

## SCANSTA112

### 7-port Multidrop IEEE 1149.1 (JTAG) Multiplexer

#### General Description

The SCANSTA112 extends the IEEE Std. 1149.1 test bus into a multidrop test bus environment. The advantage of a multidrop approach over a single serial scan chain is improved test throughput and the ability to remove a board from the system and retain test access to the remaining modules. Each SCANSTA112 supports up to 7 local IEEE1149.1 scan chains which can be accessed individually or combined serially.

Addressing is accomplished by loading the instruction register with a value matching that of the Slot inputs. Backplane and inter-board testing can easily be accomplished by parking the local TAP Controllers in one of the stable TAP Controller states via a Park instruction. The 32-bit TCK counter enables built in self test operations to be performed on one port while other scan chains are simultaneously tested.

The STA112 has a unique feature in that the backplane port and the LSP0 port are bidirectional. They can be configured to alternatively act as the master or slave port so an alternate test master can take control of the entire scan chain network from the LSP0 port while the backplane port becomes a slave.

#### Features

- True IEEE 1149.1 hierarchical and multidrop addressable capability
- The 8 slot inputs support up to 249 unique addresses, an Interrogation Address, Broadcast Address, and 4 Multi-cast Group Addresses (address 000000 is reserved)

- 7 IEEE 1149.1-compatible configurable local scan ports
- Bi-directional Backplane and LSP<sub>0</sub> ports are interchangeable slave ports
- Capable of ignoring  $\overline{\text{TRST}}$  of the backplane port when it becomes the slave.
- Stitcher Mode bypasses level 1 and 2 protocols
- Mode Register<sub>0</sub> allows local TAPs to be bypassed, selected for insertion into the scan chain individually, or serially in groups of two or three
- Transparent Mode can be enabled with a single instruction to conveniently buffer the backplane IEEE 1149.1 pins to those on a single local scan port
- General purpose local port passthrough bits are useful for delivering write pulses for Flash programming or monitoring device status.
- Known Power-up state
- $\overline{\text{TRST}}$  on all local scan ports
- 32-bit TCK counter
- 16-bit LFSR Signature Compactor
- Local TAPs can become TRI-STATE via the  $\overline{\text{OE}}$  input to allow an alternate test master to take control of the local TAPs (LSP<sub>0-3</sub> have a TRI-STATE notification output)
- 3.0-3.6V V<sub>CC</sub> Supply Operation
- Supports live insertion/withdrawal

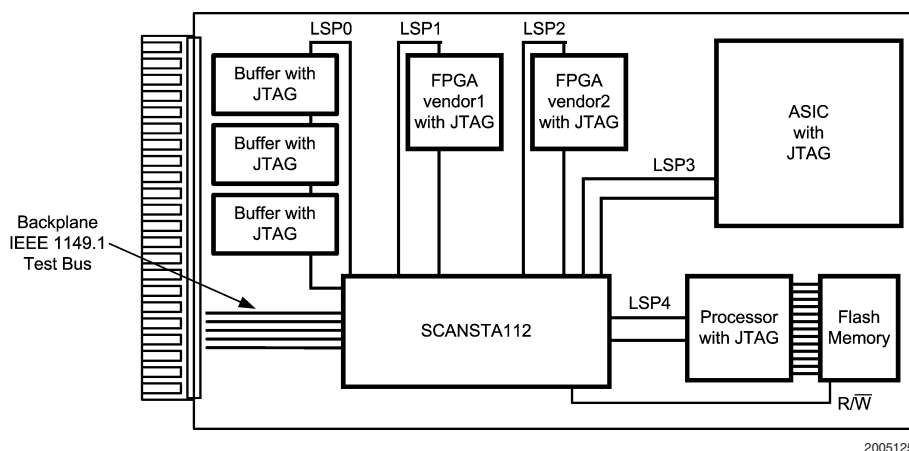


FIGURE 1. Typical use of SCANSTA112 for board-level management of multiple scan chains.

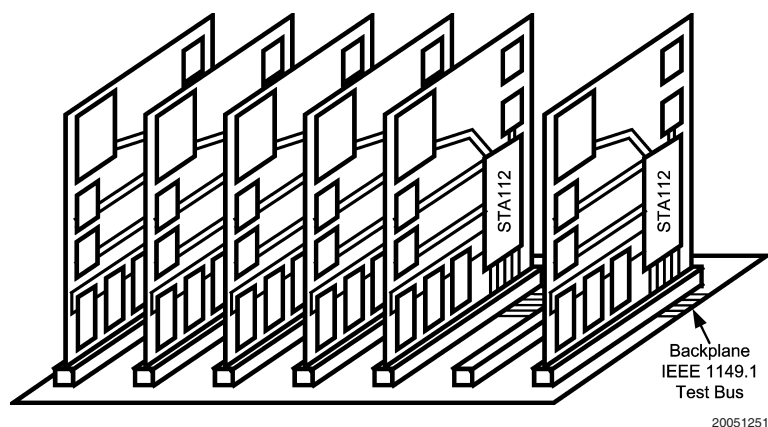


FIGURE 2. Example of SCANSTA112 in a multidrop addressable backplane.

