Monastic Color Reproduction: A Software Tool for Printing and Assessing the Monk Skin Tone Scale

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FDA headquarter campus in Silver Spring, Maryland

Center for Devices and Radiological Health (CDRH)

~1900
EMPLOYEES

18k
Medical Device Manufacturers

183k
Medical Devices
On the U.S. Market

22k/year
Premarket Submissions
including supplements and amendments

25k
Medical Device Facilities Worldwide

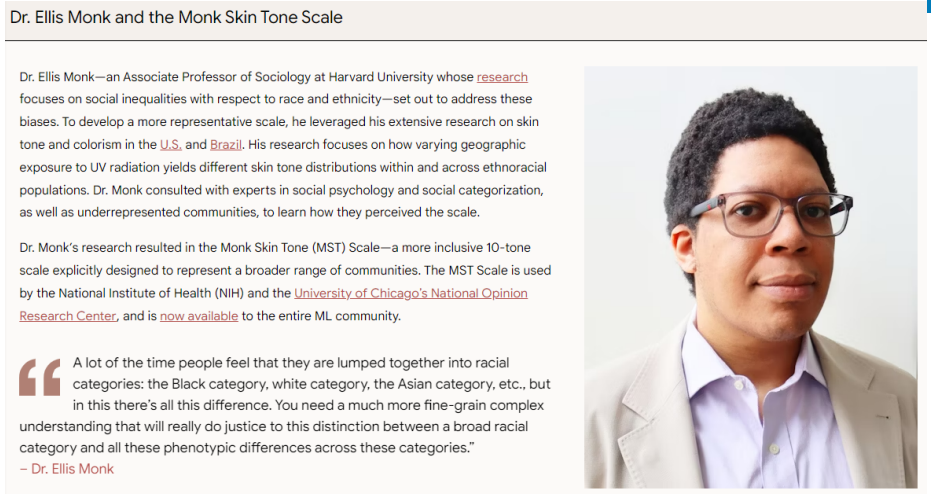
1.4MILLION/year
Reports on medical device adverse events and malfunctions

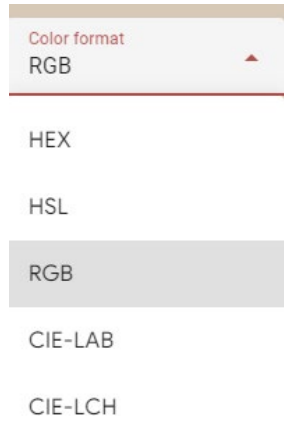
Pulse Oximeter

- An optical device that measures blood oxygen saturation level
- Regulated as Class II medical devices in the U.S.
- Widely used in the COVID19 pandemic
- However, research showed pulse oximeter performance may be affected by skin tones
- FDA is revising guidance to request human subjects with dark skin tones to be included in clinical trials
- **How to define dark skin tones?**

Monk Skin Tone (MST) Scale

- Ellis Monk, Harvard University
- MST has been used by Google in their products
  - 10 patches defined in CIELAB and RGB
  - 5 data formats provided for each patch
    - CIELAB = CIELCH: absolute standard color space
    - RGB=HEX=HSL: device-dependent values
- These patches are defined digitally
- There is no validated printed MST chart available to the public
- **How to print/validate an MST chart?**





https://skintone.google/

Considerations when making a color test target

1. **Reference**: How to define the target?

2. **Figure of merit**: How to evaluate the accuracy?

3. **Acceptance criteria**: How accurate do we need?

4. **Implementation**: How to print it?

1. Reference

Characteristics of the MST Scale

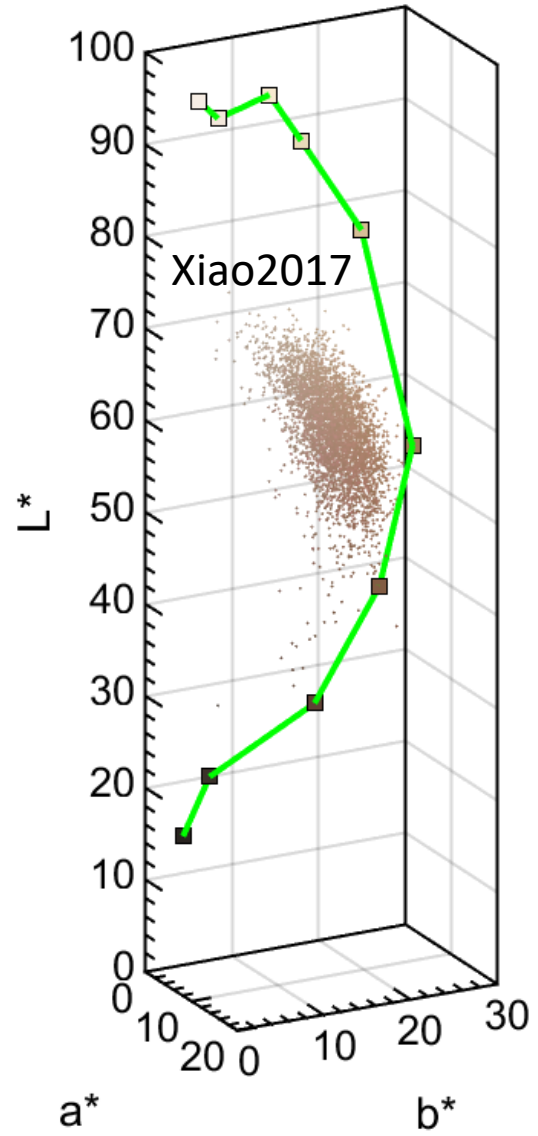
MST Characteristics

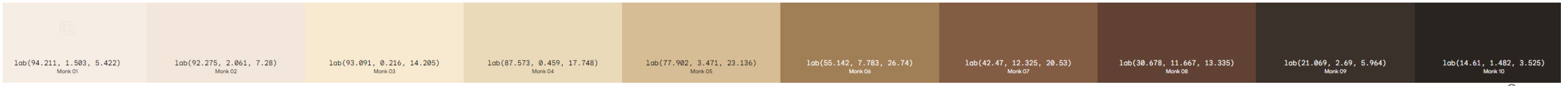
MST Level	L^*	a^*	b^*
1	94.2	1.5	5.4
2	92.3	2.1	7.3
3	93.1	0.2	14.2
4	87.6	0.5	17.7
5	77.9	3.5	23.1
6	55.1	7.8	26.7
7	42.5	12.3	20.5
8	30.7	11.7	13.3
9	21.1	2.7	6.0
10	14.6	1.5	3.5

Between	ΔE^*_{ab}
MST1 – MST2	2.74
MST2 – MST3	7.21
MST3 – MST4	6.56
MST4 – MST5	11.47
MST5 – MST6	23.44
MST6 – MST7	14.82
MST7 – MST8	13.83
MST8 – MST9	15.07
MST9 – MST10	7.01

- #1, #2, and #3 very bright
- #1 and #2 very similar
- #2 and #3 reversed in L*
- #10 very dark

- **Challenging to reproduce**





Previous work

- ***Variability of Printed Monk Skin Tone Scales May Cause Misclassification of Clinical Study Participants: Caveats On Printing***. Anesthesia & Analgesia 138.6 (2024): e43-e44.
- Tested 16 different printers
- Printed the MST charts using the device-dependent RGB values without color management
- Resulted in pronounced deviations from the target CIELAB values
- Recommended changing the MST reference values and proposed new values

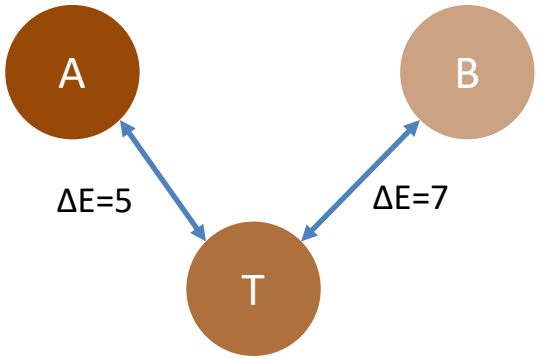
2. Figure of Merit

How to evaluate the accuracy?

