

# TMC2242A/TMC2242B Digital Half-Band Interpolating/Decimating Filter 12-bit In/16-bit Out, 60 MHz

## Features

- TMC2242A and TMC2242B are pin-compatible with TMC2242
- User selectable interpolate gain, -6 dB or 0 dB (2242B)
- 30, 40 and 60 MHz speed grades
- User selectable 2:1 decimation, 1:2 interpolation, and equal-rate filter modes
- Passband ripple < ±0.01 dB
- Stopband rejection 59.4 dB from 0.28 to 0.50 x fs
- Cascading two TMC2242A or TMC2242B meets CCIR 601 low-pass filter requirement
- Dedicated 12-bit 2's complement input data port and 16-bit output data port with user-selectable rounding from 9 to 16 bits
- · Two's complement or offset binary output format
- · Built-in limiter prevents overflow

- Single +5 Volt power supply operation
- Small 44-Lead PLCC and 44-Lead MQFP

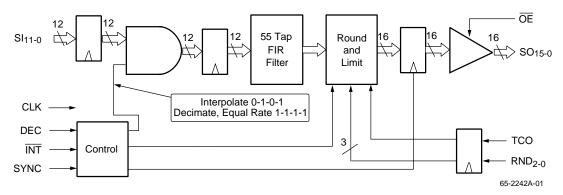
## **Applications**

- Low-cost video filtering
- Chrominance bandwidth limiter
- Simple, inexpensive video D/A post-filters
- · Reduced cost and complexity for A/D anti-aliasing filters
- · High-performance digital low-pass filters
- · Digital waveform reconstruction post-filtering
- Telecommunications
- · Direct digital synthesis
- Radar

## Description

The TMC2242A and TMC2242B are fixed-coefficient linear-phase half-band (low-pass) digital filters. They can be used to halve or double the sampling rate of a digital signal. When used as a decimating post-filter with a double-speed oversampling A/D converter, they greatly reduce the cost and complexity of anti-aliasing filters required ahead of the A/D converter. When used as an interpolating pre-filter with a double-speed oversampling D/A converter, the TMC2242A and TMC2242B significantly reduce the design complexity and production cost of reconstruction filters used on D/A outputs. The TMC2242A and TMC2242B user selects the mode of operation (decimate, interpolate, or equal-rate) and rounding. The TMC2242A and TMC2242B accept 12-bit 2's complement data at up to 60 MHz and output saturated (overflow-protected) 2's complement or offset binary data rounded to from 9 to 16 bits. Within the speed grade I/O limit, the output sample rate may be 1/2, 1, or 2 times the input sample rate.

## **Block Diagram**



### **Description** (continued)

The filter response is flat to within  $\pm 0.01$  dB from 0.00 to 0.22 x f<sub>s</sub>, with stopband attenuation greater than 59.4 dB from 0.28 x f<sub>s</sub> to the Nyquist frequency. The response is 6 dB down at 0.25 x f<sub>s</sub>. Symmetric-coefficient filters such as the TMC2242A and TMC2242B have linear phase response. Full compliance with the CCIR-601 standard of 12 dB attenuation at 0.25 x f<sub>s</sub> is achieved by cascading two parts.

The TMC2242A and TMC2242B are fabricated on an advanced submicron CMOS process. They are available in a 44-lead J-lead PLCC package. Performance is guaranteed from 0°C to 70°C.

## **Functional Description**

The TMC2242A and TMC2242B implement a fixed-coefficient linear-phase Finite Impulse Response (FIR) filter of 55 effective taps, with special rate-matching input and output structures to facilitate 2:1 decimation and 1:2 interpolation. The faster of either the input or output registers will operate at the guaranteed maximum clock rate (speed grade). The total internal pipeline latency from the input of an impulse to the corresponding output peak (digital group delay) is 34 cycles; the 55-value output response begins after 7 clock cycles and ends after 61 cycles.

To perform interpolation, the chip slows the effective input register clock rate to half the output rate. It internally inserts zeroes between the incoming data samples to "pad" the input data rate to match the output rate. To perform decimation, the chip sets the output register clock rate to half of the input rate. One output is then obtained for every two inputs.

