Revised Minutes
Calibration slide for histopathology task force
Teleconference
29 August 2013 • 15:00 (UK) / 10:00 (EDT)

The meeting was called to order at 10:15 am (EDT) by Craig Revie, acting chair with the following in attendance:

Aldo Badano	FDA
Pinky Bautista	Partners Healthcare
Vipul Baxi	GE Omnyx
Stephen Conley	MGH / Harvard
Scott Blakely	Hamamatsu
Scott Forster	Roche Ventana
Stephen Hewitt	NIH, NCI
Bas Hulsken	Philips Digital Pathology Solutions
Megumi Kondo	SAKURA Finetek Japan Co., Ltd.
Tom Lianza	X-Rite
Michael Montalto	GE Omnyx
Allen Olson	Leica/Aperio
Debbie Orf	NPES
Craig Revie	Fujifilm
Darren Treanor	Leeds Hospital
Yukako Yagi	MGH / Harvard

Mr. Revie proceeded to review the agenda for the meeting as follows:

1. Participants in the group
2. Proposed face-to-face meetings
3. Objectives
4. Scope of the project
5. Next steps
6. Next meeting

The agenda was approved.

Prior to introductions there was a discussion on Intellectual Property. Mr. Badano suggested that the group set up rules regarding IP issues in terms of what is shared and what is not shared. It might be possible, somewhere midway through our work, that a company takes these ideas and obtains a product (calibration target) for their use. In the eventuality of this, there should be an explicit understanding of what the rules are so that there are no surprises down the line.

Mr. Lianza noted that there has been discussion within the ICC to create a new class of group called a liaison working group, since so many members of the Medical Imaging Working Group don't belong to the ICC. This is something that would have to be approved by the Steering Committee.

Mr. Revie stated that the ICC IP policy operates on the same basis as ISO and IEC in that when we create a work product an IP review is conducted and members of the group are invited to bring any IP they are aware of to the group. At the end of a work product, under US law, you have to conduct an IP notice, because once a document is published as an ISO standard it can become part of the legal system; therefore if there is an intention to assert IP it must be disclosed.

Mr. Revie stated that it has been difficult for everyone to keep in touch with the group. He suggested that all members of this group join the Medical Imaging Group mailing list from the ICC. The group can have temporary access to this mailing list until people are able to join the ICC. He encouraged everyone on the call to visit http://lists.color.org/mailman/listinfo/medical and submit a request to join the mailing list. In addition when communicating with the group an email message can be sent directly to medical@lists.color.org.

1. Participants in the group

Participants were asked to introduce themselves and to state what they want to accomplish within the group to help in forming a consensus on the scope of work.

Michael Montalto, GE Omnyx
We would like to pull together as an industry to drive a standard around colour calibration and colour measurement. Going forward the registrations with the FDA will be an issue, so hopefully we can work towards finding the best solutions and eventually develop standards that will align with everyone's needs.

Bas Hulsken, Philips Digital Pathology Solutions
We hope to create recognized standards for colour related to image quality for digital pathologies with a focus on both a commercial and regulatory point of view.

Scott Forster, Roche Ventana
Agree with standardization and look forward to an alignment on a proposal for a generic overview of an overarching set of rules for imaging colour.

Allen Olson, Leica / Aperio
Currently Mr. Olson develops the ICC profile which has been a difficult task due to differences in staining not only within systems but on the monitor in trying to see what is in the microscope. We would like to see a close loop experimental methodology where one could view a slide, scan it, then put on the monitor and measure at both ends to confirm the accuracy. We hope to create a standard approach where the industry can discuss the accuracy of the colour in the scanners in histology. This will help in reducing variability which is now quite extreme. Anything we can do to reduce that variability and get to the point where what we view on the screen resembles what we see in the microscope will add value and help differentiate between good and bad products.

Vipul Baxi, GE Omnyx
The key things to add to a standard are accuracy and reproducibility of colour from system to system. The 2nd focus would be to come up with a standard that explains how low should a ΔE be from what we are measuring to a reference.

Stephen Hewitt, NIH, NCI
We have a long and complicated interested in colour calibration within our own laboratories as well as with collaborations with the FDA. Interexchange for images is critical. We are actively constructing tests and have recently produced objects that real machines can focus on and reproduce.

Aldo Badano, FDA
Our group (DIAM/OSEL/CDRH/FDA) is interested in the development of bench testing methodologies for the characterization of the performance of WSI systems for regulatory evaluation purposes.

