



Arthrex Synergy^{UHD4™} / Synergy^{ID™} Camera Head

Instructions for Use Manual

Warnings/Cautions



WARNING: Prior to use, Read this Manual carefully and become familiar with the operation of the device and the accessories before use during surgical procedures.



WARNING: Prior to use, Read either the entire Arthrex, Inc. Synergy^{UHD4™} System [950-0047-XX] or Synergy^{ID™} System [DFU-0332-XX] Instructions for Use manual before use during surgical procedures.



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Camera Head Overview

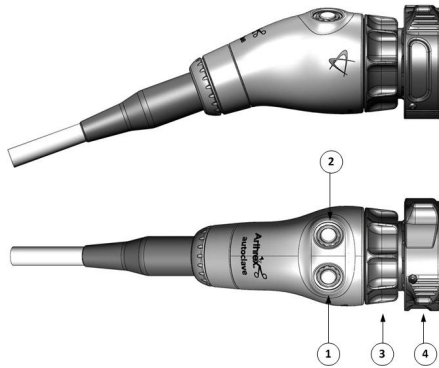


Figure 1- AR-3210-0023 [4K Synergy^{UHD4} Camera Head, autoclavable]



Figure 2-AR-3210-0018 [HD, Synergy^{UHD4} Camera Head, autoclavable]



Figure 3-AR-3210-0025 [4K Synergy^{UHD4} C-Mount Camera Head, autoclavable], AR-3210-0028 [4K Synergy^{UHD4} C-Mount Camera Head w/20 foot cable, autoclavable] and Not Pictured AR-3210-0026 [4K Synergy^{UHD4} C-Mount Camera Head, 0 Degree, autoclavable]



Figure 4-AR-3210-0021 [HD Synergy^{UHD4} C-Mount Camera Head, autoclavable], and Not Pictured AR-3210-0022 [HD Synergy^{UHD4} C-Mount Camera Head, 0 Degree, autoclavable]

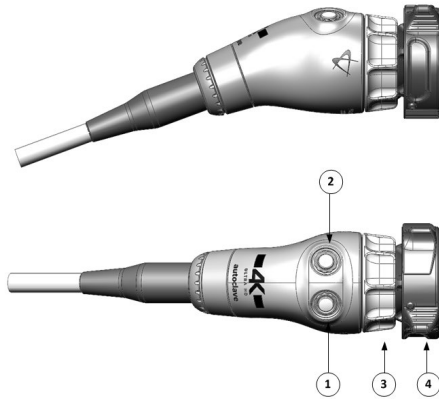


Figure 5- AR-3210-0029 [4K Synergy^{UHD4} Broadband Camera Head, autoclavable]



Figure 6- AR-3210-0030 [4K Synergy^{UHD4} C-Mount Broadband Camera Head, autoclavable]

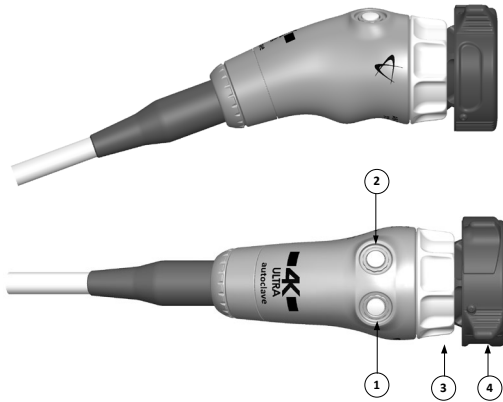


Figure 7- AR-3210-0031 [4K Ultra Synergy^{UHD4} Camera Head, autoclavable]



Figure 8- AR-3210-0032 [4K Ultra Synergy^{UHD4} C-Mount Camera Head, autoclavable]

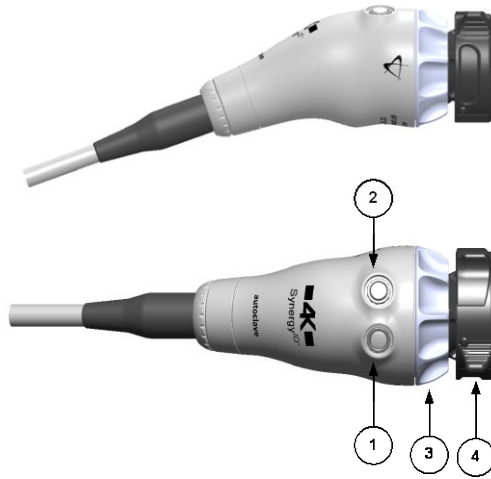


Figure 9- AR-3210-0033 [4K Synergy^{ID} 4MOS Camera Head, autoclavable]

AR-3210-XXXX Camera Head

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 [Integrated Optics Only]**— Used to sharpen, or bring into focus, the image detail.
4. **Grasping Mechanism [Integrated Optics Only]** — Accepts and locks into place the compatible scope. DIN 58105 compliant endoscope interface.

