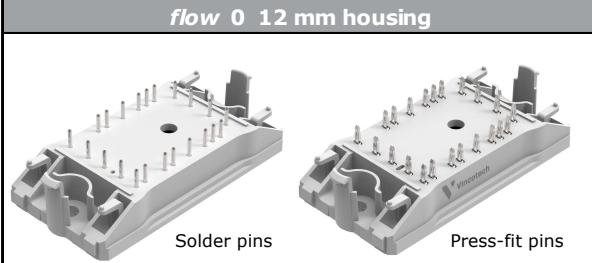
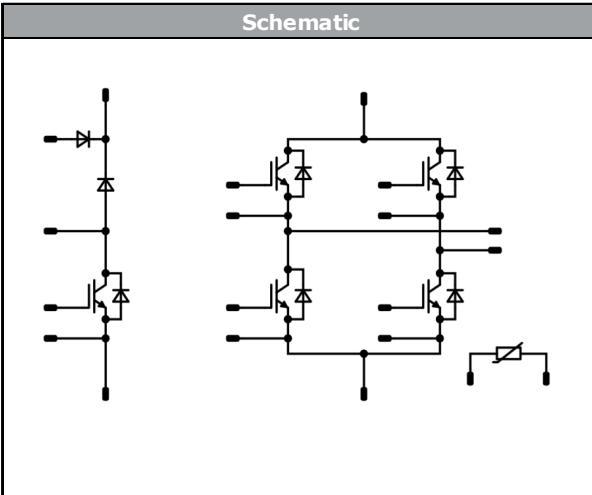




10-FZ07BIA030S5Y-P894E78
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flow SOL 0 BI		650 V / 30 A
Features		
	<ul style="list-style-type: none">• High efficiency Solar Inverter with Booster• Ultra fast switching frequency• IGBT S5 H-bridge configuration• IGBT H5 in Booster• Low inductive design	
Target applications		Schematic
	<ul style="list-style-type: none">• Solar Inverters	
Types		
	<ul style="list-style-type: none">• 10-FZ07BIA030S5Y-P894E78• 10-PZ07BIA030S5Y-P894E78Y	

Maximum Ratings

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

Parameter	Symbol	Condition	Value	Unit
Boost Switch				
Collector-emitter voltage	V_{CES}		650	V
Collector current	I_C	$T_j = T_{jmax}$ $T_s = 80^\circ\text{C}$	31	A
Repetitive peak collector current	I_{CRM}	t_p limited by T_{jmax}	90	A
Total power dissipation	P_{tot}	$T_j = T_{jmax}$ $T_s = 80^\circ\text{C}$	60	W
Gate-emitter voltage	V_{GES}		± 20	V
Maximum Junction Temperature	T_{jmax}		175	$^\circ\text{C}$



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Maximum Ratings

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

Parameter	Symbol	Condition	Value	Unit
Boost Diode				
Peak Repetitive Reverse Voltage	V_{RRM}		650	V
Continuous (direct) forward current	I_F	$T_j = T_{jmax}$ $T_s = 80^\circ\text{C}$	21	A
Total power dissipation	P_{tot}	$T_j = T_{jmax}$ $T_s = 80^\circ\text{C}$	13	W
Maximum Junction Temperature	T_{jmax}		175	$^\circ\text{C}$
Boost Sw. Protection Diode				
Peak Repetitive Reverse Voltage	V_{RRM}		650	V
Continuous (direct) forward current	I_F	$T_j = T_{jmax}$ $T_s = 80^\circ\text{C}$	14	A
Repetitive peak forward current	I_{FRM}	$T_j < 150^\circ\text{C}$	20	A
Total power dissipation	P_{tot}	$T_j = T_{jmax}$ $T_s = 80^\circ\text{C}$	33	W
Maximum Junction Temperature	T_{jmax}		175	$^\circ\text{C}$
ByPass Diode				
Peak Repetitive Reverse Voltage	V_{RRM}		1600	V
Continuous (direct) forward current	I_F	$T_j = T_{jmax}$ $T_s = 80^\circ\text{C}$	46	A
Surge (non-repetitive) forward current	I_{FSM}	50 Hz Single Half Sine Wave $t_p = 10 \text{ ms}$	270	A
Surge current capability	I^2t		370	A^2s
Total power dissipation	P_{tot}	$T_j = T_{jmax}$ $T_s = 80^\circ\text{C}$	56	W
Maximum Junction Temperature	T_{jmax}		150	$^\circ\text{C}$
H-Bridge Switch				
Collector-emitter voltage	V_{CES}		650	V
Collector current	I_C	$T_j = T_{jmax}$ $T_s = 80^\circ\text{C}$	36	A
Repetitive peak collector current	I_{CRM}	t_p limited by T_{jmax}	90	A
Total power dissipation	P_{tot}	$T_j = T_{jmax}$ $T_s = 80^\circ\text{C}$	64	W
Gate-emitter voltage	V_{GES}		± 20	V
Maximum junction temperature	T_{jmax}		175	$^\circ\text{C}$



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Maximum Ratings

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

Parameter	Symbol	Condition	Value	Unit
H-Bridge Diode				
Peak Repetitive Reverse Voltage	V_{RRM}		650	V
Continuous (direct) forward current	I_F	$T_j = T_{jmax}$ $T_s = 80 \text{ }^\circ\text{C}$	21	A
Total power dissipation	P_{tot}	$T_j = T_{jmax}$ $T_s = 80 \text{ }^\circ\text{C}$	13	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_{op}		-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		Solder pins / Press-fit pins	8,66 / 9,17	mm
Comparative Tracking Index	CTI		> 200	

*100 % tested in production



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Characteristic Values

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

Boost Switch

Static

Gate-emitter threshold voltage	$V_{GE(th)}$	$V_{GE} = V_{CE}$			0,0003	25		3,3	4	4,7	V
Collector-emitter saturation voltage	V_{CESat}		15		30	25 125 150			1,67 1,80 1,84	2,22	V
Collector-emitter cut-off current	I_{CES}		0	650		25				40	µA
Gate-emitter leakage current	I_{GES}		20	0		25				120	nA
Internal gate resistance	r_g								none		Ω
Input capacitance	C_{ies}	$f = 1\text{MHz}$	0	25	25				2100		pF
Reverse transfer capacitance	C_{res}								7,7		
Gate charge	Q_g		15	520	30	25			70		nC

Thermal

Thermal resistance junction to sink	$R_{th(j-s)}$	$\lambda_{paste} = 3,4 \text{ W/mK}$ (PSX)							1,57		K/W
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Dynamic

Turn-on delay time	$t_{d(on)}$	$R_{goff} = 16 \Omega$ $R_{gon} = 16 \Omega$	15/0	400	30	25		20			ns
Rise time	t_r					125		19			
						150		17			
						25		8			
						125		9			
						150		10			
Turn-off delay time	$t_{d(off)}$					25		137			mWs
Fall time	t_f					125		155			
						150		159			
						25		4			
						125		9			
						150		10			
Turn-on energy (per pulse)	E_{on}	$Q_{fFWD} = 1,1 \mu\text{C}$ $Q_{rFWD} = 2,3 \mu\text{C}$ $Q_{tFWD} = 2,7 \mu\text{C}$				25		0,618			
Turn-off energy (per pulse)	E_{off}					125		0,894			
						150		0,962			
						25		0,172			
						125		0,305			
						150		0,326			



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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		

Boost Diode

Static

Forward voltage	V_F				15	25 125 150		1,44 1,20 1,14			V
Reverse leakage current	I_r			650		25			5		µA

Thermal

Thermal resistance junction to sink	$R_{th(j-s)}$	$\lambda_{paste} = 3,4 \text{ W/mK}$ (PSX)						1,81			K/W
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Dynamic

Peak recovery current	I_{RRM}	$di/dt = 2879 \text{ A/µs}$ $di/dt = 2826 \text{ A/µs}$ $di/dt = 2747 \text{ A/µs}$	15/0	400	30	25 125 150		33 50 56			A
Reverse recovery time	t_{rr}					25 125 150		92 113 121			ns
Recovered charge	Q_r					25 125 150		1,102 2,280 2,721			µC
Reverse recovered energy	E_{rec}					25 125 150		0,213 0,489 0,605			mWs
Peak rate of fall of recovery current	$(di_{rf}/dt)_{max}$					25 125 150		2721 1492 1645			A/µs

Boost Sw. Protection Diode

Static

Forward voltage	V_F				10	25 125		1,67 1,56	1,87		V
Reverse leakage current	I_r			650		25			0,14		µA

Thermal

Thermal resistance junction to sink	$R_{th(j-s)}$	$\lambda_{paste} = 3,4 \text{ W/mK}$ (PSX)						2,87			K/W
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Characteristic Values

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

ByPass Diode

Static

Forward voltage	V_F			35	25 125	0,8	1,17 1,13	1,4	V
Reverse leakage current	I_r		1600		25 145			50 1100	μA

Thermal

Thermal resistance junction to sink	$R_{th(j-s)}$	$\lambda_{paste} = 3,4 \text{ W/mK}$ (PSX)						1,25		K/W
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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		

H-Bridge Switch

Static

Gate-emitter threshold voltage	$V_{GE(th)}$	$V_{GE} = V_{CE}$			0,0003	25	3,2	4	4,8	V
Collector-emitter saturation voltage	V_{CESat}		15		30	25 125 150		1,35 1,54 1,57	1,75	V
Collector-emitter cut-off current	I_{CES}		0	650		25			50	µA
Gate-emitter leakage current	I_{GES}		20	0		25			100	nA
Internal gate resistance	r_g							none		Ω
Input capacitance	C_{ies}	$f = 1 \text{ MHz}$	0	25	25	1800	55	7	nC	pF
Output capacitance	C_{oes}									
Reverse transfer capacitance	C_{res}									
Gate charge	Q_g		15	520	30	25		70		

Thermal

Thermal resistance junction to sink	$R_{th(j-s)}$	$\lambda_{\text{paste}} = 3,4 \text{ W/mK}$ (PSX)						1,48		K/W
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Dynamic

Turn-on delay time	$t_{d(on)}$	$R_{goff} = 16 \Omega$ $R_{gon} = 16 \Omega$	± 15	400	30	25		63		ns
Rise time	t_r					125		64		
						150		64		
Turn-off delay time	$t_{d(off)}$					25		8		
Fall time	t_f	$Q_{rFWD} = 1 \mu\text{C}$ $Q_{rFWD} = 2,4 \mu\text{C}$ $Q_{rFWD} = 2,9 \mu\text{C}$	± 15	400	30	125		9		mWs
Turn-on energy (per pulse)	E_{on}					150		9		
						25		82		
Turn-off energy (per pulse)	E_{off}					125		102		
						150		106		
						25		26		
						125		50		
						150		56		
						25		0,515		
						125		0,751		
						150		0,817		
						25		0,355		
						125		0,544		
						150		0,598		



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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			

H-Bridge Diode

Static

Forward voltage	V_F			15	25 125 150		1,44 1,20 1,14			V
Reverse leakage current	I_r		650		25			5		µA

Thermal

Thermal resistance junction to sink	$R_{th(j-s)}$	$\lambda_{paste} = 3,4 \text{ W/mK}$ (PSX)					1,81		K/W
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Dynamic

Peak recovery current	I_{RRM}	$di/dt = 4059 \text{ A/µs}$ $di/dt = 3683 \text{ A/µs}$ $di/dt = 3801 \text{ A/µs}$	± 15	400	30	25		47		A
Reverse recovery time	t_{rr}					125		68		
						150		75		
Recovered charge	Q_r					25		60		ns
Recovered charge	Q_r					125		94		
Recovered charge	Q_r					150		99		
Reverse recovered energy	E_{rec}					25		1,048		µC
Reverse recovered energy	E_{rec}					125		2,423		
Reverse recovered energy	E_{rec}					150		2,924		
Peak rate of fall of recovery current	$(di_{rf}/dt)_{max}$					25		0,203		mWs
Peak rate of fall of recovery current	$(di_{rf}/dt)_{max}$					125		0,562		
Peak rate of fall of recovery current	$(di_{rf}/dt)_{max}$					150		0,704		
Peak rate of fall of recovery current	$(di_{rf}/dt)_{max}$					25		5766		A/µs
Peak rate of fall of recovery current	$(di_{rf}/dt)_{max}$					125		3731		
Peak rate of fall of recovery current	$(di_{rf}/dt)_{max}$					150		4055		

Thermistor

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. ±1 %			25		3962			K
B-value	$B_{(25/100)}$	Tol. ±1 %			25		4000			K
Vincotech NTC Reference								I		



