NOTE

The folders and the data associated with the selected examination (image data, case data, and exported images) will be removed during the deletion process.

3. Click the [OK] button on the examination data deletion screen (see Figure 6.93). The selected examination data will be deleted. A progress screen is displayed while the examination data is being deleted.

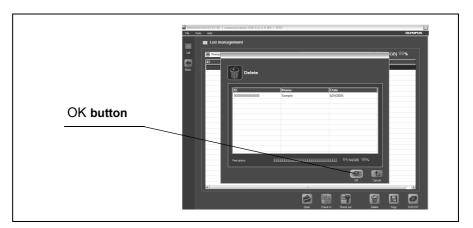


Figure 6.93

4. When the deletion of examination data is complete, you will be returned to the examination list screen.

Writing examination and thumbnail data onto a DVD

 Select the examination data you wish to write onto a DVD and click the [DVD] button on the examination list screen (see Figure 6.94). The DVD writing screen is displayed.

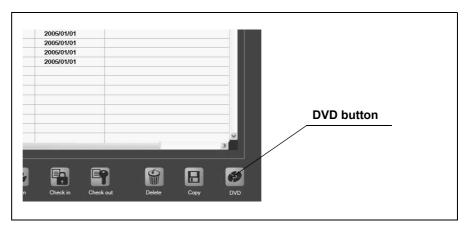


Figure 6.94

NOTE

You can select multiple examination data simultaneously. The thumbnail data associated with the selected examination data will be written automatically.

2. Use the drive selection box to select the destination drive to write the data to (see Figure 6.95). The amount of available disk space on the selected drive is displayed.

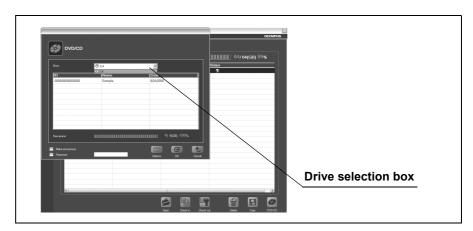


Figure 6.95

NOTE

 The folder for the examination data will be created automatically during the writing process. The following DVD formats are supported:

DVD : DVD-R, DVD+R

- Though you use DVD-RW or DVD+RV, you cannot rewrite or delete data.
- While it is possible to copy the data to an USB HDD, the safety of data on the USB HDD cannot be assured, so it is advised that the user first back up the examination data to a DVD.
- 3. The selected examination data which you wish to write is displayed (see Figure 6.96).

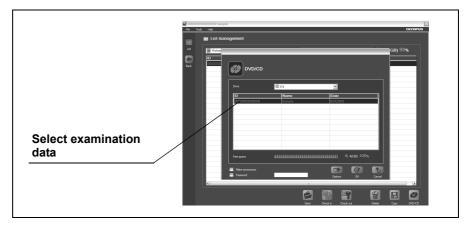


Figure 6.96

4. Click the [Option] button to display the DVD writing options screen (see Figure 6.97).

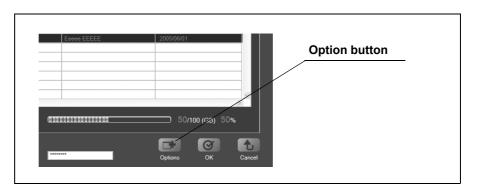


Figure 6.97

5. Select the type of files to be written together with the examination data. Click the [Picture] button to write still images, and the [Movie] button to write video files (see Figure 6.98).

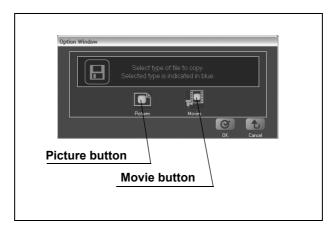


Figure 6.98

NOTE

All items are selected by default.

6. Click the [OK] button to save the settings and exit the DVD writing options screen (see Figure 6.99).

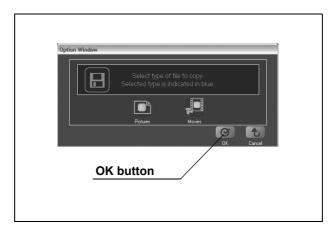


Figure 6.99

7. Check the "Password" checkbox to set a password (see Figure 6.100).

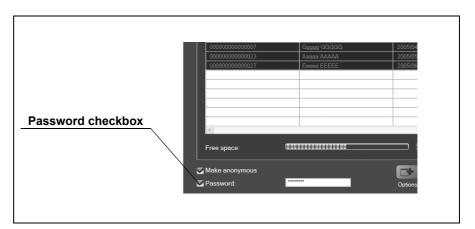


Figure 6.100

NOTE

If you specify a password when writing the examination data, you will be required to enter the password to open the written examination data.

8. Check the "Make anonymous" checkbox to write the examination data with the individual information removed (see Figure 6.101).



Figure 6.101

- Individual information removed include "Patient name" and "Image showing individual information".
- To remove "Image showing individual information", you will need to set the hiding feature. For more information, refer to "Hiding images" on page 216.

9. Click the [OK] button on the DVD writing screen (see Figure 6.102). The selected examination data will be written. The progress screen is displayed while the examination data is being written.

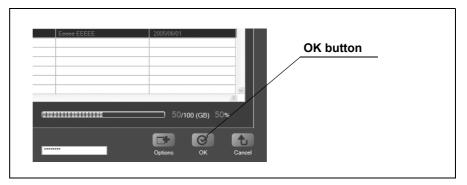


Figure 6.102

NOTE

- To stop the writing process, click the [Cancel] button on the progress screen.
- If there is insufficient storage space on the writing destination, an error message will be displayed. In that case, refer to Chapter 8, "Troubleshooting" on page 233.
- The DVD drive will open after writing the data and close automatically to verify the written data. Please wait until the verification is completed.
- 10. When writing of examination data is complete, the examination list screen will be displayed.

CAUTION

Finalize the report before you write the report onto the DVD.

Hiding images

You can specify images that contain the facial portrait of a patient to be hidden when copying or exporting examination data.

CAUTION

To hide images, the "Make anonymous" checkbox must be checked when copying or writing the examination data.

NOTE

- Specify the first image and the last image of the display range. Images between the first and last images will be included, and all other images will be excluded (hidden).
- By default, the first and last images of each examination are used as the first and last images of the display range.
- 1. On the main screen, open the examination data which contains the images to be hidden ("Opening examination data and thumbnail data from the examination list screen" on page 148).
- 2. Display your desired first image in the image display area (6.3 "Image observation" on page 155).
- **3.** Right-click on the image and select "First" from "Display range" in the context menu (see Figure 6.103).

