Contents

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™ – 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 amazing 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.

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.

- 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.

- 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 cm H_2O. In the unlikely event of certain fault conditions, pressures of up to 30 cm H_2O 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.

- 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.

- 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.

◈ **CAUTION:**

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

Getting to Know Your Z1 CPAP System

Package Contents

Description	Z1 Base Model	Z1 Unplugged
Z1 CPAP Device	✔	✔
Power Supply	✔	✔
Power Cord, EU	✔[1]	✔[1]
Power Cord, UK	✔[1]	✔[1]
USB A to Micro B Cable	✔	✔
CPAP Tube Adapter	✔	✔
CPAP Tube	✔	✔
End Cap	✔	✔
Filter	✔	✔
Heat/Moisture Exchange Unit (HME)	✔	✔
Z1 Getting Started Guide	✔	✔
User Guide	✔	✔
Overnight Battery		✔
Battery Shuttle		✔
PowerShell		✔
PowerShell Getting Started Guide		✔

[1] Only one power cord is in the package.

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**. The **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.

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 8 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:

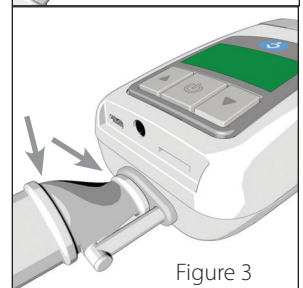PowerShell

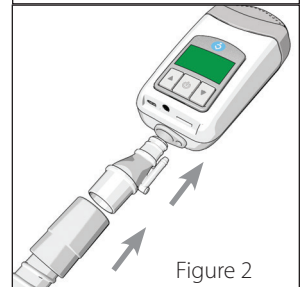Battery Shuttle and Overnight Battery

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 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 mask.

3. Ensure all connections are tight to avoid air leaks. (Figure 3)

Figure 1

Figure 2

Figure 3

Power Supply

> ⚠️ **WARNING:** The *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.
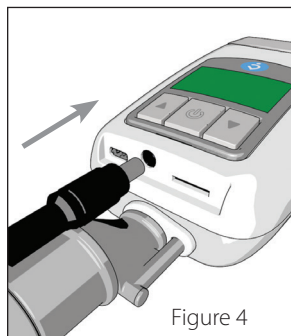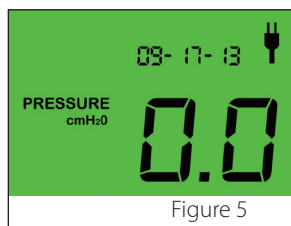

Figure 4

Figure 5

PowerShell and Battery
(Available Separately or as Part of Z1 Unplugged)

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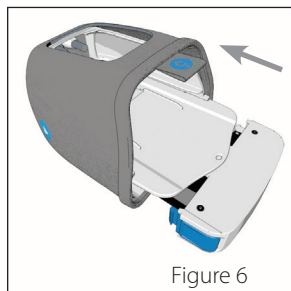
2. Slide the *Z1* all the way into the upper bay of the *PowerShell* until you hear a "click" sound, indicating the *Z1* has locked into place. (Figure 7)

> ⚠️ **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.
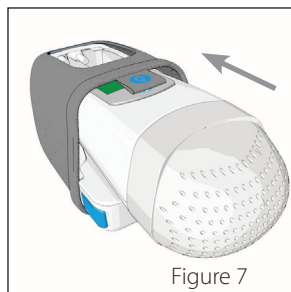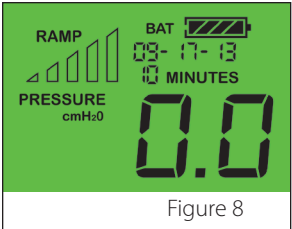

