ALPHA & OMEGA SEMICONDUCTOR

AOZ1374DI

ECPower™ 23 V 36 mΩ Protection Switch Programmable Current Limit and True Reverse Current Blocking

General Description

AOZ1374DI is a current-limiting protection switch targeting applications that require comprehensive protections. Both VIN and VOUT terminals are rated at 28 V absolute maximum. There is a programable soft-start feature up to 10ms to limit the inrush current for highly capacitive loads. The supply current reduces to 5 µA in shutdown. It also has Input Under-Voltage Lock Out (UVLO), Input Over-Voltage Protection (OVP), and Thermal Shut Down Protection (TSD).

AOZ1374DI has True Reverse Current Blocking (TRCB) protection to avoid undesired reverse-current from VOUT to VIN. It also features an internal current-limiting circuit that protects the supply from large load current. The current limit threshold can be set externally with a resistor.

AOZ1374DI-01 will auto-restart when the fault conditions are cleared.

AOZ1374DI-02 will latch the power switch off in case of a fault condition and EN must be reset to restart the device.

AOZ1374DI is available in small 3 mm x 3 mm 10-pin DFN package.

Features

- 28 V abs max voltage rating on VIN and VOUT pin
- Typical R_{ON}: 36 m Ω
- Programmable current limit
- True Reverse Current Blocking (TRCB)
- Input Over-Voltage Protection (OVP)
- Short-Circuit Protection (SCP)
- Input Under-Voltage Lock Out (UVLO)
- Thermal Shut Down Protection (TSD)
- HBM ESD rating: ±4 kV on all pins
- CDM ESD rating: ±1 kV
- IEC 61000-4-2: ±8 kV on VOUT
- IEC 61000-4-5: 45 V on VOUT, no cap
- IEC 62368-1: 2014 E326264-A6008-CB-1

Applications

- USB PD power source switch
- Smartphones and tablets
- Notebooks, ultra-books and desktops
- Portable devices

Green Product
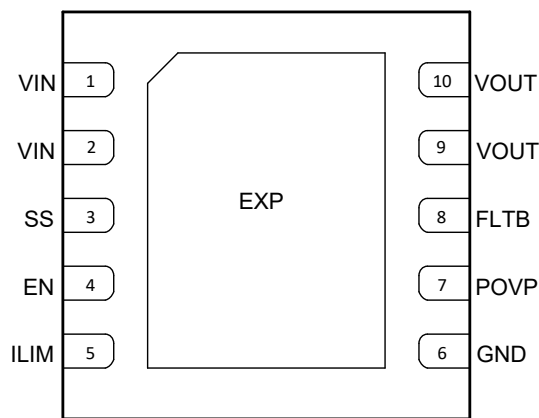
Typical Application
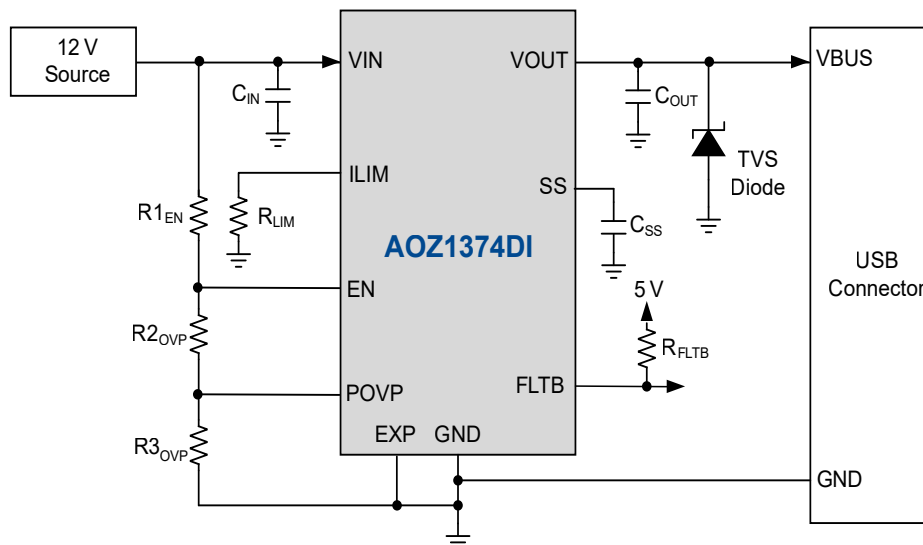
Ordering Information

Part Number	Fault Recovery	Junction Temperature Range	Package	Environmental
AOZ1374DI-01	Auto-Recovery	-40°C to + 125°C	DFN3x3-10L	RoHS
AOZ1374DI-02	Latch-Off	-40°C to + 125°C	DFN3x3-10L	RoHS

AOS products are offered in packages with Pb-free plating and compliant to RoHS standards.
Please visit https://aosmd.com/sites/default/files/media/AOSGreenPolicy.pdf for additional information.

Pin Configuration

DFN3x3-10L
(Top Transparent View)

Pin Description

Pin Number	Pin Name	Pin Function
1, 2	VIN	Supply input. Connected to internal power regulator. They are internally connected together.
3	SS	Soft Start control. Connect a capacitor CSS from SS to GND to set the soft start time.
4	EN	Enable input. Active high.
5	ILIM	Current limit set pin. Connect a 1% resistor RLIM from ILIM to GND to set the current limit threshold.
6	GND	Ground
7	POVP	Programmable Over Voltage Protection. Use resistor divider from VIN to GND to set the OVP threshold.
8	FLTB	Open-drain Fault indicator.
9, 10	VOUT	Power output. Connect to Type C port. They are internally connected together.
EXP	EXP	Exposed Thermal Pad. It must be connected to GND plane for optimal thermal dissipation. Solder to a metal surface directly underneath the EXP and connect to PCB ground on multiple layers through VIAs for multi-layer PCB design. For best thermal performance make the ground copper pads as large as possible and connect to EXP with multiple VIAs.

Absolute Maximum Ratings

Exceeding the Absolute Maximum ratings may damage the device.

Parameter	Rating
VIN, VOUT to GND	-0.3 V to +28 V
EN, ILIM, SS, FLTB, OVP to GND	-0.3 V to +6 V
Junction Temperature (T_J)	+150 °C
Storage Temperature (T_S)	-65 °C to +150 °C
ESD Rating HBM All Pins	±4 kV
IEC 61000-4-2 at VOUT	±8 kV

Recommended Operating Conditions

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

Parameter	Rating
VIN, VOUT to GND	3.4 V to 23 V
EN, ILIM, SS, FLTB to GND	0 V to 5.5 V
OVP to GND	0 V to 3 V
Switch DC Current (I_{SW})	0 A to 3.5 A
Junction Temperature (T_J)	-40 °C to +125 °C
Package Thermal Resistance (Θ_{JA})	50 °C/W

Electrical Characteristics

T_A = 25 °C, VIN = 12 V, EN = 5 V, unless otherwise specified.

