



Rigel Test Certificates

1.Site :Servicio Tecnico
Location :GREX TECHNICA
Asset :CERTIFICADO 2009/015
Description :DESFIBRILADOR
SerialNo :31316022
Applied Parts :[2BF]
Manufacturer :Medtronic
Model :LIFEPAK 20

Test	Mains	SFC	AP	Type	Limit	Result	Unit	Status
Earth Bond DC(200mA)	-----	-----	--	None	0.30	0.095	Ohms	P
Live PE Voltage	-----	-----	--	----	----	132	V	P
Neutral PE Voltage	-----	-----	--	----	----	132	V	P
Load Current	-----	-----	--	----	----	0.3	A	P
Load(kVA)	-----	-----	--	----	----	0.0	kVA	P
Equipment Leakage(Dir)	Normal	-----	--	----	500	143	µA	P
Equipment Leakage(Dir)	Reversed	-----	--	----	500	187	µA	P
AP Leakage(Dir)	Normal	-----	1	BF	5000	<25	µA	P
AP Leakage(Dir)	Reversed	-----	1	BF	5000	<25	µA	P

Comments :Mediciones correctas
TEST CORRECTO

Overall Status :Passed
Date-of-Test :24/12/2009
Test Instrument :Rigel288 Z48-0369
Tested by :Marc Salomo

PHASE 3 DEFIBRILLATOR ANALYZER
Datrend Systems Inc.

TEST REPORT No. 10

DATE OF TEST: dic 24, 2009
TIME OF TEST: 02:53:41 PM
PHASE 3 I.D.: MY PHASE 3
DEVICE I.D.: 31316022
DUT TYPE: AED
TEST TYPE: Autosequence 32

1.0 DEFIB TESTS

1.1 AED Performance

Tests performed: 13/32

TEST	ECG		SHOCKABLE?	ENERGY	RESULT
	SIMULATOR				
-----Wave	-----Scale			(J)	-----
1	AFIB1	x1	NO	0.0	PASS
2	AFIB2	x1	NO	0.0	PASS
3	ASYS1	x1	NO	0.0	PASS
4	ASYS2	x1	NO	0.0	PASS
5	SVTACH	x1	NO	0.0	PASS
6	VTACH1	x1	NO	0.0	PASS
7	VFIB1	x1	YES	200.4	PASS
8	VFIB1	x1	YES	301.9	PASS
9	PVTACH	x1	YES	361.2	PASS
10	ASYS1	x1	NO	0.0	PASS
11	VTACH3	x1	YES	361.3	PASS
12	PVTACH	x1	YES	361.3	PASS
13	SVTACH	x1	NO	0.0	PASS

Technician: Ramón Fernández // Marc Salomó□□□Date: 24/12/2009

PHASE 3 DEFIBRILLATOR ANALYZER
Datrend Systems Inc.

TEST REPORT No. 9

DATE OF TEST: dic 24, 2009
TIME OF TEST: 12:48:55 PM
PHASE 3 I.D.: MY PHASE 3
DEVICE I.D.: LIFEPACK20-----
DUT TYPE: Defibrillator
TEST TYPE: Autosequence 14

1.0 DEFIB TESTS

1.1 Energy

Tests performed: 9/10

TEST	RNG	PEAK AMPLITUDE	PULSE WIDTH @10%	PULSE WIDTH @50%	ECG SIMULATOR	ENERGY	TARGET	TOL	RESULT		
		(V)	(A)	(msec)	(msec)	Wave	Scale	(J)	(J)	(%)	
1	L	140	2.80	13.13	8.85	VFIB1	x1	2.0	2.0	15	PASS
2	L	222	4.44	13.14	8.75	VFIB1	x1	5.0	5.0	15	PASS
3	L	313	6.26	13.11	8.75	VFIB1	x1	10.0	10.0	15	PASS
4	L	443	8.86	13.06	8.72	VFIB1	x1	20.0	20.0	15	PASS
5	H	703	14.07	13.05	8.72	VFIB1	x1	50.7	50.0	15	PASS
6	H	992	19.85	13.07	8.73	VFIB1	x1	100.7	100.0	15	PASS
7	H	1403	28.08	13.09	8.70	VFIB1	x1	201.5	200.0	15	PASS
8	H	1720	34.43	13.09	8.72	VFIB1	x1	302.9	300.0	15	PASS
9	H	1883	37.69	13.07	8.72	VFIB1	x1	363.3	360.0	15	PASS

