Low-Sensitivity, Highpass Filter Design with Parasitic Compensation

Introduction

This Application Note covers the design of a Sallen-Key highpass biquad. This design gives low component and op amp sensitivities. It also shows how to compensate for the op amp's bandwidth (pre-distortion) and parasitic capacitances. A design example illustrates this method. These biquads are also called KRC or VCVS [voltage-controlled, voltage-source].

Changes in component values over process, environment and time affect the performance of a filter. To achieve a greater production yield, the filter needs to be insensitive to these changes. This Application Note presents a design algorithm that results in low sensitivity to component variation. See [6] for information on evaluating the sensitivity performance of your filter.

To achieve the best production yield, the nominal filter design must also compensate for component and board parasitics. The components are pre-distorted [5] to compensate for the op amp bandwidth. This Application Note expands the pre-distortion method in [5] to include compensation for parasitic capacitances. This method is valid for either voltage-feedback or current-feedback op amps.

Parasitic Compensation

To pre-distort your filter components and compensate for parasitic capacitances:

- 1. Use the method in [5] to include the op amp's effect on the filter response. The result is a transfer function of the same order whose coefficients include the op amp group delay (τ_{oa}) evaluated at the passband edge frequency (f_c) .
- 2. For all parasitic capacitances in parallel with capacitors:
 - Add the capacitors together
 - Simplify the resulting coefficients
 - Use the sum of time constants form for the coefficients when possible
- 3. For all parasitic capacitances in parallel with resistors:
 - Replace the resistor R_x in the filter transfer function with the parallel equivalent of R_x and C_n.

$$\frac{R_x \leftarrow R_x}{\left(1 + R_x C_p s\right)}, s = j\omega$$

- Alter this impedance to a convenient form and simplify:
- Do not create new terms (a coefficient times a new power of s) in the transfer function after simplifying

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— The most useful approximations are:

$$\begin{split} &\frac{R_x}{\left(1 + R_x C_p s\right)} \approx R_x \left(1 - R_x C_p s\right) \\ &\approx R_x e^{-R_x C_p s} \end{split}$$

These approximations are valid when:

$$\frac{\omega << 1}{\left(R_x C_p\right)}$$

- Convert $(1 + R_x C_p s)$ to the exponential form (a pure time delay) when it multiplies, or divides, the entire transfer function
- Do not change the gain at $\omega \approx \omega_p$ in allpass sections
- When simplifying, discard any terms that are products of the error terms ($k\tau_{oa}$ and R_xC_p); they are negligible
- Use the sum of time constants form for the coefficients when possible

Use an op amp with adequate bandwidth (f_{3dB}) and slew rate (SR):

$$f_{3dB} \ge 10f_H$$

SR > $5f_HV_{peak}$

where $f_{\rm H}$ is the highest frequency in the passband of the filter, and $V_{\rm peak}$ is the largest peak voltage. This increases the accuracy of the pre-distortion algorithm. It also reduces the filter's sensitivity to op amp performance changes over temperature and process. Make sure the op amp is stable at a gain of $A_V = K.$

KRC Highpass Biquad Design

The biquad shown in *Figure 1* is a Sallen-Key highpass biquad. V_{in}needs to be a voltage source with low output impedance.

The transfer function is:

$$\frac{V_o}{V_{in}} \approx \frac{H_\infty \Biggl(\frac{1}{\omega_p^2}\Biggr) s^2}{1 + \Biggl(\frac{1}{\left(\omega_p Q_p\right)}\Biggr) s + \Biggl(\frac{1}{\left(\omega_p^2\right)}\Biggr) s^2}$$

KRC Highpass Biquad Design

(Continued)

$$\begin{split} K &= 1 + \frac{R_f}{R_g} \\ H_{\infty} &= K \\ \frac{1}{\left(\omega_p Q_p\right)} &= R_5 C_1 + R_5 C_3 - R_4 C_3 (K-1) \\ \frac{1}{\omega_p^2} &= R_4 R_5 C_1 C_3 \end{split}$$

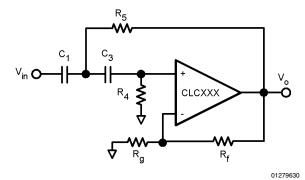


FIGURE 1. Highpass Biquad

To achieve low sensitivities, use this design algorithm:

- 1. Partition the gain for good $\mathbf{Q}_{\mathbf{p}}$ sensitivity and dynamic range performance:
 - Use a low noise amplifier before this biquad if you need a large gain
 - Select K with this empirical formula:

$$K = \begin{cases} 1, \ 0.1 \leq Q_p \leq 1.1 \\ \\ \frac{2.2 \, Q_p - 0.9}{Q_p + 0.2}, \ 1.1 < Q_p < 5 \end{cases}$$

These values also reduce the op amp bandwidth's impact on the filter response. This biquad's sensitivities are too high when $Q_{\rm p} \ge 5$

Select an op amp with adequate bandwidth (f_{3dB}) and slew rate (SR):

$$\begin{split} f_{3dB} &\geq f_{H} \\ f_{3dB} &\geq 10 f_{c} \\ SR &> 5 f_{H} V_{peak} \end{split}$$

where f_H is the highest signal frequency, f_c is the corner frequency of the filter, and V_{peak} is the largest peak voltage. Make sure the op amp is stable at a gain of $A_v = K$.

3. For current-feedback op amps, use the recommended value of $R_{\rm f}$ for a gain of $A_{\rm V}=K$. For voltage-feedback op amps, select $R_{\rm f}$ for noise and distortion performance. Then set $R_{\rm g}$ for the correct gain:

$$R_g = \frac{R_f}{(K-1)}$$

- 4. Initialize the resistance level $\left(R = \sqrt{R_4 R_5}\right)$ Increasing R will:
 - Increase the output noise
 - Reduce the distortion
 - Improve the isolation between the op amp outputs and C₁ and C₃
 - Make the parasitic capacitances a larger fraction of $\rm C_1$ and $\rm C_3$
- 5. Initialize the capacitance level $\mathbf{S}_{\alpha_i}^{\mathbf{H}_\infty}$, and the component ratios

$$\begin{split} &\left(c^2 = \frac{C_3}{C_1} \text{ and } r^3 = \frac{R_5}{R_4}\right): \\ &c = \frac{1}{\left(\omega_p R\right)} \\ &c^2 = 0.10 \\ &r^2 = max \Bigg\{0.10, \left(\frac{1 + \sqrt{1 + 4Q_p^2} \left(1 + c^2\right) \left(K - 1\right)}{2 \cdot Q_p \cdot \left(1 + c^2\right) \left/c\right}\right) \end{split}$$

6. Recalculate C^2 and initialize the capacitors:

$$c^{2} = \left(\frac{2 \cdot r \cdot Q_{p}}{1 + \sqrt{1 + 4Q_{p}^{2}} \left(K - 1 - r^{2}\right)}\right)^{2}$$

$$C_{1} = \frac{C}{c}$$

$$C_{3} = cC$$

7. Set C₁ and C₃ to the nearest standard values.

KRC Highpass Biquad Design

(Continued)

8. Recalculate C, C2, R and r2:

$$\begin{split} C &= \sqrt{C_1 C_3} \\ c^2 &= \frac{C_3}{C_1} \\ R &= \frac{1}{\left(\omega_p C\right)} \\ r^2 &= \left(\frac{1 + \sqrt{1 + 4Q_p^2 \left(1 + c^2\right) \left(K - 1\right)}}{2 \cdot Q_p \cdot \left(1 + c^2\right) \middle/c}\right)^2 \end{split}$$

9. Calculate the resistors:

$$R_4 = \frac{R}{r}$$

$$R_5 = rF$$

The component sensitivity formulas are in the table below. The sensitivities formulas are in the table below. The sensitivities to $\alpha_i = K$ are a measure of this biquad's sensitivity to the op amp group delay [5]. To evaluate this biquad is sensitivity performance, use the method in [6].

α_{i}	$S^{H_{\infty}}_{\alpha_i}$	$S_{\alpha_{_{i}}}^{\omega_{_{p}}}$	$S_{lpha_{_{1}}}^{Q_{_{p}}}$
C ₁	0	$-\frac{1}{2}$	$-\bigg(Q_p\cdot\frac{r}{c}-\frac{1}{2}\bigg)$
C ₃	0	$-\frac{1}{2}$	$\left(Q_p\cdot\frac{r}{c}-\frac{1}{2}\right)$
R ₄	0	$-\frac{1}{2}$	$\left(\left(K-1 \right) \cdot Q_p \cdot \frac{c}{r} + \frac{1}{2} \right)$
R ₅	0	$-\frac{1}{2}$	$-\bigg(\big(K-1\big)\cdot Q_p\cdot \frac{c}{r}+\frac{1}{2}\bigg)$
R _f	<u>K-1</u>	0	$\left(\left(K-1\right) \cdot Q_{p}\cdot \frac{c}{r}\right)$
R _f	$-\frac{K-1}{K}$	0	$-\left(\left(K-1\right)\cdot Q_{p}\cdot\frac{c}{r}\right)$
К	1	0	$\left(\mathbf{K}\cdot\mathbf{Q}_{\mathbf{p}}\cdot\frac{\mathbf{c}}{\mathbf{r}}\right)$

