PHILIPS

NightBalance

Sleep position therapy

Instructions for use

Content

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. When sleep apnea occurs mainly when people sleep on their back (supine position), it is called positional obstructive sleep apnea.

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 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. The device is to be used only on the instruction of a licensed 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 ≤ AHI ≤ 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 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.

NOTE

- Do not exchange NightBalance with someone else. Use NightBalance only for your own therapy.
- Note all warnings and cautions throughout these Instructions for Use and on labels on the components.

Warnings & Cautions

⚠ Warnings

- NightBalance is only to be used for the purpose as specified in the 'Intended Use'.
- 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.
- Always CONSULT your physician if you are using another electronic medical device (e.g. pacemaker) prior to using NightBalance. NightBalance vibrations may interfere with the operation of another electronic 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 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.

⚠ Cautions

- USE, and CHARGE NightBalance in temperatures between 10ºC and 40ºC (50ºF and 104ºF). STORE NightBalance in temperatures between -20ºC and 45ºC (-4ºF and 113ºF).
- 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 33 and 34) has passed. After the service life has passed, performance of sensors and electronics can degrade.
- DO NOT attach other accessories or components than specified in these instructions to NightBalance components. This may damage the device. Respironics cannot ensure continued safe use of a damaged device.
- 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.

NOTE

Any serious incident that has occurred in relation to this device should be reported to Philips and the competent authority of the Member State in which the user and/or patient is established.

NOTE

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.

Getting Started

Step 1: Check packaging contents

Upon receiving, make sure your packaging contains:

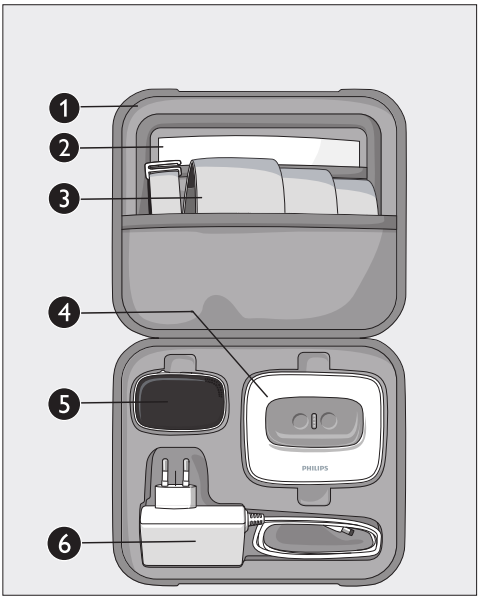
1. Travel case
2. Instructions for Use
3. Chest Strap
4. Docking Station
5. Sensor Device
6. Power Adapter

⚠ WARNING

Upon receipt, if any of these items are missing or damaged, contact your distributor or customer service (see page 43).

NOTE

The Power Adapter as visualized here is an example only, yours might look different.



