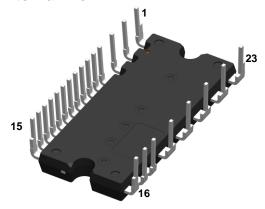


AIP5D10K060Q4(S/U)

Dual-In-Line Package Intelligent Power Module

External View



Size: 33.4 x 15 x 3.6 mm



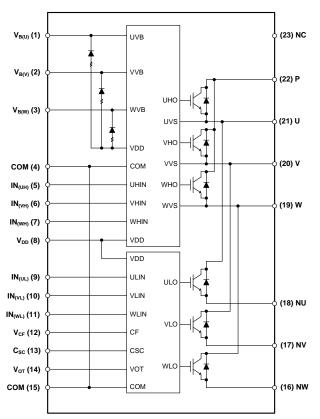
Features

- UL Recognized
- 600V-10A (Trench Shielded Planar Gate IGBT)
- 3 phase Inverter module including HVIC drivers
- Built-in bootstrap diodes with integrated current-limiting resistor
- Control supply under-voltage lockout protection (UVLO)
- Over-temperature (OT) protection and temperature monitoring (V_{OT}) - pin open
- Temperature monitoring only (V_{OT}) 10kΩ resistor connection
- Short-circuit current protection (C_{SC})
- Controllable fault out signal (V_{CF}) corresponding to SC, UV and OT fault
- Wide input interface (3-18V), Schmitt trigger receiver circuit (Active High)
- Isolation ratings of 2000Vrms/min

Applications

- AC 100-240Vrms class low power motor drives
- Washing machines, Compressors, Fan Motors, Refrigerators, Dishwashers and Air-conditioners

Internal Equivalent Circuit / Pin Configuration





Ordering Information

| Part Number Temperature Range | | Package | Pin Length Description | |
|-------------------------------|----------------|---------|------------------------|--|
| AIP5D10K060Q4 | -40°C to 150°C | IPM-5 | Normal | |
| AIP5D10K060Q4S | -40°C to 150°C | IPM-5A | Short | |
| AIP5D10K060Q4U | -40°C to 150°C | IPM-5C | Ultra Short | |



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 Description

| Pin Number | Pin Name | Pin Function |
|------------|--------------------|---|
| 1 | $V_{B(U)}$ | High-Side Bias Voltage for U-Phase IGBT Driving |
| 2 | $V_{B(V)}$ | High-Side Bias Voltage for V-Phase IGBT Driving |
| 3 | $V_{B(W)}$ | High-Side Bias Voltage for W-Phase IGBT Driving |
| 4 | COM | Common Supply Ground |
| 5 | IN _(UH) | Signal Input for High-Side U-Phase |
| 6 | IN _(VH) | Signal Input for High-Side V-Phase |
| 7 | IN _(WH) | Signal Input for High-Side W-Phase |
| 8 | V_{DD} | Common Bias Voltage for IC and IGBTs Driving |
| 9 | IN _(UL) | Signal Input for Low-Side U-Phase |
| 10 | IN _(VL) | Signal Input for Low-Side V-Phase |
| 11 | IN _(WL) | Signal Input for Low-Side W-Phase |
| 12 | V _{CF} | Controllable Fault Output |
| 13 | C _{SC} | Capacitor (Low-Pass Filter) for Short-circuit Current Detection Input |
| 14 | V _{OT} | Voltage Output of LVIC Temperature |
| 15 | COM | Common Supply Ground |
| 16 | NW | Negative DC-Link Input for W-Phase |
| 17 | NV | Negative DC-Link Input for V-Phase |
| 18 | NU | Negative DC-Link Input for U-Phase |
| 19 | W | Output for W-Phase |
| 20 | V | Output for V-Phase |
| 21 | U | Output for U-Phase |
| 22 | Р | Positive DC-Link Input |
| 23 | NC | No Connection |

Rev.1.1 December 2020 www.aosmd.com Page 2 of 15



Absolute Maximum Ratings

 $T_J = 25$ °C, unless otherwise specified.