Symbol	Parameter	Conditions	Min	Typ	Max	Unit
General						
V_{IN}	Input Supply Voltage		3.4		23	V
V_{UVLO_R}	Under-Voltage Lockout Threshold	VIN rising	2.9		3.35	V
V_{UVLO_HYS}	Under-Voltage Lockout Hysteresis	VIN falling		250		mV
I_{IN_ON}	Input Quiescent Current	I_{OUT} = 0A		0.9		mA
I_{IN_OFF}	Input Shutdown Current	EN = 0V		5		µA
R_{ON}	Switch On Resistance	VIN = 20 V, I_{OUT} = 1A		36		mΩ
		VIN = 5 V, I_{OUT} = 1A		39		
V_{EN_H}	Enable Input Logic High Threshold	EN rising	1.05	1.15	1.32	V
V_{EN_L}	Enable Input Logic Low Threshold	EN falling	0.88	1.00	1.15	V
I_{EN_BIAS}	Enable Input Bias Current	EN = 1.8 V		20		nA
V_{FLTB_LO}	FLTB Pull-down Voltage	I_{SINK} = 3mA			0.3	V
Dynamic Characteristics						
t_{D_ON}	Turn-On Delay Time (From EN 50% to VOUT = 0.5 V)	VIN = 12 V, C_{SS} = 22 nF, R_{LIM} = 3.26 kΩ		1.1		ms
t_{ON}	Turn-On Time (VOUT from 10% to 90% of 12V VIN)	VIN = 12 V, C_{SS} = 22 nF, R_{LIM} = 3.26 kΩ		2.6		ms
t_{REC}	FLTB Recovery Time	Fault is removed (AOZ1374DI-01 Only)		150		ms
True Reverse-Current Blocking (TRCB)						
V_{T_TRCB}	TRCB Protection Trip Point	VOUT-VIN, VOUT rising		30		mV
t_{TRCB}	TRCB Response Time	VOUT-VIN > V_{T_TRCB} + 500 mV		1		µs

Electrical Characteristics

T_A = 25 °C, VIN = 12 V, EN = 5 V, unless otherwise specified.

Symbol	Parameter	Conditions	Min	Typ	Max	Unit
Input Over-Voltage Protection (OVP)						
V_{OVP}	Over-voltage Lockout Threshold	VIN rising		1.2		V
V_{OVP_HYS}	Over-voltage Lockout Hysteresis	AOZ1374DI-01		200		mV
I_{OVP_BIAS}	OVP Input Bias Current	POVP = 2 V		20		nA
t_{DELAY_OVP}	OVP Turn-Off Delay			1.5		µs
Over Current Protection (OCP)						
I_{LIM}	Current Limit Threshold	R_{LIM} = 1.74 kΩ		3.56		A
		R_{LIM} = 2.8 kΩ		2.21		
		R_{LIM} = 3.26 kΩ	1.61	1.90	2.18	
		R_{LIM} = 8.25 kΩ		0.75		
t_{OCP}	Over-Current Duration before Switch Off	From $I_{OUT} \geq I_{LIM}$ to Switch Off		1		ms
t_{OCP_FLTB}	Over-Current Flag Delay	From $I_{OUT} \geq I_{LIM}$ to FLTB pulled low		1		ms
Short-Circuit Protection (SCP)						
$t_{SC\_RESPONSE}$	Response time to open the switch after a VOUT short circuit condition is detected	VIN - VOUT > 500 mV		1		µs
Thermal Shutdown (TSD)						
T_{SD}	Thermal Shutdown Threshold	Temperature rising		140		°C
T_{SD_HYS}	Thermal Shutdown Hysteresis	Temperature falling		30		

Functional Block Diagram
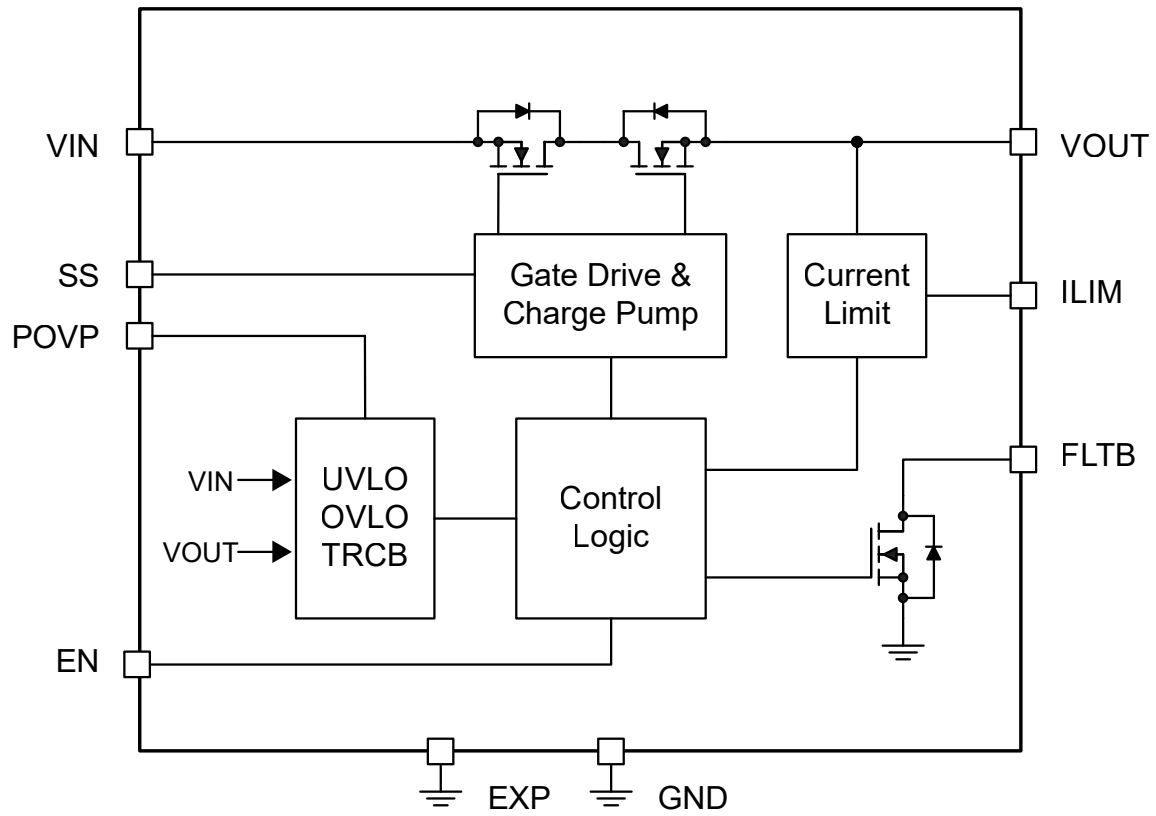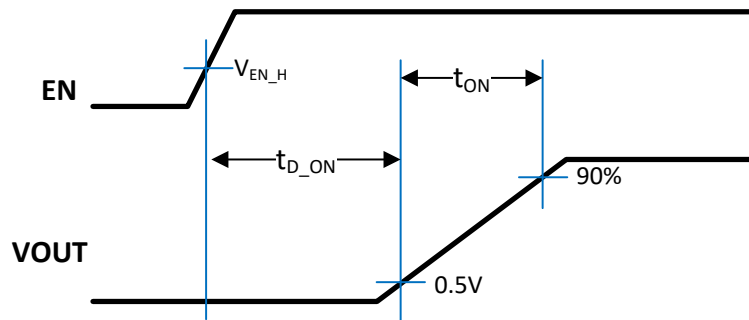
Timing Diagrams

