

DESCRIPTION

The GMT26xx family of extremely low dropout voltage regulators features very low ground current and offers high initial accuracy with a logic compatible ON/OFF switching input.

Designed especially for hand-held, battery-powered devices, this family includes a CMOS or TTL logic compatible enable/shutdown control input, and an internal under voltage monitor. When shutdown, power consumption drops nearly to zero. Dropout ground current is also minimized to prolong battery life.

The GMT26xx also features vastly improved LINE and LOAD regulation characteristics for better system performance, and a Loop Stability characteristic that is INDEPENDENT of output Capacitor value as well as ESR.

Key options include an under-voltage monitor with an error flag output, a reference bypass pin to improve already low-noise performance, current limiting, and over-temperature shutdown.

The GMT26xx is available in adjustable output configuration, as well as, 3.0 V, 3.3 V, 3.6 V, 3.8 V, 4.0 V, 4.75 V, and 5.0 V fixed voltage configurations. Full featured fixed and adjustable output voltage versions, with the low noise bypass option, remote enable/shutdown, and error flag output are available in the 8-lead GMT Mini 8™, 8-lead MSOP. Limited feature options are available in ultra tiny GMT SOT packages for applications where "real estate" is at a premium.

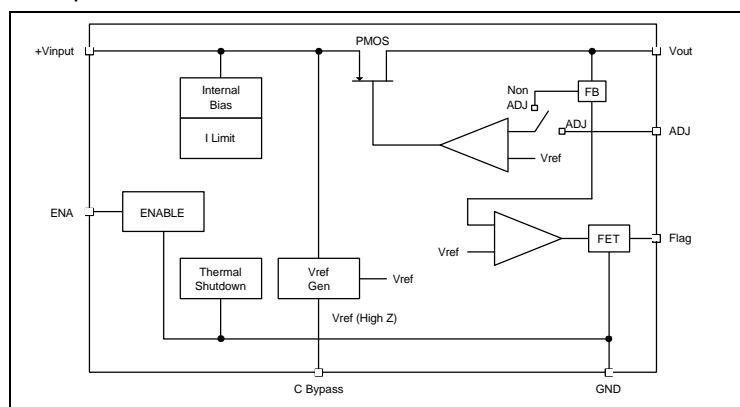
FEATURES

- Wide selection of output voltages: 3.0, 3.3, 3.6, 3.8, 4.0, 5.0 & adjustable.
- Guaranteed 200 mA output drive.
- High initial accuracy.
- Current and thermal limiting.
- Zero OFF mode current.
- Logic-controlled electronic shutdown.
- High output voltage accuracy.
- Low 1.0 μ A quiescent current.
- Low dropout voltage: 140 mV typical @ 100 mA,
- Extremely tight load and line regulation.
- Very low temperature coefficient.
- Error flag option indicates UV fault.
- Ultra low-noise output.
- Ground Current 1/10 of leading BiPolar LDO's.

APPLICATIONS

- Cellular telephones.
- Laptop, notebook, and palmtop computers.
- Battery powered equipment.
- Bar code scanners.
- SMPS post-regulator/DC to DC modules.
- High efficiency linear power supplies.
- PCMCIA V_{CC} and V_{PP} regulation/switching.
- Consumer/personal electronics.

**26xx BLOCK
DIAGRAM**



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ABSOLUTE MAXIMUM RATINGS

Absolute Maximum Ratings indicate limits beyond which damage to the device may occur. Electrical specifications do not apply when operating the device beyond its specified Recommended Operating Conditions.