AR-3210-XXXX Camera Head Synergy^{UHD4/ID} Firmware Compatibility

CAUTION:

- **Some AR-3210-XXXX camera heads are only compatible with specific Synergy^{UHD4/ID} firmware versions as shown in the following table. Attempting to use these camera heads with incompatible Synergy^{UHD4/ID} firmware may fail to produce an acceptable quality video output on the surgical display.**

Camera Head	Compatible Synergy ^{UHD4/ID} Firmware Version
AR-3210-0029	850-0026-01-A or higher
AR-3210-0030	850-0026-01-A or higher
AR-3210-0031	850-0026-02-B or higher
AR-3210-0032	850-0026-02-B or higher
AR-3210-0033	850-0026-03-A or higher
All other camera head models mentioned in this IFU	All versions

Determining the Firmware Version of the Synergy^{UHD4/ID} System

Firmware can be verified on the **About** screen, which is accessed by double tapping on the open blue area of the home login screen and tapping the About option. The firmware version is listed under Video FPGA as seen in the image below.

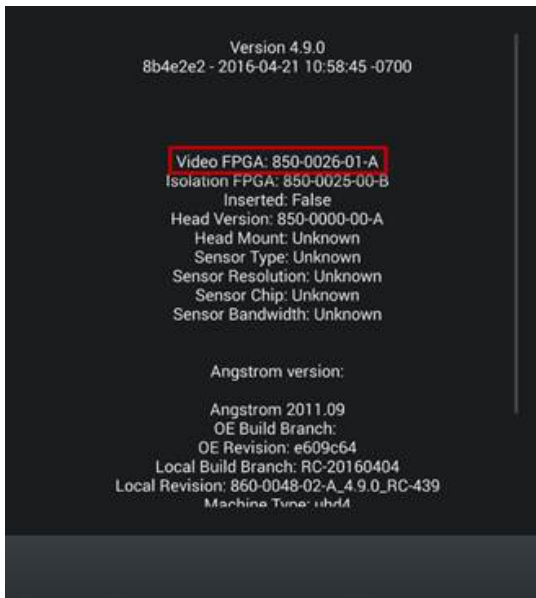


Figure 9- Synergy^{UHD4/1D} Firmware Version

Cleaning the AR-3210-XXXX 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 ultrasonic 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.

Automated Cleaning

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

1. Transfer the camera head into the washer for processing.
2. Make sure that the camera head has been securely fixed to the unit's trays or baskets. Make sure that the camera head does not touch other instruments.
3. Do not overload the washer.
4. Remove the camera heads immediately after the automatic procedure has stopped.
5. Set up and run 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°C [140°F]	NA
Drying	06:00	90°C [194°F]	NA

6. 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.**
7. After cleaning, inspect the camera head assembly and camera head cable for cleanliness and damage.
8. **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.
9. 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.

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 Enzo[®], 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

Sterilization of the AR-3210-XXXX Camera Heads



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.

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

DEVICE STERILIZATION METHODS

The following cycles have been validated for AR-3210-XXXX Camera Heads to provide a sterility assurance level (SAL) of 10^{-6} .

System	Cycles
STERIS® Systems	<ul style="list-style-type: none">V-PRO® 1 Low Temperature Sterilization System [Standard Cycle] V-PRO® 1 Plus Low Temperature Sterilization System [Lumen and Non-lumen Cycles] V-PRO® maX Low Temperature Sterilization System [Lumen, Non-lumen and Flexible Cycles] V-PRO® 60 Low Temperature Sterilization System [Lumen and Non-lumen Cycles]
STERRAD® Systems	<ul style="list-style-type: none">STERRAD® System 100S [Short Cycle] STERRAD® System NX [Short Cycle] STERRAD® System 100NX [Standard Cycle]

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.

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