Color matching vs 2AFC

- Matching a target color T with 10 MST colors

- Equivalent to a series of two-alternative forced choice (2AFC) trials
  - Initialize a pool with 10 MST colors
  - Randomly pick 2 colors, A and B, from the pool
  - Compare them with the target color, T
  - Determine the 2 color differences (**using ΔE = ideal observer**)
  - Discard the bad one; put the good one back to the pool
  - Repeat until only one left



3. Acceptance Criteria

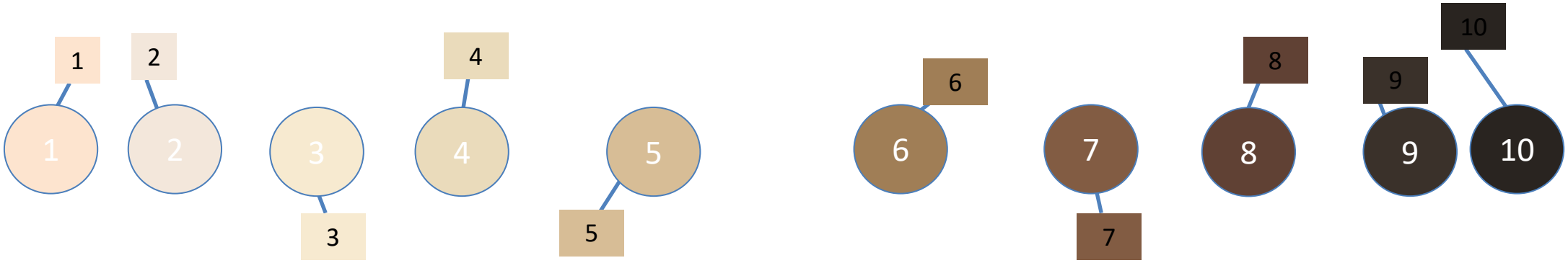
How accurate do we need?

Acceptance criteria

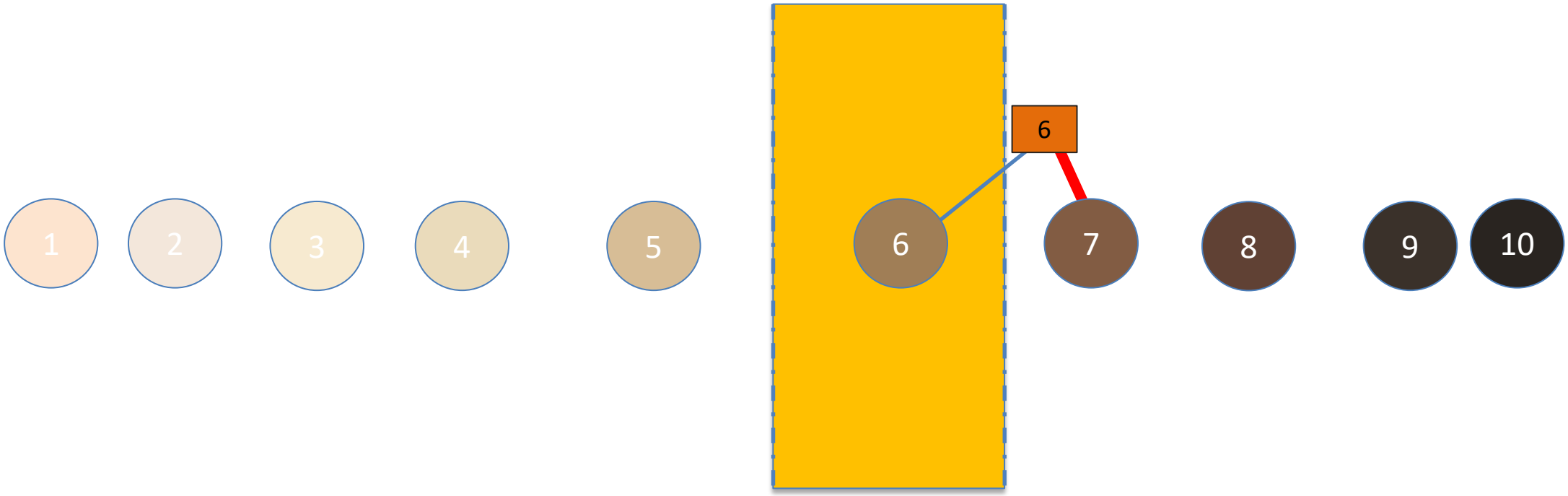
- *Correct classification (C-criterion)*
  - Matched MST# must be the intended MST#

- *Belongingness (B-criterion)*
  - No other MST# can match the intended MST# better

