

Manufactured by

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Device Name: L.E. PRO All-in-One Endoscopy Camera System | Z007800

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Introduction

Thank you for choosing Prosidio's L.E. PRO All-in-One Endoscopy Camera System. This User Manual contains important instructions for use, safety and technical information.

Read the instructions for use If the instructions are not followed, patients, users, and third parties may be injured or the product may be damaged.

Read the instructions for use carefully and follow all safety notes and warnings.

Read the instructions for use of compatible products carefully and follow the manufacturer's instructions recommendations.

Please contact us at **<u>support@prosidio.com</u>** with any questions.

Symbol	Meaning
${R \over R}$ Only	Medical prescription only
REF	Article no.
SN	Serial number
\sim	Date of manufacture
	Manufacturer
Ť	Keep dry
J erc	Upper limit of temperature
ĺĺ	Consult instructions for use
\triangle	Caution
	Pay attention to static protection

Symbols

Table of Contents

Introduction Symbols	3 3
Getting started with L.E. PRO All-in-One Endoscopy Camera System	5
Chapter 1. Overview 1.1 Device Features 1.2 Warnings 1.3 Intended Use 1.4 Contraindications 1.5 Patient Population 1.6 Operator 1.7 Normal Operating Conditions 1.8 Storage and Transport Conditions 1.9 Operating Conditions 1.10 Environmental Protection 1.11 Device Lifespan	5 5 6 6 6 6 7 7 7 7 7 7
Chapter 2. Device Characteristics 2.1 Device Composition 2.2 Device Type	8 8 8
Chapter 3. Technical Features 3.1 Safety Features 3.2 Key Technical Features	11 11 11
Chapter 4. Installation Instructions 4.1 Installation	11 11
Chapter 5. Instruction Manual 5.1 Instruction 5.2 White Balance 5.3 Picture Taking And Video Recording 5.4 Video Playback 5.5 Flexible vs Rigid Scope Mode	12 12 12 12 12 12 13
Chapter 6. OSD (On-Screen Display) Settings	13
Chapter 7. Troubleshooting	18
 Chapter 8. Cleaning and Disinfection 8.1 Precautions 8.2 Cleaning and Disinfection Methods 	20 20 20
 Chapter 9. Maintenance 9.1 Daily Inspection and Maintenance 9.2 Regular Inspection and Maintenance 	21 21 21
Chapter 10. After-Sales Service	21
Chapter 11. Limited Liability	22
Appendix A: Description of the Device's Electromagnetic Environment	22

Getting started with L.E. PRO All-in-One Endoscopy Camera System

NOTE: Read all instructions before using your L.E. PRO All-in-One Endoscopy Camera System.

Chapter 1. Overview

1.1 Device Features

The L.E. PRO All-in-One Endoscopy Camera System is a device that combines the following functions: (1) a light source for endoscopes, (2) a camera head to attach to endoscopes, (3) an image display and an image processing unit to capture and display endoscope exams. It is designed for in-office diagnostic purposes only and should not be used for procedures beyond this scope.

1.2 Warnings

- To reduce the risk of fire or electric shock, do not expose the device to rain or moisture.
- The product is not disinfected or sterile when delivered. The use of non-sterile products poses a risk of infection. Reprocess the product following the reprocessing instructions before initial use and every subsequent use.
- The high level of light intensity produced by the light source may lead to permanent eye damage or blindness, and may cause tissue and items facing the light output to heat up. Do not look into the light output. Set the output of the adjustable light source to a level that is high enough to ensure optimal illumination of the area of interest, but not higher than necessary. Ensure the light output is sufficiently far enough away from tissue and operating accessories.
- Do not connect peripheral device wiring with excessive voltage to the device.
- Use the power cables and accessories that come with this device, or choose power cables from approved manufacturers according to the specifications, to avoid fire or electric shock.
- To reduce the risk of fire or electric shock, do not pull, bend or bundle device cables or damage the cable insulation casing.
- Do not service the device or replace parts.
- Do not block the device vent outlet to avoid overheating.
- If the cable appears worn or aged, stop using it immediately.
- Installation, operation, and storage of the device at any of the locations listed below are strictly prohibited and may result in injury or equipment failure:
- Locations where flammable chemicals or items such as alcohol, thinners, benzene, etc. are stored.
- Locations close to liquids or exposed to rain.
- Locations in direct sunlight.

