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Synchrony™

User Guide

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Made In USA

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Patents

Synchrony
Manufactured under one or more of the following United States patents:
7,567,233; 7,747,960; 8,242,972; 8,244,824; 8,799,792; 8,806,359

Other patents issued and pending.

Stereotaxis Trademarks

- *Cardiodrive* and *Navigant* are trademarks of Stereotaxis, Inc., registered in the United States, the European Community, and Japan.
- *Genesis* and *GenesisX RMN* is a trademark of Stereotaxis, Inc., registered in the United States.
- *Synchrony* and *SynX* are trademarks of Stereotaxis, Inc.

All other brand names, product names, or trademarks are the property of their respective owners.

Other Trademarks

- CARTO 3 is a registered trademark of Biosense Webster.
- EnSite X is a registered trademark of Abbott.

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 Edition 4.1:2020 CISPR11:2015/AMD2:2019, Class A (Professional Healthcare Facility Environment)
Immunity:	IEC 60601-1-2 Edition 4.1:2020, IEC 61000-4-2:2008, IEC 61000-4-3:2006/AMD2:2010, IEC 61000-4-4:2012, IEC 61000-4-5:2014/AMD1:2017, IEC 61000-4-6:2013, IEC 61000-4-8:2009, IEC 61000-4-11:2004/AMD1:2017 IEC 61000-4-39:2017

When operating this equipment, verify that other devices installed near it conform to the applicable EMC standards for that device. *Synchrony* 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	ANSI/AAMI ES60601-1:2005/AMD 2:2021 *ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]*

Related documents

HDW-0270 *Cardiodrive* User Guide
HDW-0358 *Genesis RMN* User Guide
HDW-0372 *Navigant* User Guide
HDW-0389 *GenesisX* User Guide
HDW-0392 *SynX* User Guide
Respective documentation for compatible devices and/or systems.

Operating conditions

Temperature: 15°C to 30°C
Humidity: 20% to 75%, non-condensing
Atmospheric pressure: 70 kPa to 106 kPa

Storage and transport conditions

Temperature: –10°C to 50°C
Humidity: 20% to 95%
Atmospheric pressure: 70 kPa to 106 kPa

Equipment information

Synchrony, Reference number 001-010700-1
Classification: Class I Medical Electrical equipment

Note: No class B applied parts. Class B limits used for patient leakage. No class BF applied parts.

Degree of protection: IPX0
Mode of operation: Continuous
Electrical ratings:

Voltage rating:	115 / 230 V ~
Currency rating:	20.0 / 10.0 A
Frequency:	50 / 60 Hz

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

WARNING: Do not connect any devices to the *Synchrony* cabinet or floor box other than those provided and approved by Stereotaxis.

WARNING: When installing the *Synchrony* system, locate the cabinet and floor box so that the On/Off switches are easily accessible.

WARNING: To avoid the risk of electrical shock, this equipment must only be connected to a supply mains with the Stereotaxis supplied power cables.

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 *Synchrony* system.
Suggested Contractor: Walch Recycling & Eldelmentalle

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

Contents

1. Overview

Introduction

The Stereotaxis Synchrony™ system is an optional display and user interface package designed to consolidate the point of control of a medical lab.

The primary goals of the *Synchrony* 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 *Synchrony* system with 4K monitors to view:

- Up to 18 video sources with a max of 16 at a time in the interventional lab on a single display
- Video sources that are sized and positioned across the screens according to a workflow requested in the *Navigant* system
- Video sources that are sized and positioned across the screens according to layouts the user can customize
- Status, caution, and warning messages on the Synchrony system are displayed in the System Status hardware status icon and dialog
- Identical video content on both the *Synchrony* Control Room display and Procedure Room display

About This User Guide

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

Companion Systems

Synchrony may also be used with the following compatible devices:

- *Navigant*
- Stereotaxis RMN System
- SynX™

Intended Use

The Stereotaxis Synchrony™ system is an optional display and user interface package designed to consolidate the point of control of a medical lab.

Intended Patient Population

The intended patient population for the *Synchrony* 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 *Synchrony* system should be used only by qualified medical professionals who have been thoroughly trained in its use.

Contraindications

There are no known contraindications.

Clinical Benefits for the Physician and Staff

Reduction of time spent looking for patient information and minimization of potential risk during a procedure because of system granting ease of reference to patient information and increasing accessibility to patient information. Reduction in orthopedic effort due to manage procedure screens and information due to simplified display with unified keyboard and mouse control of all inputs.

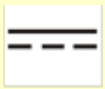
Graphics and Symbols

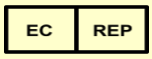
The following graphics and symbols are used in this User Guide:

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.

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.

The following graphical symbols are used in this document and/or on system components:

Symbol	Name	Description
	**AC Power**	Indicates the status of the AC power.
	**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.
	**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.
	**Equipment Power Off**	“Off” (part of equipment).
	**Equipment Power On**	“On” (part of equipment).

Symbol	Name	Description
	**European Representative**	Name and address of the authorized representative in the European Community.
	**Ground**	Protective earth (ground).
	**Importer**	Name and address of the entity importing the medical device into the locale.
	**Manufacturer**	Name and address of the manufacturer of the product.
	**Medical Device**	Indicates the item is a medical device.
	**Power**	Power status of the system.
	Power On	"On" (power).
	**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.

Symbol	Name	Description
SN	**Serial Number**	The manufacturer's serial number so a specific medical device can be identified.
intertek Total Quality. Assured.	**Testing Organization**	The logo of the organization responsible for testing the device.
UKRP	**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 appear in this document:

Term	Description
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.
Clinical Workflow Manager (CWM)	Component of *Navigant* application software that executes clinical workflow scripts to guide medical procedures, only for magnetic procedures.
EMC	Electromagnetic compatibility.
Global control video window	Window that can receive keyboard and mouse events from *Synchrony* global keyboard and mouse.
Layout	Set of video windows in a particular configuration on *Synchrony* display.
Mapping System	System that combines 3D mapping and navigation systems with the Stereotaxis GenesisX MNS.
Manual procedure	Non-magnetic procedure that can be performed in magnetic lab or non-magnetic lab.
***Navigant* Workstation (NWS)**	Platform of software applications designed to simplify clinical workflows that works in conjunction with an RMN System to provide enhanced integration of catheterization and electrophysiology labs and improved automation of medical devices.

Term	Description
SynX	Optional add-on product for *Synchrony* platform that provides remote viewing of live procedure video in real time via a mobile device or PC with its system or app and video chat with host and other users to collaborate with other physicians during procedures or enable fellows to view procedures for training purposes.
RF	Radiofrequency.
Robotic Magnetic Navigation (RMN) System	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 *Navigant* Workstation.
TPI	Third Party Interface.
4K	Display with four times the resolution of standard HD display. 4K has pixel resolution of 3840 x 2160.
Screen layout	Set of video windows in specific layout configuration.
UTSC	Universal Tableside Controller for Genesis® and GenesisX® systems. An optional touchscreen controller positioned on the side of the patient table in the Procedure Room.
VDM	Video Display Manager.
Video window	Window on *Synchrony* display that contains video display from one application (e.g., *Navigant*, 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.

Safety

Warnings/Precautions

WARNING: Federal (USA) law restricts this device to sale by or on the order of a physician.

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

WARNING: The user should not attempt to upgrade, configure, or run any other software programs on the *Synchrony* system, other than those specifically installed by Stereotaxis personnel or authorized representative.

WARNING: There are no user serviceable parts inside the *Synchrony* system. The user should not remove any covers, guards, or attempt to disassemble any portion of the workstation.

CAUTION: Please ensure the *Synchrony* keyboard and mouse control the appropriate window before performing any function using the workstation.

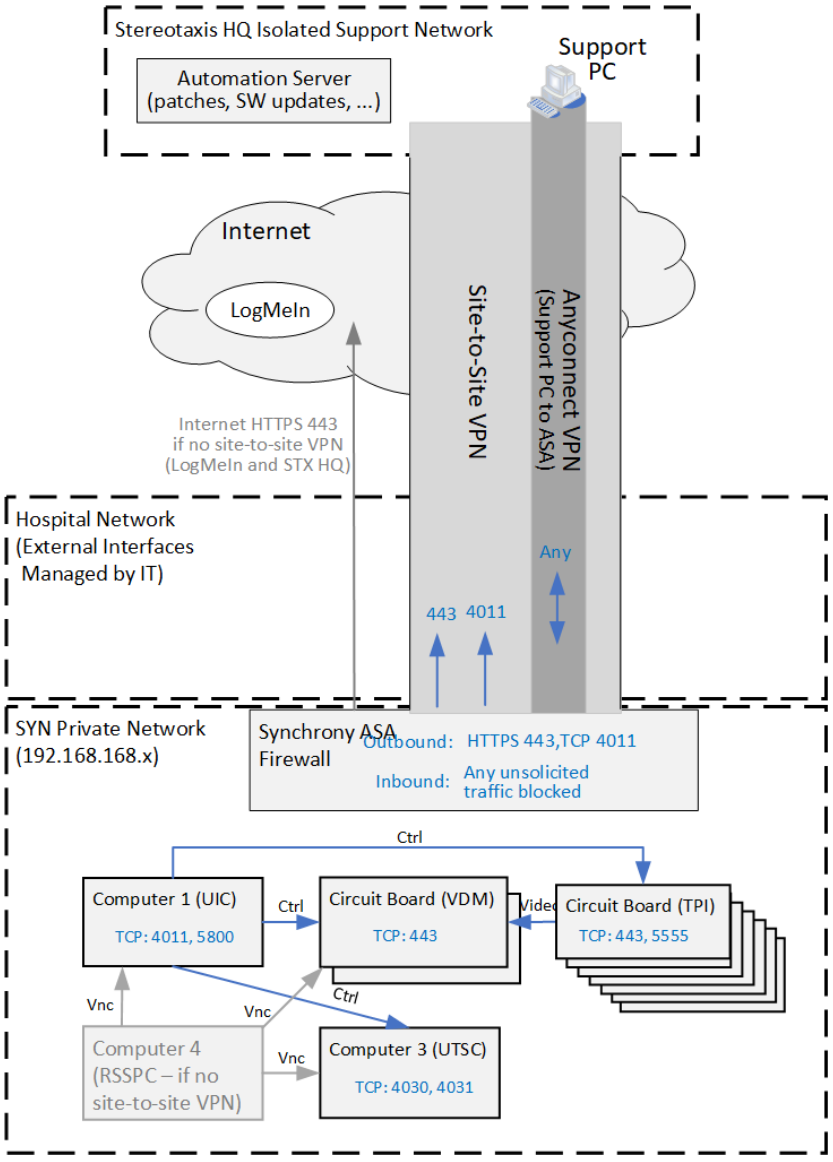
Refer to the applicable RMN System User Guide for a full list of warnings and precautions associated with magnetic navigation.