1.2 Charge Time

Pre-test Discharges: 0

RNG	CHARGE TIME	MAXIMUM CHARGE TIME	ECG SIMULATOR	ENERGY	TARGET	TOL	RESULT	
		(sec)	(sec)	Wave	Scale	(J)	(J)	(%)
H	9.6	15.0	VFIB1	x1	363.2	360.0	15	PASS

1.3 Cardioversion (Sync)

Tests performed: 2/4

TEST	RNG	SYNC TO:	SYNC DELAY	SYNC LIMITS	ECG SIMULATOR	ENERGY	TARGET	TOL	RESULT	
		(msec)			Wave	Scale	(J)	(J)	(%)	
1	H	R-Wave	+27	+20/+65	ECG120	x1	30.1	30.0	15	PASS
2	H	R-Wave	+26	+20/+65	AFIB1	x1	100.4	100.0	15	PASS

2.0 ECG PERFORMANCE TESTS

Tests performed: 12/12

TEST	WAVEFORM	SCALE	RESULT
1	Square Wave, 2 Hz (SQR2HZ)	x1	PASS
2	DC Pulse, 4 sec (PULSE)	x1	PASS
3	Triangle Wave, 2 Hz (TRI2HZ)	x1	PASS
4	Sinewave, 10 Hz (SIN10)	x1	PASS
5	Sinewave, 40 Hz (SIN40)	x1	PASS
6	Sinewave, 60 Hz (SIN60)	x1	PASS
7	Sinewave, 100 Hz (SIN100)	x1	PASS
8	ECG 60 BPM (ECG60)	x1	PASS
9	ECG 30 BPM (ECG30)	x1	PASS
10	ECG 120 BPM (ECG120)	x1	PASS
11	ECG 180 BPM (ECG180)	x1	PASS
12	ECG 240 BPM (ECG240)	x1	PASS

Technician: Ramón Fernández // Marc Salomó

Date: 24/12/2009

PHASE 3 DEFIBRILLATOR ANALYZER
Datrend Systems Inc.

TEST REPORT

DATE OF TEST: dic 24, 2009
TIME OF TEST: 01:45:21 PM
PHASE 3 I.D.: MY PHASE 3
DEVICE I.D.: 31316022
TEST TYPE: PER IEC 60601-2-4 2002(E)
SECTION 6.8.3

MANUFACTURER: Medtronic MODEL: Lifepak 20
SERIAL NO: 31316022 FACILITY: Selector a 175 Julios
LOCATION: Servicio Tecnico TECH ID: Marc Salomó

----- TEST LOAD -----

--25-----50-----75----100----125----150----175-

ACTUAL LOAD (ohms)	24,96	49,95	74,95	99,84	124,7	149,5	174,3
DISCHARGE ENERGY (J)	171,3	175,8	176,3	176,1	176,5	176,3	177,0
PEAK (+) Voltage (Volts)	1179	1312	1386	1447	1503	1554	1599
PEAK (+) CURRENT (Amps)	47,23	26,26	18,49	14,49	12,05	10,39	9,16
PULSEWIDTH (+):							
WIDTH @ 10% (msec)	5,53	7,31	8,57	9,52	10,33	10,93	11,61
WIDTH @ 50% (msec)	4,40	7,30	8,55	9,51	10,31	10,92	11,61