For interpolation, the user should bring SYNC HIGH for at least one clock cycle, returning it LOW with the first desired input data value. When interpolating, the chip will then continue to accept a new data input on each alternate rising edge of the clock. When decimating, the chip will present one output value for every two clock cycles. The user may leave SYNC LOW or toggle it once per rising clock edge, with equivalent performance.

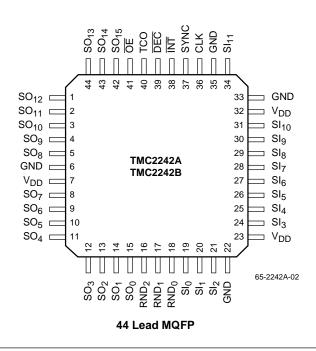
The output data format is two's complement if TCO is HIGH, inverted offset binary if LOW. The user can tailor the output data word width to his/her system requirements using the Rounding control. As shown in Table 4, the output is half-LSB rounded to the resolution selected by the value of RND<sub>2-0</sub>. The asynchronous three-state output enable control simplifies connection to a data bus with other drivers.

#### Table 1. Operating Modes

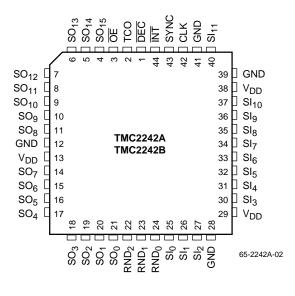
DEC	INT	TMC2242A	TMC2242B
0	0	Equal Rate	Interpolate (0 dB)
0	1	Decimate	Decimate
1	0	Interpolate (-6 dB)	Interpolate (-6 dB) <sup>1</sup>
1	1	Equal Rate	Equal Rate

#### Note:

1. With 15-bit overflow protection. All other modes on both parts limit to 16 bits.



## Pin Assignments



# **Pin Descriptions**

	Pin N	umber	
Pin Name	PLCC	MQFP	Pin Function Description
Timing Cor	ntrols		
INT	44	38	<b>Interpolate.</b> When INT is LOW and DEC is HIGH, the input data register runs at 1/2 the CLK rate and zeros are inserted in the data stream between valid input values, reducing gain by 6dB. The TMC2242A and TMC2242B interpolate and output results at the full CLK rate.
DEC	1	39	<b>Decimate.</b> When $\overline{\text{DEC}}$ is LOW and $\overline{\text{INT}}$ is HIGH, the input data register runs at the full CLK rate. In this mode, the TMC2242A and TMC2242B decimate and output results at 1/2 the CLK rate.
			When $\overline{INT} = \overline{DEC}$ , the TMC2242A is in equal rate mode. When both $\overline{INT}$ and $\overline{DEC}$ are HIGH, the TMC2242B is likewise in equal-rate mode, but when both $\overline{INT}$ and $\overline{DEC}$ are LOW, the TMC2242B interpolates with unity gain.
			In equal-rate mode, the input and output sample rates equal the chip clock rate.
SYNC	43	37	<b>Synchronization.</b> Incoming data are synchronized by holding SYNC HIGH on CLK N–1 and LOW on CLK N when the first input data word is present on SI <sub>11-0</sub> . If $\overline{\text{DEC}} = \overline{\text{INT}} = 1$ (equal rate mode), SYNC is inactive. SYNC may be held LOW until resynchronization is desired, or it may be toggled at 1/2 the CLK rate.
CLK	42	36	<b>Clock.</b> The TMC2242A and TMC2242B operate from a single master clock. All internal registers, except the output register in decimation mode, are strobed on the rising edge of CLK. All timing parameters are referenced to the rising edge of CLK.
Data Inputs	5	1	
SI11-0	40, 37-30, 27-25	34, 31-24, 21-19	<b>Input Data Port.</b> A 12-bit 2's-complement input word is registered by the rising edge of CLK. In Interpolate Mode, SI11-0 is registered on every other CLK (synchronized by SYNC). SI11 is the MSB.
Data Outpu	Its		
SO <sub>15-0</sub>	4-11, 14-21	42-44, 1-5, 8-15	<b>Output Data Port.</b> A 16-bit 2's-complement output result is available after the rising edge of CLK. In Decimate Mode, SO <sub>15-0</sub> is registered on every other CLK (synchronized by SYNC). SO <sub>15-0</sub> is rounded according to the state of RND <sub>2-0</sub> . SO <sub>15</sub> is the MSB.
			The limiter circuitry ensures that for internal overflow, a valid full-scale output (7FFF or 8000) will be generated. With the TMC2242B in interpolate mode with -6dB gain, limits are 3FFF and C000 (TCO=1).
Output Cor	ntrols		
ŌĒ	3	41	<b>Output Enable.</b> When LOW, SO <sub>15-0</sub> are enabled. When HIGH, SO <sub>15-0</sub> are in a high-impedance state. $\overline{OE}$ is asynchronous with respect to CLK.
тсо	2	40	<b>Output Format.</b> When TCO is HIGH, output data are in signed 2's-complement format. When LOW, the output is inverted offset binary.
RND <sub>2-0</sub>	22-24	16-18	<b>Rounding Select.</b> These inputs set the position of the effective LSB of the output result. Outputs below the rounding bit are zeroed (Table 4).
Power			
Vdd	13,29, 38	7, 23, 32	<b>Supply Voltage.</b> +5 Volt power inputs. These should come from the same power source and be decoupled to GND.
GND	12,28, 39,41	6, 22, 33, 35	Ground. Ground inputs should be connected to the system digital ground plane.

