MEDEA: Metrology – Enabling Developing Economies in Asia

ACTIVITY REPORT FOR TRAINING COURSE ON Non-Invasive Sphygmomanometers

Dates: 11-15 November 2019

Venue: Concorde Hotel Shah, Kuala Lumpur, Malaysia

Host: National Metrology Institute of Malaysia **(**NMIM**)**, SIRIM Berhad

Trainers:

1. Dr. Stephan Mieke, PTB retired, ISO expert
2. Mr Chen Chuan Hung,CMS/ ITRI, Chinese Taipei
3. Mr**.** Mohd Mazid Mansor (Co-trainer)

APLMF Rep: Mrs Haslina ABDUL KADIR

1. Introduction

Non-invasive blood pressure (NIBP) monitoring using sphygmomanometers is a readily available method to ascertain blood pressure (BP). In order to maintain the quality of NIBP devices, we must have an accurate NIBP device measurement system and qualified personnel in charge of quality assurance. This includes the establishment of a consistent method of metrology in medicine, a standard traceability chain for NIBP devices, and the implementation of legal metrology regulations, and the administrative operation of the measurement infrastructure. Hence, the quality assurance of the measurements should be ensured by metrological tools, e.g., calibrations, legal metrological control and reference measurement methods.

2. Objective of the Training

This training was composed of lectures and practical activities which used a blood pressure simulator instrument**.**

This course provided participants with the knowledge and skills to:

- implement global standards, traceability and regulations for non-invasive sphygmomanometer within their own economy;
- calibrate and test non-invasive sphygmomanometer; and
- understand the linkage between scientific metrology and legal metrology for non-invasive sphygmomanometer.

3. Target Group

Participants were officers and technical experts who work in national/regional authorities or research institutes in metrology, who are involved in developing traceability systems for NIBP measurement or capacity building activities in their economy. There were 24 participant from 14 economies attended this training course, which represented 16 institutes. On completion of the program, the participants have agreed to lead the establishment of sound traceability systems within their economy by delivering training to their colleagues.

A list of participants is found at Annex 1.

4. Training Course Programme

The training was opened by Dr Osman Zakaria, Senior Director of the National Metrology Institute of Malaysia, SIRIM Berhad and Mrs Haslina Abdul Kadir, representing the APLMF Secretariat also made opening remarks. They thanked PTB, APLMF and the host economy for all their support in making this training possible.

The training course started with an explanation of the schedule and an outline of the training course. A full copy of the program can be found at Annex 2. The participants took some time to introduce each other and later each participant shared the action plan they intend to implement with respect to sphygmomanometer within six months when they return to their own country. Questions were asked to clarify understanding of their action plans. They were advised their action plan would be sent to them and their Director after the training and that a follow-up email will be sent in 6 months asking them to report on their progress against their plans. Participants from Bhutan, China, Thailand, Malaysia and Myanmar amended their action plans. A summary of the economy reports, and action plan summary is found in Annex 3 and 4 respectively.

On day 4, a round table discussion was also held to determine the future program, continuation of this sphygmomanometer training course. Data was collected about what to do to enhance the metrological control of sphygmomanometer measurement within the region as well as what training we could offer to those at beginner level and what could be suitable training content.

The practical session was held at NMIM on the last day followed by a technical visit to pressure and length laboratories in NMIM's Mechanical group. A selection of photographs can be found in Annex 5.

5. Highlights/ Lessons Learned

This training course was classified as intermediate to advance level. Therefore, selection of the right candidate for this training is very important to ensure their participation during the course. Some participants who had previous knowledge in this field and have already applied the calibration of sphygmomanometer and actively asked trainers questions. The objectives of the training were certainly achieved, and the training ran very smoothly. Participants gained a lot of new skills and knowledge from the training based on the feedback received from the participants.

Almost half of the participants are considered as beginner in this field and they felt that the practical session provided in this training course was not enough. Below are topics that participants would like to have in the future:

Suggested training topics for beginner

1- Calibration and uncertainty evaluation

2- Practical training on verification of NIBP

3- Practical training on data collection and simulation
4- Beginner training

- Principle of sphygmomanometer (NIBP)
- OIML document in details
- Practical (verification & pattern approval)
- Introduction of verification system and calibration system
- Steps of verification and calibration
- How to record and calculate the data
- Documentation of result/report
- Technical specification and list of instrument needed to setup the calibration/verification sphygmomanometer laboratory.

