



Vision

User Guide



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Patents

7,567,233; 7,747,960; 8,242,972; 8,244,824; 8,799,792; 8,806,359

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EMC Directive Statement

| | |
|--------------------------|---|
| EMC Directive Compliance | This equipment was tested and found to conform to the Medical Directive 93/42/EEC for electromagnetic compatibility. Compliance with this Directive is based upon compliance with the following harmonized standards: |
| Emissions: | IEC 60601-1-2:2012 4th Ed., EN55011:2016 + A1:2017, EN61000-3-2:2014, EN61000-3-3:2013 |
| Immunity: | IEC 60601-1-2:2012 4th Ed., EN61000-4-2:2009, EN61000-4-3:2007, EN61000-4-4:2012, EN61000-4-5:2007, EN61000-4-6:2014, EN61000-4-8:2010, EN61000-4-11:2005 |

When operating this equipment, verify that other devices installed near it conform to the applicable EMC standards for that device. The *Odyssey Vision* system is designed to be installed and operated in a Professional Healthcare Facility Environment.

Safety Standard Statement

| | |
|----------------------------|---|
| Safety Standard Compliance | This equipment was tested and found to conform to the following IEC 60601-1 Medical Electrical Equipment General Requirements for basic safety and essential performance test specifications: |
| Standard: | CAN/CSA-C22.2 No. 60601-1:14 ANSI/AAMI ES60601-1:2005+A2 (R2012) +A1 IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint) |

Related documents

HDW-0311 *Odyssey Vision* User Guide
 HDW-0209 *Odyssey Cinema* User Guide
 HDW-0312 *Niobe ES* User Guide

HDW-0358 *Genesis RMN* User Guide
 HDW-0295 *Vdrive* User Guide

Site planning information

Information needed by the hospital for proper installation of an *Odyssey* system (001-007010-2) is provided in PRO-727, *Odyssey Vision* Version 1.5 System Site Planning Guide. The document includes the following information:

1. General information
2. Equipment details
3. Room planning
4. Electrical requirements
5. Mechanical requirements

The hospital will provide a disconnect circuit breaker rated at 30A (120V) or 15A (230V) that removes all power to the *Odyssey Vision* system when activated.

Storage and transport conditions

Temperature: -10°C to 50°C
 Relative Humidity: 20% to 95%
 Atmospheric pressure (kPa): 700 hPa to 1060 hPa

Operating conditions

Temperature: 15°C to 30°C
 Humidity: 20% to 75%, non-condensing
 Atmospheric pressure (kPa): 700 hPa to 1060 hPa

Equipment information

Model no.: 001-007010-2
 Classification: Class I Medical Electrical equipment
 Mode of operation: Continuous
 Electrical ratings:

| | |
|-----------------|---------------------------|
| Voltage rating: | 115 / 230 V ^{3W} |
| Current rating: | 20.0 / 10.0 A |
| Frequency: | 50 / 60 Hz |



WARNING: No modification of this equipment is allowed. No user-serviceable parts are inside the *Odyssey Vision*. The user should not attempt to disassemble any portion of the *Vision*.



WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains that have a protective earth ground.

Maintenance information

Any part of the system (001-007010-2) shall be maintained only by authorized service personnel. Such parts include those in the list below, as referenced in HDW-0310, *Odyssey Quad HD Workstation Maintenance and Service Manual*:

1. UIC cooling fans
2. MDM cooling fans
3. Cabinet cooling fans

Correct replacement of interchangeable or detachable parts

Any part of the system (001-007010-2) shall be serviceable and replaceable only by authorized service personnel. System parts include those in the list below, as referenced in HDW-0310, *Odyssey Quad HD Workstation Maintenance and Service Manual*:

1. KVM over IP Device (P/N 500-006484-1)
2. UIC (P/N 500-006702-1)
3. MDM (P/N 500-005253-1)
4. DVI DL Splitter/Scaler (P/N 500-006906-1)
5. Cisco Router (P/N 500-006495-1)
6. 24-Port Ethernet Switch (P/N 500-006495-1)
7. Power Control CCA (P/N 060-007160-1)
8. Power Injector CCA (P/N 060-007880-1)
9. DVI 4-Port Splitter (P/N 500-006675-3)
10. Cabinet Fan Assembly (P/N 530-006235-1)
11. Power Strip (P/N 504-002576-7)
12. UPS (P/N 540-006423-2)
13. Isolation Transformer (P/N 360-006422-1)
14. Power Supply PS1 (P/N 540-006493-1)
15. Power Supply PS2 (540-006494-1)
16. Contactor CR1 (P/N 416-006092-2)
17. Circuit Breaker CB4 or CB5 (P/N 415-006091-2)
18. Circuit Breaker CB1 (P/N 415-006091-6 (U.S.) or 415-006091-5 (EU))

Installation information

Any part of the system (001-007010-2) shall be installed only by authorized service personnel. Installations include those in the list below, as referenced in HDW-0188, *Odyssey Quad HD Workstation Global Installation Manual*:

1. Document instructions
2. Site requirements
3. Placement of equipment
4. Control Room setup
5. Connecting a third-party computer to a TPI
6. Installing *Odyssey* cabinet
7. Initial power-up of system

8. Global installation
9. Quad HD installation
10. *Odyssey Cinema* components

Network/data coupling to *Odyssey Cinema* system

The hospital shall provide 100 Mbit network/data coupling for connection from *Odyssey Vision* to the *Odyssey Cinema* Server located remotely in the hospital.

If the network/data coupling for connection from *Odyssey Vision* to the *Odyssey Cinema* Server fails, remote viewing and archiving of the *Odyssey Vision* media files will not be possible.

The network/data coupling should connect *Odyssey Vision* only to the *Odyssey Cinema* Server. Connection to any other equipment could result in previously unidentified RISKS to PATIENTS, OPERATORS, or third parties.

The hospital should identify, analyze, evaluate, and control these RISKS.

Subsequent changes to the network/data coupling could introduce new RISKS and require additional analysis.

Changes to the network/data coupling include:

- Changes in network/data coupling configuration
- Connection of additional items to the network/data coupling
- Disconnecting items from the network/data coupling
- Update of equipment connected to the network/data coupling
- Upgrade of equipment connected to the network/data coupling

Disposal

This product should be recycled and not disposed of as general waste (subject to WEEE annex IV resp. EN 50419).

Waste and Recycling

A contractor is responsible for the disposal and recycling of scrap metals and electronics found in the *Odyssey Vision*.

Suggested Contractor: Walch Recycling & Edelmentalle



Notice to the User and/or Patient

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Cover art

Cover art © 2018, 2023 Stereotaxis, Inc.

Contents

| | |
|---|-----------|
| Section 1: Overview | 9 |
| Intended Use | 9 |
| Intended Patient Population | 9 |
| Intended Users | 9 |
| About the System | 9 |
| Required Training | 10 |
| Warnings/Precautions | 10 |
| Electrical Safety Compliance | 11 |
| Electromagnetic Compatibility Information | 11 |
| Emissions..... | 12 |
| Immunity—General electromagnetic effects..... | 13 |
| Immunity—RF interference..... | 14 |
| Separation distances | 15 |
| Graphics and Symbols | 16 |
| Glossary..... | 19 |
| Section 2: Basics | 21 |
| Primary <i>Vision</i> Components | 21 |
| Typical <i>Vision</i> Toolbar | 22 |
| Toolbar button states | 25 |
| System status messages..... | 26 |
| Special Window Types | 26 |
| Changing Video Window Focus..... | 26 |
| Tableside Controller..... | 27 |
| Tableside Controller for <i>Niobe</i> | 27 |
| Cleaning the Tableside Controller | 27 |
| UTSC for <i>Genesis</i> | 27 |
| Connecting a Third-Party System to <i>Odyssey</i> | 29 |
| Procedure Room Hub..... | 29 |
| TPI Box..... | 29 |
| Video graphics array (VGA) | 30 |
| Sync-on-Green (SOG) Video..... | 31 |
| Digital video interface (DVI) | 31 |
| Section 3: Magnetic Lab | 33 |
| <i>Niobe</i> | 33 |
| Siemens, Neusoft, and Philips..... | 34 |
| <i>Genesis</i> | 35 |
| Stereotaxis Imaging Model S | 36 |
| Siemens/Neusoft | 36 |
| Start Window..... | 37 |

| | |
|--|-----------|
| Procedure Information Window | 38 |
| Magnetic procedures | 40 |
| Manual procedures in magnetic labs | 41 |
| Section 4: Non-Magnetic Lab | 42 |
| Getting Started | 42 |
| Start Window | 43 |
| Procedure Information Window | 43 |
| Section 5: Altering Layouts | 46 |
| Add/delete video source..... | 46 |
| Resize video source..... | 46 |
| Use <i>Navigant</i> drop-down menus | 46 |
| Use Quick Layouts..... | 47 |
| Saving Layouts | 48 |
| Emergency Layout..... | 48 |
| Section 6: <i>Odyssey Cinema</i> | 49 |
| <i>Cinema</i> Overview | 49 |
| Connection Status Buttons | 50 |
| Record / Pause Buttons..... | 52 |
| Bookmark Button | 53 |
| Section 7: System Information | 54 |
| Companion Systems | 54 |
| Optional <i>Vision</i> control | 54 |
| Monitors | 54 |
| Video display resolution | 55 |
| Auto-resolution | 56 |
| Configurable key mappings to third-party systems | 57 |
| <i>CARTO</i> Mouse Control..... | 59 |
| Start Panel Utilities..... | 59 |
| Configure Video | 60 |
| Show All Video Sources..... | 62 |
| <i>Navigant</i> Only..... | 63 |
| Shutdown System | 63 |
| TeleRobotic Support Team..... | 63 |
| Troubleshooting | 63 |
| Section 8: Index | 65 |

Section 1: Overview

Intended Use

The Stereotaxis Odyssey Vision® system (also called “*Vision*”) is an optional display and user interface package designed to consolidate the point of control of the catheterization lab. This user guide describes how to operate the *Odyssey Vision* system. It does not describe how to operate the Navigant™ software or any other devices in an interventional lab.

Intended Patient Population

The intended patient population for the *Odyssey Vision* system is patients undergoing diagnostic and interventional procedures in the following areas: right and left heart, and the coronary, peripheral, and neurovasculature.

Intended Users

The *Odyssey Vision* system should be used only by qualified medical professionals who have been thoroughly trained in its use.

About the System

The primary goals of the *Odyssey Vision* system are to:

- Integrate with external data providers
- Simplify the user interface and allow customization
- Streamline clinical workflows
- Consolidate a multitude of video sources, keyboards, and mice to a combined output onto a single display controlled by a single mouse and keyboard

The user may employ the *Odyssey Vision* system with QuadHD monitors to view:








- Up to 16 video sources in the interventional lab on a single display
- Screen representations of video sources that are sized and positioned according to a workflow requested in the *Navigant* system
- Screen representations of video sources that are sized and positioned according to layouts the user can customize

- Status, caution, and warning messages display at all times on the *Odyssey Vision* system during a procedure
- Identical video content on both the *Odyssey Vision* Control Room display and Procedure Room display

Required Training

The Stereotaxis Training Department provides physician technologist and nurse training and associated materials for safe and effective use of the *Odyssey Vision* system's primary operating functions based on the intended use of the system.

Warnings/Precautions

-  **WARNING:** Federal (USA) law restricts this device to sale by or on the order of a physician.
-  **WARNING:** The *Odyssey Vision* system should be used only by qualified medical professionals who have been thoroughly trained in its use.
-  **WARNING:** Only third-party devices that have been validated by Stereotaxis should be connected to the *Odyssey Vision* system.
-  **WARNING:** The user should not attempt to upgrade, configure, or run any other software programs on the *Odyssey Vision* system, other than those specifically installed by Stereotaxis personnel or authorized representative.
-  **WARNING:** There are no user serviceable parts inside the *Odyssey Vision* system. The user should not remove any covers, guards, or attempt to disassemble any portion of the workstation.
-  **CAUTION:** Please ensure the *Odyssey Vision* keyboard and mouse control the appropriate window before performing any function using the workstation.
-  Refer to the applicable RMNS User Guide for a full list of warnings and precautions associated with magnetic navigation.