Figure 6

Figure 7

12

3. The **Z1** will power up and cycle through a series of startup displays.

4. After about 10 seconds, the **Z1** will enter standby mode. The display will read 0.0. (Figure 8)

Figure 8

NOTE: Remove the *Battery* from the *PowerShell* when the **Z1** is not in use, unless the *Power Supply* is plugged into the *PowerShell* to charge the *Battery*. Otherwise the **Z1** and *PowerShell* will drain the battery completely within 2-3 days.
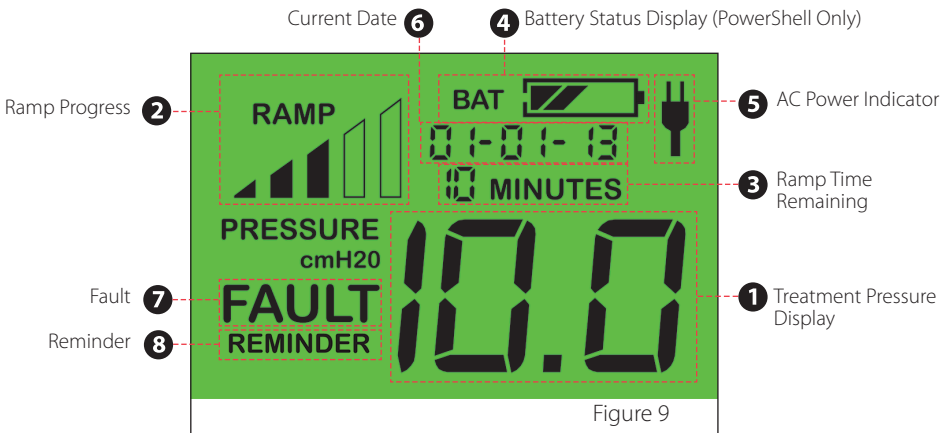
Using Your Z1

LCD Display

❶ Treatment Pressure Display

The current treatment pressure is shown on the LCD display. Once set, the prescribed treatment pressure will be retained in the **Z1**'s memory even during loss of power. For example, a treatment pressure setting of 10.0 cm H_2O is displayed in Figure 9 .

❷ Ramp Progress & ❸ Ramp Time Remaining Indicators

Ramp Mode allows you to gradually acclimate to the prescribed treatment pressure. Ramp Mode gradually increases the pressure from a low initial starting pressure to the prescribed treatment pressure over a programmed interval of time. See "Programming Ramp Mode".

If you program the **Z1** for Ramp Mode, the Ramp Progress and Ramp Time Remaining indicators will appear on the LCD display. For example, Figure 9 indicates that the Ramp is just over half complete, with a Ramp Time remaining of 10 minutes.

Current Date ❻   ❹ Battery Status Display (PowerShell Only)

Ramp Progress ❷   ❺ AC Power Indicator

❸ Ramp Time Remaining

Fault ❼   ❶ Treatment Pressure Display

Reminder ❽

Figure 9

❹ Battery Status Display

This icon is displayed when the optional *PowerShell* and *Battery* are connected. The level of charge remaining on the *Battery* is indicated by the number of solid bars in the icon. The bars flash when the *Battery* is charging. For example, the icon shown in Figure 9 indicates that the *Battery* has between 25-50% of charge remaining. Make sure the *Battery* is fully charged before each use.

Number of Solid Bars	Charge Remaining
1	10-25%
2	25-50%
3	50-75%
4	75-100%

❺ AC Power Indicator

This icon is displayed when the *Z1* is connected to an AC power outlet via the *Power Supply*.

❻ Current Date

The current date is displayed automatically on the *Z1*. It is pre-programmed at the factory.

❼ FAULT

"FAULT" is displayed if one of several conditions has occurred that require your attention. See "Fault Conditions" (page 19) for explanations of the FAULT codes.

❽ REMINDER

"REMINDER" is displayed if there is excessive air leakage. See "Reminder Alert (Air Leak Detection)" (page 18) for an explanations of REMINDER conditions.

Starting and Stopping Treatment

1. Press the *Start/Stop Button* on the *Z1* to initiate treatment using the programmed treatment setting. The Treatment Pressure Display will show the actual pressure being delivered at all times. If the Ramp Mode has been programmed, the Ramp start pressure will be displayed upon pressing the *Start/Stop Button* and the indicated pressure will rise as the *Z1* Ramps up to prescribed treatment pressure. If the incorrect pressure is displayed, contact your health care provider before commencing CPAP therapy. (Figure 10)

   > ◆ **CAUTION** (When using the *PowerShell* Only): Make sure your *Battery* is fully charged before commencing CPAP therapy using the *PowerShell*. The battery life of a fully charged battery in the *PowerShell* is typically 8 hours or longer and treatment will terminate when the charge is expended.