## **Absolute Maximum Ratings**

(beyond which the device may be damaged)<sup>1</sup>

Parameter	Conditions	Min	Max	Units
Supply Voltage		-0.5	7.0	V
Input Voltage		-0.5	V <sub>DD</sub> + 0.5	V
Output Applied Voltage <sup>2</sup>		-0.5	VDD + 0.5	V
Externally Forced Current <sup>3,4</sup>		-3.0	+6.0	mA
Short Circuit Duration	Single output in HIGH state to ground		1	sec
Operating Temperature (Case)		-20	110	°C
Junction Temperature			140	°C
Lead Soldering Temperature	10 seconds		300	°C
Storage Temperature		-65	150	°C

Notes:

1. Functional operation under any of these conditions is NOT implied. Performance and reliability are guaranteed only if Operating Conditions are not exceeded.

2. Applied voltage must be current limited to specified range.

3. Forcing voltage must be limited to specified range.

4. Current is specified as conventional current flowing into the device.

## **Operating Conditions**

Param	neter	Conditions	Min	Nom	Max	Units	
Vdd	Power Supply Voltage		4.75	5.0	5.25	V	
fCLK	Clock frequency	TMC2242A, B			30	MHz	
		TMC2242A-1,B-1			40	MHz	
		TMC2242A-2,B-2			60	MHz	
tpwH	CLK pulse width, HIGH		6			ns	
tPWL	CLK pulse width, LOW		6			ns	
ts	Input Data Set-up Time		6			ns	
tH	Input Data Hold Time		1			ns	
VIH	Input Voltage, Logic HIGH		2.0			V	
VIL	Input Voltage, Logic LOW				0.8	V	
ЮН	Output Current, Logic HIGH				-2.0	mA	
IOL	Output Current, Logic LOW				4.0	mA	
TA	Ambient Temperature, Still Air		0		70	°C	

