

iSwitch

Wireless Universal Foot Control



Operation and Maintenance Manual



PATENTS PENDING

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Warnings and Cautions

Please read this manual and follow its instructions carefully. The words **warning**, **caution**, and **note** carry special meanings and should be carefully reviewed:

WARNING The personal safety of the patient or physician may be involved. Disregarding this information could result in injury to the patient or physician.

Caution Special service procedures or precautions must be followed to avoid damaging the instrument.

Note Special information to make maintenance easier or important information more clear.



An exclamation mark within a triangle is intended to alert the user to the presence of important operating and maintenance instructions in the literature accompanying the product.



A lightning bolt within a triangle is intended to warn of the presence of hazardous voltage. Refer all service to authorized personnel.

WARNING To avoid injury to the user and the patient and/or damage to this device, the user must:



1. Read this operating manual thoroughly and be familiar with its contents prior to using this equipment.
2. Carefully unpack the unit and check if any damage occurred during shipment. If damage is detected, please refer to the Service section in this manual.
3. Avoid removing covers on the unit and attempting internal repairs or adjustments not specifically detailed in this operating manual.
4. Pay close attention to the care and cleaning instructions in this manual. A deviation may cause damage to the device.
5. Never sterilize the Wireless Universal footswitch components.
6. Be completely familiar and comfortable with the operation of the Wireless Universal footswitch. Training may be required before some operators are thoroughly familiar with how to properly operate the footswitch.

7. When the Receiver is interconnected with other medical electrical equipment, leakage currents may be additive. Ensure all systems are installed according to the requirements of IEC 60601-1-1.

The Wireless Universal footswitch warranty is void if any of these warnings are disregarded.

WARNING *Federal law (United States of America) restricts this device to use by, or on order of, a physician.*



Stryker Endoscopy reserves the right to make improvements to the product described herein. The product therefore may not agree in detail to the published design or specifications. All specifications are subject to change without notice. Please contact your local Stryker Endoscopy Distributor listed in the Other Service section or phone your local Stryker Endoscopy sales representative or agent for information on changes and new products.

Symbol Definitions



Protective Earth Ground



Equipotentiality



Denotes compliance to CSA 22.2 No.601.1-M90 and UL60601-1.

Product Description and Intended Use

The Stryker Wireless Universal footswitch system is a wireless remote-control system that centralizes control of the various footswitch-operated devices found in the operating room.

The iSwitch is intended for use in surgical procedures where footswitch-operated devices, such as the Stryker TPS or SERFAS systems, are normally used. The iSwitch consolidates the functions of these devices into one wireless footswitch, freeing the operating room from excessive cables and foot controls.

The iSwitch consists of two main components:

1. A wireless **footswitch**, which provides pedals similar to those found on other footswitches and transmits radio signals to a radio receiver console
2. A radio **receiver** console, which routes commands from the footswitch to devices that connect to the receiver's rear panel.

Each component and its functions are described in the following pages.

Note The iSwitch is a wireless footswitch designed to replace multiple wired footswitches that surgeons are accustomed to using. Operators should ensure that they are completely familiar and comfortable with the operation of the device. Training may be required before some operators are thoroughly familiar with how to properly operate the footswitch. Users should be sure that they have received adequate training before using this device in surgical practice.

Note It is recommended to have a wired footswitch available in case of electromagnetic interference problems with the wireless connection.



This device includes RF transmitters and emits non-ionizing radiation.

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. See the "Electromagnetic Compatibility" section of this manual for more information.

To prevent radio interference with any licensed service, this device is intended to be operated indoors and away from windows to provide maximum shielding.

This device complies with FCC RF exposure limits set for indoor use only. Do not co-locate this device in close proximity to another transmitter antenna.

The Footswitch

The footswitch rests on the operating-room floor and provides foot control of all devices connected to the iSwitch system. The footswitch houses three buttons and two pedals, which enable the user to alternate between operating-room devices and perform device-specific functions. When a button or pedal is pressed, the footswitch transmits a radio signal to the receiver, where the command is then routed to the appropriate device.

The footswitch and its features are described in Figure 2 below.

