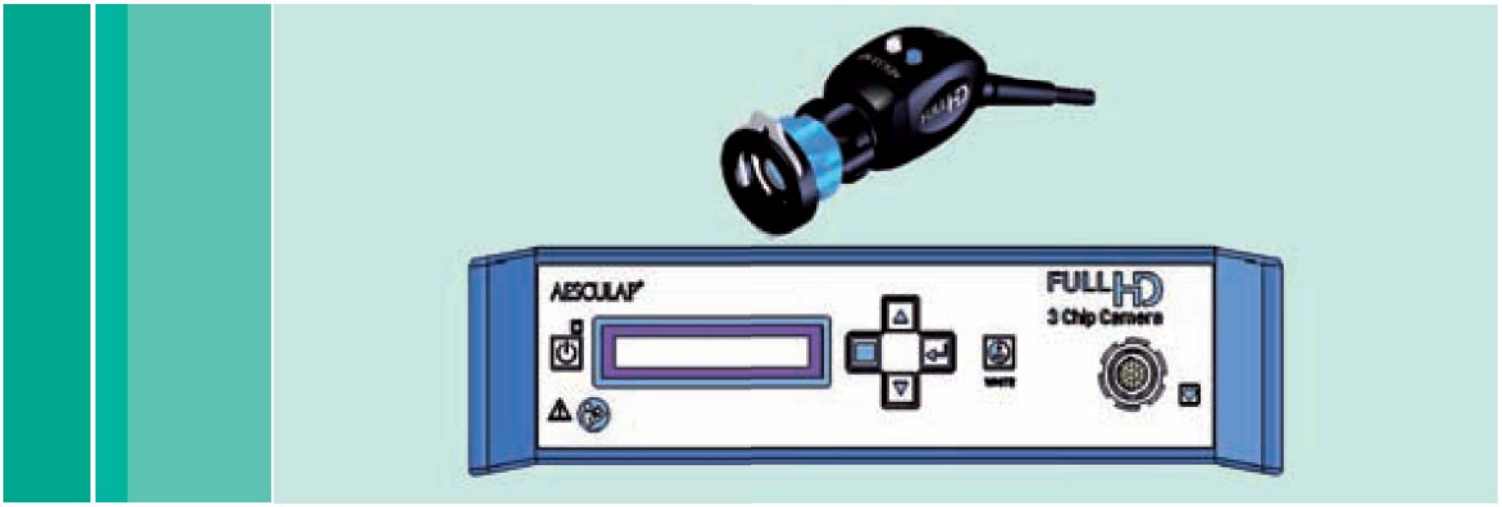
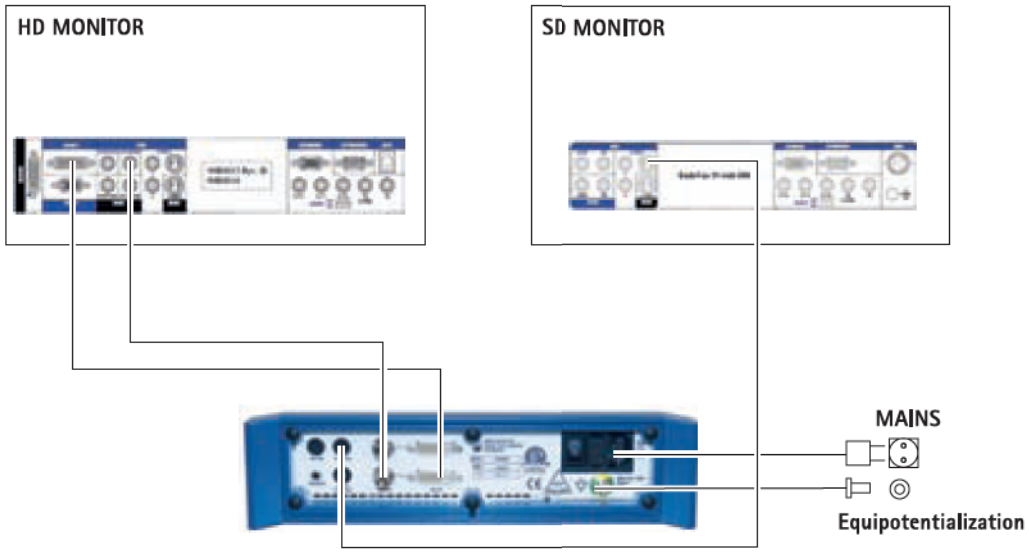
Aesculap®

