

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

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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 1.4 MILLION/year

Reports on medical device adverse events and malfunctions

Pulse Oximeter

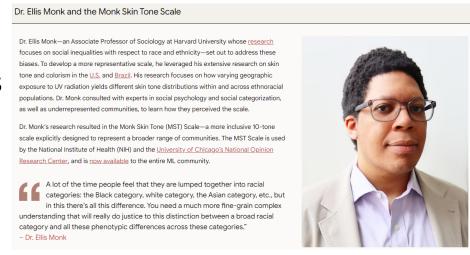


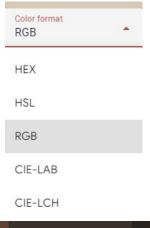
- An optical device that measures blood oxygen saturation level
- Regulated as Class II medical devices in the U.S.
- Widely used in the COVID19 pandemic
- However, research showed pulse oximeter performance may be affected by skin tones
- FDA is revising guidance to request human subjects with <u>dark skin tones</u> 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
- However, a printed MST chart is required for visual comparison
- How to print/validate an MST chart?





1ab (94.211, 1.503, 5.422) 1ab (92.275, 2.061, 7.28) 1ab (93.091, 0.216, 14.205) 1ab (87.573, 0.459, 17.748) 1ab (77.902, 3.471, 23.136) 1ab (55.142, 7.783, 26.74) 1ab (42.47, 12.325, 20.53) 1ab (30.678, 11.667, 13.335) 1ab (21.069, 2.69, 5.964) 1ab (14.61, 1.482, 3.525) Morit Of M

