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Welcome to Your Z1 CPAP System

Thank you for choosing the **Z1 CPAP System** from **Breas**.

The **Z1** is specially designed with these features:

- Z-Breathe® Comfort Feature – Z-Breathe is designed to minimize the impact of spikes and drops while keeping the pressure constant, thereby delivering more comfortable therapy.
- Z-Breathe® – the **Z1** automatically reduces the air pressure in the mask to relieve pressure when you exhale and to level out the pressure differences in your natural breathing pattern.
- Leak Compensation – the **Z1** automatically compensates for minor air leakage helping ensure the proper treatment pressure is maintained.
- Auto Altitude Adjustment – the **Z1** adjusts to altitudes up to 2400 meters above sea level.
- Air Travel – The **Z1** adjusts to an airplane's cabin pressure and is approved for use on airplanes.
- Upgradable Operating System– the **Z1** firmware and software can be easily updated via the **USB Cable** and your computer.

This User Guide will help you take advantage of the features and capabilities of this portable CPAP device. Please read this User Guide carefully before using your **Z1**.

Owner/User Responsibility

The owner/user of the **Z1 CPAP System** is responsible for reading and understanding this User Guide. The user is responsible for any injury or damage that results from:

- Operation of the **Z1** other than in accordance with the operating instructions contained in the User Guide supplied.
- Unauthorized maintenance or modifications to the device or attached accessories.

Physician Responsibility

The physician is responsible for explaining contraindications and instructions for use to the patients/users.


Replacement Z1 Parts and Supplies

Use only genuine **Z1** replacement filters, parts and supplies. To purchase replacement filters, parts and supplies visit www.breas.com. Use of unauthorized filters, parts or replacement supplies can damage the device and void the warranty.

Terms Used in this User Guide

This User Guide contains special terms and icons that appear in the text to draw your attention to specific and important information.

WARNING alerts you to possible injury or hazard.

 **CAUTION** explains special measures for the safe and effective use of the device.

NOTE is an informative or helpful note.

Medical Information

Indications for Use

Your **Z1 CPAP System** is a single user, reusable device that provides continuous positive airway pressure (CPAP) to support treatment of adults weighing over 30 kg (66 lbs) with obstructive sleep apnea (OSA).

Contraindications

Positive airway pressure therapy may be contraindicated in some individuals with the following pre-existing conditions:

- Severe bullous lung disease
- Pneumothorax
- Pathologically low blood pressure
- Dehydration
- Cerebrospinal fluid leak, recent cranial surgery, or trauma.

Adverse Effects

Users should report unusual chest pain, severe headache, or increased breathlessness to their prescribing physician. An acute upper respiratory tract infection may require temporary discontinuation of treatment.

The following side effects may arise during the course of therapy with CPAP devices:

- Drying of the nose, mouth, or throat
- Eye irritation
- Nosebleed
- Bloating
- Skin rashes
- Ear or sinus discomfort.

Z1 Warnings and Cautions

WARNINGS:

- Read the entire User Guide before using your **Z1**. Consult your health care provider if there is any part of this User Guide you do not understand.
- Use your **Z1** and its accessories only for their intended use as described in this User Guide and as directed by your physician, clinician or health care provider.
- The **Z1** is not approved for use with oxygen. Do not use supplemental oxygen or any other type of supplementary gas with your **Z1**. Do not connect supplementary oxygen or other gas to any accessory or patient interface which is connected to your **Z1**.
- If you notice any unexplained changes in the performance of your **Z1** or your **Z1** is making unusual or harsh sounds, or if the **Z1** or **Power Supply** are dropped or mishandled, discontinue use and contact Breas or your health care provider.
- If your **Z1**, **Power Supply**, **PowerShell** or **Battery** is dropped or mishandled, or if water is spilled into an enclosure, or if an enclosure is broken, discontinue use and contact Breas or your health care provider.
- A mask is not provided. Your **Z1** should only be used with masks and connectors recommended by your physician, clinician, respiratory therapist or health care provider.
- Your **Z1** is intended to be used with CPAP masks (or connectors) which have vent holes to allow continuous flow of air out of the mask. When your **Z1** is turned on and functioning properly, new air from the **Z1** flushes the exhaled air out through the mask vent holes. However, when the **Z1** is not operating properly (e.g., at low pressure) or the **Z1** is off, insufficient fresh air may be provided through the mask and the exhaled air may be rebreathed. Rebreathing exhaled air for longer than several minutes can, in some circumstances, lead to suffocation. This applies to most CPAP devices. Your health care provider will recommend a mask and air tubing to suit your needs. The **Z1** supports several CPAP mask types including nasal masks, full face masks, and nasal prongs that meet the ISO 17510-2 standard.
- Do not use your **Z1** with a mask unless the **Z1** is turned on. Once the mask is fitted, confirm that air is flowing from your **Z1**.
- Do not block the vent hole or holes in the mask. Follow the mask manufacturer's instructions for proper use of the mask.
- In the event of a power failure or machine malfunction, remove the mask immediately.
- At low pressures some exhaled gases may remain in the mask.
- **Electrocution Hazard** – Your **Z1** is an electrical device, and as such, you should not immerse your **Z1**, **Power Supply**, **PowerShell** or **Battery** in water. Always unplug your **Z1** and its accessories before cleaning (and clean only as instructed in this User Guide) and make sure your **Z1** and its accessories are dry before plugging back in.

