MIZUHO

Near-Infrared (NIR) Color Camera System
HyperEye Medical System Handy
MNIRC-501

Instructions for use

Ver.3 (2017.10)
MES-CK08-704-00EN

CE

Introduction

This instruction manual (hereinafter referred to as "this manual") guides you on how to use this device. This manual is useful for both first time users and those who have used this device before to confirm how to handle the device. Before use, be sure to carefully read this manual and fully understand its contents. We recommend that you keep this manual in an easily accessible place when using this device.

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Safety precautions

Correct operation and periodic maintenance are essential for ensuring safe use of this device. Read the safety precautions given in this manual and do not use or perform maintenance on this device until you have fully understood them. The operating instructions and safe precautions are given in this manual only apply to when this device is used for its intended purpose.

In this manual, precautions are given below the symbols [WARNING] and [CAUTION].

⚠ [WARNING]

Failure to follow these instructions may result in serious physical injury or serious damage to the equipment.

⚠ [CAUTION]

Failure to follow these instructions may result in injury or cause the equipment to fail or damage other nearby equipment.

Precautions for use of medical electrical equipment (safety and hazard prevention)

1. The equipment should only be used by a skilled technician.
2. When installing the equipment, be careful of the following:
   1) Install the equipment in an area where it is not exposed to water.
   2) Install the equipment in an area where there is no possibility of it being adversely affected by atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, or air containing salt or sulfur.
   3) Be sure to keep the equipment stable (i.e. avoid inclinations, vibration, and shock, including during transport).
   4) Do not install the equipment in an area where chemical products are stored or gas is generated.
   5) Pay attention to the power supply frequency and voltage and the allowable current value (or the power consumption).
   6) Use a medical outlet.
   7) Install the controller in a sanitary area (reference: at least 1.5 m away from the patient).
   8) Do not place any objects or another equipment on top of the equipment.
3. Before using the equipment, be careful of the following:
   1) Turn on the power by following the specified procedure.
   2) Make sure all cords and cables are connected correctly and ensure safety.
   3) Check the contact condition of the switches to make sure the equipment operates normally.
   4) Make sure the equipment and other pieces of equipment used with this equipment do not adversely affect each other.
   5) When the equipment is used in combination with equipment that generates high-frequency radiation with high voltage and power, such as an electrosurgical unit, make sure the equipment will not malfunction or be damaged by electromagnetic interference by referring to the package insert and instruction manual of the equipment that generates high-frequency radiation.

6) Before using an SDHC card, format it to the FAT32 file system.
7) When using the equipment on a patient, use a sterile drape.

4. While using the equipment, be careful of the following:
1) Keep monitoring the equipment and patient for abnormalities.
2) If any abnormality occurs in the equipment or patient, take appropriate action, such as stopping the operation of the equipment, while ensuring the safety of the patient.
3) Do not stare at operating lamps or LED lights on the camera unit.

5. After using the equipment, be careful of the following.
1) Turn off the power by following the specified procedure.
2) When disconnecting a cord or cable, do not apply excessive force to it by pulling it out forcibly by the cord or cable.
3) When storing the equipment, be careful of the following:
i. Store the equipment in an area where it is not exposed to water.
ii. Store the equipment in an area where there is no possibility of it being adversely affected by atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, or air containing salt or sulfur.
iii. Be sure to keep the equipment stable (i.e. avoid inclinations, vibration, and shock, including during transport).
iv. Do not store the equipment in an area where chemical products are stored or gas is generated.
4) Clean the accessories, cords, and cables and store them in an organized fashion.
5) Be sure to clean the equipment for the next use.

6. When the equipment fails, do not attempt to repair it by yourself. Contact MIZUHO local distributor to repair it.

7. Do not disassemble or modify the equipment.

8. Maintenance and inspection
1) Be sure to periodically inspect the equipment and its parts.
2) When the equipment is not used for a prolonged period of time, be sure to check that the equipment operates normally and safely before use.

When handling the equipment, follow the instructions are given in this manual.

⊙ The information contained in this manual may be subject to change without prior notice.
⊙ This manual has been prepared with due care. However, if any errors or omissions are noted, please contact us.

Warranty and Disclaimers

1. Warranty
   1) Warranty repair is provided for one year after the date of purchase except for the cases shown in 2).
   2) Warranty repair is not provided in the following cases even before the warranty period expires:
      i. Failure or damage result from incorrect use or unauthorized repair or modification
      ii. Failure or damage result from this device being dropped after purchase
      iii. Failure or damage result from a fire disaster, natural disasters such as earthquake, flood, and lightning, abnormal power supply voltage, or use of a power supply other than that specified (voltage or frequency)
      iv. Failure or damage result from failure to observe the warnings and precautions given in this manual
      v. The problem is with consumables or accessories that have deteriorated with use
      vi. Failure caused by other devices
      vii. Failure or damage result from this device being used in a way other than that described in this manual.

2. Disclaimers

   MIZUHO is not responsible for the following:
      i. Failure, damage, or accidents result from maintenance or repair not provided by MIZUHO or a company designated by MIZUHO
      ii. Failure, damage, or accidents result from maintenance or repair using repair parts not designated by MIZUHO
      iii. Failure, damage, or accidents caused by a product not delivered by MIZUHO or MIZUHO local distributor
      iv. Failure, damage, or accidents result from failure to observe the safety precautions and operating instructions given in this manual
      v. Failure, damage, or accidents result from a deviation from the operating conditions of this device specified in this manual, such as those specified for the power supply, installation, and storage conditions.
      vi. Failure, damage, or accidents result from unauthorized repair or modification
      vii. Failure, damage, or accidents result from a fire disaster or natural disaster such as an earthquake, flood, and lightning
      viii. Damage to recorded data or inability to record due to a damaged or faulty SDHC card

Table of Contents

I Overview

1. Intended use

This device is to observe near-infrared light and is used for general and dynamic observation of infrared light.

2. Operating principle

The image sensor enables to take simultaneously visible light and near-infrared images.

The signals captured by the image sensor are processed to produce a video.

3. Major features

A. Color video

This device can be used to observe near-infrared light videos in visible light (color videos). This makes it possible to display and observe videos containing information about blood vessels under tissue surfaces, lymphatic flow, and so on in a more realistic manner. In addition, monochrome video (black-and-white) is available as needed.

Image (normal)

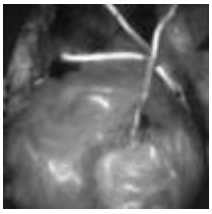


Image (monochrome)

B. Camera adjustment function and LED illumination ON/OFF

This device has a camera adjustment function by which the IRIS and CONTRAST can be set and adjusted. In addition, the built-in LED light (visible light and near-infrared light) can be turned on and off.

C. Recording/playback function

This device has a video recorder in its controller unit, allowing you to record video images to an SDHC memory card. Before using an SDHC card, be sure to format it to the FAT32 file system and perform an operation check. (Do not use quick format.)

The observation videos saved to the SDHC card can be played back on a monitor connected to DVI 2 or BNC 2.

⊙ The encoding used by this device is H.264 and the bit rate is 2 Mbps. The videos recorded with this device may be grainy depending on the object being observed.

4. After received the product

After you have received this device, check the appearance and accessories for damage. If any damage is found, any contents are missing, or if you have any problem in using this device, contact the local

MIZUHO distributor you purchased it from or the nearest MIZUHO service office.

This device is unpacked for an operation check before shipping. Therefor, the packing box is taped twice.

5. Components

A. Standard components

This device includes the items shown in the table below.

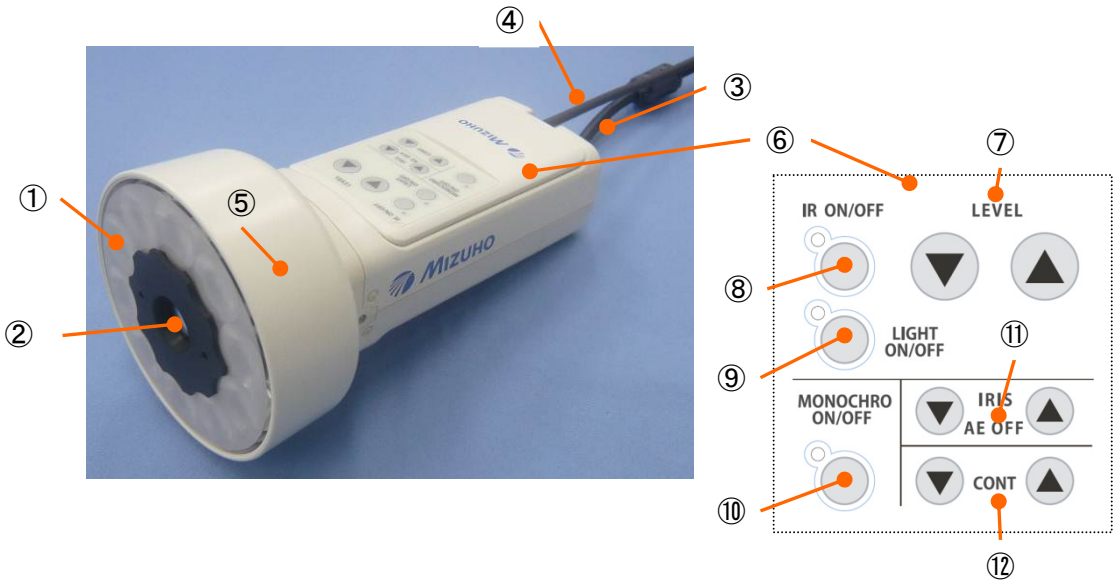
Code	Product description	Remarks
08-704-00	Near-Infrared (NIR) Color Camera System HyperEye Medical System Handy MNIRC-501 Set J	
Consists of :		
08-704-10	HyperEye Medical System Handy Camera Unit	
08-704-11	HyperEye Medical System Handy Controller Unit	
08-704-12	AC Adaptor	Model : MPU51-201
-	Instructions for use	This manual
-	Powercord	

