PENTAX® MEDICAL

Instructions For Use

PENTAX Medical Video Processor

Model Name:

VERSA EPK-V1500c

Instructions for Use

Please read and fully understand the Instructions for Use (hereinafter referred to as "IFU") of this equipment and the endoscope used in combination, and the instruction manuals for the related products before use, and ensure to use properly. Failure to do so may result in damage to the product or any unforeseen injury to the user or the patient.
Prior to use of the instrument, it is important for operators to have received sufficient training in clinical endoscopic techniques and to be familiar with the intended use, warnings, cautions, indications and contraindications mentioned in this IFU.
This IFU describes how to inspect and prepare this equipment before use, how to operate the processor, how to perform maintenance after use, and so on. It does not describe how an actual procedure is to be performed nor does it attempt to teach a beginner the proper techniques or any medical aspects regarding the use of the equipment.
If you have any questions regarding the information in this IFU, contact your local PENTAX Medical service facility. The content of this IFU is subject to change without notice.

Keep this IFU and the instruction manuals for the related products in a secure place for future reference.

Signal Words and Symbols

Signal Words

The following signal words are used throughout this IFU.

 Danger	Indicates an imminently hazardous situation, if not be avoided, will result in death or serious injury.
 Warning	Indicates a potentially hazardous situation that could result in death or serious injury if not avoided.
 Caution	Indicates a potentially hazardous situation that could result in minor or moderate injury if not avoided. It may also be used to alert about unsafe practices or potential equipment damage.
 Note	Indicates additional helpful information.

Symbols

The meaning(s) of the symbol(s) on the video processor, accessories, and/or on their packaging are as follows:

Symbol	Title
	Manufacturer
	Authorized representative in the European Community / European Union
	Date of manufacture
	Serial number
	Importer
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Temperature limit
	Caution
	Medical device
	Unique device identifier
	Refer to instruction manual/booklet (This symbol is colored blue on the product.)

Symbol	Title
	Stacking limit by number
	This way up
	The CE mark confirms the compliance to applicable European (EU) requirements.
	Do not dispose of as unsorted waste
	“ON”/“OFF” (push-push)
	General warning sign (This symbol is colored yellow on the product.)
	Equipotentiality
	Protective earth; protective ground

Contents

Important Information — Please Read Before Use

Intended Use

This video processor is designed to be used with PENTAX Medical video endoscopes for the lower and upper G.I (excluding duodenum), upper respiratory tract, tracheal and bronchial video observation for the purpose of performing diagnosis and treatment.
Do not use this video processor for any purpose other than its intended use.

Contraindications

(1) Severe heart disease, such as severe arrhythmias, especially slow ventricular rate, acute phase of myocardial infarction and severe heart failure
(2) Severe lung disease, such as bronchial asthma attacks, respiratory failure, etc.
(3) Acute perforation of hollow organs such as the esophagus, stomach and duodenum
(4) Acute severe pharyngeal disease where the endoscope cannot be inserted
(5) Acute phase of corrosive esophageal and gastric injury
(6) Persons who are confused or mentally disordered and unable to cooperate
(7) Patients fitted with pacemakers

Intended Users

The operator of this instrument must be a trained and qualified physician.

Repair and Modification

This video processor does not contain any user-serviceable parts. Do not disassemble, modify or attempt to repair it, otherwise patient or operator injury, equipment damage and/or the failure to obtain the expected functionality can result. This equipment should be repaired by authorized personnel only.

Notice to the User and/or Patient

As per the Regulation (EU) 2017/745 (EU-MDR), any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Dangers, Warnings, and Cautions

Follow the dangers, warnings and cautions below when handling this video processor.

Danger

- As a TYPE BF applied part, the endoscope connected to the video processor must never be applied directly to the heart. Leakage current from the TYPE BF applied part may be dangerous and cause ventricular fibrillation or seriously affect the cardiac function of the patient. Always adhere to the following points.
- Never apply the endoscope connected to this video processor to the heart or any area near the heart.
- Never allow an endo-therapy accessory or another endoscope applied to or near the heart to contact with the endoscope connected to this video processor.
- Strictly observe the following precautions. Failure to do so may place the patient and the medical personnel in danger.
- When this equipment is used to examine a patient, do not allow metal parts of the endoscope or its accessories to touch metal parts of other system components.
- Keep fluids away from all electrical equipment. If fluids are spilled on or into the unit, stop operation of the video processor immediately and contact us.
- Do not prepare, inspect or use this video processor with wet hands.
- Never install and operate the video processor in locations where:
  – The concentration of oxygen is high.
  – Oxidizing agent (such as nitrous oxide) or flammable anesthetics are present in the atmosphere.

Warning

- The system should be established with equipment complied with relevant EMC standards for safety reason.
- Equipment which does not comply with EMC standard may cause interference and its function or performance may be affected.
- Portable or mobile phones may influence the medical electrical equipment by their emitting energy.
- Please connect the items that only have been specified as part of PENTAX Medical Video Endoscopes or specified as being compatible with these endoscopes.
- Assembly of endoscopes and modifications during actual service life shall be evaluated based on the requirements of IEC 60601.
- Surface temperatures on an APPLIED PART are likely to exceed 41°C.
- High energy radiated light may be transmitted from the light emission window of the ENDOSCOPE, giving rise to high temperatures in front of the light emission window, and please do not use the endoscope for a long time.
- Before each use or after a change of viewing modes/settings, the OPERATOR should check to ensure the view observed through the ENDOSCOPE provides a live image (rather than a stored one) and has the correct image orientation.

Warning

- INTERCONNECTIONS CONDITIONS require the APPLIED PARTS of other ME EQUIPMENT used within the CONFIGURATION FOR ENDOSCOPIC APPLICATION to be TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.
- Gas embolism caused by, for example, over-insufflation of air, inert gas prior to HIGH FREQUENCY surgery, or laser assist gas will lead to patient feeling uncomfortable.
- Before each use, the compatibility of the ENDOSCOPIC Equipment with any ACCESSORIES and/or ENERGIZED ENDOTHERAPY DEVICES should be checked according to any criteria for safe use defined in the instructions for use.
- ENDOSCOPIC EQUIPMENT is used with ACCESSORIES, other ME EQUIPMENT and/or non-ME EQUIPMENT within a CONFIGURATION FOR ENDOSCOPIC APPLICATION, on the avoidance of RISKS caused by their use together (see also 16.2 of the general standard (IEC 60601-1)).

Caution

- Do not touch the electrical contacts inside the connectors of the video processor.
- Do not connect or disconnect the light guide connector while this video processor is turned ON. This action may destroy the endoscope.
- When this equipment is used with other non-medical auxiliary equipment, such as video recorder or printer, the isolated transformer or insulating socket must be used to ensure the safety.
- Do not use a sharp or hard object to press the buttons on the front panel. This may damage the buttons.
- Avoid applying excessive force to the connectors, as this may damage the equipment.
- Instructions for installation, assembly, and modification of PENTAX Medical Video Endoscopes to ensure continued compliance with this standard (IEC 60601-1).
- Service personnel should confirm that the equipment still complies to IEC 60601 series standards after installation, assembly, and modification of PENTAX Medical Video Endoscopes.

Note

Manufacturer: PENTAX-Aohua Medical Technologies Co., Ltd.

1 Checking the Package Contents

Caution

Match all items in the package with the components shown below. Inspect each item for damage. If a component is missing or damaged, please contact us.

■ Package Contents

Item code	Item	Quantity
—	EPK-V1500c	1
—	Power cable	1
AGS00450	CVBS cable	4
AGS00451	S-video cable	1
EP91003	Fuse	4
GM00872	White balance cap	1
AGS00452	Image printer trigger cable	1
DX00350	IFU (EPK-V1500c)	1

Note

Above accessories are dedicated to the Video Processor EPK-V1500c. Do not use other accessories out of above table.

■ General optional accessories

Item code	Item
AGS00399	EU power cable
AGS00054	US power cable
AGS00049	India power cable
AGS00386	Brazil power cable
AGS00050	UK power cable
AGS00616	Keyboard
AGS00379	Kingston 32G USB

