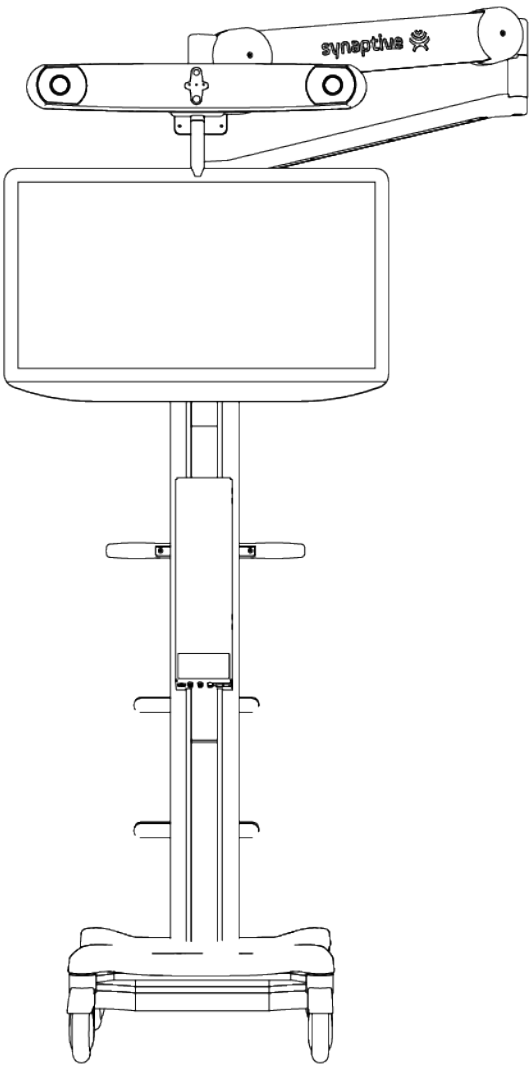
Auxiliary Cart - 3D Monitor Cart 31" with Camera

User Manual

MAN-0674 Revision B



Synaptive

User Manual

Synaptive™ Auxiliary Cart - 3D Monitor Cart 31" with Camera

SYN-0793

Synaptive

MAN-0674 – Revision B issued on May 28, 2021.

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.

Auxiliary Cart - 3D Monitor Cart 31" with Camera fulfills 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

Australian Sponsor:
KD&A Pty Ltd
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Adelaide
South Australia, 5000

Synaptive Medical Inc.
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Toronto Ontario M5V 3B1 Canada
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EC REP EU Authorized Representative:
Medical Device Safety Service (MDSS)
Schiffgraben 41
30175 Hannover, Germany

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1.0 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	To identify the manufacturer of a product.
	Operator's manual	ISO 7000-1641	To identify the location where the operator's manual is stored or to identify information that relates to the operating instructions. To indicate that the operating instructions should be considered when operating the device or control close to where the symbol is placed.
	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.
	Mass; weight	ISO 7000-1321B	To indicate mass. To identify a function related to mass.
	Locked.	ISO 7000-1655	To identify the locking control. To indicate that a control is locked. To indicate that the function cannot be changed or adjusted because its operation is locked. To identify the location of a lock.
	Unlocked.	ISO 7000-3305	To identify the control that effects an unlocking function. To indicate that the component or function is in its unlocked state.
	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.

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
	Keep away from rain	ISO 7000-0626	To indicate that the transport package shall be kept away from rain and in dry conditions.
	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.

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 pushing	ISO 7010-P017	To prohibit pushing 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.
	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).
	Video input	IEC 60417-5525B	To identify video equipment input controls and connecting terminals.
	Video output	IEC 60417-5529B	To identify video equipment output controls and connecting terminals.

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	European Community Representative	N/A	Appears next to the European Community representative's name and address.
TUV SUD C US	cTUVus Certification Mark	N/A	Certified as meeting North American safety standards by TUV.

Table 5 Other Symbols

Symbol	Description
Rx only	U.S. Federal law restricts this device to sale by or on the order of a licensed healthcare provider.
MD	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.

2.0 Warnings and Precautions

WARNING: Risk of Operator Injury and Damage to Equipment

The Auxiliary Cart - 3D Monitor Cart 31" with Camera system may be installed, maintained, repaired, and serviced only by qualified Synaptive Medical service representatives. There are no user-serviceable parts in the Auxiliary Cart - 3D Monitor Cart 31" with Camera system.

No modification of the Auxiliary Cart - 3D Monitor Cart 31" with Camera system is allowed.

The Auxiliary Cart - 3D Monitor Cart 31" with Camera contains non-permanent fasteners that may become loose over time, potentially causing mounted components to become loose and fall. Inspect the Auxiliary Cart before each use to ensure that there are no loose components. If any loose components are discovered, do not use the cart and report the problem to Synaptive Customer Service.

