BxCamera Validation Template

Purpose

Establish a standard procedure for verifying the AI measurement accuracy of the BxCamera.

Scope

For initial install validations of the BxCamera, or if the BxCamera is moved or not used for a significant period of time.

Definitions

1. BxCamera – An imaging device (camera) at a preset distance to generate a digital image of tissues submitted within a specimen cassette and to provide suggested length and width measurements to the user.

Reference Documents

1. Surgical Pathology Dissection, An Illustrated Guide, 2nd ed. Westra
2. BxCamera Quick Start Guide (https://resources.lumeadigital.com/2025/04/02/quickstart-guide-bxcamera/)
3. BxCamera User Interface (computer must be connected to the BxCamera for this link to work)
4. Setting up the BxCamera (https://resources.lumeadigital.com/2025/03/31/bx-chip-grossing/)

Responsibilities

1. Lab Personnel

    1. Identify and document measurements, errors, and resolutions.
    2. Verify ongoing measurement accuracy.
2. Medical Director

    1. Specify pass/fail thresholds.
    2. Approve validation results.

Materials, Supplies, and Equipment Needed

Equipment

1. BxCamera

Supplies

1. Histology Ruler
2. Tissue Samples
3. Histology Cassettes
4. Histology Sponges (if needed, according to your protocol)

Personal Protective Equipment

1. Nitrile Gloves
2. Protective clothing; Gown, lab coat, scrubs, apron
3. Eye protection
4. Eye wash in an area with open containers

Safety Concerns

1. Biohazardous Materials
2. 10% Neutral Buffered Formalin

Procedure

1. Set a measurement threshold for pass/fail. For example:

    1. PASS (< +/- 1.0 mm)
    2. FAIL (> +/- 1.0mm)
    3. Your lab's SOP should reflect this threshold and be approved by the Medical Director
2. Set up gross description templates here → Set up the BxCamera
   (https://resources.lumeadigital.com/2025/04/02/quickstart-guide-bxcamera/)
3. Validation of AI measurements.

    1. Navigate to the BxCamera User Interface

Your computer must be connected to the BxCamera in order to access the user interface.

BxChip   BxBoard   Cassette
(A≠S)   (A≠D)   (A≠F)
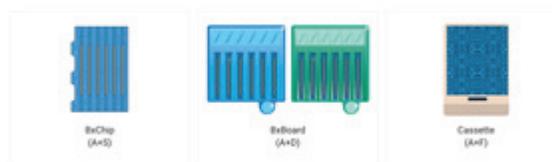
1. We recommend using small biopsies that are measurable with the human eye and are not sectioned or inked, or the majority specimen type handled by the lab.
2. Take the gross image of the sample in the BxCamera by selecting the image type (BxChip, BxBoard, or Cassette).

Standard tissue samples in a cassette should use the "Cassette" option. If taking a picture of tissue in a BxChip or BxBoard, select one of those options.
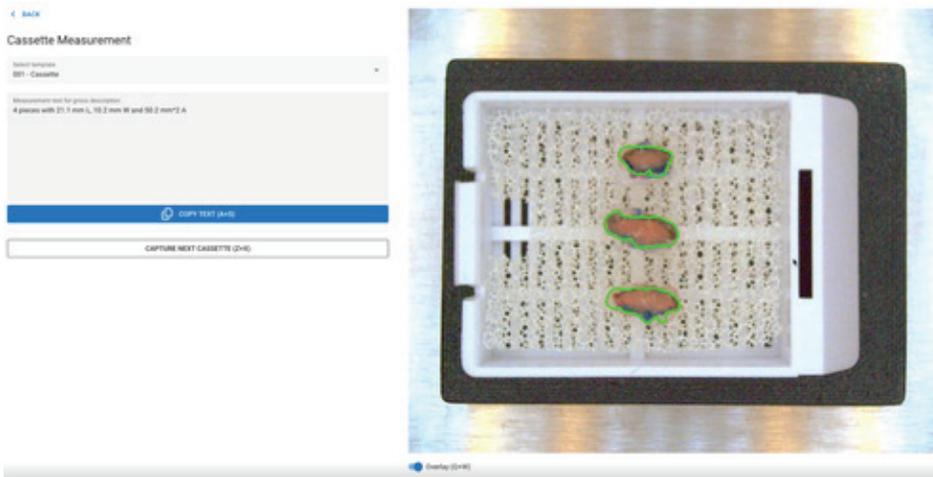
1. Select a pre-defined grossing template from step 2 above.

