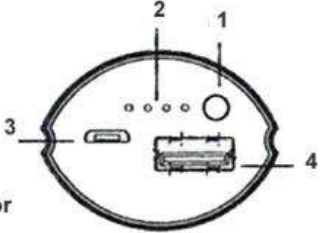


Brand Name of Product	EndoPro-Cam®
Generic Name of Product	Endoscopy Camera System
Product Code Number(s)	EPRO-001SK, EPRO-001, EPRO-CPL28, USAF-1951, EPRO-EPS, EPRO-LS, EPRO-BATT
Intended Use	Designed for evaluating the condition of rigid endoscopes, the EndoPro-Cam® is a portable endoscopic video system providing 1080p high resolution HD imaging that assists with inspection of rigid scopes for damage, residual soil and debris.
Range of Applications for Product	Designed for evaluating the condition of rigid endoscopes.
Key Specifications of Product	<p>EndoPro-Cam®</p> <ul style="list-style-type: none"> • HD imaging • Power- DC 5V • Display- 4.3” 800*480 TFT-LCD • Light weight ergonomic design • 1080p resolution for optimal viewing • Still image: <ul style="list-style-type: none"> ○ JPG 1920*1080, 1280*720, 640*480 • Video capture: <ul style="list-style-type: none"> ○ Recording format: MOV 1920*1080, 1280*720, 640*480 ○ Function: Snapshot, video recording, double display • Industry standard coupler • 2 rechargeable lithium batteries- up to 1000 charges and discharge cycle • Mini HDMI cable • Mini USB 2.0 / Video out / TF card • 32GB Micro SD card- TF card up to 32G • 10W portable LED light source with battery and charger • EndoPro-Cam® camera stand • Coupler <p>EndoPro-Cam® Power Bank</p> <ul style="list-style-type: none"> • Model-Victor K1 • Capacity- 5000mAh • Input- 5V/2A (MAX) • Output- 5V/2A (MAX) • Size- 1.50 x 3.97 x 1.16in • Weight- 120g <p>C-Mount Coupler</p> <ul style="list-style-type: none"> • Rear adapter (camera end) • Focusing ring • Endobody clamp • Endobody (scope end)

Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions	<p>EndoPro-Cam®- Store at room temperature: 20°C-60°C. Do not dispose of the protective box or any other shipping materials. These items should be retained for future storage or transport of the equipment.</p> <p>EndoPro-Cam® Power Bank- Store at room temperature. Avoid excessive heat and humidity. Storage temperature- 20°C – 60°C.</p> <p>AED-C-Mount Coupler- Transport and Storage Conditions- Temperature: -10-50°C, Relative Humidity: 10-75%, Atmospheric pressure: 700-1060 hPa.</p>

	Operating Conditions- Temperature: 10-30°C, Relative Humidity: 30-75%, Atmospheric Pressure: 700-1060 hPa.
Packaging Contents	N/A
Shelf Life	N/A

Instructions for Using Product	
Description of Use(s)	Designed for evaluating the conditions of rigid endoscopes.
Preparation for Use	<p>Charging Instructions for the power bank</p> <ol style="list-style-type: none"> 1. Plug the micro-USB port into the power bank (3) and connect the USB port (4) to the AC charger (not included), then start charging. 2. LED light flashing indicates charging, LED steady light indicates fully charged (2). Power bank charge time: Approximately 3 hours by 2A input. <div style="text-align: center;">  <p>1 Power Button 2 Power Level Indicator 3 Micro USB Input 4 USB Output</p> </div> <p>Power Levels Display-</p> <ol style="list-style-type: none"> 3. 4 lights on: 75%-100% 4. 3 lights on: 50%-75% 5. 2 lights on: 25%-50% 6. 1 light on: 0-25% <p>Tray Pattern Card</p> <ol style="list-style-type: none"> 1. Attach the tray pattern card to the stand.
Diagrams (drawings, pictures)	N/A
Steps for Use of Product	<p>Using EndoPro-Cam®</p> <ol style="list-style-type: none"> 1. Insert the SD card in the SD card slot. 2. Connect the hand piece to the external power source. The controller will turn on automatically. 3. Press the POWER button for 3-5 seconds to turn the power off (unplugging the external power source will automatically shut down the controller). 4. Below is a description of the buttons on the hand piece and screen display of the EndoPro-Cam®. Fig. 1, 2, 3

