The Arthrex Synergy\textsuperscript{HD3} System Camera Controller and Camera Head User’s Guide provides important information for the safe operation of all components of the Synergy\textsuperscript{HD3} Camera System, including accessories. Read this User’s Guide thoroughly prior to using this system and keep it in an easily accessible place for use by all operating personnel. Read and follow all safety warnings, cautions and precautions.
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Product Warranty

Arthrex expressly warrants to customer that all Arthrex Products purchased by customer shall be free from defects in materials and workmanship for 1 year from date of purchase. Arthrex’s liability shall include replacing or repairing those Products shown to be defective either in materials or workmanship. Claim of defect in materials or workmanship in any Product shall be considered when it is submitted to Arthrex in writing within thirty (30) days after discovery. No claim shall be allowed on Products that have been altered, neglected, damaged or stored improperly. Arthrex shall promptly replace or repair any Product which malfunctions, fails to operate, fails to meet specifications, or which is otherwise defective.

Use of Sterilants or Chemicals other than those listed in the “Cleaning and Sterilization” section shall void the product’s warranty.

This warranty shall not apply to any Product which has been misused, adulterated or modified by the customer.

Arthrex’s repair or replacement of defective Product shall be customer’s exclusive remedy under this express warranty.

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1.0 Introduction

It is recommended that personnel study this manual before attempting to operate, clean, and/or sterilize the Arthrex SynergyHD3 System and accessories. The safe and effective use of this equipment requires the understanding of and compliance with all warnings, precautionary notices, and instructions marked on the product, and included in this manual.

1.1 Intended Use

The Arthrex SynergyHD3 System is comprised of:

- AR-3200-0001T Camera Control Unit.
- AR-3210-0001 Camera Head with Integrated Optics
- AR-3210-0003 Camera Head, C-Mount.
- AR-3210-0004 Camera Head, C-Mount 20 foot.
- AR-3210-0007 Camera Head, C-Mount, Zero Degree

This system is designed for use by physicians and surgeons and is intended for endoscopic camera use in a variety of endoscopic surgical procedures, including but not limited to, orthopedic, laparoscopic, urologic, sinuscope and plastic surgical procedures. It is also intended to be used as an accessory for microscopic surgery.

1.2 Contraindications

Do not use the device if endoscopic surgery is contraindicated.

Do not use the device if the environmental conditions for use do not meet the standards or regulations defined in the accompanying documents.

1.3 Warnings and Precautions

The words WARNING, PRECAUTION, and NOTE carry special meanings and they should be read carefully.

WARNING: The safety and/or health of the patient, user, or a third party is at risk. Comply with this warning to avoid injury to the patient, user, or third party.

PRECAUTION: This contains information concerning the intended use of the device or accessory. Damage to the equipment is possible if these instructions are not followed.

NOTE: A note is added to provide additional, focused, information.

1.3.1 WARNINGS

- This equipment is designed for use by medical professionals completely familiar with the required techniques and instructions for use of the equipment. Prior to using the device, read and follow all warning and precautionary notices and instructions marked on the product and included in this manual. Become familiar with the operation and function of this device and associated accessories. Failure to follow these instructions can lead to:
  - Life-threatening injuries to the patient
  - Severe injuries to the surgical team, nursing or service personnel, or
  - Damage or malfunction of the device or accessories.

1. Do not open or attempt to service this system, as this may void your warranty. There are no user-serviceable parts inside. Removing the cover may introduce an electric shock hazard by exposing you to dangerous high voltages or other risks. If the system malfunctions, return it for service immediately.
2. For the protection of the patient it is recommended that a back-up camera system for the Arthrex Synergy\textsuperscript{HD3} video system be maintained, sterilized, and ready to be implemented.

3. For the protection of the patient it is essential that the endoscopic video system interconnection is complete and produces a viable color picture on the surgical monitor PRIOR to administration of patient anesthesia.

4. Disconnect camera head from patient prior to applying cardiac defibrillation to patient.

5. Only the physician can evaluate the clinical factors involved with each patient and determine if the use of this device is indicated. The physician must determine the specific technique and procedure that will accomplish the desired clinical effect.

6. This device and its accessories are to be used only by physicians and medical assistants under the direction of a physician with appropriate technical qualifications.

7. This device shall only be used with original and manufacturer's accessories and replacement parts. Use of other parts or materials may degrade safety.

8. Do not use in the presence of flammable anesthetics, gases, disinfecting agents, cleaning solutions, or any material susceptible to ignition due to electrical sparking.

9. Equipment grounding is vital for safe operation. Plug the power cord into a properly earthed mains supply outlet whose voltage and frequency characteristics are compatible with those listed on the unit or in this manual. Do not use plug adapters or extension cords; such devices defeat the safety ground and could cause injury.

10. This equipment should not share an electrical outlet or grounding with life supporting or life sustaining equipment.

11. If one or more mains powered units are connected simultaneously to one socket by the means of a distribution box, the sum of the individual leakage currents may exceed the tolerated limits.

12. The scope light guide tip can get extremely hot as result of high intensity light, giving rise to high temperatures in front of the light emission window which may cause severe burns. Always keep the light source in the STANDBY mode when not in use.

13. Before each use, the outer surface of the portions of the Endoscope and any Endoscopically Used Accessory, which are intended to be inserted into the patient, should be checked to ensure there are no unintended rough edges, sharp edges or protrusions which may cause a safety hazard.

14. Safety hazards to patients may result from gas embolism caused by, for example, over-insufflation of air or inert gas prior to high frequency surgery or laser assist gas.

15. The leakage current through the patient could increase using endoscopes with powered accessories.

16. When Endoscopes are used with Energized Endoscopically Used Accessories, the Patient Leakage Currents may be additive. This is particularly true if a CF Applied Part is used, in which case a Type CF Endoscopically Used Accessory should be used to minimize total Patient Leakage Current.

17. Explosive gas concentrations inside the patient can cause hazards while using High-Frequency Endoscopically Used Accessories.

18. For the protection of service personnel, and for safety during transportation, all devices and accessories that are returned for repair must be prepared for shipment as described in "Returning the Device" of this manual. The manufacturer has the right to refuse to carry out repairs if the product is contaminated.

19. This equipment/system is intended for use by healthcare professionals only. This equipment/system 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 Synergy\textsuperscript{HD3} Video System or shielding the location.


21. Applied Parts of other ME Equipment used within the configuration for Endoscopic
Application shall be type BF or CF Applied Parts.

22. NO Modifications of this equipment is allowed.

23. Connecting any equipment that has not been supplied as part of this ME System to Multiple Socket Outlets may result in increased leakage currents. Use an IEC Approved Isolation Transformer to isolate any such interconnections from the ME System.

24. Before each use or after changing viewing modes/settings the Operator should check to ensure that the view observed through the Endoscope provides a live image (rather than a stored one) and has the correct image orientation.