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

WARNING: Risk of Operator Injury and Damage to Equipment

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 the cart from the supply mains. Do not position the cart such that it is difficult to unplug.

Use only the approved power cord supplied with the Auxiliary Cart - 3D Monitor Cart 31" with Camera. The use of non-approved power cords can result in damage to the Auxiliary Cart - 3D Monitor Cart 31" with Camera 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.

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

Before moving a cart, always ensure that all cart casters are unlocked. Push the carts using the cart handles only. Never push on surfaces marked with the Do Not Push symbol. Applying excessive force to the cart or its components may present a tipping hazard.

Do not move the Auxiliary Cart - 3D Monitor Cart 31" with Camera with the tracking camera arm extended. Collapse the tracking camera arm and lock it in place before moving the cart. If the arm is not locked in place, it may extend unexpectedly and cause the Auxiliary Cart to tip over.

Always use caution around the tracking camera arm. If the internal gas spring fails, the camera may drop suddenly.

Use caution when moving the Auxiliary Cart - 3D Monitor Cart 31" with Camera to prevent collisions with people or stationary objects such as equipment, doorways, or walls.

Do not roll the Auxiliary Cart - 3D Monitor Cart 31" with Camera over cabling. Doing so may damage the cables and cause the Auxiliary Cart to become unusable. If a cart rolls over cabling, inspect the cable for damage. If a cart rolls over any object, inspect the castors for damage.

The Auxiliary Cart - 3D Monitor Cart 31" with Camera contains a pressurized gas cylinder, which, although extremely unlikely, may suddenly rapidly decompress, potentially causing damage to equipment and injury to persons standing nearby.

After prolonged use, the monitor may overheat, becoming hot enough to burn a person who touches it. Overheating may also damage the monitor. To minimize the risk of overheating, always turn the monitor off when it is not in use.

WARNING: Risk of Operator or Patient Injury Due to Laser Light Emission

Do not look directly into the laser-emitting aperture on the tracking camera. The Class 2 laser module on the Position Sensor emits radiation that is visible and may be harmful to the human eye. Direct viewing of the laser diode emission at close range may cause eye damage.

WARNING: Risk of Operator or Patient Injury Due to Laser Light Emission

Take precautions to ensure that people with restricted movement or reflexes (for example, patients undergoing medical procedures) do not look directly into the laser-emitting aperture. Patients undergoing medical procedures may not have normal adverse-effects reflexes (turning away eyes and/or head, closing eyes) due to pharmaceutical influences and/or mechanical restraints. The Class 2 laser module on the Position Sensor emits radiation that is visible and may be harmful to the human eye. Direct viewing of the laser diode emission at close range may cause eye damage.

Use of laser controls or adjustments or performance of laser-related procedures other than those specified herein may result in hazardous radiation exposure.

WARNING: Risk of Patient Injury Due to Incorrect Video Display

The pre-defined Synaptive picture settings have been optimized for tissue differentiation in a surgical setting. Using other settings may result in poor tissue differentiation, potentially leading to suboptimal treatment.

Always ensure that the monitor is set to the correct mode (2D or 3D) for circumstances of the procedure. The monitor displays colors differently in 2D and 3D mode, which may result in poor tissue differentiation if not used correctly.

Due to the nature of LCD displays, image display characteristics (such as brightness, contrast, and the appearance of colors) may change over time. Turn the monitor off when it is not in use to prevent unnecessary wear. If the image display is inadequate when using the default Synaptive picture settings, contact Synaptive Customer Service.

WARNING: Risk of Electric Shock

Use caution when handling the Auxiliary Cart - 3D Monitor Cart 31" with Camera. If it develops a buildup of electric charge, anyone who touches the Auxiliary Cart may experience a mild shock.

WARNING: Risk of Patient Injury Due to Contamination of the Sterile Field

Always follow the manufacturer's instructions for use when assembling and wearing the 3D eye shields. Assembling or wearing the 3D eye shields incorrectly may cause them become loose or fall during the procedure, potentially contaminating the sterile field.

WARNING: Risk of Procedure Delay Due to Loss of Tracking

Infrared sources in the operating room may interfere with tracking camera tracking. Remove any non-Synaptive sources of infrared signals from the operating room before performing a procedure using the tracking camera.

The tracking camera cannot track multiple instances of the same tool simultaneously. Use only one of each tool in the camera’s field of view at a time.

Loss of power will result in loss of tracking capability. If power to the cart is cut off, restore the power or follow your site’s established protocols to end the procedure.

WARNING: Risk of Procedure Delay Due to Loss of Display

Always verify that the cables connecting the monitor cart to other Synaptive equipment are securely connected. Applying excessive force to the cables may cause them to become disconnected, leading to a loss of system operation.

The displayed image quality is adversely affected if the monitor is subjected to an electrostatic discharge (such as by coming into contact with persons or equipment that have a buildup of electrostatic energy). This effect is temporary but may last up to several minutes.