| Symbol | Parameter | Conditions | Ratings | Units | | | |
|------------------------|--|---|----------------------|-----------|--|--|--|
| Inverter | | | | | | | |
| V_{PN} | Supply Voltage | Applied between P - NU,NV,NW | 450 | V | | | |
| V _{PN(surge)} | Supply Voltage (surge) | Applied between P - NU,NV,NW | 500 | V | | | |
| V _{CES} | Collector-Emitter Voltage | | 600 | V | | | |
| | 0 | T _C =25°C, T _J <150°C | 10 | Α | | | |
| Ic | Output Phase Current | T _C =100°C, T _J <150°C | 5 | Α | | | |
| ±I _{PK} | Output Peak Phase Current | T _C =25°C, less than 1ms pulse width | 20 | Α | | | |
| t _{SC} | Short Circuit Withstand Time | V _{PN} ≤400V, T _J =150°C, V _{DD} =15V | 5 | μs | | | |
| Pc | Collector Dissipation | T _C =25°C, per chip | 23 | W | | | |
| TJ | Operating Junction Temperature | | -40 to 150 | °C | | | |
| Control (P | rotection) | | | | | | |
| V _{DD} | Control Supply Voltage | Applied between V _{DD} -COM | 25 | V | | | |
| V_{DB} | High-Side Control Bias Voltage | Applied between V _{B(U)} -U, V _{B(V)} -V, V _{B(W)} -W | 25 | V | | | |
| V _{IN} | Input Voltage | Applied between $IN_{(UH)}$, $IN_{(VH)}$, $IN_{(WH)}$, $IN_{(UL)}$, $IN_{(UL)}$, $IN_{(WL)}$ — COM | V _{DD} ±0.5 | V | | | |
| V_{CF} | Fault Output Supply Voltage | Applied between V _{CF} -COM | 5±0.5 | V | | | |
| I _{CF} | Fault Output Current | Sink current at V _{CF} terminal | 1 | mA | | | |
| V _{SC} | Current Sensing Input Voltage | Applied between C _{SC} -COM | 5±0.5 | V | | | |
| V _{OT} | Temperature Output | Applied between V _{OT} -COM | 5±0.5 | V | | | |
| Total Syst | em | | | | | | |
| V _{PN(PROT)} | Self Protection Supply Voltage Limit (Short-Circuit Protection Capability) | V _{DD} =13.5-16.5V, Inverter part T _J =150°C, Non-repetitive, less than 2μs | 400 | V | | | |
| T _C | Module Case Operation Temperature | Measurement point of T _C is provided in Figure 1 | -30 to 125 | °C | | | |
| T _{STG} | Storage Temperature | | -40 to 150 | °C | | | |
| V _{ISO} | Isolation Voltage | 60Hz, sinusoidal, AC 1min, between connected all pins and heat sink plate | 2000 | V_{rms} | | | |

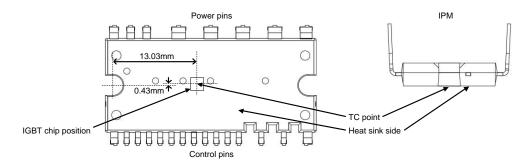


Figure 1. T_C Measurement Point

Thermal Resistance

| Symbol | Parameter | Conditions | Min. | Тур. | Max. | Units |
|-----------------------|---|--------------------------------|------|------|------|-------|
| R _{th(j-c)Q} | Junction to Case Thermal Resistance (1) | Inverter IGBT (per 1/6 module) | - | - | 5.4 | K/W |
| R _{th(j-c)F} | | Inverter FWD (per 1/6 module) | - | - | 6.9 | K/W |

Note:

1. For the measurement point of case temperature (T_{C}), please refer to Figure 1.

Rev.1.1 December 2020 **www.aosmd.com** Page 3 of 15



Electrical Characteristics

 $T_J = 25$ °C, unless otherwise specified.