Power Dissipation	Internally Limited
Junction Temperature	125°C
Lead Temperature (Soldering, 5 seconds)	260°C
Storage Temperature Range.....	-60°C to +150°C
Input Supply Voltage	-0.3 V to +7.0 V
ENABLE Input Voltage	-0.3 V to +7.0 V

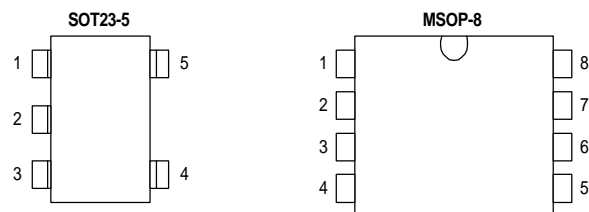
RECOMMENDED OPERATING CONDITIONS

Input Voltage	2.5 V to 6.0 V
Operating Temperature Range, T _A	-40°C to +85°C
ENABLE Input Voltage	0.0 V to V _{CC}
SOT23-5 θ_{JA}	220°C/W (See Note 1)
MSOP-8 θ_{JA}	200°C/W (See Note 1)

Table 1: PACKAGE PIN ASSIGNMENTS

2605-xx (SOT23-5)	2605-Adj. (SOT23-5)	2606-xx (MSOP8)	2606-Adj. (MSOP8)	2608-xx (SOT23-5)	Pin Name	Pin Functions
1	1	8	8	1	V+	+ Supply
2	2	4 & 6	4 & 6	2	Gnd	Ground
3	3	7	7	3	V _{EN}	Enable
N/A	N/A	3	3	4	Flag	Error Flag Output
4	N/A	5	N/A	N/A	Byp	Bypass
N/A	4	N/A	5	N/A	Adj	V _{OUT} Adjust
5	5	1 & 2	1 & 2	5	V _{OUT}	Output

PIN DIAGRAMS



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Table 2: PRODUCT FAMILY (GMT26xx) SELECTION GUIDE

Part Number	Output Voltage	Output Current	Accuracy	Features	Operating Temp Range	Package
GMT2605-3.0S	3.0	200mA	1%	Enable/Shutdown, Bypass	-40°C to +85°C	SOT23-5
GMT2605-3.3S	3.3	200mA	1%	Enable/Shutdown, Bypass	-40°C to +85°C	SOT23-5
GMT2605-3.6S	3.6	200mA	1%	Enable/Shutdown, Bypass	-40°C to +85°C	SOT23-5
GMT2605-3.8S	3.8	200mA	1%	Enable/Shutdown, Bypass	-40°C to +85°C	SOT23-5
GMT2605-4.0S	4.0	200mA	1%	Enable/Shutdown, Bypass	-40°C to +85°C	SOT23-5
GMT2605-5.0S	5.0	200mA	1%	Enable/Shutdown, Bypass	-40°C to +85°C	SOT23-5
GMT2605-AdjS	Adjustable	200mA	1%	Enable/Shutdown, Adj.	-40°C to +85°C	SOT23-5
GMT2606-3.0R	3.0	200mA	1%	Enable/Shutdown, Flag, Bypass	-40°C to +85°C	MSOP-8
GMT2606-3.3R	3.3	200mA	1%	Enable/Shutdown, Flag, Bypass	-40°C to +85°C	MSOP-8
GMT2606-3.6R	3.6	200mA	1%	Enable/Shutdown, Flag, Bypass	-40°C to +85°C	MSOP-8
GMT2606-3.8R	3.8	200mA	1%	Enable/Shutdown, Flag, Bypass	-40°C to +85°C	MSOP-8
GMT2606-4.0R	4.0	200mA	1%	Enable/Shutdown, Flag, Bypass	-40°C to +85°C	MSOP-8
GMT2606-5.0R	5.0	200mA	1%	Enable/Shutdown, Flag, Bypass	-40°C to +85°C	MSOP-8
GMT2606-AdjR	Adjustable	200mA	1%	Enable/Shutdown, Flag, Adjustable	-40°C to +85°C	MSOP-8
GMT2608-3.0S	3.0	200mA	1%	Enable/Shutdown, Flag	-40°C to +85°C	SOT23-5
GMT2608-3.3S	3.3	200mA	1%	Enable/Shutdown, Flag	-40°C to +85°C	SOT23-5
GMT2608-3.6S	3.6	200mA	1%	Enable/Shutdown, Flag	-40°C to +85°C	SOT23-5
GMT2608-3.8S	3.8	200mA	1%	Enable/Shutdown, Flag	-40°C to +85°C	SOT23-5
GMT2608-4.0S	4.0	200mA	1%	Enable/Shutdown, Flag	-40°C to +85°C	SOT23-5
GMT2608-5.0S	5.0	200mA	1%	Enable/Shutdown, Flag	-40°C to +85°C	SOT23-5

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Table 3: ELECTRICAL CHARACTERISTICS - GMT2605-3.0, 3.3, 3.6, 3.8, 4.0, 5.0 & Adj.

