

**AOZ1031AI** EZBuck<sup>™</sup> 3A Synchronous Buck Regulator Not Recommended For New Designs

## **General Description**

The AOZ1031A is a high efficiency, easy to use, 3A synchronous buck regulator. The AOZ1031A works from 4.5V to 18V input voltage range, and provides up to 3A of continuous output current with an output voltage adjustable down to 0.8V.

The AOZ1031A comes in a SO-8 package and is rated over a -40°C to +85°C operating ambient temperature range.

# **Replacement Part: AOZ6683CI**

#### Features

- 4.5V to 18V operating input voltage range
- Synchronous Buck: 80mΩ internal high-side switch and  $30m\Omega$  internal low-side switch with integrated schottky diode
- High efficiency: up to 95%
- Internal soft start
- Output voltage adjustable to 0.8
- 3A continuous output current
- Fixed 600kHz PWM operation
- Pulse skipping at light load for high efficiency over entire load range
- Cycle-by-cycle current limit
- Pre-bias start-up
- Short-circuit protection
- Thermal shutdown
- SO-8 package

# Applications

- Point of load DC/DC converters
- LCD TV
- Set top boxes
- DVD/Blu-ray players/recorders
- Cable modems
- PCIe graphics cards
- Telecom/Networking/Datacom equipment



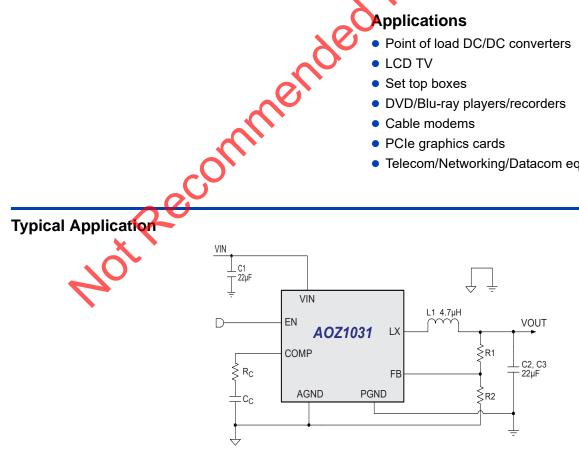


Figure 1. 3.3V 3A Synchronous Buck Regulator

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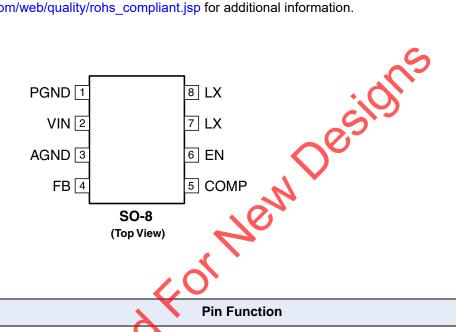
# **Ordering Information**

Part Number	Ambient Temperature Range	Package	Environmental
AOZ1031AI	-40°C to +85°C	SO-8	RoHS Compliant Green Product



AOS Green Products use reduced levels of Halogens, and are also RoHS compliant. Please visit www.aosmd.com/web/quality/rohs\_compliant.jsp for additional information.

# **Pin Configuration**



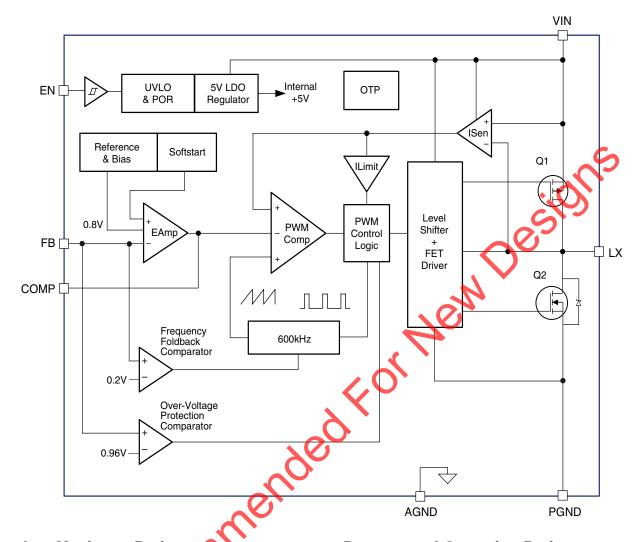
# **Pin Description**

Pin Number	Pin Name	Pin Function		
1	PGND	Power ground. PGND needs to be electrically connected to AGND.		
2	VIN	Supply voltage input. When VIN rises above the UVLO threshold and EN is logic high, the device starts up		
3	AGND	Analog ground. AGND is the reference point for controller section. AGND needs to be electrically connected to PGND.		
4	FB	Feedback input. The FB pin is used to set the output voltage via a resistive voltage divider between the output and AGND.		
5	COMP	External loop compensation pin. Connect a RC network between COMP and AGND to compensate the control loop.		
6	EN	Enable pin. Pull EN to logic high to enable the device. Pull EN to logic low to disable the device. Do not leave it open.		
7, 8	LX	Switching node. PWM output connection to inductor.		



