

LM117JAN

3-Terminal Adjustable Regulator

General Description

The LM117 adjustable 3-terminal positive voltage regulator is capable of supplying either 0.5A or 1.5A over a 1.2V to 37V output range. It is exceptionally easy to use and requires only two external resistors to set the output voltage. Further, both line and load regulation are better than standard fixed regulators.

In addition to higher performance than fixed regulators, the LM117 series offers full overload protection available only in IC's. Included on the chip are current limit, thermal overload protection and safe area protection. All overload protection circuitry remains fully functional even if the adjustment terminal is disconnected.

Normally, no capacitors are needed unless the device is situated more than 6 inches from the input filter capacitors in which case an input bypass is needed. An optional output capacitor can be added to improve transient response. The adjustment terminal can be bypassed to achieve very high ripple rejection ratios which are difficult to achieve with standard 3-terminal regulators.

Besides replacing fixed regulators, the LM117 is useful in a wide variety of other applications. Since the regulator is

“floating” and sees only the input-to-output differential voltage, supplies of several hundred volts can be regulated as long as the maximum input to output differential is not exceeded, i.e., avoid short-circuiting the output.

Also, it makes an especially simple adjustable switching regulator, a programmable output regulator, or by connecting a fixed resistor between the adjustment pin and output, the LM117 can be used as a precision current regulator. Supplies with electronic shutdown can be achieved by clamping the adjustment terminal to ground which programs the output to 1.2V where most loads draw little current.

For the negative complement, see LM137 series data sheet.

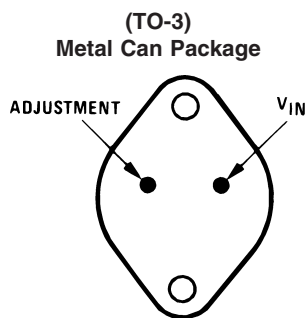
Features

- Guaranteed 0.5A or 1.5A output current
- Adjustable output down to 1.2V
- Current limit constant with temperature
- 80 dB ripple rejection
- Output is short-circuit protected

Ordering Information

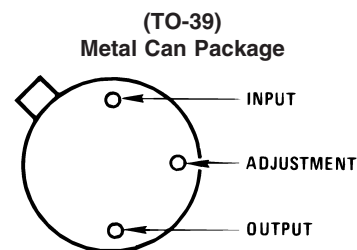
NS Part Number	JAN Part Number	NS Package Number	Package Description
JL117BXA	JM38510/11703BXA	H03A	3LD T0-39 Metal Can
JL117SXA	JM38510/11703SXA	H03A	3LD T0-39 Metal Can
JL117BYA	JM38510/11704BYA	K02C	2LD T0-3 Metal Can
JL117SYA	JM38510/11704SYA	K02C	2LD T0-3 Metal Can

Connection Diagrams



CASE IS OUTPUT

Bottom View
Steel Package
NS Package Number K02C



CASE IS OUTPUT

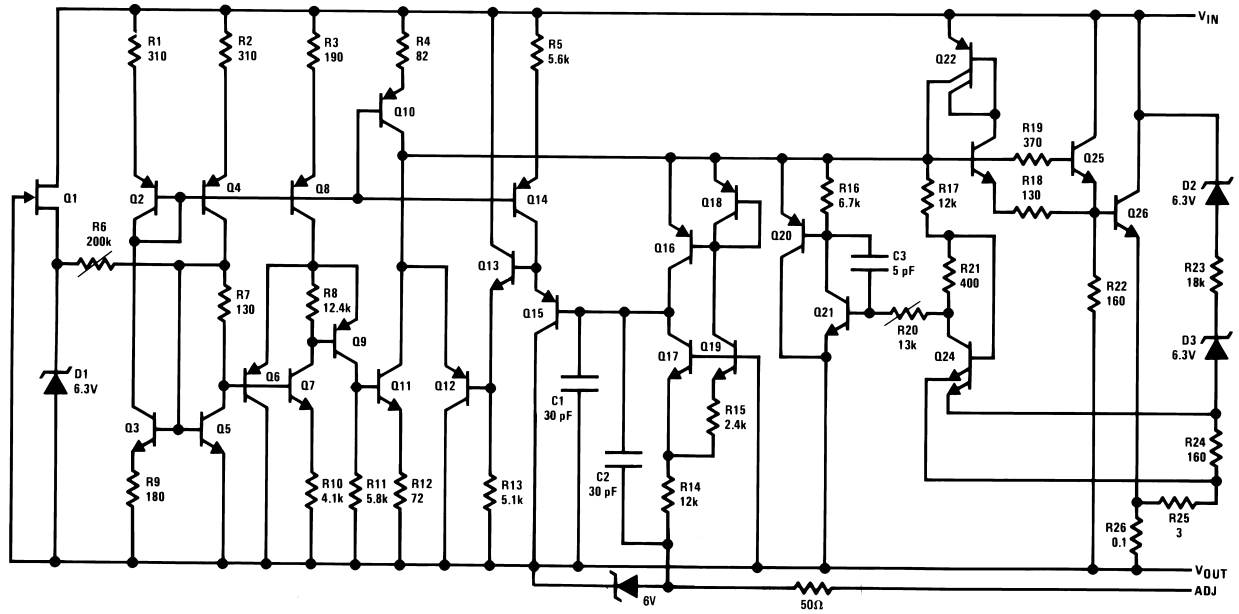
Bottom View
NS Package Number H03A

Connection Diagrams (Continued)

LM117 Series Packages

Part Number Suffix	Package	Design Load Current
K	TO-3	1.5A
H	TO-39	0.5A

Schematic Diagram



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Absolute Maximum Ratings (Note 1)

Power Dissipation (Note 2)	Internally Limited
Input-Output Voltage Differential	+40V, -0.3V
Storage Temperature	$-65^{\circ}\text{C} \leq T_A \leq +150^{\circ}\text{C}$
Maximum Junction Temperature (T_{Jmax})	+150°C
Lead Temperature Metal Package	300°C
Thermal Resistance	
θ_{JA}	
T0-3 Still Air	39°C/W
T0-3 500LF/Min Air flow	14°C/W
T0-39 Still Air	186°C/W
T0-39 500LF/Min Air flow	64°C/W
θ_{JC}	
T0-3	1.9°C/W
T0-39 Metal Can	21°C/W
ESD Tolerance (Note 3)	3KV

Recommended Operating Conditions

Operating Temperature Range	$-55^{\circ}\text{C} \leq T_A \leq +125^{\circ}\text{C}$
Input Voltage Range	4.25V to 41.25V

Quality Conformance Inspection

MIL-STD-883, Method 5005 - Group A

Subgroup	Description	Temp °C
1	Static tests at	25
2	Static tests at	125
3	Static tests at	-55
4	Dynamic tests at	25
5	Dynamic tests at	125
6	Dynamic tests at	-55
7	Functional tests at	25
8A	Functional tests at	125
8B	Functional tests at	-55
9	Switching tests at	25
10	Switching tests at	125
11	Switching tests at	-55
12	Settling time at	25
13	Settling time at	125
14	Settling time at	-55