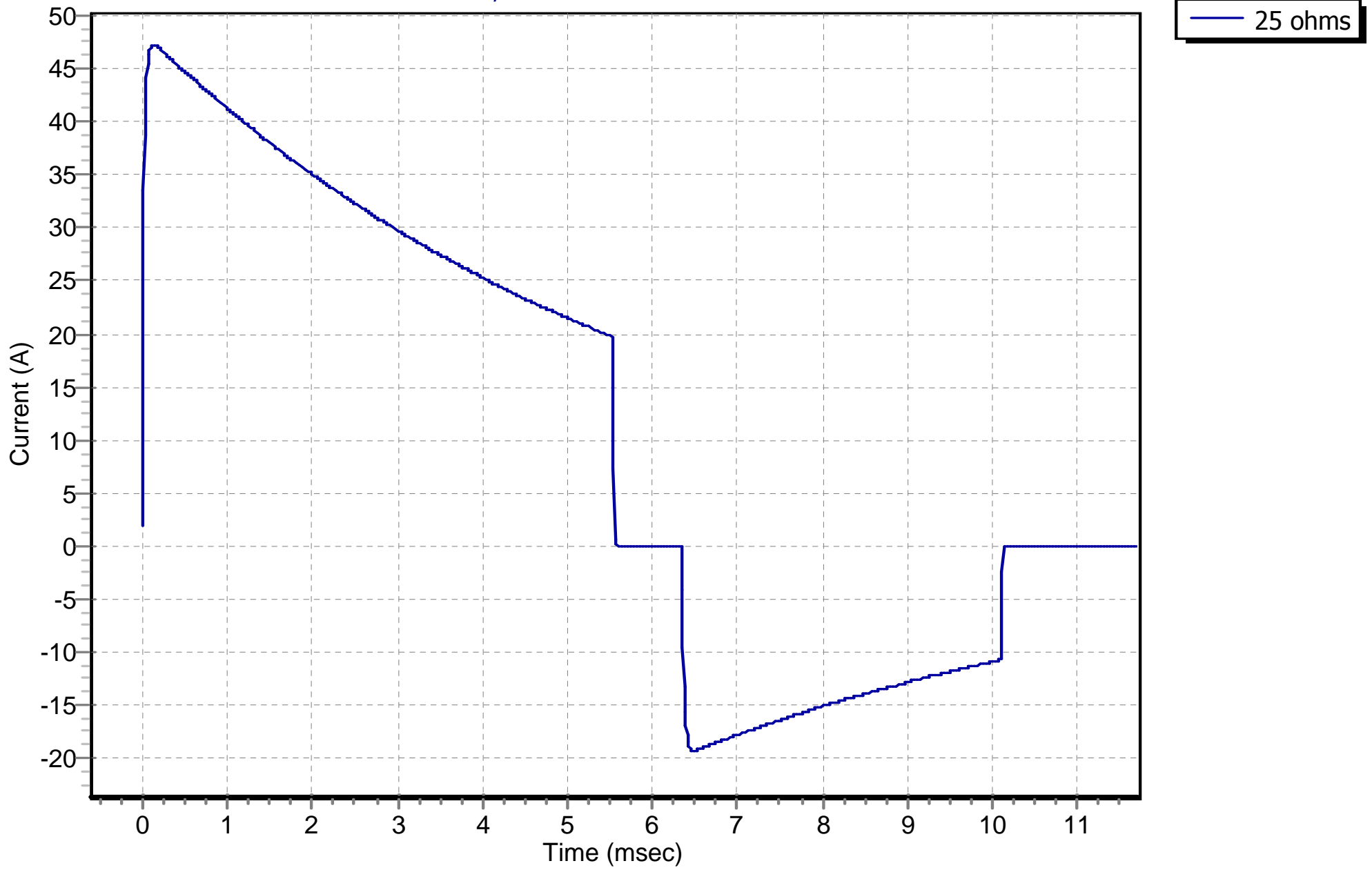
PEAK (-) VOLTAGE (Volts)	481	684	818	925	1015	1097	1159
PEAK (-) CURRENT (Amps)	19,28	13,69	10,92	9,26	8,14	7,33	6,64
PULSEWIDTH (-):							
WIDTH @ 10% (msec)	3,76	4,94	5,77	6,42	6,94	7,36	7,81
WIDTH @ 50% (msec)	3,74	4,92	5,77	6,40	6,94	7,34	7,80