## Introduction

The SCANSTA112 is the third device in a series that enable multi-drop address and multiplexing of IEEE-1149.1 scan chains. The SCANSTA112 is a superset of its predecessors - the SCANPSC110 and the SCANSTA111. The STA112 has all features and functionality of these two previous devices.

The STA112 is essentially a support device for the IEEE 1149.1 standard. It is primarily used to partition scan chains into manageable sizes, or to isolate specific devices onto a separate chain (*Figure 1*). The benefits of multiple scan chains are improved fault isolation, faster test times, faster programming times, and smaller vector sets.

In addition to scan chain partitioning, the device is also addressable for use in a multidrop backplane environment (*Figure 2*). In this configuration, multiple IEEE-1149.1 accessible cards with an STA112 on board can utilize the same backplane test bus for system-level IEEE-1149.1 access. This approach facilitates a system-wide commitment to structural test and programming throughout the entire system life cycle.

## Architecture

*Figure 3* shows the basic architecture of the 'STA112. The device's major functional blocks are illustrated here.

The TAP Controller, a 16-state state machine, is the central control for the device. The instruction register and various test data registers can be scanned to exercise the various functions of the 'STA112 (these registers behave as defined in IEEE Std. 1149.1).

The 'STA112 selection controller provides the functionality that allows the 1149.1 protocol to be used in a multi-drop environment. It primarily compares the address input to the slot identification and enables the 'STA112 for subsequent scan operations.

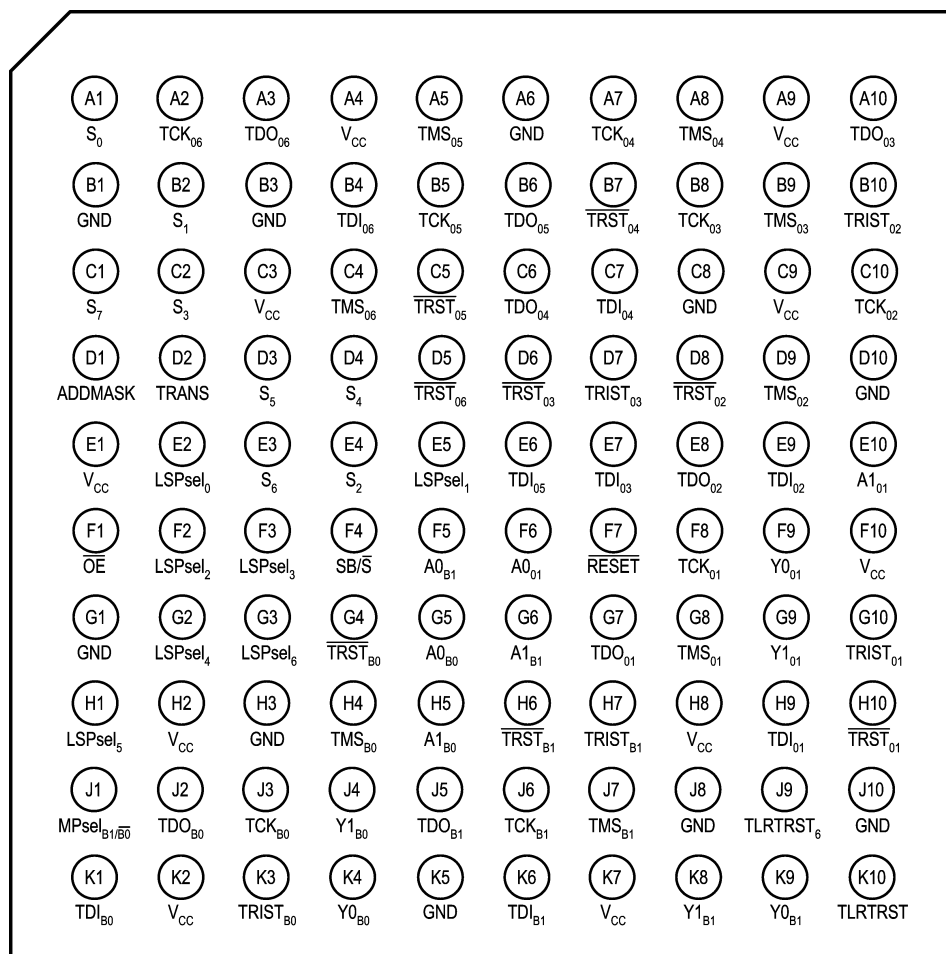
The Local Scan Port Network (LSPN) contains multiplexing logic used to select different port configurations. The LSPN control block contains the Local Scan Port Controllers (LSPC) for each Local Scan Port ( $LSP_0, LSP_1 \dots LSP_n$ ). This control block receives input from the 'STA112 instruction register, mode registers, and the TAP controller. Each local port contains all four boundary scan signals needed to interface with the local TAPs plus the optional Test Reset signal (TRST).