After prolonged use, the monitor may overheat and shut down. To minimize the risk of overheating, always turn the monitor off when it is not in use.

WARNING: Risk of Procedure Delay Due to Loss of Registration

Always lock all casters on the Auxiliary Cart carts to prevent them from moving during the procedure.

WARNING: Risk of Damage to Equipment

Always verify that the cables connecting the Auxiliary Cart- 3D Monitor Cart 31" with Camera to other Synaptive equipment are securely connected. Applying excessive force to the cables may cause them to become disconnected, potentially damaging the system.

When setting up equipment, avoid bending the cables excessively. Extreme bends may damage the cables and lead to loss of function.

Use only the cleaning agents described in this manual to clean the Auxiliary Cart - 3D Monitor Cart 31" with Camera. Using other cleaning agents may damage the Auxiliary Cart.

3.0 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.

4.0 Intended Use Environment

The Auxiliary Cart - 3D Monitor Cart 31" with Camera is intended for use in hospitals, clinics, and other medical institutions.

5.0 Device Lifetime

The Auxiliary Cart - 3D Monitor Cart 31" with Camera has an expected lifespan of seven years. This lifespan assumes that regular maintenance and service is performed by qualified Synaptive Medical authorized service providers.

6.0 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

7.0 About the Auxiliary Cart - 3D Monitor Cart 31" with Camera

The Auxiliary Cart - 3D Monitor Cart 31" with Camera provides tool tracking and video display for Synaptive systems like BrightMatter Guide and Modus V.

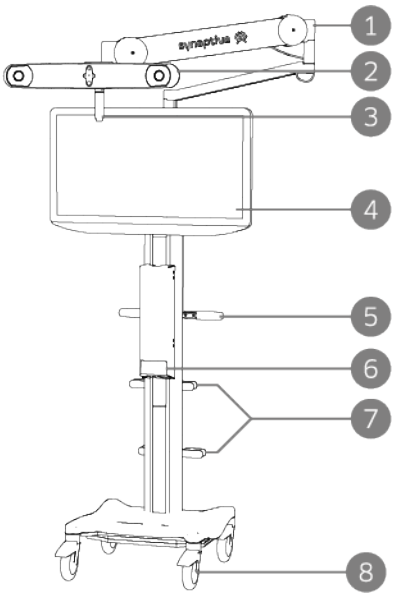


Figure 1 Monitor Cart 31" with Camera components

1. Articulated camera arm
2. Tracking camera
3. Tracking camera handle
4. 31" 3D Monitor
5. Cart handle
6. I/O box
7. Cable cleats
8. Locking casters

A monitor cover is provided with the Auxiliary Cart - 3D Monitor Cart 31" with Camera to protect the monitor during transportation and storage. Remove the monitor cover before using the Cart during a procedure and store it outside the sterile field.

Users of the Auxiliary Cart - 3D Monitor Cart 31" with Camera are surgeons and surgical staff members such as OR nurses.

7.1 3D Eye Shields

WARNING: Risk of Patient Injury Due to Contamination of the Sterile Field

Always follow the manufacturer's instructions for use when assembling and wearing the 3D eye shields. Assembling or wearing the 3D eye shields incorrectly may cause them become loose or fall during the procedure, potentially contaminating the sterile field.

Stereoscopic visualization requires the use of a 3D eye shield composed of a frame and a disposable 3D lens.

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.

Figure 2 3D eye shield showing lens assembled to frame

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

8.0 Cart Connections

WARNING: Risk of Damage to Equipment

Always verify that the cables connecting the Auxiliary Cart- 3D Monitor Cart 31" with Camera to other Synaptive equipment are securely connected. Applying excessive force to the cables may cause them to become disconnected, potentially damaging the system.

When setting up equipment, avoid bending the cables excessively. Extreme bends may damage the cables and lead to loss of function.

The Auxiliary Cart - 3D Monitor Cart 31" with Camera has an input/output box for connecting the carts to each other or to other Synaptive systems.

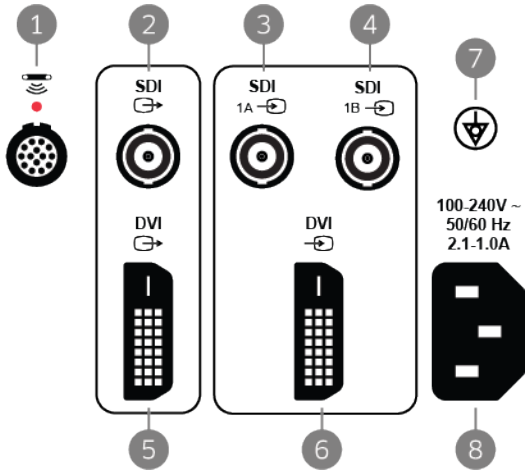


Figure 3 Input/output box connections

1 Tracking camera. Use this connector to connect the cart to the BrightMatter Guide operator cart or the Modus V mobile base.
2 SDI out. Use this connector to send the SDI signal coming in to the cart to another monitor.
3 SDI 1A in. Connect the Modus V SDI 1A out to this connector.
4 SDI 1B in. Connect the Modus V SDI 1B out to this connector.
5 DVI out. Use this connector to send the DVI signal coming in to the cart to another monitor.
6 DVI in. Connect the source of the DVI signal (for example, Modus V, or the BrightMatter Guide operator cart) to this connector.
7 Equipotential grounding pin (potential equilization point).
8 Power. Use the supplied power cable to connect the cart to a power outlet.

