

SDC CLASSIC HD CAPTURE DEVICE	œ
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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	Warnings indicate risks to the safety of the patient or user. Failure to follow warnings may result in injury to the patient or user.
Caution	Cautions indicate risks to the equipment. Failure to follow cautions may result in product damage.
Note	Notes married an axial information to elarify instructions on massant

Note Notes provide special information to clarify instructions or present additional useful information.

# Warning To avoid potential serious injury to the user and the patient and/or damage to this device, the user must obey the following warnings:

- 1. Federal law (United States of America) restricts this device to use by, or on order of, a physician.
- 2. Read this operating manual thoroughly and be familiar with its contents prior to setting up or using this equipment.
- 3. Carefully unpack the unit and check for any damage that may have occurred during shipment. If damage is detected, refer to the "Service and Claims" section in this manual.
- 4. Use of this device is restricted to qualified health care professionals who have a complete knowledge of the use of this equipment and the devices to which it can be connected.
- 5. Test this equipment prior to using it in a surgical procedure. This unit was fully tested at the factory before shipment; however, it must be tested for proper function in the environment and setup configuration in which it will be used.
- 6. To avoid risk of electric shock, use only a hospital-grade power cord furnished with the unit. Disconnect the unit from the power supply to make connections or to inspect the equipment.
- 7. Install this device in an operating room that complies with all applicable IEC, CEC, and NEC requirements for safety of electrical devices.
- 8. Use only clean, dry, undamaged Stryker brand media. The use of damaged, wet, or incompatible media will void the warranty and may result in the malfunctioning of this equipment.
- 9. Unplug the power cord from the mains outlet before making any connections.

- 10. Ensure that all equipment connected to the SDC Classic<sup>™</sup> has proper isolations.
- 11. To avoid risk of fire, do not use this device in the presence of flammable anesthetics.
- 12. Avoid direct exposure to the laser beam of the DVD/CD drive, as it is harmful to the eyes.
- 13. Pay close attention to the care and cleaning instructions in this manual. Failure to follow these instructions may result in product damage.
- 14. Attempt no internal repairs or adjustments not specifically detailed in this operating manual. Refer any readjustments, modifications, and/or repairs to Stryker Endoscopy or its authorized representatives.

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

# Symbols and Definitions

This device and its labeling contain symbols that provide important information for the safe and proper use of the device. These symbols are defined below.

### **Warning Symbols** Warning/Caution: See Hazardous voltage Instructions for Use present **Device Symbols** Keyboard Mouse Լիր Network Monitor USB Out )( Serial port In VGA/Monitor **Packaging/Labeling Symbols** Authorized EC REP Legal manufacturer representative in



Date of manufacture



Atmospheric pressure range

Europe



LOT

SN

Ambient temperature range

Lot number

Serial Number

Equipotentiality



Relative humidity range



Product number



Denotes compliance to CSA C22.2 No. 601.1-M90, and UL 2601-1.



Protective earth ground



Denotes compliance to 93/42/EEC, Medical Device Directive



This product contains electrical waste or electronic equipment. It must not be disposed of as unsorted municipal waste and must be collected separately.

### **Product Description/Intended Use**

The Stryker Digital Capture Classic (SDC Classic<sup>™</sup>) is a computer-based unit that records, manages, and archives digital images and videos of surgical procedures. The SDC Classic simplifies file management by recording surgical photos and videos to compact digital media, such as CDs, DVDs, Compact Flash Cards, USB Hard Drives, or USB dongles, for later viewing on a personal computer, a DVD player, or from the SDC Classic itself.

The SDC Classic records images on a built-in hard drive, where they can be easily accessed after the surgical procedure. The images stored on the hard drive can be named and burned to a CD or DVD through a control panel located on the front of the unit.

In addition to the control panel, the SDC Classic can be controlled by a handheld remote control, buttons located on the surgical camera head, or the SIDNE<sup>®</sup> voice-activation system.

