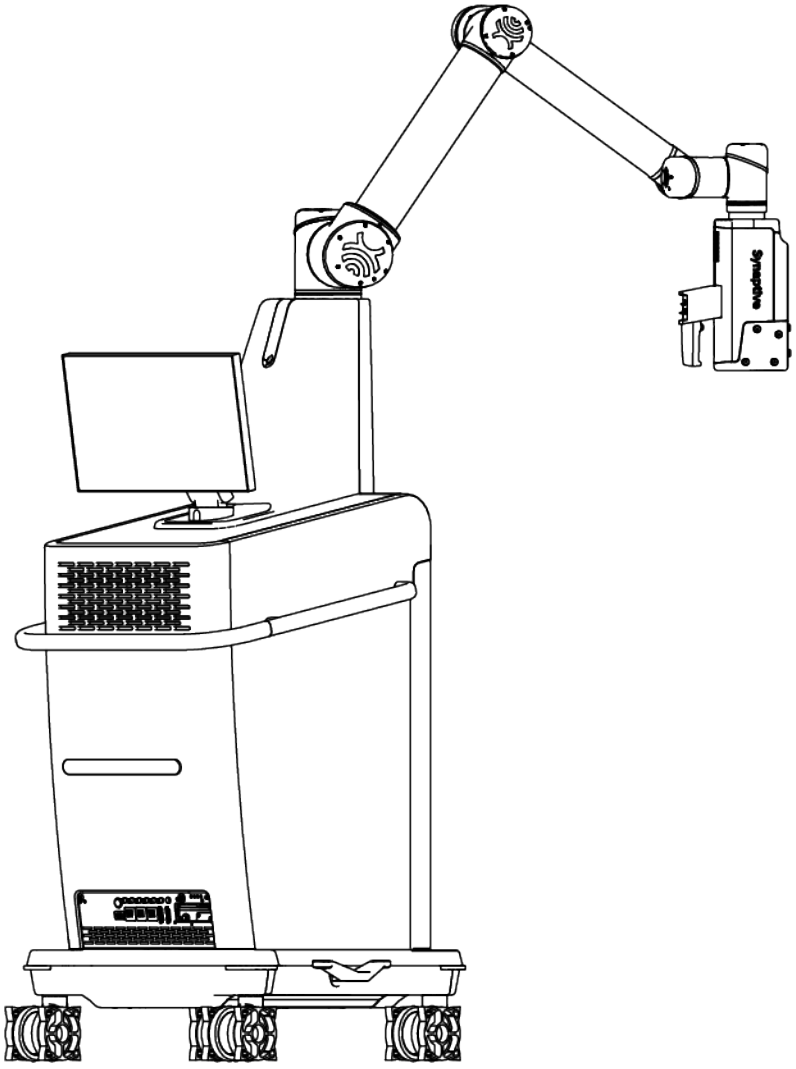
Modus™ X 4.3
User Manual

MAN-0677 Revision F



Synaptive

User Manual

Synaptive™ Modus™ X 4.3

SYN-0976, SYN-0988, SYN-0989, SYN-0990

Synaptive

SYN-0976 Basic UDI-DI: 67008200007LV
SYN-0988 Basic UDI-DI: 67008200008LX
SYN-0989 Basic UDI-DI:67008200009LZ
SYN-0990 Basic UDI-DI:67008200010LJ

MAN-0677 – Revision F issued on April 15, 2025.

These instructions for use are also available in electronic form at www.synaptivemedical.com/eIFU. The electronic instructions for use may be viewed on any device that can access the internet and display PDF files. Access to the electronic instructions for use requires a password; to obtain the password, contact Synaptive customer service.

Australian Sponsor:
Inovanz Pty Ltd
10/ 24 Lakeside Drive
Burwood East
Victoria, 3151
AUSTRALIA

Modus X, Modus Yellow, and Modus Blue fulfill all the relevant provisions in Regulation (EU) 2017/745 of the European Parliament and of the Council. Based on this regulation, the CE mark is hereby affixed:

CE

EC REP EU Authorized Representative:
Medical Device Safety Service (MDSS)
Schiffgraben 41
30175 Hannover, Germany

CH REP Swiss Authorized Representative:
MDSS CH GmbH
Laurenzenvorstadt 61
5000 Aarau, Switzerland

Modus IR is not CE marked and not authorized for sale in the European Union.

Synaptive Medical Inc.
555 Richmond Street West, Suite 800
Toronto Ontario M5V 3B1 Canada
1-844-462-7246
www.synaptivemedical.com

Table of Contents

1.0 Introduction

Modus X is a fully-automated exoscope for surgical visualization. This manual describes the Modus X system components and how to use them. Read and become familiar with the information in this manual before using the Modus X system.

NOTE: The graphics and medical images in this manual are examples only. The actual design and display on your system may vary.

1.1 Intended Use

1.1.1 Modus X Intended Use

Modus X is a positioning system for optical devices used for extracorporeal visualization of the operating field during surgery.

Modus X is ideally suited for visualizing open procedures such as those performed in cranial, spinal, and ENT surgery.

The system may be operated only by trained personnel such as surgeons and other clinic staff.

1.1.2 Fluorescence Modules Intended Use

NOTE: The fluorescence modules are separately licensed features and are subject to regional availability limitations. They may not be available with your Modus X system. For information about enabling the fluorescence modules, contact Synaptive customer service.

Modus Blue is a Modus X accessory intended to be used for fluorescence observation of fluorophores with an excitation range between 390 – 410 nm and emission in the 450 – 710 nm spectral band.

Modus Yellow is a Modus X accessory that aids in viewing intra-operative blood flow in the cerebral vascular area with an excitation range between 460 – 500 nm and emission in the 520 – 710 nm spectral band.

Modus IR is a Modus X accessory that aids in viewing intra-operative blood flow in the cerebral vascular area including, but not limited to, inspection of cerebral aneurysms, vessel bypass and vessel patency, as well as blood flow following plastic and reconstructive surgery.

1.1.3 Intended Use Environment

The Modus X system is intended for use in hospitals, clinics, and other medical institutions.

1.1.4 Contraindications

Modus X is not an endoscope and must therefore only be used outside the body.

1.2 Clinical Benefits

Modus X is a fully-automated surgical exoscope featuring 4K 3D optics, delivering next-generation surgical visualization. Modus X can be controlled hands-free using tracked instruments and AI enabled voice control, as well as using manual modes, giving surgeons unparalleled control and efficiency during surgery.

Modus X provides fluorescence visualization to support fluorescence guided surgery. Additionally, Fluorescence Fusion software can combine white light with fluorescence visualization for added anatomical context during critical steps in the procedure. With a high depth of field, and digital augmentation for optimal color reproduction and lighting, Modus X provides a clear view of important anatomical structures with superior visualization[1] and tissue differentiation over conventional imaging[2,3].

Modus X has been found to reduce complications such as blood loss[2,13] and those associated with patient positioning and surgical approach[4], and to improve resection while reducing the need for aggressive retraction[5] when compared with conventional technology. Modus X enables MIS approaches due to optimal light delivery and clear visualization[4,6], which have been found to further reduce complications[6-9,

---

1. Schupper et al. Contemporary intraoperative visualization for GBM with use of exoscope, 5-ALA fluorescence-guided surgery and tractography. JNS Neurosurgical Focus Video, 2022.
2. Baron et al., Postoperative outcomes following glioblastoma resection using a robot-assisted digital surgical exoscope: a case series. Journal of Neuro-Oncology, 2020.
3. Schupper et al. Robotic-Assisted Digital Exoscope for Resection of Cerebral Metastases: A Case Series. Operative Neurosurgery, 2021.
4. Roa et al., Use of the 3D exoscope for the supracerebellar infratentorial approach in the concorde position: an effective and ergonomic alternative. Illustrative cases. J NeuroSurg, 2022.
5. Hines et al., Exoscope improves visualization and extent of hippocampal resection in temporal lobectomy. Acta Neurochir, 2022.
6. Doers, Initial Experience with a Robotics Guided Optics Platform in Spine Surgery. Presented at NASS, 2016.

[14, 15], as well as anesthesia[7,10], length of stay[6,10,13], and OR time[6,10,13], and contribute to significant cost reduction[8,11,12].

1.3 Device Lifetime

Modus X has an expected lifespan of five years. This lifespan assumes that regular maintenance and service is performed by qualified Synaptive Medical authorized service providers.

1.4 Product and Safety Symbols

Table 1 ISO 7000 - Graphical symbols for use on equipment - Registered symbols and ISO 15223-1 - Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

Symbol	Title	Reference	Description
	Caution	ISO 7000-0434A	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Manufacturer	ISO 7000-3082	Indicates the medical device manufacturer. The date of manufacture, as well as the name and address of the manufacturer, can be combined in this symbol.
	Date of manufacture	ISO 7000-2497	To indicate the date on which a product was manufactured.

7. Chakravarthi et al., Awake Surgical Management of Third Ventricular Tumors: A Preliminary Safety, Feasibility, and Clinical Applications Study. Operative Neurosurgery, 2019.
8. Hofstetter et al., Economic impact of minimally invasive lumbar surgery. World Journal of Orthopedics, 2015.
9. Parker et al., Post-Operative Infection after Minimally Invasive versus Open Transforaminal Lumbar Interbody Fusion (TLIF): Literature Review and Cost Analysis. Minimally Invasive Neurosurgery, 2011.
10. Banczerowskiet al., Minimally invasive spine surgery: systematic review. Neurosurgery Review, 2015.
11.Coppens, Minimally Invasive Parafascicular Surgery in ICH: Economic argument for early surgery. Presented at SSG, 2018.
12.Parker et al., Minimally Invasive versus Open Transforaminal Lumbar Interbody Fusion for Degenerative Spondylolisthesis: Comparative Effectiveness and Cost-Utility Analysis. World Neurosurgery, 2014.
13.Nawabi et al., Intraoperative Performance with the Exoscope in Spine Surgery: An Institutional Experience. World Neurosurgery, 2023.
14.Schupper et al., A Multicenter Study Investigating the Surgeon Experience with a Robotic-Assisted Exoscope as Part of the Neurosurgical Armamentarium. World Neurosurgery, 2023.
15.Kusyk et al., Surgical Posture with Microscopic Versus Exoscopic Visualization in Anterior Cervical Procedures. World Neurosurgery, 2023.

Table 1 ISO 7000 - Graphical symbols for use on equipment - Registered symbols and ISO 15223-1 - Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied (continued)

Symbol	Title	Reference	Description
	Consult instructions for use or consult electronic instructions for use	ISO 7000-1641	Indicates the need for the user to consult the instructions for use.
	Circuit breaker	ISO 7000-2400	To identify the circuit breaker.
	Sterilized using ethylene oxide	ISO 7000-2501	To indicate that the device is provided sterile and has been sterilized using ethylene oxide.
	Do not reuse	ISO 7000-1051	To indicate that the item is for single use only and must not be used more than once, for example on packages of medical disposables.
	Catalog number	ISO 7000-2493	To identify the manufacturer's catalog number, for example on a medical device or the corresponding packaging.
	Serial number	ISO 7000-2498	To identify the manufacturer's serial number, for example on a medical device or its packaging.
	Batch code	ISO 7000-2492	To identify the manufacturer's batch or lot code, for example on a medical device or the corresponding packaging.
	Mass; weight	ISO 7000-1321B	To indicate mass. To identify a function related to mass.
	Do not use if package is damaged	ISO 7000-2606	Indicates a medical device that should not be used if the package has been damaged or opened.
	Fragile; handle with care	ISO 7000-0621	To indicate that the contents of the transport package are fragile and the package shall be handled with care.
	Keep dry	ISO 7000-0626	Indicates a medical device that needs to be protected from moisture.

Table 1 ISO 7000 - Graphical symbols for use on equipment - Registered symbols and ISO 15223-1 - Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied (continued)

Symbol	Title	Reference	Description
	Use by date	ISO 7000-2607	To indicate that the device should not be used after the date accompanying the symbol, for example on a medical device or its packaging.
	Humidity limitation	ISO 7000-2620	To indicate the acceptable upper and lower limits of relative humidity for transport and storage.
	Temperature limit	ISO 7000-0632	To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used.
	Air	ISO 7000-0537	To indicate air.
	Caution, infrared radiation	ISO 7000-6151	To indicate openings through which possibly hazardous infrared radiation can be emitted, and areas where exposure to infrared radiation can be expected.

Table 2 ISO 7010 - Graphical symbols - Safety colors and safety signs - Registered safety signs

Symbol	Title	Reference	Description
	General warning sign	ISO 7010-W001	To signify a general warning.
	Refer to instruction manual/booklet	ISO 7010-M002	To signify that the instruction manual/booklet must be read.
	No leaning against.	ISO 7010-P041	To prohibit leaning against an object.

Table 3 IEC 60417 — Graphical Symbols for Use on Equipment

Symbol	Title	Reference	Description
	Alternating current	IEC 60417-5032	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.

Table 3 IEC 60417 — Graphical Symbols for Use on Equipment (continued)

Symbol	Title	Reference	Description
	Emergency stop	IEC 60417-5638	To identify an emergency stop control device.
	Equipotentiality	IEC 60417-5021	To identify the terminals which, when connected together, bring the various parts of a system to the same potential, not necessarily being the earth (ground) potential (for example, for local bonding).
	Stand-by	IEC 60417-5529B	To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition, and to identify the control to shift to or to indicate the state of low power consumption. Each of different states of power consumption may be indicated using a corresponding color.
	Video output	IEC 60417-5529B	To identify video equipment output controls and connecting terminals.
	Battery check	IEC 60417-5546	To identify a control to check the condition of a primary or secondary battery or to identify the battery condition indicator.

Table 4 Product Safety Certification Marks

Symbol	Title	Reference	Description
CE	CE mark	N/A	Conformity with the essential requirements set out in the European Directives.
EC REP	Authorized representative in the European Community/ European Union	N/A	Indicates the authorized representative in the European Community/European Union.
CH REP	Authorised representative for Switzerland	N/A	Indicates the authorised representative in Switzerland.
TÜV SÜD C US	cTUVus Certification Mark	N/A	Certified as meeting North American safety standards by TUV.

Table 5 Other Symbols

Symbol	Description
	U.S. Federal law restricts this device to sale by or on the order of a licensed healthcare provider.
	Indicates the item is a medical device.
	To indicate that the device may not be disposed of in landfill but must be recycled according to the European Waste Electrical and Electronic Equipment (WEEE) directive.

1.5 Warnings and Precautions

CAUTION

Federal law (U.S.A.) restricts this device to sale by or on the order of a surgeon.

WARNING: Risk of Patient Death or Permanent Disability Due to Improper Use of the System

Use the system for the indications specified in this user manual only.

Exercise caution when operating Modus X to prevent unintended or unexpected system behavior.

Failure to follow the instructions for use and understand system behavior may result in unexpected system performance, procedure delay and patient or operator injury.

WARNING: Risk of Patient Death or Permanent Disability Due to Malfunctioning Equipment

Inspect Modus X upon receiving the system and prior to first use. Do not use the Modus X system if it appears to be damaged or malfunctioning in any way. Ensure that no damage has occurred during the shipping process.

Always inspect the Modus X system prior to surgery. Do not use the system if it appears to be damaged or malfunctioning in any way. Damaged or malfunctioning equipment may cause:

- Components of the system to fall under gravity and collide with the patient, surgeon, surgical tools, or surgical site
- Unexpected behavior, including unexpected arm movements causing collisions with itself, the patient, surgeon, or surgical tools, and loss of function causing procedure delay
- Damage to Modus X or nearby equipment

Always route the cable bundle as described in this manual. An improperly routed cable may become taut during arm motion causing loosening of external components that may fall and strike the surgical site.

WARNING: Risk of Patient Death or Permanent Disability Due to Malfunctioning Equipment

Do not lean on the Modus X positioning arm. Leaning on the arm may damage it, causing it, or parts of it to collide with the patient.

External electromagnetic interference (EMI) may lead to damaged or malfunctioning equipment. Damaged or malfunctioning equipment may cause components of the system to fall or drop and collide with the patient, surgeon, surgical tools or surgical site.

A loss of mains power may cause equipment to malfunction. Malfunctioning equipment may cause components of the system to fall or drop and collide with the patient, surgeon, surgical tools or surgical site.

Do not connect any equipment not specified in this manual to the Modus X system. The Ethernet ports on the Modus X mobile base may be used to connect Modus X to other Synaptive equipment only. The USB port on the Modus X mobile base is for file export purposes only. Do not use the USB port to connect any device other than a USB storage device to Modus X.

Use of Modus X adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, observe Modus X and the other equipment to verify that they are operating normally.

Blocking the vents on the Modus X positioning arm or mobile base can cause the system to overheat, damaging internal components, creating hot external surfaces, or causing components to ignite.

Sources of infrared light in the operating room will interfere with the Modus X optical system when it is using an infrared (IR) optical preset. This interference can cause flickering in the video field which may interfere with the view of the surgical field or trigger an epileptic seizure in susceptible persons.

WARNING: Risk of Infection Due to Contamination of Sterile Equipment

Use caution when draping patients and equipment. Always drape the positioning arm outside of the patient environment. Always follow the draping instructions in this manual, all applicable draping protocols in use at your site, and protocols for maintaining a sterile field.

When draping the positioning arm, ensure that there is enough slack in the drape that the drape will not become torn during arm movement.

Only those parts of the Modus X system that have been draped are sterile. Use caution during surgery to prevent contaminating the sterile field.

A torn sterile drape will compromise the sterile field. Exercise clinical judgment in cases where the drape is suspected to have been compromised. Re-draping is at the discretion of qualified clinical staff.

Failure to properly secure the microphone and its cable may cause them to fall or dangle and possibly contact the surgical site.

Touching parts of the system that have sterility requirements with non-sterile objects, or vice versa, will compromise the sterile field.

WARNING: Risk of Infection Due to Contamination of Sterile Equipment

Failure to properly clean the Modus X device, peripherals, or accessories may lead to cross-contamination.

No part of the Modus X unit or peripheral components is sterilizable by the user.

WARNING: Risk of Patient Injury Due to Light Sources

Although it is very unlikely, the Modus X light sources are capable of producing light intense enough to cause tissue burns. The risk of tissue burns is affected by factors such as:

- The length of exposure (longer surgical procedures increase the risk)
- Materials adjacent to the surgical site (such as incision drapes) and local vasoconstrictive medications
- The location of the procedure (some areas of the body may be more sensitive than others)
- The patient's skin type and general health
- Medications that affect sensitivity to light
- The distance between the end effector and the body.

To reduce the risk of injury to the patient, take protective measures such as:

- Regularly irrigating the illuminated surgical field to keep it moist
- Covering illuminated areas with moistened sterile gauze
- Regularly re-moistening any drapes in use in illuminated areas

Never leave Modus X unattended when the light sources are on.

During certain electromagnetic compatibility (EMC) events, the auxiliary light source may be influenced by RF energy. Use external light sources if the performance of the Modus X is insufficient or leads to patient discomfort.

WARNING: Risk of Patient Death or Permanent Disability Due to Modus X Collision with Patient, Surgeon or Surgical Tools During General Use

Although Modus X includes numerous safety controls, when the positioning arm is moving in the patient environment there is always a risk of components of the system accidentally colliding with themselves, the patient, surgeon, or surgical tools. Always observe the positioning arm carefully when it is moving and stop motion if necessary.

To avoid accidentally colliding with the patient, surgeon, or surgical tools, never start up, restart, or shut down Modus X while the positioning arm is within range of the patient.

Using surgical tools that extend past the Modus X standoff distance may result in a collision between the end effector and the surgical tools. For more information, see 2.1.7.4 End Effector Standoff Distance on page 34.

WARNING: Risk of Patient Death or Permanent Disability Due to Modus X Collision with Patient, Surgeon or Surgical Tools During General Use

To prevent a collision between Modus X and the surgeon, surgical tools, and/or surgical site, always move the positioning arm away from the surgical site before moving the surgical table (including vertical movement of the surgical table) or moving the Modus X mobile base.

The positioning arm may not always follow the same route when moving into memory positions or when moving backward and forward through history positions. Observe the positioning arm carefully when it is moving into these positions and stop motion if necessary.

Modus X cannot prevent a collision between the positioning arm and untracked surgical tools or instrumentation that extend past the skin surface.

No part of Modus X is intended to support a person's weight. Do not lean on the positioning arm. This may damage the positioning arm and cause it, or parts of it, to collide with the patient. Do not lean, sit, or step on the mobile base. This may cause the mobile base to move unexpectedly in such a way as to collide with the patient.

When Modus X is moving into the stored positions specified in the Arm Movement controls, there are no controls in place to enforce a minimum standoff distance and avoid a collision with the patient, surgeon or surgical tools. Never move Modus X using the Arm Movement screen when it is in the patient environment.

Always ensure that the e-stop is accessible when positioning and using Modus X. The e-stop can be used to stop movement of the positioning arm.

The positioning of Modus X may interfere with responding to patients in an emergency situation. Always move the positioning arm away from the patient before moving the Modus X mobile base in an emergency situation.

WARNING: Risk of Patient Death or Permanent Disability Due to Modus X Collision with Patient, Surgeon or Surgical Tools When Aligning to a Position

When moving into a saved position (memory or history position, or one of the stored positions listed on the Arm Movement screen) Modus X does not enforce a minimum standoff distance to prevent a collision with the patient, surgeon or surgical tools. Observe the positioning arm carefully when moving into these positions and stop motion if necessary.

The positioning arm may not always follow the same route when moving into memory positions or when moving backward and forward through history positions. Observe the positioning arm carefully when it is moving into these positions and stop motion if necessary.

WARNING: Risk of Patient Death or Permanent Disability Due to Modus X Collision with Patient, Surgeon or Surgical Tools When Aligning to a Trajectory

If the Synaptive patient reference is moved relative to the patient after the patient registration has been accepted in Modus Nav, Modus X cannot accurately align to the trajectory. This may result in unexpected movement of the positioning arm, causing a potential collision with the patient, surgeon, or surgical tools. Always observe the positioning arm carefully when it is moving and stop motion if necessary.

WARNING: Risk of Patient Death or Permanent Disability Due to Modus X Collision with Patient, Surgeon or Surgical Tools When Aligning to a Trajectory

Modus X communicates with Modus Nav to receive real-time information about the trajectory being aligned to. Changing the trajectory in Modus Nav, or shutting down Modus Nav while aligning to a trajectory, may result in unexpected movement of the positioning arm causing a potential collision with the patient, surgeon, or surgical tools. Always observe the positioning arm carefully when it is moving and stop motion if necessary.

WARNING: Risk of Patient Death or Permanent Disability Due to Modus X Collision with Patient, Surgeon or Surgical Tools When Moving the Positioning Arm

To avoid accidentally colliding with the patient, surgeon, or surgical tools, never perform individual joint moves using the Arm Movement screen in the Modus X software when the Modus X positioning arm is positioned within range of the patient.

Modus X cannot prevent a collision between the positioning arm and tracked tools in the surgical site when tracking is disabled while an infrared (IR) optical preset is in use.

To avoid accidentally colliding with the patient, surgeon, or surgical tools, always be aware of the surgical site when moving the positioning arm manually or using the motion controls. The arm should always be positioned at a safe distance from the surgical site.

WARNING: Risk of Patient Death or Permanent Disability Due to Obscured View of Surgical Site

Clip recording playback will partially or completely obscure the view of the surgical site on the monitor(s). Use the advanced playback controls to control how clip recording playback is displayed.

WARNING: Risk of Patient Injury Due to Improper Treatment

Clearing the video clip recordings list will result in the clip recordings being unavailable for playback on the external monitor. The inability to play back a clip recording may result in improper treatment for the patient, or a delay in completing the procedure.

Operating outside of the recommended fluorescence mode parameters may result in unreliable visualization of the fluorescent areas. These parameters include:

- Working distance too large
- Zoom setting too high

For information about using the Modus X fluorescence modules, see 9.0 Fluorescence on page 112.

The fluorescence optical presets have been designed to optimize viewing of the fluorescence signal. Any changes to the optical settings, including light intensity, when using the fluorescence optical presets may result in unreliable visualization of the fluorescent areas.

Always use the designated Modus IR drape for procedures that will use a Modus IR optical preset. Using the incorrect drape may result in a reduction of the IR signal. For more information, see 2.3 Drapes on page 42.

WARNING: Risk of Patient or Operator Injury Due to Unexpected Positioning Arm Movement

Improper draping may cause unintended actuation of end effector buttons and unexpected arm movements and collision with the patient, surgeon, surgical tools or surgical site.

Incorrectly calibrated tools may cause unexpected arm movements and collision with the patient, surgeon, surgical tools or surgical site.

Stowing the pedal while it is connected to the system may result in accidental actuation of the pedal and unintended arm movements.

The positioning arm may drop slightly if power is cut to it (for example when the emergency stop is pressed). To avoid the possibility of unexpected contact with the positioning arm, do not stand directly under the arm.

Commanding arm motion from the touchscreen UI while the surgeon is operating may cause operator or patient harm.

WARNING: Risk of Patient Injury

Movement of the mobile base or surgical table during a procedure can cause components of the system to collide with the patient, surgeon, surgical tools or surgical site. Use caution when adjusting the height of the surgical table to ensure the patient does not collide with the Modus X positioning arm.

The light from illuminators on the end effector is bright enough to cause temporary blindness or patient discomfort. Use caution when moving the positioning arm around the patient's face.

Always attach the tracking spheres firmly to the end effector and tool posts. Loosely attached spheres may fall and strike the surgical site.

WARNING: Risk of Operator Injury Due to Electrical Shock

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

Unplugging the power cord is the means to isolate Modus X from the supply mains. Do not position Modus X such that it is difficult to unplug.

The Modus X system contains electrical components that may cause shock if the system is damaged or malfunctioning.

WARNING: Risk of Operator Injury Due to Tipping Hazard

Do not apply excessive force to the Modus X positioning arm or mobile base. This may cause the Modus X system to tip.

No part of Modus X is intended to support a person's weight. Do not lean on the positioning arm. Do not lean, sit, or step on the mobile base. This may cause the Modus X system to tip.

WARNING: Risk of Operator Injury Due to Pinch Hazard

The Modus X system contains moving parts that may create pinch hazards.

WARNING: Risk of Operator Injury Due to Sharp Edges

Damage to the Modus X system may expose sharp edges.

WARNING: Risk of Operator Injury Due to Burn Hazard

Damaged or malfunctioning equipment may cause components of the Modus X system to overheat and create hot surfaces.

WARNING: Risk of Operator Injury Due to Tripping Hazards

The cables connecting Modus X to other equipment are a potential tripping hazard. When positioning Modus X for a procedure, always ensure that there is sufficient cable length to allow the cables to reach the floor. Use caution when walking around Modus X to avoid tripping over cables.

The Modus X mobile base is a potential tripping hazard. Use caution when walking around Modus X to avoid tripping.

WARNING: Risk of Operator Injury Due to Contact with Hazardous Materials

Wear all necessary personal protective equipment when handling contaminated components and cleaning supplies.

WARNING: Risk of Operator Injury

Poor management of external cables may interfere with movement of Modus X or other equipment in the operating room.

WARNING: Risk of Procedure Delay Due to Loss of Modus X Functionality

Modus X should only be used with accessories, tools and equipment made or validated by Synaptive Medical Inc. Do not use any tools or equipment not listed in the user manual with Modus X. Using Modus X with accessories, tools and equipment not made or validated by Synaptive may result in unexpected behavior, damage to the system or loss of function.

Do not bring any trackable tools not made by Synaptive Medical Inc. into the tracking camera's field of view.

Applying the arm drape improperly may cause tracking issues.

WARNING: Risk of Procedure Delay Due to Loss of Modus X Functionality

If there is insufficient data storage space available on Modus X, the system will not be able to record video or capture still image snapshots. Export and/or delete unneeded videos and snapshots regularly to ensure that sufficient data storage space is available.

Removing the main light source control key will cause the main light source to turn off and will prevent the system from passing the self-test when starting up.

Only the main light source can emit infrared light. If the main light source is turned off or is not functioning, infrared light will not be available and the infrared (IR) optical presets will not function as intended.

Applying excessive force to the end effector handle when initating a manual arm movement may cause the arm to become unresponsive. Reduce the force applied to the handle and try moving the arm again.

Use caution and observe cables when moving the Modus X mobile base to prevent cables from accidentally becoming disconnected.

CAUTION: Risk of Patient or Operator Discomfort

Modus X generates noise while in use, which may be startling or cause discomfort for patients or operators.

CAUTION: Risk of Procedure Delay

Obstructing the tracking camera's view of the end effector tracking array will result in loss of function due to Modus X being unable to track the end effector.

There is a risk of photobleaching of the fluorophores if high intensity fluorescence light is used for an extended period of time.

If the Ethernet cable connecting Modus X to the monitor is disconnected when the Modus IR picture in picture (PIP) feature is in use, the monitor will continue to display the PIP window and you will not be able to stop viewing the PIP window until you reconnect the Ethernet cable.

Storing the system for an extended period of time without powering on the system may cause the battery to have insufficient charge capacity.

CAUTION: Risk of Poor Quality Images of the Surgical Field

Modus X should only be used with monitors provided by Synaptive Medical. The use of a monitor other than that provided by Synaptive Medical could impact color, tissue differentiation or image quality. If using a monitor other than that provided by Synaptive Medical, image quality must be validated by surgical staff. Ensure that the image quality on the monitor is adequate for performing surgery.

Improper draping, or a damaged, dirty, or obscured drape window, may result in poor optical performance and an inadequate surgical image.

CAUTION: Risk of Poor Quality Images of the Surgical Field

Using picture-in-picture display may obstruct the view of the surgical overlay or the surgical site. See 10.3 Monitors on page 120 for information on how to toggle the picture-in-picture feature on or off.

Damaged or malfunctioning equipment may produce an inadequate surgical image.

CAUTION: Risk of Operator Injury or Damage to Equipment

Always route the optical cable bundle as described in this manual. An improperly routed cable may fray and cause an electrical shock hazard.

Use caution when moving Modus X system equipment to prevent collisions with people or stationary objects such as equipment, doorways, or walls. To prevent damage to the end effector and positioning arm, always move the Modus X positioning arm into the defined "stowed" position before moving Modus X through doorways or other spaces where there is a risk of the system colliding with walls or other objects.

Always use the mobile base handle to push and steer the mobile base when moving Modus X. Do not push on the positioning arm or any other part of the mobile base to move Modus X.

Use only the approved power cord supplied with Modus X. The use of non-approved power cords can result in damage to the Modus X system. The use of other accessories, transducers, and cables may result in increased electromagnetic emissions or decreased immunity of this equipment and may result in improper operation. If a cable becomes damaged, contact Synaptive customer service for assistance.

No modification of the Modus X system is allowed. Service or modification of the system by untrained persons may result in injury and/or damage to the system.

Use caution when transporting Modus X to prevent accidents, such as tipping or collisions, which may result in injury and damage to equipment.

CAUTION: Risk of Damage to Equipment

The Modus X system may be installed, maintained, repaired, and serviced only by qualified Synaptive Medical service representatives. There are no user-serviceable parts in the Modus X system.

Connecting the system to supply mains with an improper voltage may result in damage to the system.

Always route the optical cable bundle as described in this manual. Do not allow the cable to bundle to wrap around the arm as this may cause the cable bundle to become taut during arm motion, causing damage to internal components or the positioning arm to bind.

To prevent damage to the battery, do not allow it to discharge completely.

No part of Modus X is intended to support a person's weight. Do not lean on the positioning arm. This may damage the positioning arm or cause Modus X to tip. Do not lean, sit, or step on the mobile base.

CAUTION: Risk of Damage to Equipment

Be aware of cables at all times. Do not allow them to become snagged on other stationary equipment in the operating room. Excessive pulling on cables may damage them.

Do not roll the Modus X mobile base over cabling. Doing so may damage the cables. If the mobile base rolls over cabling, inspect the cable for damage. If the mobile base rolls over any object, inspect the castors for damage.

Use caution when rolling Modus X over bumps and thresholds to avoid damaging the system.

To avoid damage to the system, never submerge or allow liquids to enter the hardware components.

Operating or storing Modus X outside of the conditions described in this manual may result in damage to the system.

Although Modus X is certified to an internationally recognized standard as it pertains to electromagnetic compatibility (EMC), there is a chance that nearby equipment may generate electromagnetic interference, leading to system damage and loss of function.

CAUTION: Risk of Damage to Equipment - Draping

When placing a rubber band around the drape on the end effector, place the rubber band above the handle and below the vents. Do not place the rubber band over the vents on the end effector as this can negatively impact the thermal environment within the end effector, causing deteriorated performance or damage to internal components.

When applying the skirt drape to the mobile base, ensure that the drape does not cover the vents at the bottom of the mobile base.

CAUTION: Risk of Damage to Equipment - Pedals

To prevent possible damage to the pedals and their cables, stow the pedals on the mobile base before moving the Modus X system.

CAUTION: Risk of Damage to Equipment - Cleaning

Before cleaning and surface disinfection, turn off Modus X and disconnect it from its power source.

Synaptive Medical makes no claims regarding the efficacy of the listed chemicals or processes as a means for controlling infection. Consult your hospital's infection control officer and/or infection control Standard Operating Procedure.

Improper cleaning or the use of incompatible cleaning agents on Modus X, peripherals, and accessories may damage the system.

Do not use Cidex or other disinfectants to clean any of the Modus X components. Use only those cleaning agents described in this manual.

CAUTION: Risk of Damage to Surrounding Equipment

Although Modus X is certified to an internationally recognized standard as it pertains to electromagnetic compatibility (EMC), there is a chance of increased electromagnetic emissions, which may result in improper operation of surrounding equipment.

Damage to the Modus X system may result in increased electromagnetic emissions and potential interference with surrounding equipment.

CAUTION: Risk of Environmental Damage

The Modus X system contains components that may cause environmental damage if not disposed of correctly. See 11.5 Disposal on page 132 for information about disposing of Modus X system components.

Electrostatic Discharge (ESD) Safety

Do not touch the Modus X positioning arm without taking ESD precautions. These include:

- Methods to prevent electrostatic charge build-up (for example air conditioning, humidification, conductive floor coverings, non-synthetic clothing)
- Discharging your body to earth or a large metal object

1.6 Incident Reporting

Immediately report any serious incident that has occurred in relation to the use of this device to Synaptive Medical and, for EU customers, the competent authority of your Member State. For customers outside of the EU, immediately report any serious incident to your local competent authority.

1.7 Synaptive Customer Service Information

For 24-hour access to clinical and technical support, contact Synaptive customer service.

Phone:	1-844-462-7246 (North America)
	1-647-925-3435 (International)
Email:	service@synaptivemedical.com

2.0 Modus X System Components

The Modus X system consists of:

- The Modus X unit (the optics, positioning arm, and mobile base)
- Peripheral components
  - Pedals
  - Monitors
  - Tracking camera (optional)
- Drapes
- Tracking spheres

The following accessories can be used with Modus X:

- Synaptive Instruments
  - Standard Pointer
  - Long Pointer
  - Trackable Suction
- Synaptive Calibration Block
- Synaptive Multi-Tool Calibration Device

The following accessories can only be used if Modus X is connected to Modus Nav.

- Synaptive Patient Reference
- Tracking Array for the NICO BrainPath

For a complete list of peripherals and accessories available for use with Modus X, see 12.4 Compatible Peripherals and Instrumentation on page 149.