# AOZ1031AI

# **Block Diagram**



# Absolute Maximum Ratings

Exceeding the Absolute Maximum ratings may damage the device.

Parameter	Rating		
Supply Voltage (VIN)	20V		
LX to AGND	-0.7V to V <sub>IN</sub> +0.3V		
LX to AGND	-3V for 20 nS		
EN to AGND	-0.3V to V <sub>IN</sub> +0.3V		
FB to AGND	-0.3V to 6V		
COMP to AGND	-0.3V to 6V		
PGND to AGND	-0.3V to +0.3V		
Junction Temperature (T <sub>J</sub> )	+150°C		
Storage Temperature (T <sub>S</sub> )	-65°C to +150°C		
ESD Rating <sup>(1)</sup>	2.0kV		

Note:

1. Devices are inherently ESD sensitive, handling precautions are required. Human body model rating: 1.5kΩ in series with 100pF.

# **Recommend Operating Ratings**

The device is not guaranteed to operate beyond the Maximum Operating Ratings.

Parameter	Rating
Supply Voltage (V <sub>IN</sub> )	4.5V to 18V
Output Voltage Range	0.8V to V <sub>IN</sub>
Ambient Temperature (T <sub>A</sub> )	-40°C to +85°C
Package Thermal Resistance SO-8 (Θ <sub>JA</sub> ) SO-8 (Θ <sub>JC</sub> )	87°C/W 30°C/W
Package Power Dissipation (P <sub>D</sub> ) @ 25°C Ambient SO-8	1.15W

### **Electrical Characteristics**

 $T_{A}$  = 25°C,  $V_{IN}$  =  $V_{EN}$  = 12V,  $V_{OUT}$  = 3.3V unless otherwise specified.<sup>(3)</sup>

Symbol	Parameter	Conditions	Min.	Тур.	Max.	Units
V <sub>IN</sub>	Supply Voltage		4.5		18	V
V <sub>UVLO</sub>	Input under-voltage lockout	V <sub>IN</sub> rising		4.1		V
	threshold	V <sub>IN</sub> falling		3.7		V
I <sub>IN</sub>	Supply current (Quiescent)	I <sub>OUT</sub> = 0, V <sub>FB</sub> = 1.2V, V <sub>EN</sub> >1.2V		1.6	2.5	mA
I <sub>OFF</sub>	Shutdown supply current	V <sub>EN</sub> = 0V		1	10	μA
$V_{FB}$	Feedback Voltage	T <sub>A</sub> = 25°C	0.788	0.8	0.812	V
	Load regulation			0.5	5	%
	Line regulation			1, (		%
I <sub>FB</sub>	Feedback voltage input current				200	nA
$V_{\text{EN}}$	EN input threshold	Off threshold On threshold	2	(C)	0.6	V V
V <sub>HYS</sub>	EN input hysteresis			100		mV
MODULAT	TOR					
f <sub>O</sub>	Frequency		500	600	700	kHz
D <sub>MAX</sub>	Maximum Duty Cycle		100			%
D <sub>MIN</sub>	Minimum Duty Cycle				9	%
	Error amplifier voltage gain			500		V / V
	Error amplifier transconductance			200		μA / \
PROTECT	ION			•	•	
I <sub>LIM</sub>	Current Limit		4.0		5.0	Α
V <sub>OVP</sub>	Over-Voltage Protection	Off threhsold On threshold		960 860		mV mV
	Over-temperature shutdown limit	To rising To falling		150 100		℃ ℃
t <sub>SS</sub>	Soft Start Interval	<b>V</b>		2.2		ms
OUTPUT S	STAGE					
	High-side switch on-resistance	V <sub>IN</sub> = 12V V <sub>IN</sub> = 5V		80 130	100 180	mΩ mΩ
	Low-side switch on-resistance	V <sub>IN</sub> = 12V V <sub>IN</sub> = 5V		30 56	36 70	mΩ mΩ