Electrical Safety Compliance

All external systems connected to the *Odyssey Vision* system through the video or USB ports provided for this purpose must be UL / IEC 60601-1 compliant to maintain isolation from power mains for all interconnected equipment. If connecting a non-compliant device to the *Odyssey* system is necessary, the non-compliant device must be powered by an isolated power panel or a medical-grade power isolation unit.

It is the customer's responsibility to ensure the whole system, when other devices are connected to the *Odyssey Vision* system, complies with IEC 60601-1-1.



WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.



NOTE: In case of a voltage interruption, the *Odyssey Vision* system might shut down, necessitating a system restart.

Electromagnetic Compatibility Information



WARNING: The use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by Stereotaxis, Inc., may result in increased emissions or decreased immunity of the *Vision* system.



WARNING: The *Vision* system should not be used adjacent to or stacked with other equipment and, if adjacent or stacked use is necessary, the *Vision* system should be observed to verify normal operation in the configuration in which it will be used.



NOTE: In addition to the requirements of the general standard for Permanently Installed Large Medical Electrical (ME) Equipment and Large ME Systems for which the exemption specified in 8.6 from the testing requirements of IEC 61000-4-3 is used, this technical description includes the following frequencies and modulations used to test the Immunity of the ME Equipment or ME System:

| | | |
|---------|--------|--------|
| 52.5Mhz | 433Mhz | 2.4GHz |
| 144Mhz | 467Mhz | |



WARNING: This equipment has been tested for radiated radiofrequency (RF) immunity only at selected frequencies, and use of nearby emitters at other frequencies could result in improper operation.

Emissions

The *Vision* system is intended for use in the electromagnetic environment specified in the following tables. The customer or the user of the *Odyssey Vision* system should ensure that it is used in such an environment.

The following table provides guidance and Stereotaxis' declaration on **electromagnetic emissions** for the *Vision* system:

| Emissions | Compliance | Electromagnetic environment—guidance |
|---|---------------------|---|
| RF emissions CISPR 11 | Group 1 | The <i>Vision</i> system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class A Complies | |
| Harmonic emissions IEC 61000-3-2 | | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | | |



WARNING: The EMISSIONS characteristics of this equipment make it suitable for use in industrial and hospital (CISPR 11 class A) settings. If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Immunity—General electromagnetic effects


The following table provides guidance and Stereotaxis' declaration on **electromagnetic immunity** regarding general electromagnetic effects for the *Vision* system:

| Immunity test | IEC 60601 test level* | Compliance level* | Electromagnetic environment—guidance |
|--|--|---|--|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 8 kV contact ± 2, 4, 8 & 15 kV air | ± 8 kV contact ± 2, 4, 8 & 15 kV air | Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst IEC 61000-4-4 | ± 2 kV for power supply lines ± 1 kV for input/output lines | ± 2 kV for power supply lines ± 1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV line(s) to line(s) ± 2 kV line(s) to earth | ± 1 kV line(s) to line(s) ± 2 kV line(s) to earth | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5 % U_T (100% dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s | <5 % U_T 100% dip in U_T for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s | Mains power quality should be that of a typical commercial or hospital environment. If the user of the <i>Vision</i> system requires continued operation during power mains interruptions, it is recommended that the <i>Vision</i> system be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 30A/m | 30A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

* U_T is the a.c. mains voltage before application of the test level.

Immunity—RF interference

The following table provides guidance and Stereotaxis’ declaration on **electromagnetic immunity** regarding radiofrequency (RF) for the *Vision* system:

| Immunity test | IEC 60601 test level* | Compliance level* | Electromagnetic environment—guidance |
|--|--|-------------------------|--|
| <p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p> | <p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 mHz to 2.7 GHz</p> | <p>3 V</p> <p>3 V/m</p> | <p>Portable and mobile RF communications equipment should be used no closer to any part of the <i>Vision</i> system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3\sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p>where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be

considered. If the measured field strength in the location in which the *Vision* system is used exceeds the applicable RF compliance level above, the *Vision* system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *Vision* system or needing to contact the TeleRobotic Support Team.

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

Separation distances



WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the *Odyssey Vision* system, including cables specified by Stereotaxis, Inc.

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

The table provides **recommended separation distances** between portable and mobile RF communications equipment and the *Vision* system.

| Rated maximum output power of transmitter* W | Separation distance according to frequency of transmitter m | | |
|---|--|--|---|
| | 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ | 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

* For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.



NOTE: If there are Electromagnetic Compatibility (EMC) issues with the *Odyssey* system, contact Stereotaxis TeleRobotic Support Team. Otherwise, there are no service requirements to maintain EMC integrity.



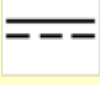



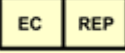





Graphics and Symbols








Warnings and Cautions precede the text and any procedure involving a clear risk to the operator(s), the patient, or the equipment. General warnings are listed in the Warnings and Precautions summary, which can be found in the *Safety* section. Pay close attention to the instructions that accompany the warnings, notes, and symbols.

| | | |
|----------------|--|---|
| WARNING | | WARNING indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury. |
| CAUTION | | CAUTION indicates a potentially hazardous situation which, if not avoided, could result in injury to patient or operator or damage to the equipment. |
| Note | | Note identifies information that could affect the outcome or results of the procedure. |

The following graphics and symbols are used in this user guide and/or on equipment associated with this product.

| Symbol | Name | Description |
|------------|-------------------------|---|
| | AC Power | Alternating current. |
| REF | Catalogue Number | Catalogue/part number. |
| | Caution | Indicates the need for the user to consult the instructions for use for important, cautionary information such as warnings and precautions that cannot be presented on the medical device. |
| | CE Marking | Product conforms to European Medical Directive 93/42/EEC and meets applicable healthy, safety, and environmental requirements. If the mark is accompanied by a number, conformity is valid. |

| Symbol | Name | Description |
|---|--------------------------------|--|
|  | Consult Instructions | See the Operating Instructions for additional information or instruction. |
|  | Date of Manufacture | The date when the medical device was manufactured. |
|  | DC Power | Direct current. |
|  | Ground | Protective earth (ground). |
|  | Equipment Power Off | “Off” (part of equipment). |
|  | Equipment Power On | “On” (part of equipment). |
|  | European Representative | Name and address of the authorized representative in the European Community. |
|  | Importer | Name and address of the entity importing the medical device into the locale. |
|  | Manufacturer | Name and address of the equipment manufacturer. |
|  | Medical Device | Indicates the item is a medical device. |
|  | Power | Power status of the system. |
|  | Power On | “On” (power). |

| Symbol | Name | Description |
|---|--|---|
|  | Power Off | "Off" (power). |
|  | Prescription Only | Caution: Federal law restricts this device to sale by or on the order of a physician. |
|  | Recycle: Electronic Equipment | Product that is subject to the European Union's Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC/EU Directive for recycling of electronic equipment. |
|  | Refer to Instruction Manual/Booklet | The instruction manual or booklet must be read. |
|  | Serial Number | The manufacturer's serial number so a specific medical device can be identified. |
|  | Testing Organization | The logo of the organization responsible for testing the device. |
|  | UK Responsible Person | A person established in the United Kingdom (UK) who acts on the behalf of a non-UK established manufacturer in relation to the manufacturer's obligations under UK regulations. |

Glossary

The following terms may appear in this document:

| Term | Definition |
|--|---|
| Active video window | Global control video window that currently has focus. |
| API | Application Program Interface. Set of classes or functions used to access capabilities of the application. |
| Cardiodrive® system | Stereotaxis <i>Cardiodrive</i> automated catheter advancement system (CAS) used to advance and retract a catheter in patient's heart while RMNS magnets precisely steer working tip of device. This function enables physician to perform an electrophysiology procedure from Control Room, greatly minimizing X-ray radiation exposure. <i>Cardiodrive</i> system is used only for magnetic procedures in magnetic labs. |
| CARTO® 3 system | Biosense Webster <i>CARTO 3</i> EP system, which combines 3D mapping and navigation systems with Stereotaxis RMNS. (Non-magnetic labs are limited to displaying video output of <i>CARTO 3</i> system.) |
| CAS | See <i>Cardiodrive</i> system. |
| Clinical Workflow Manager (CWM) | Component of <i>Navigant</i> application software that executes clinical workflow scripts to guide medical procedures. CWM is available only for magnetic procedures. |
| EMC | Electromagnetic compatibility. |
| Global control video window | Window that can receive keyboard and mouse events from <i>Odyssey Vision</i> global keyboard and mouse. |
| Layout | Set of video windows in a particular configuration on <i>Odyssey Vision</i> display. |
| Manual procedure | Non-magnetic procedure that can be performed in magnetic lab or non-magnetic lab. |
| <i>Navigant</i> Workstation (NWS) | Platform of software applications designed to simplify clinical workflows. <i>Navigant</i> works in conjunction with a Robotic Magnetic Navigation System to provide enhanced integration of catheterization and electrophysiology labs and improved automation of medical devices. |

| Term | Definition |
|--|---|
| Odyssey Cinema® system | Optional recording system for <i>Odyssey Vision</i> platform, referred to as “Cinema,” that provides remote viewing of live and recorded procedures. |
| RF | Radiofrequency. |
| Robotic Magnetic Navigation System (RMNS) | A medical platform that enables physicians to navigate catheters, guidewires and other magnetic interventional devices through the blood vessels and chambers of the heart to treatment sites and then to effect treatment; system consists of computer-controlled magnets that assist physicians in orienting and steering compatible, magnetically-adapted devices and works in conjunction with <i>Navigant</i> Workstation. |
| Tableside Controller | Optional 4- x 5-inch touchscreen for Niobe® systems, attached to patient table accessory mounting rail, providing basic control of <i>Odyssey Vision</i> system in Procedure Room. |
| TPI | Third Party Interface. |
| QuadHD | Display with four times resolution of standard HD display. QuadHD has pixel resolution of 3840 x 2160. |
| Screen layout | Set of video windows in specific layout configuration. |
| UTSC | Universal Tableside Controller for Genesis® systems. Touchscreen controller positioned on the side of the patient table in the Procedure Room. |
| Video window | Window on <i>Odyssey Vision</i> display that contains video display from one application (e.g., <i>Navigant</i> , ECG, X-ray). |
| View-only window | Window for viewing only that cannot receive keyboard focus or mouse input; therefore, cursor cannot display on this type of window. One example is ultrasound window. |



NOTE: Historical Stereotaxis documentation uses the term *Magnetic Navigation System* (e.g., *Niobe* MNS) instead of *Robotic Magnetic Navigation System* (e.g., *Genesis* RMN System). While the term has evolved, the two systems are comparable in design and function.

Section 2: Basics

Primary *Vision* Components

A number of hardware and software components are required to achieve such device consolidation. The primary *Vision* components are listed in the following table.

| Component | Description |
|--|--|
| Odyssey cabinet | The <i>Odyssey</i> cabinet contains video processing components, power supply, power transformer, routers, and circuitry for the <i>Vision</i> system, which allows for up to 16 inputs with potential for more. |
| QuadHD display | The QuadHD display has four times the resolution of an HD display (3840 x 2160). |
| Procedure Room hub | The user can connect up to two auxiliary systems at the same time to the Procedure Room hub. Auxiliary systems are systems that are not permanently installed in the Procedure Room, such as ultrasound machines or PV loop machines on carts. |
| Third-Party Interface (TPI) boxes | TPI boxes are used to connect devices in the interventional lab to the <i>Vision</i> system. They route the video and USB keyboard/mouse signals of all devices connected to the <i>Vision</i> system, enabling video display and global keyboard and mouse control. |

Typical *Vision* Toolbar

The *Vision* toolbar (**Figure 1**) displays horizontally at the bottom of the monitor. It contains several buttons, described in **Table 1**.






