

RIGID BLUE LIGHT CYSTOSCOPY

Operating Room Quick Reference Guide

KARL STORZ Photodynamic Diagnosis (PDD) System, in combination with the optical imaging agent Cysview, is indicated for blue light (BL) cystoscopy as an adjunct to white light (WL) cystoscopy for the detection of non-muscle invasive bladder cancer in patients suspected or known to have lesion(s) on the basis of prior cystoscopy.

The aim of this document is to provide a guide for physicians on the use of the KARL STORZ equipment in combination with Cysview. It includes important information on the set up and use of the equipment, and a troubleshooting guide for consultation when undertaking PDD blue light cystoscopy.

For further assistance please call your local Photocure or KARL STORZ representative.

Prior to the Procedure

Cysview Pre-Op Instructions

- Cysview should be reconstituted according to Cysview approved labeling
- Cysview should be retained in the bladder for 1 hour, and max 3 hours prior to the start of the cystoscopy

****IMPORTANT**** Power up the PDD System as Follows:

STEP 1: Turn on Monitor.

STEP 2: Plug the PDD camera head into the camera control unit (CCU).

STEP 3: Power up the CCU.

STEP 4: Power up the D-LIGHT C light source.

STEP 5: Power up remaining components (i.e., KARL STORZ AIDA® recorder, AUTOCON® II 400).

Equipment Overview

KARL STORZ D-LIGHT C PDD Light Source
(P/N 20133620-134)

Besides standard cysto- and resection equipment specialized components are required for PDD:

- Two mode light source for white and blue light.
Check light bulb operating hours while light source is booting (first number appearing on screen). When higher than 350 inform service to exchange and make sure PDD mode is selected (PDD must appear on screen)

Light intensity regulation



Standby

Manual switch WL/BL

Contact KARL STORZ Technical Support at (800) 421-0837
for help with device-related troubleshooting.

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Equipment Overview (cont.)

TRICAM® SL II CCU (P/N 20223011U1)

- Increased sensitivity for PDD performance.
- Increased image brightness

Shutter speed: 1/15

Brightness: medium

White balance



PDD TRICAM Pendulum Camera Head (P/N 20221139)

PDD TRICAM Standard Camera Head (P/N 20221137)

- Feature a high light transmission chip
- Provide control for transition from white light to blue light



CABLE, FLUID LIGHT, 2 MM X 220 CM (P/N 495FS)

- Fluid is used instead of fibers for optimal light transmission while in blue light mode



PDD TELESCOPES: 12° (27005FIA), 30° (27005BIA), 70° (27005CIA)

- Feature an optical filter located in the eyepiece of the PDD telescope
- Provide contrast between fluorescing and non-fluorescing tissue



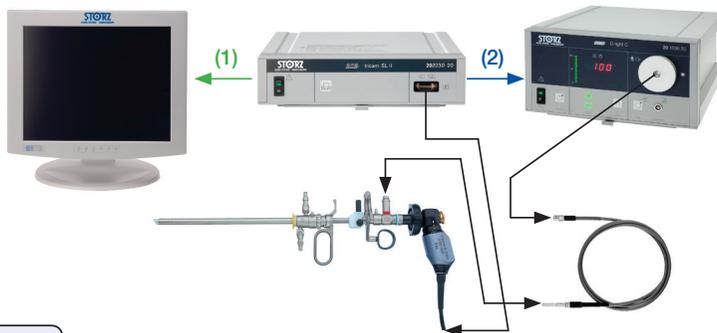
****IMPORTANT****

The FDA has approved the manufacture of PDD components exclusively by KARL STORZ Endoscopy. All repairs made to the PDD components (D-LIGHT C PDD Light Source, TRICAM SL II, Camera Heads, Fluid Light Cable and Telescopes) MUST BE made ONLY by KARL STORZ. Any third-party repair services will compromise the integrity of the device and may adversely affect the PDD functionality and fluorescence image. Product warranty will be voided if repairs are performed to the KARL STORZ PDD system by a third-party service provider.

