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# FSDL0365RN, FSDM0365RN

## Green Mode Fairchild Power Switch (FPS™)

### Features

- Internal Avalanche Rugged Sense FET
- Consumes only 0.65W at 240VAC & 0.3W load with Advanced Burst-Mode Operation
- Frequency Modulation for EMI Reduction
- Precision Fixed Operating Frequency
- Internal Start-up Circuit
- Pulse-by-Pulse Current Limiting
- Abnormal Over Current Protection (AOCP)
- Over Voltage Protection (OVP)
- Over Load Protection (OLP)
- Internal Thermal Shutdown Function (TSD)
- Auto-Restart Mode
- Under Voltage Lockout (UVLO)
- Low Operating Current (3mA)
- Adjustable Peak Current Limit
- Built-in Soft Start

### Applications

- SMPS for VCR, SVR, STB, DVD & DVCD Player
- SMPS for Printer, Facsimile & Scanner
- Adapter for Camcorder

### Related Application Notes

- AN-4137, 4141, 4147(Flyback) / AN-4134(Forward)

### Description

Each product in the FSDx0365RN (x for L, M) family consists of an integrated Pulse Width Modulator (PWM) and Sense FET, and is specifically designed for high performance off-line Switch Mode Power Supplies (SMPS) with minimal external components. Both devices are integrated high voltage power switching regulators which combine an avalanche rugged Sense FET with a current mode PWM control block. The integrated PWM controller features include: a fixed oscillator with frequency modulation for reduced EMI, Under Voltage Lock Out (UVLO) protection, Leading Edge Blanking (LEB), an optimized gate turn-on/turn-off driver, Thermal Shut Down (TSD) protection, Abnormal Over Current Protection (AOCP) and temperature compensated precision current sources for loop compensation and fault protection circuitry. When compared to a discrete MOSFET and controller or RCC switching converter solution, the FSDx0365RN devices reduce total component count, design size, weight while increasing efficiency, productivity and system reliability. Both devices provide a basic platform that is well suited for the design of cost-

effective flyback converters.

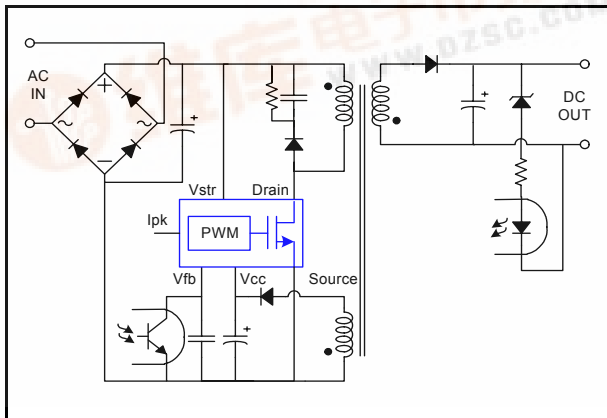
OUTPUT POWER TABLE

PRODUCT	230VAC $\pm 15\%$ <sup>(3)</sup>		85-265VAC	
	Adapt-er <sup>(1)</sup>	Open Frame <sup>(2)</sup>	Adapt-er <sup>(1)</sup>	Open Frame <sup>(2)</sup>
FSDL321	11W	17W	8W	12W
FSDH321	11W	17W	8W	12W
FSDL0165RN	13W	23W	11W	17W
FSDM0265RN	16W	27W	13W	20W
FSDH0265RN	16W	27W	13W	20W
FSDL0365RN	19W	30W	16W	24W
FSDM0365RN	19W	30W	16W	24W
FSDL321L	11W	17W	8W	12W
FSDH321L	11W	17W	8W	12W
FSDL0165RL	13W	23W	11W	17W
FSDM0265RL	16W	27W	13W	20W
FSDH0265RL	16W	27W	13W	20W
FSDL0365RL	19W	30W	16W	24W
FSDM0365RL	19W	30W	16W	24W

#### Notes:

1. Typical continuous power in a non-ventilated enclosed adapter with sufficient drain pattern as a heat sinker, at 50°C ambient.
2. Maximum practical continuous power in an open frame design with sufficient drain pattern as a heat sinker, at 50°C ambient.
3. 230 VAC or 100/115 VAC with doubler.

