Synergy^{HD3} System Service Manual

The Arthrex Synergy^{HD3} System Camera Controller and Camera Head User's Guide provides important information for the safe operation of all components of the Synergy^{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.

AR-3200-0001T
AR-3210-0001
AR-3210-0003
AR-3210-0004
AR-3210-0007

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This is not a warranty document. For all warranty information, including disclaimers, exclusions, terms, conditions and related provisions, refer to the "Arthrex U.S. Product Warranty" section of the Arthrex, Inc. website, found at www.arthrex.com whose provisions are incorporated herein by reference.

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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 Synergy^{HD3} 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.

The Arthrex Synergy^{HD3} System is comprised of:

- AR-3200 Console with Wolf Light Guide Port.
- 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

NOTE: the AR-3200T Synergy^{HD3} Console is identical to the AR-3200 except that it incorporates a Turret Light Guide Adapter which accepts various light guides.

1.1 Intended Use

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, sinuscopic 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^{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^{HD3} Video System or shielding the location.
20. NOT for use in an Oxygen Rich Environment.
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 to 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 EN 60601-1-2:2002. 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 or clause 16 or the 3rd edition of IEC 60601-1, respectively). 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 60601-1-1. 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 EN 60601-1 and EN60601-1-2:2002. 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.

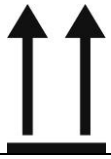
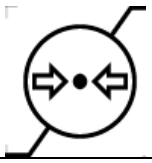
    This unit was not evaluated for use with electrosurgical devices which access the site via the same endoscope as the light source and camera. The unit must be re-evaluated prior to use with electrosurgical devices when they will operate through the same endoscope as the light source and camera.
18. After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

	**Safety Sign** **Follow Operating Instructions**
	**Power Standby/On**
	**Attention, Consult Accompanying Documents**
	**Precaution of Warning Notice**
	**Type BF Equipment**
	**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.**
	**Alternating Current**
	**Protective Earth [Ground]**

RX ONLY	**Caution: Federal Law Restricts this device to sale by or on the order of a Physician.**
	**Not for use in the Presence of Flammable Anesthetics.**
	**Fragile**
	**This Side Up**
	**Keep Dry**
	**Temperature Limits for Storage and Transport**
	**Pressure Limits for Storage and Transport**
	**Humidity Limits for Storage and Transport**

	**Equipotential [Equipment Potential]**
	**WEEE [Waste Electronics and Electrical Equipment] Symbol. Regarding European Union End-of-Life of Product.**
	**White Balance Symbol**

	**Universal Serial Bus**
	**RF Symbol. Non-ionizing Electromagnetic Radiation**
	**Color Video Camera**

1.5 End of Life, Environmental Directives

WEEE Directive [2002/96/EC] 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.**

CAUTION: Do not install the device in a location near heat sources such as air ducts or radiators and do not expose the device to direct sunlight, excessive dust, or mechanical vibration.

1.7 Unpacking and Inspecting the Device

Upon receipt, carefully unpack the Synergy^{HD3} 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

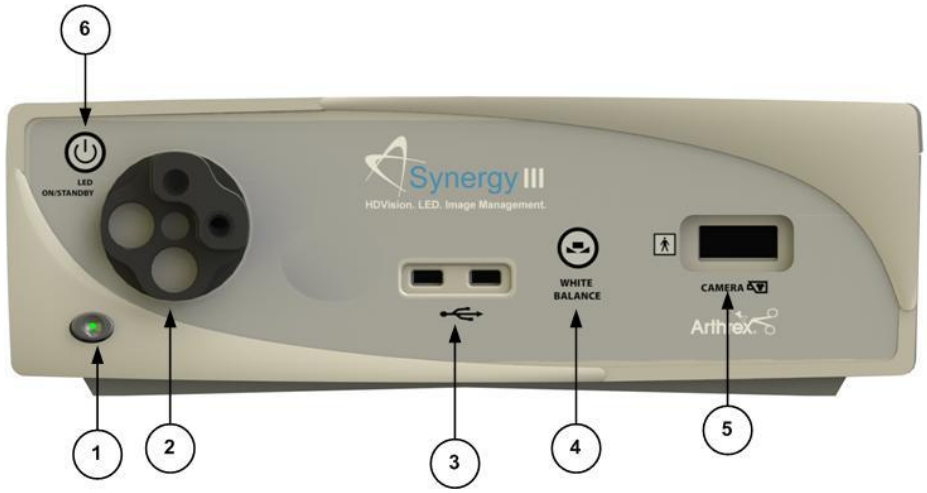


Figure 1- Synergy^{HD3} Front Panel [AR-3200-0001T]

1.9 System Indicators

1.9.1 Synergy^{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 [xxx]-** Turret for Light Guide input
3. **USB Ports [2x] —** Connect USB devices here.
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.

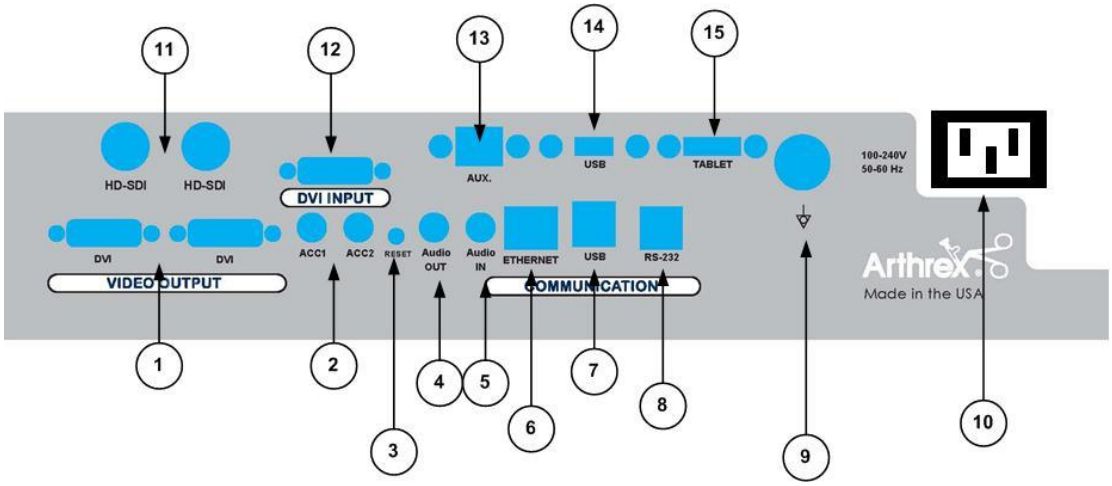


Figure 2- Synergy^{HD3} Rear Panel

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.
9. **Potential Equalization Connector (POAG)** — Potential Equalization Connector per DIN 42801.

   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.

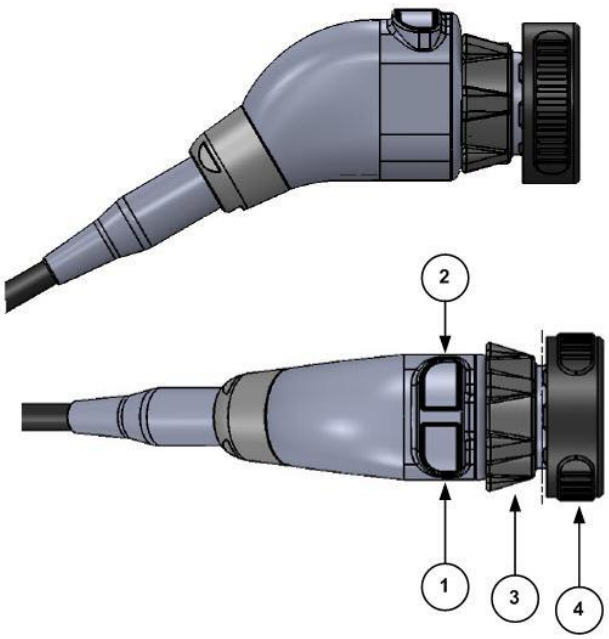


Figure 3-AR-3210-0001 3 CCD Camera Head with Integrated Optics

1.9.3 AR-3210-0001 Camera Head with Integrated Optics

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.

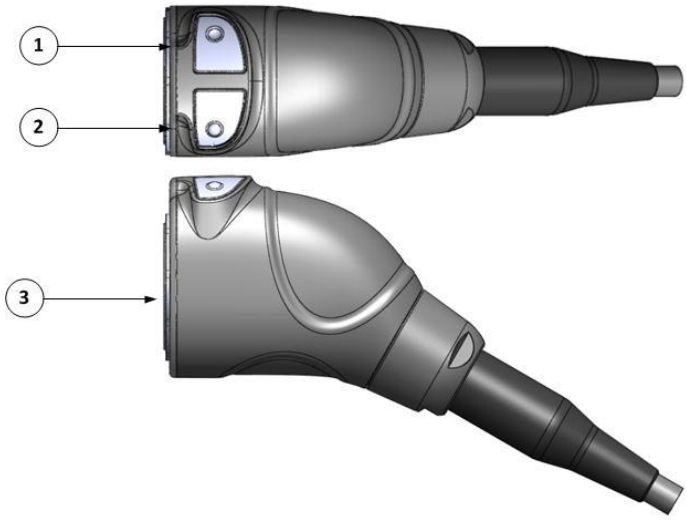


Figure 4-AR-3210-0003 [C-MT], AR-3210-0004 [C-MT, 20 Foot]

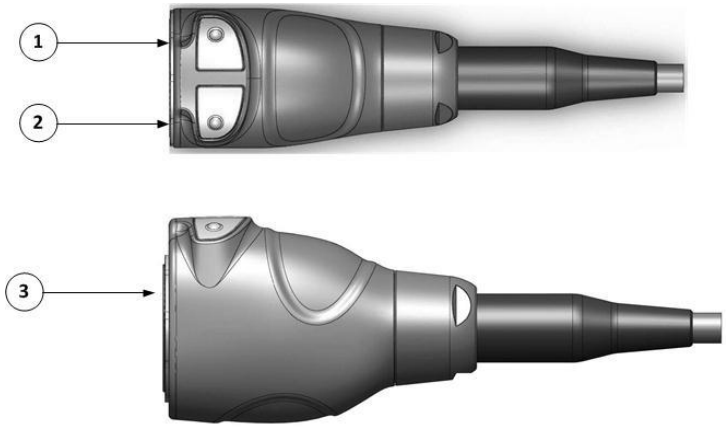


Figure 5-AR-3210-0007 [C-MT, Zero Angle]

1.9.4 C-Mount Camera Heads

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 Synergy^{HD3} 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 Synergy^{HD3} 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 Synergy^{HD3} Tablet docking station to secondary tower arm. Connect the cable from the docking cable to the connector labeled "tablet" on the back of the Synergy^{HD3} console.
4. Connect a DVI cable to the DVI output on the rear panel of the Synergy^{HD3} 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 Synergy^{HD3} console. Connect other end of printer cable to the printer.
6. Plug the AC power cord into the Synergy^{HD3} 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.

8. Connect the Light Guide cable into the Light Guide receptacle on the front panel of the Synergy^{HD3} console. Attach the other end of the Light Guide cable to the endoscope.
10. Insert the endoscope into the Synergy^{HD3} camera head grasping mechanism.
11. Press the Light Source On/Standby Switch to activate LED light engine.

NOTE: If there is no Light Guide cable connected to the Synergy^{HD3} console, pressing the On/Standby Switch will not activate the LED light engine until one is connected.

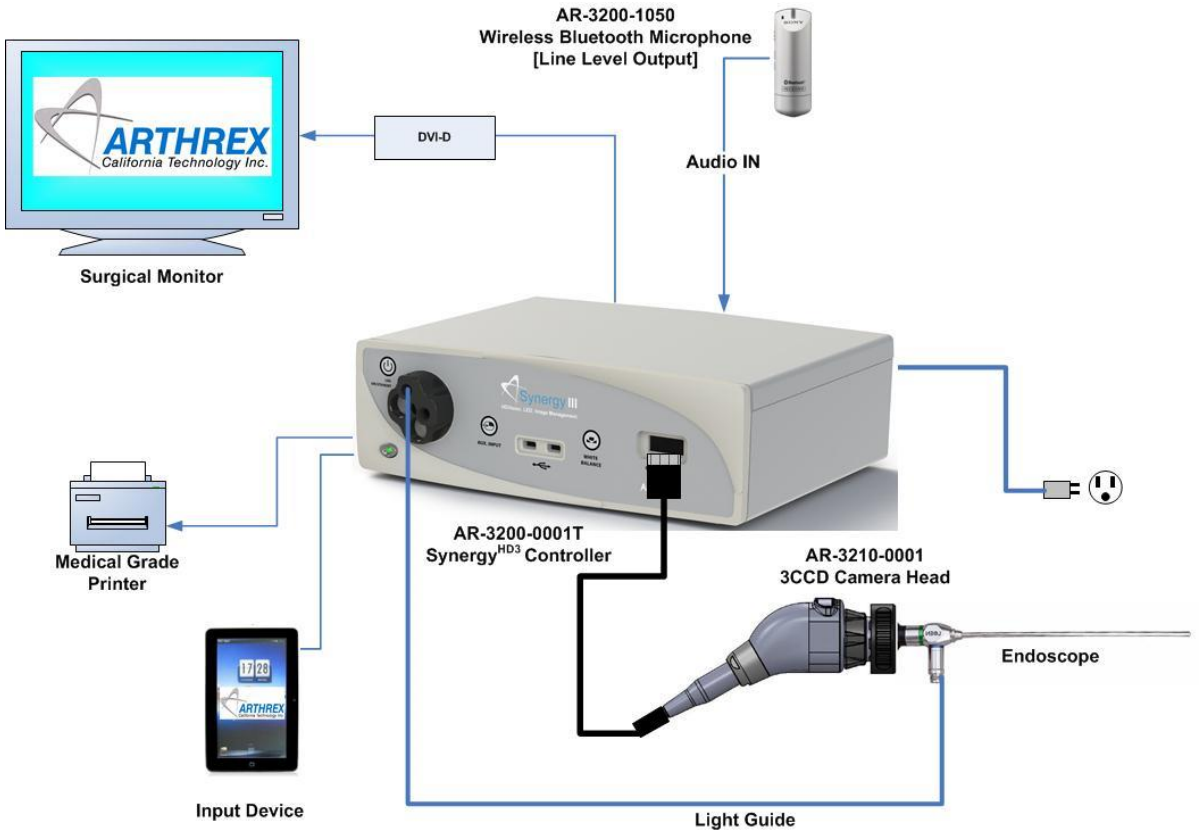


Figure 6- Synergy^{HD3} Typical Interconnect Diagram With OPTIONAL Tablet Data Input Device