Limits are for $T_A=25^\circ\text{C}$, and unless specified otherwise, limits which apply over the operating ambient temperature range of -40°C to $+85^\circ\text{C}$ will be determined by device characterization. Unless otherwise specified, $V_{IN}=V_{OUT}+1.0\text{ V}$, $I_L=1.0\text{ mA}$, $C_L=1.0\text{ uF}$ and $V_{EN}\geq 2.0\text{ V}$.

Symbol	Parameter	Conditions	Min	Typ	Max	Units
V_O	Output Voltage Accuracy	$T_A = 25^\circ\text{C}$ $T_A = -40^\circ\text{C to } +85^\circ\text{C}$	-1.0 -2.0		+1.0 +2.0	% %
$\Delta V_O/\Delta T$	Output Voltage Tempco	(Note 2)		6.0	140	ppm/ $^\circ\text{C}$
$\Delta V_O/V_O$	Line Regulation	$V_{IN}=V_{OUT}+1.0\text{ V to } +6.0\text{ V}$, $T_A=25^\circ\text{C}$ $T_A = -40^\circ\text{C to } +85^\circ\text{C}$			0.25 0.3	% %
$\Delta V_O/V_O$	Load Regulation (Note 3)	$I_L = 0.1\text{ mA to } 150\text{ mA}$, $T_A=25^\circ\text{C}$ $T_A = -40^\circ\text{C to } +85^\circ\text{C}$.2 .5	% %
$V_{IN}-V_O$	Dropout Voltage (Note 4)	$I_L=100\text{ mA}$, $T_A = 25^\circ\text{C}$ $I_L=100\text{ mA}$, $T_A = -40^\circ\text{C to } +85^\circ\text{C}$ $I_L=150\text{ mA}$, $T_A = 25^\circ\text{C}$ $I_L=150\text{ mA}$, $T_A = -40^\circ\text{C to } +85^\circ\text{C}$		140 165	250 300 275 350	mV mV mV mV
I_Q	Quiescent Current	$V_{EN}\leq 0.4\text{ V}$, $T_A = -40^\circ\text{C to } +85^\circ\text{C}$			0.15	μA
I_{GND}	Ground Pin Current	$V_{EN}\leq 2.0\text{ V}$, (active), $I_L = 1.0\text{ mA}$ $T_A = +25^\circ\text{C}$ $T_A = -40^\circ\text{C to } +85^\circ\text{C}$			210 257	μA μA
$I_{GND}@V_{DO}$	Ground Pin Current @ Dropout	$V_{IN} = V_{OUT} - 0.5\text{ V}$ $T_A = 25^\circ\text{C}$ $T_A = -40^\circ\text{C to } +85^\circ\text{C}$			700 943	μA μA
PSRR	Ripple Rejection	$f = 100\text{ Hz}$, $I_L = 100\text{ uA}$		49.5		dB
I_{LIMIT}	Current Limit	$V_{OUT} = 0.0\text{ V}$ $T_A = +25^\circ\text{C}$ $T_A = -40^\circ\text{C to } +85^\circ\text{C}$	330 260		350 450	mA mA
$\Delta V_O/\Delta P_D$	Thermal Regulation (Note 5)	$I_L = 200\text{ mA @ } V_{IN}=+6.0\text{ V}$ 10 mS Pulse		0.05	0.1	%/W
V_{IL} V_{IH}	Input Voltage Logic Low Logic High	Regulator Shutdown Regulator Enabled	2.0		0.4	V V
I_{IL} I_{IL} I_{IH} I_{IH}	Control Input Current Logic Low Logic Low Logic High Logic High	$V_{IL}\leq 0.4\text{ V}$ $V_{IL}\leq 0.18\text{ V}$, $-40^\circ\text{C}\leq T_A\leq +85^\circ\text{C}$ $V_{IH}\geq 2.0\text{ V}$ $V_{IH}\geq 2.0\text{ V}$, $-40^\circ\text{C}\leq T_A\leq +85^\circ\text{C}$			-1.0 -2.0 1.0 2.0	μA μA μA μA
e_{no}	Output Voltage Noise	$C_{byp} = 470\text{ pF}$		250		nV/ $\sqrt{\text{Hz}}$

