

INSTRUCTIONS FOR USE

FocESS™ HD Wireless Camera

Read all instructions prior to use

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

1. INTRODUCTION

Intended Use

The FocESS HD Wireless Camera is intended for use in a physician's office during endoscopic sinus examinations and procedures. The Wireless Camera is not intended for use in the sterile field.

Indication for Use

The FocESS HD Wireless Camera is indicated for use in endoscopic procedures to allow visualization of the nasal and sinus cavities when used with an appropriately indicated endoscope.

Description

The Entellus Medical Wireless Camera is a non-sterile reusable device that consists of a paired wireless HD camera and receiver. The camera module incorporates a transmitter that delivers an uncompressed wireless high definition video signal to a receiver module. The receiver module is connected to a video display using a standard HDMI cable, and it is designed to be mounted on a compatible video monitor using the provided mounting bracket. An integrated LED light source eliminates the need for a separate light source and light cable, and the camera is powered by a rechargeable battery pack.

The Wireless Camera includes the camera module (with attached C-mount coupler), wireless receiver, LED light source, battery charger, two lithium ion battery packs, a receiver mounting bracket (with screw), an HDMI cable and power cords. Refer to Figure 1 below.

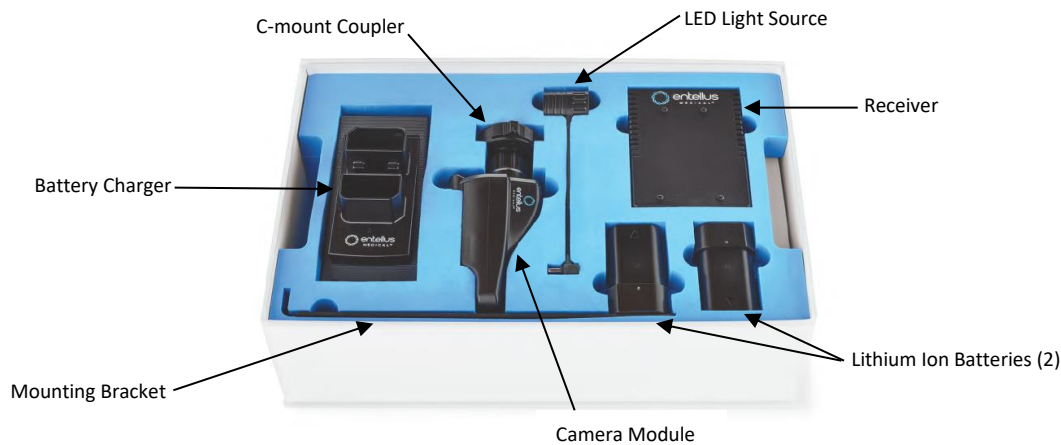


Figure 1 – FocESS HD Wireless Camera (Catalog Number WCS-100)

Contraindications

None known

Warnings

- Do not use the camera within a sterile field as this may result in cross contamination, since the camera is unable to be sterilized.
- Use only the supplied battery charger (WCC-100) with the Entellus Medical WCB-100 battery pack. Use of another battery may present a risk of fire or explosion.
- Do not attempt to modify or disassemble the Wireless Camera or any component. Doing so may damage the device or create a safety hazard.

Precautions

- Clean and low-level disinfect the camera module and C-mount coupler prior to use and after every subsequent use, employing only the procedures listed in this manual.
- Do not sterilize the Wireless Camera using any method, as this will destroy the camera.
- Do not submerge or allow liquids to enter the Wireless Camera, as it is not waterproof and this will destroy the device.
- Use only the supplied cables and components with the Wireless Camera. Test the system prior to any procedure to ensure functionality.
- Do not stare directly at the LED light source or point it directly at anyone's eyes while illumination is active.

Recommended Supplies and Compatible Equipment

The following supplies and/or equipment are not provided but are required to use the Wireless Camera:

- Compatible endoscope with 32 mm eye cup
- Compatible HD video monitor with HDMI input
- CaviWipes low-level disinfectant, or equivalent product
- 70% Isopropyl alcohol (IPA)
- Lint-free cloths

- Refer to appropriate Instructions for Use and safety procedures when preparing and using compatible supplies or equipment.

Care and Handling

- The Wireless Camera is constructed of sensitive electronics and optical components. Special care must be taken to prevent damage to the device and to maintain functionality and longevity. Negligent care and/or handling may void warranty. Refer to Section 3. Cleaning, Disinfection & Maintenance for additional information.