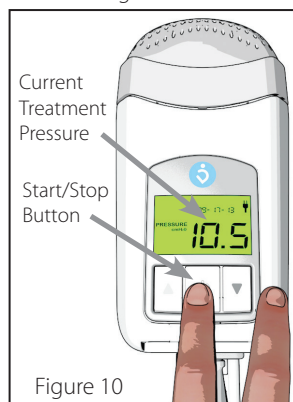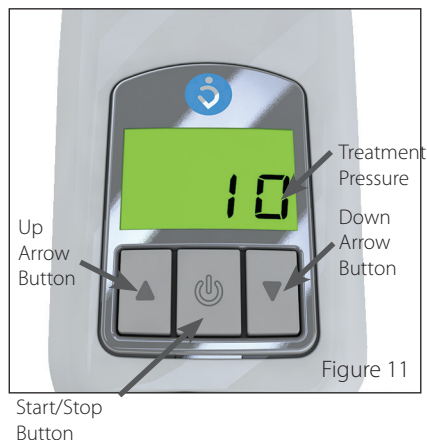2. Press the *Start/Stop Button* a second time to stop treatment.

Current Treatment Pressure

Start/Stop Button

Figure 10

Programming Treatment Pressure

When the *Z1* is in standby mode, press and hold the *Start/Stop Button* for 3 seconds until the pressure value flashes. While it is flashing, repeatedly press either the *Up* or *Down Arrow Buttons* to increase or decrease the pressure (Figure 11). When you have reached the prescribed pressure, press and hold the *Start/Stop Button for approximately 3 seconds to save the treatment pressure setting* (this setting will be saved even when the *Z1* is not powered). The *Z1* will return to standby mode. To return to standby mode without saving the new setting, press and release the *Start/Stop Button* momentarily instead of holding it down.

Up Arrow Button

Treatment Pressure

Down Arrow Button

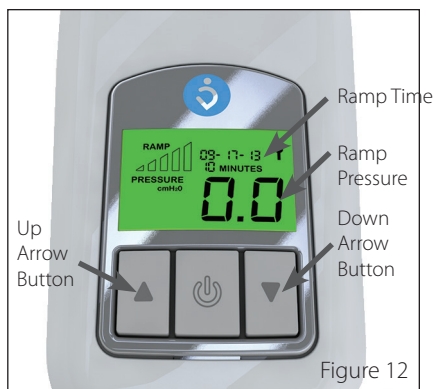Figure 11

Start/Stop Button

Programming Ramp Mode

Some users find it comforting to acclimate to CPAP therapy each session. This can be accomplished by programming the Ramp Mode which allows you to start with a low initial pressure and gradually increase to the prescribed treatment pressure.

Setting Ramp Time

When the *Z1* is in standby mode, press and hold the *Up Arrow Button* for approximately 3 seconds until the "00 MINUTES" value flashes. While it is flashing, repeatedly press either the *Up* or *Down Arrow Buttons* to increase or decrease the Ramp Time in 5 minute increments. (Figure 12) Set the Ramp Time to "00 MINUTES"" to disable the Ramp Mode.

Ramp Time

Ramp Pressure

Down Arrow Button

Up Arrow Button

Figure 12

When the desired Ramp Time value is reached, press and hold the *Start/Stop Button* for approximately 3 seconds to save your Ramp Time setting (this setting will be saved even when the *Z1* is not powered). The *Z1* will return to standby mode. To return to standby mode without saving the new setting, press and release the *Start/Stop Button* momentarily instead of holding it down.

Setting Ramp Start Pressure

Press and hold the *Down Arrow Button* for 3 seconds until the Ramp start pressure value flashes. While flashing, repeatedly press either the *Up* or *Down Arrow Buttons* to increase or decrease the Ramp start pressure by 0.5 cm H_2O increment. (Figure 11) Ramp start pressure must be lower than prescribed pressure.

When the desired value for Ramp start pressure is reached, hold down the *Start/Stop Button* for approximately 3 seconds to save your setting. The *Z1* will return to standby mode. To return to standby mode without saving the new setting, press the *Start/Stop Button* momentarily instead of holding it down.