### Typical Circuit



Rev.1.0.8

Figure 1. Typical Flyback Application

## Internal Block Diagram

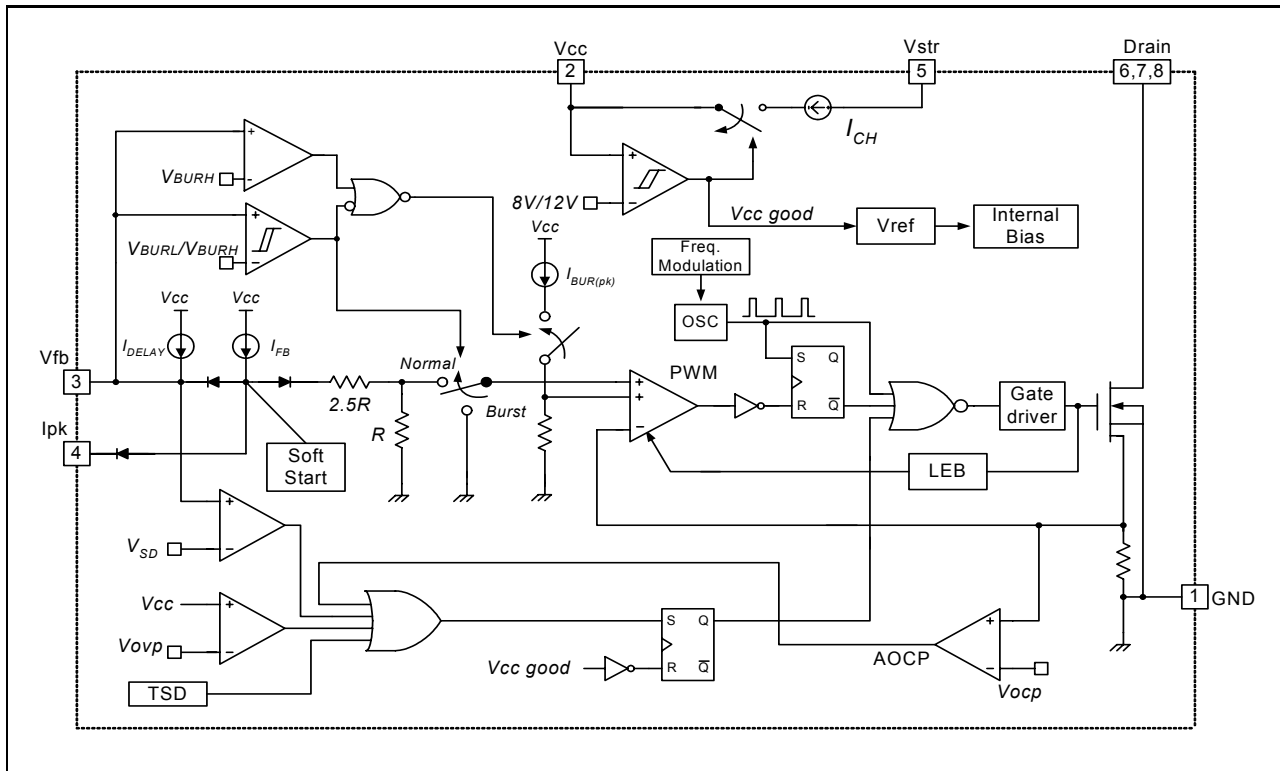


Figure 2. Functional Block Diagram of FSDx0365RN

## Pin Definitions

Pin Number	Pin Name	Pin Function Description
1	GND	Sense FET source terminal on primary side and internal control ground.
2	Vcc	Positive supply voltage input. Although connected to an auxiliary transformer winding, current is supplied from pin 5 (Vstr) via an internal switch during startup (see Internal Block Diagram section). It is not until Vcc reaches the UVLO upper threshold (12V) that the internal start-up switch opens and device power is supplied via the auxiliary transformer winding.
3	Vfb	The feedback voltage pin is the non-inverting input to the PWM comparator. It has a 0.9mA current source connected internally while a capacitor and optocoupler are typically connected externally. A feedback voltage of 6V triggers over load protection (OLP). There is a time delay while charging external capacitor Cfb from 3V to 6V using an internal 5uA current source. This time delay prevents false triggering under transient conditions, but still allows the protection mechanism to operate under true overload conditions.
4	l <sub>pk</sub>	This pin adjusts the peak current limit of the Sense FET. The feedback 0.9mA current source is diverted to the parallel combination of an internal 2.8kΩ resistor and any external resistor to GND on this pin to determine the peak current limit. If this pin is tied to Vcc or left floating, the typical peak current limit will be 2.15A.
5	Vstr	This pin connects directly to the rectified AC line voltage source. At start up the internal switch supplies internal bias and charges an external storage capacitor placed between the Vcc pin and ground. Once the Vcc reaches 12V, the internal switch is opened.
6, 7, 8	Drain	The drain pins are designed to connect directly to the primary lead of the transformer and are capable of switching a maximum of 650V. Minimizing the length of the trace connecting these pins to the transformer will decrease leakage inductance.

## Pin Configuration

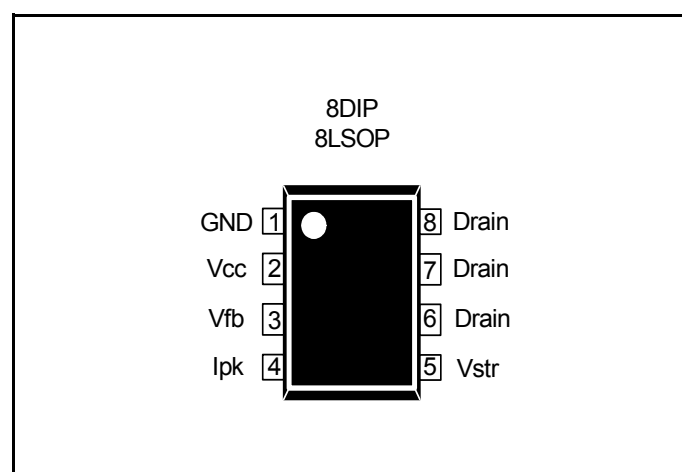


Figure 3. Pin Configuration (Top View)

## Absolute Maximum Ratings

(Ta=25°C, unless otherwise specified)

Characteristic	Symbol	Value	Unit
Drain Pin Voltage	VDRAIN	650	V
Vstr Pin Voltage	VSTR	650	V
Drain Current Pulsed <sup>(1)</sup>	IDM	12.0	A
Single Pulsed Avalanche Energy <sup>(2)</sup>	EAS	127	mJ
Supply Voltage	VCC	20	V
Feedback Voltage Range	VFB	-0.3 to VCC	V
Total Power Dissipation	PD	1.56	W
Operating Junction Temperature	TJ	Internally limited	°C
Operating Ambient Temperature	TA	-25 to +85	°C
Storage Temperature	TSTG	-55 to +150	°C

**Note:**

1. Repetitive rating: Pulse width is limited by maximum junction temperature
2. L = 51mH, starting TJ = 25°C

## Thermal Impedance

(Ta=25°C, unless otherwise specified)

Parameter	Symbol	Value	Unit
<b>8DIP</b>			
Junction-to-Ambient Thermal <sup>(1)</sup>	$\theta_{JA}$	80.01	°C/W
Junction-to-Case Thermal <sup>(2)</sup>	$\theta_{JC}$	18.85	°C/W
Junction-to-Top Thermal <sup>(3)</sup>	$\psi_{JT}$	33.70	°C/W

**Note:**

1. Free standing with no heatsink; Without copper clad.  
/ Measurement Condition : Just before junction temperature TJ enters into OTP.
2. Measured on the DRAIN pin close to plastic interface.
3. Measured on the PKG top surface.

- all items are tested with the standards JESD 51-2 and 51-10 (DIP).



## Electrical Characteristics

(Ta = 25°C unless otherwise specified)