KRC Highpass Biquad Parasitic Compensation

To pre-distort this biquad, and compensate for the [parasitic] non-inverting input capacitance of the op amp (C_{ni}) , do the following (see *Appendix A* for the derivation of the formulas):

1. Start the iterations by ignoring the parasitics:

$$\tau^2 = 0$$

$$\tau^2_{A} = 0$$

2. Estimate the pre-distorted values of ω_p and Q_p ($\omega_{p(pd)}$ and $Q_{p(pd)}$ that will compensate for τ_{oa} and C_{ni} :

$$\begin{split} \frac{\omega_{p(pd)} = \omega_{p(nom)}}{\sqrt{1 - \tau_4^2 \omega_{p(nom)}^2}} \\ Q_{p(pd)} = Q_{p(nom)} \\ \hline \left(\frac{\omega_{p(pd)}}{\omega_{p(nom)}} - Q_{p(nom)} \tau_2 \omega_{p(pd)} \right) \end{split}$$

Where $\omega_{\text{p(nom)}}$ and $Q_{\text{p(nom)}}$ are the nominal values of ω_{p} and Q_{p}

3. Recalculate the resistors and capacitors using $\omega_{p(\text{pd})}$ and $Q_{p(\text{pd})}$:

$$\begin{split} &\frac{1}{\omega_{p(pd)}^{2}} = R_{4}R_{5}C_{1}C_{3}\\ &\frac{1}{\left(\omega_{p(pd)}Q_{p(pd)}\right)} = R_{5}C_{1} + R_{5}C_{3} - R_{4}C_{3}\left(K - 1\right) \end{split}$$

The *Design Example* accomplishes this by recalculating R and r^2 , then R₄ and R₅:

$$\begin{split} R &= \frac{1}{\left(\omega_{p(pd)}C\right)} \\ r^2 &= \left(\frac{1+\sqrt{1+4Q_{p(pd)}^2\left(1+c^2\right)\left(K-1\right)}}{2\cdot Q_{p(pd)}\cdot \left(1+c^2\right)\middle/c}\right)^2 \\ R_4 &= \frac{R}{r} \\ R_5 &= rR \end{split}$$

4. Calculate the resulting parasitic correction factors:

$$\tau^2 = R_4 C_{ni}$$

$$\tau^2_4 = K \tau_{oa} R_4 C_3 + R_4 R_5 (C_1 + C_3) C_{ni}$$

5. Calculate the resulting filter response parameters ω_p and Q_p

$$\begin{split} \frac{\omega_p &= \omega_{p(pd)}}{\sqrt{1 + \tau_4^2 \omega_{p(pd)}^2}} \\ Q_p &= \frac{Q_{p(pd)}}{\left(\frac{\omega_p}{\omega_{p(pd)}} + Q_{p(pd)} \tau_2 \omega_p\right)} \end{split}$$

6. Repeat steps 2-5 until:

$$\omega_p = \omega_{p(nom)}$$
 $Q_p = Q_{p(nom)}$

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KRC Highpass Biquad Parasitic Compensation (Continued)

7. Estimate the high frequency gain:

$$\frac{H_{\infty}\approx K}{\left(1+\tau_4^2\omega_{p(pd)}^2\right)}$$

If this reduces the gain too much, then repartition the gain

Design Example

The circuit shown in *Figure 2* is a 3rd-order Butterworth highpass filter. Section A is a buffered single pole section, and Section B is a highpass biquad. Use a voltage source with low output impedance, such as the CLC111 buffer, for $V_{\rm in}$:

The nominal filter specifications are:

 $f_c = 50 MHz$ (passband edge frequency) $f_s = 10 MHz$ (stopband edge frequency) $f_H = 200 MHz$ (highest signal frequency) $A_p = 3.0 dB$ (maximum passband ripple) $A_s = 40 dB$ (minimum stopband attenuation) $H_\infty = 0 dB$ (passband voltage gain)

