

November 1988 Revised February 2000

# 74AC163 • 74ACT163 Synchronous Presettable Binary Counter

#### **General Description**

The AC/ACT163 are high-speed synchronous modulo-16 binary counters. They are synchronously presettable for application in programmable dividers and have two types of Count Enable inputs plus a Terminal Count output for versatility in forming synchronous multistage counters. The AC/ACT163 has a Synchronous Reset input that overrides counting and parallel loading and allows the outputs to be simultaneously reset on the rising edge of the clock.

#### **Features**

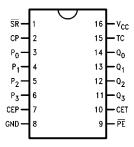
- I<sub>CC</sub> reduced by 50%
- Synchronous counting and loading
- High-speed synchronous expansion
- Typical count rate of 125 MHz
- Outputs source/sink 24 mA
- ACT163 has TTL-compatible inputs

#### **Ordering Code:**

Order Number	Package Number	Package Description
74AC163SC	M16A	16-Lead Small Outline Integrated Circuit (SOIC), JEDEC MS-012, 0.150" Narrow Body
74AC163SJ	M16D	16-Lead Small Outline Package, (SOP), EIAJ TYPE II, 5.3mm Wide
74AC163MTC	MTC16	16-Lead Thin Shrink Small Outline Package (TSSOP), JEDEC MO-153, 4.4mm Wide
74AC163PC	N16E	16-Lead Plastic Dual-In-Line Package (PDIP), JEDEC MS-001, 0.300" Wide
74ACT163SC	M16A	16-Lead Small Outline Integrated Circuit (SOIC), JEDEC MS-012, 0.150" Narrow Body
74ACT163SJ	M16D	16-Lead Small Outline Package, (SOP), EIAJ TYPE II, 5.3mm Wide
74ACT163MTC	MTC16	16-Lead Thin Shrink Small Outline Package (TSSOP), JEDEC MO-153, 4.4mm Wide
74ACT163PC	N16E	16-Lead Plastic Dual-In-Line Package (PDIP), JEDEC MS-001, 0.300" Wide

Device also available in Tape and Reel. Specify by appending suffix letter "X" to the ordering code.

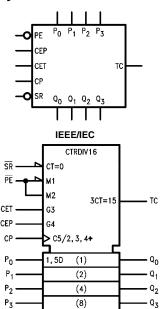
#### **Connection Diagram**



#### **Pin Descriptions**

Pin Names	Description				
CEP	Count Enable Parallel Input				
CET	Count Enable Trickle Input				
CP	Clock Pulse Input				
SR	Synchronous Reset Input				
P <sub>0</sub> -P <sub>3</sub>	Parallel Data Inputs				
PE	Parallel Enable Input				
Q <sub>0</sub> -Q <sub>3</sub>	Flip-Flop Outputs				
TC	Terminal Count Output				

#### **Logic Symbols**



#### **Mode Select Table**

SR	PE	CET	CEP	Action on the Rising
				Clock Edge (✓)
L	Х	Х	Х	Reset (Clear)
Н	L	Χ	Χ	$\label{eq:Reset_Clear} \begin{aligned} & \text{Reset (Clear)} \\ & \text{Load (P}_n \rightarrow Q_n) \\ & \text{Count (Increment)} \end{aligned}$
Н	Н	Н	Н	Count (Increment)
Н	Н	L	Χ	No Change (Hold)
Н	Н	Χ	L	No Change (Hold)