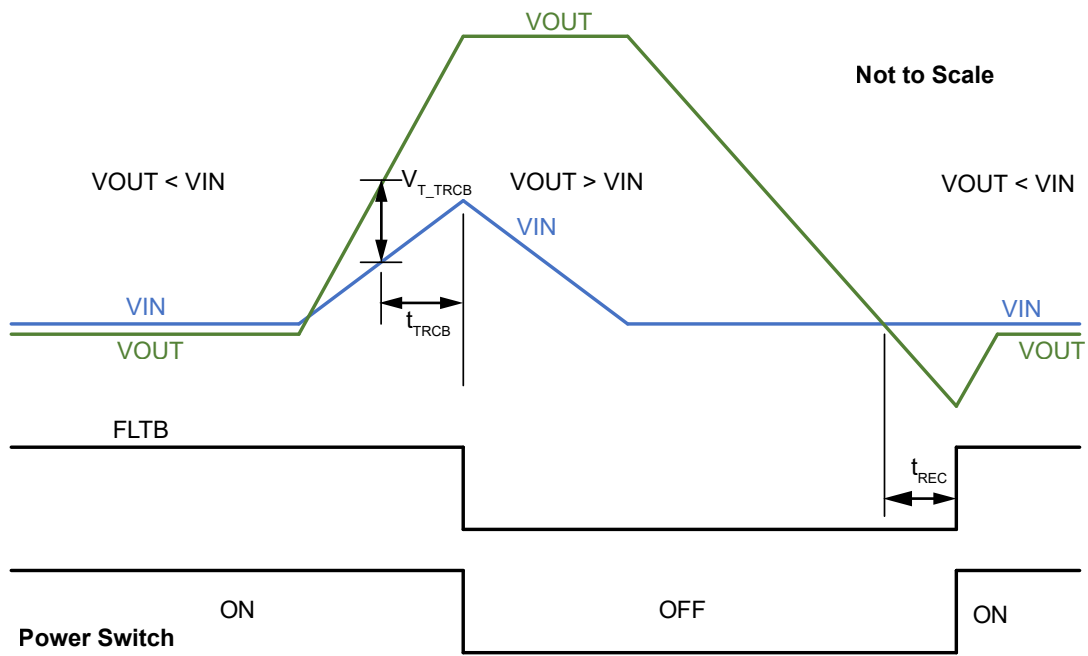**Figure 1. Turn On Delay and Soft-Start Time**

Figure 2. True Reverse Current Blocking (TRCB) Operation (AOZ1374DI-01)
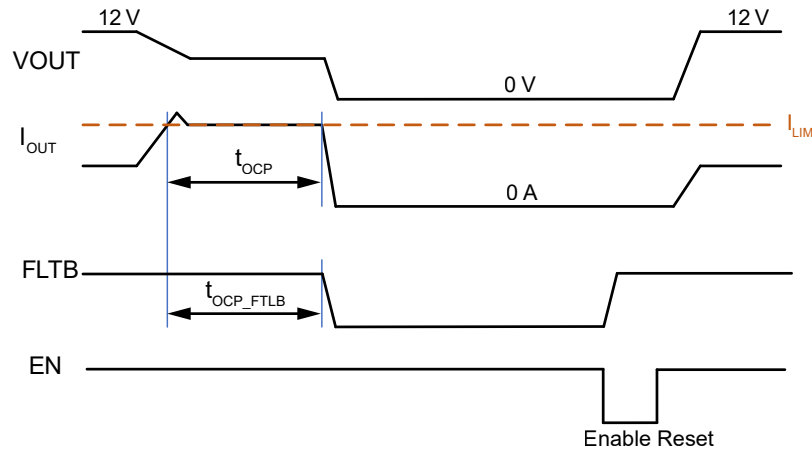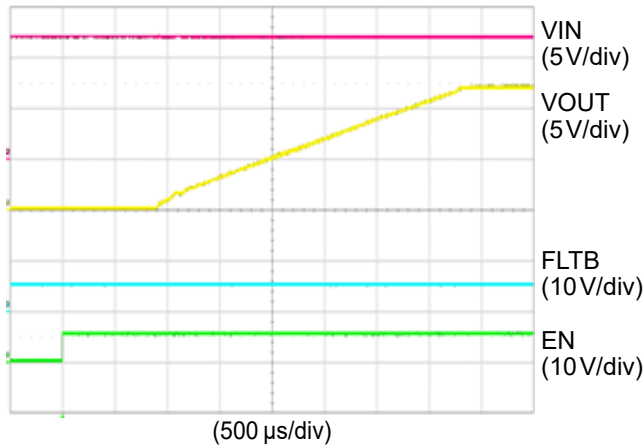
Timing Diagrams *(Continued)*

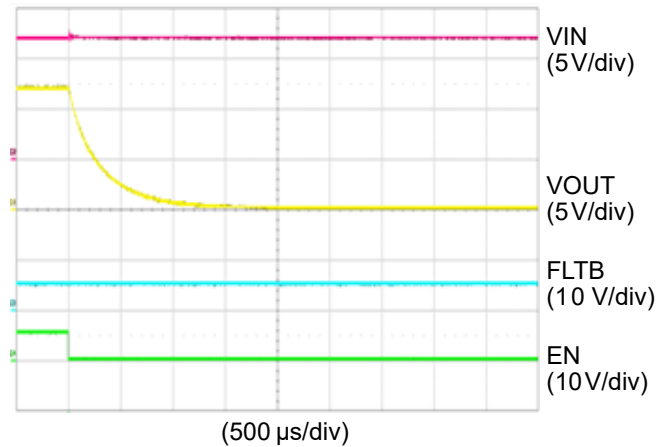**Figure 3. Over Current Protection (OCP) Operation for Latch Off Version. AOZ1374DI-02. VIN = 12 V**

Typical Characteristics for Sink Mode

T_A = 25 °C, VIN = 12 V, C_{IN} = 10 µF, C_{OUT} = 3 x 47 µF, C_{SS} = 134 nF, R_{LIM} = 1.74 kΩ, unless otherwise noted.

Soft Start by EN
(LOAD = 6.5 Ω, C_{OUT} = 4x10 µF, C_{SS} = 22 nF)

VIN (5 V/div)
VOUT (5 V/div)
FLTB (10 V/div)
EN (10 V/div)
(500 µs/div)

Shutdown by EN
(LOAD = 6.5 Ω, C_{OUT} = 4x10 µF, C_{SS} = 22 nF)

VIN (5 V/div)
VOUT (5 V/div)
FLTB (10 V/div)
EN (10 V/div)
(500 µs/div)

Soft Start by EN
(LOAD = 6.5 Ω, C_{SS} = 134 nF)

VIN (5 V/div)
VOUT (5 V/div)
IOUT (1 A/div)
EN (10 V/div)
(5 ms/div)

Shutdown by EN
(LOAD = 6.5 Ω, C_{SS} = 134 nF)

VIN (5 V/div)
VOUT (5 V/div)
IOUT (1 A/div)
EN (10 V/div)
(5 ms/div)

Soft Start by VIN
(LOAD = 6.5 Ω, C_{SS} = 134 nF)

VIN (5 V/div)
VOUT (5 V/div)
IOUT (1 A/div)
EN (10 V/div)
(5 ms/div)

Shutdown by VIN
(LOAD = 6.5 Ω, C_{SS} = 134 nF)

