Instruction Guide

VitaBreath

PHILIPS

Know your Device

Device Features

Ⓐ Charger Cover and Plug
Ⓑ Charge Level Indicator (Green LED)
Ⓒ On/Off Button
Ⓓ Status Indicator (White LED)
Ⓔ Mouthpiece and Cap
Ⓕ Carry Strap
Ⓖ Air Intake Cover
Ⓗ Inlet Screen

Intended Use

The Philips VitaBreath dyspnea relief device is intended as an adjunct therapy for Chronic Obstructive Pulmonary Disease (COPD) patients to provide short-term relief of shortness of breath associated with physical exertion. It is for use in the home and hospital/institutional environments.

The device is designed for use by patients under the supervision of a physician.

Note: *Use only the power supply recommended by Philips Respironics with the following VitaBreath device model numbers.*

Power Supply Recorder Numbers
REF 1121743 (Model 1122023 - Australia)
REF 1116862 (Model 1122089 - India)
REF 1121742 (Model 1116847 - United Kingdom)

ABOUT THE DEVICE

Warnings

A warning indicates the possibility of injury to the user or operator.

- This device is designed for use by patients under the supervision of a physician.
- This instruction guide serves as a reference. The instructions in this guide are not intended to supersede a health care professional's instructions regarding use of the device.
- The VitaBreath is not intended to replace bronchodilators, anti-inflammatory medicines, and/or supplemental oxygen. Follow your doctor's instructions for your currently prescribed treatment regimen while using VitaBreath.
- The operator should read and understand this entire guide before using the device.
- Never operate the device if any parts are damaged or if it is not working properly.
- Do not open or disassemble the device except as instructed by this guide. Repairs and adjustments must be performed by Philips Respironics authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly device damage.
- Do not use this device outside of the environmental conditions stated in this guide. Temperatures higher than 40˚ C (104˚ F) or lower than 0˚ C (32˚ F) could cause irritation or injury to the airway.
- If there are any unexplained changes in the performance of the device, discontinue use and contact Philips Respironics for service. Examples include, but are not limited to: unusual sounds, device is dropped, enclosure is cracked or broken, or water is spilled into the device enclosure.
- When charging the device, route the power cord from the power supply in a way that will prevent the cord from being tripped over or interfered with by chairs or other furniture.
- Periodically inspect electrical cords and cables for damage or signs of wear. Discontinue use and replace electrical cords and cables if damaged.
- To avoid electrical shock, always unplug the power supply from the wall outlet before cleaning the device.
- Do not place the device under a running faucet or submerge in liquid.
- When charging, always insure that the power supply is securely connected to both an AC outlet and the device's power inlet to prevent arcing.
- Only use the power supply recommended by Philips Respironics with this device. Use of a power supply not supplied by Philips Respironics may cause overheating or damage to the device.
- A properly installed, undamaged Inlet Screen and Mouthpiece are required for proper operation. Wash prior to use and periodically as instructed by this guide and replace when damaged for proper operation. Allow cleaned parts to dry completely before using.
- Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
- Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this guide.
- Medical Electrical Equipment may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.
- The use of a power supply or accessory other than those specified may result in increased emissions or decreased immunity of the Medical Electrical Equipment.
- This product contains a lithium ion battery. It is important to dispose of this device in a safe manner in accordance with local regulations.
- This device has not been tested for use on airplanes.
- Do not use the device in the presence of a flammable anaesthetic mixture in combination with oxygen or air, or in the presence of nitrous oxide.
- It can be unsafe to use accessories, detachable parts or other materials with this device that are not described in the instructions for use or are approved by Philips Respironics.
- This device is designed for non-continuous use only and should only be operated for less than 10 minutes at a time. After such time, the device should be turned off for at least 30 minutes. If it is necessary to use the device longer than 10 minutes, consult with a physician.

WARNINGS

Cautions

A caution indicates the possibility of damage to the device.

- When charging or not using the device, place it on a firm, flat surface to prevent damage. Do not place the device in a location where it can be accidentally dropped from an elevated position such as the edge of a table or countertop.
- Do not store this device outside of the environmental storage specifications stated in this guide.
- Moisture and condensation may damage the device. If this device has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature (operating temperature) before starting. Do not operate the device outside of the operating temperature range shown in the specifications section.
- Do not use extension cords with this device.
- Do not place the device directly onto carpet, fabric, or other flammable materials.
- When removing the Inlet Screen for cleaning, do not insert anything into the interior of the device.