H = HIGH Voltage Level

L = LOW Voltage Level X = Immaterial

#### **Functional Description**

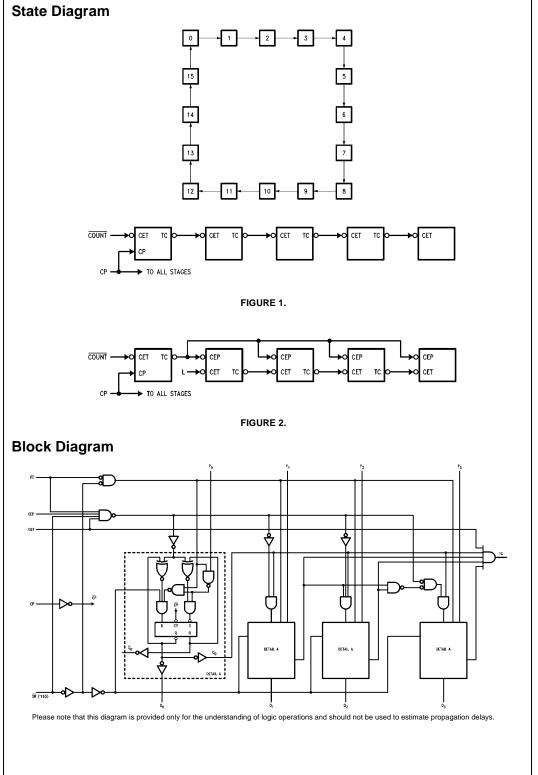
The AC/ACT163 counts in modulo-16 binary sequence. From state 15 (HHHH) it increments to state 0 (LLLL). The clock inputs of all flip-flops are driven in parallel through a clock buffer. Thus all changes of the Q outputs occur as a result of, and synchronous with, the LOW-to-HIGH transition of the CP input signal. The circuits have four fundamental modes of operation, in order of precedence: synchronous reset, parallel load, count-up and hold. Four control inputs—Synchronous Reset (SR), Parallel Enable (PE), Count Enable Parallel (CEP) and Count Enable Trickle (CET)—determine the mode of operation, as shown in the Mode Select Table. A LOW signal on SR overrides counting and parallel loading and allows all outputs to go LOW on the next rising edge of CP. A LOW signal on PE overrides counting and allows information on the Parallel Data (Pn) inputs to be loaded into the flip-flops on the next rising edge of CP. With PE and SR HIGH, CEP and CET permit counting when both are HIGH. Conversely, a LOW signal on either CEP or CET inhibits counting.

The AC/ACT163 uses D-type edge-triggered flip-flops and changing the  $\overline{SR}$ ,  $\overline{PE}$ , CEP and CET inputs when the CP is in either state does not cause errors, provided that the recommended setup and hold times, with respect to the rising edge of CP, are observed.

The Terminal Count (TC) output is HIGH when CET is HIGH and counter is in state 15. To implement synchronous multistage counters, the TC outputs can be used with the CEP and CET inputs in two different ways.

Figure 1 shows the connections for simple ripple carry, in which the clock period must be longer than the CP to TC delay of the first stage, plus the cumulative CET to TC delays of the intermediate stages, plus the CET to CP setup time of the last stage. This total delay plus setup time sets the upper limit on clock frequency. For faster clock rates, the carry lookahead connections shown in Figure 2 are recommended. In this scheme the ripple delay through the intermediate stages commences with the same clock that causes the first stage to tick over from max to min in the Up mode, or min to max in the Down mode, to start its final cycle. Since this final cycle takes 16 clocks to complete, there is plenty of time for the ripple to progress through the intermediate stages. The critical timing that limits the clock period is the CP to  $\overline{\text{TC}}$  delay of the first stage plus the CEP to CP setup time of the last stage. The TC output is subject to decoding spikes due to internal race conditions and is therefore not recommended for use as a clock or asynchronous reset for flip-flops, registers or

Logic Equations: Count Enable = CEP • CET •  $\overline{PE}$   $TC = Q_0 • Q_1 • Q_2 • Q_3 • CET$ 



#### **Absolute Maximum Ratings**(Note 1)

 $V_1 = -0.5V$  $V_1 = V_{CC} + 0.5V$ 

DC Input Voltage (V<sub>I</sub>)  $-0.5V \text{ to V}_{CC} + 0.5V$ 

DC Output Diode Current (I<sub>OK</sub>)

 $V_{O} = -0.5V$  -20 mA  $V_{O} = V_{CC} + 0.5V$  +20 mA

DC Output Voltage ( $V_O$ ) -0.5V to  $V_{CC} + 0.5V$ 

DC Output Source

or Sink Current ( $I_O$ )  $\pm 50 \text{ mA}$ 

DC V<sub>CC</sub> or Ground Current

per Output Pin ( $I_{CC}$  or  $I_{GND}$ )  $\pm 50$  mA Storage Temperature ( $T_{STG}$ )  $-65^{\circ}\text{C}$  to  $+150^{\circ}\text{C}$ 

Junction Temperature (T<sub>J</sub>)

PDIP 140°C

## Recommended Operating Conditions

Supply Voltage (V<sub>CC</sub>)