LM117H JAN Electrical Characteristics

DC Parameters

Symbol	Parameter	Conditions	Notes	Min	Max	Unit	Sub-group
V_O	Output Voltage	$V_I = 4.25V, I_L = -5mA$		1.2	1.3	V	1, 2, 3
		$V_I = 4.25V, I_L = -500mA$		1.2	1.3	V	1, 2, 3
		$V_I = 41.25V, I_L = -5mA$		1.2	1.3	V	1, 2, 3
		$V_I = 41.25V, I_L = -50mA$		1.2	1.3	V	1, 2, 3
V_{RLine}	Line Regulation	$4.25V \leq V_I \leq 41.25V,$ $I_L = -5mA$		-9.0	9.0	mV	1
				-23	23	mV	2, 3
V_{RLoad}	Load Regulation	$V_I = 6.25V,$ $-500mA \leq I_L \leq -5mA$		-12	12	mV	1, 2, 3
			$V_I = 41.25V,$ $-50mA \leq I_L \leq -5mA$		-12	12	mV
θ_R	Thermal Regulation	$V_I = 14.6V, I_L = -500mA$		-12	12	mV	1
I_{Adj}	Adjust Pin Current	$V_I = 4.25V, I_L = -5mA$		-100	-15	μA	1, 2, 3
		$V_I = 41.25V, I_L = -5mA$		-100	-15	μA	1, 2, 3
$\Delta I_{Adj} / \text{Line}$	Adjust Pin Current Change	$4.25V \leq V_I \leq 41.25V,$ $I_L = -5mA$		-5.0	5.0	μA	1, 2, 3
$\Delta I_{Adj} / \text{Load}$	Adjust Pin Current Change	$V_I = 6.25V,$ $-500mA \leq I_L \leq -5mA$		-5.0	5.0	μA	1, 2, 3
I_{OS}	Output Short Circuit Current	$V_I = 4.25V$		-1.8	-0.5	A	1, 2, 3
		$V_I = 40V$		-0.5	-0.05	A	1, 2, 3
$V_O \text{ Recov}$	Output Voltage Recovery	$V_I = 4.25V, R_L = 2.5\Omega,$ $C_L = 20\mu F$		1.2	1.3	V	1, 2, 3
		$V_I = 40V, R_L = 250\Omega$		1.2	1.3	V	1, 2, 3
I_Q	Minimum Load Current	$V_I = 4.25V,$ Forced $V_O = 1.4V$		-3.0	-0.5	mA	1, 2, 3
		$V_I = 14.25V,$ Forced $V_O = 1.4V$		-3.0	-0.5	mA	1, 2, 3
		$V_I = 41.25V,$ Forced $V_O = 1.4V$		-5.0	-1.0	mA	1, 2, 3
V_{Start}	Voltage Start-Up	$V_I = 4.25V, R_L = 2.5\Omega,$ $C_L = 20\mu F, I_L = -500mA$		1.2	1.3	V	1, 2, 3
V_O	Output Voltage	$V_I = 6.25V, I_L = -5mA$	(Note 4)	1.2	1.3	V	2

AC Parameters

Symbol	Parameter	Conditions	Notes	Min	Max	Unit	Sub-group
V_{NO}	Output Noise Voltage	$V_I = 6.25V, I_L = -50mA$			120	μV_{RMS}	7
$\Delta V_O / \Delta V_I$	Line Transient Response	$V_I = 6.25V, \Delta V_I = 3V,$ $I_L = -10mA$			6	mV/V	7
$\Delta V_O / \Delta I_L$	Load Transient Response	$V_I = 6.25V, \Delta I_L = -200mA,$ $I_L = -50mA$			0.6	mV/mA	7
$\Delta V_I / \Delta V_O$	Ripple Rejection	$V_I = 6.25V, I_L = -125mA$ $e_i = 1V_{RMS}$ at $f = 2400Hz,$		65		dB	4

LM117H JAN Electrical Characteristics (Continued)**DC Drift Parameters**

Deltas performed on JAN S devices at Group B, Subgroup 5, only.

Symbol	Parameter	Conditions	Notes	Min	Max	Unit	Sub-group
V_O	Output Voltage	$V_I = 4.25V, I_L = -5mA$		-0.01	0.01	V	1
		$V_I = 4.25V, I_L = -500mA$		-0.01	0.01	V	1
		$V_I = 41.25V, I_L = -5mA$		-0.01	0.01	V	1
		$V_I = 41.25V, I_L = -50mA$		-0.01	0.01	V	1
V_{RLine}	Line Regulation	$4.25V \leq V_I \leq 41.25V,$ $I_L = -5mA$		-4.0	4.0	mV	1
I_{Adj}	Adjust Pin Current	$V_I = 4.25V, I_L = -5mA$		-10	10	μA	1
		$V_I = 41.25V, I_L = -5mA$		-10	10	μA	1

LM117K JAN Electrical Characteristics

DC Parameters

Symbol	Parameter	Conditions	Notes	Min	Max	Unit	Sub-group
V_O	Output Voltage	$V_I = 4.25V, I_L = -5mA$		1.2	1.3	V	1, 2, 3
		$V_I = 4.25V, I_L = -1.5A$		1.2	1.3	V	1, 2, 3
		$V_I = 41.25V, I_L = -5mA$		1.2	1.3	V	1, 2, 3
		$V_I = 41.25V, I_L = -200mA$		1.2	1.3	V	1, 2, 3
V_{RLine}	Line Regulation	$4.25V \leq V_I \leq 41.25V,$ $I_L = -5mA$		-9.0	9.0	mV	1
				-23	23	mV	2, 3
V_{RLoad}	Load Regulation	$V_I = 6.25V,$ $-1.5A \leq I_L \leq -5mA$		-3.5	3.5	mV	1
				-12	12	mV	2, 3
		$V_I = 41.25V,$ $-200mA \leq I_L \leq -5mA$		-3.5	3.5	mV	1
				-12	12	mV	2, 3
θ_R	Thermal Regulation	$V_I = 14.6V, I_L = -1.5A$		-12	12	mV	1
I_{Adj}	Adjust Pin Current	$V_I = 4.25V, I_L = -5mA$		-100	-15	μA	1, 2, 3
		$V_I = 41.25V, I_L = -5mA$		-100	-15	μA	1, 2, 3
$\Delta I_{Adj} / \text{Line}$	Adjust Pin Current Change	$4.25V \leq V_I \leq 41.25V,$ $I_L = -5mA$		-5.0	5.0	μA	1, 2, 3
$\Delta I_{Adj} / \text{Load}$	Adjust Pin Current Change	$V_I = 6.25V,$ $-1.5A \leq I_L \leq -5mA$		-5.0	5.0	μA	1, 2, 3
I_{OS}	Output Short Circuit Current	$V_I = 4.25V$		-3.5	-1.5	A	1, 2, 3
		$V_I = 40V$		-1.0	-0.18	A	1, 2, 3
$V_O \text{ Recov}$	Output Voltage Recovery	$V_I = 4.25V, R_L = 0.833\Omega,$ $C_L = 20\mu F$		1.2	1.3	V	1, 2, 3
		$V_I = 40V, R_L = 250\Omega$		1.2	1.3	V	1, 2, 3
I_Q	Minimum Load Current	$V_I = 4.25V,$ Forced $V_O = 1.4V$		-3.0	-0.2	mA	1, 2, 3
		$V_I = 14.25V,$ Forced $V_O = 1.4V$		-3.0	-0.2	mA	1, 2, 3
		$V_I = 41.25V,$ Forced $V_O = 1.4V$		-5.0	-0.2	mA	1, 2, 3
V_{Start}	Voltage Start-Up	$V_I = 4.25V, R_L = 0.833\Omega,$ $C_L = 20\mu F, I_L = -1.5A$		1.2	1.3	V	1, 2, 3
V_O	Output Voltage	$V_I = 6.25V, I_L = -5mA$	(Note 4)	1.2	1.3	V	2

AC Parameters

Symbol	Parameter	Conditions	Notes	Min	Max	Unit	Sub-group
V_{NO}	Output Noise Voltage	$V_I = 6.25V, I_L = -100mA$			120	μV_{RMS}	7
$\Delta V_O / \Delta V_I$	Line Transient Response	$V_I = 6.25V, \Delta V_I = 3V,$ $I_L = -10mA$	(Note 5)		18	mV	7
$\Delta V_O / \Delta I_L$	Load Transient Response	$V_I = 6.25V, \Delta I_L = -400mA,$ $I_L = -100mA$	(Note 6)		120	mV	7
$\Delta V_I / \Delta V_O$	Ripple Rejection	$V_I = 6.25V, I_L = -500mA$ $e_i = 1V_{RMS}$ at $f = 2400Hz,$		65		dB	4

LM117K JAN Electrical Characteristics (Continued)

DC Drift Parameters

Deltas performed on JAN S devices at Group B, Subgroup 5, only.