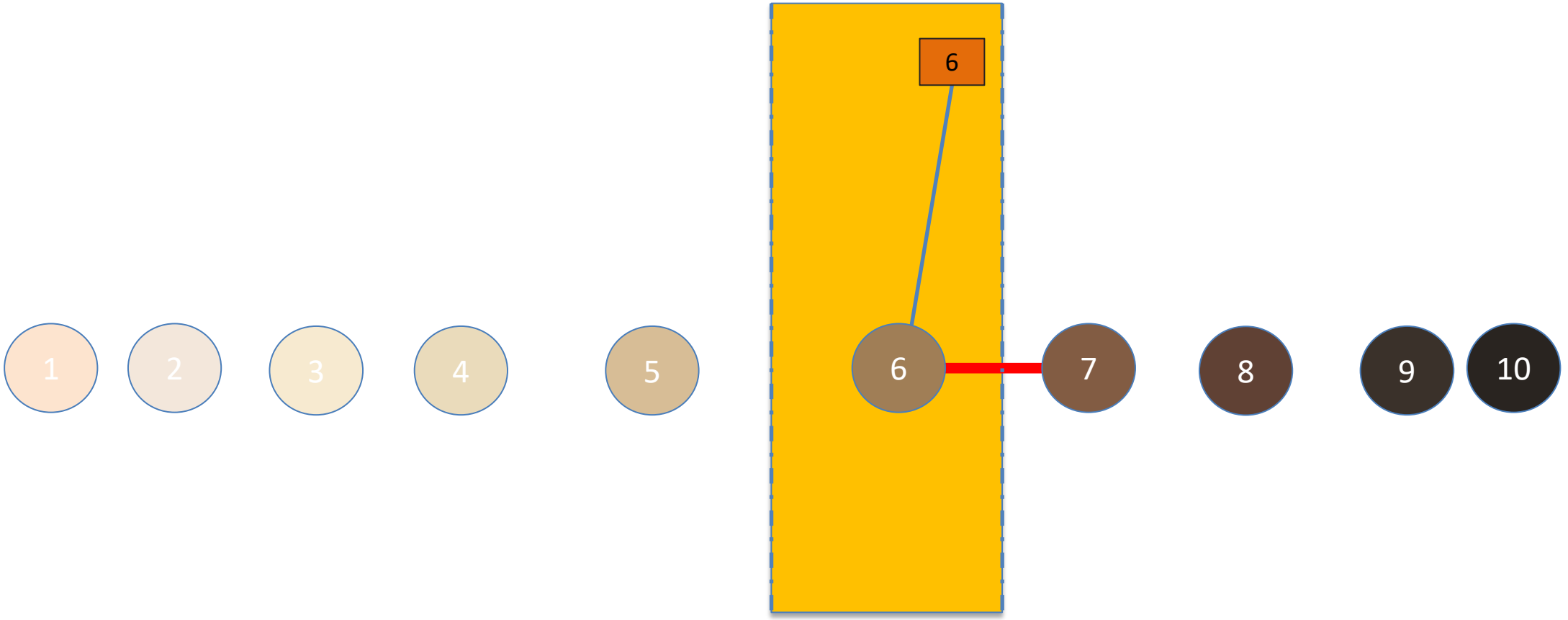
Correct classification criterion



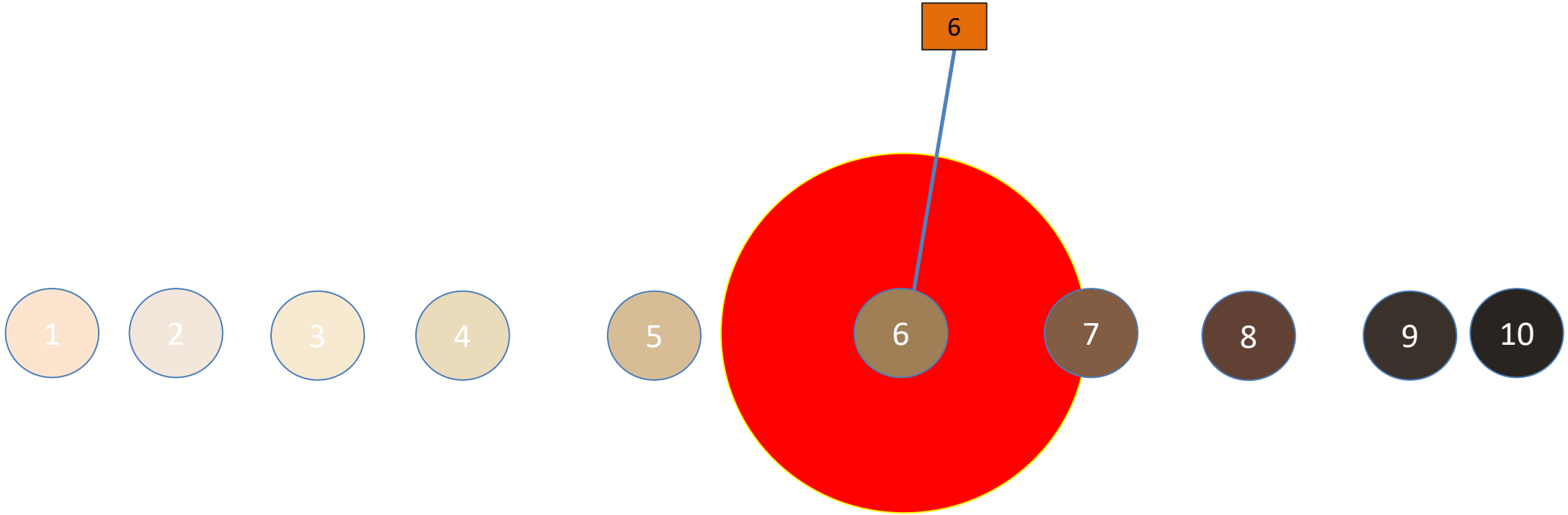
Correct classification criterion (C-criterion)



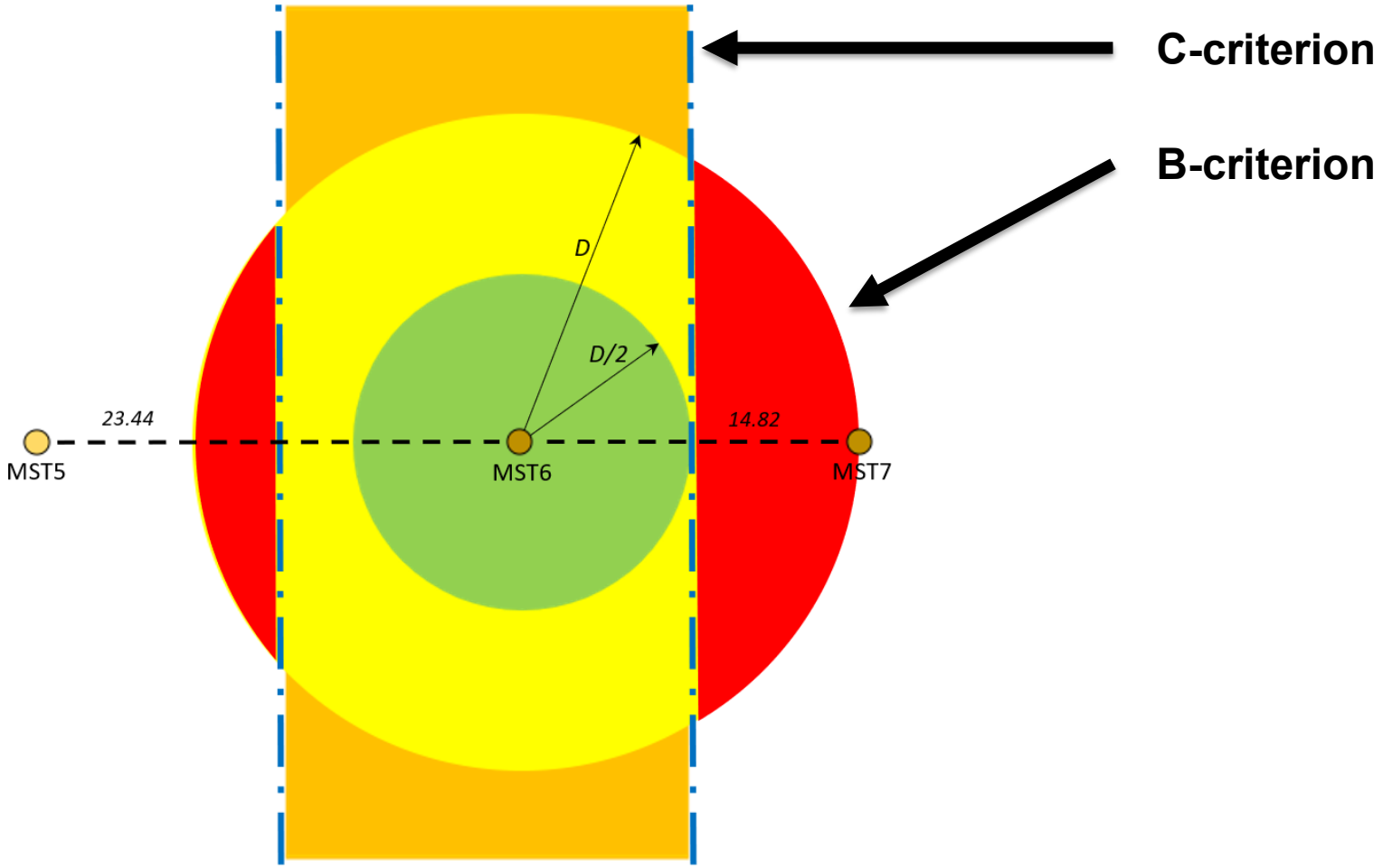
Belongingness criterion (B-criterion)



