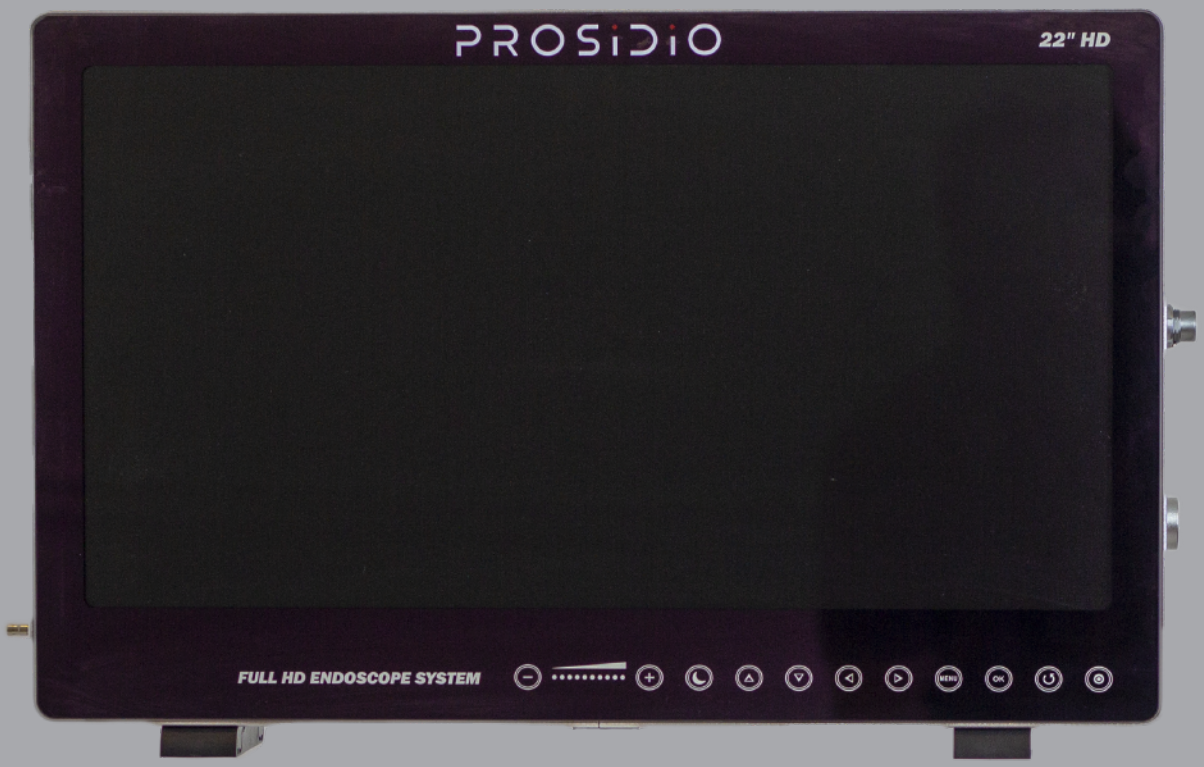
PROSIDIO

Product Instruction Manual



L.E. All-in-one endoscopy system

Model: v1.1

IFU Version: 2.0

Please read this manual carefully before use and keep in a safe location.

If the device fails, call the service hotline at **+1 (914) 510-2314** or contact **support@prosidio.com**

Manufactured by

PROSIDIO

Purchase, NY 10577

United States

Phone: +1 (914) 510-2314

Email: support@prosidio.com

Device Name: L.E. all-in-one endoscopy system

This manual was first published on Dec 15th, 2021

Introduction

Thank you for choosing Prosidio's L.E. all-in-one endoscopy camera system. This Instruction Guide contains important SAFETY and TECHNICAL information. To ensure your safety and maximize the benefit from the system, please review all the sections carefully before using, including technical requirements, how to operate, maintenance, cleaning, and troubleshooting the device. **This manual only applies to the use of the device as intended by the manufacturer. It is recommended to check the suitability of the device for the intended procedure prior to use.**

WARNING: Unless indicated, PROSIDIO medical devices are not considered clean and disinfected when delivered. Please clean the device as specified below prior to its use.