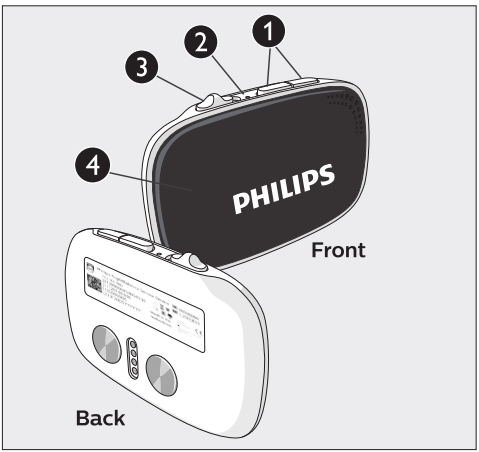
NightBalance Components

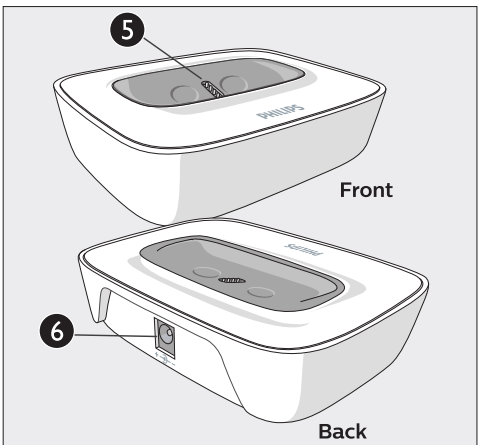
Sensor Device

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

Docking Station

5. Contact pins
6. Power port

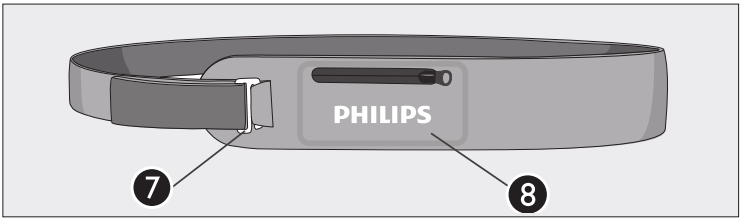




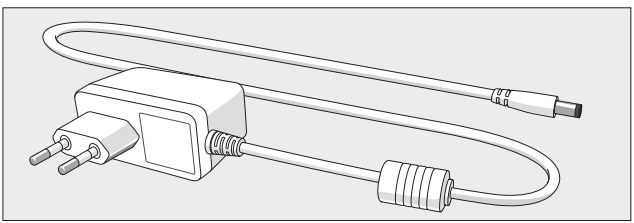
Chest Strap

7 Buckle

8 Device pocket



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



NOTE

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

Step 2: Install the App and Register

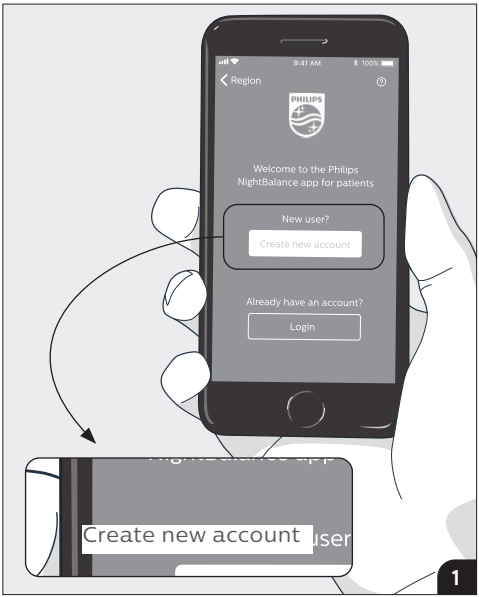
1. Download the Philips NightBalance app on your smartphone from the Play Store (for Android) or App Store (for iPhone).

2. Open the Philips NightBalance app. Select and confirm your region (Country of residence).

NOTE

It is important to select your region of residence so that the data can upload to the correct region.
App images displayed here may vary per version

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.



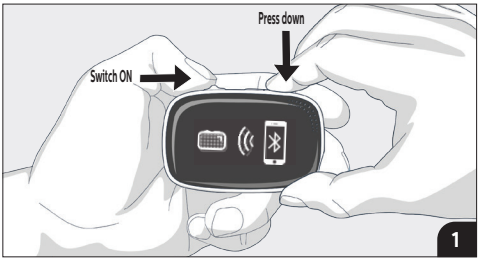
Step 3: Login and Pair your Sensor Device

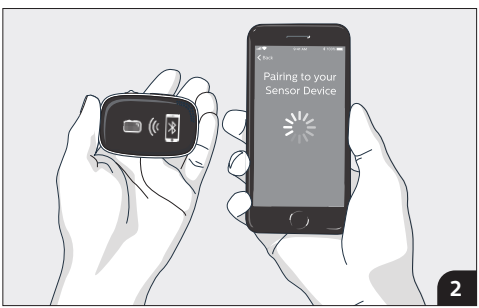
1. Login to the Philips NightBalance app after activating your account. Follow the instructions in the app to complete your account.

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

NOTE

Pairing ensures a secure connection between your Sensor Device and your smartphone and is to be performed once. Therefore, only activate the pairing mode of the Sensor Device on first use. For daily synchronization of your therapy data, see page 27.





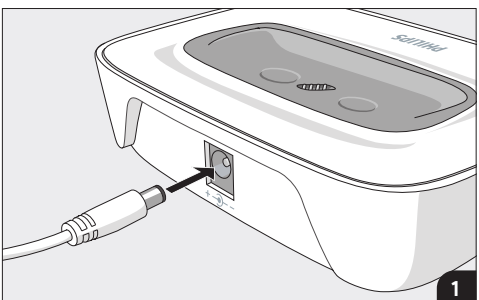
Step 4: Setting up the Docking Station

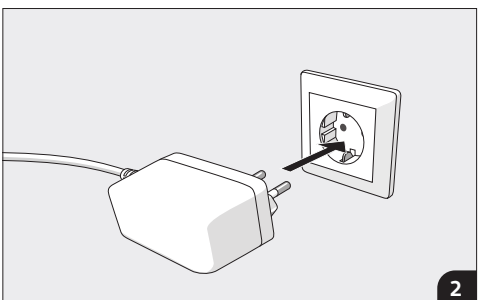
1. Insert the Power Adapter cable completely into the back of the Docking Station.

   ⚠ **CAUTION**
   Only use the Power Adapter provided with NightBalance (100-240 V, 50-60 Hz).