2.2 Accessories for Intended Use

Arthrex Synergy^{HD3} System Accessories	
Part Number	**Description**
AR-3200-1004	Tablet Computer Data Input Device
SONY UP-PR80MD SONY UP-PR80MD with upDR80MD/NKIT	Medical Grade Printers
AR-3250-2601 AR-3250-2602 AR-3250-2603 AR-3250-3201 AR-3250-3203 AR-3250-3204	Medical Grade Surgical Monitor 26” Medical Grade Surgical Monitor 25” Medical Grade Surgical Monitor 26” Medical Grade Surgical Monitor 32” Medical Grade Surgical Monitor 32” Medical Grade Surgical Monitor 32”
AR-3240-3527 AR-3240-5027	Light Guide 3.5mm x 274cm Light Guide 5.0mm x 274cm

Arthrex Synergy^{HD3} System Accessories	
Part Number	**Description**
AR-3240-5040	Light Guide 5.0mm x 400cm
AR-3200-1050	Bluetooth Wireless Microphone
AR-3210-0005	C-Mount Optical Zoom Coupler
AR-3210-1005	Video Input/Output Converter

2.3 System Setup Facility and Surgeon Settings

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

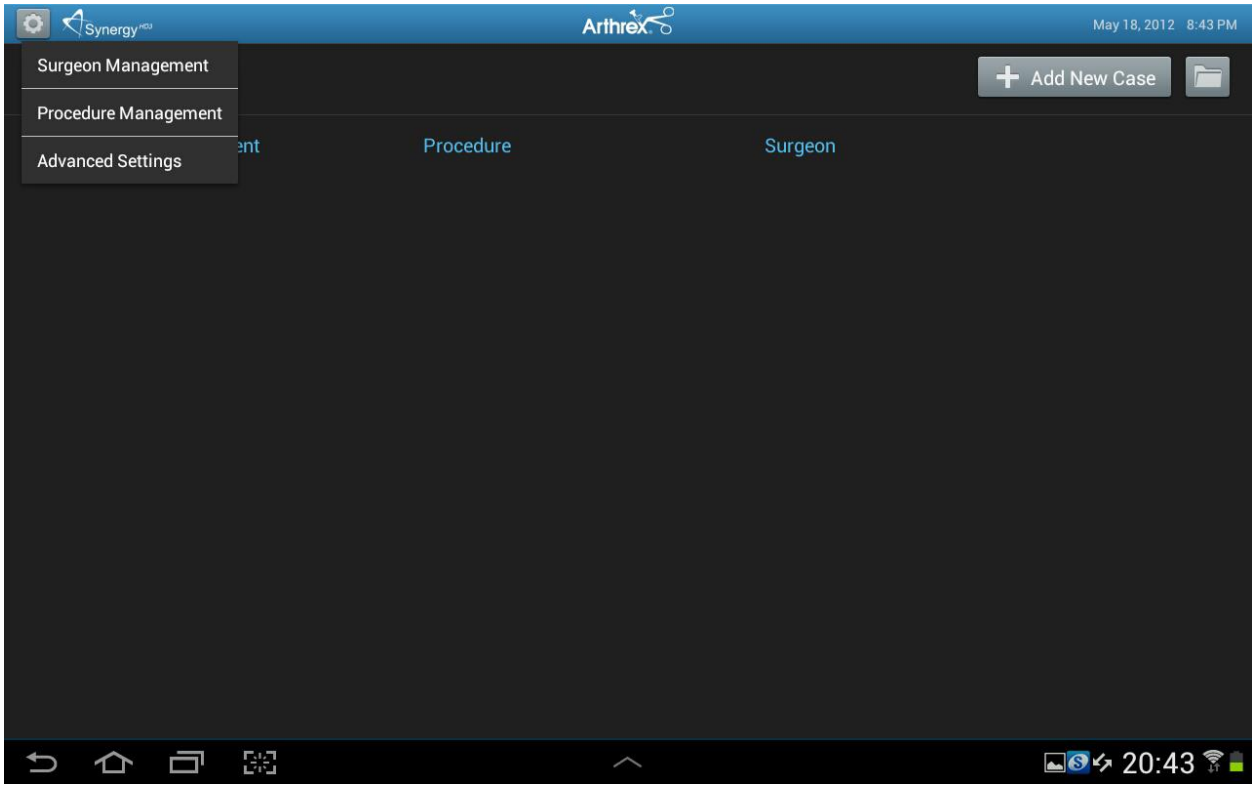


Figure 7-System Maintenance

2.3.1 System Set-Up can be accessed by pressing the **Maintenance Icon**  on the Synergy^{HD3} Tablet Data Input Device and then selecting **"Advanced Settings"**

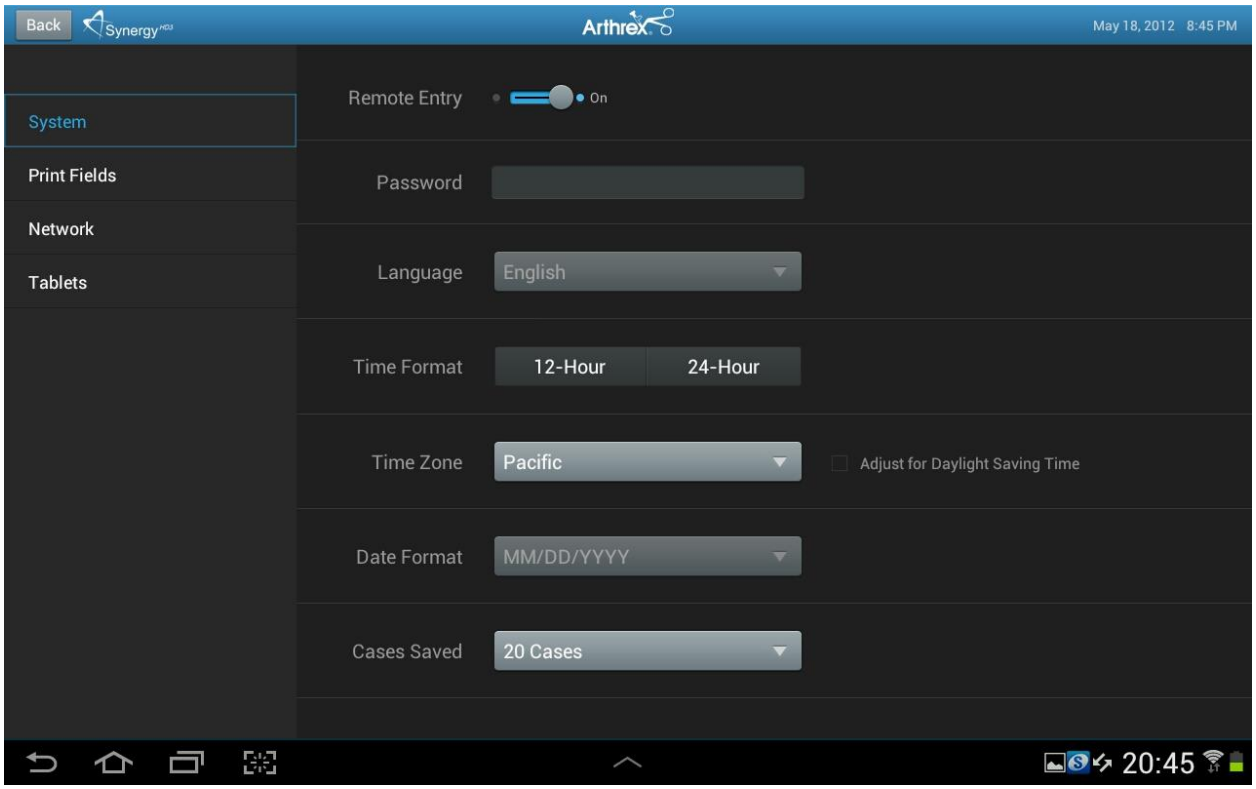


Figure 8-System Maintenance Screen

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 add patients remotely.
- Users can also select "language, time format, Date format, the number of cases saved.

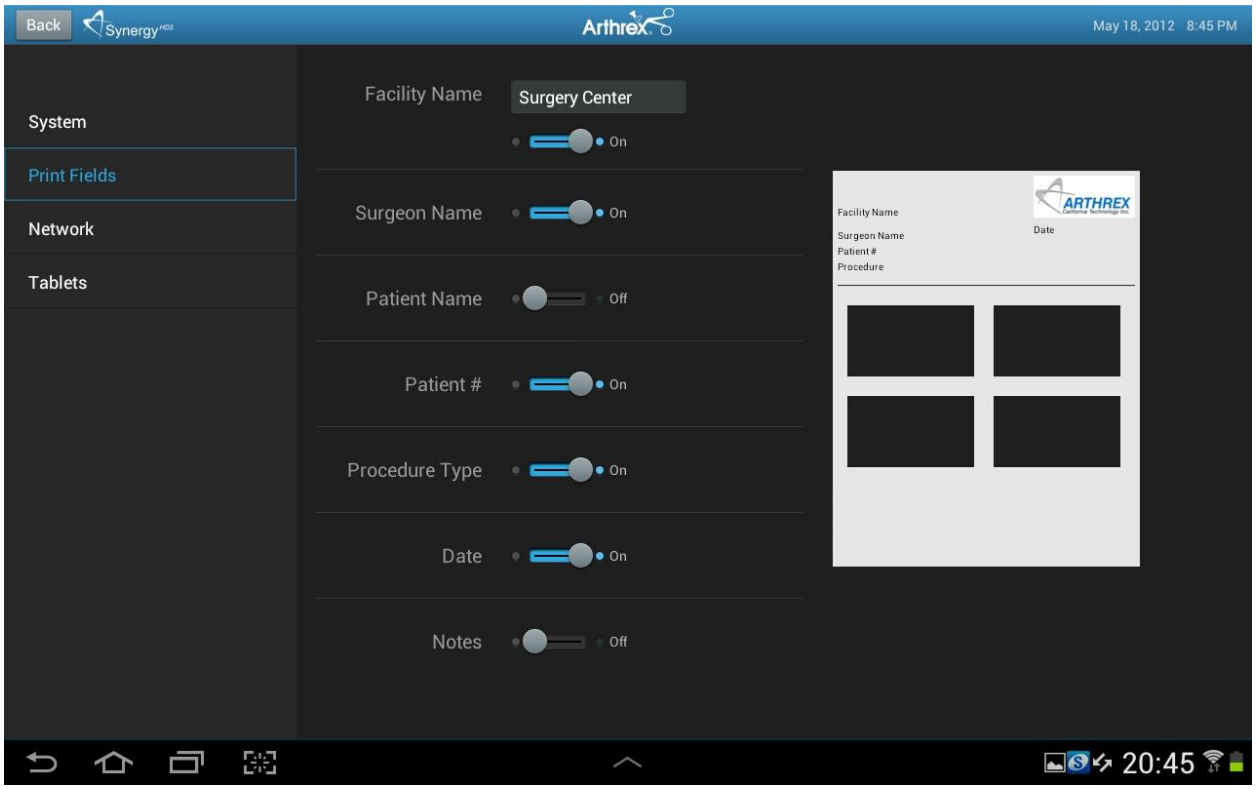


Figure 9-System Maintenance Print Fields

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.

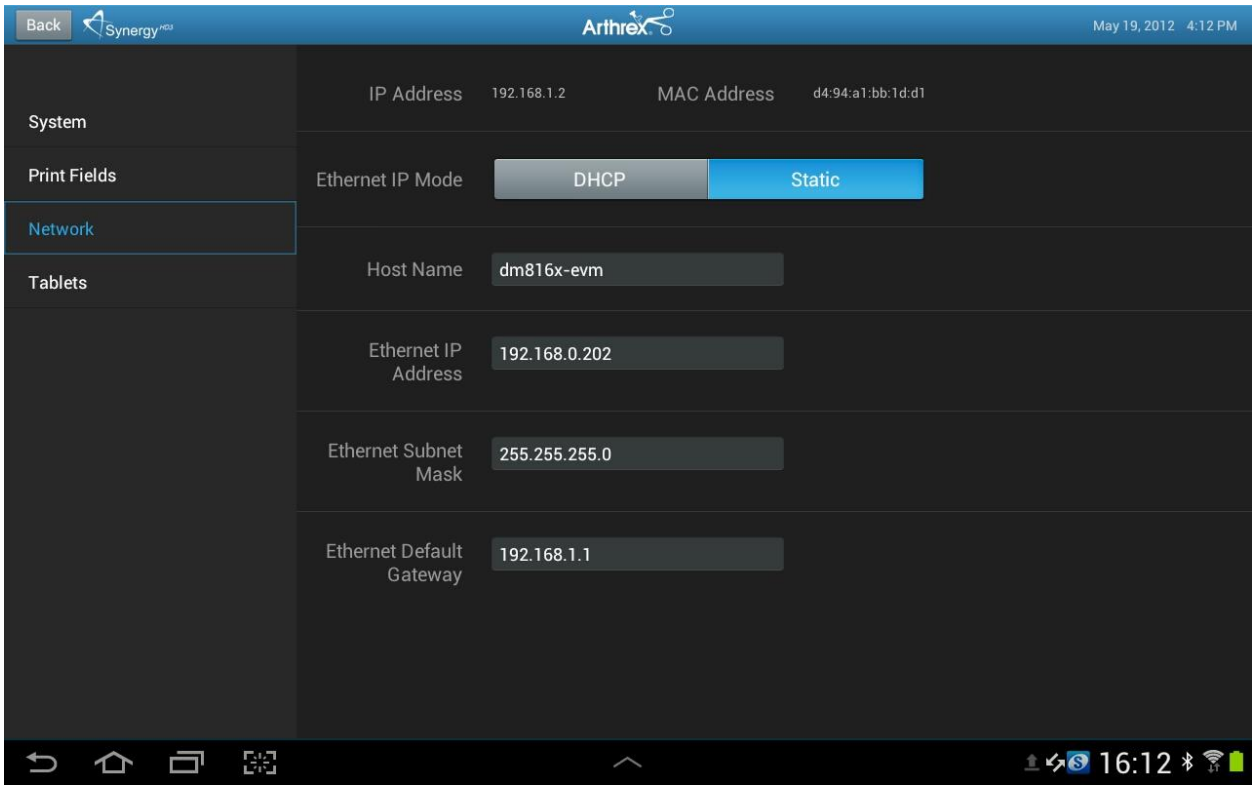


Figure 10-System Maintenance Network

2.3.4 Selecting "**Network**" allows for connecting the Synergy^{HD3} system to a facility network. Fields are:

- Ethernet IP Mode
- Host Name
- Ethernet IP Address
- Ethernet Subnet Mask
- Ethernet Default Gateway