25. Risk of burns!

Light sources emit large amounts of light energy and thermal energy. As a result:

- Surface temperatures of the insertion portion of the endoscope as well as light guide connectors on the CCU and the endoscope rise during use. This can cause the temperature of the body tissue to rise in excess of 106 °F (41°C).
- Potential Thermal injury to the patient’s tissue (e.g. from prolonged exposure to the intense illumination in small cavities, or if the endoscope’s distal end is placed in close proximity with the tissue) may result, as well as burns to the patient’s or user’s skin. Burns or thermal damage to surgical equipment may also result.
- Avoid prolonged exposure to intense illumination.
- Use the minimum level of illumination necessary to satisfactorily illuminate the target area.
- Do not place the endoscope’s distal end or light guide connector on the patient’s skin, on flammable materials or on heat sensitive materials.
- Turn the light source off when detaching the endoscope from the light guide cable.
- Allow the endoscope and light guide cable to cool down after use.

26. High Frequency [HF] electrical surgical instruments may lead to severe patient injuries and/or damage to the endoscope. Please take caution to insure that the working element is kept within field of view to prevent accidental burns. A sufficient distance from the tip of the endoscope to other conductive accessories and instruments should be maintained (10 mm) before activating the HF output to prevent burns and damage to the endoscope. Refer to the HF Surgical Device Instructions for proper and safe use.

27. HF surgical Instruments may interfere with video images. To prevent such interference, HF equipment and video imaging equipment should be connected to different power supply circuits.

28. Use of Lasers in surgery may result in Eye Damage or damage to the endoscope from reflected laser energy. Refer to the Laser Device Instructions for proper and safe use.

- When using a laser always wear protective glasses designed for the laser’s wavelength.
- Cover the patient’s eyes, or use protective glasses designed for the laser’s wavelength.
- To prevent damage to the Endoscope, the Laser should be activated only after the tip of the laser can be seen thought the endoscope.

1.3.2 PRECAUTIONS

1. United States Federal law restricts sale of this device to or on the order of a physician.

2. Do not use the camera with incompatible equipment or accessories that are not authorized by Arthrex. Doing so may void certifications and/or warranties.

3. The warranty becomes void and the manufacturer is not liable for direct or resulting damage if:

- The device or the accessories are improperly used, prepared or maintained;
- The instructions in the manual are not adhered to;
Non-authorized persons perform repairs, adjustments or alterations to the device.

Non-authorized persons open the device.

**NOTE:** Receipt of technical documentation from the manufacturer does not authorize individuals to perform repairs, adjustments, or alterations to the device or accessories.

Only authorized service personnel may perform repairs, adjustments or alterations on the device and accessories. Any violation will void the manufacturer’s warranty. Authorized service technicians are trained and certified only by the manufacturer. The Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions and other information required for service to any Arthrex Authorized Service Center.

4. This device should only be used in compliance with its intended use.

5. Prior to each use, the CCU and all associated equipment must be inspected for proper operation. Visually inspect lenses to assure there are no scratches, chips or cracks.

6. To carry out safe operation, it is absolutely necessary to carry out proper care and maintenance of the device and accessories. See “Maintenance” section of this manual.

7. Ensure that the available mains voltage matches the mains voltage data on the rear of the device which is located near the appliance inlet module.

8. This device may only be connected to endoscopes which, in their intended use and technical specifications, are appropriate for use with the device for the intended medical procedure. The endoscopes must comply with the latest version of DIN EN 60601-2-18 and ISO 8600.

9. This equipment has been tested and found to comply with Class A limits of IEC 60601-1-2:. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. However, if interference does occur with other equipment, it may be corrected by one or more of the following measures:

- Reorient or relocate this equipment, the other equipment, or both;
- Increase the distance between the different pieces of equipment;
- Consult a biomedical engineer.

10. Do not expose the Camera Control Unit [CCU] to moisture, or operate it in a wet area, or store liquids above the CCU.

11. Do not excessively bend or kink instrument power cord or camera head cable.

12. Handle all equipment carefully. If the CCU or camera head is dropped or damaged in any way, return it immediately for service.

13. If the camera head or camera head cable are damaged in any way, or cable or connector jacket are cut, do not autoclave camera head, or immerse camera head in liquid (water, chemical disinfectants or sterilants, etc.). Notify your Arthrex Sales Representative. If it is necessary to return the camera head to Arthrex for service, disinfect the camera head before shipping and reference “Returning the Device”.

14. Store camera head and all accessories in a protective container to prevent damage during storage. Do not store CCU where it will be exposed to temperatures in excess of 140°F (+ 60°C).

15. Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1 ). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative, or the technical department.
16. Any person who connects external equipment to signal input and signal output ports or other connectors has formed a system and is therefore responsible for the system to comply with the requirements of IEC 60601-1. If in doubt, contact a qualified Biomedical technician or your local representative.

17. This equipment has been tested and found to comply with the Class A limits for medical devices to the IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other device(s) in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

(a) Reorient or relocate the receiving device.
(b) Increase the separation between the equipment.
(c) Connect the equipment into an outlet on a circuit different from that to which the other devices are connected.
(d) Consult the manufacturer or field service technician for help.

This unit was not evaluated for use with electrosurgical devices which access the site via the same endoscope as the light source and camera. The unit must be re-evaluated prior to use with electrosurgical devices when they will operate through the same endoscope as the light source and camera.

18. After each use, thoroughly clean unit and accessories (See “Cleaning and Sterilizing”).

NOTES:

1. Observe all national waste management regulations.
2. Do not dispose of WEEE as unsorted municipal waste.
### 1.4 Symbol Definitions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Safety Sign" /></td>
<td>Follow Operating Instructions</td>
</tr>
<tr>
<td><img src="image" alt="Power Standby/On" /></td>
<td>Power Standby/On</td>
</tr>
<tr>
<td><img src="image" alt="Attention" /></td>
<td>Attention, Consult Accompanying Documents</td>
</tr>
<tr>
<td><img src="image" alt="Warning" /></td>
<td>Precaution of Warning Notice</td>
</tr>
<tr>
<td><img src="image" alt="Type BF Equipment" /></td>
<td>Type BF Equipment</td>
</tr>
<tr>
<td><img src="image" alt="Electrical Hazard" /></td>
<td>Electrical Hazard, Dangerous Voltages are Present. Never attempt to repair the equipment. Only Trained Service Personnel may remove the cover, or obtain access to system components.</td>
</tr>
<tr>
<td><img src="image" alt="Alternating Current" /></td>
<td>Alternating Current</td>
</tr>
<tr>
<td><img src="image" alt="Protective Earth" /></td>
<td>Protective Earth [Ground]</td>
</tr>
<tr>
<td><img src="image" alt="RX ONLY" /></td>
<td>Caution: Federal Law Restricts this device to sale by or on the order of a Physician.</td>
</tr>
<tr>
<td><img src="image" alt="Flammable Anesthetics" /></td>
<td>Not for use in the Presence of Flammable Anesthetics.</td>
</tr>
<tr>
<td><img src="image" alt="Fragile" /></td>
<td>Fragile</td>
</tr>
<tr>
<td><img src="image" alt="This Side Up" /></td>
<td>This Side Up</td>
</tr>
<tr>
<td><img src="image" alt="Keep Dry" /></td>
<td>Keep Dry</td>
</tr>
<tr>
<td><img src="image" alt="Temperature Limits" /></td>
<td>Temperature Limits for Storage and Transport</td>
</tr>
<tr>
<td><img src="image" alt="Pressure Limits" /></td>
<td>Pressure Limits for Storage and Transport</td>
</tr>
<tr>
<td><img src="image" alt="Humidity Limits" /></td>
<td>Humidity Limits for Storage and Transport</td>
</tr>
<tr>
<td>Icon</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>-------------</td>
</tr>
<tr>
<td><img src="image1" alt="Equipotential Symbol" /></td>
<td>Equipotential [Equipment Potential]</td>
</tr>
<tr>
<td><img src="image3" alt="White Balance Symbol" /></td>
<td>White Balance Symbol</td>
</tr>
<tr>
<td><img src="image4" alt="Catalog Number" /></td>
<td>Catalog Number</td>
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<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image6" alt="Do Not Use If Package is Damaged" /></td>
<td>Do Not Use if Package is Damaged</td>
</tr>
<tr>
<td><img src="image7" alt="Universal Serial Bus" /></td>
<td>Universal Serial Bus</td>
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<tr>
<td><img src="image8" alt="RF Symbol" /></td>
<td>RF Symbol. Non-ionizing Electromagnetic Radiation</td>
</tr>
<tr>
<td><img src="image9" alt="Color Video Camera" /></td>
<td>Color Video Camera</td>
</tr>
<tr>
<td><img src="image10" alt="Serial Number" /></td>
<td>Serial Number</td>
</tr>
<tr>
<td><img src="image11" alt="Authorized Representative in the European Community" /></td>
<td>Authorized Representative in the European Community</td>
</tr>
</tbody>
</table>
1.5 End of Life, Environmental Directives

