



sedasys™

**SEDASYS® Connectivity Unit Operator's Manual**

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Ethicon  
Endo-Surgery

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## PRODUCT INFORMATION

Product Code	Product
SEDSCU01	SEDASYS Connectivity Unit (SCU)

## MANUFACTURED BY:

ETHICON ENDO-SURGERY, INC.  
4545 Creek Road  
Cincinnati, Ohio 45242-2839 USA



**External Standard Conformance TBD**

## OWNERSHIP

The SCU is the property of Ethicon Endo-Surgery, Inc., and is placed in the facility in accordance with the contractual arrangement between Ethicon Endo-Surgery and the facility.

## COMPLIANCE AND CERTIFICATE

### CE Declaration:

CE marking is a visible declaration by the manufacturer or his authorized representatives that the electrical equipment to which it relates satisfies all the provisions of the 1994 Regulations.

### FCC Compliance:

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

- This device may not cause harmful interference.
- This device must accept any interference that may cause undesired operation.

This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause interference to radio communications. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to

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provide reasonable protection against harmful interference. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the antenna of the radio/television receiver.
- Increase the separation between this equipment and the radio/television receiver.
- Plug the equipment into a different outlet so that the equipment and the radio/television receiver are on different power mains branch circuits.
- Consult a representative of EES or an experienced radio/television technician for additional suggestions.



**Note**

Changes or modification not expressly approved by EES for compliance could void the user's authority to operate the equipment.

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## SERVICE AND SUPPORT INFORMATION

### Within the USA contact:

EES Customer Support Center, 1-800-SEDASYS, 1-800-733-2797  
(English speaking only)

### Outside of USA contact:

Local Johnson & Johnson Affiliate office or closest Authorized  
Service Center

### Authorized Service Centers locations:

#### USA

#### Ethicon Endo-Surgery, Inc.

4480 Lake Forest Drive Suite 318

Cincinnati, OH 45242

1-800-SEDASYS (U.S.), 1-800-733-2797

**Phone:** 1-513-337-8901 (International calls - English speaking only)

**Email:** [sedasytechsupport@its.jnj.com](mailto:sedasytechsupport@its.jnj.com)



### WARNING

#### CMOS Battery Damage

Replace system's CMOS RAM battery only with the identical CR-2032 3V Lithium-ion coin cell (or equivalent) battery type to avoid risk of personal injury or physical damage to the equipment. Improper installation might cause battery to explode. Always dispose of used batteries according to the manufacturer's instructions, or as required by the local ordinance (where applicable).

Perchlorate Material – Special Handling May Apply.

See <http://www.dtsc.ca.gov/hazardouswaste/perchlorate/>

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## DOCUMENT CONVENTIONS

The following conventions are used throughout this manual:



Describes serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. Warnings alert the clinician to the possibility of serious injury, death, or other serious adverse reactions associated with the use or misuse of the system.



Pertains to information regarding any special care to be exercised by the practitioner and/or patient for the safe and effective use of the device. Precautions alert the clinician to the possibility of minor or moderate injury to the clinician or patient, or damage to the device associated with the use or misuse of the system.



Notes emphasize important details.

**Intended Use:** Refers to the objective intent of the persons legally responsible for the labeling of the device.

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### **SYMBOLS**

The following symbols will be physically located on one or more components of the system.

<b>Symbol</b>	<b>Description</b>
<b>NOT COMPLETE – TBD</b>	<b>NOT COMPLETE – TBD</b>

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# Chapter 1 Introduction

## SCU Overview

The SEDASYS<sup>®</sup> Connectivity Unit (SCU) is a communications interface device for use with the SEDASYS<sup>®</sup> System. The SCU automatically collects data from the SEDASYS<sup>®</sup> System that is required for usage billing, and transmits that information via the facility's IT network to Ethicon Endo-Surgery for processing and preparing an invoice for the facility.