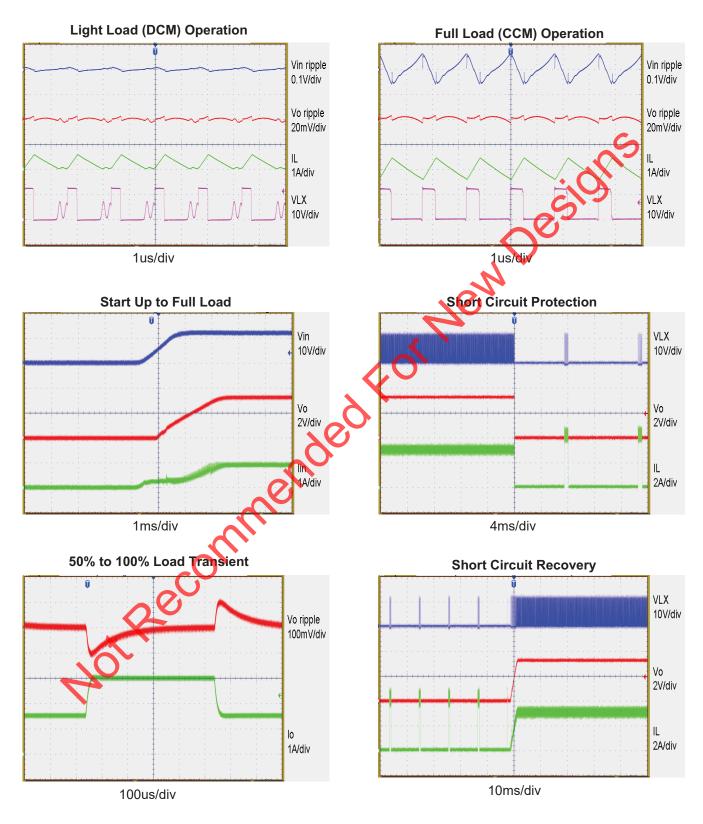
# Notes:

3. The device is not guaranteed to operate beyond the Maximum Operating ratings.



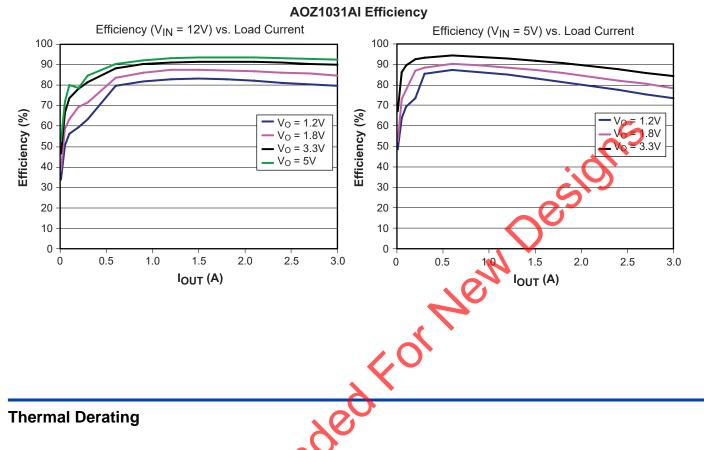


**Typical Performance Characteristics** Circuit of Figure 1.  $T_A$  = 25°C,  $V_{IN}$  =  $V_{EN}$  = 12V,  $V_{OUT}$  = 3.3V unless otherwise specified.

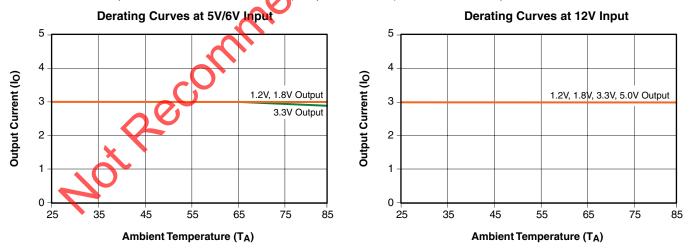




# Efficiency



Thermal de-rating curves for SO-8 package part under typical input and output condition based on the evaluation board. 25°C ambient temperature and natural convection (air speed < 50LFM) unless otherwise specified.



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# **Detailed Description**

The AOZ1031A is a current-mode step down regulator with integrated high-side PMOS switch and a low-side NMOS switch. It operates from a 4.5V to 18V input voltage range and supplies up to 3A of load current. The duty cycle can be adjusted from 6% to 100% allowing a wide range of output voltage. Features include enable control, Power-On Reset, input under voltage lockout, output over voltage protection, active high power good state, fixed internal soft-start and thermal shut down.

The AOZ1031A is available in SO-8 package.

# **Enable and Soft Start**

The AOZ1031A has internal soft start feature to limit in-rush current and ensure the output voltage ramps up smoothly to regulation voltage. A soft start process begins when the input voltage rises to 4.1V and voltage on EN pin is HIGH. In soft start process, the output voltage is ramped to regulation voltage in typically 2.2ms. The 2.2ms soft start time is set internally.