   ⚠ **CAUTION**
   Do NOT position the Docking Station in such a way that it is difficult to reach the power adapter.

2. Connect the Power Adapter into a standard wall outlet.

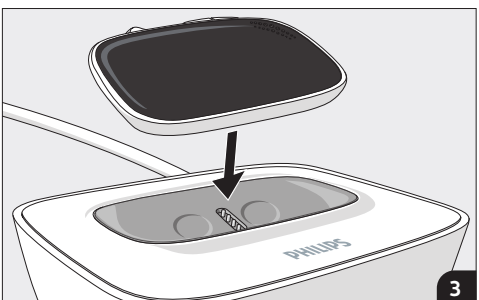




3. Place the Sensor Device on the Docking Station with the buttons on top and display towards you.
   Once on the Docking Station, the Sensor Device charges automatically.

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

The setup process is now complete. Please ensure your device is charged before using.



Getting to sleep

Step 1: Placing the Chest Strap

1. Wrap the Chest Strap around your chest.

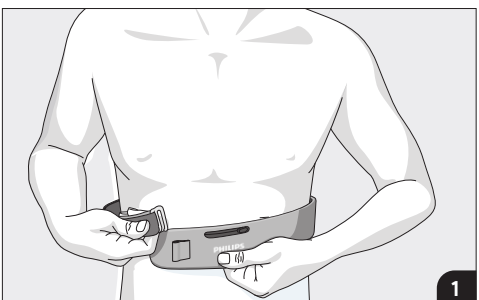
NOTE

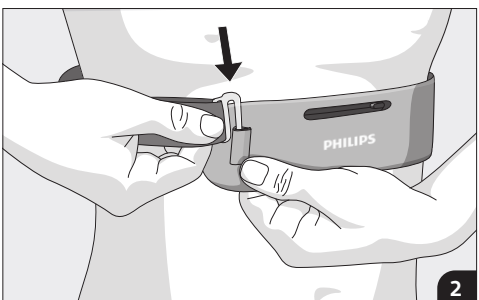
- If the Chest Strap is too loose, the sensor may stop collecting data and providing appropriate therapy.
- In case the Chest Strap is too loose, adjust the tightness (see next page).

⚠ CAUTION

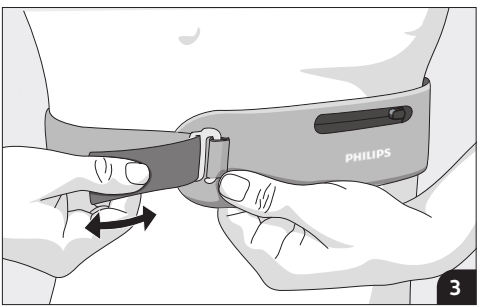
DO NOT place the Chest Strap on damaged skin.

2. Hook the buckle through the opening.

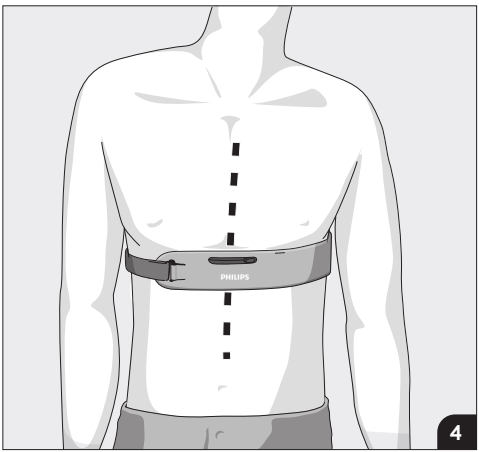




3. Adjust the tightness if needed by adjusting the hook and loop position of the Chest Strap. The Chest Strap should fit tight enough to stay in place and feel comfortable to wear at the same time.



4. Make sure the Device pocket is placed in the middle of your chest as shown in the image below.



Step 2: Placing the Sensor Device

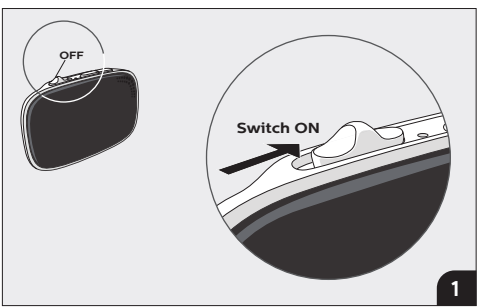
1. Power on the Sensor Device by sliding the ON/OFF switch to the ON position.