VIN (5 V/div)
VOUT (5 V/div)
IOUT (1 A/div)
EN (10 V/div)
(5 ms/div)
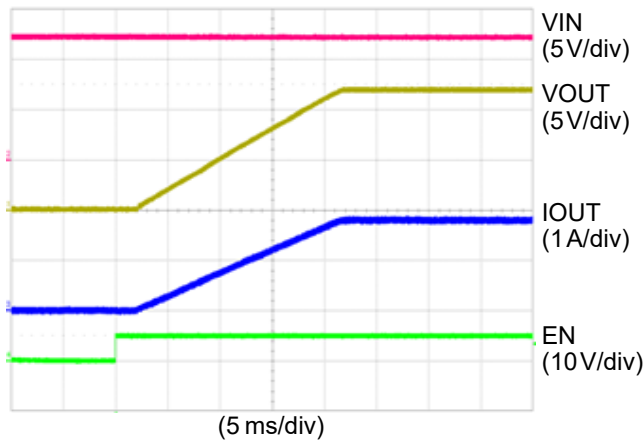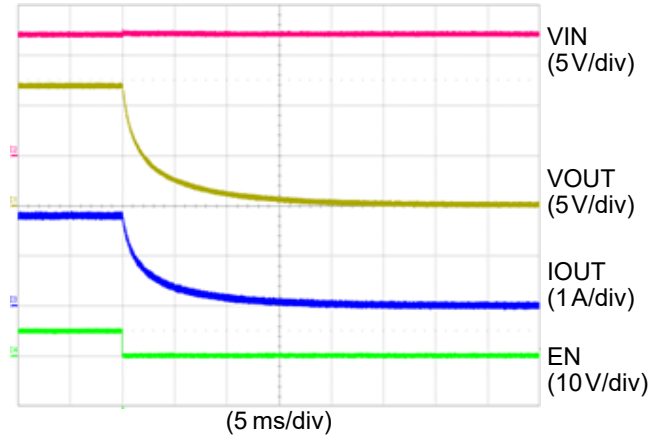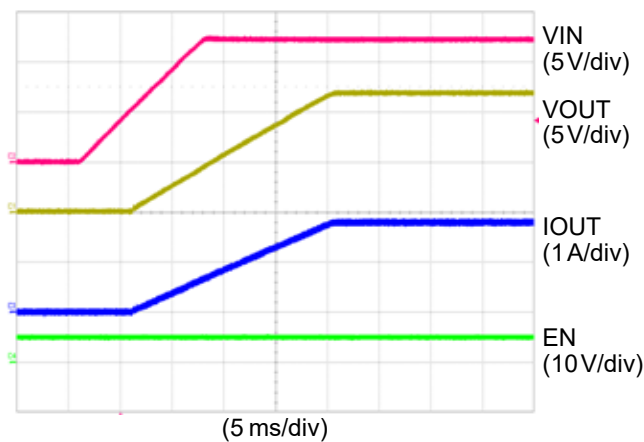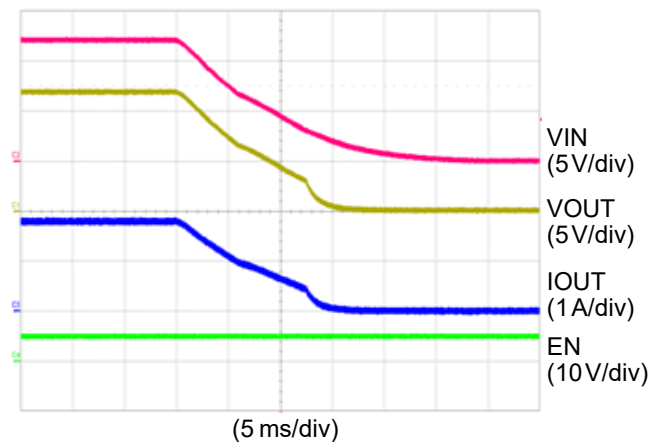
Typical Characteristics for Sink Mode

T_A = 25 °C, VIN = 12 V, C_{IN} = 10 µF, C_{OUT} = 3 x 47 µF, C_{SS} = 134 nF, R_{LIM} = 1.74 kΩ, unless otherwise noted.

Over Current Protection
(LOAD = 5Ω Plugged In)

VIN
(5 V/div)

VOUT
(5 V/div)

IOUT
(1 A/div)

EN
(10 V/div)

(200 µs/div)
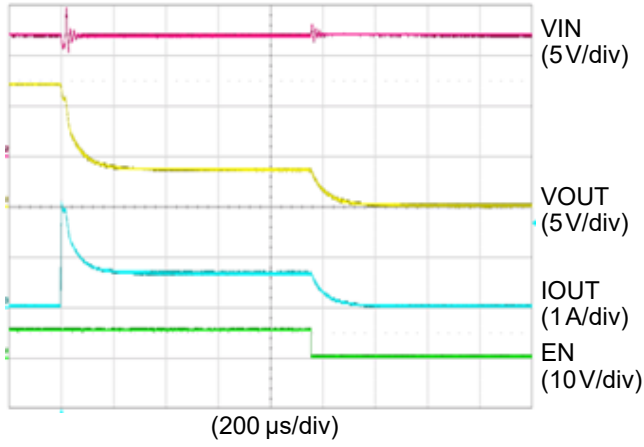
Reverse Current Blocking
(VIN = 12 V, VOUT pulled up to 20 V)

VOUT
(5 V/div)

VIN
(5 V/div)

FLTB
(10 V/div)

EN
(10 V/div)

(10 µs/div)
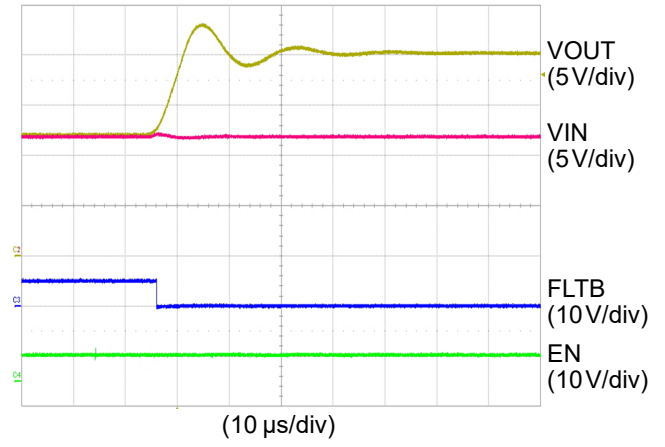
Typical Characteristics for Sink Mode

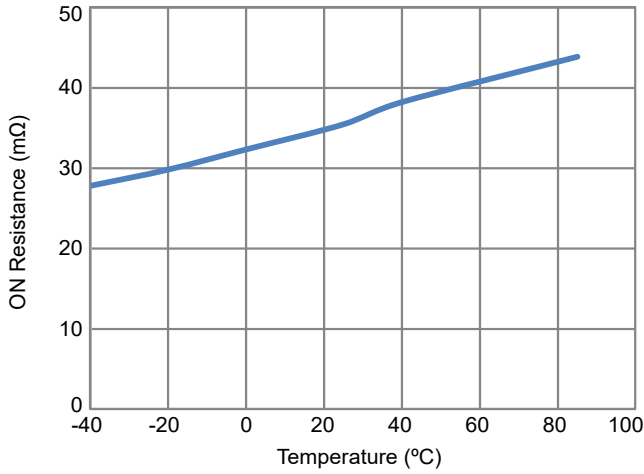T_A = 25 °C , unless otherwise specified.

