

USB wireless monitor & controller

User's Manual


SCIE-OM-01

Statement:

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The Gastrointestinal Wireless Capsule Endoscope System conforms to the SFDA Authentication of State Food and Drug Administration of the People's Republic of China.

Environmental protection:

- Since capsule contains battery, corresponding treatment shall be made according to the local environment protection law after used, to avoid environment pollution.
- As to waste disposal of recorder in Gastrointestinal Wireless Capsule Endoscope System, please see the regulations of local electric product retirement for reference and corresponding treatment.

This manual is subject to change without notice.

This manual is for the USB wireless monitor of Gastrointestinal Wireless Capsule Endoscope System (hereafter called "OMOM Capsule Endoscopy"), which is the complement user manual of the 《Gastrointestinal Wireless Capsule Endoscope System》

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Special Mark Description:

: **Notice**: Instruct user operating correctly to avoid the operation failed.

: **Hint**: Un-ideal but rational result description, or rational suggestion and description.

: **Warning**: Prompt for prohibiting operation that will bring serious consequence or destroy equipment.

: caution: US Federal Law restricts this device to sale by or on the order of a physician.

SAFETY ALERT DESCRIPTIONS

The following is a list of Capsule Endoscope System safety alerts that appear in this section and throughout this manual. You must read, understand, and heed these safety alerts before attempting to operate the Capsule Endoscope System.

⚠ CAUTION: The Capsule cannot be chewed by the patient and should be swallowed under the doctor's supervision.

⚠ CAUTION: The Capsule is disposable.

⚠ CAUTION: The disposal of used products should be complied with the national laws/regulations.

⚠ CAUTION: The recorder should be worn outside of the clothing, or hurts of skin could occur.

⚠ CAUTION: The charger should not be used in the patient environment. The device cannot be operated while charging.


⚠ CAUTION: SIP/SOP only be connected the equipment in situations where no risk of external voltage exists.

EMC ALERT DESCRIPTIONS

The following is a list of Capsule Endoscope System EMC alerts that appear in this section and throughout this manual. You must read, understand, and heed these EMC alerts before attempting to operate the Capsule Endoscope System.

⚠ CAUTION: User must regard EMC, please install and put in service OMOM capsule endoscope system according to the EMC information provided in the accompanying documents.


⚠ CAUTION: Portable and mobile RF communications equipment may interfere the medical electrical equipment.

⚠ CAUTION: The pins of connectors identified with  should not be touched and that connections should not be made to these connectors unless ESD precautionary procedures are used.

-Methods to prevent build-up of electrostatic charge.

-Discharging one's body to the frame of OMOM capsule endoscope system or to earth or a large metal object.

-Bonding oneself by means of a wrist strap to OMOM capsule endoscope system or to earth.

Staff that could touch connectors identified  mark should read this instruction before. This includes clinical and biomedical engineering and health-care staff.

⚠ CAUTION: ESD training should include an introduction to the physics of electrostatic charge, the voltage levels that can occur in normal practice and the damage that can be done to electronic components if they are touched by an operator who is electrostatically charged. Further, an explanation should be given of methods to prevent build-up electrostatic charge, and how and why to

discharge one's body to earth or to the frame of OMOM capsule endoscope system, or bond oneself by means of a wrist strap to OMOM capsule endoscope system or to earth prior to making a connection.

⚠ CAUTION: A list of all cables and maximum lengths of cables, transducers and other accessories with Chongqing Jinshan Science & Technology (Group) Co. Ltd. claims compliance with the requirements of Emission and Immunity. Accessories that do not affect compliance with the requirements of Emission and Immunity need not be listed. Accessories, transducers and cables may be specified either generically or specifically.

⚠ CAUTION: The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Chongqing Jinshan Science & Technology (Group) Co., Ltd. as replacement parts for internal components, may result in internal Emissions or decreased Immunity of OMOM capsule endoscope system.

⚠ CAUTION: Table 101 - Guidance and manufacturer's declaration-electromagnetic emissions-for OMOM capsule endoscope system.

⚠ CAUTION: OMOM capsule endoscope system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, OMOM capsule endoscope system should be observed to verify normal operation in the configuration in which it will be used.

