

# High Performance Audio Electronics

# Model 990Enh-Ticha Discrete Operational Amplifier

The 990Enh is a high performance discrete operational amplifier designed for professional audio applications and areas where ultralow noise and low distortion is required. It was designed as an enhanced higher performance upgrade replacement for the Jensen JE990, Automated Processes Inc. API-2520, John Hardy Co. 990A-990C, FiveFish Studios DOA series, Seventh Circle Audio SC10, SC25, SC99, and Avedis Audio 1122 op-amp gain block. The pinouts conform to the 990 package, allowing direct replacement. See **TABLE 1**. on page 4 for additional discrete opamps which can be upgraded.

The all-discrete SMT design is similar to the JE990 basic topology but has been completely redesigned to use an ultra-precision differential super-matched transistor pair specifically designed to meet the requirements of ultra-low noise and ultra-low THD audio systems.

In addition to the enhanced input stage, the 990Enh-Ticha uses high precision temperature stable power supply independent current sources. Supply independent current sources allow the bias to remain locked at the optimum operating point regardless of power supply voltage.

Dual matched pair temperature stable current mirrors, dual matched pair active current loads give the Model 990Enh it's outstanding power supply rejection performance. The enhanced low distortion Class-A output driver stage can sink or source 250mA allowing this module to drive transformers easily.



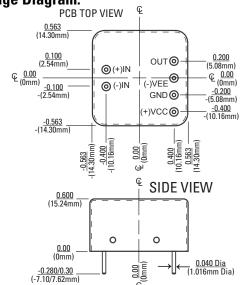
#### **Features:**

- Ultra Low Total Harmonic Distortion, 0.00045 THD+N @ 1kHz
- Ultra Low Noise 890pV/rtHz typical
- High Current Output Drive (250mA into 75 ohms)
- +26dBu Output Levels (into 600 ohms)
- Standard Gain Block Footprint
- Operates over ±10V to ±24V supply rails
- Lower output offset voltage than existing counterparts
- Lower input leakage current than existing counterparts
- Particular emphasis on audio performance
- Designed, assembled and produced in the USA
- 3 Year Warranty

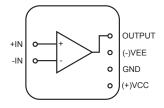
#### **Applications:**

- Low Impedance Line Amplifiers and Drivers
- Active Filters and Equalizers
- Summing/Mixer Amplifiers
- High Performance Microphone Preamplifiers
- High Performance A/D and D/A front end Preamplifier
- High Performance D/A I-V convertors
- High Current Buffer Amplifier

### **Package Diagram:**



#### **Connection Diagram:**



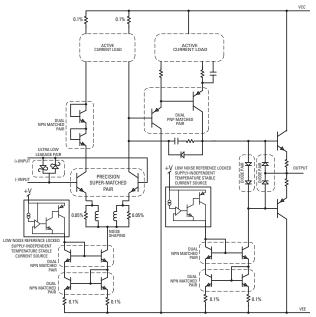
Professional Audio Products Datasheet

High Performance Audio Electronics

# Model 990Enh-Ticha Discrete Operational Amplifier

Integrated power transistor heatsinks coupled to a anodized aluminum enclosure keeps the 990Enh-Ticha operating within a wide SOA (safe operating area) and does not suffer from Beta droop when driving transformers or low impedance loads. Each amplifier is fully tested and meets or exceeds published specifications.

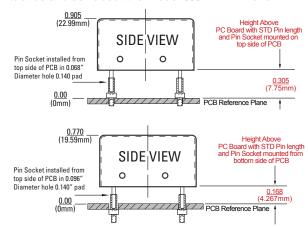
Because of the 990Enh high current drive capability, supporting circuitry impedances can be scaled down within the application circuit. This can reduce the overall system noise, without increased distortion and provides higher headroom compliance performance.



Simplified Schematic of the Model 990Enh-Ticha

If the user is upgrading or replacing vintage or retro-clone gear, take note of the pin length required for your particular application. Older gear typically used modules with 0.480 to 0.510 inch long 0.040 pins. Sonic Imagery Labs offers this longer pin length variant at no additional charge. See the Model 990Enh-Ticha and 995FET-Ticha Mechanical Options Application Note AN-18 for additional mechanical details.

