pde-neoII
C10935

Operator's Manual

Thank you for your purchase.

CAUTION	Follow the safety precautions in Chapter 1 of this manual in order to avoid personal injury and damage to property when using the PDE system. The manual describes the correct handling procedures for using the system and provides cautions in order to avoid accidents. Read the entire manual carefully before using the system and store it in a location where you can refer to it at any time.

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RX only

HAMAMATSU PHOTONICS K.K.

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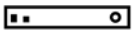
1 SAFETY PRECAUTIONS

1.1 SYMBOLS AND KEY TERMS

The symbols shown below are included in the pde-neoII system manual.

Controller		Remote Controller	
	Alternating Current		CONTROLLER
	ON (power)		BRIGHTNESS
	OFF (power)		CONTRAST
	Green LED: Power ON indicator		CAMERA / LOCAL
	CAMERA port		IR LIGHT
	VIDEO OUTPUT port		IR LIGHT INTENSITY
	Y/C OUTPUT port		STATUS
	REMOTE CONTROLLER port		IMAGE IMPROVEMENT (Pseudo-color display of the fluorescence image)
	Fuse		WHITE LIGHT
	Equipotentiality		COLOR / FLUORESCENCE
	Protective earth		
	Earth (ground)		
Camera Unite			
	Fluorescence Mapping (Pseudo-color display of the fluorescence image)		IR LIGHT
	COLOR / FLUORESCENCE		Signal Strength Indicator

OTHER LABELS			
	Consult instructions for use		Year of manufacture
	Federal law restricts this device to sale by or on the order of a physician		Manufacturer

The key terms shown below are used for this device.

Key Terms	Contents
pde-neoII	Name of this device
Image Enhancement	Function to improve the fluorescence image by controlling the contrast and brightness
ICG (Indocyanine Green)	Biocompatible fluorescent dye that can be visualized by pde-neoII
Excitation Light	The light irradiated to the patient to excite the fluorescence of ICG in the body.
Fluorescence Mapping Mode	Function to display the fluorescence image in a pseudo color (Green) form.
Sterile drape	Disposable sterilized plastic bag specially designed to drape the Camera Unit of the pde-neoII when it is used in a sterile area

1.2 CLASSIFICATION OF WARNING

The warning symbols that appear in this Operator's manual and on the device are listed in the following table. Be sure that you fully understand and follow the warning symbols and instructions.

 **WARNING**	Improper handling of the system. Not observing this warning could lead to serious injury to the user, possibly even death.
 **CAUTION**	Improper handling of the system. Not observing this caution could lead to personal injury to the user or damage to property.
	This symbol indicates a note to help you get the best performance from the system. Read the contents of the note carefully to ensure correct and safe use. Failure to observe one of these notes might impair the performance of the system.
	This symbol indicates a cautionary item that should be obeyed when handling the system. Read the contents carefully to ensure correct and safe use.
	This symbol indicates an action that is forbidden. Read and follow the instructions carefully.
	This symbol indicates a compulsory action or instruction. Read and follow the instructions carefully.

The following warning and instructions may appear during your use of the pde-neoII system.

⚠ WARNING	
	**The pde-neoII device is not intended for patient diagnosis.** Do not use the pde-neoII to diagnose patients or make clinical decisions using only the images observed with the pde-neoII.
	**Do not bring this device into contact with the patient's body.**
	**This device is not sterile.** Put the Camera Unit into the sterile drape when it is used in a sterile area. Parts of the pde-neoII other than the Camera Unit must be placed outside of the sterile area.
⚠ WARNING	
	**Power supply** Use the device with the voltage indicated on the rating label. Using a different voltage can damage the system and lead to fire or electric shock.
	**Cables** Be careful not to place heavy objects on the cables or to bend them excessively. Doing so can damage the cables and lead to fire or electric shock.
	**Power supply cord** Use the accessory power supply cord when the device is used.
	Do not touch the plug with wet hands. Doing so can lead to electric shock.
	Do not touch connector pins when the connector is not connected. Particularly do not touch connector pins and the patient at the same time.

CAUTION	
	**Power supply cord** When unplugging the power supply cord, always pull the plug and not the cord. Pulling the cord can lead to fire or electric shock.
	Remove the power supply cord from the outlet when the device is not in use for long periods of time. Leaving the power supply cord in the outlet for long periods of time when the device is not in use can damage the cable and lead to fire or electric shock.
	**Connecting and disconnecting cables** Always turn off the power before connecting and disconnecting the cables.
	Do not use the Equipotentiality terminal for the purpose of protective earth.

WARNING	
	**Do not attempt to dismantle or modify the system.** Doing so can also lead to damage and even injury, as some internal components become very hot or utilize high voltage. Only touch parts as indicated in this manual.
	**Do not allow foreign objects into the device** Foreign objects such as combustible substances, metal objects or water can damage the device and lead to fire or electric shock.
	Place the pde-neoII where the cables can be easily connected and disconnected.
	Class 1 ME EQUIPMENT To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
	**If an abnormality occurs:** If the image suddenly disappears, or if there is a strange noise or smell or one sees smoke coming from the system, immediately turn off the power switch and unplug the power supply cord and contact the local distributor. Never attempt to repair the device by yourself.

⚠ CAUTION	
The pde-neoII is classified as a Class 1M LED product (IEC60825-1:1993+A1:1997+A2:2001). **VISIBLE AND INVISIBLE LED RADIATION** **WAVELENGTH: 760 nm** **Please adhere to the following precautions:**	
🚫	An invisible component is contained in the ICG excitation light from the "pde-neoII". Although the irradiation is within the Class 1M level, do not look into the light source directly with optical instruments.
🚫	Do not leave the ICG excitation light irradiating the skin for a long period of time without performing image observation.
🚫	Do not irradiate the ICG excitation light to a patient with hypersensitivity to infrared light. Doing so may damage the skin.
Note	ICG excitation light itself is classified as Class 1.
🚫	The pde-neoII system should not be used for visualizing blood vessels of the heart including a coronary artery bypass graft.

CAUTION	
	**Shipping precautions** When transporting the pde-neoII system, be sure the device is securely packaged in the original packaging material or a similar protective packaging.
	**Mechanical shocks** Do not subject the device to strong shocks, such as by dropping it. Doing so can damage the device. The front part of the Camera Unit, which is equipped with optical components, is particularly susceptible to mechanical shocks.
	**Avoid using or storing this system in the following places:** • When the ambient temperature for using this system might fall below +10 °C or rise above +30 °C. • When the ambient temperature for storing this system might fall below -10 °C or rise above +50 °C. • Where the temperature varies extremely. • In direct sunlight or near a heater. • Where the humidity is below 20 % or above 90 % or where there is dripping water.(Storage) • Where the humidity is below 20 % or above 70 % or where there is dripping water(Operation) • Close to a strong source of magnetism or electromagnetic waves. • Where there is vibration. • Where it might come into contact with corrosive gases (such as chlorine or fluorine). • Where there is a lot of dust.
	Place the controller on a horizontal (plane inclined an angle plane of under 10° from the horizontal plane).
	**Do not allow the ventilation ports to become blocked.** To prevent overheating in the device, do not wrap the Controller in cloth or any other material, or allow the ventilation ports of the power supply unit to become blocked in any way. If the pde-neoII is being operated in an enclosed environment, be sure there is clearance of at least 10 cm from both the inlet and exhaust vents when setting up the system.

CAUTION	
	**Vapor condensation on the camera window** When the pde-neoII is brought into a cold room from a warm place, vapor may condense on the camera window and make the observed image foggy. Wait to operate the pde-neoII until after the image becomes clear.
	**Disposal of the pde-neoII and the related atricles** The pde-neoII and the articles used in conjunction with it should be disposed of in accordance with hospital rules and other similar regulations to avoid risks such as infection and environmental pollution.
Note	Intended operator: medical doctors, nurses and medical engineers.
	**The pde-neoII should not be used for visualizing blood vessels of the heart including a coronary artery bypass graft**

2 CHECK THE CONTENTS OF PACKAGE

When you open the package, please ensure that the items listed in the table below are included before use. If the contents are incorrect, insufficient, or damaged in any way, contact the local distributor without attempting to operate the system.

Basic Configurations

Camera Unit	1
Controller	1
Remote Controller	1
Camera Cable (5 m)	1
Remote Controller Cable (2 m)	1
BNC-BNC Cable (3 m)	2
Y/C Cable(3 m)	1
BNC-RCA Conversion Connector	2
Power supply cord (2 m)	1
Spare fuse T2 A 250 V	2
C10935 Operators Manual (this book)	1

Option

pde-neoII Kit (ICG, Sterile water and Sterile drape)	1 set
A11285-02 Mechanical Arm Adapter (an adapter used to fix the Camera Unit to ASSISTO® Arm System, GEOMED® Medizin-Technik GmbH & Co.)	1 set

3 OVERVIEW

The pde-neoII is a medical infrared camera designed to observe the fluorescent images from indocyanine green (ICG) in the patient's body. It is equipped with Light Emitting Diodes (LEDs) used to excite the fluorescence from ICG.
The pde-neoII is also equipped with Image Enhancement designed to improve image quality, thus enabling high sensitivity observations of the fluorescent image. Observation of normal color images is also possible in the same field of view as that of the fluorescence image by using the image switching function.

Indications for Use

The pde-neoII is an imaging system used in capturing and viewing fluorescent images for the visual assessment of blood flow as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used during plastic, micro-, reconstructive and organ transplant surgeries.