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

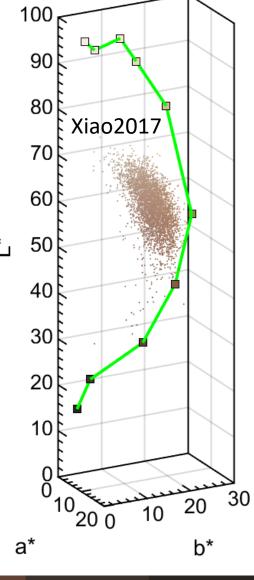
MST Characteristics

MST Level	L*	a*	<i>b</i> *
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







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

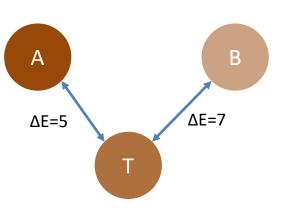


Matching a target color T with 10 MST colors





- 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

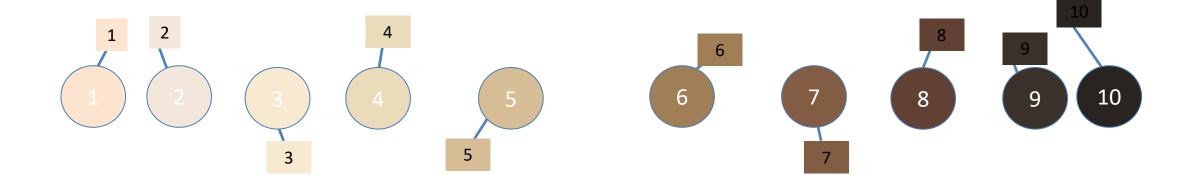


- Correct classification (C-criterion)
 - Matched MST# must be the intended MST#

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

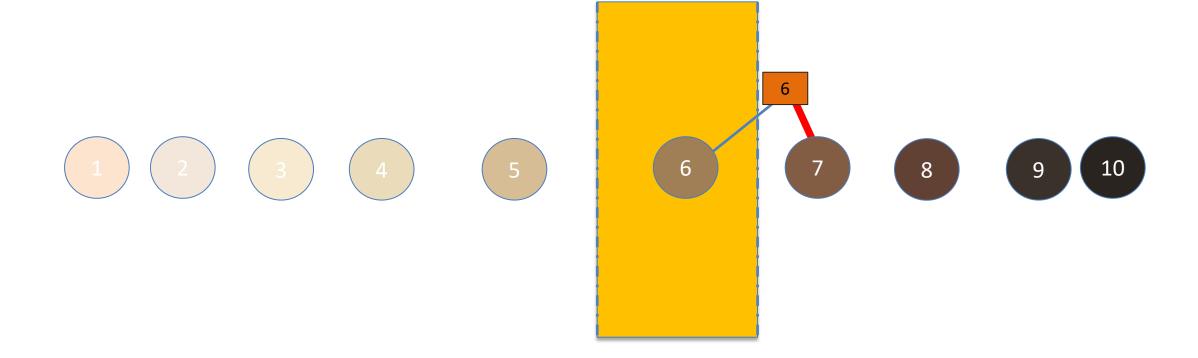
Correct classification criterion





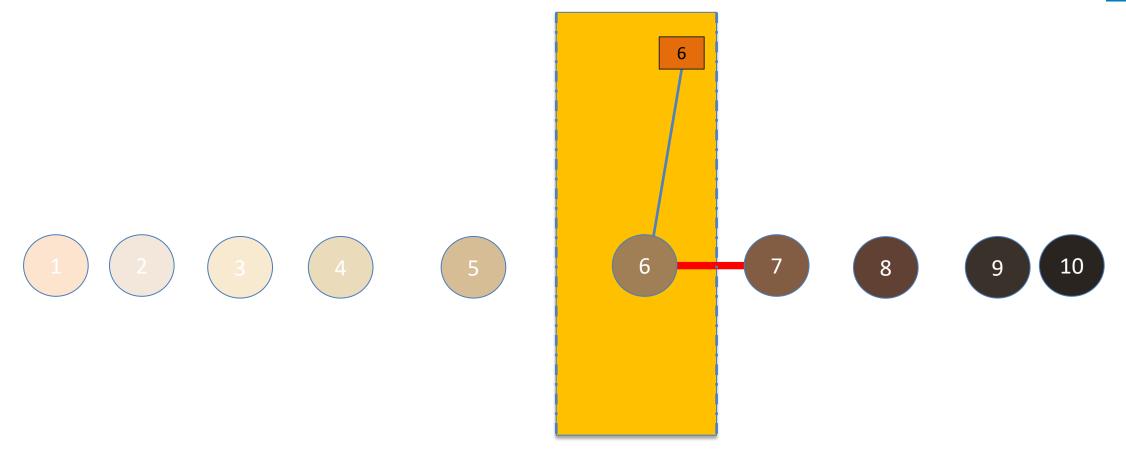
Correct classification criterion (C-criterion)





Belongingness criterion (B-criterion)

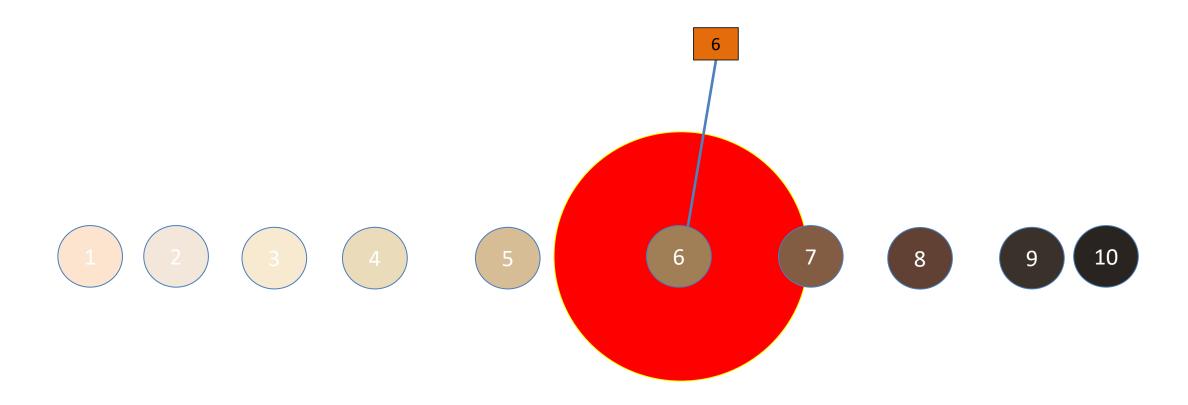




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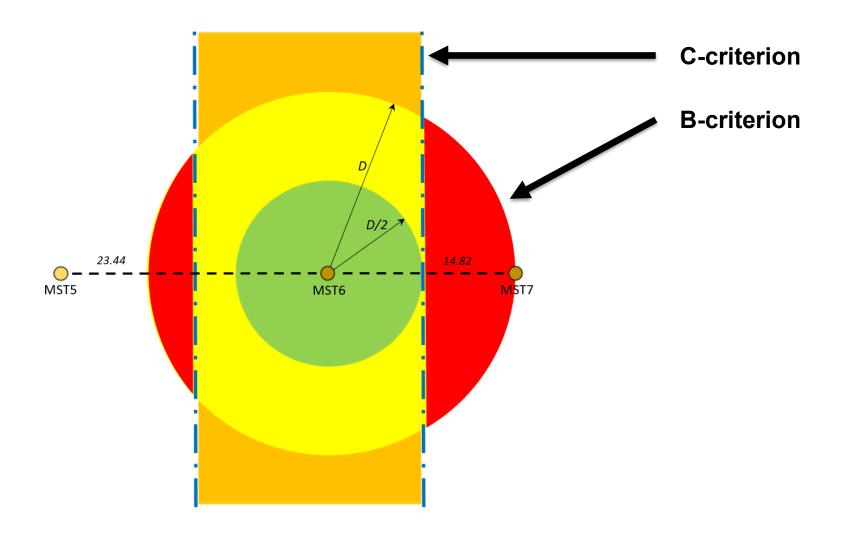
Belongingness criterion (B-criterion)