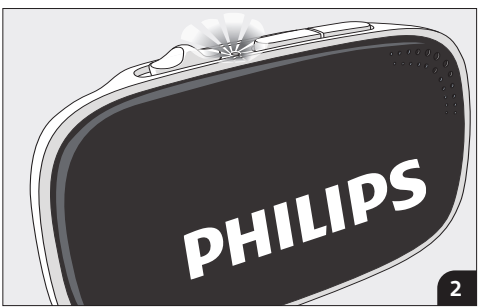
NOTE

Ensure the Sensor Device is charged before using it during sleep.

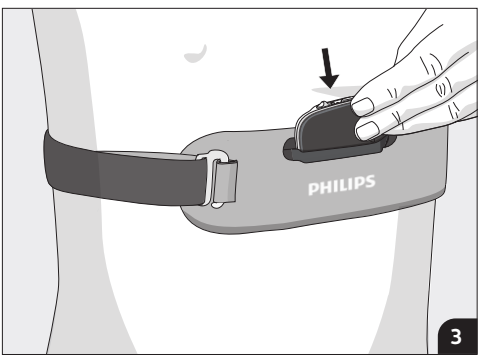
2. Confirm that the white LED light on the Sensor Device starts blinking. This indicates it is switched on.

   If the white LED light does not start blinking, it may mean the battery is depleted. See the troubleshooting section.





3. Place the Sensor Device into the Device pocket of the Chest Strap with the Sensor Device buttons on top and the display facing away from your body.



4. Close the zipper of the pocket of the Chest Strap.

5. Check that the Device pocket is placed on the middle of your chest.

Now you can go to sleep.

Understanding the Adaptation Period

If this is your first time using your NightBalance device, you will start your therapy with a 10 day adaptation program. 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

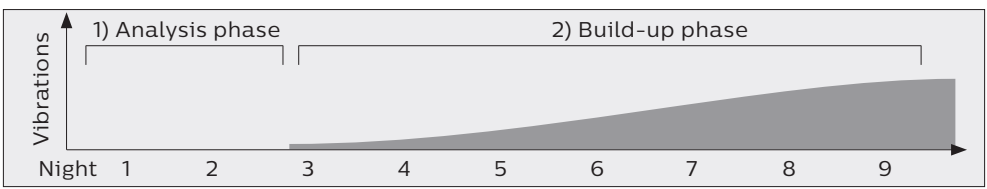
No vibrations are given during the first two nights of the therapy. NightBalance gathers baseline data on your sleep patterns during night 1 and 2. This data is used to tailor the therapy to your individual sleeping behavior later on.

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.

NOTE

The recommendation is to use NightBalance every night, or as agreed with your physician for best therapy results.



Step 3: Sleeping with the Sensor Device

1. Now that you understand how the adaptation program works, you can fall asleep in any position you desire.

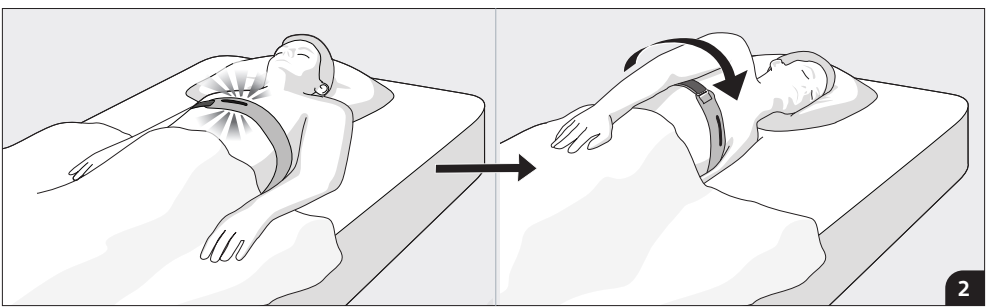
NOTE

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.

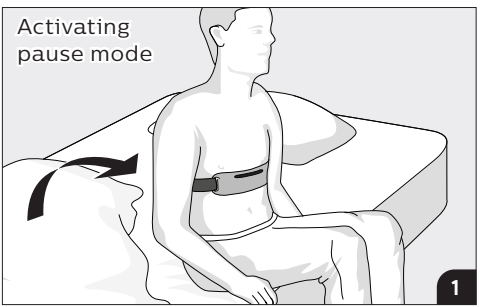
NOTE

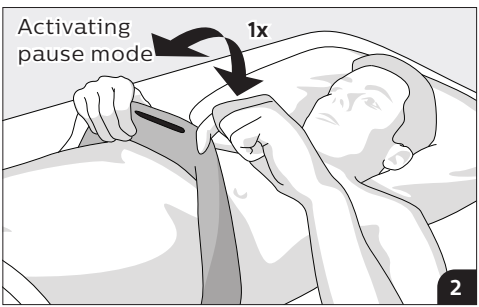
- NightBalance regulates the intensity of the vibrations based on your sleeping behavior.
- The Sensor Device will not vibrate during the first two nights of the adaptation program. See page 18.



