

KA78LXXA/KA78L05AA

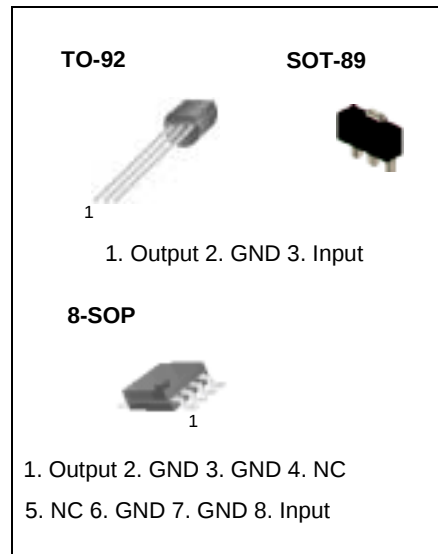
3-Terminal 0.1A Positive Voltage Regulator

Features

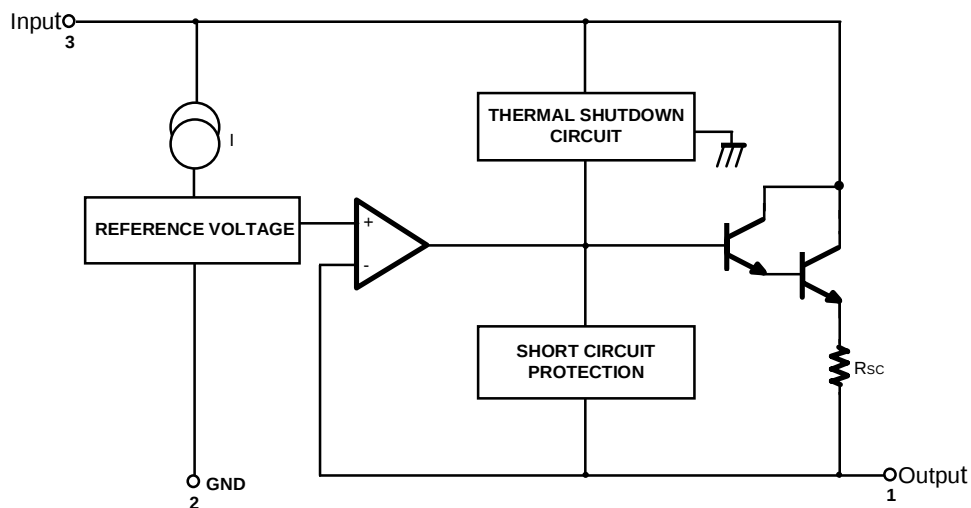
- Maximum Output Current of 100mA
- Output Voltage of 5V, 6V, 8V, 9V, 10V, 12V, 15V, 18V and 24V
- Thermal Overload Protection
- Short Circuit Current Limiting
- Output Voltage Offered in $\pm 5\%$ Tolerance

Description

The KA78LXXA/KA78L05AA series of fixed voltage monolithic integrated circuit voltage regulators are suitable for application that required supply current up to 100mA.



Internal Block Diagram



Absolute Maximum Ratings

Parameter	Symbol	Value	Unit
Input Voltage (for $V_O = 5V, 8V$) (for $V_O = 12V$ to $18V$) (for $V_O = 24V$)	V_I	30 35 40	V V V
Operating Junction Temperature Range	T_J	0 ~ +150	°C
Storage Temperature Range	T_{STG}	-65 ~ +150	°C

Electrical Characteristics(KA78L05A)

($V_I = 10V$, $I_O = 40mA$, $0^\circ C \leq T_J \leq 125^\circ C$, $C_I = 0.33 \mu F$, $C_O = 0.1 \mu F$, unless otherwise specified. (Note 1))

Parameter		Symbol	Conditions		Min.	Typ.	Max.	Unit
Output Voltage		V _O	T _J = 25 °C		4.8	5.0	5.2	V
Line Regulation (Note1)		ΔV _O	T _J = 25 °C	7V ≤ V _I ≤ 20V	-	8	150	mV
				8V ≤ V _I ≤ 20V	-	6	100	mV
Load Regulation (Note1)		ΔV _O	T _J = 25 °C	1mA ≤ I _O ≤ 100mA	-	11	60	mV
				1mA ≤ I _O ≤ 40mA	-	5.0	30	mV
Output Voltage		V _O	7V ≤ V _I ≤ 20V	1mA ≤ I _O ≤ 40mA	-	-	5.25	V
			7V ≤ V _I ≤ V _{MAX} (Note 2)	1mA ≤ I _O ≤ 70mA	4.75	-	5.25	V
Quiescent Current		I _Q	T _J = 25 °C		-	2.0	5.5	mA
Quiescent Current Change	with line	ΔI _Q	8V ≤ V _I ≤ 20V		-	-	1.5	mA
	with load	ΔI _Q	1mA ≤ I _O ≤ 40 mA		-	-	0.1	mA
Output Noise Voltage		V _N	T _A = 25 °C, 10Hz ≤ f ≤ 100KHz		-	40	-	μV/V _O
Temperature Coefficient of V _O		ΔV _O /ΔT	I _O = 5mA		-	-0.65	-	mV/ °C
Ripple Rejection		RR	f = 120Hz, 8V ≤ V _I ≤ 18V, T _J = 25 °C		41	80	-	dB
Dropout Voltage		V _D	T _J = 25 °C		-	1.7	-	V