Parameter	Symbol	Condition	Min.	Typ.	Max.	Unit
SENSE FET SECTION						
Zero-Gate-Voltage Drain Current	IDSS	VDS=650V, VGS=0V	-	-	50	μA
		VDS=520V, VGS=0V, TC=125°C	-	-	200	μA
Drain-Source On-State Resistance <sup>(1)</sup>	RDS(ON)	VGS=10V, ID=0.5A	-	3.6	4.5	Ω
Input Capacitance	CISS	VGS=0V, VDS=25V, f=1MHz	-	315	-	pF
Output Capacitance	COSS		-	47	-	pF
Reverse Transfer Capacitance	CRSS		-	9	-	pF
Turn-On Delay Time	td(on)	VDS=325V, ID=1.0A	-	11.2	-	ns
Rise Time	tr		-	34	-	ns
Turn-Off Delay Time	td(off)		-	28.2	-	ns
Fall Time	tf		-	32	-	ns
CONTROL SECTION						
Switching Frequency	fOSC	FSDM0365R	61	67	73	KHz
Switching Frequency Modulation	ΔfMOD		±1.5	±2.0	±2.5	KHz
Switching Frequency	fOSC	FSDL0365R	45	50	55	KHz
Switching Frequency Modulation	ΔfMOD		±1.0	±1.5	±2.0	KHz
Switching Frequency Variation <sup>(2)</sup>	ΔfOSC	-25°C ≤ Ta ≤ 85°C	-	±5	±10	%
Maximum Duty Cycle	DMAX		71	77	83	%
Minimum Duty Cycle	DMIN		0	0	0	%
UVLO Threshold Voltage	VSTART	VFB=GND	11	12	13	V
	VSTOP	VFB=GND	7	8	9	V
Feedback Source Current	IFB	VFB=GND	0.7	0.9	1.1	mA
Internal Soft Start Time	ts/S	VFB=4V	10	15	20	ms
BURST MODE SECTION						
Burst Mode Voltage	VBURH	-	0.4	0.5	0.6	V
	VBURL	-	0.25	0.35	0.45	V
PROTECTION SECTION						
Peak Current Limit	ILIM	Max. inductor current	1.89	2.15	2.41	A
Current Limit Delay Time <sup>(3)</sup>	tCLD		-	500	-	ns
Thermal Shutdown Temperature	TSD	-	125	140	-	°C
Shutdown Feedback Voltage	VSD		5.5	6.0	6.5	V
Over Voltage Protection	VOVP		18	19	-	V
Shutdown Delay Current	IDELAY	VFB=4V	3.5	5.0	6.5	μA
Leading Edge Blanking Time	tLEB		200	-	-	ns
TOTAL DEVICE SECTION						
Operating Supply Current (control part only)	IOP	VCC=14V	1	3	5	mA
Start-Up Charging Current	ICH	VCC=0V	0.7	0.85	1.0	mA
Vstr Supply Voltage	VSTR	VCC=0V	35	-	-	V

### Note:

1. Pulse test: Pulse width ≤ 300us, duty ≤ 2%
2. These parameters, although guaranteed, are tested in EDS (wafer test) process
3. These parameters, although guaranteed, are not 100% tested in production



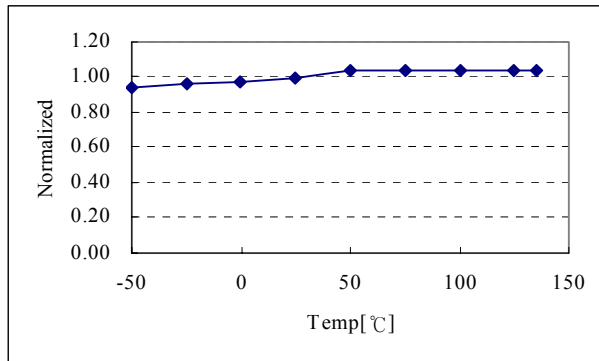
## Comparison Between KA5x0365RN and FSDx0365RN

Function	KA5x0365RN	FSDx0365RN	FSDx0365RN Advantages
Soft-Start	not applicable	15ms	<ul style="list-style-type: none"> <li>• Gradually increasing current limit during soft-start further reduces peak current and voltage stresses</li> <li>• Eliminates external components used for soft-start in most applications</li> <li>• Reduces or eliminates output overshoot</li> </ul>
External Current Limit	not applicable	Programmable of default current limit	<ul style="list-style-type: none"> <li>• Smaller transformer</li> <li>• Allows power limiting (constant over-load power)</li> <li>• Allows use of larger device for lower losses and higher efficiency.</li> </ul>
Frequency Modulation	not applicable	$\pm 2.0\text{KHz}$ @67KHz $\pm 1.5\text{KHz}$ @50KHz	<ul style="list-style-type: none"> <li>• Reduces conducted EMI</li> </ul>
Burst Mode Operation	not applicable	Built into controller	<ul style="list-style-type: none"> <li>• Improves light load efficiency</li> <li>• Reduces power consumption at no-load</li> <li>• Transformer audible noise reduction</li> </ul>
Drain Creepage at Package	1.02mm	7.62mm	<ul style="list-style-type: none"> <li>• Greater immunity to arcing provoked by dust, debris and other contaminants</li> </ul>

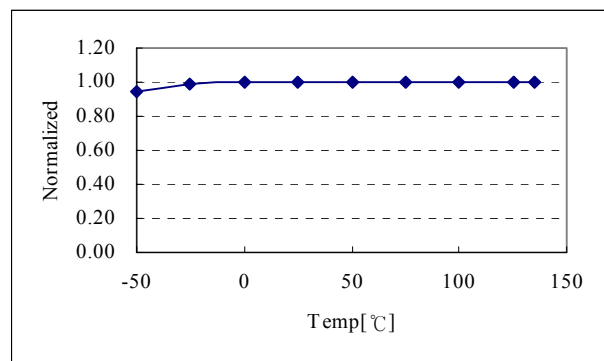


## Typical Performance Characteristics (Control Part)

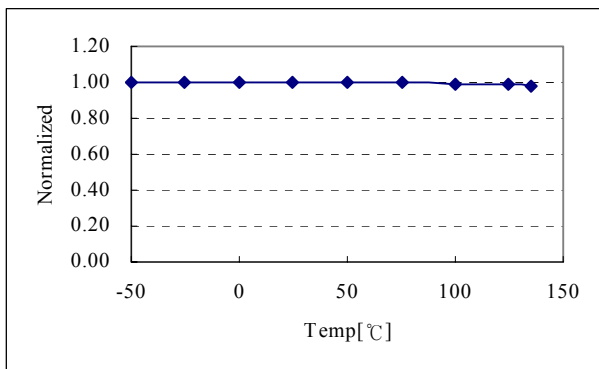
(These characteristic graphs are normalized at Ta = 25°C)



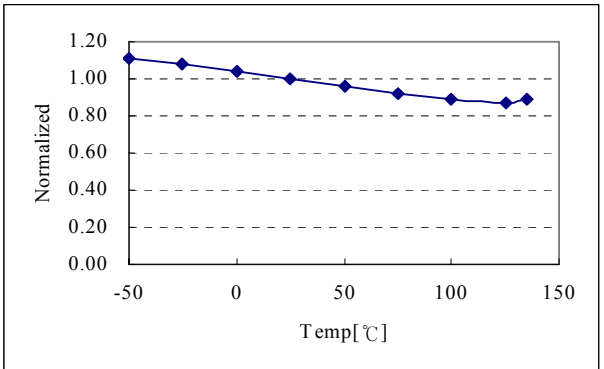
Operating Frequency (Fosc) vs. Ta



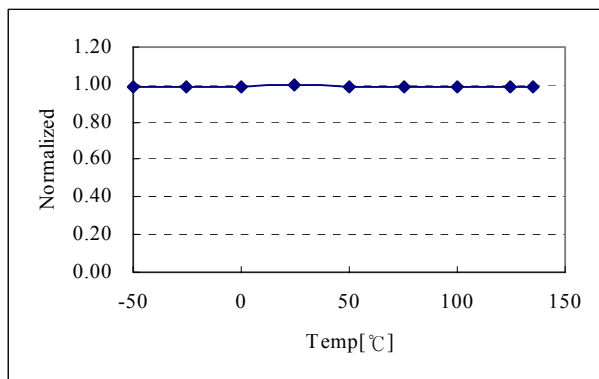
Frequency Modulation ( $\Delta F_{mod}$ ) vs. Ta