Cybersecurity Information

Please note the following important information concerning cybersecurity:

- Cybersecurity controls operate in the background of *Navigant* Workstation. No user actions are required to maintain the security of the system, but any suspected cybersecurity incidents should be reported to the Stereotaxis Telerobotic Support Team (TST).
- During the site-planning process hospital IT and Stereotaxis IT/security should coordinate to establish a secure networking solution that allows the device to securely access a Stereotaxis server for software and security updates.
- Only trusted users should be allowed physical access to the *Synchrony* System.
- Confidentiality of system passwords should be maintained. Only trusted users should have access to them.
- Caution should be used when using removable media, e.g., CD, DVD, Blu-ray disks, flash drives, USB hard drives, with *Synchrony* System. Independent virus scanning is recommended before insertion or connection to the system.

Network Ports



The following ports will send/receive data in/out of the MNS system's private network through approved endpoints:

Outbound from MNS if Site-to-Site VPN is used for support:

- Https 443 or Http 4011 to Automation Server at STX HQ for support (e.g. software/patch downloads)
- Any ports when support PC connects to ASA using Anyconnect VPN (i.e. VPN within the VPN).

Outbound from MNS if Site-to-Site VPN is not used for support:

- Https 443 to Automation Server at STX HQ for support (e.g. software/patch downloads)
- Https 443 to LogMeIn to provide remote control service.

Inbound to Synchrony:

- Any unsolicited traffic is blocked.

Responding to Cyber Incident

The *Synchrony* system operates as a self-contained system with all necessary communications for normal clinical use occurring within its internal network, protected by a dedicated hardware firewall. No additional networking or encryption infrastructure is required from the hospital to support standard clinical operation. The system functions independently and does not rely on an external network for its primary functionality.

For remote support only, an external network connection is required. This connection may be established via a site-to-site VPN or a cloud-based remote access solution (e.g., LogMeIn). The configuration and security of these remote-access connections must be coordinated between Stereotaxis and the hospital's Information Technology (IT) personnel to ensure a secure and reliable connection that aligns with cybersecurity best practices and institutional cybersecurity policies.

If you need further clarification or specific technical guidance on secure network deployment and servicing, please contact Stereotaxis TeleRobotic Support Team.

> ⚠ **WARNING:** If there is a cybersecurity breach during a procedure, press the E-stop button to stop all device activities. Contact the Emergency call center to report the suspicious activity prior to resumption of the procedure.

Software Bill of Materials (SBOM)

To support effective cybersecurity risk management and asset tracking, a **machine-readable Software Bill of Materials (SBOM)** is available for this device NWS-472 Navigant SBOM). The SBOM provides a structured inventory of software components, including open-source and third-party dependencies, to help users assess potential vulnerabilities and apply appropriate security measures.

The SBOM is provided in **CycloneDX v1.3 JSON** format and can be requested as needed for security assessments, compliance purposes, or vulnerability management. To obtain the latest SBOM for this device, please contact the Stereotaxis TeleRobotic Support Team.

User Involvement in Software Updates

To ensure the security, performance, and reliability of this device, all software updates and patches are managed directly by Stereotaxis. No user action is required to install updates; however, users may need to provide support when field service technicians visit for scheduled maintenance.

- **Automated Updates**: Operating system security patches and antivirus updates are automatically downloaded and installed as part of the device's built-in maintenance process. These updates help protect against cybersecurity threats and ensure continued compliance with security best practices. When the update downloads to the computer, the user is presented with the following message window when they close their procedure. It is important that the system is left on with the procedure closed as the update's installation occurs overnight.

- **Field Service Updates**: Updates to clinical software and other critical system components are performed on-site by authorized field service technicians. If access or coordination is required during a service visit, users will be notified in advance.

For questions regarding software updates or to schedule a service visit, please contact Stereotaxis TeleRobotic Support Team.

System Response to Anomalous Events

The device continuously monitors for potential security threats and system anomalies to ensure safe and reliable operation. When an anomalous condition is detected, the system responds as follows:

- **Malware Detection**: If malware is detected on the system, a real-time alert is automatically sent to **Stereotaxis's TeleRobotic Support Team**. The event is also recorded in system log files for further analysis. No user action is required, but support personnel may reach out if additional assistance is needed.
- **Compromised Device Communication**: If the system detects any compromise in communications between internal components, a real-time alert is sent to the call center. This ensures that any potential security risks or operational disruptions are promptly addressed. The event is also logged in system files for diagnostic purposes.

If users observe any other unexpected behavior or suspect an issue not covered by the automated monitoring system, they should promptly contact the Stereotaxis call center for further assistance.

System Protective Features

The system is designed with multiple layers of cybersecurity protections to ensure the confidentiality, integrity, and availability of critical operations. These measures help safeguard the system against unauthorized access, tampering, and potential cybersecurity threats.

- **Protected Private Network**: All communication between system components occurs within a **dedicated private network** that is isolated from external networks using a **hardware ASA firewall**. This prevents unauthorized access from outside sources.
- **Firewall Protections**: The **ASA firewall blocks all unsolicited incoming traffic**, ensuring that only necessary and explicitly allowed communication can occur. Outbound traffic is restricted to a **limited set of service-related ports** to minimize exposure.
- **Encrypted Communication**: Even within the **secure private network**, communications between system components are **encrypted** to prevent data tampering, eavesdropping, and replay attacks, further securing critical operations.
- **Endpoint Security**: All Windows-based system components have **Windows Defender and Windows Firewall enabled**, with **real-time scanning** to detect and mitigate potential malware or unauthorized activity.
- **System Backup & Recovery**: To ensure **rapid restoration** in the event of a failure or compromise, **disk images are created** at the time of installation and updated during preventive maintenance visits by authenticated authorized users. These backups provide a reliable means of recovery.
- **Multi-Factor Authentication (MFA)**: **Administrative access to system computers requires MFA**, adding an additional layer of security to prevent unauthorized access to system settings and sensitive functions.

These protections work together to ensure the system remains secure, reliable, and resistant to cybersecurity threats. For additional security-related inquiries, please contact the Stereotaxis TeleRobotic Support Team.

User-Configurable Changes

Secure Configuration of the System

The system is shipped **fully configured** with all cybersecurity protections enabled to ensure a secure operational state from installation. **No user configuration is required** to maintain or enhance cybersecurity protections. The following security measures are pre-configured and enforced:

- **Hardware Firewall Configuration**: The ASA firewall is preconfigured to **block all unsolicited inbound traffic** and restrict outbound traffic to essential service ports only, preventing unauthorized access.
- **Account Security**: User accounts and permissions are pre-set to enforce **role-based access contro**l, with **Multi-Factor Authentication (MFA)** required for administrative accounts.
- **Cryptographic Protections**: Encryption keys for secure communication between system components are **pre-installed** and managed internally, ensuring data integrity and confidentiality.

- **Anti-Malware and Software Firewall**: Windows Defender is **enabled with real-time protection**, and the Windows Firewall is configured to allow only required services while blocking unauthorized network access.
- **Security Event Logging**: The system is configured to **log security events**, including malware detection and communication anomalies, which are **automatically reported to the manufacturer's call center** for monitoring and response.
- **Backup and Recovery**: Disk images are created at installation and updated during preventive maintenance visits to ensure **quick restoration** if needed by authenticated authorized users.
- **Physical Security Protections**: System access is restricted to authorized personnel, with **administrator credentials managed securely** and changed as needed to maintain security.

User-Configurable Settings and Potential Security Risks

Since the system is fully secured at shipment, **no user-configurable changes** are required for cybersecurity. Any unauthorized modifications to system security settings—such as disabling the firewall, modifying cryptographic settings, or altering administrative accounts—**could compromise the security and integrity of the device**. Users should not attempt to make changes to system security settings and should contact the Stereotaxis TeleRobotic Support Team if modifications or access adjustments are necessary.

Capturing of Forensic Evidence

Forensic Evidence and Security Event Logging

The system maintains detailed log files to capture forensic evidence of system activity, including security events such as **malware detection and communication anomalies**. These logs provide valuable insights for troubleshooting, incident response, and security monitoring.

