

January 2001 Revised August 2001

FSTUD16450

Configurable 4-Bit to 20-Bit Bus Switch with -2V Undershoot Protection and Selectable Level Shifting

General Description

The Fairchild Universal Bus Switch FSTUD16450 provides 4-bit, 5-bit, 8-bit, 10-bit, 16-bit, 20-bit of high-speed CMOS TTL-compatible bus switching. The low On Resistance of the switch allows inputs to be connected to outputs without adding propagation delay or generating additional ground bounce noise.

The FSTUD16450 is designed to allow "customer" configuration control of the enable connections. The device is organized as either a 4-bit, 5-bit, 10-bit or 20-bit bus switch. 8-bit and 16-bit configurations are also achievable (see Functional Description). The device's bit configuration is chosen through select pin logic. (see Truth Table). When $\overline{\text{OE}_x}$ is LOW, Port A_x is connected to Port B_x . When $\overline{\text{OE}_x}$ is HIGH, the switch is OPEN.

The A and B Ports are "undershoot hardened" with UHC™ protection to support an extended range to 2.0V below ground. Fairchild's integrated "Undershoot Hardened Circuit" (UHC) senses undershoot at the I/O's, and responds by preventing voltage differentials from developing and turning on the switch.

Another key device feature is the addition of a level shifting select pin, " S_2 ". When S_2 is LOW, the device behaves as a standard N-MOS switch. When S_2 is HIGH, a diode to V_{CC} is integrated into the circuit allowing for level shifting between 5V inputs and 3.3V outputs.

Features

- Undershoot hardened to -2V (A and B Ports)
- Voltage level shifting
- \blacksquare 4 Ω switch connection between two ports
- Minimal propagation delay through the switch
- Low I_{CC}
- Zero bounce in flow-through mode
- Control inputs compatible with TTL level
- See Applications Note AN-5008 for details
- Also packaged in plastic Fine-Pitch Ball Grid Array (FBGA) (Preliminary)

Applications Note

Select pins S_0 , S_1 , S_2 are intended to be used as static user configurable control pins. The AC performance of these pins has not been characterized or tested. Switching of these select pins during system operation may temporarily disrupt output logic states and/or enable pin controls.

Ordering Code:

Order Number	Package Number	Package Description
FSTUD16450GX (Note 1)	BGA54A (Preliminary)	54-Ball Fine-Pitch Ball Grid Array (FBGA), JEDEC MO-205, 5.5mm Wide [Tape and Reel]
FSTUD16450MTD	MTD56	56-Lead Thin Shrink Small Outline Package (TSSOP), JEDEC MO-153, 6.1mm Wide

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

Note 1: BGA package available in Tape and Reel only.

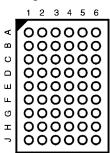
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Connection Diagrams

Pin Assignment for TSSOP

	9			
OE ₁	1	\cup	56	− ŌE ₂
1A ₁ —	2		55	$-\overline{OE}_5^{L}$
1A ₂ —	3		54	- 1B ₁
1A ₃ —	4		53	- 1B ₂
1A ₄ —	5		52	— 1В ₃
1A ₅ —	6		51	− 1B ₄
1A ₆ —	7		50	— 1В ₅
1A ₇ —	8		49	— 1В ₆
1A ₈ —	9		48	— 1В ₇
1A ₉	10		47	− 1B ₈
1A ₁₀ —	11		46	- 1B ₉
GND -	12		45	— 1В ₁₀
NC -	13		44	— GND
V _{CC} _	14		43	— NC
2A ₁	15		42	− V _{CC}
2A ₂ —	16		41	− 2B ₁
2A ₃ —	17		40	- 2B ₂
2A ₄ —	18		39	— 2B ₃
2A ₅ —	19		38	— 2B ₄
2A ₆ _	20		37	— 2B ₅
2A ₇ —	21		36	— 2B ₆
2A ₈ —	22		35	_ 2B ₇
2A ₉ —	23		34	_ 2B ₈
2A ₁₀ —	24		33	— 2B ₉
OE ₄	25		32	— 2B ₁₀
s ₀ –	26		31	$-\overline{\text{OE}}_3$
S ₁ _	27		30	– s ₂
NC -	28		29	— NC

