

20140521

University of Maryland, College Park 1107 Jeong H. Kim Bldg.

International Workshop on Tissue Phantoms and Standardization in Biophotonics

# Development of an IEC/ISO standard on functional NIRS

Prof. Hideo EDA

Graduate School for the Creation of New  
Photonics Industries, Hamamatsu, Japan

## Multichannel time-resolved optical tomographic imaging system

Hideo Eda, Ichiro Oda, Yasunobu Ito, Yukihiisa Wada, Yukio Oikawa, Yoshio Tsunazawa, and Michinosuke Takada

*Technology Research Laboratory, Shimadzu Corporation, Hori-yamashita, Hadano, Kanagawa 259-1304, Japan*

Yutaka Tsuchiya, Yutaka Yamashita, and Motoki Oda

*Central Research Laboratory, Hamamatsu Photonics KK., 5000 Hirakuchi, Hamakita, Shizuoka 434-8601, Japan*

Angelo Sassaroli and Yukio Yamada

*Mechanical Engineering Laboratory, Ministry of International Trade and Industry, 1-2 Namiki, Tsukuba, Ibaraki 305-8564, Japan*

Mamoru Tamura

*Research Institute for Electronic Science, Hokkaido University, Nishi-6, Kita-12, Kita-ku, Sapporo 060-0812, Japan*

(Received 8 March 1999; accepted for publication 14 June 1999)

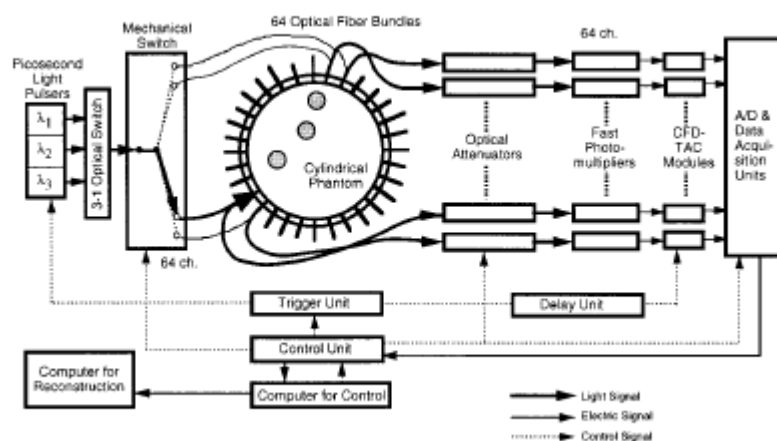
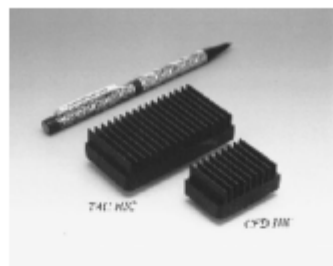
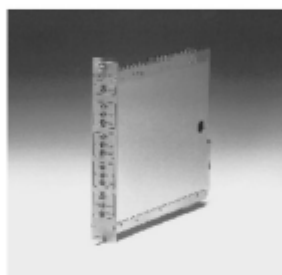


FIG. 1. Schematics of the new time-resolved optical tomographic imaging system.



(a)



(b)



(c)

FIG. 4. (a) A constant fraction discriminator (CFD) and a time-to-amplitude converter (TAC) miniaturized as hybrid IC. (b) A CFD/TAC module: a single-width NIM-standard module containing four couples of CFD and TAC. (c) The picture of the whole system.

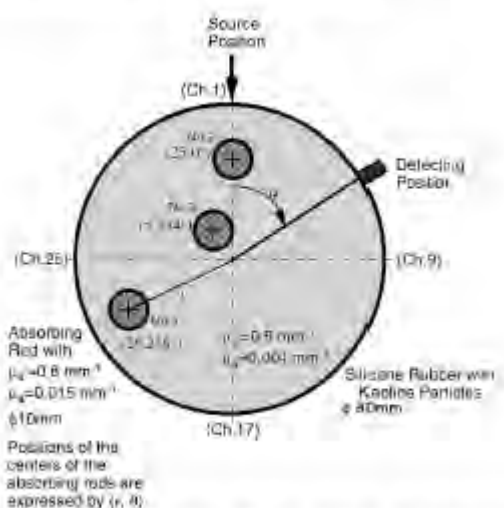


FIG. 5. Solid cylindrical phantom with three small rods. Small rods can be either absorbing for inhomogeneity or nonabsorbing for homogeneity.