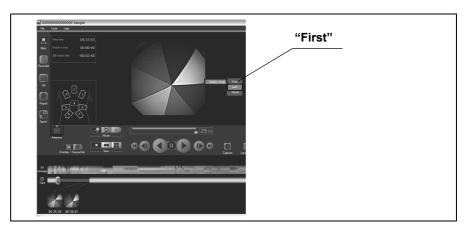


Figure 6.103

4. Display your desired last image in the image display area (6.3 "Image observation" on page 155).

5. Right-click on the image and select "Last" from "Display range" in the context menu (see Figure 6.104).

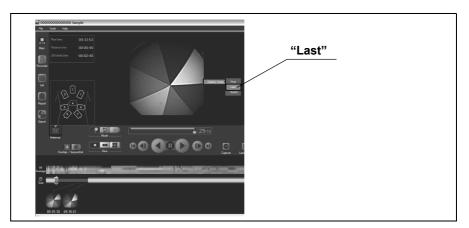


Figure 6.104

6. To reset the display range, right-click on an image and select "Reset" from "Display range" in the context menu (see Figure 6.105).

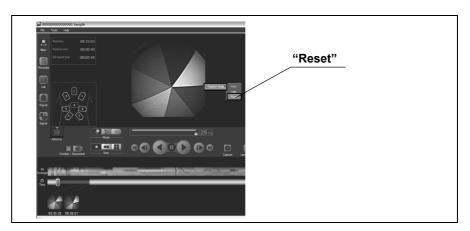


Figure 6.105

6.6 Exporting image data

You can export image data as still images or videos. Export settings can be configured on the export screen.

Export screen

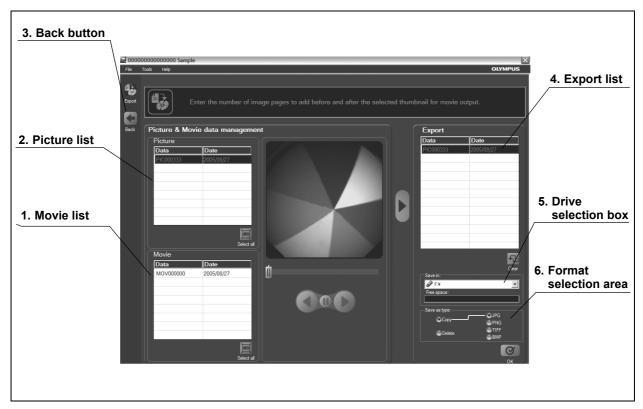


Figure 6.106

1. Movie list

Displays the list of movie files to be created.

2. Picture list

Displays the list of picture files to be created.

3. Back button

Returns to the main screen.

4. Export list

Displays the list of movie files and picture files to be exported.

5. Drive selection box

Selects the drive to which the movie files and picture files are exported.

6. Format selection area

Selects the picture format used for exporting the picture files.

Movie type

Movie

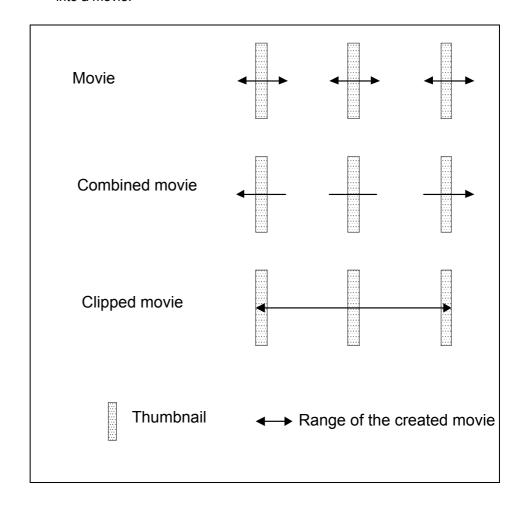
The images before and after the selected thumbnail change into a movie. The number of images is defined in the movie settings.

Combined movie

The movies created for each thumbnail are combined. The number of images is defined in the movie settings.

Clipped movie

The images between the first and last of the selected thumbnails change into a movie.



Movie settings

The number of images used to form a movie is set on the movie settings screen.

- 1. Select "Settings" from the "Tools" menu on the main screen.
- 2. Click the "Clips" tab. The movie settings screen is displayed (see Figure 6.107).

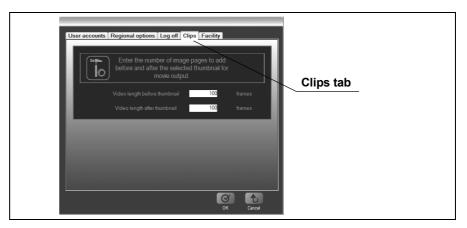


Figure 6.107

3. Set the number of images to be added before and after the selected thumbnail (see Figure 6.108).



Figure 6.108

NOTE

You can specify a number between 1 and 999.

4. Click the [OK] button on the movie settings screen.

Creating pictures / movies / combined movies / clipped movies

NOTE

The created pictures and movies are stored on the workstation. To export a picture or movie file, refer to "Exporting picture / movie files" on page 225.

- 1. On the main screen, open the examination data (see "Opening thumbnail data from the menu" on page 152).
- 2. Create thumbnails you wish to include in your export (see "Creating thumbnails" on page 163).
- **3.** Select the thumbnails you wish to include in your export (see Figure 6.109).

NOTE

To select multiple thumbnails, click the thumbnails while holding down the [Shift] key on the keyboard.



Figure 6.109

4. To create pictures, right-click on one of the selected thumbnails and select "Export" and then "Picture" from the context menu (see Figure 6.110).

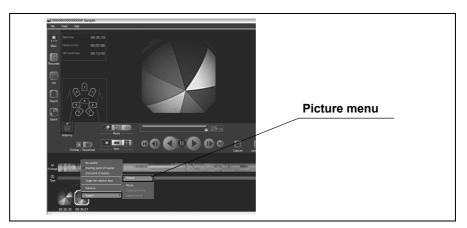


Figure 6.110

NOTE

The exported file name is determined automatically. The data is exported to the D drive as generic image files.

5. To create movies, right-click on one of the selected thumbnails and select "Movie" from the context menu (see Figure 6.111).

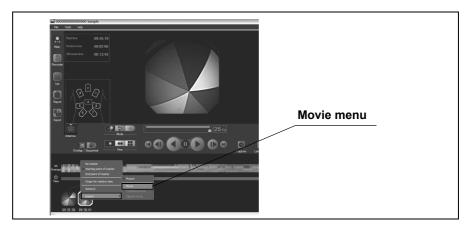


Figure 6.111

- The exported file name is determined automatically.
- · The file is exported in AVI format.

6. To create a combined movie, right-click on one of the selected thumbnails and select "Combined movie" from the context menu (see Figure 6.112).

NOTE

The images for the selected thumbnails are combined into a movie.

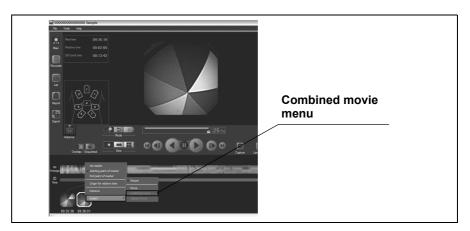


Figure 6.112

- The "Combined movie" context menu item can be selected only when multiple thumbnails have been selected.
- The exported file name is determined automatically. The data is exported as generic image files.
- · The file is exported in AVI format.
- If the number of images that form the combined video exceeds 10000, the video will be divided into multiple files.

7. To create a clipped movie, right-click on one of the selected thumbnails and select "Clipped movie" from the context menu (see Figure 6.113).

NOTE

All images between the first and the last selected thumbnails are combined into a movie.

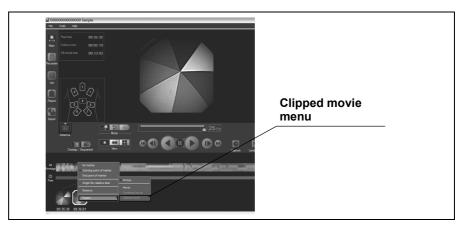


Figure 6.113

- The "Combined movie" context menu item can be selected only when multiple thumbnails have been selected.
- · The export file name is determined automatically.
- The file is exported in AVI format.
- If the number of images that form the combined video exceeds 10000, the video will be divided into multiple files.

Exporting picture / movie files

1. Click the [Export] button on the main screen (see Figure 6.114). The export screen is displayed.

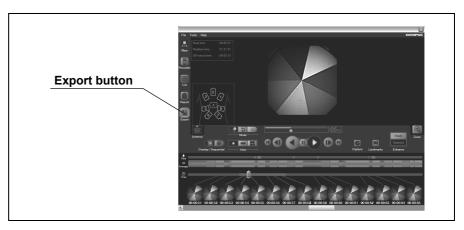


Figure 6.114

2. Use the drive selection box to select the destination drive for the export (see Figure 6.115). The amount of available disk space on the selected drive is displayed.



Figure 6.115

3. Select the picture and/or movie files you wish to export (see Figure 6.116).

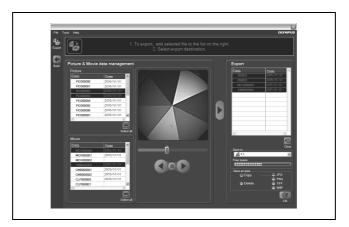


Figure 6.116

4. Click the [▶] button to add the picture and/or movie files you wish to export to the export list from the picture list or the movie list (see Figure 6.117).

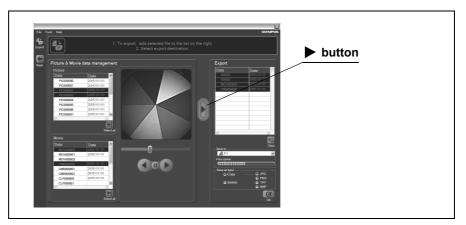


Figure 6.117

NOTE

To clear a picture or movie file from the export list select the file you wish to clear and click the [Clear] button.

5. Select "Copy" or "Delete".

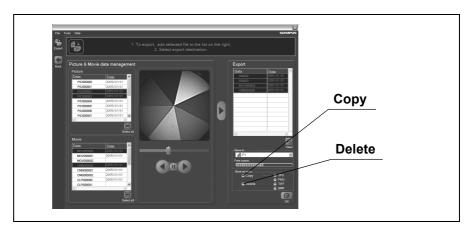


Figure 6.118

- **6.** You can copy the picture files in one of the following four formats (see Figure 6.119).
 - BMP (bitmap)
 - JPEG
 - TIFF
 - PNG

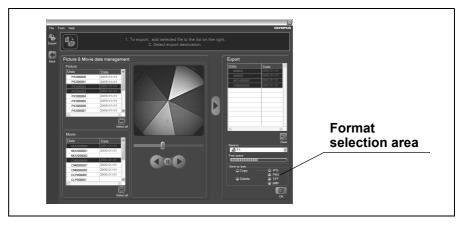


Figure 6.119

 Click the [OK] button on the export screen (see Figure 6.120). The selected files will be exported. The progress screen is displayed while the files are being exported.

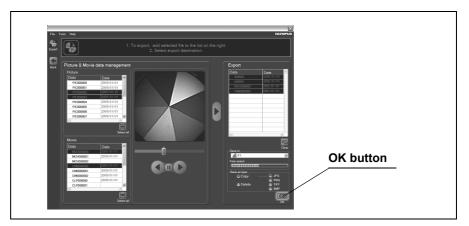


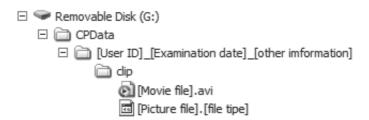
Figure 6.120

NOTE

- To stop the export process, click the [Cancel] button on the progress screen.
- If there is insufficient storage space on the export destination, an error message will be displayed. In this case, refer to Chapter 8, "Troubleshooting" on page 233.
- **8.** When exporting is complete, you will be returned to the export screen.

NOTE

The picture or movie files is exported to the following location.



(*) Words in parentheses vary according to the exported data.

6.7 Browsing the image observation operation history

Operation history for the image observation is automatically recorded.

1. From the "Tools" menu on the main screen, select "Diagnosis log" and then "View" (see Figure 6.121). The diagnosis log screen is displayed.

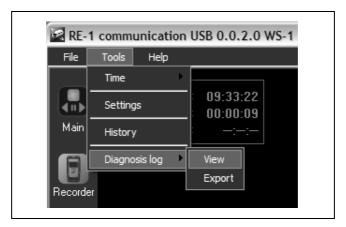


Figure 6.121

- Date, time, and user name for each operation are recorded in the log.
- To export a diagnosis log, select "Diagnosis log" and then "Export" from the "Tools" menu on the main screen.
- The log can be exported in text format.