WARNINGS:

- Before use, make sure the power cord and plug are in good condition and that the cord is not damaged.
- Do not use bleach, chlorine, alcohol, or aromatic-based solutions, moisturizing or antibacterial soaps or scented oils to clean your **Z1**, **Power Supply**, **PowerShell** or **Battery**. These solutions may create a shock hazard, cause damage and reduce the life of these items.
- **Explosion Hazard** — Do not use or store your **Z1**, **Power Supply**, **PowerShell** or **Battery** in the vicinity of flammable anesthetics or oxygen.
- Do not use your **Z1** near toxic or harmful vapors.
- Do not drop your **Z1** or any of its accessories or expose it to any crushing forces. Should your **Z1** be dropped and fail to operate properly, contact Breas or your health care provider before using the **Z1** for treatment.
- Do not insert any object into any tubing or opening of your **Z1** except as described in this User Guide.
- Do not operate your **Z1** in any area which may block its air intake. Blocking the **CPAP Tube** and/or air inlet of your **Z1** while in operation could lead to overheating of the **Z1**.
- If you put the **Z1** on the floor, make sure the area is free from dust and clear of bedding, clothes or other objects that could block the air inlet or cover the **Power Supply** unit.
- Only store or transport the **Z1** and accessories within the storage and transport temperature, humidity and altitude conditions specified in the Technical Specifications section of this User Guide.
- Do not operate your **Z1**, **Power Supply**, **PowerShell** or **Battery** in an area which may cause overheating.
- Do not cover the **Power Supply**, **PowerShell** or **Battery** with any object or material which would cause them to overheat.
- Keep the power cord, **Power Supply**, **Battery** and **Z1** away from hot or flammable surfaces, gases or materials.
- Do not open your **Z1** or tamper with its accessories. There are no user serviceable parts inside. Repairs and servicing should only be performed by an authorized Breas service agent.
- Only power the **Z1** with the **Z1 Power Supply** (AC-to-DC power adapter) or the optional **Z1 PowerShell** with Breas Medical **Battery**. Do not use any other AC adapters, batteries, or other power sources to power the **Z1**. Do not use the **Z1 Power Supply**, **PowerShell** or **Battery** to power any device other than the **Z1**.
- Your **Z1** should only be used with standard CPAP air tubing as recommended by your physician, clinician or health care provider.
- Do not leave long lengths of air tubing around the top of your bed. The tube could twist around your head or neck while you are sleeping.

WARNINGS:

- Do not connect or insert any device, cable or articles into the Micro USB or Micro SD ports of your **Z1** except as described in this User Guide. Connecting other devices could result in injury to you or damage to the **Z1** and void the warranty.
- Do not locate your **Z1** in an unapproved place or where the air intake can be blocked during treatment. This will lead to overheating of the **Z1**. If a blocked intake should occur during operation, the unit may stop supplying pressurized air and cause a fault condition. Refer to "Troubleshooting" in this User Guide to interpret this fault and instructions for corrective action.
- The **Z1** is designed to deliver pressures from 4 to 20 cmH₂O. In the unlikely event of certain fault conditions, pressures of up to 30 cmH₂O are possible.
- Blocking the **CPAP Tube** while in operation could lead to overheating of the **Z1**.
- In the clinical environment, any personal computer that is used with your CPAP system must be at least 1.5 meters (5 ft) away from, or at least 2.5 meters (8 ft) above, the patient. It must also comply with the relevant test standard. For personal computers the international standard is IEC 60950 or equivalent.