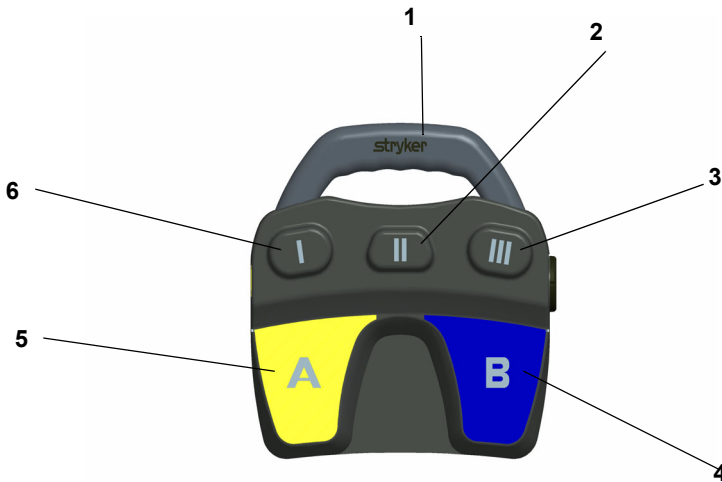


Figure 2: The footswitch

1. **Footswitch Handle**

2. **Button II (Mode Button):** Selects which device the footswitch will control. See the “System Settings” section of this manual for Mode options.

Note Button/pedal function for all other buttons and pedals depends on which operating-room device, or “mode,” is selected. See the “Using the footswitch controls” section in this manual for device-specific button functions.

3. **Button III**

4. **Pedal B**

5. **Pedal A**

6. **Button I**

The Receiver

The receiver connects to the devices that will be controlled by the iSwitch system. It receives commands sent from the footswitch and routes them to the appropriate device. The receiver also determines how footswitches are used and which devices they will control.

The features of the receiver are listed in Figures 4 and 5.

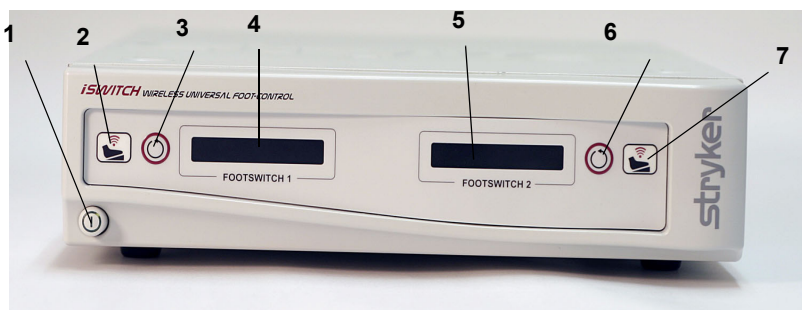


Figure 4: The receiver front panel

Front Panel

1. **Power Switch:** Powers on and off the receiver. The switch will illuminate when the unit is on.
2. **Synchronize port 1:** Enables a footswitch to work with the receiver when aligned with the synchronize logo on that footswitch. The footswitch will be designated as “footswitch 1.”
3. **Mode button 1:** Selects which device footswitch 1 will control (which “mode” the footswitch is in). Pressing and holding this button will clear the Footswitch.
4. **Active-device display 1:** Displays which device is currently active and can be controlled by footswitch 1 (which “mode” footswitch 1 is in).
5. **Active-device display 2:** Displays which device is currently active and can be controlled by footswitch 2 (which “mode” footswitch 2 is in).
6. **Mode button 2:** Selects which device footswitch 2 will control (which “mode” the footswitch is in). Pressing and holding this button will clear the Footswitch
7. **Synchronize port 2:** Enables a second footswitch to work with the receiver when aligned with the synchronize logo on that footswitch. The footswitch will be designated as “footswitch 2.”