- Locations close to the air outlet of air conditioning or ventilation equipment.
- Locations close to a heat source, such as a space heater.
- Unstable power supply locations.
- Environments with high salt or sulfur concentration.
- Extremely cold or hot environments.
- Extremely humid or dusty environments.
- Locations prone to mechanical vibration or instability.
- Locations near the source of a strong magnetic field.
- Locations near strong electromagnetic sources.

1.3 Intended Use

The L.E. PRO All-in-One Endoscopy Camera System is intended to aid in endoscopic procedures outside of the operating room.

1.4 Contraindications

No contraindications relating directly to the medical device are currently known. The responsible physician must decide whether the anticipated application is indicated based on the general condition of the patient.

1.5 Patient Population

Age: There are no restrictions in terms of patient groups for this product.

- Weight **Warning:** Sensitivity to Heat Transmission in Smaller Patients. For smaller patients, particularly those under a body weight of 5 kg (11 lbs), the heat generated by the light source through the endoscope may be more perceptible and could potentially cause discomfort or thermal injury. It is recommended to lower the light source intensity to reduce the heat at the tip of the endoscope. Monitor the temperature of the endoscope tip periodically during prolonged procedures. If the temperature exceeds 41°C, immediately reduce the light source intensity or suspend the use to allow cooling before resuming the procedure.
- Health: Only perform endoscopic procedures on those who, in the view of the operating physician, are able to tolerate the procedure without complication.

1.6 Operator

Only licensed physicians who have the required training for endoscopic procedures should use this device.

1.7 Normal Operating Conditions

- 1. Ambient temperature:
- 2. Relative humidity:
- 3. Atmospheric pressure:
- **4.** Power requirements:

 5° C to 35° C (41°F to 95° F) ≤ 80 percent

86 KPa to 106 KPa

~230V, frequency 50Hz

5. The device should be kept away from strong magnetic field interference when in use

1.8 Storage and Transport Conditions

Temperature: Relative humidity: -10°C - 60°C (14°F to 140°F) 20-95%

1.9 Operating Conditions

Temperature: 5 Relative humidity (non-condensing): 2

5°C to 35°C (41°F to 95°F) 20–95%

1.10 Environmental Protection

Waste related to the device and its accessories at the end of their useful life and during use should be disposed of in accordance with local laws and regulations.

1.11 Device Lifespan

The device lifespan is 5 years, starting from the device manufacture date, which is indicated on the label.

Chapter 2. Device Characteristics

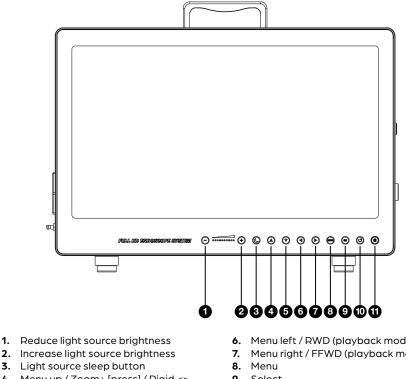
2.1 **Device Composition**

The L.E. PRO All-in-One Endoscopy Camera System consists of a control host, a camera, a cold light source, a display, an optical interface, and a supporting cable.

2.2 Device Type

Type / Model	Control host	Camera	Cold light source	Display
L.E. PRO All-in-One Endoscopy Camera System	Yes	Yes	Yes	24 inches

Figure 1: Front panel



- 4. Menu up / Zoom+ [press] / Rigid <> Flexiscope mode [hold]
- 5. Menu down / Zoom-

- 6. Menu left / RWD (playback mode)
- 7. Menu right / FFWD (playback mode)
- 9. Select
- 10. Video playback
- 11. Record video

Figure 2: Left side panel

- 1. USB 2: port for USB memory stick
- 2. USB 1: USB port for keyboard
- 3. HDMI signal output
- 4. DVI signal output
- 5. SDI signal output
- 6. Power switch
- 7. Fuse
- 8. Power input
- **9.** Equipotential grounding post