CAUTIONS:

- Be careful not to place your **Z1** where it can be bumped or where someone is likely to trip over the power cord.
- Make sure your **Z1**, **Power Supply**, **PowerShell** and **Battery** are kept clean, dry, and free of dust.
- Always make sure the power cord and plugs are in good condition and the equipment is not damaged before use.
- Make sure the area around your **Z1** and accessories is dry and clean.
- During partial (below rated minimum voltage) or total power failure, therapy pressures will not be delivered. When power is restored, your **Z1** will enter standby mode and all prior settings will be retained in memory.
- Follow the storage and cleaning instructions provided with your **CPAP Tube** and mask.
- The air filter should be changed at intervals specified in this User Guide. Accumulation of filtered particles over time can reduce the efficiency and shorten the life of any CPAP device, including the **Z1**. Replacement filters are available at www.breas.com.
- Do not wash the air filter. The air filter is not washable or reusable.
- The **End Cap** protects the **Z1** in the event of a minor collision. Always ensure that the **End Cap** is securely fitted in accordance with instructions at all times. The **Z1** may not operate if the **End Cap** is not properly installed.

CAUTIONS:

- The temperature of the airflow for breathing produced by CPAP devices can be higher than the temperature of the room. This is true of all CPAP devices. Caution should be exercised when using your **Z1** at room temperatures warmer than 32°C (90°F).
- Only operate the **Z1** and accessories within the operating temperature, humidity and altitude conditions specified in the Technical Specifications section of this User Guide.
- Only store or transport the **Z1** and accessories within the storage and transport temperature, humidity and altitude conditions specified in the Technical Specifications section of this User Guide.
- Damage to the **CPAP Tube** may result in air leaks. If this occurs, stop using the damaged **CPAP Tube** and replace immediately.

Battery Warnings and Cautions

The **PowerShell** comes with a removable **Lithium Ion Battery**. Careful attention must be paid to the warnings and cautions described below relating to the **Battery**. Misusing the **Battery** may cause the **Battery** to get hot, rupture, ignite and cause serious injury.

WARNINGS:

- Do not place the **Battery** in fire or heat the **Battery**.
- Do not install the **Battery** backwards so that the polarity is reversed.
- Do not connect the positive terminal and the negative terminal of the **Battery** to each other with any metal object (such as wire).
- Do not carry or store the **Battery** together with necklaces, hairpins, or other metal objects.
- Do not pierce the **Battery** with nails, strike the **Battery** with a hammer, step on the **Battery** or otherwise subject it to strong impacts or shocks.
- Do not solder onto the **Battery**.
- Do not expose the **Battery** to water or salt water, or allow the **Battery** to get wet.
- Do not disassemble or modify the **Battery**. The **Battery** contains safety and protection devices which, if damaged, may cause the **Battery** to generate heat, rupture or ignite.
- Do not place the **Battery** on or near fires, stoves or other high-temperature locations. Do not place the **Battery** in direct sunlight, or use or store the **Battery** inside cars in hot weather. Doing so may cause the **Battery** to generate heat, rupture or ignite. Using the **Battery** in this manner may also result in a loss of performance and a shortened life expectancy.
- Immediately discontinue use of the **Battery** if, while using, charging or storing the **Battery**, the **Battery** emits an unusual smell, feels hot, changes color, changes shape or appears abnormal in any other way. Contact Breas or your health care provider if any of these problems are observed.

WARNINGS:

- Do not place the **Battery** in microwave ovens, high-pressure containers, or on induction cookware.
- In the event that the **Battery** leaks and the fluid gets into one's eye, do not rub the eye. Rinse well with water and immediately seek medical care. If left untreated the battery fluid could cause damage to the eye.
- Only charge the **Battery** with the supplied **Z1 PowerShell** and the supplied **Z1 Power Supply**. Do not use any other removeable battery charger, AC adapter, or other device to charge the **Battery**.
- Do not attach the **Battery** directly to a vehicle cigarette lighter or to the **Power Supply** plug.
- Do not continue charging the **Battery** if it does not recharge within the specified charging time. Doing so may cause the **Battery** to become hot, rupture or ignite.
- Remove the **Battery** from the **PowerShell** if the **Z1** is not likely to be used for some time. Do not use the **Battery** to power any device other than the **Z1**.
- Only use or charge the **Battery** within the operating temperature, humidity and altitude conditions specified in the Technical Specifications section of this User Guide.
- Only store or transport the **Battery** within the storage and transport temperature and humidity conditions specified in the Technical Specifications section of this User Guide.