The TDI/TDO Crossover Master/Slave logic is used to define the bidirectional B0 and B1 ports in a Master/Slave configuration.



**FIGURE 3. SCANSTA112 Block Diagram**

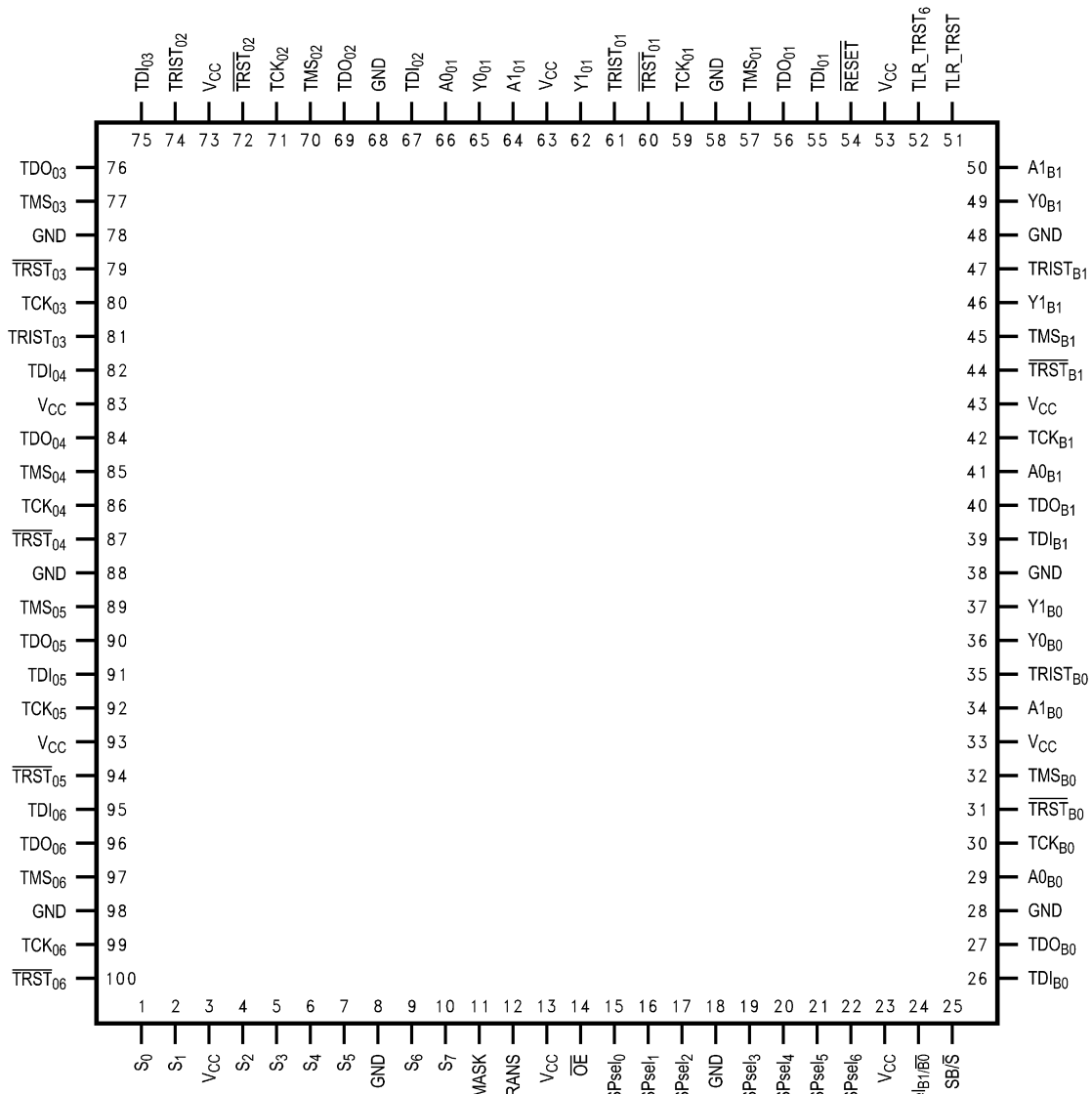
## Connection Diagrams



(BGA Top view)

20051201

Connection Diagrams (Continued)