-20 mA

+20 mA

 $\begin{array}{ccc} AC & 2.0 V \text{ to } 6.0 V \\ ACT & 4.5 V \text{ to } 5.5 V \\ \text{Input Voltage (V_I)} & 0 V \text{ to } V_{CC} \\ \text{Output Voltage (V_O)} & 0 V \text{ to } V_{CC} \\ \end{array}$ 

Output Voltage ( $V_O$ ) 0V to  $V_{CC}$ Operating Temperature ( $T_A$ ) -40°C to +85°C

Minimum Input Edge Rate  $(\Delta V/\Delta t)$ 

AC Devices

 $V_{\mbox{\footnotesize{IN}}}$  from 30% to 70% of  $V_{\mbox{\footnotesize{CC}}}$ 

 $V_{CC} @ 3.3V, 4.5V, 5.5V$  125 mV/ns

Minimum Input Edge Rate ( $\Delta V/\Delta t$ )

**ACT Devices** 

 $V_{\text{IN}}$  from 0.8V to 2.0V

V<sub>CC</sub> @ 4.5V, 5.5V 125 r

140°C Note 1: Absolute maximum ratings are those values beyond which damage to the device may occur. The databook specifications should be met, without exception, to ensure that the system design is reliable over its power supply, temperature, and output/input loading variables. Fairchild does not recommend operation of circuits outside databook specifications.

#### **DC Electrical Characteristics for AC**

Parameter .	$V_{CC}$ $T_A = +25^{\circ}C$		$T_A = -40^{\circ}C$ to $+85^{\circ}C$	Units	Conditions	
	(V)	Тур	Gua	ranteed Limits	Ullits	Conditions
Minimum HIGH Level	3.0	1.5	2.1	2.1		V <sub>OUT</sub> = 0.1V
Input Voltage	4.5	2.25	3.15	3.15	V	or V <sub>CC</sub> – 0.1V
	5.5	2.75	3.85	3.85		
Maximum LOW Level	3.0	1.5	0.9	0.9		V <sub>OUT</sub> = 0.1V
Input Voltage	4.5	2.25	1.35	1.35	V	or V <sub>CC</sub> - 0.1V
	5.5	2.75	1.65	1.65		
Minimum HIGH Level	3.0	2.99	2.9	2.9		
Output Voltage	4.5	4.49	4.4	4.4	V	$I_{OUT} = -50 \mu A$
	5.5	5.49	5.4	5.4		
						$V_{IN} = V_{IL}$ or $V_{IH}$
	3.0		2.56	2.46		$I_{OH} = -12 \text{ mA}$
	4.5		3.86	3.76	V	$I_{OH} = -24 \text{ mA}$
	5.5		4.86	4.76		I <sub>OH</sub> = -24 mA (Note 2)
Maximum LOW Level	3.0	0.002	0.1	0.1		
Output Voltage	4.5	0.001	0.1	0.1	V	$I_{OUT} = 50 \mu A$
	5.5	0.001	0.1	0.1		
						$V_{IN} = V_{IL} \text{or } V_{IH}$
	3.0		0.36	0.44		I <sub>OL</sub> = 12 mA
	4.5		0.36	0.44	V	I <sub>OL</sub> = 24 mA
	5.5		0.36	0.44		I <sub>OL</sub> = 24 mA (Note 2)
Maximum Input Leakage Current	5.5		± 0.1	± 1.0	μА	$V_I = V_{CC}$ , GND
Minimum Dynamic	5.5			75	mA	V <sub>OLD</sub> = 1.65V Max
Output Current (Note 3)	5.5			-75	mA	V <sub>OHD</sub> = 3.85V Min
Maximum Quiescent	5.5		4.0	40.0	μΑ	$V_{IN} = V_{CC}$
Supply Current						or GND
	Input Voltage  Maximum LOW Level Input Voltage  Minimum HIGH Level Output Voltage  Maximum LOW Level Output Voltage  Maximum Input Leakage Current Minimum Dynamic Output Current (Note 3)  Maximum Quiescent Supply Current	Minimum HIGH Level         3.0           Input Voltage         4.5           5.5         5.5           Maximum LOW Level         3.0           Input Voltage         4.5           5.5         3.0           Output Voltage         4.5           5.5         3.0           4.5         5.5           Maximum LOW Level         3.0           Output Voltage         4.5           5.5         3.0           4.5         5.5           Maximum Input Leakage Current         5.5           Minimum Dynamic         5.5           Output Current (Note 3)         5.5           Maximum Quiescent         5.5           Supply Current         5.5	Minimum HIGH Level 3.0 1.5 Input Voltage 4.5 2.25 5.5 2.75  Maximum LOW Level 3.0 1.5 Input Voltage 4.5 2.25 5.5 2.75  Minimum HIGH Level 3.0 2.99 Output Voltage 4.5 4.49 5.5 5.49  Maximum LOW Level 3.0 0.002 Output Voltage 4.5 5.5  Maximum LOW Level 3.0 0.002 Output Voltage 4.5 0.001 5.5 0.001  Maximum Input Leakage Current 5.5 Minimum Dynamic 5.5 Output Current (Note 3) Maximum Quiescent 5.5 Supply Current	Minimum HIGH Level       3.0       1.5       2.1         Input Voltage       4.5       2.25       3.15         5.5       2.75       3.85         Maximum LOW Level       3.0       1.5       0.9         Input Voltage       4.5       2.25       1.35         5.5       2.75       1.65         Minimum HIGH Level       3.0       2.99       2.9         Output Voltage       4.5       4.49       4.4         5.5       5.49       5.4         Maximum LOW Level       3.0       0.002       0.1         Output Voltage       4.5       0.001       0.1         5.5       0.001       0.1         5.5       0.001       0.1         3.0       0.36       0.36         4.5       0.36       0.36         4.5       0.36       0.36         4.5       0.36       0.36         4.5       0.36       0.36         4.5       0.36       0.36         4.5       0.36       0.36         4.5       0.36       0.36         5.5       0.36       0.36         5.5       0.00       0.00	Minimum HIGH Level         3.0         1.5         2.1         2.1           Input Voltage         4.5         2.25         3.15         3.15           Maximum LOW Level         3.0         1.5         0.9         0.9           Input Voltage         4.5         2.25         1.35         1.35           Minimum HIGH Level         3.0         2.99         2.9         2.9           Output Voltage         4.5         4.49         4.4         4.4           4.5         4.5         4.80         4.76           Maximum LOW Level         3.0         0.002         0.1         0.1           Output Voltage         4.5         0.001         0.1         0.1           Maximum LOW Level         3.0         0.002         0.1         0.1           Output Voltage         4.5         0.001         0.1         0.1           5.5         0.001         0.1         0.1         0.1           0utput Voltage         4.5         0.001         0.1         0.1           4.5         0.001         0.1         0.1         0.1           5.5         0.001         0.1         0.1         0.1           4.5         0	Minimum HIGH Level Input Voltage         3.0         1.5         2.1         2.1         V           Input Voltage         4.5         2.25         3.15         3.15         V           Maximum LOW Level Input Voltage         3.0         1.5         0.9         0.9         0.9           Input Voltage         4.5         2.25         1.35         1.35         V           Minimum HIGH Level         3.0         2.99         2.9         2.9           Output Voltage         4.5         4.49         4.4         4.4         V           3.0         2.99         2.6         4.6         4.6 <t< td=""></t<>

