

General Description

The AOZ6682CI is a high efficiency, easy to use, 2A synchronous buck regulators at fixed switching frequency for small form factor solution. AOZ6682CI works from 4.5V to 18V input voltage range, and provides up to 2A of continuous output current with an output voltage adjustable down to 0.8V.

The AOZ6682CI features fixed frequency operation at heavy load and Pulse Energy Mode (PEM) at light load, providing best efficiency across whole load range. The control loop of AOZ6682CI is internally compensated, allowing for simple system design and minimal component count by eliminating the need of external compensation network.

AOZ6682CI also features built-in enable control, internal soft-start and many protection functions, including cycle-by-cycle current limit, short-circuit protection, output over-voltage protection, input under-voltage lockout and over-temperature protection.

AOZ6682CI comes in an ultra-thin TSOT23-6L package and is rated from -40°C to +125°C junction temperature range.

Features

- 4.5V to 18V operating input voltage range
- 2A continuous output current
- Synchronous Buck with Low on-resistance:
 - 125mΩ High-Side
 - 55mΩ Low-Side
- Up to 95% efficiency
- Pulse energy mode for high light load efficiency
- ($V_{IN}=12V$, $V_{OUT}=5V$, 89% efficiency at 10mA)
- Output voltage adjustable down to 0.8V
- 750kHz PWM operation
- Internal compensation
- Internal soft start
- Capable to handle pre-bias start-up
- Cycle-by-cycle current limit
- Output over-voltage protection
- Short-circuit protection
- Thermal shutdown
- Ultra-thin TSOT23-6L package

Applications

- General Point-of-load
- High performance LCD TV
- High performance cable modems



Typical Application

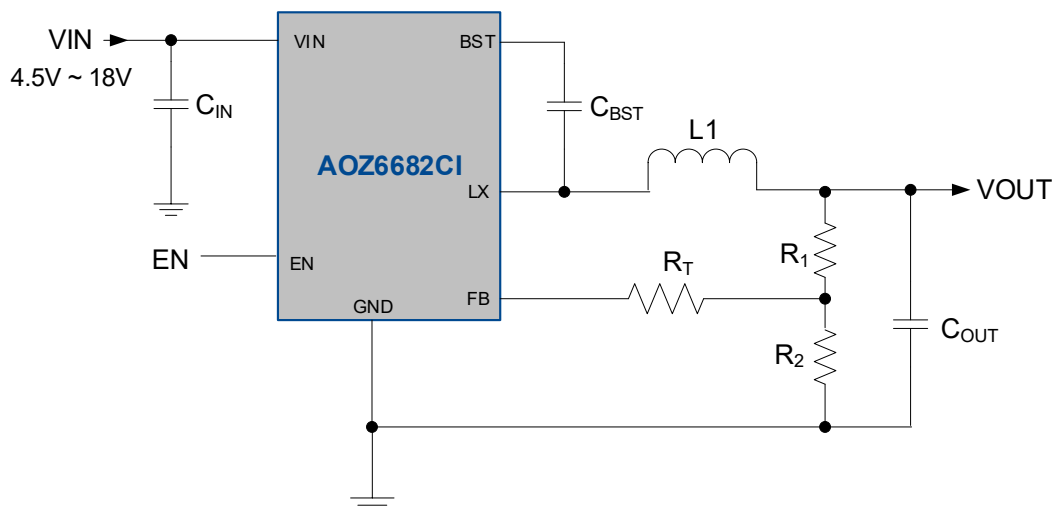


Figure 1. 2A Synchronous Buck Regulator

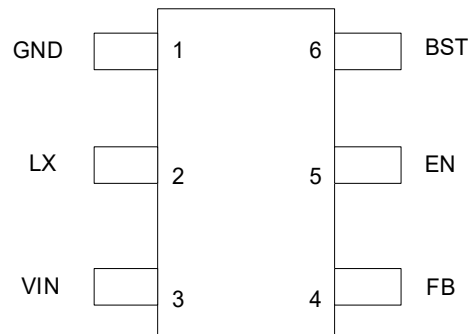
Ordering Information

| Part Number | Junction Temperature Range | Package | Environmental |
|-------------|----------------------------|-----------|---------------|
| AOZ6682CI | -40°C to +125°C | TSOT23-6L | RoHS |



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

Pin Configuration



**TSOT23
(Top View)**

Pin Description

| Pin Number | Pin Name | Pin Function |
|------------|----------|--|
| 1 | GND | System ground. |
| 2 | LX | Switching node. Connect to main inductor terminal. |
| 3 | VIN | Supply voltage input. When VIN rises above the UVLO threshold and EN is logic high, the device will start up. |
| 4 | FB | Feedback input. The FB pin is used to set the output voltage via a resistor voltage divider between the output and GND. |
| 5 | EN | Enable input. Pull up EN to logic high will enable the device. Pull EN to logic low will disable the device. If no enable control signal is available, this pin can be connected directly to VIN to enable the part. Do not leave it open. |
| 6 | BST | Bootstrap input for High-Side driver. Connect a capacitor to LX pin. Typical value is 0.1µF. |

Absolute Maximum Ratings⁽¹⁾

Exceeding the Absolute Maximum ratings may damage the device.

