

General Description

The AOZ8310DI is a series of one-line, high-power transient voltage suppressor designed to protect power rail/bus from surge and ESD events, with an operating voltage range from 2.5V to 36V.

This device incorporates one unidirectional TVS diode in an ultra-small 1.6mm x 1.0mm DFN package. It may be used to meet the ESD immunity requirements of IEC 61000-4-2, Level 4 ($\pm 15\text{kV}$ air, $\pm 8\text{kV}$ contact discharge).

The AOZ8310DI comes in an RoHS compliant package and is rated over a -40°C to $+125^{\circ}\text{C}$ ambient temperature range.

Features

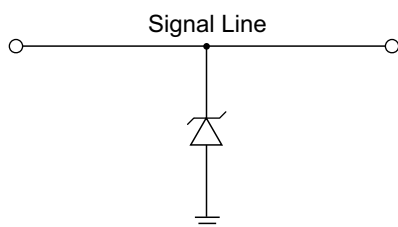
- Surge protection for power rail
- IEC 61000-4-5 8/20 μs 22-85A
- IEC 61000-4-2 (ESD) $\pm 30\text{kV}$ (air and contact)
- Human body model (HBM) $\pm 30\text{kV}$
- IEC 61000-4-4 (EFT) 80A (5/50ns)
- Peak pulse power 1100W to 1500W
- Operating voltage: 2.5V, 5V, 8V, 9V, 12V, 18V, 20V, 26V, 36V
- Green product

Applications

- USB voltage bus
- Battery protection
- Mobile devices
- Screen panels
- Other power rails

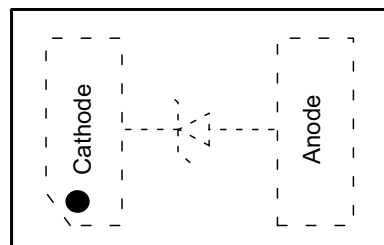


Typical Application



Unidirection Protection of Single Line

Pin Configuration



DFN1.6x1.0_2L

Ordering Information

| Part Number | Ambient Temperature Range | Package | Environmental |
|--------------|---------------------------|----------------------|---------------|
| AOZ8310DI-02 | -40°C to +125°C | 1.6mm x 1.0mm DFN-2L | Green Product |
| AOZ8310DI-05 | | | |
| AOZ8310DI-08 | | | |
| AOZ8310DI-09 | | | |
| AOZ8310DI-12 | | | |
| AOZ8310DI-18 | | | |
| AOZ8310DI-20 | | | |
| AOZ8310DI-26 | | | |
| AOZ8310DI-36 | | | |



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

Absolute Maximum Ratings

Exceeding the Absolute Maximum ratings may damage the device.

| Parameter | Rating |
|---|-----------------|
| VP-VN | 2.5V to 36V |
| Peak Pulse Current (I_{PP}), $t_P = 8/20\mu s$ | 22A to 85A |
| Peak Pulse Power (P_{PP}), $t_P = 8/20\mu s$ | 1100W to 1500W |
| Storage Temperature (T_S) | -65°C to +150°C |
| ESD Rating per IEC61000-4-2, Contact ⁽¹⁾ | ±30kV |
| ESD Rating per IEC61000-4-2, Air ⁽¹⁾ | ±30kV |
| ESD Rating per Human Body Model ⁽²⁾ | ±30kV |

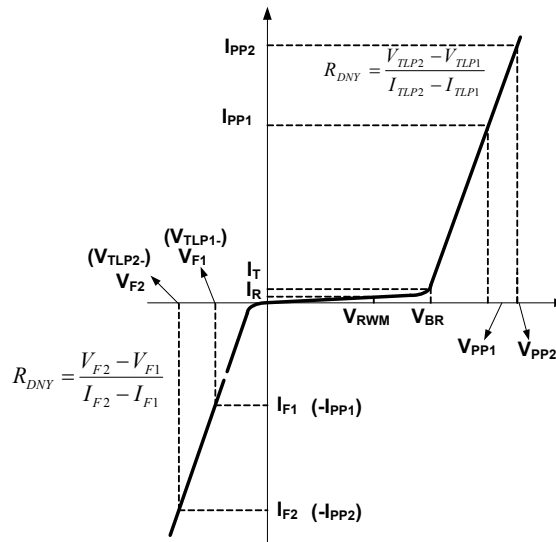
Notes:

- IEC 61000-4-2 discharge with $C_{Discharge} = 150pF$, $R_{Discharge} = 330\Omega$.
- Human Body Discharge per MIL-STD-883, Method 3015 $C_{Discharge} = 100pF$, $R_{Discharge} = 1.5k\Omega$.