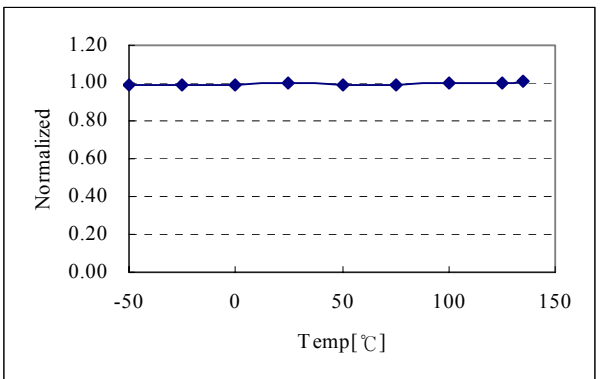
Maximum Duty Cycle (Dmax) vs. Ta



Operating Supply Current (IOP) vs. Ta

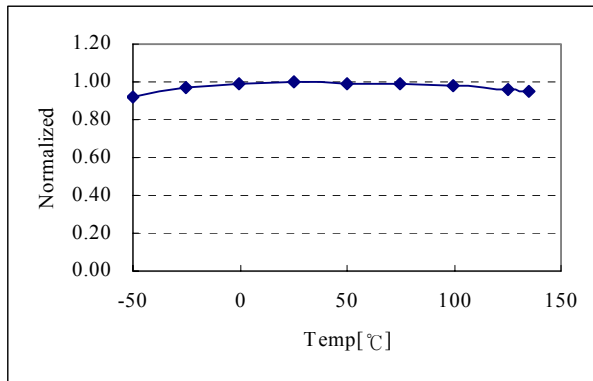


Start Threshold Voltage (VSTART) vs. Ta

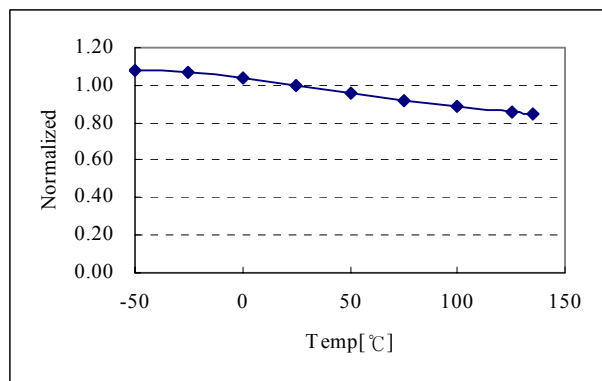


Stop Threshold Voltage (VSTOP) vs. Ta

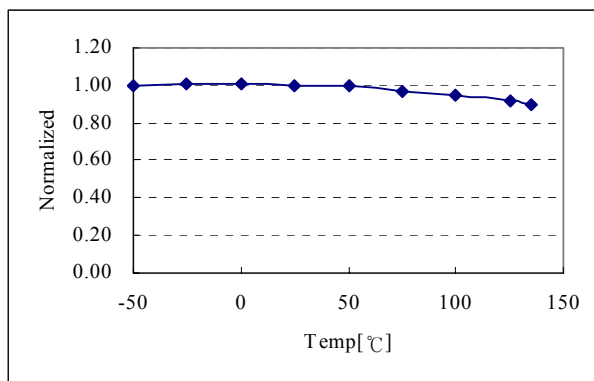
## Typical Performance Characteristics (Continued)



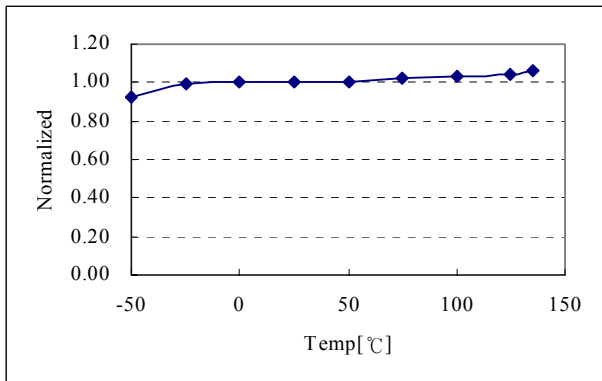
Feedback Source Current ( $I_{FB}$ ) vs.  $T_a$



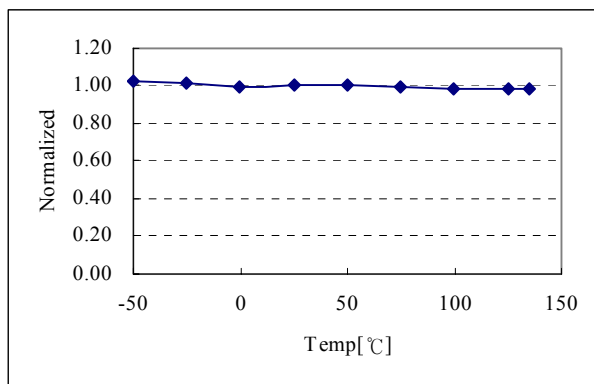
Start Up Charging Current ( $I_{CH}$ ) vs.  $T_a$



Peak Current Limit ( $I_{LIM}$ ) vs.  $T_a$



Burst Peak Current ( $I_{BUR(pk)}$ ) vs.  $T_a$



Over Voltage Protection ( $VOVP$ ) vs.  $T_a$





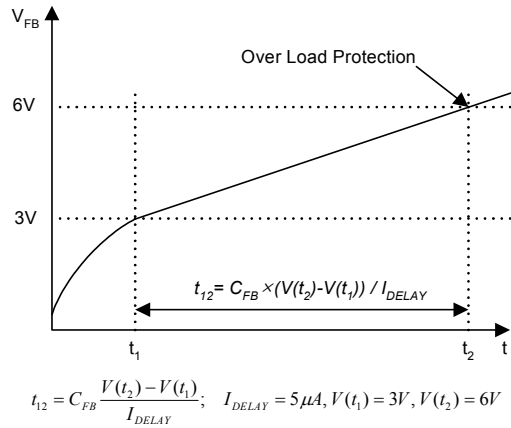


Figure 6. Over Load Protection (OLP)

**4.2 Thermal Shutdown (TSD) :** The Sense FET and the control IC are integrated, making it easier for the control IC to detect the temperature of the Sense FET. When the temperature exceeds approximately 140°C, thermal shutdown is activated.