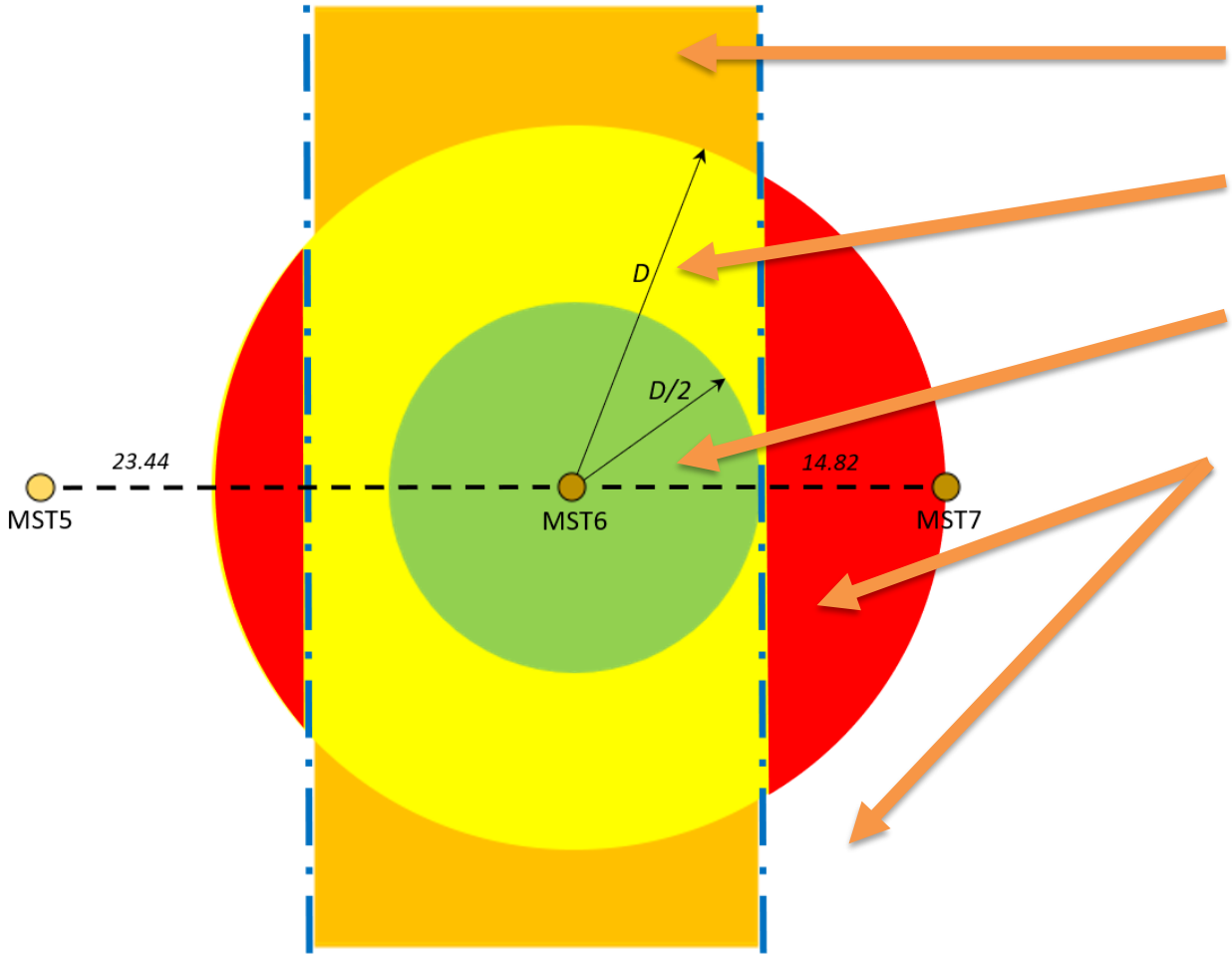
Belongingness criterion (B-criterion)



Combine B- and C-criteria

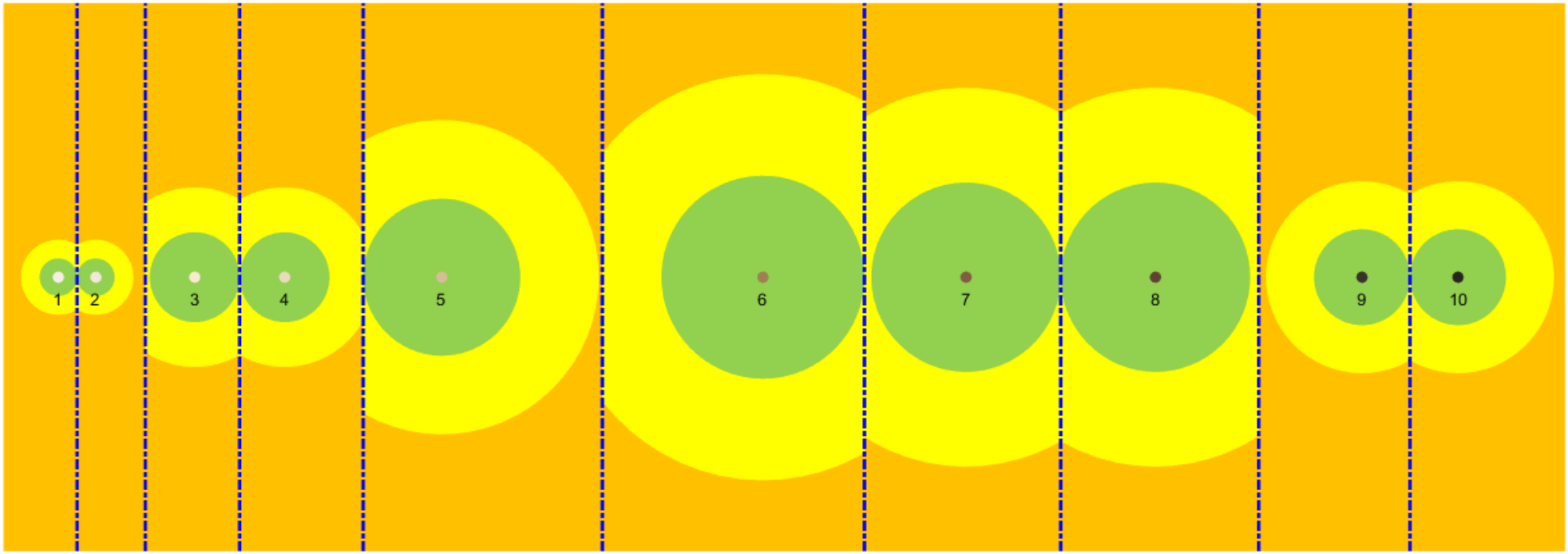


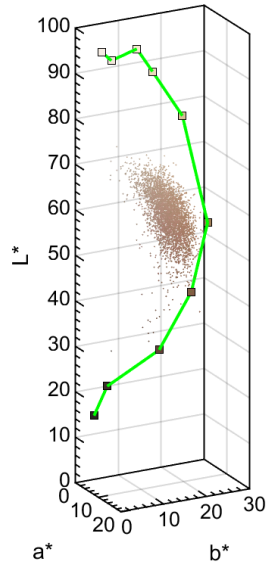
Grading system



Grade A	Meet both B-criterion and C-criterion; ΔE is bounded by $D/2$
Grade B	Meet both B-criterion and C-criterion; ΔE is bounded by D
Grade C	Meet C-criterion only; ΔE is greater than D
Grade F	Fail both B-criterion and C-criterion