Note 2: All outputs loaded; thresholds on input associated with output under test.

Note 3: Maximum test duration 2.0 ms, one output loaded at a time.

Note 4:  $I_{IN}$  and  $I_{CC}$  @ 3.0V are guaranteed to be less than or equal to the respective limit @ 5.5V  $V_{CC}$ .

#### **DC Electrical Characteristics for ACT** $T_A = +25^{\circ}C$ $T_A = -40^{\circ}C$ to $+85^{\circ}C$ V<sub>CC</sub> Symbol Units Conditions Guaranteed Limits (V) Тур $V_{OUT} = 0.1V$ $V_{\mathsf{IH}}$ Minimum HIGH Level 4.5 Input Voltage 5.5 1.5 2.0 2.0 or V<sub>CC</sub> – 0.1V Maximum LOW Level $V_{OUT} = 0.1V$ $V_{\mathsf{IL}}$ 4.5 1.5 0.8 0.8 ٧ Input Voltage 5.5 1.5 8.0 0.8 or $V_{CC} - 0.1V$ Minimum HIGH Level 4.5 4.49 4.4 4.4 $V_{OH}$ $I_{OUT} = -50 \ \mu A$ Output Voltage 5.5 5.49 5.4 5.4 $V_{IN} = V_{IL}$ or $V_{IH}$ 4.5 3.86 3.76 V $I_{OH} = -24 \text{ mA}$ $I_{OH} = -24 \text{ mA (Note 5)}$ 5.5 4.86 4.76 $V_{OL}$ Maximum LOW Level 4.5 0.1 0.1 $I_{OUT} = 50 \; \mu A$ Output Voltage $V_{IN} = V_{IL} \text{ or } V_{IH}$ 4.5 0.36 0.44 I<sub>OL</sub> = 24 mA I<sub>OL</sub> = 24 mA (Note 5) 5.5 0.36 0.44 Maximum Input Leakage Current ±0.1 ±1.0 $V_I = V_{CC}$ , GND 5.5 μΑ $I_{IN}$ Maximum 5.5 1.5 $V_I = V_{CC} - 2.1V$ I<sub>CCT</sub> I<sub>CC</sub>/Input

