

QHD







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Patents

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

Trademarks

- Cardiodrive, Navigant, and Niobe are trademarks of Stereotaxis, Inc., registered in the United States, the European Community, and Japan.
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- Vdrive is a trademark of Stereotaxis, Inc., registered in the United States.

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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* QHD 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 Client User Guide

HDW-0312 Niobe ES User Guide

PRO-727 *Odyssey* Vision Version 1.5 System Site Planning Guide (for safety information on connecting external systems to the *Odyssey* platform)

HDW-0188 Odyssey Quad HD Workstation Global Installation Manual

HDW-0310 Odyssey Quad HD Workstation Maintenance and Service Manual (used only by authorized service personnel)

HDW-0295 Vdrive User Guide (if the optional Vdrive unit is installed)

Site planning information

Information needed by the hospital to have an *Odyssey* system (001-007010-2) properly installed is provided in PRO-727, *Odyssey* Vision Version 1.5 System Site Planning Guide. The PRO-727 guide includes the following information:

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

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 Currency rating: 20.0 / 10.0 A Frequency: 50 / 60 Hz

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.



Refer to PRO-727, *Odyssey* Vision Version 1.5 System Site Planning Guide, for disconnect information.



WARNING: No modification of this equipment is allowed.

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
- 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. Philips installation
- 10. Quad HD installation
- 11. 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

Cover art

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Section 1: Overview

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Intended Use

The Stereotaxis *Odyssey Vision* system (also called "Vision" in this user guide) is an optional display and user interface package designed to consolidate the point of control of the catheterization lab.

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 (Figure 1)
- 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.

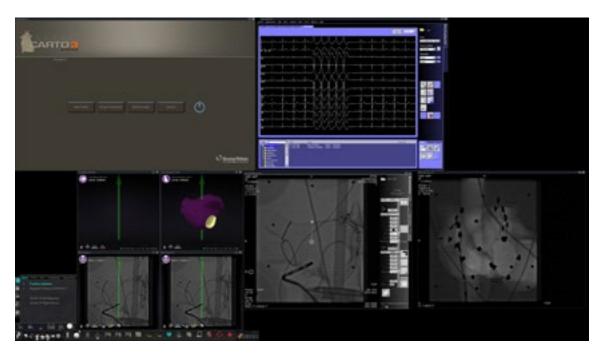


Figure 1. Sample Odyssey Vision screen

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 Niobe ES 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.

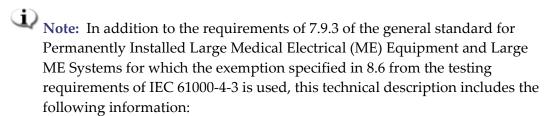
Electromagnetic Compatibility Information



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.





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.

Following are the frequencies and modulations used to test the Immunity of the ME Equipment or ME System:

52.5Mhz	433Mhz	2.4GHz
144Mhz	467Mhz	

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 Vision 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		
Harmonic emissions IEC 61000-3-2	Class A Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	-	

Immunity—General electromagnetic effects

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

Immunity	IEC 60601	Compliance	Electromagnetic environment—guidance
test	test level*	level*	
Electrostatic	± 8 kV contact	± 8 kV contact	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
discharge (ESD)	± 2, 4, 8 & 15 kV	± 2, 4, 8 &15 kV	
IEC 61000-4-2	air	air	
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.

Immunity test	IEC 60601 test level*	Compliance level*	Electromagnetic environment—guidance
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 % <i>U</i> _T (100% dip in <i>U</i> _T) for 0.5 cycle 40 % <i>U</i> _T (60 % dip in <i>U</i> _T) for 5 cycles 70 % <i>U</i> _T (30 % dip in <i>U</i> _T) for 25 cycles <5 % <i>U</i> _T (>95 % dip in <i>U</i> _T) for 5 s	<5 % <i>U</i> _T 100% dip in <i>U</i> _T) for 0.5 cycle 40 % <i>U</i> _T (60 % dip in <i>U</i> _T) for 5 cycles 70 % <i>U</i> _T (30 % dip in <i>U</i> _T) for 25 cycles <5 % <i>U</i> _T (>95 % dip in <i>U</i> _T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Vision system requires continued operation during power mains interruptions, it is recommended that the Vision 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	IEC 60601	Compliance	Electromagnetic environment—
test	test level*	level*	guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 mHz to 2.7 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Vision system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity test	IEC 60601 test level*	Compliance level*	Electromagnetic environment— guidance
			Recommended separation distance
			$d = 1.2\sqrt{P}$
			$d = 1.2\sqrt{P} \ 80 \text{ MHz to } 800 \text{ MHz}$
			$d = 2.3\sqrt{P} 800 \text{ MHz to } 2.5 \text{ GHz}$
			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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b
			Interference may occur in the vicinity of equipment marked with the following symbol:
			((•))

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

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

- 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.
- 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 QHD* 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	Separation distance according to frequency of transmitter m		
transmitter*	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* QHD system, please contact Stereotaxis Service. Otherwise, there are no specific service requirements to maintain *Odyssey* QHD EMC integrity.

About This User Guide

This user guide describes how to operate the *Odyssey Vision* QHD 1.5 system. It does not describe how to operate the Navigant software or any other devices in an interventional lab.

The manual is divided into six sections:

- Overview
- 2. Basics that apply to all configurations

- 3. User information for a non-magnetic lab with a QuadHD monitor
- 4. User information for a *Niobe* magnetic lab with a QuadHD monitor
- 5. *Odyssey Cinema* system ("Cinema")
- 6. System information

Graphics and Symbols

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

Symbol	Name	Description
\wedge	WARNING	Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.
\wedge	CAUTION	Indicates a potentially hazardous situation that, if not avoided, could result in injury to patient or operator or damage to the equipment.
①	NOTE	Identifies information that could affect the outcome or results of the procedure.
(i	REF	Reference to an instruction manual or operating instructions.
Electrical hazard Disconnect power Before servicing	Danger	Electrical shock hazard.
	Ground	Protective earth (ground).
ባ	Power	Power status of the system.
\sim	AC Power	Alternating current.

Symbol	Name	Description
	DC Power	Direct current.
1	Power On	"On" (power).
0	Power On	"Off" (power).
0	Equipment Power On	"On" (part of equipment).
Ċ	Equipment Power Off	"Off" (part of equipment).
***	Manufacturer	Name and address of the equipment manufacturer.
EC REP	European Representative	Name and address of the authorized representative in the European Community.

Glossary

The following terms may appear in this document:

Acronym / 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.

Acronym / Term	Definition
Cardiodrive system	Stereotaxis <i>Cardiodrive</i> automated catheter advancement system (CAS) used to advance and retract a catheter in patient's heart while <i>Niobe</i> 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 CARTO® 3 EP system, which combines 3D mapping and navigation systems with Stereotaxis <i>Niobe</i> magnetic navigation system. (Magnetic and <i>Niobe</i> references apply only to magnetic labs. Nonmagnetic labs are limited to displaying video output of CARTO® 3 system.)
CAS	See Cardiodrive 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.
Magnetic navigation system	See Niobe magnetic navigation system.
Manual procedure	Non-magnetic procedure that can be performed in magnetic lab or non-magnetic lab.
<i>Navigant</i> system	Platform of software applications designed to simplify clinical workflows. It provides enhanced integration of catheterization and electrophysiology labs and improved automation during magnetic navigation of medical devices. (Available only in magnetic labs.)
Niobe magnetic navigation system	Stereotaxis system that enables physicians to more effectively navigate catheters, guidewires, and other magnetic interventional devices through blood vessels and chambers of the heart to treatment sites and then to effect treatment. (<i>Niobe</i> system is available only in magnetic labs.)

Acronym / 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.
Tableside Controller	Optional 4- x 5-inch touchscreen attached to patient table accessory mounting rail, providing basic control of <i>Odyssey Vision</i> system in Procedure Room.
QuadHD (or QuadHDTV)	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.
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.

Section 2: Basics

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Typical Vision Toolbar

The Vision toolbar (**Figure 2**—split into **Figures 2A** and **2B** for illustration only) displays horizontally at the bottom of the monitor. It contains 6 main sections.



Figure 2A

Key to Figure 2A

- Section 1 contains three Cinema buttons (*Odyssey Cinema* Studio and *Odyssey Cinema* LT products; *see* Section 5 in this guide).
- ② Section 2 is the *Navigant* button (shown here in the selected state).
- 3 Section 3 contains three Quick Layout buttons.

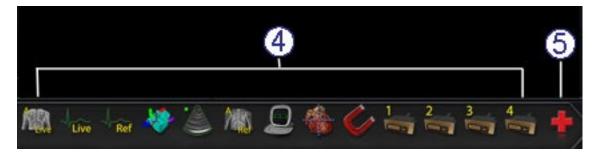


Figure 2B

Key to Figure 2B

- 4 Section 4 contains the third-party device buttons.
- Section 5 contains the digital video connection buttons (up to 4).
- 6 Section 6 is the Emergency Layout button.

Toolbar buttons

The following table describes each button within the Vision toolbar.

Button	Name	Description	
Cinema buttons			
	Connections	Displays the status of remote connections through the Cinema system. (See <u>Connection Status Buttons</u> .)	
	Record and Pause	Starts and pauses recording in the Cinema system. It is disabled when Cinema is not available. (See <u>Record / Pause Buttons</u> .)	
	Bookmark	Enables the user to bookmark the timeline during a Cinema recording session. The button is disabled when Cinema is not available. (See Bookmark Button.)	
Navigant but	ton		
\triangle	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		
1 2 1 3	Quick Layouts 1, 2, and 3	Each button displays a layout the user can customize and save.	

Button Name **Description** Third-party device buttons Clicking a third-party device button displays the video source at its maximum size and original resolution, if possible. Only one video source at a time can be displayed. **ECG Real Time** Emphasizes the Live ECG video window. Live **Live Fluoro A** Emphasizes the Live Fluoro A video window. Emphasizes the Biosense Webster CARTO® 3 **CARTO® RMT** video window. Emphasizes the ultrasound machine connected **Ultrasound** in the Procedure Room. Emphasizes the Fluoro A Reference video **Reference Fluoro A** window. Emphasizes the Auxiliary Input connected to **Auxiliary Input Procedure Room 2** the Procedure Room hub box port #2. Emphasizes the Siemens Leonardo® Siemens Leonardo® Workstation. The icon would be different for Philips Interventional Tools. Click to access the Stereotaxis *Niobe* magnetic Niobe navigation system Service Menu in a magnetic lab. Additional third-party device buttons These device buttons display as needed, depending on system configuration. Emphasizes the Reference (Control) ECG video **ECG Image Reference** window. Emphasizes the patient view in the Procedure **Patient** Room.

Button	Name	Description
M	Philips Allura® Live	Emphasizes the Philips Allura® video window.
Page 1	Philips Allura® Admin Live	Emphasizes the Live Philips Allura® Admin video window.
1	Philips Allura® Reference 1	Emphasizes the Live Philips Allura® Reference 1 video window.
3	Philips Allura® Reference 2	Emphasizes the Live Philips Allura® Reference 2 video window.
2	Videoconferencing	Emphasizes the videoconferencing video window.
Explane	Biplane X-ray system	Emphasizes the biplane X-ray system video window.
10	Camera 1	Emphasizes the Camera 1 video window.
2	Camera 2	Emphasizes the Camera 2 video window.
	Anesthesia Cart	Emphasizes the anesthesia cart system video window.
9	EP Nav	Emphasizes the EP Nav system video window.
Hemo	Hemodynamics	Emphasizes the hemodynamics video window.

HDW-0309 Rev. J Effective Date: 12/17/2019

Button	Name	Description
	IVUS Imaging System	Emphasizes the IVUS imaging system video window.
*	NavX	Emphasizes the NavX system video window.
District Control of the Control of t	Picture archiving and communication system (PACS)	Emphasizes the PACS video window.
2	Digital Video Connections 1, 2, 3, and 4	Emphasizes up to 4 additional digital video windows for systems with 15 video displays.
Emergency La	ayout 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.

Enabled state



Clicked or selected state



Disabled state:



The three most common states for Vision toolbar buttons are enabled, selected, and disabled.

System status messages

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



Figure 3 is a sample System Status message.



Figure 3. Sample System Status message

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 "no" 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 (Optional)

In a typical *Odyssey Vision* lab, the physician controls a catheter from the Control Room. However, the Tableside Controller (**Figure 4**) may be added as an option if the ability to control Vision windows from the Procedure Room is desired.

Tableside Controller guide

- ① Patient table.
- 2 Patient table accessory mounting rail. Devices may vary.
- 3 Tableside Controller mirrors the Figure 4 buttons.

Figure 4.
Tableside
Controller on
patient table
accessory rail



Connecting Third-Party Systems to Procedure Room Hub

Digital video interface (DVI)

Following are general instructions for connecting a third-party computer by way of a third-party interface (TPI) to one of two TPI circuit boards (top or bottom) in the Procedure Room hub (**Figure 5** shows a TPI box). Included in this process are the digital video interface (DVI) and USB (for mouse and keyboard control, if desired) connections. Duplicate these steps (indicated in **Figure 6**) for each computer (video source).



Figure 5. TPI box

- 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 circuit board.
- **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 circuit board.
- **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 circuit board.
- **5.** Connect the appropriate *Odyssey Vision* system Ethernet cable to TPI-J1 on the system's associated TPI circuit board.
- **6.** Connect the appropriate *Odyssey Vision* system fiberoptic DVI cable to TPI-J2 on the system's associated TPI circuit board.

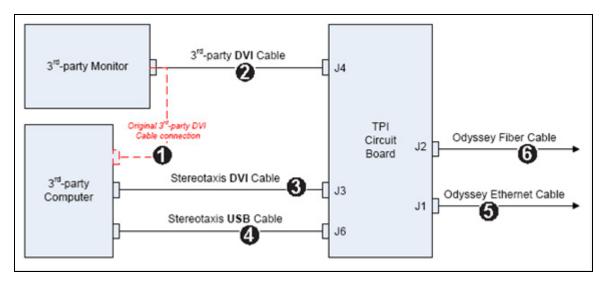


Figure 6. Procedure Room TPI connectivity for DVI

When connections are complete, the TPI system is available as a video window on the Odyssey Vision screen when its digital video connection button is selected.