TQFP pinout

20051260

**TABLE 1. Pin Descriptions**

Pin Name	No. Pins	I/O	Description
VCC	10	N/A	Power
GND	10	N/A	Ground
RESET	1	I	RESET Input: will force a reset of the device regardless of the current state.
ADDMASK	1	I	ADDRESS MASK input: Allows masking of lower slot input pins.
MPsel <sub>B1/B0</sub>	1	I	MASTER PORT SELECTION: Controls selection of LSP <sub>B0</sub> or LSP <sub>B1</sub> as the backplane port. The unselected port becomes LSP <sub>00</sub> . A value of "0" will select LSP <sub>B0</sub> as the master port.
SB/S	1	I	Selects ScanBridge or Stitcher Mode.
LSPsel <sub>(0-6)</sub>	7	I	In Stitcher Mode these inputs define which LSP's are to be included in the scan chain
TRANS	1	I	Transparent Mode enable input: The value of this pin is loaded into the TRANSENABLE bit of the control register at power-up. This value is used to control the presence of registers and pad-bits in the scan chain while in the stitcher mode.
TLR_TRST	1	I	Sets the driven value of TRST <sub>0-5</sub> when LSP TAPs are in TLR and the device is not being reset. During RESET = "0" or TRST <sub>B</sub> = "0" (IgnoreReset = "0") TRST <sub>n</sub> = "0". This pin is to be tied low to match the function of the SCANSTA111
TLR_TRST <sub>6</sub>	1	I	This pin affects TRST of LSP <sub>6</sub> only. This pin is to be tied low to match the function of the SCANSTA111
TDI <sub>B0</sub> , TDI <sub>B1</sub>	2	I	BACKPLANE TEST DATA INPUT: All backplane scan data is supplied to the 'STA112 through this input pin. MPsel <sub>B1/B0</sub> determines which port is the master backplane port and which is LSP <sub>00</sub> . This input has a 25KΩ internal pull-up resistor.
TMS <sub>B0</sub> , TMS <sub>B1</sub>	2	I/O	BACKPLANE TEST MODE SELECT: Controls sequencing through the TAP Controller of the 'STA112. Also controls sequencing of the TAPs which are on the local scan chains. MPsel <sub>B1/B0</sub> determines which port is the master backplane port and which is LSP <sub>00</sub> . This bidirectional TRISTATE pin has 24mA of drive current, with a 25KΩ internal pull-up resistor.
TDO <sub>B0</sub> , TDO <sub>B1</sub>	2	I/O	BACKPLANE TEST DATA OUTPUT: This output drives test data from the 'STA112 and the local TAPs, back toward the scan master controller. This bidirectional TRISTATE pin has 12mA of drive current. MPsel <sub>B1/B0</sub> determines which port is the master backplane port and which is LSP <sub>00</sub> . Output is sampled during interrogation addressing.
TCK <sub>B0</sub> , TCK <sub>B1</sub>	2	I/O	TEST CLOCK INPUT FROM THE BACKPLANE: This is the master clock signal that controls all scan operations of the 'STA112 and of the local scan ports. MPsel <sub>B1/B0</sub> determines which port is the master backplane port and which is LSP <sub>00</sub> . These bidirectional TRISTATE pins have 24mA of drive current with hysteresis.
TRST <sub>B0</sub> , TRST <sub>B1</sub>	2	I/O	TEST RESET: An asynchronous reset signal (active low) which initializes the 'STA112 logic. MPsel <sub>B1/B0</sub> determines which port is the master backplane port and which is LSP <sub>00</sub> . This bidirectional TRISTATE pin has 24mA of drive current, with a 25KΩ internal pull-up resistor.
TRIST <sub>B0</sub> , TRIST <sub>B1</sub>	2	O	BACKPLANE TRI-STATE NOTIFICATION OUTPUT: This signal is high when the backplane scan port is TRI-STATEd. This pin is used for backplane physical layer changes (i.e.; TTL to LVDS). This TRISTATE output has 12mA of drive current. MPsel <sub>B1/B0</sub> determines which port is the master backplane port and which is LSP <sub>00</sub> .
A0 <sub>B0</sub> , A1 <sub>B0</sub> , A0 <sub>B1</sub> , A1 <sub>B1</sub>	4	I	BACKPLANE PASS-THROUGH INPUT: A general purpose input which is driven to the Y <sub>n</sub> of a single selected LSP. (Not available when multiple LSPs are selected). This input has a 25KΩ internal pull-up resistor. MPsel <sub>B1/B0</sub> determines which port is the master backplane port and which is LSP <sub>00</sub> .
Y0 <sub>B0</sub> , Y1 <sub>B0</sub> , Y0 <sub>B1</sub> , Y1 <sub>B1</sub>	4	O	BACKPLANE PASS-THROUGH OUTPUT: A general purpose output which is driven from the A <sub>n</sub> of a single selected LSP. (Not available when multiple LSPs are selected). This TRISTATE output has 12mA of drive current. MPsel <sub>B1/B0</sub> determines which port is the master backplane port and which is LSP <sub>00</sub> .
S <sub>(0-7)</sub>	8	I	SLOT IDENTIFICATION: The configuration of these pins is used to identify (assign a unique address to) each 'STA112 on the system backplane