Contraindications

If the patient has had any of the following conditions, consult their health care professional before using the device.

- Recent pneumothorax
- Recent barotrauma to the chest region

Charging the Device

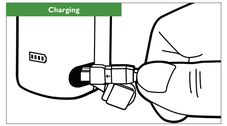
Read and understand this Instruction Guide before using the device for the first time.

Charge the device battery before use.

- The Charge Level Indicator will cycle green LEDs while charging.
- Solid green bars are displayed when completely charged.
- The number of solid green bars will decrease as the battery charge is depleted.

Note: *Device functionality is disabled while charging.*

Note: *The device will turn off 30 seconds after the battery is fully charged. The Charge Level Indicator will not stay lit after the charging is completed.*



When the battery is not charging the green LEDs will indicate the battery capacity as follows:

LED	Battery Capacity
4 LEDs are lit *	> 75%
3 LEDs are lit	51-75% capacity
2 LEDs are lit	26-50% capacity
1 LED is lit	0-25% capacity
1 LED blinks	Low

* If 4 LEDs blink, the battery temperature is out of range and the device will not operate. Let the device return to room temperature.

CAUTIONS, CONTRAINDICATIONS, CHARGING THE DEVICE

Using the Device

Before Use

- Unplug the charger from device.
- Remove the cap from mouthpiece.

Note: *Clean the mouthpiece before using (see "Cleaning the Device" section).*

Note: *If this Charge Level Indicator (green LEDs) are flashing, let the device sit at room temperature for a few minutes. Then press the On/Off Button to activate the device.*

Use

- Press the On/Off Button.

The Status Indicator will cycle (White LEDs) during power up. When the LEDs stop spinning, the device is ready for use.

Note: *When functioning, it is normal to hear the sound of the device as it is cycling.*

- Seal lips around the mouthpiece.
- Breathe through the mouth through the device until relief.

Note: *The device should be in hand positioned upright when in use.*

Shutdown

- Press the power On/Off Button.
- Clean the mouthpiece (see "Cleaning the Device" section).
- Replace the cap.

Note: *The device will automatically shut down after 10 minutes of continuous use.*

Note: *If the device is not used for 30 seconds, it will automatically turn off.*

Single Patient Use

Use of a bacteria filter is optional, but can help maintain device cleanliness. A compatible bacteria filter and mouthpiece are available separately.

Caution: *The duration of filter use will vary by patient and usage. Monitor for blockage by secretions or other particulate and replace as necessary.*

Note: *This filter is not intended to be disinfected or cleaned. Philips Respironics cannot guarantee the performance specifications once this filter has been disinfected or cleaned after patient use.*

Multi-Patient Use

Philips Respironics Patient Filter Kit (Reorder Number 1122088) must be used when multiple patients are using the same device. The Patient Filter Kit is sold separately. Contact Philips Respironics for ordering information.

The following activities must be completed between users:

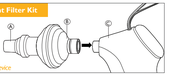
- Replace bacteria filter and mouthpiece.
- Inspect the device and all parts for damage or wear.
- Clean the Inlet Filter (and perform additional cleaning where needed).
- Charge the device.

Note: *Refer to the Cleaning the Device section for instructions on how to clean the outside of the device.*

Assembly

- Remove the device cap and mouthpiece.
- Replace the mouthpiece with the Patient Filter Kit, attaching the bacteria filter between the new mouthpiece and device.

Note: *A protective cap is provided with every Patient Filter Kit. The cap should be placed on the device when it is not being used.*



USING THE DEVICE

How to reach Philips Respironics:

www.philips.com/healthcare
healthcare@philips.com

Contact Philips Respironics Customer Service at:
Philips Respironics
1010 Murry Ridge Lane
Murrysville, PA 15668
1-724-387-4000

Deutschland
Gewerbestrasse 17
82211 Herrsching Germany
+49 8152 93060

Please visit www.philips.com/healthcare to find out more.

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

Respironics Deutschland
Gewerbestrasse 17
82211 Herrsching, Germany

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Cleaning the Device

Clean routinely to extend the life of the device.

Mouthpiece and Cap

Assure the device is unplugged from the charger before completing the following steps.

