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LMC6064

Precision CMOS Quad Micropower Operational Amplifier

General Description

The LMC6064 is a precision quad low offset voltage, micropower operational amplifier, capable of precision single supply operation. Performance characteristics include ultra low input bias current, high voltage gain, rail-to-rail output swing, and an input common mode voltage range that includes ground. These features, plus its low power consumption make the LMC6064 ideally suited for battery powered applications.

Other applications using the LMC6064 include precision full-wave rectifiers, integrators, references, sample-and-hold circuits, and true instrumentation amplifiers.

This device is built with National's advanced double-Poly Silicon-Gate CMOS process.

For designs that require higher speed, see the LMC6084 precision quad operational amplifier.

For single or dual operational amplifier with similar features, see the LMC6061 or LMC6062 respectively.

PATENT PENDING

Features

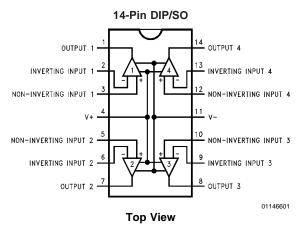
(Typical Unless Otherwise Noted)

- Low offset voltage: 100 µV
- Ultra low supply current: 16 µA/Amplifier
- Operates from 4.5V to 15V single supply
- Ultra low input bias current: 10 fA
- Output swing within 10 mV of supply rail, 100k load
- Input common-mode range includes V⁻
- High voltage gain: 140 dB
- Improved latchup immunity

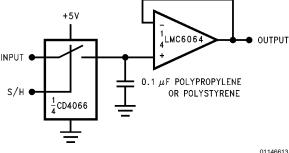
Applications

- Instrumentation amplifier
- Photodiode and infrared detector preamplifier
- Transducer amplifiers
- Hand-held analytic instruments
- Medical instrumentation
- D/A converter
- Charge amplifier for piezoelectric transducers

Connection Diagram



Low-Leakage Sample and Hold



011466

Absolute Maximum Ratings (Note 1)

If Military/Aerospace specified devices are required, please contact the National Semiconductor Sales Office/ Distributors for availability and specifications.

Differential Input Voltage \pm Supply Voltage Voltage at Input/Output Pin (V^+) +0.3V, (V^-) -0.3V Supply Voltage $(V^+ - V^-)$ 16V Output Short Circuit to V^+ (Note 11) Output Short Circuit to V^- (Note 2) Lead Temperature

(Soldering, 10 sec.) 260°C Storage Temp. Range –65°C to +150°C

Junction Temperature 150°C ESD Tolerance (Note 4) 2 kV

Current at Input Pin ±10 mA
Current at Output Pin ±30 mA
Current at Power Supply Pin 40 mA
Power Dissipation (Note 3)

Operating Ratings (Note 1)

Temperature Range

 $\begin{array}{ll} LMC6064AM & -55^{\circ}C \leq T_{J} \leq +125^{\circ}C \\ LMC6064AI, \ LMC6064I & -40^{\circ}C \leq T_{J} \leq +85^{\circ}C \\ \\ Supply \ Voltage & 4.5V \leq V^{+} \leq 15.5V \\ \end{array}$

Thermal Resistance (θ_{JA}) (Note 12)

 14-Pin Molded DIP
 81°C/W

 14-Pin SO
 126°C/W

 Power Dissipation
 (Note 10)

DC Electrical Characteristics

Unless otherwise specified, all limits guaranteed for $T_J = 25^{\circ}C$. **Boldface** limits apply at the temperature extremes. $V^+ = 5V$, $V^- = 0V$, $V_{CM} = 1.5V$, $V_{O} = 2.5V$ and $R_L > 1M$ unless otherwise specified.

