

Contents

| | |
|--|----|
| Welcome to Your Z1 CPAP System | 3 |
| Owner/User Responsibility | 3 |
| Physician Responsibility | 3 |
| Replacement Z1 Parts and Supplies | 3 |
| Terms Used in this User Guide | 4 |
| Medical Information | 4 |
| Z1 Warnings and Cautions | 5 |
| Battery Warnings and Cautions | 9 |
| Getting to Know Your Z1 System | 11 |
| Package Contents - Z1 CPAP Base Model | 11 |
| Package Contents - PowerShell Module | 11 |
| Z1 Unplugged | 11 |
| Z1 CPAP Device | 12 |
| Tube Adapter | 12 |
| CPAP Tube | 12 |
| End Cap | 12 |
| Filter | 12 |
| USB Micro Cable | 12 |
| PowerShell (Optional Accessory) | 12 |
| Initial Set Up | 12 |
| Unpacking the Z1 Box | 12 |
| Assembling and Powering Up | 14 |
| Using Your Z1 | 16 |
| LCD Display | 16 |
| Starting and Stopping Treatment | 18 |
| Programming Treatment Pressure | 19 |
| Programming Ramp Mode | 19 |
| Z-Breathe® Algorithm Selection | 20 |
| Charging the Battery (PowerShell Only) | 21 |
| Care | 21 |
| Inspections | 22 |
| Cleaning | 22 |
| CPAP Tube Replacement | 23 |
| Fault Conditions | 23 |
| Troubleshooting | 23 |

Z1®, Z-Breathe® and PowerShell® are trademarks of Breas Medical Inc.
US Patent Pending. © Copyright 2014-2018, Breas Medical AB. All rights reserved.

Guidance and Manufacturer's Declaration
Electromagnetic Emissions & Immunity26
Technical Specifications31
 Performance Specifications31
 PowerShell with Extended Life Battery Specifications32
Symbol Explanation33
The following symbols may appear on your device, power supply unit, or packaging.....33
Servicing34
Limited Warranty34
Disposal34
Replacement Z1 Parts and Supplies35
Contact Information35

Welcome to Your Z1 CPAP System

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

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

- The **Z1** motor and firmware combination along with the **Qtube** are designed to minimize both dynamic and static noise at the device and within the mask.
- 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.

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.

Any serious incident that has occurred in relation to this device should be reported to the competent authority and the manufacturer.

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** system is not suitable for patients requiring continuous ventilator support.
- 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**.
- The responsible organization shall assess the therapeutic settings for individual patients, with considerations for the system configuration being used. The settings should be periodically reassessed for effectiveness.
- 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.

 **WARNINGS:**

- **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.
- **Risk of Fire** — The *Z1* must not be used closer than 1 meter to any oxygen source, to avoid the risk of fire and burns.
- **Risk of Reduced Safety and Performance** — The accessories covered in this document have been validated and approved for use with the *Z1*. Use of unapproved or incompatible parts or accessories may result in degraded performance.
The responsible organization (i.e. the care provider) is accountable for ensuring the compatibility of the ventilator and all parts used to connect to the patient before use.
- **Risk of Cross-Contamination** — The parts of the *Z1* system that constitutes the breathing gas pathway may become contaminated by the patient's exhalation gas or body fluids, in normal use as well as in single fault conditions.
Do not reuse the *Z1* to new patients, as it may cause cross-infection.
- **Risk of Asphyxiation** — Failure to use a mask or accessory that permits spontaneous breathing can cause asphyxiation.
- **Risk of Asphyxiation** — Failure to use a mask or accessory that minimizes rebreathing of carbon dioxide or permits spontaneous breathing can cause asphyxiation.
- **Precautions for Use of Humidification** — The humidifier must be placed lower than the patient, to prevent condensate and spillage water from flowing to the patient.
If using a breathing system filter, humidification can increase the resistance of the filter. The operator must monitor the breathing filter frequently for increased resistance or blockage to ensure the delivery of the therapeutic pressure.
- 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.