#### Indications/Contraindications

The SDC Classic<sup>™</sup> is indicated for use with compatible endoscopic cameras or other medical devices that output a standard video signal. The SDC Classic can be used in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery wherever a laparoscope/endoscope/arthroscope is indicated for use. (A few examples of the more common endoscopic surgeries are laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic and thorascopic anterior spinal fusion, anterior cruciate ligament reconstruction, knee arthroscopy, shoulder arthroscopy, small joint arthroscopy, decompression fixation, wedge resection, lung biopsy, pleural biopsy, dorsal sympathectomy, pleurodesis, internal mammary artery dissection for coronary artery bypass, coronary artery bypass grafting where endoscopic visualization is indicated, and examination of the evacuated cardiac chamber during performance of valve replacement.

There are no known contraindications.

### **Operator Profile**

The users of SDC Classic are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, urologists and operating room nurses.

#### **Package Contents**

Carefully unpack the SDC Classic and verify that all components have been received intact. You should receive:

105-033-001	(1) Medical grade power cord
105-198-707	(1) 6-foot DVI-I cable
105-187-988	(1) 6-foot USB cable
105-198-102	(1) Blank DVD+RW
1000-401-087	(1) User guide

Save all packing materials for future storage or transport.

#### Accessories

The following accessories are available for purchase separately:

240-080-211	HP D5460 Photosmart Printer Kit
240-050-891	Multi-card reader with media (256MB Compact Flash card, 256MB multi-media card, 256MB Sony memory stick)
240-050-902	USB 2.0 hard drive, 60GB
240-050-893	USB 2.0 hard drive, 512MB
240-050-840	VGA cable kit (6-foot VGA cable and DVI-VGA adapter)
240-050-845	DVI cable kit
105-208-352	SDC Classic remote control

#### **System Overview**

#### **Front Panel**



- 1. LCD status screen see the "LCD Status Screen" section of this manual.
- 2. Menu navigation use the arrow keys to navigate through the menu.
- 3. Remote control
- 4. USB Port
- 5. Write to USB drive
- 6. Write to DVD drive
- 7. DVD drive
- 8. Preview previous four images
- 9. Print
- 10. Stop
- 11. Record/Pause
- 12. Capture
- 13. Power
- 14. New case

#### **Rear Panel**



- 1. Remote 2
- 2. Remote 1
- 3. Mic in
- 4. SIDNE<sup>®</sup> in
- 5. SIDNE out
- 6. S-Vid in
- 7. S-Vid out
- 8. Comp in
- 9. Comp out
- 10. Power
- 11. Equipotential ground plug
- 12. DVI out
- 13. DVI in
- 14. SIDNE port
- 15. USB port
- 16. Monitor
- 17. VGA/monitor
- 18. Keyboard (not intended for the user)
- 19. Mouse (not intended for the user)
- 20. Serial port

#### **Remote Control**



- 1. Channel 1 video and image: capture, record, stop
- 2. Channel 2 not available
- 3. Print images
- 4. Display previous image on OSD
- 5. Voice annotation (reserved for future use)
- 6. Navigation and Select (reserved for future use)

#### LCD Status Screen

The status screen provides information about currently selected options for capturing and printing images. These options can be edited in the **Printer Settings** menu.

#### **Recording mode**



- 1. Video timer
- 2. Size of video
- 3. Number of images captured
- 4. Number of videos captured
- 5. Number of images to print per page
- 6. Number of copies to print

Non-recording mode



- 1. Signal status
- 2. Number of images captured
- 3. Number of videos captured
- 4. Number of images to print per page
- 5. Number of copies to print

# **Setup and Interconnection**

Stryker Endoscopy considers instructional training an integral part of the SDC Classic<sup>™</sup> system. Your Stryker Endoscopy sales representative will perform at least one in-service at your convenience to help you set up your equipment and instruct you and your staff on its operation and maintenance. Please contact your local Stryker Endoscopy representative to schedule an in-service after your equipment has arrived.

- 1. Choose a location for the SDC Classic.
  - Place the SDC Classic on a Stryker cart or other sturdy platform.
  - Provide at least four to six inches of space around the sides and top of the SDC Classic to ensure proper ventilation.
- 2. Connect the AC power cable.



To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth. To isolate the device from the supply mains, use only hospital-grade power cords.

3. Connect peripheral devices according to the interconnection diagrams on the following pages.



The SDC Classic is a non-sterile device intended for use outside the patient environment. When setting up the device, select a location that will ensure optimal ease of use while maintaining separation between the device and the patient.