NOTE: If you want to use a video out connector, you must use the same video type as the signal coming in. For example, if you have an SDI signal coming in, you must use the SDI out connector.

9.0 About the Tracking Camera

The tracking camera works by emitting flashes of invisible (infrared) light that reflect off passive reflective markers on tracked instruments. The reflected light is captured by sensors on the tracking camera and is used to determine the position of the markers.

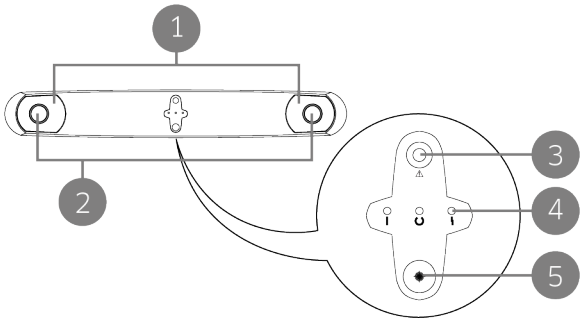


Figure 4 Tracking camera front view

1 Illuminators
2 Sensors
3 Laser aperture
4 Indicator LEDs (from left to right: Power, Camera Status, Error)
5 Laser activation button

NOTE: The tracking camera has a sensor that halts tracking if the camera is bumped with sufficient force to affect the tracking calibration. When the sensor is tripped, the camera Error LED flashes. If this occurs, you must contact Synaptive Service to re-calibrate the camera.

9.1 Using the Tracking Camera Positioning Laser

The tracking camera includes a positioning laser that indicates the center of the camera's tracking volume. Use this feature to orient the tracking camera towards the surgical site so all tools and the cranial reference are in the field of view. The laser beam is emitted from an aperture on the front of the tracking camera (item 4 in Figure 4 above).

WARNING: Risk of Operator or Patient Injury Due to Laser Light Emission

Do not look directly into the laser-emitting aperture on the tracking camera. The Class 2 laser module on the Position Sensor emits radiation that is visible and may be harmful to the human eye. Direct viewing of the laser diode emission at close range may cause eye damage.

Take precautions to ensure that people with restricted movement or reflexes (for example, patients undergoing medical procedures) do not look directly into the laser-emitting aperture. Patients undergoing medical procedures may not have normal adverse-effects reflexes (turning away eyes and/or head, closing eyes) due to pharmaceutical influences and/or mechanical restraints. The Class 2 laser module on the Position Sensor emits radiation that is visible and may be harmful to the human eye. Direct viewing of the laser diode emission at close range may cause eye damage.

Use of laser controls or adjustments or performance of laser-related procedures other than those specified herein may result in hazardous radiation exposure.

To use the positioning laser, press and hold the laser activation button on the front of the tracking camera (item 5 in Figure 4 above). The laser remains on only while the button is pressed.

9.2 Positioning Laser Battery

The laser can be activated whether the tracking camera is powered on or off. When the tracking camera is powered on, the laser draws power through the system from the mains supply. When the system is not powered on, the laser derives its power from an internal battery. If the laser battery needs to be replaced, contact Synaptive Service (for contact information, see 6.0 Synaptive Customer Service Information on page 10).

9.3 Using the Tracking Camera Arm

Use the tracking camera arm to position the tracking camera so that the patient reference and tracked surgical tools will be within the tracking camera's field of view throughout the surgical procedure.

The arm has three joints that rotate in the horizontal plane and two that rotate in the vertical plane allowing it to be moved into a wide range of positions.