Yukako Yagi, MGH / Harvard
We create calibration slides for colour in the laboratory not for the industry, but for use with different types of scanners. We work with many pathologies and with many different institutions and need a standard way to evaluate quality in colour.

Pinky Bautista, MGH / Harvard
Some departments at Harvard have asked for the ability to standardize colours for calibration slides. We thought we can do more in this area with this working group.

Darren Treanor, Leeds Hospital
This is about more than just colour; it is also about image quality or fidelity. Previously, we did some work with digital pathology workstations and found that image quality affects the pathologist's performance in terms of accuracy and also their efficiency. We want to be sure we can trust these images when making diagnoses with them.

Scott Blakely, Hamamatsu
Our primary concern is in the development of the colour targets. We want to understand how different types of illumination may affect colour quality and how different types of detection impact the quality of the final image in making an accurate diagnosis. We would like to see standardization of how these will all be represented and viewed on a monitor to a pathologist.

Megumi Kondo, Sakura Finetek
Although Kondo-san was on the call he did not have a microphone so was unable to participate in introductions.

Tom Lianza, X-Rite
Primary background was in design of scanners, currently design display calibration equipment and software. X-Rite is looking at the medical market as an opportunity to apply off the shelf technology and our years of experience. We are more interested in the hardware rather than the display aspect of this program.

The proposed scope was discussed and the question was asked should this group be limited to colour only or shall we broaden the scope.

It was stated that digital pathology and all aspects of image quality have no clear identification for certain applications, and that it would be helpful to standardize with minimum requirements. It would be valuable to look at all aspects of image quality because there will be a degree of overlap.

Mr. Lianza stated that when working with densitometry and scanners there are many things that have an effect on image quality that are more important than colour. He has a concern with developing a measure of diagnostic capabilities and the various limitations. He suggested that we develop baseline conformance and that this should be included in the focus.

There was a concern that if we broaden the scope too much that it may become impossible to align with vendors as well as become unmanageable for this group. It was noted that there is a difference between establishing minimum requirements and developing procedures to measure against those requirements. Since the methodologies for assessment already exist, what is needed are minimum requirements for colour which is where the current weakness exists.

During a discussion on fluorescence Mr. Lianza stated that the next generation ICC architecture will carry a fluorescence matrix as well as being spectral in nature. It was noted that this will enable the user to move into other spaces in the future outside of multispectral and fluorescence. How to image multispectral is different, but there is a format designed for capturing and transmitting data. Mr. Lianza stated that any input to the team within the ICC that is working on the next generation would be welcomed.

There was a concern regarding multi-spectral fluorescence and whether a method can be developed that is generic for all Brightfield microscopy. After discussion it was agreed that the initial focus would be on colour calibration on whole slide imaging, specifically Brightfield RGB imaging, with a focus on H&E and possibly a broader look at other stains as used for cellular histopathology.

Mr. Revie suggested two options for standardization, defining a calibration methodology with a solution or developing a calibration system test method. With the 2nd approach each manufacturer would decide how to perform a calibration adjustment for their system. The standard would document the method for testing such a system.

Mr. Lianza explained that within the general colour area there are 2 modes of operation: characterization (measurement) and calibration (build a transform to bring into a known state). With a characterization that is very general, otherwise referred to as metadata, the data can then be transformed into a different set of requirements. Generally when characterizing colour measurement devices, scanners or cameras the characterization is the trickiest part. Once you have the characterization data it can be applied to whatever mechanism is being calibrated. It is important to work toward generating robust characterization data that could be used in different spaces.

There was a suggestion that one or more examples of a calibration method be included to help those who may struggle to come up with a calibration method on their own. It was stated that the most straightforward method when dealing with colour fidelity is to develop a definition of a ground truth that can be manufactured for a ground target and then define a set of measurements for each device characterized and find how far away you are from the ground truth. This would avoid going into a great deal of detail about how to achieve the final result.

There was a discussion of diagnostic systems and how they should be defined. It was felt this may be very demanding. Mr. Badano requested a definition of Diagnostic as would apply to this standard; he felt that

Diagnostic should be removed unless it applies to something specific. It was stated that the objective should be to develop something that pathologists can use as a primary diagnostic tool for pathology. After further discussion it was agreed to remove Diagnostic from the scope.