4 NAMES AND FUNCTIONS OF PDE-NEOII PARTS

4.1 CAMERA UNIT

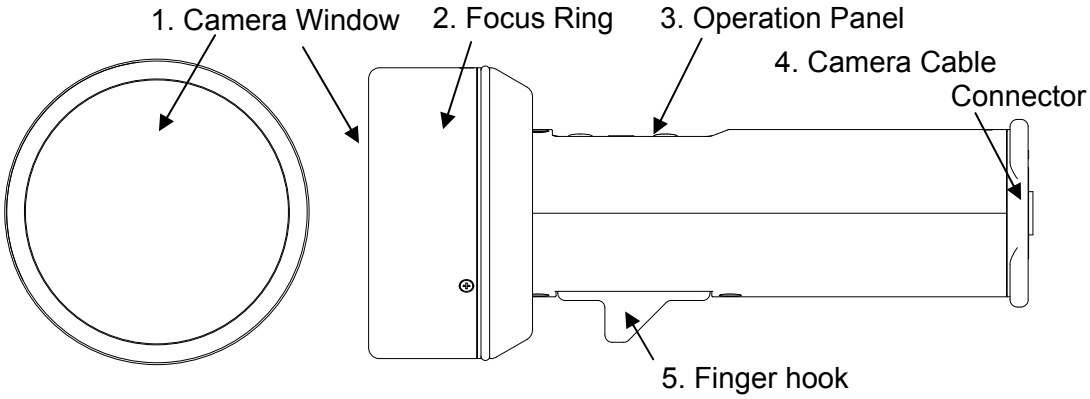


Figure 4-1: Camera unit

1 Camera Window

Face the camera window toward the observed area using a distance of 5 cm to 30 cm. The Excitation Light is irradiated from the camera window to the observed area and the images are observed through the camera window.

CAUTION	Do not loosen or remove the camera window. To protect the eye, do not look into the camera window when the excitation light is being irradiated.

2 Focus Ring

Adjust the image focus by rotating the ring. The adjustable range is from 5 cm to 30 cm.

3 Operation Panel

The following operations are possible with the operation panel:

- To switch the observed images (Fluorescence image ↔ Colour image)
- To turn on/off the Fluorescence Mapping image.
  *This function dose not working in "Color Mode".
- To adjust the intensity of Excitation light.

4 Camera Cable Connector

The Camera Cable, which connects the Camera Unit with the Controller, is connected here.

CAUTION	Do not pull the cable to prevent damage to the cable or break the internal wires.
	Do not connect any other unit except the pde-neoII controller provided by the manufacturer.

Note	The sterile drape must be used when the Camera Unit is operated in a sterile area or in cases where there is danger of infectious material from the patient being transferred to the Camera Unit.

5. Finger hook

Hook a finger around the finger hook when holding the Camera Unit by a hand. When the Camera Unit is fixed to a mechanical arm, the finger hook is replaced with the mechanical arm adapter.

4.2 CONTROLLER (FRONT PANEL)

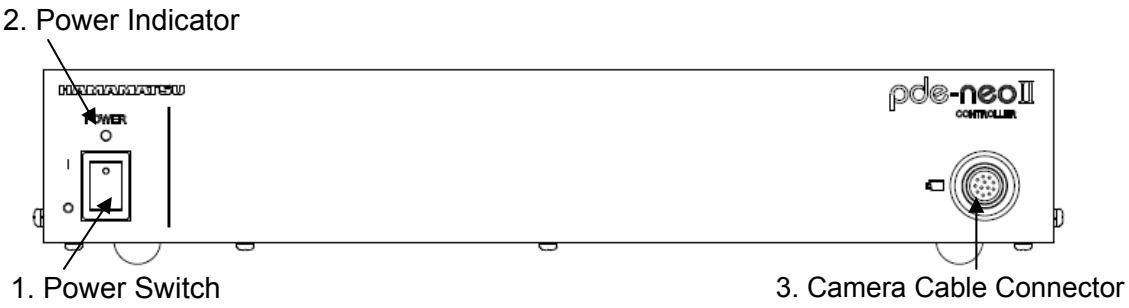


Figure 4-2: Controller front panel

1 Power Switch

The power switch to turn the power to the system ON or OFF.

Pressing the "|" side of the switch turns ON the power. Pressing the "○" side of the switch turns OFF the power.

	When the power supply has been turned OFF, wait at least 10 seconds before turning it ON again.

2 Power Indicator

The Green LED to indicate that the power is ON.

3 Camera Cable Connector

The Camera Cable, which connects the Controller with the Camera Unit, is connected here.

	Do not connect any other devices except the pde-neoII Camera Unit provided by the manufacturer.

4.3 CONTROLLER (REAR PANEL)

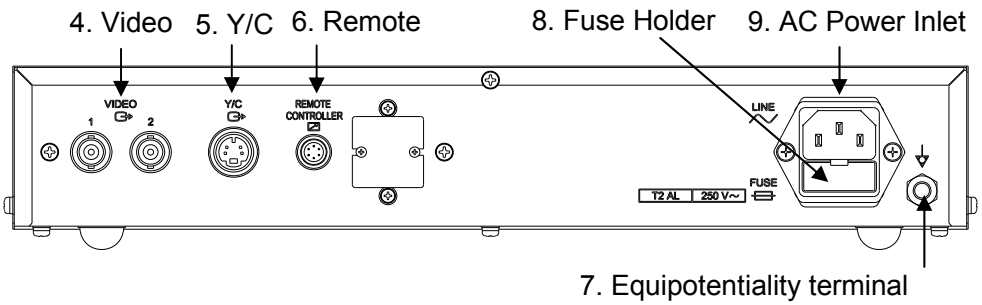


Figure 4-3: Controller rear panel

4 VIDEO (BNC type video connector)

Output terminals of the observed image (NTSC video signal). External video monitor and recorder are connected to these terminals. Use a video monitor and recorder that comply with IEC60601-1-1.

Video Specification	
Signal system	NTSC
Horizontal frequency	15.734 kHz
Vertical frequency	59.94 Hz
Scanning system	2:1 Interlaced
Video output	1.0 V p-p ,negative, 75 Ω termination

5 Y/C (Y/C type video connector)

Output terminals of the observed image (NTSC video signal). External video monitor and recorder are connected to these terminals. Use a video monitor and recorder that comply with IEC60601-1-1.

6 REMOTE

The Remote Controller is connected here. (See page 21)

	Do not connect any other devices except the pde-neoII Remote Controller provided by the manufacturer.

7 Equipotentiality terminal

The connector to connect equalize the potential voltage with other devices in case of necessity.

Connect the equalization cable with a connector that conforms to DIN42801.

WARNING	Do not use the Equipotentiality terminal for the purpose of protective earth.

8 Fuse Holder

The holder for power supply fuses
(AC250 V, 2 A, Time lag type Low-breaking capacity,Φ5 x 20mm).

Note	Refer to Chapter 7-1 when replacing the fuse.

9 AC Power Inlet

Connect the accessory power supply cord here.

	Do not cover the vent holes with cloth or anything else to prevent a rise in the internal temperature.
 **WARNING**	Do not open the outer cover. Doing so may cause an electric shock or damage the device.

4.4 REMOTE CONTROLLER

(1) Fluorescence Mapping Functions
Green zone

(2) Fluorescence Control Functions
Red zone

(3) Common Functions
Blue zone

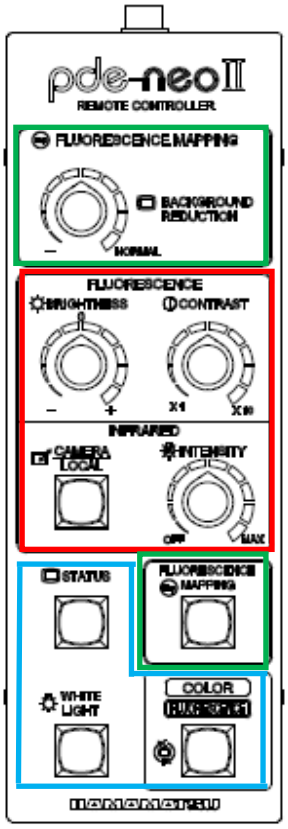


Figure 4-4: Remote Controller panel

(1) Fluorescence Mapping Functions (Green zone)

[Fluorescence Mapping]
Function to display the fluorescence image in a pseudo-color (Green) form

[BACKGROUND REDUCTION]
Background Reduction of the Background image in Fluorescence Mapping is controlled by this volume.

(2) Fluorescence Control Functions (Red zone)

[BRIGHTNESS]
Brightness of the fluorescence image is controlled by this volume

[CONTRAST]
Contrast of the fluorescence image is controlled by this volume

EXCITATION LIGHT (IR)

[CAMERA/LOCAL]

Intensity control of the excitation light with the Remote Controller is enabled by pushing this switch.

Intensity of the excitation light can be controlled either with the Camera Unit or Remote Controller. When this switch is lightning, the intensity can be controlled with the Remote Controller. When the switch is not lightning, push this switch (so the switch lights) to enable the intensity control with the Remote Controller.

[INTENSITY]

Intensity of the excitation light is controlled by this volume.

(3) Common Functions (Blue zone)

[STATUS]

Display of the parameters' status is turned on/off by pushing this switch.

