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ALPHA & OMEGA
SEMICONDUCTOR

General Description

The AOZ6643DI is a current-mode step down regulator with integrated high-side NMOS switch and low-side NMOS switch that operates up to 18V. The device is capable of supplying 3A of continuous output current with an output voltage adjustable down to 0.8V (±1.5%).

Features include, enable control, Power-On Reset, input under-voltage lockout, output over-voltage protection, internal soft-start and thermal shutdown.

The AOZ6643DI is available in a 3mm x 3mm DFN-8L package and is rated over a -40°C to +85°C ambient temperature range.

Features

- 4.5V to 18V wide input voltage range
- Low $R_{DS(ON)}$ internal NFETs
  - 80mΩ high-side
  - 30mΩ low-side
- Internal soft start
- Output voltage adjustable down to 0.8V (±1.5%)
- 3A continuous output current
- 500kHz PWM operation
- Cycle-by-cycle current limit
- Ceramic capacitor stable
- Pre-bias start-up
- Extensive protection features
- Small 3mm x 3mm DFN-8L package

Applications

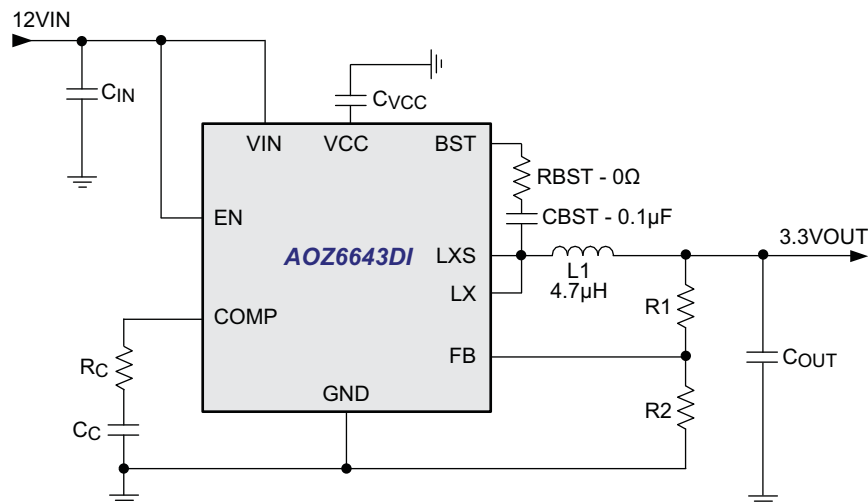- Point-of-load DC/DC converters
- LCD TVs
- Cable modems

Green Product

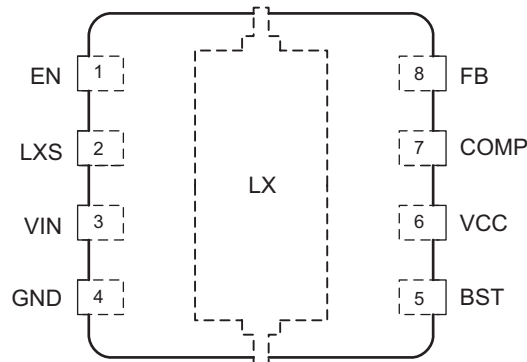## Typical Application

Figure 1. 3A Synchronous Buck Regulator, Fs = 500kHz

Ordering Information

Part Number	Ambient Temperature Range	Package	Environmental
AOZ6643DI	-40°C to +85°C	8-Pin 3mm x 3mm DFN	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

```
        EN  ┌ 1 ┐          ┌ 8 ┐  FB
        LXS ┌ 2 ┐          ┌ 7 ┐  COMP
                      LX
        VIN ┌ 3 ┐          ┌ 6 ┐  VCC
        GND ┌ 4 ┐          ┌ 5 ┐  BST
```

8-Pin 3mm x 3mm DFN
(Top View)

Pin Description

Pin Number	Pin Name	Pin Function
1	EN	Enable Input. Logic high to enable the device.
2	LXS	Source of the internal HS FET. This pin has to be externally connected to exposed pad LX through the PCB.
3	VIN	Supply Input. When VIN rises above the UVLO threshold and EN is logic high, the device starts up.
4	GND	Power Ground.
5	BST	Bootstrap. Requires a capacitor connection between LX and BST to form a floating supply across the high-side switch driver.
6	VCC	Internal LDO Output.
7	COMP	External Loop Compensation Pin. Connect a RC network between COMP and GND to compensate the control loop.
8	FB	Feedback Input. The FB pin is used to set the output voltage with a resistive voltage-divider between the regulator's output and AGND.
Exposed Pad	LX	Switching Node. LX is the drain of the internal LS power FETs.