Log File Capture and Storage

- **Event Logging**: Almost all system actions are recorded in log files, including security-related events.
- **Security Event Logs**: **Malware detection events** and **communication anomalies** are logged and **reported in real time** to the Stereotaxis support center for immediate response and investigation.
- **Windows Event Logs**: In the event of a security incident or system compromise, **Windows Event Logs** can be examined to provide additional forensic evidence, including system activity, login attempts, and security alerts.
- **Log File Location & Format**: Logs are stored locally on system components in **standard text-based log file formats**, compatible with manual review and automated analysis tools. Log files are uploaded daily for diagnostics purposes (no PHI is in the logs).

- **Retention & Recycling**: Log files are **automatically rotated** to maintain storage efficiency. Historical logs may be archived for forensic analysis as needed.

Forensic Analysis & Automated Consumption

- **Manufacturer Monitoring**: Security event data is sent to the Stereotaxis TeleRobotic Support Team, allowing for **real-time monitoring and response**.
- **Windows Event Log Analysis**: In case of a suspected compromise, Windows Event Logs can be reviewed by authorized personnel to trace system activity and identify potential security incidents.
- **No IDS or SIEM Integration**: The system does not integrate **with Intrusion Detection Systems (IDS)** or **Security Information and Event Management (SIEM)** solutions. However, logged events are structured to allow for external review if necessary.

For assistance with log file analysis or forensic investigation, users should contact the Stereotaxis TeleRobotic Support Team.

Decommissioning

If a component containing sensitive data needs to be removed or replaced, or for system removal, contact the Stereotaxis TeleRobotic Support Team for the appropriate steps to be taken.

The expected lifetime of the *Synchrony* system is defined as at least ten (10) years from the date of manufacture, based on technology and part obsolescence. Stereotaxis regularly monitors devices, parts, and components (including software/firmware) for potential End of Life (EOL) and End of Service / Support (EOS). If a component is declared EOL/EOS, Stereotaxis will update the device to a supported version or alternative supported component to prevent premature device EOL/EOS. When a Stereotaxis device is declared EOL/EOS, direct customer notification will be sent to the applicable personnel according to the relevant Service Contracts / Records. Please contact the Stereotaxis TeleRobotic Support Team for further information on device lifecycle and EOL/EOS.

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 *Synchrony* system.

WARNING: The *Synchrony* system should not be used adjacent to or stacked with other equipment and, if adjacent or stacked use is necessary, the *Synchrony* 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.

Electrical Safety Compliance

All external systems connected to the *Synchrony* 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 *Synchrony* 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 *Synchrony* system, complies with IEC 60601-1-1.

WARNING: To avoid the risk of electrical shock, this equipment must only be connected to a supply mains with the Stereotaxis supplied power cables.

Note: In case of a voltage interruption, the *Synchrony* system might shut down, necessitating a system restart.

Emissions

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

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

Emissions	Compliance	Electromagnetic environment—guidance
RF emissions CISPR 11	Group 1	The *Synchrony* 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		

Emissions	Compliance	Electromagnetic environment—guidance
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 *Synchrony* 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.

Immunity test	IEC 60601 test level*	Compliance level*	Electromagnetic environment—guidance
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 *Synchrony* system requires continued operation during power mains interruptions, it is recommended that the *Synchrony* 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.

Note: Degradation of performance due to EM disturbances are considered to be acceptable if less than 10 minute loss of video and less than 30 minute loss of system control.

WARNING: Should performance degrade due to EM disturbances, the operator should reboot the affected components (TPI/VDM/monitor, etc.).

Immunity—RF Interference

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 mHz to 2.7 GHz	3 V RMS 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the *Synchrony* system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. ***Recommended separation distance***

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
			$d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strengths from fixed transmitters such as base stations for radio (cellular/cordless), telephones, and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *GenesisX RMN* is used exceeds the applicable RF compliance level above, the *GenesisX RMN* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *GenesisX RMN* 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 *Synchrony* system, including cables specified by Stereotaxis, Inc.

The *Synchrony* system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *Synchrony* system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Synchrony* 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 *Synchrony* 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 t0 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, 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 *Synchrony* system, contact Stereotaxis TeleRobotic Support Team. Otherwise, there are no service requirements to maintain EMC integrity.

2. Basic Information

Primary *Synchrony* Components

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

Component	Description
***Synchrony* cabinet**	The *Synchrony* cabinet contains network switch and routers.
4K display	The 4K display has four times the resolution (3840 x 2160) of an HD display.
Sychrony extension box	The user can connect up to six auxiliary systems at the same time to the Synchrony extension box. 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)	TPIs are used to connect devices to the *Synchrony* system. They connect the video and USB keyboard/mouse signals of all devices connected to the *Synchrony* system, enabling video display and global keyboard and mouse control.
Video Display Manager (VDM)	VDM combines video signals from all TPIs into a composite image.

Start Window

The *Synchrony* start window (**Figure 1**) is shown on the 4K screen — as are all *Navigant*-specific windows. The next display is the Case Details window.

Figure 1. Start Window (Magnetic Lab)

Start window for magnetic lab

① *Synchrony* opens to a full-screen window with a physician login screen on the right.

② **Main Menu**. In this menu, you can open an existing procedure, access the Physician Management dialog, System Status dialog, Help Guide, Service Mode, 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). The toolbar only shows icons for systems that are not operating properly (displayed with a "no" symbol (⃠) overlay). Clicking an icon will open the System Status dialog where there is more information about the errors.

④ **Physician Select.** A list of physicians to use for new procedures. Physicians can be added using the Main Menu or by clicking the "Add Physician" item in the physician select list. Alternatively, there is a "Guest" account option, which always starts a procedure with default settings and layouts.

⑤ **RMN Procedure.** A toggle switch to say whether or not the new procedure will be using a magnetic system.

⑥ **Next button.** Open the Case Details page to start a new procedure using the selected physician.

Click the **Next** button.

Case Details Window

When starting a new procedure, the next display after the start window is the Case Details window (**Figure 2**).

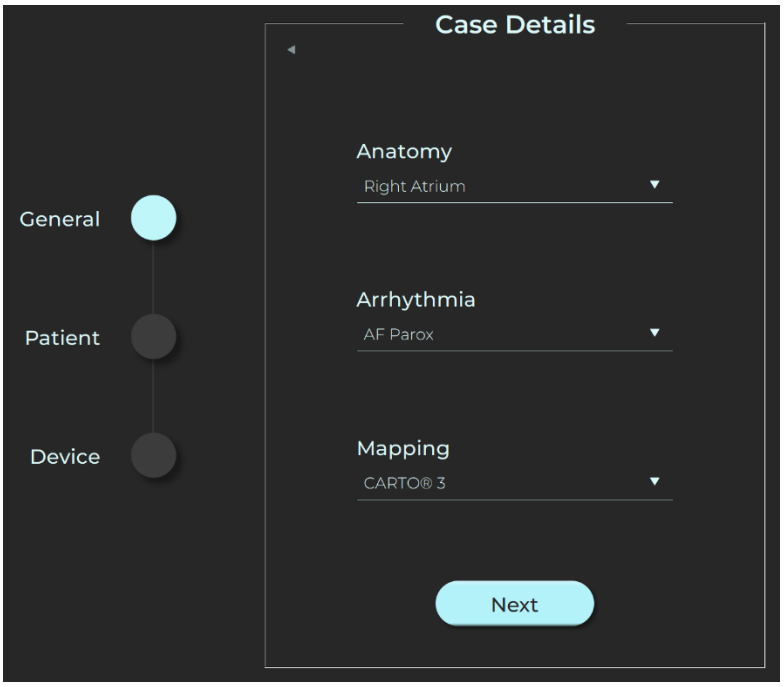


Figure 2. Case Details Window

Fill out procedure information fields:

1. **Anatomy field.** From the drop-down menu, select the type of anatomy involved. The anatomy is separated by procedure type:

   Electrophysiology (EP)

   Coronary for Interventional Cardiology (IC)

   CRT (Cardiac Resynchronization Therapy)

2. **Arrhythmia field.** From the drop-down menu, select the type of arrhythmia involved.
3. **Mapping field.** From the drop-down menu, select the type of mapping system involved.

Click the **Next** button.

Patient Details Window

The next display after the Case Details window is the Patient Details window (**Figure 3**). (At this point, the X-ray system will still not be displayed; a procedure must first be started.)

Entered patient information will then be automatically imported into the appropriate fields on the *Synchrony* screen.

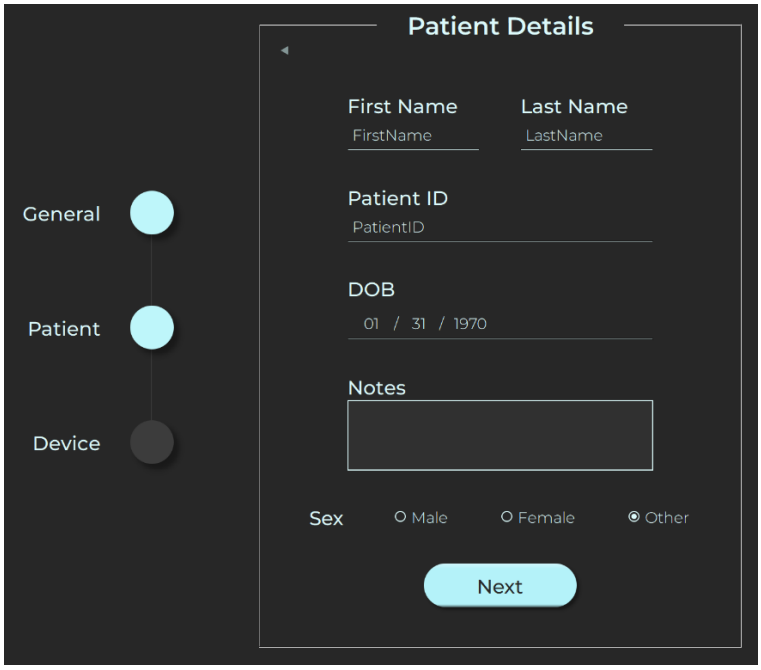


Figure 3. Patient Details Window

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. **Notes field.** Type any desired (optional) information about the case or procedure.