Z-Breathe™ Algorithm Selection

Your **Z1** unit adjusts its airflow automatically on a breath-by-breath basis so that you can maintain a more comfortable, normal breathing pattern. You can choose from the following two Z-Breathe Algorithm settings:

- **CPAP – 1 Setting**– enables the Z-Breathe Algorithm at a gentle response rate which adjusts the airflow gradually during the inhalation-exhalation cycle. In this setting, the algorithm will initially adjust rapidly to breathing, but the adjustments will become gentle and gradual after a few inhalation-exhalation cycles.

- **CPAP – 2 Setting** – enables the Z-Breathe Algorithm at an aggressive response rate which adjusts the airflow rapidly during the inhalation-exhalation cycle.

You can change the setting of the Z-Breathe Algorithm when your **Z1** unit is in Standby Mode (pressure of "0.0" indicated on the display). To change the setting, hold down both the up and down arrow buttons at the same time until you see "CPAP – 1" or "CPAP – 2" flashing on the display. Press the up or down arrow buttons until you observe your desired setting on the display. To lock-in the setting, hold down the Start/Stop button until the "CPAP – X" indicator no longer flashes on the display.

Your selected setting for the Z-Breathe Algorithm will be retained in the memory of your **Z1** unit after it is turned off. The currently selected Z-Breathe Algorithm setting will be displayed when the **Z1** is delivering treatment pressure.

User Software

See separate **Z1** Software Guide for information on data viewing software. This guide may only be available online.

Charging the Battery (PowerShell Only)

> ⚠️ **WARNING:** Only charge the **Battery** with the supplied **Z1 PowerShell** and the supplied **Z1 Power Supply.** Do not use any other battery charger, AC adapter, or other device to charge the **Battery**.

Figure 13

With both the **Z1** and the **Battery** fully inserted into the **PowerShell**, plug the **Power Supply** into the **PowerShell** as shown and into a power outlet. (Figure 13)

> 🔶 **CAUTION:** Make sure your **Battery** is fully charged before commencing CPAP therapy using the **PowerShell**. The battery life of a fully charged battery in the **PowerShell** is typically 8 hours or longer, after which treatment will terminate. To recharge the **Battery**, see "Charging the Battery"
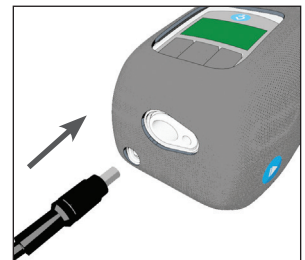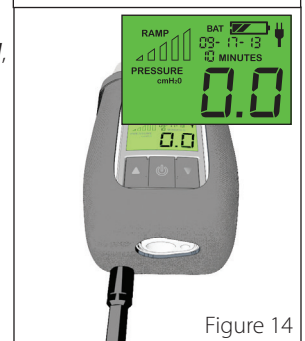

Figure 14

Ensure the **Z1** is in standby mode (display reads 0.0). The **Battery** will not charge unless the **Z1** is in standby mode. The **Battery** status indicator on the **Z1** will flash when the **Battery** is charging. The number of solid bars indicates the current level of charge. (Figure 14)

Care

The **Z1 System** needs periodic care. It is the user's responsibility to be aware of the following items for care:

- Inspections
- Cleaning
- *Filter* Replacement
- *CPAP Tube* Replacement
- Reminders and Fault Conditions

Inspections

Before each use carefully inspect the **Z1**, **CPAP Tube**, **Filter**, and mask for signs of wear, damage or discoloration. For replacement parts visit www.breas.com.

Cleaning

Regular cleaning should be performed in accordance with the instructions below.

> ⚠️ **WARNING:** This device can expose you to electrocution. Do not immerse the **Z1**, **Power Adapter, Power Cord** or **Battery** in water. Always unplug these devices before cleaning (only as instructed in this User Guide) and make sure they are dry before plugging back in.

> ◈ **CAUTION:** Do not use bleach, chlorine, alcohol, or aromatic-based solutions, moisturizing or antibacterial soaps or scented oils to clean the **Z1**. Never attempt to clean the **Power Adapter, PowerShell, Battery** or accessories with any of these solutions. These solutions may create a shock hazard, cause damage and reduce the life of these products.

Daily

1. Remove the **CPAP Tube** and the mask from the **Z1**.

2. Refer to the instructions for cleaning, maintenance and replacement provided with your **CPAP Tube** and mask.

3. Before next use, reconnect the **CPAP Tube** and the **Tube Adapter** to the **Z1** and mask.

Weekly

1. Remove the **CPAP Tube**, **Tube Adapter** and mask from the **Z1**. Wash the **Tube Adapter** in warm water using a mild detergent. Rinse thoroughly and allow to dry.

