

# AOZ2151QI-01

28V/4A Synchronous EZBuck™ Regulator

## **General Description**

The AOZ2151QI-01 is a high-efficiency, easy-to-use DC/DC synchronous buck regulator that operates up to 28V. The device is capable of supplying 4A of continuous output current with an output voltage adjustable down to 0.8V ±1%.

The AOZ2151QI-01 integrates an internal linear regulator to generate 5.3V  $V_{CC}$  from input. If input voltage is lower than 5.3V, the linear regulator operates at low drop output mode, which allows the  $V_{CC}$  voltage is equal to input voltage minus the drop-output voltage of the internal linear regulator.

A proprietary constant on-time PWM control with input feed-forward results in ultra-fast transient response while maintaining relatively constant switching frequency over the entire input voltage range.

The device features multiple protection functions such as  $V_{CC}$  under-voltage lockout, cycle-by-cycle current limit, output over-voltage protection, short-circuit protection, and thermal shutdown.

The AOZ2151QI-01 is available in a 3mm×3mm QFN-18L package and is rated over a -40°C to +85°C ambient temperature range.

#### **Features**

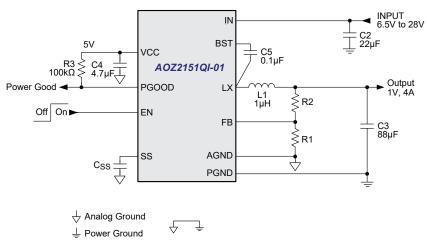
- Wide input voltage range
  - -6.5V to 28V
- 4A continuous output current
- Output voltage adjustable down to 0.8V (±1.0%)
- Low R<sub>DS(ON)</sub> internal NFETs
  - $-28m\Omega$  high-side
  - $-28m\Omega$  low-side
- Constant On-Time with input feed-forward
- Ceramic capacitor stable
- Adjustable soft start
- Power Good output
- Integrated bootstrap diode
- Cycle-by-cycle current limit
- Short-circuit protection
- Thermal shutdown
- Thermally enhanced 3mm x 3mm QFN-18L package

# **Applications**

- Compact desktop PCs
- Graphics cards
- Set-top boxes
- LCD TVs
- Cable modems
- Point-of-load DC/DC converters
- Telecom/Networking/Datacom equipment

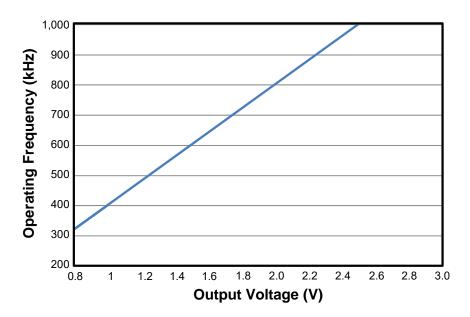


# **Typical Application**



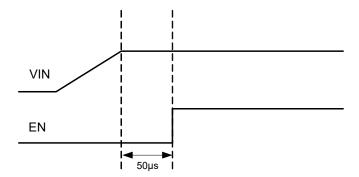


# **Output Voltage vs. Operating Frequency**





# **Recommended Start-up Sequence**



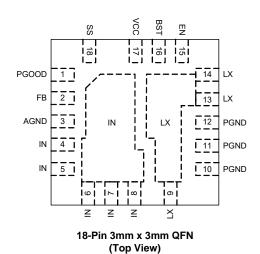
# **Ordering Information**

Part Number	Ambient Temperature Range	Package	Environmental		
AOZ2151QI-01	-40°C to +85°C	18-Pin 3mm x 3mm QFN	Green Product		



AOS Green Products use reduced levels of Halogens, and are also RoHS compliant. Please visit www.aosmd.com/media/AOSGreenPolicy.pdf for additional information.