Figure 4. ON Resistance vs. Temperature
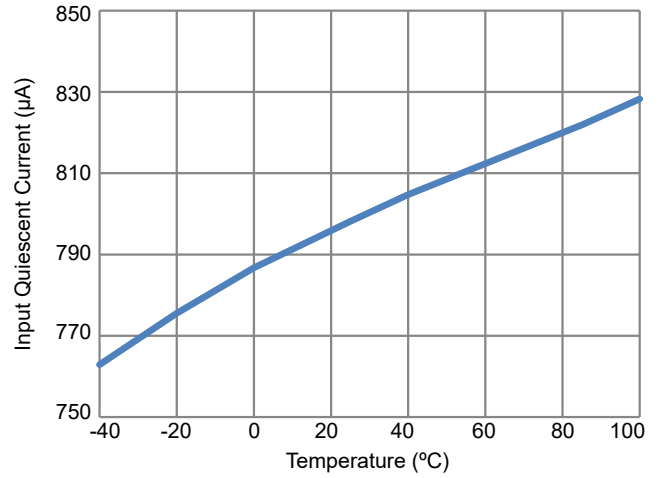(VIN = 20 V)

Figure 5. Quiescent Current vs. Temperature
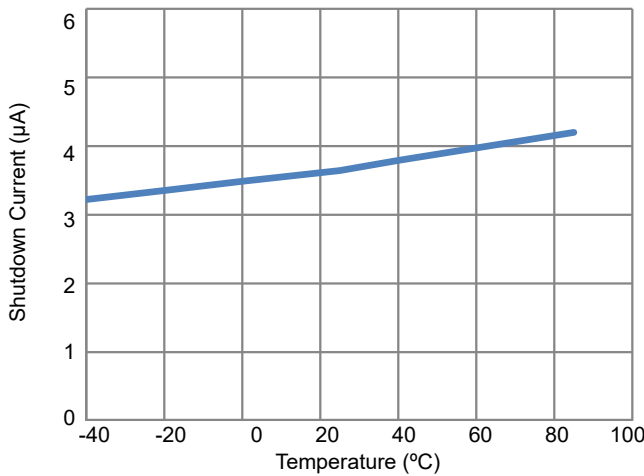(VIN = 20 V)

Figure 6. Shutdown Current vs. Temperature
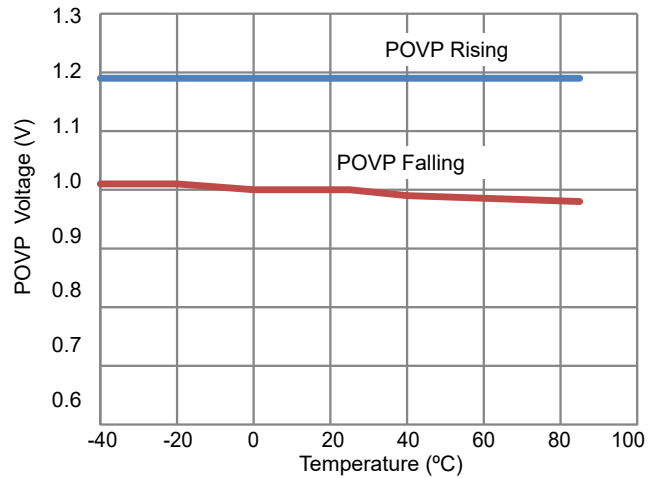(VIN = 20 V)
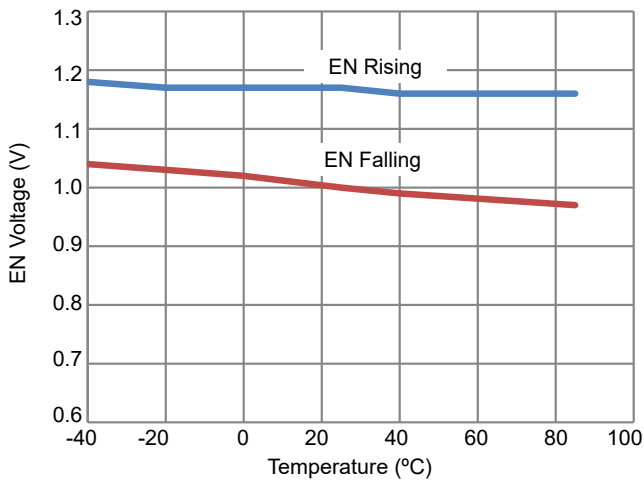

Figure 7. POVP Pin Threshold vs. Temperature

Figure 8. EN Threshold vs. Temperature
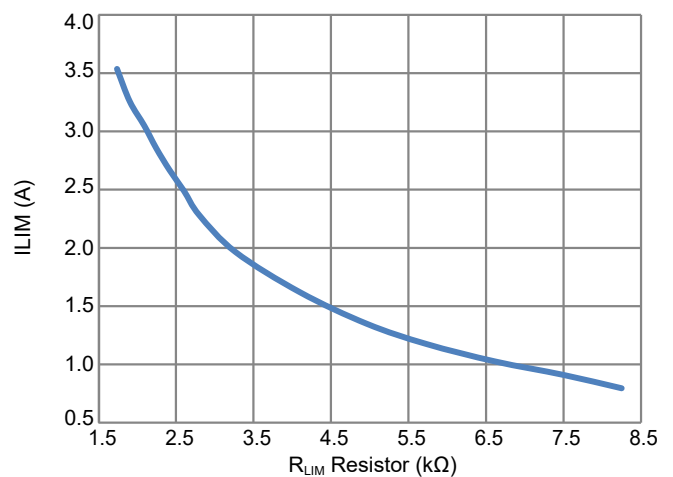

Figure 9. Current Limit vs. R_{LIM}

Typical Characteristics for Source Mode

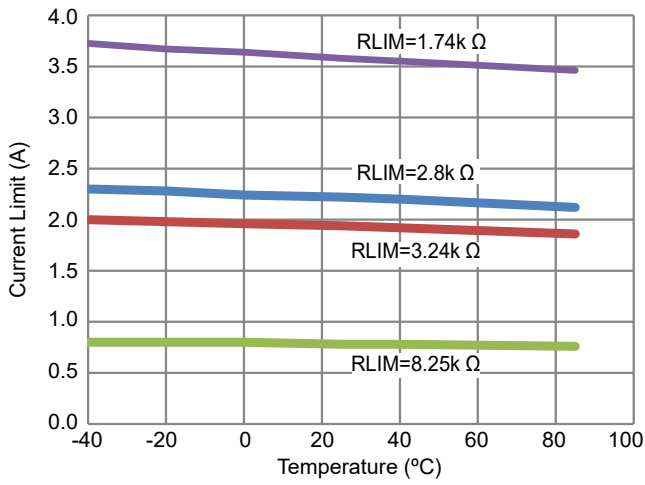T_A = 25 °C , unless otherwise specified.

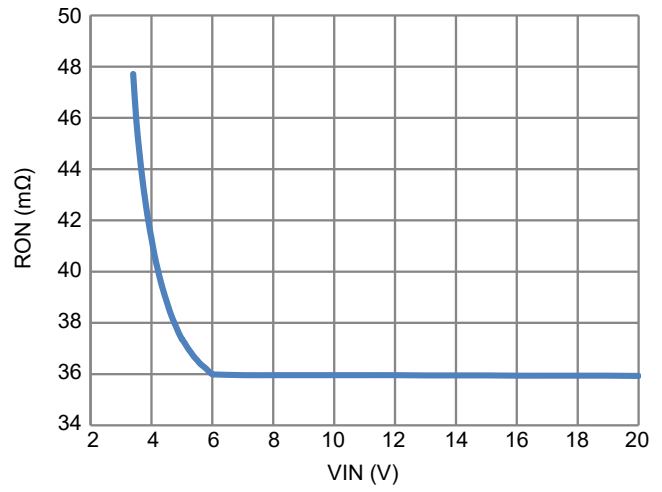**Figure 10. Current Limit vs. Temperature**

Figure 11. ON Resistance vs. VIN

Functional Description

The AOZ1374DI is a current limited power switch with over-voltage, over-current, reverse-current and thermal shutdown protections. The VIN and VOUT pin are rated 28 V abs max.