Refer to the manufacturer's instructions for cleaning the **CPAP Tube** and mask.

2. Before next use, reconnect the **CPAP Tube** to the **Tube Adapter** and then to the **Z1** and mask.

As Needed

1. Clean the exterior of the *Z1* with a soft damp cloth and mild detergent and wipe clean. Never submerge the *Z1* in water. Do not allow soap or water to enter the *Z1*.

Filter Replacement

The *Filter* should be inspected weekly for holes and blockage by dirt and dust, and should be replaced every month (or more often if necessary). The *Filter* is accessed by removing the *End Cap* as described in "Assembling and Powering Up: *Filter* and *End Cap*".

> **NOTE:** The *Z1* uses a specially designed Filter that is only available from Breas. To purchase replacement filters visit www.breas.com.

> ⚠️ **WARNING:** Do not attempt to use any air filter which is not supplied by Breas for the *Z1.* The *Z1* is designed to only work with approved materials. A filter which is not approved may cause damage to the *Z1* from overheating.

> ◈ **CAUTION:** Do not operate the *Z1* without the *Filter*. The *Z1* must operate with a filter installed; failure to do so may damage the *Z1* and allow impurities into the respiratory system.

CPAP Tube Replacement

The *CPAP Tube* should be replaced according to the instructions provided with the *CPAP Tube*.

Reminder Alert (Air Leak Detection)

"REMINDER" is displayed on the LCD screen to indicate an excessive air leak. This could be because you are not wearing your mask. Placing the mask on your face should remove REMINDER from the display. If you are wearing the mask and REMINDER is displayed check the following connections for air leaks:

- *Tube Adapter* to *Z1*
- *CPAP Tube* to *Tube Adapter*
- *CPAP Tube* to mask
- Mask to face (adjust position of mask and headgear to eliminate the air leak)

Fault Conditions

The **Z1** has the ability to detect operational problems and will display the word FAULT on the LCD screen. (Figure 15)

The LCD screen should be checked for any FAULT messages and visible damage daily.

A fault condition is indicated when the word "FAULT" is displayed accompanied by a two digit flashing number in place of the pressure reading.
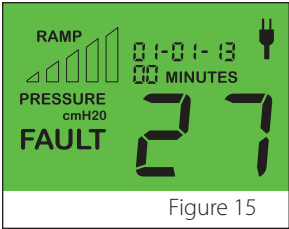

Figure 15

The table below provides a listing of fault codes and recommended actions to be taken by the user.

Fault Code	Explanation	Action
21 Flashing	Treatment pressure not programmed	Discontinue use and contact your health care provider or Breas.
27 Flashing	Overheating	Discontinue use and contact your health care provider or Breas.
32 Flashing	Over current	Discontinue use and contact your health care provider or Breas.
33 Flashing	Over pressure	Discontinue use and contact your health care provider or Breas.

Troubleshooting

Problem	Possible Causes & Solutions
No Display	Power is not present. Ensure the **Power Supply** is connected and the power outlet has power.
	Loose connection of the **Power Supply** at the **Z1** or loose connection of the **Power Cord** at the AC Adapter. Check the connections.
	Z1 is not locked into position in the **PowerShell**. Slide the **Z1** into the **PowerShell** until it clicks and locks into place.
	Battery is not locked into position in the **PowerShell**. Slide the **Battery** into the **PowerShell** until the **Battery Shuttle** clicks and locks into place.
	Battery is not charged. Charge the **Battery**.
	A power supply not designed for the **Z1** is connected to the **Z1**. Remove the power supply unit and replace with a Breas approved unit.

