

# Z2 Auto<sup>®</sup> System

## AUTO-ADJUSTING CONTINUOUS POSITIVE AIRWAY PRESSURE SYSTEM Clinician's Guide

### 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 Auto System** is a single patient, 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 healthcare 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 healthcare 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 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 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 healthcare 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 healthcare 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 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 service agent.
- Only power the **Z2** with the Breas **Power Supply** (AC-to-DC power adapter, 005755) or the optional Breas **PowerShell** with Breas **Battery**. Do not use any other AC adapters, batteries, or other power sources to power the **Z2**. Do not use the Breas **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 healthcare 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<sub>2</sub>O. In the unlikely event of certain fault conditions, pressures of up to 30 cm H<sub>2</sub>O 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 **Z2** 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 1-855-436-8724.
- 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.

## 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 the Breas Service Center at 1-855-436-8724 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 Breas **PowerShell** and the supplied Breas **Power Supply**. Do not use any other removeable battery charger, AC adapter, or other device to charge the **Battery**.
- Do not attach the **Battery** directly to a vehicle cigarette lighter or to the **Power Supply** plug.
- Do not continue charging the **Battery** if it does not recharge within the specified charging time. Doing so may cause the **Battery** to become hot, rupture or ignite.
- Remove the **Battery** from the **PowerShell** if the **Z2** is not likely to be used for some time. Do not use the **Battery** to power any device other than the **Z2**.
- Only use or charge the **Battery** within the operating temperature, humidity and altitude conditions specified in the Technical Specifications section of this User Guide.
- Only store or transport the **Battery** within the storage and transport temperature and humidity conditions specified in the Technical Specifications section of this User Guide.

### **CAUTION:**

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

# Clinician's Set Up Steps

To set-up the **Z2 Auto** for patient delivery, please follow the steps in the order listed below based on the physician prescription. Detailed instructions are on the following pages.

## 1. Turn on Bluetooth®

Turn the Bluetooth on (BT on) for use with Nitelog®

## 2. Unlock Z2 Device

To enable Mode and Pressure setting  
Device re-locks after each power cycle

## 3. Set Mode

Choose the APAP or CPAP mode.

## 4. Set Pressure

A Minimum and Maximum (min/max) pressure setting is required for APAP and default is 4 and 10 cm H<sub>2</sub>O.  
A fixed pressure setting is required for CPAP and default is 8 cm H<sub>2</sub>O.

## 5. Set Ramp Time

If ordered, set the ramp time (0-45 min) or patient may chose after delivery.  
Default is 15 min for APAP and no ramp for CPAP.

## 6. Set Ramp Start Pressure

This is typically used in CPAP mode to accommodate for Ramp settings.  
Default is 4 cm H<sub>2</sub>O for both APAP and CPAP.

## 7. Set Z-Breathe®

If ordered, set the Z-Breathe to APAP 1, 2 or 3 (default is APAP-3).  
If using CPAP mode, the choices are CPAP 1, 2 or 3 (default is CPAP-2).

## 8. Set the Auto Start / Stop Feature

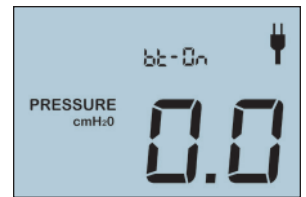
The Auto Start / Stop Feature can be turned off or on based on the patient's preference.

## 1. Turn on Bluetooth

In order for the **Z2** to connect to the **Z2 Nitelog® Mobile App**, the **Z2's** Bluetooth must be turned on. Once the **Z2** has connected to the **NiteLog App** via Bluetooth, access between the **NiteLog App** and **Z2** device is password protected. If the password is incorrect the Mobile App will be denied access to the **Z2** device.

Immediately after plugging the Power Adapter into your **Z2**, hold the **Up Arrow Button**. "bt-On" will display on the screen to indicate your Bluetooth has been turned on. (Figure 1)

To turn off the Bluetooth capability on your **Z2** (Airplane Mode), unplug the **Power Adapter** from your **Z2**. Plug your **Power Adapter** back into your **Z2** and immediately hold down the **Down Arrow Button**. "bt-Off" will display on the screen to indicate your Bluetooth has been turned off. (Figure 2)



(Figure 1)

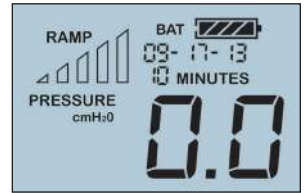


(Figure 2)

## 2. Unlock Z2 Device

The device is locked after each power cycle. In order to modify the treatment pressure settings and switch between function modes, you may follow the instructions below to unlock the **Z2** device.