Chapter 7 Care Storage and Disposal

7.1 Care

WARNING

- · After wiping with a place of moistened gauze, dry the capsule endoscope system thoroughly before using it again. If it is used while still wet, there is the risk of electrical shock.
- When cleaning the capsule endoscope system, always wear appropriate personal protection equipment. Blood, mucous and other potentially infectious material adhering the video system center could pose and infection control risk.

CAUTION

- Do not soak the system components in water, or sterilize them using autoclave or gas. Doing so will damage the system.
- Do not wipe the external surfaces with hard or abrasive wiping material. Doing so will scratch the surface.

After using the system, immediately perform the following cleaning procedure.

- 1. Remove dust, dirt, and other stains on the surface of the antenna pads and the antenna lead set using a piece of gauze moistened with a neutral detergent, then wipe the surfaces using a piece of gauze moistened with 70% ethyl or isopropyl alcohol.
- 2. Remove dust, dirt, and other stains on the surface of the following equipment using a piece of gauze moistened with a neutral detergent, then wipe the surfaces using a piece of gauze moistened with 70% ethyl or isopropyl alcohol. After doing so, dry them thoroughly.
 - Recorder unit
- Recorder unit cradle
- Real time viewer

- Real time viewer cable Recorder unit cradle cable Battery charger
- Recorder unit harness
 Capsule activator

NOTE

Do not soak the equipment in any liquid. It may damage the equipment.

3. If the recorder unit harness has become stained, first clean off the stain using a piece of gauze moistened with a neutral detergent, then wipe off with a piece of cloth moistened with water. Alternatively, the recorder unit harness can be machine-washed.

CAUTION

Do not iron or dry clean the recorder unit harness to shrink slightly.

NOTE

Note that machine-washing may cause the recorder unit harness to shrink slightly.

4. If the recorder unit harness becomes wet, be sure to dry it completely.

7.2 Storage

CAUTION

- Store the unused capsule endoscopes in a dark place, at temperature from 0°C/32°F to 25°C/77°F. Avoid storing the capsule endoscopes in a refrigerator or a freezer, as it may cause condensation.
- Keep water and any other liquid away from the system components. It may cause equipment damage.
- Do not store the system in a location exposed to direct sunlight, UV rays, X-rays, radio activity, or strong electromagnetic radiation (e.g. near microwave therapy equipment, shortwave therapy equipment, MRI equipment, radio, or mobile phones). They may damage the system.
- Do not store the system in a location affected by high temperature, high humidity, barometric pressure, dust, salt or ozone. They may damage the system.
- Store the system in a location immune to vibrations and impacts. They may damage the system.

After cleaning the equipment according to the procedure given in Section 7.1, "Care", be sure to dry it off thoroughly. When the equipment is dry, place them into their designated positions in the carrying cases for storage.

Store the carrying cases in a clean and dry location.

For details of the storage environment, refer to "Operating/storage environment" on page 240 in the Appendix.

7.3 Disposal

- When disposing of any item, follow all applicable national and local laws and guidelines.
- The capsule endoscope is discharged naturally.

Chapter 8 Troubleshooting

If, during the inspections described in Chapter 5, "Capsule Endoscope Procedures" on page 96, the system or any of its components appears to have problems, refer to 8.1 "Troubleshooting" on page 233 to correct the problem. If the problem persists, stop using the system, and refer to 8.2 "Returning the system for repair" on page 239 to correct the situation. If the problem cannot be resolved by these countermeasures, contact Olympus.

WARNING

Never use the system if any abnormality is suspected. Damage to or irregularity in the system not only causes malfunctioning, but may also cause injury to the patient's body cavity.

8.1 Troubleshooting

The following table lists the possible causes of and countermeasures for troubles that may occur due to equipment setting errors or deterioration of consumables. Also refer to "Recorder unit error messages" on page 235 and "Real time viewer error messages" on page 236 on pages 235 to 236.

Troubles or failures other than those listed in the following table require repair. As repair performed by persons who are not qualified by Olympus could cause patient or user injury and/or equipment damage, be sure to contact Olympus for repair (refer to Section 8.2).

Irregularity	Possible Cause	Solution
Capsule endoscope's LED	The power is not turned ON.	Use the capsule activator to turn the power ON.
fails to illuminate.	The capsule endoscope is broken.	Use a new capsule endoscope.
Recorder unit's	The battery pack is missing.	Insert a charged battery pack.
power fails to come ON.	The battery pack is low.	Recharge the battery pack.
Recorder unit's power lamp fails to illuminate.	The recorder unit is broken.	Try turning on the recorder unit power again. If problem persists, contact Olympus.
Real time viewer's	The battery pack is missing.	Insert a charged battery pack.
power fails to come ON.	The battery pack is low.	Recharge the battery pack.

Irregularity	Possible Cause	Solution
The real time viewer's power lamp fails to illuminate.	The real time viewer is broken.	Try turning on the viewer power again. If the problem persists, contact Olympus.
Images from the capsule endoscope are not displayed by the	The real time viewer is broken. The capsule endoscope is broken.	Contact Olympus. Use a new capsule endoscope.
real time viewer. (When using the real time viewer alone.)	The real time viewer is too far from the capsule endoscope.	Reduce the distance between the real time viewer and the capsule endoscope.
Images from the capsule	The antenna lead set cable is broken.	Contact Olympus.
endoscope are not displayed by the	The real time viewer cable is not connected.	Connect the real time viewer cable properly.
real time viewer. (When connected to the recorder	The antenna lead set is not connected to the recorder unit.	Connect the antenna lead set to the recorder unit properly.
unit.)	The antenna lead set is too far from the capsule endoscope.	Reduce the distance between the antenna and the capsule endoscope.
The recorder unit fails to turn OFF.	The power switch is not held down long enough.	Hold down the power switch for 2 seconds or more.
The battery charger's charge lamp blinks in yellow. (1.5 second intervals)	The battery pack cannot be recharged because its temperature is below 0°C (32°F).	Charge the battery at or above 0°C (32°F).
The battery charger's charge lamp blinks in yellow. (0.5 second intervals)	The battery pack or the battery charger is broken.	Use another battery pack or battery charger.