**TABLE 1. Pin Descriptions** (Continued)

Pin Name	No. Pins	I/O	Description
$\overline{OE}$	1	I	OUTPUT ENABLE for the Local Scan Ports, active low. When high, this active-low control signal TRI-STATes all local scan ports on the 'STA112, to enable an alternate resource to access one or more of the local scan chains.
$TDO_{(01-06)}$	6	O	TEST DATA OUTPUTS: Individual output for each of the local scan ports . These TRISTATE outputs have 12mA of drive current.
$TDI_{(01-06)}$	6	I	TEST DATA INPUTS: Individual scan data input for each of the local scan ports. This input has a 25K $\Omega$ internal pull-up resistor.
$TMS_{(01-06)}$	6	O	TEST MODE SELECT OUTPUTS: Individual output for each of the local scan ports. $TMS_n$ does not provide a pull-up resistor (which is assumed to be present on a connected TMS input, per the IEEE 1149.1 requirement) . These TRISTATE outputs have 24mA of drive current.
$TCK_{(01-06)}$	6	O	LOCAL TEST CLOCK OUTPUTS: Individual output for each of the local scan ports. These are buffered versions of $TCK_B$ . These TRISTATE outputs have 24mA of drive current.
$\overline{TRST}_{(01-06)}$	6	O	LOCAL TEST RESETS: A gated version of $\overline{TRST}_B$ . These TRISTATE outputs have 24mA of drive current.
$A0_{01}, A1_{01}$	2	I	LOCAL PASS-THROUGH INPUTS: General purpose inputs which can be driven to the backplane pin $Y_B$ . (Only on $LSP_0$ and $LSP_1$ . Only available when a single LSP is selected) . These inputs have a 25K $\Omega$ internal pull-up resistor.
$Y0_{01}, Y1_{01}$	2	O	LOCAL PASS-THROUGH OUTPUT: General purpose outputs which can be driven from the backplane pin $A_B$ . (Only on $LSP_0$ and $LSP_1$ . Only available when a single LSP is selected) . These TRISTATE outputs have 12mA of drive current.
$TRIST_{(01-03)}$	3	O	LOCAL TRI-STATE NOTIFICATION OUTPUTS: This signal is high when the local scan ports are TRI-STATed . These pins are used for backplane physical layer changes (i.e.; TTL to LVDS). These TRISTATE outputs have 12mA of drive current.

## Application Overview

**ADDRESSING SCHEME** - The SCANSTA112 architecture extends the functionality of the IEEE 1149.1 Standard by supplementing that protocol with an addressing scheme which allows a test controller to communicate with specific 'STA112s within a network of 'STA112s. That network can include both multi-drop and hierarchical connectivity. In effect, the 'STA112 architecture allows a test controller to dynamically select specific portions of such a network for participation in scan operations. This allows a complex system to be partitioned into smaller blocks for testing purposes. The 'STA112 provides two levels of test-network partitioning capability. First, a test controller can select individual 'STA112s, specific sets of 'STA112s (multi-cast groups), or all 'STA112s (broadcast). This 'STA112-selection process is supported by a Level-1 communication protocol. Second, within each selected 'STA112, a test controller can select one or more of the chip's seven local scan-ports. That is, individual local ports can be selected for inclusion in the (single) scan-chain which a 'STA112 presents to the test controller. This mechanism allows a controller to select specific scan-chains within the overall scan network. The port-selection process is supported by a Level-2 protocol.

**HIERARCHICAL SUPPORT** - Multiple SCANSTA112's can be used to assemble a hierarchical boundary-scan tree. In such a configuration, the system tester can configure the local ports of a set of 'STA112s so as to connect a specific set of local scan-chains to the active scan chain. Using this capability, the tester can selectively communicate with specific portions of a target system. The tester's scan port is connected to the backplane scan port of a root layer of

'STA112s, each of which can be selected using multi-drop addressing. A second tier of 'STA112s can be connected to this root layer, by connecting a local port (LSP) of a root-layer 'STA112 to the backplane port of a second-tier 'STA112. This process can be continued to construct a multi-level scan hierarchy. 'STA112 local ports which are not cascaded into higher-level 'STA112s can be thought of as the terminal leaves of a scan tree. The test master can select one or more target leaves by selecting and configuring the local ports of an appropriate set of 'STA112s in the test tree.

**STANDARD SCANBRIDGE MODE** - ScanBridge mode refers to functionality and protocol that has been used by National since the introduction of the PSC110 in 1993. This functionality consists of a multidrop addressable IEEE1149.1 switch. This enables one (or more) device to be selected from many that are connected to a parallel IEEE1149.1 bus or backplane. The second function that ScanBridge mode accomplishes is to act as a mux for multiple IEEE1149.1 local scan chains. The Local Scan Ports (LSP) of the device creates a connection between one or more of the local scan chains to the backplane bus.