## **Electrical Characteristics**

Param	eter	Conditions	Min	Тур	Max	Units
IDD	Total Power Supply	V <sub>DD</sub> = Max, C <sub>LOAD</sub> =25pF, f <sub>CLK</sub> =Max				
	Current	TMC2242A,B			150	mA
		TMC2242A-1,B-1			195	mA
		TMC2242A-2,B-2			290	mA
Iddu	Power Supply Current,	$V_{DD} = Max, \overline{OE} = HIGH, f_{CLK} = Max$				
	Unloaded	TMC2242A,B			120	mA
		TMC2242A-1,B-1			155	mA
		TMC2242A-2,B-2			230	mA
IDDQ	Power Supply Current, Quiescent	V <sub>DD</sub> = Max, CLK = LOW			5	mA
CPIN	I/O Pin Capacitance			5		pF
Iн	Input Current, HIGH	VDD = Max, VIN = VDD			±10	μΑ
IIL	Input Current, LOW	V <sub>DD</sub> = Max, V <sub>IN</sub> = 0 V			±10	μΑ
Iozh	Leakage Current, HIGH	$\overline{OE}$ = HIGH, VOUT = VDD			±10	μΑ
Iozl	Leakage Current, LOW	OE = HIGH, V <sub>OUT</sub> = 0 V			±10	μΑ
los	Short-Circuit Current	VDD = Max, Output = HIGH, one pin to ground, one second duration max.	-20		-80	mA
Vон	Output Voltage, HIGH	SO15-0, I <sub>OH</sub> = Max	2.4			V
Vol	Output Voltage, LOW	SO15-0, IOL = Max			0.4	V

# **Switching Characteristics**

Parameter		Conditions	Min	Тур	Max	Units
tDO	Output Delay Time	CLOAD = 25 pF			15	ns
tHO	Output Hold Time	CLOAD = 25 pF	2.5			ns
tena	Output Enable Time	CLOAD = 0 pF			12	ns
tDIS	Output Disable Time	CLOAD = 0 pF			12	ns

#### Table 2. Impulse Response

Hex	Decimal Equivalent	
FFF2	-0.000875473	start & end
0000	0.0	
0017	0.001390457	
0000	0.0	
FFDB	-0.002265930	
0000	0.0	
0039	0.003501892	
0000	0.0	
FFA8	-0.006366836	
0000	0.0	
007D	0.007621765	
0000	0.0	
FF51	-0.01071167	
0000	0.0	
00F3	0.01483154	
0000	0.0	
FEB5	-0.02018738	
0000	0.0	
01CA	0.02796364	
0000	0.0	
FD79	-0.03949928	
0000	0.0	
03CD	0.05937767	
0000	0.0	
F95E	-0.1036148	
0000	0.0	
145B	0.3180542	
2010	0.5009766	center

 $\begin{array}{l} Input = 0, \, 0, \, 0, \, ..., \, 0, \, 400h, \, 0, \, ..., \, 0, \, 0, \, 0 \\ \overline{INT} = \overline{DEC} = TCO = 1 \end{array}$ 

#### Table 3. Step Response

Input	INT=1 DEC=1 TCO=0	INT=1 DEC=1 TCO=1	INT=0 DEC=1 TCO=1	INT=1 DEC=0 TCO=1	
400	ХХ	ХХ	ХХ	ХХ	
400	ХХ	ХХ	ХХ	ХХ	
 400	 3FE7	 4018	 2008	 4018	DC Gain
400 000	3FE7 3FE7	4018 4018	2010 2008	4018 4018	
 000	 3B90	 446F	 245F	 446F	Max Ringing
000	3B90	446F	2010	446F	
000	4FEB	3014	1004	1004	
000	6FFB	1004	0000	1004	
000	8456	FBA9	FBA9	FBA9	Min Ringing
 000	 7FFF	 0000	 0000	 0000	Steady State

## Table 4a. Input Data Format

-2 <sup>0</sup>	2 <sup>-1</sup>	2 <sup>-2</sup>	 2 <sup>-10</sup>	2 <sup>-11</sup>

#### Table 4b. Output Data Formats and Bit Weighting for TCO = 1

Interpolation Mode (TMC2242A and TMC2242B when  $\overline{INT} = 0$  and  $\overline{DEC} = 1$ )

|--|

**Decimation, Equal Rate Modes** (and TMC2242B in unity gain interpolate mode with  $\overline{INT} = \overline{DEC} = 0$ )