| Symbol | Parameter | Co | onditions | Min. | Тур. | Max. | Units |
|----------------------|---|--|---|------|------|------|-------|
| Inverter | | | | | | | |
| | Collector-Emitter Saturation | V _{DD} =V _{DB} =15V, | I _C =5A, T _{J=} 25°C | - | 1.60 | 2.00 | V |
| $V_{CE(SAT)}$ | Voltage | V _{IN} =5V | I _C =5A, T _J =125°C | - | 1.90 | - | V |
| V _F | FWD Forward Voltage | V _{IN} =0 | I _F =5A, T _J =25°C | - | 1.35 | 1.80 | V |
| t _{ON} | | | | | 0.60 | 1.10 | μs |
| t _{C(ON)} | - | V _{PN} =300V, V _{DD} =V _{DB} =15V | | - | 0.10 | 0.40 | μs |
| t _{OFF} | Switching Times | I _C =5A, T _J =25°C, V _{IN} | $I_C=5A$, $T_J=25$ °C, $V_{IN}=0V \leftrightarrow 5V$ | | 1.00 | 1.50 | μs |
| t _{C(OFF)} | | Inductive load (high- | -side) | - | 0.10 | 0.30 | μs |
| t _{rr} | | | | - | 0.10 | - | μs |
| 1 | Collector-Emitter Leakage | V _{CE} =V _{CES} | T _J =25°C | - | - | 1 | mA |
| I _{CES} | Current | VCE-VCES | T _J =125°C | - | - | 10 | mA |
| Control (P | Protection) | | | | | | |
| I_{QDD} | Quiescent V _{DD} Supply Current | V_{DD} =15V, $IN_{(UH,VH,WH,UL,VL,WL)}$ =0V | V _{DD} -COM | - | - | 2.1 | mA |
| I _{QDB} | Quiescent V _{DB} Supply Current | V _{DB} =15V, IN _(UH, VH, WH) =0V | $V_{B(U)}\text{-}U,\ V_{B(V)}\text{-}V,\ V_{B(W)}\text{-}W$ | - | - | 0.3 | mA |
| V _{SC(ref)} | Short-Circuit Trip Level | V _{DD} =15V (2) | | 0.45 | 0.48 | 0.51 | V |
| UV_{DT} | | Trip Level | | 10.3 | 11.4 | 12.5 | V |
| UV_DR | Supply Circuit Under-Voltage | Reset Level | | 10.8 | 11.9 | 13.0 | V |
| UV_DBT | Protection | Trip Level | | 8.5 | 9.5 | 10.5 | V |
| UV_DBR | | Reset Level | | 9.5 | 10.5 | 11.5 | V |
| V_{OT} | Temperature Output | Pull-down | LVIC Temperature=80°C | 2.36 | 2.45 | 2.55 | V |
| | Tomporature Gutput | R=10kΩ ⁽³⁾ | LVIC Temperature=25°C | 0.77 | 1.00 | 1.25 | V |
| OT _T | Over-Temperature | V _{DD} =15V, Detect | Trip Level | 110 | 130 | 150 | °C |
| OT _{HYS} | Protection (4) | LVIC Temperature | Hysteresis of Trip Reset | - | 30 | - | °C |
| V _{CFH} | Fault Output Voltage | V _{SC} =0V, V _{CF} Circuit: | | 4.9 | - | - | V |
| V_{CFL} | r dan Garpar Voltago | V _{SC} =1V, V _{CF} Circuit: | : 10kΩ to 5V pull-up | - | - | 0.5 | V |
| V _{CF+} | CF positive going threshold | | | - | 1.9 | 2.2 | V |
| V _{CF} - | CF negative going threshold | | | 0.8 | 1.1 | - | V |
| t _{FO} | Fault Output Pulse Width (5) | | | 20 | - | - | μs |
| I _{IN} | Input Current | V _{IN} =5V | | - | 1.0 | - | mA |
| $V_{th(on)}$ | ON Threshold Voltage | | | | 2.3 | 2.6 | V |
| V _{th(off)} | OFF Threshold Voltage | Applied between IN _(UH) , IN _(VH) , IN _(WH) , IN _(UL) , IN _(UL) , IN _(WL) -COM | | 8.0 | 1.2 | | V |
| $V_{\text{th(hys)}}$ | ON/OFF Threshold Hysteresis Voltage | | | - | 1.1 | - | V |
| $V_{F(BSD)}$ | Bootstrap Diode Forward Voltage | I _F =10mA Including Voltage Drop by Limiting Resistor ⁽⁶⁾ | | 0.5 | 1.0 | 1.5 | V |
| R _{BSD} | Built-in Limiting Resistance | Included in Bootstrap Diode | | 80 | 100 | 120 | Ω |

Notes:

- 2. Short-circuit protection works only for low sides.
- 3. The IPM does not shutdown IGBTs and output fault signal automatically when temperature rises excessively. When temperature exceeds the protective level that the user defined, the controller (MCU) should stop the IPM. Temperature of LVIC vs. V_{OT} output characteristics is described in Figure 3.
- $4. \quad \text{When the LVIC temperature exceeds OT Trip temperature level (OT_T), OT protection is triggered and fault outputs. } \\$
- Fault signal (F_O) outputs when SC, UV or OT protection is triggered. F_O pulse width is different for each protection mode. At SC failure, F_O pulse width is a fixed width (minimum 20μs), but at UV or OT failure, F_O outputs continuously until recovering from UV or OT state. (But minimum F_O pulse width is 20μs).
- 6. The characteristics of bootstrap diodes are described in Figure 2.