NOTE: Modus X accessories and peripheral components are optional and subject to regional availability limitations. Your system may not include all the accessories and peripheral components listed in this manual. Refer to the manuals and instructions provided with Synaptive accessories and peripheral components for complete information about them, including their intended use, contraindications, and instructions for use.

2.1 Modus X Components

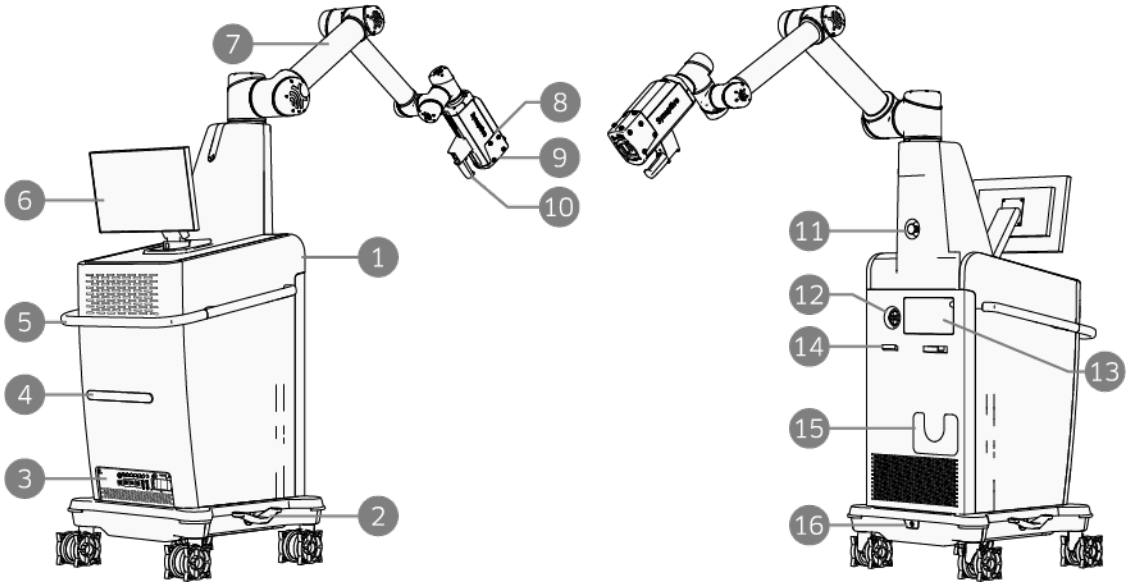


Figure 1 Modus X components (back and front views)

1	Mobile base	9	Optics
2	Caster brake	10	End effector handle
3	I/O panel	11	Emergency stop (e-stop)
4	Cable cleat	12	Auxiliary light source connectors
5	Mobile base handle	13	Main light source connector cover
6	Touchscreen monitor	14	Hook for stowing multi-input pedal
7	Positioning arm	15	Pocket for stowing single-input pedal
8	End effector tracking array	16	Foot pedal connection

2.1.1 Mobile Base

The mobile base houses the computers that run the Modus X software, a battery to provide backup power to Modus X, and connectors for external components including the foot pedals, light sources, display monitors, and the Modus Nav operator cart.

CAUTION: Risk of Operator Injury or Damage to Equipment

Always use the mobile base handle to push and steer the mobile base when moving Modus X. Do not push on the positioning arm or any other part of the mobile base to move Modus X.

2.1.2 Emergency Stop (e-stop)

WARNING: Risk of Patient Death or Permanent Disability Due to Modus X Collision with Patient, Surgeon or Surgical Tools During General Use

Always ensure that the e-stop is accessible when positioning and using Modus X. The e-stop can be used to stop movement of the positioning arm.

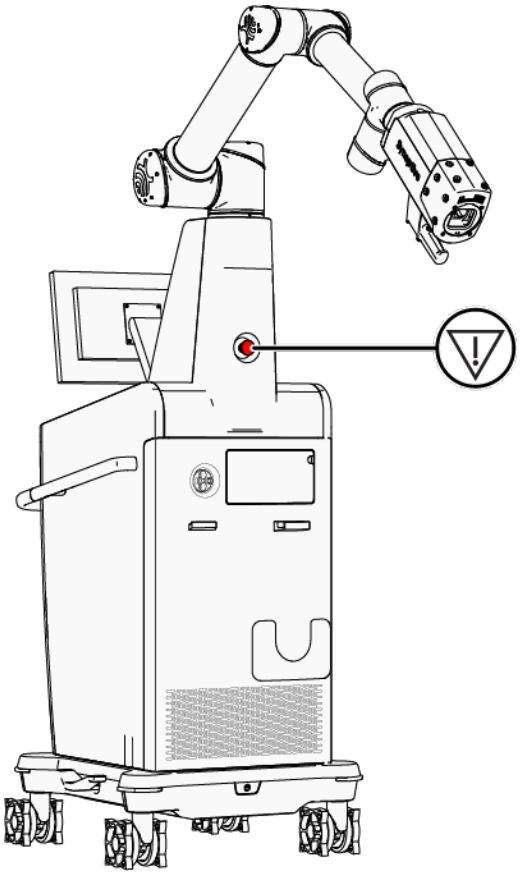


Figure 2 E-stop location on the mobile base

The emergency stop (e-stop) is an important safety feature on Modus X. Pressing the e-stop cuts power to the arm, halting motion immediately and freezing the arm in place. When pressing the e-stop, power to the mobile base is not cut and some functions will remain usable.

When the e-stop is pressed, the button remains locked in the pressed position and you cannot continue with a procedure until it is released. To release the e-stop, turn the button clockwise until it pops up.

2.1.3 Caster Brakes

Use the brake pedals (located on each side of the mobile base) to control how the Modus X mobile base moves.

The brake pedals operate in three modes:

- When the green side is down, the front casters are locked and only the rear casters swivel. This is useful for moving Modus X in a straight line.
- In the neutral position, movement is permitted in all directions.
- When the red side is down, all casters are locked and the mobile base cannot be moved.

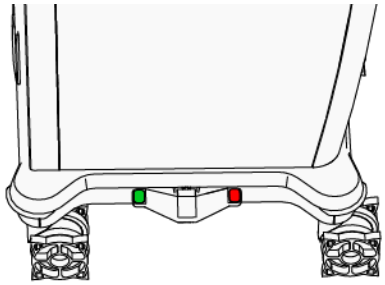


Figure 3 Modus X caster brake pedal

When you are not moving Modus X, always lock the caster brakes (with the red side down) to prevent unintended motion.

NOTE: The positioning arm can only be moved when the caster brakes are locked.

2.1.4 I/O Panel

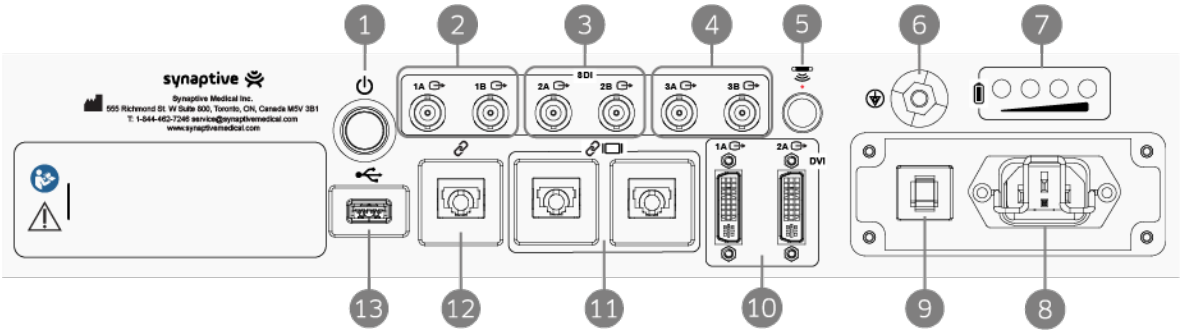


Figure 4 Modus X I/O panel

1 Power button
2 SDI outputs (A & B) to main monitor
3 SDI outputs (A & B) to auxiliary monitor
4 Raw SDI outputs (A & B)
5 Lemo connection for tracking camera input
6 Equipotential grounding pin (potential equalization point)
7 Battery status LEDs
8 Power inlet*
9 Circuit breaker
10 Main and auxiliary DVI outputs
11 Ethernet ports for connecting to monitors
12 Ethernet port for connecting to Modus Nav
13 USB 3.0 port

* Refer to the product labels affixed to your Modus X system for specific ratings information.

WARNING: Risk of Patient Death or Permanent Disability Due to Malfunctioning Equipment

Do not connect any equipment not specified in this manual to the Modus X system.

Do not use the Ethernet ports (items 11 and 12 in Figure 4) to connect Modus X to any system other than the monitors and the Modus Nav operator cart.

The USB port (item 13 in Figure 4) is for video, snapshot, and log file export purposes only. Do not use the USB port to connect any device other than a USB storage device to Modus X.

WARNING: Risk of Operator Injury or Damage to Equipment

Use only the approved power cord supplied with Modus X. The use of non-approved power cords can result in damage to the Modus X system. The use of other accessories, transducers, and cables may result in increased electromagnetic emissions or decreased immunity of this equipment and may result in improper operation. If a cable becomes damaged, contact Synaptive customer service for assistance.

NOTE: When connecting cables to Modus X, always tighten the screws on the connectors to ensure that cables do not become disconnected when moving Modus X.

NOTE: Using a power cord that is not approved for use with Modus X, or operating Modus X in too hot of an environment may cause the Modus X circuit breaker to trip. In the event that the circuit breaker trips, contact Synaptive service.

2.1.5 Light Sources

CAUTION: Risk of Procedure Delay Due to Inappropriate Functionality

If Modus X light sources do not function as intended, use an external source of light to continue with the procedure.

Modus X is equipped with two light sources:

- A main light source that provides light to the illuminators on the end effector
- An auxiliary light source that can be used to provide light to other equipment you are using with Modus X or as a backup if the main light source fails (white light only)

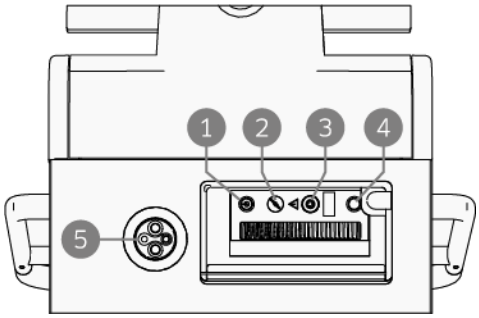


Figure 5 Modus X light source connectors

1 Main light source power button

NOTE: The light source powers on automatically when Modus X starts up. Do not use this power button.

2 Main light source key control

3 Main light source connector

4 Main light source interlock reset button

5 Auxiliary light source connector

The light guide coming from the Modus X positioning arm is plugged in to the main light source. If you need to access the light guide (for example to switch to the auxiliary light source in the event that the primary light source fails) open the panel on the front of the Modus X mobile base and unplug the light guide.

The main light source provides light modes appropriate to the optical presets available in Modus X. When you select an optical preset on the Procedure screen, Modus X automatically switches to the light mode appropriate for that preset. Use the MAIN LIGHTS controls on the Procedure screen turn the main light

source on or off and to adjust the main light intensity. For more information, see 5.4 Adjusting Lights and Image Brightness on page 86.

You can adjust the light intensity for the auxiliary light source on the Light Sources settings screen. For more information, see 10.4 Light Sources on page 121. For information about using the auxiliary light source, see 3.3.10 Using the Auxiliary Light Source on page 69.

NOTE: When a light guide is not connected to a light source, the light source is in an interlock state.

- **To reset the main light source, plug the light guide into the main light source connector and press the interlock reset button (item 4 in Figure 5).**
- **To reset the auxiliary light source, plug an appropriate cable into any of the connectors.**

NOTE: The main light source has a control key that must be inserted and turned to the "ON" position in order for the light source to function. Do not remove the control key from the main light source. If the control key is misplaced, contact Synaptive customer service for assistance.

2.1.6 Battery

Modus X is equipped with a battery that will provide power to keep the system running in emergency power loss situations for five minutes. If using the Modus X battery for non-power loss situations, ensure that Modus X is reconnected to a power supply within five minutes.

NOTE: To ensure the proper charge capacity of the battery, do not store Modus X for extended periods of time without plugging in the system to fully charge the battery.

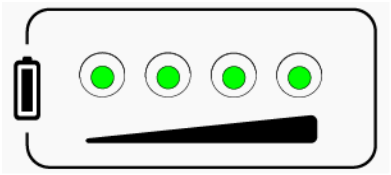


Figure 6 Battery indicator LED lights on Modus X rear panel

The battery recharges when Modus X is plugged in. The battery LED lights on the Modus X mobile base indicate the remaining battery charge. When Modus X is unplugged, a notification sounds (two beeps) until you plug Modus X into a power outlet. For more information about the battery indicator LED lights, see 12.3 LED Indicators on page 146.

CAUTION: Risk of Damage to Equipment

To prevent damage to the battery, do not allow it to discharge completely.

2.1.7 Positioning Arm

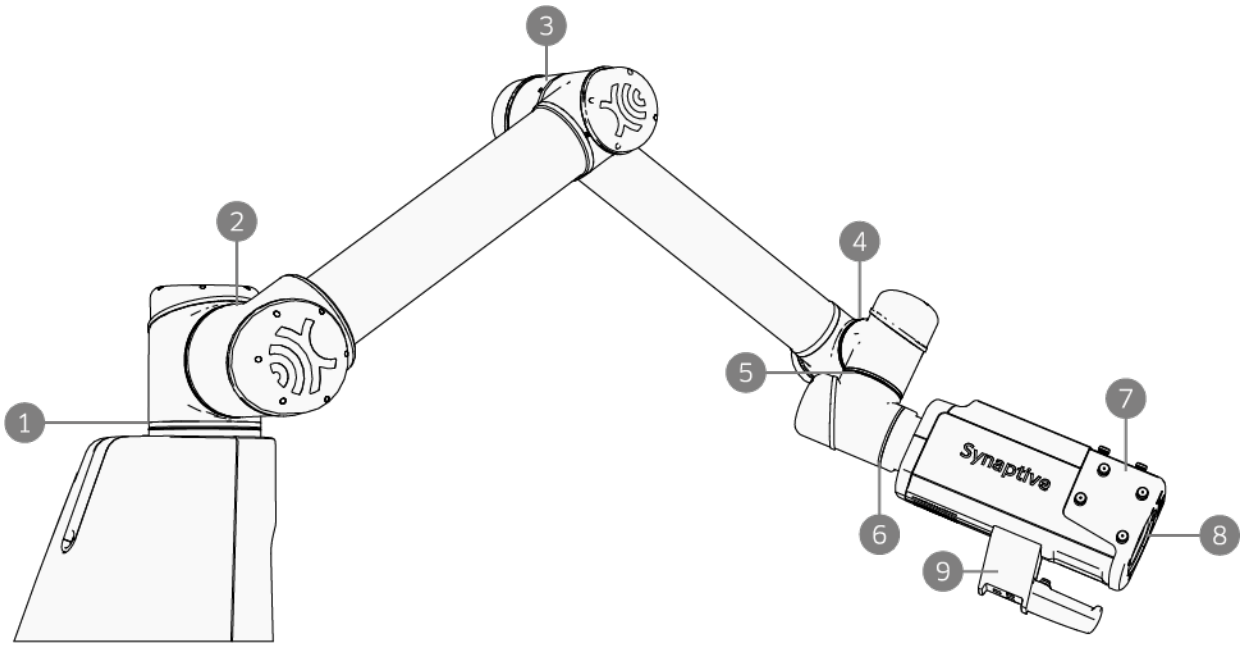


Figure 7 Positioning arm components

1	Joint A (base joint)	6	Joint F (end effector joint)
2	Joint B (shoulder joint)	7	End effector tracking array
3	Joint C (elbow joint)	8	Optics (surgical cameras and illuminators)
4	Joint D (wrist joint 1)	9	End effector handle
5	Joint E (wrist joint 2)		

The Modus X positioning arm positions the surgical cameras at your desired location in relation to the surgical field. There are several ways to use the positioning arm:

- Manually move the arm into an appropriate position using the end effector handle controls. For more information, see 2.1.7.2 End Effector Handle Controls on page 31.
- Use the pedal to command the arm to align to a tracked surgical tool or a trajectory from Modus Nav. For more information, see 7.1 Aligning to a Tool on page 99 or 7.2 Aligning to a Trajectory on page 107.
- Use the voice nudge feature and the pedal to move the arm small distances from its current position. For more information, see 4.4 Voice Nudge on page 80.
- Use the pedal to command the arm to move into a "saved" or "stored" position. This is a position that you have recorded, or a position that the arm has previously been in. For more information, see 6.0 Aligning to a Position on page 94. Stored positions include the Modus X default positions for storage and transportation. These positions are available from the Arm Movement screen in the Modus X software interface.
- Adjust the angles of individual joints in the arm using the software interface as described in 10.1 Arm Movement on page 117.

NOTE: To prevent unexpected movements, the arm will only respond to one input (for example, a pedal or the touchscreen UI) at a time.

2.1.7.1 Optics

The optics in the end effector consist of the surgical cameras and illuminators.

There are two surgical cameras in the end effector that provide the video feeds required for stereoscopic viewing. For more information, see 8.0 Stereoscopic Visualization on page 111. Video from the surgical camera can also be recorded in both 2D and 3D. For more information, see 5.5.1 Case Recording on page 88.

A light guide delivers light from the light source to the illuminators on the end effector. The light source connection is evenly split amongst the illuminators to provide uniform light to the surgical field. Use the light control features in the Modus X software to adjust the light intensity from the illuminators. For more information, see 5.4 Adjusting Lights and Image Brightness on page 86. For more information about the Modus X light sources, see 2.1.5 Light Sources on page 28.

2.1.7.2 End Effector Handle Controls

Use the switches and trigger on the end effector handle to access features in the surgical overlay, adjust zoom and focus, and manually position the arm.

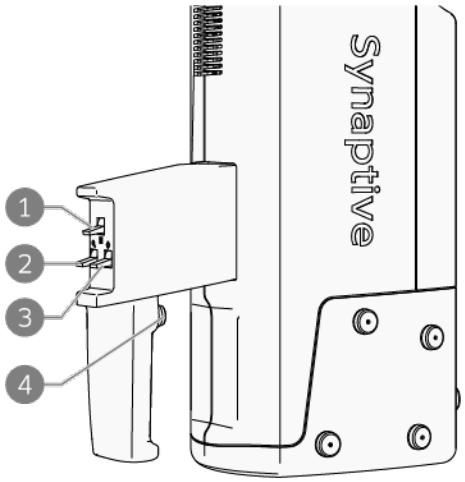


Figure 8 End effector controls

1 Quick menu and positioning mode switch. The behavior of this switch depends on whether the surgical overlay is currently being displayed. Use the Surgical Overlay settings to show or hide the overlay (see 10.7 Surgical Overlay on page 125).

When the surgical overlay is displayed:

Push up to access the brightness control options, then push up or down to adjust the brightness of the image on the monitors. Push down to change the end effector positioning mode and access the quick menu. When the quick menu is active, push up or down to move through the menu items. For more information, see 2.7 Quick Menu on page 53.

When the surgical overlay is not displayed:

Push up or down to toggle between the end effector positioning modes. For more information, see 2.1.7.3 End Effector Positioning Modes on page 32.

2 Zoom adjustment switch. Push up to zoom in and down to zoom out.

3 Focus adjustment switch.

When tool auto focus is enabled:

Push up or down to increase or decrease the tool auto focus offset. For more information, see 7.4 Auto Focusing on a Tool on page 108.

When tool auto focus is not enabled:

Push up or down to increase or decrease the focus distance.

4 Trigger.

When the quick menu is active:

Press the trigger to select the currently-highlighted menu item.

When the quick menu is not active:

Hold down the trigger to manually position the arm using the currently-selected positioning mode.

2.1.7.3 End Effector Positioning Modes

WARNING: Risk of Procedure Delay or Damage to Equipment Due to Loss of Modus X Function

Applying excessive force to the end effector handle when initating a manual arm movement may cause the arm to become unresponsive. Reduce the force applied to the handle and try moving the arm again.

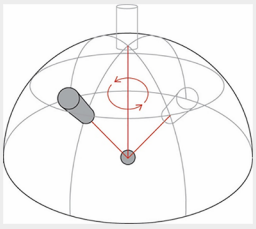
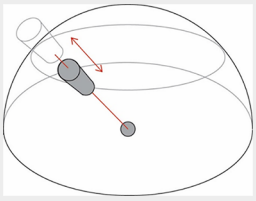
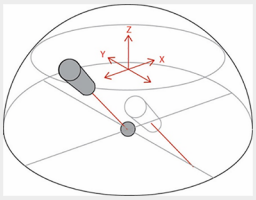
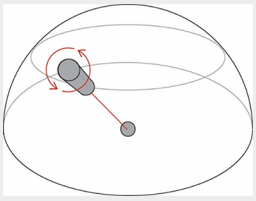
Modus X has six end effector modes that determine how the arm will move when the trigger on the end effector is held down. There are four ways to select an end effector mode:

- Select it from the list on the Procedure screen
- Activate the quick menu and select it from the **Mode** menu (when the surgical overlay is being displayed)

  NOTE: When selecting an arm mode from the quick menu, holding down the trigger on the end effector handle both selects the mode from the quick menu and initiates arm movement.
- Use the center toggle switch on the end effector (when the video overly is not being displayed)
- Use the voice command "OK Vimo, select <arm mode>" (where <arm mode> is one of "Free", "Orbit", "Standoff", "Translate", "Rotate", or "Manual")

The currently-selected end effector mode is displayed on the Procedure screen in the Modus X software and on the surgical overlay.

Table 6 End Effector Modes

Mode	Description	Icon
Free	The positioning arm moves freely in all directions and is assisted by the force moment sensor (see below). **NOTE: In this mode, the speed at which the arm moves scales with the zoom level.**	
Orbit	 The end effector always points to the same location but can be moved around that location at a fixed distance. This is useful if you want to view the same point from different orientations.	
Standoff	 The end effector retains its orientation relative to where the camera is currently pointing but can be moved toward or away from that point. The end effector can also be rotated using this mode. When you move the positioning arm in Standoff mode, the camera retains focus on the surgical field.	
Translate	 The end effector retains its orientation relative to where the camera is currently pointing but can be moved in the x, y, and z directions. This is useful if you want to view a different point in the surgical field without changing the orientation of the camera. **NOTE: In this mode, the speed at which the arm moves scales with the zoom level.**	
Rotate	 The position of the end effector is fixed in space but it can be rotated to change the orientation of the camera feed displayed on the monitor.	
Manual	The arm moves freely in all directions, but is not assisted by the force moment sensor (see below). Use this mode if you need to move only one joint at a time (for example, to reposition the arm if a self collision occurs).	

WARNING: Risk of Patient Death or Permanent Disability Due to Modus X Collision with Patient, Surgeon or Surgical Tools

To avoid accidentally colliding with the patient, surgeon, or surgical tools, always be aware of the surgical site when moving the positioning arm manually or using the motion controls. The arm should always be positioned at a safe distance from the surgical site.

To position the arm, hold down the trigger button on the end effector and adjust the arm position. When the arm is in the desired position, release the trigger button to lock the arm in place. Be careful to position the arm so that it is at a safe distance from the surgical site.

NOTE: You cannot manually position the arm until Modus X is powered up and has completed its system tests. For more information, see 3.2 Starting Up, Restarting, and Shutting Down Modus X on page 56.

The arm is equipped with a force moment sensor that reduces the amount of force required to move the arm by sensing the force you are applying to the handle and driving the arm in the same direction.

2.1.7.4 End Effector Standoff Distance

WARNING: Risk of Patient Death or Permanent Disability Due to Modus X Collision with Patient, Surgeon or Surgical Tools

When Modus X is moving into the stored positions specified in the Arm Movement controls, there are no controls in place to enforce a minimum standoff distance and avoid a collision with the patient, surgeon or surgical tools. Never move Modus X using the Arm Movement screen when it is in the patient environment.

When moving into a saved position (memory or history position, or one of the stored positions listed on the Arm Movement screen) Modus X does not enforce a minimum standoff distance to prevent a collision with the patient, surgeon or surgical tools. Observe the positioning arm carefully when moving into these positions and stop motion if necessary.

The standoff distance is the distance between the end effector and a tracked tool.

- For the Pointers and Tracked Suction tools, the standoff distance is measured from the distal end of the end effector to the tip of the tool.
- For the port reference tool, Modus X determines the standoff distance based on system configuration. For more information, see 7.1.4 Working with a NICO BrainPath Brain Sheath (Port) on page 106.
- For a trajectory from Modus Nav, the standoff distance is measured from the distal end of the end effector to the trajectory's engagement point.

The default standoff distance for an initial position at the beginning of a procedure is 540 mm.

For safety reasons, Modus X enforces a minimum standoff distance of 276 mm when the positioning arm is moving to align to a tool. If Modus X calculates that an align movement would result in the end effector being less than 276 mm from the tool, Modus X will enunciate a "Standoff too small" notification.

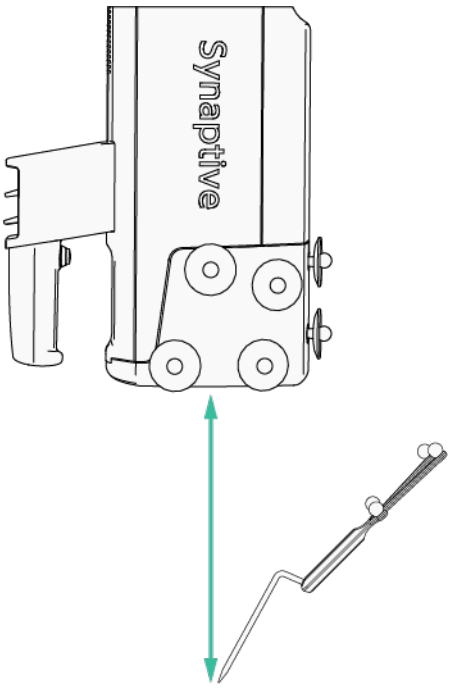


Figure 9 Standoff distance for the Pointer tool

Modus X maintains the pose standoff distance when the positioning arm is aligning to a tool or position unless you change it. You can change the standoff distance by:

- Moving the positioning arm using the Standoff End Effector Mode (see 2.1.7.2 End Effector Handle Controls on page 31)
- Using the multi-input pedal (see 2.2.2 Pedals on page 39)

2.1.7.5 Safety Capsules

In addition to the standoff distance, Modus X defines a "safety capsule" at a safe distance from the edge of each tool in all directions, and surrounding the end effector. Modus X will not allow the end effector to enter the safety capsule even if the scope would be more than 276 mm from the tool's tip. The Modus X system will display a warning if the end effector moves within 10 cm of the surface of any tool in view of the tracking camera. Modus X calculates this distance from the closest point of the end effector to the closest point of the nearest tracked tool.

In the case of a trajectory from Modus Nav, the safety capsule is based on the patient skin surface determined in Modus Nav.

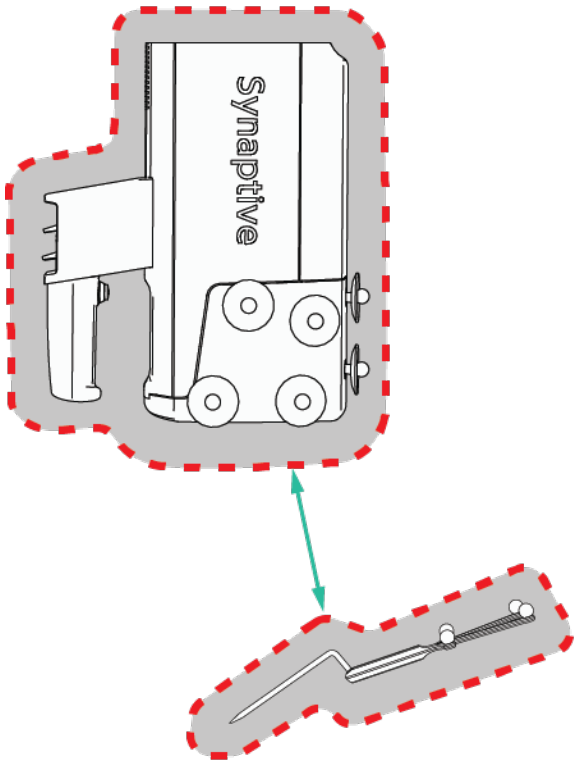


Figure 10 Safety Capsule for the end effector and Pointer tool

2.1.7.6 Cable Management

CAUTION: Risk of Operator Injury or Damage to Equipment

Always route the optical cable bundle as described in this manual. Do not allow the cable to bundle to wrap around the arm as this may cause the cable bundle to become taut during arm motion, causing damage to internal components or the positioning arm to bind.

A bundle containing the optical cables runs along the length of the positioning arm from the mobile base to the end effector and is secured to the positioning arm with Velcro straps. The cable bundle has four blue markings placed along its length to indicate the recommended locations of the Velcro straps. **The cable bundle must not become wrapped around the positioning arm and must always have enough slack to allow the arm to move freely during a procedure.**

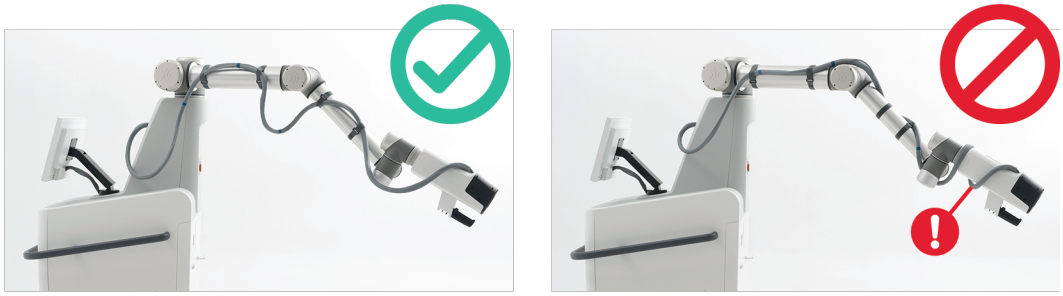


Figure 11 Correct and incorrect cable positions. The red callout indicates incorrect cable positioning wrapped around the end effector.

The cable bundle is most at risk of becoming wrapped around the positioning arm and losing slack when the arm is moved from one side of the mobile base to the other or if the end effector is rotated significantly at the end effector joint. To prevent this, check the cable bundle's position whenever you make large arm movements and manually adjust it if necessary. You should be able to move the cable bundle without removing the Velcro straps.

2.1.8 Touchscreen Monitor

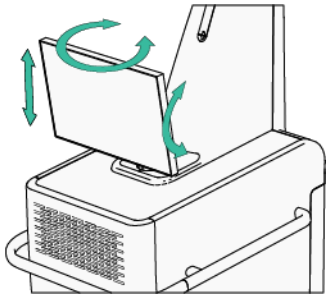


Figure 12 Touchscreen monitor adjustments

Use the touchscreen monitor to interact with the Modus X software. For more information, see 2.5 Modus X Software on page 45.

The touchscreen monitor is attached to an adjustable arm which allows the monitor to be raised, lowered, tilted, and swiveled. The touchscreen monitor can also be folded flat against the mobile base to improve sight-lines during transportation. To adjust the position of the monitor, push on the edge of the monitor in the direction you want it to move.

2.2 Peripheral Components

2.2.1 Monitor Carts

The video feed from the surgical camera on the end effector is displayed on a main monitor and, optionally, a secondary monitor. To use the stereoscopic visualization feature, at least one of the monitors must be a 3D monitor.

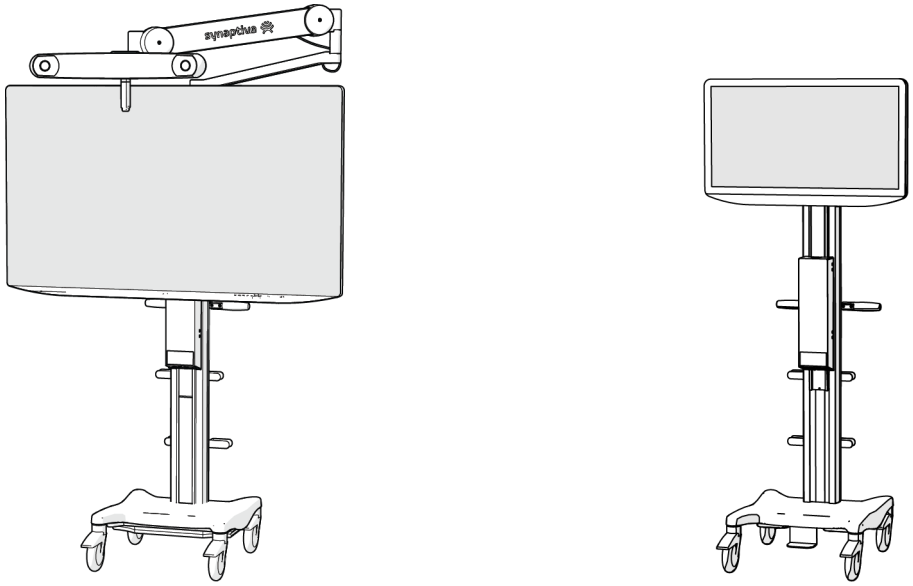


Figure 13 Examples of Synaptive monitor carts

CAUTION: Risk of Procedure Delay or Poor Image Quality of the Surgical Field

Modus X should only be used with monitors provided by Synaptive Medical. The use of a monitor other than that provided by Synaptive Medical could impact color, tissue differentiation or image quality. If using a monitor other than that provided by Synaptive Medical, image quality must be validated by surgical staff. Ensure that the image quality on the monitor is adequate for performing surgery.

Modus X must be connected to a monitor viewed by the surgeon. The monitor displays the video feed from the surgical cameras. Optionally, information from the Modus X software can be overlaid on the video feed displayed on this monitor. For more information about this option, see 2.6 Surgical Overlay on page 52.

Connect Modus X to an additional secondary monitor if there are other people who need to view the procedure, for example a second surgeon working on the opposite side of the patient. The video feed from the surgical cameras can be rotated and flipped on the Monitors settings screen so that the display on the secondary monitor corresponds to the view of the surgical site as observed from someone opposite the surgeon.

For information about connecting Modus X to the monitor carts, see 3.3.8 Connect Modus X to Monitors and/or Synaptive Navigation on page 67.

2.2.2 Pedals

Modus X can be controlled with one of two pedals: a single-input pedal that controls arm align movement and camera focus only, or a multi-input pedal that controls arm movement and camera zoom and focus functions.

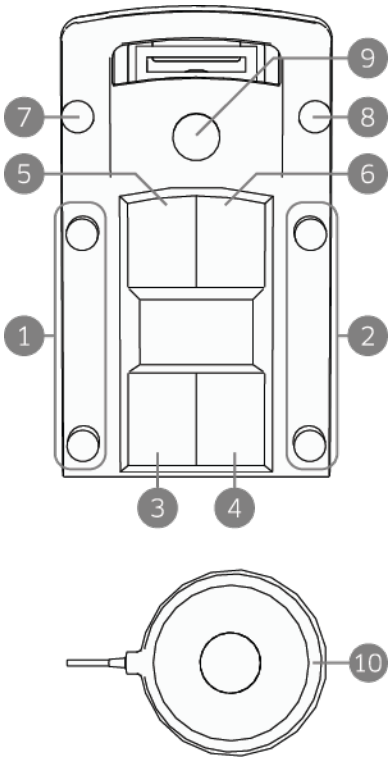


Figure 14 Pedals: multi-input pedal (top), single-input pedal (bottom)

1 Press and hold to auto-align the positioning arm or move the arm in voice nudge mode.*

A short press initiates the snap focus feature.

