Designing Active High Speed Filters

Filters built from resistors (R), inductors (L) and capacitors (C) are known as RLC or passive filters and are the dominant type of filter for high frequency applications. The performance of these filters is typically limited by the inductors which are large, expensive and far from ideal in an electrical sense. By using amplifiers and feedback, the same filter characteristics can be achieved without the use of inductors, these filters are known as "active filters". An active filter will perform well only to the extent that the amplifiers in it behave in an ideal sense, so traditionally active filters have been limited to applications at frequencies below 1MHz. With the advent of low cost, very high speed operational amplifiers, it is now feasible to realize active filters with frequency ranges in the tens of MHz. With some of the newer high speed amplifiers such as the CLC449 - a 1.2GHz bandwidth amplifier, filters with corner frequencies above 100MHz have

This application note will provide a recipe to realize active filters using low cost, high speed operational amplifiers. The filter topology that is used is the Sallen-Key Filter which uses the operational amplifier as a fixed gain block. This filter topology can be used with current feed-back or voltage feedback amplifiers, and you will be shown how to design low pass, high pass and band pass filters using this filter topology. This application note discusses a printed circuit board which will allow you to prototype active filters of up to 8 pole complexity. This is not a complete treatment of the subject of active filters, there are several good books published on that topic, some of which are listed in the bibliography. This is a simple method of getting a circuit that will work for most applications. The topics covered are:

1) Filter Types

been built.

- Introduction to the second order, low pass Sallen-Key Filter
- 3) RC:CR Transformations to realize second order, high pass Sallen-Key Filters.
- Cascading filter sections to achieve higher order filters and Band Pass Filters
- 5) Sensitivities to component values
- 6) How to select an Op-amp for use in an active filter
- 7) Compensation for finite Bandwidth Amplifiers
- 8) The National active filter evaluation boards

Filter Types

There are a large number of different types of filter responses. In this application note, we will concern ourselves with the three which I have found to be the most useful.

National Semiconductor OA-26 Mark Sauerwald September 1997



Butterworth Response

The Butterworth response maximizes the flatness in the pass band of the filter. The response is very flat near DC then begins to slowly roll off so that it is at -3dB at the cutoff frequency, and approaches an ultimate rolloff rate of -20ndB/decade where n is the order of the filter. Butterworth filters are used it is very important to maintain gain flatness, especially at low frequencies.

Bessel Response

In addition to altering the magnitude of the input signal depending upon its frequency, filters introduce a delay into the signal which is dependent upon frequency. This introduces a frequency dependent phase shift which distorts non-sinusoidal signals. Just as the Butterworth response maximizes the amplitude flatness through the passband, a Bessel Response minimizes the phase non-linearity in the passband.

Chebyshev Response

In some applications, the most important factor is how fast the filter cuts off the unwanted signal. Faster rolloff than what is seen by the Butterworth filter can be achieved if you are willing to accept some ripple in the passband.

Appendix A contains tables with the parameters required to design filters up to order 8 with Butterworth, Bessel, and Chebyshev responses. There are two tables for the Chebyshev response: one for 0.1dB maximum ripple in the passband, and one for 1dB of ripple in the passband.

Introduction to the Second Order, Low Pass Sallen-Key Filter

The circuit shown in figure 1 is a two pole, Sallen-Key Low Pass Filter. This filter (and any two pole filter) can be characterized by three parameters: K, ω_0 and Q. K is the DC gain of the filter. ω_0 is a measure of the corner frequency of the filter, while Q is a measure of how closely spaced the two poles are in the S plane. The values of K, Q and ω_0 are given by:

$$K=1+\frac{R_f}{R_g} \quad Q=\frac{m}{1+m^2} \quad \omega_0=\frac{1}{mRC}$$

Q, K are unitless

 ω_0 is in units of radians/sec. Divide ω_0 by 2π to get it in Hz.