⚠ CAUTION: Table 102 -- Guidance and manufacturer's declaration -- Electromagnetic Immunity for OMOM capsule endoscope system.

⚠ CAUTION: Table 103 - Guidance and manufacturer's declaration-electromagnetic immunity-for OMOM capsule endoscope system. Table 104 Recommended separation distances between portable and mobile RF communications equipment and OMOM capsule endoscope system.

⚠ CAUTION: OMOM capsule endoscope system can be affected by portable and mobile RF communications equipment.

⚠ CAUTION: OMOM capsule endoscope system may be interfered by other equipment, even if that other equipment complies with CISPR emission requirements.

⚠ CAUTION: Use only Approved Equipment. Do not use cables other than those approved by Chongqing Jinshan Science & Technology (Group) Co., Ltd., which may cause the function improperly.



Classifications specified

USB wireless monitor & controller

Type of protection against electric shock: Internally powered equipment

Degree of protection against electric shock: Not classified - no applied parts

Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529: IPX0

Equipment not suitable for use in the presence of flammable mixtures

Mode of operation: continuous operation

Table 101: Guidance and manufacturer's declaration-electromagnetic emissions		
The capsule endoscope system is intended for use in the electromagnetic environment specified below. The customer or the user of the capsule endoscope system should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR11	Group1	The capsule endoscope system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class [B]	
Harmonic emissions IEC61000-3-2	Class [A]	
Voltage fluctuations/ Flicker emissions IEC61000-3-3	Complies	The capsule endoscope system 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.

Table 102:Guidance and manufacturer’s declaration-electromagnetic immunity


The capsule endoscope system is intended for use in the electromagnetic environment specified below. The customer or the user of the capsule endoscope system should assure that it is used in such an environment.

Immunity test	IEC60601 Test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) IEC61000-4-2	± 6KV contact ± 8KV air	± 6KV contact ± 8KV air	Floors should be wood, concrete or ceramic tile.If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC61000-4-4	± 2KV for power Supply lines	± 2KV for power Supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	± 1KV line(s) to line(s) ± 2KV line(s) to earth	± 1KV line(s) to line(s) ± 2KV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% U _T (>95% dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5 sec	<5% U _T (>95% dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the capsule endoscope system requires continued operation during power mains interruptions, it is recommended that the capsule endoscope system be powered from an uninterruptible power supply or a battery
Power frequency (50/60Hz) Magnetic field IEC61000-4-8	3A/m	0, 3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

NOTE: U_T is the a.c mains voltage prior to application of the test level

Table 103:Guidance and manufacture’s declaration – electromagnetic immunity

The capsule endoscope system is intended for use in the electromagnetic environment specified below. The customer or the user of the capsule endoscope system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the capsule endoscope system. Including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800MHz to 2.5 GHz Where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.

Note2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the capsule endoscope system is used exceeds the applicable RF compliance level above, the capsule endoscope system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the capsule endoscope system.

b Over the frequency range 150 KHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.

Table 104: Recommended separation distances between portable and mobile RF communications equipment and the capsule endoscope system

The capsule endoscope system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the capsule endoscope system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the capsule endoscope system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 KHz to 80 MHz $d = \left[\frac{3.5}{V1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E1} \right] \sqrt{P}$	800 MHz to 2.5GHz $d = \left[\frac{7}{E1} \right] \sqrt{P}$
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

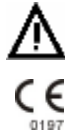
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.


Description of system flags

Description of system flags



Usage of Referenced Instruction

CE Mark: The Product system conforms to essential requirements of the Medical Device Directive 93/42/EEC

5V 

5V Direct Current

IPX0

The enclosure of the Product is not protected against water jets



Forbidding to be thrown in the garbage

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误！未定义书签。

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Preface

This manual is for the USB wireless monitor of Gastrointestinal Wireless Capsule Endoscopy System (hereafter called “OMOM Capsule Endoscopy”), which is the complement user manual of the 《Gastrointestinal Wireless Capsule Endoscopy System》, it consists of five parts.

Part I: Brief Introduction

Part II: The installation and debugging of the USB wireless monitor, instructing users to install and debug the drivers and settings of the USB wireless monitor.