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Boost Switch Characteristics

figure 1. IGBT

Typical output characteristics

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

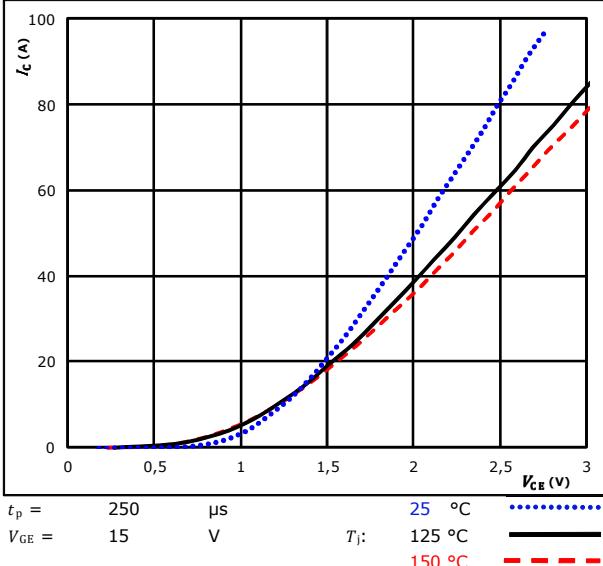


figure 2. IGBT

Typical output characteristics

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

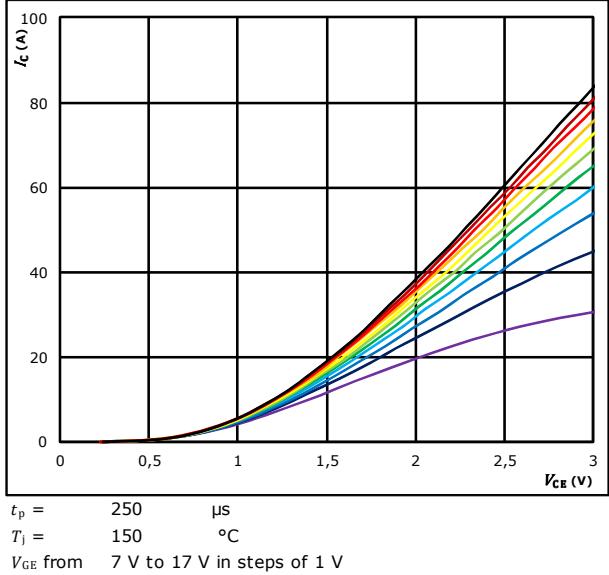


figure 3. IGBT

Typical transfer characteristics

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

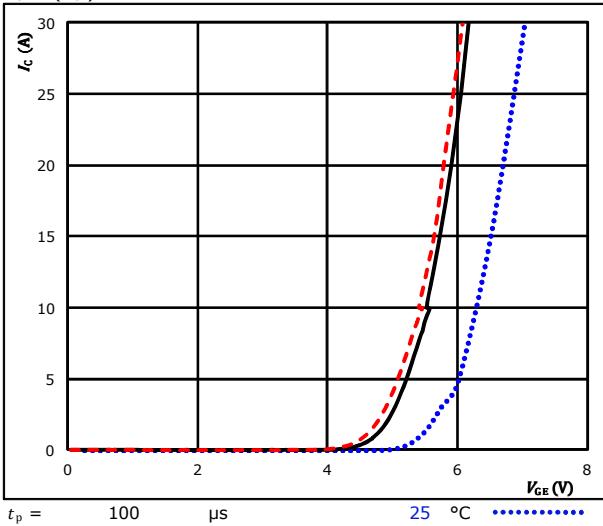
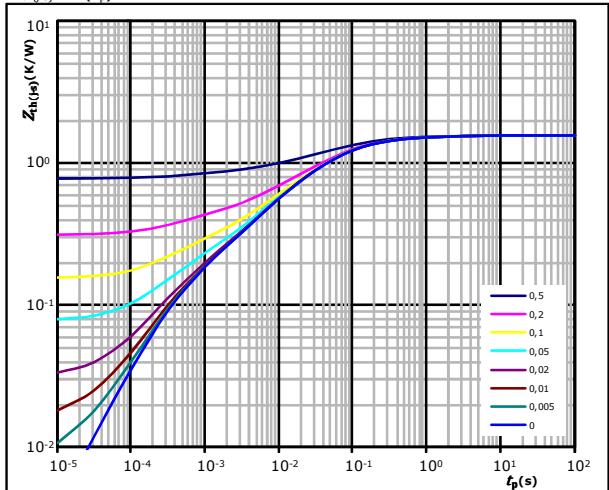


figure 4. IGBT

Transient Thermal Impedance as function of Pulse duration

$$Z_{th(\mu\text{s})} = f(t_p)$$

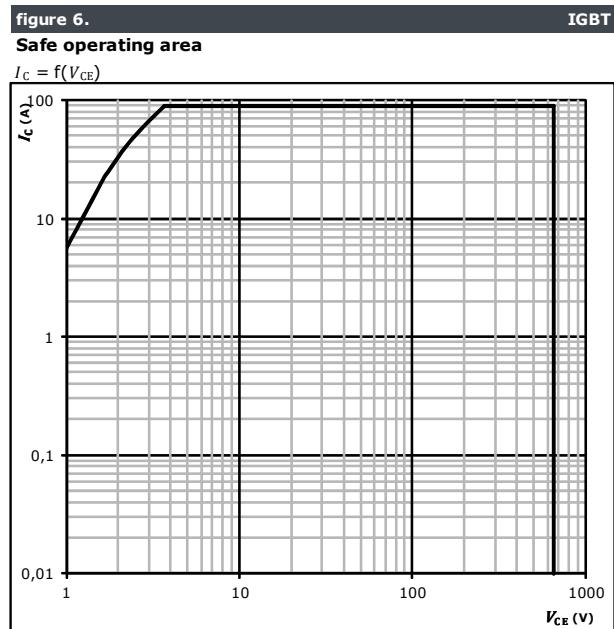
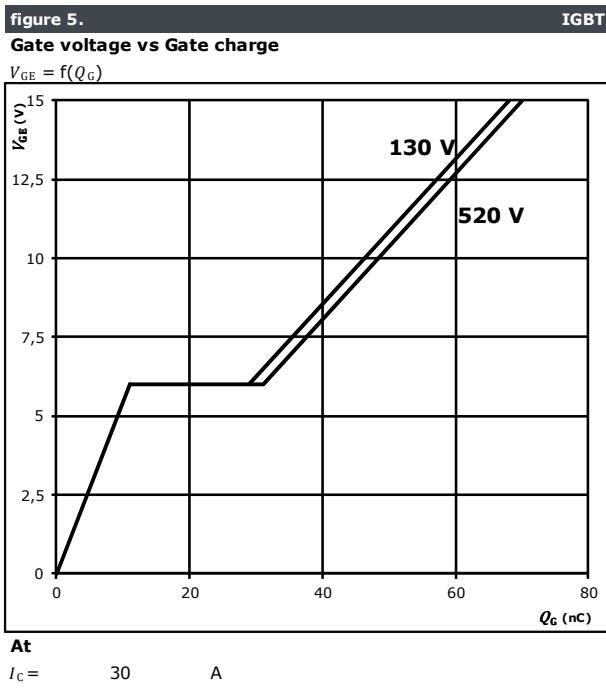




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Boost Switch Characteristics

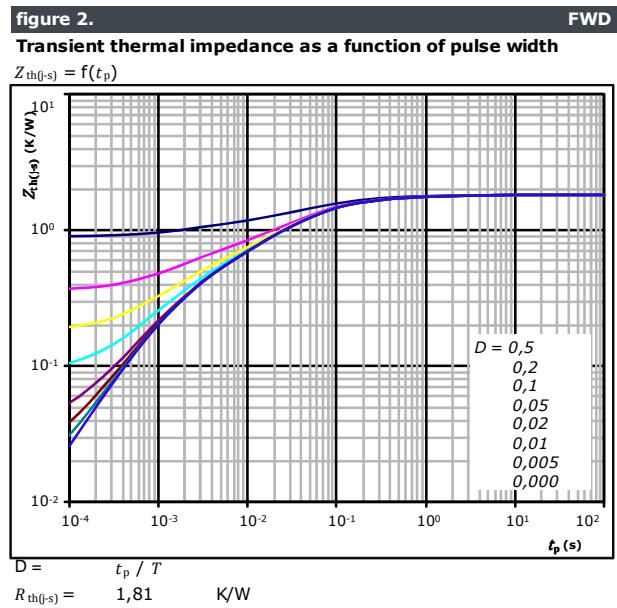
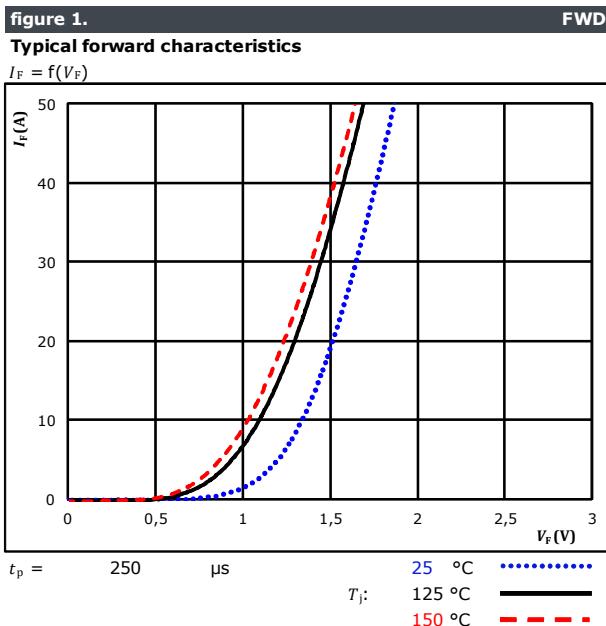




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Boost Diode Characteristics



FWD thermal model values

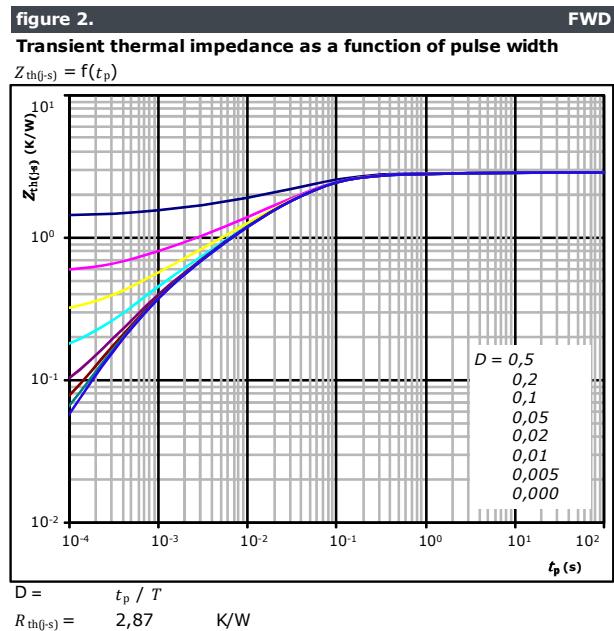
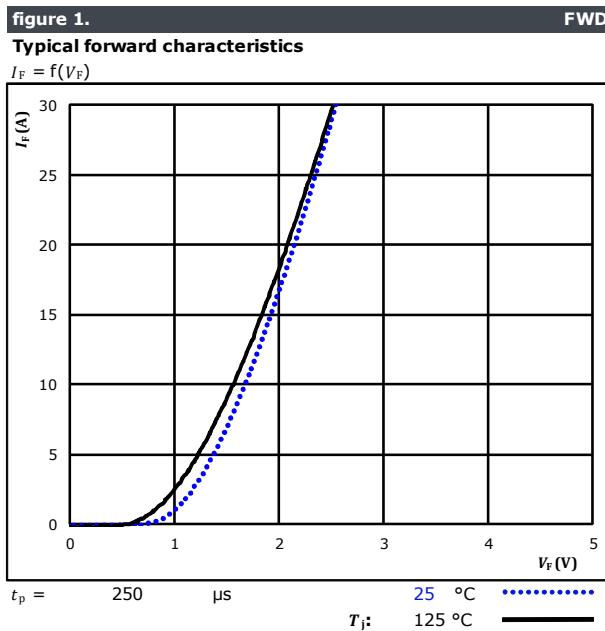
R (K/W)	τ (s)
7,18E-02	2,84E+00
2,48E-01	2,83E-01
8,26E-01	5,02E-02
3,94E-01	8,85E-03
2,67E-01	1,33E-03



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Boost Sw. Protection Diode Characteristics



FWD thermal model values

R (K/W)	τ (s)
6,53E-02	3,94E+00
1,48E-01	4,48E-01
1,31E+00	5,96E-02
7,32E-01	1,36E-02
4,04E-01	2,79E-03
2,11E-01	5,37E-04