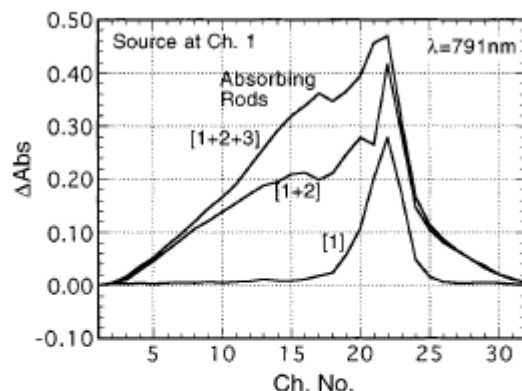


FIG. 7. Angular distributions of the changes in the cw absorbances from those of the homogeneous phantom when the absorbing rods No. 1, No. 2, and No. 3 were inserted one by one. The ordinate indicates the difference in the absorbance ( $\Delta Abs$ ) which is defined by  $\log_{10}[I(\theta)/I_0(\theta)]$ , where  $I_0(\theta)$  and  $I(\theta)$  are the integrated intensities for the homogeneous and inhomogeneous phantoms, respectively, and  $\theta$  is the angle between the source and detector positions. The abscissa is expressed by the detector channel number instead of  $\theta$ . The source with the wavelength of 791 nm is incident at Ch. 1 as shown in Fig. 5.

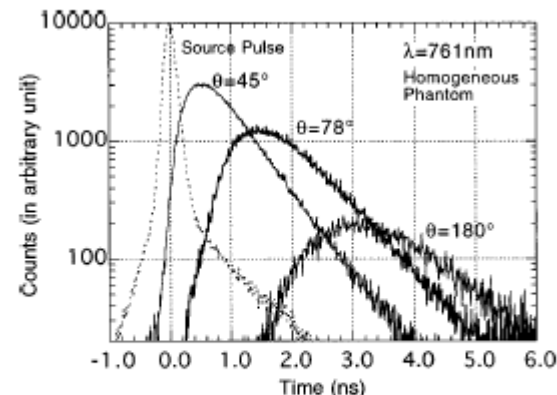


FIG. 6. Measured time-resolved transmittances for the homogeneous phantom at the angles of 45°, 78°, and 180° from the source position. The ordinate is the photon counts (in an arbitrary unit) in the photon counting measurement. The source pulse is normalized to have the maximum of 10000.