PULSEWIDTH TOTAL:
WIDTH @ 10% (msec) 10,09 13,05 15,15 16,74 18,08 19,11 20,22

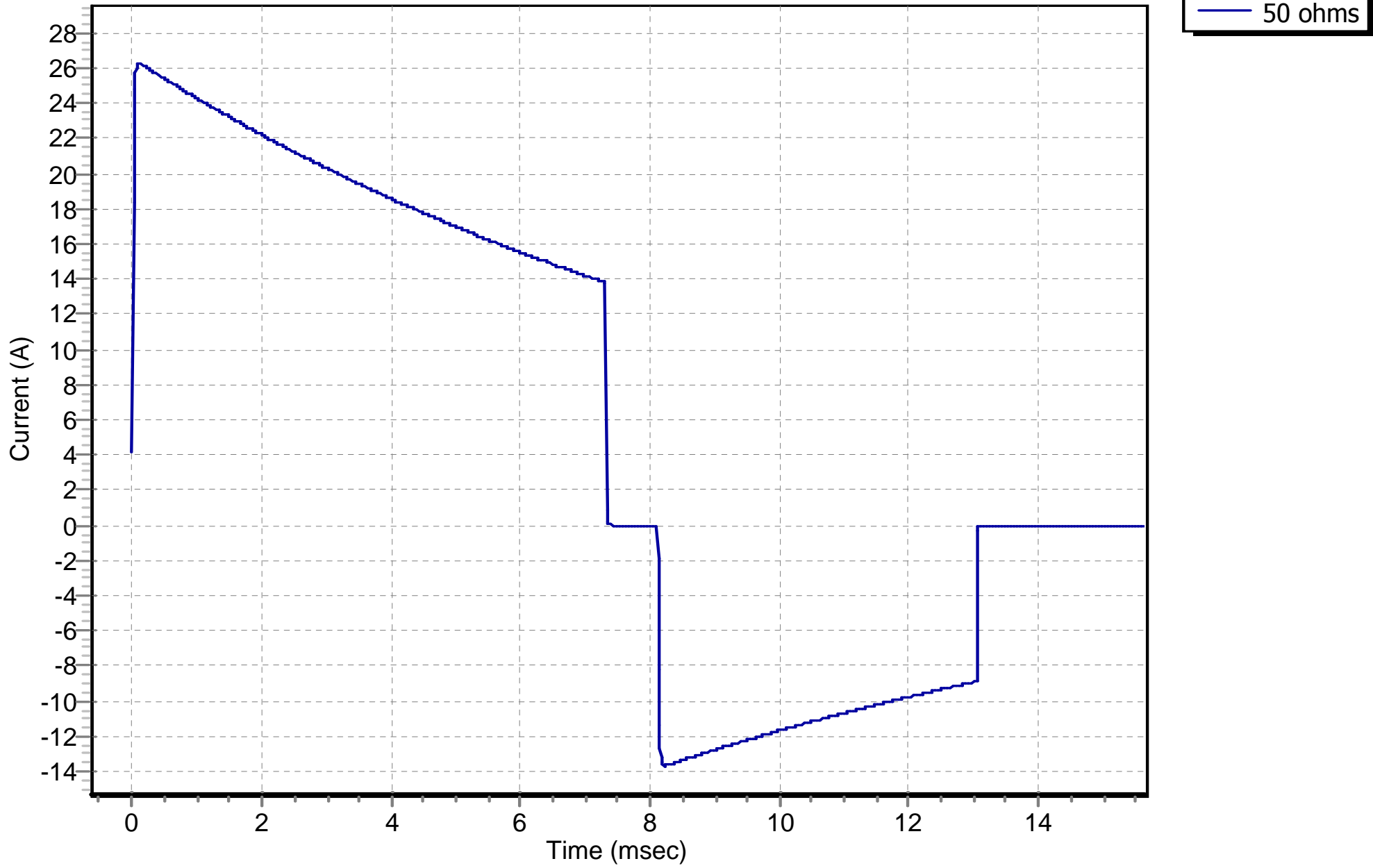
Technician: Ramón Fernández // Marc Salomó

