



Medical Imaging Working Group

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Zamdorfer Straße 40
81677 München
Germany
16 February 2016

Craig Revie, MIWG chair, opened the meeting at 13:15 and introduced the agenda as follows:

1. Update on Petri Dish calibration
2. Color measurements through band-sequential LED spectral imaging
3. Review of the updated ICC White Paper for displays and next steps
4. FDA draft guidance Display Devices for Diagnostic Radiology
5. Comparing GSDF with Whittle luminance scales
6. Update on skin colour database activities
7. Medical photography best practices white paper update
8. ICC profiles for colour vision deficient observers

1. Update on Petri Dish calibration

Jérémie Pescatore presented a proposal for a set of guidelines for spectral imaging of Petri plates [see attached]. He summarised the user needs in this area, and described the importance of chromogenic plates and the colour of the imaging back light in colony identification. His goal was to minimise metamerism through reliable spectral information, with good repeatability and minimal imaging system dependence.

The project had been established in MIWG 12 months ago. The focus was on measurement and control – display colour was being dealt with in other activity areas. He showed a draft White Paper [see attached]. This included a fixed gamut for displaying information to microbiologists, and also defined the background, mass and isolates that are the primary areas of interest when reading Petri plates.

He had used principal component analysis to reconstruct spectra from measurements, and proposed to store the data using the CGATS measurement file format, using the range 390-730nm. Fluorescence is not currently handled.

It was suggested that he could use iccMAX, with a LUT to transform from the input channels to spectra, and then perform a visualisation. Max Derhak agreed to discuss this, and the possible use of Material Connection Space and Material Identification profiles with Dr Pescatore.

It was also suggested to coordinate regarding the data format with Kaida Xiao, who is developing a database for skin colour measurements.

It was agreed to circulate the draft guidelines for review by the working group.

2. Color measurements through band-sequential LED spectral imaging

Michael Carstensen of Videometer presented information about band-sequential LED measurement technology [see attached]. He showed the problem case of sorting mink pelts so they can be combined in a garment. The Videometer system uses a series of LED sources triggered sequentially, with intensities adjusted to optimise the fit to D65 XYZ. The system gives good performance on the ColorChecker, and supports measurement of samples outside the sRGB gamut.

He showed examples of applications in brewing, butchery, milk powder and skin colour. The system can provide NIR sensitivity at a much lower cost than InGaAs IR. Measurement systems are typically customised for the particular requirement of the industrial application.

The HIPS file format is used for spectral data, and C and Matlab readers are provided to customers. Systems are calibrated to absolute reflectance, traceable to NIST. Videometer systems can also measure transmission, with darkfield, front and backlight options.

The LED intensities can be adjusted to give optimal signal-to-noise ratio. Due to the lack of LEDs at 550nm with good stability and sufficient power, adjacent wavelengths 540 and 570nm are used. The sensor is silicon with sensitivity over 230-100, but the optics limit the practical range to 360-1000nm. The sensors are 6 and 9.1 megapixel Sony CCDs, capturing 12-14 bits and storing in a 16-bit format. Fluorescence information can be obtained through additional filtering. The usual implementation has four filters, but for particular applications additional specific filters may be used.

3. Review of the updated ICC White Paper for displays and next steps

Tom Kimpe summarised White Paper 44 [see attached] and comments received [see attached]. The document had been balloted as an ICC White Paper but had not passed owing to insufficient votes. It had been discussed at the Steering Committee meeting in Munich, where it was agreed that it was important not to position the guidelines as requirements. Chris Bai of BenQ noted that in AAPM there were different levels of tolerance for GSDF, and suggested a secondary recommendation in the guidelines of 20% for grayscale (GSDF) and 25% for colour (CSDF). Dr Kimpe responded that the recommended 10% was not a hard specification but was a reasonable number, since higher deviations will result in banding artefacts.

One recommendation in the document was to disable the CMM if it performs auto-update of calibration; it was agreed that this was only needed if there was a front sensor on the display rather than just an internal backlight sensor. The recommendation only addressed auto-calibration, which can make the display unstable. It was confirmed that the recommendation is to use CSDF rather than ICC for pseudo-colour images, and ICC for 'true-colour' images.

It was agreed that Kimpe, Bai, Revie would review and update the document by the end of February to allow time for a vote at the next Steering Committee meeting.

4. FDA draft guidance Display Devices for Diagnostic Radiology

The meeting reviewed the FDA document [see attached]. It specifies how to describe a display device for FDA evaluation, with more stringent requirements for mammography. It provides a number of descriptors for technical attributes (mostly unrelated to colour), and physical lab testing. Dr Kimpe observed that the document is guidance and not binding.

Mr Revie suggested a telecon to discuss the colour-related recommendations. Martin, Nagashima-san, Bai, Kimpe, Pescatore and Vogh agreed to participate and provide comments.

5. Comparing GSDF with Whittle luminance scales

Phil Green presented a summary of recent work by his student Kwame Baah on luminance functions for grayscale displays [see attached]. A psychophysical experiment had been performed in which 23 observers judged perceptibility thresholds of neutral samples centred on three different gray levels, for three different peak white luminances. The Whittle function being discussed by CIE TC1-93 performed very similarly to the GSDF function in predicting the visual results, with a small but not significant improvement by the Whittle function at very low luminances.

6. Update on skin colour database activities

Phil Green presented an update on behalf of Kaida Xiao [see attached]. Dr Xiao had emphasised the importance of skin colour measurement, and noted some issues around its measurement. He showed the range of skin colours in CIELAB and in spectral reflectance for four different ethnic groups, together with the variability. The measurements are complete and the data will be posted on the ICC web site when it is published in a peer-reviewed publication in April

7. Medical photography best practices white paper update

John Penczek presented the latest version of the medical photography guidelines [see attached]. He emphasised that the goal was to improve the quality of medical photography, and had modified the title to better reflect this. It was intended to minimise colour errors by collecting best practices currently used in professional photography. The guidelines were intended to apply to a wide range of digital cameras.

Dr Penczek showed additions and changes made since the last revision. He asked the meeting for help in locating suitable clinical images. Other suggestions included the need for an assessment of calibration accuracy using a test data set; and setting a tolerance of around 5 in CIELAB ΔE^*_{ab} (or possibly less). Dr Po-Chieh Hung had recommended following the terminology of ISO 17321, and he was asked to provide further input to the document and especially the workflow diagram. Dr Penczek agreed to consider the request for an annex giving recommendations for situations where it is not feasible to follow all the guidelines – such as the illumination recommendations in field work. This might be in the form of a simple checklist.

Dr Penczek concluded by summarising the status and draft outline, and indicated that he would ask other contributors to work on the sections they had undertaken to provide with a target of 2 months. He indicated he would seek publication in a peer-reviewed journal such as J. Digital Imaging, and Dr Efthimia Bilissi agreed to investigate and report back on possible publication channels.

8. ICC profiles for colour vision deficient observers

Phil Green presented recent work on using ICC profiles to generate transforms for colour deficient observers [see attached]. The work was also being presented at the Electronic Imaging conference in San Francisco. Both simulation and Daltonization transforms were described, and profiles had been made and tested using ICC v4 and iccMAX. Mr Revie asked whether the transforms could be made available for other tools such as Gimp and ImageJ.

Mr Revie thanked all the presenters, and the attendees for their participation. The meeting closed at 5:10pm.

Action items

MIWG-2016-01 Send Petri plate imaging guidelines for review by MIWG (Pescatore)

MIWG-2016-02 Edit WP44 and circulate for review by end February (Kimpe, Bai, Revie)

MIWG-2016-03 Circulate revised WP44 for member review ending before next steering committee meeting (Green)

MIWG-2016-04 Circulate draft recommendation on display devices for radiology to members (Revie)

MIWG-2016-05 Provide comments on draft recommendations on display devices for radiology to Revie (Martin, Nagashima-san, Bai, Kimpe, Pescatore, Vogh).

MIWG-2016-6 Consider providing annex for white paper on medical photography describing some basic steps that can be taken in situations where full guidelines cannot be followed (Penczek)

MIWG-2016-7 Provide further input on medical photography guidelines and workflow figure to Penczek (Hung)

MIWG-2016-8 Request input from contributors with two months target for submissions (Penczek)

MIWG-2016-9 Investigate possible publication channels for guidelines (Bilissi)

ICC Medical Imaging Working Group

Munich

16th February 2016

What is unusual about this equation?

$$\frac{(12 + 144 + 20) + (3 \times \sqrt{4})}{7} + (5 \times 11) = 9^2 + 0$$

What is unusual about this equation?

$$\frac{(12 + 144 + 20) + (3 \times \sqrt{4})}{7} + (5 \times 11) = 9^2 + 0$$

English translation:

A dozen, a gross, and a score


Plus three times the square root of four

Divided by seven

Plus five times eleven

Is nine squared and not a bit more.

ICC MIWG ICC web page



International Color Consortium
*MAKING COLOR SEAMLESS BETWEEN
DEVICES AND DOCUMENTS*

ABOUT ICC
RESOURCES
INFORMATION
MEMBERS
GETTING STARTED
V4

ICC: EVENTS:

[All ICC Events](#)

2016

[ICC Meetings - Munich](#)

[2016 ICC DevCon](#)

[Display & 3D print, Taipei 2016](#)

2015

[iccMAX Webinar April 22](#)

[Medical Imaging Experts Day Mar 4](#)

[Other ICC Medical Imaging meetings](#)

[NPES-ICC Color Management Conference Feb 12](#)

[Upcoming ICC Meetings](#)

2014

[ICC Developer Conference: iccMAX](#)

ICC Medical Imaging Working Group

The Working Group arose out of the **Summit on Color in Medical Imaging** held in Silver Spring, Maryland in May 2013. It exists to enable and promote the correct and effective use of ICC color management for medical imaging.

Current activities:
[Calibration slide for histopathology](#)
[Medical RGB color space - mRGB / dRGB](#)
[Color eye model](#)
[Best practices for digital color photography in medicine](#)
[Colour support for mobile devices](#)
[Framework for multispectral imaging](#)
[Petri plate calibration](#)
[Imaging and reproduction of skin](#)
[DICOM camera raw support and EXIF tags](#)
[Open source reference implementation](#)
[Best practice papers for colour in DICOM](#)

[Summary of all MIWG work items](#)

Upcoming MIWG meetings

Date	Location	Topic
16 February 2016	Munich	Full WG meeting

Details of meetings will be posted when available. If you wish to participate in a meeting, please contact the [ICC Secretary](#)

Previous meetings
[Meetings and minutes](#)
[Action items](#)

SEARCH ICC:

GO

Got a question about ICC Profiles or colour management?

[Ask Phil...](#)

ICC: LIVE TOPICS:

- [iccMAX](#)
- [iccMAX Reference Implementation](#)
- [Research fund](#)
- [ICC Medical Imaging Working Group](#)
- [Display calibration](#)
- [New PRMG-based exchange profile for digital print](#)
- [Profiling tools](#)
- [ICC Profile Registry](#)
- [sRGB profiles](#)
- [ICC user forum](#)
- [Membership benefits](#)
- [What is an ICC Profile?](#)

ICC MIWG Working group meeting

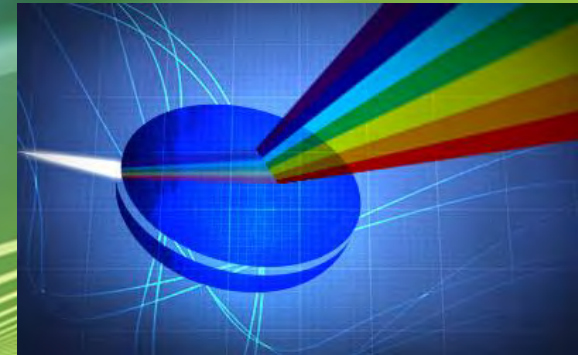
Tuesday 16th February, 13:00-16:30

- | | | |
|-------|--|--------------------|
| 13:00 | 1. Petri Dish Calibration | Jérémie Pescatore |
| 13:45 | 2. Color measurements through band-sequential LED spectral imaging | Michael Carstensen |
| 14:30 | 3. Review of the ICC White Paper for displays and next steps | Tom Kimpe |
| 14:55 | 4. FDA draft guidance Display Devices for Diagnostic Radiology | |
| 15:00 | Coffee | |
| 15:15 | 5. Comparing GSDF with Whittle luminance scales | Phil Green |
| 15:35 | 6. Update on skin colour database activities | Kaida Xiao |
| 15:55 | 7. ICC profiles for colour vision deficient observers | Phil Green |
| 16:25 | 8. Medical photography best practices white paper update | John Penczek |
| 16:40 | Finish | |

Spectral Characterization for Microbiology Imaging

« Guideline » Proposal

MIWG ICC Meeting Munich 16th February 2016



PIONEERING DIAGNOSTICS

Jeremie Pescatore (*Imaging System Design Architect*)

bioMérieux Contributors :

Frederic Pinston & Denis Leroux (innovation unit)

Corine Fulchiron & Delphine Archeny (clinical unit)

Eric Laloum (industry unit)



■ **microBiology Imaging :**

- *Main Application : Clinical Laboratory Automation*
- *Imaging User Needs : « reminder »*
- *Imaging System Requirement : « reminder »*
- *Imaging Calibration : Why and How ? « reminder »*

■ **MIWG involvement :**

- *Petri dish imaging Scope*
 - *Spectral Characterization Guideline Proposal*
 - *Spectral Knowledge : Data Interoperability*
-

Microbiology (or Petri Dishes) Imaging

PIONEERING DIAGNOSTICS



Lab Automation in μ biology : an example



4 UNLOADING AND
DISCARDING

3 INCUBATION

2 SAMPLE RECORDING
(Image Acquisition)

1 SAMPLE
STREAKING

5 SCREENING (Image Display) ,
READING AND PICKING

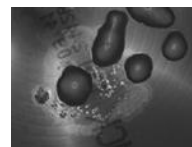
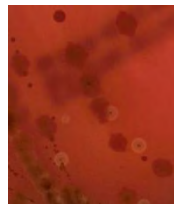


Imaging User Needs



Virtual Reading

- Detect growing colonies of a **minimum size**
- Reliably distinguish different **types** of colonies on the same plate
- Distinguish colonies by **their color**
- Detect **hemolysis** at the surrounding of the colonies
- Detect **swarming** at the surrounding of the colonies
- Detect accurately the **MIC** for anti-biograms (i.e. : AST)



Virtual reading **shall be at least equivalent** to manual reading (ie : reference method)



Manual Reading = *physically* read an inoculated plate

Virtual Reading = reading an inoculated plate on a *display*

Imaging System Requirements



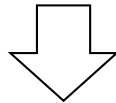
Image Acquisition

Image Processing

Image Display



- Darkfield-FlatField Correction
- Noise reduction
- Color Correction
- Shuttering
- Resizing
- Etc....



“Perceived” Contrast

no standard metric

Color Resolution

Spatial Resolution

ISO 12233:2000 (E)

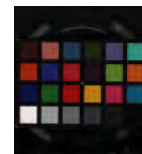
Metric

Measurement Method

ΔE_{2000}



-



No standard metric or measurement method

Acquisition Imaging Calibration : Why ?

- Provide a **consistent diagnostic value** to petri plate imaging systems .

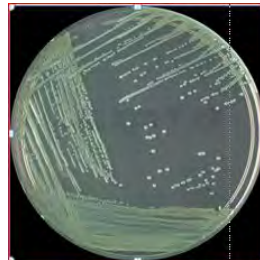
→ 2 goals are pursued with strong interest :

- **Reliable** image rendering based on **spectral knowledge** of the biological media and samples
- **Image calibration** provides repeatable and reproducible diagnostic value **independent** from an imaging system



system A

≠



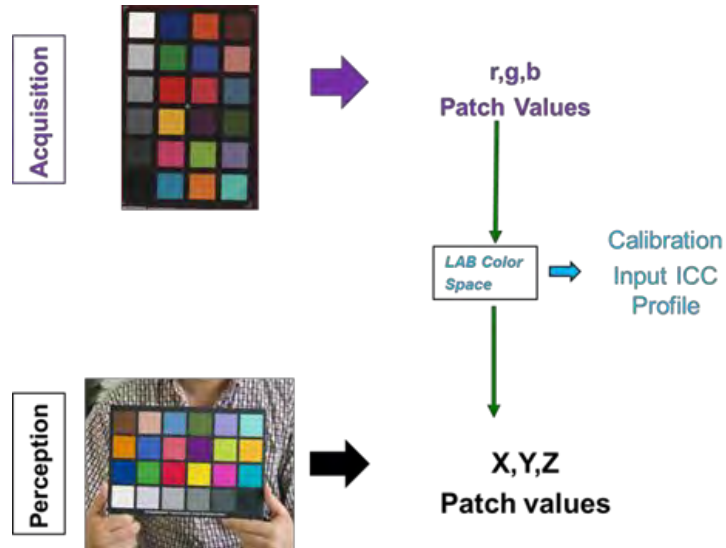
system B



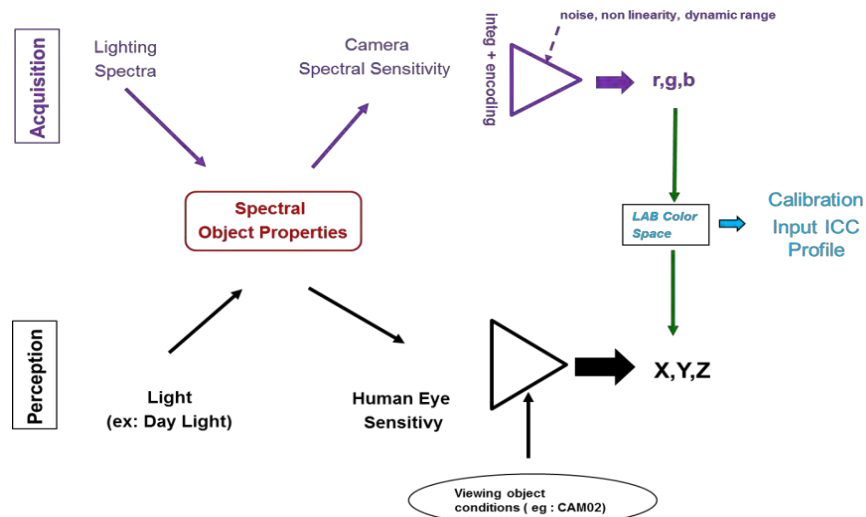
Calibration = Provide consistent rendering

Acquisition Imaging Calibration : How ?

Color Chart Method



Spectral Based Method



MIWG Petri dishes imaging activities

PIONEERING DIAGNOSTICS

http://www.color.org/groups/medical/petri_plate.xalter



MIWG scope : Petri Plate calibration



Problem Statement

Currently, there is no agreement among manufacturers on the way to handle these Petri plate images from a color acquisition and a visualization perspective.

Proposal

Interested parties should develop a proposal for assessing Petri plate readers and display management.

The following activities are included:

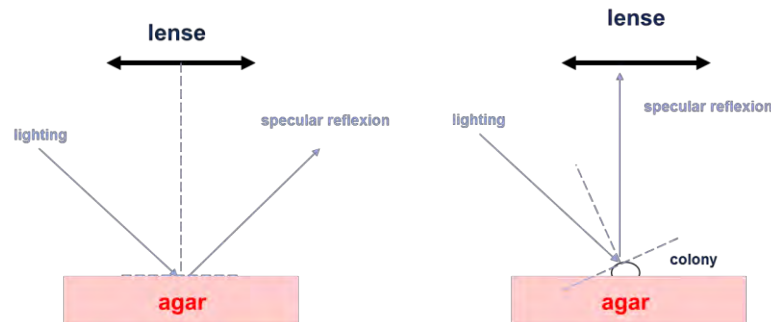
1. Establish a measurement setup and associated protocol (ie : **guidelines**) in order to allow **spectral data interoperability** in microbiology imaging (both in reflectance & transmittance)
2. Establish a common **control** colorimetric method to assess the color image quality of a Petri plate reader system
3. Propose a **unified display management** framework for Petri plate images : color and potentially multispectral.

Reflectance Factor *versus* Spectral Reflectance

- **Spectral Imaging systems** (Hyper or Multi) contain **1 detector** used to capture the reflected flux, the incident flux cannot be measured directly.
- **Incident flux** is indirectly measured by using a perfect white diffuser able to reflect the incident light uniformly over the hemisphere without absorbing it.
- ➔ spectral imaging systems shall illuminate **with the same geometry** the object to assess and **the white standard**. The measured ratio R of the flux from the object to the flux from the white standard is called **reflectance factor**.
- ➔ The reflectance factor is not a spectral reflectance. They coincide with a spectra reflectance in the case of Lambertian reflectors.

Problem :

- 1) μ Biological samples are not **necessarily** lambertian reflectors.
- 2) μ biological objects reflects more light toward the detector than the perfect diffuser (ie : specular component)



Spectral Characterization « Guideline »

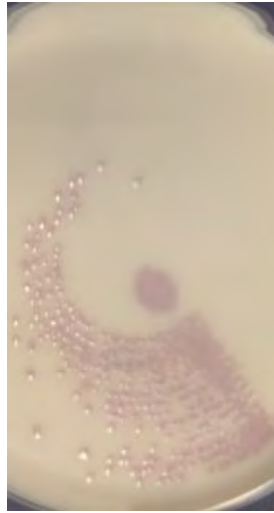
Proposal : Define a set of features that must be described in a spectral characterization procedure :

1. Lighting Calibration : spectra and geometry (ie : specular management)
2. Camera Configuration : spectral resolution, etc
3. Geometrical Object Configuration : spatial resolution, etc....
4. White Field Calibration : object characteristics, acquisition conditions, etc....
5. Color Information Display : image, hypercube visual representations
6. Spectral Reconstruction Configuration : objects type , format type, etc....
7. Spectral Quality Metrics : pSNR, deltaE2000, etc
8. Culture medium variability

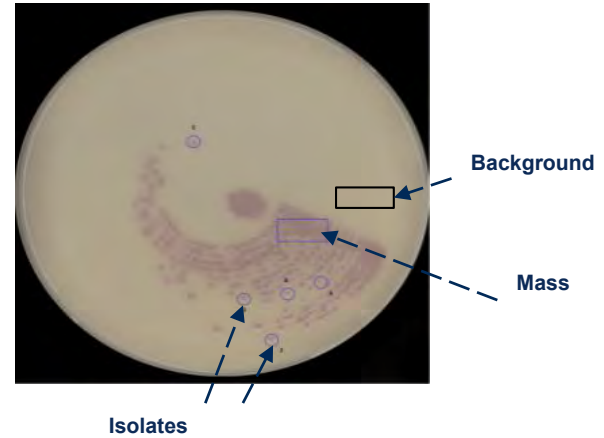
[→ Link to guideline document](#)

Color Information Display

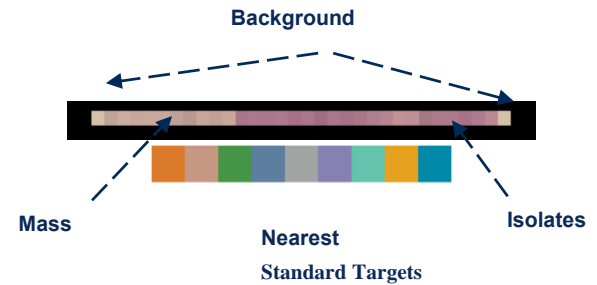
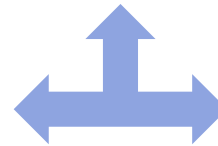
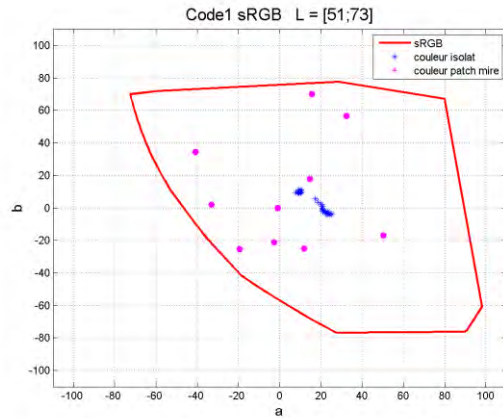
sRGB hypercube



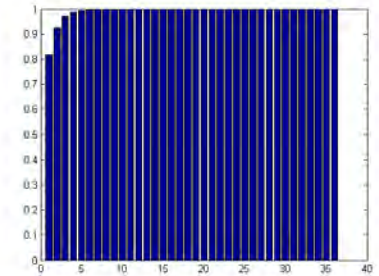
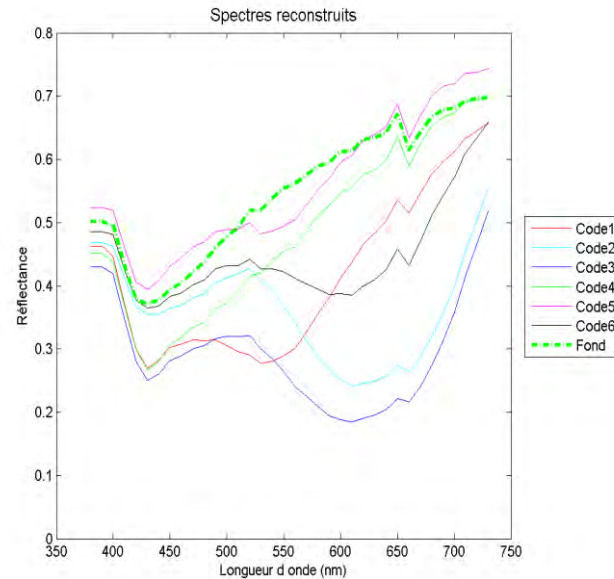
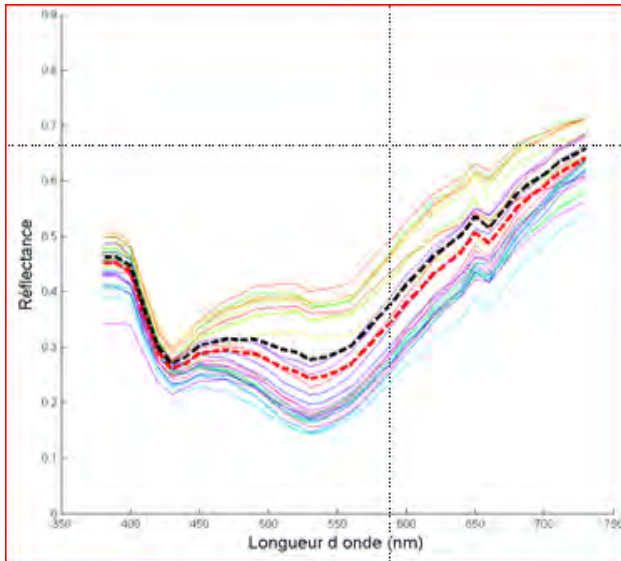
ROI Definition



Patch Visualisation



Spectral reconstruction from a set of measurements



$$S_{reconstructed} = S_{mean} + \sum_{i=1}^3 u_i * \lambda_i$$

With

u_i : i^{th} principal component

λ_i : i^{th} eigen value

S_{mean} : mean spectrum

Spectral & Color Quality indicators with a reference

1	2.37	1.84	1.29	0.51	4.1	1.12	1.21	1.43	0.43	10.53	11.15	16.43	10.96	9.51	9.75	11.17	11.98	7.24	10.06	17.21	16.12	18.07	18.5	15.09	19.63	19.86	21.54	21.15
2	4.21	3.55	5.61	4.2	4.28	8.58	5.34	8.55	6.66	6.36	4.13	2.3	3.73	3.43														
3	8.36	7.39	5.48	2.95	7.87	1.72	1.72	2.12	2.43	3.88	0.09	5.6	5.16	5.03	3.58	2.31	4.77	3.68	2.21	4.16	3.13	2.88	4.66	4.65	6.5			
4	1.7	2.34	0.24	0.63	2.29	1.75	2.18	2.93	3.53	2.88	2.53	3.21	2.25	2.24	0.78	1.66	1.52	25.15	23.19	23.15	16.99							
5	2.53	2.93	2.15	0.86	3.18	1.61	1.97	2.22	2.96	1.61	1.28	2.89	4.56	2.46	7.59	8.93	9.49	10.4	9.62	8.71	7.97	8.04	8.04	7.83	8.27			
6	13.47	10.25	8.79	9.01	6.84	3.5	2.91	3.5	4.31	3.99	2.77	5.41	6.23	6.48	9.75													

Spectral Indicators

Peak Signal-to-Noise Ratio

$$pSNR = 20 * \log_{10} (1/RMS) \text{ with } RMS = \sqrt{\frac{1}{l} \sum_{i=1}^l [S(\lambda_i) - S_{ref}(\lambda_i)]^2} \text{ and } l = \text{nbr of wavelengths}$$

Spectral Angle Map

$$\alpha = \cos^{-1}(GFC) \text{ ou } GFC = \frac{\sum S(\lambda_i) * S_{ref}(\lambda_i)}{\sqrt{\sum S(\lambda_i)^2} \sqrt{\sum S_{ref}(\lambda_i)^2}}$$

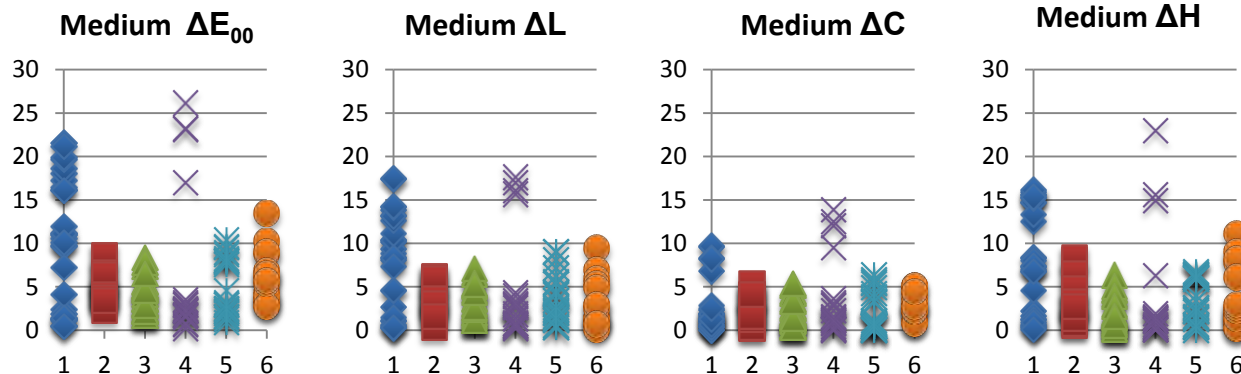
Spectral Information Divergence

$$SID = \sum \left(\frac{S(\lambda_i)}{\sum S(\lambda_i)} - \frac{S_{ref}(\lambda_i)}{\sum S_{ref}(\lambda_i)} \right) * \left(\log \frac{S(\lambda_i)}{\sum S(\lambda_i)} - \log \frac{S_{ref}(\lambda_i)}{\sum S_{ref}(\lambda_i)} \right)$$

Spectral Similarity values

$$SSV = \sqrt{RMS^2 + s^2} \text{ ou } s^2 = 1 - \left(\frac{\frac{1}{l} \sum (S(\lambda_i) - \mu(S(\lambda_i))) * (S_{ref}(\lambda_i) - \mu(S_{ref}(\lambda_i)))}{\sigma(S(\lambda_i)) \sigma(S_{ref}(\lambda_i))} \right)^2$$

Color Indicators



Culture medium variability

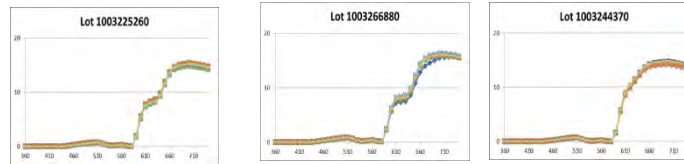
Spectrophotometer :
 (∅): 8 ou 3 mm
 Range : 360 nm à 740 nm
 Resolution : 10 nm



Inoculated plate

Background plate

Non Inoculated Plate



T0+1h



T0+24h

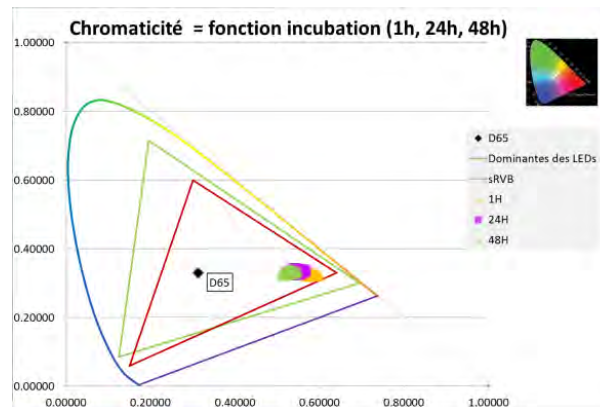


T0+48h



→ Product Batch Variability

→ Incubation Time & Environment (O₂, CO₂, other)



→ The culture medium batch number and the incubation conditions such as environment, time and temperature shall be indicated in the acquired measurements



Spectral Raw Format

Proposal : store the characterization data in the ANSI CGATS 17-2005 format.

Example :

LGOROWLENGTH 12
 CREATED "12/2013"
 INSTRUMENTATION "HSI system"
 MEASUREMENT_SOURCE "Company Name"
 ILLUMINATION_NAME D50

OBSERVER_ANGLE 2
 KEYWORD "SampleID"
 KEYWORD "SAMPLE_NAME"
 NUMBER_OF_FIELDS 38

BEGIN_DATA_FORMAT

Sample_ID	SAMPLE_NAME	nm380	nm390	nm400	nm410	nm420	nm430	nm440	nm450
	nm460	nm470	nm480	nm490	nm500	nm510	nm520	nm530	nm540
	nm550	nm560	nm570	nm580	nm590	nm600	nm610	nm620	nm630
	nm640	nm650	nm660	nm670	nm680	nm690	nm700	nm710	nm720
	nm730								

END_DATA_FORMAT

NUMBER_OF_SETS 288

BEGIN_DATA

0	[MediumName_ Class_ROI_TYPE]	0.2815	0.2849	0.2901	0.3004	0.3124	0.3210	0.3295
	0.3398	0.3561	0.3724	0.3888	0.4068	0.4188	0.4231	0.3965
	0.3733	0.3484	0.3227	0.3021	0.2841	0.2720	0.2617	0.2532
	0.2592	0.2849	0.3433	0.4540	0.5990	0.7346	0.8367	0.8994
	0.9474	0.9500						0.9320....

example in Mass Spectroscopy → Institute for Systems Biology

- JCAMP-DX


This format was one of the earliest attempts to supply a standardized file format for data exchange in mass spectrometry. JCAMP-DX was initially developed for infrared spectrometry.

- mzXML is a XML (eXtensible Markup Language) based common file format for proteomics mass spectrometric data.[7][8]
This format was developed at the Seattle Proteome Center/Institute for Systems Biology while the HUPO-PSI was trying to specify the standardized mzData format, and is still in use in the proteomics community.

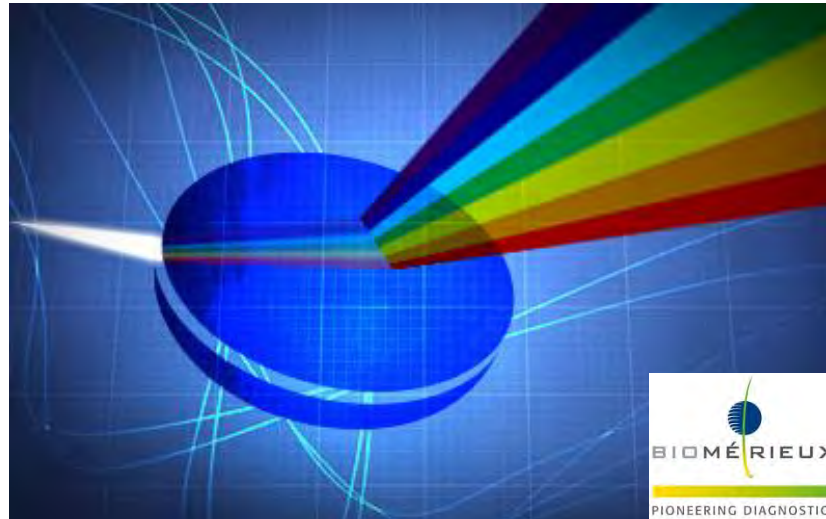
- mzML

SPC/ISB and instrument vendors to create a unified standard . Originally called dataXML, it was officially announced as mzML. The first specification was published in June 2008. This format was officially released at the 2008 American Society for Mass Spectrometry Meeting, and is since then relatively stable with very few updates.

Open Points :

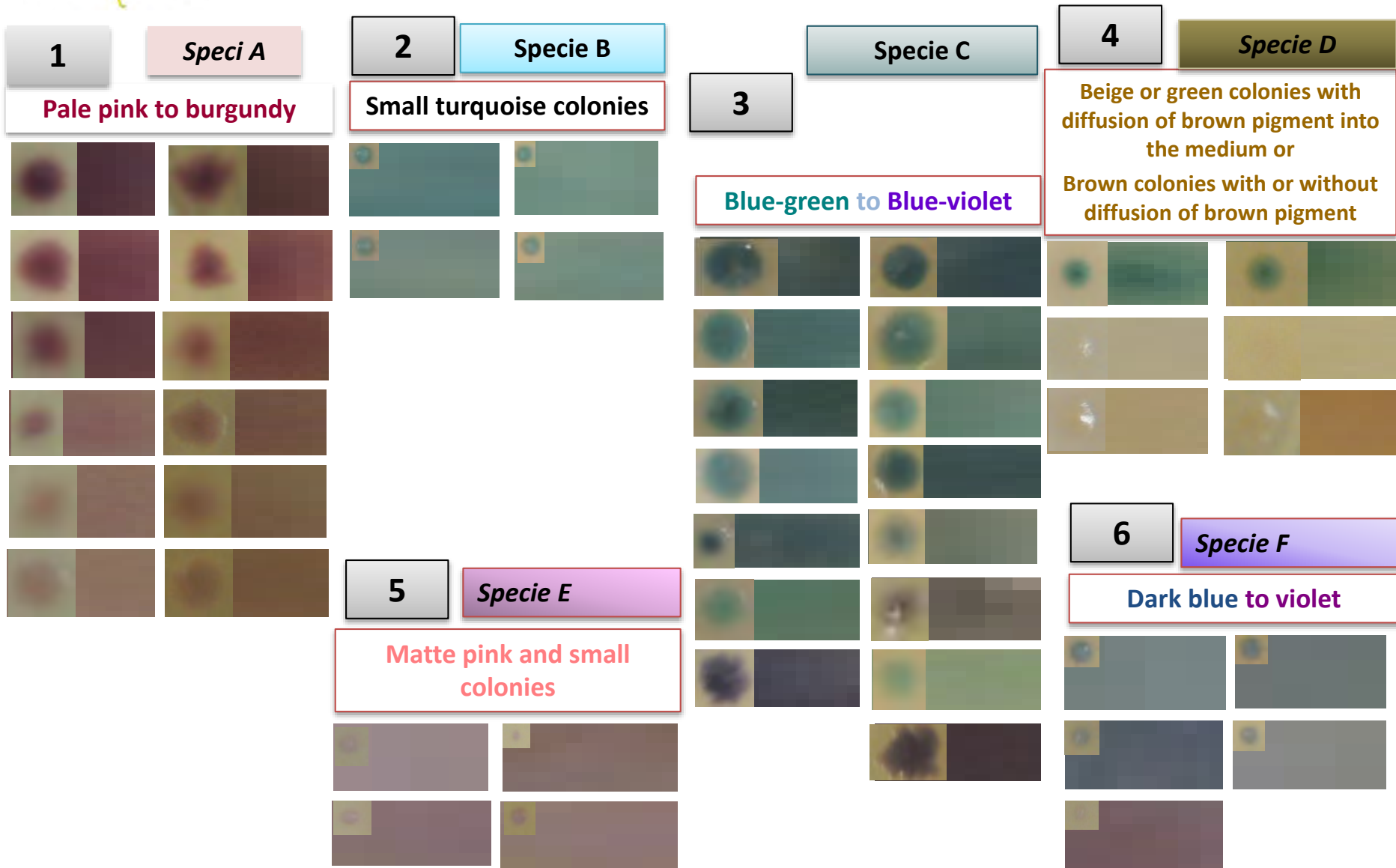
- 
- What about reflectance & transmittance spectra inter-operability ?
 - could the MIWG comes with a common proposal using ICC profile ?
-

Thank you



Jeremie.pescatore@biomerieux.com

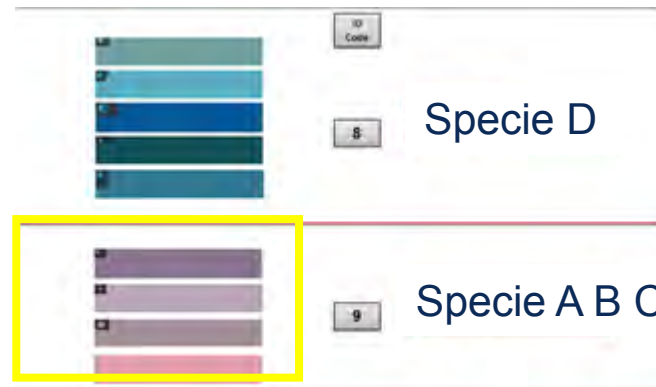
Colors Reading Scale Complexity



Color Resolution Problematic

Example

chromogenic scale



Specie A



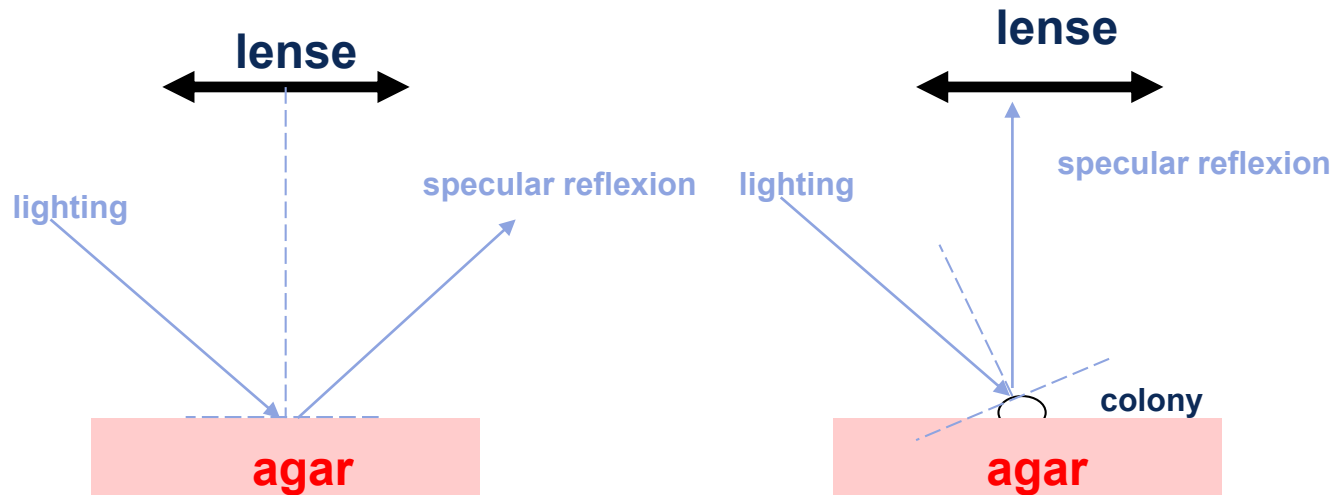
Specie B



Specie C



→ Optimize & Control Color through Spectral Modelisation



Name	Illumination	Capture
Diffuse / 8° geometry, specular component included (di:8°)	Diffuse	Radiance detector (8°)
Diffuse / 8° geometry, specular component excluded (de:8°)	Diffuse	Radiance detector (8°)
Diffuse / diffuse geometry (d:d)	Diffuse	Integrating sphere
Alternative diffuse geometry (d:0°)	Diffuse	Radiance detector (0°)
45° annular / normal geometry (45°a:0°)	Directional	Radiance detector (0°)
45° directional / normal geometry (45°x:0°)	Directional	Radiance detector

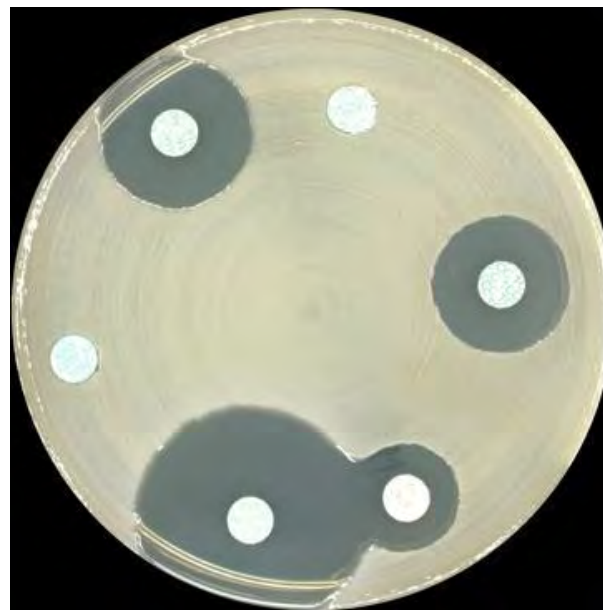
AST = Antimicrobial susceptibility testing

In-vitro antimicrobial growth-based susceptibility testing:

- Expose a pure culture of a microorganism to a range of concentrations of antimicrobial agents.
- Observe the presence or absence of growth after a period of incubation.



Etest



Kirby-Bauer

Spectral Characterization for Microbiology Imaging : measurement guidelines



Jérémie Pescatore
bioMérieux, System Core Asset Architect

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I. Introduction

Microbiology consists in the culture of biological samples in a medium allowing microorganisms to multiply. This is a core technology to identify microorganisms and their antibiotic / antifungal susceptibility.

Microbiology labs are increasingly automating the process of assessing Petri plates through scanning and image processing. This can significantly increase productivity and reduce resources, but the challenge is to provide equivalent information to manual plate reading. Direct visual reading does not suffer from the distortions of the imaging chain, including the variable accuracy of the capture and display systems used. Progress is being made in this area on defining a measurement protocol for spectral characterization, a colorimetric image quality assessment method, and a unified display management framework for colorimetric and multispectral images.

Thus, this whitepaper aims at defining some “standardized” measurements method for spectral characterization of microbiology samples.

II. Acknowledgements

Jeremie Pescatore, **bioMérieux**, System Core Asset Architect

+ TBD

III. Microbiology

In this section, we described basic notions around microbiology in order to better understand the application field of microbiology imaging.

A. Basic notions

Microbiology is the study of microscopic organisms, their identification, their characterization as well as their relationship with their environment.

They are split into 5 groups :

- algae : they are typically eukaryotic microorganisms that carry out photosynthesis
- protozoe : they are typically unicellular, microscopic, eukaryotic organisms that lack a cell wall
- fungi : yeast and molds
 - Yeasts are typically unicellular, microscopic, eukaryotic fungi that reproduce asexually by budding
 - Molds are typically filamentous, eukaryotic fungi that reproduce by producing asexual reproductive spores.
- Viruses : they are typically submicroscopic, acellular infectious particles that can only replicate inside a living host cell.
- Bacteria : a typically unicellular, microscopic, prokaryotic organisms that reproduce by binary fission.

In order to develop, microorganism need a source of energy (light or chemical), macro and micro elements (Azotes, Carbon, ...), and specific physico-chemical conditions (pH, temperature, etc....)

A culture medium [WIKI2015] is a liquid or gel designed to support the growth of microorganisms. These culture media can be solid, liquid or semi-solid. Indeed, liquid media are often mixed with agar and poured via sterile media dispenser into Petri dishes to solidify. These agar plates provide a solid medium on which microbes may be cultured. They remain solid, as very few bacteria are able to decompose agar.



Figure 1 : Example of a culture medium

Microbiological cultures can be grown in Petri dishes of different sizes that have a thin layer (\approx 5 mm) of agar-based growth medium. Once the growth medium in the Petri dish is inoculated with the desired specimen, the plates are incubated at the best temperature for the growing of the bacteria : for example, usually at 37 degrees Celsius from cultures of microorganisms collected from humans or animals.



Figure 2 : Blood agar plates are often used to diagnose infection.

On the right is a positive *Streptococcus* culture;
on the left a positive *Staphylococcus* culture.

A culture medium holds a **variety** of colors (c.f. next figure).



Figure 3 An example of the same grown culture medium from 3 manufacturers :

(left) : bioRAD - CandiSelect **(center)** : BD BBL CHROMagar Candida- **(right)** : bioMerieux chromID Candida

Thus in microbiology imaging, we shall consider only solid media [WI 2015]

Selective media are used for the growth of only selected microorganisms. For example, if a microorganism is resistant to a certain antibiotic, such as ampicillin or tetracycline, then that antibiotic can be added to the medium in order to prevent other cells, which do not possess the resistance, from growing.

Enriched media contain the nutrients required to support the growth of a wide variety of organisms, including some of the most fastidious ones. They are commonly used to harvest as many different types of microbes as are present in the specimen. Blood agar is an enriched medium in which nutritionally rich whole blood supplements the basic nutrients. Chocolate agar is enriched with heat-treated blood (40–45 °C), which turns brown and gives the medium the color for which it is named.

Culture media may also be used to perform an antibiogram. **An antibiogram** is the result of an antibiotic sensitivity test, a laboratory test for the sensitivity of an isolated bacterial strain to different antibiotics. Once a culture is established, there are 2 possible ways to get an antibiogram : a semi quantitative way based on **diffusion** or a quantitative way based on **dilution**.

Antibiogram based on diffusion consists in dropping small discs or impregnated paper (cf next figure) containing different antibiotics in different zones of the culture on culture medium. The antibiotic will diffuse in the area surrounding each tablet, and a disc of bacterial lysis will become visible. Since the concentration of the antibiotic was the highest at the center, and the lowest at the edge of this zone, the diameter is suggestive for the Minimum Inhibitory Concentration, or MIC. Once the MIC is calculated, it can be compared to known values for a given bacterium and antibiotic. Such information may be useful to the clinician, who can change the empirical treatment, to a more custom-tailored treatment that is directed only at the causative of the bacterium [WIKI 2015].

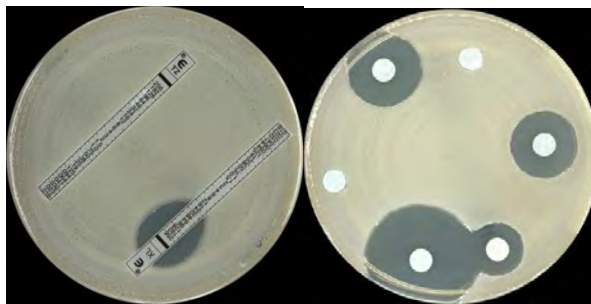


Figure 4 : left - E-test (bioMerieux) and right - Kirby-Bauer (discs) AST tests

B. Medical microbiology

Medical microbiology is a branch of medical science concerned with the prevention, diagnosis and treatment of infectious diseases. In addition, this field of science studies various clinical applications of microbes for the improvement of health. There are four kinds of microorganisms that cause infectious disease: bacteria, fungi, parasites and viruses and one type of infectious protein called a prion.

A **medical microbiologist** studies the characteristics of pathogens, their modes of transmission, mechanisms of infection and growth. Using this information a treatment can be devised. Medical microbiologists often serve as consultants for physicians, providing identification of pathogens and suggesting treatment options.

Microbiological culture is the primary method used for isolating infectious disease for study in the laboratory. Tissue or fluid samples are tested for the presence of a specific pathogen, which is determined by growth in a selective or differential medium.

1. User Imaging Needs

In a Laboratory Automation workflow (see next section), images provide a **diagnostic value** as the user performs a “virtual reading” of the inoculated Petri dishes. Therefore, one can define

the critical imaging user needs that the “virtual reading” shall fulfill. For this we propose to define the 6 following needs when performing “virtual reading” :

- UN1 : Detect growing colonies of a **minimum** size
- UN2 : Reliably distinguish different **shapes** of colonies on the same plate
- UN3 : Distinguish colonies by their **color**
- UN4 : Detect **hemolysis** at the surrounding of the colonies
- UN5 : Detect **swarming** at the surrounding of the colonies
- UN6 : Detect the **MIC** on antibiograms



Manual Reading = *physically* read an inoculated petri dish **Virtual Reading** = reading an inoculated petri dish on a *display*

This white-paper principally focuses on the *UN3 which aims at distinguishing colonies by their color*

2. Chromogenic Media

chromogenic media can be referred to as microbiological media suitable for incubation, differentiation, or selection of different microorganisms by means of **color production**



Figure 5. Medium A

There exist several chromogenic specie that grow on chromogenic media. Therefore, we group them by **classes (or species)** . These classes are defined with respect to the color of the colonies specie. In the following figures, we provide the **chromogenic scale** for Medium A (c.f. figure 6).

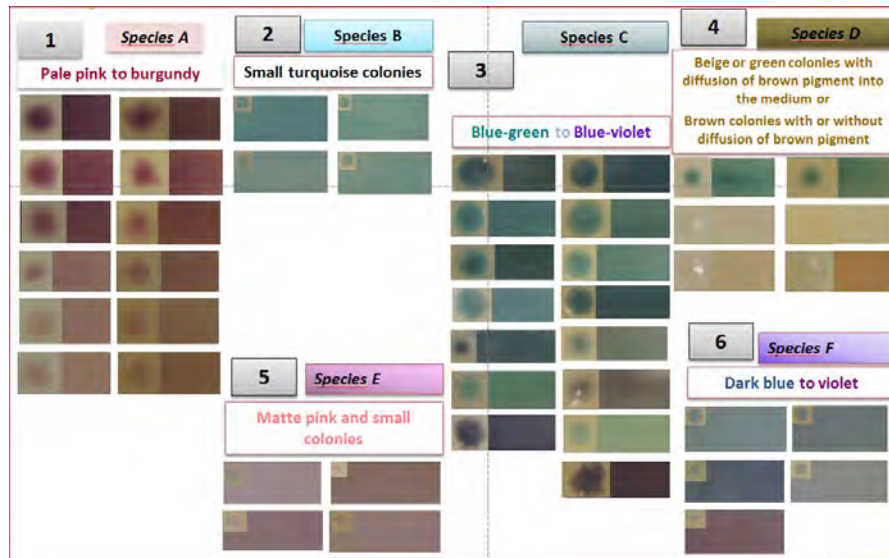


Figure 6 : Example Chromogenic scale for given medium. There are 6 classes corresponding to 6 species.

3. Other Color “Enabling” Culture Media

Some non-chromogenic media may also produces distinct colors. For example :

- Media containing a pH indicator that changes colors of the colonies (cf. next figure).

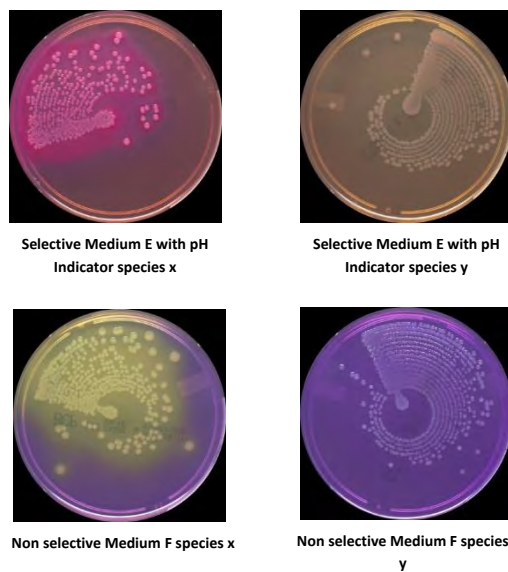


Figure 7.a

- Media that change their color when colonies consume “glucides” from the medium

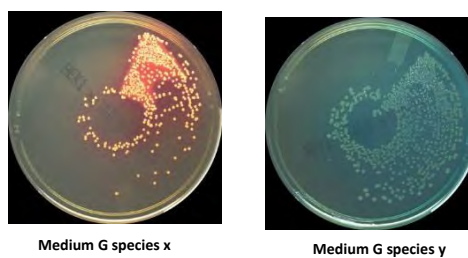


Figure 7.b

IV. Microbiology Imaging

A. Microbiology Laboratory Automation

One of the major disadvantages of Clinical Microbiology is the predominantly manual processing of specimens. In comparison to chemistry specimens, microbiology specimens are much more complex. Thus, for years the common opinion was that microbiology was too complex to automate and that no machine could replace a human here. It has been shown, however, that automated inoculation of samples can indeed be superior to manual inoculation with regard to pathogen recovery [MI 2012]. Furthermore, by manually processing samples, incubation times and processing itself are not guaranteed to be standardized and qualitatively equivalent. Automation enables a higher degree of standardization, which may be beneficial not only in terms of cost-effectiveness, but also in terms of **gaining diagnostic quality and traceability**. Recently, laboratory automation systems have been developed by several companies but only few laboratories have implemented them so far.

Currently, 2 solutions are available : Kiestra TLA (*BD Kiestra B.V., Drachten, Netherlands*), and WASPLab (*Copan Diagnostics, Murrieta, CA*). They both include track systems to move plates, digital cameras to capture plate images and automated incubators.

An essential aspect of laboratory automation is the **standardized, automated image acquisition of cultures** and thus coherently the possibility of digital image analysis and interpretation. This represents the means to standardize and reduce incubation times and accelerate samples processing and susceptibility testing.

Additionally, Lab automation solutions introduce a **quality assurance tool** that allows even after a long time to assess bacterial growth retrospectively.