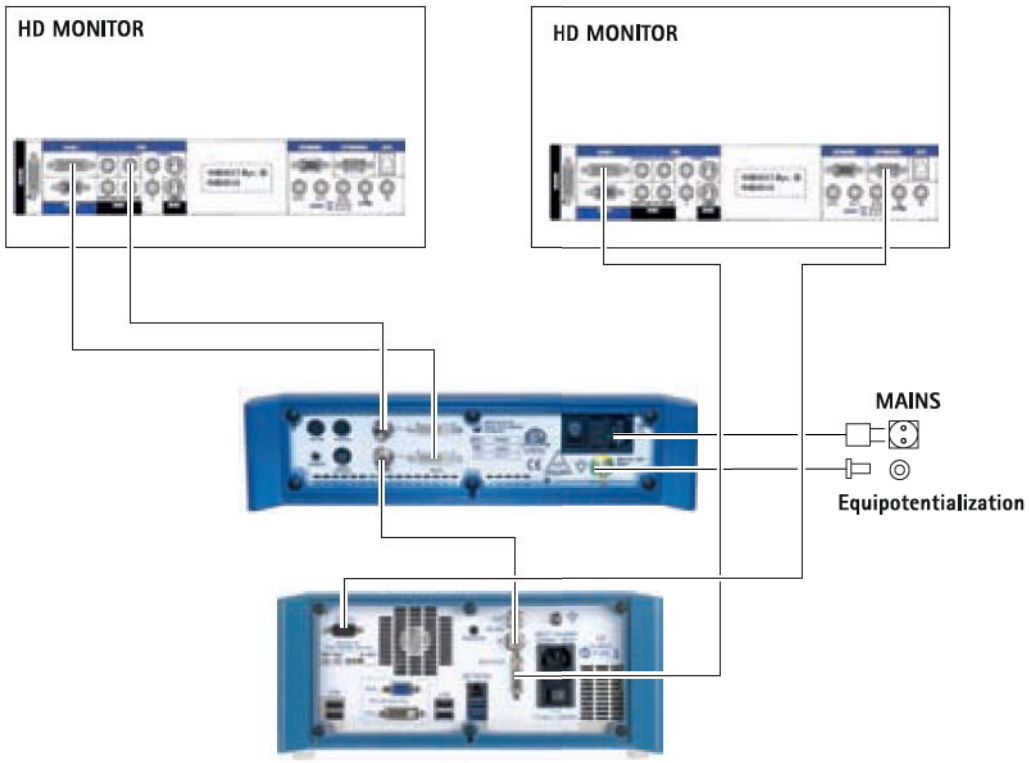


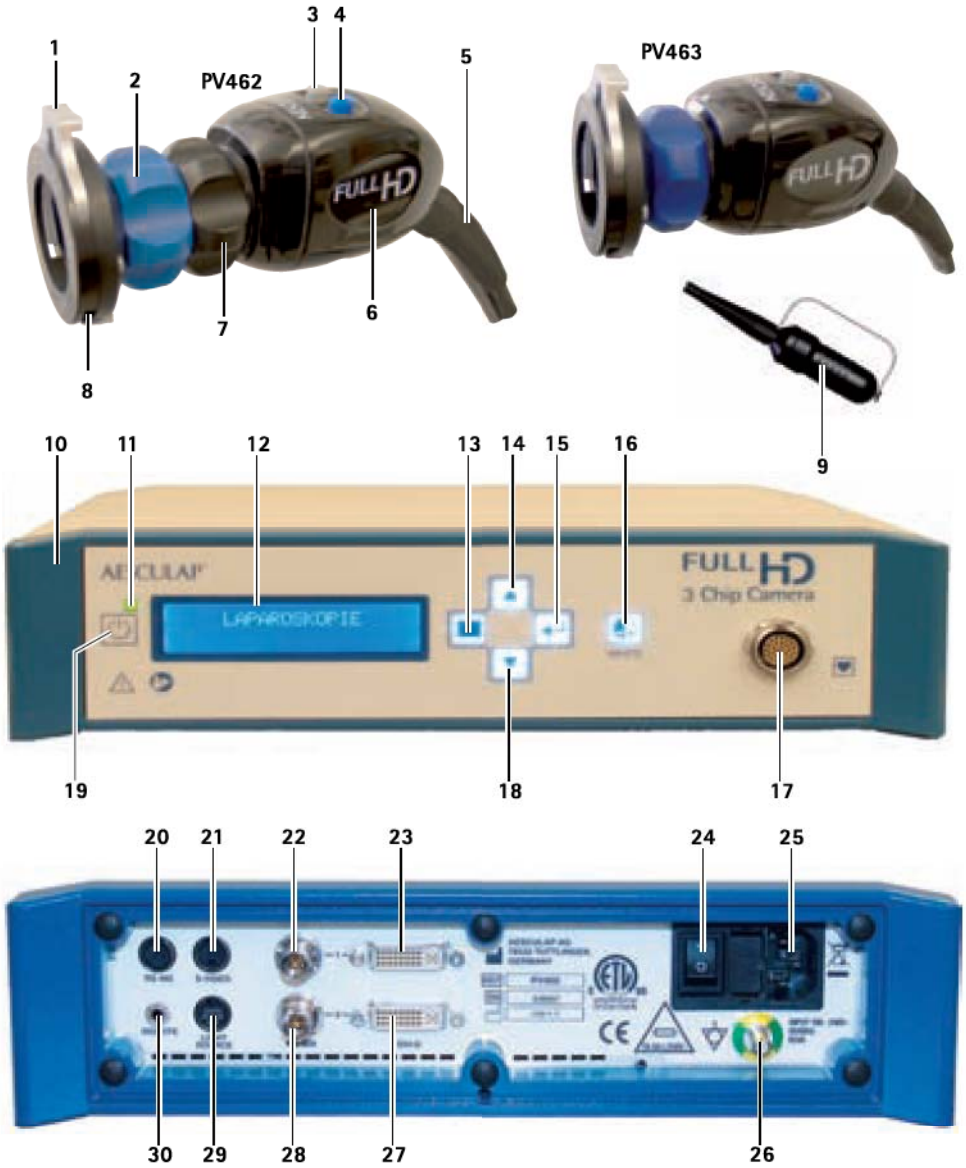
Aesculap Endoscopic Technology

GB USA **Instructions for use/Technical description**
Full HD 3CCD Camera system PV460/PV462/PV463

B BRAUN
SHARING EXPERTISE


HD MONITOR
SD MONITOR
MAINS
Equipotentialization


HD MONITOR
HD MONITOR
MAINS
Equipotentialization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LAPAROSKOPIE
FULL HD
3 Chip Camera
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GB USA

Aesculap®

Full HD 3CCD Camera system PV460/PV462/PV463

Legend

1 Locking device (for the endoscope eyepiece)
2 Focusing ring
3 Gray pushbutton
4 Blue pushbutton
5 Camera cable
6 Camera head
7 Zoom ring (only for PV462)
8 Anti-rotation lock
9 Camera plug
10 Camera control unit
11 ON/OFF LED
12 Backlit LCD (2 line x 20 column)
13 Pushbutton (for access to menus)
14 Pushbutton (for navigating menus)
15 Pushbutton (for selection from menus)
16 Pushbutton (for automatic white balance)
17 Camera socket
18 Pushbutton (for navigating menus)
19 Pushbutton (ON/STANDBY)
20 RS485 connector output
21 S-VIDEO output (standard definition)
22 HD-SDI video output 1 (High Definition)
23 DVI-D video output 1 (High Definition)
24 ON/OFF switch
25 Mains connection
26 Equipotentialization connector
27 DVI-.D video output 2 (High Definition)
28 HD-SDI video output 2 (High Definition)
29 LED Light Source connector output
30 Mono jack for remote control (3.5 mm)

Symbols on product and packages

	Caution, general warning symbol Caution, see documentation supplied with the product
	Follow the instructions for use
	Equipotentialization connector
	Fuse
	Type CF applied part
	Power ON/STANDBY
	Pushbutton for automatic white balance
	Pushbutton for "up" in camera menus
	Pushbutton for "down" in camera menus
	Menu
	Select item in camera menu
	Marking of electric and electronic devices according to directive 2002/96/EC (WEEE), see Disposal
REF	Catalogue number
SN	Serial number
	Manufaturer
	Date of manufacture
CE 0123	Identification in conformity with medical devices directive 93/42/EEC only valid if the product and/or packaging is marked with this symbol.
	Trademark of Intertek Testing Services NA, Inc., a nationally Recognized Testing Laboratory, listing compliance as Medical Electrical Equipment to standard UL 60601 and CAN/CSA C 22.2 No. 601.1
	Atmospheric pressure limitation
	Humidity limitation
	Temperature limitation
	Fragile
	Keep dry

Contents

1. Applicable to

► For item-specific instructions for use and information on material compatibility, see also the Aesculap Extranet at www.extranet.bbraun.com

2. Safe handling

CAUTION

Federal law restricts this device to sale by, or on order of a physician!