-2 <sup>0</sup> 2 <sup>-1</sup> 2 <sup>-2</sup>	2 <sup>-7</sup> 2 <sup>-8</sup> 2 <sup>-9</sup>	2 <sup>-10</sup> 2 <sup>-11</sup> 2 <sup>-12</sup>	2 <sup>-13</sup> 2 <sup>-14</sup> 2 <sup>-15</sup>
-------------------------------------------------	-------------------------------------------------	----------------------------------------------------	----------------------------------------------------

#### Rounded LSBs as a function of RND<sub>2-0</sub>

												RND2-0
SO <sub>15</sub>	SO <sub>14</sub>	SO <sub>13</sub>	 SO8	SO7	SO <sub>6</sub>	SO5	SO4	SO3	SO <sub>2</sub>	SO1	SO <sub>0r</sub>	000
SO <sub>15</sub>	SO14	SO13	 SO8	SO7	SO6	SO5	SO4	SO3	SO2	SO1r	0	001
SO15	SO <sub>14</sub>	SO <sub>13</sub>	 SO8	SO7	SO <sub>6</sub>	SO5	SO4	SO3	SO <sub>2r</sub>	0	0	010
SO <sub>15</sub>	SO14	SO13	 SO8	SO7	SO6	SO5	SO4	SO3r	0	0	0	011
SO15	SO <sub>14</sub>	SO <sub>13</sub>	 SO8	SO7	SO <sub>6</sub>	SO5	SO <sub>4r</sub>	0	0	0	0	100
SO <sub>15</sub>	SO14	SO13	 SO8	SO7	SO6	SO <sub>5</sub> r	0	0	0	0	0	101
SO <sub>15</sub>	SO <sub>14</sub>	SO <sub>13</sub>	 SO8	SO7	SO <sub>6r</sub>	0	0	0	0	0	0	110
SO <sub>15</sub>	SO14	SO <sub>13</sub>	 SO8	SO7r	0	0	0	0	0	0	0	111

#### Notes:

1. A leading minus sign denotes the two's complement sign bit.

2. When TCO=0, the most significant bit of the output is positive instead of negative.

3. In all operating modes except INT = 0 and DEC = 1, the gain is approximately unity. When INT = 0 and DEC = 1, the output gain is -6 dB.

4. The "r" indicates that the trailing significant output bit has been rounded to the nearest 1/2 LSB. (Internally, the chip adds 1 to the next lower bit, to allow the user to obtain a properly rounded output)

	$\overline{INT} = 1 \text{ or } \overline{DEC} = 0$		$\overline{INT} = 0$ and $\overline{DEC} = 1$		
Input	TCO = 0	TCO = 1	TCO = 0	TCO = 1	Interpretation
7FF	0000 (L)	7FFF (L)	3FF7 / 3FE7	4008 / 4018	+ full-scale
400	3FE7	4018	5FF7 / 5FEF	2008 / 2010	+1/2 scale
001	7FEF	0010	7FF7	0008	+1 LSB
000	7FFF	0000	7FFF	0000	Zero
FFF	800F	FFF0	8007	FFF8	-1 LSB
C00	C017	BFE8	A007 / A00F	DFF8 / DFF0	-1/2 scale
801	FFFF (L)	8000 (L)	C007 / C017	BFF8 / BFE8	- full-scale

#### Table 5. TMC2242A Steady-State Output Values and Limiter Triggers (L) versus Input Data

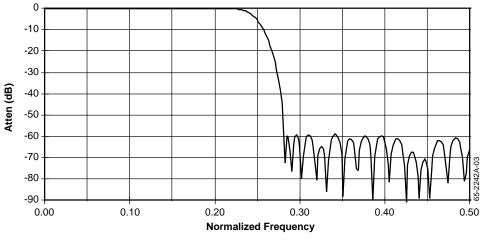
# Table 6. TMC2242B Steady-State Output Values and Limiter Triggers (L) versus Input Data Interpolation Modes