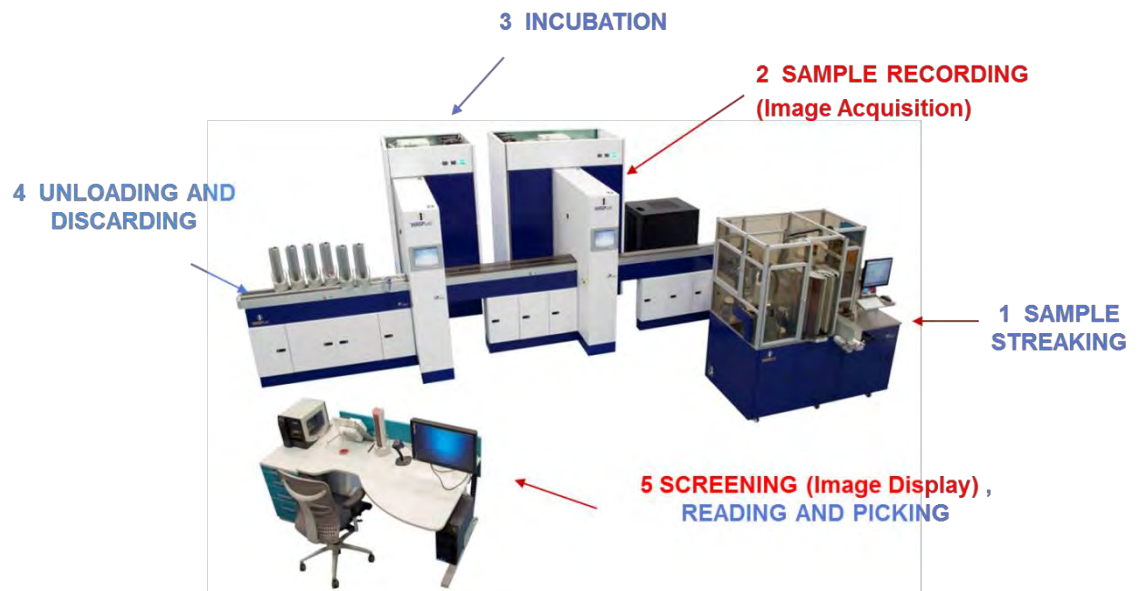


Figure 8 : Wasplab™ – Copan Automation Solution [COP2015]

B. Imaging System

In this section, we will define an imaging system applied to microbiology imaging.

1. Definition

The imaging system can be decomposed into three sub-systems :

- **Image acquisition** : This system includes the gathering of the various image data taken under different conditions (i.e. : lightings, etc..).
- **Image processing**. This system includes all the required processing in order to produce an image as realistic as possible The type of processing includes correction (darkfield, flatfield , noise and color), resizing and shuttering.
- **Image display** : this system includes all the type of media (i.e.: colorimetric monitor, tablets, etc..) used to display an image.

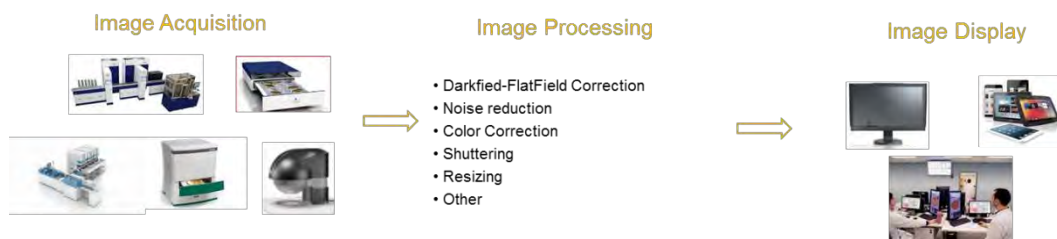


Figure 9 Imaging System

An imaging system shall fulfill at least the 3 following system requirements :

- **Contrast** : no perceptual color contrast metric exists in the microbiology imaging. One often considers a set of exposure time which is empirically defined for a set of media. This set will “visually” show that the contrast is based on the arbitrary judgment of the operator.
- **Spatial Resolution** : one may use the ISO 12233:2000 (E) standard to measure the spatial resolution of the imaging system.
- **Colorimetric resolution** : Color difference may be measured after color correction according to the CIE delta E 2000 definition using specific color patches (colorChecker, IT8.3, others) and illuminants

2. Acquisition Sub-System

When considering the acquisition sub-system, special component specifications shall be precisely defined such as

- The lighting spectrum
- The lighting geometry
- The acquisition system spectral sensitivity
- The object background spectral characteristics

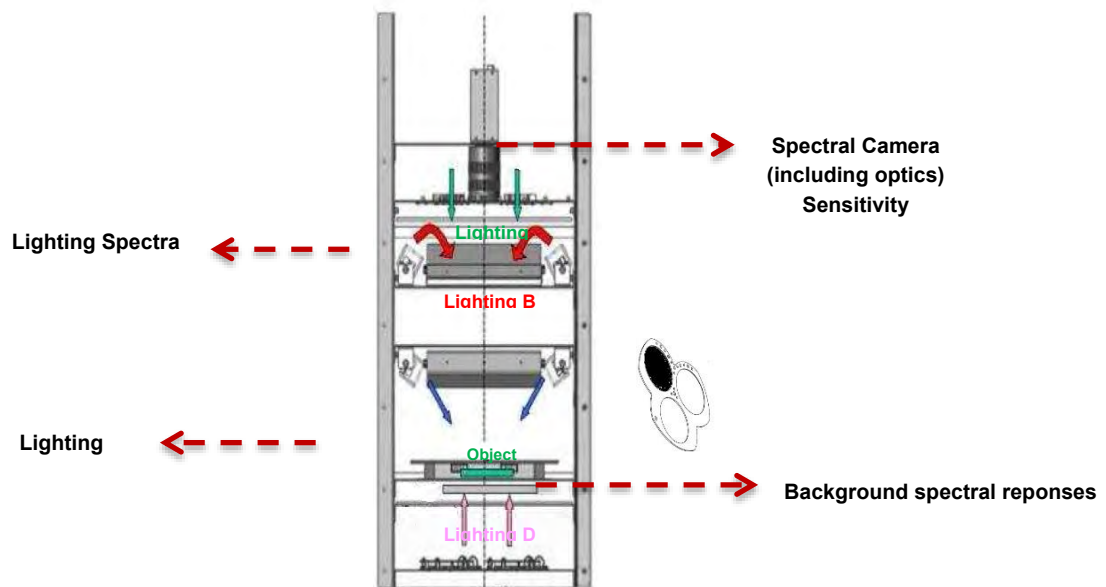


Figure 10 Acquisition Sub-System

3. Image Processing Sub-system

The image processing chain is a set operator which is applied on the raw imaging system in order to produce an adequate « image » to be displayed on a monitor. It may include :

- **A darkfield correction or dark-frame subtraction** : it is a way to minimize image noise for pictures. It takes advantage of the fact that a component of image noise, known as fixed-pattern noise, is the same from shot to shot: noise from the sensor, dead or hot pixels. It works by taking a picture with the shutter closed. Dark-frame subtraction has been done for some time in scientific imaging; many newer consumer digital cameras offer it as an option, or may do it automatically for exposures beyond a certain time.
- **A flatfield and/or lighting correction** : it is a technique used to improve quality in digital imaging. The goal is to remove artefacts from 2-D images that are caused by variations in the pixel-to-pixel sensitivity of the detector and/or by distortions in the optical path (induced by poor illumination at the peripheries of the object). It is a standard calibration procedure in everything from pocket digital cameras to giant telescopes.

- **A noise correction** : Images taken with digital cameras will pick up noise from a variety of sources. Further use of these images will often require that the noise be (partially) removed for visual purposes
- **A High Dynamic Range processing (HDR)** is a technique used in imaging and photography to reproduce a greater dynamic range of luminosity than is possible with standard digital imaging or photographic techniques.
- **An image resizing** : Images acquired may need to be resize to fit the display screen in either a full-mode or an zoom mode. Thus, this resizing may induce an impact on the contrast to noise ratio of the image.
- **A color correction** : this correction applies a white balance and an ICC profile on the image. **White balance** is a feature many digital cameras and video cameras use to accurately balance color. It defines what the color white looks like in specific lighting conditions, which also affects the hue of all other colors. Therefore, when the white balance is off, digital photos and recordings may appear to have a certain hue cast over the image. Then, **an ICC profile** is a set of data that characterizes a color input or output device, or a color space, according to standards promulgated by the International Color Consortium (ICC).

4. Display Sub-system

Most display sub-systems use a RGB space which is an additive colorspace based on the RGB color model. A particular RGB color space is defined by the three chromaticities of the red, green, and blue additive primaries, and can produce any chromaticity that is included in a triangle defined by the primary colors (cf figure 11). The complete specification of an RGB color space also requires a white point chromaticity and a gamma correction curve. As of 2007, sRGB is by far the most commonly used RGB color space particularly in consumer grade digital cameras, HD video cameras, and computer monitors. HDTVs use a similar space, commonly called Rec. 709, sharing the sRGB primaries. The sRGB space is considered adequate for most consumer applications. Having all devices use the same color space is convenient in that an image does not need to be converted from one color space to another before being displayed. However, **sRGB's limited gamut leaves out many highly saturated colors** that can be produced by microbiology samples (cf figure) , and thus is not ideal for the visualization of some culture media plates. The wider gamut **Adobe RGB** is being built into more medium-grade digital cameras, and may be favored for its larger gamut.

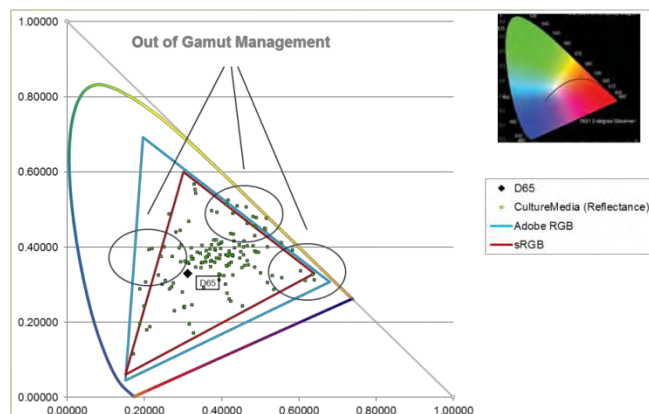


Figure 11 : Culture Media and colony species colors displayed as green dots in a sRGB and Adobe gamut chromaticity diagram.

C. Acquisition Sub-System Color Calibration

Calibration of an acquisition sub-system is generally performed using 2 methods :

- **Color Chart Method** : this method uses a color chart (example : colorChecker or other) in order to estimate the transformation between image acquired color chart colors and manufactured measured colors charts (c.f .figure 10)

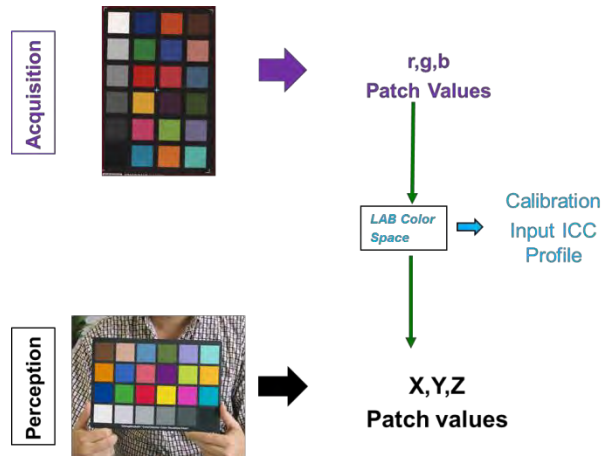


Figure 10 Color Chart Calibration

- **Spectral Based Method** : this method (cf figure 11) uses the spectral properties of the samples (i.e.: knowledge base) and the acquisition system in order to estimate the transformation between acquired colors and measured colors. In this method, it is important to measure accurately the spectral properties of the object in order to avoid any artefacts in the calibration. Therefore, we propose in chapter V some measurement guidelines in order to characterize spectral properties of microbiological samples

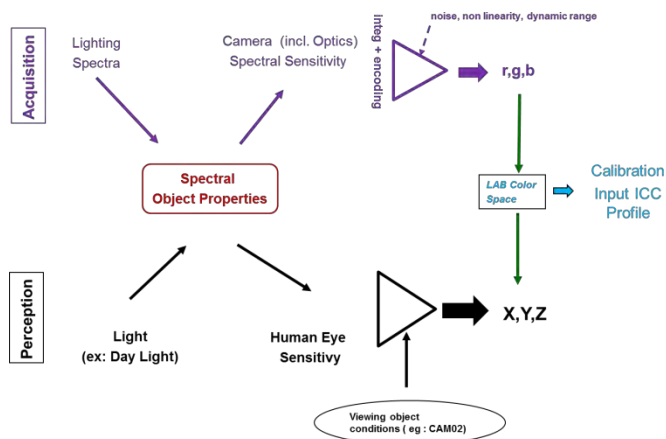


Figure 12 : Spectral Base Calibration

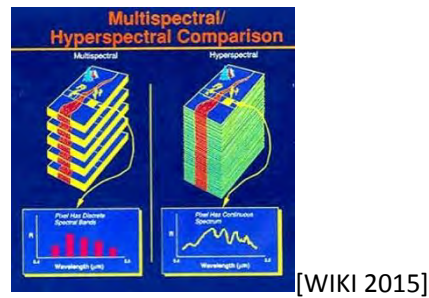
Note : for measuring colors drifts of an acquisition system, both methods can also be used.

V. Spectral Characterization

A. Spectral imaging acquisition system

Spectral characteristics are acquired using a spectral imaging system.

2 different types of systems exist : Hyper and Multi spectral systems. The distinction between hyper- and multi-spectral is based on an arbitrary "number of bands" and the fact that they are co-continuous or not :



[WIKI 2015]

- **Hyper Spectral systems** : those systems are often “pushbroom” systems, this means that the camera will scan and record spectral data line after a line. (cf. next figure)

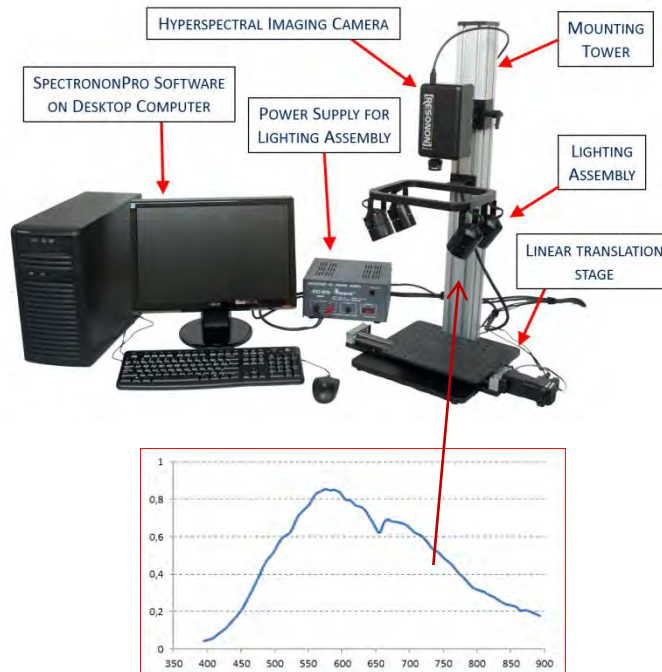


Figure 13. An example of a hyper spectral acquisition benchtop system (ie : [RES2015]) system (up) and the light source spectrum (down).

- *Multi Spectral systems* : those systems can be based on multiple LEDs lighting with a limited number of channels (~ 20 channels) and an area camera. They can produce high spatially resolved images (cf. figure 14)



Figure 14. VideoMeterLab 3 : An example of multispectral imaging system (left) and the lighting spectrum (right). [VID 2015]

Most spectral systems contain one detector used to capture the reflected flux, the incident flux cannot be measured directly. It is measured indirectly by using a perfect white diffuser able to reflect the incident light uniformly over the hemisphere without absorbing it. The flux captured by the detector is therefore proportional to the incident flux. The ideal white standard is a perfectly Lambertian, nonabsorbing and diffusing sample. Its reflectance is equal to 1 and its BRDF (cf. glossary) is $1/\pi$ for every couple of incidence and reflexion directions. In practice, white standards approaching these properties are made of pressed barium sulfate or PTFE (commercialized under the names of Algoflon, Halon or Spectralon).

Thus, spectral imaging systems shall **illuminate with the same geometry** both the object to assess and the white standard. Under these conditions, the ratio R of the flux Φ from the object to the flux Φ_{ref} from the white standard is called **reflectance factor** [HEB 2015]. The reflectance factor **is not** rigorously a spectral reflectance. They coincide with a spectra reflectance in the case of Lambertian reflectors. This **is not** necessarily the case for microbiological samples. Moreover, in some cases, the colonies microbiological objects reflect more light toward the detector than the perfect diffuser with as a result a reflectance factor which is greater than one (i.e : **specular artefact**).

Note : This analysis applies to spectral transmittance.

Therefore, in order to give a spectral measure, we propose to define a set of features that must be described in a spectral characterization procedure :

- Lighting Configuration : Spectra and Geometry
- Camera Configuration
- Geometrical Object Configuration
- White Field Calibration
- Spectral Reconstruction Configuration
- Color Information Display
- Spectral Quality Metrics

B. Lighting Configuration : Spectra and Geometry

Direct lighting on a microbiological samples may produce specular artefacts (cf figure 15). When the incident light reaches a colony, a portion of this light, due to its curvature will be directly be reflected on the camera lens. This reflexion will saturate the camera sensor and produce a specular artefact.

Specular reflexion – total reflexion artefact : explanation

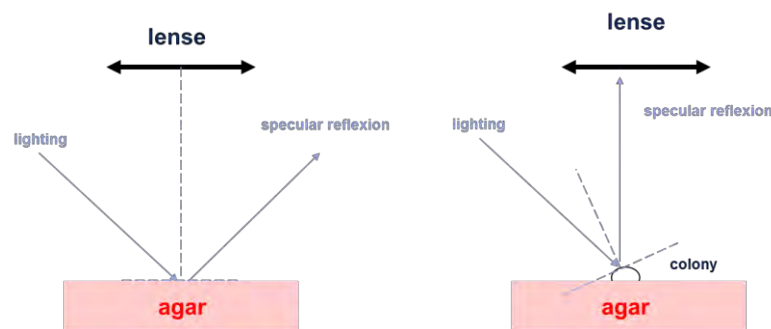


Figure 15 : specular reflexion artefact

Thus, spectral measurement devices designed for color reproduction applications shall contain either directional or Lambertian white light source and capture the reflected light either in one direction (radiance measurement) or over the hemisphere thanks to an integrating sphere (irradiance measurement). The spectrum of the source generally tends to reproduce the color of a standard illuminant, typically the D65 illuminant, despite the difficulty to reproduce reliably the illuminant spectra defined by the CIE with artificial lightings (see Figure 8). Once captured, light is transferred to a spectrophotometer which measures the flux in the different wavelength bands 1, 5 or 10 nm wide. The next table presents some geometries recommended by the CIE for reflectance measurements

Name	Illumination	Capture
Diffuse / 8° geometry, specular component included (di:8°)	Diffuse	Radiance detector (8°)
Diffuse / 8° geometry, specular component excluded (de:8°)	Diffuse	Radiance detector (8°)
Diffuse / diffuse geometry (d:d)	Diffuse	Integrating sphere
Alternative diffuse geometry (d:0°)	Diffuse	Radiance detector (0°)
45° annular / normal geometry (45°a:0°)	Directional	Radiance detector (0°)
45° directional / normal geometry (45°x:0°)	Directional	Radiance detector

Therefore the protocol setup shall indicate as precisely as possible the lighting conditions such as :

- [GUIDE 001] The *type of lighting (LED, incandescent) with its associated spectrum or spectra* (for an MSI system)
- [GUIDE 002] The *geometrical configuration of the lighting* (angle, number)
- [GUIDE 003] The *geometry used for measuring reflectance*. **The used geometrie shall be those recommended by the CIE - TBC.** In the next figure, there is an example of the usage of a spherical mirror + a specific lighting to remove as much as possible the specular effect produced by the colonies (species) in a culture medium. The geometry appears to be poorly described and may not remove all the specular artefact.

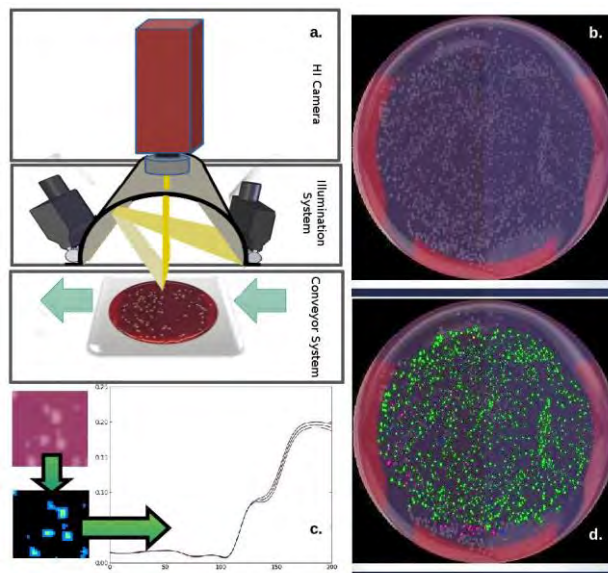


Figure 16 : an example [TU 2015] of a measuring spectral reflectance setup using an half cylinder mirror in front of an hyper spectral camera. Some spectral reflectance factor of a colony (displayed in green in the lower right image).

- [GUIDE005] The *background color (usually black or white, or semi-transparent) of the object with it is associated spectral properties*. Indeed some culture media are semi-transparent. Thus, the spectral properties of the sample is the combination of the object of interest (culture media or colonies) with the background color. **Recommendations shall be given about the distances between the background and the petri dish.**

C. Camera Configuration

The measurement protocol shall also include some important specifications coming from the camera signal such as

- [GUIDE 006] The spectral range (nm)
- [GUIDE 007] The spectral resolution (in nm). For MSI system, it might be interesting to indicate the spectral reconstruction method especially if it uses some specific **prior** knowledge (example : sensor sensitivity, known object reflectance)
- [GUIDE 008] The bit depth
- [GUIDE 008] The applied darkfield correction (if applicable)
- [GUIDE 010] The acquisition time if it is different than the acquisition time used for the white field calibration (cf. section E)

D. Geometrical Object Configuration

Field of view and pixel size of the spectral measurement system are important parameters to set in a spectral measuring protocol. This is linked to the geometrical configuration (cf. figure).

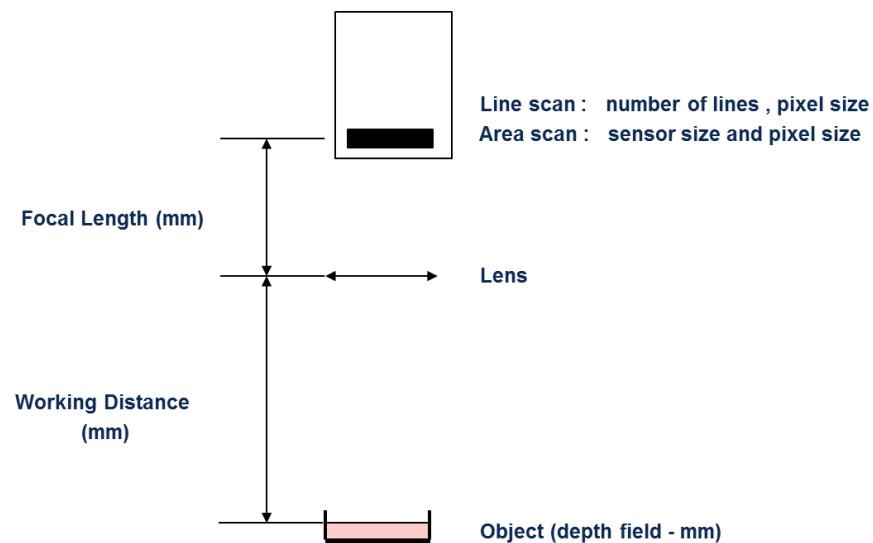


Figure 17: Geometrical acquisition parameters .

Based on the geometrical acquisition configuration, the magnification factor can be computed as followed (ie : hypothesis , infinity focus)

$$G = \text{image} / \text{field of view} = \text{focal length} / \text{working distance}$$

This allows to compute the object field of view and the system resolution.

For example for a line scan system (or push broom), we have :

- $(\text{number of lines} \times \text{sensor pixel size}) / \text{field of view} = \text{focal length} / \text{working distance}$ and
- $\text{Field view} / \text{number of lines} = \text{object resolution}$

Therefore the spectral characterization protocol shall at least define :

- [GUIDE 011] The acquisition type (line or area)
- [GUIDE 012] The acquisition field of view (in cm) and resolution (pixel size in μm). The recommendations would be to set the 3 following field of views : 55 mm, 95 mm and 130 mm (TBC)
- [GUIDE 013] The Lens focal length
- [GUIDE 014] The working distance or distances
- [GUIDE 015] The object field depth . (TBC)

E. White Field Calibration

As seen in section A, the reflectance or transmittance factor is computed by measuring an ideal white standard that is a perfectly Lambertian, non-absorbing and highly diffusing.

Therefore the measurement protocol shall indicate :

- [GUIDE 017] The reference spectral reflectance of the white standard and its product reference.
- [GUIDE 018] The acquisition time used during white field calibration. This parameter shall be indicated in particular if the microbiological sample is acquired with a different acquisition time than the white field calibration.
- [GUIDE 019] The geometrical configuration of the white standard. In fact, if the white standard is acquired at a different height than the microbiological sample, it may for some non-diffusing lighting has an effect on the data. This information needs therefore to be known.

F. Spectral Reconstruction Configuration

1. Spectral data

Both systems (HSI or MSI) produces for each pixel a reflectance (resp. transmittance) factor of an image. We shall define a ROI (ie : Region of Interest) within a spectral hypercube (i.e. : spectral factor for a set of pixels).

Therefore, the measurement protocol shall indicate :

- [GUIDE 020] The ROI type on which a **mean** reflectance (resp. transmittance) factor has been computed. For example on figure 18 , we define 3 different type of regions (background, mass and isolate).
 - The background is a uniform ROI without any colonies
 - The mass is a ROI with a set of colonies merging in each other
 - The isolate is a ROI with an isolated colony

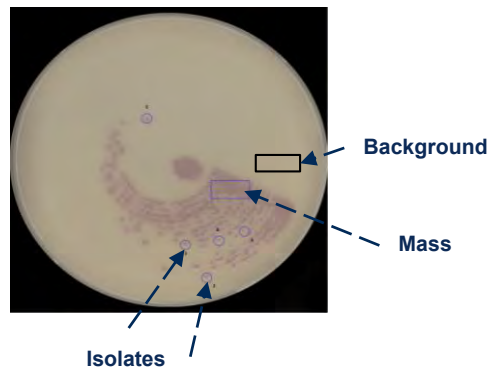


Figure 18 : The different ROIS definition and localization in a petri dish

- [GUIDE 021] The size of the ROI. If there is some specular artefact, the protocol shall indicate if the ROI mean spectrum computation includes or not the specular artefact pixels or not
- [GUIDE 022] The ROI mean reflectance (resp. transmittance) factor shall be sampled at least between 390 nm and 730 nm with a sample factor of 5 or 10 nm. **If an interpolation/extrapolation is applied on the raw data, it might be interesting to indicate how this processing was applied.**

2. Spectral reconstruction from a set of measurements

A Principal Component Analysis is often performed on a set of spectral measurements for understanding the statistical spectral distribution of a color object [IM 1996]. Therefore, one shall take care to give enough details about this spectral reconstruction using this PCA.

The way to compute a reconstruction is as followed [FA 2003]

$$S_{reconstructed} = S_{mean} + \sum_{i=1}^3 u_i * \lambda_i$$

with u_i : i^{th} principal component
 λ_i : i^{th} eigen value
 S_{mean} : mean spectrum

Where the 3 first component accounts for most of the information (> 95%) as shown in the following figure :

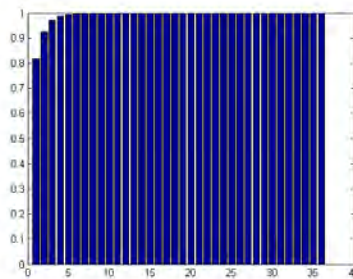


Figure 19 : % of cumulated eigen values for a reconstructed spectrum. The 3 first components accounts for more than 95% of the information.

Thus if spectral reconstruction are given from a set of spectral measurements, then :

- [GUIDE 023] The reflectance factor for a set of identical objects (isolate, background or mass) shall be reconstructed using a principal component analysis. In particular, the following information shall appear
 1. The number of spectral data used for the PCA
 2. The way data were constructed (example : by class, by type of ROI , other)
 3. The number of principal components used in the reconstruction with the percentage of variance (ie : 95% 99% or other) used for the spectral reconstruction

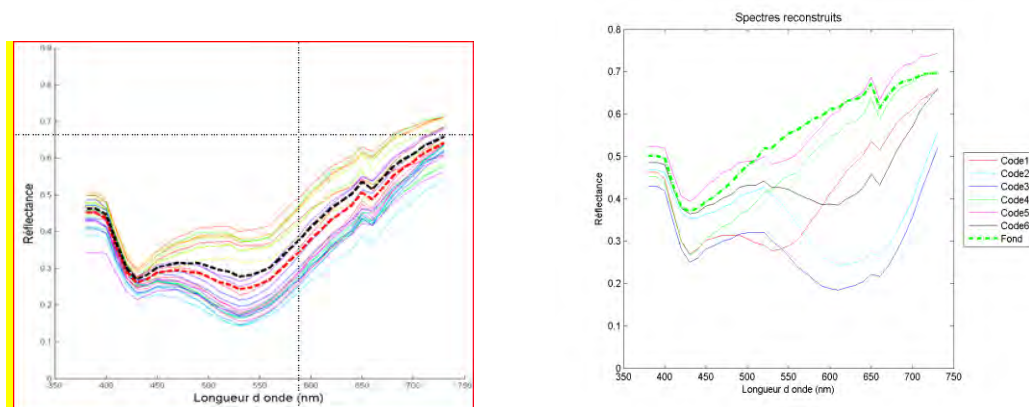


Figure 20 : left PCA reconstructed spectra (in dotted black) – right : PCA reconstructed spectra for each code or class (ie : species).

G. Color Information Display

From a spectral hypercube (ROI or all image), it is possible to visualize an image on a display and thus to convert the hypercube into an image. Therefore the conversion from a spectral hypercube shall be specified when displaying such spectral data.

- [GUIDE 024] The protocol shall defined the used gamut (example : sRGB, adobeRGB or other) for each reflectance (resp transmittance) factor **hypercube** “visually” displayed on a screen.

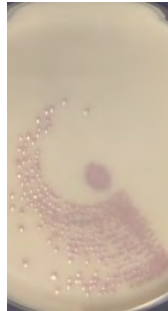


Figure 21 an sRGB hypercube visualisation

Then, for each measured reflectance (resp. transmittance) factor, we propose to represent them in a color patch reference in order to enable an easy reading of the color scale of the measurements. Thus :

- [GUIDE 025] : For each ROI mean reflectance (resp. transmittance) factors, it is also recommended to display the results in the LAB colorspace with a defined gamut boundary representation and associated color patches as shown in the next figure. This helps in understanding where the spectral data are located from a color display management point of view.

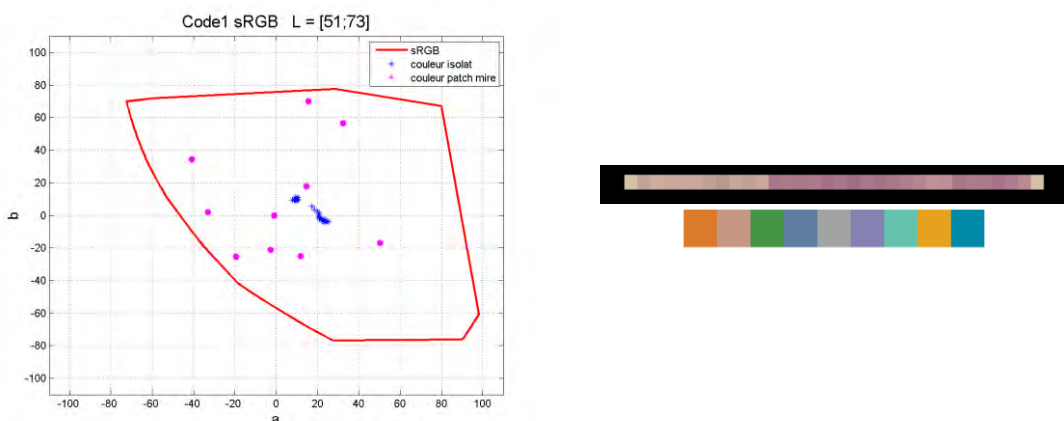


Figure 22 : left – each ROI mean reflectance (i.e.: purple dot) is displayed w.r.t to the sRGB gamut and compared to the nearest patch of a standard (example : colorChecker) target (blue dots) right- each ROI mean reflectance is displayed as a sRGB patch and visually compared to the nearest color patches of a standard target

H. Spectral Quality Metrics

Once a **reference** reflectance (resp. transmittance) factor is computed, this reference may be compared to a set of reflectance (resp. transmittance) factors. From [SH2014] spectral metrics proposal, we propose to use the following ones.

- **pSNR** (Peak Signal-to-Noise Ratio) : it is based on the computation of the root mean square (RMS) error. RMS calculates the cumulative squared error between a reference **Sref** reflectance (resp. transmittance) factor (ie : the reconstructed spectra) and a sample **S** reflectance (resp. transmittance) factor. Thus,

$$\text{pSNR} = 20 * \log_{10} (1/\text{RMS}) \text{ with } \text{RMS} = \sqrt{\frac{1}{t} \sum_{i=1}^t [S(\lambda_i) - S_{ref}(\lambda_i)]^2} \text{ and } i = \text{number of wavelengths}$$

- **SAM** (Spectral Angle Map) : this measure provides a measure of the difference in terms of spectral angle (α) between two spectra. This measure is relatively insensitive to lighting variations or albedo. Thus,

$$\alpha = \cos^{-1}(GFC) \text{ ou } GFC = \frac{\sum S(\lambda_i) * S_{ref}(\lambda_i)}{\sqrt{\sum S(\lambda_i)^2} \sqrt{\sum S_{ref}(\lambda_i)^2}}$$

- **SID** (Spectral Information Divergence) : This measure views each spectrum as a random variable, and then measures the discrepancy of probabilistic behaviors between two spectra, thereby determining similarity and variability more effectively than SAM. A small value of this measure indicates that 2 spectra are similar

$$SID = \sum \left(\frac{S(\lambda_i)}{\sum S(\lambda_i)} - \frac{S_{ref}(\lambda_i)}{\sum S_{ref}(\lambda_i)} \right) * \left(\log \frac{S(\lambda_i)}{\sum S(\lambda_i)} - \log \frac{S_{ref}(\lambda_i)}{\sum S_{ref}(\lambda_i)} \right)$$

- **SSV** (Spectral Similarity Values) : This measure combines magnitude (ie : RMS error) and the shape (ie : standard deviation) differences between 2 spectral vectors, giving each equal weighting. A small value of this measures indicates that 2 spectra are similar.

$$SSV = \sqrt{RMS^2 + s^2} \text{ ou } s^2 = 1 - \left(\frac{\frac{1}{t} \sum (S(\lambda_i) - \mu(S(\lambda_i))) * (S_{ref}(\lambda_i) - \mu(S_{ref}(\lambda_i)))}{\sigma(S(\lambda_i)) \sigma(S_{ref}(\lambda_i))} \right)$$

Where

μ is a mean the mean of spectrum (reference or sample)

σ is the standard of a spectrum (reference or sample)

- [GUIDE 026] In the case measurement spectral comparisons are performed on spectral data, the used metric may be at least the following metrics **pSNR, SAM, SID and SSV**.

Spectral comparisons can also be performed through some perceived color metrics in a defined colorspace. Thus if measurement spectral comparisons are performed on the spectral data, we propose to compute some specified perceived color metrics as followed .

- [GUIDE 027] In the case measurements spectral comparisons are performed on spectral data the used perceived metric(s) **shall be(TBC)** at least the **ΔE_{00}** . The spectral comparisons shall also include the associated ΔL luminosity, ΔC saturation and ΔH hue.

A patch chromscale may be proposed with the computation of the **ΔE_{00}** . The graphs in the following figures is a proposal of display of the different indexes.

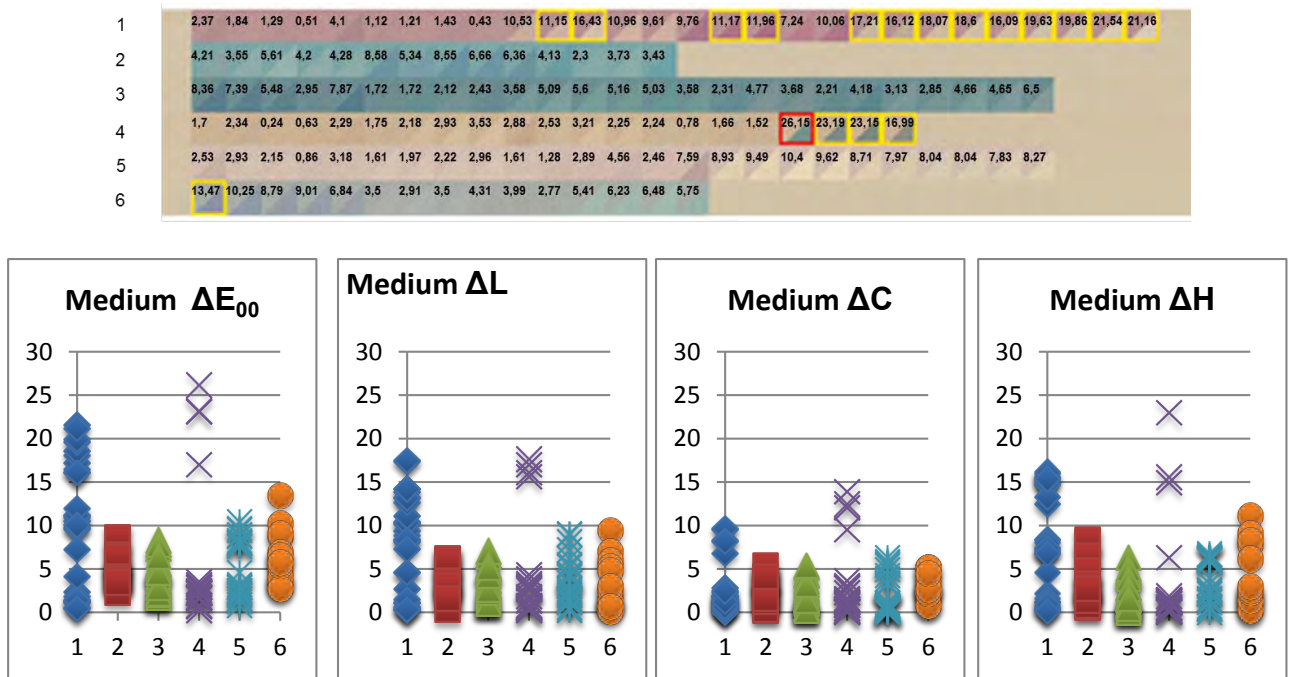


Figure 23 : ΔE_{00} comparisons with color comparisons between a set of samples and a reference for each specie from class 1 to 6 (top), graphical representation of the ΔE_{00} , ΔL , ΔC and ΔH hue for each class. In this example, the medium holds 6 classes maximum from the different species. The background color (top) around the patches correspond to the PCA spectrum reconstruction of the background region of the culture medium.

I. Culture Medium Variability

In microbiology Imaging [PESC 2014] may be more or less sensitive to production variability of culture medium and environmental conditions.

- [GUIDE 028] The culture medium batch number and the incubation conditions **such as environment, time and temperature shall be indicated in the acquired measurements**

VI. Spectral Knowledge Base Inter-operability

A. Raw Format

[GUIDE 029] The proposal is to store spectral characterization measurement data in the ANSI **CGATS 17-2005 format**.

The ANSI CGATS 17-2005 format consists of a Preamble section containing originator information, keyword definitions, etc. and then one or more data sections, each consisting of header and data subsections. The BEGIN_DATA_FORMAT and END_DATA_FORMAT delimiters define the actual data types / units contained in the following tables. The BEGIN_DATA and END_DATA delimiters mark the subsection containing the actual color information in tabular form. CGATS 17 text files can contain device, colorimetric (Lab, XYZ, etc.), densitometric, spectral, naming and other information.

Example :

```
LGOROWLENGTH          12
CREATED                "12/2013"
INSTRUMENTATION        "HSI system"
MEASUREMENT_SOURCE     "Company Name : Reflectance or Transmittance"
ILLUMINATION_NAME      D50
OBSERVER_ANGLE         2
KEYWORD                "SampleID"
KEYWORD                "SAMPLE_NAME"
NUMBER_OF_FIELDS       38

BEGIN_DATA_FORMAT

Sample_ID SAMPLE_NAME  nm380  nm390  nm400  nm410  nm420  nm430  nm440  nm450
          nm460  nm470  nm480  nm490  nm500  nm510  nm520  nm530  nm540  nm550
          nm560  nm570  nm580  nm590  nm600  nm610  nm620  nm630  nm640  nm650
          nm660  nm670  nm680  nm690  nm700  nm710  nm720  nm730

END_DATA_FORMAT

NUMBER_OF_SETS  288

BEGIN_DATA

0      [sample_name_UID] 0.2815  0.2849  0.2901  0.3004  0.3124  0.3210  0.3295  0.3398
      0.3561  0.3724  0.3888  0.4068  0.4188  0.4231  0.4154  0.3965  0.3733  0.3484
      0.3227  0.3021  0.2841  0.2720  0.2617  0.2566  0.2532  0.2592  0.2849  0.3433
      0.4540  0.5990  0.7346  0.8367  0.8994  0.9320  0.9474  0.9500

1      [sample_name UID] 0.0180  0.0189  0.0205  0.0230  0.0257  0.0279  0.0299  0.0318
      0.0337  0.0357  0.0374  0.0389  0.0404  0.0419  0.0430  0.0440  0.0450  0.0459
```

0.0467	0.0475	0.0481	0.0488	0.0493	0.0498	0.0502	0.0508	0.0511	0.0514
0.0519	0.0522	0.0526	0.0529	0.0532	0.0533	0.0532	0.0531		

.
.
.

END_DATA

B. Data Inter-operability

TO BE DEFINED

VII. Conclusion

TO BE DEFINED

VIII. Glossary

Specie : referring especially to a group of organisms sharing common characteristics, can be either singular (e.g., *that species is purple*) or plural (e.g., *these species are yellow*). This is the convention in scientific writing, and it is usually followed elsewhere.

ΔE_{00} Metric [LI 2009] : The color difference, or ΔE (CIE 2000), between a sample color $L_2a_2b_2$ and a reference color $L_1a_1b_1$ is

$$\Delta E = \sqrt{\left(\frac{\Delta L'}{K_L S_L}\right)^2 + \left(\frac{\Delta C'}{K_C S_C}\right)^2 + \left(\frac{\Delta H'}{K_H S_H}\right)^2 + R_T \left(\frac{\Delta C'}{K_C S_C}\right) \left(\frac{\Delta H'}{K_H S_H}\right)}$$

Where :

$$\bar{L}' = (L_1 + L_2)/2$$

$$C_1 = \sqrt{a_1^2 + b_1^2}$$

$$C_2 = \sqrt{a_2^2 + b_2^2}$$

$$\bar{C}' = (C_1 + C_2)/2$$

$$G = \left(1 - \sqrt{\frac{\bar{C}'}{\bar{C}' + 25}}\right) / 2$$

$$a'_1 = a_1(1 + G)$$

$$a'_2 = a_2(1 + G)$$

$$C'_1 = \sqrt{a_1'^2 + b_1^2}$$

$$C'_2 = \sqrt{a_2'^2 + b_2^2}$$

$$\bar{C}' = (C'_1 + C'_2)/2$$

$$h'_1 = \begin{cases} \tan^{-1}(b_1/a'_1) & \tan^{-1}(b_1/a'_1) \geq 0 \\ \tan^{-1}(b_1/a'_1) + 360^\circ & \tan^{-1}(b_1/a'_1) < 0 \end{cases}$$

$$h'_2 = \begin{cases} \tan^{-1}(b_2/a'_2) & \tan^{-1}(b_2/a'_2) \geq 0 \\ \tan^{-1}(b_2/a'_2) + 360^\circ & \tan^{-1}(b_2/a'_2) < 0 \end{cases}$$

$$\bar{H}' = \begin{cases} (h'_1 + h'_2 + 360^\circ)/2 & |h'_1 - h'_2| > 180^\circ \\ (h'_1 + h'_2)/2 & |h'_1 - h'_2| \leq 180^\circ \end{cases}$$

$$T = 1 - 0.17 \cos(\bar{H}' - 30^\circ) + 0.24 \cos(2\bar{H}') + 0.32 \cos(3\bar{H}' + 6^\circ) - 0.20 \cos(4\bar{H}' - 63^\circ)$$

$$\Delta H' = \begin{cases} h'_2 - h'_1 & |h'_2 - h'_1| \leq 180^\circ \\ h'_2 - h'_1 + 360^\circ & |h'_2 - h'_1| > 180^\circ; h'_2 \leq h'_1 \\ h'_2 - h'_1 - 360^\circ & |h'_2 - h'_1| > 180^\circ; h'_2 > h'_1 \end{cases}$$

$$\Delta L' = L_2 - L_1$$

$$\Delta C' = C'_2 - C'_1$$

$$\Delta H' = 2\sqrt{C'_1 C'_2} \sin(\Delta H'/2)$$

$$S_L = 1 + \frac{0.015(L' - 50)^2}{\sqrt{20 + (L' - 50)^2}}$$

$$S_C = 1 + 0.045\bar{C}'$$

$$S_H = 1 + 0.015\bar{C}'T$$

$$\Delta\theta = 30 \exp\left\{-\left(\frac{\bar{H}' - 275^\circ}{25}\right)^2\right\}$$

$$R_C = 2\sqrt{\frac{\bar{C}'^{17}}{\bar{C}'^{17} + 25^{17}}}$$

$$R_T = -R_C \sin(2\Delta\theta)$$

$$K_L = 1 \quad \text{default}$$

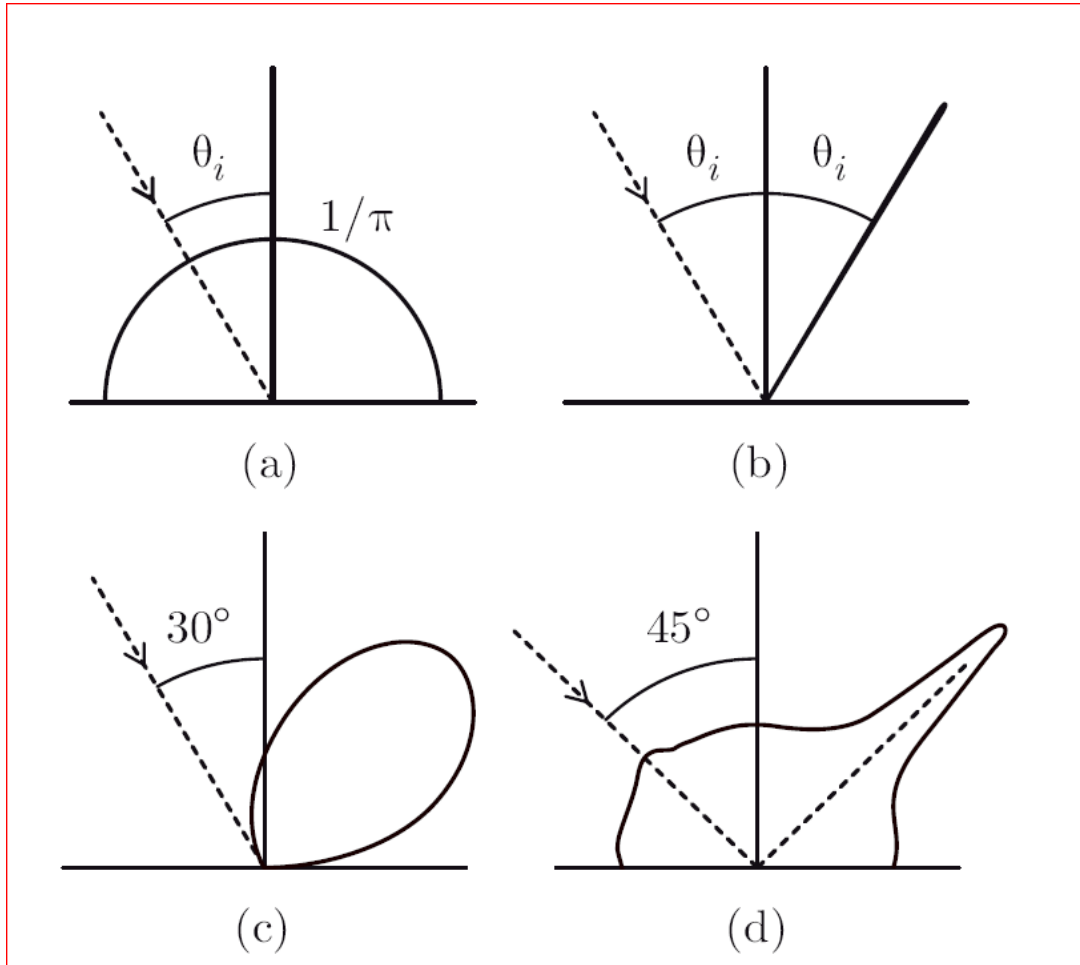
$$K_C = 1 \quad \text{default}$$

$$K_H = 1 \quad \text{default}$$

BRDF [HEB 2015] : the reflexion process of light by a surface is embodied in the fundamental equation relating the elemental irradiance dE_i coming from each direction (θ_i, φ_i) and the radiance $dL_r(\theta_r, \varphi_r)$ reflected into each direction (θ_r, φ_r) :

$$dL_r(\theta_r, \varphi_r) = fR(\theta_i, \varphi_i; \theta_r, \varphi_r) dE_i(\theta_i, \varphi_i)$$

Function fR is called *bidirectional reflectance distribution function (BRDF)*.



Sections of BRDF in the incidence plane ($\phi_i = \phi_r = 0$), plotted in polar coordinates as a function of θ_r , of (a) a Lambertian reflector, (b) a smooth surface, (c) a roughened aluminium surface and (d) a glossy paper

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 2. Antibioqram : <https://en.wikipedia.org/wiki/Antibiogram>
 3. Hyperspectral imaging : https://en.wikipedia.org/wiki/Hyperspectral_imaging

Color measurements through band-sequential LED spectral imaging

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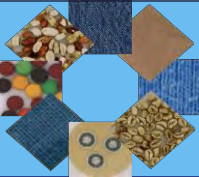
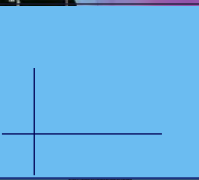
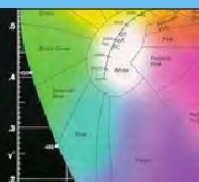
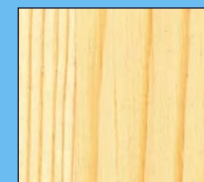
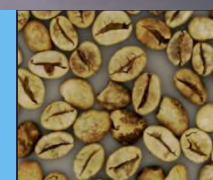
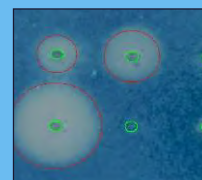
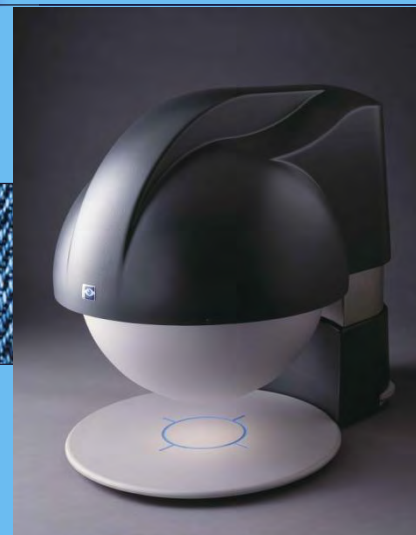
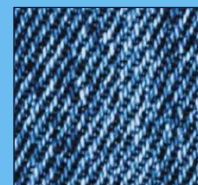
Videometer A/S

www.videometer.com

DTU Compute

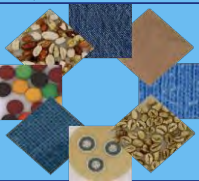
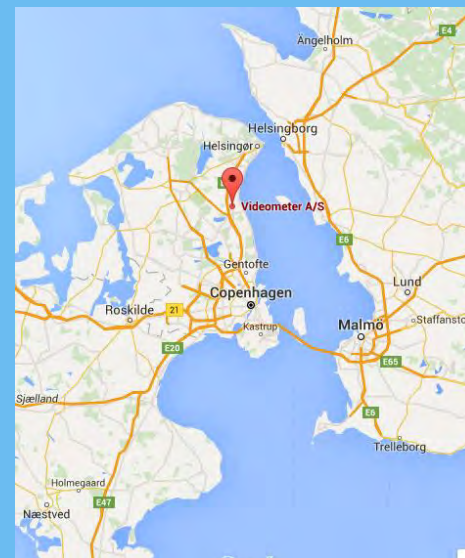
www.compute.dtu.dk

ICC MIWG meeting
Munich, Feb 16, 2016

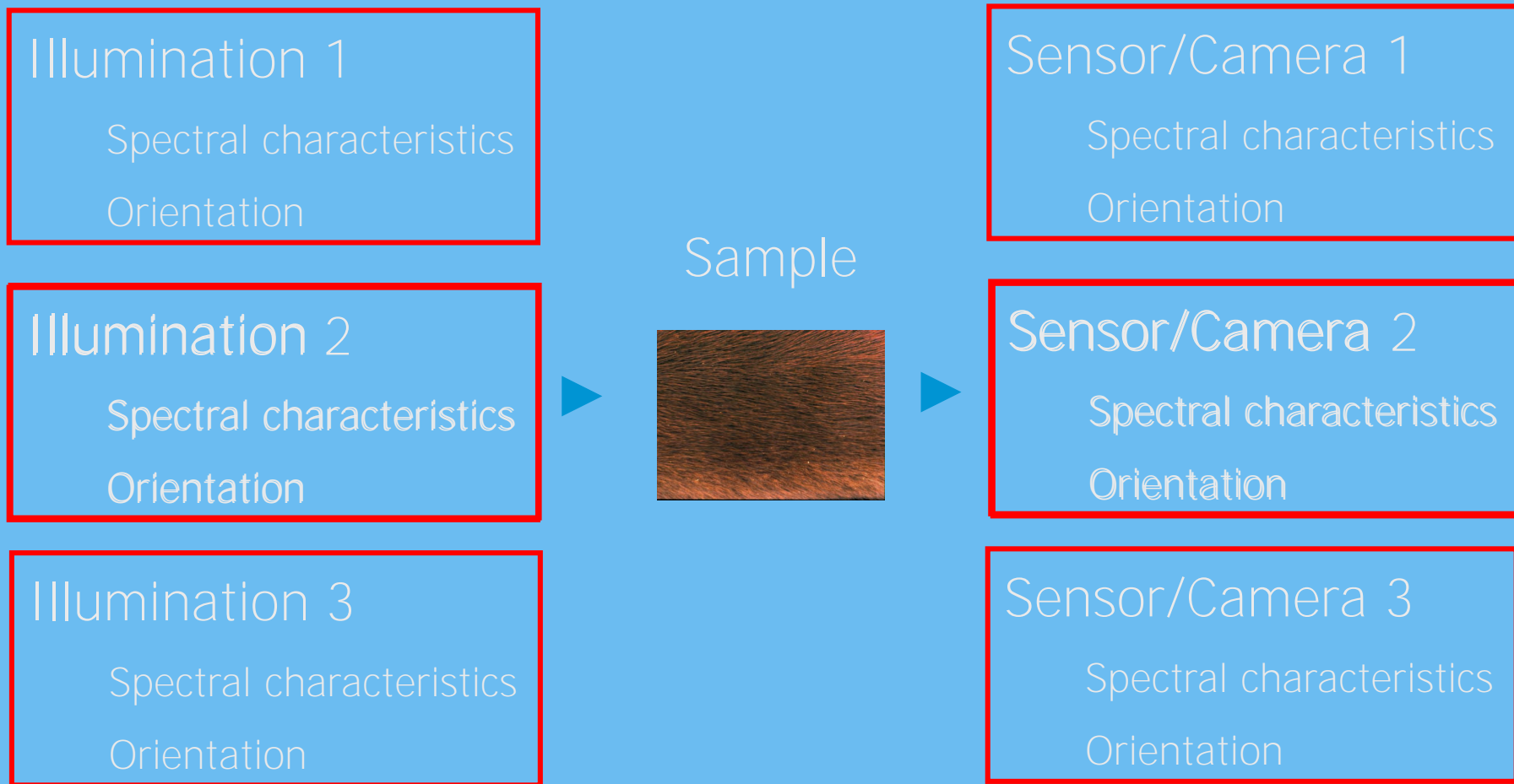


Videometer A/S

- Spectral imaging company
- Founded 1999
- A track record of 450 imaging R&D projects since 2000
- In-line 24/7 spectral imaging since 2002
- Markets R&D projects, instruments, and software
- Patented technology
- Based in Hørsholm, Denmark



Redundancy imaging



Moving from appearance to physics and chemistry



Sorting of mink pelts

- Color and purity
- Before: highly skilled sorters educated for 4 years
- Today: 8 lines using multispectral imaging
- High reproduceability
- High accuracy
- Robust
- Fast return on investment

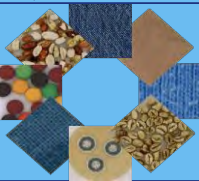
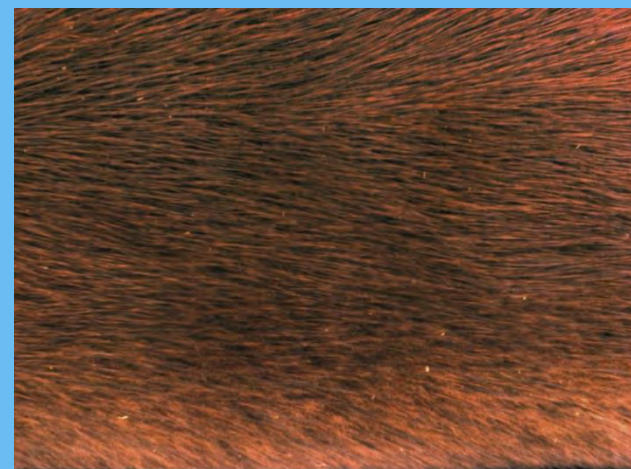


Color Sorting of Mink Pelts

Color Sorting at **Kopenhagen Fur**



Black, brown, and pearl
types sorted into 20
classes

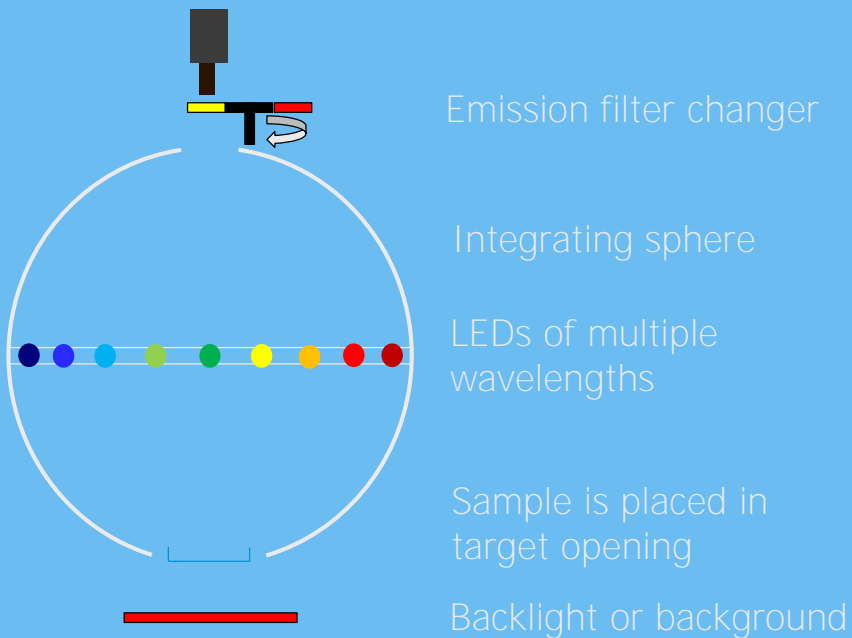


How does it look February 2016?

