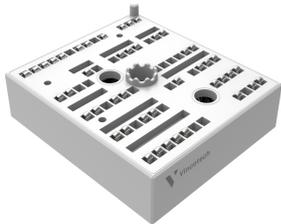
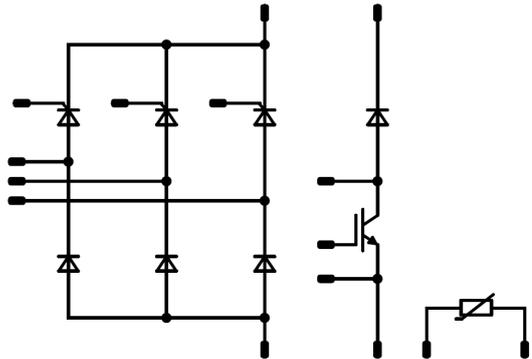




MiniSKiiP® CON 2	1600 V / 75 A
<p data-bbox="375 443 475 470">Features</p> <ul data-bbox="135 499 694 600" style="list-style-type: none">• Three-phase half controlled input rectifier with brake chopper• M7 IGBT and diode in the brake chopper• Integrated NTC	<p data-bbox="986 443 1305 470">MiniSKiiP® 2 16 mm housing</p> 
<p data-bbox="316 864 539 891">Target applications</p> <ul data-bbox="135 913 300 940" style="list-style-type: none">• Industrial Drives	<p data-bbox="1086 831 1209 857">Schematic</p> 
<p data-bbox="391 992 459 1019">Types</p> <ul data-bbox="135 1041 411 1068" style="list-style-type: none">• 80-M2166BA075AS-K369G71	



Vincotech

Maximum Ratings

$T_j = 25\text{ °C}$, unless otherwise specified

Parameter	Symbol	Conditions	Value	Unit
Brake Switch				
Collector-emitter voltage	V_{CES}		1200	V
Collector current	I_C	$T_j = T_{jmax}$ $T_s = 80\text{ °C}$	119	A
Repetitive peak collector current	I_{CRM}	t_p limited by T_{jmax}	200	A
Total power dissipation	P_{tot}	$T_j = T_{jmax}$ $T_s = 80\text{ °C}$	240	W
Gate-emitter voltage	V_{GES}		± 20	V
Short circuit ratings	i_{SC}	$V_{GE} = 15\text{ V}$, $V_{CC} = 800\text{ V}$ $T_j = 150\text{ °C}$	9,5	μs
Maximum junction temperature	T_{jmax}		175	$^{\circ}\text{C}$

Brake Diode

Peak repetitive reverse voltage	V_{RRM}		1200	V
Continuous (direct) forward current	I_F	$T_j = T_{jmax}$ $T_s = 80\text{ °C}$	83	A
Repetitive peak forward current	I_{FRM}	t_p limited by T_{jmax}	200	A
Total power dissipation	P_{tot}	$T_j = T_{jmax}$ $T_s = 80\text{ °C}$	149	W
Maximum junction temperature	T_{jmax}		175	$^{\circ}\text{C}$

Rectifier Thyristor

Repetitive peak reverse voltage	V_{RRM}		1600	V
Forward average current	I_{FAV}	$T_j = T_{jmax}$ $T_s = 80\text{ °C}$	150	A
Surge forward current	I_{FSM}	Single Half Sine Wave, $t_p = 10\text{ ms}$ $T_j = 130\text{ °C}$	1250	A
I2t value	I^2t	Single Half Sine Wave, $t_p = 10\text{ ms}$ $T_j = 130\text{ °C}$	7810	A^2s
Mean total power loss	$P_{tot(AV)}$	$T_j = T_{jmax}$ $T_s = 80\text{ °C}$	168	W
Maximum Junction Temperature	T_{jmax}		130	$^{\circ}\text{C}$

**Maximum Ratings** $T_j = 25\text{ °C}$, unless otherwise specified

Parameter	Symbol	Conditions	Value	Unit
Rectifier Diode				
Peak repetitive reverse voltage	V_{RRM}		1600	V
Forward average current	I_{FAV}	$T_j = T_{jmax}$ $T_s = 80\text{ °C}$	85	A
Surge (non-repetitive) forward current	I_{FSM}	Single Half Sine Wave, $t_p = 10\text{ ms}$ $T_j = 150\text{ °C}$	890	A
Surge current capability	I^2t		3960	A ² s
Total power dissipation	P_{tot}	$T_j = T_{jmax}$ $T_s = 80\text{ °C}$	119	W
Maximum junction temperature	T_{jmax}		150	°C

Module Properties**Thermal Properties**

Storage temperature	T_{stg}		-40...+125	°C
Operation temperature under switching condition	T_{jop}		-40...+($T_{jmax} - 25$)	°C

Isolation Properties

Isolation voltage	V_{isol}	DC Test Voltage* $t_p = 2\text{ s}$	5500	V
Creepage distance		With std lid For more informations see handling instructions	6,3	mm
Clearance		With std lid For more informations see handling instructions	6,3	mm
Comparative Tracking Index	CTI		≥ 600	

*100 % tested in production



Vincotech

Characteristic Values

Parameter	Symbol	Conditions					Values			Unit
		V_{GE} [V] V_{GS} [V]	V_{CE} [V] V_{DS} [V] V_F [V]	I_C [A] I_D [A] I_F [A]	T_j [°C]	Min	Typ	Max		

Brake Switch

Static

Gate-emitter threshold voltage	$V_{GE(th)}$		10	0,01	25	5,4	6	6,6	V
Collector-emitter saturation voltage	$V_{CE(sat)}$	15		100	25 125 150		1,53 1,7 1,75	1,85 ⁽¹⁾	V
Collector-emitter cut-off current	I_{CES}	0	1200		25			100	μA
Gate-emitter leakage current	I_{GES}	20	0		25			0,5	μA
Internal gate resistance	r_g						None		Ω
Input capacitance	C_{ies}						21000		pF
Output capacitance	C_{oes}	0	10		25		700		pF
Reverse transfer capacitance	C_{res}						280		pF
Gate charge	Q_g	$V_{CC} = 600$ V	15		100	25	700		nC

Thermal

Thermal resistance junction to sink ⁽²⁾	$R_{th(j-s)}$	$\lambda_{paste} = 2,5$ W/mK (HPTP)					0,4		K/W
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Dynamic

Turn-on delay time	$t_{d(on)}$					25 125 150		165 157 157	ns
Rise time	t_r	$R_{gon} = 8$ Ω $R_{goff} = 8$ Ω				25 125 150		91 102 100	ns
Turn-off delay time	$t_{d(off)}$		0/15	600	100	25 125 150		485 521 533	ns
Fall time	t_f					25 125 150		49,22 95,43 100,22	ns
Turn-on energy (per pulse)	E_{on}	$Q_{tFWD} = 7,88$ μC $Q_{tFWD} = 13,45$ μC $Q_{tFWD} = 15,58$ μC				25 125 150		13,9 17,69 18,13	mWs
Turn-off energy (per pulse)	E_{off}					25 125 150		5,99 8,31 8,78	mWs



Vincotech

80-M2166BA075AS-K369G71
datasheet

Characteristic Values

Parameter	Symbol	Conditions					Values			Unit
		V_{GE} [V] V_{GS} [V]	V_{CE} [V] V_{DS} [V] V_F [V]	I_C [A] I_D [A] I_F [A]	T_j [°C]	Min	Typ	Max		
Brake Diode										
Static										
Forward voltage	V_F			100	25 125 150		1,82 1,96 1,96	2,1 ⁽¹⁾		V
Reverse leakage current	I_R	$V_T = 1200$ V			25			40		μA
Thermal										
Thermal resistance junction to sink ⁽²⁾	$R_{th(j-s)}$	$\lambda_{paste} = 2,5$ W/mK (HPTP)					0,64			K/W
Dynamic										
Peak recovery current	I_{RRM}	$di/dt=652$ A/μs $di/dt=808$ A/μs $di/dt=707$ A/μs	0/15	600	100	25		38,03		A
Reverse recovery time	t_{rr}					125		48,61		
						150		50,56		
						25		341,78		
Recovered charge	Q_r					125		519,83		
						150		568,44		
		25		7,88						
Reverse recovered energy	E_{rec}	125		13,45						
		150		15,58						
		25		2,31						
Peak rate of fall of recovery current	$(di_r/dt)_{max}$	125		4,42						
		150		5,24						
		25		274,74						
						125		169,52		A/μs
						150		155,74		



Vincotech

80-M2166BA075AS-K369G71
datasheet

Characteristic Values

Parameter	Symbol	Conditions					Values			Unit
		V_{GE} [V] V_{GS} [V]	V_{CE} [V] V_{DS} [V] V_F [V]	I_C [A] I_D [A] I_F [A]	T_j [°C]	Min	Typ	Max		

Rectifier Thyristor

Static

Forward voltage	V_F				110	25 125		1,09 1,02	1,5 ⁽¹⁾	V
Reverse blocking current	I_R	$V_i = 1600$ V				25			200	μA
Holding current	I_H					25			220	mA
Latching current	I_L	$t_p = \mu s$ $I_G = A$ $dI_{Gd}/dt = A/\mu s$				25			550	mA
Gate trigger voltage	V_{GT}					25			1,98	V
Gate trigger current	I_{GT}					25			100	mA

Thermal

Thermal resistance junction to sink ⁽²⁾	$R_{th(j-s)}$	$\lambda_{paste} = 2,5$ W/mK (HPTP)						0,3		K/W
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Rectifier Diode

Static

Forward voltage	V_F				60	25 125 150		1,04 0,972 0,956	1,5 ⁽¹⁾	V
Reverse leakage current	I_R	$V_i = 1600$ V				25 150			100 2	μA

Thermal

Thermal resistance junction to sink ⁽²⁾	$R_{th(j-s)}$	$\lambda_{paste} = 2,5$ W/mK (HPTP)						0,59		K/W
--	---------------	-------------------------------------	--	--	--	--	--	------	--	-----



Vincotech

Characteristic Values

Parameter	Symbol	Conditions					Values			Unit
		V_{GS} [V]	V_{GE} [V]	V_{DS} [V]	V_{CE} [V]	T_j [°C]	Min	Typ	Max	

Thermistor

Static

Rated resistance	R					25		1		kΩ
Deviation of R_{100}	$A_{R/R}$	$R_{100} = 1670 \Omega$				100	-2		2	%
Maximum Current	I_{max}							3		mA
Power dissipation constant	d					25		0,76		mW/K
A-value	A							$7,635 \times 10^{-3}$		1/K
B-value	B							$1,73 \times 10^{-5}$		1/K ²
Vincotech Thermistor Reference									E	

⁽¹⁾ Value at chip level

⁽²⁾ Only valid with pre-applied Vincotech thermal interface material.



Brake Switch Characteristics

figure 1. IGBT

Typical output characteristics
 $I_C = f(V_{CE})$

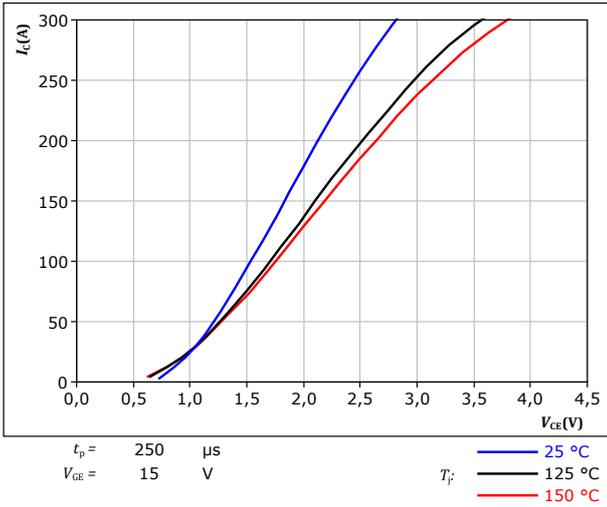


figure 2. IGBT

Typical output characteristics
 $I_C = f(V_{CE})$

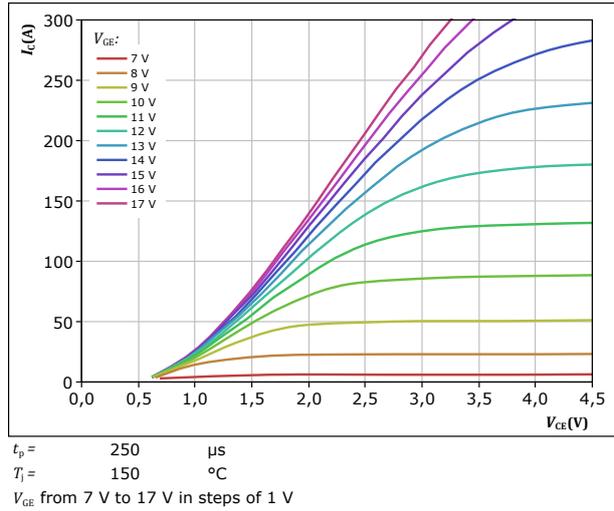


figure 3. IGBT

Typical transfer characteristics
 $I_C = f(V_{GE})$

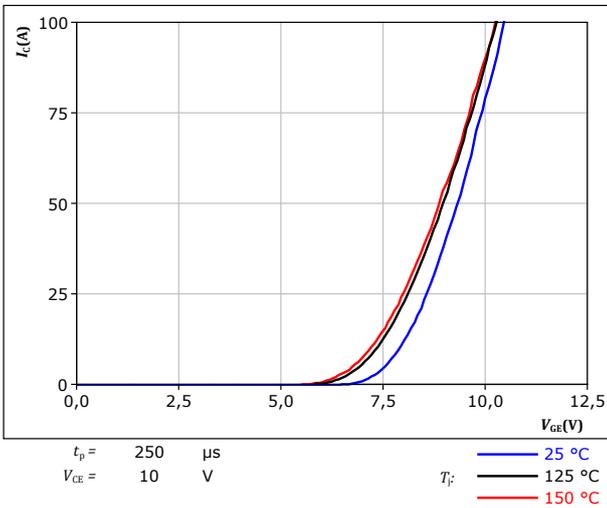
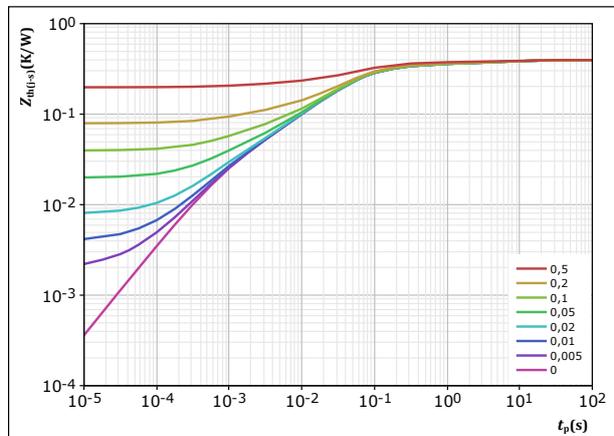


figure 4. IGBT

Transient thermal impedance as a function of pulse width
 $Z_{th(j-s)} = f(t_p)$



$D = t_p / T$
 $R_{th(j-s)} = 0,396 \text{ K/W}$

IGBT thermal model values

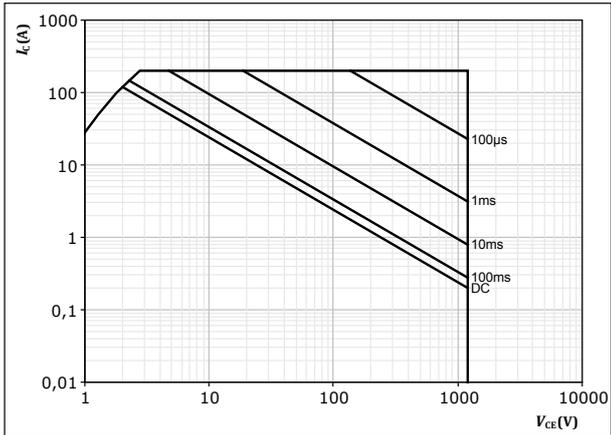
R (K/W)	τ (s)
3,69E-02	7,70E+00
4,21E-02	4,31E-01
1,87E-01	6,42E-02
8,56E-02	2,35E-02
2,75E-02	3,81E-03
1,70E-02	7,57E-04



Brake Switch Characteristics

figure 5. IGBT

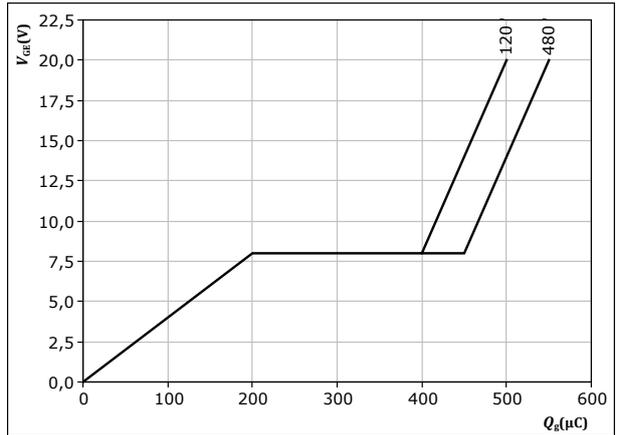
Safe operating area
 $I_C = f(V_{CE})$



$D =$ single pulse
 $T_s = 80$ °C
 $V_{GE} = 15$ V
 $T_j = T_{jmax}$

figure 6. IGBT

Gate voltage vs gate charge
 $V_{GE} = f(Q_g)$



At $I_C = 100$ A



Brake Diode Characteristics

figure 7. FWD

Typical forward characteristics

$$I_F = f(V_F)$$

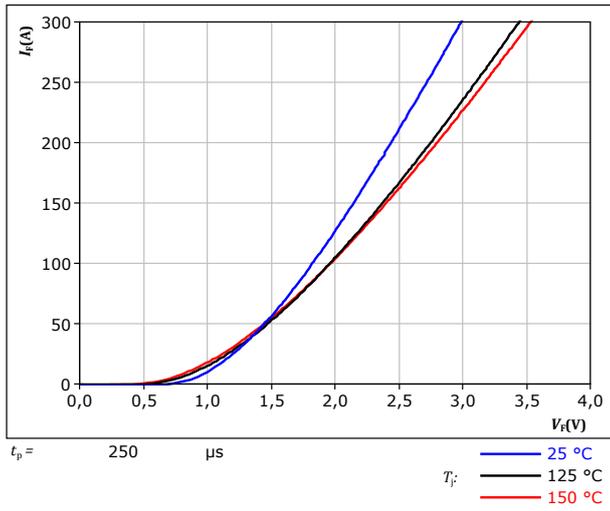
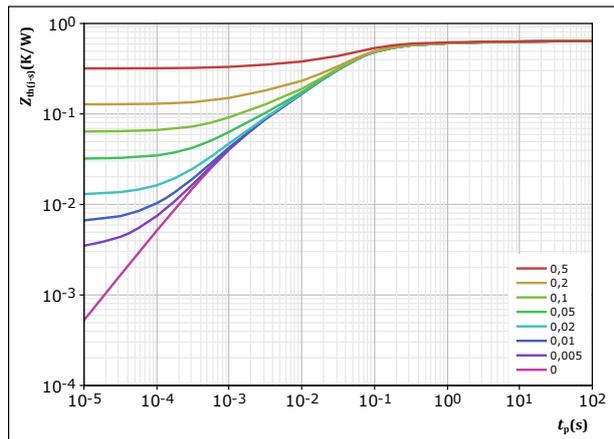


figure 8. FWD

Transient thermal impedance as a function of pulse width

$$Z_{th(j-s)} = f(t_p)$$



$D = \frac{t_p}{T}$
 $R_{th(j-s)} = 0,638 \text{ K/W}$
 FWD thermal model values

R (K/W)	τ (s)
2,37E-02	8,76E+00
4,45E-02	7,46E-01
1,18E-01	1,33E-01
3,42E-01	4,45E-02
6,37E-02	8,66E-03
4,28E-02	1,33E-03
2,95E-03	6,42E-04



Rectifier Thyristor Characteristics

figure 9. Thyristor

Typical forward characteristics

$$I_F = f(V_F)$$

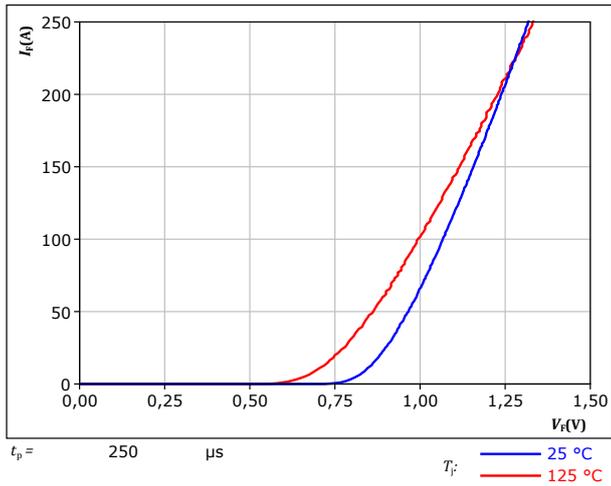
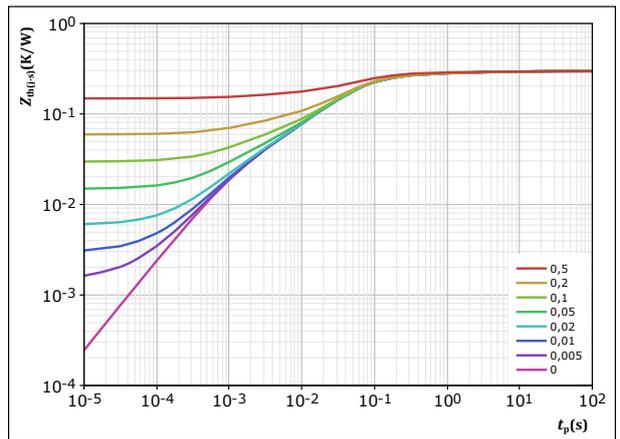


figure 10. Thyristor

Transient thermal impedance as a function of pulse width

$$Z_{th(j-s)} = f(t_p)$$



$$D = \frac{t_p}{T}$$

$$R_{th(j-s)} = 0,297 \text{ K/W}$$

Thyristor thermal model values

R (K/W)	τ (s)
1,11E-02	8,76E+00
2,07E-02	7,46E-01
5,50E-02	1,33E-01
1,59E-01	4,45E-02
2,97E-02	8,66E-03
1,99E-02	1,33E-03
1,37E-03	6,42E-04



Rectifier Diode Characteristics

figure 11. Rectifier

Typical forward characteristics

$$I_F = f(V_F)$$

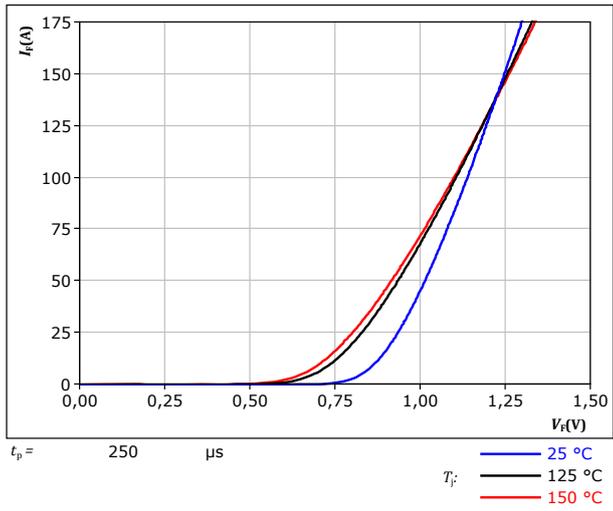
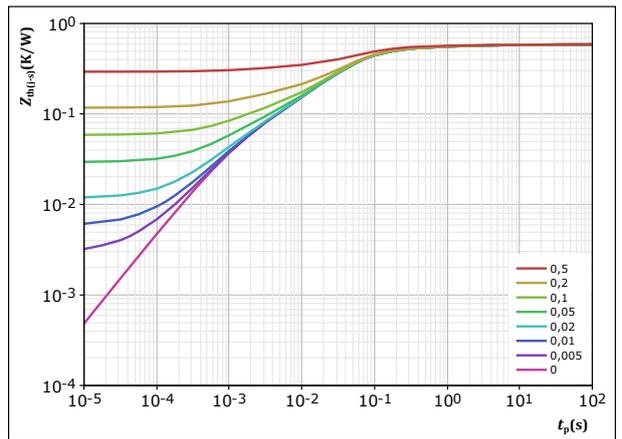


figure 12. Rectifier

Transient thermal impedance as a function of pulse width

$$Z_{th(j-s)} = f(t_p)$$



$D = \frac{t_p}{T}$
 $R_{th(j-s)} = 0,586 \text{ K/W}$

Rectifier thermal model values

R (K/W)	τ (s)
2,18E-02	8,76E+00
4,09E-02	7,46E-01
1,08E-01	1,33E-01
3,14E-01	4,45E-02
5,85E-02	8,66E-03
3,93E-02	1,33E-03
2,71E-03	6,42E-04

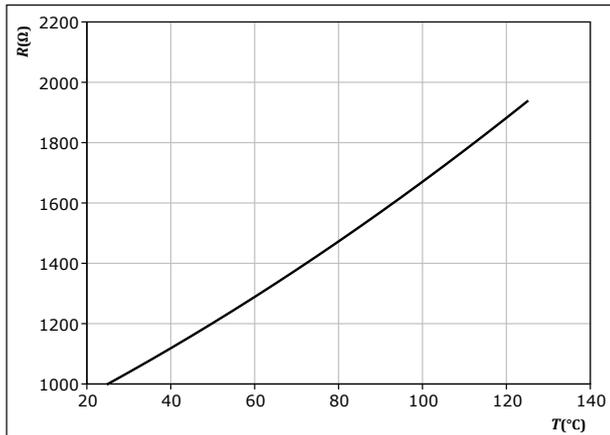


Thermistor Characteristics

figure 13. Thermistor

Typical PTC characteristic as function of temperature

$$R_T = f(T)$$

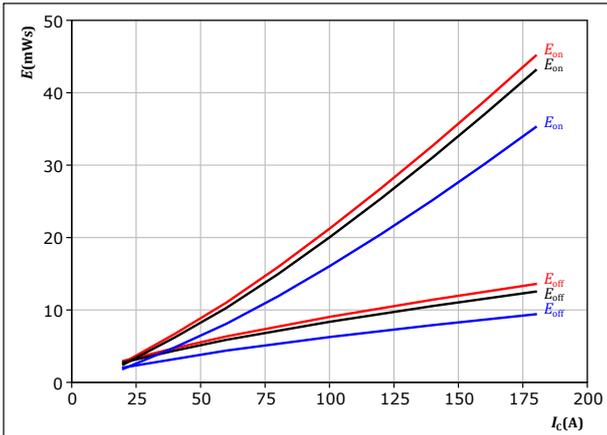




Brake Switching Characteristics

figure 14. IGBT

Typical switching energy losses as a function of collector current
 $E = f(I_c)$

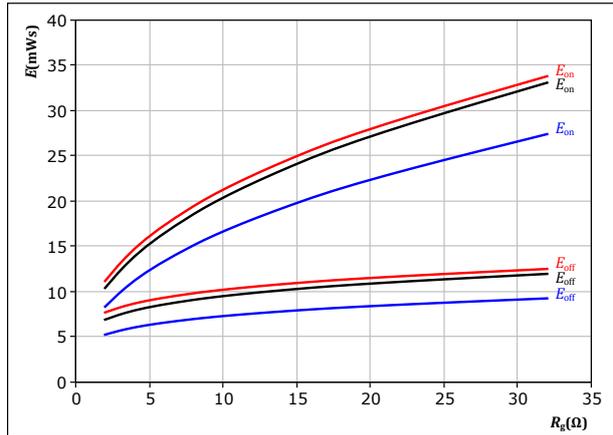


With an inductive load at

$V_{CE} = 600$ V	$T_j = 25$ °C
$V_{GE} = 0/15$ V	$T_j = 125$ °C
$R_{g(on)} = 8$ Ω	$T_j = 150$ °C
$R_{g(off)} = 8$ Ω	

figure 15. IGBT

Typical switching energy losses as a function of gate resistor
 $E = f(R_g)$

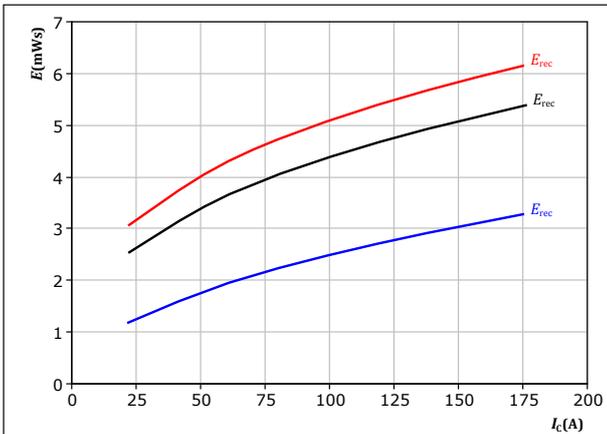


With an inductive load at

$V_{CE} = 600$ V	$T_j = 25$ °C
$V_{GE} = 0/15$ V	$T_j = 125$ °C
$I_c = 100$ A	$T_j = 150$ °C

figure 16. FWD

Typical reverse recovered energy loss as a function of collector current
 $E_{rec} = f(I_c)$

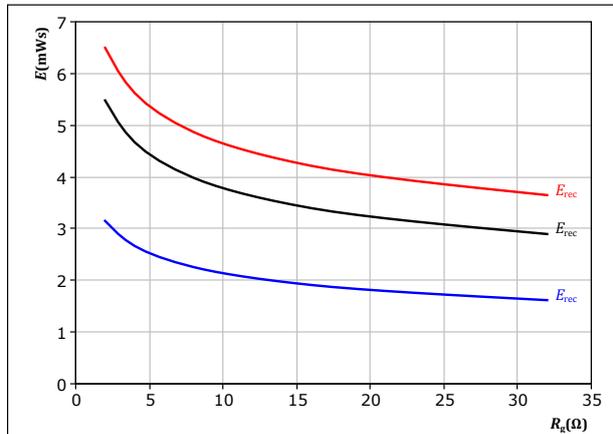


With an inductive load at

$V_{CE} = 600$ V	$T_j = 25$ °C
$V_{GE} = 0/15$ V	$T_j = 125$ °C
$R_{g(on)} = 8$ Ω	$T_j = 150$ °C

figure 17. FWD

Typical reverse recovered energy loss as a function of gate resistor
 $E_{rec} = f(R_g)$



With an inductive load at

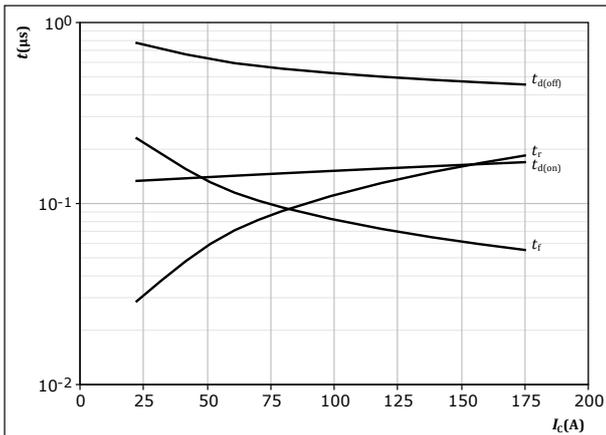
$V_{CE} = 600$ V	$T_j = 25$ °C
$V_{GE} = 0/15$ V	$T_j = 125$ °C
$I_c = 100$ A	$T_j = 150$ °C



Brake Switching Characteristics

figure 18. IGBT

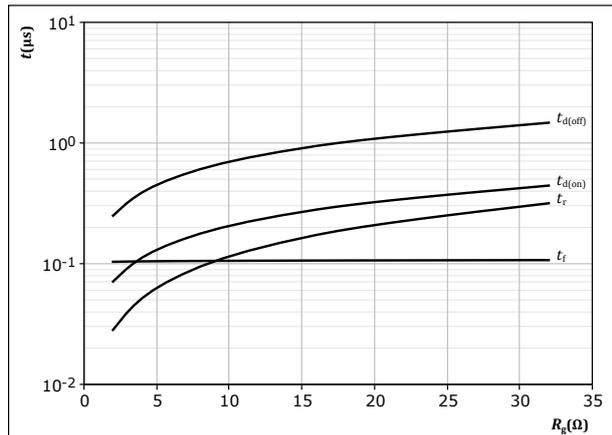
Typical switching times as a function of collector current
 $t = f(I_c)$



With an inductive load at
 $T_j = 150 \text{ }^\circ\text{C}$
 $V_{CE} = 600 \text{ V}$
 $V_{GE} = 0/15 \text{ V}$
 $R_{gon} = 8 \text{ } \Omega$
 $R_{goff} = 8 \text{ } \Omega$

figure 19. IGBT

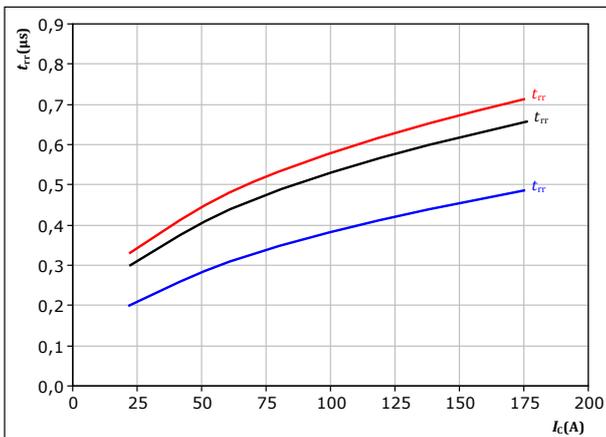
Typical switching times as a function of gate resistor
 $t = f(R_g)$



With an inductive load at
 $T_j = 150 \text{ }^\circ\text{C}$
 $V_{CE} = 600 \text{ V}$
 $V_{GE} = 0/15 \text{ V}$
 $I_c = 100 \text{ A}$

figure 20. FWD

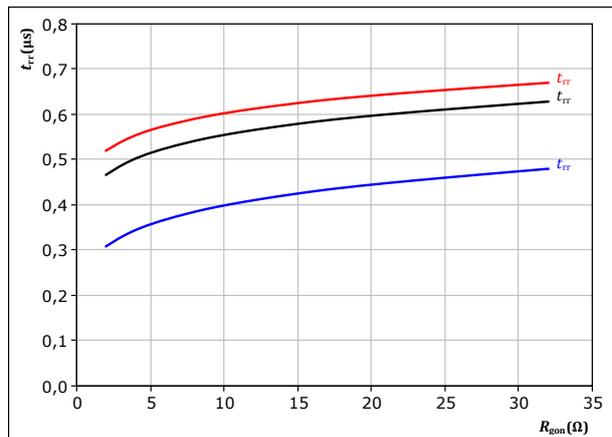
Typical reverse recovery time as a function of collector current
 $t_{rr} = f(I_c)$



With an inductive load at
 $V_{CE} = 600 \text{ V}$
 $V_{GE} = 0/15 \text{ V}$
 $R_{gon} = 8 \text{ } \Omega$
 $T_j:$ — 25 °C
 — 125 °C
 — 150 °C

figure 21. FWD

Typical reverse recovery time as a function of IGBT turn on gate resistor
 $t_{rr} = f(R_{gon})$



With an inductive load at
 $V_{CE} = 600 \text{ V}$
 $V_{GE} = 0/15 \text{ V}$
 $I_c = 100 \text{ A}$
 $T_j:$ — 25 °C
 — 125 °C
 — 150 °C

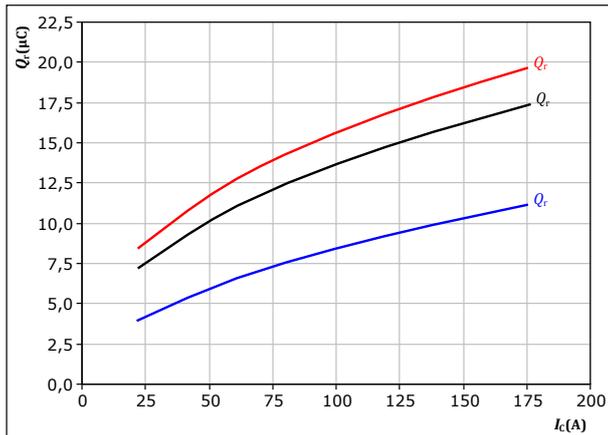


Brake Switching Characteristics

figure 22. FWD

Typical recovered charge as a function of collector current

$$Q_r = f(I_c)$$



With an inductive load at

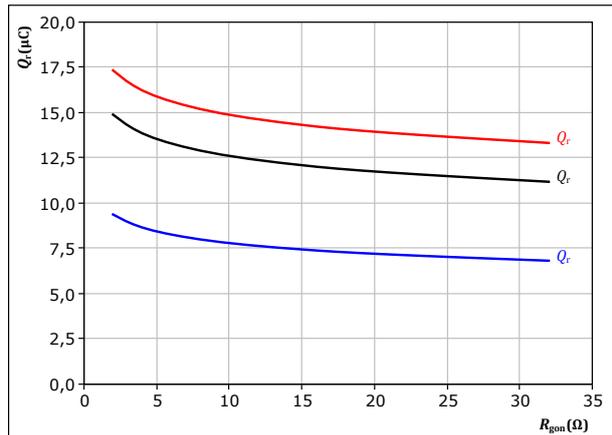
$V_{CE} = 600$ V
 $V_{GE} = 0/15$ V
 $R_{gon} = 8$ Ω

T_j : — 25 °C
— 125 °C
— 150 °C

figure 23. FWD

Typical recovered charge as a function of turn on gate resistor

$$Q_r = f(R_{gon})$$



With an inductive load at

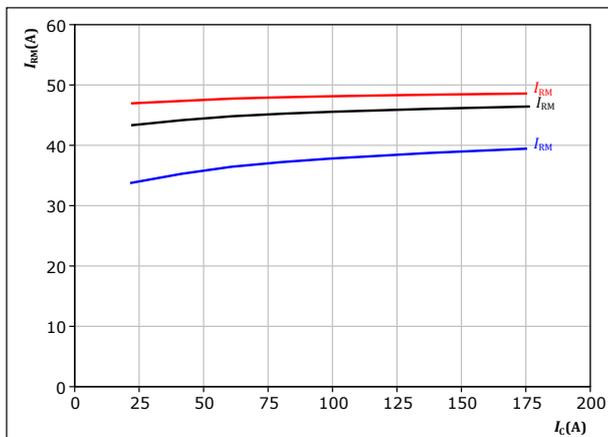
$V_{CE} = 600$ V
 $V_{GE} = 0/15$ V
 $I_c = 100$ A

T_j : — 25 °C
— 125 °C
— 150 °C

figure 24. FWD

Typical peak reverse recovery current as a function of collector current

$$I_{RM} = f(I_c)$$



With an inductive load at

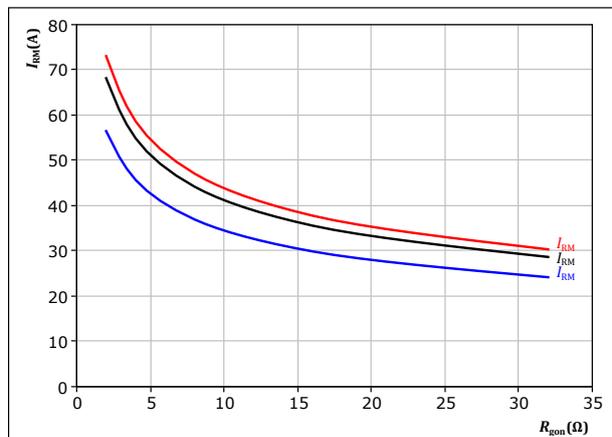
$V_{CE} = 600$ V
 $V_{GE} = 0/15$ V
 $R_{gon} = 8$ Ω

T_j : — 25 °C
— 125 °C
— 150 °C

figure 25. FWD

Typical peak reverse recovery current as a function of turn on gate resistor

$$I_{RM} = f(R_{gon})$$



With an inductive load at

$V_{CE} = 600$ V
 $V_{GE} = 0/15$ V
 $I_c = 100$ A

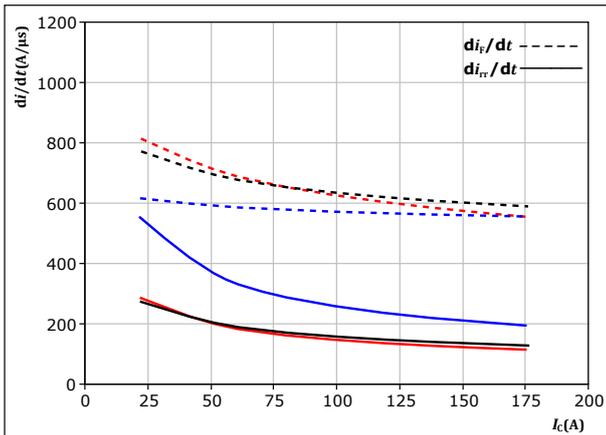
T_j : — 25 °C
— 125 °C
— 150 °C



Brake Switching Characteristics

figure 26. FWD

Typical rate of fall of forward and reverse recovery current as a function of collector current
 $di_f/dt, di_{rr}/dt = f(I_C)$



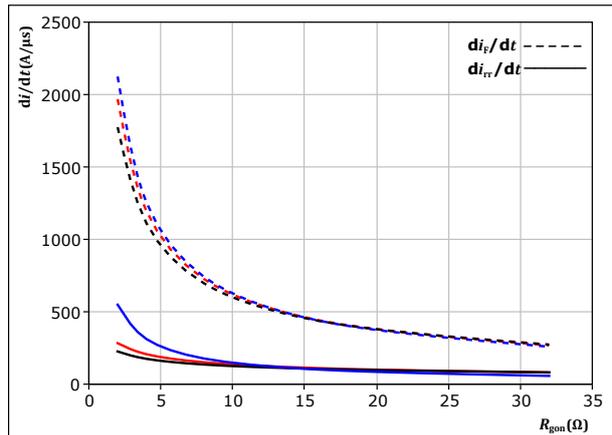
With an inductive load at

$V_{CE} = 600$ V
 $V_{GE} = 0/15$ V
 $R_{gon} = 8$ Ω

$T_j =$ 25 °C
 125 °C
 150 °C

figure 27. FWD

Typical rate of fall of forward and reverse recovery current as a function of turn on gate resistor
 $di_f/dt, di_{rr}/dt = f(R_{gon})$



With an inductive load at

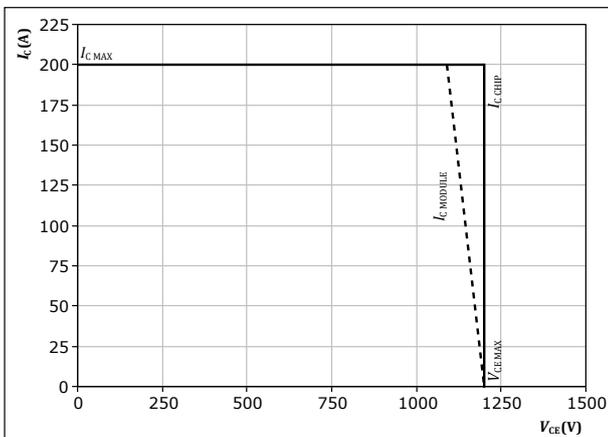
$V_{CE} = 600$ V
 $V_{GE} = 0/15$ V
 $I_C = 100$ A

$T_j =$ 25 °C
 125 °C
 150 °C

figure 28. IGBT

Reverse bias safe operating area

$I_C = f(V_{CE})$



At $T_j = 150$ °C
 $R_{gon} = 8$ Ω
 $R_{goff} = 8$ Ω



Brake Switching Definitions

figure 29. IGBT

Turn-off Switching Waveforms & definition of t_{doff} , t_{Eoff} (t_{Eoff} = integrating time for E_{off})

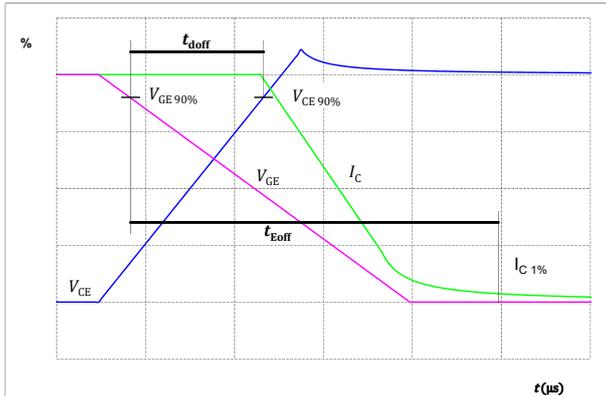


figure 30. IGBT

Turn-on Switching Waveforms & definition of t_{don} , t_{Eon} (t_{Eon} = integrating time for E_{on})

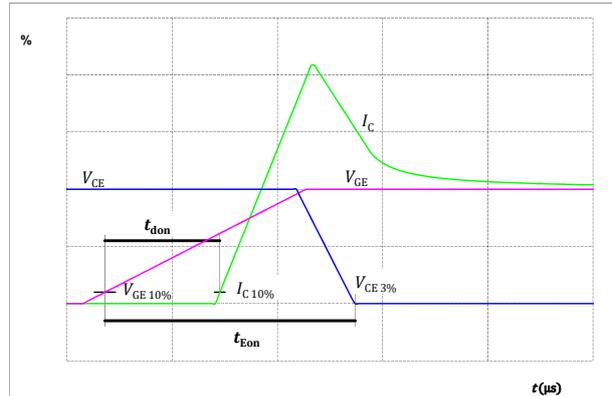


figure 31. IGBT

Turn-off Switching Waveforms & definition of t_f

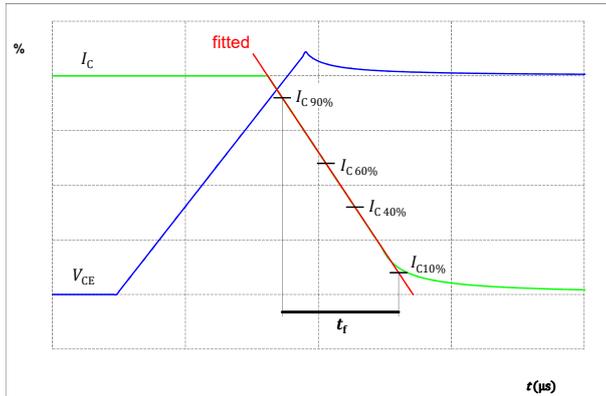
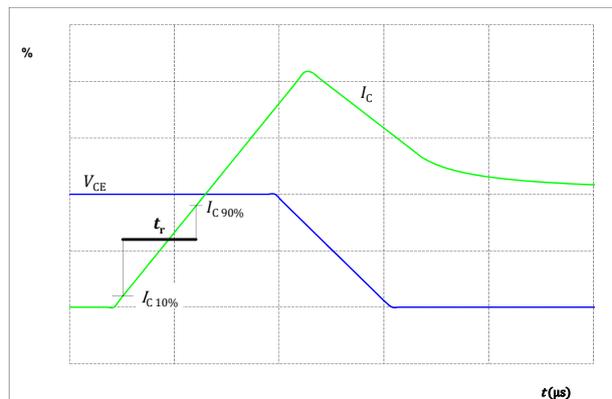


figure 32. IGBT

Turn-on Switching Waveforms & definition of t_r





Brake Switching Definitions

figure 33. FWD

Turn-off Switching Waveforms & definition of t_{rr}

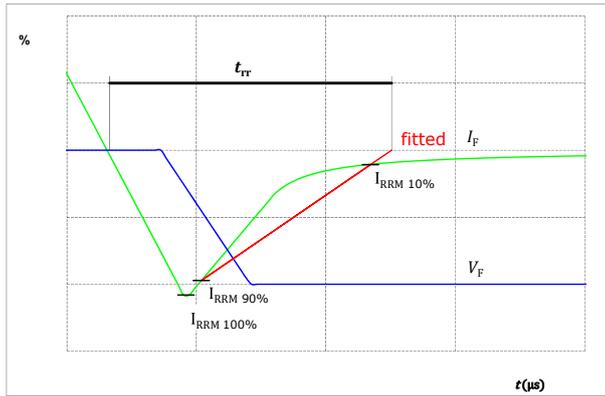
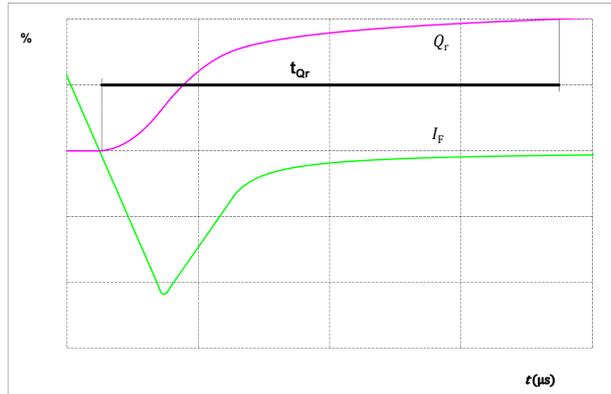


figure 34. FWD

Turn-on Switching Waveforms & definition of t_{Qr} (t_{Qr} = integrating time for Q_r)





Vincotech

Ordering Code	
Version	Ordering Code
With std lid (6.5mm height) + no thermal grease	80-M2166BA075AS-K369G71-/0A/
With thin lid (2.8mm height) + no thermal grease	80-M2166BA075AS-K369G71-/0B/
With std lid (6.5mm height) + thermal grease (0,8 W/mK, P12, silicone-based)	80-M2166BA075AS-K369G71-/1A/
With thin lid (2.8mm height) + thermal grease (0,8 W/mK, P12, silicone-based)	80-M2166BA075AS-K369G71-/1B/
With std lid (6.5mm height) + thermal grease (2,5 W/mK, TG20032, silicone-free)	80-M2166BA075AS-K369G71-/4A/
With thin lid (2.8mm height) + thermal grease (2,5 W/mK, TG20032, silicone-free)	80-M2166BA075AS-K369G71-/4B/
With std lid (6.5mm height) + thermal grease (2,5 W/mK, HPTP, silicone-based)	80-M2166BA075AS-K369G71-/5A/
With thin lid (2.8mm height) + thermal grease (2,5 W/mK, HPTP, silicone-based)	80-M2166BA075AS-K369G71-/5B/