A summary of discussion on the way forward for each economy to develop and enhance their metrological control of sphygmomanometer measurement after completion of this training can be found in Annex 6.

6. Next Steps/ Follow-up

(i) Sharing on resources related to sphygmomanometer.

1- Sharing of pattern approval document (developed by NMI's) for all APLMF & APMP members

- NIM China willing to share their pattern approval document, but the document is written in Chinese.
- to be checked whether could be share/translate to english

2- Sharing of personnel experience on the verification of NIBP through practical session.

- Indonesia – subject to decision of BPFK
- India – subject to decision of Ministry of Consumer Affairs
- Malaysia

3- To provide support in terms of pattern approval of NIBP?

- China – to advise after discussion with Director

(ii) Development of guideline on calibration and verification of sphygmomanometer

Several training participants volunteered to be involved for the development of the guideline. Among them are participants from South Africa, Malaysia, Philippines and Sri Lanka.

(iii) Alternatives if sphygmomanometer pattern approval is not available.

Q2 - If there is no pattern approval available for sphygmomanometer, what is the alternative?

- Ask the manufacturer wherether the instrument has obtained pattern approval from other country
- Check wherether the instrument has CE marking
- Has the instrument obtained FDA approval?

Annex 1: Training Course on Calibration and Testing of Non- Invasive Sphygmomanometer Programme

11-15 November 2019 at Malaysia

Day 1 Monday 11 Nov	08:00-09:00	Registration
	09:00-9.30	Opening addresses by APLMF/APMP and host. A group photo.
	9.30-10:00	Explanation of schedule and outline, Ice breaking session
	10.00-10.30	Coffee / tea break
	10.30-11:30	Economy reports (APLMF).
	11:30-12:30	Sphygmomanometer calibration--why, how and how often (Dr Stephan Mieke)
	12.30-13.30	Lunch break
	13.30-15:00	The traceability of Spygmomanometer (non-invasive) in Malaysia (Mr Mazid Mansor)
	15.00-15:30	Coffee / tea break
	15.30-16.30	Blood pressure measurement technique & Metrology in medicine (Dr Stephan Mieke)
	18:00-21:00	Welcome dinner hosted by MEDEA
Day 2 Tuesday 12 Nov	9:00-10:20	Technical tests of automated intermittent non-invasive sphygmomanometers IEC 80601-2-30 (Dr Stephan Mieke)
	10:20-10.40	Coffee / tea break
	10:40-12:00	Continue the Technical tests of automated intermittent non-invasive sphygmomanometers IEC 80601-2-30 (Dr Stephan Mieke)

	12:00-13:00	Lunch break
	13.00-14.30	Non-invasive automated sphygmomanometers OIML R16-2 (Mr Chen Chuan Hung)
	14:30-15:00	Coffee / tea break
	15:00-16:30	Continue the Non-invasive automated sphygmomanometers OIML R16-2 (Mr Chen Chuan Hung)
Day 3 Wednesday 13 Nov	9:00-10:20	Verification of non-invasive sphygmomanometers in Europe (Dr Stephan Mieke)
	10:20-10.40	Coffee / tea break
	10:40-12:00	Clinical test of automated intermittent of non-invasive sphygmomanometers ISO 81060-2 (Mr Chen Chuan Hung)
	12:00-13:00	Lunch break
	13:00-14:30	Clinical blood pressure data collection and demonstration (Mr Chen Chuan Hung))
	14:30-15:00	Coffee / tea break
	15:00-16:30	Clinical test of continuous non-invasive sphygmomanometers ISO 81060-3, Draft (Dr Stephan Mieke)
Day 4 Thursday 14 Nov	9:00-10:20	Simulators to test automated intermittent non-invasive sphygmomanometers ISO/TS 81060-5, Draft (Dr Stephan Mieke)
	10:20-10.40	Coffee / tea break
	10:40-12:00	APMP Focus-Group Initiative Project: Pilot Study on Automated Sphygmomanometer Accuracy Test by Using Blood Pressure Simulation Technique (Mr Chen Chuan Hung)
	12.00-13:00	Lunch
	13:00-14:30	Testing of oscillometric shygmomanometer in the presence of motion artifact caused by vehicular patient transport ISO/TS 81060-4, Draft (Dr Stephan Mieke)
	14:30-15:00	Coffee / tea break