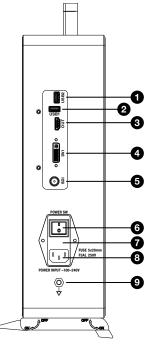
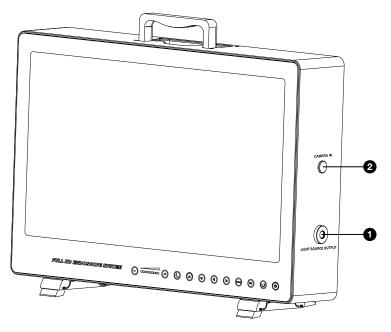
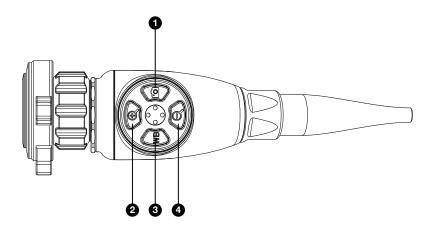


Figure 3: Right side panel



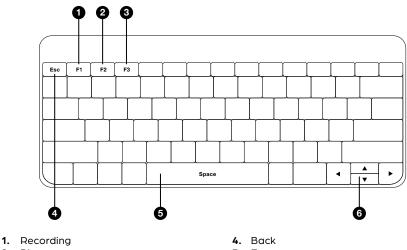
- 1. LED light output
- 2. Camera input





- 1. 🖸 Quick press = image capture. Hold (1s) & release = start/stop video capture
- 2. Đ Image zoom in
- 3. WB Manual white balance
- 4. Ø Image zoom out

Figure 5: Optional keyboard use



- 2. Photo capture
- 3. Edit file Name

- 5. Enter
- 6. Up/Down

Chapter 3. Technical Features

3.1 Safety Features

- Type (protection type): The application portion of the camera is BF type
- Power supply type: 110-240V 50Hz
- Input power: ≤150VA
- Non-AP/APG device
- Non-infusion protection device
- Operation mode: Runs continuously

3.2 Key Technical Features

- Photoreceptor total pixels: PAL: 1920H×1080V (2.1 million pixels)
- 1/3-inch photosensitive chip
- Optical interface, F16, F18, F20, F24, F28, F32 optional
- Brightness adjustment range: flexible linear brightness adjustment knob
- Photoreceptor minimum illumination: 0.5 Lux
- Photoreceptor resolution: ≥ 900TVL
- Signal-to-noise ratio: 50 dB
- White balance: Auto / manual
- Video signal output: HDMI, DVI, CVBS

Chapter 4. Installation Instructions

4.1 Installation

- 1. After de-boxing, make sure the devices, hosts and accessories match the packing list, and carefully read the instruction manual.
- 2. Place the device on a stable surface, away from any flammable or corrosive material and where it cannot be accidently knocked over. The device may be mounted on the Prosidio L.E. PRO Carello Cart.
- 3. Connect the camerahead to the corresponding jack "CAMERA IN".
- Plug one end of the light source cable to the corresponding "LIGHT SOURCE OUTPUT" jack and secure it.
- 5. Insert the three-way power cord into the "AC IN" jack.
- 6. Check that the connection is correct and plug into a grounded 110-230V power supply.
- 7. Turn the power on and put the switch to position 1, the power LED should turn on.
- 8. After the display image is shown, the image from the camerahead should be displayed on the screen. In the lower left side of the screen, the correct time and date should be displayed. The system is ready for use.

Chapter 5. Instruction Manual

5.1 Instruction

- 1. If the object being photographed is not clear, adjust the focus on the camerahead and or on the endoscope itself.
- 2. Make sure that the power plug is not loose, plug in before turning on the power switch.
- 3. $\angle \underline{!}$ Keep away from high-interference devices.
- 4. FIRE HAZARD: If the device is on, keep the end of the endoscope or the end of the bare light source away from paper, sheets, or any flammable material.
- 5. When done using the device, turn off the power, remove the power cable, remove the endoscope, unplug each cable, and restore the device to its original state. Finally, store the device in a flat, clean and dry place for safekeeping.

5.2 White Balance

The system should automatically white balance. To manually white balance the picture, focus the camerahead onto a white object and press the **WB** button on the camerahead buttons.

5.3 Picture Taking And Video Recording

- To take a picture: quickly press and release the 🙆 button on the camerahead. The word "**PIC**" will pop up on the screen.
- To start/stop video recording: hold the O button for 2 seconds, until a audible sound is heard, and then release. After the button is released, a red circle will be displayed on the top right corner of the screen when a recording is started. Alternatively, press the O record button on the display. The file name is automatically created and contains the date and time of the recording. If desired, change the name of the recordings on the device using an external keyboard as discussed in Chapter 2.