Note:

1. The maximum steady state usable output current and input voltage are very dependent on the heat sinking and/or lead length of the package. The data above represent pulse test conditions with junction temperature as indicated at the initiation of tests.
2. Power dissipation $P_D \leq 0.75W$.

Electrical Characteristics(KA78L06A)

($V_I = 12V$, $I_O = 40mA$, $0^\circ C \leq T_J \leq 125^\circ C$, $C_I = 0.33\mu F$, $C_O = 0.1\mu F$, unless otherwise specified. (Note 1))

Parameter		Symbol	Conditions	Min.	Typ.	Max.	Unit
Output Voltage		V_O	$T_J = 25^\circ C$	5.75	6.0	6.25	V
Line Regulation (Note1)		ΔV_O	$T_J = 25^\circ C$				
			$8.5V \leq V_I \leq 20V$	-	64	175	mV
Load Regulation (Note1)		ΔV_O	$T_J = 25^\circ C$				
			$1mA \leq I_O \leq 100mA$	-	12.8	80	mV
			$1mA \leq I_O \leq 70mA$	-	5.8	40	mV
Output Voltage		V_O	$8.5 \leq V_I \leq 20V$, $1mA \leq I_O \leq 40mA$	5.7	-	6.3	V
			$8.5 \leq V_I \leq V_{MAX}(\text{Note})$, $1mA \leq I_O \leq 70mA$	5.7	-	6.3	V
Quiescent Current		I_Q	$T_J = 25^\circ C$	-	-	5.5	mA
			$T_J = 125^\circ C$	-	3.9	6.0	mA
Quiescent Current Change	with line	ΔI_Q	$9 \leq V_I \leq 20V$	-	-	1.5	mA
	with load	ΔI_Q	$1mA \leq I_O \leq 40mA$	-	-	0.1	mA
Output Noise Voltage		V_N	$T_A = 25^\circ C$, $10Hz \leq f \leq 100KHz$	-	40	-	$\mu V/V_O$
Temperature Coefficient of V_O		$\Delta V_O/\Delta T$	$I_O = 5mA$	-	0.75	-	mV/ $^\circ C$
Ripple Rejection		RR	$f = 120Hz$, $10V \leq V_I \leq 20V$, $T_J = 25^\circ C$	40	46	-	dB
Dropout Voltage		V_D	$T_J = 25^\circ C$	-	1.7	-	V

Note:

1. The maximum steady state usable output current and input voltage are very dependent on the heat sinking and/or lead length of the package. The data above represent pulse test conditions with junction temperature as indicated at the initiation of tests.
2. Power dissipation $P_D \leq 0.75W$.

Electrical Characteristics(KA78L08A)

($V_I = 14V$, $I_O = 40mA$, $0^\circ C \leq T_J \leq 125^\circ C$, $C_I = 0.33 \mu F$, $C_O = 0.1 \mu F$, unless otherwise specified. (Note 1))

Parameter	Symbol	Conditions	Min.	Typ.	Max.	Unit
Output Voltage	V_O	$T_J = 25^\circ C$	7.7	8.0	8.3	V
Line Regulation (Note1)	ΔV_O	$T_J = 25^\circ C$				
		$10.5V \leq V_I \leq 23V$	-	10	175	mV
		$11V \leq V_I \leq 23V$	-	8	125	mV
Load Regulation (Note1)	ΔV_O	$T_J = 25^\circ C$				
		$1mA \leq I_O \leq 100mA$	-	15	80	mV
		$1mA \leq I_O \leq 40mA$	-	8.0	40	mV
Output Voltage	V_O	$10.5V \leq V_I \leq 23V$				
		$1mA \leq I_O \leq 40mA$	7.6	-	8.4	V
Output Voltage	V_O	$10.5V \leq V_I \leq V_{MAX}$ (Note 2)				
		$1mA \leq I_O \leq 70mA$	7.6	-	8.4	V
Quiescent Current	I_Q	$T_J = 25^\circ C$	-	2.0	5.5	mA
Quiescent Current Change	with line	ΔI_Q				
	with load	ΔI_Q				
		$11V \leq V_I \leq 23V$	-	-	1.5	mA
		$1mA \leq I_O \leq 40mA$	-	-	0.1	mA
Output Noise Voltage	V_N	$T_A = 25^\circ C$, $10Hz \leq f \leq 100KHz$	-	60	-	$\mu V/V_O$
Temperature Coefficient of V_O	$\Delta V_O/\Delta T$	$I_O = 5mA$	-	-0.8	-	mV/ $^\circ C$
Ripple Rejection	RR	$f = 120Hz$, $11V \leq V_I \leq 21V$, $T_J = 25^\circ C$	39	70	-	dB
Dropout Voltage	V_D	$T_J = 25^\circ C$	-	1.7	-	V