| | | | | Тур | LMC6064AM | LMC6064AI | LMC6064I | |
|-----------------|-----------------------|---|----------|----------------------|----------------------|----------------------|----------------------|--------|
| Symbol | Parameter | Condit | ions | (Note 5) | Limit | Limit | Limit | Units |
| | | | | | (Note 6) | (Note 6) | (Note 6) | |
| Vos | Input Offset Voltage | | | 100 | 350 | 350 | 800 | μV |
| | | | | | 1200 | 900 | 1300 | Max |
| TCVos | Input Offset Voltage | | | 1.0 | | | | μV/°C |
| | Average Drift | | | | | | | |
| I _B | Input Bias Current | | | 0.010 | | | | pА |
| | | | | | 100 | 4 | 4 | Max |
| I _{os} | Input Offset Current | | | 0.005 | | | | pА |
| | | | | | 100 | 2 | 2 | Max |
| R _{IN} | Input Resistance | | | >10 | | | | Tera Ω |
| CMRR | Common Mode | 0V ≤ V _{CM} ≤ 12 | 2.0V | 85 | 75 | 75 | 66 | dB |
| | Rejection Ratio | V ⁺ = 15V | | | 70 | 72 | 63 | Min |
| +PSRR | Positive Power Supply | 5V ≤ V ⁺ ≤ 15V | ' | 85 | 75 | 75 | 66 | dB |
| | Rejection Ratio | $V_{O} = 2.5V$ | | | 70 | 72 | 63 | Min |
| -PSRR | Negative Power Supply | 0V ≤ V ⁻ ≤ - 10V | | 100 | 84 | 84 | 74 | dB |
| | Rejection Ratio | | | | 70 | 81 | 71 | Min |
| V _{CM} | Input Common-Mode | V ⁺ = 5V and 15V for CMRR ≥ 60 dB | | -0.4 | -0.1 | -0.1 | -0.1 | V |
| | Voltage Range | | | | 0 | 0 | 0 | Max |
| | | | | V ⁺ – 1.9 | V ⁺ - 2.3 | V ⁺ - 2.3 | V ⁺ - 2.3 | V |
| | | | | | V+ - 2.6 | V+ - 2.5 | V+ - 2.5 | Min |
| A_{V} | Large Signal | $R_L = 100 \text{ k}\Omega$ | Sourcing | 4000 | 400 | 400 | 300 | V/mV |
| | Voltage Gain | (Note 7) | | | 200 | 300 | 200 | Min |
| | | | Sinking | 3000 | 180 | 180 | 90 | V/mV |
| | | | | | 70 | 100 | 60 | Min |
| | | $R_L = 25 \text{ k}\Omega$ | Sourcing | 3000 | 400 | 400 | 200 | V/mV |
| | | (Note 7) | | | 150 | 150 | 80 | Min |
| | | | Sinking | 2000 | 100 | 100 | 70 | V/mV |
| | | | | | 35 | 50 | 35 | Min |

DC Electrical Characteristics (Continued)

Unless otherwise specified, all limits guaranteed for $T_J = 25^{\circ}\text{C}$. **Boldface** limits apply at the temperature extremes. $V^+ = 5V$, $V^- = 0V$, $V_{CM} = 1.5V$, $V_O = 2.5V$ and $R_L > 1M$ unless otherwise specified.