Date: 24/12/2009

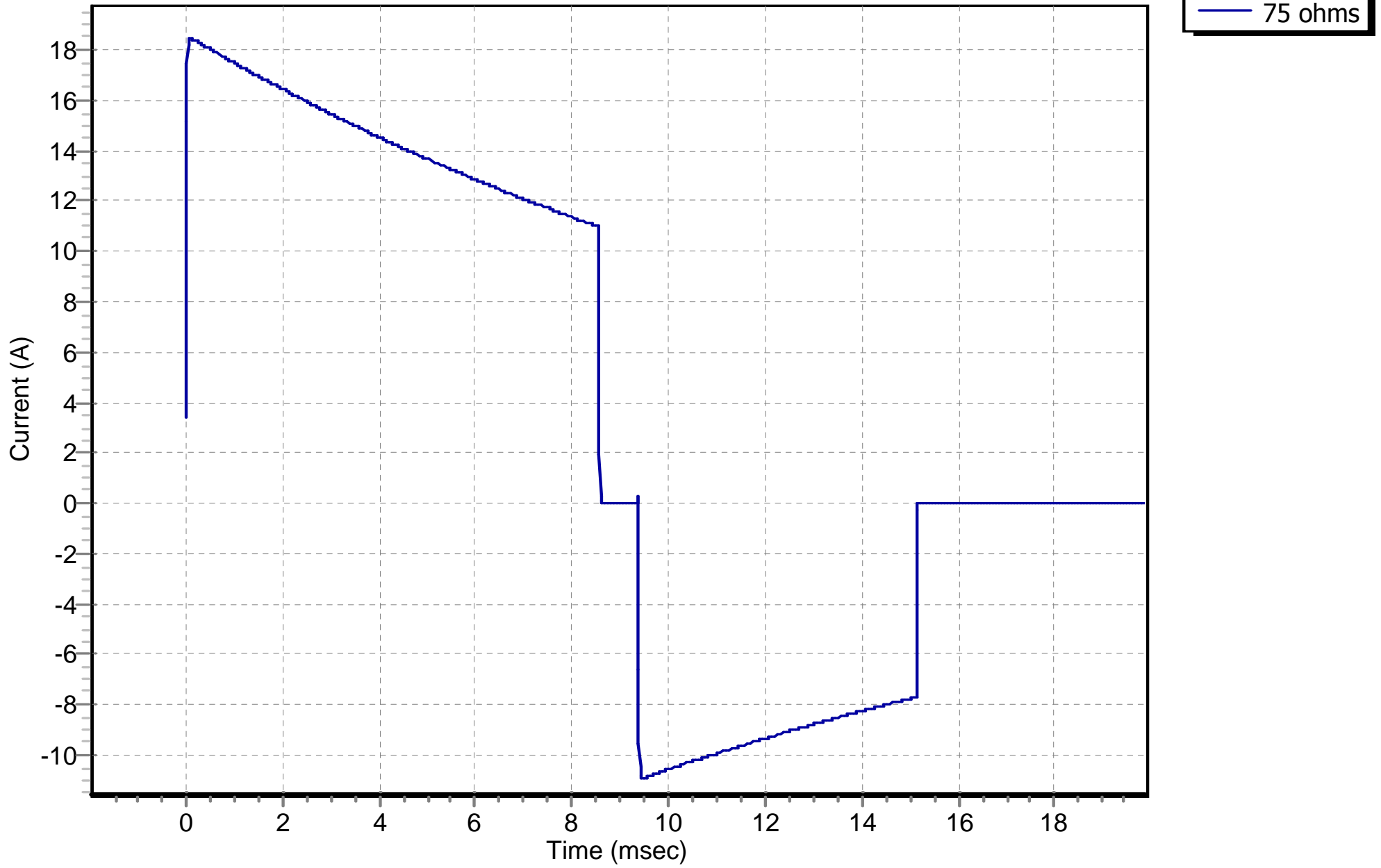
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