The device has true reverse-current blocking (TRCB) features that will prevent undesired current flow from output to its input in either enabled or disabled state.

Enable

The EN pin is the ON/OFF control for the power switch. The device is enabled when EN pin is high and not in under-voltage lockout state. The EN pin must be driven to a logic high or logic low state to guarantee operation.

Alternatively, EN pin can be biased with resistor divider network from VIN so that device enable will be tracking the input voltage. While disabled, the AOZ1374DI draws 5 µA from supply.

Input Under-Voltage Lockout (UVLO)

The under-voltage lockout (UVLO) circuit monitors the input voltage. The power switch is only allowed to turn on when input voltage is higher than UVLO threshold. Otherwise the switch is off.

Over-Voltage Protection (OVP)

The voltages at VIN pin is constantly monitored once the device is enabled. The over-voltage protection threshold can be programmed externally through POVP pin. In case input voltage exceeds the over-voltage protection threshold (V_{OVP}) of 1.2 V at POVP pin, the power switch is either turned off immediately or kept off, depending on its initial state. FLTB will be pulled low to indicate a fault condition.

AOZ1374DI-01 can be restarted when voltage at POVP pin drops below the hysteresis voltage of V_{OVP_HYS}. Once the device detects that the OVP condition no longer exists, it will turn back on the switch after FLTB recovery time blanking (t_{REC}).

Alternatively, POVP pin can also be biased with resistor divider from VIN to track the input voltage.

Programmable Current Limit and Over-Current Protection (OCP)

The AOZ1374DI implemented current limit to ensure that the current through the switch does not exceed current limit threshold set by the external resistor $R_{LIM.}$

The current limit threshold can be estimated using the equations below:

$$I_{LIM} = \frac{1.24}{R_{LIM}} \times 5000$$

where R_{LIM} unit is in ohm and ILIM unit is in Amperes.

For examples, a 3.26 kΩ R_{LIM} resistor should be selected for 1.9 A current limit threshold. Resistor with 1% tolerance is recommended for R_{LIM}.

AOZ1374DI continuously limits the output current when output is overloaded. The output current will be under regulation for 1 ms (t_{OCP}). If the overloaded output condition still exists after this 1 ms blanking time, the power switch will be off. FLTB is also pulled low after a 1 ms delay (t_{OCP_FLTB}) from over-current condition is detected.

For AOZ1374DI-01 Auto-Restart version, the power switch with be turn on again to restart after FLTB recovery time of 150 ms (t_{REC}).

For AOZ1374DI-02 Latch Off version, the power switch will only be turned on after toggling the EN input logic to reset the device.

Severe overload causes power dissipation and die temperature to increase and may trigger thermal shutdown.

Short Circuit Protection (SCP)

When VOUT drops significantly lower than VIN, the system interprets that as a VOUT shorted to GND condition. From that point it takes 1 µs ($t_{SC\_RESPONSE}$) to respond and open the switch which will isolate VIN from VOUT.

For AOZ1374DI-01 Auto-Restart version, the power switch with be turn on again to restart after the recovery time of 150 ms (t_{REC}).

For AOZ1374DI-02 Latch Off version, the power switch will only be turned on after toggling the EN input logic to reset the device.

Programming Soft Start

The AOZ1374DI start up delay and soft start time are programmable externally through SS pin. The soft start delay and ramp time can be estimated using the equations below:

$$t_{ON} = C_{SS} \times \frac{VIN}{80}$$

$$t_{DON} = 0.55 + \frac{C_{SS}}{80}$$

where C_{SS} is in nF, VIN is in V, t_{ON} and t_{D_ON} is in ms.

For example, for a VIN of 12 V and a 22 nF soft start capacitor will generate soft start time (t_{ON}) of 2.6 ms after start up delay (t_{D_ON}) of 1.1 ms.

For prebias condition, part of the soft start time is incorporated in the delay time. The following equations can be used to estimate the soft start delay and ramp time for pre-bias condition:

$$t_{ON} = C_{SS} \times \frac{VIN - VOUT_{PREBIAS}}{80}$$

$$t_{D\_ON} = 0.55 + \frac{C_{SS}}{80} \quad \frac{C_{SS} \times VOUT_{PREBIAS}}{80}$$

where C_{SS} is in nF, $VOUT_{PREBIAS}$ is the Output PreBias voltage in V, t_{ON} and t_{D_ON} is in ms

The actual soft start time may not be equal to the estimated value from the above equation if the operating condition exceeds the Safe Operation Area (SOA) of the power switch.

Safe Operating Area (SOA)

It is important to design the soft start ramp that should avoid reaching the SOA limits current during startup. The main purpose is to provide additional safety feature for abnormal or faulty conditions.

The current limit level is a function of the voltage difference between VIN and VOUT. If the combination of the load current, the output capacitor charging current and the programmed soft start time exceeds the power delivery SOA of the device, the current from VIN and VOUT will be limited for at least a portion of the soft start time. This may cause the device to abort the soft start and turn off.

If the total output current (load current and output capacitor charging current) is large enough such that VOUT cannot increase to the next SOA level voltage within 1 ms (typical) the system will automatically shut down. For AOZ1374DI-02 latch-off version, the system will only restart after EN toggles or VIN power recycles. For AOZ1374DI-01 auto-restart version, the system will retry after 150 ms (typical).

The device has internal SOA management to protect the internal power switch. To ensure the output can be started up linearly, it is recommended to selected soft start capacitor, C_{SS}, must be selected based on load resistance and capacitance. Figure 12 shows the C_{SS} selection curve for 12V input. For example, if the input voltage is 12V, I_{LIM} is 3.5A, the total output capacitor is 100 μF, and load resistor is 6 Ω, the minimum allowed C_{SS} is 52 nF.
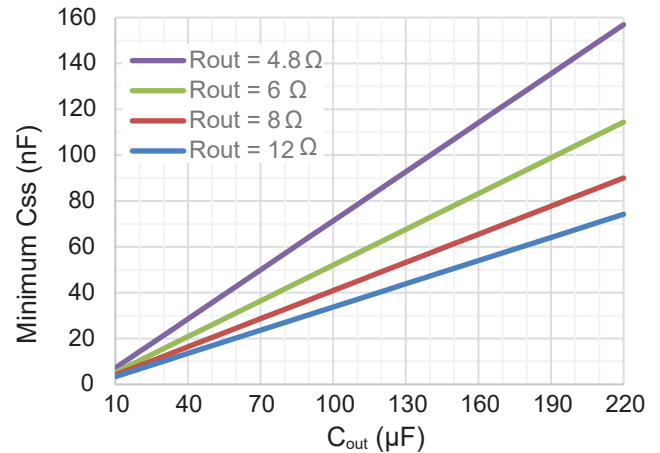

Figure 12. Minimum C_{SS} vs Output capacitor (VIN = 12 V, I_{LIM} = 3.5 A)

True Reverse Current Blocking (TRCB)

True reverse-current blocking prevents undesired current flow from output to input when power switch is in either on or off state. When device is enabled, power switch is quickly turned off whenever output voltage is higher than input voltage by 30 mV (V_{T_TRCB}). Once the device detects the TRCB condition it will quickly turn off the switch in 1 μs (t_{TRCB}).

For AOZ1374DI-01 Auto-Restart version, the power switch is turned on again when VOUT < VIN. Once the device detects that the TRCB condition no longer exists, it will turn back on the switch after FLTB recovery time blanking (t_{REC}).