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ByPass Diode Characteristics

figure 1.
Typical forward characteristics

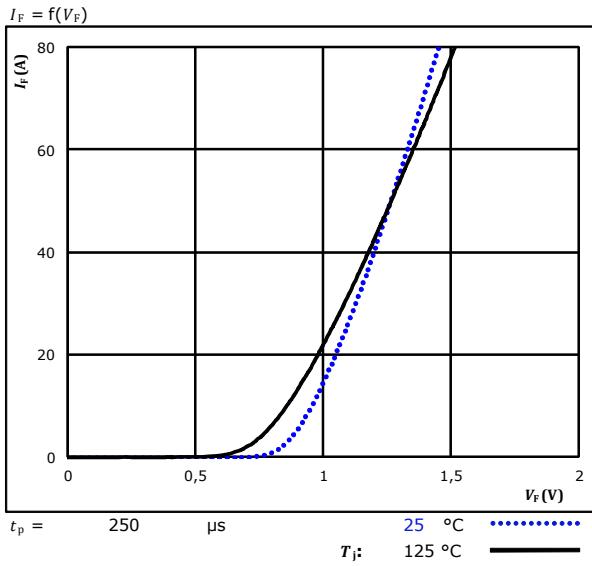
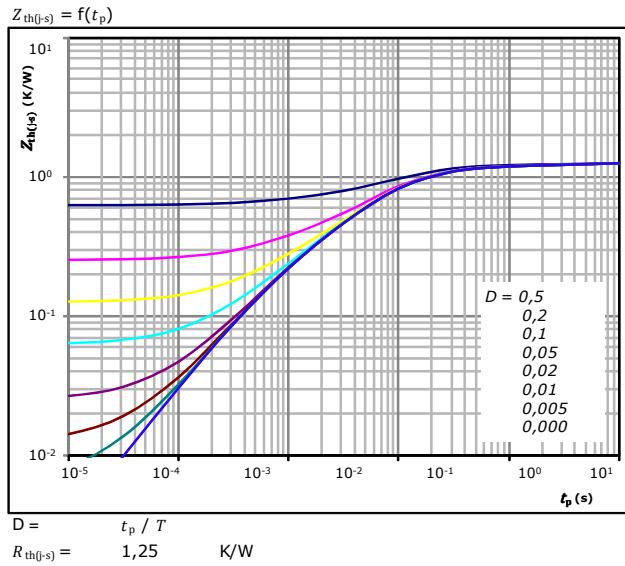


figure 2.
Transient thermal impedance as a function of pulse width



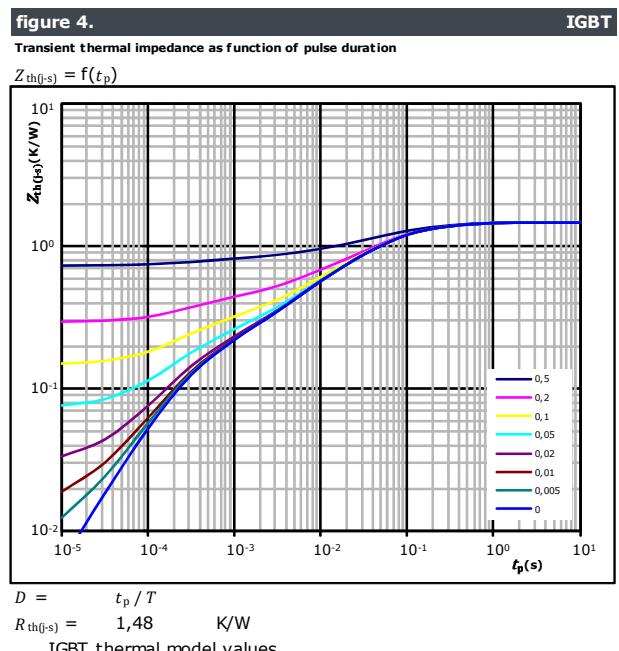
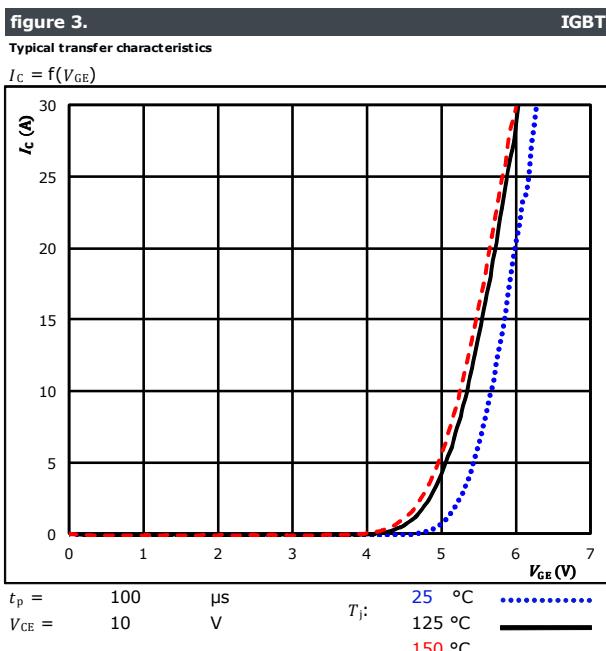
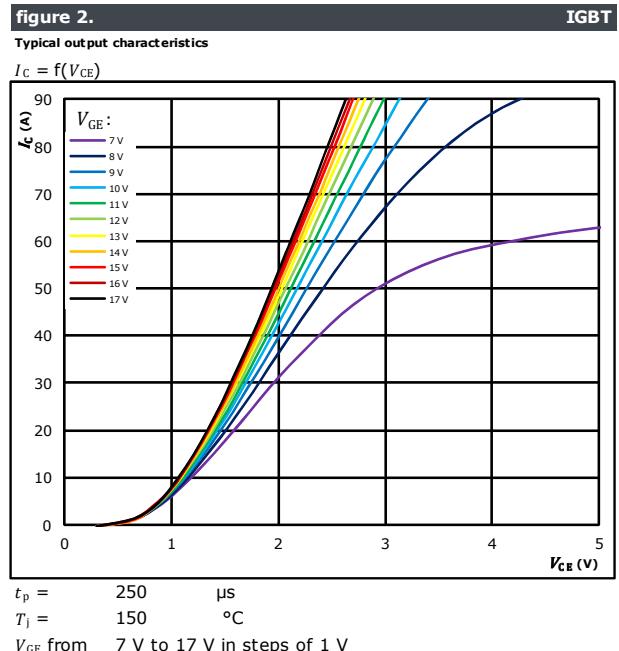
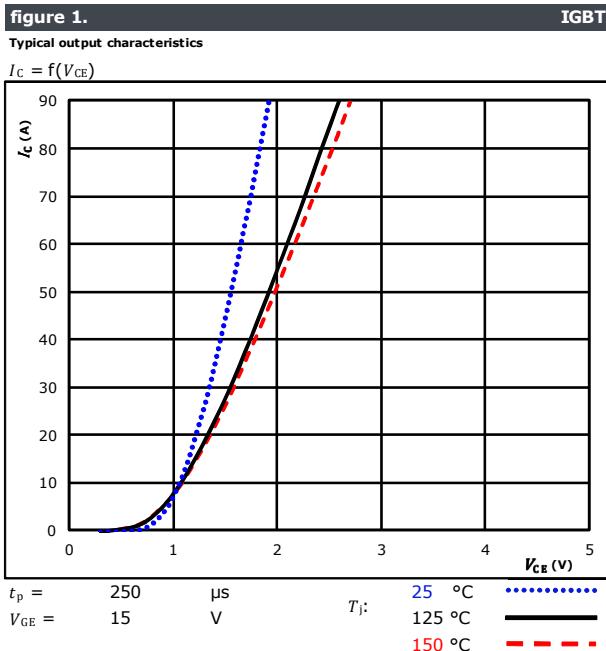
Diode thermal model values

R (K/W)	τ (s)
8,00E-02	5,22E+00
1,56E-01	4,18E-01
6,95E-01	8,82E-02
2,23E-01	3,07E-02
9,97E-02	5,99E-03



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H-Bridge Switch Characteristics

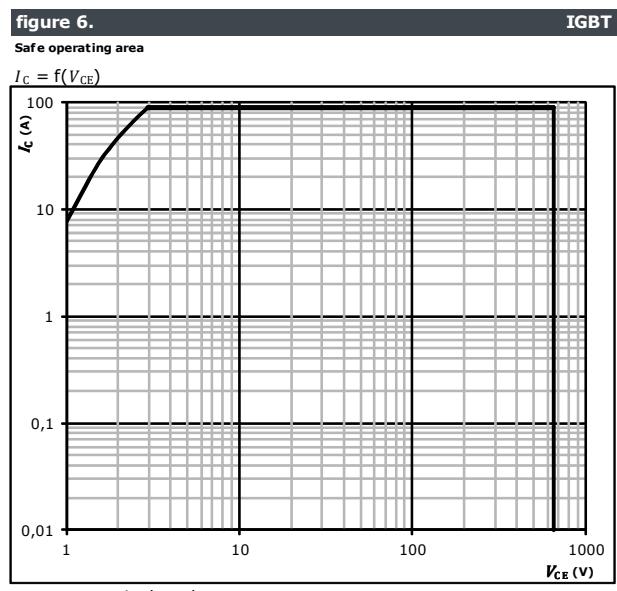
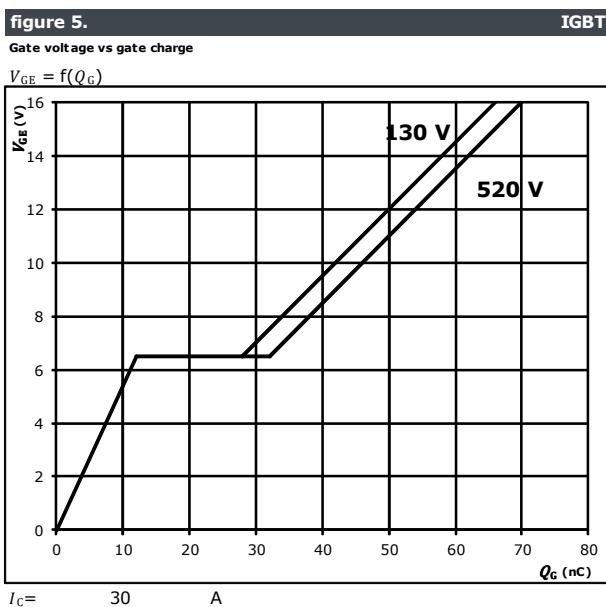




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H-Bridge Switch Characteristics



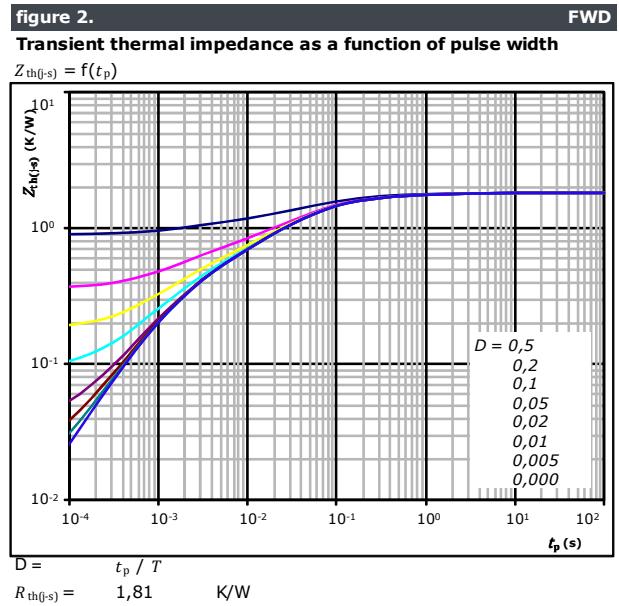
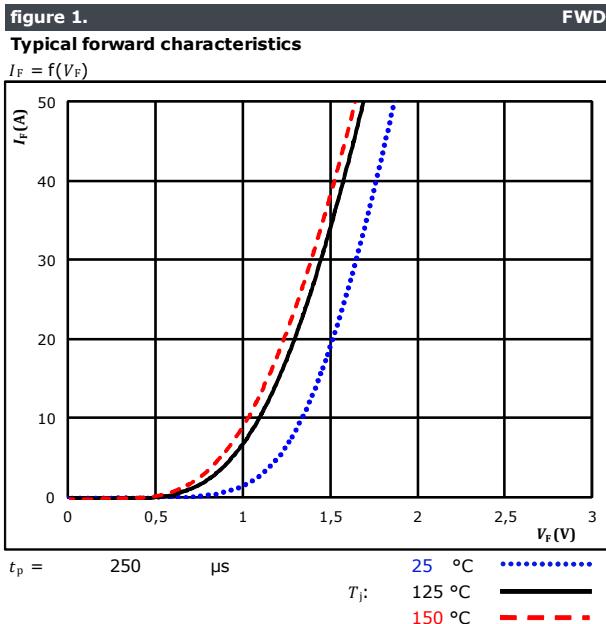
$D =$ single pulse
 $T_s =$ 80 °C
 $V_{GE} =$ ±15 V
 $T_j =$ T_{jmax}