The EN pin of the AOZ1031A is active high. Connect the EN pin to VIN if enable function is not used. Pull it to ground will disable the AOZ1031A. Do not leave it open. The voltage on EN pin must be above 2V to enable the AOZ1031A. When voltage on EN pin falls below 0.6V, the AOZ1031A is disabled. If an application circuit requires the AOZ1031A to be disabled, an open drain or open collector circuit should be used to interface to EN pin.

# **Steady-State Operation**

Under steady-state conditions, the converter operates in fixed frequency and Continuous-Conduction Mode (CCM).

The AOZ1031A integrates an internal P-MOSFET as the high-side switch. Inductor current is sensed by amplifying the voltage drop across the drain to source of the high side power MOSFET Output voltage is divided down by the external voltage divider at the FB pin. The difference of the FB pin voltage and reference is amplified by the internal transconductance error amplifier. The error voltage, which shows on the COMP pin, is compared against the current signal, which is sum of inductor current signal and ramp compensation signal, at PWM comparator input. If the current signal is less than the error voltage, the internal high-side switch is on. The inductor current flows from the input through the inductor to the output. When the current signal exceeds the error voltage, the high-side switch is off. The inductor current is freewheeling through the internal low-side N-MOSFET switch to output. The internal adaptive FET driver guarantees no turn on overlap of both high-side and low-side switch.

Comparing with regulators using freewheeling Schottky diodes, the AOZ1031A uses freewheeling NMOSFET to realize synchronous rectification. It greatly improves the converter efficiency and reduces power loss in the low-side switch.

The AOZ1031A will enter the discontinuous conduction mode at light load. Several pulses may be skipped in between switching cycles at very light load, it further improving light load efficiency.

The AOZ1031A uses a P-Channel MOSFET as the high-side switch. It saves the bootstrap capacitor normally seen in a circuit which is using an NMOS switch. It allows 100% turn-on of the high-side switch to achieve linear regulation mode of operation. The minimum voltage drop from  $V_{IN}$  to  $V_O$  is the load current times DC resistance of MOSFET plus DC resistance of buck inductor. It can be calculated by equation below:

$$V_{O_{MAX}} = V_{IN} + Q + R_{DS(ON)}$$

Vo MAX is the maximum output voltage;,

V<sub>IN</sub> is the input voltage from 4.5V to 18V,

is the output current from 0A to 3A, and

 $R_{DS(ON)}$  is the on resistance of internal MOSFET. The value is between 97m $\Omega$  and 200m $\Omega$  depending on input voltage and junction temperature.

# **Switching Frequency**

where;

The AOZ1031A switching frequency is fixed and set by an internal oscillator. The practical switching frequency could range from 500kHz to 700kHz due to device variation.

# **Output Voltage Programming**

Output voltage can be set by feeding back the output to the FB pin by using a resistor divider network. In the application circuit shown in Figure 1. The resistor divider network includes  $R_1$  and  $R_2$ . Usually, a design is started by picking a fixed  $R_2$  value and calculating the required R1 with equation below.

$$V_{\rm O} = 0.8 \times \left(1 + \frac{R_1}{R_2}\right)$$

Some standard value of  $R_1$ ,  $R_2$  and most used output voltage values are listed in Table 1 on the next page.

#### Table 1.

Vo (V)	<b>R1 (k</b> Ω)	<b>R2 (k</b> Ω)
0.8	1.0	open
1.2	4.99	10
1.5	10	11.5
1.8	12.7	10.2
2.5	21.5	10
3.3	31.1	10
5.0	52.3	10

The combination of  $R_1$  and  $R_2$  should be large enough to avoid drawing excessive current from the output, which will cause power loss.

Since the switch duty cycle can be as high as 100%, the maximum output voltage can be set as high as the input voltage minus the voltage drop on upper PMOS and inductor.

# **Protection Features**

The AOZ1031A has multiple protection features to prevent system circuit damage under abnormal conditions.

### **Over Current Protection (OCP)**

The sensed inductor current signal is also used for over current protection. Since the AOZ1031A employs peak current mode control, the COMP pin voltage is proportional to the peak inductor current. The COMP pin voltage is limited to be between 0.4V and 2.5V internally. The peak inductor current is automatically limited cycle by cycle.

When the output is shorted to ground under fault conditions, the inductor current decays very slow during a switching cycle because of  $V_0=0V$ . To prevent catastrophic failure, AOZ1031A detects the duration the overcurrent condition occurs. If the over-current condition occurs for certain period AOZ1013A totally turns off for a period of time, then restarts. If the fault is still there, then the chip will be off again. The converter will initiate a soft start once the over-current condition disappears.

#### Power-On Reset (POR)

A power-on reset circuit monitors the input voltage. When the input voltage exceeds 4.1V, the converter starts operation. When input voltage falls below 3.7V, the converter will be shut down.