To accomplish this functionality the ScanBridge has two levels of protocol and an operational mode. Level 1 protocol refers to the required actions to address/select the desired ScanBridge. Level 2 protocol is required to configuring the mux'ing function and enable the connection (UNPARK) between the local scan chain and the backplane bus via an LSP. Upon completion of level 1 and 2 protocols the ScanBridge is prepared for its operational mode. This is where scan vectors are moved from the backplane bus to the desired local scan chain(s).

## Application Overview (Continued)

**STITCHER MODE** - Stitcher Mode is a method of skipping level 1 and 2 protocol of the ScanBridge mode of operation. This is accomplished via external pins. When in stitcher mode the SCANSTA112 will go directly to the operational mode.

**TRANSPARENT MODE** - Transparent mode refers to a condition of operation in which there are no pad-bits or SCANSTA112 registers in the scan chain. The Transparent mode of operation is available in both ScanBridge and

Stitcher modes. Only the activation method differs. Once transparent mode has been activated there is no difference in operation. Transparent mode allows for the use of vectors that have been generated for a chain where these bits were not included.

Check with your ATPG tool vendor to ensure support of these features.

For details regarding the internal operation of the SCANSTA112 device, refer to applications note AN-1259 SCANSTA112 Designers Reference.



**Absolute Maximum Ratings** (Note 1)

Supply Voltage ( $V_{CC}$ )	-0.3V to +4.0V
DC Input Diode Current ( $I_{IK}$ )	
$V_I = -0.5V$	-20 mA
DC Input Voltage ( $V_I$ )	-0.5V to +3.9V
DC Output Diode Current ( $I_{OK}$ )	
$V_O = -0.5V$	-20 mA
DC Output Voltage ( $V_O$ )	-0.3V to +3.9V
DC Output Source/Sink Current ( $I_O$ )	±50 mA
DC $V_{CC}$ or Ground Current	±50 mA
per Output Pin	
DC Latchup Source or Sink Current	±300 mA
Junction Temperature (Plastic)	+150°C
Storage Temperature	-65°C to +150°C
Lead Temperature (Solder, 4sec)	
100L FBGA	220°C
100L TQFP	220°C
Max Package Power Capacity @ 25°C	
100L FBGA	3.57W
100L TQFP	2.11W
Thermal Resistance ( $\theta_{JA}$ )	

100L FBGA	35°C/W
100L TQFP	59.1°C/W
Package Derating above +25°C	
100L FBGA	28.57mW/°C
100L TQFP	16.92mW/°C
ESD Last Passing Voltage (HBM Min)	1000V

**Recommended Operating Conditions**

Supply Voltage ( $V_{CC}$ )	
'STA112	3.0V to 3.6V
Input Voltage ( $V_I$ )	0V to $V_{CC}$
Output Voltage ( $V_O$ )	0V to $V_{CC}$
Operating Temperature ( $T_A$ )	
Industrial	-40°C to +85°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. National does not recommend operation of SCAN STA products outside of recommended operation conditions.

**DC Electrical Characteristics**

Over recommended operating supply voltage and temperature ranges unless otherwise specified

Symbol	Parameter	Conditions	Min	Max	Units
$V_{IH}$	Minimum High Input Voltage	$V_{OUT} = 0.1V$ or $V_{CC} - 0.1V$	2.1		V
$V_{IL}$	Maximum Low Input Voltage	$V_{OUT} = 0.1V$ or $V_{CC} - 0.1V$		0.8	V
$V_{OH}$	Minimum High Output Voltage All Outputs and I/O Pins	$I_{OUT} = -100 \mu A$ $V_{IN} = V_{IH}$ or $V_{IL}$	$V_{CC} - 0.2v$		V
$V_{OH}$	Minimum High Output Voltage TDO <sub>B0</sub> , TDO <sub>B1</sub> , TRIST <sub>B0</sub> , TRIST <sub>B1</sub> , Y0 <sub>B0</sub> , Y1 <sub>B0</sub> , Y0 <sub>B1</sub> , Y1 <sub>B1</sub> , TDO <sub>(01-06)</sub> , Y0 <sub>01</sub> , Y1 <sub>01</sub> , TRIST <sub>(01-03)</sub>	$I_{OUT} = -12 \text{ mA}$ All Outputs Loaded	2.4		V
$V_{OH}$	Minimum High Output Voltage TMS <sub>B0</sub> , TMS <sub>B1</sub> , TCK <sub>B0</sub> , TCK <sub>B1</sub> , $\overline{\text{TRST}}_{B0}$ , $\overline{\text{TRST}}_{B1}$ , TMS <sub>(01-06)</sub> , TCK <sub>(01-06)</sub> , $\overline{\text{TRST}}_{(01-06)}$	$I_{OUT} = -24\text{mA}$	2.2		V
$V_{OL}$	Maximum Low Output Voltage All Outputs and I/O Pins	$I_{OUT} = +100 \mu A$ $V_{IN} = V_{IH}$ or $V_{IL}$		0.2	V
$V_{OL}$	Maximum Low Output Voltage TDO <sub>B0</sub> , TDO <sub>B1</sub> , TRIST <sub>B0</sub> , TRIST <sub>B1</sub> , Y0 <sub>B0</sub> , Y1 <sub>B0</sub> , Y0 <sub>B1</sub> , Y1 <sub>B1</sub> , TDO <sub>(01-06)</sub> , Y0 <sub>01</sub> , Y1 <sub>01</sub> , TRIST <sub>(01-03)</sub>	$I_{OUT} = +12 \text{ mA}$		0.4	V
$V_{OL}$	Maximum Low Output Voltage TMS <sub>B0</sub> , TMS <sub>B1</sub> , TCK <sub>B0</sub> , TCK <sub>B1</sub> , $\overline{\text{TRST}}_{B0}$ , $\overline{\text{TRST}}_{B1}$ , TMS <sub>(01-06)</sub> , TCK <sub>(01-06)</sub> , $\overline{\text{TRST}}_{(01-06)}$	$I_{OUT} = +24\text{mA}$		0.55	V
VIKL	Maximum Input Clamp Diode Voltage	I <sub>IK</sub> = -18mA		-1.2	V
$I_{IN}$	Maximum Input Leakage Current (non-resistor input pins)	$V_{IN} = V_{CC}$ or GND		±5.0	μA