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H-Bridge Diode Characteristics



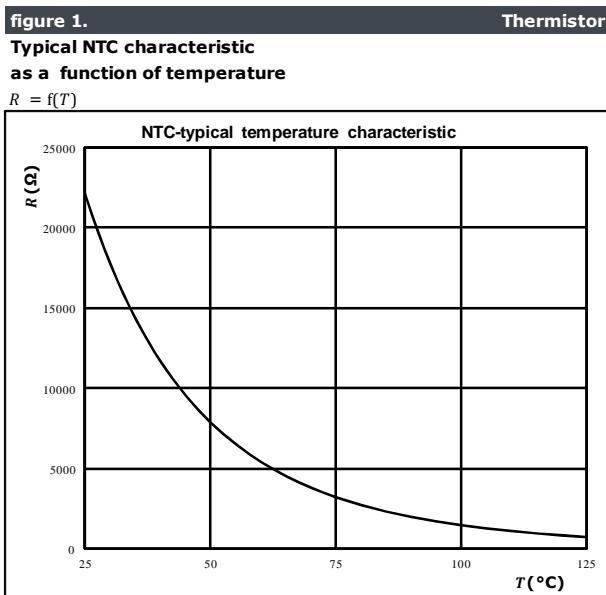
FWD thermal model values

R (K/W)	τ (s)
7,18E-02	2,84E+00
2,48E-01	2,83E-01
8,26E-01	5,02E-02
3,94E-01	8,85E-03
2,67E-01	1,33E-03



Vincotech

Thermistor Characteristics





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Boost Switching Characteristics

figure 1.
Typical switching energy losses as a function of collector current

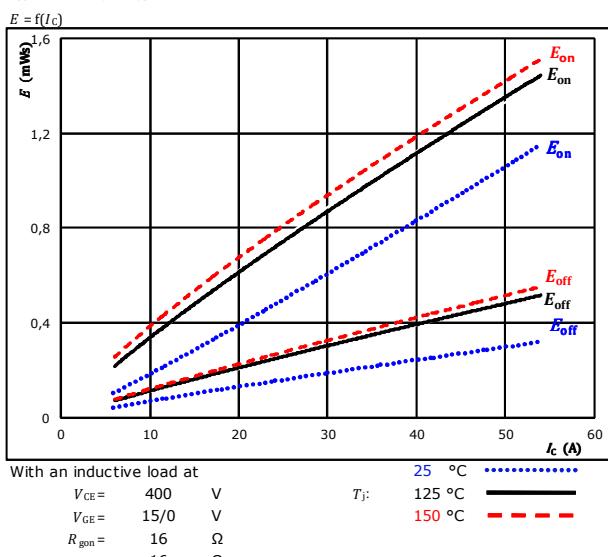


figure 2.
Typical switching energy losses as a function of gate resistor

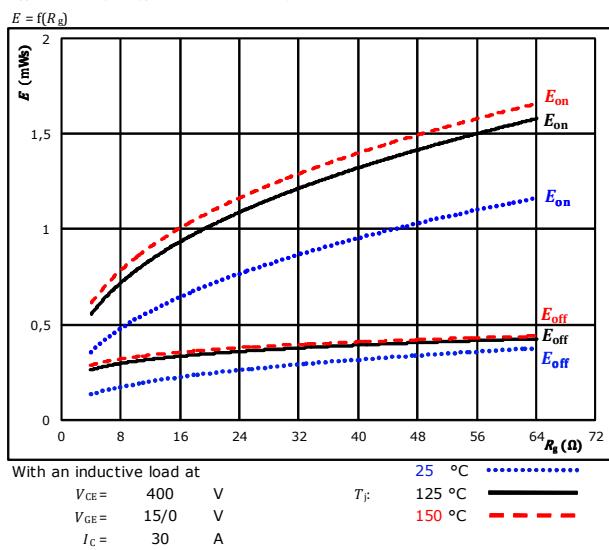


figure 3.
Typical reverse recovered energy loss as a function of collector current

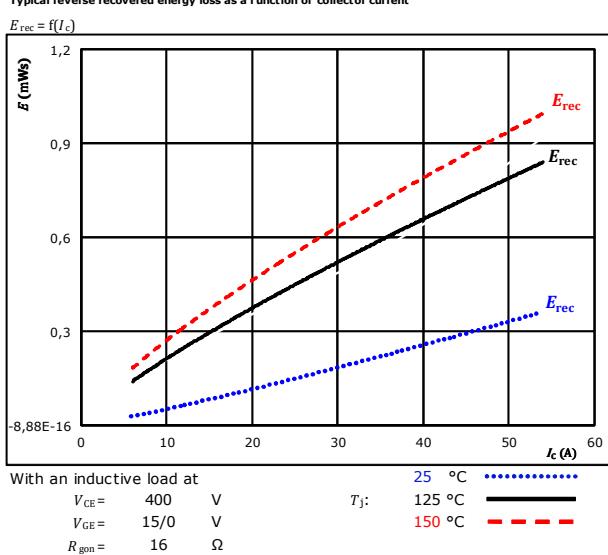
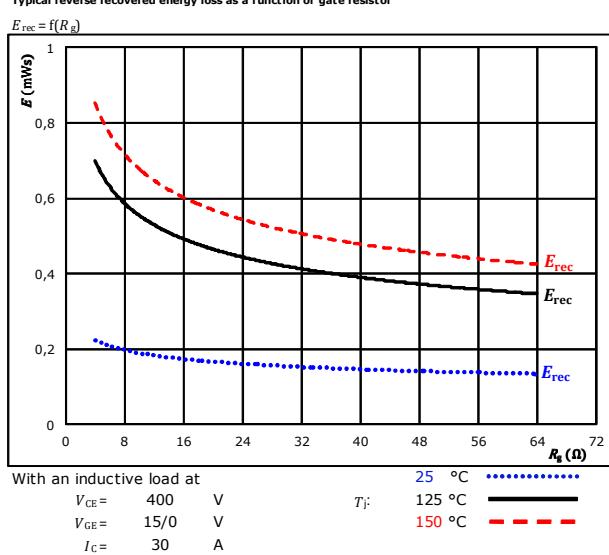


figure 4.
Typical reverse recovered energy loss as a function of gate resistor

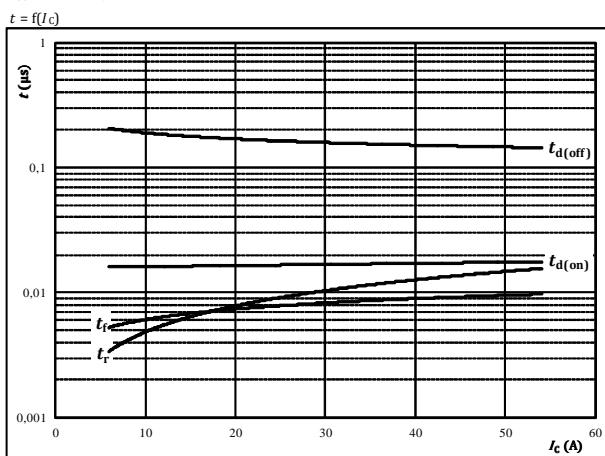




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Boost Switching Characteristics

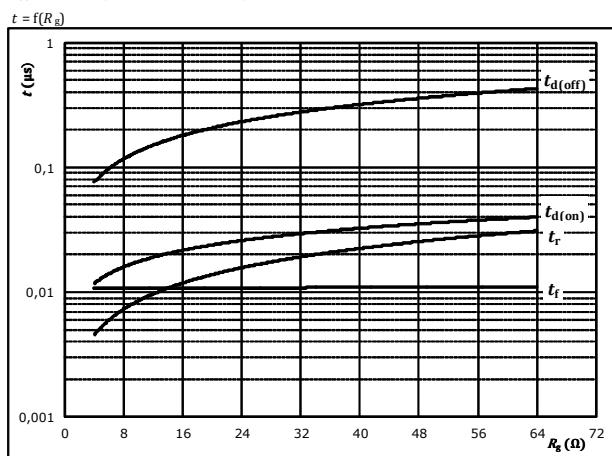
figure 5.
Typical switching times as a function of collector current



With an inductive load at

$T_J =$	150	°C
$V_{CE} =$	400	V
$V_{GE} =$	15/0	V
$R_{gon} =$	16	Ω
$R_{goff} =$	16	Ω

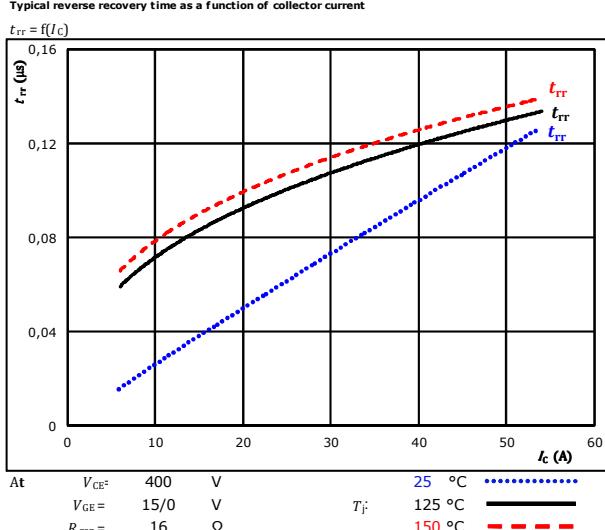
figure 6.
Typical switching times as a function of gate resistor



With an inductive load at

$T_J =$	150	°C
$V_{CE} =$	400	V
$V_{GE} =$	15/0	V
$I_C =$	30	A

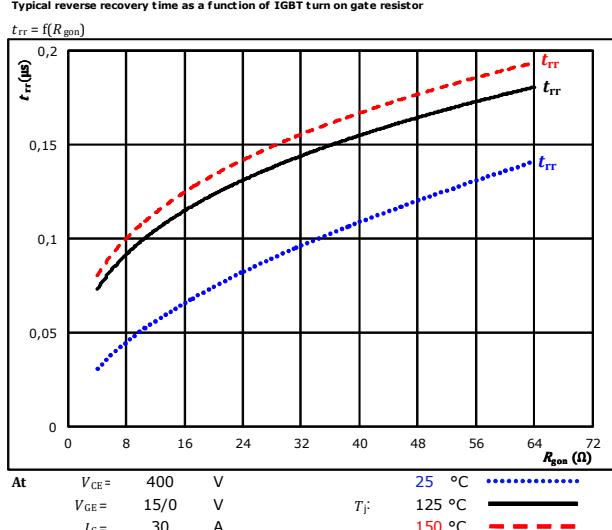
figure 7.
Typical reverse recovery time as a function of collector current



At

$V_{CE} =$	400	V	25 °C
$V_{GE} =$	15/0	V	$T_J =$	125 °C —
$R_{gon} =$	16	Ω		150 °C - - -

figure 8.
Typical reverse recovery time as a function of IGBT turn on gate resistor