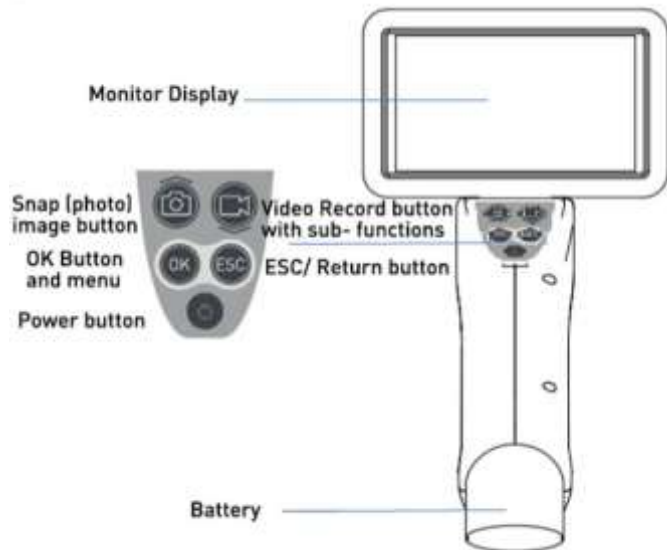


Figure 1

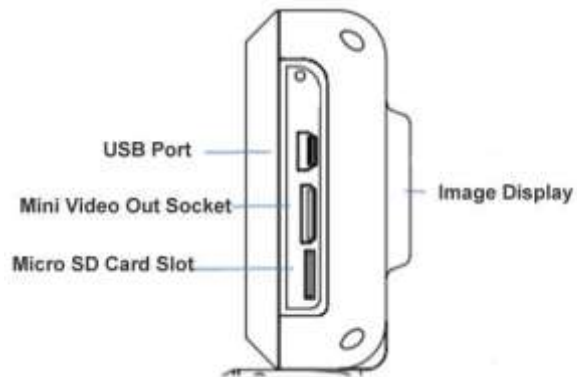


Figure 2

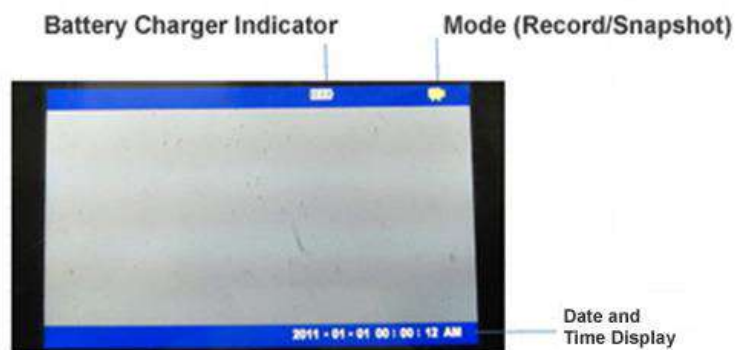


Figure 3

Menu Setup

5. Press the Power Button to turn the unit on. Ensure that status screen shows up briefly and clock is running. **Fig. 4**

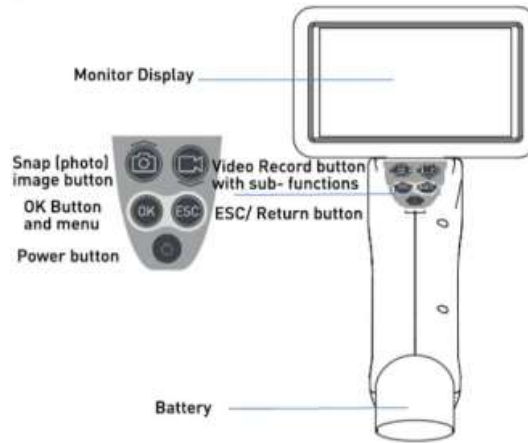


Figure 4

6. Press the OK button to access the menus. Use the UP or DOWN button to select the menu item.
7. Press OK to confirm.
8. The options displayed in the MENU are as follows: **Fig. 5**
 - STORAGE DEVICE MANAGEMENT
 - DATE/TIME SETUP
 - RESET/RESOLUTION CONFIGURATION
 - STORED IMAGE/VIDEO FOLDER/FILE NAVIGATION
 - VIDEO OUTPUT



Figure 5

9. Navigate to DELETE ALL in the menu, press the OK button. **Fig. 6** Select YES or NO using the UP or DOWN buttons. **Fig. 7** Confirm with the OK button.

