INTUITIVE SURGICAL®

da Vinci[®] Surgical System User Manual



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Equipment/Software Version

This user manual provides technical information about the use and operation of the IS1200 **da Vinci** Surgical System. The equipment described herein is designed to work with the **da Vinci** Surgical System operating system version 4.3.

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How to Use This Manual

This version of the *da Vinci*® *Surgical System User Manual* was released to update information specific to the 4.3 software release. In addition, Appendix B, "Understanding *EndoWrist*® Instruments," was added to provide detailed reference information specific to *EndoWrist*® instruments.

The *da Vinci*® *Surgical System User Manual* and the *InSite*® *Vision System User Manual* are intended to be used together to support the **da Vinci** System. The *da Vinci*® *Surgical System User Manual* is organized to provide you with the steps you need to get things done first, then provide reference information should you decide to learn more about each task or component.

Chapters 2-5 provide the basic instructions for setting up, using and shutting down the system. Chapters 6-8 contain detailed reference information about the components, how to clean and maintain them, and information on how the system intelligence functions. The final sections contain a glossary, a clinical appendix describing results from clinical trials, a reference appendix for EndoWrist® instruments, and an index. A brief description of each chapter is provided below.

Front Matter (the chapter you are reading now)

This section contains regulatory and safety information that must be read by every user of the da Vinci System. Examples include details on general precautions, precautions specific to procedures, power information, and so on.

Chapter 1, Introduction to the da Vinci System

Chapter 1 provides a basic overview of the system, including high-level information on the components and a brief description of how the system is used, as well as features and benefits.

Chapter 2, Setting Up the da Vinci System for Surgery

This chapter offers step-by-step instructions for preparing the **da Vinci** System for surgery. The task-oriented steps include instructions for orienting and connecting the components with cabling, and how to power up the system.

Chapter 3, Draping the da Vinci System

Chapter 3 explains how to drape the system, how to connect the camera/endoscope assembly, and how to calibrate the camera and endoscope.

Chapter 4, Using the da Vinci System During a Procedure

Chapter 4 describes step-by-step use of the **da Vinci** System during a surgical procedure. Tasks include setting up the Surgeon's Console for the comfort of the surgeon; details on using the Surgical Cart; and instructions on how to use specific instruments. Chapter 4 also contains a brief discussion on the use of the **InSite** Vision System.

Chapter 5, Shutting Down the da Vinci System

This chapter explains how to prepare for a shutdown, and explains how to track instrument usage.

Chapter 6, da Vinci Component Reference

Chapter 6 describes each system component in detail. Use this chapter to get more information if the basic steps in Chapters 2-5 do not provide enough detail. For detailed reference information on instruments, see Appendix B, "Understanding EndoWrist® Instruments."

Chapter 7, Cleaning and Maintenance

The instructions for recommended care of all parts of the **da Vinci** System are explained in detail. Suggested methods for sterilization are included as well.

Chapter 8, System Intelligence

This reference-oriented chapter contains descriptions of Faults and the Emergency Stop state, when faults can occur, and how to manage them. A listing of all system icons is provided as well.

Chapter 9, Glossary of Terms

Chapter 9 provides an explanation of terms and acronyms used in this manual.

Appendix A, Clinical Appendix

The Clinical Appendix provides specific details of clinical trials using the da Vinci System.

Appendix B, Understanding EndoWrist® Instruments

This appendix provides reference information for da Vinci 5mm and 8mm *EndoWrist* instruments, including their handling, use and cleaning.

General Information



The Intuitive Surgical **da Vinci** Endoscopic Instrument Control System, Model IS1200, is in conformance with the Medical Device Directive, 93/42/EEC.

Contact Information

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The da Vinci Endoscopic Instrument Control System (Model IS1200) is manufactured in the USA.

General Information for U.S. Only

The information in this section is intended for U.S. customers. General information continues in the next section, "General Precautions, Warnings, and Contra indications" on page xv.

Essential Prescribing Information

CAUTION: Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Indications for Use Statement

Device Name: Intuitive Surgical® **da Vinci**® Endoscopic Instrument Control System and Endoscopic Instruments.

Indications for Use: The Intuitive Surgical da Vinci Endoscopic Instrument Control System (hereinafter referred to as the "da Vinci System") is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing during general laparoscopic surgical procedures, general non-cardiovascular thoracoscopic surgical procedures, and thoracoscopically-assisted cardiotomy procedures. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Professional Instructions for Use

General Indication fe Use:	The da Vinci System is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing.
Representat Uses:	ive The da Vinci System has been successfully used in the following procedures, among others:
	 General laparoscopic surgical procedures such as cholecystectomy, Nissen fundoplication, radical prostatectomy, Heller myotomy, gastric bypass, donor nephrectomy, adrenalectomy, splenectomy and bowel resection.
	• General non-cardiovascular thoracoscopic surgical procedures such as internal mammary artery mobilization.
	• Thoracoscopically-assisted cardiotomy procedures such as mitral valve repair and totally endoscopic atrial septal defect closure.
WARNING:	The system should be used only by surgeons who have developed adequate robotic skills to perform the tasks associated with each procedure and who have received specific training provided by Intuitive Surgical, Inc., in the use of this device.
WARNING:	Performance characteristics for conduct of totally endoscopic or minimally invasive coronary artery bypass surgery using the da Vinci System have not been established

- **WARNING:** The clinical evaluation of the **da Vinci** System supporting its use for mitral valve repair was not performed totally endoscopically. Introduction and manipulation of the endoscopic instruments were controlled by the **da Vinci** System through port incisions (< 1 cm) while accessory technologies, such as atrial retractor and cardioplegia line, etc., were introduced through a mini-thoracotomy. Performance characteristics for conduct of totally endoscopic mitral valve repair using the **da Vinci** System have not been established. Therefore, the system should be used only by surgeons who have developed adequate robotic skills to perform the tasks associated with each procedure and who have received specific training provided by Intuitive Surgical, Inc. in the use of this device.
- **WARNING:** The friable nature of pulmonary tissue enhances the risk of vascular, bronchiolar, or other injury that will be difficult to control when using this device. Published clinical experience as well as clinical studies performed to support this marketing clearance have demonstrated that even surgeons considered expert in laparoscopy/ thoracoscopy have substantial learning curves of 10 to 12 cases.¹ Therefore, the system should be used only by surgeons who have developed adequate robotic skills to perform the tasks associated with each procedure and who have received specific training provided by Intuitive Surgical, Inc., in the use of this device.

General Precautions, Warnings, and Contra indications

The **da Vinci** System is to be used in accordance with this manual and should not be moved or used by any person who has not been trained by an Intuitive Surgical, Inc. Representative. Read all instructions carefully. Failure to properly follow instructions, notes, cautions, warnings and danger messages associated with this equipment may lead to serious injury or surgical complications for the patient. While these messages appear throughout the manual, this chapter provides some general precautions.

Any and all relative and absolute contra indications to endoscopic surgical technique applicable to the use of conventional endoscopic surgical instruments apply to the use of the **da Vinci** System. General, non-procedure specific, contra indications to endoscopic surgery include bleeding diathesis, morbid obesity and pregnancy.

Conversion to Non-Minimally Invasive Technique

CAUTION: Although the **da Vinci** System is safe and reliable, anatomical characteristics of a patient may preclude using minimally invasive techniques. Environmental or equipment failures may cause the **da Vinci** System to be unavailable. The surgical team should always have backup equipment and instrumentation available, and be prepared to convert to alternative surgical techniques.

^{1.} Falk, et al., Total endoscopic computer enhanced coronary artery bypass grafting, Eur J Cardiothorac Surg 2000; 17: 38-45.

Endoscopic Procedure Precautions

Only physicians having adequate training and experience with endoscopic techniques should perform endoscopic procedures with the **da Vinci** System. Medical literature should be consulted regarding techniques, complications, and hazards prior to performing any endoscopic procedure.

- **CAUTION:** When using the **da Vinci** System with insufflation, only CO₂ should be used as the insufflating gas. Insufflation should **only** be performed by personnel having adequate training and experience with this technique.
- **CAUTION:** Thermal hazards may exist from high temperatures. Eye hazards may exist from the high energy radiated light by the endoscopic camera and illumination system. Only personnel having adequate training and experience with the endoscopic camera and illumination system should operate such equipment. All **WARNING** and **CAUTION** messages provided with the endoscopic camera and illumination system must be followed.
- **CAUTION:** The force feedback associated with the **da Vinci** System is different from feedback experienced when using conventional instruments. As with any endoscopic procedure, the surgeon should rely on visual cues to enhance force feedback.
- **CAUTION:** This device should not be used near flammable anesthetics.

High Frequency Electrosurgery Precautions

The safe and effective use of endoscopic electrosurgery largely depends on factors solely under the control of the operating surgeon. Only surgeons having adequate training and experience with endoscopic electrosurgery should perform endoscopic procedures involving electrosurgery. The instructions, warnings and cautions provided with the Electrosurgical Generator Unit (ESU) must be followed or else serious injury or surgical complications may occur to the patient.

- **CAUTION:** Do not use electrosurgical equipment unless properly trained in the specific procedure being undertaken. Follow all instructions, warnings, and cautions provided with the ESU.
- **CAUTION:** The Intuitive Surgical Electrosurgical Instrument is designed for use with the coagulation (COAG) waveform of high frequency ESUs and a maximum peak voltage of 3kV (6kV peak-to-peak). Do not use settings on the ESU that exceed 3kV peak. Do not attempt to use the Foot Switch on the Surgeon Console with ESUs that are not compatible with the **da Vinci** System. Consult with your Intuitive Surgical Representative regarding compatible models.

Note: Only the COAG function is wired to the Foot Switch control.

CAUTION: Do not use the **da Vinci** System with CUT waveforms of the ESU.

- **CAUTION:** Electrosurgery may produce interference with internal or external pacemakers. Electrosurgery may cause these devices to enter an asynchronous mode or may inhibit pacemaker operation entirely. Consult the pacemaker manufacturer for further information when using electrosurgery in patients with cardiac pacemakers.
- **CAUTION:** Always check the cables, ESU, and instruments for insulation damage and proper function prior to use.
- **CAUTION:** Do not clean the tip with another instrument using directional movements away from the tip.
- **CAUTION:** To avoid inadvertent thermal damage to surrounding tissue and other hazards, the following should be observed.
 - Place the neutral electrode as close as possible to the operating field.
 - Always use the lowest output setting that achieves the desired surgical effect.
 - Do not deliberately or unintentionally energize other endoscopic instruments. Energizing other endoscopic instruments may cause tissue damage inside or outside the field of view.
 - Secure and route the ESU cable to the Intuitive Surgical Instrument to prevent cable damage and unintended disconnection.
 - Keep patient from coming in contact with grounded metal parts.
 - Place any monitoring electrodes as far as possible from the surgical electrodes or grounding pad when high frequency (HF) surgical equipment and physiological monitoring equipment are used simultaneously on the same patient.
 - Avoid using flammable anesthetics or oxidizing gases such as nitrous oxide and oxygen.
 - Use only non-flammable agents for cleaning and disinfecting. If flammable agents are used for cleaning or disinfecting or as solvents, they must be allowed to evaporate before application of HF energy.
- **CAUTION:** Make certain that the ESU audible output can be heard by the operating surgeon during ESU use with the **da Vinci** System.

Installation and Service Precautions

CAUTION: The **da Vinci** System may only be installed and serviced by Intuitive Surgical personnel. **DO NOT** attempt to install or service equipment without Intuitive Surgical personnel.

Transportation and Storage Precautions

When transporting or storing the **da Vinci** System, the Surgical Cart should have the instruments and camera removed and the Set-up Joints folded-in toward the center column. The Surgeon Console should have the Foot Switch Assembly attached to the base of the console. Always use the handle on the Surgeon Console to move the console. Always use the handle on the Surgical Cart to move the cart. See Chapter 1, "Introduction to the da Vinci System" and Chapter 9, "Glossary of Terms" for definitions.

CAUTION: The Surgeon Console and Surgical Cart are heavy and may present a hazard if control is lost when moving. Only trained personnel should attempt to move the **da Vinci** System.

International Electrotechnical Commission (IEC) 601 General Information

The **da Vinci** System is designed to be in compliance with IEC 60601-1, with the following mode of operation, and type and degree of protection against electric shock:

Mode of Operation:	Continuous
Type of Protection:	Class 1
Degree of Protection:	CF for all patient applied parts (inserted portion of Instruments)
Ingress Protection:	Ordinary, except Foot Switch which is watertight (IPX8)

Instrument and Endoscope Isolation

The Cannula Mount, Sterile Adapters and Instrument insulation are isolation barriers to electrical current. These parts need to be maintained unmodified for patient safety.

CAUTION: Do not modify the Cannula Mount, Sterile Adapters or instruments. Modifications can result in electrical hazards or performance degradation.

Accessory Equipment Interconnection

Accessory equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment.) All configurations shall comply with the system standard IEC 60601-1-1. Anyone connecting additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible for ensuring that the system complies with requirements of the system standard IEC 60601-1-1. If you have any questions, please contact your Intuitive Surgical Representative.

- **CAUTION:** Leakage current from interconnected electrical equipment may exceed safe levels. In order to maintain patient and user safety, it is important to interconnect only with devices in compliance with IEC 60601-1-1 requirements. It is the responsibility of the user to ensure that any interconnected equipment not supplied by Intuitive Surgical maintains compliance with IEC 60601-1-1 requirements.
- **CAUTION:** Leakage currents from other endoscopic instruments may be additive. To ensure maximum safety for the patient, only CF endoscopic accessories should be used with the **da Vinci** System.

General Requirements

Power Requirements

The **da Vinci** System is configured at the factory for two input voltages: 115V or 230V. Please refer to the electrical rating label on the rear panel of the Surgeon Console for the specific rating of the unit:

Voltage	Frequency	Input Current
115V	50/60Hz	12A
230V	50/60Hz	6A
100V	50/60Hz	12A
100/115V	50/60Hz	12A

Environmental Conditions: Operating

- Temperature: $10 \text{ to } 35^{\circ}\text{C} / 50 \text{ to } 95^{\circ}\text{F}$
- Humidity: 10 to 85% non-condensing

Environmental Conditions: Storage and Transport

Temperature:	10 to 50°C / 50 to 122°F
Humidity:	5 to 95% non-condensing for transport
	10 to 85% non-condensing for storage

Electromagnetic Compatibility

To ensure optimum performance, make sure the **da Vinci** System is connected to a dedicated, noise-free and well-grounded outlet.

The **da Vinci** System has been tested and found to comply with the emission and immunity limits for medical devices to the IEC 60601-1-2 and the Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency (RF) energy. If not installed and used in accordance with the instructions, the equipment may cause harmful interference will not occur in a particular installation.

If the **da Vinci** System does cause harmful interference to other devices, the user is encouraged to try to correct the interference by one of more of the following measures:

- Reorient or relocate the affected device(s)
- Increase the separation between the **da Vinci** System and the affected device(s)
- Connect the **da Vinci** System into an outlet on a circuit different from that to which the affected device(s) is connected
- Contact your Intuitive Surgical Representative for help
- **Note:** This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Battery Disposal Information

The **da Vinci** System contains a non-spillable, lead acid battery pack module that is not user serviceable. This battery pack must be disposed of in accordance with local regulations. Contact your local Intuitive Surgical Representative for disposal information.

Chapter 1

Introduction to the da Vinci System

The **da Vinci**® System is intended to control endoscopic instruments during thoracoscopic and laparoscopic surgical procedures. It is intended to be used by professionals in operating room environments.

The da Vinci System consists of three main components:

- The Surgeon Console with two Master controls and an integrated 3D display Stereo Viewer
- The Surgical Cart with a camera arm and up to three instrument arms
- The Vision Cart, which contains camera and image processing equipment



Figure 1-1 From left to right, the Surgeon's Console, the Vision Cart, and the Surgical Cart

Seated at the Surgeon Console, the surgeon operates using two Masters positioned directly under a magnified 3D display of the operative field. The surgeon rests his/her head between Head Sensors (located on either side of the View Port) in order to see the 3D display in the Stereo Viewer. Instrument tips viewed in the display are aligned with the Masters to ensure natural and predictable instrument movements. The hand/eye orientation and natural operative feel found in open surgery is maintained for the surgeon.

The **da Vinci** System places instrument movements under the direct, real-time control of the surgeon. The **da Vinci** System employs a kinematic (or joint movement) structure allowing the surgeon to use open surgery techniques at the Console. These open surgery techniques are instantly converted into minimally invasive surgery (MIS) movements at the surgical site. Using the **da Vinci** System, surgeons gain the benefits of access through small incisions without giving up the dexterity, precision and instinctive movements of open surgery.

The **da Vinci** System electronics allow the use of motion scaling of surgeon hand movements. Motion scaling reduces hand movements to correspondingly smaller instrument tip movements in the surgical field. Several settings allow surgeons to optimize scaling for different clinical applications. Natural tremor of the surgeon's hand is reduced which helps ensure stable and predictable instrument control.

Instruments have a total of six degrees of freedom plus grip, two more at the tip than traditional endoscopic instruments. Tip articulations mimic the up/down and side-to-side flexibility of the human wrist. These articulations extend the surgeon's MIS capabilities to a new level, enabling the surgeon to perform complex, reconstructive surgery through small incisions.

Surgeon's Console Overview

The surgeon sits at the Console to operate. The Console is located outside the sterile field. A high-resolution 3D display system is integrated into the Console and is viewed through the Stereo Viewer.

Masters

The surgeon holds the Master grips to control surgical instruments and an endoscopic camera which are attached to the arms on the Surgical Cart. The Masters' range of motion allows full, natural hand movements by the surgeon. The Masters follow the surgeon's movements precisely, translating those movements to the Surgical Arms.

3D Display System and Stereo Viewer

Two independent optical channels displayed on cathode ray tube (CRT) monitors are fused together to form a life-like 3D image of the surgical field. The **da Vinci** System delivers status messages using text and icons through the Stereo Viewer.

Controls and Indicators

The surgeon and assistant operate critical **da Vinci** System functions through buttons and foot switches. The **da Vinci** System functions that are used during a procedure, but not while actually operating, are located on the armrest. Functions that the surgeon needs to access while operating are located on Console Foot Switches. The Power, Emergency Stop, Standby and Ready buttons are located on the armrest and are available to the surgeon at all times.



Figure 1-2 The Surgeon's Console

Surgical Cart Overview

The Surgical Cart consists of a column and a base, to which the camera and instrument arms are attached. The cart is connected by cabling to the Surgeon's Console. When the surgeon moves the masters, the arms on the Surgical Cart respond to the surgeon's movements. Each cart contains one camera arm, to which the camera/endoscope assembly is attached. The cart also has two or more instrument arms, which support the full range of instruments provided by ISI.



Surgical Cart Legend:

- A. Camera Arm
- B. Instrument Arm
- C. Center Column
- D. Set-up Joint Rail
- E. Handle
- F. Base
- G. Anchor Pad

Figure 1-3 Side View of the Surgical Cart

Each arm is attached to the Setup Joint, which itself is attached to the column. The Setup Joint is used to position the arm in the best location for use during surgery. The arm contains the carriage to which instruments are attached, and also has a mount where cannulae are secured.



Instrument Arm Legend:

- H. Instrument Clutch Button
- I. Sterile Adapter Carriage
- J. Sterile Cannula Adapter
- K. Set-up Joint Release

Figure 1-4 Example of an Instrument Arm

The camera arm functions in a similar way, with a Setup Joint used to position the camera/ endoscope assembly. The arm has a mount for the camera/endoscope, and supports the attachment of a camera cannula.