Absolute Maximum Ratings

Exceeding the Absolute Maximum Ratings may damage the device.

Parameter	Rating
Supply Voltage (V_{IN})	20V
EN	20V
LX to GND	-0.7V to V_{IN}+0.3V
LX to GND (20ns)	-5V to 22V
VCC, FB, COMP to AGND	-0.3V to 6V
VBST to LX	6V
Junction Temperature (T_J)	+150°C
Storage Temperature (T_S)	-65°C to +150°C
ESD Rating[1]	2kV

Note:

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

Maximum Operating Ratings

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

Parameter	Rating
Supply Voltage (V_{IN})	4.5V to 18V
Output Voltage Range	0.8V to 0.85*V_{IN}
Ambient Temperature (T_A)	-40°C to +85°C
Package Thermal Resistance	
(θ_{JA})[2]	50°C/W

Note:

2. The value of θ_{JA} is measured with the device mounted on a 1-in^2 FR-4 four layer board with 2oz copper and Vias, in a still air environment with T_A = 25°C. The value in any given application depends on the user's specification board design.

Electrical Characteristics

T_A = 25°C, V_{IN} = V_{EN} = 12V, V_{OUT} = 3.3V, unless otherwise specified[3].

Symbol	Parameter	Conditions	Min.	Typ.	Max	Units
V_{IN}	Supply Voltage		**4.5**		**18**	V
V_{CC_UVLO}	Under-Voltage Lockout Threshold	V_{IN} rising V_{IN} falling	3.3	4.2 3.7	4.45	V
V_{CC}	VCC Regulator			5		V
	VCC Load Regulation	I_{CC} = 5mA		3		%
I_{IN}	Supply Current (Quiescent)	I_{OUT} = 0V, VFB = 1.2V, V_{EN} > 2V			0.8	mA
I_{OFF}	Shutdown Supply Current	V_{EN} = 0V		**2**	**5**	μA
V_{FB}	Feedback Voltage	T_A = 25°C	0.788	0.800	0.812	V
	Load Regulation	0.1A < I_{OUT} < 2.9A		0.5		%
	Line Regulation	8V < V_{IN} < 16V		1		%
I_{FB}	FB Input Current				200	nA
V_{EN}	EN Input Threshold	Off threshold On threshold	**2**		**0.6**	V
V_{EN_HYS}	EN Input Hysteresis			250		mV
	EN Leakage Current				**10**	μA
	SS Time			4		ms
Modulator						
f_O	Frequency		400	500	600	kHz
D_{MAX}	Maximum Duty Cycle			85		%
T_{MIN}	Controllable Minimum On Time			90		ns
	Current Sense Transconductance			8		A/V
	Error Amplifier Transconductance			500		μA/V

Electrical Characteristics *(Continued)*

T_A = 25°C, V_{IN} = V_{EN} = 12V, V_{OUT} = 3.3V, unless otherwise specified[3].

Symbol	Parameter	Conditions	Min.	Typ.	Max	Units
Protection						
I_{LIM}	Current Limit		3.5	4.5	6.5	A
V_{OVP}	Over Voltage Protection	OVP shutdown threshold OVP hysteresis	850	950 100	1050	mV
	Over Temperature Shutdown Limit	T_J rising T_J falling		150 100		°C
Output Stage						
HS $R_{DS(ON)}$	High-Side Switch On-Resistance	V_{BST-LX} = 5V		80		mΩ
LS $R_{DS(ON)}$	Low-Side Switch On-Resistance	V_{CC} = 5V		30		mΩ

Note:

3. The device is not guaranteed to operate beyond the Maximum Operating Ratings. Specifications in **Bold** indicate an ambient temperature range of -40°C to +85°C. These specifications are guaranteed by design.
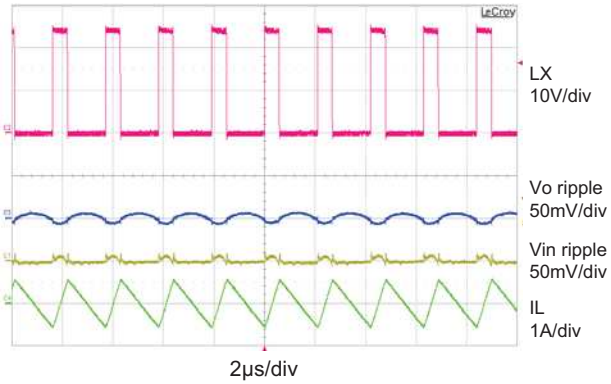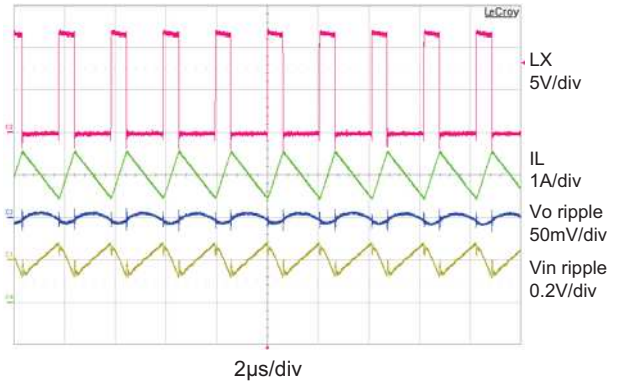
Functional Block Diagram
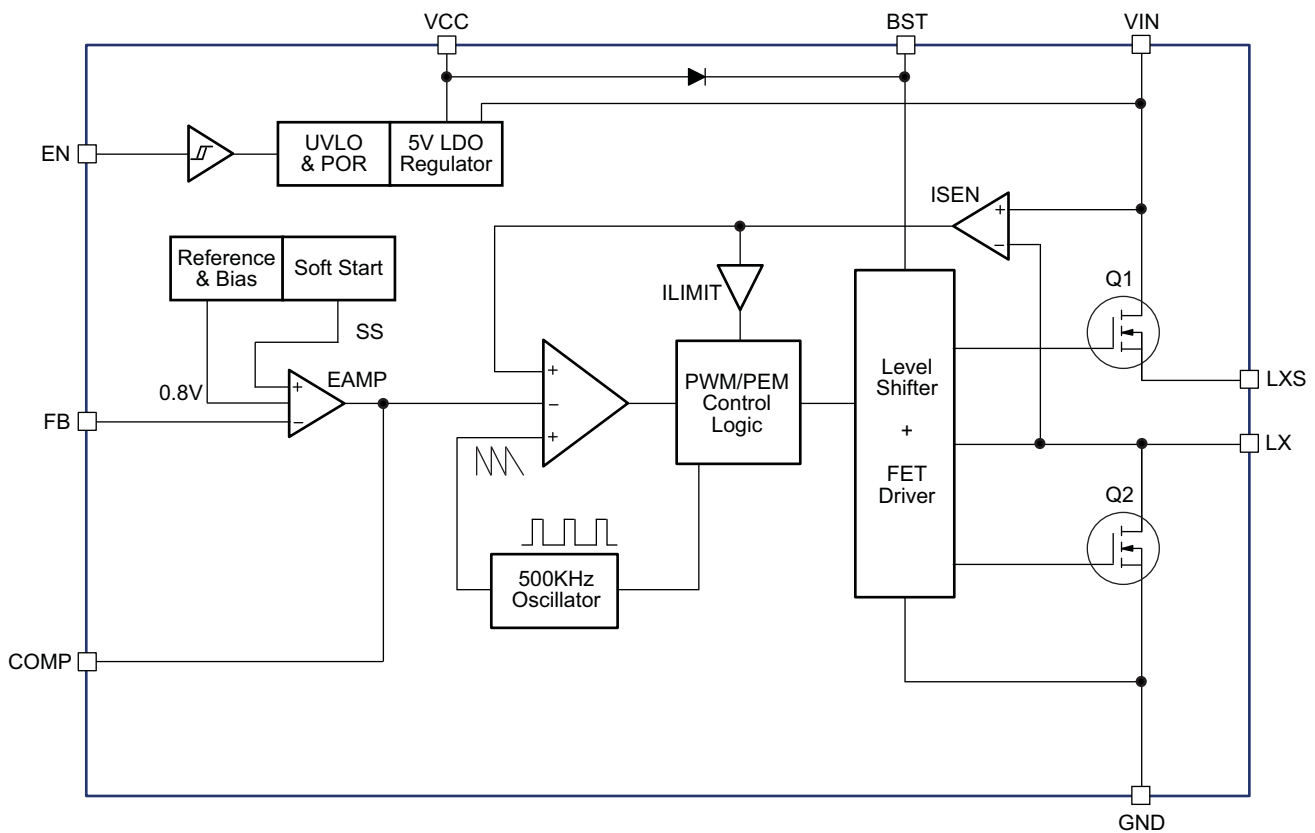
Typical Performance Characteristics