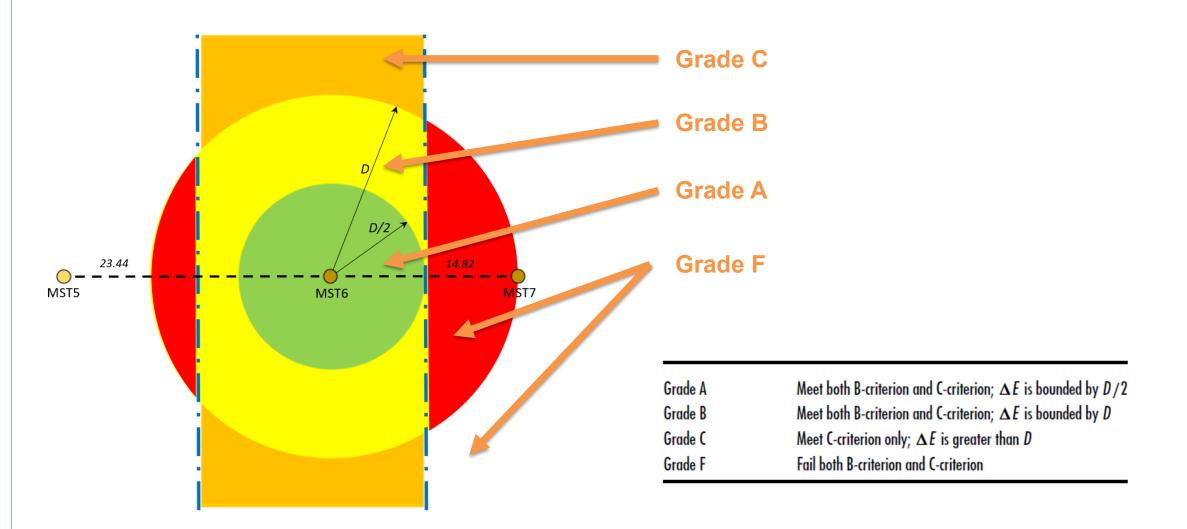
Combine B- and C-criteria





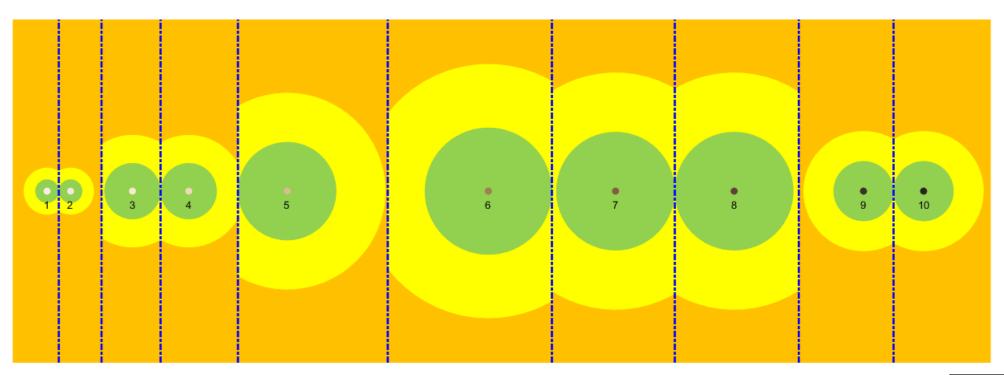
Grading system

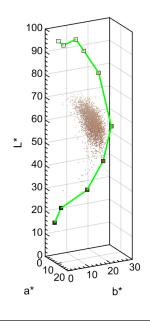




Acceptance criteria for all 10 MST levels







MST level <i>i</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	
		24	



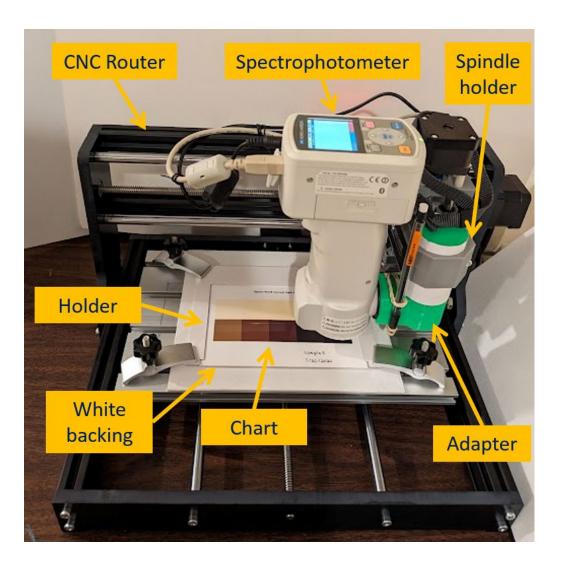
4. Implementation

How to print an accurate MST chart

Measuring hardware



- Spectrophotometer
 - Minolta CM-700d
 - o 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

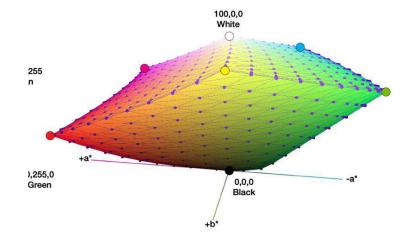


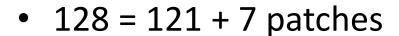
- 1. Color gamut check
- 2. Octal search

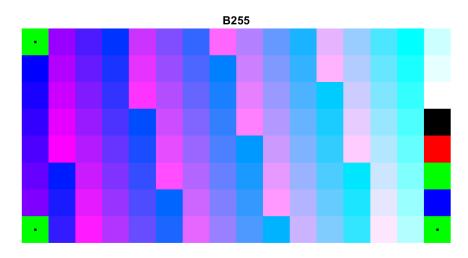