Symbol	Parameter	Conditions	Notes	Min	Max	Unit	Sub-group
V_O	Output Voltage	$V_I = 4.25V, I_L = -5mA$		-0.01	0.01	V	1
		$V_I = 4.25V, I_L = -1.5A$		-0.01	0.01	V	1
		$V_I = 41.25V, I_L = -5mA$		-0.01	0.01	V	1
		$V_I = 41.25V, I_L = -200mA$		-0.01	0.01	V	1
V_{RLine}	Line Regulation	$4.25V \leq V_I \leq 41.25V,$ $I_L = -5mA$		-4.0	4.0	mV	1
I_{Adj}	Adjust Pin Current	$V_I = 4.25V, I_L = -5mA$		-10	10	μA	1
		$V_I = 41.25V, I_L = -5mA$		-10	10	μA	1

Note 1: Absolute Maximum Ratings indicate limits beyond which damage to the device may occur. Operating Ratings indicate conditions for which the device is functional, but do not guarantee specific performance limits. For guaranteed specifications and test conditions, see the Electrical Characteristics. The guaranteed specifications apply only for the test conditions listed. Some performance characteristics may degrade when the device is not operated under the listed test conditions.

Note 2: The maximum power dissipation must be derated at elevated temperatures and is dictated by T_{Jmax} (maximum junction temperature), θ_{JA} (package junction to ambient thermal resistance), and T_A (ambient temperature). The maximum allowable power dissipation at any temperature is $P_{Dmax} = (T_{Jmax} - T_A)/\theta_{JA}$ or the number given in the Absolute Maximum Ratings, whichever is lower. "Although power dissipation is internally limited, these specifications are applicable for power dissipations of 2W for the TO39 package and 20W for the TO3 package."

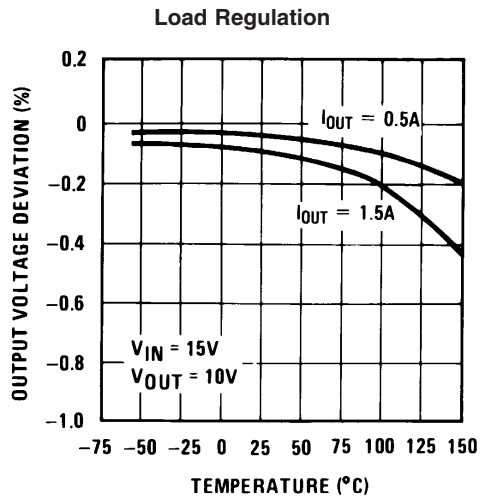
Note 3: Human body model, 100 pF discharged through a 1.5 k Ω resistor.

Note 4: Tested @ $T_A = 125^\circ C$, correlated to $T_A = 150^\circ C$

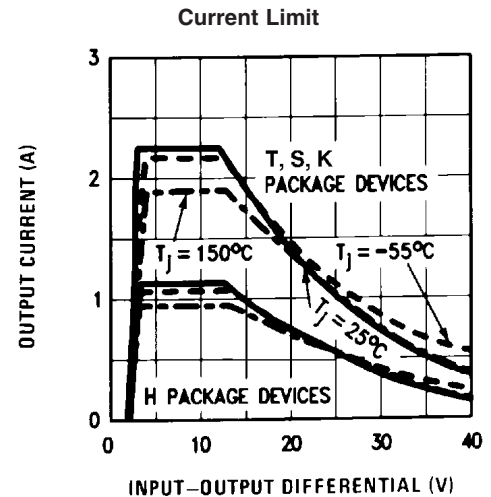
Note 5: SS limit of 6mV/V is equivalent to 18mV

Note 6: SS limit of 0.3mV/V is equivalent to 120mV

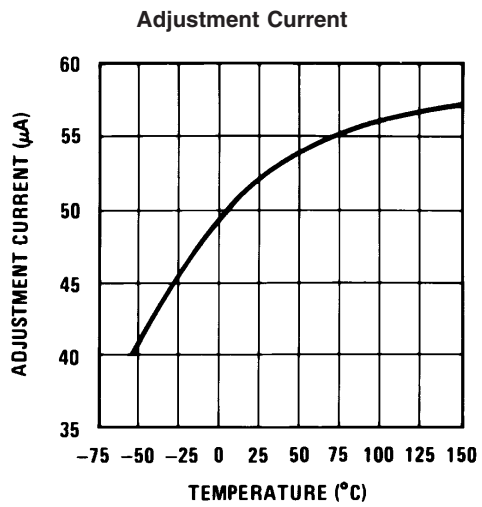
Typical Performance Characteristics Output Capacitor = 0 μ F unless otherwise noted