Maximum Operating Ratings

| Parameter | Rating |
|--------------------------------|-----------------|
| Junction Temperature (T_J) | -40°C to +125°C |

Electrical Characteristics



T_A = 25°C unless otherwise specified.

| Symbol | Parameter | Condition | Min. | Typ. | Max. | Units |
|---------------------|---|--|------|-------------|-----------|-------|
| AOZ8310DI-02 | | | | | | |
| V _{RWM} | Reverse Working Voltage | I/O Pin-to-Ground | | | 2.5 | V |
| V _{BR} | Reverse Breakdown Voltage | I _T = 1mA, I/O Pin-to-Ground | 2.8 | 3.3 | 5 | V |
| I _R | Reverse Leakage Current | Max. V _{RWM} , I/O Pin-to-Ground | | 100 | 1000 | nA |
| I _{PP} | Peak Pulse Current | IEC61000-4-5, 8/20μs, I/O Pin-to-Ground | | | 75 | A |
| V _{CL} | Clamping Voltage ⁽³⁾ (100ns Transmission Line Pulse, I/O Pin-to-Ground) | I _{TLP} = 1A I _{TLP} = -1A | | 4.5 -1 | 6 -2 | V |
| | | I _{TLP} = 30A I _{TLP} = -30A | | 5.5 -3.5 | 7.5 -5 | V |
| | Clamping Voltage ⁽³⁾ (IEC61000-4-5 8/20μs, I/O Pin-to-Ground) | I _{PP} = 10A I _{PP} = -10A | | 5.5 -2.5 | 7.5 -4 | V |
| | | I _{PP} = 75A I _{PP} = -75A | | 13 -10 | 15 -12 | V |
| R _{DNY} | Dynamic Resistance ⁽³⁾ | I _{TLP} = 1A to 30A I _{TLP} = -1A to -30A | | 0.05 0.1 | | Ω |
| P _{PP} | Peak Pulse Power | IEC61000-4-5, 8/20μs, I/O Pin-to-Ground | | | 1100 | W |
| C _J | Junction Capacitance | V _{I/O} = 0V, f = 1MHz, I/O Pin-to-Ground | | 100 | | pF |