Data from each image capture is not preserved on-device nor communicated to Lumea. Poorly performing images may be sent to Lumea to improve the accuracy of the AI by selecting "Share Image With Lumea".

1. Use a histology ruler to take a manual measurement of the same sample. Document the measurement using the example template below or using your own documentation.

Shadows, lighting, and excess fluid around the tissues can cause BxCamera to misidentify the tissue outlines.

1. Image each tissue 2-3 times and compare the measurements of the same specimen's gross images.
2. Compare the results of the BxCamera measurements and the manual measurement. Result as Pass or Fail. For example:

BxCamera 1	BxCamera 2	Manual 1	Result	Discrepancies
13.7 mm	13.8 mm	14 mm	PASS	n/a

1. Record any discrepancies (> +/- 1mm).
2. If the BxCamera fails the validation, run the calibration procedure (see below) and perform the validation again.

3. If the measurements are acceptable, record the result and produce appropriate reports as per your institution's policies and proceed with use of the BxCamera.

The grosser should **ALWAYS** verify the BxCamera measurements are accurate. The grosser is responsible for the gross description record even if they are using the BxCamera interface to assist in generating the gross description.

Document Template

| Sample #	BxCamera 1	BxCamera 2	Manual 1	Result	Discrepancies
example_sample_1	10.1	10.2	10	PASS	n/a
example_sample_2	10.1	10.2	13	FAIL	Manual measurement is 1.9mm larger. Image outline missed a small piece of fragmented tissue