For a FET based discrete opamp version with this architecture, see the Sonic Imagery Labs Model 995FET-Ticha datasheet. Sonic Imagery Labs also can provide a variation of this model that can operate down to  $\pm 4.5 \text{V}$  for low power, low voltage applications. Contact us and ask about the Model 990LV-Enh-Ticha.



**DETAIL A.** (Above) Standard pin length height specifications and mounting options for Sonic Imagery Labs Model 990Enh-Ticha opamp module.

## **Recommended Operating Conditions:**

Positive Supply Voltage VCC +10V to +24V
Negative Supply Voltage VEE -10V to -24V
Signal Current (inverting mode) lin 50nA to >200 uA

Stresses above those listed under "Absolute Maximum Ratings" may cause permanent damage to the device. These are stress ratings only; the functional operation of the device at these or any other conditions above those indicated in the operational sections is not implied. Exposure to absolute maximum rating conditions for extended periods may affect device reliability.



Professional Audio Products Datasheet

## High Performance Audio Electronics

# Model 990Enh-Ticha Discrete Operational Amplifier

## **Absolute Maximum Ratings**

Supply Voltage VCC-VEE 56V

Differential Input Voltage  $V_{ID}$  13.9Vrms (+25dBu) @ unity gain Input Voltage Range  $V_{IC}$   $\pm 12.5V$ 

#### **DC Electrical Characteristics** (Ta=25°C, Vs=±24V unless otherwise noted)

Symbol	Parameter	Conditions	Min	Тур	Max	Units
V <sub>OS</sub> I <sub>OS</sub> I <sub>B</sub> A <sub>VOL</sub> V <sub>OM</sub> V <sub>OM</sub> CMRR PSRR I <sub>Q</sub>	Input Offset Voltage Input Offset Current Input Bias Current Voltage Gain (open loop) Output Voltage Swing Output Voltage Swing Input Common-Mode Range Common-Mode Rejection Ratio Power Supply Rejection Ratio Supply Current	$R_s = 0\Omega \text{ Av=Unity}$ $-$ $-3dB @ 43Hz$ $Vs = \pm 24V R_1 = 600\Omega \text{ Av=10}$ $Vs = \pm 24V R_1 = 75\Omega \text{ Av=10}$ $R_1 = 600\Omega$ $-$ $-$ $Vo=0, \text{ inputs gnd, Vcc=24V}$ $Vo=0, \text{ inputs gnd, Vee=24V}$	- 0.8 118 41 38 ±12 80 88 17 23	0.22 1 10 120 42 38.5 ±12.5 100 104 18 25	0.45 8 50 122.5 - - - - 19.5 26.5	mV nA uA dB Vpp Vpp V dB dB mA

## AC Electrical Characteristics (Ta=25°C, Vs=±24V unless otherwise noted)

Symbol	Parameter	Conditions	Min	Тур	Max	Units
SR SR GBW	Slew Rate Slew Rate Gain Bandwidth Product Maximum Peak Output Drive Current	$R_{\rm L}$ =600 $\Omega$ $R_{\rm L}$ =75 $\Omega$ 10kHz to 100kHz $R_{\rm L}$ =75 $\Omega$	18 17 - 250	19 18 >50 260	20 19	V/uS V/uS MHz mA