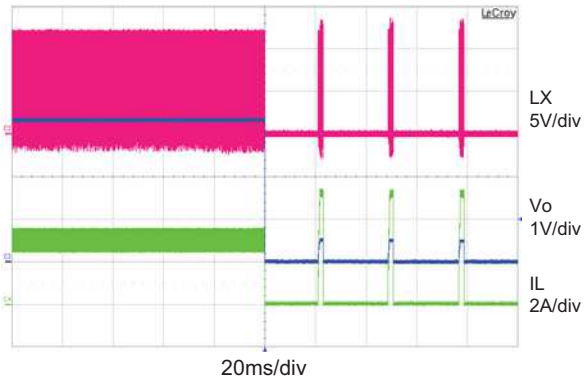Circuit of Typical Application. T_A = 25°C, V_{IN} = V_{EN} = 12V, V_{OUT} = 3.3V, unless otherwise specified.

Light Load Operation

LX
10V/div

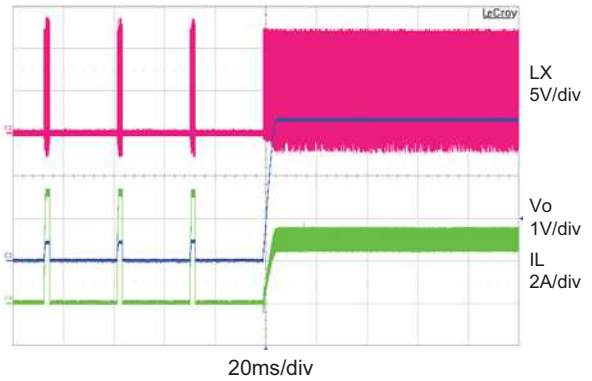Vo ripple
50mV/div

Vin ripple
50mV/div

IL
1A/div

2µs/div

Full Load Operation

LX
5V/div

IL
1A/div

Vo ripple
50mV/div

Vin ripple
0.2V/div

2µs/div

Short Circuit Protection

LX
5V/div

Vo
1V/div

IL
2A/div

20ms/div

Short Circuit Recovery

LX
5V/div

Vo
1V/div

IL
2A/div

20ms/div

Full Load Start-up

Vin
5V/div

Vo
1V/div

Io
1A/div

2ms/div

50% to 100% Load Transient

Vo
0.2V/div

IL
2A/div

100µs/div

Efficiency

Efficiency vs. Load Current
(VIN=12V, f=500kHz)

- 5VOUT, L=6.8µH
- 3.3VOUT, L=4.7µH
- 2.5VOUT, L=4.7µH
- 1.8VOUT, L=2.2µH
- 1.2VOUT, L=2.2µH
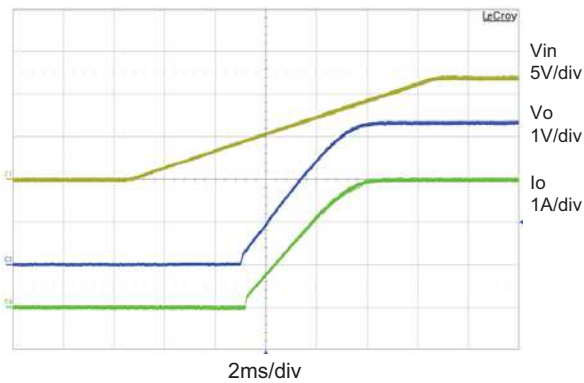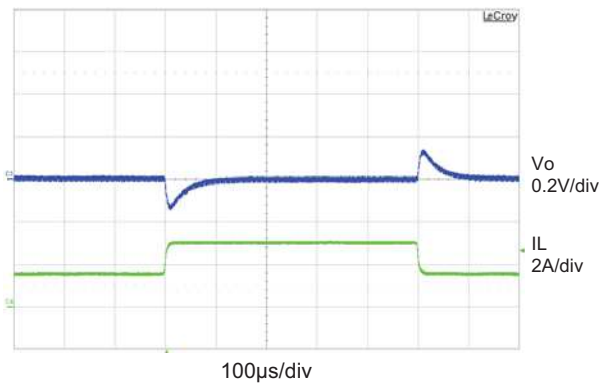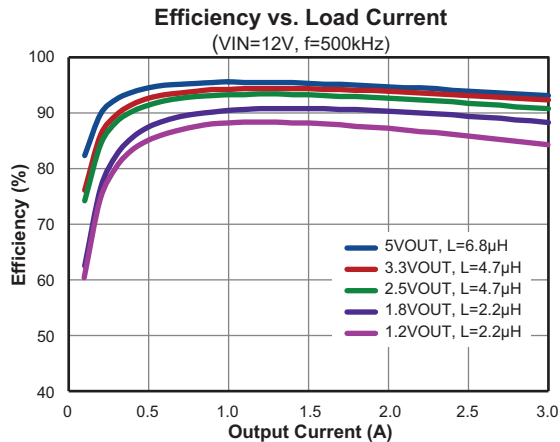
Detailed Description