The SEDASYS<sup>®</sup> System transmits the data, in an encrypted form, to the SCU. This communication is wireless and complies with IEEE 802.11-2007. The data is delivered to the SCU only when the SEDASYS<sup>®</sup> System detects communication with the SCU. The SCU then transmits the encrypted data through the facility's IT network to Ethicon Endo-Surgery. This communication can be wireless (IEEE 802.11-2007) or wired (IEEE 802.3). For either wireless or wired communication, the facility's IT network configuration should allow outbound communication to the internet with ports 80 and 443 open.

The encrypted data is typically a packet of TBD size delivered in 15 minute intervals. Data transferred will contain the case related data including identification of the hardware unit, case identification, and patient identification number. The clinician is instructed, in the SEDASYS<sup>®</sup> System manual, not to use a patient identifier (such as Social Security number or phone number) that is traceable to the patient outside of the clinical facility records.

The SCU can also deliver a printout, containing usage details, to the printer used in conjunction with the SEDASYS<sup>®</sup> System.

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## Chapter 2 Intended Use, Warnings and Precautions

The SEDASYS<sup>®</sup> Connectivity Unit (SCU) is intended only for use with the SEDASYS<sup>®</sup> System for the purpose of collecting and transferring usage data. Applying the SCU for use in another application, or modifying or tampering with the SCU, may affect the business agreement with Ethicon Endo-Surgery.

If it should become necessary to re-position after the initial installation, the following orientation information is provided.



**Figure 2-1 Approved and Preferred Orientation**

Figure 2-1 represents placement of the SCU on a flat surface and oriented with the front of the SCU facing the installer. Placement of the SCU shall be located a minimum of 1.5 meters (approximately five feet) from patients. Figure 2-1 represents an approved and the preferred placement orientation.



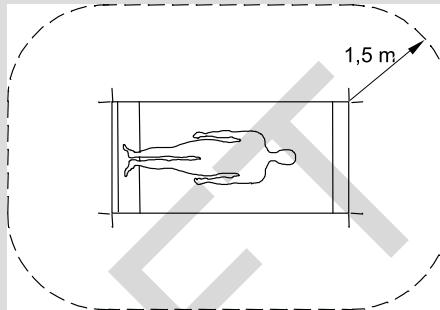
**Figure 2-2 Approved Orientation**

Figure 2-2 represents placement of the SCU on a flat surface and oriented with the front of the SCU facing down. This is not a stable orientation, and can only be used when the SCU is secured to prevent falling or tipping. Placement of the SCU shall be located a minimum of 1.5 meters (approximately five feet) from patients. Figure 2-2 represents an approved placement orientation but not preferred.

## Warnings

The following WARNINGS alert the user to the possibility of serious injury, death, or other serious adverse events associated with the use or misuse of the SEDASYS® System.

- 1 Do not place items on, or hang items from, the SCU. Doing so may result in a physical and/or electrical hazard.
- 2 Do not modify the installation (electrical or mounting) of the system. The SCU must be kept outside the “patient environment” to maintain electrical safety. The patient environment is defined as an area 1.5 m (4.92 feet) from the patient.



- 3 Do not store or place liquids on or near the SCU. Entry of liquids into the SCU may result in electric shock.
- 4 To help protect against electrical shock due to leakage current, use only power accessories (power cord, adaptor) supplied with the SCU.
- 5 In order to comply with FCC RF exposure limits, the antenna should be located at a minimum distance of 20 cm (8 inches) or more from the body of all persons.
- 6 Due to fire safety reasons the SCU must not be oriented in the positions shown below :



The above figure represents placement of the SCU on a flat surface and orientated with the back of the SCU facing down. This orientation represents an unstable condition and is not an approved placement orientation.



The above figure represents placement of the SCU on a flat surface and orientated with the side of the SCU facing down. This represents a placement orientation that is not approved.



**WARNING**



The above figure represents placement of the SCU on a flat surface and orientated with the top of the SCU facing down. This represents a placement orientation that is not approved.

## Precautions

The following PRECAUTIONS alert the user to the possibility of minor or moderate injury or damage to the device associated with the use or misuse of the SCU.