CAUTIONS:

- When the **Battery** is worn out, insulate the terminals with adhesive tape or similar materials before disposal.

Getting to Know Your Z1 System

Package Contents - Z1 CPAP Base Model

Description
Z1 CPAP Device
Power Supply with Power Cord
USB A to Micro B Cable
CPAP Tube Adapter
CPAP Tube
End Cap
Filter
Heat/Moisture Exchange Unit (HME)
Z1 CPAP Getting Started Guide
User Guide

Package Contents - Powershell Module

Description
Extended Life Battery
Battery Shuttle
PowerShell
PowerShell Getting Started Guide

Z1 Unplugged

The Z1 Unplugged package contains Z1 CPAP base model plus the Powershell module.

Z1 CPAP Device

The **Z1** supplies continuous positive airway pressure and can be programmed to fit the patient's prescriptive needs.

Power Supply (AC to DC Power Adapter)

The **Power Supply** provides power to the **Z1**. It takes AC power (voltage ranging from 100-240 volts) from a wall outlet and converts it to DC voltage to power the **Z1**. The **Power Supply** can be used with international power sources provided the appropriate plug adapter is used.

Tube Adapter

The **Tube Adapter** attaches the **CPAP Tube** to the **Z1**.

CPAP Tube

The **Z1 System** is provided with a **CPAP Tube**. **CPAP Tube** connects the **Z1** to your mask. Always consult with your physician or health care provider regarding the selection of tubing for your treatment. Follow the instructions provided with the tubing. To purchase replacement tubing visit www.breas.com.

End Cap

The **End Cap** attaches to the air intake end of the **Z1** and houses the **Filter**. For proper operation of the **Z1**, the **Filter** should be replaced monthly or more often if necessary.

Filter

The **Z1** uses a specially designed filter. The material has been specifically chosen for the **Z1** and has been designed to be much larger than other CPAP filters. The unique shape of the **Filter** fits into the **End Cap** of the **Z1**, which was designed to allow for more effective filter surface area.

NOTE: To purchase replacement **Filters** visit www.breas.com.

USB Micro Cable

The **USB Cable** allows the **Z1** to communicate with a computer to collect and view user data.

Heat Moisture Exchanger (HME)

The disposable **HME** works by capturing moisture as you exhale and provides it back to you as you breathe. The **HME** does not use any electricity or complex moving parts and avoids the problems encountered with electrical humidification systems.

To install the **HME**, connect the large diameter end of the **HME** to your mask and the smaller diameter end to your **CPAP Tube**. Be sure both connections are fully seated and secure. Store the **HME** in a sealed plastic bag between uses to extend its life. Discard when it is no longer providing humidification.

PowerShell (Optional Accessory)

The **PowerShell** houses both the **Z1** and the **Battery** which allows temporary usage of the **Z1** without the **Power Supply**. To purchase the **PowerShell** visit www.breas.com.

Initial Set Up

Unpacking the Z1 Box

You will need to perform a few minor setup steps before using your new **Z1**. The instructions below will guide you through the setup process. Some of the steps outlined below may have been performed by your health care provider prior to delivering the **Z1** to you. If you have any questions or problems as you go through the setup process, please contact Breas or your health care provider for assistance. Breas wants your user experience with the **Z1** to be trouble and frustration free.

1. Carefully remove the contents of the box.
2. Some of the **Z1** components have their own packaging material. Remove this material carefully. Avoid using anything sharp when opening the packaging.
3. Carefully inspect all contents against the Package Contents list on page 9 to assure all components are present. Keep in mind that your health care provider might have completed some of the setup steps prior to delivery, so if a component appears to be missing, check to see if it has already been connected. Also inspect all contents to ensure there is no obvious or visible damage or defects. If you have any concerns or questions, contact Breas or your health care provider before use.
4. Place all the components in an area where you can easily access the **Z1** for set up and programming.

WARNING Do not use this product if you have any concerns about the condition of the contents or if there are any missing parts.