Do not connect the SDC Classic to extension cords or multiple portable socket outlets (power strips) other than those built into the Stryker cart.

Do not connect items to the SDC Classic that are not intended for use with the system.

RF and other mobile communications equipment may affect the normal function of the SDC Classic. When placing the SDC Classic, follow the instructions located in the "Electromagnetic Compatibility" section of this manual.



When the SDC Classic is interconnected with other electrical devices, leakage currents may be additive, resulting in electromagnetic emissions that can interfere with the normal function of electronic medical equipment. To properly control electromagnetic emissions and avoid potential harm to the patient or user, ensure all electrical devices are installed and interconnected according to the requirements of IEC 60601-1-1.

4. Prior to the surgical procedure, verify proper setup by recording sample images and video. Consult the "Troubleshooting" section of this manual as needed.

### **Connecting a Printer**



The printer must be properly connected to the isolation transformer prior to use. Failure to do so may result in a higher leakage current for the printer.

Note

See the "Technical Specifications" for approved printers and transformers.



3. Connect the AC power.

- Connect the provided power cord to the AC inlet on the rear console panel.
- Connect the other end to a hospital-grade power outlet.



Do not use extension cords or three-prong to two-prong adapters when connecting the AC power.

Check the power cord assembly periodically for damaged insulation or connectors.

#### Connecting the 1188 Camera and SIDNE®



Caution The other ports not listed in this section are intended for use by service technicians or for future device upgrades. Do not connect any devices to these ports as unexpected results may occur.

### **Operation**

#### **Powering the System On and Off**

Press the **power** button on the console to power the system on or off.

#### **Starting a New Case**

- 1. Press the **New Case** button.
- 2. Select Yes or Cancel.
- 3. Press OK.

#### **Capturing Images**

Press the **Capture Image** button.

#### **Recording Video**

- 1. Press the **Record** button to begin recording video. 🕥
- 2. Press the **Record** button again to pause. 🖤
- 3. Press the **Stop** button to stop recording.

#### **Saving Images and Videos**

- 1. Select the images to be saved.
  - Press and hold the **Preview Images** button to see the image album.
  - To deselect an image, highlight the image number and press **OK**. Images with a checkmark next to the number indicates the image will be saved.
- 2. Connect a USB device or insert a blank DVD.
- 3. Press the **USB** button to save images and video to an external USB device.
- 4. Press the **DVD** button to save images and video to DVD.

#### **Printing Images**

- 1. Select the images to be printed.
  - Press and hold the **Preview Images** button to see the image album.
  - To deselect an image, highlight the image number and press **OK**. Images with a checkmark next to the number indicates the image will be printed.
- 2. Press the **Print** button.

### **Editing Device Settings**

#### **Editing Printer Settings**

To edit printer settings, use the navigational buttons on the control panel.

Menu	Sub-menu	Options	Description
		Print all	Prints all selected images
		Print	Reprints the previous print
	Print	previous	job
		Cancel all	Cancels all pending print jobs
		4	Select the number of images
	Images per page	6	the images per page and auto
	mages per page	8	print is set to on, a page will
		12	automatically print.
	s Print Copies	1	Select the number of copies
		2	per page to be printed.
Printer Settings		3	
		4	
		5	
		On	Select either <b>on</b> or <b>off</b> . If auto
Auto Print	Off	print is on, a page of images will automatically print when the images captured equals the number of images per page.	
		Brightness	Select a number from -5 to 5.
		Contrast	
	Adjustments	Phase	
		Chroma	
	Sharpness		

#### **Editing Video Settings**

To edit video settings, use the navigational buttons on the control panel.

Menu	Sub-menu	Options	Description
		DVI	Select the video input source
		RGBHV	for live video recording and
	Video Source	S-Video	image capture.
		Composite	
	Video Downoot	NTSC	Select NTSC or PAL mode
	video Format	PAL	
		1188	Select the camera to be used
		1088	for recording and capturing
	Camera	GI	images.
		Other	
Video Settings	D 10	MPEG 1	Select the format for
	Record Format	MPEG 2	encoding video files.
	Auto Cut Off	DVD	Select the storage option.
		CD	Recording will automatically
		Off	reaches 4GB for DVD and 650MB for CD. If the storage option is set to off, recording will stop when the case size is maxed out or when the system hard drive is out of space.