B. Optional Accessories

Code	Product name	Remarks
08-701-41	Sterile Drape II for the camera unit	20 piece per pack
08-701-31	19 inch coloe Monitor	
08-701-20	Cart	

II Location and function of parts and controls

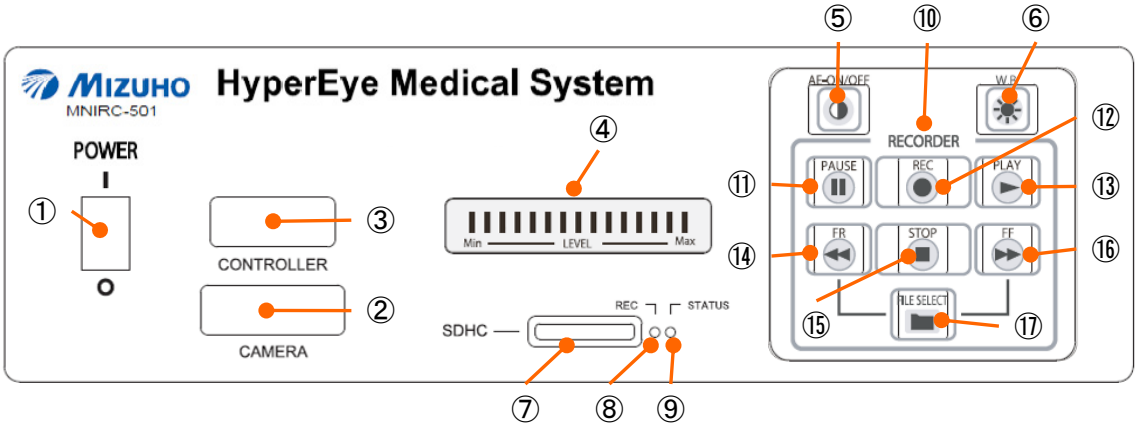
1. Camera unit



	Name	Function
①	LED light	LEDs arranged in a ring shape for illumination (white light and near-infrared light)
②	Lens	Lens used when the distance from the object is 100 mm to 300 mm
③	Camera cable	Cable connected to the controller unit
④	Sub-controller cable	Cable connected to the controller unit
⑤	Focus ring	The focus can be finely tuned by rotating this ring
⑥	Sub-controller	Detachable from the camera
⑦	LEVEL button	Button used to adjust the intensity of the near-infrared light
⑧	IR ON/OFF button	Button used to turn on and off the near-infrared light When this button is pressed and held for 2 seconds, near-infrared light is flashed. To exit the flashing mode, press this button again.
⑨	LIGHT ON/OFF button	Button used to turn on and off the white light (3 levels: OFF / Weak / Intense)
⑩	MONOCHROME ON/OFF button	Button used to switch between color (orange) and monochrome (green)
⑪	IRIS button	Button used to adjust the shutter speed
⑫	CONT button	Button used to finely adjust the edge enhancement (3 levels)

2. Controller unit

A. Front panel



	Name	Function
①	Power switch	Switch used to turn on and off the power
②	Camera cable connection terminal	Terminal to which the camera cable is to be connected
③	Sub-controller cable connection terminal	Terminal to which the sub-controller cable is to be connected
④	Indicator	Indicator that indicates the currently set output level of the near-infrared light of the LED. When the power is turned on (during initial setting), the indicator lamps turn on from left (Min) to right (Max).
⑤	AE	Used to turn on and off automatic exposure. When the power is turned on, AE is on. When the IRIS button is pressed, AE turns off (manual). Green: OFF (manual), Orange: ON (automatic)
⑥	W.B.	Used to adjust the white balance. When the power is turned on, HOLD (fixed) is selected. AUTO (automatic) is selected only while this button is being pressed. When the button is released, the white balance is fixed at the displayed value (HOLD). When this button is pressed and held for 3 seconds or more, AUTO remains on. When the button is pressed again, AUTO is cancelled. The white balance can be stored for when the light is turned on and when it is off. Set the white balance for each. Green: HOLD (fixed), Orange: AUTO (automatic)
⑦	SDHC card slot	Slot into which an SDHC card (class 10 recommended) is to be inserted. Before using an SDHC card, be sure to format it to the FAT32 file system. Compression format: H.264

⑧	REC lamp	This lamp stays on while recording to an SDHC card. OFF : Recording is stopped or playback is in progress. No video signal is being input. ON : Recording is in progress. Flashing : The SDHC card does not have enough space available, write protection is engaged, etc.
⑨	STATUS lamp	This lamp indicates the status of the SDHC card slot. OFF : No SDHC card is in the slot. No video signal is being input. ON : An SDHC card is in the slot. Flashing : Startup is in progress, the SDHC card does not have enough space available, write protection is engaged, etc.
⑩	RECORDER function	Buttons used for recording. For details, refer to "5. Basic functions of the recorder" in "IV Operation." (The same applies hereinafter.)
⑪	PAUSE	Button used to pause playback of the recorded video
⑫	REC	Button used to start recording the observed video (and save it on the SDHC card)
⑬	PLAY	Button used to start playback of the recorded video
⑭	FR	For use while a recorded video is being played back. When this button is pressed, the previous file is played back. When this button is pressed and held, the file currently being played back is rewound (the rewinding speed changes from ×2 to ×4, ×8, and ×16).
⑮	STOP	Button used to stop recording and playback
⑯	FF	For use while a recorded video is being played back. When this button is pressed, the next file is played back. When this button is pressed and held, the file currently being played back is fast-forwarded (the fast-forwarding speed changes from ×2 to ×4, ×8, and ×16).
⑰	FILE SELECT	Button used to display the list of files saved on the SDHC card and the Setup screen on the monitor. When this button is pressed: The list of saved files is displayed. When this button is pressed and held (3 seconds): The Setup (menu) screen is displayed. To exit the screen, press this button again.

The general illumination conditions of each button and the illumination conditions of the AE and WB buttons are as shown below. For the illumination conditions of the buttons for the recorder function, refer to "9. Recorder indication and button operations" in "IV Operation."
If a setting is adjusted beyond its threshold value, the buzzer sounds when the button is pressed.

General illumination conditions of each button

Button illumination color	Status
Green	Ready
Orange	The button is operated or the device is operating
Flashing green or orange	A communication error has occurred

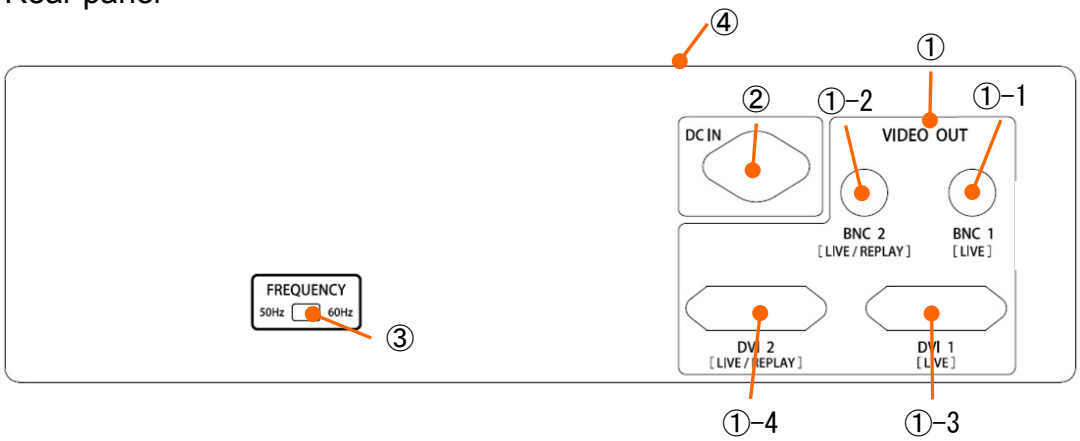
Indications of AE and WB buttons

Status	Indication
When the power is off or the cable is not connected	OFF
When AE is ON and WB is AUTO (automatic adjustment is in progress)	Orange
While initial adjustment is in progress immediately after the power is turned on	Green (flashing)
When AE is OFF and WB is HOLD (fixed)	Green
When a communication error occurs, or a connector is not connected or is improperly connected	Green and orange (alternate flashing)

Indicator indications

Status	Status of IR button lamp	Illumination		Indication	Light (IR)
When the power is off	○	OFF	■■·····■	OFF	OFF
While initial adjustment is in progress immediately after the power is turned on	–	OFF	All the segments turn on from left to right (green).		OFF
Light (IR) OFF	●	Green	■■·····■	OFF	OFF
Light (IR) ON	●	Orange	■■·····■ etc.	ON	ON