	$\overline{INT} = 0$ and $\overline{DEC} = 0$		$\overline{INT} = 0$ and $\overline{DEC} = 1$		
Input	TCO = 0	TCO = 1	TCO = 0	TCO = 1	Interpretation
7FF	0000 (L)	7FFF (L)	4000 (L)	3FFF (L)	+ full-scale
400	3FEF / 3FDF	4010 / 4020	5FF7 / 5FEF	2008 / 2010	+1/2 scale
001	7FEF	0010	7FF7	0008	+1 LSB
000	7FFF	0000	7FFF	0000	Zero
FFF	800F	FFF0	8007	FFF8	-1 LSB
C00	C00F / C01F	BFF0 / BFE0	A007 / A00F	DFF8 / DFF0	-1/2 scale
801	FFFF	8000 (L)	BFFF	C000 (L)	- full-scale

#### **Decimation and Equal-Rate Modes**

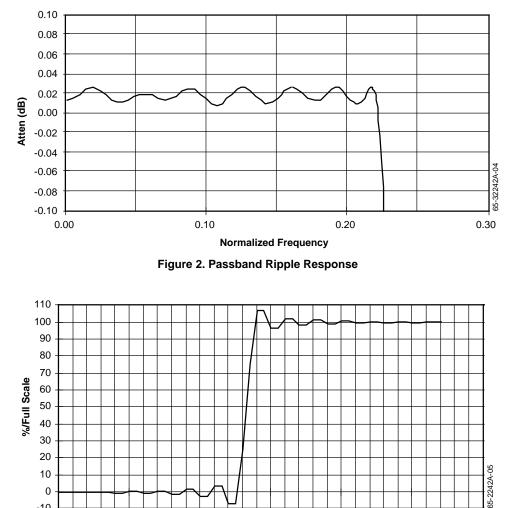
	INT		
Input	TCO = 0	TCO = 1	Interpretation
7FF	0000 (L)	7FFF (L)	+ full-scale
400	3FE7	4018	+1/2 scale
001	7FEF	0010	+1 LSB
000	7FFF	0000	Zero
FFF	800F	FFF0	-1 LSB
C00	C017	BFE8	-1/2 scale
801	FFFF (L)	8000 (L)	- full-scale

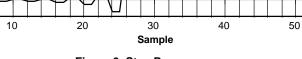
## **Performance Curves**





## Performance Curves (continued)

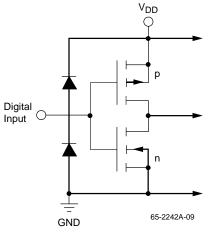




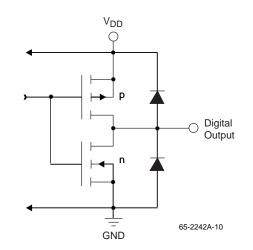




-10 ↓ 0



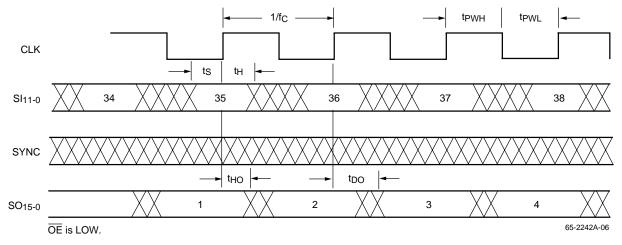




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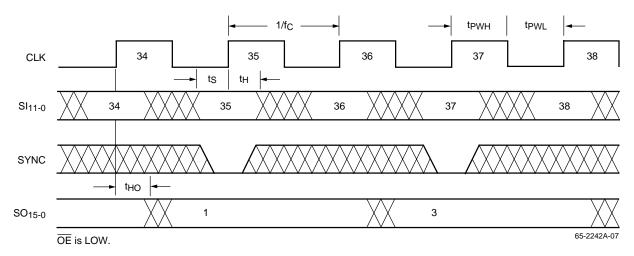


## **Timing Diagrams**

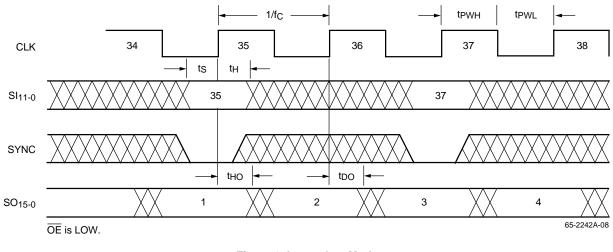


Note: Values at SO15-0 are impulse response centers (peaks) corresponding to same-numbered inputs.

