Elektrilised meditsiiniseadmed. Osa 2-13: Erinõuded anasteesiasüsteemide ohutusele ja olulisele toimivusele

Medical electrical equipment Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 60601-2-13:2006 sisaldab Euroopa standardi EN 60601-2-13:2006 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-13:2006 consists of the English text of the European standard EN 60601-2-13:2006.
Standard on kinnitatud Eesti Standardikeskuse 22.09.2006 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 22.09.2006 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 28.06.2006.	Date of Availability of the European standard text 28.06.2006.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.10

Võtmesõnad:

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-13

June 2006

ICS 11.040.10

English version

Medical electrical equipment
Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems
(IEC 60601-2-13:2003)

Appareils électromédicaux
Partie 2-13: Règles particulières de sécurité et performance essentielle pour les systèmes d'anesthésie
(CEI 60601-2-13:2003)

Medizinische elektrische Geräte
Teil 2-13: Besondere Festlegungen für die Sicherheit von Anästhesiesystemen
(IEC 60601-2-13:2003)

This European Standard was approved by CENELEC on 2006-05-01. CENELEC 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 Central Secretariat or to any CENELEC 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 CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Ref. No. EN 60601-2-13:2006 E

Foreword

The text of the International Standard IEC 60601-2-13:2003, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, and ISO TC 121/SC 1, Breathing attachments and anaesthetic machines, was submitted to the Unique Acceptance Procedure and was approved by CENELEC as EN 60601-2-13 on 2006-05-01.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2007-05-01
- latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2009-05-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

This European Standard partly replaces EN 740:1998, *Anaesthetic workstations and their modules - Particular requirements.*

Other European Standards relating to anaesthetic workstations and their components prepared or in preparation by CEN/TC215 which, when all published will together with EN 60601-2-13:2006 replace EN 740:1998 in total, are:

– prEN ISO/DIS 8835-2:2005, *Inhalational anaesthesia systems – Part 2: Anaesthetic breathing systems for adults*

– prEN ISO/DIS 8835-3.2:2005, *Inhalational anaesthesia systems – Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems*

– EN ISO 8835-4:2004, *Inhalational anaesthesia systems – Part 4: Anaesthetic vapour delivery devices*

– EN ISO 8835-5:2004, *Inhalational anaesthesia systems – Part 5: Anaesthetic ventilators*

Attention is also drawn to ISO/TS 18835:2004, *Inhalational anaesthesia systems — Draw-over vaporizers and associated equipment.*

In this standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: roman type;

– explanations, advice, notes, general statements, exceptions and references: small roman type;

– *test specifications: italic type;*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR OF THIS PARTICULAR STANDARD: SMALL CAPITALS.

Annexes ZA and ZZ have been added by CENELEC.

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Endorsement notice

The text of the International Standard IEC 60601-2-13:2003 was approved by CENELEC as a European Standard without any modification.

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60079-4	1975	Electrical apparatus for explosive gas atmospheres Part 4: Method of test for ignition temperature	-	-
IEC 60079-11	1999	Electrical apparatus for explosive gas atmospheres Part 11: Intrinsic safety "i"	-	-
ISO 32	1977	Gas cylinders for medical use - Marking for identification of content	-	-
ISO 407	1991	Small medical gas cylinders - Pin-index yoke-type valve connections	-	-
ISO 3746	1995	Acoustics - Determination of sound power levels of noise sources using sound pressure Survey method using an enveloping measurement surface over a reflecting plane	-	-
ISO 4135	2001	Anaesthetic and respiratory equipment - Vocabulary	-	-
ISO 5145	1990	Cylinder valve outlets for gases and gas mixtures - Selection and dimensioning	-	-
ISO 5356-1	1996	Anaesthetic and respiratory equipment - Conical connectors Part 1: Cones and sockets	-	-
ISO 5356-2	1987	Anaesthetic and respiratory equipment - Conical connectors Part 2: Screw-threaded weight-bearing connectors		-
ISO 5359	2000	Low-pressure hose assemblies for use with medical gas systems	-	-
ISO 5362	2000	Anaesthetic reservoir bags	-	-
ISO 7396-1	2002	Medical gas pipeline systems Part 1: Pipelines for compressed medical gases and vacuum	-	-