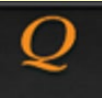

Figure 1. *Vision* Toolbar

Table 1. *Vision* Toolbar Buttons

| Button | Name | Description |
|-----------------------------------|----------------------------------|---|
| Cinema buttons | | |
| | Connections | Displays the status of remote connections through the <i>Cinema</i> system. |
| | Record and Pause | Starts and pauses recording in the <i>Cinema</i> system. It is disabled when <i>Cinema</i> is not available. |
| | Bookmark | Enables the user to bookmark the timeline during a <i>Cinema</i> recording session. The button is disabled when <i>Cinema</i> is not available. |
| Navigant button | | |
| | Navigant | This functions as a home button for the <i>Navigant</i> system. It returns you to the current layout in Clinical Workflow Manager if you are viewing a Quick Layout or emphasized video source. |
| Quick Layout buttons | | |
| | Quick Layouts 1, 2, and 3 | Each button displays a layout the user can customize and save. |
| Third-party device buttons | | |

| Button | Name | Description |
|---|---|---|
|  | ECG Real Time | Emphasizes the Live ECG video window. |
|  | Live Fluoro A | Emphasizes the Live Fluoro A video window. |
|  | CARTO RMT | Emphasizes the Biosense Webster <i>CARTO 3</i> video window. |
|  | Ultrasound | Emphasizes the ultrasound machine connected in the Procedure Room. |
|  | Reference Fluoro A | Emphasizes the Fluoro A Reference video window. |
|  | Auxiliary Input Procedure Room 2 | Emphasizes the Auxiliary Input connected to the Procedure Room hub box port #2. |
|  | Siemens Leonardo® | Emphasizes the Siemens <i>Leonardo</i> Workstation. The icon would be different for Philips Interventional Tools. |
|  | RMNS | Click to access the Stereotaxis robotic magnetic navigation system Service Menu in a magnetic lab. |
| Additional third-party device buttons | | |
|  | ECG Image Reference | Emphasizes the Reference (Control) ECG video window. |
|  | Patient | Emphasizes the patient view in the Procedure Room. |
|  | Philips Allura® Live | Emphasizes the Philips <i>Allura</i> video window. |

| Button | Name | Description |
|---|-----------------------------------|---|
|  | Philips Allura Admin Live | Emphasizes the Live Philips <i>Allura</i> Admin video window. |
|  | Philips Allura Reference 1 | Emphasizes the Live Philips <i>Allura</i> Reference 1 video window. |
|  | Philips Allura Reference 2 | Emphasizes the Live Philips <i>Allura</i> Reference 2 video window. |
|  | Videoconferencing | Emphasizes the videoconferencing video window. |
|  | Biplane X-ray system | Emphasizes the biplane X-ray system video window. |
|  | Camera 1 | Emphasizes the Camera 1 video window. |
|  | Camera 2 | Emphasizes the Camera 2 video window. |
|  | Anesthesia Cart | Emphasizes the anesthesia cart system video window. |
|  | EP Nav | Emphasizes the EP Nav system video window. |
|  | Hemodynamics | Emphasizes the hemodynamics video window. |
|  | IVUS Imaging System | Emphasizes the IVUS imaging system video window. |

| Button | Name | Description |
|---|--|---|
|  | NavX | Emphasizes the NavX system video window. |
|  | Picture archiving and communication system (PACS) | Emphasizes the PACS video window. |
|  | Digital Video Connections 1, 2, 3, and 4 | Emphasizes up to 4 additional digital video windows for systems with 15 video displays. |
|  | Acutus AcQMap System | High resolution imaging and mapping system. |
| Emergency Layout button | | |
|  | Emergency Layout | Click to display the Emergency Layout window with the video sources Live Fluoro A and ECG Real Time. This is a toggle icon. Click the Emergency Layout button to return to the previous layout. |

Toolbar button states

All of the toolbar buttons display slight differences in appearance, depending on their state. The example below is the Real Time ECG button. The three most common states for *Vision* toolbar buttons are enabled, selected, and disabled.



Enabled



Selected



Disabled


System status messages

To check system status, double-click the system icon (*right*) on the hardware status indicator toolbar.



Special Window Types

Some applications with the *Odyssey Vision* system have special window types:

View-only windows are for the display of information only. The *Vision* global keyboard/mouse never sends input to this type of window. The cursor can move across the window, but it will change from a white arrow to a white arrow with a  symbol to remind the user the mouse cannot affect this window.

Another special window type is an application that has an extended desktop, such as ECG. These windows can be positioned in any orientation on the consolidated display.

Changing Video Window Focus

When the mouse is clicked in a video window of an application, the *Odyssey Vision* system delivers mouse move and mouse click events to the window under the cursor. When the user assigns keyboard focus to one of the video windows by clicking in it, the *Vision* system sends keyboard and mouse events to the system with keyboard focus. In this way, the user can change which application is being controlled simply by moving the mouse and clicking the mouse in that application's video window on the *Vision* display.

For example, if the user clicks in the *Navigant* video window, the *Vision* system sets keyboard focus to the *Navigant* window and subsequent keyboard events are directed to the *Navigant* system. If the user then clicks in the ECG video window, the *Vision* system would then send subsequent keyboard events to the ECG application. Mouse move and click events are always directed to the window in which the cursor is located.

The window model for the *Vision* system is the same as that for the Windows operating system. One window will have focus. The user moves the cursor over other windows, but focus does not change until some mouse click event (left-click, right-click, double-click) occurs in a window other than the one that currently has focus.

Tableside Controller

Tableside Controller for *Niobe*

In a typical *Odyssey Vision* lab with *Niobe*, the physician controls a catheter from the Control Room. However, if the ability to control *Odyssey Vision* from the Procedure Room is desired, the Tableside Controller (**Figure 2**) may be added.

Tableside Controller guide

- ① Patient table.
- ② Patient table accessory mounting rail. Devices may vary.
- ③ Tableside Controller — *Odyssey* screen to the left.



Figure 2. Tableside Controller on patient table accessory rail

Cleaning the Tableside Controller

The *Odyssey Vision* tableside controller can be wiped clean between each case. The cleaning solutions used should be a pH neutral hospital-grade, EPA-registered germicidal solution (e.g., CIDEX® Activated Dialdehyde).

UTSC for *Genesis*

In a typical *Odyssey Vision* lab with *Genesis*, the UTSC is *not* an optional component. The UTSC controls magnet movement and *Odyssey* function. **Figure 3** shows the UTSC main screen with magnet controls on the left. **Figure 4** shows the *Odyssey* screen with available video sources. Selecting one will emphasize and enlarge the video source.

i NOTE: When a Stereotaxis RMNS is paired with Stereotaxis Imaging Model S, the UTSC does not have an E-Stop button.



Figure 3. UTSC: Main Screen



Figure 4. UTSC: Odyssey Screen

Connecting a Third-Party System to Odyssey

Procedure Room Hub

The Procedure Room Hub (**Figure 5**) will be situated on the ground, near the patient table. The enclosure will contain two TPI circuit cards. VGA, DVI, and SOG connections may be established, all of which are detailed in the following sections.



Figure 5. Procedure Room Hub

TPI Box

A TPI box (**Figure 6**), connected to a third party system may be in the Procedure Room or Control Room. VGA, DVI, and SOG connections may be established, all of which are detailed in the following sections.



Figure 6. TPI Box

Video graphics array (VGA)

Included in this process are the video graphics array (VGA), VGA adapter, and USB (for mouse and keyboard control) connections. Duplicate these steps (detailed in **Figure 7**) for each computer (video source).

1. Unhook the VGA cable currently attached to the back of the third-party computer, leaving it connected to the third-party monitor.
2. By way of a provided VGA-DVI adapter, connect the unhooked VGA cable to the TPI-J4 port on the system's associated TPI assembly.
3. By way of a provided VGA-DVI adapter, connect the Stereotaxis-provided VGA cable between the back of the third-party computer and the TPI-J3 port on the system's associated TPI assembly.
4. Connect the Stereotaxis-provided USB cable between the back of the third-party computer and the TPI-J6 port on the system's associated TPI assembly.
5. Connect the appropriate *Odyssey* system Ethernet cable to TPI-J1 on the system's associated TPI assembly.
6. Connect the appropriate *Odyssey* system fiberoptic DVI cable to TPI-J2 on the system's associated TPI assembly.

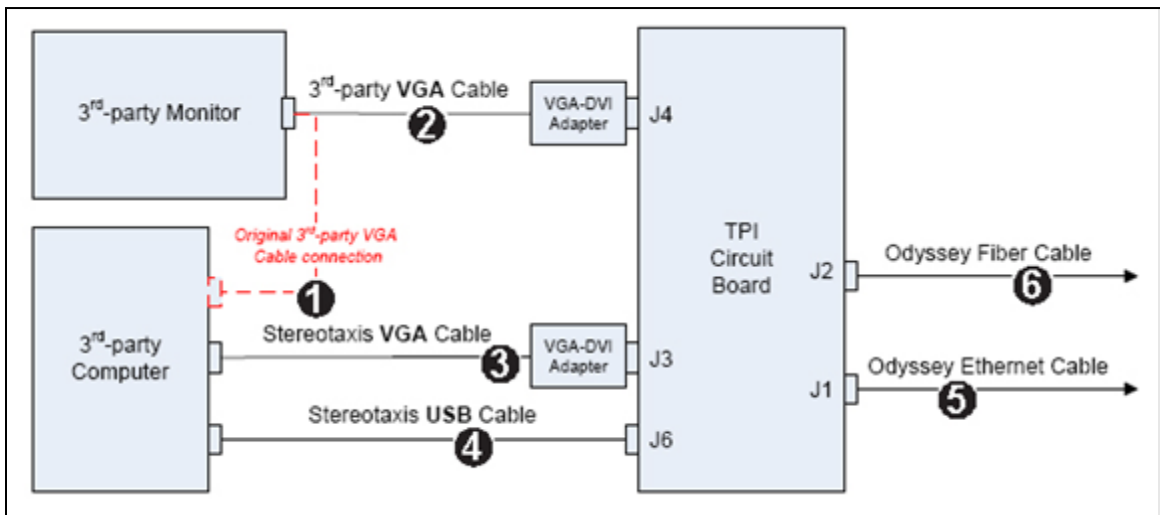


Figure 7. Procedure Room TPI connectivity for VGA and SOG

When connections are complete, the TPI system is available as a video window on the *Odyssey* screen when selected on the *Odyssey* toolbar.

Sync-on-Green (SOG) Video

Analog X-ray systems typically use SOG video. This type of source can be connected to *Odyssey* as follows. Duplicate these steps (detailed in **Figure 7**) for each computer (video source).

1. Unhook the BNC cable attached to the back of the third-party computer, leaving it connected to the third-party monitor.
2. By way of a provided BNC-DVI adapter, connect the unhooked BNC cable to the TPI-J4 port on the system's associated TPI assembly.
3. By way of a provided BNC-DVI adapter, connect the Stereotaxis-provided BNC cable between the back of the third party computer and the TPI-J3 port on the system's associated TPI assembly.
4. Connect the Stereotaxis-provided USB cable between the back of the third-party computer and the TPI-J6 port on the system's associated TPI assembly.
5. Connect the appropriate *Odyssey* system Ethernet cable to the TPI-J1 on the system's associated TPI assembly.
6. Connect the appropriate *Odyssey* system fiberoptic DVI cable to the TPI-J2 on the system's associated TPI assembly.

When connections are complete, the TPI system is available as a video window on the *Odyssey* screen when selected on the *Odyssey* toolbar.

Digital video interface (DVI)

Following are general instructions for digital video interface (DVI) and USB (for mouse and keyboard control) connections. Duplicate these steps for each computer (video source).

1. Unhook the DVI cable currently attached to the back of the third-party computer, leaving it connected to the third-party monitor.
2. Connect the unhooked DVI cable to the TPI-J4 port on the system's associated TPI assembly.
3. Connect the Stereotaxis-provided DVI cable between the back of the third-party computer and the TPI-J3 port on the system's associated TPI assembly.
4. Connect the Stereotaxis-provided USB cable between the back of the third-party computer and the TPI-J6 port on the system's associated TPI assembly.
5. Connect the appropriate *Odyssey Vision* system Ethernet cable to TPI-J1 on the system's associated TPI assembly.

- Connect the appropriate *Odyssey Vision* system fiberoptic DVI cable to TPI-J2 on the system's associated TPI assembly

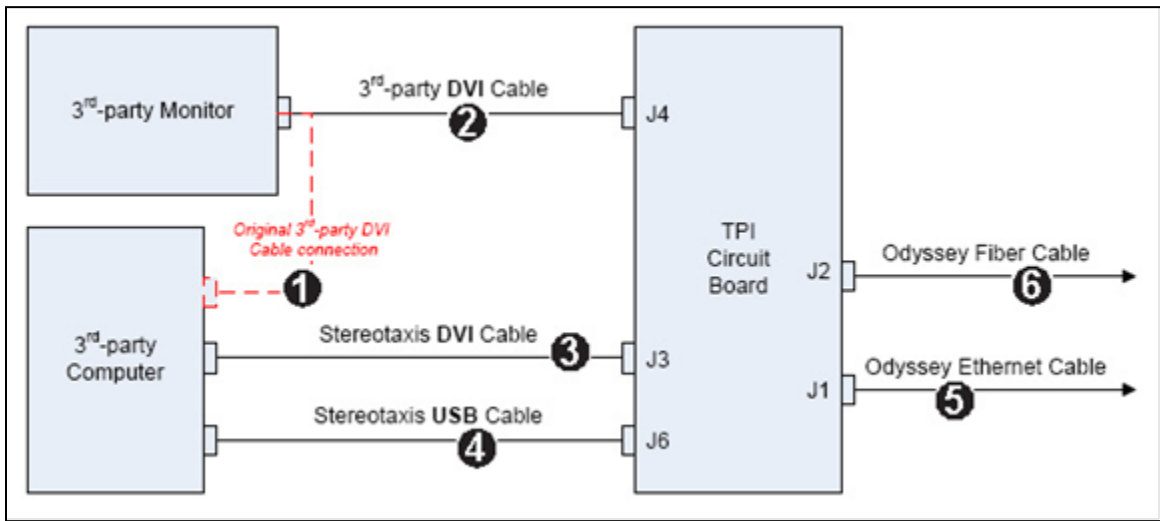


Figure 8. Procedure Room TPI connectivity for DVI

When connections are complete, the TPI system is available as a video window on the *Odyssey* screen when selected on the *Odyssey* toolbar.

Section 3: Magnetic Lab

Niobe

Follow this sequence of steps when starting the *Odyssey Vision* system:

- Turn on all non-Stereotaxis system computers (such as X-ray, ECG, and mapping systems).
 - *Niobe* communicates with a variety of digital fluoroscopy systems:
 - Siemens AXIOM Artis™ dFC MN
 - Siemens AXIOM Artis dBC MN
 - Siemens Artis zee™ Floor MN
 - Siemens Artis zee Biplane MN
 - Philips Allura Xper FD10C
 - Stereotaxis Imaging Model S
 - Neusoft
- When using a *Niobe*, turn on the *Niobe* system by pressing the switch labeled “NIOBE” to the **1** position on the *Vision* Remote Power Box. The switch is a momentary-contact switch that will return to the middle position when released.
- Turn on the *Vision* computer by pressing the switch labeled, “ODYSSEY” to the **1** position on the *Vision* Remote Power Box. Like the NIOBE switch, this is a momentary-contact switch.

Siemens, Neusoft, and Philips

The *Vision* Remote Power Box, found in labs with Siemens, Neusoft, and Philips X-ray systems, are detailed in **Figure 9**.

Key to Figure 9

- 1a** Siemens/Neusoft E-stop button
- 1b** E-stop button hole is plugged for Philips and non-magnetic labs
- 2** *Odyssey Vision* system is on when green LED is lit
- 3** E-stop is activated when red LED is lit
- 4** In a magnetic lab, *Niobe* system is on when green LED is lit
- 5** Turns *Odyssey Vision* system ON when pressed
- 6** Turns *Odyssey Vision* system OFF* when pressed
- 7** In a magnetic lab, turns the *RMNS* system ON when pressed
- 8** In a magnetic lab, toggles *Niobe* system OFF* when pressed

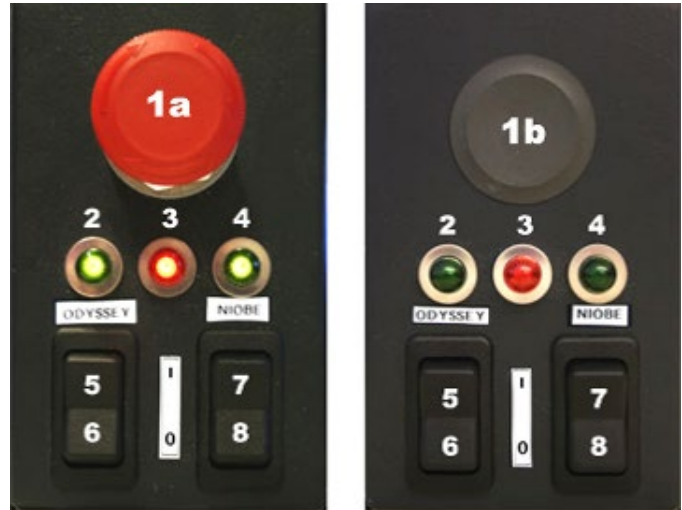


Figure 9. *Vision* Remote Power Box: Siemens/Neusoft labs (left), Philips labs (right)

*Use the manual switches **only** when unable to shut down the system through the *Vision* software. When using the switches, press and hold them (for ~4 seconds) until the system shuts down.



NOTE: The large red button displayed above is the E-Stop when *Niobe* is used with a Neusoft/Siemens *AXIOM Artis* dFC MN X-ray system. A similar *Vision* Remote Power Box is provided when other approved systems are used.

Genesis

Follow this sequence of steps when starting the *Odyssey Vision* system:

- Turn on all non-Stereotaxis system computers (such as X-ray, ECG, and mapping systems).
 - *Genesis* communicates with a variety of digital fluoroscopy systems:
 - Siemens *AXIOM Artis dFC MN*
 - Siemens *AXIOM Artis dBC MN*
 - Stereotaxis Imaging Model S
 - Neusoft
- A **Remote System Power Box** is present in the Control Room (**Figure 10**).
 - Push the black switch so the green light on the box lights up. *Genesis* and *Odyssey* will power on.



Figure 10. Remote System Power Box

Stereotaxis Imaging Model S

The Stereotaxis Model S Control Panel (**Figure 11**) is present in the Control Room and in the Procedure Room. In the Procedure Room, it is positioned to hang off the side of the table.

Pushing the large red button, seen below, will stop both the Stereotaxis Imaging Model S and Stereotaxis RMNS. When a Stereotaxis RMNS is paired with Stereotaxis Imaging Model S, there is not an E-Stop on the System Power Box in the Control Room (**Figure 10**).

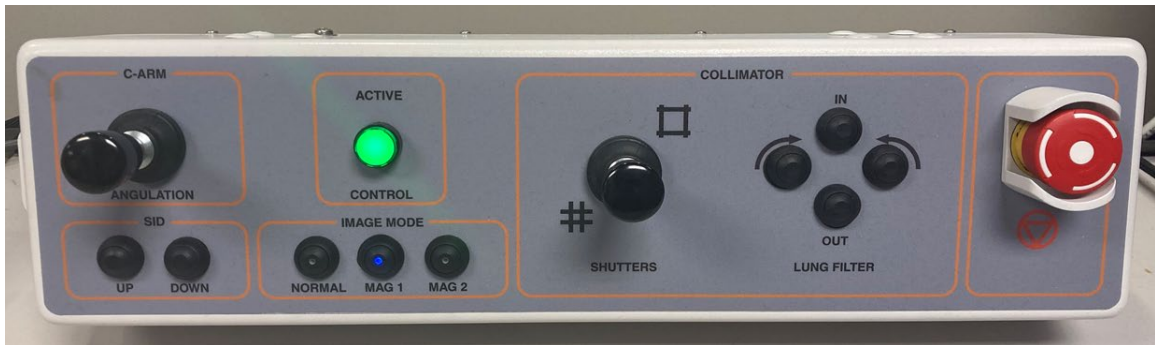


Figure 11. Stereotaxis Imaging Model S Control Panel

Siemens/Neusoft

An E-Stop is present on the **Remote System Power Box** (**Figure 12**) when *Genesis* is connected to a compatible Siemens/Neusoft X-ray system. Pushing the red button will stop the *Genesis* and *Odyssey* systems.



Figure 12. Remote System Power Box: *Genesis* with Siemens/Neusoft

Start Window

The *Odyssey Vision* start window (**Figure 13**) is shown in the lower left corner of the QuadHD screen — as are all *Navigant*-specific windows.

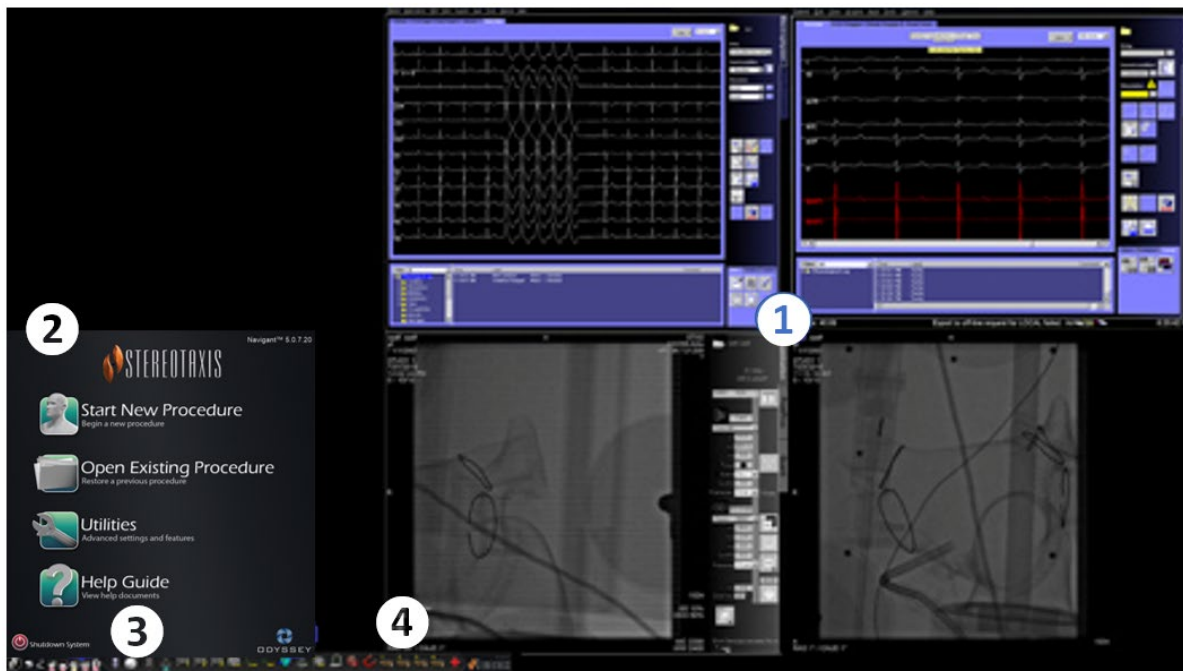


Figure 13. Start window (magnetic lab)

Start window for magnetic lab

- ① *Vision* opens to a **layout** with Live and Reference ECG on the top right and Live Fluoro and Reference Fluoro on the bottom right (if those systems are powered on).
- ② **Start panel.** On this panel, you can open a new or existing procedure, access the Utilities dialog or Help Guide, or shut down the system.
- ③ **System indicators.** These icons indicate the status of systems such as X-ray, and mapping (depending on what is in use). Each symbol displays a “no” symbol (⊘) overlay when the system is not operating properly, or not communicating.
- ④ ***Vision* toolbar.** Contains *Cinema* buttons, *Navigant* button, Quick Layout buttons, Third-party device buttons, and the Emergency Layout button.


Click **Start New Procedure**.