⚠ WARNINGS:

- 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 cmH₂O. In the unlikely event of certain fault conditions, pressures of up to 40 cmH₂O are possible.
- Blocking the **CPAP Tube** while in operation could lead to overheating of the **Z1**.

 **WARNINGS:**

- 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.

CAUTIONS:

- 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**.

 **WARNINGS:**

- 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 |
| 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 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**. 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 11 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

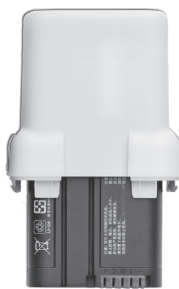


Z1 Unplugged

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 **End Cap** from the **Z1**. Hold the body of the **Z1** in one hand. With the other hand, squeeze firmly on the sides of the **End Cap** and pull it up and away from the **Z1**. (Figure 1)
2. Discard used **Filter**.
3. Remove the new **Filter** from its packaging.
4. Insert the **Filter** into the **End Cap**, aligning the arched side of the **Filter** with the top of the **End Cap**.
5. 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**.
6. Press the **End Cap** onto the **Z1**.

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

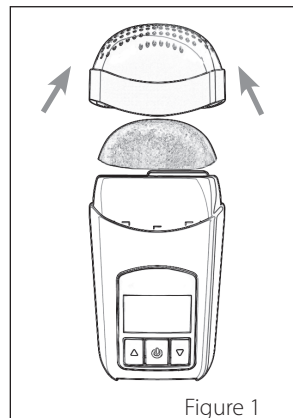


Figure 1

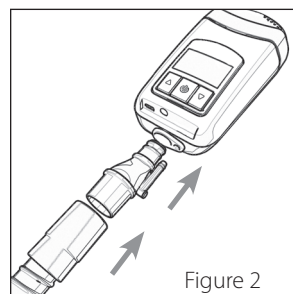


Figure 2

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)

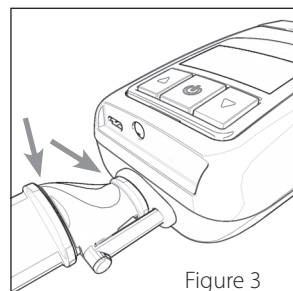


Figure 3

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.

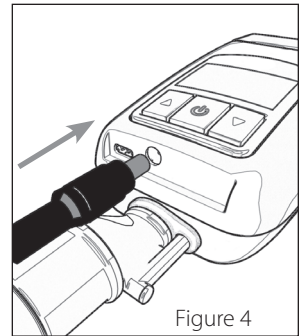


Figure 4

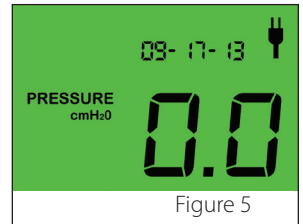


Figure 5

PowerShell and Battery (Available Separately)

⚠ 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.

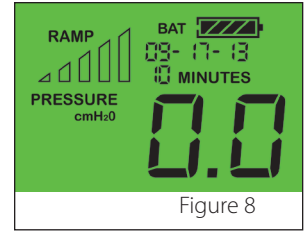


Figure 6



Figure 7

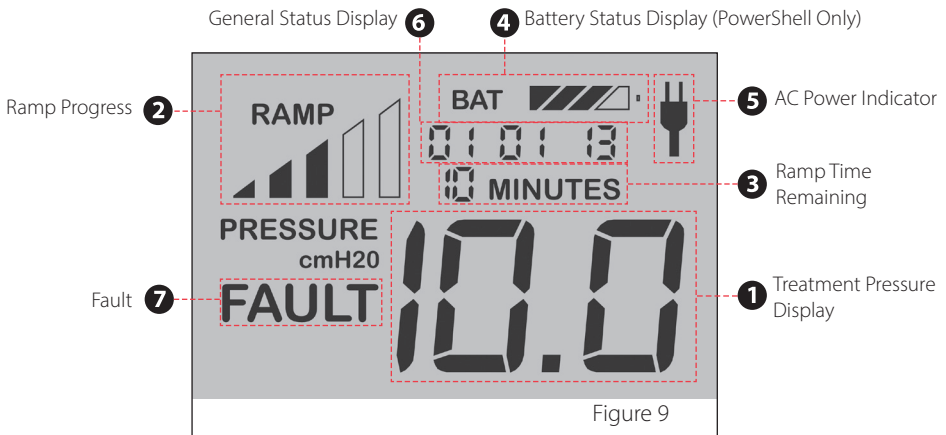
- The **Z1** will power up and cycle through a series of startup displays.
- After about 10 seconds, the **Z1** will enter standby mode. The display will read 0.0. (Figure 8)



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



1 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 cmH₂O is displayed in Figure 9.