| | | | Тур | LMC6064AM | LMC6064AI | LMC6064I | |
|----------------|----------------------|--|----------|-----------|---|---|-------|
| Symbol | Parameter | Conditions | (Note 5) | Limit | Limit | Limit | Units |
| | | | | (Note 6) | (Note 6) | (Note 6) | |
| Vo | Output Swing | V ⁺ = 5V | 4.995 | 4.990 | 4.990 | 4.950 | V |
| | | $R_{L} = 100 \text{ k}\Omega \text{ to } 2.5 \text{V}$ | | 4.970 | 4.980 | 4.925 | Min |
| | | | 0.005 | 0.010 | 0.010 | 0.050 | V |
| | | | | 0.030 | 0.020 | 0.020 0.075 4.975 4.950 4.965 4.850 0.020 0.050 0.035 0.150 14.975 14.950 14.965 14.925 0.025 0.050 0.035 0.075 14.900 14.850 14.850 14.800 | Max |
| | | V+ = 5V | 4.990 | 4.975 | 4.975 | 4.950 | V |
| | | $R_L = 25 \text{ k}\Omega \text{ to } 2.5\text{V}$ | | 4.955 | 4.965 | 4.850 | Min |
| | | | 0.010 | 0.020 | 0.020 | 0.050 | V |
| | | | | 0.045 | 0.035 | 0.150 | Max |
| | | V ⁺ = 15V | 14.990 | 14.975 | 14.975 | 14.950 | V |
| | | $R_{L} = 100 \text{ k}\Omega \text{ to } 7.5 \text{V}$ | | 14.955 | 14.965 | 14.925 | Min |
| | | | 0.010 | 0.025 | 0.025 | 0.050 | V |
| | | | | 0.050 | 0.035 | 0.075 | Max |
| | | V ⁺ = 15V | 14.965 | 14.900 | 14.900 | 14.850 | V |
| | | $R_L = 25 \text{ k}\Omega \text{ to } 7.5 \text{V}$ | | 14.800 | 14.850 | 14.800 | Min |
| | | | 0.025 | 0.050 | 0.050 | 0.100 | V |
| | | | | 0.200 | 0.150 | 0.200 | Max |
| Io | Output Current | Sourcing, V _O = 0V | 22 | 16 | e 6) (Note 6) 90 4.990 70 4.980 10 0.010 30 0.020 75 4.975 55 4.965 20 0.020 45 0.035 975 14.975 955 14.965 25 0.025 50 0.035 900 14.850 50 0.050 00 0.150 6 16 6 16 7 8 7 10 8 76 90 92 4 94 | 13 | mA |
| | V ⁺ = 5V | | | 8 | | 8 | Min |
| | | Sinking, $V_O = 5V$ | 21 | 16 | 16 | 16 | mA |
| | | | | 7 | 14.900 14.850 0.050 0.150 16 10 16 8 | 8 | Min |
| I _O | Output Current | Sourcing, V _O = 0V | 25 | 15 | 15 | 15 | mA |
| | V ⁺ = 15V | | | 9 | 10 | 10 | Min |
| | | Sinking, V _O = 13V | 26 | 20 | 20 | 20 | mA |
| | | | 8 | Min | | | |
| I _S | Supply Current | All Four Amplifiers | 64 | 76 | 76 | 92 | μΑ |
| | | $V^{+} = +5V, V_{O} = 1.5V$ | | 120 | 92 | 112 | Max |
| | | All Four Amplifiers | | 94 | 94 | 114 | μΑ |
| | | $V^{+} = +15V, V_{O} = 7.5V$ | 80 | 140 | 110 | 132 | Max |

AC Electrical Characteristics

Unless otherwise specified, all limits guaranteed for $T_J = 25^{\circ}C$, **Boldface** limits apply at the temperature extremes. $V^+ = 5V$, $V^- = 0V$, $V_{CM} = 1.5V$, $V_O = 2.5V$ and $R_L > 1M$ unless otherwise specified.

| | | | Тур | LMC6064AM | LMC6064AI | LMC6064I | |
|----------------|------------------------------|---|----------|-----------|-----------|----------|----------------------|
| Symbol | Parameter | Conditions | (Note 5) | Limit | Limit | Limit | Units |
| | | | | (Note 6) | (Note 6) | (Note 6) | |
| SR | Slew Rate | (Note 8) | 35 | 20 | 20 | 15 | V/ms |
| | | | | 8 | 10 | 7 | Min |
| GBW | Gain-Bandwidth Product | | 100 | | | | kHz |
| θ_{m} | Phase Margin | | 50 | | | | Deg |
| | Amp-to-Amp Isolation | (Note 9) | 155 | | | | dB |
| e _n | Input-Referred Voltage Noise | F = 1 kHz | 83 | | | | nV∕r∕ H z |
| i _n | Input-Referred Current Noise | F = 1 kHz | 0.0002 | | | | pA∕v∕ Hz |
| T.H.D. | Total Harmonic Distortion | $F = 1 \text{ kHz}, A_V = -5$ | | | | | |
| | | $R_L = 100 \text{ k}\Omega, V_O = 2 V_{PP}$ ±5V Supply | 0.01 | | | | % |

AC Electrical Characteristics (Continued)

Note 1: Absolute Maximum Ratings indicate limits beyond which damage to the device may occur. Operating Ratings indicate conditions for which the device is intended to be 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.

