Z2™ CPAP System

CONTINUOUS POSITIVE AIRWAY PRESSURE SYSTEM

User Guide

BREAS

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Z2™ by Breas

User Guide
English

Contents

Welcome to Your Z2 CPAP System

Thank you for choosing the ***Z2 CPAP System*** from ***Breas Medical***– designed, engineered, and assembled in the USA with you in mind.

The ***Z2*** is specially designed with these features:

- The ***Z2*** 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.
- Leak Compensation – the ***Z2*** automatically compensates for minor air leakage helping ensure the proper treatment pressure is maintained.
- Auto Altitude Adjustment – the ***Z2*** adjusts to altitudes up to 8000 ft above sea level.
- Air Travel – The ***Z2*** adjusts to an airplane's cabin pressure and is approved for use on airplanes.
- Upgradable Operating System– the ***Z2*** firmware and software can be easily updated via the ***USB Cable*** and your computer.

This User Guide will help you take advantage of the features and capabilities of this portable CPAP device. Please read this User Guide carefully before using your ***Z2***.

Owner/User Responsibility

The owner/user of the ***Z2 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 ***Z2*** other than in accordance with the operating instructions contained in the User Guide supplied.
- Unauthorized maintenance or modifications to the device or attached accessories.

Healthcare Provider Responsibility

Your healthcare provider is responsible for explaining contraindications and instructions for use to the patients/users.

Replacement Z2 Parts and Supplies

Use only genuine ***Z2*** replacement filters, parts and supplies. Replacement filters, parts and supplies can be purchased from a retail medical supplier or at www.smallcpap.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 ***Z2 CPAP System*** is a single user, reusable device that provides continuous positive airway pressure (CPAP) to support treatment of adults weighing over 66 lbs (30 kg) 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.

Z2 Warnings and Cautions

⚠ WARNINGS:

- Read the entire User Guide before using your ***Z2***. Consult your health care provider if there is any part of this User Guide you do not understand.
- US Federal law restricts this device to sale by or on the order of a physician.
- Use your ***Z2*** 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 ***Z2*** is not approved for use with oxygen. Do not use supplemental oxygen or any other type of supplementary gas with your ***Z2***. Do not connect supplementary oxygen or other gas to any accessory or patient interface which is connected to your ***Z2***.
- If you notice any unexplained changes in the performance of your ***Z2*** or your ***Z2*** is making unusual or harsh sounds, or if the ***Z2*** or ***Power Supply*** are dropped or mishandled, discontinue use and contact the Breas Medical Service Center at 1-855-436-8724.
- If your ***Z2***, ***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 the Breas Medical Service Center at 1-855-436-8724.
- A mask is not provided. Your ***Z2*** should only be used with masks and connectors recommended by your physician, clinician, respiratory therapist or health care provider.
- Your ***Z2*** 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 ***Z2*** is turned on and functioning properly, new air from the ***Z2*** flushes the exhaled air out through the mask vent holes. However, when the ***Z2*** is not operating properly (e.g., at low pressure) or the ***Z2*** 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 ***Z2*** 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 ***Z2*** with a mask unless the ***Z2*** is turned on. Once the mask is fitted, confirm that air is flowing from your ***Z2***.
- 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 ***Z2*** is an electrical device, and as such, you should not immerse your ***Z2***, ***Power Supply, PowerShell*** or ***Battery*** in water. Always unplug your ***Z2*** and its accessories before cleaning (and clean only as instructed in this User Guide)

