

## Xecom XE24S100 the Smallest, Complete 2.4 GHZ FHSS Transceiver

### Description

The Xecom XE24S100 is a miniature 2.4 GHz Spread Spectrum transceiver. It includes all RF hardware and a micro-controller to manage the communications link. The micro-controller manages all communications task including configuration, data packaging, and Frequency Hopping. The result is a complete wireless data communications solution.

The XE24S100 package is unique because of its size (less than 1.4 square inches), its leadless surface-mount design, and the availability of an on-board chip antenna. No competitive products can offer a solution as flexible, convenient, and easy to integrate,

There are two XE24S100 models; the XE24S100C with the on-board chip antenna and the XE24S100D with dipole antenna connector. The dipole antenna improves range while the chip antenna lowers system cost and simplifies integration. Development Kits are available for each version. A pin-compatible, higher power variant is also available, the XE24St00, for applications with longer range requirements.

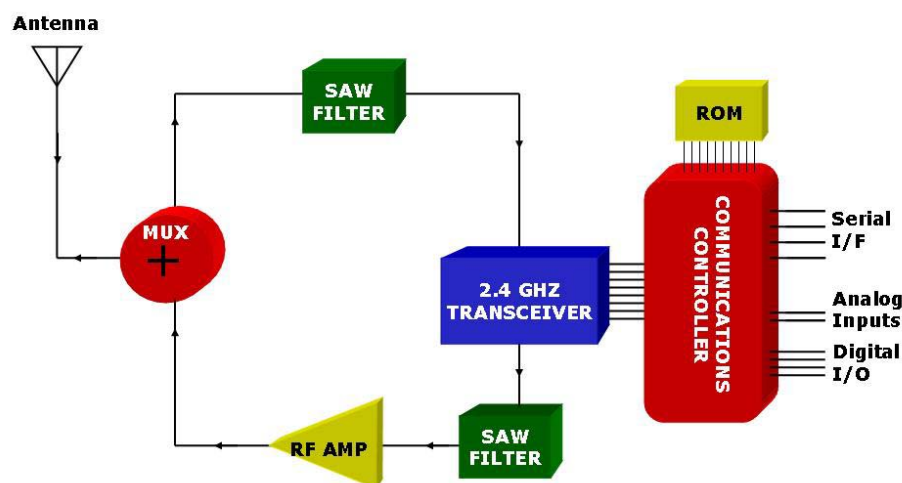
### Models

- XE24S100C: Includes on-board chip antenna
- XE24S100D: Includes Dipole Antenna connector
- XE24S100DK-C: XE24S100C Development Kit
- XE24S100DK-D: XE24S100D Development Kit