| Parameter | Rating |
|---|------------------------|
| Supply Voltage (V_{IN}) | -0.3V to 20V |
| High Voltage Input (EN) | -0.3V to 20V |
| Switching Node DC (LX to GND) | -0.3V to $V_{IN}+0.3V$ |
| Switching Node Transient (20ns) (LX to GND) | -5V to 22V |
| Low Voltage Input (FB) | -0.3V to 6V |
| Bootstrap Voltage (BST to LX) | 6V |
| Junction Temperature (T_J) | +150°C |
| Storage Temperature (T_S) | -65°C to +150°C |
| ESD Rating ⁽²⁾ | 2kV |

Notes:

- Exceeding the Absolute Maximum ratings may damage the device.
- Devices are inherently ESD sensitive, handling precautions are required.
Human body model rating: 1.5kΩ in series with 100pF

Recommended Operating Conditions⁽³⁾

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

| Parameter | Rating |
|--|-----------------|
| Supply Voltage (V_{IN}) | 4.5V to 18V |
| Output Voltage Range | 0.8V to 6V |
| Junction Temperature (T_J) | -40°C to +125°C |
| Package Thermal Resistance (θ_{JA}) | 90°C/W |

Notes:

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

Electrical Characteristics

$T_A = 25^\circ\text{C}$, $V_{IN} = V_{EN} = 12\text{V}$, $V_{OUT} = 3.3\text{V}$, unless otherwise specified. Specifications in BOLD indicate a temperature range of -40°C to +125°C. These specifications are guaranteed by design.

| Symbol | Parameter | Conditions | Min | Typ | Max | Unit |
|---------------|---------------------------------------|---|------------|------------|------------|------|
| V_{IN} | Supply Voltage | -40°C < T_J < 125°C | 4.5 | | 18 | V |
| V_{UVLO} | Input Under-Voltage Lockout Threshold | V_{IN} rising | | 4.1 | 4.3 | V |
| | | V_{IN} falling | 3.2 | 3.7 | | |
| I_{IN} | Quiescent Supply Current | $I_{VOUT} = 0\text{A}$, FB = 1.2V, EN=5V | | 200 | 290 | μA |
| I_{OFF} | Shutdown Supply Current | EN = 0V, -40°C < T_J < 125°C | | 0.1 | 1 | μA |
| V_{FB} | Feedback Voltage | | 0.784 | 0.8 | 0.816 | V |
| R_O | Load Regulation | 0.5A < I_{OUT} < 2A | | 0.5 | | % |
| S_V | Line Regulation | 4.5V < V_{IN} < 18V | | 1 | | % |
| I_{FB} | Feedback Input Current | FB=0.8V | | | 200 | nA |
| V_{EN} | Enable Threshold | EN falling -40°C < T_J < 125°C | | | 0.6 | V |
| | | EN rising -40°C < T_J < 125°C | 2 | | | |
| V_{EN_HYS} | Enable Hysteresis | | | 300 | | mV |
| I_{EN} | Enable Input Current | EN = 5V | | 3 | 6 | μA |
| t_{SS} | Soft Start Time | | | 2.8 | | ms |

Electrical Characteristics

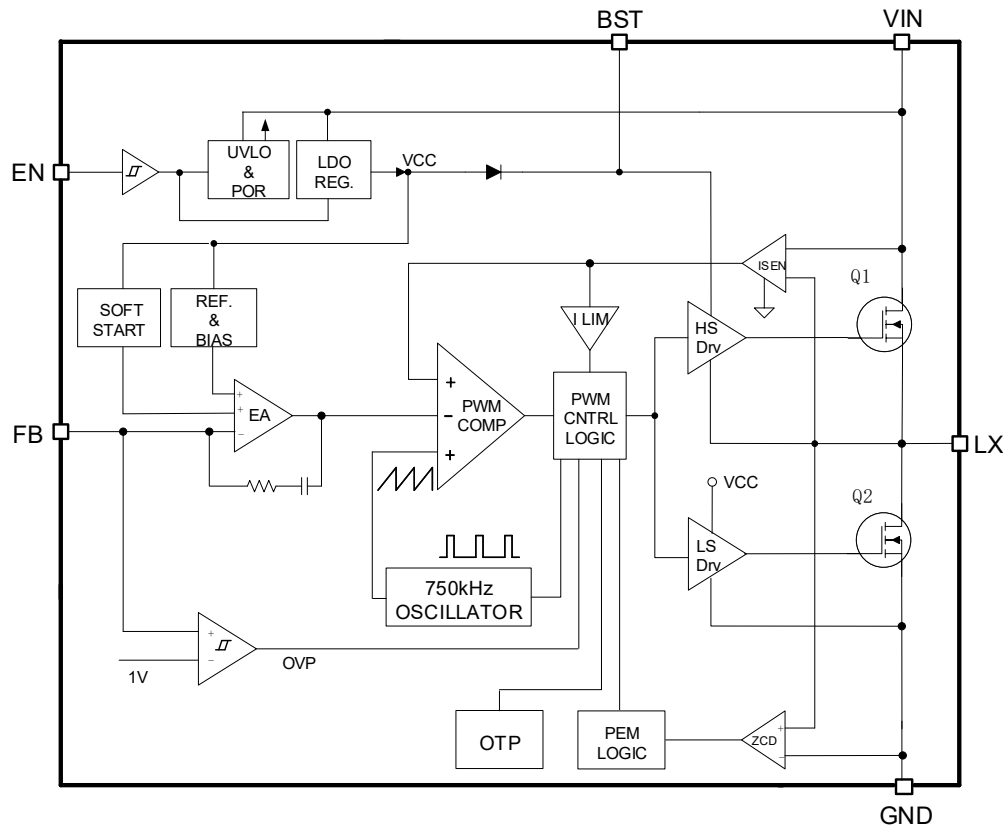
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| Symbol | Parameter | Conditions | Min | Typ | Max | Unit |
|---------------------|---|-------------------------|-----|-----|-----|------------------|
| Modulator | | | | | | |
| f_O | Switching Frequency | $I_{OUT} > 0.5\text{A}$ | | 750 | | kHz |
| D_{MAX} | Maximum Duty Cycle | | | 80 | | % |
| t_{MIN} | Controllable Minimum On-Time ⁽⁴⁾ | | | 60 | | ns |
| D_{MIN} | Controllable Minimum Duty Cycle ⁽⁴⁾ | | | | 8 | % |
| Protection | | | | | | |
| I_{LIM} | Current Limit | | 2.5 | | | A |
| T_{OTP} | Over Temperature Shutdown Limit | Temperature rising | | 150 | | $^\circ\text{C}$ |
| | | Temperature falling | | 100 | | $^\circ\text{C}$ |
| VOVP | Output Over-Voltage Protection Threshold | With respect to FB=0.8V | | 125 | | % |
| V_{OVP_REC} | Output Over-Voltage Protection Recovery Threshold | With respect to FB=0.8V | | 110 | | % |
| Output Stage | | | | | | |
| R_{ON_HS} | High-Side Switch On-Resistance | BST - LX = 5V | | 125 | | m Ω |
| R_{ON_LS} | Low-Side Switch On-Resistance | | | 55 | | m Ω |