Pin Assignment for FBGA



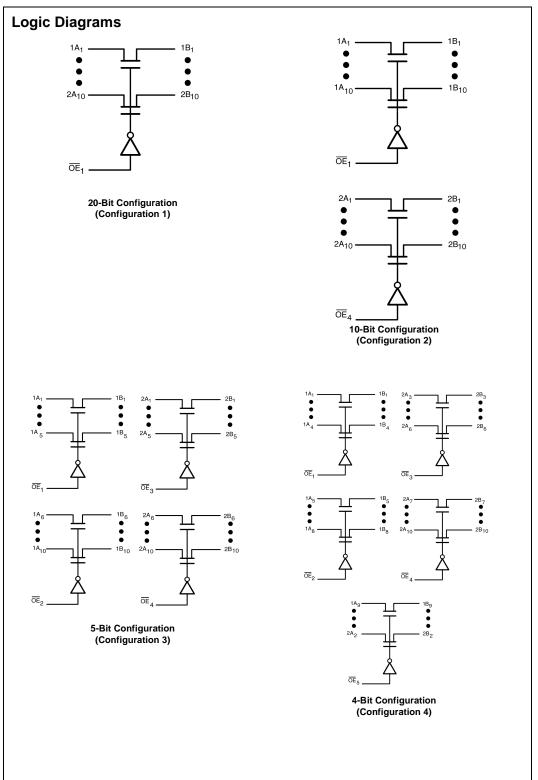
(Top Thru View)

Pin Descriptions

Pin Name	Description
$\overline{OE}_1, \overline{OE}_2$	Bus Switch Enables
1A, 2A	Bus A
1B, 2B	Bus B
S ₀ , S ₁	Bit Configuration Enables
S ₂	Level Shifting Diode Enable
NC	No Connect

FBGA Pin Assignments

	1	2	3	4	5	6
Α	1A ₃	1A ₂	OE ₁	OE ₂	1B ₂	1B ₃
В	1A ₅	1A ₄	1A ₁	1B ₁	1B ₄	1B ₅
С	1A ₇	1A ₆	GND	OE ₅	1B ₆	1B ₇
D	1A ₉	1A ₈	GND	V_{CC}	1B ₈	1B ₉
E	2A ₁	1A ₁₀	S ₀	V_{CC}	1B ₁₀	2B ₁
F	2A ₃	2A ₂	S ₁	S ₂	2B ₂	2B ₃
G	2A ₅	2A ₄	V _{CC}	GND	2B ₄	2B ₅
Н	2A ₇	2A ₆	2A ₁₀	2B ₁₀	2B ₆	2B ₇
J	2A ₉	2A ₈	OE4	OE ₃	2B ₈	2B ₉



Functional Description

The device can also be configured as an 8 and 16-bit device by grounding the unused pins in Configurations 2 and 1 respectively. The 8-bit configuration may also be achieved by tying two of the 4-bit enables from configuration together and tying the remaining enable pin $\overline{(OE)}$ HIGH.

Truth Tables $(x = v_{CC} \text{ or GND})$

(see Functional Description)

Select Pin								
S ₂	Mode							
L	Std. NMOS Switch							
Н	Level Shifting Diode Enabled							

Configuration 1 $S_0 = S_1 = L$				20-Bit Configuration	
Inputs				In most of Continued on	
OE ₁	OE ₂	OE ₃ OE ₄		OE ₅	Inputs/Outputs
L	Х	Х	Х	Х	$1A_{1-10} = 1B_{1-10}, 2A_{1-10} = 2B_{1-10}$
Н	Х	Х	Х	Χ	Z

Configu	Configuration 2 $S_0 = L, S_1 = H$				10-Bit Configuration			
		Inputs		Inputs/Outputs				
OE ₁	OE ₂	\overline{OE}_3 \overline{OE}_4 \overline{OE}_5		$1A_{1-10} = 1B_{1-10}$	$2A_{1-10} = 2B_{1-10}$			
L	Х	Х	L	Х	$1A_X = 1B_X$	$2A_X = 2B_X$		
L	Х	Х	Н	Х	$1A_X = 1B_X$	Z		
Н	Х	X L X		Z	$2A_X = 2B_X$			
Н	Х	Х	Н	Х	Z	Z		