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Table 4: ELECTRICAL CHARACTERISTICS - GMT2606-3.0, 3.3, 3.6, 3.8, 4.0, 5.0 & Adj.

Limits are for $T_A=25^\circ\text{C}$, and unless specified otherwise, limits which apply over the operating ambient temperature range of -40°C to $+85^\circ\text{C}$ will be determined by device characterization. Unless otherwise specified, $V_{IN}=V_{OUT}+1.0\text{ V}$, $I_L=1.0\text{ mA}$, $C_L=1.0\text{ }\mu\text{F}$ and $V_{EN}\geq 2.0\text{ V}$.

Symbol	Parameter	Conditions	Min	Typ	Max	Units
V_O	Output Voltage Accuracy	$T_A = 25^\circ\text{C}$ $T_A = -40^\circ\text{C}$ to $+85^\circ\text{C}$	-0.5 -1.5		+0.5 +1.5	% %
$\Delta V_O/\Delta T$	Output Voltage Tempco	(Note 2)		6	140	ppm/ $^\circ\text{C}$
$\Delta V_O/V_O$	Line Regulation	$V_{IN} = V_{OUT}+1.0\text{ V}$ to $+6.0\text{ V}$, $T_A=25^\circ\text{C}$ $T_A=-40^\circ\text{C}$ to $+85^\circ\text{C}$			0.25 0.3	% %
$\Delta V_O/V_O$	Load Regulation (Note 3)	$I_L = 0.1\text{ mA}$ to 150 mA , $T_A=25^\circ\text{C}$ $T_A=-40^\circ\text{C}$ to $+85^\circ\text{C}$			0.2 0.5	% %
$V_{IN}-V_O$	Dropout Voltage (Note 4)	$I_L=100\text{ mA}$, $T_A = 25^\circ\text{C}$ $I_L=100\text{ mA}$, $T_A = -40^\circ\text{C}$ to $+85^\circ\text{C}$ $I_L=150\text{ mA}$, $T_A = 25^\circ\text{C}$ $I_L=150\text{ mA}$, $T_A = -40^\circ\text{C}$ to $+85^\circ\text{C}$		140 165	250 300 275 350	mV mV mV mV
I_Q	Quiescent Current	$V_{EN}\leq 0.4\text{ V}$, $T_A = -40^\circ\text{C}$ to $+85^\circ\text{C}$			0.15	μA
I_{GND}	Ground Pin Current	$V_{EN}\geq 2.0\text{ V}$ (active), $I_L = 1.0\text{ mA}$ $T_A = +25^\circ\text{C}$ $T_A = -40^\circ\text{C}$ to $+85^\circ\text{C}$			210 257	μA μA
$I_{GND}@V_{DO}$	Ground Pin Current @ Dropout	$V_{IN} = V_{OUT} - 0.5$ $T_A = 25^\circ\text{C}$ $T_A = -40^\circ\text{C}$ to $+85^\circ\text{C}$			700 943	μA μA
PSRR	Ripple Rejection	$f=100\text{ Hz}$, $I_L = 100\text{ }\mu\text{A}$		49.5		dB
I_{LIMIT}	Current Limit	$V_{OUT}=0.0\text{ V}$ $T_A = 25^\circ\text{C}$ $T_A = -40^\circ\text{C}$ to $+85^\circ\text{C}$	330 260		350 450	mA mA
$\Delta V_O/\Delta P_D$	Thermal Regulation (Note 6)	$I_L=200\text{ mA}$ @ $V_{IN}=+6.0\text{ V}$ 10 mS Pulse		0.05	0.1	%/W
V_{IL} V_{IH}	Input Voltage Logic Low Logic High	Regulator Shutdown Regulator Enabled	2.0		0.4	V V
I_{IL} I_{IL} I_{IH} I_{IH}	Control Input Current Logic Low Logic Low Logic High Logic High	$V_{IL}\leq 0.4\text{ V}$ $V_{IL}\leq 0.18\text{ V}$, $-40^\circ\text{C}\leq T_A\leq +85^\circ\text{C}$ $V_{IH}\geq 2.0\text{ V}$ $V_{IH}\geq 2.0\text{ V}$, $-40^\circ\text{C}\leq T_A\leq +85^\circ\text{C}$			-1.0 -2.0 1.0 2.0	μA μA μA μA
V_{ERR}	Flag Threshold	Under voltage (below nominal)			5.0	%
e_{no}	Output Voltage Noise	$C_{byp}=470\text{ pF}$		250		nV/ $\sqrt{\text{Hz}}$
VOL	Output logic low voltage	$I_L = 1.0\text{ mA}$, under-voltage condition			0.4	V
I_{FL}	Flag leakage current	Flag off, $0.0\text{ V} \leq V_{FLAG} \leq 6.0\text{ V}$	-1		+1	μA