[WHITE LIGHT]

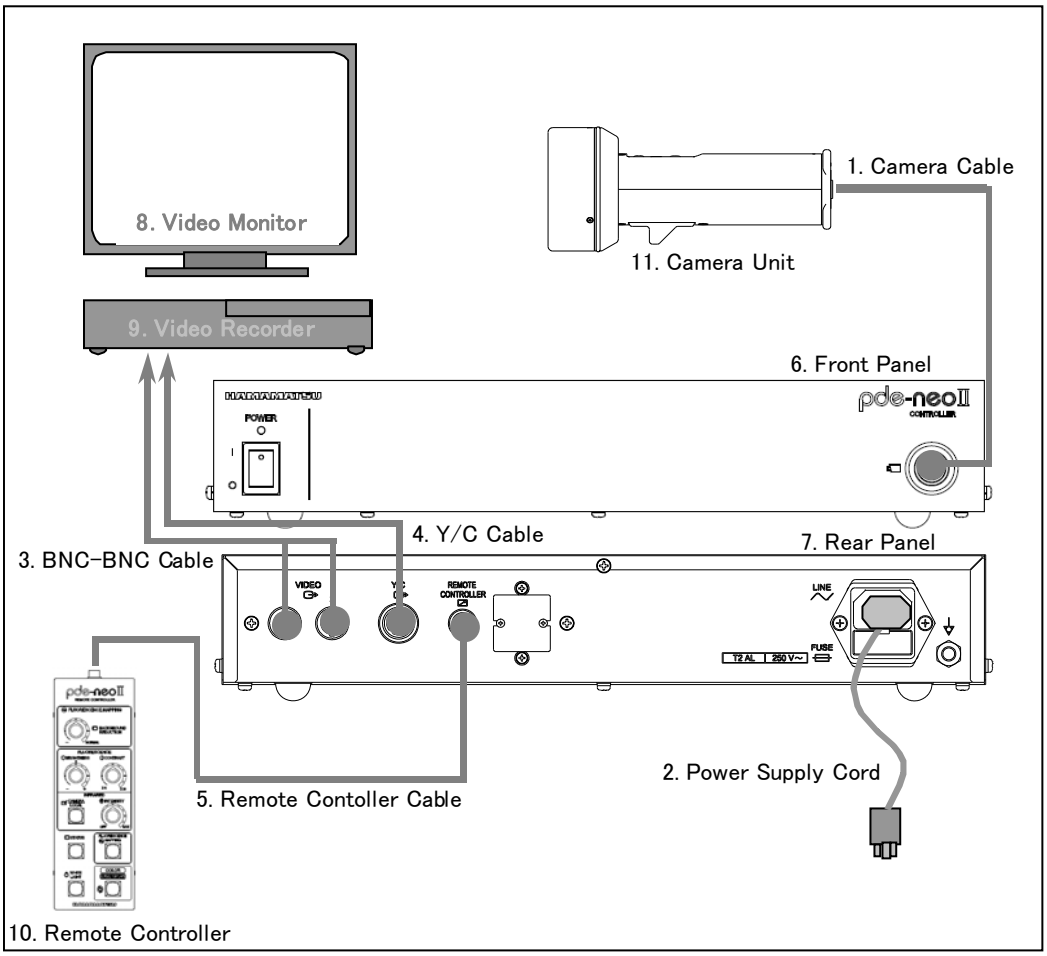
The white light to observe the color images is turned on/off by pushing this switch.

[COLOR/FLUORESCENCE]

The observed images are changed by pushing this switch.
(Fluorescence image ↔ Color image).

5 CONNECTING CABLES

Connect the cables according to the following diagram:



1	Camera Cable	7	Rear Panel
2	Power Supply Cord	8	Video Monitor (not included in the configuration of pde-neoII system)
3	BNC-BNC Cable (with BNC-RCA conversion connector if necessary)	9	Video Recorder (not included in the configuration of pde-neoII system)
4	Y/C Cable	10	Remote Controller
5	Remote Controller Cable	11	Camera Unit
6	Front Panel		

Figure 5-1: Connection overview

	When the cables are connected, make sure that the power switch is in OFF position.

1 Camera Cable
The cable to connect the Camera Unit with the Controller.

2 Power Supply Cord
The cord to supply AC power.
Connect the cord after confirming that the power switch of the pde-neoII is turned OFF.

	Use the power supply cord supplied with the pde-neoII as an accessory.

3 BNC-BNC Cable
The cable to connect the pde-neoII with an external video monitor or recorder.
Use the attached BNC-RCA conversion connector if the input terminal of the external device is the jack plug type, and confirm that it is terminated by 75 Ω.

	The video monitor and recorder are not included in the configurations of pde-neoII. Use the video monitor and recorder that comply with EN60601-1-1.

4 Y/C Cable

The cable to connect the pde-neoII with an external video monitor or recorder.

5 Remote Controller Cable
The cable to connect the Remote Controller
The following parameters can be controlled by the Remote

Enhancements of contrast and brightness of the observed image, and
- Intensity of the Excitation light.

6 OPERATIONS

6.1 PRECAUTIONS

Focus

To observe the images in focus, the distance between the camera window and the area of the patient's body to be observed should be 5 cm to 30 cm.

Ambient Light

It is recommended that the pde-neoII is operated under general indoor fluorescent lamps. Since the pde-neoII employs an infrared camera with high sensitivity, ambient infrared light might deteriorate the quality of the observed image of the patient's body. Therefore, it is further recommended that infrared light sources, such as surgical lights and halogen and tungsten lamps, are turned off. The room should also be shielded from sunlight.

External Video Monitor

Use the external video monitor with the pde-neoII after returning the settings of contrast, brightness, etc., to their normal positions according to the manual.

Cables

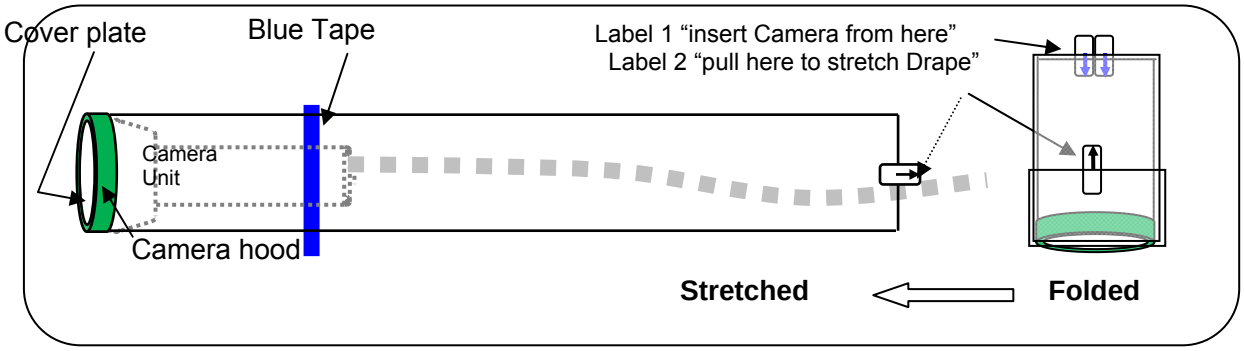
Make sure that every cable is correctly connected.

Power Supply

If the power switch has been turned off, wait at least 10 seconds before turning it on again.

6.2 PREPARATION FOR OPERATIONS

Use only the optional Sterilized Drape for the pde-neoII.
Use the Sterilized Drape properly after carefully reading the following descriptions.



WARNING	Do not reuse the Drape. It may cause infection to patients or damage to the product. Store Drapes in dark, dry and clean conditions. Sterility is guaranteed if the package is unopened and undamaged. Do not scratch the device with needles or instruments with sharp edges.

[Guarantee]

Three years after the date of sterilization under the conditions of storage in a cool, dry and dark place.

CAUTION	The Drapes should be disposed of in accordance with hospital rules and other similar regulations. Confirm that the Sterilized Drape is within the period sterilization is valid. Do not drop the Camera Unit into the Drape when you insert it. Dropping it may damage the Camera Unit or the Drape. Do not pull the Camera Cable when you cover or remove the Drape. Doing so may cause poor wire connections. Insert the Camera Unit into the Drape so that the Camera Unit can be positioned straight into the camera hood without dislodging the cover plate. Before operating the pde-neoII confirm there are no holes and no scratches on the Drape. Examine carefully to make certain the Camera Unit is correctly secured to the camera hood before operating the pde-neoII. The sterilized drape is not waterproof. Soaking it in liquid may damage the Camera Unit.

Sterilized Drape

1. Make sure that the sterilization indicator on the package is red.
2. Open the sterilization bag and take out the Sterilized Drape.
3. Insert the camera unit into the Sterilized Drape by picking up Label 1 "insert Camera from here" and opening the Sterilized Drape.
4. Set and fix the camera window into the Camera hood.

⚠CAUTION Insert the camera unit straight to set it into the Camera hood without causing excessive stress. Make sure that there is no distortion or damage to the Sterilized Drape. If there is, change to a new drape.

5. Stretch the Sterilized Drape by pulling Label 2 "pull here to stretch Drape" to cover the Camera Cable.
6. Fasten the Drape around the Camera Unit with the blue tape.

⚠CAUTION Do not drop the Camera Unit into the Sterilized Drape.
Do not suspend the Camera Unit from the Camera Cable while inserting it into the Sterilized Drape or while removing it from the Sterilized Drape.

Operate the pde-neoII according to the following procedures:

1. Make sure that the power switch has been turned off, and then connect each cable according to Figure 5-1.
2. Put the Camera Unit into the Sterilized Drape when the pde-neoII is being operated in a sterile area or when it is being used on a patient who has an infectious disease that may be transferred to the Camera Unit.