Procedure Information Window

Whether starting a new procedure or opening an existing one, the next display after the start window is the Procedure Information window (**Figure 14**). Entering all patient information into the X-ray system before starting a procedure on *Navigant* is recommended. The information will then be automatically imported into the appropriate fields on the *Odyssey* screen.

Figure 14. Magnetic Procedure Information window

You may also fill out procedure information fields manually:

1. **Patient fields.** Supply the Patient First and Last name, the Patient ID, and Date of Birth (DOB), and then select the appropriate Sex.
2. **Physician field.** Click the down arrow to the right of the field to choose a physician if working with previously entered information, or click the  button to add a physician to the list.
3. **Profile field.** Click the down arrow to the right of the field to choose a procedure if working with previously entered information.



NOTE: You may enter new information for the Physician and Profile fields to be stored for future procedures. The Physician and Profile fields are used to display the customized layouts that a physician has created.

4. **Arrhythmia field.** From the drop-down menu, select the type of arrhythmia involved.
5. **Notes field.** Type any desired (optional) information about the case or procedure.
6. **Heart Chamber panel.** First click the desired procedure type tab:
 - Electrophysiology (EP)
 - Coronary for Interventional Cardiology (IC)
 - CRT (Cardiac Resynchronization Therapy)

Then click the appropriate anatomy icon:

- EP: Right Atrium, Left Atrium, Right Ventricle, or Left Ventricle
 - Coronary: Coronary arteries
 - CRT: Coronary sinus
7. Selecting **Use Mapping** or **Use RMN** changes the procedure layout to include mapping or *Navigant* options.
 8. After procedure information has been entered and procedure type options have been selected, click **OK**. The layout associated with this procedure displays. The procedure is now open, and the main window displays.



NOTE: Patient and Physician fields must be filled out to continue with the procedure. Enter the patient information exactly as it appears on the X-ray system.

Magnetic procedures

To start a magnetic procedure from the *Vision* Procedure Information window, ensure the **Use RMN** checkbox is selected. Magnetic procedures can run only with a Stereotaxis RMNS. *Vision* procedures can run with or without a Stereotaxis RMNS.

1. Select or clear the **Use Mapping** checkbox to start a procedure with or without a mapping system.
2. Click **OK** to begin the procedure.

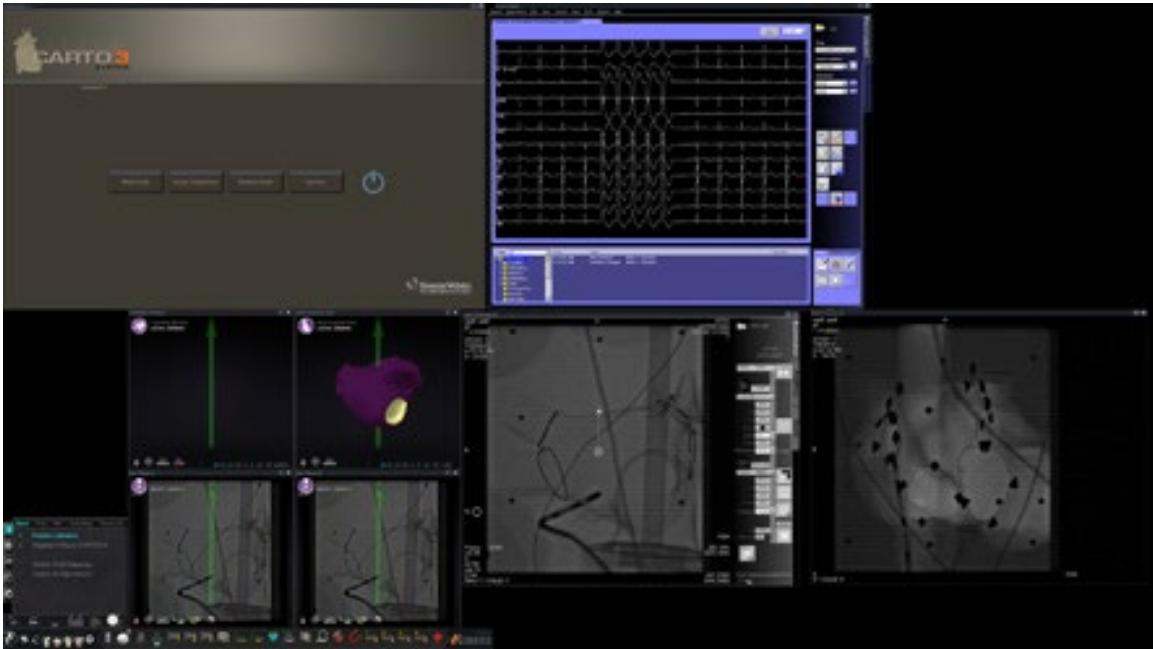


Figure 15. Magnetic procedure with *CARTO 3*

The Clinical Workflow Manager displays in the lower-left corner of the bottom quadrant of the QuadHD screen. The Clinical Workflow Manager controls the opening layout for any procedure. If you want to change the video source display, you can:

- Drag a video input icon on the *Vision* toolbar up to the screen to add a video source.
- Click on the video input icon in the toolbar to emphasize the source.
- Click the **X** button of the title bar of any video source to close it.

Manual procedures in magnetic labs

The *Vision* Procedure Information window also allows you to perform manual procedures without using the Stereotaxis robotic magnetic navigation system. If you are starting a manual procedure, clear the **Use RMN** checkbox on the Procedure Information window.

The Clinical Workflow Manager will not display on the *Vision* screen. However, *CARTO 3*, ECG, X-ray, and other systems will still display. Most *Navigant* features also display, such as control panels, and guidance dialogs. Click **OK** to begin the procedure (**Figure 16**).

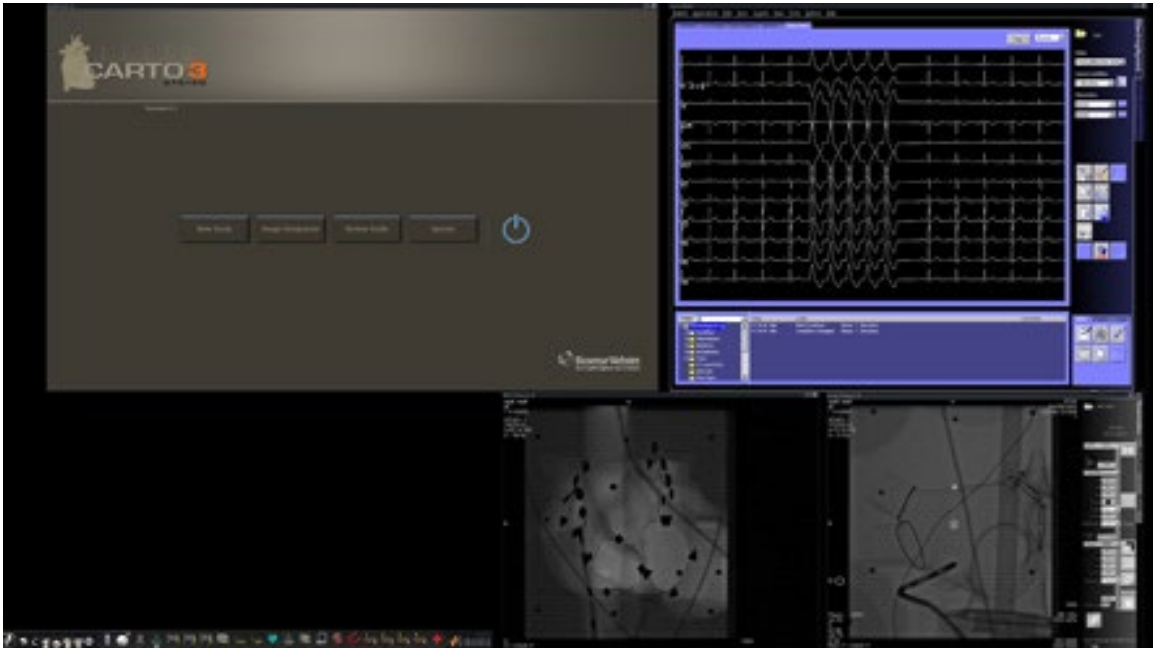


Figure 16. Manual procedure in magnetic lab with *CARTO 3*

This opening window of a manual procedure displays default video sources based on the selected procedure. If you want to change the video source display, you can:

- Select a device button from the *Vision* toolbar to open a single, emphasized video source, displaying at or near full resolution.
- Add a source by dragging its toolbar icon up to the screen.
- Delete a source from the screen by clicking the **X** in its title bar.
- Select one of the three Quick Layout buttons.

Section 4: Non-Magnetic Lab

Getting Started

Follow this sequence of steps when starting the *Odyssey Vision* system:

Turn on all non-Stereotaxis system computers (such as X-ray, ECG, and mapping systems).

Turn on the *Odyssey Vision* computer by pressing the switch labeled “ODYSSEY” to the **1** position on the *Vision Remote Power Box* (**Figure 17**). This is a momentary-contact switch that will return to the middle position when released.

Key to Figure 17

- 1** *Odyssey Vision* system is on when green LED is lit
- 2** Turns *Odyssey Vision* system ON when pressed
- 3** Turns *Odyssey Vision* system OFF* when pressed

* Use the manual switches only when you cannot shut down the system through the *Vision* software. If you do need to use the switches, press and hold them for approximately 3 seconds until the system shuts down.



Figure 17. *Vision Remote Power Box* for non-magnetic labs


Start Window

The *Odyssey Vision* start window is shown in the lower left corner of the QuadHD screen – as are all *Navigant*-specific windows. Click **Start New Procedure**. The next display is the Procedure Information window.

Procedure Information Window

We recommend entering all patient information into the X-ray system before starting a procedure on the *Odyssey Vision* system. The information will then be automatically imported into the appropriate fields on the *Vision* system.

You may also fill out procedure information fields manually:

1. **Patient fields.** Supply the Patient First and Last name, the Patient ID, and Date of Birth (DOB), and then select the appropriate Sex.
2. **Arrhythmia field.** From the drop-down menu, select the type of arrhythmia involved.
3. **Physician field.** Click the down arrow to the right of the field to choose a physician if working with previously entered information, or click the  button to add a physician to the list.
4. **Profile field.** Click the down arrow to the right of the field to choose a procedure if working with previously entered information.



NOTE: You may enter new information for the Physician and Profile fields to be stored for future procedures. The Physician and Profile fields are used to display the customized layouts that a physician has created.

5. **Notes field.** Type any desired (optional) information about the case or procedure.
6. **Heart Chamber panel.** First click the desired procedure type tab:
 - Electrophysiology (EP), highlighted in Figure 18
 - Coronary for Interventional Cardiology (IC)
 - CRT (Cardiac Resynchronization Therapy)

Then click the appropriate anatomy icon (Figure 18 shows **Right Atrium** selected):

- EP: Right Atrium, Left Atrium, Right Ventricle, or Left Ventricle
- Coronary: Coronary arteries
- CRT: Coronary sinus

7. **Checkbox.** Selecting **3D Mapping** changes the procedure layout to include the mapping video source. The example in Figure 18 shows **Use 3D Mapping** selected.
8. After procedure information has been entered and procedure type options have been selected, click **OK**. The layout associated with this procedure displays. The procedure is now open, and the main window displays.



NOTE: Patient (First and Last Name, ID, DOB, and Sex) and Physician fields **must** be filled out to continue with the procedure. Enter the patient information exactly as it appears on the X-ray system.

Figure 18. Non-magnetic Procedure Information window

After entering procedure information and selecting procedure type options, click **OK**. The layout associated with this procedure displays. The procedure is now open and the main window (**Figure 19**) displays.