Recorder unit error messages

Error code on Recorder Unit's Display Panel	Possible Cause	Solution
↑ ERROR	System error	 Restart the system. If the error persists, contact Olympus.
⚠ ERROR	RTC error	Connect the recorder unit to the workstation, and perform initialization. If error persists after initialization, contact Olympus.
⚠ ERROR	Internal memory error	Contact Olympus.
€ ERROR	Battery pack error	Replace with a new battery pack.
⚠ NO DISK SPACE	Internal memory full	Connect the recorder unit to the workstation, and download the data from the Recorder Unit.
⚠ LOW BATTERY	Uncharged battery pack	Recharge the battery pack, or replace it with a charged battery pack.
M INITIALIZE	Patient Information not registered	Connect the recorder unit to the workstation, and perform initialization.
CHARGE BATTERY	Low battery pack	Recharge the battery pack, or replace it with a charged battery pack.
⚠ DOWNLOAD DATA	Less than 8 hours of storage space left in internal memory	Connect the recorder unit to the workstation, and download the data from the Recorder Unit.

Error code on Recorder Unit's Display Panel	Possible Cause	Solution
⚠ CHANGE BATTERY	Time to replace battery pack.*	Order a new battery pack from Oympus, and replace it. If you continue to use the battery pack for a prolonged period with these warning icons are displayed, the
		low battery pack icon (
⚠ Antenna	Antenna lead set disconnected	Connect the antenna lead set to the recorder unit.

* The life span of a battery pack is approximately 1 year from the date of purchase, or 320 recharging cycles, whichever is first. When the battery pack approaches its end-of-life, the recorder unit will prompt for replacement. Order a new battery pack and replace.

Real time viewer error messages

Error Code on Real Time Viewer's Display Panel	Possible Cause	Solution
	Uncharged battery pack	Recharge the battery pack, or replace it with a charged battery pack.
↑ ERROR E000	System error	 Restart the system. If the error persists, contact Olympus.

Workstation error messages

Message	Solutions
System error occurred. (E***) Contact service center.	Contact Olympus.
System is unstable. Shutdown and restart workstation.	Shut down and restart workstation.
User ID and/or password is incorrect. Enter correct user ID/password (case sensitive).	Enter correct user ID/password (case sensitive) with the right uppercase/lowercase combination.
Invalid value entered in date and/or time.	Enter correct value.

Message	Solutions
Possible recorder failure.	Contact Olympus.
Error occurred during communication with recorder.	Check connection between workstation and recorder
Invalid value entered in date of birth.	Enter correct value.
Invalid value entered in height.	Enter correct value.
Invalid value entered in weight.	Enter correct value.
Invalid value entered in waist size.	Enter correct value.
Possible recorder failure. If initialization fails, send recorder for repair.	Try again. Contact Olympus if the initialization fails again.
Cannot download because there is not enough disk space available.	Back up examination data to the workstation to free up space for download.
Low disk space on workstation for saving download data.	Back up examination data from the workstation to free up space for download.
If the recorder can not be recognized, turn off the recorder and remove it from the cradle. Then, connect the recorder to the cradle again.	Connect the recorder to the cradle again.
Unusable file.	Contact Olympus.
Cannot open file because password is incorrect.	Enter correct password.
Cannot open thumbnail data because examination data and thumbnail data are for different examinations.	Open the appropriate findings file that matches the examination data.
Cannot check out data because destination does not have sufficient disk space.	Create enough disk space to check out.
Examination data contains multiple capsule IDs. Before starting the observation, check the images before and after the capsule ID change to determine whether to use this examination data in the diagnosis.	Before starting the observation, check the images before and after the capsule ID change to determine whether to use this examination data in the diagnosis.
Cannot check in data because destination does not have sufficient disk space.	Create sufficient disk space to check in.
Cannot copy data because destination does not have sufficient disk space.	Create sufficient disk space to copy data.
Cannot write data because destination does not have sufficient disk space.	Create sufficient disk space to write data.
Cannot import data because workstation does not have sufficient disk space. Create sufficient disk space to import data.	Create sufficient disk space to import data.
Cannot open history because report file does not exist.	Contact Olympus.

Message	Solutions
The old password you typed is incorrect.	Retype the old password.
Please retype the old password.	
This disk is write-protected.	Remove the write protection, or use
Remove the write protection, or use another disk.	another disk.
One of the hard drives is corrupt.	Contact Olympus.
Contact Service Center for repairs.	
The DVD type is not supported.	Use a DVD of the type specified in
	the manual.
Printer power is off.	Turn on the printer.
Cannot display print preview because printer	Install the printer driver.
driver is not installed.	
Invalid data.	Contact Olympus.
The system cannot find the file specified.	Contact Olympus.
The system cannot find the path specified.	Contact Olympus.
The specified module could not be found.	Contact Olympus.
A file name cannot contain any of following	Contact Olympus.
charactors :	
¥/:*?"<>	
The media is write protected.	Remove the write protection or use
	another media.
The process cannot access the file because it is	Contact Olympus.
being used by another process.	
The specified file is read only.	Contact Olympus.
The system cannot open the file.	Contact Olympus.
Access is denied.	Contact Olympus.
The process cannot access the file because	Contact Olympus.
another process has locked a portion of the file.	
The directory or file cannot be created.	Contact Olympus.
The file name is too long.	Shorten the file name and retry.
There is not sufficient disk space in workstation.	Contact Olympus.
The process cannot access the file.	Contact Olympus.

NOTE

In the case that you have lost your password, contact Olympus.

8.2 Returning the system for repair

CAUTION

Olympus is not liable for any injury or damage occurring as a result of repairs attempted by non-Olympus personnel.

Before sending the system for repair, contact Olympus. With the system, include a description of malfunction or damage and the name and telephone number of the individual at your location who is most familiar with the problem.

NOTE

To purchase accessories and consumables, contact Olympus.

Appendix

Operating/storage environment

Capsule endoscope

	Operating Environment	Storage Environment
Ambient temperature	10 to 40°C (50 to 104°F)	0 to 25°C (32 to 77°F) *1
Relative humidity	N/A	30 to 85% *2
Barometric pressure	700 to 1060 hPa	700 to 1060 hPa
	(10.2 to 15.4 psia)	(10.2 to 15.4 psia)

^{*1} Storage outside the storage environment range may cause condensation and/or deterioration of the battery.