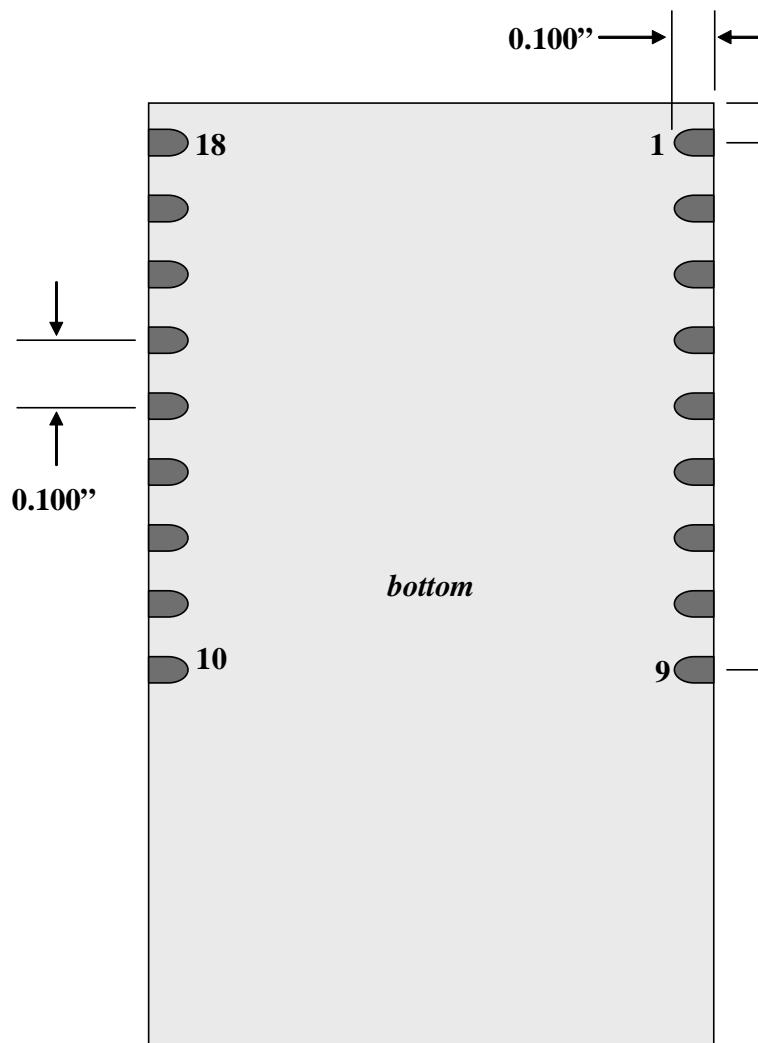
### Features

- 1.55" x 0.9" x 0.12" Leadless Surface-Mount package
- Utilizes globally available 2.4 GHz ISM band
- Control and Configuration with AT commands.
- 254 unique node addresses plus 254 unique Group IDs allow multiple large networks to coexist.
- Programmable Transmit Power Output, max. 100 mW
- Typical Receiver Sensitivity -87 dBm
- Typical Throughput rate 20,000 bps
- Obstructed signal range 150 feet (XE24S100D)
- Multiple Low Power Operating modes
- SensorOnAir™ (patent pending) allows direct connection of sensors to the Smart Transceiver
- Count-Off™ (patent pending) allows the host node to download the status of all nodes in under 10 seconds.
- FCC Part 15 Modular Certification

### XE24S100 Block Diagram



## XE24S100 MECHANICAL SPECIFICATIONS



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## Using the XE24S100 Power Saving Modes

The XE24S100 includes three low power operating modes (Sleep, Power-Down and RF Monitor) to allow the host application to make maximum use of the available power. The #P command selects the transceiver operating mode when it is not actively transmitting or receiving data. Below are descriptions of all of the available selections.

**IDLE:** In Idle Mode all XE24S100 circuits are powered and available for immediate action. This includes the RF receiver which actively monitors the air for an incoming communications request.

**SLEEP:** In Sleep Mode all XE24S100 circuits are powered-down to minimize power consumption. The XE24S100 cannot accept commands or respond to incoming RF communications requests from Sleep mode. Any input on TXD will wake the transceiver and return it to the previous mode, either the Idle or Power-Down Mode. Current draw in Sleep Mode is less than 50 microamps.

**POWER-DOWN:** In Power-Down Mode all RF circuitry is shut down but the communications controller remains active to accept AT commands. The XE24S100 cannot respond to incoming RF communications requests. If a transmit RF or receive RF command is received, the XE24S100 can activate the RF section in under 200 microseconds. Current draw in Power-Down Mode is less than 2 milliamps.

**RF MONITOR MODE:** RF Monitor Mode holds the transceiver in power down mode for an interval set by Register S110. The transceiver then activates, turns on its receiver, and checks the air for incoming messages. If no messages are detected within 200 milliseconds, the transceiver returns to power down mode. If carrier is detected, the transceiver completes the transaction before returning to power down mode. S110 selects an interval of 1 to 60 seconds. Power consumption in RF Monitor Mode ranges from 1 to 10 milliamps depending upon the activation interval.

### AT COMMAND CONTROL

The XE24S100 power saving modes are controlled by the AT#Pn command as described below.

AT#P0    Select Idle mode.

AT#P1    Select Sleep Mode.

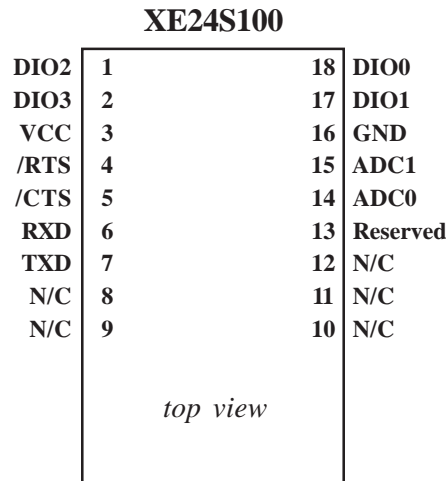
AT#P2    Select Power-Down Mode.