WEEE Directive [2012/19/EU] on Waste Electrical and Electronic Equipment

The Directive on Waste Electrical and Electronic Equipment obliges manufacturers, importers, and/or distributors of electronic equipment to provide for recycling of the electronic equipment at the end of its useful life. Do not dispose of WEEE in unsorted municipal waste. The WEEE symbol on the product or its packaging indicates that this product must not be disposed of with other waste. Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of Waste Electrical and Electronic Equipment. The separate collection and recycling of your waste equipment at the time of disposal will help conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your medical endoscopic video equipment at the end of its useful life for recycling, please contact Arthrex Customer Service Department.

The Camera Controller contains a Lithium Coin BATTERY. The BATTERY must be recycled or disposed of properly.

NOTE for State of California, USA:

State of California Requirement: Lithium Batteries contain Perchlorate Material -special handling may apply. See www.dtsc.ca.gov/HazardousWaste/Perchlorate

In the US a list of recyclers in your area can be found at www.eiae.org/

1.6 Initial Use of the Device

WARNINGs:

1. The device is only completely isolated from the mains if the power plug is disconnected from the device’s power inlet module.

2. The electrical installation of the operating room where the device is used must comply with applicable national requirements.

3. Loss of the Mains Voltage may result in an unacceptable risk due to loss of Essential Performance. An Uninterruptable Power Supply [UPS] is recommended to mitigate this risk.

4. The device is not intended for use in areas of explosion hazards. If explosive nitrous gases are used the Camera Control Unit may not be operated in the danger zone.

4. Do not simultaneously touch the Camera Control Unit and the patient. Camera Control Unit is intended to be used outside the Patient Vicinity.

6. Additional peripheral equipment connected as part of the Endoscopic Video System must meet the requirements of the following specifications:
   - EN 60950 for Information Technology Equipment.
   - EN 60601-2-18 for endoscopic devices.
   - EN 60601-1 for electro medical devices.

7. All final Endoscopic Video Systems must meet the requirements of EN 60601-1-1.

8. Whoever connects additional equipment to signal input or signal output is obligated to meet the requirements of the EN 60601-1-1 standard.
1.7 Unpacking and Inspecting the Device

Upon receipt, carefully unpack the Synergy<sup>HD3</sup> Controller Unit (CCU) and accessories. Ensure contents are complete and are free from damage. If any damage is noted contact your Arthrex Customer Service. Contact the Manufacturer for Return Authorization PRIOR to shipping your device for service. Save ALL packaging materials; they may be needed to verify any claims of damage by the shipper.
1.8 Returning the Device

If it becomes necessary to return the device, always use the original packaging. The manufacturer does not take responsibility for damage that has occurred during transportation if the damage was caused by inadequate transport packaging. Please make sure that all required information has been supplied. Call Arthrex for a RMA Number for the device return for service.

- Owner’s Name
- Owner’s Address
- Owner’s Daytime Telephone Number
- Device type and model.
- Serial Number
- Detailed explanation of the damage.

NOTE:

1. The CCU shall be cleaned per section Cleaning and Sterilization prior to returning for service.
2. The Camera Head shall be cleaned and Sterilized per Cleaning and Sterilization prior to returning for service. Camera Head shall be clearly labeled as “Sterile.”

Arthrex shall not implement repairs on equipment which is not returned cleaned and sterile.
1.9 System Indicators

1.9.1 Synergy\textsuperscript{HD3} Front Panel

1. **On/Standby Switch** — The On/Standby switch toggles the (CCU) between ON [operational mode], and STANDBY. The Green LED will illuminate when the CCU is in the ON mode. Press and HOLD the switch to toggle between ON and STANDBY.

2. **Light Guide Turret** - Turret for Light Guide input


4. **“WHITE BALANCE” Button** — Press to initiate camera white balance.

5. **“CAMERA” Input Connection** — Insert the camera head connector here. The camera head connector and receptacle are specially keyed to prevent the camera head from being improperly connected. Ensure that the “UP” label on the camera head connector is facing upwards when the camera head connector is inserted.

**PRECAUTION:** Ensure camera head contacts are clean and dry and cool 15 minutes prior to insertion.

6. **Light Source On/Standby Switch** — The Light Source On/Standby Switch toggles the Light Source between ON [Operational Mode], and STANDBY.

**PRECAUTION:**

1. Use Only FUSED Light Guides to ensure proper operation of LED Engine.

2. LED Engine Cleaning Requirements.
   - Allow LED Engine to cool for ½ hour before cleaning.
   - Dampen one end of a cotton swab with isopropyl alcohol.
   - Clean any residue from optic using circular motion.
   - Use the DRY END of the cotton swab to dry the face of the optics.
   - Inspect the optics for residue or cotton fibers and clean as required.
   - Allow to AIR DRY for 5 minutes prior to use.
1.9.2 Rear Panel

1. "DVI" Video Output Connectors — Supplies a digital video signal output in DVI-D format.

2. Accessory Ports (Inputs/Outputs - 2X mini Stereo-Phone Connectors) — Accessory ports allow for control of the Camera Control Unit (CCU) with a footswitch, or for the CCU to control external devices through the camera head buttons.

3. Reset Button — Resets CCU to factory Defaults.

4. Audio Out - Line Level audio output to Medical Grade devices.

5. Audio IN - Line Level audio input for Microphone.

6. Ethernet Connector - Isolated-10/100 MB/Sec.

7. USB Connector - Connect USB devices here.

8. RS-232 Connector - Isolated-connection to devices requiring Serial Control.


NOTE: The purpose of the Potential Equalization Connector is to equalize the potentials between different metal parts of the various Medical Electrical [ME] equipment which make up a Medical Electrical system, or to reduce differences of potential which can occur during operation between the bodies of the Medical Electrical devices and conductive parts of other objects. The Potential Equalization Connector may be connected directly between any ME Devices, or to a common busbar of the electrical installation. Reference IEC 60601-1 for ME Systems.