| Symbol | Parameter | Condition | Min. | Typ. | Max. | Units |
|---------------------|--|--|------|--------------|------------|-------|
| AOZ8310DI-05 | | | | | | |
| V _{RWM} | Reverse Working Voltage | I/O Pin-to-Ground | | | 5 | V |
| V _{BR} | Reverse Breakdown Voltage | I _T = 1mA, I/O Pin-to-Ground | 6 | 7.5 | 8.5 | V |
| I _R | Reverse Leakage Current | Max. V _{RWM} , I/O Pin-to-Ground | | 100 | 1000 | nA |
| I _{PP} | Peak Pulse Current | IEC61000-4-5, 8/20μs, I/O Pin-to-Ground | | | 85 | A |
| V _{CL} | Clamping Voltage ⁽³⁾ (100ns Transmission Line Pulse, I/O Pin-to-Ground) | I _{TLP} = 1A I _{TLP} = -1A | | 8 -1 | 9.5 -2 | V |
| | | I _{TLP} = 30A I _{TLP} = -30A | | 9.5 -3.5 | 11 -5 | V |
| | Clamping Voltage ⁽³⁾ (IEC61000-4-5 8/20μs, I/O Pin-to- Ground) | I _{PP} = 20A I _{PP} = -20A | | 9.5 -2.5 | 11 -4 | V |
| | | I _{PP} = 85A I _{PP} = -85A | | 14.3 -6 | 16 -8 | V |
| R _{DNY} | Dynamic Resistance ⁽³⁾ | I _{TLP} = 1A to 30A I _{TLP} = -1A to -30A | | 0.05 0.09 | | Ω |
| P _{PP} | Peak Pulse Power | IEC61000-4-5, 8/20μs, I/O Pin-to-Ground | | | 1500 | W |
| C _J | Junction Capacitance | V _{I/O} = 0V, f = 1MHz, I/O Pin-to-Ground | | 675 | | pF |
| AOZ8310DI-08 | | | | | | |
| V _{RWM} | Reverse Working Voltage | I/O Pin-to-Ground | | | 8 | V |
| V _{BR} | Reverse Breakdown Voltage | I _T = 1mA, I/O Pin-to-Ground | 9 | 10 | 12 | V |
| I _R | Reverse Leakage Current | Max. V _{RWM} , I/O Pin-to-Ground | | 10 | 100 | nA |
| I _{PP} | Peak Pulse Current | IEC61000-4-5, 8/20μs, I/O Pin-to-Ground | | | 70 | A |
| V _{CL} | Clamping Voltage ⁽³⁾ (100ns Transmission Line Pulse, I/O Pin-to-Ground) | I _{TLP} = 1A I _{TLP} = -1A | | 10.5 -0.9 | 12 -1.5 | V |
| | | I _{TLP} = 30A I _{TLP} = -30A | | 12 -3.7 | 13.5 -5 | V |
| | Clamping Voltage ⁽³⁾ (IEC61000-4-5 8/20μs, I/O Pin-to- Ground) | I _{PP} = 10A I _{PP} = -10A | | 12 -2.4 | 14 -4 | V |
| | | I _{PP} = 70A I _{PP} = -70A | | 21 -9 | 24 -11 | V |
| R _{DNY} | Dynamic Resistance ⁽³⁾ | I _{TLP} = 1A to 30A I _{TLP} = -1A to -30A | | 0.05 0.1 | | Ω |
| P _{PP} | Peak Pulse Power | IEC61000-4-5, 8/20μs, I/O Pin-to-Ground | | | 1500 | W |
| C _J | Junction Capacitance | V _{I/O} = 0V, f = 1MHz, I/O Pin-to-Ground | | 425 | | pF |