Acceptance criteria for all 10 MST levels





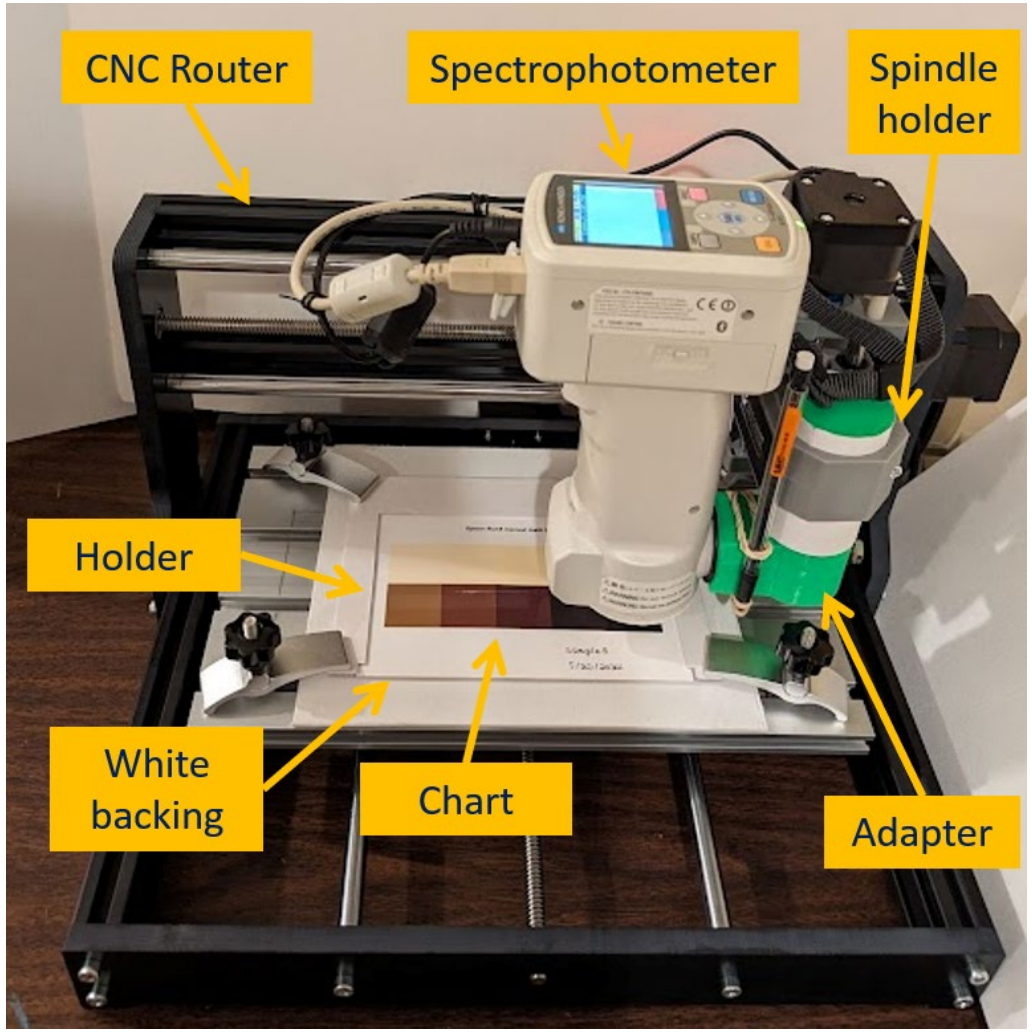
MST level i	$D(i)/2$	$D(i)$
1	1.37	2.74
2	1.37	2.74
3	3.28	6.56
4	3.28	6.56
5	5.73	11.47
6	7.41	14.82
7	6.91	13.82
8	6.91	13.82
9	3.50	7.00
10	3.50	7.00

4. Implementation

How to print an accurate MST chart

Measuring hardware

- Spectrophotometer
  - Minolta CM-700d
  - D65, de/8°
- Automated measurement
  - CNC router (US $200)
  - 3D-printed adapter
  - Matlab driving the meter and CNC router
- Time
  - Color gamut: 18 min / 121 patches x 6
  - Octal search: 6 min / 32 patches x 10

