



Instructions for Use: Fiberscope and LED Light Source

Brand Name of Product	Fiberscope, LED Light Source
Generic Name of Product	Fiberscope
Product Code Number(s)	FBR-001, FBR-002, FBR-ULB-100, ULB-35I, 5163-100, FPH-001, PHN-001, FBR-BC, FBR-LS.
Intended Use	Used for visual inspection of items with an LED light source for use as illumination for instruments.
Range of Applications for Product	Provides illumination for fiberscopes during visual inspection.
Key Specifications of Product	<p>Fiberscope</p> <ol style="list-style-type: none"> 1. Eyecup Working Length- Model C2-350: 35cm (13.8”), Model C1-800 80cm (31.8”). Standard eyecup for viewing directly or connecting to a B-mount camera. 2. Eyepiece- Converts the image for the fiber optic section of an instrument to an image usable to the eye. 3. ACMI Light Source Connector- Point of entry for light used for illumination utilizing a standard ACMI male light source connector. 4. Integral Hub- The hub combines the eyepiece, ACMI light connector, and the instrument shaft into an integrated unit. 5. Flexible Working Length- Portion of the Fiberscope that is inserted into an instrument during visual inspection. 6. Distal Lens- The objective lens on the distal end of the instrument. <p>LED Light Source</p> <ol style="list-style-type: none"> 1. Input: 100-240 V, 50/60 Hz, 1.4 A max 2. Output: +12, 5.0 A 3. Recommended PS: UAI Part: UPS-00 4. Voltage: +12 DC; 14V DC maximum 5. Current: 3.4 amp 6. Battery: UR battery rated at 12V/9Ah or equivalent with a minimum 3.5 amp current limit rating. 7. Color Temperature: 5700 K-6500 K nominal 8. Power: 35 Watts 9. Average LED Life: 50,000+ Hours <p>Light Cable</p> <ol style="list-style-type: none"> 1. 10 ft. (3 meters) lengths, 0.3 in. (8 mm) approximate diameter. 2. Light Source Connector: <ul style="list-style-type: none"> ● ACMI 3. Instrument Connector: <ul style="list-style-type: none"> ● AMCI Female 4. Fiber Bundle: <ul style="list-style-type: none"> ● 1.0 mm diameter bundle ● High performance glass fiber

Shipping & Storage	
Shipping Conditions & Requirements	N/A
Storage Conditions	N/A
Packaging Contents	N/A

Instructions for Using Product	
Description of Use(s)	When illumination is required for visible inspection of instruments.
Preparation for Use	<p>LED Light Source</p> <ol style="list-style-type: none"> 1. The light source power switch should be in the OFF position. Plug the external 12vdc power supply into the 12vdc connector. Fig. 1

2. Plug the external power supply cord into AC power outlet.
3. Plug the fiber-optic bundle into the light port and connect the opposite end to the equipment being used. **Fig. 2**

Light Cables

1. Attach the ACMI female connector to the Fiberscope.
2. Connect the light cable into the light port.
3. To prevent the user from being exposed to the light, make sure the connections to both the light source and instrument are made before turning on the light source.

Diagrams (drawings, pictures)

Light Source

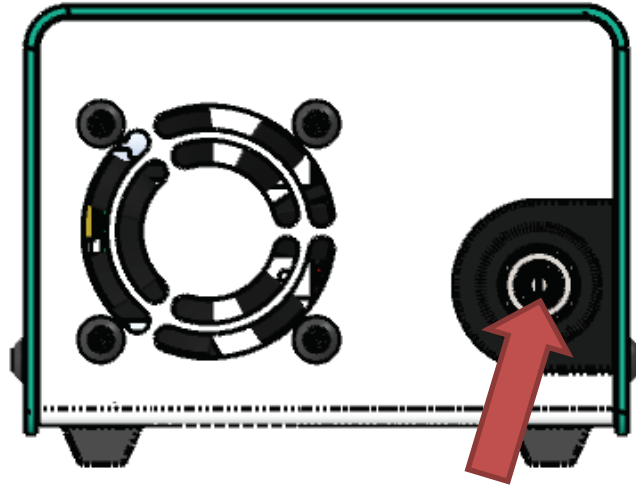


Figure 1 Back View 12vdc Power Plug



Figure 2 Fiber-Optic Bundle

Attaching the Quick Adapter to the Cell Phone



Figure 3



Figure 4



Figure 5



Figure 5



Figure 6

Steps for Use of Product

Light Source

1. Turn the power switch to the ON position. LED indicator light will turn on when light source is powered on.
2. Adjust the intensity control to set the light intensity to the desired light output level.
3. Be sure to turn the unit to the OFF position when not in use.