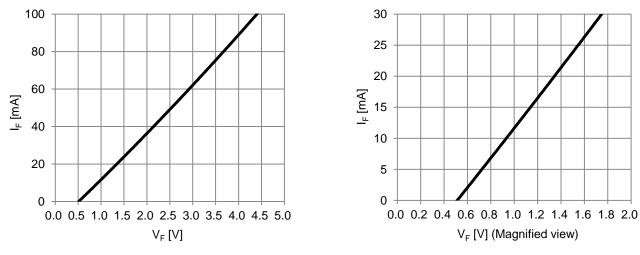


Figure 2. Built-in Bootstrap Diode V_F-I_F Characteristic (@T_A=25°C)

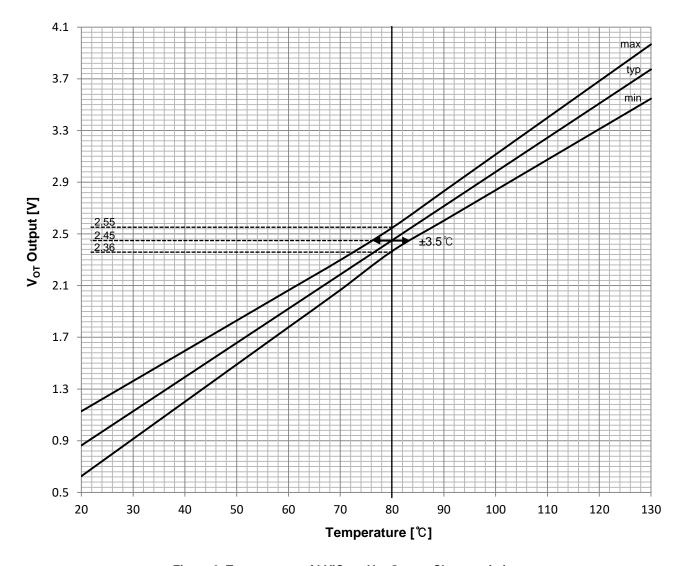


Figure 3. Temperature of LVIC vs. V_{OT} Output Characteristics

Rev.1.1 December 2020 www.aosmd.com Page 5 of 15



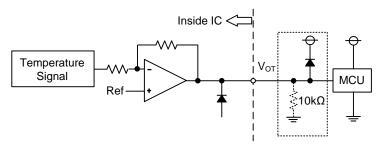


Figure 4. VoT Output Circuit

- If the V_{OT} pin is left unconnected, the internal over-temperature protection function and temperature monitoring function are used simultaneously.
- (2) If pull-down resistor of $10k\Omega$ connected to V_{OT} pin, the temperature monitoring function is only used.
- (3) In the case of using V_{OT} with low voltage controller like 3.3V MCU, V_{OT} output might exceed control supply voltage 3.3V when temperature rises excessively. If system uses low voltage controller, it is recommended to insert a clamp diode between control supply of the controller and V_{OT} output for preventing over voltage destruction.

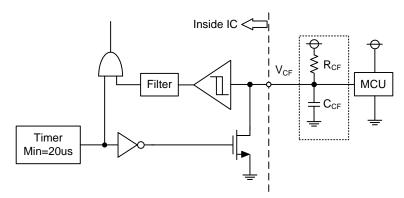


Figure 5. V_{CF} Output Circuit

- (1) The V_{CF} pin provides an enable functionality that allows it to shut down the all low-side IGBTs. When the V_{CF} pin is in the high state the IPM is able to operate normally. If the V_{CF} pin is in a low state, the low-side IGBTs are turned off until the enable condition is restored. In addition, the V_{CF} pin can provide the fault output signal with the fixed or controlled fault out pulse width.
- (2) If only a pull-up resistor of $10k\Omega$ connected to the V_{CF} pin, the fault output pulse width is fixed at minimum 20us.
- (3) If a capacitor is connected with a pull-up resistor together, the fault output pulse width can be controlled according to the resistor and the capacitor values. The length of fault output pulse width is determined by the following formula;
 - $t_{FO} = -(R_{CF} * C_{CF}) * ln(1 V_{CF} + /V_{DD}) + 20us(min.)$
 - ex) $V_{DD}=5V$, $R_{CF}=2.2M\Omega$, $C_{CF}=1nF$, $t_{FO}\approx1.07ms$. Recommended parameters in the design are C_{CF} of $\leq 1nF$ and R_{CF} of 0.1M to 2.2M Ω .

Rev.1.1 December 2020 **www.aosmd.com** Page 6 of 15



Mechanical Characteristics and Ratings

| Symbol | Parameter | Conditions | Min. | Тур. | Max. | Units |
|-----------------|------------------------|------------|------|------|------|-------|
| Mounting Torque | Mounting Screw: M3 (7) | | 0.59 | 0.69 | 0.78 | N m |
| Weight | | | - | 5.25 | - | g |
| Flatness | Refer to Figure 6 | | -50 | 1 | 100 | μm |

Note:

7. Plain washers (ISO 7089-7094) are recommended.

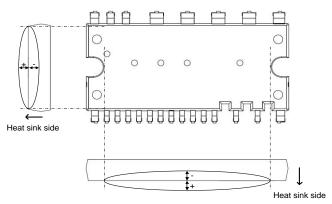


Figure 6. Flatness Measurement Positions

Recommended Operation Conditions

| Symbol | Parameter | Conditions | Min. | Тур. | Max. | Units |
|-----------------------------|------------------------------------|---|------|------|------|-------|
| V_{PN} | Supply Voltage | Applied between P-NU, NV, NW | 0 | 300 | 400 | V |
| V_{DD} | Control Supply Voltage | Applied between V _{DD} -COM | 13.5 | 15.0 | 16.5 | V |
| V_{DB} | High-Side Bias Voltage | Applied between $V_{B(U)}$ -U, $V_{B(V)}$ -V, $V_{B(W)}$ -W | 13.5 | 15.0 | 18.5 | V |
| dV_{DD}/dt , dV_{DB}/dt | Control Supply Variation | | -1 | - | 1 | V/µs |
| t _{dead} | Arm Shoot-Through Blocking Time | For each input signal | 1.0 | - | - | μs |
| f _{PWM} | PWM Input Frequency | -40°C < T _J < 150°C | - | - | 20 | kHz |
| PW _{IN(ON)} | Minimum Input Pulse Width (8) | | 0.5 | - | - | μs |
| PW _{IN(OFF)} | - Minimum Input Pulse Wiath | | 0.5 | - | - | μs |
| СОМ | COM Variation | Between COM-NU, NV, NW (including surge) | -5.0 | - | 5.0 | V |

Note:

8. IPM may not respond if the input pulse width is less than $PW_{IN(ON)}$, $PW_{IN(OFF)}$.

Rev.1.1 December 2020 www.aosmd.com Page 7 of 15



Time Charts of the IPM Protective Function

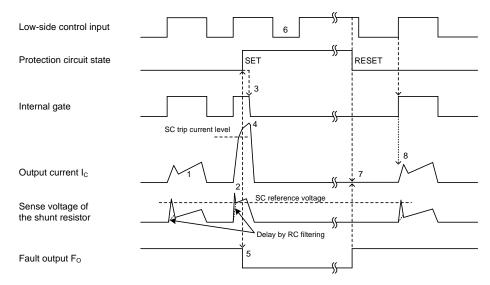


Figure 7. Short-Circuit Protection (Low-side Operation Only with the External Shunt Resistor and RC Filter)

- (1) Normal operation: IGBT turns on and outputs current.
- (2) Short-circuit current detection (SC triggered).
- (3) All low-side IGBTs' gates are hard interrupted.
- (4) All low-side IGBTs turn OFF.
- (5) F_O output time (t_{FO})=minimum 20 μ s.
- (6) Input = "L": IGBT OFF.
- (7) Fault output finishes, but output current will not turn on until next ON signal (L→H).
- (8) Normal operation: IGBT turns on and outputs current.

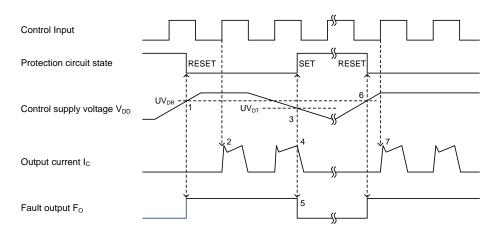


Figure 8. Under-Voltage Protection (Low-side, UV_D)

- (1) Control supply voltage V_{DD} exceeds under voltage reset level (UV_{DR}), but IGBT turns on by next ON signal (L→H).
- (2) Normal operation: IGBT turns on and outputs current.
- (3) V_{DD} level drops to under voltage trip level (UV_{DT}).
- (4) All low-side IGBTs turn OFF regardless of control input condition.
- (5) F_O output time (t_{FO})=minimum 20 μ s, and F_O stays low as long as V_{DD} is below UV_{DR} .
- (6) V_{DD} level reaches UV_{DR} .
- (7) Normal operation: IGBT turns on and outputs current.

Rev.1.1 December 2020 www.aosmd.com Page 8 of 15



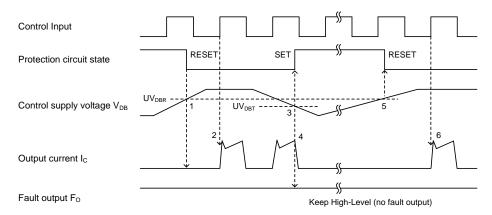


Figure 9. Under-Voltage Protection (High-side, UVDB)

- (1) Control supply voltage V_{DB} rises. After the voltage reaches under voltage reset level UV_{DBR}, IGBT turns on by next ON signal (L→H).
- (2) Normal operation: IGBT turns on and outputs current.
- (3) V_{DB} level drops to under voltage trip level (UV_{DBT}).
- (4) All high-side IGBTs turn OFF regardless of control input condition, but there is no F_0 signal output.
- (5) V_{DB} level reaches UV_{DBR}.
- (6) Normal operation: IGBT turns on and outputs current.

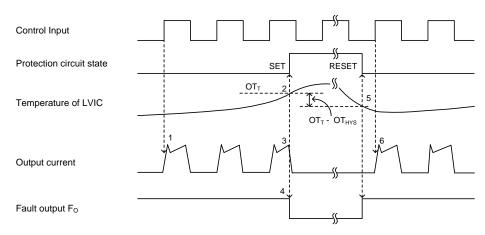


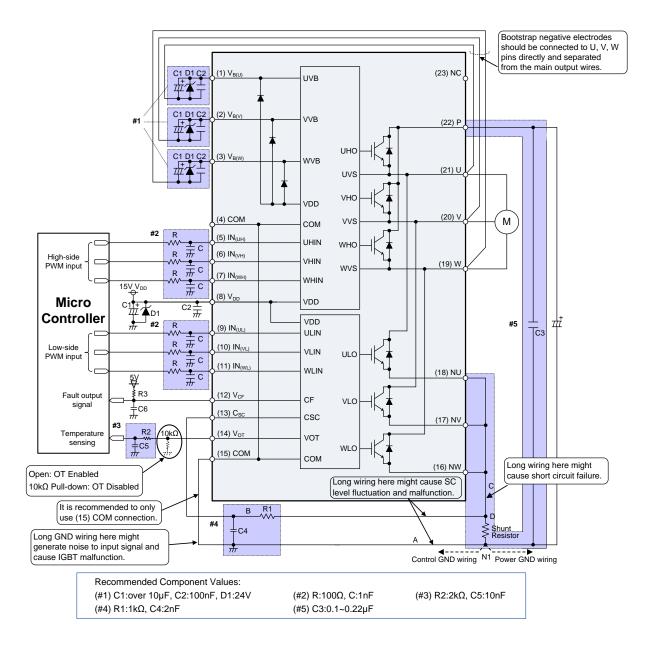
Figure 10. Over-Temperature Protection (Low-side, Detecting LVIC Temperature)

- (1) Normal operation: IGBT turns on and outputs current.
- (2) LVIC temperature exceeds over-temperature trip level (OT_T).
- (3) All low-side IGBTs turn off regardless of control input condition.
- (4) F_O output time (t_{FO})=minimum 20µs, and F_O stays low as long as LVIC temperature is over OT_T.
- (5) LVIC temperature drops to over-temperature reset level (OT_T - OT_{HYS}).
- (6) Normal operation: IGBT turns on by the next ON signal ($L\rightarrow H$).

Rev.1.1 December 2020 **www.aosmd.com** Page 9 of 15



Example of Application Circuit



- (1) If the control GND is connected with the power GND by common broad pattern, it may cause malfunction by power GND fluctuation. It is recommended to connect the control GND and power GND at a single point (N1), near the terminal of the shunt resistor.
- (2) There are two COM pins in the IPM but it is recommended to only use the (15) COM pin to minimize SC detection noise.
- (3) A zener diode D1 (24V/1W) is recommended between each pair of control supply pins to prevent surge destruction.
- (4) Prevention of surge destruction can further be improved by placing the bus capacitor as close to pin P and N1 as possible. Generally a 0.1-0.22μF snubber capacitor C3 between the P-N1 terminals is recommended.
- (5) Selection of the R1*C4 filter components for short-circuit protection is recommended to have tight tolerance, and is temperature-compensated type. The R1*C4 time constant should be set such that SC current is shut down within 2μs; (typically 1.5-2μs). R1 and C4 should be placed as close as possible to the C_{SC} pin. SC interrupting time may vary with layout patterns and components selection, therefore thorough evaluation in the system is necessary.
- (6) Tight tolerance and temperature-compensated components are also recommended when selecting the R2*C5 filter for V_{oT}. The R2*C5 time constant should be set such that V_{oT} is immune to noise. Recommended values of R2 and C5 are 2kΩ and 10nF.
- (7) To prevent malfunction, traces A, B, and C should be as short as possible.
- (8) It is recommended that all capacitors are mounted as close to the IPM as possible. (C1: electrolytic type with good temperature and frequency characteristics. C2: ceramic type with 0.1-2µF, good temperature, frequency and DC bias characteristics.)