	15:00-16:30	Discussion on the participants way forward plan
Day 5 Friday 15 Nov	09:00 to 10:00	Regulation of non-invasive sphygmomanometers in Taiwan and China (Mr Chen Chuan Hung)
	10:00 to 10:20	Coffee / tea break
	10:20 to 12:00	Practical demonstration for testing and calibration of non-invasive sphygmomanometers (Mr Chen Chuan Hung, Mr Mazid Mansor)
	12:00 to 13:00	Lunch
	13:00 to 16:00	Closing ceremony with bestowal of the certificate Technical Tour – NMIM Laboratory

Annex 2: List of Participants

No	Name	Institution	Economy
1	Mr MD Zahid HASAN	BSTI (NML-BSTI)	Bangladesh
2	Mr Pujan KARMAKAR	BSTI	Bangladesh
3	Mr Namkha DORJI	Bhutan Standards Bureau	Bhutan
4	Ms Tshewang LHADEN	Ministry of Health	Bhutan
5	Mrs Yan XIA	Jiangsu Institute of Metrology	China
6	Ms Lijie HUANG	Shanghai Institute of Measurement and Testing Technology	China
7	Mr Afaqul ZAFER	NPL, India	India
8	Mr/Dr Premshankar DUBEY	NPL, India	India
9	Mr Gigin GINANJAR	SNSU-BSN	Indonesia
10	Mr Adindra Vickar EGA	SNSU-BSN	Indonesia
11	Mr Waheed AL-ALI	Jordan National Metrology Institute	Jordan
12	Mr Ahmad Zamir Zulkifli	National Metrology Institute of NMIM	Malaysia
13	Mr Mohd Faizol Ruslee	National Metrology Institute of Malaysia	Malaysia

14	Mr Wai Moe KYAW	National Institute of Metrology (NIMM)	Myanmar
15	Mrs Bayarjargal SUKHBAATAR	MASM	Mongolia
16	Mrs Zesmaa GANBOLD	Mongolia	Mongolia
17	Mrs Danish KHAN	National Physical & Standards Laboratory	Pakistan
18	Ms Mohsina ANDLEEB	National Physical & Standards Laboratory	Pakistan
19	Mrs Sarah Jane DIGAY	NML - Industrial Technology Development	Philippines
20	Ms Mary Ness SALAZAR	NML - Industrial Technology Development Institute	Philippines
21	Mr Brian YALISI	NMISA	South Africa
22	Mrs Shanika SILVA	MUSSD	Sri Lanka
23	Mr Kaushalya GANAPATHI	MUSSD	Sri Lanka
24	Dr Patcharapol GORGITRATTANAGUL	NIMT	Thailand

Annex 3: Summary of Economy Reports

Summary of Economy reports 11–15 November 201

MEDEA: Training Course on the Calibration and Verification of Sphygmomanometer

Economy	Law	Who does verify	Verification period	MPEs	Type approval	Integrity	OIML R49 Implemented	Pr
Bangladesh (2)	No. The government has a plan to formulate proper legislation to regulate the Non-invasive sphygmomanometer	Inspectors	1 year		No.	At present, the integrity of these instrument has not been fully ensured. The government is planning to develop a mechanism to ensure the integrity of the BP devices.	Partially implemented	Te ex fu m
Bhutan (2)	No. Our economy does not have legal metrology act and it is in drafting stage. It seems the Ministry of Health does not have medical metrology in placed.	other	1 year – in house calibration by BMED		Yes.		Partially implemented	Ou im ef bu No de to de

Summary of Economy reports 11–15 November 201

MEDEA: Training Course on the Calibration and Verification of Sphygmomanometer

Economy	Law	Who does verify	Verification period	MPEs	Type approval	Integrity	OIML R49 Implemented	Pr
China (2)	Yes	Inspectors	1 year		Yes		Fully implemented /Partially implemented	To co do R1
India (2)	Yes	Other	1 year / 2 years		Yes		Fully implemented	Fu eq co su ne Fu eq

								de sy
Indonesia (2)	Yes	3rd party and inspectors	1 year		Yes		Partially implemented	BP or pe au sp si te is st
Jordan (1)	Yes	3rd party	2 years		Yes		Fully implemented	Ac ex