# **Pin Configuration**





# **Pin Description**

Pin Number	Pin Name	Pin Function
1	PGOOD	Power Good Signal Output. PGOOD is an open-drain output used to indicate the status of the output voltage. It is internally pulled low when the output voltage is 15% lower than the nominal regulation voltage or 20% higher than the nominal regulation voltage. PGOOD is pulled low during soft-start and shut down.
2	FB	Feedback Input. Adjust the output voltage with a resistive voltage-divider between the regulator's output and AGND.
3	AGND	Analog Ground.
4, 5, 6, 7, 8	IN	Supply Input. IN is the regulator input. All IN pins must be connected together.
9, 13, 14 LX		Switching Node.
10, 11, 12	PGND	Power Ground.
15	EN	Enable Input. The AOZ2151QI-01 is enabled when EN is pulled high. The device shuts down when EN is pulled low.
16	BST	Bootstrap Capacitor Connection. The AOZ2151QI-01 includes an internal bootstrap diode. Connect an external capacitor between BST and LX as shown in the Typical Application diagram.
17 VCC		Supply Input for analog functions. Bypass VCC to AGND with a 4.7μF~10μF ceramic capacitor. Place the capacitor close to VCC pin.
18	SS	Soft-Start Time Setting Pin. Connect a capacitor between SS and AGND to set the soft-start time.



# **Absolute Maximum Ratings**

Exceeding the Absolute Maximum Ratings may damage the device.

Parameter	Rating
IN to AGND	-0.3V to 30V
LX to AGND <sup>(1)</sup>	-0.3V to 30V
BST to AGND	-0.3V to 36V
SS, PGOOD, FB, EN, VCC 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>(2)</sup>	2kV

#### Notes:

- 1. LX to PGND Transient (t<20ns) ----- -7V to  $V_{IN}$ +7V.
- 2. Devices are inherently ESD sensitive, handling precautions are required. Human body model rating: 1.5k $\Omega$  in series with 100pF.

# **Maximum Operating Ratings**

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

Parameter	Rating
Supply Voltage (V <sub>IN</sub> )	6.5V to 28V
Output Voltage Range	0.8V to 0.85*V <sub>IN</sub>
Ambient Temperature (T <sub>A</sub> )	-40°C to +85°C
Package Thermal Resistance	
$\theta_{JA}$	40°C/W
$\theta_{JC}$	6°C/W

#### **Electrical Characteristics**

 $T_A = 25$ °C,  $V_{IN}$ =12V, EN = 5V, unless otherwise specified. Specifications in **BOLD** indicate a temperature range of -40°C to +85°C.

Symbol	Parameter	Conditions	Min.	Тур.	Max	Units
V <sub>IN</sub>	IN Supply Voltage		6.5		28	V
V <sub>UVLO</sub>	Under-Voltage Lockout Threshold	V <sub>IN</sub> rising V <sub>IN</sub> falling	3.2	4.0 3.7	4.4	V
Iq	Quiescent Supply Current	I <sub>OUT</sub> = 0, V <sub>EN</sub> > 2V, PFM		0.16		mA
I <sub>OFF</sub>	Shutdown Supply Current	V <sub>EN</sub> = 0V		15		μΑ
$V_{FB}$	Feedback Voltage	T <sub>A</sub> = 25°C T <sub>A</sub> = 0°C to 85°C	0.792 0.788	0.800 0.800	0.808 0.812	V
	Load Regulation			0.5		%
	Line Regulation			1		%
I <sub>FB</sub>	FB Input Bias Current				200	nA
Enable						
V <sub>EN</sub>	EN Input Threshold	Off threshold On threshold	1.6		0.5	V
V <sub>EN_HYS</sub>	EN Input Hysteresis			100		mV
Modulator						
T <sub>ON_MIN</sub>	Minimum On Time			60		ns
T <sub>OFF_MIN</sub>	Minimum Off Time			300		ns
Soft-Start			,			
I <sub>SS_OUT</sub>	SS Source Current	$V_{SS} = 0$ $C_{SS} = 0.001 \mu F \text{ to } 0.1 \mu F$	7	11	15	μА