2 Ramp Progress & 3 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.

4 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 63-90% of charge remaining. Make sure the *Battery* is fully charged before each use. The bars will stop flashing when the charging is complete.

| Number of Solid Bars | Charge Remaining |
|----------------------|------------------|
| 1 | 10-35% |
| 2 | 35-63% |
| 3 | 63-90% |
| 4 | 90-100% |


5 AC Power Indicator

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

6 General Status Display

In *Standby Mode*, this display field alternates between a display of the current date, the current function mode, the *Z-Breathe* setting and the *Auto Stop* feature. During treatment and while setting treatment parameters, this display field shows the currently selected function mode (*CPAP*) and *Z-Breathe* setting (1, 2 or 3).

The General Status Display field may also give notification of certain events which will NOT prevent the *Z1* from operating normally but may need to be addressed by the user.

| Code | Event | Resolution |
|---|--|--|
| FAIL 1 | Attempt to restart while motor is still running. | Wait at least 10 seconds before attempting to restart treatment again. |
| FAIL 2 | Attempt to set ramp start pressure while ramp time = 0. | Set ramp time to a minimum of 5 minutes to enable the ability to set ramp start pressure. |
| FAIL 3 | Attempt to save treatment pressure while device is locked. | Treatment pressure changes can only be made by a trained healthcare provider while the device is unlocked. |
|  dPR OFF | Data is no longer getting logged. Therapy will continue. | Internal battery needs replacement, so the device has stopped logging data. Call Breas to arrange for the battery to be replaced. Until then therapy will continue to be provided. |

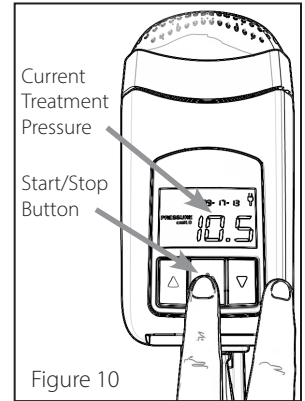
7 FAULT

"FAULT" is displayed if one of several conditions has occurred that require your attention. See "Fault Conditions" (page 23) for explanations of the FAULT codes.

Starting and Stopping Treatment

NOTE: Make sure that the patient interface is placed according to the instructions for the patient interface. Correct placement and positioning of the patient interface is critical for consistent 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 **Extended Life Battery** in the *PowerShell* is typically 8.9 hours or longer and treatment will terminate when the charge is expended.

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

Auto Stop Feature

The **Z1** is equipped with an **Auto Stop Feature**. This will stop the treatment automatically after the mask has been removed. To restart the treatment, place the mask back on your face and press the **Start/Stop Button**.

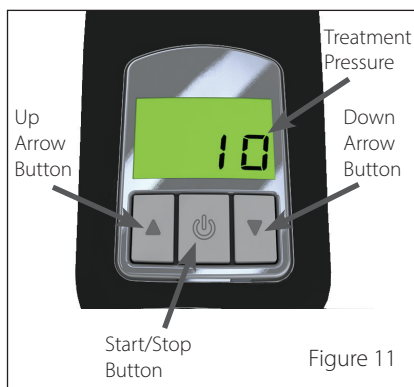
NOTE: The **Auto Stop Feature** will stop the therapy if a large air leak is detected between the **Z1** outlet and the mask. This may also happen at times when the mask is not being worn properly. This common condition should be resolved once all connections are secure, the mask is properly worn, and the **Start/Stop Button** has been pushed.