2. INSTRUCTIONS FOR USE

Preparation and Installation of Receiver

- Align the receiver mounting bracket in the rear, center position of the video monitor such that the top of the bracket is flush with the top of the monitor.
 - Attach the mounting bracket to the video monitor. The mounting bracket is compatible with the 100 mm x 100 mm VESA standard hole configuration.
 - Install the receiver module to the mounting bracket using the supplied screw.
 - Mounting the receiver as described provides optimal line-of-sight video signal transmission from the camera module and is therefore the recommended mounting configuration.
- Connect the HDMI cable from the receiver module to the HDMI input on the video monitor.
- Connect the barrel connector of the AC power supply to the 12V input on the receiver.

Using the Wireless Camera Battery Charger

- Plug the power cord into a 110V wall outlet. Then connect the AC power adapter to the DC input jack.
- Place one or both of the supplied battery packs into the charging bays, ensuring that the electrical contacts are inserted first and fully seated in the bay. The dual charging bays allow both battery packs to be charged at the same time.
- The charger indicates charging status with three LED indicators. One indicator is for power and the other two are for charging status. The meaning of each LED indicator state is provided in the table below:

Indicator Meaning	Power	Status	
		Bay 1	Bay 2
Power off or Power low	Off	Off	Off
Power On or Stand By	Solid Green	Off	Off
Charging	Solid Green	Solid Red	Solid Red
Charge Complete	Solid Green	Solid Green	Solid Green
Fault	Solid Green	Blinking Red	Blinking Red

Preparation of the Camera Module

- Verify that the camera module and coupler have been manually cleaned and low-level disinfected prior to device preparation and use.
- Attach the coupler, if necessary, using the following method:
 - Grasping the rear adapter, screw the coupler onto the camera head (clockwise) until it forms a tight seal. Do not overtighten the coupler.
- Remove the dust cap from the coupler, if present.
- Push the slider button on the C-mount coupler and insert the eye cup of the endoscope into the scope end of the coupler. Release the slider button.
- Connect the LED light source to the endoscope light source connector, and attach the LED light source cable to the LED power connector on the side of the camera module.
- Ensure that the battery pack is sufficiently charged prior to insertion into camera module. If necessary, charge batteries using the supplied 110V AC battery charger.
 - A camera module equipped with a fully charged battery will have enough power to achieve a minimum of 90 minutes of run time using the maximum image brightness setting.
- Slide the battery into the base of the camera. Slide forward until the battery clicks into place.

Powering up the Wireless Camera

- Plug the receiver module's AC power adapter into a 110V outlet and power on the video monitor. Ensure the monitor is set to the correct HDMI input.
- Push the power button on the top of the camera module. The power button LED will illuminate blue on the camera module and video will appear on the monitor within 10 seconds of powering up the device.
- The blue LED indicators on the receiver module are as follows:
 - Power: This LED will illuminate as soon as power is applied to the receiver.
 - Link: This LED will illuminate to show that the receiver has a link to the camera module transmitter.
 - Video: This LED will illuminate to indicate that the transmitter module has a valid video signal to transmit.

Setting the White Balance

- Point the tip of the endoscope at a white object under good lighting conditions.
- Push and hold the WB button on the camera module. Release the WB button when the "WB" symbol appears on the monitor. Hold the camera still while observing the video monitor.
- Once this symbol disappears from the monitor, the operation is complete.

Manually Focusing the Camera Image

- The camera can be manually focused if desired by adjusting the focusing ring located on the C-mount coupler.
- Hold the endoscope at the approximate expected focal distance from any object. Adjust the focusing ring until the center of the image on the monitor is in sharp focus.

Using the Wireless Camera

- Once the camera has been successfully set up, it may be used to provide visualization of the nasal and sinus cavities.
- When the distal tip of the endoscope approaches nasal or sinus structures, the LED will automatically adjust the light to an optimal setting so as not to over expose the image.
- If the image is not illuminated correctly or to a desired preference, manually adjust the LED level up or down using the "+" or "-" buttons on the camera module.
- Once an adequate illumination level is set, the setting does not need to continually be changed, since the device will automatically adjust the light intensity.
- After completion of the procedure, the camera module may be powered down by pushing the power button. The receiver module can be powered down by removing the barrel connector from the device, or by disconnecting the AC adapter from the 110V outlet.