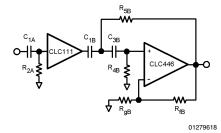


FIGURE 2. Highpass Filter

The 3rd-order Butterworth filter [1-4] meets our specifications. The pole frequencies and quality factors are:

Section	Α	В
ω _p /2π [MHz]	50.00	50.00
Q _p []	_	1.000

Overall Design

- 1. Restrict the resistor and capacitor ratios to:
- 2.

$$0.1 \le c^2, r^2 \le 10$$

- 3. Use 1% resistors (chip metal film, 1206 SMD)
- 4. Use 5% capacitors (ceramic chip, 1206 SMD)
- 5. Use standard resistor and capacitor values

Section A Design and Pre-distortion:

- 1. Use the CLC111. This is a close-loop buffer.
 - $f_{3dB} = 800MHz > f_{H} = 200MHz$
 - $--f_{3dB}$ = 800MHz > 10 f_c = 500MHz
 - SR = 3500V/ μ s, while a 200MHz, 2V $_{pp}$ sinusoid requires more than 100V/ μ s

- $τ_{oa}$ ≈ 0.28ns at 10MHz
- C_{ni(111)} = 1.3pF (input capacitance)
- Select R_{2A} for noise, distortion and to properly isolate the CLC111's output and C_{1A}. The pre-distorted value of R_{2A}, that also compensates for C_{ni(111)}, is [5]:

$$R_{2A} = \frac{\left(\frac{1}{\omega_p - \tau_{oa}}\right)}{\left(C_{1A} + C_{ni(111)}\right)}$$

The results are in the table below:

- The Initial Value column shows ideal values that ignore any parasitic effect
- The Adjusted Value column shows the component values that compensate for $C_{ni(111)}$ and CLC111 is group delay (τ_{oa})
- The Standard Value column shows the nearest standard 1% resistors and 5% capacitors

Component	Initial Value		Standard	
		Adjusted		
C _{1A}	30pF	30pF	30pF	
R _{2A}	106Ω	92.8Ω	93.1Ω	
C _{ni(111)}	_	1.3pF	1.3pF	

Section B Design:

- 1. Since $Q_p = 1.000$, set K_B to 1.00
- 2. Use the CLC446. This is a current-feedback op amp
 - $--f_{3dB} = 400MHz > f_{H} = 200MHz$
 - $\rm f_{3dB}$ \leq 10 $\rm f_{c}$ = 500MHz; the design will be sensitive to the op amp group delay
 - SR = 2000V/µs > 1000V/µs (see Item #1 in 'Section A Design')
 - τ_{oa} ≈ 0.56ns at 10MHz
 - -- C_{ni(446)} = 1.0pF (input capacitance)
- 3. Use the CLC446's recommended R_f at $A_v = 1.0$:

$$R_{fB} = 453\Omega$$

Then leave R_{aB} open so that $K_B = 1.00$

4. Initialize the resistor level:

$$R \approx 100\Omega$$

5. Initialize the capacitor level, and the component ratios:

$$C \approx \frac{1}{2\pi \big(50.00 MHz\big) \cdot \big(100\Omega\big)} = 31.83 pF$$

$$c^2 \approx 0.1000$$

$$r^2 \approx max \big\{0.10, 0.0826\big\} = 0.1000$$

6. Recalculate C² and initialize the capacitors:

$$C^2\approx 0.127 \quad C_{1B}\approx 89.3 pF \quad C_{3B}\approx 11.3 pF$$

7. Set the capacitors to the nearest standard values:

$$C_{1B} \approx 91 pF$$
 $C_{3B} \approx 11 pF$

Recalculate the capacitor level and ratio, and the resistor level and ratio:

Design Example (Continued)

9. Calculate the resistors:

$$R_{4B} = 324\Omega$$
 $R_{3B} = 31.2\Omega$

10. The sensitivities for this design are:

$$\begin{split} C &= \sqrt{\left(91 pF\right) \cdot \left(11 pF\right)} = 31.64 pF \\ c^2 &= \frac{\left(11 pF\right)}{\left(91 pF\right)} = 0.1209 \\ R &= \frac{1}{2\pi \left(50.00 MHz\right) \cdot \left(31.64 pF\right)} \\ &= 100.6 \Omega \\ r^2 &= 0.1056 \end{split}$$