2 Auto focus toggle.*

A short press initiates the snap focus feature. When tool auto focus is off, a long press turns it on. When tool auto focus is on, any press (long or short) turns it off.

3 Video zoom out. A sustained press adjusts the zoom continuously. A short press zooms out by 2% increments.

4 Video zoom in. A sustained press adjusts the zoom continuously. A short press zooms in by 2% increments.

5 Video focus out. A sustained press adjusts the focus distance continuously.

When tool auto focus is on, a short press decreases the auto focus offset. Otherwise, a short press decreases the focus distance by 0.25 depth of field increments.

6 Video focus in. A sustained press adjusts the focus distance continuously.

When tool auto focus is on, a short press increases the auto focus offset. Otherwise, a short press increases the focus distance by 0.25 depth of field increments.

7 Positioning arm stand-off in.

8 Positioning arm stand-off out.

9 This control is not currently used by Modus X.

10 Press and hold to auto-align the positioning arm or move the arm in voice nudge mode.

A short press initiates the snap focus feature.

* Both controls perform the same function.

NOTES:

- **For safety reasons, it is not possible to decrease the standoff distance to less than 276 mm using the multi-input pedal.**
- **The pedal is only functional during the Procedure phase of the Modus X workflow. Pressing the pedal locks most software user interface functions to prevent the positioning arm from moving in an unexpected way. For more information, see 2.5 Modus X Software on page 45.**

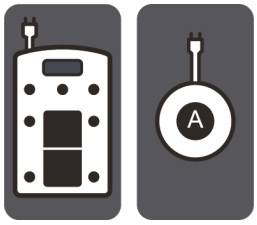


Figure 15 Pedal input icon

To connect a pedal, plug it into the pedal input on the mobile base. The pedal input is identified by the icon in Figure 15. Red dots on the pedal cable and Modus X pedal input indicate how to align the cable when plugging it in.

To prevent possible damage to the pedals and their cables, before moving the mobile base disconnect the pedal if it is connected and stow it securely.

WARNING: Risk of Patient or Operator Injury Due to Unexpected Positioning Arm Movement

Stowing the pedal while it is connected to the system may result in accidental actuation of the pedal and unintended arm movements.

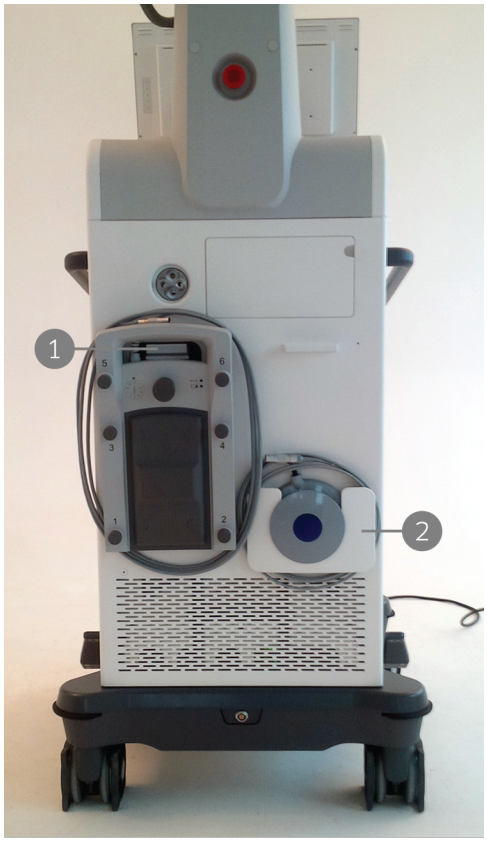


Figure 16 Pedals stowed in mobile base

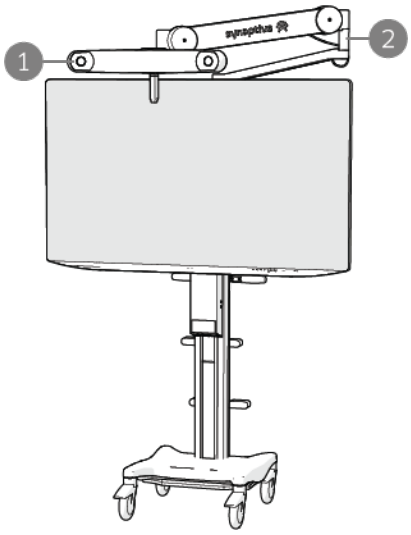
1 Hook for hanging multi-input pedal
2 Pocket for stowing single-input pedal

To stow the multi-input pedal, wrap the cable around the pedal and use the metal bar on the back of the pedal to hang the pedal over the hook on the front of the mobile base.

To stow the single-input pedal, loop the cable and place both the cable and the pedal in the pocket on the front of the mobile base. Note that the pedal button will be outside the slot on the front of the pocket. This is to prevent the pedal from being stowed with the button in the pressed position.

2.2.3 Tracking Camera

To use the automation features, Modus X must be connected to a tracking camera, usually located on the main surgeon monitor cart. The tracking camera is attached to a moveable arm that can be positioned so that the tracking camera maintains a clear line of sight on the surgical field.



1 Tracking camera
2 Camera arm

For more information about the tracking camera and the camera arm, see the user manual accompanying the monitor cart.

Figure 17 Tracking camera on main surgeon monitor cart

2.2.4 Voice Control

The voice control feature requires the use of a microphone and transmitter. If your system supports voice control, the microphones and transmitters are included with Modus X.

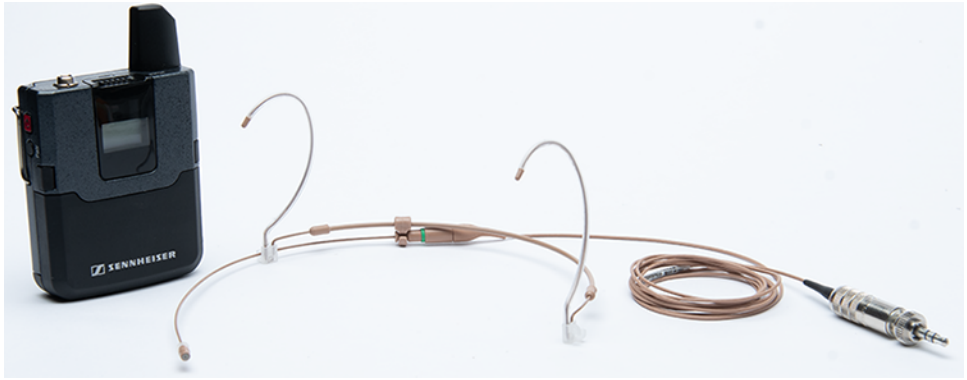


Figure 18 Voice control transmitter (left) and microphone (right)

2.2.5 Stereoscopic Visualization

The stereoscopic visualization feature requires the use of a 3D eye shield composed of a frame and a disposable 3D lens. These 3D eye shields are provided with Modus X.

Figure 19 3D eye shield showing lens assembled to frame

Additional frames and lenses can be purchased as accessories, if necessary. For more information, see 11.4 Ordering Accessories on page 132.

For more information about the eye shields, consult their accompanying documentation.

2.2.6 Modus Nav

Modus X can be used with Synaptive Modus Nav. In this configuration, both systems use the same tracking camera to track the location of the surgical tools and Modus Nav shares the following information with Modus X:

- If you are performing a navigated port procedure, Modus Nav provides Modus X with the length of the brain sheath you are using for the procedure. For more information about how Modus X uses this information, see 7.1.4 Working with a NICO BrainPath Brain Sheath (Port) on page 106.
- The calibration status of the Synaptive port reference and Trackable Suction tools.
- The coordinates of the surgical trajectory you are using during the procedure. Modus X uses this information to perform align to trajectory moves. For more information, see 7.2 Aligning to a Trajectory on page 107.
- The coordinates for a safety capsule around the patient's head, based on the registration accepted in Modus Nav. For more information, see 2.1.7.5 Safety Capsules on page 36.

2.3 Drapes

WARNING: Risk of Patient Death or Permanent Disability Due to Contamination of Sterile Equipment

Use caution when draping patients and equipment. Always drape the positioning arm outside of the patient environment. Always follow the draping instructions in this manual, all applicable draping protocols in use at your site, and protocols for maintaining a sterile field.

Only those parts of the Modus X system that have been draped are sterile. Use caution during surgery to prevent contaminating the sterile field.

Exercise clinical judgment in cases where the drape is suspected to have been compromised. Re-draping is at the discretion of qualified clinical staff.

The following drapes are available for use with Modus X:

1. Modus X arm drape
2. Modus X arm drape - infrared fluorescence (designated by the IR symbol on the drape label)

3. Skirt drape (optional)
4. Touchscreen drape (optional)

Patch drapes are also supplied with Modus X in case a drape becomes torn.

The Modus X drapes have been sterilized using ethylene oxide. Handle them appropriately to preserve their sterility.

NOTES:

- **A Modus X arm drape is always required; the touchscreen drape is only required if a sterile staff person will operate the computer.**
- **Drapes are not made with natural rubber latex.**

For information about applying the drapes see:

- 3.3.4 Applying the Arm Drape on page 60
- 3.3.5 Applying the Skirt Drape on page 64
- 3.3.3 Applying the Touchscreen Drape on page 59

2.4 Synaptive Instrumentation

NOTE: Synaptive tools may not be included with Modus X but may be ordered separately, subject to regional availability limitations. For more information, contact Synaptive customer service.

Modus X can track and align to the following Synaptive tools:

- Standard Pointer
- Long Pointer
- Trackable Suction tools
- Tracking array for the NICO BrainPath, also known as the port reference tool

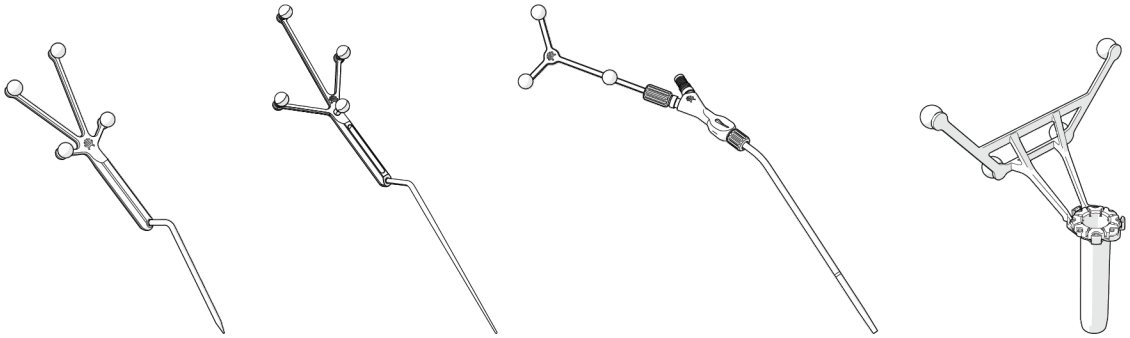


Figure 20 Synaptive instrumentation from left to right: Standard Pointer, Long Pointer, Trackable Suction, tracking array for the NICO BrainPath (shown attached to the BrainPath sheath)

Refer to the manuals and other instructions provided with Synaptive tools for complete information about them, including their intended use, contraindications, and instructions for use.

Use the Modus X software interface to indicate which tool you want to track and to switch between tools during a procedure.

When used together with Modus Nav, Modus X tracks the Synaptive patient reference. When the patient reference is visible, Modus X can make alignment moves even when the end effector is not visible to the tracking camera.

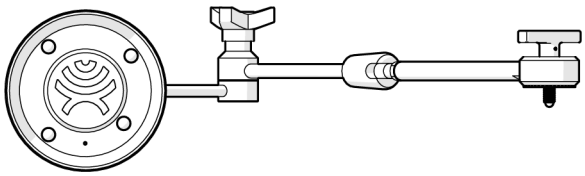


Figure 21 Synaptive patient reference

NOTE: Modus X must have made at least one alignment move with both the Synaptive patient reference and the end effector visible to the tracking camera before it can make alignment moves when only the patient reference is visible.

WARNING: Risk of Procedure Delay or Damage to Equipment Due to Use of Inappropriate Equipment

Modus X should only be used with tools and equipment made or validated by Synaptive Medical Inc. Do not use any tools or equipment not listed in the user manual with Modus X.

Do not bring any trackable tools not made by Synaptive Medical Inc. into the tracking camera's field of view.

2.5 Modus X Software

Modus X is controlled through software displayed on the touchscreen monitor.

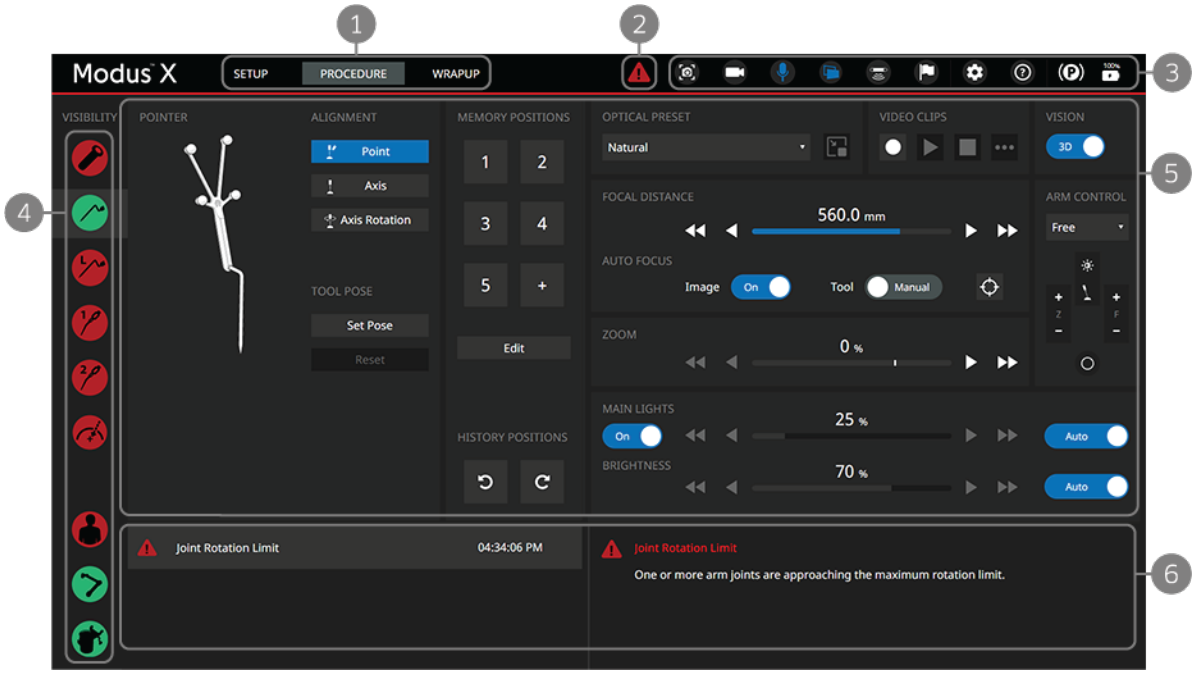


Figure 22 Modus X software

1 Workflow ribbon. The Modus X workflow is divided into three phases that walk through performing a surgical procedure using Modus X: Setup, Procedure, and Wrapup. Tap on a workflow phase name to move to that phase.

NOTE: You cannot move to the Procedure phase until all tasks in the Setup phase are complete. You cannot move directly to the Wrapup phase from the Setup phase, you must first move to the Procedure phase.

2 Notification icon. An icon appears here if there are notifications available for you to view. For more information, see 2.5.3 Notification Icons on page 48.

3 Status and task icons. For more information, see 2.5.2 Status and Task Icons on page 47.

4 Tool and reference icons (on Procedure screen only). For more information, see 2.5.1 Tool and Reference Icons on page 46.

5 Task area. Options and information relevant to the current workflow phase appear here.

6 Notification area. Warnings or notifications about the task you are performing appear here. For more information, see 2.5.4 Modus X Notifications on page 49.

2.5.1 Tool and Reference Icons

The tool and reference icons on the left side of the Procedure screen provide information about the tracking status of the surgical tools and other tracked objects.

Table 7 Modus X Tool Icons

Icon	Description
	Synaptive tracking array for the NICO BrainPath (port reference tool)
	Standard Pointer
	Long Pointer
	Synaptive Trackable Suction tool with tracking array 1 connected
	Synaptive Trackable Suction tool with tracking array 2 connected
	Synaptive surgical trajectory. This feature can only be used when Modus X is connected to Modus Nav.

Table 8 Modus X Reference Icons

Icon	Description
	Synaptive patient reference. The Synaptive patient reference is necessary for the Modus X arm to perform Align to Trajectory movements. This accessory can only be used when Modus X is connected to Modus Nav.
	Modus X end effector
	Synaptive calibration block.
	Synaptive Multi-Tool Calibration Device

The icon's color indicates the tracking status:

- Green: The instrument is being tracked by the tracking camera and has been calibrated/verified (when applicable)

- Yellow: The instrument is being tracked by the tracking camera but has not been calibrated/verified (when applicable)
- Red: The instrument is not visible to the tracking camera

NOTE: The calibration/verification process is different depending on whether Modus X is connected to Modus Nav or is directly connected to the tracking camera on the main surgeon monitor. For more information, see 2.4 Synaptive Instrumentation on page 43.

NOTE: Modus X accessories and peripheral components are optional and subject to regional availability limitations. The tool and reference icons for items not available with your system will show as red. The icon for aligning to a Synaptive surgical trajectory will show as red if Modus X is not connected to Modus Nav.

2.5.2 Status and Task Icons

The status and task icons at the top of the Modus X user interface provide information about the status of Modus X components. You can also use some icons to turn features on and off.

Table 9 Modus X Status and Task Icons

Icon	Description
	Snapshot. Tap this icon to take a snapshot of the video from the surgical camera. If the storage space for snapshots is running low, this icon displays an exclamation point. For more information, see 5.5.4 Snapshots on page 92.
	Video case recording. Tap this icon to start or stop video recording. If the storage space for video recordings is running low, this icon displays an exclamation point. For more information, see 5.5.1 Case Recording on page 88.
	Mark log. Tap this icon to add a flag to the Modus X system logs. This can help the Synaptive Service team troubleshoot an issue that occurs when you are using Modus X.
	Voice control. Tap this icon to turn voice control on or off. For more information, see 4.0 Voice Control on page 74.
	Surgical overlay. Tap this icon to show or hide the overlay elements on the main monitor.
	Tracking camera. This icon indicates the status of the Modus X connection to the tracking camera. Tap this icon to open the Tracking Camera settings page. For more information, see 10.2 Tracker on page 119.
	Settings icon. Tap this icon to access the Modus X settings options. For more information, see 10.0 Modus X Settings on page 117.

Table 9 Modus X Status and Task Icons (continued)

Icon	Description
	Help. Tap this icon to access Modus X help topics.
	Caster brake. This icon indicates the caster brake status (locked or unlocked).
	Battery. This icon indicates the current battery charge level. When Modus X is not connected to A/C power, this icon displays an exclamation point in the battery symbol.

The color of the status and task icons indicate the state of the Modus X components.

- White: Indicates the component is available and functioning normally.
- Blue: Indicates the component is currently active. For example, the surgical overlay icon is blue when the overlay is being displayed on the main monitor.
- Red: Indicates that there is an issue with the component or the component needs attention. For example, the brake icon turns red when the caster brake is unlocked.

2.5.3 Notification Icons

A notification icon appears at the top of the screen when there are one or more Modus X notifications available for you to view. In the Procedure screen, the text of the notification appears automatically in the notification area at the bottom of the screen. If you are working in the Setup, Wrapup, or Settings screens, you can tap the notification icon to bring up the notification text.

The notification icon disappears when the issue that caused the notification has been resolved.

Table 10 Modus X Notification Icons

Icon	Description
	Information. These notifications provide information about changes in the system when Modus X is functioning normally and the change is not likely to affect your ability to use Modus X. For example, an information notification appears when you set a memory position.
	Advisory. These notifications provide information about changes in the system when Modus X is functioning normally and the change may affect your ability to use one or more Modus X features. For example, an advisory notification appears when Modus X has run out of space for video storage or when one or more arm joints is reaching its maximum rotation limit.
	Infrared (IR) light. This notification appears in the status bar when an optical preset using infrared light is selected. For more information about using near-infrared optical presets, see 9.0 Fluorescence on page 112.

Table 10 Modus X Notification Icons (continued)

Icon	Description
	Alert. These notifications provide information about changes in the system which may require acknowledgment from the user. Events which may prevent Modus X from continuing with the procedure (for example, when Modus X detects that a collision is imminent) also require acknowledgment from the user.

For a list of notifications, see 12.2 User Notifications on page 136.

2.5.4 Modus X Notifications

Modus X uses three types of notifications to inform you about the current state of the system:

- Spoken notifications
- Text notifications
- Sounds

Spoken Notifications

Modus X provides spoken notifications that confirm your input or inform you about actions being performed. For example, when you select memory position one, Modus X says "Position one selected". In most cases, these notifications are self-explanatory.

In some cases, Modus X provides a spoken notification to inform you of an issue with the system. Modus X may also display a text message in the software user interface with information about the issue and any action you can take to resolve it. For more information about common messages, see 12.2 User Notifications on page 136.

Text Notifications

When you are working in the Procedure screen, text notifications appear at the bottom of the screen. A notification icon also appears beside the status and task icons at the top of the screen (for more information, see 2.5.3 Notification Icons on page 48). If you are working in the Setup, Wrapup, or Settings screens, you can tap the notification icon to bring up the notification in a dialog. Tap the "close" icon (X) to dismiss the notification dialog.

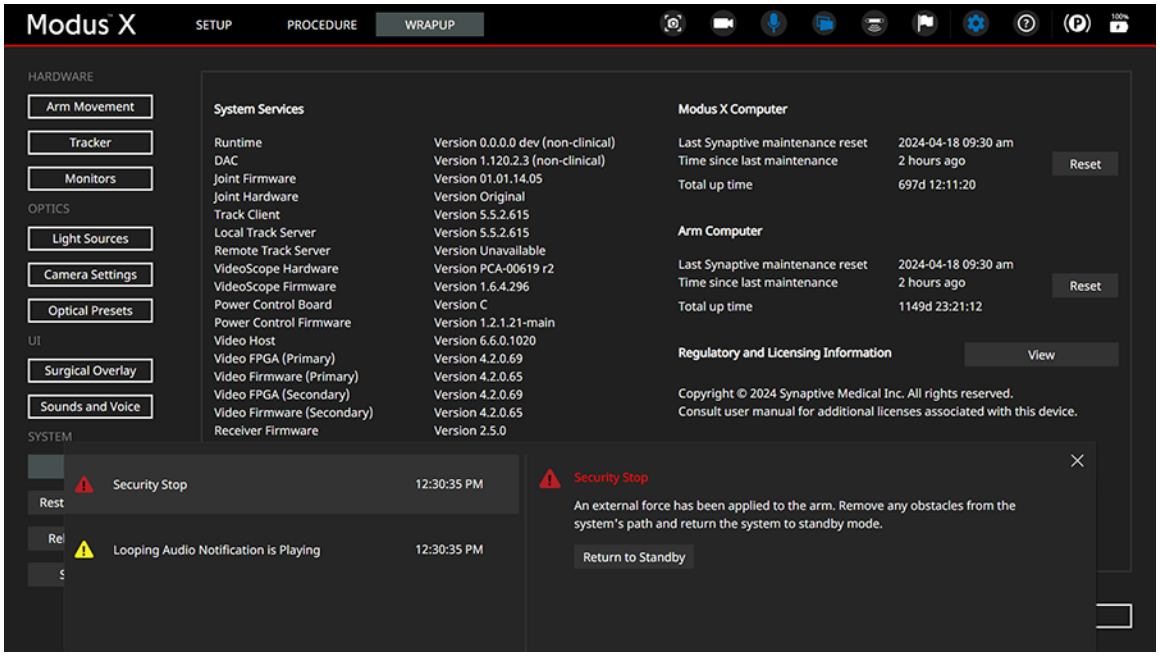


Figure 23 Settings screen showing notification dialog

Notifications are displayed until they are resolved in one of three ways:

- They time out. Some notifications disappear automatically after a few seconds. This type of resolution is most common for simple informational notifications.
- The underlying condition that caused the notification changes. For example, the "Brakes not engaged" notification disappears when you engage the brakes.
- You acknowledge the notification. Some notifications require you to acknowledge the information in them by tapping a button on the screen. For example, when Modus X is in a security stop, you must tap the **Return to Standby** button in the notification before you can continue using Modus X.

For a complete list of notifications, see 12.2 User Notifications on page 136.

Modus X Sounds

Modus X uses sounds to acknowledge your inputs and inform you about certain system states.

Table 11 Modus X Sounds

Notification	Sound	Description
Battery charge	Beep every ten seconds	Modus X is running on battery power. Plug Modus X into a power outlet.
Battery charge	Two beeps every five seconds	Modus X is low on battery power. Plug Modus X into a power outlet.

Table 11 Modus X Sounds (continued)

Notification	Sound	Description
Alert	Two tones, the second higher than the first, repeated	Something has occurred that has stopped the positioning arm, for example an e-stop was pressed or an external force was applied to the arm. Follow the instructions in the notification message that appears on the screen to resolve the issue.
Cannot comply	A descending tone	Modus X cannot complete the requested action, for example because the pedal was pressed while the e-stop was pressed or because you tried to set a pose for a tool that is not visible to the tracking camera. Follow the instructions in the notification message that appears on the screen to resolve the issue.
Awaiting input	Two tones, the second lower than the first	Modus X is waiting for you to resolve an issue. Follow the instructions in the notification message on the screen to resolve the issue.
Selection acknowledged	A single high-pitched tone	Modus X has registered the selection you made in the software user interface.
End effector trigger pressed	A single tone	Modus X has registered that the mode trigger on the end effector has been pressed.
Movement imminent *	Two tones, the second higher than the first	The positioning arm is about to move.
Movement started *	An ascending tone	The positioning arm has begun to move.
Movement complete *	A single echoing tone	The positioning arm has reached its target position.

* These notification sounds only occur if your system has been configured not to use spoken notifications.

2.6 Surgical Overlay

Modus X can display information about the state of the system over the video feed on the monitors connected to the Modus X mobile base.

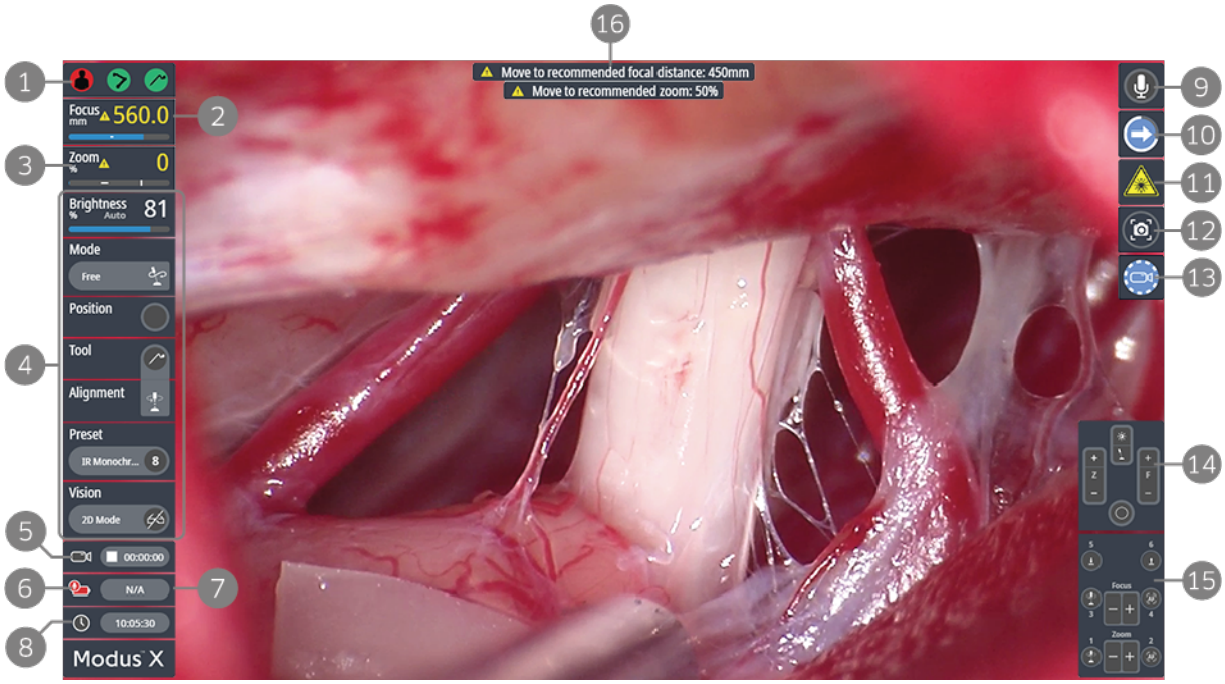


Figure 24 Modus X information overlaid on video feed

1 Tool visibility

2 Current focus distance

3 Current zoom level

4 Quick menu items (see 2.7 Quick Menu below)

5 Video recording status

6 Modus X battery status

7 Voice control transmitter battery status

8 Clock

9 Voice control status

10 Nudge mode status (appears when nudge mode is active)

11 IR status (appears when an IR optical preset is selected and the lights are on)

12 Snapshot status (appears when a snapshot is being captured)

13 Clip recording (appears only when a video clip is recording)

14 End effector handle control status

15 Multi-input pedal status

16 If you select a fluorescence optical preset and the current focus distance and/or zoom level do not match its recommended parameters, a notification appears on the surgical overlay

You can show or hide the overlay by tapping the surgical overlay icon on any Modus X software screen. You can also control which details appear in the overlay by changing the Surgical Overlay settings (for more information, see 10.7 Surgical Overlay on page 125).

NOTE: If the overlay components are blocking your view of the surgical site, you can:

- Hide some or all of the overlay components
- Move the arm to display a different view of the surgical site
- Switch to viewing the raw video feed

2.7 Quick Menu

Use the quick menu switch and trigger button on the end effector to toggle between the quick menu options.

NOTE: To use the quick menu, the surgical overlay must be displayed. For more information, see 10.7 Surgical Overlay on page 125.

- To activate the Brightness quick menu, push the center toggle switch on the end effector **up**.
- To activate the Arm Mode quick menu, push the center toggle switch on the end effector **down**.
- To access the other quick menu options:
  a. Push the center toggle switch on the end effector **down**.
  b. Push the center toggle switch **up** to jump to the BACK option.
  c. Press the trigger button.
- When the quick menu is active, push the center toggle switch on the end effector up or down to toggle through the menu items.
- To select a menu item, press the trigger button on the end effector.
- To close the quick menu, hold down the trigger button.

Figure 25 Quick menu showing arm mode options

1 Brightness. The current image brightness is displayed here. Push the center toggle switch up to access the brightness control menu. When the menu is active push up or down once to increase or decrease the image brightness by fine increments. Push and hold the center toggle switch up or down to continuously increase or decrease the image brightness until the toggle switch is released.

When the auto brightness feature is on, "Auto" is displayed beside the brightness level. For more information about the Modus X lights and brightness behavior, see 5.4 Adjusting Lights and Image Brightness on page 86.

2 End effector positioning mode. The current end effector mode is displayed here. Select this menu item to view and select from a sub-menu of positioning modes.

3 Memory positions. If a memory position is currently selected for arm align moves, the number of the position is displayed here. Select this menu item to view and select from a sub-menu of memory positions.

4 Alignment tool. The tool that is currently selected for arm align moves is displayed here. Select this menu item to view and select from a sub-menu of tools.

5 Auto focus tool. The tool that is currently selected for auto focusing is displayed here. When auto focus is enabled, a blue auto focus icon appears over the tool.

6 Alignment type. The alignment type that is currently selected for arm align moves is displayed here. Select this menu item to view and select from a sub-menu of alignment types.

7 Optical preset. Select this menu item to view and select from a sub-menu of optical presets.

8 Vision mode. Select this menu item to toggle between 2D and stereoscopic (3D) visualization.

3.0 Modus X Setup

3.1 Operating Room Setup

Set up the Modus X components well in advance of the procedure to ensure that there is adequate space in the operating room to position the carts as required for the procedure. For information about how to connect the Modus X components, see 3.3.8 Connect Modus X to Monitors and/or Synaptive Navigation on page 67.

NOTE: To minimize the possibility that the Modus X mobile base will shift during positioning arm movements, set up Modus X only on flooring that is smooth, level, and dry.

Considerations For Connecting to Monitors

Set up monitor carts so that they are easily viewed by the surgeons and anyone else who needs to view the procedure.

If you are connecting to a 3D monitor cart, the monitor should be directly opposite the surgeon's position and between 5.5' (168 cm) and 10' (300 cm) away.

Considerations For Connecting to a Tracking Camera

Position the tracking camera so that the end effector tracking array and surgical tools will be within the tracking camera's field of view (see Figure 26 below). The tracking camera must have an unobstructed view of the end effector tracking array and the surgical tools.

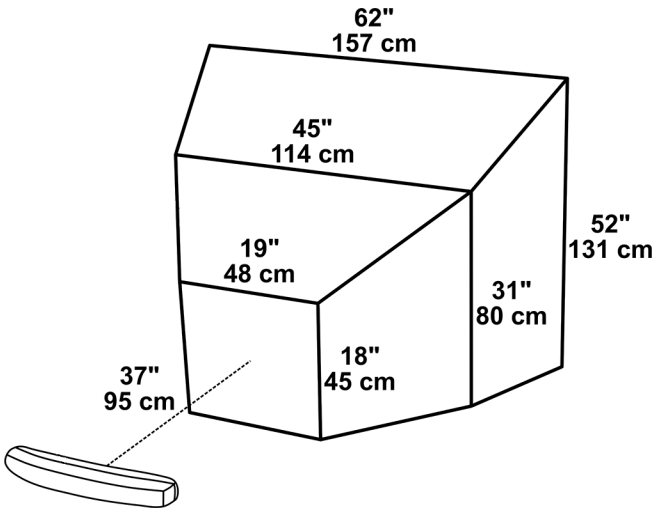


Figure 26 Tracking camera field of view

NOTE: The tracking camera provides optimal tracking when the objects being tracked are located near the center of the tracking volume. For more information on viewing the tracking camera's field of view, see 10.2 Tracker on page 119.

3.2 Starting Up, Restarting, and Shutting Down Modus X

WARNING: Risk of Patient Death or Permanent Disability Due to Modus X Collision with Patient, Surgeon or Surgical Tools

To avoid accidentally colliding with the patient, surgeon, or surgical tools, never start up, restart, or shut down Modus X while the positioning arm is within range of the patient.

3.2.1 Starting Up Modus X

To start Modus X:

1. Plug Modus X into a power outlet. Modus X **must** be plugged in when starting up.
2. Press and hold the power button on the mobile base until the battery status LED lights flash in ascending order. Release the power button once the LED lights display the status of the battery power.

   NOTE: It may take up to five minutes for Modus X to complete the start up process. Do not press the power button again during start up. The start up process is complete when the Start button appears on the touchscreen.
3. Tap the **Start** button on the touchscreen. Modus X runs through a series of system tests and displays the results. The system tests are listed as "Passed" or "In progress".
4. If the system passes all of the tests, tap **Continue to Setup** where you can begin setting Modus X up for the procedure.

   If the system tests reveal issues that might compromise Modus X's performance during the procedure, these issues are displayed in yellow. If you want to continue with the procedure without resolving these issues, tap **Continue to Setup**.