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Table 5: ELECTRICAL CHARACTERISTICS - GMT2608-3.0, 3.3, 3.6, 3.8, 4.0, 5.0 & Adj

Limits are for $T_A=25^\circ\text{C}$, and unless specified otherwise, limits which apply over the operating ambient temperature range of -40°C to $+85^\circ\text{C}$ will be determined by device characterization. Unless otherwise specified, $V_{IN}=V_{OUT}+1.0\text{ V}$, $I_L=1.0\text{ mA}$, $C_L=1.0\text{ }\mu\text{F}$ and $V_{EN}\geq 2.0\text{ V}$.

Symbol	Parameter	Conditions	Min	Typ	Max	Units
V_O	Output Voltage Accuracy	$T_A = 25^\circ\text{C}$ $T_A = -40^\circ\text{C to } +85^\circ\text{C}$	-0.5 -1.5		+0.5 +1.5	% %
$\Delta V_O/\Delta T$	Output Voltage Tempco	(Note 2)		6	140	ppm/ $^\circ\text{C}$
$\Delta V_O/V_O$	Line Regulation	$V_{IN} = V_{OUT}+1.0\text{ V to } +6.0\text{ V}$, $T_A=25^\circ\text{C}$ $T_A=-40^\circ\text{C to } +85^\circ\text{C}$			0.25 0.3	% %
$\Delta V_O/V_O$	Load Regulation (Note 3)	$I_L = 0.1\text{ mA to } 150\text{ mA}$, $T_A = 25^\circ\text{C}$ $T_A=-40^\circ\text{C to } +85^\circ\text{C}$			0.2 0.5	% %
$V_{IN}-V_O$	Dropout Voltage (Note 4)	$I_L=100\text{ mA}$, $T_A = 25^\circ\text{C}$ $I_L=100\text{ mA}$, $T_A = -40^\circ\text{C to } +85^\circ\text{C}$ $I_L=150\text{ mA}$, $T_A = 25^\circ\text{C}$ $I_L=150\text{ mA}$, $T_A = -40^\circ\text{C to } +85^\circ\text{C}$		140 165	250 300 275 350	mV mV mV mV
I_Q	Quiescent Current	$V_{EN}\leq 0.4\text{ V}$, $T_A = -40^\circ\text{C to } +85^\circ\text{C}$			0.15	μA
I_{GND}	Ground Pin Current	$V_{EN}\geq 2.0\text{ V (active)}$, $I_L = 1.0\text{ mA}$ $T_A = +25^\circ\text{C}$ $T_A = -40^\circ\text{C to } +85^\circ\text{C}$			210 257	μA μA
$I_{GND@V_{DO}}$	Ground Pin Current @ Dropout	$V_{IN} = V_{OUT}-0.5\text{ V}$ $T_A = 25^\circ\text{C}$ $T_A = -40^\circ\text{C to } +85^\circ\text{C}$			700 943	μA μA
PSRR	Ripple Rejection	$f=100\text{ Hz}$, $I_L = 100\text{ }\mu\text{A}$		49.5		dB
I_{LIMIT}	Current Limit	$V_{OUT}= 0.0\text{ V}$ $T_A = 25^\circ\text{C}$ $T_A = -40^\circ\text{C to } +85^\circ\text{C}$	330 260		350 450	mA mA
$\Delta V_O/\Delta P_D$	Thermal Regulation (Note 5)	$I_L=200\text{ mA @ } V_{IN}=+6.0\text{ V}$ 10 mS Pulse		0.05	0.1	%
V_{IL} V_{IH}	Input Voltage Logic Low Logic High	Regulator Shutdown Regulator Enabled	2.0		0.4	V V
I_{IL} I_{IL} I_{IH} I_{IH}	Control Input Current Logic Low Logic Low Logic High Logic High	$V_{IL}\leq 0.4\text{ V}$ $V_{IL}\leq 0.18\text{ V}$, $-40^\circ\text{C}\leq T_A\leq +85^\circ\text{C}$ $V_{IH}\geq 2.0\text{ V}$ $V_{IH}\geq 2.0\text{ V}$, $-40^\circ\text{C}\leq T_A\leq +85^\circ\text{C}$			-1.0 -2.0 1.0 2.0	μA μA μA μA
e_{no}	Output Voltage Noise	$C_{byp}=470\text{ pF}$		250		nV/ $\sqrt{\text{Hz}}$