Figure 1-5 The Camera Arm

Camera Arm Legend:

- L Set-up Joint Release
- M. Camera Clutch Button
- N. Camera Sterile Adapter Mount



Figure 1-6 Example of Surgical Cart Components Specific to Camera and Instrument Arms

The InSite[®] Vision System Overview

Please review "Accessory Equipment Interconnection" on page xviii for important details. For specifics on **InSite** components, please see the *InSite*® *Vision System User Manual*.



Figure 1-7 Example of Vision Cart Components

Chapter 2

Setting up the da Vinci System

This chapter explains how to organize and connect the **da Vinci** System components. Tasks include the following:

- Aligning the da Vinci System components.
- Connecting the components with cabling.
- Starting the system.

Setting Up the Operating Room

Positioning the **da Vinci** System and ancillary equipment in the operating room should maximize safety and efficiency. Care should be taken to avoid interference with other operating room functions and equipment. Intuitive Surgical personnel will be on site for installation. Contact your Intuitive Surgical Representative with any questions.

Surgeon Console Positioning

The Surgeon Console is non-sterile and should be placed outside of the sterile field. The Console is on wheels and can be rolled into place just prior to surgery. The wheels on the side with the handle are the only ones that are steerable.

- **Note:** When positioning the Console, use the handle on the back of the Console. Never push or pull the Console body or armrest to maneuver the Console into place.
- 1. Orient the Console so that the surgeon, when seated, has a view of the operative field and a clear line of communication with the assistant.
- 2. After final positioning, the rear Console Wheel Locks should be depressed and the power cord plugged into a dedicated outlet.
- 3. Lay out the cables between the Surgical Cart and the Console. All cables should be positioned on the floor in such a way as to avoid interference with other operating room equipment and also to allow easy removal of the Surgical Cart.

Main Circuit Breakers

Located on the back of the Surgeon Console, the main breakers control the primary power inputs for the **da Vinci** System. They need to be left in the "On" position at all times in order to charge the battery and/or maintain the charge in the battery. (The Power-On sequence is completed using the SYSTEM button on the User Switch Panel.) The upper main switch controls the Stereo Viewer and the lower main switch controls the **da Vinci** System.

- **Note:** It is important to connect the Surgeon Console power cord to a wall outlet at least ten hours before the first use in order to fully charge the battery. For best battery performance, the power cord should remain plugged in when system is not in use.
- **Note:** If the main circuit breakers are placed into the OFF position, it is important to wait until the AC Low LED light goes off before turning the main circuit breakers back ON. This takes approximately twenty seconds. The **da Vinci** System will not start-up using the SYSTEM button until the LED light is off.

Surgical Cart Positioning

To prepare for the Power-Up sequence, the Surgical Cart should be placed in an open space in the operating room to home the position of the arms.

- 1. Connect the cable ends marked P1, P2, P3 and P4 to the respective sockets on the Surgical Cart.
- 2. Connect the cable ends marked S1, S2, S3 and S4 to the respective sockets on the Surgeon Console before beginning the Start-Up sequence and arm calibration.
- **Note:** The cable sockets labeled P4 on the Surgical Cart and S4 on the Surgeon's Console are used for systems with a fourth arm.



Surgeon's Console Rear Panel

Color-coded Cable Ends and Connectors

Surgical Cart Cable Connections



Figure 2-1 Cable Connection Locations

Note: Some systems have color coding to facilitate the connection process.

The two wheels closest to the Surgical Cart are the only ones that are steerable. Use the handle to steer the Cart into position. Once the Cart is positioned, turn the two rear anchor pads to lock the Cart in place and avoid unwanted movement.

Note: Whenever the Surgical Cart is not in motion, it should be locked in place using the anchor pads.

Vision Cart Positioning

- 1. Move the Vision Cart into a position where it can be easily viewed by the assisting surgeon or nurse while they are working at the surgical table.
- **CAUTION:** It is recommended that the Vision Cart and the Surgeon Console be connected to separate electrical circuits to avoid overloading the circuits.
- 2. Connect the vision cabling to the Surgeon Console. Use the Cable Connection Guide provided below for specific instructions. The cables and connectors are color-coded to ease connection.



Figure 2-2 Rear View of Vision Cable Connections

Cable Connection Guide

Connect cables when noted in instructions. This table is meant as a guide for connection only.

Cable End	Connects To	Comments
S1, S2, S3 and S4	Back of Surgeon Console port marked S1, S2, S3 and S4, respectively	S1 cable end to S1 port, S2 cable end to S2 port, S3 cable end to S3 port, and S4 cable end to S4 port
P1, P2, P3 and P4	Rear of Surgical Cart port marked P1, P2, P3 and P4 respectively	P1 cable end to P1 port, P2 cable end to P2 port, P3 cable end to P3 port, and P4 cable end to P4 port

Audio Intercom Connector	Back of Surgeon Console port marked "INTERCOM."	Audio Intercom System.
Purple wire from video cable	Back of Surgeon Console port marked with purple ring	SVIDEO Input
White wire from video cable	Back of Surgeon Console port marked with a white ring	SVIDEO OUTPUT Y
Red wire from video cable	Back of Surgeon Console port marked with red ring	SVIDEO OUTPUT C
Blue wire from video cable	Back of Surgeon Console port marked with blue ring	SERIAL DIGITAL INPUT L
Green wire from video cable	Back of Surgeon Console port marked with green ring	SERIAL DIGITAL INPUT R
Wire marked: "Focus Control – Console" from the video cable	Back of Surgeon Console	FOCUS CONTROL
Intuitive Integrated Device Network	Back of Surgeon Console port marked by the letters i ² DN	i ² DN (ISI use only)
RS232 Serial Connector	Back of Surgeon Console	ISI use only.
IEEE 1394 FireWire Connector	Back of Surgeon Console	For future use.
10BASE-T Connector	Back of Surgeon Console	API customer use.
Console Fiber-Optic Connector	Back of Surgeon Console	For future use.
ESU Cautery Connector	Back of Surgeon Console	Foot Switch for cautery device.
		<u></u>

Note: Use only Electrosurgical Units (ESUs) approved for use with the **da Vinci** System. For compatibility information, please call your Intuitive Surgical Representative.

<u>Start-Up</u>

Surgeon Console and Surgical Cart

1. Press SYSTEM on the User Switch Panel to Power-On the **da Vinci** System. All lights briefly illuminate while the **da Vinci** System performs a Selftest and the following message is displayed on the monitor screens:



Selftest in progress...

Subsequently, the START-UP SEQUENCE and POWER LEDs are illuminated.

Note: Attempting to activate any **da Vinci** System controls (such as the User Interface buttons, Foot Switches, Head Sensor, etc.) while the Start-up sequence is in progress may cause the **da Vinci** System to fail the Selftest. While most buttons on the user interface panel are ignored during startup, some may cause a failure. Moving the Set-up Joints, Masters, instrument arms, or camera arm during the Start-up will also cause a failure of the Selftest. Restarting the **da Vinci** System will be necessary.

Note: The only functional controls that are active during Start-up are:

- SYSTEM
- EMERGENCY STOP
- COAG
- +/- (Focus)

The message below is displayed upon successful completion of the Selftest. Should the Selftest fail, an unrecoverable error message is displayed. The **da Vinci** System only completes start-up if all internal functions check out as fully operational.

Once the Selftest operation is successfully completed (approximately 30 seconds) the **da Vinci** System is ready to proceed with Surgical Arm homing maneuvers.

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Prepare Masters and Surgical Cart Arms for homing. Remove Instruments. Press READY when done.

Note: Prior to homing, you can view the system error log to view any previous error conditions. See "Viewing the Error Log" on page 8-4.

Homing is the process by which the **da Vinci** System moves the arms to a calibrated neutral position. To prepare for homing, the user must ensure there is adequate space for the arms to reach the neutral position without interference. Use the Set-up Joints to position the arms apart from one another.

- 2. Press READY to instruct the **da Vinci** System that it is safe to move the Masters, instrument arms and camera arm to their home locations. An advisory beep will sound once every three seconds until the process has begun, and three beeps will sound when the process is complete.
- **Note:** If homing fails, the system displays an error message and the following icon designating which instrument arm failed to home:



The system waits to try again. The probable cause of failure is an object obstructing the path of any of the arms (Masters, instrument arms, and camera arm). Ensure the arms are free to move and press READY again.

Note: Instruments and the camera/endoscope cannot be present on the **da Vinci** System during the homing process. The Instruments will be detected and the **da Vinci** System will notify the user if they are found on the **da Vinci** System during homing. The camera will not be detected. The entire procedure will last approximately fifteen seconds during which the following messages are displayed on the screen:

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Start-up in progress. Please wait... Press STAND BY to abort.

If it is necessary to interrupt the homing process, press STANDY BY and the **da Vinci** System returns to the previous stage. The homing operation must be restarted before the **da Vinci** System can be used.

Immediately after homing successfully completes for a particular arm, the system initiates a mechanical integrity test for that arm's mechanics. The test detects any broken or off-track wire rope cables prior to draping and wheeling of the system up to the table.

During this step, the appropriate joints move briefly while the system monitors normal error checks. A lack of errors indicates a successful test.

- **Note:** The test is skipped for all arms if a sterile adapter has been present on any PSM since power up. No additional user feedback is displayed during the test. If a system error occurs during the test, the system transitions to a non-recoverable error state and a system restart is necessary.
- 3. Place the Foot Switch assembly and the surgeon's chair in a comfortable position. The Stereo Viewer can be raised or lowered to a comfortable working height by pressing the Viewer Height buttons located on the left side of the User Interface Panel.
- 4. Power on the Vision cart components. See the InSite Vision System User Manual for details.

Draping the da Vinci System

At this point in the preparation process, the Surgeon Console, the Surgical Cart and the Vision Cart should all be connected and powered up. The Surgical Cart has homed the arms and is ready to be draped.

Prepare the Sterile Accessories

Part of the draping process involves attaching Sterile Adapters to the instrument arms. Before draping, organize the sterile accessories as shown below.



Figure 3-1 Example of Sterile Accessories

- **CAUTION:** The use of "Flash" sterilization is not recommended for any instruments or accessories.
- **Note:** The picture above is representative of the sterile set-up accessories. Individual **da Vinci** Systems may have alternative components depending on the specific configuration of the system. For example, the type of camera/endoscope and the length of the cannulae may be different.

Sequence of Draping

Each arm has its own drape. Intuitive Surgical recommends two people, a sterile and non-sterile staff member, complete proper placement of the sterile drapes.

The sequence is effectively the same regardless of how many arms your system has (three or four).

- 1. Using the Setup Joint buttons, move one instrument arm and the camera arm aside. (If your system has four arms, move two instrument arms and the camera arm aside.)
- 2. Drape the other instrument arm and then move it away from the undraped arms.
- 3. Drape the camera arm and move it away from the adjacent undraped instrument arm.
- 4. Drape the next instrument arm. If another instrument arm is present, move the draped arm away and drape the final arm.

Guidelines for Instrument Arm Draping

Two types of drapes are used for the instrument arm: an older version with adhesive to attach the sterile adapter, and a newer version using a plastic clip. Sterile adapters are changed at the same time new drapes are attached. Please refer to the chart on "Instrument Arm Sterile Adapters Compatibility" on page 3-13 to ensure proper component compatibility.

Attaching Sterile Adapters to the Drapes

- **Note:** Sterile adapters have a design life of 50 uses. The system tracks the usage of each adapter, and displays the number of uses left at the end of each procedure. If you have more than one **da Vinci** system, group the sterile adapters by system to ensure proper tracking of usage.
- 1. Partially unfold the instrument arm drape to the sterile adapter reinforcement (white plastic).
- 2. Slide the instrument arm sterile adapter into the sterile adapter reinforcement (white plastic).

Note: For adhesive backed drapes, remove the adhesive covering and slide the sterile adapter into the opening.





- 3. Once instrument arm sterile adapter has been completely inserted into sterile adapter reinforcement (white plastic), raise the hinged portion so that the two components lock together.
- **Note:** For adhesive backed drapes, firmly press the sterile adapter onto the adhesive to ensure a uniform seal



Figure 3-3 Example of the Locked Tab

4. Insert the sterile adapter/drape onto the instrument arm in the usual manner. Listen for the disc synchronization of the sterile adapter before proceeding.



Figure 3-4 Adapter Secured to Instrument Arm

To remove the sterile adapter from instrument arm:

- 1. Push down on the release tab (or push up for the old style).
- 2. Pivot the sterile adapter forward.

3. Lift the adapter away from instrument arm.



Figure 3-5 Pushing Down on the Sterile Adapter Release Tab

Attaching Cannulae to the Instrument Arms

- 1. Open the drape to expose the Cannula Mount Reinforcement.
- 2. Align it with the Cannula Mount on the instrument arm.
 - a. If you are using a traditional Cannula Mount, align the pins on the Cannula Mount with the holes in the drape's Cannula Mount Reinforcement. Place the Cannula Mount on the instrument arm and tighten the screws using the Cannula Mount wrench. Proceed to Step 3.



Cannula Mount

Cannula Mount Reinforcement



Wrench, Cannula Mount

Cannula Mount

Figure 3-6 Attaching the Cannula Mount to the Instrument Arm

b. If you are using the twist-lock Cannula Mount, align the mount with the hole in the drape's Cannula Mount reinforcement. Insert the key into the slot on the instrument arm, then twist the lock in a clockwise direction to secure the Cannula Mount to the instrument arm.



Mounting Plate

Twist-lock Cannula Mount



Rotate Lock Clockwise to Secure

Figure 3-7 Attaching the Twist-lock Cannula Mount to the Instrument Arm

3. Install the instrument arm cannula seals onto the cannula with the reducer flap facing forward.

Note: Cannula seals should be installed in <u>all</u> cases.
4. Attach the cannula to the Cannula Mount. First align the cannula to the pin on the bottom of the Cannula Mount. Then, hand tighten the screws.



The following steps are performed by the non-sterile person:

- 5. Take the open inside edge of the drape and pull it over the remainder of the instrument arm and Setup Joints.
- 6. Ensure that there is adequate drape material for the instrument arm to function through the full range of motion.



Figure 3-8 Locations for Drape Straps

- 7. Attach the drape straps in the appropriate locations as shown above.
- **Note:** See the Instructions for Use corresponding to each drape and sterilizable accessory for additional information.

Camera Arm Draping Instructions

Sterile Person:

- 1. Open the sterile drape package and place the arrow toward your body.
- 2. Unfold according to the arrows.
- 3. Insert one hand into center of drape.

4. Extend the closed end of drape until the adhesive strip and reinforcement section are exposed (adhesive side faces out).



- A. Sterile Camera Arm Adapter
- B. Adhesive strip
- C. Reinforcement section

Figure 3-9 Preparing the Camera Arm Drape

5. Remove the liner of the adhesive strip and mate to the Sterile Camera Arm Adapter.



Figure 3-10 Attaching the Sterile Camera Arm Adapter

- 6. Hold the drape open and slide it over the top of the camera arm until the sterile adapter is near the carriage.
- 7. Align the pins on the Camera Cannula Mount with the reinforcement and the hole in the drape.
- 8. Snap the Cannula Mount into place.



Figure 3-11 Attaching the Camera Cannula Mount

Note: Make sure that there are no folds of drape material behind the Camera Cannula Mount before installing. Ensure the drape is straight and that the seam runs along the top of camera arm.

9. Align the Sterile Camera Arm Adapter with the carriage on the camera arm, create a trough for the endoscope, and push it firmly into place.



Figure 3-12 Creating the Trough in the Camera Arm Adapter

- 10. Extend the drape over the elbow of the camera arm.
- 11. Take the open end of the drape and pull it over the remainder of the arm and Set-up Joints.
- 12. Attach the drape straps in the appropriate locations as shown in Figure 3-8 on page 3-5.
- 13. Move the draped camera arm close to adjacent draped instrument arm.

Repeat "Camera Arm Draping Instructions" on page 3-5 for the remaining instrument arms.

Draping Instructions For the Stereo 3D Camera

Sterile Person:

- 1. Open sterile drape package, place the arrow toward your body, and unfold according to the arrows.
- 2. Attach the recessed end of Sterile Camera Adapter to the sterile endoscope.



Recessed end



Figure 3-13 Attaching the Sterile Camera Adapter to the Endoscope

3. Insert the endoscope into the drape, sterile adapter end first.

4. Push the Sterile Camera Adapter through the elastic end of the drape until it fits around the sterile adapter.





Figure 3-14 Pushing the Adapter through the Drape

5. Fix the drape to the endoscope with supplied adhesive tape.



Figure 3-15 Taping the Drape to the Endoscope

- 6. While holding the camera head, the non-sterile person connects the Sterile Camera Adapter to the camera head.
- 7. While holding the camera head, the non-sterile person inverts the drape over the camera head and pulls it along the cables.





Figure 3-16 Connecting the Camera and Inverting the Drape

The InSite® Vision System Set-Up

Refer to the InSite® Vision System User Manual.

Camera and Endoscope Calibration

Normal usage can alter the factory calibration of the 3D endoscope image over time. To ensure maximum image quality, every camera head and endoscope should be calibrated prior to each case. An angled endoscope requires calibration in both the Up and Down directions.

- 1. Select and attach an endoscope to the camera head, if you have not already done so.
- 2. Attach the endoscope Alignment Target, with the crosshairs running vertically and horizontally, to the end of the endoscope.
- 3. Press the SCOPE ANGLE button to select a direction, choosing either Straight, Up or Down. The selection changes each time you press the button.



Figure 3-17 The Scope Angle Button and Direction LEDs

4. Press TEST IMAGE. While looking into the Stereo Viewer, use the arrow keys to align the image of the crosshairs displayed in the Stereo Viewer until the green and magenta images completely overlap.



Figure 3-18 Test Image Button and Calibration Arrows

- 5. When finished, press and hold the TEST IMAGE button until three chimes are heard. This process stores the calibration information for that specific Scope Direction in memory. Repeat for any other Scope Direction selections.
- **Note:** You can abort the calibration process without storing any information by quickly pressing the TEST IMAGE button.
- **Note:** Previous calibration information is stored through Power-On and Power-Off unless calibration is intentionally changed.

After storing the calibration parameters by pressing TEST IMAGE for three seconds, the Calibration mode is exited and the **da Vinci** System returns to normal operation.

Note: Each time a camera head is changed, all endoscope angles should be recalibrated. The black balance (ABC) and white balance (AWC) functions should be performed on the Vision cart as well. See the *"InSite Vision System User Manual"* for details.

Operating Modes

The **da Vinci** System has four operating modes: Stand By, Ready, Follow and Emergency Stop, each of which is reviewed below.

Stand By Mode

Stand By is a state where the **da Vinci** System does not respond to the Head Sensor or camera control movements at the Surgeon Console (though you can perform Master clutching). In effect, the instrument and camera arms are disabled. There are a number of ways to enter Stand By Mode:

- The **da Vinci** System automatically goes to Stand By upon completion of the camera/endoscope alignment process.
- The STAND BY button is pressed while the system is in Ready Mode.
- The **da Vinci** System defaults to Stand By Mode from Ready Mode after one minute of elapsed time without activation of the Head Sensor.
- The da Vinci System defaults to Stand By Mode after recovery from an error state.
- The **da Vinci** System defaults to Stand By Mode when the Power button is pushed. This prevents the system from shutting down without the surgeon's knowledge if the Power button is pressed accidently while in Follow Mode.