Part III :Operating method, detailed operating introduction of the USB wireless monitor

Part IV: Trouble-shooting

Part V: Maintenance

Part I Introduction

1.1 About the system

OMOM capsule endoscope system is an innovative tool designed for the comfortable diagnosis of gastro intestinal tract manufactured by Chongqing Jinshan Science & Technology (Group) Co. Ltd.

OMOM capsule endoscope consists of three main parts: a smart Capsule, an Image Recorder, and a computer with Image Workstation Software. Once patient has swallowed the capsule, it moves along esophagus, stomach, duodenum, ileum and jejunum, colon and rectum by natural peristalsis, taking snap shot automatically. The images acquired by capsule are auto-coded and sent to the Image Recorder wirelessly. With the help of Image Workstation software, doctors can browse and evaluate images and make a diagnostic conclusion.

OMOM capsule endoscope system allows a comfortable, painless and safe visualization of entire small intestine as well as colon with significant high rate of disease finding.

The advanced design on hardware and software of OMOM capsule endoscope dominates its unique features:

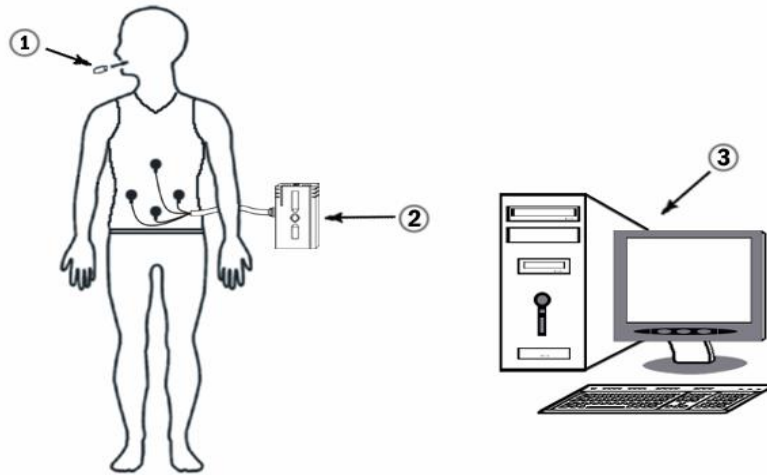
- Real time monitoring.

- Command control and parameter adjust.


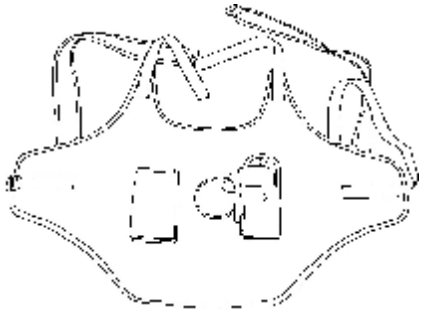
- Multi-diagnosis is allowed at same time and same place (Up to 10).



1.2 System components

OMOM capsule endoscope system consists of smart capsule, image recorder and workstation. Please see the picture below:



OMOM capsule endoscope system

Smart capsule		<p>Taking snap shot, coding and sending images wirelessly, composed by lens, CMOS sensor, battery, and RF module and shell. Can be swallowed after initializing.</p>
Image recorder		<p>Receiving and storing image information, composed by antenna elements, recording box and memory unit. Antenna is located on a fixed place in the Jacket to receive image information.</p>

<p>Image workstation software</p>		<p>Can be installed into normal PC or laptop. Integrated hardware from the manufacturer is composed of housing, computer, printer and preinstalled software.</p>
<p>USB wireless monitor</p>		<p>A transceiver connecting recorder and image workstation</p>

① : The instruction of smart capsule、image recorder and image work station please refer to the user manual of the 《Gastrointestinal Wireless Capsule Endoscope System》

1.3 USB wireless monitor Introduction

USB wireless monitor & controller is a wireless transceiver connecting USB port of the computer, through which, the operating like system preparing、real time monitoring、system controlling become true in wireless method.

Please see the picture as below:



USB wireless monitor

1) Technical Characteristics

main technical standards:

Communication distance:	≥5m
Working current:	≤0.1A
Working voltage:	5V±10%
Working temperature	0~40℃
Working humidity	≤75%
Storage humidity	≤80%
Storage temperature	0~50℃

2) status instruction

When USB wireless monitor connecting the USB port of the computer, the instruction light on the USB wireless monitor will power on.