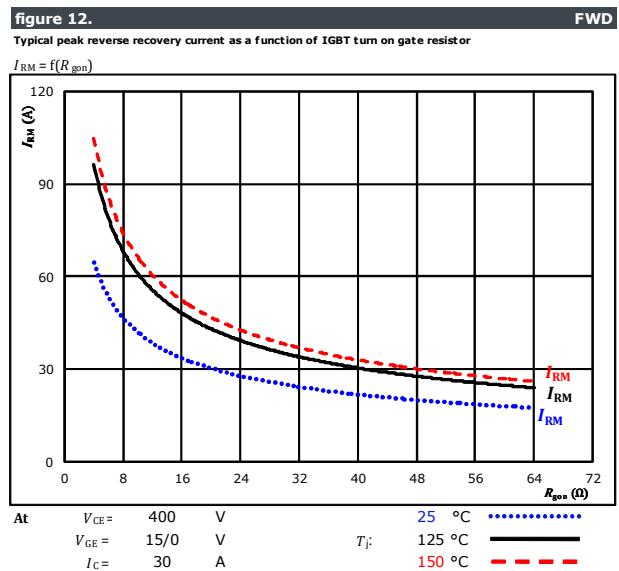
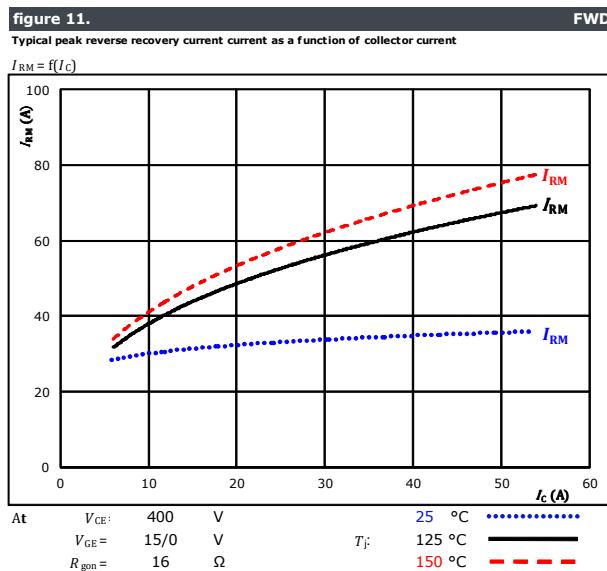
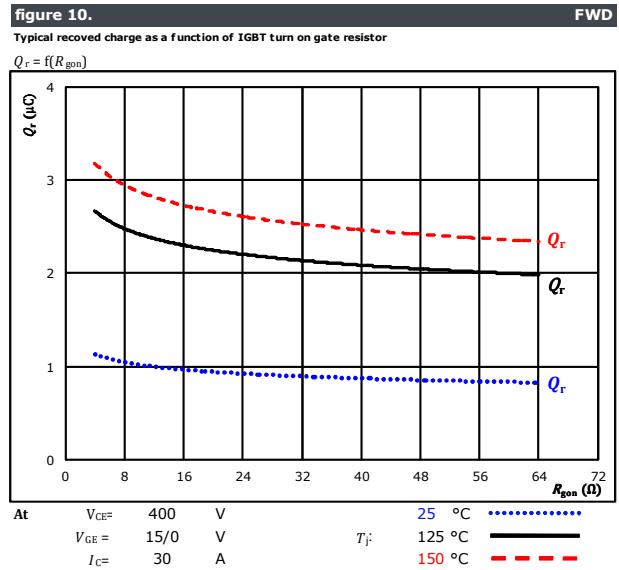
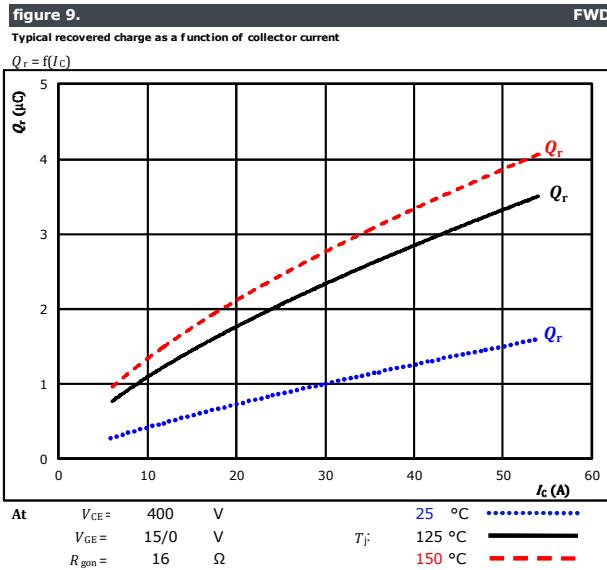
At

$V_{CE} =$	400	V	25 °C
$V_{GE} =$	15/0	V	$T_J =$	125 °C —
$I_C =$	30	A		150 °C - - -



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Boost Switching Characteristics





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Boost Switching Characteristics

figure 13.

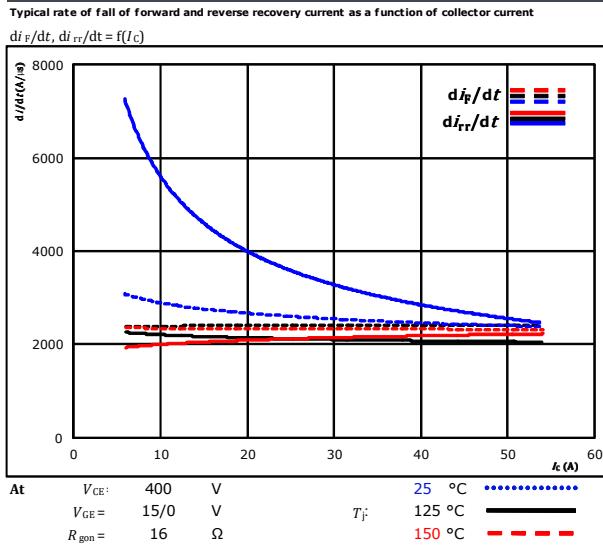


figure 14.

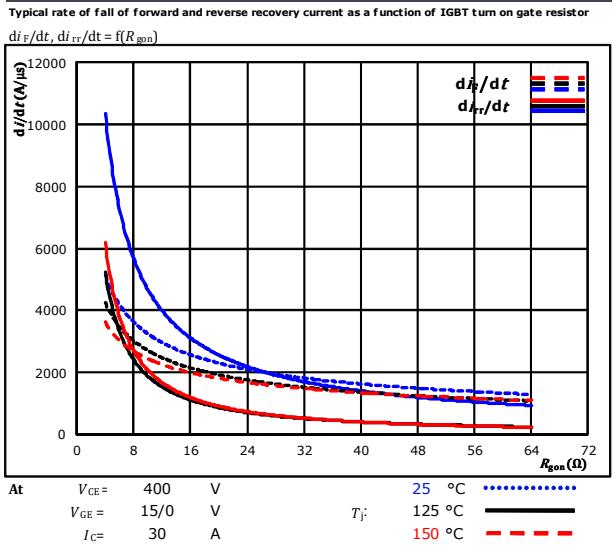
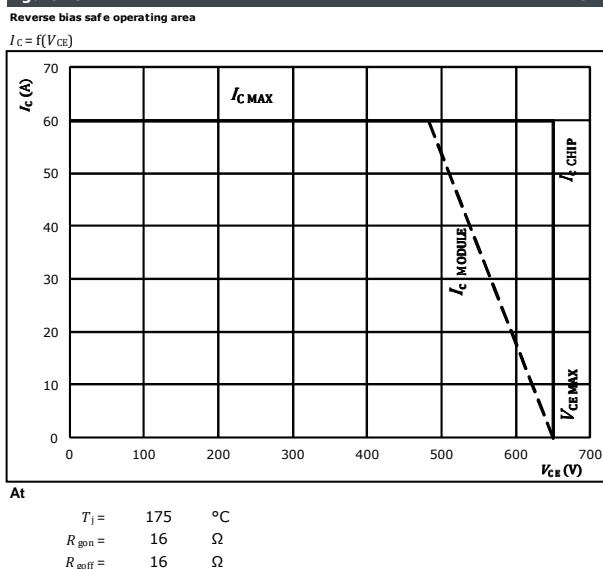


figure 15.





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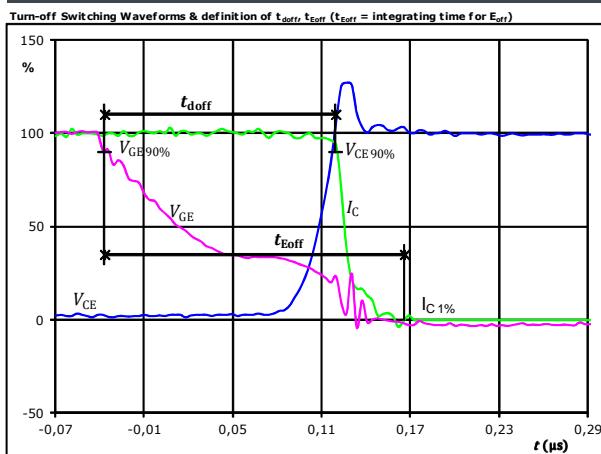
Boost Switching Definitions

General conditions

T_j	=	125 °C
R_{gon}	=	16 Ω
R_{goff}	=	16 Ω

figure 1.

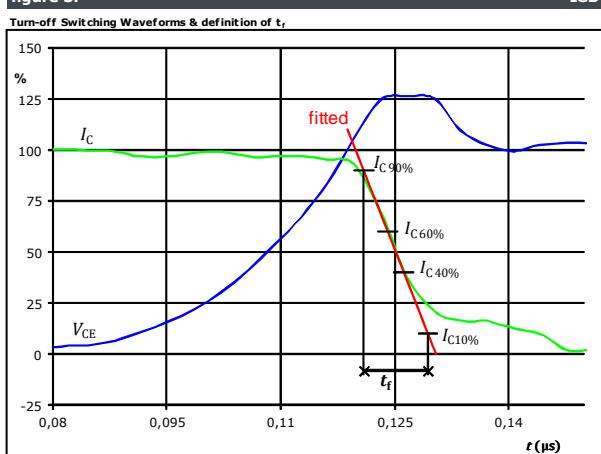
IGBT



$V_{GE}(0\%) =$	0	V
$V_{GE}(100\%) =$	15	V
$V_C(100\%) =$	400	V
$I_C(100\%) =$	30	A
$t_{doff} =$	0,155	μs
$t_{Eoff} =$	0,202	μs

figure 3.

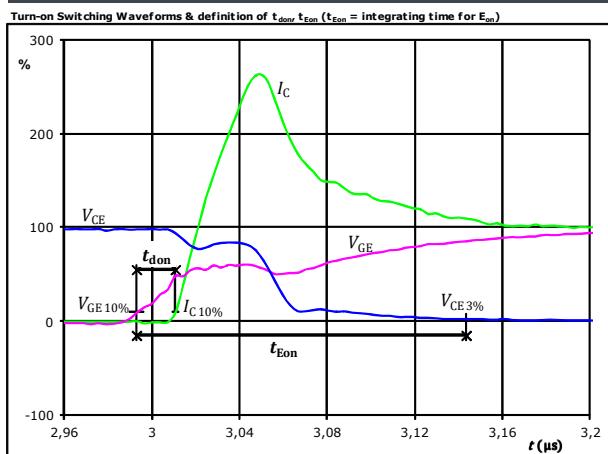
IGBT



$V_C(100\%) =$	400	V
$I_C(100\%) =$	30	A
$t_f =$	0,009	μs

figure 2.

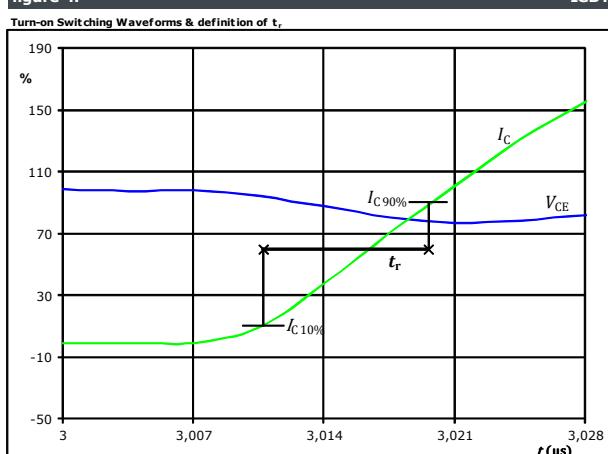
IGBT



$V_{GE}(0\%) =$	0	V
$V_{GE}(100\%) =$	15	V
$V_C(100\%) =$	400	V
$I_C(100\%) =$	30	A
$t_{don} =$	0,019	μs
$t_{Eon} =$	0,150	μs

figure 4.