6.3 START OF OPERATIONS

（1） Make sure that the power switch has been turned off, and then connect each cable according to Figure 5-1.

（2） Put the Camera Unit into a sterile drape when the pde-neoII is being operated in a sterile area or when it is being used on a patient who has an infectious disease that may be transferred to the Camera Unit.

（3） Turn on the power switch after confirming that all cables have been connected. The power indicator lights with the signal sound "pip", then the observed image appears on the external video monitor.

∗ Fluorescence image appears after turning on the power. Switch the images (fluorescence ↔ color) as the needs arise.

NOTE After turning on the power, color image temporarily appears and is soon switched to fluorescence image for the initial check of the device.

1. Fundamental operations to observe the fluorescence image

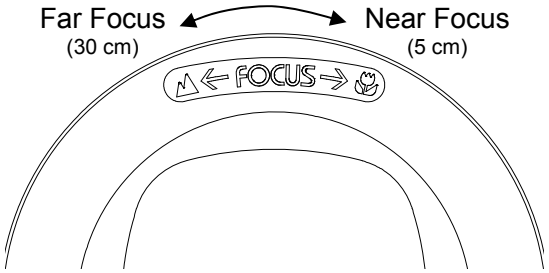
Turn off the surgical lamp

Since general surgical lamps emit a large amount of infrared light, observation of the ICG fluorescence, which is also infrared light, is impossible under the illumination of such surgical lamps.
Some of the LED surgical lamps emit only few amount of infrared light and the fluorescence observation may be possible without turning it off.

Adjust the focus on the field to be observed

Adjust the focus manually by rotating the focus ring as shown in the figure

When the focus is adjusted at a distance close to 5 cm to observe a close-up image, illumination pattern and intensity of the excitation light automatically changes to the "close-up mode" so as to properly illuminate the close field.



When the excitation light changes to the close-up mode, the indication "Near Focus" appears at the upper right of the screen.

NOTE

When the excitation light changes to the close-up mode, the intensity becomes weak (so the fluorescence) to observe a close-up fluorescence image properly.

Adjust the intensity of the excitation light manually to obtain a proper fluorescence image

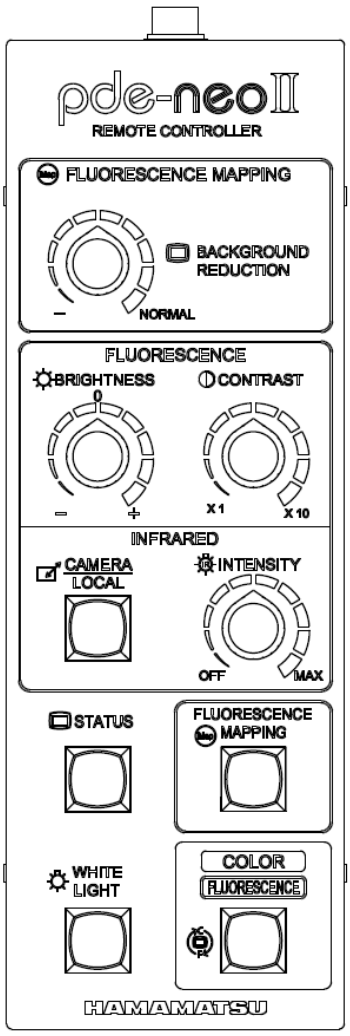
Intensity of the excitation light can be adjusted either with the Camera Unit or Remote Controller. The adjustment with the Camera Unit is always possible.
When the intensity control with the Remote Controller is needed, push "CAMERA/LOCAL" switch on the Remote Controller (then the switch lights) then adjust the INTENSITY volume.

Make further adjustments to obtain a better fluorescence image

Make fine adjustments with the brightness and contrast volumes on the Remote Controller.

2. Operation with the Remote Controller

The pde-neoII is controlled with the Camera Unit and Remote Controller.
The Camera Unit is used in the sterile area and has only fundamental functions for the surgeon or assistant to handle simply.
On the other hand, the Remote Controller is used outside of the sterile area and has more functions to control various parameters as shown here.



Fluorescence Mapping

(Fluorescence Mapping Functions)

● **BACKGROUND REDUCTION**

Intensity of the background image of the fluorescence mapping is adjusted with this volume.

FLUORESENCE

(Fluorescence Control Functions)

● **BRIGHTNESS**

Brightness of the fluorescence image is adjusted with this volume.
Dark (-5) ← 0 → Bright (+5)
(This function is only for Black and white mode.)

● **CONTRAST**

Contrast of the fluorescence image is enhanced with this volume.
Normal (x1) ← 0 → High (x10)

INFRARED

● **CAMERA / LOCAL**

Intensity of the excitation light can be adjusted with the Remote Controller by pushing this switch (then the switch lights) before starting the adjustment with the INTENSITY volume.
(The adjustment with the Camera Unit has the priority and is always possible.)

●**INTENSITY**

Intensity of the excitation light is adjusted with this volume so as to obtain a proper fluorescence image.
OFF (0) ← 0 → MAX (10)

NOTE

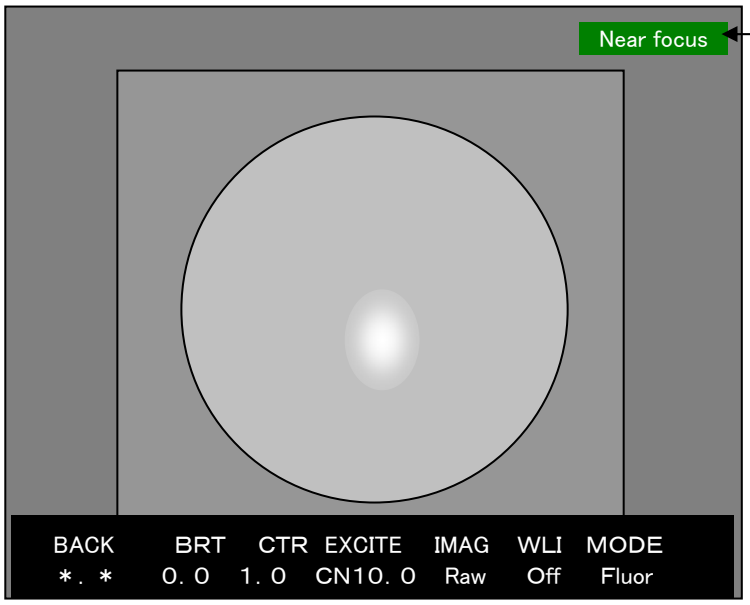
The displayed number associated with a volume position is a rough indication, and the maximum and minimum values may differ from the standard numbers shown in this page.

Common Functions

● STATUS

The current status of the parameters is displayed by pushing this switch. The display mode changes rotationally at every pushing (A→B→C→A→).

(A) All the parameters are displayed as shown in the next figure
(B) Only when a parameter is changed, it is temporarily displayed (with green characters)
(C) No parameter is displayed



This indication appears when the focus becomes close to 5 cm and the excitation light changes to the close-up mode.

An example of the fluorescence image mode

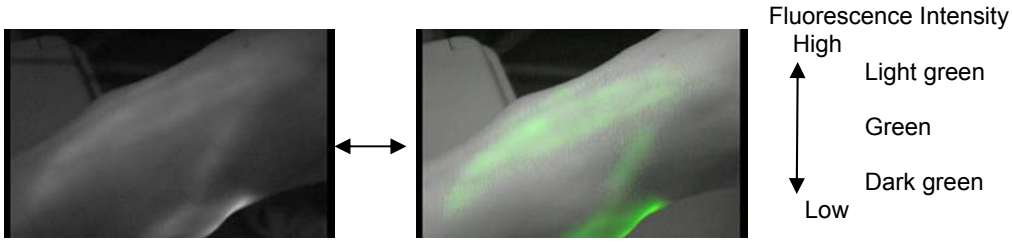
Symbols		Parameters	Contents
BACK		0 ↔ -10	Background image of Fluorescence Mapping
BRT		+5 ↔ -5	Brightness of the fluorescence image
CTR		x1 ↔ x10	Contrast of the fluorescence image
EXCITE		0 ↔ 10	Intensity of the infrared (excitation) light
	R or C	R*	Adjustment with the Remote Controller is possible
		C	Adjustment only with the Camera Unit is possible (Local adjustment is impossible)
	N or F	N	In near focus (the close-up illumination mode)
		F	In far focus (the normal illumination mode)
IMAG	Mapp or Raw	Mapp	Fluorescence Mapping is on state
		Raw	Fluorescence Mapping is off state
WLI	On or Off	On	White light is on state
		Off*	White light is off state
MODE	Fluor or Color	Color	Color image mode
		Fluor*	Fluorescence image mode

Parameters with asterisk (*) are initially set when the power is turned on.
Initial values of the other parameters show the positions of the volumes and focus ring when the power is turned on.

● Fluorescence Mapping

Function to display the fluorescence image in a pseudo color form

When the ambient light contains a certain amount of infrared component, the fluorescence image contains the infrared-illuminated tissue image, which sometimes makes it less easy to distinguish the fluorescence from the infrared tissue image. Therefore, the purpose to observe the pseudo-color image (green) is to confirm the (real) fluorescence in such a condition.



