SVENSK STANDARD
SS-EN ISO 80601-2-13:2022

Elektrisk utrustning för medicinskt bruk – Del 2-13: Särskilda krav på grundläggande säkerhet och funktion för anestesiarbetsstationer (ISO 80601-2-13:2022)

Medical electrical equipment – Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation (ISO 80601-2-13:2022)

Svenska Institutet för Standarder

Språk: engelska/English
Utgåva: 2

Denna standard är såld av
SEK Svensk Elstandard som även lämnar
allmänna upplysningar om svensk och utländsk standard.
Postadress: SEK, Box 1284, 164 29 Kista
Telefon: 08-444 14 00.
E-post: sek@elstandard.se Internet: www.elstandard.se

Svenska Institutet för Standarder

Den här standarden kan hjälpa dig att effektivisera och kvalitetssäkra ditt arbete. SIS har fler tjänster att erbjuda dig för att underlätta tillämpningen av standarder i din verksamhet.

SIS Abonnemang
Snabb och enkel åtkomst till gällande standard med SIS Abonnemang, en prenumerationstjänst genom vilken din organisation får tillgång till all världens standarder, senaste uppdateringarna och där hela din organisation kan ta del av innehållet i prenumerationen.

Utbildning, event och publikationer
Vi erbjuder även utbildningar, rådgivning och event kring våra mest sålda standarder och frågor kopplade till utveckling av standarder. Vi ger också ut handböcker som underlättar ditt arbete med att använda en specifik standard.

Vill du delta i ett standardiseringsprojekt?
Genom att delta som expert i någon av SIS 300 tekniska kommittéer inom CEN (europeisk standardisering) och/eller ISO (internationell standardisering) har du möjlighet att påverka standardiseringsarbetet i frågor som är viktiga för din organisation. Välkommen att kontakta SIS för att få veta mer!

Kontakt
Skriv till kundservice@sis.se, besök sis.se eller ring 08 - 555 523 10

Upplysningar om sakinnehållet i standarden lämnas av Svenska institutet för standarder, telefon 08 - 555 520 00. Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.

Standarden är framtagen av kommittén för Anestesi- och respiratorutrustning, SIS/TK 329.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

Fastställd: 2022-06-21
ICS: 11.040.10

Svenska Institutet för Standarder

Europastandarden EN ISO 80601-2-13:2022 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 80601-2-13:2022.

Denna standard ersätter SS-EN ISO 80601-2-13:2012, utgåva 1 och
SS-EN ISO 80601-2-13:2012/A1:2019, utgåva 1 och SS-EN ISO 80601-2-13:2012/A2:2019, utgåva 1.

The European Standard EN ISO 80601-2-13:2022 has the status of a Swedish Standard. This document contains the official version of EN ISO 80601-2-13:2022.

This standard supersedes the SS-EN ISO 80601-2-13:2012, edition 1 and
SS-EN ISO 80601-2-13:2012/A1:2019, edition 1 and SS-EN ISO 80601-2-13:2012/A2:2019, edition 1.

Svenska Institutet för Standarder

LÄSANVISNINGAR FÖR STANDARDER

I dessa anvisningar behandlas huvudprinciperna för hur regler och yttre begränsningar anges i standardiseringsprodukter.

Krav
Ett krav är ett uttryck i ett dokuments innehåll som anger objektivt verifierbara kriterier som ska uppfyllas och från vilka ingen avvikelse tillåts om efterlevnad av dokumentet ska kunna åberopas.Krav uttrycks med hjälpverbet **ska** (eller **ska inte** för förbud).

Rekommendation
En rekommendation är ett uttryck i ett dokuments innehåll som anger en valmöjlighet eller ett tillvägagångssätt som bedöms vara särskilt lämpligt utan att nödvändigtvis nämna eller utesluta andra. Rekommendationer uttrycks med hjälpverbet **bör** (eller **bör inte** för avrådanden).

Instruktion
Instruktioner anges i imperativ form och används för att ange hur något görs eller utförs. De kan underordnas en annan regel, såsom ett krav eller en rekommendation. De kan även användas självständigt, och är då att betrakta som krav.

Förklaring
En förklaring är ett uttryck i ett dokuments innehåll som förmedlar information. En förklaring kan uttrycka tillåtelse, möjlighet eller förmåga. Tillåtelse uttrycks med hjälpverbet **får**. Inom standardiseringen saknas rekommenderad nekande motsats till hjälpverbet får, förbud uttrycks med **ska inte** enligt reglerna för krav. Möjlighet och förmåga uttrycks med hjälpverbet **kan** (eller motsatsen **kan inte**).

READING INSTRUCTIONS FOR STANDARDS

These instructions cover the main principles for the use of provisions and external constraints in standardization deliverables.

Requirement
A requirement is an expression, in the content of a document, that conveys objectively verifiable criteria to be fulfilled, and from which no deviation is permitted if conformance with the document is to be claimed. Requirements are expressed by the auxiliary **shall** (or **shall not** for prohibition).

Recommendation
A recommendation is an expression, in the content of a document, that conveys a suggested possible choice or course of action deemed to be particularly suitable, without necessarily mentioning or excluding others. Recommendations are expressed by the auxiliary **should** (or **should not** for dissuasion).