### **Design Electrical Characteristics** (Ta=25°C, Vs=±24V unless otherwise noted)

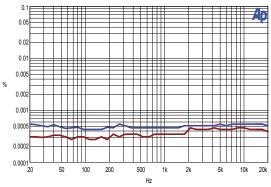
Symbol	Parameter	Conditions	Min	Тур	Max	Units
THD THD e n PBW f U Zin	Distortion+Noise Distortion+Noise Distortion+Noise Input Refered Noise Voltage Input Refered Noise Current Power Bandwidth Unity Gain Frequency Input Resistance	$R_{\rm L} = 600\Omega \; \text{Unity Gain @1kHz} \\ R_{\rm L} = 600\Omega \; \text{20dB Gain inverting @1kHz} \\ R_{\rm L} = 600\Omega \; \text{20dB Gain non-invert @1kHz} \\ \text{Input shorted to ground} \\ \text{-} \\ \text{Large-signal BW R}_{\rm L} = 600\Omega \\ \text{Small-signal BW at unity gain (ft)} \\ \text{Noninverting Input} \\$	- - - - -	0.00045 0.0003 0.00034 850 <1.0 >180 13.5 >10M	- - - 1000 - -	% % pV√ Hz pA√ Hz kHz MHz

## High Performance Audio Electronics

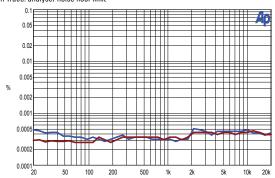
# Model 990Enh-Ticha Discrete Operational Amplifier

**THD+N Characteristics** (Ta=25°C, Vs=±24V, 1.0Vrms input, Rs=600 unless otherwise noted)

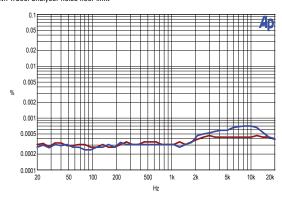
Total Harmonic Distortion+Noise Inverting Unity Gain vs Frequency
Blue Trace: measured 990Enh THD+N
Brown Trace: analyser noise floor limit



Total Harmonic Distortion+Noise Inverting 20db Gain vs Frequency
Blue Trace: measured 990Enh THD+N
Brown Trace: analyser noise floor limit



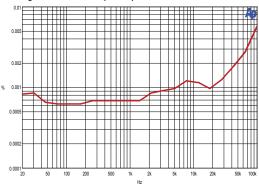
Total Harmonic Distortion+Noise Non-Inverting 20db Gain vs Frequency
Blue Trace: measured 990Enh THD+N
Brown Trace: analyser noise floor limit



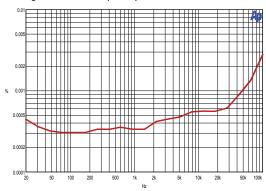
# **THD+N Large Signal Performance** (Ta=25°C, Vs=±24V, +24dBu Voutput, Rload variant, Gain variant as noted below)

Non-Inverting Condition Rload = 75  $\Omega$ , Gain= 40dB 0.0011% Rload = 75  $\Omega$ , Gain= 20dB 0.0006% Rload = 600  $\Omega$ , Gain= 40dB 0.00085%

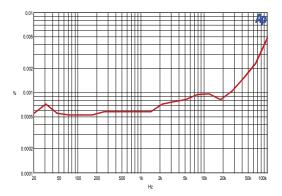
Total Harmonic Distortion+Noise, Non-Inverting, Rload=75  $\Omega$ , +24dBu output, 40dB gain verses Frequency



Total Harmonic Distortion+Noise, Non-Inverting, Rload=75  $\Omega$ , +24dBu output, 20dB gain verses Frequency



Total Harmonic Distortion+Noise, Non-Inverting, Rload=600  $\Omega$ , +24dBu output, 40dB gain verses Frequency



www.sonicimagerylabs.com



## High Performance Audio Electronics

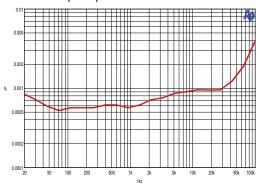
## THD+N Large Signal Performance (20kHz, Vs=±24V,

+24dBu Voutput, Rload variant, Gain variant as noted below)

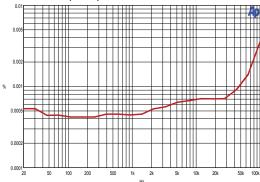
**Inverting Condition** 

Rload = 75  $\Omega$ , Gain= 40dB 0.00095% Rload = 75  $\Omega$ , Gain = 20dB 0.00071% Rload =  $600 \Omega$ , Gain = 40 dB0.00075%