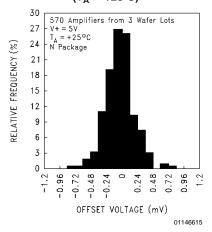
Note 2: Applies to both single-supply and split-supply operation. Continous short circuit operation at elevated ambient temperature can result in exceeding the maximum allowed junction temperature of 150°C. Output currents in excess of ±30 mA over long term may adversely affect reliability.

Note 3: The maximum power dissipation is a function of $T_{J(Max)}$, θ_{JA} , and T_A . The maximum allowable power dissipation at any ambient temperature is $P_D = (T_{J(Max)} - T_A)/\theta_{JA}$.

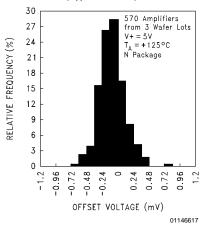
- Note 4: Human body model, 1.5 k Ω in series with 100 pF.
- Note 5: Typical values represent the most likely parametric norm.
- Note 6: All limits are guaranteed by testing or statistical analysis.
- Note 7: $V^+ = 15V$, $V_{CM} = 7.5V$ and R_L connected to 7.5V. For Sourcing tests, $7.5V \le V_O \le 11.5V$. For Sinking tests, $2.5V \le V_O \le 7.5V$.
- Note 8: V⁺ = 15V. Connected as Voltage Follower with 10V step input. Number specified is the slower of the positive and negative slew rates.
- Note 9: Input referred V⁺ = 15V and R_L = 100 k Ω connected to 7.5V. Each amp excited in turn with 100 Hz to produce V_Q = 12 V_{PP} .
- Note 10: For operating at elevated temperatures the device must be derated based on the thermal resistance θ_{JA} with $P_D = (T_J T_A)/\theta_{JA}$.
- Note 11: Do not connect output to V+, when V+ is greater than 13V or reliability witll be adversely affected.
- Note 12: All numbers apply for packages soldered directly into a PC board.
- Note 13: For guaranteed Military Temperature Range parameters see RETSMC6064X.

Typical Performance Characteristics

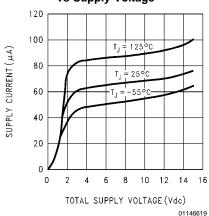
Distribution of LMC6064 Input Offset Voltage (T_A = +25°C)



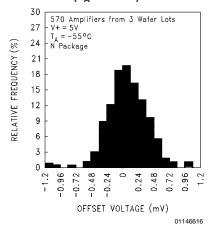
Distribution of LMC6064 Input Offset Voltage (T_A = +125°C)



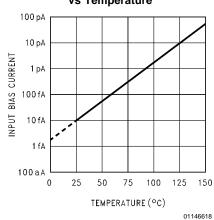
Supply Current vs Supply Voltage



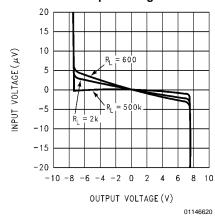
Distribution of LMC6064 Input Offset Voltage (T_A = -55°C)



Input Bias Current vs Temperature

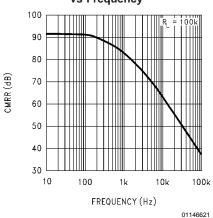


Input Voltage vs Output Voltage

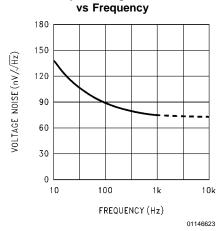


Typical Performance Characteristics (Continued)

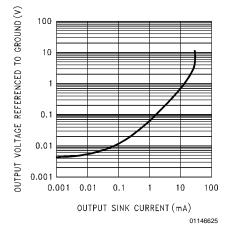
Common Mode Rejection Ratio vs Frequency