#### **Thermal Protection**

An internal temperature sensor monitors the junction temperature. It shuts down the internal control circuit and high side PMOS if the junction temperature exceeds 150°C. The regulator will restart automatically under the control of soft-start circuit when the junction temperature decreases to 100°C.

# Application Information

The basic AOZ1031A application circuit is show in Figure 1. Component selection is explained below.

#### Input Capacitor

The input capacitor must be connected to the  $V_{IN}$  pin and PGND pin of AOZ1031A to maintain steady input voltage and filter out the pulsing input current. The voltage rating of input capacitor must be greater than maximum input voltage plus ripple voltage.

The input ripple voltage can be approximated by equation below:

$$\Delta V_{IN} = \frac{I_O}{f \times C_{IN}} \times \left(1 - \frac{V_O}{V_{IN}}\right) \times \frac{V_O}{V_{IN}}$$

Since the input current is discontinuous in a buck converter, the current stress on the input capacitor is another concern when selecting the capacitor. For a buck circuit, the RMS value of input capacitor current can be calculated by:

$$I_{CIN\_RMS} = I_{O} \times \sqrt{\frac{V_{O}}{V_{IN}} \left(1 - \frac{V_{O}}{V_{IN}}\right)}$$

if we let *m* equal the conversion ratio:

$$\frac{V_0}{V_{IN}} = m$$

The relation between the input capacitor RMS current and voltage conversion ratio is calculated and shown in Figure 2 on the next page. It can be seen that when  $V_O$  is half of  $V_{IN}$ ,  $C_{IN}$  is under the worst current stress. The worst current stress on  $C_{IN}$  is 0.5 x  $I_O$ .



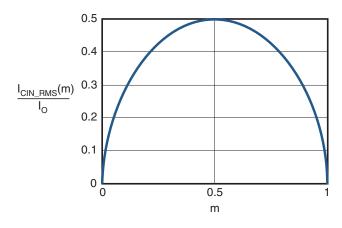


Figure 2. I<sub>CIN</sub> vs. Voltage Conversion Ratio

For reliable operation and best performance, the input capacitors must have current rating higher than I<sub>CIN\_RMS</sub> at worst operating conditions. Ceramic capacitors are preferred for input capacitors because of their low ESR and high current rating. Depending on the application circuits, other low ESR tantalum capacitor may also be used. When selecting ceramic capacitors, X5R or X7R type dielectric ceramic capacitors should be used for their better temperature and voltage characteristics. Note that the ripple current rating from capacitor manufactures are based on certain amount of life time. Further de-rating may be necessary in practical design.

#### Inductor

The inductor is used to supply constant current to output when it is driven by a switching voltage. For given input and output voltage, inductance and switching frequency together decide the inductor ripple current, which is:

$$\Delta I_{L} = \frac{V_{O}}{f \times L} \times \left(1 - \frac{V_{O}}{V_{IN}}\right)$$

The peak inductor current

$$I_{Lpeak} = I_0 + \frac{\Delta I_L}{2}$$

High inductance gives low inductor ripple current but requires larger size inductor to avoid saturation. Low ripple current reduces inductor core losses. It also reduces RMS current through inductor and switches, which results in less conduction loss. Usually, peak to peak ripple current on inductor is designed to be 20% to 30% of output current.

When selecting the inductor, make sure it is able to handle the peak current without saturation even at the highest operating temperature. The inductor takes the highest current in a buck circuit. The conduction loss on inductor need to be checked for thermal and efficiency requirements.

Surface mount inductors in different shape and styles are available from Coilcraft, Elytone and Murata. Shielded inductors are small and radiate less EMI noise. But they cost more than unshielded inductors. The choice depends on EMI requirement, price and size.

#### **Output Capacitor**

The output capacitor is selected based on the DC output voltage rating, output ripple voltage specification and ripple current rating.

The selected output capacitor must have a higher rated voltage specification than the maximum desired output voltage including ripple. De-rating needs to be considered for long term reliability.

Output ripple voltage specification is another important factor for selecting the output capacitor. In a buck converter circuit, output ripple voltage is determined by inductor value, switching frequency, output capacitor value and ESR. It can be calculated by the equation below:

 $\Delta V_{O} = \Delta I_{L} \times \left( ESR_{CO} + \frac{1}{8 \times f \times C_{O}} \right)$ 

where;

C<sub>O</sub> is output capacitor value, and

ESR<sub>CO</sub> is the Equivalent Series Resistor of output capacitor.