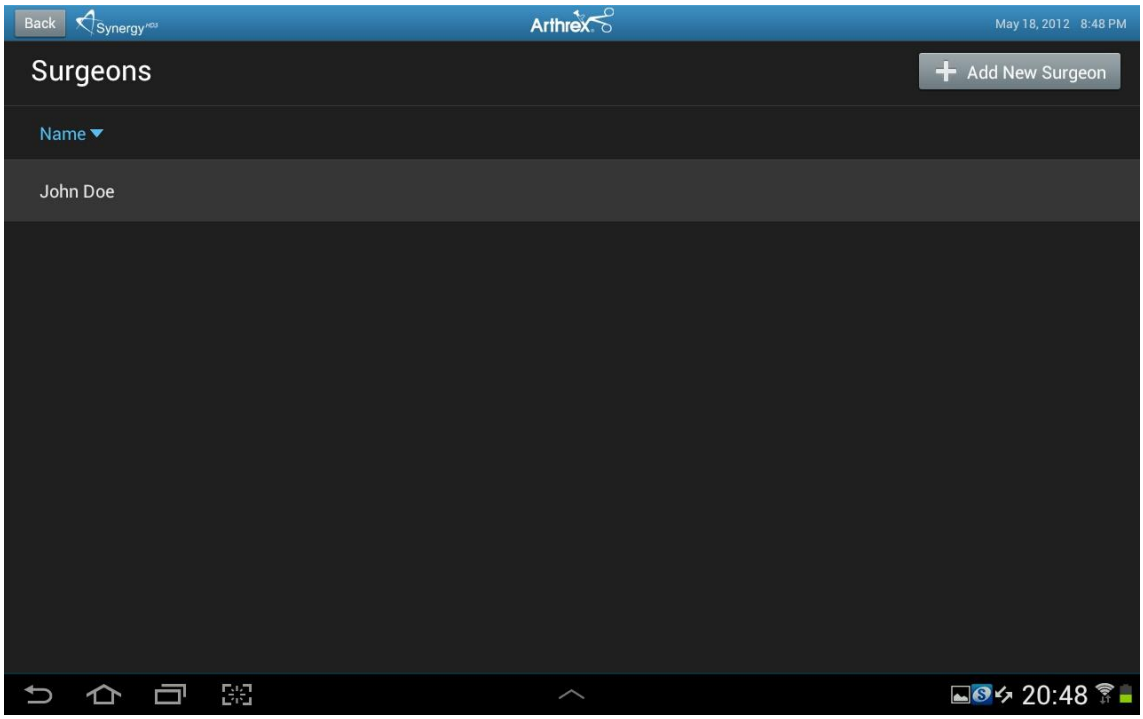


Figure 11-Surgeon Management List

2.3.5 Surgeons can be added to the Synergy[HD3] with their own system preferences.

2.3.6 To add surgeons and their preferences, press the **maintenance icon**  on the Synergy[HD3] Tablet Data Input Device and then select **Surgeon Management**. A list of surgeons will appear.

2.3.7 To add a surgeon, press the "+ **Add New Surgeon**" button, enter the first and last name of a surgeon, then press the "**Preferences**" button

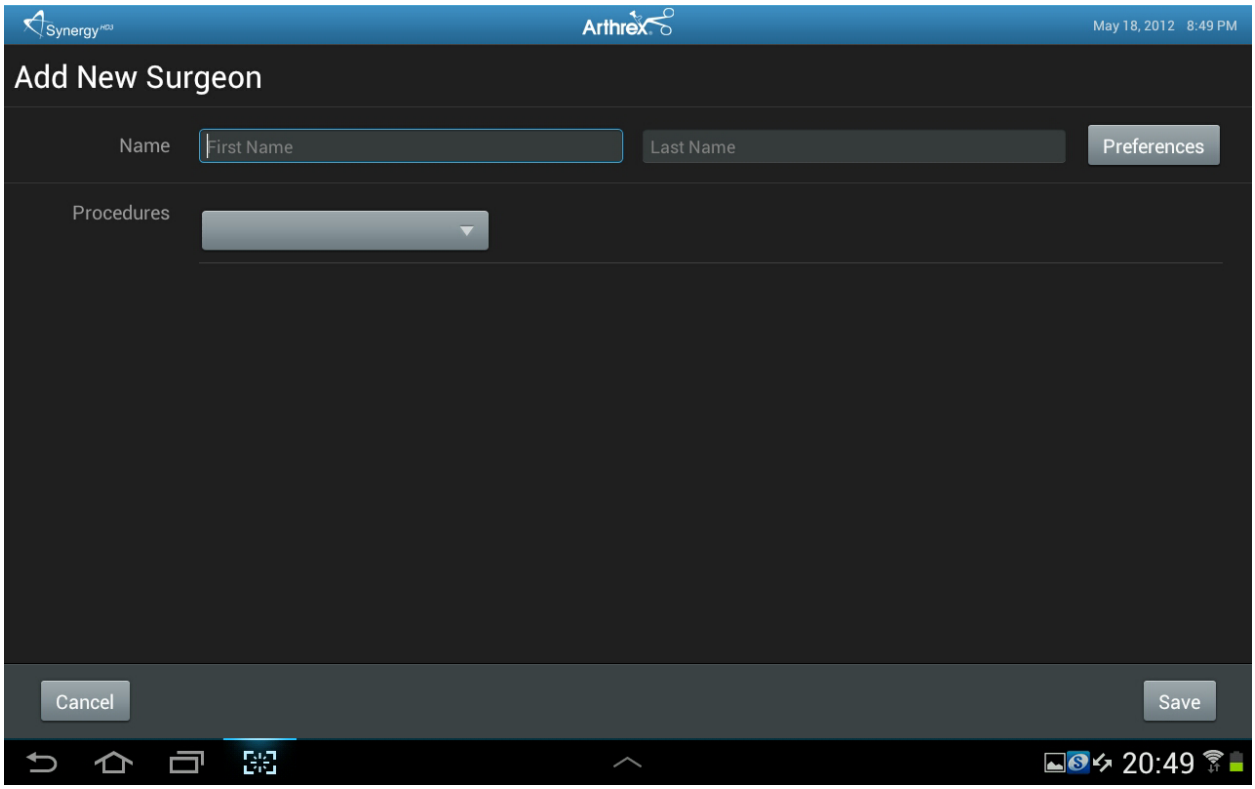


Figure 12-Surgeon Management Preferences

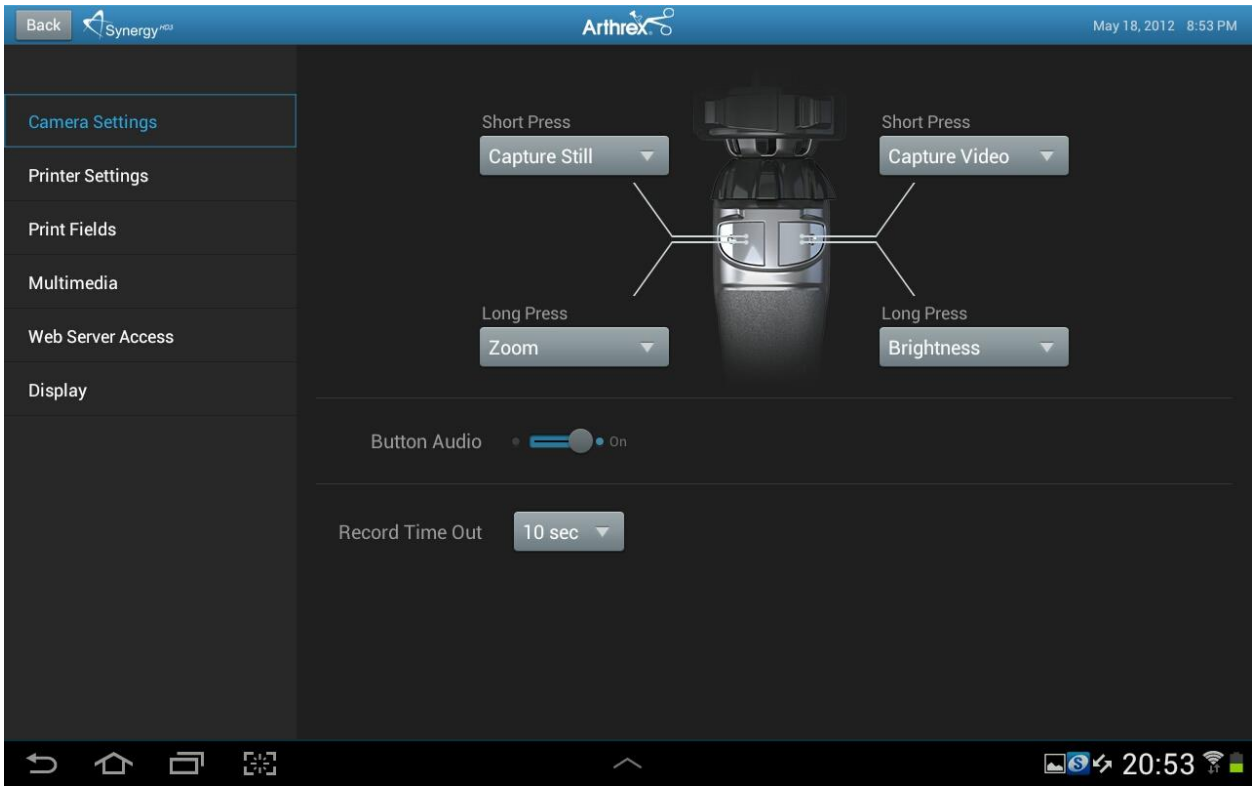


Figure 13-Surgeon Preferences Settings

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

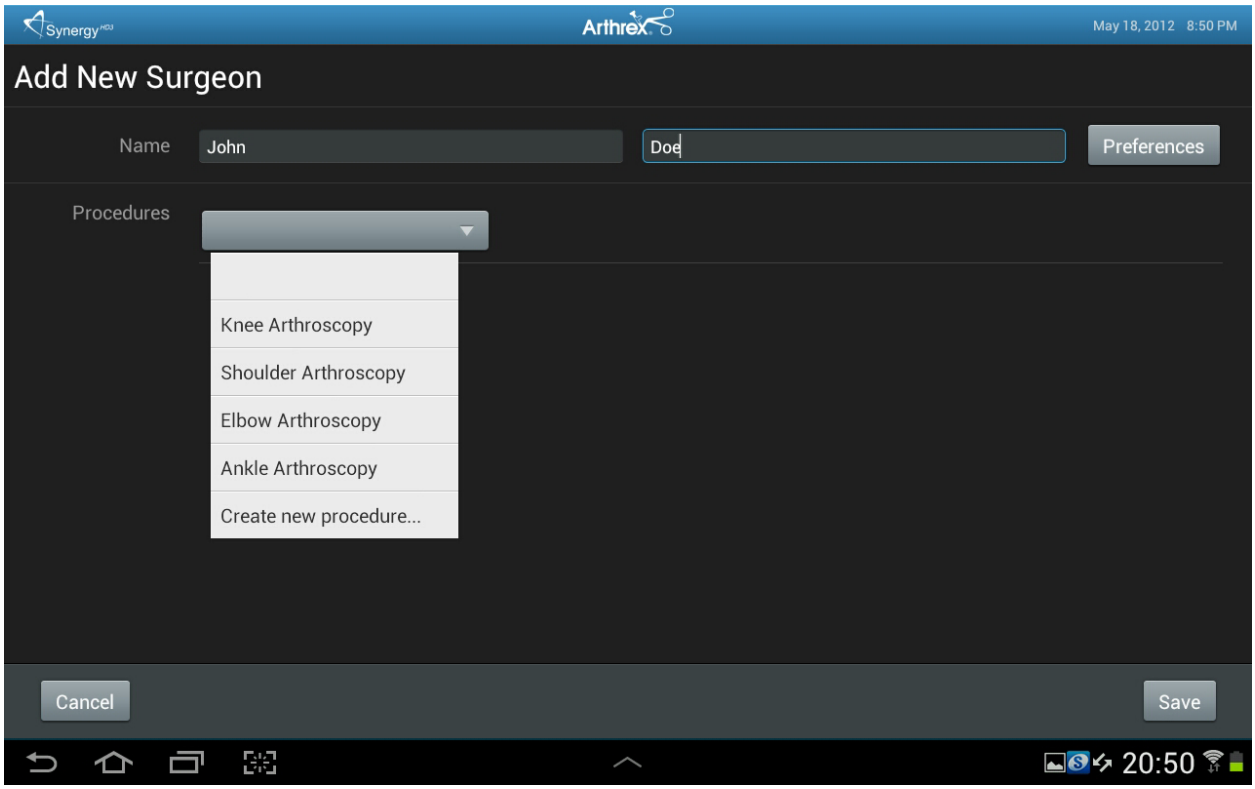


Figure 14-Surgeon Management Procedures Select

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.