Kopenhagen Fur
Color sorting
February 2016
Videometer A/S



Videometer BSQ Spectral Imaging



- LEDs: Stable, durable, large selection, rapidly developing technology
- Up to 20 different high-resolution bands acquired sequentially in 0.5-1.5 seconds depending on camera



Band-sequential spectral imaging

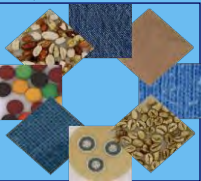
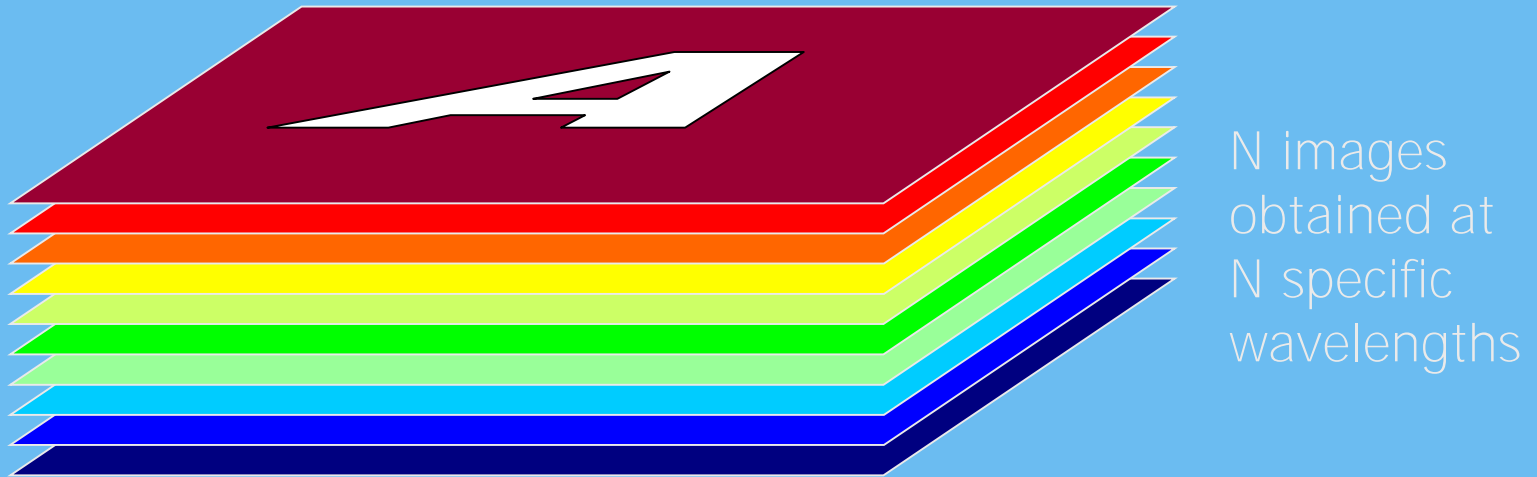
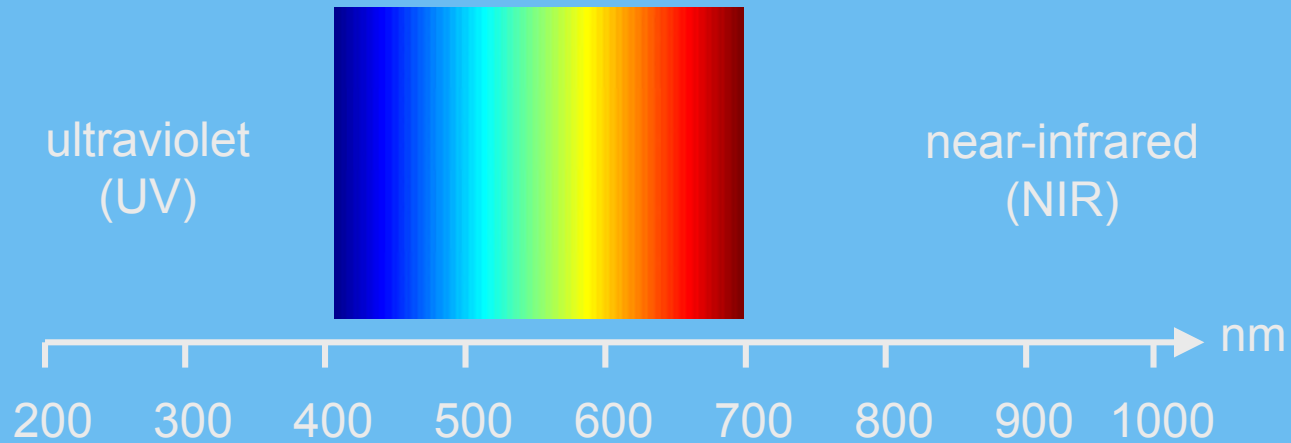


Image example (Rice *Oryza sativa* L.)

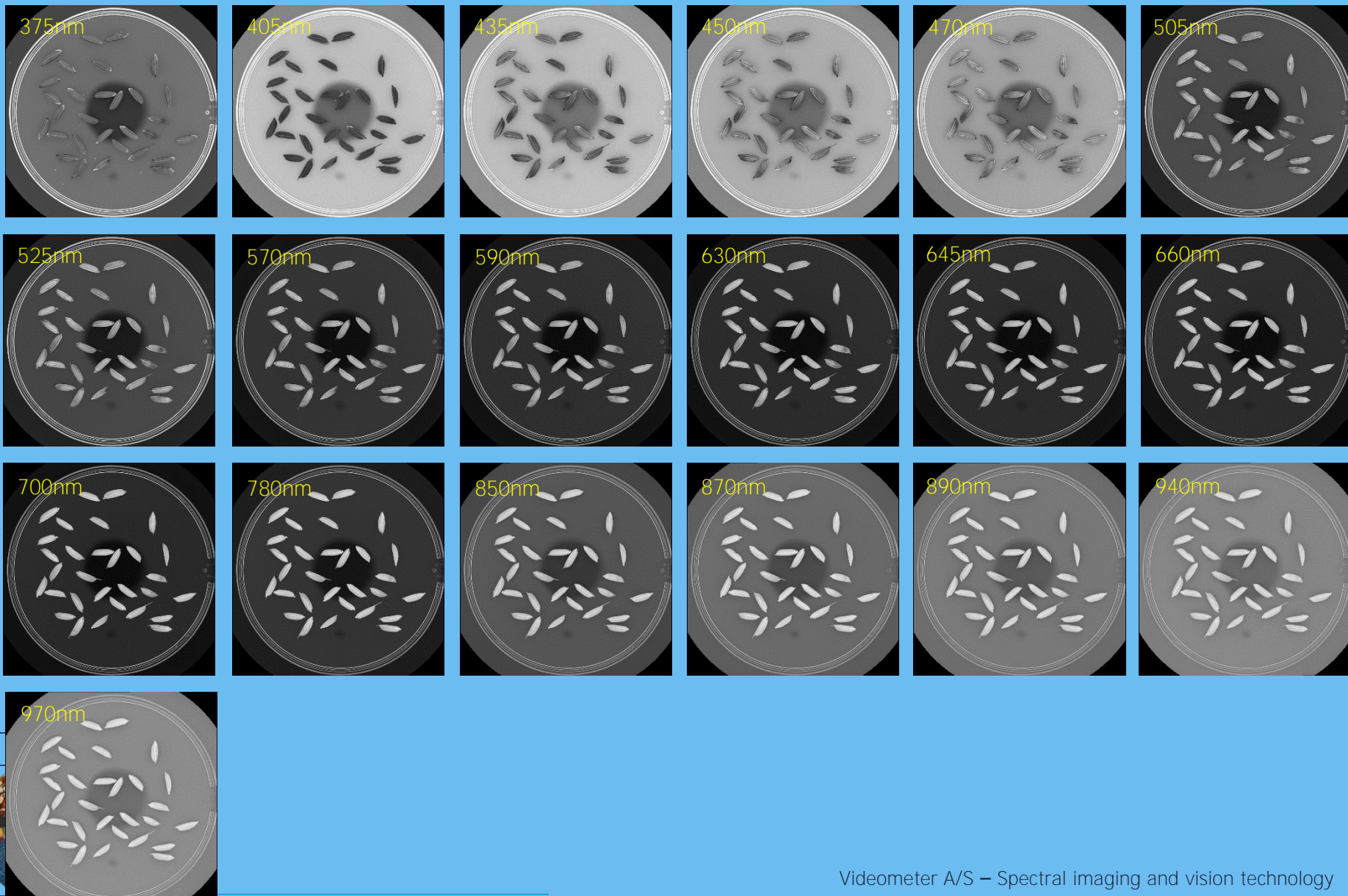
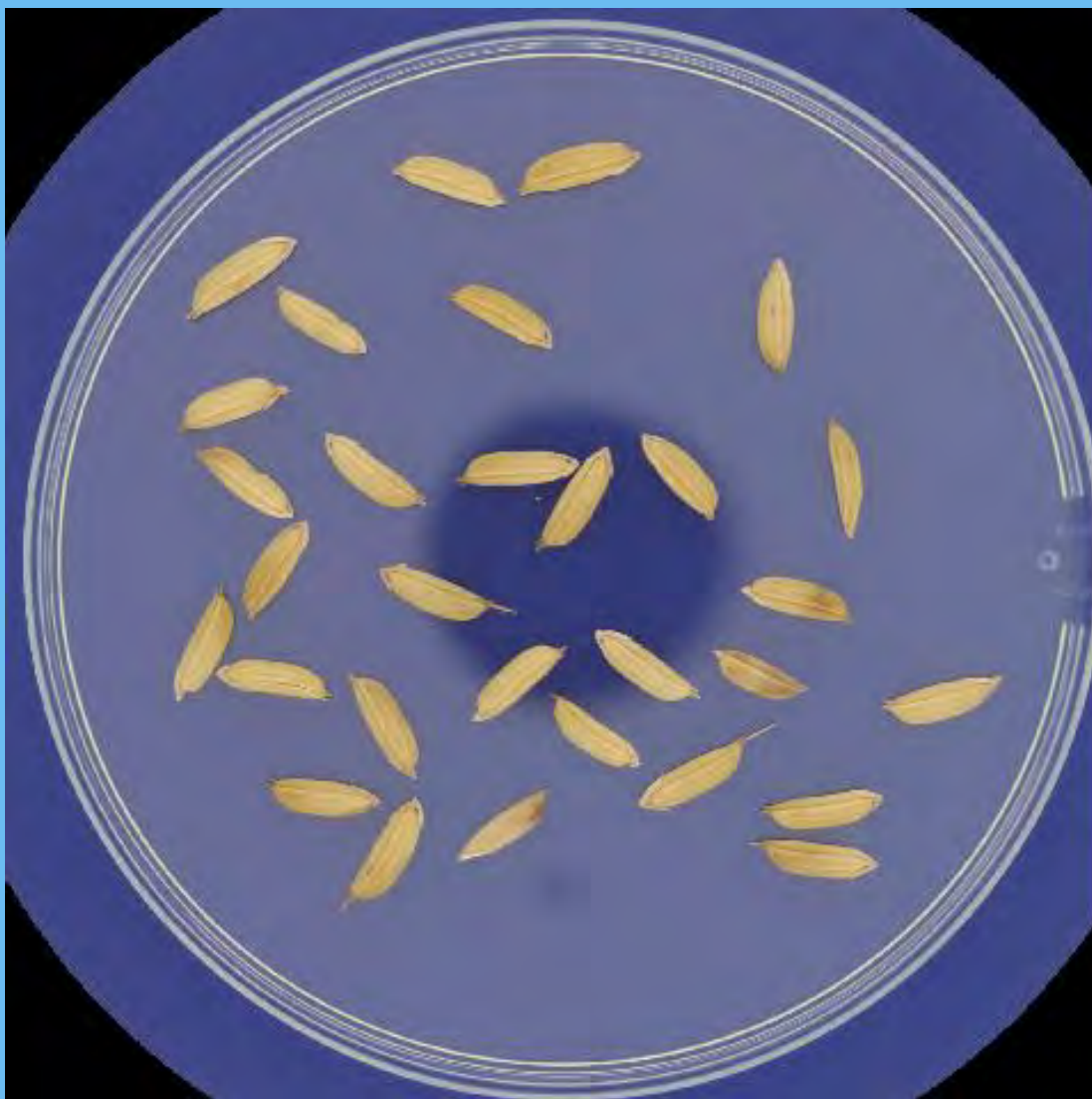
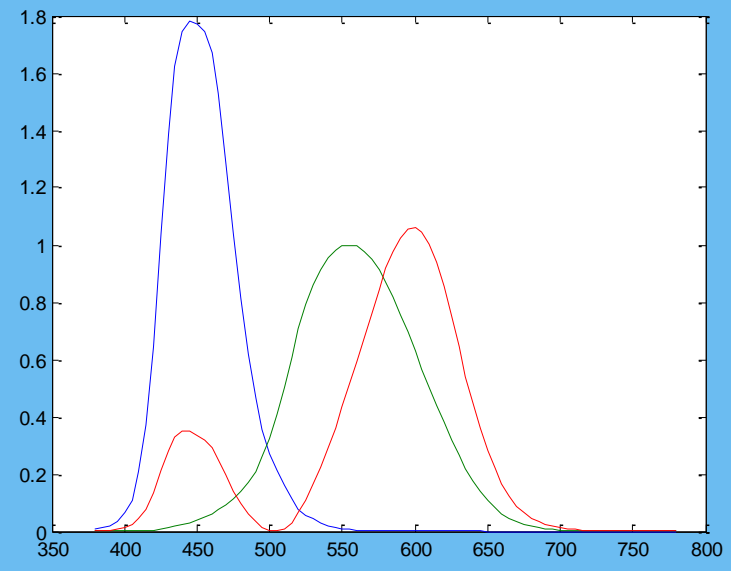


Image Data (example)

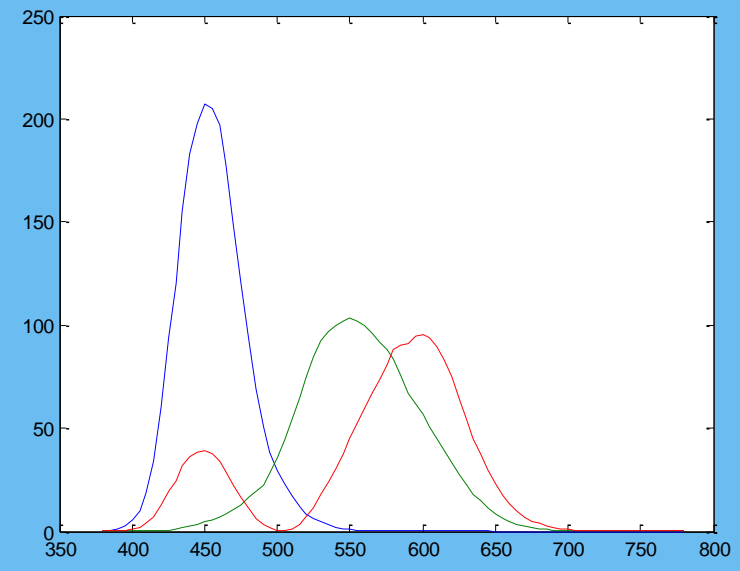


117264_2

CIE XYZ curves



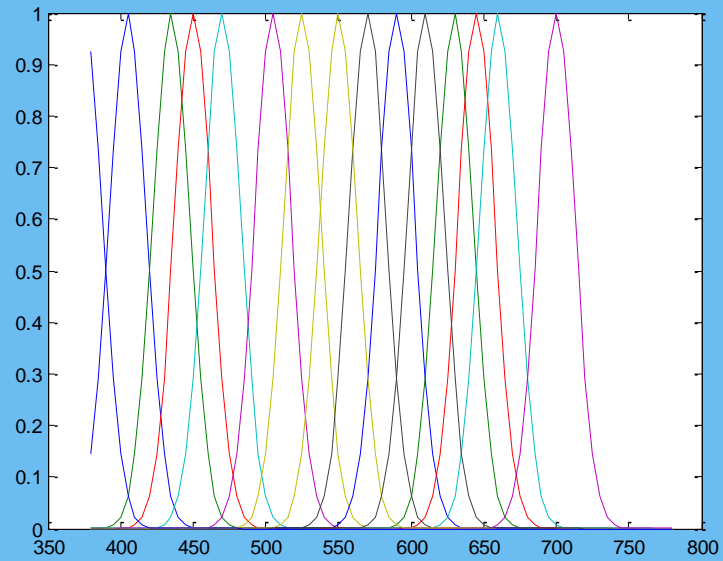
CIE XYZ



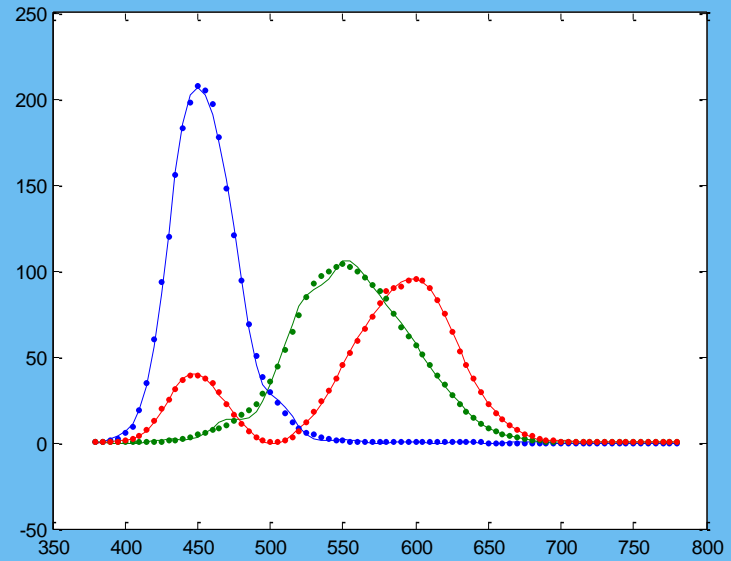
CIE XYZ under D65



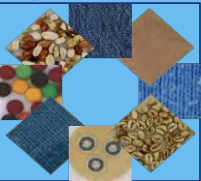
Modelling CIE XYZ curves



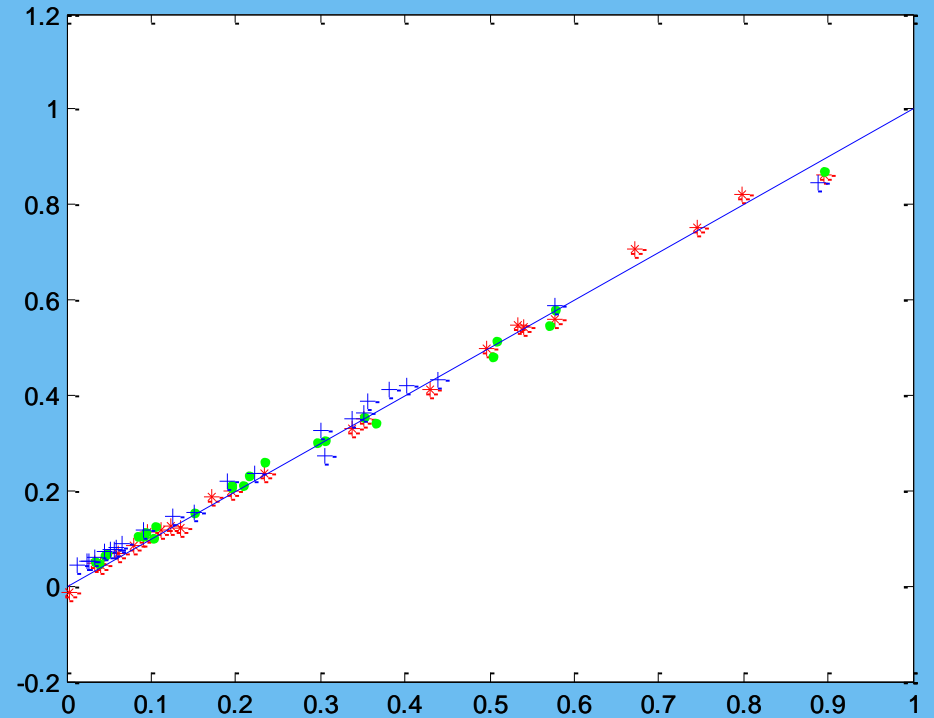
Normalized LED spectra



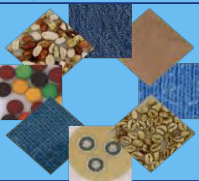
Modelled CIE XYZ
under D65



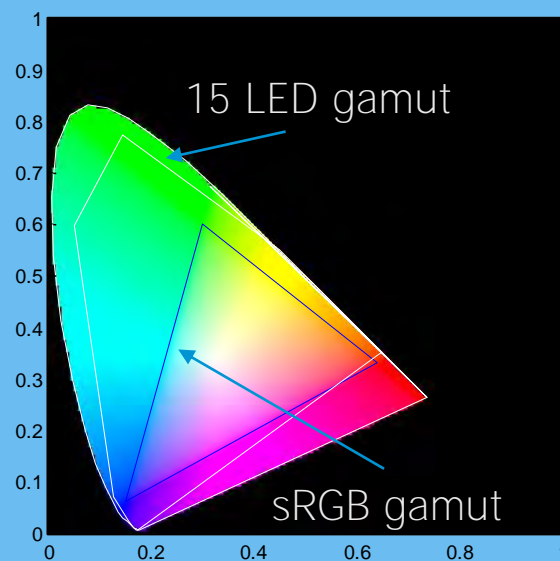
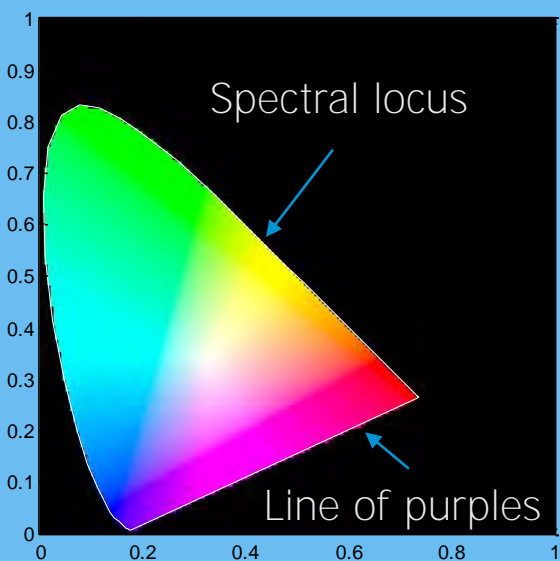
Colorchecker linRGB vs linRGBref



G+B blacklevel corrected



CIE XYZ 1931 chromaticity diagram



Emulation of illuminants



D65



D50



F11

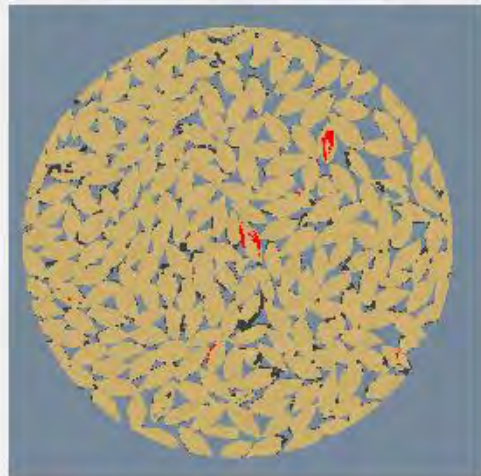


Use case of reflectance spectral imaging



Recipe: Red Fusarium grey moulds ver 3-2

Plan: No Plan



Sample ID	Red Fusarium	Red Fusarium	Red Fusarium	Red Fusarium	Red Fusarium
EF01 Prestice 3_Capture1	2.674436	0	2.44979525	2	0
EF01 Prestice 3_Capture2	0.222490549	1.44846332	0	0	1
EF01 Prestice ny_Capture1	0.482127368	0	0.3215661	1	0
EF01 Prestice ny_Capture2	3.59720349	2.03966546	3.03879118	4	2

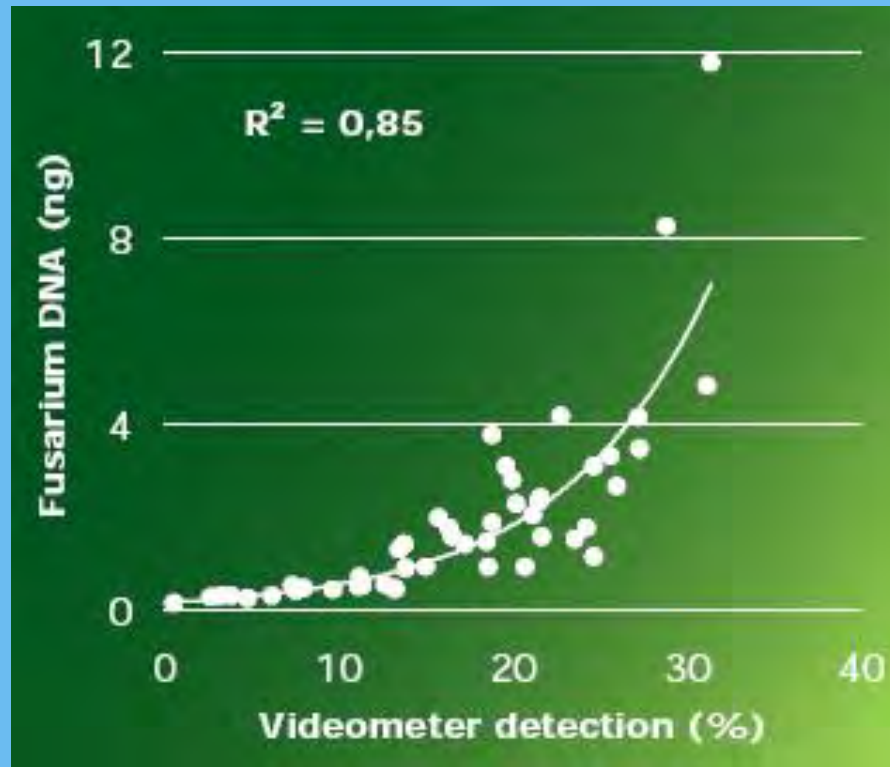
Next Sample Data

Sample ID: Sample Note:

Auto Number: Filename: Red Fusarium grey moulds ver 3-2_Capture1

Capture Number: 1 of 2 *SessionName_SampleID_CaptureNumber*

Comparison between **VideometerLab[®]** measurements and the level of *Fusarium* DNA quantified by **Real-time PCR**



→ **Excellent correlation with Fusarium DNA level ($R^2=0,85$)**



Color measurement on meat



Contents lists available at ScienceDirect

Meat Science

journal homepage: www.elsevier.com/locate/meatsci



Comparison of a multispectral vision system and a colorimeter for the assessment of meat color



Camilla H. Trinderup^{a,*}, Anders Dahl^a, Kirsten Jensen^b, Jens Michael Carstensen^{a,c}, Knut Conradsen^a

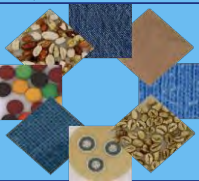
^a Technical University of Denmark, Richard Petersens Plads, 2800 Kongens Lyngby, Denmark

^b Danish Meat Research Institute, Magleåsvej 2, 4000 Roskilde, Denmark

^c Videometer A/S, Lyngsø Alle 3, 2970 Hørsholm, Denmark



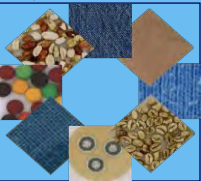
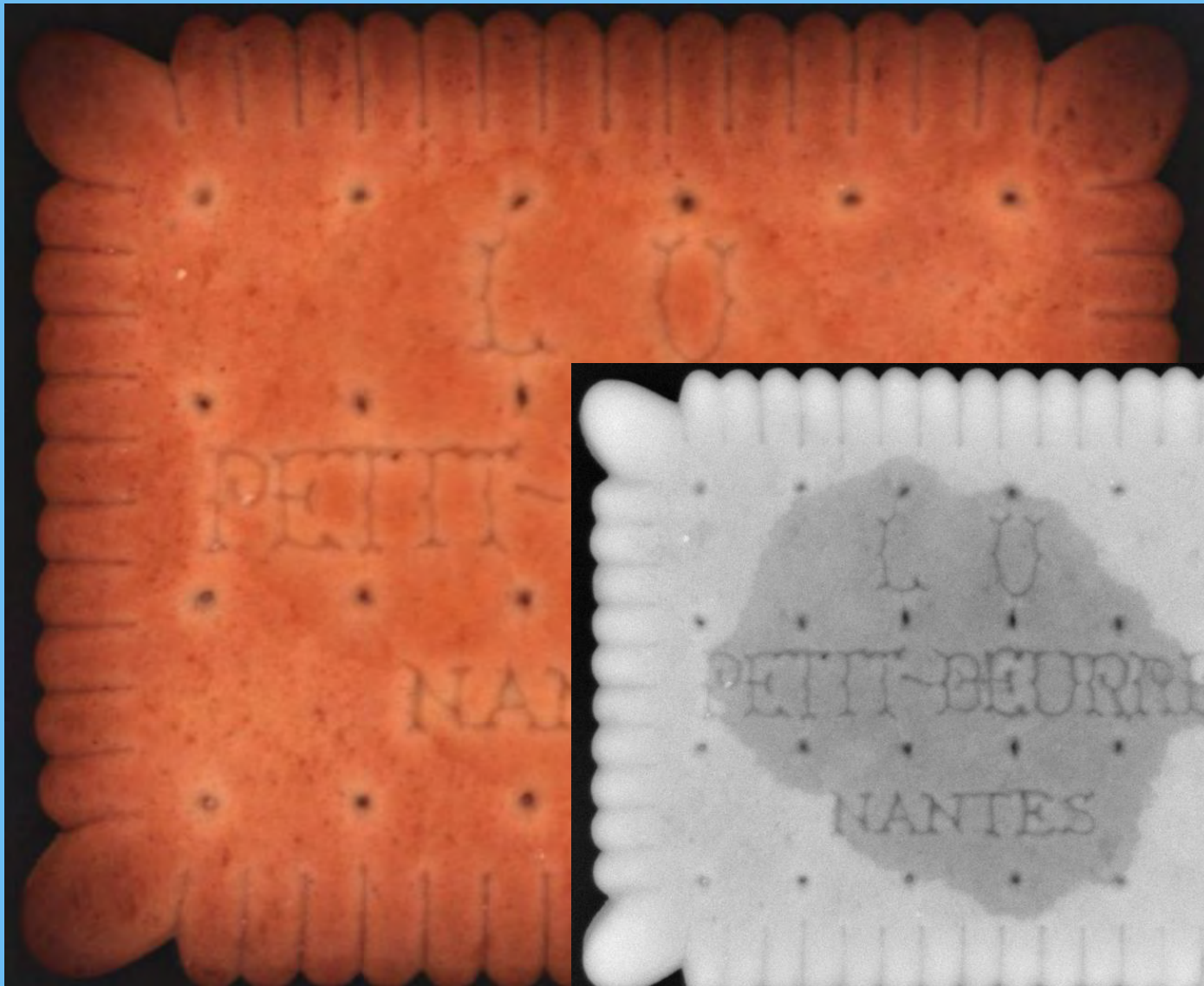
Fig. 4. Colors of the twelve different product types, as evaluated by the two instruments. Here shown in sRGB colors. Left column: Example of product type. Middle column (five blocks): Colorimeter colors. Right column (five blocks): Colors from the vision system. Colors displayed are averages of four site measurements on each sample.



Biscuit with wet spot



Moisture detection on biscuit

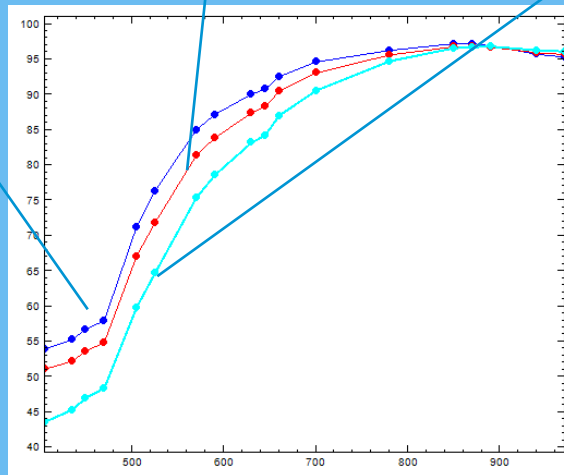
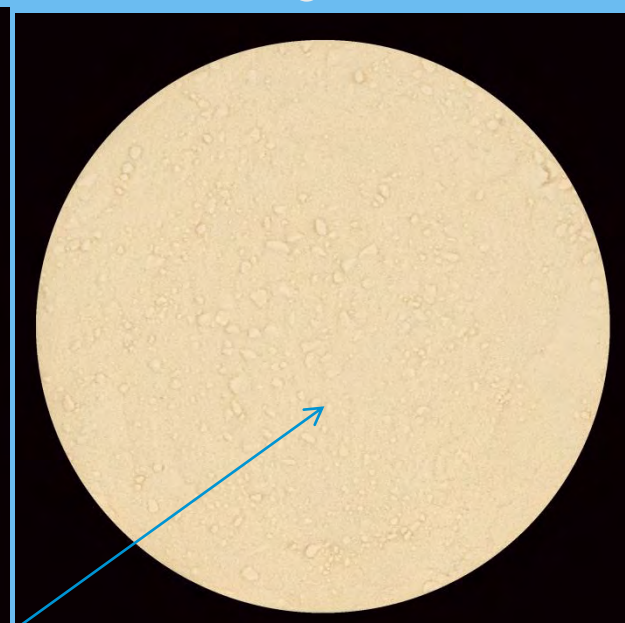
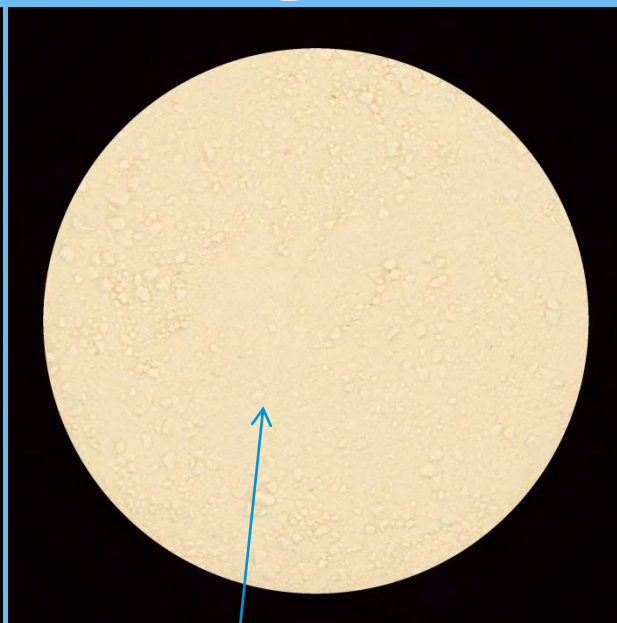
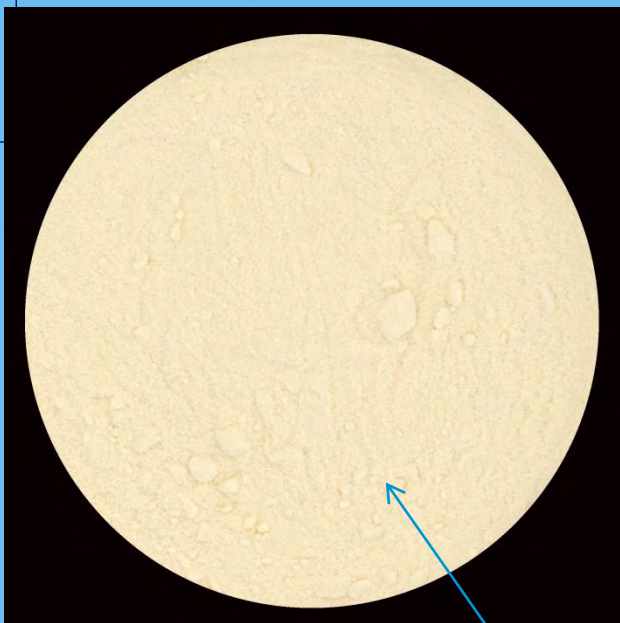


Three milk powders

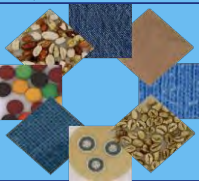
A

B

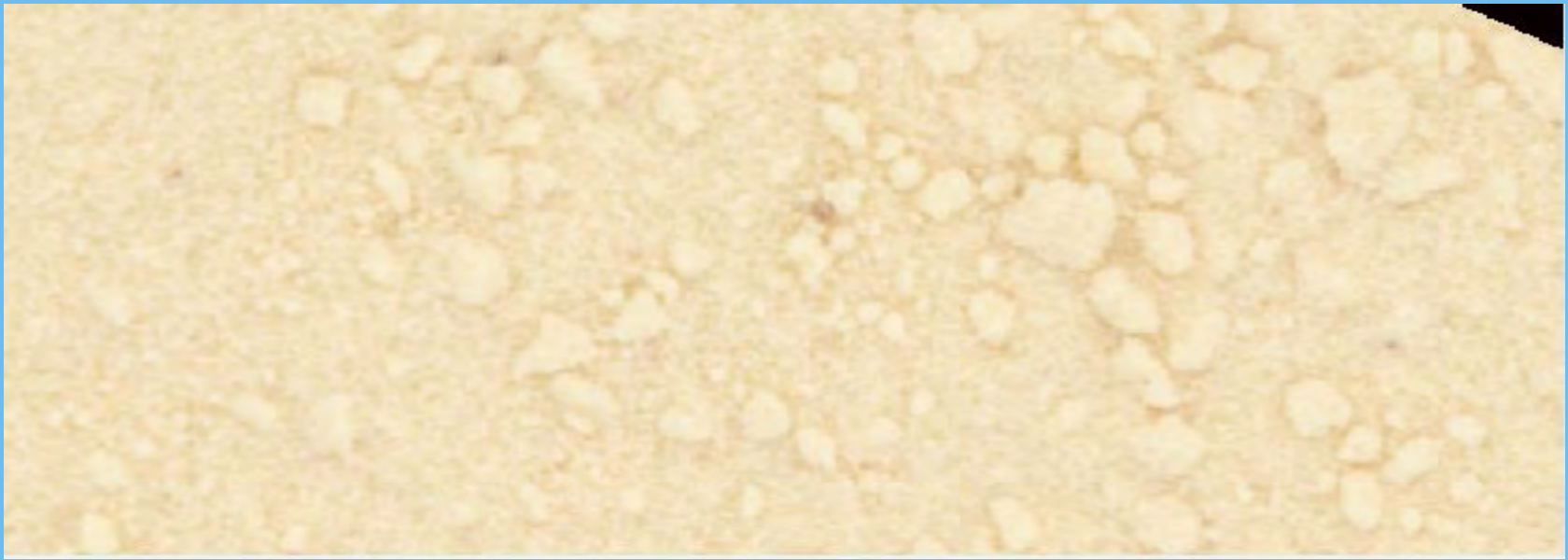
C



Clear color difference



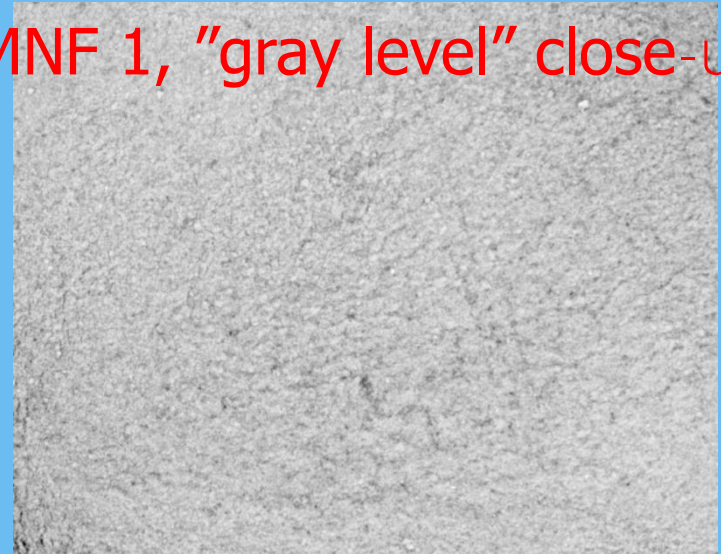
RGB close-up with burned marked



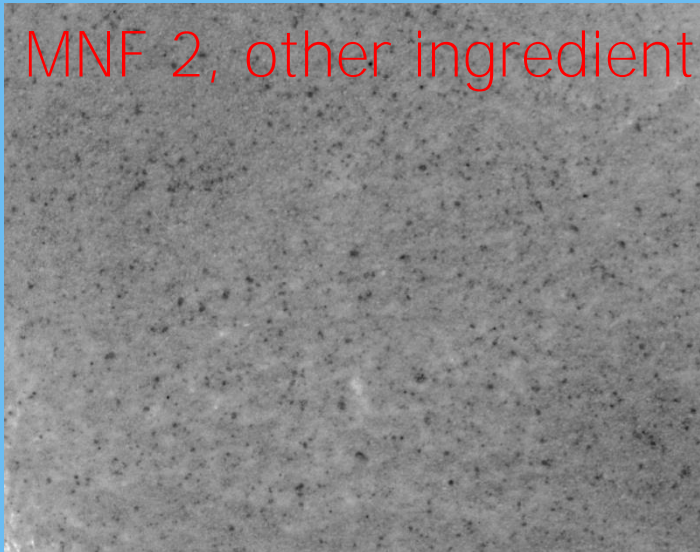
Pharmaceutical powder



MNF 1, "gray level" close-up



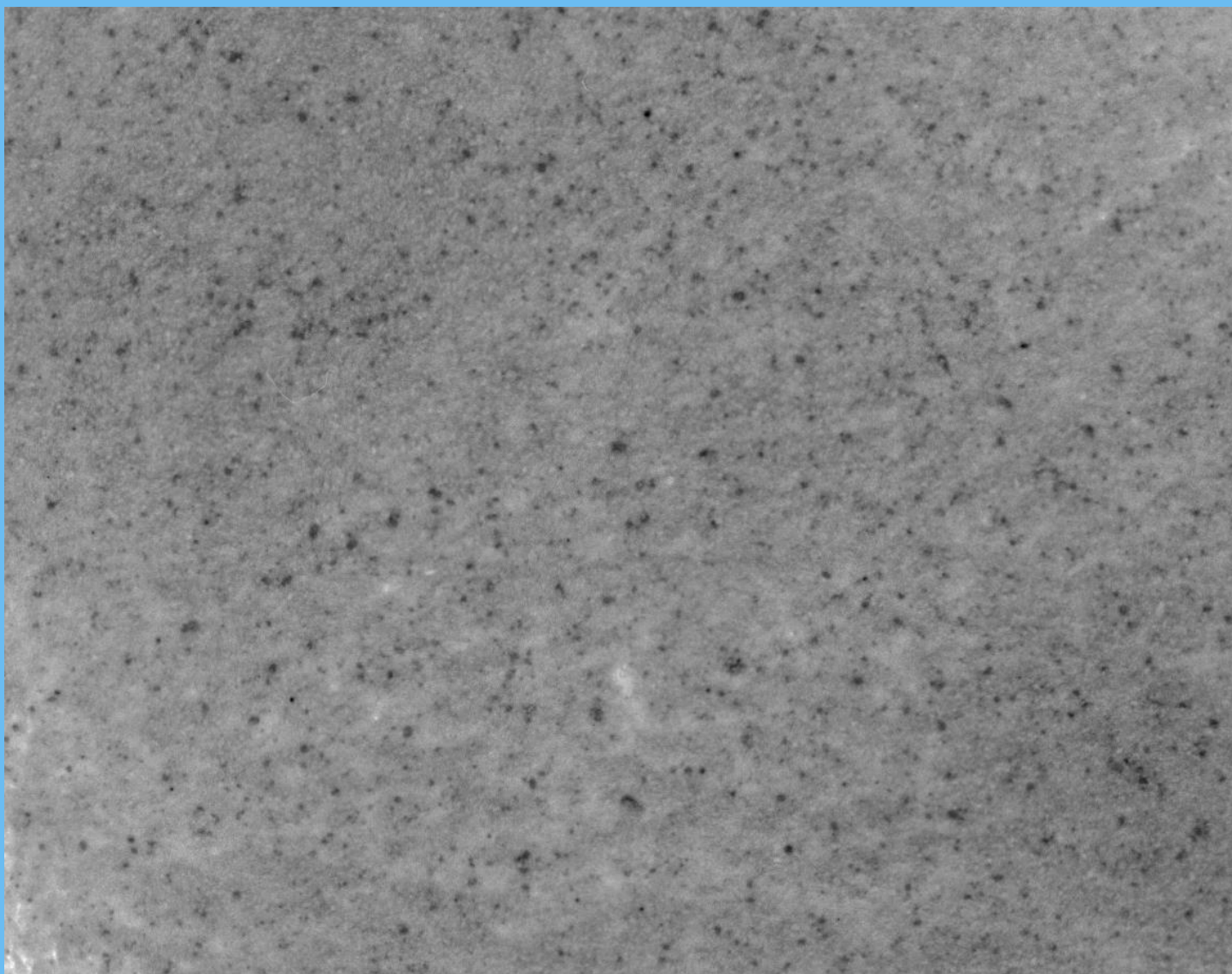
MNF 2, other ingredient



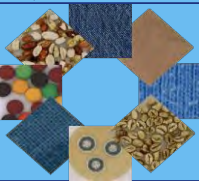
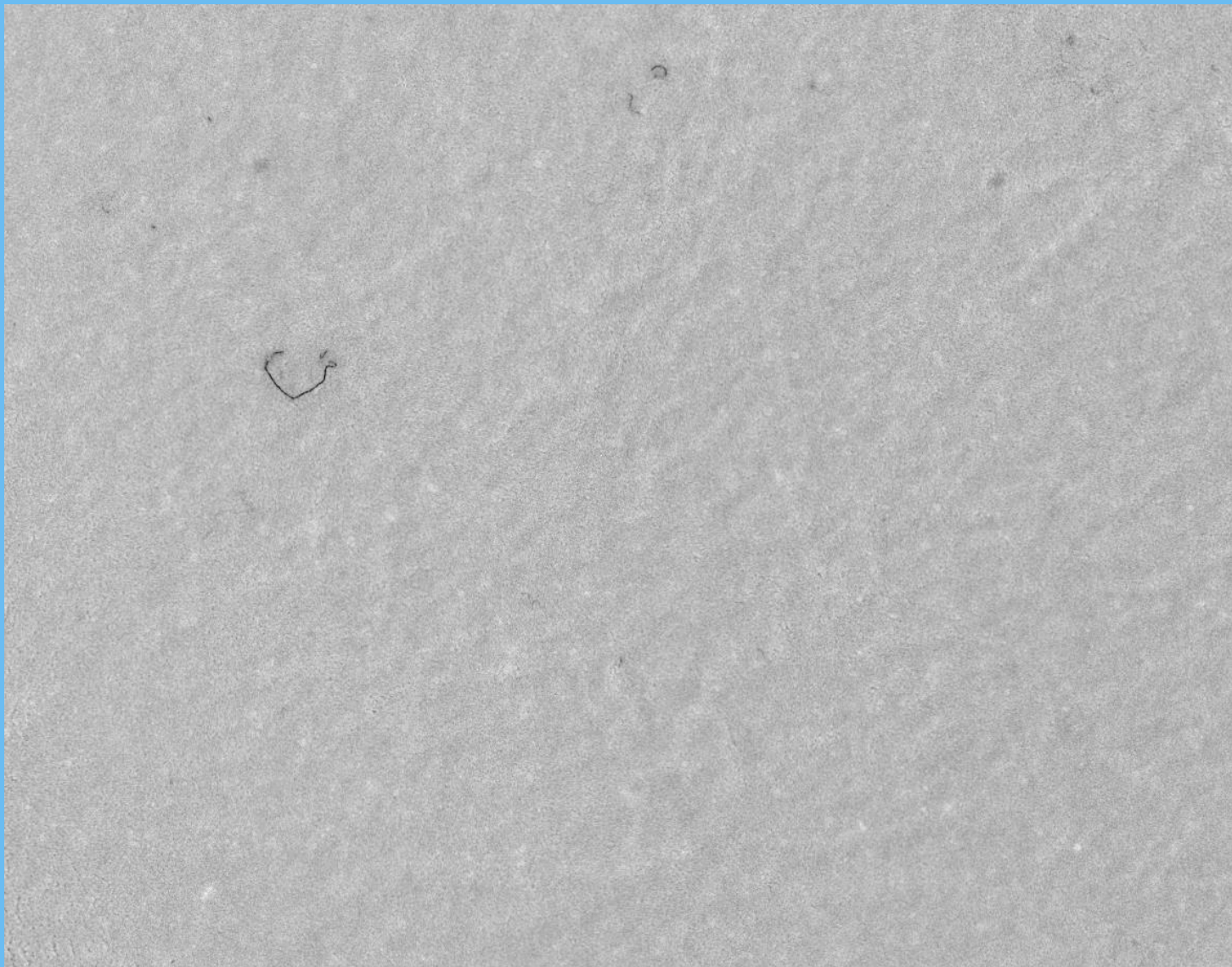
MNF 3, impurities



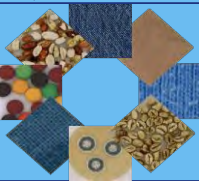
Other ingredient



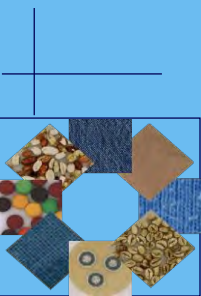
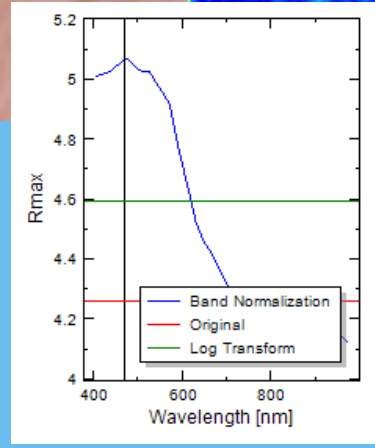
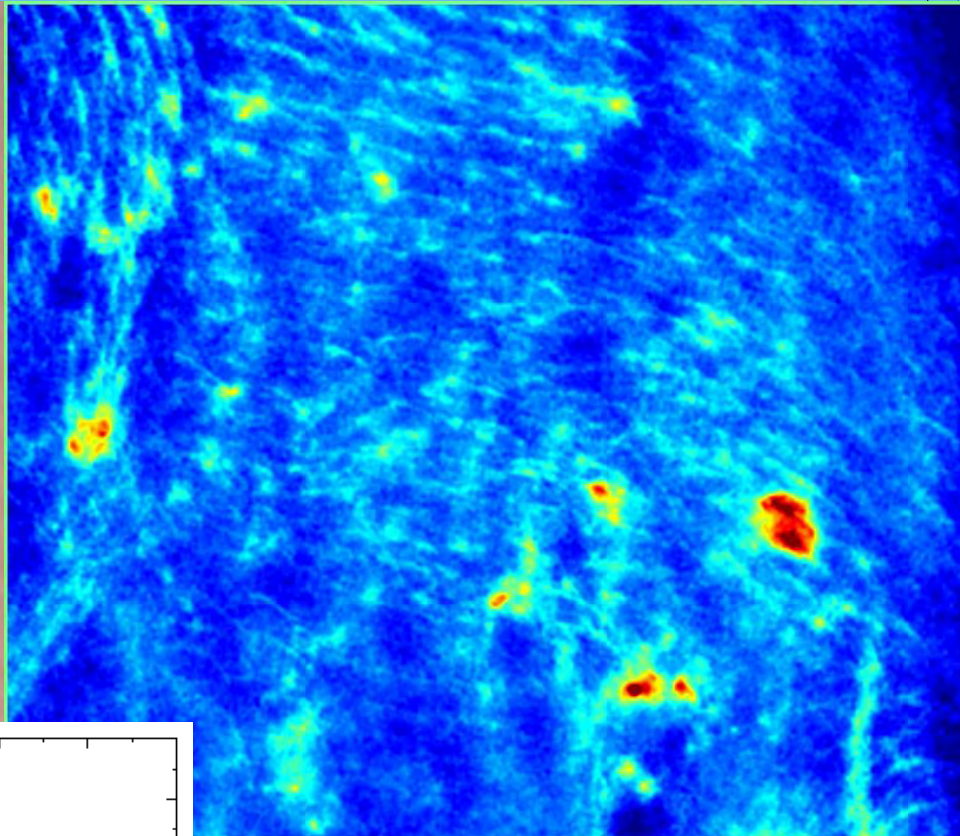
Impurities



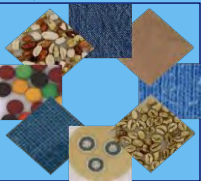
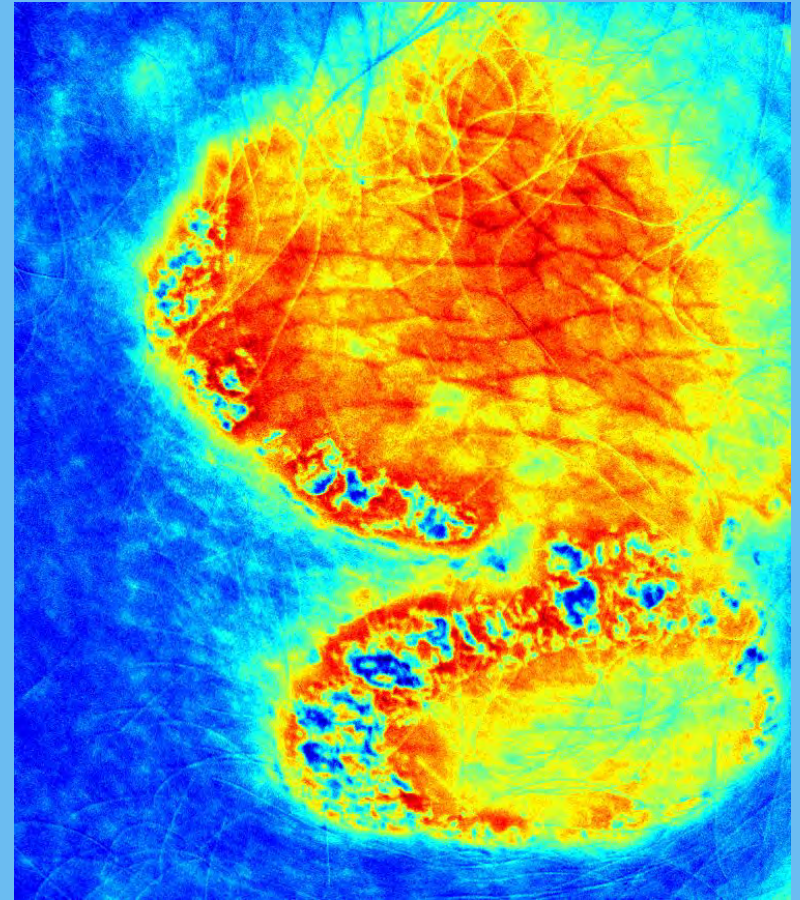
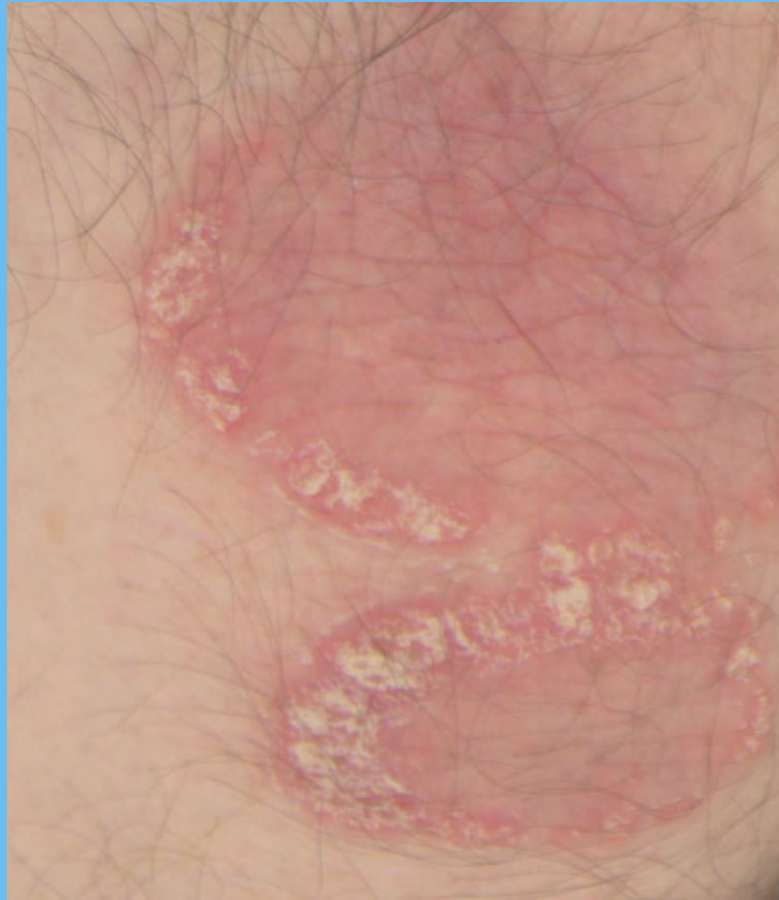
VideometerLab Agile



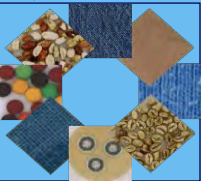
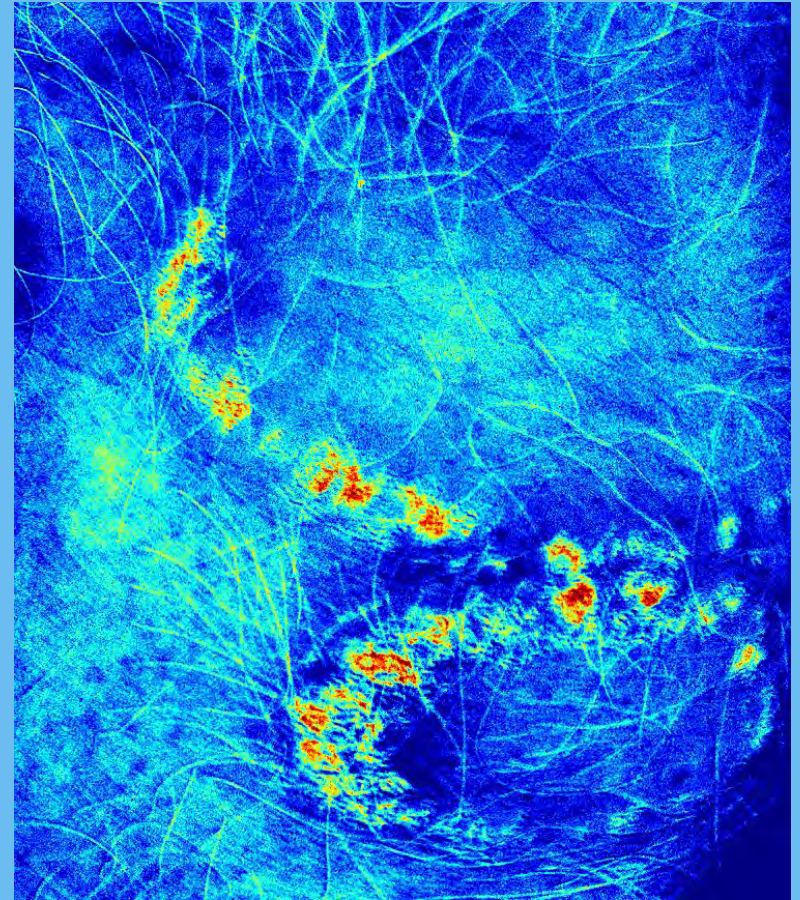
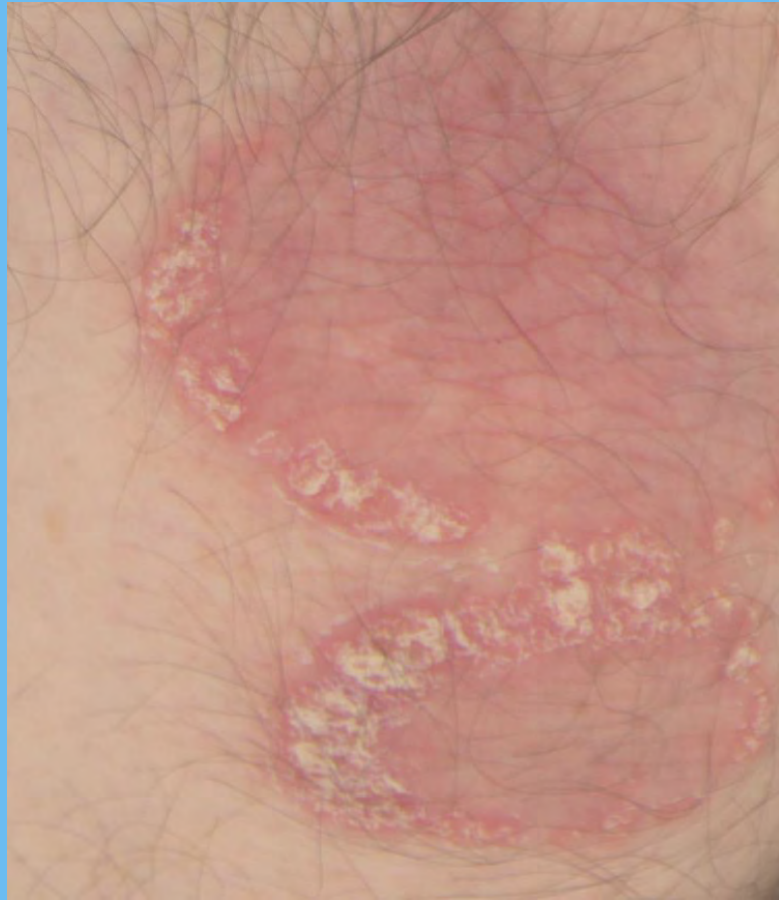
Solar freckle detector



Psoriasis redness scoring



Psoriasis scaling score



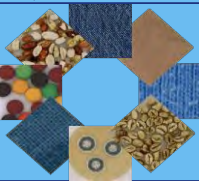
Spectral vs. spatial resolution

Hyperspectral

- Dense spectral sampling
- More mixed spectra
- Same dynamic range
- Potentially unmixes 30+

High-resolution

- Discrete spectral sampling
- Less mixed spectra
- Spectral HDR imaging
- Typically unmixes 2-10

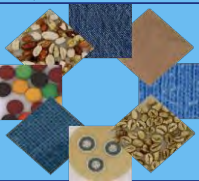


Light setup and dynamic range



NIST 100%
light setup

Auto light
setup





ICC Medical Imaging Working Group meeting

“Visualization of medical content on color display systems”

Tom Kimpe
Barco NV
(tom.kimpe@barco.com)

February 16th 2016
Munich, Germany

Summary of white paper #44

How can we ensure a consistent representation of medical images on color displays?