| Symbol | Parameter | Condition | Min. | Typ. | Max. | Units |
|---------------------|--|--|------|--------------|-------------|-------|
| AOZ8310DI-09 | | | | | | |
| V _{RWM} | Reverse Working Voltage | I/O Pin-to-Ground | | | 9 | V |
| V _{BR} | Reverse Breakdown Voltage | I _T = 1mA, I/O Pin-to-Ground | 10 | 11 | 13 | V |
| I _R | Reverse Leakage Current | Max. V _{RWM} , I/O Pin-to-Ground | | 10 | 100 | nA |
| I _{PP} | Peak Pulse Current | IEC61000-4-5, 8/20μs, I/O Pin-to-Ground | | | 65 | A |
| V _{CL} | Clamping Voltage ⁽³⁾ (100ns Transmission Line Pulse, I/O Pin-to-Ground) | I _{TLP} = 1A I _{TLP} = -1A | | 11.5 -0.9 | 13 -1.5 | V |
| | | I _{TLP} = 30A I _{TLP} = -30A | | 13.3 -3.7 | 15 -5 | V |
| | Clamping Voltage ⁽³⁾ (IEC61000-4-5 8/20μs, I/O Pin-to- Ground) | I _{PP} = 10A I _{PP} = -10A | | 13.5 -2.4 | 15 -4.5 | V |
| | | I _{PP} = 65A I _{PP} = -65A | | 21.5 -8.5 | 24 -10.5 | V |
| R _{DNY} | Dynamic Resistance ⁽³⁾ | I _{TLP} = 1A to 30A I _{TLP} = -1A to -30A | | 0.05 0.1 | | Ω |
| P _{PP} | Peak Pulse Power | IEC61000-4-5, 8/20μs, I/O Pin-to-Ground | | | 1500 | W |
| C _J | Junction Capacitance | V _{I/O} = 0V, f = 1MHz, I/O Pin-to-Ground | | 385 | | pF |
| AOZ8310DI-12 | | | | | | |
| V _{RWM} | Reverse Working Voltage | I/O Pin-to-Ground | | | 12 | V |
| V _{BR} | Reverse Breakdown Voltage | I _T = 1mA, I/O Pin-to-Ground | 13.2 | 15 | 17 | V |
| I _R | Reverse Leakage Current | Max. V _{RWM} , I/O Pin-to-Ground | | 5 | 100 | nA |
| I _{PP} | Peak Pulse Current | IEC61000-4-5, 8/20μs, I/O Pin-to-Ground | | | 45 | A |
| V _{CL} | Clamping Voltage ⁽³⁾ (100ns Transmission Line Pulse, I/O Pin-to-Ground) | I _{TLP} = 1A I _{TLP} = -1A | | 15.5 -0.9 | 18 -1.5 | V |
| | | I _{TLP} = 30A I _{TLP} = -30A | | 17 -3.5 | 19 -5 | V |
| | Clamping Voltage ⁽³⁾ (IEC61000-4-5 8/20μs, I/O Pin-to- Ground) | I _{PP} = 10A I _{PP} = -10A | | 18 -2.4 | 21 -4.5 | V |
| | | I _{PP} = 45A I _{PP} = -45A | | 26 -6.8 | 30 -8.5 | V |
| R _{DNY} | Dynamic Resistance ⁽³⁾ | I _{TLP} = 1A to 30A I _{TLP} = -1A to -30A | | 0.05 0.1 | | Ω |
| P _{PP} | Peak Pulse Power | IEC61000-4-5, 8/20μs, I/O Pin-to-Ground | | | 1500 | W |
| C _J | Junction Capacitance | V _{I/O} = 0V, f = 1MHz, I/O Pin-to-Ground | | 275 | | pF |