Storage Device Management



Figure 6



Figure 7

Note: Stored files (images, videos) will be deleted from the SD card.



Date/Time Setup

10. Select the DATE and TIME ICON on the screen of the unit.
11. Adjust the date and the time and the AUTO POWER OFF Time as show in the below picture. **Fig. 8**

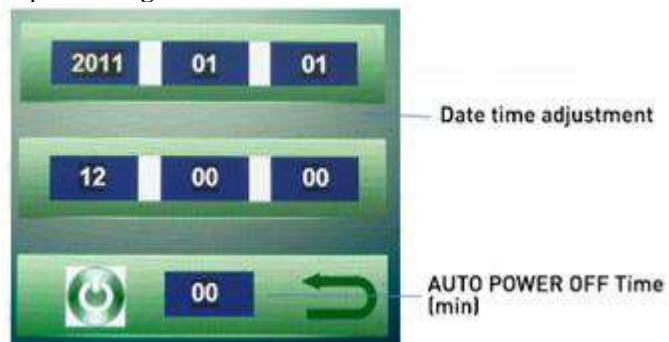


Figure 8

12. After entering the DATE/TIME SETTING, press the PHOTO and VIDEO button to adjust the date and time.
13. Press OK to move to the next column.
14. Return to the main screen to display the adjusted DATE/TIME.
15. AUTO POWER OFF TIME (min): press the camera/video button to adjust the automatic shutdown time (unit: minute).



Video Format

16. This function allows live images seen by the probe to be displayed on a TV screen or beamer through a transmission line (Pre-set NTSC format). **Fig. 9**



Figure 9



RESET/RESOLUTION CONFIRGURATION

- 17. Factory Default: Reset to default setting. **Fig. 10**
- 18. Resolution: Select to choose the preferred resolution.
- 19. Return: Go back to the previous screen.
- 20. Display the F/W version.

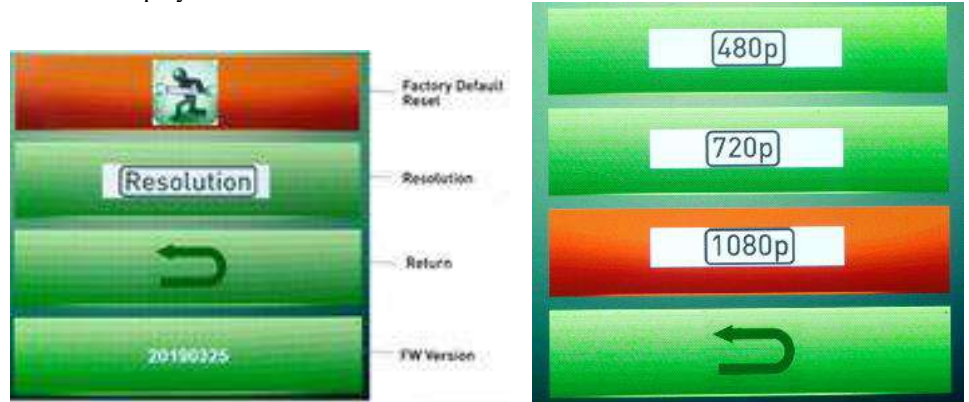


Figure 10

STORED IMAGE/VIDEO FOLDER/FILE NAVIGATION

- 21. Use this menu to view stored videos and images on the controller. **Fig. 11**



Figure 11

- 22. Navigate to video or image file, choose the file you want to view, press OK to open the video or image.