Figure 4. Equal Rate Mode



#### Figure 5. Decimate Mode



#### Figure 6. Interpolate Mode

## Timing Diagrams (continued)

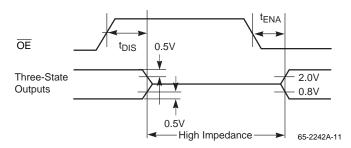


Figure 9. Threshold Levels for Three State Measurements

## **Applications Discussion**

The TMC2242A and TMC2242B are well-suited for filtering digitized composite NTSC or PAL video. In Figure 10, the TMC1175A 8-bit video A/D converter outputs, D7-0, are connected to the TMC2242B inputs, SI<sub>11</sub>-4, respectively (grounding SI<sub>3</sub>-0). The RND<sub>2</sub>-0 controls are set to 111 for a 9-bit rounded decimated output on SO<sub>15</sub>-7.

In Figure 11, the TMC2242B drives a fast D/A converter to reconstruct analog composite video. The TMC3003 10-bit digital-to-analog converter inputs, D9-0 are connected to the TMC2242B outputs SO15-6, respectively. The TMC2242B RND2-0 controls are set to 110 for rounded 10-bit interpolation operation.

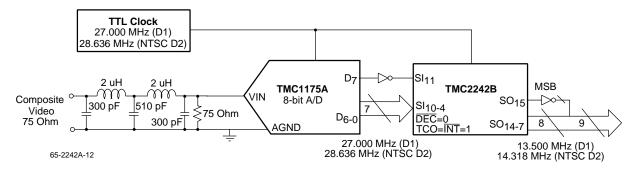
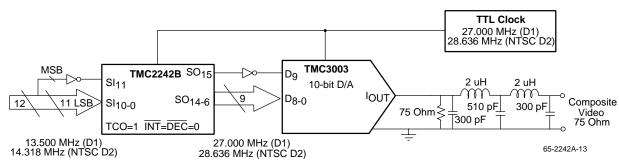


Figure 10. Decimating Oversampled Video With a Low Cost 8-bit A/D



Note: Data buses are unsigned binarys; TMC2242 input is two's complement.

Figure 11. Interpolating Digital Video Signals before Reconstruction

## Notes:

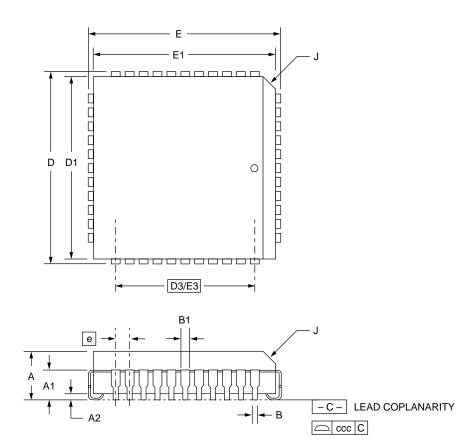
## Notes:

## Mechanical Dimensions – 44-Pin PLCC Package

Symbol	Inches		Millimeters		Notes
	Min.	Max.	Min.	Max.	Notes
А	.165	.180	4.19	4.57	
A1	.090	.120	2.29	3.05	
A2	.020		.51	—	
В	.013	.021	.33	.53	
B1	.026	.032	.66	.81	
D/E	.685	.695	17.40	17.65	
D1/E1	.650	.656	16.51	16.66	3
D3/E3	.500 BSC		12.7 BSC		
е	.050 BSC		1.27 BSC		
J	.042	.056	1.07	1.42	2
ND/NE	11		11		
Ν	44		44		
CCC	_	.004	_	0.10	