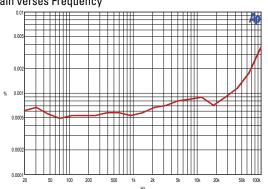
Total Harmonic Distortion+Noise, Inverting, Rload=75 Ω, +24dBu output, 40dB gain verses Frequency



Total Harmonic Distortion+Noise, Inverting, Rload=75  $\Omega$ , +24dBu output, 20dB gain verses Frequency



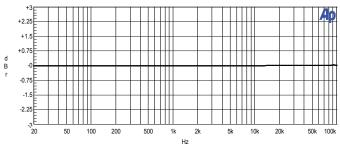
Total Harmonic Distortion+Noise, Inverting, Rload=600  $\Omega$ , +24dBu output, 40dB gain verses Frequency



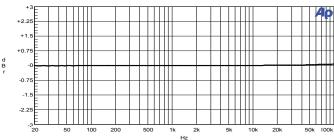
# Model 990Enh-Ticha **Discrete Operational Amplifier**

**Gain Accuracy vs Frequency** (Ta=25°C, Vs=±24V unless otherwise noted)

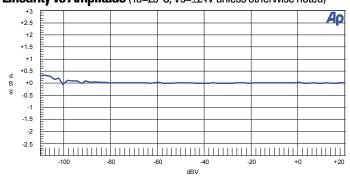
20dB (Av=10) Non inverting gain vs Frequency



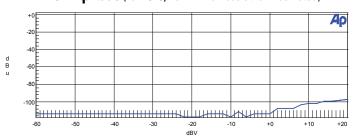
40dB (Av=100) Non inverting gain vs Frequency



## **Linearity vs Amplitude** (Ta=25°C, Vs=±24V unless otherwise noted)



**THD+N vs Amplitude** (Ta=25°C, Vs=±24V unless otherwise noted)



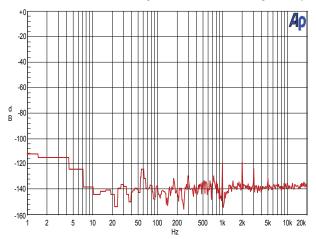
www.sonicimagerylabs.com

## High Performance Audio Electronics

## Model 990Enh-Ticha **Discrete Operational Amplifier**

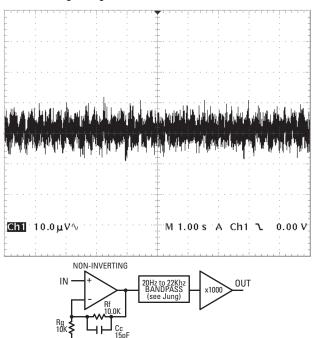
THD Residual+N Characteristics (Ta=25°C, Vs=±24V, 0dBV input, Rs=600  $\Omega$  Rload=10K  $\Omega$  unless otherwise noted)

1kHz Fundamental @ 0dBV, 6dB gain (Av=2) Non inverting vs Frequency



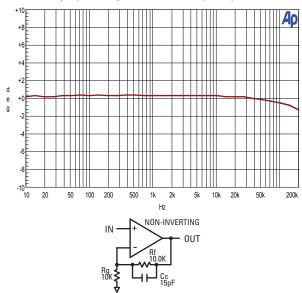
**Broadband Noise Characteristics** (Ta=25°C, Vs= $\pm$ 24V, Rs=0  $\Omega$  to gnd, Rload=10K  $\Omega$  unless otherwise noted)

Non inverting, 6dB gain (Av=2) 22Hz to 22kHz NBW vs Time

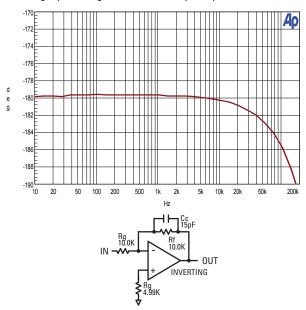


Input-Output Phase Characteristics (Ta=25°C, Vs=±24V, 0dBV input, Rs=600  $\Omega$  Rload=10K  $\Omega$  unless otherwise noted)