Note:

1. The maximum steady state usable output current and input voltage are very dependent on the heat sinking and/or lead length of the package. The data above represent pulse test conditions with junction temperature as indicated at the initiation of tests.
2. Power dissipation $P_D \leq 0.75W$.

Electrical Characteristics(KA78L09A)

($V_I = 15V$, $I_O = 40mA$, $0^\circ C \leq T_J \leq 125^\circ C$, $C_I = 0.33 \mu F$, $C_O = 0.1 \mu F$, unless otherwise specified. (Note 1))

Parameter	Symbol	Conditions	Min.	Typ.	Max.	Unit
Output Voltage	V_O	$T_J = 25^\circ C$	8.64	9.0	9.36	V
Line Regulation (Note1)	ΔV_O	$T_J = 25^\circ C$	$11.5V \leq V_I \leq 24V$	-	90	200 mV
			$13V \leq V_I \leq 24V$	-	100	150 mV
Load Regulation (Note1)	ΔV_O	$T_J = 25^\circ C$	$1mA \leq I_O \leq 100mA$	-	20	90 mV
			$1mA \leq I_O \leq 40mA$	-	10	45 mV
Output Voltage	V_O	$11.5V \leq V_I \leq 24V$	$1mA \leq I_O \leq 40mA$	8.55	-	9.45 V
		$11.5V \leq V_I \leq V_{MAX}$ (Note 2)	$1mA \leq I_O \leq 70mA$	8.55	-	9.45 V
Quiescent Current	I_Q	$T_J = 25^\circ C$	-	2.1	6.0	mA
Quiescent Current Change	with line	ΔI_Q	$13V \leq V_I \leq 24V$	-	-	1.5 mA
	with load	ΔI_Q	$1mA \leq I_O \leq 40mA$	-	-	0.1 mA
Output Noise Voltage	V_N	$T_A = 25^\circ C$, $10Hz \leq f \leq 100KHz$	-	70	-	$\mu V/V_O$
Temperature Coefficient of V_O	$\Delta V_O/\Delta T$	$I_O = 5mA$	-	-0.9	-	mV/ $^\circ C$
Ripple Rejection	RR	$f = 120Hz$, $12V \leq V_I \leq 22V$, $T_J = 25^\circ C$	38	44	-	dB
Dropout Voltage	V_D	$T_J = 25^\circ C$	-	1.7	-	V

Note:

1. The maximum steady state usable output current and input voltage are very dependent on the heat sinking and/or lead length of the package. The data above represent pulse test conditions with junction temperature as indicated at the initiation of tests.
2. Power dissipation $P_D \leq 0.75W$.

Electrical Characteristics(KA78L10A)

($V_I = 16V$, $I_O = 40mA$, $0^\circ C \leq T_J \leq 125^\circ C$, $C_I = 0.33 \mu F$, $C_O = 0.1 \mu F$, unless otherwise specified. (Note 1))

Parameter		Symbol	Conditions	Min.	Typ.	Max.	Unit	
Output Voltage		V _O	T _J = 25 °C		9.6	10.0	10.4	V
Line Regulation (Note1)		ΔV _O	T _J = 25 °C	12.5 ≤ V _I ≤ 25V	-	100	220	mV
				14V ≤ V _I ≤ 25V	-	100	170	mV
Load Regulation (Note1)		ΔV _O	T _J = 25 °C	1mA ≤ I _O ≤ 100mA	-	20	94	mV
				1mA ≤ I _O ≤ 70mA	-	10	47	mV
Output Voltage		V _O	12.5V ≤ V _I ≤ 25V, 1mA ≤ I _O ≤ 40mA		9.5	-	10.5	V
			12.5V ≤ V _I ≤ V _{MAX} (Note2) 1mA ≤ I _O ≤ 70mA		9.5	-	10.5	
Quiescent Current		I _Q	T _J = 25 °C		-	-	6.0	mA
			T _J =125 °C		-	4.2	6.5	
Quiescent Current Change	with line	ΔI _Q	12.5 ≤ V _I ≤ 25V		-	-	1.5	mA
	with load	ΔI _Q	1mA ≤ I _O ≤ 40mA		-	-	0.1	mA
Output Noise Voltage		V _N	T _A = 25 °C, 10Hz ≤ f ≤ 100KHz		-	74	-	μV/V _O
Temperature Coefficient of V _O		ΔV _O /ΔT	I _O = 5mA		-	0.95	-	mV/ °C
Ripple Rejection		RR	f = 120Hz, 15V ≤ V _I ≤ 25V, T _J = 25 °C		38	43	-	dB
Dropout Voltage		V _D	T _J = 25 °C		-	1.7	-	V

Notes:

1. The maximum steady state usable output current and input voltage are very dependent on the heat sinking and/or lead length of the package. The data above represent pulse test conditions with junction temperature as indicated at the initiation of tests.
2. Power dissipation $P_D \leq 0.75W$.