We are always working to improve our devices. The content of this manual is designed to be correct and complete, but we periodically request a copy of the latest version. We reserve the right to modify the devices described in the manual, and the manual itself, without notice. If you have any questions, please contact us at support@prosidio.com. This manual does not cover all variations of this device. For precise specifications and configurations of this device, please consult your vendor. Keep this guide in a safe place to use as a reference.

Document symbols

The L.E. all-in-one endoscopy system Instruction Guide uses different font styles and symbols to quickly and clearly convey information:

- Standard text for information.
- Bold text to emphasize words.
- NOTE: to add or emphasize information that may affect user actions.

 Dangerous high voltage

 Precaution, refer to device materials

 Do not discard in garbage directly

 BF-type device classification

 This side up

 Fragile

 Avoid rain

 Avoid sun exposure

 Do not stack

 Ground equipment

 Pay attention to static protection

 Equipotential

Table of Contents

Getting started with L.E. all-in-one endoscopy

NOTE**:** Read all instructions before using your L.E. all-in-one endoscopy.

Chapter 1 Overview

1.1 Essential performance

"Essential performance" as defined by the international standard IEC60601-1:2017 is the performance of clinical functions that are not related to basic safety, and the loss or reduction of that performance beyond the manufacturer's limits can lead to unacceptable risks.

Essential performance focuses on three main aspects: (1) the performance is a function related to the intended clinical use; (2) the performance is not a basic safety function; (3) the loss or reduction of the performance will lead to unacceptable risks. This performance is considered "essential performance" when all three of these requirements are met.

"Essential performance" should be clearly stated by the manufacturer in the materials provided with the device. If the manufacturer does not specify "essential performance," then all functions of the device are considered "essential performance." When determining the "essential performance" of medical electrical equipment, one should refer to the relevant standards and consider the equipment's intended environment for usage and any special functions. The manufacturer is required, based on the definition of "essential performance" in the standard and using the recommended industry standard YY/T0316-2016 "Medical Device Risk Management Application of Medical Devices," to conduct a comprehensive risk analysis and describe these "essential performance" in the materials provided with the device.

1.2 Device Features

The L.E. all-in-one endoscopy 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.

1.3 Warnings

- To reduce the risk of fire or electric shock, do not expose the device to rain or moisture. Operators are strictly prohibited from installing and operating the device with wet hands.
- 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.
- Pulling, bending, or bundling device cables or damaging the cable insulation casing is strictly prohibited, as it may result in fire or electric shock.
- Self-replacement of internal components of the device is strictly prohibited.
- Do not block the device vent outlet to avoid overheating and fire.
- When 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 fire, personal 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.

1.4 Precautions

- Please check the suitability of the device for the intended purpose before use.

- The device should be used in a clean and well-ventilated room, with at least 5 cm of clearance around the device for ventilation. Other devices or systems should not be used in close proximity or stacked on top of or underneath this device.

- The installation and configuration of the device can only be completed by trained and qualified medical technicians.

- During device installation, place the device on a flat surface to prevent damage.

- Device's supporting cables:

  - Strictly follow the instructions to make the correct connections.
  - Confirm that the connection is correct before powering up.
  - Do not plug or unplug the supporting cables while powered.
  - Do not twist the cables during operation.
  - Prevent the cables from being crushed by heavy objects (medical equipment, device carts, operating tables, operators, etc.), as it may cause the device to malfunction.
  - Do not pull, knead, squeeze/bend the camera handle cable.

- Do not use excessive force.

- When powered, do not move or shake the device.

- Do not disassemble any parts of the device.

- During normal use, do not deliberately rotate the handle connector, as it may cause line failure and result in failure to display the image.

- When the light source is illuminated, do not touch the metal part of the light source outlet, as it could cause discomfort or burns.

- After using the device, please turn off the power and then remove the supporting cable.

- Note: Remove the cable from the device after the power is off for 2 minutes to avoid burns due to the high temperature in the device's light source outlet.

- Before each use, check the endoscope and endoscope attachment section for safety hazards, such as rough surfaces, sharp edges, or protrusions.