The AOZ6643DI is a current-mode step down regulator with integrated high-side NMOS switch and low-side NMOS switch. It operates from a 4.5V to 18V input voltage range and supplies up to 3A of load current. Features include, enable control, Power-On Reset, input under voltage lockout, output over voltage protection, internal soft-start and thermal shut down.

The AOZ6643DI is available in 8-pin 3mm x 3mm DFN package.

Enable and Soft Start

The AOZ6643DI 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 typically ramped to regulation voltage in 4ms. The 4ms soft start time is set internally.

The EN pin of the AOZ6643DI is active high. Connect the EN pin to VIN if enable function is not used. Pull it to ground will disable the AOZ6643DI. Do not leave it open. The voltage on EN pin must be above 2V to enable the device. When the voltage on EN pin falls below 0.6V, the AOZ6643DI is disabled.

Steady-State Operation

The AOZ6643DI switching frequency is fixed and set by an internal oscillator. The practical switching frequency could range from 400kHz to 600kHz due to device variation.

The AOZ6643DI integrates an internal N-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 AOZ6643DI uses freewheeling NMOSFET to realize synchronous rectification. It greatly improves the converter efficiency and reduces power loss in the low-side switch.

The AOZ6643DI uses a N-Channel MOSFET as the high-side switch. Since the NMOSFET requires a gate voltage higher than the input voltage, a boost capacitor is needed between LXS pin and BST pin to drive the gate. The boost capacitor is charged while LX is low

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.

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

Some standard value of R_1, R_2 and most used output voltage values are listed in Table 1.

VO (V)	R1 (kΩ)	R2 (kΩ)
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

Table 1.

Combination of R1 and R2 should be large enough to avoid drawing excessive current from the output, which will cause power loss.

Protection Features

The AOZ6643DI 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 AOZ6643DI employs peak current mode control, during over current conditions. The peak inductor current is automatically limited to cycle-by-cycle, and if output is shorted to GND, then the AOZ6643DI will shutdown and auto restart approximately every 25ms.

Power-On Reset (POR)

A power-on reset circuit monitors the VCC 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 NMOS 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 AOZ6643DI application circuit is shown in Figure 1. Component selection is explained below.

Input Capacitor

The input capacitor must be connected to the VIN pin and GND pin of the AOZ6643DI 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 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 2 below. 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.
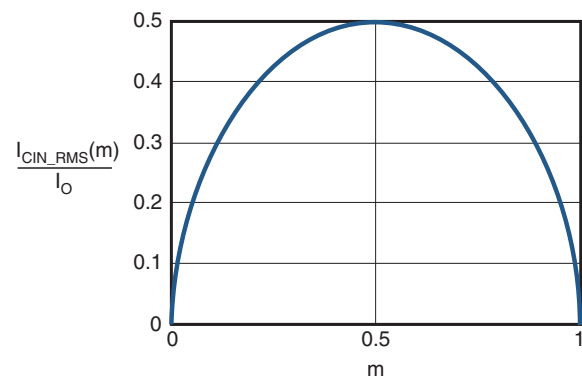

Figure 2. I$_{CIN}$ vs. Voltage Conversion Ratio

For reliable operation and best performance, the input capacitors must have current rating higher than I$_{CIN-RMS}$ 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 a 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 40% 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 the inductor needs to be checked for thermal and efficiency requirements.

Surface mount inductors in different shapes and styles are available from Coilcraft, Elytone and Murata. Shielded inductors are small and radiate less EMI noise, but they do 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_O is output capacitor value and

ESR_{CO} is the Equivalent Series Resistor of output capacitor.

When a 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, the output capacitor could be overstressed.