	<ol style="list-style-type: none"> 4. Do not obstruct airflow paths. This device is designed to have proper forced air-cooling paths to maintain thermal stable operation. 5. Place in an area that provides adequate ventilation to prevent unit from overheating. Do not drape the LED Light Source with cloth or objects restricting airflow. 6. The airflow outlets are shown below with red arrows. ¼-20 UNF mount stud located in the middle of the box bottom side. <p>Fiberscope</p> <ol style="list-style-type: none"> 7. Attach the 1mm light cable to the ACMI connector. 8. Attach the camera to eyecup. 9. Grasp the Fiberscope near its end and gently insert into the instrument. 10. Adjust light source for ideal lighting. 11. Use short advancements, while keeping your fingers close to the instrument’s opening. 12. View through the eyepiece or camera monitor while inserting into the instrument. 13. If an obstruction hinders the path of the Fiberscope, then gently attempt to manipulate or rotate the instrument to avoid the obstacle. 14. Once the Fiberscope has reached the end of the area you are inspecting, retract it slowly while looking for debris or damage. <p>Attaching the Quick Adapter to the Cell Phone</p> <ol style="list-style-type: none"> 15. Loosen the grippers on the phone adapter to accommodate the size of the cell phone. Fig. 3 16. Position the phone holder near the bottom of the cell phone and tighten the grips to hold the mobile phone to make sure it is securely in place. Fig. 4 17. Align the eyepiece of the adapter with the picture window on the back of the mobile phone and attach the eyecup of the Fiberscope into the back of the adapter. Fig. 5 18. Turn counter-clockwise to tighten the eyecup to the lens. This will allow you to see the image on the phone screen and visually inspect from the screen. Fig. 6 <p>Using Mobile Phone and Phone Adapter with Fiberscope</p> <ol style="list-style-type: none"> 19. To enhance the image on the phone screen, take your index finger and thumb and slide them apart to expand the image, and slide index finger and thumb close together to decrease the image. 20. To further improve the zoom capabilities, download a zoom enhancer app to your smartphone such as “Magnifier Camera”.
Interpretation of Results	N/A
Contraindications of Test Results	N/A
Documentation	N/A
Special Warnings and Cautions	<p>Fiberscope</p> <ul style="list-style-type: none"> ● Do not attempt to service the Fiberscope. ● Do not bend the Fiberscope into a sharp bend, or this will damage it. ● Avoid looking directly at the emitted light or directing it toward others. ● Do not apply excessive force to the Fiberscope, as it will cause damage. ● If there is resistance or an obstruction hinders the path look through the eyepiece and gently attempt to manipulate or rotate the instrument to avoid the obstacle. You can withdraw a short distance and try advancing again. ● Avoid rubbing the Fiberscope against sharp edges, or this will damage it. ● Do not use caustic or harsh detergent to clean Fiberscope. The optical surfaces will be damaged from exposure to aggressive cleaning agents. ● Do not reprocess using steam sterilization, autoclave, or dry heat. ● The optics of the Fiberscope will be damaged or degraded if left exposed to cleaning or disinfecting solutions for extended periods of time. Do not exceed the disinfectant solution manufacturer’s recommended exposure times for cleaning and disinfecting. ● Do not allow liquids to dry on the lens of the distal tip. This will leave deposits that obscure the image.

	<ul style="list-style-type: none"> Do not process the Fiberscope or accessories in an ultrasonic cleaner, washer sanitizer, washer pasteurizer, washer sterilizer, steam autoclave, or in any method with a processing temperature above 60°C (140°F). <p>LED Light Source</p> <ul style="list-style-type: none"> There are no serviceable or replacement parts. Do not attempt to dismantle box or remove top cover. Only qualified personnel should make electrical inspections and repair of the LED Light Source. The high intensity light at the front of the LED Light Source and at the tip of the fiber optic bundle will create high temperatures and bright light. Avoid direct viewing or contact to minimize risk or injury. Plug the fiber optic bundle into the LED Light Source before turning the power on to prevent temporary blinding. Do not use the LED Light Source directly in medical applications. Allow unit to cool before handling. Use in a horizontal position for operation. Any changes or modifications made to this device that are not expressly approved by the manufacturer may void the user’s authority to operate the equipment. Provide adequate ventilation to prevent overheating. DO NOT IMMERSE or store liquids above or on the LED Light Source. Do not operate without cover in place. Do not obstruct the airway paths (sufficient cooling is required). Protection provided by the equipment may be impaired if not used in accordance with the manufacturer’s recommendations. <p>Light Cables</p> <ul style="list-style-type: none"> Do not disconnect the light cable from the light source while it is turned on. Intense light can be emitted from the light source. The connector attached to the light source can become hot. It is advised to allow a cooling period of 5 minutes after the light source is turned off before removing the connector. Do not attempt to service the light cables, unless instructed to do so by the manufacturer. The user cannot service any part of the light cables. Do not pull, stretch, or kink the light cables. Do not allow the ends to strike the floor or other hard surfaces. Do not use or store the cables in a tightly coiled diameter.
Disposal	