Summary of Economy reports 11–15 November 201

MEDEA: Training Course on the Calibration and Verification of Sphygmomanometer

Economy	Law	Who does verify	Verification period	MPEs	Type approval	Integrity	OIML R49 Implemented	Pr
Mongolia (2)	Yes	Other (Verification officers) / inspectors	Mechanic NIBP (1 year) Automat NIBP (2 years)		No	All non-invasive sphygmomanometers which are using in the hospitals are verified every year	Partially implemented	La ec pr
Myanmar (1)	No. Drafting the metrology law including legal metrology	N/A	N/A		N/A	N/A	N/A	N/
Pakistan (2)	Yes	Other /3rd party	1 year		No	N/A	Not implemented yet / Fully implemented	N/

Summary of Economy reports 11–15 November 201

MEDEA: Training Course on the Calibration and Verification of Sphygmomanometer

Economy	Law	Who does verify	Verification period	MPEs	Type approval	Integrity	OIML R49 Implemented	Pr
Philippines	No. Currently there is no regulation for the sphygmomanometers in particular	Other, NML-ITDI carry out the testing of sphygmomanometers	N/A		No	Integrity of sphygmomanometers in particular is not ensured. Some regulation from the department of health such as the Administrative Order no. 2012-0012 – "Rules and Regulations Governing the New Classification of Hospitals and other Health Facilities in the Philippines" requires hospitals to have a calibration program, prevention maintenance and repair of equipment, depending on the declared intervals of hospitals. However, this order does not state on who will be responsible for the said calibrations.	Partially implemented. initial and subsequent verification required tests are done in NML, however, some tests such as the a.) electrical safety is not done since there is no national regulation on electrical safety of this device and b.) resistance to vibration and shock due to absence of facilities.	Fa la te ve ne th Th m al su in

Summary of Economy reports 11–15 November 201

MEDEA: Training Course on the Calibration and Verification of Sphygmomanometer

Economy	Law	Who does verify	Verification period	MPEs	Type approval	Integrity	OIML R49 Implemented	Pr
Sri Lanka (2)	Yes	Other	1 year		No	still no legal regulation publish for type approval for Non-Invasive sphygmomanometers. Plan to make regulations 2020 calibrating by primary standards	Partially implemented	Ge he bu
Thailand	No. Currently for import the Non-invasive sphygmomano meter to sell in Thailand, it only needs a quality of product document from its manufacturer	3rd party	1 year		No	Only from document provided by manufacturer	Fully implemented	La re bu

Annex 4 Summary of Action Plans

Summary of Action Plans

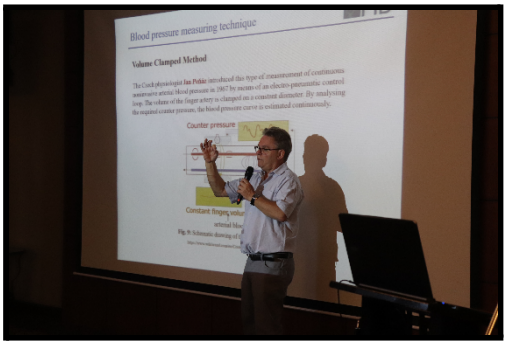
alibration and Testing of Non- Invasive Sphygmomanometer 11-15, November 2019, Sepang, Malaysia

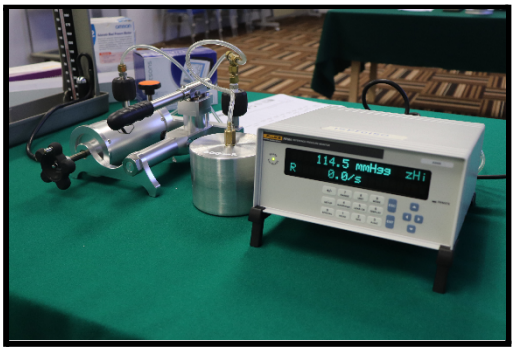
	Participants	Action Plan
	Mr MD Zahid HASAN	**11/2021** Project will be implemented to expand the facility to the calibration of using the knowledge from this training
	Mr Pujan KARMAKAR	
	Mr Namkha DORJI	1. **01/2020** Prepare procedure for testing and calibration of non-invasive sphygmomanometer Per OIML recommendation 2. **05/2020** Recommend to BSB management to procure necessary equipment in 2020 testing and calibration