Non inverting input 6dB gain (Av=2) vs Frequency



Inverting input 0dB gain (Av=0) vs Frequency

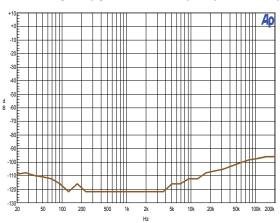


# High Performance Audio Electronics

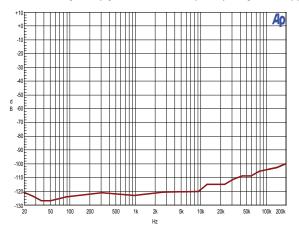
## Model 990Enh-Ticha **Discrete Operational Amplifier**

### Power Supply Rejection Ratio Characteristics (Ta=25°C, Vs= $\pm$ 24V, Rs=0 $\Omega$ to Gnd Rload=10K $\Omega$ unless otherwise noted)

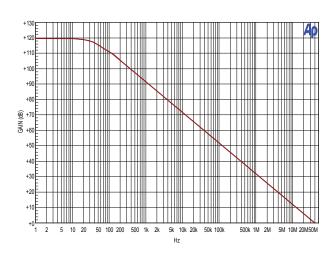
Non inverting, Unity gain (Av=1) vs Frequency, Positive Supply



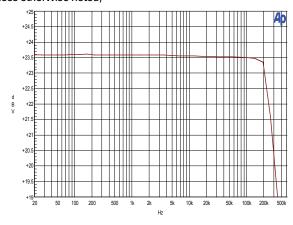
#### Non inverting, Unity gain (Av=1) vs Frequency, Negative Supply



### **Open Loop Frequency Response** (Ta=25°C, Vs= $\pm$ 24V, Rload=100K $\Omega$ unless otherwise noted)



## Full Power Frequency Response (Ta=25°C, Vs=±24V, Rload=600 Ω unless otherwise noted)

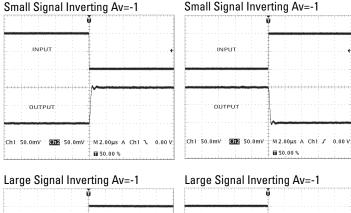


Professional Audio Products Datasheet

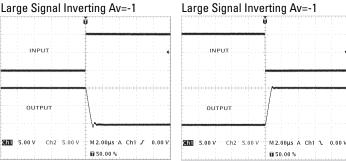
## High Performance Audio Electronics

## Model 990Enh-Ticha **Discrete Operational Amplifier**

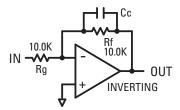
Pulse Response Ta=25°C, Vs=±24V RL=600Ω Cc=30pF

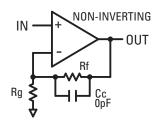


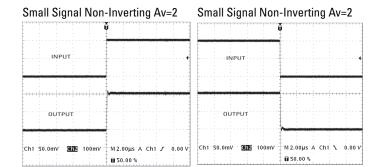
Small Signal Inverting Av=-1

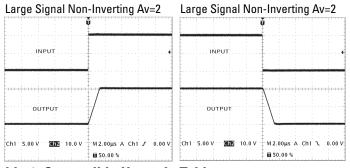


#### Pulse Response Test Setup









### Table 1. Compatible Upgrade Table

The Model 990Enh-Ticha can be used to upgrade and/or replace these obsolete or end of life discrete operational amplifiers. This list is by no means comprehensive. Contact Sonic Imagery Labs for additional information.