Rev. 2.0 February 2017 www.aosmd.com Page 5 of 16



## **Electrical Characteristics**

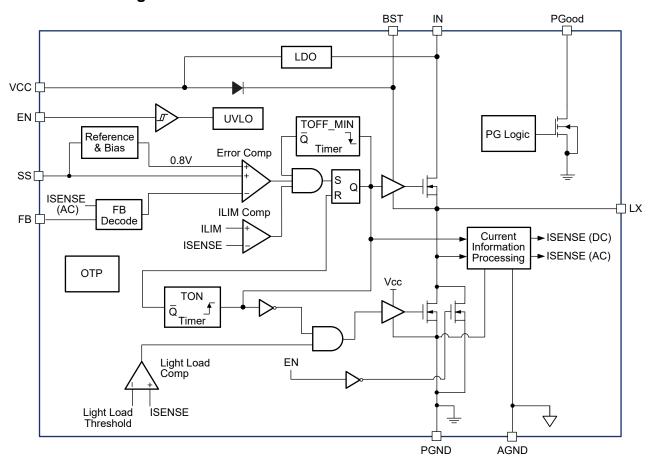
 $T_A = 25^{\circ}C$ ,  $V_{IN} = 12V$ , EN = 5V, unless otherwise specified. Specifications in **BOLD** indicate a temperature range of -40°C to +85°C.

Symbol	Parameter	Conditions	Min.	Тур.	Max	Units
Power God	od Signal		L	l		
V <sub>PG_LOW</sub>	PGOOD Low Voltage	I <sub>OL</sub> = 1mA			0.5	V
	PGOOD Leakage Current				±1	μΑ
$V_{PGH}$	PGOOD Threshold (Low Level to High Level)	FB rising		90		%
V <sub>PGL</sub>	PGOOD Threshold (High Level to Low Level)	FB rising FB falling		120 85		%
	PGOOD Threshold Hysteresis			5		%
Under Volt	age and Over Voltage Protection					
V <sub>PL</sub>	Under Voltage Threshold	FB falling		70		%
T <sub>PL</sub>	Under Voltage Delay Time			32		μS
V <sub>PH</sub>	Over Voltage Threshold	FB rising		120		%
Power Sta	ge Output					
R <sub>DS(ON)</sub>	High-Side NFET On-Resistance	V <sub>IN</sub> = 12V		28		mΩ
	High-Side NFET Leakage	V <sub>EN</sub> = 0V, V <sub>LX</sub> = 0V			10	μΑ
R <sub>DS(ON)</sub>	Low-Side NFET On-Resistance	V <sub>LX</sub> = 12V		28		mΩ
	Low-Side NFET Leakage	V <sub>EN</sub> = 0V			10	μΑ
Over-curre	ent and Thermal Protection					
I <sub>LIM</sub>	Current Limit		6			А
	Thermal Shutdown Threshold	$T_J$ rising $T_J$ falling		150 100		°C

Rev. 2.0 February 2017 **www.aosmd.com** Page 6 of 16



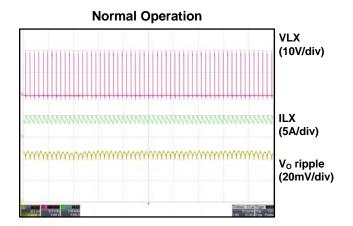
# **Functional Block Diagram**

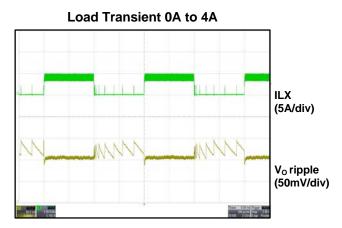


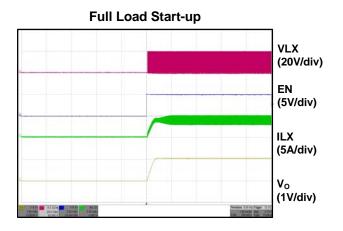


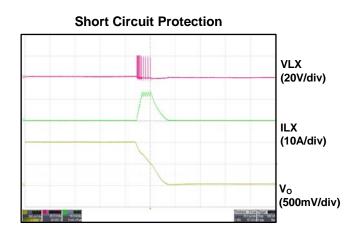
# **Typical Performance Characteristics**