Instruction
An instruction is expressed in the imperative mood and is used in order to convey an action to be performed. It can be subordinated to another provision, such as a requirement or a recommendation. It can also be used independently and is then to be regarded as a requirement.

Statement
A statement is an expression, in the content of a document, that conveys information. A statement can express permission, possibility or capability. Permission is expressed by the auxiliary **may**. There is no recommended opposite expression for the auxiliary may in standardization, prohibition is expressed by the use of **shall not** in accordance with the rules for requirements. Possibility and capability are expressed by the auxiliary **can** (its opposite being **cannot**).

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-13

June 2022

ICS 11.040.10

Supersedes EN ISO 80601-2-13:2012

English Version

Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation (ISO 80601-2-13:2022)

Appareils électromédicaux - Partie 2-13: Exigences particulières de sécurité de base et de performances essentielles pour les postes de travail d'anesthésie (ISO 80601-2-13:2022)

Medizinische elektrische Geräte - Teil 2-13: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für Anästhesie-Arbeitsplätzen (ISO 80601-2-13:2022)

This European Standard was approved by CEN on 25 May 2022.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives or www.iec.ch/members_experts/refdocs).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents) or the IEC list of patent declarations received (see patents.iec.ch).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html. In the IEC, see www.iec.ch/understanding-standards.

This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*, and Technical Committee IEC/TC 62 *Electrical equipment in medical practice*, Subcommittee SC 62D *Electromedical equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 80601-2-13:2011), which has been technically revised. It also incorporates the Amendments ISO 80601-2-13:2011/Amd 1:2015 and ISO 80601-2-13:2011/Amd 2:2018.

The main changes are as follows:

— update of normative references;

— update of terms and definitions;

— consideration of *anaesthetic workstations* using Oxygen 93;

— addition of requirements for *expected service life*;

— amendment of the requirements on test equipment;

— amendment of the requirements on warning and safety notices, on the instructions for use and on the technical description as well as design documentation;

— addition of marking requirements regarding the suitability of *anaesthetic workstations* and its components for use in a magnetic resonance environment;

— amendment of the requirements on compatibility with substances used with the *anaesthetic workstation* and its components;

— amendment of the requirements on *internal electrical power source*;

— amendment of the requirements on the exhaled volume *monitoring equipment*;

— amendment of the requirements on detachable, flow-direction-sensitive parts and accessories;

— amendment of the requirements on *multiple socket-outlets*;

— amendment of the requirements and recommendations for signal input/signal output part;

— amendment of the requirements on the flow-rate adjustment control;

— amendment of the requirements on the *maximum limited pressure protection device*;

— amendment of the requirements on the reservoir bag port connection port connector;

— amendment of the requirements on the inspiratory and expiratory pressure/flow rate characteristics

— amendment of the requirements on *breathing tubes* and *breathing tube* sets;

— amendment of the requirements on circle absorber assemblies;

— addition of requirements on ventilation modes;

— amendment of the requirements on *anaesthetic gas scavenging systems* by differentiation between active and non-active systems;

— amendment of the requirements on *anaesthetic ventilators* in case of interruption of the electrical or pneumatic *power supply*.

A list of all parts in the ISO 80601 and the IEC 80601 series can be found on the ISO and IEC websites.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html and www.iec.ch/national-committees.

European foreword

This document (EN ISO 80601-2-13:2022) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2022, and conflicting national standards shall be withdrawn at the latest by June 2025.

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

This document supersedes EN ISO 80601-2-13:2012.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-13:2022 has been approved by CEN as EN ISO 80601-2-13:2022 without any modification.

Introduction

In this document, the following print types are used:

— Requirements and definitions: roman type.

— Terms defined in Clause 3 of the general standard, in this particular standard and test specifications: italic type.

— Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

In referring to the structure of this document, the term

— “clause” means one of the eight numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);

— “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.12 are all subclauses of Clause 201.7).

References to clauses within this document are preceded by the term “Clause” followed by the clause number. References to subclauses within this document are by number only.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

For the purposes of this document, the auxiliary verb:

— “shall” means that conformance with a requirement or a test is mandatory for conformity with this document;

— “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

— “may” is used to describe permission (e. g. a permissible way to achieve conformance with a requirement or test);

— "can" is used to describe a possibility or capability; and

— "must" is used to express an external constraint.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

This document considers both an *anaesthetic workstation* supplied complete and its individual components in combination with its *accessories*. It has been structured to allow *responsible organizations* to configure an *anaesthetic workstation* from individual components in conformance with professional guidelines and to meet the needs of their clinical practice. In order to achieve this aim, this document identifies particular requirements pertinent to specific *anaesthetic workstation* components, including associated *monitoring equipment*, *alarm system(s)* and *protection device(s),* and defines the interfaces.

Thus this document also defines requirements for individual components that can be used to form *an anaesthetic workstation*.

The following table identifies the individual components of an *anaesthetic workstation* and provides an overview of the structure of this document.