Loop Compensation

The AOZ6643DI 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:

$$f_{z1} = \frac{1}{2\pi \times C_O \times ESR_{CO}}$$

where,

C_O is output filter capacitor,

R_L is load resistor value and

ESR_{CO} is the Equivalent Series Resistor 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 AOZ6643DI. 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 AOZ6643DI, 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,

G_{EA} is the error amplifier transconductance, which is $500 \cdot 10^{-6}$ A/V;

G_{VEA} is the error amplifier voltage gain, which is 7000 V/V;

C_C 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_C 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 strategy for choosing R_C and C_C is to set the cross over frequency with Rc and set the compensator zero with C_C. Using selected crossover frequency, f_C, to calculate R_3:

$$R_C = f_C \times \frac{V_O}{V_{FB}} \times \frac{2\pi \times C_O}{G_{EA} \times G_{CS}}$$

where,

f_C is desired crossover frequency. For best performance, f_C is set to be about 1/10 of switching frequency;

V_{FB} is 0.8V;

G_{EA} is the error amplifier transconductance, which is $500 \cdot 10^{-6}$ A/V;

G_{CS} is the current sense circuit transconductance, which is 8 A/V.

The compensation capacitor C_C and resistor R_C together make a zero. This zero is put somewhere close to the dominate pole f_{p1} but lower than 1/5 of selected crossover frequency. C_2 can is selected by:

$$C_C = \frac{1}{2\pi \times R_C \times f_{p1}}$$

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 www.aosmd.com.

Thermal Management and Layout Consideration

In the AOZ6643DI 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 returns to the input capacitor through ground. Current flows in the first loop when the high side switch is on. The second loop starts from the inductor, to the output capacitors and load, to the low side switch. Current flows in the second loop when the 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 the input capacitor, output capacitor and GND pin of the AOZ6643DI.

In the AOZ6643DI buck regulator circuit, the major power dissipating components are the AOZ6643DI and output inductor. The total power dissipation of the 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.

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

The actual junction temperature can be calculated with power dissipation in the AOZ6643DI and thermal impedance from junction to ambient.

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

The maximum junction temperature of AOZ6643DI is 150ºC, which limits the maximum load current capability.

The thermal performance of the AOZ6643DI 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.

1. The exposed pad (LX), which is the low-side NFET drain, has to be externally connected to internal high-side NFET source (LXS). Place a large copper plane to LX pin to help thermal dissipation.

2. Do not use thermal relief connection to VIN and the GND pin. Pour a maximized copper area to the GND pin and the VIN pin to help thermal dissipation.

3. Input capacitor should be connected to the VIN pin and the GND pin as close as possible. Make the current trace from LX pins to L to C_O to the GND as short as possible.