Note: If Auto-resolution is enabled on this connection, it will be applied and be noticeable in the associated video source's window.

Video graphics array (VGA)

Following are general instructions for connecting a third-party computer by way of a third-party interface (TPI) to one of two TPI circuit boards (top or bottom) in the Procedure Room hub. Included in this process are the video graphics array (VGA), VGA adapter, and USB (for mouse and keyboard control, if desired) connections. Duplicate these steps (indicated 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 circuit board.
- 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 circuit board.
- 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 circuit board.
- **5.** Connect the appropriate *Odyssey* system Ethernet cable to TPI-J1 on the system's associated TPI circuit board.
- Connect the appropriate *Odyssey* system fiberoptic DVI cable to TPI-J2 on the system's associated TPI circuit board.

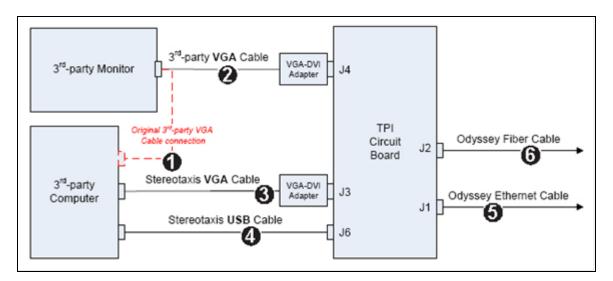


Figure 7. Procedure Room TPI connectivity for VGA

When connections are complete, the TPI system is available as a video window on the *Odyssey Vision* screen when its digital video connection button is selected.

Note: If Auto-resolution is enabled on this connection, it will be applied and be noticeable in the associated video source's window.

Getting Started

Following this sequence of steps when starting the *Odyssey Vision* system is important:

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

Key to Figure 8

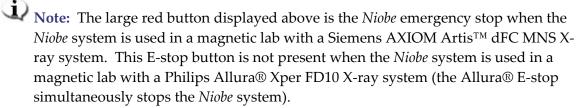
- 1a Siemens E-stop button
- **1b** E-stop button hole is plugged for Philips and non-magnetic labs
- 2 Odyssey Vision system is on when green LED is lit
- 3 E-stop is activated when red LED is lit
- 4 In a magnetic lab, *Niobe* system is on when green LED is lit
- 5 Turns *Odyssey Vision* system ON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





Figure 8. Vision Remote Power Box for Siemens labs (*left*) and Philips labs (*right*)

- 8 In a magnetic lab, toggles *Niobe* 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.





Note: In case of a Voltage Interruption, the Odyssey Vision QHD system might shut down, necessitating a system restart.

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Getting Started

It is important to 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 9**). This is a momentary-contact switch that will return to the middle position when released.

Key to Figure 9

- 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 9. Vision Remote Power Box for non-magnetic labs



Start Window

The *Odyssey Vision* start window (**Figure 10**) is shown in the lower left corner of the QuadHD screen — as are all *Navigant*-specific windows.



Figure 10. Start window

Click **Start New Procedure** (**Figure 11**). The next display is the Procedure Information window (**Figure 12**).



Figure 11. Start New Procedure

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 from a 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 12
 - Coronary for Interventional Cardiology (IC)
 - CRT (Cardiac Resynchronization Therapy)

Then click the appropriate anatomy icon (Figure 12 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 12 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.

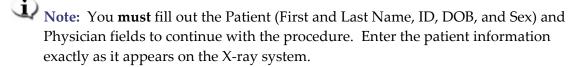




Figure 12. Non-magnetic Procedure Information window

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 13**) displays.

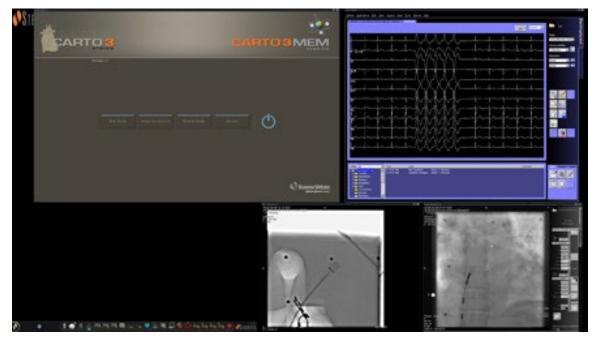


Figure 13. Main window for procedure in non-magnetic lab

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 (**Figure 14**) on the Vision toolbar. The QuadHD screen displays Live ECG, Live Fluoro A, and, if available, Reference Fluoro A (**Figure 15**).





Figure 14. Emergency Layout button—Left: available; right: clicked

The Emergency Layout button acts as a toggle. Clicking it once displays the Emergency Layout; clicking again returns to the previous screen.

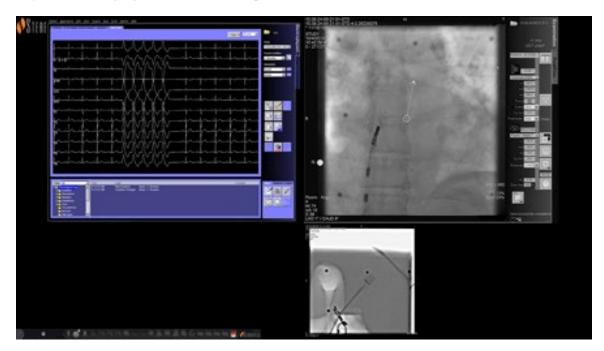


Figure 15. Emergency Layout

Altering Layouts

The Vision system offers several options for altering a layout in a non-magnetic lab:

- Emphasize a video source
- Add or delete a source
- Resize a source
- Customize the default Quick layouts

Emphasize video source

Clicking a video source button on the Vision toolbar displays the video source in an emphasized state at or near full resolution on the screen (**Figure 16**).



Figure 16. Emphasized video source - CARTO® 3

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 (e.g., Figure 13) 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, as for Reference Fluoro A in **Figure 17**.

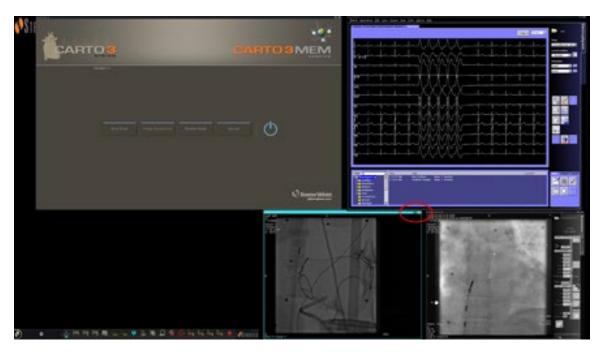


Figure 17. Highlighted video input source (Ref Fluoro A)

At the right end (red oval in Figure 17) of the title bar are the **Expand** and **Close** buttons, as shown in **Figure 18**.



Figure 18. Video source title bar's Expand and Close buttons

- Clicking the **Expand** button (highlighted in Figure 18) or double-clicking the title bar *expands* the video source to fill the empty area.
- Clicking the **Close** button highlights it (**Figure 19**) and *deletes* the video source from the display area.



Figure 19. Video source Close button highlighted



Note: For more information on the window currently in use or changing focus, see <u>Changing Video Window Focus</u>.