   If the system tests reveal issues that prevent Modus X from safely continuing with the procedure, these issues are displayed in red. Follow the instructions displayed with the test result to resolve the issues. The **Continue to Setup** button is not available until all these issues are resolved.

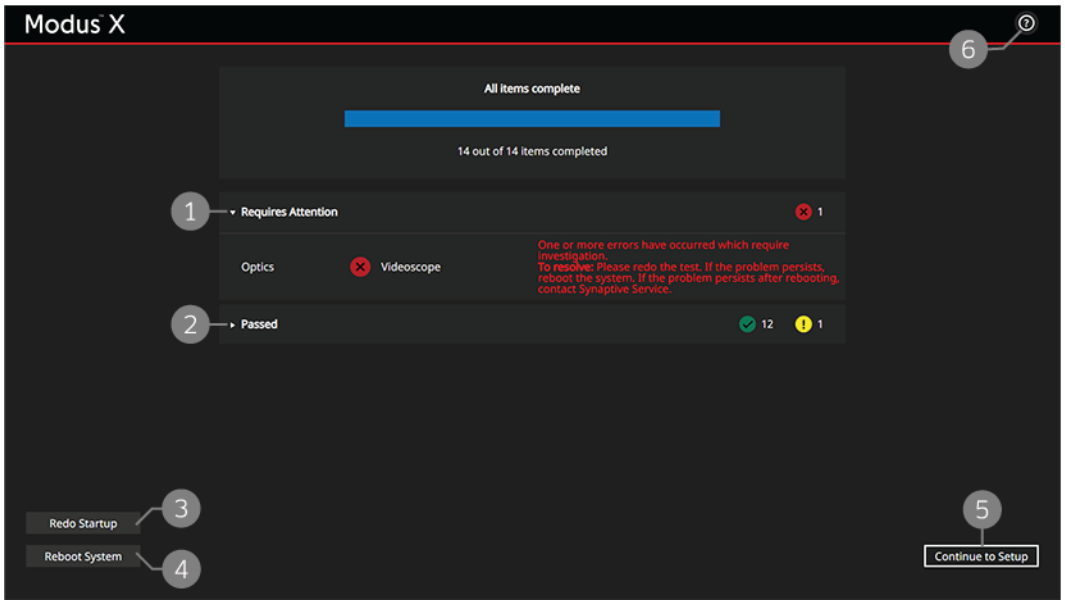


Figure 27 Modus X System test report

1 System tests that require action are listed here.
2 System tests that have passed are listed here.
3 Redo Test. Tap this button to repeat the system test.
4 Reboot System. Tap this button to perform a system reboot.
5 Continue to Setup. Tap this button to continue to the Setup screen.
6 Help. Tap this icon to access Modus X help topics.

3.2.2 Restarting Modus X

If Modus X encounters an issue, it may display a notification indicating that you need to restart the procedure or reboot the system.

- Restarting the procedure will return you to the Start screen. When you tap **Start**, Modus X runs through its system tests and displays the results. For more information, see 3.2.1 Starting Up Modus X on page 56.
- Rebooting the system will initiate a full system shut down and start up.

To restart the procedure or reboot the system, tap the settings icon then tap the appropriate button on the Settings screen.

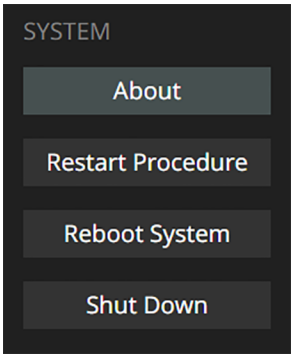


Figure 28 Restart Procedure and Reboot System buttons on the Settings screen

3.2.3 Shutting Down Modus X

To shut down Modus X, complete all the tasks in the Wrap-up checklist then tap **Shut Down Modus X**. A dialog appears indicating that Modus X will shut down in 10 seconds. Tap **Cancel** if you do not want to shut down Modus X.

You can also shut down Modus X by tapping the **Shut Down** button on the Settings screen. If the Modus X software is unavailable, you can shut down Modus X by pressing the power button on the mobile base. Modus X enunciates the spoken notification "Shutting down" and powers down.

NOTE: If you use the power button to shut down Modus X, avoid holding the button down. Holding down the power button will cut power to the system and repeated power cuts can potentially damage the Modus X system.

3.3 Setting Up for a Procedure

Before you can begin a procedure you must set up Modus X. The Setup screen displays the list of required setup tasks.

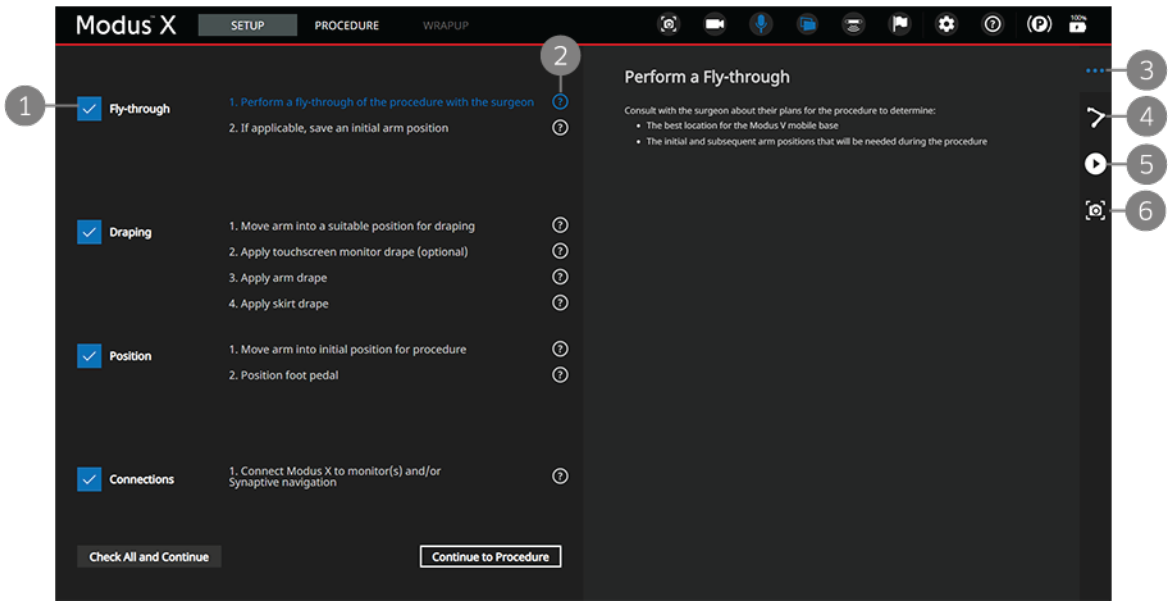


Figure 29 Setup phase

1 Setup tasks. Tap the checkbox for each task to mark it as done.

2 Help. Tap the help icon beside each task to view instructions for how to complete the task.

3 More information. Tap this icon to display instructions for how to complete the currently-selected task if they are not currently displayed in the right panel.

4 Arm movement. Tap this icon to access the Arm Movement screen. For more information, see 10.1 Arm Movement on page 117.

5 Videos. If you plan to record the video from the surgical camera during the procedure, tap this icon to access the Videos screen and verify that there is enough storage space available on Modus X to hold the video recording. For more information, see 5.5.1 Case Recording on page 88.

6 Snapshots. If you plan to take snapshots of the video from the surgical camera during the procedure, tap this icon to access the Snapshots screen and verify that there is enough storage space available on Modus X to hold the images. For more information, see 5.5.4 Snapshots on page 92.

Complete the tasks listed on the Setup screen. When you have completed a task or set of tasks, tap the corresponding checkbox to mark it as done, then tap **Continue to Procedure**. Alternatively, you can complete all the tasks at once then tap the **Check All and Continue** button to continue to the Procedure phase.

3.3.1 Perform a Fly-through

Consult with the surgeon about their plans for the procedure to determine:

- The best location for the Modus X mobile base
- The initial and subsequent arm positions that will be needed during the procedure

3.3.2 Save an Initial Arm Position

If, during the procedure fly-through, you decide on an initial arm position, you can set it as one of Modus X's "stored" positions. This will make it easy to return to that exact position after the Modus X positioning arm has been draped. The "stored" positions are listed on the Arm Movement screen. You will most likely want to save your initial position as "Position A" or "Position B".

- To access the Arm Movement screen, tap the arm icon on the right side of the screen.
- To set a "stored" position, move the arm into the desired position then tap **Set** beside the position you want to set. Tap **Reset** to set the position back to its default position.

3.3.3 Applying the Touchscreen Drape

NOTE: The touchscreen drape is only required if a sterile person will operate the computer.

To apply the touchscreen drape:

1. Remove the drape from the packaging.
2. Unfold the drape.
3. Remove the paper backing from the adhesive strips on the sides of the drape.
4. Apply the drape to the monitor with the adhesive strips along the edges of the monitor.
5. Apply pressure to the adhesive strips to ensure that the drape is securely affixed to the monitor.

Figure 30 Monitor drape applied to touchscreen monitor

3.3.4 Applying the Arm Drape

Before applying the Modus X arm drape:

- Move the positioning arm into a position corresponding to where Modus X will be situated relative to the surgeon during the procedure (that is, on the surgeon's left or right side).

  NOTE: Once the arm is draped, making large arm movements (such as positioning the Modus X arm on the opposite side of the surgeon) may increase the risk that the drape may become torn.

- Extend the positioning arm enough that the drape can be unfolded easily over all the joints and lower it if necessary to ensure that the whole arm can be reached.
- Determine the procedure type. If a Modus IR optical preset will be used, obtain the infrared fluorescence arm drape (designated by the IR symbol on the drape label). If not, obtain the non-IR arm drape.
- Prepare a sterile surface to unfold the drape on.

To apply the Modus X arm drape:

1. Remove the drape from the packaging.
2. On a sterile surface, unfold the drape until the drape window for the end effector is exposed.

Figure 31 Drape unfolded to expose drape window for the end effector

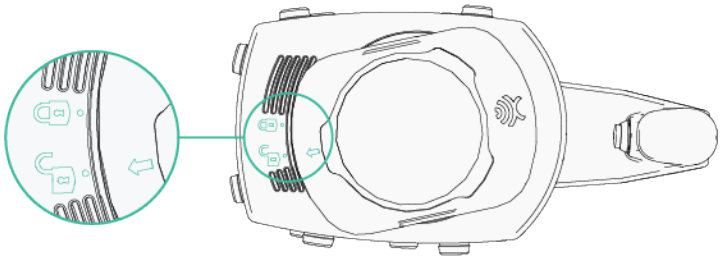
3. Insert your hands into the folds above and below the drape window for the end effector.

Figure 32 Inserting hands into drape folds

4. Position the drape opening around and over the end effector.

Figure 33 Drape over end effector

5. Push the drape over the length of the positioning arm until you reach the mobile base.
6. Arrange the narrow pocket near the drape window so that it covers the end effector handle.
7. Arrange the drape window frame so that the arrow on the window points to the unlocked symbol on the end effector.



8. Push the drape window frame in and twist it clockwise until the arrow points to the locked symbol.
9. If present, remove the plastic cover from the drape window.
10. Press the marker posts on the drape onto the posts on the end effector. Press firmly to ensure that the marker posts are fully seated on the end effector posts.

Figure 34 Pressing the marker posts onto the end effector

11. If the procedure will use the tracking camera, press a tracking sphere onto each marker post on the drape. Press firmly to ensure that the tracking spheres are fully seated on the marker posts.

Figure 35 Pressing markers onto the marker posts

12. Use the rubber bands and hooks supplied with the drape to take up some of the slack in the drape around the arm.

Figure 36 Applying rubber bands

13. Place one rubber band around the end effector above the end effector handle. Place the other two rubber bands on the arm segments between joints B and C, and joints C and D.

CAUTION: Risk of Damage to Equipment

When placing a rubber band around the drape on the end effector, place the rubber band above the handle and below the vents. Do not place the rubber band over the vents on the end effector as this can negatively impact the thermal environment within the end effector, causing deteriorated performance or damage to internal components.

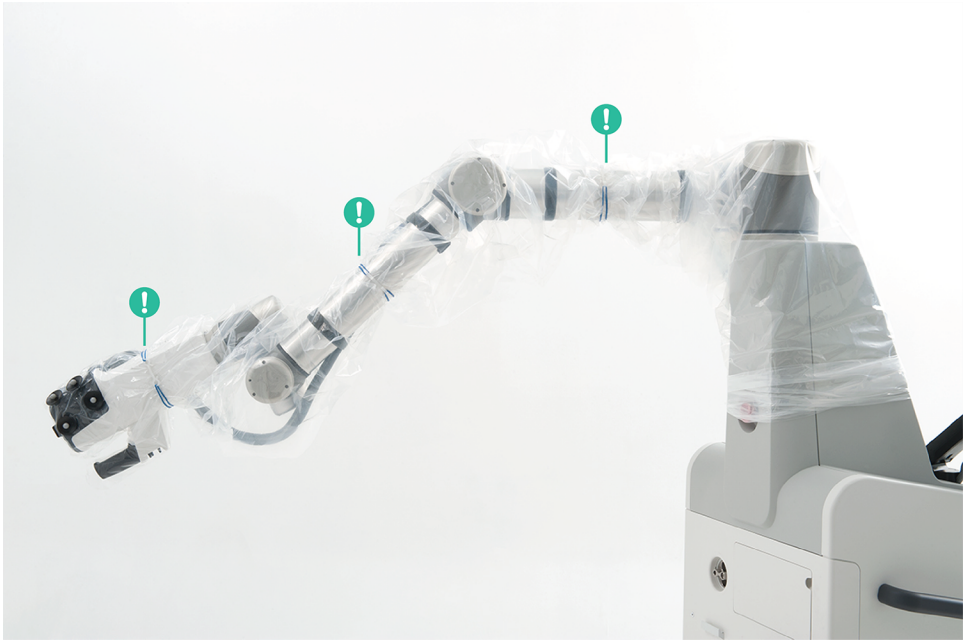


Figure 37 Drape secured with rubber bands. Green callouts indicate proper positioning of rubber bands.

3.3.5 Applying the Skirt Drape

To apply the skirt drape:

1. If the pedal is not already connected to Modus X, plug it into the input on the front of the mobile base.

   NOTE: The pedal and its connector are not sterile. To avoid the risk of contamination, ensure proper handling to maintain the sterility of the skirt drape.

2. Remove the skirt drape from its packaging.
3. Unfold the drape.
4. Remove the paper backing from the adhesive strip.
5. Carefully apply the drape around the base of the positioning arm over the arm drape, taking care not to cover the vents at the bottom of the mobile base.

Figure 38 Applying the skirt drape

6. If the skirt drape is not long enough to adequately cover the mobile base for sterility, apply a second skirt drape to the bottom of the first one.

Figure 39 Skirt drape applied around positioning arm base

WARNING: Risk of Damage to Equipment - Draping

When applying the skirt drape to the mobile base, ensure that the drape does not cover the vents at the bottom of the mobile base.

3.3.6 Move Arm into Initial Position

1. If you saved an initial position for the procedure, use the Arm Movement screen to move the positioning arm into that position.
   - To access the Arm Movement screen, tap the arm icon on the right side of the screen.
   - To move the arm into a "stored" position, press and hold on the name of the position you want to move into.

   If you did not save an initial position for the procedure, you can manually move the positioning arm into an appropriate position now or after moving the Modus X mobile base into position near the surgical bed.
2. Move the Modus X mobile base to the appropriate location near the surgical bed and lock the caster brakes.

3.3.7 Position the Foot Pedal

Position the pedal so that it is within easy reach of the surgeon.

3.3.8 Connect Modus X to Monitors and/or Synaptive Navigation

Connect the Modus X mobile base to the main monitor, and optionally to a tracking camera and/or a secondary monitor. If you are using Modus X with Modus Nav, connect Modus X to the Modus Nav operator cart.

WARNING: Risk of Operator Injury Due to Tripping Hazards

The cables connecting Modus X to other equipment are a potential tripping hazard. When positioning Modus X for a procedure, always ensure that there is sufficient cable length to allow the cables to reach the floor. Use caution when walking around Modus X to avoid tripping over cables.

Connecting Modus X to the Main Monitor

Table 12 3D Monitor Connection

	Modus X I/O Panel		Monitor I/O Panel
Connect	SDI 1A	to	SDI 1A
Connect	SDI 1B	to	SDI 1B
Connect*		to	

* This connection is only necessary if you want to control the monitor using the Modus X software.

Table 13 2D Monitor Connection

	Modus X I/O Panel		Monitor I/O Panel
Connect	SDI 1	to	SDI

Connecting Modus X to a Tracking Camera

Use the tracking camera port on the Modus X rear panel to connect the tracking camera on the monitor cart or camera cart to Modus X.

Table 14 Tracking Camera Connection

	Modus X I/O Panel		Monitor I/O Panel
Connect		to	

Connecting Modus X to a Secondary Monitor

Table 15 3D Monitor Connection

	Modus X I/O Panel		Monitor I/O Panel
Connect	SDI 2A	to	SDI 1A
Connect	SDI 2B	to	SDI 1B
Connect*		to	

* This connection is only necessary if you want to control the monitor using the Modus X software.

Table 16 2D Monitor Connection

	Modus X I/O Panel		Monitor I/O Panel
Connect	SDI 2	to	SDI

Connecting Modus X to Modus Nav

To connect Modus X to Modus Nav:

1. Connect the tracking camera port on the main monitor to the tracking camera port on the Modus Nav operator cart.
2. Connect the Modus Nav operator cart to Modus X using an Ethernet cable.

To use the same monitor for both Modus Nav and Modus X (using the picture-in-picture feature):

1. Connect Modus X to the main monitor as described above.
2. Connect the tracking camera port on the main monitor to the tracking camera port on the Modus Nav operator cart.
3. Connect the DVI output on the Modus Nav operator cart to the DVI input on the main monitor.
4. Connect Modus X to the Modus Nav operator cart with an Ethernet cable.

For information about using the picture-in-picture feature, see 10.3 Monitors on page 120.

3.3.9 Using the Raw Video Feed

The video feed from the surgical cameras on the positioning arm is split into two streams. One stream undergoes video processing and is output from the SDI and DVI ports 1 and 2 on the Modus X I/O panel. The second stream is left raw and is output from the SDI 3 ports.

Use the raw video feed in the event that the video processing module in Modus X is malfunctioning, or if you need to view the unprocessed video stream for some other reason.

Table 17 Raw Video Feed Monitor Connection

	Modus X I/O Panel		Monitor I/O Panel
Connect	SDI 3A	to	SDI 1A
Connect	SDI 3B	to	SDI 1B

3.3.10 Using the Auxiliary Light Source

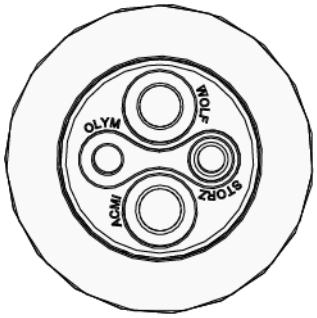


Figure 40 Auxiliary light source connectors

The Modus X auxiliary light source has connectors for connecting four common light cable formats: ACMI, Olympus, Storz, and Wolf.

To use the auxiliary light source to provide illumination for another piece of equipment, or as a backup light source if the primary light source fails, rotate the auxiliary light source wheel until the appropriate connector for your equipment is in the 12 o'clock position then plug the light cable into the connector.

NOTE: Use the Wolf connector to use the auxiliary light source as a backup for the Modus X main light source.

3.4 Wrapping Up After a Procedure

When the procedure is complete, you must complete specific wrap-up tasks to prepare Modus X for shutdown and storage.

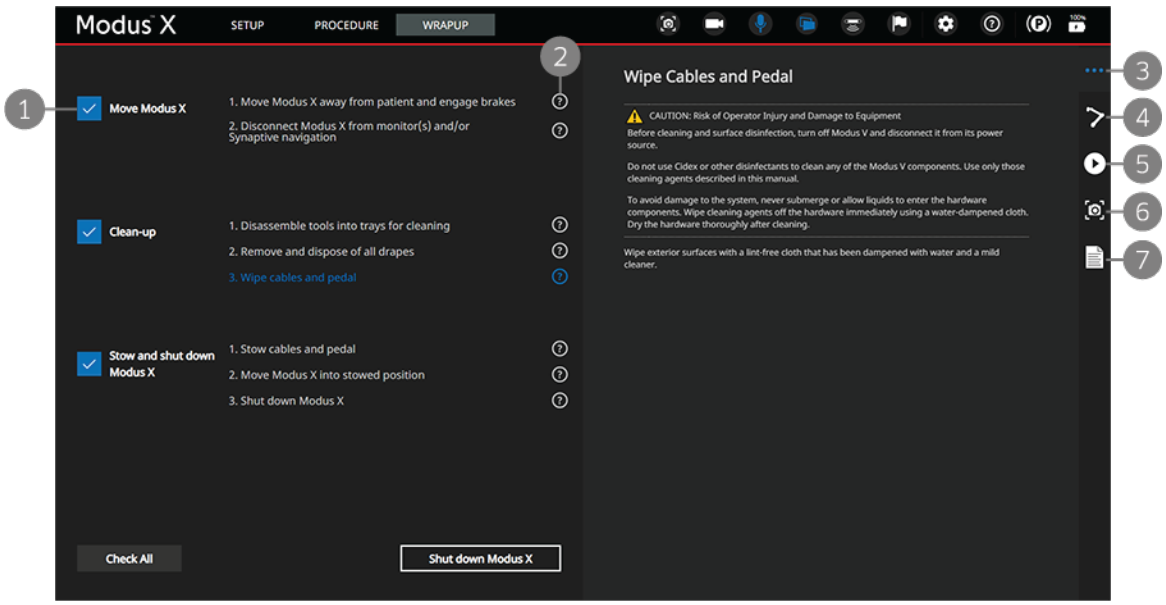


Figure 41 Wrapup phase

1 Wrapup tasks. Tap the checkbox for each task to mark it as done.

2 Help. Tap the help icon beside each task to view instructions for how to complete the task.

3 More information. Tap this icon to display instructions for how to complete the currently-selected task if they are not currently displayed in the right panel.

4 Arm movement. Tap this icon to access the Arm Movement screen. For more information, see 10.1 Arm Movement on page 117.

5 Videos. Tap this icon to access the Videos screen. For more information, see 5.5.1 Case Recording on page 88.

6 Snapshots. Tap this icon to access the Snapshots screen. For more information, see 5.5.4 Snapshots on page 92.

7 Export logs. Tap this icon to export log files to a USB drive. For more information, see 3.4.8 Exporting Logs on page 72.

Complete the tasks listed on the Wrapup screen. When you have completed a task or set of tasks, tap the corresponding checkbox to mark it as done. Alternatively, you can complete all the tasks at once then tap the **Check All** checkbox to indicate that all wrap-up tasks are complete.

When all the checkboxes are check-marked, the Shut Down Modus X button becomes available. Tap **Shut Down Modus X** to power off Modus X. You have 10 seconds to cancel the shut down if necessary.

3.4.1 Move Modus X away from Patient

Disconnect the pedal and move Modus X to a safe distance from the patient. Engage the caster brakes.

3.4.2 Disconnect Modus X from the Monitors and/or Synaptive Navigation

Disconnect Modus X from the main surgeon monitor and the secondary monitor, if one was connected. If Modus X was connected to Modus Nav, disconnect it.

3.4.3 Wipe Cables and Pedal

CAUTION: Risk of Operator Injury and Damage to Equipment

Before cleaning and surface disinfection, turn off Modus X and disconnect it from its power source.

Do not use Cidex or other disinfectants to clean any of the Modus X components. Use only those cleaning agents described in this manual.

To avoid damage to the system, never submerge or allow liquids to enter the hardware components. Wipe cleaning agents off the hardware immediately using a water-dampened cloth. Dry the hardware thoroughly after cleaning.

Wipe exterior surfaces with a lint-free cloth that has been dampened with water and a mild cleaner.

3.4.4 Stow Cables and Pedal

When the cables and pedal are clean, wrap the cables around the cable cleats on the Modus X mobile base and monitor carts.

Figure 42 Modus X power cable wrapped around cable cleat on mobile base

Stow the pedal on the Modus X mobile base:

- To stow the multi-input pedal, wrap the cable around the pedal and use the metal bar on the back of the pedal to hang the pedal over the hook on the front of the mobile base.
- To stow the single-input pedal, loop the cable and place both the cable and the pedal in the pocket on the front of the mobile base. Note that the pedal button will be outside the slot on the front of the pocket. This is to prevent the pedal from being stowed with the button in the pressed position.

For more information, see 2.2.2 Pedals on page 39.

3.4.5 Disassemble the Tools into Their Sterilizable Storage Trays for Cleaning

1. Remove the tracking spheres from the Synaptive tools used during the procedure, including the Pointers, Trackable Suction tools, and calibration block or Multi-Tool Calibration Device.
2. Dispose of the tracking spheres and port reference tool (if used) as pathological waste.
3. Place the tools in their sterilizable storage trays as indicated by the markings in the tray. Refer to the manuals and sterilization instructions accompanying Synaptive tracked tools for detailed sterilization instructions.

3.4.6 Remove and Dispose of Drapes

Remove all the drapes from Modus X and dispose of them as pathological waste.

3.4.7 Move Modus X into its Stowed Position

To safely transport Modus X, and to minimize the amount of space Modus X takes up in storage, use the Arm Movement screen to move it into its "stowed" stored position.

- To access the Arm Movement screen, tap the arm icon  on the right side of the screen.
- To move the arm into a "stored" position, press and hold on the name of the position you want to move into.

NOTE: Moving Modus X into its stowed position is a two-step process. Watch the arm carefully when it is moving. If necessary, adjust the position of the touchscreen monitor to ensure that the positioning arm does not collide with it.

Avoid handling the arm when transporting Modus X.

3.4.8 Exporting Logs

To export a ZIP file containing the log files for the last 30 days:

1. Connect a USB drive to the USB port on the Modus X mobile base.
2. On the Wrapup screen, tap the export logs icon  on the right side of the screen. Modus X displays the USB drive.

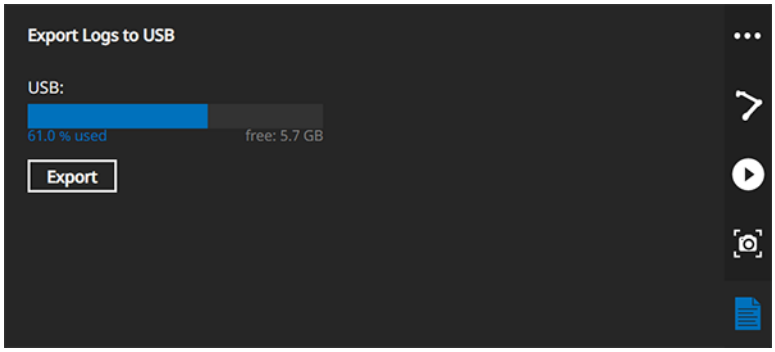


Figure 43 Exporting logs to a USB drive

NOTE: A minimum of 1 GB of free space on the drive is recommended.

3. Tap **Export**. Modus X exports a ZIP file named with the current date and time.
4. When the export is complete, remove the USB drive from the Modus X mobile base.

4.0 Voice Control

Use the voice control feature to adjust settings or select actions by speaking commands. The voice control feature can be enabled or disabled on the Sounds and Voice settings screen (see 10.8 Sounds and Voice on page 126).

4.1 Voice Control Setup

To set up voice control:

1. Turn on the transmitter and verify that the battery level is sufficient (battery level is indicated on the screen). If the battery level is not sufficient to last the anticipated length of the procedure, use a different transmitter.
2. Pair the transmitter to Modus X:
   a. Navigate to the Sounds and Voice screen in Modus X. (Tap the settings icon at the top of any screen and then tap **Sounds and Voice** on the left side of the screen).
   b. Hold down the pair button on the transmitter and tap **Start Pairing** on the Sounds and Voice screen in Modus X.
3. Put on the microphone and plug it into the transmitter. Make sure that the microphone and its cable are secure to prevent them from falling or dangling and possibly contacting the surgical site.
4. Test the microphone:
   a. Navigate to the Sounds and Voice screen in Modus X. (Tap the settings icon at the top of any screen and then tap **Sounds and Voice** on the left side of the screen).
   b. Tap **Test Microphone** on the Sounds and Voice screen then speak into the microphone. The microphone level displayed on the meter should be green. If the meter is mostly red, lower the microphone gain. If the meter is mostly blue, raise the microphone gain.

Tips for wearing the microphone:

- Put the microphone on before donning a surgical gown. This will ensure that the microphone cable is contained out of the way under the gown.

  NOTE: If you want to adjust the microphone fitting yourself, put the microphone on before scrubbing in. Otherwise, have a non-sterile person put the microphone on you and adjust the fitting.
- Always wear the microphone headset over both ears. Adjust the ear wires for your head size as necessary to ensure a snug fit and accurate microphone placement.
- Wear the microphone over the surgical mask. Adjust the microphone boom so that the microphone capsule is approximately 0.5” from the corner of your mouth. For best results, position the microphone boom so that it rests in a fold in the mask.

- Position the wire connecting the microphone to the transmitter so that it runs down your back. Optionally, use the collar clip to secure the wire to the collar of your scrubs.
- Use the belt clip to fasten the transmitter to the waistband of your scrubs, or put the transmitter in a pocket.

To switch voice control users:

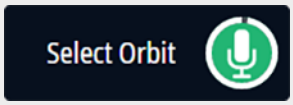
1. Unpair the currently paired transmitter by pressing the pair button on the transmitter.
2. Pair the new transmitter to Modus X by holding down the pair button on the transmitter and tapping **Start Pairing** on the Sounds and Voice screen in Modus X.
3. Tap **Reset Adaptive Voice** on the Sounds and Voice screen.

4.2 Using Voice Control

To initiate a voice command, say "OK Vimo". When Modus X recognizes this activation phrase, the voice control icon in the surgical overlay turns blue and displays a 10 second countdown. During those 10 seconds you can speak commands without repeating the activation phrase.

When Modus X recognized a spoken command, the voice control icon turns green and displays the command. If the command was not recognized, the icon turns red.

Table 18 Voice Control Icon States

Icon Appearance	Description
	Voice control inactive
	Voice control active and waiting for a voice command
	Voice control is processing speech
	Voice command recognized
	Voice command not recognized

NOTE: It is possible that Modus X may interpret speech or other sounds as a recognized command when a command was not intended.

To view a list of the possible voice commands, say "Ok Vimo, show help". The list appears in the surgical overlay (note that this will obscure much of the optics image on the screen). To hide the list of commands, say "Ok Vimo, hide help".

4.3 Voice Commands

NOTE: For safety reasons, voice commands alone never trigger the arm to move. You can use voice commands to specify a movement type, but to initiate movement you must use the pedal.

Commands marked with a dagger (†) are only available when Modus X is connected to a tracking camera.

Table 19 Voice Control Commands

Category	Command (Ok Vimo...)	Description
Optics	3D on/off Toggle 3D/stereo	Turn stereoscopic visualization on or off.
Zoom	Zoom in/out	Adjust the zoom level by 10% increments.
	Fine-zoom in/out	Adjust the zoom level by 2% increments.
	Set zoom to <#> (where <#> is a specific zoom level)	Set the zoom to a specific level (5% increments). Note that due to the similarity between "fifteen" and "fifty", "set zoom to fifteen" is not a recognized command.

Table 19 Voice Control Commands (continued)

Category	Command (Ok Vimo...)	Description
Focus	Focus in/out	Adjust the focal distance by 0.5 depth of field increments.
	Focus here Focus now	Trigger the snap focus feature. For more information about how the snap focus feature works, see 5.2.2 Image Auto Focus on page 83 and 7.4 Auto Focusing on a Tool on page 108.
	Fine-focus in/out	Adjust the focal distance by 0.25 depth of field increments.
	Image auto focus on/off	Toggle the image auto focus feature.
	Tool auto focus on/off†	Toggle the continuous tool auto focus feature.
	Auto focus † • Pointer • Long Pointer • Port • Suction 1 • Suction 2	Set the tool auto focus tool and turn the continuous tool auto focus feature on.
	Focus † • Pointer • Long Pointer • Port • Suction 1 • Suction 2	Set the tool auto focus tool and focus to that tool (snap focus).
Lights	Lights on Turn on lights	Turn the lights on at the default intensity for the currently selected optical preset.
Brightness	Brightness up/down Increase/decrease brightness Lights up/down	Adjust the image brightness by 5% increments.

Table 19 Voice Control Commands (continued)

Category	Command (Ok Vimo...)	Description
Position	Select position <#> (where <#> is the number of the position you want to select)	Select a recorded memory position.
	Save position <#> Set position <#> (where <#> is the number of the position you want to save)	Save the current position (including the current zoom and focus) as the stated memory position number.
	Select last/previous position	Select the previous position in the history position stack.
	Select next position	Select the next position in the history position stack.
Tool†	Select • Pointer • Long Pointer • Port • Suction 1 • Suction 2 • Trajectory	Select the tool to align to or to set a pose for.
	Focus • Pointer • Long Pointer • Port • Suction 1 • Suction 2	Set the tool auto focus tool and focus to that tool (snap focus).
Alignment†	Align to • Point • Axis • Rotation	Select the alignment behavior for the next align move.

Table 19 Voice Control Commands (continued)

Category	Command (Ok Vimo...)	Description
Arm mode	Select • Free • Orbit • Standoff • Translate • Rotate • Manual	Select an end effector alignment mode.
Optical presets	Select • Natural • Warm • Cool • Deep • Glare reduction	Select an optical preset.
	Blue light on/off Yellow light on/off IR fusion on/off IR monochrome on/off Fluorescence off	Switch between a fluorescence preset and the previously selected white light optical preset. These commands are only available with the applicable fluorescence module license.
Video clips	Record/Stop [video] clip	Start or stop video clip recording.
	Play/Stop/Pause [video] clip	Play, pause, or stop playing a video clip.
Snapshots	Take snapshot	Take a snapshot of the image currently displayed on the surgeon monitor.
Pose†	Set tool pose	Save the current tool pose for alignment moves.

Table 19 Voice Control Commands (continued)

Category	Command (Ok Vimo...)	Description
Nudge†	Nudge • Up • Down • Left • Right Stand in/Stand out	Move the end effector slowly in the specified direction upon sustained pedal input. Note that Modus X will not comply with the "stand in" command if the end effector is below the minimum standoff distance for the tracked tool.
Help	Show/hide help Toggle help	Show or hide the list of voice commands over the video on the monitor.

4.4 Voice Nudge

Use the voice nudge feature to move the end effector small distances using a voice command and the pedal. When nudging the end effector in one of the four directions (up, down, left, or right) the direction of movement is relative to the image on the main monitor. When using voice nudge to stand the end effector in or out, Modus X maintains the focus on the surgical field.

NOTES:

- **The voice nudge feature does not require connection to a tracking camera with the exception of the "stand in" command. To use voice nudge to stand in, Modus X must be connected to a tracking camera and both the end effector and tracked tool must be visible to the tracking camera.**
- **The speed at which the arm moves scales with the zoom level.**

To enter nudge mode, use the voice command "OK Vimo..."

- "Nudge <direction>" (where <direction> is one of "Up", "Down", "Left", or "Right")

  -OR-

- "Stand in*" or "Stand out"

* The "Stand in" command is only available when the end effector is above the minimum standoff distance for the tracked tool. For more information, see 2.1.7.4 End Effector Standoff Distance on page 34.