Rev.1.1 December 2020 www.aosmd.com Page 10 of 15



AIP5D10K060Q4 / AIP5D10K060Q4S / AIP5D10K060Q4U

- (9) Input drives are active-high. There is a minimum 3.5kΩ pull-down resistor in the input circuit of IC. To prevent malfunction, the layout to each input should be as short as possible. When using RC coupling circuit, make sure the input signal levels meet the required turn-on and turn-off threshold voltages.
- (10) V_{CF} output is open drain type. It should be pulled up to MCU or control power supply (max= 5±0.5V), limiting the current (I_{CF}) to no more than 1mA. I_{CF} is estimated roughly by the formula of control power supply voltage divided by the pull-up resistor R3. For example, if control supply is 5V, a $10k\Omega$ (over $5k\Omega$) pull-up resistor R3 is recommended.
- (11) If only a pull-up resistor R3 of 10kΩ connected to V_{CF} pin, the fault output pulse width is fixed at minimum 20us. If a capacitor C6 is connected with a pull-up resistor R3, the fault output pulse width can be controlled according to the resistor value and capacitor value. For the design guide, please refer to the Figure 5.
- (12) Direct drive of the IPM from the MCU is possible without having to use opto-coupler or isolation transformer.
- (13) The IPM may malfunction and erroneous operations may occur if high frequency noise is superimposed to the supply line. To avoid such problems, line ripple voltage is recommended to have dV/dt ≤ ±1V/µs, and Vripple ≤2Vp-p.
- (14) It is not recommended to use the IPM to drive the same load in parallel with another IPM or inverter types.

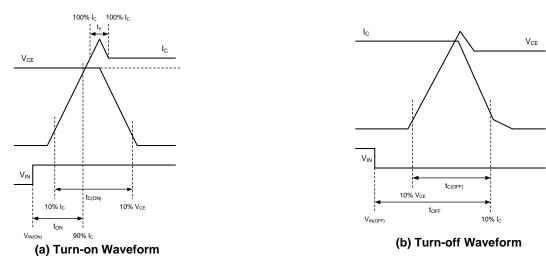
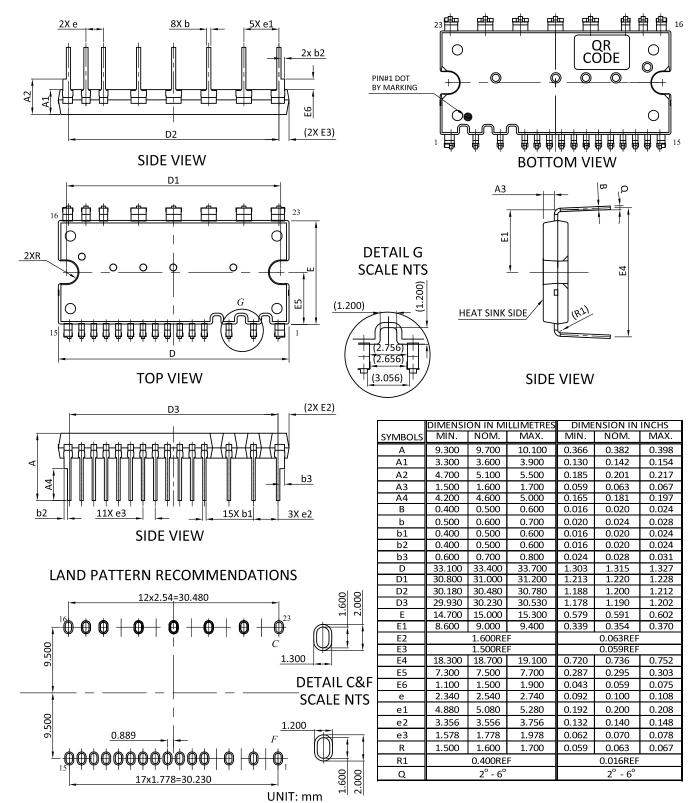