Additional Features

- Standby Mode

- When the camera module is not needed for a period of time, place the device on a stable surface such as a table. There is no need to power the device down.
- After approximately three minutes of no movement, the camera module will go into a low power, standby mode.
- If the camera is picked up or moved within 30 minutes of entering standby mode, it will re-enter full power mode and continue operating where it had left off.
- If the device is left in standby mode for 30 minutes, it will automatically shut down. The receiver module will stay powered on indefinitely.

- Low Battery Indication

- At 15% battery life remaining, the battery life indicator appears on screen.
- Once the battery reaches the final 5% of its operating duration, the lowest battery level indicator on the camera module will start flashing.
- At this point it is recommended that the camera module is shut down, and the battery is replaced with a fully charged battery.

3. CLEANING, DISINFECTION & MAINTENANCE

The Wireless Camera is not intended to come into contact with the patient. The camera module and C-mount coupler may be cleaned and low level disinfected, but not sterilized. Endoscopes used with the Wireless Camera should be reprocessed and maintained according to their labeling.

Cleaning of the Camera Module and Coupler

1. Turn off the camera module and remove the battery pack.
2. Using a wipe such as a CaviWipe, thoroughly wipe the device for a minimum of 2 minutes, ensuring surfaces remain visibly wet for the entire exposure duration. Use new wipes as needed.
3. Actuate the slider button of the coupler to ensure thorough cleaning of the occluded area.
4. Allow the devices to air dry. Once dry, visually inspect the device for any residual soil. Repeat cleaning instructions if visible soil is present.
5. Proceed with disinfection process.

Low-level Disinfection of the Camera Module and Coupler

1. Low-level disinfection should be performed immediately prior to use in a procedure.
2. Ensure that the device has been cleaned and no residual soil remains.
3. Using a wipe such as a CaviWipe, thoroughly wipe the device for a minimum of 3 minutes, ensuring surfaces remain visibly wet the entire exposure duration. Use new wipes as needed.
4. Actuate the slider button of the coupler to ensure thorough disinfection of the occluded area.
5. Perform a final wipe of all surfaces with 70% IPA for a minimum of 1 minute.
6. Allow the devices to air dry before continuing with procedure.

Additional Maintenance

The lens window of the camera module and coupler may be cleaned with a lint-free cloth as necessary.

4. STORAGE & DISPOSAL

The Wireless Camera and components may be stored at normal room temperature. There are no special storage requirements.

Follow local governing ordinances and recycling plans regarding the recycling or disposal of the device or components. Lithium ion batteries in particular may have specific regional requirements for recycling or disposal.

5. MAINTENANCE OF QUALITY OF SERVICE & SECURITY

The FocESS HD Wireless Camera is designed to maintain an adequate quality of service during its use in an office environment. The camera module and receiver use Beam Forming Non Line-of-Site technology (BFNLOS). As a result, the signal will not transmit through solid walls or doors. It is recommended that the camera module is operated no more than 15 feet from the receiver without physically obstructing the signal's line-of-sight to ensure the best possible video quality.

The technology provides an intrinsic level of security by limiting the distance from which the signal can be intercepted. The Wireless Camera will only pair with the receiver provided with the camera, and will not function with any other receiver. In addition, all transmitted data is protected using the HDCP protocol with 128-bit AES encryption.

6. TROUBLESHOOTING, TECHNICAL SPECIFICATIONS & COMPLIANCE

Troubleshooting

Problem	Possible Cause	Action
The camera module will not power up	Battery not fully inserted	Slide the battery into the base of the camera until it clicks into place.
	Battery not charged	Place the battery into the charger. When the charger indicator light turns green, the battery is fully charged and ready for use.
No image	Receiver not powered up	Ensure that power is connected to the receiver and that the receiver power indicator is lit.
	Receiver not connected to monitor	Check the HDMI connection on the receiver and the monitor to ensure the HDMI connector is fully seated.
	Monitor set to incorrect input	Check the monitor to ensure the correct HDMI input is selected
"No Link" displayed on screen	Camera not powered on	Turn the camera module on by pressing the power button. An image should appear on the screen within 10 seconds of power on the device
	Distance between camera and receiver too great	Move the camera closer to the receiver to see if this corrects the issue. It is recommended that the camera be operated no more than 15 feet from the receiver.
Image freezes on screen / "choppy" video quality	Obstruction between camera and receiver	Ensure that you have a clear line of sight between the camera and the receiver. The preferred location for the receiver is above the monitor.
	Distance between camera and receiver too great	Move the camera closer to the receiver to see if this corrects the issue. It is recommended that the camera be operated no more than 15 feet from the receiver.
Loss of light from LED light source	LED Light Source cable not connected to the camera	Check the LED light source cable connector to ensure that it is fully inserted into the jack on the side of the camera.
Image not in focus	Coupler not tightened onto camera	If the image cannot be brought into focus by using the focus ring on the coupler, check to ensure that the coupler is tightened onto the camera.
	Coupler or endoscope lenses dirty	Check the lenses of the endoscope and clean with a lint-free cloth if necessary. Remove the coupler from the camera by unscrewing it from the camera body. Clean the coupler lenses with a lint-free cloth if necessary. Reattach the coupler to the camera, ensuring that it is tightened properly.