Introduction to the Second Order, Low Pass Sallen-Key Filter (Continued)

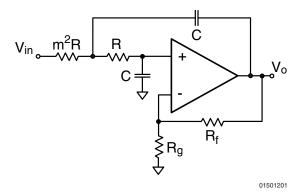


FIGURE 1. Sallen-Key Low Pass Filter with Equal Cs

The methodology to design a particular filter is to select the desired values for K, Q and ω_0 and then to use the above equations to determine the component values required. Q can be obtained from the filter table in appendix A. ω_0 is your cutoff frequency and will be given to you from the design specification. In most filters, the actual value of ω_0 that you design for must be adjusted by the factor found in the filter table to get the proper -3dB frequency. K is another parameter that will be provided as part of the filter specification.

Since these three parameters are not completely independent, it may not be possible to meet all three points simultaneously. In this case, you should select another value of K, and then use an amplifier before or after the filter to make the overall gain meet the system requirements. For example if a Butterworth filter is desired (Q = 0.707) with a DC gain of 4, then we find that there is no positive value of m which will provide the required filter. Since a negative value of m implies the use of a negative value resistor, we need to find another solution. If however we select K = 1.5, then by using an m of 0.707 we obtain the required Q, and to obtain the proper overall gain, we can place an amplifier with a gain of 2.66 in front of the filter.

Even doing these things, it is possible that there will not be a solution to the desired filter, especially for high Q sections. In this case, see the methodology for a filter with non equal $C_{\rm S}$ shown in appendix B. This is a much more versatile circuit, but somewhat more difficult to design.

The methodology to use in selecting component values is outlined below:

- 1) Select R_f and R_g to obtain the desired K. If the amplifier that you are using is a current feedback amplifier, follow the guidelines in the datasheet to select appropriate values of R_f and R_g
- 2) Determine the value of m required using the following equation and the value of Q found in the design table:

$$m = \frac{1 \pm \sqrt{1 - 4Q^2(2 - K)}}{2Q(2 - K)}$$

- 3) If you cannot get a positive real solution for m, then select another value of K and go back to step 1. For Q < 1.3 select K = 1, for 1.3 < Q < 5 select K = 2, for Q > 5 select K ≈ √Q. If this still does not work, then see appendix B.
- 4) Arbitrarily select a value for C.
- 5) Determine the value of ω_0 to use by multiplying your desired cutoff frequency by the value of μ found in the filter design table. If your frequency specification is in Hz, remember to multiply it by 2π to get it into radians/sec.
- 6) Determine the value of R required using the equation below:

$$R - \frac{1}{\omega_0 mC}$$

7) If R turns out to be too large or too small for practical purposes, select another value for C (if R is too big, select a larger value for C, if R is too small select a smaller value of C) then go back to step 6.

Example:

Design a Butterworth filter, with a cutoff frequency of 10MHz, and a DC gain of 1.5. The CLC430 will be used in this example.

- 1) Select R_f = 700Ω , R_g = $1.4k\Omega$ as per the CLC430 data sheet.
- 2) Find Q from table: 0.707, use this to determine m = 0.707
- 3) Not required
- 4) No Arbitrarily select C = 0.1μF
- 5) $\omega_0 = 62.8E6$ for a 10MHz filter

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Introduction to the Second Order, Low Pass Sallen-Key Filter (Continued)

- 6) Calculate R. R turns out to be 0.23Ω
- R is too small, therefore try a smaller C, and return to step 6. Select C = 100pF.
- 8) $R = 225\Omega$, much better.

Figure 2 illustrates the final filter topology.

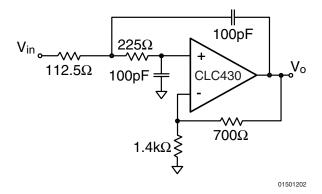


FIGURE 2. Example of Low Pass Filter

With slight modifications, the CLC430's evaluation board, CLC730013, can be used to test this circuit.

In some cases, it may be difficult to realize the desired filter with the constraint of equal valued capacitors. If this is the case, see appendix B to obtain expressions for Q and ω_0 where the capacitors can take on different values. This is most often necessary when trying to realize a filter with a high Q.