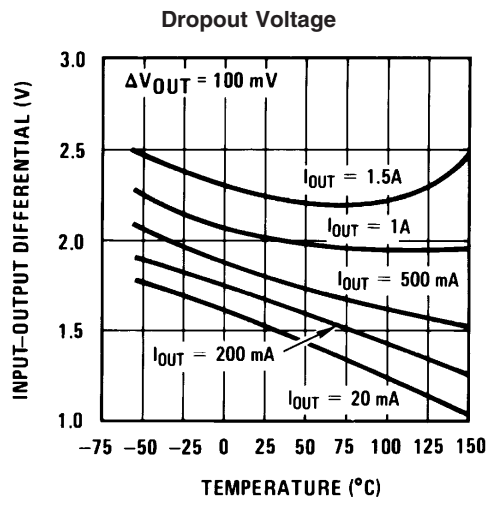
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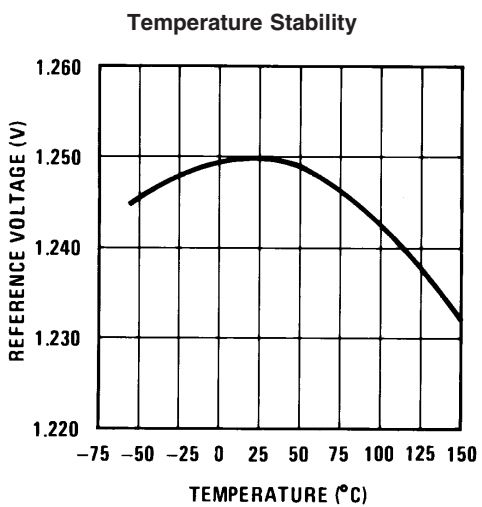
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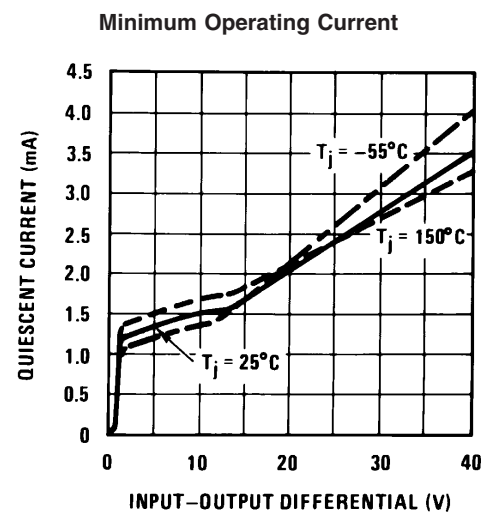
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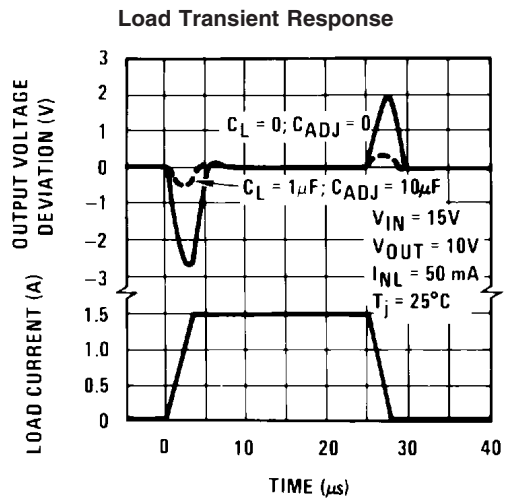
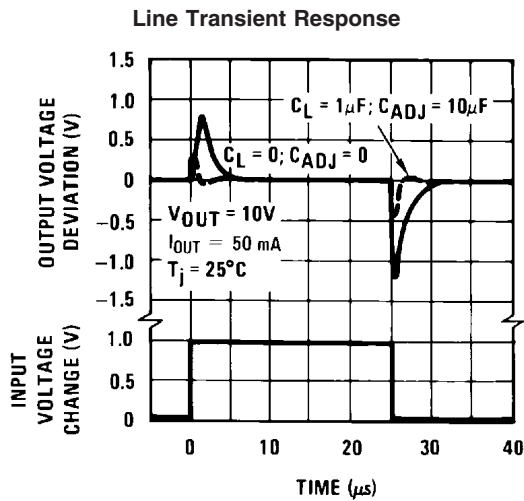
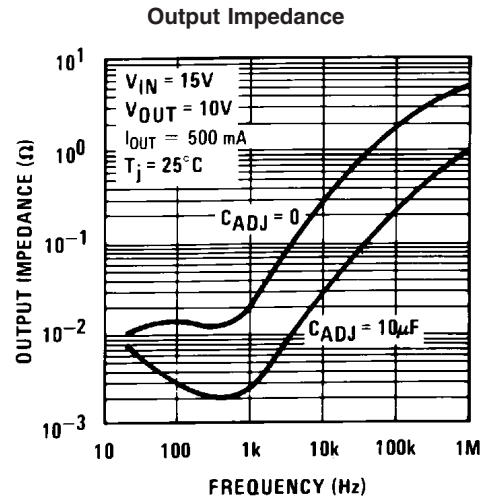
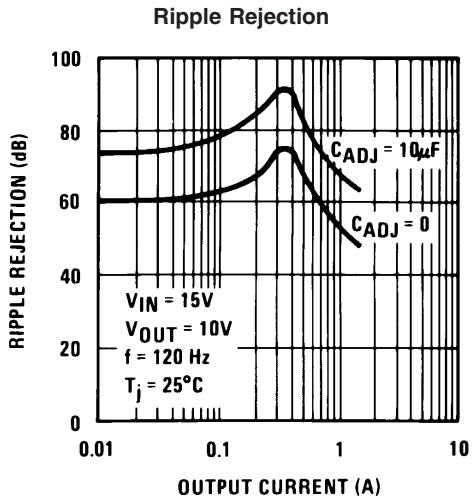
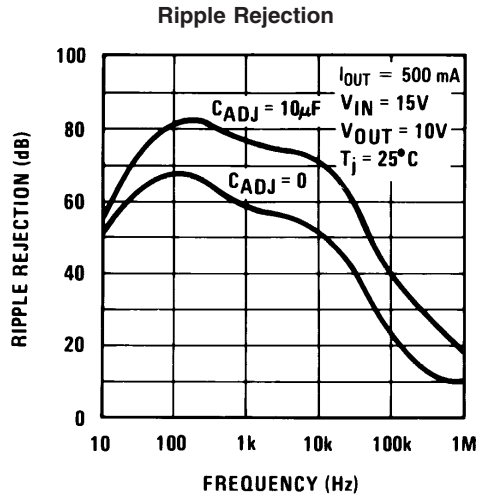
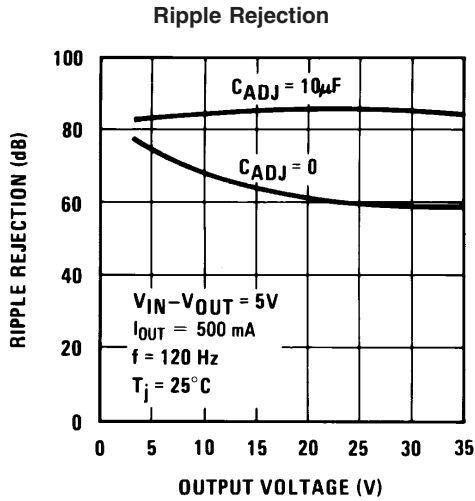


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Typical Performance Characteristics Output Capacitor = 0 μ F unless otherwise noted (Continued)



Application Hints

In operation, the LM117 develops a nominal 1.25V reference voltage, V_{REF} , between the output and adjustment terminal. The reference voltage is impressed across program resistor R1 and, since the voltage is constant, a constant current I_1 then flows through the output set resistor R2, giving an output voltage of

$$V_{OUT} = V_{REF} \left(1 + \frac{R_2}{R_1} \right) + I_{ADJ} R_2$$

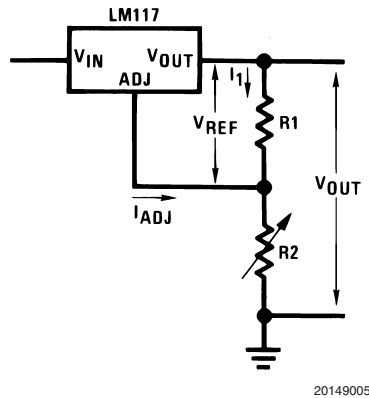


FIGURE 1.

Since the 100 μ A current from the adjustment terminal represents an error term, the LM117 was designed to minimize I_{ADJ} and make it very constant with line and load changes. To do this, all quiescent operating current is returned to the output establishing a minimum load current requirement. If there is insufficient load on the output, the output will rise.

EXTERNAL CAPACITORS

An input bypass capacitor is recommended. A 0.1 μ F disc or 1 μ F solid tantalum on the input is suitable input bypassing for almost all applications. The device is more sensitive to the absence of input bypassing when adjustment or output capacitors are used but the above values will eliminate the possibility of problems.

The adjustment terminal can be bypassed to ground on the LM117 to improve ripple rejection. This bypass capacitor prevents ripple from being amplified as the output voltage is increased. With a 10 μ F bypass capacitor 80dB ripple rejection is obtainable at any output level. Increases over 10 μ F do not appreciably improve the ripple rejection at frequencies above 120Hz. If the bypass capacitor is used, it is sometimes necessary to include protection diodes to prevent the capacitor from discharging through internal low current paths and damaging the device.

In general, the best type of capacitors to use is solid tantalum. Solid tantalum capacitors have low impedance even at high frequencies. Depending upon capacitor construction, it takes about 25 μ F in aluminum electrolytic to equal 1 μ F solid tantalum at high frequencies. Ceramic capacitors are also good at high frequencies; but some types have a large decrease in capacitance at frequencies around 0.5MHz. For this reason, 0.01 μ F disc may seem to work better than a 0.1 μ F disc as a bypass.

Although the LM117 is stable with no output capacitors, like any feedback circuit, certain values of external capacitance

can cause excessive ringing. This occurs with values between 500 pF and 5000 pF. A 1 μ F solid tantalum (or 25 μ F aluminum electrolytic) on the output swamps this effect and insures stability. Any increase of the load capacitance larger than 10 μ F will merely improve the loop stability and output impedance.

