

July 15, 2021

Minimal Risk Registry of Endoscopic Image and Pathology Correlation for Fujifilm

NCT03440047

July 15, 2021

Minimal Risk Registry of Endoscopic Image and Pathology Correlation using Fujifilm 7000 imaging system with 4-LED Multi Light technology

PI: Nayantara Coelho-Prabhu, MBBS

Hypothesis: Advanced endoscopic imaging has the potential to guide therapy of endoscopically- identified pathology. It also has the potential to accurately distinguish pathological tissue from normal tissues, thus avoiding unnecessary biopsy and treatment.

Background: Advanced white light and image enhancing technology have been widely used to guide endoscopic therapy and detect abnormal tissue. Narrow Band Imaging is the classical form of this which uses filtered white light to enhance contrast between vascular and non vascular structures. A recently modified version of the image enhancing technology, Fujifilm's 4-LED Multi Light technology system (4-LED system; Fujifilm's Digital Video Processor VP-7000 and LED Light Source BL-7000) is a new system considered non-significant risk by the US FDA. We plan to evaluate this system at Mayo to gain experience with Blue Light Imaging (BLI), BLI-bright, and Linked Color Imaging (LCI) capabilities and correlated images with routinely obtained biopsy-confirmed histological changes.

Specific Aims

1. To establish a registry of matched endoscopic images with standard of care endoscopic biopsies in a variety of relevant gastrointestinal conditions. These will include but not be limited to Barrett's esophagus, colon polyps, colitis, celiac sprue, gastritis, and early gastroesophageal neoplasia.
2. Based on aim 1, to assess the potential for prospective clinical trials of the 4-LED system to improve detection and classification of gastrointestinal mucosal disorders

Methods

In this registry, the Fujifilm 4-LED system, which is considered non significant risk, will be used for routine endoscopic procedures at Mayo Clinic Florida and Rochester. Where indicated and based on clinical standards of care, a biopsy or tissue removal will be performed. Immediately prior to tissue removal, a standard set of electronic images will be captured including white light, BLI, BLI-bright, LCI. Each image will be stored in high resolution lossless format and later correlated with the final clinical and histological diagnosis.

Consenting

No study procedure or data collection will be carried out prior to the signing of the informed consent form. Subjects will be considered enrolled after the signing of the informed consent form.

Documentation of informed consent will involve the use of the Research Participant Tracking (PTrax) Digital Signature Capture technology for research informed consent forms. This is an institutionally approved process for documenting consent only while the subject, and/or the subject's representative, is in the physical presence of the person authorized to Wallace, Michael MD

FUJIFILM Medical Systems, U.S.A., Inc.

Proprietary and Confidential

July 15, 2021

obtain consent. The study team may print a copy of the signed consent form for the subject. The consent form will also be available to the subject via the patient portal.

Note: If the subject prefers not to use the Digital Signature Capture technology, the study team will provide a paper consent form for signature.

Sample size:

This is an exploratory study to gain sufficient data for future prospective studies. We plan to include up to 500 procedures with representative (at least 20) images of the following conditions:

1. Barrett's esophagus without dysplasia
 - a. with low grade dysplasia
 - b. with high grade dysplasia or cancer
2. Ulcerative colitis without dysplasia
 - a. Mild, moderate and severe inflammation
 - b. Dysplasia (discrete lesion)
 - c. Dysplasia (non-discrete lesion)
3. Crohn's disease
 - a. Mild, moderate and severe inflammation
4. Colon polyps
 - a. Hyperplastic
 - b. Adenoma
 - c. Villous adenoma
 - d. Invasive Cancer
 - e. Serrated adenoma
5. Gastritis
 - a. H pylori
 - b. Non H pylori
 - c. Atrophic
 - d. Autoimmune
 - e. Intestinal metaplasia
6. Celiac Disease
7. Normal mucosa
 - a. Esophagus, stomach, duodenum, colon

Inclusion Criteria:

1. All patients age 18-100 undergoing planned upper or lower endoscopy at Mayo Clinic Rochester
2. Informed Consent

Exclusion Criteria:

Wallace, Michael MD
FUJIFILM Medical Systems, U.S.A., Inc.

Proprietary and Confidential

July 15, 2021

1. Patient unwilling to provide informed consent

Data collection: See attached clinical report form.

Data sharing: Fully de-identified images and matching histopathological diagnosis will be shared (all PHI removed) with the sponsor (Fujifilm)

Equipment:

DEVICE DESCRIPTION

Fujifilm's Digital Video Processor VP-7000 and LED Light Source BL-7000 is a class II Endoscopic Video Imaging System under 21 C.F.R. 876.1500. It is the next generation of Fujifilm's VP-4440HD Digital Video Processor with FICE (Flexible-spectral Imaging Color Enhancement) and Light Source (K140149).

Intended Use/Indications for Use

The VP-7000, like the predicate VP-4440HD, is intended to be used in conjunction with Fujifilm endoscopes to provide illumination, visual display and data storage during endoscopic procedures.