Left is the video storage image; right is the photo storage image. **Fig. 12, Fig. 13**



Figure 12

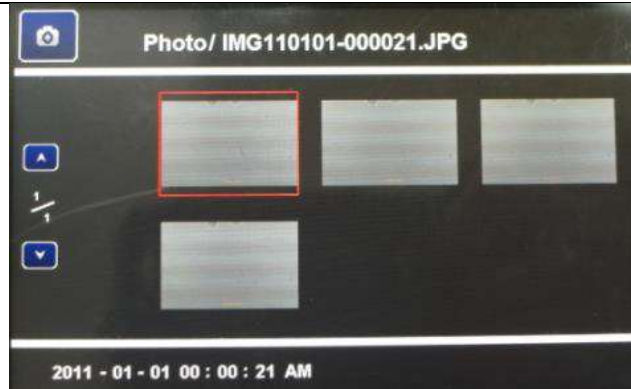


Figure 13

23. To delete a video or image, navigate to the file and choose DELETE. Hold the OK button for three seconds, a deleting window will appear, and press OK to delete the file. **Fig. 14.**



Figure 14

VIDEO OUTPUT

24. Connect the video output cable to the mini video output port, the image below will appear. **Fig. 15**



Figure 15 AV Output (Single Display): Same operation method

NOTE: Controller and AV Output displays simultaneously (Dual Display): under dual display mode, only snapshot and recording are functional, other functions are disabled.

Portable LED Light Source

25. Inspect for cleanliness. If there is visible soil, clean/disinfect as described in the cleaning and disinfection sections below.
26. Prior to use, inspect the outer surface of the light source and the endoscope for damage.
27. Hold the light source so that the main body fits comfortably in one hand, allowing easy manipulation of the adapter.

28. To attach to an endoscope, remove any adaptors from the light post by turning clockwise.
29. Turn on the light source by pressing the switch.
30. At the completion of use, turn the light source off by depressing the switch.
31. Remove the light source from the endoscope by rotating the light source counterclockwise.
32. Avoid leaving the light source on for extended periods of time when not in use, as this will drain the battery unnecessarily.

Light Source Battery and Charger

33. The lithium-ion battery provides approximately 45 minutes of continuous operation when a new battery is fully charged.
34. Once a charged battery is inserted into the light source body, replace the battery cap by screwing the cap clockwise until a tight seal is made.
35. To remove the battery, simply unscrew the battery cap and turn the light source upright until the battery falls out. (Please take care not to let the battery fall to the floor or onto a hard object, which could damage the battery).
36. The light intensity switch controls the ON/OFF.
37. The battery cap seals the battery and electronics within the control body.

AED C- Mount Coupler

Parts of the coupler:

1. Rear adapter (camera end)
2. Focusing ring
3. Endobody clamp
4. Endobody (scope end)



38. Gripping the rear adaptor, screw the coupler into the camera head until it forms a tight seal. **Fig. 16**



Figure 16 Connecting the coupler and camera head

39. Rotate the endobody clockwise until the endobody clamp is aligned with the camera as shown in Figure 17.

Caution: Rotating the endobody counterclockwise may cause the coupler to unscrew from the camera head.

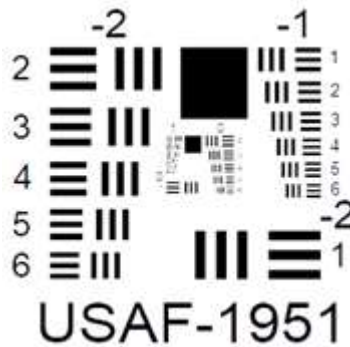


Figure 17 Aligning the endobody clamp with the camera

40. Depress the endobody clamp with your thumb and insert a scope into the endobody.
41. Release the endobody clamp to secure the scope.
42. With the camera console turned on, rotate the focusing ring to establish a short focus.
43. To remove the coupler, grip the rear adapter and unscrew the coupler from the camera head.

Checking the rigid scope for damage

44. With the rigid scope attached to the EndoPro® Cam point the distal tip of the scope downward to face the test pattern card.
45. Check for colors that are showing on the display monitor from the Color Bar.
46. Make sure the lines on the test pattern card are visible and not blurry when looking at the display monitor from the Resolution Target.
47. Look for damage such as cracks, cloudy vision shown on the lens of the rigid scope, residual soil and debris.