and make sure your ***Z2*** 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 ***Z2***, ***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 ***Z2***, ***Power Supply***, ***PowerShell*** or ***Battery*** in the vicinity of flammable anesthetics or oxygen.
- Do not use your ***Z2*** near toxic or harmful vapors.
- Do not drop your ***Z2*** or any of its accessories or expose it to any crushing forces. Should your ***Z2*** be dropped and fail to operate properly, contact the Breas Medical Service Center at 1-855-436-8724 before using the ***Z2*** for treatment.
- Do not insert any object into any tubing or opening of your ***Z2*** except as described in this User Guide.
- Do not operate your ***Z2*** in any area which may block its air intake. Blocking the ***CPAP Tube*** and/or air inlet of your ***Z2*** while in operation could lead to overheating of the ***Z2***.
- If you put the ***Z2*** 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 ***Z2*** 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 ***Z2***, ***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 ***Z2*** away from hot or flammable surfaces, gases or materials.
- Do not open your ***Z2*** or tamper with its accessories. There are no user serviceable parts inside. Repairs and servicing should only be performed by an authorized Breas Medical service agent.
- Only power the ***Z2*** with the Breas Medical ***Power Supply*** (AC-to-DC power adapter) or the optional Breas Medical ***PowerShell*** with Breas Medical ***Battery***. Do not use any other AC adapters, batteries, or other power sources to power the ***Z2***. Do not use the Breas Medical ***Power Supply***, ***PowerShell*** or ***Battery*** to power any device other than the ***Z2***.
- Your ***Z2*** should only be used with standard or slim style 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 ***Z2*** except as described in this User Guide. Connecting other devices could result in injury to you or damage to the ***Z2*** and void the warranty.
- Do not locate your ***Z2*** in an unapproved place or where the air intake can be blocked during treatment. This will lead to overheating of the ***Z2***. 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 ***Z2*** 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 ***Z2***.
- In the clinical environment, any personal computer that is used with your CPAP system must be at least 5 feet (1.5 m) away from, or at least 8 feet (2.5 m) 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 ***Z2*** where it can be bumped or where someone is likely to trip over the power cord.
- Make sure your ***Z2***, ***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 ***Z2*** 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 ***Z2*** 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 ***Z2***. Replacement filters are available at your retail medical supplier or at www.smallcpap.com.
- Do not wash the air filter. The air filter is not washable or reusable.
- The ***End Cap*** protects the ***Z2*** in the event of a minor collision. Always ensure that the ***End Cap*** is securely fitted in accordance with instructions at all times. The ***Z2*** 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 ***Z2*** at room temperatures warmer than 90˚F (32˚C).

- Only operate the ***Z2*** 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 ***Z2*** 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.

Getting to Know Your Z2 CPAP System

Package Contents

Z2 CPAP Device

Power Supply (AC Adapter and Power Cord)

Custom USB A to Micro B Cable

Custom CPAP Tube Adapter

4 ft. Slim Style CPAP Tube

Filters (2- 1 installed in Z2, 1 in box)

Heat / Moisture Exchanger (HME)

Qtube Muffler

8 in. Slim Style CPAP Tube

Z2 CPAP Quick Start Guide

Z2 CPAP User Guide

Z2 CPAP Device

The ***Z2*** supplies continuous positive airway pressure and can be programmed to fit the patient's prescriptive needs.

Power Supply (AC Adapter and Power Cord)

The ***Power Supply*** provides power to the ***Z2***. It takes AC power (voltage ranging from 100-240 volts) from a wall outlet and converts it to DC voltage to power the ***Z2***. 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 ***Z2***.

CPAP Tube

The ***Z2 System*** is provided with a 4 ft slim style ***CPAP Tube***. The ***CPAP Tube*** connects the ***Z2*** 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.

Filter

The ***Z2*** uses a specially designed filter. The material has been specifically chosen for the ***Z2*** 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 ***Z2***, which was designed to allow for more effective filter surface area.

For proper operation of the ***Z2***, the ***Filter*** should be replaced monthly or more often if necessary.

USB A to Micro B Cable

The ***USB Cable*** allows the ***Z2*** to communicate with a computer to collect and view user data. It can also be used to install new firmware when it becomes available.

Heat Moisture Exchanger (HME)

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

To install the ***HME***, connect the large diameter end of the ***HME*** to your mask and the smaller diameter end to your ***CPAP Tube***. Be sure both connections are fully seated and secure. Store the ***HME*** in a sealed plastic bag between uses to extend its life. Discard after 7 days or when it is no longer providing humidification.

Qtube Muffler

The ***Qtube*** is a single patient reusable accessory designed to reduce acoustic noise which may be transmitted to the patient mask through the CPAP tube. The ***Qtube*** has standard end fittings and may be used with any standard (22mm) or slim-style (15 mm) CPAP tube. The ***Qtube*** comes ready for use with the foam baffling material installed. Instructions for dissassembling the ***Qtube*** can be found at ***https://breas.us/cpap-user-guides-and-software/***. Replacement foam can be purchased at your retail medical supplier or at www.smallcpap.com.

The ***Qtube*** is designed to be used with the waterless ***HME*** humidifier. If a water-based humidifier is used special care must be used to dry the foam insert between uses.