Part II: The installation and trials of USB Wireless Monitor

i: The installation of Imaging workstation software system and computer installation is according to <<Intelligent Capsule Endoscope System User Manual>> for reference.

2.1 USB Wireless Monitor Hardware Installation

Connection of USB Wireless Monitor to the USB port of computer



2.2 settings of the USB wireless monitor

USB wireless monitor driver is same as the image recorder driver program.

1) Press power switch of image recorder to power on, and then the Found New Hardware window will pop up; select “Install from List or from Specific Location” and click next. If the window does not pop up, click Search for New Hardware.



Searching for new hardware:

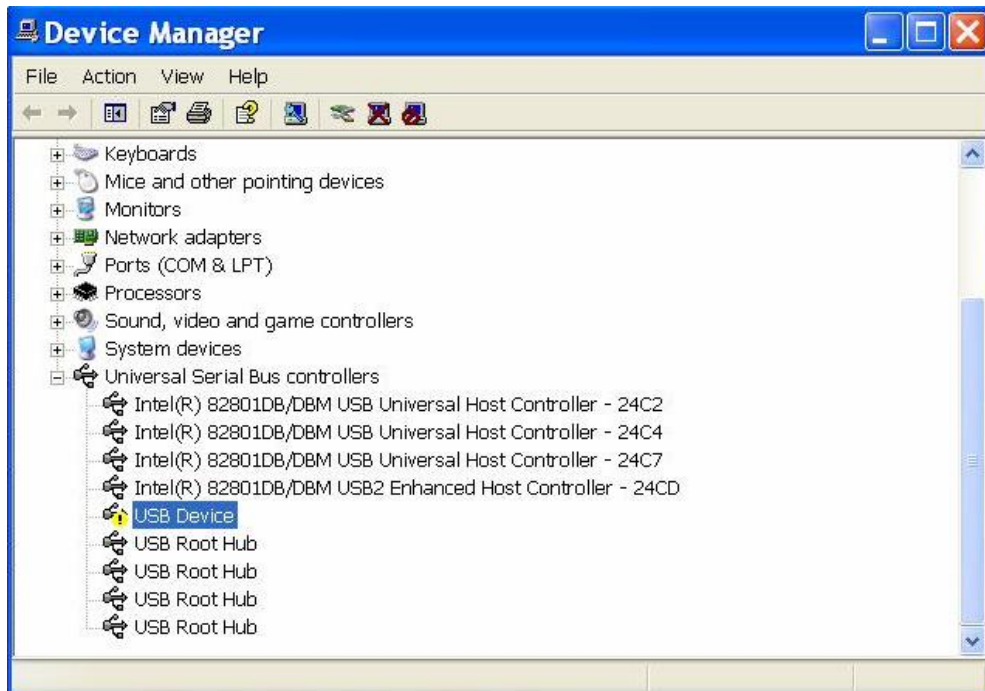
A. Right click My Computer on desktop and select property in the pop-up shortcut menu.