LOAD REGULATION

The LM117 is capable of providing extremely good load regulation but a few precautions are needed to obtain maximum performance. The current set resistor connected between the adjustment terminal and the output terminal (usually 240 Ω) should be tied directly to the output (case) of the regulator rather than near the load. This eliminates line drops from appearing effectively in series with the reference and degrading regulation. For example, a 15V regulator with 0.05 Ω resistance between the regulator and load will have a load regulation due to line resistance of 0.05 Ω \times I_L . If the set resistor is connected near the load the effective line resistance will be 0.05 Ω (1 + R_2/R_1) or in this case, 11.5 times worse.

Figure 2 shows the effect of resistance between the regulator and 240 Ω set resistor.

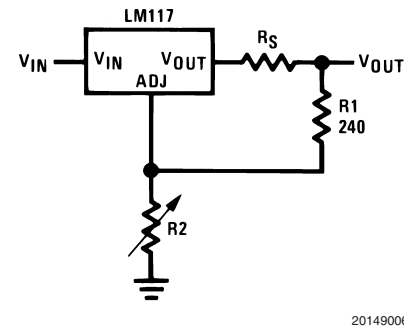


FIGURE 2. Regulator with Line Resistance in Output Lead

With the TO-3 package, it is easy to minimize the resistance from the case to the set resistor, by using two separate leads to the case. However, with the TO-39 package, care should be taken to minimize the wire length of the output lead. The ground of R_2 can be returned near the ground of the load to provide remote ground sensing and improve load regulation.

PROTECTION DIODES

When external capacitors are used with any IC regulator it is sometimes necessary to add protection diodes to prevent the capacitors from discharging through low current points into the regulator. Most 10 μ F capacitors have low enough internal series resistance to deliver 20A spikes when shorted. Although the surge is short, there is enough energy to damage parts of the IC.

When an output capacitor is connected to a regulator and the input is shorted, the output capacitor will discharge into the output of the regulator. The discharge current depends on the value of the capacitor, the output voltage of the regulator, and the rate of decrease of V_{IN} . In the LM117, this discharge path is through a large junction that is able to sustain 15A surge with no problem. This is not true of other types of positive regulators. For output capacitors of 25 μ F or less, there is no need to use diodes.

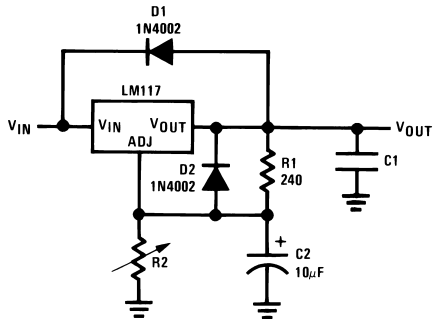
The bypass capacitor on the adjustment terminal can discharge through a low current junction. Discharge occurs

Application Hints (Continued)

when *either* the input or output is shorted. Internal to the LM117 is a 50Ω resistor which limits the peak discharge current. No protection is needed for output voltages of 25V or less and 10μF capacitance. *Figure 3* shows an LM117 with protection diodes included for use with outputs greater than 25V and high values of output capacitance.

When a value for $\theta_{(H-A)}$ is found using the equation shown, *a heatsink must be selected that has a value that is less than or equal to this number.*

$\theta_{(H-A)}$ is specified numerically by the heatsink manufacturer in the catalog, or shown in a curve that plots temperature rise vs power dissipation for the heatsink.



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$$V_{OUT} = 1.25V \left(1 + \frac{R_2}{R_1} \right) + I_{ADJ}R_2$$

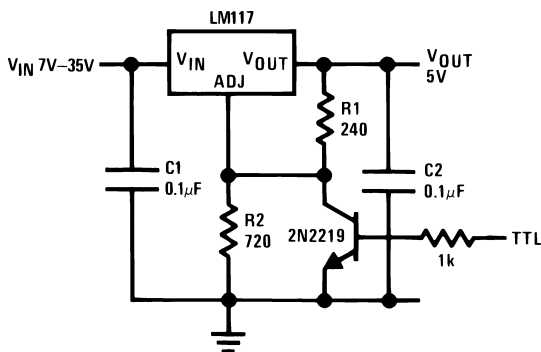
D1 protects against C1

D2 protects against C2

FIGURE 3. Regulator with Protection Diodes

Typical Applications

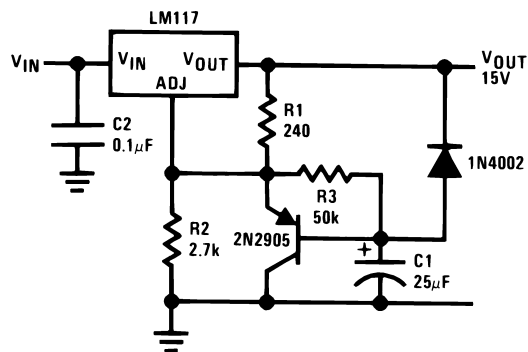
5V Logic Regulator with Electronic Shutdown*



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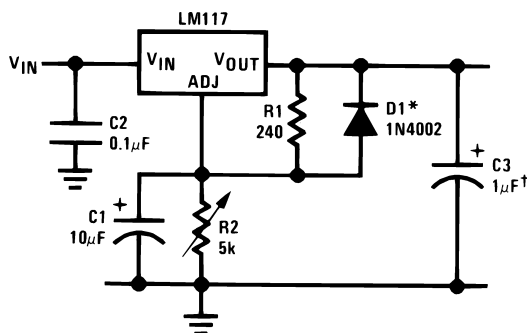
*Min. output \cong 1.2V

Slow Turn-On 15V Regulator



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Adjustable Regulator with Improved Ripple Rejection



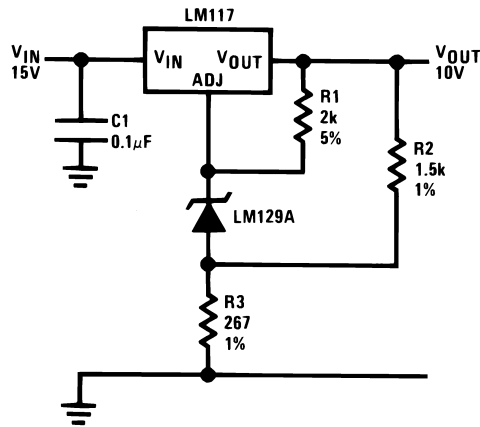
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†Solid tantalum

*Discharges C1 if output is shorted to ground

Typical Applications (Continued)