Notes:

4. Guaranteed by design and not production tested.

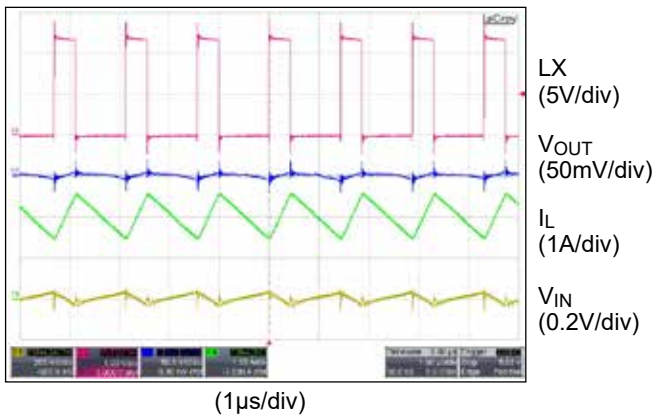
Functional Block Diagram



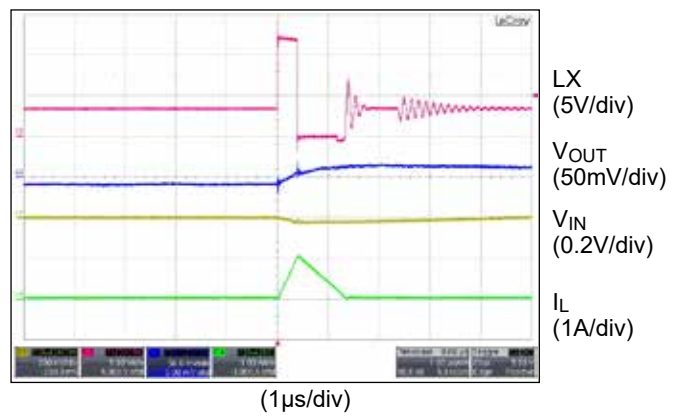
Typical Characteristics

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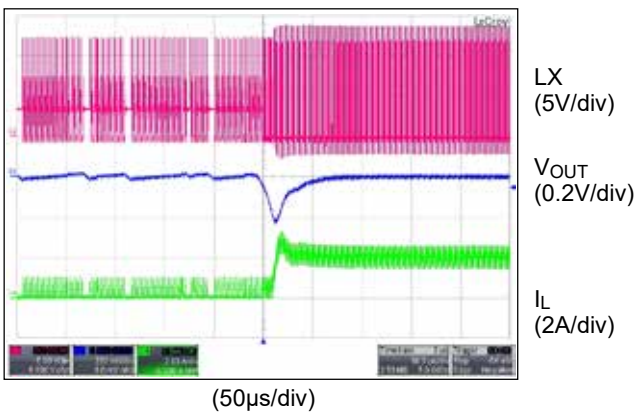
PWM Mode Operation