DANGER

Risk of fatal injury from electric shock!

- **► Do not open the product.**
- **► Connect the product only to a grounded power supply.**

WARNING

Risk of injury caused by incorrect operation of the product!

- **► Attend appropriate product training before using the product.**
- **► For information about product training, please contact your national B. Braun/ Aesculap agency.**

WARNING

Risk of injury caused by explosion!

- **► Do not operate the product in the vicinity of flammable anesthetics.**
- **► Check the power cord for leakage currents and correct grounding at regular intervals.**

► Remove the transport packaging and clean the new product, either manually or mechanically, prior to its initial sterilization.

► Prior to use, check that the product is in good working order.

► Observe "Notes on Electromagnetic Compatibility (EMC)", see TA022130.

► To prevent damage caused by improper setup or operation, and in order not to compromise warranty and manufacturer liability:

- Use the product only according to these instructions for use.
- Follow the safety and maintenance instructions.
- Only combine Aesculap products with each other.
- Follow the application advisories acc. to standard, see Extracts from relevant standards.

► Ensure that the product and its accessories are operated and used only by persons with the requisite training, knowledge, or experience.

► Keep the instructions for use accessible for the user.

► Always adhere to applicable standards.

Aesculap®

Full HD 3CCD Camera system PV460/PV462/PV463

2.1 Power Connection

DANGER

Risk of fatal injury from electric shock!

- **Routinely examine the power cord and plug. Do not use if inspection reveals damage.**
- **Replace only with approved hospital grade power cord and plug with appropriate electrical rating.**

- Position equipment so that it is easy to remove power cord.
- Use a proper power cord for your local mains supply.
- Use the approved Power Cord (3-core mains lead)/Appliance Connector/Plug with earthing-contacts that conform to the safety regulations of each country if applicable.
- Use the Power Cord (3-core mains lead)/Appliance Connector/Plug conforming to the proper rating (Voltage, Ampere).

  If you have questions on the use of the above Power Cord/Appliance Connector/Plug, please contact qualified service personnel.

3. Product description

3.1 System components

Full HD 3CCD camera system PV460, consisting of:

- Full HD camera control unit
- Full HD 3CCD camera head, two versions available:
  - Zoom camera head PV462 (to be ordered separately)
  - Fixed focus camera head PV463 (to be ordered separately)
- DVI-D cable
- Instructions for use

3.2 Components necessary for use

In addition to the camera system, the following components are required for an endoscopic intervention:

- Power cord
- Endoscope
- Light source
- Light cable
- Monitor

3.3 Intended use

The Aesculap Full HD camera (HD = High Definition) is an endoscopic video camera for the transmission of real-time video images from a rigid or flexible endoscope to a video monitor or other documentation equipment.

The Aesculap Full HD camera can be used for any endoscopic application.

For their present applications, the camera includes a lens (zoom of fixed focus) fitted with an endocoupler. An endoscope with standard eyepiece is then connected to the endocoupler and held in place by the holding mechanism of the endocoupler.

With its superior image quality of 1920 x 1080 pixels and progressive scan mode, the Full HD camera is the preferred camera for endoscopic procedures.

3.4 Contraindications

Operating surgeons who are not trained and qualified to perform endoscopic or laparoscopic surgery should not use this device.

3.5 Operating principle

The endoscope visualizes the operation area and the lens focuses this image onto the three CCD sensors, where it is converted into digital signals. The image brightness is automatically adjusted according to the light intensity (autoshutter).

Through camera cable **5**, the digital image signals are transferred to camera control unit **10**, where the digital data are processed for display on the monitor.

The video signal processed in this way can be picked up at the video output monitor and by digital documentation devices.

The camera system features automatic, electronic brightening for areas that are particularly difficult to illuminate. It offers six programmed modes and three user modes for various surgical situations.

The video camera system is also equipped with an automatic white adjustment system for optimal color representation.

The lens zoom function (PV462 camera head only) allows displaying the image on the monitor with optimal enlargement.

4. Preparation and setup

Non-compliance with the following instructions will result in complete exclusion of any responsibility and liability on the part of Aesculap.

- When setting up and operating the product, always observe the following:
  - national regulations for installation and operation
  - national regulations on fire and explosion protection

4.1 Connecting the accessories

WARNING

Risk of injury and/or product malfunctions due to incorrect operation of the medical electric system!

► Adhere to the instructions for use of any medical device.

Combinations of accessories that are not mentioned in the present instructions for use may only be employed if they are specifically intended for the respective application, and if they do not compromise the performance and safety characteristics of the products.

All devices connected at the interfaces must demonstrably meet the respective IEC standards (e.g., IEC 60950 for data processing equipment, IEC/DIN EN 60601-1 for electromedical devices).

All configurations must meet the system standard IEC/DIN EN 60601-1-1. The person connecting the units is responsible for the configuration and must ensure compliance with system standard IEC/DIN EN 60601-1-1 or equivalent national standards.

► If you have any questions about that, contact your Aesculap partner or Aesculap customer service.

4.2 Setting the correct voltage

The mains voltage must correspond to the voltage indicated on the unit back panel.

4.3 Connecting the power supply

WARNING

Risk of electric shock!

► Only connect the equipment to a mains supply with protective earth.

► Plug in the power cord at the mains connection **25** of the camera control unit **10**.

► Connect the mains plug of the power cord to the building mains.

► Plug in the equipotentialization cable at the equipotentialization connector **26** of the camera control unit.

► Connect the plug of the equipotentialization cable to the building mains equipotentialization connector.