Resize video source

You may resize the video source display by dragging on the edges or corners as for a Windows display, as indicated in **Figure 20**.

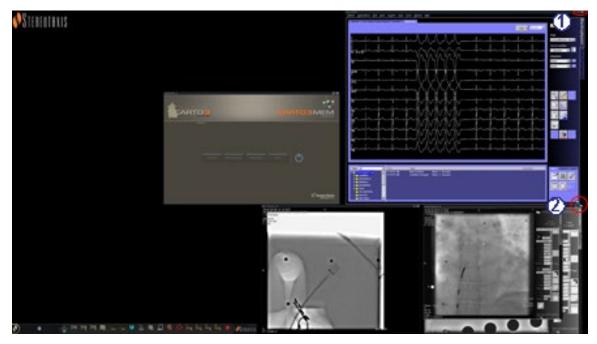


Figure 20. ECG video source resized by using arrows: **(1)** Oval encircles title bar **Expand** and **Close** buttons (see previous section); **(2)** Circle surrounds resizing arrow

Use Quick Layouts

Configurations

The Quick Layouts are grouped by clinical specialty and procedure type for manual, CARTO® 3, and non–CARTO® 3 equipment combinations.

Each Electrophysiology category has separate Quick Layouts (1, 2, and 3):

- Right Atrium (CARTO® 3 and non-CARTO® 3)
- Left Atrium (CARTO® 3 and non–CARTO® 3)
- Right Ventricle (CARTO® 3 and non-CARTO® 3)
- Left Ventricle (CARTO® 3 and non-CARTO® 3)

The three Quick Layouts (1, 2, and 3) may be used for the following Interventional Cardiology categories:

- Coronary
- Peripheral (Femoral or Tibial).
- Cardiac Resynchronization Therapy—Coronary Sinus—procedures use the same three Quick Layouts (1, 2, and 3) for all 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, use the Altering Layouts features described previously. The next time you click the same Quick Layout button, the new layout displays.

Figure 21. Three Quick Layout buttons on Vision toolbar







Note: You must click one of the Quick Layout buttons first to customize Quick Layout 1, 2, or 3.

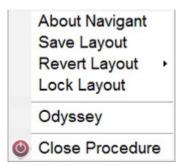
Saving Layouts

Saved layouts pertain to the particular physician for the procedure type. To save a layout, click the system options icon (**Figure 22**) on the hardware status indicator toolbar:



Figure 22. System options icon

The System Options menu appears (Figure 23). Select Save Layout.



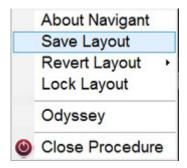
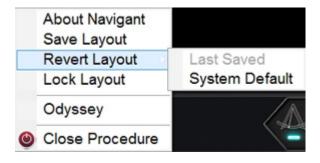


Figure 23. System Options menu, with Save Layout highlighted (*right*)

You may also choose to revert to the last saved layout by selecting **Revert Layout** and then **Last Saved** (if available) or **System Default**, as shown in **Figure 24**.



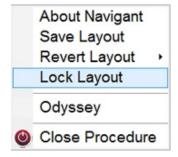


Figure 24. Revert Layout options

Figure 25. Lock Layout selected

When you have the layout you want but don't wish to save yet, you may lock it by selecting **Lock Layout** from the System Options menu (**Figure 25**).

Locking a layout removes the title bars from the video source displays, as shown in **Figure 26**.

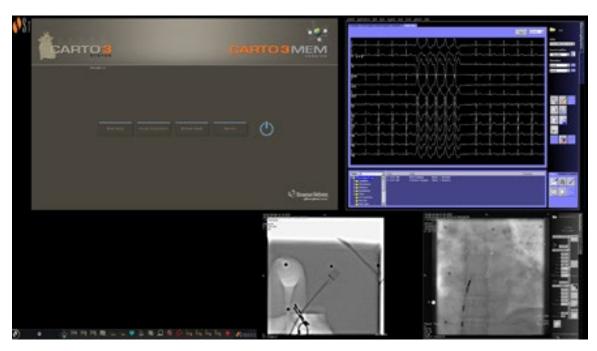


Figure 26. Display resulting from locking layout (example)

If you choose not to save this layout, you may unlock it by selecting Unlock Layout from the System Options menu (Figure 27).

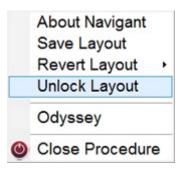


Figure 27. System Options menu, with Unlock Layout selected

Selecting Unlock Layout redisplays video source title bars for further manipulation of the layout if desired.



Note: Saved layouts pertain to a particular physician for a particular procedure type, as mentioned previously.

Section 4: Magnetic Lab with QuadHD

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Start Window

The *Odyssey Vision* start window (**Figure 28**) is shown in the lower left corner of the QuadHD screen — as are all *Navigant*-specific windows.

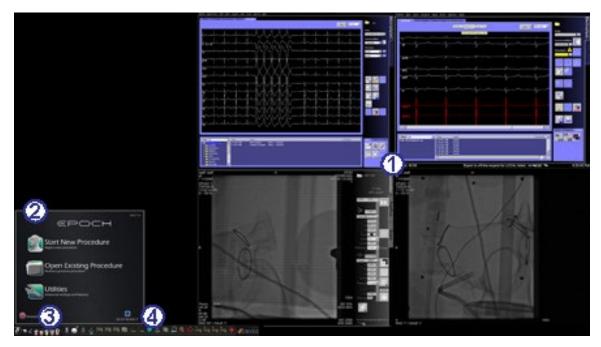


Figure 28. Start window (magnetic lab)

Start window for magnetic lab

- 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).
- **Start panel.** On this panel, you can open a new or existing procedure, access the Utilities dialog, 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.
- **Vision toolbar.** Contains Cinema buttons, *Navigant* button, Quick Layout buttons, Third-party device buttons, and the Emergency Layout button.

Click Start New Procedure (Figure 29).



Figure 29. Start New Procedure

Procedure Information Window

Whether you are starting a new procedure or opening an existing one, the next display after the start window is the Procedure Information window (**Figure 30**). We recommend you enter all patient information into the X-ray system before starting a procedure in the Vision system. The information will then be automatically imported into the appropriate fields on the Vision screen.



Figure 30. 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 from a 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), highlighted in Figure 30
 - Coronary for Interventional Cardiology (IC)
 - CRT (Cardiac Resynchronization Therapy)

Then click the appropriate anatomy icon (Figure 30 shows **Right Atrium** selected):

- EP: Right Atrium, Left Atrium, Right Ventricle, or Left Ventricle
- Coronary: Coronary arteries
- CRT: Coronary sinus
- 7. **Checkboxes.** Selecting **Use CARTO® 3** or **Use Niobe** changes the procedure layout to include CARTO® 3 or *Navigant* options. The example in Figure 30 shows **Use CARTO® 3** and **Use Niobe** 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: You **must** fill out the Patient (First and Last Name, ID, DOB, and Sex) and Physician fields to continue with the procedure. Enter the patient information exactly as it appears on the X-ray system.