Treatment Will Not Start	Check the display for a fault condition. Refer to the Fault Codes table in "Fault Conditions". Contact Breas or your health care provider.
Insufficient Air Flow Delivered from *Z1*	Air filter is dirty or clogged. Replace air filter.
	Air intake is blocked. Clear blockage.
	CPAP Tube is not connected properly. Check *CPAP Tube, Tube Adapter* and connections to your *Z1* and your mask.
	Ramp Mode is in use. Wait for air pressure to reach prescribed treatment pressure or stop treatment and adjust Ramp time.
	CPAP Tube is blocked, pinched or punctured. Unblock *CPAP Tube.* Check the *CPAP Tube* for punctures. Replace a damaged *CPAP Tube* immediately.
	Mask and/or headgear are not positioned correctly and mask is leaking. Adjust position of the mask and headgear until leak ceases.
	Incorrect *CPAP Tube* selected. Do not use tubing which was not recommended by your clinician.
	Check the display for a fault condition. Refer to fault codes in "Fault Conditions".
Pressure Rises Inappropriately	Talking, coughing or breathing in an unusual manner. For example, avoid talking with a nasal mask on and breathe as normally as possible.
	There may be an air leak caused by improperly connected tubing. Check for leaks.
	Follow mask manufacturer's instructions.
Mask Cushion is Vibrating Against the Skin and an Air Leak is Occurring	Stop treatment. Remove and reposition the mask and, if necessary, adjust the headgear. Resume treatment.
	Follow mask manufacturer's instructions.
Z1 Has Been Left in a Hot Environment	Allow *Z1* to cool before use. Disconnect the power cord and then reconnect it to restart the *Z1*.

Technical Specifications

30W Power Adapter	Unit Input range 100–240V, 50–60Hz
	Typical power consumption 20W (30VA)
	Maximum power consumption 35W (70VA)
Operating temperature	5ºC to 35ºC (41ºF to 95ºF)
Operating humidity	10–80% Relative Humidity, Non-Condensing
Operating altitude	Sea level to 2400 m (8000 ft)
Operating atmospheric pressure	101 to 75.3 kPA
Storage and transport temperature	-20ºC to +60ºC (-4ºF to +140ºF)
Storage and transport humidity	10–80% Relative Humidity, Non-Condensing
Storage and transport altitude	No limit
Storage and transport atm. pressure	No limit
Electromagnetic compatibility	Compatible with IEC 60601-1-2
Aircraft use	Complies with RTCA DO-160G Standard for use in flight
IEC 60601-1 classification	Class II (double insulation), Type BF
Available modes	Standby, CPAP and CPAP with Ramp
Operating pressure range	4 to 20 cm H_2O
Maximum single fault steady pressure state	30 cm H_2O
Deliverable pressure accuracies	±0.6 cm H_2O ± 4% of the measured reading
Sound pressure level	< 26 dBA
Nominal dimensions (L x W x H)	16.46 cm x 8.38 cm x 5.13 cm (6.48" x 3.30" x 2.02")
Weight	238 g (10 oz.)
Housing construction	Flame retardant engineered thermoplastic
Supplemental oxygen	Not for use with oxygen
Standard air filter	Polyester
Air outlet	The 22 mm air outlet complies with ISO 5356-1
PowerShell Battery Specifications	45 Watt-hours capacity
	Lithium Ion Battery Pack
	4S1P
	Weight approx. 225 g (8 oz.)

The following symbols may appear on your device, power supply unit, or packaging.

⚠ Caution; 🏃 type BF equipment; ▣ Class II equipment; ⏻ Start/stop; ▰ Manufacturer; LOT Batch code; REF Catalog number; SN Serial number; ▭ Direct current; ⮾ Not for use on more than one patient; 🗑 Product disposal warning to EN50419; CE 0123 CE marking applies in accordance with the directive MDD 93/42/EEC.

Servicing

The **Z1 System** is intended to provide safe and reliable operation when operated in accordance with the instructions provided by Breas. Breas recommends that the **Z1 System** be inspected and serviced by an authorized Breas Service Center if there is any sign of wear or concern with **Z1** function. Otherwise, service of the **Z1** generally should not be required during the warranty period (see 'Limited Warranty' for details) of the device.

Limited Warranty

Breas warrants that your Breas product shall be free from defects in material and workmanship from the date of purchase for the period specified below.

Component	Warranty Period
Z1 device	3 years
PowerShell	2 years
Overnight Battery	9 months
Power Supply	2 years

If product fails to perform in accordance with product specifications, Breas will repair or replace, at its option, the defective material or part. This warranty is only available to the initial purchaser. It is not transferable. If the product fails under conditions of normal use, Breas will repair or replace, at its option, the defective product or any of its components. This limited warranty does not cover: a) any damage caused as a result of accident, improper use, abuse, modification or alteration of the product; b) repairs carried out by any service organization that has not been expressly authorized by Breas to perform such repairs; c) any damage or contamination due to cigarette, pipe, cigar or other smoke; d) damage caused by water entering the product. Warranty claims on defective product must be made by the initial purchaser by contacting Breas.