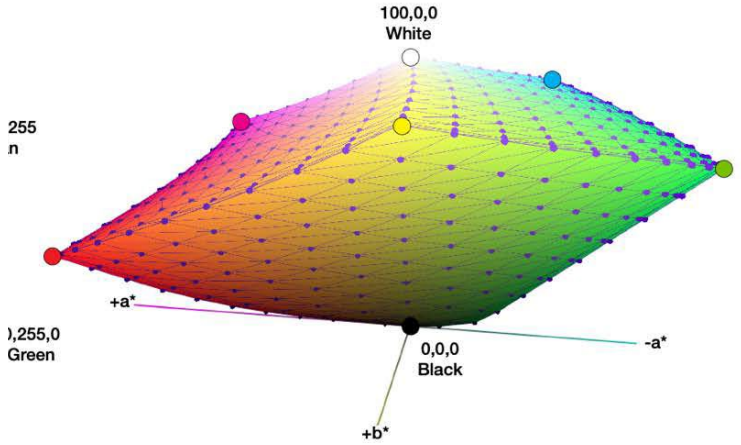


Printing method

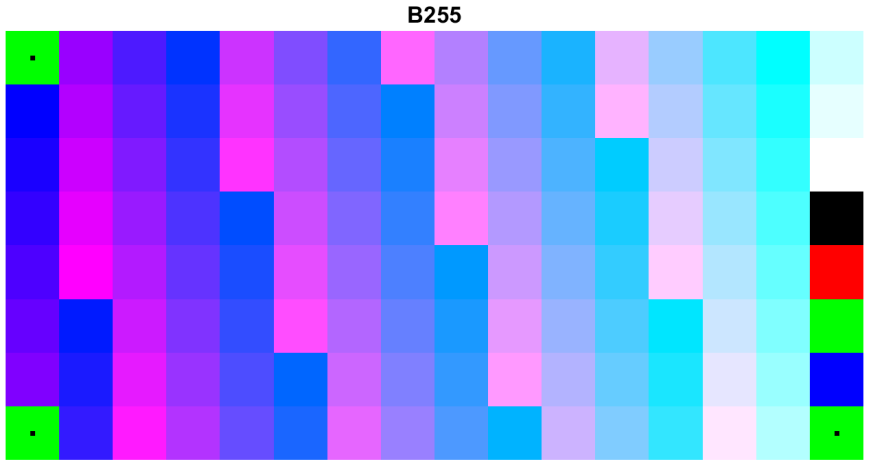
1. Color gamut check
2. Octal search

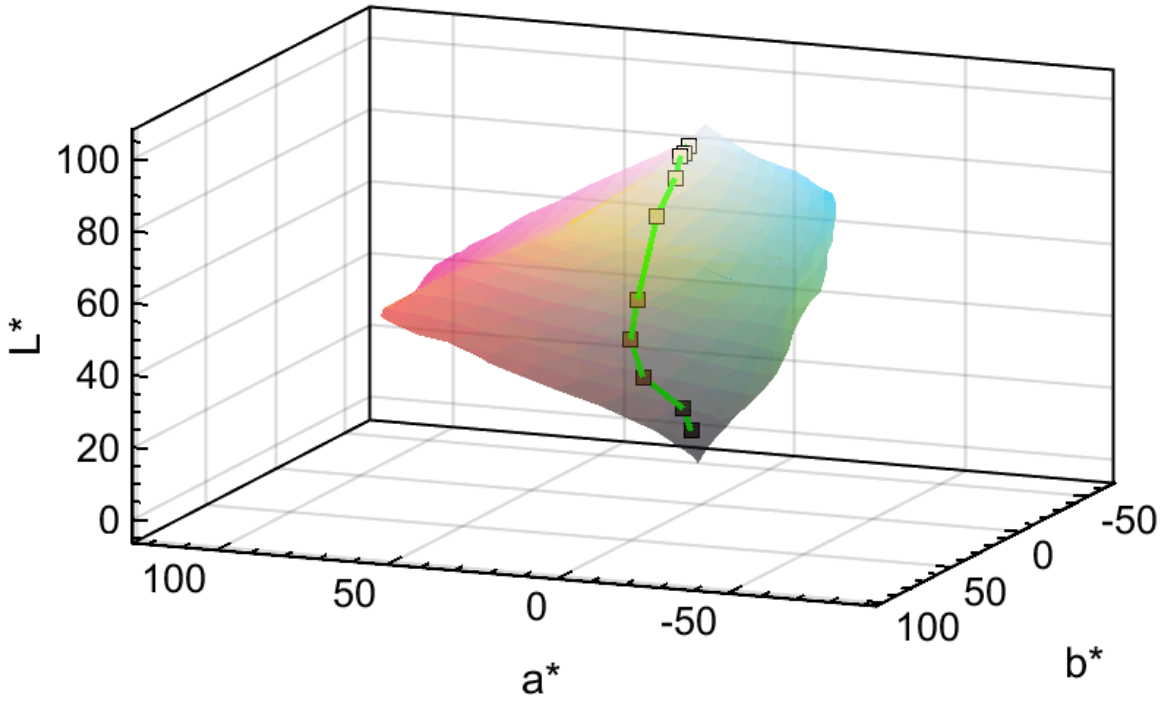
1. Color gamut check

- IEC 62977-2-1
  - 6 sides
  - 11x11 grid per side
  - 602 measurements



- 128 = 121 + 7 patches





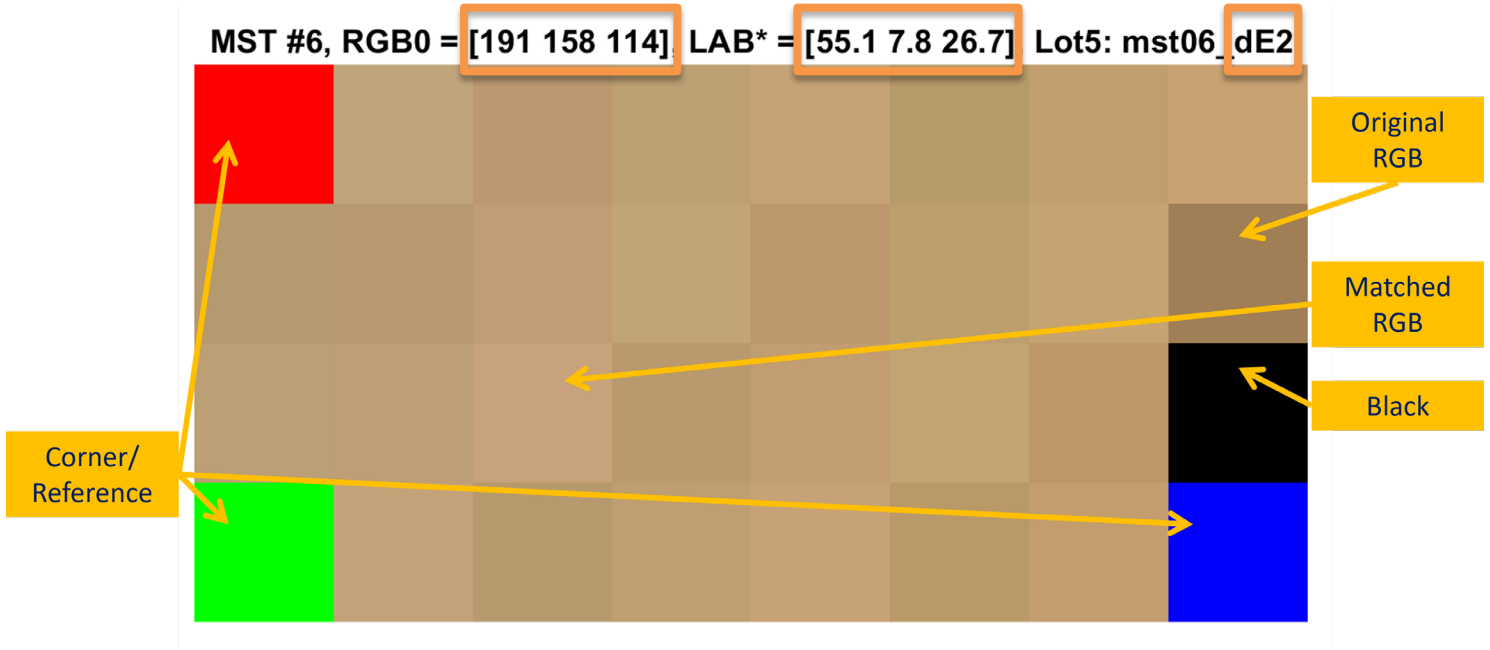
2. Octal search

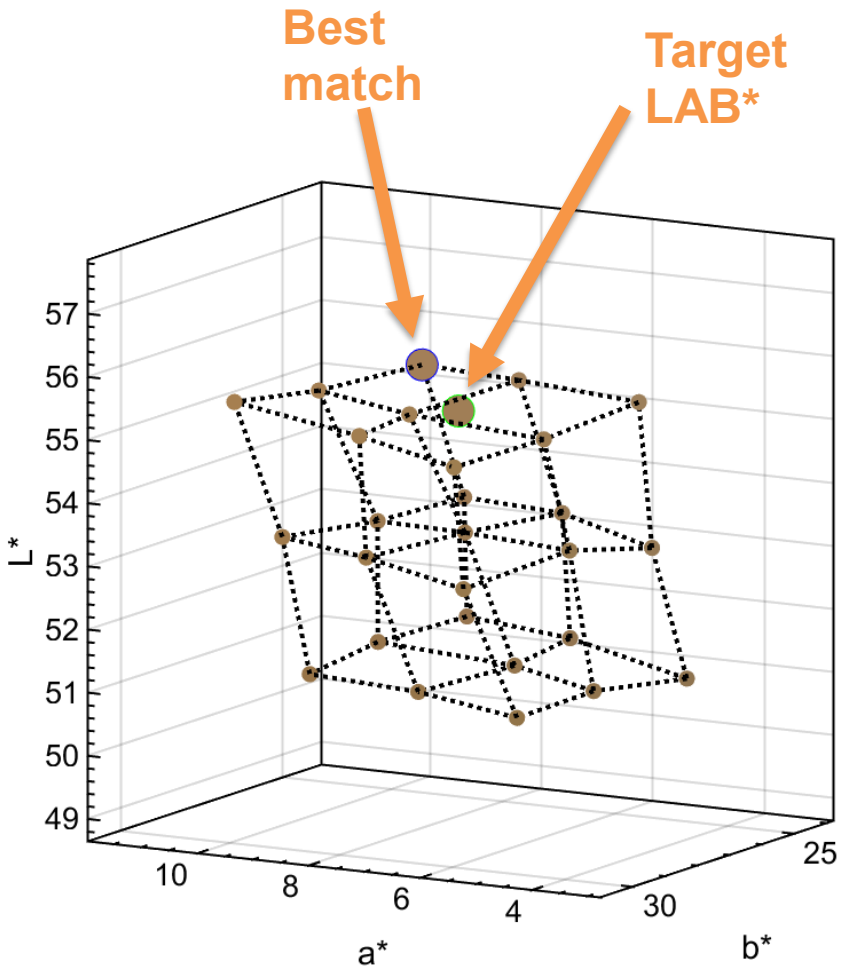
- Binary search
  - Divide a line segment into two
  - Calculate error of the mid point
  - Stop if a solution is found
  - Determine where the target is and repeat

