TECHNICAL REPORT

ISO/IEC TR 20017

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Information technology — Radio frequency identification for item management — Electromagnetic interference impact of ISO/IEC 18000 interrogator emitters on implantable pacemakers and implantable cardioverter defibrillators

Technologies de l'information — Identification par radiofréquence pour la gestion des objets — Impact des interférences électromagnétiques des émetteurs d'interrogateurs de l'ISO/CEI 18000 sur les stimulateurs cardiaques et les défibrillateurs implantables

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of information technology, ISO and IEC have established a joint technical committee, ISO/IEC JTC 1.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of the joint technical committee is to prepare International Standards. Draft International Standards adopted by the joint technical committee are circulated to national bodies for voting. Publication as an International Standard requires approval by at least 75 % of the national bodies casting a vote

In exceptional circumstances, when the joint technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide to publish a Technical Report. A Technical Report is entirely informative in nature and shall be subject to review every five years in the same manner as an International Standard.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/IEC TR 20017 was prepared by Joint Technical Committee ISO/IEC JTC 1, *Information technology*, Subcommittee SC 31, *Automatic identification and data capture techniques*.

Introduction

In *The Joy of Science* (2001), Robert Hazen notes the definition of science and the scientific method

— Science is a way of knowing about the natural world based on reproducible observations and experiments.

— The idealized scientific method is a cyclic process of inquiry based on observations, synthesis, hypothesis, and predictions that lead to more observations. At the centre of this idealized cycle there is always a paradigm — a prevailing system of expectations about the natural world.

This scientific method can be visualized in Figure 1, below.

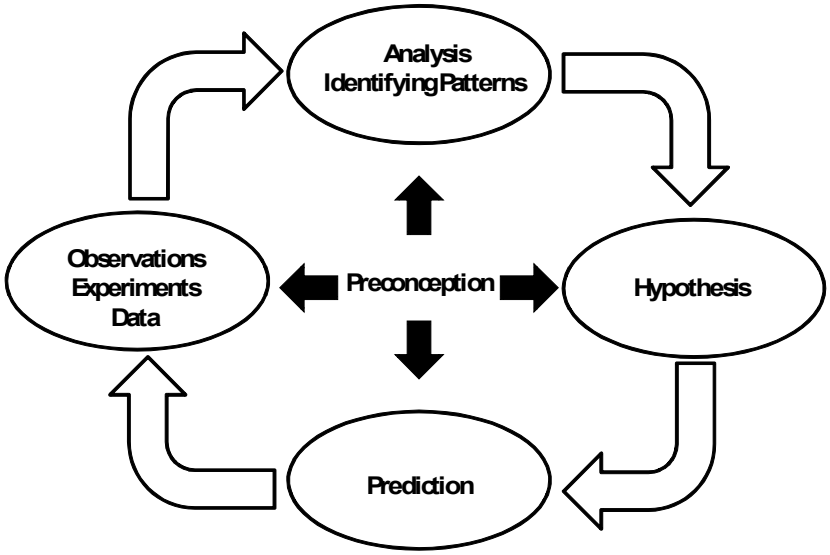

Figure 1 — The Scientific Method

In the world of radio frequency identification there have been numerous applications of this scientific method that have not always yielded reproducible observations.

In the *Journal of the American Medical Association* (JAMA), June 25, 2008—Vol 299, No. 24, Remko van der Togt, MSc, Erik Jan van Lieshout, MD, Reinout Hensbroek, MSc, E. Beinat, PhD, J. M. Binnekade, PhD, and P. J. M. Bakker, MD, PhD [47][1)]. reported that “In 123 EMI tests (3 per medical device), RFID induced 34 EMI incidents: 22 were classified as hazardous, 2 as significant, and 10 as light. The passive 868-MHz RFID signal induced a higher number of incidents (26 incidents in 41 EMI tests; 63%) compared with the active 125-kHz RFID signal (8 incidents in 41 EMI tests; 20%); difference 44% (95% confidence interval, 27%-53%; P<0,001). The passive 868-MHz RFID signal induced EMI in 26 medical devices, including 8 that were also affected by the active 125-kHz RFID signal (26 in 41 devices; 63%). The median distance between the RFID reader and the medical device in all EMI incidents was 30 cm (range, 0.1-600 cm).”

1) Square bracket references can be found in the Bibliography to this Technical Report.

Yet another publication from BlueBean noted a study of radio frequency identification (RFID) testing that was completed on March 10, 2008 at Community North Hospital, Indianapolis, Indiana. This study determined that RFID systems, including near and far field antennas and passive tags, did not influence the performance of commonly used medical devices such as physiological monitors and intravenous pumps.

Would either of these studies be scientific fraud because their experiments yielded different results? Or would it be more likely that different makes and models of RFID interrogators were tested? Or were different makes and models of clinical equipment tested? Or were there variations in both input variables?

In reality, there are multiple studies and there is not agreement between the studies. The differences between the studies are most likely based on different test protocols and different devices tested. The science of implanted devices is one of constant improvement and today's devices are likely to exhibit significantly different results from those used in this test.

This Technical Report looks at the various public reports on the electromagnetic compatibility between RFID interrogators, implantable cardiac pacemakers (pacemakers), and implantable cardioverter defibrillators (ICDs). This Technical Report further recommends the development of a uniform testing protocol and a repository of test results from experiments using those test protocols.

Information technology — Radio frequency identification for item management — Electromagnetic interference impact of ISO/IEC 18000 interrogator emitters on implantable pacemakers and implantable cardioverter defibrillators

1 Scope

This Technical Report presents a test method and results for the evaluation of ISO/IEC 18000 radio frequency identification (RFID) interrogator electromagnetic interference (EMI) on implantable pacemakers and implantable cardioverter defibrillators.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14708-1, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

ISO 14708-2, *Implants for surgery — Active implantable medical devices — Part 2: Cardiac pacemakers*

ISO/IEC 19762-1, *Information technology — Automatic identification and data capture (AIDC) techniques — Harmonized vocabulary — Part 1: General terms relating to AIDC*

ISO/IEC 19762-3, *Information technology — Automatic identification and data capture (AIDC) techniques — Harmonized vocabulary — Part 3: Radio frequency identification (RFID)*

ISO/IEC 19762-4, *Information technology — Automatic identification and data capture (AIDC) techniques — Harmonized vocabulary — Part 4: General terms relating to radio communications*

ANSI/AAMI/IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

AAMI TIR18:2010, *Guidance on electromagnetic compatibility of medical devices in healthcare facilities*

ANSI/AAMI PC69, *Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators*