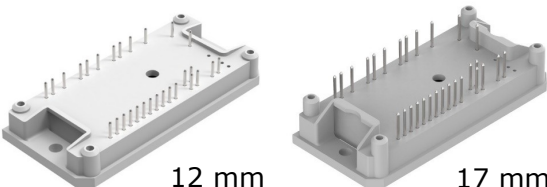
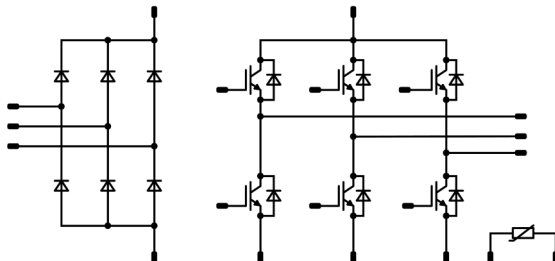




Vincotech

10-FY12PNA035M7-P589C78
10-F112PNA035M7-P589C79
 datasheet

flow PIM 1		1200 V / 35 A	
Features <ul style="list-style-type: none"> • IGBT M7 with low V_{CEsat} and improved EMC behavior • Open emitter configuration • Compact and low inductive design • Built-in NTC 		flow 1 housing 	
Target applications <ul style="list-style-type: none"> • Industrial Drives 		Schematic 	
Types <ul style="list-style-type: none"> • 10-FY12PNA035M7-P589C78 • 10-F112PNA035M7-P589C79 			

Maximum Ratings

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

Parameter	Symbol	Condition	Value	Unit
Rectifier Diode				
Peak repetitive reverse voltage	V_{RRM}		1600	V
Continuous (direct) forward current	I_F		45	A
Surge (non-repetitive) forward current	I_{FSM}	50 Hz Single Half Sine Wave $T_j = 150\text{ °C}$	350	A
Surge current capability	I^2t	$t_p = 10\text{ ms}$	610	A ² s
Total power dissipation	P_{tot}	$T_j = T_{jmax}$ $T_s = 80\text{ °C}$	65	W
Maximum junction temperature	T_{jmax}		150	°C



Vincotech

10-FY12PNA035M7-P589C78
10-F112PNA035M7-P589C79
 datasheet

Maximum Ratings

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

Parameter	Symbol	Condition	Value	Unit
Inverter Switch				
Collector-emitter voltage	V_{CES}		1200	V
Collector current	I_C		35	A
Repetitive peak collector current	I_{CRM}	t_p limited by T_{jmax}	70	A
Total power dissipation	P_{tot}	$T_j = T_{jmax}$ $T_s = 80\text{ °C}$	107	W
Gate-emitter voltage	V_{GES}		± 20	V
Short circuit ratings	t_{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	$^{\circ}\text{C}$

Inverter Diode				
Peak repetitive reverse voltage	V_{RRM}		1200	V
Continuous (direct) forward current	I_F		35	A
Repetitive peak forward current	I_{FRM}		70	A
Total power dissipation	P_{tot}	$T_j = T_{jmax}$ $T_s = 80\text{ °C}$	75	W
Maximum junction temperature	T_{jmax}		175	$^{\circ}\text{C}$

Module Properties

Thermal Properties				
Storage temperature	T_{stg}		-40...+125	$^{\circ}\text{C}$
Operation temperature under switching condition	T_{jop}		-40...($T_{jmax} - 25$)	$^{\circ}\text{C}$

Isolation Properties				
Isolation voltage	V_{isol}	DC Test Voltage* $t_p = 2\text{ s}$	6000	V
		AC Voltage $t_p = 1\text{ min}$	2500	V
Creepage distance			min. 12,7	mm
Clearance		For 12 mm housing	7,91	mm
		For 17 mm housing	min. 12,7	mm
Comparative Tracking Index	CTI		> 200	

*100 % tested in production



Vincotech

10-FY12PNA035M7-P589C78
10-F112PNA035M7-P589C79
datasheet

Characteristic Values

Parameter	Symbol	Conditions					Value			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 Diode

Static

Forward voltage	V_F				45	25 125		1,15 1,12		V
Reverse leakage current	I_R			1600		25			50	μA

Thermal

Thermal resistance junction to sink	$R_{th(j-s)}$	$\lambda_{paste} = 3,4 \text{ W/mK}$ (PSX)						1,08		K/W
-------------------------------------	---------------	---	--	--	--	--	--	------	--	-----



Vincotech

10-FY12PNA035M7-P589C78
10-F112PNA035M7-P589C79
 datasheet

Characteristic Values

Parameter	Symbol	Conditions					Value			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	

Inverter Switch

Static

Gate-emitter threshold voltage	$V_{GE(th)}$			10	0,0035	25	5,4	6,0	6,6	V
Collector-emitter saturation voltage	V_{CEsat}		15		35	25 125 150		1,48 1,64 1,68	1,85	V
Collector-emitter cut-off current	I_{CES}		0	1200		25			80	μA
Gate-emitter leakage current	I_{GES}		20	0		25			500	nA
Internal gate resistance	r_g							none		Ω
Input capacitance	C_{ies}		0	10		25		7900		pF
Output capacitance	C_{oes}							270		
Reverse transfer capacitance	C_{res}							97		
Gate charge	Q_g		15	600	35	25		260		nC

Thermal

Thermal resistance junction to sink	$R_{th(j-s)}$	$\lambda_{paste} = 3,4 \text{ W/mK}$ (PSX)						0,89		K/W
-------------------------------------	---------------	---	--	--	--	--	--	------	--	-----

Dynamic

Turn-on delay time	$t_{d(on)}$	$R_{gon} = 8 \Omega$ $R_{goff} = 8 \Omega$	± 15	600	35	25 125 150		124 122 121		ns
Rise time	t_r					25 125 150		14 17 18		
Turn-off delay time	$t_{d(off)}$					25 125 150		179 203 208		
Fall time	t_f					25 125 150		95 118 119		
Turn-on energy (per pulse)	E_{on}					25 125 150		1,45 1,92 2,09		mWs
Turn-off energy (per pulse)	E_{off}					25 125 150		2,40 3,17 3,42		



Vincotech

10-FY12PNA035M7-P589C78
10-F112PNA035M7-P589C79
 datasheet

Characteristic Values

Parameter	Symbol	Conditions					Value			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	

Inverter Diode

Static

Forward voltage	V_F				35	25 125 150		1,66 1,76 1,75	2,1	V
Reverse leakage current	I_R			1200		25 150			40	μA

Thermal

Thermal resistance junction to sink	$R_{th(j-s)}$	$\lambda_{paste} = 3,4 \text{ W/mK (PSX)}$						1,27		K/W
-------------------------------------	---------------	--	--	--	--	--	--	------	--	-----

Dynamic

Peak recovery current	I_{RRM}	$di/dt = 2681 \text{ A/}\mu\text{s}$ $di/dt = 2670 \text{ A/}\mu\text{s}$ $di/dt = 2690 \text{ A/}\mu\text{s}$	± 15	600	35	25 125 150		77 76 77		A
Reverse recovery time	t_{rr}					25 125 150		157 284 311		ns
Recovered charge	Q_r					25 125 150		4,34 6,18 6,90		μC
Reverse recovered energy	E_{rec}					25 125 150		1,96 2,82 3,13		mWs
Peak rate of fall of recovery current	$(di_{rt}/dt)_{max}$					25 125 150		2734 2205 2101		A/μs

NTC

Rated resistance	R					25		22		kΩ
Deviation of R_{100}	$\Delta_{R/R}$	$R_{100} = 1484 \Omega$				100	-5		5	%
Power dissipation	P					25		5		mW
Power dissipation constant						25		1,5		mW/K
B-value	$B_{(25/50)}$	Tol. $\pm 1 \%$				25		3962		K
B-value	$B_{(25/100)}$	Tol. $\pm 1 \%$				25		4000		K
Vincotech NTC Reference									I	



Vincotech

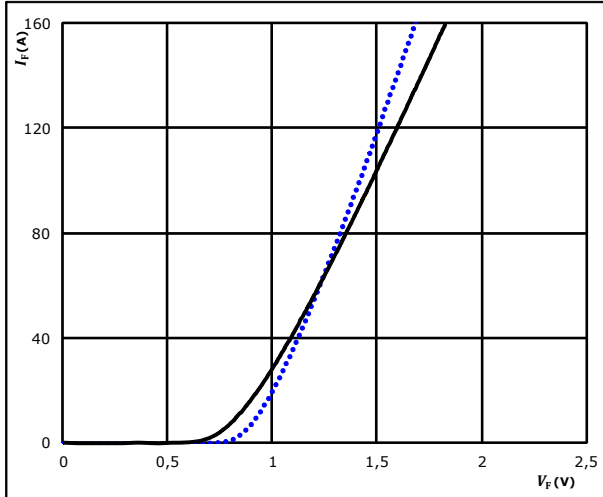
10-FY12PNA035M7-P589C78
10-F112PNA035M7-P589C79
datasheet

Rectifier Diode Characteristics

figure 1. Rectifier Diode

Typical forward characteristics

$$I_F = f(V_F)$$

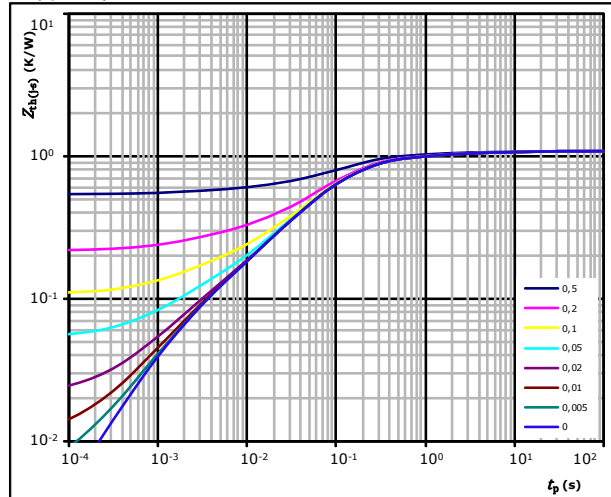


$t_p =$ 250 μ s
 T_j : 25 °C (dotted blue line)
125 °C (solid black line)

figure 2. Rectifier Diode

Transient thermal impedance as a function of pulse width

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



$D =$ t_p / T
 $R_{th(j-s)} =$ 1,08 K/W

Diode thermal model values

R (K/W)	τ (s)
4,60E-02	9,93E+00
1,23E-01	1,00E+00
4,58E-01	1,51E-01
3,31E-01	5,61E-02
7,76E-02	9,34E-03
4,64E-02	1,55E-03



Vincotech

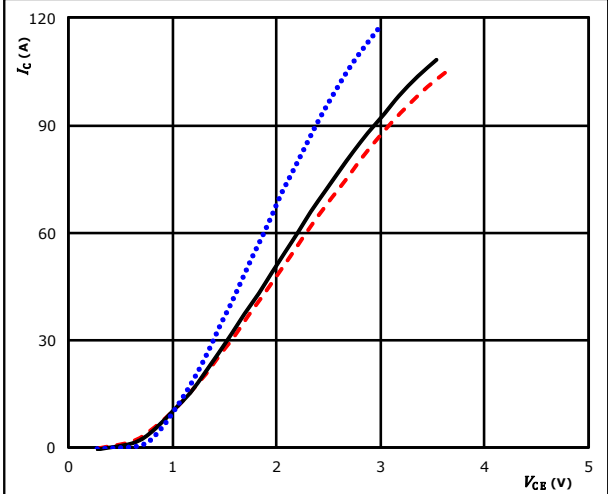
10-FY12PNA035M7-P589C78
10-F112PNA035M7-P589C79
 datasheet

Inverter Switch Characteristics

figure 1. IGBT

Typical output characteristics

$$I_C = f(V_{CE})$$

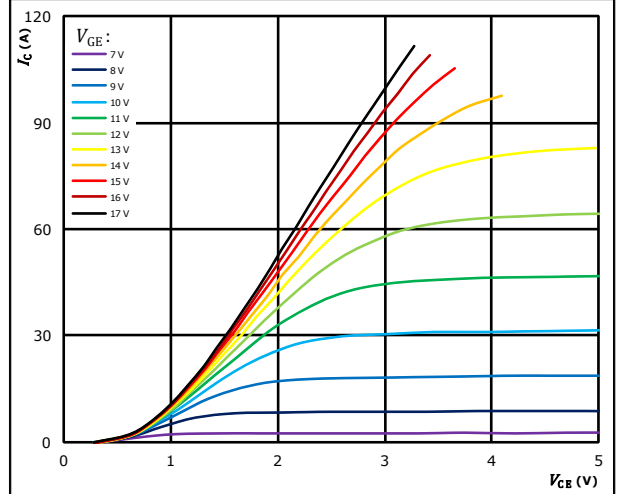


$t_p = 250 \mu s$
 $V_{GE} = 15 V$
 $T_j: 25 \text{ } ^\circ C$ (blue dotted line)
 $125 \text{ } ^\circ C$ (black solid line)
 $150 \text{ } ^\circ C$ (red dashed line)

figure 2. IGBT

Typical output characteristics

$$I_C = f(V_{CE})$$

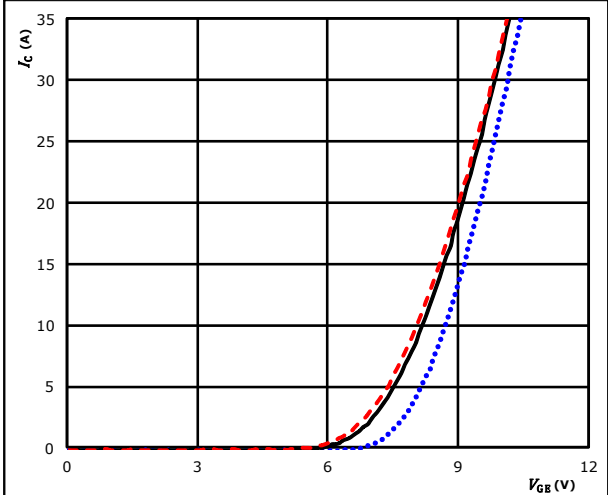


$t_p = 250 \mu s$
 $T_j = 150 \text{ } ^\circ C$
 V_{GE} from 7 V to 17 V in steps of 1 V

figure 3. IGBT

Typical transfer characteristics

$$I_C = f(V_{GE})$$

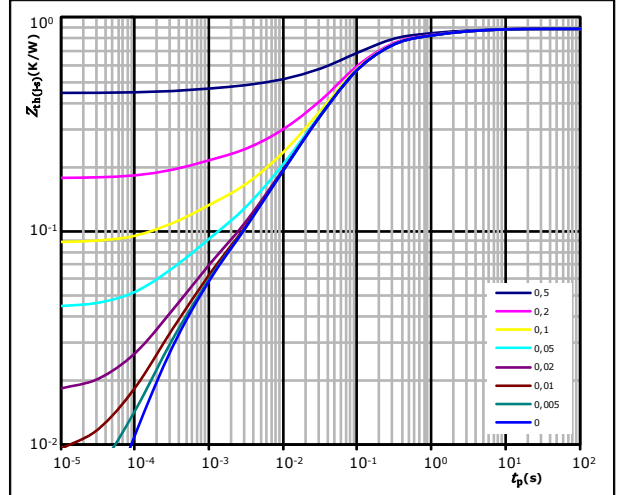


$t_p = 100 \mu s$
 $V_{CE} = 10 V$
 $T_j: 25 \text{ } ^\circ C$ (blue dotted line)
 $125 \text{ } ^\circ C$ (black solid line)
 $150 \text{ } ^\circ C$ (red dashed line)

figure 4. IGBT

Transient thermal impedance as function of pulse duration

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



$D = t_p / T$
 $R_{th(j-s)} = 0,89 \text{ K/W}$
 IGBT thermal model values

$R \text{ (K/W)}$	$\tau \text{ (s)}$
4,56E-02	3,89E+00
8,84E-02	7,65E-01
3,30E-01	1,35E-01
2,86E-01	4,71E-02
8,94E-02	7,49E-03
3,24E-02	8,15E-04
1,67E-02	2,52E-04



Vincotech

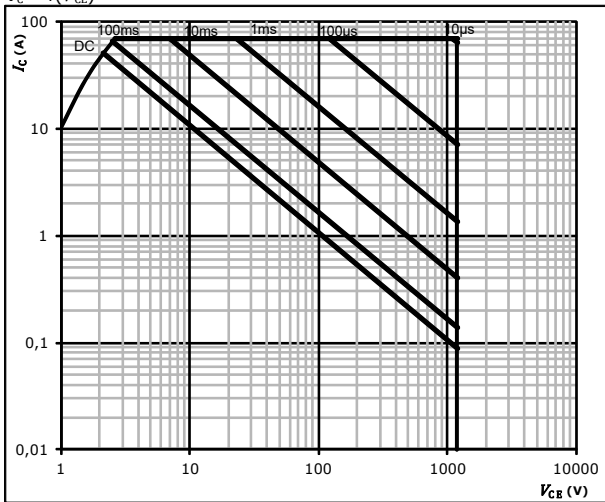
10-FY12PNA035M7-P589C78
10-F112PNA035M7-P589C79
 datasheet

Inverter 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}



Vincotech

10-FY12PNA035M7-P589C78
10-F112PNA035M7-P589C79
 datasheet

Inverter Diode Characteristics

figure 1. FWD

Typical forward characteristics

$$I_F = f(V_F)$$

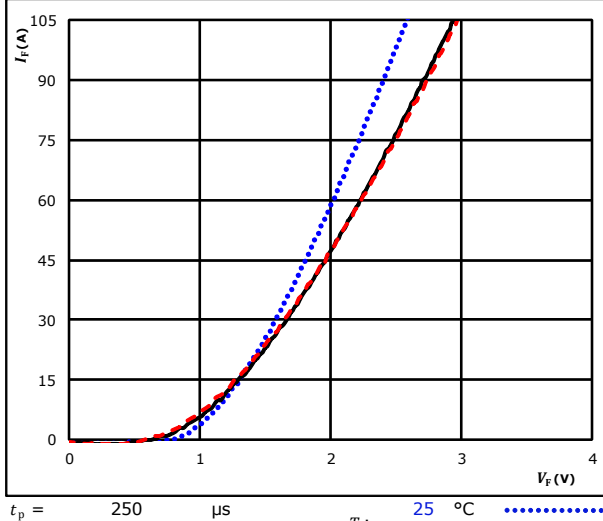
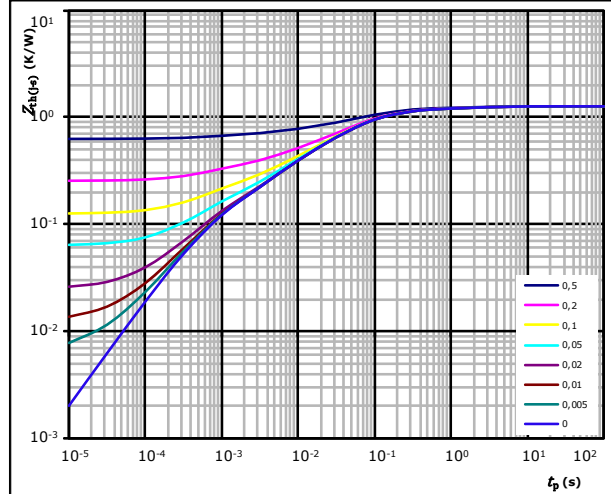


figure 2. FWD

Transient thermal impedance as a function of pulse width

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



$$D = t_p / T$$

$$R_{th(j-s)} = 1,27 \text{ K/W}$$

FWD thermal model values

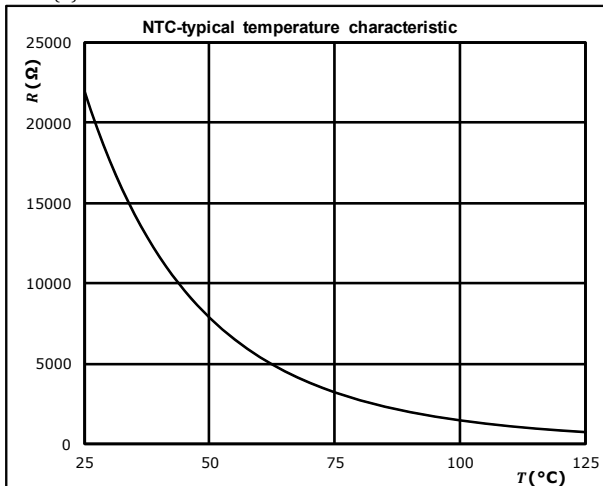
R (K/W)	τ (s)
5,82E-02	3,40E+00
1,11E-01	5,24E-01
4,63E-01	9,20E-02
3,72E-01	2,94E-02
1,72E-01	5,46E-03
9,36E-02	6,17E-04

NTC Characteristics

figure 1. Thermistor

Typical NTC characteristic as a function of temperature

$$R = f(T)$$





Vincotech

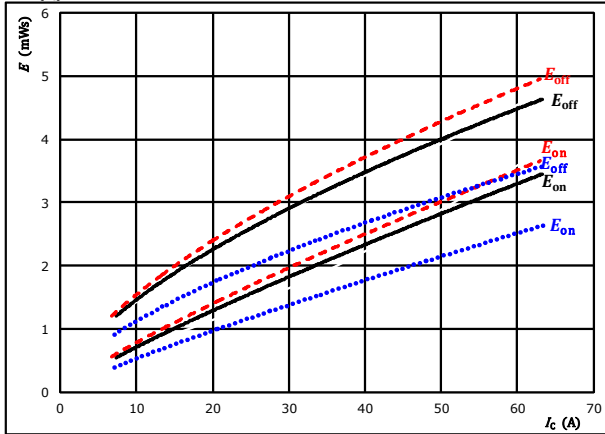
10-FY12PNA035M7-P589C78
10-F112PNA035M7-P589C79
 datasheet

Inverter Switching Characteristics

figure 1. IGBT

Typical switching energy losses as a function of collector current

$$E = f(I_C)$$



With an inductive load at

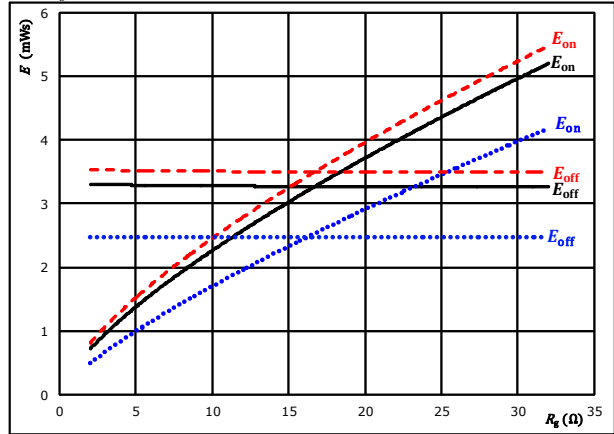
$V_{CE} = 600$ V
 $V_{GE} = \pm 15$ V
 $R_{gon} = 8$ Ω
 $R_{goff} = 8$ Ω

T_j : 25 °C
 125 °C
 150 °C

figure 2. IGBT

Typical switching energy losses as a function of gate resistor

$$E = f(R_g)$$



With an inductive load at

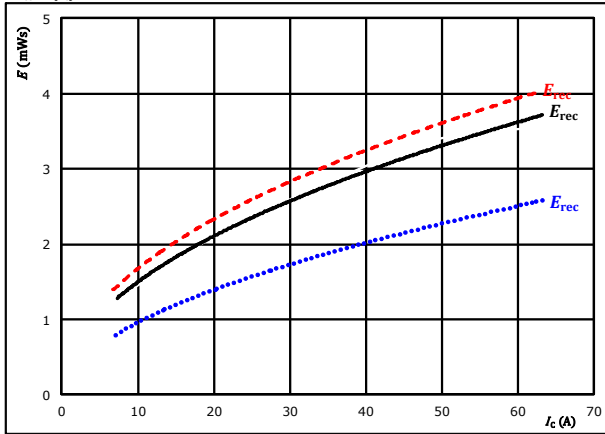
$V_{CE} = 600$ V
 $V_{GE} = \pm 15$ V
 $I_C = 35$ A

T_j : 25 °C
 125 °C
 150 °C

figure 3. FWD

Typical reverse recovered energy loss as a function of collector current

$$E_{rec} = f(I_C)$$



With an inductive load at

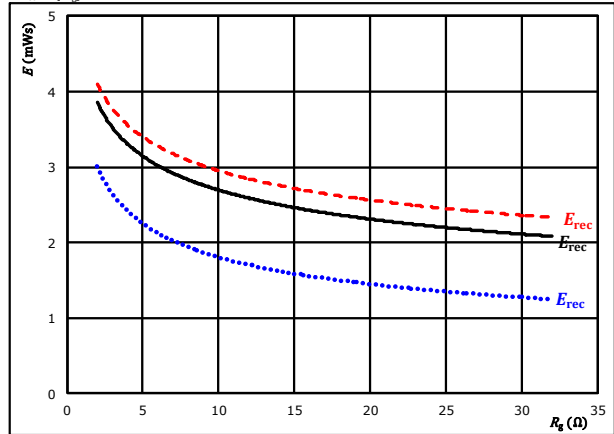
$V_{CE} = 600$ V
 $V_{GE} = \pm 15$ V
 $R_{gon} = 8$ Ω

T_j : 25 °C
 125 °C
 150 °C

figure 4. 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
 $V_{GE} = \pm 15$ V
 $I_C = 35$ A

T_j : 25 °C
 125 °C
 150 °C



Vincotech

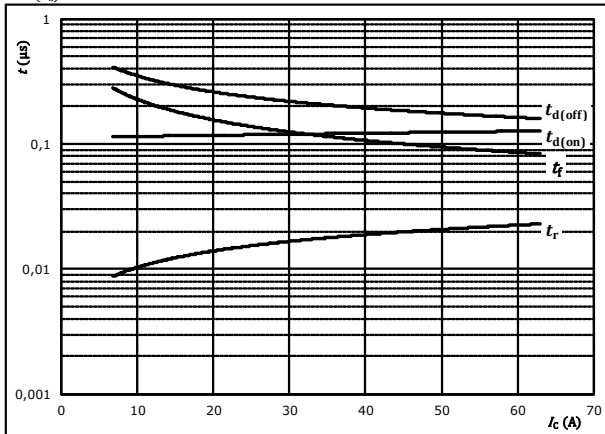
10-FY12PNA035M7-P589C78
10-F112PNA035M7-P589C79
datasheet

Inverter Switching Characteristics

figure 5. IGBT

Typical switching times as a function of collector current

$$t = f(I_C)$$



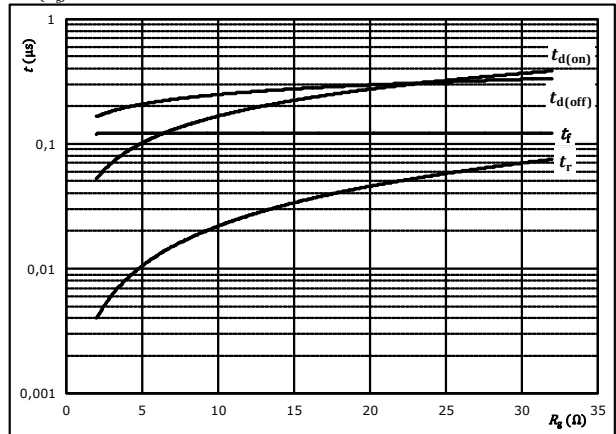
With an inductive load at

$T_j =$	150	°C
$V_{CE} =$	600	V
$V_{GE} =$	±15	V
$R_{gon} =$	8	Ω
$R_{goff} =$	8	Ω

figure 6. IGBT

Typical switching times as a function of gate resistor

$$t = f(R_g)$$



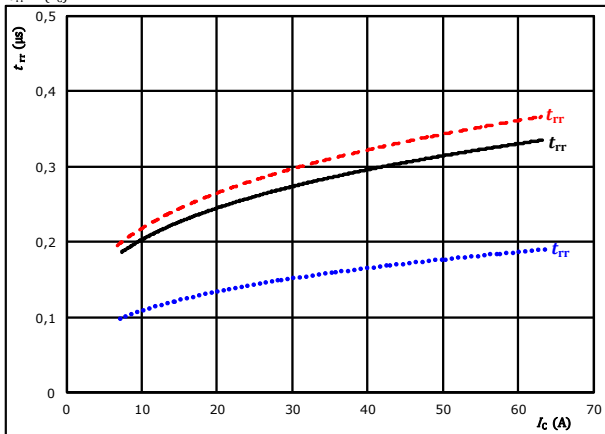
With an inductive load at

$T_j =$	150	°C
$V_{CE} =$	600	V
$V_{GE} =$	±15	V
$I_C =$	35	A

figure 7. FWD

Typical reverse recovery time as a function of collector current

$$t_{rr} = f(I_C)$$

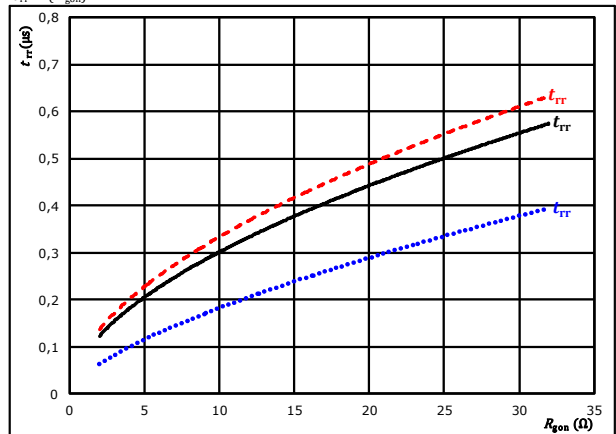


At	$V_{CE} =$	600	V	$T_j:$	25 °C
	$V_{GE} =$	±15	V		125 °C	————
	$R_{gon} =$	8	Ω		150 °C	-----

figure 8. FWD

Typical reverse recovery time as a function of IGBT turn on gate resistor

$$t_{rr} = f(R_{gon})$$



At	$V_{CE} =$	600	V	$T_j:$	25 °C
	$V_{GE} =$	±15	V		125 °C	————
	$I_C =$	35	A		150 °C	-----



Vincotech

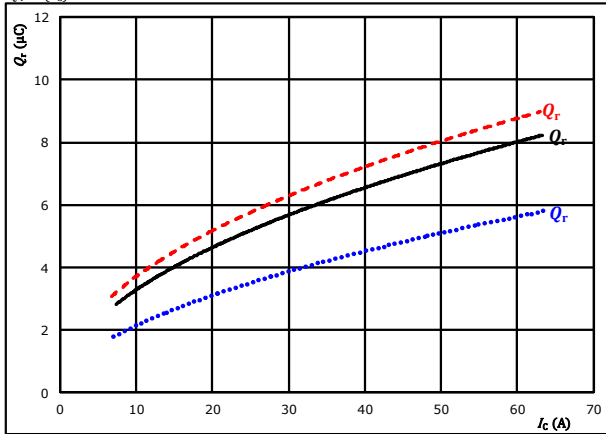
10-FY12PNA035M7-P589C78
10-F112PNA035M7-P589C79
 datasheet

Inverter Switching Characteristics

figure 9. FWD

Typical recovered charge as a function of collector current

$$Q_r = f(I_C)$$

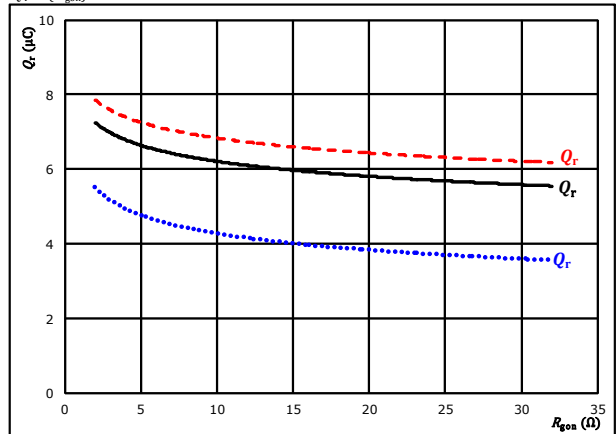


At $V_{CE} = 600$ V
 $V_{GE} = \pm 15$ V
 $R_{gon} = 8$ Ω
 T_j : 25 °C (blue dotted), 125 °C (black solid), 150 °C (red dashed)

figure 10. FWD

Typical recovered charge as a function of IGBT turn on gate resistor

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

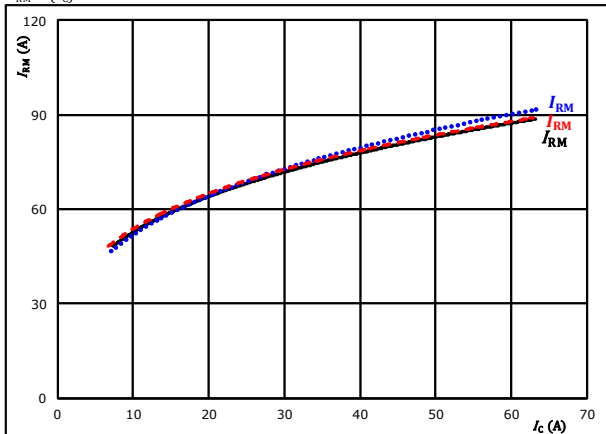


At $V_{CE} = 600$ V
 $V_{GE} = \pm 15$ V
 $I_C = 35$ A
 T_j : 25 °C (blue dotted), 125 °C (black solid), 150 °C (red dashed)

figure 11. FWD

Typical peak reverse recovery current as a function of collector current

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

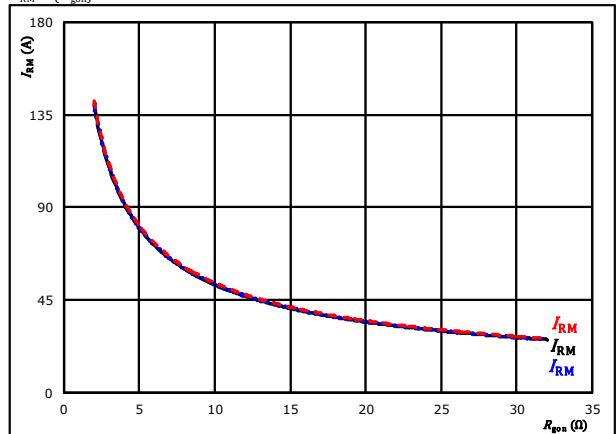


At $V_{CE} = 600$ V
 $V_{GE} = \pm 15$ V
 $R_{gon} = 8$ Ω
 T_j : 25 °C (blue dotted), 125 °C (black solid), 150 °C (red dashed)

figure 12. FWD

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

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



At $V_{CE} = 600$ V
 $V_{GE} = \pm 15$ V
 $I_C = 35$ A
 T_j : 25 °C (blue dotted), 125 °C (black solid), 150 °C (red dashed)



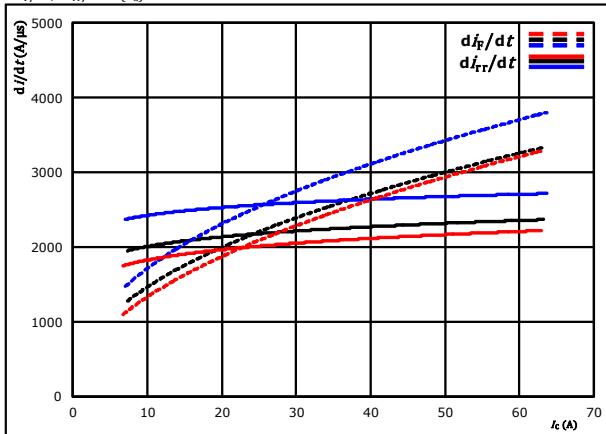
Vincotech

10-FY12PNA035M7-P589C78
10-F112PNA035M7-P589C79
 datasheet

Inverter Switching Characteristics

figure 13. FWD

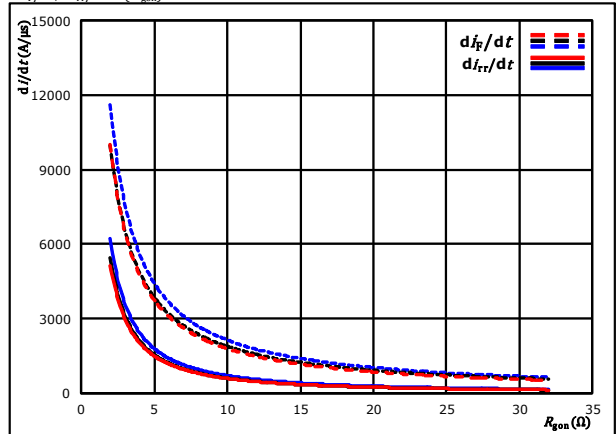
Typical rate of fall of forward and reverse recovery current as a function of collector current
 $di_F/dt, di_{rr}/dt = f(I_C)$



At $V_{CE} = 600$ V $T_j = 25$ °C
 $V_{GE} = \pm 15$ V $T_j = 125$ °C ———
 $R_{g0n} = 8$ Ω $T_j = 150$ °C - - - - -

figure 14. FWD

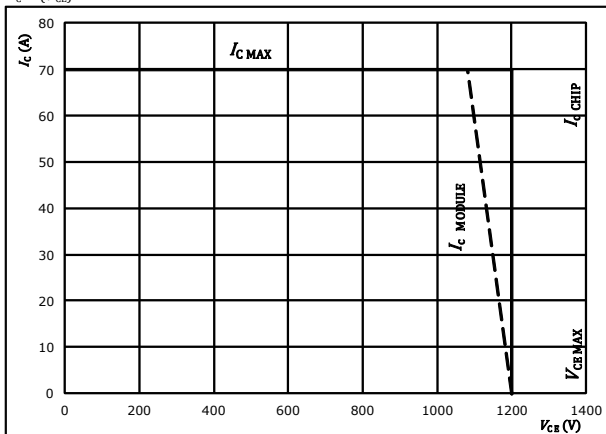
Typical rate of fall of forward and reverse recovery current as a function of IGBT turn on gate resistor
 $di_F/dt, di_{rr}/dt = f(R_{g0n})$



At $V_{CE} = 600$ V $T_j = 25$ °C
 $V_{GE} = \pm 15$ V $T_j = 125$ °C ———
 $I_C = 35$ A $T_j = 150$ °C - - - - -

figure 15. IGBT

Reverse bias safe operating area
 $I_C = f(V_{CE})$



At $T_j = 125$ °C
 $R_{g0n} = 8$ Ω
 $R_{g0ff} = 8$ Ω



Vincotech

10-FY12PNA035M7-P589C78
10-F112PNA035M7-P589C79
 datasheet

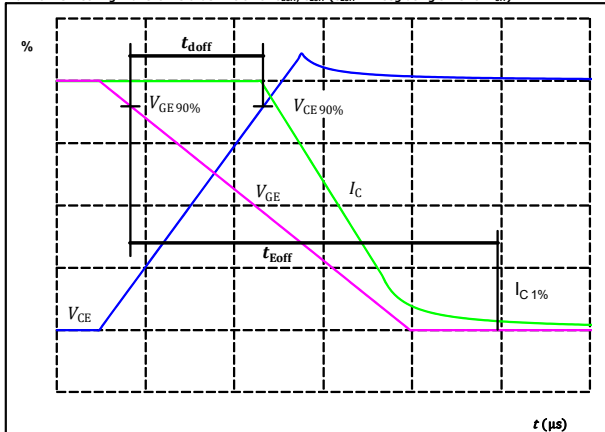
Inverter Switching Definitions

General conditions

T_j	=	125 °C
R_{gon}	=	8 Ω
R_{goff}	=	8 Ω

figure 1. IGBT

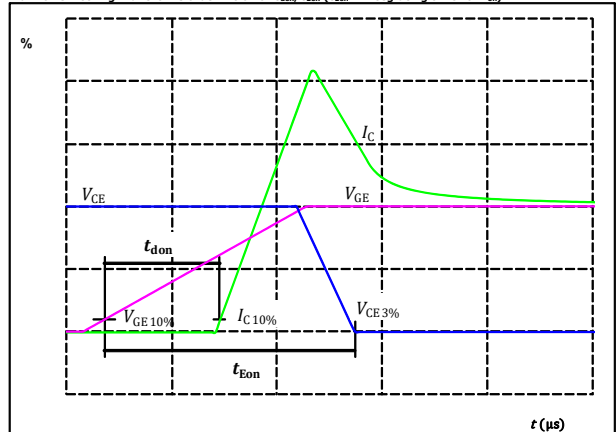
Turn-off Switching Waveforms & definition of t_{doff} , t_{Eoff} (t_{Eoff} = integrating time for E_{off})



$V_{GE}(0\%) =$	-15	V
$V_{GE}(100\%) =$	15	V
$V_C(100\%) =$	600	V
$I_C(100\%) =$	35	A
$t_{doff} =$	203	ns

figure 2. IGBT

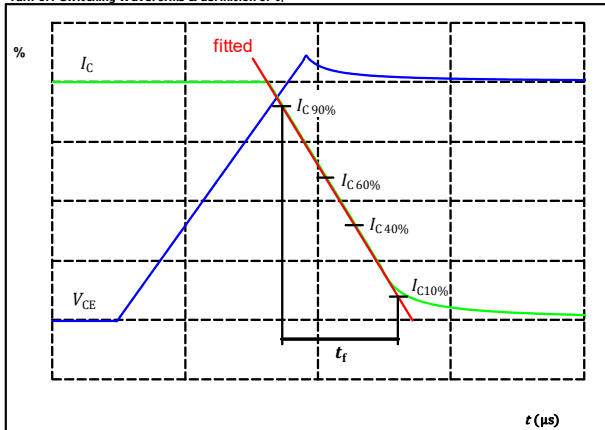
Turn-on Switching Waveforms & definition of t_{don} , t_{Eon} (t_{Eon} = integrating time for E_{on})



$V_{GE}(0\%) =$	-15	V
$V_{GE}(100\%) =$	15	V
$V_C(100\%) =$	600	V
$I_C(100\%) =$	35	A
$t_{don} =$	122	ns

figure 3. IGBT

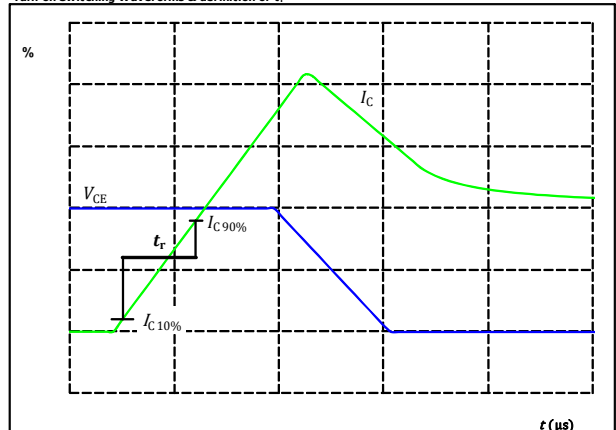
Turn-off Switching Waveforms & definition of t_f



$V_C(100\%) =$	600	V
$I_C(100\%) =$	35	A
$t_f =$	118	ns

figure 4. IGBT

Turn-on Switching Waveforms & definition of t_r



$V_C(100\%) =$	600	V
$I_C(100\%) =$	35	A
$t_r =$	17	ns

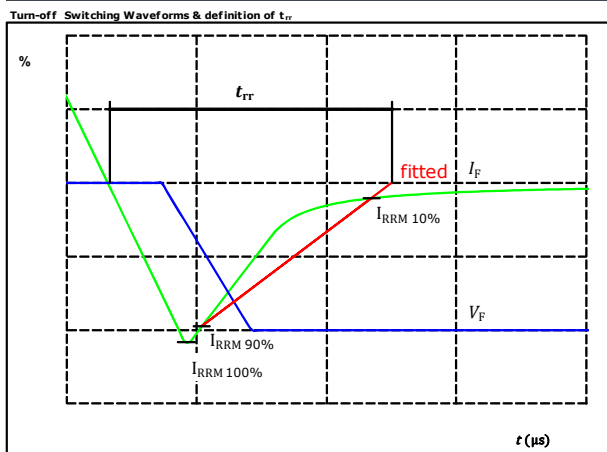


Vincotech

10-FY12PNA035M7-P589C78
10-F112PNA035M7-P589C79
 datasheet

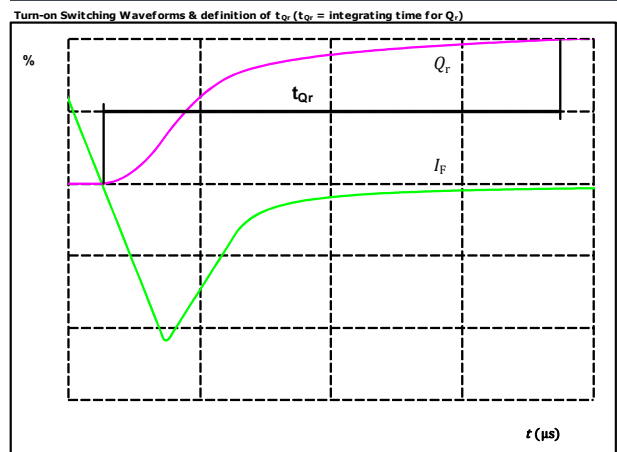
Inverter Switching Characteristics

figure 5. FWD



V_F (100%) =	600	V
I_F (100%) =	35	A
I_{RRM} (100%) =	76	A
t_{rr} =	284	ns

figure 6. FWD





I_F (100%) =	35	A
Q_r (100%) =	6,18	μC



Vincotech

10-FY12PNA035M7-P589C78
10-F112PNA035M7-P589C79
datasheet

Ordering Code & Marking									
Version			Ordering Code						
without thermal paste 12 mm housing with solder pins			10-FY12PNA035M7-P589C78						
with thermal paste 12 mm housing with solder pins			10-FY12PNA035M7-P589C78-/3/						
without thermal paste 17 mm housing with solder pins			10-F112PNA035M7-P589C79						
with thermal paste 17 mm housing with solder pins			10-F112PNA035M7-P589C79-/3/						
<div><div>NN-NNNNNNNNNNNN TTTTTIV WWYY UL VIN LLLLL SSSS</div><div></div><div></div></div>			Text	Name		Date code	UL & VIN	Lot	Serial
				NN-NNNNNNNNNNNN-TTTTTIV		WWYY	UL VIN	LLLLL	SSSS
			Datamatrix	Type&Ver	Lot number	Serial	Date code		
			TTTTTIV	LLLLL	SSSS	WWYY			

Pin table			
Pin	X	Y	Function
1	Not assembled		
2	47,7	0	DC-Rect
3	44,8	0	DC-Rect
4	37,8	0	DC+Rect
5	37,8	2,8	DC+Rect
6	35	0	DC+Inv
7	35	2,8	DC+Inv
8	28	0	Therm1
9	25,2	0	Therm2
10	22,4	0	DC- 3
11	19,6	0	G15
12	16,8	0	S15
13	14	0	DC- 2
14	11,2	0	G13
15	8,4	0	S13
16	5,6	0	DC- 1
17	2,8	0	G11
18	0	0	S11
19	0	28,5	Ph1
20	2,8	28,5	G12
21	7,5	28,5	S12
22	14,5	28,5	Ph2
23	17,3	28,5	G14
24	22	28,5	S14
25	29	28,5	Ph3
26	31,8	28,5	G16
27	36,5	28,5	S16
28	43,5	28,5	ACIn1
29	52,55	25	ACIn2
30	52,55	16,9	ACIn3
31	Not assembled		
32	Not assembled		

P589C78

Technical drawing of P589C78. The side view shows a component with a base and a top section. The top section has a series of pins. The dimensions are: $\phi 1 \pm 0.05$ for the pin diameter, 16.2 ± 0.05 for the height of the top section, and 14.25 for the height of the base. The top view shows the component with a central circular feature and a series of pins. The dimensions are: 26.25 for the width of the component, 14.25 for the height of the base, and Y for the distance from the base to the top section. The pin locations are numbered 1 through 32.

P589C79

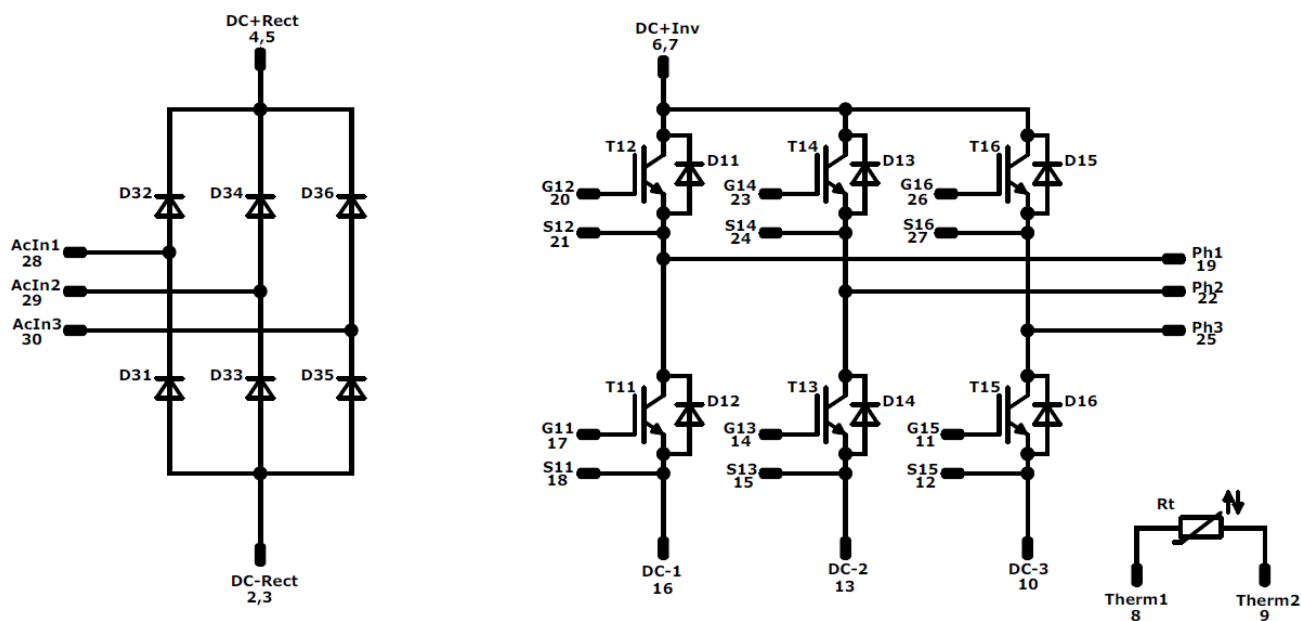
Technical drawing of P589C79. The side view shows a component with a base and a top section. The top section has a series of pins. The dimensions are: 1 ± 0.05 for the pin diameter, 21.2 ± 0.05 for the height of the top section, and 14.25 for the height of the base. The top view shows the component with a central circular feature and a series of pins. The dimensions are: 26.25 for the width of the component, 14.25 for the height of the base, and $Y1$ for the distance from the base to the top section. The pin locations are numbered 1 through 32.



Vincotech

10-FY12PNA035M7-P589C78
10-F112PNA035M7-P589C79
datasheet

Pinout



Identification

ID	Component	Voltage	Current	Function	Comment
D31, D32, D33, D34, D35, D36	Rectifier	1600 V	45 A	Rectifier Diode	
T11, T12, T13, T14, T15, T16	IGBT	1200 V	35 A	Inverter Switch	
D11, D12, D13, D14, D15, D16	FWD	1200 V	35 A	Inverter Diode	
Rt	Thermistor			NTC	




Vincotech

10-FY12PNA035M7-P589C78
10-F112PNA035M7-P589C79
datasheet

Packaging instruction			
Standard packaging quantity (SPQ) 100	>SPQ	Standard	<SPQ Sample

Handling instruction
Handling instructions for <i>flow</i> 1 packages see vincotech.com website.

Package data
Package data for <i>flow</i> 1 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
10-Fx12PNA035M7-P589C7x-D2-14	13 Jun. 2019	P589C79 version added	1, 2, 16

DISCLAIMER

The information, specifications, procedures, methods and recommendations herein (together "information") are presented by Vincotech to reader in good faith, are believed to be accurate and reliable, but may well be incomplete and/or not applicable to all conditions or situations that may exist or occur. Vincotech reserves the right to make any changes without further notice to any products to improve reliability, function or design. No representation, guarantee or warranty is made to reader as to the accuracy, reliability or completeness of said information or that the application or use of any of the same will avoid hazards, accidents, losses, damages or injury of any kind to persons or property or that the same will not infringe third parties rights or give desired results. It is reader's sole responsibility to test and determine the suitability of the information and the product for reader's intended use.

LIFE SUPPORT POLICY

Vincotech products are not authorised for use as critical components in life support devices or systems without the express written approval of Vincotech.

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, or (c) whose failure to perform when properly used in accordance with instructions for use provided in labelling can be reasonably expected to result in significant injury to the user.
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.