Jensen JE990 Series Automated Processes Inc. API-2520, 2520H, 2525 John Hardy Co. 990A-990C FiveFish Studios DOA series Avedis Audio 1122 Seventh Circle Audio SC10, SC25, SC99 Sound Skulptor SK25, SK99, SK47 Yamaha NE80100, NE80200 **TOA PC2011** ProTech Audio Model 1000 Purple Audio KDJ3, KDJ4 Modular Devices 1731, 1757 Modular Audio Products (MAP) 5000 Series, 1731 1731A Melcor 1731 JLM Audio 99V **Inward Connections SPA690** BTI 0A400 FAX Audio FA-100 Analog Devices 111

## High Performance Audio Electronics

# Model 990Enh-Ticha Discrete Operational Amplifier

## **Application Notes**

Low leakage film capacitors with high-quality dielectric (polypropylene or COG-NPO ceramic) should be used. Low-ESR power supply bypass capacitors with a small resistance in series with the power supply rails are essential for low noise operation. Precision low noise 1% metal film resistors should always be used. Since these components can represent high impedance, lead length and trace lengths should be minimized. Assembled circuits and PCB's should be carefully cleaned of flux residue to prevent leakage paths or other spurious behavior.

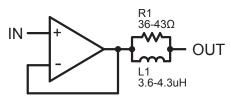


Figure 1. Isolating capacitive loads with an inductor. The non-inductive resistor avoids resonance problems with load capacitance by reducing  $\mathbf{Q}$ .

The 990Enh is normally stable with resistive, inductive or smaller capacitive loads. Larger capacitive loads interact with the open-loop output resistance to reduce the phase margin of the feedback loop, ultimately causing oscillation.

With loop gains greater than unity, a speedup capacitor across the feedback resistor will aid stability. In all cases, the op amp will behave predictably only if the supplies are properly bypassed, ground loops are controlled and high-frequency feedback is derived directly from the output terminal.

So-called capacitive loads are not always capacitive. A high-Q capacitor in combination with long leads or PCB traces can present a series-resonant load to the op amp. In practice, this is not usually a problem; but the situation should be kept in mind.

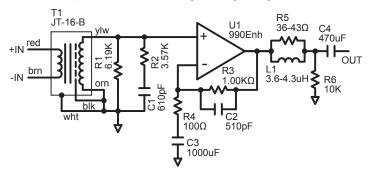
Large capacitive loads (including series-resonant) can be accommodated by isolating the feedback amplifier from the load as shown in **Figure 1**. The inductor gives low output impedance at lower frequencies while providing an isolating impedance at high frequencies.

The resistor kills the  $\Omega$  of series resonant circuits formed by capacitive loads. A low inductance resistor is recommended. Optimum values of L and R depend upon the feedback gain and expected nature of the load, but are not critical.

### **Typical Applications**

**Figure 2** shows a simple traditional transformer input mic preamp, with a fixed gain of 26.5dB (Av=21.2). The Jensen JT-16-B mic input transformer is perfectly suited for this application.

Figure 2. Transformer input mic preamp



R1, R2 and C3 provide match and termination for the JT-16-B input transformer. The step up nature of the transformer provides 5.6dB of voltage gain. R3 and R4 set ac voltage gain of the 990Enh opamp. Whereas, R3/R4+1=Av, 20logAv=Gain\_dB. Other values can be chosen depending on gain desired. C2 provides phase-lead compensation and sets the upper frequency BW cutoff point. 270pf= 410kHz, 510pF=260kHz, 750pF=180kHz and 1000p= 150kHz. C3 keeps the DC gain of the 990Enh at unity so that a small difference between the DC volatges at the inputs will not produce large offset voltages at the output.

With multiple stages of gain, the accumulation of DC offsets of various amplifiers can lead to problems. The classical solution to decoupling the offset has been to employ capacitors C3 and C4. A superior method which eliminates the need for C3 and C4, which has come into vogue over the last couple of decades, is the use of a servo amplifier stage, for output DC-offset elimination. The circuit shown in **Figure 3**. is the basic noninverting audio preamp (U1) from **Figure 2**. with a noninverting integrator feedback stage (U2) connected around it. For normal audio range input signals, the gain of this stage is defined conventionally.