10. IEC 320 Power Inlet Module (100-240V~, 50/60 Hz) — The CCU is equipped with a switching power supply that automatically adjusts to the line voltage being used. Accepts the supplied hospital grade power cord.

11. HDSDI- 3G Serial Video Output

12. DVI Input – 1080P/60 input from other medical devices

13. AUX- Ethernet connection

14. USB – USB Connection

15. USB TABLET CONNECTION – Connect Tablet Data Input device here. Provides for data interchange and tablet charging.
1. **Button 1** — A programmable button that can activate various functions of the camera. See “Optional Tablet Data Input Device” for programming information.

2. **Button 2** — A programmable button that can activate various functions of the camera. See “Optional Tablet Data Input Device” for programming information.

3. **Focus Ring** — Used to sharpen, or bring into focus, the image detail.

4. **Grasping Mechanism** — Accepts and locks into place the compatible scope. DIN 58105 compliant endoscope interface.
1. **Button 1** — A programmable button that can activate various functions of the camera. See “Optional Tablet Data Input Device” for programming information.

2. **Button 2** — A programmable button that can activate various functions of the camera. See “Optional Tablet Data Input Device” for programming information.

3. **C-Mount Threads** — Accepts standard C-Mount Optical Couplers.
2.0 System Installation and Operation with Data Input Device

2.1 Installation

NOTE:

1. Your SynergyHD3 Camera Control Unit will indicate which software configuration is enabled at boot up, on the Video Monitor’s Splash screen.

2.1.1 Typical System Installation

NOTE: See “Typical System Interconnect Diagram, Figure 6

1. Place SynergyHD3 console (CCU) on tower shelf.
2. Attach monitor to the tower and connect monitor DC power cable to the rear panel of the monitor as shown.
3. Attach SynergyHD3 Tablet docking station to secondary tower arm. Connect the cable from the docking cable to the connector labeled “tablet” on the back of the SynergyHD3 console.
4. Connect a DVI cable to the DVI output on the rear panel of the SynergyHD3 console. Connect the other end of the DVI cable to the DVI input of the display monitor. (An HD-SDI cable may be used instead of DVI).
5. If using a printer, connect printer cable to USB connector on the rear panel of the SynergyHD3 console. Connect other end of printer cable to the printer.
6. Plug the AC power cord into the SynergyHD3 power inlet module and a standard grounded AC Mains outlet (100-240 V~ 50-60Hz).
7. Insert the card edge connector the SynergyHD3 camera head into the camera receptacle on the front of the console.

NOTE: Ensure the camera head connector contacts are clean and dry prior to insertion.

9. Insert the endoscope into the SynergyHD3 camera head grasping mechanism.
10. Press the Light Source On/Standby Switch to activate LED light engine.

NOTE: If there is no Light Guide cable connected to the SynergyHD3 console, pressing the On/Standby Switch will not activate the LED light engine until one is connected.
2.2 Accessories for Intended Use

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AR-3200-1008</td>
<td>SynergyHD3 Digital Documentation Tablet, 12”</td>
</tr>
<tr>
<td>AR-3200-1014</td>
<td>SynergyHD3 Digital Documentation Tablet</td>
</tr>
<tr>
<td>SONY UP-PR80MD</td>
<td>Medical Grade Printers</td>
</tr>
<tr>
<td>SONY UP-PR80MD with upDR80MD/NKIT</td>
<td>Medical Grade Printers</td>
</tr>
<tr>
<td>AR-3250-2601</td>
<td>Medical Grade Surgical Monitor 26”</td>
</tr>
<tr>
<td>AR-3250-2602</td>
<td>Medical Grade Surgical Monitor 25”</td>
</tr>
<tr>
<td>AR-3250-2603</td>
<td>Medical Grade Surgical Monitor 26”</td>
</tr>
<tr>
<td>AR-3250-3201</td>
<td>Medical Grade Surgical Monitor 32”</td>
</tr>
<tr>
<td>AR-3250-3203</td>
<td>Medical Grade Surgical Monitor 32”</td>
</tr>
<tr>
<td>AR-3250-3204</td>
<td>Medical Grade Surgical Monitor 32”</td>
</tr>
</tbody>
</table>
### Arthrex Synergy<sup>HD3</sup> System Accessories

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AR-3240-3527</td>
<td>Light Guide 3.5mm x 274cm</td>
</tr>
<tr>
<td>AR-3240-5027</td>
<td>Light Guide 5.0mm x 274cm</td>
</tr>
<tr>
<td>AR-3240-5040</td>
<td>Light Guide 5.0mm x 400cm</td>
</tr>
<tr>
<td>AR-3200-1050</td>
<td>Bluetooth Wireless Microphone</td>
</tr>
<tr>
<td>AR-3210-0005</td>
<td>C-Mount Optical Zoom Coupler</td>
</tr>
<tr>
<td>AR-3210-1005</td>
<td>Video Input/Output Converter</td>
</tr>
</tbody>
</table>

#### 2.3 System Setup Facility and Surgeon Settings

**NOTE:** Facility, surgeon, and procedural settings are made from the SynergyHD3’s tablet Data Input Device.

2.3.1 System Set-Up can be accessed by pressing the Maintenance Icon on the Synergy<sup>HD3</sup> Tablet Data Input Device and then selecting “Advanced Settings”
2.3.2 Selecting “System” button enables several facility preferences to be setup:

- “Remote Entry” enables users that have networked the Synergy$^{HD3}$ system to add patients from a networked computer.
- “Password Access” can be set to on or off. On will require a password in order to enter and add patients remotely.
- Users can also select “language, time format, Date format, the number of cases saved.

Figure 8-System Maintenance Screen
2.3.3 Selecting "Print Fields" allows facilities preferences to be setup for the fields that will be included on a print. Available Fields are:

- Facility Name
- Surgeon Name
- Patient Name
- Patient I.D.#
- Procedure Type
- Date
- Notes

Note: It should be noted that “Print Fields” are also selectable as surgeon preferences, although any conflict between facility preference and surgeon preference would be reconciled to facility preference.
Selecting "Network" allows for connecting the SynergyHD3 system to a facility network. Fields are:

- Ethernet IP Mode
- Host Name
- Ethernet IP Address
- Ethernet Subnet Mask
- Ethernet Default Gateway
2.3.5 Surgeons can be added to the Synergy\textsuperscript{HD3} with their own system preferences.

2.3.6 To add surgeons and their preferences, press the \textit{maintenance icon} on the Synergy\textsuperscript{HD3} Tablet Data Input Device and then select \textbf{Surgeon Management}. A list of surgeons will appear.

2.3.7 To add a surgeon, press the “\textit{+ Add New Surgeon}” button, enter the first and last name of a surgeon, then press the “\textit{Preferences}” button.
Add New Surgeon

Name

First Name

Last Name

Preferences

Procedures

Figure 12-Surgeon Management Preferences
2.3.8 Surgeon preferences can be defined for the following:

- Camera Settings (including camera head button setup)
- Printer Settings
- Print Fields
- Multimedia
- Web Server Access
- Display
2.3.9 Procedure preferences can be added to individual surgeon preferences. On the surgeon management list, select a surgeon, and a list of procedures will appear.