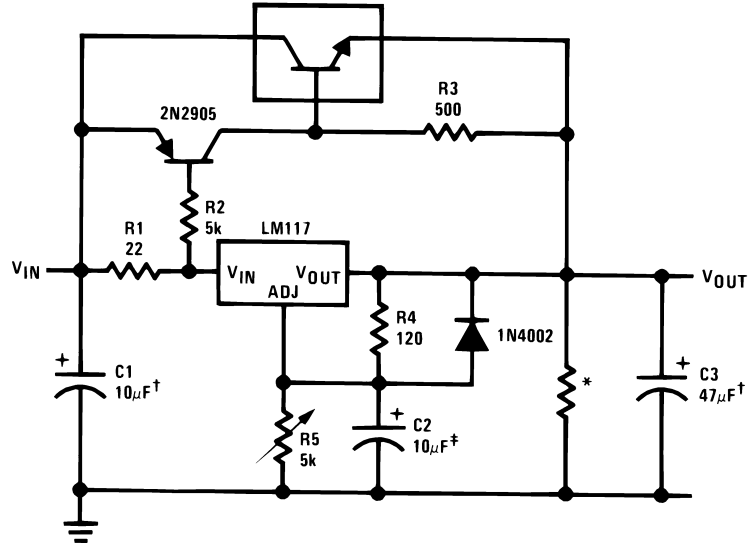
High Stability 10V Regulator



20149011

High Current Adjustable Regulator

3-LM195'S IN PARALLEL



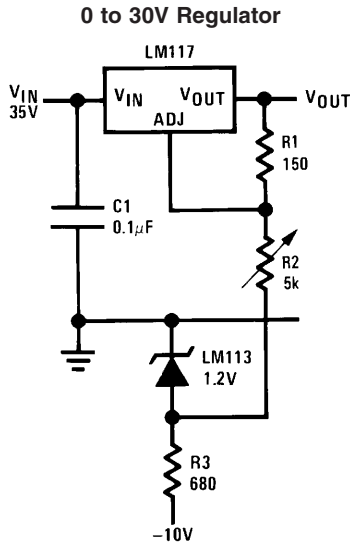
20149012

‡Optional—improves ripple rejection

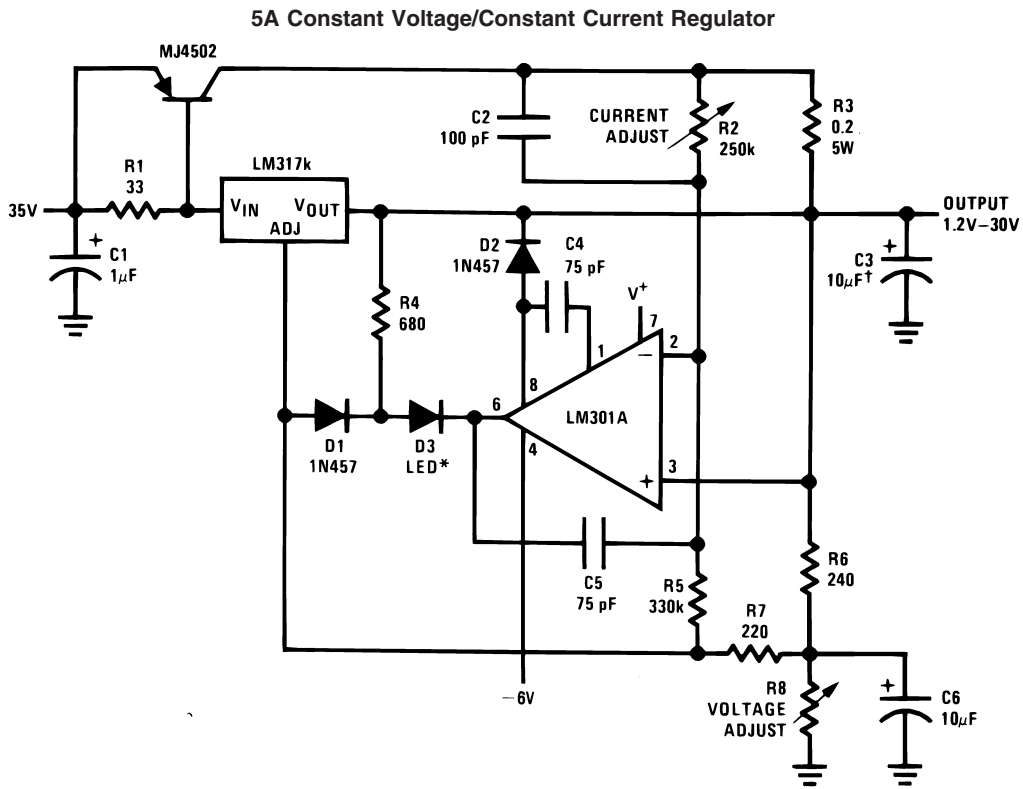
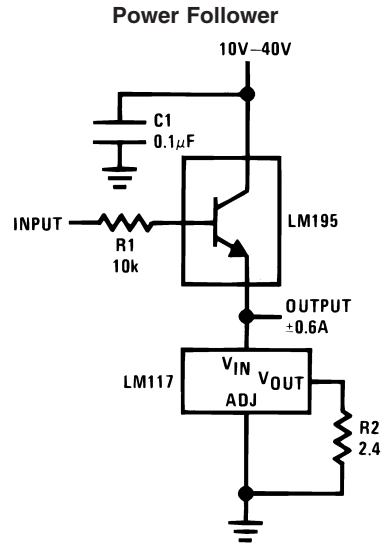
†Solid tantalum

*Minimum load current = 30 mA

Typical Applications (Continued)



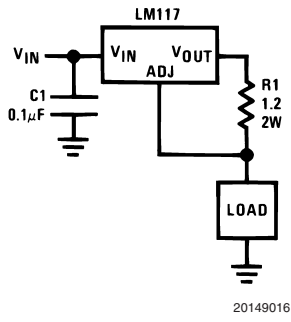
Full output current not available at high input-output voltages



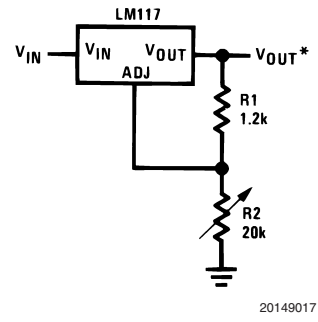
†Solid tantalum
*Lights in constant current mode

Typical Applications (Continued)