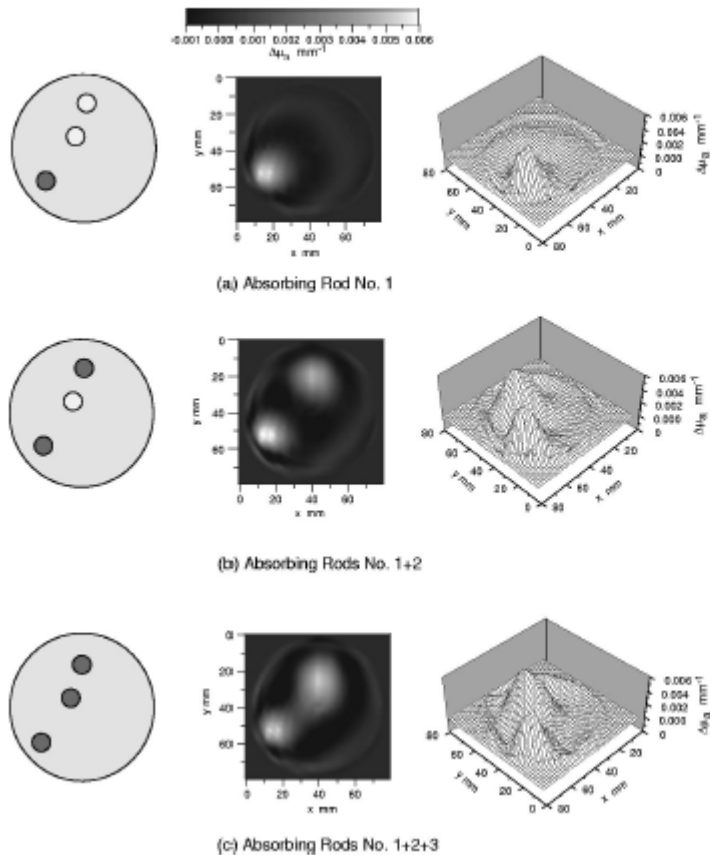


FIG. 8. Images reconstructed by the ART algorithm for the case of (a) one, (b) two, and (c) three absorbers at the wavelength of 791 nm.

Development of Optical tomography, NEDO project (1992-1999),  
*Shimadzu Corp.*, Kyoto, Japan

Brain research, NICT (1999-2005),

*National Institute of Information and Communications Technology.*

Kansai Advanced Research Center, Kobe, Japan

*Graduate School for the Creation of New Photonics Industries*, (2005-now)

Hamamatsu, Japan

# Agenda

- Background of IEC proposal
- New work item; “functional oximeter”
- History of our proposal
- Conclusion

# NIRS status in Japan

There had been many NIRS instruments (not Tomographic, but Topographic imaging) from different companies.

<http://www.hitachi-medical.co.jp/opt-e/index.html>



<http://www.hpk.co.jp/eng/products/SYSE/Niro300E.htm>



<http://www.med.shimadzu.co.jp/products/om/index.html> (in Japanese)



# Some users had some NIRSSs.

## We needed a standard for NIRS

- Working group for Japanese standardization was started in 2003.
  - The main members of the group were from companies.
- This was a subcommittee organized in *The Japan Electronics and Information Technology Industries Association (JEITA)*.
  - We were planning to propose testing protocols for NIRS instruments to *Japanese Industrial standard (JIS)* and *IEC*.

# We had discussed from 2003 to 2011

- **But**, we did not reach an agreement of NIRS Japanese standardization.

MEDPHOT Workshop in 2004


## NIRS status in Japan

1. There are many NIRS instruments from different companies.

<http://www.hitachi-medical.co.jp/opt-e/index.html>

<http://www.hpj.co.jp/eng/products/SYSE/Niro300E.htm>

<http://www.med.shimadzu.co.jp/products/om/index.html> (in Japanese)

A collage of images related to NIRS technology. On the left, a person in a white lab coat is seated at a desk, operating a computer monitor. In the center, there is a circular inset showing a surgical team in an operating room. To the right, there are several pieces of NIRS equipment, including a small desktop unit and a larger, mobile cart-mounted unit with a screen and various cables.

*They* already sold hundreds of equipment.

*They* did not want to change the system of their company.

# We must change our mind

- From “*what companies must do*” to “*what users must know!*”
- Open discussion. International discussion first, Japanese next.
- We planned to make a platform to discuss, in IEC or ISO.

# Agenda

- Background of IEC proposal
- New work item; “functional oximeter”
- History of our proposal
- Conclusion

After 9 years discussion.

*Checkpoints of functional oximeter equipment are included in the NWIP draft.*

- AVERAGE OPTICAL POWER
- PEAK WAVELENGTH
- FULL WIDTH AT HALF MAXIMUM of spectral distribution
- PATHLENGTH DEPENDENT HAEMOGLOBIN CHANGE
- Signal stability
- RESPONSE TIME
- SIGNAL-TO-NOISE RATIO
- SIGNAL CROSS-TALK

# History, to IEC proposal

- We asked for help to specialists of IEC standardization in Japan, in Apr. 2011.
  - They finished Pulse oximeter standard (ISO9919 etc.).
  - SpO2 is not measured value, but calculated value.
  - In ISO discussion, human validation was needed for the calculated value.
  - There is no phantom for Pulse Oximeter.
- We contacted Mr. Schmidt, who is a secretary of IEC TC62/SC62.