Technical Specifications & Compliance

Item	Specification
Wireless signal type	WirelessHD™ (IEEE 802.11ad)
Frequency band	60 GHz
Transmitter to receiver range	Maximum of 15 ft., line-of-sight required


Item	Specification
Image latency	< 0.10 seconds
Data rate	10 – 28 Gbps
Signal encryption	HDCP 1.4 (128-bit AES)
Weight (camera module with coupler, LED and battery installed)	< 400 grams
Camera native resolution	720p
Supported video	Up to 1080p
Video output (Receiver Module)	HDMI
Expected service life (Wireless Camera)	Minimum of 1,560 hours of use
Battery type	Lithium Ion, 7.4V, 3400 mAh
Mode of operation	Continuous
Battery life at full LED power	Minimum of 90 minutes
Battery lifetime/recharge cycles	250 recharges
Safe operating ambient temperature range	15 – 33°C (59 - 91°F)
Safe storage and transport temperature range	0 – 50°C (32 - 122°F)
Safe operating, storage, & transport relative humidity range	0 – 95% RH
Complies with industrial electrical standards:	UL, IEC 60950, IEC 62133:2013, RoHS, WEEE
Complies with medical safety standards:	IEC 60601-1:2005/(R)2012; CAN/CSA-C22.2 No. 60601-1-08
Complies with medical EMC standard:	IEC 60601-1-2:2007; Type BF Applied Part
Complies with FCC standard:	47 CFR Part 15, Class A Digital Device

Electromagnetic Compatibility (EMC)

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this section. Portable and Mobile RF communications equipment can affect Medical Electrical Equipment.

Guidance and Manufacturer's Declaration - Emissions		
The Wireless Camera is intended for use in the electromagnetic environments specified below. The customer or the user of the Wireless Camera should assure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Wireless Camera uses RF energy only for its internal function. Therefore, its emissions are very low and are not likely to cause any interference in nearby electrical equipment.
RF Emissions CISPR 11	Class A	The Wireless Camera is suitable for use in all establishments, other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	N/A	
Flicker IEC 61000-3-3	N/A	

Guidance and Manufacturer's Declaration – Immunity			
The Wireless Camera is intended for use in the electromagnetic environments specified below. The customer or the user of the Wireless Camera should assure that it is used in such an environment.			
Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD EN/IEC 61000-4-2	±6kV Contact, ±8kV Air	±6kV Contact, ±8kV Air	Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the RH should be at least 30%.
EFT EN/IEC 61000-4-4	±2kV Mains, ±1kV I/Os	±2kV Mains, ±1kV I/Os	
Surge EN/IEC 61000-4-5	±1kV Differential, ±2kV Common	±1kV Differential, ±2kV Common	Main power should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout EN/IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	
Power Frequency 50/60Hz, Magnetic Field EN/IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Immunity			
The Wireless Camera is intended for use in the electromagnetic environments specified below. The customer or the user of the Wireless Camera should assure that it is used in such an environment.			
Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF EN/IEC 61000-4-6	3Vrms, 150kHz to 80MHz	3Vrms, 150kHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to the Wireless Camera than the distances calculated or listed below. Recommended Separation Distance $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5MHz Where P is the maximum output power rating of the transmitter in watts and d is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance level (E1). Interference may occur in the vicinity of equipment containing a transmitter or marked with the following symbol: 
Radiated RF EN/IEC 61000-4-3	3Vrms, 80MHz to 2.5GHz	3V/m (E1)	