The displayed text message for Stand By is:

Standing By... Press READY to continue.

Ready Mode

The **da Vinci** System enters Ready mode when READY is pressed on the User Switch Panel. The displayed text message for Ready is:

Ready. Place head in View Port to operate.

In Ready mode, the user starts operating by first taking hold of the Masters, and then placing his or her head in the View Port. This action will result in three beeps. Matching Grip icons may be visible. If visible, the user then matches the grip of the Masters to the tip of the instrument they are designated to control. Once a Matching Grip icon disappears for a specific arm, the **da Vinci** System arm enters Follow mode. If no instruments are in place on the instrument arms, movement of the Masters will not affect the instrument arms.

- **WARNING:** When the Head Sensor in the View Port is activated, the Matching Grip icons appear in the Stereo Viewer. When they appear, the surgeon MUST match the grip of the Masters to the tip of their respective instruments in order to enter Follow mode.
- **WARNING:** The **da Vinci** System should be placed in Stand By mode whenever the surgeon is <u>not</u> actively performing surgery with the **da Vinci** System.
- **CAUTION:** Activation of the Head Sensor is caused by any interruption of the infrared signal between the two sensors.

Follow Mode

The manipulators located at the Surgeon's Console and the instrument arms have a "master/slave" relationship. The "master" refers to the Master Tool Manipulators, or MTMs, used by the surgeon to control the instruments. The instruments themselves have a "slave" relationship to the masters; whatever movements the masters make, the slaves will follow exactly.

Follow Mode contains a feature called Follow On Matching Grip (FOMG). FOMG ensures that the grip position at the master matches the grip position at the instrument before instruments are allowed to "follow" any movement made with the masters. This feature ensures that:

- An item held by an instrument tip will not be accidentally dropped.
- No movement of the instrument tip can occur until the surgeon makes a voluntary motion on the master, signifying that he or she is ready to enter Follow Mode.

This design feature prevents the instruments from accidentally moving without the specific intent of the surgeon. For example, without FOMG the surgeon could accidentally bump one of the masters; if the slave instrument moved immediately, injury to the patient could occur. Follow Mode thus ensures that any movement of the instrument is the result of deliberate action by the surgeon.

Matching the grip position may require either squeezing the master grip (if the slave is closed and the master is open) or opening the master grip (if the slave is open and the master grip closed). In some cases, the master and slave grips may coincidentally agree. When this occurs Follow Mode requires that the master grip be moved to the opposite extreme and then back to agreement with the slave.

To access Follow Mode, the **da Vinci** System must be in Ready mode with instrument(s) installed, camera selected and the Head Sensor activated. The surgeon must view the position of the instrument in the Stereo Viewer, then "confirm" the position by gently squeezing or opening the grip to match the position of the instrument on each arm.

A few additional considerations exist for certain instruments:

- "Single-finger" tools such as cautery hooks, scalpels and spatulas require deliberate motion, but nothing more.
- Masters controlling clip appliers must be more than 90% open to begin following. (Clip application starts with an open clip.) Again, deliberate motion is required.

- Any instrument tips with a previous grip more than 95% closed will be considered matched when the Master grip is 95% closed.
- **Note:** The **da Vinci** System "Follows" even if no camera is present in the camera arm, provided that a camera has been selected on the User Interface Panel.
- **Note:** The Matching Grip icon disappears once the master's grip matches the tip of the instruments they are designated to control. The matching grip can be opening or closing the grip, or a slight movement of the Master.
- **Note:** The Matching Grip icons may appear if the system changes from Ready mode with an inactivated Head Sensor in the View Port to Ready mode with an activated Head Sensor in the View Port.

Again, if the Matching Grip icon appears, the degree of Master Grip closure must match that of the corresponding Instrument.

Emergency Stop

When EMERGENCY STOP is pressed, the Masters are immediately disconnected from the instrument arms and camera arm. The Masters and instrument arms are viscously damped and will move due to gravity or other external forces. The camera arm feels stiff but can be moved. Set-up Joints remain active and are able to be positioned as necessary. Once EMERGENCY STOP is pressed, the following message is displayed:

EMERGENCY STOP activated. Press FAULT OVERRIDE to continue.

- **WARNING:** Energy instruments may still be energized. The system does not cut power to instruments which can be energized. Immediately stop energizing these instruments if an Emergency Stop occurs.
- **WARNING:** Instrument tips will move slowly if external forces are applied. Remove instruments immediately to prevent tips from contacting tissue.
- **WARNING:** If the **da Vinci**® Ultrasonic Shears are on an instrument arm in an Emergency Stop or Fault Condition, immediately stabilize the instrument arm to prevent unintended movement. This instrument may move due to gravity or other external forces, at a greater rate than with other instruments. Remove the instrument immediately to prevent tips from inadvertently contacting tissue.

Press FAULT OVERRIDE to recover from Emergency Stop mode. The **da Vinci** System transitions to Stand By mode and is ready to return to normal operation.

Instrument Arm Sterile Adapters Compatibility



da Vinci® Surgical System User Manual

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Use During a Procedure

This chapter provides instructions for performing the following basic tasks:

- Selecting port locations
- Using the Surgeon's Console before and during surgery
- Using the Surgical Cart before and during surgery
- Working with instruments
- Working with endoscopes

Selecting Port Locations

The initial port location should be selected giving consideration to the procedure, specific anatomy and the camera/endoscope to be used. The basic steps are described below; specific instructions are provided later in this chapter.

- 1. Identify the specific camera port location and approximate instrument port locations.
- 2. Lock the surgical table in place to avoid unexpected patient movements relative to the **da Vinci** System.
- 3. Insert the camera cannula, then manually insert the camera/endoscope to assess the patient's anatomy prior to positioning the **da Vinci** System and accessory ports for surgery.
- **DANGER:** Once the **da Vinci** System is positioned, cannulae are placed in the patient and manipulator arms are attached to the cannulae, the surgical table MUST NOT BE MOVED in any way. Serious injury could result.
- 4. Once the balance of the port locations are identified, insert the remaining cannulae and roll the surgical cart up to the table.
- 5. Anchor the Surgical Cart in place using the Anchor Pads.

The following sections describe the use of the **da Vinci** System functions during a procedure. The instructions assume that the system is turned on and the Start-Up sequence has completed normally. If you have not read the explanation of the different system modes starting on page 3-10, do so now before continuing.

Using the Surgeon's Console

Adjusting the Console for Comfort

- 1. Adjust the chair seat and back to maximize comfort the surgeon's comfort relative to the Surgeon Console arm rest.
- 2. Adjust the Stereo Viewer height if necessary by pressing the Up/Down buttons located on the left side of the User Interface Panel. The viewer will move up or down, while the armrest stays in place.
- 3. Adjust the intra-ocular spacing of the image if needed by rotating the knob located on the underside of the Stereo Viewer. This adjustment modifies the left/right spacing of the images to match the spacing of the surgeon's eyes.
- 4. Adjust the volume of the Audio Intercom System. The speaker is mounted within the headrest; after turning on the system at the Vision Cart, have a co-worker speak while standing near the Vision Cart and adjust the volume as necessary.

Working with the Video Image

Note: Camera angle and magnification can be adjusted as necessary, but as in traditional laparoscopic surgery the surgeon works within a limited field of view. Before moving any instrument be sure that the tips are within the field of view.

Selecting the Scope Angle

Part of the setup process included calibrating the camera/endoscope. If you have not performed this step, see "Camera and Endoscope Calibration" on page 3-9.

- 1. After using the endoscope to view the patient's anatomy, mount the camera/endoscope onto the camera arm.
- 2. Press the Scope Angle button on the User Interface Panel to match the endoscope tip in use, if you have not already done so. Options include Straight (no angle on the tip), Up or Down (angled tip inserted facing up or facing down).

When the Scope Angle is changed and the **da Vinci** System is in Ready Mode, the Masters will realign to match the instrument tips. The following message appears in the Stereo Viewer and Assistant Monitor:

Scope selection changed to ______ Aligning Masters...

Note: You cannot enter Follow Mode before making a Scope selection.

WARNING: If the wrong Scope Angle selection is made, instrument tip motion may appear to be non-instinctive.

Switching Display from 3D to 2D

The **da Vinci** System uses the 3-dimensional (3D) display at the Surgeon Console by default at start-up.

- 1. To switch to a 2-dimensional (2D) display at the Surgeon Console, press DISPLAY on the User Interface Panel.
- 2. To return to a 3D view on the Stereo Viewer, press DISPLAY again.

Focusing the Video Image

The +/- (Focus) foot switch is used with the toe or heel to focus the endoscope. The **da Vinci** System remains in Follow Mode and the surgeon maintains active control of the instrument arms throughout the focus change process.

- 1. To focus in, press the top of the foot switch marked with the plus (+) sign.
- 2. To focus out, press the bottom of the foot switch marked with the minus (-) sign.

Alternatively, a non-sterile attendant can focus the camera using the Focus IN and Focus OUT function on the Focus Controller, located on the Vision Cart.

Repositioning the Camera/Scope Image

Once the camera/endoscope assembly is mounted to the camera arm and positioned, the image can be maneuvered. For example, to increase magnification or change viewing angle, complete the following steps:

- 1. Put the da Vinci System in Ready mode.
- 2. Activate the Head Sensor.
- 3. Press and hold the CAMERA foot switch.
- 4. Move the Masters to reposition the image.
- 5. Release the CAMERA Foot Switch to re-engage the Masters with the instruments.

When the CAMERA foot switch is pressed, the instruments are electronically held in place and are not controlled by the Masters. The Masters are linked to the camera arm. When the CAMERA foot switch is released, the Masters resume their connection with the instruments. During repositioning, the camera control icon is displayed in the center of the top edge of the screen.



Note: The da Vinci System uses active sensing and controls which ensure that the alignment of pointing direction is maintained between the masters and the instrument tips. If an instrument does not move or point in the direction expected, remove and inspect the instrument for broken cables or other damage. If the problem persists or cannot be isolated to an instrument, contact an Intuitive representative.

Note: After the repositioning is complete, the Masters will realign to match the orientation of the instrument tip locations. The surgeon should maintain a light touch on the Masters to allow them to move automatically to the appropriate position. The following message is displayed:

Camera movement complete. Aligning Masters...

Camera Orientation Line

The orientation of the camera with respect to the floor is represented as a Camera Orientation Line located in the lower right-hand corner of the Assistant Monitor and Stereo Viewer. Representative Camera Orientation Lines are shown below:



Camera is horizontal to the floor.



To re-establish a horizontal view, press the Camera foot switch and move the Masters counter-clockwise.

Using the Auxiliary Instrument Arm

If your system has a "fourth arm" (auxiliary instrument arm), you can assign it to either the left or right Master, or leave it unassigned (which prevents the arm from swapping). The instrument arms are colored green, red, or yellow for easy identification.

Assigning the Auxiliary Arm to a Master

- 1. Identify an instrument arm by its color.
- 2. Identify the LEFT and RIGHT Master buttons corresponding to the color of the instrument arm.
- 3. Press either the RIGHT or LEFT MASTER button on the UIP until the LED lights up next to the desired Master. (The default settings for a system with only two instrument arms are shown in Figure 4-1. See "SELECT MASTER" on page 6-7 for all default information).



Figure 4-1 UIP Buttons used to Select Masters for Instrument Arms

See "SELECT MASTER" on page 6-7 for important information about assigning instrument arms to the Masters.

Swapping Instrument Arms

The surgeon can swap control of the instrument arms during a procedure by using the Clutch foot switch.

- 1. Ensure that each instrument arm is assigned to a Master.
- 2. When ready to swap arms, briefly tap the Clutch foot switch (called a "pedal-click"). The system displays a message indicating the change of control, and displays the "Matching Grip" icon.
- 3. Using the Masters, match the grip and continue.

For details on matching the grip and viewing auxiliary instrument arm information, see "Viewing Auxiliary Arm Information" on page 6-9.

Operating the Masters

Repositioning the Masters

During use, the Masters may become positioned too close to the console or armrest. The Masters can be repositioned to avoid collisions with the Console or to optimize the ergonomic position of the surgeon, without affecting the location of the instrument tips. To reposition the Masters:

- 1. Activate the Head Sensor.
- 2. Press and hold the CLUTCH foot switch to disconnect the Masters from the instruments.
- 3. Reposition the Masters for surgeon comfort.
- 4. Release the foot switch to re-engage the Masters with the instruments.

When the foot switch is pressed, the instruments are electronically held in place and disconnected from the Masters. When the pedal is released, the Masters resume their connection to the instruments and the surgeon can proceed.

During the repositioning process the Master repositioning icon is displayed in the center at the top edge of the screen.

Scaling

Scaling can be changed in Stand By and Ready modes when the Head Sensor is inactive. The default scale is Fine scaling.

Three scaling options are available. To change the scaling, press the button indicating your selection: No Scale, Fine or Ultra Fine.

Working with the Surgical Cart

Cannula Insertion and Connection

After port incisions are made, the instrument arms and camera arm can be put into position. The arms are placed by releasing the Set-up Joints and moving the arms to their optimal position. The Set-up Joints can be unlocked by pressing the release button. There are two release buttons on each instrument arm and one on the camera arm. See "Surgical Cart Overview" on page 1-4. for details.

During a Set-up Joint move, the Stereo Viewer and Assistant Monitor display an icon in the appropriate location to signify which one is being moved.



Set-up Joint Positioning in Progress

The following screen message is displayed after the move is completed.

Surgical Cart Arm positioning complete.

If the camera or instrument arm set-up joints are inadvertently moved during a procedure (for example, someone leans against an instrument arm without pressing a Set-up joint release button), the system will sound an auditory warning and post an icon and a message on the stereo viewer and instrument monitor:



Unexpected Set-up Joint Movement... Press Set-up Joint button to clear.

This warning does not prevent use of the system. The icon is displayed next the arm that experienced the movement. Press any Set-up joint release button on the arm to clear the message and continue.

Selecting the Cannula Length

The **da Vinci** System is equipped to function with two different instrument arm cannula lengths: SHORT (100mm) and LONG (150mm).

To select the cannula length, press the CANNULA button on the User Interface Panel until the LED next to the desired length illuminates.





Note: The Cannula button can only be used to change the length in two modes: when the system is in STANDBY mode and no instruments are present on the instrument arms, and when the system is in READY-HEAD-OUT mode, and no instruments are present.

Note: If a cannula length is not actively selected by the user, the setting defaults to SHORT.

Note: The same cannula length setting applies to all instrument arms.

See "CANNULA" on page 6-6 for important Warning information about cannula length selections.

Camera Cannula Connection to Camera Arm

Instrument arms and the camera arm should be positioned so that they have maximum range of motion without interfering with each other during the course of the operation.

To position the camera arm:

- 1. Identify the camera port and instrument ports.
- 2. Insert the disposable Camera Cannula into the patient according to its Instruction for Use.
- 3. Clutch the camera arm such that the plane of the camera's Cannula Mount roughly matches the plane of the Camera Cannula. Be sure to release the clutch after alignment; the Set-up Joint cannot be manipulated while the camera arm is clutched.
- 4. Move the surgical cart towards the patient. Direct the non-sterile person to steer the cart in a direction such that the camera's Cannula Mount aligns with the Camera Cannula.
- 5. Using the Set-up Joint Release button, bring the Camera Cannula Mount to the Camera Cannula. Avoid large side-to-side movements of the camera arm Set-up Joints as these movements should be made by steering the surgical cart. Lock the surgical cart in place using the Anchor Pads.
- 6. Connect the Camera Cannula to the camera's Cannula Mount.
- 7. Insert the endoscope into Camera Cannula and survey the anatomy and proposed instrument arm cannula ports.

Instrument Arm Cannula Insertion and Connection

Instrument arms should be positioned so that they have maximum range of motion without interfering with each other during the course of the operation. To accomplish this, use one of two recommended approaches:

Option 1: Instrument Arm Cannula Not Attached To The Instrument Arm

- 1. Insert the obturator into the instrument arm's cannula.
- 2. Insert instrument arm's cannula into patient under direct visualization.
- 3. Remove the obturator.

Intuitive Surgical, Inc.

- 4. Use the Set-up Joint release button to orient the instrument arm Cannula Mount with the instrument arm cannula.
- 5. Attach the instrument arm cannula to the instrument arm Cannula Mount, while stabilizing the cannula in the patient. The **da Vinci** System will hold the arm in the middle of it's range of motion.
- 6. Use the Set-up Joints to position the cannula towards the target anatomy.
- 7. Align the remote center using the Set-Up Joint release to slide the cannula into the patient until the remote center is appropriately aligned.
- 8. Repeat this process for the remaining instrument arms.
- **WARNING:** When using the sharp obturator, the recommended method is to insert the instrument arm cannula into the patient, as described above, rather than inserting the cannula while it is connected to the instrument arm.

Option 2: Instrument Arm Cannula Attached To The Instrument Arm

- 1. Insert the obturator into the instrument arm cannula.
- 2. Use the Set-up Joints to orient the cannula perpendicular to the body wall at the incision site. During these steps, the **da Vinci** System will hold the arm in the middle of its range of motion.
- 3. Under direct visualization, insert the cannula into the patient using the Set-up Joint release button. Hold the cannula during insertion.
- 4. Remove the obturator.
- 5. Use the Set-up Joints to position the cannula towards the target anatomy.
- 6. Align the remote center using the Set-up Joint release to slide the cannula into the patient until the remote center is appropriately aligned.

Instrument Arm and Camera Arm Clutching

The instrument arms and camera arm may be positioned relative to their remote center using the Clutching function. During clutching, the screens will show an instrument arm/camera arm clutching icon (see below) in the appropriate location to signify which one is being moved. Clutching is generally used to introduce instruments into the surgical field.



After clutching is complete, the instrument tips will be in a different location. The Masters will be automatically realigned to match the orientation of the new instrument tip locations. The surgeon should maintain light touch on the Masters to allow them to move automatically to the appropriate position. The following screen is displayed:

Surgical Cart Arm positioning complete. Aligning Masters...

Working with Instruments

Instrument Placement and Removal

The *Intuitive Surgical EndoWrist*[®] instruments are available in both 5mm and 8mm shaft sizes. The original instruments were designed with the 8mm shaft size, and are used in most general surgical applications.

The reduced shaft and jaw diameter of the 5mm instruments allows for a sleeker profile, as well as enhanced usage in general and pediatric surgery. The 5mm design also allows for a smoother manipulation.

The 5mm and 8mm families of instruments operate in the same fashion: both are attached to the sterile adapter in the same way, and both require the use of a cannula sized to fit the instrument.

The following points illustrate differences and/or special requirements for the 5mm instruments:

- To use 5mm instruments, your system must have operating system software A4.2, Patch 6 or greater installed. Please contact your ISI clinical representative if you are not sure about your current software version.
- 5mm instruments must be used with the Intuitive Surgical 5mm cannula (P/N 313147) or with the Intuitive Surgical 8mm cannula (P/N 311954) and the Intuitive Surgical Cannula Reducer (P/N 371051).
- The *EndoWrist* 5mm Monopolar Cautery Instrument must **ALWAYS** be used in conjunction with *Intuitive Surgical* 5mm metal cannula (P/N 313147) or with *Intuitive Surgical* 8mm metal cannula (P/N 311954) and *Intuitive Surgical* metal cannula reducer (P/N 371051).

WARNING: Failure to do so will result in electrical arcs from the wrist and alternate site burns due to capacitive coupling.