Ms Tshewang LHADEN	1. 12/2019: Share the training materials to different sections (unit) under BME advocate them on the calibration and verification of medical devices from m point of view. 2. 01/2020: Consultation meeting with BSB and other relevant stakeholders or verification and calibration of non-invasive sphygmomanometer (how to go way forward since BMED already has commercial simulators to perform PVS sphygmomanometers and some other types of medical equipment). 3. 03/2010: Review and refine SOP on PVST of non-invasive sphygmomanomet commercial simulators in line with the training materials of NMIM training. D the SOP with BSB and finalize it.
Mrs Yan XIA	1. **12/2019** Training course to my colleagues in my department about the cali sphygmomanometer 2. **Dec 2019** Discuss with my leader and colleagues about the establishment o of dynamic blood pleasure calibration
Ms Lijie HUANG	1. **11/2019** Compare the items between JJG692-2010 Verification Regulation a and outline the difference 2. **12/2019** Compare and make analysis of the experiment results because of t differences by implementing different technical standards. 3. **01/2020** Make analysis of the present status of non-invasive automated sphygmomanometers laboratory in SLMT, and provide the improvement sug to meet the requirement of OIML-CS system according to R16.
Mr Afaqul ZAFER	within 2-3 month provide training to internal NPLI staff, industry and Legal Met department, action plan specified after the training
Mr/Dr Premshankar DUBEY	1. **03/2020** Design and development of digital sphygmomanometer 2. **03/2020** Development of calibration facility for digital sphygmomanometers 3. **03/2021** Development of BP simulator to provide traceability to dynamic pr Sphygmomanometer.
Mr Gigin GINANJAR	1. **12/2019** Finishing the development of the recording unit. 2. **12/2019** Reporting of the 1st research project and submission of the 2nd re project for sphygmomanometer. 3. **03/2020** Continuation of the 2nd research project for sphygmomanometer university. 4. **05/2020** Transfer knowledge to the stakeholder. 5. **05/2020** Survey to the hospitals for the sphygmomanometer used.
Mr Adindra Vickar EGA	1. **12/2019** develop national blood pressure simulator in Indonesia from the re project INSINAS and research publication (project leader) 2. **12/2020** provide technical support to the BPFK as the legal organisation for calibration and testing of sphygmomanometers

	Mr Waheed AL-ALI	1. **11/2019** seminar for knowledge transfer to other sectors in the country 2. **04/2020** apply new procedures and verification methods
	Mr Ahmad Zamir Zulkifli	**1. 4/2020** Conduct an awareness program to the health industry player. 2. **1/2020** Draft a training module for verification and calibration of sphygmomanometer.
	Mr Mohd Faizol Ruslee	3. **4/2020** Co- operation with government or government agencies to improve sphygmomanometer verification and calibration in Malaysia. 4. **2021** Improve facilities for verification and calibration of sphygmomanomet NMIM.
	Mrs Bayarjargal SUKHBAATAR	1. **12/2019** Develop procedure for testing and verification 2. **01/2020** training course for regional centres 3. **02/2020** training course for Centre of Health
	Mrs Zesmaa GANBOLD	OIML R 16-2
	Dr Wai Moe KYAW	1. **12/2019** Provide report to the Director of NIMM and Ministry 2. **11/2019** Share the training knowledge on sphygmomanometer calibration, importance of metrology and legal metrology, blood pressure measurement technique and metrology in medicine, verification of non-invasive sphygmomanometer. 3. **5/2020** Cooperation with Food and Drug Administration (FDA), Ministry of H Sport, Government and private hospitals and relevant ministries.
	Mrs Danish KHAN Ms Mohsina ANDLEEB	**04/2020** development of facility for calibration and testing of NIBP
	Mrs Sarah Jane DIGAY	**01/2020** draft training module **02/2020** draft proposal of setting up simulator technique in calibration of auton
	Ms Mary Ness SALAZAR	sphygmomanometer. **07/2020** offer training on testing
	Mr Brian YALISI	**05/2019** Feasibility studies for Blood Pressure devices calibration and verificati (Completed) **12/2019** Sphygmomanometer calibration verification and regulation training **03/2020** Procurement of standard, preparation of Uncertainty budgets and commissioning of services for calibration of non-invasive sphygmoma **06/2020** Full calibration services of sphygmomanometers
	Mrs Shanika SILVA	**12/2019** Presentation about training **02/2020** develop procedures, make complete set up for testing
	Mr Kaushalya GANAPATHI	**07/2020** conduct training for customers and health service **11/2020** make regulation and pattern approval procedure for NIBP
	Dr Patcharapol GORGITRATTANAGUL	**02/2020** Arrange a meeting/seminar/workshop on sphygmomanometer to tra knowledge from this training to relevant individual/sector.