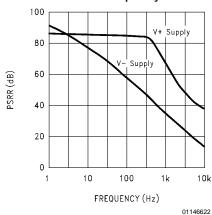
Input Voltage Noise



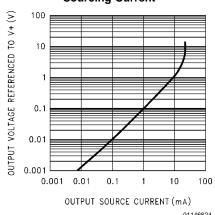
Output Characteristics Sinking Current



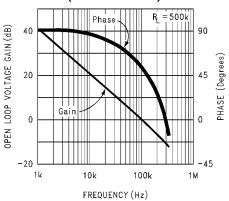
Power Supply Rejection Ratio vs Frequency



Output Characteristics Sourcing Current



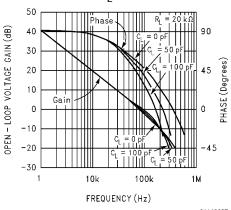
Gain and Phase Response vs Temperature (-55°C to +125°C)



01146626

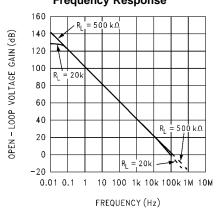
Typical Performance Characteristics (Continued)

Gain and Phase Response vs Capacitive Load with $R_L = 20 \text{ k}\Omega$



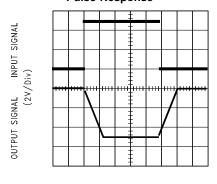
01146627

Open Loop Frequency Response



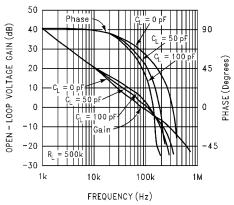
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Inverting Large Signal Pulse Response



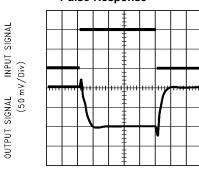
TIME (100 μ s/Div) 01146631

Gain and Phase Response vs Capacitive Load with $R_L = 500 \text{ k}\Omega$



01146628

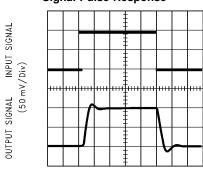
Inverting Small Signal Pulse Response



TIME (10 μ s/Div)

01146630

Non-Inverting Small Signal Pulse Response

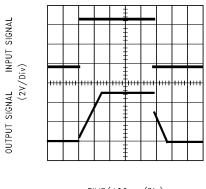


TIME (10 μ s/Div)

01146632

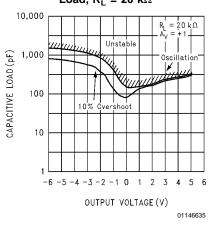
Typical Performance Characteristics (Continued)



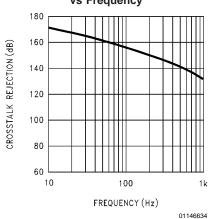


TIME (100 μ s/Div) 01146633

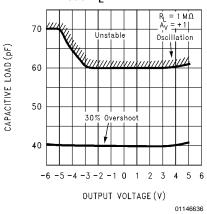
Stability vs Capacitive Load, $R_L = 20 \text{ k}\Omega$



Crosstalk Rejection vs Frequency



Stability vs Capacitive Load $R_L = 1 M\Omega$



Applications Hints

AMPLIFIER TOPOLOGY

The LMC6064 incorporates a novel op-amp design topology that enables it to maintain rail-to-rail output swing even when driving a large load. Instead of relying on a push-pull unity gain output buffer stage, the output stage is taken directly from the internal integrator, which provides both low output impedance and large gain. Special feed-forward compensation design techniques are incorporated to maintain stability over a wider range of operating conditions than traditional micropower op-amps. These features make the LMC6064 both easier to design with, and provide higher speed than products typically found in this ultra-low power class.

COMPENSATING FOR INPUT CAPACITANCE

It is quite common to use large values of feedback resistance for amplifiers with ultra-low input current, like the LMC6064.