2.3.10 Select the appropriate Procedure for the Surgeon. If the procedure is not currently in the list, select the “Create New Procedure” from the Procedures drop down list, and enter the name of the new procedure.
2.3.11 After entering Procedure Name, select "Camera Settings". Surgeon preferences may be entered for:

- Brightness
- Zoom
- Scene
- Gain
- Auto Exposure Window
- Enhancement

**NOTE:** If a surgeon performs multiple types of procedures and it is necessary to add additional procedures, press the “Add Procedure” icon.
2.4 Scheduling and Starting Cases

![Figure 16-Scheduling a case](image)

2.4.1 To schedule a case, press the “+ Add New Case” icon
2.4.2 Select the “**Surgeon**” and/or “**Procedure**,” and enter data in the following required fields.

- Patient First Name
- Patient Last Name
- Patient I.D. #

2.4.3 Press the “**Save**” icon
To start a case, select the case/patient from the Case List and press the "Start" icon.

NOTE: Cases may also be started from the "Add Case" screen by entering the required fields and pressing the "Start" icon.
2.4.5 Changes to SETTINGS may be made during the procedure by pressing the "Maintenance Icon". Changes may be made to the following:

- Camera Head Button Functions
- Camera Settings
- Print Settings
Figure 20 - Camera Change; During Case

Figure 21 - Print Changes; During Case
2.4.6 Ending a Case; to end a case, press the "End Case" Icon.

**NOTE**: An “End Case” confirmation message will appear. If confirmed, the case will end and the Synergy™ HD3 Tablet Data Input Device will transition to the case review screen.
2.5 System Operation without Tablet Data Input Device

1. Connect the Synergy\textsuperscript{HD3} System per “Typical System Installation”, Figure 6.

2. The camera will take approximately 30-40 seconds to fully load its boot software. When the software has fully loaded you will see the Synergy\textsuperscript{HD3} Initial Screen shown below in Figure 23.

3. The Synergy\textsuperscript{HD3} Initial Screen will indicate the Factory Default settings for the Camera Head Button programming.

4. Both buttons SHORT presses will capture Still Images.

5. Long Press on the LEFT BUTTON will control Brightness.
   - After a LONG press on the LEFT BUTTON, pressing the Right Button will INCREASE Brightness.
   - After a LONG press on the LEFT BUTTON, pressing the Left Button will DECREASE Brightness.

   - After a LONG PRESS on the RIGHT BUTTON, pressing the RIGHT Button will INCREASE ZOOM.

7. The Synergy\textsuperscript{HD3} Initial Screen will also indicate that the Printer is Active and that it is set to 8 prints per page.

8. The center screen of the Synergy\textsuperscript{HD3} Initial Screen shows that Both Buttons are now set to White Balance, and that a White Balance Operation is required to initialize the Synergy\textsuperscript{HD3} use.

9. Turn on the LED Light Source.

10. Using a stack of 4 x 4 white gauze, hold the tip of the Endoscope approximately 1 inch away from the gauze until the gauze image fills the screen completely.

11. Press either of the Camera Head buttons to start the White Balance Operation.
12. The Surgical monitor will display one of the following.

- When the White Balance has been completed successfully, a Green Check Mark with WHITE BALANCE below will be shown on screen.

![Figure 24-White Balance OK](image)

- When the White Balance has not been completed successfully, a Red X with WHITE BALANCE below will be shown on screen.

![Figure 25-White Balance Fail](image)

13. If the White Balance Operation has been successful, the camera will enter the Surgical Ready Mode and be ready for surgical operation.

14. If the White Balance Operation has not been successful, you must move the Tip of the Endoscope closer or farther from the White Gauze until the operation can be completed successfully.

15. Once the White Balance Operation has been successfully completed, the Camera Head buttons will function as defined on the Synergy®HD3 Initial Screen Figure 23.
2.6 Picture in Picture Operation

Figure 26 - Picture in Picture System Set Up

Figure 27 - Tablet PIP Control
2.6.1 The Synergy HD3 Camera Control Unit [AR-3200-0001T] can be used in the Picture in Picture Mode to display a Picture in Picture [PIP] on the surgical monitor.

2.6.2 Second video source for PIP is connected to the Camera Controller's DVI Input.

2.6.3 The Synergy HD3 Camera Control Unit [AR-3200-0001T] will accept ONLY DVI 1080P/60 video.

2.6.3.1 This can be accomplished by connecting a DVI 1080P/60 VIDEO SOURCE directly to the Camera Control Unit's DVI Input, or by using the optional AR-3210-1005 Video Input/Output Converter.

2.6.3.2 The AR-3210-1005 Video Input/Output Converter is connected to the Camera Control Unit DVI Input, and the NON 1080P/60 video source is connected to the AR-3210-1005, which will convert the source to the needed 1080P/60 video format for PIP.

2.6.4 The Tablet Data Input Device is utilized to configure PIP.

2.6.4.1 PIP Enable/Disable

2.6.4.2 PIP Location

2.6.4.3 Still Capture from External Source

2.6.4.4 Streaming Video Capture from External Source
3.0 Maintenance

Regular and proper maintenance of your Synergy\textsuperscript{HD3} and/or AR-3210 Camera Heads are the best ways to protect your investment and avoid non-warranty repairs.

Recommended care and handling of the Synergy\textsuperscript{HD3} Camera Control Unit (CCU) and camera head includes proper day-to-day operation, cleaning, and sterilization which are extremely important to ensure safe and efficient operation. It is important to visually inspect the camera head, cable and card edge before each use.

Your authorized Arthrex service department is the most knowledgeable about the Arthrex Medical Camera Systems and/or camera heads and will provide competent and efficient service. Any services and/or repairs done by any unauthorized repair facility may result in reduced performance of the instruments or instrument failure.

3.1 Life Expectancy

The standard warranty for this product is twelve months. Life expectancy for the product is expected to meet and exceed this period for approximately 5 years under normal use and standard of care.

3.2 Periodic Maintenance

The product should be inspected prior to and after each use to ensure that the camera head, cable, strain relief, overmold, or connector contacts are not damaged or worn. If it becomes necessary to return the camera head to Arthrex for service, please sterilize the camera head before shipping.

3.3 Cleaning and Sterilizing

Follow universal precautions for protective apparel when handling and cleaning contaminated instruments.

3.3.1 Cleaning the Camera Control Unit (CCU)

1. Turn the CCU power off. Disconnect the power cord from the electrical power source and from the rear of the CCU.
2. Remove the camera head from the CCU.
3. Wipe the CCU with a clean, soft cloth dampened with a mild, pH-balanced detergent.
4. Wipe the CCU again with Tap or sterilized water.
5. Dry the CCU with a clean, soft cloth.

CAUTION: Do not sterilize the CCU or immerse it in liquids or disinfectant solution.
3.3.2 Cleaning the Camera Head

CAUTIONS:
- If the camera head is dented or damaged, or if the connector jacket is cut, DO NOT autoclave or immerse in liquid (water, chemical disinfectants or sterilants, etc.). Notify your Arthrex Sales Representative.
- Do not place the camera head or accessories in an ultrasonic cleaner or washer/sterilizer.

Preparation for Cleaning and Sterilization
Immediately after use, place the camera head assembly in a container and soak with neutral pH (PH 6.0 – 8.0) enzymatic cleaning solution (e.g. Enzol, Metrizyme or equivalent diluted to proper concentrations per manufacturer’s instructions), in order to prevent blood, protein and other contaminants from drying onto the camera head.