Table 201.101 — Configuration of an *anaesthetic workstation* and corresponding organization of this document

<table>
<tr><td colspan="3">anaesthetic workstation</td></tr>
<tr><td>General requirements
Clauses 201.1 – 201.17, 201.106, 201.107, 202-212</td><td rowspan="3">including associated monitoring equipment, alarm systems and protection devices</td><td rowspan="3">These are mandatory components;
see also Table AA.1</td></tr>
<tr><td>anaesthetic gas delivery system
Clause 201.101</td></tr>
<tr><td>anaesthetic breathing system
Clause 201.102</td></tr>
<tr><td>anaesthetic gas scavenging system (AGSS)
Clause 201.103</td><td rowspan="3">including associated monitoring equipment, alarm systems and protection devices</td><td rowspan="3">These are optional components;
see also Table AA.1</td></tr>
<tr><td>anaesthetic vapour delivery system
Clause 201.104</td></tr>
<tr><td>anaesthetic ventilator
Clause 201.105</td></tr>
</table>

Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation

201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

NOTE The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

201.1.1 * Scope

Replacement:

This document is applicable to the *basic safety* and *essential performance* of an *anaesthetic workstation* for administering inhalational anaesthesia whilst continuously attended by a professional *operator*.

This document specifies particular requirements for a complete *anaesthetic workstation* and the following *anaesthetic workstation* components which, although considered as individual devices in their own right, may be utilized, in conjunction with other relevant *anaesthetic workstation* components, to form an *anaesthetic workstation* to a given specification:

— *anaesthetic gas delivery system;*

— *anaesthetic breathing system;*

— *anaesthetic gas scavenging system (AGSS);*

— *anaesthetic vapour delivery system;*

— *anaesthetic ventilator;*

— *monitoring equipment;*

— *alarm system;*

— *protection device.*

NOTE 1 *Monitoring equipment, alarm systems* and *protection devices* are summarized in Table AA.1.

An *anaesthetic workstation* supplied complete and its individual components are considered as *ME equipment* or *ME systems* with regard to the general standard.

NOTE 2 The applicability of this document is indicated in Table AA.2.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to an *anaesthetic workstation* where the characteristics of those *accessories* can affect the *basic safety* and *essential performance* of the *anaesthetic workstation.*

If a clause or subclause is specifically intended to be applicable to *anaesthetic workstation* components or its *accessories* only, the title and content of that clause or subclause will say so. If that is not the case,

the clause or subclause applies both to an *anaesthetic workstation* and its individual components including *accessories*, as relevant.

Hazards inherent in the intended physiological function of an *anaesthetic workstation* and its individual components including *accessories* within the scope of this document are not covered by specific requirements in this document except in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.2.13 and 8.4.1.

NOTE 3 See also IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.2.

This document is not applicable to any *anaesthetic workstation* intended for use with flammable anaesthetic agents, as determined by Annex BB.

201.1.2 Object

Replacement:

The object of this document is to establish particular *basic safety* and *essential performance* requirements for an *anaesthetic workstation* and its individual components designed for use in the *anaesthetic workstation* (as defined in 201.3.210) and its *accessories*.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this document.

IEC 60601-1-3:2008+AMD1:2013+AMD2:2021, IEC 60601-1-9:2007+AMD1:2013+AMD2:2020, IEC 60601-1-11:2015+A1:2020 do not apply.

201.1.4 *Particular standards

Addition:

The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1 (the general standard) with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 206.4 in this document addresses the content of Clause 4 of the IEC 60601-1-6 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this document.

"Addition" means that the text of this document is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 to 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 206 for IEC 60601-1-6, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

If an *anaesthetic workstation* is supplied with physiological monitoring, having more than one *applied part* on the *patient*, then IEC 80601-2-49:2018 applies. Measured parameters related to the inherent function of an *anaesthetic workstation* (i.e. *airway pressure*, ventilation volume, oxygen concentration, volatile anaesthetic agent concentration, CO_2/N_2O), including derived and related parameters such as spontaneous ventilation volume or CO_2 production, are not considered to be a *physiological monitoring unit* as per IEC 80601-2-49.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

Clause 2 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

Addition:

ISO 407:2021, *Small medical gas cylinders — Pin-index yoke-type valve connections*

ISO 5145:2017, *Gas cylinders — Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning*

ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5356-2:2012+AMD1:2019, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 5359:2014 +AMD1:2017, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

ISO 5360:2016, *Anaesthetic vaporizers — Agent-specific filling systems*

ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 7396-1:2016+AMD1:2017, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 7396-2:2007, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems*

ISO 9170-1:2017, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 9170-2:2008, *Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems*

ISO 10524-1:2018, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 10993-1:2018, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 18082:2014+AMD1:2017, *Anaesthetic and respiratory equipment — Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases*

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 80369-7:2016, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ISO 80601-2-55:2018, *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

ISO/IEC 80079-20-1:2017, *Explosive atmospheres — Part 20-1: Material characteristics for gas and vapour classification — Test methods and data*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-10:2007+AMD1:2013+AMD2:2020, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral standard: Requirements for the development of physiologic closed-loop controllers*

IEC 60601-1-12:2014+AMD1:2020, *Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment*

IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*