Reprocessing Instructions	
Point of Use	N/A
Preparation for Decontamination	N/A
Disassembly Instructions	N/A
Cleaning – Manual	<p><u>Fiberscope</u></p> <p>Cleaning Between Uses:</p> <ul style="list-style-type: none"> Use a pre-moistened cleaning wipe. See Chemical Compatibility Chart for approved cleaning agents: click here. Follow the wipe manufacturer’s IFU. <p>For Thorough Cleaning:</p> <ul style="list-style-type: none"> See Chemical Compatibility Chart for approved cleaning agents: click here Follow the cleaning agent manufacturer’s instructions for use. Turn OFF and then disconnect the light source from the Fiberscope prior to cleaning. Place the Fiberscope and the components in a bath of enzymatic detergent that has been prepared according to the manufacturer’s instructions and follow the detergent manufacturer’s recommended soaking cycle. Use clean, non-linting wipes that are saturated with the detergent solution to wipe down all surfaces of the Fiberscope and the LED. Use soft brushes with the detergent solution to remove any residues from areas that cannot be reached with gauze pads.

	<ul style="list-style-type: none"> ● Rinse Fiberscope with copious amounts of cool (NOT COLD) flowing utility tap water for 45 to 60 seconds. ● Rinse all components of the LED light source adapter in cool (NOT COLD) flowing deionized water for 45 to 60 seconds. ● Dry off the Fiberscope with a non- linting wipe or sponge. ● Blot dry the components of the LED light source adapter using non-linting wipes. <p><u>LED Light Source</u></p> <ul style="list-style-type: none"> ● Turn the LED Light Source off and unplug the power cord from both the wall outlet and the rear of the unit. ● Wipe the external surfaces clean with a cloth dampened with mild soap and water. DO NOT IMMERSE. ● Wipe the power cords clean with a clean, dampened cloth with mild soap and water. DO NOT IMMERSE. DO NOT RECONNECT WET. ● Do not plug the power source into a wall outlet until it is thoroughly dry. ● It is recommended to periodically clean the reflective optical surface near the LED. <p><u>Light Cables</u></p> <ul style="list-style-type: none"> ● Turn off the power to the light source and disconnect the light cable from the light source and instrument. Be careful because the light cable connector at the light source end may be hot. ● The light cable is now ready for the cleaning and sterilization procedure. ● Rinse the light cables in lukewarm tap water. Use a mild enzymatic detergent to remove any resistant debris. Do not use oily or highly concentrated soap solutions. ● Dry with a non-linting wipe. The fiber bundle exposed at each connector should be wiped dry. <p>For Chemical Compatibility Chart click here:</p>
Cleaning – Automated	N/A
Disinfection	<p><u>Fiberscope</u></p> <ol style="list-style-type: none"> 1. Select only the disinfecting solutions listed in the Chemical Compatibility Chart. 2. Follow all recommendations regarding health hazards, dispensing, measuring and storage from the manufacturer of the cleaning and disinfecting agents. 3. Soak the Fiberscope and LED light source adapter components in the selected disinfecting solution per the solution manufacturer’s instructions for high level disinfection. 4. Rinse the Fiberscope with critical (sterile) water, again following the instructions of the disinfecting solution manufacturer. 5. Rinse the LED with copious amounts of sterile water while following the instructions of the disinfecting solution manufacturer. 6. Dry with a non-linting wipe. Ensure that the distal tip and proximal end are dried. Blot the LED dry with a non-linting wipe. <p><u>LED Light Source</u></p> <ul style="list-style-type: none"> □ Use a soft cotton Q-tip dipped Isopropyl Alcohol and wipe the reflective optical surfaces and allow to thoroughly dry prior to use. <p><u>Light Cables</u></p> <ol style="list-style-type: none"> 1. The light cables may be disinfected with 2% glutaraldehyde solution and soak (refer to the solution manufacturer’ instructions for the recommended disinfection time). 2. After soaking, rinse in sterile water to remove the soaking solution. <p>For Chemical Compatibility Chart click here:</p>
Drying	<ul style="list-style-type: none"> ● Blot dry components using sterile towel. ● Blot dry the LED with a clean and sterile cloth. ● Dry with a soft, non-linting wipe or sponge.