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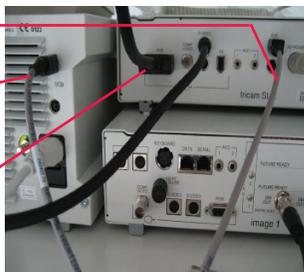
System setup



CCU-TRICAM SL II
+ D-LIGHT C

SCB® connection:
D-LIGHT C
AND
TRICAM SL II

Monitor connection:
(recommended)
RGB



(1) 547 S
S-Video (Y/C) Connecting Cable (length 180 cm)



547 RG
RGB Connecting Cable (length 180 cm)



(2) 20090170
SCB Connecting Cable (length 100 cm)

Pre-Op Checklist

Action	Completed
PDD specific telescope(s), D-LIGHT C light source, TRICAM SL II CCU, camera head(s) & fluid light cable(s) have been pre-tested before surgery.	
Check for cable connections tightness. NOTE: SCB connection between CCU and light source are required for switching between WL and BL.	
Perform white balance. NOTE: LONG PRESS the BLUE BUTTON (1) on the PDD camera head for three seconds or press button on the CCU while in white light mode.	
Check that the transition from white light to blue light from the PDD camera head operates correctly by depressing the blue button (1) briefly. Note: Press again to return to white light.	

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Tips for Optimal Performance

Empty the patient's bladder and then fill the bladder with a clear fluid in order to have optimal visibility. Ensure adequate irrigation during examination of the bladder; blood, urine or floating particles in the bladder may interfere with visualization under both white light and blue light.

To avoid false negative diagnosis, ensure that Cysview is retained in the bladder for 1 hour and max 3 hours after bladder instillation.

Perform a complete cystoscopic examination of the entire bladder under white light (Mode 1) and then repeat the examination of the entire bladder surface under blue light (Mode 2) unless the white light cystoscopy reveals extensive mucosal inflammation. The margins of the abnormal lesions are typically well-demarcated and in contrast to the normal urothelium, which appears blue.

**A red fluorescence is expected at the bladder outlet and the prostatic urethra; this fluorescence occurs in normal tissue and is usually less intense and more diffuse than the bladder mucosal fluorescence associated with malignant lesions.

Tangential light may give false fluorescence. To help avoid false fluorescence, hold the endoscope perpendicular and close to the bladder wall with the bladder distended. Tangential view might also result from a wrinkled bladder wall. This can be avoided by ensuring the bladder is filled completely.

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Tips for Optimal Performance

Light source default output is 100% for both blue light and white light modes. Adjusting down will have a negative effect on image quality.

In order to optimize image fluorescence of the target tissue, move the telescope closer to target tissue in BL than is typical in WL.

False positive fluorescence may result from scope trauma from a previous cystoscopic examination and/or bladder inflammation for instance as a result of BCG and intravesical treatment < 90 days from the procedure.

Take biopsies in WL mode to ensure better depth control.

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Troubleshooting during surgery

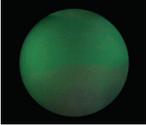
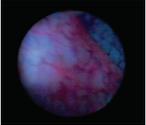
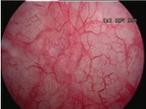
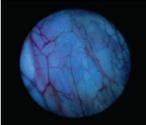
Observation	Cause	Possible solution
No fluorescence	Standard white light mode activated instead of PDD mode	Follow power up procedures specified on the front page **IMPORTANT NOTE** Change start-up mode to “PDD mode” from the camera head main menu to ensure proper future operation
	Incorrect startup procedure	Follow startup procedure as directed on front page of the OR Guide. Simultaneously press and hold both buttons on the PDD camera head, scroll to “Start Up Mode” and change the setting to (PDD) mode
	Blue light does not activate from the camera head	<ul style="list-style-type: none"> • Change start up menu to (PDD) mode • Ensure that blue button (#1) is quick pressed and released firmly • Ensure that blue light telescopes and light cable are used • Ensure that the SCB cable connection between the D-LIGHT C and CCU is tight
	Cysview instilled incorrectly (Cysview has been in the bladder less than 1 hour or longer than 3 hours)	Review Cysview instillation procedures
	Incorrect equipment	Must use PDD-specific telescopes, camera, light source and fluid light cable
	SCB Cable defective or not connected	Assure SCB cable is connected properly to CCU and Light source
Unclear Image	Camera not in focus	Adjust focus ring (gold) on camera head
	Telescopes are damaged	Remove the camera and check the optics are not damaged
	Camera is dirty	Ensure the camera is clean and free of dirt
	Floating particles in the bladder	Empty the bladder and refill with bladder irrigation fluid
The light in blue light mode is weak	The light cable is not correctly positioned	Ensure that the light cable is securely inserted into the light source
	The light cable ends are damaged	Inspect the light cable at both ends; if there are signs of damage it must be replaced
	Light cable is damaged	Always have a new fluid light cable on hand; replace if in doubt
	Telescope damaged	Always have a new telescope on hand; replace if in doubt
Blurred or “slow motion” visual effect when the telescope is moved around the bladder while in the blue light mode	Shutter speed too fast. Must be set to either 1/15 or 1/30	Change shutter speed to 1/15 or 1/30 by long pressing the silver button (#2) on the camera head for three seconds while in the blue light mode