► To disconnect the camera from the mains, pull out the power cord from the mains connection **25**.

4.4 Connecting the video cable

► Connect the video cable at the camera back panel and the monitor or the documentation system etc. Depending on the choice of the monitor and documentation system, use the following camera outputs:

HD Monitor (High Definition):

- DVI-D for digital HD 1080p quality (recommended)

  – or –

- HD-SDI for digital HD 1080i quality

  – or –

- S-Video for analog SD quality

5. Working with the Full HD camera

5.1 System set-up

► Position the camera as close as possible to the patient so that the camera cable length of 4 m can be fully utilized.

► Connect camera plug **9** to camera socket **17** at the front panel of camera control unit **10**.

5.2 Function checks

WARNING

Risk of injury and/or malfunctions!

► Carry out function checks before every use.

► Check camera control unit **10** and camera head **6** for external damage and signs of knocks or other violent dents.

► Check that camera cable **5** is not broken, kinked or twisted.

► To switch on the camera system, press pushbutton **19**.

The current camera settings are displayed on the monitor:

AESCULAP Full HD 3 Chip Camera

MODE (current mode)

PERFORM WHITE BALANCE

► Make certain the front window of the camera head **6** is absolutely clean. If necessary, clean the window with isopropyl alcohol (70 %).

► If applicable, check that the zoom adjusting ring turns without resistance.

► Make certain that focusing ring turns freely without sticking.

► Align camera head **6** to an object in the room, focus the image and check for good image quality.

► To finish using the Full HD camera system, press pushbutton **19**.

Aesculap®

Full HD 3CCD Camera system PV460/PV462/PV463

5.3 Safe operation

DANGER

Risk of injury due to improper configuration!

► **Ensure that applied parts from other suppliers of electromedical devices, or any accessories used for endoscopic application in this configuration, are of type BF or type CF.**

Connecting an endoscope with a sterile drape

► Verify that locking slide on the endocoupler is opened (unlock position).

► Press and hold pushplate.

► Insert the sterile endoscope with the sterile camera drape and release pushplate.

► To secure the endoscope against rotation, close locking slide (lock position).

► Cover the camera head and the camera cable with the sterile camera drape fastened to the sterile endoscope.

Note

Endocoupler can be positioned as required. To do this, swivel endocoupler clockwise to the required position!

Performing automatic white balance

Upon insertion of the camera plug **9** into the camera socket **17**, the following message will appear on the monitor as a reminder to perform white balance:

AESCULAP Full HD 3 Chip Camera

MODE (current mode)

PERFORM WHITE BALANCE

This message only disappears on the monitor if a white balance is performed.

Perform the white balance as follows:

► Attach endoscope connected to the light source via light cable to the camera head.

► Switch on light source and put light level indicators in appropriate position.

► Point the endoscope to a white object (e.g., a sterile swab) at a distance of about 2 cm.

► Press pushbutton **16** at the control unit while keeping the endoscope pointing to the white object.

- or -

► Press gray push button **2** on the camera head for longer than 2.5 s and keep the endoscope pointed at the white object.

The following message appears on the camera display and on the monitor:

WHITE BALANCE IN PROCESS

MODE (current mode)

► If the automatic white balance is performed properly, the following message appears on the camera display and on the monitor:

WHITE BALANCE OK

MODE (current mode)

The white object will be displayed in pure white. This procedure ensures the authentic representation of all colors.

► If the automatic white balance did not work properly, the following message appears on the camera display and on the monitor:

WHITE BALANCE FAILED

MODE (current mode)

► In this case repeat the automatic white balance procedure.

Menu navigation

The User Interface functions are provided via Controller Front Panel Buttons, camera head buttons, camera display and the monitor On-Screen-Display (OSD). Navigation through the menu structure and selections are performed with Up, Down and Select buttons.

► Press Up **14** or Down **18** to navigate to a menu item.

► Press Select button **15** to select a menu item.

Each time a list of selections is displayed, the current active item (e.g., procedure mode or language) is shown in blinking text.

Each time the OSD is in a state of showing a lower hierarchy menu, pressing the Menu button returns the system to the next higher hierarchy menu screen.

Unless selection is explicitly made by pressing Select button **15** the OSD will time out after 3.5 seconds and automatically select the blinking item.

Short System Menu (Camera Head unplugged)

With the camera head unplugged and the unit powered On, all video outputs display the color bar test pattern. In this state the short system menu is available for setting parameters that do not require live video during selection. An abbreviated version of this menu is also repeated on the LCD display **12** for medical staff and service personnel to perform changes when a monitor is not available. Menu button press activates the following OSD menu:

MODE (blinking)

LANGUAGE

50/60 HZ

SHOW SOFTWARE VERSION

RESET FACTORY DEFAULTS

Mode Setting

Upon selection of procedure mode from the short system menu the list of available mode settings is displayed

LAPAROSCOPY

NEUROENDOSCOPY

ARTHROSCOPY

UROLOGY

HYSTEROSCOPY

FIBERSCOPE

USER 1

USER 2

USER 3

The current active mode type is shown in blinking text. Navigation to and selection of procedural mode type is performed as described above, see Menu navigation.

User 1, User 2 or User 3 custom mode types may be selected from the Short System Menu. However, no adjustment to the custom mode settings may be made at this point as the camera head is unplugged. For re-setting User 1, User 2 and User 3 custom mode types, see Main Menu.

The selected mode is saved in non-volatile memory and restored on the next power-on event.

Language Setting

Upon selection of Language from the short system menu the list of available languages is displayed

ENGLISH

DEUTSCH

FRANCAIS

ITALIANO

ESPANOL

The current active language is shown in blinking text. Navigation to and selection of the language is performed as described above, see Menu navigation.

The selected Language is saved in non-volatile memory and restored on the next power-on event.

Show Software Version

Upon selection of Show Software Version from the Short System Menu the current software version is displayed on the OSD screen.

Resetting Factory Defaults

Upon selection of Reset Factory Defaults from the Short System Menu the factory default values for all parameters except Language, 50/60 Hz and USER 1, 2, 3 settings get restored.