Rear Panel

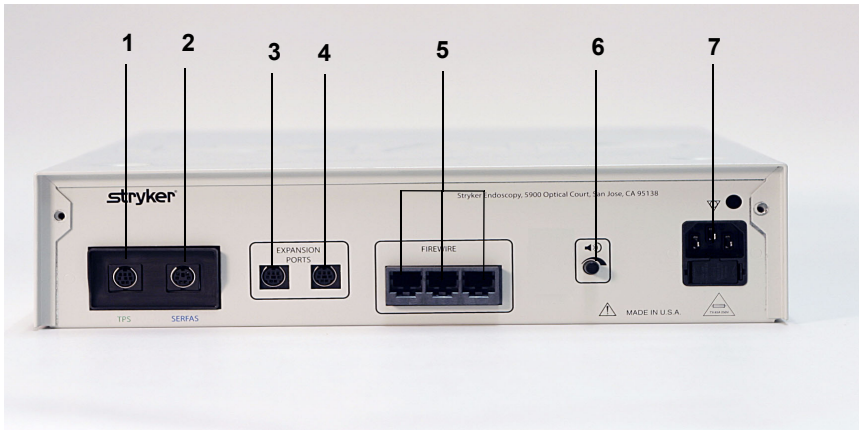


Figure 5: The receiver rear panel

1. **TPS output:** Provides a dedicated connection to the TPS console, enabling the commands issued from the footswitch to be routed to the TPS console.
2. **SERFAS output:** Provides a dedicated connection to the SERFAS console, enabling the commands issued from the footswitch to be routed to the SERFAS console.
3. **Expansion port:** Provides a generic connection to addition devices, enabling the commands issued from the footswitch to be routed to the console.
4. **Expansion port:** Provides a generic connection to addition devices, enabling the commands issued from the footswitch to be routed to the console.
5. **SFB Serial Connectors:** Enables firewire connection with newer devices, such as CORE and SERFAS Energy, eliminating the need for multiple connection cables.
6. **Volume control:** Controls the output volume.
7. **AC-power input:** Connects to the AC Power cord, which connects to a hospital-grade power outlet.

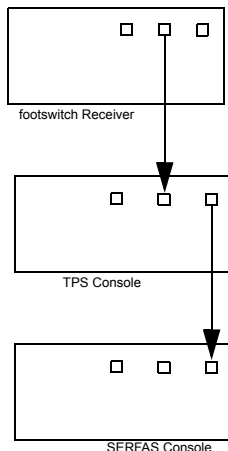
Setting up the iSwitch

Setting Up the Receiver

1. **Position the receiver on a Stryker cart or other sturdy platform.**
2. **Connect the AC Power.**
 - Connect the AC power cord to the AC input on the rear receiver panel.
 - Connect the other end to a hospital-grade receptacle.
3. **Connect the devices that will be controlled by the footswitch System.**
 - For older TPS and SERFAS consoles, connect a device cable to the appropriate port on the rear receiver panel, and then connect the other end to the footswitch port on the front console panel.
 - For newer CORE and SERFAS Energy consoles, connect a firewire cable to the firewire port on the rear receiver panel, and then connect the other end to the firewire port on the console rear panel.

Contact your local Stryker Representative for applicable device cable part numbers.

Note When connecting devices to the footswitch receiver SFB serial cable, connect the devices in series (see Figure 6 below).



NOTE: Devices may also be connected directly to the iSwitch Receiver.

Figure 6: Connecting devices in series to the footswitch receiver

4. **Power on the receiver and all devices connected to it.**

Setting Up the Footswitch

1. Insert the Stryker Battery Pack (P/N 277-300-100).

Note It is recommended to use the Stryker Battery Pack to achieve maximum battery life and prevent improper insertion.

- Twist off the cap on the side of the footswitch by turning 1/2 turn counterclockwise.
- Insert the batteries.
- Replace the cap and lock in place by turning 1/2 turn clockwise.

2. Synchronize the footswitch with the receiver.

- Press buttons I and III simultaneously and release.
- Align the footswitch synchronize logo with the footswitch 1 synchronize logo on the receiver.
- Hold the footswitch one inch away from the receiver. The LED will appear red while synchronization is in process, and will change to green when the footswitch has been synchronized.

3. Synchronize a second footswitch if needed.

- Press buttons I and III simultaneously and release.
- Align the second footswitch synchronize logo with the footswitch 2 synchronize logo on the receiver.
- Hold the footswitch one inch away from the receiver. The LED indicator will change to green when the footswitch has been synchronized.

Note A single footswitch cannot be synchronized to two channels.

4. Position the footswitch on the floor where it can be comfortably accessed.

Note The Footswitch needs to be synchronized when a Receiver is powered on or when the Footswitch enters a new room. A Footswitch is disconnected from the Receiver by powering off the Receiver or pressing and holding the Receiver Mode button.

System Settings

Using the 2 mode buttons on the Receiver, the system Settings may be modified as listed below:

To enter the Settings mode

Press and hold both mode buttons on the Receiver for 5 seconds

- In this mode, the left (Footswitch 1) mode button toggles among options.
- In this mode, the right (Footswitch 2) button enables or disables the settings.