2 Nomenclature and Functions

2-1. Nomenclature

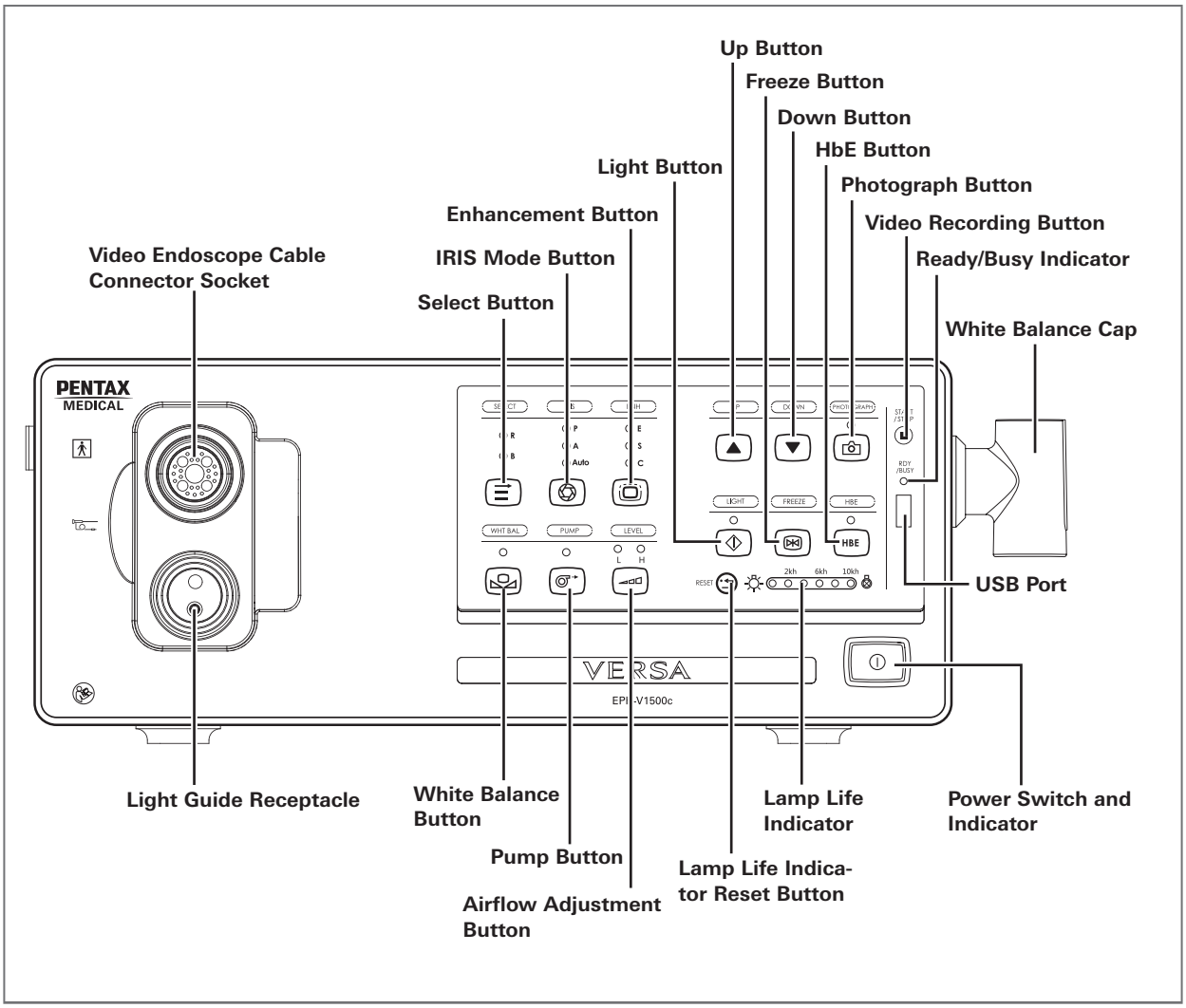

Figure 2.1 (front panel)

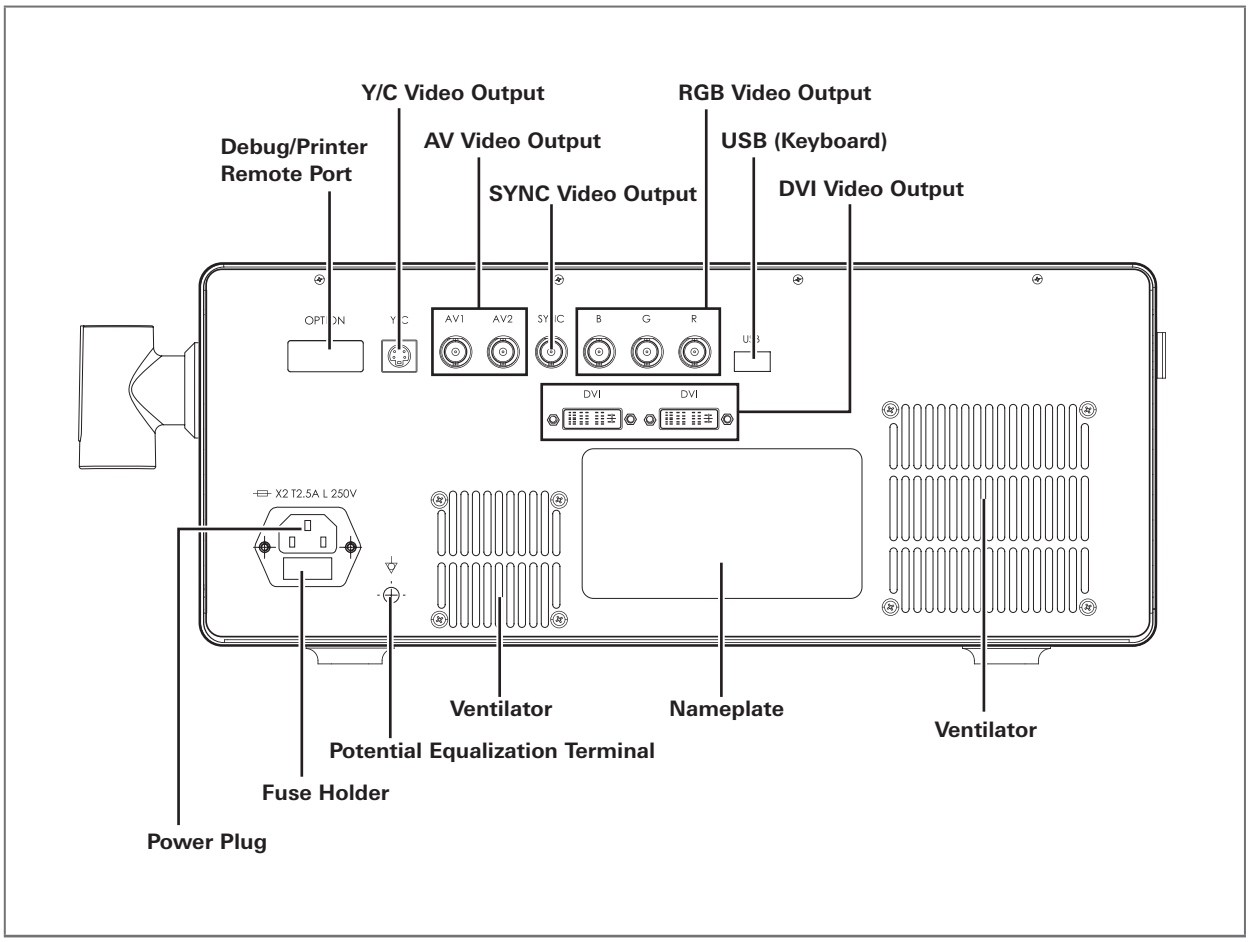

Figure 2.2 (rear panel)

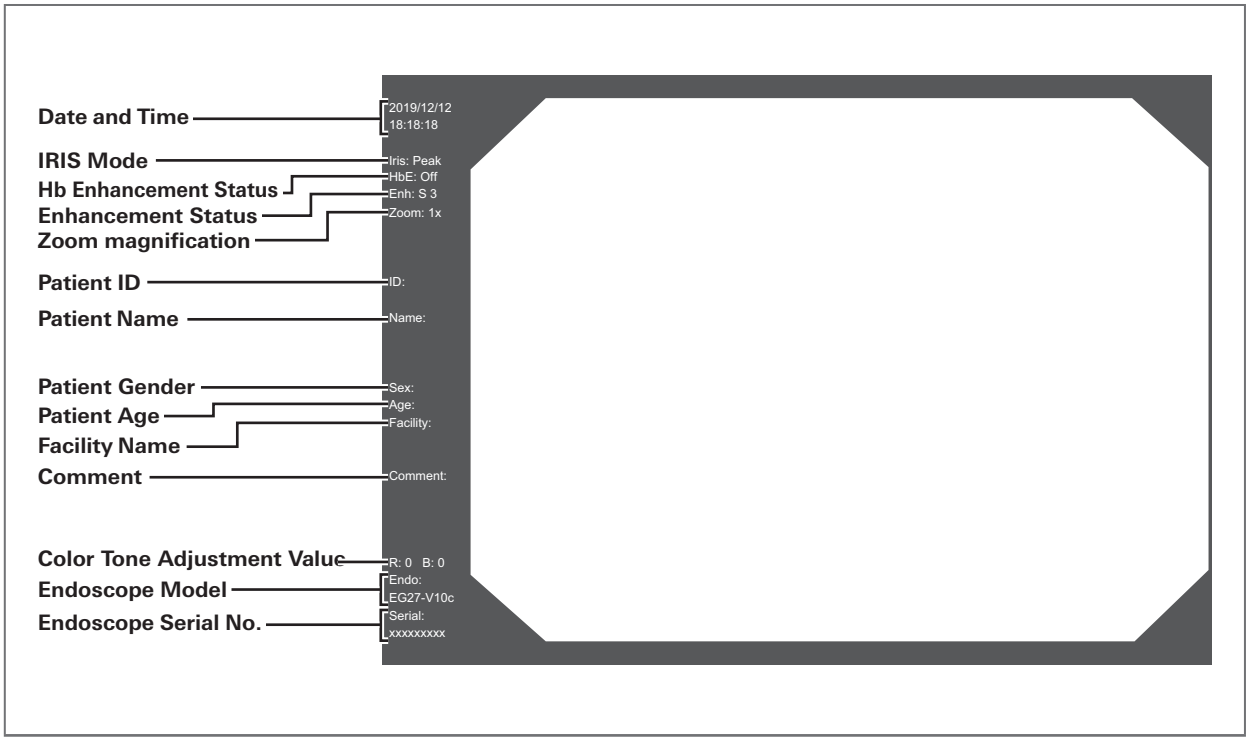

Figure 2.3 (monitor display)

2-2. Functions

1. Medical categorization

Equipment Class: Class I
Equipment Type: BF

2. White balance adjustment

The equipment can conduct white balance adjustment.