The OSD confirmation:

RESET FACTORY DEFAULTS OK

appears for approximately 5 seconds followd by the prompt:

AESCULAP Full HD 3 Chip Camera MODE LARPAROSCOPY

Main Menu

With the camera head plugged in and the unit powered On, all video outputs display the live video. The OSD displays the current procedure mode and prompts to perform the White Balance. Upon successful completion of the White Balance the system is ready to use. Pressing button Menu **13** at any time during live video activates the Main Menu:

MODE (Blinking)

BRIGHTNESS

ENHANCEMENT

IMAGE SIZE SMALL/LARGE

COLOR

PEAK/AVERAGE

SYSTEM CONFIGURATION

Mode Setting

The mode setting is described above, see Short System Menu (Camera Head unplugged).

Custom Mode Setting

If any of the "User N" where N = 1, 2, or 3 entries is selected the OSD appears as follows (positions of the asterisks display the current active settings, and are shown below in arbitrary positions):

SETTINGS USER N

BRIGHTNESS	-....*....+
ENHANCEMENT	-....*....+
PEAK/AVERAGE	-....*....+
COLOR	-....*....+
IMAGE SIZE	SMALL MEDIUM LARGE
FIBERSCOPE	OFF ON

EXIT

Adjusting Custom Mode Setting

- ► The selected setting to be adjusted is shown in blinking text. Press the UP button **14** or DOWN button **18** to select the item to be adjusted.
- ► Press the Select button **15** when the desired item to be adjusted is active (blinking).

Brightness Setting

- ► Press the UP button **14** to move the cursor on the Brightness slider to the right (increase) and DOWN button **18** to move the cursor to the left (decrease).
- ► Observe the change of brightness in the live video. Press the Select button **15** when the desired brightness level is attained. Pressing of the Select button **15** will automatically activate the next line Enhancement (blinks).

Enhancement Setting

- ► Press UP button **14** to move the cursor on the Enhancement slider to the right (increase) and DOWN button **18** to move the cursor to the left (decrease).

► Observe the change of contour enhancement (contrast) in the live video. Press Select button **15** when the desired enhancement level is attained. Note that excessive enhancement may increase the noise or graininess of the image. Pressing of Select button **15** will automatically make the next line Scene Peak/Average active (blinking).

Peak/Average Setting

► Use the Peak/Average setting to minimize blooming or "hot spots" artifacts. Note that excessive decrease of Peak/Average may darken the image. Use the setting cautiously decreasing it for applications having highly reflective bright scenes (e.g. knee arthroscopy).

► Press UP button **14** to move the cursor on the Peak/Average slider to the right (increase) and Down button **18** to move the cursor to the left (decrease).

► Observe the change in the scene blooming and "hot spots". Press Select button **15** when the desired Peak/Average level is attained. Pressing Select button **15** will automatically make the next line Color active (blinking).

Color Setting

Increasing the Color setting enhances the color content of Red details.

► Press UP button **14** to move the cursor on the Color slider to the right (increase) and Down button **18** to move the cursor to the left (decrease).

► Observe the color change in live video. Press Select button **15** when the desired color balance is attained. Pressing of Select button **15** will automatically make the next line Image Size active (blinking).

Image Size Setting

The currently active Image Size setting is shown highlighted on the OSD.

► Use UP button **14** and DOWN button **18** to change the selection according to the active image area that is created by the attached endoscope.

► Press Select to activate the selection. Pressing of Select button **15** will automatically make the next line Fiberscope active (blinking).

Fiberscope Setting

► Fiberscope setting is used for suppression of unwanted stripes (aliasing) and "chicken wire" patterns appearing in the image when fiberscopes are utilized.

► Use Up button **14** and Down button **18** to change the selection to ON when using a Fiberscope as an input device for the camera.

► Press Select button **15** to automatically advance the active line to Exit.

Note

Changing the Fiberscope setting to ON automatically disables Enhancement setting. Never enable Fiberscope setting when other types of endoscopes are used, otherwise resolution and contrast of the image will be adversely affected.

Upon selection of EXIT in the User Settings menu the following OSD prompt appears:

PRESS SELECT TO SAVE SETTINGS

OR MENU TO RETURN TO EDITING

After the editing is completed the OSD prompt appears as follows for approximately 5 seconds:

USER N (N= 1, 2; 3)

SETTINGS SAVED

The user menu settings are saved in non-volatile memory and restored on the next power-ON event.

Setting of Brightness, Enhancement, Image Size and Color from Main Menu

Brightness, Enhancement and Color sliders as well as Image Size options may be accessed from the Main Menu, see Main Menu.

► Select the menu entry using Up **14**, Down **18** and Select buttons **15** as described above in Menu Navigation section.

► Adjust the parameter to the desired value using Up **14** and Down **18** buttons.

► Observe the change in the live video and press Select button **15** when the desired adjustment level is attained.

Note

The selected values are saved in volatile memory and WILL NOT get restored on the next power-ON event. The next power-ON will reset all of the above parameters to their pre-set values for each procedural Mode.

System Configuration Settings

System Configuration sub-menu may be accessed from the Main Menu by selecting System Configuration entry. The following OSD appears on the screen:

SYSTEM CONFIGURATION

LANGUAGE (blinking)

50/60 HZ

SHOW SOFTWARE VERSION

RESET FACTORY DEFAULTS

BLACK BALANCE

Language Setting

The setting of the "Language" from the System Configuration Menu is performed in the same manner as described above, see Short System Menu (Camera Head unplugged).

The selected Language is saved in non-volatile memory and restored on the next power-on event.

50/60 Hz Setting

► Select "50/60 Hz" entry from System Configuration menu.

50Hz and 60Hz selection options will appear on the screen. The active selection is shown in blinking text.

The 50/60 Hz setting configures the output vertical refresh rate of the SDI and DVI outputs.

The 50/60 Hz options are also applicable to the Standard Definition S-VIDEO output port. When set to 50Hz, the output format will be PAL. When set to 60Hz, the output video format will be NTSC.

► Select 50Hz or 60Hz according to your peripheral device's specifications.

The selection is saved in non-volatile memory and restored on the next power-ON event.

Software Version

Selection of Show Software Version from the System Configuration menu will display the software version of the camera system. This information may be necessary for servicing the product.

Resetting Factory Defaults

Selection of Reset Factory Default entry from System Configuration menu will restore the factory default settings for all parameters except Language, 50/60 HZ, and USER 1, 2, 3.

Black Balance

Black Balance function may only be performed by Aesculap service department or authorized representative. This operation is protected by Pass Code as its incorrect execution may permanently damage the Camera Head.