AT#P3    Select RF Monitor Mode

**RF MONITOR INTERVAL:** S110=n

Values of 1 to 60 set the RF Monitor interval in 1 second increments

## XE24S100 PIN CONFIGURATION



SIGNAL	PINS	DESCRIPTION
DIO2	1	DIO2 may be programmed as either a digital input or digital output. It connects directly to the communications controller in the XE24S100.
DIO3	2	DIO3 may be programmed as either a digital input or digital output. It connects directly to the communications controller in the XE24S100.
VCC	3	3.3 Volt power for the XE24S100.
/RTS	4	Request to Send provides hardware flow control from the host system. The host system drives /RTS high to signal the XE24S100 to temporarily stop the flow of data on RXD.
/CTS	5	Clear to Send provides hardware flow control from the XE24S100. The XE24S100 drives /CTS high to signal the host to temporarily stop the flow of data on the TXD.
RXD	6	Received Data is the data output from the XE24S.
TXD	7	Transmit Data is the data input to the XE24S
N/C	8-12	No Connection
Reserved	13	This Pin is reserved for future use
ADC0	14	Analog Input 0 to the XE24S100 communications controller. ADC0 connects to an internal 12-bit Analog to Digital Convertor. ADC0 may also be configured as a digital input if no analog inputs are required.
ADC1	15	Analog Input 1 to the XE24S100 communications controller. ADC1 connects to an internal 12-bit Analog to Digital Convertor. ADC1 may also be configured as a digital input if no analog inputs are required.
Ground	16	Common voltage reference for the XE24S100.
DIO1	17	DIO1 may be programmed as either a digital input or digital output. It connects directly to the communications controller in the XE24S100.
DIO0	18	DIO0 may be programmed as either a digital input or digital output. It connects directly to the communications controller in the XE24S100.

## ABSOLUTE MAXIMUM RATINGS

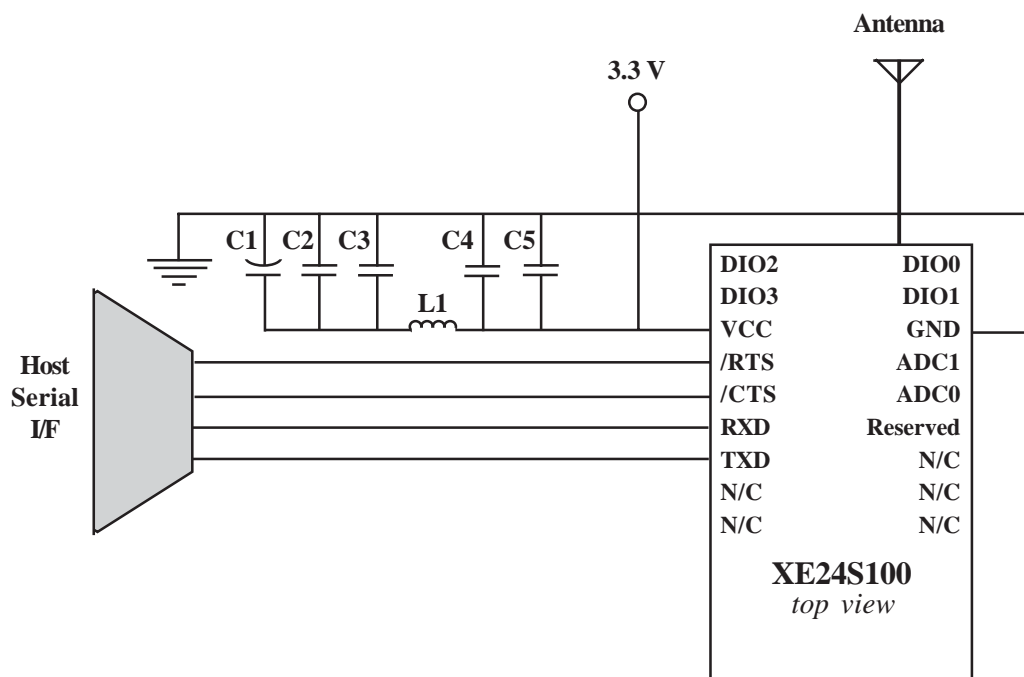
VCC	3.6 Volts
Storage Temperature	-55° C to +125° C
Operating Temperature Range	-40° C to +85° C

WARNING: Exceeding any of these ratings will void the warranty and may damage the device

## XE24S100 ELECTRICAL SPECIFICATIONS

Parameter	Min	Typ	Max	Units	Comments
VCC	3.0	3.3	3.6	Volts	
ICC			200	mA	Transmit (100 mW output)
		30		mA	Receive Mode
		20		mA	Idle Mode
	1		10	mA	RF Monitor
			1.0	mA	Power-Down Mode
			0.050	mA	Sleep Mode
Output Power:	4.5		100	mW	50 Ohm Load
Wireless Receive Sensitivity		-87		dBm	
Range thru Physical Obstructions		150		feet	500 mW output
Frequency Hopping Channels		TBD			
Frequency Band	2.400		2.4835	GHz	
Antenna Output Impedance		50		Ohms	
Latency		TBD		mSec	
Voh	2.4			Volts	
Vol			0.8	Volts	
Vih	2.0			Volts	
Vil			0.4	Volts	

**XE24S100 TYPICAL CONNECTION DIAGRAM**



**Parts List for XE24S100 Typical Connection Diagram**

Reference Designation	Qty	Description
C1	1	Capacitor, Electrolytic, 100 ufd, 10 Volts
C2, C4	2	Capacitor 0.1 ufd, 10 Volts
C3, C5	2	Capacitor 47 pfd, 10 Volts
L1	1	TBD
Antenna *	1	50 Ohm, 1/4 Wave;

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## XE24S100 COMMUNICATIONS CONTROLLER

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An internal micro-controller serves as the XE24S100 communications controller. This micro-controller manages the host interface, manages the wireless link, and formats data for the RF communications.