1. Use cases
2. Method
3. Results
4. Recommendations

Use cases

Accurate color reproduction is out-of-scope of this document.

Relative Grayscale Calibration must follow DICOM GSDF Standard.

Relative Color Calibration can be achieved by following for example CSDF which is one possible candidate for standardization.

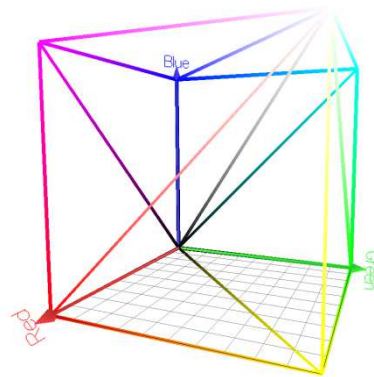
DICOM GSDF:

Grayscale Standard Display Function

- GSDF is a relative calibration aiming to linearize the perception of luminance of a display without reducing its luminance dynamic range.

CSDF: Color Standard Display Function

- CSDF is a proposed calibration extending the concept of DICOM GSDF to color.
 - Gray levels follow DICOM GSDF standard.
 - Saturated colors are perceptually linearized according to ΔE_{2000} (CIEDE2000) color difference metric.

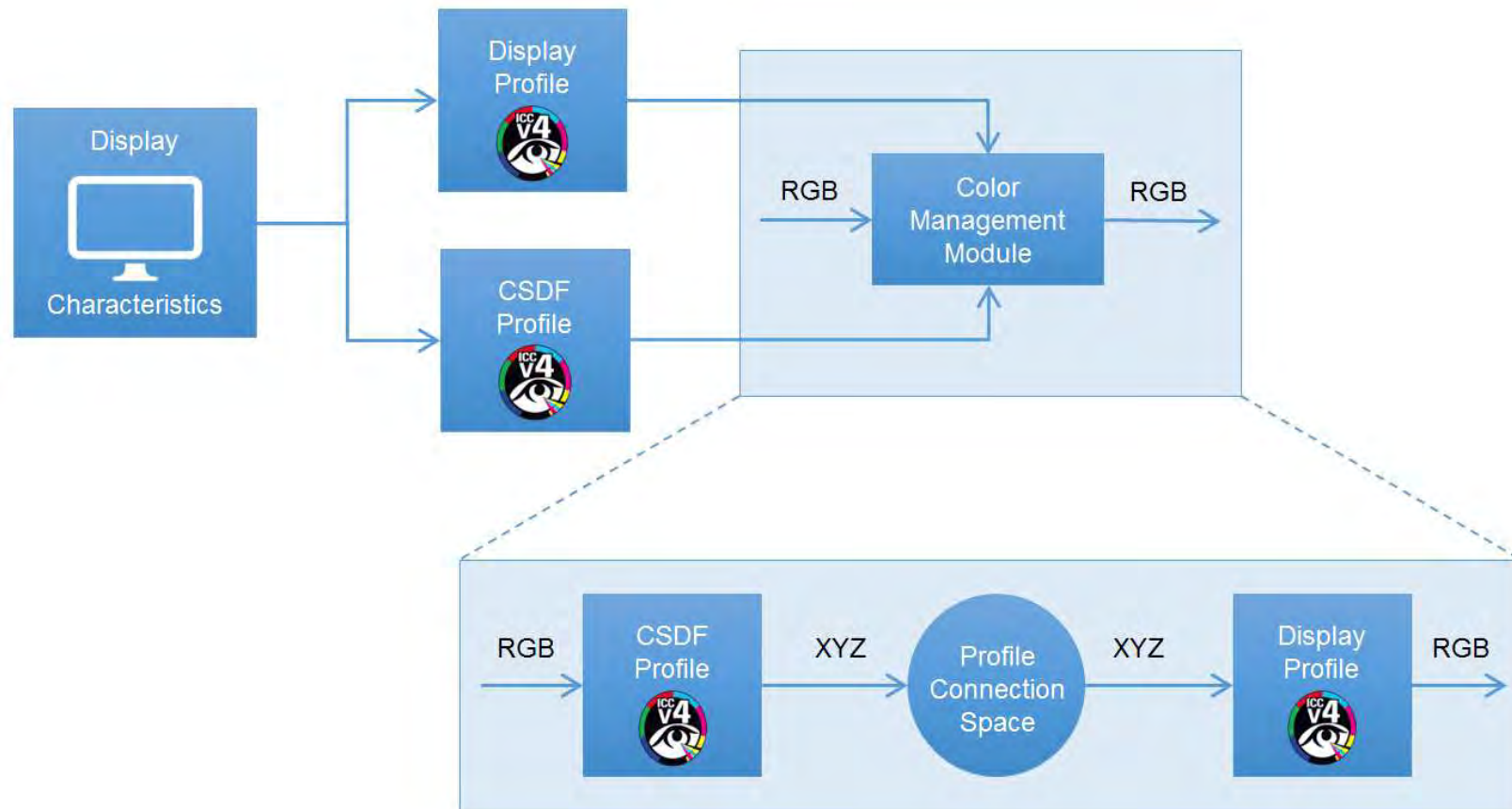


Color sweeps represented in the RGB cube that are made perceptually linear by CSDF. The Gray scale is linearized according to DICOM JND, and the others lines according to ΔE_{2000} .

Method

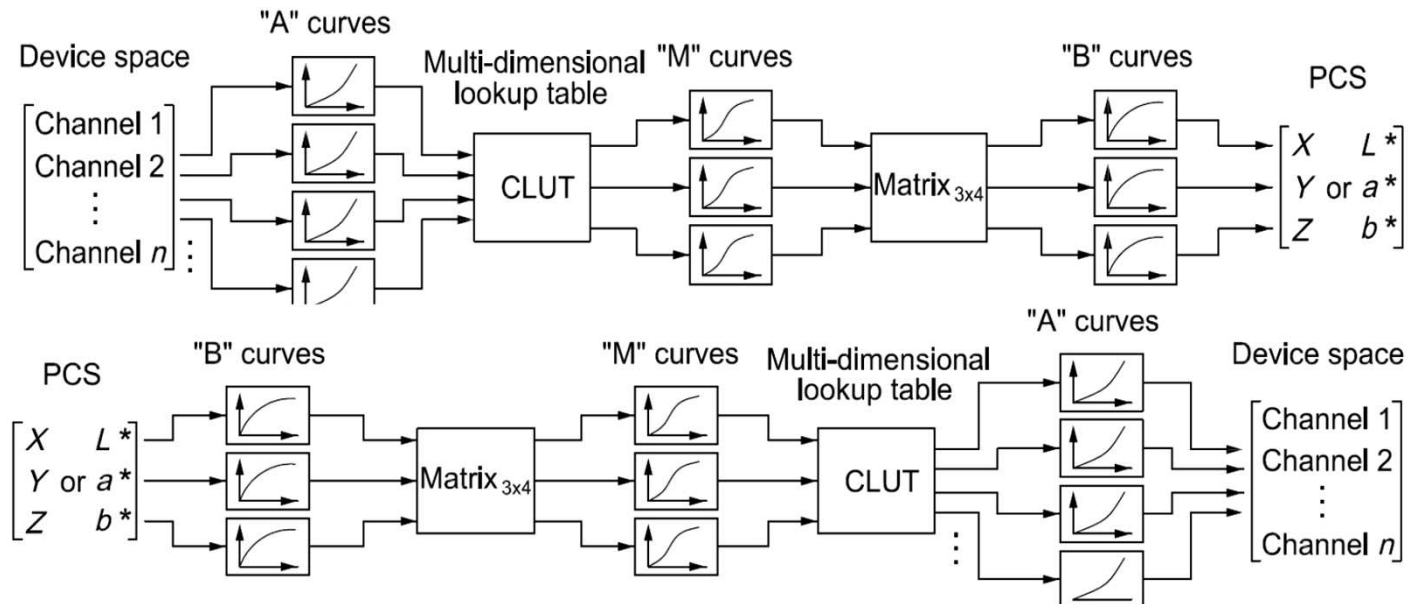
- The proposed method consists in creating two ICC profiles while characterizing a display:
 - The first one describes its native color behavior.
 - The second one describes the ideal calibration based on its properties.
- Connecting these profiles with a colorimetric intent ends up in a calibrated viewing system.

Calibration framework



Workflow of ICC based CSDF display calibration.

Profile specifics



Device-to-PCS and PCS-to-Device conversion workflows for LUT based profiles. The different elements around the Color LUT (CLUT) can be used to create a nonlinear repartition of the input values of the LUT, or set to identity.

Profiles were constructed using the XYZ PCS.

- A-curves are unused in both Device-to-PCS and PCS-to-Device conversions and were thus set to be identity tone curves.
- CLUT stages are used for RGB-to-RGB conversions. The tables may contain individual point corrections to make the profile more faithful to the display it represents.
- M-curves are used to apply inverse RGB companding in Device-to-PCS conversion and RGB companding in PCS-to-Device conversion. This handles the RGB-XYZ non linearity and makes RGB linear.
- The matrix is used to finish the linear RGB-to-XYZ conversion and thus contains RGB reference primaries as XYZ values, written in column order. For encoding reasons, these values are all divided by 2.
- B-curves, as A-curves, were unused in both tags and were set to identity curves.

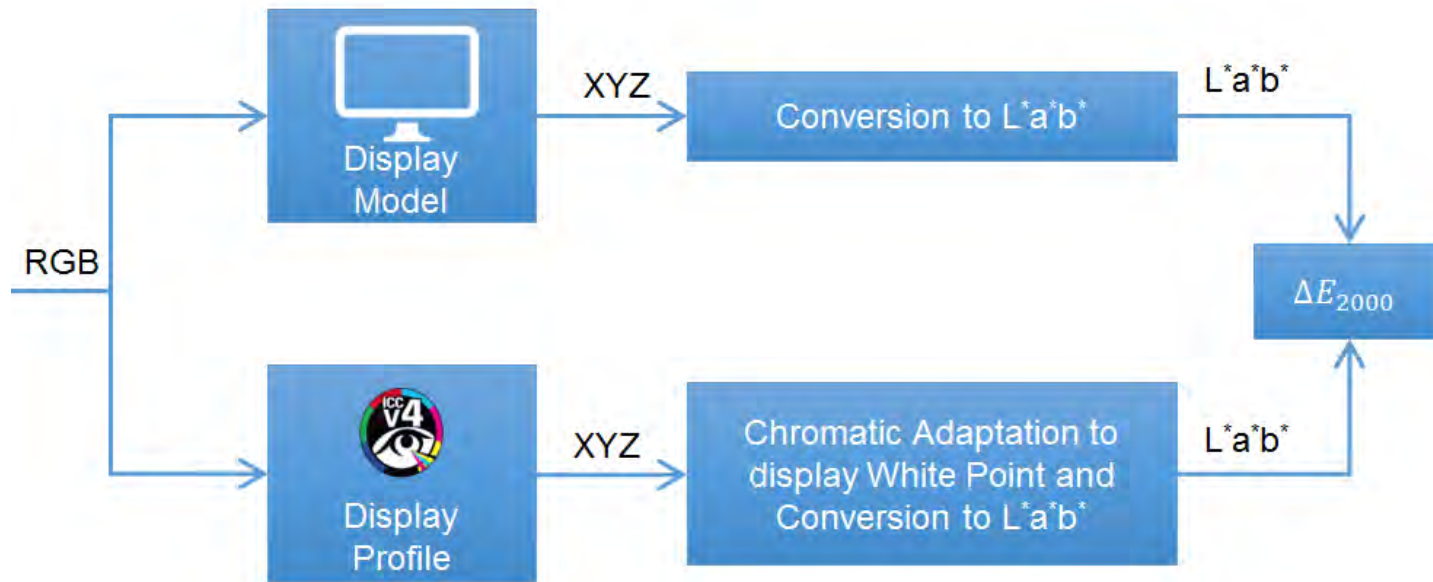
Profile quality assessment

- Fidelity test:
 - Estimate how well the profiles emulate the display they represent
- Roundtrip test:
 - Evaluate mismatches between colors issued from the Device-to-PCS conversion of the profile, and colors similarly obtained after prior application of additional Device-to-PCS and PCS-to-Device conversions

Profile quality assessment

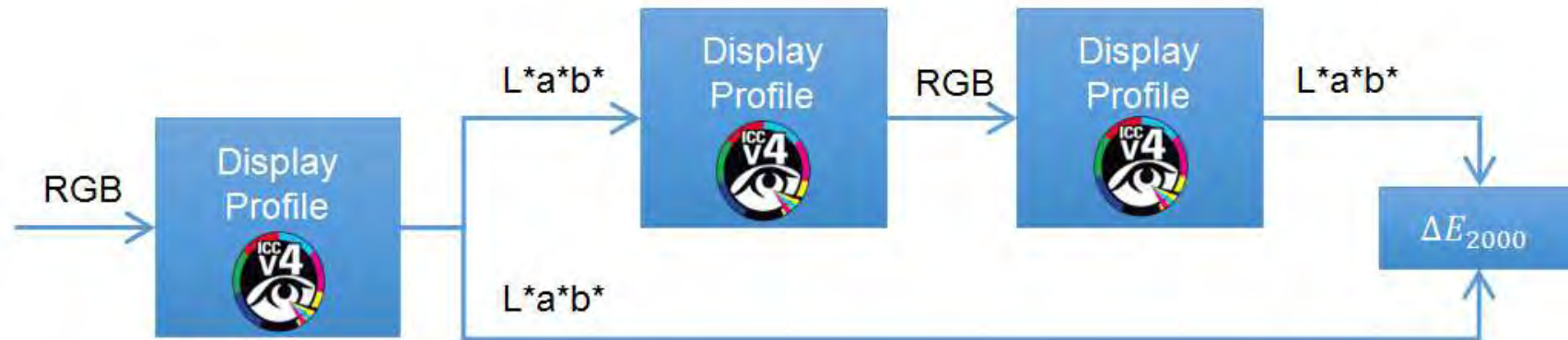
- Complementarity of these tests:
 - Fidelity test controls the Device-To-PCS conversion.
 - Rountrip test controls the “symmetry” of Device-To-PCS and PCS-To-Device conversions.
 - PCS-To-Device conversion is controlled indirectly.

Fidelity test



1. A $18 * 18 * 18$ grid of RGB digital driving levels (DDL) is generated.
2. The DDLs are fed to both a display model and its corresponding ICC profile to perform a Device-to-PCS conversion.
3. Both values are converted to the $L^*a^*b^*$ color space and the perceptual color difference between the two values is calculated by using ΔE_{2000} .

Roundtrip test



1. A $18 * 18 * 18$ grid of RGB digital driving levels (DDL) is generated.
2. The DDLs are fed to the ICC profile to perform a Device-to-PCS conversion.
3. The PCS color is fed again the ICC profile for a PCS-To-Device conversion
4. The new RGB is fed to the ICC profile for a last Device-To-PCS conversion
5. The mismatch between the outputs of steps 2 and 4 is evaluated thanks to ΔE_{2000}

Calibration quality assessment

The quality of the resulting calibration is evaluated on 3 criteria:

- Grayscale calibration
- Color calibration
- Calibration smoothness

Grayscale calibration QA

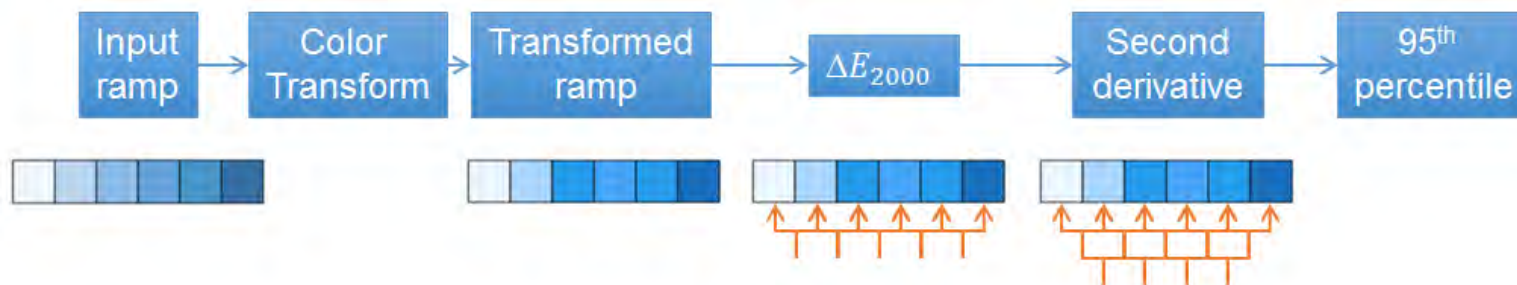
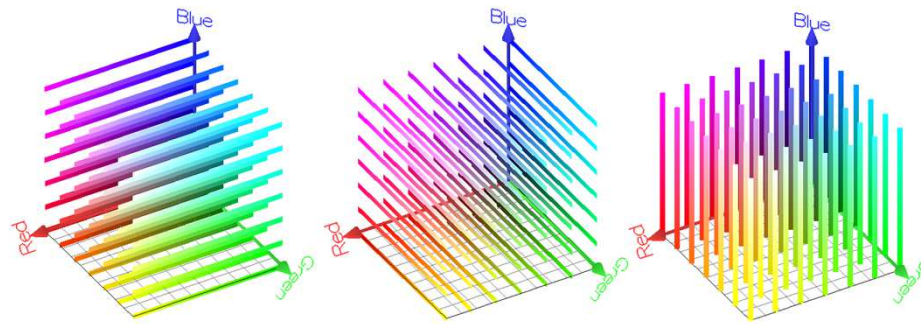
Assessed according to DICOM definition and AAPM recommendations (*Assessment of display performance for medical imaging systems, 2005*).

Relative deviation from calibration target must be $< 10\%$.

Color calibration QA

- Evaluate the uniformity of 6 color sweeps (from Black to Primary colors and Secondary colors)
- 18 colors evenly spread on the ramp are measured.
- ΔE_{2000} is measured between successive points on a sweep.
- Each color difference must fall within $\pm 15\%$ of the average along the sweep

Smoothness QA



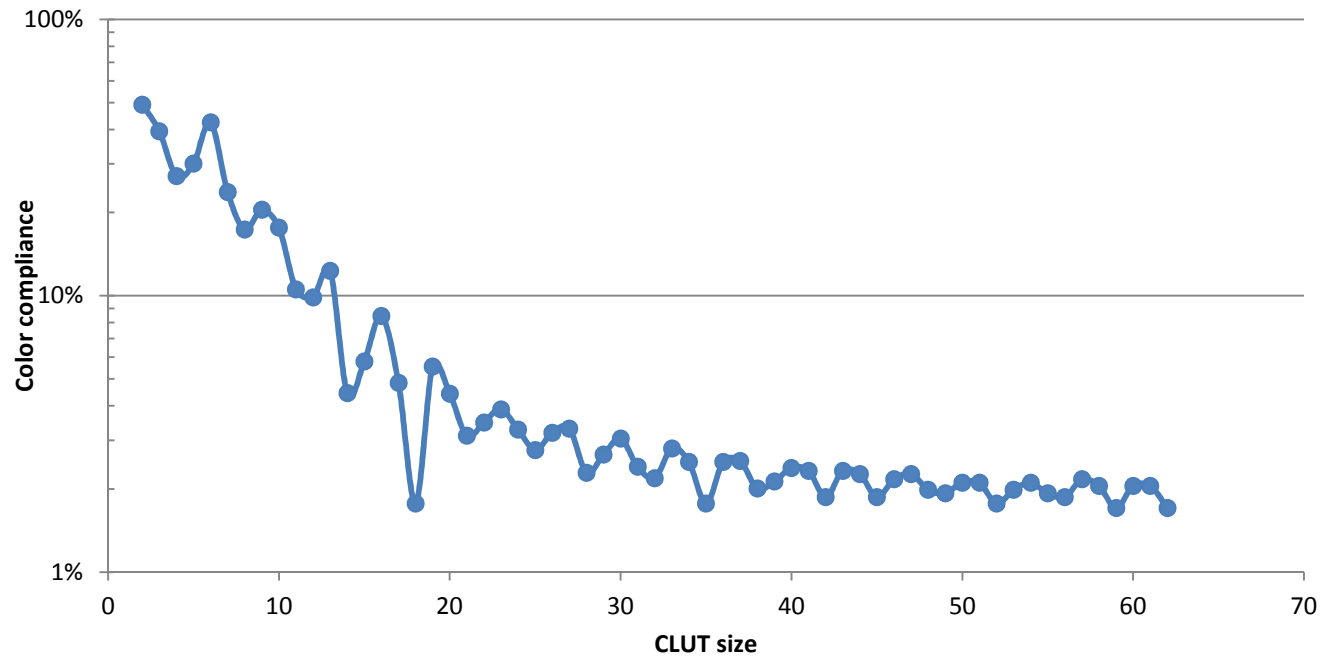
Consider the global smoothness as the average of all the different sweeps.
A perfect smoothness would have a value of 0.

Bit depth and CLUT size

Color compliance obtained by using different display models and different size of CLUT in the source profile

Destination Profile	Source profile LUT size	Color max deviation	Color max deviation 10 bits	Color max deviation 8 bits
sRGB	11	10.5925%	12.2006%	15.3341%
	18	1.8321%	2.6243%	9.0303%
	33	2.8383%	2.9012%	9.4645%
	65	1.9395%	2.6244%	9.0303%
Gamma 3.5	11	10.5638%	10.3971%	10.2444%
	18	1.8040%	2.1415%	7.4469%
	33	2.8245%	3.3183%	7.4469%
	65	1.9400%	2.1415%	7.4469%
Gamma 2.2	11	10.5470%	12.0502%	21.5339%
	18	1.7700%	1.6746%	7.5699%
	33	2.7996%	2.0485%	7.5699%
	65	1.9292%	1.6773%	7.5699%
Gamma 1.8	11	10.5730%	13.7676%	19.4952%
	18	1.7920%	3.2202%	14.7574%
	33	2.7895%	4.0300%	14.7572%
	65	1.9337%	3.2202%	14.7574%
DICOM	11	10.5868%	10.7014%	13.1294%
	18	1.8044%	2.0298%	7.3060%
	33	2.8373%	3.2150%	7.3060%
	65	1.9508%	1.8503%	7.3060%

CLUT size



Observed Color compliance as a function of the source profile CLUT size when used with 600 cd/m^2 with contrast ratio of 1000:1 in logarithmic scale on vertical axes.

DeviceLink profiles

Color compliance obtained by using different display models and different size of CLUT in the source profile

Destination Profile	Source profile LUT size	Color max deviation	Color max deviation 10 bits	Color max deviation 8 bits
sRGB	11	10.5925%	12.2006%	15.3341%
	18	1.8321%	2.6243%	9.0303%
	33	2.8383%	2.9012%	9.4645%
	65	1.9395%	2.6244%	9.0303%
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Gamma 2.2	11	10.5470%	12.0502%	21.5339%
	18	1.7700%	1.6746%	7.5699%
	33	2.7996%	2.0485%	7.5699%
	65	1.9292%	1.6773%	7.5699%
Gamma 1.8	11	10.5730%	13.7676%	19.4952%
	18	1.7920%	3.2202%	14.7574%
	33	2.7895%	4.0300%	14.7572%
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DICOM	11	10.5868%	10.7014%	13.1294%
	18	1.8044%	2.0298%	7.3060%
	33	2.8373%	3.2150%	7.3060%
	65	1.9508%	1.8503%	7.3060%

Source + Display profiles

Color compliance obtained by using different display models and different size of CLUT in the deviceLink profile

Display type	DeviceLink CLUT size	Color max deviation	Color max deviation 10 bits	Color max deviation 8 bits
sRGB	11	10.6857%	12.2002%	15.3342%
	18	1.6437%	2.6242%	9.0305%
	33	2.7166%	2.9011%	9.4647%
	65	1.8263%	2.6242%	9.0305%
Gamma 3.5	11	10.6814%	10.3971%	10.2447%
	18	1.6617%	2.1421%	7.4467%
	33	2.7019%	3.3184%	7.4467%
	65	1.8059%	2.1415%	7.4467%
Gamma 2.2	11	10.7047%	10.4162%	21.5097%
	18	1.6421%	2.0440%	7.5883%
	33	2.7141%	2.0441%	7.5883%
	65	1.8054%	2.0440%	7.5883%
Gamma 1.8	11	10.7046%	13.7609%	19.4955%
	18	1.6445%	3.2260%	14.7570%
	33	2.7225%	4.0295%	14.7568%
	65	1.8032%	3.2260%	14.7570%
DICOM	11	10.6627%	10.5930%	13.1297%
	18	1.6512%	2.0268%	7.3060%
	33	2.6934%	3.5371%	7.3060%
	65	1.8053%	2.0268%	7.3060%

DeviceLink profiles

Experimental validation

Medical grade displays

Simulated calibration compliance on the 3 tested configurations with CLUTs of 33 * 33 * 33 points

Simulated

Profile	Color max deviation 10 bits	Color max deviation 8 bits	Grayscale max deviation 10 bits	Grayscale max deviation 8 bits
Gamma 2.2	3.0232%	6.5642%	3.2522%	4.7499%
Gamma 1.8	3.0781%	14.0312%	3.0253%	11.0677%
DICOM	2.6797%	8.1791%	3.1320%	5.2659%

Measured calibration compliance on the 3 tested displays with CLUTs of 33 * 33 * 33 points

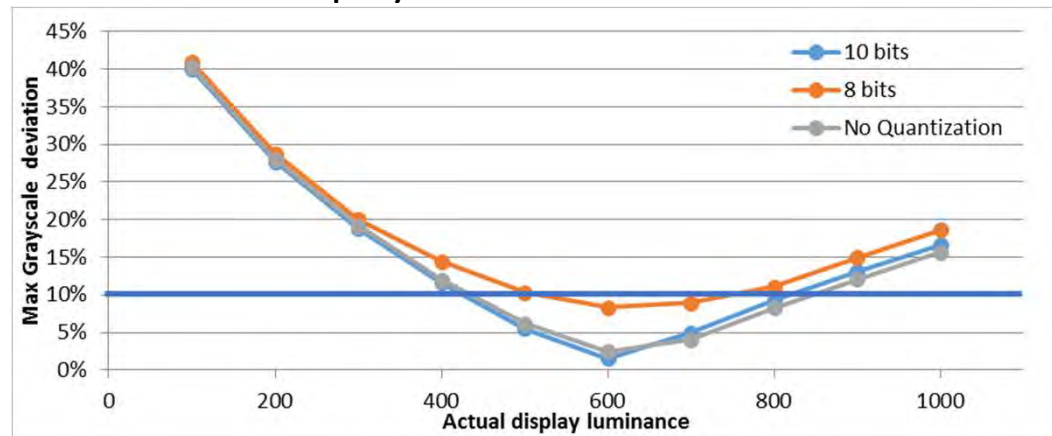
Measured

Profile	Color max deviation 10 bits	Color max deviation 8 bits	Grayscale max deviation 10 bits	Grayscale max deviation 8 bits
Gamma 2.2	6.0509%	6.6622%	3.1515%	4.7057%
Gamma 1.8	6.1227%	9.4180%	1.5607%	10.3248%
DICOM	6.2429%	6.5765%	2.3443%	5.7139%

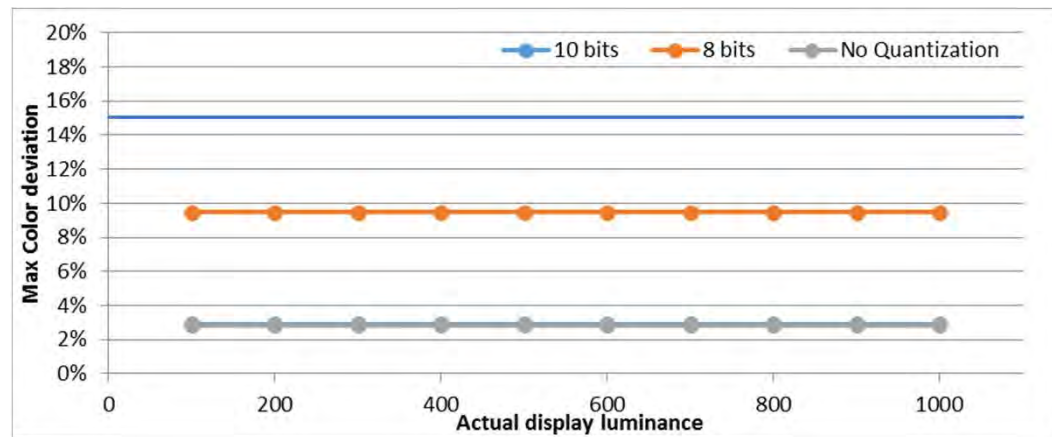
Impact of inaccurate display characterization (1)

Influence on compliance of Luminance mismatch between an sRGB profile describing a luminance of 600 cd/m^2 relatively to the actual display.

Grayscale Compliance



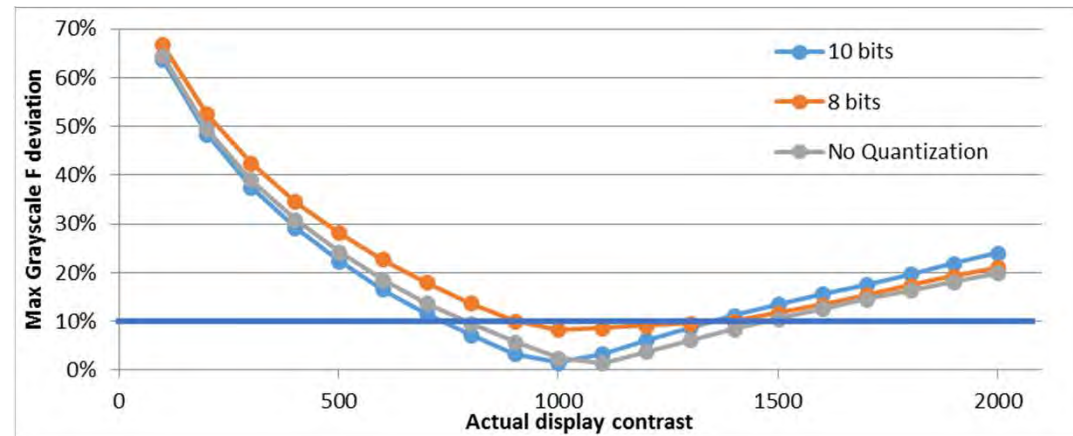
Color Compliance



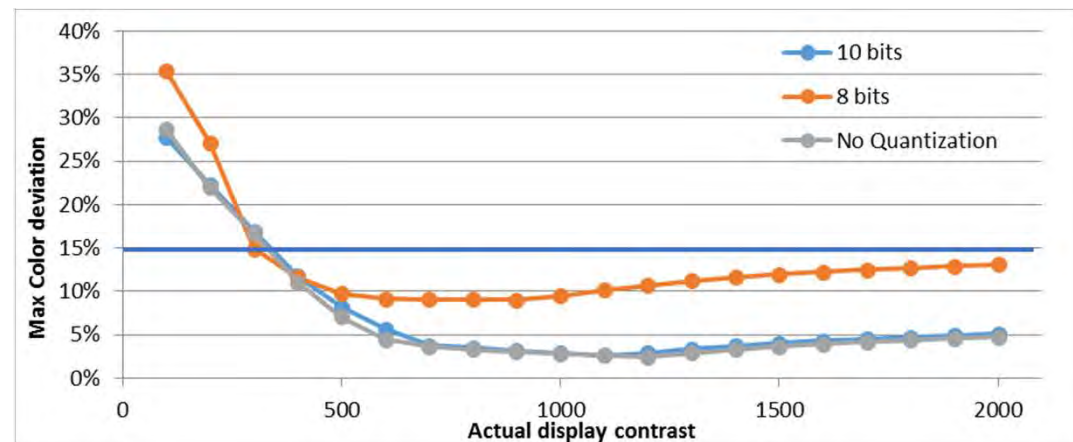
Impact of inaccurate display characterization (2)

Influence of contrast mismatch between an sRGB profile describing a 1000:1 contrast ratio and the actual display.

Grayscale Compliance



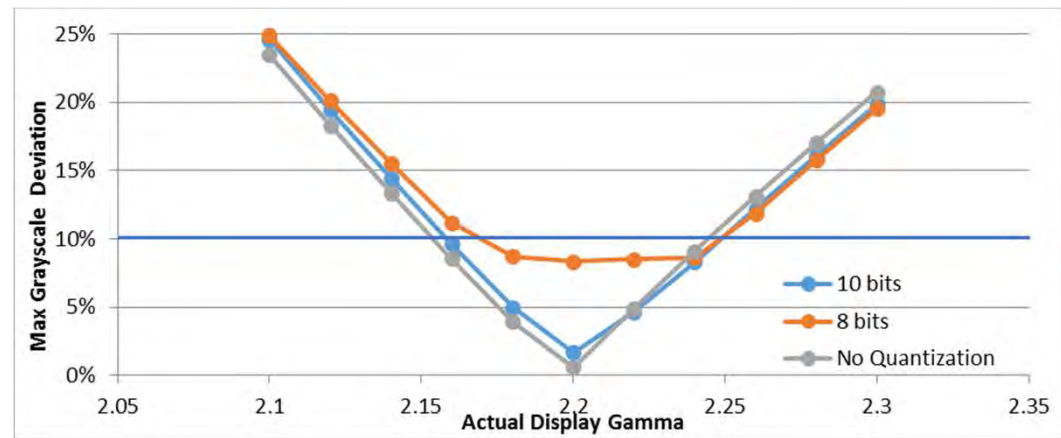
Color Compliance



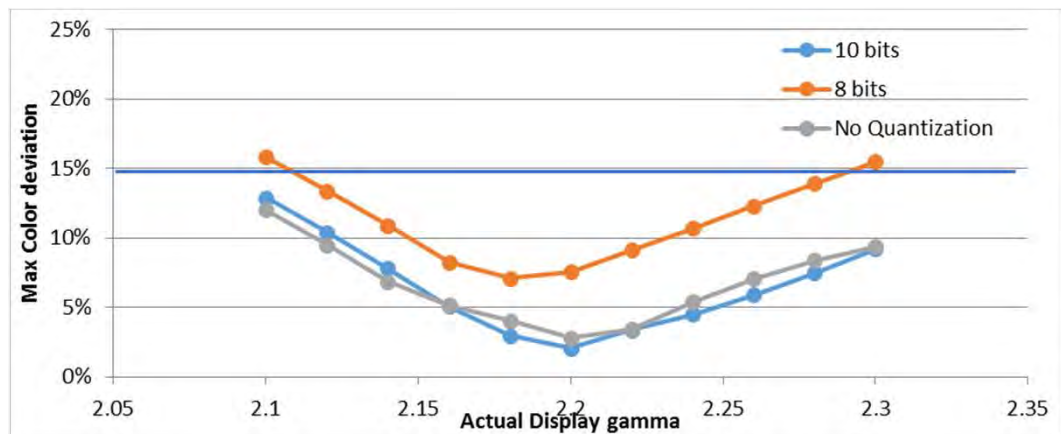
Impact of inaccurate display characterization (3)

Influence of display function mismatch between a gamma2.2 profile and the actual display

Grayscale Compliance



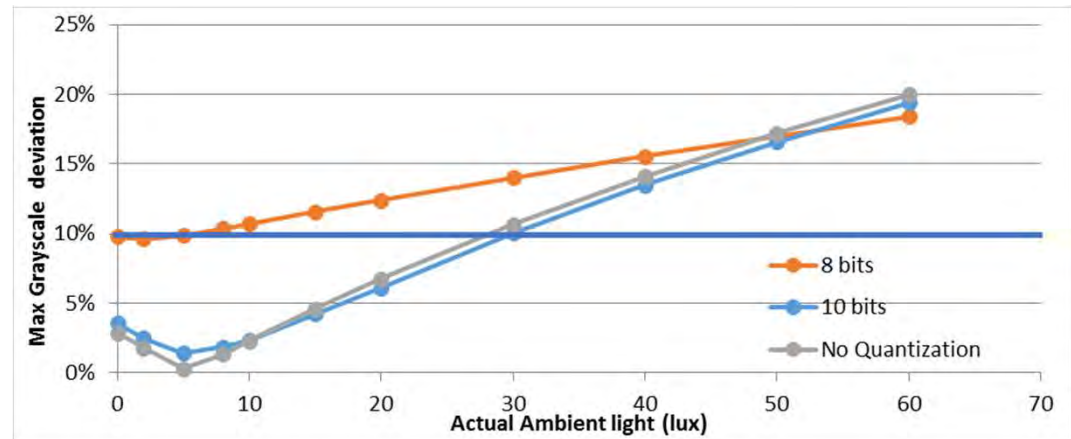
Color Compliance



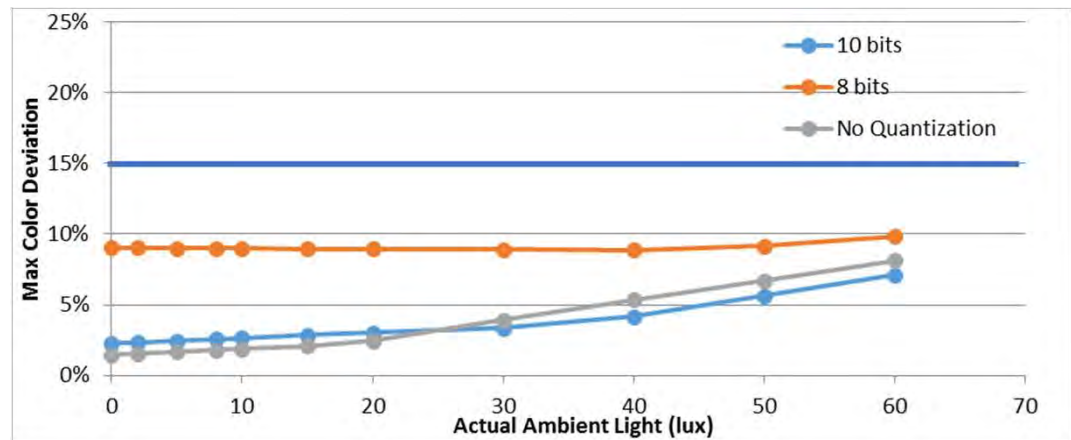
Impact of inaccurate display characterization characterization (4)

Effect of the ambient light when ICC profiles used for calibration are built for an illumination of 5 Lux

Grayscale Compliance



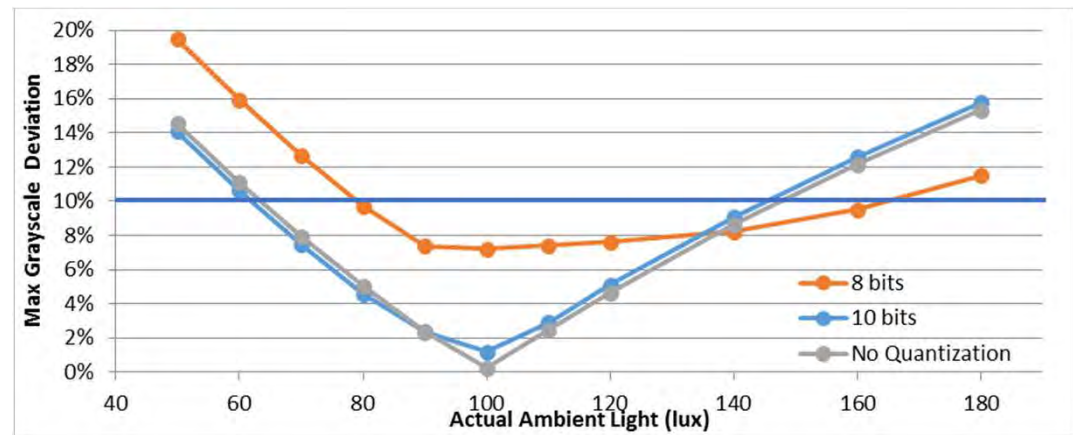
Color Compliance



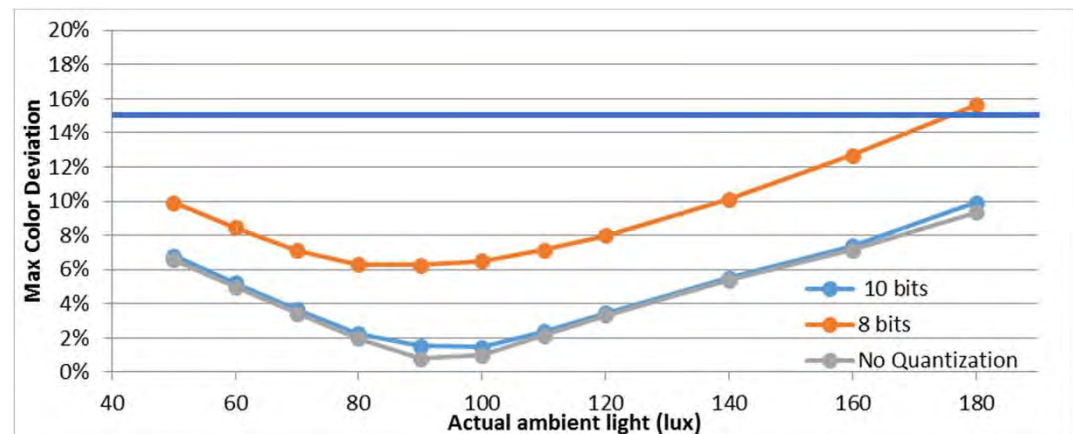
Impact of inaccurate display characterization (4')

Effect of the ambient light when ICC profiles used for calibration are built for an illumination of 100 Lux

Grayscale Compliance



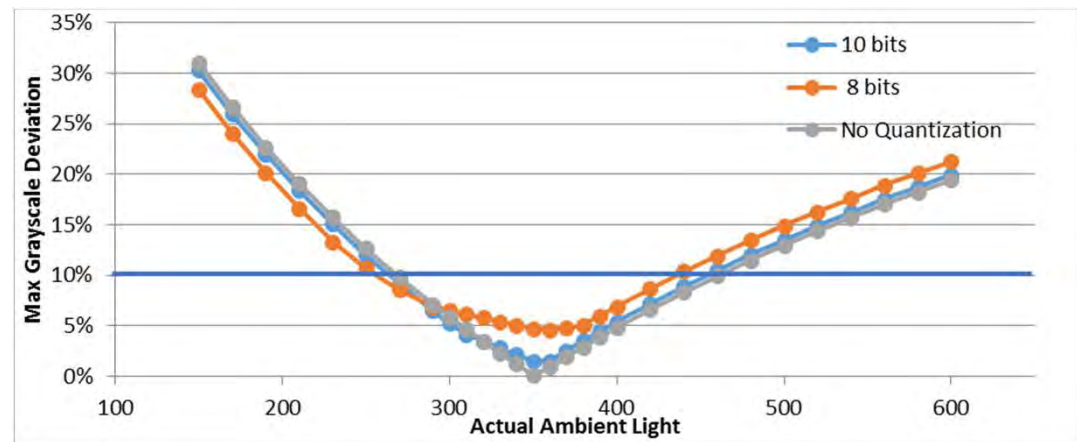
Color Compliance



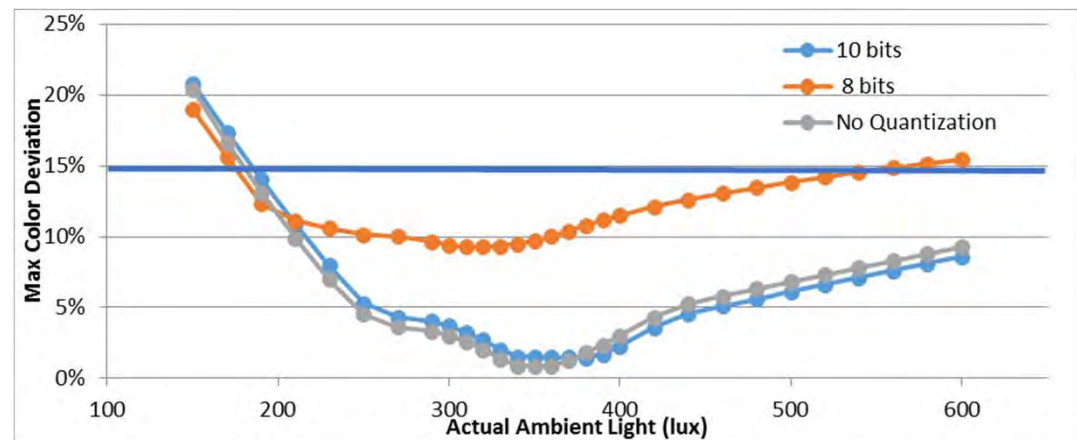
Impact of inaccurate display characterization (4'')

Effect of the ambient light when ICC profiles used for calibration are built for an illumination of 350 Lux

Grayscale Compliance

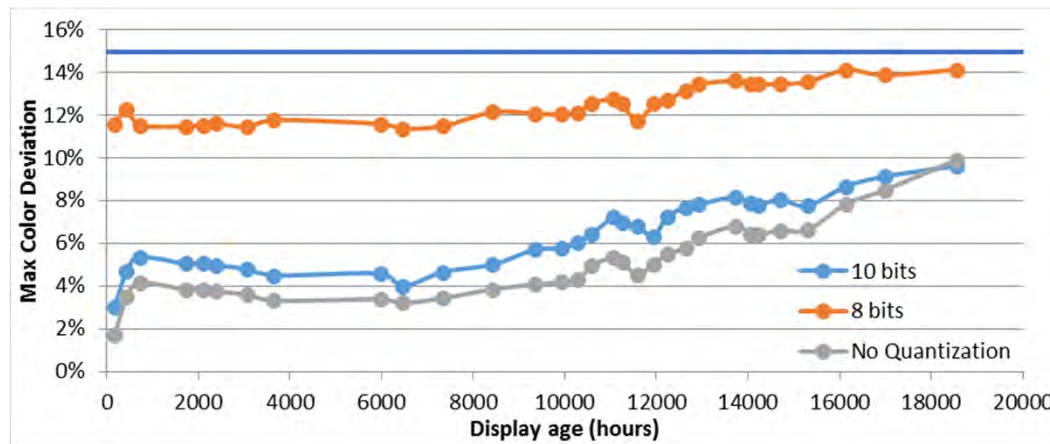


Color Compliance

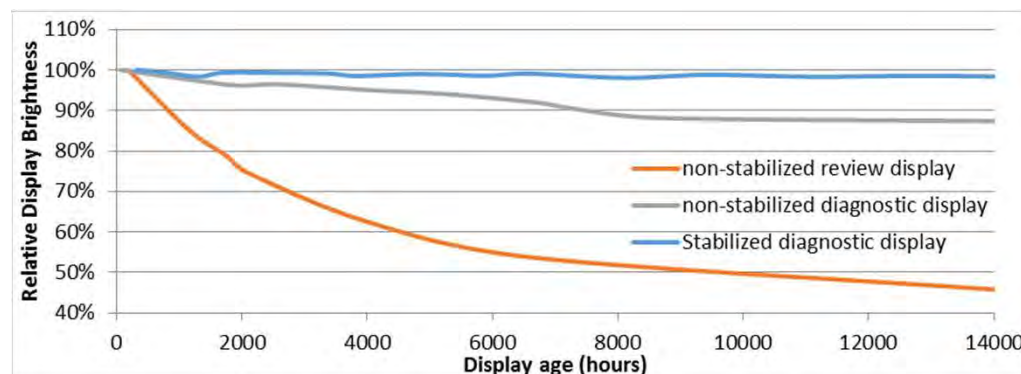


Impact of inaccurate display characterization (5)

Effect of the aging of a diagnostic display on the Color compliance of a calibration calculated at its production



(effect on grayscale compliance follows the display luminance drop-off)



Recommendations (1)

For non-calibrated displays, the following recommendations are provided with the goal to stay within 10% tolerance of the Grayscale target and within 15% tolerance of the Color target:

- **System configuration:**
 - Only use ICC profiles that have been specifically created for the specific display. Generic profiles do not offer sufficient accuracy, even if the display can be set to a reference state.
 - Every time a display setting is changed (e.g. display luminance or contrast settings), new source and destination profiles need to be created and used.
 - Use at least 10 bit connections from application to software when a most accurate calibration is needed, since 8 bit ones are clearly not sufficient for these use cases.
 - Display luminance and contrast should be stabilized to the value given by the profile since luminance and contrast deviations result into reduced calibration accuracy.
 - If the luminance cannot be stabilized, a “warming-up” period should be respected before the display can be used. A period of 2 hours is recommended, but this time may be reduced if the stability and warm-up of the display is known and reproducible.

Recommendations (2)

For non-calibrated displays, the following recommendations are provided with the goal to stay within 10% tolerance of the Grayscale target and within 15% tolerance of the Color target:

- **ICC Profile and CMM:**

- Both source and destination profiles must take the ambient light into account.
- Both source and destination profiles should be LUT based profiles using XYZ color space as PCS. It is also possible to use DeviceLink profiles.
- For DICOM GSDF calibration of grayscale display, the use of monochrome profile is possible, and recommended.
- For CSDF calibration, the CLUT of the source profile (describing the calibration) must have a size of at least $13 * 13 * 13$ points to be compliant, but using at least $31 * 31 * 31$ points is recommended for a more accurate calibration. The display profile can be matrix-based, but we recommend using a more accurate LUT-based profile.
- Special attention must be given to PCS-To-Device conversion of the Black point. This is critical to achieve an acceptable calibration.

Recommendations (3)

For non-calibrated displays, the following recommendations are provided with the goal to stay within 10% tolerance of the Grayscale target and within 15% tolerance of the Color target:

- **Calibration process:**

- The calibration compliance must be verified at least every 50 calendar days since typical display behavior changes over. If the compliance test fails, the whole calibration process has to be repeated. This means renewing display measurements and regenerating the display profile based on these measurements. More frequent measurements are possible and could guide determining when recalibration is needed.
- Ambient light must be stable. Otherwise, the calibration process must be repeated every time the ambient light conditions change.

Formal approval as ICC whitepaper

- Formal comments received
 - 24 comments were received from various members/member companies
 - All of the comments have been taken into account and the whitepaper was adapted in line with the comments
- Ballot
 - A first ballot failed because of insufficient number of members voting (only 2 members voted)
 - There was also an additional request from the steerco to better describe the context
 - A new ballot will be organized

Visualization of medical content on color display systems

1. Introduction

Since 1993, the International Color Consortium (ICC) has worked on standardization and evolution of color management architecture. The architecture relies on profiles which describe the color characteristics of a device in a reference color space.

The ICC¹ describes its profiles as “... tools to translate color data created on one device into another device's native color space [...] permitting tremendous flexibility to both users and vendors. For example, it allows users to be sure that their image will retain its color fidelity when moved between systems and applications”.

This document focuses on results and recommendations for the correct use of ICC profiles for visualization of grayscale (GSDF [1]) and color medical images on color displays. The results and recommendations in this document were first discussed in the ICC Medical Imaging Working Group.

1.1. Absolute color reproduction for medical images

Depending on the specific field of medicine, requirements for the representation of colors may vary. For instance, for the interpretation of wound photographs, color is an indicator of the healing state of the wound and absolute correct representation of colors is important, and dermatologist are demanding for standardization [2].

The use of ICC profiles for achieving a good color reproduction across devices [3] is already a well-established practice in different fields including pathology [4], [5]. By connecting the acquisition device profile to the display profile, it is possible to achieve good absolute and media relative color reproducibility thanks to colorimetric rendering intents.

¹ <http://color.org/abouticc.xalter>

ICC MIWG is currently working on a definition of best practices for digital color photography in medicine², which will cover the use cases where high color fidelity is required.

1.2. Perceptually linear visualization of medical images

1.2.1. DICOM Grayscale Standard Display Function (GSDF)

A known issue with the distribution of images on hardcopy or softcopy media is that images are usually inconsistent and can have different perceptions [6]. This means that depending on the hardware, images will have different contrast values or luminance differences. DICOM [1] has proposed a standard, called GSDF, for the purpose of having grayscale radiology images which are consistent over different devices.

GSDF is a relative calibration aiming to linearize the perception of luminance of a display without reducing its luminance dynamic range. The perceived variation is expressed as Just Noticeable Difference (JND) and is based on Barten's Contrast Sensitivity Function [7], [8]. A good introduction to GSDF is available by Fetterly et al. [9].

This standard display calibration is applicable for any grayscale medical imaging modality, even if combined with pseudo colors (annotations, fusion of modalities like PET-CT...), and it has positive impact on diagnostic performances [10]. However, true color medical images like endoscopy or dermatology are out-of-scope.

1.2.2. Color Standard Display Function (CSDF)

In recent years, medical imaging data has been evolving from pure grayscale images to color images. As of this writing, color medical imaging has not been standardized, although there are several works in progress on this matter [11] [12].

As described in paragraph 1.1, certain medical disciplines require absolute color representation. However some modalities use colors to display numerical/quantitative information on top of grayscale images as illustrated by Figure 1. The exact absolute color used to visualize quantitative information is less of importance, as long as differences are easily perceivable and it is easy for the observer to visually determine what quantitative value is being represented by a specific color.