Operating camera head pushbutton controls

For the convenience of the operator such functions as white balance, brightness, remote activation of peripheral devices and Aesculap LED light source may be accessed via camera head pushbutton controls.

► Prepare the automatic white balance as described above, see Performing automatic white balance.

► Press gray pushbutton **3** on the camera head for longer than 2.5 s and keep the endoscope pointed at the white object.

► Follow the OSD prompts, see Performing automatic white balance

Performing brightness adjustment by camera head pushbutton controls

► Apply a short press of less than 2.0 s to gray pushbutton **2** on the camera head.

Camera brightness slider will display.

BRIGHTNESS ....*....+

► Press the gray pushbutton **3** to move the cursor on the Brightness slider to the right (increase) and blue pushbutton **4** to move the cursor to the left (decrease).

► Stop when the desired brightness has been achieved. The slider OSD will time out in about 10 seconds.

Performing remote activation of peripheral devices by camera head pushbutton controls

► For Remote 1 output apply a short press of less than 2.0 s to blue pushbutton **4** on the camera head. The remote output beeper will beep once.

► For Remote 2 output apply a long press of greater than 2.0 s to blue pushbutton **4** on the camera head. The remote output beeper will beep twice.

Activation of LED light source by camera head pushbutton controls

► Connect Aesculap LED light source to the camera control unit **10** via Light Source connector output **29.**

► Press both gray pushbutton **3** and blue pushbutton **4** at the same time for less than 2.0 s.

The Aesculap LED light source will activate (turn ON) if initially OFF or deactivate (turn OFF) if initially ON.

Adjusting light, focus and optical zoom

► Adjust the intensity of the light source until sufficient illumination is achieved.

► To adjust the focus for a sharp image, turn focusing ring.

► To adjust the image enlargement (zoom factor), turn zoom adjusting ring (PV462 camera head only).

Remote control of an external documentation system

To connect an external documentation system (e.g. Aesculap Eddy Full HD or any other suitable documentation system) at the mono jack for remote control **30** of a peripheral (REMOTE):

► Connect remote control cable PV968 between the camera and the documentation system.

► For remote control of the external documentation system, see Operating camera head pushbutton controls.

6. Validated reprocessing procedure

6.1 General safety instructions

Note

Adhere to national statutory regulations, national and international standards and directives, and local, clinical hygiene instructions for sterile processing.

Note

For patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants of CJD, observe the relevant national regulations concerning the reprocessing of products.

Note

Mechanical reprocessing should be favored over manual cleaning as it gives better and more reliable results.

Note

Successful processing of this medical device can only be ensured if the processing method is first validated. The operator/sterile processing technician is responsible for this.

The recommended chemistry was used for validation.

Note

If there is no final sterilization, then a virucidal disinfectant must be used.

Note

For the latest information on reprocessing and material compatibility see also the Aesculap extranet at www.extranet.bbraun.com

The validated steam sterilization procedure was carried out in the Aesculap sterile container system.

6.2 General information

Dried or affixed surgical residues can make cleaning more difficult or ineffective and lead to corrosion. Therefore the time interval between application and processing should not exceed 6 h; also, neither fixating precleaning temperatures >45 °C nor fixating disinfecting agents (active ingredient: aldehydes/alcohols) should be used.

Excessive measures of neutralizing agents or basic cleaners may result in a chemical attack and/or to fading and the laser marking becoming unreadable visually or by machine for stainless steel.

Residues containing chlorine or chlorides e.g. in surgical residues, medicines, saline solutions and in the service water used for cleaning, disinfection and sterilization will cause corrosion damage (pitting, stress corrosion) and result in the destruction of stainless steel products. These must be removed by rinsing thoroughly with demineralized water and then drying.

Additional drying, if necessary.

Only process chemicals that have been tested and approved (e.g. VAH or FDA approval or CE mark) and which are compatible with the product's materials according to the chemical manufacturers' recommendations may be used for processing the product. All the chemical manufacturer's application specifications must be strictly observed. Failure to do so can result in the following problems:

- Optical changes of materials, e.g. fading or discoloration of titanium or aluminum. For aluminum, the application/process solution only needs to be of pH >8 to cause visible surface changes.
- Material damage such as corrosion, cracks, fracturing, premature aging or swelling.

► Do not use metal cleaning brushes or other abrasives that would damage the product surfaces and could cause corrosion.

► Further detailed advice on hygienically safe and material-/value-preserving reprocessing can be found at www.a-k-i.org, link to Publications, Red Brochure – Proper maintenance of instruments.

6.3 Preparations at the place of use

► Remove any visible surgical residues to the extent possible with a damp, lint-free cloth.

► Transport the dry product in a sealed waste container for cleaning and disinfection within 6 hours.

6.4 Preparing the device

Camera head

► Reprocess the product immediately after use.

► Use suitable cleaning/disinfecting agents if the product is put away in wet condition.

6.5 Preparation before cleaning

CAUTION

Damage to the product due to incorrect handling during processing!

► **Prior to processing, separate the camera head from the camera control unit.**

► **Separately process the camera head and the camera control unit.**

6.6 Cleaning/disinfection

Product-specific safety instructions for the reprocessing procedure

DANGER

Risk of electric shock and fire hazard!

► **Prior to cleaning, unplug the power plug.**

► **Do not use flammable or explosive cleaning or disinfecting solutions.**

► **Make certain that no fluids will penetrate the product.**

CAUTION

Damage to, or destruction of the product caused by mechanical cleaning/disinfecting!

► **Only clean and disinfect the product manually.**

CAUTION

Damage to the product due to inappropriate cleaning/disinfecting agents!

► **Only use a cleaning/disinfecting agents approved for surface cleaning. Follow the manufacturer's instructions for the respective cleaning/disinfecting agent.**

CAUTION

Damage to the product due to inappropriate cleaning/disinfecting agents and/or excessive temperatures!

- ► **Use cleaning and disinfecting agents according to the manufacturer's instructions. The cleaning and disinfecting agents must**
  - **be approved for anodized aluminum, plastic, and high-grade steel,**
  - **not attack softeners (e.g. silicone).**
- ► **Observe specifications regarding concentration, temperature and exposure time.**
- ► **Do not exceed the maximum allowable cleaning temperature of 60 °C.**

CAUTION

Damage to the camera control unit due to inappropriate cleaning/disinfecting processes!