Coi	nfiguratio	n 3	S ₀ = H,	, S ₁ = L	5-Bit Configuration					
		Inputs			Inputs/Outputs					
OE ₁	OE ₂	OE ₃	OE ₄	OE ₅	1A ₁₋₅ , 1B ₁₋₅	1A ₆₋₁₀ , 1B ₆₋₁₀	2A ₁₋₅ , 2B ₁₋₅	2A ₆₋₁₀ , 2B ₆₋₁₀		
L	L	L	L	Х	$1A_X = 1B_X$	$1A_y = 1B_y$	$2A_X = 2B_X$	$2A_y = 2B_y$		
L	L	L	Н	Х	$1A_X = 1B_X$	$1A_y = 1B_y$	$2A_X = 2B_X$	Z		
L	L	Н	L	Х	$1A_X = 1B_X$	$1A_y = 1B_y$	Z	$2A_y = 2B_y$		
L	L	Н	Н	Х	$1A_X = 1B_X$	$1A_y = 1B_y$	Z	Z		
L	Н	L	L	Х	$1A_X = 1B_X$	Z	$2A_X = 2B_X$	$2A_y = 2B_y$		
L	Н	L	Н	Х	$1A_X = 1B_X$	Z	$2A_X = 2B_X$	Z		
L	Н	Н	L	Х	$1A_X = 1B_X$	Z	Z	$2A_y = 2B_y$		
L	Н	Н	Н	Х	$1A_X = 1B_X$	Z	Z	Z		
Н	L	L	L	Х	Z	$1A_y = 1B_y$	$2A_X = 2B_X$	$2A_y = 2B_y$		
Н	L	L	Н	Х	Z	$1A_y = 1B_y$	$2A_X = 2B_X$	Z		
Н	L	Н	L	Х	Z	$1A_y = 1B_y$	Z	$2A_y = 2B_y$		
Н	L	Н	Н	Х	Z	$1A_y = 1B_y$	Z	Z		
Н	Н	L	L	Х	Z	Z	$2A_X = 2B_X$	$2A_y = 2B_y$		
Н	Н	L	Н	Х	Z	Z	$2A_X = 2B_X$	Z		
Н	Н	Н	L	Х	Z	Z	Z	$2A_y = 2B_y$		
Н	Н	Н	Н	Х	Z	Z	Z	Z		