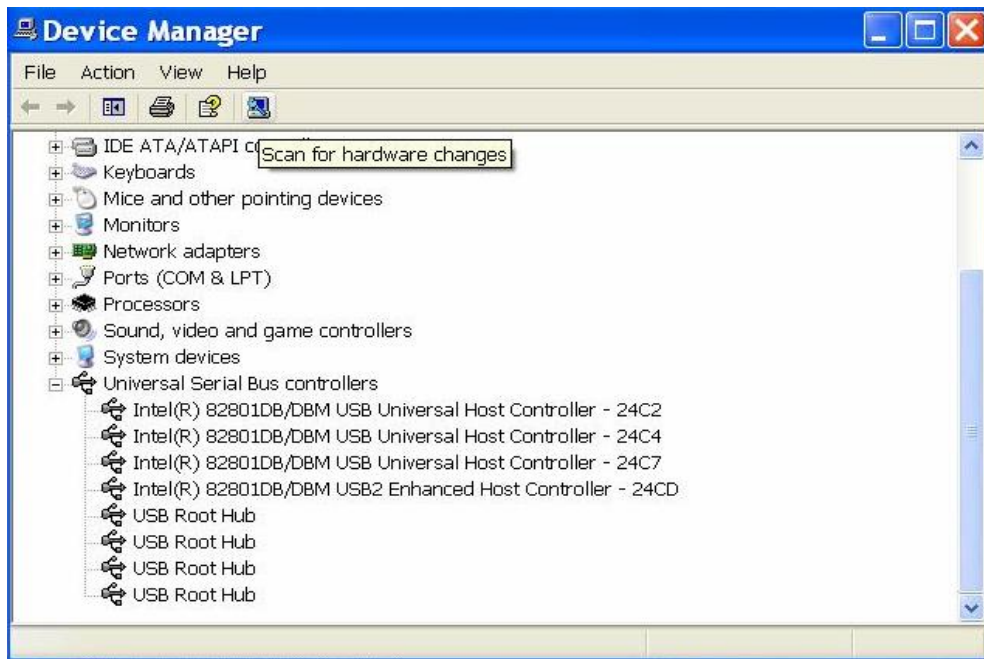


B. Select Hardware from System Property, and click Device Manager.

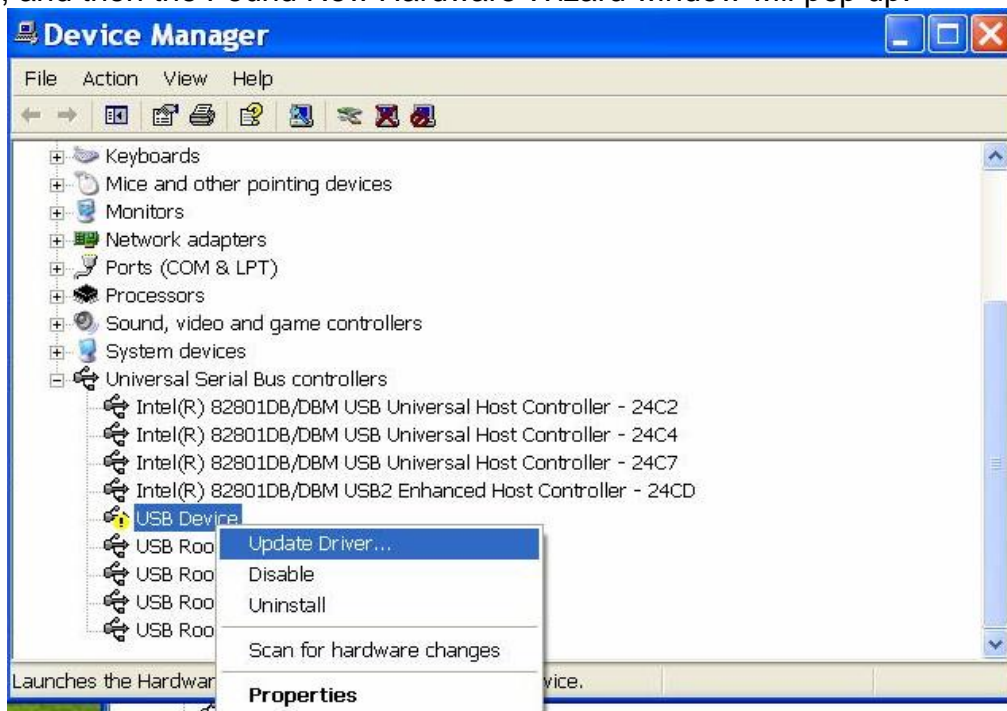


C. In Device Manager, watch whether the “! USB Device” is listed in Universal Serial Bus Controller or not. If there is not, select Universal Serial Bus Controller and click the shortcut button of Scan for Hardware Changes in the window, and then the “! USB Device” will display.