Black-and-white fluorescence image

Pseudo-color fluorescence image

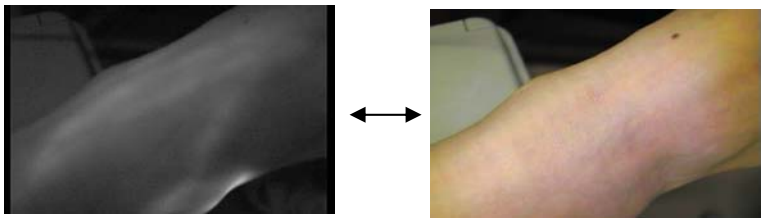
The purpose to observe the color image is to confirm from what parts the fluorescence comes when it is difficult to recognize only by the black and white fluorescence image.

● WHITE LIGHT

The white light to observe the color image is turned on or off by pushing this switch. Since the white light does not affect the fluorescence image, it can be turned on during the fluorescence observation (with the surgical lamp turned off) as an illumination to observe the surgical area with naked eyes.
(This function is also available with the Camera Unit)

● COLOR/FLUORESCENCE

Color and fluorescence images are changed alternately by pushing this switch.
(This function is also available with the Camera Unit)

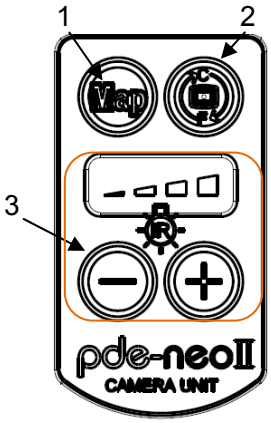


Black-and-white Fluorescence Image

Color Image

3. Operation with the Camera Unit

The following functions are available with the Camera Unit for the surgeon or assistant in the sterile area.



1. Map (Pseudo-color Display of the fluorescence image)
Pseudo-color display is turned ON and OFF by pushing this switch
(This function is also available with the Remote Controller)

2. COLOR / FLUORESCENCE
Color and Fluorescence images are changed alternately by pushing this switch.
(This function is also available with the Remote Controller)

3. INFRARED (Excitation Light)
(Switches in the orange area)

- Intensity Indicator
  Intensity of the excitation light is indicates with four steps.

- Increase (+) and Decrease (-) Switches
  Intensity of the excitation light is increased and decreased by pushing [+] and [–] switches respectively.

Pip sound is activated when [+] or [-] switches are pushed, and the sound tone changes when the intensity reaches the maximum or minimum.

NOTE

Adjustments of the excitation light
Intensity of the excitation light can be adjusted either the Camera Unit or Remote Controller. In both cases, the adjustment starts from the current position of the INTENSITY volume in the Remote Controller.

6.4 END OF OPERATIONS

(1) Turn OFF the power of the pde-neoII and the external video monitor and recorder.

(2) Remove the Camera unit from the sterile drape.

NOTE

When the control parameters are changed, these are memorized after 10 seconds. If the power is turned OFF within the 10 seconds, the newly set parameters are not memorized.

⚠CAUTION

Hold the Camera unit when removing it from the sterile drape. Do not suspend it by the Camera cable while doing so in order not to damage the cable and connector

7 MAINTENANCE

7.1 FUSE REPLACEMENT

Replace a fuse in accordance with the following process.

1 Turn off the power switch.

2 Before the replacement, make sure that the new Fuse is a correct one (T2 AL, 250 V).

3 Pull out the Fuse holder from the AC power inlet and replace the new Fuse.

4 After the replacement, fix the Fuse holder to the AC power inlet.

CAUTION	Use the fuse "T2 AL 250 V, Φ5 x 20mm". Be careful not to exert excessive force when fixing the fuse holder in order not to damage the Fuse.

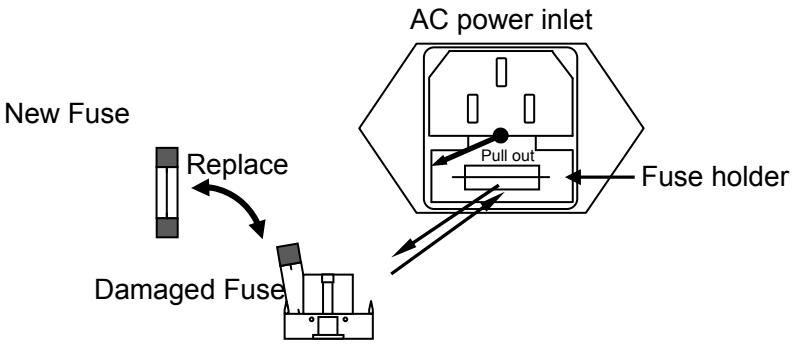


Figure 7-1: Fuse holder

7.2 CLEANING AND CHECKING

Clean the device before and after each use.

7.2.1 MAIN UNIT

Wipe the main unit with an ethanol- or isopropanol-dampened soft cloth or absorbent cotton pad. Be careful that the liquid doesn't enter into the device.

CAUTION	Organic solvents other that the ones mentioned above may dissolve the paint on the body of the device. Use a clean cloth or cotton pad to clean the pde-neoII.

7.2.2 CAMERA WINDOW

The Camera window should be kept clean to ensure the performance of irradiating the Excitation light and observing the fluorescent image.

Clean the Camera window with a soft and clean cloth such as a lens cleaner.

	Do not wipe the Camera window with a stiff or dirty cloth.

Use an ethanol- or isopropanol-dampened soft cloth or absorbent cotton pad only when the dirt is tough or extreme.

	The Camera window is made from acrylic acid resin and has only a weak tolerance for organic solvents.
CAUTION	Unplug the power supply cord before cleaning. Do not use organic solvents other than ethanol or isopropanol.

Check the Camera cable before and after use.
The Camera cable is the part most likely to be mechanically stressed in daily use. Check the following items:

Make sure that the cable has no tears or abnormal bends.

Make sure that there are no mechanical distortions or other abnormalities at the connector points.

Make sure that there are no signs of poor cable connections, such as unstable operations of monitor display.

Note	Contact your local distributor in case any of the above abnormalities are observed.

7.3 WARNING / CAUTION LABEL

The following warnings and caution labels have been affixed to the enclosure of the device.
(If the warning words become unreadable, contact your local distributor.)

Figure 7-2: Controller label

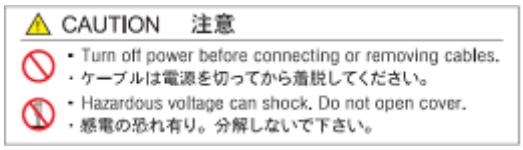


Figure 7-3: Camera unit label

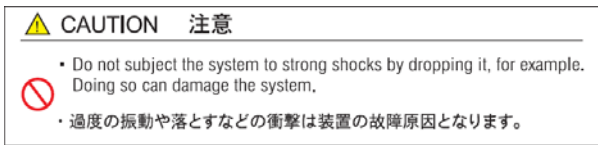


Figure 7-4: Camera unit label

8 TROUBLESHOOTING

If a problem occurs, please refer to the tables below for the possible causes, and if necessary, report the details to your local distributor.

8.1 CABLE CONNECTION IS IMPOSSIBLE

Possible Cause	Measures	Chapter
The Camera cable and the remote controller cable are used in the wrong positions (mistakenly interchanged).	Use the correct cables.	5
Misuse of male with female side.	Connect the correct sides.	-

8.2 OPERATION IS IMPOSSIBLE

Power supply LED does not light

Possible Cause	Measures	Chapter
Fuse has blown.	Replace the fuse.	7.1
Improper connection of the power supply cord.	Reconnect the cord firmly with the AC inlet and wall socket.	5
Damaged Power supply cord.	Contact your local distributor.	-
Damaged LED circuit.		
Damaged power switch.		

Image does not appear on the video monitor

Possible Cause	Measures	Chapter
Improper cable connection.	Reconnect the cables after turning off the power.	5
Either camera unit or remote controller or both are not connected to the controller. (Image appears on the video monitor only when both the units are connected.)	Connect both the camera unit and the remote controller to the controller.	
Different type of PDE from the pde-neoII is connected.	Connect the right type of camera unit (pde-neo II).	5
Damage in the Camera cable or power supply cord.	Contact your local distributor.	-

(In case of that the whole screen is green) System initialization is not properly done.	Turn off the power of the controller and wait 10 seconds or more then turn on the power again.	6.1
(In the case of a dark image) Brightness level is too low.	Increase the brightness level. (Check with room light)	6.3
(In the case of a white image) Contrast level is too high.	Decrease the contrast level.	6.3

Control of the operation panel on the Camera unit is not possible

Possible Cause	Measures	Chapter
Damage to the Camera cable.	Contact your local Distributor.	-

Operation of the Remote Controller unit is not possible

Possible Cause	Measures	Chapter
Damage in the Remote Controller Cable.	Contact your local Distributor.	-
The operation mode is not set to the remote control. Check the Camera/Local switch. If the indicator is not lighting, it is the camera control mode.	Push the Camera/Local switch to change to the remote control mode.	6.3

8.3 PICTURE IS NOT DISPLAYED CLEARLY ON THE SCREEN

The color image is not displayed.

Cause	Measures	Chapter
Operation is not set to the color mode.	Push the Color/Fluorescence switch to change to the color image mode.	6.3

Large foggy areas are seen on the screen.

Possible Cause	Measures	Chapter
Dirt on the camera window.	Wipe the camera window with neutral detergent-damped soft cloth.	7.2.2

White points are seen on the screen.

Possible Cause

White flecks

Although the CCD image sensors are produced with high-precision technologies, fine white flecks may be generated on the screen in rare cases caused by cosmic rays etc.

This is related to the principle of CCD image sensors and is not a malfunction.