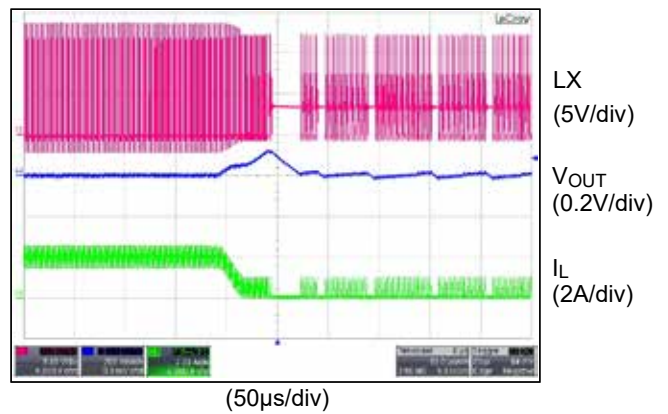
PEM Mode Operation



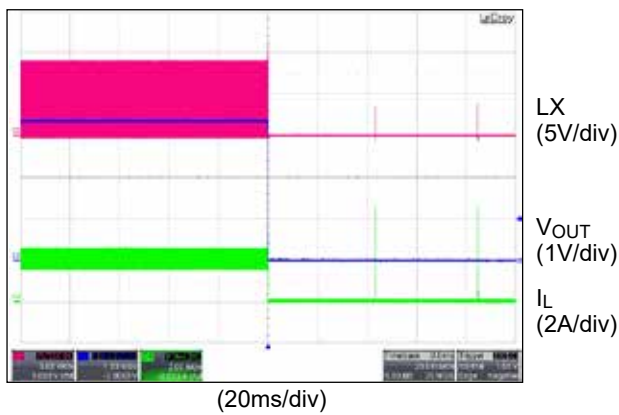
PEM to PWM Mode Change



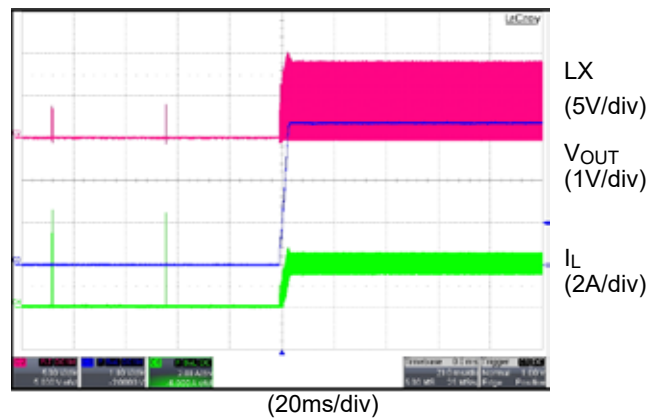
PWM to PEM Mode Change



Output Short Protection



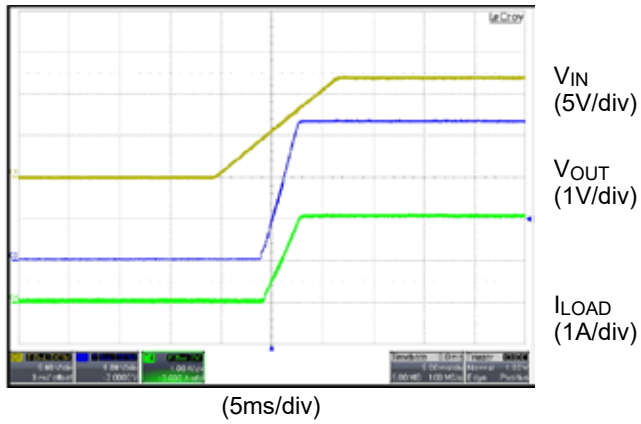
Short Circuit Recovery



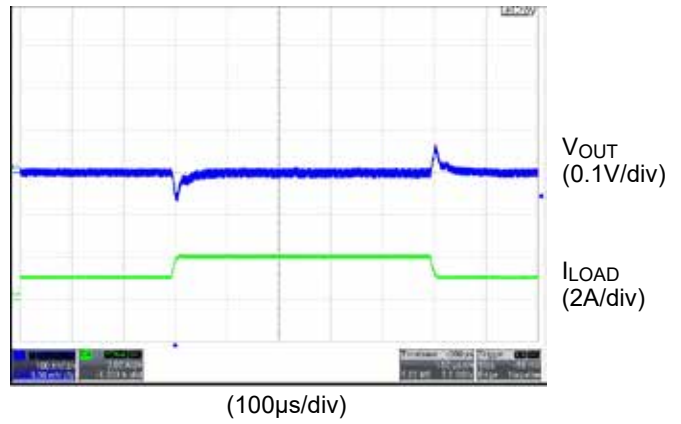
Typical Characteristics

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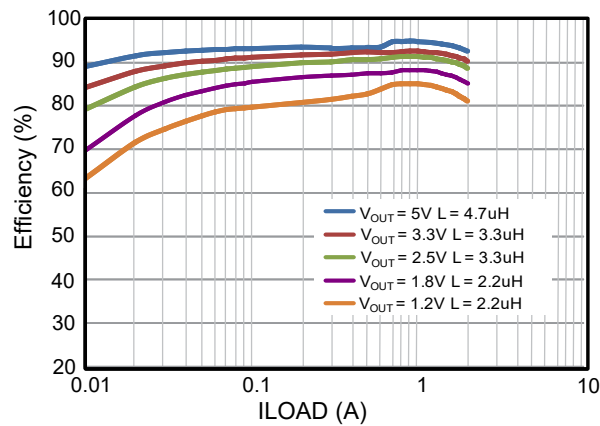
Start Up to Full Load



50% to 100% Load Transient



Efficiency vs Output Current. $V_{IN}=12\text{V}$



Detailed Description

AOZ6682CI is a current-mode step down regulator with integrated high-side and low-side power switches. It operates from 4.5V to 18V input voltage range and supplies up to 2A of continuous load current. Functional features such as Enable control, Power-On Reset (POR), input Under-Voltage Lock-Out (UVLO), Cycle-by-cycle current limit, Output Over-Voltage Protection (OVP), internal soft-start, and Over-Temperature protection (OTP) shut down are built in. AOZ6682CI is available in compact TSOT23-6L package.

