A Quantitative Test Method for Assessing Color Performance of Endoscopy Devices

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# Abstract

**Objective:** To quantitatively compare color performance of different endoscopy devices, a bench test method was developed to characterize and analyze the color characteristics of an endoscopy system.

**Results:** The protocol of the proposed test method is described in the paper. The proposed method was used to test a conventional flexible endoscope and a modern capsule endoscope.

**Keywords:** Color performance, endoscopy device, color medical imaging, flexible endoscope, capsule endoscope, colorimetry

# Introduction

Endoscope is a general name of medical imaging devices for visually examining internal organs via orifices of the human body. For example, a gastroscope can be used to examine the esophagus, stomach, and small bowel via the digestive track. A colonoscope is used to examine colon and remove polyps through the rectum. A bronchoscope is used to examine the airways through the nose or mouth. More than ten million colonoscopies are conducted in the US every year [].

An endoscope is a complete imaging system that consists of the light source, camera (including optical lenses and imaging sensor), image processor, and display. The working principal is to project the light and camera into the human body near the area of interest for image acquisition, and then transmit the image data out of the human body for image reproduction. For instance, a *flexible endoscope* uses a flexible tube to manually position the camera with lighting while retrieving the image data through electrical conduits in real time. In contrast, a *capsule endoscope* is passively propelled by the gastrointestinal tract and takes images at a much slower rate. The image data is wirelessly sent to an outside recorder for offline review [].

In the US, endoscopy devices are classified as Class II medical devices and regulated by the US Food and Drug Administration []. A *premarket notification* needs to be submitted and cleared before a Class II device can be legally marketed. To clear a Class II device, the manufacturer needs to provide test data to show that the subject device is substantially equivalent to at least one legally marketed device, called *predicate*. As a color medical imaging device, an endoscopy device needs to provide not only optical performance [] but also color performance test data. Testing color performance is important because the device characteristics need to be documented for traceability and post-market surveillance. Furthermore, quantitative color performance test data is crucial for devices that claim using color enhancement techniques to improve detection capability. The emerging of using artificial intelligent-alike algorithms to detect lesions also demands consistent color presentation of the endoscopic images. Color performance test is usually conducted as bench tests without commissioning clinical or animal studies. However, due to lack of a standardized color performance test method, the bench test data collected from different devices with different and impossible to compare.

In this paper, we introduce a bench test method for characterizing the color behavior of an endoscopy device and an analysis method for comparing different endoscopy devices.

# Main text

## Method for Color Characterization

The workflow of the color performance test method is depicted in Figure 1. The basic idea is to use a color target with known truth to test the device and then compare the device responses with the truth in the standard, device-independent CIELAB color space. Tutorials of basic colorimetry terms such as CIEXYZ, CIELAB, dE, reference white, and sRGB can be found in [] and [].

**Color Target +**

**Ref. White**

**Scope**

**Video**

**Processor**

**Display**

**dE**

**CIEXYZ**

**Color**

**CIELAB**

**Truth**

**CIEXYZ**

**White**

**CIEXYZ**

**Color**

**CIELAB**

**Device**

**CIEXYZ**

**White**

**sRGB**

Figure 1: Workflow of the color performance test for a flexible endoscope (see text).

The upper arm in Figure 1 depicts the imaging chain of the endoscope. A reflective color target with a number of various color patches is used to test the device. Standard reflective color targets designed for photographic devices such as the 24-patch X-Rite ColorChecker are commercially available and widely used for color calibration purposes.

As an imaging system, a flexible endoscope usually consists of three components: the *scope* that illuminates the scene and acquires the image, the *video processor* that includes hardware and software to generate light, to control the scope and to process/display the image, and a *display* device that reproduces the image. The input to the endoscope system is the optical signals of the scene, and the output is the optical signals of the display. For devices that do not include a display, the output is the digital pixel data sent from the video processor to the display through the display interface (e.g., SDI).

The component structure of a capsule endoscope is slightly different. Instead of a detachable scope, the *capsule* includes the light source and imaging subsystems. Instead of using a video processor, the imaging data is transferred to the *review workstation* for offline review after the procedure is finished.

The endoscope is tested by imaging the color target illuminated by its built-in light source. A meter (i.e., a colorimeter or a spectroradiometer) is used to measure the optical output in the CIEXYZ color space if a display is included as part of the device.