The revised scope as shown in attachment A is as follows:

- General image fidelity with initial focus on colour calibration
- Digital microscopes with initial focus on whole slide imaging digital microscopes
- Brightfield RGB imaging with possible future in fluorescence and spectral imaging
- Stained cellular pathology, histopathology as initial focus (in particular H&E) Calibration system test methods
- ICC colour management solution to be determined within the context of the ICC Medical Imaging Working Group

8. Next meeting

Mr. Revie suggested that a face to face meeting be scheduled. There is a possibility to meet in conjunction with the ICC meeting this November in Vancouver, BC. A half day could be allocated to this topic with several teleconferences scheduled between now and then. Mr. Hewitt stated that Vancouver may not be possible for several members and suggested that a teleconference capability be provided.

Another date discussed was May 2014 at Pathology Informatics in Pittsburgh. Mr. Hewitt stated that he would look into having this placed on the schedule.

It was agreed that the group would schedule monthly teleconferences.

Action: Orf/Revie to set up a doodle poll to determine the best date for the next teleconference

Mr. Revie invited members to come up with straw man proposals for a calibration test for targets that can be discussed during the next teleconference. It was suggested that members share data that is generated for methodologies for this task. Members were asked to inform Mr. Revie via email about what they will present at the meeting to help in scheduling the agenda.

There being no further business the meeting was adjourned at 11:15 a.m. EDT

Respectfully submitted,

Debra Orf
ICC Secretary

International Color Consortium

Calibration slide for histopathology

Teleconference

August 29th 2013

Agenda

- Participants in the group
- Proposed face-to-face meetings
- Objectives
- Scope of the project
- Next steps
- Next meeting

Participants

Company / Organisation	Primary contact name	Primary contact email	Status
FFEI Limited, ICC	Craig Revie	craig.revie@ffei.co.uk	ICC project coordinator
GE Omnyx	Michael Montalto	Michael.Montalto@omnyx.com	Vendor representative
Philips Digital Pathology Solutions	Bas Hulsken	bas.hulsken@philips.com	Vendor representative
Roche Ventana	Scott Forster	scott.forster@ventana.roche.com	Vendor representative
Leica / Aperio	Allen Olson	allen.olson@leicabiosystems.com	Vendor representative
GE Omnyx	Vipul Baxi	Vipul.Baxi@omnyx.com	Vendor representative
NIH, NCI	Stephen Hewitt	hewitts@mail.nih.gov	Organisation representative
FDA	Aldo Badano	Aldo.Badano@fda.hhs.gov	Organisation representative
FDA	Wei-Chung Cheng	Wei-Chung.Cheng@fda.hhs.gov	Organisation representative
GE Omnyx	Michael Meissner	Michael.Meissner@omnyx.com	DICOM WG26 Chair
MGH / Harvard	Yukako Yagi	YYAGI@PARTNERS.ORG	Research participant
MGH / Harvard	Pinky Bautista	PBAUTISTA@PARTNERS.ORG	Research participant
Leeds Hospital	Darren Treanor	darrentreanor@nhs.net	Research participant
Hamamatsu	Scott Blakely	SBlakely@hamamatsu.com	Vendor representative
Sakura Finetek	Megumi Kondo	m.kondo@sakura-finetek.com	Vendor representative
XRite	Tom Lianza	TLianza@Xrite.com	Vendor representative
3D Histech	Viktor Varga	viktor.varga@3dhistech.com	Vendor representative

In order to make email communication easier participants of this group could be given temporary access to the ICC Medical Imaging Working Group until they can make the arrangements necessary to join the ICC
The list is **medical@lists.color.org**, subscribe at **http://lists.color.org/mailman/listinfo/medical**

Scope

- General image fidelity with initial focus on colour calibration
- Digital microscopes with initial focus on whole slide imaging digital microscopes
- Brightfield RGB imaging with possible future in fluorescence and spectral imaging
- Stained cellular pathology, histopathology as initial focus (in particular H&E)
- Calibration system test methods
- ICC colour management solution to be determined within the context of the ICC Medical Imaging Working Group

Proposed face-to-face meetings

- **ICC Medical Imaging working group meeting**
  - 18th November 2013, Vancouver, Canada
  - half a day's discussion of digital microscope calibration
  - half a day's discussion for other topics including displays
  - teleconference support to allow remote participants
- **Other possible meeting times and location**
  - USCAP March 1-7, 2014 (San Diego) [clashes with ICC Tokyo meeting]
  - ***Pathology Informatics, May 13-16, 2014, (Pittsburgh)***
  - Pathology Visions, September 30 2013, (San Antonio)
- **Monthly teleconferences to be set up – participants invited to present 'straw man' ideas for calibration test materials**