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.

Click the **Next** button.

Device Details Window

The next display after the Patient Details window is the Device Details window (**Figure 4**). Device information is not required at this screen because the device can be selected and activated in the procedure.

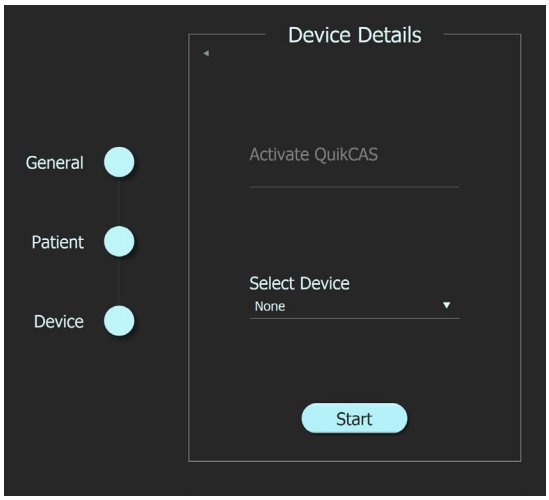


Figure 4. Device Details Window

Fill out the device information fields:

1. **QuikCAS field.** Scan a valid QuikCAS barcode to activate CAS.
2. **Device field.** From the drop-down menu, select the type of device involved.

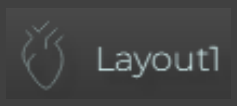
After procedure information has been entered and procedure type options have been selected, click **Start**. The default layout for the physician displays. The procedure is now open, and the main window displays.

Typical *Synchrony* Toolbar

While in a procedure, the *Synchrony* toolbar (**Figure 5**) displays horizontally at the bottom of the monitor. It contains several buttons, described in **Table 1**.

Figure 5. *Synchrony* Toolbar

Table 1. *Synchrony* Toolbar Buttons

ICON	Name	Description
	***SynX***	Opens *SynX* configuration window.
	***Navigant***	This functions as a home button for the *Navigant* system. It adds a ***Navigant*** window to the current layout.
	**User Layouts**	The layout selector button displays the current layout. Clicking on the layout name will open a menu () where other layouts can be selected. If a layout is already present, clicking on it brings it to the top of the Z-order so that it is visible.
	**ECG Real Time**	Opens a Live ECG video window.
	**Mapping System**	Opens the Mapping System video window.
	**Ultrasound**	Opens a window for the ultrasound machine connected in the Procedure Room.
If there is not a Fluoro B:  If there is a Fluoro B: 	**Live Fluoro A**	Opens the Live Fluoro A video window.
	**Live Fluoro B**	Opens the Live Fluoro B video window.

If there is not a Fluoro B:  **If there is a Fluoro B:**  	**Reference Fluoro A**	**Opens the Fluoro A Reference video window.**
 	**Reference Fluoro B**	Opens the Fluoro B Reference video window.
	**Imaging Workstation**	Opens the Imaging Workstation.
	**RMN System**	Click to access the Stereotaxis robotic magnetic navigation system Service Menu in a magnetic lab.
 	**ECG Image Reference**	Opens the Reference (Control) ECG video window.
If there is no 2:  If there is a 2:  	**Camera 1**	Opens the Camera 1 video window.
 	**Camera 2**	Opens the Camera 2 video window.
	**Patient Monitoring System**	Opens the anesthesia cart system video window and the hemodynamics video window.
	**IVUS Imaging System**	Opens the IVUS imaging system video window.

	**Picture Archiving and Communication System (PACS)**	Opens the PACS video window.
	**Generic Input 1-5**	Emphasizes up to 5 additional digital video displays not already listed in this table.

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 two most common states for *Synchrony* toolbar buttons are detected and present.

Detected

Present

Detected

The toolbar button is present and accessible with its video window ready for use due to the TPI being connected to the system, but it's not currently active. It's shown as a picture on the toolbar.

Present

The toolbar button has now been clicked on, which means its video window has been brought forward and is being currently displayed. A light is now below the toolbar button.

Additionally, if your cursor hovers over the toolbar icon, it will highlight and display the name in a popup. This can be done regardless of state. If you click a cursor while it's highlighted, it will be added to the layout and be made present (if it wasn't already).

Special Window Types

Some applications with the *Synchrony* system have special window types:

View-only windows are for the display of information only. The *Synchrony* 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 that 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 *Synchrony* 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 *Synchrony* 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 *Synchrony* display.

For example, if the user clicks in the *Navigant* video window, the *Synchrony* 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 *Synchrony* 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 *Synchrony* 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.

UTSC

In a Magnetic *Synchrony* lab with *Genesis* or *GenesisX*, the UTSC (Universal Table Side Controller) is ***not*** an optional component. In a Standard *Synchrony* lab, the UTSC is an optional component. When present, it allows the physician to select the current layout from the tableside; the UTSC controls magnet movement and *Synchrony* function. **Figure 6** shows the UTSC main screen with magnet controls on the left. **Figure 7** shows the *Synchrony* screen with available video sources. Selecting one will make that the current layout.

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

Figure 6. UTSC: Main Screen

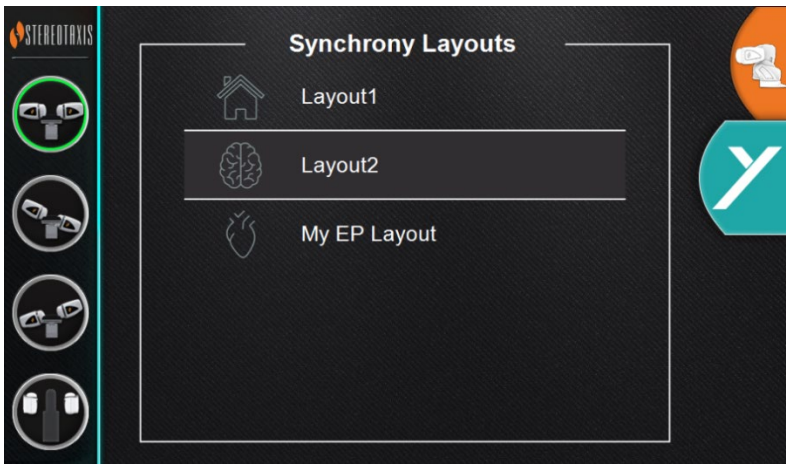


Figure 7. UTSC: *Synchrony* Screen

Connecting a Third-Party System to *Synchrony*

Synchrony Extension Box

The Synchrony Extension Box (**Figure 8**) will be attached to the patient table rail. The Extension box provides a means to connect up to 6 TPIs using the provided fiber optic cables.

Figure 8. Synchrony Extension Box

Video Display Manager (VDM)

The VDM (**Figure 9**) converts the network video stream into HDMI video which is displayed on the Quad monitor. Connect a fiber cable from the "10G" port to the Synchrony cabinet and connect an HDMI cable from the "HDMI OUT" port to the Quad monitor using the provided cables.

Figure 9. VDM (Front & Rear)

TPI

A TPI (**Figure 10**) connected to a third party system may be located in the Procedure Room or Control Room. DVI, VGA, SOG and HDMI connections are available, all of which are detailed in the following sections.

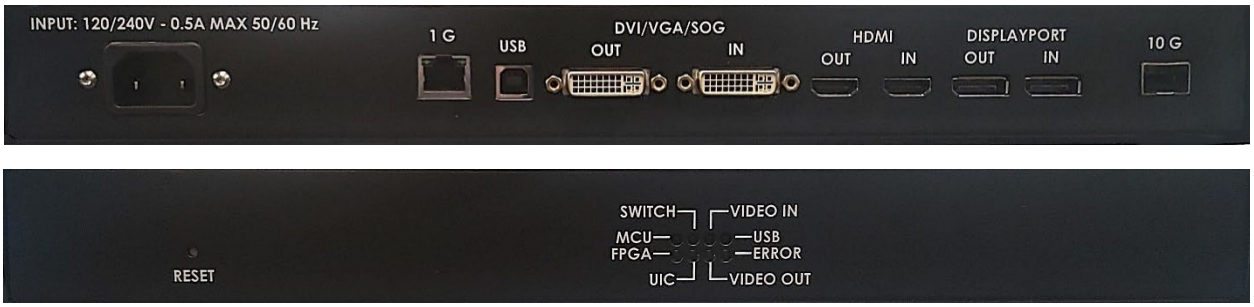


Figure 10. TPI (Front & Rear)

Synchrony Video Types

VGA Video

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 DVI/VGA/SOG OUT 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 DVI/VGA/SOG IN port on the system's associated TPI assembly.
    a. As an option, you can connect the Stereotaxis-provided USB cable between the back of the third-party computer and the USB port on the system's associated TPI assembly.
4. Connect the appropriate Synchrony system fiberoptic cable to the 10G port on the system's associated TPI assembly.