Calibration

Proceed with caution when changing the BxCamera's default settings. Reach out to Lumea with any questions.
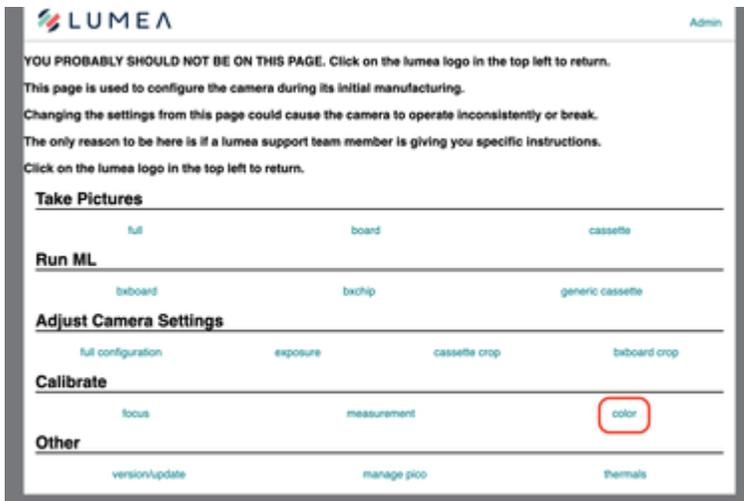
1. Place the color calibration card and associated holder plate onto the BxCamera with the label facing to the right (included with BxCamera kit contents).
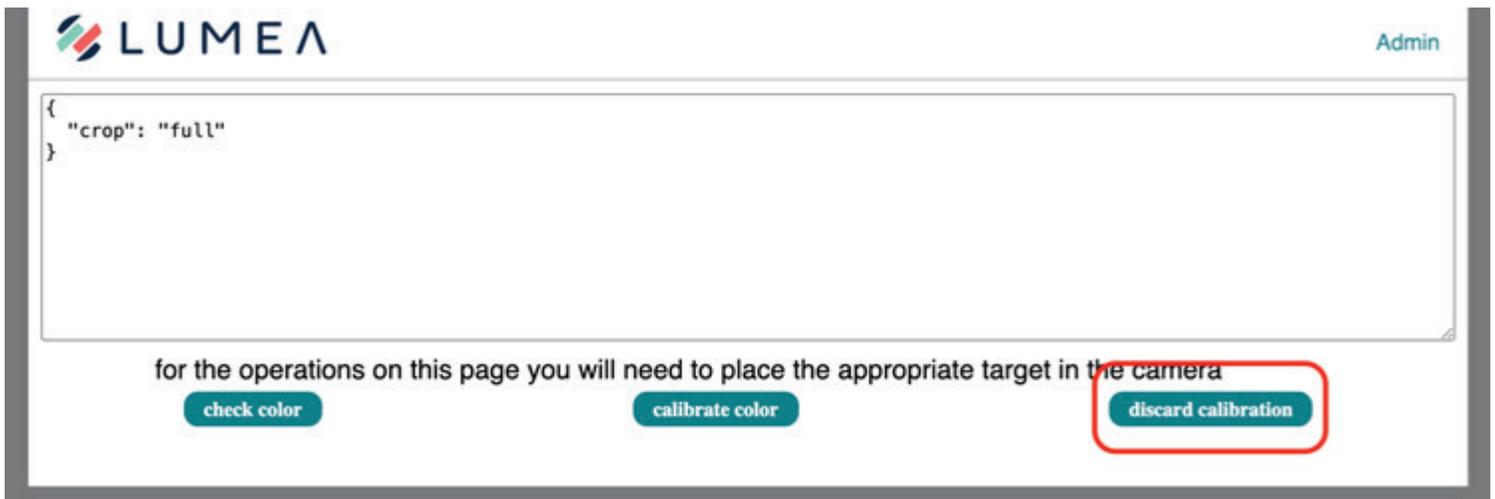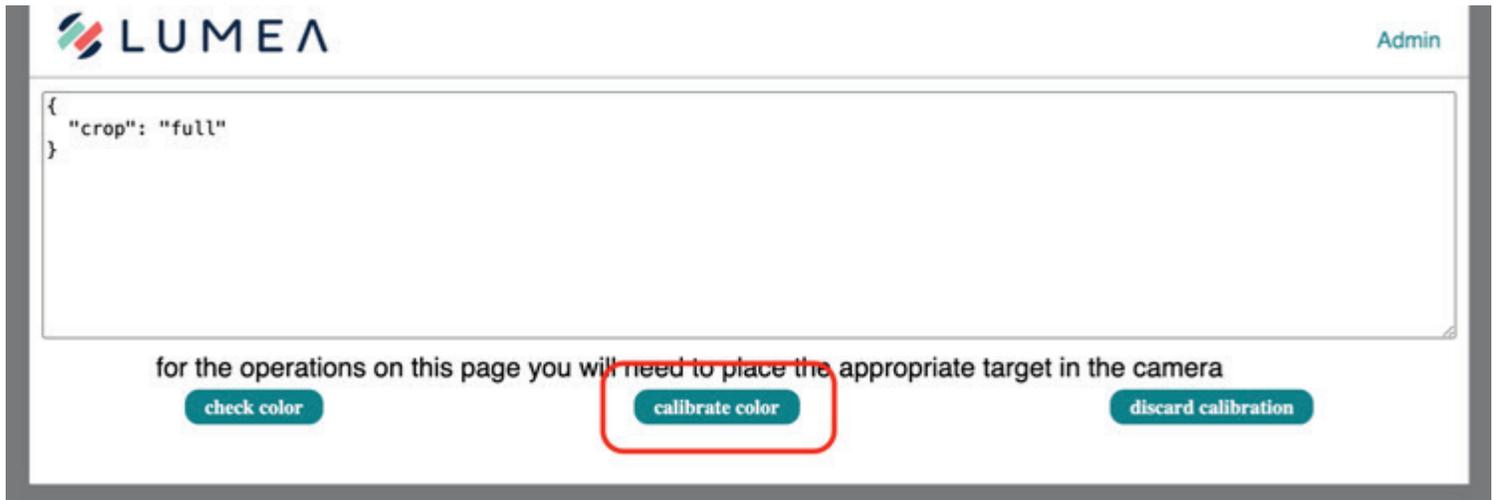