IGBT

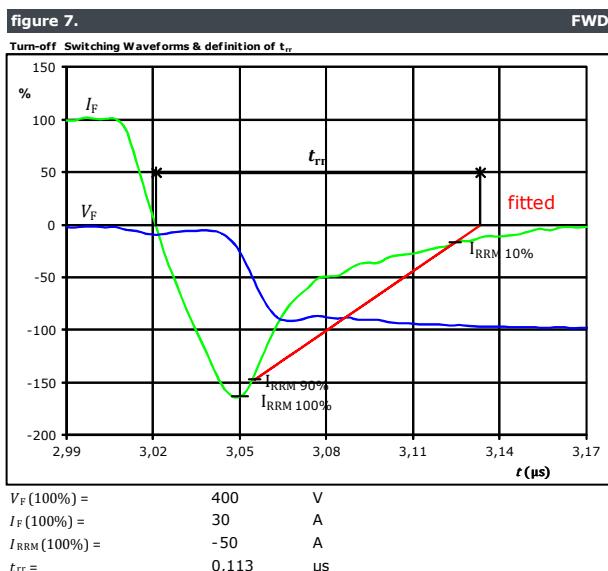
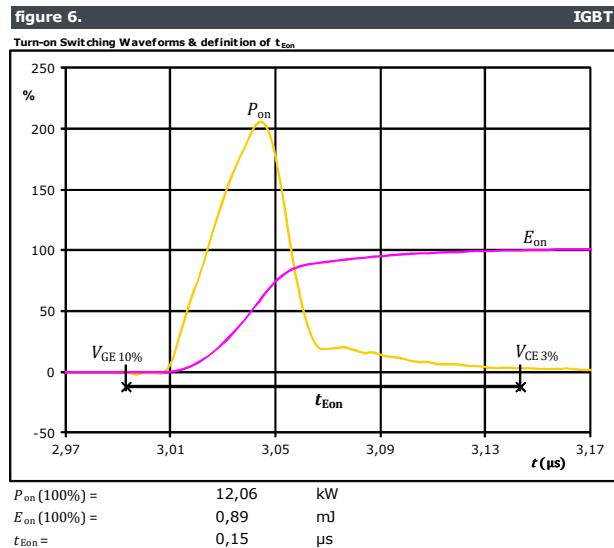
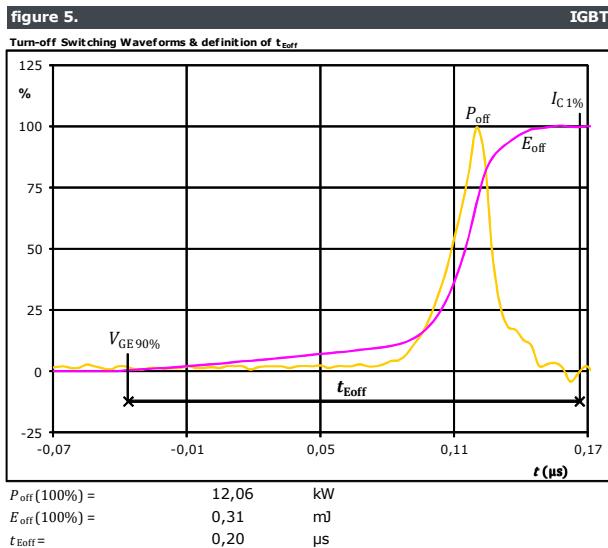


$V_C(100\%) =$	400	V
$I_C(100\%) =$	30	A
$t_r =$	0,009	μs



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Boost Switching Characteristics

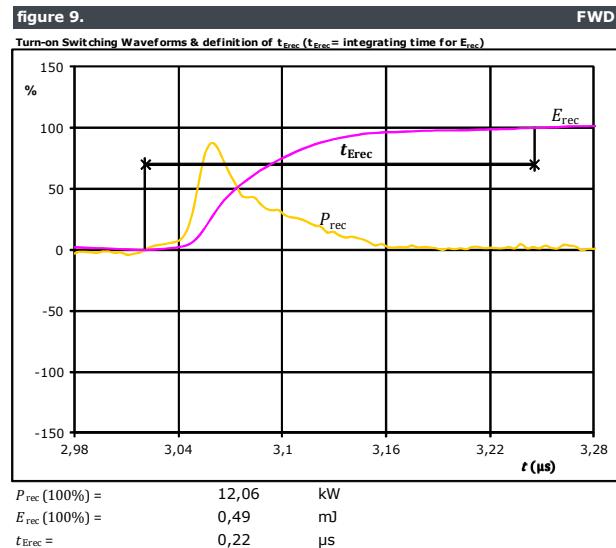
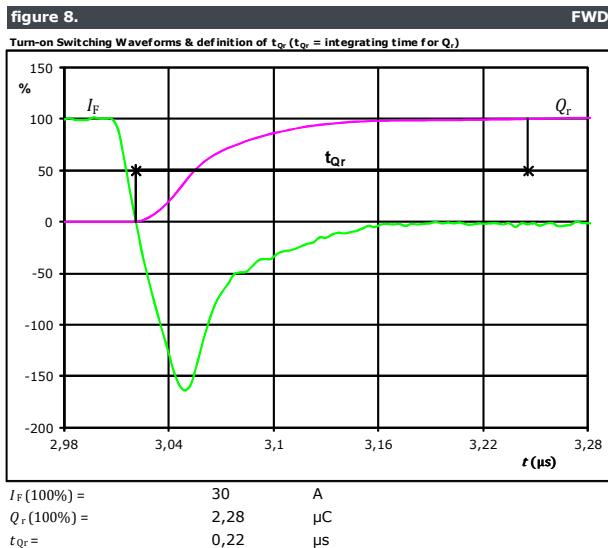




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Boost Switching Characteristics





H-Bridge Switching Characteristics

figure 1.

Typical switching energy losses as a function of collector current

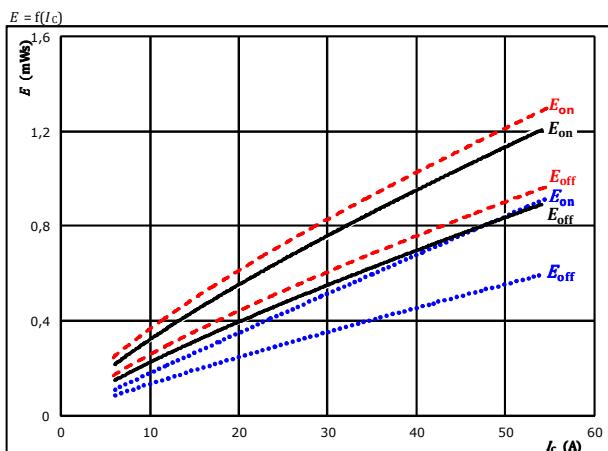


figure 2.

Typical switching energy losses as a function of gate resistor

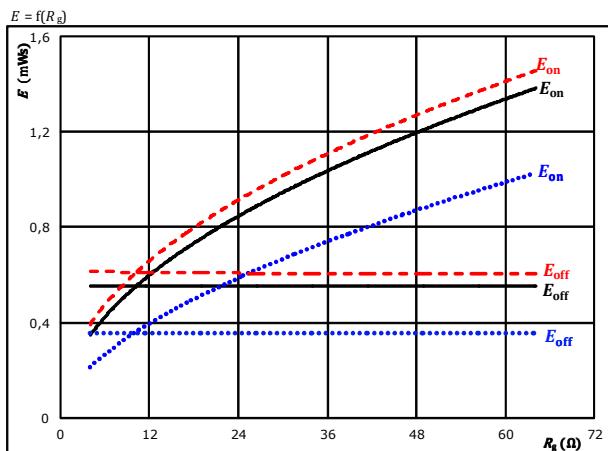


figure 3.

Typical reverse recovered energy loss as a function of collector current

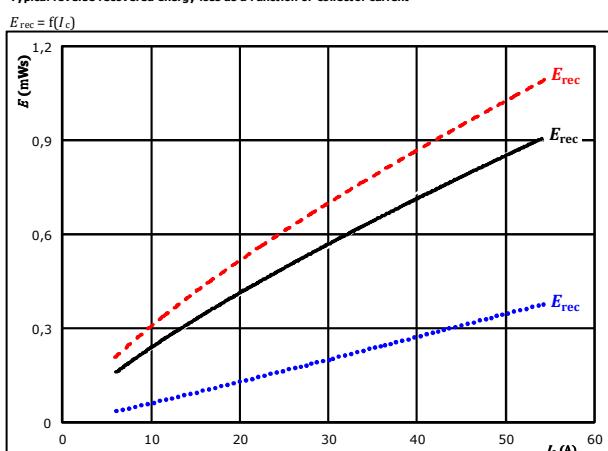
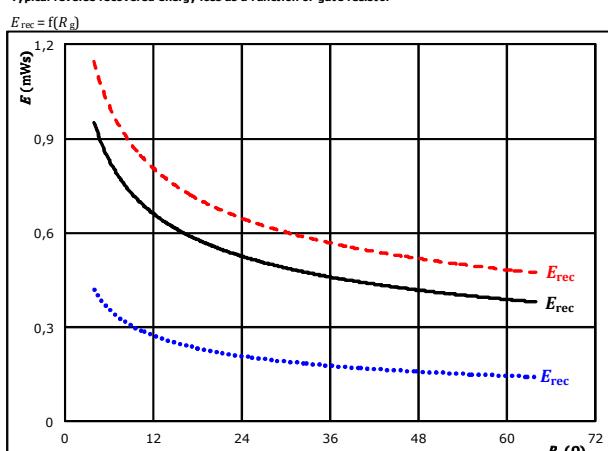


figure 4.

Typical reverse recovered energy loss as a function of gate resistor

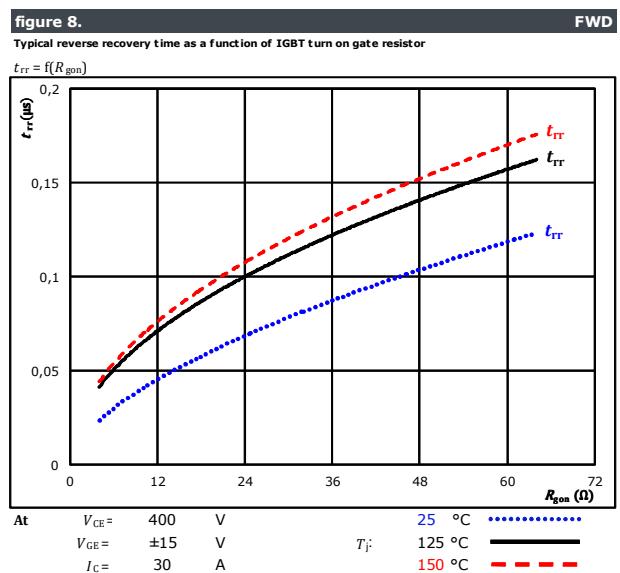
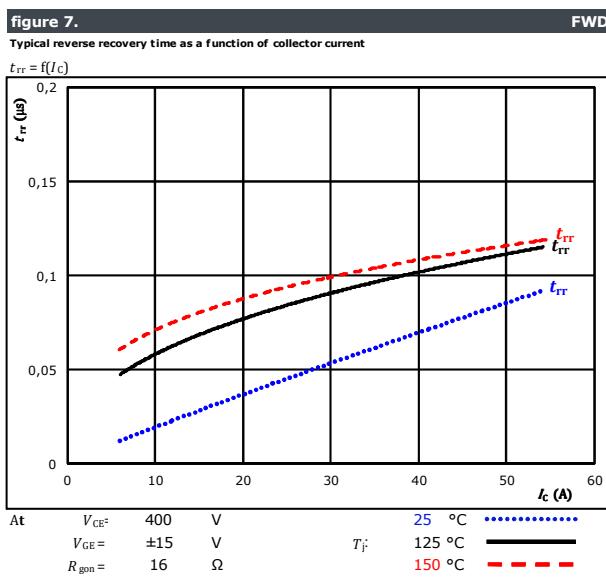
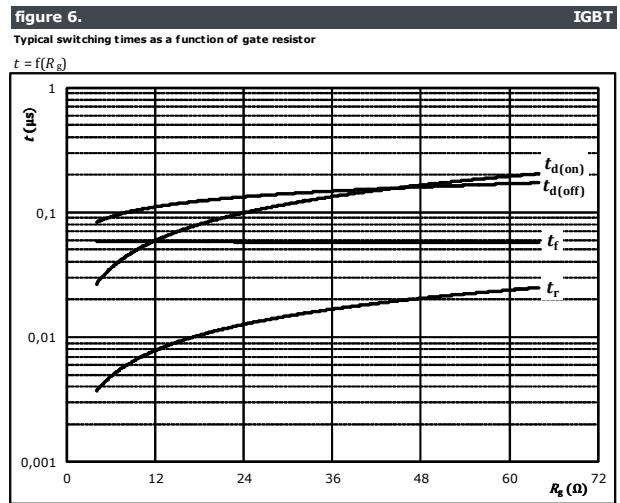
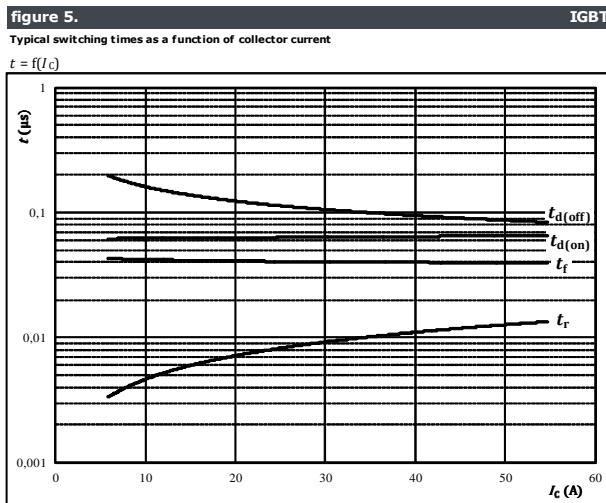