Setting the Auto Stop Feature

If you prefer to stop the **Z1** using the **Start / Stop Button**, you can disable the **Auto Stop Feature**. To do this press and hold the **Up Arrow Button** and **Down Arrow Button** at the same time until the **Z-Breathe** setting flashes. Release the buttons. Then press and hold the **Up Arrow Button** and **Down Arrow Button** at the same time again until **OFF-ON** flashes. Release both buttons and press the **Down Arrow Button** to change to **OFF-OFF**. Press and hold the **Start / Stop Button** to save the setting. To enable the feature, repeat the steps above, but press the **Up Arrow Button** to change to **OFF-ON**.

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.



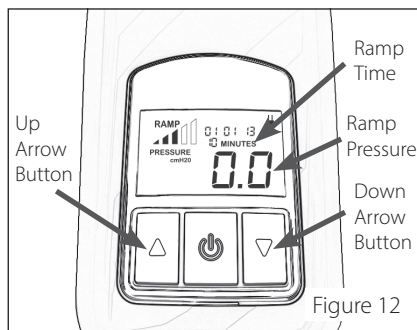
Programming Ramp Mode

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.

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.



NOTE: Ramp Time must be set to a minimum of 5 minutes prior to attempting to program Ramp Start Pressure or the change to Ramp Start Pressure will not take effect and "FAIL 2" will be shown in the General Status Display field.

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 cmH₂O increment. (Figure 12) 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.

User Software

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

Z-Breathe® Algorithm Selection

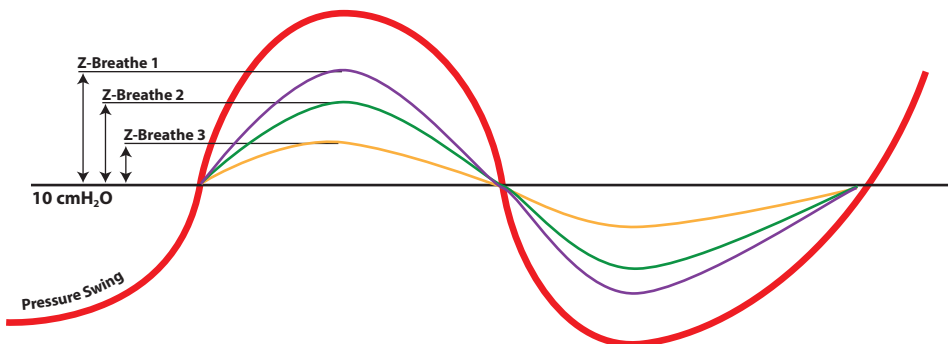
Z-Breathe is a proprietary algorithm engineered in the **Z1** to smooth out the breathing cycle while enjoying the benefits of CPAP therapy. Typically users experience pressure swings while breathing on a fixed pressure CPAP device. Pressure swings occur as a spike in pressure during exhalation and a drop in pressure during inhalation. Z-Breathe is designed to eliminate the spikes and drops while keeping the pressure constant, thereby delivering more comfortable therapy.

Pressure swings can vary between users and this is due to the lung capacity of the person breathing on the machine. Larger individuals will typically have greater lung capacity that will require a more aggressive setting and for this reason we have created 3 levels of Z-Breathe:

- **CPAP 1** offers mild pressure swing relief
- **CPAP 2** is the **Default Setting** and offers moderate pressure swing relief
- **CPAP 3** is the most aggressive setting for pressure swing relief

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", "CPAP - 2" or "CPAP - 3" 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.

The Z-Breathe settings in relation to the fixed pressure are illustrated in the following graph. We encourage you to experiment with the settings to achieve maximum comfort.