Antenna lead set

	Operating Environment	Storage Environment
Ambient temperature	0 to 50°C (32 to 122°F)	-20 to +70°C (-4 to +158°F)
Relative humidity	30 to 90% *	10 to 95% *
Barometric pressure	700 to 1060 hPa	700 to 1060 hPa
	(10.2 to 15.4 psia)	(10.2 to 15.4 psia)

^{*} no condensation

Recorder unit

	Operating Environment	Storage Environment
Ambient temperature	0 to 50°C (32 to 122°F)	–20 to +70°C (–4 to +158°F)
Relative humidity	30 to 90% *	10 to 95% *
Barometric pressure	700 to 1060 hPa	700 to 1060 hPa
	(10.2 to 15.4 psia)	(10.2 to 15.4 psia)

^{*} no condensation

^{*2} no condensation (inside the capsule endoscope)

Real time viewer

	Operating Environment	Storage Environment
Ambient temperature	10 to 40°C (50 to 104°F)	–20 to +50°C (–4 to +122°F)
Relative humidity	30 to 85% *	10 to 95% *
Barometric pressure	700 to 1060 hPa	700 to 1060 hPa
	(10.2 to 15.4 psia)	(10.2 to 15.4 psia)

^{*} no condensation

Recorder unit cradle

	Operating Environment	Storage Environment
Ambient temperature	10 to 40°C (50 to 104°F)	–20 to +70°C (–4 to +158°F)
Relative humidity	30 to 85% *	10 to 95% *
Barometric pressure	700 to 1060 hPa	700 to 1060 hPa
	(10.2 to 15.4 psia)	(10.2 to 15.4 psia)

^{*} no condensation

Battery charger

	Operating Environment	Storage Environment
Ambient temperature	0 to 40°C (32 to 104°F)	-20 to +50°C (-4 to +122°F)
Relative humidity	30 to 85% *	10 to 95% *
Barometric pressure	700 to 1060 hPa	700 to 1060 hPa
	(10.2 to 15.4 psia)	(10.2 to 15.4 psia)

^{*} no condensation

Battery pack

	Operating Environment	Storage Environment
Ambient	0 to 50°C (32 to 122°F)	0 to 50°C
temperature	Recharging: 0 to 40°C (32 to 104°F) Discharging: 0 to +50°C (–4 to +140°F)	(–32 to 122°F) Avoid prolonged storage at temperatures exceeding 40°C/104°F.
Relative humidity	30 to 90% *	10 to 95% *
Barometric pressure	700 to 1060 hPa (10.2 to 15.4 psia)	700 to 1060 hPa (10.2 to 15.4 psia)

^{*} no condensation

Recorder unit harness

	Operating Environment	Storage Environment
Ambient temperature	0 to 50°C (32 to 122°F)	–20 to +70°C (–4 to +158°F)
Relative humidity	30 to 90% *	10 to 95% *
Barometric pressure	700 to 1060 hPa	700 to 1060 hPa
	(10.2 to 15.4 psia)	(10.2 to 15.4 psia)

^{*} no condensation

Antenna lead cover

	Operating Environment	Storage Environment
Ambient temperature	10 to 45°C (50 to 113°F)	Up to 27°C (80.6°F)
Relative humidity	30 to 90% *	40 to 60% *
Barometric pressure	700 to 1060 hPa	700 to 1060 hPa
	(10.2 to 15.4 psia)	(10.2 to 15.4 psia)

^{*} no condensation

Workstation hardware

	Operating Environment	Storage Environment
Ambient temperature	5 to 35°C (41 to 95°F)	-40 to +60°C (-40 to +140°F)
Relative humidity	8 to 85%	8 to 90% *
Barometric pressure	700 to 1060 hPa	700 to 1060 hPa
	(10.2 to 15.4 psia)	(10.2 to 15.4 psia)

Printer

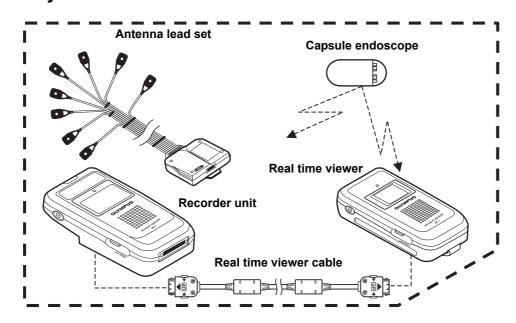
	Operating Environment	Storage Environment
Ambient temperature	15 to 35°C (59 to 95°F)	-40 to +70°C (-40 to +158°F)
Relative humidity	20 to 80%	20 to 80%
Barometric pressure	700 to 1060 hPa	700 to 1060 hPa
	(10.2 to 15.4 psia)	(10.2 to 15.4 psia)

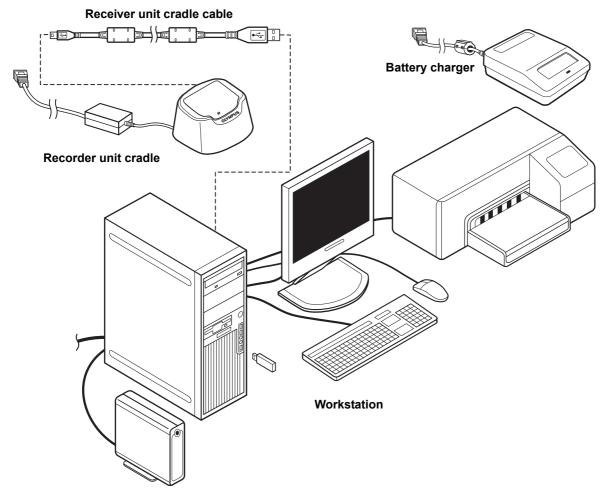
LCD monitor

	Operating Environment	
Ambient temperature	15 to 35°C (59 to 95°F)	
Relative humidity	20 to 80%	
Barometric pressure	700 to 1060 hPa	
	(10.2 to 15.4 psia)	

Specifications

System chart





The system (components within the bold dotted line) is IEC 60601-1 certified in a configuration that includes the capsule endoscope, antenna lead set, recorder unit, real time viewer, and real time viewer cable. The recorder unit cradle, recorder unit cradle cable, battery charger, and workstation are IEC 60950 certified.

WARNING

- In order to provide the intended functionality, the system emits RF energy while in operation. This may affect electrical devices in the vicinity. The patient should keep a distance from such devices.
- Testing has shown only minimal effect on other electrical equipment while the system is operating. However, when inspecting or using the capsule endoscope, do so in a location such as a shielded room, where there is no risk that the system will interfere with the operation of other electrical equipment.
- The system conducts weak radio communication. Images may be lost or distorted when operating in an environment affected by electromagnetic transmissions (such as that of portable RF communication devices). Avoid use in such environments.