Truth	Table	es (C	ontinued	1)					
Con	figuration	on 4	S ₀ = S	S ₁ = H		4-	Bit Configurati	on	
		Inputs					Inputs/Outputs	i	
OE ₁	OE ₂	OE ₃	OE ₄	OE ₅	1A ₁₋₄ , 1B ₁₋₄	1A ₅₋₈ , 1B ₅₋₈	2A ₃₋₆ , 2B ₃₋₆	2A ₇₋₁₀ , 2B ₇₋₁₀	1A ₉₋₁₀ , 2B ₉₋₁₀ 2A ₁₋₂ , 2B ₁₋₂
L	L	L	L	L	$1A_X = 1B_X$	$1A_y = 1B_y$	$2A_X = 2B_X$	$2A_y = 2B_y$	$1A_z = 1B_z$ $2A_z = 2B_z$
L	L	L	L	Н	$1A_X = 1B_X$	$1A_y = 1B_y$	$2A_X = 2B_X$	$2A_y = 2B_y$	Z
L	L	L	Н	L	$1A_x = 1B_x$	$1A_y = 1B_y$	$2A_X = 2B_X$	Z	$1A_z = 1B_z$ $2A_z = 2B_z$
L	L	L	Н	Н	$1A_X = 1B_X$	$1A_y = 1B_y$	$2A_X = 2B_X$	Z	Z
L	L	Н	L	L	$1A_x = 1B_x$	$1A_y = 1B_y$	Z	$2A_y = 2B_y$	$1A_z = 1B_z$ $2A_z = 2B_z$
L	L	Н	L	Н	$1A_X = 1B_X$	$1A_y = 1B_y$	Z	$2A_y = 2B_y$	Z
L	L	Н	Н	L	$1A_x = 1B_x$	$1A_y = 1B_y$	Z	Z	$1A_z = 1B_z$ $2A_z = 2B_z$
L	L	Н	Н	Н	$1A_X = 1B_X$	$1A_y = 1B_y$	Z	Z	Z
L	Н	L	L	L	$1A_x = 1B_x$	Z	$2A_x = 2B_x$	$2A_y = 2B_y$	$1A_z = 1B_z$ $2A_z = 2B_z$
L	Н	L	L	Н	$1A_X = 1B_X$	Z	$2A_X = 2B_X$	$2A_y = 2B_y$	Z
L	Н	L	Н	L	$1A_x = 1B_x$	Z	$2A_x = 2B_x$	Z	$1A_z = 1B_z$ $2A_z = 2B_z$
L	Н	L	Н	Н	$1A_X = 1B_X$	Z	$2A_X = 2B_X$	Z	Z
L	Н	Н	L	L	$1A_x = 1B_x$	Z	Z	$2A_y = 2B_y$	$1A_z = 1B_z$ $2A_z = 2B_z$
L	Н	Н	L	Н	$1A_X = 1B_X$	Z	Z	$2A_y = 2B_y$	Z
L	Н	Н	Н	L	$1A_x = 1B_x$	Z	Z	Z	$1A_z = 1B_z$ $2A_z = 2B_z$
L	Н	Н	Н	Н	$1A_X = 1B_X$	Z	Z	Z	Z
Н	L	L	L	L	Z	$1A_y = 1B_y$	$2A_X = 2B_X$	$2A_y = 2B_y$	$1A_z = 1B_z$ $2A_z = 2B_z$
Н	L	L	L	Н	Z	$1A_y = 1B_y$	$2A_X = 2B_X$	$2A_y = 2B_y$	Z
Н	L	L	Н	L	Z	$1A_y = 1B_y$	$2A_X = 2B_X$	Z	$1A_z = 1B_z$ $2A_z = 2B_z$
Н	L	L	Н	Н	Z	$1A_y = 1B_y$	$2A_X = 2B_X$	Z	Z
Н	L	Н	L	L	Z	$1A_y = 1B_y$	Z	$2A_y = 2B_y$	$1A_z = 1B_z$ $2A_z = 2B_z$
Н	L	Н	L	Н	Z	$1A_y = 1B_y$	Z	$2A_y = 2B_y$	Z
Н	L	Н	Н	L	Z	$1A_y = 1B_y$	Z	Z	$1A_z = 1B_z$ $2A_z = 2B_z$
Н	L	Н	Н	Н	Z	$1A_y = 1B_y$	Z	Z	Z
Н	Н	L	L	L	Z	Z	$2A_X = 2B_X$	$2A_y = 2B_y$	$1A_z = 1B_z$ $2A_z = 2B_z$
Н	Н	L	L	Н	Z	Z	$2A_X = 2B_X$	$2A_y = 2B_y$	Z
Н	Н	L	Н	L	Z	Z	$2A_X = 2B_X$	Z	$1A_z = 1B_z$ $2A_z = 2B_z$
Н	Н	L	Н	Н	Z	Z	$2A_X = 2B_X$	Z	Z
Н	Н	Н	L	L	Z	Z	Z	$2A_y = 2B_y$	$1A_z = 1B_z$ $2A_z = 2B_z$
Н	Н	Н	L	Н	Z	Z	Z	$2A_y = 2B_y$	Z
Н	Н	Н	Н	L	Z	Z	Z	Z	$1A_z = 1B_z$ $2A_z = 2B_z$
Н	Н	Н	Н	Н	Z	Z	Z	Z	Z

Absolute Maximum Ratings(Note 2)

 $\begin{array}{lll} \mbox{Supply Voltage (V$_{CC}$)} & -0.5 \mbox{V to } +7.0 \mbox{V} \\ \mbox{DC Switch Voltage (V$_S) (Note 3)} & -2.0 \mbox{V to } +7.0 \mbox{V} \\ \end{array}$

DC Input Control Pin Voltage

Recommended Operating Conditions (Note 5)

 $\begin{array}{lll} \mbox{Power Supply Operating (V$_{CC}$)} & 4.0 \mbox{V to } 5.5 \mbox{V} \\ \mbox{Input Voltage (V$_{IN}$)} & 0 \mbox{V to } 5.5 \mbox{V} \\ \mbox{Output Voltage (V$_{OUT}$)} & 0 \mbox{V to } 5.5 \mbox{V} \\ \mbox{Free Air Operating Temperature (T$_{A}$)} & -40 \mbox{ }^{\circ}\mbox{C to } +85 \mbox{ }^{\circ}\mbox{C} \\ \end{array}$

Note 2: The "Absolute Maximum Ratings" are those values beyond which the safety of the device cannot be guaranteed. The device should not be operated at these limits. The parametric values defined in the Electrical Characteristics tables are not guaranteed at the absolute maximum rating. The "Recommended Operating Conditions" table will define the conditions for actual device operation.