Electrical Characteristics(KA78L12A)

($V_I = 19V$, $I_O = 40mA$, $0^\circ C \leq T_J \leq 125^\circ C$, $C_I = 0.33 \mu F$, $C_O = 0.1 \mu F$, unless otherwise specified. (Note 1))

Parameter	Symbol	Conditions	Min.	Typ.	Max.	Unit
Output Voltage	V_O	$T_J = 25^\circ C$	11.5	12	12.5	V
Line Regulation (Note1)	ΔV_O	$T_J = 25^\circ C$				
		$14.5V \leq V_I \leq 27V$	-	20	250	mV
		$16V \leq V_I \leq 27V$	-	15	200	mV
Load Regulation (Note1)	ΔV_O	$T_J = 25^\circ C$				
		$1mA \leq I_O \leq 100mA$	-	20	100	mV
		$1mA \leq I_O \leq 40mA$	-	10	50	mV
Output Voltage	V_O	$14.5V \leq V_I \leq 27V$				
		$1mA \leq I_O \leq 40mA$	11.4	-	12.6	V
Output Voltage	V_O	$14.5V \leq V_I \leq V_{MAX}$ (Note 2)				
		$1mA \leq I_O \leq 70mA$	11.4	-	12.6	V
Quiescent Current	I_Q	$T_J = 25^\circ C$	-	2.1	6.0	mA
Quiescent Current Change	with line	ΔI_Q				
	with load	ΔI_Q				
		$16V \leq V_I \leq 27V$	-	-	1.5	mA
		$1mA \leq I_O \leq 40mA$	-	-	0.1	mA
Output Noise Voltage	V_N	$T_A = 25^\circ C$, $10Hz \leq f \leq 100KHz$	-	80	-	$\mu V/V_O$
Temperature Coefficient of V_O	$\Delta V_O/\Delta T$	$I_O = 5mA$	-	-1.0	-	mV/ $^\circ C$
Ripple Rejection	RR	$f = 120Hz$, $15V \leq V_I \leq 25V$, $T_J = 25^\circ C$	37	65	-	dB
Dropout Voltage	V_D	$T_J = 25^\circ C$	-	1.7	-	V

Note:

1. The maximum steady state usable output current and input voltage are very dependent on the heat sinking and/or lead length of the package. The data above represent pulse test conditions with junction temperature as indicated at the initiation of tests.
2. Power dissipation $P_D \leq 0.75W$.

Electrical Characteristics(KA78L15A)

($V_I = 23V$, $I_O = 40mA$, $0^\circ C \leq T_J \leq 125^\circ C$, $C_I = 0.33 \mu F$, $C_O = 0.1 \mu F$, unless otherwise specified. (Note 1))

Parameter		Symbol	Conditions		Min.	Typ.	Max.	Unit
Output Voltage		V _O	T _J = 25 °C		14.4	15	15.6	V
Line Regulation (Note1)		ΔV _O	T _J = 25 °C	17.5V ≤ V _I ≤ 30V	-	25	300	mV
				20V ≤ V _I ≤ 30V	-	20	250	mV
Load Regulation (Note1)		ΔV _O	T _J = 25 °C	1mA ≤ I _O ≤ 100mA	-	25	150	mV
				1mA ≤ I _O ≤ 40mA	-	12	75	mV
Output Voltage		V _O	17.5V ≤ V _I ≤ 30V	1mA ≤ I _O ≤ 40mA	14.25	-	15.75	V
			17.5V ≤ V _I ≤ V _{MAX} (Note 2)	1mA ≤ I _O ≤ 70mA	14.25	-	15.75	V
Quiescent Current		I _Q	T _J = 25 °C		-	2.1	6.0	mA
Quiescent Current Change	with line	ΔI _Q	20V ≤ V _I ≤ 30V		-	-	1.5	mA
	with load	ΔI _Q	1mA ≤ I _O ≤ 40mA		-	-	0.1	mA
Output Noise Voltage		V _N	T _A = 25 °C, 10Hz ≤ f ≤ 100KHz		-	90	-	μV/V _o
Temperature Coefficient of V _O		ΔV _O /ΔT	I _O = 5mA		-	-1.3	-	mV/ °C
Ripple Rejection		RR	f = 120Hz, 18.5V ≤ V _I ≤ 28.5V, T _J = 25 °C		34	60	-	dB
Dropout Voltage		V _D	T _J = 25 °C		-	1.7	-	V

Note:

1. The maximum steady state usable output current and input voltage are very dependent on the heat sinking and/or lead length of the package. The data above represent pulse test conditions with junction temperature as indicated at the initiation of tests.
2. Power dissipation $P_D \leq 0.75W$.