Magnetic procedures



Figure 31. Selected **Use** *Niobe* checkbox on Vision Procedure Information screen for magnetic procedure

To start a magnetic procedure from the Vision Procedure Information window, leave the Use *Niobe* checkbox selected as shown in **Figure 31**. *Niobe* ES procedures can run only with the *Niobe* magnetic navigation system. Vision procedures can run with or without the *Niobe* system.

- **1.** Select or clear the Use CARTO® 3 checkbox to start a procedure with or without CARTO® 3.
- **2.** Click **OK** to begin the procedure.

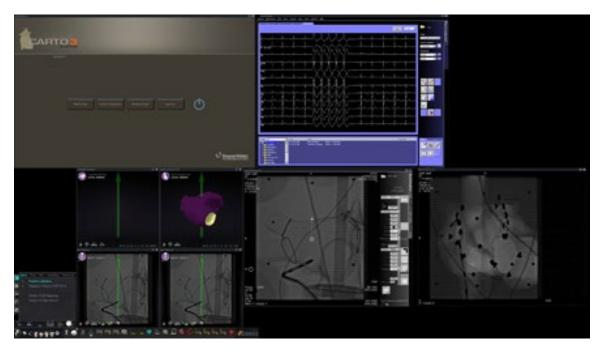


Figure 32. Magnetic procedure with CARTO® 3

The Clinical Workflow Manager displays in the lower-left corner of the bottom quadrant of the QuadHD screen (**Figure 32**). 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.

Note: See Altering Layouts for more details about changing video source displays.

Manual procedures in magnetic labs



Figure 33. Cleared **Use** *Niobe* checkbox on Vision Procedure Information window for manual procedure in magnetic lab

The Vision Procedure Information window also allows you to perform manual procedures without using the *Niobe* magnetic navigation system. If you are starting a manual procedure, clear the **Use** *Niobe* checkbox on the Procedure Information window (**Figure 33**).

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, guidance dialogs, and Layout Editor.

Click **OK** to begin the procedure. **Figure 34** displays.

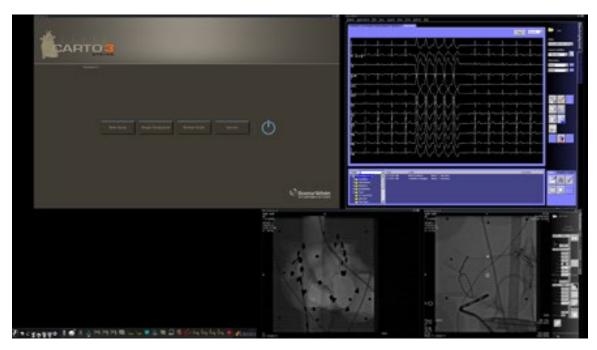


Figure 34. Manual procedure in magnetic lab with CARTO® 3 main window

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.

Emergency Layout

The Emergency Layout is available when the Vision system starts and can be accessed at any time during the procedure by clicking the red cross icon (**Figure 35**) on the Vision toolbar. The QuadHD screen displays Live ECG and Live Fluoro A (**Figure 36**); if a Reference Fluoro A is available, it will also display.





Figure 35. Emergency Layout button—Left: available; right: clicked

The Emergency Layout button acts as a toggle. Clicking it once displays the Emergency Layout; clicking again returns to the previous screen.

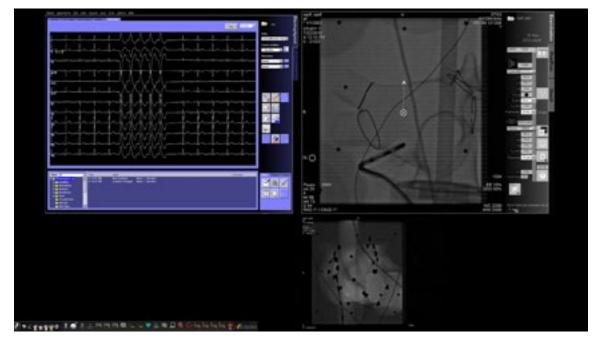


Figure 36. Emergency Layout

Altering Layouts

The Vision system offers several options for altering a layout for a magnetic lab:

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

Emphasize video source

Clicking in a video input area makes the source active. When you click the video source's icon on the Vision toolbar, the video source you selected displays in an emphasized state on the screen at or near full resolution, as represented by the CARTO® 3 source in **Figure 37**.

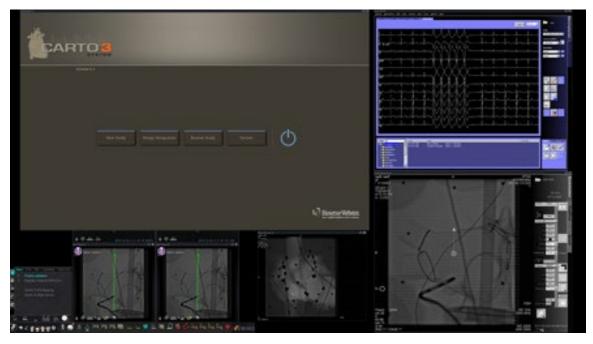


Figure 37. Emphasized video source - CARTO® 3

To return to the previous procedure layout when done with the emphasize layout, select the *Navigant* icon (**Figure 38**) on the toolbar.



Figure 38. Navigant toolbar icon

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 (e.g., Figure 28) 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, as for Reference Fluoro A in **Figure 39**.



Figure 39. Highlighted video input source (Ref Fluoro A)

At the right end (red oval in Figure 39) of the title bar are the **Expand** and **Close** buttons, as shown in **Figure 40**.



Figure 40. Video source title bar's Expand and Close buttons

- Clicking the **Expand** button (highlighted in Figure 40) or double-clicking the title bar *expands* the video source to fill the empty area.
- Clicking the **Close** button highlights it (**Figure 41**) and *deletes* the video source from the display area.



Figure 41. Video source Close button highlighted



Note: For more information on the window currently in use or changing focus, see <u>Changing Video Window Focus</u>.

Resize video source

You may resize the video source display by dragging on the edges or corners as for a Windows display, as indicated in **Figure 42**.

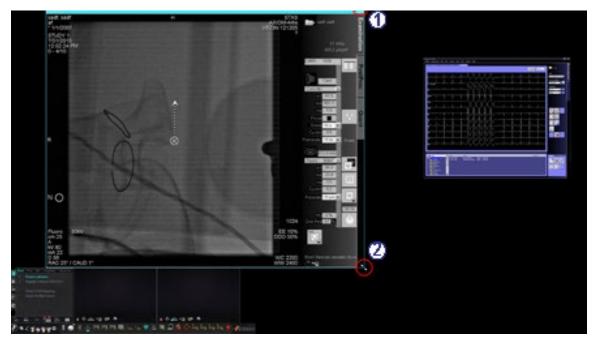


Figure 42. Fluoro A video source resized by using arrows: **(1)** Oval encircles title bar **Expand** and **Close** buttons (see next section); **(2)** Circle surrounds resizing arrow

Use Navigant drop-down menus

The *Navigant* video source area, as shown in **Figure 43**, includes icons with drop-down menus that enable selection of a different display within the window.