Note 3: V_S is the voltage observed/applied at either the A or B Ports across the switch.

Note 4: The input and output negative voltage ratings may be exceeded if the input and output diode current ratings are observed.

Note 5: Unused control inputs must be held HIGH or LOW. They may not float.

DC Electrical Characteristics

		V _{CC}	T _A = -	–40 °C to +	85 °C		
Symbol	Parameter	(V)	Min	Typ (Note 6)	Max	Units	Conditions
V _{IK}	Clamp Diode Voltage	4.5			-1.2	V	I _{IN} = -18 mA
V _{IH}	HIGH Level Input Voltage	4.0-5.5	2.0			V	IF $S_2 = HIGH 4.5V \le V_{CC} \le 5.5V$
V _{IL}	LOW Level Input Voltage	4.0-5.5			0.8	V	IF S ₂ = HIGH 4.5V ≤ V _{CC} ≤ 5.5V
V _{OH}	HIGH Level Output Voltage	4.5-5.5	5	See Figure	4	V	$S_2 = V_{CC}$
I	Input Leakage Current	5.5			±1.0	μΑ	$0 \le V_{IN} \le 5.5V$
		0			10	μΑ	V _{IN} = 5.5V
l _{OZ}	OFF-STATE Leakage Current	5.5			±1.0	μΑ	0 ≤ A, B ≤ V _{CC}
R _{ON}	Switch On Resistance	4.5		4	7	Ω	$V_{IN} = 0V$, $I_{IN} = 64$ mA, $S_2 = 0V$ or V_{CC}
	(Note 7)	4.5		4	7	Ω	$V_{IN} = 0V$, $I_{IN} = 30$ mA, $S_2 = 0V$ or V_{CC}
		4.5		8	12	Ω	$V_{IN} = 2.4V$, $I_{IN} = 15$ mA, $S_2 = 0V$
		4.0		11	20	Ω	$V_{IN} = 2.4V$, $I_{IN} = 15$ mA, $S_2 = 0V$
		4.5		35	50	Ω	$V_{IN} = 2.4V$, $I_{IN} = 15$ mA, $S_2 = V_{CC}$
I _{CC}	Quiescent Supply Current				3	μΑ	$S_2 = GND$, $V_{IN} = V_{CC}$ or GND , $I_{OUT} = 0$
		5.5			10	μΑ	$S_2 = V_{CC}$, $\overline{OE}_x = V_{CC}$, $V_{IN} = V_{CC}$ or GND, $I_{OUT} = 0$
					1.5	mA	$S_2 = V_{CC}$, $\overline{OE}_x = GND$, $V_{IN} = V_{CC}$ or GND , $I_{OUT} = 0$
ΔI _{CC}	Increase in I _{CC} per Input				2.5	mA	One Input at 3.4V Other Inputs at V_{CC} or GND, $S_2 = 0V$
		5.5			4.0	mA	One Input at 3.4V Other Inputs at V_{CC} or GND, $S_2 = V_{CC}$
V _{IKU}	Voltage Undershoot	5.5			-2.0	V	$\frac{0.0 \text{ mA} \ge I_{\text{IN}} \ge -50 \text{ mA}}{\overline{\text{OE}}_{x} = 5.5 \text{V}}$

Note 6: Typical values are at $V_{CC} = 5.0V$ and $T_A = +25$ °C

Note 7: Measured by the voltage drop between A and B pins at the indicated current through the switch. On Resistance is determined by the lower of the voltages on the two (A or B) pins.

