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STORZ
Karl Storz Endoscopy

Components of the Autofluorescence System

Components

① Flexible PDD Bronchoscope

② D-light AF System
20133320

③ PDD camera head

④ Camera control unit

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Specifications:

Model Number	11001 BI	11004 BI	11009 BI
Working shaft diameter:	5.0 mm	6.4 mm	5.6 mm
Working channel diameter:	2.3 mm	2.8 mm	2.6 mm
Working shaft length:	54 cm	65 cm	54 cm

Lamp type	300 W Xenon lamp
Dimensions	305 mm x 164 mm x 320 mm
Weight	Approx. 11 kg

	Telecam® 20212137U	Tricam® 20221137U
Minimum sensitivity - WL	2 lux	3 lux
AF -	0.05 lux	0.05 lux
Weight	178 g	240 g

	Telecam® SL-PDD 20212120U 020	Tricam® SL-PDD 20222120U 020
Image sensor	1/2" CCD-chip	3 x 1/2" CCD-chip
Picture format	6.4 mm x 4.8 mm	6.4 mm x 4.8 mm

Required Accessory

11301CE Disposable Suction Valve
Package of 20 STERILE, single-use disposable suction valves

Abbreviations Used
PDD = photodynamic diagnostics
WL = white light
AF = autofluorescence
CCU = camera control unit

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Description of Device

The Karl Storz Autofluorescence System is an integrated system for inducing and viewing tissue autofluorescence. The system has two modes of operation - white light (WL) for routine bronchoscopy, and autofluorescence (AF). In AF mode, the system visually identifies normal tissue as "green" and abnormal tissue as "red/brown".

The Autofluorescence System consists of the Flexible PDD bronchoscope, the D-light AF light source, the Telecam® SL or Tricam® SL camera, PDD camera head and fluid light cables.

Caution: Unauthorized conversions or modifications of the device will VOID the warranty.

Indications for Use

The Autofluorescence System is indicated for use in white light and autofluorescence bronchoscopy to identify and locate abnormal bronchial tissue for biopsy and histological evaluation. It is indicated in patients who:

- are suspected of having bronchogenic carcinoma and are scheduled for bronchoscopy as part of a standard diagnostic staging or workup
- have been previously diagnosed with lung cancer and who are at high risk for recurrence
- have abnormal sputum cytology
- have abnormal chest X-ray, CT scan or similar technology

Contraindications for Use

For WL examination, the Autofluorescence System is contraindicated for the following:

- Uncontrolled angina, uncontrolled heart failure, or serious uncontrolled ventricular arrhythmias
- Uncontrolled hypertension
- Bleeding disorder or use of anticoagulants
- White blood cell count < 2,000 or > 20,000 and/or platelet count < 50,000

For AF examination, the Autofluorescence System is contraindicated for the following:

- Use of photosensitizing agents within 90 days of the procedure
- Use of chemopreventive agents within 90 days of the procedure
- Exposure to ionizing radiation treatment within 3 months of the procedure
- Exposure to systematic cytotoxic chemotherapy within 4 months of the procedure

Safety warnings when using the AUTOFLUORESCENCE SYSTEM

WARNING: The use of the Autofluorescence System was not evaluated in patients younger than 18 years. However, the risks and benefits are not expected to be different than those in an adult population. Use caution when operating the device in patients less than 18 years.

WARNING: The AF mode of the Karl Storz Autofluorescence System must be used as an adjunct to the WL mode. The AF mode of the Karl Storz Autofluorescence System is not indicated for use as a stand-alone diagnostic tool and should not be used as such.

WARNING: The physician should first perform a complete WL bronchoscopy, switch light modes, and then repeat the examination in the AF mode. The physician should perform the biopsy procedure only after completing both examinations. The physician should biopsy all abnormal areas that are identified in either WL or AF mode.

WARNING: Do not use the Karl Storz Autofluorescence System to determine the histology of tissue. The Karl Storz Autofluorescence System is intended to identify and locate abnormal bronchial tissue for biopsy. All final diagnoses must be determined by histological review.

WARNING: Physicians who have red/green color blindness should not attempt to use the Karl Storz AF System, because they will not be able to acccurately judge the colors associated with normal and abnormal bronchial tissue.

WARNING: The Autofluorescence System may only be used with accessories that have been designated by Karl Storz as suitable for the system.

WARNING: The Karl Storz Autofluorescence System is restricted to use only by physicians who have completed appropriate training in flexible fiberoptic bronchoscopy, and who have been trained in the use of the Karl Storz AF System. The physician should use his/her judgment and experience in interpreting the fluorescence images.