### HOST INTERFACE

The XE24S100 has two primary system interfaces; the serial interface and the direct sensor interface supported by SensorOnAir™. The communications controller manages both interfaces.

#### Serial Interface

The XE24S100 supports a 4-line serial interface. Control and configuration of the transceiver takes place through the serial interface using modem-like AT commands. The serial data rate is configurable from 1200 to 115.2K bits per second. The supported serial interface signals are listed below.

TXD - Transmit Data; input for commands and for Data to be transmitted on the wireless link.

RXD - Received Data; the output for received RF data and responses to AT commands.

/RTS - Request to Send, hardware flow control input. The host raises /RTS to tell the XE24S100 to stop passing data on RXD.

/CTS - Clear to Send, is the hardware flow control output. The XE24S100 raises /CTS to stop data input on the TXD lead.

#### XE24S100 AT Command Format

Each command follows a standard command format as described below. Commands are accepted at data rates from 1200 to 115,200 bps. The default serial data rate is 9600 bps and is changed using register S23.

**Command Prefix** - Each command, except A/, begins with the AT prefix. The "A" and "T" may be either both upper case or both lower case but cannot be of different cases. The prefix identifies parity of the commands sent to the XE24S100 by comparing the parity bits of the "A" and the "T" characters.

**Command Line** - Commands may be strung together in a single command line of up to 30 characters. Commands in the command string are executed in the sequence they appear. An "ERROR" response will be issued if the command buffer is overfilled and none of the commands will be executed.

**Omitted Parameters** - Many commands include a parameter which determines the function setting. When the command parameter is omitted from the command string, it is assumed to be a 0.

**Result Codes** - Result codes are normally issued after each action. Result codes may be provided as full words, numeric codes, or may be disabled. When numeric result codes are chosen, each result code ends with a Carriage Return. Full word result codes are preceded and followed by a Line Feed and Carriage Return.

**Disconnect Sequence** - A 3-character sequence initiates a disconnect of the wireless link. The sequence "~~~" is assigned to disconnect the link.

#### DIRECT CONNECTION OF SENSORS

SensorOnAir™ permits sensors to be connected directly to the XE24S100 without an application controller. The XE24S100 communications controller controls the operation of the sensors.

#### Sensor I/O Lines™

SensorOnAir™ controls the operation of 6 I/O lines. This includes 2 analog inputs, ADC0 and ADC1, and 4 digital I/O lines, DIO0, DIO1, DIO2, and DIO3. ADC0 and ADC1 are connected to a 12-bit analog to digital converter and use a 2.5 volt reference derived from VCC as their reference voltage. The digital I/O lines can be programmed to act as either inputs or outputs.

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## XE24S100 COMMUNICATIONS CONTROLLER (continued)

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### Configuring for Sensor Operation

All SensorOnAir™ functions are performed by the XE24S100 communications controller. Modem-like AT commands loaded through the serial interface, program the functions of the analog and digital lines. The configuration is then stored in Flash memory. This allows the XE24S100 to be programmed and then installed in the application.

### SensorOnAir Commands™

Below is a list of the commands and registers used to program SensorOnAir™ operation.

**S107** - Defines the I/O lines. The two analog inputs, ADC0 and ADC1, can also be defined as digital I/O lines if needed. The four digital lines, DIO0, DIO1, DIO2, and DIO3; can be set as either inputs or outputs. The value of this register is stored in flash memory.

**AT&IA<sub>n</sub>?** - This command allows a local host to read the value of Analog Input “n.”

**AT&ID<sub>n</sub>?** - This command allows a local host to read the status of Digital I/O “n.”

**AT&ID<sub>n</sub>=z** - This command allows a local host to set the condition of the digital output “n.” When z=0 the output is set to a logic low; when z=1 the output is set to a logic high.

**AT#IxxxAn?** - This command allows the value of Analog Input “n” on node address “xxx” to be read remotely.

**AT#IxxxDn?** - This command allows the status of Digital I/O “n” on node address “xxx” to be read remotely

**AT#IxxxDn=z** - This command allows the state of digital output “n” on node address “xxx” to be set remotely. When z=0 the output is set to a logic low; when z=1 the output is set to a logic high.