Transform a Low Pass Filter into a High Pass Filter

By changing capacitors into resistors, and resistors into capacitors, a low pass filter can be changed into a high pass filter. To make a high pass filter from a lowpass filter, replace each capacitor of value C with a resistor of value $1/\omega_0$ C, and each resistor with a capacitor of value $1/\omega_0$ R. For example the 100pF capacitors in the example circuit from the previ-

ous section should be replaced with 159 Ω resistors, the 225 Ω resistor should be replaced with a 71pF capacitor, and the 112 Ω resistor should be replaced with a 142pF cap.

Alternately you can calculate component values using a method similar to that shown in the previous section. Figure 3 is a second order Sallen-Key High pass filter. Q and $\omega 0$ are given by

$$Q = \frac{1}{2n + \frac{1}{n}(1 - K)} \quad \text{and} \quad \omega_0 = \frac{1}{nRC}$$

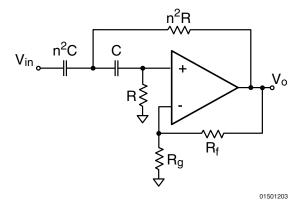


FIGURE 3. Sallen-Key High Pass Filter

Cascading Filter Sections

Higher order filters can be realized by cascading lower order filters. A filter of order n can be realized by cascading n/2 second order sections. Note that to obtain a fourth order Butterworth filter you do not cascade two second order Butterworth filter sections. The pole locations for the fourth order filter are all different and different values of Q and ω_0 will need to be used for each section. Cascading active filters of the Sallen-Key topology is easy. Since the output impedances of the filters are very small, cascading them consists of just connecting one section to the next (each filter section is designed assuming 0 source impedance.)

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Cascading Filter Sections (Continued)

If a filter of odd order is desired, the last pole can be added with a simple passive filter at the output of the active filter as shown in *Figure 4*.

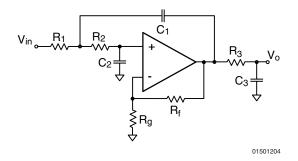


FIGURE 4. Order Sallen-Key Filter

When cascading filters, one question that arises is what order the sections should be placed. The answer to this is the same as the answer to all filter questions – "it depends". Two factors that need to be considered when cascading filter sections are "Am I liable to have intermediate signals that might clip or distort?" and "How important is noise to me?"

In filters with sections where there are large Qs, the maximum amplitude of the signal in between stages may be larger than the input or the output amplitude. This can lead to undue distortion of the signal. This will most likely be an issue if there are filter sections with large Qs, and the input signals are large. Strategies that can be used to combat this effect are to put the stages with the lowest Qs and gains first, and cascade the higher gain sections later. Another way that the dynamic range could be increased would be to use an op-amp with larger dynamic range. The CLC432 is a dual, current feedback op-amp that is well suited to active filter applications and has an output voltage swing of 28V_{PP} when driving a light load.

In order to minimize the broadband noise that is present in an active filter, stages should be cascaded with the highest Q, and highest gain sections first, then followed by lower gain sections. Other strategies that should be considered when trying for low noise are using the lowest possible value resistors to reduce thermal noise and to select low noise op amps such as the CLC428, dual, voltage feedback op amp. As you can see from the previous two paragraphs, the order in which to place the filter stages is dependent upon the requirements of your application. There is no best way to cascade your filter stages.

Component Value Sensitivities

If the component values used in realizing the filter are not exactly what the calculations arrive at, and they won't be, then the filter characteristics will be different from what was desired. Even if time is spent trimming components to the exact desired value, variations caused by temperature shifts, aging and other external and internal sources will cause the filter characteristics to vary. A good design will result in minimal variation in the filter characteristics as a result of the component value variations that might be expected. To estimate the effect on the filter characteristics as component values vary, sensitivity figures are used.