- The *EndoWrist* 5mm Monopolar Cautery Instrument should **NEVER** be used with any other cannula or trocar system. This restriction includes:
 - Use without a cannula
 - Use with a plastic cannula
 - Use with a non-Intuitive Surgical metal cannula system
 - Use with a metal cannula inserted through a plastic cannula

WARNING: Doing so will result in electrical arcs from the wrist and alternate site burns due to capacitive coupling.

Inspect the instruments before each use for broken, cracked, chipped, or worn parts. Discontinue the use of instruments that have these characteristics. To attach both 5mm and 8mm instruments:

- 1. Ensure that sterile adapter carriage is at the top of the arm and the instrument wrist is straight.
- 2. Attach the instrument by inserting the tip of the instrument into the cannula and then sliding the instrument base into the Sterile Adapter until fully seated.

3. Ensure both sides of the instrument are engaged in the Sterile Adapter rail.



Figure 4-3 Attaching the Instrument to the Sterile Adapter

- **CAUTION:** The instrument wrist must be straight prior to insertion through cannula to prevent potential damage to the instrument.
- **Note:** Prior to attaching an instrument, the sterile adapter carriage must be at the top of arm and the input pulleys must be stationary. Attempting to attach an instrument while the carriage is traveling, or while the pulleys are spinning, will result in the need to remove the instrument. The system will display a message instructing you to remove the instrument, and a white "X" on a blue field flashes next to the PSM icon in the display until the instrument is removed. In addition to the visual and auditory warnings, the system will stop the movement of any joint or input pulley involved with that instrument until the instrument is removed.
- Note: Ensure the drape is not captured between the instrument and Sterile Adapter.

Once in position, the instrument is automatically identified and mechanically engaged by the **da Vinci** System. When the process is complete, the icon disappears.

The instrument may be introduced into the surgical field using two methods: manual insertion or with a Guided Tool Change.

Manually Inserting Instruments

The following instructions are valid for both 5mm and 8mm instruments.

- **Note:** The instructions listed below assume that you are using the appropriate cannula for the instrument: 5mm cannulae for 5mm instruments, and 8mm cannulae for 8mm instruments. If you are using both 5mm and 8mm instruments during the same procedure, you can use the 8mm to 5mm cannula reducer to introduce 5mm instruments in an 8mm cannula.
- 1. Press the Clutch button on the instrument arm (one beep and the Clutch icon appears for the corresponding arm) to allow the full range of motion of the instrument arm.

- 2. While watching the Stereo Viewer or Assistant monitor, slowly introduce the instrument until the instrument tip is just visible emerging from the distal end of the cannula, then guide it into the surgical field.
- 3. Once the desired instrument tip location is reached, press the Clutch button again (one beep and the Clutch icon disappears), transferring control of the instrument to the surgeon at the Surgeon Console.

Guided Tool Change

You can also use the Guided Tool Change procedure to reach the location of the previous instrument tip in the surgical field (available for most ordinary instrument exchanges).

- **Note:** The instructions listed below assume that you are using the appropriate cannula for the instrument: 5mm cannulae for 5mm instruments, and 8mm cannulae for 8mm instruments. If you are using both 5mm and 8mm instruments during the same procedure, you can use the 8mm to 5mm cannula reducer to introduce 5mm instruments into an 8mm cannula.
- 1. Slowly guide the instrument into the cannula. The system displays a blinking green icon during the instrument insertion, as shown below:



- 2. The system will stop the movement of the instrument slightly farther away then the exact point where the previous instrument tip was located, in order to provide a safety margin. At that point, control is automatically returned to the surgeon.
- **Note:** At any time during this type of instrument insertion, the instrument arm may be Clutched and the instrument introduced into the surgical field with full range of motion of the instrument arm, as explained in above.
- **Note:** The Guided Tool Change procedure is aborted if the Setup Joint or instrument arm clutch are activated before the instrument tip returns to the pre-determined location. For example, if the patient-side surgeon uses the Setup Joint release button to modify the position of the instrument arm before a new instrument is attached, the system will not allow the patient-side surgeon to move the sterile adapter, except as described in "Manually Inserting Instruments" above. In situations where the a Setup Joint move occurs during a tool change, the patient-side surgeon must manually insert the tool to place the tip correctly.
- **Note:** When changing "single-finger" tools such as scalpels, the Guided Tool Change procedure allows the return of the new instrument to approximately the same tip location as previous tool, but with a safety margin equal to the difference between the longest and shortest available tip lengths. This prevents a longer scalpel or cautery blade from being introduced to the same point and potentially coming into unexpected contact with tissue. In a situation where the safety margin results in the instrument tip being aligned within the cannula, the system will require Instrument Clutching to move the tip within the correct range.

Note: Under certain circumstances, the **da Vinci** System requires the use of the Clutch button to slide the instrument along the instrument arm. Examples include the first time an instrument is inserted for a specific instrument arm or when the instrument exchange is interrupted by a Setup Joint repositioning.



Figure 4-4 Location of the Clutch Button

- **WARNING:** There may be a zone where the instrument tip is emerging beyond the end of the cannula and <u>not yet</u> in view on the screen. Caution should be maintained during this movement of the instrument. Move the camera to follow the instrument at all times.
- **CAUTION:** Ensure the surgeon is ready to resume control of the instrument before inserting an instrument into the surgical field.
- **WARNING:** Removal of instruments during a procedure should be done very carefully and only under full knowledge and view of the surgeon.
- **CAUTION:** Always use caution when inserting or removing instruments through the cannula. Any lateral pressure on the instrument during removal may damage the working tip or bend the shaft. Be sure to pull the instrument straight out until it is completely clear of the cannula.

Removing Instruments

- 1. Prior to instrument removal, the surgeon should move the instruments away from tissue, straighten the wrist and open the instrument jaws.
- 2. Once the instrument is positioned for removal, squeeze the release levers on the sides of the instrument and pull the instrument out of the Sterile Adapter.
- **CAUTION:** The instrument will not disengage from Sterile Adapter with the instrument jaws closed or gripping.

When removing instruments, remember to verify that the sterile adapter returns to the top of the instrument arm after removal. If this movement does not occur, the pulleys will not spin into position and the new instrument cannot be engaged. When inserting a new instrument, verify that the sterile adapter is at the top of the instrument arm to ensure that the tool will be engaged properly.

In the event that the sterile adapter does not return to the top of the instrument arm, an error message is displayed indicating the error condition. For example, it is possible that the sterile adapter may snag on the draping, preventing it from coming completely to the top of the range. In this case the system presents an error message; the drape must be moved and the sterile adapter moved to the top of the camera arm.





Figure 4-5 Removing an Instrument

During the attachment and removal process, the screen displays an instrument change icon (see below) in the appropriate location to signify which instrument arm is affected by the instrument change. The color and blinking/non-blinking status of the icon signifies the state of the **da Vinci** System during each phase of the change process (see "Icons" on page 6-12).



WARNING: Do not perform an instrument arm clutch at the same time as instrument removal. Otherwise, the instrument wrist will not be free to pivot through the cannula.

For specific instructions on using instrument accessories, such as blade protectors, please see Appendix B, "Understanding *EndoWrist* Instruments."

Instrument Grip Release

Typically during instrument removal, the instruments are placed in a neutral position and the tips are open. In the event of a fault or an emergency stop, the instrument tips may be holding tissue or an object. In this case, the instrument tips must be opened manually.

Please see "Instrument Grip Release" on page B-10 for specific instructions.

The InSite® Vision System

Please refer to the *InSite*® *Vision System User Manual* for step-by-step instructions and additional details.

Camera/Endoscope Attachment and Removal

The camera/endoscope is attached to the camera arm using a two-step process.

- 1. Insert the distal end of the endoscope into the camera cannula.
- 2. Then insert the Sterile Camera Adapter into the Sterile Camera Arm Adapter and until it clicks into place.



Figure 4-6 Release Levers Located on the Sterile Camera Adapter

Release Levers

CAUTION: Ensure that the Sterile Camera Adapter is securely engaged with the Sterile Camera Arm Adapter. If not properly engaged, the camera/endoscope may fall out.

Removal of the endoscope is accomplished by squeezing the release levers and gently pulling the camera/endoscope straight up and out of the cannula.

Shutting Down the System

Preparing for Shutdown

First, remove the instruments, camera/endoscope and cannulae from the patient as described below.

- 1. Remove the instruments from the instrument arms.
- 2. Release the Set-up Joints and remove cannulae from the patient under direct vision.
- 3. Press the SYSTEM button. The system should shut down in 10 seconds.
- 4. Remove the camera/endoscope from the camera arm.
- 5. Manually release the Anchor Pads at the corners of the Surgical Cart base.
- 6. Move the Cart away from the patient table using the Surgical Cart handle to move the Cart.

Next, remove the Sterile Adapters, Cannulae, Cannula Mounts, and Drapes.

- 1. Remove the Sterile Camera Arm Adapter, cannulae, and cannula mounts for cleaning and sterilization.
 - a. To remove the Sterile Camera Arm Adapter, squeeze together the two latches on the bottom.
 - b. To remove the camera cannula mount, push in the button on the left side behind the mount.
- 2. Remove the instrument arm Sterile Adapters, cannulae, cannula mounts and drapes.
 - a. Remove the instrument Sterile Adapters by pulling on the tab at the top of the adapter and removing as shown below.



Figure 5-1 Removing the Sterile Adapter

b. Unscrew the thumbscrews holding the Cannula; use an Instrument Cannula Mount Wrench to remove the cannula mount and detach them from the arm.

Note: If your system uses Twist-Lock Cannulae, twist the locking mechanism to the left (counterclockwise) and remove it from the arm.

Instrument Usage Summary Display

At the end of a case, when all instrument Sterile Adapters have been removed, the system displays a summary table on the Surgeon's Console and Assistant's Monitor. The summary table displays the name of the instruments used during the procedure and other information, which is explained below:

Micro Forceps	5/10
Large Needle Driver	12/18
Medium Clip Applier	5:35/100
Scalpel/Cautery	10/18
Micro Forceps	5/10
Large Needle Driver	12/18
Medium Clip Applier	5:35/100
Large Needle Driver	12/18
Medium Clip Applier	5:35/100
Micro Forceps	5/10
1/2	

Figure 5-2 Example of Summary Display

For instruments that expire by procedure:

• the number of uses remaining on that instrument, followed by the total number of procedures available on that instrument at the time of purchase. In the example below, the Larger Needle Driver was used five times out of 10 potential uses, resulting in five more uses available.

Larger Needle Driver

5/10

For instruments that expire by "fires:"

- the number of "fires" used during existing case, followed by a colon (:)
- the number of "fires" remaining on that instrument, followed by a forward slash (/)
- the total number of "fires" available on that instrument at the time of purchase

For example:

Small Clip Applier

5:35/100

If there are more instruments used than can be displayed on the first screen, a second screen replaces the first, one minute after the first screen appears. These screens will alternate at one minute intervals while the Sterile Adapters are off.

The summary display is turned off automatically when any instrument Sterile Adapter is replaced on the system. The display can be toggled off and on prior to the start of a new case using the Stand By button. To turn off the summary display after all sterile adapters are removed, press the Stand By button once. To view the display, press the Stand By button again.

In addition, the system tracks the usage of Sterile Adapters, which have a design life of 50 procedures. At the end of each case, the system displays the serial number of the Sterile Adapter (or a series of dashes if the number is not available), along with the number of uses remaining.

For example:



The Sterile Adapters themselves do not maintain the usage information; that is tracked by the system. Therefore it is recommended that you group your Sterile Adapters by system if you have more than one da Vinci system at your site.

Shutdown Process

To prepare the **da Vinci**® Surgical System for Shutdown:

- 1. Fold the Set-up Joints into a compact position.
- 2. Press SYSTEM on the User Switch Panel to turn the **da Vinci** System Off. The following text is displayed on the screen:

System turned Off.

Press System On to reverse within 10 seconds.

In this state, the **da Vinci** System will shutdown unless SYSTEM is pressed again within the time displayed on the screen. The display will countdown from 10 to 1 (with beeps) at which time it shuts down.

Note: If you restart the system within 10 minutes from the time it was shutdown, the system will continue the procedure (or case) in progress prior to the shutdown. If the system is restarted 10 minutes or more after a shutdown, the system will view any activity as a new procedure or case.

Conversion to Open Surgery

If a situation arises where a conversion to open surgery is required, perform the following steps to remove the **da Vinci** System from the patient:

- 1. Remove the instruments and the endoscope from the patient.
- 2. Disconnect the cannulae from the instrument and camera arms.
- 3. Move the instrument and camera arms away from the patient, then roll the Surgical Cart away from the patient.
- **Note:** If a loss of power occurs, the setup joints and brakes can be overpowered with the application of a moderate amount of force. In situations involving a power loss where the auxiliary arm may be positioned under the operating table, it may be necessary to move the table and other equipment in order to move the auxiliary arm.

Chapter 6

Understanding the da Vinci Components

Tasks using the **da Vinci** System components are explained in chapters 2-5. This reference chapter is designed to provide more detail about each component. Reference information about the Surgeon's Console, the Surgical Cart, and instruments is provided throughout the chapter. Details about the InSite Vision System are available in the *InSite Vision System User Manual*.

Surgeon's Console

The surgeon sits at the Console to operate. The surgeon holds the Master grips to control surgical instruments and an endoscopic camera which are attached to the arms on the Surgical Cart. The surgical field is viewed through the Stereo Viewer, which uses two independent optical channels fused together to form a life-like 3D image of the surgical field. The **da Vinci** System delivers status messages using text and icons through the Stereo Viewer.

Controls and Indicators

The surgeon and assistant operate critical **da Vinci** System functions through buttons and foot switches. The **da Vinci** System functions that are used during a procedure, but not while actually operating, are located on the armrest. Functions that the surgeon needs to access while operating are located on Console Foot Switches. The Power, Emergency Stop, Standby and Ready buttons are located on the armrest and are available to the surgeon at all times.

The figures on the following page show the User Interface Panel and the User Switch Panel functions.

User Interface Panel (UIP) and User Switch Panel (USP)

Height adjustment buttons located on left side of User Interface Panel





User Interface Panel



User Switch Panel

Figure 6-1 Examples of User Controls Located on the Armrest

User Switch Panel – Mode Control

The User Switch Panel contains buttons used to control the **da Vinci** System operating modes. The sections below describe each function.

SYSTEM (On/Off)

This button turns the **da Vinci** System On and Off. There are three states controlled by this function:

- 1. On
- 2. Shut-Down Sequence
- 3. Off

When the SYSTEM button is pressed it is illuminated by a green light, indicating that the **da Vinci** System is On. The system is on in either the Ready Mode (green lighted button) or Stand By Mode (yellow lighted button), as indicated by the light of the appropriate Mode button.

To turn Off the **da Vinci** System, press SYSTEM (down position for OFF) and the Shut-Down Sequence is initiated. During Shut-Down, there is a countdown of 10 seconds before the system turns off. During this interval the system automatically goes into Stand By mode. The 10-second window allows the user to recover from an inadvertent activation of the button. To reactivate, push SYSTEM (up position for ON) again, before the 10 seconds expire.

CAUTION: The green light remains illuminated during the 10 second countdown. If SYSTEM is not reactivated during the countdown, the **da Vinci** System will shut down.

EMERGENCY STOP

This button removes power from the instrument arms on the Surgical Cart and the Masters on the Surgeon Console. The EMERGENCY STOP indicator light illuminates when this button is pressed.

To recover from an emergency stop, press the FAULT OVERRIDE button on the User Interface Panel.

- **CAUTION:** The instrument arms and camera arm may move slowly due to body wall, gravity and/or other forces after pressing EMERGENCY STOP.
- **CAUTION:** If the **da Vinci**® Ultrasonic Shears are on an instrument arm in an Emergency Stop or Fault Condition, immediately stabilize the instrument arm to prevent unintended movement. This instrument may move due to gravity or other external forces, at a greater rate than with other instruments. Remove the instrument immediately to prevent tips from inadvertently contacting tissue.
- **CAUTION:** If the instrument is holding any object at the time of an Emergency Stop, the user must open the instrument tips using the Grip Release in order to remove it. See "Instrument Grip Release" on page 4-13.

STAND BY

This button causes the **da Vinci** System to enter a Stand By Mode, with the instrument arms and camera arm on the Surgical Cart disengaged from the Masters on the Surgeon Console. The Masters, instrument arms and the camera arm will maintain their current position when the **da Vinci** System is in Stand By Mode. The **da Vinci** System will <u>not</u> automatically engage the arms when the surgeon puts his/her head in the View Port while in Stand By Mode.

WARNING: The **da Vinci** System should be placed in Stand By Mode whenever the surgeon is <u>not</u> actively performing surgery with the **da Vinci** System.

READY

Pressing this button puts the **da Vinci** System in Ready Mode. READY Mode with instrument(s) installed, camera selected and activation of the Head Sensor in the View Port, and the Masters matching the grip of the instrument tips engages the Surgical Cart arms to "follow" the movement of the Masters (see "Follow Mode" on page 3-11 for details). The Head Sensor detects the presence of the surgeon's head. If the Head Sensor is not activated, the Surgical Arms are not engaged, even if READY has been pressed. If an operator is absent for more than one minute, the **da Vinci** System transitions out of the Ready Mode and into Stand By Mode.

CAUTION: The **da Vinci** System should never be placed in Ready Mode unless the surgeon is seated at the Console and prepared to perform surgery. Interrupting the infrared signal in the View Port when in Ready Mode may engage the Instrument Arms. Forces acting on the Masters will result in a corresponding movement of the instrument arms if the Masters and instruments have matching grip angles.

User Switch Panel – Status Indicators

The indicators in the upper left quadrant of the User Switch Panel report the **da Vinci** System status only.

- <u>START-UP SEQUENCE</u>: The green Start-up Sequence light illuminates when the SYSTEM button is first pressed, and the **da Vinci** System goes through its Start-up Sequence.
- <u>SERVICE REQUIRED</u>: This yellow light indicates that the internal **da Vinci** System diagnostics have determined that service by an Intuitive Surgical Representative is required. The **da Vinci** System allows the procedure to be finished, but no new procedures should be initiated.
- <u>POWER LOSS</u>: A yellow light illuminates when a loss of AC power occurs. The **da Vinci** System will operate on battery power for 5 minutes with a fully charged battery pack before turning off in a power loss situation.
- **CAUTION:** During loss of AC power, the 3D Display System does not receive back-up power. The battery is intended to retain the **da Vinci** System status and position information so that when AC power is restored the procedure can continue without a total restart of the **da Vinci** System.

<u>CAMERA SIGNAL LOSS</u>: A yellow light indicates the **da Vinci** System detection of a loss of Camera image due to a fault in the optical components or processing equipment.

User Interface Panel – Controls and Indicators

This section describes the buttons and controls on the User Interface Panel. Each section of the panel is explained below. See Chapter 8, "System Intelligence" for additional details about faults and alarms.

System Status

- <u>ALARM</u>: Indicator only. The light illuminates when the **da Vinci** System alarm is activated. Alarms may indicate critical faults or recoverable faults, which may be cleared with the FAULT OVERRIDE button.
- <u>SILENCE ALARM</u>: Indicator and control. For certain fault conditions, pushing this button allows the audible alarm to be silenced for two minutes.
- <u>CRITICAL ERROR</u>: Indicator only. Illuminates when a **da Vinci** System error occurs that will not allow a procedure to proceed. If this light is illuminated, the **da Vinci** System must be turned Off and then restarted to attempt to continue normal operation.
- <u>FAULT OVERRIDE</u>: This function clears a previous "recoverable" fault and allows the **da Vinci** System function to resume. If there is a continuation of the condition that caused the fault, it will stop the **da Vinci** System again.