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General Information fo. .ne Safe Use of the Autofluorescence System

WARNING: The Karl Storz Autofluorescence System may display fluorescent images that could be incorrectly interpreted by the physician. Images that appear bronchoscopically positive may be caused by inflammation, scope or suction trauma, scar tissue, the presence of photosensitizing agents or chemopreventive agents. Images that appear bronchoscopically negative may not always accurately indicate the absence of abnormal tissues, i.e., not all abnormal bronchial tissue will be detected.

WARNING: Biopsies may be retrieved in either WL or AF modes. For lesions that are less than 5 mm in diameter which are not visible using WL bronchoscopy, the physician should perform the biopsy in the AF mode.

WARNING: The presence of acute pulmonary infection, including bronchitis and pneumonia, may increase the risks associated with bronchoscopy and the risk of obtaining false positive readings from this examination.

WARNING: The Flexible PDD Bronchoscope is supplied NON-STERILE and must be cleaned and sterilized/disinfected prior to use and reuse. Please refer to the Flexible PDD Bronchoscope instruction manual for instructions on sterilizing prior to use.

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Of the 821 evaluable biopsies derived from the study population, 85 of them were rated as histologically positive (or abnormal). The sensitivity of the AF mode to detect histologically positive biopsies increased by 51% (10.6% to 61.2%) over WL. Sensitivity of the combined modalities (WL+AF) was 65.9%. These sensitivities are overestimates of the true sensitivities because the nature of the study is such that their denominators were undercounted. However, the relative sensitivity, or the ratio of the sensitivity of WL+AF as compared to WL alone, is unbiased and was 6.22 (95% CI: 3.15-12.31, $p<0.0001$). The false positive ratio of WL+AF versus WL is also unbiased and was 5.03 (95% CI: 3.56-7.09, $p<0.0001$).

When Class IV biopsies or tumors are included in the analysis, the number of biopsies positive for moderate/severe dysplasia or worse (including tumors) increases to 114 out of a total of 855 biopsies. Sensitivity of WL versus AF to detect moderate/severe dysplasia to tumors is 28.1% versus 66.7%. The combined modalities (WL+AF) provide a 71.9% sensitivity rate to detect abnormal areas and tumor lesions (relative sensitivity was 2.56). Please see complete data summary presented in the following table:

Summary of Efficacy Results

	Class III (based on 821 biopsies)			Class III+tumor (based on 855 biopsies)		
	WL	**AF**	**WL+AF**	**WL**	**AF**	**WL+AF**
Sensitivity	10.6%*	61.2%*	65.9%*	28.1%	66.7%	71.9%
Specificity	94.6%*	75.3%*	72.7*%	93.9%	74.9%	72.2%
Positive Predictive Value	18.4%	22.2%	21.8%	41.6%	29.0%	28.5%
Negative Predictive Value	90.2%*	94.9%*	94.9%	89.5%	93.6%	94.4%
False Positive Rate	5.4%	24.7%	27.3%	6.1%	25.1%	27.8%
Relative Sensitivity			6.22†			2.56
False Positive Ratio			5.03†			4.56

* Estimate is biased because the nature of the study precludes proper determination of its denominator.

† 95% confidence intervals were (95% CI: 3.15-12.31) for relative sensitivity and (95% CI: 3.56-7.09) for ratio of false positive rate.

The results indicate that there was a decrease in AF specificity compared to WL specificity due to an increase in the false positive rate found with the AF mode when compared to the WL mode.

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Gender-Based Analysis: Sensitivity of the Autofluorescence System was 58.2% in males and 66.7% in females. While the sensitivity was slightly higher in females, there was no statistically significant difference between the gender-based cohorts, indicating that the AF System was equally effective for both gender groups.

Age-Based Analysis: Median age in the study population was 66 years, consistent with the lung cancer prevalence data from the American Cancer Society. Patients were stratified for analysis by less than 66 years of age and greater than age 66. Sensitivity and specificity estimates were better in biopsies obtained from patients over age 66.

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Safety Warnings and Precautions at the Site of Installation

WARNING: Do not use the Autofluorescence System in the presence of flammable anesthetics or fluids. There is a risk of explosion.

WARNING: Keep out of the reach of patients.

WARNING: DO NOT open the D-light or the PDD Camera unit; there is a risk of electrical shock. Refer servicing of the unit to qualified personnel. Removal of the instrument's cover by unauthorized personnel will VOID the manufacturer's warranty for the product.

WARNING: Connect the light source and camera systems to properly grounded "Hospital Use" or "Hospital Grade" electrical outlets. Check ground continuity regularly. Routinely inspect the power cords and the plugs. DO NOT use the power cords if either the cords or the plugs are damaged. Check ground continuity regularly.

Caution: Before connecting the unit to the electrical supply, verify that the line voltage stated on the instrument's identification plate is the same as the electrical supply to be used.

Caution: Use only fuses with the correct rating.

Caution: Unauthorized conversions or modifications of the unit will VOID the warranty and compromise the safety of the unit.

Caution: Do not allow any cleaning fluid to get into the unit.

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