Resolution Target



Color Bar

Interpretation of Test Results

N/A

Contraindications of Test Results

N/A

Documentation

N/A

Special Warnings and Cautions

EndoPro-Cam®

- Do not modify or disassemble the unit.
- Do not use this item in explosive atmospheres.
- Keep the EndoPro-Cam® out of reach of children.
- Do not look directly into the objective lens at the end of the insertion tube, eyesight may be seriously damaged.
- Do not forcibly bend, twist or elongate the insertion tube.
- Strong impact on the device may result in the breakage of the objective lens (made of glass) at the tip of the insertion tube.
- Do not use or store the EndoPro-Cam® at a temperature higher than 60°C or lower than -20°C.
- Do not use the EndoPro-Cam® in the direct sunshine.
- Store the EndoPro-Cam® in a dry and adequately ventilated environment.

- Keep the EndoPro-Cam® away from acid or alkaline solutions, oil or petrol, and do not use it in an atmosphere containing their vapors.
- Do not remove the SD Memory Card while data is being saved to the card. This may cause the data to be lost or the card to be damaged.

EndoPro-Cam® Power Bank Battery

- Use caution when handling, using and testing batteries.
- Do not short circuit, crush, drop, mutilate, puncture, apply reverse polarity, expose to high temperature or disassemble. Misuse or abuse could cause physical injury.
- Read and understand all warnings, cautions, and directions completely and carefully before use. Failure to do so may result in serious injury.
- Do not use if the individual package is opened or if the package or the product is damaged. Carefully inspect the product for damage or defects prior to use.
- Disposal for the EndoPro-Cam® power bank battery:
 - The rechargeable battery contains the following components that must be disposed of in accordance with local regulations: Lithium-Ion cells.
- When the battery is worn out, insulate the connector terminals with adhesive tape or similar material before disposal. Misuse or improper disposal of the battery pack may cause the battery to become very hot, ignite, or explode.
- When disposing of a battery pack, contact your local waste disposal service provider regarding local restrictions on the disposal and recycling of batteries.
- Do not expose to high temperature.
- Do not put into water or get wet.
- Please do not disassemble or reinstall.
- Please place this product away from children.
- Before using this product, please check the voltage specification requirements.
- Unplug this product when not in use.
- Do not cover or package the power bank with paper or other items during charging.
- If this product becomes smelly, noisy or overheats, please place it away from person(s) and other items immediately. Contact Healthmark Customer Care.

Portable LED Light Source

- Do not soak and do not autoclave.
- This equipment is not suitable for the use in the presence of flammable mixtures.
- In order to avoid potential safety hazards, the user of the LED light source should consult the manuals of all medical electrical equipment used in conjunction with this light source. If the light source is used with high frequency equipment, and the user should consult the manuals of all devices for safe operating voltage levels.
- Please be sure to handle the light source with care at all times. The electrical and optical components can be damaged by physical trauma, extreme temperatures, or fluid invasion into the light source.
 - The light source is intended for use by persons thoroughly trained in the techniques that employ a light source.
 - Avoid direct viewing of the high intensity light at the front of the portable light source. Always connect and disconnect the light source with the light turned off.
- Avoid storing or using the light source in areas of heavy traffic where the light source may sustain physical damage.
- Avoid immersing the light source in liquid.
- Do not attempt to disassemble the light source in any way. There are no user-serviceable parts - disassembly will void all warranties.
- Avoid looking directly into the light source when it is on.

Light Source Battery and Charger

- Do not incinerate the battery.
- Do not expose the battery to high temperatures above 122°F/50°C.
- Do not disassemble the battery.