3. Pump airflow selection

The equipment can switch pump airflow levels.

4. Video output

The equipment can provide variety types of video output including Y/C, SYNC, RGB, AV, and DVI.

5. IRIS mode selection

Using the IRIS mode button, you can select the IRIS mode (exposure control method) from Average (A), Peak (P), and Auto modes. The field brightness is automatically adjusted based on the selected IRIS mode.

6. Keyboard (optional)

Using the keyboard, necessary information can be input, such as Date/Time, Facility and Patient information. The processor can be operated even without inputting the information. Any keyboard with a USB connector can be connected.
Keyboard function keys are assigned as follows:
F1: HbE; F2: IRIS; F3: Enhancement Mode; F4: Enhancement Level; F6: Freeze; F7: Playback; F8: Switching to Previous Frozen Image; F9: Record; F10: Photograph; F11: Zoom; F12: Date/Time Adjustment

7. Color tone adjustment

Using the select button and up/down buttons, you can adjust the color tone R/B levels.

8. Enhancement

The equipment can provide image with edge enhancement, structure enhancement, or combination of both. Enhancement is an image processing technique that electronically sharpens the image.

9. Hb enhancement

The equipment can provide image with Hb enhancement. Hb enhancement is an image processing technique that highlights the blood vessels to make it easier to observe tissue with enriched blood supply.

10. Freeze

The freeze function creates a stationary view of the moving image. Using the up and down buttons, you can review frozen images.

11. Image/Video recording to USB storage devices

Using the photograph button and video recording button, you can save captured images and recorded videos in a USB storage device.

12. Zoom

Both the live image and the frozen image can be magnified.

2-3. Specifications

Item			Specification
Power Requirements	Voltage		100 to 240 VAC
	Frequency		50 / 60 Hz
	Power requirement		150 VA
	Voltage fluctuation		±10%
Operating Environment	Ambient temperature		5 to 40°C
	Relative humidity		≤80% (40°C)
	Air pressure		700 to 1060 hPa
Storage Environment	Ambient temperature		-40 to 55°C
	Relative humidity		≤93% (40°C)
	Air pressure		595 to 1060 hPa
Illumination	Lamp		35 W LED lamp
	Average life span		10,000 h
	Color temperature		4500 to 6500 K
	Brightness control		Auto
Scope Compatibility	PENTAX Medical video endoscopes		This processor can be used with • PENTAX Medical video endoscopes
Air Feed System	Air pump system		DC diaphragm
	Standard air feed volume at inlet of water bottle		Low: 4.0 L/min ± 2 L/min High: 7.0 L/min ± 2 L/min
Water Feed System	Water bottle assembly pressurized by pump		Bottle capacity = 150 mL
Exposure Control System	Automatic		Selection: Average / Peak / Auto
Freeze Function			Freeze screen is displayed as normal screen.
Cooling			Forced air cooling
Video Signals	Digital output	DVI	2 sets
	Analog output	RGB	1 set
		Y/C	1 set
		AV	1 set
		SYNC	1 set
Control Signals	Remote		1 set

Item		Specification	
Classification as Electro Medical Equipment	Type of protection against electric shock	Class I equipment	
	Degree of protection against electric shock	Type BF (Body Floating), using insulated endoscope. Use on a heart is prohibited.	
	Degree of explosion proofing	Do not use in potentially flammable surroundings. * The processor is not suitable for use in a mixture of air and flammable anesthetic gas or a mixture of oxygen/nitrous oxide and flammable anesthetic gas.	
Electro Magnetic Compatibility	Designed in accordance with	EN 60601-1-2 for EU IEC 60601-1-2 for other countries	
Compliance	Designed in accordance with	UL 60601-1	IEC 60601-1
Size	Excluding protrusions	Width 452 mm × Height 167 mm × Depth 456 mm	
Weight	Main body	11.5 kg	
Software Version		SWI7	

3 Installation and Inspection

3-1. System Configuration

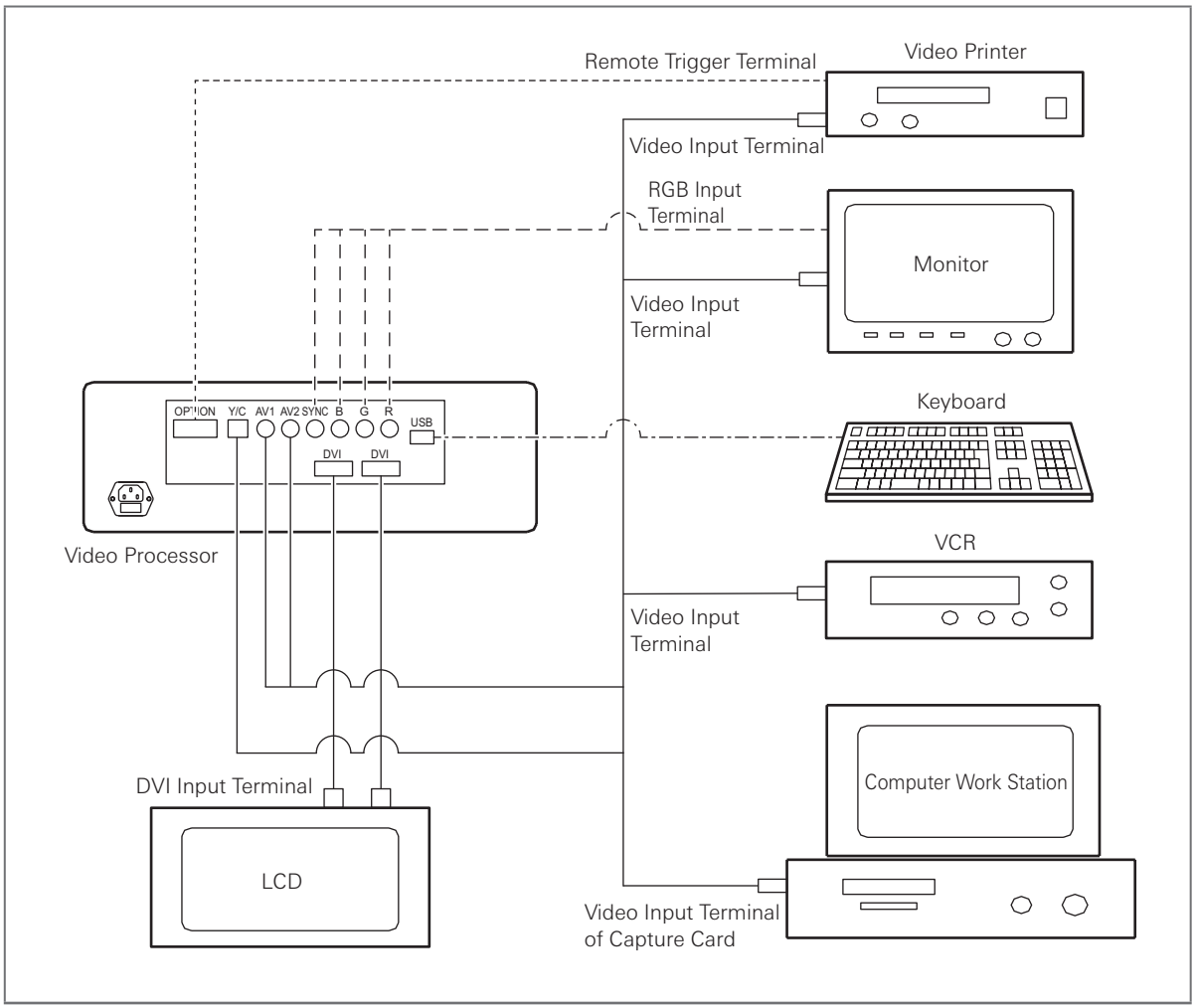

Figure 3.1

Caution

- Turn OFF all system components before connecting them. Use appropriate cables only. Otherwise, equipment damage or malfunction can result.
- When non-medical electrical ancillary equipment is used, connect its power cord via an isolation transformer prior to connecting it to this video processor. Failure to do so can cause electric shock, burns and/or fire.
- The cable should not be sharply bent, pulled, twisted or crushed.
- Do refer to the instruction manuals and install the equipment as follows:

3-2. Installation of Equipment

Caution

- Do not place any equipment on the top of the video processor. Otherwise, equipment damage may result.
- Keep the air inlet of the video processor clean. Clean the air inlet, when it is covered with dust, blockage can cause overheating and equipment damage.
- Do not install the video processor near a source of strong electromagnetic radiation (microwave treatment equipment, short-wave treatment equipment, MRI, etc.). Otherwise, the video processor may malfunction.

1. Place the mobile workstation on a level surface. Lock the caster brakes as shown in Figure 3.2.

Figure 3.2

2. Place the EPK-V1500c on the workstation.
3. Connect the video processor and peripheral devices using cables.
   - Connect a cable between the DVI terminal on the video processor and the DVI input terminal on the monitor.
   - Connect a cable between the R/G/B/SYNC terminals on the video processor and the RGB input terminal on the monitor.
   - Connect a cable between the Y/C terminal on the video processor and the video input terminal on the monitor, video printer, etc.
   - Connect a cable between the AV1/AV2 terminals on the video processor and the video input terminal on the monitor, video printer, etc.
   - Connect a cable between the OPTION terminal on the video processor and the remote trigger terminal on the video printer.

4. Insert the light guide connector into the scope socket on the front panel of the light source until it clicks into place (see Figure 3.3).