1A Current Regulator

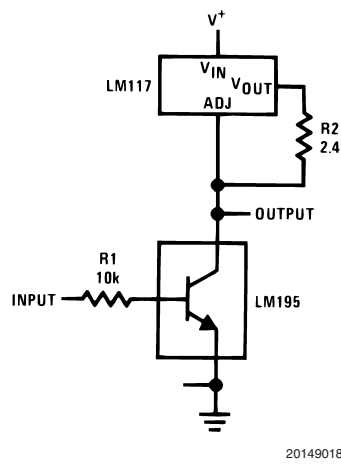


1.2V–20V Regulator with Minimum Program Current

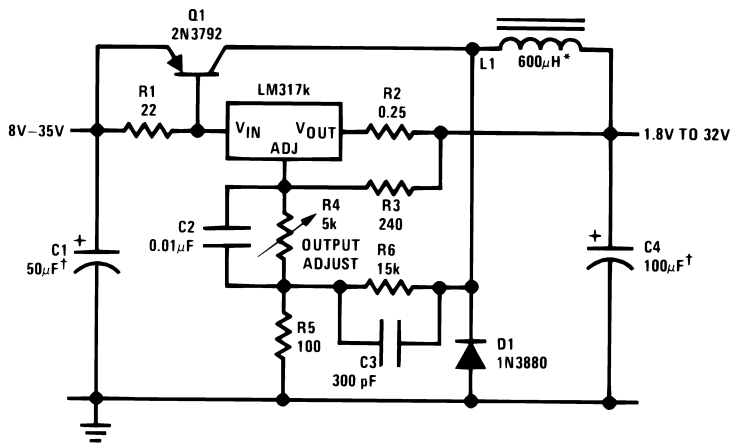


*Minimum load current \cong 4 mA

High Gain Amplifier



Low Cost 3A Switching Regulator

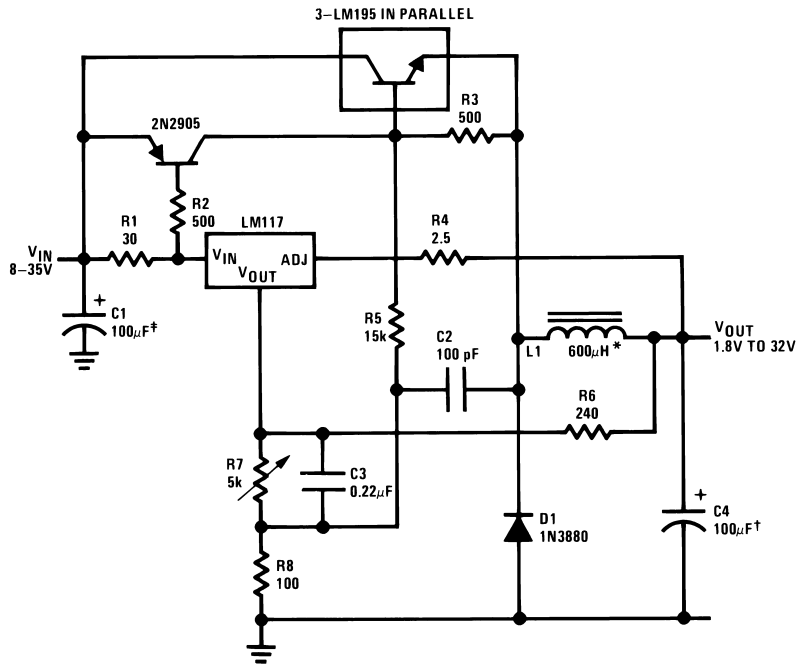


†Solid tantalum

*Core—Arnold A-254168-2 60 turns

Typical Applications (Continued)

4A Switching Regulator with Overload Protection

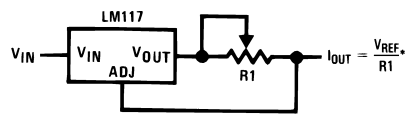


20149020

†Solid tantalum

*Core—Arnold A-254168-2 60 turns

Precision Current Limiter

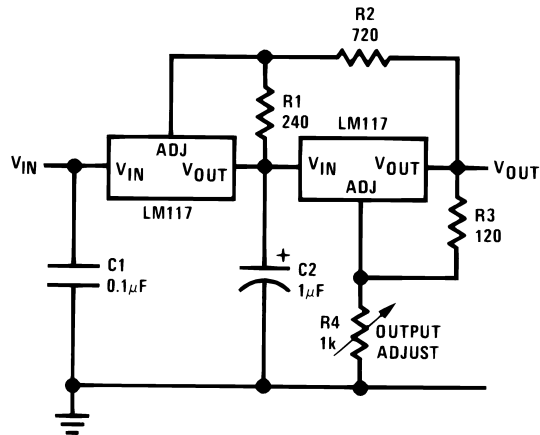


$$I_{OUT} = \frac{V_{REF}}{R1}$$

* $0.8\Omega \leq R1 \leq 120\Omega$

20149021

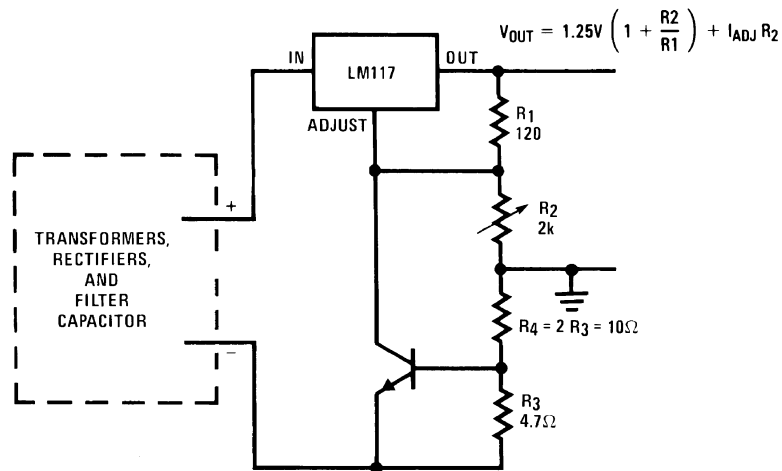
Tracking Preregulator



20149022

Typical Applications (Continued)

Current Limited Voltage Regulator



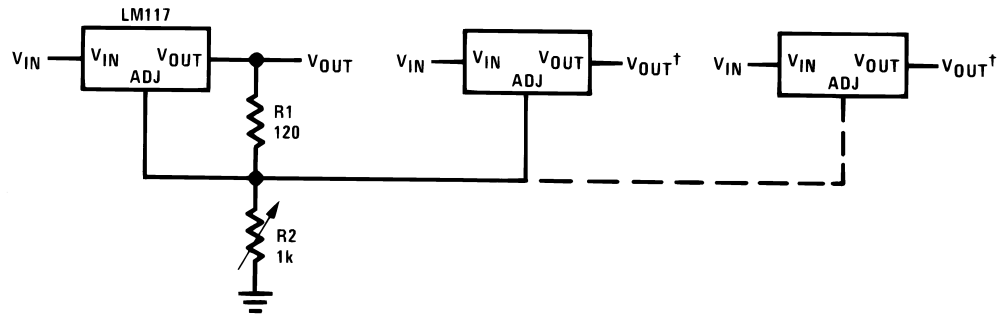
20149023

— Short circuit current is approximately $\frac{600 \text{ mV}}{R_3}$, or 120 mA

(Compared to LM117's higher current limit)

— At 50 mA output only $\frac{3}{4}$ volt of drop occurs in R_3 and R_4

Adjusting Multiple On-Card Regulators with Single Control*



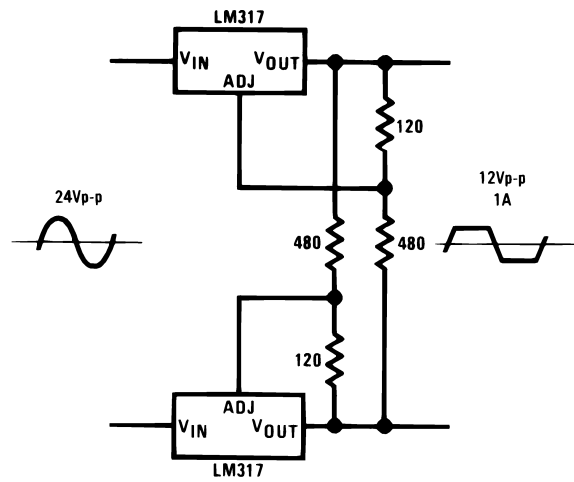
20149024

*All outputs within $\pm 100 \text{ mV}$

†Minimum load — 10 mA

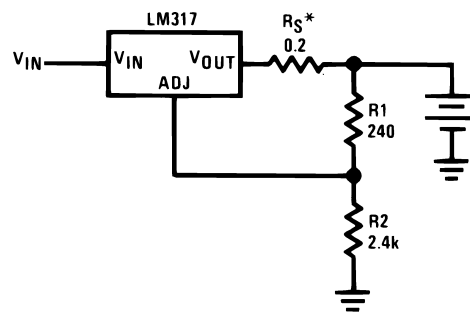
Typical Applications (Continued)

AC Voltage Regulator



20149025

12V Battery Charger

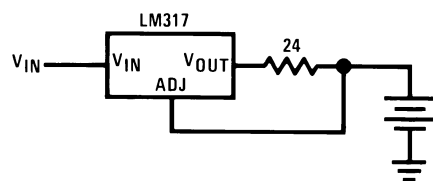


20149026

$$*R_S \text{—sets output impedance of charger: } Z_{OUT} = R_S \left(1 + \frac{R_2}{R_1} \right)$$

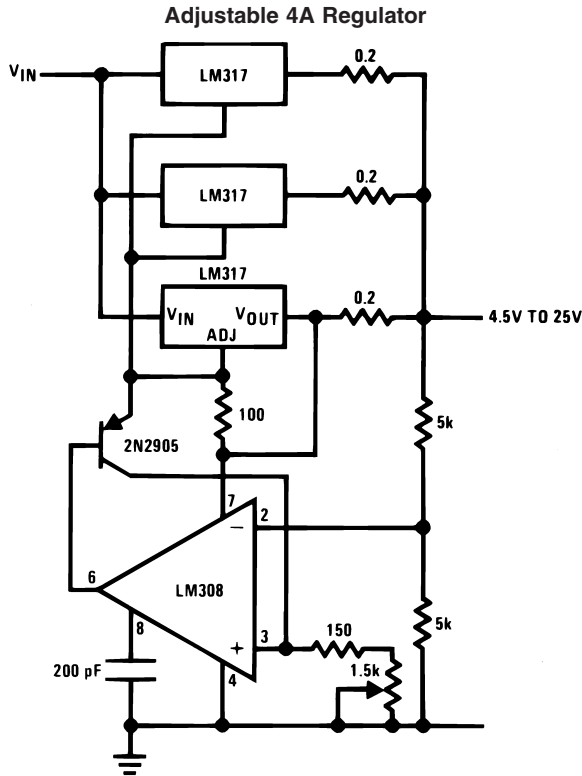
Use of R_S allows low charging rates with fully charged battery.