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 ❶, or if you turn the Device pocket of the Chest Strap vertical for a second ❷.





Step 4: Removing the Sensor Device

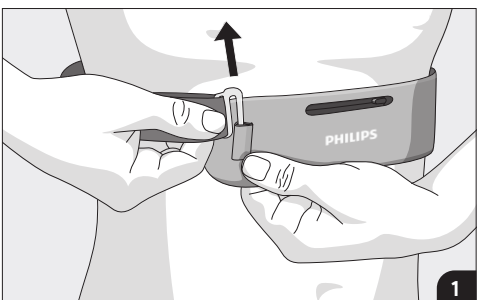
1. Use the buckle to remove the Chest Strap.

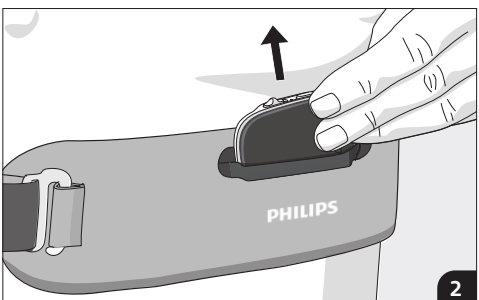
2. Take the Sensor Device out of the Chest Strap.

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

NOTE

Sleep data from short naps (<2 hours) is excluded from any data calculations and visualizations.



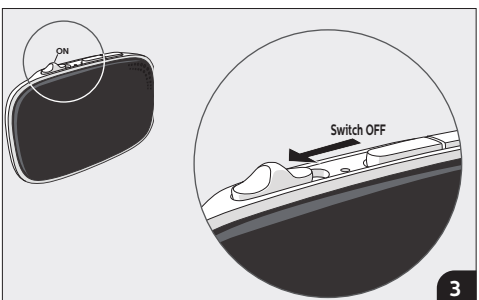


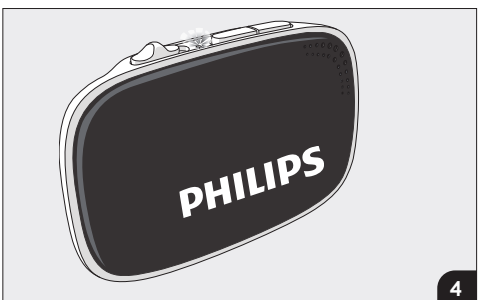
4. Power off the Sensor Device by sliding the ON/OFF switch to the OFF position.

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

NOTE

It might take some time before the LED is switched OFF in case the Sensor Device is transmitting data.



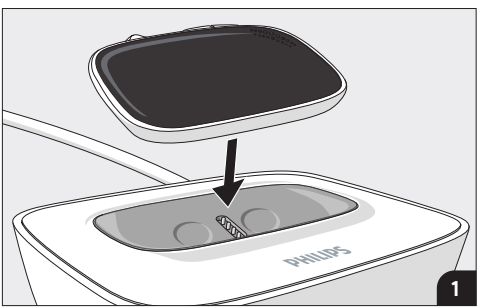


Step 5: Charging the Sensor Device

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

NOTE

In order to stop charging the Sensor Device, remove it from the Docking Station to disconnect the power.



WARNING

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

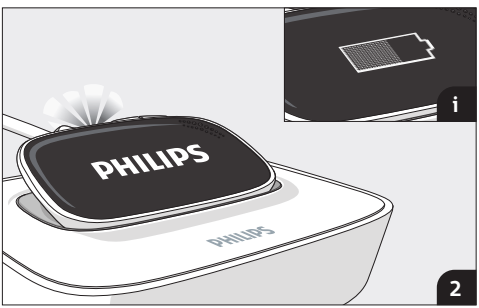
NOTE

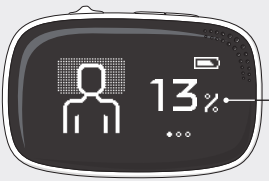
To disconnect power from the Docking Station, unplug the power adapter cable from the back of the Docking Station.

2. Upon correct placement onto the Docking Station, the Sensor Device display becomes active and the LED starts to blink.

NOTE

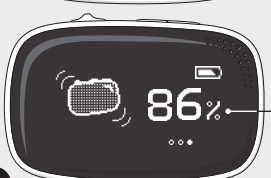
When the Sensor Device first begins to charge, the display shows a battery icon and the white LED blinks. After some time, the icon will disappear and the white LED blinking will stop.





Percentage of time you slept on your back last session

Total time you used the Sensor Device the session before



Your daily response to the vibrations of the Sensor Device

Battery level

NOTE

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

3

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. New data will only appear in the app after synchronization.