A *reference white* is required to convert the measured color from the CIEXYZ to the CIELAB color space. The white point of the display (i.e., driven at RGB=255,255,255 for an 8-bit display) can be used as the reference white. The CIEXYZ values of the color (*X*, *Y*, and *Z*) and the reference white (*Xn*, *Yn*, and *Zn*) are used to calculate the CIELAB values with the following formulas.

(1)

(2)

(3)

(4)

(5)

If the device does not include a display, the manufacturer needs to specify the intended color space of the display that is expected by the video processor to send pixel data. In this case, the pixel data needs to be captured on the display interface by a hardware or software tool. Most endoscopes require the display to be calibrated to the standard *sRGB* color space. The pixel values in the sRGB color space (*R*, *G*, and *B*) with the D65 white point can be converted into the CIEXYZ color space (*X*, *Y*, and *Z*) with the following formulas.

()

()

()

(9)

The lower arm in Figure 1 depicts how the truth of the color target is obtained. Frequently, the color target comes with measurement data provided by the vendor that can be used as the truth after converted into the CIELAB color space. If the color target is out of calibration (e.g., due to fading) or is custom-made, optical measurement with a meter is required to obtain the truth. In this case, a standard, stable light source (e.g., a light booth) should be used to illuminate the target for the meter to obtain the CIEXYZ values. Similarly, a reference white object is required to convert the CIEXYZ into the CIELAB color space. The reference white object should have flat, near-100% reflectance in the visible wavelength (e.g., a reflective white standard or a white balance calibration target included in the device).

The color difference (dE) between two colors can be calculated by the following formulas.

## Methods for Data Analysis

Two methods are recommended for examining the collected CIELAB data. Given the following measurement data collected with the abovementioned measurement method:

*:* CIELAB of the j-th patch in the test target

: CIELAB generated by the subject device for the j-th patch

: CIELAB generated by the predicate device for the j-th patch

Method 1 Color Transformation

Visually show the color transformation as vectors in the 3D CIELAB color space. For each color patch, draw a vector from the to to show how the color is reproduced by the subject device. The length of the vector indicates the color difference (dE), which is useful for evaluating devices that claim to reproduce color faithfully. The direction of the vector indicates the how the color is shifted in the CIELAB color space, which is useful for evaluating devices that claim to increase the color difference between two specific colors (e.g., hemoglobin vs oxyhemoglobin for emphasizing blood vessels). Repeat the same process to draw the vectors for the predicate device for comparison.

Method 2 Color Contrast

For each pair of patches (j,k), calculate the following color differences:

: The color difference between the j-th and k-th patches in the target

: The color difference generated by the subject device between the j-th and k-th patches

The ratio is named Color Contrast Enhancement (CCE). The color contrast enhancement metric determines whether the color contrast of the test target can be preserved by an imaging system. If the CCE is greater than 1, the color difference (between the j-th and k-th patches) is increased by the imaging device. If the CCE is less than 1, the color difference is reduced by the device. If the CCE is 1, the color difference remains the same.

The ratio of the color differences between the subject device and the truth is defined as color contrast enhancement as follows.

The color contrast enhancement metric predicates whether the color difference between two shades will be preserved by the device. If the CCE is greater than one, the color difference is increased by the device. If the CCE is less than one, the color difference is reduced by the device. If the CCE is one, the color difference remains the same regardless the color transformation may or may not be faithful.

The CCE for the predicate device can be calculated similarly as follows for comparison.

The CCE values of all pairs of the color patches can be calculated numerically for statistical analysis. Alternatively, the color differences of the device vs. the truth can be plotted on the X-Y axes for visualization.

## Results

A flexible endoscope (Olympus) and a capsule endoscope (PillCam SB3, GivenImaging) were tested with the proposed methods. The results are presented in Figure XXX.

## Discussion

In the proposed methods, the device is presumed to have a fixed, constant, global color transformation. However, some devices may apply local color enhancement to some features (e.g., edges) or different color transformation depending on the image content. In this case, need to use a different characterization method.

# Limitations

* The proposed method evaluates only one frame of the video stream, so the test result may not completely reflect the real-world performance of the endoscopy device if the device does not perform deterministically.
* The spectral reflectance of the standard color target may be different from that of human organs. no water as media
* 2D target does not mimic 3D structure
* Selection of color patches may bias results

# Declarations

## Ethics approval and consent to participate

Not applicable.

## Consent for publication

Not applicable. CDRH disclaimer.

## Availability of data and material

GitHub.

## Competing interests

The authors duties are reviewing technical bench data .

## Funding

Not applicable.

## Author’s contributions

WCC: Method development. QW: Experiment design.

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