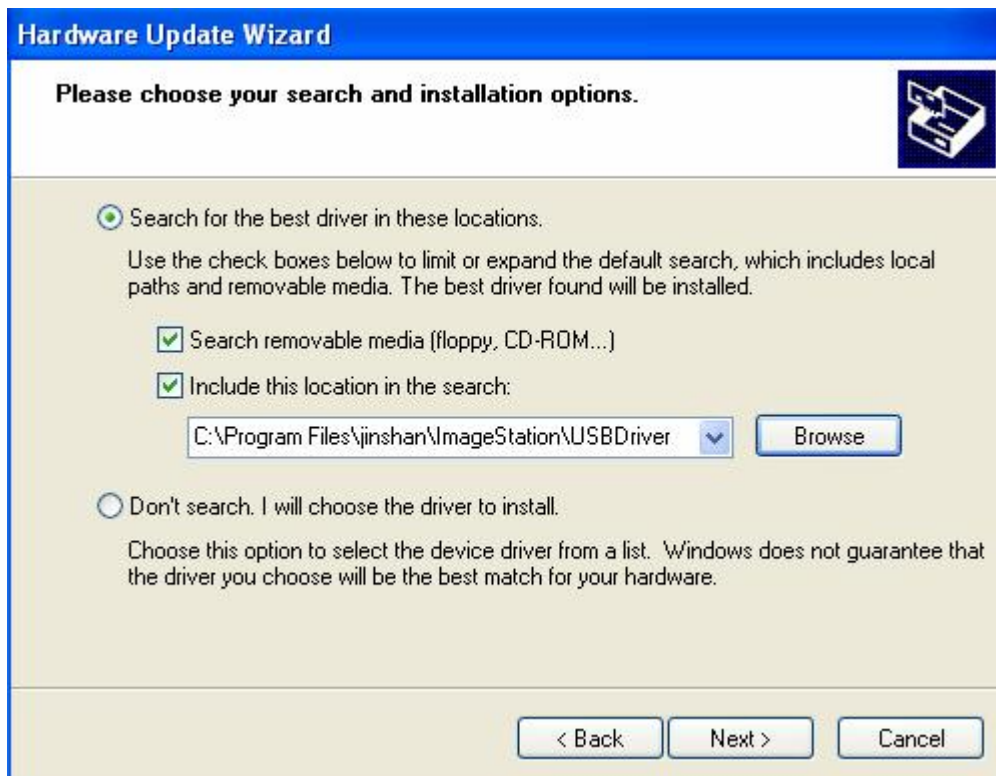




D. Right click the item and select Updating Driver in the pop-up shortcut menu, and then the Found New Hardware Wizard window will pop up.



2) From the window "New hardware found", Click **Next**, and then the following window will pop up.



C:/program files /jinshan/ ImageStation/UsbDriver 安装驱动。Button “browse” on the window and appoint the installation path of wireless monitor driver program which is in the file of “UsbDriver” on installation disk or appoint to the path: c:/program files/jinshan/ImageStation/UsbDriver for Driver installation.

3) Click **Next**, and then the system begins to search for driver.



4) After the driver is found, the following window will pop up. **Select the second item** and click **Next**.

5) Installation of USB Wireless Monitor Driver Program.



6) After the installation is finished, a window will pop up to prompt that the recorder driver is installed successfully. At this time, on the right bottom of screen, it will prompt that the new hardware is found and installed, and can be used.



i: It is only valid between installed driver program with present the computer USB port connected by USB wireless monitor. It will be unrecognized to connect USB wireless monitor with uninstalled driver program USB port. If needing connection of USB wireless monitor to other USB port on the computer, please make installation process of other USB port according to Section 2.1 again.

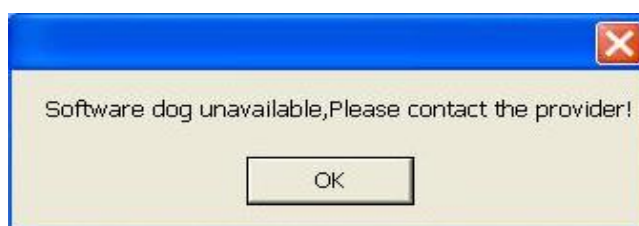
Part III How to use USB wireless monitor

i In this part, we simply introduce the way how to use USB wireless monitor, for Image Workstation usage, please refer to “The User Manual of Capsule Endoscopy System”

1) Plug on a valid SoftDog to computer parallel port or USB port.

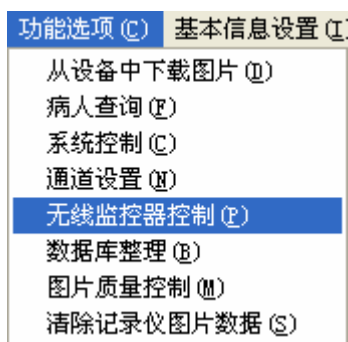


2) Double click the icon “OMOM ImageStation II” to run the main program.