#### **Editing Save Settings**

To edit save settings, use the navigational buttons on the control panel.

Menu	Sub-menu	Options	Description
	DVD Format	DVD Data	Select the DVD format. If <b>DVD Data</b> is selected, the system will save the case as video and image data files.
Save Settings		Bitmap	Select the image format. If
cure certings	Image Format	IPEG	<b>bitmap</b> is selected, image
		, -	files are converted to 24-bit
			bitmap files. If <b>JPEG</b> is
		selected, image files are	
			converted to JPEG format.

#### **Editing Audio Settings**

To edit audio settings, use the navigational buttons on the control panel.

Menu	Sub-menu	Options	Description
		1	Select the microphone input
		2	volume.
	Volume	3	
		4	
Audio Settings		5	
		On	Select on or off. If mute is
	Mute	Off	on, the audio stream will not be recorded to the video file.

#### **Editing System Settings**

To edit system settings, use the navigational buttons on the control panel.

Menu	Sub-menu	Options	Description
		English	Select the language that will
		French	display on the LCD screen.
		German	
	Language	Spanish	
		Italian	
		Chinese	
		Japanese	
	S Date Format	mm/dd/yyyy	Select the date format to be
System Settings		dd/mm/yyyy	printed on each page.
System Settings		yyyy/mm/dd	
		Month	Select the month, day, and
	Date	Day	year to set in the system.
		Year	
		Hour	Select the time to set in the
	Time	Minute	system.
		AMPM	
	Version	-	Displays the system version information.

### Troubleshooting

The table below shows the most common errors and possible solutions to each.

Problem	Solution
New case error	Reboot the system.
Video limit reached	Begin a new case to record more videos.
Image limit reached	Begin a new case to capture more images.
SIDNE <sup>®</sup> comm error	Ensure that SIDNE is connected properly. Reboot the SDC Classic <sup>™</sup> and SIDNE.
Error printing. No image captured/ selected	Capture images and then select them to print.
Error saving settings	To restore previous settings, reboot the system.
Error: Media unavailable	Insert/connect a valid media to the SDC Classic.
USB space insufficient	Ensure that there is free space available on the media.
Error: Disk corrupt. Please try again	The media is corrupt. Insert a new disc to continue.
Error: Disc drive busy	Ensure that the disc drive is not being currently used. Reboot the machine if the error persists.
Error: Upgrading software	Insert the upgrade dongle properly.
Application has encountered a critical error and is shutting down.	Reboot the system.

No live video on the monitor	<ul> <li>Check the cable connections.</li> <li>Ensure that the camera is powered on.</li> <li>Ensure that the proper video source is selected.</li> <li>If the video is routed through SIDNE*, ensure that SIDNE is powered on.</li> </ul>
Print errors	<ul> <li>Ensure there aren't any paper jams.</li> <li>Ensure the printer has enough ink.</li> <li>Ensure the printer door is closed.</li> <li>Ensure the printer has paper.</li> <li>Ensure the printer is powered on.</li> <li>Ensure the printer cable is connected.</li> </ul>
Error saving more than 4GB files to the USB	Ensure that the USB is formatted as NTFS. FAT 32 will not support any file size bigger than 4GB.

# **Cleaning and Maintenance**

### Cleaning

Should the unit need cleaning, wipe it down with a sterile cloth.

Warning	To avoid electric shock and potentially fatal injury, unplug the SDC Classic <sup>™</sup> from the electrical outlet before cleaning.
Caution	Do not immerse the console in any liquid as product damage will result.
Caution	Do not use alcohol, solvents, or cleaning solutions that contain ammonia to clean the unit, as product damage may result.
Caution	Do not sterilize the unit as product damage may result.

#### Maintenance

SDC Classic requires no preventative or periodic maintenance. However, Stryker recommends you reboot the system daily for best performance.

### Disposal



This product contains electrical waste or electronic equipment. It must not be disposed of as unsorted municipal waste and must be collected separately. Please contact the manufacturer or other authorized disposal company to decommission your equipment.