The nudge mode icon appears in the surgical overlay indicating the direction of movement. The icon also displays a timer. You can make nudge moves until the timer times out.

Figure 44 Example surgical overlay icon showing the direction of movement (left and stand in)

To nudge the end effector:

- If you are using the single-input pedal, press on the pedal
- If you are using the multi-input pedal, press on the positioning arm auto-align control on the pedal

The end effector moves for as long as you hold the pedal pressed, up to a maximum of 10 cm.

Modus X exits nudge mode when:

- The timer times out
- The arm is moved manually
- You change the arm mode on the Procedure screen (for example, by selecting a different tool, or by selecting a memory or history position)
- Modus X detects a potential collision or initiates a precautionary halt for another reason

5.0 Optics Features

5.1 Using Optical Presets

Modus X includes several optical presets for a variety of common surgical conditions. You can also specify your own custom presets. For more information about optical presets, see 10.6 Optical Presets on page 123.

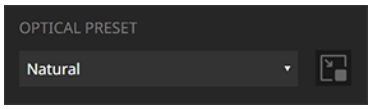


Figure 45 OPTICAL PRESET drop-down

To use an optical preset:

- Select it from the OPTICAL PRESET drop-down list on the Procedure screen.

  -OR-

- Activate the quick menu and select the desired preset from the **Preset** menu.

  -OR-

- Use the voice command "OK Vimo, select preset <preset name>" (where <preset name> is one of "Natural", "Warm", "Cool", "Deep", "Glare Reduction", ["Blue Light", "Yellow Light", "IR Fusion" or "IR Monochrome"]*).

* Only available when the applicable fluorescence module is licensed.

5.2 Adjusting Focal Distance

Use the FOCAL DISTANCE controls to adjust the focal distance of the surgical cameras. Modus X has a focal distance range of 300 mm to 650 mm.

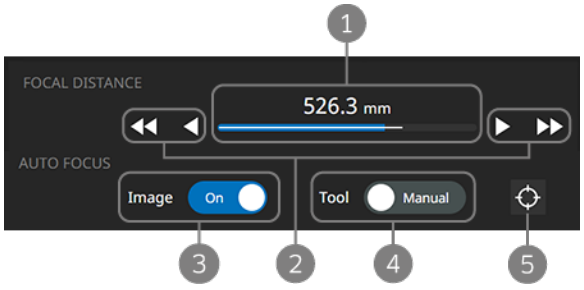


Figure 46 FOCAL DISTANCE controls on the Procedure screen

1 Current focal distance. If the optical preset you are using has a recommended focal distance range, that range is displayed as a white line within the total a focal distance range.

2 Manual focal distance adjustment controls.

3 Image auto focus toggle control. Tap to turn the image auto focus feature on or off.

4 Tool auto focus control. For more information, see 7.4 Auto Focusing on a Tool on page 108.

5 Snap focus. Tap to let Modus X adjust the focal distance. For more information, see 5.2.2 Image Auto Focus below or 7.4 Auto Focusing on a Tool on page 108.

5.2.1 Manual Focus

To manually adjust the focal distance:

- Tap the fine or coarse increment arrows on the Procedure screen.

  -OR-

- Use the focus adjustment switch on the end effector (see 2.1.7.2 End Effector Handle Controls on page 31).

  -OR-

- Adjust the end effector standoff distance (see 2.1.7.4 End Effector Standoff Distance on page 34).

  -OR-

- Use the multi-input pedal (see 2.2.2 Pedals on page 39).

  NOTE: If the focal distance is adjusted using the multi-input pedal or the end effector handle controls, a veil will appear over the optical controls on the touchscreen monitor.

  -OR-

- Use the voice command "OK Vimo..."

  "Focus in" / "Focus out" (to adjust the focal distance by 0.75 depth of field increments)

  "Fine-focus in" / "Fine-focus out" (to adjust the focal distance by 0.25 depth of field increments)

5.2.2 Image Auto Focus

When the image auto focus feature is enabled, Modus X automatically adjusts the focal distance to keep the image on the monitor(s) in focus. The activities that trigger focus adjustment are configurable and can include positioning arm movements, zoom level changes, or when Modus X cannot snap focus on a tool. For more information about configuring image auto focus, see 10.5 Camera Settings on page 122.

NOTES:

- **The image auto focus feature is not available when a fluorescence optical preset is selected.**
- **If tool auto focus is on, turning image auto focus on will turn tool auto focus off.**

To turn image auto focus on:

- Tap the **Image** toggle control on the Procedure screen.

  -OR-

- Use the voice command "OK Vimo, image auto focus on".

About the Auto Focus Area Indicator

Modus X displays a square on the surgical overlay to indicate the area of the image that it will focus to.

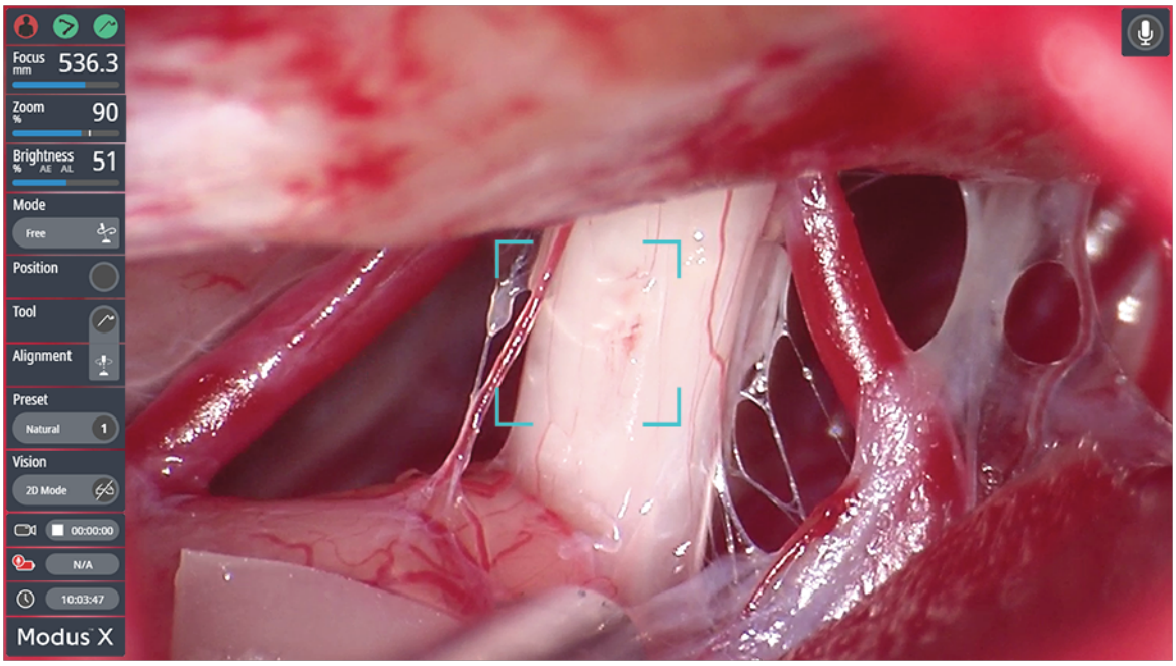


Figure 47 Focus area indicator on surgical overlay when auto focus is in progress

While the field of view is changing, the focus area indicator is displayed with white corners on the surgical overlay. Stop moving the positioning arm when the focus area indicator is in the desired location and Modus X will focus on that location.

The focus area indicator color changes to teal while Modus X is adjusting the focal distance. If Modus X is not able to focus at the current location, the focus area indicator is displayed in red. Manually adjust the focus if necessary.

Using Snap Focus with Image Auto Focus

Use the snap focus feature with image auto focus to restore focus if the surgical scene has changed and you do not want to move the positioning arm or adjust the zoom level (which would automatically trigger an image auto focus adjustment if Modus X is configured to do so).

To snap focus on the image:

- Tap the focus icon on the Procedure screen.

  -OR-

- Press the auto focus button on the multi-input pedal or tap the single-input pedal (see 2.2.2 Pedals on page 39).

  -OR-

- Use the voice command "OK Vimo, focus here".

5.3 Adjusting Zoom

Use the ZOOM controls to zoom in or out on the images coming from the surgical camera. Modus X uses optical zoom to increase the magnification by 7 times, then switches to using digital zoom to increase the magnification by an additional 40%.

The ZOOM controls on the Procedure screen indicate the current zoom level. A vertical white line on the zoom range bar indicates the switch from optical to digital zoom. If the optical preset you are using has a recommended zoom level range, that range is displayed as a horizontal white line within the total a zoom level range.

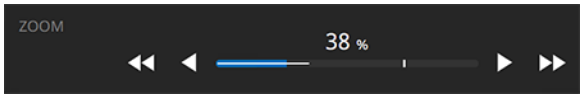


Figure 48 ZOOM controls on the Procedure screen

To adjust the zoom level:

- Tap the fine or coarse increment arrows on the ZOOM control on the Procedure screen.

  -OR-

- Use the zoom switch on the end effector handle (see 2.1.7.2 End Effector Handle Controls on page 31).

  -OR-

- Use the multi-input pedal (see 2.2.2 Pedals on page 39).

  NOTE: If the zoom is adjusted using the multi-input pedal or the end effector handle controls, a veil will appear over the optical controls on the touchscreen monitor.

  -OR-

- Use a voice command "OK Vimo..."
  - "Zoom in" / "Zoom out" (to adjust the zoom level by 10% increments)
  - "Fine-zoom in" /"Fine-zoom out" (to adjust the zoom level by 2% increments)
  - "Set zoom to <#>" (where <#> is a specific zoom level from 0 to 140%)

5.4 Adjusting Lights and Image Brightness

WARNING: Risk of Patient Injury Due to Light Intensity

Although it is very unlikely, the Modus X light sources are capable of producing light intense enough to cause tissue burns. The risk of tissue burns is affected by factors such as:

- The length of exposure (longer surgical procedures increase the risk)
- Materials adjacent to the surgical site (such as incision drapes) and local vasoconstrictive medications
- The location of the procedure (some areas of the body may be more sensitive than others)
- The patient's skin type and general health
- Medications that affect sensitivity to light
- The distance between the end effector and the body.

To reduce the risk of injury to the patient, take protective measures such as:

- Regularly irrigating the illuminated surgical field to keep it moist
- Covering illuminated areas with moistened sterile gauze
- Regularly re-moistening any drapes in use in illuminated areas

Never leave Modus X unattended when the light sources are on.

Each optical preset has appropriate light and brightness values set by default but you can adjust the Modus X lighting if necessary. There are two ways to control how bright the image on the main and secondary monitors appears:

- By changing the intensity of the light from the illuminators on the Modus X end effector (the main lights)
- By changing the image brightness

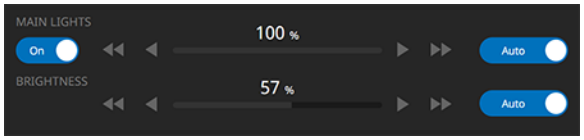


Figure 49 MAIN LIGHTS and BRIGHTNESS controls on the Procedure screen

5.4.1 Main Lights

To turn the main lights on or off:

- Tap the MAIN LIGHTS On/Off toggle control on the Procedure screen.

  -OR-

- Use the voice command "OK Vimo, Lights on"

  (Note that it is not possible to turn the lights off using a voice command.)

NOTE: The lights always turn on at the default intensity for the currently selected optical preset, not at the intensity they were set to when they were turned off.

To adjust the intensity of the lights, tap the coarse or fine increment arrows on the **MAIN LIGHTS** slider on the Procedure screen.

NOTE: If auto exposure is enabled, adjustments to the light level may not change the image brightness on the monitors. For more information about the auto exposure feature, see 5.4.2 Brightness below.

You can also allow Modus X to automatically adjust the light intensity based on the current zoom level and focus distance. When auto light intensity is enabled, Modus X automatically increases the light intensity when the zoom level and/or focus distance increase.

To enable auto light intensity, tap the MAIN LIGHTS Manual/Auto toggle control on the Procedure screen.

NOTE: When auto light intensity is enabled:

- **The MAIN LIGHTS slider is disabled**
- **If you turn the lights off, Modus X still calculates the appropriate light level as the zoom and/or focus distance change to ensure that the light level is correct when the lights are turned back on**

5.4.2 Brightness

Use the **BRIGHTNESS** controls to adjust the brightness of the image displayed on the main and secondary monitors. Each optical preset has default brightness behavior set for it, but you can manually adjust the image brightness if necessary. Manually adjusting the image brightness may have the effect of changing the main light intensity, the camera settings, or both, depending on the currently selected optical preset.

If the current optical preset supports automatic adjustments, a Manual/Auto toggle control appears next to the BRIGHTNESS slider:

- For supported white light presets, when the toggle is set to Auto, Modus X automatically adjusts the camera settings to achieve the target exposure level based on the surgical scene. For example, Modus X will reduce the exposure level when a shiny surgical tool is brought into the field.
- For the IR Fusion preset, when the toggle is set to Auto, Modus X automatically adjusts the camera settings to optimize the fluorescence signal.
- When the toggle is set to Manual, Modus X does not adjust any values. If the image displayed on the monitors is not satisfactory, you can adjust it as described below.

NOTE: The BRIGHTNESS slider is disabled when auto brightness is enabled.

To manually adjust the image brightness:

- Tap the coarse or fine increment arrows on the **BRIGHTNESS** slider on the Procedure screen.

  -OR-

- On the end effector, push the center toggle switch up to activate the Brightness quick menu option, then push the center toggle switch up or down to increase or decrease the image brightness. For more information, see the description of the Brightness quick menu option on page 53.

  -OR-

- Use a voice command "Ok Vimo..."
  - "Brightness up" / "Brightness down"
  - "Increase brightness" / "Decrease brightness"
  - "Lights up" / "Lights down"

  Voice commands adjust the brightness by 5% increments.

NOTE: Changing the brightness using the quick menu or a voice command will disable auto brightness if it is currently enabled.

5.5 Videos, Clips, and Snapshots

WARNING: Risk of Procedure Delay or Damage to Equipment Due to Loss of Modus X Function

If there is insufficient data storage space available on Modus X, the system will not be able to record video or capture still image snapshots. Export and/or delete unneeded videos and snapshots regularly to ensure that sufficient data storage space is available.

5.5.1 Case Recording

Modus X can record and store 795 GB of video data from the surgical cameras.

To start or stop procedure video recording, tap the video recording icon at the top of any Modus X software screen.

You can export your recorded video to a USB drive. For more information, see 5.5.3 Exporting Videos and Clips on page 90.

NOTE: Recording is disabled while video is being exported. Wait for the export to finish before starting recording.

5.5.2 Video Clips

WARNING: Risk of Patient Death or Permanent Disability Due to Obscured View of Surgical Site

Clip recording playback will partially or completely obscure the view of the surgical site on the monitor(s). Use the advanced playback controls to control how clip recording playback is displayed.

WARNING: Risk of Patient Injury Due to Improper Treatment or Procedure Delay

Clearing the video clip recordings list will result in the clip recordings being unavailable for playback on the external monitor. The inability to play back a clip recording may result in improper treatment for the patient, or a delay in completing the procedure.

WARNING: Risk of Procedure Delay Due to Loss of Modus X Function

If there is insufficient data storage space available on Modus X, the system will not be able to record video or capture still image snapshots. Export and/or delete unneeded videos and snapshots regularly to ensure that sufficient data storage space is available.

Use the VIDEO CLIPS controls on the Procedure screen to record and play back short video clips.

Figure 50 VIDEO CLIPS controls on the Procedure screen

1 Start/stop recording. Tap this icon to start recording a video clip, or to stop recording if recording is already in progress.

NOTE: Clip recording is not available when a clip is being played back or if there is insufficient data storage space for new clips.

2 Play/pause video clip. Tap this icon to play the most recently recorded video clip on the surgeon monitor(s), or to pause the playback if the clip is currently playing.

NOTE: Clicking this Play icon will play the most recently recorded clip. If you want to play an earlier clip, use the advanced clip recording playback controls (see below).

3 Stop playback. Tap this icon to stop a video clip that is currently playing and stop showing the video clip on the surgeon monitor(s).

4 Advanced playback controls. Tap this icon to access the advanced playback controls. For more information, see Using the Advanced Playback Controls below.

NOTE: The surgical overlay components are not included in clips.

NOTE: You can record both case video and clips at the same time.

- **If case recording is not already active, it starts when clip recording starts.**
- **If case recording was not active when clip recording started, it stops when clip recording stops.**
- **If you stop case recording while clip recording is active, clip recording also stops.**

Using the Advanced Playback Controls

Tap the advanced playback controls icon ••• on the VIDEO CLIPS controls to access the advanced playback controls.

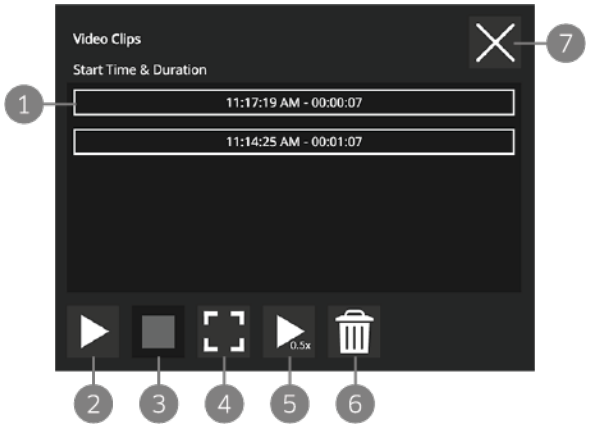


Figure 51 Advanced video clip playback controls

1 Clip list. Tap on a clip to start playing it on the surgeon monitor(s).

2 Play/pause video clip. Tap this icon to play the selected clip on the surgeon monitor(s), or to pause the playback if the clip is currently playing.

3 Stop playback. Tap this icon to stop a video clip that is currently playing and stop showing the video clip on the surgeon monitor(s).

4 Full screen mode. Tap this icon to toggle between displaying the video clip in full screen mode and picture-in-picture mode on the surgeon monitor(s).

5 Playback speed. Tap this icon to toggle between playing the video clip at 50% or full speed.

6 Clear clip list. Tap this icon to clear all the clips in the clip list.

NOTE: Cleared clip recordings are no longer available for playback but can still be exported. For more information, see 5.5.3 Exporting Videos and Clips on page 90. To prevent clip recordings from accidentally being viewed in a subsequent procedure, always clear the clip list at the end of each procedure.

7 Close. Tap this icon to close the advanced playback controls dialog.

NOTE: This will also stop playback if a clip is playing.

NOTE: Clips are always recorded and played back in the standard monitor orientation, even if they are played on a monitor that has been set to flip and mirror the images from the Modus X surgical cameras.

5.5.3 Exporting Videos and Clips

WARNING: Risk of Patient Death or Permanent Disability Due to Malfunctioning Equipment

The USB port on the Modus X mobile base is for file export purposes only. Do not use the USB port to connect any device other than a USB storage device to Modus X.

To view the list of videos and clips available for export, tap the video export icon on the right side of the Setup or Wrapup screen.

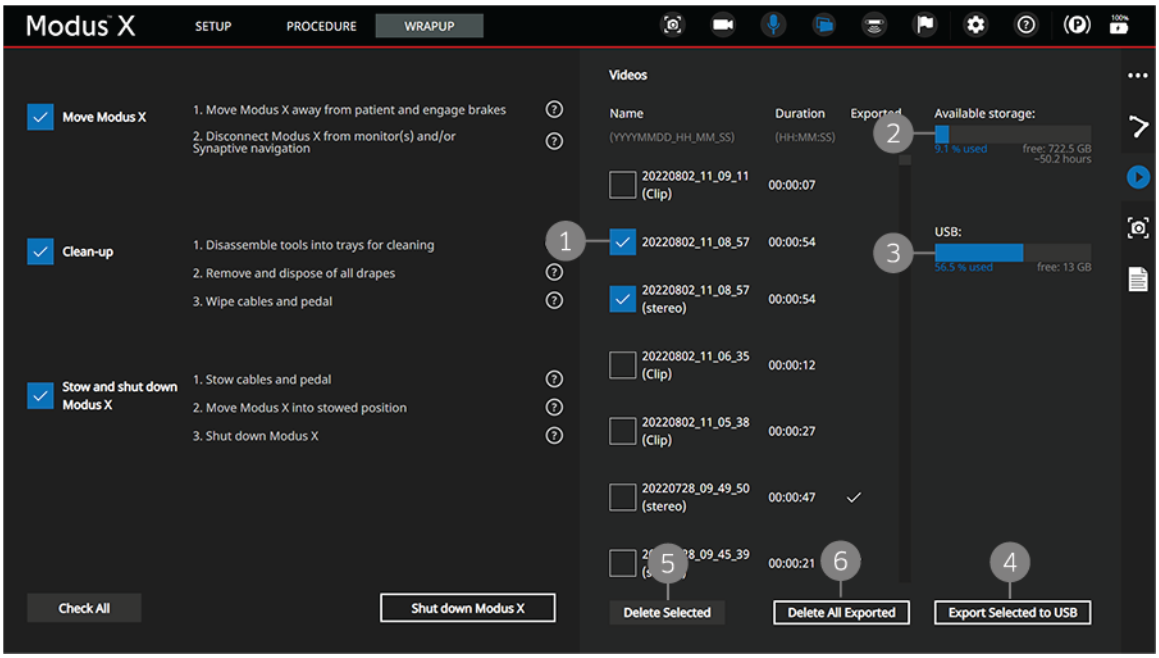


Figure 52 Videos screen

1 File list. Files are named by the date and time they were recorded. Clips have "(clip)" in the file name. Videos that were recorded in 3D have "(stereo)" appended to the file name.

Tap the checkbox beside a file to select it for export or deletion. A check mark appears in the Exported column if the file has already been exported from Modus X.

2 Modus X storage. The amount of storage space available on Modus X is displayed here.

3 USB storage available. When a USB drive is plugged in to the Modus X mobile base, the amount of storage space available on the drive is displayed here.

4 Export Selected to USB. Tap this button to export the selected files to a USB drive.

5 Delete Selected. Tap this button to delete the selected files from Modus X.

6 Delete All Exported. Tap this button to delete all files that have been exported from Modus X.

Modus X saves videos and clips with a file name based on the date and time the video or clip was recorded. Items are listed on the Videos screen in reverse chronological order.

To export a video or clip:

1. Connect a USB drive to the USB port on the Modus X mobile base.
2. On the Videos screen, tap the checkbox corresponding to the item you want to export.
3. Tap **Export Selected to USB**. Modus X displays a progress bar indicating the time remaining to copy the file to the USB drive.
4. When the export is complete, remove the USB drive from the Modus X mobile base.

NOTES:

- **You cannot export while video is being recorded. Stop recording before exporting.**
- **If you connect a USB drive with multiple partitions, Modus X always exports the video file to the first partition.**

To delete a video or clip, tap the checkbox corresponding to the item you want to delete and tap **Delete Selected**.

To delete all items that have been exported, tap **Delete All Exported**.

5.5.4 Snapshots

WARNING: Risk of Patient Death or Permanent Disability Due to Malfunctioning Equipment

The USB port on the Modus X mobile base is for file export purposes only. Do not use the USB port to connect any device other than a USB storage device to Modus X.

Modus X can record and store 5 GB of snapshot images from the surgical camera.

To capture a snapshot:

- Tap the snapshot icon at the top of any Modus X software screen.

  -OR-

- Use a voice command "OK Vimo, take snapshot".

To view the list of snapshots available for export, tap the snapshot export icon on the right side of the Setup or Wrapup screen.

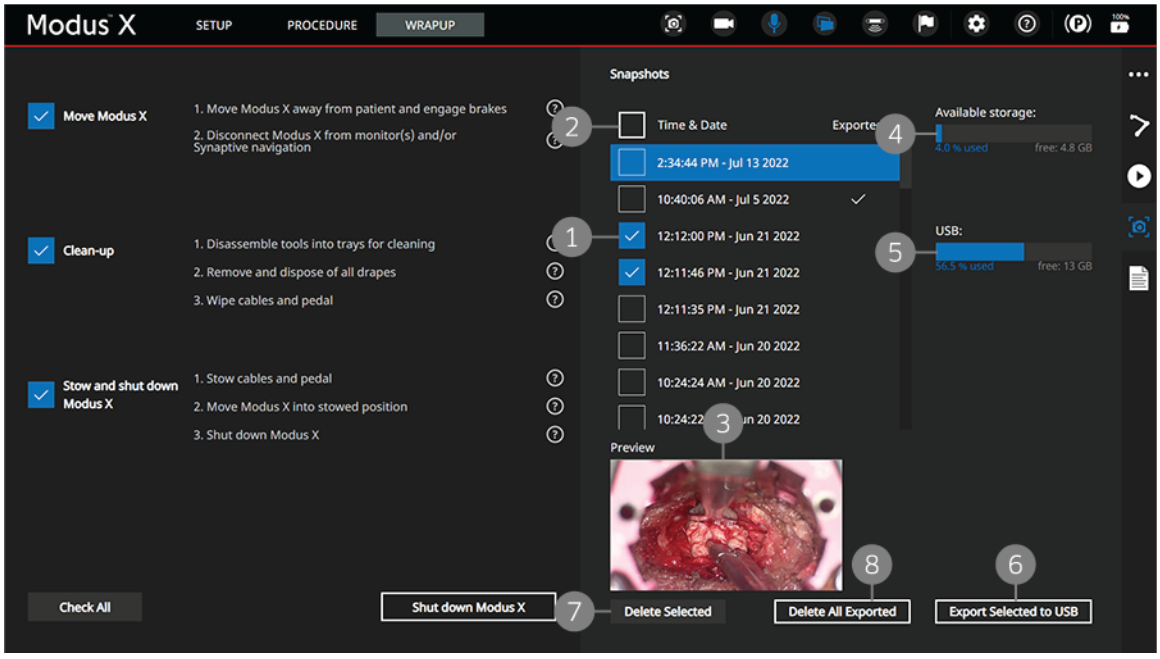


Figure 53 Snapshots screen

1 Snapshots list. Snapshot files are named by the date and time they were captured.

Tap the checkbox beside a snapshot to select it for export or deletion. A check mark appears in the Exported column if the snapshot has been exported from Modus X.

2 Select/deselect all. Tap this checkbox to select or deselect all the snapshots in the list.
3 Tap on a snapshot file name to view a preview of the image in the Preview area.
4 Modus X storage. The amount of storage space available on Modus X is displayed here.
5 USB storage available. When a USB drive is plugged in to the Modus X mobile base, the amount of storage space available on the drive is displayed here.
6 Export Selected to USB. Tap this button to export the selected snapshots to a USB drive.
7 Delete Selected. Tap this button to delete the selected snapshots from Modus X.
8 Delete All Exported. Tap this button to delete all snapshots that have been exported from Modus X.

To delete a snapshot, tap the checkbox corresponding to the snapshot you want to delete and tap **Delete Selected**.

To delete all snapshots that have been exported, tap **Delete All Exported**.

6.0 Aligning to a Position

WARNING: Risk of Patient Death or Permanent Disability Due to Modus X Collision with Patient, Surgeon, or Surgical Tools

When moving into a saved position (memory or history position, or one of the stored positions listed on the Arm Movement screen) Modus X does not enforce a minimum standoff distance to prevent a collision with the patient, surgeon or surgical tools. Observe the positioning arm carefully when moving into these positions and stop motion if necessary.

The positioning arm may not always follow the same route when moving into memory positions or when moving backward and forward through history positions. Observe the positioning arm carefully when it is moving into these positions and stop motion if necessary.

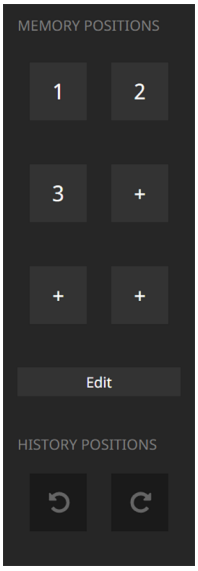


Figure 54 Position alignment features on the Procedure screen

Use the Memory Positions and History Positions features to move the end effector into a recorded position.

- Memory positions are positions which you can set and return to on demand.
- History positions are the previous positions the end effector has been in.

6.1 Working with Memory Positions

Use the Modus X memory positions feature to save up to six end effector positions and move to them during the procedure. When saving a memory position, Modus X records the position of the end effector, the focal distance and zoom level of the surgical camera, so that it can be restored when moving into the memory position.

NOTE: Memory positions are erased when the Modus X mobile base caster brakes are disengaged, there is a software restart, or there is a system restart. Memory positions become unavailable in these instances but can be re-set.

You can save and select memory positions using the Procedure screen, the quick menu, or voice commands. Memory positions can only be overwritten and deleted on the Procedure screen.

To delete all memory positions, on the Procedure screen, tap **Edit** under the memory positions then tap the trashcan icon.

NOTE: It is not possible to delete a single memory position. Individual memory positions can only be reset.

Using the Procedure Screen

To save a memory position:

1. Move the positioning arm into the desired pose (either by manually moving the arm or by completing an align move) and set the desired zoom and focus distance.
2. Tap a + icon to record that memory position. A confirmation message appears.
3. Repeat this process to save up to six memory positions.

To move Modus X into a saved memory position:

1. Press the number icon corresponding to the desired position. The icon turns green to indicate that the position is selected.
2. Press and hold the pedal to move the arm into the memory position. When the arm movement is complete, the icon turns green to indicate that the arm is now in that position.

To overwrite a memory position:

Figure 55 Memory positions in edit mode

1. Move the positioning arm into the new desired pose.
2. Tap **Edit** under the memory positions. A pencil icon appears on the memory positions that have previously been set.
3. Tap the number icon corresponding to the memory position that you want reset.
4. If you want to reset another memory position, repeat steps 1 - 3, otherwise, tap the arrow icon to exit from the editing mode.

NOTES:

- **The Edit option only appears when at least one memory position has been set.**
- **Modus X disables the pedal when you are in edit mode.**

Using the Quick Menu

To save a memory position:

1. Move the positioning arm into the desired pose (either by manually moving the arm or by completing an align move) and set the desired zoom and focus distance.
2. Activate the quick menu and select the **Position** menu item.
3. In the submenu, select an unsaved position.

To move Modus X into a saved memory position:

1. Activate the quick menu and select the **Position** menu item.
2. In the submenu, select the saved memory position you want to move to. The number of the saved position appears in the quick menu to indicate that the position is selected.
3. Press and hold the pedal to move the arm into the memory position.

Using Voice Commands

To save a memory position:

1. Move the positioning arm into the desired pose (either by manually moving the arm or by completing an align move) and set the desired zoom and focus distance.
2. Use the voice command "OK Vimo, save position <#>" (where <#> is the number of the position you want to save).
3. Repeat this process to save up to six memory positions.

To move into a memory position:

1. Use the voice command "OK Vimo, select position <#>" (where <#> is the number of the position you want to select).
2. Press and hold the pedal to move the arm into the memory position.

6.2 Working with History Positions

Modus X records each arm position that is completed, including manual moves and auto-align moves, as a history position. This allows Modus X to “undo” or “redo” movements into these positions. Each position is recorded in a “stack” of history positions.

Like using the forward and back buttons in an Internet browser to move forward and backward in your viewing history, the Modus X undo and redo features move the arm backwards and forwards through the stack of history positions. If an undo or redo movement is not available, the icon on the Procedure screen is displayed with a dark gray background color.

You can move the arm into a history position using the Procedure screen or voice commands.

Using the Procedure Screen

To move Modus X into its last arm position:

1. Tap the left undo icon. The icon turns blue to indicate that the history position has been selected.
2. Press and hold the pedal to move the arm into position. Modus X moves the positioning arm into the previous position in the stack and stops movement when it reaches that position or the pedal is released.

To move the arm into the previous position in the stack, press and hold the pedal again (the undo feature remains active until you switch to another position option such as a memory position or tracking at tool).

To move forward in the stack of history positions:

1. Tap the right redo icon.
2. Press and hold the pedal to move the arm. Modus X moves the positioning arm back into the original position. The positioning arm stops movement when it reaches that position or the or the pedal is released.

Using Voice Commands

To move Modus X into the previous arm position (backward in the history stack):

1. Use the voice command "OK Vimo, select previous position" or "OK Vimo, select last position" (both commands perform the same function).
2. Press and hold the pedal to move the arm into position. Modus X moves the positioning arm into the previous position in the stack and stops movement when it reaches that position or the pedal is released.

To move Modus X into the next arm position (forward in the history stack):

1. Use the voice command "OK Vimo, select next position".
2. Press and hold the pedal to move the arm into position. Modus X moves the positioning arm into the previous position in the stack and stops movement when it reaches that position or the pedal is released.

NOTES:

- **The saved history positions include only the arm position, unlike memory positions where the zoom and focus values are saved in addition to the arm position.**
- **The stack of history positions is erased when the Modus X mobile base caster brakes are disengaged, the procedure is restarted, or there is a system restart. The Undo/Redo functionality becomes unavailable in these cases.**
- **Modus X cannot undo movements that result in a collision of the positioning arm. Use the manual mode switch to manually move the positioning arm out of a collision.**
- **Movements that result in the positioning arm reaching its mechanical limit are not added to the stack of history positions. If the positioning arm reaches a mechanical limit, undo the movement to return to the previous position.**

6.3 Modus X Safety Measures When Aligning to a Position

Modus X enforces the following safety measures when aligning to a position.

- Movement stops immediately when the pedal is released.
- The positioning arm will not move the end effector more than 40 cm or rotate the arm more than 90 degrees from its previous position. Perform several shorter moves if you need to move to a distance greater than 40 cm, or adjust the arm position using the manual mode switch.
- The positioning arm will not move to your requested position if Modus X detects that the arm would collide with itself.

7.0 Automation Features

To use automation features, Modus X must be connected to a tracking camera.

7.1 Aligning to a Tool

Use the tool alignment features to position the end effector at a consistent distance, angle and rotation relative to a tool. Modus X tracks the location of the tool as you work and moves the end effector into your specified “pose” for the tool when you command an align move.

NOTE: Synaptive tools may not be included with Modus X but may be ordered separately, subject to regional availability limitations. For more information, contact Synaptive customer service.

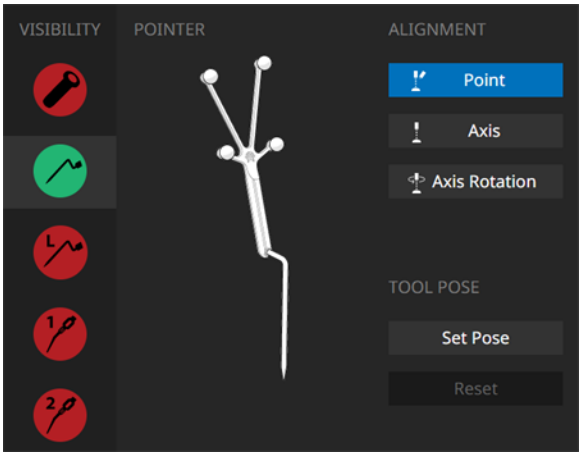


Figure 56 Tool alignment features on the Procedure screen

7.1.1 Setting a Tool Pose

The position of the end effector relative to a tracked tool is called the “pose”. A pose includes:

- The angle of the end effector relative to the tracked tool
- The rotation of the end effector relative to the tracked tool

Modus X is configured with a default pose for each tracked tool but you can set your own pose if you prefer. To restore the default pose for the tool, tap **Reset Pose** on the Procedure screen.

