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## Medical Devices Safety Standards (BME Training)

*In collaboration with Fluke Biomedical and Taiwanese Society of  
Biomedical Engineering*

12-13 January 2015

NTUH Convention Centre,  
Taipei, Taiwan

### TOPICS:

- Risk Management
- Medical Device Risk Overview
- How to test (how to perform electrical safety, preventive maintenance & performance testing):
  1. Electrical Safety
  2. Ventilators
  3. Electrosurgical Units

### SPEAKER:

#### Jerry Zion

Global Training Manager  
Fluke Biomedical  
Education & Training

*Jerry spent 10 years as a hospital-based biomedical engineer and supervisor/manager. During the past 35 years he has worked in the following capacities for well-known medical device manufacturers:*

- *9 years, Siemens Life Support Systems (now Maquet Life Support Systems) as product manager and clinical specialist for the Servo 900 anesthesia system and Sirecust patient monitors.*
- *5 years, Product Marketing Manager for Welch Allyn Monitoring for EMS and Military Segments for Propaq monitors and the Acuity central monitoring system,*
- *1 year, Marketing Manager for Perioperative Care Products and Emergency Care Products at Spacelabs Medical prior to joining Fluke Biomedical.*
- *10 years, Fluke Biomedical in a variety of roles: global marketing manager, product manager, training manager*

*Mr. Zion is an AAMI certified biomedical equipment technician, holds a Bachelor of Science degree in Electrical Engineering Technology from Purdue University, and a Masters Degree in Management in Science and Technology from Oregon Graduate Institute (now part of Oregon Health Sciences University). He is based in the USA at Fluke Electronics headquarters*

## Monday, 12 January 2015

9:00 AM	Registration	All
9:15 AM	Welcome Speech	Mark. Procyshyn
9:30 AM	Introduction to Risk Management	Jerry Zion
10:00 AM	Medical Risk Overview	Jerry Zion
10:15 AM	Tea Break	All
10:30 AM	<b>Medical Device Safety Standards:</b> <ul style="list-style-type: none"><li>• IEC 60601-1 2<sup>nd</sup> edition</li><li>• IEC 60601-1 3<sup>rd</sup> edition</li><li>• IEC 62353 (VDE 751 in ISA 601proXL)</li></ul>	Jerry Zion
11:00 AM	Recommended Practices of Electro-surgery	Clarissa Khoo
12:00 PM	Lunch	All
1:00 PM	Force FX Technical Overview	Andre Yeo
2:15 PM	What, when and how to test ESU? <ul style="list-style-type: none"><li>• Electrical Safety Test</li><li>• Function Test</li></ul>	Jerry Zion
3:00 PM	Break	All
3:15 PM	PB Ventilators overview Breath Delivery Unit	Amy Peng
4:15 PM	What, when and how to test ventilator? <ul style="list-style-type: none"><li>• Electrical Safety Test</li><li>• Function Test</li></ul>	Jerry Zion
5:00 PM	Adjourn	All

## Tuesday, 13 January 2015

9:00 AM	Housekeeping on breakout session	Facilitator
9:30 AM	<b>Breakout session:</b> Demonstration: What and How to Test Group 1: Ventilators (3 stations) Group 2: ESU (5 stations)	Jerry Zion <b><u>Facilitators:</u></b> Local engineers
12:00 PM	Lunch	All
1:00 PM	<b>Breakout session:</b> Demonstration: What and How to Test Group 1: Ventilators (3 stations) Group 2: ESU (5 stations)	Jerry Zion <b><u>Facilitators:</u></b> Local engineers
3:00 PM	Tea Break & Adjourn	All
3:30 PM	Voice of Customer (by invite only)	By invite only