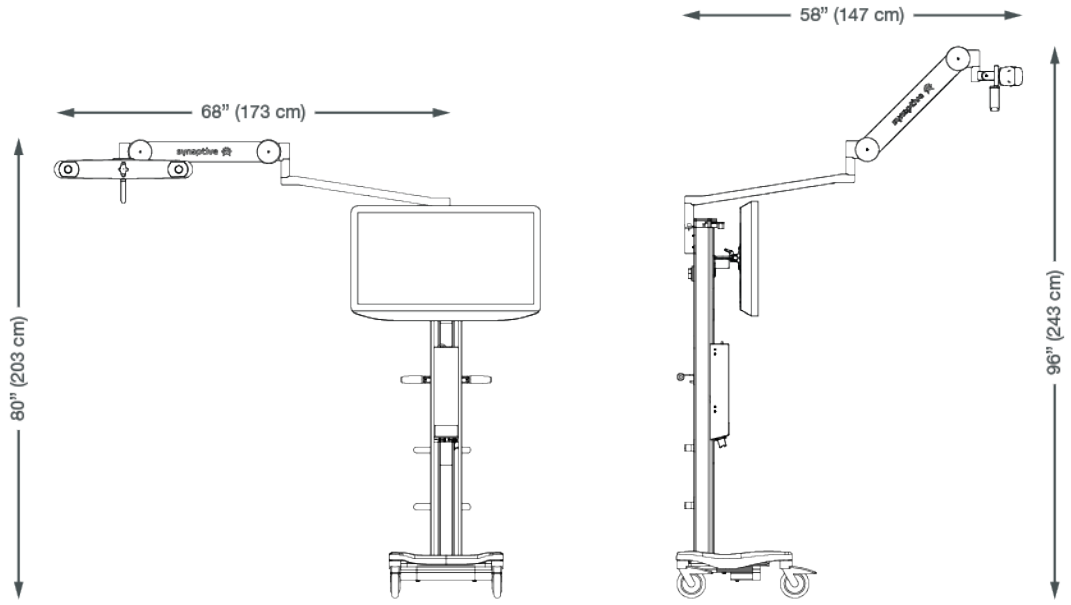


Figure 5 Reach of the tracking camera arm when fully extended horizontally and vertically

WARNING: Risk of Operator Injury and Damage to Equipment

Do not move the Auxiliary Cart - 3D Monitor Cart 31" with Camera with the tracking camera arm extended. Collapse the tracking camera arm and lock it in place before moving the cart. If the arm is not locked in place, it may extend unexpectedly and cause the Auxiliary Cart to tip over.

Always use caution around the tracking camera arm. If the internal gas spring fails, the camera may drop suddenly.

Use the handle on the tracking camera arm to adjust the arm position.

If the handle is out of reach when the tracking camera arm is extended to its highest position, it is acceptable to lower the arm by pulling on the upper arm bar instead of using the handle.

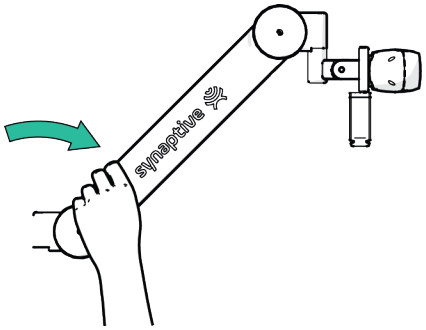
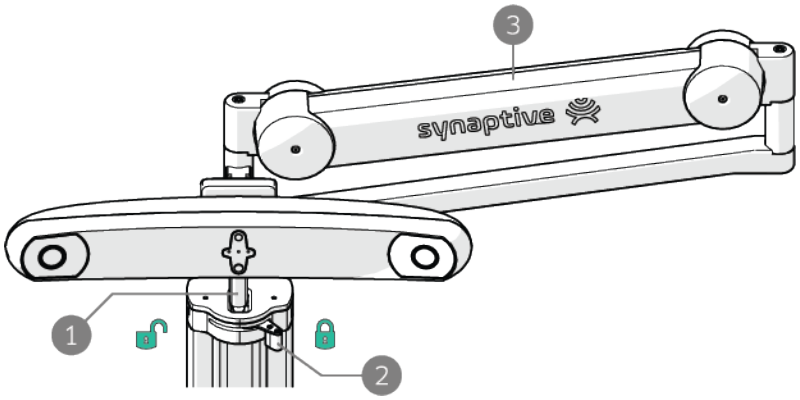


Figure 6 Lowering the arm when the handle is out of reach

The tracking camera arm has a lock feature that prevents the arm from moving when transporting or storing the cart.



1 Handle in dock on top of cart post.
2 Locking lever in locked position.
3 Arm parallel with cart handle.

Figure 7 Arm in locked position (monitor hidden to show detail)

To lock the arm:

1. Position the arm so that the handle is in its dock on the top of the cart post.
2. Turn the locking lever to the locked position.
3. Rotate the arm to the right until it is parallel with the cart handle and the locking latch snaps into place. Note that there are alignment indicators on the arm and arm base to indicate when the arm is in the proper locked position.

To unlock the arm, turn the locking lever to the unlocked position.