Electrical Characteristics(KA78L18A)

($V_I = 27V$, $I_O = 40mA$, $0^\circ C \leq T_J \leq 125^\circ C$, $C_I = 0.33 \mu F$, $C_O = 0.1 \mu F$, unless otherwise specified. (Note 1))

Parameter	Symbol	Conditions	Min.	Typ.	Max.	Unit
Output Voltage	V_O	$T_J = 25^\circ C$	17.3	18	18.7	V
Line Regulation (Note1)	ΔV_O	$T_J = 25^\circ C$	$21V \leq V_I \leq 33V$	-	145	300 mV
			$22V \leq V_I \leq 33V$	-	135	250 mV
Load Regulation (Note1)	ΔV_O	$T_J = 25^\circ C$	$1mA \leq I_O \leq 100mA$	-	30	170 mV
			$1mA \leq I_O \leq 40mA$	-	15	85 mV
Output Voltage	V_O	$21V \leq V_I \leq 33V$	$1mA \leq I_O \leq 40mA$	17.1	-	18.9 V
		$21V \leq V_I \leq V_{MAX}$ (Note 2)	$1mA \leq I_O \leq 70mA$	17.1	-	18.9 V
Quiescent Current	I_Q	$T_J = 25^\circ C$	-	2.2	6.0	mA
Quiescent Current Change	with line	ΔI_Q	$21V \leq V_I \leq 33V$	-	-	1.5 mA
	with load	ΔI_Q	$1mA \leq I_O \leq 40mA$	-	-	0.1 mA
Output Noise Voltage	V_N	$T_A = 25^\circ C$, $10Hz \leq f \leq 100KHz$	-	150	-	$\mu V/V_O$
Temperature Coefficient of V_O	$\Delta V_O/\Delta T$	$I_O = 5mA$	-	-1.8	-	mV/ $^\circ C$
Ripple Rejection	RR	$f = 120Hz$, $23V \leq V_I \leq 33V$, $T_J = 25^\circ C$	34	48	-	dB
Dropout Voltage	V_D	$T_J = 25^\circ C$	-	1.7	-	V

Note:

1. The maximum steady state usable output current and input voltage are very dependent on the heat sinking and/or lead length of the package. The data above represent pulse test conditions with junction temperature as indicated at the initiation of tests.
2. Power dissipation $P_D \leq 0.75W$.

Electrical Characteristics(KA78L24A)

($V_I = 33V$, $I_O = 40mA$, $0^\circ C \leq T_J \leq 125^\circ C$, $C_I = 0.33 \mu F$, $C_O = 0.1 \mu F$, unless otherwise specified. (Note 1))

Parameter		Symbol	Conditions		Min.	Typ.	Max.	Unit
Output Voltage		V _O	T _J = 25 °C		23	24	25	V
Line Regulation (Note1)		ΔV _O	T _J = 25 °C	27V ≤ V _I ≤ 38V	-	160	300	mV
				28V ≤ V _I ≤ 38V	-	150	250	mV
Load Regulation (Note1)		ΔV _O	T _J = 25 °C	1mA ≤ I _O ≤ 100mA	-	40	200	mV
				1mA ≤ I _O ≤ 40mA	-	20	100	mV
Output Voltage		V _O	27V ≤ V _I ≤ 38V	1mA ≤ I _O ≤ 40mA	22.8	-	25.2	V
			27V ≤ V _I ≤ V _{MAX} (Note 2)	1mA ≤ I _O ≤ 70mA	22.8	-	25.2	V
Quiescent Current		I _Q	T _J = 25 °C		-	2.2	6.0	mA
Quiescent Current Change	with line	ΔI _Q	28V ≤ V _I ≤ 38V		-	-	1.5	mA
	with load	ΔI _Q	1mA ≤ I _O ≤ 40mA		-	-	0.1	mA
Output Noise Voltage		V _N	T _A = 25 °C, 10Hz ≤ f ≤ 100KHz		-	200	-	μV/V _o
Temperature Coefficient of V _O		ΔV _O /ΔT	I _O = 5mA		-	-2.0	-	mV/ °C
Ripple Rejection		RR	f = 120Hz, 28V ≤ V _I ≤ 38V, T _J = 25 °C		34	45	-	dB
Dropout Voltage		V _D	T _J = 25 °C		-	1.7	-	V

Note:

1. The maximum steady state usable output current and input voltage are very dependent on the heat sinking and/or lead length of the package. The data above represent pulse test conditions with junction temperature as indicated at the initiation of tests.
2. Power dissipation $P_D \leq 0.75W$.