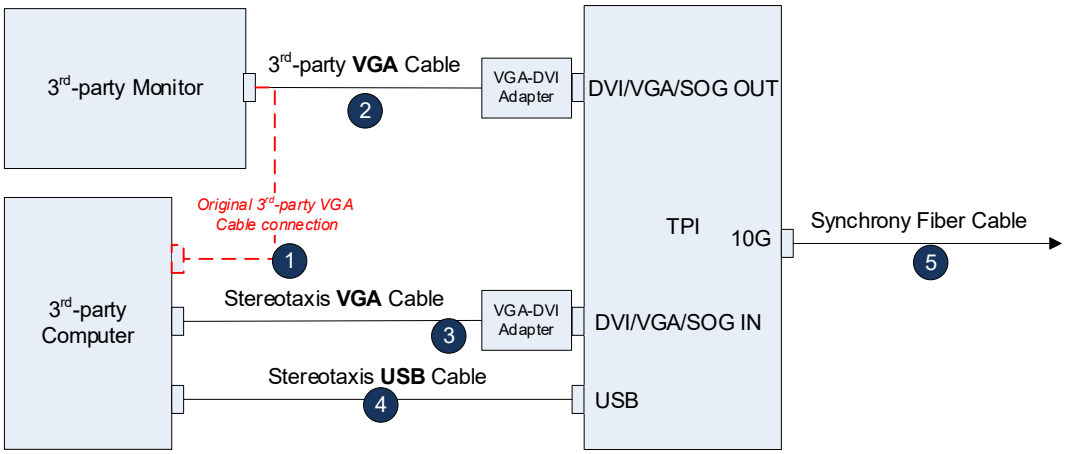


Figure 11. TPI Connectivity for VGA and SOG

When connections are complete, the 3rd Party computer video is available as a video window on the *Synchrony* screen when selected on the *Synchrony* toolbar.

Sync-on-Green (SOG) Video

Analog X-ray systems typically use SOG video. This type of source can be connected to *Synchrony* as follows. Duplicate these steps (detailed in **Figure 11**) 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 DVI/VGA/SOG OUT port on the system's associated TPI.
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 DVI/VGA/SOG IN port on the system's associated TPI.
    a. As an option, you can connect the Stereotaxis-provided USB cable between the back of the third-party computer and the USB port on the system's associated TPI.
4. Connect the appropriate *Synchrony* system fiberoptic cable to the 10G port on the system's associated TPI.

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

Digital Video Interface (DVI) Video

The 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 DVI/VGA/SOG OUT 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 DVI/VGA/SOG IN port on the system's associated TPI assembly.
    a. As an option, you can connect the Stereotaxis-provided USB cable between the back of the third-party computer and the USB port on the system's associated TPI assembly.
4. Connect the appropriate *Synchrony* system fiberoptic cable to 10G port on the system's associated TPI assembly.

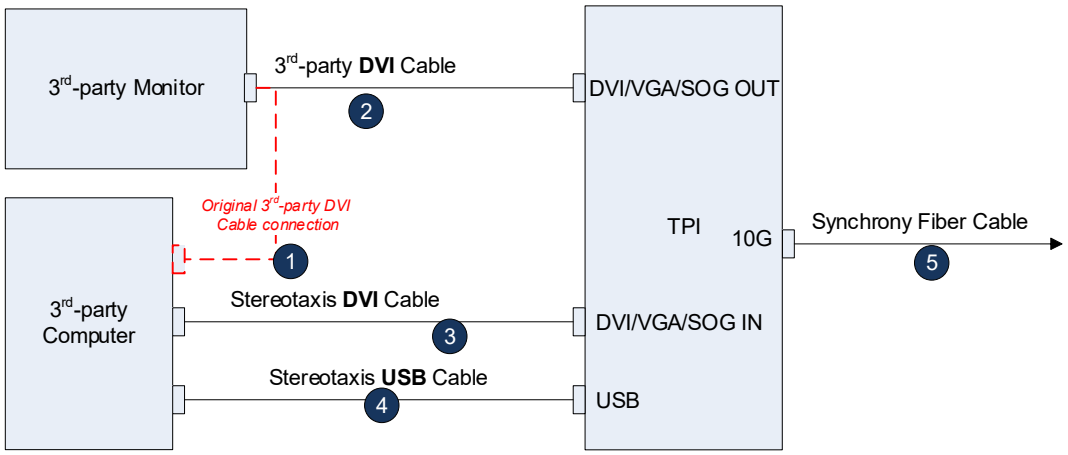


Figure 12. TPI Connectivity for DVI

When connections are complete, the 3rd Party computer video is available as a video window on the *Synchrony* screen when selected on the *Synchrony* toolbar.

High-Definition Multimedia Interface (HDMI) Video

The following are general instructions for HDMI video and USB (for mouse and keyboard control) connections. Duplicate these steps for each computer (video source).

1. Unhook the HDMI cable currently attached to the back of the third-party computer, leaving it connected to the third-party monitor.

2. Connect the unhooked HDMI cable to the HDMI OUT port on the system's associated TPI assembly.
3. Connect the Stereotaxis-provided HDMI cable between the back of the third-party computer and the HDMI IN port on the system's associated TPI assembly.
    a. As an option, you can connect the Stereotaxis-provided USB cable between the back of the third-party computer and the USB port on the system's associated TPI assembly.
4. Connect the appropriate *Synchrony* system fiberoptic cable to 10G port on the system's associated TPI assembly.

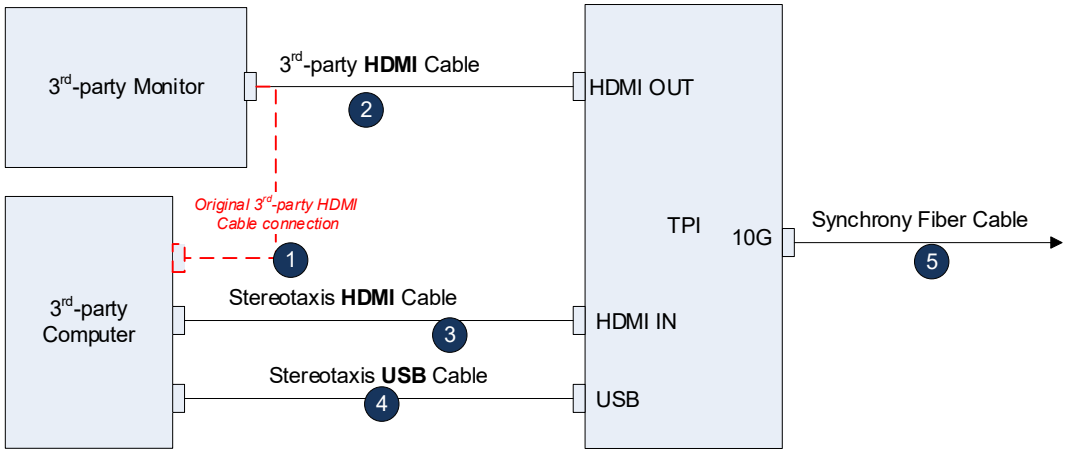


Figure 13. TPI Connectivity for HDMI

5. When connections are complete, the 3rd Party computer video is available as a video window on the *Synchrony* screen when selected on the *Synchrony* toolbar.

3. Magnetic Lab

Genesis and *GenesisX*

Magnetic labs have clear differences from non-magnetic labs, such as *Navigant* functions that can be moved and closed or how *Synchrony* can be powered.

Follow this sequence of steps when starting the *Synchrony* system:

- Turn on all non-Stereotaxis system computers (X-ray, ECG, mapping systems, etc.).
  - *Genesis* communicates with a variety of different digital fluoroscopy systems.
- Turn on *Genesis* according to their IFU.
  - HDW-0358 for *Genesis* or HDW-0389 for *GenesisX*.
- Turn on the *Synchrony* system by pushing the power button (**Figure 16**) on the front cover. The blue light on the cover lights up, then powering on *Synchrony*.

Magnetic Procedures

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

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.