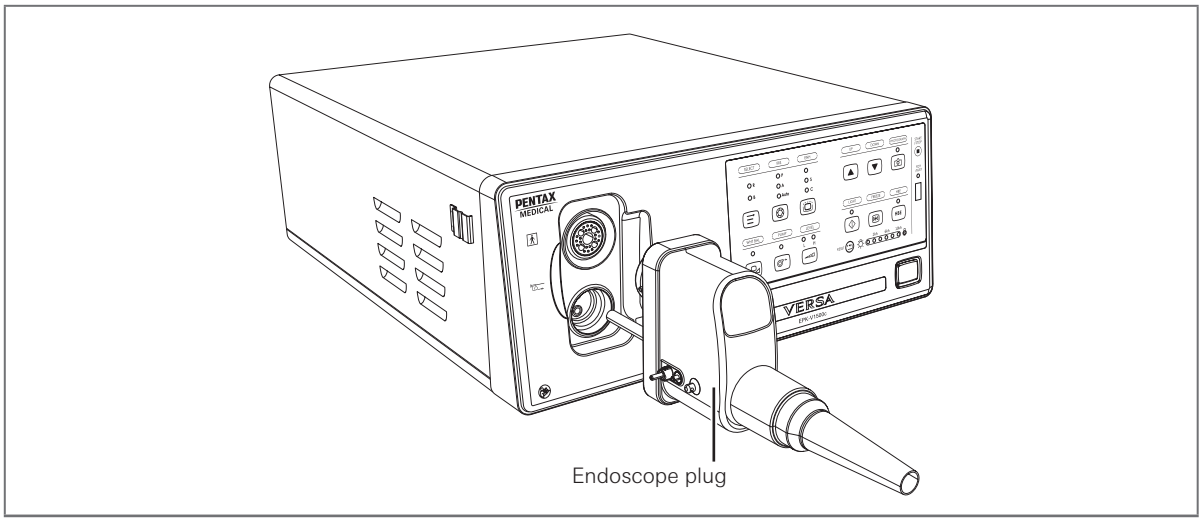

Figure 3.3

Caution

Before connecting the light guide connector to the video processor, make sure that it is completely dry. Otherwise, electric shock or equipment damage may occur.

5. Confirm that the video processor is OFF.
6. Connect the power cord to the AC mains inlet and to a wall mains outlet.

Danger

Connect the power plug of the power cord directly to a grounded wall mains outlet. It can cause an electric shock and/or fire, if the video processor is not grounded properly.

Warning

- Do not allow the power cord wet. Otherwise, it may cause electric shock.
- Do not bend, pull or twist the power cord. Electric shock, equipment damage or fire can result.
- Keep the power switch ON in daily use. If the instrument is not used for a period, turn OFF the power switch.
- Make sure the electrical capacity of the power source is enough. Otherwise, malfunction of equipment can also result.
- User must provide a stable power supply. Strong fluctuations in power supply must be regulated with power regulator or a UPS power.

3-3. Inspection of the Power Supply

Warning

- Before each case, inspect this video processor as instructed below.
- If any malfunction be suspected, do not use the equipment and check with Chapter 5, “Troubleshooting”.
- If the malfunction is still suspected after consulting Chapter 5, contact us. Using a defective video processor may compromise patient or user safety and may result in more severe equipment damage.

1. Confirm that the light guide connector is connected to the scope socket of the video processor.
2. Turn the main power switch on the front panel ON.
3. Confirm that the power indicator is lit.

If the Power Fails to Come ON

If the power fails to come on, turn the video processor OFF and inspect the system as follows:

1. Confirm the power cord is connected securely to the wall mains outlet and to the AC mains inlet on the video processor.
2. Turn the power switch on the front panel ON.
3. Confirm that the power indicator is lit.

3-4. Inspection of the Monitor Display

Warning

- Turn OFF the power switch and remove the power cord from the wall mains outlet before replacing the fuses. Otherwise, electric shock may occur.
- Turn the video processor OFF and disconnect the power cord from the wall mains outlet.
- When changing the fuses, refer to Section 4-2, “Replacement of the Fuse”.
- If the power fails to come on after replacing the fuses with new ones, contact us.
- 5 seconds after the power switch is set ON, the image and settings will be displayed at the left of the monitor screen. If the power fails to come on after replacing the fuses, contact us.

3-5. Inspection of the Freeze and Defreeze Function

1. Press the “Freeze” button on the handle of the endoscope.
2. Confirm that the real-time endoscopic image is frozen on monitor.
3. Press the “Freeze” button again, and confirm that the real-time image reappears.

Warning

If the image fails to freeze or defreeze, press the power switch to turn OFF the video processor, wait for 8 seconds, and then press the power switch to turn ON the video processor again. If this action still cannot resolve the problem, contact us.

4 Operation

The operator of this video processor must be a physician who has received sufficient training in clinical endoscopic technique. This manual, therefore, does not explain or discuss clinical endoscopic procedures. It only describes basic operation and precautions related to the operation of this video processor.

⚠ Warning

- Anytime you suspect an abnormality in any function, stop the examination immediately. Take action according to the procedures described below. Using a defective video processor may cause injury.
- If the endoscopic image disappears or the image freezes cannot be restored, turn the video processor OFF and wait for about 8 seconds. Then turn it back ON again.
- If any other abnormality occurs or is suspected, stop using the equipment immediately and withdraw the endoscope from the patient slowly following the instructions given in the endoscope's instruction manual. Then refer to Chapter 5, "Troubleshooting" and take the described remedial action. If the problem cannot be resolved, contact us.
- Do not leave the examination light illuminated from the endoscope before and/or after examination. Otherwise, it will cause the distal end of the endoscope to become overheated and could cause operator and/or patient burns.
- Do not use the video processor in a location exposed to strong electromagnetic radiations direct may cause malfunction. (For example, microwave treatment device, short wave treatment device, and MRI or radio equipment.)

4-1. Specific Operation

4.1.1 Turning the Video Processor ON

1. Confirm that the power switch of the video processor is OFF.
2. Confirm that the light guide connector is connected to the scope socket of the video processor.
3. Press the power switch to turn the video processor ON.
4. Confirm that the power indicator of the video processor is lit.

4.1.2 Setting the Date and Time

1. Press the F12 key on the keyboard.
2. Press the up, down, left, and right keys on the keyboard to adjust the numbers.
3. The format of date and time are YYYY/MM/DD (Year/Month/Day) and HH:MM:SS (Hour:Minute:Second).
4. When all set, press the F12 key again.

4.1.3 Inputting the Patient Information

1. Press the ENTER key on the keyboard to shift between patient information columns and input data by keyboard.

4.1.4 Turning the Lamp ON

1. Press the light button to turn ON the lamp (see Figure 4.1).
   The processor lamp and LIGHT indicator will light. After the lamp lights, any scope connected to the processor will emit light out of its distal end.
   Pressing the light button again will turn OFF the lamp.

Caution

- The lamp life for the EPK-V1500c video processor is about 10,000 hours. Check the lamp life indicator on the front panel before you use the processor. If all 6 indicators are all lit, contact us to replace the lamp.
- Do not look directly at the light emitted from the distal end of the scope.

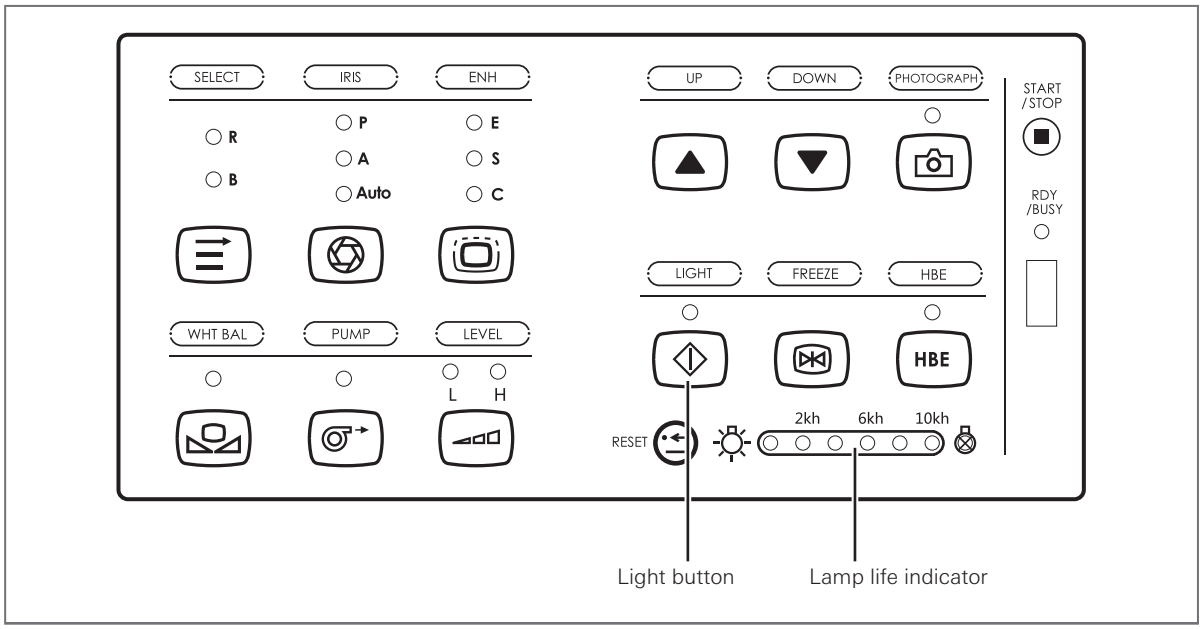

Figure 4.1

Note

After use, be sure to press the light button to turn the lamp OFF.