B. Rear panel



	Name	Function
①	VIDEO OUT	See below.
①-1	BNC 1 (video output terminal)	NTSC video output terminal for live images only. When a monitor is connected, use a device compliant with the safety regulations for medical electrical equipment (IEC 60601-1, etc.).
①-2	BNC 2 (video output terminal)	NTSC video output terminal for live images and recorded videos can be played back on a monitor. This also has the same function as ①-1.
①-3	DVI 1 (video output terminal)	DVI-I video output terminal for live images only. When a monitor is connected, use a device compliant with the safety regulations for medical electrical equipment (IEC 60601-1, etc.).
①-4	DVI 2 (video output terminal)	DVI-I video output terminal for live images and recorded videos can be played back on a monitor. This also has the same function as ①-3.
②	DC IN	Terminal to which the DC plug (AC adapter) is to be connected
③	50/60 Hz selection switch	Used to switch between 50 Hz and 60 Hz. By selecting 50 Hz or 60 Hz according to the power supply frequency, image flicker can be prevented.
④	Label	Product Label

III Setup

⚠ [WARNING]

- ⊙ When connecting this device to other devices, make sure the power is off and the main plug is not connected to an outlet.
- ⊙ When using this device for a patient, use a sterile drape.
- ⊙ Before using an SDHC card, be sure to format it to the FAT32 file system. Failure to do so may corrupt the data. (Do not use quick format.)

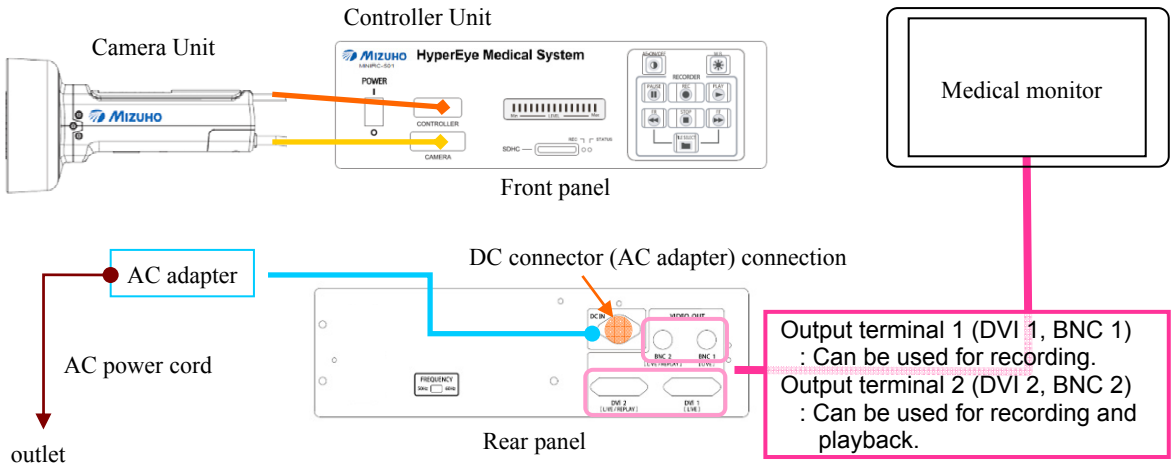
⚠ [CAUTION]

- ⊙ Use accessories and relevant products designated by MIZUHO.
- ⊙ Check the operation of this device before use.
- ⊙ Do not pull out or connect a cable with excessive force. Do not pull the cord, but hold the connector and handle the cable properly. (The connectors have a lock function.)
- ⊙ When connecting this device to a product not designated by MIZUHO, make sure the product is compliant with the safety regulations for medical electrical equipment (IEC 60601-1, etc.).
- ⊙ Use a Class 10 SDHC card and perform an operation check before use. SD memory cards and SDXC memory cards cannot be used. The only UHS (Ultra High Speed) type available is UHS-I.
- ⊙ Do not use a conversion adapter.

1. How to connect devices and cables

Connect each device to this device using the designated and recommended accessories. (Do not turn on the switch before all devices are connected properly.)

- ⊙ The connector has a lock mechanism and cannot be disconnected without holding it and pulling it out. Never hold the cable when pulling out the connector, as doing so can break or damage the cable.



Schematic connection diagram

2. Connection with a monitor

⚠ [WARNING]

⊙ Carefully read the instruction manual for the monitor and follow the instructions in the manual.

⚠ [CAUTION]

⊙ Use a monitor that fits the specifications of this device and complies with the safety regulations for medical electrical equipment (IEC 60601-1, etc.).

⊙ When connecting a monitor to this device, make sure the monitor is turned off and the main plug is unplugged.

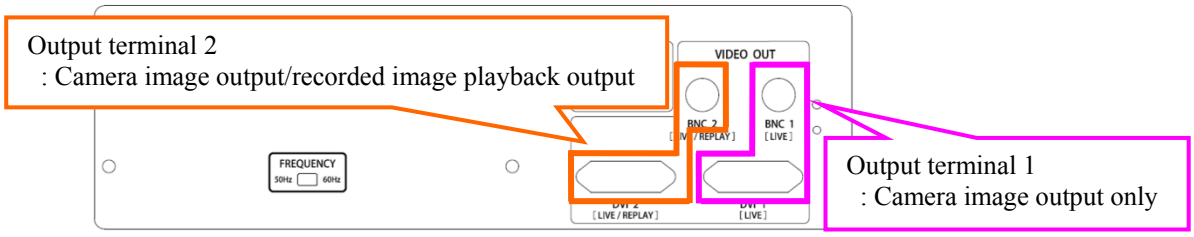
⊙ Check for loose or missing screws before use.

⊙ Check the operation of this device before use.

When connecting a monitor to the controller, connect a BNC or DVI cable to the BNC or DVI terminal on the back of the controller.

⊙ Before connecting a monitor to the controller, make sure they are both turned off.

The specifications of the output terminals are as follows:



⊙ Purchase and use a monitor (option code 08-701-31) that fits the specifications of this device and complies with the safety regulations for medical electrical equipment (IEC 60601-1, etc.).

⊙ No video output cable (DVI cable or BNC cable) is provided as a standard component. Use the cable provided with the monitor, or prepare an appropriate cable.

3. Sterile drape

⚠ [WARNING]

- ⊙ Do not reuse the sterile drape.
- ⊙ This device is an optical precision instrument.
  Extra care should be taken while putting sterile drape on.

⚠ [CAUTION]

- ⊙ Before putting a sterile drape on the device, make sure the power is off and the main plug is unplugged.
- ⊙ Do not hold the device by cable.

Refer to the drape instructions for use.

IV Operation

[WARNING]

- Remove any dust that accumulates on the plug of the detachable power supply cord, outlet, main socket, the connectors of the connection cables, and the terminals of this device. Using this device with dust on it may lead to fire.
- When using this device for a patient, put a sterile drape over the camera. (Do not reuse the sterile drape.)
- While operating and using this device, do not allow the device to come in contact with the patient.
- This device is an optical precision equipment. Take extra care not to drop it or subject it to shock.
- Keep magnetic devices away from this device.
- Before using an SDHC card, be sure to format it to the FAT32 file system. Failure to do so may corrupt the data. (Do not use quick format.)
- Use the SDHC card properly by referring to the instruction manual for the SDHC card.
- Plug this device into a medical outlet with protective earth (to prevent electric shock).

[CAUTION]

- When connecting the detachable power supply cord, make sure the power switch of the main unit is turned off.
- Do not operate this device in a manner other than as specified in this manual.
- Use a Class 10 SDHC card and perform an operation check before use. SD memory cards and SDXC memory cards cannot be used.
- Do not install ME devices or other devices that will be an obstacle to the detachment of the cord around the plug of the detachable power supply cord and outlet.
- Install the controller in a sanitary area (at least 1.5 m away from the patient).
- Possibly hazardous optical radiation emitted from this device.
  Do not stare at LED light while LED is on. It may be harmful to the eyes. (IEC 62471:2006, risk group 2)

1. Before use/power-on

1) Set up this device using the standard components.
2) Put a sterile drape on it when necessary.
3) Make sure the power switch is off and insert the detachable power supply cord into a medical outlet.
4) Turn the power switch on. The device automatically starts initial setup.
   - If a function is unavailable due to a disconnected cable or for any other reason, the lamp of the corresponding button goes off.
   - If the lamp flashes (green and orange alternately) after this device is restarted with the cable connected, the device may have a problem. It may need to be repaired..

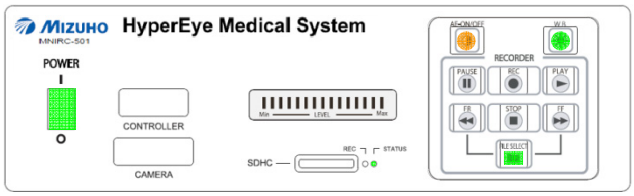


Image just after the setup is complete and power swich on

2. Observation procedure

1) Direct the camera toward the observation object and observe it.
   - ⊙ This device uses a lens designed for a distance of 100 mm to 300 mm between the lens and observation object. Note that if the distance is longer or shorter than the range between 100 mm and 300 mm, the image is likely to be out of focus.
   - ⊙ The focus can be adjusted by rotating the focus ring. If the image remains blurry, the distance between the lens and observation object is likely outside of the specified range. Move the camera closer to or away from the observation object until the distance is within the specified range, and rotate the focus ring again to adjust the focus.
2) Make the following settings and adjustments as needed. (For details, refer to the following pages.)
   a) Camera adjustment
      - According to the intended use and environment, set up and adjust the camera with the IRIS, CONT, AE, and WB buttons.
   b) Near-infrared light/white light adjustment
      - Adjust the near-infrared light with the IR ON/OFF and LEVEL buttons, and the white light with the LIGHT ON/OFF button.
   c) Recording to an SDHC card
      - Insert an SDHC card into the SDHC card slot and press the REC button.
      - To stop recording, press the STOP button.
   d) Playback of the video recorded to the SDHC card on the monitor
      - Make sure the SDHC card is in the slot and the monitor is connected properly to DVI 2 or BNC 2.
      - Press the PLAY button.

3. After use

1) After use, turn the near-infrared light/white light off and turn the recorder off. Then, turn the power switch off.
2) Hold the main plug and unplug it.
3) When moving this device, disconnect the power supply cord and connection cables properly.
4) Clean, maintain, and inspect this device for the next use.

4. Capacity and maximum recordable time of SDHC card

⚠ [WARNING]

- ⊙ Handle SDHC cards properly by referring to the instruction manual for the SDHC card.
- ⊙ Before using an SDHC card, be sure to format it to the FAT32 file system. Failure to do so may corrupt the data. (Do not use quick format.)
- ⊙ Use a Class 10 SDHC card and perform an operation check before use. SD memory cards and SDXC memory cards cannot be used. The only UHS type available is UHS-I.

⚠ [CAUTION]

- ⊙ Do not get the SDHC card wet, touch it with wet hands, or touch the terminals with metal or bare hands.
- ⊙ When inserting or removing an SDHC card, be careful of the direction of the SDHC card, Do not bend it or subject it to strong force or shock.
- ⊙ If it takes two or more seconds to recognize an SDHC card after it is inserted into this device, the SDHC card may not have sufficient writing speed and would thus be unusable. Choose another SDHC card.
- ⊙ Do not pull the SDHC card out of the card slot or turn off the power while the SDHC card is in use (while recording or playback is in progress). Before pulling out the SDHC card, be sure to press the STOP button to shut down all the functions.
- ⊙ The approximate maximum recordable time of an SDHC card is a theoretical value. It changes depending on the object being observed. Use an SDHC card with sufficient capacity.
- ⊙ MIZUHO will not undertake any restoration of data recorded onto an SDHC card corrupted due to a write failure.
- ⊙ Never insert anything other than SDHC cards into the card slot.
- ⊙ Do not expose the SDHC card to liquids. When cleaning it, use soft cloth.

• The capacity and theoretical recordable time of each SDHC card is as shown in the table below. The recordable time is just for reference, as the actual recordable time changes depending on what is observed and movement. The maximum recordable time for one file is 30 minutes. A new file is automatically created every 30 minutes.

Approximate maximum recordable time

Indicated capacity of SDHC card	Approximate maximum recordable time	Indicated capacity of SDHC card	Approximate maximum recordable time
4 GB	Approx. 1.6 h	16 GB	Approx. 6.5 h
8 GB	Approx. 3.2 h	32 GB	Approx. 13 h

5. Basic functions of the recorder

⚠ [WARNING]

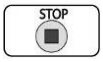
- ⊙ Handle SDHC cards properly by referring to the instruction manual for the SDHC card.
- ⊙ Before using an SDHC card, be sure to format it to the FAT32 file system. (Do not use quick format.)

⚠ [CAUTION]

- ⊙ MIZUHO will not undertake any restoration of data recorded onto an SDHC card corrupted due to a write failure.
- ⊙ Do not pull out the SDHC card or turn off the power while recording or playback is in progress.
- ⊙ After the STOP button is pressed, it takes about three seconds to create a file. Wait a while before starting playback or performing other operations.
- ⊙ There is a time lag between the operation of a button and the response of the device. Operate this device slowly and carefully.
- ⊙ Do not operate this device in a manner other than specified in this manual.
- ⊙ The recorder function of this device encodes videos in H.264. The bit rate is 2 Mbps. When the observation object moves significantly, or depending on what is being observed, the video quality may be rough.
- ⊙ The recorder function may be unavailable depending on the performance of the SDHC card. Be sure to check the operation of the SDHC card before using this device.

The basic functions of the recorder are as follows:

Basic functions of the recorder buttons

Button		Function
PAUSE		Pauses playback. (Recording cannot be paused.)
REC		Starts recording.
PLAY		Starts playback.
FR		Plays back the previous video file when pressed once and rewinds the video when pressed and held. (The rewind speed changes from ×2 to ×4, ×8, and ×16, and is selected when the button is released. To stop rewinding, press the PLAY button.)
STOP		Stops recording or playback.
FF		Plays back the next video file when pressed once and fast-forwards the video when pressed and held. (The fast-forwarding speed changes from ×2 to ×4, ×8, and ×16, and is selected when the button is released. To stop fast-forwarding, press the PLAY button.)
FILE SELECT		Displays the list of saved files when pressed once and displays the Setup (Menu) screen when pressed and held for 3 seconds. (They are displayed on the monitor that is connected to the output terminal 2.)

6. Recording procedure

Before recording an observation video, be sure to check its functionality.

⊙ Before using an SDHC card, format it to the FAT32 file system on your PC.

1) Insert the SDHC card into the SDHC card slot.

⊙ Only the buttons available are lit. If the REC button is not lit, the SDHC card may not be suitable for use with this device or be damaged.

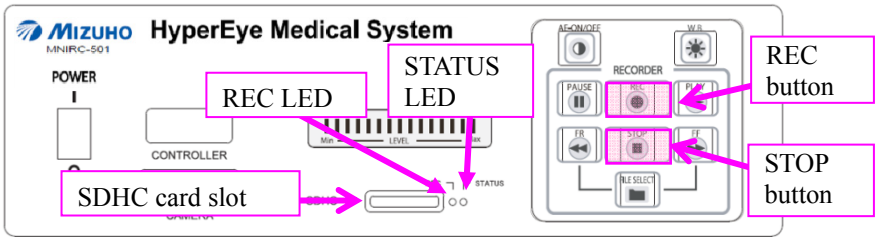
2) Starting and stopping recording

a) Start

- Press the REC button. The device starts recording a video of the observation object.
- While recording is in progress, the REC button is lit orange and the REC lamp next to the SDHC card port is lit.

b) Stop

- To save the video on the SDHC card, press the STOP button.
- The REC button lights up in green and the REC lamp next to the SDHC card port goes off.



7. Playback function

The following describes how to play back videos saved on the SDHC card on a monitor connected to this device.

⊙ When using the playback function, make sure the monitor is connected to video output terminal DVI 2 or BNC 2.

1) Starting and stopping playback

a) Playback

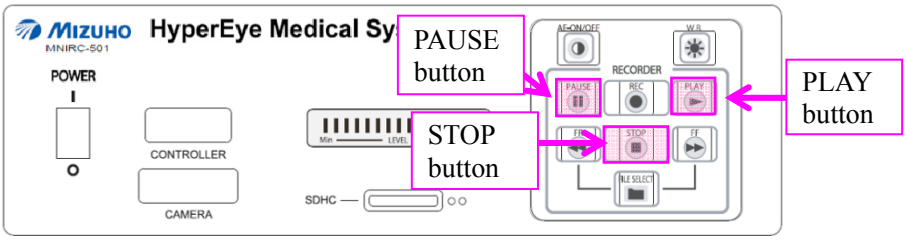
- Press the PLAY button. The saved file is played back. While recording is in progress or at other times when the SDHC is in use, press the STOP button before starting playback.
- To select a video to play back from those saved on the SDHC card, refer to "3) When you want to select another file."

b) Stop

- Press the STOP button. Playback of the video is stopped and the live image is displayed.

c) Pause (while playback is in progress)

- Press the PAUSE button. Playback of the video is paused.



2) Rewinding and fast-forwarding

a) Rewinding

- Press and hold the FR button.

  While the button is held down, the rewinding speed changes from ×2 to ×4, ×8, and ×16. The speed is selected when the button is released. To stop rewinding, press the PLAY button.

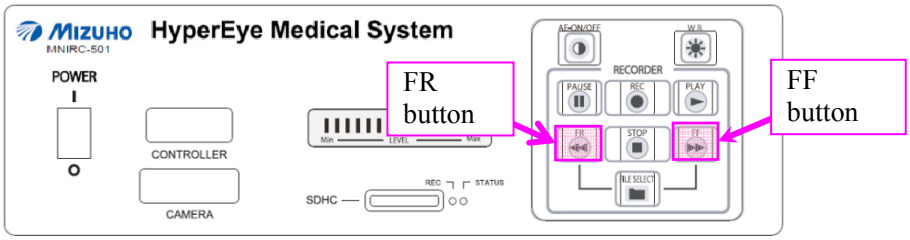
- When the FR button is pressed, the previous file is played back.

b) Fast-forwarding

- Press and hold the FF button.

  While the button is held down, the fast-forwarding speed changes from ×2 to ×4, ×8, and ×16. The speed is selected when the button is released. To stop fast-forwarding, press the PLAY button.