SPECIFICATION NOTES

Note 1: The maximum power dissipation is a function of the maximum junction temperature, $T_{J(max)}$, the junction-to-ambient thermal resistance, θ_{JA} , and the ambient temperature, T_A . The maximum allowable power dissipation at any ambient temperature is calculated using: $P_{D(max)} = (T_{J(max)} - T_A) \theta_{JA}$. Exceeding the maximum allowable power dissipation will result in excessive die temperature, and the device will go into thermal shutdown.

Note 2: Output voltage temperature coefficient is defined as the worst case voltage change divided by the total temperature range.

Note 3: Regulation is measured at constant junction temperature using low duty cycle pulse testing.

Note 4: Dropout voltage is defined as the input to output differential at which the output voltage drops 2% below its nominal value measured at 1.0 V differential.

Note 5: Thermal regulation is defined as the change in output voltage at a time "t" after a change in power dissipation is applied, excluding load or line regulation effects.

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APPLICATIONS INFORMATION

General Device Description. The GMT26xx family of LDO regulators represent a new approach to LDO design. These devices offer all of the CMOS advantages of low current consumption, low forward drop and efficiency, plus added enhancements that are unique in the industry.

For example, the stability of the 26xx LDO family is INDEPENDENT of the output capacitor ESR, as well as the actual capacitance value. Not only does that mean no more struggling with marginal stability over operational extremes, but smaller, cheaper C_{out} values for most general applications. The input capacitor can typically assume a value of between 0.1 and 1.0 for most applications. Line and Load rejection have also been dramatically improved at high frequencies, which is a significant advantage in many of today's products that have noisy, switched-mode environments.

Input Capacitor. Good design practice dictates that a 0.1 to 1.0 μF capacitor be placed from the GMT26xx input directly to GND, close to the actual package. Long trace runs leading to the LDO may require larger values to keep the ripple at acceptable levels.

Output Capacitor. Because the GMT26xx family does not depend on either ESR or capacitance value for stability, an inexpensive ceramic capacitor may typically be used for C_{out} ; 1.0 μF should be adequate for many applications. The actual determination is driven by what level of ripple is desired for a given load.