Publication	Year	Title	EN/HD	Year
ISO 7767[1)]	1997	Oxygen monitors for monitoring patient breathing mixtures - Safety requirements	-	-
ISO 8835-2	1999	Inhalational anaesthesia systems Part 2: Anaesthetic breathing systems for adults	-	-
ISO 8835-3	1997	Inhalational anaesthesia systems Part 3: Anaesthetic gas scavenging systems - Transfer and receiving systems	-	-
ISO 8835-4	2004	Inhalational anaesthesia systems Part 4: Anaesthetic vapour delivery devices	-	-
ISO 8835-5	2004	Inhalational anaesthesia systems Part 5: Anaesthetic ventilators	-	-
ISO 9170-1	1999	Terminal units for medical gas pipeline systems Part 1: Terminal units for use with compressed medical gases and vacuum	-	-
ISO 9703-1[2)]	1992	Anaesthesia and respiratory care alarm signals Part 1: Visual alarm signals	-	-
ISO 9703-2[2)]	1994	Anaesthesia and respiratory care alarm signals Part 2: Auditory alarm signals	-	-
ISO 9703-3[2)]	1998	Anaesthesia and respiratory care alarm signals Part 3: Guidance on application of alarms	-	-
ISO 9918[1)]	1993	Capnometers for use with humans - Requirements	-	-
ISO 10524[3)]	1995	Pressure regulators and pressure regulators with flow-metering devices for medical gas systems	-	-
ISO 11196[1)]	1995	Anaesthetic gas monitors	-	-
ISO 15223	2000	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied		-

[1)] ISO 7767:1997, ISO 9918:1993 and ISO 11196:1995 are superseded by ISO 21647:2004, which is harmonized as EN ISO 21647:2004, *Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors.*

[2)] The ISO 9703 series is superseded by IEC 60601-1-8:2003, which is harmonized as EN 60601-1-8:2004.

[3)] ISO 10524:1995 is superseded by ISO 10524-1:2006, which is harmonized as EN ISO 10524-1:2006, *Pressure regulators for use with medical gases -- Part 1: Pressure regulators and pressure regulators with flow-metering devices.*

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

INTERNATIONAL STANDARD

IEC 60601-2-13

Third edition
2003-05

Medical electrical equipment –

Part 2-13:
Particular requirements for the safety and essential performance of anaesthetic systems

Appareils électromédicaux –

Partie 2-13:
Règles particulières de sécurité et performance essentielle pour les systèmes d'anesthésie

Reference number
IEC 60601-2-13:2003(E)

Publication numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series. For example, IEC 34-1 is now referred to as IEC 60034-1.

Consolidated editions

The IEC is now publishing consolidated versions of its publications. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

Further information on IEC publications

The technical content of IEC publications is kept under constant review by the IEC, thus ensuring that the content reflects current technology. Information relating to this publication, including its validity, is available in the IEC Catalogue of publications (see below) in addition to new editions, amendments and corrigenda. Information on the subjects under consideration and work in progress undertaken by the technical committee which has prepared this publication, as well as the list of publications issued, is also available from the following:

- **IEC Web Site (www.iec.ch)**

- **Catalogue of IEC publications**

  The on-line catalogue on the IEC web site (http://www.iec.ch/searchpub/cur_fut.htm) enables you to search by a variety of criteria including text searches, technical committees and date of publication. On-line information is also available on recently issued publications, withdrawn and replaced publications, as well as corrigenda.

- **IEC Just Published**

  This summary of recently issued publications (http://www.iec.ch/online_news/justpub/jp_entry.htm) is also available by email. Please contact the Customer Service Centre (see below) for further information.

- **Customer Service Centre**

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  Email: custserv@iec.ch
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INTERNATIONAL STANDARD

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PRICE CODE X

For price, see current catalogue

CONTENTS

SECTION 101 – ADDITIONAL CLAUSES SPECIFIC TO ANAESTHETIC GAS DELIVERY SYSTEMS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-13 has been developed by a Joint Working Group consisting of IEC/SC 62D, Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and ISO TC 121/SC 1, Breathing attachments and anaesthetic machines.

It is published as double logo standard.

This third edition cancels and replaces the second edition published in 1998. This edition constitutes a technical revision.