4.1.5 Turning the Pump ON and Changing the Airflow Level

1. Press the pump button to turn ON the pump (see Figure 4.2).
   The PUMP indicator will light and air will be supplied.
   Pressing the pump button again will turn OFF the pump.
2. Press the airflow adjustment button to adjust the airflow level (see Figure 4.2).
   Pressing the airflow adjustment button will switch the airflow level between “H” (High) and “L” (Low). The H and L indicators indicate the present status of the airflow.

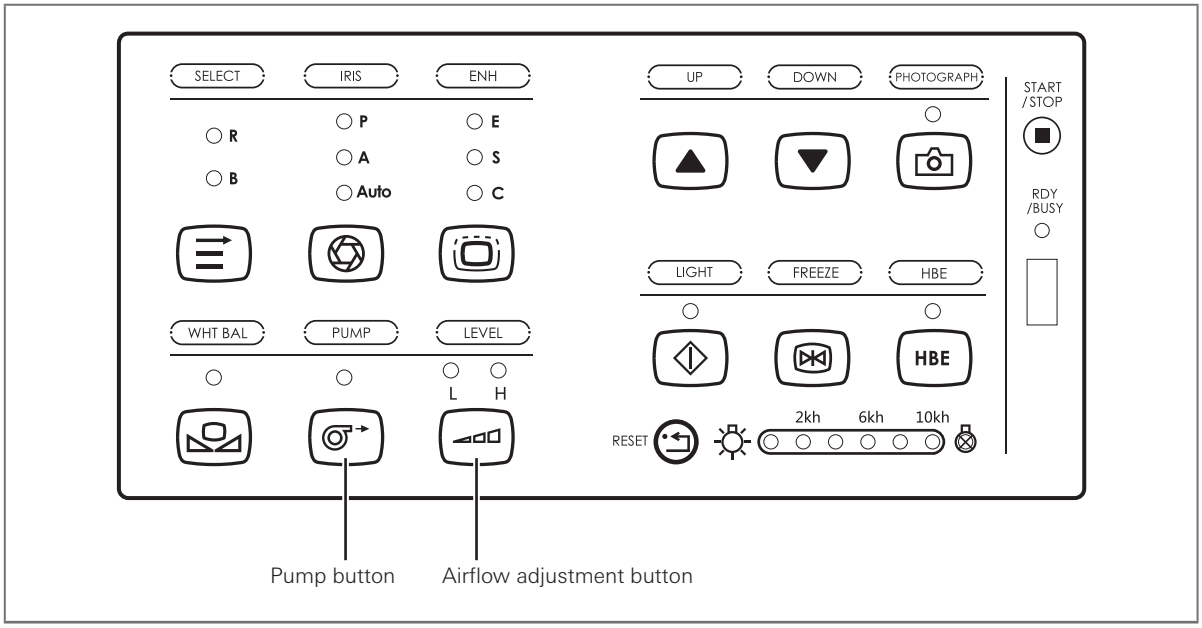

Figure 4.2

Warning

It must be recognized that variations in airflow (pressure and volume) for patient insufflation may exist from one manufacturer’s equipment (processor and/or scope type) to another. It is, therefore, important to closely monitor the patient at all times and to aspirate excessive air to prevent over-insufflation and potential pneumatic perforation.

Caution

- Regardless of pump level setting selected, avoid delivering too much air to minimize the potential for pneumatic perforation or barotrauma.
- Be careful not to deliver too much air.
- Monitor the patient continuously, and ensure that an air embolism does not occur due to excessive air supply.

Note

Should debris on the objective lens be difficult to clean, one can temporarily use a higher pump level setting on the video processor.
While doing so, simultaneously activate the air and suction control valves to minimize air insufflation. After the lens has been cleared return the air pressure to its original setting for routine use. Regardless of pump level setting selected, avoid delivering too much air.

4.1.6 Adjusting the White Balance

The white balance adjustment is required to reproduce colors in their original tones.

Warning

- Be sure to adjust the white balance every time after the endoscope is changed, to ensure accurate color reproduction is obtained.
- Always control the image according to the purpose of observation. Setting an inappropriate color tone or color enhancement condition may result in overlooking or wrong diagnosis.

1. Confirm that the endoscope is connected to the video processor.
2. Confirm that the video processor and the lamp are turned ON.
3. Insert the distal end of the endoscope into the white balance cap as shown in Figure 4.3. Hold the white balance cap and endoscope steady to avoid washing out of the monitor image.

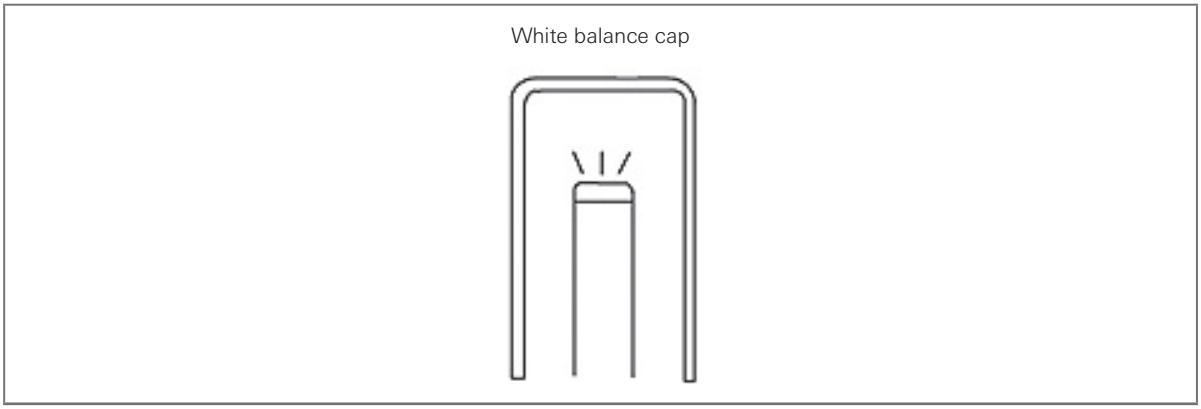

Figure 4.3

4. Press and hold the white balance button for at least two seconds (see Figure 4.4). The On Screen Display (OSD) will show “WB done” on the screen which means the finish of the adjustment.

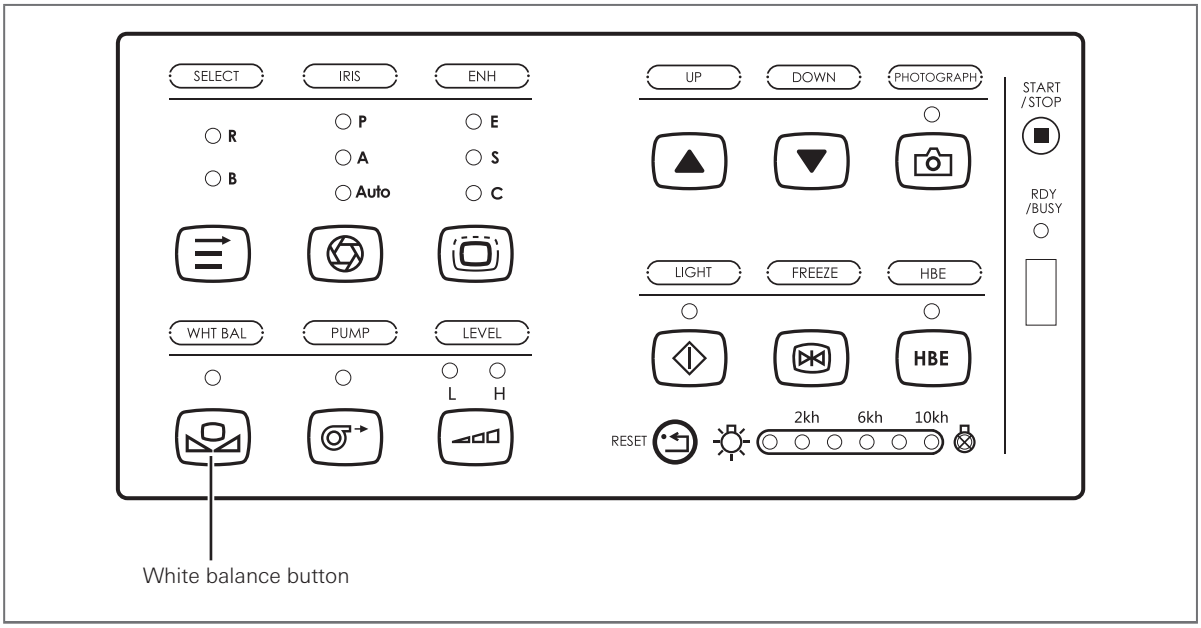

Figure 4.4

4.1.7 Selecting the IRIS Mode

1. Press the IRIS mode button or the F2 key on the keyboard to select the IRIS mode (exposure control method) (see Figure 4.5).
   Pressing the IRIS mode button will switch the IRIS mode between "A" (Average), "P" (Peak), and Auto. The indicators indicate the present status of the IRIS mode.
   When "A" is selected, exposure is controlled based on the average brightness value of the field.
   When "P" is selected, exposure is controlled based on the maximum brightness value of the field.
   When "Auto" is selected, exposure is balanced automatically.