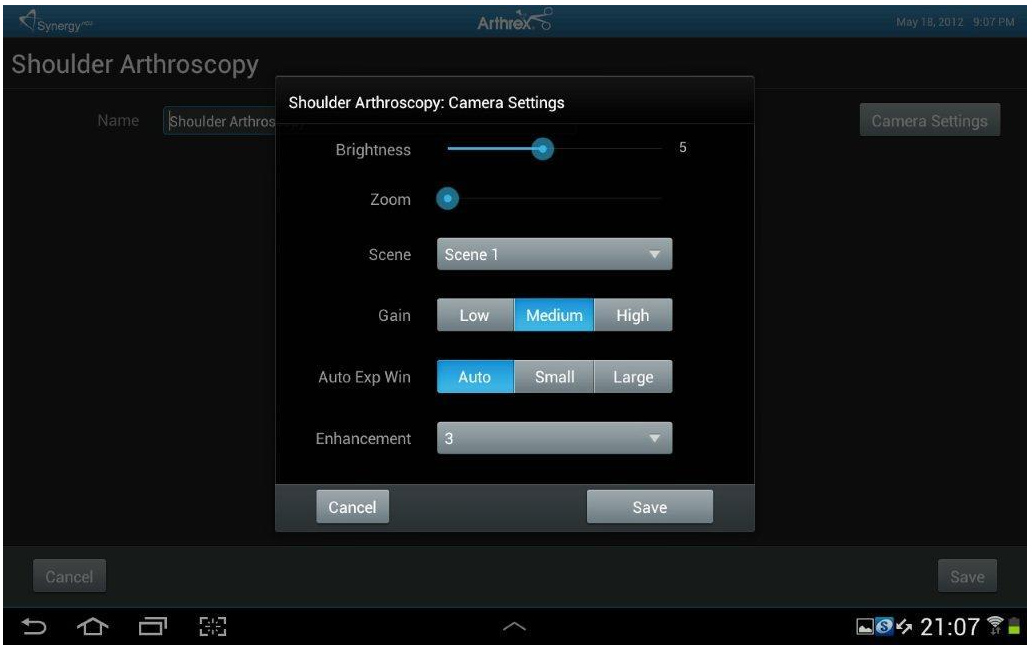


Figure 15-Surgeon Preferences Camera Settings

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

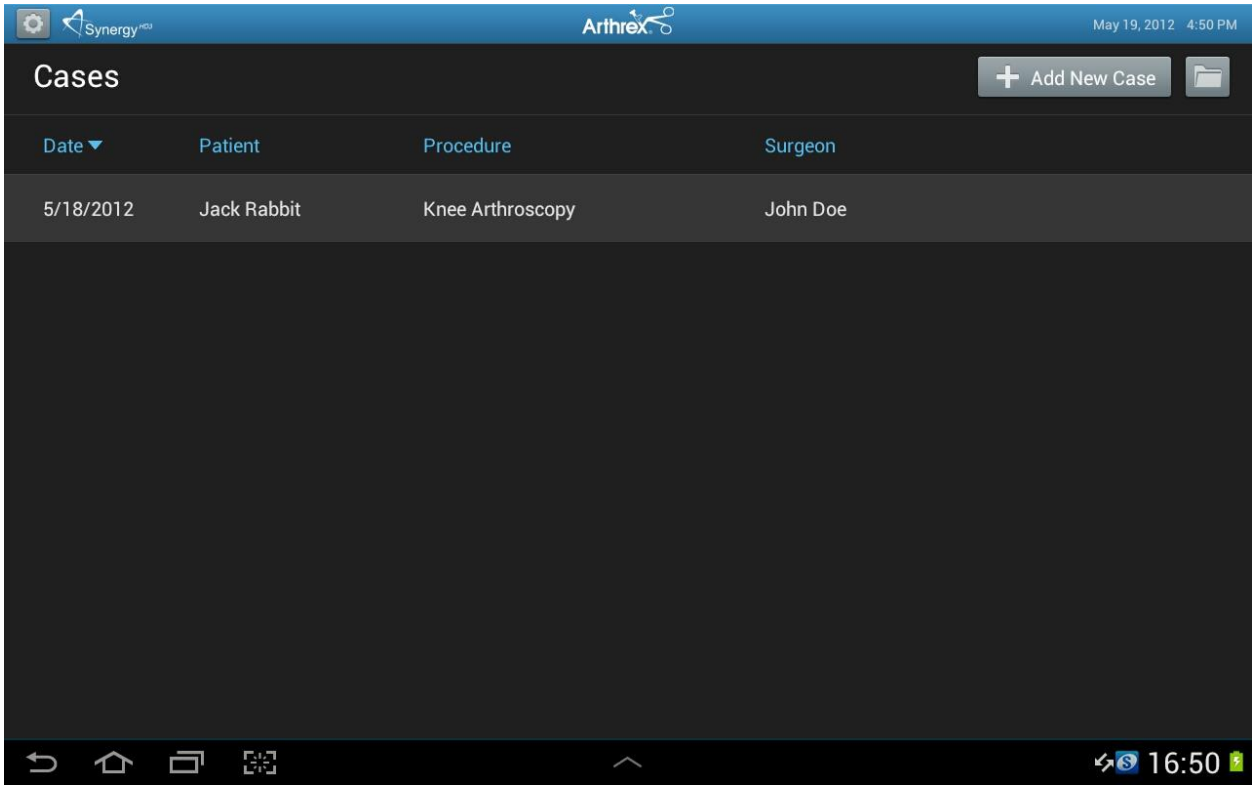


Figure 16-Scheduling a case

2.4.1 To schedule a case, press the **"+ Add New Case**" icon

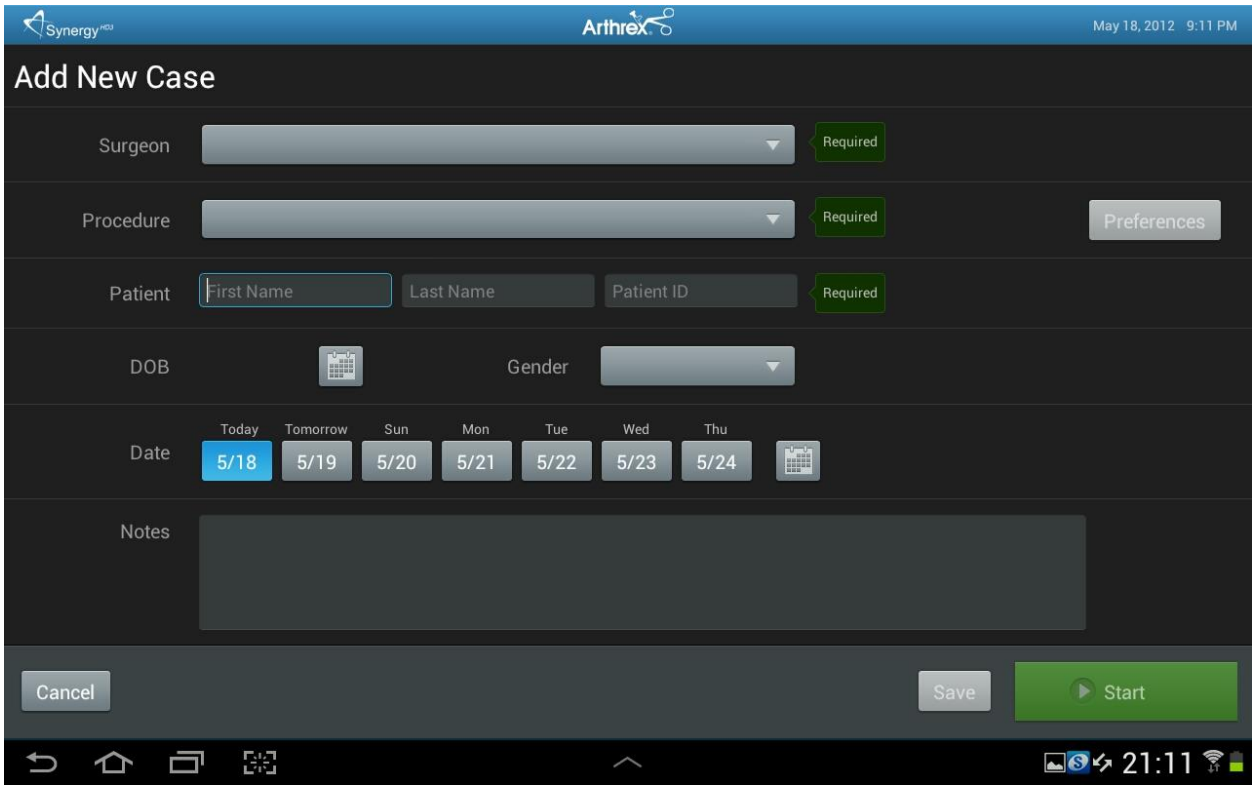


Figure 17-Scheduling a Case

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

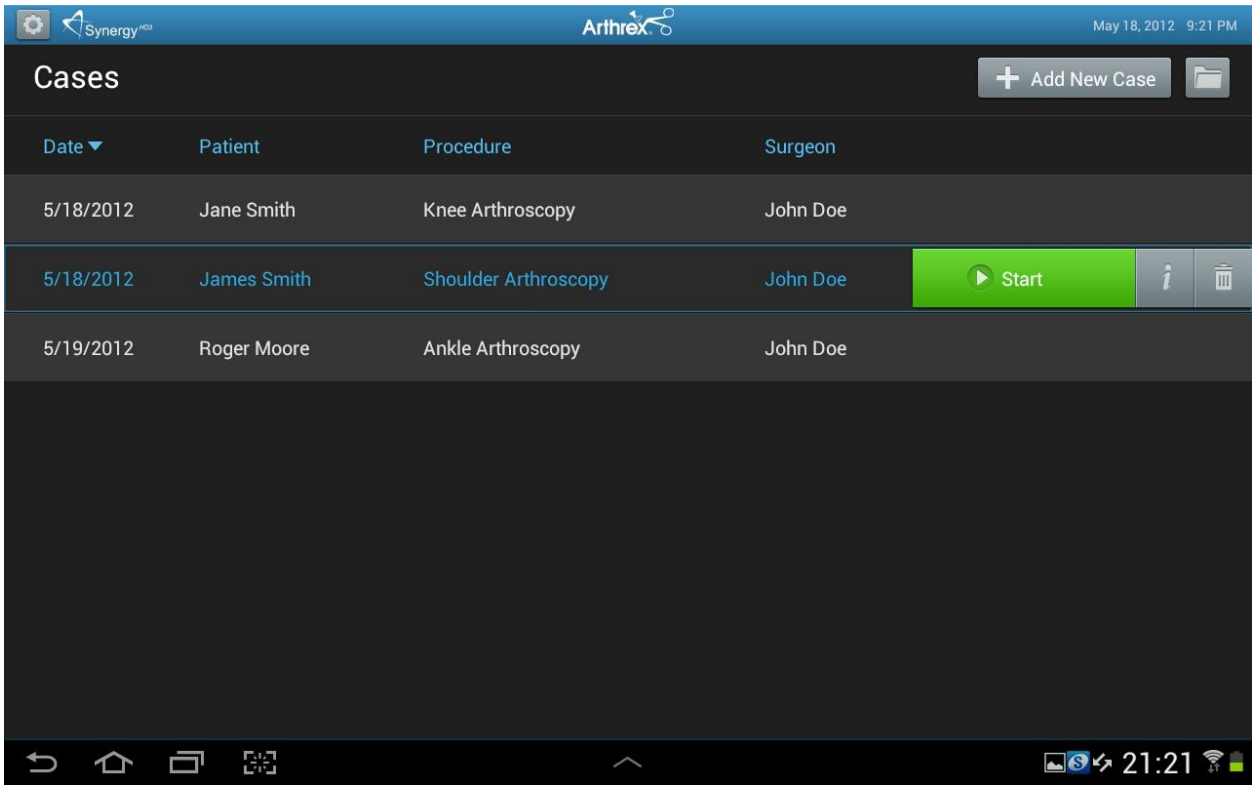


Figure 18-Starting a Case

2.4.4 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.