A sensitivity figure tells how much variation there will be in one characteristic when a parameter is changed. Hence $_{S_{i}^{\omega}}$ refers to the incremental change in ω for an incremental change in R. If is $_{S_{i}^{\omega}}$ 2 then there will be a 2% variation in ω for a 1% variation in R. The two parameters with which we are most concerned in our filter designs are Q and $\omega 0$, therefore it would be useful to look at what component variations have an effect on these parameters, and to determine what these sensitivities are. $_{S_{i}^{\omega}}$ is defined as:

$$S_x^A = \frac{d(InA)}{d(Inx)} = \frac{x}{A} \frac{dA}{dx}$$

In the lowpass filter of *Figure 1*, the equation that describes Q, has n and K as its variables, hence Q is only sensitive to the ratio of resistor values and to K which is determined by $R_{\rm f}$ and $R_{\rm g}$. For this filter the sensitivity that we have worry the most about is the sensitivity to K, which is very large for high Q sections.

Selecting an Op Amp for Use in an Active Filter

Although there are many factors that go into selecting an op amp for use in any application, most filter applications can be satisfied by looking at a just four parameters: Bandwidth Recommended Gain range Noise Dynamic Range

- Bandwidth
- Recommended Gain Range
- Noise
- Dynamic Range

Bandwidth

As a general rule, when selecting an op amp for a filter, make certain that it has a bandwidth of at least 10x the intended filter frequency, and preferably 20x. As an example to design a 10MHz low pass filter, use an op amp with at least 100MHz of bandwidth. If designing a high pass filter, make certain that the bandwidth of the op amps will be sufficient to pass all of your signal. Another point to watch is that your op amp must have this band-width under the conditions that you intend to use it, for example, the same gain, signal level and power supply voltage. An op amp that is specified as a 100MHz op amp because it has 100MHz bandwidth with ±15V supplies, 50mV output level and a gain of 1 is not likely to be useful in a 10MHz filter application. If in doubt, configure the amplifier that you are considering at the gain that you are intending to use (K) and measure its bandwidth.

Recommended Gain Range

Your filter design will be dictating to you the gains at which you will be setting your op amps. If the chosen op amp is a voltage feedback op amp, use at gains outside the recommended gain range is liable to lead to lower than expected bandwidth at best and oscillation at worst. For a current feedback op amp, operation at gains outside of the recommended range is liable to force you to use resistor values for $R_{\rm f}$ and $R_{\rm g}$ which are way too small or large for practical realization.

Noise

The input voltage and current noises of the op amp will contribute to the noise at the output of the filter. In applications where noise is a major concern, you will need to calculate these contributions (as well as the contributions of the thermal noise of the resistors in the circuit) to determine if the added noise encountered with an active filter is acceptable. Noise can be reduced by selecting low noise, high speed op amps such as the CLC425 or CLC428.

Dynamic Range

In filters which have high Q sections, it is possible that there will be intermediate signals that are larger than either the

input signal or the output signal. For the filter to operate properly, all of these signals must be passed without clipping or excessive distortion.

Secondary Specifications

In addition to the four primary specifications above, there are several secondary parameters that you may want to take into consideration. These would include phase linearity (this is generally better in current feedback op amps), packaging (duals, quads available?), power dissipation, price and availability of technical support.

Summary of High Speed Dual Op Amps

	Bandwidth (with	Recommended	Noise Voltage	Noise Current	Output Dynamic
	500mV output,	Gain Range in	(nV√Hz)	(pA√Hz)	Range (100Ω
	$A_V = 2)$ (MHz)	Filter			Load (V)
		Applications			
CLC412	250	1-8	3	12/2	+3.1/–2.9
CLC416	80	1-5	2	2	+3.5/-3.5
CLC428	80	1-5	2	2	+3.5/-3.5
LM6172	50	1-5	12	1	+9/-8.5
LM6182	100	1-5	4	16/3	±11
CLC5602	120	1-5	3	8.5/6.9	±3.8
CLC5622	150	1-5	2.8	10/7.5	±3.8
CLC432	62	1-20	3.3	13/2	+6/-6
	$(V_O = 4V)$				