4. Pour copper plane on all unused board area and connect it to stable DC nodes, like VIN, GND or VOUT.

5. Keep sensitive signal traces such as feedback trace far away from the LX pins.

## Package Dimensions, DFN 3x3B, 8 Lead EP1_P
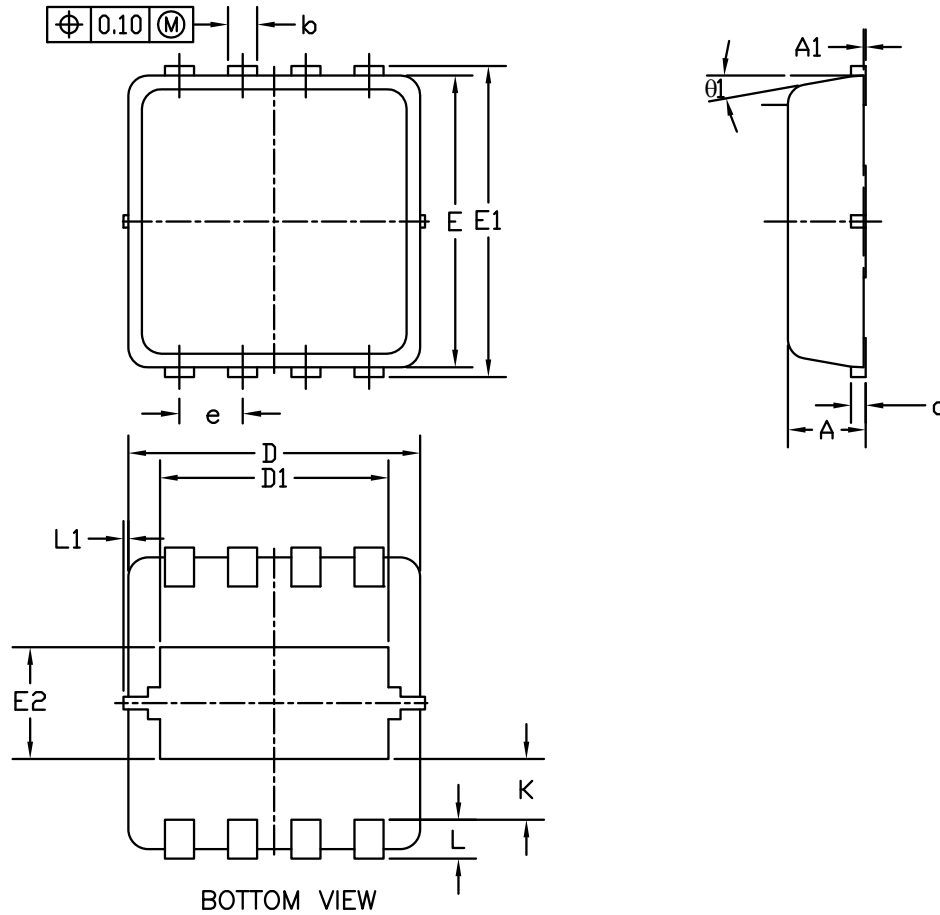
RECOMMENDED LAND PATTERN
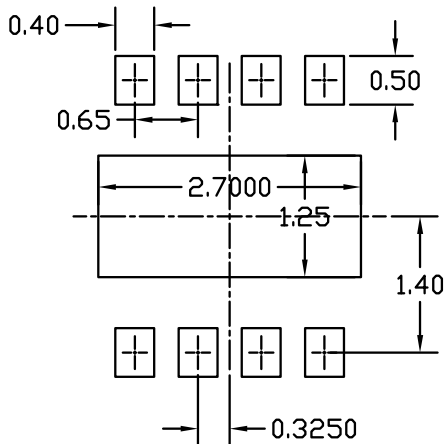
SYMBOLS	DIMENSIONS IN MILLIMETERS			DIMENSIONS IN INCHES		
	MIN	NOM	MAX	MIN	NOM	MAX
A	0.70	0.80	0.90	0.028	0.031	0.035
A1	0.00	———	0.05	0.000	———	0.002
b	0.24	0.30	0.35	0.009	0.012	0.014
c	0.10	0.15	0.25	0.004	0.006	0.010
D	2.90	3.00	3.10	0.114	0.118	0.122
D1	2.15	2.35	2.55	0.085	0.093	0.100
E	2.90	3.00	3.10	0.114	0.118	0.122
E1	3.05	3.20	3.35	0.120	0.126	0.132
E2	1.10	1.15	1.20	0.043	0.045	0.047
e	0.60	0.65	0.70	0.024	0.026	0.028
K	0.575	0.625	0.675	0.023	0.025	0.027
L	0.30	0.40	0.50	0.012	0.016	0.020
L1	0	———	0.10	0	———	0.004
θ1	0	10	12	0	10	12

NOTE
1. PAKCAGE BODY SIZES EXCLUDE MOLD FLASH AND GATE BURRS.
   MOLD FLASH AT THE NON-LEAD SIDES SHOULD BE LESS THAN 6 MILS EACH.
2. CONTROLLING DIMENSION IS MILLIMETER.
   CONVERTED INCH DIMENSIONS ARE NOT NECESSARILY EXACT.
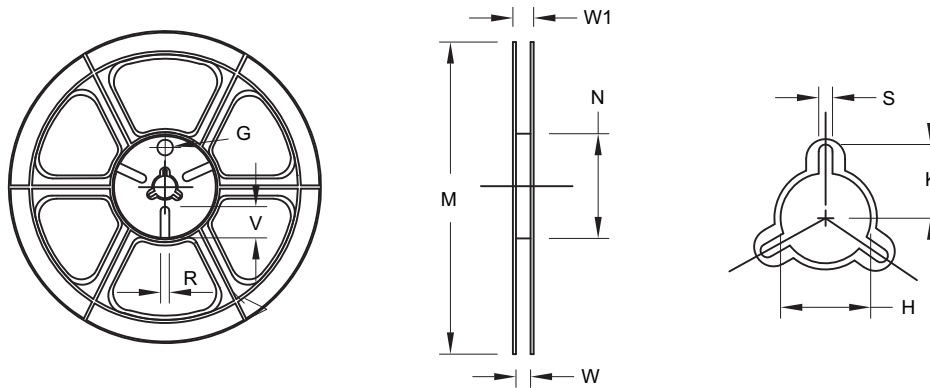
Tape and Reel Dimensions, DFN 3x3, EP