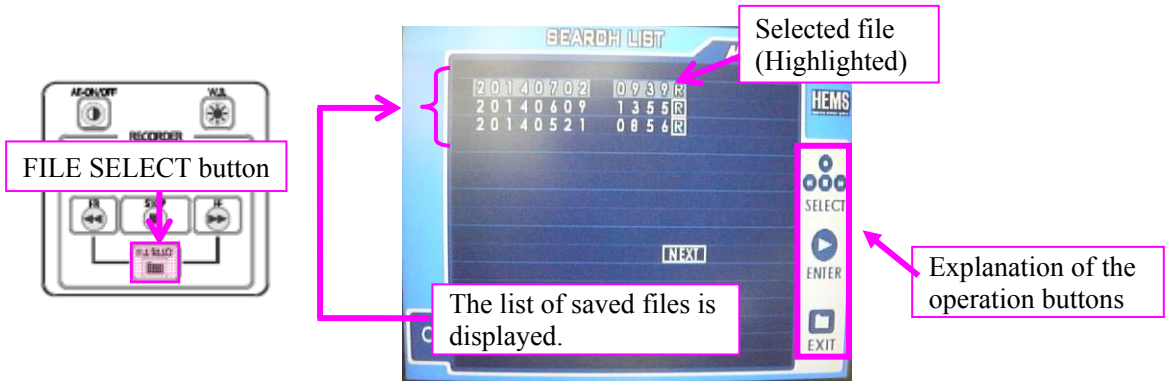
- When the FF button is pressed, the next file is played back.



3) When you want to select (play back) another file (when the monitor is connected to video output terminal DVI 2 or BNC 2)

For details, refer to "Recorder indications and button operations."

- Press the FILE SELECT button.
- The list of files saved on the SDHC card (search list) is displayed on the monitor.
- Press the REC button (move up) or STOP button (move down) to select the file to play back. The selected file is highlighted.
- Press the PLAY button (ENTER) to enter standby mode. Press the PLAY button again to start playback.
- Pressing the FR or FF button plays back the previous or next file in the search list.

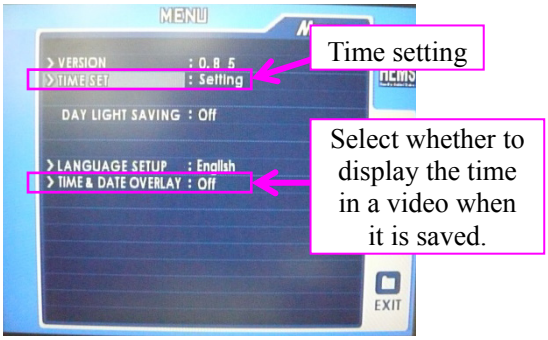


8. Setup (Menu) screen

⚠ [CAUTION]

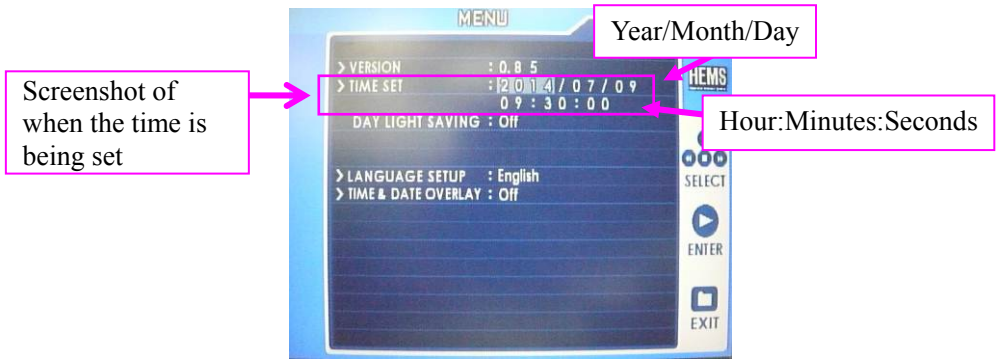
- ⊙ Do not pull out the SDHC card or turn off the power while recording or playback is in progress.
- ⊙ There is a time lag between the operation of a button and the response of the device. Operate this device slowly and carefully.
- ⊙ Do not operate this device in a manner other than specified in this manual.
- ⊙ Before use, make sure the time display is set up properly. Once a file is saved, the time display setting cannot be changed.

- Set up the clock and select whether to display the time in the videos.
- Make sure the monitor is connected to video output terminal DVI 2 or BNC 2 and press and hold the FILE SELECT button (for approx. 3 seconds).
- The Setup (Menu) screen is displayed on the monitor.
- Change the settings using the buttons on the controller. The selected item is highlighted.
- The items displayed on the left of the monotor correspond to those on the controller unit. For details, refer to "Recorder indications and button operations."



A. Setting the time

- Press and hold the FILE SELECT button (for approx. 3 seconds). The Setup (Menu) screen is displayed on the monitor.
- Press the REC button (move up) or the STOP button (move down) to set the time. (The selected item is highlighted.)
- Press the PLAY button (ENTER). (The image shown below is displayed.)
- Press the REC button (move up) or the STOP button (move down) to set the current time.
- To move the cursor to the next item, press the FF button (move to the right) or the FR button (move to the left).
- After setup is complete, press the PLAY button (ENTER) to apply the setting and display the main Setup (Menu) screen.
- Press the FILE SELECT button (EXIT) to exit the screen. (The live image is displayed.)

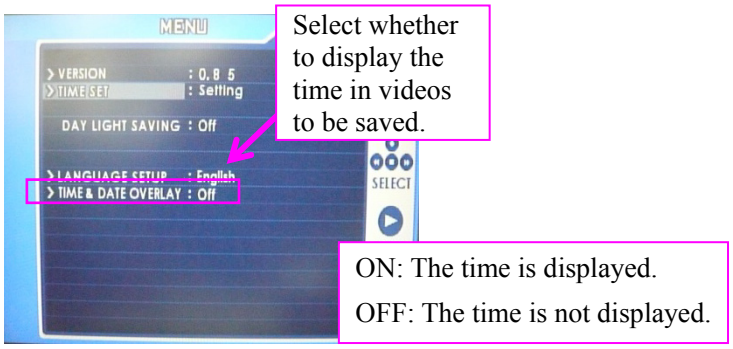


B. Time display ON/OFF

- Select whether to display the current time in videos to be saved on the SDHC card.

⊙ This setting is for videos to be recorded and saved, and cannot be changed for videos that have already been saved.

- Press and hold the FILE SELECT button (approx. 3 seconds). The Setup (Menu) screen is displayed on the monitor.
- Press the REC button (move up) or the STOP button (move down) to move the cursor over the time setting. (The selected item is highlighted.)
- Press the PLAY button (ENTER). Press the REC button (move up) or the STOP button (move down) to select ON (the time is displayed in the video) or OFF (the time is not displayed in the video).
- After the setup is complete, press the PLAY button (ENTER) to apply the setting and display the main Setup (Menu) screen.
- Press the FILE SELECT button (EXIT) to exit the screen. (The live image is displayed.)

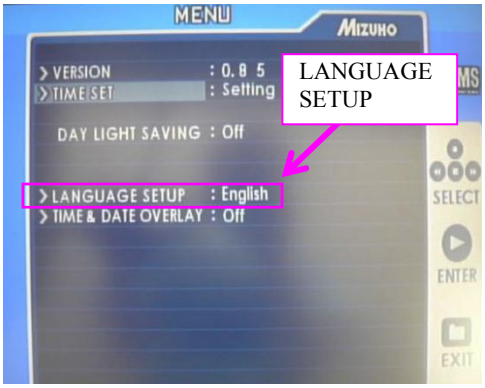


C. Setting the language

- Set up the device using the standard components. Connect the DVI cable to DVI 2 terminal.
- Press and hold the FILE SELECT button (approx. 3 seconds). The Setup (Menu) screen is displayed on the monitor.
- Press the REC button (move up) or the STOP button (move down) to move the cursor over the LANGUAGE SETUP (The selected item is highlighted.)
- Press the PLAY button (ENTER). The selected language is highlighted.

Selectable languages: Japanese, English, Dutch, French, German, Spanish

• Select the language by the FR button (move to the left).
• After the setup is complete, press the PLAY button (ENTER)
• Press the FILE SELECT button (EXIT) to exit the screen. (The live image is displayed.)