When low ESR ceramic capacitor is used as output capacitor, the impedance of the capacitor at the switching frequency dominates. Output ripple is mainly caused by capacitor value and inductor ripple current. The output ripple voltage calculation can be simplified to:

$$\Delta V_{O} = \Delta I_{L} \times \frac{1}{8 \times f \times C_{O}}$$

If the impedance of ESR at switching frequency dominates, the output ripple voltage is mainly decided by capacitor ESR and inductor ripple current. The output ripple voltage calculation can be further simplified to:

$$\Delta V_{\rm O} = \Delta I_{\rm L} \times ESR_{\rm CO}$$

For lower output ripple voltage across the entire operating temperature range, X5R or X7R dielectric type of ceramic, or other low ESR tantalum are recommended to be used as output capacitors.



In a buck converter, output capacitor current is continuous. The RMS current of output capacitor is decided by the peak to peak inductor ripple current. It can be calculated by:

$$I_{CO\_RMS} = \frac{\Delta I_{L}}{\sqrt{12}}$$

Usually, the ripple current rating of the output capacitor is a smaller issue because of the low current stress. When the buck inductor is selected to be very small and inductor ripple current is high, output capacitor could be overstressed.

#### Loop Compensation

The AOZ1031A employs peak current mode control for easy use and fast transient response. Peak current mode control eliminates the double pole effect of the output L&C filter. It greatly simplifies the compensation loop design.

With peak current mode control, the buck power stage can be simplified to be a one-pole and one-zero system in frequency domain. The pole is dominant pole can be calculated by:

$$f_{P1} = \frac{1}{2\pi \times C_O \times R_L}$$

The zero is a ESR zero due to output capacitor and its ESR. It is can be calculated by: mer

$$f_{Z1} = \frac{1}{2\pi \times C_0 \times ESR_{CC}}$$

where;

Co is the output filter capacitor,

R<sub>I</sub> is load resistor value, and

ESR<sub>CO</sub> is the equivalent series resistance of output capacitor.

The compensation design is actually to shape the converter control loop transfer function to get desired gain and phase. Several different types of compensation network can be used for the AOZ1031A. For most cases, a series capacitor and resistor network connected to the COMP pin sets the pole-zero and is adequate for a stable high-bandwidth control loop.

In the AOZ1031A, FB pin and COMP pin are the inverting input and the output of internal error amplifier. A series R and C compensation network connected to COMP provides one pole and one zero. The pole is:

$$f_{P2} = \frac{G_{EA}}{2\pi \times C_C \times G_{VEA}}$$

where:

GFA is the error amplifier transconductance, which is 200 x 10<sup>-6</sup> A/V.

 $G_{VEA}$  is the error amplifier voltage gain, which is 500 V/V, and

C<sub>2</sub> is compensation capacitor in Figure 1.

The zero given by the external compensation network, capacitor  $C_2$  and resistor  $R_3$ , is located at:

$$f_{Z2} = \frac{1}{2\pi \times C_C \times R_C}$$

To design the compensation circuit, a target crossover frequency f<sub>C</sub> for close loop must be selected. The system crossover frequency is where control loop has unity gain. The crossover is the also called the converter bandwidth. Generally a higher bandwidth means faster response to load transient. However, the bandwidth should not be too high because of system stability concern. When designing the compensation loop, converter stability under all line and load condition must be considered.

Usually, it is recommended to set the bandwidth to be equal or less than 1/10 of switching frequency. The AOZ 1031A operates at a frequency range from 500kHz to 700kHz. It is recommended to choose a crossover frequency equal or less than 40kHz.

$$c = 40 kHz$$

The strategy for choosing  $R_C$  and  $C_C$  is to set the cross over frequency with  $\mathsf{R}_\mathsf{C}$  and set the compensator zero with C<sub>C</sub>. Using selected crossover frequency, f<sub>C</sub>, to calculate R<sub>C</sub>:

$$R_{C} = f_{C} \times \frac{V_{O}}{V_{FB}} \times \frac{2\pi \times C_{2}}{G_{EA} \times G_{CS}}$$

where:

f<sub>C</sub> is desired crossover frequency. For best performance, f<sub>C</sub> is set to be about 1/10 of switching frequency,

V<sub>FB</sub> is 0.8V,

GEA is the error amplifier transconductance, which is 200 x 10<sup>-6</sup> A/V, and

 $G_{CS}$  is the current sense circuit transconductance, which is 6.68 A/V.

The compensation capacitor C<sub>C</sub> and resistor R<sub>C</sub> together make a zero. This zero is put somewhere close to the dominate pole f<sub>P1</sub> but lower than 1/5 of selected crossover frequency. C<sub>C</sub> can is selected by:

$$C_{\rm C} = \frac{1.5}{2\pi \times R_{\rm C} \times f_{\rm P1}}$$

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Equation above can also be simplified to:

$$C_{C} = \frac{C_{O} \times R_{L}}{R_{C}}$$

An easy-to-use application software which helps to design and simulate the compensation loop can be found at <u>www.aosmd.com</u>.