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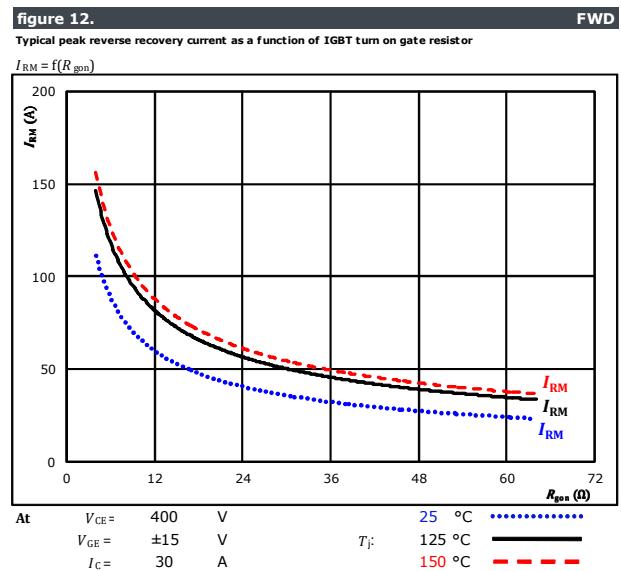
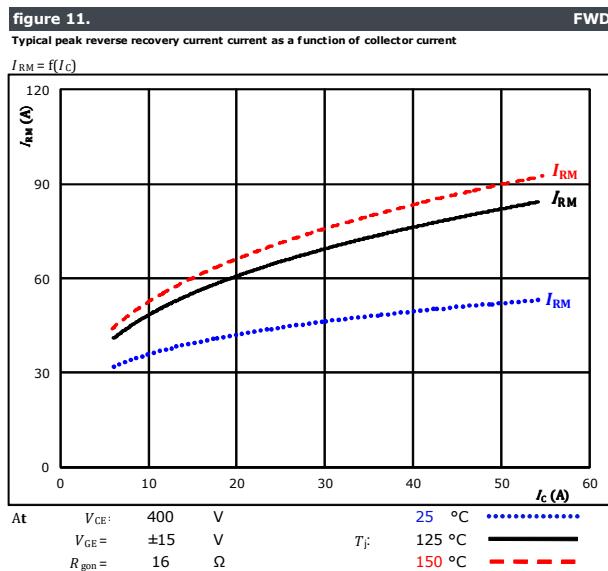
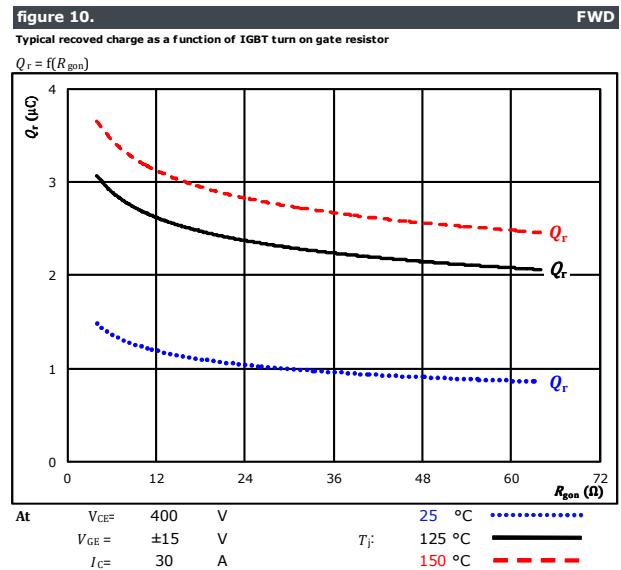
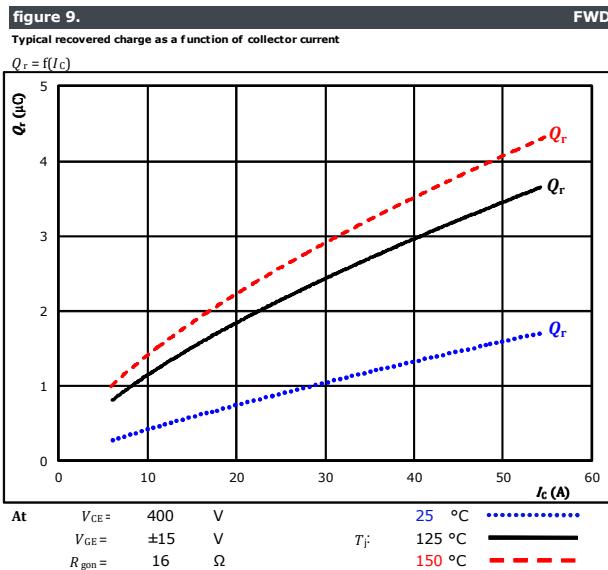
H-Bridge Switching Characteristics





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H-Bridge Switching Characteristics





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H-Bridge Switching Characteristics

figure 13.

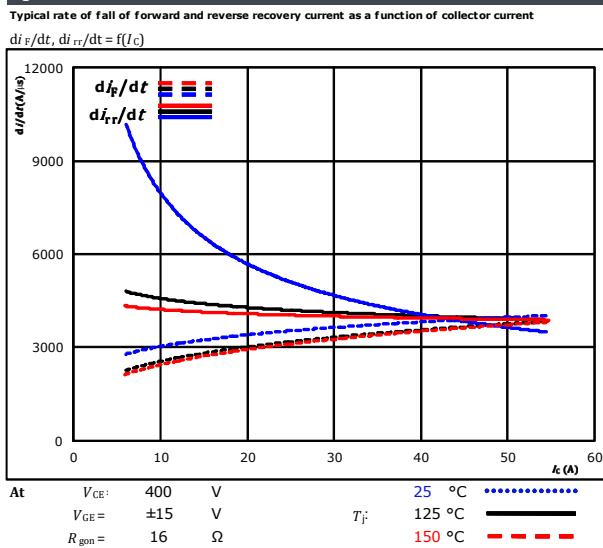


figure 14.

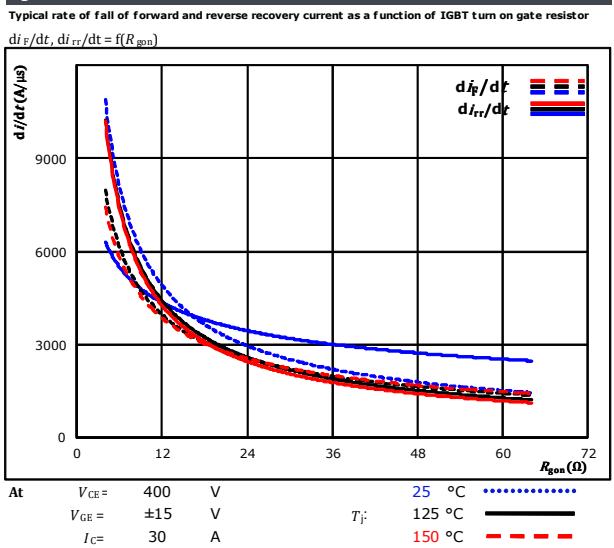
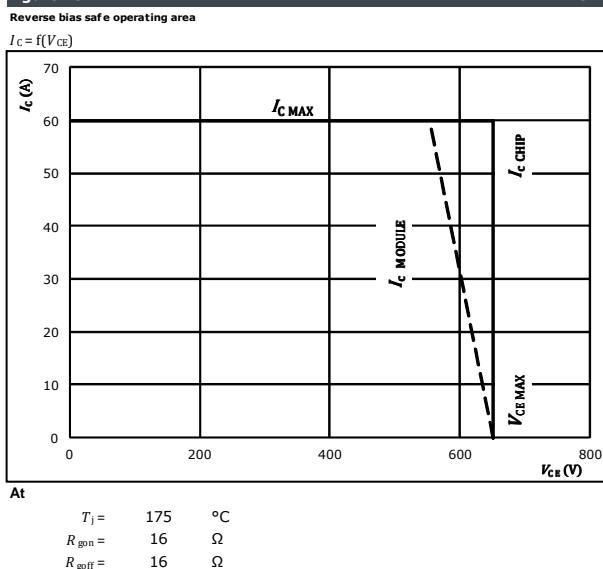


figure 15.





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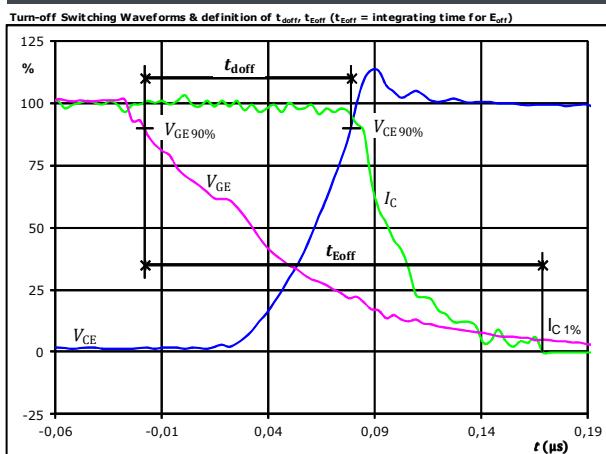
H-Bridge Switching Definitions

General conditions

T_j	=	150 °C
R_{gon}	=	16 Ω
R_{goff}	=	16 Ω

figure 1.

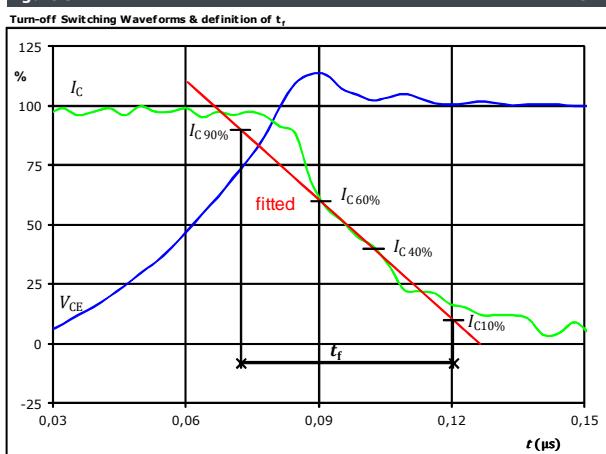
IGBT



$V_{GE\ (0\%)} = -15 \text{ V}$
 $V_{GE\ (100\%)} = 15 \text{ V}$
 $V_C\ (100\%) = 400 \text{ V}$
 $I_C\ (100\%) = 30 \text{ A}$
 $t_{doff} = 0,102 \mu\text{s}$
 $t_{Eoff} = 0,186 \mu\text{s}$

figure 3.

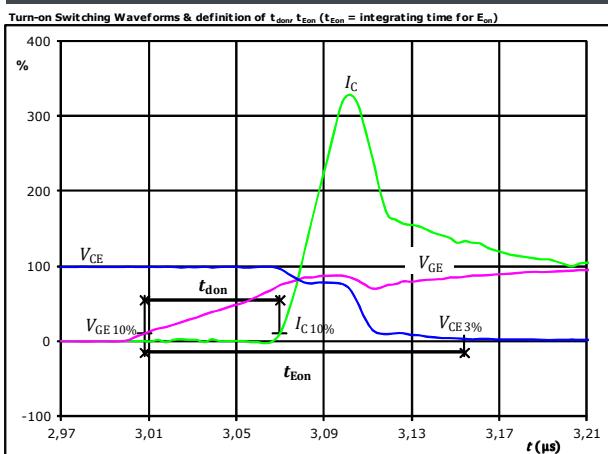
IGBT



$V_C\ (100\%) = 400 \text{ V}$
 $I_C\ (100\%) = 30 \text{ A}$
 $t_f = 0,050 \mu\text{s}$

figure 2.

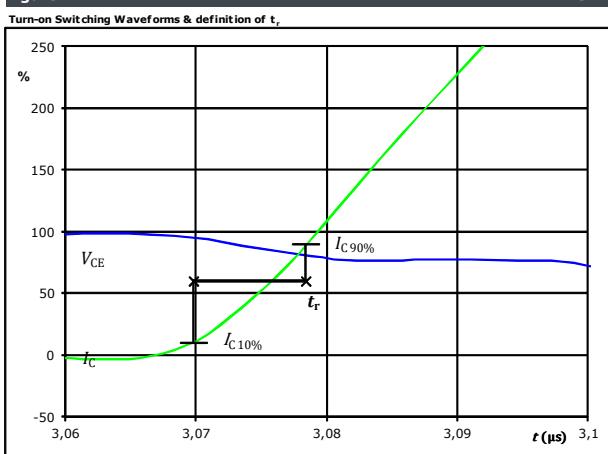
IGBT



$V_{GE\ (0\%)} = -15 \text{ V}$
 $V_{GE\ (100\%)} = 15 \text{ V}$
 $V_C\ (100\%) = 400 \text{ V}$
 $I_C\ (100\%) = 30 \text{ A}$
 $t_{don} = 0,064 \mu\text{s}$
 $t_{Eon} = 0,146 \mu\text{s}$

figure 4.