5.4 Video Playback

To view videos that have been recorded, press the 🔘 video playback button. Use the up and down arrows to select the video to play which are logged by the time and date when recorded. When done, press 🔘 again to exit the playback menu.

Ensure that a USB drive formatted to FAT32 is inserted into the USB port **before** powering on the device.

All picture and video data is recorded directly to the USB drive, with no data stored on the device itself.

To view recorded videos, press the video playback button and use the up and down arrows to navigate through your recordings. Videos are named by the date and time of recording by default.

Once a video is selected, press **"OK"** to begin playback. During playback, on-screen controls allow you to fast forward, rewind, step forward, step backward, pause, and play.

Please move **Figure 5: Optional Keyboard Use** here. A standard US keyboard can be connected to the USB 1 port, allowing you to rename files and navigate the video playback menu (**Figure 5**). When finished, press the video playback button again to exit the menu.

5.5 Flexible vs Rigid Scope Mode

By default, the device is in the rigid scope **"E.N.T**" mode for Otolaryngology (ENT) based rigid sinuscopes, otoscopes, laryngoscopes. If a flexible nasopharyngoscopy or laryngoscope is used, the image quality can be improved by switching the device to the **"FLEXISCOPE"** mode. To change this mode, press and hold the **UP** button on the device monitor until an audible tone is heard (2-3s). The name of the current imaging mode will be displayed. Press and hold the **UP** button again to see the mode change either from **"E.N.T"** to **"FLEXISCOPE"** or vice versa.

Chapter 6. OSD (On-Screen Display) Settings

The OSD Settings menu allows for customization of on-screen display features to enhance image quality, control exposure, and adjust for specific procedural needs. Access these settings through the **Menu button** on the control panel.

MENU

EXPOSURE	┙
WHITE BAL	┙
BACKLIGHT	BLC 🎝
DNR	OFF
	LOW
	HIGH
IMAGE	┙
SYSTEM	ل ہ
RESET	ON
SCENE MODE	Ļ
EXIT	┙

1. Exposure

Controls the brightness and gain for optimal image clarity.

EXPOSURE

BRIGHTNESS AGC RETURN 6 |---|-----| 3 |---|-----| 4

(Automatic Gain Control)

Recommendation: Increase **brightness** to improve visibility in dark areas or decrease to reduce overexposure. Use **AGC** in low-light conditions to enhance image clarity, but be aware that higher AGC settings may increase graininess.

2. White Balance

Adjusts color balance based on lighting conditions.

WHITE BAL

AWB	PUSH LOCK	
	AUTO	
	MANUAL	
	COLOR GAIN	1
RETURN	Ļ	

Recommendation: Use **Push Lock** for consistent color under stable lighting. With Push Lock selected, press and hold the **AWB** button on the camerahead while viewing a white object to calibrate the color balance. We do not recommend using **Auto**, **Autoext**, or **Manual** modes, as they may result in inconsistent colors.

3. BLC (Backlight Compensation)

Balances exposure in reflective areas, reducing glare.

BLC

MODE	E.N.T
LEVEL	4
H-POS	5
V-POS	3
H-SIZE	9
V-SIZE	12
RETURN	Ļ

Recommendation: Keep **BLC ON** at a low level (eg: level 3) to reduce glare from reflective surfaces, such as mucus-covered tissues, especially during ENT procedures.

4. DNR (Digital Noise Reduction)

Reduces image noise for smoother visuals.

On | Off

Default: Off.

Recommendation: Keep off for general use, but enable in very dark environments (e.g., deep within sinuses) to reduce graininess and improve image clarity.

5. Image Settings

Sharpness: Adjusts edge clarity for detailed visualization.

IMAGE

SHARPNESS	18
IMAGE RANGE	FULL
	COMP
	USER
GAMMA	0.55
	0.45 - 0.75
FLIP	OFF
	H-FLIP
	V-FLIP
	HV-FLIP
D-ZOOM	1.0X
	1.1X - 1.2X
ACE	OFF
	LOW
	MIDDLE
	HIGH
SHADING	OFF
	ON
RETURN	₊

5.1 Sharpness

Adjusts edge clarity for detailed visualization.

Recommendation: Start at a low setting and gradually increase to reveal fine details without adding noise.

5.2 Image Range

Sets contrast range for optimal viewing.

IMAGE RANGE	FULL
	COMP
	USER

Recommendation: Use **Full** for high contrast, **Comp** for balanced lighting, or **User** for custom settings. Start at a low setting and gradually increase to reveal fine details without adding noise.