### **Technical Specifications**

#### **Environmental Specifications**

Operating temperature:	10 – 40°C
Operating humidity:	30 – 75% RH
Transport/storage temperature:	-20° – 60°C
Transport/storage humidity:	10 – 85% RH

#### System Type

MPEG -1 or -2 compression engine with full IP encoding

#### **Video Inputs**

Input	Resolution
(1) S-Video:	(NTSC) 720 × 480,
(1) Composite:	(PAL) 720 × 576
(1) DVI:	(SXGA) 1280 × 1024,
(1) RGBHV (via DVI-I connectors)	(XGA) 1024 × 768, (720p) 1280 × 720

#### **Video Outputs**

Same as video inputs

#### Audio

Stereo line and microphone input (2) speaker outputs

#### **Image Resolution**

Progressive scan image capture; same as video input resolution

#### **Disc Capacity**

50 images and 50 video files, with auto cutoff for CD (600 MB), DVD (4 GB), or none (8 GB, maximum case size permitted)

#### **File Format**

Images: Bitmap (BMP), JPEG, Videos: MPEG-1 and MPEG-2

#### **Disc Recording Formats**

CD-R, DVD-R, DVD+R (single session), DVD+RW

#### USB

NTFS format supported MAC users will only have read capabilities

#### **Remote Control**

Wireless infrared, camera-head triggering

#### **Power Consumption**

100 - 240VAC~ 50/60Hz, 4A maximum

#### **Safety and EMC Compliance**

IEC 60601-1:1988 + A1:1991 + A2:1995 CAN/CSA C22.2 No.601.1-M90 UL 60601-1:2003 AS/NZS 3200.1.0:1998 IEC 60601-1-1:2000 IEC 60601-1-2:2001 + A1:2004 IEC 60601-1-4:1996 + A1:1999

#### **Equipment Classification**

Class I ME equipment No applied part Water ingress protection, IPX0 Continuous Operation

#### Size (control unit)

12.5" W  $\times$  16.2" D  $\times$  4.0" H

#### Network

10/100 Mbps ethernet

#### **Auto Printing**

4, 6, 8, or 12 images per page

#### **Printers Supported**

HP D7260 HP D5460 Stryker SDP1000 Kodak ESP 7250 HP Photosmart Premium C310

#### **Isolation Transformer**

Stryker 240-099-050 (2KVA transformer) Stryker 240-050-705 (180VA transformer)

#### Display

 $128 \times 64$  pixel LCD screen

### **Electromagnetic Compatibility**

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

The SDC Classic has been designed and tested to comply with IEC 60601-1-2:2001 requirements for EMC with other devices. It has not been tested for immunity to electromagnetic disturbances.

Caution	Portable and mobile RF communications equipment may affect the normal function of the SDC Classic.
Caution	Do not use cables or accessories other than those provided with the SDC Classic, as this may result in increased electromagnetic emissions or decreased immunity to such emissions.
Caution	If the SDC Classic is used adjacent to or stacked with other equipment, observe and verify normal operation of the SDC Classic 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 SDC Classic <sup>™</sup> .

#### Guidance and Manufacturer's Declaration: Electromagnetic Emissions

SDC Classic<sup>™</sup> is intended for use in the electromagnetic environment specified below. The customer or the user of SDC Classic should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic Environment - guidance	
RF emissions CISPR 11	Group 1	SDC Classic uses RF energy only for its internal function; therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class A	SDC Classic 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, provided the following warning is heeded:	
Harmonic emissions IEC61000-3-2	Class B		
Voltage Fluctuations/ flicker emissions IEC61000-3-3	Complies	Warning: This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigating measures such as reorienting or relocating the system or shielding the location.	

Guidance and Manufacturer's DeclarationElectromagnetic Immunity			
The SDC Classic <sup>™</sup> system is intended for use in the electromagnetic environment specified below. The user of the SDC Classic system should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the SDC Classic system, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	d = 1.17√P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.17√P 80 MHz to 800 MHz d = 2.33√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 that 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 SDC Classic system is used exceeds the applicable RF compliance level above, the SDC Classic™ system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SDC Classic unit.

(b) Over the frequency range 150 kHz to 80 Mhz, field strengths should be less than 3 V/m.