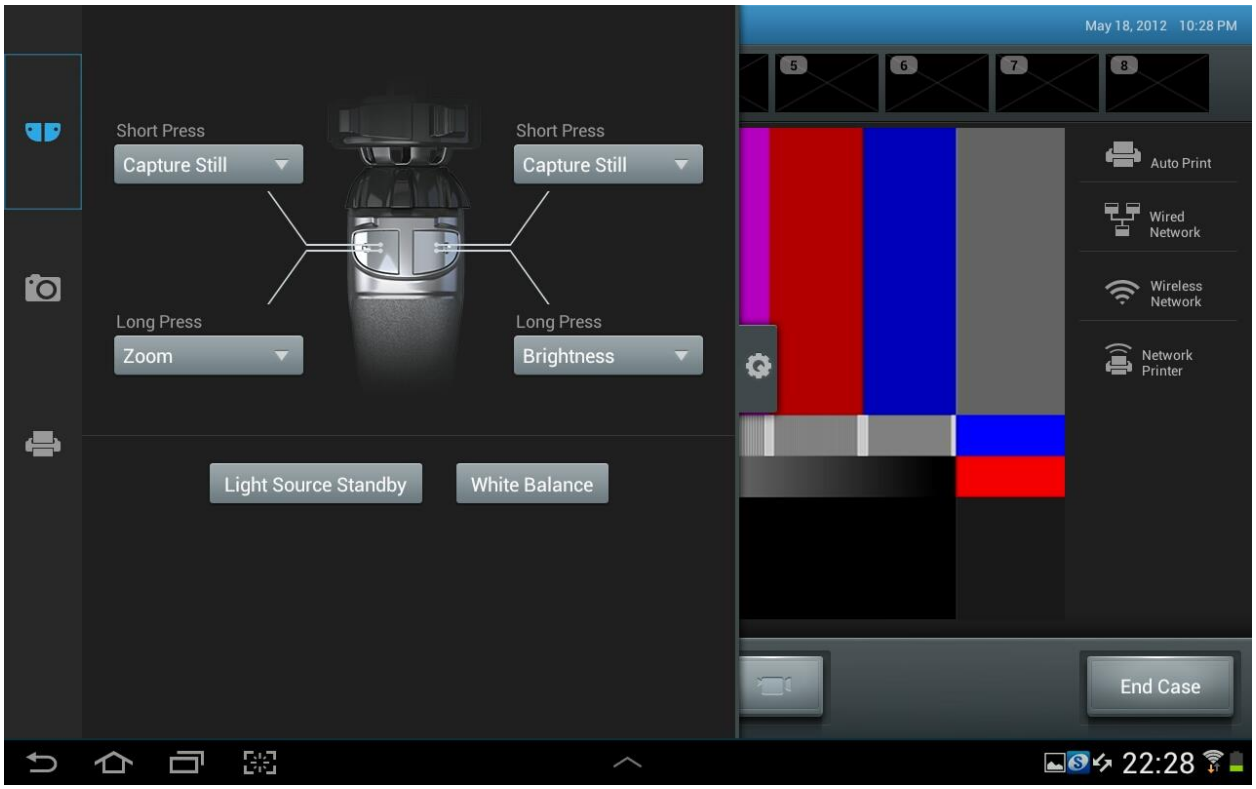


Figure 19-Camera Head Button Change; During Case

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

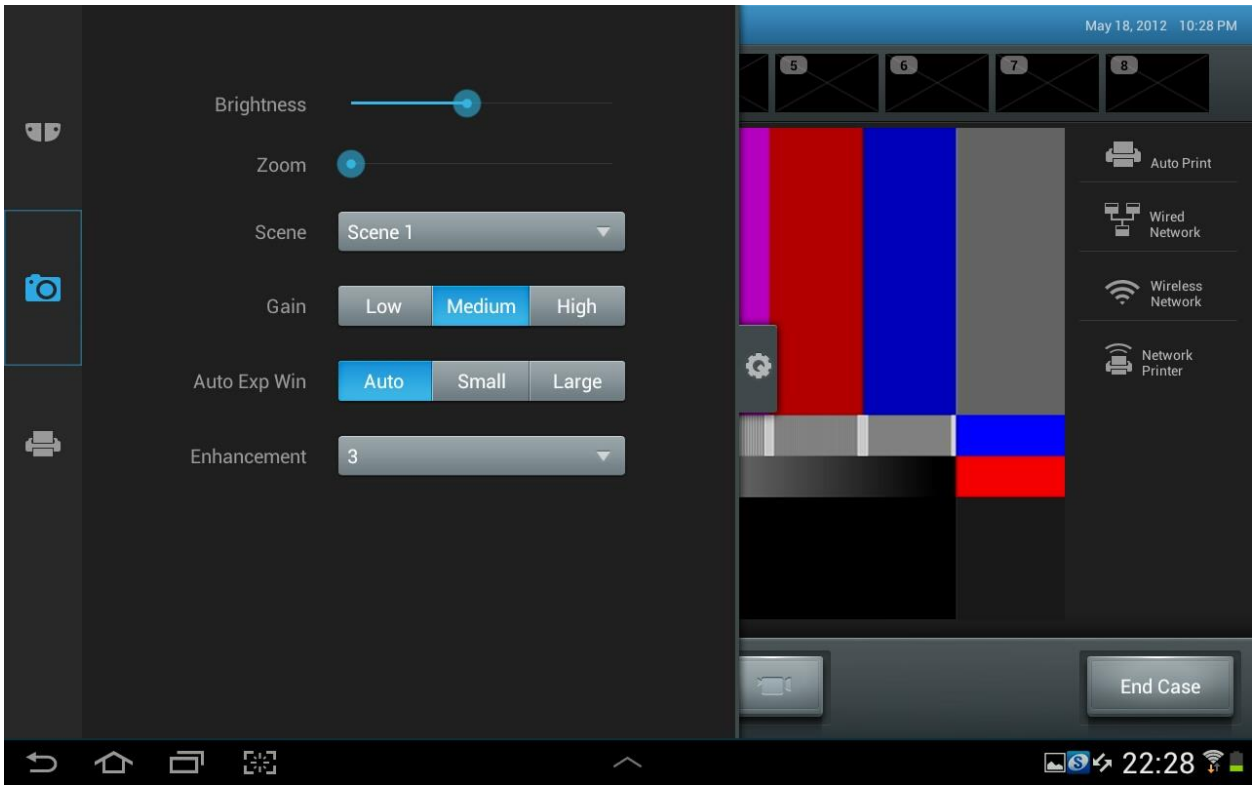


Figure 20-Camera Change; During Case

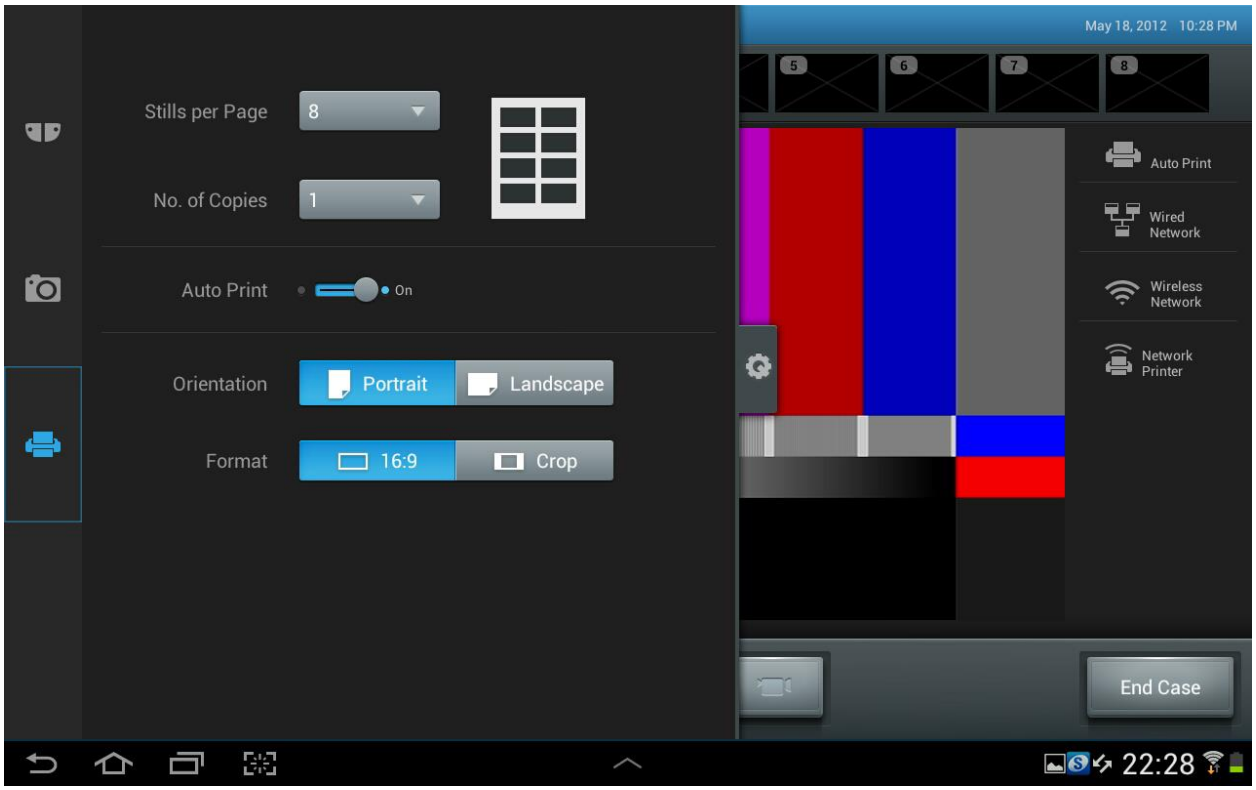


Figure 21-Print Changes; During Case

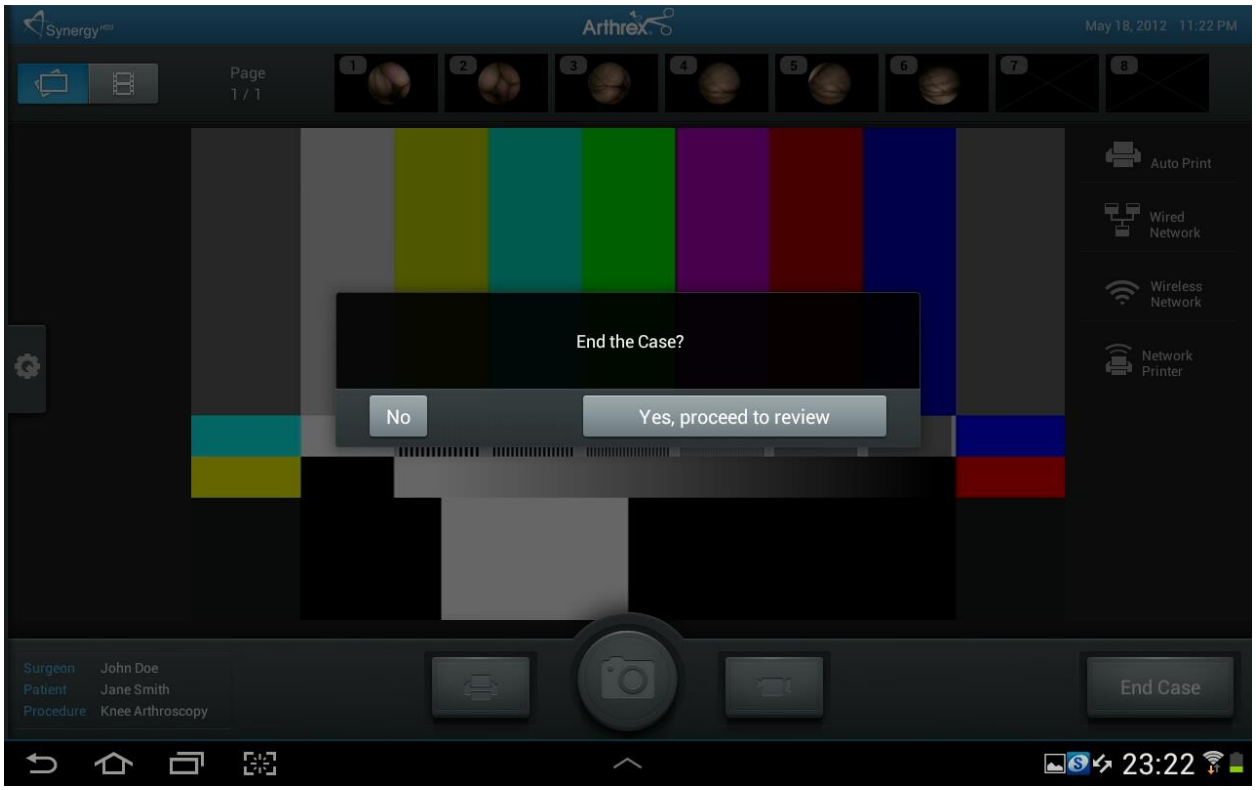


Figure 22-Ending a case

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^{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^{HD3} Initial Screen shown below in Figure 23

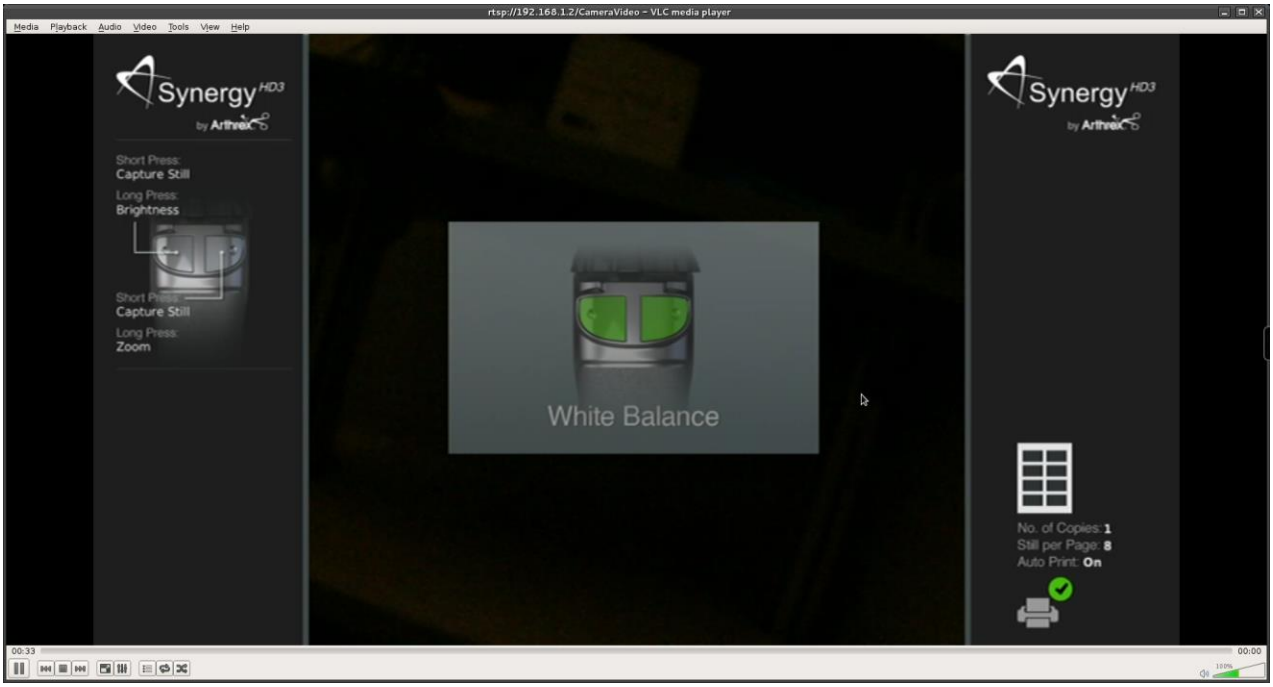


Figure 23- Synergy^{HD3} Initial Screen

3. The Synergy^{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.
6. Long Press on the RIGHT BUTTON will control Digital Zoom.
   - After a LONG PRESS on the RIGHT BUTTON, pressing the RIGHT Button will INCREASE ZOOM.
   - After a LONG PRESS on the RIGHT BUTTON, pressing the LEFT Button will DECREASE ZOOM.
7. The Synergy^{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^{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^{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.