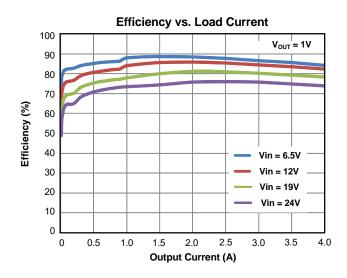
Circuit of Typical Application.  $T_A$  = 25°C,  $V_{IN}$  = 19V,  $V_{OUT}$  = 1V, unless otherwise specified.











Rev. 2.0 February 2017 **www.aosmd.com** Page 8 of 16



#### **Detailed Description**

The AOZ2151QI-01 is a high-efficiency, easy-to-use, synchronous buck regulator optimized for notebook computers. The regulator is capable of supplying 4A of continuous output current with an output voltage adjustable down to 0.8V.

The input voltage of AOZ2151QI-01 can be as low as 6.5V. The highest input voltage of AOZ2151QI-01 can be 28V. Constant on-time PWM with input feed-forward control scheme results in ultra-fast transient response while maintaining relatively constant switching frequency over the entire input range. True AC current mode control scheme guarantees the regulator can be stable with ceramics output capacitor. Protection features include  $V_{CC}$  under-voltage lockout, current limit, output over voltage and under voltage protection, short-circuit protection, and thermal shutdown.

The AOZ2151QI-01 is available in 18-pin 3mm×3mm QFN package.

#### **Input Power Architecture**

The AOZ2151QI-01 integrates an internal linear regulator to generate 5.3V ( $\pm 5\%$ ) V<sub>CC</sub> from input. If input voltage is lower than 5.3V, the linear regulator operates at low drop-output mode; the V<sub>CC</sub> voltage is equal to input voltage minus the drop-output voltage of internal linear regulator.

#### **Enable and Soft Start**

The AOZ2151QI-01 has external 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  $V_{CC}$  rises to 4.5V and voltage on EN pin is HIGH. An internal current source charges the external soft-start capacitor; the FB voltage follows the voltage of soft-start pin  $(V_{SS})$  when it is lower than 0.8V. When  $V_{SS}$  is higher than 0.8V, the FB voltage is regulated by internal precise band-gap voltage (0.8V). When  $V_{SS}$  is higher than 3.3V, the PGOOD signal is high. The soft-start time for PGOOD can be calculated by the following formula:

 $T_{SS}(\mu s) = 330 \times C_{SS}(nF)$ 

If  $C_{SS}$  is 1nF, the soft-start time will be 330 $\mu$  second; if  $C_{SS}$  is 10nF, the soft-start time will be 3.3m second.

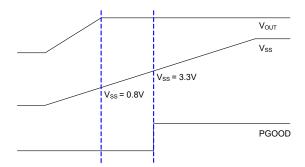


Figure 1. Soft Start Sequence of AOZ2151QI-01

# Constant-On-Time PWM Control with Input Feed-Forward

The control algorithm of AOZ2151QI-01 is constant-ontime PWM control with input feed-forward. The simplified control schematic is shown in Figure 2. The high-side switch on-time is determined solely by a one-shot whose pulse width is inversely proportional to input voltage (IN). The one-shot is triggered when the internal 0.8V is higher than the combined information of FB voltage and the AC current information of inductor, which is processed and obtained through the sensed lower-side MOSFET current once it turns-on. The added AC current information can help the stability of constant-on time control even with pure ceramic output capacitors, which have very low ESR. The AC current information has no DC offset, which does not cause offset with output load change, which is fundamentally different from other V<sup>2</sup> constant-on time control schemes.