Absolute Maximum Ratings

Parameter	Symbol	Value	Unit
Input Voltage (for $V_O = 5V, 8V$) (for $V_O = 12V$ to $18V$) (for $V_O = 24V$)	V_I	30 35 40	V V V
Operating Junction Temperature Range	T_J	0 ~ +150	°C
Storage Temperature Range	T_{STG}	-65 ~ +150	°C

Electrical Characteristics(KA78L05AA)

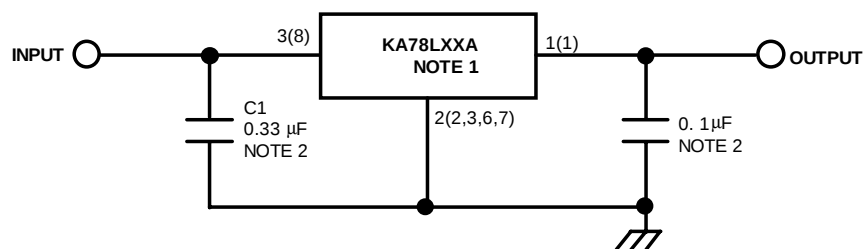
($V_I = 10V$, $I_O = 40mA$, $0^\circ C \leq T_J \leq 125^\circ C$, $C_I = 0.33 \mu F$, $C_O = 0.1 \mu F$, unless otherwise specified. (Note 1))

Parameter		Symbol	Conditions		Min.	Typ.	Max.	Unit
Output Voltage		V _O	T _J = 25 °C		4.9	5.0	5.1	V
Line Regulation (Note1)		ΔV _O	T _J = 25 °C	7V ≤ V _I ≤ 20V	-	8	150	mV
				8V ≤ V _I ≤ 20V	-	6	100	mV
Load Regulation (Note1)		ΔV _O	T _J = 25 °C	1mA ≤ I _O ≤ 100mA	-	11	50	mV
				1mA ≤ I _O ≤ 40mA	-	5.0	25	mV
Output Voltage		V _O	7V ≤ V _I ≤ 20V	1mA ≤ I _O ≤ 40mA	-	-	5.15	V
			7V ≤ V _I ≤ V _{MAX} (Note 2)	1mA ≤ I _O ≤ 70mA	4.85	-	5.15	V
Quiescent Current		I _Q	T _J = 25 °C		-	2.0	5.5	mA
Quiescent Current Change	with line	ΔI _Q	8V ≤ V _I ≤ 20V		-	-	1.5	mA
	with load	ΔI _Q	1mA ≤ I _O ≤ 40 mA		-	-	0.1	mA
Output Noise Voltage		V _N	T _A = 25 °C, 10Hz ≤ f ≤ 100KHz		-	40	-	μV/V _O
Temperature Coefficient of V _O		ΔV _O /ΔT	I _O = 5mA		-	-0.65	-	mV/ °C
Ripple Rejection		RR	f = 120Hz, 8V ≤ V _I ≤ 18V, T _J = 25 °C		41	80	-	dB
Dropout Voltage		V _D	T _J = 25 °C		-	1.7	-	V

Note:

1. The maximum steady state usable output current and input voltage are very dependent on the heat sinking and/or lead length of the package. The data above represent pulse test conditions with junction temperature as indicated at the initiation of tests.
2. Power dissipation $P_D \leq 0.75W$.