3.3.2.1 Automated Cleaning

- Use only washers according to the International Standard ISO 15883.
- Refer to the washer’s instruction manual.

1. Transfer the camera head into the washer for processing.
2. Make sure that the camera head has been securely fixed to the unit’s trays or baskets. Make sure that the camera head does not touch other instruments.
3. Do not overload the washer.
4. Remove the camera heads immediately after the automatic procedure has stopped.
5. Set up washer for the wash cycle listed below.

<table>
<thead>
<tr>
<th>Automatic Washer Cycle Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase</td>
</tr>
<tr>
<td>Pre-Wash 1</td>
</tr>
<tr>
<td>Enzyme Wash</td>
</tr>
<tr>
<td>Rinse 1</td>
</tr>
<tr>
<td>Drying</td>
</tr>
</tbody>
</table>

3.3.2.2 Manual Cleaning

CAUTION: Wear protective gloves, clothing and face mask for cleaning of contaminated equipment.

1. Immediately after use, Rinse the camera head under cool running tap water to remove the gross soil. Use a soft bristled brush to aid in the removal of soil paying particular attention to hard-to-clean areas.
2. Prepare a neutral enzymatic detergent, such as Enzol®, using tap water at 1 oz/gallon.
3. Fully immerse the camera head in the prepared solution and allow it to soak for a minimum of 10 minutes. Flush hard to reach areas to ensure all soil is removed. While soaking activate movable parts.
4. After soaking, use a soft bristled nylon brush to remove all visible evidence of debris and soil. Pay close attention to the card edge connector.
5. Rinse the camera head by immersing it in a basin of warm tap water. Allow the camera head to sit in the water for a minimum of 1 minute, while soaking activate movable parts.
a. Repeat step 5 two additional times using fresh warm tap water each time.

b. Rinse under running tap water to ensure water reaches hard to reach areas. Activate while rinsing until all visible evidence of detergent is removed.

6. Visually inspect the camera head for visible soil and remove if required.

7. Dry the equipment with a lint-free soft cloth. Wipe the card edge connector with 70% isopropyl alcohol to remove any residual detergent.
   a. Do not allow exposed glass windows to air dry. 70% isopropyl alcohol may be applied to glass surfaces with a soft cotton applicator to prevent streaks and spots. Dry the surfaces thoroughly with a cotton applicator after applying the alcohol.

8. After cleaning, inspect the camera head assembly and camera head cable for cleanliness and damage.

9. **CAUTION:** Inspect the camera head cable for breaks and cuts. Camera heads with damaged cables should not be sterilized or disinfected. Return camera heads with damaged cables to Arthrex for repair.

10. Before sterilization and/or disinfection, coil the camera head cable into loops at least six inches in diameter. Do not kink or twist the cable.

### 3.3.3 Sterilization of the AR-3210 Camera Heads

<table>
<thead>
<tr>
<th>Sterilization Protocol</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Steris Systems</strong></td>
<td>AR-3210-XXXX Camera Heads are validated for Sterilization Assurance using the Steris systems listed below, and following the manufacturer’s instructions.</td>
</tr>
<tr>
<td></td>
<td>‣ V-PRO 1 Plus [Non-Lumen Cycle]</td>
</tr>
<tr>
<td></td>
<td>‣ V-PRO maX [Non-Lumen Cycle]</td>
</tr>
<tr>
<td></td>
<td>‣ V-PRO 1</td>
</tr>
<tr>
<td><strong>Sterrad System 100S</strong></td>
<td>AR-3210 Camera Heads are validated for Sterilization Assurance using the Sterrad System 100S, System NX and System 100NX. Follow the Sterrad Instructions for use.</td>
</tr>
<tr>
<td><strong>Sterrad System NX</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Sterrad System 100NX</strong></td>
<td></td>
</tr>
</tbody>
</table>

#### STEAM STERILIZATION PARAMETERS

<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle</th>
<th>Minimum Exposure Temperature</th>
<th>Exposure Time</th>
<th>Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam (Wrapped)</td>
<td>Pre-vacuum</td>
<td>132° C (270° F)</td>
<td>4 Minutes</td>
<td>30 Minutes</td>
</tr>
<tr>
<td>Steam (Wrapped)</td>
<td>Gravity</td>
<td>132° C (270° F)</td>
<td>15 Minutes</td>
<td>30 Minutes</td>
</tr>
<tr>
<td>Steam (Un-Wrapped)</td>
<td>Gravity</td>
<td>132° C (270° F)</td>
<td>10 Minutes</td>
<td>NA</td>
</tr>
</tbody>
</table>
3.3.4 Material Compatibilities

In addition to the Sterilization chemicals listed above, the AR-3210 camera heads are Material Compatible with Cidex OPA. No SAL claims are made with Cidex OPA.

⚠️ WARNING: Use of Sterilants or Chemicals other than those listed in the Cleaning and Sterilization section may result in the compromise of the device's safety and effectiveness. Use of Sterilants or Chemicals other than those listed in the “Cleaning and Sterilization” section shall void the product's warranty.

3.4 Troubleshooting

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Possible Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
</table>
| Camera does not power up. Standby LED does not illuminate. | • Power cord is unplugged.  
• Suspect power cord. | • Plug power cord into CCU and/or a properly grounded receptacle.  
• Replace power cord. |
| Intermittent picture.                        | • Verify camera head connector card edge is fully inserted into the CCU camera receptacle.  
• Suspect video and/or power cables.  
• Suspect camera head or cable. | • Reinsert camera head connector card edge.  
• Flex video and power cables. If picture is affected, inspect cables and replace as necessary.  
• Flex camera cable. If picture is affected, return to factory for repair or replacement. |
| Camera will not white balance.              | • Too much light.  
• Too little light.  
• Wrong Color Temperature light. | • If monitor indicates “White Balance Fail”, move the scope further away from the white gauze when you white balance, or turn down the light source brightness.  
IF this does not resolve the problem,  
• If monitor indicates “White Balance Fail”, move the scope closer to the white gauze when you white balance, or turn up the light source brightness. |
| Camera Head Buttons do not function as programmed. | • Incorrect camera head button programming. | • Reprogram camera head buttons.  
NOTE: Tablet Data Input device option only. |
<table>
<thead>
<tr>
<th>Symptom</th>
<th>Possible Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>No video image on monitor.</td>
<td>• CCU and/or monitor are not ON and/or plugged in.</td>
<td>• Plug CCU and/or monitor in and/or turn power ON.</td>
</tr>
<tr>
<td></td>
<td>• Equipment is not connected properly or cable(s) damaged.</td>
<td>• Confirm cable connections and reroute video cables, if necessary per interconnect diagram. Check video cables for damage, replace as necessary.</td>
</tr>
<tr>
<td></td>
<td>• Suspect camera head and/or cable.</td>
<td>• Replace the camera head with a working unit and verify image on monitor. If image is now viewed, the original camera head and/or cable were faulty, return them to Arthrex for repair.</td>
</tr>
<tr>
<td></td>
<td>• Camera head cable connector not inserted correctly or completely.</td>
<td>• Insert camera head cable connector completely into the console’s camera head receptacle on the front panel.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Check monitor using color bars from the CCU.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Try the CCU on a different monitor.</td>
</tr>
<tr>
<td>Poor color reproduction.</td>
<td>• White Balance Issues.</td>
<td>• White Balance camera head</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Check monitor settings using color bars from the CCU.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Try the CCU on a different monitor.</td>
</tr>
</tbody>
</table>
3.5 Recommended Annual Camera Control Unit Maintenance Requirements

