Z1 Auto[™] System Auto-Adjusting continuous positive Airway pressure system Clinician User Guide

To set-up the Z1 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 Z1 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_20 . A fixed pressure setting is required for CPAP and default is 8 cm H_20 .

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_20 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).

1. Turn on Bluetooth

In order for the *Z1* to connect to the *Z1 NiteLog Mobile App*, the *Z1's* Bluetooth must be turned on. Once the *Z1* has connected to the *NiteLog App* via Bluetooth, access between the *NiteLog App* and *Z1* device is password protected. If the password is incorrect the Mobile App will be denied access to the Z1 device.

Immediately after plugging the Power Adapter into your Z1, 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 *Z1* (Airplane Mode), unplug the *Power Adapter* from your *Z1*. Plug your *Power Adapter* back into your *Z1* 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)

2. Unlock Z1 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 *Z1* device.

- Power up the *Z1* 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 *Z1* 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.

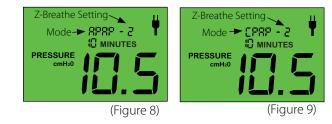
3. Set Mode

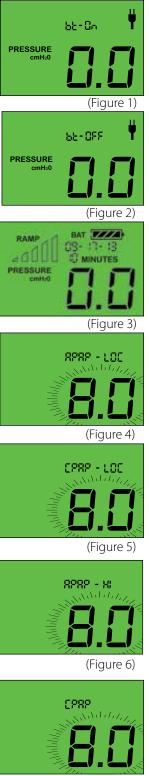
Choosing Between CPAP Mode or APAP Mode

If the *Z1* device is locked, you need to unlock the device before switching function modes. To unlock the *Z1* device, please see section "Unlock Z1 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 But-ton* 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 7)

4. Set Pressure

Setting the Treatment Pressure in CPAP Mode

If the *Z1* device is locked, you need to unlock the device before modifying CPAP treatment pressure. To unlock the *Z1* device, please see section "Unlock Z1 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*.

Setting the Minimum and Maximum Pressures in APAP Mode

If the *Z1* device is locked, you need to unlock the device before modifying APAP maximum and minimum pressures. To unlock the Z1 device, please see section "Unlock Z1 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 12)

5. Set Ramp

Setting Ramp Time

When the *Z1* is in standby mode, press and hold the *Up Arrow Button* for approximately 3 seconds until the "00 MINUTES" value flashes. While it is flashing, repeatedly press either the *Up* or *Down Arrow Buttons* to increase or decrease the ramp time in 5 minute increments. (Figure 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 *Z1* is not powered). The *Z1* will return to standby mode. To return to standby mode without saving the new setting, press and release the *Start/Stop Button* momentarily instead of holding it down.

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



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_2O 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 *Z1* will return to standby mode. To return to standby mode without saving the new setting, press the *Start/Stop Button* momentarily instead of holding it down.

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 *Z*¹ unit after it is turned off. The currently selected *Z*-*Breathe Algorithm* setting will be displayed when the *Z*¹ is delivering treatment pressure.

Z-*Breathe* is a proprietary algorithm engineered in the *Z*1 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 accomodate individual users' preferences:

- -1 offers mild pressure swing relief
- $-\mathbf{2}$ is the *Default Setting* and offers moderate pressure swing relief
- -3 is the most aggressive setting for pressure swing relief

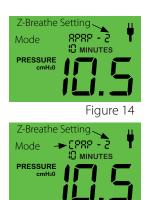


Figure 15