THIS WARRANTY REPLACES ALL OTHER EXPRESSED OR IMPLIED WARRANTIES, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. SOME REGIONS OR STATES DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, SO THE ABOVE LIMITATION MAY NOT APPLY TO YOU.

BREAS MEDICAL SHALL NOT BE RESPONSIBLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES CLAIMED TO HAVE RESULTED FROM THE SALE, INSTALLATION OR USE OF ANY BREAS MEDICAL PRODUCT. SOME REGIONS, STATES OR COUNTRIES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, 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 region to region. For further information on your warranty rights, contact Breas or your health care provider.

Replacement Z1 Parts and Supplies

Use only genuine Z1 replacement filters, parts and supplies. Replacement filters, parts and supplies can be purchased by visiting www.breas.com.

Product	Description
Z1™ Base CPAP System	Z1 Base System includes: Z1 Device, Tube Adapter, Slim-Style Tube, Power Supply, Custom USB Cable, User Manual and Getting Started Guide.
Z1 Unplugged™ CPAP System	Z1 Unplugged System includes: Z1 Base System and PowerShell Module.
Z1 PowerShell™ Module	Z1 PowerShell includes: PowerShell Battery Cradle, Neoprene Cover & Lanyard, Overnight Battery and Battery Shuttle.
Z1 Overnight Battery	14.4V rechargeable lithium ion battery pack for the Z1 PowerShell.
Z1 Custom USB Cable	USB to micro USB cable with custom tip for software downloads and data extraction.
Slim-Style Tube	Special lightweight, thin pressure delivery tube for use with the Z1 Device.
Z1 Polyester Filter (2 pack)	2 each, Z1 Polyester Air Filters
Z1 Polyester Filter (6 pack)	6 each, Z1 Polyester Air Filters
Z1 Custom Tube Adapter	Z1 custom outlet Tube Adapter (required for Z1 operation)
Heat/Moisture Exchange Unit (HME)	In-line humidification for the Z1 Device
Z1 Power Supply	AC Adapter, 100 - 240V
Z1 Power Cord, EU	AC Power Cord with EU Plug
Z1 Power Cord, UK	AC Power Cord with British Plug
Z1 Plastic Filter End Cap	Z1 Filter Housing and Cover
Z1 DC Mobile Adapter	Enables the Z1 to be powered by plugging into a 12-volt vehicle outlet.

Contact Information

BREAS

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Order:	+46 31 86 88 20
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BREAS

FAA Compliance

To whom it may concern:

The US Department of Transportation (DOT) Final Rule, "Nondiscrimination on the Basis of Disability in Air Travel" (73 FR 27614 which updates Title 14 CFR Part 382), effective May 13, 2009 provides important requirements for the accomodation of passengers with respiratory assistive devices (Ventilators, Respirators and CPAP machines).

In line with these requirements, respiratory assistive devices may be used onboard an aircraft, without further testing by the carrier, provided they have been tested for Electromagnetic Compatibility (EMC) in accordance with the current version of RTCA/DO-160, Section 21, Category M.

Breas Medical has successfully completed testing for the Z1 CPAP System. The Z1 CPAP System complies with RTCA/DO-160, Section 21, Category M and can be considered FAA compliant.

Some airlines may require advance notification before travel, and devices may need to be operated by battery. Breas Medical recommends that customers check with their airline.

BREAS

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BREAS

Register your new device.

Registering your device allows us to provide better customer service. Please register as soon as possible.

About you.

NAME:

First	Last

EMAIL ADDRESS:

MAILING ADDRESS:

Street or PO Box

City	Zip

PHONE NUMBER:

About the device.

WHAT DEVICE DID YOU PURCHASE?

WHERE DID YOU PURCHASE THE DEVICE?   PURCHASE DATE:

_____-_____-_____

[YY-MM-DD]

Z1 SERIAL NUMBER   POWERSHELL SERIAL NUMBER

The device serial number can be found on the back of the unit. Look for the string of numbers following **SN**

11042013