# IEC TC62/SC62 (Electrical equipment in medical practice), from A to D

- TC 62/SC **62A** Common aspects of electrical equipment used in medical practice
- TC 62/SC **62B** Diagnostic imaging equipment
- TC 62/SC **62C** Equipment for radiotherapy, nuclear medicine and radiation dosimetry
- TC 62/SC **62D** Electromedical equipment

# TC62/SC62D

TC 62/SC 62D	TC 62/SC 62D/AG 32	CAG Chairman Advisory Group
TC 62/SC 62D	TC 62/SC 62D/JMT 29	Requirements for lung ventilators
TC 62/SC 62D	TC 62/SC 62D/JMT 30	Requirements for cardiac pacemakers
TC 62/SC 62D	TC 62/SC 62D/JWG 1	Medical electrical equipment -: Particular requirements for basic safety and essential performance of critical care ventilators
TC 62/SC 62D	TC 62/SC 62D/JWG 2	Medical electrical equipment - Particular requirements for basic safety and essential performance of an anaesthetic workstation
TC 62/SC 62D	TC 62/SC 62D/JWG 3	Cardiac Pacemakers and Implantable Defibrillators
TC 62/SC 62D	TC 62/SC 62D/JWG 4	Medical Beds
TC 62/SC 62D	TC 62/SC 62D/JWG 5	Pulse Oximeters
TC 62/SC 62D	TC 62/SC 62D/JWG 6	Respiratory Gas Monitors
TC 62/SC 62D	TC 62/SC 62D/JWG 7	Non-Invasive sphygmomanometers - Clinical validation of automated measurement type
TC 62/SC 62D	TC 62/SC 62D/JWG 8	Clinical thermometers
TC 62/SC 62D	TC 62/SC 62D/JWG 9	Lens removal and vitrectomy devices for ophthalmic surgery
TC 62/SC 62D	TC 62/SC 62D/JWG 10	Small bore connectors for liquids and gases in healthcare applications
TC 62/SC 62D	TC 62/SC 62D/JWG 11	Electrical aspects of dental equipment
TC 62/SC 62D	TC 62/SC 62D/JWG 12	Home respiratory equipment
TC 62/SC 62D	TC 62/SC 62D/MT 16	Electro-optical equipment
TC 62/SC 62D	TC 62/SC 62D/MT 17	High frequency surgical equipment
TC 62/SC 62D	TC 62/SC 62D/MT 18	Therapy equipment
TC 62/SC 62D	TC 62/SC 62D/MT 19	Defibrillators
TC 62/SC 62D	TC 62/SC 62D/MT 20	Haemodialysis equipment
TC 62/SC 62D	TC 62/SC 62D/MT 21	Paediatric equipment
TC 62/SC 62D	TC 62/SC 62D/MT 22	Electromedical diagnostic and patient monitoring equipment
TC 62/SC 62D	TC 62/SC 62D/MT 23	Infusion pumps
TC 62/SC 62D	TC 62/SC 62D/MT 24	Extra-corporeal lithotripsy equipment
TC 62/SC 62D	TC 62/SC 62D/MT 26	Electromyographs and evoked response equipment
TC 62/SC 62D	TC 62/SC 62D/MT 27	Luminaires for surgery and diagnosis
TC 62/SC 62D	TC 62/SC 62D/MT 28	Operating tables
TC 62/SC 62D	TC 62/SC 62D/PT 60601-2-62	High intensity therapeutic ultrasound (HITU) systems

TC 62/SC 62D

# Electromedical equipment

TC 62/SC 62D	TC 62/SC 62D/JWG 1	Medical electrical equipment -: Particular requirements for basic safety and essential performance of critical care ventilators
TC 62/SC 62D	TC 62/SC 62D/JWG 2	Medical electrical equipment - Particular requirements for basic safety and essential performance of an anaesthetic workstation
TC 62/SC 62D	TC 62/SC 62D/JWG 3	Cardiac Pacemakers and Implantable Defibrillators
TC 62/SC 62D	TC 62/SC 62D/JWG 4	Medical Beds
TC 62/SC 62D	TC 62/SC 62D/JWG 5	Pulse Oximeters
TC 62/SC 62D	TC 62/SC 62D/JWG 6	Respiratory Gas Monitors