## DC Electrical Characteristics (Continued)

Over recommended operating supply voltage and temperature ranges unless otherwise specified

Symbol	Parameter	Conditions	Min	Max	Units
$I_{ILR}$	Input Current Low (Input and I/O pins with pull-up resistors: $TDI_{B0}$ , $TDI_{B1}$ , $TMS_{B0}$ , $TMS_{B1}$ , $\overline{TRST}_{B0}$ , $\overline{TRST}_{B1}$ , $A0_{B0}$ , $A1_{B0}$ , $A0_{B1}$ , $A1_{B1}$ , $TDI_{(01-06)}$ , $A0_{01}$ , $A1_{01}$ )	$V_{IN} = GND$	-45	-200	$\mu A$
$I_{IH}$	Input High Current (Input and I/O pins with pull-up resistors: $TDI_{B0}$ , $TDI_{B1}$ , $TMS_{B0}$ , $TMS_{B1}$ , $\overline{TRST}_{B0}$ , $\overline{TRST}_{B1}$ , $A0_{B0}$ , $A1_{B0}$ , $A0_{B1}$ , $A1_{B1}$ , $TDI_{(01-06)}$ , $A0_{01}$ , $A1_{01}$ )	$V_{IN} = V_{CC}$		5.0	$\mu A$
$I_{OZ}$	Maximum TRI-STATE Leakage Current Outputs and I/O pins without pull-up resistors			$\pm 5.0$	$\mu A$
$I_{CC}$	Maximum Quiescent Supply Current	$V_{IN} = V_{CC}$ or GND		3.8	mA
$I_{CCD}$	Maximum Dynamic Supply Current	$V_{IN} = V_{CC}$ or GND, Input Freq = 25MHz		68	mA

## AC Electrical Characteristics: Stitcher Transparent Mode

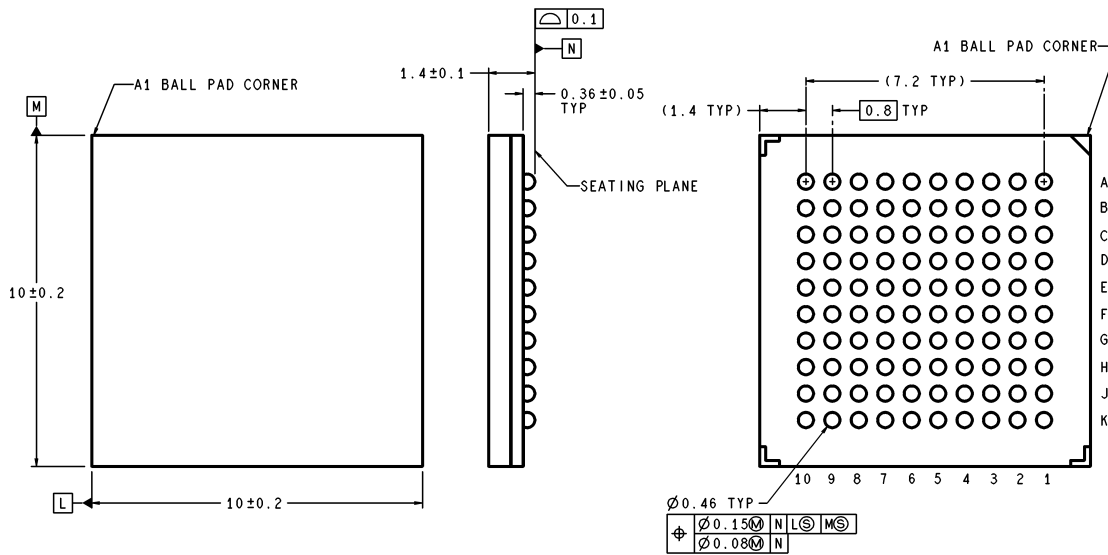
Over recommended operating supply voltage and temperature ranges unless otherwise specified.