10.0 Using the Monitor

10.1 Monitor Controls

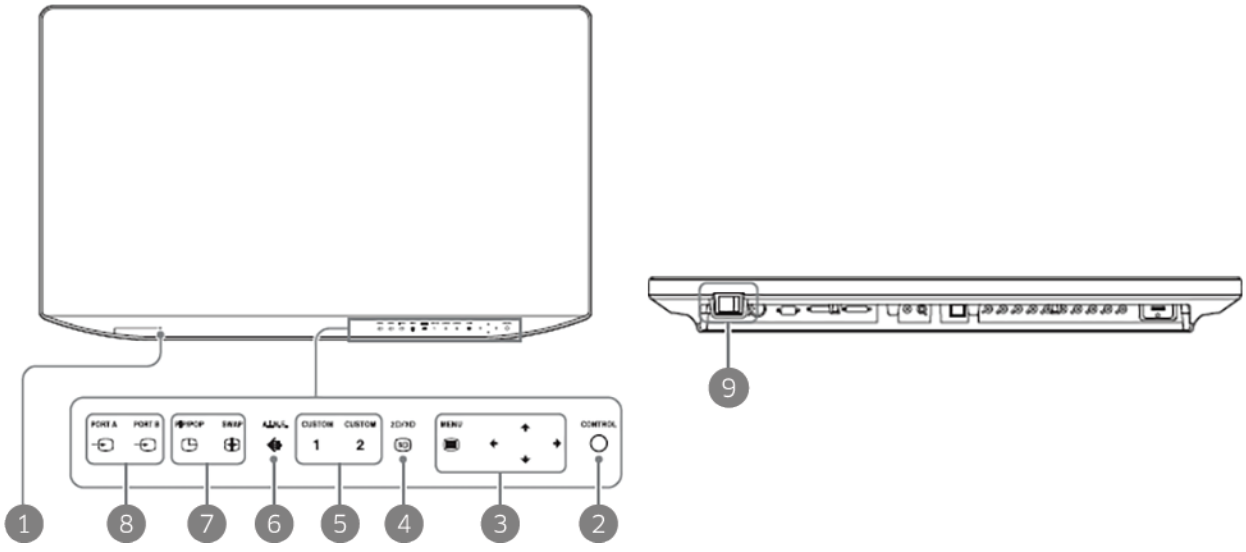


Figure 8 Monitor controls

1 Power indicator. This light is green when the power is on. The monitor has a safety function that reduces the display brightness if the monitor becomes too hot. This light flashes amber when the display brightness is reduced.
2 CONTROL button. Press to activate the other controls on the monitor and to select certain menu items.
3 MENU and arrow buttons. Press the MENU button to show or hide the on-screen menu. Press the arrow buttons to navigate through the menu items.
4 2D/3D select button. Press to switch between 2D and 3D displays.
5 CUSTOM buttons. Press to access the functions associated with the buttons. By default, the CUSTOM buttons are mapped to the following functions:
   - CUSTOM 1: Brightness
   - CUSTOM 2: Contrast
6 A.I.M.E. button. This function is not supported.
7 Multi-screen display setting buttons. Press the PIP/POP button to toggle between multi-screen (picture in picture and picture out of picture) modes. Press the SWAP button to swap the primary and secondary displays when in a multi-screen mode. For more information, see 10.5 Displaying Multiple Inputs on page 17.
8 Input selection buttons. Press once to display the input associated with the button on the monitor. Press again to specify the input associated with the button.
9 Power switch.

10.2 Picture Settings

WARNING: Risk of Patient Injury Due to Incorrect Video Display

The pre-defined Synaptive picture settings have been optimized for tissue differentiation in a surgical setting. Using other settings may result in poor tissue differentiation, potentially leading to suboptimal treatment.

Due to the nature of LCD displays, image display characteristics (such as brightness, contrast, and the appearance of colors) may change over time. Turn the monitor off when it is not in use to prevent unnecessary wear. If the image display is inadequate when using the default Synaptive picture settings, contact Synaptive Customer Service.

The monitor is shipped with the optimal picture settings already configured, but users may change them. If necessary, you can restore the optimal picture settings.

1. Press the **MENU** button then press the down arrow button to move to the **Preset** option then press the right arrow button to select it.
2. If the **Load User Setting** tab is not already selected, use the left or right arrow button to move to that tab.
3. Press the down arrow button to move to the **SYNAPTIVE** option then press the right arrow button to select it.
4. Press the right arrow button to move to the **Yes** option then press the **CONTROL** button to load the Synaptive default settings.

10.3 Using the 3D Monitor Without 3D Eye Shields

By default, when the monitor is in 3D mode a color temperature correction is automatically applied to compensate for a user wearing 3D eye shields. If the monitor is in 3D mode (that is, if one or more SDI

video inputs is connected to the monitor) but the user is **not** wearing 3D eye shields, this color correction should be removed.

1. Press the **CONTROL** button on the monitor to access the other monitor buttons.
2. Press the **MENU** button and use the down arrow to navigate to the **System Configuration** item, then press the right arrow button to access the system configuration options.
3. Navigate to the **Panel Display** > **3D Color Temp Offset** option and set it to **Off**.