Charging the Battery (PowerShell Only)

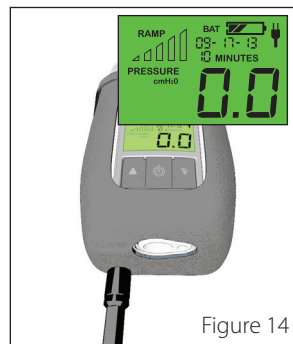
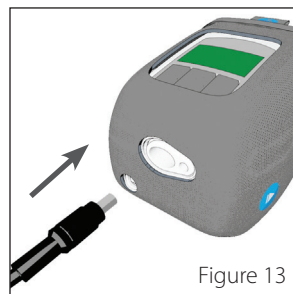
⚠ WARNING: Only charge the **Battery** with the supplied **Z1 PowerShell** and the supplied **Z1 Power Supply**. Do not use any other battery charger, AC adapter, or other device to charge the **Battery**.

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 8.9 hours or longer, after which treatment will terminate. To recharge the **Battery**, see “Charging the Battery”

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)

The battery status indicator will stop flashing when the battery is fully charged. Typically it will take 6.5 hours to fully charge the battery. After a few minutes, the back lit display will turn off. This is to conserve power. It does **not** indicate that the battery is fully charged.



NOTE: The battery will not charge if you are using the device at the same time.

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
- 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.

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**.

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.

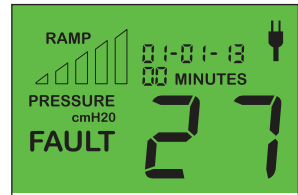


Figure 15

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 | <p>Power is not present. Ensure the Power Supply is connected and the power outlet has power.</p> <p>Loose connection of the Power Supply at the Z1 or loose connection of the Power Cord at the AC Adapter. Check the connections.</p> <p>Z1 is not locked into position in the PowerShell. Slide the Z1 into the PowerShell until it clicks and locks into place.</p> <p>Battery is not locked into position in the PowerShell. Slide the Battery into the PowerShell until the Battery Shuttle clicks and locks into place.</p> <p>Battery is not charged. Charge the Battery.</p> <p>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.</p> |

| Problem | Possible Causes & Solutions |
|---|---|
| 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. |
| Treatment Shuts Off | Treatment automatically turns off when the mask is removed. Replace the mask and push the Stop/Start button. If problem continues check for leaks in the connections between all of the pieces between the mask and the unit. Or turn off the Auto Stop Feature . |
| Insufficient Air Flow Delivered from Z1 | <p>Air filter is dirty or clogged. Replace air filter.</p> <p>Air intake is blocked. Clear blockage.</p> <p>CPAP Tube is not connected properly. Check CPAP Tube, Tube Adapter and connections to your Z1 and your mask.</p> <p>Ramp Mode is in use. Wait for air pressure to reach prescribed treatment pressure or stop treatment and adjust Ramp time.</p> <p>CPAP Tube is blocked, pinched or punctured. Unblock CPAP Tube. Check the CPAP Tube for punctures. Replace a damaged CPAP Tube immediately.</p> <p>Mask and/or headgear are not positioned correctly and mask is leaking. Adjust position of the mask and headgear until leak ceases.</p> <p>Incorrect CPAP Tube selected. Do not use tubing which was not recommended by your clinician.</p> <p>Check the display for a fault condition. Refer to fault codes in "Fault Conditions".</p> |
| Pressure Rises Inappropriately | <p>Talking, coughing or breathing in an unusual manner. For example, avoid talking with a nasal mask on and breathe as normally as possible.</p> <p>There may be an air leak caused by improperly connected tubing. Check for leaks.</p> <p>Follow mask manufacturer's instructions.</p> |
| Mask Cushion is Vibrating Against the Skin and an Air Leak is Occurring | <p>Stop treatment. Remove and reposition the mask and, if necessary, adjust the headgear. Resume treatment.</p> <p>Follow mask manufacturer's instructions.</p> |

| Problem | Possible Causes & Solutions |
|--|---|
| Noise from Mask | <p>Please note that the Z1 (like other small CPAP devices) has a very small motor that turns much faster than the CPAP you have at home to achieve the same therapeutic pressure. With some mask types it is possible that a different sound may be generated from the mask due the proximity of the vent holes and the velocity of air coming up the tube. Most users who have experienced this consider it to be white noise and a trade off for the convenience of the worlds smallest and lightest CPAP. If you experience this and it is a problem for you there are three steps that you can try to help minimize this:</p> <p>Try a standard bore (22mm) CPAP Tube. Often these larger bore tubes come with your home device and they are approved to use with your Z1.</p> <p>Use a stand alone Heated Humidifier with your Z1 while at home. The volume in the water chamber will greatly reduce any mask noise.</p> |
| 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 . |
| Electromagnetic Compability | The Z1 and PowerShell meet all applicable electromagnetic compatibility standards. However, if you suspect performance of the device is affected by interference from wireless sources, move the Z1 and PowerShell further away from those sources. |