- ► **For cleaning and disinfecting the camera control unit, only apply wipe disinfection followed by drying with a lint-free cloth.**

Validated cleaning and disinfection procedure

Validated procedure	Special features	Reference
Wipe disinfection for electrical devices without sterilization ■ Camera control unit	■ When cleaning products with movable hinges, ensure that these are in an open position and, if applicable, move the joint while cleaning.	Chapter Wipe disinfection for electrical devices without sterilization
Manual cleaning with immersion disinfection ■ Camera head	■ Suitable cleaning brush ■ Disposable syringe 20 ml ■ When cleaning products with movable hinges, ensure that these are in an open position and, if applicable, move the joint while cleaning. ■ Drying phase: Use a lint-free cloth or compressed air for medical purposes	Chapter Manual cleaning/disinfecting and subsection: ■ Chapter Manual cleaning with immersion disinfection

6.7 Wipe disinfection for electrical devices without sterilization

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	**Wipe disinfection**	RT	≥1	-	-	Meliseptol HBV wipes 50 % Propan-1-ol

RT: Room temperature

Phase I

- ► Remove any visible residues with a disposable disinfectant wipe.
- ► Wipe all surfaces of the optically clean product with a fresh, disposable disinfectant wipe.
- ► Observe the specified application time (1 min minimum).

6.8 Manual cleaning/disinfecting

- ► Prior to manual disinfecting, allow water to drip off for a sufficient length of time to prevent dilution of the disinfecting solution.
- ► After manual cleaning/disinfection, check visible surfaces visually for residues.
- ► Repeat the cleaning/disinfection process if necessary.

Manual cleaning with immersion disinfection

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	**Disinfecting cleaning**	RT (cold)	>15	2	D-W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH ~ 9*
II	**Intermediate rinse**	RT (cold)	1	-	D-W	-
III	**Disinfection**	RT (cold)	15	2	D-W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH ~ 9*
IV	**Final rinse**	RT (cold)	1	-	FD-W	-
V	**Drying**	RT	-	-	-	-

D-W: Drinking water
FD-W: Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)
RT: Room temperature
*Recommended: BBraun Stabimed

- ► Note the information on appropriate cleaning brushes and disposable syringes, see Validated cleaning and disinfection procedure.

Phase I

- ► Fully immerse the product in the cleaning/disinfectant for at least 15 min. Ensure that all accessible surfaces are moistened.
- ► Clean the product with a suitable cleaning brush in the solution until all discernible residues have been removed from the surface.
- ► If applicable, brush through non-visible surfaces with an appropriate cleaning brush for at least 1 min.
- ► Mobilize non-rigid components, such as set screws, links, etc. during cleaning.
- ► Thoroughly rinse through these components with the cleaning disinfectant solution (at least five times), using a disposable syringe.

Phase II

- ► Rinse/flush the product thoroughly (all accessible surfaces) under running water.
- ► Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.
- ► Drain any remaining water fully.

Phase III

- ► Fully immerse the product in the disinfectant solution.
- ► Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.
- ► Rinse lumens at least 5 times at the beginning of the exposure time using an appropriate disposable syringe. Ensure that all accessible surfaces are moistened.

Phase IV

- ► Rinse/flush the product thoroughly (all accessible surfaces).
- ► Mobilize non-rigid components, such as set screws, joints, etc. during final rinse.
- ► Rinse lumens with an appropriate disposable syringe at least five times.
- ► Drain any remaining water fully.

Phase V

- ► Dry the product in the drying phase with suitable equipment (e.g. cloth, compressed air), see Validated cleaning and disinfection procedure.

6.9 Inspection, maintenance and checks

- ► Remove the moisture from the camera plug and check that the contacts are dry.
- ► Allow the product to cool down to room temperature.
- ► Inspect the product after each cleaning and disinfecting cycle to be sure it is: clean, functional, and undamaged.

6.10 Packaging

- ► Follow the instructions for use for the applied packaging and storage systems (e.g. instructions for use TA009721 for Aesculap Eccos storage system).
- ► Insert the product in its proper position in the Eccos holder, or put it on a tray in such a way that the product is protected against damage. Ensure that all cutting edges are protected.
- ► Pack trays appropriately for the sterilization process (e.g. in Aesculap sterile containers).
- ► Ensure that the packaging will prevent a recontamination of the product.

6.11 Sterilization method and parameters

CAUTION

Damage to the camera control unit by sterilization!

- ► **Do not sterilize the camera control unit under any circumstances.**
- ► **Clean the camera control unit by surface disinfection only.**

CAUTION

Damage to the camera head or the optical zoom coupler caused by inappropriate sterilization processes!

- ► **Never sterilize the camera head or the optical zoom coupler with steam or in an autoclave.**
- ► **Do not carry out chemical sterilization.**

Working with single-use sterile drapes

- ► Use appropriate Aesculap single-use sterile drapes. Follow the instructions for use of the sterile drapes.

Sterilization through the Sterrad® sterilization process 50, 100S, 200

Note

The Sterrad® sterilization process can cause cosmetic changes to the camera head and cable. These changes however do not affect its functionality.

- ► Sterilize through the Sterrad® sterilization processes 50, 100S, 200 and adhere to the following rule:
  - Place the coupler Anti-Lock slider in the middle position to allow steriliant penetration on both sides off cavity.
  - Arrange the camera head cable in loose coils to allow good flow of sterilant. Avoid tightly packed coils that may obstruct sterilant penetration to the surface of the cable.

  Follow the manufacturer's advisories for use of the Sterrad® system. Use of a biological indicator is recommended to confirm effective sterilization.

6.12 Storage

- ► Store sterile products in germ-proof packaging, protected from dust, in a dry, dark, temperature-controlled area.

7. Functional test, maintenance and safety checks

7.1 Functional test at installation

Prior to putting the camera into service for the first time, the device and its accessories should be visually inspected and tested for operability by a camera technician or bio-technician. Visual inspection requires examining the control unit and camera head case for cracks, verifying that all connectors are properly fastened, checking for insulation damage to the power cord and other accessory cables, and inspecting for wall plug and equipment damage.

- ► Verify operation by turning on the camera and checking functionality as outlined in the setup and before procedure begins section of this manual.

7.2 Maintenance

To ensure reliable operation, the product must be maintained in accordance with the maintenance label.