1. Power up the **Z2** device, hold **Start/Stop** button while in standby mode (pressure of "0.0" indicated on the display) (Figure 3) to enter Treatment Pressure Setting mode (APAP-LOC (Figure 4) or CPAP-LOC (Figure 5)).
2. Hold **Up and Down Buttons** at the same time while in Treatment Pressure Setting mode to unlock the **Z2** device. (Figures 6 & 7) To continue set the CPAP treatment pressure or APAP-High/Low, please see Section "Setting the Treatment Pressure in CPAP Mode" and "Setting the Minimum and Maximum Pressures in APAP Mode" for details.



(Figure 3)



(Figure 4)

## 3. Set Mode

### Choosing Between CPAP Mode or APAP Mode

If the **Z2** device is locked, you need to unlock the device before switching function modes. To unlock the **Z2** device, please see section "Unlock Z2 Device" for details.

The mode, CPAP or APAP is set simultaneously with the selection of the **Z-Breathe** setting.

APAP mode is designated by the word "APAP" on the LCD screen and CPAP is designated by the word "CPAP" on the LCD screen. The **Z-Breathe** setting of 1-3 is indicated by the number following the APAP or CPAP designation on the LCD screen. For example, APAP-2 means APAP mode with **Z-Breathe** setting of 2 (Figure 8) and CPAP-3 means the CPAP mode with a **Z-Breathe** setting of 3. (Figure 9) To set the APAP or CPAP mode and **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 CPAP or APAP indicator on the LCD screen, you can select the desired mode and **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.



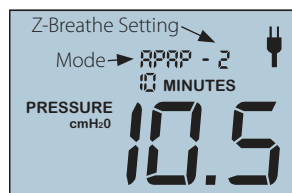
(Figure 5)



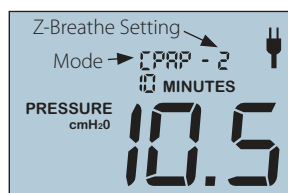
(Figure 6)



(Figure 7)



(Figure 8)



(Figure 9)

## 4. Set Pressure

### Setting the Treatment Pressure in CPAP Mode

If the **Z2** device is locked, you need to unlock the device before modifying CPAP treatment pressure. To unlock the **Z2** device, please see section "Unlock Z2 Device" for details.

1. Once you have chosen the CPAP mode you can set your CPAP Treatment Pressure. To do this, press and hold down the **Start/Stop Button** while in standby mode (pressure of "0.0" indicated on the display). You will see the current treatment pressure setting flashing on the LCD display with the words "CPAP" above the pressure value. (Figure 10) Use the **Up Arrow Button** and **Down Arrow Button** to adjust the pressure settings then press and hold the **Start/Stop Button** to save it.
2. You will then be returned to standby mode and can start your treatment at any time by pressing the **Start/Stop Button**.

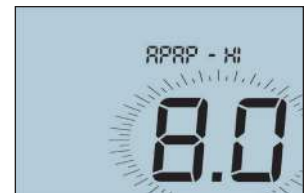


(Figure 10)

### Setting the Minimum and Maximum Pressures in APAP Mode

If the **Z2** device is locked, you need to unlock the device before modifying APAP maximum and minimum pressures. To unlock the **Z2** device, please see section "Unlock Z2 Device" for details.

1. Once you have chosen the APAP mode you can set your Maximum and Minimum treatment pressures. To do this, press and hold down the **Start/Stop Button** while in standby mode (pressure of "0.0" indicated on the display). You will see the current maximum pressure setting flashing on the LCD display with the words "APAP HI" above the pressure value. (Figure 11) Use the **Up Arrow Button** and **Down Arrow Button** to adjust the pressure settings then press and hold the **Start/Stop Button** to save it.
2. Once the maximum pressure has been saved, you can adjust and save the minimum pressure. You will see the current minimum pressure setting flashing on the LCD display with the words "APAP LO" (Figure 12) above the pressure value. Use the **Up Arrow Button** and **Down Arrow Button** to adjust the pressure settings then press and hold the **Start/Stop Button** to save it.
3. You will then be returned to standby mode and can start your treatment at any time by pressing the **Start/Stop Button**.



(Figure 11)



(Figure 12)

## 5. Set Ramp

### 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 13) 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 **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.

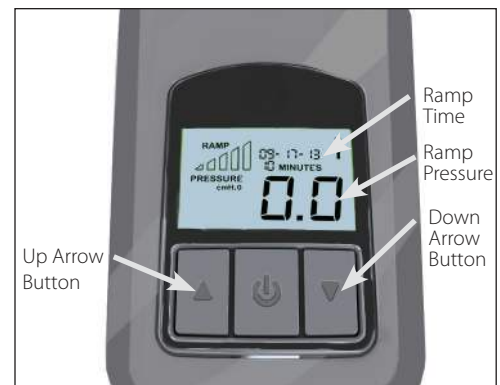


Figure 13

## 6. Set 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<sub>2</sub>O increment. (Figure 13) 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.

## 7. Set Z-Breathe®

The Function Mode Setting is shown in the General Status Display field on the LCD. APAP mode is designated by the word “APAP” and CPAP is designated by the word “CPAP”.

**NOTE:** Function Modes can ONLY be set by a healthcare provider.

The **Z-Breathe** setting of 1-3 is indicated by the number following the APAP or CPAP designation on the LCD screen. For example, APAP-2 means APAP mode with **Z-Breathe** setting of 2 (Figure 14) and CPAP-3 means the CPAP mode with a **Z-Breathe** setting of 3. (Figure 15) 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 the **Z-Breathe Algorithm** will be retained in the memory of your Z2 unit after it is turned off. The currently selected **Z-Breathe Algorithm** 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

## 8. Set Auto Start / Stop

The Z2 is equipped with an **Auto Start / Stop** feature. This feature will start the treatment automatically when the mask is placed on the face and you start to breathe. It will stop the treatment after the mask has been removed. To restart the treatment, place the mask back on your face and start to breathe through the mask.

The Z2 is shipped with this setting turned on. See Setting **Auto Start / Stop** Feature (below) for instructions on turning it off or on.

**NOTE:** The **Auto Start / 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 or you start breathing into the mask.

**NOTE:** The **Auto Start / Stop** feature may not work with the use of a full face mask due to its design. In this case you will need to press the **Start/Stop Button** to start the therapy.

If you prefer to start and stop the Z2 using the **Start / Stop Button**, you can disable the **Auto Start / 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 **POFF-ON** flashes. Release both buttons and press the **Down Arrow Button** to change to **POFF-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 **POFF-ON**.

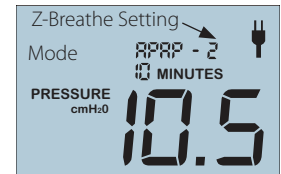


Figure 14

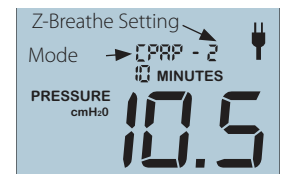


Figure 15



## 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** Auto 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.

<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment — guidance</b>
RF emissions CISPR 11	Group 1	The Z2 Auto 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 Auto 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** Auto System is intended for use in the electromagnetic environment specified below. The customer or the user of the **Z2** Auto System should assure that it is used in such an environment.

<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment – guidance</b>
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 <b>Z2</b> Auto System requires continued operation during power mains interruptions, it is recommended that the <b>Z2</b> Auto 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 Auto System is intended for use in the electromagnetic environment specified below. The customer or the user of the Z2 Auto System should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Z2 Auto System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> $d = 1.2 \sqrt{P}$ <p><math>d = 1.2 \sqrt{P}</math> 80 MHz to 800 MHz</p> $d = 2.3 \sqrt{P}$ 80 MHz to 2.5 GHz <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	

**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.

<sup>a</sup> 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 Auto System is used exceeds the applicable RF compliance level above, the Z2 Auto 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 Auto System.

<sup>b</sup> 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 Auto System

The Z2 Auto System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Z2 Auto System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Z2 Auto 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 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 Nitelog® App

The Z2 and the Nitelog® App utilize only a very small fraction of the available bandwidth and throughput. Based on this, the Z2 and the Nitelog® 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 Z2 Nitelog® 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.

## Contact Information

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# BREAS

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Z2 Auto Clinician Guide- English v1  
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