Settings

Speed Mode (Default: Enabled)

- When enabled, a single press of button II on the Footswitches changes the mode.
- When disabled, press and hold to select the device.

Note If using 2 handpieces in Speed Mode, press and hold the Mode button to change handpieces.

Teacher Mode (Default: Disabled)

- When enabled, 2 Footswitches may select the same device. Pressing button II on either Footswitch will give it primary control. To transfer control, simply press button II on the second Footswitch.
- When disabled, the Footswitch will function as normal. Only one Footswitch will control the selected device.

Global Merge (Default: Disabled)

- When enabled, two Footswitches may select the same device. The Footswitch pressed first will receive primary control. Control may then alternate between Footswitches when the pedals on the primary Footswitch are not pressed and the pedals on the second Footswitch are depressed.
- When disabled, the Footswitch will function as normal. Only one Footswitch will control the selected device.

Exiting Settings Mode

To exit the Settings Mode, press and hold both Mode buttons for 5 seconds. The selected settings will remain unchanged.

Operating the iSwitch System

Note Using Stryker disposable bags (P/N 277-500-100) is recommended to keep the footswitch clean during use. Contact your local Stryker representative for ordering information.

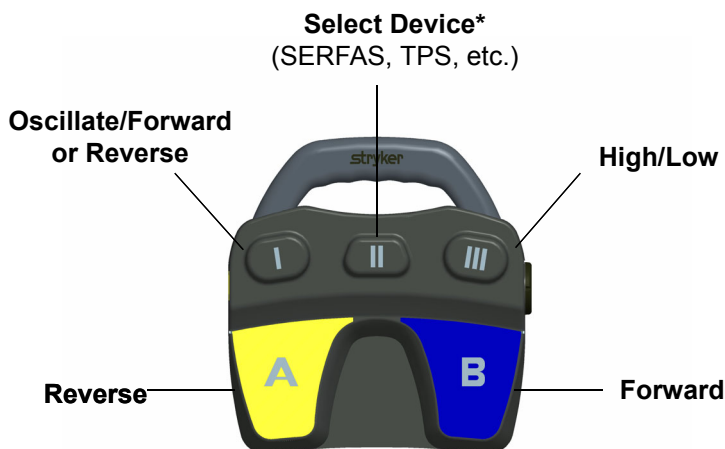
The iSwitch system is operated through the controls on the footswitch and the controls on the receiver.

Using the Footswitch Controls

1. Press the mode button to select which device the footswitch will control. The footswitch buttons will perform according to the mode selected.

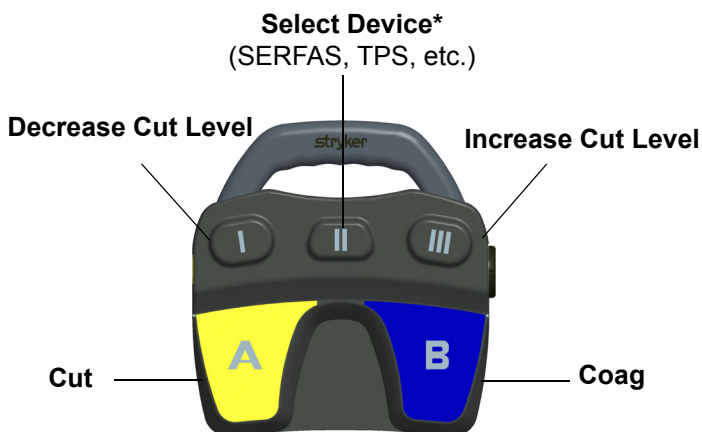
TPS Mode

Note The Wireless Universal footswitch can be programmed like the TPS Wired footswitch. Default controls are shown.



*In Speed Mode, press to select the device. Press and hold to change the handpiece.

SERFAS Mode



Using the Receiver Controls

While the footswitch controls the devices connected to the iSwitch system, the receiver controls how the footswitch functions. Receiver controls are used for selecting which device the footswitch will control, unsynchronizing footswitches, and merging footswitches.

Selecting which device the footswitch will control

Press the mode button to toggle through the connected devices. The selected device will appear on the display screen.

Note Mode button 1 selects the devices footswitch 1 will control; mode button 2 selects the devices footswitch 2 will control.