- Remove the mouthpiece and cap.
- Hand wash the mouthpiece and cap. The following cleaning agents may be used:
  - Mild Detergent
  - Water
  - 70% Isopropyl Alcohol
- Rinse thoroughly and air dry away from direct sunlight.

Note: *The Mouthpiece and Cap should be cleaned before the first use and after each use.*

After cleaning, inspect the device and all parts for damage or wear (cracking, crazing, tears, punctures, etc.).

Carry Strap

The Carry Strap may be cleaned as needed.

- Remove the Air Intake Cover.
- Slide strap out of its port.
- The following cleaning agents may be used:
  - Mild Detergent
  - Water
  - 70% Isopropyl Alcohol
- Air dry the strap. Allow the strap to dry completely before replacing.

Inlet Screen

The Inlet Screen should be cleaned every month.

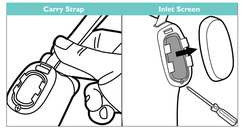
- Remove the Air Intake Cover.
- Loosen the screw holding the Inlet Screen until the screen can be removed.

Note: *The screw is designed to be loosened, but not removed.*

- Inspect the Inlet Screen for damage or wear. Discard and replace if necessary.
- Hand wash the Inlet Screen. The following cleaning agents may be used:
  - Mild Detergent
  - Water
  - 70% Isopropyl Alcohol
- Rinse thoroughly and air dry away from direct sunlight.
- Reattach the Inlet Screen and retighten the screw.
- Replace Air Intake Cover.

Note: *The Inlet Screen should be cleaned before first use and daily.*

Warning: *Do not insert anything into the interior of the device when the Inlet Screen is removed.*



External Surface

The external surface may be cleaned as needed.

- Use a cloth to wipe down the enclosure. The following cleaning agents may be used:
  - Mild Detergent
  - Water
  - 70% Isopropyl Alcohol
  - Oxy Diswelettes
  - 10% Bleach Solution
- Allow the device to dry completely before use.

Warning: *Do not place the device under a running faucet or submerge in liquid.*

Transport and Storage

When transporting or storing the device, these steps will prevent debris from entering the device.

- Replace the cap over the mouthpiece.
- Make certain the charger cover is in place.

Note: *Refer to the "Specifications" section for environmental information regarding storage and operation.*

CLEANING THE DEVICE

Troubleshooting

The following tips will help to assure that your device will provide uninterupted therapy.

- Assure the connector end of the power supply is properly attached to the charger plug.
- If the Charge Level Indicator continues to cycle, the device is not fully charged and needs additional charging time.
- Assure the Inlet screen, mouthpiece and cap, are routinely cleaned and properly installed.

Maintenance

There are no user servicable parts in this device. Service must be performed by Philips Respironics authorized service personnel only.

Tips for Use

- Charge the device battery before use.

Note: *Device functionality is disabled while charging.*

- Practice using the device.
- Inhale through the device mouthpiece.
- Exhale through the mouthpiece.
- Become comfortable with using the device.

Note: *Breathe through the mouth as breathing through the nose decreases the benefit.*

Note: *Contact Philips Respironics if assistance is needed to setup, use, or maintain this device.*

TRANSPORT AND STORAGE, TROUBLESHOOTING, TIPS FOR USE

Symbols

REF	Reorder Number
IP22	Degree of Protection against Ingress of Water: Drip Proof, IP22
SN	Serial Number
EC REP	Authorized representative in the European Community.
	Manufacturer
	Date of Manufacture
	Read the instructions for use.
	Type BF Applied Part
	DC Power
	Li-ion Battery Recycling
CE 0123	CE Marking for Class II products
	Compliant with the Waste Electrical and Electronic Equipment/Restriction of the Use of Electronic Equipment (WEEE/RoHS) recycling directives

Specifications

Environmental

	Operating	Storage
Temperature	0° C to 40° C (32° F to 104° F)	-25° C to 60° C (-13° F to 140° F)
Relative Humidity	15 to 95% (non-condensing)	15 to 95% (non-condensing)
Atmospheric Pressure	101 kPa to 57 kPa (approximately 0-15,000 feet)	N/A

Electrical

AC/DC Power Supply: 100 to 240 V AC at 50 to 60 Hz

Li-ion Rechargeable Battery:
- Voltage: 14.8 V DC
- Current: 2.3 Ah
- Power: 34 Wh

Type of Protection Against Electric Shock: Class II

Degree Protection Against Electric Shock:
- Type BF Applied Part

Degree Protection Against Ingress of Water: IP22

Mode of Operation: Non-continuous

Note: *AC/DC Power Supply is used for charging battery only.*

	Maximum Activation (ON) Time	Minimum Deactivation (OFF) Time
Duty Cycle	< 10 minutes	≥ 30 minutes

Expected Service Life

- Handheld Recovery Device (including power supply and strap): 3 years
- Mouthpiece (including cap): 6 months
- Inlet Screen: 6 months

Disposal

Separate collection for electrical and electronic equipment per EC Directive 2012/19/EU. Dispose of this device in accordance with local regulations.