1. Color gamut check

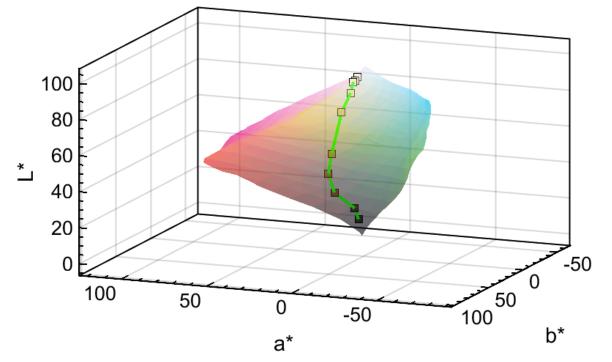
FDA

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









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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

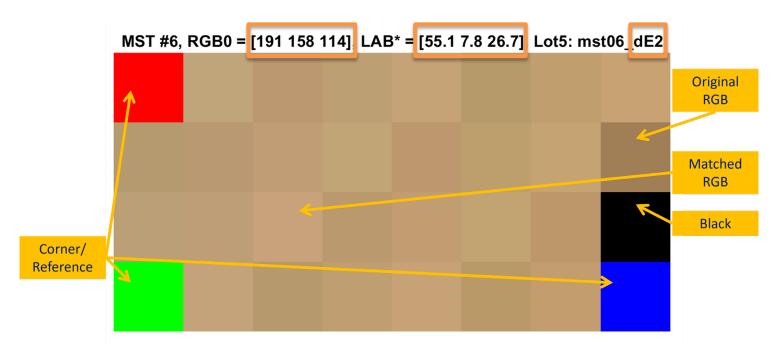
Octal search

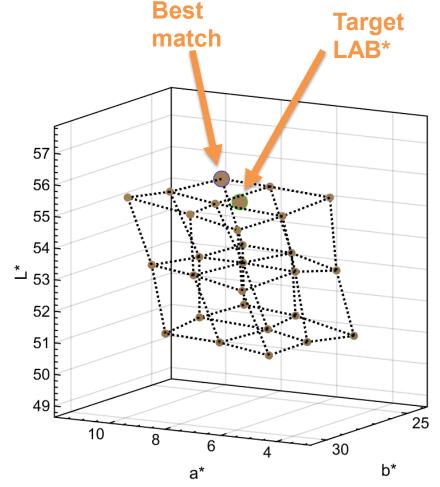
- Divide a 3D cube into 8 sub-cubes with a 3x3x3 grid
- Calculate errors of 27 points
- Stop if a solution is found
- Pick the best match and repeat

Design of the octal search patterns



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





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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