**Precaution**

- 1 To remove the device from external power, the power cable must be disconnected from wall outlet.
- 2 The system may not meet performance requirements if operated outside the specified temperature and humidity ranges.
- 3 Electronic equipment, such as portable and mobile RF communications equipment, can cause electrical interference with the system. Avoid operating the system near equipment that emits strong electromagnetic or radio frequency signals.
- 4 Do not place a covering or otherwise interfere with the ventilation of the SCU. Doing so may result in overheating.

## Notes

The following NOTES provide important information.



### Note

- 1 Placement of additional walls or structure between the SCU and SEDASYS<sup>®</sup> System or the SCU and IT network (if wireless), after installation, may interfere with the transfer of data.
- 2 Do not disconnect the SCU from power or the IT network.
- 3 Contact EES prior to changes to either the network configuration (hardware or setting) or the printer configuration.
- 4 Contact EES if SCU power indication is not "ON".
- 5 Contact EES if usage detail printout are not being printed as expected.
- 6 SCU is intended for use only with the SEDASYS<sup>®</sup> System.
- 7 The SCU and its supplied parts (for example the power cord and antenna) are to be handled carefully.
- 8 Only those parts supplied with the SCU are to be used in conjunction with the SCU.
- 9 Replacement parts are to be obtained only from EES.
- 10 Contact EES for instructions regarding the proper disposal of the SCU.

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# Appendix A Technical Information

**TBD-specifics to be confirmed**

Table A-1: Power Specifications

Characteristic	Performance
Input line voltage	100 to 240 volts AC
Input line frequency	50 to 60 Hz
Phase	Single

Table A-2: Environmental Specifications

Characteristic	Performance
Operating temperature	10 to 40 C (50 to 104 F)
Relative humidity	30% to 75%, noncondensing
Operating altitude	0 to 10,000 feet
Transport and storage temperature	0 to 60 C (32 to 104 F)

Table A-3: Electromagnetic Emissions

Characteristic	Compliance	Electromagnetic Environment - Guidance
RF Emissions	CISPR 22 Class B, FCC	The SCU is suitable for use in domestic environments.
RF Emissions	VCCI Class B, Japan	
RF Emissions (Digital Apparatus)	ICES-003 Class B, Canada	

Table A-4: Electromagnetic Immunity

Characteristic	Compliance
RF Immunity	CISPR 24 (EN55024)
Electromagnetic Magnetic Compatibility	Directive 2004/108/EC

Table A-5: Facility Communications Requirements

Characteristic	Performance
Wireless format	IEEE 802.11 b/g
Wired format	IEEE 802.3 (100BASE-T Ethernet)
Wireless encryption protocol	WEP-40 or WEP-104 or CCMP or TKIP
Wireless key structure	((Alpha, hexadecimal, alphanumeric, case sensitivity))
Wireless SSID	((Broadcast/not broadcasted))
Wired encryption protocol	WPA-PSK or WPA2-PSK AES

Table A-6: Electrical Safety Specifications

Characteristic	Compliance
Electrical Safety Standards	IEC 60950-1
	EN 60950-1
	UL 60950-1
	CAN/CSA-C22.2 No. 60950-1
	AS/NZS 60950-1
	AS/NZS 60950-1Amt1
	AS/NZS 60950-1Amt2
AS/NZS 60950-1Amt3	
Low Voltage	Directive 2006/95/EC2

Table A-7: Data Packet Information

Characteristic	Performance
Data packet size – typical	
Data transmission frequency - default	

Table A-8: Hazardous Material Information

Characteristic	Compliance
Restrictions on Hazardous Substances	RoHS Directive 2002/95/EC
Waste Equipment	WEEE 2002/96/EC

Table A-9: Telecommunications Information

<b>Characteristic</b>	<b>Compliance</b>
Radio Communication Devices	RSS-210: 2007
Exposure to RF	RSS-102: 2005
Radio Communication	FCC CFR Title 47, Part 15 Class B
Radio Communication	R&TTE Directive 1999/5/EC
Radio Communication	EN 300 328 V1.7.1
Radio Communication	EN 301 893 V1.4.1
Radio Communication	EN 301 489-1 V1.8.1
Radio Communication	EN 301 489-17 V1.3.2
Radio Communication	AS/NZS 4771:2000

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