	<ul style="list-style-type: none"> • Do not short circuit the battery • The battery should be removed if the equipment is not likely to be used for some time. • Do not expose the charger to fire, water or moisture. • To avoid electrical shock, do not disassemble the charger. • No user-serviceable parts inside the charger. • Follow local regulations for disposal of electrical components or batteries. • The battery is not a medical device and should not be used in a room where a patient may be present. <p>Warranty</p> <ul style="list-style-type: none"> • The LED light source is warranted to be free from defects in materials and workmanship for a period of one (1) year from the date of purchase. • All non-warranty repairs will be warranted to be free from defects in materials and workmanship for a period of ninety (90) days from the date of invoice. Accidental damage and damage resulting from misuse, abuse, excessive sterilization disinfection and sterilization methods not approved, as well as fluid invasion and normal wear and tear, will be subject to prevailing repair charges. • Disassembly, alteration, or repair performed by any person will result in immediate loss of warranty. <p>AED C- Mount Coupler</p> <ul style="list-style-type: none"> • Read instructions thoroughly before using the coupler. • Inspect the coupler for any damage that may have occurred during shipment or prior use. • The coupler contains optomechanical parts that are precisely aligned. Dropping the coupler may cause mechanical damage and/or misalignment. • Clean the coupler prior to the first use, at a frequency determined by facility policy and whenever visibly soiled. Follow the cleaning, disinfection, and sterilization instructions provided in these instructions. • The camera head surface may exceed 41°C (106°F) in operating conditions with high ambient temperatures and should be handled with caution. • No modification of this equipment is allowed. <p>Warranty</p> <ul style="list-style-type: none"> • Warranted to the original purchaser for a period of one year from the date of purchase to be free from defects in material and workmanship. • Warranty does not cover damages caused by misuse or by failure to follow the procedures outlined in this IFU.
Disposal	Battery- must be sent to a separate collection facility for recovery and recycling.

Reprocessing Instructions	
Point of Use	N/A
Preparation for Decontamination	N/A
Disassembly Instructions	<p>AED C-Mount Coupler</p> <ol style="list-style-type: none"> 1. Clean the coupler prior to use at a frequency determined by the facility and whenever visibly soiled. 2. Separate the camera head, coupler, and scope prior to cleaning, disinfection, or sterilization.
Cleaning – Manual	<ol style="list-style-type: none"> 1. No portion of the EndoPro-Cam® should be opened for cleaning or disinfecting. 2. The following wipes were tested for cleaning/disinfection the EndoPro-Cam®: CaviWipes®, PDI SANI-CLOTH® AF3, Clinell® universal sanitizing wipes. 3. Throughout the cleaning/disinfection process, orient the hand piece in a manner that prevents liquid from entering the electrical connection area of the hand piece (with the opening to the electrical connections facing upward). Do not wet the opening or inside of the hand piece housing the electrical connection components. 4. Pay particular attention to the seams around the edge of the display and the back of the screen where it attaches to the hand piece. When cleaning the hand piece, pay careful attention to the seams around the edge of the button panels and labels.