To set a pose:

1. Select the tool you want to set the pose for:
   - Tap the tool icon on the left side of the Procedure screen.

     -OR-
   - Use the voice command "OK Vimo, select <tool>" (where <tool> is the name of the tool you want to select).
2. Position the end effector at your desired rotation and angle from the tool.
3. Set the pose:

- Tap **Set Pose** on the Procedure screen.

  -OR-

- Use the voice command "OK Vimo, set tool pose".

When setting a pose, the end effector must be far enough from the tool that there is no risk of it colliding with the tool, but close enough to the tool to provide adequate magnification and focus for the camera. For the Trackable Suction tools, it is a good idea to set the pose when holding the tool in a comfortable position and with the tool tip centered on main surgeon monitor.

NOTE: The currently-selected Camera Alignment option does not affect setting a pose. Modus X always records the angle and rotation of the tracked tool when setting a pose. For more information about using the Alignment Type options, see below.

7.1.2 Setting an Alignment Type

The alignment types determine how Modus X will position the end effector when you command an align move. Although Modus X knows the complete position of the end effector for the currently set pose (including the rotation, angle, and distance from the tracked tools), you may not always want to recreate the pose exactly. For example, when tracking a Pointer tool, you may want to track only the location of the tool tip and not the tool's angle or rotation.

Select an alignment type to specify how you want to track the currently selected tool.

Table 20 Arm Alignment Types

Type	Description	Icon
Point	The arm will position the camera so that it points at the tip of the Pointer or suction tool, or the bottom of the brain sheath. The tool's angle and rotation are ignored. For more information about aligning to a brain sheath, see 7.1.4 Working with a NICO BrainPath Brain Sheath (Port) on page 106.	
Axis	The arm will position the camera so that it points to the location of the tool and is aligned at the angle relative to the tool's axis as specified by the pose set for this tool. If no pose is set, Modus X aligns the camera to the tool's axis.	
Axis Rotation	The arm will position the camera so that: • It points to the location of the tool • It is aligned at the angle relative to the tool's axis as specified by the pose set for this tool (if no pose is set, the camera is aligned to the tool's axis) • It is aligned with the tool's rotation as specified by the pose set for this tool (if no pose is set, the camera is aligned so that the tool's marker tree corresponds to the "up" direction on the monitor)	

NOTES:

- **If a Trackable Suction tool is selected and was calibrated using the Synaptive calibration block, the Axis and Axis Rotation options are not available until a pose has been set for the tool. For more information, see 7.1.3 Working with Suction Tools below.**
- **When the Synaptive surgical trajectory item is selected, only the Axis alignment type is available.**

To set the alignment type:

- Tap the desired alignment type on the Procedure screen.

  -OR-

- Activate the quick menu and select the desired alignment type from the **Alignment** menu.

  -OR-

- Use the voice command "OK Vimo, align to <alignment type>" (where <alignment type> is one of "point", "axis", or "rotation").

7.1.3 Working with Suction Tools

In order for Modus X to align to a Trackable Suction tool, the tool must be calibrated in Modus X. During the two-part calibration process, Modus X "learns" where the tip of the suction tool is relative to the tool's tracking spheres.

Your Modus X system is configured to use either the Synaptive Multi-Tool Calibration Device or the Synaptive calibration block for calibrating Trackable Suction tools.

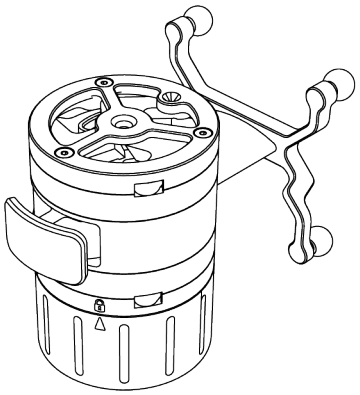


Figure 57 Multi-Tool Calibration Device

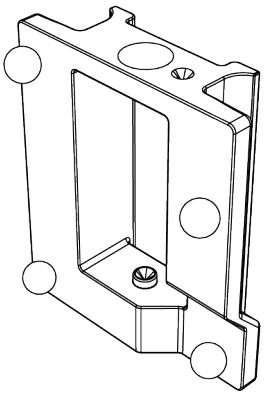


Figure 58 Calibration block

For more information, see:

- 7.1.3.1 Calibrating Suction Tools Using the Synaptive Multi-Tool Calibration Device on page 102
- 7.1.3.2 Calibrating Suction Tools Using the Synaptive Calibration Block on page 105

To maintain accurate calibration, you **must** re-calibrate Trackable Suction any time you change the suction tube attached to the handle, bend or alter the malleable suction tube, or adjust the position of the suction tube or marker tree relative to the tool handle.

To re-calibrate the Trackable Suction tool, tap **Re-calibrate** on the Procedure screen and repeat the calibration steps.

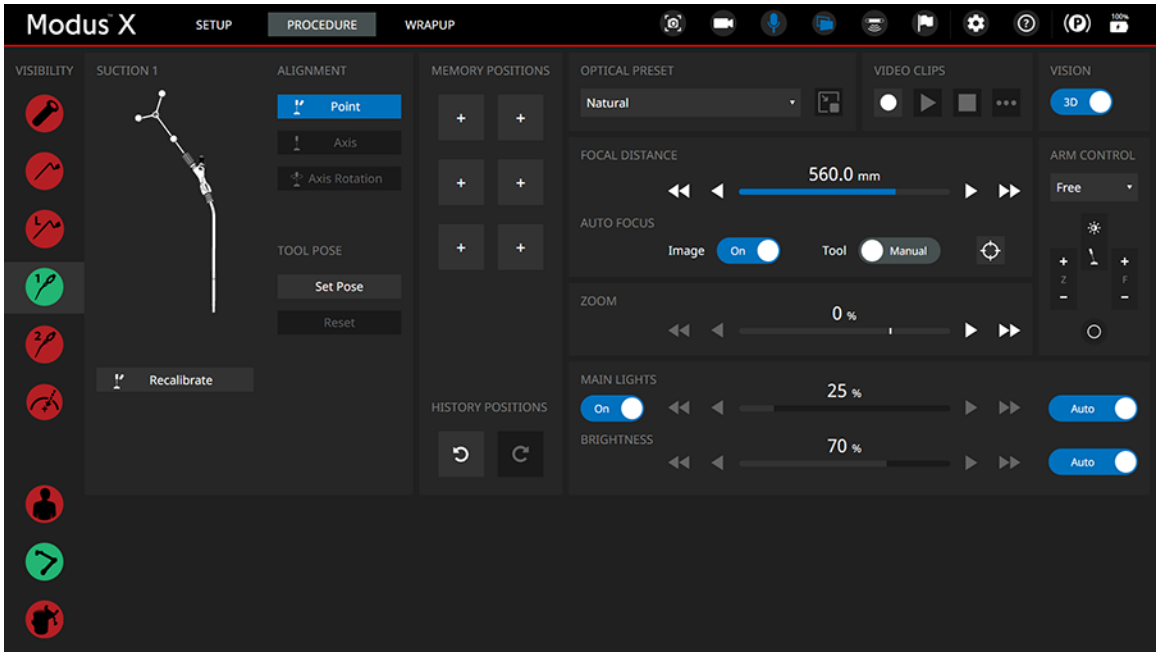


Figure 59 Procedure screen for Trackable Suction tool

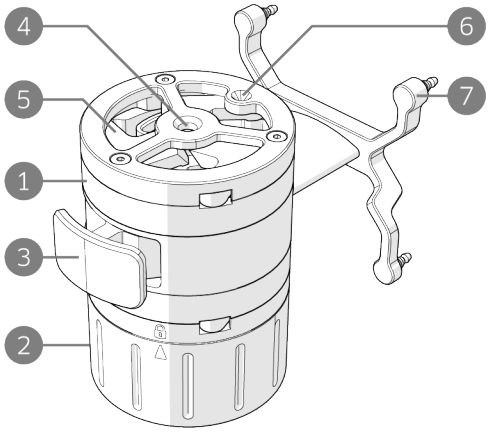
NOTE: If you connect Modus X to Modus Nav after you have calibrated a suction tool in Modus X, the calibration data from Modus Nav will override the calibration in Modus X.

- If the suction tool was not calibrated in Modus Nav, you will be prompted to re-calibrate the suction tool in Modus X.
- If the suction tool was calibrated in Modus Nav, after connecting Modus X to Modus Nav, verify that Modus X is still tracking the suction tool correctly and re-calibrate the tool if necessary.

7.1.3.1 Calibrating Suction Tools Using the Synaptive Multi-Tool Calibration Device

The Synaptive Multi-Tool Calibration Device must be assembled and inspected before it is used to calibrate a Suction tool.

Calibration Device Features



1 Body
2 Removable base
3 Release lever
4 Instrument aperture
5 Holder arms
6 Verification divot
7 Tracking array

Figure 60 Multi-Tool Calibration device features

Calibration Device Assembly

Figure 61 Assembling the Multi-Tool Calibration Device

1 Attach the removable base to the body by aligning the arrow indicator on the base with the "unlock" symbol on the body and rotating the base until the arrow aligns with the "locked" symbol.

2 Attach a tracking sphere to each post. Push the spheres as far down onto the posts as they will go. You should feel the spheres snap into place. Verify that each sphere is securely attached to its post.

NOTE: You must attach new tracking spheres to the sterile Multi-Tool Calibration Device for each procedure.

Calibration Device Inspection

WARNING: Risk of Patient Death, Permanent Disability, or Injury Due to Inappropriate Tool Use

Always inspect the Calibration Device for damage prior to surgery. Never use a tool that appears corroded, damaged, bent, or otherwise distorted from its intended shape. If the Calibration Device does not meet the inspection criteria, Modus X may not function as intended.

If the Calibration Device does not meet the criteria listed below, do not use it. Contact Synaptive customer service for assistance.

- The Calibration Device must be free of corrosion
- The Calibration Device must be free of nicks, dents, or cracks
- The tracking array must not be bent or otherwise distorted from its original shape, and the posts for attaching the tracking spheres must be undamaged and perpendicular to the tool
- The release lever must move smoothly and the holder arms must open and close freely when the lever is pressed and released

Holding the Calibration Device

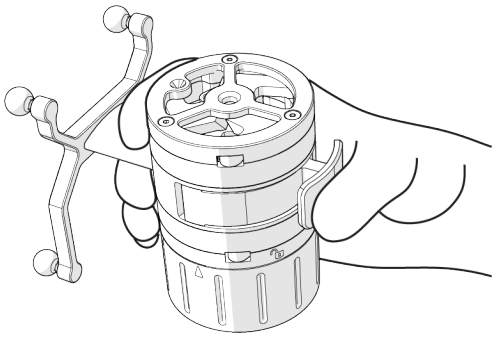


Figure 62 Holding the Calibration Device

Hold the Calibration Device securely in the palm of your hand with the tracking array between your index and middle fingers.

Use your thumb to squeeze the release lever, which opens the holder arms.

Calibration

To calibrate a Trackable Suction tool using the Multi-Tool Calibration Device:

1. Tap the suction tool icon on the left side of the Procedure screen that corresponds to the Suction tool tracking array you are using. The icons for tracking arrays 1 and 2 are labeled.
2. Squeeze the release lever on the Calibration Device to open the holder arms.
3. Insert the Trackable Suction tip into the Calibration Device aperture as far as it will go. Orient the Trackable Suction tool so that its tracking array is roughly in the same plane as the Calibration Device tracking array.
4. Release the lever on the Calibration Device to close the holder arms around the Trackable Suction tool.
5. Hold the Calibration Device so that its tracking array is visible to the tracking camera. Modus X sounds an audible notification and displays the progress of the calibration.

   When the calibration step is complete, the display changes from Calibrate to Verify.

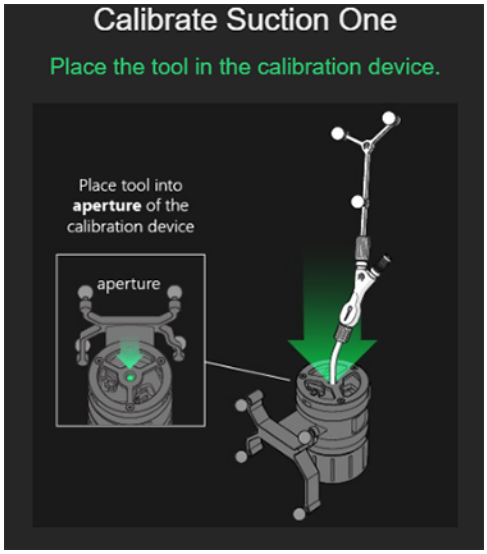


Figure 63 Calibrating a Trackable Suction tool

6. Squeeze the release lever to open the holder arms and remove the Trackable Suction tool from the Calibration Device aperture.

7. Place the tip of the Trackable Suction tool in the verification divot on the top of the Calibration Device. Orient the Trackable Suction tool so that its tracking array is in roughly the same plane as the Calibration Device tracking array.
8. Hold the Calibration Device and Trackable Suction tool so that their tracking arrays face the tracking camera and wait for Modus X to indicate that verification is complete.

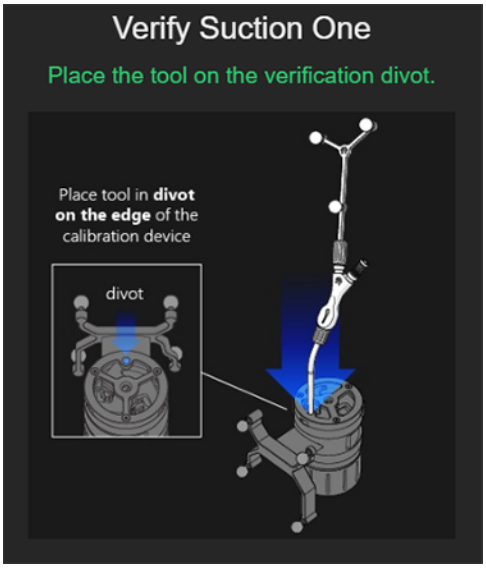


Figure 64 Verifying a Trackable Suction tool

7.1.3.2 Calibrating Suction Tools Using the Synaptive Calibration Block

To calibrate a Trackable Suction tool tip using the Synaptive calibration block:

1. Tap the suction tool icon on the left side of the Procedure screen that corresponds to the Suction tool tracking array you are using. The icons for tracking arrays 1 and 2 are labeled.
2. Place the tip of the tool in the divot on the top of the calibration block and orient the tool and calibration block so that all of the tracking spheres are visible to the tracking camera. Modus X displays the progress of the calibration and sounds an audible notification during the calibration.

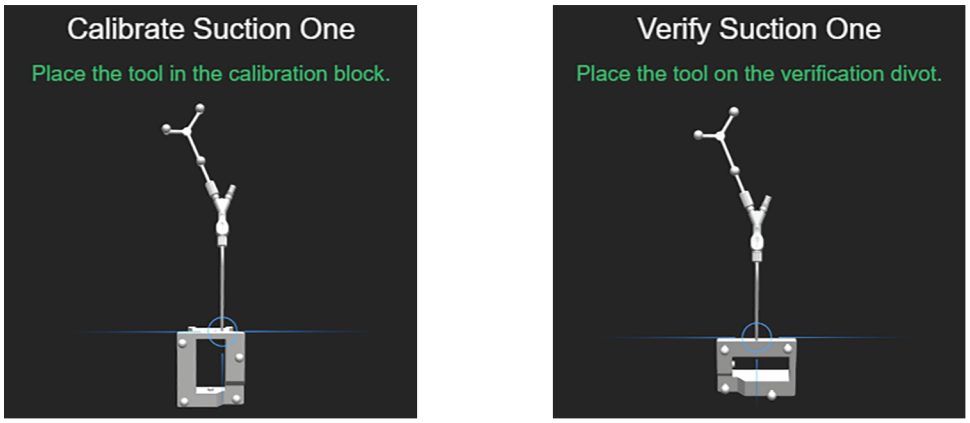


Figure 65 Two-part tool calibration process: part one (left), part two (right)

3. When the calibration step is complete, the display changes from Calibrate to Verify. To continue with verification:
   a. Rotate the calibration block 90°.
   b. Place the tip of the tool in the middle divot on the side of the calibration block.
   c. Orient the tool and calibration block so that all seven tracking spheres are visible to the tracking camera.

Modus X displays the progress of the verification. When the verification is complete, an audible notification will sound and the tool will be highlighted green in the tool icon bar, indicating that it is ready to use.

NOTE: During calibration, Modus X is very sensitive to any movement of the Trackable Suction tool relative to the calibration block. To successfully calibrate the tool, hold the tool steady until calibration is complete.

7.1.4 Working with a NICO BrainPath Brain Sheath (Port)

When the port reference tool is selected and Modus X is connected to Modus Nav, Modus X receives information about the brain sheath length from Modus Nav. During align moves, Modus X positions the end effector so that the camera is focused at the bottom of the brain sheath. If you are not navigating a planned trajectory, or if Modus X is not connected to Modus Nav, Modus X positions the end effector so that the camera is focused at the top of the brain sheath.

NOTE: Modus X continuously monitors the plan that is being used in Modus Nav. If during a procedure you change to a plan that uses a shorter brain sheath, this may decrease the distance between the end effector and the bottom of the brain sheath to less than the minimum standoff distance allowed by Modus X (300 mm). If this occurs, Modus X will not perform align moves until you increase the standoff distance.

7.1.5 Tracking a Tool

To align to a tool:

1. Select the tool you want to align to:
   - Tap the tool's icon on the left side of the Procedure screen.

     -OR-
   - Activate the quick menu and select the tool from the **Tool** menu.

     -OR-
   - Use the voice command "OK Vimo, select <tool> (where <tool> is one of "Pointer", "Long Pointer", "Port", "Suction 1", "Suction 2", or "Trajectory").
2. Use the pedal to align the optical device to the tool:
   - If you are using the multi-input pedal, press and hold the auto-align pedal.
   - If you are using the single-input pedal, press and hold the pedal.

Observe the arm as it is moving and release the pedal to stop the arm motion if necessary.

7.2 Aligning to a Trajectory

WARNING: Risk of Patient Death or Permanent Disability Due to Modus X Collision with Patient, Surgeon or Surgical Tools When Aligning to a Trajectory

If the Synaptive patient reference is moved relative to the patient after the patient registration has been accepted in Modus Nav, Modus X cannot accurately align to the trajectory. This may result in unexpected movement of the positioning arm, causing a potential collision with the patient, surgeon, or surgical tools. Always observe the positioning arm carefully when it is moving and stop motion if necessary.

Modus X communicates with Modus Nav to receive real-time information about the trajectory being aligned to. Changing the trajectory in Modus Nav, or shutting down Modus Nav while aligning to a trajectory, may result in unexpected movement of the positioning arm causing a potential collision with the patient, surgeon, or surgical tools. Always observe the positioning arm carefully when it is moving and stop motion if necessary.

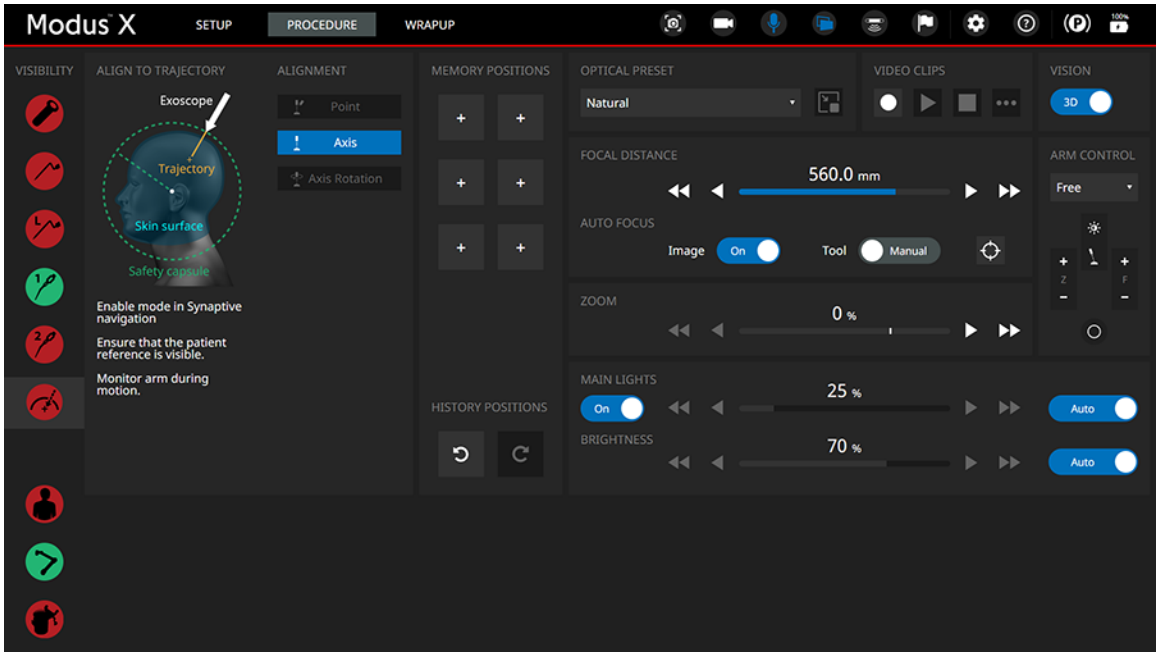


Figure 66 Procedure screen for aligning to a trajectory

When Modus X is connected to Modus Nav, you can align to the trajectory you are working with in Modus Nav. Aligning to a trajectory is similar to aligning to a tool, except that you cannot set a pose for aligning to a trajectory and you can only align to the trajectory axis. Modus X receives information about the engagement point, the point where you will enter the brain to follow the trajectory, from Modus Nav. The minimum standoff distance for a trajectory is 300 mm from the engagement point.

To align to a trajectory, the following conditions must be met:

- Modus X must be connected to Modus Nav and the Modus Nav software application must be running. If the connection is broken, or if the Modus Nav software application is closed, the Trajectory option will be disabled in the Procedure screen.

- The Align to Trajectory feature must have been enabled in Modus Nav. For more information, see the user manual accompanying Modus Nav.
- The Synaptive patient reference must be visible to the tracking camera.

7.3 Safety Measures During Align Moves to a Tool or Trajectory

Modus X enforces the following safety measures when aligning to a tool or trajectory.

- Movement stops immediately when the pedal is released.
- The positioning arm will not move the end effector more than 40 cm or rotate the arm more than 90 degrees from its previous position. Perform several shorter moves if you need to move to a distance greater than 40 cm, or adjust the arm position using the manual mode switch.
- The positioning arm will not move to your requested position if Modus X detects that the arm would collide with either itself or a tracked tool.
- When the arm is moving, movement is halted if a situation occurs which creates a risk of collision. For more information, see the description of the precautionary halt notification on page 141.
- When Modus X is not connected to Modus Nav and tracking the patient reference, the positioning arm will not move unless all the tracking spheres on the currently selected tracked tool and at least four tracking spheres on the end effector tracking array are visible to the tracking camera.
- When Modus X is connected to Modus Nav, the positioning arm will not move unless at least one of the Modus Nav patient reference or the end effector tracking array is visible to the tracking camera, and the tool being aligned to is visible.
- When using Modus X with the Modus Nav patient reference, if a movement occurs that could affect the end effector's position when it is not visible to the tracking camera (such as releasing the caster brakes), and the Modus Nav patient reference's position is changed relative to the tracking camera, the positioning arm will not move until both the patient reference and end effector are visible to the tracking camera. For more information about using the Modus Nav patient reference with Modus X, see 2.4 Synaptive Instrumentation on page 43.

7.4 Auto Focusing on a Tool

Modus X can automatically adjust the focal distance based on the location of a tool, either continuously (tool auto focus) or momentarily (snap focus with a tool). When focusing with a tool, Modus X sets a default focal distance for the selected tool, but you can change this with a focus offset if necessary. By default, Modus X sets the focal distance to the tip of the Pointers and Suction tools, and to the appropriate point on the brain sheath (for more information see 7.1.4 Working with a NICO BrainPath Brain Sheath (Port) on page 106).

NOTES:

- **Tool auto focus functionality is only available when Modus X is connected to a tracking camera and the end effector is visible to the tracking camera.**

- **In order to automatically focus on a tool, the tip of the tool must be within the surgical camera's field of view (which is different from the tracking camera's field of view). As long as the tip of the tool can be recognized in the surgical camera's field of view at the lowest level of zoom, tool auto focus will function even if the camera is zoomed in and the tip of the tool is not visible on the main surgeon monitor.**

Continuous Tool Auto Focus

When tool auto focus is enabled, Modus X automatically adjusts the focal distance as the tool moves within the tracking camera's field of view. Focus is maintained even if the zoom level changes.

NOTE: If you move the tool quickly out of the tracking camera's field of the view, Modus X recognizes this action and returns to the last focal distance before you moved the tool. If Modus X does not automatically return to the last focus distance, you can manually adjust the focal distance to bring the image back into focus.

To enable tool auto focus:

- Tap the **Tool** toggle control on the Procedure screen.

  -OR-

- Press and hold the auto focus button on the multi-input pedal (see 2.2.2 Pedals on page 39).

  -OR-

- Use the voice command "OK Vimo, tool auto focus on".

To specify the auto focus tool:

- Select the desired tool from the drop-down list on the Camera Settings screen (for more information, see 10.5 Camera Settings on page 122).

  -OR-

- Use the voice command "OK Vimo, focus <tool>" (where <tool> is one of "Pointer", "Long Pointer", "Port", "Suction 1", or "Suction 2").

To set a focus offset for the current auto focus tool:

- With tool auto focus enabled, push up or down on the focus adjustment switch on the end effector handle (see 2.1.7.2 End Effector Handle Controls on page 31).

  -OR-

- Use the focus in or focus out control on the multi-input pedal (see 2.2.2 Pedals on page 39).

  -OR-

- Use the **FOCUS OFFSET** controls on the Camera Settings screen (see 10.5 Camera Settings on page 122).

NOTE: If the current focus tool is not visible to the tracking camera, adjusting the focal distance using the end effector handle control or the multi-input pedal disables tool auto focus.

Using Snap Focus with a Tool

Use the snap focus feature with a tool to focus to the current tool location but not change the focal distance as you move the tool.

To snap focus on the auto focus tool:

- Tap the focus icon on the Procedure screen.

  -OR-

- Press the auto focus button on the multi-input pedal (see 2.2.2 Pedals on page 39).

  -OR-

- Use the voice command "OK Vimo, focus here".

NOTES:

- **If tool auto focus is enabled, performing a snap focus while the tool is visible will disable tool auto focus.**
- **Modus X can be configured to perform an image auto focus if the current focus tool is not visible when you attempt a snap focus. For more information, see 10.5 Camera Settings on page 122.**

8.0 Stereoscopic Visualization

The two cameras in the Modus X end effector allow for stereoscopic (3D) visualization. To view the video from the end effector in three dimensions, Modus X must be connected to a 3D monitor cart and you must be wearing a 3D eye shield.

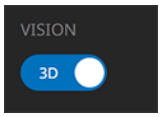


Figure 67 VISION control on the Procedure screen

To toggle between 2D and 3D:

- Tap the VISION control on the Procedure screen.

  -OR-

- Activate the quick menu and select the Vision option.

  -OR-

- Use the voice command "OK Vimo, toggle 3D", or "Ok Vimo, 3D on" or "Ok Vimo, 3D off".

NOTE: If 3D images are not available, or the image quality is not acceptable, or if stereoscopic visualization induces headaches or nausea, switch back to 2D visualization.

Tips for wearing the 3D eye shield:

- Always verify that the lenses are securely attached to the frames. For information about attaching the lenses, consult their accompanying documentation.
- Wear the frames underneath your protective headwear.
- Secure the frames over the bridge of your nose.

9.0 Fluorescence

WARNING: Risk of Patient Injury Due to Improper Treatment

Operating outside of the recommended fluorescence mode parameters may result in unreliable visualization of the fluorescent areas. These parameters include:

- Working distance too large
- Zoom setting too high

The fluorescence optical presets have been designed to optimize viewing of the fluorescence signal. Any changes to the optical settings, including light intensity, when using the fluorescence optical presets may result in unreliable visualization of the fluorescent areas.

CAUTION: Risk of Procedure Delay

There is a risk of photobleaching of the fluorophores if high intensity fluorescence light is used for an extended period of time.

Three fluorescence modules are available with Modus X with different excitation and observation wavelengths as described below.

NOTE: The fluorescence modules are separately licensed features and are subject to regional availability limitations. They may not be available with your Modus X system. For information about enabling the fluorescence modules, contact Synaptive customer service.

Recommended Fluorescence Parameters

For optimal visualization when using the fluorescence modules, the Modus X focal distance and zoom level must match the recommended parameters defined in the sections below. If you select a fluorescence optical preset and the current focal distance and zoom level do not match its recommended parameters, a notification appears on the surgical overlay and on the Procedure screen. These notifications disappear when you adjust the focal distance and/or zoom level to match the recommended parameters. The notification on the surgical overlay will also disappear automatically after a few seconds, and you can dismiss the notification on the Procedure screen by tapping **Acknowledge**.

9.1 Modus Blue

Table 21 Modus Blue Fluorescence Module Properties

Optical preset	**Blue Light**

Table 21 Modus Blue Fluorescence Module Properties (continued)

Excitation	390 – 410 nm
Observation	450-710 nm
Recommended parameters	Focal distance: 300-635 mm Zoom: 1-60%

To use the Modus Blue fluorescence module:

1. Verify that the excitation and observation wavelengths of the Modus Blue module align with your fluorescence medium.
2. Set the focal distance and zoom level to be within the ranges described in Table 21.
3. Select the **Blue Light** optical preset from the OPTICAL PRESET drop-down list.

9.2 Modus Yellow

Table 22 Modus Yellow Fluorescence Module Properties

Optical preset	**Yellow Light**
Excitation	460 – 500 nm
Observation	520 – 710 nm
Recommended parameters	Focal distance: 450 mm Zoom: 50%

To use the Modus Yellow fluorescence module:

1. Verify that the excitation and observation wavelengths of the Modus Yellow module align with your fluorescence medium.
2. Set the focal distance and zoom level to be within the ranges described in Table 22.
3. Select the **Yellow Light** optical preset from the OPTICAL PRESET drop-down list.

9.3 Modus IR

WARNING: Risk of Patient Death or Permanent Disability Due to Malfunctioning Equipment

Sources of infrared light in the operating room will interfere with the Modus X optical system when it is using an infrared (IR) optical preset. This interference can cause flickering in the video field which may interfere with the view of the surgical field or trigger an epileptic seizure in susceptible persons.

WARNING: Risk of Patient Death or Permanent Disability Due to Modus X Collision with Patient, Surgeon or Surgical Tools When Moving the Positioning Arm

Modus X cannot prevent a collision between the positioning arm and tracked tools in the surgical site when tracking is disabled while an infrared (IR) optical preset is in use. To avoid accidentally colliding with the patient, surgeon, or surgical tools, always be aware of the surgical site when moving the positioning arm manually or using the motion controls. The arm should always be positioned at a safe distance from the surgical site.

WARNING: Risk of Procedure Delay Due to Loss of Modus X Functionality

Only the main light source can emit infrared light. If the main light source is turned off or is not functioning, infrared light will not be available and the infrared (IR) optical presets will not function as intended.

WARNING: Risk of Patient Injury Due to Improper Treatment

Always use the designated Modus IR drape for procedures that will use a Modus IR optical preset. Using the incorrect drape may result in a reduction of the IR signal. For more information, see 2.3 Drapes on page 42.

Table 23 Modus IR Fluorescence Module Properties

Optical presets	IR Fusion	IR Monochrome
Excitation	748 to 802 nm	
Observation	820 to 1000 nm	
Recommended parameters	Focal distance: 300-550 mm Zoom: 0-50%	Focal distance: 300 mm Zoom: 40%

When the IR optical presets are selected, if Modus X is connected to a tracking camera, the tracking function is disabled to prevent IR interference with the Modus X video feed. When tracking is disabled, Modus X cannot perform auto-alignments and cannot prevent collisions with tracked tools.

Before using an IR optical preset with a fluorescence medium, check whether there are any other sources of IR interference in the operating room. If any are found, turn them away from the surgical site while using the IR optical preset to prevent interference with the Modus X video feed. It is recommended that you perform a functional test prior to using an IR preset with a fluorescence medium to verify that there are no sources of IR interference.

NOTE: When an IR optical preset is active and the main lights are on, the illuminators on the end effector are emitting invisible infrared light. This is indicated by the IR icons that appear on the touchscreen monitor and the surgical overlay.

To use the Modus IR fluorescence module:

1. Verify that the excitation and observation wavelengths of the Modus IR module align with your fluorescence medium.
2. Set the focal distance and zoom level to be within the ranges described in Table 23.
3. Select the **IR Fusion** or **IR Monochrome** optical preset from the OPTICAL PRESET drop-down list.
4. Administer the fluorescence medium to the patient.
5. Use the VIDEO CLIPS controls to record and play back video of the surgical field. For more information, see 5.5.2 Video Clips on page 88.

Using the Picture in Picture Feature with Modus IR

NOTE: To use this feature, at least one monitor must be connected to Modus X by an Ethernet cable. For more information, see 3.3.8 Connect Modus X to Monitors and/or Synaptive Navigation on page 67.

CAUTION: Risk of Procedure Delay

If the Ethernet cable connecting Modus X to the monitor is disconnected when the Modus IR picture in picture (PIP) feature is in use, the monitor will continue to display the PIP window and you will not be able to stop viewing the PIP window until you reconnect the Ethernet cable.

Use the picture in picture (PIP) feature to display a second view of the surgical field when using an IR optical preset.

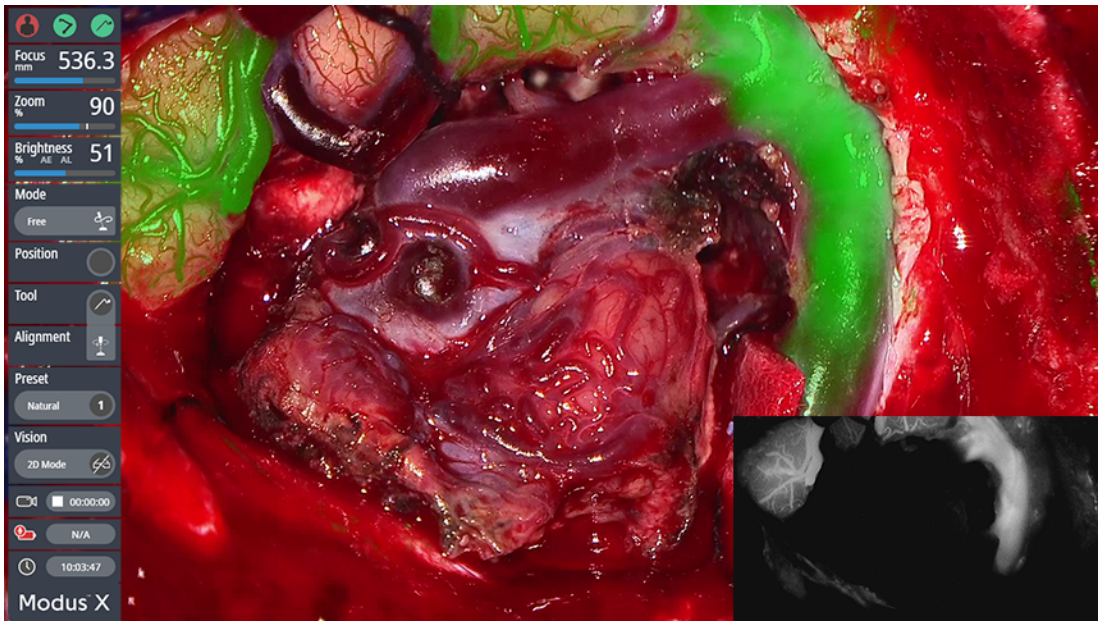


Figure 68 Picture in picture window for IR Fusion optical preset

When the IR Fusion optical preset is selected, the PIP window displays the IR monochrome view. When the IR Monochrome optical preset is selected, the PIP window displays the white light view.