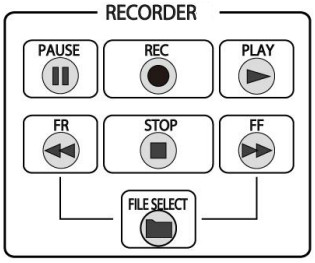


Display Example (English)

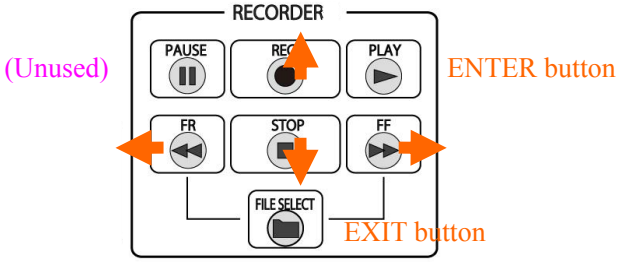
Display Example (Japanese)

9. Recorder indications and button operations

The status indications and operations of the recorder are as follows:

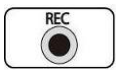
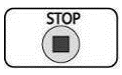


(a) At normal times
(assigned as indicated)



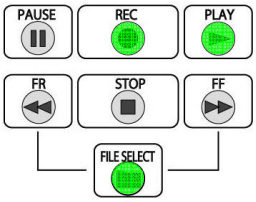
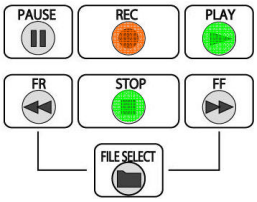
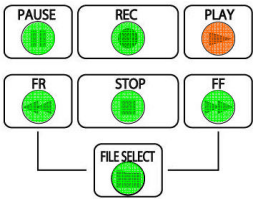
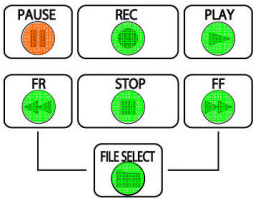
(b) When the list of saved files or the Setup
(Menu) screen is displayed

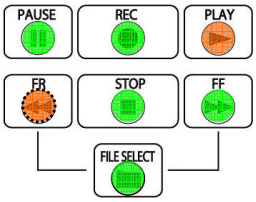
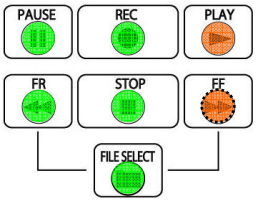
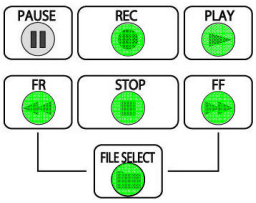
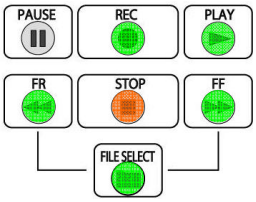
Operations of the controller unit on the monitor

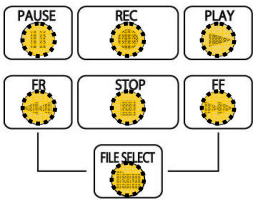
Action on the monitor	Indication on the left of the monitor	Operation button (controller)	Remarks
Move up			Moves the cursor up. Used to select the item to change.
Move down			Moves the cursor down. Used to select the item to change.
Move to the right			Moves the cursor to the right. Used to select the item to change.
Move to the left			Moves the cursor to the left. Used to select the item to change.

ENTER			Enter button used to apply the setting.
EXIT			Finishes the setup.

Recorder button indications and operations

Status	Lamp indication	Button operation	
		Button	Action
Stop (SDHC card in slot/ready to record)		REC	Record
		PLAY	Playback
		FILE SELECT	File list screen
		FILE SELECT (3-second press-and-hold)	Setup (Menu) screen
Recording		REC	No function
		PLAY	Playback
		STOP	Stop
Playback		PAUSE	Pause
		REC	Recording
		PLAY	No function
		FR	Playback of the previous video file
		FR (press-and-hold)	Rewind
		STOP	Stop
		FF	Playback of the next video file
		FF (press-and-hold)	Fast-forward
		FILE SELECT	File list screen
		FILE SELECT (3-second press-and-hold)	Setup (Menu) screen
Pause		PAUSE	Playback
		REC	Record
		PLAY	Playback
		FR	Playback of the previous video file
		FR (press-and-hold)	Rewind
		STOP	Stop
		FF	Playback of the next video file
		FF (press-and-hold)	Fast-forward
		FILE SELECT	File list screen
		FILE SELECT (3-second press-and-hold)	Setup (Menu) screen

Rewinding		PAUSE	Pause
		REC	Record
		PLAY	Playback
		FR	Rewinds the previous video file
		FR (press-and-hold)	Increases the rewind speed
		STOP	Stop
		FF	Playback of the next video file
		FF (press-and-hold)	Fast-forward
		FILE SELECT	File list screen
		FILE SELECT (3-second press-and-hold)	Setup (Menu) screen
Fast-forwarding		PAUSE	Pause
		REC	Record
		PLAY	Playback
		FR	Fast-forwards the previous video file
		FR (press-and-hold)	Rewind
		STOP	Stop
		FF	Fast-forwards the next video file
		FF (press-and-hold)	Increases the fast-forward speed
		FILE SELECT	File list screen
		FILE SELECT (3-second press-and-hold)	Setup (Menu) screen
File list screen Setup (Menu)		REC	"↑" Move up
		PLAY	Enter
		FR	"←" Move left
		STOP	"↓" Move down
		FF	"→" Move right
		FILE SELECT	Cancel
When the video file is selected on the file list screen		REC	Record
		PLAY	Playback
		FR	Selection of the previous video file
		STOP	Stop (exits search mode)
		FF	Selection of the next video file
		FILE SELECT	File list screen
		FILE SELECT (3-second press-and-hold)	Setup (Menu) screen

When a communication error occurs (alternate flashing of green and orange)		Buttons	No function

Indications of the lamps next to the SDHC card port

Status		Lamp indication	
		REC (orange)	STATUS (green)
When stopped and while playback is in progress		○ OFF	● ON
While recording is in progress		● ON	● ON
While startup is in progress		○ OFF	◌ Slow flash
SDHC card	Inserted	–	● ON
	Not inserted	–	○ OFF
	Pulled out	–	◌ Fast flash
	Insufficient space available	◌ Fast flash	◌ Fast flash
	Write protection engaged (when locked)	◌ Fast flash	◌ Fast flash
	I/O error	● ON	● ON
	Playback button pressed when no file to play back exists	○ OFF	○ OFF
No video signal input		○ OFF	○ OFF
Memory error		● ON	● ON

10. After use

[WARNING]

- Do not drop this device or subject it to shock.
- When disconnecting this device, make sure the power is turned off.

[CAUTION]

- Shut down this device according to the specified procedure and turn off the power.
- When disconnecting the detachable power supply cord and connection cables, do not hold and pull out the cord or cable, or apply excessive force to them.
- Check this device and accessories for the next use according to the Daily Check Record.
- Clean and maintain this device and accessories for the next use.
- When putting a sterile drape on and removing them from this device, be sure to hold this device and properly put them on and remove them from this device. Do not hold the device by cable.

1) Stop the recording/playback function (press the STOP button) and turn off the LED light.
2) Turn off the power switch.
3) Properly unplug the detachable power supply cord plug from the outlet.
4) If necessary, disconnect the connection cables from this device while holding their connectors.

V Maintenance

Definitions of maintenance and repair

Maintenance : Cleaning, calibration, and replacement of consumables

Repair : Restoration of faulty, damaged, or aged parts to their original condition

1. Daily care

⚠ [CAUTION]

- ⊙ When performing daily care, make sure the power is off and the main plug is unplugged from the outlet.
- ⊙ Do not use benzene or thinner.
- ⊙ Read the instructions for the disinfectant used and make sure it does not adversely affect metallic or plastic parts.
- ⊙ When cleaning the camera lens and diffuser of LED illumination part, use soft and clean cloth, such as lens cleaning cloth, and handle them with care.

A. Cleaning and disinfection

1) When wiping dirt off this device and accessories, use a soft, clean cloth dampened with rubbing alcohol or the like. Do not allow the alcohol to get into this device. Benzene and thinner may cause discoloration or corrosion.
2) Read the instructions for the disinfectant used, and make sure it does not adversely affect metallic or plastic parts.
3) When wiping the front face of the camera of this device (lens and LED illumination part), use soft, clean cloth, such as lens cleaning cloth.
4) Do not allow any liquid to get into the SDHC card port.

B. Sterilization

1) Do not sterilize this device. Sterilization may cause deformation or deterioration, resulting in damage or failure. This device is not designed to be in contact with a patient while in use. Whenever necessary use sterile drape (08-701-41).

2. Daily check

⚠ [CAUTION]

⊙ Perform daily checks before and after use.

⊙ When need to repair, send all the accessories together with the device.

A. Main unit

1) Appearance inspection

   Visually inspect the operation (front) panel and the main unit for damage and dirt, such as noticeable scratches, loose or missing screws, and loose cable and terminal connections.

2) Operational/functional inspection

   Turn on the power to inspect that the lamp built into the power switch lights up normally and that the setting buttons work normally.

3) Time setting

   Check that the time is set correctly. For details, refer to "A. Setting the time" of "IV Operation."

⊙ Photocopy the Daily Check Record Sheet as needed.

B. Accessories

1) Appearance inspection

   Visually inspect for damage and dirt.

2) Electrical continuity test

   Check for disconnections using a tester (circuit tester and multimeter).

Photocopy this page as needed.

HyperEye Medical System (MNIRC-501) Daily Check Record Sheet			
Name of institution		Checked on	
Installed at		Checked by	
Controlled by		Serial No.	No.
Purchased on		Control No.	No.