- Octal search
  - **Divide a 3D cube into 8 sub-cubes with a 3x3x3 grid**
  - Calculate errors of 27 points
  - Stop if a solution is found
  - Pick the best match and repeat

Design of the octal search patterns

- 3 corners (RGB) + black + original
- 27 patches (3x3x3)





5. Case studies

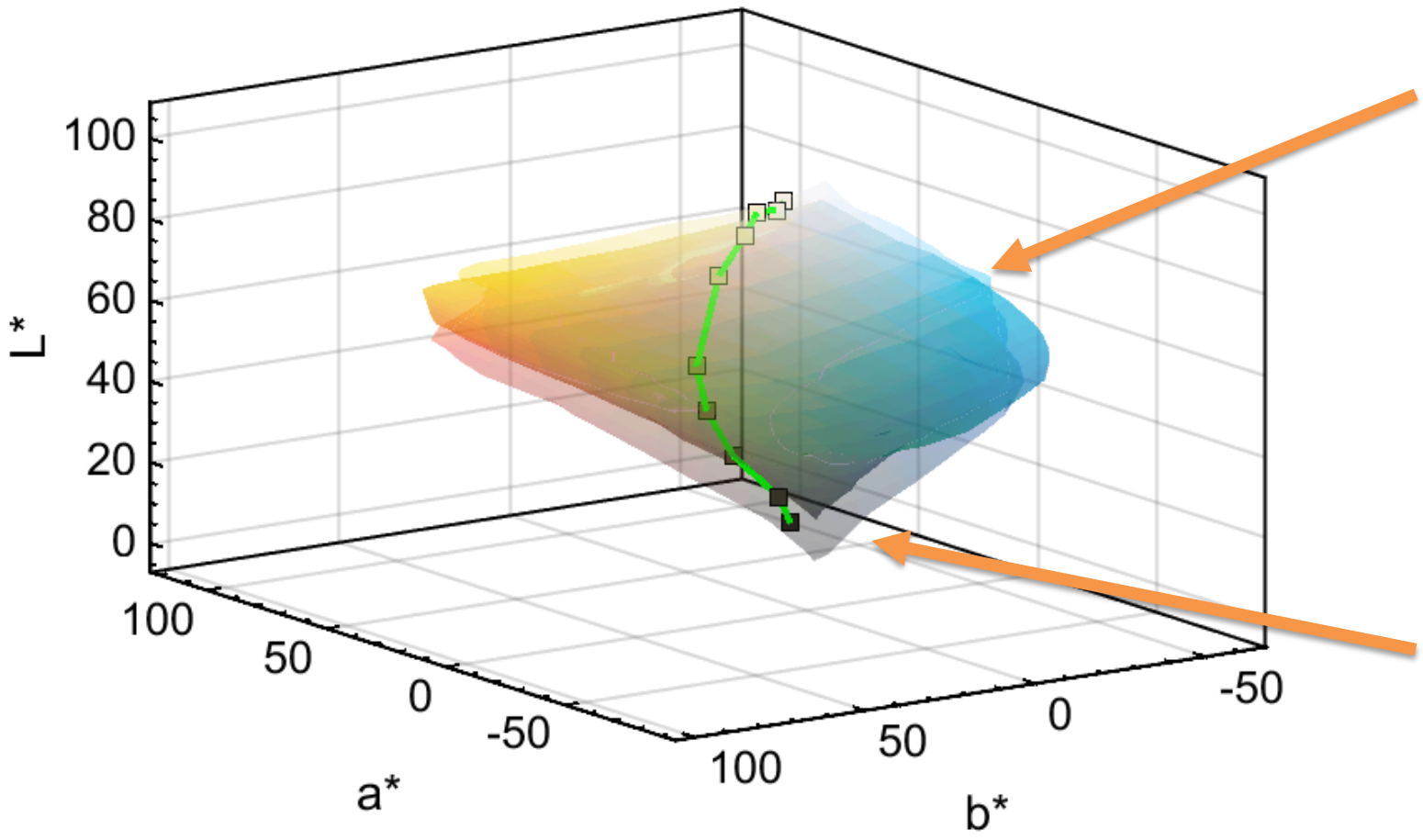
Epson ink jet printer + glossy paper

- The octal search stopped when all 10 patches achieved A-grade
- ΔE between 0.74 and 2.21
- $300 consumer-grade printer

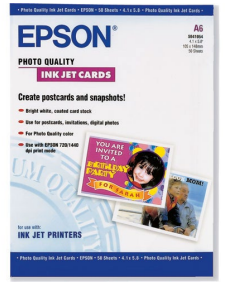
MST	Matched RGB	Measured CIELAB	ΔE^*_{ab}	ΔL^*	Δa^*	Δb^*	ΔC^*_{ab}	Δh_{ab}	ΔRGB	Grade
1	(254,251,230)	(93.60, 2.42, 5.95)	1.22	0.61	−0.92	−0.53	−0.80	6.64	16.25	A
2	(254,248,225)	(92.69, 2.68, 7.95)	1.00	−0.41	−0.62	−0.67	−0.82	2.82	21.12	A
3	(255,249,219)	(93.04, 1.93,13.21)	1.98	0.05	−1.71	0.99	0.86	7.44	20.25	A
4	(240,239,202)	(87.12, 1.58,17.74)	1.21	0.45	−1.12	0.01	−0.06	3.61	27.07	A
5	(229,214,175)	(77.37, 4.84,21.49)	2.21	0.53	−1.37	1.65	1.37	4.16	38.03	A
6	(191,158,114)	(55.83, 7.85,27.39)	0.95	−0.69	−0.07	−0.65	−0.64	−0.24	52.62	A
7	(163,115,093)	(42.95,12.43,21.08)	0.74	−0.48	−0.11	−0.55	−0.53	−0.45	47.90	A
8	(137,089,073)	(32.13,12.18,14.11)	1.72	−1.45	−0.51	−0.77	−0.92	−0.38	51.94	A
9	(090,076,055)	(21.76, 3.54, 6.27)	1.14	−0.69	−0.85	−0.31	−0.66	5.17	43.84	A
10	(056,061,035)	(15.73, 2.63, 3.97)	1.66	−1.12	−1.15	−0.45	−0.94	10.72	29.31	A

Epson ink jet printer + matte paper

- Same Ink jet printer, matte paper has smaller gamut
- Cannot cover MST1, MST9, and MST10