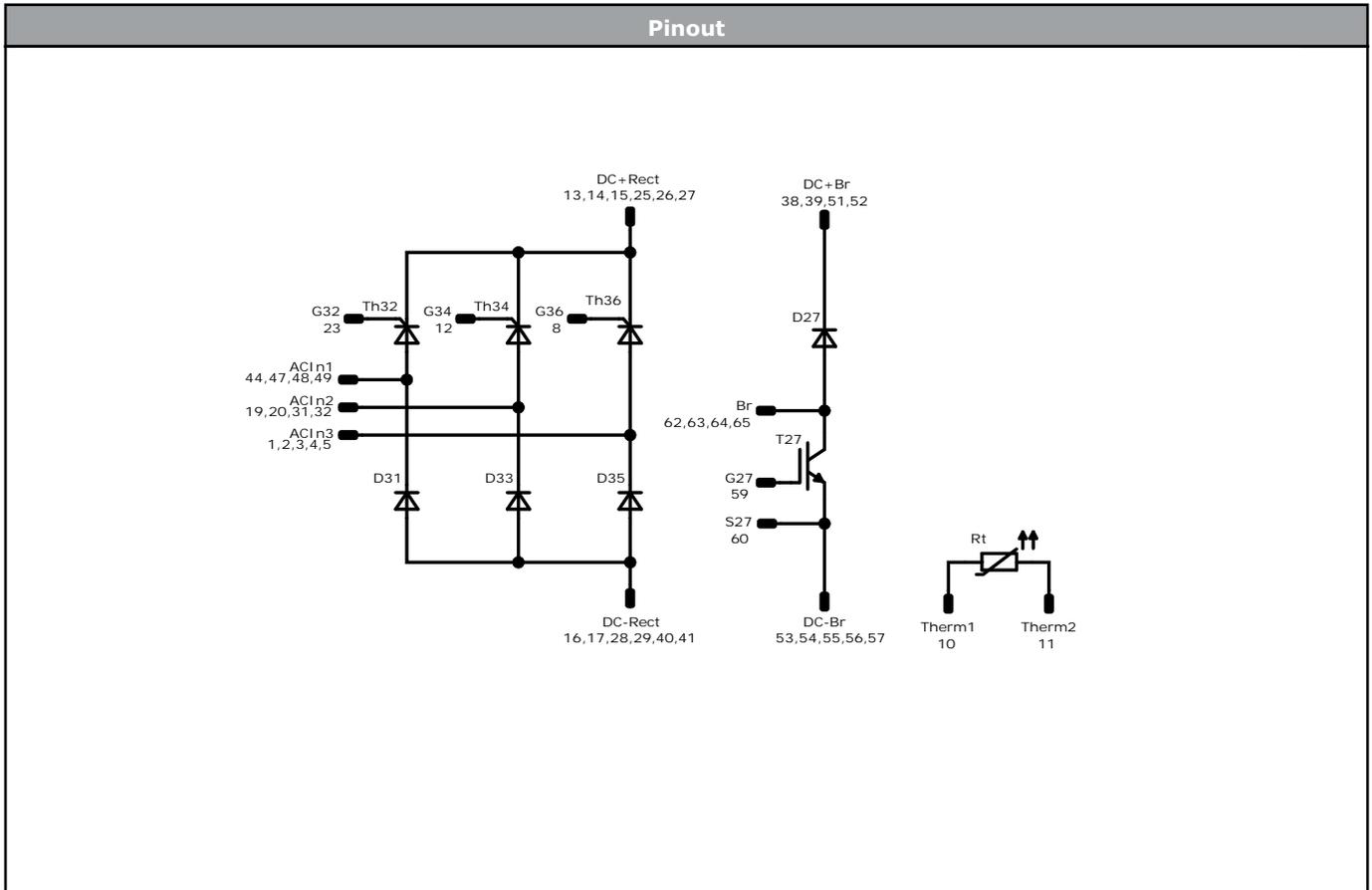
Marking						
Text	Name		Date code	UL & VIN	Lot	Serial
		NN-NNNNNNNNNNNNNNNN- TTTTIVV		WWYY	UL VIN	LLLLL
Datamatrix		Type&Ver	Lot number	Serial	Date code	
	TTTTTIVV	LLLLL	SSSS	WWYY		

Outline									
Pin table [mm]									
Pin	X	Y	Function	34	not assembled				
1	24,38	-21,8	ACIn3	35	not assembled				
2	24,38	-18,6	ACIn3	36	not assembled				
3	24,38	-15,4	ACIn3	37	not assembled				
4	24,38	-12,2		38	0,03	18,6	DC+Br		
5	24,38	-9		39	0,03	21,8	DC+Br		
6	not assembled			40	-8,5	-21,8	DC-Rect		
7	not assembled			41	-8,5	-18,6	DC-Rect		
8	24,38	12,2	G36	42	not assembled				
9	not assembled			43	not assembled				
10	24,38	18,6	Therm1	44	-12,22	-9	ACIn1		
11	24,38	21,8	Therm2	45	not assembled				
12	16,58	12,2	G34	46	not assembled				
13	16,58	15,4	DC+Rect	47	-12,22	3,9	ACIn1		
14	16,58	18,6	DC+Rect	48	-12,22	7,1	ACIn1		
15	16,58	21,8	DC+Rect	49	-12,22	10,3	ACIn1		
16	13,42	-21,8	DC-Rect	50	not assembled				
17	13,42	-18,6	DC-Rect	51	-12,22	18,6	DC+Br		
18	not assembled			52	-12,22	21,8	DC+Br		
19	13,42	-12,2	ACIn2	53	-24,38	-21,8	DC-Br		
20	13,42	-9	ACIn2	54	-24,38	-18,6	DC-Br		
21	not assembled			55	-24,38	-15,4	DC-Br		
22	not assembled			56	-24,38	-12,2	DC-Br		
23	8,38	5,8	G32	57	-24,38	-9	DC-Br		
24	not assembled			58	not assembled				
25	8,38	15,4	DC+Rect	59	-24,38	-2,5	G27		
26	8,38	18,6	DC+Rect	60	-24,38	0,7	S27		
27	8,38	21,8	DC+Rect	61	not assembled				
28	2,46	-21,8	DC-Rect	62	-24,38	7,1	Br		
29	2,46	-18,6	DC-Rect	63	-24,38	15,4	Br		
30	not assembled			64	-24,38	18,6	Br		
31	2,46	-12,2	ACIn2	65	-24,38	21,8	Br		
32	2,46	-9	ACIn2						
33	not assembled								

Pad positions refers to center point. For more informations on pad design please see package data



Vincotech



Identification					
ID	Component	Voltage	Current	Function	Comment
T27	IGBT	1200 V	100 A	Brake Switch	
D27	FWD	1200 V	100 A	Brake Diode	
Th32, Th34, Th36	Thyristor	1600 V	95 A	Rectifier Thyristor	
D31, D33, D35	Rectifier	1600 V	60 A	Rectifier Diode	
Rt	PTC			Thermistor	



Packaging instruction				
Standard packaging quantity (SPQ) 72	>SPQ	Standard	<SPQ	Sample

Handling instruction
Handling instructions for MiniSKiiP® 2 packages see vincotech.com website.

Package data
Package data for MiniSKiiP® 2 packages see vincotech.com website.

UL recognition and file number
This device is certified according to UL 1557 standard, UL file number E192116. For more information see vincotech.com website. 

Document No.:	Date:	Modification:	Pages
80-M2166BA075AS-K369G71-D1-14	17 Jun. 2020		

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2. A critical component is 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.