αί	$S_{\alpha_{i}}^{H_{_{\infty}}}$	$S_{lpha_{i}}^{\omega_{p}}$	$s_{lpha_i}^{Q_p}$
C _{1B}	0.00	-0.50	-0.39
Сзв	0.00	-0.50	0.39
R _{4B}	0.00	-0.50	0.50
R _{5B}	0.00	-0.50	-0.50
R _{fB}	0.00	0.00	0.00
R_{gB}	0.00	0.00	0.00
K	1.00	0.00	1.12

Section B Pre-distortion:

1. The design gives these values:

$$\begin{split} &\omega_{p(nom)} = 2\pi(50.00\text{MHz}) \\ &Q_{p(nom)} = 1.000 \\ &K_B = 1.00 \\ &C_{1B} = 91\text{pF} \\ &C_{3B} = 11\text{pF} \end{split}$$

2. Iteration 1 shows the initial design results. Iterations 2-4 pre-distort R_{4B} and R_{5B} to compensate for the CLC446's group delay, and for $C_{\rm ni(446)}$:

Iteration #		1	2	3	4
$\frac{\omega_{p(pd)}}{2\pi}$	[MHz]	50.00	59.73	56.81	57.54
$Q_{p(pd)}$	[]	1.000	0.9320	0.9561	0.9505
R	$[\Omega]$	10.6	84.22	88.54	87.42
r ²	$[\Omega]$	0.0962	0.1108	0.1053	0.1065
R _{4B}	$[\Omega]$	324.3	253.0	272.9	267.9
R _{5B}	$[\Omega]$	31.21	28.03	28.73	28.53
τ ₂	[ns]	0.324	0.253	0.273	0.268
τ ₄	[ns]	1.741	1.511	1.575	1.559

Iterati	ion #	1	2	3	4
$\frac{\omega_{p}}{2\pi}$	[MHz]	43.87	51.96	49.52	50.13
Q_p	[]	1.034	0.984	1.003	0.999

The midband gain estimate is:

$$H_{\infty} \approx 0.770 \text{[/V/V]}$$
. Iteration 1 $\approx 0.759 \text{ [V/V]}$. Iteration 4

The simulations gave a lower value for $H_{\hbox{\tiny so.}}$ Increasing K could help overcome this loss, but would also increase the sensitivities.

3. The resulting components are:

Component	Initial	Value	Standard
		Adjusted	
C _{1B}	91pF	91pF	91pF
Сзв	11pF	11pF	11pF
C _{ni(446)}	_	1.0pF	1.0pF
R _{4B}	324Ω	268Ω	267Ω
R _{5B}	31.2Ω	28.5Ω	28.7Ω
R _{fB}	453Ω	453Ω	453Ω
R_{gB}	∞	∞	8

Figure 3 and Figure 4 show simulated gains. The curve numbers are:

- 1. Ideal (Initial Design Values, $\tau_{oa} = 0$, $C_{ni} = 0$)
- 2. Without pre-distortion (Initial Design Values, $\tau_{oa} \neq 0$, $C_{ni} = 0$)
- 3. With pre-distortion (Pre-distorted Values, $\tau_{oa} \neq 0, \; C_{ni} = 0)$

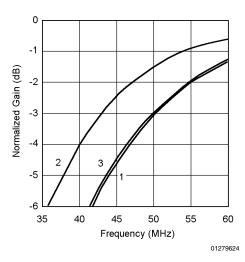


FIGURE 3. Simulated Filter Magnitude Response

Design Example (Continued)

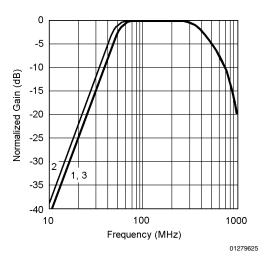


FIGURE 4. Simulated Filter Magnitude Response

SPICE Models

SPICE Models are available for most of Comlinear's amplifiers. These models support nominal DC, AC, AC noise and transient simulations at room temperature.

We recommend simulating with Comlinear's SPICE model to:

- · Predict the op amp's influence on filter response
- Support quicker design cycles

Include board and component parasitic models to obtain a more accurate prediction of the filter's response.

To verify your simulations, we recommend bread-boarding your circuit.