PowerShell (Optional Accessory)

The ***PowerShell*** houses both the ***Z2*** and the ***Battery*** which allows temporary usage of the ***Z2*** without the ***Power Supply***. It can be purchased at your retail medical supplier or at www.smallcpap.com.

Set Up Guide

Unpacking the Z2 Box

You will need to perform a few minor setup steps before using your new ***Z2***. 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 ***Z2*** to you. If you have any questions or problems as you go through the setup process, please call Breas Medical Customer Service at 1-855-436-8724 for assistance. Breas Medical wants your user experience with the ***Z2*** to be trouble and frustration free.

1. Carefully remove the contents of the box.
2. Some of the ***Z2*** 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 7 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 Medical Customer Service at 1-855-436-8724, or your service or health care provider before use.
4. Place all the components in an area where you can easily access the ***Z2*** 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.

Z2 CPAP - Assembling and Powering Up

Filter and End Cap

Your ***Z2*** comes with the first filter already installed. Replacement filters may be installed as follows:

1. Remove the ***End Cap*** from the ***Z2.*** Hold the body of the ***Z2*** in one hand. With the other hand, squeeze firmly on the sides of the ***End Cap*** and pull it down and away from the ***Z2***.
2. Discard used ***Filter***.
3. Remove new ***Filter*** from its packaging.
4. Insert the new ***Filter*** into the ***End Cap***, aligning the arched side of the ***Filter*** with the top of the ***End Cap***.

   Ensure the ***Filter*** covers all holes in the ***End Cap***, so that all air entering the ***Z2*** passes through the ***Filter*** and no air bypasses the ***Filter***.
5. Press the ***End Cap*** onto the ***Z2***. (Figure 1)

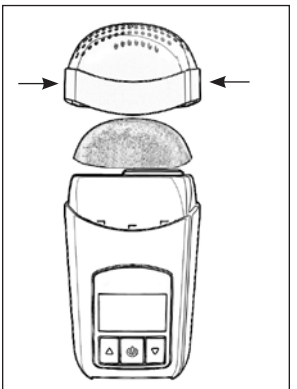


Figure 1

Tube Adapter, Qtube, CPAP Tube, HME and Mask

1. Connect one end of the ***8" CPAP Tube*** to the round end of the ***Tube Adapter*** then insert the other end of the ***Tube Adapter*** into the outlet of the ***Z2***. (Figure 2)
2. Connect the other end of the ***8" CPAP Tube*** to one end of the ***Qtube.*** Connect the other end of the ***Qtube*** to the ***4' CPAP Tube.*** Connect the end of the ***4' CPAP Tube*** to the ***HME*** and the ***HME*** to the mask. (Figure 3)
3. Ensure all connections are tight to avoid air leaks. (Figure 4)

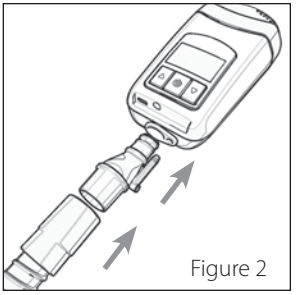


Figure 2

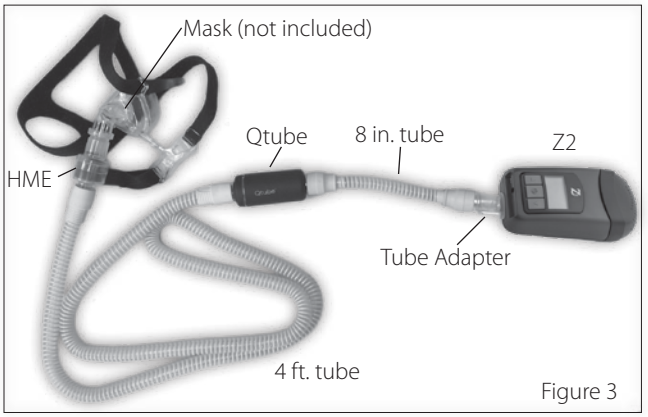


Figure 3

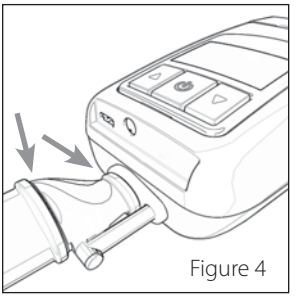


Figure 4

Power Supply

> ⚠ **WARNING:** The ***Z2*** must only be used with the Breas Medical ***Power Supply*** (or the optional Breas Medical ***PowerShell*** and ***Battery***). DO NOT use any other power source with the ***Z2***.