Set the **3D Color Temp Offset** value back to **Auto** for 3D visualization.

10.4 Assigning Inputs to the PORT Buttons

If you have two video inputs connected to the monitor, assign the inputs to the PORT A and PORT B buttons to switch between displaying the two inputs, or to view both inputs simultaneously (see 10.5 Displaying Multiple Inputs below).

NOTE: If only one video input is connected to the monitor, the monitor automatically displays that input. It is not necessary to assign that input to a PORT button.

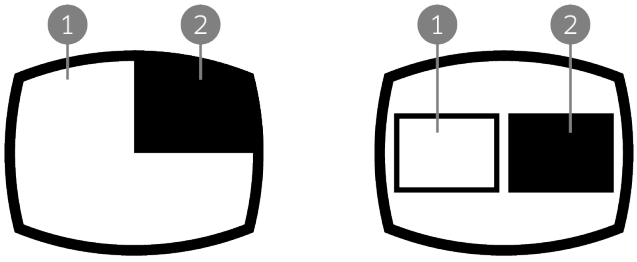
To assign the inputs to the PORT buttons:

1. Press the CONTROL button on the monitor to access the other monitor buttons.
2. Press the **PORT A** button. (If the monitor is currently displaying PORT B, press the **PORT A** button twice to access the menu).
3. Use the arrow buttons to select either **SDI 2** or **DVI-D** as the primary display.
4. Wait for the screen to refresh (it will flash once) then press the **PORT A** button again to accept the selection and close the menu.
5. Repeat the steps above to set PORT B to the input for the secondary display.

To display the input associated with a PORT button, press that button.

10.5 Displaying Multiple Inputs

If you have more than one video source coming in to the monitor, you can display two inputs at once using the picture in picture (PIP) or picture out of picture (POP) display options.



1 Primary display
2 Secondary display

Figure 9 Picture in picture (left) and picture out of picture (right)

To use the PIP/POP feature:

1. Press the CONTROL button on the monitor to access the other monitor buttons.
2. Set PORT A and PORT B to the inputs you want to be the primary and secondary displays, respectively. For more information, see 10.4 Assigning Inputs to the PORT Buttons on page 17.
3. Press the **MENU** button then use the down arrow button to move to the **PIP / POP** option in the menu then press the right arrow button access the PIP/POP options.
4. Use the right arrow button to move to the **Sub Screen Position** tab, then use the down arrow button to move to the **PIP** option to configure picture in picture settings or the **POP** option to configure picture out of picture settings.
5. Use the left and right arrow buttons to toggle through the secondary display location options.
6. When the menu displays your preferred secondary display location, press the **MENU** button to accept your selection and close the menu.
7. Press the **PIP/POP** button on the monitor. This button acts as a toggle so you may need to keep pressing it until your desired PIP or POP configuration is displayed on the monitor.

11.0 Cleaning

WARNING: Risk of Damage to Equipment

Use only the cleaning agents described in this manual to clean the Auxiliary Cart - 3D Monitor Cart 31" with Camera. Using other cleaning agents may damage the Auxiliary Cart.

The Auxiliary Cart components can be cleaned as described below.

Table 6 Hardware Cleaning

Component	Cleaning Instructions
Cart surfaces	Cart surfaces may be cleaned with the following solutions: • Water • Mild Soap Solutions • Hydrogen Peroxide Solution, 3% • Iodine Solutions • Bleach Solutions, 10% • Isopropyl Alcohol Solutions, 70%, 91% • Cavicide® The cart 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. Never submerge or allow liquids to enter a cart or components on the cart. Doing so may irreparably damage the system. Wipe cleaning agents off surfaces immediately using a water-dampened cloth. Dry surfaces thoroughly after cleaning.

Table 6 Hardware Cleaning (continued)

Component	Cleaning Instructions
Monitor	Prior to cleaning and surface disinfection, turn off the monitor and disconnect it from its power source. Cleaning: Thoroughly wipe all exterior surfaces with a lint-free cloth that has been dampened with vinegar (distilled white vinegar, 5% acidity) or an 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 monitor to air dry. Do not allow liquids to penetrate the monitor housing, and do not permit exterior surfaces to come into contact with unacceptable solvents such as MEK (Methyl Ethyl Ketone), Toluene, and Acetone as these may damage the monitor.
Monitor cover	The monitor cover may be cleaned with most mild, non-abrasive solutions commonly used in hospital environment (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.Wipe cleaning agents off surfaces immediately using a water-dampened cloth. Dry surfaces thoroughly after cleaning.

CAUTION

Synaptive Medical makes no claims regarding the efficacy of the listed chemicals or processes as a means for controlling infection. Consult your hospitals' infection control officer or epidemiologist.

12.0 Troubleshooting Problems

Table 7 Auxiliary Cart Problems and Possible Solutions

Problem	Possible Solutions
No power on monitor.	• Check monitor power connection. • Check power switch on back of monitor.
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.