**4.3 Abnormal Over Current Protection (AOCP) :** Even though the FPS has OLP (Over Load Protection) and current mode PWM feedback, these are not enough to protect the FPS when a secondary side diode short or a transformer pin short occurs. In addition to start-up, soft-start is also activated at each restart attempt during auto-restart and when restarting after latch mode is activated. The FPS has an internal AOCP (Abnormal Over Current Protection) circuit, as shown in Figure 7. When the gate turn-on signal is applied to the power Sense FET, the AOCP block is enabled and monitors the current through the sensing resistor. The voltage across the resistor is then compared with a preset AOCP level. If the sensing resistor voltage is greater than the AOCP level, pulse-by-pulse AOCP is triggered regardless of uncontrollable LEB time. Here, pulse-by-pulse AOCP stops the Sense FET within 350ns after it is activated.

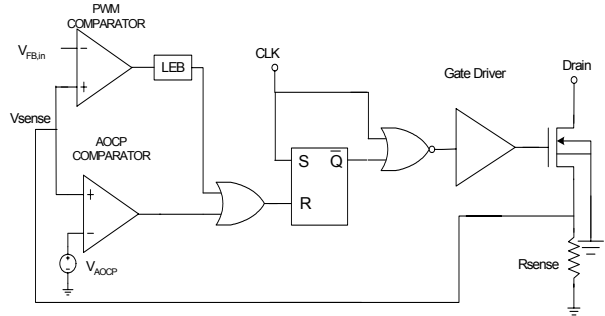


Figure 7. Abnormal Over Current Protection (AOCP)

**4.4 Over Voltage Protection (OVP) :** In the event of a malfunction in the secondary side feedback circuit, or an open feedback loop caused by a soldering defect, the current through the opto-coupler transistor becomes almost zero (refer to Figure 5). Then, V\_FB climbs up in a similar manner to the over load situation, forcing the preset maximum current to be supplied to the SMPS until the over load protection is activated. Because excess energy is provided to the output, the output voltage may exceed the rated voltage before the over load protection is activated, resulting in the breakdown of the devices in the secondary side. In order to prevent this situation, an over voltage protection (OVP) circuit is employed. In general, V<sub>CC</sub> is proportional to the output voltage and the FPS uses V<sub>CC</sub> instead of directly monitoring the output voltage. If V<sub>CC</sub> exceeds 19V, OVP circuit is activated resulting in termination of the switching operation. In order to avoid undesired activation of OVP during normal operation, V<sub>CC</sub> should be properly designed to be below 19V.



**5. Soft Start :** The FPS has an internal soft start circuit that slowly increases the feedback voltage together with the Sense FET current after it starts up. The typical soft start time is 15msec, as shown in Figure 8, where progressive increments of the Sense FET current are allowed during the start-up phase. The pulse width to the power switching device is progressively increased to establish the correct working conditions for transformers, inductors, and capacitors. The voltage on the output capacitors is progressively increased with the intention of smoothly establishing the required output voltage. It also helps to prevent transformer saturation and reduce the stress on the secondary diode.

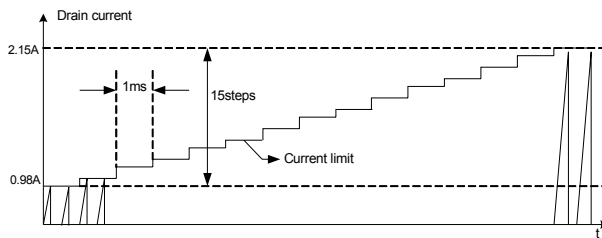


Figure 8. Soft Start Function

**6. Burst Operation :** In order to minimize power dissipation in standby mode, the FPS enters burst mode operation. As the load decreases, the feedback voltage decreases. As shown in Figure 9, the device automatically enters burst mode when the feedback voltage drops below  $V_{BURH}$  (500mV). Switching still continues but the current limit is set to a fixed limit internally to minimize flux density in the transformer. The fixed current limit is larger than that defined by  $V_{FB} = V_{BURH}$  and therefore,  $V_{FB}$  is driven down further. Switching continues until the feedback voltage drops below  $V_{BURL}$  (350mV). At this point switching stops and the output voltages start to drop at a rate dependent on the standby current load. This causes the feedback voltage to rise. Once it passes  $V_{BURH}$  (500mV), switching resumes. The feedback voltage then falls and the process repeats. Burst mode operation alternately enables and disables switching of the power Sense FET thereby reducing switching loss in Standby mode.

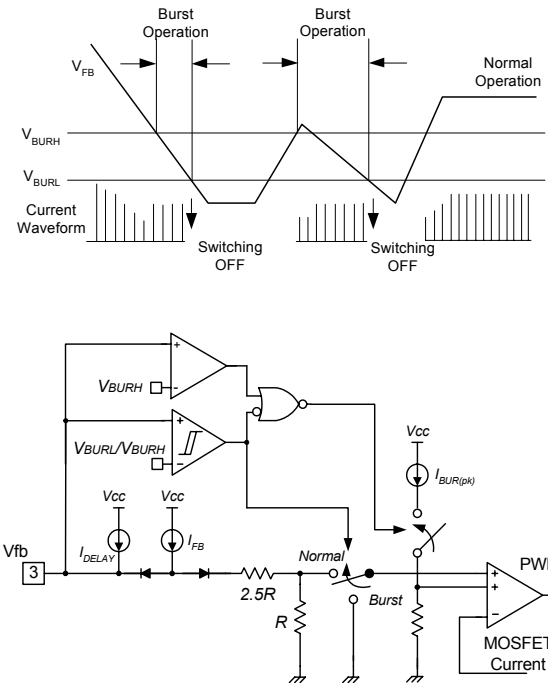


Figure 9. Burst Operation Function

**7. Frequency Modulation :** Modulating the switching frequency of a switched power supply can reduce EMI. Frequency modulation can reduce EMI by spreading the energy over a wider frequency range than the bandwidth measured by the EMI test equipment. The amount of EMI reduction is directly related to the depth of the reference frequency. As can be seen in Figure 10, the frequency changes from 65KHz to 69KHz in 4ms for the FSDM0365RN (48.5KHz to 51.5KHz for FSDL0365RN). Frequency modulation allows the use of a cost effective inductor instead of an AC input mode choke to satisfy the requirements of world wide EMI limits.