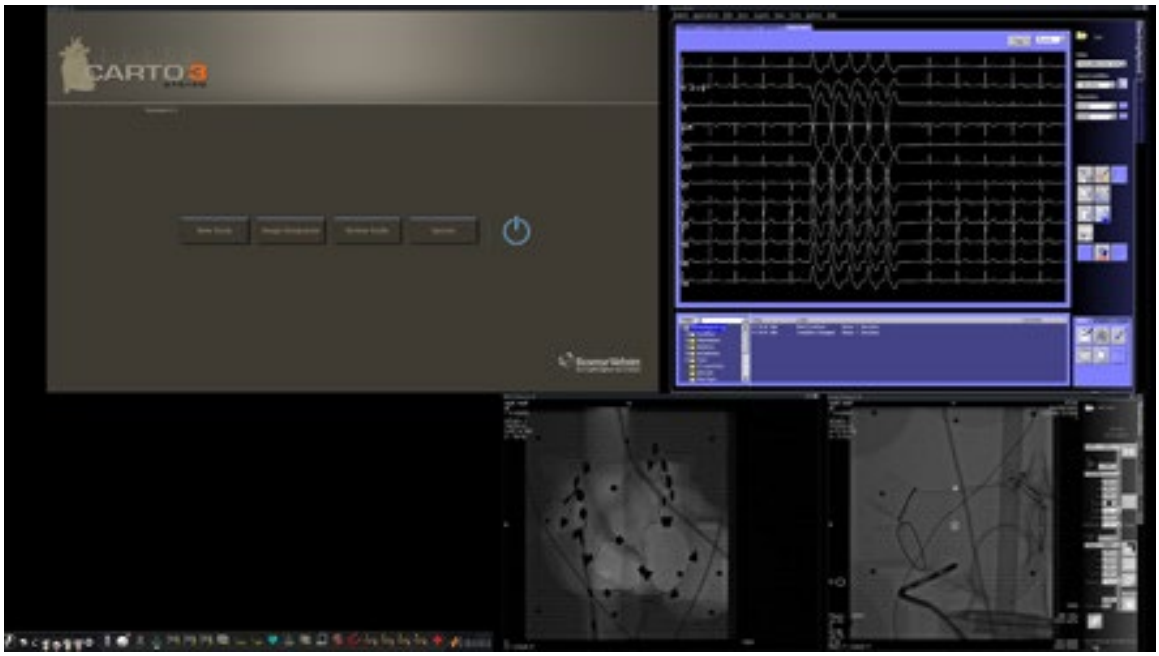


Figure 14. Magnetic Procedure with *CARTO* 3

The Clinical Workflow Manager displays in the lower-left corner of the bottom quadrant of the 4K screen. The Clinical Workflow Manager controls the opening layout for any procedure. If you want to change the video source display, you can:

- Click on the video input icon in the toolbar to add the given source or pop the given source to the front.
- Click the **X** button of the title bar of any video source to close it.

Manual Procedures in Magnetic Labs

The *Synchrony* 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 *Synchrony* screen. However, EnSite™ X, 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 15**).

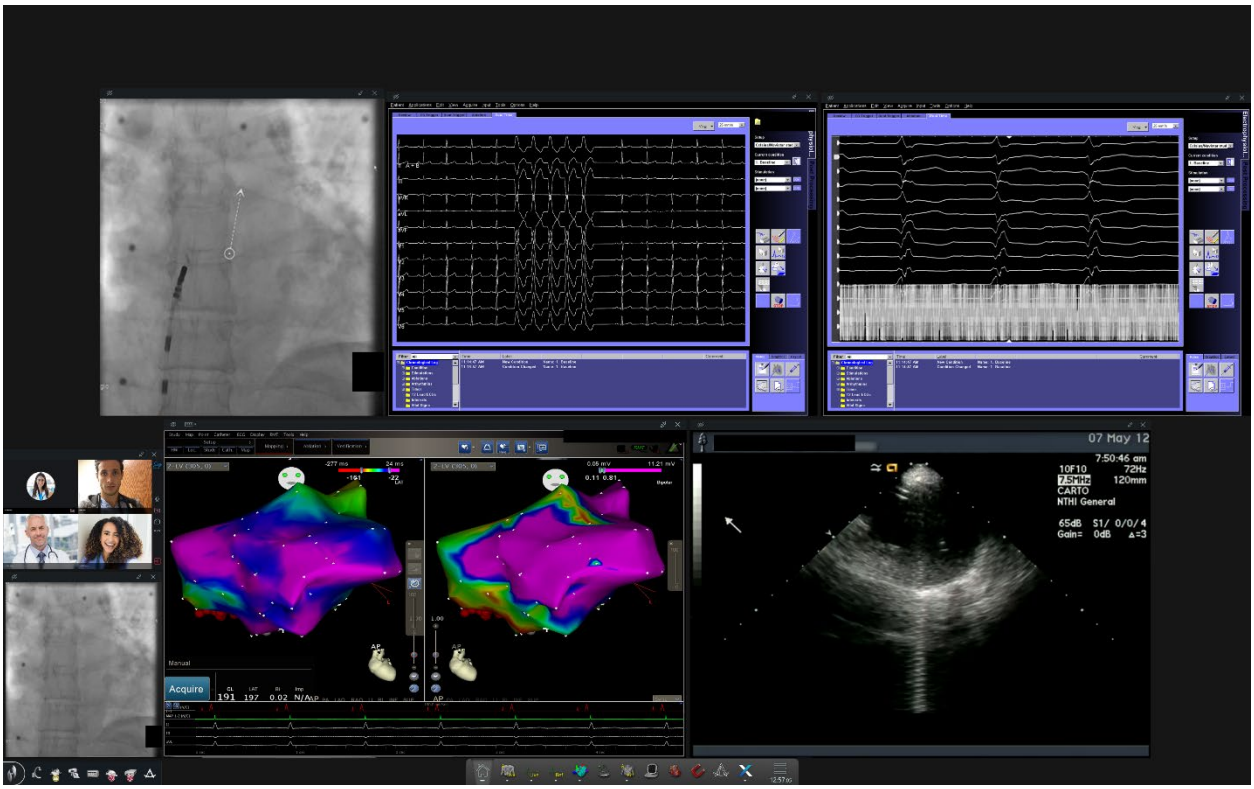


Figure 15. Manual Procedure in Magnetic Lab with *CARTO* 3

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 *Synchrony* toolbar to open a single video source (displaying at or near full resolution) or pop an already open video source to the front.
- Delete a source from the screen by clicking the **X** in its title bar.
- Select a User Layout button from the Layout menu.

4. Non-Magnetic Lab

Getting Started

Follow this sequence of steps when starting the *Synchrony* system:

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

Turn on the *Synchrony* system by pressing the power button on the front of the Synchrony Cabinet (**Figure 16**).

Key to Figure 16

1. *Synchrony* system is on when blue LED is lit
2. Turns *Synchrony* system ON when pressed
3. Turns *Synchrony* system OFF when pressed

Figure 16. *Synchrony* Front Cover with Power Button

5. Altering Layouts

There are multiple options for how a window can be changed:

- Add a window
    - Click the User Layout icon on the Synchrony toolbar; if that video source is already showing, it will be brought top-most.
- Delete a window
    - Click the X in the upper-right corner
- Resize a window
    - Drag a corner or side of the window
- Move a window
    - Drag a window at its title bar

Clicking in a video input area activates the source and highlights its title bar. There is an **Expand** button, which is only enabled if the window is not overlapping any other window. Clicking it (or double-clicking the title bar) will *expand* the window to take up the available empty space.

When altering a layout, the creation of a teal dot is triggered, and it's placed by the current layout (**Figure 17**). A teal dot signifies that a layout has been changed, but the change has not yet been saved. Once the layout is saved, the teal dot will disappear.

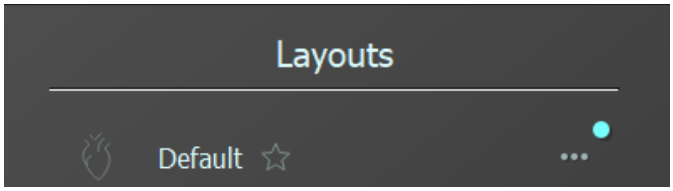


Figure 17. Teal Dot Example

Here's how a *Navigant* Window can be altered:

- Adding a *Navigant* Window
    - Click the *Navigant* icon on the Synchrony toolbar.
- Changing the type of *Navigant* Window
- Use the window swap drop-down menu (**Figure 19**).
    - *Navigant* Windows take priority over other windows and will be top-most, only ever on top other windows.
    - Selected or most recently selected *Navigant* Windows go over the *Navigant* Window(s) one that isn't currently selected.
    - Normal windows will always be behind *Navigant* Windows.

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

- Add or delete a source
- Resize a source
- Use *Navigant* Window Swap button/menus
- Renaming a layout
    - Go to the Layout Select
    - Choose the desired layout
    - Go to the three dots and choose **Rename**. (Duplicate layout names will not be accepted and an alternative name will be needed.)

Active normal windows are brightly colored (white for normal windows and teal for *Navigant* Windows) and these active windows save keystrokes. It's important to have a normal window active if intending to work with a normal window. Otherwise, by default, keystrokes register to a *Navigant* Window, regardless of what was last active. To bring a normal window one in front of another, they must be clicked on the edges of the window to select them.

Here's how a given layout can be changed:

- Click on the current icon
- Select from the list of icons to assign a new icon to the layout
    - There is no limit to how many times a layout's icon can be changed, and multiple different layouts can have duplicate icons across different layouts.

For brand-new procedures, the starting layout is called Default. Other layouts can become the default layout over the starting Default layout if desired by following these steps:

- Go to the Layout Select
- Choose the desired layout
- Go to the three dots
- Choosing **Set Default**.

If this is done, a star icon is added after the layout's name. From now on, that is the new default layout, and there can only be one default layout at a time.

If for any reason it's desired to delete a layout (such as there being too many), follow these steps:

- Go to the Layout Select
- Choose the desired layout
- Go to the three dots
- Select **Delete**.

Note: Deleting a layout is permanent and cannot be undone. Also, default layouts cannot be deleted without first choosing another layout as the default layout.