Enable and Soft Start

AOZ6682CI has internal soft start feature to limit the in-rush current and ensure the output voltage ramps up smoothly to regulation voltage during start up. A soft start process begins when the input voltage rises above 4.1V and voltage on EN pin is higher than 2V. The soft start time is pre-programmed to 2.8ms typical.

The EN pin of the regulator is active high. The voltage at EN pin must be above 2V to enable the device. When the voltage at EN pin falls below 0.6V, the device is disabled. To ensure proper operation, EN pin must be biased to solid voltage level in either enable or disable state. EN pin is rated up to VIN voltage. This feature allows for simple design with EN pin directly tied to VIN to minimize component count and system complexity, if no enable control signal is available.

Steady-State Operation

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

AOZ6682CI uses current mode control for regulation. Inductor current is sensed through the current being conducted by the power MOSFET. Output voltage is determined by the external voltage divider between VOUT, FB, and GND. The difference of the FB voltage and internal reference voltage is amplified by the transconductance error amplifier. The error voltage is compared against the current signal (sum of inductor current signal and input ramp compensation signal) at PWM comparator stage. If the current signal is less than the error voltage, the High-Side switch is turned on. The inductor current flows from the VIN through the inductor to the VOUT. When the current signal exceeds the error voltage, the High-Side switch is turned off. The inductor current is freewheeling through the Low-Side switch from GND to VOUT.

The internal adaptive gate drivers guarantee no turn on overlap between High-Side and Low-Side switches to prevent any shoot-through condition.

Comparing with non-synchronous converters using freewheeling Schottky diodes, the AOZ6682CI uses synchronous power switch to greatly improve the converter efficiency by reducing power loss in the Low-Side switch.

Light Load Operation

Under low output current settings, AOZ6682CI will operate with pulse energy mode (PEM) to obtain high efficiency. The main goal of PEM is to reduce the switching loss as it is the main source of energy loss at low load. Under this mode, the High-Side switch will not turn off until its on-time reaches a controlled duration which is determined by input voltage (VIN), output voltage (VOUT), and switching frequency (f_o). The Low-Side switch will be turned off eventually when inductor current is close to 0A. Both switches are off and LX is in high impedance state until VOUT drops to a pre-determined level and more energy is needed to bring the VOUT back to regulated voltage. The High-Side switch will then be turned on at the beginning of the clock cycle.

Bootstrap Supply for High-side Switch

This converter uses a N-Channel MOSFET as the High-Side switch. Since the N-Channel MOSFET requires a gate voltage higher than the input voltage to turn on, a bootstrap capacitor is needed between LX pin (Pin 2) and BST pin (Pin 6) to drive the gate of the MOSFET. The boost capacitor is being charged while LX is low. Typical 0.1µF capacitor is recommended for most applications.

Output Voltage Programming

Output voltage (VOUT) can be set by feeding back the VOUT to the FB pin through a resistor divider network as shown in Figure 1. Design starts by selecting a fixed R2 value and then calculates the required R1 using the equation below.

$$V_{OUT} = FB \times \left(1 + \frac{R1}{R2}\right)$$

Combination of R1 and R2 should be large enough to avoid drawing excessive current from the output, which will cause power loss. Some standard value of R1, R2 and most used output voltage values are listed in Table 1.

Table 1. Typical Resistor Divider Values for FB input

| VOUT (V) | R1 (kΩ) | R2 (kΩ) |
|----------|---------|---------|
| 0.8 | 1.0 | open |
| 1.2 | 5.0 | 10.0 |
| 1.5 | 10.0 | 11.5 |
| 1.8 | 12.7 | 10.2 |
| 2.5 | 21.5 | 10.0 |
| 3.3 | 31.1 | 10.0 |
| 5.0 | 52.3 | 10.0 |

Protection Features

AOZ6682CI has multiple protection features to prevent system circuit damage under abnormal conditions.

Over Current Protection (OCP)

The output current from LX pin is being monitored cycle by cycle. If the output current exceeds the preset limit, the switch will be turned off to prevent excessive power being dissipated by the converter. If output drops to certain level during OC condition, the part will shut down and auto restart with hiccup mode.

Output Over-voltage Protection (OVP)

The FB pin voltage is monitored for any output over-voltage event. Once an over-voltage condition happens and FB voltage rises above 1V, both High-Side and Low-Side switches will be turned off. Once output discharges and FB voltage drops below 0.88V, device will resume operation by allowing both High-side and Low-Side switches to switch normally.

Power-On Reset (POR)

A power-on reset circuit monitors the VIN voltage. When the VIN voltage exceeds 4.1V, the converter starts to operate if EN > 2V. When VIN 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 both High-Side and Low-Side switches 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

Operating Range

For any output voltage setting, minimum input voltage supported by AOZ6682CI is governed by maximum duty cycle allowed by the regulator. The minimum input voltage required for certain output voltage setting is shown in Figure 2.