75

-75

40.0

V<sub>OLD</sub> = 1.65V Max

V<sub>OHD</sub> = 3.85V Min

 $V_{IN} = V_{CC}$ or GND

mΑ

mΑ

Note 5: All outputs loaded; thresholds on input associated with output under test.

5.5

5.5

5.5

Note 6: Maximum test duration 2.0 ms, one output loaded at a time.

Minimum Dynamic

Output Current (Note 6)

Maximum Quiescent

 $I_{OLD}$ 

 $\mathsf{I}_{\mathsf{OHD}}$ 

 $I_{CC}$ 

#### **AC Electrical Characteristics for AC**

	Parameter	V <sub>CC</sub>	$T_A = +25^{\circ}C$ $C_L = 50 \text{ pF}$			$T_A = -40^\circ$	Units	
Symbol		(V)				$C_L = 50 \text{ pF}$		
		(Note 7)	Min	Тур	Max	Min	Max	
f <sub>MAX</sub>	Maximum Clock	3.3	70	95		60		MHz
	Frequency	5.0	110	140		95		IVIHZ
t <sub>PLH</sub>	Propagation Delay, CP to Q <sub>n</sub>	3.3	2.0	7.5	12.5	1.5	13.5	ns
	(PE Input HIGH or LOW)	5.0	1.5	5.5	9.0	1.0	9.5	
t <sub>PHL</sub>	Propagation Delay, CP to Q <sub>n</sub>	3.3	1.5	8.5	12.0	1.5	13.0	ns
	(PE Input HIGH or LOW)	5.0	1.5	6.0	9.5	1.5	10.0	
t <sub>PLH</sub>	Propagation Delay	3.3	3.0	9.5	15.0	2.5	16.5	
	CP to TC	5.0	2.0	7.0	10.5	1.5	11.5	ns
t <sub>PHL</sub>	Propagation Delay	3.3	3.5	11.0	14.0	2.5	15.5	
	CP to TC	5.0	2.0	8.0	11.0	2.0	11.5	ns
t <sub>PLH</sub>	Propagation Delay	3.3	2.0	7.5	9.5	1.5	11.0	ns
	CET to TC	5.0	1.5	5.5	6.5	1.0	7.5	
t <sub>PHL</sub>	Propagation Delay	3.3	2.5	8.5	11.0	2.0	12.5	
	CET to TC	5.0	2.0	6.0	8.5	1.5	9.5	ns

Note 7: Voltage Range 3.3 is 3.3V ±0.3V Voltage Range 5.0 is 5.0V ±0.5V

## AC Operating Requirements for AC

		V <sub>CC</sub>	T <sub>A</sub> = +25°C		$T_A = -40^{\circ}C$ to $+85^{\circ}C$	
Symbol	Parameter	(V)	C <sub>L</sub> =	50 pF	C <sub>L</sub> = 50 pF	Units
		(Note 8)	Тур	Guara	nteed Minimum	
t <sub>S</sub>	Setup Time, HIGH or LOW	3.3	5.5	13.5	16.0	ns
	P <sub>n</sub> to CP	5.0	4.0	8.5	10.5	ns
t <sub>H</sub>	Hold Time, HIGH or LOW	3.3	-7.0	-1.0	-0.5	no
	P <sub>n</sub> to CP	5.0	-5.0	0	0	ns
t <sub>S</sub>	Setup Time, HIGH or LOW	3.3	5.5	14.0	16.5	ns
	SR to CP	5.0	4.0	9.5	11.0	115
t <sub>H</sub>	Hold Time, HIGH or LOW	3.3	-7.5	-1.0	-0.5	ns
	SR to CP	5.0	-5.5	-0.5	0	110
t <sub>S</sub>	Setup Time, HIGH or LOW	3.3	5.5	11.5	14.0	ns
	PE to CP	5.0	4.0	7.5	8.5	
t <sub>H</sub>	Hold Time, HIGH or LOW	3.3	-7.5	-1.0	-0.5	ns
	PE to CP	5.0	-5.0	-0.5	0	115
t <sub>S</sub>	Setup Time, HIGH or LOW	3.3	3.5	6.0	7.0	20
	CEP or CET to CP	5.0	2.5	4.5	5.0	ns
t <sub>H</sub>	Hold Time, HIGH or LOW	3.3	-4.5	0	0	20
	CEP or CET to CP	5.0	-3.0	0	0.5	ns
t <sub>W</sub>	Clock Pulse Width (Load)	3.3	3.0	3.5	4.0	ns
	HIGH or LOW	5.0	2.0	2.5	3.0	115
t <sub>W</sub>	Clock Pulse Width (Count)	3.3	3.0	4.0	4.5	ns
	HIGH or LOW	5.0	2.0	3.0	3.5	115