Compensation for Finite Bandwidth Amplifiers

In all of the analysis that we have done, we have assumed that the op amps are ideal op amps with infinite bandwidth. Unfortunately, price and delivery of these op amps makes them a poor choice for actual realizable filters. The effect of using a real op amp in place of an ideal one is to slightly lower the corner frequency of the filter, and if we are somewhat clever, we can compensate for this by pre-distorting the component values of the components so that the final filter is much closer to what we wanted. The mathematical background for this is explained in application note OA-21. Since the goal of this application note is to make the design of active filters easy, we are going to skip all of the development work, and go directly to the final result. To make use of this method there is a parameter that you will need to know for the op amp that you intend to use, and this is the time delay through the amplifier, called T. The value of T can be obtained in a few different ways: one is to look at the frequency response plots for the op amp that you are considering using. Find the frequency at which the phase delay is 180°, multiply this frequency by 2 and take the reciprocal to obtain the time delay through the amplifier. In the case of the CLC412, the 180° frequency is about 300MHz, multiplying by two and taking the reciprocal yields a time delay, T, of 1.7ns. Another way that you can get a value for T with a National op amp is to use the spice model, and provide the amplifier, configured as you want it, with a pulse, and measure the delay between the input edge and the output edge.

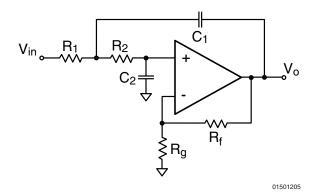


FIGURE 5. Low Pass Sallen-Key Filter

For the filter shown in Figure 5, you can calculate the values of R_1 and R_2 in the following way: Calculate R_2 by solving:

Compensation for Finite Bandwidth Amplifiers (Continued)

$$R_2^2 - bR_2 - d = 0$$

where:

$$\begin{split} b &= \frac{1}{\omega_0 C_2} \bigg[\frac{1}{Q} - \omega_0 KT \bigg] \quad d = \bigg(\frac{1}{\omega_0 C_2} \bigg)^2 \bigg(\frac{KT \omega_0}{Q} + K - 1 - \frac{1}{\alpha} \bigg) \\ \alpha &= \frac{C_1}{C_2} \end{split}$$

Once you have R2, you can get R1 with:

$$R_1 = \frac{R_2 - \frac{1}{\omega_0 C_2 Q}}{\alpha(K-1)-1}$$

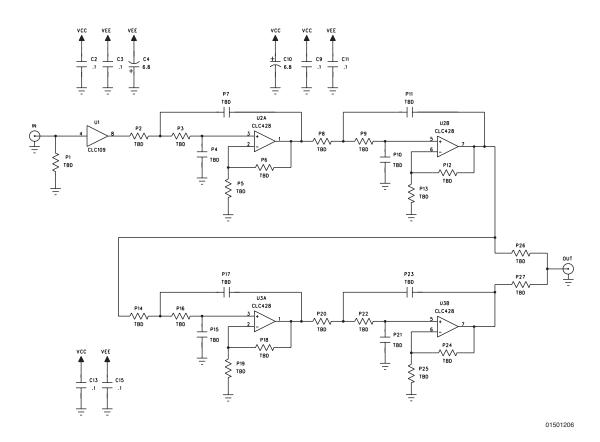


FIGURE 6. Schematic for Active Filter Board

The Active Filter Boards

To make prototyping active filters easier, Comlinear has designed two different active filter evaluation boards. A schematic of the first board is shown in *Figure 6*. It consists of a CLC109 (or CLC111) input buffer, followed by four cascaded Sallen Key filter sections, realized with two dual op amps. The board was designed using surface mount components, so the resistors and capacitors are interchangeable. This board is available from National Semiconductor as the CLC730061 board and is shipped as a bare PCB. The top and bottom views of the evaluation board are shown in *Figure 7*. The other board also allows for up to four cascaded biquad sections but restricts the user to designs using K=1

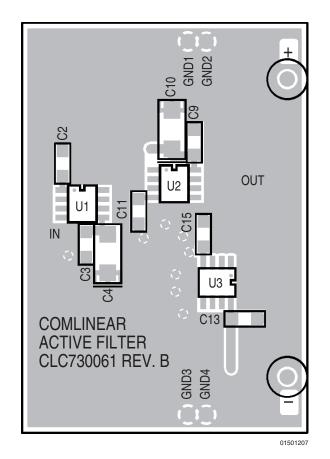
since rather than op amps, this board uses a quad, unity gain buffer. The board can be ordered as part number CLC730023 and is fully documented in the CLC114 evaluation board datasheet, available as National Semiconductor Literature #660114-001 or in the 1997 Comlinear Databook.

Conclusion

Using the principles outlined in this application note, an active filter design need not be a daunting task. You can feel free to impress your friends at a cocktail party by whipping out pencil and paper and doing a design for a 5MHz low pass filter. You don't have to tell them how easy it really is, just wow them and bask in their awed looks.

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Conclusion (Continued)



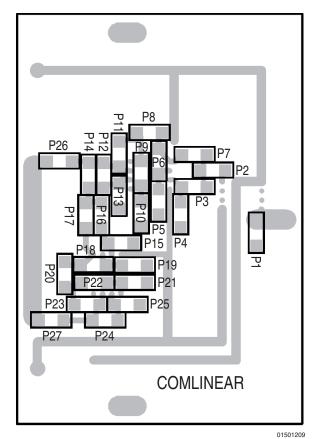


FIGURE 7. Top & Bottom Views of Active Filter Evaluation Board

Appendix A Filter Design Tables

Butterworth Low Pass Filter

n	ω ₁	Q ₁	ω_2	Q ₂	ω3	Qз	ω_{4}	Q_4	Attenuation
									at 2f _C (dB)
2	1	0.707	1						15
3	1	1.000	1						21
4	1	0.541	1	1.306					27
5	1	0.618	1	1.620	1				33
6	1	0.518	1	0.707	1	1.932			39
7	1	0.555	1	0.802	1	2.247	1		45
8	1	0.510	1	0.601	1	0.900	1	2.563	51

Bessel Low Pass Filter

n	ω ₁	Q ₁	ω2	Q ₂	ω3	Q ₃	ω_{4}	Q_4
2	1.274	0.577						
3	1.453	0.691	1.327					
4	1.419	0.522	1.591	0.806				
5	1.561	0.564	1.760	0.917	1.507			
6	1.606	0.510	1.691	0.611	1.907	1.023		

Appendix A Filter Design Tables (Continued)

Bessel Low Pass Filter (Continued)

7	1.719	0.533	1.824	0.661	2.051	1.127	1.685	
8	1.784	0.506	1.838	0.560	1.958	0.711	2.196	1.226

dB Ripple Chebyshev Filter

n	ω ₁	Q ₁	ω2	Q ₂	ω3	Q ₃	ω4	Q ₄	Attenuation at 2f _c (dB)
2	1.82	0.767							3.31
3	1.300	1.341	0.969						12.24
4	1.153	2.183	0.789	0.619					23.43
5	1.093	3.282	0.797	0.915	0.539				34.85
6	1.063	4.633	0.834	1.332	0.513	0.599			46.29
7	1.045	6.233	0.868	1.847	0.575	0.846	0.377		57.72
8	1.034	8.082	0.894	2.453	0.645	1.183	0.382	0.593	69.16

1.00dB Ripple Chebyshev Filter

n	ω ₁	Q ₁	ω ₂	Q ₂	ω3	Q ₃	ω ₄	Q_4	Attenuation at 2f _C (dB)
2	0.050	0.957							11.36
3	0.997	2.018	0.494						22.46
4	0.993	3.559	0.529	0.785					33.87
5	0.994	5.556	0.655	1.399	0.289				45.31
6	0.995	8.004	0.747	2.198	0.353	0.761			56.74
7	0.996	10.899	0.808	3.156	0.480	1.297	0.205		68.18
8	0.997	14.240	0.851	4.266	0.584	1.956	0.265	0.753	79.62

Appendix B Non-Equal C Sallen-Key Filter Methodology

The circuit shown in Figure 8 is a two pole, Sallen-Key low pass filter similar to the one seen in the body of this application note. The difference is that in this figure we have removed the constraint that the two capacitors remain equal by adding the "n" as an additional degree of freedom. Like the filter from Figure 1, this filter can be characterized three parameters: K, ω_0 and Q. K is the DC gain of the filter. ω_0 is a measure of the corner frequency of the filter, while Q is a measure of how closely spaced the two poles are in the S plane. The values of K, Q and ω_0 are given by:

$$K = 1 + \frac{R_f}{R_g}$$

$$Q = \frac{mn}{1 + m^2 + (mn)^2 (1 - K)}$$

$$\omega_0 = \frac{1}{mnPC}$$

Q.K are unitless

 ω_0 is in units of radians/sec. Divide ω_0 by 2π to get it in Hz.

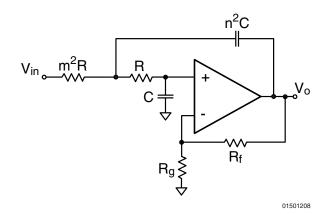


FIGURE 8. Pole Sallen-Key Low Pass Filter with Unequal Capacitors

The methodology to design a particular filter is to select the desired values for K, Q and ω_0 and then to use the above equations to determine the component values required. Q can be obtained from the filter table in appendix A. ω_0 is your cutoff frequency and will be given to you from the design

Appendix B Non-Equal C Sallen-Key Filter Methodology (Continued)

specification. In most filters, the actual value of $\omega_{0}\text{that}$ you design for must be adjusted by the factor found in the filter table to get the proper -3dB frequency. K is another parameter that will be provided as part of the filter specification.

The methodology to use in selecting component values is outlined below:

- 1) Select R_f and R_g to obtain the desired K. If the amplifier that you are using is a current feedback amplifier, follow the guidelines in the data sheet to select appropriate values of R_f and R_g
- 2) Arbitrarily select a value for n. This value should be small for low Q filters and should be larger for higher Q filters. Remember that the standard values for capacitors are limited, and n should be chosen with this in mind.
- 3) Determine the value of m required using the following equation and the value of Q found in the design table:

$$m = \frac{\frac{n}{Q} \pm \sqrt{\left(\frac{n}{Q}\right)^2 - 4\left(1 + n^2(1 - K)\right)}}{2\left(1 + n^2(1 - K)\right)}$$

- 4) If you cannot get a positive real solution for m, then select another value of K or n and go back to step 1.
- 5) Arbitrarily select a value for C.
- 6) Determine the value of $\boldsymbol{\omega}_{0}$ to use by multiplying your desired cutoff frequency by the value of ω found in the filter design table. If your frequency specification is in Hz, remember to multiply it by 2π to get it into radians/sec.
- 7) Determine the value of R required using the equation

$$R = \frac{1}{\omega_0 mnC}$$

8) If R turns out to be too large or too small for practical purposes, select another value for C (if R is too big, select a larger value for C, if R is too small select a smaller value of C) then go back to step 7.

Appendix C Transfer Functions for Some of the Filters

Transfer function for filter in Figure 5:

$$\frac{V_o}{V_{in}} = \frac{\frac{K}{R_1 R_2 C_1 C_2}}{s^2 + s \left(\frac{1}{C_2 R_2} - \frac{K}{C_2 R_2} + \frac{1}{R_2 C_1} + \frac{1}{R_1 C_1}\right) + \frac{1}{R_1 R_2 C_1 C_2}}$$

Transfer function for filter in Figure 3:

$$\frac{V_o}{V_{in}} = \frac{s^2 K}{s^2 + \frac{s}{RC} \left[2 + \frac{1}{n^2} (1 - K)\right] + \frac{1}{C^2 R^2 n^2}}$$

Appendix D 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

LIFE SUPPORT POLICY

NATIONAL'S PRODUCTS ARE NOT AUTHORIZED FOR USE AS CRITICAL COMPONENTS IN LIFE SUPPORT DEVICES OR SYSTEMS WITHOUT THE EXPRESS WRITTEN APPROVAL OF THE PRESIDENT AND GENERAL COUNSEL OF NATIONAL SEMICONDUCTOR CORPORATION. As used herein:

- 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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