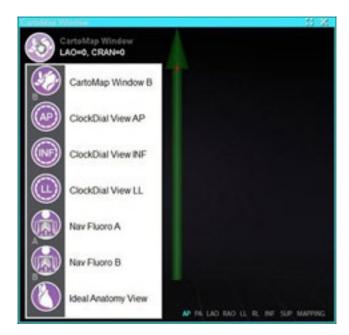


Figure 43. Navigant video sources with menu icons

Following are the menu icons for these windows:

Window	Menu icon	Window	Menu icon
CartoMap		Nav Fluoro A	
Ideal Anatomy		Nav Fluoro B	

Clicking on the icon circle displays a menu similar to the one shown in Figure 44.



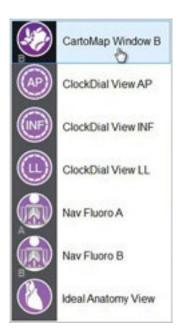


Figure 44. Left, CartoMap Window displaying menu options; **right**, CartoMap Window B selected

Selecting CartoMap Window B, as shown on the right in Figure 44, changes the display to that selection in the current window.

Use Quick Layouts

Configurations

The Quick Layouts are grouped by clinical specialty and procedure type for manual, CARTO® 3, and non-CARTO® 3 equipment combinations.

Each Electrophysiology category has separate Quick Layouts (1, 2, and 3):

- Right Atrium and Left Atrium (*Niobe* CARTO® 3 and non–CARTO® 3, Manual CARTO® 3 and non–CARTO® 3)
- Right Ventricle and Left Ventricle (Niobe CARTO® 3 and non-CARTO® 3, Manual CARTO® 3 and non-CARTO® 3)

The three Quick Layouts (1, 2, and 3) may be used for the following Interventional Cardiology categories:

- Coronary (*Niobe* and Manual)
- Peripheral (Femoral or Tibial) (*Niobe* and Manual)
- Cardiac Resynchronization Therapy—Coronary Sinus—procedures use the same three Quick Layouts (1, 2, and 3) for all procedures.

For example, assume you are in an Electrophysiology Left Atrium procedure and have selected to use both *Niobe* and CARTO® 3. You can make and save changes to Quick Layout 1.

You will still see these changes if you open Quick Layout 1 in a Right Atrium procedure, as long as you have selected both *Niobe* and CARTO® 3.

Buttons

To view and customize alternative (quick) layouts, click one of the Quick Layout buttons (**Figure 45**) on the Vision toolbar. To modify the Quick Layout, use the Altering Layouts features described previously. The next time you click the same Quick Layout button, the new layout displays.



Figure 45. Three Quick Layout buttons on Vision toolbar

Note: You must click one of the Quick Layout buttons first to customize Quick Layout 1, 2, or 3.

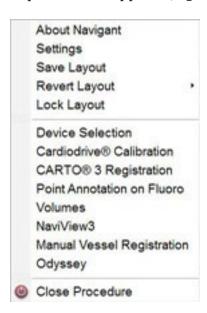
Saving Layouts

Saved layouts pertain to the particular physician for the procedure type. To save a layout, click the system options icon (**Figure 46**) on the hardware status indicator toolbar:



Figure 46. System options icon

The System Options menu appears (Figure 47). Select Save Layout.



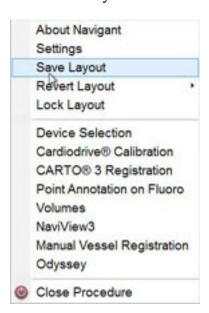
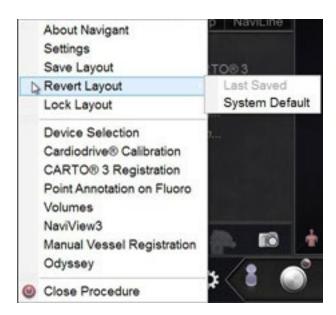


Figure 47. System Options menu, with Save Layout highlighted (right)

You may also choose to revert to the last saved layout by selecting **Revert Layout** and then **Last Saved** (if available) or **System Default**, as shown in **Figure 48**.



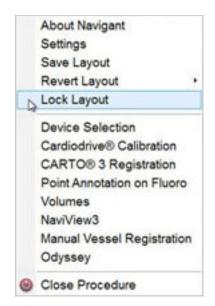


Figure 48. Revert Layout options

Figure 49. Lock Layout selected

When you have the layout you want but don't wish to save yet, you may lock it by selecting **Lock Layout** from the System Options menu (**Figure 49**).

Locking a layout removes the title bars from the video source displays, as shown in **Figure 50**.

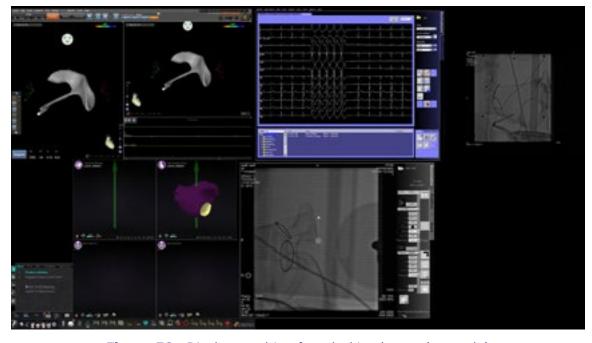


Figure 50. Display resulting from locking layout (example)

If you choose not to save this layout, you may unlock it by selecting **Unlock Layout** from the System Options menu (**Figure 51**).

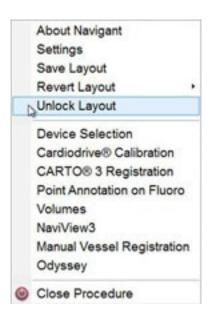


Figure 51. System Options menu, with Unlock Layout selected

Selecting Unlock Layout redisplays video source title bars for further manipulation of the layout if desired.



Note: Saved layouts pertain to a particular physician for a particular procedure type, as mentioned previously.

Section 5: Odyssey Cinema

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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 (see below). 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.

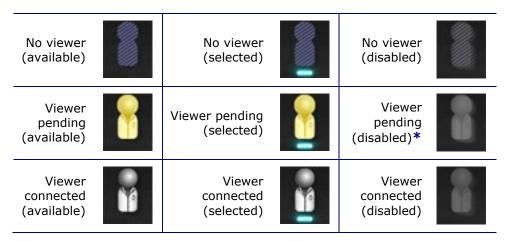


If your system is configured for semi-automatic recording, the Pause button will be available as soon as you start a session because the system will already be recording. (Record / Pause is a toggle button.) For alternate button states, see Record / Pause Buttons.

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 Customer Care Center, 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).



* 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 (highlight) Dr. A's name and click **Accept** (**Figure 52** does not show "Dr. A" but rather an example). Now the Connection button shows a connected user:



One or more viewers are connected:



Figure 52. Remote Viewer Connections dialog – Viewer 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, as in these two figures.



Figure 53. Remote Viewer Connections dialog - One viewer, multiple pending

The Remote Viewer Connections dialog (Figure 52 and Figure 53) 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.



Note: How to know if the viewer disconnected or reconnected:

If Dr. A is the only viewer, and he disconnects, the Connection button changes from Viewer connected to No viewer. However, if more than one viewer is connected, you see no change in the Connection button if only one viewer disconnects. The Viewer connected button is still displayed. The Connection button shows a connected viewer until there are no more connected viewers.