# The secretary arranged my talk in IEC meeting, Nuremberg 2011

- An IEC TC62/SC62D meeting was held from **Sep 20 to 23** in Nuremberg.
- I proposed our NWIP in the last “other business” session.
- **5 min talk.**

# Objection to NIRS proposal Nuremberg 2011

- Two men opposed strongly to my talk.
- They said **ISO already started NIRS standardization discussion a few years before.**

# Resolution of Nuremberg meeting 2011

**-JWG 5, Pulse oximeters** - Recently Japan submitted a new work item proposal to the Secretary. The new project would develop a standard on functional oximeters. It was noted that this work can be undertaken by the current JWG5 (pulse oximeters) and the draft submitted by the Japanese will be included when the NWIP is circulated. Also ISO/TC 121/SC3 currently has a draft on this topic which will be included as an annex to the proposal.

## **RESOLUTION NUREMBERG 5**

A new work item proposal regarding functional oximeters will be circulated. JWG5 will be designated as the developer of this work, if approved. The draft sent in by the Japanese delegation as well as a draft from ISO/TC 121/SC 3 will be included in the NWIP.

# Circulation on Nov 25 2011

- New Work Item proposal on 62D/966/NP: Medical electrical equipment - Part 2-xx: Particular requirements for the basic safety and essential performance of functional oximeter equipment
- We were so surprised at the circulated file.
- ISO proposal also was attached.
- These are different.

This is the draft of the particular standard on functional oximeter equipment, which is being circulated as the Working Draft of the New Work Item Proposal proposed by the Japanese National Committee

## **INTERNATIONAL STANDARD**

### **IEC 80601-2-XX**

**Medical electrical equipment –**

**Part 2-xx: Particular requirements for the basic safety and essential performance of functional oximeter equipment**

NOTE - The Japanese national mirror committee of IEC/SC62D has accepted the resolution at the IEC/SC62D meeting in Nuremberg, Germany on 22 September 2011, which says that this particular standard, if approved, will be developed jointly with ISO/TC121/SC3. Hence the number of the standard is denoted as IEC 80601-2-xx.

# IEC proposal of NIRS equipment



## 62D/966/NP NEW WORK ITEM PROPOSAL

	Proposer Japan	Date of proposal 2011-09-19
	TC/SC 62D	Secretariat ANSI
	Date of circulation 2011-11-25	Closing date for voting 2012-03-02

A proposal for a new work item within the scope of an existing technical committee or subcommittee shall be submitted to the Central Office. The proposal will be distributed to the P-members of the technical committee or subcommittee for voting, and to the O-members for information. The proposer may be a National Committee of the IEC, the secretariat itself, another technical committee or subcommittee, an organization in liaison, the Standardization Management Board or one of the advisory committees, or the General Secretary. Guidelines for proposing and justifying a new work item are given in ISO/IEC Directives, Part 1, Annex C (see extract overleaf). **This form is not to be used for amendments or revisions to existing publications.**

The proposal (to be completed by the proposer)

Title of proposal  
IEC/ISO 80601-2-xx (ed. 1), Medical electrical equipment - Part 2-xx:  
Particular requirements for the basic safety and essential  
performance of functional oximeter equipment

Standard       Technical Specification       Publicly Available Specification

Scope (as defined in ISO/IEC Directives, Part 2, 6.2.1)