Although the LMC6064 is highly stable over a wide range of operating conditions, certain precautions must be met to achieve the desired pulse response when a large feedback resistor is used. Large feedback resistors and even small values of input capacitance, due to transducers, photodiodes, and circuit board parasitics, reduce phase margins. When high input impedances are demanded, guarding of the LMC6064 is suggested. Guarding input lines will not only reduce leakage, but lowers stray input capacitance as well. (See *Printed-Circuit-Board Layout for High Impedance*

The effect of input capacitance can be compensated for by adding a capacitor. Place a capacitor, C_f, around the feedback resistor (as in *Figure 1*) such that:

$$\frac{1}{2\pi R_1 C_{IN}} \geq \frac{1}{2\pi R_2 C_f}$$

or
$$R_1 C_{IN} \le R_2 C_f$$

Since it is often difficult to know the exact value of $C_{\rm IN}$, $C_{\rm f}$ can be experimentally adjusted so that the desired pulse response is achieved. Refer to the LMC660 and the LMC662 for a more detailed discussion on compensating for input capacitance.

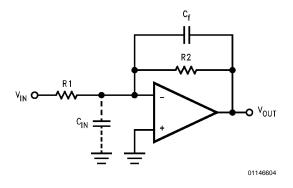


FIGURE 1. Canceling the Effect of Input Capacitance

CAPACITIVE LOAD TOLERANCE

All rail-to-rail output swing operational amplifiers have voltage gain in the output stage. A compensation capacitor is normally included in this integrator stage. The frequency

location of the dominate pole is affected by the resistive load on the amplifier. Capacitive load driving capability can be optimized by using an appropriate resistive load in parallel with the capacitive load (see typical curves).

Direct capacitive loading will reduce the phase margin of many op-amps. A pole in the feedback loop is created by the combination of the op-amp's output impedance and the capacitive load. This pole induces phase lag at the unity-gain crossover frequency of the amplifier resulting in either an oscillatory or underdamped pulse response. With a few external components, op amps can easily indirectly drive capacitive loads, as shown in *Figure 2*.

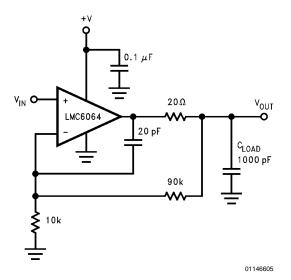


FIGURE 2. LMC6064 Noninverting Gain of 10 Amplifier, Compensated to Handle Capacitive Loads

In the circuit of *Figure 2*, R1 and C1 serve to counteract the loss of phase margin by feeding the high frequency component of the output signal back to the amplifier's inverting input, thereby preserving phase margin in the overall feedback loop.

Capacitive load driving capability is enhanced by using a pull up resistor to V $^+$ (*Figure 3*). Typically a pull up resistor conducting 10 μ A or more will significantly improve capacitive load responses. The value of the pull up resistor must be determined based on the current sinking capability of the amplifier with respect to the desired output swing. Open loop gain of the amplifier can also be affected by the pull up resistor (see Electrical Characteristics).

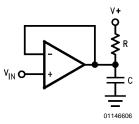


FIGURE 3. Compensating for Large Capacitive Loads with a Pull Up Resistor

Applications Hints (Continued)

PRINTED-CIRCUIT-BOARD LAYOUT FOR HIGH-IMPEDANCE WORK

It is generally recognized that any circuit which must operate with less than 1000 pA of leakage current requires special layout of the PC board. When one wishes to take advantage of the ultra-low bias current of the LMC6064, typically less than 10 fA, it is essential to have an excellent layout. Fortunately, the techniques of obtaining low leakages are quite simple. First, the user must not ignore the surface leakage of the PC board, even though it may sometimes appear acceptably low, because under conditions of high humidity or dust or contamination, the surface leakage will be appreciable.