For technical service, please contact your national B. Braun/Aesculap agency, see Technical Service.

CAUTION

No modification of this equipment is allowed! This product has no user serviceable parts.

- **Do not modify this equipment without authorization of the manufacturer.**
- **If any part of the control unit and camera head are damaged, contact your representative.**
- **Do not remove the cover or attempt to do any repairs yourself.**

Note

It is recommended that the user should test the camera for operability and also visually inspect the camera and its accessories (e.g., power cord, cables) prior to each use as outlined in the section above.

Note

In your inquiries or correspondence please always indicate the model and serial number printed on the identification plate. Further documentation is available from the manufacturer on request.

If there is insulation damage to the power cord or accessory cables or if any of the wall or equipment plugs are damaged, please replace the part and dispose as outlined in this manual, see Disposal.

7.3 Safety checks

WARNING

Risk of injury and/or malfunctions!

- **Don't use the device if technical and safety inspection reveals a defect which could harm the patient, clinicians, or third parties.**
- **Don't use the device until it has been properly repaired**
- **Immediately notify your representative of these defects.**

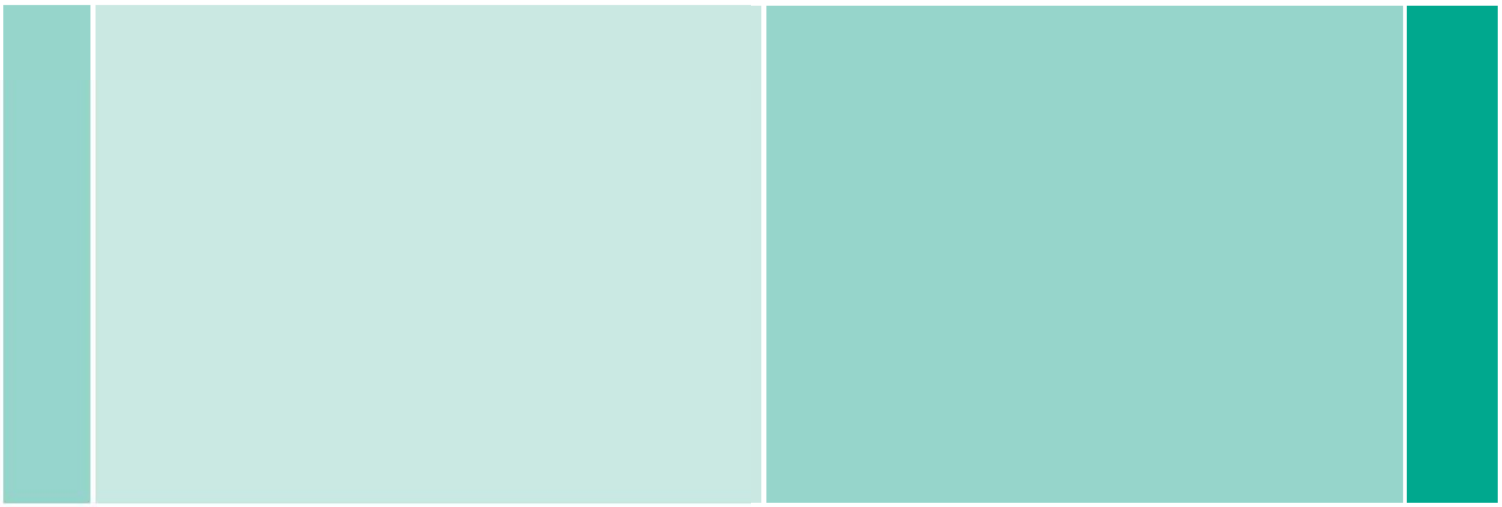
Safety checks require a functional test and electrical safety tests once a year. It is not necessary that technical and safety inspections are performed by qualified personnel; however, technical and safety inspections of the camera and its accessories must be performed by persons, who, based on their training, knowledge, and practical experience, are capable of adequately performing such inspections and who do not require instructions with regards to technical and safety inspection.

Required electrical safety according to IEC/DIN EN 60601-1 clause 18 & 19 or IEC 62353

Tests	Requirements
Impedance between earth connection and housing	≤0.1 Ω
Enclosure leakage current	≤0.1 mA
Earth leakage current	≤0.5 mA
Patient leakage current	≤0.1 mA
Patient auxiliary current D.C.	≤0.01 mA
Patient auxiliary current A.C.	≤0.1 mA

8. Troubleshooting list

Malfunction	Cause	Remedy
No image on the monitor	Device not powered	Verify that all units are connected to mains power and switched on
	Fuse blown	Fuse in camera T 0.5 A L/250 V~ (TA020394)
	Wrong video input activated	If the monitor supports several channels: Make certain the monitor is switched to the channel that is connected to the camera system
	Video cable defective	Replace video cable
	Video cable not connected	Connect video cable
Image too dark	Camera cable not connected or defective	Ensure that the camera head is connected to the camera control unit and the camera plug is dry
	Light cable not connected	Verify that the light cable is connected at the light source and the light cable input of the endoscope
	Light cable defective	Connect new light cable
	Light source dimmed down	Turn up the light source intensity
	Endoscope optical system defective	If the image is too dark even without the camera: Use a different endoscope and have the defective endoscope repaired by the manufacturer
Image fuzzy or poorly defined	Object out of focus	Turn the focus adjustment ring of the endo coupler until there is a sharp image
	Debris on the endoscope tip	Clean tip with a sterile cloth and isopropyl alcohol (70 %)
	Moisture on the camera cable plug	Dry plug with gauze before plugging it in at the camera plug
Image fogged	Contaminated or fogged endoscope	Check that the front and rear windows of the endoscope and the front window of the endo coupler are clean; if necessary, clean windows with isopropyl alcohol (70 %)
		Use Aesculap Anti Fog Solution JG910 on the distal window of the endoscope
Noise or excessive grain in the picture	Brightness enhancement function is active	Increase intensity of the light source
Image too bright or glary	Light metering not at its optimum setting	Press MENU for mode setting and select the optimum light metering mode
Color bar displayed on the monitor	Camera cable not connected to the camera control unit	Connect camera cable at the camera control unit
Unrealistic color representation on the monitor	Automatic white balance failed	Start automatic white-adjustment
	Monitor color setting misadjusted	Reset to factory setting
	Video cable defective	Replace video cable



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