> **CAUTION:** Make sure the AC power cord IS NOT plugged into a wall outlet before continuing to the next step.

1. Plug the AC power cord into the AC Adapter.
2. Plug the power cord into a wall outlet.
3. Plug the AC Adapter into the ***Z2***. (Figure 5)
4. The ***Z2*** will power up and cycle through a series of startup displays.
5. After about 10 seconds, the ***Z2*** will enter standby mode. The display will read 0.0. (Figure 6)

> **NOTE:** The ***Z2*** display will be active whenever the device is receiving power.

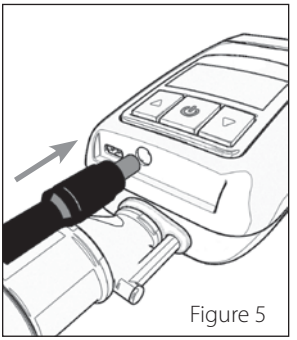


Figure 5

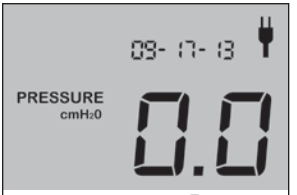


Figure 6

Using Your Z2

LCD Display

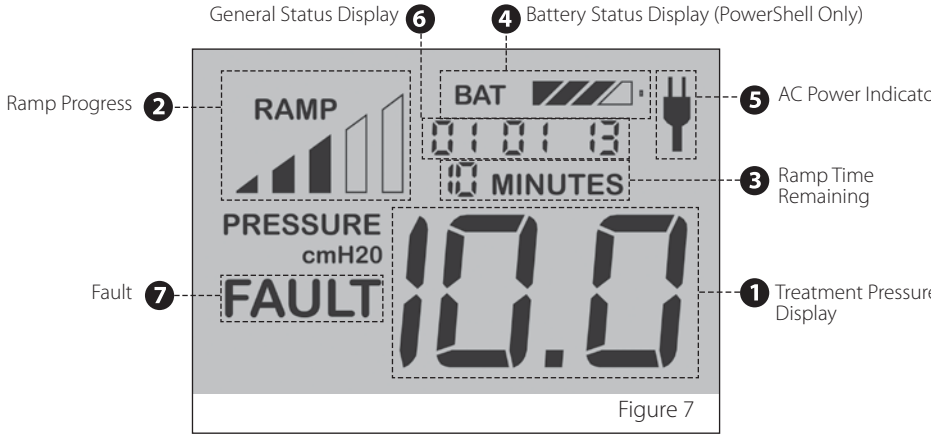


Figure 7

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 ***Z2***'s memory even during loss of power. For example, a treatment pressure setting of 10.0 cm H_2O is displayed in Figure 7.

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 ***Z2*** for Ramp Mode, the Ramp Progress and Ramp Time Remaining indicators will appear on the LCD display. For example, Figure 7 indicates that the ramp is just over half complete, with a ramp time remaining of 10 minutes.

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 7 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%

❺ AC Power Indicator

This icon is displayed when the ***Z2*** is connected to an AC power outlet via the ***Power Supply***.

❻ 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 ***Z2*** 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.
dAtA 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.

❼ FAULT

"FAULT" is displayed if one of several conditions has occurred that require your attention. See Fault Conditions (page 16) for explanations of the FAULT codes.

Starting and Stopping Treatment

1. Press the ***Start/Stop Button*** on the ***Z2*** to initiate treatment using the pre-programmed prescription 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 ***Z2*** ramps up to prescribed treatment pressure. If the incorrect pressure is displayed, contact your health care provider before commencing CPAP therapy. (Figure 8)
2. Press the ***Start/Stop Button*** a second time to stop treatment.

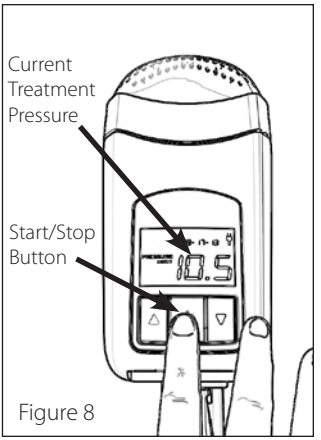


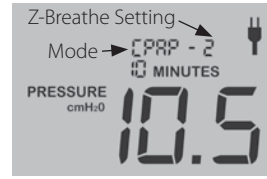
Figure 8

Auto Stop Feature

The ***Z2*** 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 ***Z2*** 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.