■ Main unit

▼ Appearance inspection

Check item	Usable	Repair	Replacement	Remarks
Paint delamination/scratch				
Power switch				
Connector connection ports				
Rubber legs				
Camera unit				
Controller unit				
Electric Mains part				

▼ Operational/functional inspection

Check item	Usable	Repair	Replacement	Remarks
Power switch				
Operation buttons				
Operation lamps				
LED illumination/intensity				
Camera unit				
Controller unit				
Electric Mains part				
Time setting				

■ Accessories

▼ Appearance inspection/electrical continuity test

Check item	Usable	Repair	Replacement	Remarks
Power supply cord				
Loose or missing screw				

Comment

3. Periodic check

[WARNING]

- Failure to check this device correctly may result in failure or injury.
- MIZUHO will not be responsible for any failure or accidents resulting from checks with the cover removed.
- When this device is not used for a prolonged period of time, perform a periodic check before use.

[CAUTION]

- Perform a periodic check once a year or so. For safe use of this product, have this device checked by MIZUHO local distributor once a year.
- When finding a problem and request repair, let MIZUHO know which part of the device has the problem and under what circumstances it occurred.
- When requesting that we repair this device or perform a periodic check, please send all the accessories with this device.

Periodic checks require sophisticated work using special measuring instruments. Periodic checks consist mainly of the following items:
1) Power supply input measurement, 2) Low-frequency leak current measurement,
3) Dielectric strength, 4) LED illuminance and output, 5) Protective earthing

Request to customers

A. Disinfection and sterilization of medical devices

Before and after you request that we repair your medical device, disinfect and sterilize it. This is to prevent infection of maintenance/repair personnel and patients.

B. Disposal of this device

Recycle where possible or return it to MIZUHO. When disposing of this device, follow the instructions given by the local government and dispose of it legally.

C. Repair

Due to the nature of this device, the performance of this device deteriorates after prolonged use or storage. While this device is in use or storage, deterioration develops but is hard to detect by inspection. Therefore, even after an identified failure is repaired, another failure may occur in a short time. In such a case, a major overhaul is needed, resulting in high repair costs. Please note that it may cost less to purchase a new one. MIZUHO will pay utmost attention to prevent such a situation.

D. When requesting the repair of this device or to perform periodic check

When this product needs repair, contact the retailer you purchased from or MIZUHO and explain what problem occurred and under what circumstances it occurred. When having this device repaired, attach the standard components to this product.

4. Troubleshooting

Symptom	Cause	Remedy
Unable to turn on device	The provided detachable power supply cord or AC adapter was not used for this device. They are not connected properly.	Use the provided cord and adapter and connect them properly.
	The power supply cord is not the right type.	Use the right type of power supply cord for your country.
AE button or WB button alternately flashes green and orange	The camera cable was connected after the power was turned on or the cable was not connected properly.	Turn off the power and connect each device properly. Then, turn on the power again.
	This device was used at a temperature above or below the specified range, causing the camera to get hot.	Turn off the power and wait until the camera gets cools off. Use this device within the specified temperature range.
	Other cause: An error, such as a communication error, occurred.	If the lamp alternately flashes green and orange even with all the devices connected properly, this device needs repair.
No video displayed on monitor	The cable is disconnected.	Check that the monitor is connected properly.
	The monitor was not turned on.	Turn on the monitor.
	The wrong mode was selected for the monitor.	Select the right mode for the monitor.
	The specifications of the monitor do not fit those of this device.	Use a monitor suitable for use with this device.
	The video cable is broken.	Use another video cable.
	The camera is faulty or the camera connection cable is broken.	Replace or repair the cable.
Unable to display color videos	Monochrome mode is selected.	Press the MONOCHROME button. (Make sure the lamp is lit green.)
	The monitor is in an environment containing near-infrared light, causing the video to look monochrome.	Turn off the light near the monitor. Use the light of this device (white light) or other light sources that do not contain infrared light.
Monitor turns white	This device is used in the environment containing much infrared light (sunlight/shadowless light).	Stop using this device in an environment containing much infrared light or block the infrared light.
Camera is out of focus	The distance between the camera and observation object is outside of the specified range. The distance is too short or too long.	Adjust the distance between the camera and observation object so that it is within the specified range and adjust the focus of the camera using the focus ring.

Symptom	Cause	Remedy
Sub-controller does not work	The connection cable of the sub-controller is not connected.	Properly connect the connection cable of the sub-controller to the controller.
	The sub-controller cable is broken.	Repair is needed.
Observation videos are not saved to SDHC card	Write error or failure due to a faulty SDHC card or a deviation from the recommended specifications	Replace the SDHC card. Use a card with the recommended specifications.
	The SDHC card was not formatted.	Be sure to format the SDHC card to the FAT32 file system before use. (Do not use quick format.)
Data recorded in SDHC card cannot be played back on monitor connected to this device	The monitor is connected to the DVI 1 terminal or BNC 1 terminal of the controller unit with a connection cable.	Properly connect the monitor to the DVI 2 terminal or BNC 2 terminal. (Playback is only available with the DVI 2 terminal or BNC 2 terminal.)
	A file other than the file you want to play back is being played back.	Pressing the PLAY button plays back the latest file. To select a file, press the SELECT button and select it on the OSD.
Corrupt data/unable to record videos	The SDHC card does not have enough space available on it, or the SDHC card is faulty.	Be sure to format the SDHC card to the FAT32 file system before use. (Do not use quick format.) Use an SDHC card suitable for use with this device. Perform an operation check before use.
	The SDHC card has a logical failure. (There is a problem with the electromagnetic record in the card.)	MIZUHO cannot offer support for this problem because the failure is in the SDHC card itself. Use a new SDHC card.
Unable to stop recording	The SDHC card does not have enough space available, or the SDHC card is faulty.	Use a Class 10 SDHC card. Format it before use. If the symptom persists, the SDHC card is faulty or does not have enough storage space available. Use another SDHC card.
Screen froze	The screen froze due to strong external noise.	Restart this device. Keep this device away from external noise so that it is not affected by electromagnetic interference.
	The video cable was damaged.	Check the video cable for damage. Use another video cable.
	This device was damaged by an unexpected problem, such as contact failure or external noise.	Turn off the power, check the setting of the device, and then restart the device. If the symptom persists after external noise or electromagnetic interference has been eliminated, repair or further checks are needed.

Symptom	Cause	Remedy
Monitor flickering	The camera unit is not secured firmly.	Check for a loose screw. Use this device on a stable surface.
	Flickering	Check if the appropriate is set (50 Hz or 60 Hz). (This can be set by using the 50/60-Hz switch on the back of the controller.)
	The screen froze due to strong external noise.	Restart the device. Keep this device away from external noise so that it is not affected by electromagnetic interference.
LED Light (near-infrared light) is flashing	IR ON/OFF button is pressed and held for 2 seconds.	To exit the flashing mode, press IR ON/OFF button again.
Unable to play back videos with video playback software.	The video was recorded with file system inconsistency or with a damaged sector (physical recording unit). The header and footer information was lost, resulting in inconsistency with the actual data.	Because the SDHC card has an internal failure, MIZUHO cannot offer support for this problem. Use a new SDHC card.

If the problem persists after the above remedies, or a problem other than the above occurs, stop using this device and take appropriate action. Then, request the retailer you purchased from or MIZUHO's sales staff to repair this device.

【MEMO】

VI Technical information

1. Specifications

Model	MNIRC-501
Product code	08-704-00
Safety requirement	IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EMC	IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests CISPR 11, group 1, class A
Ambient temperature	Operation: 10 ºC to 35 ºC storage and transport: 0 ºC to 50 ºC No freezing or condensation allowed.
Relative humidity	Operation: 30 % to 75 % storage and transport: 10 % to 80 % No freezing or condensation allowed.
Atmosphere pressure	Operation, storage, and transport: 700 hPa to 1060 hPa
Power input	100 V~ to 240 V~, 50 Hz to 60 Hz, 1.35 A to 0.53 A (Use a power supply cord suitable for use in your country.)
AC adapter	Sinpro Electronics Co., Ltd. Model : MPU51-201 Input : 100 V~ to 240 V~, 50 Hz to 60 Hz, 1.35 A to 0.53 A Output : output 1 5 V⎓, 5 A output 2 12 V⎓, 2 A max. output power 42 W Standards : ANSI/AAMI ES 60601-1: 2005 (UL/cUL 3rd Edition) EN 60601-1:2006 (TUV/T-mark 3rd Edition) Safety approvals : PSE, cURus, CE
Protection against electric shock	Class I
Image sensor	330 000 effective pixels
Recordable wavelength range	420 nm to 640 nm, 840 to 900 nm
Distance from the object	100 mm to 300 mm

LIGHT ON/OFF	Turns the white light on and off (When the distance from the object is 250 mm: Max. 1500 lx or so)
IR ON/OFF	Turns IR (peak emitted light wavelength: 730 nm) on and off.
IRIS	Manually adjusts the brightness of the observation video in combination with the UP and DOWN switches.
CONT	Finely adjusts the edge enhancement.
MONOCHROME	Switches to monochrome mode (turns on the visible light cut filter).
AE	Turns on and off the AE function.
WB	Switches the white balance between HOLD and AUTO.
Recording function	SDHC card slot × 1 Videos can be recorded onto SDHC cards (Class 10).
Video output terminal/video output	BNC terminal × 2 : Interlace, analog NTSC DVI-I terminal × 2 : Progressive, digital RGB
Compatible monitors	IEC 60601-1-compliant product Input terminal: DVI-I terminal or BNC (NTSC) terminal Input signal: DVI-compliant product, NTSC signal
LED modules (LED light)	IEC 62471:2006, risk group 2 Possibly hazardous optical radiation emitted from this product. Do not stare at operating lamps. May be harmful to the eyes.
External dimensions (excluding protrusions, etc.) and weight	Camera unit :Approx. 100 mm (diameter) × 185 mm (depth) Approx. 0.6 kg Controller unit :Approx. 300 mm (width) × 360 mm (depth) 100 mm (height) Approx. 5.4 kg AC adapter :Approx. 76 mm (width) × 146 mm (depth) 45 mm (height) Approx. 0.6 kg
Expected service life	The service life is 6 years when this device is maintained as designated by MIZUHO. [Self-certification] * Inspection or repair is needed before the end of the service life if a sudden failure occurs or a component wears down significantly or is damaged depending on how this device is used.