The indications for use for the VP-7000 are:

The VP-7000 unit is used for endoscopic observation, diagnosis, treatment, and image recording. It is intended to process electronic signals transmitted from a video endoscope (a video camera in an endoscope). This product may be used on all patients requiring endoscopic examination and when using a Fujifilm medical endoscope, light source, monitor, recorder and various peripheral devices. BLI, BLI-bright, LCI and FICE are adjunctive tools for gastrointestinal endoscopic examination which can be used to supplement Fujifilm white light endoscopy. BLI, BLI-bright, LCI and FICE are not intended to replace histopathological sampling as a means of diagnosis.

Technological Characteristics

The device consists of three principal components:

July 15, 2021

1. A video processor that picks up the image and relays it to the monitoring screen (referred to as VP-7000);
2. A light source for illumination of the body cavity (referred to as BL-7000);
3. A keyboard for user control of the processor (referred to as DK-7000);

The VP-7000 Digital Processor and BL-7000 Light Source is for use in conjunction with Fujifilm's endoscopes and video display monitors for observation, diagnosis, endoscopic treatment, and image recording. For example, the Fujifilm 500 series, 600 series, and 700 series endoscope models.

1. VP-7000 Video Processor

The Processor relays the image from the endoscope to a video monitor. Projection can be either analog or digital at the user's preference. The Processor also incorporates internal or external digital storage capacity. The Processor controls the light projected to the body cavity. The Processor provides for optional image enhancement (BLI, BLI-bright, LCI mode and FICE) at the user's option. Spectral image processing and special light observation are achieved through proprietary software. The device is AC operated at a power setting of 120V/60Hz, 0.8A. The Processor is housed in a steel-polycarbonate case measuring 390x485x110mm. There are three kinds of new image enhancing modes (BLI, BLI-bright, and LCI) in addition to FICE. In each, the ratio of a wavelength is changed, respectively, and contrast, brightness and color emphasis intensity are changed.

The BLI (Blue Light Imaging), BLI-bright (Blue Light Imaging-Bright) , LCI (Linked Color Imaging) are described below.

● Description of BLI (Blue Light Imaging) and BLI-brt (Blue Light Imaging-Bright)

BLI is the function which indicates an image suitable for observation of superficial vascular and mucosal patterns by applying short-wavelength light suitable for getting superficial information and processing the image in a signal of the obtained high contrast.

BLI-bright is the brighter mode than BLI by controlling the intensity of LED to provide better illumination.

● Description of LCI (Linked Color Imaging)

LCI is the function which enhances the mucosal color changes using the 4-LED technology and LCI signal processing, to increase the slight difference within the red color compared to White light images.

2. BL-7000 Light Source

The Fujifilm endoscope employs fiber bundles to transmit light from the light source and subsequently to the body cavity. The Light Source employs four LED lamps. Brightness control is performed by the user. The device is AC operated at a power setting of 120V /60Hz 1A. The Light Source is housed in a steel-polycarbonate case measuring 390x505x155mm.

Since the desired intensity ratio between each LED can be controlled, illumination of various spectral characteristics can be achieved. BL-7000 has 3 illumination modes and the intensity ratio between the 4 LEDs is different in each mode.

The user can select the standard observation mode either by pressing the scope switch on the scope or the light mode switch on the BL-7000.

The light Source has a One Step LG connector in a joint with endoscope.

In the case of the 700 series endoscope (with 1(single) connector), the electric signal and power are connected with the light source through this connector. In the case of the 500 series, 600 series (with 2 (double) connector), the electric signal and power are not connected with the light source through this connector but are connected with the video processor VP-7000.

3. DK-7000 Keyboard

The Keyboard is used to enter pertinent procedural information (patient, physician, date, etc.) for display on the video monitor and digital/analog storage systems. The Keyboard is also used to control operational features of the VP-7000 Processor. The Keyboard resembles a standard computer keyboard in size and shape.

Specification

		Fujifilm
		VP-7000
		Video Processor
Power Rating	120V AC 60Hz 0.8A	
Endoscope	Fujifilm 500 series scope, 600 series scope, 700 series scope	
Key Board	USB Keyboard DK-7000 (Key bind of Function-key are different from DK-4440E)	
Peripheral	Printer, Video Recorder	
Digital Output	HD-SDI: HDTV (Resolution: 1920x1080 pixels) DVI (Digital Visual Interface) (Resolution: 1280x1024 pixels, 1920x1080 pixels) Ethernet	
Analog Output	RGB,Y/C, Composite	
Color Adjustment	Red: 9 steps Green: 9steps Blue: 9steps Black: 9steps Chrome: 9steps R-Hue: 9steps	

		Fujifilm
	Image Enhancement	Hyper-Sharpness (Structure enhancement) Color Enhancement
	Spectral Image Processing function (Post process)	FICE (Flexible-spectral Imaging Color Enhancement) Provided: 10 presets
	Special Light Observation mode (Pre process)	3 mode: Blue Light Imaging (BLI), BLI-bright, Linked Color Imaging (LCI)
	Iris mode selection	Average/Peak/Auto
	Image Storage	USB Memory
	Size (WxHxD)	390x110x485mm
	Weight	11kg
		BL-7000 Light Source

July 15, 2021

		Fujifilm
	Power Rating	120V AC 60Hz 1.0A
	Main Lamp Type	4 LED lamps
	Emergency Lamp Type	LED lamp
	Air feeding	4 levels available (off, low, mid, high)
	Size (Wahid)	390x155x520 mm
	Weight	14kg