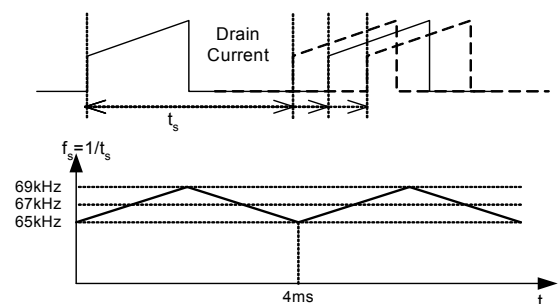


Figure 10. Frequency Modulation Waveform

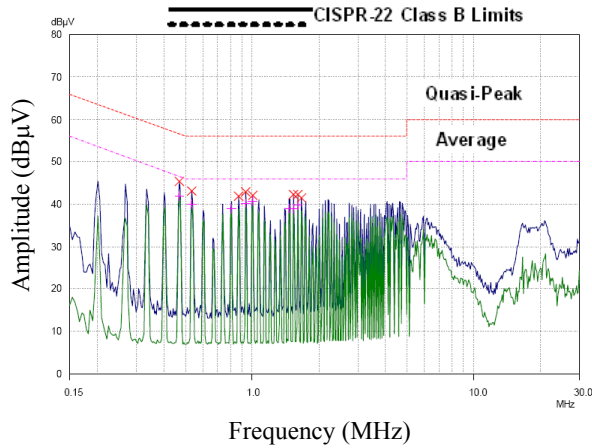


Figure 11. KA5-series FPS Full Range EMI scan(67KHz, no Frequency Modulation) with DVD Player SET

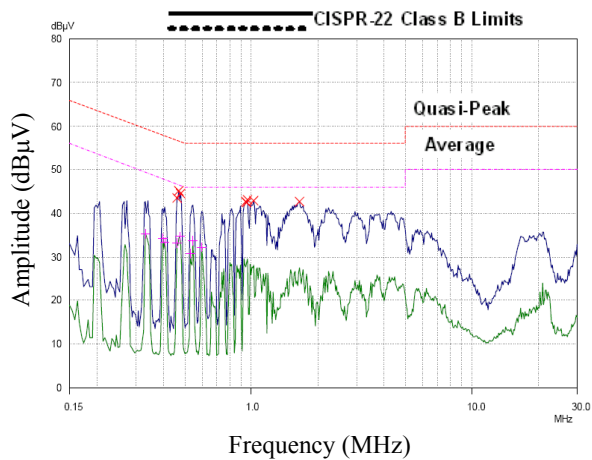


Figure 12. FSDX-series FPS Full Range EMI Scan (67KHz, with Frequency Modulation) with DVD Player SET

**8. Adjusting Peak Current Limit :** As shown in Figure 13, a combined  $2.8\text{k}\Omega$  internal resistance is connected to the non-inverting lead on the PWM comparator. A external resistance of  $R_x$  on the current limit pin forms a parallel resistance with the  $2.8\text{k}\Omega$  when the internal diodes are biased by the main current source of  $900\mu\text{A}$ .

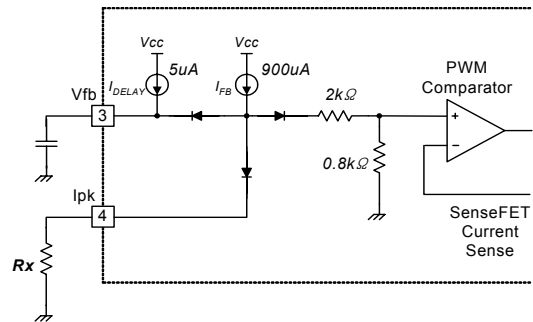


Figure 13. Peak Current Limit Adjustment

For example, FSDx0365RN has a typical Sense FET peak current limit ( $I_{LIM}$ ) of  $2.15\text{A}$ .  $I_{LIM}$  can be adjusted to  $1.5\text{A}$  by inserting  $R_x$  between the  $I_{pk}$  pin and the ground. The value of the  $R_x$  can be estimated by the following equations:

$$2.15\text{A} : 1.5\text{A} = 2.8\text{k}\Omega : X\text{k}\Omega ,$$

$$X = R_x \parallel 2.8\text{k}\Omega .$$

(X represents the resistance of the parallel network)



## Typical Application Circuit

Application	Output power	Input voltage	Output voltage (Max current)
DVD Player	21W	Universal input (85-265Vac)	3.3V (1.0A)
			5.1V (0.8A)
			12V (0.5A)
			16V (0.5A)

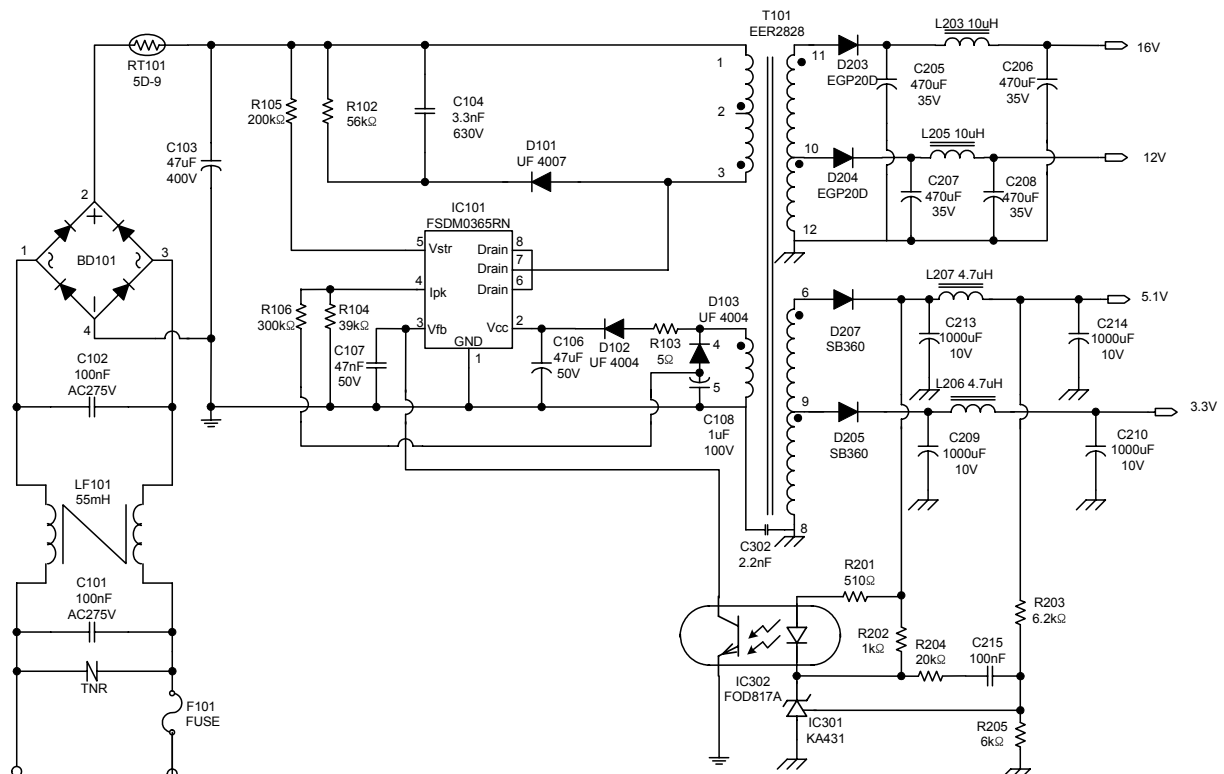
### Features

- High efficiency (>76% at universal input)
- Low standby mode power consumption (<1W at 230Vac input and 0.6W load)
- Low component count
- Enhanced system reliability through various protection functions
- Low EMI through frequency modulation
- Internal soft-start (15ms)