### WIRELESS COMMUNICATIONS

The communications controller manages the RF Link including the frequency hopping algorithm; collision avoidance, node addressing, and data packets. The communications controller supports point-to-point, point-to-multipoint or multipoint networks.

### Carrier Sense Multiple Access (CSMA)

To prevent collisions between nodes, the XE24S100 uses a Carrier Sense Multiple Access protocol at each transceiver. All nodes listen for link activity before initiating a session. If a wireless link already exists, the transceiver waits until that session is complete before initiating a new wireless link.

### Data Packets

Data presented by the system host is placed into packets by the XE24S100 communications controller for transmission across the wireless link. These packets provide addressing and error correction for the wireless communications. The received data is extracted from the packets before being passed to the serial interface.



## XE24S COMMUNICATIONS CONTROLLER (continued)

### Sample File Transfer

Transmitter		Receiver		Description
TXD	RXD	TXD	RXD	
AT#T01<cr>				Initiate File Transfer
	:<cr>		FILE<cr>	Link Established
abc...z			abc...z	File Data
3 sec pause in data			A718<cr>	Checksum at End of File Transfer
			OK<cr>	File Transfer Successful
			<i>or</i> ERROR<cr>	Error Detected in File Transfer

Note: In the above example that the file transfer is assumed to be completed when three seconds pass with no data being presented to the TXD input on the serial port.

### Multipoint Network

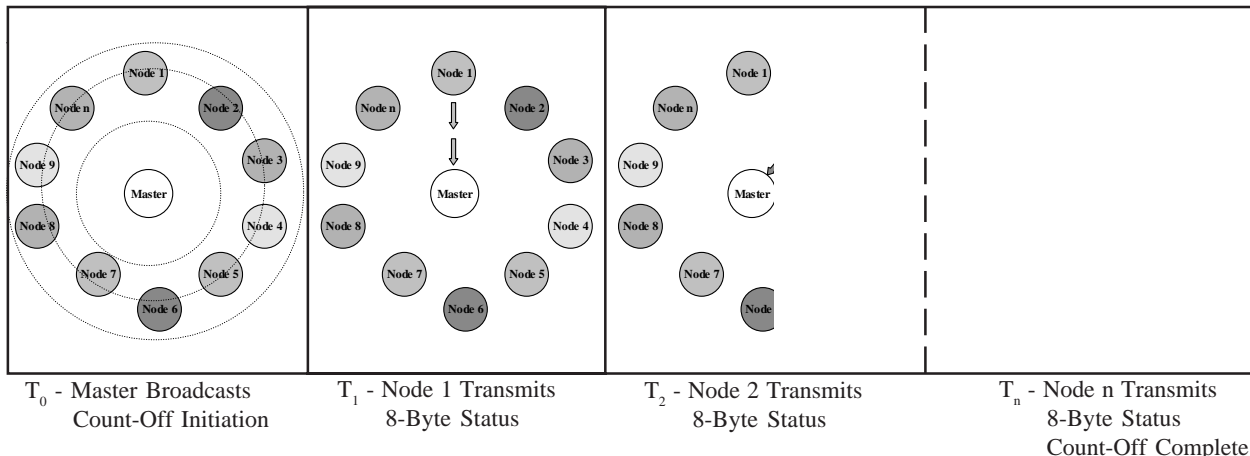
System designers can create a point-to-multipoint network with up to 253 remote nodes. The master node is assigned address 1. The remote nodes use addresses 2 to 254. For efficient network operation, Count-Off™ allows the master node to poll the entire network in under 10 seconds.

Count-Off™ permits the master node in a point-to-multipoint system to quickly check the status of all network nodes. It creates a temporary time division multiplexing scheme which permits each node to report its status without the handshaking sequence normally required for a wireless data exchange.

Count-Off™ is initiated by the AT#C command, from the host system. The master node broadcasts the command to all network nodes. Upon receipt of the command each remote node initializes an internal timer. Then in sequence by address each node transmits an 8-byte status message. The status message is programmed with the AT#E: or AT#E= command. The status byte is passed to the host system in the correct sequence upon receipt of the Count-Off message from the master node.

Using Count-Off™ network reporting will be completed in less than 10 seconds. Based on the status information the host can then elect to service any of the remote nodes.