Annex 5: Photographs





Annex 6: Way forward

ITEM	ECONOMY									
	BGD	BTN	CHN	IND	IDN	JOR	MYS	MMR	MNG	
Do you hope to be a consultant or a trainer of sphygmomanometer in your Institute?	Yes	Yes	Yes	Yes	Yes (by other institute)	Yes (as trainer)	Yes	Yes (and to other Institute)	Yes	Y
Do you hope to establish a verification laboratory of sphygmomanometer in your Institute?	Yes	MOH -No BSB- Yes	Yes (already establish-ed)	Yes	No (by labs under MOH)	No (by labs under MOH)	Yes	Yes	Yes	Y (2 pr
Do you hope to establish a calibration laboratory of sphygmomanometer in your Institute?	Yes	Yes (by BSB)	Yes (already establish-ed)	Yes	Yes (by other institute)	Yes	Yes	Yes	Yes (by MOH)	Y
Do you hope to establish clinical blood pressure database in your Institute (including to establish a recording unit)?	No	Yes	Yes (intended to. Depends on director's approval)	Yes (currently develop-ping)	Yes	No	Yes (in long term plan)	Yes	Yes	N Y (s pl

Note:

BGD- Bangladesh **BTN- Bhutan** **CHN- China** **IND- India** **IDN-Indonesia**
JOR- Jordan **MYS- Malaysia** **MMR- Myanmar**
MNG- Mongolia **PAK- Pakistan** **PHL- Philippines** **ZAF- South Afrika** **LKA- Sri Lanka**
THA- Thailand

ITEM	ECONOMY									
	BGD	BTN	CHN	IND	IDN	JOR	MYS	MMR	MNG	
Do you hope to establish blood pressure simulation system in order to simulate the overall system accuracy of automated sphygmomanometer in your Institute?	No	Yes (need support)	Yes (has to be decided by other institution)	Yes (in process)	Yes	No	Yes	Yes	Yes	Y fu

Do you hope to develop your own recording unit or simulator	No	Not decided	Yes (in future)	Yes (in process)	Yes (record-ing in process)	No	Yes	Yes	Yes	Y pl
Do you hope to develop new blood pressure device?	No	No	Not decided	Yes (under scientific project)	No	No	No	No	No	N
Do you hope to help your country's manufacturer to improve their quality of automated sphygmomanometer?	No	No	Yes	Yes	Yes	No	Yes	Yes	No	Y

ITEM	ECONOMY									
	BGD	BTN	CHN	IND	IDN	JOR	MYS	MMR	MNG	
Do you hope to participate APMP MMFG pilot study in the future?	No	Not decided (depend ing on facility)	Not decided	Not decided (dependi ng on facility)	Yes	No	Not decided (depen ding on facility)	Yes	Yes	Y
Who is interested/ supporting the testing (i.e. quality assurance) of NIBP? Who is opposing it?	Undecided	Yes	Already establishe d	Yes	There is demand	Undeci -ded	Undeci-ded	Yes	Already establis h-ed	Y
Are you already or do you intended to get in contact with national/regional medical societies or opinion leaders?	Not in contact –intended to contact	Intended to contact	Yes	Intended to contact	Intended to contact	Inten-d ed to contact	Already in contact	Not in contact	Already in contact	N co –i d co