Matte



Glossy

Epson ink jet printer + matte paper

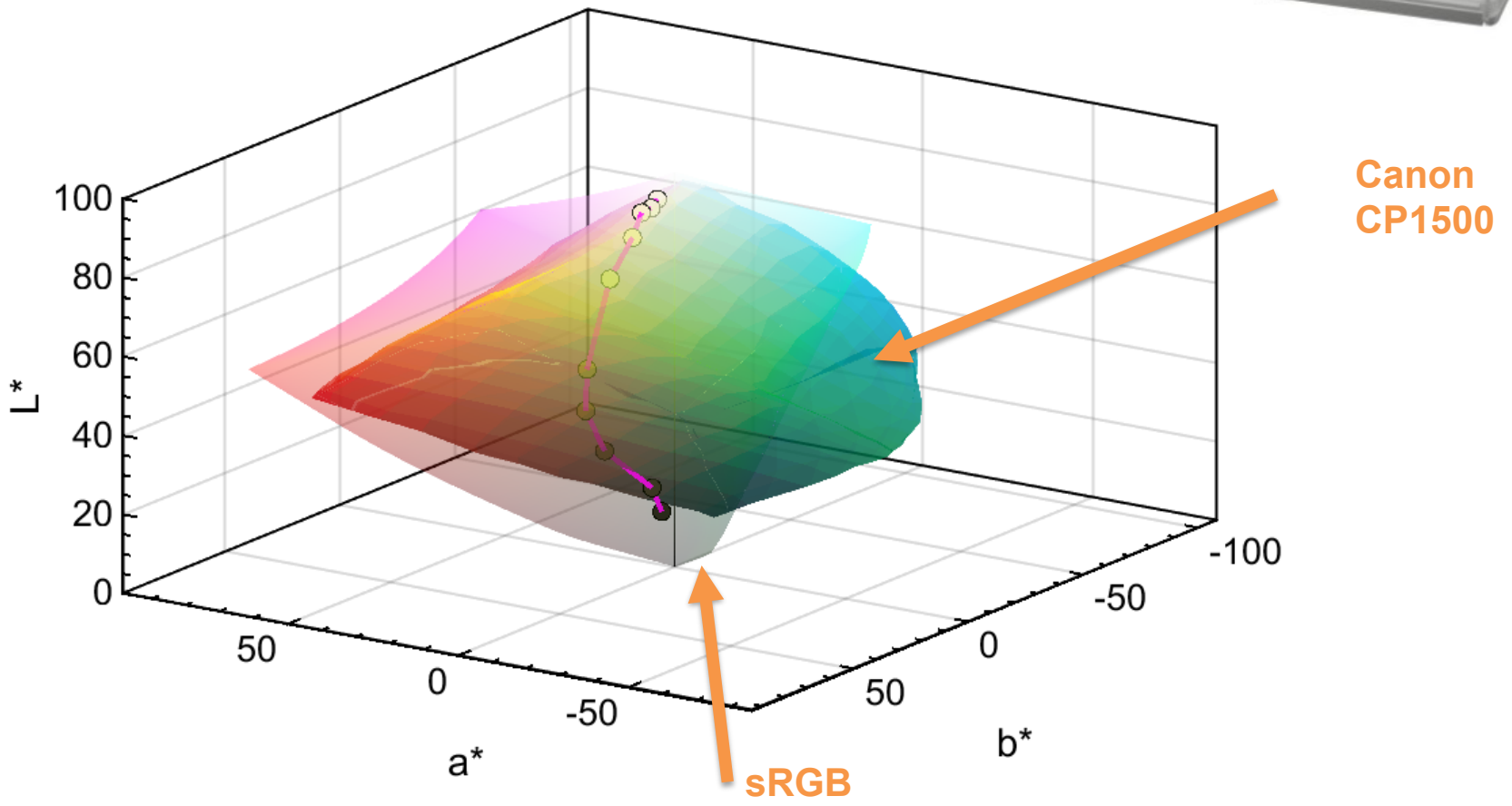
- F-grade: MST10
- B-grade: MST1 and MST9

Table VI. An F-grade MST chart printed with the Epson XP970 on matte paper.

Intended MST	Input RGB	Measured CIELAB	ΔE^*_{ab}	Grade	Incorrectly matched MST (ΔE^*_{ab})
1	(246,237,228)	(92.77, 0.55, 5.23)	1.74	B	–
2	(243,231,219)	(91.30, 2.60, 6.66)	1.27	A	–
3	(247,234,208)	(91.93,–0.42,13.95)	1.35	A	–
4	(234,218,186)	(85.83, 2.34,18.52)	2.68	A	–
5	(215,189,150)	(75.60, 3.78,22.49)	2.41	A	–
6	(160,126,086)	(53.36, 8.94,26.70)	2.13	A	–
7	(130,092,067)	(41.49, 9.62,20.37)	2.88	A	–
8	(096,065,052)	(32.76, 8.05,12.31)	4.30	A	–
9	(058,049,042)	(25.80, 1.52, 3.26)	5.57	B	–
10	(041,036,032)	(21.56,–1.16,–1.07)	8.74	F	**9 (8.03)**

Canon CP1500 portable photo printer

- Extended gamut in the green region vs sRGB
- Reduced gamut in the black region (MST10)
- Sharp tip in the white region (MST1, 2)



Canon CP1500 portable photo printer

- B-grade: MST1, MST2 and MST10

Table VII. A B-grade MST chart printed with the Canon CP1500.

Intended MST	Input RGB	Measured CIELAB	ΔE^*_{ab}	Grade
1	(248,230,207)	(90.20, 2.25, 4.94)	4.11	B
2	(243,231,219)	(90.86, 1.72, 1.67)	5.80	B
3	(255,228,186)	(90.29,−0.20,13.76)	2.87	A
4	(218,212,174)	(85.19, 0.03,16.46)	2.74	A
5	(195,181,135)	(74.65, 3.14,21.43)	3.69	A
6	(147,114,065)	(51.86, 8.47,23.91)	4.39	A
7	(131,082,047)	(41.21,12.38,18.23)	2.62	A
8	(093,057,033)	(29.84,10.41,12.00)	2.02	A
9	(060,049,027)	(21.97, 2.18, 2.80)	3.33	A
10	(049,037,025)	(17.19, 2.38,−1.80)	5.98	B

Recommended MST by previous work

- Recommended CIELAB values by previous work
- F-grade: MST3 and MST10
- C-grade: MST1, MST2, MST4, and MST9
- B-grade: MST5, MST6, MST7, and MST8

Intended MST	Measured CIELAB	ΔE^*_{ab}	Grade	Incorrectly matched MST (ΔE^*_{ab})
1	(88, 3, −1)	9.06	C	–
2	(86, 3, 1)	8.93	C	–
3	(86, 2, 7)	10.27	F	**2 (6.28)**
4	(81, 2, 10)	10.28	C	–
5	(73, 4, 18)	7.12	B	–
6	(53, 7, 21)	6.18	B	–
7	(43, 8, 14)	7.85	B	–
8	(33, 7, 8)	7.46	B	–
9	(27, 1, 2)	7.33	C	–
10	(24, 0, 0)	10.14	F	**9 (7.17)**

Verkruijsse, Wim, et al. "Variability of Printed Monk Skin Tone Scales May Cause Misclassification of Clinical Study Participants: Caveats On Printing." *Anesthesia & Analgesia* 138.6 (2024): e43-e44.

Canon laser printer

- Reproduce testing in previous work
- Laser printer without color management
- F-grade: MST3, MST4 and MST10
- C-grade: MST1, MST2, MST5, and MST9
- B-grade: MST6, MST7, and MST8
- Similar results

Intended MST	Measured CIELAB	ΔE^*_{ab}	Grade	Incorrectly matched MST (ΔE^*_{ab})
1	(86.79, 7.50, −3.82)	13.28	C	–
2	(84.98, 7.39, −2.25)	13.13	C	–
3	(85.95, 8.15, 2.19)	16.07	F	**2 (10.15)**
4	(80.40, 7.77, 3.71)	17.38	F	**2 (13.65)**
5	(74.26, 8.64,12.08)	12.74	C	–
6	(60.40,12.40,21.30)	8.86	B	–
7	(49.62,16.56,17.10)	8.99	B	–
8	(39.23,14.04,11.42)	9.08	B	–
9	(32.48, 3.80, 4.13)	11.61	C	–
10	(28.53, 2.13, 0.34)	14.29	F	**9 (9.36)**

Conclusion

- Without the right tool, manually making an accurate MST chart can be a tedious task that requires monastic dedication to accurate color reproduction
- Provided a free software tool, *Monastic Color Reproduction*, to take on this tedious task
- Used basic colorimetry to solve a practical problem
- By introducing this problem to the community, we hope more experts will contribute to solving color problems in the medical field

U.S. FOOD & DRUG ADMINISTRATION

Thank you