(Troubleshooting continued next page.)

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Troubleshooting during surgery (cont.)

Observation	Cause	Possible solution
Insufficient brightness or too bright	Incorrect gain or brightness setting. NOTE: Recommended setting should be "Medium"	Adjust gain or brightness by long pressing the silver button (#2) on the camera head for three seconds while in the white light mode
Green hue 	Urine in the bladder	Always drain the bladder at the start of the procedure. It may be necessary to flush the bladder intermittently during the procedure
Weak fluorescence 	Equipment malfunction	Examine cables and their attachment to plugs for secure connection and proper maintenance
	Blood in the bladder	If blood is present, flush the bladder and stop bleeding if necessary
	Concealed tumor	Check behind any folds
	Inadequate instillation time	Ensure that Cysview is instilled 1 hour and max 3 hours prior to cystoscopy
Entire bladder appears red under white light and blue light   BCG Nodules	Recent BCG treatment	<ul style="list-style-type: none"> • Cysview is contraindicated for use in patients with BCG immunotherapy or intravesical chemotherapy within 90 days • Avoid blue light cystoscopy until 90 days after last BCG treatment and in patients with bladder infections
	Recent infection	<ul style="list-style-type: none"> • It may be possible to continue the procedure under white light alone, but tumour detection may be compromised • Either continue the procedure without the benefit of blue light diagnosis, or reschedule for a subsequent session
Lateral walls fluoresce red but the fluorescence is prone to 'disappearing' 	Tangential view	Consider changing the angle of view and position the telescope perpendicular to the bladder wall

Photocure is pleased to offer toll-free customer support and documentation for coding and reimbursement related to Cysview. For additional questions, please contact Photocure's reimbursement helpline at 1-855-CYSVIEW (1-855-297-8439)

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Important safety information for Cysview® (hexaminolevulinate HCl)

Limitations of Use

Cysview is not a replacement for random bladder biopsies or other procedures used in the detection of bladder cancer.

Warnings and Precautions

Anaphylactoid shock, hypersensitivity reactions, bladder pain, cystitis, and abnormal urinalysis have been reported after administration of Cysview. The most common adverse reactions seen in clinical trials were bladder spasm, dysuria, hematuria, and bladder pain.

Contraindications

Cysview should not be used in patients with porphyria, gross hematuria, or with known hypersensitivity to hexaminolevulinate or any derivative of aminolevulinic acid. Cysview may fail to detect some malignant lesions. False-positive fluorescence may occur due to inflammation, cystoscopic trauma, scar tissue, previous bladder biopsy, and recent BCG therapy or intravesical chemotherapy. No specific drug interaction studies have been performed.

Use in Specific Populations

Safety and effectiveness have not been established in pediatric patients. There are no available data on Cysview use in pregnant women. Adequate reproductive and developmental toxicity studies in animals have not been performed. Systemic absorption following administration of Cysview is expected to be minimal. There are no data on the presence of hexaminolevulinate in human or animal milk, the effects on a breastfed infant, or the effects on milk production. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for Cysview and any potential adverse effects on the breastfed infant from Cysview or from the underlying maternal condition.

Use of the KARL STORZ D-Light C Photodynamic Diagnostic (PDD) System

Cysview is approved for use with the KARL STORZ D-Light C Photodynamic Diagnostic (PDD) system. For system set up and general information for the safe use of the PDD system, please refer to the KARL STORZ instruction manuals for each of the components.

Prior to Cysview administration, read the Full Prescribing Information and follow the preparation and reconstitution instructions.



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