² http://color.org/groups/medical/photography_best_practices.xalter

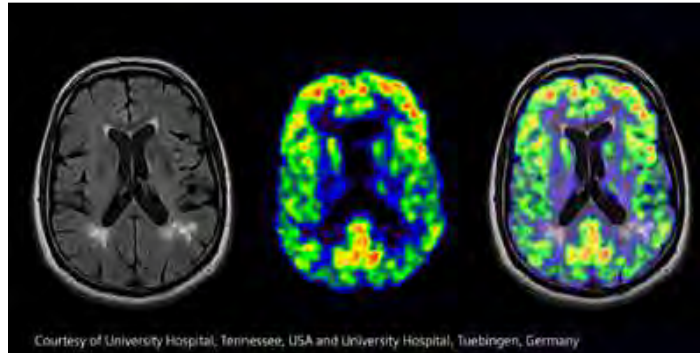


Figure 1: Example of PET-CT hybrid image. Positron Emission Tomography gives a quite accurate localization of metabolic activities represented in color and super projected on an X-ray Computed Tomography.

This quantitative imaging approach typically relies on color scales to represent calculated values. Figure 2 is an example of a commonly used “rainbow” color scale. This example associates colors with values from 0 to 1000. A large part of the color scale is covered by green, making it difficult to differentiate values from 350 to 650. On the other hand, only a thin band close to 750 is yellow, making this value clearly distinguishable. Also, depending on the exact absolute value of a quantitative value (and the corresponding color) it may be easy or difficult to perceive small differences in that quantitative value.

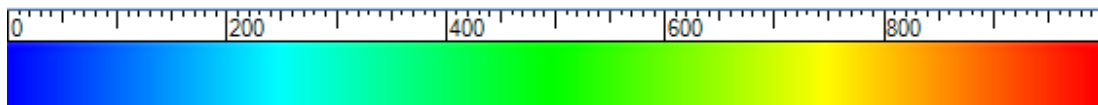


Figure 2: Rainbow color scale

Because the display is the component that in the end generates the colors, the choice of color scale and display hardware [13] affects the visual comparative analysis of pseudo-color images [14].

A perceptually linear color scale could help to optimize the visualization of the quantitative colors and reveal hidden details in the image. This can only be accomplished by taking into account the gamut of the display used for visualization.

The goal of a perceptually linear display calibration is that equal differences in RGB drive levels at the display input produce equal perceptual differences in the display output. For instance, DICOM Grayscale Standard Display Function (GSDF) is a perceptually linear calibration of the grayscale. Unfortunately, the definition of a Just Noticeable Difference (JND) given by DICOM [1] only considers luminance, and does not take chromaticity into account. For this reason, an extension of the GSDF to color cannot be achieved by using the same metric. ΔE_{2000} [15], a commonly used color difference metric appears to be a good candidate for extending towards perceptually linear color behavior.

As a drawback, a completely perceptual linear display purely based on the ΔE_{2000} metric would not be DICOM GSDF compliant on gray. Moreover, calibrating a display in such a way that it is perceived as being linear throughout its complete color gamut in terms of ΔE_{2000} is not an easy task and obtaining a completely

uniform color space requires reducing the display gamut and to decrease display luminance and display contrast. This means that the full hardware capabilities of the display cannot be used. Such a calibration is described in [16].

Recently a calibration using the ΔE_{2000} color difference metric to make a display as perceptually linear as possible has been proposed without shrinking its gamut and preserving the DICOM GSDF calibration of the grayscale [17]. This calibration is called CSDF (Color Standard Display Function) and is positioned as an extension of GSDF towards color. CSDF is a possible candidate for a standardized color behavior for medical displays. The standardization process for CSDF has been started but currently CSDF is not yet an accepted standard and other candidates may be investigated as well. CSDF relies on several color sweeps through the RGB cube as depicted on Figure 3:

- the GSDF calibration of the grayscale (from Black $(0,0,0)_{RGB}$ to White $(1,1,1)_{RGB}$)
- the ΔE_{2000} calibration of:
 - The different edges of the RGB cube.
 - Sweeps from Primary colors (Red $(1,0,0)_{RGB}$, Green $(0,1,0)_{RGB}$ and Blue $(0,0,1)_{RGB}$) to White $(1,1,1)_{RGB}$
 - Sweeps from Secondary colors (Cyan $(0,1,1)_{RGB}$, Magenta $(1,0,1)_{RGB}$ and Yellow $(1,1,0)_{RGB}$) to Black $(0,0,0)_{RGB}$

The average ΔE_{2000} step varies from one line to another to maintain the gamut integrity. The rest of the gamut colors are then adapted to ensure a smooth transition for the Gray GSDF to the ΔE_{2000} calibrated colors.

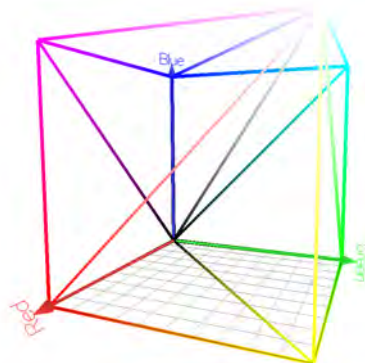


Figure 3: Color sweeps represented in the RGB cube that are made perceptually linear by CSDF. The Gray scale is linearized according to DICOM JND, and the others lines according to ΔE_{2000} .

2. Proposed calibration method

Medical display systems are usually able to perform automatic GSDF calibration and internally stabilize their brightness. In such situations the display continuously or periodically measures its own characteristics and the ambient light conditions by means of sensors and consequently adapts its behavior when necessary. For example, a medical display could alter internal look up tables and other settings to make sure it remains compliant with the DICOM GSDF standard. It is also possible

that such a display reacts to changes in ambient light by changing its display luminance or by changing the calibration curve. For these reasons, the display behavior and therefore the “display profile” can change whenever the display adapts its internal calibration settings.

Therefore it is not possible to use a Color Management Module (CMM) with these self-calibrating displays without having their ICC profiles updated each time they change their behavior. However, the following calibration method based on ICC profiles can be consistently applied for non-self-calibrating displays (provided that the calibration procedure is repeated at a sufficient frequency, see sections 6.4 and 7).

In the ICC architecture, profiles connect source and destination data encodings (devices, or reference encodings, color space data, color names...). The most typical usage is to connect two profiles corresponding to an acquisition device and a rendering device. In the present case, the rendering device is a display but there is no acquisition device defined.

The proposed method consists in creating two ICC profiles while characterizing a display. The first one describes its native color behavior and a second one describes the ideal calibration based on its properties. The proposed color management workflow is schematized on Figure 4.

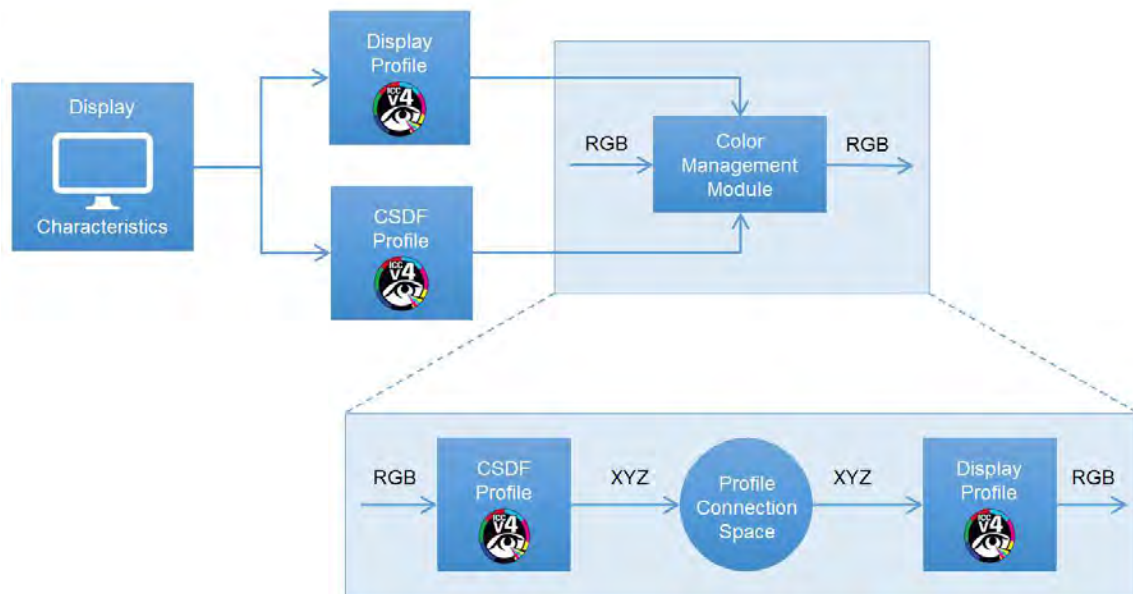


Figure 4: Workflow of ICC based CSDF display calibration.

The ICC framework proposes several rendering intents. The method focuses on the Absolute and Relative colorimetric intents as it aims to perfectly match the colors from the source profile on the display. As the gamuts described by source and destination profiles cover the same volume, there is no need for gamut mapping methods from Perceptual or Saturation rendering intents.

Both DICOM GSDF and CSDF are relative calibrations which aim at linearizing the perceptual differences between levels without shrinking the gamut of the display. It

is therefore critical to accurately estimate the gamut of the device. The calibration profile will also have the same White Point chromaticity as the display that has to be calibrated.

By having the same White point chromaticity in both source and destination profiles, there is no difference in the use of Relative or Absolute Colorimetric intent.

3. Creation of the profiles

ICC specifies different type of profiles balancing between performance and memory footprint. Annex A details the structure of each of them for the present use-case.

To achieve a DICOM GSDF only calibration, the use of monochrome profiles is possible. Monochrome profiles are designed to be used with monochromatic devices. They can be used to calibrate grayscale displays to DICOM GSDF at a low processing cost. They can also be used to calibrate color displays to DICOM GSDF. By combining a monochrome source profile and a color display profile, CMM will return RGB triplets where $R = G = B$. Thus, the color monitor will not display colors anymore.

Matrix-TRC profiles and N-component LUT based profiles are designed for color devices. Matrix profiles have a pretty simple structure. They perform very well in describing theoretical display standards or models as the ones we use in this study (Annex B), but are unable to describe the internal constraints of a real LCD display (section A.2). In a lot of application this limitations is not really an issue, but it could be the case here.

LUT based profiles are much more powerful, but also more complex. The N-dimensional Color Look-up table (CLUT) is the core element of this structure, and is the one allowing describing a CSDF calibration in an ICC profile (see section A.3).

A last possibility is to use deviceLink profiles. Unlike ordinary source or destination profiles, deviceLink profiles do not describe a specific color space but the conversion from a source to a destination color space. In the present use case, it is possible to use a deviceLink profile to describe the color transformation to be applied on a display to calibrate it. This does not influence the performances of the calibration process (see section B.2.4).

4. Profile quality assessment methods

When creating ICC profiles, it is important to control their correctness. Two complementary tests are proposed to validate profiles.

- The first test compares a given display model $L^*a^*b^*$ output with the corresponding ICC profile output to estimate the accuracy of the Device-To-PCS conversion of the profile (see section 4.1).
- The second test consists in Device-To-PCS followed by PCS-To-Device conversions using the same profile in order to perform a roundtrip. This second

test indirectly estimates the precision of the PCS-To-Device conversion (section 4.2).

Both tests are detailed below.

The first test is sufficient to show that Matrix-based profiles cannot be used to describe the target CSDF calibration (see Table 3). Other profiles architectures perform very well to this test.

The second test reveals the importance of the size of the CLUT in LUT-based profiles to correctly calibrate to CSDF (see Table 8 in section B.1.2.3).

4.1. Fidelity test

To estimate how well the generated profiles would emulate the display model they were based on, the following fidelity test is performed:

1. A $18 * 18 * 18$ grid of RGB digital driving levels (DDL) is generated.
2. The DDLs are fed to both a display model and its corresponding ICC profile to perform a Device-to-PCS conversion.
3. Both values are converted to the $L^*a^*b^*$ color space and the perceptual color difference between the two values is calculated by using ΔE_{2000} .

A more detailed description of this test can be observed on Figure 5.

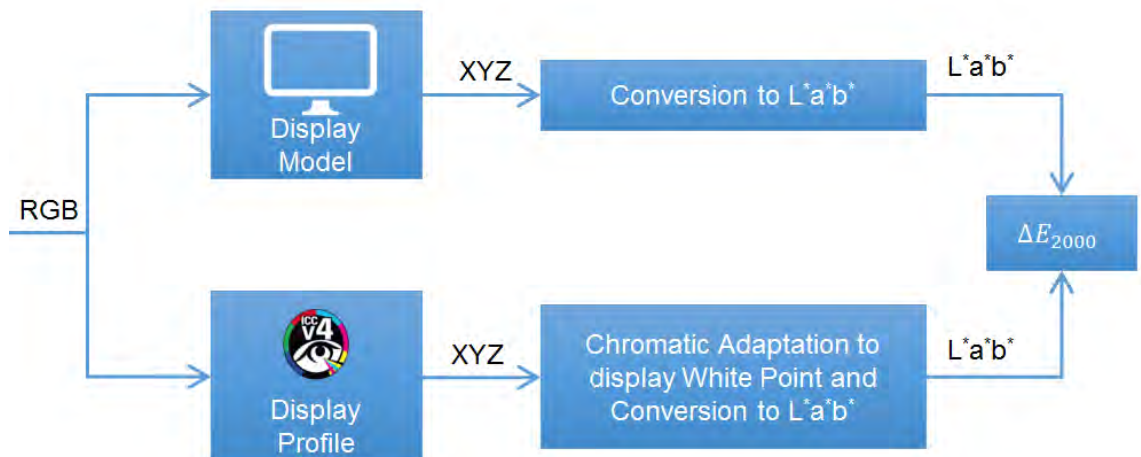


Figure 5: ICC Profile Model Fidelity test

The goal of this test is to assess whether or not the color variations induced by the creation of the profile regarding the model it is based on will be significant and may introduce perceptually critical color differences. Generally, a color difference below $1 \Delta E_{2000}$ is considered to be indistinguishable by the human eye.

Fidelity results are assessed regarding the average and maximal color differences.

4.2. Roundtrip test

Roundtrip test consists in connecting a profile with itself and assessing the error that is introduced by this match on an evenly spread set of $18 * 18 * 18$ points. For instance, a roundtrip test result showing a null error would assess that Device-to-

PCS and PCS-to-Device conversions are exactly reversing each other, as they are theoretically meant to. Conversely, observing a large error on this test would imply that these conversions do not accurately match each other and that the profile itself induces errors in the color management process. However, the roundtrip test does not provide information about the specific cause of the conversion mismatches.

This test evaluates mismatches by calculating the ΔE_{2000} perceptual color difference between two $L^*a^*b^*$ values. The first one is issued from the Device-to-PCS conversion of the profile. The second one is similarly obtained after prior application of additional Device-to-PCS and PCS-to-Device conversions as illustrated on Figure 6.

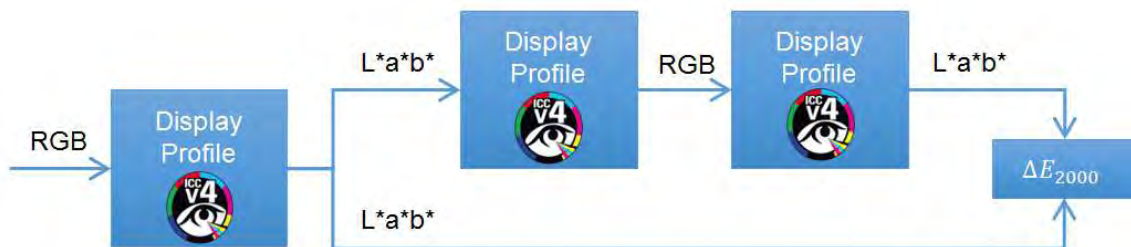


Figure 6: ICC profile roundtrip test

5. Calibration quality assessment methods

CSDF defines a different behavior for grayscale and saturated colors. For this reason they have to be evaluated separately, and a valid calibration must comply on both criteria. This means that for a display system to be CSDF compliant, both the metrics/graphs of sections 5.1 and 5.2 need to be generated and the results need to be within the described tolerances.

5.1. How to evaluate the quality of the grayscale calibration

As grayscale must comply with the DICOM GSDF standard, the quality assessment procedure for grayscale also matches the DICOM definition.

Quantitative assessment of luminance response is accomplished by using defined test patterns and luminance meters to measure the display device's luminance response for a limited number of values. The measurement protocol is similar to the one described in Annex C of the DICOM standard [1].

The grayscale compliance evaluations presented hereafter are based on luminance measurements of 18 evenly spread driving levels. These correspond to RGB triplets that can be represented as:

$$(R, G, B) = (0,0,0), \left(\frac{1}{17}, \frac{1}{17}, \frac{1}{17}\right), \dots, \left(\frac{17}{17}, \frac{17}{17}, \frac{17}{17}\right)$$

For each of them the relative difference from the theoretical Grayscale target to the observed luminance value, but also perceptual difference (JND) from one patch to the next one is evaluated.

Grayscale compliance of a system is summarized as the maximal error encountered on those 18 points. The lower the value, the better the calibration compliance score is. This score must fall within 10% ([18] section 4.3) for devices used for the interpretation of medical images (diagnostic).

Recommendations for display quality other than luminance response can be found in [18] and [19].

5.2. How to evaluate the quality of the color calibration

This section suggests a methodology for quantifying compliance/accuracy of the color component of the CSDF calibration. It is very important to stress that in this section only a metric is being described for specifically assessing the *color* aspects of CSDF calibration. As explained before, CSDF calibration also requires that the neutral grey diagonal of the display complies with DICOM GSDF (see section 5.1). For clarity reasons however, and to be able to clearly separate greyscale from color calibration performance, the reported results and graphs for “color” only refer to the metric described in 5.2.

In this recommendation, we quantify perceptual linearity of colors of a display based on the output obtained by sweeping primary and secondary colors. We define a series of 18 RGB triplets between Black and Red, with equal steps in the R channel value between them. Corresponding values are:

$$(R, G, B) = (0,0,0), \left(\frac{1}{17}, 0,0\right), \dots, \left(\frac{17}{17}, 0,0\right)$$

Likewise, evenly spread series of 18 RGB triplets are defined between Black and the other Primary colors (Green and Blue) as well as between Black and the Secondary colors (Cyan, Magenta, and Yellow). Corresponding sweep values from Black to Yellow, for example, are:

$$(R, G, B) = (0,0,0), \left(\frac{1}{17}, \frac{1}{17}, 0\right), \dots, \left(\frac{17}{17}, \frac{17}{17}, 0\right)$$

Leaving out the Black duplicates this results in 120 unique RGB triplets for which the corresponding display output is obtained as XYZ. Because discrimination between colors is less relevant at low luminance levels, we discard measurements corresponding to a driving level which results in a luminance below 5 cd/m^2 in the sweep between Black and White.

For example, if the triplet $(R, G, B) = (4/17, 4/17, 4/17)$ is the first measurement in the Black-To-White sweep presenting a Y value of at least 5 cd/m^2 , then the measurements $(R, G, B) = (0,0,0), \dots, (3/17,0,0)$ of the Black-To-Red sweep are discarded. The same logic is applied on the other sweeps.

All non-discarded measurements are then converted to $L^*a^*b^*$ values by taking the XYZ of full White as the reference White point. Next, we calculate ΔE_{2000} between consecutive points in each of the six sweeps for the Primary and Secondary colors, resulting in six series of ΔE_{2000} values noted Δ_i with i representing the color sweep (Red, Green, Blue Cyan, Magenta or Yellow). Each value $\Delta_{i,j}$ within the set Δ_i is then normalized by dividing them by the series average.

$$\bar{\Delta}_i = \sum_{j=1}^N \frac{\Delta_{i,j}}{N} \quad \forall j, \delta_{i,j} = \frac{\Delta_{i,j}}{\bar{\Delta}_i}$$

For an ideal perceptually linear display, the resulting normalized curves would all be constant with value 100% ($\forall i \forall j, \delta_{i,j} = 1$). For each of the six sweeps, we quantify the perceptual linearity D_i as the maximum deviation from 100%.

$$D_i = \begin{cases} \max_j(\delta_{i,j}), & \max_j(\delta_{i,j}) - 1 \geq 1 - \min_j(\delta_{i,j}) \\ \min_j(\delta_{i,j}), & \max_j(\delta_{i,j}) - 1 < 1 - \min_j(\delta_{i,j}) \end{cases}$$

The overall perceptual linearity is quantified as the maximum deviation encountered in any of the six curves.

$$D = \max_i(D_i)$$

If the perceptual linearity metric value is within a predefined tolerance range, e.g. $\pm 15\%$ (i.e. $0.85 < D < 1.15$), the display calibration is considered to be perceptually linear.

The color compliance evaluations below are presented as the relative deviation from the target (i.e. values below 15% are compliant, values above are not).

The tolerance threshold is defined as a relative value because absolute values can vary a lot depending on the gamut of the device (e.g. Adobe RGB gamut presents superior $\Delta_{i,j}$ than sRGB, and thus the same variation of R, G or B would induce a larger ΔE_{2000} on Adobe RGB than on sRGB). The limit of 15% is fixed regarding what is achievable in practice and is proposed in this document as a general limit. It is possible that based on future studies specific thresholds could be defined for different modalities.

In parallel to the perceptual linearity of the colors, the DICOM GSDF compliance of the Grayscale must be controlled too, as GSDF is part of CSDF calibration. The method to assess the GSDF quality is described in section 5.1 and [1], [19].

5.3. Calibration smoothness

Green proposed in 2008 [20] a methodology for estimating the smoothness of a color transform from a transformed ramp. The color transform can be the result of the application of a colored 3D LUT or of ICC profiles. The method is represented by Figure 7.

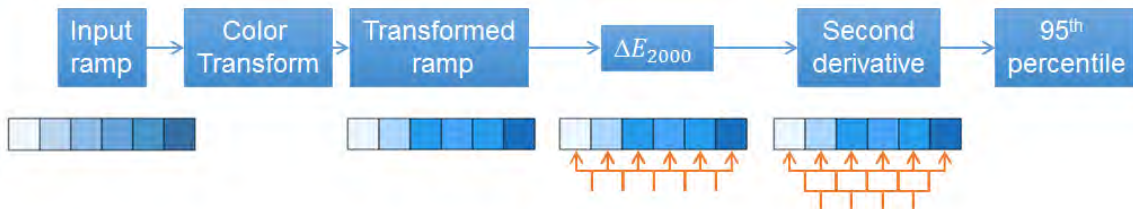


Figure 7: Green' smoothness workflow

For any input colored ramp with n pixels, the metric ΔE_{2000} defined by the CIE is computed between CIELAB consecutive triplets of the ramp, resulting in $n - 1$

ΔE_{2000} values. From this resulting ramp, a second derivative is calculated by simply subtracting two consecutive elements of the ΔE_{2000} ramp resulting in a set of $n - 2$ values for which the 95th percentile³ is calculated representing the smoothness of the color transform of the input ramp.

In order to consider the entire calibration, Green's metric is applied on a large number of gradients through the RGB cube: The RGB cube is sampled to $50 * 50 * 50$ RGB triplets from which are built a total of 7500 ramps of 50 color shades.

Based on the 3D representation of the RGB cube, in the directions defined by the 3 main axes, 50-elements ramps are extracted as illustrated on Figure 8.

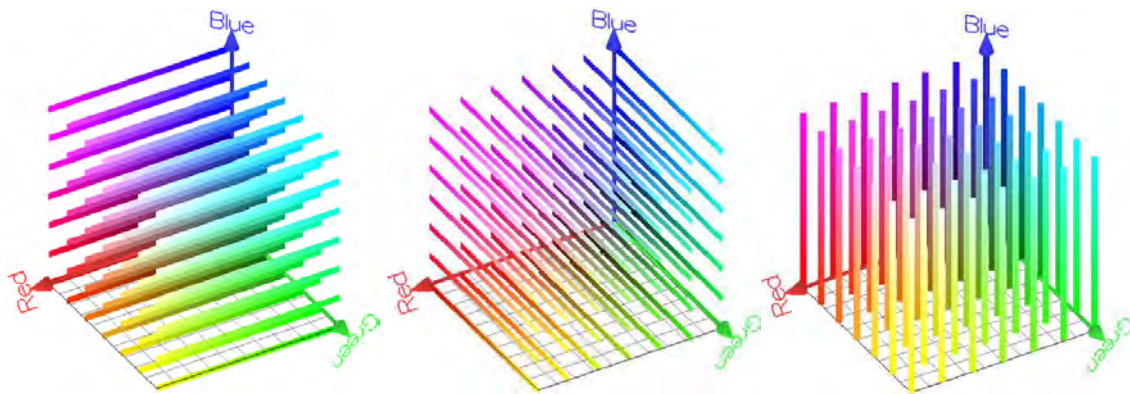


Figure 8: Examples of ramps used to evaluate the smoothness of a calibration. Here only 3 sets of $7 * 7$ ramps are represented while the tests involved a total of $3 * 50 * 50$ ramps

The smoothness of the color transform for each input ramp is computed. Simple statistics can be calculated based on the 7500 smoothness values obtained: average, standard deviation, minimum and maximum. A perfect smoothness would have a value of 0.

6. Impact of inaccurate profiling

Building ICC profiles relies on measurements which are sensitive to noise and ambient conditions. Since profiles must have a reasonable size and generation time, measuring every display color is not a viable approach. The content of a LUT-based profile may therefore rely on interpolation in the cases where all the color points of the 3D CLUTs were not necessarily measured.

Furthermore, a lot of display OSDs (on-screen-displays) make it possible for the user to select a display function in a collection of reference presets such as Gamma 2.2, Gamma 1.8, sRGB... In this situation, one could be tempted to use generic ICC profiles instead of characterizing the display in its actual configuration. However, the same preset on different displays can result in very different color rendering, and not even close to the standard they supposedly match [21].

³ From a study published in 2010 [29], the authors have shown that the optimum percentile level was determined to be 95th to best fit the subjective data from the measurement of the magnitude of tone jumps of 96 test gradations.

Simulations presented in Annex B represent ideal situations where the display is perfectly characterized and its ICC profiles built on exact data (section 0 is an exception since this data is generated based on real measurements). This situation is barely realistic in practice.

The following paragraphs present the results of different simulations evaluating the impact of a misvaluation of different characteristics of the monitor or the ambient conditions.

6.1. Display luminance

A potential mismatch between profile luminance and the actual display may affect Grayscale compliance, since it is based on luminance. The display profile was fixed to 600 cd/m^2 and the influence of the difference between its luminance and the actual display luminance was assessed. Results are observable on Figure 9.

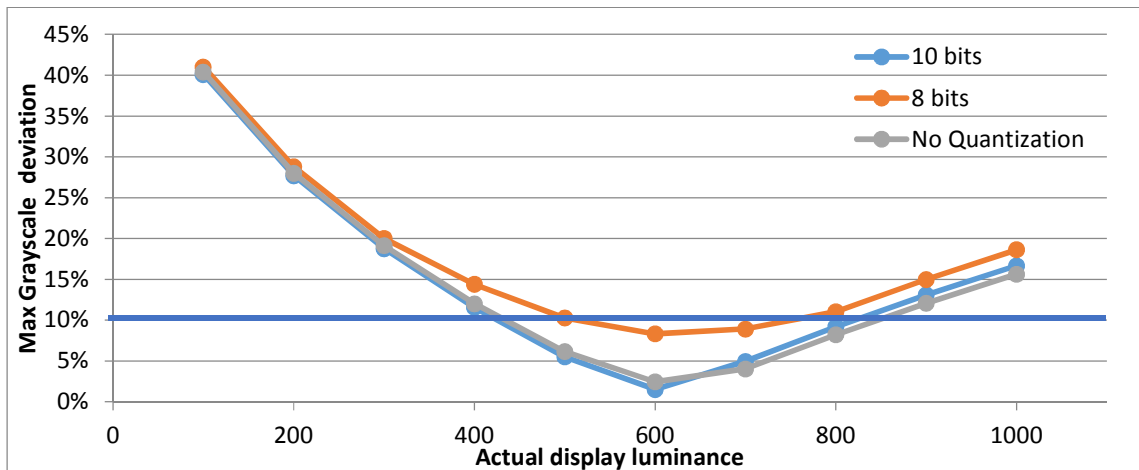


Figure 9: Influence on Grayscale compliance of Luminance mismatch between an sRGB profile describing a luminance of 600 cd/m^2 relatively to the actual display.

Misestimating a display luminance in its ICC profile leads to large deviations from Grayscale calibration: up to 14% error for a 200 cd/m^2 overestimation and 11% error for a 200 cd/m^2 underestimation.

For 8 bit systems, profile luminance misestimating invalidates the grayscale component of the calibration from a 100 cd/m^2 overestimation and approximately a 150 cd/m^2 underestimation. On the other hand, results remain compliant for both theoretical and 10 bit values if overestimation and underestimation does not respectively surpass 175 cd/m^2 and 215 cd/m^2 .

With the presented method, a display's Grayscale calibration will thus remain valid if the ICC profile describing the display does not encompass a luminance value that deviates largely from the actual one.

Tests have been repeated with different display profile architectures and different display native behaviors without observing noticeable differences.

It is also interesting to notice that misestimating the luminance of a display has no impact on the color component of the Color compliance, as depicted by Figure 10.

There is no visible difference between the theoretical values and 10 bit quantization.

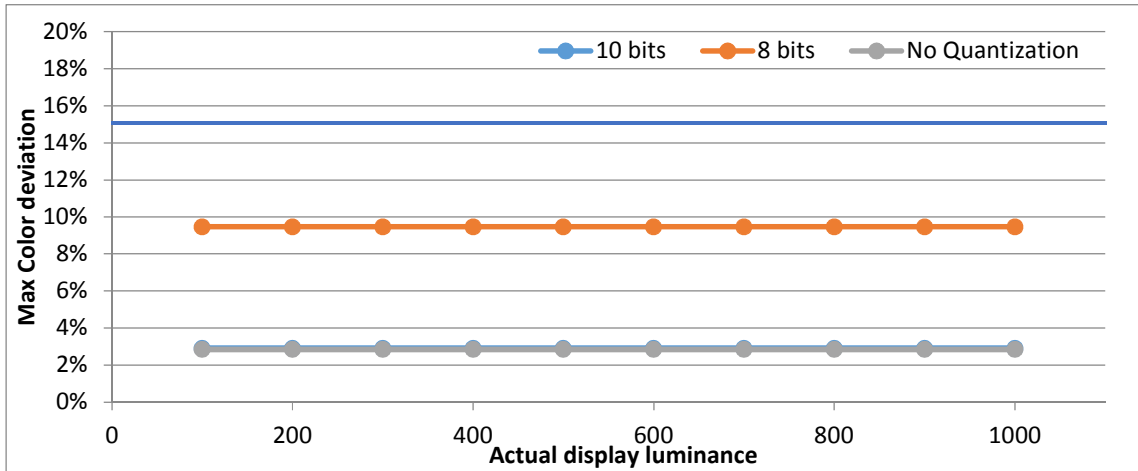


Figure 10: Influence on Color compliance of Luminance mismatch between an sRGB profile describing a luminance of 600 cd/m^2 relatively to the actual display.

It is possible to observe some variations of luminance on short term because of temperature variations within the display. Backlight efficiency depends on the lamps temperature. Liquid Crystals are also sensitive to temperature.

Figure 11 shows how a display's luminance evolves from the moment it is turned on.

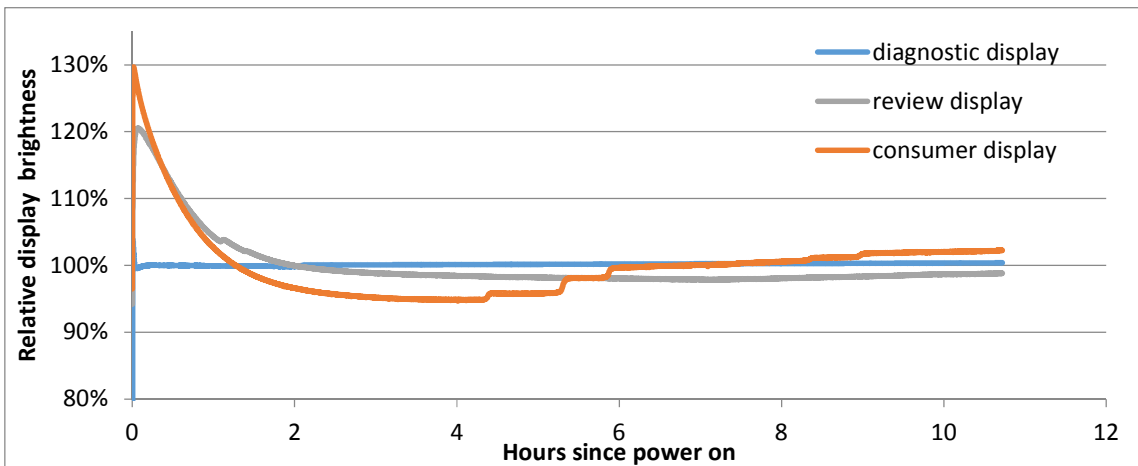


Figure 11: Short term evolution of a display luminance from start up. Diagnostic display is equipped with front and back sensors for real time stabilization. Clinical Review only has a back sensor. Consumer display is not stabilized at all. The different curves have been normalized to their average for an easier comparison. Some of the data presented here comes from [22].

Warming up creates an important overshoot during the display's first 2 hours of use, making it un-calibrated until the luminance has reached a normal level if the display cannot compensate it.

6.2. Display contrast

As with luminance inaccuracies, errors profiling contrast induce error in calibration accuracy.

Results for grayscale are assessed by evaluating Grayscale compliance for several differences between display profile contrast and actual display model contrast. Results are presented in Figure 12.

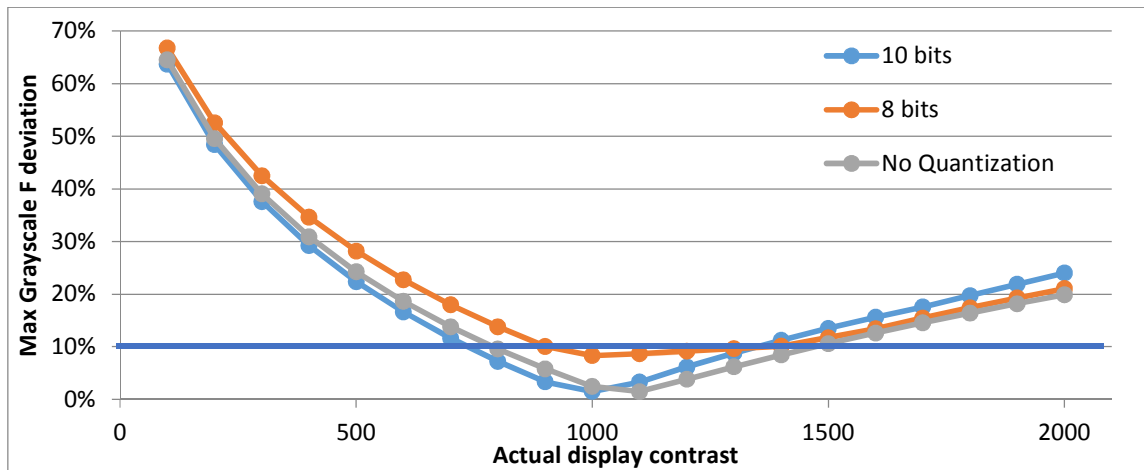


Figure 12: Influence on Grayscale compliance of contrast mismatch between an sRGB profile describing a 1000:1 contrast ratio relatively and the actual display on GSDF deviation.

Measurement devices used to quantify a display's luminance are usually much more accurate on bright levels than they are on dim ones. Even low end devices would not return an error of more than 20 cd/m^2 while measuring luminance close to 600 cd/m^2 . As it is observable on Figure 9, this kind of error, which would already be considered as huge, would not impact Grayscale compliance significantly.

However, contrast ratio is both much more sensitive than luminance to small variations and has a bigger impact on the calibration results. For instance, the reference display model has a luminance of 600 cd/m^2 and a contrast ratio of 1000:1, which means that the Black point luminance of this display is 0.6 cd/m^2 . Measurement devices are much more likely to return an erroneous value for the dimmest luminance level of a display. In this case, even an 0.2 cd/m^2 error would lead to a drop from 1000:1 to 750:1 contrast ratio, which would invalidate the Grayscale calibration.

Perceptual linearity of colors is evaluated in a similar fashion, and the influence of contrast differences on the color component of the calibration are shown in Figure 13.

Contrast overestimation by the profile has a much larger influence on perceptual linearity of colors than a corresponding underestimation. For instance, if the assumes a contrast of 1000:1 while the display has a contrast of 500:1 only (contrast is overestimated), the color calibration deviation grows from 3% to 8%.

Contrarily, for the same profile, if the display has a contrast of 2000: 1 (contrast is underestimated), the deviation is only 5% inaccurate.

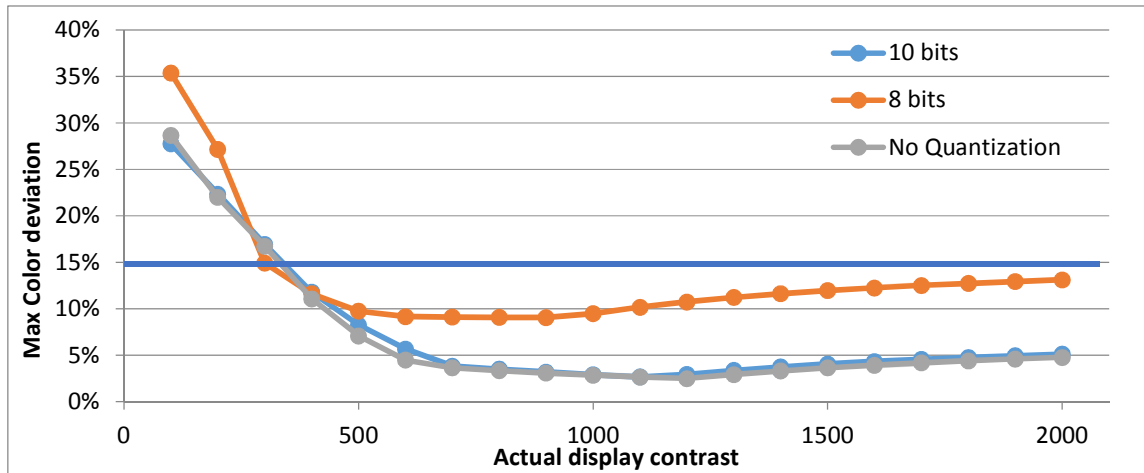


Figure 13: Influence on Color compliance of contrast mismatch between an sRGB profile describing a 1000: 1 contrast ratio relatively and the actual display contrast

6.3. Display function (gamma)

The display function is typically the parameter that can be tuned from the display settings menu. Such menus usually propose to choose among a limited number of presets. Those presets are often common to different devices, and sRGB and Gamma 2.2 are available in almost every display. One could be tempted to use the display OSD in combination with a pre-created ICC profile.

Unfortunately, display presets are usually not accurate enough to allow such practices [21].

Figure 14 illustrates the fact that Grayscale compliance is highly sensitive to imprecisions of the display functions contained in an ICC profile. An error of 0.05 in the estimation of the Gamma is indeed enough to invalidate the Grayscale calibration.

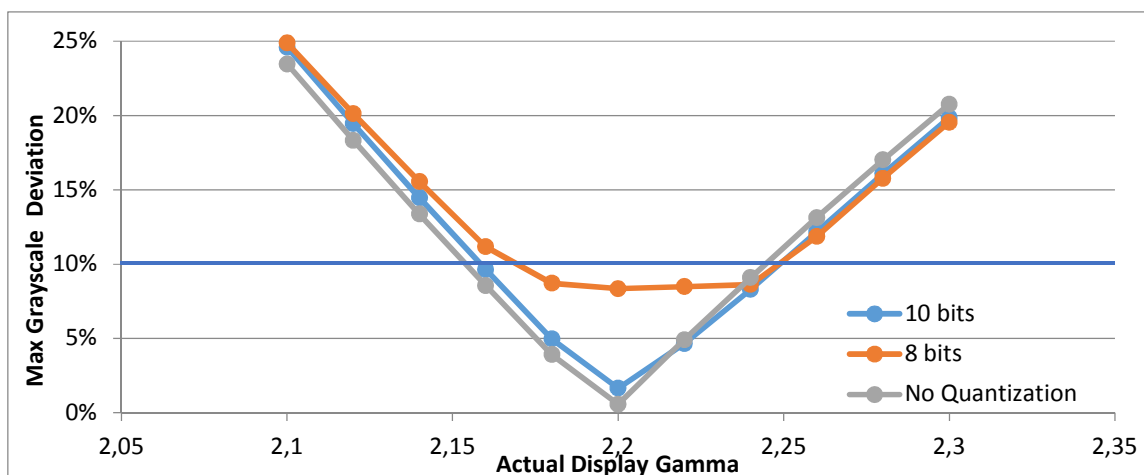


Figure 14: Influence of display function mismatch between a gamma2.2 profile and the actual display on Grayscale compliance

On the other hand, the accuracy of the display function seems to be less critical for the calibration of the colors (see Figure 15) but remains a disturbing factor.

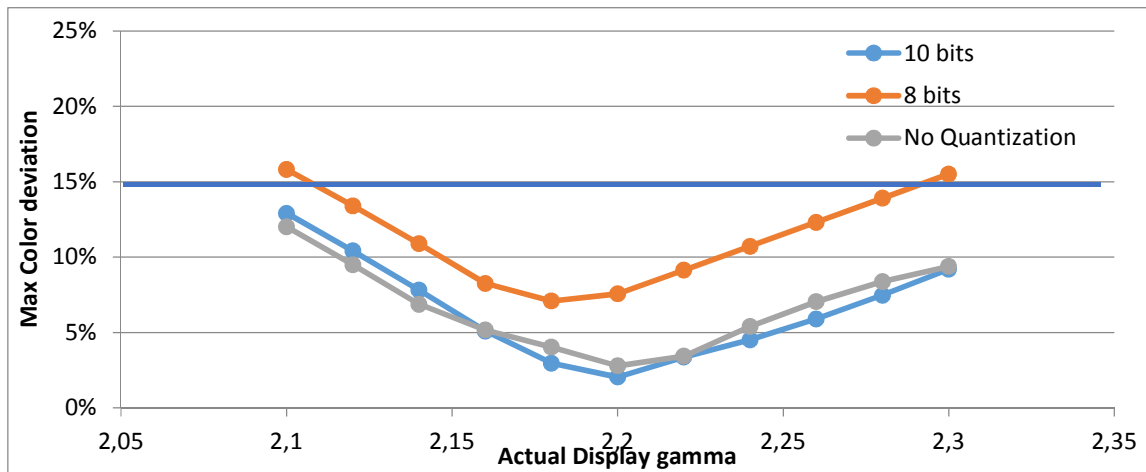


Figure 15: Influence of display function mismatch between a gamma2.2 profile and the actual display on Color compliance

6.4. Display age

Because of the degradation of the materials composing the display, the colors it emits are susceptible to change in both chrominance and luminance over the lifetime of the device. Avanaki et al [23] have studied the effects of both of these variations on the interpretation of digital pathology images.

Figure 16 summarizes the variations observed while testing non-stabilized and stabilized displays of different types. By referring at section 6.1 and Figure 16, it appears that aging is crucial in the grayscale compliance of the calibration.

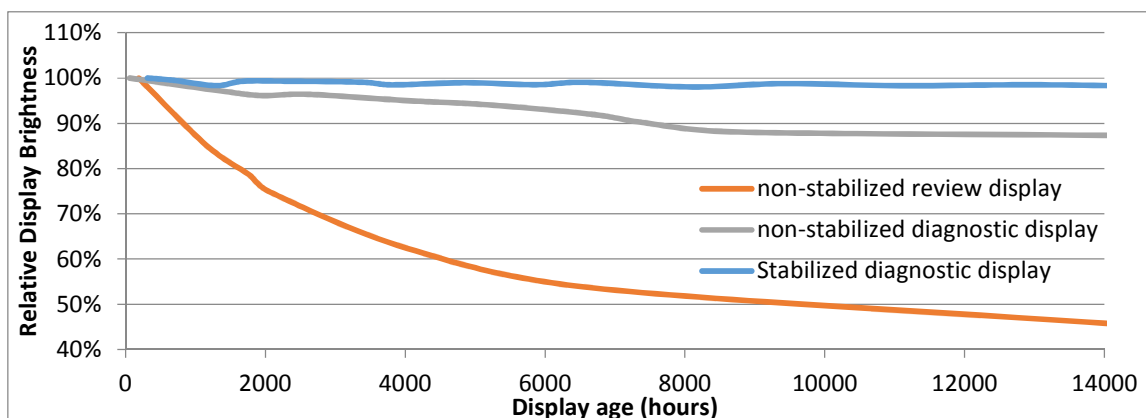


Figure 16: Long term evolution of the maximum luminance of different non-stabilized displays compared to stabilized displays

Please notice that different display systems can have a large difference in terms of performance and stability. Luminance variation is almost only related to the decreasing efficiency of the backlight (CCFL or LED, where typically LED backlights are more stable over time [24]), and can be compensated by giving more power to the light sources. The color shift is more difficult to anticipate as it

depends on the evolution of the optical properties of different layers of diffusers and filters. To evaluate the impact of this color shift on the calibration, a medical display has been characterized over its entire lifetime.

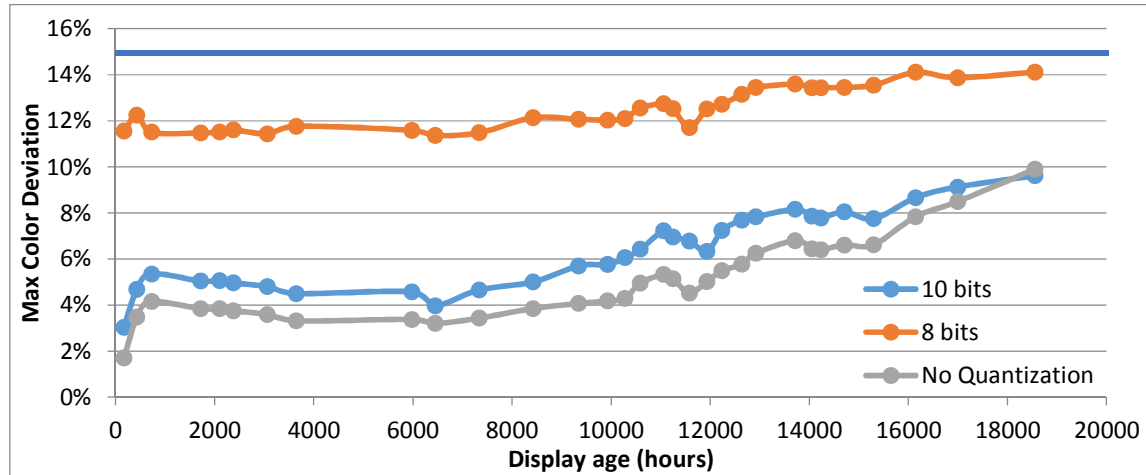


Figure 17: Effect of the aging of a diagnostic display on the Color compliance of a calibration calculated at its production.

A calibration has been calculated based on the first measurements, and evaluated over the complete dataset. Figure 17 presents the results of these tests and shows that aging has a limited impact on the color compliance of the calibration.

6.5. Ambient light

The present study also takes into account ambient light chromaticity by considering a lighting color temperature of 5000K (D50).

Impact of the ambient light is modelled as an offset applied on the XYZ output of the display model. This offset is defined as follows with I being the illuminance level (in lux) and 0.01 the reflection coefficient of the display.

$$Y_{amb} = 0.01 * I$$

This offset differs from X and Z channel, according to the proportion of X Y and Z of White D50 (0.96422, 1.0, 0.82521):

$$X_{amb} = 0.96422 * Y_{amb}$$

$$Z_{amb} = 0.82521 * Y_{amb}$$

6.5.1. Why considering the ambient light?

Ambient light partly reflects on any surface, including displays. The proportion of reflected light mainly depends on the material and reflecting surfaces geometries. This is usually characterized by a Reflection Coefficient associated with the display.

On medical displays, this coefficient is usually higher than on consumer level displays because of the presence of a front glass adding two more interfaces (air-glass and glass-air) on top of the air-panel interface, creating even more reflections.

For this reason we decided to use a reflection coefficient of 0.01 in our simulations. In other words, we consider that the display reflects 1% of the ambient light. Figure 18 shows how the additional light from the reflection can adversely affect the Grayscale part of a calibration if ambient light's effect is not taken into account.

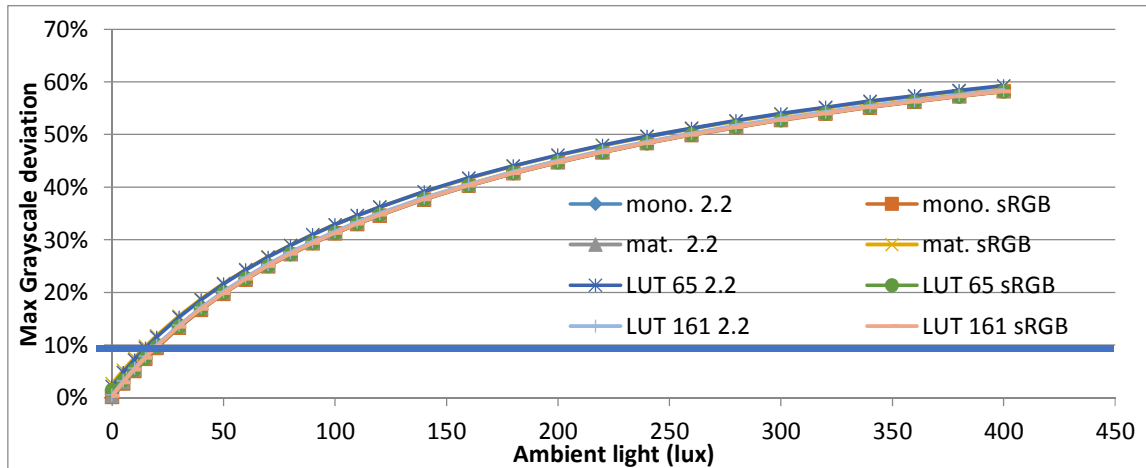


Figure 18: Effect of the ambient light on the Grayscale compliance of a calibration evaluated with different type of display profiles.

It appears on Figure 18 that the effect of ambient light on the calibration is not linear. For this reason, it is important to detail its impact in different environments.

6.5.2. Diagnostic rooms

Diagnostic reading rooms are already used when establishing a diagnostic from quantitative imaging modalities, X-rays and other grayscale modalities where lighting conditions are controlled and illumination maintained low (2 to 10 lux for x-rays, 15 to 60 lux for CT and MR) [18]. In these conditions, knowing precisely the ambient light has its importance. Figure 19 shows how Grayscale compliance varies with the ambient light while profiles were built considering an illumination of 5 lux.

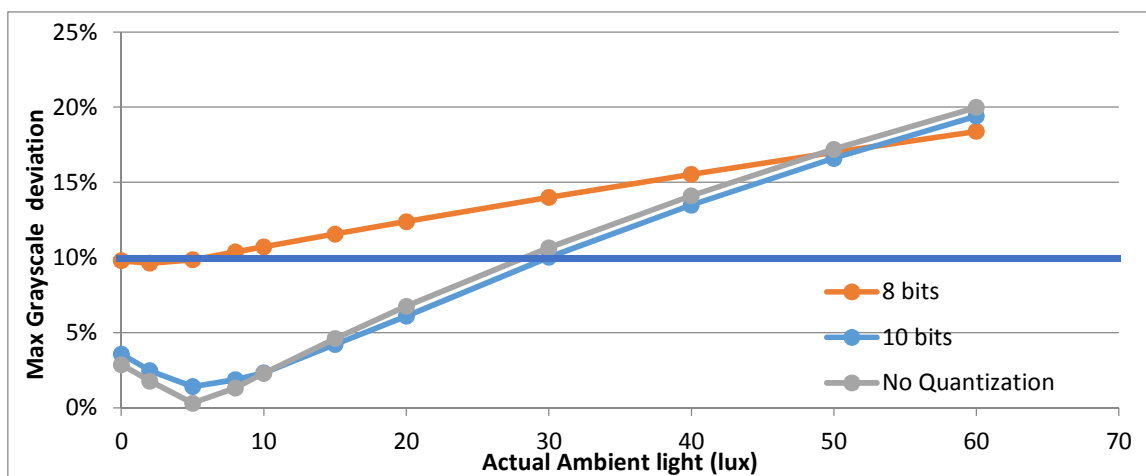


Figure 19: Effect of the ambient light on Grayscale compliance when ICC profiles used for calibration are built for an illumination of 5 lux with an 18 * 18 * 18 color LUT

If the lighting conditions are correctly controlled (no windows...) it is possible to assess a correct calibration by having a single estimation of the ambient light at the profile generation time and monitoring ambient light afterwards may not be required.

Figure 20 presents the impact of ambient light on the calibration of colors.

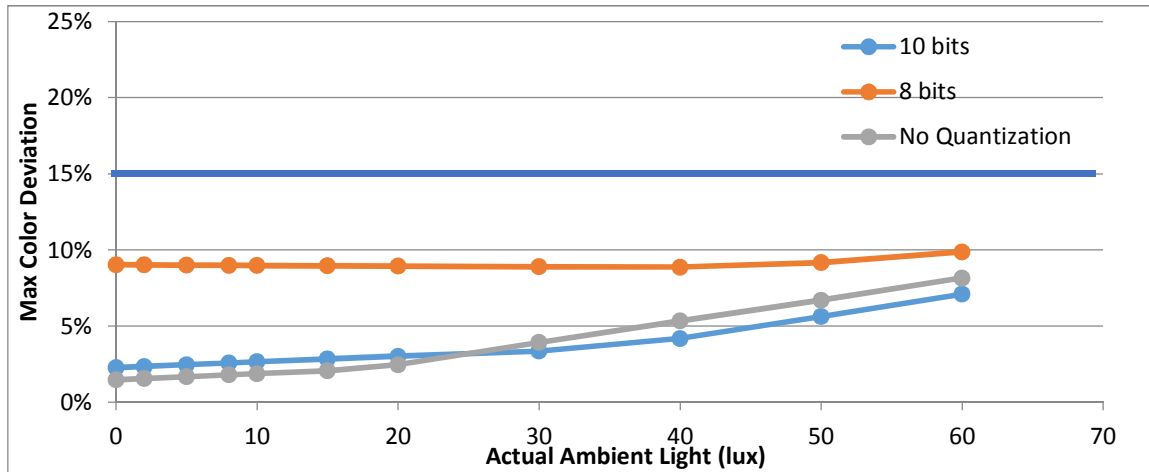


Figure 20: Effect of the ambient light on Color compliance when ICC profiles used for calibration are built for an illumination of 5lux with an 18 * 18 * 18 color LUT

It is clear here that Color calibration does not suffer from an approximate estimation of the ambient light during the calibration process, at least for low illumination levels.

6.5.3. Staff offices

While quantitative imaging modalities are to be examined in dedicated reading rooms with reduced ambient light, pathology diagnostics are usually established in physician offices, where lighting conditions are not controlled and can vary from 50 to 180 lux [18]. In such conditions, it is much more difficult to control the office's illumination as it highly depends on external parameters such as the weather which might abruptly and unpredictably change. It is therefore necessary to continuously measure ambient light and regenerate calibration profiles several times a day.

Figure 22 shows that higher relative variations of ambient light between the profile and the display it describes, have a larger influence on Color compliance for staff offices than they do for diagnostic rooms. For instance, a 50% underestimation of the ambient light led to 9%, 3% and 2% maximal Color deviations in diagnostic rooms, respectively for 8 bit, 10 bit, and floating point precisions. In the case of staff offices, a 45% underestimation already leads to 16%, 10% and 9% Color deviations for 8 bit, 10 bit, and floating point precisions, respectively.

These variations of color calibration compliance remain rather limited in 10 bit systems compared to 8 bit architectures and could be considered as acceptable. However, this is not the case for Grayscale calibration, as misestimating the ambient light by 30% is enough to make the calibration incompliant in an office (Figure 21), where the illumination is susceptible to drastically change throughout the day.

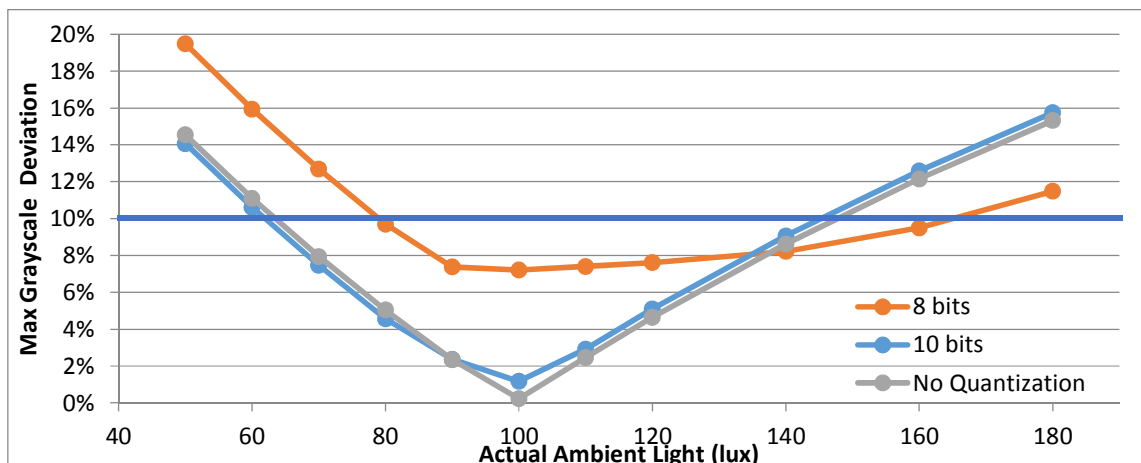


Figure 21: Effect of the ambient light on Grayscale compliance when ICC profiles used for calibration are built for an illumination of 100 lux with an 18 * 18 * 18 color LUT

In order to preserve an accurate Grayscale calibration using this method, ICC profiles would have to be regularly recreated according to the office’s ambient light variations. If the presented method were used to obtain the most accurate Grayscale calibration, staff offices would be improper for diagnostic purposes.

