.9 x 6.7 x 2.7 inch)
Weight:	250 gr (8.8 oz)
Material:	Nylon, Polyester, EVA
In-use life:	3 years








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








Model references		
System	Model	Device Identifier
NightBalance	US	L2US01US
	NL	L2EU01NL
	FR	L2EU01FR
	DE	L2EU01DE
	UK	L2EU01UK

- i** *IEC 60601-1 Classifications: This device is Class II Equipment, 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*
- i** *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°.*




Symbols




	CE mark
	Type BF medical equipment
	Caution
	General warning sign
IP22	Ingress protection
+  -	Polarity
	Direct Current
	Consult Instructions for Use

	Refer to instruction manual/booklet
	Waste Electrical and Electronical Equipment
	Do not bleach
	Do not iron
	Do not dry clean
	Do not tumble dry
	Machine wash, 30°C (86°F)

	Prescription
	Manufacturer
	Serial Number
	Batch code
	Reference code
	Keep dry
	Non-ionizing electromagnetic radiation

Environmental conditions

Storage conditions	
 -25°C 70°C	NightBalance components can be safely stored at temperatures between -25°C (-13°F) and 70°C (158°F), a relative humidity up to 90%, and an atmospheric pressure between 700 and 1060 hPa.
 0% 90%	
 700hPa 1060hPa	

Operating conditions	
 -5°C 40°C	NightBalance components can be safely used at temperatures between -5°C (23°F) and 40°C (104°F), a relative humidity between 15% and 90%, and an atmospheric pressure between 700 and 1060 hPa.
 15% 90%	
 700hPa 1060hPa	

i The device is ready for use when within the operating conditions.

Regulatory information

Data privacy & security

NightBalance 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.

NightBalance 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 30 cm (12 inches) 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

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	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.
RF Emissions CISPR 11	Class B	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.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC61000-3-3	Complies	

Electromagnetic immunity

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 %. ESD may cause the Docking Station to stop functioning, upon which it will automatically reboot, indicated by the LED switching off momentarily (5-10 seconds).
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line(s) to line(s)	±0.5 kV, ±1 kV line(s) to line(s)	

<p>Voltage dips, short interruptions and voltage variations on power supply IEC61000-4-11</p>	<p><5 % U_T (>95 % dip in U_T) for 0,5 cycle</p> <p>40 % U_T (60 % dip in U_T) for 5 cycles</p> <p>70 % U_T (30 % dip in U_T) for 25 cycles</p> <p><5 % U_T (>95 % dip in U_T) for 5 s</p>	<p><5 % U_T (>95 % dip in U_T) for 0,5 cycle</p> <p>40 % U_T (60 % dip in U_T) for 5 cycles</p> <p>70 % U_T (30 % dip in U_T) for 25 cycles</p> <p><5 % U_T (>95 % dip in U_T) for 5 s</p>	
<p>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</p>	<p>30 A/m</p>	<p>30 A/m</p>	
<p>NOTE: U_T is the a.c. mains voltage prior to application of the test level.</p>			

Warranty

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.

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

Manufactured by NightBalance B.V.

*Benoordenhoutseweg 46-13
2596 BC, The Hague
The Netherlands*

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

Visit **www.mynightbalance.com/support** for product updates on NightBalance.

- ① *Store NightBalance components inside the Travel Case when sending it for repairs or returns.*



Directive 93/42/EEC
Concerning medical devices

Instructions for use for NightBalance sleep position therapy
Document number: DOC-1060 rev1.0 (EU English)
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