- When the surface temperature of the application part of the device exceeds 41 degrees Celsius, suspend usage and let it cool down before continuing to use to avoid burns.

- Do not suddenly move the device from a cold temperature to a warm temperature (temperature difference ≥ 10 degrees C) or suddenly raise the indoor temperature, as the external surface and interior of the device may form water vapor (i.e., condensation phenomenon).

    - If condensation occurs turn off the power and let the condensation evaporate before resuming operation; operating the device with condensation may cause equipment failure or damage.
- After using the camera handle, remove the mirror and optical connector and place the handle protection cover.
- The surface of the device may accumulate dust. Before wiping, disconnect the power and wipe with a soft, lint-free cotton wipe to avoid surface scratches.
- When there is dust on the lens surface of the camera, wipe it with a fine cotton pad and alcohol wipe.
- Please avoid frequent powering on and off the device, as it may cause damage.

- When the device is not in use, turn off the power, unplug the external power supply, and keep it covered. When not in use for an extended period of time, wipe it clean and store it in the box.
- If the device is stored for an extended period of time, turn it on and run it periodically (recommended every other month).
- Replacement fuses are provided with the device. Do not replace the fuse with any other fuse except those provided by Prosidio.
    - When replacing the fuse, **disconnect the power cord**, use a tool to pry open the fuse cap on the filter, remove the fuse tube (fuse), and replace the fuse cap back on.
- Replacing the LED light source must be done by Prosidio or a licensed professional. Replacement must choose the same supplier model: M80W-001 (input voltage DC 12V, current ≤6.6 A, output power: ≤80 VA).
- If the device fails, users are prohibited from opening the case of the device themselves and should contact Prosidio for repair.
- The L.E. all-in-one endoscopy camera systems' EMC requires special precautionary measures and must be installed and used in accordance with the manual.

- Portable and mobile RF communication devices may affect this device.

1.5 Intended use

The L.E. all-in-one endoscopy camera system is intended to aid in diagnostic endoscopic procedures outside of the operating room

1.6 Contraindications

This device is not designed to be used for procedures that require sterility or non-diagnostic endoscopic procedures such as endoscopic sinus surgery and those of a similar ilk.

1.7 Patient Population

Age: Infant to geriatric

Weight: Not relevant

Health: Only perform endoscopic procedures on those who, in the view of the operating physician, are able to tolerate the procedure without complication.

1.8 Operator

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

1.9 Normal Operating Conditions

1. The ambient temperature: 5 to 35 degrees Celsius.
2. Relative humidity: ≤ 80 percent.
3. Atmospheric pressure: 86 KPa to106 KPa.
4. Power requirements: ～230V, frequency 50Hz.
5. The device should be kept away from strong magnetic field interference when in use

1.10 Transport and Storage

1. Ambient temperature:10 to 40 degrees Celsius.
2. Relative humidity: ≤ 80 percent.

3. Atmospheric pressure: 50 KPa to106 KPa.

Transportation: During transportation, direct contact with rain and snow should be prevented. Do not store with corrosive articles.

Storage: Packaged devices should be stored in a dry and ventilated indoor space without non-corrosive substances.

1.11 Safety instructions

1. The safety requirements of the device comply with GB9706.1-2007 Medical Electrical Equipment Part 1: General Safety Requirements and YY0505-2012 Medical Electrical Equipment Part 1-2: Safety General Requirements and Standards: Electromagnetic Compatibility.
2. The indoor power supply outlet for the device should be a standard three-pronged power outlet, such as the one provided with its purchase. The protective ground contact (terminal) should be connected to your facility's protection ground wire. If your facility does not have a grounded contact terminal, or if you are unsure if it does, have a licensed electrician connect a conductive metal wire (16 gauge or larger) to the protective ground post on the device and the other end to the ground.

1.12 Environmental Protection Requirements

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.