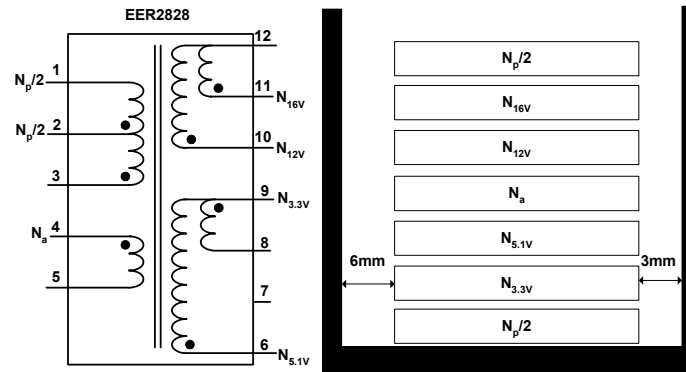
### Key Design Notes

- The delay time for over load protection is designed to be about 30ms with C106 of 47nF. If faster/slower triggering of OLP is required, C106 can be changed to a smaller/larger value(eg. 100nF for about 60ms).
- Using a resistor R104(39k $\Omega$ ) on Ipk pin (#4), the pulse-by-pulse peak current limit level(I<sub>LIM</sub>) is adjusted to about 2A.
- The branch formed by D103, C108 and R106 provides another I<sub>LIM</sub> adjustment having a negative slope to the input voltage. The I<sub>LIM</sub> value decreases as the input voltage level increases.

### 1. Schematic



## 2. Transformer Schematic Diagram



## 3. Winding Specification

	Pin(S → F)	Wire	Turns	Winding Method
$N_p/2$	3 → 2	0.25 $\phi$ × 1	50	Center Solenoid winding
Insulation : Polyester Tape t = 0.050mm, 2Layers				
$N_{3.3V}$	9 → 8	0.33 $\phi$ × 2	4	Center Solenoid winding
Insulation : Polyester Tape t = 0.050mm, 2Layers				
$N_{5.1V}$	6 → 9	0.33 $\phi$ × 1	2	Center Solenoid winding
Insulation : Polyester Tape t = 0.050mm, 2Layers				
$N_a$	4 → 5	0.25 $\phi$ × 1	16	Center Solenoid winding
Insulation : Polyester Tape t = 0.050mm, 2Layers				
$N_{12V}$	10 → 12	0.33 $\phi$ × 1	14	Center Solenoid winding
Insulation : Polyester Tape t = 0.050mm, 3Layers				
$N_{16V}$	11 → 12	0.33 $\phi$ × 1	18	Center Solenoid winding
Insulation : Polyester Tape t = 0.050mm, 2Layers				
$N_p/2$	2 → 1	0.25 $\phi$ × 1	50	Center Solenoid winding
Insulation : Polyester Tape t = 0.050mm, 2Layers				

## 4. Electrical Characteristics

	Pin	Spec.	Remark
Inductance	1 - 3	1.4 mH $\pm$ 10%	100kHz, 1V
Leakage	1 - 3	25 $\mu$ H Max.	Short all other pins

## 5. Core & Bobbin

Core : EER2828 (  $A_e = 86.66 \text{ mm}^2$  )

Bobbin : EER2828

## 6. Demo Circuit Part List

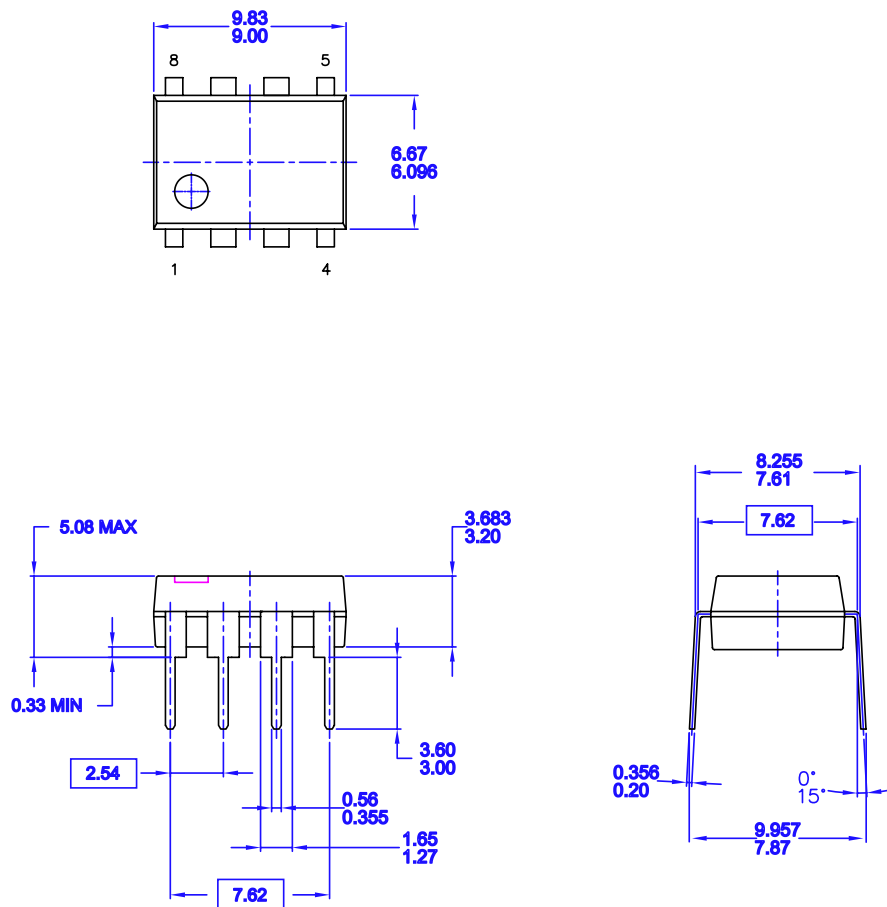
Part	Value	Note	Part	Value	Note
<b>Resistor</b>			<b>Inductor</b>		
R102	56K	1W	L203	10uH	-
R103	5	1/4W	L205	10uH	-
R104	39K	1/4W	L206	4.7uH	-
R105	200K	1/4W	L207	4.7uH	-
R106	300K	1/4W	<b>Diode</b>		
R201	510	1/4W	D101	UF4007	PN Ultra Fast
R202	1K	1/4W	D102	UF4004	PN Ultra Fast
R203	6.2 K	1/4W	D103	UF4004	PN Ultra Fast
R204	20K	1/4W	D203	EGP20D	PN Ultra Fast
R205	6K	1/4W	D204	EGP20D	PN Ultra Fast
<b>Capacitor</b>			D205	SB360	Schottky
C101	100nF/275AC	Box	D207	SB360	Schottky
C102	100nF/275AC	Box	<b>IC</b>		
C103	47uF/400V	Electrolytic	IC101	FSDM0365RN	FPS™
C104	3.3nF/630V	Film	IC301	KA431(TL431)	Voltage reference
C106	47uF/50V	Electrolytic	IC302	FOD817A	Opto-Coupler
C107	47nF/50V	Ceramic			
C108	1uF/100V	Electrolytic	<b>Fuse</b>		
C205	470uF/35V	Electrolytic	FUSE	2A/250V	
C206	470uF/35V	Electrolytic			
C207	470uF/35V	Electrolytic	<b>NTC</b>		
C208	470uF/35V	Electrolytic	RT101	5D-9	
C209	1000uF/10V	Electrolytic			
C210	1000uF/10V	Electrolytic	<b>Bridge Diode</b>		
C213	1000uF/10V	Electrolytic	BD101	2KBP06M 2N257	Bridge Diode
C214	1000uF/10V	Electrolytic			
C215	100nF/50V	Ceramic	<b>Line Filter</b>		
C302	2.2nF	AC Ceramic	LF101	55mH	-