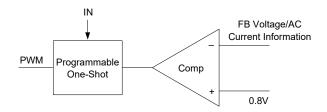


Figure 2. Simplified Control Schematic of AOZ2151QI-01

#### **True Current Mode Control**

The constant-on-time control scheme is intrinsically unstable if output capacitor's ESR is not large enough as an effective current-sense resistor. Ceramic capacitors usually can not be used as output capacitor.

The AOZ2151QI-01 senses the low-side MOSFET current and processes it into DC current and AC current information using AOS proprietary technique. The AC current information is decoded and added on the FB pin on phase. With AC current information, the stability of constant-on-time control is significantly improved even without the help of output capacitor's ESR; and thus the



pure ceramic capacitor solution can be applicant. The pure ceramic capacitor solution can significantly reduce the output ripple (no ESR caused overshoot and undershoot) and less board area design.

#### **Current-Limit Protection**

The AOZ2151QI-01 has the current-limit protection by using  $R_{\rm dson}$  of the low-side MOSFET to be as current sensing. To detect real current information, a minimum constant off (300ns typical) is implemented after a constant-on time. If the current exceeds the current-limit threshold, the PWM controller is not allowed to initiate a new cycle. The actual peak current is greater than the current-limit threshold by an amount equal to the inductor ripple current. Therefore, the exact current-limit characteristic and maximum load capability are a function of the inductor value and input and output voltages. The current limit will keep the low-side MOSFET on and will not allow another high-side on-time, until the current limit.

After 8 switching cycles, the AOZ2151QI-01 considers this is a true failed condition and thus turns-off both high-side and low-side MOSFETs and latches off. Only when triggered, the enable can restart the AOZ2151QI-01 again.

#### **Output Voltage Under-Voltage Protection**

If the output voltage is lower than 70% by over-current or short circuit, AOZ2151QI-01 will wait for  $32\mu s$  (typical) and turns-off both high-side and low-side MOSFETs and latches off. Only when triggered, the enable can restart the AOZ2151QI-01 again.

#### **Output Voltage Over-voltage Protection**

The threshold of OVP is set 20% higher than 0.8V. When the  $V_{FB}$  voltage exceeds the OVP threshold, high-side MOSFET is turn-off and low-side MOSFETs is turn-on 1uS, then latch-off.

#### **Power Good Output**

The power good (PGOOD) output, which is an open drain output, requires the pull-up resistor. When the output voltage is 15% below than the nominal regulation voltage for, the PGOOD is pulled low. When the output voltage is 20% higher than the nominal regulation voltage, the PGOOD is also pull low.

When combined with the under-voltage-protection circuit, this current-limit method is effective in almost every circumstance.

#### **Application Information**

The basic AOZ2151QI-01 application circuit is shown in the Typical Application section. The component selection is explained below.

#### Input capacitor

The input capacitor must be connected to the IN pins and PGND pin of the AOZ2151QI-01 to maintain steady input voltage and filter out the pulsing input current. A small decoupling capacitor, usually 4.7 $\mu$ F, should be connected to the V<sub>CC</sub> pin and AGND pin for stable operation of the AOZ2151QI-01. 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 let *m* equal the conversion ratio:

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

The relation between the input capacitor RMS current and voltage conversion ratio is calculated and shown in Figure 3. It can be seen that when  $V_O$  is half of  $V_{IN}$ ,  $C_{IN}$  it is under the worst current stress. The worst current stress on  $C_{IN}$  is 0.5 x  $I_O$ .

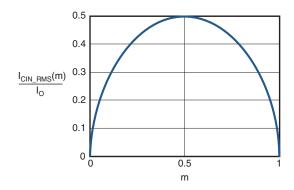


Figure 3. I<sub>CIN</sub> vs. Voltage Conversion Ratio



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 ripple current rating. Depending on the application circuits, other low ESR tantalum capacitor or aluminum electrolytic capacitor may also be used. When selecting ceramic capacitors, X5R or X7R type dielectric ceramic capacitors are preferred for their better temperature and voltage characteristics. Note that the ripple current rating from capacitor manufactures is based on certain amount of life time. Further de-rating may be necessary for practical design requirement.