## High Performance Audio Electronics

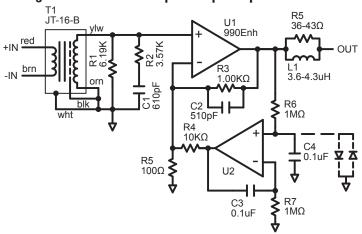
# Model 990Enh-Ticha Discrete Operational Amplifier

## **Typical Applications (continued)**

In this instance, the resistance to ground is made up of the parallel equivalent resistances of R4 and R5; basically Av=1+R3/(R4//R5).

C3-R7 and C4-R6 form the integration time constants, which are set equal in this form of integrator. The DC feedback from the U2 stage is applied to the inverting input of U1, via R4.

Figure 3. Transformer input mic preamp with servo.



By virtue of the integrator stages' infinite gain at DC, the overall loop will force the output of U1 to an extremely low DC level. In practice, the residual DC output offset of U1 becomes essentially the offset voltage of U2.

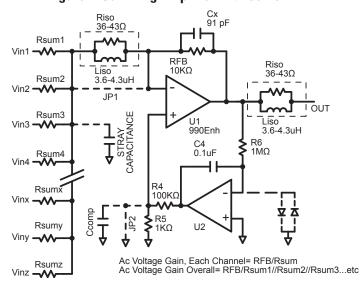
The DC feedback resistor, R4 is chosen to be 10X higher than R3, while the integrator time constant sets the basic low frequency rolloff point. In this example, the rolloff is set at about 0.165Hz. Low leakage clamping diodes can be added across C4 to prevent latchup. U2 should be a precision low offset voltage, low input bias current, FET input type device similar to an AD711.

An inverting summing amplifier with servo correction is shown in **Figure 4**; it uses the more familiar form of inverting integrator for DC offset correction. In this circuit U1 is a basic inverting gain stage, with a voltage gain of RFB/Rsumn. The DC feedback from from the U2 integrator stage is applied to U1 through the divider R4-R5. The time constant and scaling of resistor values are the same as the circuit in **Figure 3**.

The power supply voltages should be sufficient enough to accommodate the worst DC offset of U1 that can be expected from inputs.

Note that, in principal, a noninverting integrator could also be used, with DC correction applied to the inverting input junction of U1. The inverting integrator is simpler overall, however, and it eliminates one RC network.

Figure 4. Summing Amplifier with servo.



With many inputs being summed, the output of the summing amplifier could become excessive. The final value for Rsum is chosen based on the number of channels, input signal levels, maximum peak voltages, etc.

If the servo (U2 R4 C4 R6) circuit is not used, the non-inverting input may be tied to ground directly, or through resistor R5. The value of this resistor should be adjusted to equal the DC source resistance of all the input resistors (Rsum) seen by the inverting input, which is the parallel resistance of all input resistors (assuming they are not AC coupled) and the feedback resistor (Rsum//RFB) When both inputs of the 990Enh see identical source resistances, the output offset voltage will be at its lowest value. This resistor can result in increased noise when compared to a grounded input. This problem can be overcome by a parallel capacitor (Ccomp). The capacitor value is not critical, with 0.1uF being a good starting point.



Professional Audio Products Datasheet

High Performance Audio Electronics

## Model 990Enh-Ticha **Discrete Operational Amplifier**

## **Typical Applications (continued)**

The physical terminating point or summing junction for the noninverting input is critical. In applications where many inputs are to be summed together, it is important to remember that although each input may be at unity gain, the overall gain of the summing amplifier is higher. If the non-inverting inputs are terminated far from the signal sources being summed and noise is coupled into this junction, the noise is amplified by the overall gain of the summing amp. The 990Enh is the lowest noise discrete operational amplifier available, but poor layout, grounding or system architecture can defeat this advantage.

Long summing busses create stray capacitance at the inverting input, resulting in phase-shift of the feedback signal. When the capacitance becomes excessive, this will cause the summing amplifier to oscillate at ultra-high frequencies. Capacitance can be added across RFB (Cx) to limit the high frequency response. Additionally Riso-Liso can be inserted between the summing buss and the inverting input. It maintains normal audio performance by providing a low impedance throughout the audio bandwidth, while isolating stray capacitance by providing high impedance at ultrahigh frequencies.