Table 7 Auxiliary Cart Problems and Possible Solutions (continued)

Problem	Possible Solutions
Tracked tools are not recognized by the tracking system.	• Ensure tracking camera has power. • Ensure tracking spheres are clean and properly attached to the tool. • Use the tracker calibration function in the BrightMatter Guide or Modus V software application to identify the positions of all tracked tools. Move the tracking camera so that all tools are inside the viewable volume.
Tracked tools cannot be verified or calibrated.	• Verify that the tracking spheres are properly attached to the tool. • For the BrainPath tracking array, verify that the tracking array is properly attached to the brain sheath. • Ensure that all tracking spheres are visible to the tracking camera when holding the tool and Calibration Device in front of the camera. • Ensure that no other tracked tools are visible to the camera during the verification/calibration process. • Tool or Calibration Device may be deformed (possibly due to being dropped). Try with another tool and Calibration Device.

13.0 Recommended Environmental Conditions

Operate, store, and transport the Auxiliary Cart system components only under the following conditions.

Table 8 Permissible Environmental Conditions

	Operating	Storage/Transport
Ambient temperature	16 °C–30 °C	-10 °C- 50 °C
Relative humidity (non-condensing)	10 %–70 %	10 %-90 %
Atmospheric Pressure	70 kPa–106 kPa	50 kPa–106 kPa

14.0 Disposal

No part of the Auxiliary Cart - 3D Monitor Cart 31" with Camera system may be disposed of in landfill.

Before disposing of any Synaptive product, contact Synaptive customer service or your supplier for further information.

15.0 System Classification and Specifications

Classification: Class I Equipment

Mode of Operation: Continuous Operation

Degree of Protection Against Ingress of Water: IPX0

Mains Supply: 100-240 V, 50/60 Hz, 2.1-1.0 A

15.1 Essential Performance

The monitor shall maintain its selected video orientation.

The camera shall transmit consistent data about the location of tracked tools.

15.2 Cable Specifications

Table 9 Cable Specifications

Cable	Specifications
Power cord*	• 6 m with C13 and NEMA 5-15P hospital grade connector • 6 m with C13 and Medical DK-2-8A connector • 6 m with C13 and CEE7/7 connector • 6 m with C13 and BS1363/A connector • 6 m with C13 and AS/NZS 3112:2000 hospital grade connector • 6 m with C13 and SEV 1011 Type 12 connector
Camera cable	• 9 m shielded cable (14 x 28 AWG) with LEMO connector
Equipotential grounding cable	• 3 m with right-angled, spring-loaded sockets

* The specific power cord supplied with your Auxiliary Cart system is dependent on regional power specifications.

WARNING

Use only the approved power cord supplied with the Auxiliary Cart - 3D Monitor Cart 31" with Camera. The use of non-approved power cords can result in damage to the Auxiliary Cart - 3D Monitor Cart 31" with Camera 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.

15.3 Tracking Camera Laser Specifications and Standards

The positioning laser on the tracking camera is a Class 2 laser with a wavelength of 635 mm and a maximum output of 1 mW. The positioning laser conforms to the following standards:

- ANSI Z136.1 (2007)
- IEC 60825-1 (2007)
- FDA/CDRH 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007

16.0 Certifications

The Auxiliary Cart - 3D Monitor Cart 31" with Camera is certified to the following standards:

- IEC 60601-1-2: 2014
- CAN/CSA C22.2 No. 60601-1: 2014-03
- ANSI/AAMI ES60601-1:2005/A1:2012-08
- CB SCHEME CERTIFICATION

All Auxiliary Cart 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).

17.0 Electromagnetic Environment Information

The Auxiliary Cart 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 Auxiliary Cart system.

Table 10 Electromagnetic Environment (Emissions)

The Auxiliary Cart system is intended for use in the electromagnetic environment specified below. The customer or the user of the Auxiliary Cart system should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The Auxiliary Cart system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Auxiliary Cart 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 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 11 Electromagnetic Environment (Immunity)

The Auxiliary Cart system is intended for use in the electromagnetic environment specified below. The customer or the user of the Auxiliary Cart 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%.

Table 11 Electromagnetic Environment (Immunity) (continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±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 0.5 cycle 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 0.5 cycle 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 Auxiliary Cart 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 12 Electromagnetic Environment (Conducted/Radiated)

The Auxiliary Cart system is intended for use in the electromagnetic environment specified below. The customer or the user of the Auxiliary Cart system should assure that it is used in such an environment.

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 Auxiliary Cart system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$
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 Auxiliary Cart 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 Auxiliary Cart system.

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

Table 13 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the System

The Auxiliary Cart system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Auxiliary Cart users can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Auxiliary Cart system as recommended below, according to the maximum output power of the communications equipment.

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	0.24
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 Auxiliary Cart system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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