The white flecks especially tend to be seen in the following cases:

- When operating at a high environmental temperature
- When you have raised the gain (sensitivity)

Image is out of focus.

Possible Cause	Measures	Chapter
Distance between the camera window and the observed area is out of focal range.	To observe the images in focus, the distance between the camera windows and the area of the patient's body to be observed should be 5 cm-30 cm.	6.1

The largest part of the screen becomes white.

Possible Cause	Measures	Chapter
Ambient infrared light. Since the pde-neoII employs an infrared camera with high sensitivity, ambient infrared light may deteriorate the quality of the observed image.	Use the pde-neoII under typical indoor fluorescent lamps. Turn off infrared light sources such as surgical lights and halogen and tungsten lamps. Shield the room from sunlight shining in through a window.	6.1
Contrast level is too high.	Decrease the contrast level.	6.3

ICG Fluorescence image is not observed.

Possible Cause	Measures	Chapter
Too much ambient infrared light.	Turn off the surgical light. The room may also need to be shielded from the sunlight.	6.1
Infrared excitation light is off.	Turn on the infrared excitation light.	6.3

Fluorescence Image becomes weak.

Possible Cause	Chapter
When the focus ring is turned to the near focus position, the excitation light intensity automatically becomes small. Therefore if the ring is unintentionally done so even the observation distance remains long, the fluorescence image may becomes weak. 	6.3

Fluorescence mapping (green image) is displayed on the area where no ICG seems to exist.

Possible Cause	Measures	Chapter
Among the cloths or adhesive tapes used in the operation field, there are ones containing fluorescence dye similar to ICG, and the fluorescence is observed by the device.	(It is not an error of the device.)	-
If an object with high reflectance is observed, the reflected excitation light may be detected and displayed as the fluorescence.	Whether the image is real fluorescence or not can be checked by changing the observation angle.	-
When the camera unit is moved quickly, the green fluorescence image may appear for a moment. (Phantom image.)	The phantom image only appears when the camera unit is moving quickly.	-
When a strong fluorescence is observed, the green area may be displayed wider beyond the real fluorescence region.	Lower the excitation light. Reduce	6.3

Other cases of extraordinary images

Possible Cause	Measures	Chapter
A volume has been turned unintentionally.	Return it to the standard position and adjust again properly. [Initial setting] Fluorescence Mapping Background Reduction: Normal Fluorescence Brightness :0 Contrast :x1 Infrared Intensity :Max	-

9 SPECIFICATIONS

9.1 RECOMMENDED ELECTROMAGNETIC ENVIRONMENTS

The **pde-neoII** is intended for use in the electromagnetic environment specified below. The customer or the user of the **pde-neoII** should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV AIR	±(2,4,6) kV contact ±(2,4,8) 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	AC power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV differential mode ±2 kV common mode	AC power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (> 95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 s	< 5 % UT (> 95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles 0 % UT (100 % dip in UT) for 5 s	AC power quality should be that of a typical commercial or hospital environment. If the intended use of the **pde-neoII** requires continued operation during power interruptions, it is recommended that the **pde-neoII** be powered from an uninterruptible power supply
Power frequency (50 Hz /60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable The equipment does not contain electrical circuits that are susceptible to the described electromagnetic disturbance.	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE : UT is the AC line voltage prior to application of the test level.)			

The **pde-neoII** is intended for use in the electromagnetic environment specified below. The customer or the user of the **pde-neoII** should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the pde-neoII (including cables) than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1.2\ (P)^{0.5}$ $d=1.2\ (P)^{0.5}$ 80 MHz to 800 MHz $d=2.3\ (P)^{0.5}$ 800 MHz to 2.5 GHz where P is the maximum power output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/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: 

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

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

[a] Field strength from fixed transmitters, such as base stations for radio (cellular or cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcasts 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 where the **pde-neoII** is used exceeds the applicable RF compliance level above, the pde-neoII should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary such as reorienting or relocating the **pde-neo**II

[b] Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

Emissions test	Compliance	Electromagnetic environment- guidance
RF emissions CISPR11	Group1	The pde-neoII uses RF energy only for its internal function. Therefore, its Rf emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	ClassB	The pde-neoII is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic IEC61000-3-2	Class A	
Voltage Fluctuation IEC61000-3-3	complies	

9.2 ELECTRICAL SPECIFICATIONS

Power supply voltage	AC 100 V to AC 240 V
Power frequency	50 Hz / 60 Hz
Power consumption	MAX 60 VA

9.3 OPERATING ENVIRONMENT

Operation temperature	+ 10 ℃ to + 30 ℃
Storage temperature	-10 °C to + 50 °C
Operation humidity	20 % to 70 % (no condensation)
Storage humidity	20 % to 90 % (no condensation)

9.4 DIMENSIONS AND WEIGHT

Camera unit	Approx. 80 mm (W) × 182 mm (D) × 80 mm (H) (not including projections)
	Approx. 0.5 kg（not including cables and accessories）
Controller	Approx.322 mm (W) × 283 mm (D) × 55 mm (H) (not including projections)
	Approx. 2.6 kg (not including cables and accessories)
Remote controller	Approx.65mm (W) × 190mm (D) × 25 mm (H) (not including projections)
	Approx. 0.4 kg（not including cables and accessories）

9.5 APPLICABLE STANDARDS

Safety	IEC60601-1:2005 Protection against electric shock: Class I ME EQUIPMENT Over Voltage category: II Pollution degree: 2 IP classification (IEC60529):IPX0
EMC	IEC60601-1-2:2007
Laser Safety	IEC60825-1:1993+A1:1997+A2:2001

10 OUTWARD APPEARANCE

10.1 CAMERA UNIT

(mm)

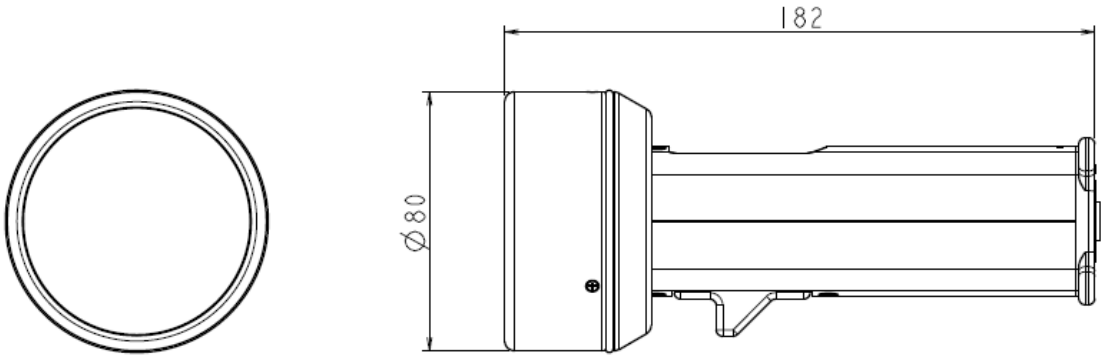


Figure 10-1: Overview camera unit

10.2 CONTROLLER

(mm)

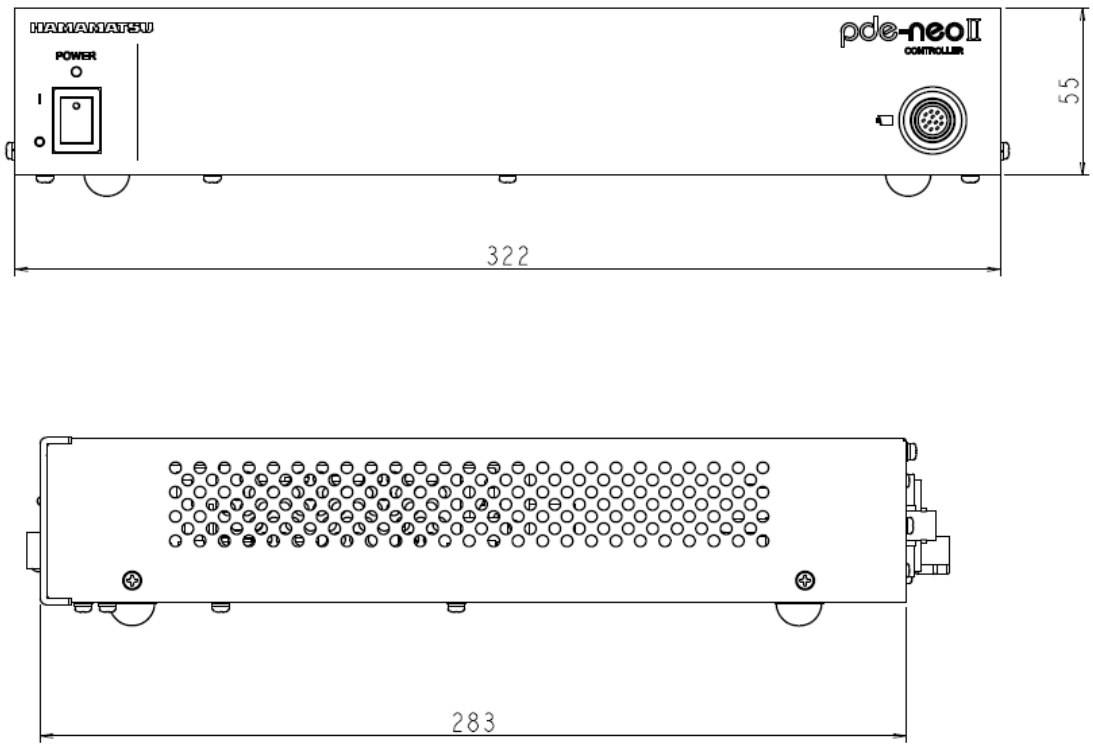


Figure 10-2: Overview controller

10.3 REMOTE CONTROLLER

(mm)