SCALING

Use this control to set the motion scaling such that a movement by the Master is translated into a smaller movement of the instrument tip. There are three options: NORMAL, FINE and ULTRA FINE. The FINE setting most closely corresponds with the Stereo Viewer magnification. FINE is the default scale setting for the **da Vinci** System.

SCOPE ANGLE

This button allows the user to toggle among the following endoscope types:



- <u>UP</u>: Select for the use of an angled endoscope facing "up" regardless of which camera head is being used.
- <u>STRAIGHT</u>: Select for the use of straight endoscopes regardless of the camera head being used.
- <u>DOWN</u>: Select for the use of an angled endoscope facing "down" regardless of which camera head is being used.

Initially no Camera/Endoscope combination is selected and all corresponding lights are off. A blinking camera icon is displayed in the middle of the Stereo Viewer and Assistant Monitor to indicate that a selection is required. Pressing the SCOPE ANGLE button allows the user to scroll through the various endoscope selections. The light next to each endoscope type will illuminate to notify the user of the active selection.



Camera/Endoscope selection required on User Interface Panel.

- **WARNING:** If the Scope Selection is does not match the installed endoscope, moving the Masters will result in non-instinctive motion seen in the display.
- **WARNING:** Use only Intuitive Surgical approved Endoscopes to ensure proper **da Vinci** System function.

DISPLAY

Pressing DISPLAY toggles between 3-dimensional (3D) viewing and 2-dimensional (2D) viewing in the Stereo Viewer. The LED next to the selected mode illuminates to indicate the selection.

CANNULA

The **da Vinci** System is equipped to function with two different instrument arm cannula lengths: SHORT (100mm) and LONG (150mm).



To select the cannula length, press the CANNULA button on the User Interface Panel. Pressing the button illuminates the LED next to the indicated cannula lengths and allows the user to toggle between the two.

- **Note:** The Cannula button can only be used to change the length in two modes: when the system is in STANDBY mode and no instruments are present on the instrument arms, and when the system is in READY-HEAD-OUT mode, and no instruments are present.
- Note: If a cannula length is not actively selected by the user, the setting defaults to SHORT.

Note: The same cannula length setting applies to all instrument arms.

WARNING: The selected cannula length on the User Interface Panel <u>must</u> match the cannula length being used on the instrument arms of the Surgical Cart. Failure to do so may result in instrument damage or improper functioning, as well as patient injury.

WARNING: Use only the same size cannulae on all instrument arms. Using a short cannula with a long instrument and selecting the Long Cannula setting can result in injury to the patient. Using a long cannula with a short instrument can result in instrument damage or improper functioning. Using different length cannulae on different arms may result in instrument damage or improper functioning.

CAMERA CALIBRATION

<u>TEST IMAGE</u>: Places the **da Vinci** System into the Calibration Mode to optimize the **InSite** Vision System performance. To exit the mode without storing the parameters, quickly press the TEST IMAGE button again.



Holding down the TEST IMAGE button for three seconds will store the calibration parameters for the selected Endoscope and exit Camera Calibration mode.

Holding down the TEST IMAGE button for 10 seconds restores the factory default settings.

When in Camera Calibration Mode, the four arrow buttons are used to align the image using the Scope Alignment Tool (see "Camera and Endoscope Calibration" on page 3-9 for more details).

Note: When the system is in Camera Calibration mode, the system will not allow changes to the Scope Angle values until the calibration values are stored.

SELECT MASTER

The Select Master buttons are used only with Surgical Carts configured with an optional third instrument arm, referred to as an auxiliary instrument arm. The surgeon can configure the system to use the auxiliary arm prior to starting the operation, or during the operation as necessary.



Figure 6-2 Buttons Used to Select Instruments Arms and Configure to the Left or Right Masters

The surgeon can assign any instrument arm to either the right or the left Master, or choose to temporarily deactivate swapping to the auxiliary arm. (If swapping is deactivated to the auxiliary arm, it still remains active for holding tissue, suction or other static functions.) By default, the green instrument arm is assigned to the left Master, and the red and yellow instrument arms are assigned to the right Master. The assignments are indicated by the illuminated LED next to the left or right Master buttons. If an instrument arm has no associated Master, it is considered to be deactivated, and swapping is disabled. An instrument inserted into an arm while deactivated is not engaged by the system.

Before or after introducing all cannula ports into the patient, the surgeon can "associate" each instrument arm with either a left or a right Master. The term "associated" has a different meaning than "assigned." The term "associated" indicates that the arm is actively under control of the "assigned" Master (left or right). The instrument arms are colored green, red, or yellow for easy identification, as shown in the figure below.



Figure 6-3 Side View of the Surgical Cart with Color-coded Instrument Arms

Cannula placement in the patient generally determines the arm selection configuration. Instrument arms associated with cannulae to the left of the camera are selected to be associated with the left master, and those to the right of the camera with the right master. An instrument arm cannula located immediately above or below the camera can be associated with either master.

Note: If the auxiliary arm is not present, the system software disables the selection of masters.

Note: Each master must be assigned at least one arm. The system will not allow any configuration that leaves a master with no associated arm.

Disabling an Auxiliary Instrument Arm

If the optional auxiliary instrument arm is installed on the system, but use of only two PSMs is desired for a procedure, the third PSM can be disabled.

Simply press the right or left Master button until no LEDs are illuminated for the arm to be disabled. The display shows any Setup Joint or clutch activity for the disabled arm, but any instrument attached to the disabled arm will not be represented with a tool icon in the display. In addition, the disabled arm cannot enter Follow mode.
Viewing Auxiliary Arm Information

Small colored icons are used to display the status of all instrument arms. The colored icons in the display are associated with the colored instrument arms, as shown in Figure 6-4.



Figure 6-4 Example of Instrument Arm Icons

The colored instrument arms must be selected on the UIP to be controlled by a given Master (left or right). Solid colored icons indicate that the corresponding instrument arms are actively associated with a Master (green and yellow in Figure 6-4), while a hollow colored icon indicates that the corresponding instrument arm is inactive at that moment (red in this example). The auxiliary arm is activated and deactivated by a "pedal-click" (quickly depressing and releasing the Master Clutch foot switch).



Figure 6-5 Example of Message Indicating Instrument Arm Swap

For example, if the auxiliary arm is set up to be controlled by the Left Master, tapping the Clutch foot switch allows the surgeon to toggle between the two instrument arms (Green and Red as shown in Figure 6-5). In this example, the right Master will always remain in control of the yellow instrument arm (yellow icon). Note that the actively associated icon is always "on top" in the display.

After a swap, activity indicating Follow Mode appears in the upper middle area of the display, with the associated PSM block icon appearing next to the Follow Mode icons. Every time the auxiliary arm swap is activated, the surgeon must ensure that the degree of closure or angle on the Master matches the degree of closure or angle of the jaw of the corresponding instrument.

Even if the degree of closure or angle matches right after the swap, the surgeon must still make some kind of intentional movement (opening or closing the grip, or moving the instrument slightly). A Matching Grip icon remains illuminated until this is accomplished, along with a message indicating that alignment is not complete.



Matching Grip (Masters must match grip of tip of the corresponding instrument in order to enter Follow Mode).

Figure 6-6 Example of Matching Grip Icon

Once the grip of both the Master Control and instrument jaw is matched, the display indicates that alignment is complete and the instrument will enter Follow Mode. See "Follow Mode" on page 3-11 for a detailed discussion on following and matching the grip.

Note: If the message "Align Master Roll" appears, simply rotate the grip to the right or to the left until the system calculates and allows for the roll.

TOOL READER

The TOOL READER button is used only when the system is in Stand By Mode. This button is used to allow a user to confirm the number of uses left in an instrument. When in Stand By, press the TOOL READER button and insert an instrument into a sterile adapter. The system will display the number of remaining uses on the Stereo Viewer and the Assistant Monitor. Press the TOOL READER button once more to exit. See "Tool Reader Mode" on page B-2 for more details.

Other Controls on the Surgeon Console

Head Sensor

The Surgeon Console has two sensors that are positioned on either side of the View Port. These sensors detect the presence of the surgeon's head, or any other opaque object, when placed between the sensors in the View Port. When the sensors are interrupted, the Masters are immediately activated if the **da Vinci** System is in Ready Mode.

CAUTION: To avoid unintended movement of the instrument arms and camera arm, the surgeon must put "hands on" the Masters before activating the Head Sensor. Follow Mode further controls movement of the arms by requiring the surgeon to match the instrument grips using the Masters. See "Follow Mode" on page 3-11 for details.

Viewer Height

These buttons are used to adjust the height of the Stereo Viewer up or down. The Stereo Viewer continues to move until the button is released or it reaches an up/down limit.

Note: The viewer height adjustment functions in all modes except Ready/Head In mode.

Intra-ocular Spacing Adjustment

The intra-ocular spacing adjustment knob is located beneath the Stereo Viewer, and is used to optimize the fusion of the 3D operative image. It adjusts left/right spacing of the image to match the spacing of the surgeon's eyes.



Beneath Stereo Viewer on Surgeon's Console

A. Intra-Ocular Spacing Adjustment

- B. Brightness and Contrast Knobs for Stereo Viewer
- C: Audio Intercom System Volume Knob



Audio Intercom System Volume Adjustment

The Surgeon's Console volume control for the Audio Intercom System (AIS) is located beneath the Stereo Viewer as shown in Figure 6-7.

Brightness and Contrast Adjustment

There are two brightness/contrast adjustment knobs, one for each optical channel. They are located beneath the Stereo Viewer on the right and left hand sides. When the knob is pushed in, the user can adjust brightness and contrast. When the knob is pulled out, factory default settings are restored. The brightness/contrast knobs are typically covered to avoid unintended adjustment.

Emergency Power Off (EPO)

The EPO button is located under a protective covering on the back of the Surgeon Console, above the Main Circuit Breaker switches. The Power Off sequence should be completed by using SYSTEM (On/Off button) on the User Switch Panel. If the **da Vinci** System has not powered down after 20 seconds from pushing SYSTEM, EPO may be depressed. After an emergency power off, the Main Circuit Breakers must be placed in the OFF position until the AC Low LED light goes out. This will take approximately twenty seconds. After this point, the Main Circuit Breaker switches may be turned ON and the **da Vinci** System re-started by using the SYSTEM button.



Back of Surgeon's Console A. Emergency Power Off (EPO) B. Main Circuit Breakers

Figure 6-8 Surgeon Console Rear Panel

Icons

Icons appear at the top of the Stereo Viewer and on the Assistant Monitor screens for the duration of a given **da Vinci** System state. The position of the icon on the screen corresponds to the location of the affected **da Vinci** System component. For example, the right upper corner of the monitor will show icons pertaining to the right instrument arm and the left upper corner of the monitor will show icons pertaining to the left instrument arm. For systems utilizing an auxiliary instrument arm, icons related to such arms are shown either on the left or right side of the screen, depending on which Master the arm is assigned to.

For the instrument change icon **only**, the following background colors indicate the different states described below:

Color	Meaning
White	No Sterile Adapter is present or is not sensed.
Blue	No instrument is present; Sterile Adapter is present.
Blinking blue with blue digits	Instrument is being engaged, remaining use displayed.
Blinking blue with a yellow "0" (zero)	Instrument expires after procedure is complete.
Yellow	Instrument is invalid.
Yellow with "0" (zero)	No uses left on instrument.



Instrument Arm or Camera Arm Clutch (positioning) in Progress



Endoscope/Camera Control in Progress



Master Clutch (positioning) in Progress



Matching Grip (grip of Masters must match the tip of the corresponding instrument in order to enter Follow Mode).



No Instrument is Present

Figure 6-9 Icon Examples

Status displays indicating Follow Mode will appear in the upper middle area of the display, with the associated PSM block icon appearing next to the Follow Mode icons.

Foot Switches

Specific **da Vinci** System functions are controlled by Foot Switches located on the Foot Switch Assembly at the base of the Surgeon Console.



Foot Switch functions include:

Clutch

The Clutch is used for two purposes: Master Clutching and Auxiliary Arm Swapping.

Master Clutching

Depressing the Clutch Foot Switch and **holding it down** allows movement of the Masters without corresponding movement of the instrument arms while in Stand By, Ready-Head-In, and Ready-Head-Out modes. This enables the surgeon to reposition the Masters in the working space at the Surgeon Console for maximum comfort, while the instrument tips remain stationary within the surgical field. Releasing the Clutch Foot Switch reconnects the Masters to the instrument arms. The **da Vinci** System resumes normal operation once alignment is complete.

This action is similar to lifting a computer mouse off the mouse pad to relocate the mouse without relocating the cursor on the computer screen. Also note that in Stand By and Ready-Head-Out, releasing the clutch will not allow a return to Follow Mode.

Auxiliary Arm Swapping

In systems equipped with an activated auxiliary instrument arm, depressing the Clutch Foot Switch and **releasing it quickly** switches control from one instrument arm to the designated auxiliary arm. This quick movement is called a "pedal-click." A tone sounds each time a swap is initiated.

Camera

The Camera foot switch is used for two functions: allowing the surgeon to move and adjust the camera/endoscope assembly, or switching between 3D and wide-angle mode (for systems using the three-channel endoscope).

Camera Clutching

Depressing the Camera foot switch and **holding it down** disengages the Masters from the instrument arms and connects the Masters to the camera arm while in Ready-Head-In Mode. With the Camera foot switch pressed, movement of the Masters result in movements of the camera arm. After releasing the Camera foot switch, the **da Vinci** System resumes normal operation once alignment is complete.

Switching to Wide Angle View

On systems equipped with a three-channel camera and endoscope, the surgeon can toggle back and forth between the 3D view and the wide angle 2D view. A pedal click on the Camera foot switch changes the image to a wide angle view in the Stereo Viewer. A second pedal click on the Camera foot switch returns the image to the 3D view. See the *InSite Vision System User Manual* for details on the three-channel components.

WARNING: When changing between 3D Stereo View and 2D Wide Angle View, ensure that the endoscopic instruments are in the field of view before resuming the motion of the masters.

Focus

This foot pedal is used to focus the operative image from the Surgeon Console ("Focusing the Video Image" on page 4-3). Rocking the pedal away from you or toward you will adjust the focus.

Unlabeled

This foot pedal is reserved for future use and is not active.

Coag

Activates the application of coagulation energy to the tip of the instrument.

Surgical Cart

The Surgical Cart is positioned next to the surgical table partially within the sterile field. The Surgical Cart contains the following a number of key components, which are described below.

Set-up Joints

Set-up Joints hold the instrument arms and the camera arm. They are used to position the Surgical Cart arms for the optimal approach to patient anatomy. Two release buttons are available for each instrument arm: one is located at the top of the grip adjacent to the setup joint, and the other is located at the side of the instrument arm itself. The camera arm setup joint release button is located at the top of the grip on the camera arm. (See "Surgical Cart Overview" on page 1-4 for details.)

By pressing and holding the buttons, you can move the entire setup joint and arm in any direction. When you release the button, the arm and setup joint lock into place.

Note: The system monitors the setup joints for any unintended movement. If a setup joint is moved without a Setup Joint Brake release button being depressed, a tone will sound when the unintended movement is recognized. At that time, following on that particular PSM is prevented until the system determines the amount of movement, automatically updates the position of the arm, and re-aligns the Master for the new position. If following mode was in use at the time of the unintended movement, following resumes automatically when the Master alignment completes.

Instrument Arms

The surgeon's hand movements at the Masters are precisely replicated at the instrument tips. The instrument arms position the instruments appropriately and permit precise instrument tip movement. The Surgical Cart arms have a mechanically fixed point of rotation (a "remote center"). The instrument arms and camera arm pivot about the remote center, and it must be positioned appropriately so that arm forces are not applied to the patient's anatomy. The remote center is marked with a wide black band on the cannula as shown below:



There are two types of instrument arm cannulae: short and long. See "CANNULA" on page 6-6 for more information.

Camera Arm

The camera arm controls the position and movement of the 3D camera from outside the patient's body.

Auxiliary Arm

Like other instrument arms, the optional auxiliary arm is positioned using a Setup Joint button. Pressing the Setup Joint button allows the user to position the arm in order to orient the instruments. However, to move the auxiliary arm up or down, certain requirements must be met. The up or down movement of the auxiliary arm is referred to as movement along the "Z-axis." The arm is mounted on the same vertical slide rail shared by the camera arm. The auxiliary arm is raised or lowered using a lift motor. Care must be taken when moving the auxiliary arm up or down along the Z-axis. Considerations include the possibility that the auxiliary arm could collide with another instrument arm or the operating table, for example. A label is mounted on the auxiliary arm as a reminder (shown below).



Figure 6-10 Example of Auxiliary Arm Label

CAUTION: The da Vinci System will alert the operator if movement of the surgical arms is detected during operation, or if a collision is detected on the vertical axis of the motorized (optional) auxiliary arm. It is imperative that the operators attending the patient side cart ensure safe placement of the surgical arms, and monitor activity near the patient side cart to prevent collisions and unintentional movement of the surgical arms.

The considerations and safety features are described below.

Moving the Auxiliary Arm (Z-axis)

The auxiliary arm is designed to move up or down along the Z-axis only when the user presses the Setup Joint button AND moves the auxiliary arm toggle switch up or down, at the same time. The buttons must be pressed and held within three seconds of each other.

The controls are located opposite each other on the auxiliary instrument arm. A beep sounds when the Setup Joint button is pressed, and an icon indicating Z-axis movement is displayed while the auxiliary arm moves up or down. The icon is displayed next to the colored icon representing the auxiliary arm.



Figure 6-11 Example of Icon Indicating Z-Axis Movement



Figure 6-12 Auxiliary Arm and Controls

If the Setup Joint button alone is pressed, the arm can be manipulated normally, but will not travel up or down. If the toggle switch is pressed by itself without pressing the Setup Joint button, the auxiliary arm cannot be manipulated and it will not move up or down.

Central Rail



Figure 6-13 Example of Auxiliary Arm Location on Central Rail

- **Note:** The auxiliary arm cannot be moved along the Z-axis during an instrument clutch or during an Emergency Stop.
- **Note:** The system recognizes when the auxiliary arm has reached the end of travel at the bottom or top of the motion range, and automatically stops the lift motor before the end of travel is reached. The stop is announced by a beep and the display of an icon, shown below. The same icon is used for any invalid movement events, and is displayed next to the colored icon representing the auxiliary arm.



Collision Detection

The system monitors the movement of the auxiliary arm as it travels up or down along the Z-axis. If the system detects movement of another surgical Setup Joint arm which is currently locked in place, the lift motor stops, three beeps are heard and the Z-axis interference icon is displayed in the Stereo Viewer and on the Assistant's Monitor. The icon is removed when the Setup Joint Z-axis button is released.

Excessive Force Detection

The auxiliary arm is constructed so the system becomes aware of any excessive force generated during movement of the arm along the Z-axis, and stops the movement of the arm in that situation. For example, it is possible that while raising the auxiliary arm, the arm could collide with the bottom of the operating table. The system recognizes when the arm begins to generate force on an object, and automatically stops the lift motor.

A repeated tone sounds and an icon is displayed until the force is removed. The force can be removed by moving the arm in the opposite direction to clear the fault, or simply removing the obstruction.