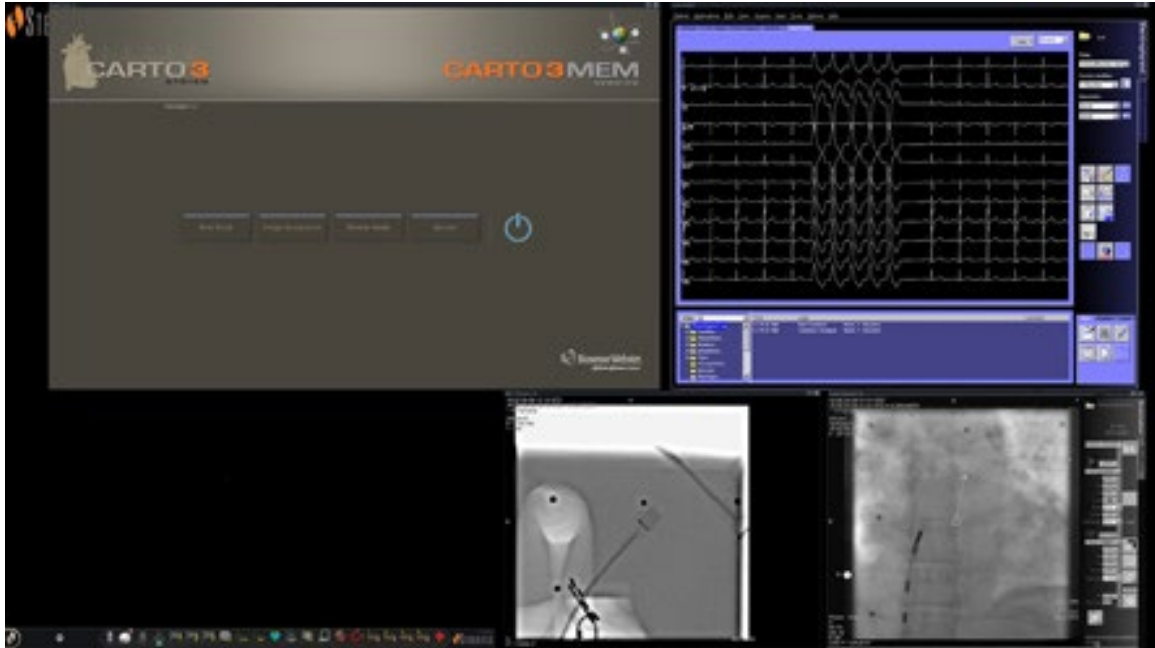


Figure 19. Main window for procedure in non-magnetic lab

Section 5: Altering Layouts

To alter a layout, the user must first make the source active by clicking the video source's icon on the *Vision* toolbar. The selected video source displays in an emphasized state on the screen at or near full resolution.

The *Vision* system offers several options for altering a layout:

- Add or delete a source
- Resize a source
- Use *Navigant* drop-down menus
- Customize the default Quick layouts

Add/delete video source

One way to **add** a video source is to drag its toolbar icon up to the display area. For instance, if Reference Fluoro A is not currently in the viewing area, click its toolbar icon and drag into the area. Once there, you will be able to resize it or move it as you wish.

When starting a new procedure, the initial screen shows video input sources with no title bars because the Device Selection dialog is open. Dismissing this dialog enables the title bars to appear.

Clicking in a video input area activates the source and highlights its title bar. At the right end of the title bar are the Expand and Close buttons.

Clicking the **Expand** button or double-clicking the title bar *expands* the video source to fill the empty area. Clicking the **Close** button highlights it and *deletes* the video source from the display area.

Resize video source

Video source displays can be resized by dragging on the edges or corners of a Windows display.

Use *Navigant* drop-down menus

The *Navigant* video source area includes purple icons in the upper, left-hand corner of each window. Selecting this icon will enable a drop-down menu (**Figure 20**) where the user can select a different display within that window.

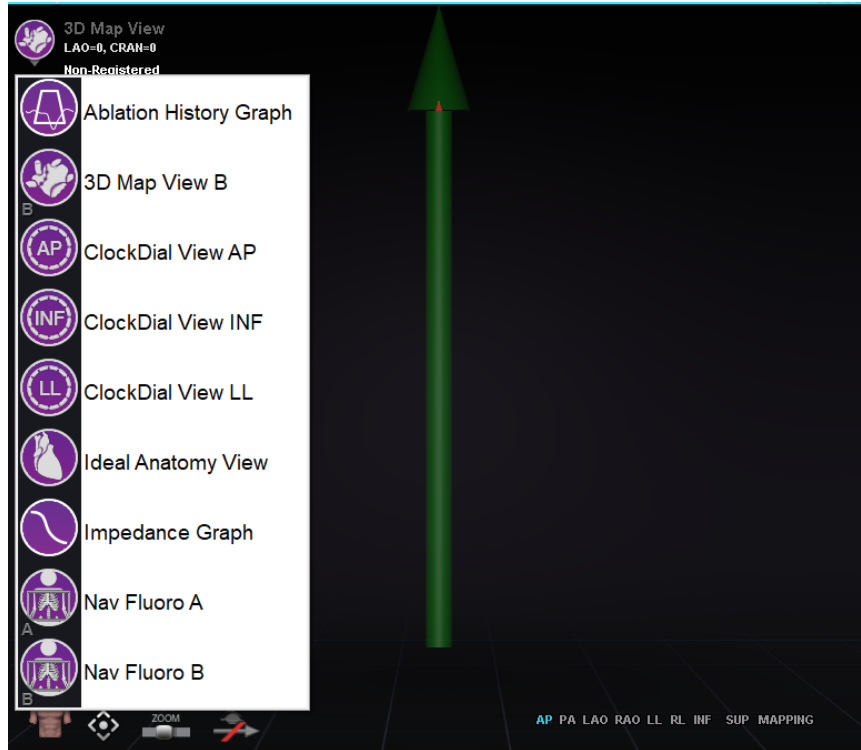


Figure 20. Window display menu options

Use Quick Layouts

Configurations

The Quick Layouts are grouped by clinical specialty and procedure type and available for magnetic and non-magnetic procedures.

Each Electrophysiology category has separate Quick Layouts. All Quick Layouts may be used for Interventional Cardiology and Cardiac Resynchronization Therapy (*Coronary Sinus*) procedures.

Buttons

To view and customize alternative (quick) layouts, click one of the Quick Layout buttons (**Figure 21**) on the *Vision* toolbar. To modify the Quick Layout, first select one of the Quick Layout buttons. Afterward, use the Altering Layouts features previously described. The next time the Quick Layout button is selected, the new layout displays.



Figure 21. Quick Layout buttons on *Vision* toolbar

Saving Layouts

To save a layout, click the System Options icon on the hardware status indicator toolbar. Select **Save Layout**.

To revert to the last saved layout, select **Revert Layout** and then **Last Saved** (if available) or **System Default**.

Select **Lock Layout** from the System Options menu to lock the layout. To save this layout, unlock it by selecting **Unlock Layout** from the System Options menu. Selecting **Unlock Layout** redisplay video source title bars for further manipulation of the layout.

Emergency Layout

The Emergency Layout is available when the *Vision* application starts and can be accessed at any time during the procedure by clicking the red cross icon on the *Vision* toolbar. The QuadHD screen displays Live ECG, Live Fluoro A, and, if available, Reference Fluoro A. The Emergency Layout button acts as a toggle. Clicking it once displays the Emergency Layout; clicking again returns to the previous screen.

Section 6: *Odyssey Cinema*

Cinema Overview

The *Cinema* system is an optional add-on to the *Odyssey Vision* product. “*Cinema*” refers to both *Odyssey Cinema Studio* and *Odyssey Cinema LT* products. When installed, the Record / Pause, Connection, and Bookmark buttons display their available states. When not installed, only the disabled states display.







If you have the *Cinema* add-on, your Stereotaxis representative configures the system to use one of four recording control modes:

- **Recording disabled.** No recording can occur on the *Vision* system.
- **Manual recording.** You fully control the recording by clicking the Record / Pause button on the *Vision* toolbar.
- **Semi-automatic recording.** The *Cinema* system automatically starts recording when a *Navigant* procedure is opened; however, you can manually pause or resume the recording at any time.
- **Automatic recording.** The *Cinema* system automatically starts recording when a *Navigant* procedure is opened; you cannot pause or resume the recording.

For all modes, the recording is automatically stopped when the *Navigant* procedure is closed.

Connection Status Buttons

The *Cinema* system enables other interested parties to view your *Vision* procedure if you give them permission. Another party could be the Stereotaxis TeleRobotic Support Team, a colleague, a professor, a resident or intern, or anyone who is interested in the procedure. The Connection button tells you if anyone is connected or if anyone is waiting to be connected (a Pending connection).

| | | | |
|------------------------------------|---|-----------------------------------|---|
| No viewer (available) |  | No viewer (disabled) |  |
| Viewer pending (available) |  | Viewer pending (disabled)* |  |
| Viewer connected (available) |  | Viewer connected (disabled) |  |

* The button can be in the viewer pending (disabled) state if you have opened the *Vision* application (so you can see the toolbar) and a potential viewer has requested permission to view but you have not started a procedure. You have to start the procedure before you can click the button and respond to the request (see the following scenario).

Scenario

Following is a sample scenario using the Connection button in various states:

1. You open the *Vision* application and start setting up your procedure. You see there are no viewers.



No viewer:

2. You know your colleague, Dr. Agamemnon, is planning to view the procedure from his office. Dr. A launches *Cinema* in his office and requests permission to view your procedure. The Viewer button turns yellow, indicating at least one pending viewer.



At least one viewer is pending:

3. You click the Connection button and the Remote Viewer Connections dialog displays with Dr. A's name listed as *Pending*.
4. Select Dr. A's name and click **Accept**. Now the Connection button shows a connected user:



One or more viewers are connected:



NOTE: If another potential viewer requests a connection, the Viewer button will again turn yellow. In addition, if no viewer or pending viewer is selected, the **Accept** and **Deny** buttons will not be available.

Remote Viewer Connections dialog

The Remote Viewer Connections dialog offers four options:

- **Auto accept all viewer requests checkbox.** If you check this box, all listed viewers (pending and connected) are able to automatically connect and disconnect at any time during the current procedure (until you close the procedure). Any qualified user may connect and disconnect at will during a procedure.
- **Accept button.** Select the pending viewer's name and click **Accept**. This is a one-time action; in other words, if you accepted a viewer, the viewer disconnects, and then the viewer wants to reconnect, you need to Accept or Deny the viewer's request again.
- **Deny button.** Select the pending viewer's name and click **Deny**. This is also a one-time action; if a viewer's request is denied and the viewer tries to connect again, you need to Accept or Deny the viewer's request again.
- **Clear All.** This button is similar to the emergency act of clearing the room. If selected:
 1. All connected viewers are immediately disconnected.
 2. All pending viewers are immediately denied.
 3. All user names in the list are cleared.
 4. If checked, the **Auto Accept All** checkbox is cleared.

To reconnect, each viewer must submit a new request, and you may respond to the viewer's request with one of the choices above.

Record / Pause Buttons

The *Cinema* system has the ability to record procedures for future reference. The Record and Pause buttons are toggles; when one is on, the other is off.

| | | | |
|---|---|---------------------------|---|
| Recording paused; Record button available |  | Record button disabled |  |
| Recording in progress; Pause button available |  | Pause button disabled |  |

Scenario 1

For example:

1. To start recording a procedure, click the Record button.



Paused / Record available:

After clicking, the button changes (toggles) to Recording / Pause available. A bright red dot (the “record light”) displays in the upper-right corner when recording.

2. If the procedure is delayed, click the Pause button to pause recording.



Recording / Pause available:

3. The button now toggles back to the Record available state.



Paused / Record available:

Bookmark Button

While recording, bookmarks may be added and annotated. The bookmarks will be stored with the recorded procedure.



Scenario 2

Another scenario using the Bookmark button:

1. While recording a procedure, an unusual arrhythmia occurs.
2. Click the Bookmark button to mark the exact time of the arrhythmia.



Bookmark selected:

3. The Archiver Bookmark dialog (**Figure 22**) displays with a blank space for annotations. Type an identifying note in the space. You may add as many bookmarks as desired.

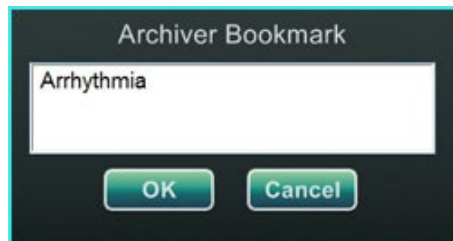


Figure 22: Archiver Bookmark dialog



See the *Odyssey Cinema* User Guide for more information.