1.13 Device Lifespan Requirements

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

Chapter 2 Device Characteristics

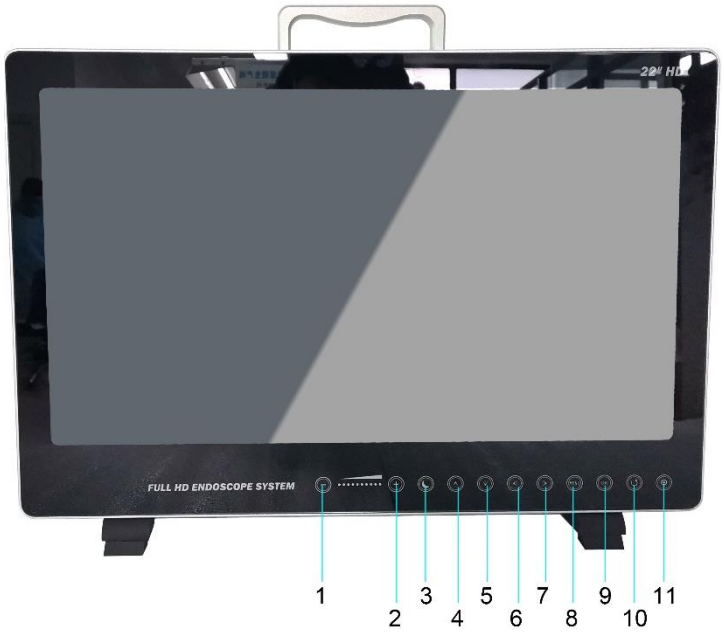
2.1 Device Composition

The endoscope camera 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. all-in-one endoscopy system	Yes	Yes	Yes	22 inches

Figure 1: **Front panel functions**



1. Reduce light source brightness
2. Increase light source brightness
3. Light source sleep button
4. Menu up / flexible <> rigid scope modes

5. Menu down
6. Menu left
7. Menu right
8. Menu
9. Menu setting confirm
10. Video playback toggle
11. Record video

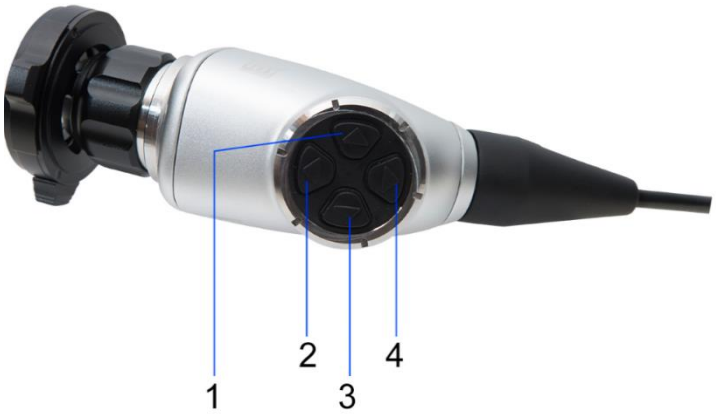
Figure 2: **Left side panel functions**

1. HDMI signal output
2. USB 2.0 port for video/picture capture and playback
3. DVI signal output
4. CVBS/BNC/SDI signal output
5. Power switch
6. Fuse
7. Power input
8. Equipotential grounding post

Figure 3: **Right side panel instructions**

1. LED light output 2. Camera input

Figure 4: **L.E. all-in-one endoscopy system Camera (Instructions)**



1. (P): Quick press = image capture. Hold (1s) & release = start/stop video capture
2. (Z+): Image zoom in
3. (W) Manual white balance
4. (Z-): Image zoom out

Chapter 3 Technical Features

3.1 Safety Features

- Device Classification: Class I
- 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.

3.3 Functional Requirements

The full image field of view should be uniform and clear, the picture should be coherent.

- The image should not have forward punch phenomenon when the object moves,
- The image edge should not be serrated, fuzzy, broken, or blurred,
- The camera system should have good black-and-white contrast and color capabilities with no obvious distortion of red, green, and blue colors,
- Signal output meets clinical requirements,

- The camera has automatic white balance, which automatically establishes color balance by pressing the white balance key,
- The device's toggle switch and regulator is flexible without poor contact and mishandling,
- The connection of each part of the device is stable and the electrical plug-in should not be exposed to bad, loose or even shedding, or flammable material.
- The connection between the interface and the endoscope is easy to operate, the positioning is correct and reliable, and the lock is secure.