<b>Relationship of project to activities of other international bodies</b> The proposed project will be carried out by ISO/TC 121/SC 3 and IEC/SC 62D JWG 5 on Pulse Oximeters.	
<b>Liaison organizations</b>	<b>Need for coordination within ISO or IEC</b>
<b>Preparatory work</b> Ensure that all copyright issues are identified. Check one of the two following boxes <input checked="" type="checkbox"/> A draft is attached for comment <input type="checkbox"/> An outline is attached We nominate a project leader as follows in accordance with ISO/IEC Directives, Part 1, 2.3.4 (name, address, fax and e-mail):  Name: Hideo Eda, Ph.D (The Graduate School for the creation of new photonics industries) Address: 1955-1, Kurematsu, Nishi-ku, Hamamatsu, Shizuoka, 431-1202, Japan Fax: +81-53-487-3012 Email: eda@gpi.ac.jp	
<b>Concerns known patented items</b> (see ISO/IEC Directives, Part 2) <input type="checkbox"/> yes If yes, provide full information as an annex <input checked="" type="checkbox"/> No	<b>Name and/or signature of the proposer</b> Dr. Hideo Eda
<b>Comments and recommendations from the TC/SC officers</b>	
1) Work allocation <input type="checkbox"/> Project team <input type="checkbox"/> New working group <input checked="" type="checkbox"/> Existing working group no: JWG 5	
2) Draft suitable for direct submission as <input checked="" type="checkbox"/> CD <input checked="" type="checkbox"/> CDV <input type="checkbox"/> Publication as a PAS	
3) General quality of the draft (conformity to ISO/IEC Directives, Part 2) <input checked="" type="checkbox"/> Little redrafting needed <input type="checkbox"/> Substantial redrafting needed <input type="checkbox"/> no draft	



## NEW WORK ITEM PROPOSAL

Date of presentation

**2011-09-19**

Reference number

(to be given by the Secretariat)

Proposer

**Japan****ISO/TC 121 / SC 3 N 1624**

Secretariat

**ANSI****Title of proposal** (In the case of an amendment, revision or a new part of an existing document, show the reference number and current title)English title **IEC/ISO 80601-2-xx (ed. 1), Medical electrical equipment – Part 2-xx: Particular requirements for the basic safety and essential performance of functional oximeter equipment**French title **Appareils électromédicaux — Partie 2-xx: Règles particulières de sécurité pour xx**  
(if available) **– xxx****Liaison organizations****CENELEC TC 62****Need for coordination with:** IEC  CEN  Other (please specify)**IEC 62D****Preparatory work** (at a minimum an outline should be included with the proposal) A draft is attached  An outline is attached. It is possible to supply a draft byThe proposer or the proposer's organization is prepared to undertake the preparatory work required  Yes  No**Proposed Project Leader** (name and address)**John Hedley-Whyte, MD****Harvard University****john\_hedley-whyte@hms.harvard.edu****Name and signature of the Proposer**

(include contact information)

Dr. Hideo Eda (Japan NC)

eda@gpi.ac.jp

# Many bosses...

- I am an IEC project leader of the PT.
- IEC/TC62/SC62D/JWG5/Project Team
- ISO/TC121/SC3/JWG10/Project Team

# NWIP to CD

- 2011/11/25 Date of circulation
- 2012/3/2 Closing date for voting
  - Project started!! IEC (3 countries) + ISO (2)
- 2012/6/12~15 ISO Kyoto meeting
  - Agreement to separate the NWIP into two NW.
  - One is IEC-lead (fNIRS), the other is ISO-lead (Tissue Oximeter).
  - No Minutes from Mr.B.
- 2012/12/6 Tokyo meeting
- 2013/2/22 CD date of circulation



## SC 62D [Electromedical equipment](#)

Work programmes > [Project: IEC 60601-2-71 Ed. 1.0](#)

### Detail

Committee	Working Group	Project Leader	Current Status	Next Pub Date	Stability Date
SC 62D	JWG5	H. Ede	CDV	2015-08	2013

### History

Stage	Document	Download	Decision Date	Target Date
PMN	<a href="#">60601-2-71P</a>	1.528 KB	2011-11-25	
JWN	<a href="#">60601-2-71JWN</a>	495 KB	2012-03-18	2012-04-15
	<a href="#">60601-2-71JWN</a>	1.528 KB		

### Project

**IEC 60601-2-71 Ed. 1.0**  
**Medical electrical equipment - Part 2-71:**  
**Particular requirements for the basic safety**  
**and essential performance of functional**  
**osimeter equipment**










**Remark:**  
 - Project plan: CDV: 2014-03, FDIS: 2014-12 - Joint project with ISO/TC 121/SC 3, under the IEC lead.

## Remark:

- Project plan: CDV: 2014-03, FDIS: 2014-12 - Joint project with ISO/TC 121/SC 3, under the IEC lead.