5.3 Gamma

Adjusts brightness and contrast.

GAMMA	0.55
	0.45 - 0.75

Default recommendation: Use lower gamma (0.45–0.55) for dim areas and higher gamma (0.65–0.75) for bright scenes.

5.4 Flip

Changes the image orientation.

FLIP

OFF
H-FLIP
V-FLIP
HV-FLIP

Recommendation: Adjust as needed for anatomical orientation during procedures.

5.5 D-Zoom

Provides digital zoom for close-up views.

D-ZOOM	1.0X
	1.1X - 1.2X

Recommendation: Use to focus on specific areas (e.g., lesions), but be mindful of potential pixelation at high zoom levels.

5.6 ACE (Automatic Contrast Enhancement)

Adjusts contrast for improved visibility in low-light conditions.

ACE

OFF LOW MIDDLE HIGH

Recommendation: Keep off unless using a small endoscope or weak light source. ACE helps illuminate darker structures, like the nasopharynx, but will increase image noise.

5.7 Shading

Corrects uneven illumination.

SHADING OFF ON

Recommendation: Activate if edges of the image appear dark to evenly distribute brightness across the frame.

6. System

SYSTEM	
FRAME RATE	1080_60P 1080_601 1080_30P 1080_301 720_60P 720_601 720_30P 720_301
FREQ	60HZ 50HZ
LANGUAGE	ENG CHN CHN (S) JPN KOR RUS SPN
APPLY VERSION REL VERSION RETURN	YES V1.0.0 V1 ل

6.1. Frame Rate

Adjusts the frames per second for smoother visuals.

Recommendation: Keep at highest setting 1080_60p for smooth, real-time imaging. Lower only if required by monitor compatibility.

6.2. Frequency (FREQ)

Prevents flickering due to electrical interference.

FREQ 60HZ 50HZ

Recommendation: Match the local power frequency (60Hz in the U.S., 50Hz elsewhere) to avoid flickering from electrical interference.

7. Scene Mode

Optimizes visualization for specific procedures.

SCENE MODE

MODE	E.N.T. LAPAROSCOPY ARTHROSCOPY SPINE FIBERSCOPE URETEROSCOPE CYSTOSCOPE NEURO CUSTOM1 CUSTOM2
BRIGHTNESS	
BRIGHTREGG	
SHARPNESS	
SHARPNESS	
SHARPNESS R-GAIN	
SHARPNESS R-GAIN G-GAIN	
SHARPNESS R-GAIN G-GAIN B-GAIN	
SHARPNESS R-GAIN G-GAIN B-GAIN COLOR GAIN	

Recommendation: Select based on the type of procedure. For example: use **Laparoscopy** for abdominal procedures. Choose **Custom** modes for unique cases where specific settings are preferred.

10. ADJUSTING TIME AND DATE:

To set the time and date, hold the "**OK**" button for 10 seconds and then release. This will open a blue menu. Use the up and down arrows to select "**System**" and press "**OK**". Navigate to "**Set Time**" and press "**OK**", then use the **left and right arrows** to select the date or time field you want to adjust. Adjust the values with the **up and down arrows**, then press "**OK**" to confirm. Finally, press the **video playback button** to exit the submenu and select "**Exit**" to leave the menu.

Chapter 7. Troubleshooting

To determine a failure, please check the following items. If you cannot solve the problem, please contact our after-sales service center.

Issue	Cause	Solution
The display does	The power cable is not connected correctly	Securely connect the cable to the socket
not show any images	The camera cable is not well connected to the light source	Reconnect the cable
The temperature of the device case is abnormally high	Fan failure or poor ventilation	Remove anything occluding the fans and reserve at least 5 cm of clearance around the device for ventilation. Listen for the sound of the cooling fans. If you cannot hear any fans, the problem may be a fan failure
The image is blurry	The surface of the camera is covered with cleaning disinfection residue or biological residue	Common issue Remove the endoscope and see if the camerahead produces a clear image on its own. Re-clean and disinfect the camera surface
	The focal length adjustment of the lens mount is not at the optimum distance	Adjust the focal length of the mount
	You are using the wrong mode for the attached scope	See Chapter 5.5