Note The device can also be selected by pressing the mode button on the footswitch.

Unsynchronizing footswitches

Press and hold the mode button to disable communication between a footswitch and the receiver. After the footswitch has been unsynchronized, the footswitch will not function again until it is resynchronized with the receiver.

Monitoring battery life

The receiver will provide feedback to alert the user when the footswitch has approximately two days of battery life remaining. The receiver will emit an audible warning and the receiver LED will flash red.

Note It is recommended to use the Stryker Battery Pack (P/N 277-300-100).

Cleaning and Maintenance

Cleaning

WARNING Unplug the receiver from the electrical outlet before cleaning the unit.



Caution Do not immerse the footswitch in any liquid, as product damage may result.



Caution Do not use solvents, such as alcohol, or cleaning solutions that contain ammonia to clean the footswitch, as product damage may result.



Caution Do not sterilize the footswitch or receiver, as product damage will result.



1. Wipe the footswitch with a soft cloth dampened in a mild cleaning solution.
2. Clean the footswitch with disinfectant if needed.

Maintenance

The Wireless Universal footswitch™ system requires no preventative or periodic maintenance.

WARNING Remove the batteries if the Footswitch is not in use for an extended period of time.



WARNING To reduce the risk of electrical shock, do not open the footswitch. There are no user-serviceable components inside. Should service be needed, notify your local Stryker representative.



Replacing the Batteries

WARNING Replace the batteries only when outside the patient's vicinity.



Caution The batteries may explode or leak if recharged, inserted improperly, or disposed of by fire.



Note Replace the battery pack with a Stryker Battery Pack (P/N 277-300-100) for optimal battery performance.

Battery Disposal

The batteries must be disposed of according to local laws and hospital practices.

Troubleshooting

Problem	Possible Solution
No results when the Footswitch is pressed.	• Press buttons I or III to wake Footswitch. • Synchronize the Footswitch. • Replace batteries.
The Footswitch will not synchronize with the receiver.	• Hold the Footswitch synchronization icon within one inch of the receiver synchronization icon. • Press buttons I and III simultaneously and release. • Replace batteries and try again.
The receiver does not indicate that an attached device is attached upon startup.	• Ensure the device is connected to the correct input on the rear receiver panel.
Footswitch 2 is stuck using the same device as Footswitch 1.	• Press the mode button to unmerge the Footswitches.
Cannot hear audio messages.	• Increase volume using control on rear of receiver.
When synching the Footswitch, the LED on the Receiver does not change color and synching fails.	• If another Footswitch is already synched to this channel, press and hold the Mode button on the Receiver for 5 seconds to clear the existing Footswitch. • Synch the new Footswitch.
The Footswitch will not synchronize with the Receiver. An adjacent Receiver is present.	• Press buttons I and III simultaneously and release to disconnect the Footswitch from the adjacent Receiver. • Synch the Footswitch to the new Receiver.
The Receiver displays “Replace batteries” even though new batteries have been inserted	• Batteries may be inserted incorrectly. Reinsert batteries.

Technical Specifications

Environmental Specifications

Operating Temperature:	10° to 40°C
Humidity:	35% to 75% RH

Shipping/Storage

Operating Temperature:	10° to 40°C
Humidity:	35% to 75% RH

System Input Power Requirements

Voltage:	100-240 VAC
Frequency:	50/60 Hz
Current:	0.6 Amps
Fuse Rating:	1.0A/250V

Classifications

Receiver: Class I Equipment	Footswitch
• No Applied Parts • Water Ingress Protection, IPXO • Continuous Operation	• Internally powered • No Applied Parts • Water Ingress Protection, IPX7 • Continuous Operation

Wireless USB Specifications

Frequency range:	2.402 Hz -- 2.478 GHz
Modulation:	Direct Sequence Spread Spectrum (DSSS)
Power:	0 dBm

RFID Specifications

Frequency:	125 KHz
Modulation:	Binary Pulse Length Modulation (BPLM)
Power:	<0.001W

FCC ID

SSH-WUF

IC ID

4919C-WUF

Standards Compliance

- IEC 60601-1:1988 + A1:1991 + A2:1995
- IEC 60601-1-2: 2001
- IEC 60601-2-2:1998
- CAN/CSA C22.2 No. 601.1-M90
- UL 60601-1:2003
- AS 3200.1.0:1998

Electromagnetic Compatibility

Like other electrical medical equipment, the iSwitch requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC), the iSwitch must be installed and operated according to the EMC information provided in this manual.