Guidance and Manufacturer's Declaration Electromagnetic Emissions & Immunity

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in this document.

Z1 system does not have Essential Performance within the meaning of IEC 60601-1. However, immunity testing was conducted in accordance with IEC 60601-1-2 and compliance was confirmed as summarized in this document.

| Guidance and manufacturer's declaration - electromagnetic emissions | | |
|---|-------------------|---|
| The Z1 CPAP System is intended for use in the electromagnetic environment specified below. The customer or the user of the Z1 CPAP System should assure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment — guidance |
| RF emissions CISPR 11 | Group 1 | The Z1 CPAP System 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 Z1 CPAP System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |

WARNINGS:

- The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
- The use of cables and accessories (eg, humidifiers) other than those specified for the device is not recommended. They may result in increased emissions or decreased immunity of the device.


Guidance and manufacturer's declaration — electromagnetic immunity

The **Z1** CPAP System is intended for use in the electromagnetic environment specified below. The customer or the user of the **Z1** CPAP System should assure that 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 | ±6 kV contact ±8 kV air | ±6 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 | ±2 kV for power supply lines ±1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1 kV line(s) to line(s) ±2 kV line(s) to earth | ±1 kV line(s) to line(s) ±2 kV line(s) to earth | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5 % 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 | <5 % 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 | Mains power quality should be that of a typical commercial or hospital environment, If the user of the Z1 CPAP System requires continued operation during power mains interruptions, it is recommended that the Z1 CPAP System 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 location in a typical commercial or hospital environment. |
| NOTE: U_T is the a.c. mains voltage prior to application of the test level. | | | |

Guidance and manufacturer's declaration — electromagnetic immunity

The **Z1** CPAP System is intended for use in the electromagnetic environment specified below. The customer or the user of the **Z1** CPAP System should assure that it is used in such an environment.

| 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 150 kHz to 80 MHz | Portable and mobile RF communications equipment should be used no closer to any part of the Z1 CPAP System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$ |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2,5 GHz | 3 V/m 80 MHz to 2,5 GHz | $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 80 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b 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 **Z1** CPAP System is used exceeds the applicable RF compliance level above, the **Z1** CPAP System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **Z1** CPAP System.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Z1 CPAP System


The **Z1** CPAP System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Z1** CPAP System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Z1** CPAP System as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter m | | |
|--|--|--|---|
| | 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 $d = 2,3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance **d** in metres (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 separation distance for 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.

 **WARNING:** Please note that mobile RF communications equipment can effect medical electrical equipment.

Wireless Quality of Service for Z1 Bluetooth Communication with Z1 Mobile App

The Z1 and *Mobile App* utilize only a very small fraction of the available bandwidth and throughput. Based on this, the Z1 and *Mobile App* are highly tolerant of reductions in wireless quality of service and performance will not be affected until service is essentially lost; Wireless connectivity is not part of the essential performance of the Z1 performance. All functions of the Z1 can be performed on the Z1 unit itself; The *Mobile App* and Z1 are tested for coexistence with other in-band radio frequency sources; The Bluetooth hardware module is FCC listed, and complies with FCC PART 15 SUBPART C.

IC Notice

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

FCC Notice

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

European Conformity according to the Radio Equipment Directive (RED)

Hereby, Breas Medical AB declares that the radio equipment type included in this device is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address:
www.breas.com/declarations.

INDUSTRY CANADA NOTICE

This device complies with Industry Canada RSS-210 (Rev.8). Operation is subject to the following two conditions

- 1) this device may not cause interference, and
- 2) this device must accept any interference, including interference that may cause undesired operation of the device.