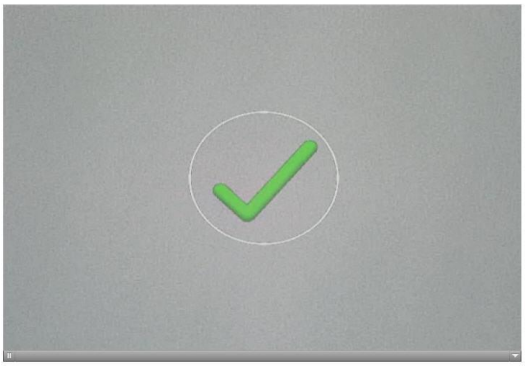


Figure 24-White Balance OK

    - 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

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

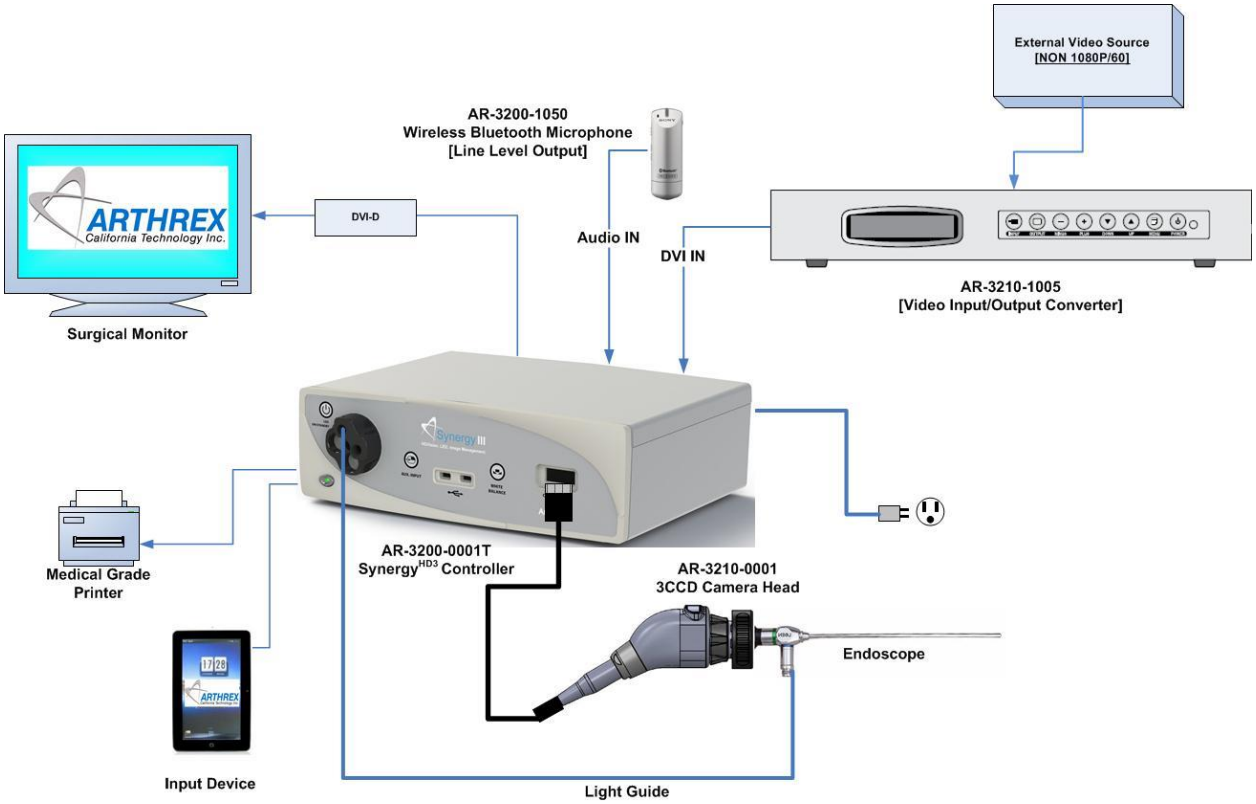


Figure 26-Picture in Picture System Set Up

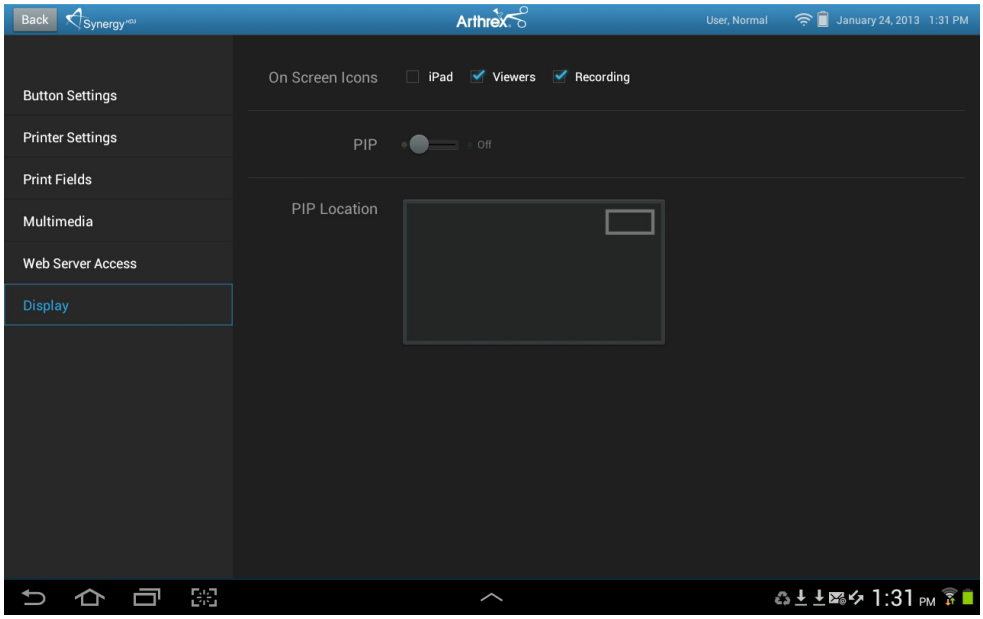


Figure 27-Tablet PIP Control

2.6.1 The Synergy HD3 Camera Controller [AR-3200 and AR-3200T] 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 Controller [AR-3200 and AR-3200T] 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 Controller'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 Controller 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 Theory of Operation

Figure 28 – Typical Synergy HD3 System and Peripherals

3.1 Scope

This document covers the theory of operation of the Synergy HD3 camera system. It includes the CCD camera Head, its connection and synchronization to the Camera Control Unit, and Video Processing to create High Definition video outputs.

This is a high level overview; refer to Software and Firmware Requirements documents for detailed descriptions of those operations.

3.2 General Design Goals

Considerations in the design of this system fall into one of two categories, Essential Performance and everything else.

3.2.1 Essential Performance

Should all else fail, it is essential that the camera system make a viable color image on the surgical monitor.
This is without undue interruption in image quality or disruption to the surgical procedure due to a malfunction.

In this regard, the signal path from CCD to video output can operate independently of any software or microprocessor functionality. This also includes control and operation of the integrated LED light source.

Additional Goals are:

- A camera system optimized for Endoscopic Surgery
- A synergy of High Definition Camera, LED light source, and Image Management functionality
- High quality and low noise video images
- Ease of operation and user interface
- Versatility for various procedures and environments
- Appropriate cost of manufacture
- Design Stability and ease of manufacture

The following design features are incorporated to achieve these goals:

- Progressive scan Three-Chip CCD and prism
- Powerful digital signal processing to enhance image quality
- No unit-to-unit adjustments or calibrations
- Interchangeable camera Heads without adjustment
- Exclusive use of differential signaling to and from camera Head
- Electrical isolation and safety independent of camera Head

3.2.2 Peripherals

The camera system is intended for use with a variety of peripherals as follows. See Figure 28 for a typical setup and also refer to the SynergyHD3 operating manual.

- Video monitors or recording devices utilizing DVI or HDSDI connections and a 1080p format
- Medical grade printers utilizing USB connections
- USB memory and mass storage devices
- Tablet computer devices as a user interface connected to a dedicated USB port
- Ethernet communication and networking
- Legacy accessory devices such as foot pedals
- Auxiliary DVI video input device for picture-in-picture functions

3.3 Camera Control Unit

The CCU is intended to sit on a rack outside of the patient's sterilized field. It provides power and connection to the Camera Head and all peripherals.

3.3.1 CCU Sections

There are three major sections within a CCU chassis. The power supply, Light Engine, and camera circuitry which consist of several boards mounted to a metal riser plate.

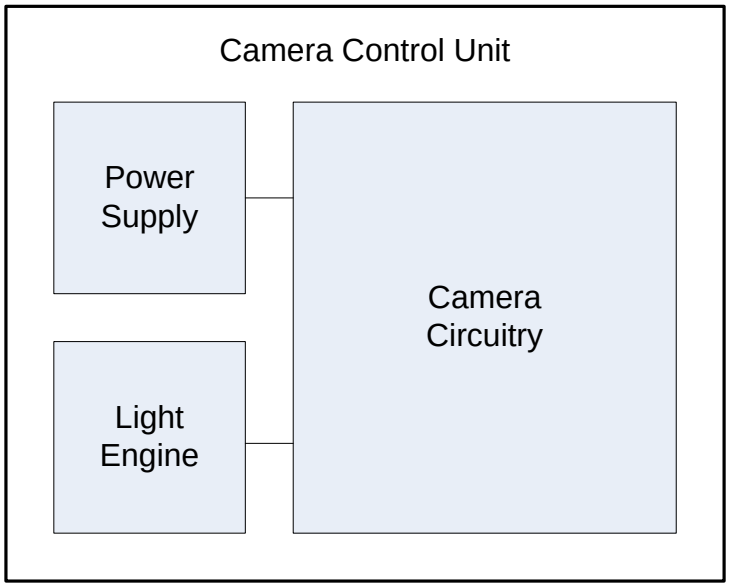


Figure 29 – CCU Sections

The power supply section accepts universal AC input voltages for use in international user environments. It provides +12V power for the entire system. This power is active whenever AC is supplied, and is then switched On and Off by the camera circuitry in response to the front power switch or software. Power defaults to On when AC is first supplied.

The Light Engine consists of a high power LED and related control circuitry. It is activated by camera control circuitry. This section also contains a cooling fan for the light engine and entire chassis. The Light Engine is defaulted to Standby when AC power is first applied to the CCU.

The Camera Circuitry handles all image processing and control functions, as described below.

3.3.2 Overall CCU Circuitry

Figure 30 depicts the camera circuitry with those blocks providing Essential Performance shown at its left. This is further discussed below, presented as a signal flow from CCD sensor to a video monitor.

Blocks depicted in the right side of Figure 30 are under software control. They provide for the user interface from a Tablet computer, recording of video stills and clips, and printouts. Refer to Software Requirements documents for further details.

Software can also overlay information onto the main video image, along with (picture-in-picture) video images from the DVI input port. This functionality is defeated should there be a software timeout error.

A membrane panel on the front of the CCU provides for control buttons and LED indicators. These are split between the essential section (for Light Engine control and White Balance) and the software section (for USB activity).

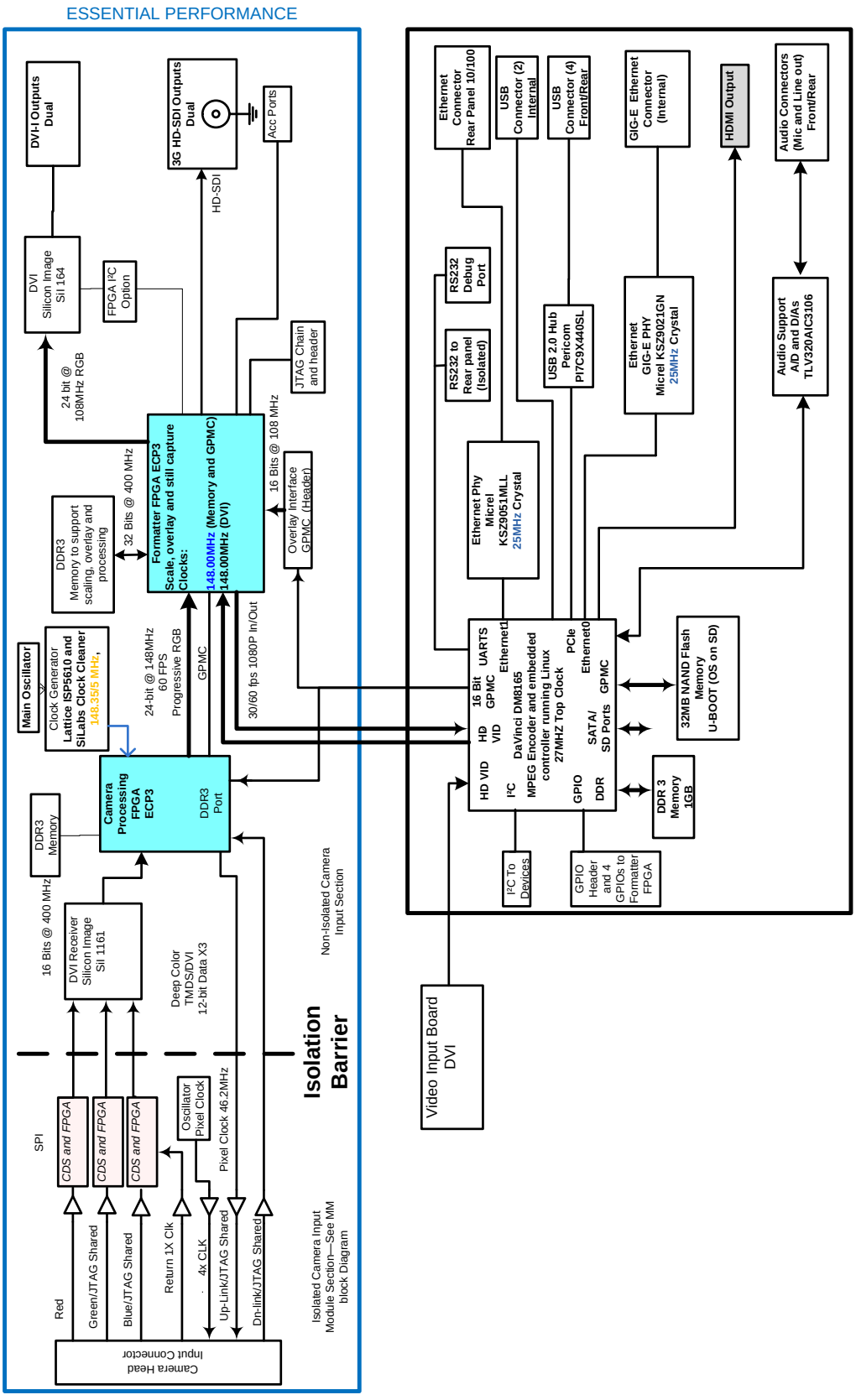


Figure 30 – CCU Circuitry Block Diagram

3.4 Camera Head

The Camera Head is a hand held device intended for use within the sterile field and contact with a patient. It connects to the front panel of a CCU through a cable. The grasping mechanism then couples to an endoscope and light guide for imaging.

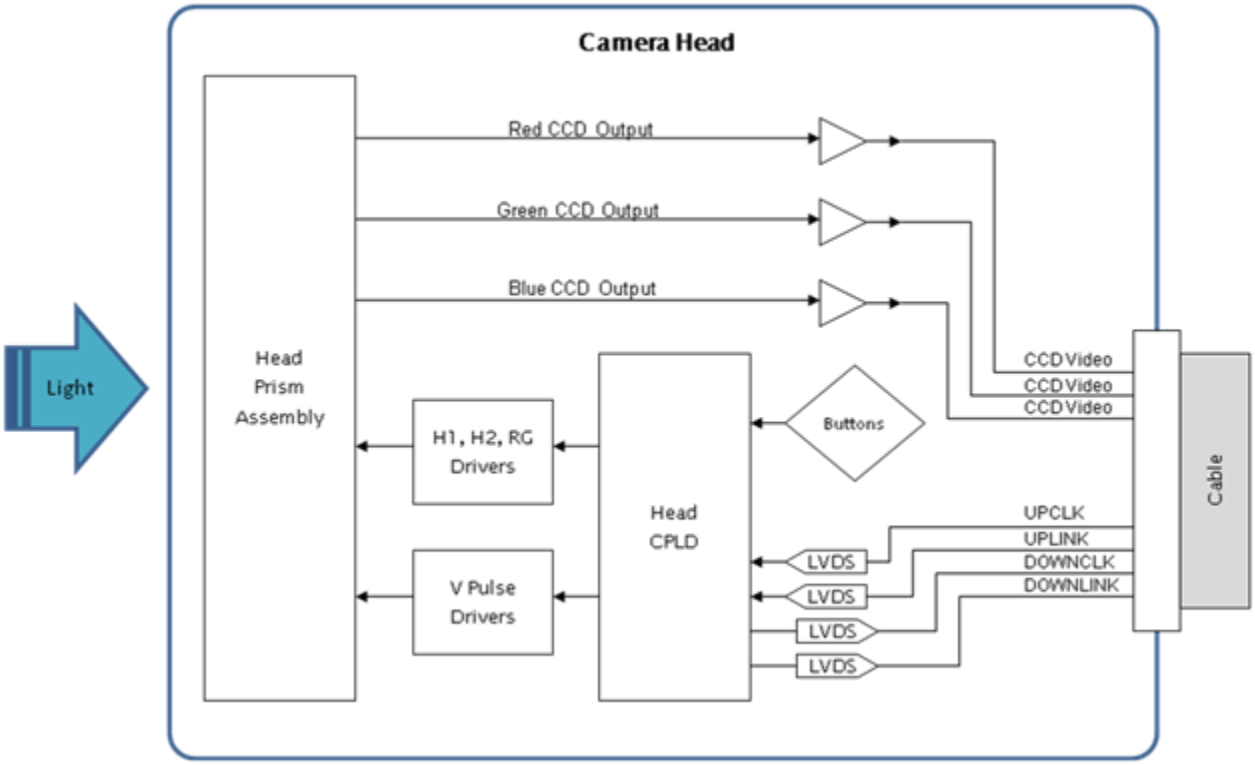


Figure 31 – Camera Head Circuitry Block Diagram

3.4.1 Power

Power is supplied to the Head in the form of four voltages which are further regulated within the Head. This secondary regulation offers enhanced noise reduction, immunity to EMI such as cautery noise, and correction for cable loss. Regulated voltages include +12V, +5V, +3.3V, and -5.5V distributed through several LDOs which also serve to separate noise sensitive areas of the circuitry.

