

# Patient monitor testing: related standards of reference

## Application Note

Patient care and safety are top of mind for hospital quality assurance professionals. Vital signs monitors affect patient care. These critical medical devices are used in diagnoses that influence patient treatment. Incorrect diagnoses due to inaccurate readings from a poorly-performing patient monitor could put a facility at risk for costly litigation.

Performance checks for patient monitors are required by a variety of standards, and are a primary area of focus for groups like The Joint Commission, AAMI and ECRI. Below are a selection of standards you can reference when building your patient monitor quality assurance plan.

### The Joint Commission (JC) hospital accreditation manual in Environment of Care (EC) section

- EC.02.02.01 EP 2
  - Requires Clinical Engineering maintain an inventory, including any new devices introduced to the system
- EC.02.02.01 EP 3
  - Requires a maintenance system is in place that assures reliable equipment function
- EC.02.02.01 EP 4
  - Requires a documented plan for maintenance intervals
- EC.02.02.01 EP 6
  - Requires written procedures for managing equipment failures
- EC.02.04.03 EP 1
  - Requires that all equipment is checked for safety and functionality before initial use
- EC.02.04.03 EP 2
  - Requires that life support equipment is maintained, within schedule, at 100%
- EC.02.04.03 EP 3
  - Requires maintenance on all non-life support, within the department's own guidelines
- EC.04.01.01 EP15
  - Requires an annual evaluation of the equipment management plan, with revisions



### NIBP and ECG standards

- OIML (Edition 2002) International Organization of Legal Metrology
  - R-16-2: Standard for non-invasive automated sphygmomanometers
  - R-90: Electrocardiographs: Metrological Characteristics – Methods and Equipment for Verification
- ANSI/AAMI SP10:2002 / A1:2003 rev 2008/ A2:rev 2006 rev 2008
  - Standard for electronic or automated sphygmomanometers
- ANSI/AAMI EC 13: 2002/ rev 2007 and IEC 60601-2-27
  - Standard for cardiac monitors, heart rate meters, and alarms
- China JJG 692 2009
  - Standard for non-invasive electronic sphygmomanometers

## **Pulse Oximetry standards**

- ISO 9919:2005(E)
  - Medical electrical equipment: particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use. (International Organization for Standardization)
- ISO 80601-2-61 (publication pending)
  - Medical electrical equipment - Part 2-61: Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use. (International Organization for Standardization)
- United States Food and Drug Administration (1992)
  - General guidance document, device: non-invasive pulse oximeter

### **About Fluke Biomedical**

Fluke Biomedical is the world's leading manufacturer of quality biomedical test and simulation products. In addition, Fluke Biomedical provides the latest medical imaging and oncology quality-assurance solutions for regulatory compliance. Highly credentialed and equipped with a NVLAP Lab Code 200566-0 accredited laboratory, Fluke Biomedical also offers the best in quality and customer service for all your equipment calibration needs.

Today, biomedical personnel must meet the increasing regulatory pressures, higher quality standards, and rapid technological growth, while performing their work faster and more efficiently than ever. Fluke Biomedical provides a diverse range of software and hardware tools to meet today's challenges.

### **Fluke Biomedical Regulatory Commitment**

As a medical test device manufacturer, we recognize and follow certain quality standards and certifications when developing our products. We are ISO 9001 and ISO 13485 medical device certified and our products are:

- CE Certified, where required
- NIST Traceable and Calibrated
- UL, CSA, ETL Certified, where required
- NRC Compliant, where required

### **Fluke Biomedical.**

*Better products. More choices. One company.*

#### **Fluke Biomedical**

6045 Cochran Road  
Cleveland, OH 44139-3303 U.S.A.

#### **Fluke Biomedical Europe**

Science Park Eindhoven 5110  
5692EC Son, The Netherlands

#### **For more information, contact us:**

In the U.S.A. (800) 850-4608 or  
Fax (440) 349-2307  
In Europe/M-East/Africa +31 40 267 5435 or  
Fax +31 40 267 5436  
From other countries +1 (440) 248-9300 or  
Fax +1 (440) 349-2307  
Email: [sales@flukebiomedical.com](mailto:sales@flukebiomedical.com)  
Web access: [www.flukebiomedical.com](http://www.flukebiomedical.com)

©2012 Fluke Biomedical. Specifications subject to change without notice. Printed in U.S.A.  
5/2012 4208019A\_EN

**Modification of this document is not permitted without written permission from Fluke Corporation.**