Choosing Between Z-Breathe® settings



The ***Z-Breathe*** setting of 1-3 is indicated by the number following the CPAP designation on the LCD screen. For example CPAP-2 means the CPAP mode with a ***Z-Breathe*** setting of 2 (Figure 9) To set the Z-Breathe setting, press and hold down the ***Up Arrow Button*** and ***Down Arrow Button*** simultaneously while in the Standby mode (pressure of "0.0" indicated on the display). Once you see the Function Mode indicator flashing on the LCD screen, you can select the desired ***Z-Breathe*** setting using the ***Up Arrow Button*** and ***Down Arrow Button***. After you have made your selection, press and hold the ***Start/Stop Button*** to save it.

Your selected setting for ***Z-Breathe*** will be retained in the memory of your ***Z2*** unit after it is turned off. The currently selected ***Z-Breathe*** setting will be displayed when the ***Z2*** is delivering treatment pressure.

Z-Breathe is a proprietary algorithm engineered in the ***Z2*** to smooth out the breathing cycle while enjoying the benefits of CPAP treatment. Typically users experience pressure swings while breathing on a CPAP device. Pressure swings occur as a spike in pressure during exhalation and a drop in pressure during inhalation. ***Z-Breathe*** is designed to minimize the impact of spikes and drops while keeping the pressure constant, thereby delivering more comfortable therapy.

Pressure swings can vary between users due to lung capacity and other factors. For this reason we have created 3 levels of ***Z-Breathe*** to accommodate individual users' preferences:

— 1 offers mild pressure swing relief

— 2 is the Default Setting and offers moderate pressure swing relief

— 3 is the most aggressive setting for pressure swing relief

Setting the Auto Stop Feature

If you prefer to stop the ***Z2*** 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 AOFF-ON flashes. Release both buttons and press the ***Down Arrow Button*** to change to AOFF-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 AOFF-ON.

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 ***Z2*** 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 10) Set the ramp time to "00 MINUTES" to disable the Ramp Mode.

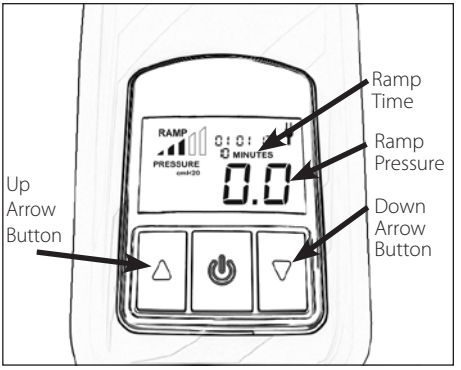


Figure 10

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 ***Z2*** is not powered). The ***Z2*** 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 cm H_2O increment. (Figure 10) 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 ***Z2*** 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

Breas Medical provides User Software for data viewing which may be downloaded from the Breas Medical website to any Windows computer. A separate user guide for this software is available for download at the Breas Medical website, www.breas.us.

Care

The ***Z2 System*** needs periodic care. It is the user's responsibility to be aware of the following items for care:

- Inspections
- Cleaning

- ***Filter*** Replacement
- Fault Conditions

Inspections

Before each use carefully inspect the ***Z2***, ***CPAP Tube***, ***Filter***, and mask for signs of wear, damage or discoloration. Contact your retail medical supplier or at www.smallcpap.com for replacement parts.

Cleaning

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

> ⚠ **WARNING:** This device can expose you to electrocution. Do not immerse the ***Z2***, ***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 ***Z2***. 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, Qtube*** and the mask from the ***Z2***.
2. Wash the ***CPAP Tube*** in warm water using mild detergent.
3. Rinse thoroughly, hang, and allow to dry.
4. Remove the inner foam sound baffling material from the ***Qtube*** to allow it and the interior of the unit to dry after each use. The disassembled ***Qtube*** and ***foam insert*** can be washed with mild detergent and water and let air dry thoroughly. Particular care should be taken to ensure that the ***Qtube*** is completely dry after replacement of inner foam sound baffling material. See ***https://breas.us/cpap-user-guides-and-software/*** for instructions on how to disassemble the ***Qtube.*** Inspect the foam and replace if there are tears or signs of wear. Replacement foam can be purchased at your medical retail store or at www.smallcpap.com
5. Before next use, reconnect the ***Qtube***, ***CPAP Tube*** and the ***Tube Adapter*** to the ***Z2*** and mask.