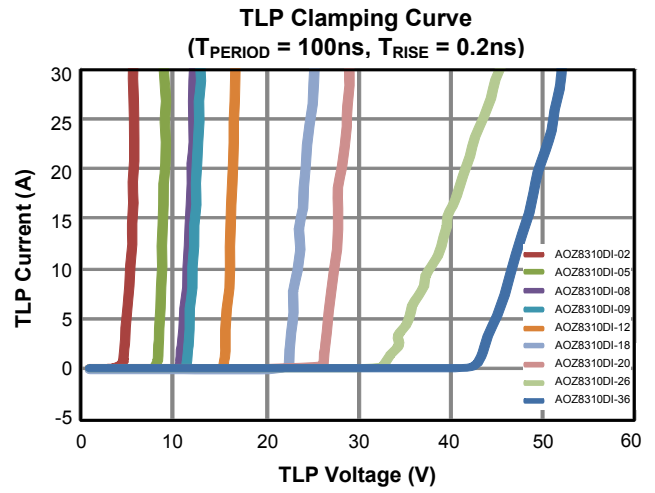
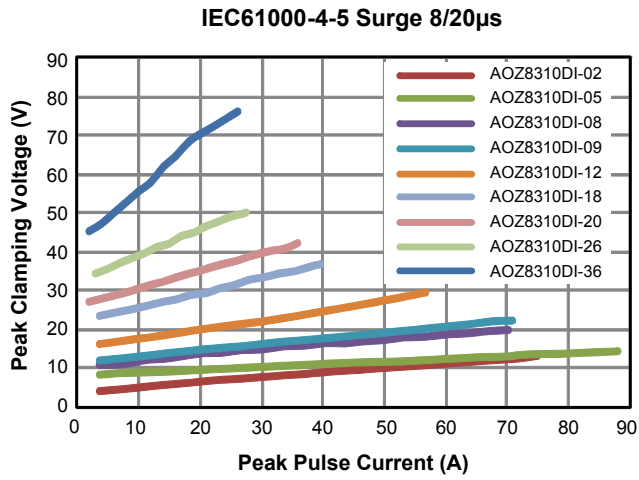
| Symbol | Parameter | Condition | Min. | Typ. | Max. | Units |
|---------------------|--|--|------|--------------|------------|-------|
| AOZ8310DI-18 | | | | | | |
| V _{RWM} | Reverse Working Voltage | I/O Pin-to-Ground | | | 18 | V |
| V _{BR} | Reverse Breakdown Voltage | I _T = 1mA, I/O Pin-to-Ground | 19 | 21.5 | 24 | V |
| I _R | Reverse Leakage Current | Max. V _{RWM} , I/O Pin-to-Ground | | 10 | 100 | nA |
| I _{PP} | Peak Pulse Current | IEC61000-4-5, 8/20μs, I/O Pin-to-Ground | | | 35 | A |
| V _{CL} | Clamping Voltage ⁽³⁾ (100ns Transmission Line Pulse, I/O Pin-to-Ground) | I _{TLP} = 1A I _{TLP} = -1A | | 22 -1 | 24 -2 | V |
| | | I _{TLP} = 30A I _{TLP} = -30A | | 26 -4 | 29 -6 | V |
| | Clamping Voltage ⁽³⁾ (IEC61000-4-5 8/20μs, I/O Pin-to- Ground) | I _{PP} = 10A I _{PP} = -10A | | 25 -2.5 | 29 -4.5 | V |
| | | I _{PP} = 35A I _{PP} = -35A | | 35 -6 | 39 -8 | V |
| R _{DNY} | Dynamic Resistance ⁽³⁾ | I _{TLP} = 1A to 30A I _{TLP} = -1A to -30A | | 0.1 0.1 | | Ω |
| P _{PP} | Peak Pulse Power | IEC61000-4-5, 8/20μs, I/O Pin-to-Ground | | | 1200 | W |
| C _J | Junction Capacitance | V _{I/O} = 0V, f = 1MHz, I/O Pin-to-Ground | | 200 | | pF |
| AOZ8310DI-20 | | | | | | |
| V _{RWM} | Reverse Working Voltage | I/O Pin-to-Ground | | | 20 | V |
| V _{BR} | Reverse Breakdown Voltage | I _T = 1mA, I/O Pin-to-Ground | 22 | 25 | 28 | V |
| I _R | Reverse Leakage Current | Max. V _{RWM} , I/O Pin-to-Ground | | 2 | 100 | nA |
| I _{PP} | Peak Pulse Current | IEC61000-4-5, 8/20μs, I/O Pin-to-Ground | | | 32 | A |
| V _{CL} | Clamping Voltage ⁽³⁾ (100ns Transmission Line Pulse, I/O Pin-to-Ground) | I _{TLP} = 1A I _{TLP} = -1A | | 25.5 -0.9 | 28 -1.5 | V |
| | | I _{TLP} = 30A I _{TLP} = -30A | | 29 -3.5 | 32 -5 | V |
| | Clamping Voltage ⁽³⁾ (IEC61000-4-5 8/20μs, I/O Pin-to- Ground) | I _{PP} = 5A I _{PP} = -5A | | 28 -2 | 31 -4 | V |
| | | I _{PP} = 32A I _{PP} = -32A | | 40 -5.5 | 44 -7.5 | V |
| R _{DNY} | Dynamic Resistance ⁽³⁾ | I _{TLP} = 1A to 30A I _{TLP} = -1A to -30A | | 0.12 0.1 | | Ω |
| P _{PP} | Peak Pulse Power | IEC61000-4-5, 8/20μs, I/O Pin-to-Ground | | | 1200 | W |
| C _J | Junction Capacitance | V _{I/O} = 0V, f = 1MHz, I/O Pin-to-Ground | | 165 | | pF |