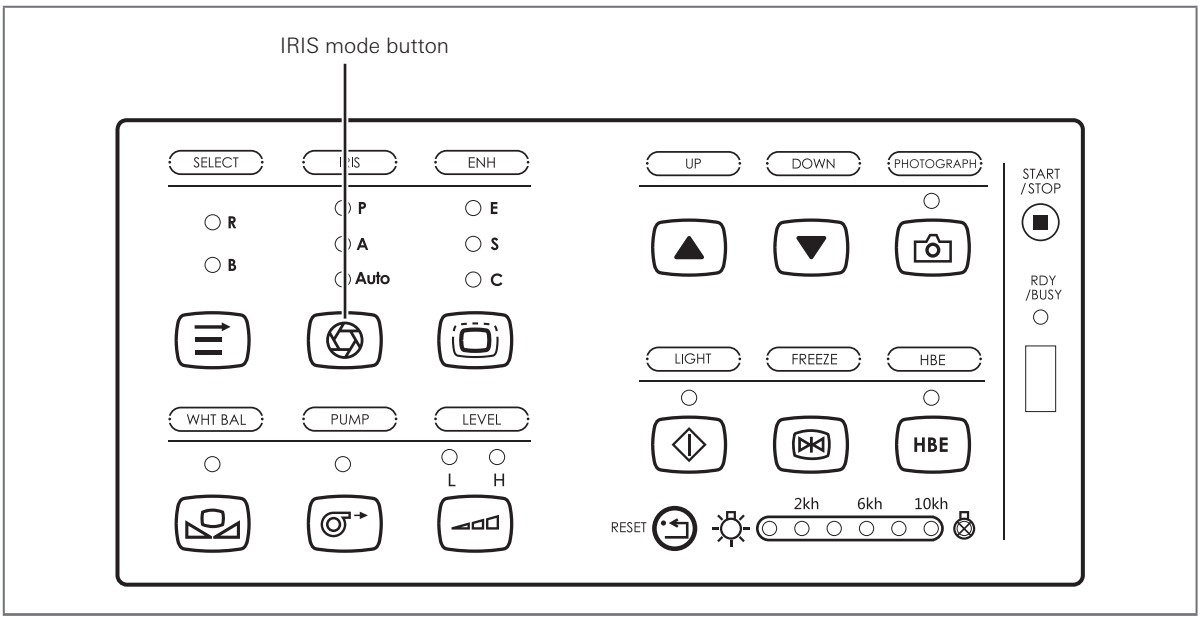

Figure 4.5

4.1.8 Zooming

This function works on a live image or frozen image. Press the F11 key to zoom in on the image at a magnification of 1.2×, 1.5×, and 2×.

4.1.9 Adjusting the Image Color Tone

You can manually adjust the color tone of images appearing on the monitor.

1. Press the select button to select the item to adjust (see Figure 4.6).
   Pressing the select button will switch the item between “R” (Red color tone) and “B” (Blue color tone). The R and B indicators indicate the current selected item.
2. Press the up and down buttons to adjust the value for the selected item.
   Each value can be adjusted in the range from -10 to +10.

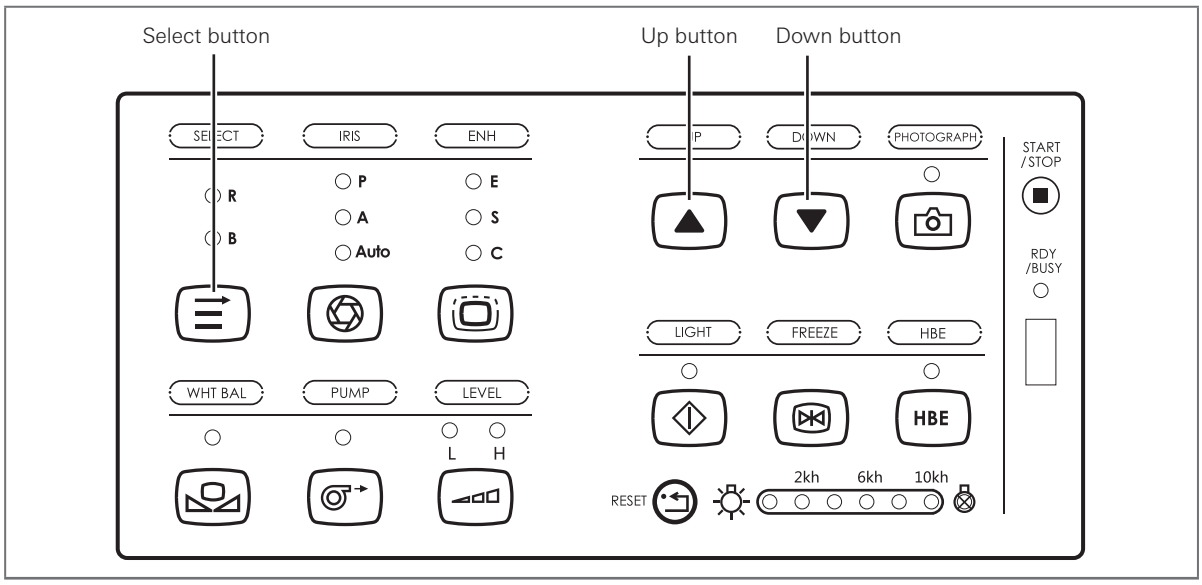

Figure 4.6

4.1.10 Changing the Image Enhancement

The equipment can provide image in enhancement. Enhancement is an image processing technique that electronically sharpens the Edge (E), Structure (S), or Combination of them (C) of an image.

1. Press and hold the enhancement button on the front panel or press the F3 key on the keyboard to select the mode (see Figure 4.7).
2. While an enhancement mode (E, S or C) is chosen, press the enhancement button on the front panel briefly or press the F4 key on the keyboard to select the enhancement level (0, 1, 2 or 3).
   The current mode and level are displayed on the screen.

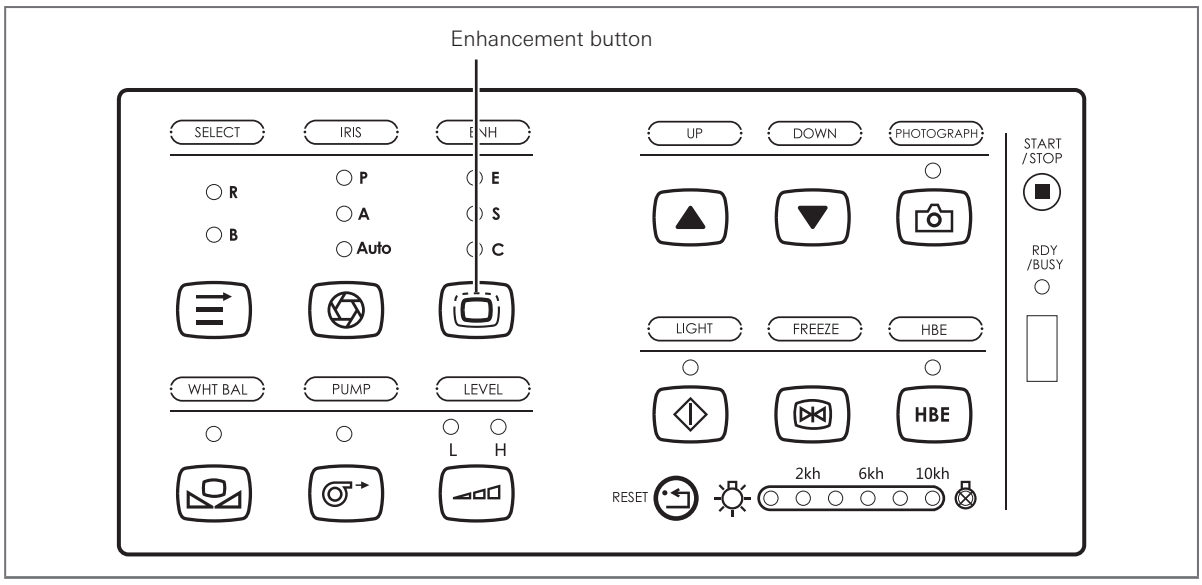

Figure 4.7

4.1.11 Turning the Hb Enhancement ON

The equipment can provide image with Hb enhancement. Hb enhancement is an image processing technique that highlights the blood vessels to make it easier to observe tissue with enriched blood supply.

Press the HbE button on the front panel (see Figure 4.8), the HbE button on the handle of endoscope or the F1 key on the keyboard to turn ON the Hb enhancement. Press the HbE button on the front panel or HbE button on the handle of endoscope again to turn OFF the HB enhancement. (Refer to the compatible video endoscopes' IFU.)