#### **PCB Sockets for 990Enh-Ticha**

It is highly recommended that the user not solder the pins directly to the mating printed circuit board. Overheating the pin creates a cold solder joint at the other end. Permanant soldering of the pin prevents easy removal of the module. Lastly, soldering prevents one from servicing components which may lie underneath the module.

Many types of sockets for 0.040" diameter pins are available from several manufacturers. Sonic Imagery Labs uses and stocks the sockets from all three listed manufacturers below. These sockets can be soldered or swaged in your printed circuit board. Additionally, users can purchase a set of six from Sonic Imagery Labs online.

Mill-Max 190 Pine Hollow Road. PO Box 300 Ovster Bay NY 11771

Part Number 0344-2-19-15-34-27-10-0

Wearnes Cambion Ltd **Peverial House** Mill Bridge, Castleton Hope Valley S33 8WR **United Kingdom** 

Part Number 450-3756-02-03

Concord Electronics Corp Part Number 09-9035-2-03 33-00 47th Ave, Level 1A Long Island City, NY 11101

THE CONTENTS OF THIS DOCUMENT ARE PROVIDED IN CONNECTION WITH Sonic Imagery Labs PRODUCTS. Sonic Imagery Labs MAKES NO REPRESENTATIONS OR WARRANTIES WITH RESPECT TO THE ACCURACY OR COMPLETENESS OF THE CONTENTS OF THIS PUBLICATION AND RESERVES THE RIGHT TO MAKE CHANGES TO SPECIFICATIONS AND PRODUCT DESCRIPTIONS AT ANY TIME WITHOUT NOTICE. NO LICENSE, WHETHER EXPRESS, IMPLIED, ARISING BY ESTOPPEL OR OTHERWISE, TO ANY INTELLECTUAL PROPERTY RIGHTS IS GRANTED BY THIS DOCUMENT.

TESTING AND OTHER QUALITY CONTROLS ARE USED TO THE EXTENT Sonic Imagery Labs DEEMS NECESSARY TO SUPPORT Sonic Imagery Labs PRODUCT WARRANTY. TESTING OF ALL PUBLISHED PARAMETERS AND SPECIFICATIONS OF EACH PRODUCT IS PERFORMED BEFORE SHIPMENT. Sonic Imagery Labs ASSUMES NO LIABILITY FOR APPLICATIONS ASSISTANCE OR BUYER PRODUCT DESIGN. BUYERS ARE RESPONSIBLE FOR THEIR PRODUCTS AND APPLICATIONS USING Sonic Imagery Labs PRODUCTS. PRIOR TO USING OR DISTRIBUTING ANY PRODUCTS THAT INCLUDE Sonic Imagery Labs COMPONENTS, BUYERS SHOULD PROVIDE ADEQUATE DESIGN, TESTING AND OPERATING SAFEGUARDS.

EXCEPT AS PROVIDED IN Sonic Imagery Labs TERMS AND CONDITIONS OF SALE FOR SUCH PRODUCTS, Sonic Imagery Labs ASSUMES NO LIABILITY WHATSOEVER, AND Sonic Imagery Labs DISCLAIMS ANY EXPRESS OR IMPLIED WARRANTY RELATING TO THE SALE AND/OR USE OF Sonic Imagery Labs PRODUCTS INCLUDING LIABILITY OR WARRANTIES RELATING TO FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY, OR INFRINGEMENT OF ANY PATENT, COPYRIGHT OR OTHER INTELLECTUAL PROPERTY RIGHT.

#### LIFE SUPPORT AND CRITICAL COMPONENTS POLICY

Sonic Imagery Labs PRODUCTS ARE NOT AUTHORIZED FOR USE AS CRITICAL COMPONENTS IN LIFE SUPPORT DEVICES OR CRITICAL SYSTEMS WITHOUT THE EXPRESS PRIOR WRITTEN APPROVAL OF THE CHIEF EXECUTIVE OFFICER AND GENERAL COUNSEL OF Sonic Imagery Labs. As used herein:

Life support devices or systems are devices 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. A critical component is any component in 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.