Sequencing within he CCU insures that the negative supply is not applied until the Head is connected and operating, to avoid damage to the CCD. Sequencing within the Head also insures that the +12V supply is not activated until +3.3V is up and running, to protect the CCD. Plug contacts are also at staggered lengths to engage ground and power before signals.

3.4.2 Timing and Synchronization

The CCU provides a clock (UPCLK) and data signal (UPLINK) for synchronizing and communicating with the Head. UPCLK provides a means for qualifying the data in UPLINK as well as providing a master clock for the Head. UPLINK is a serial data stream containing vertical sync information for synchronizing the head. UPLINK also contains data for setting exposure time.

Both UPCLK and UPLINK are transmitted up the cable to the head via LVDS transmitters and twisted-pairs in the cable. The LVDS signals are received in the head with LVDS receivers and then sent directly to the head CPLD.

3.4.3 CCD Control

Three CCD sensors are attached to a prism assembly with color separation into Red, Green, and Blue spectrums. These sensors are driven by a complete timing generator within the CPLD. Horizontal signals are sent through drivers for H1, H2, HL, and RG pulses for each sensor. Vertical clocks V1, V2, V3, V4 and shutter pulses are sent through a shutter pulse driver for each sensor.

3.4.4 CCD Video Output

The analog signal from each CCD is then buffered with a wide bandwidth emitter follower. The buffered signal is AC coupled into a high speed differential amplifier which provides 2X gain. These differential CCD video signals are then driven down a twisted pair cable and received by the CCU.

3.4.5 Return Clock and Data

The Head provides the CCU with a clock (DOWNCLK) and data (DOWNLINK) for returned information. This DOWNCLK is at the CCD pixel rate and is used by the CCU circuitry to synchronize video data conversion. Data from the Head is encoded into the DOWNLINK path which is qualified by the DOWNCLK.

Both DOWNCLK and DOWNLINK are transmitted down the cable to the CCU via LVDS transmitters and twisted-pairs in the cable. The LVDS signals are received in the CCU with LVDS receivers and then sent directly to its FPGA.

3.4.6 Buttons

The Head CPLD detects the movement of two Hall-effect buttons through the use of an ADC converter. This position information is continuously sent down the DOWNLINK for interpretation by the CCU.

3.5 Head Interface

Within the CCU is a receptacle for the Head cable and interface circuitry for the Head. The Head Isolation Board provides this interface. Camera Heads are interchangeable and can be connected and disconnected at any time.

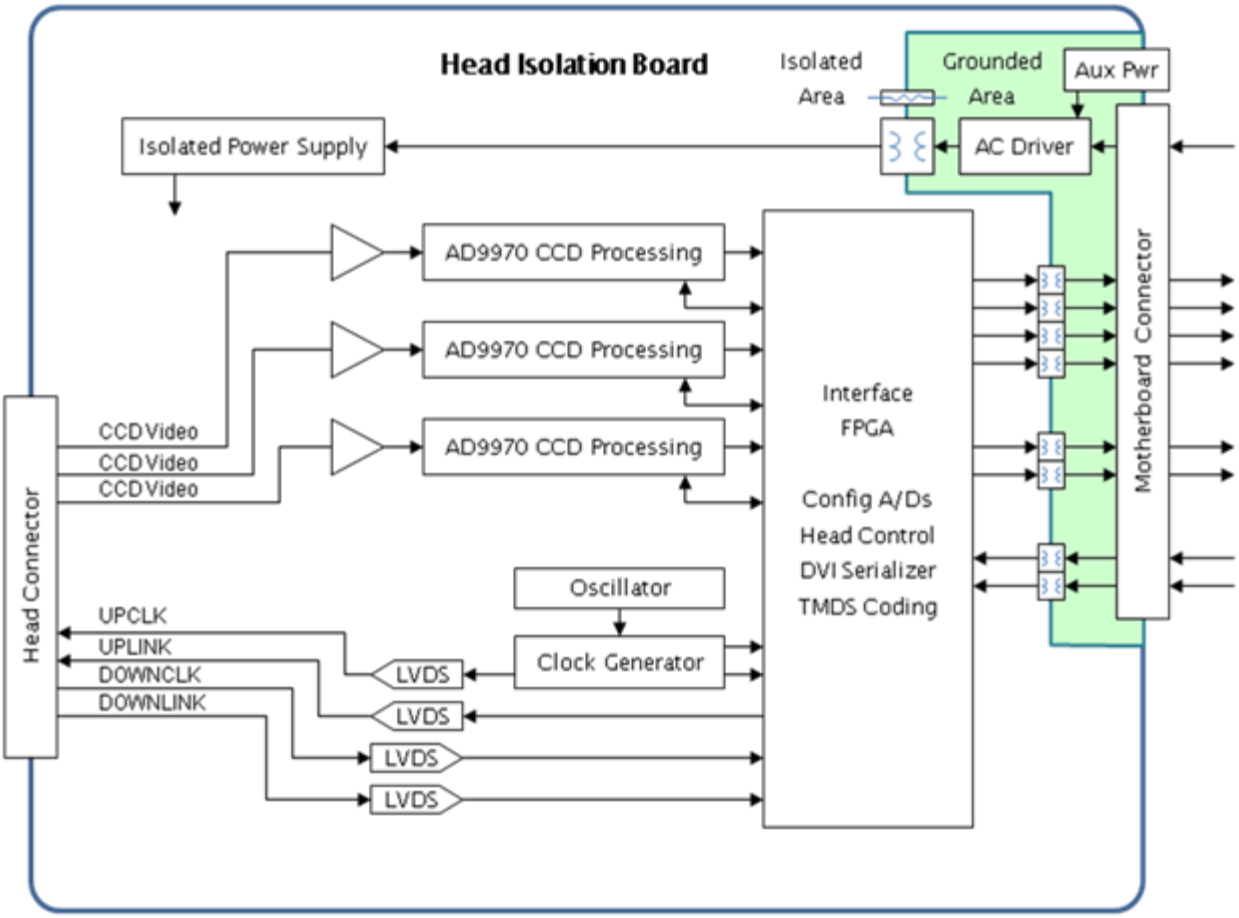


Figure 32 – Head Isolation Board Circuitry Block Diagram

3.5.1 Power

Regulated power is supplied to the head at voltages high enough to accommodate cable losses and LDO dropout voltages within the Head. The FPGA has control of the negative voltage rail which is held off until a DOWNCLK is detected.

3.5.2 Clocking

A crystal oscillator on the Isolation board provides the reference clock to a clock synthesizer chip. This synthesizer can then generate any desired frequency to drive the Head UPCLK and CCD. This UPCLK also is used to clock UPLINK data.

3.5.3 Data

Data and clock from the Head is received by differential receivers and sent directly to the FPGA circuitry.

3.5.4 Video Input

Differential video signals from the Head are received and converted to digital form by high speed ADC converters which incorporate Correlated Double Sampling (CDS) front ends. Each of the three colors is converted to two serial data streams and an associated data clock for conveyance to the FPGA. This FPGA includes a timing generator driving

the CDS with VD and HD pulses synchronized to the DOWNCLK. ADC conversion timing is driven directly by the DOWNCLK.

The ADC internally generates CDS video sampling pulses (SHP, SHD) which can be adjusted through its SPI interface to the FPGA.

3.6 Isolation

Patient safety is provided by an isolation barrier within the CCU. In the event that a patient or camera Head inadvertently becomes electrically energized, the CCU will not provide a path to ground. In the event that the patient becomes grounded, the CCU will not induce unsafe leakage currents to that ground.

3.6.1 Power

The isolation board provides up to 10W of isolated power for its circuitry and the Head.

3.6.2 Control

Communication with the remaining camera circuitry is isolated through data transformers. This provides synchronization and control of the Head and reading of button presses.

3.6.3 Video Data

Video signals from the Head receive preliminary processing within the isolation board Interface FPGA and is serialized for transmission across the isolation barrier through data transformers. This serialization utilizes DVI protocols with 12 bit deep color data encoding.

3.7 Motherboard

The CCU motherboard forms a hub of connectivity and control for the entire system, as shown in Figure 30.

3.7.1 Power

The single +12V power supplied to the motherboard is switched on and off in response to the front panel push button. It is then regulated and distributed further.

3.7.2 Video Processing

Video from the isolation board is received and deserialized on the motherboard and fed to the Video Processing FPGA.

A White Balance block provides independent gain for the red, green, and blue data values. The white balance system averages the red, green, and blue pixel values within a window in the center of the active image. The color with the highest average has its corresponding gain set to 1. The system then calculates the gain for the remaining two colors, which will each be greater than 1. This operation is performed in response to pressing the front panel White Balance button or a Head button so programmed.

A gamma correction block consists of three lookup tables for each of the RGB channels. Each table contains the same gamma function, which is designed to provide the most natural looking image without excessive gain in the dark areas of the image.

The RGB data is colorspace-converted to YCrCb for the purpose of edge enhancement. There are three components to the edge enhancement block. The luminance (Y) component is passed through a convolution kernel which has a zero DC component (Laplace). This kernel is designed for accentuating mid spatial frequencies. The resulting edge information is multiplied by a constant, and the result is added back in to the original Y data. The degree of edge enhancement is controlled by the multiplication constant.

3.7.3 Video Formatting

Data from the Video Processing FPGA is then sent to the Formatting FPGA to drive video outputs to a monitor. Data is passed through a scaler to expand the image size to 1080p.

The YCrCb data is serialized and passed to an HDSDI driver to provide two serial video outputs.

Data is converted back to RGB space and passed to the DVI Driver. The Formatter FPGA also provides the sync signals to the DVI driver. Two DVI drivers output the DVI signals to the DVI connectors on the back panel of the CCU.

The entire system frame rate, from the Head down, is synchronized to this DVI output formatting.

3.8 Programming

Proper functioning of the camera system relies on programming of software and firmware.

3.8.1 Head

When plugged into a special version of the isolation board, the camera Head goes into programming mode. The UPLINK and DOWNLINK lines are switched over to JTAG lines when +12V in not present. This allows for JTAG connection to the CPLD for programming.

3.8.2 Isolation FPGA

A JTAG cable must be connected to the isolation board during manufacturing in order to program its FPGA.

3.8.3 Motherboard FPGAs

A JTAG cable connected to the motherboard during manufacturing allows for programming both the Processor and Formatter FPGAs.

3.8.4 Software

An SD Card inserted into the motherboard provides software for the operation of its CPU.

4.0 Maintenance

Regular and proper maintenance of your Synergy^{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^{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.

4.1 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.

4.2 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.

4.3 Cleaning and Sterilizing

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

4.3.1 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.

4.3.2 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.

4.3.2.1 Automated Cleaning

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

1. Transfer the camera had 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.

Automatic Washer Cycle Definition			
Phase	**Recirculation Time (Minutes)**	**Temperature**	**Detergent Type and Concentration.**
Pre-Wash 1	02:00	Cold Tap Water	NA
Enzyme Wash	03:00	Hot tap water	Enzol® 1oz/gallon
Rinse 1	00:15	Hot tap Water 60^{o}C	NA
Drying	06:00	90^{o}C	NA

4.3.2.2 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.

4.3.3 Sterilization of the AR-3210 Camera Heads

Sterilization Protocols Validated **PRECAUTION:** After sterilization, set the AR-3210 Camera Heads aside for 15 minutes to allow equipment to cool before connecting to the CCU or attaching to a scope.	
Sterilization Protocol	**Details**
Steris Systems	AR-3210-XXXX Camera Heads are validated for Sterilization Assurance using the Steris systems listed below, and following the manufacturer's instructions. • V-PRO 1 Plus [Non-Lumen Cycle] • V-PRO maX [Non-Lumen Cycle] • V-PRO 1
Sterrad System 100S Sterrad System NX Sterrad System 100NX	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.

STEAM STERILIZATION PARAMETERS				
Method	**Cycle**	**Minimum Exposure Temperature**	**Exposure Time**	**Dry Time**
Steam (Wrapped)	**Pre-vacuum**	132° C (270° F)	4 Minutes	30 Minutes
Steam (Wrapped)	**Gravity**	132° C (270° F)	15 Minutes	30 Minutes
Steam (Un-Wrapped)	**Gravity**	132° C (270° F)	10 Minutes	NA

4.3.4 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.

4.4 Troubleshooting

Symptom	Possible Cause	Corrective Action
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.

Symptom	Possible Cause	Corrective Action
No video image on monitor.	• CCU and/or monitor are not ON and/or plugged in. • Equipment is not connected properly or cable(s) damaged. • Suspect camera head and/or cable. • Camera head cable connector not inserted correctly or completely.	• Plug CCU and/or monitor in and/or turn power ON. • Confirm cable connections and reroute video cables, if necessary per interconnect diagram. Check video cables for damage, replace as necessary. • 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. • Insert camera head cable connector completely into the console's camera head receptacle on the front panel. • Check monitor using color bars from the CCU. • Try the CCU on a different monitor.
Poor color reproduction.	• White Balance Issues.	• White Balance camera head • Check monitor settings using color bars from the CCU. • Try the CCU on a different monitor.

