

# ISO 17593:2007-04 (E)

## Clinical laboratory testing and in vitro medical devices - Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy

---

<b>Contents</b>		<b>Page</b>
Foreword .....		v
Introduction .....		vi
1	Scope .....	1
2	Normative references .....	1
3	Terms and definitions .....	2
4	Design and development .....	8
4.1	General requirements .....	8
4.2	Measuring interval .....	8
4.3	Safety .....	8
4.4	Risk management .....	8
4.4.1	Acceptability of risks .....	8
4.4.2	Risk assessment .....	8
4.5	Ergonomic and human factor aspects .....	9
4.6	Quality assurance and risk controls .....	9
4.6.1	General .....	9
4.6.2	Measurement verification .....	10
4.6.3	Control of system performance .....	10
4.6.4	Verification of self-testing performance .....	10
4.6.5	Evaluation of user compliance in following the manufacturer's and the physician's instructions .....	10
4.7	Metrological traceability .....	10
5	Information supplied by the manufacturer .....	11
5.1	General requirements .....	11
5.2	Labels for the oral-anticoagulation monitoring instrument .....	11
5.3	Instructions for use of the oral-anticoagulation monitoring system .....	12
5.4	Labels for the reagents and control material .....	13
5.5	Instructions for use for reagents and control material .....	13
6	Safety and reliability testing .....	14
6.1	General requirements .....	14
6.1.1	Protocol .....	14
6.1.2	Instruments and reagents .....	15
6.1.3	Acceptance criteria .....	15
6.2	Protection against electric shock .....	15
6.3	Protection against mechanical hazards .....	15
6.4	Electromagnetic compatibility .....	15
6.5	Resistance to heat .....	15
6.6	Resistance to moisture and liquids .....	15
6.7	Protection against liberated gases, explosion and implosion .....	15
6.8	Instrument components .....	15
6.9	Performance test .....	15
6.10	Mechanical resistance to shock, vibration and impact .....	16
6.10.1	Vibration test protocol .....	16
6.10.2	Drop test protocol .....	16
6.11	Temperature exposure limits .....	16

6.11.1	High-temperature test protocol .....	16
6.11.2	Low-temperature test protocol .....	17
6.12	Humidity-exposure test protocol .....	17
6.13	Reagent storage and use testing .....	17
7	Training and education programs .....	17
7.1	Training of healthcare providers .....	17
7.2	Education of patients and other users .....	18
8	System performance verification .....	19
8.1	General .....	19
8.2	Contributors to measurement uncertainty .....	19
8.3	System performance verification study .....	19
8.4	Verification of measurement precision .....	20
8.4.1	General .....	20
8.4.2	Verification of measurement repeatability .....	20
8.4.3	Verification of intermediate measurement precision .....	21
8.4.4	Data analysis .....	22
8.5	Verification of system accuracy .....	24
8.5.1	General requirements .....	24
8.5.2	Study population .....	24
8.5.3	Samples .....	25
8.5.4	Instruments and reagents .....	25
8.5.5	Manufacturer's selected measurement procedure .....	26
8.5.6	Study design .....	26
8.5.7	Procedure .....	27
8.5.8	Data analysis .....	28
8.6	Minimum acceptable system accuracy .....	31
8.6.1	System accuracy requirement .....	31
8.6.2	System accuracy assessment .....	31
8.6.3	Data presentation .....	32
9	User performance evaluation .....	32
9.1	General .....	32
9.2	Study sites .....	32
9.3	Subjects .....	33
9.4	Instruments and materials .....	33
9.5	Evaluation of user proficiency .....	33
9.6	Acceptance criteria and data assessment .....	34
9.7	Evaluation of instructions for use .....	34
Annex A (normative) Additional requirements for electromagnetic compatibility .....		35
Annex B (informative) Traceability chain examples .....		37
Annex C (informative) Sample size calculation to estimate bias ([42] in the Bibliography) .....		40
Annex D (informative) Example of an uncertainty calculation for a prothrombin INR determination using an oral anticoagulation monitoring system .....		41
Annex E (informative) Elements of quality assurance of oral-anticoagulation monitoring systems ..		45
Annex F (informative) Application of performance criteria to published evaluations of oral- anticoagulation monitoring systems .....		46
Bibliography .....		51