> **NOTE:** Soaking the CPAP Tube in water for longer than 10 minutes may shorten the life of the tube.

Every 90 days

The CPAP tube should be replaced every 90 days or earlier if it becomes discolored, cracked or damaged.

> **CAUTION:** Do not use bleach, chlorine, alcohol, or aromatic-based solutions, moisturizing or antibacterial soaps or scented oils to clean the CPAP tube. Never attempt to clean the CPAP tube with any of these solutions. These solutions may cause damage and reduce the life of the CPAP tube.

CAUTION: Prolonged exposure to sunlight may cause the CPAP Tube to discolor and degrade

As Needed

1. Clean the exterior of the ***Z2*** with a soft damp cloth and mild detergent and wipe clean. Never submerge the ***Z2*** in water. Do not allow soap or water to enter the ***Z2***.

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 *Z2* uses a specially designed Filter that is only available from your retail medical supplier or at www.smallcpap.com.

⚠ **WARNING:** Do not attempt to use any air filter which is not supplied by Breas Medical for the ***Z2***. The ***Z2*** is designed to only work with approved materials. A filter which is not approved may cause damage to the ***Z2*** from overheating.

CAUTION: Do not operate the ***Z2*** without the ***Filter***. The ***Z2*** must operate with a filter installed; failure to do so may damage the ***Z2*** and allow impurities into the respiratory system.

Fault Conditions

The ***Z2*** has the ability to detect operational problems and will display the word FAULT on the LCD screen. (Figure 11)

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.

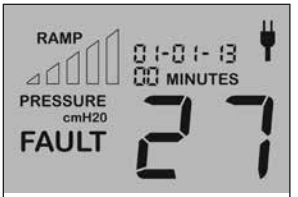


Figure 11

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	Let cool. Check to see if the fault code goes away. 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.*

*Breas Medical Service Center at 1-855-436-8724.

USB Firmware Upgrade

Z2 firmware upgrades and instructions can be found on www.breas.us when they become available.

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 ***Z2*** or loose connection of the ***Power Cord*** at the AC Adapter. Check the connections. ***Z2*** is not locked into position in the ***PowerShell***. Slide the ***Z2*** 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 ***Z2*** is connected to the ***Z2***. Remove the power supply unit and replace with a Breas Medical approved unit.
Treatment Will Not Start	Check the display for a fault condition. Refer to the Fault Codes table in "Fault Conditions". Contact the Breas Medical Service Center at 1-855-436-8724
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 ***Z2***	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 ***Z2*** 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 and Air Leak is Occurring	Stop treatment. Remove and reposition the mask and, if necessary, adjust the headgear. Resume treatment. Follow mask manufacturer's instructions.
Z2 Has Been Left in a Hot Environment	Allow ***Z2*** to cool before use. Disconnect the power cord and then reconnect it to restart the ***Z2***.
Electromagnetic Compatibility	The ***Z2*** 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 ***Z2*** 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.

The ***Z2*** 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 ***Z2*** CPAP System is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Z2*** System should assure that it is used in such an environment.

Emissions test	**Compliance**	**Electromagnetic environment — guidance**
RF emissions CISPR 11	Group 1	The Z2 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 Z2 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 ***Z2*** CPAP System is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Z2*** 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 % UT (>95 % dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ***Z2*** CPAP System requires continued operation during power mains interruptions, it is recommended that the ***Z2*** 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: UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration — electromagnetic immunity

The *Z2* CPAP System is intended for use in the electromagnetic environment specified below. The customer or the user of the *Z2* CPAP System should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the *Z2* CPAP System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF	3 Vrms	3V	$d = 1.2\sqrt{P}$
IEC61000-4-6	150 kHz to 80 MHz		$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF	3 V/m	3V/m	$d = 2.3\sqrt{P}$ 80 MHz to 2.5 GHz
IEC 61000-4-3	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 meters (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 Z2 CPAP System is used exceeds the applicable RF compliance level above, the Z2 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 Z2 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 Z2 CPAP System

The Z2 CPAP System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Z2 CPAP System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Z2 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	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
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 meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the 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.

⚠ **WARNINGS**:

Please note that mobile RF communications equipment can affect medical electrical equipment.