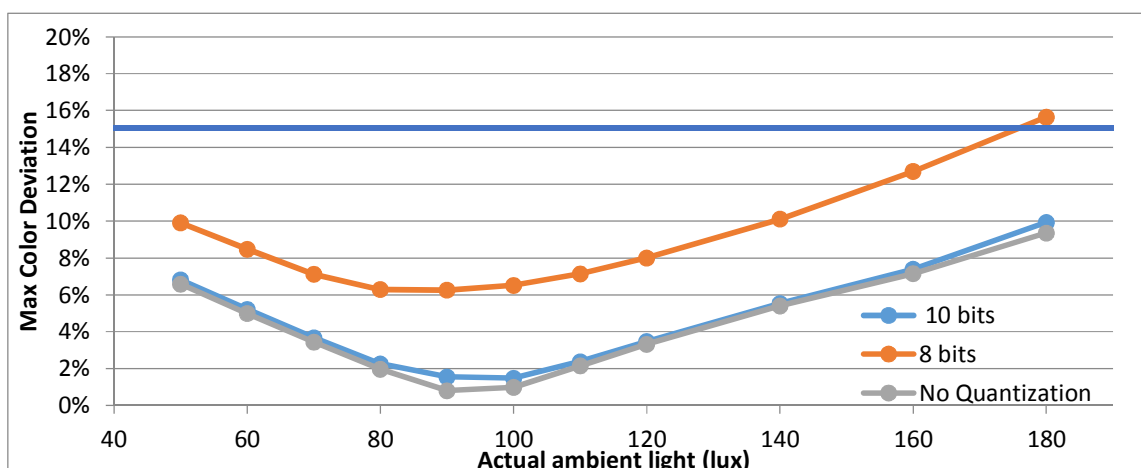


Figure 22: Effect of the ambient light on Color compliance when ICC profiles used for calibration are built for an illumination of 100 lux with an 18 * 18 * 18 color LUT

6.5.4. Operating rooms

Color Management and display calibration is also a concern for surgery. Reviewing scans and radios in an operating room happens and in this case DICOM GSDF calibration must also be respected.

AAPM estimates that operating room illumination usually varies from 300 lux to 400 lux. This is quite high and can produce important reflections, especially on displays equipped with a front glass.

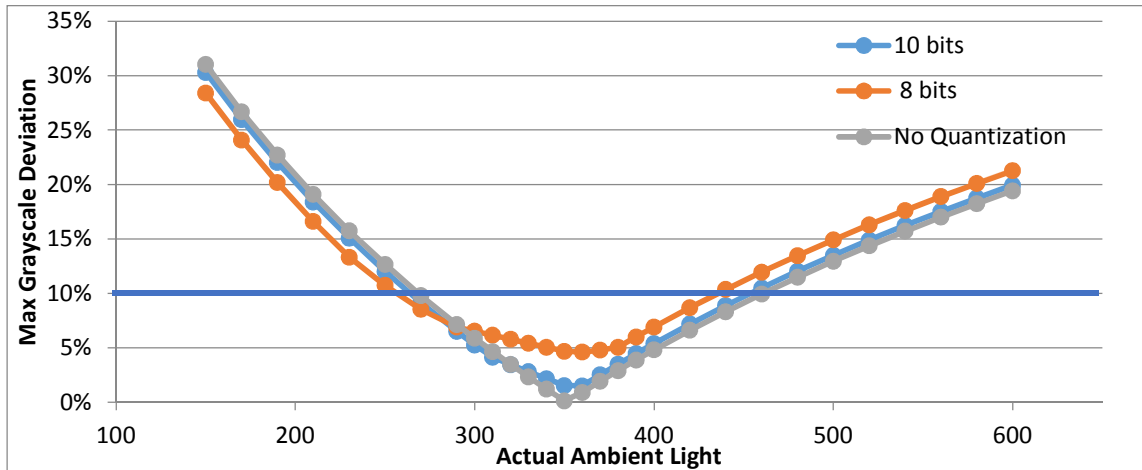


Figure 23: Effect of the ambient light on Grayscale compliance when ICC profiles used for calibration are built for an illumination of 350lux with an 18 * 18 * 18 color LUT

Figure 23 and Figure 24 show that ambient light variation in these conditions has a lower impact on the calibration compliance than it does in diagnostic rooms or staff offices. Relative variation appears to be similar: an 42% underestimation of ambient light by the profile leads to 15.5%, 9.3% and 8.6% Color deviations for 8 bit, 10 bit and floating point precisions.

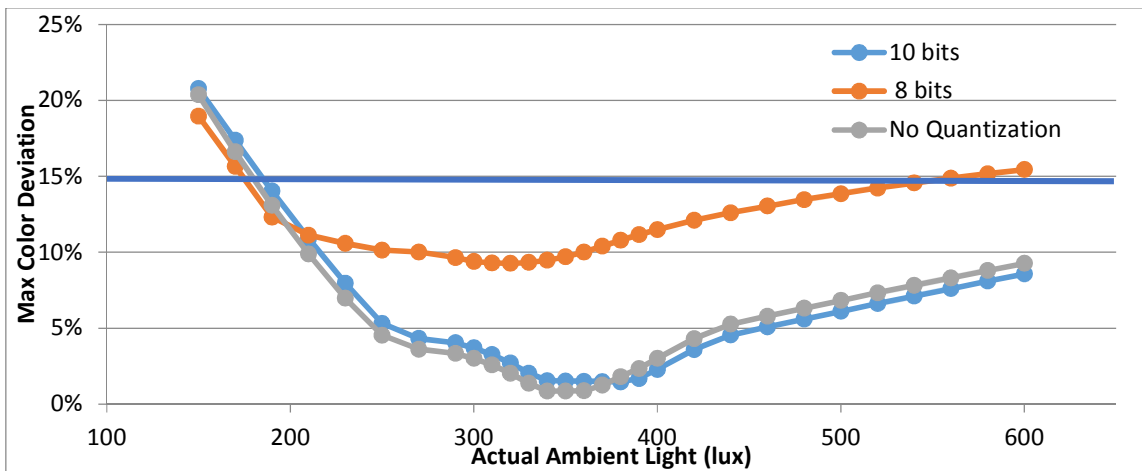


Figure 24: Effect of the ambient light on Color compliance when ICC profiles used for calibration are built for an illumination of 350lux with an 18 * 18 * 18 color LUT

However, influence of absolute variation has far less impact than in other use cases, but the presence of very powerful directional light sources can be a concern for the quality of the color calibration.

7. Recommendations

For display systems which already have embedded DICOM GSDF / CSDF calibration and stabilization, it is recommended to disable the CMM or make sure that an identity profile is used.

For non-calibrated displays, the following recommendations are provided with the goal to stay within 10% tolerance of the Grayscale target and within 15% tolerance of the Color target:

- System configuration:
 - Only use ICC profiles that have been specifically created for the specific display. Generic profiles do not offer sufficient accuracy, even if the display can be set to a reference state.
 - Every time a display setting is changed (e.g. display luminance or contrast settings), new source and destination profiles need to be created and used.
 - Use at least 10 *bit* connections from application to software when a most accurate calibration is needed, since 8 *bit* ones are clearly not sufficient for these use cases.
 - Display luminance and contrast should be stabilized to the value given by the profile since luminance and contrast deviations result into reduced calibration accuracy (See Figure 9 and Figure 12).
 - If the luminance cannot be stabilized, a “warming-up” period should be respected before the display can be used. A period of 2 *hours* (see Figure 11) is recommended, but this time may be reduced if the stability and warm-up of the display is known and reproducible.

- ICC Profile and CMM:
 - Both source and destination profiles must take the ambient light into account.
 - Both source and destination profiles should be LUT based profiles using XYZ color space as PCS as described in section A.3. As explained in section 3 and B.2.4, it is also possible to use DeviceLink profiles.
 - For DICOM GSDF calibration of grayscale display, the use of monochrome profile is possible, and recommended.
 - For CSDF calibration, the CLUT of the source profile (describing the calibration) must have a size of at least 13 * 13 * 13 points to be compliant (see Figure 30), but using at least 31 * 31 * 31 points is recommended for a more accurate calibration. The display profile can be matrix-based, but we recommend using a more accurate LUT-based profile as depicted in section A.3.
 - Special attention must be given to PCS-To-Device conversion of the Black point. This is critical to achieve an acceptable calibration. See section 6.2.

- Calibration process:
 - The calibration compliance must be verified at least every 50 calendar days since typical display behavior changes over time as Figure 16 shows. If the compliance test fails, the whole calibration process has to be repeated. This means renewing display measurements and regenerating the display profile based on these measurements. More frequent measurements are possible and could guide determining when recalibration is needed.
 - Ambient light must be stable. Otherwise, the calibration process must be repeated every time the ambient light conditions change (see Figure 21).

Annex A. Detailed structure of the ICC profiles

Version 4.3 of the ICC specification [24] makes it possible to use different architectures to build ICC profiles.

A.1. Monochrome profiles

ICC defined monochrome profiles to describe grayscale devices. As DICOM GSDF is a calibration of grayscale systems, it makes sense to use monochrome DICOM profiles, and let the CMM return RGB triplets where $R = G = B$.

The monochrome profiles are very simple. They also present the advantage of requiring the same tags whether they are input, output or display profiles. However, as their name suggest they are only suitable for grayscale devices.

Apart from the copyright and description tags, there are:

- Media White Point Tag:

This tag contains the White point of the device, normalized and chromatically adapted to the PCS illuminant. For a display profile, this is equivalent to the PCS illuminant itself. The capture device White point of an input profile is “the encoding maximum White for the capture encoding”.

- Gray TRC Tag:

This tag contains the Gray Tone Reproduction Curve, representing the conversion from the device Digital Driving Level to the achromatic channel of the PCS. This curve can be composed of up to 4096 points, or being a predefined parametric curve.

The display profile then contains an accurate description of the “native” display function, while the input profile describes the exact DICOM target for the given display luminance and contrast.

- Chromatic adaptation Tag:

This tag contains a linear Bradford chromatic adaptation matrix corresponding to the adaptation from the actual illuminant to the PCS adopted White Chromaticity as represented by the equation hereafter.

$$\begin{bmatrix} X_{PCS} \\ Y_{PCS} \\ Z_{PCS} \end{bmatrix} = \begin{bmatrix} a_{00} & a_{01} & a_{02} \\ a_{10} & a_{11} & a_{12} \\ a_{20} & a_{21} & a_{22} \end{bmatrix} * \begin{bmatrix} X_{SRC} \\ Y_{SRC} \\ Z_{SRC} \end{bmatrix}$$

In addition to those required tags, the luminance tag was included because of the necessity to ensure the input profile contains a DICOM calibration corresponding to the luminance of the display, as the calibration depends on both the maximum and minimum luminance of the device.

A.2. Three-component Matrix-TRC-based profiles

This profile architecture assumes the conversion from device color space to PCS is a simple linear combination of their respective channels as shown on Figure 25. It

can be understood as a set of three tone curves modeling the non-linearity of the response of each input channel.

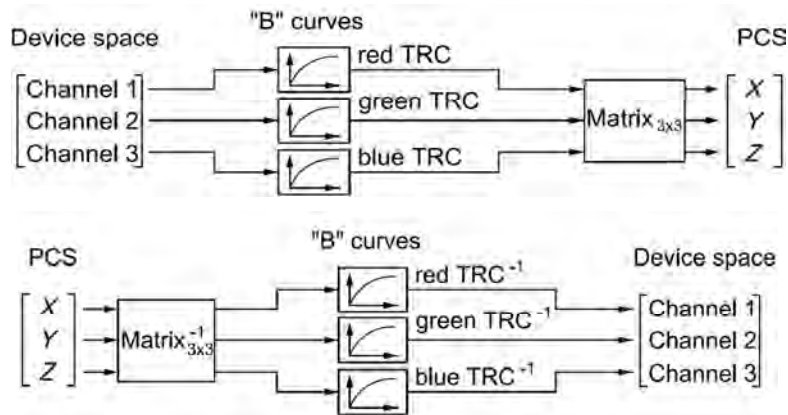


Figure 25: Model of conversion from device space to PCS and from PCS to device space as it is used in display matrix-based profiles.

Those curves are contained in the three Red, Green and Blue TRC Tags. Similarly the tags Red, Green and Blue Column matrix represent the three columns of the conversion matrix. They also are the values of the 3 primaries of the device expressed in the PCS.

Matrix-based profiles perform very well in describing theoretical display standards or models as the ones we use in this study, but are unable to describe the internal constraints of a real LCD display. For instance, this architecture cannot deal with cross-talk in between the sub-pixels of a Liquid Crystal Panel. On an actual display, the Red TRC depends on the levels of Green and Blue as shown on Figure 26, and the simplicity of this model does not allow this phenomenon to be taken into account.

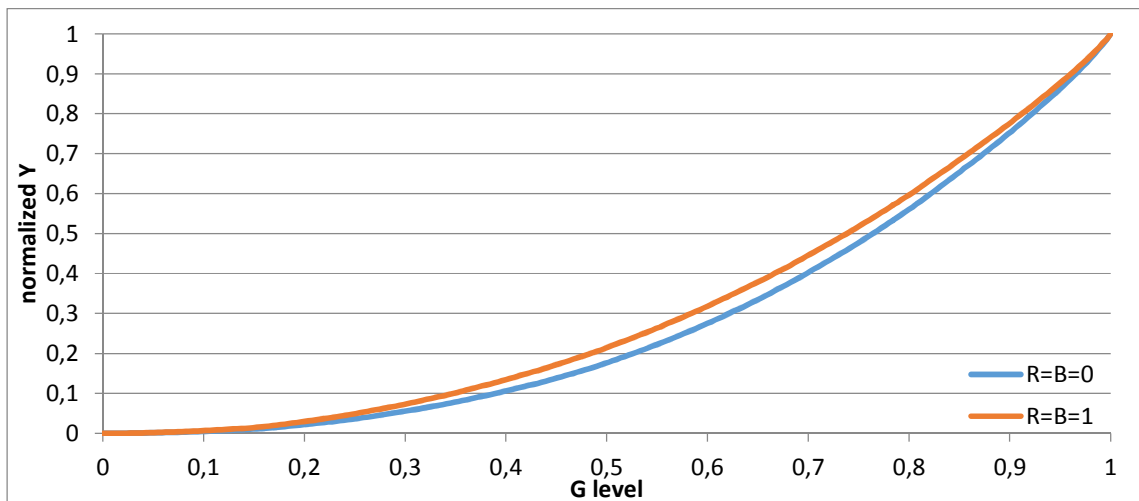


Figure 26: Comparison of the Green Luminance curve of a diagnostic color display, when Red and Blue Channel are both set to 0% and 100%. The curves have been normalized for better readability. The horizontal axis represents the Green ddi, and the vertical axis is the normalized luminance $(Y - Y_{min}) / (Y_{max} - Y_{min})$.

This approximation may be acceptable depending on the use-case.

For the same reason, this profile architecture cannot be used to represent the CSDF calibration as the light output of the display for a given RGB triplet is no longer directly proportional to the light of the three primaries in this case.

For instance, ΔE_{2000} calibration of the Black-to-Green sweep can be represented by the Green TRC tag, but this TRC is also applied on the Magenta-to-White sweep whereas its calibration is completely different. Figure 27 illustrates this by presenting an example of how the Green channel is impacted by the CSDF on different parallel color sweeps in the RGB cube.

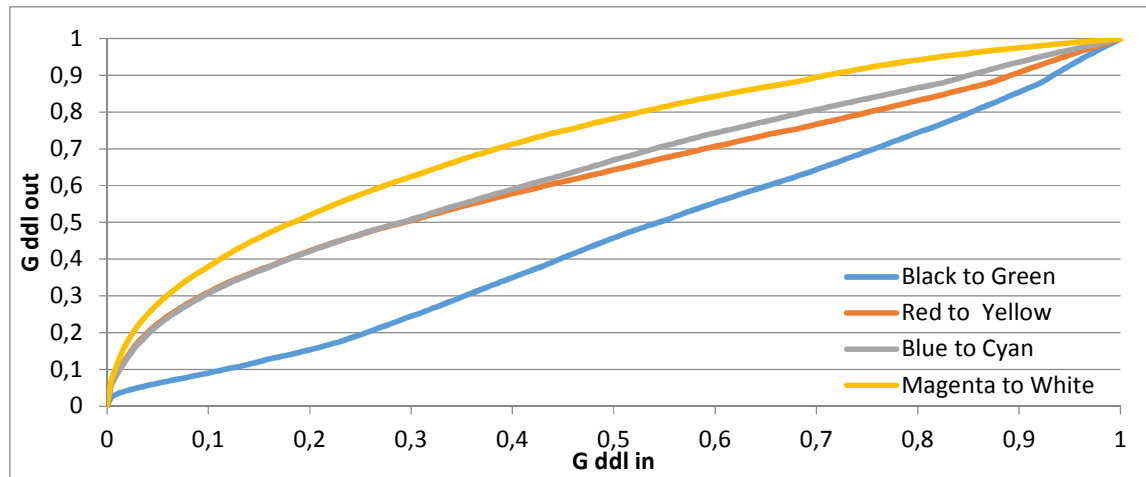


Figure 27: Green-to-Green 1D LUT for CSDF calibration of different color sweeps. All these sweeps are defined in RGB by a changing G value from 0 to 1 and with R and B constant.

A.3. N-component LUT-based profiles

LUT based profiles are far more complex than the previously described architecture (see Figure 28). LUT profiles have N-dimension tables with entries for every combination (or a range large enough to allow interpolation) of input values and their corresponding PCS values. There is one table per direction (PCS-To-Device and Device-To-PCS) and per rendering intent (Perceptual, Saturation and Colorimetric).

Not all six tables are required for every profile. Firstly, having a single rendering intent is enough to build a profile, and only display profiles require the two directions of conversion. Nevertheless, this is enough to make these profiles larger, but also more accurate in their description of the color behavior of a device.

Several other elements can be combined with the LUT to make the device characterization even more accurate.

A, B and M curves behave just like TRC described in section A.2. The CLUT is organized as an i -dimensional array with a variable number of grid points in each dimension, where i is the number of input channels in the transform. Each grid point value is an o -integer array, where o is the number of output channels.

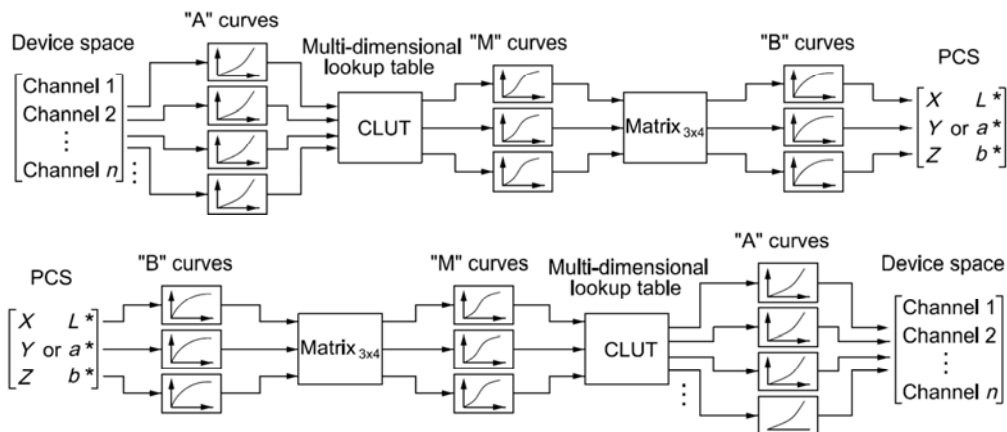


Figure 28: Device-to-PCS and PCS-to-Device conversion workflows for LUT based profiles.
The different elements around the Color LUT (CLUT) can be used to create a nonlinear repartition of the input values of the LUT, or set to identity.

During our experiments, both i and o were equal to 3. We used only cubic LUTs (same size on every dimension) and only a few sizes have been tested.

Profiles were constructed using the XYZ PCS.

- A-curves are unused in both Device-to-PCS and PCS-to-Device conversions and were thus set to be identity tone curves.
- CLUT stages are used for RGB-to-RGB conversions. The tables may contain individual point corrections to make the profile more faithful to the display it represents.
- M-curves are used to apply inverse RGB companding in Device-to-PCS conversion and RGB companding in PCS-to-Device conversion. This handles the RGB-XYZ non linearity and makes RGB linear.
- The matrix is used to finish the linear RGB-to-XYZ conversion and thus contains RGB reference primaries as XYZ values, written in column order. For encoding reasons, these values are all divided by 2.
- B-curves, as A-curves, were unused in both tags and were set to identity curves.

In the case of the aforementioned display models, identity 3D CLUTs were used in the CLUT stage since there is no physical display color point correction to apply on them. For CSDF profiles, a 3D color correction LUT is calculated and encompassed in the CLUT stage of the pipeline. CSDF profiles are always built from a DICOM model to ensure a good DICOM calibration by storing the GSDF in the profile M-curves.

A.4. DeviceLink profiles

In the classical workflow presented in section A.2, the color space of the input device is transformed to the color space of the output device via the device-independent color space (PCS) by connecting two different profiles (a source profile and a destination profile). A device link profile is a special kind of ICC profile

that converts the color space of the input device directly into the color space of the output device without any intermediate step.

DeviceLink profiles contain a single table similar to the one presented at the top of Figure 28. The deviceLink profile can be built similarly to the N-component LUT based profile; except that every elements related to PCS can be removed. In the end, only the RGB-To-RGB conversion is preserved in the CLUT element, and if necessary the 1-dimensional RGB-To-RGB LUT ensuring GSDF calibration can be stored in the B-Curves.

DeviceLink profiles present as main drawback a lack of flexibility. Indeed each profile corresponds to a single very precise situation. While the classical workflow allows for example to use the same source profile when a display's internal calibration state is changed from sRGB to DICOM, and only update the display profile, Here it is necessary to update the deviceLink profile, and so to recalculate the RGB-To-RGB calibration LUT.

Annex B. Application of the calibration method and results

The calibration method has been tested with all of the profile models presented in Annex A for both source and destination profiles, though one architecture is designed for monochromatic devices and can only be used for GSDF calibration purpose.

The different profiles do not represent physical displays, but follow some simple models: Gamma 1.8, Gamma 2.2, Gamma 3.5, sRGB and DICOM GSDF.

For all of them, a Luminance of $Y_{max} = 600 \text{ cd/m}^2$ and a contrast of 1000:1 ($Y_{min} = 0.6 \text{ cd/m}^2$) are considered since these are typical values. Color coordinates of White, Red, Green and Blue primaries follow the sRGB standard [25] as summarized in Table 1.

Table 1: Color coordinates of Black Point, White Point and Primary Colors common to the different display models used during this study.

Color	Y (cd/m^2)	x	y
White	600	0.3127	0.329
Black	0.60	0.3127	0.329
Red	128.08	0.64	0.33
Green	429.26	0.30	0.60
Blue	43.86	0.15	0.06

This choice was made in order to ensure a good reproducibility of the experiments, but the method has been tested with physical displays in section 0.

Figure 29 shows the resulting luminance response curves of those models.

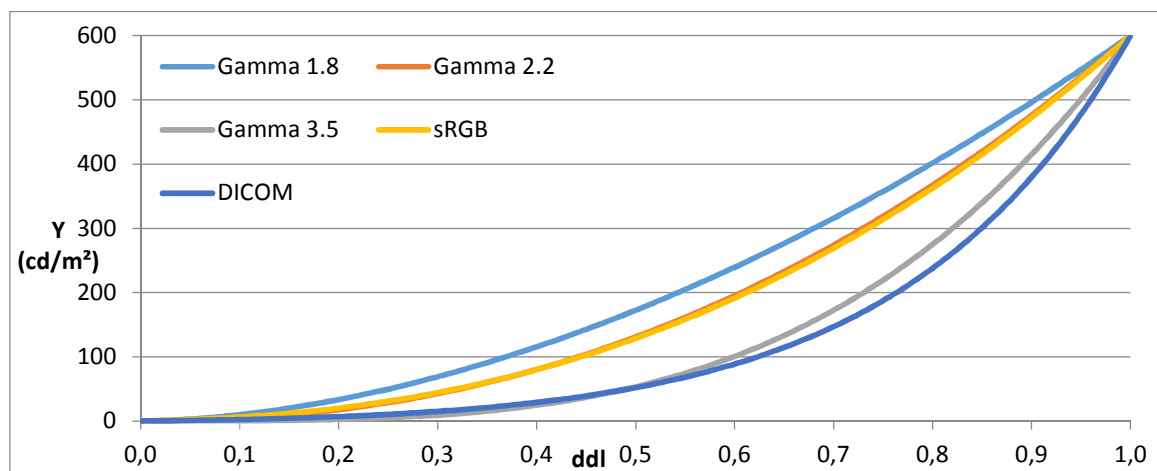


Figure 29: Luminance curves of the different display models considered during this study.

B.1. Profile quality assessment

Created profiles were tested in following the methods presented in section 4 to assess their quality before using them for calibration purpose.

All the results presented in Table 2 to Table 8 represent ΔE_{2000} values resulting of simulations and computations based on the profiles themselves. No quantization has been applied as this phenomenon is due to the display itself. ICC profiles as they are used here have an inherent precision of 16bits.

B.1.1. Fidelity test

B.1.1.1. Monochrome profiles results

In case of a DICOM GSDF calibration for pure grayscale modalities, the use of grayscale monitors and monochrome profiles is possible. For this reason, monochrome profiles are also evaluated with the difference that the previously presented input test sample is reduced to RGB triplets with $R = G = B$. Results are presented in Table 2 and reveal a very good accuracy of monochrome profiles.

Table 2: Monochrome profiles fidelity results as a function of the display model (ΔE_{2000}).

Display Model	Average Profile Fidelity	Worst Profile Fidelity
sRGB	0.0182519	0.031728
Gamma 3.5	0.0145193	0.031728
Gamma 2.2	0.0180893	0.031728
Gamma 1.8	0.0195657	0.031728
DICOM	0.0149173	0.031728

B.1.1.2. Matrix-TRC profiles results

In this paragraph we estimate the accuracy of Matrix based profiles. Results summarized in Table 3 are perfectly acceptable for every profile except CSDF.

Table 3: Matrix-TRC profiles fidelity as a function of the display model (ΔE_{2000}).

Display Model	Average Profile Fidelity	Worst Profile Fidelity
sRGB	0.0068204	0.034245
Gamma 3.5	0.005613	0.034245
Gamma 2.2	0.00671118	0.034245
Gamma 1.8	0.00734149	0.034245
DICOM	0.00562321	0.034245
CSDF	7.09157	24.9025

This confirms the assumption of section A.2 about the impossibility to describe complex color systems with such profiles. According to the results presented here this profile architecture will not be considered anymore in the next sections.

B.1.1.3. Reference LUT-based profiles results

Since CLUTs that are used for creating profiles based on display models are completely linear, their sizes do not impact the results of the tests for reference profiles. This parameter will thus not be used in the interpretation of the reference results presented in Table 4.

Table 4: Reference Profiles Fidelity results as a function of the display model (ΔE_{2000}).

Display Model	Average Profile Fidelity	Worst Profile Fidelity
sRGB	0.0205527	0.0784756
Gamma 3.5	0.0175035	0.0701783
Gamma 2.2	0.0205474	0.0793607
Gamma 1.8	0.0217619	0.0844731
DICOM	0.0172126	0.0631233

For these profiles, induced color differences are far below the perceptual limit and thus even the maximal measured difference would not be perceivable in real conditions.

B.1.1.4. CSDF LUT-based profiles results

Fidelity test results for CSDF profiles are presented in Table 5.

As it is observable in the table, the chosen CLUT size does influence Fidelity test results for CSDF profiles. However, this influence appears to be relatively minor. Similarly to the reference profiles, color differences induced by profile generation are not perceptually significant.

Table 5: CSDF Profiles Fidelity results as a function of the CLUT size (ΔE_{2000}).

CLUT size	Average Model Fidelity	Worst Model Fidelity
11	0.0199861	0.106663
18	0.0199088	0.111355
33	0.0199288	0.111493
65	0.0199219	0.107764

B.1.2. Roundtrip test

B.1.2.1. Monochrome profiles results

The results are presented in Table 6 and show a maximal error of $0.213944 \Delta E_{2000}$ and a mean error of $0.0126455 \Delta E_{2000}$ for Gamma 3.5 profiles,

while the others present values comparable to the reference LUT-based profiles presented in section B.1.2.2.

Table 6: Monochrome profiles roundtrip results with luminance of 600 cd/m² and contrast ratio of 1000 (ΔE_{2000})

Profile	Roundtrip Mean	Roundtrip Max
sRGB	0.00031189	0.00170167
Gamma 3.5	0.0126455	0.213944
Gamma 2.2	0.000646326	0.00548937
Gamma 1.8	0.00113504	0.000117576
DICOM	0.000130997	0.0014838

B.1.2.2. Display LUT-based profiles results

According to [26], when using transforms containing CLUTs larger than $2 * 2 * 2$, accuracy requirements stipulate that “round tripping color differences in CIELAB ΔE_{ab}^* should be less than 1 mean and less than 3 maximum”. However, reference profiles use identity RGB-to-RGB CLUTs, thus comparable to a $2 * 2 * 2$ CLUT. In that case, still according to [26], “color differences should be less than 0.5 mean and less than 1 max”.

Results for reference profiles are presented in Table 7. Roundtrip tests for created profiles show maximal errors of $0.0963472 \Delta E_{2000}$ and mean errors below $0.00389718 \Delta E_{2000}$. These are far below the thresholds given above.

Table 7: Reference profiles roundtrip results with luminance of 600 cd/m² and contrast ratio of 1000 (ΔE_{2000})

Profile	Roundtrip Mean	Roundtrip Max
sRGB	0.00152663	0.022604
Gamma 3.5	0.00389718	0.0963472
Gamma 2.2	0.000834971	0.00580855
Gamma 1.8	0.000662107	0.00549094
DICOM	0.0015788	0.0280541

B.1.2.3. CSDF LUT-based profiles results

The chosen CLUT size is of major influence on the roundtrip quality of these profiles. Extreme values in function of the LUT size are shown in Table 8.

The maximal observed color differences can thus be very high for small accuracy profiles such as the ones based on $11 * 11 * 11$ CLUTs. Conversely, the mean color differences, while still being greatly influenced by the LUT size parameter, still show good overall results.

The high maximal values obtained here are due to the difficulty to properly reverse the CSDF 3D LUT, especially near White. Due to the fact that the ΔE_{2000} calibration

makes colors brighter than they are with DICOM GSDF, the LUT tends to group the colors close to White as it is observable on Figure 27 where the Green-To-Green 1D LUT corresponding to the Magenta-to-White color scale extracted from the 3D LUT appears. This effect can be compensated by using a bigger CLUT.

Table 8: LUT-based CSDF profiles maximal roundtrip errors relatively to the chosen LUT size (ΔE_{2000}). A color scale is applied on the values to emphasize the results compared to the thresholds defined in [26].

CLUT size	Roundtrip Mean	Roundtrip Max
11	0.34892	6.92059
18	0.176271	4.93752
33	0.0516545	3.90132
38	0.0382301	2.97002
65	0.0149188	0.819532

B.2. Calibration quality assessment

Results were assessed by connecting generated CSDF profiles with their corresponding display profile (regarding luminance & contrast) using the ICC Absolute Colorimetric intent.

Compliance of the calibration on grayscale and colors were assessed separately, since grayscale and colors do not share the same metrics.

To evaluate the influence of the bit depth, a quantization step is applied on the output of the ICC framework, before the resulting RGB triplet is fed to the display model.

Nowadays, a vast majority of display systems supports 8bits only input signals, but some high end devices propose to use 10 bits signals. For medical applications, 8bits does not guarantee the best image quality [27] while using more than 10 bits is not necessary as the human visual system is only able to distinguish up to 900 shades of gray, even on high luminance displays [28].

However being able to observe images with 10bits precision requires the complete video chain to be compatible. Of course the display itself must support 10 bits input signals (typically provided by DisplayPort connection), but also the workstation (the Graphic Process Unit and its driver) has to support 10 bits output, the software used to read the images must be able to render 10 bits, and the image itself must be encoded on 10bits (or more). If only one of those components is limited to 8 bits, the final result would be viewed with 8 bits quantization. Windows 7 and above, OSX 10.11 (El Capitan), and Linux are all able to support 10 bits color output with compatible hardware.

B.2.1. Grayscale calibration quality assessment

B.2.1.1. Monochrome calibration

Here are presented the results of simulations obtained when calibrating grayscale displays to DICOM GSDF by using monochrome profiles. Results are summarized in Table 9.

Table 9: Grayscale compliance results for monochrome profiles generated with luminance of 600 cd/m² and a contrast ratio of 1000:1

Destination Profile	Grayscale compliance	Grayscale compliance 10 bits	Grayscale Compliance 8 bits
sRGB	0.1450%	1.5220%	8.3260%
Gamma 3.5	0.1380%	1.1900%	6.8230%
Gamma 2.2	0.1450%	1.6610%	8.3750%
Gamma 1.8	0.4540%	2.1630%	12.6360%

This method seems to be reliable, at least for 10 bits systems. 8 bits quantization is not necessarily non-compliant except when calibrating a Gamma 1.8 (12.636%). In that case the deviation is quite high and the conditions are not optimum.

B.2.1.2. Color calibration

Here colors displays are calibrated to CSDF by using LUT-based profiles. Grayscale calibration compliance within CSDF is assessed according to the DICOM standard, as explained in section 5.1. Results are summarized in Table 10.

Table 10: Grayscale compliance results for profiles generated with luminance of 600 cd/m² and a contrast ratio of 1000:1

Destination Profile	Grayscale compliance	Grayscale compliance 10 bits	Grayscale compliance 8 bits
sRGB	2.4550%	1.5218%	8.3261%
Gamma 3.5	0.4421%	1.1865%	6.8272%
Gamma 2.2	0.5731%	1.6488%	8.3524%
Gamma 1.8	0.7859%	2.2271%	12.7721%
DICOM	2.4830%	1.9760%	0.0787%

Without applying quantization, results show good compliance scores. In this case, deviation amplitude appears to be inversely correlated to the display model's gamma. 10 bit compliance results are much better than the 8 bit ones with deviation ranging from 1.1865% for the Gamma 3.5 reference to 2.2271% for the Gamma 1.8 profile, which showed the worst compliance score with 8 bit quantization.

It is interesting to note that the quantization does not necessarily make the simulated calibration worse. This is due to the fact that the ICC framework introduces some errors in the process (These errors are estimated during the roundtrip test). Quantization, by rounding the output of the ICC framework can

correct or reduce the Framework imprecision. This is especially visible when applying the color calibration on a DICOM compliant display model.

Grayscale compliance test relies on 18 gray levels, evenly spread from Black-to-White:

$$(R, G, B)_{in} = \left(\frac{i}{17}, \frac{i}{17}, \frac{i}{17} \right) \quad i \in \llbracket 0; 17 \rrbracket$$

Transformed by the profiles connection, these triplets become:

$$(R, G, B)_{out} = \left(\frac{i}{17} + \varepsilon_r, \frac{i}{17} + \varepsilon_g, \frac{i}{17} + \varepsilon_b \right) \quad i \in \llbracket 0; 17 \rrbracket$$

Then quantization is applied:

$$(R, G, B)_{quantized} = \left(\frac{\text{round}\left(\left(\frac{i}{17} + \varepsilon_r\right) * q\right)}{q}, \frac{\text{round}\left(\left(\frac{i}{17} + \varepsilon_g\right) * q\right)}{q}, \frac{\text{round}\left(\left(\frac{i}{17} + \varepsilon_b\right) * q\right)}{q} \right)$$

$$i \in \llbracket 0; 17 \rrbracket$$

$$q = 255 \text{ or } 1023$$

If $-1/2q \leq \varepsilon_r < 1/2q$ (and similarly for ε_g and ε_b), the imprecision introduced by the connection is simply erased by the quantization.

This is exactly what happens when applying the calibration on a DICOM display. The DICOM GSDF grayscale described in the source profile is exactly identical to the one in the destination profile. Connecting those two profiles and transforming gray levels with this connection results in a very accurate roundtrip, introducing minor imprecisions on each RGB triplet along the grayscale. Imprecisions are within the range $-1/2q \leq \varepsilon < 1/2q$ resulting in $(R, G, B)_{8bit} = (R, G, B)_{in}$. As the display is already DICOM calibrated, an evenly spread set of input RGB results in a perfect theoretical DICOM GSDF compliance. However, this is strictly specific to the definition of the quality assessment method, and does not reflect the final image quality which depends on all the existing levels and not only 18 of them.

B.2.2. Color calibration quality assessment

Color compliance is assessed with an arbitrary tolerance of 15% deviation for $6 * 18$ color samples. The simulated results of the proposed calibration method are summarized in Table 11.

B.2.2.1. Without quantization

Without quantization, Color compliance scores are below the tolerance limit for all of the tested LUT sizes. However, compliance scores of the $11 * 11 * 11$ profiles clearly demonstrate that this particular size is unsuited when accurate calibration is needed, with Color deviation spanning from 10.5470% to 10.5925%.

Since compliance is evaluated with 18 points samples along RGB sweeps, the $18 * 18 * 18$ results depicts the accuracy of Color calibration with a minimal influence of interpolation (see Figure 30). With the tested set of display models and $18 * 18 * 18$ CLUTs, Color deviation ranges from 1.7700% to 1.8321%.

Table 11: Color compliance obtained by using different display models and different size of CLUT in the source profile

Destination Profile	Source profile LUT size	Color max deviation	Color max deviation 10 bits	Color max deviation 8 bits
sRGB	11	10.5925%	12.2006%	15.3341%
	18	1.8321%	2.6243%	9.0303%
	33	2.8383%	2.9012%	9.4645%
	65	1.9395%	2.6244%	9.0303%
Gamma 3.5	11	10.5638%	10.3971%	10.2444%
	18	1.8040%	2.1415%	7.4469%
	33	2.8245%	3.3183%	7.4469%
	65	1.9400%	2.1415%	7.4469%
Gamma 2.2	11	10.5470%	12.0502%	21.5339%
	18	1.7700%	1.6746%	7.5699%
	33	2.7996%	2.0485%	7.5699%
	65	1.9292%	1.6773%	7.5699%
Gamma 1.8	11	10.5730%	13.7676%	19.4952%
	18	1.7920%	3.2202%	14.7574%
	33	2.7895%	4.0300%	14.7572%
	65	1.9337%	3.2202%	14.7574%
DICOM	11	10.5868%	10.7014%	13.1294%
	18	1.8044%	2.0298%	7.3060%
	33	2.8373%	3.2150%	7.3060%
	65	1.9508%	1.8503%	7.3060%

Results for 33 * 33 * 33 and 65 * 65 * 65 CLUT sizes illustrate Color compliance scores on a larger grid, thus encompassing interpolation induced error but giving a better idea of the accuracy of the calibration on the whole gamut. That is why observed deviations for these two sizes are superior to the ones observed with 18 * 18 * 18. For 33 * 33 * 33 CLUT size, deviation scores show a minimal value of 2.78952% and a maximal value of 2.83832%. Using more entries in the CLUT enhances the accuracy of the calibration, as depicted by the 65 * 65 * 65 results that ranges from 1.9292% minimum to 1.95078% maximum deviations.

B.2.2.2. With 8 bit quantization

With 8 bit quantization applied, results obtained with 11 * 11 * 11 LUT based profiles show a very high maximal color deviation from CSDF color targets, ranging from 10.2444% to 21.5339%. This corroborates the assessment that 11 * 11 * 11 entries LUTs are unsuited for accurate calibration targets, especially on a 8 bit system.

Results for all the other profiles show very similar maximum deviation values: around 9% for sRGB reference profiles and 7.5% for Gamma & DICOM profiles.

Since LUT size does not seem to influence these values much, it may be deducible that this is the maximal accuracy obtainable with the presented architecture on 8 bits.

B.2.2.3. With 10 bit quantization

As for Grayscale results, using 10 bit quantization instead of a 8 bit quantization effectively reduce the maximal observed deviation. Beneficial influence of a larger bit depth is not consequently significant when using $11 * 11 * 11$ LUTs, with the lowest maximal deviation being 10.3971% (which is even higher than the 8 bit minimum deviation) and an overall maximum deviation of 13.7676%. That makes the results Color compliant for the whole set of tested profiles, despite giving globally poor results.

Results for $18 * 18 * 18$ and $65 * 65 * 65$ LUTs show very similar Color compliance results. For $18 * 18 * 18$ LUTs, maximum deviations span from 1.67457% to 3.22018% . For $65 * 65 * 65$ LUTs, it ranges from 1.67725% to the same 3.22018% maximum.

Since the influence of interpolation errors is reduced with higher LUT sizes (because interpolated values are closest), it is minimal with $65 * 65 * 65$ LUT size. The surprisingly good results obtained with $18 * 18 * 18$ are explained in section B.2.2.4.

With $33 * 33 * 33$ LUTs, maximum deviations show a minimal value of 2.0485% and a maximal value of 4.0300%. This specific size presents relative deviations which are much more impacted by interpolation than its $18 * 18 * 18$ and $65 * 65 * 65$ counterparts. However, $33 * 33 * 33$ produces still very good compliance scores.

B.2.2.4. Conclusion

The chosen CSDF Color validation method induces different interpolation errors for every LUT-size. Since there are arbitrarily 18 samples used on RGB sweeps and because a 3D LUT containing these samples as internal nodes will return non-interpolated values, all LUT sizes having $N * 18 - (N - 1)$ side points will return better results than other chosen sizes would (with N being an integer factor) without guaranteeing a better calibration accuracy on daily use.

Figure 30 depicts observed relative Color compliance of a profile connection using a CSDF profile as source and a destination profile as a function of CLUT size.

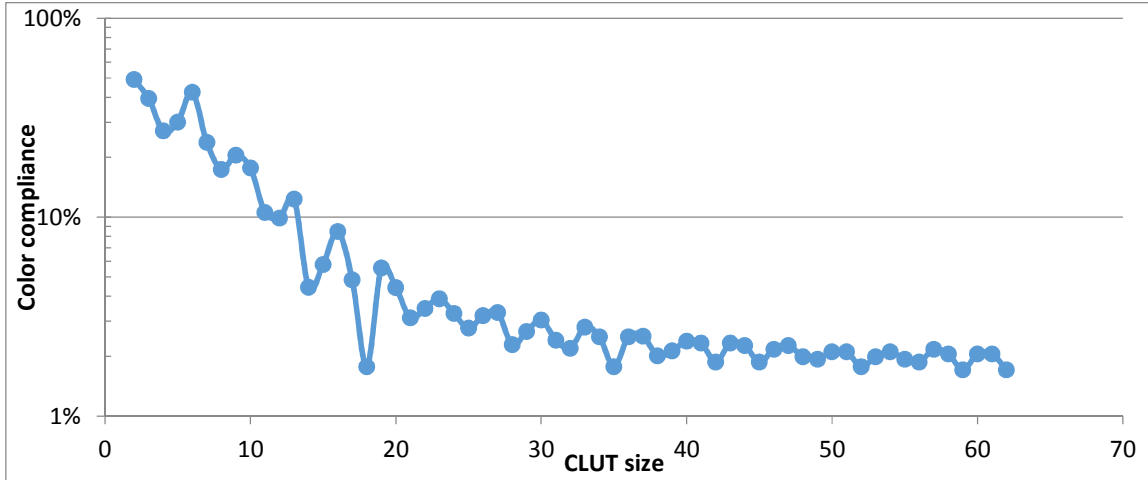


Figure 30: Observed Color compliance as a function of the source profile CLUT size when used with 600 cd/m^2 with contrast ratio of 1000:1 in logarithmic scale on vertical axes.

It is clearly observed that results obtained with a number of CLUT side points matching the aforementioned equation are the most compliant. Therefore minimal deviation is observed for 18, 35 and 52 CLUT side points when tested on 18 points. Nevertheless, we can observe from the trend of the graph, but also from the profile validations that a LUT size of at least 32 is advised.

B.2.3. Calibration smoothness

The resulting smoothness corresponding to the different display models and calibrations mentioned in the present document are presented in Table 12.

Table 12: Smoothness of different display models, without quantization or ICC color transform

Calibration	Average	Standard deviation	Minimum	Maximum
sRGB	0.1842	0.1497	0.0267	1.0289
Gamma 3.5	0.2548	0.1722	0.052	0.9767
Gamma 2.2	0.2175	0.1894	0.0245	1.3444
Gamma 1.8	0.2122	0.2091	0.0252	2.3454
GSDF	0.2202	0.1522	0.0457	1.3098
CSDF	0.1955	0.125	0.0429	1.1279

One can notice that CSDF calibration presents the lowest average value (0.1955) after sRGB (0.1842), revealing a pretty smooth calibration, but also the best standard deviation (0.125) which means the smoothness is more homogeneous over the entire gamut.

The smoothness of the CSDF calibration applied on different displays has also been studied and is presented in Table 13.

Table 13: Smoothness of different display models calibrated to CSDF by using ICC profiles, without quantization

Display model	Average	Standard deviation	Minimum	Maximum
sRGB	0.187	0.1499	0.027	1.0392
Gamma 3.5	0.1958	0.1249	0.0432	1.1333
Gamma 2.2	0.1958	0.1249	0.0436	1.1306
Gamma 1.8	0.1958	0.1249	0.0435	1.131
GSDF	0.1961	0.1248	0.0433	1.1291

Applying the calibration on a sRGB display seems to result in a better average smoothness (0.187) compared to Gamma models (0.1958) and GSDF (0.1961). And while it presents the highest standard deviation announcing homogeneity (i.e. some parts of the color gamut will present sharper transitions), CSDF calibration of sRGB display has the lowest maximum score and is - in terms of smoothness - the best configuration.

Table 14 focuses on the effects on smoothness of quantization and of the size of the CLUT in the profiles used perform for the color transform. Only the calibration of the sRGB display is presented in the table, but similar trends have been observed with the other models.

Table 14: Effect of the quantization and the profiles CLUT size on the average smoothness of a color calibration applied on a sRGB display model.

CLUT Size	Average smoothness	Average smoothness 10 bits	Average smoothness 8 bits
11	0.1941	0.2204	0.4338
18	0.1907	0.2136	0.4334
33	0.187	0.208	0.4342
65	0.1855	0.203	0.4268

Quantization has a huge impact on the final calibration smoothness. While quantizing to 10 bits slightly deteriorate the smoothness of a system, passing from 10 bits to 8 bits more than doubles the average smoothness value. This makes other consideration such as CLUT size, but also the display model on which to apply the calibration of far less importance.

B.2.4. Using deviceLink profiles

Using deviceLink profiles to calibrate a system is possible as explained in section A.4. This method has also been evaluated here and results for grayscale and color compliance are presented respectively in Table 15 and Table 16.

Table 15: Grayscale compliance results with deviceLink profiles generated with luminance of 600 cd/m² and a contrast ratio of 1000:1

Display type	Grayscale compliance	Grayscale compliance 10 bits	Grayscale Compliance 8 bits
sRGB	0.1102%	1.5218%	8.3261%
Gamma 3.5	0.1097%	1.1859%	6.8280%
Gamma 2.2	0.0943%	1.6618%	8.3753%
Gamma 1.8	0.1027%	3.7603%	12.7721%
DICOM	0.1062%	1.4408%	0.0787%

Table 16: Color compliance obtained by using different display models and different size of CLUT in the deviceLink profile

Display type	Devicelink CLUT size	Color max deviation	Color max deviation 10 bits	Color max deviation 8 bits
sRGB	11	10.6857%	12.2002%	15.3342%
	18	1.6437%	2.6242%	9.0305%
	33	2.7166%	2.9011%	9.4647%
	65	1.8263%	2.6242%	9.0305%
Gamma 3.5	11	10.6814%	10.3971%	10.2447%
	18	1.6617%	2.1421%	7.4467%
	33	2.7019%	3.3184%	7.4467%
	65	1.8059%	2.1415%	7.4467%
Gamma 2.2	11	10.7047%	10.4162%	21.5097%
	18	1.6421%	2.0440%	7.5883%
	33	2.7141%	2.0441%	7.5883%
	65	1.8054%	2.0440%	7.5883%
Gamma 1.8	11	10.7046%	13.7609%	19.4955%
	18	1.6445%	3.2260%	14.7570%
	33	2.7225%	4.0295%	14.7568%
	65	1.8032%	3.2260%	14.7570%
DICOM	11	10.6627%	10.5930%	13.1297%
	18	1.6512%	2.0268%	7.3060%
	33	2.6934%	3.5371%	7.3060%
	65	1.8053%	2.0268%	7.3060%

Using DeviceLink profiles ensures a better conservation of the Black Point resulting in a better Grayscale compliance without quantization. However, when taking the

quantization into account, this benefit compared to the classical framework is lost making them essentially similar in performance.

Regarding the presented results, there is no reason to recommend the use of one system or another. Decision to use deviceLink profile or not is at the user discretion.

B.3. Experimental validation

B.3.1. Medical grade display

The described method was experimentally validated on a medical grade display set to three different display functions: gamma2.2, gamma1.8, and DICOM GSDF. Measurements were performed using a Konica Minolta CA-210 on an evenly spread set of 18 color points as it was previously described.

The exact values of the display primary colors, but also Black and White are given in Table 17.

Table 17: Measured luminance and chromaticity values used for the display model

Color	Y(cd/m^2)	x	y
White	462	0.305	0.334
Black	0.46	0.262	0.273
Red	82.11	0.643	0.327
Green	324.9	0.319	0.622
Blue	48.15	0.150	0.081

Based on these measurements, display models used for experimental validation have been generated. These models thus have a luminance of $462cd/m^2$ and a contrast ratio of 1004: 1. It is important to stress that these models were generated based on a limited number of measurements (see Table 17). Therefore it is to be expected that the generated models will not perfectly match the true display behavior (see section 6 for a more detailed description on the effects of this non-perfect modeling). These models then were used to calibrate the display systems.

Simulation results are presented in Table 18 and corresponding measurement results are presented in Table 19.

Table 18: Simulated calibration compliance on the 3 tested configurations with CLUTs of $33 * 33 * 33$ points

Profile	Color max deviation 10 bits	Color max deviation 8 bits	Grayscale max deviation 10 bits	Grayscale max deviation 8 bits
Gamma 2.2	3.0232%	6.5642%	3.2522%	4.7499%
Gamma 1.8	3.0781%	14.0312%	3.0253%	11.0677%
DICOM	2.6797%	8.1791%	3.1320%	5.2659%

As could be expected, experimental results show larger deviations than the simulation results. This is normal since in case of the experimental results the actual display behavior was measured while assessing calibration compliance, while in case of simulation results the assumption is that the display correctly follows the theoretical display model.

Especially for 10 bits color signals, the experimental results show larger Color deviations than the simulation results for a 10 bits color signal. On the other hand, measurement results obtained with an 8 bit per channel system are much closer to the simulated results. The reason is that the inaccuracies introduced by the quantization when using 8 bits channels are larger than the inaccuracies due to non-perfect display modeling.

Table 19: Measured calibration compliance on the 3 tested displays with CLUTs of 33 * 33 * 33 points

Profile	Color max deviation 10 bits	Color max deviation 8 bits	Grayscale max deviation 10 bits	Grayscale max deviation 8 bits
Gamma 2.2	6.0509%	6.6622%	3.1515%	4.7057%
Gamma 1.8	6.1227%	9.4180%	1.5607%	10.3248%
DICOM	6.2429%	6.5765%	2.3443%	5.7139%

B.3.2. Consumer off-the-shelf display

The same protocol as above has been repeated on a consumer off-the-shelf (COTS) display. This one was set to gamma 2.2, and only supported 8 bit input. Here again, every measurements have been done with a Konica Minolta CA-210 after having respected a warm-up period of 3 hours. The measured values of the display Black, White and primary colors are given in Table 20 and its contrast is 1114:1.

Table 20: COTS display measured luminance and chromaticity values used for the display model

Color	Y(cd/m ²)	x	y
White	200.5	0.313	0.3262
Black	0.18	0.263	0.250
Red	46.17	0.632	0.334
Green	137.9	0.312	0.643
Blue	17.23	0.148	0.065

The ICC profiles created for these experiments were LUT-based profiles with 33 * 33 * 33 CLUT in the case of CSDF profile. The display profiles have a purely linear CLUT, and no attempt to improve the profile fidelity by introducing some corrections in there, as it is suggested in section A.3.

At a first attempt of calibrating this display to CSDF, we trusted the preset and generated a display profile having perfect gamma 2.2 TRC. This ends up with a

very bad calibration compliance presented in the first row of Table 21 and confirming the results of section 6.3.

A second calibration has been executed, this time after having measured 256 gray levels on the display to model more accurately the real display TRC. Here the observed Grayscale compliance is in line with the simulation, and the observed Color compliance is even slightly better than expected as presented in the second row of Table 21.

Table 21: Simulated and Measured calibration compliances on the COTS display with CLUTs of 33*33*33 points with 8bit quantization

Display TRC	Simulated		Measured	
	Color max deviation	Grayscale max deviation	Color max deviation	Grayscale max deviation
Assumed Gamma 2.2	6.5676%	6.1170%	12.6456%	18.8480%
Measured Gray TRC	12.0587%	6.4462%	9.5275%	6.8788%

Observations also match pretty well to the predictions presented in Table 10 and Table 11 for 8 bits systems with similar display functions and CLUT sizes.

These measurements suggest that calibrating a display to with the presented method using only a LUT-based profile without correction or matrix-based profile (which is equivalent when following the recommendations of sections A.2 and A.3) is possible. A 33 * 33 * 33 CLUT for the CSDF profile is enough to obtain a compliant calibration, but the observed deviation are already pretty high, and the calibration would have to be repeated regularly to maintain the display calibrated.

It also appears that using 8bits system is possible as it produces compliance results just below the rejection threshold. However, the chances of passing this threshold because of some variations of the usage conditions are high.

Annex C. Relationship to dRGB

Michael Flynn (Henry Ford Health System) proposed a new color space called medical RGB (dRGB) which tries to merge the DICOM GSDF and sRGB color space⁴. dRGB is also one of the ICC MIWG projects.

dRGB is not only a color space but also a complete framework giving specifications for medical display performances and calibration. It also includes the use of ICC profiles to perform dRGB to PCS conversions.

When linking this to the Color Space draft [29], being worked out in the context of AAPM TG196; one can say that the present document covers use cases 1A, 1C and 2C presented on Figure 31.

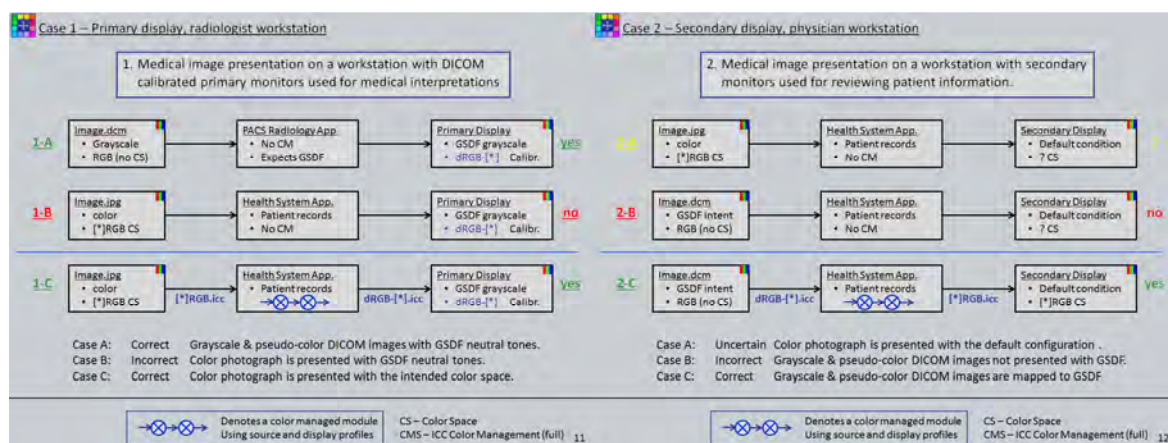


Figure 31: Grayscale and color medical images as described by Michael Flynn in [29].

⁴ <http://www.color.org/groups/medical/Flynn.pdf>

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Remarks on Whitepaper #44 „Visualization of medical content on color display systems“

The white paper describes how a color display can be calibrated for displaying medical data in false colors. The aim is to be consistent with the Grayscale Standard Display Function (GSDf) on the one hand and use the full gamut of the display for the visualization of data as false-colors on the other hand. Equal distances in the visualized data should result in equal Delta E2000.

I have the following suggestion for improvement:

On page 13, the authors address the warm up period of the display. Here, the differences between LED and CCFL backlight might be interesting.

On page 14/15, the authors state “Contrast underestimation by the profile has a much larger influence on perceptual linearity of colors than a corresponding overestimation”. To my understanding, the terms underestimation and overestimation are exchanged. Figure 13 shows that the deviation is found when the actual display contrast is lower than the display contrast assumed by the sRGB profile. This means to my understanding that the profile overestimates the actual display contrast.

In Table 6 on page 33, the column titles are exchanged. The Roundtrip Mean has to be lower equal the Roundtrip Max.

On pages 30-44, Delta E2000 values are given with a precision with up to seven decimal places. Are really all digits significant? For 10bit colors, the quantization errors are on the order of Delta E=0.1 which makes it hard for me to trust the last digits.

Display Devices for Diagnostic Radiology

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance is being distributed for comment purposes only.

Document issued on February 9, 2016.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Mary Pastel (OIR) at 301-796-6887 or by e-mail at mary.pastel@fda.hhs.gov.

When final, this guidance will supersede Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems- Premarket Notification (510(k)) Submissions issued May 30, 2008



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Division of Radiological Health

Office of Science and Engineering Laboratories
Division of Imaging Diagnostics and Software Reliability

Preface

29

30

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32

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34

35

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1500022 to identify the guidance you are requesting.

DRAFT

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53
54 **Display Devices for Diagnostic**
55 **Radiology**

56 **Guidance for Industry and**
57 **Food and Drug Administration Staff**
58
59

60 *This draft guidance, when finalized, will represent the current thinking of the Food and Drug*
61 *Administration (FDA or Agency) on this topic. It does not establish any rights for any person*
62 *and is not binding on FDA or the public. You can use an alternative approach if it satisfies*
63 *the requirements of the applicable statutes and regulations. To discuss an alternative*
64 *approach, contact the FDA staff responsible for this guidance as listed on the title page.*
65

66 **I. Introduction**

67 The Food and Drug Administration (FDA or “we”) is issuing this draft guidance to assist
68 industry in preparing premarket notification submissions for display devices intended for use in
69 diagnostic radiology.
70

71 This draft guidance is intended to apply to current technologies; however, FDA may request new
72 or alternative test methods to fully evaluate the safety and effectiveness of future display
73 technologies. In such instances, we recommend that you contact FDA to determine the
74 appropriate regulatory pathway and testing for your device prior to submitting a premarket
75 notification. See Section III - Scope for more details on types of devices covered by this draft
76 guidance document.
77

78 FDA's guidance documents, including this draft guidance, do not establish legally enforceable
79 responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should
80 be viewed only as recommendations, unless specific regulatory or statutory requirements are
81 cited. The use of the word *should* in Agency guidances means that something is suggested or
82 recommended, but not required.
83

84 **II. Background**
85

86 This guidance, when finalized, will apply to display devices intended for diagnostic radiology as
87 identified in Section III – Scope, and currently classified under 21 CFR 892.2050 as class II
88 devices.