Drapes and Sterile Adapters

Sterile Adapters provide a mechanical and sterile connection between:

- the instrument arm and instruments
- the camera arm and the endoscope
- the camera and endoscope

The Sterile Adapters and drapes work together to maintain the sterile field. See "Draping the da Vinci System" on page 3-1 for details.

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Cleaning and Maintenance

The da Vinci System

Surgeon Console

As necessary, the Console can be wiped down with a soft, lint-free cloth which has been wetted with a mild anti-bacterial soap and water solution. Particular attention should be paid to the Master Grips, the View Port, the Stereo Viewer, and the armrest.

Surgical Cart

As necessary, with drapes removed, wipe down the Cart with a soft, lint-free cloth wetted with a mild anti-bacterial soap and water solution.

Note: Do not wipe down the vertical slide rails on the Surgical Cart.

Instruments

Instruments should be cleaned and prepared for sterilization according to the *Instructions for Use* for each instrument. *Instructions for Use* are packaged with the instruments. Also see cleaning instructions in Appendix B, "Understanding EndoWrist Instruments."

CAUTION: The use of "Flash" sterilization is not recommended for any Instruments or Accessories. Do not sterilize at temperatures over 285°F or 140°C. Do not use EtO, Steris, or other sterilization methods.

Accessories

Reusable Intuitive Surgical® accessories should be cleaned and sterilized before each use. Clean by soaking in an enzymatic cleaner. Scrub with a brush, if necessary, and then rinse.

Please refer to the following chart for compatible cleaning and sterilization methods for the **da Vinci** System Accessories and Instruments.

Accessory	Steris®	Sterrad®	EtO	Autoclave (Pre-vacuum)	Enzymatic Cleaner	Ultrasonic Bath
Type 1 Endoscopes (Straight and angled)		\checkmark	~		\checkmark	
Type 2 Endoscopes (Straight and angled)	~	\checkmark	~		\checkmark	
Type 3 Endoscopes (Straight and angled)	~	\checkmark	~		\checkmark	
Light Guide Cable			✓a	~	\checkmark	
Sterile Camera Arm Adapter				✓	\checkmark	✓
Sterile Camera Adapter				✓	\checkmark	✓
Sterile Instrument Arm Adapter				✓	\checkmark	✓
Scope Alignment Targets				✓	\checkmark	\checkmark
Light Guide Cable Adapter				✓	\checkmark	✓
Camera Cannula Mount				✓	\checkmark	✓
Instrument Arm Cannula Mount				✓	\checkmark	✓
Instrument Arm Cannula				✓	\checkmark	\checkmark
Endowrist Instruments				✓	\checkmark	\checkmark

a. The Bifurcated Light Guide is *not* compatible with EtO sterilization.

Process	Restricting Condition	
EtO sterilization	Temperature: $55 \pm 2^{\circ}C$	
	Relative Humidity: $70 \pm 5\%$	
	Pressure Set Point: 25.4 PSIA	
	Ethylene Oxide Concentration: 600 ± 30 mg/L	
	Gas Exposure Time: 2 hours	
	Detoxification Time: 0 hours	
	Drying time: 0 hours	
	Aeration: 12 hours at 55± 2°C	

Autoclave	Cycle: Pre-vacuum	
	Temperature: 270° - 272°F or 132° - 134°C	
Note: Do not autoclave endoscopes.	Minimum Exposure Time: 4 minutes*	
	Average Dry Time: 20 minutes	
Sterrad® 100 Sterilization	Vacuum Phase: 5-20 minutes	
System	Injection Phase: 6 minutes	
	Diffusion Phase: 44 minutes	
	Plasma Phase: 15 minutes	
	Vent Phase: 5 minutes	
	Total Cycle Time: Approximately 75 minutes	
Steris System 1 [®] Sterile Processing System	Sterilant: Peracetic Acid Sterilization time: 12 minutes Process temperature: 50 - 56°C Total processing time: 30 minutes	
	Note: Please consult the <i>Steris System 1</i> [®] <i>Sterile</i> <i>Processing System Operators Manual</i> for detailed instructions for use.	

Note: * Exact exposure times may vary based on the component or instrument. See the Instructions for Use for each instrument or component for exact exposure times.

- **Note:** The methods of sterilization and the parameters previously listed are the manufacturer's recommendations. Sterility is the responsibility of the hospital or site performing the sterilization.
- **CAUTION:** The performance characteristics of the accessories have not been validated for the combination of sterilization methods. Do not mix sterilization methods.

All Other Maintenance

Preventive maintenance in addition to the items above is required and must be performed by an authorized Intuitive Surgical Representative.

There are no user-repairable components to the **da Vinci** System. If the **da Vinci** System performance diminishes, please contact an Intuitive Surgical Representative for repair.

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System Intelligence

Fault and Emergency Stop State Philosophy

The **da Vinci** System detects failures of sensors, motors, amplifiers, networks, processors, electrical wiring and mechanical cables. Although these failures are unlikely, should one occur, the **da Vinci** System transitions to a protective Emergency Stop state where motor amplifiers are turned off.

Faults are classified as recoverable or non-recoverable, depending on how they occur. You can safely attempt to clear a fault by pressing the FAULT OVERRIDE button for recoverable faults.

Note: The FAULT OVERRIDE button may not be enabled until two seconds after a recoverable fault occurs.

You must power the **da Vinci** System Off and back On in the case of a non-recoverable fault. The **da Vinci** System will not operate with a major fault present. In some cases, faults occur with subsystems that are not safety-related. In these cases an error message is displayed once, but the system will keep functioning. An example of such a fault could be a failure of the battery that keeps the clock running. The system triggers a fault message, but allows the case to continue.

When the **da Vinci** System faults, it performs the following actions:

- The System transitions into the appropriate "error landing" state, where the error is described to the user and appropriate actions are taken by the system. This could result in an Emergency Stop, or simply an audible tone and an error message.
- In most cases the motor amplifiers are immediately deactivated and the motors shunted to supply regenerative braking. This causes all motion to be damped out quickly, although the arms can still be manually moved. This damping reduces any possibility that the error could be causing movement outside the of the control of the surgeon. In some cases, the system goes into a "soft-lock" state where power is maintained to the instrument arms, but they are prevented from entering Follow mode.
- **Note:** An additional small set of user behavior safety checks can trigger error beeps and messages, which do not require a system restart or the use of the Fault Override button. Safety checks are not considered faults. For example, movement of the auxiliary arm along the Z-axis can result in a safety check if the arm encounters an obstacle and begins to generate force against it. In this example, recovering from the check would only require that the obstacle be removed, or the user could simply move the arm in the opposite direction to clear the check. See "Audible Alarms" on page 8-3 for more information.

- **WARNING:** During any fault, the camera arm is locked and will not move. When the system is dampened, the Masters and instrument arms are not powered or locked. They will move under the influence of gravity and external forces. The instrument arms are not held in position, and will not resist accidental or purposeful contact with surgical staff or other mechanisms. Instrument tips can harm the patient, and should be removed carefully but immediately.
- **WARNING:** If the **da Vinci**® Ultrasonic Shears are on an instrument arm in an Emergency Stop or Fault condition, immediately stabilize the Instrument Arm to prevent unintended movement. This instrument may move due to gravity or other external forces, at a greater rate than with other instruments. Remove the instrument immediately to prevent tips from inadvertently contacting tissue.
- **CAUTION:** The Fault Override button should only be used with a thorough understanding of the **da Vinci** System operation and the cause of the fault. Restoring the **da Vinci** System or overriding a fault without understanding the cause of the fault could cause uncontrolled motion of the instrument arm or camera arm of up to two centimeters, or uncontrolled motion of the Masters up to five centimeters.

Non-recoverable Faults

The occurrence of a non-recoverable fault requires the **da Vinci** System to be removed from the patient. Normal operation is not allowed to continue. Non-recoverable faults by design should not be recoverable except by the **da Vinci** System restart. By restarting the **da Vinci** System normal operation could continue.

When a non-recoverable fault occurs, the following message is displayed:

Internal System fault (reference: xxxx). Restart System to continue.

Recoverable Faults

For recoverable faults, the **da Vinci** System is designed purposefully to err on the side of conservatism. That is, when in doubt, the **da Vinci** System will trigger a fault condition. Therefore, recoverable faults are designed to be overridden easily by pressing the Fault Override button. Even if the **da Vinci** System overrides a fault, (1) it continues to be sensitive to all faults after recovery, including the fault that just occurred, and (2) the **da Vinci** System performance is not restricted in any way. Should a recoverable fault be caused by a broken component, any attempt to recover will fail and the **da Vinci** System will remain in its Error State.

Note: Some faults may trigger an error message once during a power cycle and allow the case to continue. These faults may include some non-safety-related systems such as battery supplies, etc.

Below is an example of a screen that displays when a Recoverable Fault occurs:

Difficulty determining Arm position. Press FAULT OVERRIDE to continue.

The following list shows some of the recoverable faults that may occur. The error message displays at the top of the screen.

- 1. Difficulty determining Arm position.
- 2. Arm movement not as expected.
- 3. Temporary motion sensor data mismatch.
- 4. Excessive force detected on Arm(s).
- 5. Power fluctuation detected.
- 6. System functioning with battery backup low.
- 7. Internal clock battery low.
- 8. System functioning without reserve power supply.

Loss of Power/Reserve Power

As a safety feature in the event of a power issue (loss of power, a temporary power spike, or a reduction of power to the operating room through internal components), the **da Vinci** System will operate for a short period of time on reserve power. The **InSite**® Vision System is not a part of the reserve power subsystem. Therefore, the Stereo Viewer will not operate should a loss of power occur. The reserve power subsystem is designed to provide power long enough to remove the instrument arms and camera arm from the patient. Reserve power <u>IS</u> intended for safe and effective removal of the **da Vinci** System components from the patient and sterile field. It <u>IS NOT</u> intended for continuing the procedure.

Note: When primary power is restored, the da Vinci System returns to full operating function.

Troubleshooting

If you experience recurring faults and cannot determine the reason, it may be an internal system problem. Please contact your Intuitive Surgical Service Representative.

Audible Alarms

Audible Alarms will sound whenever a fault occurs and during most safety check events, as appropriate.

If the fault is unrecoverable, press SILENCE ALARM to turn off the audible alarm for two minutes.

If the fault is recoverable, press FAULT OVERRIDE to recover, or SILENCE ALARM to turn off the audible alarm for two minutes. Pressing FAULT OVERRIDE will not only turn off the audible alarm, but will also clear the fault condition, allowing the procedure to continue if no other faults occur.

In the case of a safety check, remedy the condition so the safety system can reset.

Viewing the Error Log

The purpose of the error log display is to support the reporting of errors to ISI Product Support (Field Service) personnel. When the system is in Recoverable Fault mode the current Error Log can be displayed on the Surgeon's Console and the Assistant Monitor. You can also view the Error Log prior to homing.

To display the error log, hold down the Silence Alarm button and simultaneously press the Standby button. The log is displayed in the stereo viewer and on the assistant monitor. The Image Alignment Up/Down arrows can be used to page up or down within the current log, and the Image Alignment Left/Right arrows can be used to select older/more recent logs from the system error log database, if available.

To exit error log viewing, press the Standby button or the Fault Override button. If you viewed the log prior to homing, you can press Ready to exit viewing of the log.

Symbols and Icons

The following table provides a list of symbols and icons used with the system, as well as a description of the icon or symbol and where they are found.

Symbol	Meaning	Where Found	Comments
	GE	NERAL USE	
\wedge	Attention: Consult accompanying documents	Several places on the da Vinci System	
	CF Applied Part	On instruments	Indicates instrument meets the requirements for a CF applied part.

Symbol	Meaning	Where Found	Comments	
	GENERAL USE			
\bigtriangledown	Equipotential Terminal	Rear panel of Surgeon Console, base of Surgical Cart and base of Vision Cart	Terminal for connecting Console or Cart to an equipotential point.	
(Focus Controller	Focus Controller Box	Indicates where Focus Control Cable is inserted into the Focus Controller.	
	Focus Out	Surgeon Console Foot Switch Assembly and on Vision Cart Focus Controller	Moves focus of endoscope in negative direction.	
+	Focus In	Surgeon Console Foot Switch Assembly and on Vision Cart Focus Controller	Moves focus of endoscope in positive direction.	
ן <u></u> גאָן	Flush Port	On instruments adjacent to Flush Port	Indicates connection point for flushing instrument.	
S/N	Serial Number			

Symbol	Meaning	Where Found	Comments		
	SURGEON CONSOLE				
	Composite Output	Rear panel of Surgeon Console	Low level composite video output (for future use).		
	Focus	Rear panel of Surgeon Console adjacent to Focus Controller connector	Denotes where the Input/Output Focus Controller serial connector from the video cable is connected to the Console.		
X	Foot Switch	Rear panel of Surgeon Console	Indicates connector controls for Foot Switch function.		
>	Input and Output	Rear panel of Surgeon Console adjacent to Focus Controller connector	Denotes where the Input/Output Focus Controller serial connector from the video cable is connected to the Console.		
Ċ	OFF for part of the da Vinci System	Rear panel of Surgeon Console adjacent to main circuit breakers	Circuit breaker indication.		
\bullet	ON for part of the da Vinci System	Rear panel of Surgeon Console adjacent to main circuit breakers	Circuit breaker indication.		
->	Serial Digital Input	Rear panel of Surgeon Console	Low level, digital video input.		
	Serial Digital Output	Rear panel of Surgeon Console	Low level, digital video output (for future use).		
$ \mathbf{ > } $	Signal Input	Rear panel of Surgeon Console adjacent to ESU Foot Switch connector	Indicates input from Foot Switch of ESU.		

Symbol	Meaning	Where Found	Comments		
	SURGEON CONSOLE				
> 00	S-Video Input	Rear panel of Surgeon Console	Low level S-video input (for future use).		
00 ->	S-Video Output	Rear panel of Surgeon Console	Low level S-video signal output.		
C	Chrominance	Rear panel of Surgeon Console	Low level video signal.		
CAMERA	Camera Control	Surgeon Console Foot Switch Assembly	If the pedal is depressed and held down, the Mas- ters disconnect from Instrument Arm control and connect to the Cam- era Arm.		
CLUTCH	Clutch/Instrument Arm Swap pedal	Surgeon Console Foot Switch Assembly	If the pedal is depressed and held down, both Masters disconnect from all Instrument Arms.		
COAG	Coagulation Function	Surgeon Console Foot Switch Assembly	Operable only if an appropriate compatible ESU is connected to the Console		
EPO	Emergency Power Off	Surgeon Console Power Supply	Instantly disables the da Vinci System, including the control electronics and Stereo Viewer.		
			CAUTION: To Power On after an EPO, turn off the main circuit breaker for 30 seconds.		
L	Left	Rear panel of Surgeon Console	Indicates left Stereo Viewer signal for 3D video.		

Symbol	Meaning	Where Found	Comments		
	SURGEON CONSOLE				
R	Right	Rear panel of Surgeon Console	Indicates right Stereo Viewer signal for 3D video.		
S1	Surgeon Console to Surgical Cart Cable 1	Rear panel of Surgeon Console	Indicates connection location for cable.		
S2	Surgeon Console to Surgical Cart Cable 2	Rear panel of Surgeon Console	Indicates connection location for cable.		
83	Surgeon Console Surgical Cart Cable 3	Rear panel of Surgeon Console	Indicates connection location for cable.		
S4	Surgical Console Surgical Cart Cable 4	Rear panel of Surgeon Console	Indicates connection location for cable.		
SYSTEM	Instrument control system circuit breaker	Rear panel of Surgeon Console next to the da Vinci System circuit breaker	Controls main power to the da Vinci System only (not the Stereo Viewer).		
VIEWER	Stereo Viewer circuit breaker	Rear panel of Surgeon Console next to Stereo Viewer circuit breaker	Controls main power to the Stereo Viewer only.		
Y	Luminance	Rear panel of Surgeon Console	Low level video signal.		

Symbol	Meaning	Where Found	Comments
	SUR	GICAL CART	
P1	Surgeon Console to Surgical Cart Cable 1	Rear of Surgical Cart	Indicates connection location for cable.
P2	Surgeon Console to Surgical Cart Cable 2	Rear of Surgical Cart	Indicates connection location for cable.
P3	Surgeon Console to Surgical Cart Cable 3	Rear of Surgical Cart	Indicates connection location for cable.
P4	Surgeon Console to Surgical Cart Cable 4	Rear of Surgical Cart	Indicates connection location for cable.
RIA	Connector designation for Intuitive Surgical Service personnel only	Non user-serviceable cables on the Surgical Cart	For Intuitive Surgical Service personnel only.

Symbol	Meaning	Where Found	Comments		
	VIEWER SYMBOLS (ICONS)				
<mark>69</mark> ↔	Camera Control in progress (at Surgeon Console)	Stereo Viewer and Assistant Monitor	Appears when Camera/ Scope is being positioned.		
	Instrument Arm or Camera Arm clutching in progress	Stereo Viewer and Assistant Monitor	Appears while Instrument Arm or Camera Arm is being clutched.		
	Instrument is invalid	Stereo Viewer and Assistant Monitor	Appears when Sterile Adapter is present and installed instrument is present and invalid.		
<mark>像</mark> ☆ <mark>0</mark>	No uses left on Instrument	Stereo Viewer and Assistant Monitor	Instrument can no longer be used.		
(flashing)	Scope selection required at Surgeon Console	Stereo Viewer and Assistant Monitor	Camera/Scope combination must be selected after Homing.		
(flashing)	Instrument expires after procedure is complete	Stereo Viewer and Assistant Monitor	Instrument can be used during current procedure, but not for a new procedure.		
(flashing)	Instrument is being engaged	Stereo Viewer and Assistant Monitor	Amount of remaining use is displayed. In this example, nine uses remain for the installed instrument.		

Symbol	Meaning	Where Found	Comments		
	VIEWER SYMBOLS (ICONS)				
(Flashing)	Remove Instruments	Stereo Viewer and Assistant Monitor	Indicates instrument inserted while carriage or discs are moving on instrument arm.		
₽ \$	No Sterile Adapter is Present	Stereo Viewer and Assistant Monitor	May also appear if Sterile Adapter is present, but not properly sensed by the da Vinci System.		
ф Э	Sterile Adapter must be Replaced After Procedure	Stereo Viewer and Assistant Monitor	Indicates end of design life for the Sterile Adapter in question.		
(Flashing)	Guided Tool Change	Stereo Viewer and Assistant Monitor	Indicates Guided Tool Change in progress.		
₩ \$	No instrument present	Stereo Viewer and Assistant Monitor	Appears while Sterile Adapter is present.		
2	Master repositioning in progress	Stereo Viewer and Assistant Monitor	Appears when Masters are being repositioned.		
*	Set-up Joint positioning	Stereo Viewer and Assistant Monitor	Appears while Set-up Joint is being positioned.		
	Unexpected Set-up Joint Movement	Stereo Viewer and Assistant Monitor	Indicates Set-up movement without using the Set-up Joint release buttons.		