To minimize the effect of any surface leakage, lay out a ring of foil completely surrounding the LMC6064's inputs and the terminals of capacitors, diodes, conductors, resistors, relay terminals etc. connected to the op-amp's inputs, as in Figure 4. To have a significant effect, guard rings should be placed on both the top and bottom of the PC board. This PC foil must then be connected to a voltage which is at the same voltage as the amplifier inputs, since no leakage current can flow between two points at the same potential. For example, a PC board trace-to-pad resistance of $10^{12}\Omega$, which is normally considered a very large resistance, could leak 5 pA if the trace were a 5V bus adjacent to the pad of the input. This would cause a 100 times degradation from the LMC6064's actual performance. However, if a guard ring is held within 5 mV of the inputs, then even a resistance of $10^{11}\Omega$ would cause only 0.05 pA of leakage current. See Figure 5 for typical connections of guard rings for standard op-amp configurations.

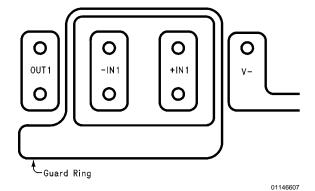
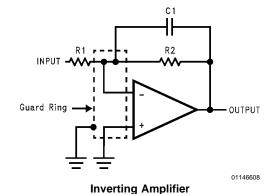


FIGURE 4. Example of Guard Ring in P.C. Board Layout



Guard Ring OUTPUT

Non-Inverting Amplifier

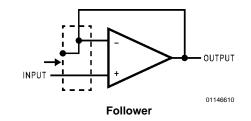


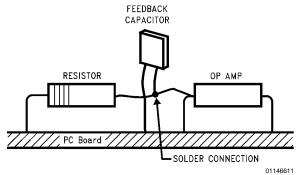
FIGURE 5. Typical Connections of Guard Rings

The designer should be aware that when it is inappropriate to lay out a PC board for the sake of just a few circuits, there is another technique which is even better than a guard ring on a PC board: Don't insert the amplifier's input pin into the board at all, but bend it up in the air and use only air as an insulator. Air is an excellent insulator. In this case you may have to forego some of the advantages of PC board construction, but the advantages are sometimes well worth the effort of using point-to-point up-in-the-air wiring. See *Figure 6*.

Latchup

CMOS devices tend to be susceptible to latchup due to their internal parasitic SCR effects. The (I/O) input and output pins look similar to the gate of the SCR. There is a minimum current required to trigger the SCR gate lead. The LMC6064 and LMC6082 are designed to withstand 100 mA surge current on the I/O pins. Some resistive method should be used to isolate any capacitance from supplying excess current to the I/O pins. In addition, like an SCR, there is a minimum holding current for any latchup mode. Limiting current to the supply pins will also inhibit latchup susceptibility.

Latchup (Continued)



(Input pins are lifted out of PC board and soldered directly to components. All other pins connected to PC board).

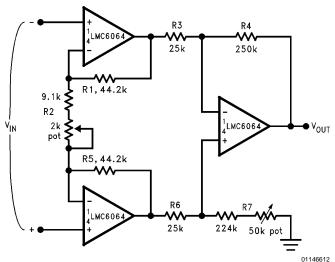
FIGURE 6. Air Wiring

Typical Single-Supply Applications

 $(V^+ = 5.0 V_{DC})$

The extremely high input impedance, and low power consumption, of the LMC6064 make it ideal for applications that require battery-powered instrumentation amplifiers. Examples of these types of applications are hand-held pH probes, analytic medical instruments, magnetic field detectors, gas detectors, and silicon based pressure transducers.

Figure 7 shows an instrumentation amplifier that features high differential and common mode input resistance (>10¹⁴Ω), 0.01% gain accuracy at $A_V=100$, excellent CMRR with 1 kΩ imbalance in bridge source resistance. Input current is less than 100 fA and offset drift is less than 2.5 μV/°C. R_2 provides a simple means of adjusting gain over a wide range without degrading CMRR. R_7 is an initial trim used to maximize CMRR without using super precision matched resistors. For good CMRR over temperature, low drift resistors should be used.



If $R_1 = R_5$, $R_3 = R_6$, and $R_4 = R_7$; then

$$\frac{v_{OUT}}{v_{IN}} = \frac{R_2 + 2R_1}{R_2} \times \frac{R_4}{R_3}$$

 $\therefore A_V \approx 100$ for circuit shown (R₂ = 9.822k).