50mA Constant Current Battery Charger



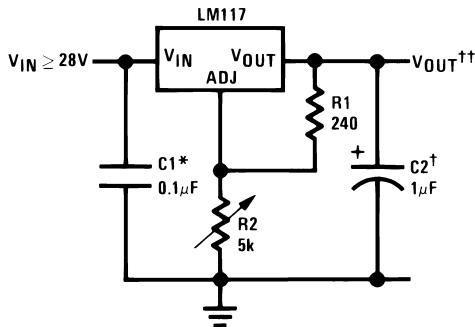
20149027

Typical Applications (Continued)



20149028

1.2V–25V Adjustable Regulator



20149001

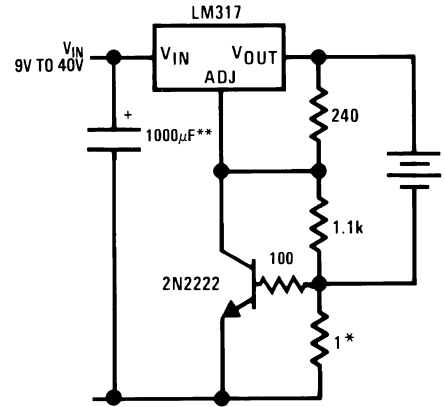
Full output current not available at high input-output voltages

*Needed if device is more than 6 inches from filter capacitors.

†Optional—improves transient response. Output capacitors in the range of 1μF to 1000μF of aluminum or tantalum electrolytic are commonly used to provide improved output impedance and rejection of transients.

$$\dagger\dagger V_{OUT} = 1.25V \left(1 + \frac{R_2}{R_1} \right) + I_{ADJ}(R_2)$$

Current Limited 6V Charger

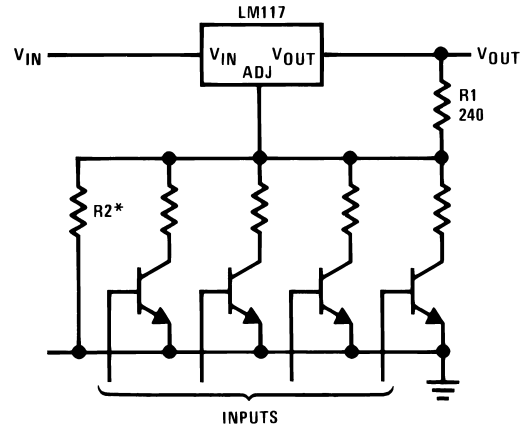


20149029

*Sets peak current (0.6A for 1Ω)

**The 1000μF is recommended to filter out input transients

Digitally Selected Outputs



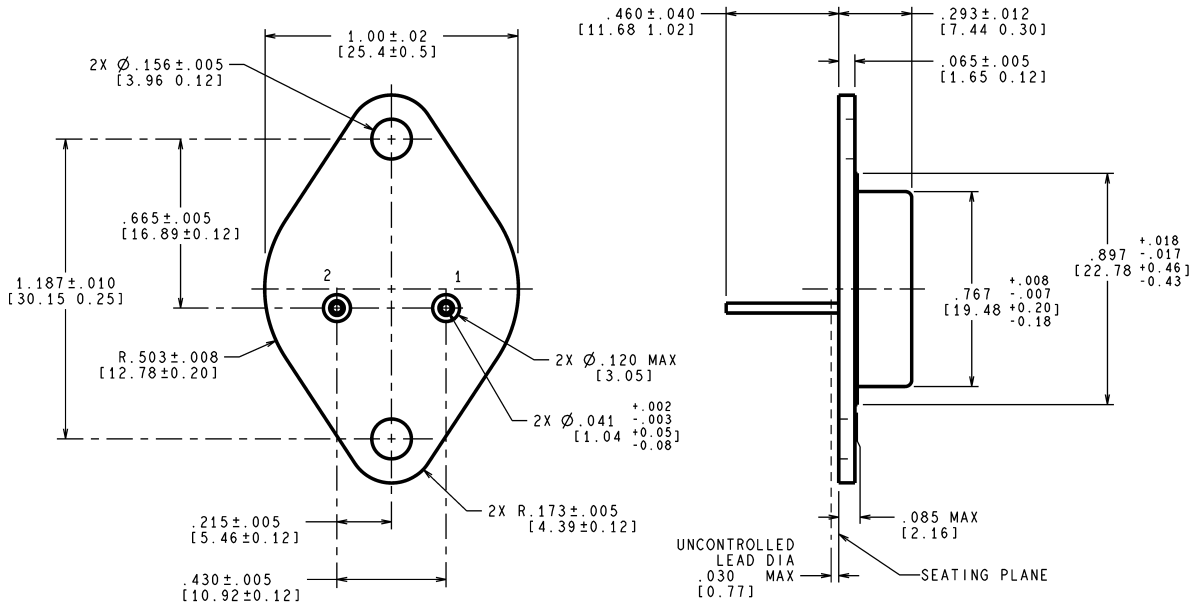
20149002

*Sets maximum VOUT

Revision History

Date Released	Revision	Section	Originator	Changes
03/14/06	A	New Release to corporate format	L. Lytle	2 MDS data sheets were consolidated into one corporate data sheet format. MJLM117-K Rev 0C1 and MJLM117-H Rev 1A1 will be archived.

Physical Dimensions inches (millimeters) unless otherwise noted

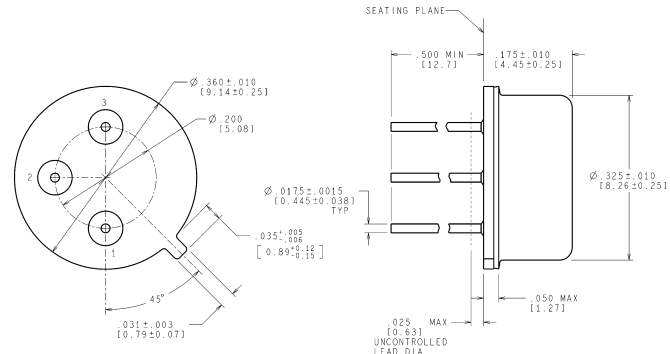


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VALUES IN [] ARE MILLIMETERS

MIL-PRF-38535
CONFIGURATION CONTROL

K02C (Rev E)

**TO-3 Metal Can Package (K)
NS Package Number K02C**



CONTROLLING DIMENSION IS INCH
VALUES IN [] ARE MILLIMETERS

MIL-PRF-38535
CONFIGURATION CONTROL

H03A (Rev D)

**(TO-39) Metal Can Package
NS Package Number H03A**

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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.

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