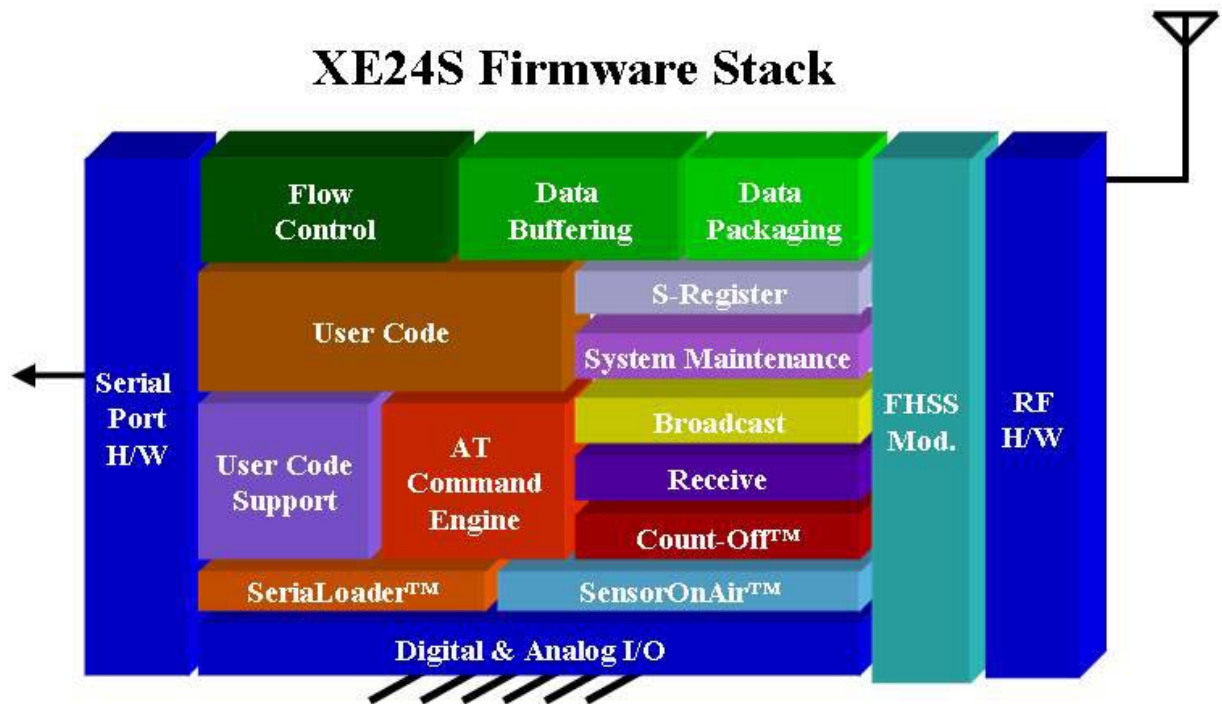
### COUNT-OFF™ SEQUENCE



## XE24S100 COMMUNICATIONS CONTROLLER (continued)

### USER CODE

The Texas Instruments MSP430F148 microcontroller serves as the communications controller in the XE24S100 transceiver modules; however, the communications functions do not fully utilize the capabilities of the microcontroller. Xecom has created a way for our customers to run their simple remote monitoring application on the transceiver's communications controller saving the complexity and cost of incorporating a separate microcontroller.



Has shown in the software block diagram above, the User Code interfaces to the rest of the XE24S code through the User Code Support block. The User Code Support block interfaces to the AT command engine and serial interface and supports other features such as sub routine calls.

To prevent the User Code from interfering with the communications responsibilities of the controller, the User Code must be written in User Tasks. Each User task is a simple state machine that can quickly complete its function. A full description of the requirements of the User Tasks can be found in the "XE24S User Application Programmers Guide.

## AT COMMANDS

**An asterisk indicates the factory default**

**A Answer Command** - force response to a link request

**Dn Initiate a Wireless Link** - attempt to connect with the transceiver at address n.

**En Echo Characters** -

n=0 Characters not Echoed

n=1 Characters Echoed \*

**In Product Identification** -

n=0 Display Product Code

n=1 Display Product Name

n=2 Display Model Number

n=3 Display Copyright

n=4 Display Firmware Revision

**Qn Result Code Display** -

n=0 Display Result Codes \*

n=1 Do not Display Result Codes

**Sn= Set Value of Register Sn**

**Sn? Read Value of Register Sn**

**Vn Response Type** -

n=0 Numeric Responses

n=1 Full Word Responses \*

**Zn Reset** - executes a soft Reset

n=0 Reset to Values in User Profile 0 \*

n=1 Reset to Values in User Profile 1

**&F Restore Factory Settings** - return commands and registers to default values.

**&IAN? Read Local Analog Input “n”** - allows the host to read local analog inputs.

n=0 Read input ADC0

n=1 Read input ADC1

**&IDn? Read Local Digital Input “n”** - read the status of the local digital inputs.

n=0 Read input DIO0

n=1 Read input DIO1

n=2 Read input DIO2

n=3 Read input DIO3

n=4 Read DIO4 (ADC0 set as digital I/O)

n=5 Read DIO5 (ADC1 set as digital I/O)