To display the PIP window, tap the PIP icon  beside the OPTICAL PRESET drop-down list. The position of the PIP window is determined by the **PIP Position** setting on the Monitors settings page. For more information, see 10.3 Monitors on page 120.

To stop displaying the PIP window, tap the PIP icon again. Modus X also stops displaying the PIP window if you switch to a different optical preset, or if the PIP window would interfere with another function (such as suction tool calibration).

NOTES:

- The IR PIP feature can only be displayed in 2D. If you are viewing the video in 3D, it will switch to 2D when you enable the IR PIP feature, but will automatically switch back to 3D when you turn the IR PIP feature off.
- The PIP window is not displayed when video clips are being played back. You can distinguish between the clip playback window and the PIP window by the time stamp information, which is only displayed on the clip playback window.
- The IR PIP feature will replace Modus Nav if Modus Nav is currently being displayed in the PIP window or if Modus Nav is being displayed on a secondary monitor. However, your previous view of Modus Nav will be restored when you stop using the IR PIP feature.

10.0 Modus X Settings

To adjust the Modus X settings, tap the settings icon in the top right corner of the screen. To return to the procedure, tap **Done** in the bottom right corner of the screen.

10.1 Arm Movement

Use the Arm Movement screen to:

- View the status of each arm joint
- Make fine adjustments to arm joint positions
- Set the Modus X “stored” positions (the saved arm positions for procedures and for storing or shipping Modus X)
- Move the arm into a "stored" position

NOTE: The features on the Arm Movement screen are only available when Modus X is in the Setup and Wrapup phases.

WARNING: Risk of Patient Death or Permanent Disability Due to Modus X Collision with Patient, Surgeon or Surgical Tools During General Use

To avoid accidentally colliding with the patient, surgeon, or surgical tools, never perform individual joint moves using the Arm Movement screen in the Modus X software when the Modus X positioning arm is positioned within range of the patient.

When Modus X is moving into the stored positions specified in the Arm Movement controls, there are no controls in place to enforce a minimum standoff distance and avoid a collision with the patient, surgeon or surgical tools. Never move Modus X using the Arm Movement screen when it is in the patient environment.

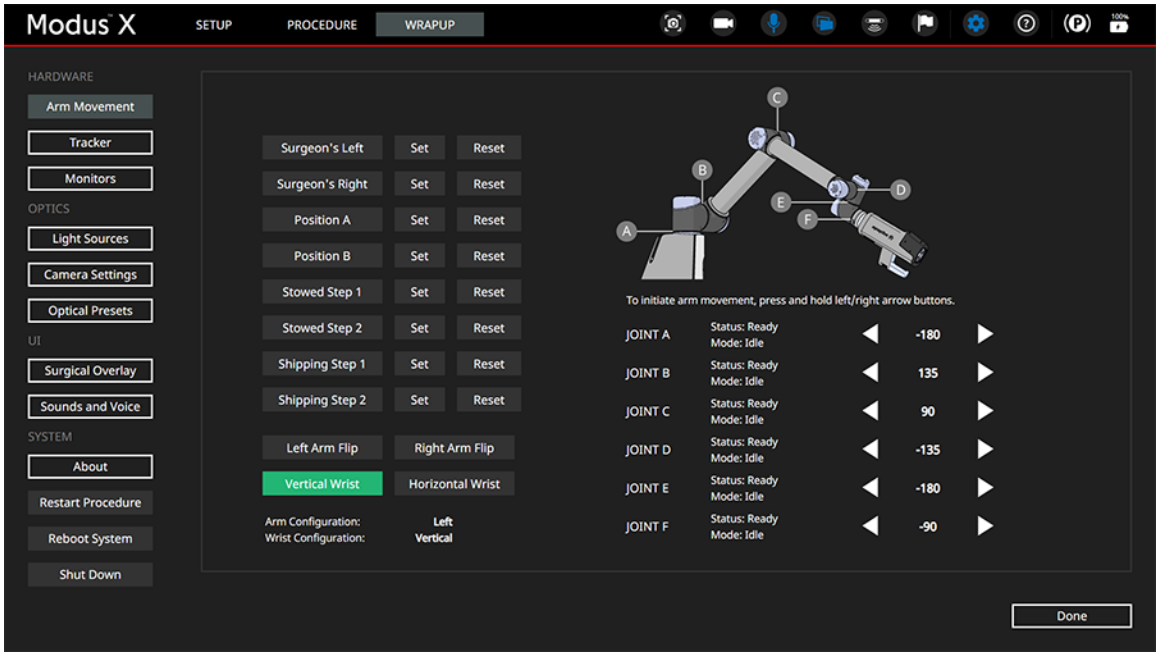


Figure 69 Arm Movement screen

To adjust an arm joint position, press and hold the left or right arrow to decrease or increase the joint's degree of rotation. Modus X moves the arm joint while you hold down on the arrow icon.

To move the arm into a "stored" position, press and hold on the name of the position you want to move into.

To set a "stored" position, move the arm into the desired position then tap **Set** beside the position you want to set. Tap **Reset** to set the position back to its default position.

About the Stored Arm and Wrist Configurations

The **Left Arm Flip** and **Right Arm Flip** buttons move the arm into a standard configuration where joint A is rotated so that the arm would be on the left or right side of someone standing with Modus X behind them.

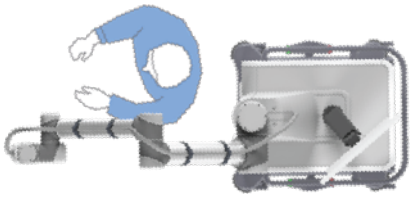


Figure 70 Left Arm configuration

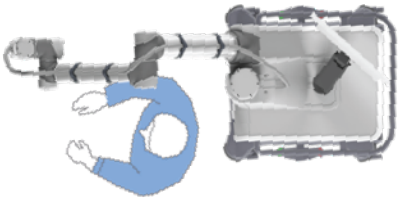


Figure 71 Right Arm configuration

The **Vertical Wrist** and **Horizontal Wrist** buttons move the wrist joints into a standard configuration where the end effector points down (vertical) or forward (horizontal).

The current **Arm Configuration** and **Wrist Configuration** is displayed on the Arm Movement screen. If the current arm or wrist position is such that the affected joints are within 45° of the final configuration, the status displays the final configuration. Otherwise, the status is displayed as '-'.

NOTE: If the Arm Configuration status is '-', the Vertical Wrist and Horizontal Wrist buttons are disabled.

To move the arm into one of these configurations, press and hold the corresponding button. The button turns green when movement is complete and the arm is in the final position.

IMPORTANT:

- Do not perform arm flip movements when the Modus X arm is draped as this could tear or otherwise damage the drape. Wrist configuration changes may be made when the arm is draped, but watch the end effector closely to ensure that the drape is not compromised during movement.
- Pay attention to the cable bundle during arm movements and adjust it as necessary to prevent it from becoming wrapped around the arm. For more information, see 2.1.7.6 Cable Management on page 36.

NOTE: The Right and Left Arm configurations position the end effector in the Vertical Wrist configuration. If you want to flip the position of both the arm and wrist, change the arm configuration first, then change the wrist configuration.

10.2 Tracker

The Tracker screen displays the tracking camera's field of view. Tool icons indicate the locations of the tools within the tracking camera's field of view. The image on the left is a top view showing the width of the volume; the image on the right is a side view showing the height of the volume.

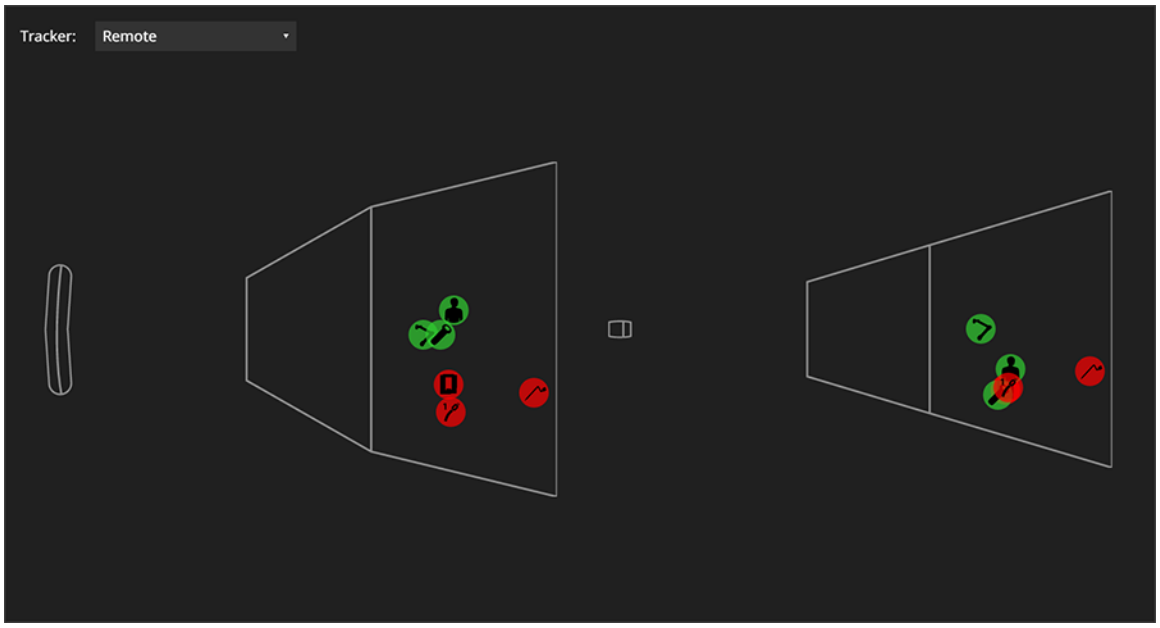


Figure 72 Tracker screen

The local tracking camera is listed as Modus X under the tracker list. If Modus X is connected to both the local tracking camera and the Modus Nav system, the Local option will become unavailable in the Tracker list.

10.3 Monitors

Use the Monitors screen to control the monitors that Modus X is connected to.

NOTE: With the exception of the Flip and Mirror setting, to control a monitor from Modus X the monitor must be connected to Modus X with an Ethernet cable.

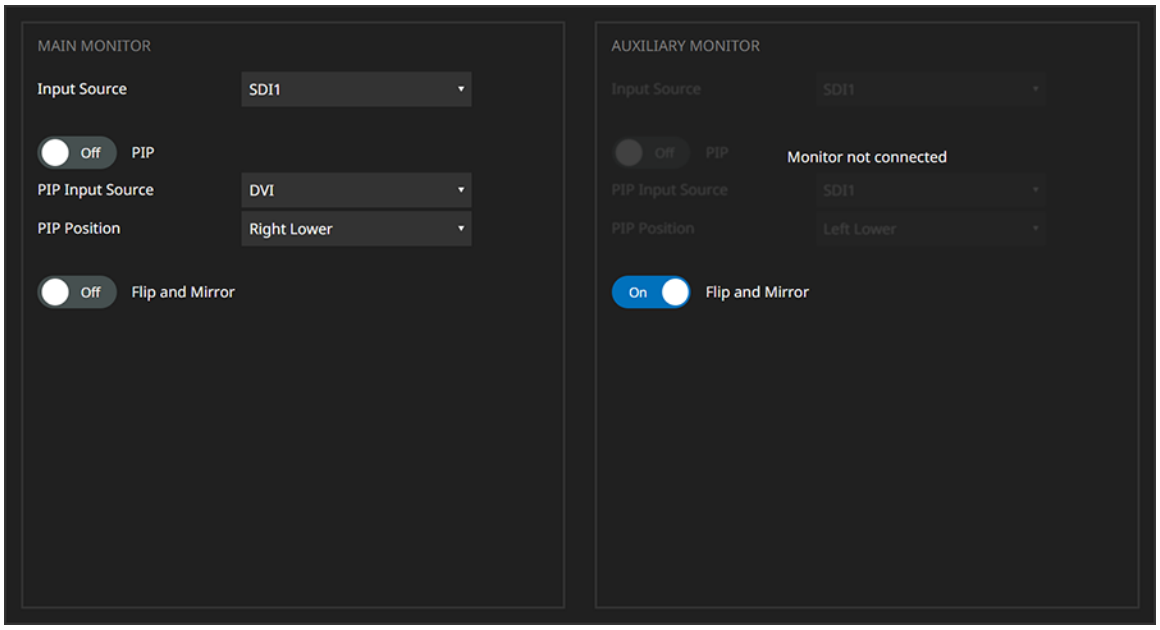


Figure 73 Monitors settings

Input Source: Select the video source for the main image that will be displayed on the monitor.

PIP: Toggle the picture in picture feature on or off.

PIP Input Source: Select the video source for the image that will be displayed in the picture in picture (PIP) window when it is on.

NOTE: Not all combinations of main and PIP input sources are valid.

- **If SDI1 is selected as the main input source, you cannot select SDI2 as the PIP input source and vice versa.**
- **If HDMI is selected as the main input source, you cannot select DisplayPort as the PIP input source and vice versa.**

If you try to select a PIP input source that is not valid with your selected main input source, Modus X reverts your PIP input source to the previous valid source.

PIP Position: When the picture in picture feature is on, select which corner of the monitor to display the secondary video input in. Be sure to position the picture-in-picture window so that it does not obstruct important surgical overlay information or important areas of the surgical site.

NOTE: This setting cannot be used to change the position of video clip playback.

Flip and Mirror: Toggle this option on or off to flip and rotate the image displayed on the monitor. When this option is on, the images on the monitor correspond to how the surgical field appears to someone standing opposite the surgeon.

NOTES:

- **If you adjust any of these settings on the monitor itself, the changes are reflected in the Monitors settings screen.**
- **The values specified on the Monitors settings screen persist when you restart a procedure but will return to their default values when you reboot or shut down Modus X.**

10.4 Light Sources

Use the Light Sources settings page to:

- Adjust the color values for the optical preset currently selected on the Optical Presets settings screen
- Turn the auxiliary light source on or off, and adjust the light intensity (for more information, see 3.3.10 Using the Auxiliary Light Source on page 69)

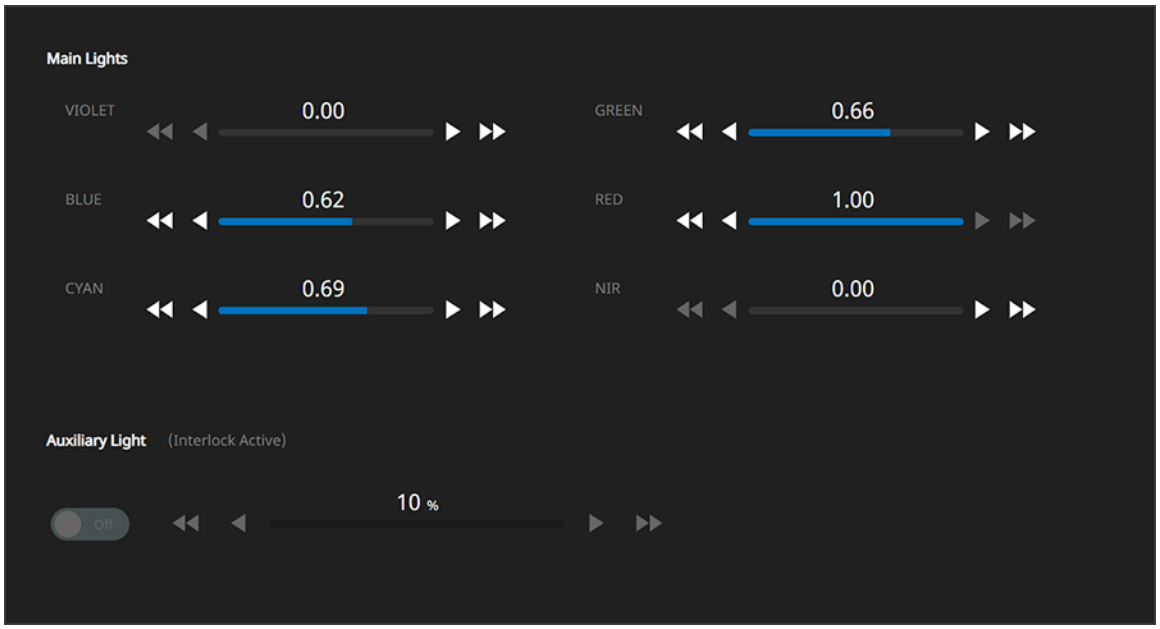


Figure 74 Light Sources settings screen

WARNING: Risk of Patient Injury Due to Light Intensity

The Modus X light sources are capable of producing light intense enough to cause tissue burns, temporary blindness, and patient discomfort.

Never leave Modus X unattended when the light sources are on.

NOTE: If a light guide is not connected to the light source, Modus X displays "Interlock Active" beside the light source on the settings screen. For information about exiting the interlock state, see 2.1.5 Light Sources on page 28.

10.5 Camera Settings

Use the Camera Settings settings screen to view and adjust settings for the surgical cameras.

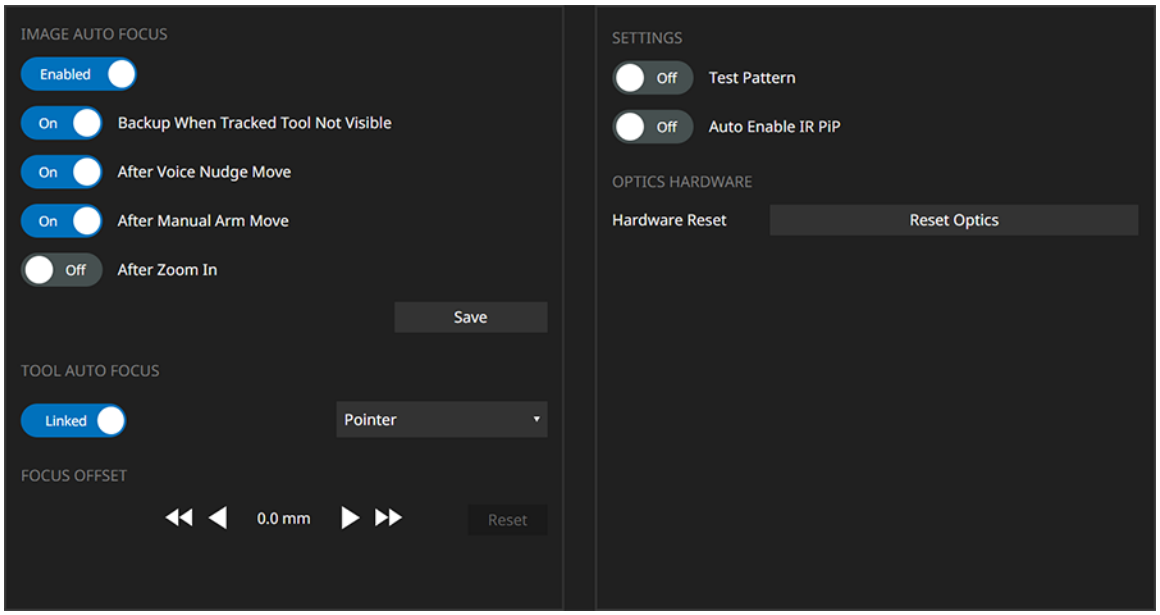


Figure 75 Camera Settings screen

Image Auto Focus

Auto Focus Enabled: Toggle the image auto focus feature on or off.

Backup When Tracked Tool Not Visible: When set to **On**, Modus X will perform an image auto focus if you attempt to snap focus on the currently-selected auto focus tool and that tool is not visible.

After Voice Nudge Move: When set to **On**, Modus X will automatically focus the image after a voice nudge arm movement.

After Manual Arm Move: When set to **On**, Modus X will automatically focus the image after you manual move the positioning arm when it is in the free, manual, or translate positioning mode.

After Zoom In: When set to **On**, Modus X will automatically focus the image after you increase the zoom level (but not after decreasing it).

Tap the **Save** button to use these values for all procedures. If you do not save your values, Modus X will revert to the default values for these settings after you reboot or shut down the system.

Tool Auto Focus

Select your desired auto focus tool to from the drop-down list. Note that the Trackable Suction tools will only appear in the tool list if they have been calibrated (see 7.1.3 Working with Suction Tools on page 101).

Set the toggle to **Linked** to link the tool auto focus feature to the tool that Modus X is currently tracking. If you change the tracked tool, the new tracked tool automatically becomes the auto focus tool.

NOTE: If you manually change the auto focus tool, tracked tool linking is disabled.

Focus Offset

Tap the fine or coarse increment arrows to specify the tool auto focus offset. Tap **Reset** to set the offset distance back to 0 mm.

Settings

Test Pattern: Toggle the display of a test pattern to verify that the color output from the surgical camera is accurate.

Auto Enable IR PIP: When set to **On**, Modus X will automatically display the PIP window when you select the IR Monochrome optical preset on the Preocedure screen.

Optics Hardware

Hardware Reset: Tap **Reset Optics** if the Modus X optics features (for example, zoom and auto focus) are not functioning properly. After the reset is complete, the optics will return to the prior focus and zoom settings.

10.6 Optical Presets

Use the Optical Presets settings to configure custom optical presets. The custom presets appear in the OPTICAL PRESET list on the Procedure screen.

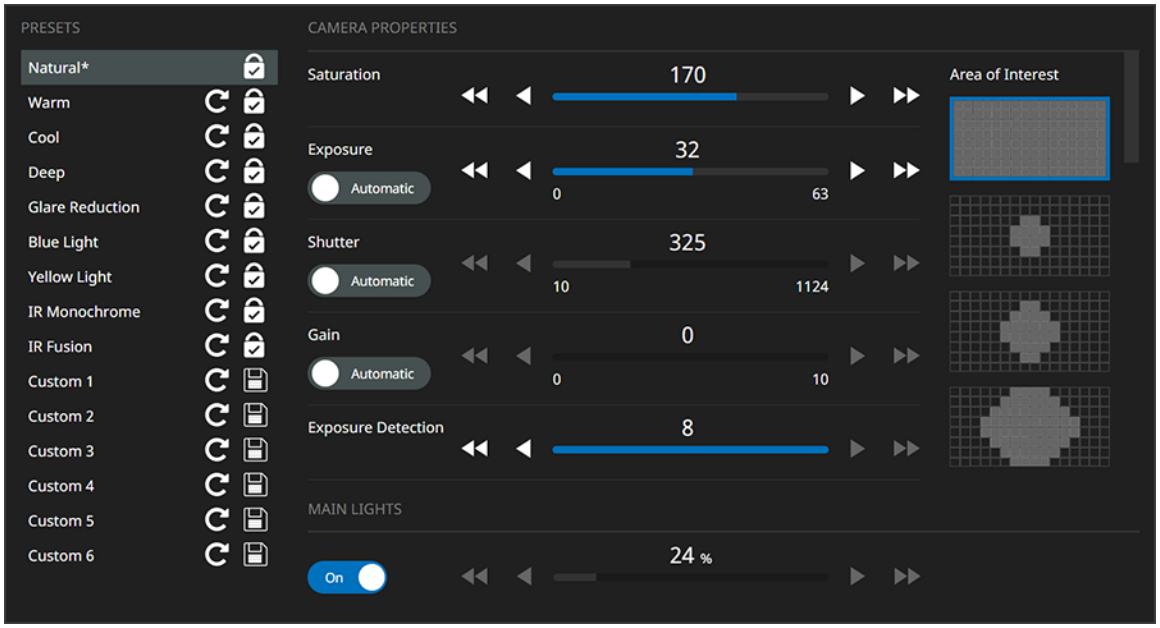


Figure 76 Optical Presets settings

Modus X provides the following presets:

- Natural

  This is the default preset. It is suitable for a wide range of procedures. Reds are muted and yellows are boosted to optimize tissue differentiation across tissue types including bone, dura, ligament, etc.

- Warm

  This preset is suitable for most applications. Warm colors such as yellow are boosted when compared to the Natural preset to offer a warmer color palate similar to conventional optics.

- Cool

  This preset has a cool palette with reds and yellows reduced compared to the Natural preset, and with boosted magenta.

- Deep

  This preset is best suited for narrow corridors and tubular retractor procedures at high magnification. It features optimized lighting for MIS/keyhole procedures.

- Glare Reduction

  This preset is optimized for use during surgical approach when glare can be produced visualizing reflective tissue such as bone or dura.

- Blue Light

  This preset is the blue fluorescence mode for fluorescence observation of fluorophores with an excitation range between 380 – 420 nm and emission in the 435 – 710 nm spectral band.

- Yellow Light

  This preset is the yellow fluorescence mode that aids in viewing intra-operative blood flow in the cerebral vascular area with an excitation range between 450 – 510 nm and emission in the 510 – 710 nm spectral band.

- IR Monochrome

  This preset is the infrared (IR) fluorescence mode that aids in viewing intra-operative blood flow in the cerebral vascular area including, but not limited to, inspection of cerebral aneurysms, vessel bypass and vessel patency, as well as blood flow following plastic and reconstructive surgery.

- IR Fusion

  This preset is the infrared (IR) fluorescence mode that combines fluorescence and white light visualization to provide additional anatomical context during IR fluorescence guided surgery.

These presets are locked and cannot be customized.

To configure a custom optical preset:

1. Tap the name of one of the custom presets on the left side of the screen.
2. Adjust the camera specifications to your desired values.
3. Tap the save icon  to save your specifications in the custom preset.

To reset the custom preset to the default camera specifications, tap the reset icon  .

10.7 Surgical Overlay

Use the Surgical Overlay settings to control the appearance of the information overlaid on the main surgeon monitor video feed.

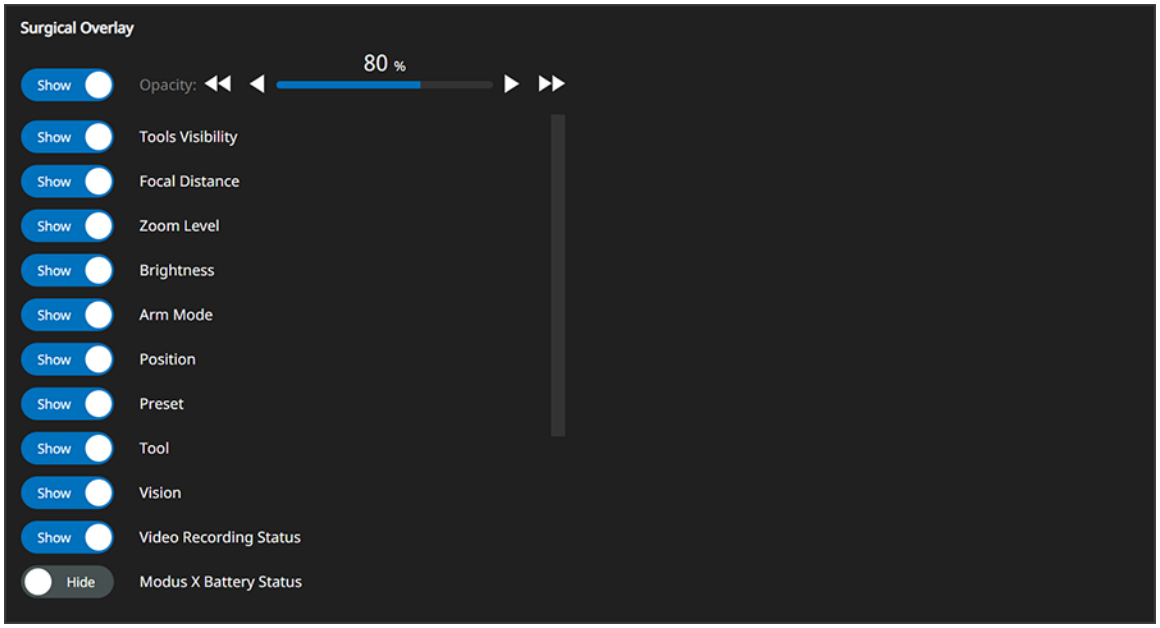


Figure 77 Surgical Overlay settings

Tap the Show/Hide toggle controls to show or hide the entire surgical overlay or individual elements of it. You can also use the fine or coarse increment arrows to adjust the overlay opacity.

10.8 Sounds and Voice

Use the settings on the Sounds and Voice screen to adjust the Modus X sound volume and to set up and configure voice control hardware.

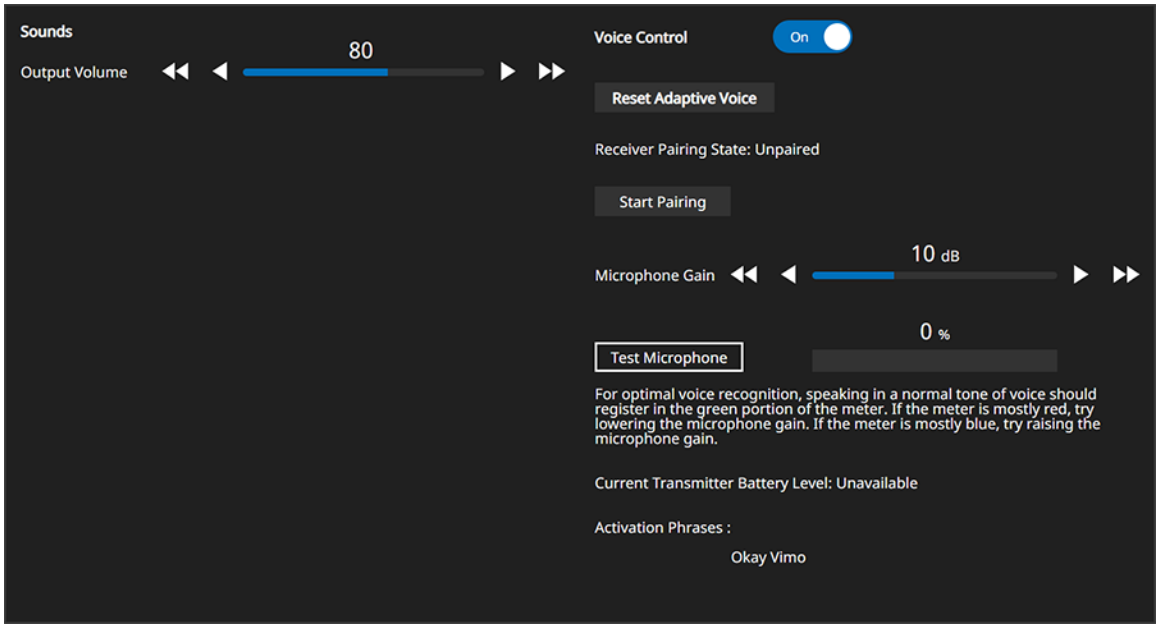


Figure 78 Sounds and Voice settings screen

Sounds

Output Volume: Press and hold on the arrow icons to increase or decrease the Modus X software sound volume. The default minimum for sound is 50% and cannot be muted.

Voice Control

Tap the **Voice Control** toggle to enable or disable the voice control feature.

Reset Adaptive Voice: Tap to reset the adaptive learning voice control feature, for example when a new surgeon will be using voice control.

Start Pairing: Tap to pair a voice control transmitter with the receiver in Modus X.

Microphone Gain: Tap the fine or coarse increment arrows to adjust the microphone gain.

Test Microphone: Tap this button then speak into the microphone in a normal tone of voice. The microphone level displayed on the meter should be green. If the meter is mostly red, lower the microphone gain. If the meter is mostly blue, raise the microphone gain.

10.9 About

The About screen displays information about the software versions running on Modus X and system maintenance dates.

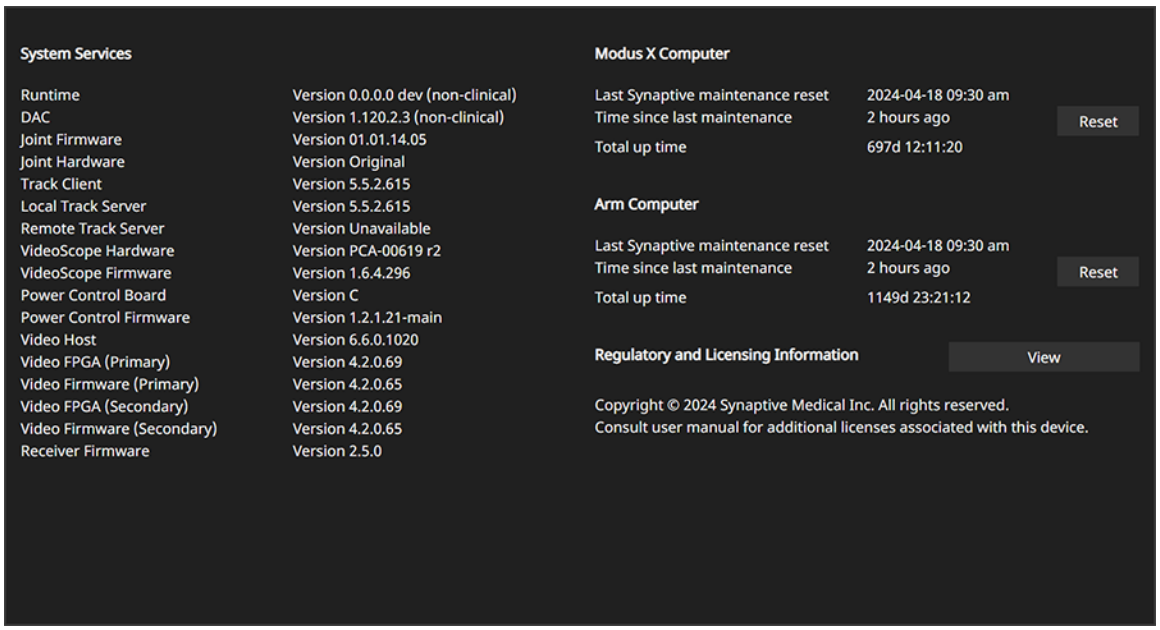


Figure 79 About screen

The **Reset** buttons on this screen are for use by Synaptive Authorized Service Providers only.

Tap **View** beside the Regulatory and Licensing Information item to view the Unique Device Identifier (UDI) and other regulatory information for the products licensed on this system.

11.0 Cleaning and Maintenance

Perform routine maintenance on the Modus X system as descibed in this chapter. Additional planned maintence activities are performed by Synaptive authorized service representatives every six months.

11.1 Cleaning

If necessary, clean the Modus X hardware components as described below.

WARNING: Risk of Infection Due to Contamination of Sterile Equipment

Failure to properly clean the Modus X device, peripherals, or accessories may lead to cross-contamination.

CAUTION: Risk of Operator Injury and Damage to Equipment

Before cleaning and surface disinfection, turn off Modus X and disconnect it from its power source.

Improper cleaning or the use of incompatible cleaning agents on Modus X, peripherals, and accessories may damage the system.

Do not use Cidex or other disinfectants to clean any of the Modus X components. Use only those cleaning agents described in this manual.

To avoid damage to the system, never submerge or allow liquids to enter the hardware components. Wipe cleaning agents off the hardware immediately using a water-dampened cloth. Dry the hardware thoroughly after cleaning.