Note 8: Voltage Range 3.3 is 3.3V ± 0.3V Voltage Range 5.0 is 5.0V ± 0.5V

### **AC Electrical Characteristics for ACT**

	Parameter	v <sub>cc</sub>	$T_A = +25^{\circ}C$ $C_L = 50 \text{ pF}$			$T_A = -40^{\circ}\text{C} \text{ to } +85^{\circ}\text{C}$ $C_L = 50 \text{ pF}$		Units
Symbol		(V)						
		(Note 9)	Min	Тур	Max	Min	Max	
f <sub>MAX</sub>	Maximum Clock Frequency	5.0	120	140		105		MHz
t <sub>PLH</sub>	Propagation Delay, CP to $Q_n$ ( $\overline{PE}$ Input HIGH or LOW)	5.0	1.5	5.5	10.0	1.5	11.0	ns
t <sub>PHL</sub>	Propagation Delay, CP to Q <sub>n</sub> (PE Input HIGH or LOW)	5.0	1.5	6.0	11.0	1.5	12.0	ns
t <sub>PLH</sub>	Propagation Delay CP to TC	5.0	2.5	7.0	11.5	2.0	13.5	ns
t <sub>PHL</sub>	Propagation Delay CP to TC	5.0	3.0	8.0	13.5	2.0	15.0	ns
t <sub>PLH</sub>	Propagation Delay CET to TC	5.0	2.0	5.5	9.0	1.5	10.5	ns
t <sub>PHL</sub>	Propagation Delay CET to TC	5.0	2.0	6.0	10.0	2.0	11.0	ns

Note 9: Voltage Range 5.0 is 5.0V ± 0.5V

## **AC Operating Requirements for ACT**

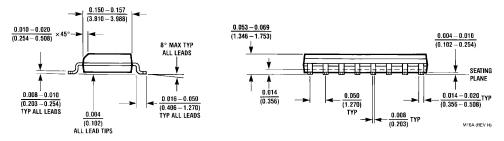
		V <sub>CC</sub>	$T_A = $	+25°C	$T_A = -40^{\circ}C \text{ to } +85^{\circ}C$		
Symbol	Parameter	(V)	C <sub>L</sub> =	50 pF	C <sub>L</sub> = 50 pF	Units	
		(Note 10)	Тур	Guara	anteed Minimum		
t <sub>S</sub>	Setup Time, HIGH or LOW Pn to CP	5.0	4.0	10.0	12.0	ns	
t <sub>H</sub>	Hold Time, HIGH or LOW P <sub>n</sub> to CP	5.0	-5.0	0.5	0.5	ns	
t <sub>S</sub>	Setup Time, HIGH or LOW  SR to CP	5.0	4.0	10.0	11.5	ns	
t <sub>H</sub>	Hold Time, HIGH or LOW  SR to CP	5.0	-5.5	-0.5	-0.5	ns	
t <sub>S</sub>	Setup Time, HIGH or LOW PE to CP	5.0	4.0	8.5	10.5	ns	
t <sub>H</sub>	Hold Time, HIGH or LOW  PE to CP	5.0	-5.5	-0.5	0	ns	
t <sub>S</sub>	Setup Time, HIGH or LOW CEP or CET to CP	5.0	2.5	5.5	6.5	ns	
t <sub>H</sub>	Hold Time, HIGH or LOW CEP or CET to CP	5.0	-3.0	0	0.5	ns	
t <sub>W</sub>	Clock Pulse Width (Load) HIGH or LOW	5.0	2.0	3.5	3.5	ns	
t <sub>W</sub>	Clock Pulse Width (Count) HIGH or LOW	5.0	2.0	3.5	3.5	ns	