Issue	Cause	Solution
	White Balance is not set correctly	The camera white balance is set to fixed mode
The image color is off	The white balance method is incorrect	Redo white balance, when using a clean gauze for white balancing, there should not be any iodine dots or other colors in front of the lens, the image window should display all white, in order to ensure that the color after the white balancing is correct, automatic white balancing takes 2-3 seconds, you can also press the WB button on the camerahead, and the screen will display OK
	The color settings are not correct	Reset the tone mode
	The camera circuit element has aged and deteriorated	Replace the appropriate accessories
The power LED is not on	The power plug and fuse are not working properly	Check the power plug and fuse
The illuminated object reflects strong light	The light source is too bright	Use the image brightness reduction key to adjust and reduce color spotting

Chapter 8. Cleaning and Disinfection

8.1 Precautions

- Before cleaning the device, be sure to disconnect the power supply.
- Clean the device in a well-lit location to see where the dust and dirt is.
- Do not use benzene, thinners, or other volatile solvents for cleaning, which may cause the coating of the device to deteriorate and peel off.
- Do not spray cleaning liquid on the surface of the device and avoid having too much liquid on cleaning wipes to avoid damage to the device through seams and connectors.

8.2 Cleaning and Disinfection Methods

8.2.1 Cleaning and Disinfecting the Device External Case

- First, gently wipe the dust off the surface of the device with a soft dry cloth; for stubborn dirt, use a cloth dampened with neutral detergent, and then wipe with a dry cloth.
- Then clean the case surface with a soft cloth or surgical gauze with isopropanol (concentration 50 v%–70v/v%), or 75% medical alcohol.

8.2.2 Cleaning and Disinfecting the Camera

- When there is debris or biological residue on the surface of the camera, first use a soft brush or cloth to brush it off.
- Clean the camera surface with a soft cloth or surgical gauze with isopropyl alcohol (concentrations from 50 to 70v/v%) or ethanol (concentrations from 76.9 to 81.4v/v%), and wipe thoroughly with the special lens paper to ensure that there are no residual stains on the lens.
- Wipe with 75% medical alcohol and finally dry with lens paper.

8.2.3 Cleaning and Disinfecting the Cables

Thoroughly clean the cables with a soft cloth or surgical gauze, if necessary, wipe it off with an appropriate amount of neutral detergent, and finally wipe off the residual moisture with a dry cloth.

8.2.4 Cleaning and Disinfecting the Display

- Blow dust from the LCD with a dust blower to ensure that no coarse particles of dirt is attached to the LCD surface.
- Wipe from the center of the screen with a slightly wet soft cloth, or wipe them with a wet wipe with an LCD-specific cleaner.
- After wiping, if the LCD surface is moist, wipe it off with a dry wipe.

Note: Avoid the use of non-specialized cleaners. Some solvents corrode the polarizer.

• Do not use chemicals such as benzene, alcohol, thinners, mosquito repellent lubricants or cleaning agents when cleaning the display. Failure to do so may change the appearance quality of the device surface.

Chapter 9. Maintenance

In order to ensure the safe use of the device, inspect the device before use, if any problems are found during the inspection process that cannot be corrected, please contact the company's after-sales service center.

9.1 Daily Inspection and Maintenance

Cable: Make sure that the cable is not damaged, the cable casing is not broken, and wrap the cables into a circle about 10 cm in diameter to avoid kinks.

Host: Make sure that the rear panel connectors are free of dust or foreign material; make sure that there are no loose screws on the external case.

Power on: Perform power-on tests to see whether the device can function properly, and whether the front panel buttons can be pressed.

9.2 Regular Inspection and Maintenance

Monthly inspection: Make sure there are no loose screws or damaged parts, and make sure there is no dust or foreign material on the rear panel connectors.

Annual inspection: after the device is turned on, carry out a comprehensive test of function and performance.

Chapter 10. After-Sales Service

Devices sold by the company have a warranty period specified on the invoice, during which the company will provide free repair for failures due to manufacturing quality. Life-long repairs are offered outside the warranty period.

Device parts sold by the company that are configured and installed by the vendor or customer, no service-call is available during the warranty period; for quality problems of the parts sold by the company, the company provides mail-in repairs.

- Failures caused by the following reasons are not covered by the warranty:
 - Failure caused by unauthorized disassembly and modification of this device.
 - Failure caused by accidental hit or fall during use.
 - Failure due to lack of reasonable maintenance or failure to meet the requirements of use environment.
 - Failure caused by failure to operate as required by this manual.
- Failure caused by self-repair without the company's permission.
- Failure caused by repair of accessories without the provision of accessories by the company's designated dealer.
- Failure caused by improper operation by non-trained technicians.
- Failure caused by not using the company's disinfection method.
- Giveaways provided with the device are not under warranty.