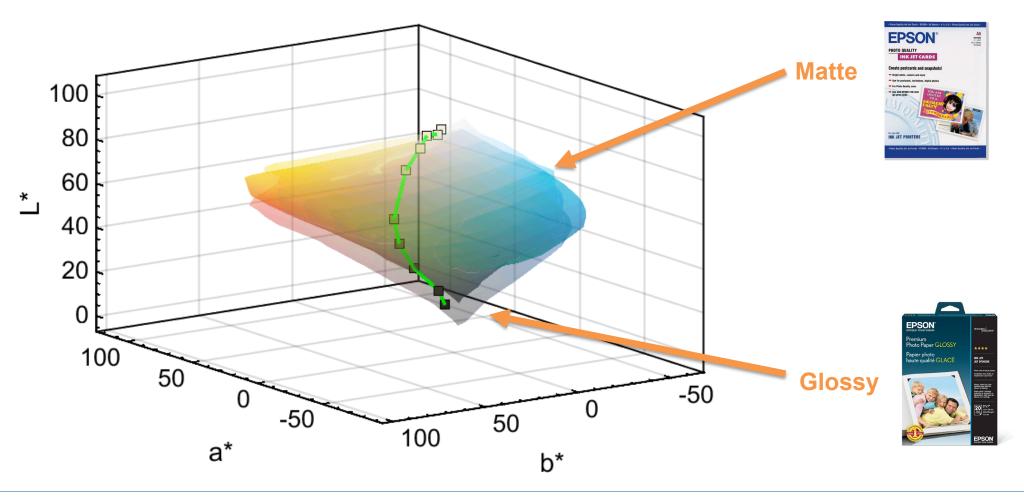


MST	Matched RGB	Measured CIELAB	ΔE_{ab}^*	ΔL*	Δa^*	∆ b*	∆(* ab	Δh_{ab}	△RGB	Grade
1	(254,251,230)	(93.60, 2.42, 5.95)	1.22	0.61	-0.92	-0.53	-0.80	6.64	16.25	A
2	(254,248,225)	(92.69, 2.68, 7.95)	1.00	-0.41	-0.62	-0.67	-0.82	2.82	21.12	Α
3	(255,249,219)	(93.04, 1.93, 13.21)	1.98	0.05	-1.71	0.99	0.86	7.44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

Epson ink jet printer + matte paper

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





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.

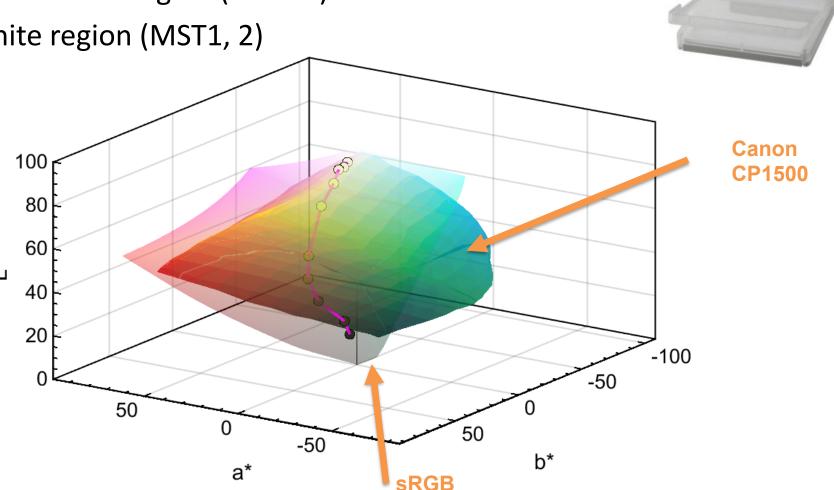
Intended MST	Input RGB	Measured CIELAB	ΔE_{ab}^*	Grade	Incorrectly matched MST (ΔE_{ab}^*)
1	(246,237,228)	(92.77, 0.55, 5.23)	1.74	В	_
2	(243,231,219)	(91.30, 2.60, 6.66)	1.27	A	_
3	(247,234,208)	(91.93, -0.42, 13.95)	1.35	A	_
4	(234,218,186)	(85.83, 2.34, 18.52)	2.68	A	_
5	(215,189,150)	(75.60, 3.78, 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	В	_
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	В
2	(243,231,219)	(90.86, 1.72, 1.67)	5.80	В
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	В

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	В	_
6	(53, 7, 21)	6.18	В	_
7	(43, 8, 14)	7.85	В	_
8	(33, 7, 8)	7.46	В	_
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	(_
6	(60.40,12.40,21.30)	8.86	В	_
7	(49.62,16.56,17.10)	8.99	В	_
8	(39.23,14.04,11.42)	9.08	В	_
9	(32.48, 3.80, 4.13)	11.61	(_
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, for printing accurate MST charts
- 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



Thank you