Wireless Quality of Service for Z2 Bluetooth Communication with Z2 Mobile App

The ***Z2*** and Mobile App utilize only a very small fraction of the available bandwidth and throughput. Based on this, the ***Z2*** 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 ***Z2.*** All functions of the ***Z2*** can be performed on the ***Z2*** unit itself. The Mobile App and ***Z2*** 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.

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.

Technical Specifications

30W Power Adapter	Unit Input range 100–240V, 50–60Hz Typical power consumption 20W (30VA) Maximum power consumption 35W (70VA)
Operating temperature	41°F to 95°F (5°C to 35°C)
Operating humidity	10–80% Relative Humidity, Non-Condensing
Operating altitude	Sea level to 8,000 ft (2,433 m)
Operating atmospheric pressure	101 to 75.3 kPA
Storage and transport temperature	-4°F to +140°F (-20°C to +60°C)
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	±0.6 cm H_2O ± 4% of the measured reading
Sound pressure level	26 dBA
Nominal dimensions (L x W x H)	6.48" X 3.30" X 2.02" (16.46 cm x 8.38 cm x 5.13 cm)
Weight	10 oz. (238 g)
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 Battery charges when Z2 not in use.

Performance Specifications

Operating pressure range	4 to 20 cm H2O
Maximum single fault steady pressure	30 cm H2O
Pressure accuracy	±(0.6 cm H2O + 4% of the measured reading)

Bluetooth Specifications

Panasonic Electronic Components
Bluetooth Module + BLE HCI W/ANTENNA

FCC ID	T7V1315
FCC Compliance	FCC PART 15 SUBPART C
Frequency	2400-2483.5 MHz
Modulation or Protocol	Bluetooth Low Energy, V4.0
Over the air data rate	1 Mbit/s
Application throughput	0.27 Mbit/s
Security	128-bit AES with Counter Mode CBC-MAC and application layer user defined
Robustness	Adaptive frequency hopping, Lazy Acknowledgement, 24-bit CRC, 32-bit Message Integrity Check

Latency (from a non-connected state)	6ms
Power-Output	10dBm
Sensitivity	-93dBm
Standard	IEEE 802.15.1

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

 Refer to Manual  type BF equipment;  Class II equipment;  Start/stop; IP22 Ingress Protection (IP) Rating;  Manufacturer;  Date of manufacture; **LOT** Batch code; **REF** Catalog number; **SN** Serial number;  Direct current;  Disengagement Mechanism; **RX ONLY** Prescription only (In US. Federal law restricts these device to sale by or on order of a physician); **FCC ID** FCC Identifier.

Servicing

The ***Z2 System*** is intended to provide safe and reliable operation when operated in accordance with the instructions provided by Breas Medical. Breas Medical recommends that the ***Z2 System*** be inspected and serviced by an authorized Breas Medical Service Center if there is any sign of wear or concern with ***Z2*** function. Otherwise, service of the ***Z2*** generally should not be required during the warranty period (see 'Limited Warranty' for details) of the device.

Limited Warranty

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

Item	Warranty Period
Z2 CPAP device	2 years
PowerShell	1 years
Extended Life Battery	6 months
Power Supply	1 years

If product fails to perform in accordance with product specifications, Breas Medical 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 Medical 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 Medical 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 calling Breas Medical service support at 1-855-436-8724.

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 OR STATES 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 your local Breas Medical dealer or Breas Medical office at 1-855-436-8724.

Contact Information

Breas Medical, Inc.
16 Esquire Road
N. Billerica, MA 01862
www.breas.us

BREAS

Main phone (customer service): 1-855-436-8724
Service support or warranty coverage: 1-855-436-8724
Email: supportUS@breas.com

If you are planning on using your Z2 on an airplane, please detach this letter and carry it with you.

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 Z2 CPAP System. The Z2 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.

* Z2 Bluetooth must be in the off (airplane mode) position similar to any other mobile device to maintain compliance

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BREAS

Mail completed form to:

Product Registration

Breas Medical, Inc.

16 Esquire Road

N. Billerica, MA 01862

Register your new device.

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

About you.

NAME:

First MI Last

EMAIL ADDRESS:

MAILING ADDRESS:

Street or PO Box

City State Zip

PHONE NUMBER:

About the device.

WHAT DEVICE DID YOU PURCHASE?

WHERE DID YOU PURCHASE THE DEVICE?

PURCHASE DATE:

____/____/____

[MM/DD/YY]

Z2 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**

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