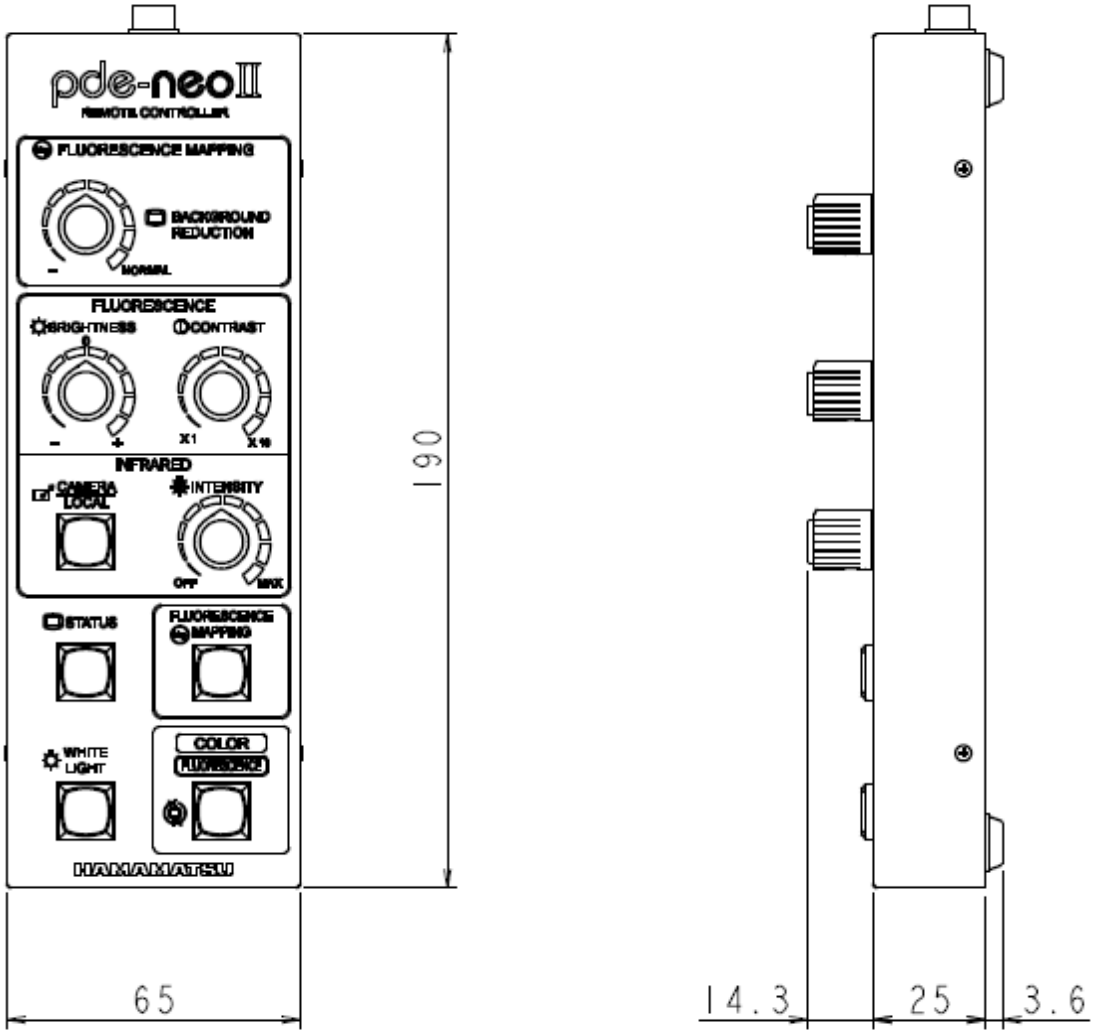


Figure 10-3: Overview Remote controller

11 WARRANTY

Hamamatsu Photonics engineers have fully inspected this system and determined that its performance conforms to specifications. In the unlikely event of breakdown or other malfunctions, contact your Hamamatsu subsidiary or local distributor.

(1) Unless otherwise stated by Hamamatsu, their subsidiary or local distributor, this system is under warranty for 12 months from the delivery date.

(2) The warranty covers only defects in the materials and manufacturing of the system. The user may be liable for repairs during the warranty period in the event of a natural disaster or if one handles the system contrary to the instructions in this manual, uses it without due caution, or attempts to modify it.

(3) Hamamatsu Photonics will repair the system or replace it, subject to availability, free of charge within the terms of the warranty.

11.1 REPAIRS

(1) If you suspect there is something wrong with the system, confirm whether or not it is malfunctioning by referring to the TROUBLESHOOTING in this instruction manual. The user must first clarify the symptoms in order to avoid any misunderstandings or errors.

(2) If you are unclear about any of these subjects or identify other problems, please contact your Hamamatsu subsidiary or local distributor and provide the product name, serial number and details of the problem. If Hamamatsu Photonics considers the problem to be a malfunction, we will decide whether to dispatch an engineer or have the pde-neoII system returned to us for repairs.

11.2 REPRESENTATIVES

Manufacturer HAMAMATSU

Hamamatsu Photonics K.K
812 Joko-Cho, Higashi-Ku, Hamamatsu-City Shizuoka-Pref,
431-3196 Japan
TEL: +81 (53) 431 - 0124
FAX: +81 (53) 435 - 1574

Distributor:

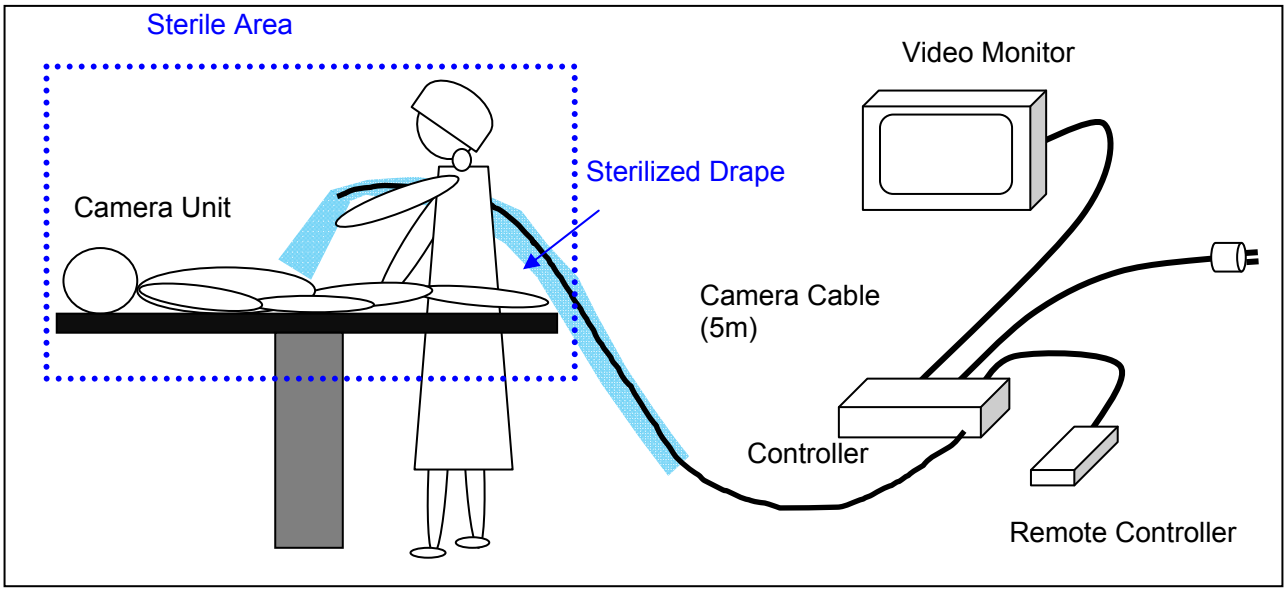
Mitaka USA, Inc.
2337 Lucky John Drive Park City,
Utah 84060 USA
Phone: 435 649 2236
FAX: 435 608 6397

- The contents of this manual are subject to change without notice.
- The unauthorized reproduction or distribution of part or all of this manual is prohibited.
- If one of the following problems occurs, contact Hamamatsu Photonics. (See the Contact Information.) We will deal with the problem immediately.

➢ Some contents of the manual are dubious, incorrect or missing.
➢ Some pages of the manual are missing or in the wrong order.
➢ The manual is missing or dirty.

APENDIX: PDE/pde-neoII Kit (ICG, Sterile water and Sterile drape)

PDE/pde-neoII Kit contains ICG, the sterile water and the sterile drape which are used during imaging procedures with the PDE/pde-neoII device. The sterile drape is used to cover the Camera Unit and Camera Cable in the sterile area as shown in the next figure.



Instructions for Use of the PDE/pde-neoII Kit

The Instructions for Use for the PDE/pde-neoII Kit is divided into two sections, one to detail the use, handling, preparation and injection of ICG, and other is to detail the use and handling of the PDE/pde-neoII Sterile Drape with the PDE/pde-neo System.

INDICATIONS FOR USE

pde-neoII is an imaging system used in capturing and viewing fluorescent images for the visual assessment of blood flow as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used during plastic, micro-, reconstructive and organ transplant surgeries.