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89
90 This guidance document provides recommendations for the types of information you should
91 provide in your 510(k) submission for display devices intended for diagnostic radiology. This
92 information supplements the requirements for a 510(k) submission found in 21 CFR 807 Subpart
93 E, as well as recommendations provided in other FDA documents concerning the specific
94 content of a 510(k) submission, including FDA’s guidance entitled, “Format for Traditional and
95 Abbreviated 510(k)s” (<http://www.fda.gov/RegulatoryInformation/Guidances/ucm084365.htm>)
96 and FDA’s guidance entitled, “Refuse to Accept Policy for 510(k)s”
97 (<http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm315014.pdf>).
98
99

100 This guidance, when finalized, will supersede a previously issued final guidance entitled
101 “Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification
102 (510(k)) Submissions” issued on May 30, 2008.
103

104 **III. Scope**

105
106 This document recommends what to include in a 510(k) submission for display devices in
107 diagnostic radiology as identified by their classification regulation (21 CFR 892.2050) and
108 product code (PGY). These devices are classified as class II devices that are intended to be used
109 in controlled viewing conditions to display and view digital images for primary image
110 interpretation. Display devices for diagnostic radiology may also be referred to as soft-copy
111 displays or medical grade monitors. The classification regulation for these devices reads as
112 follows:

113 **21 CFR 892.2050 Picture archiving and communications system**

114
115 (a) **Identification.** A picture archiving and communications system is a device that
116 provides one or more capabilities relating to the acceptance, transfer, display, storage,
117 and digital processing of medical images. Its hardware components may include
118 workstations, digitizers, communications devices, computers, video monitors, magnetic,
119 optical disk, or other digital data storage devices, and hardcopy devices. The software
120 components may provide functions for performing operations related to image
121 manipulation, enhancement, compression or quantification.
122

123 (b) **Classification.** Class II (special controls; voluntary standards--Digital Imaging and
124 Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG)
125 Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).
126

127 Typically, the 510(k) submission for display devices is separate from the 510(k) submissions of
128 other image acquisition or management devices (e.g., hardware/software for image acquisition,
129 long term storage, data transfer between computer systems, or image analysis). However, this
130 guidance may apply when displays intended for diagnostic interpretation classified under

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131 892.2050 (product code, PGY) are included as part of a 510(k) submission along with other
132 software and/or hardware.

133
134 This guidance does not apply to real-time displays that are part of the image acquisition device
135 classified under other regulations (e.g., the display on a fluoroscopy system classified under 21
136 CFR 892.1650 (product code OWB) or the display on an ultrasonic pulsed doppler imaging
137 system classified under 21 CFR 892.1550 (product code IYN)).

138
139 This guidance does not apply to medical image hardcopy devices under 21 CFR 892.2040, for
140 information on these types of devices see FDA’s guidance entitled “Enforcement Policy for
141 Premarket Notification Requirements for Certain *In Vitro* Diagnostic and Radiology Devices”
142 (<http://www.fda.gov/RegulatoryInformation/Guidances/ucm283904.htm>).

143
144 This guidance does not apply to imaging software and software applications, for information on
145 these types of devices see FDA’s guidance entitled “Guidance for the Submission of Premarket
146 Notifications for Medical Image Management Devices”
147 ([http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocu](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073721.pdf)
148 [ments/ucm073721.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM401996.pdf)) and FDA’s guidance entitled “Medical Device Data Systems, Medical
149 Image Storage Devices, and Medical Image Communications Devices
150 ([http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocu](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM401996.pdf)
151 [ments/UCM401996.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM401996.pdf)).

152
153 This guidance does not apply to ophthalmic image management systems (product code NFJ)
154 classified under 21 CFR 892.2050; medical cathode-ray tube (product code DXJ) classified
155 under 21 CFR 870.2450; displays intended for whole-slide imaging and digital surgical or
156 anatomical pathology, or displays for other non-radiological applications. The guidance also
157 does not apply to displays in handheld or mobile devices; for information on these types of
158 devices see FDA’s guidance entitled “Mobile Medical Applications”
159 ([http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocu](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf)
160 [ments/UCM263366.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf)). Sponsors may wish to submit a pre-submission to the appropriate
161 review divisions to receive guidance for displays not covered by this guidance. For information
162 on FDA’s pre-submission process, see FDA’s guidance entitled “Requests for Feedback on
163 Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug
164 Administration Staff”
165 ([http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocu](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf)
166 [ments/UCM311176.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf)).

167
168 If you are submitting a 510(k) for modification(s) to a cleared display or the same
169 modification(s) apply to a number of display models, please refer to Appendix B and C for
170 further information.

171

172 **IV. Describing Your Device in a 510(k) Premarket**
173 **Notification**

174

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175 When submitting a 510(k), you should identify your device by regulation and product code as
176 described in Section III Scope and include the information discussed below. You must provide
177 information to FDA showing how your device is substantially equivalent (SE) to a predicate
178 device (sections 513(f)(1) and 513(i) of the Federal Food, Drug, and Cosmetic Act (FD&C act));
179 21 CFR 807.87(f)). We recommend your 510(k) include the information described below, if
180 applicable.

181 **A. Indications for Use**

182 The Indications for Use statement (IFU) should provide a general description of the disease(s) or
183 condition(s) that your device will be used to help diagnose and the patient population for which
184 the device is intended. The IFU should state whether your device is or is not intended for
185 mammography.

186
187 We recommend the IFU address how your device will be used, for example, if the device is
188 intended for mammography:

189
190 The _____ is indicated for use in displaying radiological images (including
191 mammography) for review, analysis, and diagnosis by trained medical practitioners.

192
193 An example IFU if the device is not intended for mammography:

194
195 The _____ is indicated for use in displaying radiological images for review, analysis,
196 and diagnosis by trained medical practitioners. The display is not intended for
197 mammography.

198
199 You should compare your device's IFU to the IFU of the predicate device, including any specific
200 intended uses. Display devices that have been cleared for mammography can also be used
201 clinically for digital breast tomosynthesis.

202
203 **B. Device Description**

204
205 We recommend that you provide a complete description of your device by including the
206 information discussed below in your 510(k) submission. The items below should be presented in
207 a tabular side-by-side comparison with the predicate device. The 510(k) submission should
208 include a discussion of any differences in the technological characteristics between your device
209 and the predicate device with additional information necessary to determine whether the
210 differences raise new questions regarding the safety or effectiveness of the new device.
211 Additional discussion in paragraph form is recommended for novel features. Your device
212 description should include information such as the following:

- 213
214
215
- **Display Technology:** A description of the technological characteristics of the display device (e.g., in-plane switching LCD panel with TFT active-matrix array with CCFL backlight).

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- 216 • **Screen size:** A description of the physical size of the viewable area in diagonal and
217 aspect ratio.
- 218 • **Backlight type (transmissive displays only):** A description of the backlight type and, if
219 substantially different from the predicate device, main properties including temporal,
220 spatial, and spectral characteristics.
- 221 • **Frame rate and refresh rate:** A description of the frame rate and refresh rate.
- 222 • **Pixel array, pitch, subpixel pattern, pixel aperture ratio:** A description of the pixel
223 array including pixel size, pixel pitch, and subpixel pattern (e.g., chevron, RGBW);
- 224 • **Subpixel driving (spatial and temporal dithering):** A description that indicates if the
225 subpixels are used to improve gray-scale or temporal resolution.
- 226 • **Display Interface:** A description of the display interface (e.g., DVI, display port, HDMI).
- 227 • **Video bandwidth:** A description of the capabilities of the information transfer pipeline
228 between the image source and the digital driving levels in all associated components
229 including the CPU/GPU, graphics card, and display interface.
- 230 • **User controls:** A description of either the on-screen display (OSD) or software available
231 for end users that relate to the display image quality (e.g., brightness and contrast controls,
232 gamma, white point, power saving options, etc.).
- 233 • **Ambient light sensing:** A description of the ambient light sensing method,
234 instrumentation, and software tool description.
- 235 • **Touch-screen technology:** A description of the method, functionality, and any
236 calibration or periodical re-tuning requirements.
- 237 • **Luminance calibration tools:** A description of the sensor hardware and associated
238 software for performing luminance calibration, and if applicable, details about the user-
239 level procedures, service-action tolerances, and centralized automatic calibration tools.
- 240 • **Quality-control procedures:** A description of the frequency and nature of quality-
241 control tests to be performed by the user and/or the physicist with associated action limits.
242 A detailed quality control manual should be included for regulatory review.
- 243 • **Software/Firmware:** A list with descriptions of any additional firmware or software
244 features for image manipulation or analysis not covered by any of the above items.
245

246 **V. Electrical Safety**

247 You should evaluate the electrical safety of your device according to one or more of the most
248 recent FDA recognized version of the following standards¹, or any equivalent method being used
249 as an alternative to evaluate electrical safety:

- 250 • International Electrotechnical Commission (IEC) 60601-1-1 *General requirements for*
251 *safety - Collateral standard: Safety requirements for medical electrical systems*; and
- 252 • Underwriters Laboratories Inc. (UL) 60601-1 *Medical Electrical Equipment: Part 1:*
253 *General Requirements for Safety.*

¹ Please refer to FDA's Recognized Consensus Standards Database
(<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>) for the currently recognized versions.

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254 For 510(k) submissions for display devices intended for diagnostic radiology, in lieu of
255 providing the actual electric safety test reports, you may simply submit a Declaration of
256 Conformity to an FDA-recognized consensus standard to indicate that your device has been
257 tested for compliance with the appropriate standards.² FDA may request to review the actual test
258 reports if the IFU, device description, and/or labeling for your device raises concerns regarding
259 the electrical safety. The features and design of your device will determine whether other
260 standards are appropriate in addition to, or in place of the standards provided above. For more
261 information on the use of standards, please refer to section 514(c)(1)(B) of the FD&C Act and
262 FDA’s guidance entitled “Use of Standards in Substantial Equivalence Determinations”
263 ([http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocu
264 ments/ucm073756.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073756.pdf)).
265

266 **VI. Firmware and Software Documentation**

267
268 Display devices intended for diagnostic radiology may include firmware and software for the
269 following functionalities:

- 270 • Display controls;
- 271 • Ambient light sensing;
- 272 • Luminance calibration tools; and/or
- 273 • Quality-control software.

274 Your 510(k) submission should include documentation for the software and firmware that you
275 have developed for use with your device. The kind of information we recommend you submit in
276 your 510(k) is determined by the “level of concern”, which is based on the risks associated with
277 a potential software failure by your device. If the software/firmware is limited to the four
278 functionalities listed above, the level of concern may be considered minor. If your device
279 contains advanced software features, you may consider asking FDA for advice on whether the
280 software would be a minor, moderate, or major level of concern. In most instances, the software
281 documentation may be submitted at a minor level of concern. When preparing the software
282 documentation for your 510(k) submission and for guidance on what information you should
283 include based on the level of concern, please see the following FDA guidance documents:

- 284 • Guidance for the Content of Premarket Submissions for Software Contained in Medical
285 Devices (<http://www.fda.gov/downloads/MedicalDevices/.../ucm089593.pdf>);
 - 286 • General Principles of Software Validation; Final Guidance for Industry and FDA Staff
287 ([http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Guidanc
288 eDocuments/ucm085371.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf)); and
 - 289 • Guidance for Off-the-Shelf Software Use in Medical Devices
290 (<http://www.fda.gov/downloads/MedicalDevices/.../ucm073779.pdf>).
- 291

² For more information on the use of consensus standards, please visit FDA’s website at
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>.

292 **VII. Physical Laboratory Testing**
293

294 We recommend that you provide the following performance testing data with a side-by-side
295 comparison of technical performance testing data to the predicate device in your 510(k)
296 submission. Table 3 below identifies what tests we recommend you perform in demonstrating
297 substantial equivalence to a predicate device based on the IFU of your display device (Table 3
298 includes recommendations for both non-mammography and mammography intended uses).
299 Please refer to Appendix A for additional guidance on each test and references for methods and
300 procedures for display characterization.
301

302 **Table 2. Recommended Physical Laboratory Tests**

Measurements	Recommended for Non-mammography Display Submissions	Recommended for Mammography Display Submissions
a. Spatial resolution	Yes	Yes
b. Pixel defects (count and map)	Yes	Yes
c. Artifacts	Yes	Yes
d. Temporal Response	Yes (Limited)	Yes
e. Luminance (maximum, minimum, achievable, and recommended)	Yes	Yes
f. Conformance to a grayscale-to-luminance function (e.g., DICOM GSDF)	Yes	Yes
g. Luminance at 30° and 45° in diagonal, horizontal, and vertical directions at center and edge spots	No	Yes
h. Luminance uniformity or Mura test	No	Yes
i. Stability of luminance response with temperature and lifetime	No	Yes
j. Spatial noise	No	Yes
k. Bidirectional reflection distribution function	No	Yes
l. Veiling glare or small-spot contrast	No	Yes
m. Gray tracking	No	Yes

303
304 We recommend that you include a brief description of the test method(s) you have used to
305 address each performance aspect identified in Table 3. If you follow a suggested test method,
306 you may cite the method rather than describing it in your 510(k) submission. If you modify a
307 suggested test method, you may cite the method but should provide sufficient information to
308 explain the nature of and reason for the modification. We recommend that you provide a
309 description of all proprietary measurement systems used for performing quantitative tests,
310 including the trade name, characteristics, and accuracy of the measurement tools.

Contains Nonbinding Recommendations

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311 For cases where the new device performs significantly lower than the predicate device on one or
312 more of the physical laboratory tests in Table 3, an additional study that further characterizes
313 underperforming features of the display may be necessary to demonstrate substantial equivalence
314 to a predicate device.

315 **VIII. Labeling**

316 The following Section is intended to assist you in preparing labeling that satisfies FDA’s labeling
317 requirements under 21 CFR Part 801.³

318
319 A prescription device, under 21 CFR 801.109, is exempt from section 502(f)(1) of the FD&C
320 Act that requires adequate directions for use by a lay person. As a prescription device, your
321 device must meet the labeling requirements for prescription devices under 21 CFR 801.109,
322 including a prescription use statement.

323
324 Your 510(k) submission must include proposed labels, labeling, and advertisements in sufficient
325 detail to satisfy the requirements of 21 CFR 807.87(e). We recommend you submit clear and
326 concise instructions for use that delineate the technological features of your device and how your
327 device is to be used. Instructions should encourage local/institutional training programs
328 designed to familiarize users with the features of your device and instruct users on how to use
329 your device in a safe and effective manner.

330
331 FDA recommends that the labeling for review workstation displays intended for mammography
332 include the following statement:

333
334 Mammographic images with lossy compression must not be reviewed for primary image
335 interpretations. Mammographic images may only be interpreted using an FDA cleared
336 display that meets technical specifications reviewed and accepted by FDA.

337
338 In addition to meeting any requirements under 21 CFR Part 801, your device’s user manual
339 should include the following information, as appropriate:

- 340
- 341 • The Indications for Use as stated in your premarket submission;
 - 342 • Warnings and precautions (and any mitigation measures);
 - 343 • Overview of the device;
 - 344 • Principles of operation;
 - 345 • Directions for use (e.g., display controls and GUI);
 - 346 • Technical specifications;
 - Performance specifications (summary of physical laboratory testing);

³ Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of 21 CFR Part 801.

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- 347 • Cleaning information;
- 348 • Hardware/software compatibility requirements;
- 349 • Conformity to any voluntary standards; and
- 350 • Manufacturer’s contact information.

351 In addition, instructions for maintenance of the system performance (quality assurance
352 processes) should include:

- 353 • A description of personnel authorized to service the system;
- 354 • Recommended maintenance schedule;
- 355 • Calibration procedures; and
- 356 • A full description of recommended quality assurance testing (with action limits),
357 including detailed procedures for performing these tests, if applicable, and the frequency
358 of testing. You may use the latest recognized version of NEMA Standards XR 22 and XR
359 23, for designing quality assurance tests.

360

361 **Appendix A – Performance Tests**

362

363 The following provides additional details on the individual tests recommended in Section VIII
364 Physical Laboratory Testing along with an explanation of what information should be included
365 for each test.

- 366 a. ***Spatial resolution:*** Measurements of the transfer of information from the image data to
367 the luminance fields at different spatial frequencies of interest typically done by reporting
368 the modulation transfer function. Non-isotropic resolution properties should be
369 characterized properly by providing two-dimensional measurements or measurements
370 along at least two representative axes.
- 371 b. ***Pixel defects:*** Measurements (counts) and location (map) of pixel defects. This is
372 typically provided as a tolerance limit. Pixel defects can interfere with the visibility of
373 small details in medical images.
- 374 c. ***Artifacts:*** Evaluate for image artifacts such as ghosting and/or image sticking from
375 displaying a fixed test pattern for a period of time.
- 376 d. ***Temporal Response:*** Measurements of the temporal behavior of the display in
377 responding to changes in image values from frame to frame. Since these transitions are
378 typically not symmetric, rise and fall time constants are needed to characterize the
379 system. Slow displays can alter details and contrast of the image when large image
380 stacks are browsed or in video mode.
 - 381 ○ *For non-mammography displays*, you should measure the rise and fall time
382 constants for 5–95% and 40–60% luminance transitions.
 - 383 ○ *For mammography monitors*, you should measure the rise and fall time constants
384 at 15 grayscale intervals between 0 and 255 (resulting in an 18 x 18 grid of
385 measured values).
- 386 e. ***Maximum and minimum luminance (achievable and recommended):*** Measurements of
387 the maximum and minimum luminance that the device outputs as used in the application
388 under recommended conditions and the achievable values if the device is set to expand
389 the range to the limit.

Contains Nonbinding Recommendations

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- 390 f. **Conformance to a grayscale-to-luminance function (e.g., DICOM GSDF):**
391 Measurements of the mapping between image values and the luminance output following
392 a target model response for 256 or more levels.
- 393 g. **Luminance at 30° and 45° in diagonal, horizontal, and vertical directions at center and**
394 **edge spots:** Measurements of the luminance response at off-normal viewing related to the
395 target model for the luminance response (see *VESA Standard: Display Specifications and*
396 *Test Procedures* for “center and edge” definitions).
- 397 h. **Luminance uniformity or Mura test:** Measurements of the uniformity of the luminance
398 across the display screen.
- 399 i. **Stability of luminance response with temperature and lifetime:** Measurements of the
400 change in luminance response with temperature and use time.
- 401 j. **Spatial noise:** Measurements of the spatial noise level as represented by the noise power
402 spectrum using an appropriate ratio of camera and display pixels. Spatial noise and
403 resolution affect the way images are presented to the viewer and can alter features that
404 are relevant to the interpretation process of the physician or radiologist.
- 405 k. **Bidirectional reflection distribution function:** Measurements of the reflection
406 coefficients of the display device. Specular and diffuse reflection coefficients can be
407 used as surrogates for the full bidirectional reflection distribution function.
- 408 l. **Veiling glare or small-spot contrast:** Measurements of the contrast obtained for small
409 targets.
- 410 m. **Gray Tracking:** Chromaticity at different luminance levels as indicated by the color
411 coordinates in an appropriate units system (e.g., CIE $u'v'$) (see *IEC 62563-1-E1A1*).
412

413 For methods and procedures for display characterization, please refer to the following:

- 414 • American Association of Physicists in Medicine, Task Group 18 (TG18). *Assessment of*
415 *Display Performance for Medical Imaging Systems*. January 2006.
416 (<http://deckard.mc.duke.edu/~samei/tg18>);
- 417 • Video Electronics Standards Association, Flat Panel Display Measurements Task Group.
418 *Flat Panel Display Measurements Standard, version 2.0*. June 2001;
- 419 • Video Electronics Standards Association, Measurement Standards Work Group. *VESA*
420 *Standard: Display Specifications and Test Procedures, version 1.0*. October 1994;
- 421 • International Electrotechnical Commission (IEC) 62563-1-E1A1. *Medical electrical*
422 *equipment - Medical image display systems – Part 1: Evaluation methods. Amendment 1*,
423 March 2016; and
- 424 • International Committee for Display Metrology (ICDM). *Information Display*
425 *Measurements Standard (IDMS), version 1.03*. June 2012. (<http://www.icdm-sid.org/>).

426

427 Appendix B – Device Modifications

428 We recommend that you refer to FDA’s guidance entitled “Deciding When to Submit a 510(k)
429 for a Change to an Existing Device”

Contains Nonbinding Recommendations

Draft – Not for Implementation

430 (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm0>
431 [80235.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm0)) for subsequent models of the same device family that have previously received
432 510(k) clearance. The sponsor should perform regression testing and physical laboratory testing
433 in conformance with relevant test standards to verify that the changes did not adversely impact
434 image quality and ensure that the device conforms to specifications as required under the Quality
435 System Regulation (21 CFR 820.70). For example, changes in the graphics driver, power supply,
436 or upgrade in the calibration software most likely would not require a new 510(k) submission,
437 but sponsors should review the appropriate regulations and standards to determine when a new
438 510(k) submission is necessary. Sponsors should contact FDA with any questions about
439 modifications made to their devices.

440 Please note that in order for FDA to make a complete evaluation, your 510(k) submission should
441 include a description of all changes made to your device since the most recent 510(k) clearance,
442 including all changes that were made without submitting a 510(k).
443

444 **Appendix C – Device Bundling**

445
446 Often, firms may make the same modification(s) to all of their display models. Instead of
447 submitting a separate 510(k) submission for each display model, FDA recommends submitting a
448 bundled submission for all impacted display models. Bundling is appropriate for devices that
449 present scientific and regulatory issues that can most efficiently be addressed during one 510(k)
450 submission review. For more information, please refer to FDA’s guidance entitled “Bundling
451 Multiple Devices or Multiple Indications in a Single Submission”
452 (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm0>
453 [89731.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm0)).
454
455
456
457

Defining Acceptable Colour Tolerances for Identity Branding in Natural Viewing Conditions

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Supervisors: Dr. Phil Green and Dr. Mike Pointer

London College of Communications
PhD viva voce in Digital Colour Imaging

January 2015

Motivation

- NHS project to improve visual colour consistency in their identity branding;
 - For all target locations, substrates, displays, wayfinding etc.
- Redesign of their identity branding toolkit to accommodate tolerance metrics;
 - CIE 1976 *or* DE2000 [$\Delta E_{ab} \pm$ *or* $\Delta E_{00} \pm$]
- Define a feasible workflow that accounts for identity branding targets;
 - Uniformity within target locations, per media type, or colour specification (eg. Hue)

Experiment 3 - Psychophysical evaluation of grey scale functions performance

- The NHS use of non- medical displays for branded content to complement medical imaging workflow – remote imaging and clinical communications;



- In branded content, specific colours might be associated with the brand;
- Medical imaging the discrimination or detection of colour is often more important than colour identification;
- Medical display luminance (c. 500 cd/m²+) accommodates grey levels exceeding non-medical (200-300 cd/m²);

Method

- 24 sample perturbations for 3 Near neutral references,
- judged at approximate peak white luminances of -
 - 282 cd/m²,
 - 229 cd/m²
 - 165 cd/m²;
- 23 observers estimate difference magnitude per peak white luminance value;

Results

- STRESS formula for testing statistical significance of the performances of GSDF and Whittle formulas for the same visual data ;

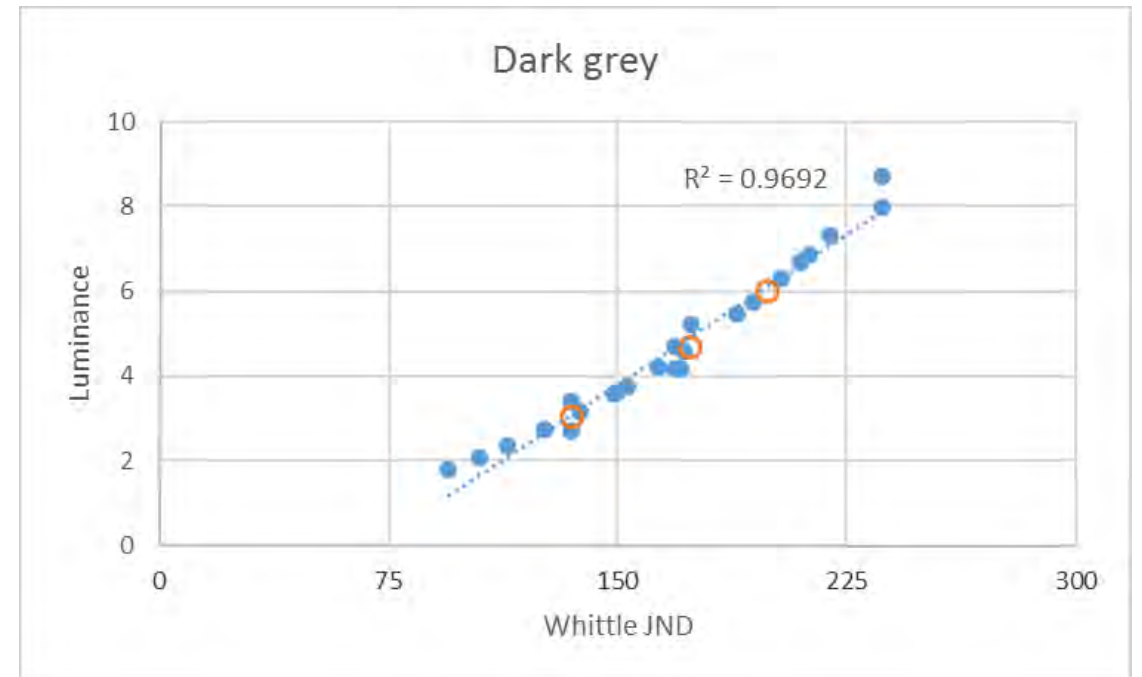
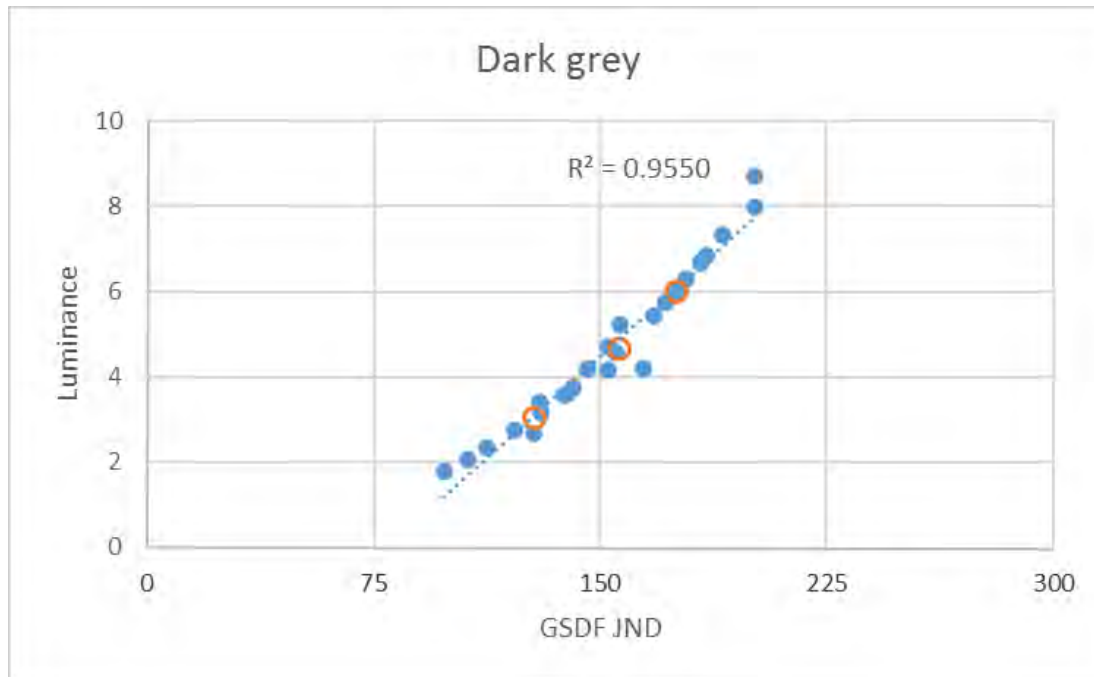
$$STRESS = \left(\frac{\sum (\Delta E_i - F_1 \Delta V_i)^2}{\sum F_1^2 \Delta V_i^2} \right)^{1/2} \quad \text{with } F_1 = \frac{\sum \Delta E_i^2}{\sum \Delta E_i \Delta V_i}$$

- STRESS data showed that Whittle performed better than GSDF, especially for dark greys;
- GSDF performed marginally better than Whittle for mid and light grey;

GSDF	Dark grey	Mid grey	Light grey
STRESS	20.47	15.28	14.05
Linear R ²	0.9550	0.9745	0.9867
Polynomial 2 nd	0.9764	0.9847	0.9928
Whittle	Dark grey	Mid grey	Light grey
STRESS	16.20	15.96	14.85
R ²	0.9692	0.9744	0.9857
Polynomial 2 nd	0.9873	0.9868	0.9928

Results

- STRESS formula for testing statistical significance of the performances of GSDF and Whittle formulas for the same visual data ;



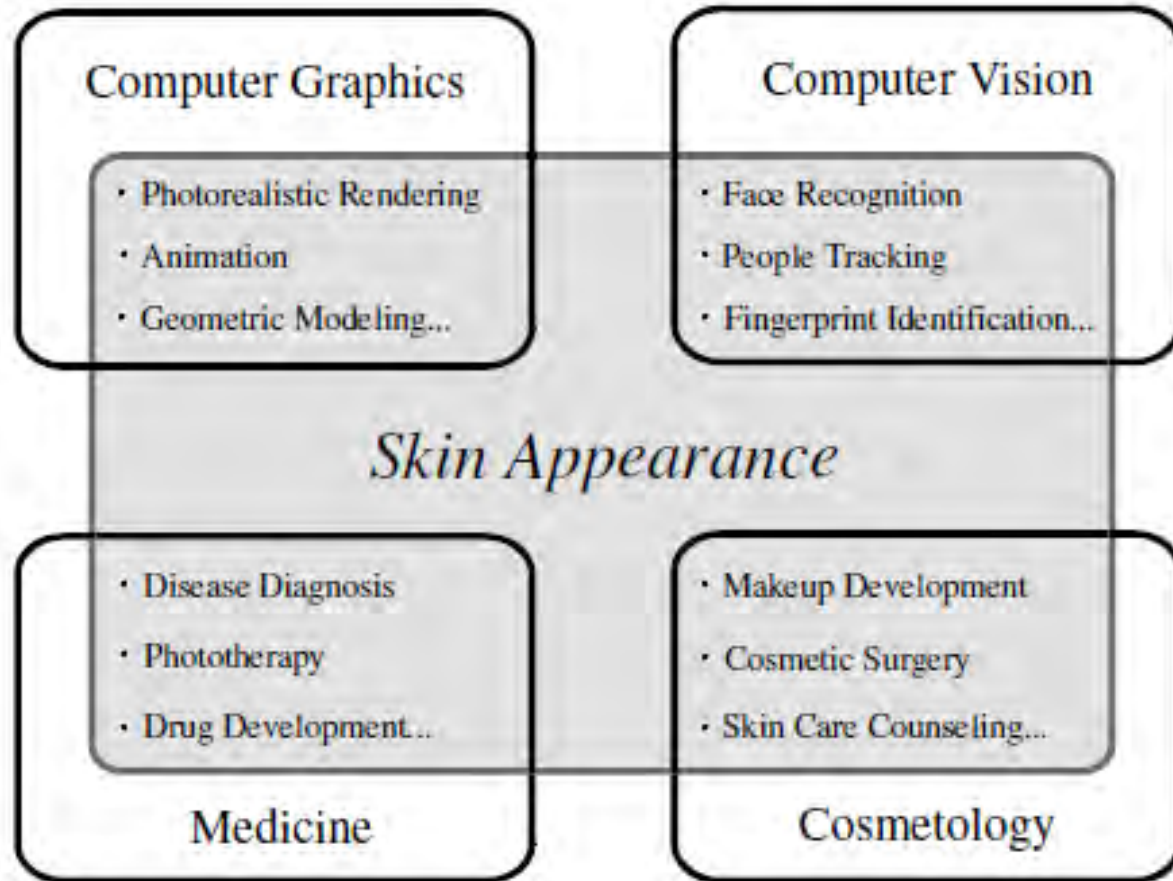


Imaging and reproduction of skin

Kaida Xiao and Phil Green



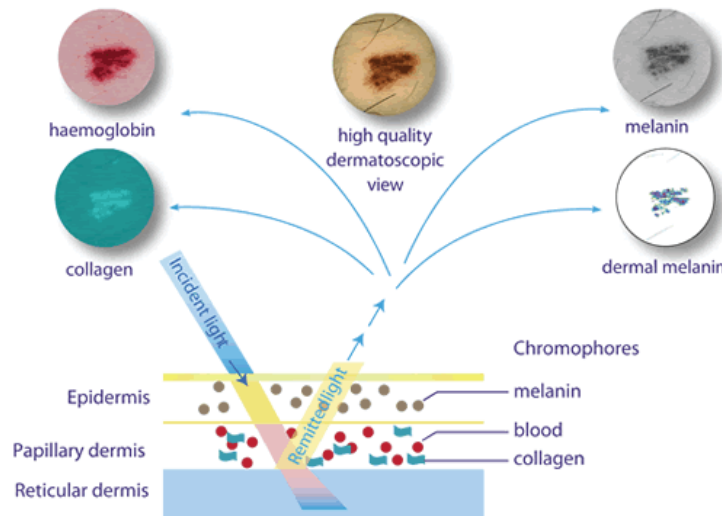
Introduction





Skin Appearance

Skin colour is determined by two chromophores, melanin and haemoglobin.



Melanin : in the basal layer of epidermis -> lightness/yellowness

Haemoglobin: contained in blood in dermis -> colour

Carotene: low concentration; only minor factor for skin colour



Skin Appearance

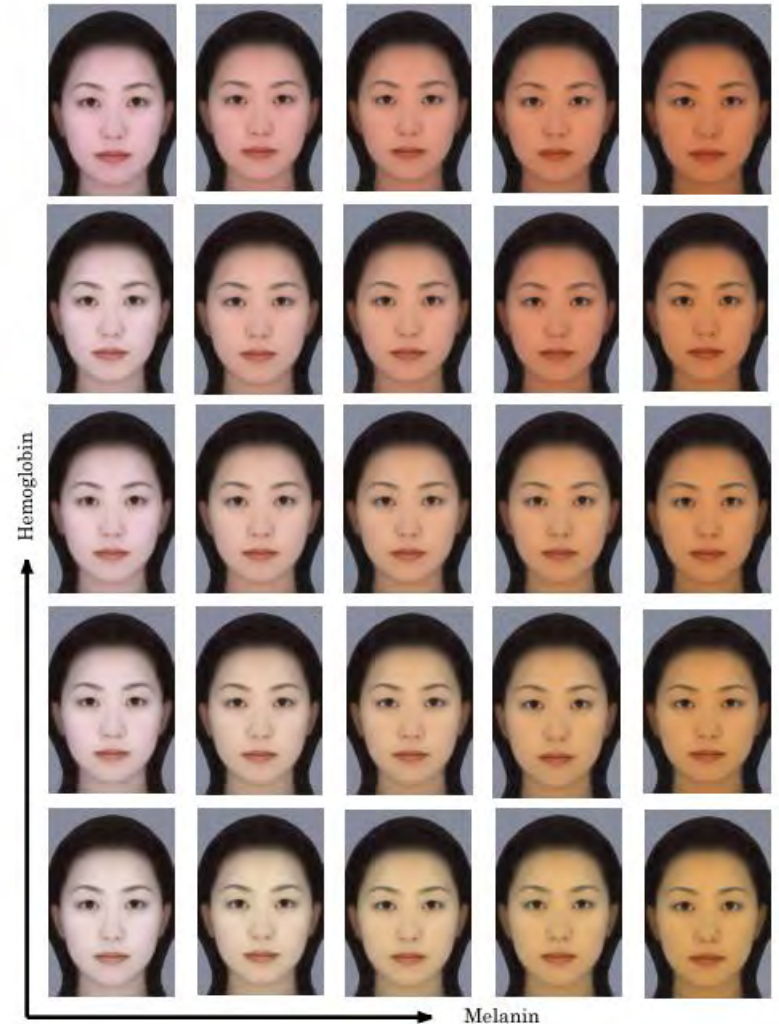
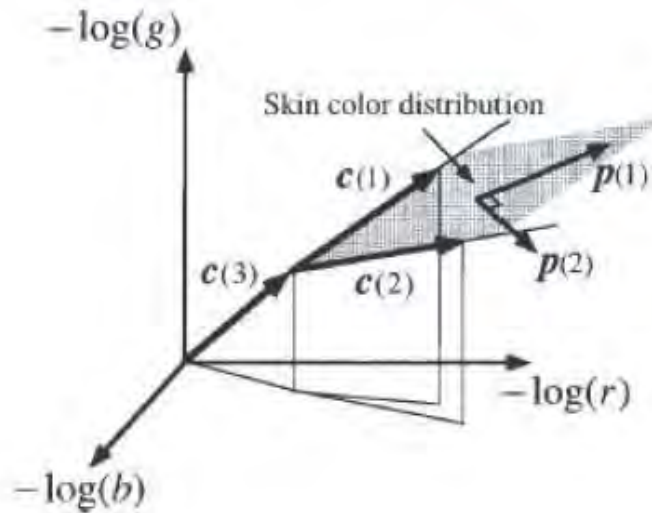


Figure 33: Skin color model in the optical density domain of the tri-stimulus space. All skin colors are distributed on a plane spanned by two independent vectors that correspond to melanin ($c(1)$) and hemoglobin ($c(2)$), respectively. (Courtesy of N. Tsumura, Figure 4 in N. Tsumura, H. Haneishi, Y. Miyake, Independent component analysis of skin color image, *Journal of Optical Society of America A*, 16, pp2169-2176, 1999, ©1999 Optical Society of America, Reprinted with permission [162].)



Skin Chromophores

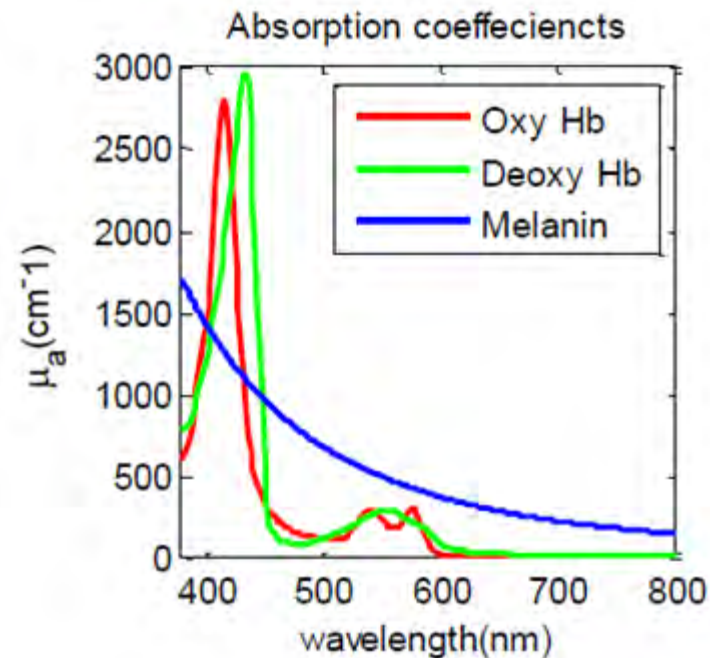
Important measure to Medicine and Cosmetology

Melanin:

- protects from UV radiation
- responsible for ethnic skin colour differences

Haemoglobin – two dimensions

- Concentration in blood
- Oxygenation saturation



Skin chromophores direct connect with skin spectral reflectance.



Current problems

- Large uncertainty of skin colour measurement and reproduction
- No comprehensive skin colour database
- Skin spectra data is highly desired for tele-medicine
- No standard method to predict skin spectra and even skin chromophores from RGB camera image



New Activity

Imaging and reproduction of skin

- Review best practices in skin measurement and reproduction
- Establish a publicly accessible database of skin colour and images
- Agree a method of estimating skin reflectance from RGB image data
- Develop a method of predicting skin chromophores

New objectives and collaboration are very welcome

New skin colour database

Liverpool-Leeds skin colour database

Spectroradiometer: PhotoResearch SpectraScan PR650/PR670

Spectrophotometer: Konica Minolta CM-700d with CM-SA skin analysis software

Nikon D7000 camera with DigiEye imaging system

3D camera: 3dMDTriosystem

>1000 individuals; 5 ethnic groups; 10 body locations

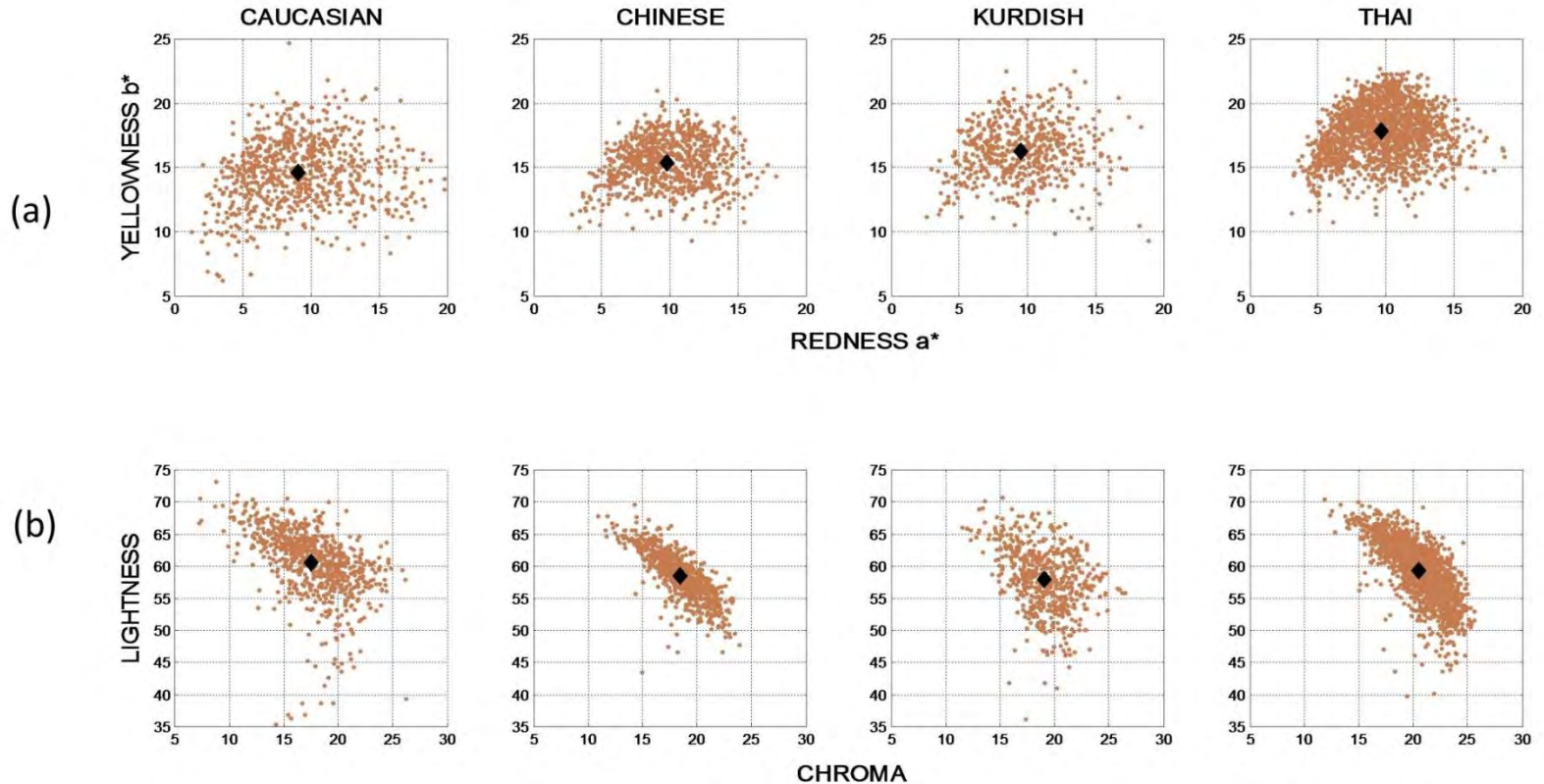




New skin colour database

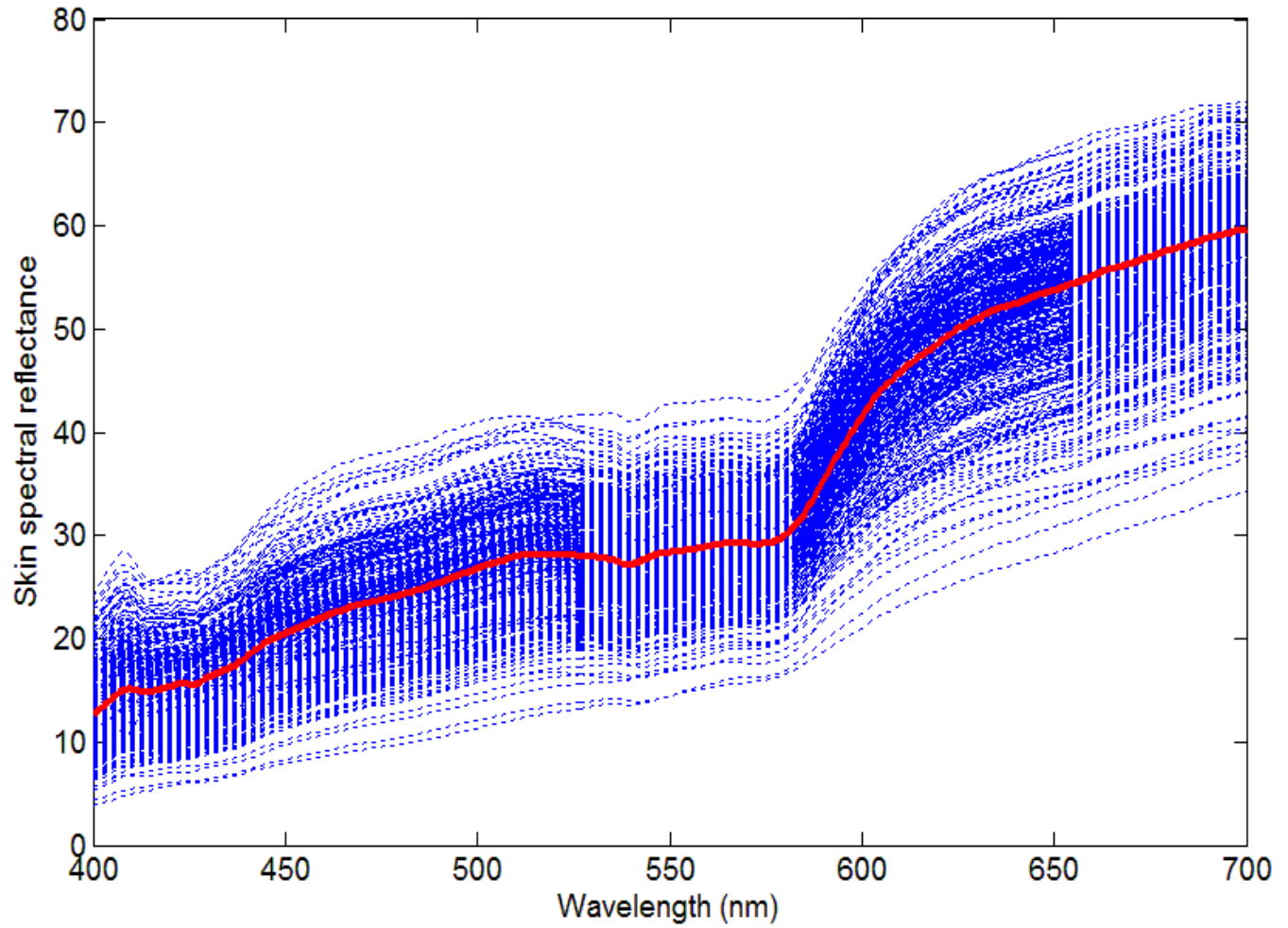


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Those skin data will be publicly accessible in early of this year

Skin spectra

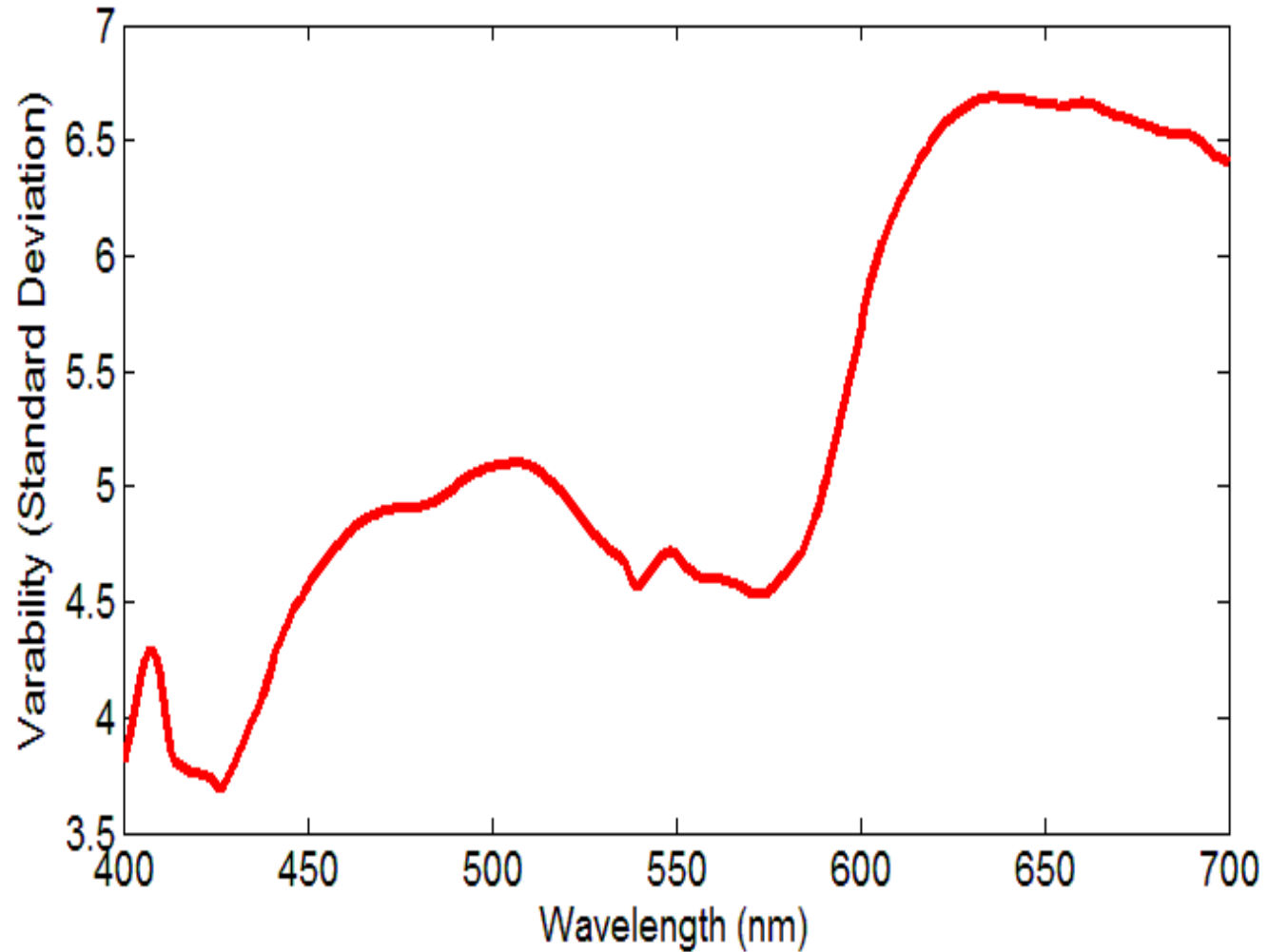




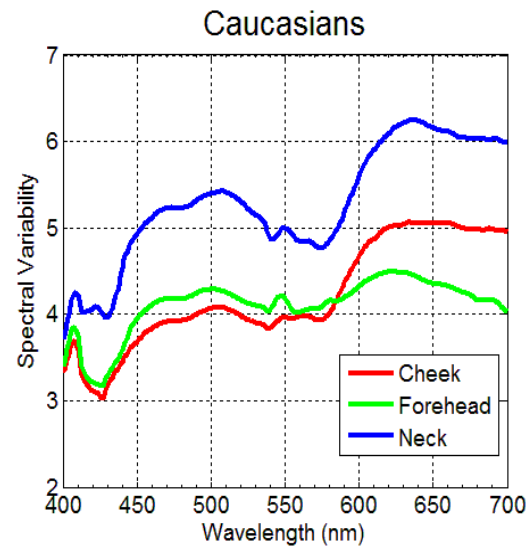
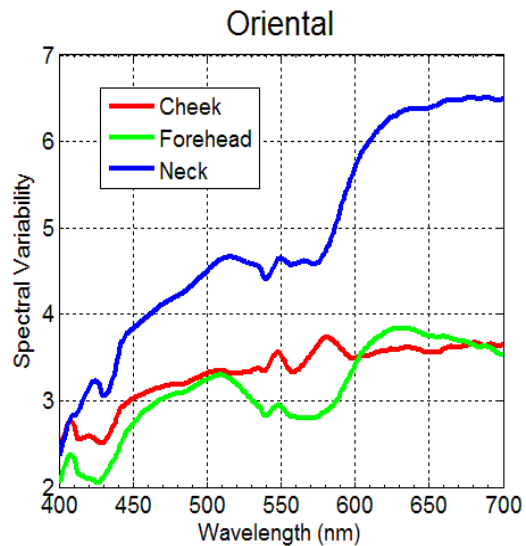
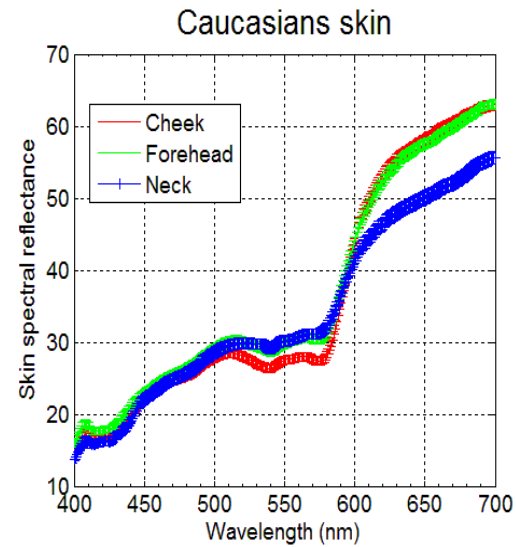
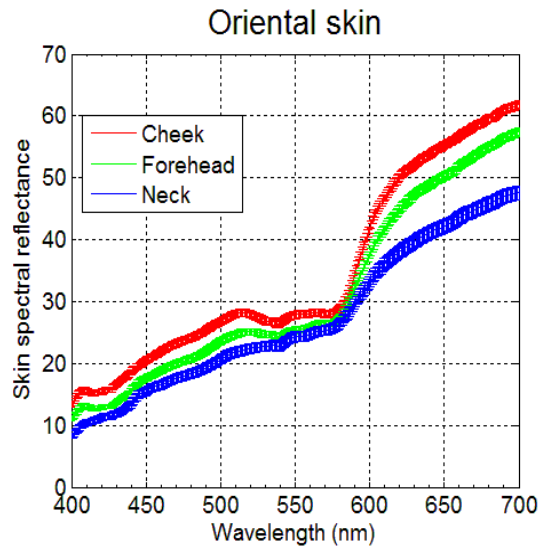
Variability of skin spectra



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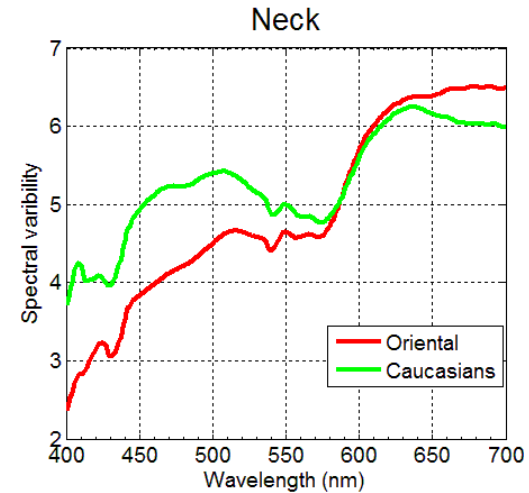
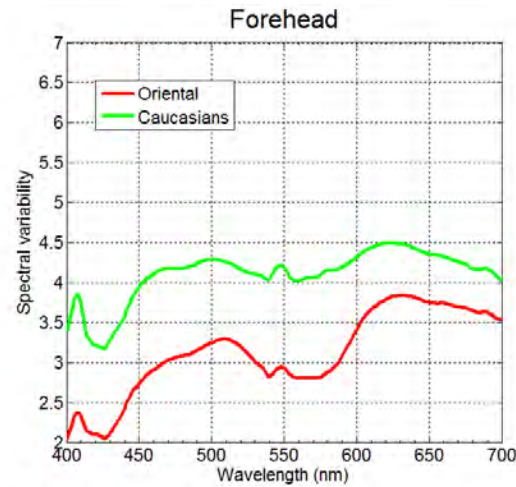
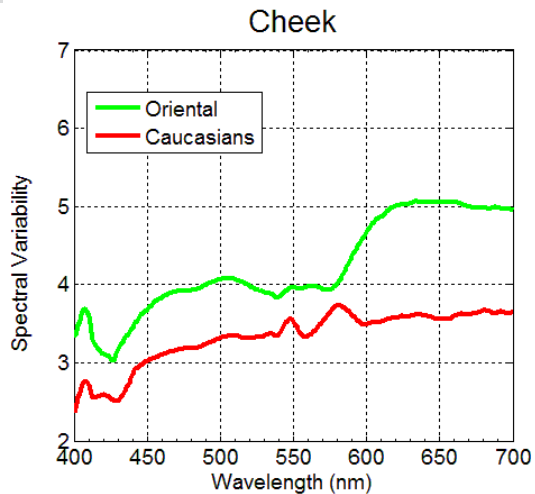
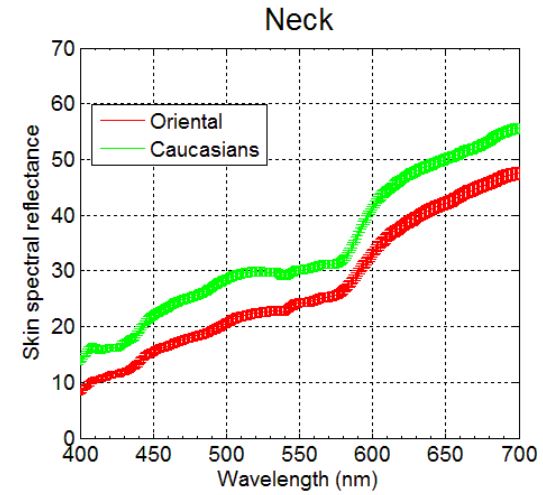
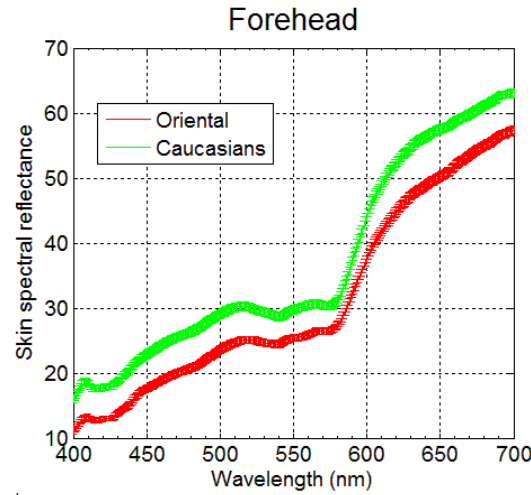
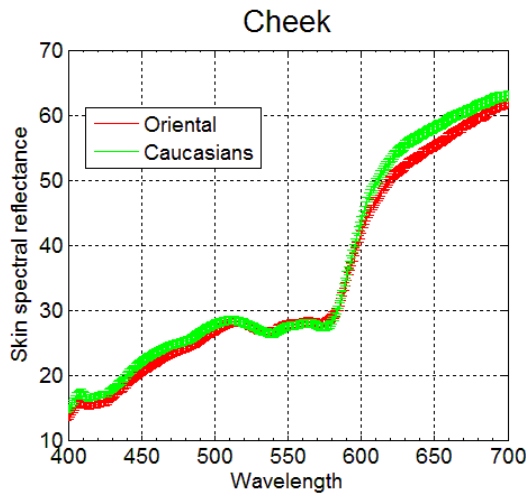


Body area difference





Ethic group difference





Current progress

- More than 200 facial images were captured
- Skin spectral are predicted from camera RGB using various methods and evaluated comparing with ground truth measurement data
- Perceived preference and healthiness are assessed for those facial images using a psychophysical experiment



Colour vision deficiency transforms using ICC profiles

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<http://www.colourlab.no>





Outline

- Introduction and motivation
- CVD simulation and Daltonization
- Packaging transforms in ICC profiles
- CVD simulation in ICC v4
- CVD simulation and Daltonization in iccMAX
- Conclusions



Introduction

- Anomalous colour vision is generally caused by mutations in cone photopigments. Colour-deficient observers most often have difficulty in distinguishing red and green.
- Colour vision deficiencies include:
 - Protanopia and protoanomaly (absent or modified peak wavelength or sensitivity of long-wavelength cone)
 - Deuteranopia and deuteranomaly (absent or modified middle-wavelength cone)
 - Tritanopia and tritanomaly (absent or modified short-wavelength cone)



Photo: Whitemay [Getty]



Introduction

- Designers often need to check that an image or graphic will be adequately clear to a CVD observer, by ‘simulating’ the effect of the colour vision loss.
- ‘Daltonization’ may also be applied to improve the colour visibility of the image to a CVD observer



Deuteranopia
simulation,
Adobe
Photoshop



Daltonization
to enhance
red-green
difference



Motivation

- Algorithms for CVD simulation and Daltonization have been published
- Tools that implement CVD simulation algorithms have been implemented on the web and in applications (e.g. Adobe Photoshop)
- The goal of this work is to provide ICC profiles encoding such algorithms so that it is possible to transform images within a colour-managed workflow, without relying on proprietary applications or having to implement source code.