Summary

This application Note contains an easy to use design algorithm for a low sensitivities Sallen-Key highpass biquad. Designing for low ω_{p} and Q_{p} sensitivities gives:

- Reduced filter variation over process, temperature and time
- · High manufacturing yield
- Lower component cost

A low sensitivity design is not enough to produce high manufacturing yields. This Application Note shows how to compensate for the op amp bandwidth, and for the [parasitic]

input capacitance of the op amp. This method also applies to any other component or board parasitics. The components must also have low enough tolerance and temperature coefficients.

Appendix A – Derivation of Pre-distortion and Parasitic Capacitance Compensation Formulas

To pre-distort this filter, and compensate for the [parasitic] input capacitance of the op amp C_{ni}):

1. Use the method in [5] to include the op amp's effect on the filter response. The result is:

$$\frac{V_{o}}{V_{in}} \approx \frac{H_{\infty} \left(\frac{1}{\omega_{p}^{2}}\right) s^{2}}{1 + \left(\frac{1}{\left(\omega_{p}Q_{p}\right)}\right) s + \left(\frac{1}{\omega_{p}^{2}}\right) s^{2}} \cdot e^{-\tau} e^{s}$$

where the op amp group delay (τ_{oa}) is evaluated at the passband edge frequency (f_c) , and:

$$\begin{split} &\frac{1}{\left(\omega_{p}Q_{p}\right)}=R_{5}C_{1}+R_{5}C_{3}-R_{4}C_{3}\left(K-1\right)\\ &\frac{1}{\omega_{p}^{2}}=R_{4}R_{5}C_{1}C_{3}+K\tau_{oa}R_{4}C_{3}\\ &K=\frac{1+R_{f}}{R_{g}} \end{split}$$

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Appendix A – Derivation of Pre-distortion and Parasitic Capacitance Compensation

Formulas (Continued)

2. Since C_{ni} is in parallel with R_4 , replace R_4 with the parallel equivalent of R_4 and C_{ni} :

$$\begin{split} \frac{R_{4} \leftarrow R_{4}}{\left(1 + R_{4}C_{ni}s\right)} &\approx \frac{H_{\infty} \left(\frac{R_{4}C_{3}\left(R_{5}C_{1} + K\tau_{oa}\right)}{1 + R_{4}C_{ni}s}\right)s^{2} \cdot e^{-\tau_{oa}s}}{\left(1 + \left(\frac{R_{4}C_{3}\left(1 - K\right)}{1 + R_{4}C_{ni}s} + R_{5}\left(C_{1} + C_{3}\right)\right)s\right)} \\ &+ \left(\frac{R_{4}C_{3}\left(R_{5}C_{1} + Kt_{oa}\right)}{1 + R_{4}C_{ni}s}\right)s^{2} \end{split}$$

3. After simplifying, we obtain:

$$\frac{V_o}{V_{in}} \approx \frac{H_\infty \Biggl(\frac{1}{\omega_p^2}\Biggr) s^2}{1 + \Biggl(\frac{1}{\left(\frac{\omega_p Q_p}\right)}\Biggr) s + \Biggl(\frac{1}{\omega_p^2}\Biggr) s^2} \cdot e^{-\tau_{oa}s}$$

where:

$$\begin{split} \frac{1}{\left(\omega_{p}Q_{p}\right)} &= t_{1} + t_{2} \\ \tau_{1} &= R_{5}C_{1} + R_{5}C_{3} - R_{4}C_{3}\left(K - 1\right) \\ \tau_{2} &= R_{4}C_{ni} \\ \frac{1}{\omega_{p}^{2}} &= \tau_{3}^{2} + \tau_{4}^{2} \\ \tau_{3}^{2} &= R_{4}R_{5}C_{1}C_{3} \\ \tau_{4}^{2} &= K\tau_{oa}R_{4}C_{3} + R_{4}R_{5}\left(C_{1} + C_{3}\right)\!C_{ni} \\ K &= \frac{1 + R_{f}}{R_{g}} \\ H_{\infty} &= \frac{K\cdot\left(\tau_{3}^{2}\right)}{\left(\tau_{3}^{2} + \tau_{4}^{2}\right)} \end{split}$$

Appendix B- Bibliography

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Note: The circuits included in this application note have been tested with National Semiconductor parts that may have been obsoleted and/or replaced with newer products. Please refer to the CLC to LMH conversion table to find the appropriate replacement part for the obsolete device.

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