Medaval Comparative-Equivalence Procedure

Authors

Roland Asmar	Yutaka Imai	Andrew Shennan
Neil Atkins	Martin Myers	Jan Staessen
Alejandro de la Sierra	Eoin O'Brien	George S. Stergiou
Peter de Leeuw	Gbenga Ogedegbe	Martin Turner
Eamon Dolan	Takayoshi Ohkubo	Paolo Verdecchia
Przemyslaw Guzik	Paolo Palatini	Bernard Waeber
Geoffrey A. Head	Gianfranco Parati	Jiguang Wang

Effective 23 March 2017

Summary

This document describes equivalence for medical devices in accordance with MEDDEV 2.7/1 revision 4.

- In compliance with Council Directive 93/42/EEC as amended by directive 2007/47/EC
- Used to compare devices described under Medaval Device Registration with Core measurement-critical items indicated as Technical, Clinical or Biological, in accordance with MEDDEV 2.7/1 revision 4
- Identifies how each item is compared to corresponding item on the paired device
- Standard critical core items compared to ensure equality or equivalence, in accordance with MEDDEV 2.7/1 revision 4.
- Identity, Features and Accessories indicted, in Device Registration, compared to identify device differences in accordance with MEDDEV 2.7/1 revision 4.
- Provides summary comparison for equivalent devices
- Identifies "Families" of devices where each pair are equivalent to each other
- Results provided in Clinical Evaluation Reports prepared in accordance with MEDDEV 2.7/1 revision 4.
- Evaluations conducted by renowned experts in Blood Pressure Measurement with proven and published experience in protocol development and validation.

Equivalence and Validation

- Equivalence is independent of validation.
- Validation is only of one functionality, normally the the measurement technology. The particular device used in a validation can be any that uses that technology.
- Validation of a measurement technology is therefore applied to all devices within a family i.e. all those with proven to be equivalent for that technology.
- Existing validations are applied immediately. Subsequent validations are applied once published.
- Equivalence of cuffs means that where one cuff was proved accurate with the technology, all equivalent cuffs can be used also.

Medaval Device Registration

Authors

Roland Asmar	Yutaka Imai	Andrew Shennan
Neil Atkins	Martin Myers	Jan Staessen
Alejandro de la Sierra	Eoin O'Brien	George S. Stergiou
Peter de Leeuw	Gbenga Ogedegbe	Martin Turner
Eamon Dolan	Takayoshi Ohkubo	Paolo Verdecchia
Przemyslaw Guzik	Paolo Palatini	Bernard Waeber
Geoffrey A. Head	Gianfranco Parati	Jiguang Wang

Effective 23 March 2017

Summary

This document provides standardised description requirements for medical devices.

- Standard details for all medical measuring devices
- Specific details for Blood Pressure Monitors
- Specific details for Blood Glucose Meters
- Details for Blood Pressure Cuffs
- Suitable for device descriptions in Clinical Evaluation Reports prepared in accordance with MEDDEV 2.7/1 revision 4.
- In compliance with Council Directive 93/42/EEC as amended by directive 2007/47/EC
- Required supporting documentation specified.
- Standardised descriptions to ensure that all requirements are provided.
- Facilities to extend lists to include new and innovative features

Equivalence and Validation

- Suitable for equivalence comparisons in accordance with MEDDEV 2.7/1 revision 4
- Core measurement-critical items indicated as Technical, Clinical or Biological, in accordance with MEDDEV 2.7/1 revision 4
- Standardised descriptions ensure that equivalence comparisons are clear.
- Critical core items identified so that data and documentary evidence required for equivalence can be provided at the outset.
- Identity, Features and Accessories indicted so that requirements to identify device differences can be provided at the outset.