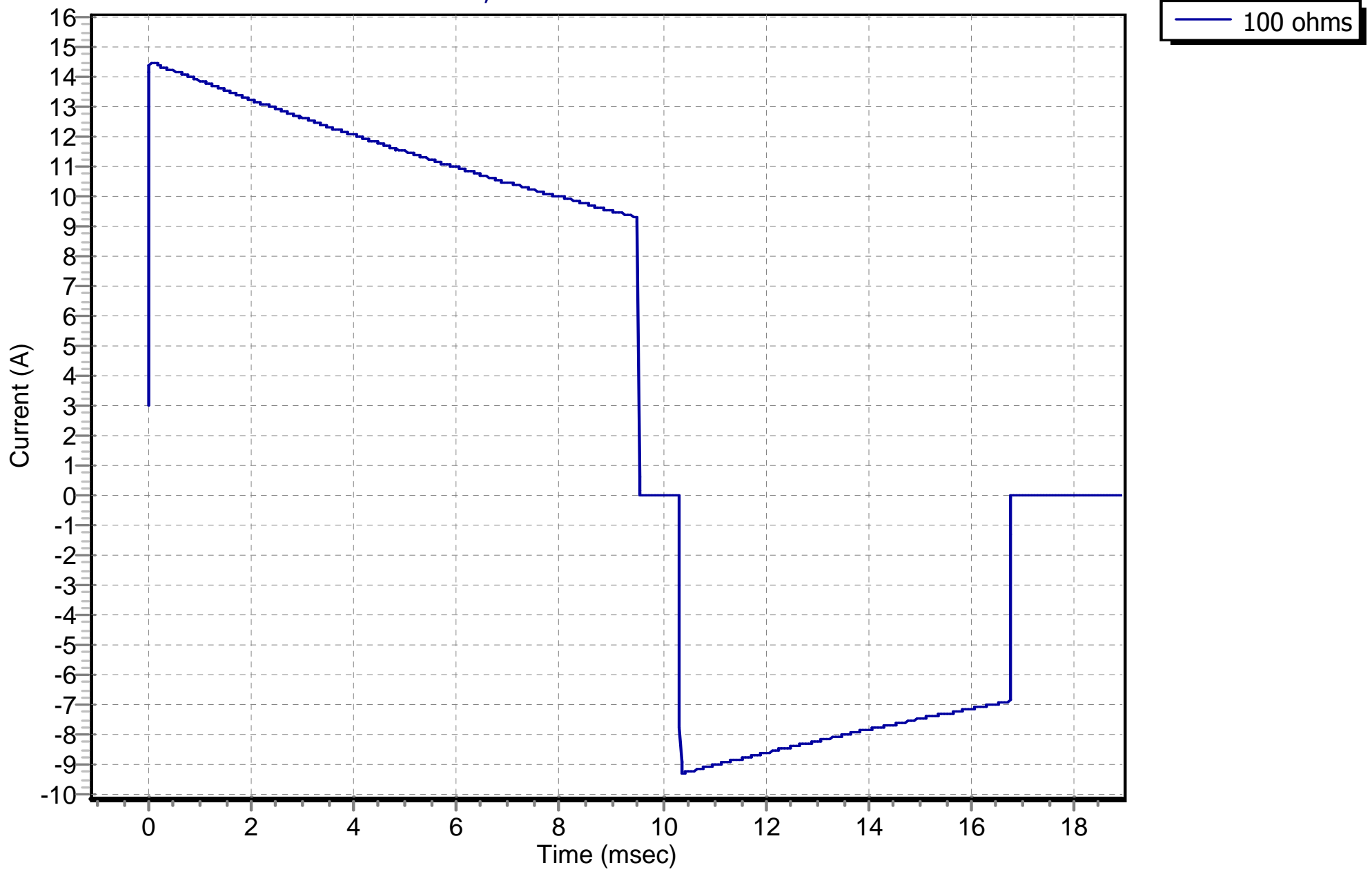
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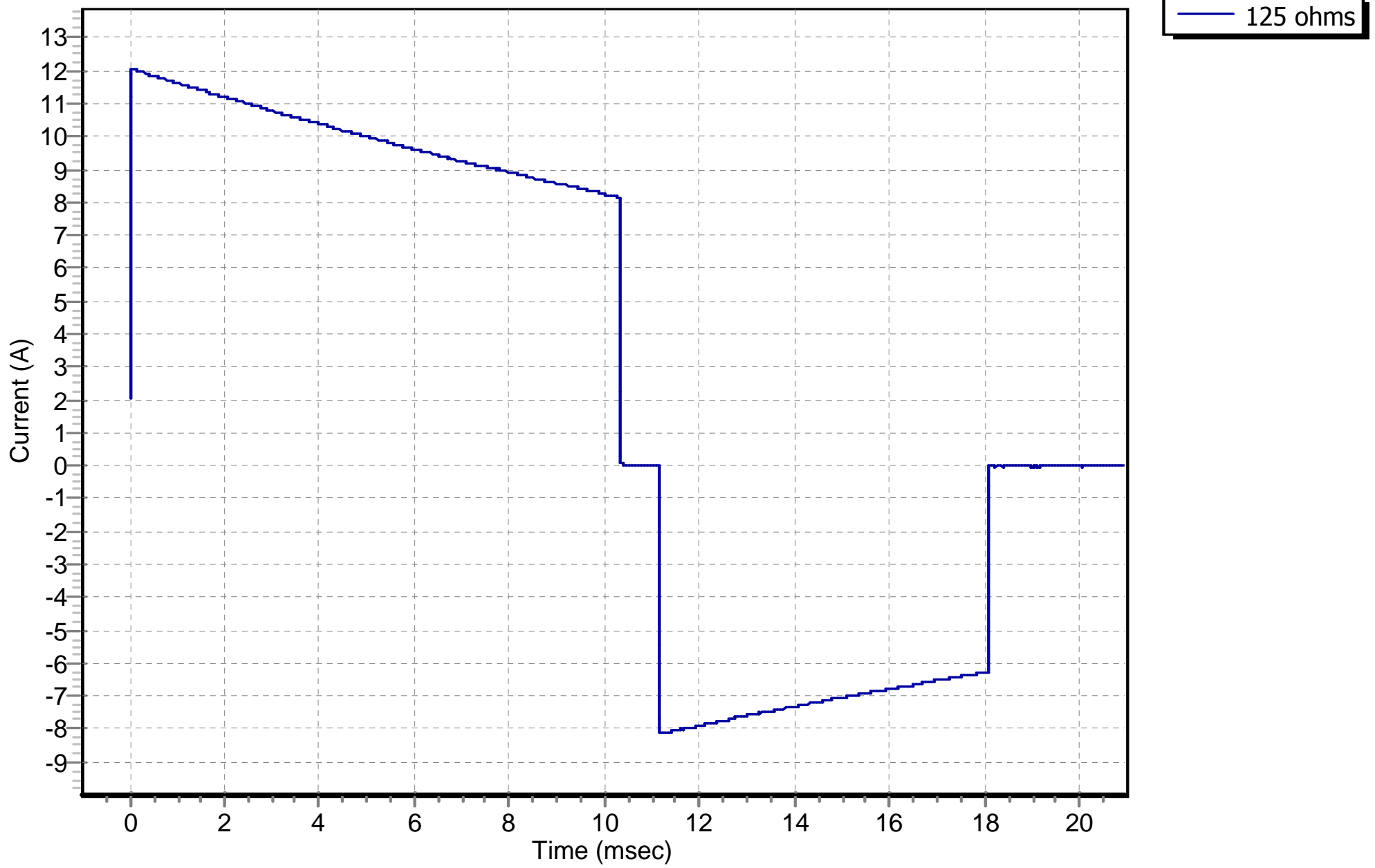