Synchronization of therapy data with your smartphone will take place automatically if the Philips NightBalance app is opened on your phone and you turn the Sensor Device ON or OFF during daily use. If the app is not opened, synchronization will not occur automatically. For synchronization progress and information, see the Philips NightBalance app.

NOTE

- *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.*

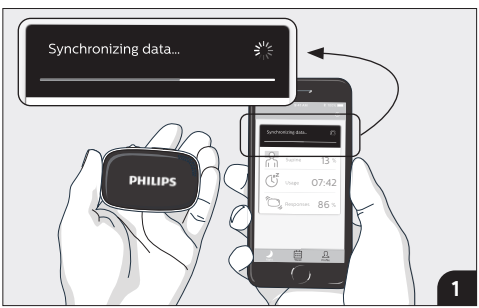
Step 1: Manually synchronizing the Sensor Device with your smartphone

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.

NOTE

The Philips NightBalance app indicates when the last successful data transfer took place. Go to 'Profile', and click 'Sensor Device'.

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



Step 2: View therapy data in the app

Viewing therapy data is possible on the Sensor Device and via a smartphone with the Philips NightBalance app. The following data views are available:

Sensor Device:	Last session
Smartphone:	Last session and last 7 days

NOTE

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

1. After synchronizing your therapy data with your smartphone, you can view your therapy data in the 'Night view' and 'Week view' tabs.

Tip: Discuss therapy progress with your physician if desired. Your physician can review your data if you grant them access.

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 23 on instructions for charging.

Caring for your Chest Strap, Sensor Device and Docking Station

- Wipe the Chest Strap and extension piece on a regular basis (e.g. weekly) or when visibly soiled with a clean cloth dampened in a mild detergent solution. Allow to air dry, do not dry in a clothes dryer. Ensure strap is completely dry before use.

⚠ CAUTION

- DO NOT use chlorine bleach or fabric softener.
- 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. Turn the Sensor Device off and unplug the power adapter from the Docking Station and wall outlet. Wipe the Sensor Device and Docking Station with a clean cloth dampened with a mild detergent if they are visibly dirty. Ensure that moisture does not penetrate the openings. Ensure that the Sensor Device and Docking Station are completely dry before connecting to power or using.

⚠ CAUTION

DO NOT use bleach or other aggressive cleaning solutions.

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.

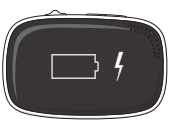
Disposal

- Dispose of this device in accordance with local collections and recycling regulations. For more information, visit www.philips.com/recycling.
- This device contains a lithium ion battery that cannot be recycled. Please contact customer service at 1-724-387-4000 or send an e-mail to service@respironics.com for safe disposal instructions of this part.
- Please note that the Sensor Device can contain data that has not been transferred by synchronizing with your smartphone. This data is encrypted.

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 NightBalance components with a new component.

Troubleshooting

Problem	Why it happened	What to do
I cannot pair the Sensor Device with the Philips NightBalance app and the Sensor Device shows the following screen: 	Bluetooth on your smartphone is switched OFF	Enable Bluetooth on your smartphone.
	The Philips NightBalance app is not ready to pair.	Follow the instructions in the app. Initiate pairing on the Sensor Device only if the app indicates to do so. See page 11.
	The smartphone and Sensor Device are not within reach.	Keep the smartphone and Sensor Device within reach (1m) of eachother
The Sensor Device is not turning ON, or shows the following screen: 	The battery is empty.	Place the Sensor Device on the powered Docking Station. After a few hours, the Sensor Device should be fully charged. See page 23, 24 and 25.

Problem	Why it happened	What to do
The Sensor Device shows the following screen: 	An error occured in the Sensor Device	Do not use NightBalance. Contact your distributor, or customer service (see page 43), and mention the error number that your Sensor Device shows.
My sleep data is not visible in the Philips NightBalance app.	The Sensor Device has not yet synchronized with the Philips NightBalance app.	Synchronize the Sensor Device with your smartphone. Follow the instructions on page 27.
	The app 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 27-28) and come back to the app.
	Short naps (<2 hours) are excluded from any data calculations and visualizations.	Sleep for a full night (>2 hours) with the Sensor Device and synchronize the Sensor Device with your smartphone.