2. Navigate to the ADMIN page.
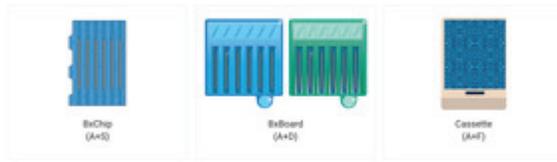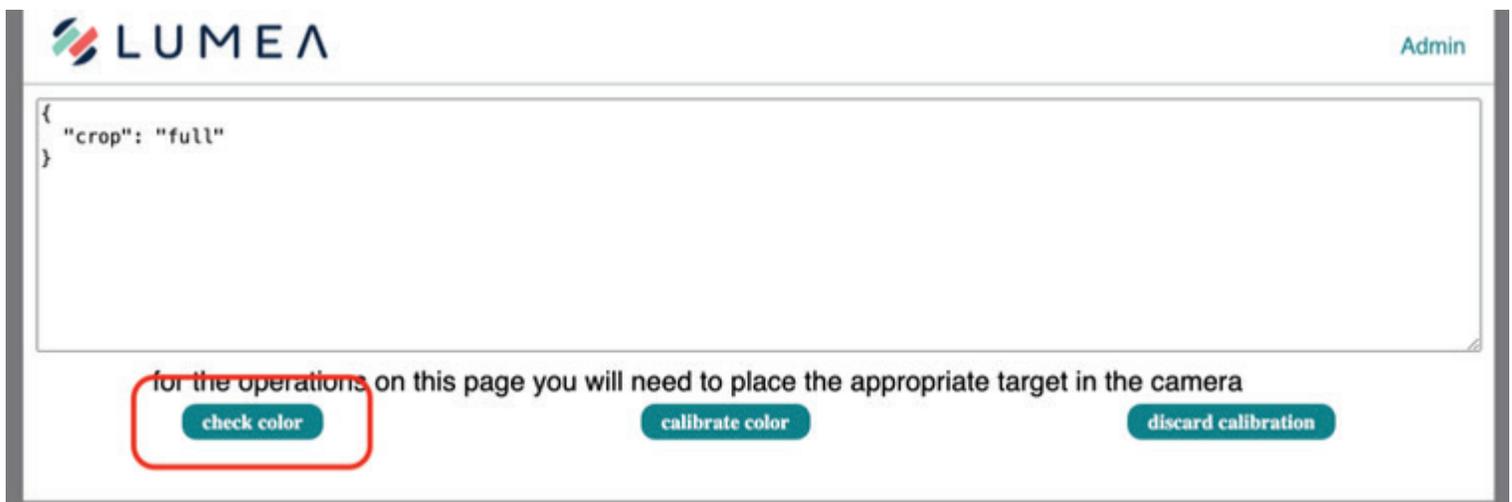
3. Select "color" in the "Calibrate" section.

4. Discard the old calibration by selecting "discard calibration".

5. Create a new calibration by selecting "calibrate color".

```
{
  "crop": "full"
}
```

for the operations on this page you will need to place the appropriate target in the camera

check color　　　**calibrate color**　　　**discard calibration**

6. Check the new calibration by selecting "check color". The output will display a "delta_e" metric which should be between 3-4, where 3 is exceptional and 4 is acceptable.

Admin

```
{
  "crop": "full"
}
```

for the operations on this page you will need to place the appropriate target in the camera

check color　　　**calibrate color**　　　**discard calibration**

7. If calibration does not produce a delta_e below 4, or if the measurements continue to fail, please contact Lumea support for additional help.

Do not attempt the color calibration more than twice in a row as this could cause the BxCamera to reset.