Figure 11. Switching Times Definition

Rev.1.1 December 2020 www.aosmd.com Page 11 of 15



Package Dimensions, IPM-5



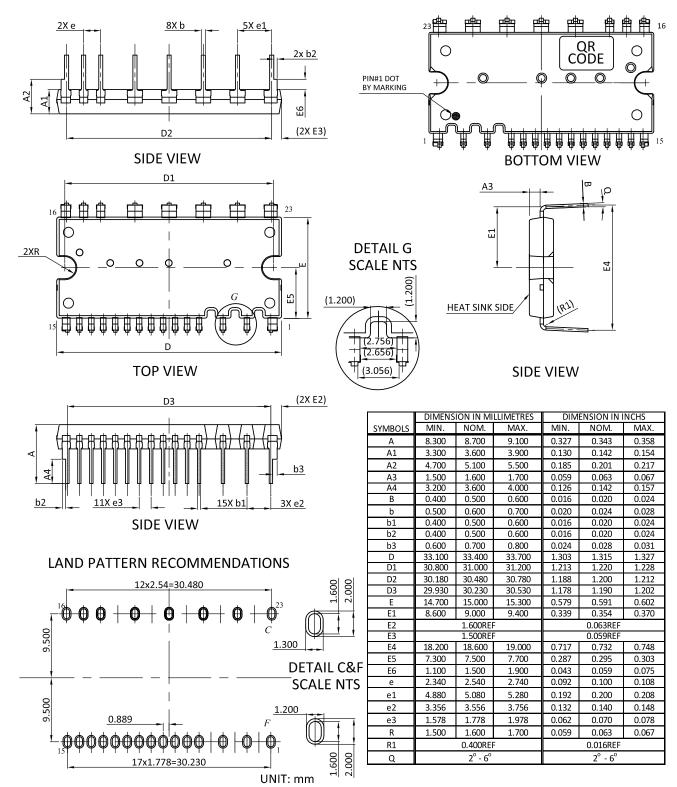
NOTES

- 1. PACKAGE BODY SIZES EXCLUDE MOLD FLASH AND GATE BURRS, MOLD FLASH SHOULD BE LESS THAN 6 MIL.
- 2. TOLERANCE 0.100 MILLIMETERS UNLESS OTHERWISE SPECIFIED.
- 3. CONTROLLING DIMENSION IS MILLIMETER, CONVERTED INCH DIMENSIONS ARE NOT NECESSARILY EXACT.

4. () IS REFERENCE.



Package Dimensions, IPM-5A



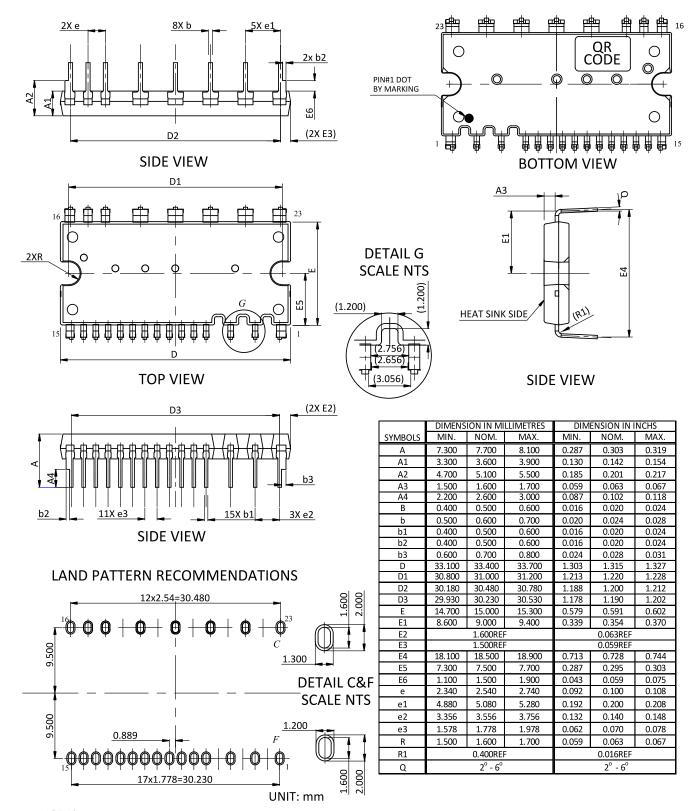
NOTES

- 1. PACKAGE BODY SIZES EXCLUDE MOLD FLASH AND GATE BURRS, MOLD FLASH SHOULD BE LESS THAN 6 MIL.
- 2. TOLERANCE 0.100 MILLIMETERS UNLESS OTHERWISE SPECIFIED.
- 3. CONTROLLING DIMENSION IS MILLIMETER, CONVERTED INCH DIMENSIONS ARE NOT NECESSARILY EXACT.

4. () IS REFERENCE.



Package Dimensions, IPM-5C



NOTES

- 1. PACKAGE BODY SIZES EXCLUDE MOLD FLASH AND GATE BURRS, MOLD FLASH SHOULD BE LESS THAN 6 MIL.
- 2. TOLERANCE 0.100 MILLIMETERS UNLESS OTHERWISE SPECIFIED.
- 3. CONTROLLING DIMENSION IS MILLIMETER, CONVERTED INCH DIMENSIONS ARE NOT NECESSARILY EXACT.

4. () IS REFERENCE.



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.

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

LIFE SUPPORT POLICY

ALPHA & 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.