Symbol	Meaning	Where Found	Comments
VIEWER SYMBOLS (ICONS)			
Î	Auxiliary Arm Z-axis movement	Stereo Viewer and Assistant Monitor	Appears while the auxiliary arm moves up or down along the Z- axis.
\odot	Auxiliary Arm Z-axis Error	Stereo Viewer and Assistant Monitor	Appears when the movement of the Z-axis results in a safety check.
	The da Vinci System is operating on back-up back-up battery power. Battery is almost empty.	Stereo Viewer and Assistant Monitor CAUTION: During a general system power failure, the Stereo Viewer does not receive power. The icon will appear on the Assistant Monitor only.	Appears when there is a general power failure or when there is an internal system power supply failure and the battery has been run long enough to consume almost all of its energy.
+	The da Vinci System is operating on back-up battery power. Battery is full.	Stereo Viewer and Assistant Monitor CAUTION: During a general system power failure, the Stereo Viewer does not receive power. The icon will appear on the Assistant Monitor only.	Appears when there is a general power failure or when there is an internal system power supply failure and the battery is fully charged.
+ -	The da Vinci System is operating on battery power. Battery is half full.	Stereo Viewer and Assistant Monitor CAUTION: During a general system power failure, the Stereo Viewer does not receive power. The icon will appear on the Assistant Monitor only.	Appears when there is a general power failure or when there is an internal system power supply failure and the battery contains half of its available energy.

Symbol	Meaning	Where Found	Comments
VIEWER SYMBOLS (ICONS)			
û ₽	Match Grip	Stereo Viewer and Assistant Monitor	Appears at the top left or right of the screen, next to the associated MTM. User must match the grip of the Master to the corresponding Instrument tip to enter Follow Mode.
×	Homing Failed	Stereo Viewer and Assistant Monitor	Appears when the homing procedure has failed.

PSMs, ECMs and MTMs each have a portion of the screen dedicated to their icons. The Match Grip and Homing Failed icons appear in the dedicated screen area for each manipulator.



Figure 8-1 Example of Message and Icon Locations in Stereo Viewer

Glossary of Terms

2D	Two-dimension.
3D	Three-dimension.
3D Display	The three dimensional image created by two cameras. The image is viewed by looking into the Stereo Viewer on the Surgeon Console.
3D Viewer	See Stereo Viewer.
ACU	Auxiliary Control Unit.
Adapter	See Sterile Adapter.
Anchor Pads	Refers to the brakes on the Surgical Cart.
Arms	The part of the da Vinci System that holds a grip, instrument or camera. There are up to five arms on the da Vinci System. Two Master arms with Master grips are located on the Surgeon Console. The Surgical Cart has up to three arms; one for the camera and two for the instruments.
Assistant Monitor	The monitor on the Vision Cart that displays a 2D image.
Auxiliary Instrument Arm	Some systems are available with a third instrument arm, also referred to as the "fourth arm." The auxiliary arm can be assigned to the left or right Master (or no Master). The arm can be activated with a pedal-click on the Clutch foot switch.
Camera Arm	The arm on the center Set-up Joint of the Surgical Cart that controls the camera/endoscope according to the surgeon's movements of the Masters.
Camera Orientation Line	Shows the orientation of the camera, with respect to the floor, in the lower right-hand corner of the Stereo Viewer and Assistant Monitor.

Cannula Mount	The accessory that attaches a cannula to an arm. There are two types: instrument arm cannulae and camera arm cannulae. Two styles exist for the instrument arms (standard and Twist-lock) and one style for the camera arm.
Cart	Refers to the Surgical Cart.
Carriage	The portion of the instrument arm to which an Instrument Sterile Adapter attaches. The carriage moves up and down the arm under control of the system, or manually by using the instrument arm clutch.
CRT	Cathode Ray Tube.
CAUTION	An important level of concern. Failure to heed a CAUTION may result in unintended motion of the da Vinci System that may result in injury to a patient.
Clutch (verb)	A. A Master clutch is the act of disengaging the Masters from the instrument arms and camera arm so the Masters can be repositioned in a more comfortable working space for the surgeon. This action is similar to lifting a computer mouse off the mouse pad and repositioning it. A clutch is also used at the Surgical Cart to position the instruments and the cam- era/endoscope.
	B. A Patient-Side clutch allows the patient-side manipulator to float, allowing manual adjustment of the instrument or camera arms.
CLUTCH (noun)	A. Foot Switch pedal used to control Master Clutching, and as part of the pedal-click to swap control of an instrument arm to the auxiliary instrument arm, if available.
	B. PSM or ECM button that allows clutching of the PSM or ECM.
COAG	Foot Switch pedal to control Coagulation.
Console	See Surgeon Console.
DANGER	The highest level of concern. Failure to heed a DANGER warning can result in injury to a patient.
Drape Clip	A reusable accessory that reinforces the interface between the adhesive strip on the instrument arm drape and the instrument arm Sterile Adapter.

ECM	Endoscopic Camera Manipulator. This acronym refers to the camera arm.
ESU	Electrosurgical Unit or Electrosurgical Generator Unit.
Endoscope	An instrument used for the examination of the interior of a canal or a hollow space; also called a "scope."
Endowrist® Instruments	Instruments with a wrist located near the tip.
Emergency Stop State	A state where the motors of are turned off and a screen message is sent to the user.
Faulting	The transition from a working state to either a soft-locked or dampened state.
Foot Switch	A pedal or switch located on the Foot Switch Assembly that has a specific function.
Foot Switch Assembly	Located at the base of the Surgeon Console, containing all of the foot controls.
Head Sensor	Infrared sensor on either side of the View Port of the Surgeon Console located above the Stereo Viewer.
Illumination System	See Light Source.
Instrument	Any one of several tools used to effect the procedure in the patient once attached to an instrument arm and inserted into the patient. Instruments include, for example, Large Needle Drivers, DeBakey Forceps and Round Tip Scissors.
Instrument Arms	The arms on the outer Set-up Joints of the Surgical Cart that manipulate the instruments according to surgeon's movement of the Masters.
LED	Light emitting diode.
Light Source	Endoscopic illumination system. In the da Vinci System, there are two light sources. Together they provide illumination inside the body for vision.
Master	The control arms and grips in the Surgeon Console that the surgeon grasps and moves. The surgeon's movements are translated to the instruments and camera attached to the Surgical Cart arms.
MIS	Minimally Invasive Surgery.

MTM	Master Tool Manipulator. Refers the Masters on the Surgeon's Console.
Notes	User information to emphasize an important point.
Pedal Click	The act of quickly tapping a foot switch at the Surgeon's Console to alter configuration. The pedal click is used with the Clutch foot switch to swap control between instrument arms, and with the Camera foot switch to toggle between Narrow (3D) and Wide (2D) angle views.
PSM	Patient-side manipulator (instrument arm and respective Set-up Joint).
READY	A button on the User Switch Panel of the da Vinci System used to change the da Vinci System state.
Scope	Endoscope.
Screen	The monitor display, located on the Stereo Viewer and/or the Assistant Monitor.
Setup Joint	The joints on the Surgical Cart that support the instrument arms and the camera arm. These joints are used to set up the initial positions of the arms on the Surgical Cart.
STANDBY	A button on the USP to put the da Vinci System into the Stand By mode.
Stereo Viewer	The fixed eyepiece located on the Surgeon Console where the surgeon looks to see the 3D image.
Sterile Adapter	Interface device that allows the sterile barrier to be maintained between the camera arm and the endoscope or the instrument arm and the instrument attached to the arm. There are various types of Sterile Adapters: a Sterile Camera Adapter, Sterile Camera Arm Adapter and an Instrument Sterile Adapter. They are not interchangeable.
Sterile Adapter Reinforcement	An adhesive strip on the drape that is adhered to the Sterile Adapter.
Surgeon Console	The part of the da Vinci System consisting of a structure that supports the Masters and the 3D Viewer. The Surgeon Console also houses most of the electronics of the complete da Vinci System and the power supply and battery.

Surgical Cart	The part of the da Vinci System that is located on the patient side and consists of the column that supports the Set-up Joints that in turn support the instrument and camera arms.
Surgical Cart Arms	The arms that are components of the Surgical Cart: two or three instrument arms and one camera arm, depending on the system.
UIP	User Interface Panel. The set of buttons and LEDs located on the left side of the Surgeon's Console, as you face it.
User Interface	The controls located on either side of the armrest of the Surgeon Console that are used to command the da Vinci System. The User Interface consists of the User Interface Panel and the User Switch Panel.
USP	User Switch Panel. The set of buttons located on the right side of the Surgeon's Console, as you face it.
View Port	The area on the Surgeon Console that includes the View Port, Stereo Viewer and infrared Head Sensors.
WARNING	High level of concern. Failure to heed a warning could result in harm to a patient.

da Vinci™ Surgical System User Manual

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Appendix A

Clinical Appendix

<u>Clinical Study</u>

A prospective, randomized controlled trial was designed to rigorously evaluate use of the **da Vinci** System in two commonly performed laparoscopic procedures - cholecystectomy and Nissen fundoplication (a surgical technique comprised of wrapping and suturing a portion of the fundus of the stomach around the lower esophageal sphincter to reduce symptoms and complications associated with gastroesophageal reflux disease ("GERD"). These two endoscopic procedures were chosen to demonstrate the safety and effectiveness of the **da Vinci** System capability over a wide range of surgical actions and techniques including blunt and sharp dissection, electrocautery, grasping, tissue approximation, and suturing. The objective was to perform 100 cholecystectomies (50 cases using the **da Vinci** System and 50 controls using conventional laparoscopy) and 100 Nissen fundoplications (50 cases using the **da Vinci** System and 50 controls using conventional laparoscopy).

Study Endpoints

For both procedures, the safety and effectiveness of the **da Vinci** System was demonstrated using conversion from the **da Vinci** System to conventional laparoscopy or laparotomy for completion of the procedure as the primary endpoint. Additional endpoints also included the comparison of type, rate, and severity of peri-operative complications, De Meester scores (for fundoplication only), duration of surgical procedure, post-operative hospitalization stay, and quality of life scores observed for case (**da Vinci** System) and control (conventional laparoscopy) subjects.

Study Design: Enrollment, Assessment and Randomization

A prospective, randomized, single center, 4 investigator controlled clinical trial was undertaken from July 1998 to October 1998 to evaluate the safety and effectiveness of the **da Vinci** System. A total of 530 subjects with suspected gall bladder disease or GERD were screened for potential participation in this study. Screening consisted of a routine medical history and complete physical exam to identify eligible subjects. Confirmation of gall bladder disease associated with the presence of gallstones was confirmed by ultrasonographic visualization of the gall bladder. Confirmation of GERD was confirmed by a comprehensive gastroenterological exam including radiography of the upper gastrointestinal system, gastroespophogeal endoscopy, eshophageal manometry, and 24-hour pH monitoring. A total of 245 subjects meeting the expressed inclusion and exclusion criteria were invited and agreed to participate in this trial (as evidenced by giving informed consent). Once informed consent was received each subject was randomized to either the case (**da Vinci** System) or control (conventional laparoscopy) groups of the study. Post-operative assessment included 30-day medical history, physical examination, as well as esophageal manometery and 24-hour pH monitoring for the subjects undergoing fundoplication.

Randomization Results

Randomization of subjects was designed to allocate approximately half the patient population to either the control (conventional laparoscopy) or the case (**da Vinci** System) group. Of the 245 subjects enrolled in this clinical evaluation, 12 were enrolled as training cases (7 cholecystecomies and 5 fundoplications) to familiarize physicians and staff with the **da Vinci** System and operating room environment. The remaining 233 subjects were randomized by an independent study monitor and not subject to post-randomization crossover. A total of 113 subjects undergoing cholecystectomy were randomized to either the case (**da Vinci** System, n=57) or control (conventional laparoscopy, n=56) groups. Of the 113 randomized subjects undergoing cholecystectomy, 3 (2 cases and 1 control) were lost to follow-up. A total of 120 subjects undergoing fundoplication were randomized to either the case (**da Vinci** System, n=60) or control (conventional laparoscopy, n=60) groups. Of the 120 randomized subjects undergoing fundoplication, 12 (6 cases and 6 controls) were lost to follow-up. Factors attributable to drop-out included moving and refusal to repeat the required follow-up testing. The number of subjects undergoing each procedure is shown in Tables 1 and 2, respectively.

Table 1

Number of Subjects (n)	Case ¹	Control ²
113	57	56
Lost to Follow-up	2	1

Randomization Data at Baseline for Subjects Undergoing Cholecystectomy

¹Case = **da Vinci** System

 2 Control = conventional laparoscopy

Table 2

Randomization Data for Subjects Undergoing Nissen Fundoplication

Number of Subjects (n)	Case ¹	Control ²
120	60	60
Lost to Follow-up	6	6

¹Case = **da Vinci** System

 2 Control = conventional laparoscopy
Complications/Adverse Events

Of the 228 subjects enrolled in this evaluation of the safety and effectiveness of the **da Vinci** System, 56 experienced peri- or post-operative procedure-related complications. Itemization of complications and adverse events stratified by group assignment and procedure is shown in Table 3. <u>There were no device-related complications associated with use the **da Vinci** System</u>. None of the complications observed in this evaluation were directly attributable to the endoscopic procedure, i.e., conventional laparoscopic tools or the **da Vinci** System. Observed peri-operative complications included bile spillage (cholecystectomy only) and tissue or serosal injury related to trocar insertion or use of the harmonic scalpel (one death in the fundoplication control group). Post-operative complications included dysphagia and wrap-migration (fundoplication only) as well as umbilical infection (a common occurrence in laparoscopic surgery which is typically related to inadequate disinfection of the site or exposure of the site to abdominal contents, e.g., peritoneal fluid or bile). In conclusion, there were no statistically significant differences for in complication rates observed for the case (**da Vinci** System) and control (conventional laparoscopy) groups.

Table 3

Adverse Events and Complications

	Case ¹	Control ²	p-value
Cholecystectomy n (%) Bile Spillage Trocar Injury Serosal Injury Infection	20/55 (36.4%) 1/55 (1.8%) 0/55 (0.0%) 0/55 (0.0%)	17/55 (30.9%) 1/55 (1.8%) 2/55 (3.6%) 1/55 (1.8%)	0.686 1.000 0.495 1.000
Fundoplication n (%) Dysphagia Wrap Migration Trocar Injury Serosal Injury	3/60 (5.0%) 2/60 (3.3%) 0/60 (0.0%) 1/60 (1.7%) ³	5/58 (8.6%) 0/58 (0.0%) 1/58 (1.7%) 2/58 (3.4%)	0.487 0.496 0.492 0.615

¹Case = **da Vinci** System

 2 Control = conventional laparoscopy

³Resulted in death 83 days post-operatively

Procedures Converted

Two (2) subjects randomized to the ISI arm were intra-operatively converted to conventional laparoscopy prior to use of the **da Vinci** System and, as such, were not included in the final data analysis. One subject presented with severe peritoneal inflammation and scarring and one with nodular hepatic cirrhosis. In both cases the surgeon opted for conventional techniques given the observed pathology.

Outcomes Analysis

All 113 cases (55 cholcystectomies and 58 fundoplications) in which the **da Vinci** System was used were successfully completed without conversion to either conventional laparoscopy or laparotomy.

Operative times stratified by group assignment and operative procedure are shown in Table 4. Subjects assigned as cases had longer operative times than controls for both cholecystectomy (137.4 \pm 60.4 v. 86.2 \pm 27.5 minutes, p<0.00001) and fundoplication (110.1 \pm 32.8 v. 66.9 \pm 25.0 minutes, p<0.00001). The longer operative time required for procedure completion in the case group is thought to be attributable to not only the novelty of the **da Vinci** System but the learning curve associated with robotic completion of the procedure.

Table 4

Operative Duration for Subjects

	Case ¹	Control ²	p-value
Cholecystectomy (m)			
Avg	110.1	66.9	0.00001
SD	32.8	25.0	
n	55	55	
Range	55-199	45-150	
Fundoplication (m)			
Avg	137.4	86.2	0.00001
SD	60.4	27.5	
n	58	60	
Range	59-355	45-150	

¹Case = **da Vinci** System

²Control = conventional laparoscopy

As is shown in Table 5, intra-operative blood loss was minimal for both the case and control groups regardless of procedure. The proportion of subjects experiencing blood loss exceeding 50 mL was greater among cases than controls for both cholecystectomy (p=0.027) and fundoplication (0.031). Blood loss was most commonly associated with tissue injury secondary to trocar insertion or use of the harmonic scalpel.

Table 5

Intra-Operative Blood Loss Among Subjects

	Case ¹	Control ²	p-value
Cholecystectomy n (%)			
$\leq 50 \text{ mL}$	49/55 (89.1%)	55/55 (100%)	0.027
Fundoplication n (%)			
$\leq 50 \text{ mL}$	51/58 (87.9%)	59/60 (98.3%)	0.031

¹Case = **da Vinci** System

 2 Control = conventional laparoscopy

Pre- and post-operative DeMeester scores are shown for the 107 subjects in the case and control groups in Table 6 (n=11 without post-operative DeMeester score). DeMeester scores were significantly lower post-operatively for both the case (-62.7%, p<0.00001) and control (-62.8%, p<0.00001) groups. There was no statistically significant difference in the degree of reduction between the case and control groups (-62.7 v. -62.8%, p=0.997). There were no statistically significant differences for the proportion of subjects experiencing any reduction in DeMeester score (case 88.5% v. control 90.9%, p=0.922) or for the proportion of subjects having a post-operative Demeester score of less than 14.8 (case 73.1% v. control 74.5%, p=0.962).

Table 6

Pre- and Post-operative DeMeester Scores for Subjects Undergoing Fundoplication

	Pre-Operative	Post-Operative	Difference	p-value
Case ¹				
Avg	132.0	27.9	-104.1	0.00001
SD	93.7	55.9	115.1	
Ν	52	52	52	
Range	14.9-334.5	0.3-214.3	-332.9 to 126.0	
Control ²				
Avg	118.7	19.9	-98.8	0.00001
SD	89.5	52.3	108.3	
N	55	55	55	
Range	17.7-295.8	0.3-312.6	-29.2 to 198.8	

 1 Case = **da Vinci** System

 2 Control = conventional laparoscopy

The majority of subjects were hospitalized 2 days or less as is shown in Table 7. The total number of hospital days was similar for all cases and cholecystectomy controls but was much greater for subjects in the fundoplication control group (due to 2 subjects having hospital stays of 18 and 83 days). In spite of these 2 extreme hospitalizations, there were no statistically significant differences in the proportion of hospital stays under 2 days.

Table 7

Post-Operative Hospitalization Duration

	Case ¹	Control ²	p-value
Cholecystectomy n (%)			
≤ 2 Days	53/55 (96.4%)	55/55 (100%)	0.495
Total Hospital Days	71	61	
Fundoplication n (%)			
≤ 2 Day	54/58 (93.1%)	57/60 (95.0%)	0.715
Total Hospital Days	83	172	

¹Case = **da Vinci** System

²Control = conventional laparoscopy

Device Failures and Replacements

No device failures occurred during the study. In all cases the **da Vinci** System performed as designed. Three separate system "faults" occurred requiring down times of 12, 13, 20 minutes each. In all cases, the **da Vinci** System behaved as designed with faults resulting in immediate transition to a safe state as directed by the software. There were no adverse clinical consequences to any of these occurrences.

Risk/Benefit Analysis

The technical features of the **da Vinci** System including an endoscopic instrument wrist with seven degrees of freedom, motion scaling providing inherent precision and tremor reduction, provide clear advantages over conventional rigid endoscopic instruments. These benefits exceed any potential risks associated with the use of this computer-assisted technology given the fail-safe and reliable **da Vinci** System design.

Safety

There were no device-related complications in this study therefore demonstrating that the **da Vinci** System is safe for its intended use.