Problem	Why it happened	What to do
My sleep data is not visible in the Philips NightBalance app.	You used the device prior to pairing it with the app.	Only data recorded after pairing will appear. Ensure that you have paired 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, 165mAh
Material:	ABS, PMMA
In-use life:	3 years
Internal clock battery:	Battery: Lithium-Ion Polymer Rechargeable Coin Cell: Lithium Rechargeable 3.0V, 5.5mAh
Frequency characteristics:	Bluetooth: version 4.2, 5.0 Band support: 2.4GHz Effective radiated power: +6 dBm
Bluetooth encryption	AES-CCM encrypted channel

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:	Input: 100-240V AC, 50-60 Hz, 0.27-0.15A Output: 5.0V DC, 2.0A, 10W MAX

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

- *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.*

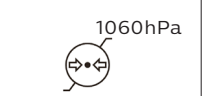
- *The Sensor Device is IP22 rated for normal use (when placed in the Chest Strap). This means that the device is protected against solid foreign objects of 12,5 mm diameter and greater, and against vertically falling water drops when enclosure tilted up to 15°.*

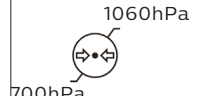
- *The Docking Station is IP21 rated for normal use. This means that the device is protected against solid foreign objects of 12,5 mm diameter and greater, and against vertically falling water drops.*

Symbols

	Warning/Caution	IP21/IP22	Ingress protection (see pg 35 for details)		Class II equipment		Importer – Indicates the entity importing the medical device into the locale.
	Note		Direct Current		Non-ionizing electromagnetic radiation	MD	Medical Device – Indicates that the item is a medical device.
	Tip		Polarity				
	Consult Instructions for Use		Machine wash, 86°F (30°C)		Manufacturer		
 www.achilles.com/IFU	Electronic instructions for use Indicates that relevant information for use of the product is available in electronic form.		Do not bleach	EC REP	Authorized rep in the European Community	SN	Serial Number
			Do not iron			CC	Country of Manufacture – Indicates the country of manufacture of the product. Note: When applied to the label, "CC" is replaced by the country code.
			Do not dry clean		Keep dry		
	Type BF medical equipment		Do not tumble dry	LOT	Batch code		
	Separate collection for electrical and electronic equipment per EC Directive 2012/19/EU.	UDI	Unique Device Identifier – Indicates the Unique Device Identifier information.		Packaging unit – Indicates the number of pieces in the package.		

Environmental Conditions

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

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

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

Regulatory Information

Hereby, Respironics, Inc. declares that the radio equipment type Class 1 Bluetooth 5.0 low energy device is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: http://incenter.medical.philips.com/PMSPublic

Data privacy & security

Respironics offers its patients the use of a 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.

NOTE *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**
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
	Electromagnetic Environment - Guidance Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.	
Radiated RF Electromagnetic Field (IEC 61000-4-3)	10 V/m 80 MHz to 2.7GHz	10 V/m
Proximity fields from RF wireless communication systems (IEC 61000-4-3)	Refer to page 42	Refer to page 42
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)
RF Common mode/Conducted usceptibility (IEC 61000-4-6)	3 Vrms, 6V in amateur radio bands. 150 kHz to 80 MHz	3 Vrms, 6V in amateur radio bands.
Power frequency (50-60 Hz) magnetic field (IEC 61000-4-8)	30 A/m	30 A/m
Voltage dips (IEC 61000-4-11)	0% U_T; 1 cycle and 70% U_T; 25/30 cycles. Single phase: at 0°. 0% U_T; 0.5 cycle 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; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
Voltage interruptions (IEC 61000-4-11)	0% U_T; 250/300 cycle	0% U_T; 250/300 cycle
NOTE: U_T is the a.c. mains voltage prior to application of the test level.		

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

Contact

1001 Murry Ridge Lane
Murrysville, PA 15668-
8550
USA

Deutschland
Gewerbestrasse 17
82211 Herrsching
Germany

Contact your local distributor for assistance and support or visit
https://www.philips.com/c-cs/support-country-selector.html

NOTE

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

Accessories

The following accessories are available for use with this device. Contact Philips or your healthcare provider for additional information.

Part Number	Description
RPL2CHST01	NightBalance Chest Strap
RPL2TRCA01	NightBalance Travel Case

Limited Warranty

Respironics, Inc., a Philips company (“Philips Respironics”) provides this non-transferable, limited warranty for NightBalance Sensor Device (including the Sensor Device batteries) and Docking Station (“Product”) to the customer who originally purchased the Product directly from Philips Respironics.

What this Warranty Covers: Philips Respironics warrants each new Product will be free from defects in materials and workmanship and will perform in accordance with the Product specifications under normal and proper use and maintenance in accordance with applicable instructions, subject to the exclusions below.

How Long does this Warranty Last: Two years for the Sensor Device, batteries, and Docking Station and 90 days for the chest strap, all from the longer of the date of shipment to the purchaser or date of setup by purchaser for the end user.