Section 7: System Information

Companion Systems

The *Odyssey Vision* platform supports importation of VGA, DVI, and RGB component video on each port with up to 1920 x 1200 pixels of resolution. The *Vision* system is compatible with:

- Stereotaxis *Navigant* versions 4.2 and newer
- Stereotaxis *Niobe* versions 4.1 and newer
- Stereotaxis *Genesis RMN*
- Lab equipment that uses USB-compatible mice and keyboards

Optional *Vision* control

The user has the option of using the native display, keyboard, and mouse controls of any of the systems connected to the *Vision* platform instead of, or simultaneously with, the *Vision* controls.

Monitors

The *Odyssey Vision* setup has two monitors: one in the Control Room and one in the Procedure Room. The output on the two monitors may vary. Sometimes, one monitor will display the *Navigant* window only. Monitors can display up to 16 video streams (input from the *Navigant* system and 15 non-*Navigant* sources, such as ECG and fluoro). Each video stream appears in its own window on the *Vision* display. The window that contains a video stream on the *Vision* display is called a video window.

Cleaning and disinfecting instructions

The *Odyssey* monitor should be cleaned in accordance with manufacturer guidelines. Caring for your LCD monitor includes the following steps:

1. Be sure the *Odyssey Vision* system is off when cleaning.
2. Take care not to scratch the front surface with any hard or abrasive material.
3. Remove dust, finger marks, grease, and so on with a soft damp cloth (a small amount of mild detergent can be used on the damp cloth).
4. Wipe off water drops immediately.

Possible cleaning solutions:

- 70% isopropyl alcohol
- 1.6% aqueous ammonia
- Cidex® (2.4% glutaraldehyde solution)
- Sodium hypochlorite (bleach) 10% “Green soap” (USP)
- 0.5 percent Chlorhexidine in 70% isopropyl alcohol (e.g., CleanSafe® optical cleaning liquid)

Specific *Barco* monitor instructions

The **Barco**® User Guide for the 56.2-inch LCD Large Screen Monitor [Quad] provides the following guidelines:

Front panel

- Clean the acrylic front panel using a soft cotton cloth, lightly moistened with a watery solution or a mild commercial glass-cleaning product.
- Wipe with a soft cotton cloth.

Cabinet

- Clean the cabinet using a soft cotton cloth, lightly moistened with a recognized cleaning product for medical equipment.
- Repeat with water only.
- Wipe with a soft cotton cloth.

LCD panel

It may be possible that dust particles have entered the display and are stuck behind the front panel.

- *This cleaning procedure has to be done in an authorized Service Center.*

The *Barco* manual also lists the following items as materials or substances to *not* use for cleaning: Lyes, acids, decalcification agents, degreasing agents, strong ammonia detergents, chlorine detergents such as Domestos, solvents, coarse millinery, and microfiber. Consult the User Guide for further information regarding the monitor.

Video display resolution

Vision QHD monitors have a video display resolution of 3840 x 2160.

Auto-resolution

The Auto-resolution feature of the *Odyssey Vision* system automatically detects the input resolution of a video source. This input resolution depends on the system connected.

When a device or system is hooked up to the Procedure Room hub, Auto-resolution detects its resolution and allows the video to “grow” or scale up inside the device’s designated window on the display while maintaining aspect ratio integrity. When adding a window to the display, the video source’s native resolution is used to calculate the Preferred Size, Maximum Size, and Minimum Size allowed.

Following are sizing limits shown in the form of an *example* for a video source with a native resolution of 1600 x 1200:

| | | |
|-----------------------|-------------|---|
| Preferred size | 1600 x 1200 | Also known as “input size” |
| Maximum size | 2880 x 2160 | 2 x input resolution, but not to exceed 3840 x 2160 |
| Minimum size | 160 x 120 | 10% of input resolution |

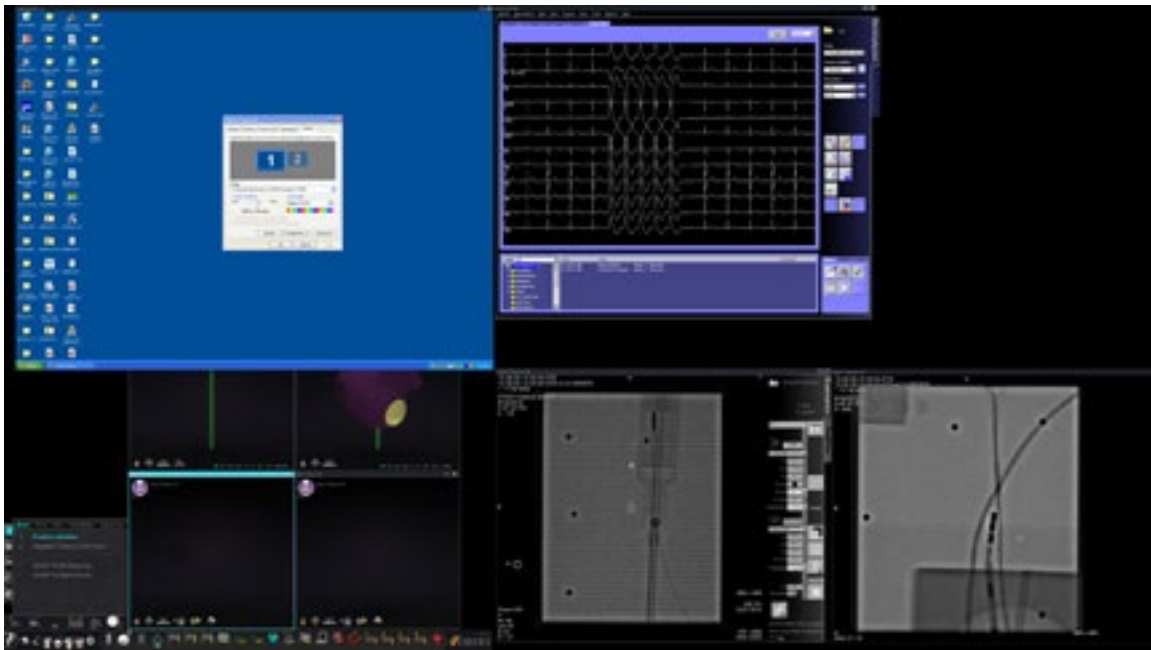


Figure 23. Video source (upper left): native resolution of 1600 x 1200

Figure 24 shows the Display Properties dialogs for the 1600 x 1200 and 1280 x 1024 resolutions respectively.

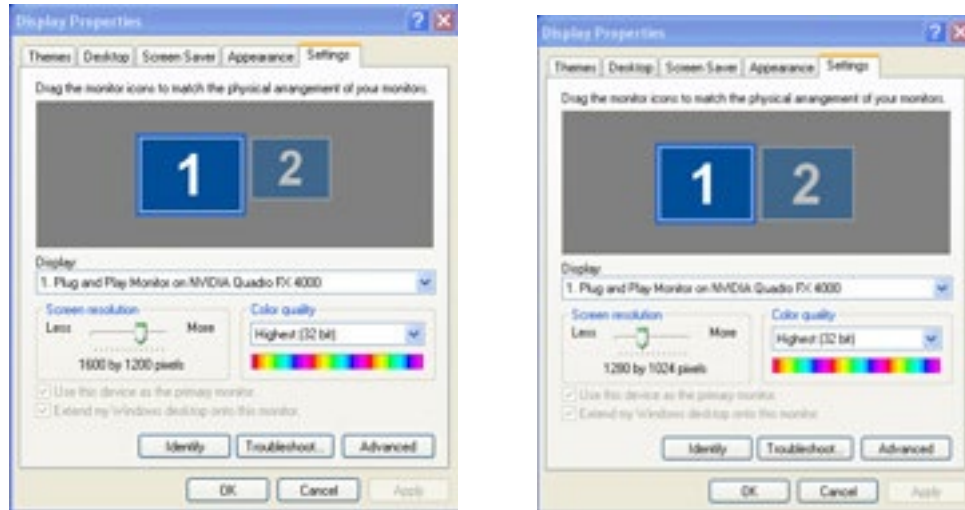


Figure 24. Display Properties dialogs for 1600 x 1200 (left) and 1280 x 1024 (right)

Configurable key mappings to third-party systems

The Key Mapping feature enables a key on the *Navigant* keyboard (F1 through F12) to cause a key press on a system with which the *Navigant* system is connected. For example, you can map the F4 key on the *Navigant* system to cause the “R” key on the *CARTO 3* system to be pressed.

1. From the *Navigant* system’s hardware status indicator toolbar, click the system options icon:



2. From the System Options menu that appears, click **Settings**.
3. Click the *Odyssey* tab to display the System Key Mappings dialog (**Figure 25**).

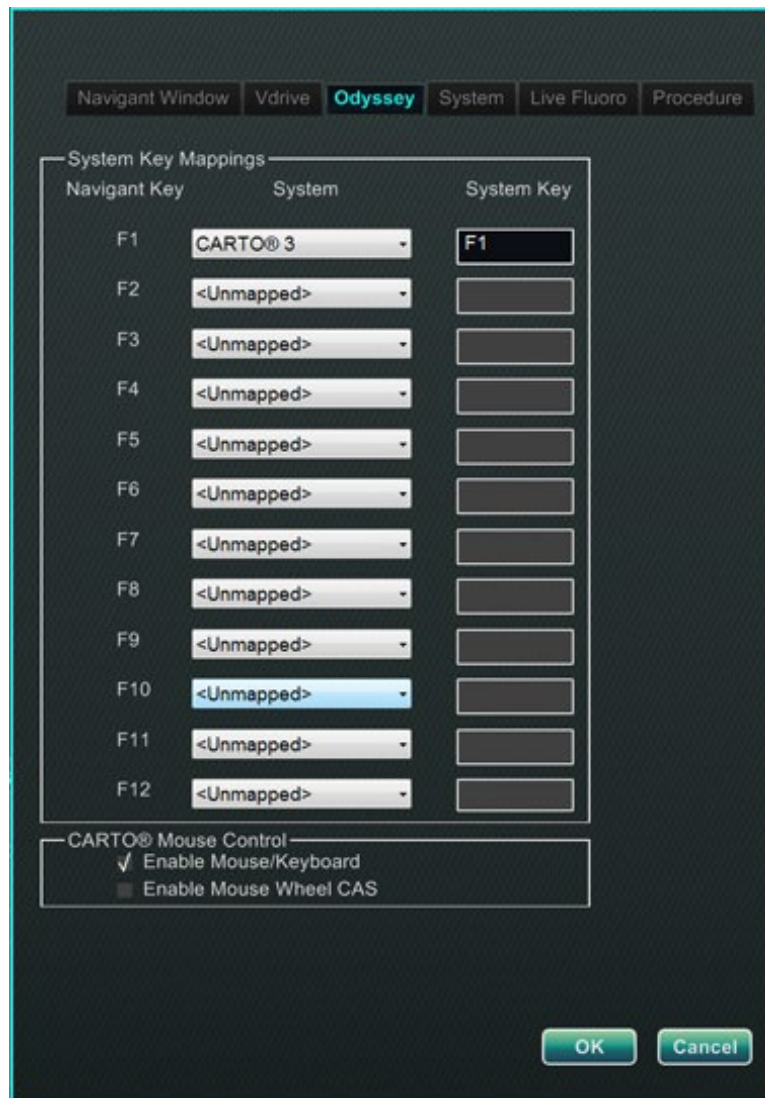


Figure 25. Odyssey System Key Mappings dialog in Navigant system

- For the specific *Navigant* function key, click the corresponding **System** down arrow to display the list of video sources available. In the Figure 25 example, **CARTO 3** is selected.
- The corresponding **System Key** initially will be mapped to the same key as the *Navigant* Key. To change, place the cursor in the System Key textbox, and then type the video source's key whose behavior you wish to initiate with the specified *Navigant* function key. In the Figure 25 example, **F1** has been retained.
- Click **OK** to save this behavior, which is dependent on the specific physician saving it.