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. You can mount the device on the Prosidio L.E. Carello cart.
3) Connect the camerahead to the corresponding jack "  ".
4) Plug one end of the light source cable to the corresponding light 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) 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 you are 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. If you would like to manually white balance the picture, focus the camerahead onto a white object and press the “W” button on the camerahead buttons

5.3 PICTURE TAKING AND VIDEO RECORDING

- To take a picture: quickly press and release the “P” button on the camerahead. A picture of a camera will pop up on the top right corner of the screen.
- To start/stop video recording: hold the “P” button for 1 second and then release. AFTER you release the button, a red circle will be displayed on the top right corner of the screen when a recording is started. Alternatively, you can press the  record button on the display. The file name is automatically created and contains the date and time of the recording. You cannot change the name of the recordings on the device.

5.3 VIDEO PLAYBACK

To view videos that have been recorded, press the  video playback button. Then use the up and down arrows to select the video you would like to play. They are logged by the time and date when recorded. When you have finished, select the "EXIT" button and press ok.

5.4 FLEXIBLE VS RIGID SCOPE MODE

By default, the device is in the "rigid scope" 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 "flexible fiberoptic" mode. To change this mode, press and hold the UP button on the device monitor for 3-4 seconds. "RIGID → FLEXIBLE" will be displayed. When "OK" appears, the device has switched mode. To return the device to the "rigid scope" mode, repeat these steps.

5.5 LAPROSCOPY MODE

To access the "laparoscopy" mode, press and hold the DOWN button on the device monitor for 3-4 seconds. "RIGID MODE → LAPROSCOPY" will be displayed. When "OK" appears, the device has switched mode. To return the device to the "rigid scope" mode, repeat these steps.

5.6 ACCESSING THE MENU

It is recommended that you do not access the menu function unless directed to by Prosidio.

There are two menu systems in the device. **The legacy menu**, which is activated by pressing the menu button after the device is turned on (appears as plain white text) and the **main device menu** (blue colored menu) which can only be accessed if the  video playback toggle button is

activated (will be illuminated).

To access the main device menu restart the device.

1. Press the video playback toggle button – this will enter the playback mode. Select exit and press ok. The monitor should display the live endoscopy camera picture and the video playback toggle button should still be illuminated.
2. Now press the menu button. After a short delay, the main device menu will be shown.

Image brightness, contrast, saturation as well as time and date functions are found on the main device menu. Your device will be fully calibrated prior to shipping so please do not adjust these settings unless directed to by Prosidio.

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 not show any images	The power cable is not connected correctly	Securely connect the cable to the socket
	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 5.4 and 5.5
The image color is off	White Balance is not set correctly	The camera white balance is set to fixed mode

	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 W 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, you can use a cloth soaked 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 rubber 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, and if you can't wipe off the obvious stains, 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 your sales agreement for specific information on your warranty. Prosidio does not provide services beyond this standard service warranty, and you should request after-sales service support from the organization or person who provided you with this device.

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

1. Third party's claim against you (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 your installation of software or hardware devices that were not provided with this device.
5. Malfunction due to your 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, high-frequency 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 and should not be connected to these connectors unless electrostatic discharge precautions are used.
Regulations on electrostatic discharge prevention measures:
The human body or object is carried with different electrostatic voltages due to charge transfer, and since electrostatic discharge is done in ns or μs magnitude, the peak current can reach tens of amperes, the instantaneous power is very large, and the generated electrostatic discharge electromagnetic pulse energy is sufficient to damage the sensitive components in the electronic components. Because the current waveform rises for a short time, i.e., the current change rate (di/dt) is very large, it can sense hundreds of volts or even thousands of volts of high potential, resulting in a strong electric field to knock the sensitive element through. To prevent damage to the device, the following measures should be taken:

1) Ensure ambient humidity.

2) Lay anti-static floors or carpets.

3) Operators should wear an anti-static handband on the wrist, such a strap should have good grounding performance, this measure is the most effective.

4) It is recommended that all relevant employees be trained on electrostatic discharge warning signs and electrostatic discharge prevention measures.