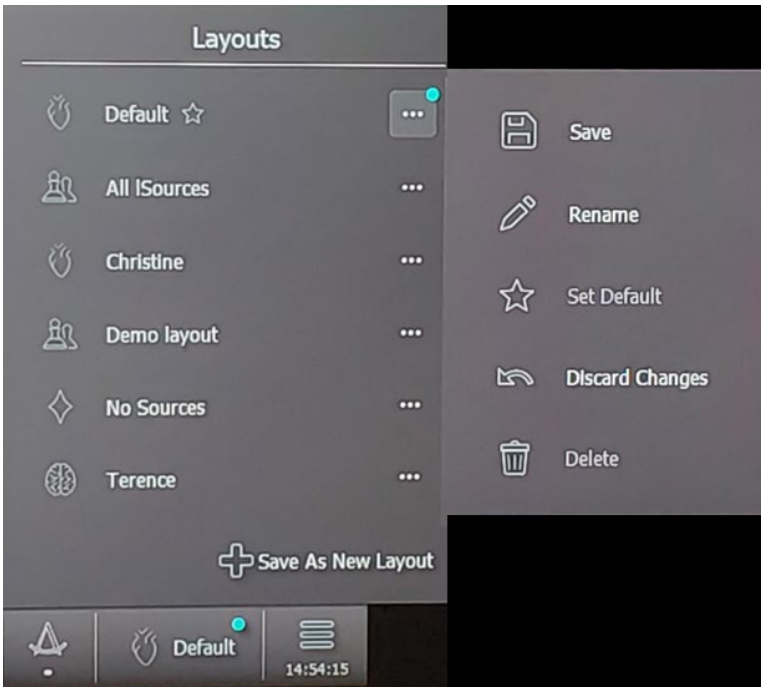


Figure 18. Layouts Menu with Options

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 19**) where the user can select a different display within that window.

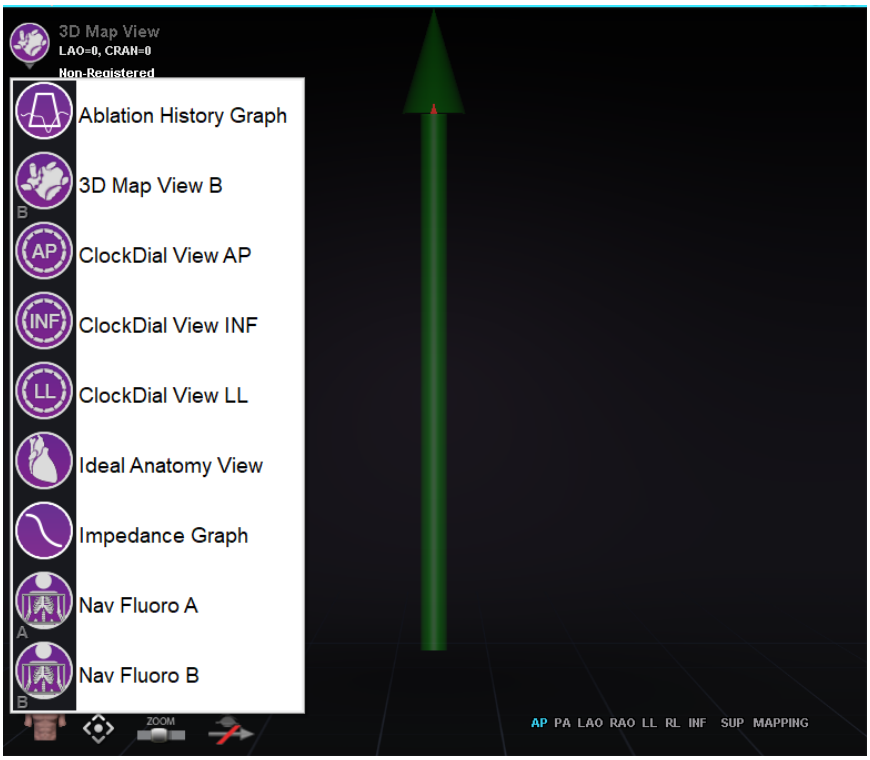


Figure 19. Window Display Menu Options

Saving Layouts

For procedures, Layouts are automatically saved and will be there if a procedure is revisited, but for new procedures Layouts must be manually saved for Layouts to carry over between different procedures. Saving a layout will remove a teal dot because of the layout modifications being saved.

Select a layout from Layout Selector, go to three dots, and click on **Save** like in **Figure 18**.

Lab Configuration Dialog

Select hamburger icon (**Figure 20**), go to Lab Configuration. Two tabs, one for TPIs sources, one for VDMs source. Click on one and you can see its information.

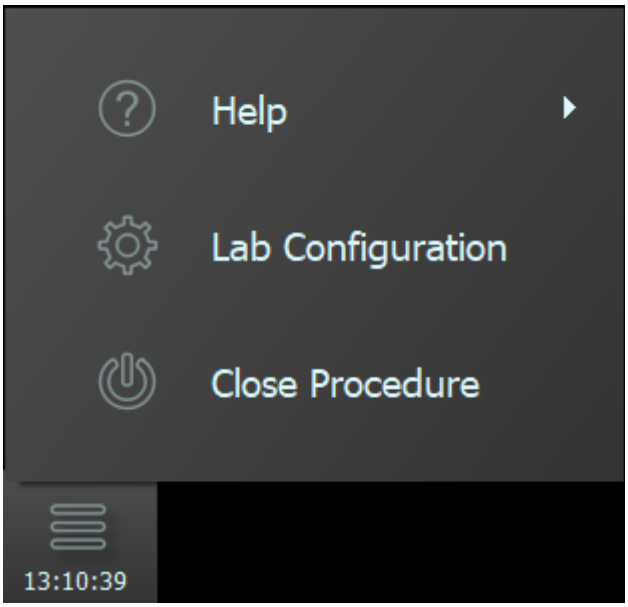


Figure 20. Hamburger Icon

For TPI sources, its name is in the configuration menu and when hovering over the icon on the toolbar, and the icon for the menu and on the toolbar can be changed to something else from the icon folder. For changing a name, select from a list of premade options or type in your own by clicking on the plus and selecting **OK** for it after typing the new name.

For USB with a source, if there is a USB connection, greying out the **Enable Synchrony Mouse and Keyboard** toggle will prevent clicking on a source with the mouse or making keystrokes. This only applies to that source.

Depending on your operating system, there might be USB configuration required. To modify this, go to **USB and select Configure USB Control**. See more in the **Mouse Control** section for this.

For Video, it's primarily for information. There will be three options: DVI or HDMI for different types of video connections, or Video Test Pattern for troubleshooting. With TPI, the source can be reset by selecting Reboot.

For VDM sources, the name can be changed by typing (no selectable list). To close diagrams that show the current layout of the TPI sources, click on the **X** in the white diagram box. An entire screen can be tested by clicking the Show Video Test Pattern toggle from grey to teal and it runs a test for a brief period; it is advised that this is only done if there is more than one screen. The entire screen can be restarted by selecting Reboot. When you turn on the **Locate** toggle, it will cause the associated TPI to beep to help service personnel physically locate the TPI.

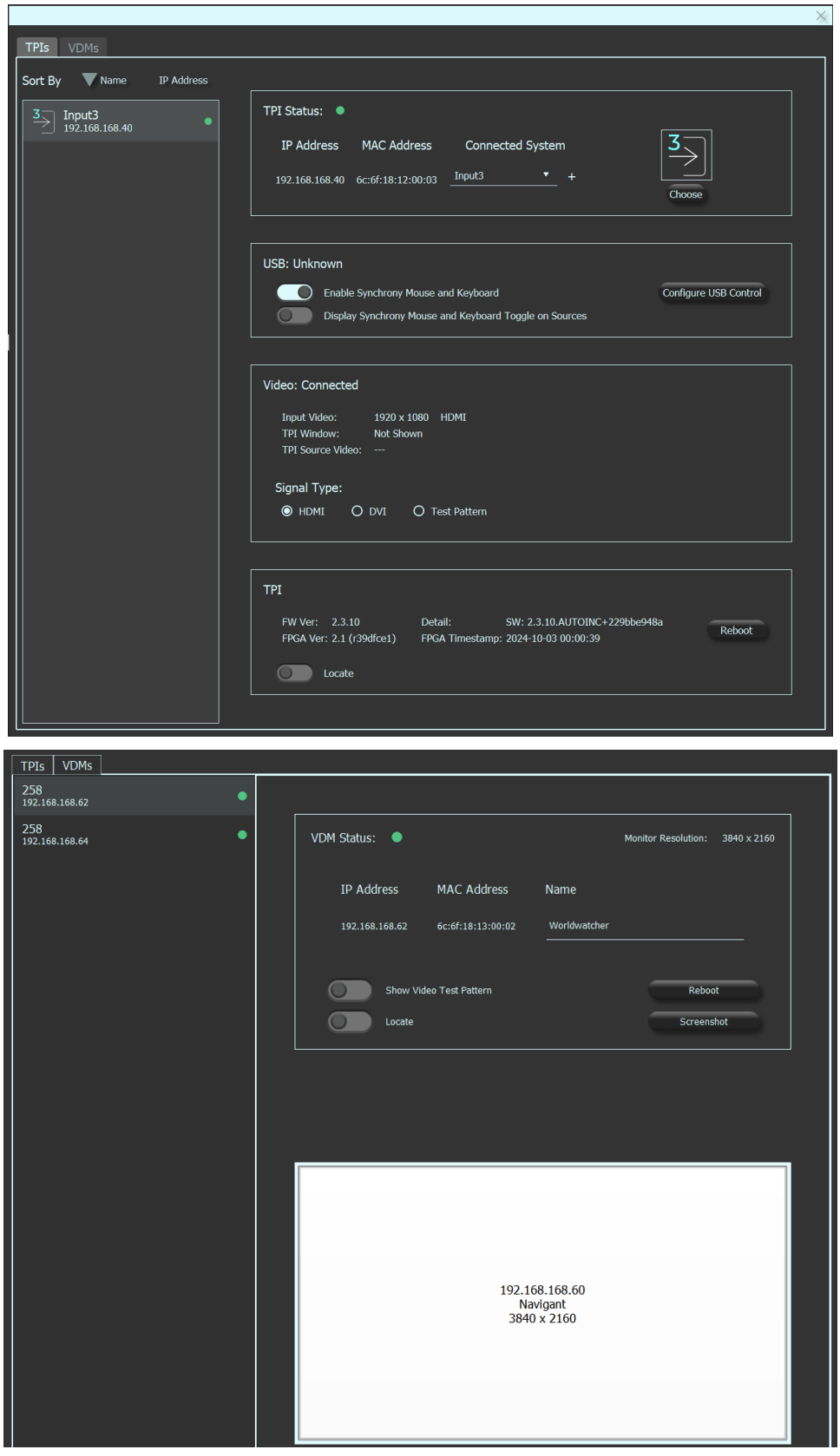


Figure 21. Lab Configuration with TPIs (Top) and VDMs (Bottom)