AC Electrical Characteristics

			T _A = -40 °C	C to +85 °C	1			
Symbol	Parameter	CL	= 50 pF, Rl	J = RD = 50	0Ω	Units	Conditions	Figure
Symbol	r ai ailletei	V _{CC} = 4	.5 – 5.5V	$V_{CC} = 4.0V$		Oilles	(S ₂ = 0V)	Number
		Min	Max	Min	Max	1		
t _{PHL} , t _{PLH}	Propagation Delay Bus-to-Bus (Note 8)		0.25		0.25	ns	V _I = OPEN	Figures 2, 3
t _{PZH} , t _{PZL}	Output Enable Time	1.5	6.5		7.0	ns	$V_I = 7V$ for t_{PZL} $V_I = OPEN$ for t_{PZH}	Figures 2, 3
t _{PHZ} , t _{PLZ}	Output Disable Time	1.5	6.7		7.2	ns	$V_I = 7V$ for t_{PLZ} $V_I = OPEN$ for t_{PHZ}	Figures 2, 3
t _{PZH} , t _{PZL}	S _{el} (S _{0, 1}) to Output Enable Time	1.5	7.0		7.5	ns	$V_I = 7V$ for t_{PZL} $V_I = OPEN$ for t_{PZH}	Figures 2, 3
t _{PHZ} , t _{PLZ}	S _{el} (S _{0, 1}) to Output Disable Time	1.5	7.5		7.7	ns	$V_I = 7V$ for t_{PLZ} $V_I = OPEN$ for t_{PHZ}	Figures 2, 3

Note 8: This parameter is guaranteed by design but is not tested. The bus switch contributes no propagation delay other than the RC delay of the typical On Resistance of the switch and the 50pF load capacitance, when driven by an ideal voltage source (zero output impedance).

AC Electrical Characteristics: Translating Diode

Symbol	Parameter	C _L = 50pF, Rl	C to +85 °C, J = RD = 500Ω 5 - 5.5V	Units	Conditions $(S_2 = V_{CC})$	Figure Number
		Min	Max			
t _{PHL} , t _{PLH}	Propagation Delay Bus-to-Bus (Note 9)		0.25	ns	V _I = OPEN	Figures 2, 3
t _{PZH} , t _{PZL}	Output Enable Time	1.5	10.0	ns	$V_I = 7V$ for t_{PZL} $V_I = OPEN$ for t_{PZH}	Figures 2, 3
t _{PHZ} , t _{PLZ}	Output Disable Time	1.5	9.0	ns	$V_I = 7V$ for t_{PLZ} $V_I = OPEN$ for t_{PHZ}	Figures 2, 3
t _{PZH} , t _{PZL}	S _{el} (S _{0, 1}) to Output Enable Time	1.5	11.0	ns	$V_I = 7V$ for t_{PZL} $V_I = OPEN$ for t_{PZH}	Figures 2, 3
t _{PHZ} , t _{PLZ}	S _{el} (S _{0, 1}) to Output Disable Time	1.5	10.0	ns	$V_I = 7V$ for t_{PLZ} $V_I = OPEN$ for t_{PHZ}	Figures 2, 3

Note 9: This parameter is guaranteed by design but is not tested. This bus switch contributes no propagation delay other than the RC delay of the typical On Resistance of the switch and the 50pF load capacitance, when driven by an ideal voltage source (zero output impedance).

Capacitance (Note 10)

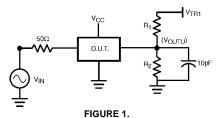
Symbol	Parameter	Тур	Max	Units	Conditions
C _{IN}	Control Pin Input Capacitance	4		pF	$V_{CC} = 5.0V, V_{IN} = 0V$
C _{I/O}	Input/Output Capacitance "OFF State"	8		pF	V_{CC} , $\overline{OE} = 5.0V$, $V_{IN} = 0V$

Note 10: T_A = +25°C, f = 1 MHz, Capacitance is characterized but not tested.

Undershoot Characteristic (Note 11)

Symbol	Parameter	Min	Тур	Max	Units	Conditions
V _{OUTU}	Output Voltage During Undershoot	2.5	V _{OH} – 0.3		V	S ₂ = 0V, Figure 1
		TBD	TBD		V	$S_2 = V_{CC}$

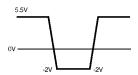
Note 11: This test is intended to characterize the device's protective capabilities by maintaining output signal integrity during an input transient voltage



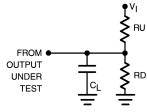
Device Test Conditions

Parameter	Value	Units		
V _{IN}	see Waveform	V		
$R_1 = R_2$	100K	Ω		
V_{TRI}	11.0	V		
V _{CC}	5.5	V		