For AOZ1374DI-02 Latch off version, It will not do auto retry. It will stay latch off after TRCB event.

Thermal Shut Down Protection (TSD)

Thermal shutdown protects device from excessive temperature. The power switch is turned off when the die temperature reaches thermal shutdown threshold of 140 °C. There is a 30 °C hysteresis. The power switch is allowed to turn on again if die temperature drops below approximately 110 °C.

Startup

The device is enabled when EN ≥ V_{EN_H} and input voltage VIN is higher than UVLO threshold. The device first checks if any fault condition exists. When no fault exists, the power switch will turn on and the output starts to ramp up. Power switch is kept off if fault condition was detected.

Fault Reporting

AOZ1374DI protects itself and load from the following fault condition: over-voltage, over-current, reverse-current, and thermal shutdown.

The FLTB pin is an open drain output. It is asserted low when an over-current, reverse-current, or over-temperature condition occurs. The FLTB pin becomes high impedance when the fault conditions are removed. A pull-up resistor (R_{FLTB}) must be connected between FLTB to 5 V to provide a logic signal.

When thermal shutdown is activated, FLTB is pulled low immediately to report fault condition to host.

For output current overload condition, FLTB pin is pulled low 1 ms (t_{OCP_FLTB}) after device is in current limiting.

Auto-restart (AOZ1374DI-01 Version)

The device will wait for FLTB recovery time blanking (t_{REC}) and try to restart after the power switch is turned off and when OVP, TRCB, or thermal shutdown fault is removed.

Input Capacitor Selection

The input capacitor prevents large voltage transients from appearing at the input, and provides the instantaneous current needed each time the switch turns on to charge output capacitors and to limit input voltage drop. It also prevents high-frequency noise on the power line from passing through to the output. The input capacitor should be located as close to the pin as possible. A minimum of 10 µF ceramic capacitor should be used. A higher capacitor value is strongly recommended to further reduce the transient voltage drop at the input.

Output Capacitor Selection

The output capacitor acts in a similar way. Also, the output capacitor has to supply enough current for a large load that it may encounter during system transient. This bulk capacitor must be large enough to supply fast transient load in order to prevent the output from dropping.

The USB specification limits the capacitance on VBUS (VOUT) to a maximum of 10 µF. Use this maximum value for noise immunity due to the system and cable plug/unplug transients.

Power Dissipation Calculation

Calculate the power dissipation for normal load condition using the following equation:

$$Power\ Dissipated = R_{ON} \times (I_{OUT})^2$$

Layout Guidelines

AOZ1374DI is a protection switch designed to deliver high current. Layout is critical to remove the heat generated by this current. For the most efficient heat sinking, connect as much copper as possible to the exposed pad. The exposed pad must be connected to GND. See Figure 13.
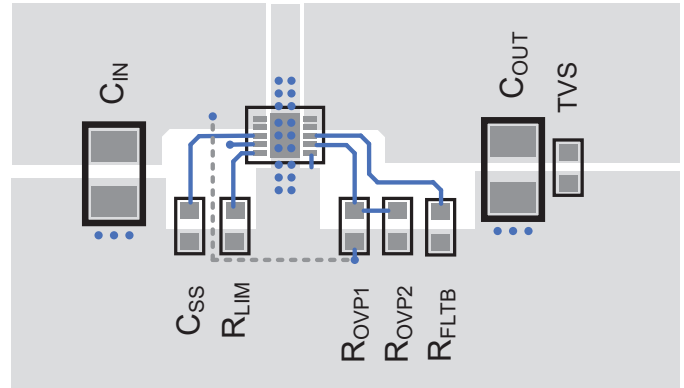

Figure 13. Top layer layout. Maximum number of VIAs from top layer exposed pad to inner layer.

For optimal thermal performance connect to GND on as many inner layers, as well as the bottom layer. Connect all GND planes (top, inner layers and bottom) together with as many VIAs as possible.

On the bottom layer, similar to the inner layers, connect to the GND plane. The top and bottom layers have better thermal performance than the inner layers because they are exposed to the atmosphere. See example in Figure 14.
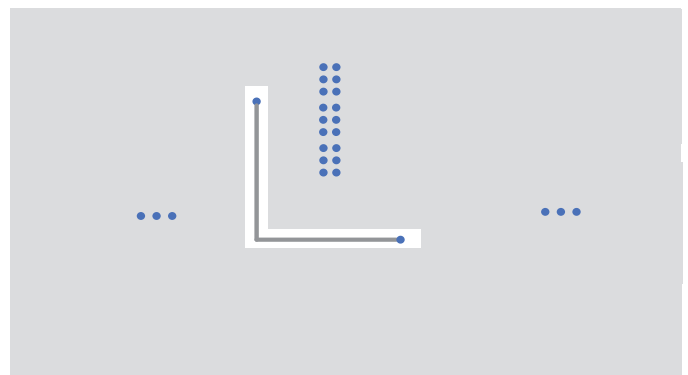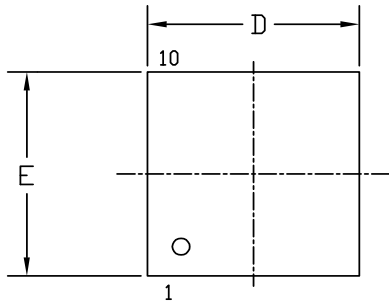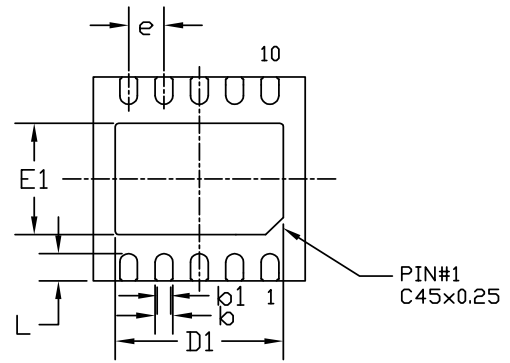

Figure 14. Bottom layer layout. Expose pad is connected to bottom GND plane.
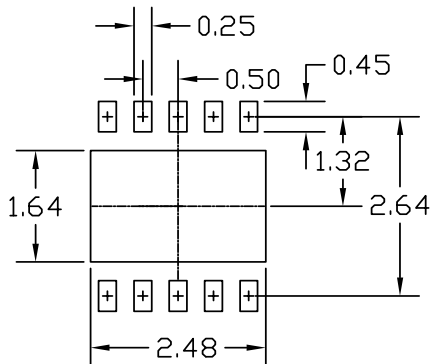
Package Dimensions, DFN3x3-10L

TOP VIEW

BOTTOM VIEW

PIN#1
C45×0.25

SIDE VIEW
A1
SEATING
PLAN

RECOMMENDED LAND PATTERN

UNIT: mm

SYMBOLS	DIMENSION IN MM			DIMENSION IN INCHES		
	MIN	NOM	MAX	MIN	NOM	MAX
A	0.80	0.90	1.00	0.031	0.035	0.039
A1	0.00	0.02	0.05	0.000	0.001	0.002
b	0.20	0.25	0.30	0.008	0.010	0.012
b1	0.09	0.19	0.29	0.004	0.007	0.011
c	0.195	0.203	0.211	0.008	0.008	0.008
D	2.90	3.00	3.10	0.114	0.118	0.122
D1	2.28	2.38	2.48	0.090	0.094	0.098
E	2.90	3.00	3.10	0.114	0.118	0.122
E1	1.54	1.64	1.74	0.061	0.065	0.069
L	0.30	0.40	0.50	0.012	0.016	0.020
e	0.50BSC			0.020BSC		