Reference Bypass Capacitor - 2605/6/8. BYP (reference bypass) is connected to the internal voltage reference. A 470 pF capacitor (C_{BYP}) connected from BYP to GND quiets this reference, providing a significant reduction in output noise. The start-up speed of the GMT2605/6/8 is inversely proportional to the size of the reference bypass capacitor. Applications requiring a slow ramp-up of output voltage should consider larger values of C_{BYP} . Conversely, if rapid turn-on is required, consider omitting C_{BYP} . If output noise is not a major concern, omit C_{BYP} and leave BYP open.

SELECTING THE ADJUSTABLE VERSION DIVIDER RESISTORS

When using the adjustable version, the external divider network must be selected to obtain the desired V_{out} . The first constraint on the divider network is the current draw, which is nominally set at 8.0 μA :

$$[V_{out} / R \text{ divider}] = 8.0 \mu A$$

One Resistor may now be selected, and the other solved for, knowing what V_{out} value is desired. The fundamental equation $V_o = V_{ref} \times (1 + (R1/R2))$ is used; therefore, $R1 = R2 \times \{[V_o/V_{ref}] - 1\}$. Please see Table 6 on the following page.

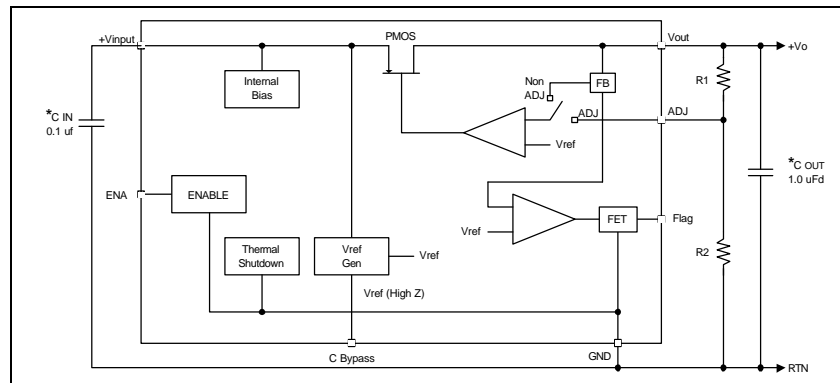
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Table 6: 26XX ADJUSTABLE VERSION RESISTOR VALUES

OUTPUT VOLTAGE	DIVIDER VALUES; % (KOHM)	
	R1	R2
2.5	182 K	165 K
3.0	249 K	165 K
3.3	294 K	165 K
3.6	332 K	165 K
4.0	392 K	165 K
4.5	464 K	165 K
5.0	523 K	165 K

The Vout range of the 26xx series may be varied from approximately 1.2 V to 5.0 V. Resistor values may require adjustment to achieve desired set-points.

26xx ADJUSTABLE REGULATOR APPLICATION DIAGRAM


*Suggested Capacitor Values Only

THERMAL CONSIDERATIONS

The GMT26xx has been designed with internal over-current limiting, set at approximately 350 mA, as well as junction temperature detection, which limits T_J to approximately 150°C. In the event of a current overload, V_o shuts down when T_J reaches 150°C. The LDO will then turn back on as the junction cools. Even though the device is well protected, the designer must still properly manage the thermal environment in order to maximize efficiency and reduce stress. Maximum power dissipation is given by **$P_d(\text{max}) = (T_{j\text{max}} - T_A) / R_{\theta JA}$** . Where $T_{j\text{max}}$ is maximum allowable junction temperature, T_A is the ambient temperature

$R_{\theta JA}$ is the package thermal coefficient. These numbers are derived under specific, controlled test conditions. Actual thermal performance ultimately depends on the application. Each individual board design must be carefully evaluated over full temperature and operational extremes. Please refer to the package data section for thermal coefficients.

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LIFE SUPPORT USAGE POLICY:

GMT's products are not authorized for use as critical components in life support devices or systems without the express written approval of the CEO of GMT. As used herein:

(a) Life support devices or systems are devices or systems which (1) are intended for surgical implant into the body, or (2) support or sustain life, and 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 to the user.

(b) 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.

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