Transient Input Voltage (V_{IN}) Waveform



AC Loading and Waveforms



Note: Input driven by 50Ω source terminated in 50Ω Note: C_L includes load and stray capacitance Note: Input Frequency = 1.0 MHz, t_W = 500 ns

FIGURE 2. AC Test Circuit

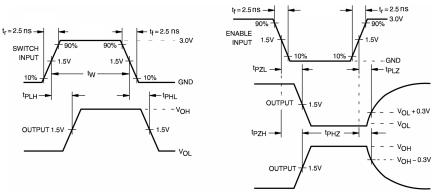
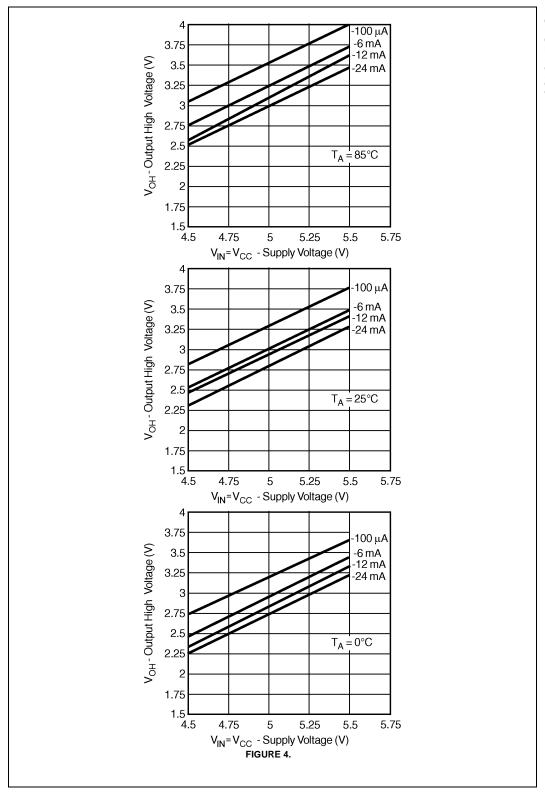
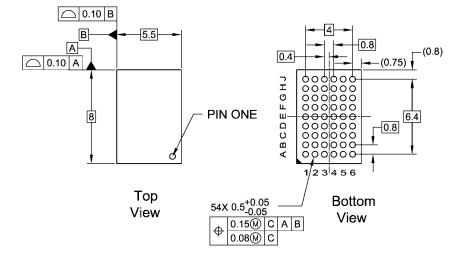
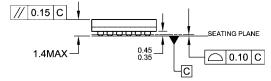


FIGURE 3. AC Waveforms



Physical Dimensions inches (millimeters) unless otherwise noted



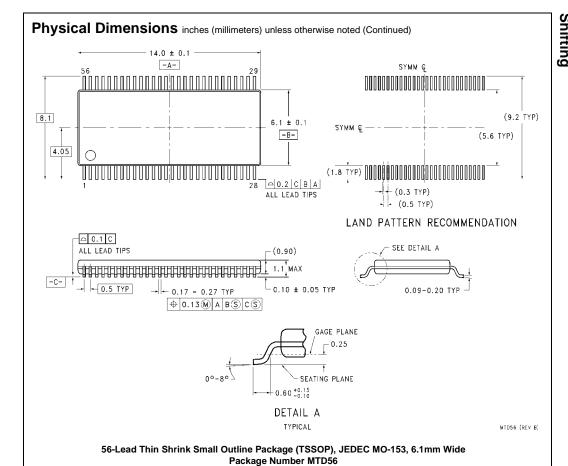


NOTES:

- A. THIS PACKAGE CONFORMS TO JEDEC M0-205
- B. ALL DIMENSIONS IN MILLIMETERS
- C. LAND PATTERN RECOMMENDATION: NSMD (Non Solder Mask Defined)
 .35MM DIA PADS WITH A SOLDERMASK OPENING OF .45MM CONCENTRIC TO PADS
 D. DRAWING CONFORMS TO ASME Y14.5M-1994

BGA54ArevD

54-Ball Fine-Pitch Ball Grid Array (FBGA), JEDEC MO-205, 5.5mm Wide Package Number BGA54A
Preliminary



Technology Description

The Fairchild Switch family derives from and embodies Fairchild's proven switch technology used for several years in its 74LVX3L384 (FST3384) bus switch product.

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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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