Carrier Tape

Feeding Direction
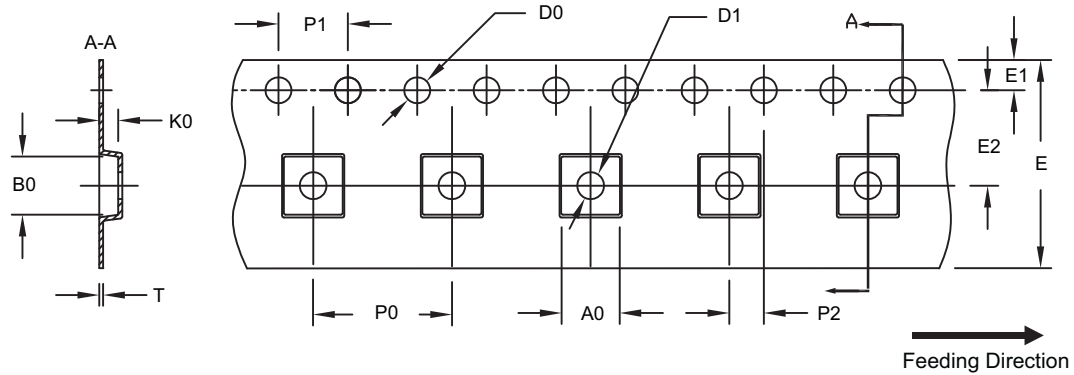
UNIT: mm

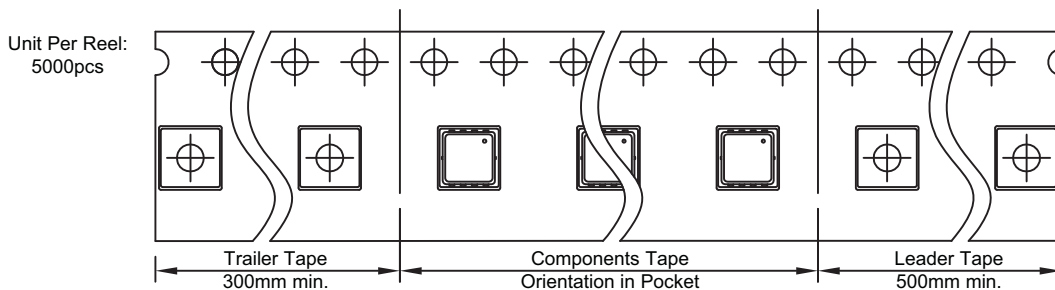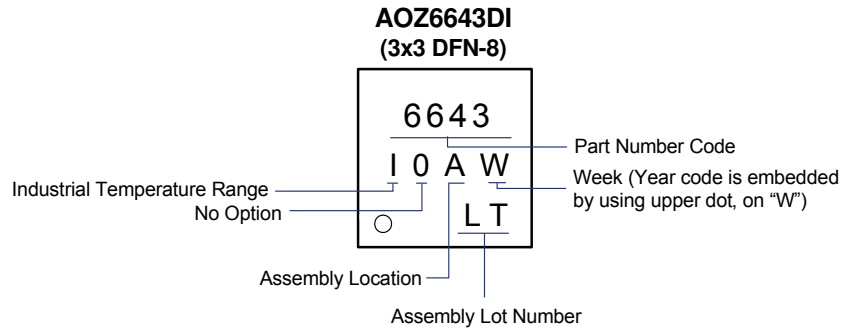| Package	A0	B0	K0	D0	D1	E	E1	E2	P0	P1	P2	T
DFN 3x3 EP	3.40 ±0.10	3.35 ±0.10	1.10 ±0.10	1.50 +0.10/-0	1.50 +0.10/-0	12.00 ±0.30	1.75 ±0.10	5.50 ±0.05	8.00 ±0.10	4.00 ±0.10	2.00 ±0.05	0.30 ±0.05

Reel

UNIT: mm

Tape Size	Reel Size	M	N	W	W1	H	K	S	G	R	V
12mm	ø330	ø330.0 ±0.50	ø97.0 ±1.0	13.0 ±0.30	17.4 ±1.0	ø13.0 +0.5/-0.2	10.6	2.0 ±0.5	—	—	—

Leader/Trailer and Orientation

Unit Per Reel: 5000pcs

| Trailer Tape 300mm min. | Components Tape Orientation in Pocket | Leader Tape 500mm min. |

Part Marking

AOZ6643DI
(3x3 DFN-8)

```
  6 6 4 3        ────── Part Number Code

  I 0 A W        ────── Week (Year code is embedded
                          by using upper dot, on "W")
      L T
   ○
```

Industrial Temperature Range ──────
No Option ──────
Assembly Location ──────
Assembly Lot Number ──────

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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.