#### Guidance and Manufacturer's Declaration: Electromagnetic Immunity

SDC Classic <sup>™</sup> is intended for use in the electromagnetic environment specified below. The customer or the user of SDC Classic 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	±2kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment	
IEC61000-4-4	±1kV for input/ output lines	±1kV for input/output lines		
Surge	±1kV differential mode	±0.5, 1kV differential mode	Mains power quality should be that of a typical commercial or hospital environment	
IEC61000-4-5	±2kV common mode	±0.5,1, 2kV common mode		
	<5% Ut (>95% dip in Ut) for 0.5 cycle	<5% Ut (>95% dip in Ut) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of SDC Classic requires continued operation during power mains interruptions, it is recommended that SDC Classic be powered from an uninterruptible power supply or a battery.	
Voltage dips, short interruptions and voltage variations	40% Ut (60% dip in Ut) for 5 cycles	40% Ut (60% dip in Ut) for 5 cycles		
on power supply input lines IEC61000-4-11	70% Ut (30% dip in Ut) for 25 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 5 sec		
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Not Applicable	
NOTE Lt is the a.c. mains voltage prior to application of the test level				

SDC Classic<sup>™</sup> is intended for use in the electromagnetic environment specified below. The customer or the user of SDC Classic should ensure that it is used in such an environment.

(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 SDC Classic system is used exceeds the applicable RF compliance level above, the SDC Classic system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SDC Classic 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 SDC Classic™ System

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

	Separation distance (m) according to frequency of transmitter			
Rated maximum output power (W) of transmitter	150 kHz to 80 MHz d = 1.17√P	80 kHz to 800 MHz d = 1.17√P	800 kHz to 2.5 GHz d = 1.17√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

Stryker Endoscopy warrants all products, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker Endoscopy with the products for a period of one year from the date of purchase (the "Warranty Period"). This warranty shall apply only to the original end-user purchaser of products directly from Stryker Endoscopy or a Stryker Endoscopy authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker Endoscopy.

If a valid warranty claim is received within the Warranty Period, Stryker will, in its sole discretion: (1) repair the product at no charge, (2) replace the product at no charge with a product that is at least functionally equivalent to the original product, or (3) refund the purchase price of the product. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker Endoscopy personnel without the prior written consent of Stryker Endoscopy; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker Endoscopy representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components, including replacement lamps.

If Stryker determines in its reasonable discretion that the claimed defect or nonconformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial Warranty Period or, if the initial Warranty Period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

The inspection, testing, acceptance or use of the products and services furnished hereunder shall not affect Stryker's obligation under this warranty, and such warranty shall survive inspection, test, acceptance and use.

Notwithstanding the above, the following products are warranted for a period of ninety (90) days from the date of purchase: Scopes, Fiber Optic Cables, VCRs, Monitors, and Printers. Replacement light bulbs are warranted for a period of sixty (60) days from the date of purchase.

TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. EXCEPT AS SPECIFICALLY PROVIDED IN THIS WARRANTY AND TO THE EXTENT PERMITTED BY LAW, STRYKER IS NOT RESPONSIBLE FOR INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.

#### **Return Policy**

A Returned Merchandise Authorization ("RMA") number must be obtained from Stryker Endoscopy before returning product. To obtain an RMA number, please contact Stryker Endoscopy Customer Service at 1-800-624-4422. Please send any returned products to: Stryker Endoscopy, Attn: Service Unit, 5900 Optical Court, San Jose, CA 95138.

With the return, please include the RMA number, the applicable purchase order number, the original invoice number, the name, address, and account number of the organization returning the product, an itemization of the items being returned, and the reason for the return. Please carefully package the product being returned. Credit will not be given for items that are damaged in return shipment due to inadequate packaging. Please clean and sterilize all potentially contaminated products prior to returning them to Stryker Endoscopy. It is unlawful to transport bio-contaminated products through interstate commerce, unless they are properly packaged and labeled as such. Stryker Endoscopy reserves the right to destroy contaminated product at the customer's expense and charge the customer for a replacement unit.





Stryker Endoscopy 5900 Optical Court San Jose, CA 95138 USA 1-800-624-4422

U.S. Patents: www.stryker.com/patents