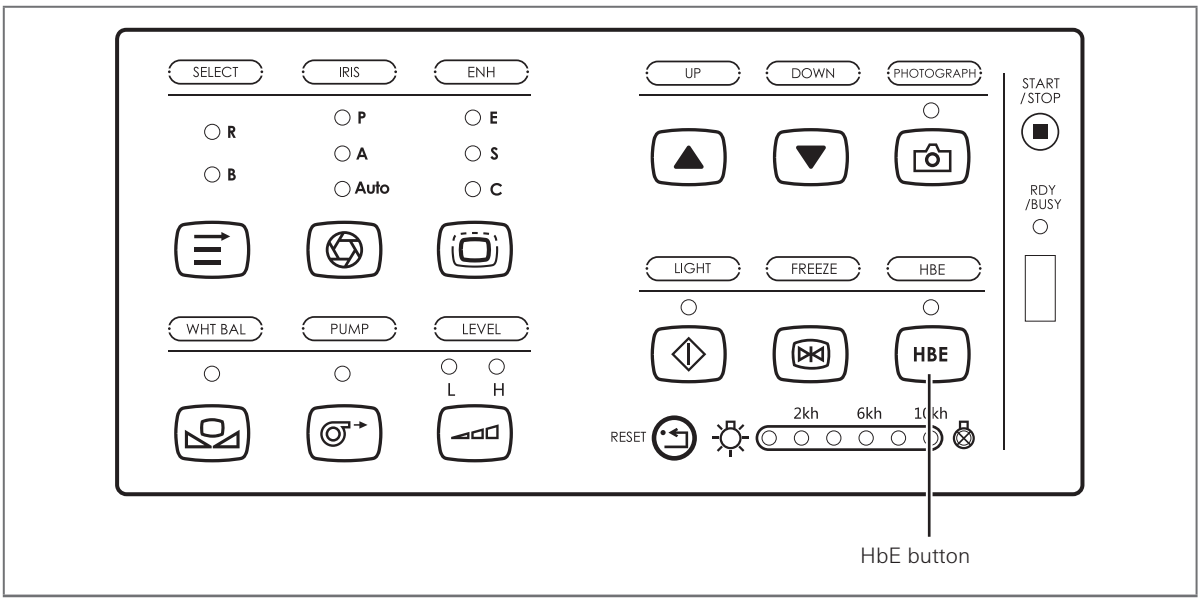

Figure 4.8

4.1.12 Freeze

The endoscopic image can be frozen for closer inspection.

Warning

If the image fails to freeze or defreeze, press the power switch to turn OFF the video processor, wait for 8 seconds, and then press the power switch to turn ON the video processor again.
If this fails to correct the problem, immediately stop using the equipment and remove the endoscope from the patient as directed in the endoscope's instruction manual.

1. Press the freeze button on the handle of the endoscope, the freeze button on the front panel (see Figure 4.9) or the F6 key on the keyboard to freeze the image. (Refer to the compatible video endoscopes' IFU.)

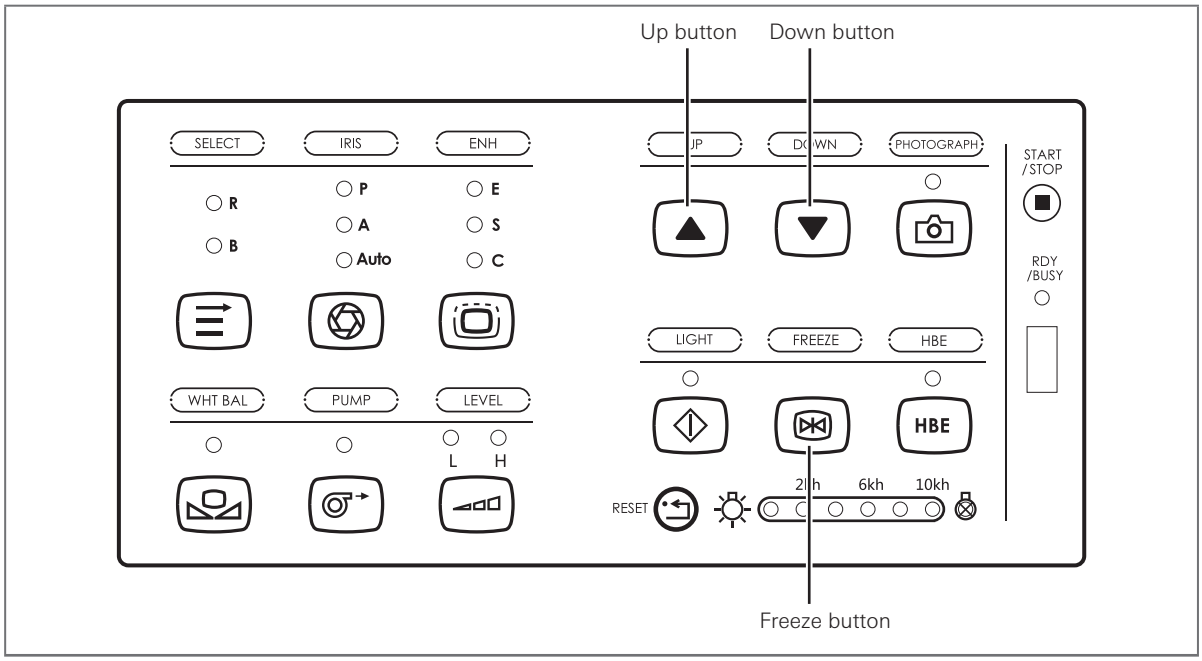

Figure 4.9

2. Press the up and down buttons on the front panel to view the frozen image on the screen frame by frame. Only 64 images are saved. If processor power is off, all saved 64 images will be deleted from processor memory. To ensure desired images saved, connect a USB storage device always.
3. Press the freeze button on the handle, the freeze button on the front panel or the F6 key on the keyboard again to restore the real-time image.

4.1.13 Saving Recorded Videos and Images

The videos and images recorded by the video processor can be saved in a USB storage device.

1. Connect a USB storage device to the USB port (see Figure 4.10).
   When a USB storage device is connected, the ready/busy indicator will light.
2. Press the photograph button or the F10 key on the keyboard to save the captured image in the USB storage device.
   Press the video recording button or the F9 key on the keyboard to start the video recording. Pressing the video recording button or the F9 key on the keyboard again will stop the video recording. The recorded video will be saved in the USB storage device.

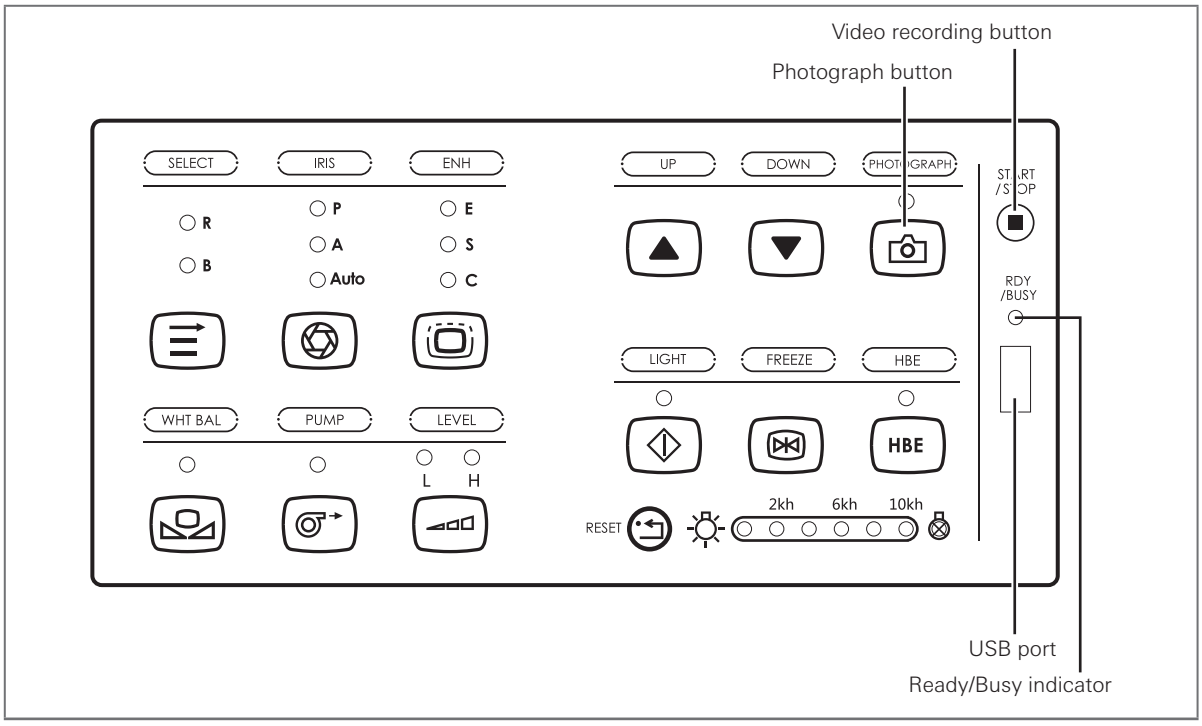

Figure 4.10

4.1.14 Remote Printing

When compatible printer (SONY, UP-25MD) was connected as Figure 3.1 shows, the remote printing is workable.

Press the remote trigger button on the handle of endoscope to trigger the image printing by compatible printer. (Refer to the compatible video endoscopes' IFU.)

4.1.15 Turning the Video Processor OFF

1. Press the power switch to turn the video processor OFF. The video processor is OFF when the power indicator is not lit.
2. If the video processor is not to be used for an extended period of time, turn the power switch OFF and disconnect the power cord.

4-2. Replacement of the Fuse

Warning

- Turn the video processor OFF and remove the power cord from the wall outlet before replacing the fuses. Otherwise, electric shock may result.
- Only use the fuses listed in the manual. Otherwise, malfunction or failure of the video processor may occur and could lead to fire or electric shock.

1. Turn OFF the power and disconnect the power cable from the wall outlet.
2. Pull out the fuse holder straight and replace the fuses (see Figure 4.11).