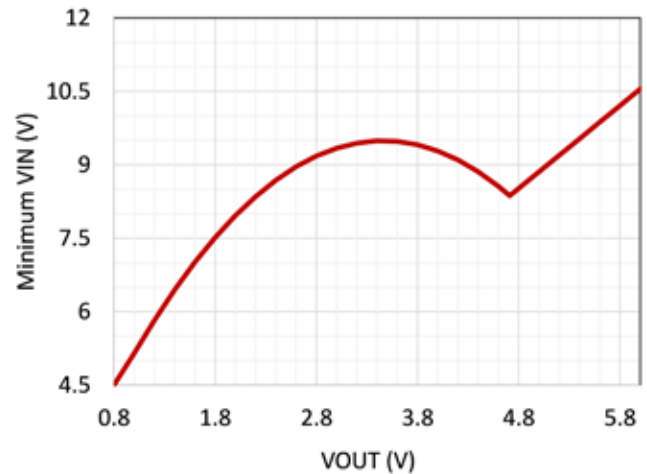


Figure 2. Minimum Input Voltage Required vs Output Voltage Setting

Input Capacitor

The input capacitor must be connected to the VIN pin and GND pin 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:

$$\Delta V_{IN} = \frac{I_{OUT}}{f_o \times C_{IN}} \times \left(1 - \frac{V_{OUT}}{V_{IN}}\right) \times \frac{V_{OUT}}{V_{IN}}$$

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:

$$I_{CIN_RMS} = I_{OUT} \times \sqrt{\frac{V_{OUT}}{V_{IN}} \left(1 - \frac{V_{OUT}}{V_{IN}}\right)}$$

if we let m equal the conversion ratio:

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

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

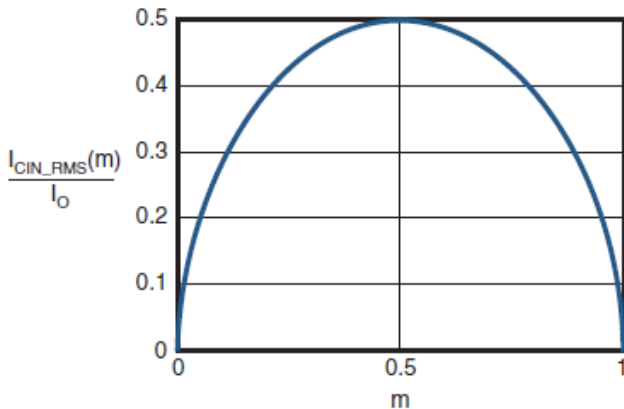


Figure 3. I_{CIN} vs. voltage conversion ratio

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

Inductor

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

$$\Delta I_L = \frac{V_{OUT}}{f_o \times LI} \times \left(1 - \frac{V_{OUT}}{V_{IN}}\right)$$

The Peak inductor current is:

$$I_{L_{peak}} = I_{OUT} + \frac{\Delta I_L}{2}$$

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

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

Output Capacitor

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

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

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

$$\Delta V_{OUT} = \Delta I_L \times \left(ESR_{COUT} + \frac{1}{8 \times f_o \times C_{OUT}}\right)$$

where C_{OUT} is output capacitor value and ESR_{COUT} 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:

$$\Delta V_{OUT} = \Delta I_L \times \frac{1}{8 \times f_o \times C_{OUT}}$$

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:

$$\Delta V_{OUT} = \Delta I_L \times ESR_{COUT}$$

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 AOZ6682CI 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 pin, 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 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 GND pin of the AOZ6682CI.

The major power dissipating components in this buck converter application are AOZ6682CI and the output inductor. The total power dissipation of converter circuit can be measured by input power minus output power.

$$P_{total_loss} = V_{IN} \cdot I_{IN} - V_{OUT} \cdot I_{OUT}$$

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

$$P_{inductor_loss} = I_{OUT}^2 \cdot R_{inductor} \cdot 1.1$$

The actual junction temperature can be calculated with power dissipation in the AOZ6682CI and thermal impedance from junction to ambient.

$$T_{junction} = (P_{total_loss} - P_{inductor_loss}) \cdot \theta_{JA} + T_{amb}$$