**&IDn=z Set Local Digital Output “n”** - sets the state of the local digital outputs. z=0 sets the output to a logic low; z=1 to a logic high.

n=0 Set output DIO0

n=1 Set output DIO1

n=2 Set output DIO2

n=3 Set output DIO3

**&Kn Flow Control** - selects the flow control used between the system host and the XE24S100

n=0 Flow Control Disabled

n=3 RTS/CTS, hardware Flow Control

n=4 XON/XOFF, in-band Flow Control

**&V View Active Configuration** - sends the active configuration data to the system host.

**&Wn Store Current Configuration** - loads the current configuration into User Profile 0 or 1.

n=0 load configuration into User Profile 0

n=1 load configuration into User Profile 1

**#B Wireless Broadcast** - initiates wireless broadcast for diagnostic purposes.

**#C Count-Off Request (ASCII)** - Initiates a “Count-off” sequence. Status report in ASCII.

**#E: Count-Off Response (ASCII)** - Programs the 8 byte ASCII “Count-off” status message.

**#E= Count-Off Response (Hex)** - Programs the 8 byte “Count-off” response in hex format.

## AT COMMANDS

### #IxxxAn? Read Analog Input “n” at Node

**Address xxx** - allows analog input values at any node to be read remotely.

n=0 Read input ADC0

n=1 Read input ADC1

### #IxxxDn? Read Digital Input “n” at Node

**Address xxx** - This command allows digital input status to be read remotely.

n=0 Read input DIO0

n=1 Read input DIO1

n=2 Read input DIO2

n=3 Read input DIO3

n=4 Read DIO4 (ADC0 set as digital I/O)

n=5 Read DIO5 (ADC1 set as digital I/O)

### #IxxxDn=z Set Digital Output “n” at Node

**Address xxx** - remotely modify digital output n. A 0 sets the output to a logic low; a 1 sets it to a logic high.

n=0 Set output DIO0

n=1 Set output DIO1

n=2 Set output DIO2

n=3 Set output DIO3

### #Pn Low Power Operation - Sets the XE24S100 reduced power modes.

0 Idle mode.

1 Sleep Mode.

2 Power-Down Mode.

3 RF Monitor Mode

### #R Receive Broadcast - Allows XE24S100 to receive a broadcasted message and present it on the serial interface.

## XE24S100 Responses

<u>Numeric</u>	<u>Full Word</u>	<u>Description</u>
0	OK	Successfully executed command line
1	CONNECT RF	Wireless Connection Established
2	RING	Wireless Link Request Detected
3	DISCONNECT	Lost Wireless Link
4	ERROR	Error in command line, or file transfer
6	NO CONNECTION	Failed to Establish Wireless Link
7	BUSY	Link Request Time Out has occurred
8	SORRY	No Response to Count-Off Request
9	WAIT	Wireless Link is not available
	FILE	File Transfer Mode

## XE24S Configuration Registers

**S0 Answer Wireless Link Request:** S0 determines if the XE24S100 automatically responds to a wireless link request.

S0=0 No response to link requests

S0=1 Automatically respond to link request

S0=128 Enter Broadcast mode on power-up. The register value must be stored in nonvolatile memory with the AT&W command.

**S2 Wireless Disconnect Character** - S2 sets the ASCII character used in the disconnect sequence. The default character is tilde "~".

Range: 0-255

Default: 126

**S7 Link Set-up Timer** - S7 sets the length of time in seconds that the transceiver attempts to create a link with the destination node.

Range: 0-60

Default: 10

**S10 Link Recovery Timer** - S10 determines the how long in seconds that the transceiver tries to recover a broken link.

Range: 0-60

Default: 10

**S12 Disconnect Guard Timer** - S12 sets the guard timer before and after the disconnect sequence in milliseconds. If any characters are received within the window defined by S12, the disconnect request will be ignored..

Range: 0-255

Default: 20

Units: Milliseconds

**S14 Bit-mapped Register** - S14 stores the values of the ATE, ATQ and ATV commands.

**S23 Serial Interface Data Rate** -

Range 1-10

1 = Set serial data rate to 1200 BPS

2 = Set serial data rate to 2400 BPS

3 = Set serial data rate to 4800 BPS

4 = Set serial data rate to 9600 BPS\*

5 = Set serial data rate to 14400 BPS

6 = Set serial data rate to 19200 BPS

7 = Set serial data rate to 28800 BPS

8 = Set serial data rate to 38400 BPS

9 = Set serial data rate to 57600 BPS

10 = Set serial data rate to 115200 BPS

Default: 4

**S39 Bit-mapped Register** - S39 stores the value of the AT&K command.

**S104 Group ID Number** - S104 sets the Group ID number. Multiple groups may be active in the same area. Only units with the same Group ID number can communicate.