| Symbol | Parameter | Condition | Min. | Typ. | Max. | Units |
|---------------------|--|--|------|---------------|------------|----------|
| AOZ8310DI-26 | | | | | | |
| V_{RWM} | Reverse Working Voltage | I/O Pin-to-Ground | | | 26 | V |
| V_{BR} | Reverse Breakdown Voltage | $I_T = 1\text{mA}$, I/O Pin-to-Ground | 28 | 31 | 35 | V |
| I_R | Reverse Leakage Current | Max. V_{RWM} , I/O Pin-to-Ground | | 1 | 100 | nA |
| I_{PP} | Peak Pulse Current | IEC61000-4-5, 8/20 μs , I/O Pin-to-Ground | | | 25 | A |
| V_{CL} | Clamping Voltage ⁽³⁾ (100ns Transmission Line Pulse, I/O Pin-to-Ground) | $I_{TLP} = 1\text{A}$ $I_{TLP} = -1\text{A}$ | | 32 -0.9 | 35 -1.5 | V |
| | | $I_{TLP} = 30\text{A}$ $I_{TLP} = -30\text{A}$ | | 45 -4.5 | 50 -5 | V |
| | Clamping Voltage ⁽³⁾ (IEC61000-4-5 8/20 μs , I/O Pin-to-Ground) | $I_{PP} = 5\text{A}$ $I_{PP} = -5\text{A}$ | | 36 -2 | 40 -4 | V |
| | | $I_{PP} = 25\text{A}$ $I_{PP} = -25\text{A}$ | | 50 -5.5 | 55 -7.5 | V |
| R_{DNY} | Dynamic Resistance ⁽³⁾ | $I_{TLP} = 1\text{A to } 25\text{A}$ $I_{TLP} = -1\text{A to } -25\text{A}$ | | 0.45 -0.12 | | Ω |
| P_{PP} | Peak Pulse Power | IEC61000-4-5, 8/20 μs , I/O Pin-to-Ground | | | 1200 | W |
| C_J | Junction Capacitance | $V_{I/O} = 0\text{V}$, $f = 1\text{MHz}$, I/O Pin-to-Ground | | 150 | | pF |
| AOZ8310DI-36 | | | | | | |
| V_{RWM} | Reverse Working Voltage | I/O Pin-to-Ground | | | 36 | V |
| V_{BR} | Reverse Breakdown Voltage | $I_T = 1\text{mA}$, I/O Pin-to-Ground | 37 | 39 | 44 | V |
| I_R | Reverse Leakage Current | Max. V_{RWM} , I/O Pin-to-Ground | | 10 | 100 | nA |
| I_{PP} | Peak Pulse Current | IEC61000-4-5, 8/20 μs , I/O Pin-to-Ground | | | 22 | A |
| V_{CL} | Clamping Voltage ⁽³⁾ (100ns Transmission Line Pulse, I/O Pin-to-Ground) | $I_{TLP} = 1\text{A}$ $I_{TLP} = -1\text{A}$ | | 43 -1 | 47 -2 | V |
| | | $I_{TLP} = 30\text{A}$ $I_{TLP} = -30\text{A}$ | | 52 -3.5 | 56 -5 | V |
| | Clamping Voltage ⁽³⁾ (IEC61000-4-5 8/20 μs , I/O Pin-to-Ground) | $I_{PP} = 2\text{A}$ $I_{PP} = -2\text{A}$ | | 45 -1.3 | 48 -2 | V |
| | | $I_{PP} = 22\text{A}$ $I_{PP} = -22\text{A}$ | | 72 -4.3 | 77 -7 | V |
| R_{DNY} | Dynamic Resistance ⁽³⁾ | $I_{TLP} = 1\text{A to } 30\text{A}$ $I_{TLP} = -1\text{A to } -30\text{A}$ | | 0.28 0.1 | | Ω |
| P_{PP} | Peak Pulse Power | IEC61000-4-5, 8/20 μs , I/O Pin-to-Ground | | | 1500 | W |
| C_J | Junction Capacitance | $V_{I/O} = 0\text{V}$, $f = 1\text{MHz}$, I/O Pin-to-Ground | | 130 | | pF |