Capsule endoscope

Product Name		Capsule endoscope (OLYMPUS EC TYPE 1)
Optics	Field of view (maximum)	145°
	Depth of field	0 to 20 mm
Sampling Rate		2 fps
Power Supply	Power source	Internal battery
	Voltage	DC 2.7 to 3.1V
	Current	1 – 30 mA
Battery Life		8 hours
Size	Weight	3.8 g
	Dimensions	ø 11 mm (diameter) × 26 mm (length)
Classification as Medical Electrical	Type of protection against electric shock	Internal power supply
Equipment	Degree of protection against electric shock	TYPE BF
	Degree of protection against explosion	Use under combustible atmosphere prohibited.
Medical Device Directive	C € 0197	This device complies with the requirements of directive 93/42/EEC concerning medical devices. Classification: Class IIa
		This device complies with the EMC requirements of EN 60601-1-2 when used in combination with devices bearing CE marking either on the products or in its instructions. Emission: Class B of EN 55011
R&TTE Directive	CEO	This device complies with the requirements of directive 1999/5/EEC. Classification: Class II
EMC	Applied standard; IEC 60601-1-2:2001 IEC 60601-2-18:1996	This instrument complies with the standard listed in the left column only when connecting with the instruments listed in the system diagram on page 244. CISPR 11 of emission: Group 1, Class B

Р	roduct Name	Capsule endoscope (OLYMPUS EC TYPE 1)
Year of Manufacturer	200 <u>5</u> 033 1	The year of manufacture is indicated by the first 4 digits of the serial number.
* The year of ma	nufacture indicates th	e serial number of MAJ-1469.
FCC ID	:38QEC-1	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
		(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
IC	:4763B-EC1	"Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired opertation of the device."

Recorder unit

Product Name		Recorder Unit (OLYMPUS RE-1)
Power Supply	Power source	Battery pack (MAJ-1473)
	Voltage	DC 6.7V – 8.4V
	Current	550 mA
Battery Life		8 hours or longer
Size	Weight	515 g (including battery)
	Dimensions	90 mm (W) × 175 mm (H) × 43 mm (D)
Classification as Medical Electrical	Type of protection against electric shock	Internal power supply
Equipment	Degree of protection against electric shock	TYPE BF
	Degree of protection against explosion	Use under combustible atmosphere prohibited.
Medical Device Directive	CE	This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class I
		This device complies with the EMC requirements of EN 60601-1-2 when used in combination with devices bearing CE marking either on the products or in its instructions. Emission: Class B of EN 55011
WEEE Directive		In accordance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment, this symbol indicates that the product must not be disposed of as unsorted municipal waste, but should be collected separately.
		Refer to your local Olympus distributor for return and/or collection systems available in your country.
Year of manufacture	1 <u>5</u> 12345 ↑	The year of manufacture is indicated by the second digit of the serial number.

	Product Name	Recorder Unit (OLYMPUS RE-1)
EMC	Applied standard; IEC 60601-1-2:2001	This instrument complies with the standard listed in the left column only when connecting with the instruments listed in the system diagram on page 244. CISPR 11 of emission: Group 1, Class B

^{* (}with battery pack inserted)

Real time viewer

Proc	duct Name	Real Time Viewer (OLYMPUS VU-1)
Power Supply	Power source	Battery pack (MAJ-1473)
	Voltage	DC 6.7V – 8.4V
	Current	750 mA
Battery Life		3 hours or longer
Size	Weight	550 g (including battery)
	Dimensions	90 mm (W) × 175 mm (H) × 43 mm (D)
Classification as Medical Electrical	Type of protection against electric shock	Internal power supply
Equipment	Degree of protection against electric shock	TYPE BF
	Degree of protection against explosion	Use under combustible atmosphere prohibited.
Medical Device Directive and R&TTE Directive	CE	This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class I
		This device complies with the EMC requirements of EN 60601-1-2 when used in combination with devices bearing CE marking either on the products or in its instructions. Emission: Class B of EN 55011
		This device complies with the requirements of directive 1995/5/EEC. Classification: Class I

Product Name		Real Time Viewer (OLYMPUS VU-1)
WEEE Directive		In accordance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment, this symbol indicates that the product must not be disposed of as unsorted municipal waste, but should be collected separately.
		Refer to your local Olympus distributor for return and/or collection systems available in your country.
Year of manufacture	1 <u>5</u> 12345	The year of manufacture is indicated by the second digit of the serial number.
EMC	Applied standard; IEC 60601-1-2:2001	This instrument complies with the standard listed in the left column only when connecting with the instruments listed in the system diagram on page 244. CISPR 11 of emission: Group 1, Class B

^{* (}with battery pack inserted)

Recorder unit cradle

Product Name		Recorder Unit Cradle (MAJ-1484)
Power Supply	Voltage	AC 100 – 240V
	Frequency	50 – 60Hz
	Current	2 A
Size	Weight	Main body:230 g AC Adapter:275 g
	Dimensions	128 mm (W) × 80.8 mm (H) × 114.5 mm (D)
Medical Device Directive	CE	This device complies with the requirements of directive 93/42/EEC concerning medical devices.
		Classification: Class I This device complies with the EMC requirements of EN 55022 and EN 55024 when used in combination with devices bearing CE marking either on the products or in its instructions.
		Emission: Class B of EN 55022

Product Name		Recorder Unit Cradle (MAJ-1484)
WEEE Directive		In accordance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment, this symbol indicates that the product must not be disposed of as unsorted municipal waste, but should be collected separately.
		Refer to your local Olympus distributor for return and/or collection systems available in your country.
Year of manufacture	1 <u>5</u> 12345	The year of manufacture is indicated by the second digit of the serial number.

Battery charger

Product Name		Battery Charger (MAJ-1476)
Power Supply	Voltage	AC 100 – 240V
	Frequency	50 – 60Hz
	Current	AC 100V 53VA / AC 240V 70VA
Size	Weight	330 g
	Dimensions	110 mm (W) × 48.6 mm (H) × 150 mm (D)
Medical Device Directive	CE	This device complies with the requirements of directive 93/42/EEC concerning medical devices.
		Classification: Class I
		This device complies with the EMC requirements of EN 55022 and EN 55024 when used in combination with devices bearing CE marking either on the products or in its instructions.
		Emission: Class B of EN 55022.
WEEE Directive		In accordance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment, this symbol indicates that the product must not be disposed of as unsorted municipal waste, but should be collected separately.
		Refer to your local Olympus distributor for return and/or collection systems available in your country.