NOTE
1. DIMENSIONING AND TOLERANCING CONFORM TO ASME Y14.5M-1994.
2. CONTROLLING DIMENSION IS MILLIMETER.
   CONVERTED INCH DIMENSIONS ARE NOT NECESSARILY EXACT.
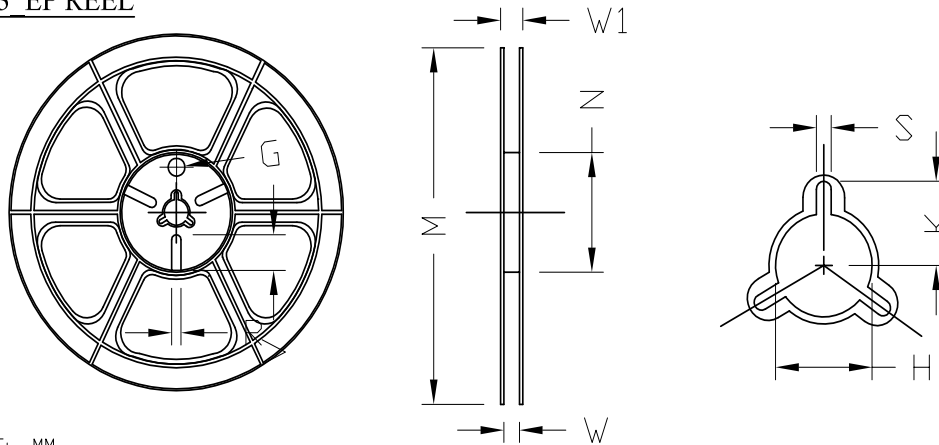
Tape and Reel Dimensions, DFN3x3-10L
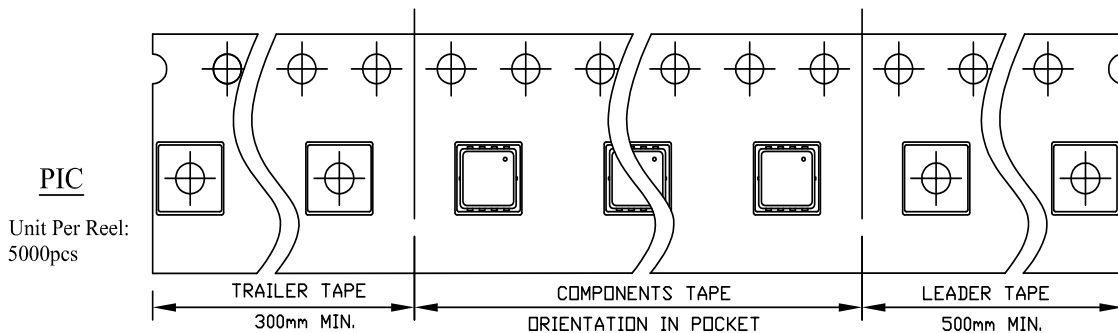
DFN3x3_EP Carrier Tape
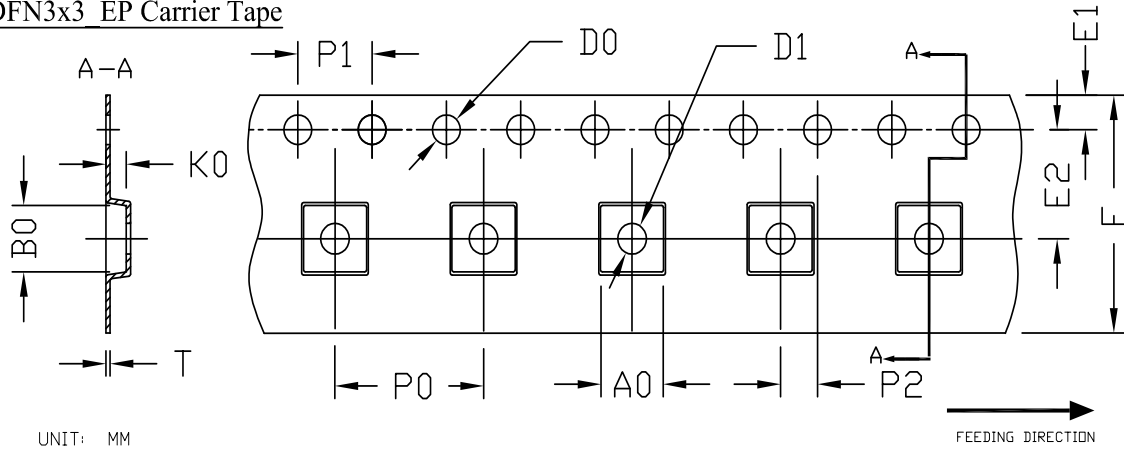
UNIT: MM

PACKAGE	A0	B0	K0	D0	D1	E	E1	E2	P0	P1	P2	T
DFN3x3_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

DFN3x3_EP REEL

UNIT: MM

TAPE SIZE	REEL SIZE	M	N	W	W1	H	K	S	G	R	V
12 mm	Ø330	Ø330.00 ±0.50	Ø97.00 ±0.10	13.00 ±0.30	17.40 ±1.00	Ø13.00 +0.50 −0.20	10.60	2.00 ±0.50	---	---	---

PIC

Unit Per Reel:
5000pcs

TRAILER TAPE
300mm MIN.

COMPONENTS TAPE
ORIENTATION IN POCKET

LEADER TAPE
500mm MIN.

Part Marking

AOZ1374DI
(DFN3x3)

A H X X
Y W   L T

Part Number Code — (A H)

Option Code — (first X)

Special Code — (second X)

Year and Week Code — (Y W)

Assembly Lot Code — (L T)
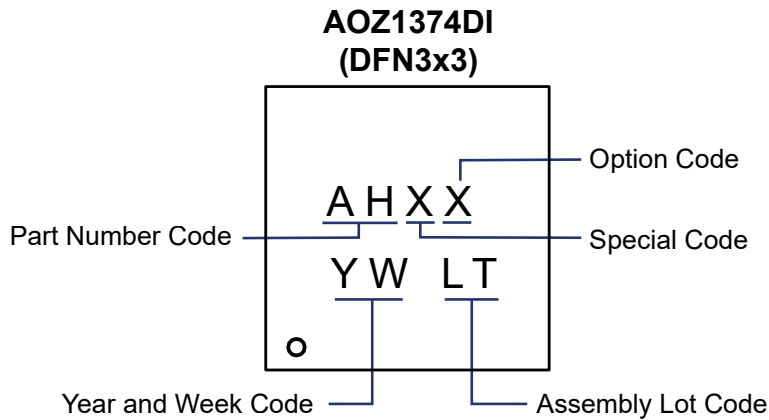
Part Number	Description	Marking Code
AOZ1374DI-01	Auto-Restart	AH01
AOZ1374DI-02	Latch-Off	AH02

LEGAL DISCLAIMER

Applications or uses as critical components in life support devices or systems are not authorized. Alpha and Omega Semiconductor does not assume any liability arising out of such applications or uses of its products. AOS reserves the right to make changes to product specifications without notice. It is the responsibility of the customer to evaluate suitability of the product for their intended application. Customer shall comply with applicable legal requirements, including all applicable export control rules, regulations and limitations.

AOS's products are provided subject to AOS's terms and conditions of sale which are set forth at:
http://www.aosmd.com/terms_and_conditions_of_sale

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.