Note 10: Voltage Range 5.0 is 5.0V ± 0.5V

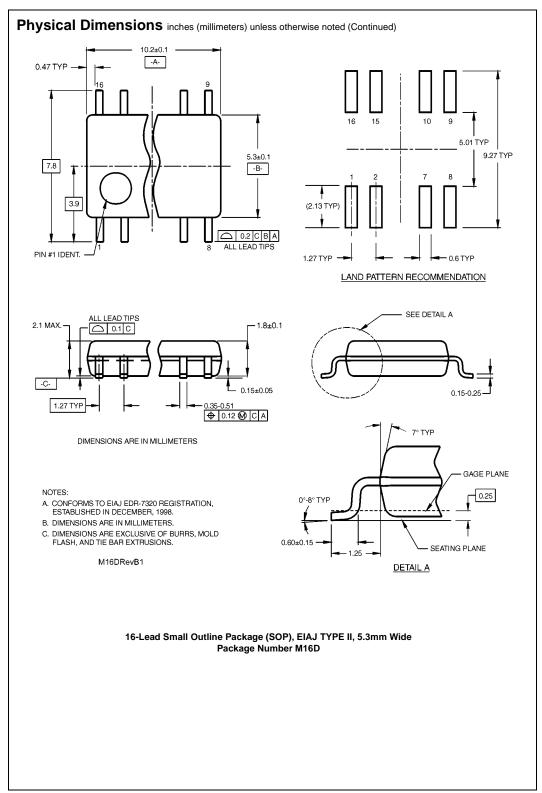
## Capacitance

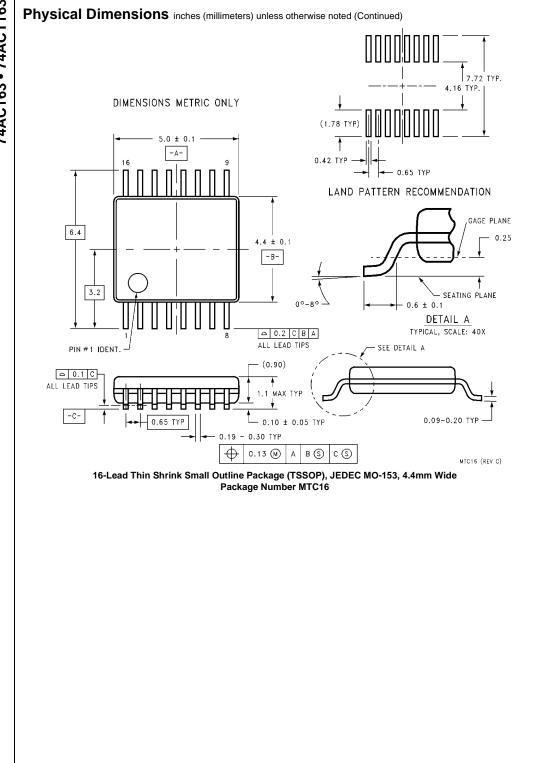
Symbol	Parameter	Тур	Units	Conditions
C <sub>IN</sub>	Input Capacitance	4.5	pF	V <sub>CC</sub> = OPEN
C <sub>PD</sub>	Power Dissipation Capacitance	45.0	pF	$V_{CC} = 5.0V$

## 

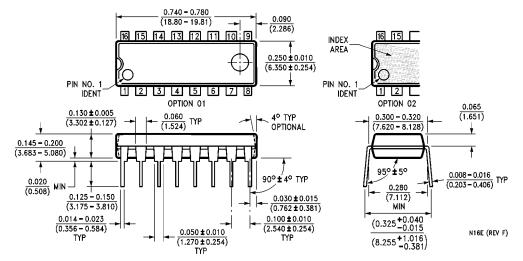


16-Lead Small Outline Integrated Circuit (SOIC), JEDEC MS-012, 0.150" Narrow Body Package Number M16A





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



16-Lead Plastic Dual-In-Line Package (PDIP), JEDEC MS-001, 0.300" Wide Package Number N16E

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- 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.

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