4.5 Recommended Annual Camera Control Unit Maintenance Requirements

Recommended Annual Camera Control Unit Maintenance Requirements

Test Type	Test Value
Ground Impedance	ZG < 100 mOhm from the ground pin on the power inlet module to the Camera Control Unit's exposed metal parts. *
Test Chassis Leakage Currents	IL < 100 uA in NORMAL Condition. IL < 500 uA in Single Fault Conditions [300 uA US deviation] *
Test Earth Leakage Currents	IL < 500 uA NORMAL Condition [300 uA US deviation] IL < 1 mA Single Fault Condition *
Test Dielectric Withstand	Test Line and Neutral to Ground @ V = 1500 V~, no breakdown *
*** See IEC 60601-1 for test methods.**	

5.0 Troubleshooting (Tests)

Required Equipment
Monitor and Power Cord
DVI or SDI Cable
Arthrex Tablet Kit (Part Number AR-3200-1004, AR-3200-1006, or AR-3200-1008)
Light Guide (Wolf)
Arthrex Camera (Part Number 983-0002-XX)
Printer and Power Cord
Printer Paper
Printer Ribbon
USB-A to USB-B Cord (for Sony Printer)
iPad with the most recent iTunes release of the Synergy HD3 Surgeon Application installed and iOS6
iPad to USB Cable
USB Stick
Endoscope
Ethernet Cable
Wireless Router and Power Cord

5.1 Physical Check

5.1.1 Place CCU on testing work bench

5.1.2 Check the CCU for external damage, including damage to the USB ports, the rear panel connections and the camera head receptacle.

5.1.3 Verify the LED ON/STANDBY and White Balance buttons can be pressed and will return to their original starting position.

5.2 CCU Set Up

5.2.1 Take a complete tablet set (Docking Station, Exoskeleton, Cord, and Tablet) and plug the USB Cord from the Tablet into the Tablet USB Port in the back of the CCU.

5.2.2 Plug the Printer USB Cord into the bottom USB port on the back of the CCU.

5.2.3 Plug a DVI, or SDI Cable into the back of the CCU. Make sure the monitor is correctly connected. Power the Tablet on and apply power to the CCU.

The printer icon on the monitor will show a green bar below. (Note: Older models will show a green circle with a black check mark in the circle.)

a. If the Tablet is in Kiosk Mode:

AR-3200-1008 (12" Tablet) only: If Tablet is in Kiosk Mode, double tap on the tablet screen (anywhere other than login fields) and tap 'Advanced Options'. A few options will display on the screen. Tap 'Toggle Kiosk Mode'. Enter 'synergy' as password.

All other Tablets: If tablet is in "Kiosk" mode press and hold the top left button on the tablet, then tap device options, enter "1111" for the pin, and tap "ok"

b. If the CCU is in Rescue Mode, indicated by alternately flashing blue front membrane LEDs, restart the CCU to get it out of Rescue Mode.

The following steps may also be used (for CCUs with v1.5 or v3.5 or previous software versions) to exit rescue mode via a wireless router. Ensure router is plugged in and on. Connect an Ethernet cable from the Ethernet port on the router to the Ethernet port on the back panel of the CCU. Navigate to the 192.168.1.2 URL on the iPad using the Safari browser. Tap the 'exit rescue mode' button. Wait for the message, "Rescue Mode disabled…" and restart the CCU. Confirm the system is not in rescue mode and is ready for use.

5.3 Verify Tablet Charges

5.3.1 Navigate to the home screen of the tablet, if you are not already there.

5.3.2 If not at home screen of the tablet, hit the home button in the lower left corner of the tablet.

5.3.3 Tap the "Settings" icon, which looks like a "gear wheel" or sprocket.

5.3.4 Scroll to and tap "Battery". Verify tablet is charging.

5.4 Force quit the Arthrex Controller Application manager

5.4.1 Scroll down to "Applications manager".

5.4.2 Tap "Applications manager".

5.4.3 Tap "Arthrex Controller" on the right side of the tablet.

5.4.4 Tap "Force stop".

5.4.5 Tap "OK".

5.4.6 Tap "Clear data"

.

5.4.7 Tap "OK".

5.5 Enter "Kiosk" mode

5.5.1 CCUs with 1.x or 3.5 or previous software versions

a. Tap the home button.

b. Tap the App icon (16 white squares).

c. Tap “KioskMode”.

d. Tap “OK”.

5.5.2 For all other CCUs

a. Tap the home button.

b. Tap the App Icon (16 white squares).

c. Navigate and select “Arthrex Controller” icon.

d. Double tap on the tablet screen (anywhere but the login fields).

e. Tap on “Advanced Options”.

f. Tap on “Toggle Kiosk Mode”.

g. Enter password, ‘synergy’.

5.6 Light guide and green LED check

5.6.1 Plug the light guide into the CCU. Press light guide button and make sure the light guide illuminates and a green LED light lights up on the button.

5.6.2 Verify a green LED light is lit on the power button.

5.7 Image Check

5.7.1 Install the endoscope onto Camera.

5.7.2 Attach Light Guide to Scope.

5.7.3 Insert the Camera Head plug into the CCU.

5.7.4 Verify a live picture is present on the monitor.

5.8 Connectivity Check

5.8.1 Restart the CCU.

5.8.2 Press and hold power button on CCU for about five seconds.

5.8.3 Press the power button to turn on.

5.8.4 Verify the Tablet reconnects to the CCU.

Note: Tap the tablet to reconnect if necessary.

5.8.5 Verify banners appear on both side of the monitor after approximately one minute from power on.

5.9 Test Case Check

5.9.1 Verify the “Cases” screen is shown.

5.9.2 Tap the “Add New Case” button.

5.9.3 Tap surgeon drop down bar and select “Surgeon”.

5.9.4 Tap procedure drop down bar and select any procedure.

5.9.5 Tap Patient “First Name” and insert the serial number of the CCU.

5.9.6 Tap “Start” and “Start” again.

5.9.7 Tap the “gear wheel” on the left side.

5.9.8 Tap the printer icon.

5.9.9 Select “No. of Copies” to 1.

5.9.10 Tap the “gear wheel” icon again to remove preference settings screen.

5.10 White balance CCU

5.10.1 Make sure the Light Engine is on.

5.10.2 Take a white object and place it in front of camera.

5.10.3 Click one of the camera buttons to white balance.

5.10.4 Verify, “White balance OK”.

5.10.5 Take one still by pressing the left camera button one time.

5.10.6 Take one video, approximately ten seconds in length, by pressing the right camera button to start, and again to stop.

5.10.7 Verify the video and still are present in the above thumb nails on the tablet
Note: Tap picture icon to view still.

5.10.8 Tap the “End Case” button in the lower right corner.

5.10.9 Tap “Yes, proceed to review”.

Note: The captured still will be auto printed at this time (print may take up to one minute to start). Verify that the CCU serial number is on the print.

5.10.10 Insert a USB stick and an iPad cord (connected to an iPad) in the front USB ports on the CCU.

Note: Tap “Trust” on iPad if prompted.

5.11 On the tablet, tap “Export” and two options appear

5.11.1 Select the USB icon and verify the LED above the USB stick on the CCU begins to blink.

5.11.2 When the LEDs stop blinking, remove the USB stick and verify that there is one JPEG, one MPEG4, and one PDF file on the USB stick.

5.11.3 Tap “Export” button again, and this time select the “Apple” icon.

5.11.4 Verify export progress bar completes.

5.11.5 If application isn’t running, navigate to the home screen of the iPad and select the Arthrex Surgeon icon.

5.11.6 On the Patient List, select the CCU Serial Number.

5.11.7 Verify the one still image and the video are present on iPad.

5.12 Tap “Finish Review” on Tablet

5.13 Delete the finished case in the archive file

5.13.1 Tap User Normal.

5.13.2 Tap the folder icon in the upper right corner, next to the “Add New Case” button.

5.13.3 Type password: synergy (if prompted).

5.13.4 Tap “OK” (if prompted).

5.13.5 Click on the case and two buttons appear on the right side, a “Review” and trash can icon

5.13.6 Select the trash can icon

5.13.7 Tap “Yes” to confirm delete.

5.13.8 Tap Log Out.

5.14 Final Check

5.14.1 Power cycle the CCU, by holding down the power button 3-5 seconds and make sure the tablet becomes paired with the CCU. Wait for the banners to be displayed on the monitor, which indicates software is loaded, for each power cycle. Tap the tablet to reconnect if necessary

5.14.2 Disconnect the iPad.

5.14.3 Shut down the CCU.

5.14.4 Shut down the Tablet by pressing and holding power button on tablet

5.14.5 Unplug the power cord, printer, video cable, tablet cable, light guide, and Camera from the CCU.

6.0 Technical Information

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

Table 3: Safety, EMC and Regulatory Requirements

Parameter	Parameter Value	
System Classification	FDA Class	Class II
	EU Class	Class I
	Health Canada Class	Class II
Safety Certifications	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] • CAN/CSA-C22.2 No. 60601-2-18:2011 [IEC 60601-2-18 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 EN 60601-1-2 Class A
Safety Certification Marking		
CE Marking	CE Marking for MDD 93/42/EEC	

Table 4: Safety, Classifications

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

Table 5: Specifications

Parameter	Parameter Value	
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	3.125” [L] x 1.5” [W], x 2.0 [H]

Parameter	Parameter Value	
	Approximately:	8 cm [L] x 4 cm [W] x 5 cm [H]
Camera Head Weight	**AR-3210-0001** Approximately: 18.7 ounces **C-MT Heads** Approximately: 16 ounces	
Transport & Storage Conditions	Ambient Temperature: -40°F to 122°F [-40°C to 50°C] Relative Humidity: 10% to 90%, non-condensing Atmospheric Pressure: 500 hPa to 1060 hPa	
Operating Conditions	Ambient Temperature: +50°F to 95°F [10°C to 35°C] Relative Humidity: 30% to 75%, non-condensing Atmospheric Pressure: Altitudes ≤ 3000 m	

Table 6: Light Source Specifications

Parameter	Parameter Value	
LED Light Source Specifications	Light output	≥ 1350 Lumens
	Color Temp	7000 K Nominal
	LED Life	> 30,000 hours
	Light Guide Port	Wolf™ Standard
	Light Guide Port Turret	ACMI™ Standard, Storz™, Wolf™ and Olympus™

Table 7: DICOM Specifications

DICOM Statement
DICOM Compatible with installation of AR-3200-1020 DICOM Key

7.0 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 EN 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 Electro-magnetic 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.		
Emissions Test	**Compliance**	**Electromagnetic environment- guidance**
RF emissions CISPR 11	Group 1	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.
RF emissions CISPR 11	Class A	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: **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. .
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Table System Cables				
Type	**Use**	**Shielded?**	**Ferrite?**	**Maximum Length**
Power Cord	Supply Line Power to the Box	No	No	2 M
BNC to BNC	Composite Video Out to Monitor	Yes	No	1.8 M
4 Pin Mini DIN	Y/C Video Out to Monitor	Yes	No	1.8 M
DVI	DVI Video Out to Monitor	Yes	No	1.8 M
3 pin mini Stereo	Accessory Port	Yes	No	1.8 M
Ethernet	CCU to Computer	Yes	No	5 M
USB	CCU to Printer	Yes	No	1.8 M

IEC 60601-1-2 Table 2 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.			
Immunity Test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic discharge [ESD] IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered by synthetic material the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV differential mode ± 1 kV for input / output lines	± 2 kV differential mode ± 1 kV for input / output lines	Mains power should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode. ± 2 kV common mode.	± 1 kV differential mode. ± 2 kV common mode.	Mains power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U^T [> 95% dip in U^T] for 0.5 cycle. 40% U^T [60% dip in U^T] for 5 cycles. 70% U^T [30% dip in U^T] for 25 cycles. < 5% U^T [> 95% dip in U^T] for 5 seconds.	< 5% U^T [> 95% dip in U^T] for 0.5 cycle. 40% U^T [60% dip in U^T] for 5 cycles. 70% U^T [30% dip in U^T] for 25 cycles. < 5% U^T [> 95% dip in U^T] for 5 seconds.	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.
Power Frequency [50/60 Hz] magnetic field. IEC 61000-4-8	3 A/m	3 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.			

IEC 60601-1-2 Table 4

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.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	**V1=3 Volt**	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 $d = [3.5/V1]\sqrt{P}$ = 1.17 $\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	**E1= 3 V/m**	$d = [3.5/V1]\sqrt{P}$ =1.17 $\sqrt{P}$ 80 MHz to 800 MHz $d = [7/E1]\sqrt{P}$ = 2.33 $\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer and d is the recommended separation in meters [m]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less that the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection 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.

IEC 60601-1-2 Table 6

Recommended separation distances between portable and mobile RF communications equipment and the ARTHREX HD3 Video System

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.

Rated maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz $d = [3.5/V1]\sqrt{P}$	**80 MHz to 800 MHz** $d = [3.5/E1]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [7/E1]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.14	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.3

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.

8.0 APPENDIX [SW Version access]

ACCESS to SW Version on Synergy HD3

1. Login to the Android application

Figure 33-Logging on to Android

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

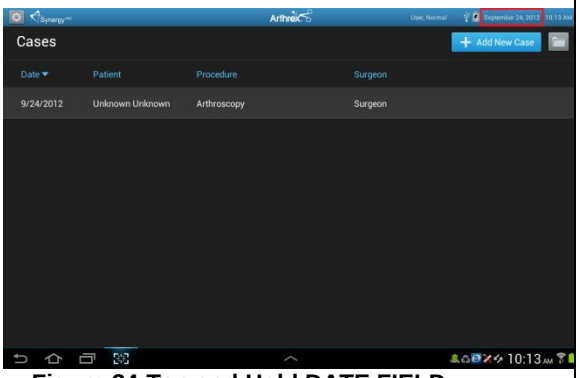


Figure 34-Tap and Hold DATE FIELD

3. Tap About

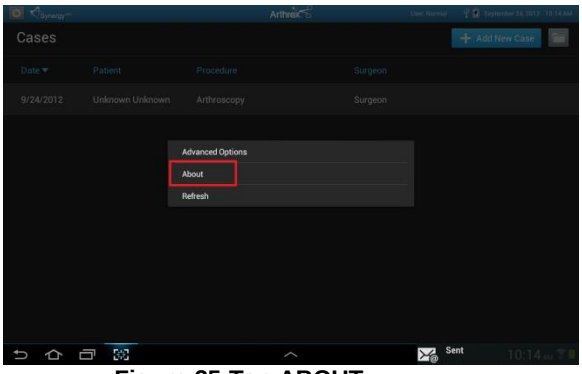


Figure 35-Tap ABOUT

4. Tablet and CCU software version are displayed

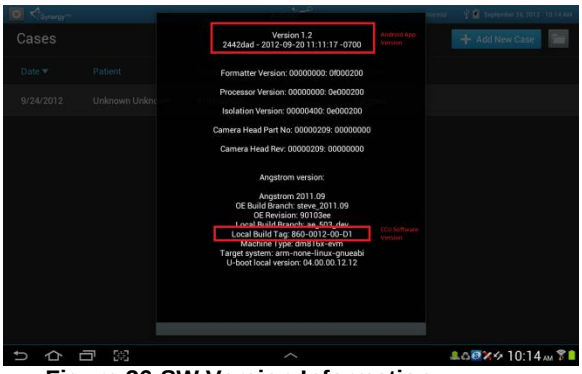


Figure 36-SW Version Information

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