- Consumables are not under warranty.
- Devices beyond the device lifespan are not under warranty.

The company cannot provide warranty without proof of the warranty certificate provided with the device.

For devices purchased from the company's agents, please contact the agent first.

Chapter 11. Limited Liability

Please refer to the sales agreement for specific information on the warranty.

To the maximum extent permitted by law, Prosidio shall not be liable under any of the following circumstances:

- 1. Third party's claim (except for personal death, injury, damages to real and related tangible property).
- 2. Data loss or damage.
- 3. Special, incidental or indirect damage or any consequential economic loss (including loss of profits and savings), even if Prosidio has been informed of the possibility of such loss.
- 4. Malfunction caused by installation of software or hardware devices that were not provided with this device.
- 5. Malfunction due to failure to use this device in the environment specified in this manual, or failure to follow the operating methods prescribed in the instruction manual.
- 6. Force majeure factors that lead to device damage.

Appendix A: Description of the Device's Electromagnetic Environment



WARNING

Pay attention to the electromagnetic environment on site, as the device may be affected by the electromagnetic field. During installation and use, the device should be kept away from devices or facilities with strong magnetic wave emission, such as radio towers, highfrequency electric knives, nuclear magnetic resonance equipment. The device may also produce certain electromagnetic field interference to other electrical equipment on site, but this device meets the requirements of electromagnetic compatibility standards, and the instructions for the use of its electromagnetic environment are shown in Table 1 - Table 4.



WARNING

Portable and mobile RF communication devices may affect the use of this device.

WARNING

The pins of connectors marked with electrostatic discharge warning symbols should not be touched.



WARNING

This device should not be used in close proximity to or stacked with other devices, and if it must be used close to or stacked, observe and verify that it is functioning properly in the configuration it is using.

WARNING

Essential Performance Instructions for EMC Inspection:

Table 1: Guide and Manufacturer's Statement – Electromagnetic Emission

Guide and Manufacturer's Statement – Electromagnetic Emission

L.E. PRO All-in-One Endoscopy Camera System is expected to be used in the following specified electromagnetic environments, and the purchaser or user should ensure that it is used in such electromagnetic environments:

Launch test	Compliance	Electromagnetic Environment – Guide
RF emission GB4824	Group 1	The L.E. PRO All-in-One Endoscopy Camera System uses RF energy only for its internal functions. As a result, its RF emission is low and the likelihood of interference with nearby electronic devices is low.
RF emission GB4824	Type A	L.E. PRO All-in-One Endoscopy Camera
Harmonic emission GB17625.1	not applicable	 System is suitable for use in all facilities that are not directly connected to the public low-voltage power supply network
Voltage fluctuations / flicker emission GB17625.2	not applicable	of non-domestic and domestic residential buildings.

Table 2: Safe Distance

Recommended safe distance between portable and mobile RF communication devices and L.E. PRO All-in-One Endoscopy Camera System

L.E. PRO All-in-One Endoscopy Camera System is expected to be used in controlled electromagnetic environments where RF radiation interference is controlled. Depending on the maximum rated output power of the communications equipment, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance recommended below between the portable and mobile RF communication equipment (transmitter) and the L.E. PRO All-in-One Endoscopy Camera System.

The transmitter's maximum rated output power, W	The safe distance /m for the different frequencies of the transmitter		
	150kHz~80MHz	80MHz~800MHz	800MHz~2.5GHz
	d=1.2 \sqrt{P}	d=1.2 \sqrt{P}	d=2.3 \sqrt{P}
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Recommended safe distance between portable and mobile RF communication devices and L.E. PRO All-in-One Endoscopy Camera System

For transmitters with maximum rated output power not listed in the table above, the safe distance recommended, d in meters(m), can be determined by the formula in the corresponding transmitter frequency bar, where P is the maximum rated output power of the transmitter provided by the transmitter manufacturer in watts (W).

Note 1: At 80 MHz and 800 MHz frequency points, the formula for the higher frequency range is used.

Note 2: These guidelines may not be appropriate in all cases where electromagnetic transmission is affected by the absorption and reflection of buildings, objects, and the human body.