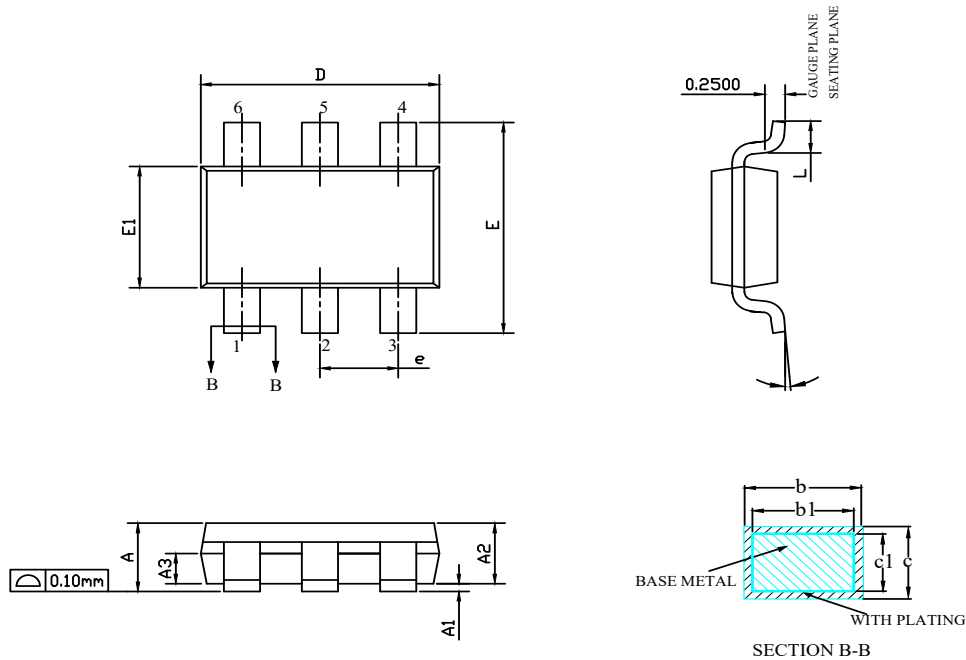
The maximum junction temperature of the AOZ6682CI is 150°C, which limits the maximum load current capability.

The thermal performance of the AOZ6682CI is strongly affected by the PCB layout. Extra care should be taken by users during design process to ensure that the IC will operate under the recommended environmental conditions.

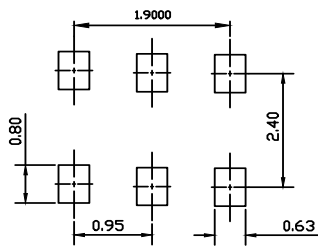
The AOZ6682CI is TSOT23-6L package. Several layout tips are listed below for the best electrical and thermal performance.

1. Do not use thermal relief connection to the VIN and the GND pin. Maximize copper area to the GND pin and the VIN pin to help thermal dissipation.
2. Input capacitor should be connected to the VIN pin and the GND pin as close as possible.
3. Make the current trace from LX pin to L to C_{OUT} 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. Place the feedback resistors as close to chip as possible
6. Keep sensitive signal trace away from the LX pin

Package Dimensions, TSOT23-6L



RECOMMENDED LAND PATTERN



UNIT: mm

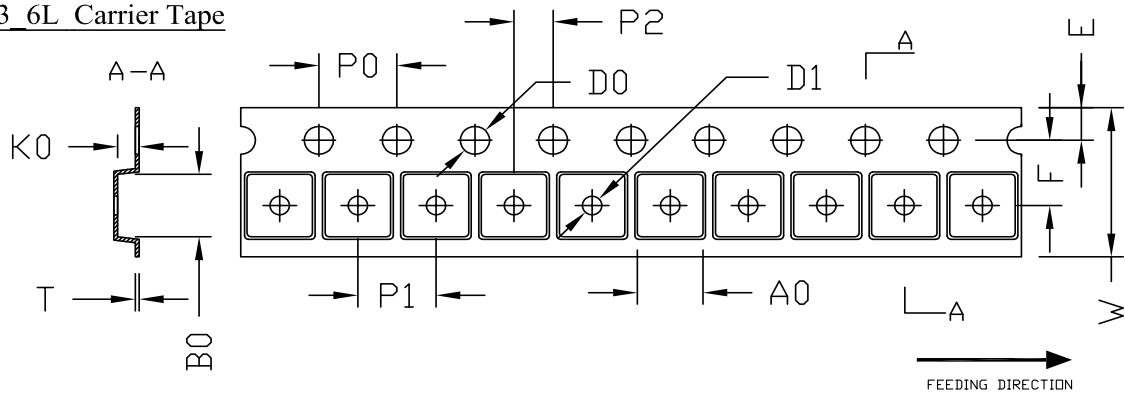
| SYMBOLS | DIMENSIONS IN MILLIMETERS | | | DIMENSIONS IN INCHES | | |
|---------|---------------------------|------|------|----------------------|-------|-------|
| | MIN | NOM | MAX | MIN | NOM | MAX |
| A | --- | --- | 0.95 | ---- | ---- | 0.037 |
| A1 | 0.00 | --- | 0.10 | 0.000 | ---- | 0.004 |
| A2 | 0.75 | 0.80 | 0.85 | 0.030 | 0.031 | 0.033 |
| A3 | 0.35 | 0.40 | 0.45 | 0.014 | 0.016 | 0.018 |
| b | 0.30 | 0.44 | 0.50 | 0.012 | 0.017 | 0.020 |
| b1 | 0.30 | 0.40 | 0.45 | 0.012 | 0.016 | 0.018 |
| c | 0.11 | 0.16 | 0.20 | 0.004 | 0.006 | 0.008 |
| c1 | 0.11 | 0.13 | 0.15 | 0.004 | 0.005 | 0.006 |
| D | 2.70 | 2.90 | 3.10 | 0.106 | 0.114 | 0.122 |
| E | 2.60 | 2.80 | 3.00 | 0.102 | 0.110 | 0.118 |
| E1 | 1.50 | 1.60 | 1.70 | 0.059 | 0.063 | 0.067 |
| e | 0.95 BSC | | | 0.037BSC | | |
| L | 0.30 | 0.40 | 0.50 | 0.012 | 0.016 | 0.020 |
| Θ | 0° | --- | 8° | 0° | ---- | 8° |

NOTE

1. PACKAGE BODY SIZES EXCLUDE MOLD FLASH OR GATE BURRS.
MOLD FLASH AT THE NON-LEAD SIDES SHOULD BE LESS THAN 6 MILS EACH.
2. TOLERANCE +/-0.100 mm (4 mil) UNLESS OTHERWISE SPECIFIED.
3. DIMENSION L IS MEASURED IN GAUGE PLANE.
4. CONTROLLING DIMENSION IS MILLIMETER. CONVERTED INCH DIMENSIONS ARE NOT NECESSARILY EXACT.
5. ALL DIMENSIONS ARE IN MILLIMETERS.