Symbol	Parameter	Conditions	Typ	Max	Units
$t_{PHL}$ , $t_{PLH}$	Propagation Delay $TDI_{B0}$ to $TDO_{B1}$ , $TDI_{B1}$ to $TDO_{B0}$			12.5	ns
$t_{PHL}$ , $t_{PLH}$	Propagation Delay $TDI_{B0}$ to $TDO_{01}$ , $TDI_{B1}$ to $TDO_{01}$			12.5	ns
$t_{PHL}$ , $t_{PLH}$	Propagation Delay $TDI_{LSPn}$ to $TDO_{LSPn+1}$			12.5	ns
$t_{PHL}$ , $t_{PLH}$	Propagation Delay $TMS_{B0}$ to $TMS_{B1}$ , $TMS_{B1}$ to $TMS_{B0}$			12.5	ns
$t_{PHL}$ , $t_{PLH}$	Propagation Delay $TMS_{B0}$ to $TMS_{(01-06)}$ , $TMS_{B1}$ to $TMS_{(01-06)}$			12.5	ns
$t_{PHL}$ , $t_{PLH}$	Propagation Delay $\overline{TRST}_{B0}$ to $\overline{TRST}_{B1}$ , $\overline{TRST}_{B1}$ to $\overline{TRST}_{B0}$			12.5	ns
$t_{PHL}$ , $t_{PLH}$	Propagation Delay $\overline{TRST}_{B0}$ to $\overline{TRST}_{(01-06)}$ , $\overline{TRST}_{B1}$ to $\overline{TRST}_{(01-06)}$			12.5	ns

## Capacitance & I/O Characteristics

Refer to National's website for IBIS models at <http://www.national.com/scan>

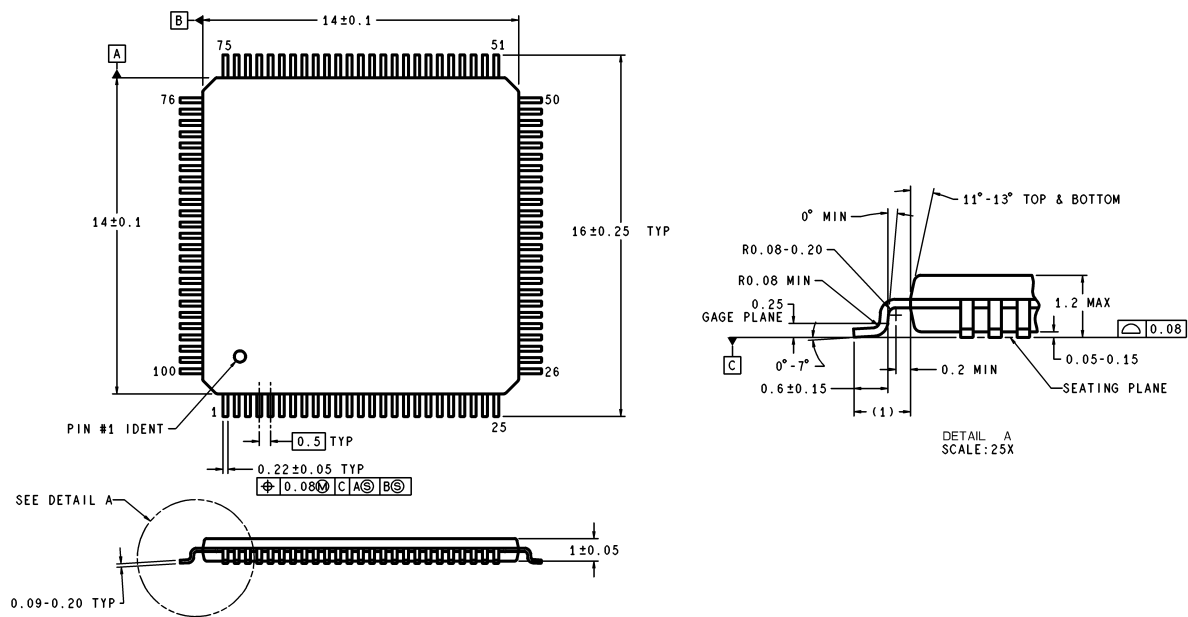
# Physical Dimensions inches (millimeters) unless otherwise noted



DIMENSIONS ARE IN MILLIMETERS

SLC100A (Rev B)

**100-Pin BGA**  
**NS Package Number SLC100a**  
**Ordering Code SCANSTA112SM**



DIMENSIONS ARE IN MILLIMETERS

VJD100A (Rev B)

**100-Pin TQFP**  
**NS Package Number VJD100a**  
**Ordering Code SCANSTA112VS**

## Notes

### LIFE SUPPORT POLICY

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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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