Note The iSwitch has been designed and tested to comply with IEC 60601-1-2:2001 requirements for EMC with other devices.

Caution  **The iSwitch may be interfered with by other equipment, including portable and mobile RF communication equipment, even if such equipment meets the applicable emissions requirements.**

WARNING  **Do not use cables or accessories other than those provided with the iSwitch, as this may result in increased electromagnetic emissions or decreased immunity to such emissions.**

WARNING  ***If the iSwitch is used adjacent to or stacked with other equipment, observe and verify normal operation of the iSwitch in the configuration in which it will be used prior to using it in a surgical procedure. Consult the tables below for guidance in placing the iSwitch.***

Guidance and Manufacturer's Declaration: Electromagnetic Emissions		
iSwitch is intended for use in the electromagnetic environment specified below. The customer or the user of iSwitch should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment - guidance
RF emissions CISPR11	Group 1	The iSwitch must emit electromagnetic energy in order to perform its intended function. NEarby electronic equipment may be affected. iSwitch is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR11	Class B	
Harmonic emissions IEC61000-3-2	Class A	
Voltage Fluctuations/ flicker emissions IEC61000-3-3	Complies	

Guidance and Manufacturer's Declaration: Electromagnetic Immunity			
iSwitch is intended for use in the electromagnetic environment specified below. The customer or the user of iSwitch should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Electrostatic Discharge (ESD) IEC61000-4-2	±6kV contact ±8kV air	±2,4,6kV contact ±2,4,8kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV line to ground ±1kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV differential mode ±2kV common mode	±0.5, 1kV differential mode ±0.5, 1, 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec.	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of iSwitch requires continued operation during power mains interruptions, it is recommended that iSwitch be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power-frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: Ut is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration: Electromagnetic Immunity			
iSwitch is intended for use in the electromagnetic environment specified below. The customer or the user of iSwitch should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the iSwitch system, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = 1.17 \sqrt{P}$ $d = 1.17 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.33 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^(a), should be less than the compliance level in each frequency range^(b). Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the iSwitch system is used exceeds the applicable RF compliance level above, the iSwitch system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the iSwitch unit. (b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the iSwitch System

The iSwitch system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the iSwitch system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the iSwitch system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power (W) of transmitter	Separation distance (m) according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.17 \sqrt{P}$	80 MHz to 800 MHz $d = 1.17 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Warranty

This Stryker Endoscopy product is warranted to the original purchaser for a period of one year from the date of purchase to be free from defects in material and workmanship. This warranty extends to all purchases and is limited to the repair or replacement of the product without charge when returned to:

Stryker Endoscopy
5900 Optical Court
San Jose, CA 95138

Stryker Endoscopy cannot accept responsibility for returns or replacements which have not been authorized. This warranty does not cover damages caused by misuse (i.e. neglect, dropping, or denting) or by failure to follow the procedures outlined in this manual or demonstrated by Stryker Endoscopy representatives. Unauthorized repair or modifications to the iSwitch may void the warranty and invalidate the user's authority to use the product.

There are no other expressed warranties.

Service and Claims

Caution  **Do not attempt to service this product yourself. If service is needed either during or after the warranty period:**

1. Contact Stryker Endoscopy at 1-800-624-4422, or phone your local Stryker Endoscopy sales representative.
2. Clean and sterilize all parts that will be returned for service. Follow the instructions provided in this manual.
3. Package all the components carefully in the original shipping container if possible.
4. Ship the unit, pre-paid and insured to:

Stryker Endoscopy Customer Service
Attention: Repair Department
5900 Optical Court
San Jose, CA 95138

Note The product described in this manual is continually being reviewed, and improvements may be made without notice.

Stryker and Stryker Endoscopy are registered trademarks of Stryker Corporation.

Other Service

For service in the U.S.A., call your Stryker Endoscopy representative or call Stryker Endoscopy Customer Service at 1-800-624-4422. Outside of the U.S.A., please contact your Stryker Endoscopy distributor at one of the following locations:

Stryker Corporation
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Kalamazoo, MI 49002
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Telex:224464 STRYKER KMZ
Fax:1-269-385-1996

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Fax:91-11-696-6020

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