

ISO 5841-2:2014-08 (E)

Implants for surgery - Cardiac pacemakers - Part 2: Reporting of clinical performance of populations of pulse generators or leads

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	General requirements	5
4.1	Frequency of publication	5
4.2	Method of publication	5
4.3	Report organization	5
4.4	Criteria for inclusion and removal of reported models and device families	5
4.5	Source of performance report data	5
4.6	Product performance report -- Required content	6
4.7	Adjustment for underreported events	8
5	Particular reporting requirements	8
5.1	Reporting pulse generator performance	8
5.2	Reporting lead performance	9
Annex A (normative)	Statistical method for survival analysis and discussion of application of results obtained	13
Annex B (informative)	Rationale	22
Bibliography		26