	<ul style="list-style-type: none"> • Air drying can leave deposits on optical surfaces, which could result in a degraded image.
Maintenance, Inspection, and Testing	<p>Fiberscope</p> <ul style="list-style-type: none"> • Inspect the Fiberscope for signs of wear or damage. Inspect the external surfaces and accessories to assure they are smooth and free of any protrusions or sharp edges. • Inspect image quality by viewing an image with the Fiberscope in a room with bright lighting and it will show a grid pattern created by the fiber optics. Defects appear as a discernible image and complete darkness. • The illumination capability of the Fiberscope can be verified by attaching it to an LED Light Source. The distal tip of the Fiberscope will cast visible light from its tip and can be observed on any surface to which it is directed. • Normal illumination will disperse a uniform circular field of light onto the target. • Optic fibers can become stressed and eventually damaged with repeated use. Replace the Fiberscope when 10% of the image or illumination has been degraded or lost. <p>LED Light Source</p> <ul style="list-style-type: none"> • If unit stops functioning under certain conditions, the overvoltage protection of the power supply might automatically turn the power supply output and the unit off to prevent damage to the unit. • The power supply must be disconnected from the main power to reset this fault condition. • If the unit suddenly turns itself off following these steps on how to fix this issue: <ol style="list-style-type: none"> 1. Manually turn the unit off. 2. Unplug the power from the main voltage (120V/230V). 3. Wait at least 5 seconds and plug the power supply back into the main voltage. 4. Turn the unit on. <p><u>Troubleshooting LED Light Source</u></p> <ul style="list-style-type: none"> • Turn OFF light source by rotating intensity control knob counterclockwise until the switch clicks off. • Completely disconnect power supply from both light source and the main source (power plug into an AC outlet). • Wait for at least 5 seconds until power supply discharges as observed on the power supply LED indicator will turn off. • Reconnect the power supply to both AC to main voltage and DC connector to light source. • Turn ON light source by rotating the knob clockwise until it clicks on and LED indicator light is on. • Rotate knob to increase light output intensity to desired output. <p>Light Cables</p> <ul style="list-style-type: none"> • Inspect the light cable prior to each use. It is important to check the fiber bundle where it appears at the end of each connector. • Any film or debris left after cleaning must be reprocessed. • Overheating of the light source connection could occur if large amounts of debris or heavy films obscure the fiber bundle. • Sterilized cables can be cleaned with a sterile wipe or sterile water rinse, and then drying. • Non-sterile cables can be cleaned with tap water and a dry wipe. • It is important to keep the connector clean that attaches to the light source. The metal surface around the fiber bundle should be kept clean and have a bright mirror-like appearance. • If it becomes discolored, the connector may become too hot during use. • The cable should be replaced or repaired if the discoloration cannot be removed.
Reassembly Instructions	N/A
Packaging	N/A
Sterilization	<p>Fiberscope</p> <ul style="list-style-type: none"> • Ethylene Oxide Gas (EtO) • STERIS V-PRO®, STERIS SYSTEM 1E®

	<ul style="list-style-type: none"> ● STERRAD® 100S, 50, 200, NX, 100NX Systems (tested up to 20 cycles) <p>Light Cables</p> <ul style="list-style-type: none"> ● ETO sterilization ● Steam Sterilization ● STERIS® ● STERRAD® <p>For Chemical Compatibility Chart click here:</p>
Storage	Keep stored at a temperature of +5°C to +40°C and the humidity at 0 to 100% (condensing).
Additional Information	Facility should perform a multidisciplinary risk assessment to determine the requirements and frequency for cleaning, disinfection, and sterilization. This assessment should be based upon clinical use of the items and reprocessing instructions.
Related Healthmark Products	Optical Inspection Products
Other Product Support Documents	ProSys™ Brochure, ProSys™ Price List
Reference Documents	N/A
Customer Service Contact	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com

2021-05-17 Suzanne Latta