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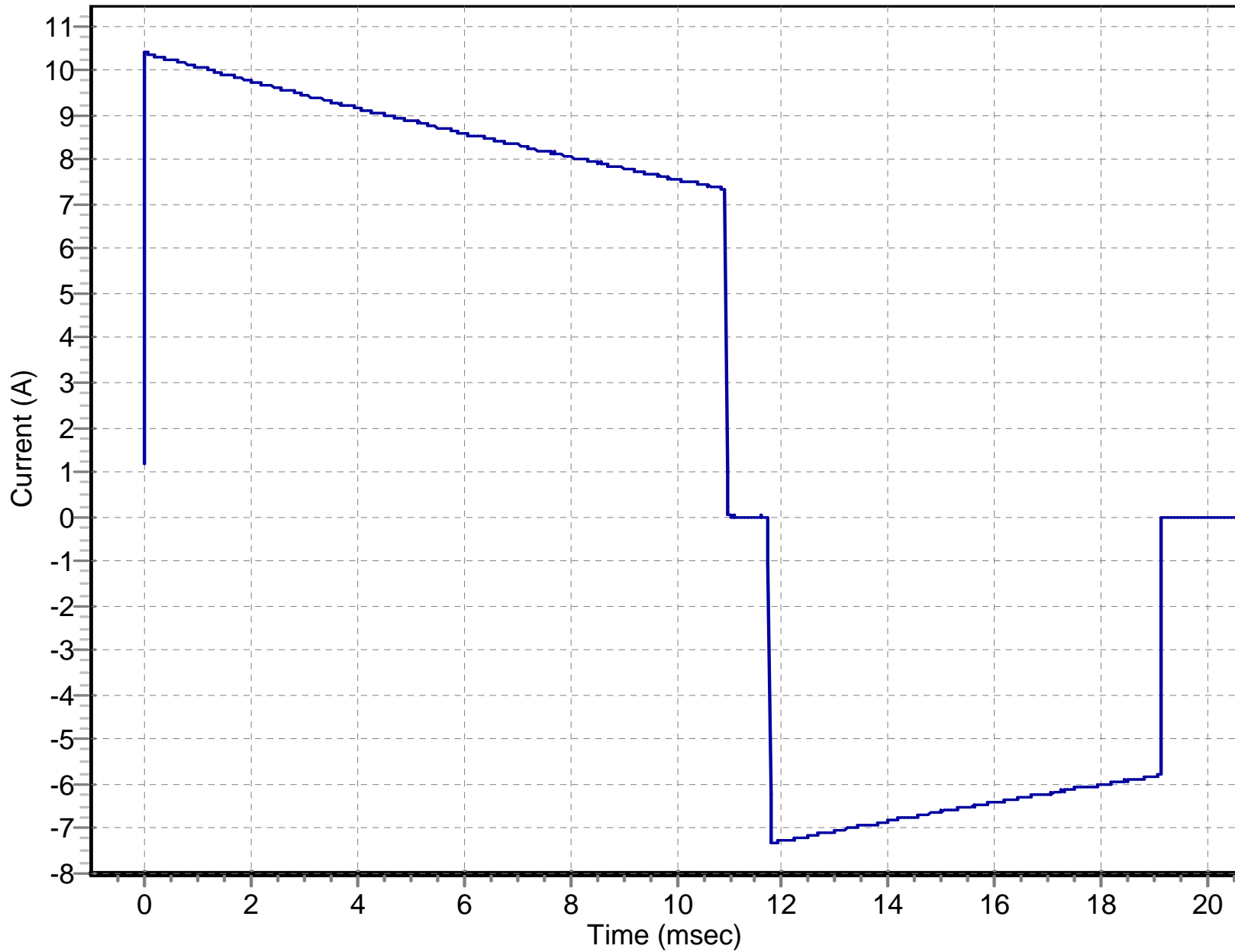
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150 ohms

Device ID: 31316022
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