Table 2: Recommended Annual Camera Control Unit Maintenance Requirements

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Test Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ground Impedance</td>
<td>ZG &lt; 100 mOhm from the ground pin on the power inlet module to the Camera Control Unit’s exposed metal parts. *</td>
</tr>
<tr>
<td>Test Chassis Leakage Currents</td>
<td>IL &lt; 100 uA in NORMAL Condition. IL &lt; 500 uA in Single Fault Conditions [300 uA US deviation] *</td>
</tr>
<tr>
<td>Test Earth Leakage Currents</td>
<td>IL &lt; 500 uA NORMAL Condition [300 uA US deviation] IL &lt; 1 mA Single Fault Condition *</td>
</tr>
<tr>
<td>Test Dielectric Withstand</td>
<td>Test Line and Neutral to Ground @ V = 1500 V~, no breakdown *</td>
</tr>
</tbody>
</table>

* See IEC 60601-1 for test methods.

3.6 Replacement of the Lithium Battery

The Camera Control Unit [CCU] main circuit board contains a Lithium Battery for use in the Real Time Clock Circuit. This battery should have a service life of 8 years.

1. If you need to replace the Lithium Battery.
   (a) Use any UL recognized CR2032 Lithium Coin Cell [Eveready CR2032 for example].
   (b) Remove the old Lithium Battery from its holder on the main circuit board.
   (c) Replace with a new Lithium Battery.

   NOTE: The Lithium Battery holder is polarized and indicates the polarity of the battery. It will not allow for incorrect insertion of the Battery into the holder.
   (d) Recycle the used battery.

⚠️ Warning: Replacement of battery by inadequately trained personnel could result in a Hazard such as Excessive Temperatures or Fire.
## 4.0 Technical Information

NOTE: Technical data is subject to modification, revision and improvement without notice.

### Table 3: Safety, EMC and Regulatory Requirements

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Parameter Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>System Classification</strong></td>
<td></td>
</tr>
<tr>
<td>FDA Class</td>
<td>Class II</td>
</tr>
<tr>
<td>EU Class</td>
<td>Class I</td>
</tr>
<tr>
<td>Health Canada Class</td>
<td>Class II</td>
</tr>
<tr>
<td><strong>Safety Certifications</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Domestic Certification    | • UL 60601-1:2003  
                           | • ANSI/AAMI ES60601-1:2005 |
| Canadian Certification    | • CAN/CSA-C22.2 No. 601.1-M90  
                           | • CAN/CSA C22.2 No. 60601-2-18-01  
                           | • CAN/CSA-C22.2 No. 60601-1:2008  
                           | • CAN/CSA-C22.2 No. 60601-2-18:2011 |
| EU Certification          | • CAN/CSA-C22.2 No. 601.1-M90 [IEC 60601-1 2nd Edition with Canadian Deviations]  
                           | • CAN/CSA C22.2 No. 60601-2-18-01 [IEC 60601-2-18 2nd Edition with Canadian Deviations]  
                           | • CAN/CSA-C22.2 No. 60601-1:2008 [IEC 60601-1 3rd Edition with Canadian Deviations]  
| **EMC Certifications**    |                 |
| CISPR 11 EMC Class        | Class A         |
| CISPR 11 EMC Group        | Group 1 [un-intentional radiator] |
| EMC Certification         | Certification to IEC 60601-1-2:2014 Class A |
| **Safety Certification Marking** |                 |
|                           | ![TÜV SUD NRTL US](image) |
| **CE Marking**            | CE Marking for MDD 93/42/EEC |
### Table 4: Safety, Classifications

<table>
<thead>
<tr>
<th>Classification of Equipment</th>
<th>Parameter Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>According to protection against electric shock.</td>
<td>Class I [Grounded]</td>
</tr>
<tr>
<td>According to degree of protection against electric shock.</td>
<td>Applied part is Type BF</td>
</tr>
<tr>
<td>According to Degree of protection against harmful ingress of water.</td>
<td>Camera Control Units are Ordinary [IPX-0] no protection. Camera Head is IXP-7 [Protected against temporary immersion in water]</td>
</tr>
<tr>
<td>According to the degree of safety in the presence of Flammable Anesthetics</td>
<td>Equipment is NOT suitable for use in the presence of flammable anesthetics.</td>
</tr>
<tr>
<td>According to the mode of operation.</td>
<td>Continuous</td>
</tr>
</tbody>
</table>

### Table 5: Specifications

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Parameter Value</th>
</tr>
</thead>
</table>
| **Power Requirements** | Rated Voltage: 100 – 240 V~  
Supply Frequency: 50-60 Hz  
Power Input: 140 VA  
Fuses: No user serviceable fuses |
| **Video Outputs** | 3G-SDI [1080P] Video: 59.94 Hz, Progressive, SMPTE 425 Standard  
DVI [1080P]: 1920 X 1080 Pixels Progressive Scan [1080P] |
| **Vertical Scanning Frequency** | 59.94 Hz |
| **Signal to Noise Ratio** | > 50 -dB |
| **White Balance Range; Integrated Optics Head** | 2000 to 10,000 K |
| **White Balance Range; C-Mount Head** | 3053 to 10,000 K |
| **CCU Dimensions** | Approximately: 16” [W] x 5” [H] x 13.5” [D]  
40.6 cm [W] x 12.7 cm [H] x 34.3 cm [D] |
| **CCU Weight** | Approximately: 18 pounds |
| **Camera Head Dimensions** | **AR-3210-0001**  
Approximately: 4.75” [L] x 2.0” [W], x 2.0 [H]  
12 cm [L] x 5 cm [W] x 5 cm [H]  
**AR-3210-0003**  
Approximately: 3.125” [L] x 1.5” [W], x 2.0 [H]  
8 cm [L] x 4 cm [W] x 5 cm [H]  
**AR-3210-0004**  
Approximately: 3.125” [L] x 1.5” [W], x 2.0 [H]  
8 cm [L] x 4 cm [W] x 5 cm [H]  
**AR-3210-0007**  
Approximately: 3.125” [L] x 1.5” [W], x 2.0 [H]  
8 cm [L] x 4 cm [W] x 5 cm [H] |
### Table 6: Light Source Specifications

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Parameter Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LED Light Source Specifications</strong></td>
<td></td>
</tr>
<tr>
<td>Light output</td>
<td>≥ 1350 Lumens</td>
</tr>
<tr>
<td>Color Temp</td>
<td>7000 K Nominal</td>
</tr>
<tr>
<td>LED Life</td>
<td>&gt; 30,000 hours</td>
</tr>
<tr>
<td>Light Guide Port</td>
<td>Wolf™ Standard</td>
</tr>
<tr>
<td>Light Guide Port Turret</td>
<td>ACMI™ Standard, Storz™, Wolf™ and Olympus™</td>
</tr>
</tbody>
</table>

### Table 7: DICOM Specifications

<table>
<thead>
<tr>
<th>DICOM Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>DICOM Compatible with installation of AR-3200-1020 DICOM Key</td>
</tr>
</tbody>
</table>
5.0 APPENDIX [Detailed EMC Information]

DETAILED EMC INFORMATION

NOTE: CE marked equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC [EN 55011 Class A and IEC 60601-1-2]. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

The Equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment to an outlet on a circuit different from that to which the other device(s) is connected.
- Consult the manufacturer or a field service technician for assistance.