FIGURE 7. Instrumentation Amplifier

Typical Single-Supply Applications (Continued)

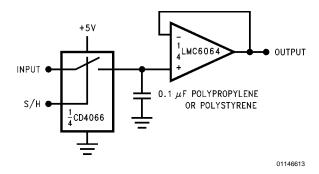


FIGURE 8. Low-Leakage Sample and Hold

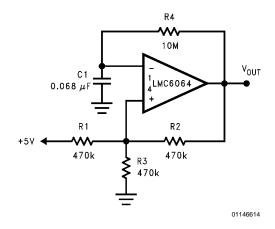
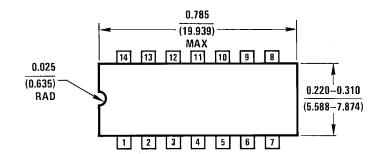


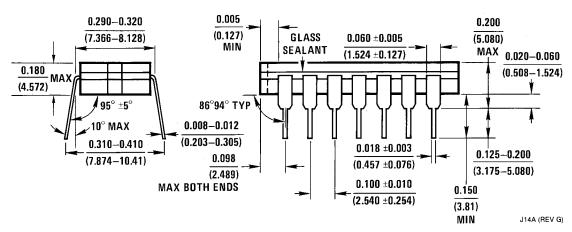
FIGURE 9. 1 Hz Square Wave Oscillator

Ordering Information

| | Tempe | NSC | Transport Media | | |
|---------------|--------------------------------|-------------------------|--------------------|---------------|---------|
| Package | Military | Industrial | | | |
| | -55°C to +125°C -40°C to +85°C | | | | Drawing |
| 14-Pin | | LMC6064AIN | N14A | Rail | |
| Molded DIP | | LMC6064IN | | | |
| 14-Pin | | LMC6064AIM, LMC6064AIMX | M14A | Rail | |
| Small Outline | | LMC6064IM, LMC6064IMX | | Tape and Reel | |
| 14-Pin | LMC6064AMJ/883 | | J14A | Rail | |
| Ceramic DIP | | | | | |

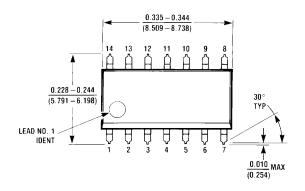
Physical Dimensions inches (millimeters) unless otherwise noted

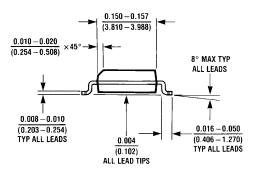


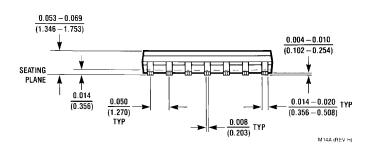


14-Pin Ceramic Dual-In-Line Package Order Number LMC6064AMJ/883 **NS Package Number J14A**

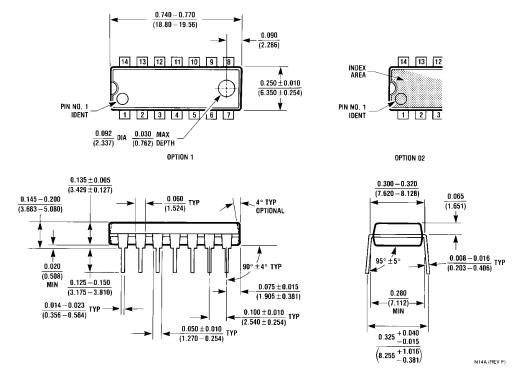
Physical Dimensions inches (millimeters) unless otherwise noted (Continued)







14-Pin Small Outline Package
Order Number LMC6064AIM, LMC6064AIMX, LMC6064IM or LMC6064IMX
NS Package Number M14A



14-Pin Molded Dual-In-Line Package
Order Number LMC6064AIN or LMC6064IN
NS Package Number N14A

Notes

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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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