	<ol style="list-style-type: none"> 5. Using a fresh, moist wipe, thoroughly wipe all surfaces of the EndoPro-Cam, the front and back of the LCD screen, hand piece section, AED C-Mount Coupler, and seams. Follow the IFU for the wipe for recommended wipe technique and contact time. 6. Use a 70% Isopropyl Alcohol (IPA) premoistened swab to swab the seams around the edge of the button panel. Follow the IFU for the wipe for recommended wipe technique and contact time. 7. Visually inspect all surfaces for any residual soil. Repeat cleaning instructions if visible soil is present. 8. Place the clean device in an appropriate dry storage area. 															
Cleaning – Automated																
Disinfection	<ul style="list-style-type: none"> • No portion of the EndoPro-Cam® should be opened for cleaning or disinfecting. • The following wipes were tested for cleaning/disinfection the EndoPro-Cam®: CaviWipes®, PDI SANI-CLOTH® AF3, Clinell® universal sanitizing wipes. • All surfaces of the EndoPro-Cam and accessories are compatible with isopropyl alcohol. 															
Drying	<p>Light Source If the light source becomes wet, thoroughly dry the exterior immediately with a non-linting wipe.</p> <p>AED C-Mount Coupler For manual drying, use a non-linting wipe</p>															
Maintenance, Inspection, and Testing	<p>EndoPro-Cam®</p> <ul style="list-style-type: none"> • 6-month warranty. • The EndoPro-Cam® has no user-serviceable parts. • The EndoPro-Cam® requires no calibration or service in the field. All electronics are tested and validated for performance at the manufacturer. If the performance of the EndoPro-Cam® is in doubt, contact Healthmark Customer Service. • If the integrity or performance of any portion of the EndoPro-Cam® is in doubt, the system should NOT be used until the issue is resolved. • The following maintenance intervals are recommended: <table border="1" data-bbox="565 972 1427 1068"> <thead> <tr> <th>Maintenance Type</th> <th>Interval</th> <th>Personnel</th> </tr> </thead> <tbody> <tr> <td>General Inspection</td> <td>Before each use</td> <td>Users</td> </tr> <tr> <td>Safety Label Integrity</td> <td>As Required</td> <td>All</td> </tr> </tbody> </table> <p>EndoPro-Cam® Power Bank</p> <ul style="list-style-type: none"> • Storage temperature range: 20°C-60°C 40% RH to 85% RH. • Usage temperature range: -10°C-50°C 45% RH to 85% RH. • If the power bank battery is completely drained, fully charge before use. • If this product is not in use, charge this product every three months. • When unable to recharge your power bank battery, please check the following: <ul style="list-style-type: none"> ○ If the charge voltage of your power bank battery is between 4.7V to 5. ○ If the product has been fully charged. ○ If the power button is on. ○ If all of the plug contacts are fully seated. ○ If there is still a problem, contact customer service. <p>Portable LED Light Source</p> <ul style="list-style-type: none"> • Warranted to be free from defects in materials and workmanship for a period of one (1) year from the date of purchase. • All non-warranty repairs will be warranted to be free from defects in materials and workmanship for a period of ninety (90) days from the date of invoice. • Check all items upon receipt to assure damage has not occurred during shipment. • Verify compatibility of all components and accessories used with the light source. • Ensure that the battery cap is fully tightened on the O-ring seal to prevent liquid intrusion into the battery compartment. • Do not permit the light source to be immersed in any cleaning or disinfectant solutions. <p>Troubleshooting</p> <table border="1" data-bbox="472 1822 1427 1913"> <thead> <tr> <th>PROBLEM</th> <th>POSSIBLE CAUSE</th> <th>ACTION</th> </tr> </thead> <tbody> <tr> <td>Loss of Illumination</td> <td>Battery power is low</td> <td>Replace battery with a freshly charged battery</td> </tr> </tbody> </table>	Maintenance Type	Interval	Personnel	General Inspection	Before each use	Users	Safety Label Integrity	As Required	All	PROBLEM	POSSIBLE CAUSE	ACTION	Loss of Illumination	Battery power is low	Replace battery with a freshly charged battery
Maintenance Type	Interval	Personnel														
General Inspection	Before each use	Users														
Safety Label Integrity	As Required	All														
PROBLEM	POSSIBLE CAUSE	ACTION														
Loss of Illumination	Battery power is low	Replace battery with a freshly charged battery														

	Light Guide does not attach properly to the endoscope	The endoscope has an adapter on the light post	Refer to the guide below and remove the adapter
	Light intensity is low	Foreign material or film on LED output taper	Clean the taper with a cotton swab wet with Isopropyl Alcohol until the debris or film is cleared off. Dry with compressed air or gas
	Light source becomes hot after prolonged use at full power	Light source has been left on for more than 30 minutes at full power	Turn the light source off for a few minutes to permit adequate cool down of the light source body
<p>AED C-Mount Coupler</p> <ul style="list-style-type: none"> Inspect the coupler on a continual basis. If a problem is observed or suspected, the coupler should be returned for repair. Inspect all components for cleanliness. If fluid or tissue buildup is present, repeat the above cleaning and disinfection procedures. 			
Reassembly Instructions	N/A		
Packaging	N/A		
Sterilization	N/A		
Storage	<p>EndoPro-Cam®- Storage temperature 20°C to 60°C. Do not dispose of protective box or any other shipping materials. These items should be retained for future storage or transport of the equipment.</p> <p>EndoPro-Cam® Power Bank- Store at room temperature. Avoid excessive heat and humidity.</p> <p>AED-C-Mount Coupler- Transport and Storage Conditions- Temperature: -10-50°C, Relative Humidity: 10-75%.</p> <p>Operating Conditions- Temperature: 10-30°C, Relative Humidity: 30-75%.</p>		
Additional Information	N/A		
Related Healthmark Products	FIS-005, FIS-006		
Other Product Support Documents	ProSys™ Brochure, ProSys™ Price List		
Reference Documents	Power Bank Battery meets GB 4643.1-2011 & GB 5296.2-2008 & GB/T 0817 18287-2000 standards		
Customer Service Contact	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com		

2021-04-28 Suzanne Latta