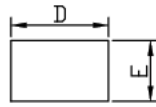
Note:

3. These specifications are guaranteed by design and characterization.

Typical Characteristics



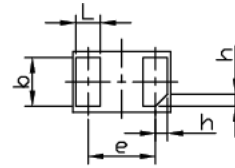
Package Dimensions, DFN1.6x1.0-2L, EPS_S



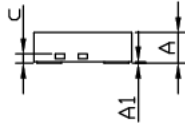
TOP VIEW



SIDE VIEW

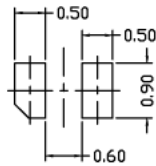


BOTTOM VIEW



SIDE VIEW

RECOMMENDED LAND PATTERN



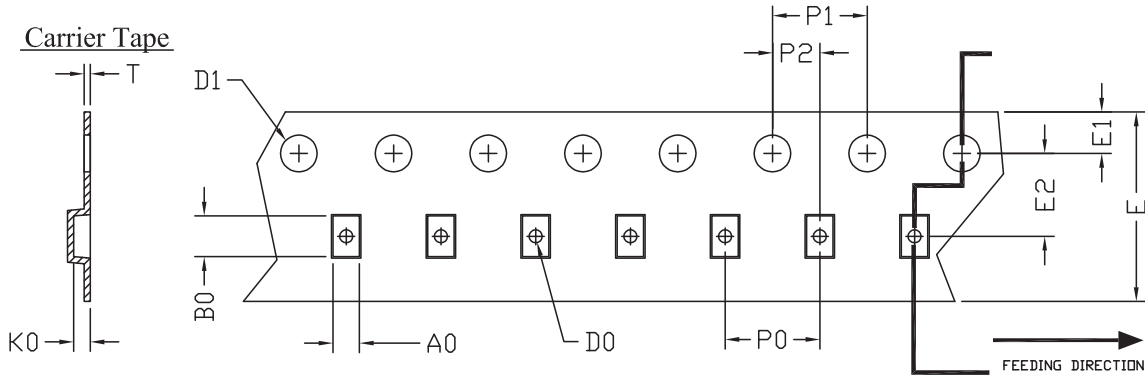
| SYMBOLS | DIMENSIONS IN MILLIMETERS | | | DIMENSIONS IN INCHES | | |
|---------|---------------------------|------|------|----------------------|-------|-------|
| | MIN | NOM | MAX | MIN | NOM | MAX |
| A | 0.45 | 0.50 | 0.55 | 0.018 | 0.020 | 0.022 |
| A1 | --- | 0.02 | 0.05 | ---- | 0.001 | 0.002 |
| b | 0.75 | 0.80 | 0.85 | 0.030 | 0.031 | 0.033 |
| c | 0.10 | 0.15 | 0.20 | 0.004 | 0.006 | 0.008 |
| D | 1.55 | 1.60 | 1.65 | 0.061 | 0.063 | 0.065 |
| e | 1.10 BSC | | | 0.043 BSC | | |
| E | 0.95 | 1.00 | 1.05 | 0.037 | 0.039 | 0.041 |
| L | 0.35 | 0.40 | 0.45 | 0.014 | 0.016 | 0.018 |
| h | 0.15 | 0.20 | 0.25 | 0.006 | 0.008 | 0.010 |

UNIT: mm

NOTE

1. CONTROLLING DIMENSION IS MILLIMETER.
CONVERTED INCH DIMENSIONS ARE NOT NECESSARILY EXACT.
2. TOLERANCE :±0.05 UNLESS OTHERWISE SPECIFIED.
3. RADIUS ON ALL CORNER ARE 0.152 MAX., UNLESS OTHERWISE SPECIFIED.
4. PACKAGE WARPAGE: 0.012 MAX.
5. NO ANY PLASTIC FLASH ALLOWED ON THE TOP AND BOTTOM LEAD SURFACE.
6. PAD PLANARITY: ±0.102
7. CRACK BETWEEN PLASTIC BODY AND LEAD IS NOT ALLOWED.

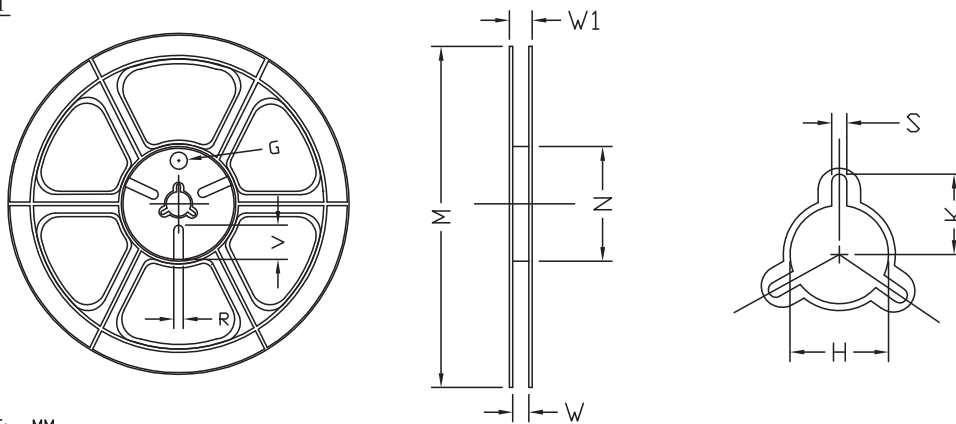
Tape and Reel Dimensions, DFN1.6x1.0-2L, EPS_S