#### 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 is:

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

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 30% to 50% 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 needs 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:

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

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.



# Thermal Management and Layout Consideration

In the AOZ2151QI-01 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 switch. Current flows in the second loop when the low side low side switch 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 AOZ2151QI-01.

In the AOZ2151QI-01 buck regulator circuit, the major power dissipating components are the AOZ2151QI-01 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 and output current.

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

The actual junction temperature can be calculated with power dissipation in the AOZ2151QI-01 and thermal impedance from junction to ambient.

$$T_{iunction} = (P_{total\_loss} - P_{inductor\_loss}) \times \Theta_{JA}$$

The maximum junction temperature of AOZ2151QI-01 is 150°C, which limits the maximum load current capability.

The thermal performance of the AOZ2151QI-01 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.

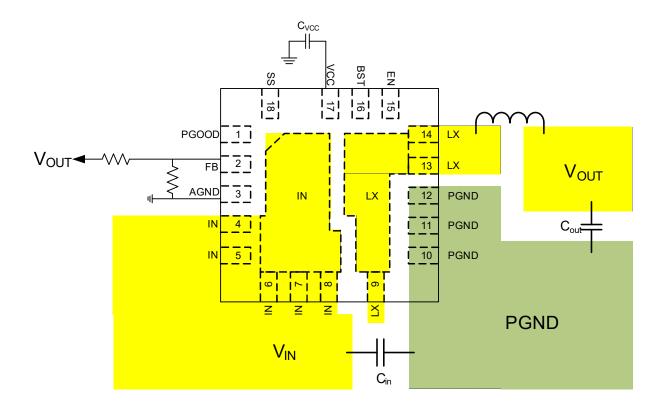


#### **Layout Considerations**

Several layout tips are listed below for the best electric and thermal performance.

- The LX pins and pad are connected to internal low side switch drain. They are low resistance thermal conduction path and most noisy switching node. Connected a large copper plane to LX pin to help thermal dissipation.
- The IN pins and pad are connected to internal high side switch drain. They are also low resistance thermal conduction path. Connected a large copper plane to IN pins to help thermal dissipation.

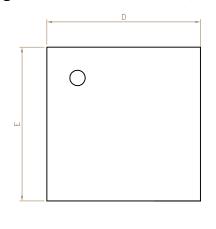
- Input capacitors should be connected to the IN pin and the PGND pin as close as possible to reduce the switching spikes.
- 4. Decoupling capacitor  $C_{VCC}$  should be connected to  $V_{CC}$  and AGND as close as possible.
- 5. Voltage divider R1 and R2 should be placed as close as possible to FB and AGND.
- 6. Keep sensitive signal traces such as feedback trace far away from the LX pins.

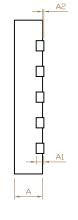


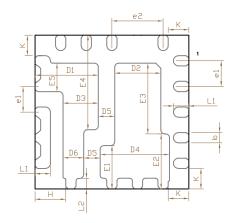
Rev. 2.0 February 2017 www.aosmd.com Page 13 of 16