Table 24 Hardware Cleaning

Component	Cleaning Instructions
Modus X mobile base, monitor cart surfaces	Clean cart surfaces with a mild, non-abrasive cleaning solution (e.g., diluted bleach, ammonia, or alcohol solutions). The surface finish will be permanently damaged by strong chemicals and solvents such as acetone and trichloroethylene. Steel wool or other abrasive material should never be used.
Foot pedals	Wipe exterior surfaces with a lint-free cloth that has been dampened with water and a mild cleaner.

Table 24 Hardware Cleaning (continued)

Component	Cleaning Instructions
Touchscreen monitor	Cleaning: Thoroughly wipe all exterior surfaces with a lint-free cloth that has been dampened with vinegar (distilled white vinegar, 5% acidity) or Ammonia-based glass cleaner. Remove residual detergent by wiping all exterior surfaces with a lint-free cloth dampened with distilled water. Disinfecting: Wipe all exterior surfaces with a lint-free cloth dampened with 80% Ethyl Alcohol. Allow the unit to air dry. Do not allow liquids to enter the interior of the unit, and do not permit exterior surfaces to come into contact with unacceptable solvents such as MEK (Methyl Ethyl Ketone), Toluene, Acetone; severe damage to the unit may occur.

CAUTION

Synaptive Medical makes no claims regarding the efficacy of the listed chemicals or processes as a means for controlling infection. Consult your hospital's infection control officer and/or infection control Standard Operating Procedure.

11.2 Sterilization

Synaptive tracked tools must be sterilized in an autoclave. For cleaning and sterilization instructions, see the sterilization information sheet accompanying the tracked tools.

NOTE: Immediately following a procedure, rinse the sterilizable components as needed to remove visible contaminants and debris. Do not let contaminants dry before cleaning.

The tracking spheres are single-use only and must be properly disposed of after each procedure. Do not attempt to sterilize the tracking spheres in an autoclave. Doing so may damage other tools in the autoclave tray.

11.3 Inspection

WARNING: Risk of Patient Death or Permanent Disability Due to Malfunctioning Equipment

Inspect Modus X upon receiving the system and prior to first use. Do not use the Modus X system if it appears to be damaged or malfunctioning in any way. Ensure that no damage has occurred during the shipping process.

Always inspect the Modus X system prior to surgery. Do not use the system if it appears to be damaged or malfunctioning in any way.

Inspect the Modus X system regularly to ensure it is in proper working order. If the system fails to meet any of the inspection criteria listed in Table 25 below, do not use it and contact Synaptive Service for assistance. For contact information, see 1.7 Synaptive Customer Service Information on page 23.

Inspect Synaptive trackable tools before each procedure. Refer to the user manuals provided with the Standard Pointer, Long Pointer, and Trackable Suction for detailed inspection instructions.

Table 25 Inspection Criteria

Component	Inspection Schedule	Inspection Criteria
Positioning arm	Monthly	• When moved manually using the manual mode switch, all joints move freely in their complete range of motion (for more information, see 2.1.7.2 End Effector Handle Controls on page 31) • Movement in all joints stops when manual mode switch is released • When moved using the arrows on the Arm Movement settings screen, joints move freely in their complete range of motion (for more information, see 10.1 Arm Movement on page 117)
Positioning arm cable	Before each procedure	• Cable running alongside the positioning arm has sufficient slack to allow the end effector to move freely in all directions. For more information, see 2.1.7.6 Cable Management on page 36.
Mobile base	Before each procedure	• Mobile base is stable and does not wobble
	Monthly	• Wheels roll smoothly when brakes are unlocked • Wheels lock securely when brakes are locked
System cables	Before each procedure	• Cables show no signs of damage, including cracked or fraying insulation
Foot pedals	Monthly	• Buttons can be pressed easily and release fully when the button is released. • Connecting cable shows no sign of wear or damage.
End effector handle controls	Monthly	• Switches can be toggled easily and release fully. • Positioning mode trigger can be easily pressed and releases fully when the trigger is released.
Single-use components	Before use	• Visually inspect for damaged packaging • Visually inspect components before use

11.4 Ordering Accessories

To order any of the following Modus X accessories contact salesorders@synaptivemedical.com or call 1-844-462-7246.

Part	Part Number
Modus X arm drape (box of 10)	SYN-1014
Modus X arm drape - infrared fluorescence (box of 10)	SYN-1013
Skirt drape (box of 10)	SYN-0043
Touchscreen drape (box of 10)	SYN-0796
Patch drape (box of 10)	SYN-0048
Tracking spheres (box of 48)	SYN-0533
3D eye shield kit	SYN-0914 (Sony part number CFV-E30SK)
3D lenses (box of 15)	SYN-0920 (Sony part number CFV-E30D)
Eye shield frame	SYN-0924 (Sony part number CFV-B100)

11.5 Disposal

No part of the Modus X system may be disposed of in landfill.

Dispose of tracking spheres and drapes as pathological waste.

Before disposing of any Synaptive product, contact Synaptive customer service or your supplier for further information.

12.0 Reference and Technical Information

12.1 Troubleshooting

If you cannot solve a problem by following the suggestions below, or if you encounter a problem not described below, contact Synaptive customer service.

Table 26 Troubleshooting Tips

Problem	Possible Solutions
Modus X does not start up	• Confirm that Modus X is plugged into a wall outlet. • If battery power is low, confirm that Modus X is plugged into a wall outlet and wait for the battery to charge.
No video signal to monitor (when monitor is powered on)	• Verify that the cable connecting the monitor to the video source is securely connected at both ends. • Verify that Port A on the monitor is set to SDI 1 and Port B on the monitor is set to DVI. For more information about assigning video inputs to the monitor Port buttons, see the user manual accompanying your monitor cart.
Upon start-up, Modus X does not begin to run through the self-test process	• Reboot the Modus X system. • If a system reboot does not resolve the issue, power down Modus X and power back up.
Main lights are not available	• Verify that the light guide is properly connected to the light source. • Verify that the main light source control key is inserted and turned to the "ON" position • Press the manual reset button for the main light source. For more information, see 2.1.5 Light Sources on page 28.
Cannot position the arm	• Lock the mobile base brakes. • Power up Modus X and wait for all self-tests to complete.

Table 26 Troubleshooting Tips (continued)

Problem	Possible Solutions
Modus X arm does not move when pedal is pressed, or a command from the user interface is ignored	• The pedal cannot be used to position the arm while in the Setup or Wrap up phases. Use the touchscreen monitor to position the arm in the Setup and Wrap up phases. • Ensure that the pedal was not pressed at the same time that an option was selected in the user interface, or that the positioning arm was moved using an End Effector Mode. Modus X cannot process commands from multiple inputs simultaneously. • Reboot the Modus X system.
End effector visibility icon in the user interface flickers between visible and not visible	• Verify that the tracking spheres on the end effector are clean and undamaged. • Verify that the tracking spheres are seated properly on the drape posts. • Verify that the drape posts are seated properly on the end effector. • Verify that the drape is not obscuring the tracking camera's view of the tracking spheres. • Verify that that end effector is not on the edge of the tracking camera's field of view.
Cannot track tool	• Ensure tool is visible to tracking camera. • Ensure the tracking spheres are clean and not damaged. • Ensure the tracking spheres are properly attached to the tool's marker tree.
Tool auto focus is enabled but not functioning	• Verify that the end effector is visible to the tracking camera. • Verify that the tool is visible to the tracking camera. • Ensure that the tip of the tool is visible to the surgical camera. As long as the tip of the tool can be recognized in the surgical camera's field of view at the lowest level of zoom, auto focus will function even if the camera is zoomed in and the tip of the tool is not visible on the main surgeon monitor.
"Tool not visible" notification is ennunciated when attempting to auto focus even though the tool is visible to the tracking camera and in the surgical cameras' field of view	Verify that the tool you are focusing to is set as the auto focus tool on the Procedure screen. For more information, see 7.4 Auto Focusing on a Tool on page 108.

Table 26 Troubleshooting Tips (continued)

Problem	Possible Solutions
“All items in the Setup phase must be marked as complete” notification appears even though all items are complete	This may occur if you try to move directly from the Setup phase to the Wrapup phase. First move to the Procedure phase, then proceed to the Wrapup phase.
"Rotation too large" or "Distance too large" notification appears even though the requested alignment move seems small	This problem can occur if you have manually reduced the standoff to a distance significantly smaller or significantly greater than the standoff distance set for the tool. To complete the alignment move, Modus X must move the arm back to the original standoff distance, which may require it to move or rotate in a way that exceeds safety limits. To move the positioning arm back to the original standoff distance, reset the pose.
Optics image appears hazy	Light reflected from white surgical gloves can create a glare. Switch to dark colored gloves.

12.2 User Notifications

NOTE: Audible verbal notifications are only enunciated if Modus X is configured to its default settings. If this setting is changed, Modus X will not enunciate audible verbal notifications.

Table 27 Alignment Motions / Trackable Tools Notifications

Category	Touchscreen monitor notification	Audible verbal notification	Reason for Notification
 Alert	Tool Requires Calibration	"Tool calibration required"	The suction tool must be calibrated before performing an alignment. For more information on calibrating suction tools, see 7.1.3 Working with Suction Tools on page 101.
 Advisory	Approaching Tool Collision	"Approaching collision (tool)"	The positioning arm will stop movement to avoid physical contact with a tracked tool. Adjust the distance between the arm and tool and retry the alignment.
 Advisory	Auto Align Error - Distance Too Large	"Distance too large"	The distance required to reach the desires position exceeds safety limits. Try moving the arm with a shorter distance. Also consider setting the pose or adjusting the standoff of the end effector.
 Advisory	Auto Align Error - Minimum Standoff Distance Reached	"Minimum standoff distance reached"	The minimum standoff distance between the end effector and the tracked tool has been reached and the arm has stopped movement.
 Advisory	Auto Align Error - Rotation Too Large	"Rotation too large"	The rotation required to reach the desired position exceeds safety limits. Try moving the arm with a smaller rotation.
 Advisory	Auto Align Error -Standoff Distance Too Small	"Standoff too small"	The standoff distance between the tool and the end effector is too small. Try aligning to a different position or adjusting the standoff distance to a greater distance.

Table 27 Alignment Motions / Trackable Tools Notifications (continued)

Category	Touchscreen monitor notification	Audible verbal notification	Reason for Notification
Advisory	Auto Align Error - Tool Visibility	"(tool) not visible"	The tracking spheres for the selected tool may not be visible to the tracking camera. Ensure you have selected the correct tool, and that its tracking spheres are visible to the tracking camera. Ensure that the tracking spheres are properly attached to the tool and are not damaged.
Advisory	Auto Align Error - Trajectory Not Available	"Trajectory not available"	The trajectory is not available. Ensure that Modus X is connected to the Modus Nav operator cart. Verify that the Modus Nav software is running. Ensure that the "Enable Align to Trajectory" feature in Modus Nav is enabled and that the patient reference is visible to the tracking camera.
Advisory	Auto Align Error - Visibility of Scope Markers	"Scope markers not visible"	The tracking spheres on the end effector are not visible to the tracking camera. Ensure that the tracking spheres on the end effector are visible. If connected to Modus Nav, ensure that both the end effector and Synaptive patient reference are visible to the tracking camera. Additionally, ensure that the tracking spheres on the end effector and the Synaptive patient reference are attached properly and are not damaged.
Advisory	Pose Reset Error	N/A	Cannot reset the alignment pose to its default. The last attempt to reset a pose has failed.
Advisory	Pose Set Error	"Cannot comply"	The last attempt to set a pose has failed. Ensure that the tool is visible and retry setting the pose.
Advisory	Standoff Pedals Disabled	"Cannot Comply"	This message occurs if the standoff pedal has been pressed while in Memory position mode. To use the standoff pedal, you must be in alignment mode.
Advisory	Unable to Clear All Positions	N/A	Removing saved positions has failed. Retry removing all saved positions.

Table 27 Alignment Motions / Trackable Tools Notifications (continued)

Category	Touchscreen monitor notification	Audible verbal notification	Reason for Notification
 Advisory	Unable to Set Position	N/A	Setting a position has failed. Retry setting the position.
 Advisory	Unable to set position to its default value	N/A	Resetting the position to its default position has failed. Try resetting the position again.
 Advisory	Calibration State Lost	N/A	This notification ocurrs if you connect to, or disconnect from Modus Nav. Verify that Modus X is still tracking the tools correctly and re-calibrate if necessary.

Table 28 Internal System Communications Notifications

Category	Touchscreen monitor notification	Audible verbal notification	Reason for Notification
 Alert	Camera Control is Unavailable	N/A	The camera connection is disconnected. To resolve, reboot the system. Note that if the issue continues to persist after rebooting, the system will not be able to continue with the procedure until Synaptive Service is consulted.
 Alert	Optics Hardware Initialization Failed	N/A	The optics hardware failed to initialize correctly. Please contact Synaptive Service.
 Alert	Disconnected from DAC	N/A	The connection to the positioning arm controller has been lost. Waiting for a minute may allow the system to self-correct, which would dismiss this notification automatically. If the condition persists, reboot the system.
 Advisory	Disconnected from Video Processor	N/A	Connection to the video processor has been lost. Video recording and surgical overlay will be disabled. Reboot the system. If the issue continues to persist after rebooting, please contact Synaptive Service.

Table 28 Internal System Communications Notifications (continued)

Category	Touchscreen monitor notification	Audible verbal notification	Reason for Notification
Advisory	Disconnected from Video Overlay Service	N/A	Communication to the surgical overlay service has been lost. Reboot the system. If the issue continues to persist after rebooting, please contact Synaptive Service.
Advisory	The Power Controller has Disconnected	N/A	The system is unable to access power related information, so the displayed battery status is not reliable. Please ensure the system is connected to A/C power.
Advisory	Transmitter Battery Warning	N/A	The wireless microphone transmitter battery is running low. Swap the battery pack or switch to a new transmitter.

Table 29 Lights Notifications

Category	Touchscreen monitor notification	Audible verbal notification	Reason for Notification
Alert	Light Control is Unavailable	N/A	The main light source is disconnected. Ensure main light source is connected connected. If the issue persists, reboot the system. Note that if the issue persists after rebooting, the system will not be able to continue with the procedure until Synaptive Service is consulted.

Table 30 Monitor Notifications

Category	Touchscreen monitor notification	Audible verbal notification	Reason for Notification
Alert	Monitor Control is Unavailable	N/A	Modus X is unable to communicate with a monitor. Ensure that all monitors are connected as described in section 3.3.8 on page 67. If the issue persists, reboot the system. If the issue continues to persist after rebooting, please contact Synaptive Service.

Table 31 Optics Notifications

Category	Touchscreen monitor notification	Audible verbal notification	Reason for Notification
 Alert	Critical Focus Fault	N/A	The focus hardware has reported a critical fault. Please contact Synaptive Service. If this notification is experienced, the focus control and auto focus will no longer function for the procedure.
 Alert	Critical Zoom Fault	N/A	The zoom hardware has reported a critical fault. Please contact Synaptive Service. If this notification is experienced, the zoom control will no longer function for the procedure.
 Alert	Focus Control is Unavailable	N/A	Focus control is unavailable. To resolve, tap **Reset Optics** on the Camera Settings screen. If the issue persists, reboot the system. Note that if the issue continues to persist after rebooting, the system will not be able to continue with the procedure until Synaptive Service is consulted.
 Alert	Zoom Control is Unavailable	N/A	Zoom control is unavailable. To resolve, tap **Reset Optics** on the Camera Settings screen. If the issue persists, reboot the system. Note that if the issue continues to persist after rebooting, the system will not be able to continue with the procedure until Synaptive Service is consulted.
 Alert	Videoscope Control is Unavailable	N/A	Videoscope control is unavailable. To resolve, tap **Reset Optics** on the Camera Settings screen. If the issue persists, reboot the system. Note that if the issue continues to persist after rebooting, the system will not be able to continue with the procedure until Synaptive Service is consulted.

Table 32 Positioning Arm Notifications

Category	Touchscreen monitor notification	Audible verbal notification	Reason for Notification
 Alert	Auto Align Error - Precautionary Halt	"Precautionary halt"	Modus X cannot complete the motion you requested because a potential collision between the arm and a tool has been detected. Ensure tools near the arm are visible and try again. For more information, see 7.3 Safety Measures During Align Moves to a Tool or Trajectory on page 108.
 Alert	Joint Rotation Error	"Cannot comply"	This message occurs if one or more of the Modus Xarm joints has reached its rotational limit. Use manual end effector mode to move the arm out of this position.
 Alert	Security Stop	"Entering security stop"	An external force has been applied to the arm. Remove any obstacles from the system's path and tap **Return to Standby**.
 Alert	Security Stop	N/A	Transitioning from security stop to standby mode has failed. Remove any obstacles from the system's path and try tapping **Return to Standby** again.
 Alert	N/A	"Arm in security stop"	Modus X is in security stop and an input that is not allowed has been pressed. Return to standby mode before proceeding.
 Advisory	Approaching Mechanical Limit	"Approaching mechanical limits"	A mechanical limit with the positioning arm has been reached. Auto-align the arm or manually move the arm out of the mechanical limit.
 Advisory	Approaching Self-Collision	"Approaching collision"	A collision of the positioning arm with itself is about to occur. Use the manual end effector mode to move the arm away from the collision point.
 Advisory	Joint Overspeed Warning	N/A	One or more arm joints are approaching or have exceeded the recommended velocity. Move the arm more slowly.
 Advisory	Joint Rotation Limit	N/A	One or more arm joints has almost reached its mechanical limit. Observe the arm's movement and be prepared to move the arm joints away from their limits.

Table 33 Power Notifications

Category	Touchscreen monitor notification	Audible verbal notification	Reason for Notification
 Alert	Power Has Been Cut for Your Safety	"Power to arm has been cut"	Power has been cut to the positioning arm most likely due to an external force applied to the arm.
 Alert	Unable to Shut Down	N/A	A system shutdown was initiated, but the system cannot shut down. Please initiate shutdown again.
 Alert	Using Battery Power	"Using battery power"	The Modus X system is running on battery power. Connect to A/C power as soon as possible.
 Advisory	Battery Level has Decreased	N/A	This notification is issued when the battery level has decreased as a reminder to connect to A/C power as soon as possible.

Table 34 System Notifications

Category	Touchscreen monitor notification	Audible verbal notification	Reason for Notification
 Alert	Brakes Not Engaged	"Brakes not engaged"	The brakes are not engaged. Ensure that the castor brakes are engaged to proceed.
 Advisory	Unable to leave safe mode	N/A	Modus X is unable to leave safe mode. Verify that the E-stop is pulled all the way out and the brake is engaged.

Table 35 Video Recording / Export Notifications

Category	Touchscreen monitor notification	Audible verbal notification	Reason for Notification
Advisory	Video Recording Failed	N/A	Video recording has failed. Try recording again.
Advisory	Video Clip Creation Failed	N/A	Modus X was unable to create the video clip, possibly because the clip was too short. Try recording a clip at least 3 seconds in length.
Advisory	Error During Video Export	N/A	An error occurred during video export. Ensure that the USB key is connected and retry the video export.
Advisory	Insufficient Storage Space on USB Device	N/A	The USB key does not have enough available space for the video export. Free up space and retry the video export.
Advisory	USB Storage Device Removed During Export	N/A	The USB key was removed before export completed. Retry the video export.
Advisory	Video Recorder Cleanup	N/A	Videos are undergoing necessary cleanup maintenance. Video recording and exporting is disabled during this process, which should take no more than 5 minutes. Wait until the process completes.
Advisory	Video Recording is Unavailable	N/A	This message occurs if the video record icon is selected and a pre-existing condition prevents video recording (e.g., video storage is full). If the problem persists after addressing typical causes for this issue, contact Synaptive Service.
Advisory	Video Storage is Full	N/A	There is no space on the hard drive to record video. Export your saved video files and delete the files from Modus X to free up space. See 5.5.1 Case Recording on page 88 for instructions on exporting and deleting video files.

Table 36 Snapshot Capture / Export Notifications

Category	Touchscreen monitor notification	Audible verbal notification	Reason for Notification
Advisory	Error During Snapshot Export	N/A	An error occurred during snapshot export. Ensure that the USB key is connected and retry the snapshot export.
Advisory	Video Snapshot Failed	N/A	could not capture the snapshot. Retry capturing the snapshot. If video snapshots continue to fail, reboot the system from the Settings screen. If that does not resolve the issue, please consult Synaptive Service.
Advisory	Insufficient Storage Space on USB Device	N/A	The USB key does not have enough available space for the snapshot export. Free up space and retry the snapshot export.
Advisory	USB Storage Device Removed During Snapshot Export	N/A	The USB key was removed before export completed. Retry the snapshot export.
Advisory	Video Snapshots are Unavailable	N/A	This message occurs when you tap the snapshot capture icon but a pre-existing condition prevents the capture (e.g., snapshot storage is full). If the problem persists after addressing typical causes for this issue, contact Synaptive Service.
Advisory	Snapshot Storage is Full	N/A	There is no space on the hard drive to capture snapshots. Export your saved snapshot files and delete the files from Modus X to free up space. See 5.5.4 Snapshots on page 92 for instructions on exporting and deleting snapshot files.

Table 37 Fluorescence Notifications

Category	Touchscreen monitor notification	Audible verbal notification	Reason for Notification
 Advisory	Outside Recommended Focal Range	N/A	The current focal distance is outside of the recommended range for the selected preset. Adjust the focal distance to be within the recommended range (see 9.0 Fluorescence on page 112).
 Advisory	Outside Recommended Zoom Range	N/A	The current zoom level is outside of the recommended range for the selected preset. Adjust the zoom level to be within the recommended range (see 9.0 Fluorescence on page 112).

12.3 LED Indicators

The LEDs on the Modus X rear panel provide information about the state of the Modus X system, including battery charge levels and system errors. If there are system errors, the LEDs will toggle through displaying the battery level and the error states for five second durations.

NOTE: Read the LEDs on the Modus X rear panel from left to right (LED 1 in the tables below is the left most LED on the panel).

Battery Charge Indicators

Table 38 LED Indicators when System is Unplugged from a Power Source and System is OFF

Approximate Battery Charge Level	Power Button Ring LED	LED 1	LED 2	LED 3	LED 4	UPS Audible Notification
N/A	OFF	OFF	OFF	OFF	OFF	OFF

Table 39 LED Indicators when System is Starting Up or Shutting Down

Approximate Battery Charge Level	Power Button Ring LED	LED 1	LED 2	LED 3	LED 4	UPS Audible Notification
N/A	Flashing	Based on current battery charge level (see Table 41)				OFF

Table 40 Battery Status Indicators when System is Unplugged from a Power Source and System is ON (Discharging)

Approximate Battery Charge Level	Power Button Ring LED	LED 1	LED 2	LED 3	LED 4	UPS Audible Notification
81-100%	ON	ON	ON	ON	ON	ON
61-80%	ON	ON	ON	ON	OFF	ON
41-60%	ON	ON	ON	OFF	OFF	ON
21-41%	ON	ON	OFF	OFF	OFF	ON
<=20%	ON	Flashing	OFF	OFF	OFF	ON

Table 41 Battery Status Indicators when System is Plugged into a Power Source and System is ON (Charging)

Approximate Battery Charge Level	Power Button Ring LED	LED 1	LED 2	LED 3	LED 4	UPS Audible Notification
96-100%	ON	ON	ON	ON	ON	OFF
81-95%	ON	ON	ON	ON	Flashing	OFF
61-80%	ON	ON	ON	Flashing	OFF	OFF
41-60%	ON	ON	Flashing	OFF	OFF	OFF
<=40%	ON	Flashing	OFF	OFF	OFF	OFF

Table 42 Battery Status Indicators when System is Plugged into a Power Source and System is OFF (Charging)

Approximate Battery Charge Level	Power Button Ring LED	LED 1	LED 2	LED 3	LED 4	UPS Audible Notification
96-100%	OFF	ON	ON	ON	ON	OFF
81-95%	OFF	ON	ON	ON	Flashing	OFF
61-80%	OFF	ON	ON	Flashing	OFF	OFF
41-60%	OFF	ON	Flashing	OFF	OFF	OFF
<=40%	OFF	Flashing	OFF	OFF	OFF	OFF

System Error Code Indicators

Use Table 43 to determine the error code represented by the LED state. Error codes are described in Table 44.

Table 43 LED System Error States

Power Button Ring LED	LED 1	LED 2	LED 3	LED 4	Error Code
ON	OFF	OFF	OFF	ON	1
ON	OFF	OFF	ON	OFF	2
ON	OFF	OFF	ON	ON	3
ON	OFF	ON	OFF	OFF	4

Table 43 LED System Error States (continued)

Power Button Ring LED	LED 1	LED 2	LED 3	LED 4	Error Code
ON	OFF	ON	OFF	ON	5
ON	OFF	ON	ON	OFF	6
ON	OFF	ON	ON	ON	7
ON	ON	OFF	OFF	OFF	8
ON	ON	OFF	OFF	ON	9
ON	ON	OFF	ON	OFF	10
ON	ON	OFF	ON	ON	11
ON	ON	ON	OFF	OFF	12
ON	ON	ON	OFF	ON	13
ON	ON	ON	ON	OFF	14
ON	ON	ON	ON	ON	15

Error Codes

Table 44 Error Codes

Code	Description
1	Cannot connect to microTCA
2	Cannot connect to PDU
3	Cannot connect to UPS
4	Firmware out of date, CRCs do not match, update firmware from computer
5	No application loaded (currently in image loader)
6	UPS failure, communicating but UPS will not power on
7	MicroTCA failure, communicating but will not power on
8	Not used
9	PDU Failure, communicating but will not power all outlets on
10	No ethernet link detected

Table 44 Error Codes (continued)

Code	Description
11	Not used
12	Not used
13	Not used
14	Not used
15	Not used

12.4 Compatible Peripherals and Instrumentation

The following parts are compatible with Modus X. See also 11.4 Ordering Accessories on page 132 for a list of accessories that can be used with Modus X.

Table 45 Tracking Camera and Monitor Carts

Name	Part Number
Auxiliary Cart - 3D Monitor Cart 55" with Camera	SYN-0907
Auxiliary Cart - 3D Monitor Cart 55"	SYN-0906
Auxiliary Cart - 3D Monitor Cart 31" with Camera	SYN-0793
Auxiliary Cart - 3D Monitor Cart 31"	SYN-0794
Auxiliary Cart - Camera Cart	SYN-0621

Table 46 Pedals

Name	Part Number
Multi-Function Foot Pedal	ASY-1151
Single-Function Foot Pedal	COS-0002

Table 47 Voice Control Components

Name	Part Number
Modus X Voice Control Rechargeable Package **NOTE: The specific voice control package supplied with your Modus X system is dependent on your region.**	SYN-0931 SYN-0965 SYN-0966 SYN-0967

Table 48 Synaptive Instrumentation

Name	Part Number
Standard Pointer	SYN-0642
Long Pointer	SYN-0975
Trackable Suction	SYN-0657, SYN-0783
Calibration Block	SYN-0014
Multi-Tool Calibration Device	SYN-0755

Table 49 Modus Nav Instrumentation

Name	Part Number
Synaptive Patient Reference	SYN-0021
Synaptive Tracking Array for the NICO BrainPath	SYN-0015

12.5 Operating and Storage Conditions

Operate and store Modus X only under the following conditions.

Only transport Modus X under appropriate conditions. For more information, contact Synaptive customer service.

Table 50 Operating and Storage Conditions

	Operating	Storage and Transport
Ambient temperature	16°C - 30°C	-10°C - +40°C
Relative humidity (non-condensing)	20% - 70%	10% - 70%
Altitude	Less than or equal to 2,000 m	Less than or equal to 3,000 m

NOTE: Avoid storing Modus X unused for long periods of time. At least once every 65 days, plug in and turn on Modus X for at least six hours.

12.6 System Classification and Specifications

12.6.1 Modus X System Classification and Specifications

Table 51 System Classification and Specifications

Classification	Class 1 ME Equipment
Mode of Operation	Continuous Operation
Mains Supply*	• 120 V 60 Hz 10A • 230-240 V 50 Hz 5A • 220 V 50 Hz 6A • 220 V 60 Hz 6A

* Refer to the product labels affixed to your Modus X system for specific rating information.

Table 52 Degree of Protection Against Ingress of Water

Mobile base and positioning arm	IPX0
Single-function foot pedal	IPX6
Multi-function foot pedal	IPX8

12.6.2 Essential Performance

The essential performance criteria for Modus X are:

- To provide visualization of the surgical field.
- To provide sufficient illumination to the surgical field.
- To hold the end effector in the desired position.

If the essential performance criteria are not met, you may experience inadequate visualization of the surgical field, insufficient or inappropriate illumination of the surgical field, and unexpected movement of the positioning arm.

12.6.3 Modus X Mass and Dimensions

Table 53 System Mass and Dimensions

Mass	320 kg
Width (Castors forward facing)	73.5 cm

Table 53 System Mass and Dimensions (continued)

Length (arm in stowed position)	115 cm
Length (arm fully outstretched)	239.5 cm
Height (arm in stowed position)	192 cm
Height (arm in typical use position)	225 cm

NOTE: The dimensions of Modus X will vary based on movement of the positioning arm.

12.6.4 Modus X Cable Specifications

Table 54 Cable Specifications

Cable	Specifications
Power cord**	• 6 m with C13 and NEMA 5-15P hospital grade connector • 6 m with C13 and AS/NZS 3112:2000 hospital grade connector • 6 m with C13 and SEV 1011 Type 12 connector • 6 m with C13 and BS1363/A connector • 6 m with C13 and CEE7/7 connector • 6 m with C13 and DK-2-8A hospital grade connector • 6 m with C13 and CEI 23-50 connector • 6 m with C13 and TIS 166-2549
Single-input pedal	• 4 m shielded cable (2 x 22 AWG) with Lemo connector
Multi-input pedal	• 4 m shielded cable (20 x 24 AWG) with Lemo connector
Video cable	• 7 m shielded cable with DVI-D Dual link connector, male to male

** The specific power cord supplied with your Modus X system is dependent on regional power specifications.

WARNING: Risk of Damage to Equipment

Use only the approved power cord supplied with Modus X. The use of non-approved power cords can result in damage to the Modus X system. The use of other accessories, transducers, and cables may result in increased electromagnetic emissions or decreased immunity of this equipment and may result in improper operation. If a cable becomes damaged, contact Synaptive customer service for assistance.

12.6.5 RF Specifications

Table 55 RF Receiver Specifications for Model SYN-0974

Frequency band of reception	2400 to 2483.5 MHz
Receiving bandwidth	6 dB Bandwidth [kHz]

Frequency	Lowest Channel 2403 MHz	Middle Channel 2443 MHz	Highest channel 2481 MHz
GFSK / Ant 1 & Ant 2	837	817	805

RF output power back channel	100 mW

Table 56 RF Receiver Specifications for Model SYN-0976

Frequency band of reception	2400 to 2483.5 MHz
Receiving bandwidth	6 dB Bandwidth [kHz]

Frequency	Lowest Channel 2403 MHz	Middle Channel 2443 MHz	Highest channel 2481 MHz
GFSK / Ant 1 & Ant 2	837	817	805

RF output power back channel	10 mW

Table 57 RF Transmitter Specifications for Model SYN-0974

Frequency band of transmission	2400 to 2483.5 MHz
Modulation type	GFSK with back channel
RF output power	100 mW/adaptive

Table 58 RF Transmitter Specifications for Model SYN-0976

Frequency band of transmission	2400 to 2483.5 MHz
Modulation type	GFSK with back channel
RF output power	10 mW

12.7 Certifications

Modus X is certified to the following standards:

- CAN/CSA-C22.2 No. 60601-1:2014
- ANSI/AAMI ES60601-1:2005/A1:2012
- IEC 60601-1-2: 2014
- IEC 60601-1:2005/A1:2012
- IEC 60601-1-6:2010/A1:2013
- CB SCHEME CERTIFICATION

All Modus X systems are designed and manufactured in an ISO:13485 registered facility that is routinely audited by medical device regulators under the Medical Device Single Audit Program (MDSAP).

12.8 Electromagnetic Environment Information

The Modus X system requires special precautions regarding electromagnetic compatibility and must be installed and used according to the electromagnetic compatibility information described in the tables below.

Portable and mobile RF (radio frequency) communications equipment can affect the performance of the Modus X system.

WARNING

The operating room may present sources of electromagnetic energy which may create disturbances greater than the recommended electromagnetic environment described in this section.

If Modus X will be used alongside potential sources of EM that exceed the recommended electromagnetic environment, the system should be observed to verify normal operation and no degradation in essential performance.

Users should periodically evaluate the video signal throughout the procedure. If a degradation is observed that is the result of an electromagnetic disturbance, RF emitters in use around Modus X should be turned off or moved away from Modus X. If the source cannot be found and Modus X continues to operate with degraded essential performance, discontinue use of Modus X and contact Synaptive support.

Table 59 Electromagnetic Environment (Emissions)

The Modus X system is intended for use in the electromagnetic environment specified below. The customer or the user of the Modus X system should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The Modus X 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.

Table 59 Electromagnetic Environment (Emissions) (continued)

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Class A	The Modus X system is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the equipment or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	
NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). 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.		

Table 60 Electromagnetic Environment (Immunity)

The Modus X system is intended for use in the electromagnetic environment specified below. The customer or the user of the Modus X system should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±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.

Table 60 Electromagnetic Environment (Immunity) (continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	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 U_T = 120 Vac	0% U_T (100% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T (100% dip in U_T) for 5 sec	0% U_T (100% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T (100% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. It is recommended that the Modus X system be powered from an uninterruptible power supply or a battery.
Power frequency (50 Hz/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 61 Electromagnetic Environment (Conducted/Radiated)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM/Amateur Radio bands inside 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM/Amateur Radio bands inside 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Modus X system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$

Table 61 Electromagnetic Environment (Conducted/Radiated) (continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz	3 V/m 80 MHz to 2,7 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 Mhz to 2.7 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].

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 Equipment is used exceeds the applicable RF compliance level above, the Modus X 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 Modus X system.

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

Table 62 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the System

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

Table 62 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the System (continued)

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz - 80 MHz $d = 1.2\sqrt{P}$	80 MHz - 800 MHz $d = 1.2\sqrt{P}$	800 MHz - 2.7 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.

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 Modus X system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

12.9 Protected Health Information Considerations

Modus X does not explicitly create, maintain, transmit, or receive protected health or electronic protected health information, and there is no receipt of patient information from a covered entity by the device prior to sale.

Refer to 12.10 Cybersecurity Considerations below.

12.10 Cybersecurity Considerations

The Modus X system is intended for use in an operating room environment and should not be connected to your institution's internal network. If you have questions regarding cybersecurity for Modus X, please contact your Synaptive service representative.

User Profiles and Permissions

- Kiosk User

  The system is deployed with a basic user, named "Kiosk". This account is configured for general use of the device, and is restricted from all other operations including configuration, system install, and system updates.

- ServiceTech User

  An administrative user account is configured for use by Synaptive support staff. This account requires a challenge-response authentication and provides expanded functionality for the purposes of system configuration, upgrade and service.

Personal Health Information

Modus X has the potential to capture and locally store the following personal health information:

- Video imagery, which may include identifiable physical features of the patient
- Video imagery, which may include patient information from visible screens, labels, etc.

Modus X does **not** explicitly capture or store the following information:

- Patient identifying meta data such as patient ID, patient name, date of birth
- Financial information

System Storage

When not in use, Modus X should be turned off and stored in a secure location.

12.11 Software Licenses

Portions of Modus X's software incorporate open source software licensed from third parties. Please contact Synaptive customer service for access to detailed licensing information.