SYMBOLS, SPECIFICATIONS

EMC Information

Guidance and Manufacturer's Declaration - Electromagnetic Emissions
This device in therapy mode while operating from a rechargeable battery is intended for use in the electromagnetic environment specified below. The user of this device should assure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device 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 device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic purpose.
Harmonic Emissions IEC 61000-3-2 *	Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3 *	Complies	

* Test requirement are applicable to AC-DC adapter only. Conformity to test standards is shown in OEM EMC test reports.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity
This device is intended for use in the electromagnetic environment specified below. The user of this device should assure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±8 kV air	±8 kV contact ±8 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%.
Electrical Fast Transient / Burst IEC 61000-4-4 *	±2 kV for Power Supply Lines ±1 kV for Input / Output Lines	N/A for Battery Operated Device N/A, Device does not have user I/O lines that are greater than 3m in length.	Mains power quality should be that of a typical home or hospital environment.
Surge IEC 61000-4-5 *	±1 kV Line to Line ±2 kV Line to Ground	N/A for Battery Operated Device N/A for Battery Operated Device	Mains power quality should be that of a typical home or hospital environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11 *	>95% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	3 Arms	Mains power quality should be that of a typical home or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical home or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.
* Test requirement are applicable to AC-DC adapter only. Conformity to test standards is shown in OEM EMC test reports.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity
This device is intended for use in the electromagnetic environment specified below.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6 *	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.
b Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.
* Test requirement are applicable to AC-DC adapter only. Conformity to test standards is shown in OEM EMC test reports.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and This Device
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Power Output of Transmitter (Watts)	Separation Distance According to Frequency of Transmitter (meters)		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
420	0.12	0.12	0.23
0.1	0.38	0.38	0.75
1	1.2	1.2	2.3
10	3.8	3.8	7.37
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

EMC INFORMATION

Limited Warranty

Respironics, Inc. warrants that the device and replaceable components (including the mouthpiece assembly, inlet screen, and cap) shall be free from defects in workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years for the device and sixty (60) days for the replaceable components from the date of sale by Respironics, Inc. to the customer, if the product is to perform in accordance with the product specifications, Respironics, Inc. will repair or replace, at its option, the defective material or part. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

RESPIRONICS, INC. DISCLAIMS ALL LIABILITY FOR INDIRECT, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES WHICH MAY BE CLAIMED TO ARISE FROM ANY USE OF THIS PRODUCT. SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU.

THIS WARRANTY IS GIVEN IN LIEU OF ALL OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. SOME STATES DO NOT ALLOW LIMITATIONS ON IMPLIED WARRANTIES, SO THE ABOVE LIMITATION MAY NOT APPLY TO YOU. THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE OTHER RIGHTS WHICH VARY FROM STATE TO STATE.

To exercise your rights under this warranty, 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 Healthcare company 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 (2) years for the device and sixty (60) days for the replaceable components from the date of purchase from an authorised 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, 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 Respironics. Respironics reserves the right to charge an evaluation and postage fee for any returned Product as to which no problem is found following investigation. 5. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to materials or workmanship. 6. The warranty provided by Respironics herein is not transferrable by the Buyer in the event of any sale or transfer of Products purchased by the Buyer from an authorised Respironics dealer. 7. To the extent permitted by law, where the Buyer has the benefit of an implied guarantee under the Australian Consumer Law, but the Product is not of a kind ordinarily acquired for personal, domestic or household use or consumption Respironics' liability shall be limited, at the option of Respironics, to the replacement or repair of the Product or the supply of an equivalent Product. 8. 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 Respironics directly at: Philips Electronics Australia Limited, 65 Epping Road, North Ryde NSW 2113, Australia. Tel: 1300 766 488. Email: prcontact@philips.com. 9. 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 goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.* 10. 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.*