Table 3: Electromagnetic Immunity 1

Guidelines and Manufacturer's Statement – Electromagnetic Immunity

L.E. PRO All-in-One Endoscopy Camera System are expected to be used in electromagnetic environments as specified below, and the purchaser or user should ensure that they are used in such electromagnetic environments:

Immunity Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment – Guide
Electrostatic discharge GB/T 17626.2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	The ground should be wood, concrete or tiles, and the relative humidity should be at least 30% if the ground is covered by synthetic materials
Electric fast ±2 kV to the power cord power cord group GB/T ± 1kV to the input/output line		The network power supply should have the quality used in a typical commercial or hospital environment	

Surge GB/T 17626.5	± 1 kV wire- to-wire ±2 kV wire-to- ground	± 1 kV wire- to-wire ±2 kV wire-to-ground	The network power supply should have the quality used in a typical commercial or hospital environment
Voltage drop, short interruption, and voltage change on the power input line GB/T 17626.11	<5% UT, lasts 0.5 cycle (on UT, temporary drop >95%) 40% UT, lasts 5 cycles (on UT, temporary drop 60%) 70% UT, lasts 25 cycles (on UT, temporary drop 30%). <5% UT lasts 5s (on UT, temporary drop >95%)	<5% UT , lasts 0.5 cycle (on UT, temporary drop >95%) 40% UT, lasts 5 cycles (on UT, temporary drop 60%) 70% UT, lasts 25 cycles (on UT, temporary drop 30%). <5% UT lasts 5s (on UT, temporary drop >95%)	The network power supply should have the quality used in a typical commercial or hospital environment. If the user of the L.E. PRO All-in-One Endoscopy Camera System needs to run it continuously during a power outage, it is recommended that the L.E. PRO All-in-One Endoscopy Camera System be powered by an uninterruptible power supply or battery.
Frequency magnet (50Hz). GB/T 17626.8	3A/m	3A/m	The frequency magnetic field should have the level characteristics of the frequency magnetic field in a typical location in a typical commercial or hospital environment.

Guidelines and Manufacturer's Statement – Electromagnetic Immunity

Note: UT refers to the AC network voltage before the test voltage is applied.

Table 4: Electromagnetic Immunity 2

Guidelines and Manufacturer's Statement – Electromagnetic Immunity

L.E. PRO All-in-One Endoscopy Camera System is expected to be used in the following electromagnetic environments, and its buyer or user should ensure that it is used in such electromagnetic environments:

Immunity Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment – Guide
Radio Frequency Conduction GB/T 17626.6 Radio Frequency Radiation GB/T 17626.3	3V (valid value) 150kHz ~ 80MHz 3V/m 80MHz ~ 2.5GHz	3V (valid value) 3V/m	Portable and mobile RF communication devices should not be used closer to any part of the L.E. PRO All-in-One Endoscopy Camera System, including cables, than the recommended safe distance. The distance is calculated by a formula corresponding to the transmitter frequency. $d = 1.2 \sqrt{P} d = 1.2 \sqrt{P} 80 \text{ MHz}$ -800 MHz $d = 2.3 \sqrt{P} 800 \text{ Hz}$ -2.5 GHz P is the transmitter's maximum output rating provided by the transmitter manufacturer, in watts (W), d is the recommended safe distance, in meters (m). The field strength of a stationary RF transmitter, as determined by surveying the electromagnetic site (a), should be lower than the conforming level in each frequency range (b). Interference may occur near devices with this symbol ()

Guidelines and Manufacturer's Statement – Electromagnetic Immunity

Note 1: At 80 MHz and 800 MHz frequency points, the formula for the higher frequency ranae is used.

Note 2: These guidelines may not be appropriate in all cases where electromagnetic transmission is affected by the absorption and reflection of buildings, objects, and the human body.

- **a** Fixed transmitters, such as base stations for wireless (cellular/cordless) phones and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts, and television broadcasts, are theoretically unpredictable. In order to assess the electromagnetic environment of fixed RF transmitters, the survey of electromagnetic fields should be considered. If the field strength of the L.E. PRO All-in-One Endoscopy Camera System is measured to be higher than the RF compliance level described above, the device should be observed to verify that it is functioning properly. If abnormal performance is observed, additional measures may be necessary, such as reorientation or position of the L.E. PRO All-in-One Endoscopy Camera System.
- ${f b}$ In the entire frequency range from 150kHz to 80MHz, the field strength should be less than 3V/m.

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