PAN131x is licensed to meet the regulatory requirements of Industry Canada (IC), license: IC 216Q-1316.

Technical Specifications

| | |
|-------------------------------------|--|
| 30W Power Adapter | Unit Input range 100–240V, 50–60Hz Typical power consumption 20W (30VA) Maximum power consumption 35W (70VA) |
| Operating temperature | 5°C to 35°C (41°F to 95°F) |
| 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 | -20°C to +60°C (-4°F to +140°F) |
| Storage and transport humidity | 10-95% 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 |
| Deliverable pressure accuracies | $\pm 0.6 \text{ cm H}_2\text{O} \pm 4\%$ 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 | 284 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 | 99.4 Watt-hours capacity Lithium Ion Battery Pack, 4S2P Weight approx. 440 g (15.5 oz.) |

Performance Specifications

| | |
|--|--|
| Operating pressure range | 4 to 20 cm H ₂ O |
| Maximum single fault steady pressure state | 40 cm H ₂ O |
| Deliverable static pressure accuracy | $\pm 0.6 \text{ cm H}_2\text{O} \pm 4\%$ of the measured reading |
| Dynamic pressure accuracy | +/- 1.5 cm H ₂ O |
| Maximum flow rate | > 80 L/min |

PowerShell with Extended Life Battery Specifications

Longevity (typical operating time)*

| Z-Breathe Setting | Treatment Pressure | Operating Time |
|-------------------|------------------------|----------------|
| 3 | 20 cm H ₂ O | 8.9 h |

* Results reflected were obtained via bench testing under simulated operating conditions at the highest machine settings. Actual run time may vary due to machine settings, machine pressure and personal breathing. Lower pressures will result in longer battery operating times.

| | |
|-----------------------------------|--|
| Capacity | 99.4 watt-hours |
| Life time | approximately 300 charge/discharge cycles |
| Shelf life | Batteries are shipped with between 30% and 50% rated capacity, providing a minimum of 6 months shelf life when stored at 25°C. If storage temperature exceeds 25°C over 6-month period then shelf life will be reduced and battery should be recharged periodically. |
| Storage and transport temperature | -20°C to +60°C (-4°F to +140°F) |
| Storage and transport humidity | 10-95% Relative Humidity, Non-Condensing |
| Battery Technology | Lithium Ion Battery Pack, 4S2P |
| Weight | Approx. 440 g (15.5 oz.). |
| Charging | Battery charges when Z1 not in use |

Symbol Explanation

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



Start/Stop



Serial number



Catalog number



Batch code



Caution



Class II equipment



Type BF equipment



Product disposal warning according to EN50419



Manufacturer



Date of Manufacture: YYYY-MM-DD



Read user instructions

IP22

Degree of protection provided by enclosure.



Direct current



Not for use on more than one patient



CE marking applies in accordance with the directive MDD 93/42/EEC



UK Conformity Assessed



Certified by Curtis-Straus

FCC ID

FCC Identifier

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 |
|------------------------------|------------------------|
| <i>Z1 device</i> | 3 years |
| <i>PowerShell</i> | 1 year |
| <i>Extended Life Battery</i> | 6 months |
| <i>Power Supply</i> | 1 year |

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.

Disposal

The Z1, any accessories and all replaced parts must be disposed of and recycled in accordance with the local environmental regulations regarding the disposal of used equipment and waste.

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, Extended Life Battery and Battery Shuttle. |
| Z1 Battery Module | 14.4V rechargeable lithium ion Extended Life 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) |
| 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 Power Cord, AU | AC Power Cord with Australian Plug |
| Z1 Plastic Filter End Cap | Z1 Filter Housing and Cover |

Contact Information

Breas Medical AB
Företagsvägen 1
SE 435 33 Mölnlycke
SWEDEN
www.breas.com
Phone:
Order:
Technical Support:
Email:

+46 31 86 88 00
+46 31 86 88 20
+46 31 86 88 60
breas@breas.com

If you are planning on using your Z1 on an airplane, please detach this letter and carry it with you.

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.