# Package Dimensions, QFN 3x3, 18 Lead EP2\_S





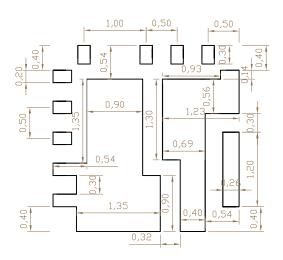


Top VIEW

SIDE VIEW

**Bottom VIEW** 

#### RECOMMENDED LAND PATTERN



UNIT: mm

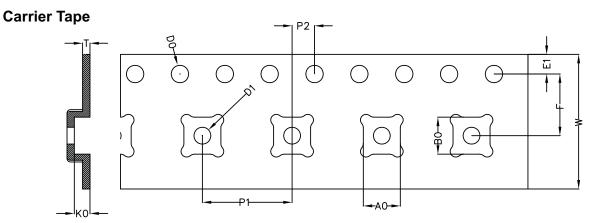
SYMBOLS	DIMENSIC	NS IN MILLIN	NETERS						
	MIN	NOM	MAX						
Α	0.45	0.55	0.65						
A1	0.10	0.15	0.20						
A2		0.020REF							
Е	2.90	3.00	3.10						
E1	0.80	0.85	0.90						
E2	1.03	1.08	1.13						
E3	1.28	1.38	1.48						
E4	1.75	1.85	1.95						
E5	0.51	0.56	0.61						
K	0.35	0.40	0.45						
Н	0.55	0.60	0.65						
D	2.90	3.00	3.10						
D1	1.13	1.23	1.33						
D2	0.85	0.90	0.95						
D3	0.64	0.69	0.74						
D4	1.25	1.35	1.45						
D5	0.27	0.32	0.37						
D6	0.35	0.40	0.45						
e1		0.50REF							
e2		1.00REF							
b	0.20REF								
L1		0.30REF							
L2		0.21REF							

NOTE CONTROLLING DIMENSION IS MILLIMETER. CONVERTED INCH DIMENSIONS ARE NOT NECESSARILY EXACT.

Rev. 2.0 February 2017 **www.aosmd.com** Page 14 of 16



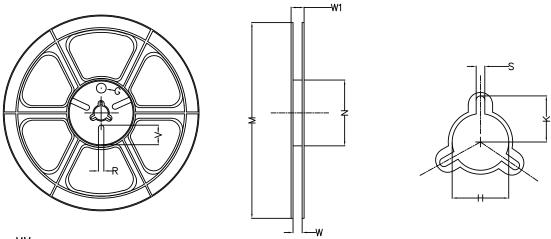
# Tape and Reel Dimensions, QFN 3x3, 18 Lead EP2\_S



UNIT:	MM
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PACKAGE	A0	В0	КО	DO	D1	w	E1	F	P0	P1	P2	Т
QFN3X3_18L	3.30 ±0.10	3.30 ±0.10	0.80 ±0.10	1.55 ±0.05	1.50 Min.	12.00 +0.30 -0.00	1.75 ±0.10	5.50 ±0.10	4.00 ±0.10	8.00 ±0.10	2.00 ±0.10	0.30 ±0.05

#### Reel

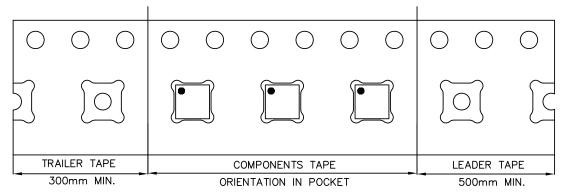


UNI	т٠	MM
OIN	١.	IVIIVI

TAPE S	ZE	REEL SIZE	М	N	W	W1	Н	S	K	G	R	٧
12 m	n	ø330	ø330.00 ±2.00	ø101.6 ±2.00	12.40 +2.00 -0.00	12.40 +3.00 -0.20	ø13.20 ±0.30	1.70-2.60				

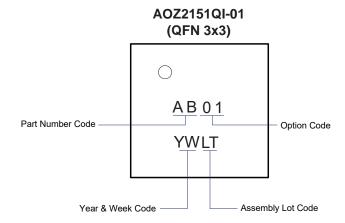
## **Leader/Trailer & Orientation**

Unit Per Reel: 5000pcs





#### **Part Marking**



#### **LEGAL DISCLAIMER**

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#### LIFE SUPPORT POLICY

ALPHA AND OMEGA SEMICONDUCTOR PRODUCTS ARE NOT AUTHORIZED FOR USE AS CRITICAL COMPONENTS IN LIFE SUPPORT DEVICES OR SYSTEMS.

As used herein:

- 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.

Rev. 2.0 February 2017 **www.aosmd.com** Page 16 of 16