- **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 you click **Clear All**, several things happen:
 - 1. All connected viewers are immediately disconnected.
 - 2. All pending viewers are immediately denied.
 - 3. All user names in the list are cleared.
 - 4. The **Auto Accept All** checkbox is cleared (if it is checked).

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



Recording paused; Record button pressed



Record button disabled



Recording in progress (red light appears lit); Pause button available



Recording in progress (red light appears lit); Pause button pressed



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:



Note: Recording can take several seconds to start.

Bookmark Button

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

Bookmark Bookmark Bookmark (available) (selected) (disabled)

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 54) displays with a blank space for annotations. Type an identifying note in the space. You may add as many bookmarks as desired.



Figure 54: Archiver Bookmark dialog



When playing back the recording in the Cinema system, a bookmark symbol appears on the timeline. Hold the cursor over the bookmark symbol to display the annotation. Click the bookmark symbol to move the video playback to that bookmark's position.



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

The bookmark time in the video marks the time the Bookmark button was clicked, not the time when **OK** on the Archiver Bookmark dialog was clicked.

Section 6: System Information

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Companion Systems

The *Odyssey Vision* platform supports importation of VGA, DVI, and RGB component video on each port with up to 3840 x 2160 pixels of resolution. The Vision system is compatible with:

- Stereotaxis Navigant versions 4.2 and newer
- Stereotaxis *Niobe* versions 4.1 and newer
- Lab equipment that uses USB-compatible mice and keyboards within the context of Microsoft Windows 2000 or newer Windows operating systems

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 EIZO monitor instructions

The **EIZO** Corporation states

The EIZO Quad monitor has a protective coating on the screen, so do not use anything abrasive such as paper towels. A very soft "Optical" quality cloth such as included in the Klear Screen HD cleaning kit listed below is required:

http://www.klearscreen.com/detail.aspx?ID=81

The following table is from the Instructions for Use (IFU) for the EIZO® monitor and contains more detailed information:

Cleaning

CAUTION

Device maintenance, cleaning and disinfecting

- The front panel is extremely sensitive to mechanical damage. Avoid all scratches, knocks etc.!
- Remove drops of liquid immediately; contact with liquids over a longer period can cause discoloration or allow calcium deposits to form on the surface.
- Clean the front panel when dirty using a microfiber cloth and, if necessary, a recommended cleaning agent. Only clean housing parts using the recommended cleaning agents.
- · The entire display must only be disinfected using the tested disinfecting agents.
- If cleaning agents are sprayed directly onto the display surface, use a microfiber cloth to catch drops which run down before they reach the edge of the panel.

Recommended cleaning agents and disinfectants for the monitor:

Agent class	Tested cleaning and disinfection agents:	Further examples
Alcohol	Ethyl alcohol, 96 %	Hospiset cloth
		Mikrozid liquid
Aldehyde	Melsitt	Aldasan 2000
	Cidex	Kohsolin
		Gigasept FF
Chlorine derivatives	Terralin	Quartamon Med
Disinfecting agents	TaskiDS5001 (Diverseylever Labs)	
	Morning Mist	
	Surfanios Fraicheur Citron (Anios Labs)	
Guanidine derivatives	Lysoformin	
Quaternary compounds	Incidur spray, undiluted	
Standard household washing-up liquid	Tempo	Fairy Ultra, Pril, Palmolive
Petroleum spirit	Petroleum ether	
Pyridine derivatives	Activ spray, undiluted	
Water	Tap water	
	Distilled water	

Specific Barco monitor instructions

The **Barco**® User Manual 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.

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 Minumum 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 55 is an example of a display whose layout was created when the video source connected to the Procedure Room hub had a native resolution of **1600** x **1200**.

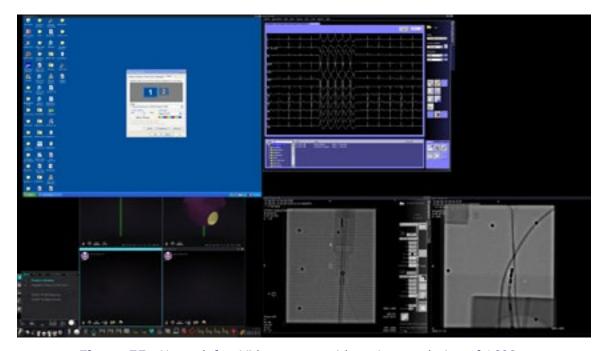


Figure 55. Upper left – Video source with native resolution of 1600 x 1200 connected to Procedure Room hub

Figure 56 shows the Display Properties dialogs for the 1600×1200 and 1280×1024 resolutions as shown in Figure 55 and Figure 57 respectively.





Figure 56. Display Properties dialogs for 1600 x 1200 (*left*) and 1280 x 1024 (*right*)

Figure 57 is an example of the same layout on the display but with a video source connected with a native resolution of **1280** x **1024**.

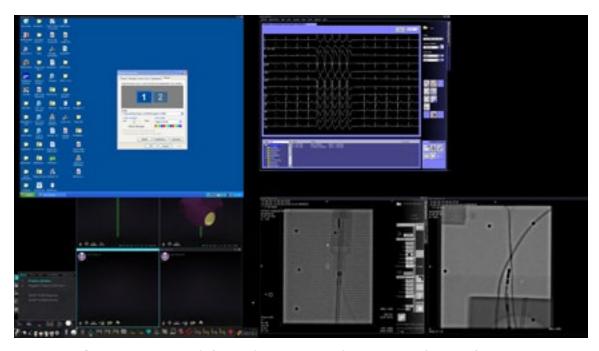


Figure 57. Upper left – Video source with native resolution of 1280 x 1024 connected to Procedure Room hub

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 (Figure 58), click Settings.

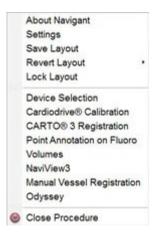


Figure 58. System Options menu

3. Click the *Odyssey* tab to display the System Key Mappings dialog (**Figure 59**).

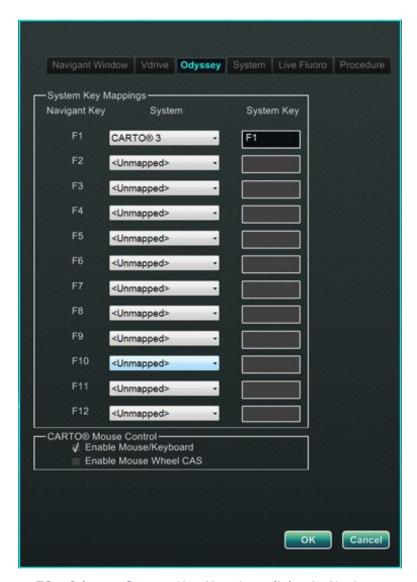


Figure 59. Odyssey System Key Mappings dialog in Navigant system

- 4. For the specific *Navigant* function key, click the corresponding **System** down arrow to display the list of video sources available. In the Figure 59 example, **CARTO® 3** is selected.
- 5. 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 59 example, **F1** has been retained.
- 6. 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 59) 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: We recommend disabling the mouse/keyboard control when 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 such as the *Niobe* system.
- 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.
- Note: For more information on the window currently in use or changing focus, see Changing Video Window Focus.