# Thermal Management and Layout Consideration

In the AOZ1031A buck regulator circuit, high pulsing current flows through two circuit loops. The first loop starts from the input capacitors, to the VIN pin, to the LX pins, to the filter inductor, to the output capacitor and load, and then return to the input capacitor through ground. Current flows in the first loop when the high side switch is on. The second loop starts from inductor, to the output capacitors and load, to the low side NMOSFET. Current flows in the second loop when the low side NMOSFET is on.

In PCB layout, minimizing the two loops area reduces the noise of this circuit and improves efficiency. A ground plane is strongly recommended to connect input capacitor, output capacitor, and PGND pin of the AOZ1031A.

In the AOZ1031A buck regulator circuit, the major power dissipating components are the AOZ1031A and the output inductor. The total power dissipation of converter circuit can be measured by input power minus output power.

$$P_{total\_loss} = V_{IN} \times I_{IN} - V_O \times I_O$$

The power dissipation of inductor can be approximately calculated by output current and DCR of inductor.

$$P_{inductor\_loss} = I_0^2 \times R_{inductor}$$
 1.1

The actual junction temperature can be calculated with power dissipation in the AOZ1031A and thermal impedance from junction to ambient.

 $T_{junction} = V_{total_loss} - P_{inductor_loss} \times \Theta_{JA}$ 

The maximum junction temperature of AOZ1031A is 150°C, which limits the maximum load current capability.

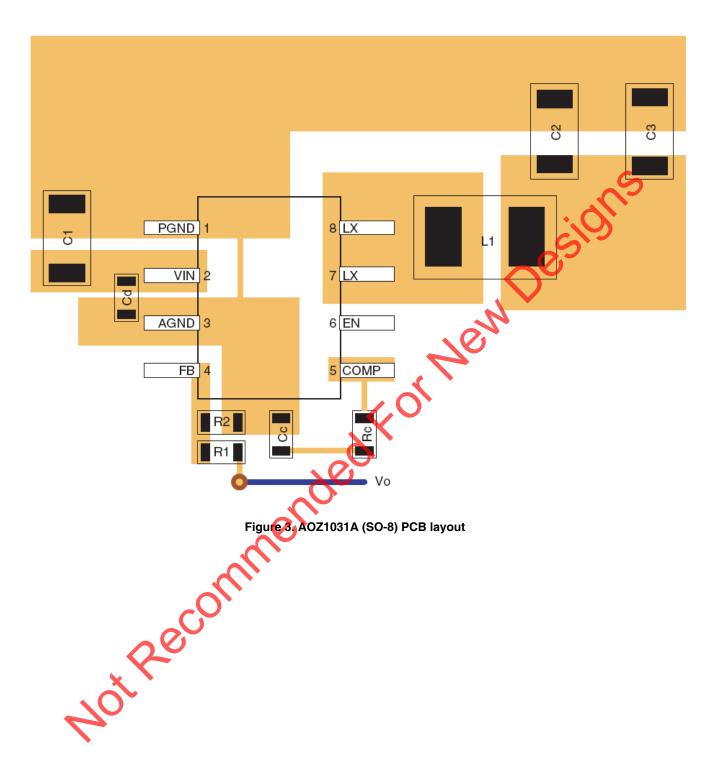
Please see the thermal de-rating curves for maximum load current of the AOZ1031A under different ambient temperature.

The thermal performance of the AOZ1031A is strongly affected by the PCB layout. Extra care should be taken by users during design process to ensure that the IC will operate under the recommended environmental conditions.

The AOZ1031A is standard SO-8 package. Several layout tips are listed below for the best electric and thermal performance. Figure 3 on the next page illustrates a PCB layout example of AOZ1031A.