Typical Application



'(' : 8SOP Type

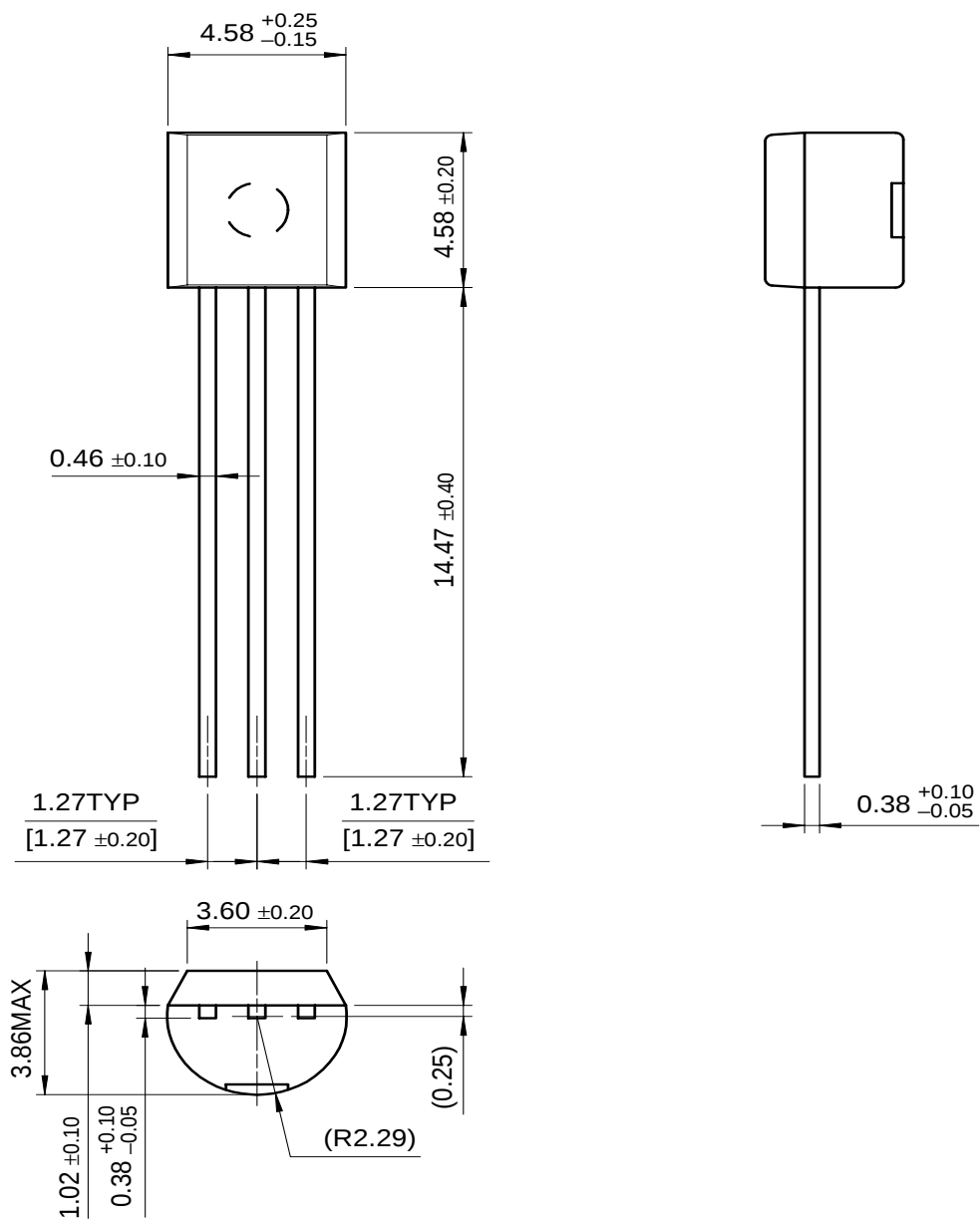
Notes:

1. To specify an output voltage, substitute voltage value for "XX".
2. Bypass Capacitors are recommend for optimum stability and transient response and should be located as close as possible to the regulator