IGBT



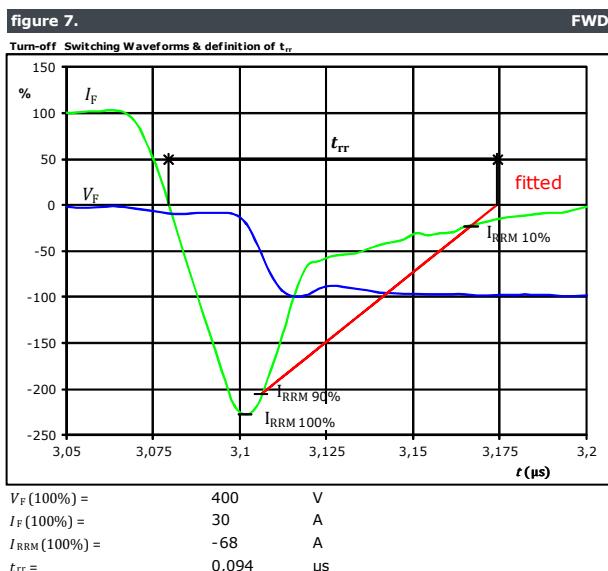
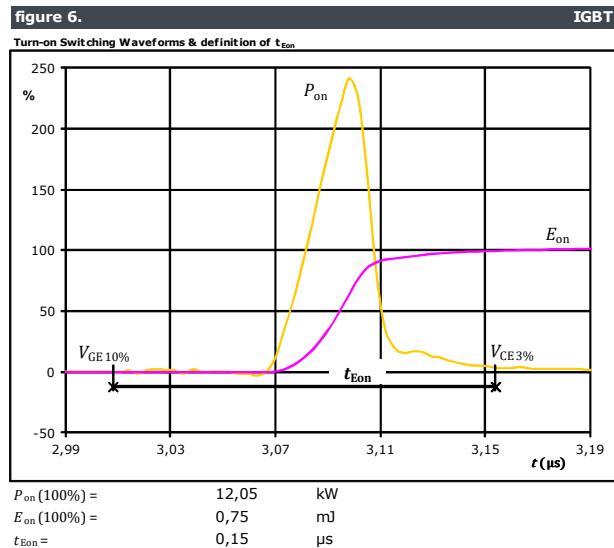
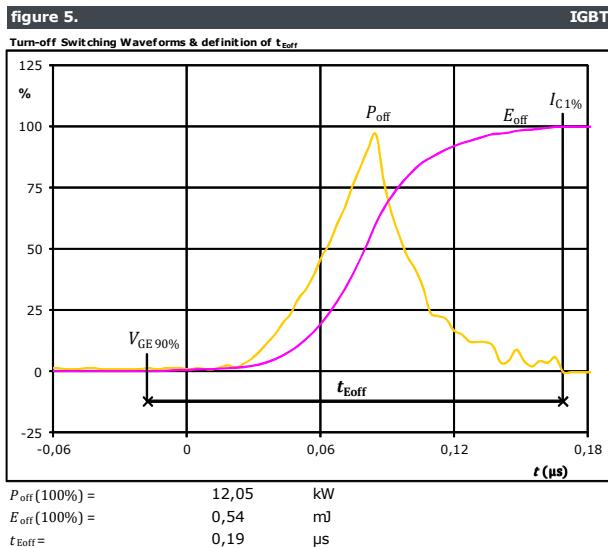
$V_C\ (100\%) = 400 \text{ V}$
 $I_C\ (100\%) = 30 \text{ A}$
 $t_r = 0,009 \mu\text{s}$



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H-Bridge Switching Characteristics

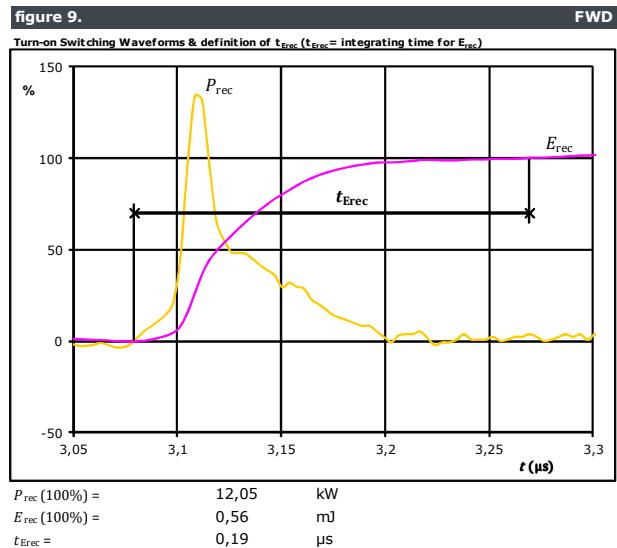
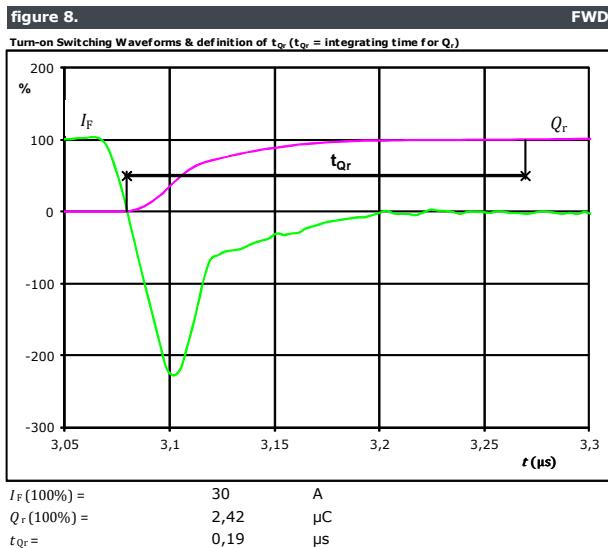




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H-Bridge Switching Characteristics





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datasheet

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Ordering Code & Marking					
Version			Ordering Code		
without thermal paste 12 mm housing with solder pins			10-FZ07BIA030S5Y-P894E78		
with thermal paste 12 mm housing with solder pins			10-FZ07BIA030S5Y-P894E78-/3/		
without thermal paste 12 mm housing with press-fit pins			10-PZ07BIA030S5Y-P894E78Y		
with thermal paste 12 mm housing with press-fit pins			10-PZ07BIA030S5Y-P894E78Y-/3/		
NN-NNNNNNNNNNNNNN TTTTTTVV WWYY UL VIN LLLL SSSS			Text	Name	Date code
			NN-NNNNNNNNNNNNNN-TTTTTTVV	WWYY	UL VIN
			Datamatrix	Type&Ver	Lot number
			TTTTTTVV	LLLLL	SSSS
				Serial	Date code
				SSSS	WWYY

Outline					
Pin table					
Pin	X	Y	Function		
1	28,7	0	G4		
2	25,9	0	S4		
3	23,1	0	-INV		
4	17,6	0	+INV		
5	12,1	0	G3		
6	9,3	0	S3		
7	2,8	0	G5		
8	0	0	S5		
9	0	5,05	-DC		
10	0	10,55	+DC		
11	0	16,15	Sol		
12	0	22,6	Boost		
13	9,3	22,6	S1		
14	12,1	22,6	G1		
15	17,6	22,6	+INV		
16	23,1	22,6	-INV		
17	25,9	22,6	S2		
18	28,7	22,6	G2		
19	33,6	20,05	L1		
20	33,6	14,55	R1		
21	33,6	8,05	R2		
22	33,6	2,55	L2		
23	Not assembled				

center of press-fit pinhead
for connection parameter see the handling instruction

Y
13

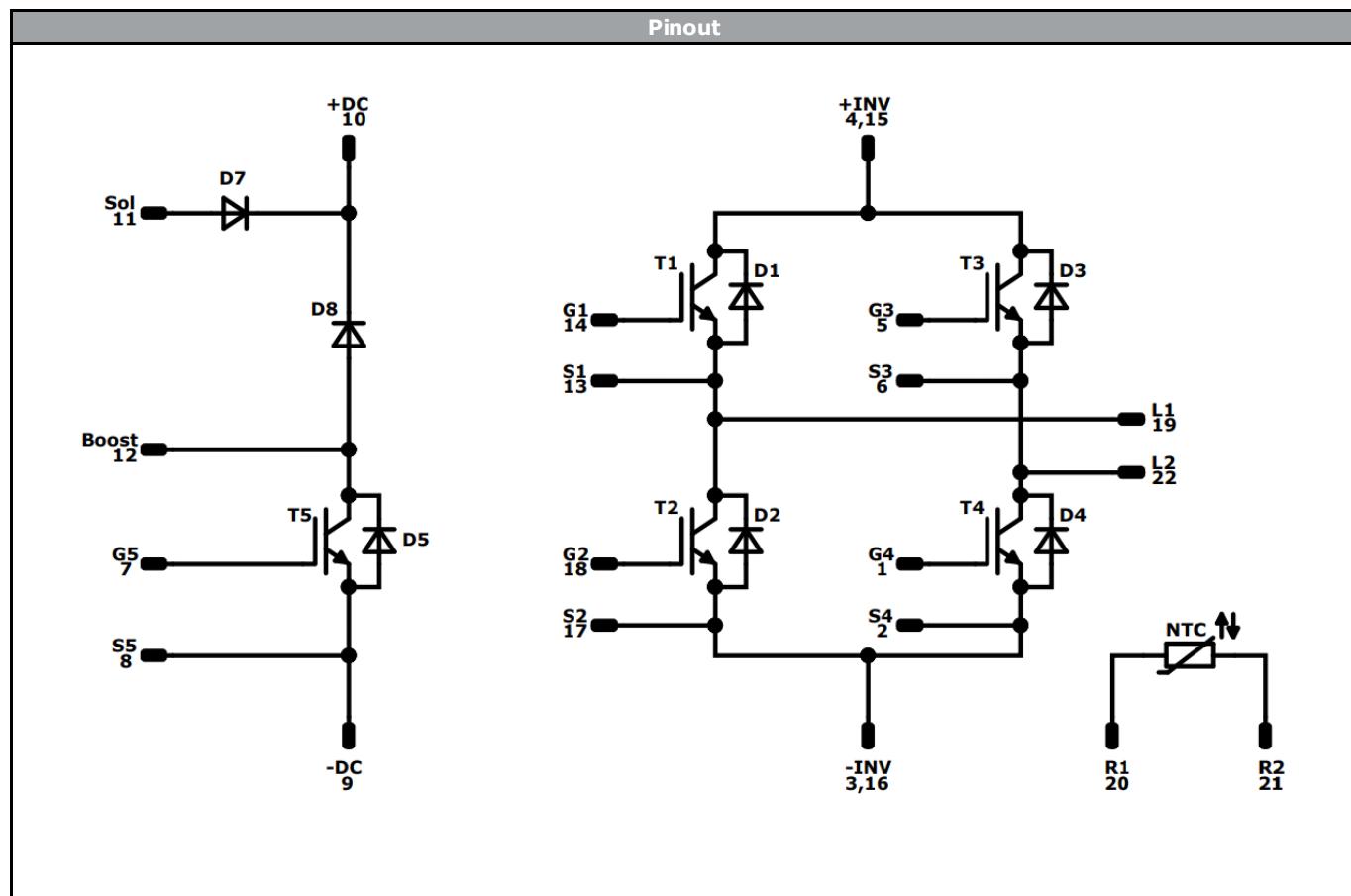
X
16.8

Tolerance of pinpositions: ±0.5mm at the end of pins
Dimension of coordinate axis is only offset without tolerance



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Identification					
ID	Component	Voltage	Current	Function	Comment
T5	IGBT	650 V	30 A	Boost Switch	
D8	FWD	650 V	15 A	Boost Diode	
D5	FWD	650 V	10 A	Boost Sw. Protection Diode	
D7	Rectifier	1600 V	35 A	ByPass Diode	
T1-T4	IGBT	650 V	30 A	H-Bridge Switch	
D1-D4	FWD	650 V	15 A	H-Bridge Diode	
NTC	NTC			Thermistor	



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Packaging instruction			
Standard packaging quantity (SPQ) 135	>SPQ	Standard	<SPQ Sample

Handling instruction			
Handling instructions for flow 0 packages see vincotech.com website.			

Package data			
Package data for flow 0 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-xZ07BIA030S5Y-P894E78x-D2-14	25 Apr. 2018	Press fit version added	

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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, 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.