Effectiveness

All procedures begun with the **da Vinci** System were successfully completed without conversion to conventional laparoscopy or laparotomy. Clinical outcomes and rates of complications/adverse events were similar for subjects in both the case and control groups.

In conclusion, the clinical results provided herein demonstrate that the **da Vinci** System is safe and effective for its intended use.

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Appendix B

Understanding EndoWrist Instruments

This appendix provides *Endowrist* reference information for the following areas:

- Instrument Overview
- Preparing Instruments for Use
- Using EndoWrist Instruments
- Cleaning EndoWrist Instruments
- Storing EndoWrist Instruments
- Available Instruments and Selected Use

Instrument Overview

The *Intuitive Surgical EndoWrist* instruments are multiple use endoscopic instruments with an end effector to be used in conjunction with the *Intuitive Surgical da Vinci* Endoscopic Instrument Control System.

EndoWrist instruments are available with both 5mm and 8mm shafts. Instruments are available in non-energized and energized 5mm and 8mm da Vinci *EndoWrist* configurations. Non-energized instruments include needle drivers, non-energized graspers, forceps, scissors, and clip appliers.

Energized instruments, or instruments with specialized end effectors, include monopolar and bipolar cautery/hemostasis instruments, as well as ultrasonic shears.

Instrument Life Cycle

EndoWrist instruments are valid for a predetermined usage amount to maintain consistent performance throughout their life. Certain instruments may be used for a limited amount of procedures while others, such as the Small Clip Applier, may be used for a limited number of instrument insertions.

Messages displayed during every instrument change indicate the number of remaining uses for a given instrument. When the screen displays " \emptyset ", the instrument can still be used to complete the procedure in progress, but cannot be used for a new procedure. See "Icons" on page 6-12 for a description of icons.

When instruments expire, they can no longer be used. All expired instruments should be returned to Intuitive Surgical by contacting your Intuitive Surgical Representative.

Tool Reader Mode

Tool Reader Mode is used to assess the remaining uses for an instrument. You can use this feature only in Stand By mode, and the assessment of the remaining uses will not decrement the amount of uses for a specific instrument. For specific instructions, see "Tool Reader Mode" on page B-9.

Instrument Types

EndoWrist instruments are available in two different shaft sizes: 8mm and 5mm. The 8mm instruments were the initial design for the *da Vinci* Surgical System, and are used extensively in general surgical applications. The 5mm instruments provide a smaller shaft size and a reduced jaw diameter, allowing more flexibility in general surgical applications.

Regardless of shaft size, the instruments can be divided into two basic categories: grasping instruments and cautery/cutting instruments. Grasping instruments are used to hold and secure tissue. Cutting instruments include instruments that can hold scalpel blades, and energized instruments that perform cautery.

Instrument Accessories

All instruments must be used with an appropriate cannula for insertion into the patient. In addition, other accessories must be used, depending on the instrument. For example, when using scalpel blades, the instrument must be used with a blade protector, which maintains not only the sharpness of the blade but the integrity of the cannula seal as well.

Please contact Intuitive Surgical Customer Service for the current product list.

- **WARNING:** When using 8mm and 5mm instruments during the same procedure, you must use the correct cannula, based on the instrument. A reusable 8mm to 5mm reducer cannula is available so that 8mm cannulae can be inserted in the patient, and then both 5mm and 8mm instruments can be introduced through the same cannula. In general, the reducer slides into the 8mm cannula and locks into place, allowing the safe use of a 5mm instrument. Specific instructions for the use of this reducer cannula are provided in "Using the 8mm to 5mm Cannula Reducer" on page B-5.
- **WARNING:** When using a 5mm cautery instrument, a metal cannula must be used. Failure to do so will result in electrical arcing from the wrist, and alternate site burns due to capacitive coupling.

Basic Instrument Design

The *Intuitive Surgical EndoWrist* Instruments consist of four main components: Release Levers (A), which are used to remove the instrument from the sterile adapter of the *da Vinci* Surgical System; the Instrument Shaft (B); the Wrist (C) and the End Effector (D).



Figure B-1 EndoWrist Instrument Example

The instrument housing contains pulleys, which are connected to the instrument wrist with cabling that runs through the instrument shaft. The movement of the manipulators on the Surgeon's Console is translated through the pulleys to the instrument wrist.



Figure B-2 Pulleys Located in Instrument Housing

The instrument housing on both 5mm and 8mm instrument have flush ports, which are used during the cleaning process. 5mm instruments also have a flush port located at the proximal end of the shaft, just below the housing.

For specific instructions on cleaning and flush port locations, see "Cleaning EndoWrist Instruments" on page B-11.

The instrument tip consists of the wrist, which moves the instrument tip in response to the movements of the surgeon. Certain instruments allow disposable tips to be inserted (a scalpel blade, for example). Other tips are fixed end effectors, such as grasping devices. See "Cleaning EndoWrist Instruments" on page B-11. These instructions are also available in the instrument's *Instructions for Use*, which are shipped with every instrument.

Working with Instruments

Inspection Prior to Use

Prior to use, all instruments should be inspected for damage or irregularities. Inspect the instruments for broken, cracked, chipped, or worn parts. Discontinue the use of instruments that have these characteristics.

CAUTION: Endoscopic instruments are designed and manufactured for a specific surgical function. Use of an instrument for a task other than the instrument's designed use may result in a damaged or broken instrument.

Instrument Placement and Removal

When you attach an instrument to an instrument arm, the system evaluates the instrument to determine if it will work with the system. If the system recognizes the instrument from a previous procedure, the instrument will be immediately available for use. If the instrument is "new" to the system, the system attempts to retrieve data from the instrument to determine it's behavior parameters.

• If the instrument is compatible with the system, a blinking blue tool change icon appears on the monitor and a text message is presented while the behavior parameters are uploaded:

Installing new instrument data. System busy, please wait ##

The transfer of data will take no more than 15 seconds, and then the instrument is available for use.

- **WARNING:** Do not interrupt the download process by activating any system function (button). Interrupting the download may result in the instrument not being recognized and may require the removal and re-placement of the instrument to re-initiate the downloading process.
- If the system determines that the instrument is incompatible, a yellow tool change icon is presented along with the following text message:

Instrument not supported.

For instrument installation and removal, please see the step-by-step instructions in Chapter 4, "Instrument Placement and Removal" on page 4-9.

Working with Instrument Accessories

Using the 8mm to 5mm Cannula Reducer

In procedures where 8mm and 5mm instruments are used at the same time, you can use the reducer to ensure safe operation of the 5mm instruments in an 8mm cannula.

The Cannula Reducer consists of two components:

- P/N 371051 The reusable 8mm to 5mm Cannula Reducer
- P/N 400161 The disposable 5mm seal
- 1. Attach the seal to the reducer by aligning it axially with the reducer, and sliding the pins of the cannula reducer into the slots on the seal. Rotate the seal clockwise to lock into place.



Figure B-3 Installing the Seal

- 2. The 3/8 OD Cannula and 10/12mm seal should be mounted on the *da Vinci* Surgical System. Slide the cannula section of the reducer into the 10/12mm seal. The front of the reducer should be facing away from the instrument arm. Slide the reducer down until the latches lock onto the 3/8 OD Cannula.
- 3. 5mm Instruments may now be used by installing them onto the system, through the 5mm seal in the reducer. Instruments may be removed from the system normally.
- 4. To remove the reducer from the system, squeeze the latch levers and lift the reducer out of the 10/12mm seal.

See the 8mm to 5mm Cannula Reducer Instructions For Use for additional details.

Using the Blade Protector

The Blade Protector is used to maintain scalpel sharpness and the integrity of the cannula seal during scalpel instrument insertion and removal.

1. Prior to scalpel instrument insertion into an instrument arm cannula, slide the Blade Protector on to the instrument shaft until the scalpel blade is covered.



Figure B-4 Example of Blade Protector on Instrument Arm Shaft

- 2. To ease insertion, rotate the Blade Protector while inserting through the cannula seal. Moistening the cannula seal with saline may also help.
- 3. After the instrument is engaged into the instrument arm, slide the Blade Protector up the instrument shaft away from the cannula seal.







Figure B-5 Sliding the Protector up the Shaft

4. Immediately prior to removing a scalpel instrument, slide the Blade Protector through the cannula seal towards the instrument tip.



Figure B-6 Sliding the Protector Down the Shaft Prior to Instrument Removal

Scalpel Blade Insertion Instructions

1. Use a needle driver with <u>serrated</u> jaws.

2. With the needle driver, grasp the scalpel base. Make sure to completely tighten the needle driver onto the blade.



Figure B-7 Using the Needle Driver to Install the Snap-Fit Scalpel

3. Slide the insertion tool over the instrument wrist to prevent the wrist from moving during blade insertion.





Figure B-8 Using the Insertion Tool to Attach the Scalpel Blade

4. Insert the scalpel blade into the wrist until it is firmly seated.



Figure B-9 Scalpel Installed in Instrument Tip

- **Note:** Apply force on the needle driver close to the tip to prevent bending of the tip during insertion.
- **CAUTION:** Scalpel blades are designed for a single insertion into an instrument. If the disposable blade is removed from the instrument tip, it should be discarded and a new one inserted.

Instructions for Loading and Firing of Clip Applier Instruments

These instructions apply to the Small Clip Applier. Specific ligating clip cartridges required for the Clip Applier instrument are available as follows:

Small Clip Applier- Weck Hemoclip Traditional small clips

• Weck part # 523835 and 523735

Loading and Firing Instructions

1. Prior to inserting clip, drive grips open by rotating the Yaw-input Pulleys in the noted directions.



Figure B-10 Location of Yaw-input Pulleys

- 2. Holding the instrument wrist completely straight, firmly press clip into grips. The clip must be flush with the tip of the Clip Applier.
- **Note:** If excessive motion of the wrist or grips occurs, the clip should be removed and a new clip inserted. If the wrist moves significantly, the grip action may be affected and the clip could become slightly compressed. This could result in the clip falling out of the grip and into the patient during insertion or engagement.
- **Note:** If clip is not flush with the tip of the Clip Applier, the clip should be removed, grips opened (see step #1) and a new clip inserted.



Instrument wrist must be straight



Figure B-11 Loading Clips and Inserting the Instrument into the Cannula

- 3. Keep the wrist straight while loading the instrument onto the system.
- **Note:** When preparing to enter Follow mode during clip application, the Master grip must be at least 90 percent open before the system will enter Follow mode. The first movement the surgeon must make is to open the grip slightly. This control is used to prevent closing the grip and compressing the clip, which could reduce its effectiveness or cause the clip to fall out of the tool altogether when the surgeon opens the grip after a small closure.
- 4. When using the system to close a clip, the Masters should be thoroughly closed at a moderate to fast speed. If the Masters are not adequately squeezed, there may be a larger clip gap than desired.

Tool Reader Mode

The Tool Reader mode may be used to assess the number of remaining uses for a given instrument. This mode can be entered only if the system is placed in Stand By mode. The Tool Reader mode will not decrement the number of remaining uses for an instrument.

- 1. On the UIP, depress the Tool Reader button. The term "TOOL READER MODE" is displayed on the monitor.
- 2. Insert an instrument into a sterile adapter.
- 3. From the monitor, read the number of remaining uses for the instrument.
- 4. Repeat for other instruments.
- 5. To exit Tool Reader mode, press the "TOOL READER" button again on the UIP. The text displayed on the monitor disappears.
- **Note:** Instruments read by the Tool Reader function are not considered as instruments used during the current procedure. Therefore, instruments attached after Tool Reader mode is engaged must be removed before continuing with the case (they will not be decremented for time and usage). Instruments that were in place when Tool Reader mode was entered will not display their usage information. These instruments do not need to be removed before continuing.

Fluid Leakage Precautions

The surgical instruments held by the auxiliary arm of the *da Vinci* Surgical System are typically held horizontally or inclined upwards during surgery, due to the configuration of that apparatus. As with any laparoscopic instrument, blood or other fluids may migrate through the instrument shaft towards its proximal end if the instrument is positioned horizontally or inclined upwards during surgery. Intuitive® instruments are designed to resist fluid migration of this nature, and thus are designed to avoid fluid leakage from the proximal end. However, in the event that blood or other fluid is noticed leaking out of an Intuitive® instrument and onto the PSM drapes or sterile adapter during surgery, please take the following action:

- 1. Remove the instrument from the auxiliary arm PSM and hold it vertically, tip down, to drain it.
- 2. Thoroughly wipe any fluid off of the sterile adapter and drape using a 4x4 or other suitable cleaning pad before engaging any other instrument.
- 3. After surgery, thoroughly clean the instrument and the sterile adapter per the instructions for use prior to reuse.

In addition, if any blood or other fluid is observed on the inside (PSM side) of the drapes or on the robotic arm apparatus itself, contact the Intuitive customer service department. Intuitive personnel will assist you in adequately cleaning the arm apparatus before the next surgery.

Instrument Grip Release

Typically during instrument removal, the instruments are placed in a neutral position and the tips are open. In the event of a fault or an emergency stop, the instrument tips may be holding tissue or an object. In this case, the instrument tips must be opened manually using the following steps.

8mm Emergency Grip Release

1. Place the Emergency Grip Release Wrench in the Grip Release on the instrument body, as pictured below.



Figure B-12 Using the Wrench to Open the Tips

2. Turn the Emergency Grip Release Wrench counter-clockwise until the instrument tips release the tissue or object held.

Note: If an object is released, place it where it can be retrieved by the assistant.

Note: Turn the Emergency Grip Release Wrench clockwise for Small Clip Appliers.

3. Once the instrument tips are open and the wrist is straight, the instrument can be removed following the normal procedure (see "Removing Instruments" on page 4-12 for details).

5mm Emergency Grip Release

The 5mm instruments have an Emergency Grip Release just like 8mm instruments. However, the release is located in a different area of the housing. See Figure B-13 for the Emergency Grip Release location for 5mm instruments.



Figure B-13 Location of 5mm Instrument Emergency Grip Release

<u>Cleaning EndoWrist Instruments</u>

Examine the instrument thoroughly after each use. If any abnormality is found, do not use the instrument.

Clean the instruments immediately after each use. Do not allow debris to dry on or inside the instrument prior to cleaning.

Use the instructions below to clean both 5mm and 8mm instruments after each procedure.

- 1. Scrub the outside of the instrument with a soft, nylon bristled brush. Move the instrument wrist joint through its full range of motion while scrubbing.
- 2. Rinse the inside of the instrument through all flush ports with pressurized water (approximately 40 psi). While flushing the instrument, hold the tip down and move the wrist through its full range of motion. The rinsing should continue until the water exiting the instrument is clear.

Flush ports are identified on the instrument housing by the following symbol:



Figure B-14 Location of 8mm Flush Ports



Figure B-15 Location of 5mm Flush Ports

- **CAUTION:** During the cleaning process, be sure to point the instrument tip down and away from you. All flush ports must be rinsed with pressurized water. After cleaning, clear water should be seen exiting the instrument. If the water is not clear, or water does not flow through all flush ports, do not use the instrument. Should this occur, contact Intuitive Surgical Customer Service.
- 3. Clean the instruments by using a syringe to inject enzymatic cleaning solution into all flush ports. Then immerse the instruments in an ultrasonic bath filled with an enzymatic cleaning solution for at least 15 minutes. We recommend using an enzymatic cleaner specifically made to clean medical instruments. Prepare the enzymatic bath according to the manufacturer's instructions.

CAUTION: The enzymatic solution should not reach a temperature above 98°F (37°C).

- 4. Scrub the outside of the instrument with a soft, nylon bristled brush. Move the instrument wrist joint through its full range of motion while scrubbing.
- 5. Rinse the inside of the instrument through all flush ports with pressurized water (approximately 40 psi). While flushing the instrument, hold the tip down and move the wrist through its full range of motion. The rinsing should continue until the water exiting the instrument is clear.
- 6. Thoroughly rinse the outside of the instrument to remove any residual debris or cleaning agents.
- 7. After cleaning, dry the outside of the instrument with a lint-free cloth.
- 8. For 5mm instruments, use a neutral pH, steam permeable instrument lubricant to lubricate the jaw and wrist mechanism. For 8mm instruments, the lubrication is recommended, but not mandatory.

Sterilizing EndoWrist Instruments

Sterilization of the instruments has been validated using pre-vacuum steam autoclaving. We recommend the sterilization parameters shown below:

Pre-vacuum sterilization:

- Pre-vacuum at 270°-272°F or 132°-134°C
- Minimum exposure time: 4 minutes
- Average dry time: 20 minutes

Following steam sterilization, allow all components to cool to room temperature. Sudden changes in temperature may damage the components.

WARNING: The use of "Flash" sterilization is not recommended.

- WARNING: Do not sterilize at temperatures over 285°F or 140° C.
- **WARNING:** This device has not been validated for Sterrad®, EtO, Steris® or other sterilization methods.

Note: The parameters listed above are only a recommendation. Sterility of the device is the responsibility of the hospital or site performing the sterilization. (Refer to the sterilizer manufacturer's manual for questions about the sterilization unit.)

Storing EndoWrist Instruments

Store this instrument in a clean, dry and well-ventilated environment.

- **WARNING:** Do not store the instrument in direct sunlight, at high temperature or high humidity. Otherwise, the instrument may be damaged or present an infection control risk.
- **WARNING:** Do not store the sterilized instrument in the box in which it was shipped; doing so may present an infection control risk.
- **WARNING:** Do not store the instrument in a place that is exposed to X-rays, radioactive rays or strong electromagnetic waves (e.g. the vicinity of a microwave therapeutic device, short-wave therapeutic device, MRI, wireless set, etc.). Otherwise, the instrument may be damaged or an infection control risk may be created.

Available Instruments and Suggested Use

This section provides examples of available EndoWrist instruments, and a brief description of their intended use.

Instrument Descriptions		
	Long Tip Forceps	
	Designed for atraumatic grasping of tissue.	
	Round Tip Scissors	
	Designed to cut tissue or suture.	
	DeBakey Forceps	
	Designed for atraumatic grasping of tissue.	

	Small Clip Applier	
	Specifically designed to apply clips to ligate vessels.	
	Scalpel	
	Designed to hold a Blue blade (similar to a 15-degree scalpel blade) or Paddle blade. The blades are disposable and can be inserted into and removed from the instrument.	
	Large Needle Driver	
	Has carbide inserts and is specifically designed to grasp and drive needles.	
	Potts Scissors	
	Designed for delicate cutting of tissue.	
	Round Tooth Forceps	
No. of Contraction	Designed for atraumatic grasping of tissue.	
	Black Diamond Micro Forceps	
	Has a delicate instrument tip and is designed to grasp smaller needles as well as tissue.	
	Cadiere Forceps	
and the second s	Designed for atraumatic grasping of tissue.	

	Cautery with Spatula
	Designed for blunt dissection and the application of cautery.
	EndoWrist ProGrasp TM
N: Car	Tissue grasper with greater grasping force than the Cadiere Forceps.
	Cichon Tissue Forceps
No.	Designed for atraumatic grasping of tissue. The Cichon Tissue Forceps provide similar capabilities as the DeBakey Forceps, but with a much smaller instrument profile that increases the surgeon's exposure to the surgical site.
	EndoWrist PreCise TM Bipolar Instrument
A CONTRACTOR	This is a fully articulating instrument that provides precise electrocautery and hemostasis. Designed for atraumatic grasping of tissue and the application of bipolar cautery.
	Ultrasonic Shears
	Designed for the rapid ligation and transection of tissue.

da Vinci® Surgical System User Manual

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