<b>Committee</b>	<b>Working Groups</b>	<b>Project Leader</b>	<b>Current Status</b>	<b>Frcst Pub Date</b>	<b>Stability Date</b>
SC 62D	JWG5	H. Eda	CCDV	2015-06	2018

## History

<b>Stage</b>	<b>Document</b>	<b>Downloads</b>	<b>Decision Date</b>	<b>Target Date</b>
PNW	62D/966/NP	 1586 kB	2011-11-25	
ANW	62D/991/RVN	 495 kB	2012-03-16	2012-04-15
	62D/991A/RVN	 1249 kB		
1CD	62D/1056/CD	 763 kB	2013-02-22	2013-03-31
ACDV	62D/1074/CC	 130 kB	2013-05-03	2013-05-31
		 848 kB		
	62D/1074A/CC	 156 kB		
		 984 kB		
CCDV	62D/1115/CDV	 659 kB	2014-04-18	2013-11-30
ADIS				2014-10-31
DEC				2014-11-30

# 1<sup>st</sup> meeting to CDV

- 2012/6/12~15 ISO Kyoto meeting
  - No Minutes from Mr.B, after 3 months
  - We planed to have another meeting to complete the comment work.
- 2012/12/6 Tokyo meeting
- 2013/6/18-20 ISO Shanghai meeting
  - Minutes was delayed.
- 2014/4/18 CDV date of circulation

# We have an ISO meeting in Incheon, Korea, next month.



**62D/1115/CDV**

**COMMITTEE DRAFT FOR VOTE (CDV)  
PROJET DE COMITÉ POUR VOTE (CDV)**

Project number Numéro de projet		IEC 80601-2-71 Ed.1.0
IEC/TC or SC: CEI/CE ou SC: <b>62D</b>		Secretariat / Secrétariat <b>United States of America</b>
<input checked="" type="checkbox"/> Submitted for parallel voting in CENELEC Soumis au vote parallèle au CENELEC	Date of circulation Date de diffusion <b>2014-04-18</b>	Closing date for voting (Voting mandatory for P-members) Date de clôture du vote (Vote obligatoire pour les membres (P)) <b>2014-07-18</b>
Also of interest to the following committees Intéresse également les comités suivants ISO TC 121/SC 3 N1843		Supersedes document Remplace le document 62D/1058/CD & 62D/1074A/CC
Proposed horizontal standard		

Voting (with comments) closes on 2014-7-18.  
Incheon meeting is held from 2014-6-16 to 6-20.

# We have to care about;

- Who needs the standard?
- Why do we need the standard?
- We have to nominate experts and attend the IEC/ISO meeting all over the world.
  - IEC: 1 meeting/year.
  - ISO: 3~4 meetings/year
- At an IEC / ISO meeting, it is difficult to have scientific discussion.
  - Comment work and comments work.
- IEC Experts are not NIRS experts.
  - Do you know BC?
  - No. Who is Britton Chance!!

# Standard can be used as a protection

- For Users
- For Manufacturers
- For *Government*
  
- From Medical lawsuit
- From Medical approval
  
- Science discussion is needed, but we must know other aspect of the IEC / ISO proposal.

# Conclusion

- IEC proposal of fNIRS is now on CDV stage.
- There are three kinds of person; researchers, manufactures, standardization.
- It is important to manage meetings, politically.
- We have to consider; who needs standard?
- Target date is set at 3 years. We cannot enjoy discussion.



## ISO/IEC Directives Part 1

Procedures for the technical work

For proposal, please  
refer ISO/IEC  
Directives 1, 2



## ISO/IEC Directives Part 2

Rules for the structure and drafting of International Standards