Recommended Separation Distances between portable and mobile RF communications equipment and the Wireless Camera			
The Wireless Camera is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Wireless Camera can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Max Output Power of Transmitter (Watts)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz $d=(1.2)(\sqrt{P})$	80MHz to 800MHz $d=(1.2)(\sqrt{P})$	800MHz to 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

7. FCC WARNINGS

This equipment has been tested and found to comply with the limits of a Class A digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against interference. This system can radiate radio frequency energy and, if not installed and used in accordance with the instructions, it may interfere with other radio communications equipment. There is no guarantee that interference will not occur in a particular installation. If this equipment is found to cause harmful interference to radio or television reception, the user is encouraged to try to correct the interference by carrying out one or more of the following measures:

1. Reorient or relocate the receiving antenna.
2. Increase the distance between this system and the subject of interference.
3. Plug this system into an outlet on a different electrical circuit than that to which the subject of interference is connected.
4. Consult the dealer or an experienced radio/TV technician for help.

NOTICES TO USER:

This device complies with the requirements of IEC 60601-1-2 and Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- 1) this device may not cause harmful interference, and
- 2) this device must accept any interference received, including interference that may cause undesired operation.

However, if used incorrectly, RF interference could hamper its operation or the operation of other nearby electrical devices. If you suspect either of these conditions, move the conflicting equipment farther apart, separate the equipment with an RF barrier, or discontinue use of the system.

This equipment generates or uses radio frequency energy. Changes or modifications to this equipment may cause harmful interference unless the modifications are expressly approved in the instruction manual. The user could lose authority to operate this equipment if an unauthorized change or modification is made.

8. WARRANTY & REPAIR SERVICE

Limited Warranty

Entellus Medical, Inc. warrants for a period of one (1) year following purchase of the product that the product will be free from defects in material and workmanship. Within the warranty period, upon receipt of Customer's prior written notice, Entellus may either repair or replace defective parts/products at no charge to Customer. Entellus Medical warrants that reasonable care has been used in the design and manufacture of this device. Entellus Medical excludes all other warranties, whether expressed or implied, by operation of law or otherwise including, but not limited to, any implied warranties of merchantability or fitness since handling and storage as well as other factors relating to the patient, diagnosis, treatment, medical procedures, and other matters beyond Entellus Medical's control directly affect the device and the results obtained from its use. Entellus Medical shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this device. Entellus Medical neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this device. Refer to *Entellus Medical, Inc. Standard Terms and Conditions*.

Warranty Assessment / Return for Service

Customers have the option of purchasing repair and replacement coverage for the Wireless Camera system, which will provide certain repair and/or replacement benefits in the event that the system has been damaged.




















Contact Customer Service for details:

Phone: (866) 620-7615

Fax: (866) 620-7616

If returning devices for assessment, all products must be cleaned and disinfected prior to shipping per one of the approved methods described within this document. Documentation must be provided stating the device has been reprocessed prior to shipping. If disposing devices, discard devices and all waste products according to appropriated environmental health safety guidelines.

9. SYMBOL DESCRIPTIONS & MANUFACTURER INFORMATION

 Consult Instructions for Use ISO 15223-1:5.4.3	 Lot Number ISO 15223-1:5.1.5	 Model Number	 Catalog Number ISO 15223-1:5.1.6	 Caution ISO 15223-1:5.4.4	WB White balance	 Battery life indicator IEC 60417-5001B	 Type BF Applied Part IEC 60417:5333
 Manufacturer ISO 15223-1:5.1.1	 Date of Manufacture ISO 15223-1:5.1.3	 Standby - Power On/Off Switch IEC 60417-5009	 Device Is Non Sterile ISO 15223-1:5.2.7	 Serial Number ISO 15223-1:5.1.7	 Prescription Use Only 21 CFR 801.109	 Non-ionizing radiation IEC/TR 60878-5140	 Tested to Comply with FCC Standards
 Brightness Level Indicator IEC 60417-5056	 Li-ion Lithium-ion Battery – recycle per local regulations	 Quantity	 When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling	<p>Symbols Reference ISO 15223-1:2012 – Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General Requirements IEC 60417:2002 – Graphical symbols for use on equipment IEC/TR 60878:2015 – Graphical symbols for electrical medical practice</p> <p>Not made with natural rubber latex</p>			

FocESS is a trademark of Entellus Medical, Inc.
patent <http://www.entellusmedical.com/patents>

WirelessHD is a registered trademark of SiBeam, Inc.

CaviWipes are a registered trademark of Metrex Research LLC.



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