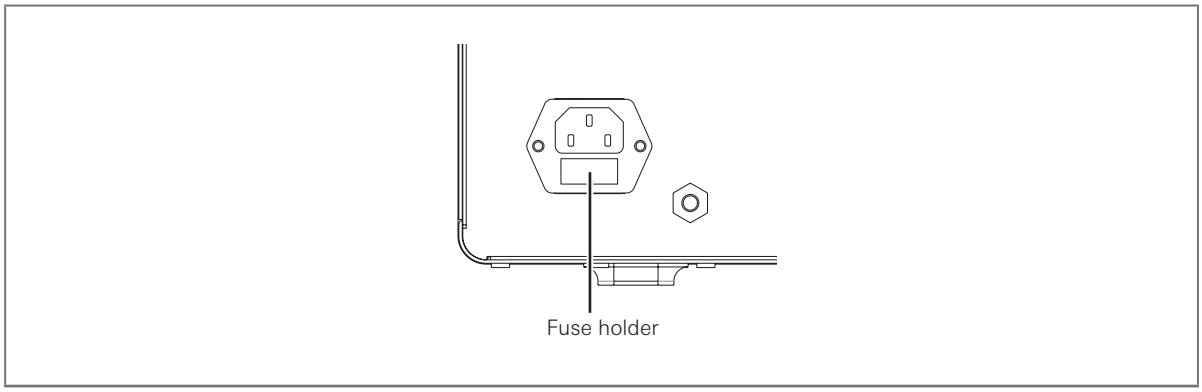

Figure 4.11

3. Reinsert the fuse holder into the video processor.
4. Plug in the power cord, press the power switch and confirm that the power indicator is lit.

Warning

If the power fails to come on after replacing the fuses with new ones, immediately turn the video processor OFF, remove the power cord from the wall outlet and contact us.

4-3. Care, Storage, and Disposal

4.3.1 Care

Warning

- Do not spill water into the machine. If the liquid spilled into the machine, be sure to dry it immediately and to ensure there is no water before operation.
- Connect the power plug of the power cord directly to a grounded wall outlet. It can cause an electric shock and/or fire, if the video processor is not grounded properly and the purchaser should take full responsibility for the accident.
- When the video processor is working, all vents of the machine must not be blocked to let air flow smoothly.
- After wiping with a piece of moistened gauze, dry the video processor thoroughly before using it again. If it is used while still wet, there is the risk of an electric shock.
- If the product has quality problems, please contact us. The company has no responsibility to the problems caused by disassembly of the equipment by user.
- Do not position the video processor to make it difficult to operate the power plug.

The video processor should be cleaned following cleaning procedure immediately after use and routinely. Monitor should be cleaned by alcohol.

1. Turn the video processor OFF and disconnect the power cord.
2. To remove dust, dirt and non-patient debris, wipe the video processor using a soft cloth moistened with 70% ethyl or isopropyl alcohol.
3. Make sure that the video processor is completely dry before use.

4.3.2 Storage

1. Turn the video processor OFF and disconnect the power cord.
2. Disconnect all ancillary equipment connected to the video processor.
3. Leave the equipment at 5 to 40°C in the horizontal position in a clean, dry and stable location.

4.3.3 Disposal

Disposing the equipment should follow the national and local laws and guidelines.

The equipment should be returned for disposal to PENTAX Medical. Contact your local PENTAX Medical representative or service facility.

■ **Information on Disposal for users in the European Union**

This product is a medical device. In accordance with European Directive 2012/19/EU on Waste Electrical and Electronic Equipment, WEEE symbol indicates that the product must not be disposed of as unsorted waste, but should be collected separately. Contact your local PENTAX Medical distributor for correct disposal and recycling.

By disposing of this product correctly you will help ensure that the waste undergoes the necessary treatment, recovery and recycling and thus prevent potential negative effects on the environment and human health which could otherwise arise due to inappropriate waste handling.

4.3.4 Maintenance and Care

- Only dry cloth can be used to clean Power Switch, otherwise it may lead to the damage of switch and cause electric shock (Power should be cut off before being cleaned).
- Please do NOT clean connector/mains plug-power supply cord, video signal terminal and socket. Cleaning may lead to distortion and corrosion of the contacts and damage EPK-V1500c Video Processor.
- Before or after using endoscope to diagnose the lesion for patients, please clean the channels of water supply, gas supply and suction of endoscopes according to the operations in IFU. Turning OFF the power supply during the cleaning can extend the life time of LED module. If the video processor was wet, users must pull off power cable firstly and then dry it.


Caution

Before cleaning, power cable should be pulled off and be ensured.

- Cleaning for outer surface of device
  Using soft cloth with dilute detergent to clean outer surface of EPK-V1500c. When cleaning interface, please do NOT bedew power socket. When cleaning front interface, please do NOT bedew cable connector. If using the video processor under wet circuit operation environment, the video processor may lead to electric shock and short problems. (Suggestion: Cleaning the video processor every day.)
- Cleaning of liquid contamination
  If liquid was sprayed on the device, users must clean the liquid on time, and ensure that there is no liquid contacting other components before operation, especially for circuit interface. If circuit interface was wet, please use the device when it is dry.


Caution

Ensure dryness of power plug and prevent from electric shock events.

5 Troubleshooting

If the video processor is visibly damaged, does not function as expected or is found to have irregularities during the inspection, do NOT use the video processor, and contact us.
Some problems that appear to be malfunctions may be corrected by referring to Section 5-1, "Troubleshooting Guide". If the problem cannot be resolved by the following action, stop using the video processor and send it to us for repair.

Warning

- Never use the video processor if an abnormality is suspected. The patient or the operator can be fatally or seriously injured.
- Manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to service personnel in parts repair.

5-1. Troubleshooting Guide

The following table shows the possible causes of abnormalities. Failures and abnormalities other than those listed in the following table need repair.
As servicing by a person other than qualified personnel may result in accidents, be sure to have the video processor serviced following the instructions given in Section 5-2, "Returning the Video Processor for Repair".

Warning

If an abnormality is suspected, turn the video processor OFF once and turn it ON again. If the abnormality cannot be solved, turn the video processor OFF, disconnect the power cord, and contact us.

Irregularity description	Possible cause	Solution
The endoscope cannot connect to the video processor.	The endoscope is not compatible with this video system.	Connect a compatible endoscope.
The power fails to be ON.	The power cord is not connected.	Connect to a hospital-grade power outlet as described.
	The power switch is not turned ON.	Turn the power switch ON.
	A fuse has blown.	Replace both fuses.

Irregularity description	Possible cause	Solution
The endoscopic image does not appear on the monitor.	The monitor mode is not set correctly.	Set the mode correctly by referring to the monitor's instruction manual.
	The endoscope is not connected.	Reconnect the endoscope with the video processor again.
	The monitor cable is not connected.	Connect a monitor cable as described.
The endoscopic image is too dark.	The monitor brightness setting is not right.	Set a proper brightness as described in the monitor's instruction manual.
	The monitor contrast setting is not right.	Set a proper contrast as described in the monitor's instruction manual.
The endoscopic image is too bright.	The monitor contrast level is improper.	Set a proper contrast as described in the monitor's instruction manual.
The endoscopic image remains frozen.	The freeze switch is still set.	Press the freeze switch to go back to real-time moving image.
The endoscopic image is drifting.	The monitor cable is connected incorrectly.	Connect the monitor cable correctly.
The endoscopic image is vibrating.	There is a strong magnetic field near the monitor.	Move the source of the magnetic field away from the monitor.

5-2. Returning the Video Processor for Repair

Warning

Any repairs attempted by non-authorized personnel will cause waiver of warranty.

EMC Information

EMI Compliance Table

Table 1: Emission		
Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class A	Professional healthcare facility environment
Harmonic distortion	IEC 61000-3-2 Class A	Professional healthcare facility environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Professional healthcare facility environment

Note

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

EMS Compliance Table

Table 2: Enclosure port		
Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz–2.7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Table 3: Proximity fields from RF wireless communications equipment		
Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380–390	Pulse modulation 18 Hz, 27 V/m
450	430–470	FM, ±5 kHz deviation, 1 kHz sine, 28 V/m
710	704–787	Pulse modulation 217 Hz, 9 V/m
745		
780		
810	800–960	Pulse modulation 18 Hz, 28 V/m
870		
930		
1720	1700–1990	Pulse modulation 217 Hz, 28 V/m
1845		
1970		
2450	2400–2570	Pulse modulation 217 Hz, 28 V/m
5240	5100–5800	Pulse modulation 217 Hz, 9 V/m
5500		
5785		

Table 4: Input a.c. power port		
Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrical fast transients/burst	IEC 61000-4-4	±2 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV
Surges Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 Vrms, 0.15 MHz–80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 cycles

Table 5: Signal input/output parts port		
Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 Vrms, 0.15 MHz–80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz

Table 6: Patient coupling port		
Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 Vrms, 0.15 MHz–80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz

Warning

1. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the VERSA Video Processor EPK-V1500c, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
2. The VERSA Video Processor EPK-V1500c is intended for use in Professional healthcare facility environment.
3. The essential performance of VERSA Video Processor EPK-V1500c: When using with compatible video endoscope, there is no unacceptable risk if the image observed by the operator has an unexpected image orientation. In practice, the essential performance of the equipment is usually preliminarily judged by visual inspection, which is for subsequent normal operation.
4. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.
5. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
6. The equipment to be connected with the signal port shall comply IEC 62368 or IEC 60601, or equipment without power supply.

Contacts

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- TÜV Süd CE0123: Medical device class: IIa CE 0123
- The product must be used only by healthcare professionals. Before usage and for detailed product specifications, please refer to the instructions for use (IFU).
- Product specifications are subject to change without notice or obligation.
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