THE PDE/pde-neo KIT

Each PDE/pde-neoII Kit contains:

- 1 vials of sterile Indocyanine Green (ICG) powder (25 mg/vial)
- 1 ampules of sterile water (10 ml/ampule)
- 1 sterile drapes

Additional ICG powder vials, ampules of sterile water, and sterile drapes may be obtained by purchasing the PDE/pde-neo Refill Kit.

IMAGING AGENT FOR THE PDE-NEO DEVICE

- The pde-neoII device uses ICG as the imaging agent.
- ICG is supplied as vials of sterile ICG powder (25 mg / vial) with ampules of sterile water (10 ml / ampule) to dissolve the ICG powder. These components are for single use only. Do NOT reuse or re-sterilize any of the individual components. Before injection of ICG for each patient's imaging procedure, ICG must be reconstituted using the sterile water.
- Optical properties of ICG are as follows:
    - Maximum absorption wavelength in blood: approx. 806 nm
    - Peak wavelength of fluorescence: approx. 830 nm

[I] DIECTIONS FOR USING ICG

General Description

ICG is a sterile, water soluble, tricarbocyanine dye with a peak spectral absorption at 800 to 810 nm in blood plasma or blood. Note that endogenous species have low light absorption in that range. ICG contains not more than 5.0% sodium iodide. ICG is to be administered intravenously.

Clinical Pharmacology

- Following intravenous injection, ICG is rapidly bound to plasma proteins, primarily lipoproteins with a lesser and variable binding to albumin (2 % to 30 % of total). Simultaneous arterial and venous blood estimations have shown negligible renal, peripheral, lung or cerebrospinal uptake of the dye. ICG is taken up from the plasma almost exclusively by the hepatic parenchymal cells and is secreted entirely into the bile. ICG does not undergo significant enterohepatic recirculation. ICG has a half-life of 2.5 minutes to 3.0 minutes.
- Drug/drug interaction studies have not been performed.

Contraindications

ICG contains sodium iodide and should be used with caution in patients who have a history of allergy to iodides or iodinated contrast agents. The pde-neo device should not be used during surgical procedures with patients who are known to be sensitive to iodides or iodinated contrast agents.

Warnings

- Anaphylactic deaths have been reported following ICG injection during cardiac catheterization.
- Use only the sterile water provided in the PDE/pde-neo Kit with the ICG. Sterile techniques must be used in handling the ICG solution.
- The outside of the ICG vials and the outside of the sterile water ampules are **NOT** sterile. The contents of the ICG vials and the contents of the pure water ampules are sterile and must be handled aseptically to maintain the sterile field during surgery.

Precautions

- Once reconstituted, the ICG imaging agent solution must only be used for one patient and within six hours. *Any prepared ICG solution remaining after a pde-neo imaging procedure must be discarded.*
- The ICG powder may cling to the vial or lump together because it is freeze-dried in the vials. This is not due to the presence of water - the moisture content is carefully controlled.
- Radioactive iodine uptake studies should not be performed for at least a week following the use of ICG.
- Pregnancy Category C: Animal reproduction studies have not been conducted with ICG. It is not known whether ICG can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. ICG should be given to a pregnant woman only if clearly indicated.
- Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ICG is administered to a nursing woman.
- Only use ICG at indicated doses and concentrations as defined in this instruction.
- Do not use ICG vials that appear to have seals that are compromised in any way.
- ICG is generally injected through a shared intravenous line with no reported difficulties or unexpected results to date. However, drug/drug interactions have not been studied.

Adverse Reactions

Anaphylactic or urticarial reactions have been reported in patients with or without history of allergy to iodides. If such reactions occur, immediate treatment with the appropriate agents (e.g., epinephrine, antihistamines, and corticosteroids) should be administered. Resuscitative measures may also be required.

Handling, Preparation and Dosage of ICG

(1) Supplies Required

- Depending on the number of images to be acquired, one or two vials of ICG and one or two ampules of sterile water should be sufficient for each patient's imaging procedure.
- One or two 10ml syringes for the preparation of ICG with the sterile water.
- Approximately 100 ml of sterile normal saline for injection.
- Depending upon the number of images being performed, usually three to four 3 ml syringes and up to three 5 ml syringes are required. Sufficient quantities of 3 ml or 5 ml syringes must be available, based on the number of imaging sequences required during the procedure, i.e., one syringe prepared for each imaging sequence.
- Each ICG injection must be followed immediately with a 10 ml sterile saline for injection bolus, which requires a sufficient number of 10 ml syringes be pre-filled with normal saline for injection in advance of the pde-neo imaging procedure(s) and available at the time of each imaging sequence.
- For the administration of ICG, use of two three-way stopcocks is recommended, one to facilitate ICG delivery, the other to facilitate the immediate injection of the saline flush. A dedicated line is not required for ICG injection.

(2) Preparation of ICG for Administration

- ICG can be reconstituted and prepared for injection either at the beginning of, or during, the surgery, depending on the preference of the surgical team, but must be used within six hours of preparation.
- The recommended injection volume is 2 ml of reconstituted ICG for most imaging sequences, except for images acquired through the patient's skin, in which case a 4 ml injection is recommended.
- Remove the necessary number of vials. Carefully break off the top of the first sterile water ampule and draw up the 10 ml into a 10 ml syringe.
- Remove the flip-off cap on the first ICG vial (25 mg) and inject the 10 ml of the pure water through the stopper into the ICG vial. This yields a 2.5 mg/ml solution of ICG. Shake the ICG vial gently to mix.
- Mix the contents of the ICG vial thoroughly and inspect the reconstituted vial for precipitation. If precipitation is noted, continue to gently shake until all ICG is dissolved in the solution. If precipitation persists, do NOT use the mixture. Discard the reconstituted vial and prepare a new vial as described above.
- In order to ensure that the reconstituted solution is used within six hours from the time of reconstitution, it is recommended that the second vial of ICG be reconstituted only after the first reconstituted solution has been used up.
- If necessary, repeat the steps above with the second sterile water ampule and second ICG vial, to ensure a sufficient amount of reconstituted ICG is prepared for the imaging procedure.
- The total dose of ICG injected should be kept to below 2 mg/kg. Prescribed dosages are at the medical discretion of the prescribing physician.
- Prior to the imaging procedure, withdraw the desired volume of ICG solution for each planned imaging sequence into separate 3 ml or 5 ml syringes.
- Place the prepared syringes in a convenient and sterile location for use at the time of imaging.

(4) Saline Flush Preparation

- With individual 10 ml syringes, withdraw 10 ml of normal saline, and place the prepared syringes in a convenient and sterile location for use at the time of imaging.
- There should be either the same number of, or more, saline syringes than the prepared ICG syringes.

(5) Administration via a Venous Line

- ICG administration is to be performed via a venous line. Ensure there are two injection ports available for the injection of ICG and the saline flush.
- Inject the prepared 2.5 mg/ml ICG solution into the venous line as a tight bolus and immediately followed by a bolus of 10 ml of normal saline for injection.

(6) Timing of ICG Administration

- ICG injection must only occur after the Camera Unit of the pde-neo device is positioned as to display the area to be observed on a TV monitor.
- Discard any unused reconstituted ICG after the surgery is complete.

(7) Storage

The ICG vials and sterile water ampules should be stored at ambient room temperatures of 20 ℃ to 25 ℃
(68 °F to 77 °F).

[II] DIRECTIONS FOR USING THE STERILE DRAPE

Warnings

The PDE/pde-neoII Sterile Drape is supplied sterile and is intended for single use only. **DO NOT RE-STERILIZE OR RE-USE**. If a drape becomes compromised during the protection of the Camera Unit of pde-neoII, or the imaging procedure, move the device away from the sterile field, remove the contaminated drape and replace with a new sterile drape, as per this ***Instructions for Use.***

Precautions

- Use only the PDE/pde-neoII Sterile Drapes.
- The PDE/pde-neo Kit and the packaging of the PDE/pde-neoII Sterile Drape are NOT sterile. The PDE/pde-neoII Sterile Drape is supplied sterile and must be handled aseptically to maintain the sterile field during surgery.
- Do not use drapes in which the seals on the package appear to be compromised in any way.

Applying the PDE/pde-neoII Sterile Drape

The sterile operator performs the following steps unless otherwise indicated.

The pouch containing the PDE/pde-neoII Sterile Drape is removed from the PDE/pde-neoII Kit. Using proper sterile technique, the pouch containing the sterile drape is opened and the drape is transferred to the sterile operator.

(1) The sterile operator holds the sterile drape by placing both hands inside the folds of the sterile drape as shown in Fig.1

(2) The sterile operator drapes the Camera Unit of pde-neo and the non-sterile operator assists by holding the Camera Unit as shown in Fig.2. ONLY THE STERILE OPERATOR MAY TOUCH THE EXTERIOR SURFACE OF THE DRAPE.

Fig.1

Fig.2

(3) As the sterile drape is passed over the Camera Unit, the sterile operator grasps the sterile drape by the exterior surface and unravels the remainder of the drape over the Camera Cable. Care is taken to ensure that the drape is not stretched too tightly.

(4) The sterile operator folds the end part of the sterile drape so as not to make wrinkles on the Camera Window as shown in Fig.3 and fastens the sterile drape including the folded part around the Camera Unit with a sterile rubber ring (an attachment of the sterile drape) at the neck part as shown in Fig.4.

Fig.3

Fig.4

If the PDE/pde-neoII Sterile Drape should become contaminated at any time during the procedure, it should be replaced with a new PDE/pde-neoII Sterile Drape and applied to the pde-neoII in the manner outlined above.