## Package Dimensions

### 8DIP



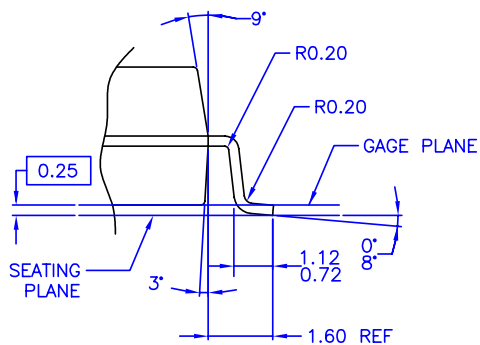
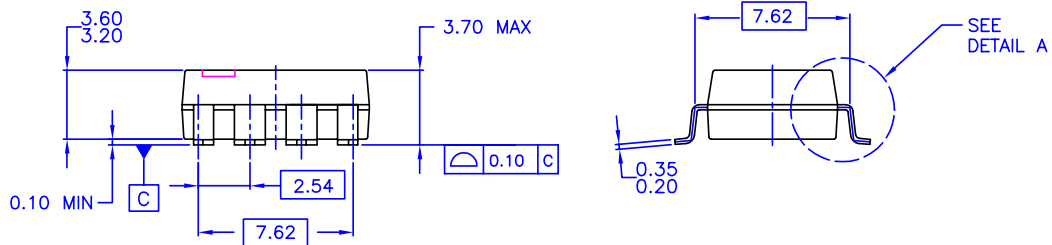
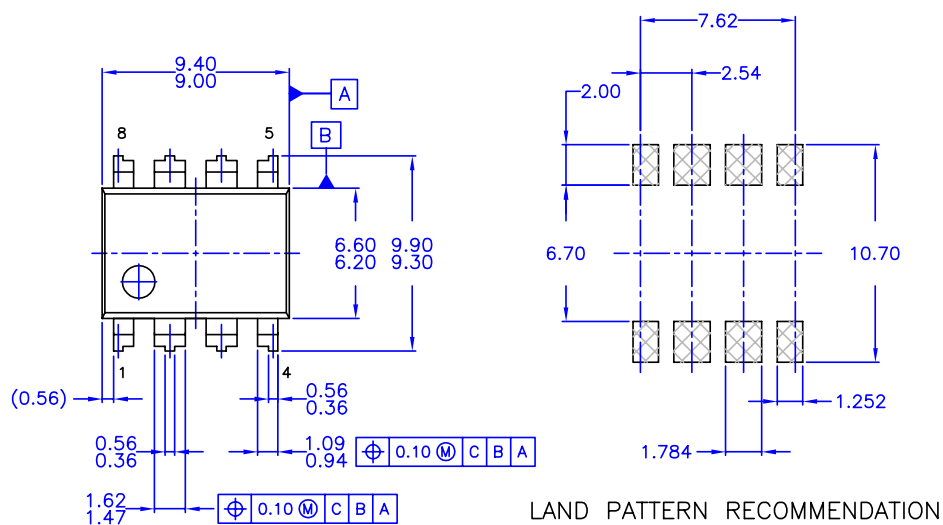
NOTES: UNLESS OTHERWISE SPECIFIED  
 A) THIS PACKAGE CONFORMS TO JEDEC MS-001 VARIATION BA  
 B) ALL DIMENSIONS ARE IN MILLIMETERS.  
 C) DIMENSIONS ARE EXCLUSIVE OF BURRS, MOLD FLASH, AND TIE BAR EXTRUSIONS.  
 D) DIMENSIONS AND TOLERANCES PER ASME Y14.5M-1994

MKT-N08FrevB



# Package Dimensions (Continued)

## 8LSOP



- NOTES: UNLESS OTHERWISE SPECIFIED
- THIS PACKAGE DOES NOT CONFORM TO ANY CURRENT PACKAGE STANDARD
  - ALL DIMENSIONS ARE IN MILLIMETERS.
  - DIMENSIONS ARE EXCLUSIVE OF BURRS, MOLD FLASH, AND TIE BAR EXTRUSIONS.
  - DIMENSIONS AND TOLERANCES PER ASME Y14.5M-1994

DETAIL A  
SCALE: 2X

## Ordering Information

Product Number	Package	Marking Code	BV <sub>DSS</sub>	f <sub>osc</sub>	R <sub>DS(ON)</sub>
FSDM0365RN	8DIP	DM0365R	650V	67KHz	3.6Ω
FSDL0365RN	8DIP	DL0365R	650V	50KHz	3.6Ω
FSDM0365RL	8LSOP	DM0365R	650V	67KHz	3.6Ω
FSDL0365RL	8LSOP	DL0365R	650V	50KHz	3.6Ω

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1. Life support devices or systems are devices or systems which, (a) are intended for surgical implant into the body, or (b) support or sustain life, and (c) whose failure to perform when properly used in accordance with instructions for use provided in the labeling, can be reasonably expected to result in a significant injury of the user.
2. A critical component in any component of a life support device or system whose failure to perform can be reasonably expected to cause the failure of the life support device or system, or to affect its safety or effectiveness.