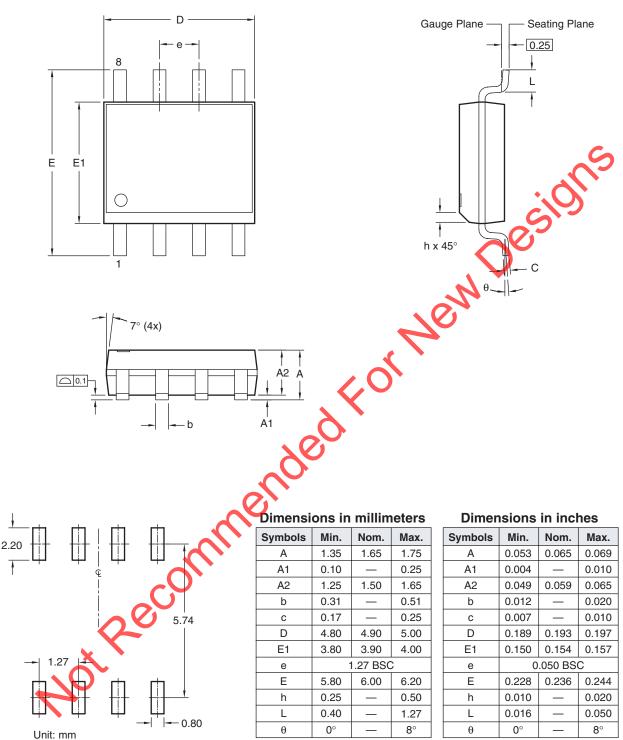
- 1. The LX pins are connected to internal PFET and NFET drains. They are low resistance thermal conduction path and most noisy switching node. Connected a large copper plane to LX pin to help thermal dissipation.
- Do not use thermal relief connection to the VIN and the PGND pin. Pour a maximized copper area to the PGND pin and the VIN pin to help thermal dissipation.
- 3. Input capacitor should be connected to the VIN pin and the PGND pin as close as possible.
- A ground plane is preferred. If a ground plane is not used, separate PGND from AGND and connect them only at one point to avoid the PGND pin noise coupling to the AGND pin.
- 5. Make the current trace from LX pins to L to Co to the PGND as short as possible.
- 6. Pour copper plane on all unused board area and connect it to stable DC nodes, like VIN, GND or VOUT.
- 7. Keep sensitive signal trace far away form the LX pins.







# Package Dimensions, SO-8L

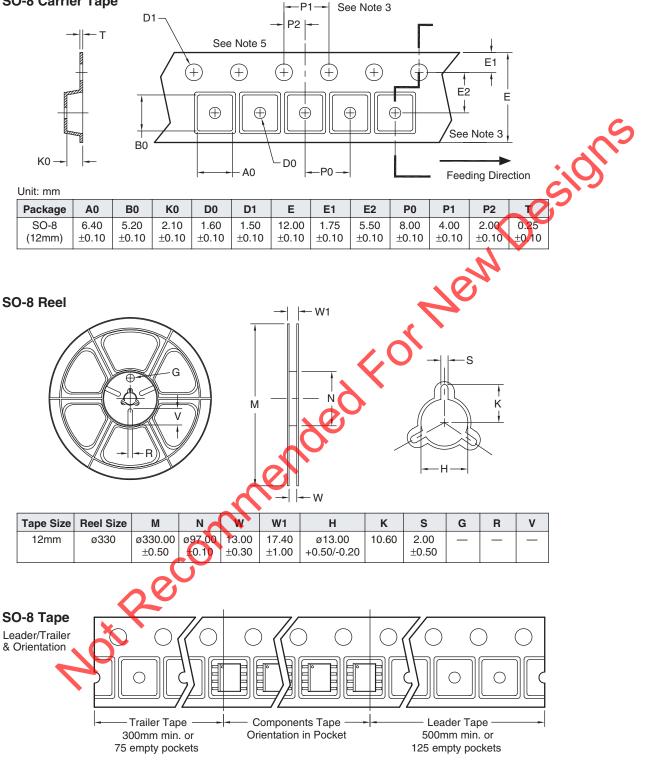


#### Notes:

- 1. All dimensions are in millimeters.
- 2. Dimensions are inclusive of plating
- 3. Package body sizes exclude mold flash and gate burrs. Mold flash at the non-lead sides should be less than 6 mils.
- 4. Dimension L is measured in gauge plane.
- 5. Controlling dimension is millimeter, converted inch dimensions are not necessarily exact.

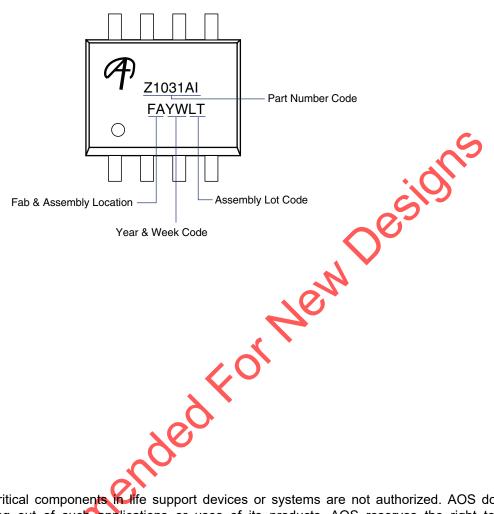
# **Tape and Reel Dimensions**







# AOZ1031 Package Marking



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1. Life support devices or systems are devices or systems which, (a) are intended for surgical implant into the body or (b) support or sustain life, and (c) whose failure to perform when properly used in accordance with instructions for use provided in the labeling, can be reasonably expected to result in a significant injury of the user. 2. A critical component in any component of a life support, device, or system whose failure to perform can be reasonably expected to cause the failure of the life support device or system, or to affect its safety or effectiveness.

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