Battery pack

Pro	duct Name	Battery pack (MAJ-1473)
Туре		Lithium-lon storage cell
Capacity		3600mAh
Voltage		7.4V
Recharging Time		Approx. 2 hours
Size	Weight	180 g
	Dimensions	72 mm (W) × 24.7 mm (H) × 60 mm (D)
Medical Device Directive		This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class I
		This device complies with the EMC requirements of EN 60601-1-2 when used in combination with devices bearing CE marking either on the products or in its instructions. Emission: Class B of EN 55011.
NI		In accordance with the EU Batteries Directive, the battery packs are marked with a recycle logo. Follow all applicable regulations in their handling. If you are unsure of the regulations for your country, contact Olympus.

Real time viewer cable

	Product Name	Real Time Viewer cable (MAJ-1485)
Length		1.05 m

Antenna lead set

Produc	t Name	Antenna Lead Set (MAJ-1474)
Size	Weight	200 g
	Dimensions	88 mm (W) × 68.7 mm (H) × 23 mm (D)
	The number of antennas	8
Medical Device Directive and R&TTE Directive	CE	This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class I
		This device complies with the EMC requirements of EN 60601-1-2 when used in combination with devices bearing CE marking either on the products or in its instructions. Emission: Class B of EN 55011
		This device complies with the requirements of directive 1995/5/EEC. Classification: Class I
WEEE Directive		In accordance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment, this symbol indicates that the product must not be disposed of as unsorted municipal waste, but should be collected separately.
		Refer to your local Olympus distributor for return and/or collection systems available in your country.

Antenna lead cover

	Product Name	Antenna Lead Cover (MAJ-1470)
Size	Dimensions	92 mm (W) × 66 mm (H)

Recorder unit harness

	Product Name	Recorder Unit Harness (MAJ-1475)	
Size	Weight	220 g	
	Dimensions	1770 mm (W) × 220 mm (H)	

Workstation hardware

Product Name Power Supply		Workstation Hardware (MAJ-1479) AC 100 – 240V / 50 – 60 Hz / 400 Hz		
Size	Weight	12.1 kg		
	Dimensions	168 mm (W) × 450 mm (H) × 456 mm (D)		
Function	Initialize	Transfer the patient information and examination data from a workstation to a recorder before the examination.		
	Download	Transfer the recorded data from a recorder to a workstation after the examination.		
	Observation	Display images downloaded from a recorder.		
	Making report	Insert the images and add comments to make a report.		
	Exporting picture / movie	Make pictures and movies from the selected thumbnails and export them.		
	Red color detection	Select images showing the suspected bleeding symptom from all the recorded images.		
Medical Device Directive	CE	This device complies with the requirements of directive 93/42/EEC concerning medical devices.		
		Classification: Class I		
		This device complies with the EMC requirements of EN 55022 and EN 55024 when used in combination with devices bearing CE marking either on the products or in its instructions. Emission: Class B of EN 55022		

Printer

Product name Power consumption Size Weight		Printer (MAJ-1480)		
		75W		
		9 kg		
	Dimensions	510 mm (W) x 210 mm (H) x 420 mm (D)		

LCD monitor

Product name Power consumption		LCD monitor (MAJ-1481)		
		25W		
Size Weight		5.7 kg		
	Dimensions	351 mm (W) x 422 mm (H) x 210 mm (D)		

EMC information

Compliance information and suggested electromagnetic environment: electromagnetic emission

The system is designed for use under the following electromagnetic environment.

Emission Standard	Applicability	Notes
Radio Frequency	Group 1	In order to provide the intended
Emission		functionality, the system must emit RF
CISPR 11		energy while in operation. This may affect
		electrical devices in the vicinity.
Radio Frequency	Class B	The amount of RF emission by the system
Emission		is very small, with little possibility of
CISPR 11		affecting nearby electrical equipment.
Harmonic Emissions	Not applicable	The system is not powered by a
IEC 61000-3-2		commercial power source.
Voltage	Not applicable	The system is not powered by a
Fluctuations/Flicker		commercial power source.
Emissions		
IEC 61000-3-3		

Compliance information and suggested electromagnetic environment: electromagnetic immunity

Immunity Test	IEC 60601-1-2 Testing Level	Compatibili ty Level	Suggested Environment
Electrostatic Discharge (ESD) IEC 61000-4-2	Contact: ±2, ±4, ±6kV Aerial: ±2, ±4, ±8kV	See left	Material unlikely to produce static electricity, such as wood, concrete, or ceramic tiles, are recommended for the floor. If the floor is made of materials that are likely to produce static electricity, maintain the relative humidity above 30%.
Electrical Fast Transient / Burst IEC 61000-4-4	Power line ±2kV I/O line ±1kV	Not applicable	The system does not have a cable for this signal.
Surge IEC 61000-4-5	Differential mode: ±0.5, ±1kV Common mode: ±0.5, ±1, ±2kV	Not applicable	The system is not powered by a commercial power source.
Voltage Dips, Short Interrutions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	<5%UT (>95% dip in U_T) for 0.5 cycle $40\%UT$ (60% dip in U_T) for 5 cycle $70\%UT$ (30% dip in U_T) for 25 cycle <5%UT (>95% dip in U_T) for 5 sec.	Not applicable	The system is not powered by a commercial power source.
Power Frequency (50/60Hz) Magnetic Field IEC 61000-4-8	3A/m	See left	Power frequency magnetic field should be similar in characteristics to general locations within a standard commercial or medical environment.

Cautions and recommended electromagnetic environment regarding portable and mobile RF communications equipment such as a cellphone

Immunity Test	IEC 60601-1-2 Testing Level	Compatibility Level	Recommended separation distance
Radiated	3V/m	See left	<i>d</i> =1.2√ <i>P</i> 80MHz to 800MHz
Immunity IEC 61000-4-3	(80MHz - 2.5GHz)		<i>d</i> =1.2√ <i>P</i> 80MHz to 2.5GHz
Conducted Immunity IEC 61000-4-6	3Vrms	Not applicable	_

Keep portable RF communication devices away from all parts of the system (including the cables) by at least the recommended separation distance, computed for the transmission frequency.

Here, P is the maximum power export of the device, as specified in watts (W) by the manufacturer, and d is the recommended separation distance in meters (m).

The system satisfies the requirements for IEC 60601-1-2 compliance, but may experience electromagnetic interference in an electromagnetic environment exceeding the requirements.

The system may experience electromagnetic interference near high frequency operating devices, and other devices marked with the following symbols.



Recommended separation distance between system and portable RF communication equipment

	Separation Distance	ce Based on Transn (m)	nission Frequency
Maximum Power Output of Transmitter P(W)	0.15 MHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

NOTE

The above table provides some calculations of the distance between the system and the transmitter. The values may vary depending on the architectural structure and the environment in which the system is used. **Appendix**

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