 Warning

In addition to cables sold by the Company as spare parts for internal components, the use of non-specified accessories and cables can lead to an increase in equipment or system emission or a decrease in immunity.

Serial No.	Name	Cable length (m)	Whether shielded	Brand	Model	Remark
1	Power cord	2.0 m	NO	Ningbo Chop Electric Co., Ltd	3*0.75*2M	
2	Camera cable	2.5 m	YES	Produced in house	Produced in house	

 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:

a) The cold light source is illuminated normally and switched to the maximum brightness.

b) The system image of the device is clearly displayed and its camera resolution ≥ 900TVL.

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

Guide and Manufacturer's Statement - Electromagnetic Emission		
L.E. all-in-one endoscopy 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. all-in-one endoscopy system endoscope camera 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	The L.E. all-in-one endoscopy system endoscope camera is suitable for use in all facilities that are not directly connected to the public low-voltage power supply network of non-domestic and domestic residential buildings.
Harmonic emission GB17625.1	not applicable	
Voltage fluctuations / flicker emission GB17625.2	not applicable	

Table 2: Safe Distance

Recommended safe distance between portable and mobile RF communication devices and L.E. all-in-one endoscopy system endoscope cameras			
L.E. all-in-one endoscopy system endoscope cameras are 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. all-in-one endoscopy system endoscope camera.			
The transmitter's maximum rated output power W	The safe distance /m for the different frequencies of the transmitter		
	150kHz~80MHz $d=1.2\sqrt{P}$	80MHz~800MHz $d=1.2\sqrt{P}$	800MHz~2.5GHz $d=2.3\sqrt{P}$
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

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. all-in-one endoscopy system Endoscope Cameras 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 transient pulse group GB/T 17626.4	±2 kV to the power cord ± 1kV to the input/output line	±2 kV to the power cord not applicable	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% U_T , lasts 0.5 cycle (on U_T, temporary drop >95%) 40% U_T, lasts 5	＜5% U_T , lasts 0.5 cycle (on U_T, temporary drop >95%) 40% U_T, lasts 5	The network power supply should have the quality used in a typical commercial or hospital environment. If the user of the L.E. all-in-one endoscopy system endoscope camera needs to run it continuously during a power outage, it is recommended that the L.E. all-in-one endoscopy system endoscope camera be powered by an uninterruptible power supply

	cycles (on $U_{T,}$ temporary drop 60%) 70% $U_{T,}$ lasts 25 cycles (on $U_{T,}$ temporary drop 30%). ＜5% U_T lasts 5s (on $U_{T,}$ temporary drop >95%)	cycles (on $U_{T,}$ temporary drop 60%) 70% $U_{T,}$ lasts 25 cycles (on $U_{T,}$ temporary drop 30%). ＜5% U_T lasts 5s (on $U_{T,}$ temporary drop >95%)	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.
Note: U_T refers to the AC network voltage before the test voltage is applied.			

Table 4: Electromagnetic Immunity 2

Guidelines and Manufacturer's Statement -------- Electromagnetic Immunity

The L.E. all-in-one endoscopy system endoscope camera 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	3V (valid value) 150kHz ~ 80MHz 3V/m	3V (valid value) 3V/m	Portable and mobile RF communication devices should not be used closer to any part of the L.E. all-in-one endoscopy system endoscope camera, 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 MHz~800 MHz $d=2.3\sqrt{P}$ 800 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).

GB/T 17626.3	80MHz ~ 2.5GHz		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  .
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.			
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. all-in-one endoscopy system endoscope camera is measured to be higher than the RF compliance level described above, the L.E. all-in-one endoscopy system endoscope camera 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. all-in-one endoscopy system endoscope camera. b - In the entire frequency range from 150kHz to 80MHz, the field strength should be less than 3V/m.			

Registrant / Manufacturer:	Prosidio
FDA Registration Number:	3019110366
Regulation Number:	878.4160
Produce Code	FWL
FDA Class	I

After-sales Service Phone: +1 (914) 510-2314

After-sales Service E-mail: support@prosidio.com

URL: http://www.prosidio.com