The text of this Particular Standard is based on the following documents:

FDIS	Report on voting
62D/475/FDIS	62D/476/RVD

Full information on the voting for the approval of this Particular Standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 13 P-members out of 13 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this Particular Standard, the following print types are used:

– requirements, compliance with which can be tested and definitions: roman type;

– explanations, advice, notes, general statements, exceptions and references: smaller type;

– *test specifications: italic type*;

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR OF THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2007. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

INTRODUCTION

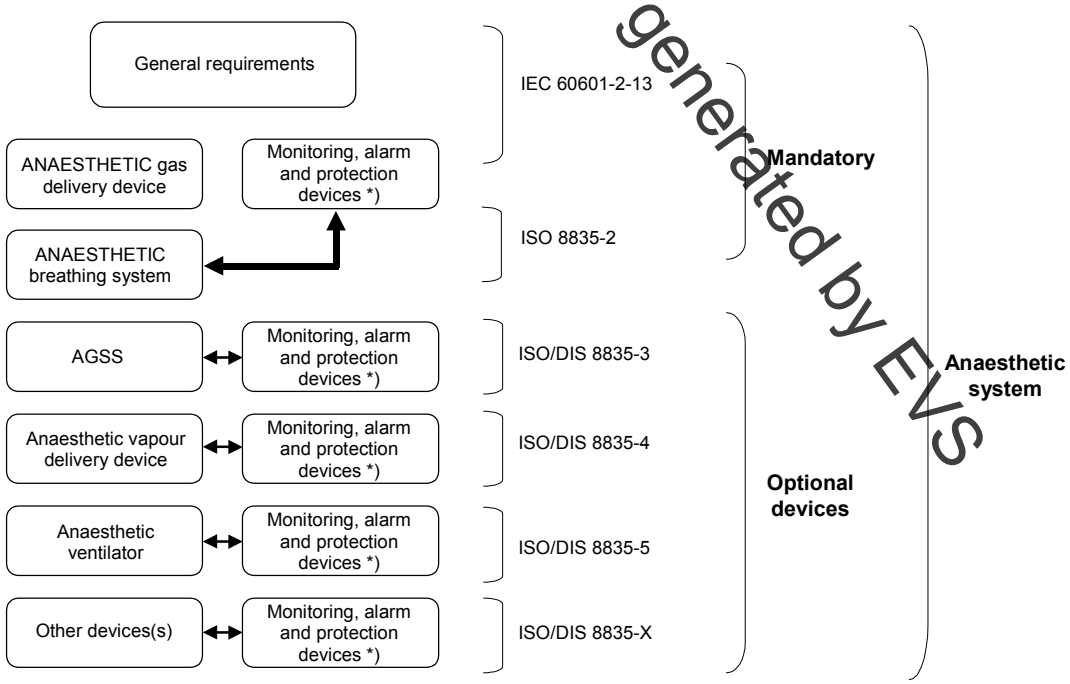
In response to requests for harmonization between the current European and International standards for anaesthetic workstations this standard has been developed by the IEC/ISO Joint Working Group to specify requirements for ANAESTHETIC SYSTEMS supplied complete, as well as requirements for individual devices which are intended to be part of an ANAESTHETIC SYSTEM. It applies in conjunction with IEC 60601-1:1988 (Including all amendments) hereafter referred to as the General Standard. As stated in 1.3 of IEC 60601-1-1988, the requirements in this standard take priority over those of the General Standard.

This standard has been structured to allow USERS to configure an ANAESTHETIC SYSTEM in conformance with professional guidelines and to meet the needs of their clinical practice. In order to achieve this aim, the standard identifies particular requirements pertinent to specific devices, and to their associated MONITORING DEVICE(S), ALARM SYSTEM(s) and PROTECTION DEVICE(S), and defines the interfaces. This standard also specifies requirements for optional devices, together with their respective MONITORING DEVICE(S), ALARM SYSTEM(S) and PROTECTION DEVICE(S).

The indicated requirements are followed by specifications for the relevant tests. An asterisk (*) denotes clauses for which there is a rationale comment in Annex AA. It is considered that knowledge of the reasons for these requirements will facilitate the proper application of the standard and be of use in any revision that may be necessitated by changes in clinical practice or as a result of developments in technology.

NOTE The decimal separator for all numeric values is "," (comma).

The following graphic representation of the structure of this standard is being provided for informational purposes only.