Start Panel Utilities

As shown previously, the start window, or panel (**Figure 60**), contains the entry point for starting a new procedure. The start panel also contains the **Utilities** option, discussed next.



Figure 60. Start panel with Utilities button

Clicking the **Utilities** button on the start panel and then the *Odyssey* tab (*or* clicking the system options button on the hardware status indicator toolbar and then selecting *Odyssey*) opens the *Odyssey* Status window, as shown in **Figure 61**.

This status window reveals the status of connections for mouse and keyboard only, categorized as follows:

- Connected
- Not Connected

Figure 61 shows the top-level "Video Multiplexor" category, under which any mouse and keyboard system connection statuses appear. The dialog also offers options geared more toward video. These utilities are discussed in the following sections.

- Configure Video
- Show All Video Sources
- Navigant Only



Figure 61. *Odyssey* utilities dialogs with connection statuses: *Left*, from start panel; *right*, from system options button

Select a utility option, or click **Close** or **OK** to exit the dialog.

Configure Video

Clicking the **Configure Video** button displays the dialog shown in **Figure 62**. Clicking the down arrow, highlighting a video source, and clicking **OK** displays the additional dialog shown in **Figure 63**.



Figure 62. Configure Video



Figure 63. Configure Video

Configure Video dialog guide (Figure 63)

- **O** Please select a video. Use the drop-down box to select the video source to configure. In the Figure 63 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.
- **Brightness and Contrast options.** The green arrow () appears on the line at the current settings for the source chosen. Move the arrow along the line as desired to change the designated feature. Moving left lessens; right increases. Because the video source is displayed on the screen, changes are immediately visible and available for review.
- **3 Gain (Red, Green, Blue) options** (not available for NTSC or analog x-ray). The green arrow (appears on the line at the current settings for the source chosen. Move the arrow along the line as desired to change the designated feature. Moving left lessens; right increases. Because the video source is displayed on the screen, changes are immediately visible and available for review.
- **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 if needed. Observe vertical lines while adjusting: Because the video source is displayed on the screen, changes are immediately visible and available for review.
- 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 then review, change as necessary, and click **OK** to save changes, close the dialog, and return to the *Odyssey* Status display.

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

Show All Video Sources

Clicking the **Show All Video Sources** button from the *Odyssey* tab displays a screen similar to the one in **Figure 64**. By viewing this screen, you can ensure all desired video sources are active. You can move the mouse cursor into any video source window configured for global keyboard and mouse control (except *Navigant* sources). These windows respond to global keyboard and mouse input and are there to verify the third-party devices are working correctly.

The screen may show 11 or 15 video windows (and an **Exit** field) depending on the number of inputs purchased (Figure 64 shows 11). In the upper left corner of each video window is the name assigned to that channel in the *Odyssey Vision* configuration file. A black rectangle indicates no device is connected to that channel. A blue rectangle indicates a device is connected, but the corresponding channel(s) are emitting no signal.

Note: If your configuration varies from the default, the name below the panel may not match the device type that is plugged in. Because so many video sources are possible, a configuration differing from the default is common.

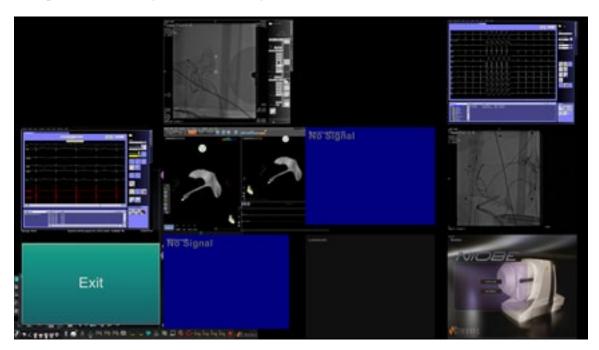


Figure 64. Show All Video Sources screen

To close the Show All Video Sources screen and return to the *Odyssey* tab, click the **Exit** window. To exit from the *Odyssey* tab 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 (which is in the bottom left corner of the screen, as shown in Figure 65). The *Navigant* Only button is for use by Stereotaxis personnel only and should not be used during a clinical procedure.

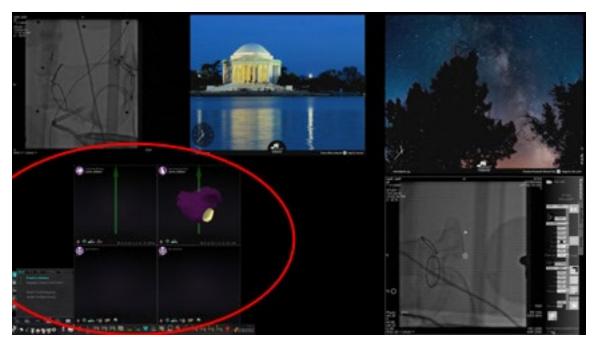


Figure 65. Sample screen when "Navigant Only" is selected

Shutdown System

Click the **Shutdown System** button in the start panel (in red oval in **Figure 66**). This shuts down the *Odyssey Vision* and *Navigant* systems.



Figure 66. Start panel with Shutdown System button

The **Shutdown** button shuts down only the Vision application and computer. Click it to shut down only the Vision computer and all associated Vision hardware. Because it shuts down the Vision power supply, it also shuts down power to the monitors of the third-party devices in the Control Room.

Primary Vision Components

A number of hardware and software components are required to achieve this level of 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 Vision 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 \times 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 all devices in the interventional lab. They route the video and USB keyboard/mouse signals of all devices connected to the Vision system, enabling video display and global keyboard and mouse control.

Clinical Workflow Manager

The Clinical Workflow Manager runs within the *Navigant* application and has the ability to control the number, size, and location of the video windows on the Vision display.

Customer Care Center

Stereotaxis offers a technical support package through the Customer Care Center.

Stereotaxis Customer Care Center representatives can view Vision video content and Vision displays at the installed site.

Troubleshooting

If you need assistance with any of the solutions in the following table, call the Customer Care Center at 866-269-5268 (from the U.S.) or 314-678-6200.

Problem	Solution
Cannot connect to the Video Controller.	Click OK to shut down the system; restart. If the problem persists, call the Customer Care Center.
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 Customer Care Center.
Error opening Odyssey.xml file.	Click OK to shut down the system; restart. If the problem persists, call the Customer Care Center.
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 Customer Care Center.
Hourglass displays on the Vision main menu window for more than 2 minutes.	Call the Customer Care Center.
Non- <i>Navigant</i> window displays improper color or a noisy image.	Refer to the <u>Configure Video</u> section. If the problem persists, call the Customer Care Center.
OAV connection is disabled.	Either the site has not purchased the Cinema system, or the connection between Vision and the Cinema server is down. If you are unable to restore the connection, call the Customer Care Center.
Received a message that "Only one instance can run at a time."	Shut down the system; restart. If the problem persists, call the Customer Care Center.

Problem	Solution
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 Vision Remote Power box to turn off the other hardware. If the problem persists, call the Customer Care Center.
Unable to use the Vision mouse in the <i>Navigant</i> window.	Restart the system. If the problem persists, call the Customer Care Center.
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 Customer Care Center.

Section 7: Index

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