NOTE: To remove a specific keystroke behavior, select **<Unmapped>** in the **System** column and then click **OK**.

CARTO Mouse Control

The *CARTO* Mouse Control box on the System Key Mappings dialog (Figure 25) contains two checkboxes to configure functionality within *CARTO* 3 procedures:

1. **Enable Mouse/Keyboard Control.** Checking this box enables *Vision* global keyboard and mouse to be used within the *CARTO* 3 system when *CARTO* 3 is the window currently in use (has focus).



NOTE: It is recommended to disable the mouse/keyboard control in a lab with two operators, one controlling the *CARTO* 3 system with the native keyboard and mouse and one controlling the global keyboard and mouse on the other systems.

2. **Enable Mouse Wheel CAS Control.** Checking this box enables the *Vision* mouse wheel to advance and retract the catheter when *CARTO* 3 has focus during a magnetic procedure.

Start Panel Utilities

Click the **Utilities** button on the start panel and then select the *Odyssey* tab. The *Odyssey* Status window opens to reveal the status of connections for mouse and keyboard only. **Figure 26** shows the top-level “Video Multiplexor” category, under which any mouse and keyboard system connection statuses appear. Select a utility option, or click **Close** or **OK** to exit the dialog.



Figure 26. *Odyssey* utilities dialog with connection statuses

Configure Video

Clicking the **Configure Video** button displays the dialog shown in **Figure 27**. Clicking the down arrow, highlighting a video source, and clicking **OK** displays the additional dialog shown in **Figure 28**.

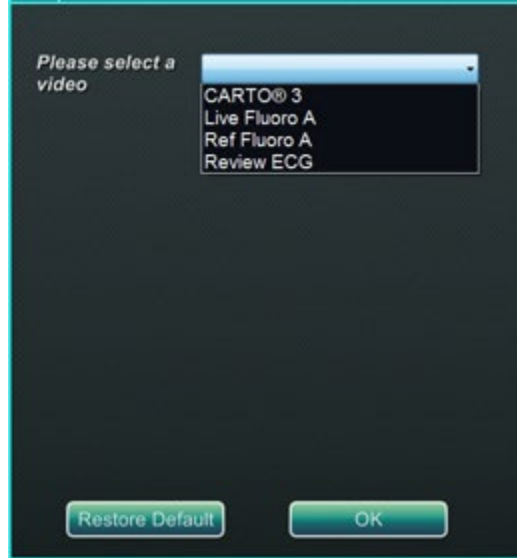


Figure 27. Configure Video

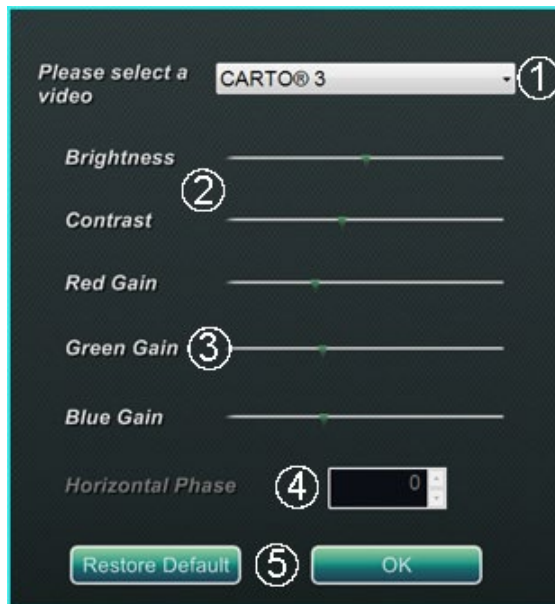


Figure 28. Configure Video

Configure Video dialog guide (Figure 28)

- ① **Please select a video.** Use the drop-down box to select the video source to configure. In the Figure 28 example, “*CARTO 3*” was chosen. Always ensure the video source is visible on the screen. If necessary, first change the layout to display the source you wish to configure.
- ② **Brightness and Contrast options.** Move the green arrow along the line to change the designated feature. Changes are immediately visible and available for review.
- ③ **Gain (Red, Green, Blue) options** (*not available for NTSC or analog x-ray*). Move the green arrow along the line to change the designated feature. Changes are immediately visible and available for review.
- ④ **Horizontal phase** (*available for VGA or analog x-ray only*). Click or scroll the up or down arrow to change the video display’s pixel alignment. Changes are immediately visible and available for review.
- ⑤ **Save choice.** Review the chosen video source display, and then select **OK** to save changes, close the dialog, and return to the *Odyssey* Status display. *Or*, click **Restore Default** to cancel current changes for the selected source and review and change if needed.

To exit from the *Odyssey* Status display or Utilities dialog, click the **Close** or **OK** button. The start panel reappears.

Navigant Only

The **Navigant Only** button displays *Navigant*-only video sources and the *Vision* toolbar in the main *Vision* window. The **Navigant Only** button is for use by Stereotaxis personnel only and **should not be used during a clinical procedure**.

Shutdown System

Click the **Shutdown System** button in the lower left of the start panel. This shuts down the *Odyssey Vision* and *Navigant* systems and if connected, the RMNS. *Odyssey* **does not** supply power to third party systems so they will remain operational.

TeleRobotic Support Team

Stereotaxis offers technical support through the **TeleRobotic Support Team (TST)** at 1-314-678-6200 or 1-866-269-5268. If a VPN connection is available, Stereotaxis TST representatives can view *Vision* video content and *Vision* displays at the installed site.

Troubleshooting

If assistance is needed with any of the solutions in the following table, call the **TeleRobotic Support Team** at 1-314-678-6200 or at 1-866-269-5268.

| Problem | Solution |
|---|--|
| Cannot connect to the Video Controller. | Click OK to shut down the system; restart. If the problem persists, call the TST. |
| Connection to the <i>Navigant</i> computer was lost. | Wait 2 minutes for the connection to automatically restore. If the connection is not restored, shut down the system; restart. If the problem persists, call the TST. |
| Error opening Odyssey.xml file. | Click OK to shut down the system; restart. If the problem persists, call the TST. |
| Failed to initialize Layout Manager. | The layout directory is missing, or a layout file is corrupted. Click OK to shut down the system; restart. If the problem persists, call the TST. |
| Hourglass displays on the <i>Vision</i> main menu window for more than 2 minutes. | Call the TST. |

| Problem | Solution |
|--|--|
| Non- <i>Navigant</i> window displays improper color or a noisy image. | Refer to the Configure Video section. If the problem persists, call the TST. |
| OAV connection is disabled. | Either the site has not purchased the <i>Cinema</i> system, or the connection between <i>Vision</i> and the <i>Cinema</i> server is down. If you are unable to restore the connection, call the TST. |
| Received a message that “Only one instance can run at a time.” | Shut down the system; restart. If the problem persists, call the TST. |
| Unable to connect to Power Shutdown hardware. Only shutting down <i>Navigant</i> computer. | Allow the system to shut down the <i>Navigant</i> computer. Then use the “ODYSSEY” switch on the <i>Vision</i> Remote Power box to turn off the other hardware. If the problem persists, call the TST. |
| Unable to use the <i>Vision</i> mouse in the <i>Navigant</i> window. | Restart the system. If the problem persists, call the TST. |
| Unexpected error occurred in opening required layout file. | A layout file is corrupt or has been removed. Shut down the system; restart. If the problem persists, call the TST. |

Section 8: Index

| | |
|---|----------------------|
| A | |
| About <i>Odyssey Vision</i> system | 9 |
| Add/delete video source | |
| Magnetic lab | 46 |
| Altering layouts | |
| Magnetic lab | 46 |
| Auto-resolution | 56 |
| B | |
| Basics | 21 |
| Brightness and contrast options | 61 |
| C | |
| CARTO® Mouse Control | 59 |
| Changing video window focus | 26 |
| Cinema | 49 |
| Bookmark button | 53 |
| Connection status buttons | 50 |
| Overview | 49 |
| Record / Pause buttons | 52 |
| Remote Connections dialog | 51 |
| Cleaning instructions for monitors ... | 54 |
| Companion systems | 54 |
| Configure Video | 60 |
| D | |
| Display resolution | 55 |
| DVI connections | 31 |
| E | |
| EC Rep | 2 |
| Electrical safety compliance | 11 |
| Electromagnetic compatibility | |
| information | 11 |
| EMC Directive Statement | 3 |
| Emergency Layout | |
| Non-magnetic lab | 48 |
| Equipment information | 4 |
| European Authorized | |
| Representative | 2 |
| G | |
| Gain options | 61 |
| Glossary | 19 |
| Graphics and symbols | 16 |
| H | |
| Horizontal phase | 61 |
| I | |
| Installation information | 5 |
| Intended use | 9 |
| K | |
| Key mappings | 57 |
| L | |
| Layouts | See Altering Layouts |
| Lock Layout | 48 |
| M | |
| Magnetic lab | |
| Add/delete video source | 46 |
| Altering layouts | 46 |
| Magnetic procedures | 40 |
| Manual procedures | 41 |
| Procedure Information window | 38 |
| Quick Layouts | 47 |
| Resize video source | 46 |
| Saving layouts | 48 |
| Start window | 37 |
| Magnetic Lab | 33 |
| Magnetic procedures | 40 |
| Maintenance information | 5 |
| Manual procedures | 41 |
| Monitors | 54 |
| N | |
| <i>Navigant</i> drop-down menus | 46 |
| <i>Navigant</i> Only | 63 |
| <i>Navigant</i> system key mappings | 57 |
| Network/data coupling | 6 |
| Non-magnetic lab | |
| Emergency Layout | 48 |
| Getting started | 42 |
| Procedure Information window | 43 |
| Start window | 43 |
| Non-Magnetic Lab | 42 |

| | |
|---|------------|
| O | |
| Odyssey cabinet..... | 21 |
| Odyssey Cinema | See Cinema |
| Odyssey Vision system | |
| About..... | 9 |
| Auto-resolution | 56 |
| Basics | 21 |
| Companion systems..... | 54 |
| Intended use | 9 |
| Monitors..... | 54 |
| Overview..... | 9 |
| Starting..... | 33 |
| System information | 54 |
| Troubleshooting | 63 |
| Operating conditions..... | 4 |
| Overview..... | 9 |
| P | |
| Patents | 2 |
| Procedure Information window | |
| Magnetic lab | 38 |
| Non-magnetic lab | 43 |
| Procedure Room hub | 21 |
| Q | |
| QuadHD display | 21 |
| Quick Layouts | |
| Magnetic lab | 47 |
| R | |
| Related documents..... | 3 |
| Replacement of parts..... | 5 |
| Required training | 9 |
| Resize video source | |
| Magnetic lab | 46 |
| Revert Layout | 48 |
| S | |
| Safety Standard Statement | 3 |
| Show All Video Sources..... | 62 |
| Shutdown System button | 63 |
| Site planning information | 4 |
| Special window types..... | 26 |
| Start Panel Utilities..... | 59 |
| Start window | |
| Magnetic lab | 37 |
| Non-magnetic lab | 43 |
| Starting <i>Odyssey Vision</i> system | 33 |
| For non-magnetic lab | 42 |
| Storage conditions | 4 |
| System information | 54 |
| System Key Mappings..... | 58 |
| T | |
| Tableside Controller | 27 |
| Third-Party Interface (TPI) boxes | 21 |
| Toolbar | |
| Button states | 25 |
| System status messages | 26 |
| Typical setup | 22 |
| Trademarks | 2 |
| Transport conditions | 4 |
| Troubleshooting | 63 |
| U | |
| Utilities | 59 |
| Button | 59 |
| Configure Video..... | 60 |
| <i>Navigant</i> Only | 63 |
| Show All Video Sources | 62 |
| V | |
| VGA connections | 30 |
| Video display resolution | 55 |
| Video source | |
| Add/delete..... | 46 |
| Drop-down menus | 46 |
| Resize..... | 46 |
| Vision components | 21 |
| Vision control..... | 54 |
| W | |
| Warnings/precautions | 10 |
| Waste and Recycling..... | 6 |