Why use ICC profiles?

- ICC profiles provide an interoperable framework for packaging a colour transform that provides considerable flexibility in constructing transforms.
- The use of a well-defined CIE-based Profile Connection Space enables connection of any colour or data encoding to any other encoding.
 - ICC profiles used as source define how to interpret the image data encoding
 - ICC profiles used as destination define how to render the source colorimetry



iccMAX

- ICC v4 provides for unambiguous connection through a fixed intermediate colorimetric PCS and a well-defined set of transform elements.
- iccMAX extends v4 functionality:
 - Colorimetric, Spectral or Material PCS
 - Choice of colorimetric observer
 - Choice of illuminant
 - Wider range of transform elements, flexibility in ordering elements
 - Support for functional transforms, run-time computation
 - Wider range of data encodings and number of data channels



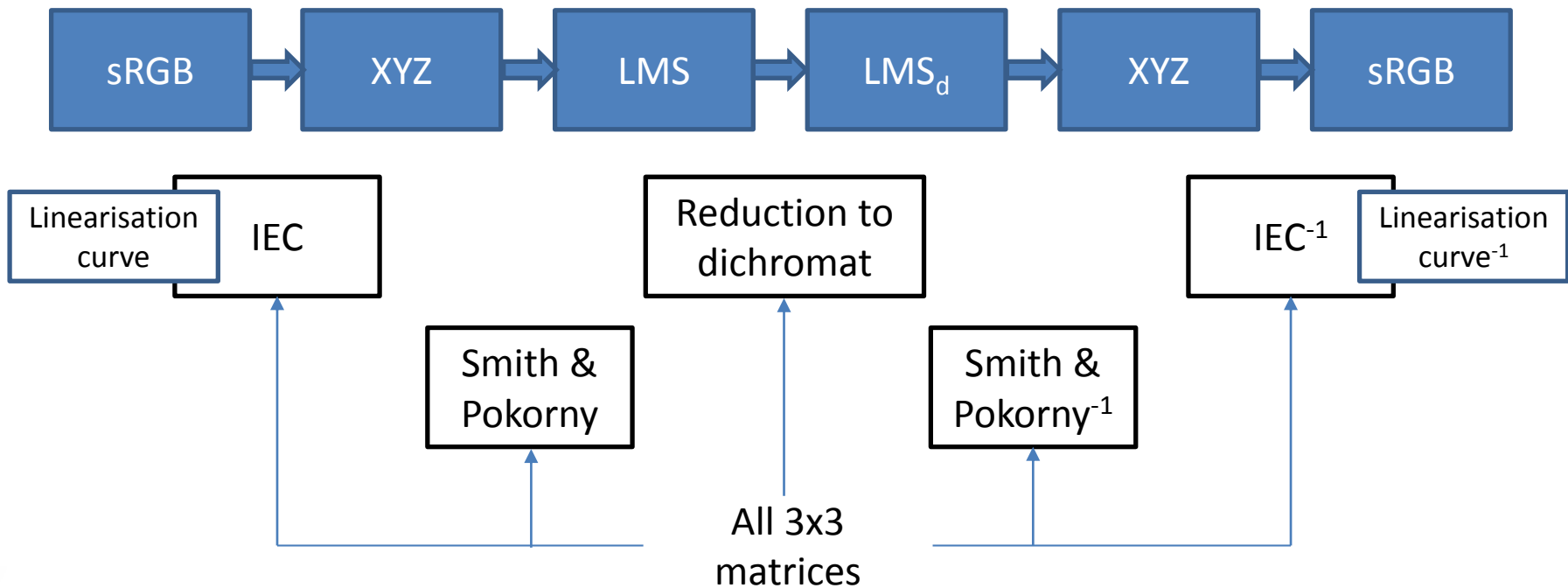
IccXml

- ICC profile is a binary format, but an XML representation is also available
- IccXml provides tools to convert between binary and XML representations
- IccXml files are human-readable, easily editable, and can reference external data files in text form



Dichromat simulation

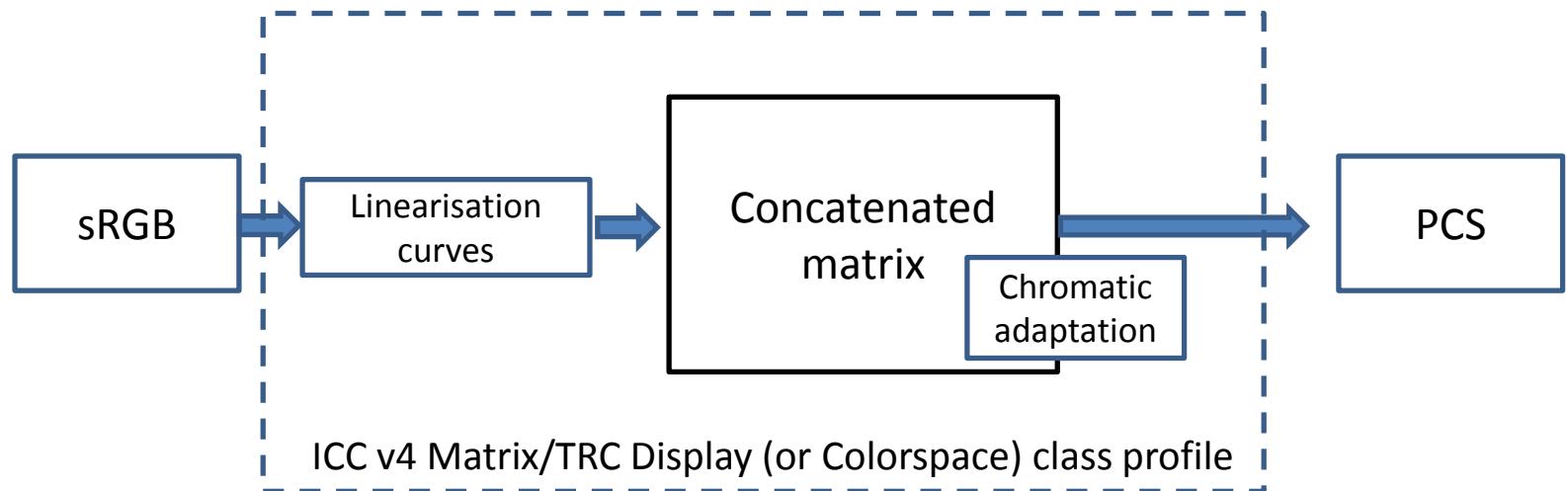
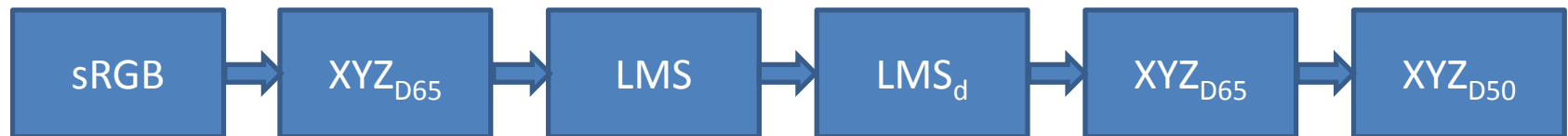
- Viénot, Brettel and Mollon (1999)





Dichromat simulation

- ICC v4 implementation as matrix/TRC profile





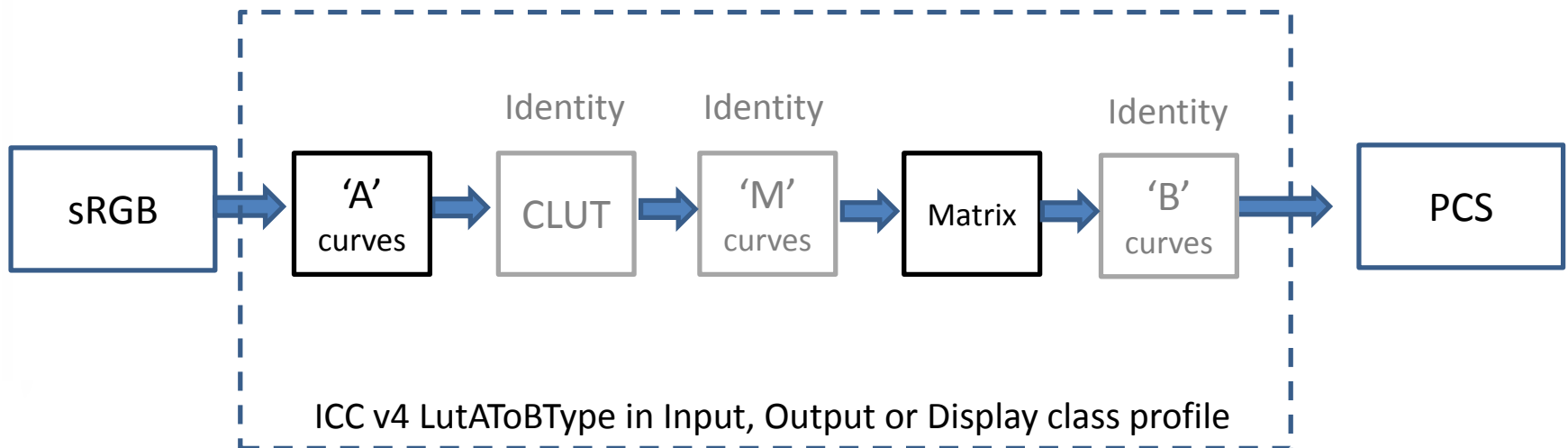
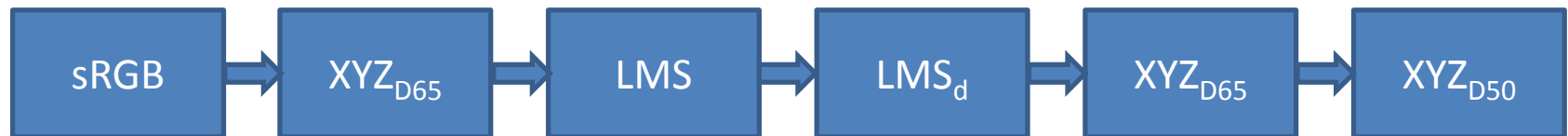
IccXml

```
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  <Header>
    <ProfileDeviceClass>mntr</ProfileDeviceClass>
    <DataColourSpace>RGB </DataColourSpace>
    <PCS>XYZ </PCS>
  <XYZType>
    <TagSignature>wtpt</TagSignature>
    <XYZNumber X="0.96418762" Y="1.00000000" Z="0.82490540"/>
  </XYZType>
  <curveType>
    <TagSignature>rTRC</TagSignature>
    <Curve> 563 </Curve>
  </curveType>
  <XYZType>
    <TagSignature>rXYZ</TagSignature>
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  </XYZType>
</IccProfile>
```



Dichromat simulation II

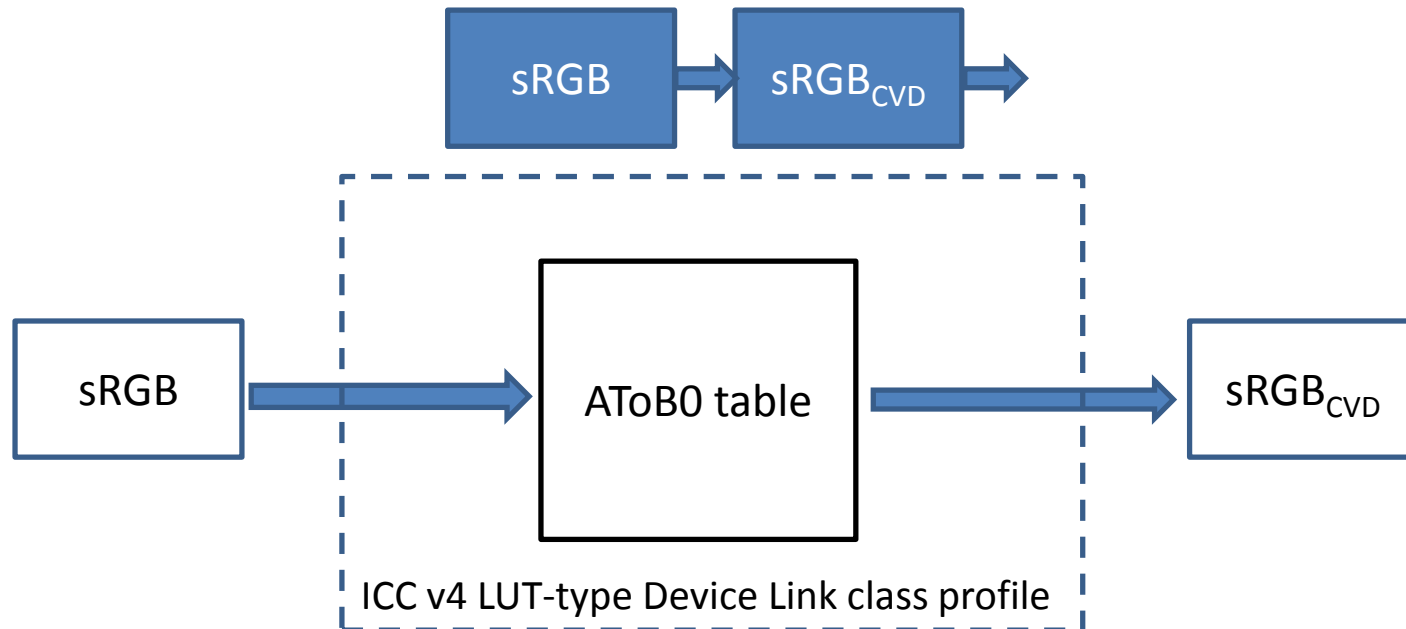
- ICC v4 implementation as LutAToBType





Dichromat simulation III

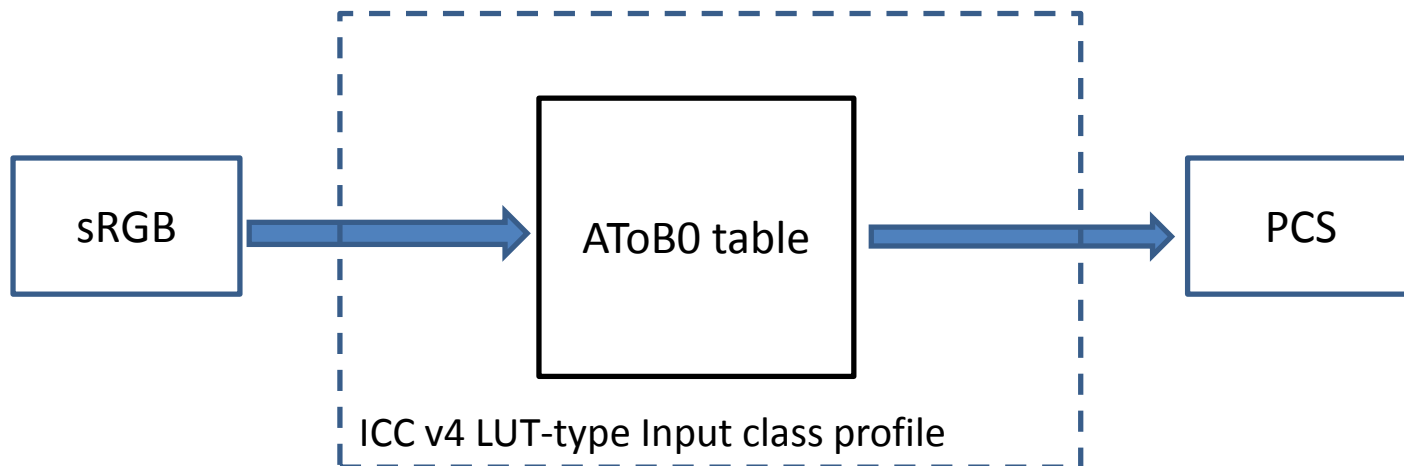
- RGB colourmap (Viénot et al) implemented as ICC v4 Device Link profile





Dichromat simulation IV

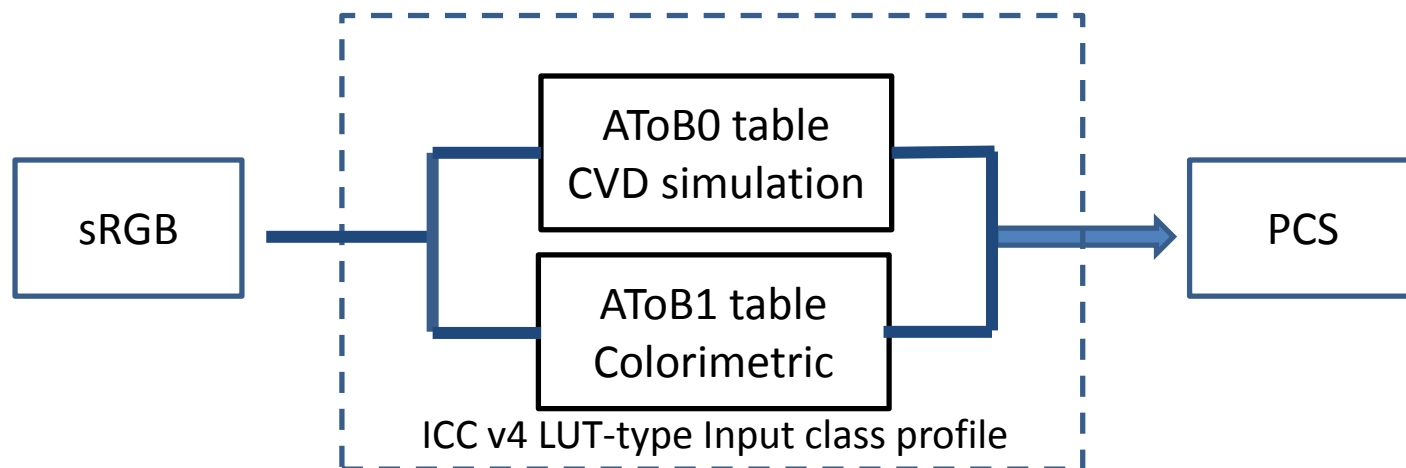
- Simulation implemented as ICC v4 Input profile





Dichromat simulation V

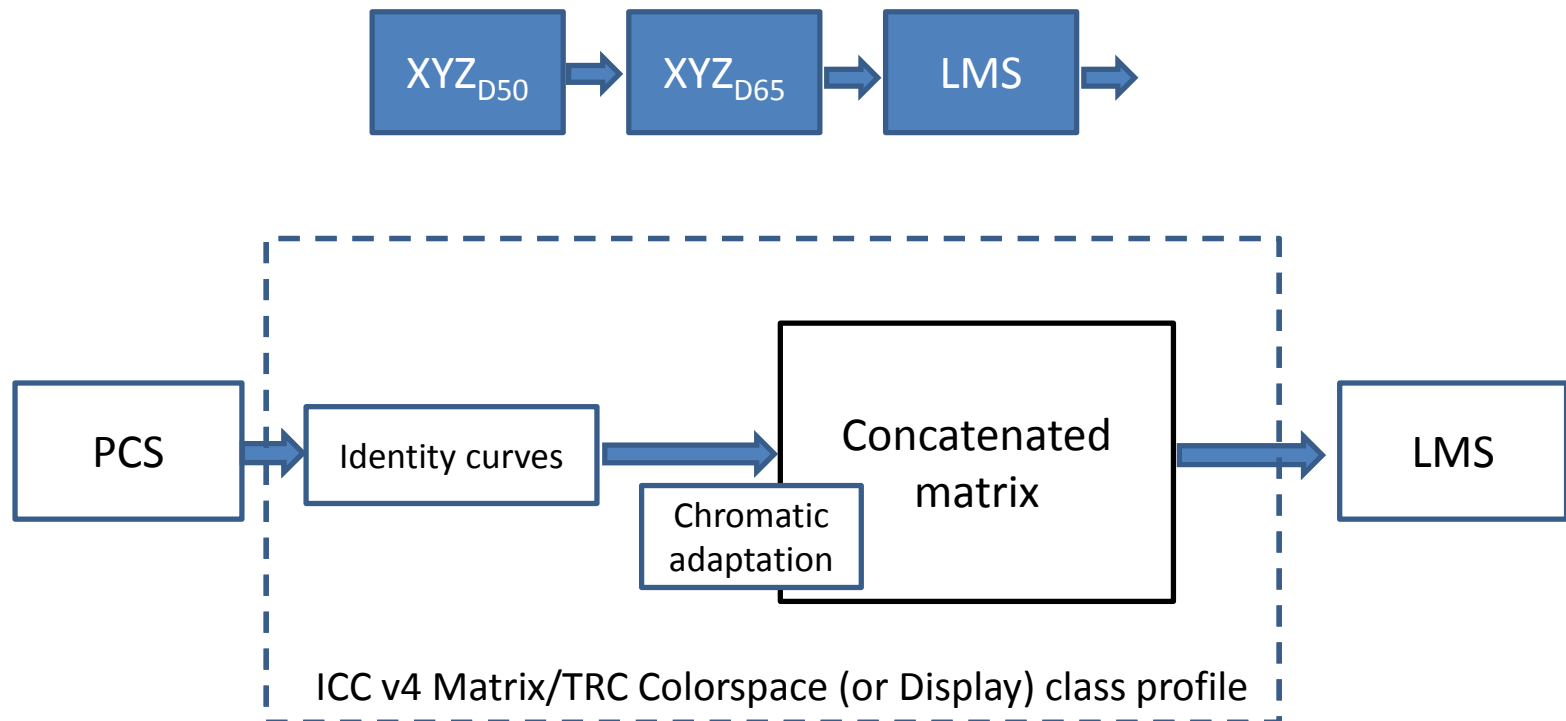
- Simulation implemented as ICC v4 Input profile





LMS profile

- ICC v4 Colorspace profile to convert to/from LMS





Why iccMAX?

ICC V4 is a highly interoperable and unambiguous framework for colour exchange, but restricted in functionality

iccMAX is a next-generation architecture that goes beyond D50 colorimetry. It includes:

- **Spectral processing**
 - Alternate PCS colorimetry, alternate illuminants and observers
- **Extended transform functionality**
 - Transform elements can be combined in any number and sequence
 - Programmable transforms

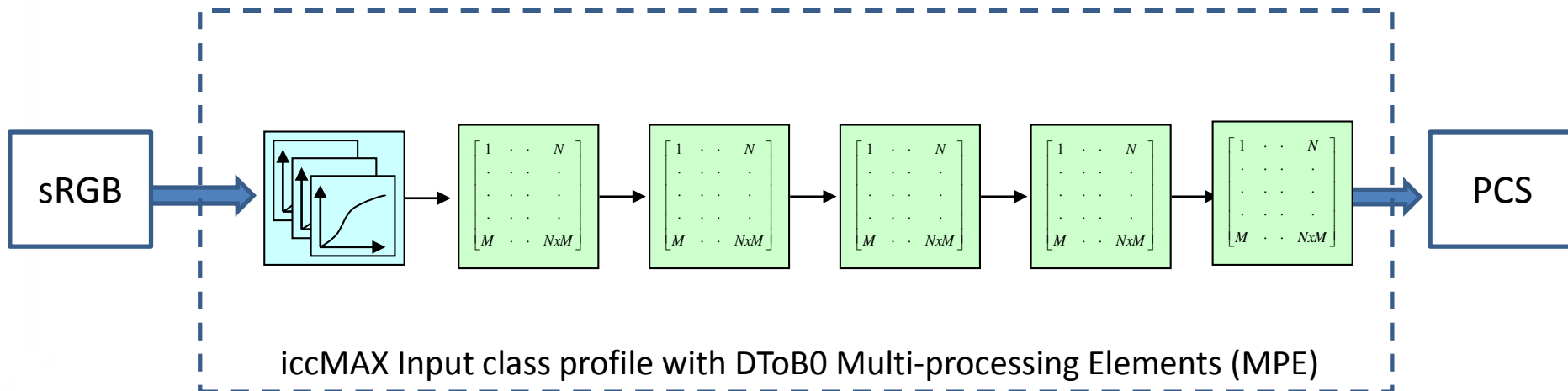
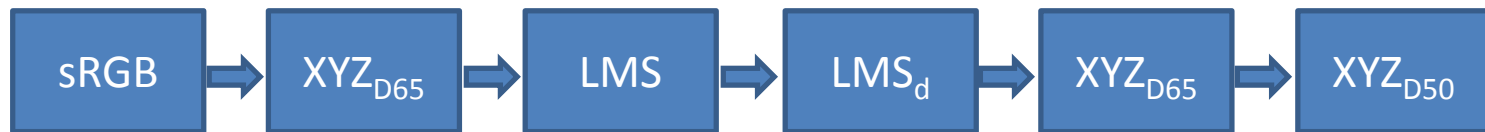




Dichromat simulation VI



- Simulation implemented as iccMAX profile

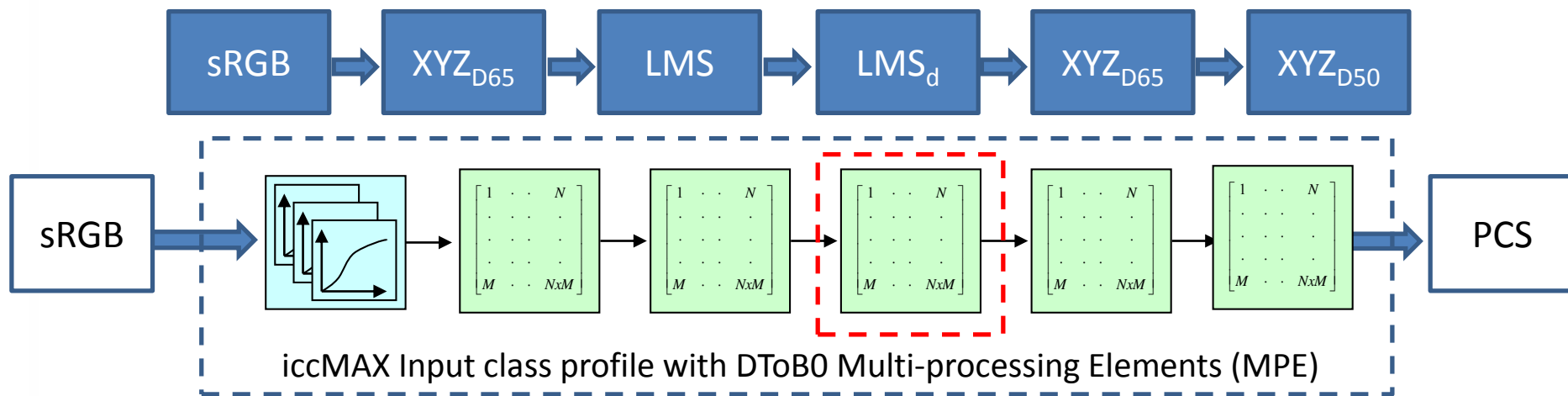




Anomalous CVD simulation



- Implemented as iccMAX profile



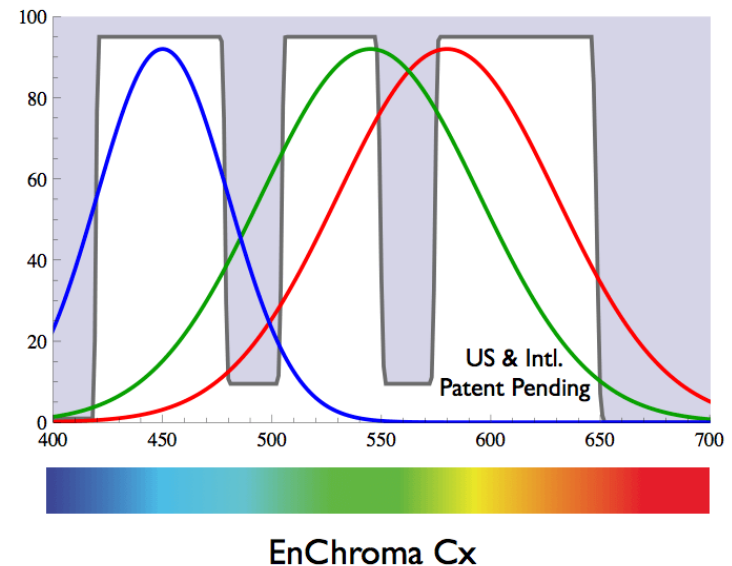
- Implementing the transform as a sequence of independent modules makes it possible to create new transforms re-using selected elements
- E.g. the LMS_d matrix can be modified to define an anomalous deuteranope or protanope simulation



CVD Daltonization



- Implemented as iccMAX custom illuminant
- Colour enhancement glasses for CVD observers are fitted with optical 'notch' filters that have stop bands at selected wavelengths in cross-over regions

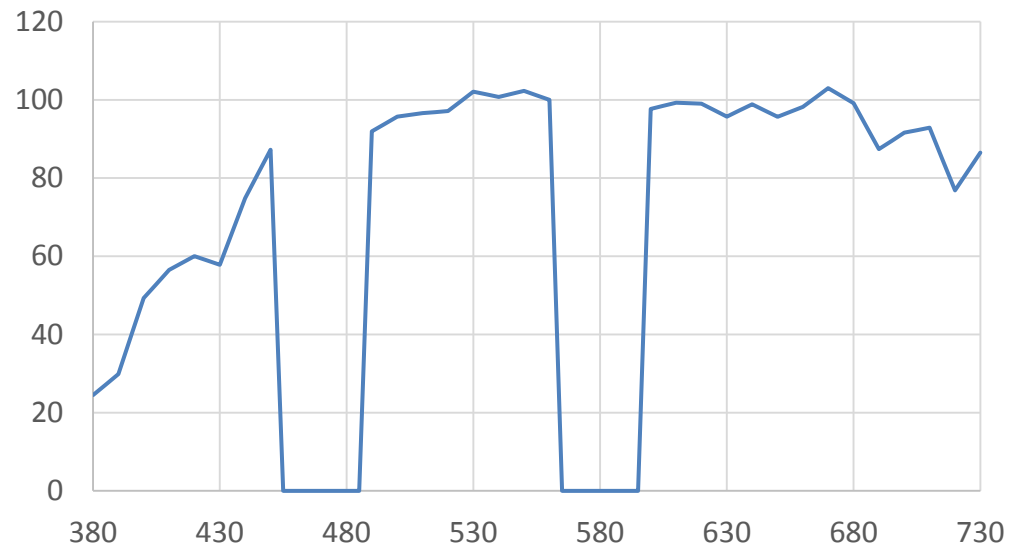




CVD Daltonization



- Implemented as iccMAX custom illuminant
- A similar Daltonization effect was achieved in an iccMAX Named Color class profile by defining a custom illuminant
- This can be applied to spectral input data
- PCS can be Spectral or Colorimetric

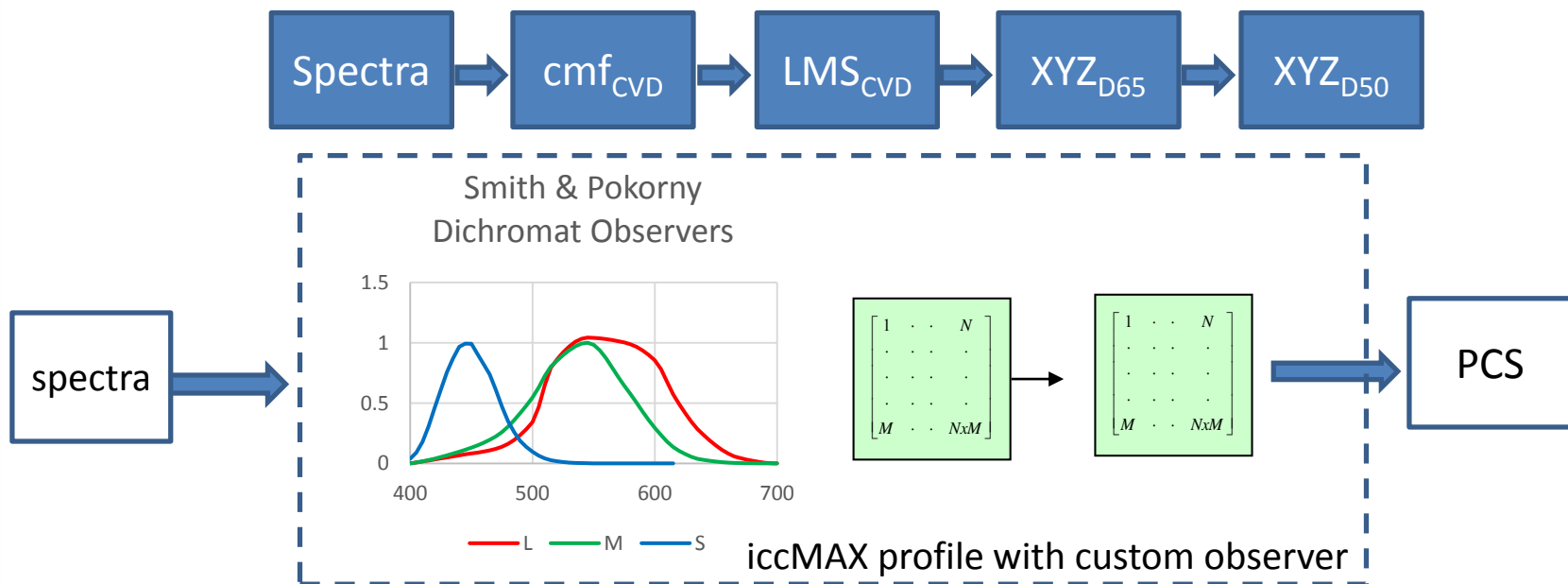




CVD observer response



- Implemented as iccMAX custom observer



- LMS_{CVD} can be transformed to D50 PCS or to other quantities



Further projects

- ICC v4 Abstract class profile to convert directly between PCS and PCS_{CVD}
- Kotera Daltonization transform implemented as iccMAX MPE transform including calc element
- Daltonization transform generated at run-time based on individual observer
- ‘Sensor equivalence’ approach (Derhak, 2015) implemented as iccMAX Material Connection Space

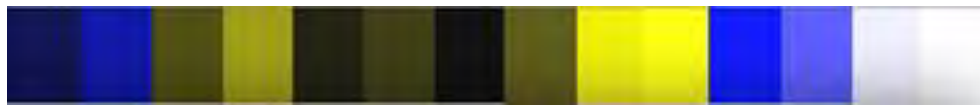


Evaluation

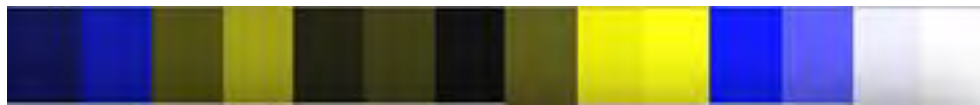
1. v4 simulation profiles, comparison with Viénot et al test data



Viénot et al test colours



Viénot et al simulation



CVDlink-protan.icc

$\Delta\text{RGB} = 0$



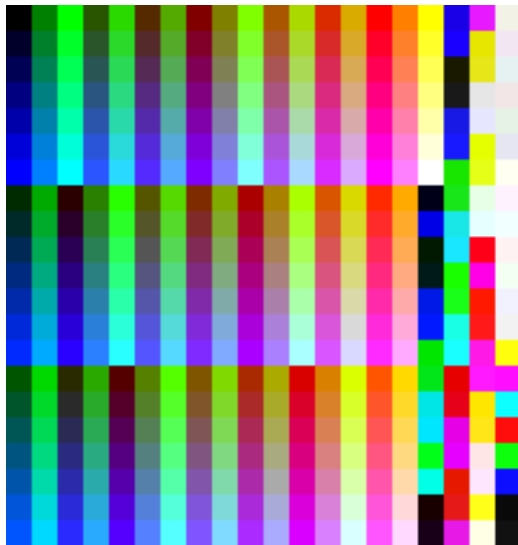
CVDlut-protan.icc

$\Delta\text{RGB} = 8.06$

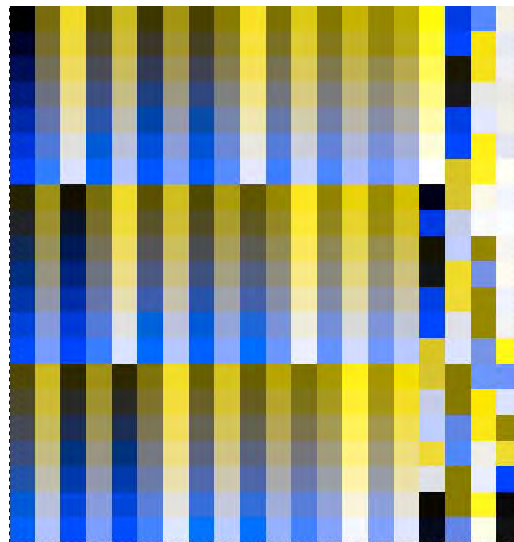


Evaluation

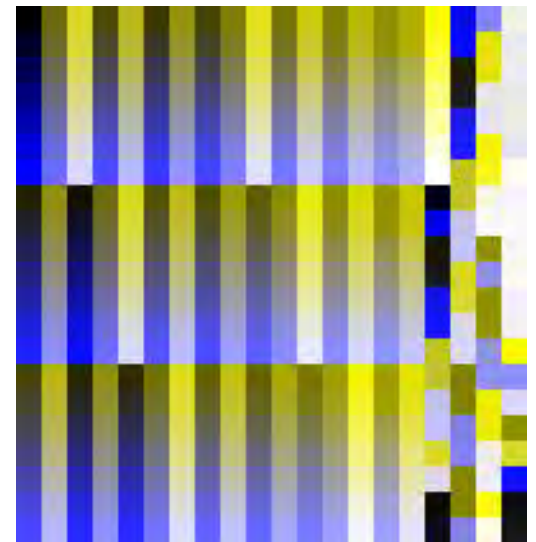
2. v4 simulation profiles, comparison with Adobe Photoshop CVD soft proofing tool



RGB test target



Photoshop simulation

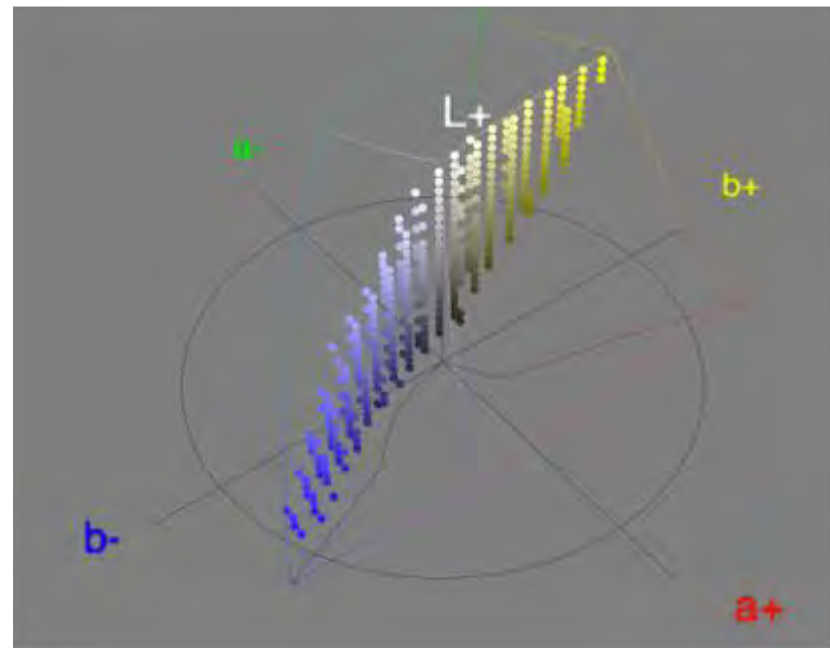


CVDcolormap-d.icc



Evaluation

3. Profile gamut

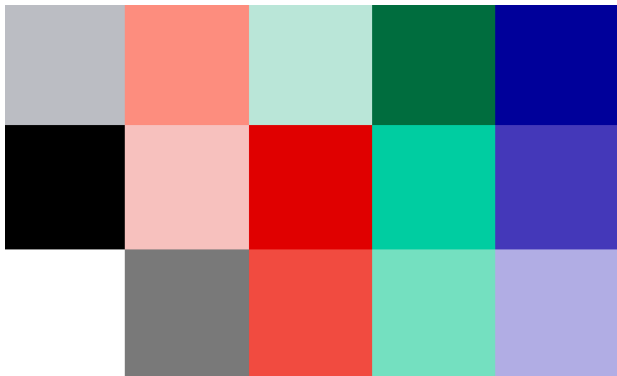


v4 CVDcolormap-deutan.icc



Evaluation

4. iccMAX notch filter



Test reflectances
(converted to sRGB)



Test reflectances with notch
filter applied (converted to
sRGB)



Conclusions

- ICC profiles can encode a wide range of different transforms
- Provides a useful toolkit for CVD researchers and developers
- CVD simulation algorithms have been implemented as ICC v4 profiles
- iccMAX extends the possibilities for implementing CVD transforms
- Binary ICC profiles and XML representations available to download at www.color.org/resources/cvd.xalter



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Improving Color Image Quality in Medicine Photography

John Penczek, et al

xxxx, 2016

Abstract:

Color images are becoming an increasingly popular means for capturing, diagnosing, and recording medical information. In medical photography, the intent is often to create images that accurately represent the original subject colors. This report summarizes digital photography best practices and provides guidance for creating an image workflow that strives to capture, store, process and accurately render the original scene colors.

Introduction:[Penczek, Krupinski, Skrovseth]

Medical imagery has played an important role in the development of modern medicine. It has provided a valuable means for capturing complex visual information. The introduction of digital cameras in areas such as digital radiography made the communication and analysis of these images easier. But much of its use was limited to gray scale digital images, especially when the images were used for diagnostics purposes. However, the prevalence of inexpensive color digital cameras has dramatically increased the use of color images in medicine. The growth of telemedicine has further enhanced the utility of these medical records.

The human visual system (HVS) is very effective in recognizing critical features by sensing the brightness and color variations in an image. If the image workflow can faithfully reproduce the original scene, the viewer of the rendered image is better able to gauge the extent of these variations. The medical industry has recognized the dependence of the HVS on the relative brightness of image features, and has implemented the digital imaging and communications in medicine (DICOM) standard in order to achieve a perceptually uniform scale for critical grayscale imagery (DICOM ref), however this standard does not address color images. Several groups are currently developing proposals to introduce a medical color imaging process that is compatible with DICOM (ref). The color image process can differ depending on the intent of the content or viewer. In some cases (for example when using false color maps), the need for accurate color reproduction may not be important since the colors used are not intended to represent the real world, but are merely used to highlight additional information that is related to the image. In fields like dermatology and pathology, an image of the original scene carries valuable color information that should be accurately rendered to a clinician viewing the image on a display. This article addresses the needs of these cases and provides guidance to medical color image users for achieving the best possible color reproduction on a display.

Modern digital color image workflows can be generically described by the functional flow illustrated in Figure 1. A digital camera captures the original scene in a proprietary format and applies corrections to the image that are specific to the camera setup. In simple point-and-shoot cameras, the camera usually stores the color image in standard compressed formats like JPEG and TIFF. These compressed formats often include image enhancements encoded into the data, and the colors are generally transformed to be viewed in a standard color space (such as sRGB) (sRGB ref). The sRGB color space is typically used as the standard color space since it is

expected that the images will likely be viewed on a display that is calibrated for that color space. Digital single-lens reflex (DSLR) cameras tend to give the user more control on how the color data is processed and formatted. The DSLRs typically offer the user the ability to store the image data in a proprietary RAW format, which is uncompressed and has minimal enhancements applied to the original image data. Since image enhancements can make it more difficult to color-correct an image in post-processing, the RAW format can have some advantages. The camera manufacturer's RAW file format is generally specific to the manufacturer, and usually requires the manufacturer's software to view the image properly. However, some third party companies have RAW image converters/decoders that are able to extract the image data from the RAW image files and transform them into a common format (such as DNG) that preserves most of the image information (DNG ref).

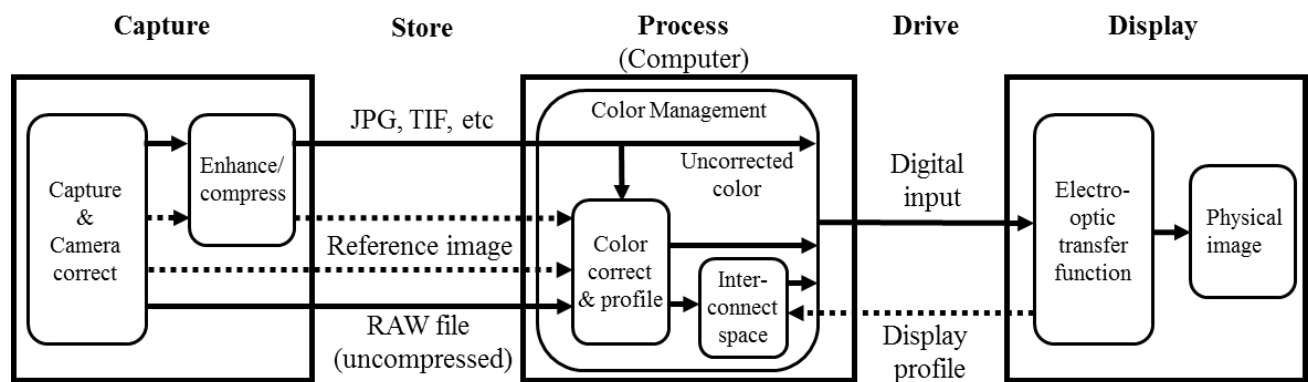


Figure 1: Functional flow diagram of a generic digital color image process, from image capture to its display.

Before an image file can be viewed, it must be processed by a computer and rendered properly on a display. In the simplest case, the computer recognizes the compressed file format and directly drives the display input. If the display was calibrated to the same color space (e.g. sRGB) as the encoded image data, then there is a chance that the rendered colors will be close to the original scene. However, as we will discuss later, directly rendering images without color-correcting can yield significant color errors. Fortunately, the accuracy and reliability of the color images can be significantly improved by employing the methods used by some professional photographers. It is common practice to place a reference color chart, with well-characterized colors, in the same scene as the object to be photographed. The images of the reference color chart taken under the same conditions as the intended object of interest can be compared and used to color-correct the object image data. The color-correction can be implemented by directly creating a new image file with the corrected color data transformed to a standard color space (e.g. sRGB) for later viewing. Alternatively, the necessary transformation needed to color-correct the original object image can be saved separately as a color preset or profile. This preset or profile must then be applied to the original image prior to being rendered by the display. This open-loop process can work well for fixed viewing environments with a stable display setup, however a more flexible closed-loop process can also be utilized using the open source ICC profile methodology (ICC4 ref). The ICC framework uses a virtual interconnection color space

that transforms the color-corrected original image to the proper color space used by the output device, either printer or display.

Given the above background information on the color image processing, we will further highlight factors that contribute to color errors, discuss proper camera and lighting setups for improved color reproduction, review the use of color charts, and dive deeper into color-corrections processing. In addition, a summation of our findings is given in terms of a recommended procedure, which describes the industry best practice for improving the rendered color accuracy.

Factors that contribute to color error:[Penczek, Krupinski, Vander Haeghen]

As suggested in Figure 1, the image colors viewed on the display can be affected by the actual image capture setup, the image processing, and the physical rendering. ...

Improving the image capture setup:[Penczek, Krupinski, Skrovseth, Vander Haeghen]

Includes the lighting conditions and camera setup.

Color-correction methods:[Penczek, Skrovseth, Vander Haeghen]

Use of reference color charts and color-corrections processing.

General color management considerations:[Green, Vander Haeghen]

Provide further color management considerations/guidance beyond what was given in Introduction.

Recommended workflow:

This general procedure outlines a recommended digital camera image capture workflow that can be used to improve image color accuracy and consistency. The process it outlined in the flowchart given in Annex A. The implementation of this workflow would be especially beneficial for use cases where color accuracy is critical, such as dermatology, plastic surgery, pathology, and wound documentation. It should also be noted that since medical photographs are part of a patient's record, they are subject to privacy considerations.

Required equipment:

- Digital color camera with white balancing capability.
- Reference color test chart. May be a commercial color chart (e.g. from X-Rite, DSC Labs, QPcard, Douglas color card, etc...) or one designed for the application. The color chart should come with the corresponding measured color data.
- Light source and background that can provide uniform hemispherical illumination over the camera field of view. The light source should produce spectrally smooth broadband white light, approximating daylight. Spectrally "spiky" spectra can produce problems.
- Color correction software that can recognize each color in an image of the reference color chart and create a colorimetric calibration profile (HSL Preset file, DNG or ICC profile, or similar), which can be used to color calibrate an image of an object photographed under the same conditions as the reference color chart. Color correction software that

does not save calibration files should embed the calibrated RGB values in the image, and export the image file with a tag corresponding to the appropriate standard color space (e.g. sRGB).

Desirable equipment:

- Digital color camera capable of exporting RAW image files, and the ability to perform an in-camera white balance. The camera should be flat-field corrected to within 2%.
- A RAW file decoder/converter which is able to import RAW images and export them as ≥ 12 -bit TIF or DNG format. Commercial software (e.g. Adobe camera RAW, Capture One, Phocus, etc...) is available, as well as open source software (such as Dcraw).
- Software that can import DNG, TIF, or similar images and perform a correction for illumination non-uniformity and white/gray balance.
- It is recommended that the color correction software provide ability to create ICC profiles. Commercial ICC-aware viewing software is available from several companies, in addition to free software (e.g Irfanview and GIMP).

Procedure:

Image capture

1. Setup up the illumination and background for photographing the object of interest. The background should be a uniform matte color, ideally a gray with 20% reflectance. The camera field of view, shall be adjusted so that it does not extend beyond the gray background. This field of view should be fixed for all photographs.
2. The light source should produce uniform diffuse hemispherical illumination over the field of view, with special attention paid to the lighting uniformity over the image area where colors will be evaluated. This will minimize glare, specular reflections and errors arising from lighting non-uniformity. Examples of diffuse lighting configurations are given in Figure 2.



Figure 2. Example of diffuse lighting setups using commercial softbox lighting (left), or a homemade lightbox with diffuse walls (right).

3. The object of interest and/or reference color chart will define the image region of interest (ROI). For the side-by-side method, the ROI is defined by the object of interest and the color chart placed adjacent to it. In the sequential method, the ROI is defined by the object of interest or the color chart, whichever is larger. Place a uniform diffuse (ideally 20% reflectance) target in the image plane at the ROI. If the gray target is large enough to fill the entire ROI, then it may be used to compensate for illumination non-uniformity during the image post-processing.
4. Position the camera in front of the gray reference and align the camera so that its optical axis is centered on the gray reference and perpendicular to it. The image ROI should be contained within about half the field of view of the camera. If the sequential method is used, it is best to use a tripod, or similar mechanism, to hold the camera stationary for the remainder of the photographs. If the side-by-side method is used, then a fixture similar to that shown in Figure 3 can be used. The side-by-side method is preferred if the illumination is not stable.
5. Use the in-camera white balance function to determine the proper white balance for this lighting condition, and maintain this white balance setting for all subsequent photographs. Some cameras have a Preset Manual or Custom white balance mode to obtain and hold that white balance setting. Omit this step if the camera does not have in-camera white balance capability.



Figure 3. Example fixture used for the side-by-side image capture method.

6. Capture the image of the gray reference in the ROI. If the illuminance is not uniform in the ROI to within 5%, an illumination non-uniformity correction should be applied in the image post-processing. This correction is only valid if the camera setting and lighting conditions are held constant.
7. Place the reference color test chart in the focus plane of the ROI, so that the camera field of view captures all of the colors in the chart. For the sequential method, the optical axis of the camera should be centered on the chart and perpendicular to it. For the side-by-side method, the edge of the color chart is positioned near the center of the camera image (see Figure 4). Photographic test charts (such as ColorChecker SG) can be used, although ideally patches should be matte rather than gloss. Custom charts with patches constructed

to be similar to the subject of the photography can also be used (e.g. PANTONE SkinTone™ Guide from X-Rite or Douglas color card may be used for skintones).

8. Set the camera exposure that the lightest color patch in the test chart is approximately 90% of the camera saturation white.
9. For the sequential method, capture the image of the reference color test chart and export the image in RAW file format, if the camera is capable. Where possible, use a “neutral” mode RAW capture setting, which minimizes any camera visual enhancements. Replace the reference color test chart with the first object to be photographed, center in the image, and capture the image of the target object. Repeat the image capture of subsequent objects in turn (see Annex A). Export the images in the same RAW file format. The lighting conditions and camera settings should not be changed. If the camera cannot export RAW files, set the camera to use the highest quality (least compression) image, use low ISO values, and export images with a tag corresponding to a standard color space (e.g. sRGB).
10. For the side-by-side method, place the color chart adjacent to the object of interest (see Figure 3) and capture the image using the “neutral” mode RAW capture setting. Export the image in the RAW file format if possible. Replace the first object of interest with other objects in sequence at the same focus plane. The lighting conditions and camera settings should be unchanged. If the camera cannot export RAW files, set the camera to use the highest quality (least compression) image, use low ISO values, and export images with a tag corresponding to a standard color space (e.g. sRGB).



Figure 4. Example alignment of the side-by-side image capture method.

Color correction

1. For RAW files, use a RAW image converter/decoder to extract the image information in all files and save them in a standard image format (e.g. ≥ 12 -bit color TIF, DNG, or similar files). The file should include the desired white balance.
2. If an illumination non-uniformity correction is deemed necessary, apply the uniformity correction to all reference color chart and object images.
3. Open the image of the reference color chart (for the sequential or side-by-side method). Use the program to ensure that the gray levels are scaled correctly. The graylevel scaling will depend on the reference color chart used. However, it is common to use a reference color chart where the whitest color patch is set to an exposure of 90%, or RGB= 230,

230, 230 for 8-bit RGB color images. Then the darkest patch is set to an exposure of 4%, or RGB= 10, 10, 10. If the black patch is below this level, then use the current setting or reshoot the photograph with brighter illumination. For the sequential method, the graylevel scaling applied to the reference color chart is also applied to all object images taken under the same shoot conditions.

4. The color-correction software should automatically find the centers of each color patch of the graylevel-scaled reference color chart image, and create an HSL Preset or color calibration profile (DNG, ICC profile, or similar) based on the known color values of the reference chart. It is recommended that ICC profiles also be created, if it is not already the primary color correction pathway.
5. For the side-by-side method, apply the HSL Preset or color calibration profile to the image and save the new color-corrected image in the desired format (e.g. a high quality TIF file). Repeat the graylevel scaling and color-correction for each side-by-side image. An example of a color-corrected image is shown in Figure 4.



Figure 4: Example of color-corrected image using Figure 3 following the side-by-side method.

6. For the sequential method, import the other photographed objects of interest into the image editing program that is capable of using HSL Presets or color calibration profiles. Apply the HSL Preset or color calibration profile to each image and save the new color-corrected image in the desired format (e.g. a high quality TIF file).

Acknowledement:

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Annex A

Flowchart of Camera Image Capture and Color Correction Workflow