MEDICAL ELECTRICAL EQUIPMENT–

Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition

This Particular Standard specifies safety and essential performance requirements for an ANAESTHETIC SYSTEM (as defined in 2.101.7) as well as individual devices designed for use in an ANAESTHETIC SYSTEM.

This Particular Standard does not apply to:

– ANAESTHETIC SYSTEM(S) intended for use with flammable anaesthetic agents, as determined by Annex DD,

– portable ANAESTHETIC SYSTEM(S) for use in remote sites, open fields for rescue operations or in disaster areas,

– dental analgesia apparatus.

1.2 Object

Replacement:

The object of this Particular Standard is to specify particular safety and essential performance requirements for individual devices designed for use in an ANAESTHETIC SYSTEM as well as specific requirements for the ANAESTHETIC GAS DELIVERY SYSTEM. This standard specifies requirements and defines interfaces for:

– individual devices designed for use in an ANAESTHETIC SYSTEM(S), and

– integrated ANAESTHETIC SYSTEMS.

1.3 Particular Standards

This Particular Standard amends and supplements a set of IEC publications consisting of IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, its amendment 1 (1991) and amendment 2 (1995), hereinafter referred to as the “General Standard”.

The General Standard takes into account IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems* and IEC 60601-1-2 2001, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.*

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with that of the General Standard. 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 is replaced completely by the text of this Particular Standard.

“Addition” means that the text of this Particular Standard is additional to the requirements of the General Standard.

“Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

The term "this standard" covers this Particular Standard, used together with the General Standard and the Collateral Standards.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

The requirements of this Particular Standard replacing or modifying requirements of the General Standard or a Collateral Standard take precedence over the corresponding general requirement(s).

1.3.101 Related International Standards

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.

IEC 60079-4:1975, *Electrical apparatus for explosive gas atmospheres – Part 4: Method of test for ignition temperature*

IEC 60079-11:1999, *Electrical apparatus for explosive gas atmospheres – Part 11: Intrinsic safety"*

ISO 32:1977, *Gas cylinders for medical use – Marking for identification of content*

ISO 407:1991, *Small medical gas cylinders – Pin-index yoke-type valve connections*

ISO 3746:1995, *Acoustics – Determination of sound power levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane*

ISO 4135:2001, *Anaesthetic and respiratory equipment – Vocabulary*

ISO 5145:1990, *Cylinder valve outlets for gases and gas mixtures – Selection and dimensioning*

ISO 5356-1:1996, *Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets*

ISO 5356-2:1987, *Anaesthetic and respiratory equipment – Conical connectors – Part 2: Screw-threaded, weight-bearing connectors*

ISO 5359:2000, *Low-pressure hose assemblies for use with medical gases*

ISO 5362:2000, *Anaesthetic reservoir bags*

ISO 7396-1:2002, *Medical gas pipeline systems – Part 1: Pipelines for compressed medical gases and vacuum*

ISO 7767:1997, *Oxygen monitors for monitoring patient breathing mixtures – Safety requirements*

ISO 8835-2:1999, *Inhalational anaesthesia systems – Part 2: Anaesthetic breathing systems for adults*

ISO 8835-3:1997, *Inhalational anaesthesia systems – Part 3: Anaesthetic gas scavenging systems – Transfer and receiving systems*

ISO 8835-4, *Inhalational anaesthesia systems – Part 4: Anaesthetic vapour delivery devices* [1)]

ISO 8835-5, *Inhalational anaesthesia systems – Part 5: Requirements for anaesthetic ventilators* [2)]

ISO 9170-1:1999, *Terminal units for medical gas pipeline systems – Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 9703-1:1992, *Anaesthesia and respiratory care alarm signals – Part 1: Visual alarm signals*

ISO 9703-2:1994, *Anaesthesia and respiratory care alarm signals – Part 2: Auditory alarm signals*

ISO 9703-3, *Anaesthesia and respiratory care alarm signals – Part 3: Guidance on application of alarms*

ISO 9918:1993, *Capnometers for use with humans – Requirements*

ISO 10524:1995, *Pressure regulators and pressure regulators with flow-metering devices for medical gas systems*

ISO 11196:1996, *Anaesthetic gas monitors*

ISO 15223:2000, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied*

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1) To be published.

2) To be published.