Mechanical Dimensions

Package

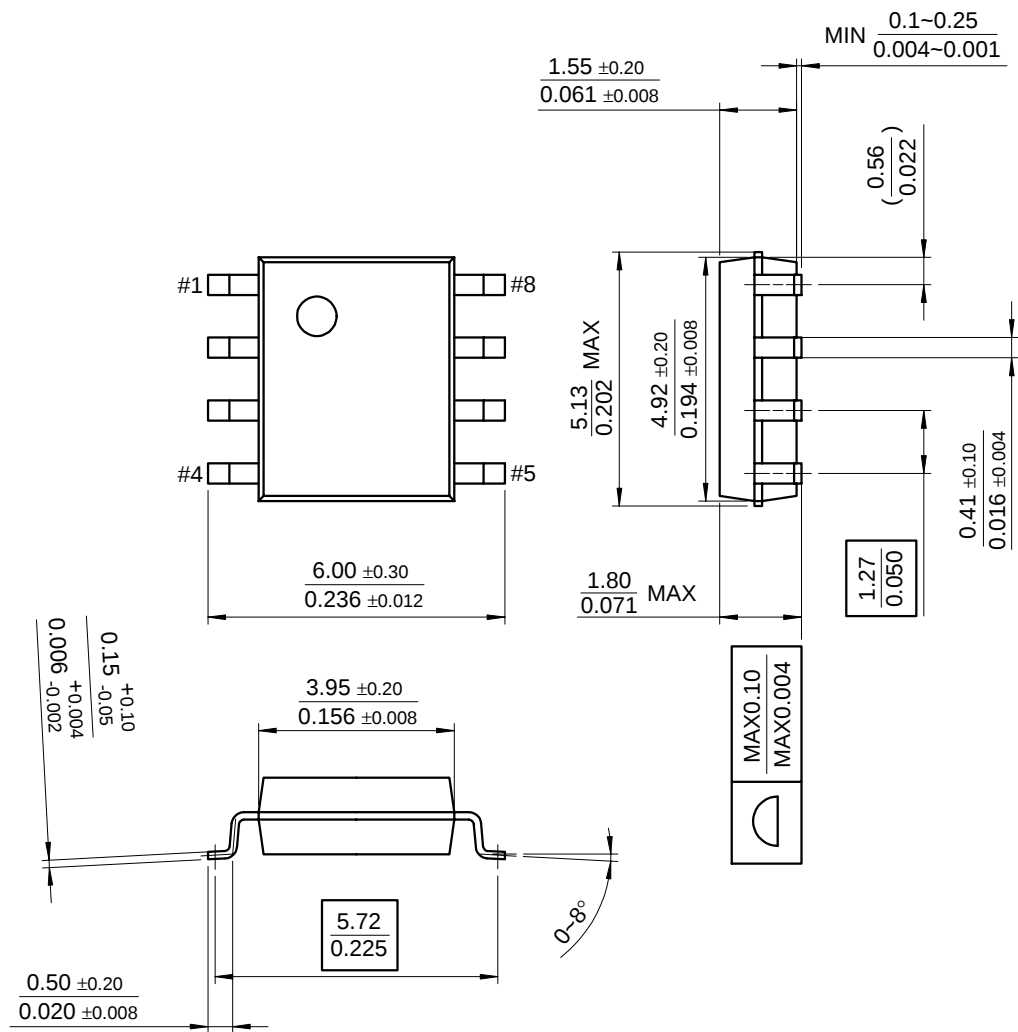
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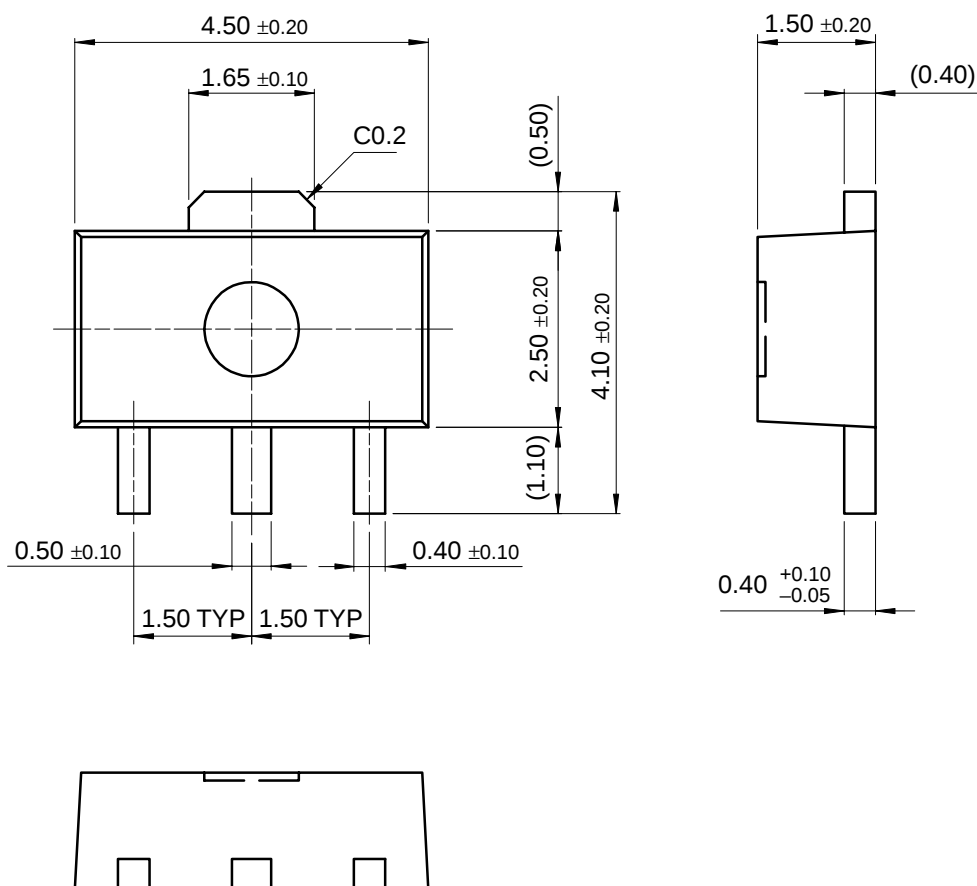


Mechanical Dimensions(Continued)

Package

8-SOP



Mechanical Dimensions (Continued)**Package****SOT-89**

Ordering Information

Product Number	Package	Output Voltage Tolerance	Operating Temperature
KA78L05AZ	TO-92	5%	0 ~ + 125 °C
KA78L06AZ			
KA78L08AZ			
KA78L09AZ			
KA78L10AZ			
KA78L12AZ			
KA78L15AZ			
KA78L18AZ			
KA78L24AZ			
KA78L05AD	8-SOP		
KA78L08AD			
KA78L12AD			
KA78L05AM	SOT-89		
KA78L08AM			
KA78L12AM			
KA78L05AAZ	TO-92	2%	

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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.