3) Connecting USB wireless monitor to computer USB port.

Enter into image workstation, click “function option” and choose “ wireless monitor control”



In the blank after “setting monitor address”, enter into it the image recorder serial number and channel number, then click “set monitor address”, when it shows “command success”,click “read monitor address” to confirm if the serial number and channel number are right, if they are right, image recorder can be connected with image workstation through USB wireless monitor, to prepare system, monitor image, control system and etc.

When you use Wireless Mnitoring function, the USB wireless monitor controls only one image recorder, if you want to control more than one image recorders

(maximum 4 image recorder), you should set the addresses respectively in “set monitor address”, as the picture shows”



Please name several recorder as device 1, device 2, device 3, device 4 etc, to start wireless monitoring, simply select the corresponding device number, you can wirelessly monitor and control the selected device. For example: to monitor images of device 1, click device 1, the text box will display the record serial No. of device 1, click "Set Monitor Address", the USB wireless monitoring device will be connected with device 1 , you can start monitoring relative recorder; If you want to monitor images of device 2, it will be same process.




1. Recorder serial channel number can only be displayed after device be pre-setted. Otherwise it will not be shown in text box.

2. The direct distance range between USB wireless monitor and image recorder is around 5 meters.

3. To download image data from recorder, USB data cable must be connected, USB wireless monitor cannot download image data to workstation directly.

4. Each computer can only connect one USB wireless monitor.

After USB Wireless monitor successfully connected with the image


recorder, a 

icon will appear at lower right corner, while the recorder is connected with workstation, the

icon will change to ,

when image recorder and workstations is disconnected, the

icon with shown  .

: To communicate image recorder and workstation, you can use USB wireless monitor for wireless communication or USB data cable for wired communication; when the recorder and workstation is connected by cable, the system will default identified as wired connection.

Part IV Trouble-shooting

If there is a problem when using the USB Wireless Monitor, please try to solve it following the suggestion here below. And contact the technical support or distributor if the problem still exists.

Trouble	Measures to take
Failed to capture images or send command(USB Wireless Monitor was recognized by system)	<ul style="list-style-type: none">◆confirm the address of USB Wireless Monitor is compatible with the channel number of connection image recorder◆reset the channel number of connection image recorder◆try to plug out then plug in USB Wireless Monitor◆connect the image recorder with USB cable to monitor the images real time
USB Wireless Monitor can not be recognized by system	<ul style="list-style-type: none">◆reinstall the driver of USB Wireless Monitor◆try to plug out then plug in USB Wireless Monitor◆check the image recorder connected with USB cable or not, USB Wireless Monitor can be recognized only without connecting the USB cable.

Part V Maintenance

5.1 Maintenance of the image recorder

(1) USB wireless monitor & controller shall be kept in a dry place with the temperature 0~50℃ and maximum humidity 80%.

(2) USB wireless monitor & controller should be kept away from heavy magnetic field to avoid interference.

(3) Keep USB wireless monitor & controller away from children;

(4) Keep USB wireless monitor & controller away from fire when use or store;

(5) Keep USB wireless monitor & controller away from water or any other liquid when use or store;

⚠ : Unauthorized disassembly or repair shall be prohibited to this system.

When a failure occurs, please promptly contact our staff for help.

Extrusion, collision, bumping or falling shall be avoided for each component of the system; keep the recorder away from fire or any substance with high temperature

AC power supply is applied for the image workstation computer with a default voltage 220v. If this system is used in any place beyond China, reset shall be made to the AC voltage according to the local condition (for the reset method, please refer to the User's Manual for PC).

The image workstation computer is exclusive for the OMOM capsule endoscope only and any installation of hardware and software beyond the regulation of this manual shall be prohibited, otherwise no free call-in service will be made when the computer failure occurs.

⚠ The device could be only repaired by the manufacturer

⚠ USB wireless monitor & controller with a specified power supply(DELL 1427)

No replaceable material used during operation USB wireless monitor & controller

Recycling of the capsule

⚠ : When the USB wireless monitor & controller at the end of their useful lives; Please dispose them according to the local regulations to protect environment.

 **Warning:**

FCC WARNING STATEMENT

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with 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