The contents of the **Z1** box includes the following:

Z1 Base Model



Z1 Unplugged

Includes everything that comes with the **Z1** Base Model, plus:

PowerShell

Battery Shuttle and
Battery

Assembling and Powering Up

Filter and End Cap

1. Remove the **Filter** from its packaging.
2. Insert the **Filter** into the **End Cap**, aligning the arched side of the **Filter** with the top of the **End Cap**.
3. Ensure the **Filter** covers all holes in the **End Cap**, so that all air entering the **Z1** passes through the **Filter** and no air bypasses the **Filter**.
4. Press the **End Cap** onto the **Z1**. (Figure 1)

NOTE: To remove the **End Cap**, squeeze firmly on the sides of the **End Cap** and pull it away from the **Z1**.

Tube Adapter, CPAP Tube, HME and Mask

1. Connect one end of the **CPAP Tube** to the round end of the **Tube Adapter** then insert the other end of the **Tube Adapter** into the outlet of the **Z1**. (Figure 2)
2. Connect the other end of the **CPAP Tube** to the **HME** and the **HME** to the mask.
3. Ensure all connections are tight to avoid air leaks. (Figure 3)



Figure 1

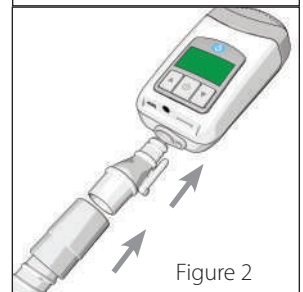


Figure 2

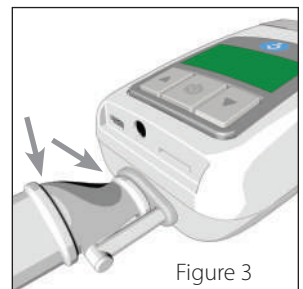


Figure 3

Power Supply

WARNINGThe Z1 must only be used with the Z1 Power Supply (or the optional Z1 PowerShell with Breas Battery). DO NOT use any other power source with the Z1.

CAUTION Make sure the AC power cord IS NOT plugged into an AC power outlet before continuing to the next step.

1. Plug the AC power cord into the AC Adapter.
2. Plug the AC power cord into a wall outlet.
3. Plug the AC Adapter into the Z1. (Figure 4)
4. The Z1 will power up and cycle through a series of startup displays.
5. After about 10 seconds, the Z1 will enter standby mode. The display will read 0.0. (Figure 5)

NOTE: The Z1 display will be active whenever the device is receiving power.

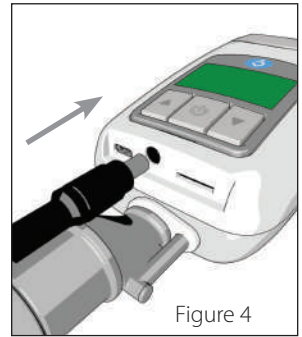


Figure 4

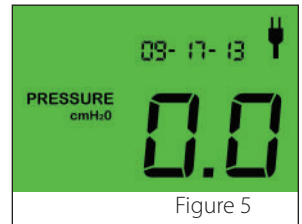


Figure 5

PowerShell and Battery (Available Separately)

WARNINGThe Z1 must only be used with the optional Z1 PowerShell with Breas Battery (or the Z1 Power Supply). DO NOT use any other power source with the Z1.

1. Slide the Battery with the attached Shuttle into the lower bay of the PowerShell until the Shuttle clicks into place. (Figure 6)


NOTE: The Battery can be removed from the PowerShell by pressing the two blue buttons on the Battery Shuttle and sliding the Battery out.



Figure 6

2. Slide the Z1 all the way into the upper bay of the PowerShell until you hear a "click" sound, indicating the Z1 has locked into place. (Figure 7)

CAUTION Insert the Z1 carefully ensuring the power barrel connector slides into the power input on the Z1.

NOTE: The Z1 can be removed from the PowerShell by pressing the two  symbols on the sides of the PowerShell and sliding the Z1 out.

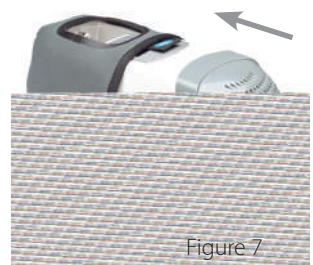


Figure 7