Range: 0-255

Default: 0

**S105 Node Address** - S105 sets the transceiver's node address. Each unit in a network is required to have a unique node address.

Range: 1-254

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## XE24S Configuration Registers

**S107 I/O Configuration** - S107 is a bit-mapped register which defines the local I/O lines.

Bit 0=0 ADC0 and ADC1 defined as digital I/O  
=1 ADC0 and ADC1 defined as Analog inputs

Bit 1 = reserved

Bit 2= 0 DIO0 defined as an output  
= 1 DIO0 defined as an input

Bit 3= 0 DIO1 defined as an output  
= 1 DIO1 defined as an input

Bit 4= 0 DIO2 defined as an output  
= 1 DIO2 defined as an input

Bit 5= 0 DIO3 defined as an output  
= 1 DIO3 defined as an input

Bit 6= 0 DIO4 defined as an output (Bit 0 must be equal to 0)  
= 1 DIO4 defined as an input

Bit 7= 0 - DIO5 defined as an output (Bit 0 must be equal to 0))  
= 1 - DIO5 defined as an input

Default: 193

**S108 Transmit Level Control** - S108 sets the XE24S100 transmitter output level

0 = 6.5 dBm (4.5 mW)  
1 = 8.5 dBm (7 mW)  
2 = 10.5 dBm (11 mW)  
3 = 12.5 dBm (18 mW)  
4 = 14.5 dBm (28 mW)  
5 = 16.5 dBm (45 mW)  
6 = 18.5 dBm (70 mW)  
7 = 20 dBm (100 mW) \*

**S110 RF Monitor Interval** - S110 sets the intervals that the XE24S100 wakes to check for a valid RF carrier signal. Values from 1 to 60 set the interval in seconds. The default value is 2 seconds.

Range: 1-60

Default: 2

## FCC PART 15 REGULATIONS

### Mounting the XE24S100 in Your Assembly

The XE24S100 must be mounted horizontally on your printed circuit board to maintain proper orientation of the transceiver. Standoffs should also be used on the side opposite the pin row to maintain clearance between the XE24S100 and your printed circuit board. The XE24S100 may not be co-located with any other antenna or transmitter.

### XE24S100 Antenna

The XE24S100 is certified for compliance to FCC Part 15 rules only using the Xecom *TBD*, 1/4 wave monopole antenna. Use of any other antenna violates FCC Part 15 rules.

### FCC Part 15 Certification

The XE24S100 has been certified per FCC Part 15 rules for integration into OEM products without further testing or certification. This certification is your assurance that the XE24S100 will not cause harmful interference.

### Labeling Requirements

FCC rules require the Original Equipment Manufacturer using the XE24S100 to place an appropriate label on the outside of the finished equipment. The label must be clearly visible and include the information shown below.

#### Contains Transmitter Module

**FCC ID: TBD**

#### **WARNING:**

This device complies with Part 15 of the FCC Rules. Its operation is subject to the following conditions:

- (1) This device may not cause harmful interference.
- (2) This device must accept any received interference including interference that may cause undesired operation.

### Limitations

The XE24S100 is registered under FCC Part 15 Rules. To utilize this registration on your OEM System you must follow the applications circuit provided in this data sheet and use the listed antennas. Any changes or modifications to the recommended circuit must be approved by Xecom. Failure to seek Xecom's approval for modifications could void certification of the end product.

### Warning: RF Exposure

The XE24S100 is approved for mobile, base station and mobile applications. A minimum separation of 20 centimeters should be maintained between the antenna and the equipment operator. For mobile applications check the minimum separation distances defined below. To ensure compliance, operation at distances closer than those defined is not recommended.

The Warning message below must be included in the user Manual for the end product.

*To comply with FCC RF exposure requirements for mobile transmitting devices, this transmitter should only be used or installed at locations where there is at least 20 cm separation distance between the antenna and all persons.*

### FCC Notifications

The XE24S100 generates radio frequency energy. It must be installed according to the manufacturer's guidelines stated in the data sheet or it has the potential to cause interference with other radio devices. Testing has been performed to assure that it conforms with the FCC Part 15 rules for intentional and unintentional radiators.

No further EMI compliance testing of the *transmitter* is required as long as the 20 cm separation and co-location requirements are observed. Each new use of the module will, however, need to be scanned for unintentional radiation from digital clocks, etc.

All necessary calibration has been performed at the time of manufacture. Any modification of the device after it leaves the factory is a violation of FCC rules.



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**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 provided in the labeling, can be reasonably expected to result in significant injury to the user.

**A Critical Component** is any component of a life support device or system whose failure to perform can be reasonably expected to cause failure of the life support device or system, or to affect its safety or effectiveness.

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