2. Electromagnetic compatibility

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this guide.

⚠ [WARNING]

- ⊙ Use accessories and relevant products designated by MIZUHO.
- ⊙ When the equipment is used in combination with equipment that generates high-frequency radiation with high voltage and power, such as an electrosurgical unit, make sure the equipment will not malfunction or be damaged by electromagnetic interference by referring to the package insert and instruction manual of the equipment that generates high-frequency radiation.
- ⊙ The MNIRC-501 should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the MNIRC-501 should be observed to verify normal operation in the configuration in which it will be used.
- ⊙ The portable and mobile RF communications equipment can affect medical electrical equipment.

A. Cables and accessories

The following cable(s) and accessory(ies) were used for the test.

code No.	Name	Shield	Notes
-	Power Cord	No	Mains to AC adapter
08-704-12	AC Adaptor	NA	Model : MPU51-201 For medical use Switch mode input: 100 V~ to 240 V~, 50 Hz to 60 Hz, 1.35 A to 0.53 A output 1: 5 V⎓, 5 A output 2: 12 V⎓, 2 A max output power: 42 W
-	BNC cable	Yes	4.8 m, 75 Ω
-	DVI cable	Yes	5 m
-	19 inch monitor	NA	Power supply cord : 125 V, 7 A, 2 m, PSE DVI cable: 1.5m Safety requirement : IEC 60601-1 :2005

B. Guidance and manufacturer's declaration - Electromagnetic emissions -

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration - Electromagnetic emissions</th></tr>
<tr><td colspan="3">The MNIRC-501 is intended for use in the electromagnetic environment specified below. The customer or the user of the MNIRC-501 should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The MNIRC-501 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The MNIRC-501 is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:

Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the MNIRC-501 or shielding the location.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

C. Guidance and manufacturer's declaration - Electromagnetic immunity -

Guidance and manufacturer's declaration - Electromagnetic immunity			
The MNIRC-501 is intended for use in the electromagnetic environment specified below. The customer or the user of the MNIRC-501 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV 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 IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input / output lines	±2 kV for power supply lines ±1 kV for input / output lines	Mains power quality should be that of hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (>95 % dip in U_T) for 0.5 cycles	< 5 % U_T (>95 % dip in U_T) for 0.5 cycles	Mains power quality should be that of hospital environment. If the user of the MNIRC-501 requires continued operation during power mains interruptions, it is recommended that the MNIRC-501 is powered from an uninterruptible power supply.
	40 % U_T (60 % dip in U_T) for 5 cycles	40 % U_T (60 % dip in U_T) for 5 cycles	
	70 % U_T (30 % dip in U_T) for 25 cycles	70 % U_T (30 % dip in U_T) for 25 cycles	
	< 5 % U_T (>95 % dip in U_T) for 5 s	< 5 % U_T (>95 % dip in U_T) for 5 s	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fileds should be at levels characteristic of hospital environment.
Note U_T is the a.c. mains voltage prior to application of the test level			

D. Guidance and manufacturer's declaration - Electromagnetic immunity -
For ME equipment that is not life-supporting

<table>
<tr><td colspan="4">Guidance and manufacturer's declaration - Electromagnetic immunity</td></tr>
<tr><td colspan="4">The MNIRC-501 is intended for use in the electromagnetic environment specified below. The customer or the user of the MNIRC-501 should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601
test level</td><td>Compliance
level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 V rms

150 kHz to
80 MHz</td><td>3 V</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the MNIRC-501, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = \left[\frac{3.5}{3}\right]\sqrt{P}$
$d = \left[\frac{3.5}{3}\right]\sqrt{P}$ 80 MHz to 800 MHz
$d = \left[\frac{7}{3}\right]\sqrt{P}$ 800 MHz 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 meters (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:  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m

80 MHz to
2.5 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">Note1 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.</td></tr>
</table>

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 MNIRC-501 is used exceeds the applicable RF compliance level above, the MNIRC-501 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MNIRC-501.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

E. Recommended separation distances between portable and mobile RF communications equipment and the ME equipment -
For ME equipment that is not life-supporting

Recommended separation distances between portable and mobile RF communications equipment and the MNIRC-501.

The MNIRC-501 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MNIRC-501 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MNIRC-501 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 $d=\left[\frac{3.5}{3}\right]\sqrt{P}$	80 MHz to 800 MHz $d=\left[\frac{3.5}{3}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d=\left[\frac{7}{3}\right]\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.2	1.2	2.4
10	3.7	3.7	7.4
100	12	12	24

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (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.

Note1 At 80 MHz and 800 MHz, the separation distance for 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.

3. Abbreviations and Acronyms

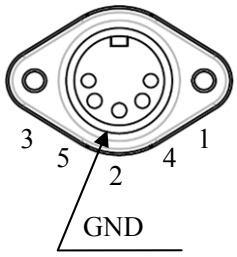
Acronym or Abbreviations	Definition
AE	Automatic exposure
Bps	Bits per second
CONT	Contrast
EMC	Electromagnetic compatibility
ESD	Electro Static Discharge
FF	Fast forward
FR	Fast rewind
I/O	Input/Output
IR	Infrared
LED	Light emitting diode
Qty	Quantity
REC	Record/Recorder
UHS	Ultra high speed
WB	White balance
WEEE	Waste electrical and electronic equipment

4. Equipment Symbols

Symbol	Meaning	reference
	General warning sign	ISO 7010-W001
	ON (power)	IEC 60417-5007
	OFF (power)	IEC 60417-5008
	Direct current	IEC 60417-5031
	Alternating current	IEC 60417-5032
	Refer to instruction manual/ booklet	ISO 7010-M002
	Date of manufacture	ISO 7000-2497
	Manufacturer	ISO 7000-3082
	Recycle where possible or return to MIZUHO.	WEEE
LOT	Manufacturer's lot code	ISO 7000-2492
REF	Manufacturer's catalog number (code)	ISO 7000-2493
SN	Manufacturer's serial number	ISO 7000-2498
EC REP	Authorized European (EC) Representative (name, address)	-

5. Pin assignment

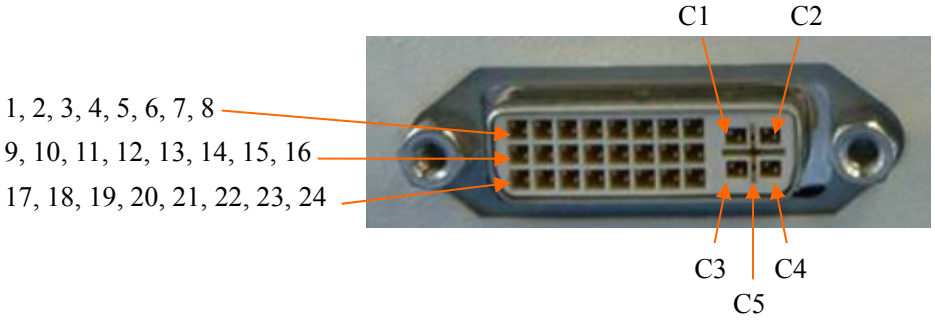
A. DC IN



No.	Signal Assignment
3	+5 V⎓ 5 A
5	+12 V⎓ 2 A
1, 2, 4	COMMON
SHELL	GND

DC IN connector (rear panel of controller unit)

B. DVI



DVI-I out-put connector (rear panel of controller unit)

No.	Signal Assignment	No.	Signal Assignment
1	T.M.D.S. Data 2-	16	Hot Plug Detect
2	T.M.D.S. Data 2+	17	T.M.D.S. Data 0-
3	T.M.D.S. Data 2/4 Shield	18	T.M.D.S. Data 0+
4	T.M.D.S. Data 4-	19	T.M.D.S. Data 0/5 Shield
5	T.M.D.S. Data 4+	20	T.M.D.S. Data 5-
6	DDC Clock	21	T.M.D.S. Data 5+
7	DDC Data	22	T.M.D.S. Clock Shield
8	Analog Vertical Sync	23	T.M.D.S. Clock+
9	T.M.D.S. Data 1-	24	T.M.D.S. Clock-
10	T.M.D.S. Data 1+	C1	Analog Red
11	T.M.D.S. Data 1/3 Shield	C2	Analog Green
12	T.M.D.S. Data 3-	C3	Analog Blue
13	T.M.D.S. Data 3+	C4	Analog Horizontal Sync
14	+5 V Power	C5	Analog Ground (analog R, G, & B return)
15	Ground (return for +5 V, HSync, and Vsync)		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