Tape and Reel Dimensions, TSOT23-6L

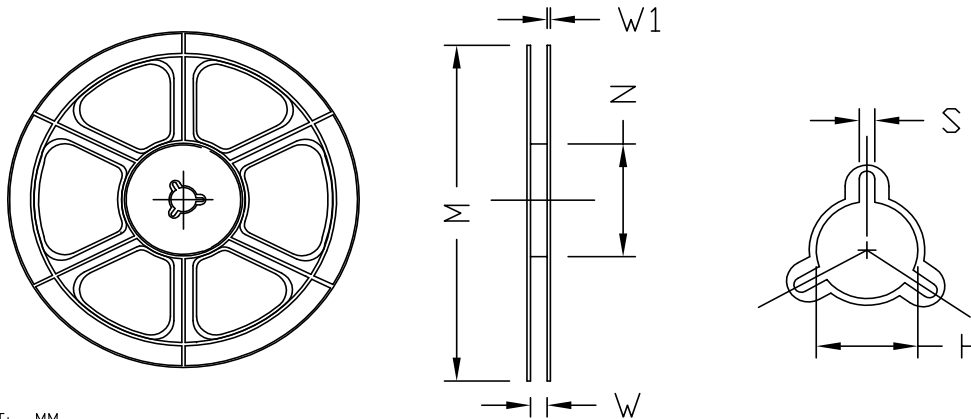
TSOT23_6L Carrier Tape



UNIT: MM

| PACKAGE | A0 | B0 | K0 | D0 | D1 | W | E | F | P0 | P1 | P2 | T |
|-----------|---------------|---------------|---------------|---------------|------------------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
| TSOT23_6L | 3.26 ±0.10 | 3.30 ±0.10 | 1.05 ±0.10 | 1.55 ±0.05 | 1.05 +0.25 -0.05 | 8.00 ±0.10 | 1.75 ±0.10 | 3.50 ±0.05 | 4.00 ±0.10 | 4.00 ±0.10 | 2.00 ±0.05 | 0.20 ±0.02 |

TSOT23_6L REEL



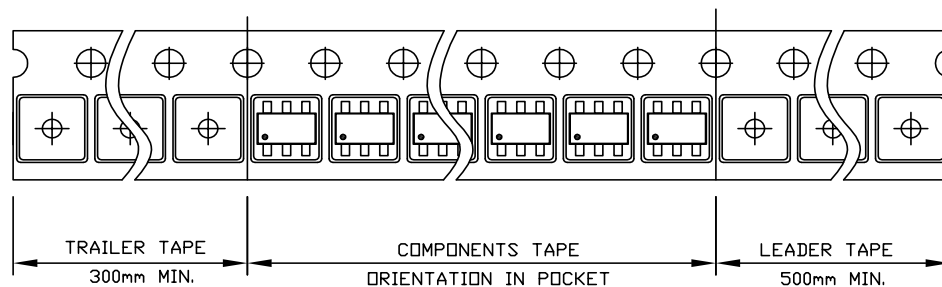
UNIT: MM

| TAPE SIZE | REEL SIZE | M | N | W | W1 | H | S | | | | |
|-----------|-----------|------------------|--------------------------|------------------------|---------------|--------------------------|------------------------|--|--|--|--|
| 8 mm | φ179 | φ179.00 ±1.00 | φ54.40 +1.00 -0.16 | 8.60 +1.00 -0.00 | 1.40 ±0.30 | φ13.00 +0.50 -0.20 | 2.00 +0.50 -0.00 | | | | |

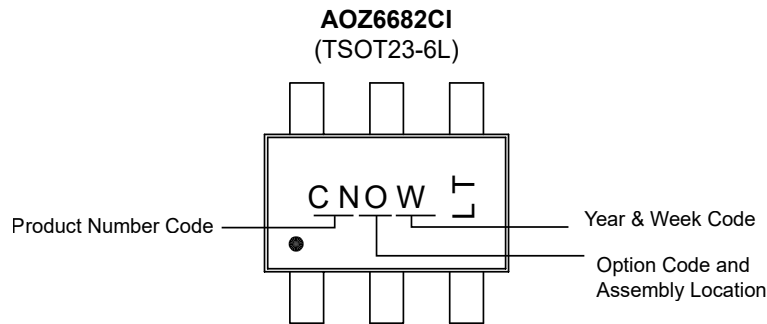
TSOT23_6L TAPE

Leader / Trailer
& Orientation

Unit Per Reel:
3000pcs



Part Marking



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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.