#### Notes:

- 1. All dimensions and tolerances conform to ANSI Y14.5M-1982
- 2. Corner and edge chamfer (J) =  $45^{\circ}$
- Dimension D1 and E1 do not include mold protrusion. Allowable protrusion is .101" (.25mm)

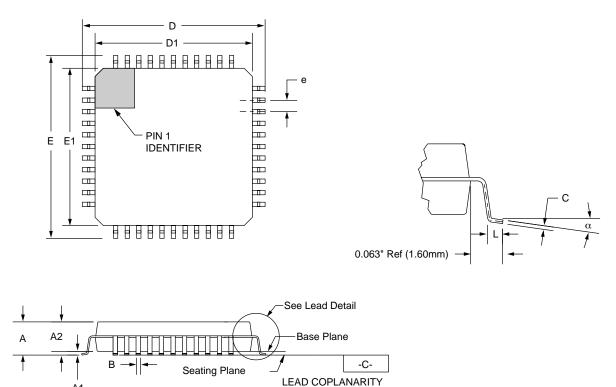


# Mechanical Dimensions – 44-Lead MQFP Package

Symbol	Inches		Millimeters		Notes
	Min.	Max.	Min.	Max.	Notes
А	.077	.093	1.95	2.35	
A1	.000	.010	.00	.25	
A2	.077	.083	1.95	2.11	
В	.012	.018	.30	.46	7
С	.005	.009	.13	.23	
D/E	.510	.530	12.95	13.45	
D1/E1	.390	.398	9.90	10.10	2
е	.032	BSC	.81 BSC		
L	.026	.037	.66	.94	6
Ν	44		44		4
ND	11		11		5
α	0°	7°	0°	7°	
CCC	_	.004	_	0.10	

#### Notes:

- 1. All dimensions and tolerances conform to ANSI Y14.5M-1982.
- 2. Dimensions "D1" and "E1" do not include mold protrusion.
- 3. Pin 1 identifier is optional.
- 4. Dimension N: number of terminals.
- 5. Dimension ND: Number of terminals per package edge.
- 6. "L" is the length of terminal for soldering to a substrate.
- 7. "B" includes lead finish thickness.



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44 Lead Metric Quad Flat Pack (MQFP) - 3.2mm Footprint Rev 1.0 11/28/95

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## **Ordering Information**

Product Number	Temperature Range	Speed Grade	Screening	Package	Package Marking
TMC2242AR2C	0°C to 70°C	30 MHz	Commercial	44-Lead PLCC	2242AR2C
TMC2242AR2C1	0°C to 70°C	40 MHz	Commercial	44-Lead PLCC	2242AR2C1
TMC2242AR2C2	0°C to 70°C	60 MHz	Commercial	44-Lead PLCC	2242AR2C2
TMC2242BR2C	0°C to 70°C	30 MHz	Commercial	44-Lead PLCC	2242BR2C
TMC2242BR2C1	0°C to 70°C	40 MHz	Commercial	44-Lead PLCC	2242BR2C1
TMC2242BR2C2	0°C to 70°C	60 MHz	Commercial	44-Lead PLCC	2242BR2C2
TMC2242AKTC	0°C to 70°C	30 MHz	Commercial	44-Lead MQFP	2242AKTC
TMC2242AKTC1	0°C to 70°C	40 MHz	Commercial	44-Lead MQFP	2242AKTC1
TMC2242AKTC2	0°C to 70°C	60 MHz	Commercial	44-Lead MQFP	2242AKTC2
TMC2242BKTC	0°C to 70°C	30 MHz	Commercial	44-Lead MQFP	2242BKTC
TMC2242BKTC1	0°C to 70°C	40 MHz	Commercial	44-Lead MQFP	2242BKTC1
TMC2242BKTC2	0°C to 70°C	60 MHz	Commercial	44-Lead MQFP	2242BKTC2

#### LIFE SUPPORT POLICY

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2. A critical component in any component of a life support device or system whose failure to perform can be reasonably expected to cause the failure of the life support device or system, or to affect its safety or effectiveness.