NOTE: The EMC tables and other guidelines that are included in the Instruction Manual provide information to the customer or user that is essential in determining the suitability of the Equipment or System for the Electromagnetic Environment of use, and in managing the Electromagnetic Environment of use to permit the Equipment or System to perform its intended use without disturbing other Equipment and Systems or non-medical electrical equipment.

NOTE: Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Accompanying Documents.

WARNINGS:

1. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

2. Use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the equipment as replacement parts for internal components, may result in increased emissions and decreased immunity of the equipment or system.

3. The video equipment / system should not be used adjacent to or stacked with other equipment, and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it is intended to be used.

4. Under extreme conditions of primary power voltage sag [Primary voltage less than 60% of mains] the device may require operator intervention to recover lost image. Device may have to be restarted by pressing On/Standby Switch.
IEC 60601-1-2 Table 1
Guidance and manufacturer’s declaration – electromagnetic emissions

The Arthrex HD3 Video System is intended for use in the electromagnetic environment specified below. The customer or the user of the Arthrex HD3 Video System should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic environment- guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions</td>
<td>Group 1</td>
<td>The Arthrex HD3 Video System uses RF energy only for its internal function. Therefore its RF emissions are very low and not likely to cause any interference in nearby equipment.</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RF emissions</td>
<td>Class A</td>
<td>The Arthrex HD3 Video 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:</td>
</tr>
<tr>
<td>CISPR 11</td>
<td></td>
<td>Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system 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 Arthrex HD3 Video System or shielding the location.</td>
</tr>
<tr>
<td>Harmonic Emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions</td>
<td>Complies</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table System Cables

<table>
<thead>
<tr>
<th>Type</th>
<th>Use</th>
<th>Shielded?</th>
<th>Ferrite?</th>
<th>Maximum Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Cord</td>
<td>Supply Line Power to the Box</td>
<td>No</td>
<td>No</td>
<td>2 M</td>
</tr>
<tr>
<td>BNC to BNC</td>
<td>Composite Video Out to Monitor</td>
<td>Yes</td>
<td>No</td>
<td>1.8 M</td>
</tr>
<tr>
<td>4 Pin Mini Din</td>
<td>Y/C Video Out to Monitor</td>
<td>Yes</td>
<td>No</td>
<td>1.8 M</td>
</tr>
<tr>
<td>DVI</td>
<td>DVI Video Out to Monitor</td>
<td>Yes</td>
<td>No</td>
<td>1.8 M</td>
</tr>
<tr>
<td>3 pin mini Stereo</td>
<td>Accessory Port</td>
<td>Yes</td>
<td>No</td>
<td>1.8 M</td>
</tr>
<tr>
<td>Ethernet</td>
<td>CCU to Computer</td>
<td>Yes</td>
<td>No</td>
<td>5 M</td>
</tr>
<tr>
<td>USB</td>
<td>CCU to Printer</td>
<td>Yes</td>
<td>No</td>
<td>1.8 M</td>
</tr>
</tbody>
</table>
## Guidance and manufacturer’s declaration – electromagnetic immunity

The ARTHREX HD3 Video System is intended for use in the electromagnetic environment specified below. The customer or user of the ARTHREX HD3 Video System should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 test level</th>
<th>Compliance Level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge [ESD]</td>
<td>± 8 kV contact ± 15 kV air</td>
<td>± 8 kV contact ± 15 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered by synthetic material the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient / burst</td>
<td>± 2 kV differential mode ± 1 kV for input / output lines 100 khz Cycling Frequency</td>
<td>± 2 kV differential mode ± 1 kV for input / output lines 100 khz Cycling Frequency</td>
<td>Mains power should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>± 1 kV differential mode ± 2 kV common mode</td>
<td>± 1 kV differential mode ± 2 kV common mode</td>
<td>Mains power should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines</td>
<td>$U_t = 0%, 0.5\text{ cycle (0, 45, 90, 135, 180, 225, 270, and 315\textdegree)}$</td>
<td>$U_t = 0%, 0.5\text{ cycle (0, 45, 90, 135, 180, 225, 270, and 315\textdegree)}$</td>
<td>Mains power should be that of a typical commercial or hospital environment. If the user of the ARTHREX HD3 Video System requires continued operation during power mains interruptions, it is recommended that the ARTHREX HD3 Video System be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
<td>$U_t = 0%, 1\text{ cycle}$</td>
<td>$U_t = 0%, 1\text{ cycle}$</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$U_t = 70%, 25/30\text{ cycles (@0 degrees)}$</td>
<td>$U_t = 70%, 25/30\text{ cycles (@0 degrees)}$</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$U_t = 70%, 250/300\text{ cycles}$</td>
<td>$U_t = 70%, 250/300\text{ cycles}$</td>
<td></td>
</tr>
<tr>
<td>Power Frequency [50/60 Hz] magnetic field.</td>
<td>3 A/m</td>
<td>3 A/m @50 &amp; 60Hz</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NOTE:** $U_t$ is the a.c. mains voltage prior to application of the test level.
## Guidance and manufacturer’s declaration – electromagnetic immunity

The ARTHREX HD3 is intended for use in the electromagnetic environment specified below. The customer or user of the ARTHREX HD3 should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>V1=3 Volt</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the ARTHREX HD3 Video System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m 80 MHz to 2.7 GHz</td>
<td>E1= 3 V/m</td>
<td>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 in meters [m]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less that the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:</td>
</tr>
</tbody>
</table>

\[
d = \left[ \frac{3.5}{V1} \right] \sqrt{P} = 1.17 \sqrt{P} \quad 80 \text{ MHz to 800 MHz}
\]

\[
d = \left[ \frac{7}{E1} \right] \sqrt{P} = 2.33 \sqrt{P} \quad 800 \text{ MHz to 2.7 GHz}
\]

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 by 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 access the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the ARTHREX HD3 Video System is used exceeds the applicable RF compliance level, above, the ARTHREX HD3 Video System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ARTHREX HD3 Video System.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
The ARTHREX HD3 Video System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ARTHREX HD3 Video System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment [transmitters] and the ARTHREX HD3 Video System as recommended below, according to the maximum output power of the communications equipment.

### Table 6

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter [W]</th>
<th>Separation distance according to frequency of transmitter [m]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td>(d = \left[\frac{3.5}{V_1}\right]\sqrt{P})</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.37</td>
</tr>
<tr>
<td>1</td>
<td>1.17</td>
</tr>
<tr>
<td>10</td>
<td>3.70</td>
</tr>
<tr>
<td>100</td>
<td>11.70</td>
</tr>
</tbody>
</table>

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 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 applies.

**NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
6.0 APPENDIX [SW Version access]

ACCESS to SW Version on Synergy HD3

1. Login to the Android application

![Figure 28-Logging on to Android](image)

2. Tap and hold the date field to bring up the Admin Options

![Figure 29-Tap and Hold DATE FIELD](image)

3. Tap About

![Figure 30-Tap ABOUT](image)

4. Tablet and CCU software version are displayed

![Figure 31-SW Version Information](image)
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