What this Warranty does not cover: This warranty does not apply to any software included with the Product as the software warranty is included in the software license. This warranty does not cover damage or injury whether to the Products, personal property, or persons caused by accident, misuse, abuse, Acts of God, water ingress, repair or alteration by anyone other than Philips Respironics or its authorized service center, failure to operate in accordance with the terms of the operating manual and instructions, lack of reasonable care, the discontinuance of a network (e.g. 2G, 3G, etc.) by a carrier (e.g. ATT, Verizon, etc., or other defects not related to material or workmanship. This warranty is not transferable. If Philips Respironics finds that a Product returned for service or the issue raised is not covered under this limited warranty, Philips Respironics may charge an evaluation fee and return shipping.

What Philips Respironics will do: If a Product does not meet the warranty above in the first 90

days after the original shipment date, Philips Respironics will replace the device with a new Product. Thereafter, if a Product fails to conform to the warranties set forth above during the applicable warranty period, Philips Respironics will repair or replace the Product or refund the original purchase price, in Philips Respironics sole discretion. Philips Respironics may use new or remanufactured assemblies, components, and parts in repair and new or recertified refurbished devices for replacement. The balance of the original warranty period will apply to any Product or component of a Product repaired or replaced under this warranty.

Warranty Disclaimer; Limitation of Liability: EXCEPT AS SET FORTH IN THIS LIMITED WARRANTY, PHILIPS RESPIRONICS MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, STATUTORY OR OTHERWISE, REGARDING THE PRODUCT OR ITS QUALITY OR PERFORMANCE. PHILIPS RESPIRONICS SPECIFICALLY DISCLAIMS THE IMPLIED WARRANTY OF MERCHANTABILITY AND THE IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL PHILIPS RESPIRONICS MAXIMUM LIABILITY UNDER THESE WARRANTIES EXCEED THE ORIGINAL PURCHASE PRICE OR WILL PHILIPS RESPIRONICS BE LIABLE FOR ANY ECONOMIC LOSS, LOSS OF PROFITS, OVERHEAD, OR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES. Repair, replacement, or return of purchase price by Philips Respironics is the original purchaser's sole and exclusive remedy under this warranty.

This warranty gives you specific legal rights, and you may also have other rights that vary from state to state. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above exclusion and limitations may not apply to you.

How to get warranty support: Patients contact your local authorized Philips Respironics dealer and dealers contact Respironics, Inc. at:

1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668-8550
+1-724-387-4000

Deutschland
Gewerbestrasse 17
82211 Herrsching, Germany
+49 8152 93060

Note: For Australian and New Zealand customers this warranty replaces the warranty contained above.

1. Respironics, Inc., a Philips company ("Philips Respironics"), warrants that the Products shall be free from defects of workmanship and materials and will perform in accordance with the Product specifications. 2. This warranty is valid for a period of two years for the Sensor Devices, batteries, and Docking Station and 90 days for the chest strap, all from the date of purchase from an authorized Philips Respironics dealer. 3 If the Product is found to contain a defect of workmanship or materials or fails to perform in accordance with the Product specifications during the applicable warranty period, Philips Respironics will repair or replace, at its option, the defective material or part. 4. The customer is responsible for returning the product to an authorised Philips Respironics dealer, and collecting the product from the authorised Philips Respironics dealer after repair or replacement, at its own cost. Philips Respironics is responsible only for the freight cost of transporting the product between the authorised Philips Respironics dealer and Philips Respironics. Philips Respironics reserves the right to charge an evaluation and postage fee for any returned Product where no problem is found following investigation. 5. This warranty does not cover:

- products purchased outside of Australia or New Zealand;
- damage caused by accident, misuse, abuse, alteration, pest infestation, liquid ingress, and other defects not related to materials or workmanship.

6. The warranty provided by Philips Respironics herein is not transferrable by the Buyer in the event of any sale or transfer of Products purchased by the Buyer from an authorized Philips Respironics dealer. 7. To exercise your rights under this warranty, contact your local authorised Philips Respironics dealer. A list of all authorised dealers is available at the following link: http://www.philips.com.au/healthcare.

Alternatively, you can make a claim under this warranty by contacting Philips Respironics directly at: Philips Electronics Australia Limited, 65 Epping Road, North Ryde NSW 2113, Australia. Tel: 1300 766 488, Email: repairs-src@philips-easyconnect.com. 8. The following statement is provided to a Buyer who is a “consumer” under the Australian Consumer Law: Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and for compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the good repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure. 9. The following statement is provided to a Buyer who is a “consumer” under the Consumer Guarantees Act 1993, New Zealand: Our goods come with guarantees that cannot be excluded under the Consumer Guarantees Act 1993. This guarantee applies in addition to the conditions and guarantees implied by that legislation.

AUSTRALIAN SPONSOR DETAILS:
Philips Electronics Australia Ltd.
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Australia.

Respironics Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668 USA

Respironics Deutschland GmbH & Co. KG
Gewerbestrasse 17
EC REP 82211 Herrsching, Germany

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