UNIT: MM

| PACKAGE | A0 | B0 | K0 | D0 | D1 | E | E1 | E2 | P0 | P1 | P2 | T |
|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| DFN1.6x1.0 | 1.07 | 1.67 | 0.65 | 0.40 | 1.45 | 7.80 | 1.75 | 3.50 | 4.00 | 4.00 | 2.00 | 0.18 |
| DFN1.6x0.8 | ~1.35 | ~1.90 | ~0.90 | ~0.60 | ~1.65 | ~8.30 | ±0.10 | ±0.05 | ±0.10 | ±0.10 | ±0.05 | ~0.30 |
| DFN1.45x1.0 | | | | | | | | | | | | |

Reel



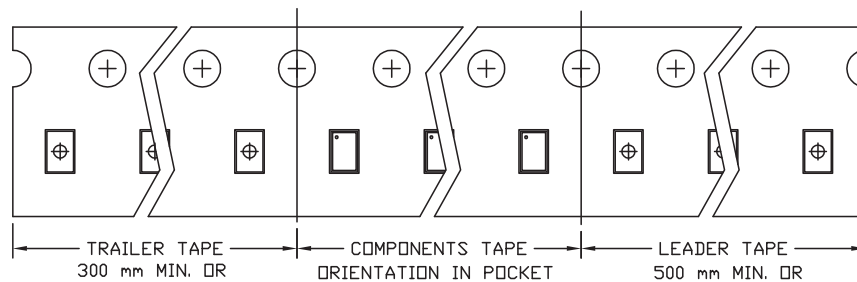
UNIT: MM

| TAPE SIZE | REEL SIZE | M | N | W | W1 | H | K | S | G | R | V |
|-----------|-----------|--------------|---------------|-------------|-----|----------------------------------|---------------|---------------|------|-----|-----|
| 8 mm | ø178 | ø178 ±1.0 | ø52.0 ±1.0 | 9.0 ±0.5 | N/A | ø13.0 ^{+0.5} -0.2 | 10.25 ±0.2 | 2.40 ±0.10 | ø9.8 | N/A | N/A |

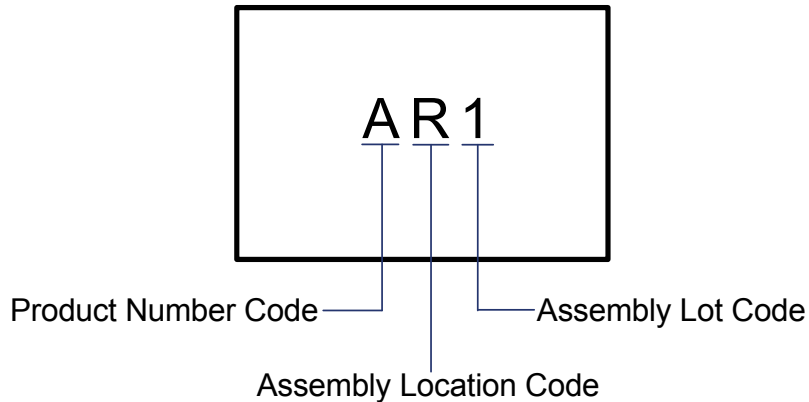
Tape

Leader / Trailer
& Orientation

Unit Per Reel:
3000pcs



Part Marking



| Part Number | Part Number Code of Marking |
|--------------|-----------------------------|
| AOZ8310DI-02 | N |
| AOZ8310DI-05 | L |
| AOZ8310DI-08 | E |
| AOZ8310DI-09 | F |
| AOZ8310DI-12 | G |
| AOZ8310DI-18 | H |
| AOZ8310DI-20 | D |
| AOZ8310DI-26 | S |
| AOZ8310DI-36 | K |

LEGAL DISCLAIMER

Applications or uses as critical components in life support devices or systems are not authorized. AOS 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.

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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.