6. System Information

Companion Systems

The *Synchrony* system is compatible with:

- Stereotaxis *Navigant* versions 5.2 and newer
- Stereotaxis *Genesis* and *GenesisX* RMN System
- Lab equipment that uses USB-compatible mice and keyboards
    - DVI-D/DVI-A (digital and analog, analog VGA is supported using a VGA->DVI-A adapter)
    - HDMI
    - SOG

Control of Third-Party System Through *Synchrony*

A third-party system can be controlled through the *Synchrony* system or through its native computer mouse and keyboard.

Monitors

The *Synchrony* setup has two monitors: one in the Control Room and one in the Procedure Room. Monitors can display up to up to 18 video streams with a max of 16 at a time, in addition to *Navigant*. Each video stream appears in its own window on the *Synchrony* display. The window that contains a video stream on the *Synchrony* display is called a video window.

Video Display Resolution

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

Mouse Control

When the **Enable Synchrony Mouse and Keyboard** toggle has been selected, **Configure USB Control** can be selected to have USB Configuration open. The **Scroll Wheel** toggle can have a mouse wheel work as normal if not selected, and if selected, it will convey the message to control the CAS in Navigant when using the mouse wheel. **Mouse Hide Position** can be selected to choose which corner will control where to hide the mouse cursor when the *Synchrony* cursor leaves the window. **Mouse Movement** controls the mouse messages sent to third-party systems and has four different options: **Standard**, **Desktop Span**, **Absolute**, and **Relative**. Additionally, there's a box that can be checked below **Mouse Movement** called **BIOS HD Mode**.

Option	Description
Standard	For most Windows PCs; the first monitor uses absolute mouse, additional monitors use relative mouse.
Desktop Span	For some multimonitor Windows PCs; all monitors treated as one absolute monitor.
Absolute	For Windows and Linux single-monitor PCs; uses absolute mouse.
Relative	For Windows and Linux; relative mouse used for all monitors.
BIOS HD Mode	Simple keyboard-only mode to temporarily override the normal mode when using the system BIOS.

Some systems will have two monitors. If this is the case, click on the **Use Multi-Monitor Arrangement** toggle to work with the two monitors to move where the screens are in the mouse space.

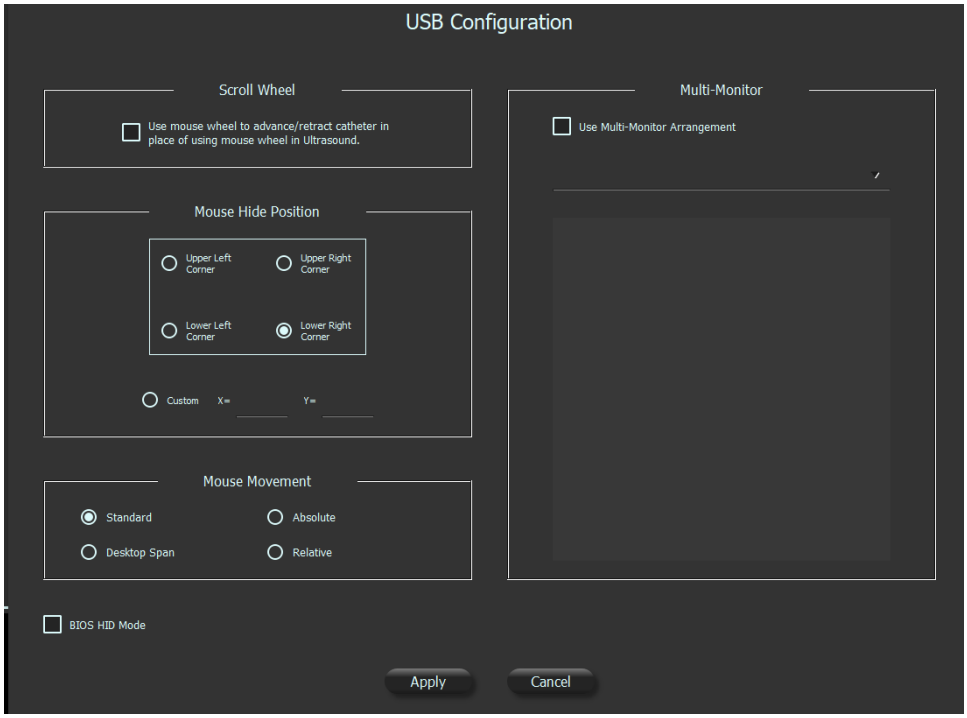


Figure 22. USB Configuration

Shutdown System

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

Cleaning and Disinfection Instructions

The *Synchrony* monitor should be cleaned in accordance with manufacturer guidelines. Clean the display with a diluted mixture of mild detergent and water. Use a soft cotton towel or swab. Use of certain detergents may cause degradation to the labels and plastic components of the product. Consult the cleanser manufacturer to see if agent is compatible. Do not allow liquid to enter the display.

⚠ **CAUTION:** Follow your hospital protocol for the handling of blood and body fluids and also follow your hospital protocol in case the display needs to be disinfected prior to installation.

⚠ **CAUTION:** Take care not to damage or scratch the front filter or LCD panel.

⚠ **CAUTION:** Do not use cloth made from synthetic material (polyester) as this may cause electrostatic dis- coloration within the LCD.

Portion of Display	Tested and Approved Cleaning Products
Cabinet	• Virex Ready-to-use Disinfectant Cleaner • Misty Clear Lemon 10 Disinfectant • Misty Multi- Purpose Disinfectant Cleaner • Misty Multi-Purpose Disinfectant Cleaner II. • Zep Heavy- duty glass & all surface cleaner. • Klear Screen Screen TFT (Kontakt Chemie). • Incidin Foam (Ecolab). • Microzid • Mild detergent. • Isopropyl alchohol with concentration < 5% • Household bleach (generic sodium hypochlorite, solutions of 5.25% sodium hypochlorite diluted with water between 1:10 and 1:100) • Precise Hospital Foam Cleaner Disinfectant

Portion of Display	Tested and Approved Cleaning Products
Front Filter	• Misty Clear Lemon 10 Disinfectant • Bohle glass cleaner. • Zep Heavy-duty glass & all surface cleaner. • Klear Screen • Screen TFT (Kontakt Chemie). • Incidin Foam (Ecolab). • Microzid • Mild detergent. • Isopropyl alcohol with concentration < 5% • Household bleach (generic sodium hypochlorite, solutions of 5.25% sodium hypochlorite diluted with water between 1:10 and 1:100)

CAUTION: Do not use on front filter:

• Alcohol/solvents at higher concentration > 5%. • Strong alkalis, strong solvents • Acid
• Detergents with fluoride. • Detergents with ammonia. • Detergents with abrasives.
• Steel wool • Sponge with abrasives • Steel blades. • Synthetic (polyester) cloth
• Cloth with steel thread

To clean the display's cabinet:

1. Using a soft cotton cloth, lightly moistened with a recognized cleaning product for medical equipment.
2. Repeat with water only.
3. Wipe dry with a dry cloth.

To clean the display's front filter:

1. Remove dust with a dry, lint-free, non-abrasive soft cotton cloth.
2. Remove fingerprints or grease using a lint-free, non-abrasive soft cotton cloth that is lightly moistened with plain water or a mild commercial glass cleaning product suited for coated glass surfaces.
3. Gently wipe dry with a dry cotton cloth

Drapes can be purchased to apply a sterile drape over the tableside user interface and maintain a sterile field to keep them clean throughout the procedure. Account Managers can assist in purchasing drapes as needed.

Periodic Maintenance

Periodically inspect the *Synchrony* fan inlets and outlets on the TPIs, VDMs and cabinet for excess dust accumulation. Use canned air or similar means to remove the excess dust. There are no parts of the *Synchrony* system that require calibration or adjustment.

TeleRobotic Support Team

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

7. Troubleshooting

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

Problem	Solution
Connection to the *Navigant* 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.
Hourglass displays on the *Synchrony* main menu window for more than 2 minutes.	Call the TST.
Non-*Navigant* window displays improper color or a noisy image.	Refer to the Configure Video section. If the problem persists, 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 *Navigant* computer.	Allow the system to shut down the *Navigant* computer. Then use the power button on the *Synchrony* cabinet to turn off the *Synchrony* hardware. If the problem persists, call the TST.
Unable to use the *Synchrony* mouse in the *Navigant* 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.

8. Index