IEC 61340-6-1

Edition 1.1 2024-10
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

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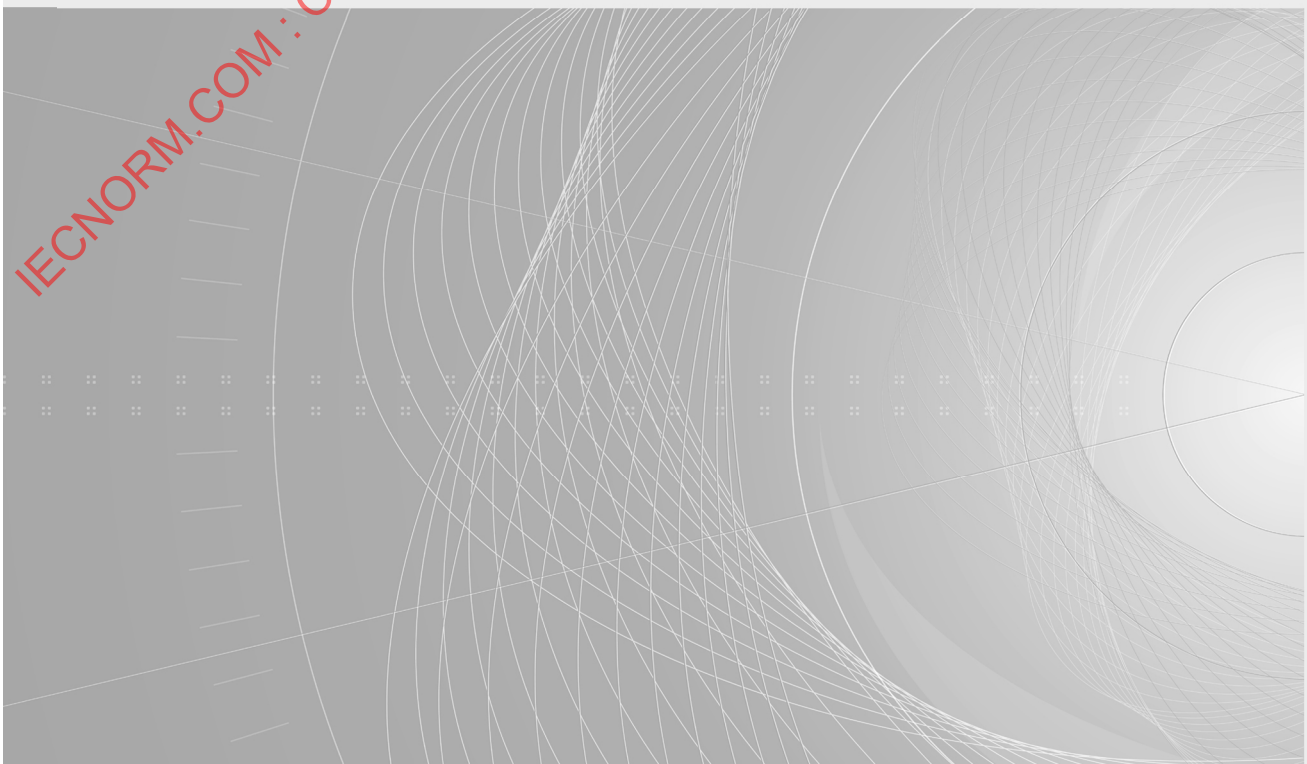
Electrostatics –
Part 6-1: ~~Electrostatic control for healthcare – General requirements for facilities~~ Electrostatic control in healthcare, commercial and public facilities – Healthcare



IEC 61340-6-1:2018-09+AMD1:2024-10 CSV(en)

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 17.220.99, 29.020, 11.020.99

ISBN 978-2-8322-9913-5

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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ELECTROSTATICS –

Part 6-1: ~~Electrostatic control for healthcare – General requirements for facilities~~ Electrostatic control in healthcare, commercial and public facilities – Healthcare

FOREWORD

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This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 61340-6-1 edition 1.1 contains the first edition (2018-09) [documents 101/566/FDIS and 101/570/RVD] and its amendment 1 (2024-10) [documents 101/713/FDIS and 101/720/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough

red text. A separate Final version with all changes accepted is available in this publication.

International Standard IEC 61340-6-1 has been prepared by IEC technical committee 101: Electrostatics.

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

A list of all parts in the IEC 61340 series, published under the general title *Electrostatics*, can be found on the IEC website.

The committee has decided that the contents of this document and its amendment will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

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INTRODUCTION

Static electricity can be the source of several hazards to patients, staff and equipment in healthcare facilities. Such hazards include:

- electromagnetic disturbance or electrostatic discharge (ESD) disruption or damage to medical instrumentation and data processing equipment;
- damage to ESD susceptible electronic components and assemblies during service and maintenance;
- electrostatic attraction (ESA) and contamination;
- ignition of flammable gases, liquids and other materials, and
- electrostatic shocks to people.

Adequate electrostatic control can eliminate these hazards, or at least reduce residual risk to tolerable levels.

ELECTROSTATICS –

Part 6-1: ~~Electrostatic control for healthcare – General requirements for facilities~~ Electrostatic control in healthcare, commercial and public facilities – Healthcare

1 Scope

This part of IEC 61340 applies to facilities that provide healthcare including hospitals, care centres and clinics.

This document provides technical requirements and recommendations for controlling electrostatic phenomena in healthcare facilities, which includes requirements for equipment, materials, and products used to control static electricity.

The requirements of this document do not apply to medical electrical equipment specified in IEC 60601-1 [1] [1] and in vitro diagnostic (IVD) medical equipment specified in IEC 61010-2-101 [2].

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.

IEC 60364-7-710, ~~*Electrical installations of buildings*~~ *Low-voltage electrical installations – Part 7-710: Requirements for special installations or locations – Medical locations*

IEC TR 61340-1, *Electrostatics – Part 1: Electrostatic phenomena – Principles and measurements*

IEC 61340-2-1, *Electrostatics – Part 2-1: Measurement methods – Ability of materials and products to dissipate static electric charge*

IEC 61340-2-3, *Electrostatics – Part 2-3: Methods of test for determining the resistance and resistivity of solid materials used to avoid electrostatic charge accumulation*

IEC 61340-4-1, *Electrostatics – Part 4-1: Standard test methods for specific applications – Electrical resistance of floor coverings and installed floors*

IEC TS 61340-4-2:2013, *Electrostatics – Part 4-2: Standard test methods for specific applications – Electrostatic properties of garments*

IEC 61340-4-3, *Electrostatics – Part 4-3: Standard test methods for specific applications – Footwear*

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1 Numbers in square brackets refer to the bibliography.

IEC 61340-4-5, *Electrostatics – Part 4-5: Standard test methods for specific applications – Methods for characterizing the electrostatic protection of footwear and flooring in combination with a person*

IEC 61340-5-1, *Electrostatics – Part 5-1: Protection of electronic devices from electrostatic phenomena – General requirements*

ISO 18080-2, *Textiles – Test methods for evaluating the electrostatic propensity of fabrics – Part 2: Test method using rotary mechanical friction*

ISO 18080-3, *Textiles – Test methods for evaluating the electrostatic propensity of fabrics – Part 3: Test method using manual friction*

ISO 18080-4, *Textiles – Test methods for evaluating the electrostatic propensity of fabrics – Part 4: Test method using horizontal mechanical friction*

ISO 20344, *Personal protective equipment – Test methods for footwear*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC TR 61340-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
acceptance test
test used to determine if systems or products meet specified requirements prior to installation or first use

Note 1 to entry: Acceptance tests may be the same as those used for qualification, or can be simpler tests more appropriate for use in a facility rather than a controlled test laboratory.

3.2
electrostatic attraction
ESA
force between two or more oppositely charged objects resulting in an increased deposition rate of particles onto charged surfaces or movement of charged particles

Note 1 to entry: This note applies to the French language only.

3.3
electrostatic discharge
ESD
transfer of electric charge between bodies of different electric potential in proximity or through direct contact

3.4
electrostatic discharge sensitive device
ESDS
sensitive devices, integrated circuit or assembly that can be damaged by electrostatic fields or electrostatic discharge

Note 1 to entry: This note applies to the French language only.

3.5
ESD protected area
EPA
area in which an ESDS can be handled with acceptable risk of damage as a result of electrostatic discharge or fields

Note 1 to entry: This note applies to the French language only.

3.6
electromagnetic compatibility
EMC
ability of an equipment or system to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to anything in that environment

3.7
functional ground
terminal used to connect parts to ground for reasons other than safety

Note 1 to entry: A functional ground can be a ground rod, stake or a separate wiring system that is bonded to the AC ground at the main service panel.

Note 2 to entry: In the absence of a dedicated functional ground, a protective earth can be used as a functional ground.

3.8
isolated conductors
non-grounded conductors

3.9
low charging material
materials with a tendency to minimize charge generation when contacting and rubbing against other materials

Note 1 to entry: As contact electrification and triboelectric charging are dependent on the nature of both contacting surfaces and the local environment, materials qualified as low charging under specific test conditions are not necessarily low charging under all possible conditions.

3.10
protective earth
terminal used to connect parts to earth for safety reasons

Note 1 to entry: Protective earth is also known as equipment grounding conductor.

3.11
qualification
process of evaluating test data or system/product data sheets to ensure that systems, materials or finished products meet specified requirements

4 Electrostatic hazards

4.1 General

Four different hazards of static electricity are generally recognized: ESD damaging or disrupting electrical equipment, contamination caused by ESA, ignition of flammable substances and electrostatic shock to people.

4.2 ESD effects on equipment

Electrostatic discharges can cause losses of the functions of instrumentation during patient care increasing the risks to human safety. Insufficient electrostatic control may also cause unnecessary repair costs of medical equipment, as well as corruption of data affecting the quality and reliability of medical operation.

Electrical installation requirements for medical equipment and locations are provided in the electrical safety rules specified in IEC 60364 (all parts) [3]. It is essential to recognize that electrical safety does not necessarily provide precautions for prevention of the risks of static electricity and electrostatic discharge (ESD). Local safety regulations shall be taken into account.

ESD immunity testing does not cover all the real discharge scenarios, such as those where metal parts having different electric potentials are touched together. A current limiting resistor used in the ESD testing specified in IEC 61000-4-2 [4] does not necessarily exist in such situations, resulting in higher discharge power in equipment under real stress. Charge accumulation in a mobile metal object can also result in high energies in uncontrolled environments. Especially in low humidity, discharge energies can exceed the stress levels used in IEC 61000-4-2 [4].

A completely integrated system in medical care is not necessarily tested against transients caused by ESD, although individual parts of the system have passed EMC qualification. Therefore, it does not always take into account all the realistic coupling and failure scenarios of the whole system.

Discharges from isolated conductors or from a human body can be prevented with grounding. Conductive parts of patient beds, intravenous stands, trolleys, delivery carts, over-bed tables, chairs, and other mobile metal objects are not normally connected to the protective earth. Therefore, grounding all conductive parts of every item through the flooring or with direct electrical connection to a functional ground becomes essential for ~~static~~ electrostatic control.

The probability of ESD can efficiently be reduced by optimization of humidity levels, bipolar ionization, adequate material selection, personnel grounding, and grounding of mobile metal objects. In general, the prevention of static charge generation and ESD is preferable compared to enhancing medical equipment EMC immunity.

If a functional ground is used for electrostatic control purposes, it should be electrically bonded to protective earth where possible so as to avoid potential differences between the two systems.

4.3 Contamination caused by ESA

Electrostatically charged surfaces attract airborne particles. Increased deposition of microorganisms onto charged surfaces, including the airways, human skin, and open wounds, can contribute to the incidence of hospital infections. Electrostatic sources of contamination and nosocomial infection can be healthcare personnel, patients, or the environment. All objects that come into contact with patients can be considered as potentially contaminated.

Cleaning, disinfection and sterilizing can prevent transmission of infective agents. However, because of the human factor, complete certainty in cleanliness cannot be achieved without adequate control of the environment. Avoidance of electrostatic attraction (ESA) decreases airborne microbe contamination and improves overall cleanliness in healthcare. The reduction in charge carried by airborne submicron contaminants will additionally reduce the deposition of such contaminants in the airways, thereby reducing the load placed on the body's immune system. Charge accumulation and high surface charge densities can be reduced to tolerable levels by grounding of personnel and other conductors, and by correct selection of materials.

4.4 Ignition of flammable substances

The use of flammable substances in healthcare facilities has decreased, but the risk of fires and explosions can still occur especially in laboratories, intensive care units and operating rooms. For example, using alcohol based sterilizing substances has caused fires due to electrostatic discharge. ESD can be an ignition source in hyperbaric oxygen facilities and other locations where the oxygen concentration exceeds 23,5 % by volume.

The risk of incendiary ESD can be reduced to tolerable levels by grounding of personnel and other conductors, and by correct selection of materials.

4.5 Electrostatic shock to people

The incidence of unpleasant electrostatic shocks to people has increased due to the increased use of highly insulating materials such as plastics. An electrostatic discharge occurs when a human body approaches close enough to an object with different electric potential to exceed the electric breakdown field strength. ESD energy can be high enough to cause painful sensations to patients and healthcare personnel, resulting in involuntary movements, which can lead to accidents.

The risk of electrostatic shock can be reduced to tolerable levels by grounding of personnel and other conductors, and by correct selection of materials.

5 Electrostatic control requirements

5.1 General

Electrostatic control requirements in healthcare depend on the medical procedures, locations and activities such as service and maintenance of medical equipment.

5.2 Medical procedures

To ensure safety of patients from electrostatic hazards, protective measures shall be applied during medical examination and treatment.

Medical procedures can require specific electrostatic control actions that are dependent on the particular requirements of instrumentation, electric equipment or cleanliness. When protective measures have not otherwise been specified, the requirements in 5.3 to 5.7 shall be applied. Consideration shall also be given to applying the recommendations in 5.3 to 5.7 and Annex B.

5.3 Medical locations

5.3.1 Classification by groups

Locations that are intended for purposes of diagnosis, treatment, monitoring and care of patients shall be classified in the following groups, as defined in IEC 60364-7-710: unclassified, G0, G1 and G2.

Selection of materials to reduce residual charge levels is recommended in all locations. Grounding of personnel and other conductors is recommended in G0~~ and~~ locations, is conditionally required in G1 locations~~,~~ (see 5.3.4) and is required in G2 locations. Electrostatic control methods for each location are summarised in Table 1.

Table 1 – Summary of electrostatic control methods for specified locations

Location	Electrostatic control method			
	Ground personnel via footwear and flooring	Ground other conductors via flooring or direct connection	Use of conductive or dissipative materials	Use of low charging materials
Unclassified	Not mandatory	Not mandatory	~~Not mandatory~~ Recommended[a]	Recommended
G0	Recommended	Recommended	Recommended[a]	Recommended
G1	~~Recommended~~ Conditionally required[b]	~~Recommended~~ Conditionally required[b]	Recommended[a]	Recommended
G2	Required	Required	Recommended[a]	Recommended

[a] Conductive and dissipative materials should only be used if grounding is provided.

[b] Electrostatic control methods are required in G1 locations if the humidity was less than 30 % RH (see 5.3.4).

5.3.2 Unclassified rooms

Waiting rooms, office areas, and corridors are not necessarily classified medical locations. It is recommended to use flooring and upholstery materials that limit human body voltage to below 2 000 V, thereby limiting occurrence of unpleasant electrostatic shocks, contaminant deposition, and errors in data processing. Temporary use of medical equipment shall be taken into account.

~~NOTE As an example, EN 1307 [5] specifies textile floor coverings with antistatic behaviour as being those giving rise to a body voltage of less than 2 000 V measured according to ISO 6356 [6] at 25 % RH.~~

5.3.3 Group 0 – Electrostatic control recommended

Typical locations are ~~consulting rooms and inpatient wards~~ massage therapy rooms.

Electrostatic control methods are recommended in G0 locations to reduce the risk of ESA based contamination, ignition accidents, unpleasant electrostatic shocks and ESD induced errors in data processing to tolerable levels.

5.3.4 Group 1 – Electrostatic control ~~recommended~~ conditionally required

~~Typical locations are endoscopic examination rooms, electrocardiogram (ECG), electroencephalogram (EEG) and electrohysterogram (EHG) rooms, computed tomography rooms, specialcare baby units, urology units and nuclear medicine rooms.~~

Typical locations are bedrooms, delivery rooms, electrocardiogram (ECG), electroencephalogram (EEG), electrohysterogram (EHG) rooms, endoscopic rooms, examination or treatment rooms, urology rooms, radiological diagnostic and therapy rooms, hydrotherapy rooms, physiotherapy rooms, haemodialysis rooms, MRI rooms and nuclear medicine rooms.

Electrostatic control methods are recommended in G1 locations to reduce the risk of ESA based contamination, ignition accidents, unpleasant electrostatic shocks and ESD induced errors in data processing to tolerable levels.

Electrostatic control methods are required in G1 locations if the humidity falls below 30 % RH, or below the humidity specified by equipment manufacturers, for a significant period of time (typically a continuous period of more than an hour), or if there is evidence of unacceptably high electrostatic charging. Evidence of unacceptably high charging can be the occurrence of any of the electrostatic hazards described in Clause 4, and can be confirmed by testing, see 5.6.2.3.3, 5.6.3.4 and 5.7 c) and d).

5.3.5 Group 2 – Electrostatic control required

~~Typical locations are operating theatre suites, operating preparation rooms, operating plaster rooms, operating recovery rooms, cardiac catheterization rooms, coronary care units and intensive care units.~~

Typical locations are anaesthetic areas, operating theatres, operating preparation rooms, operating plaster rooms, operating recovery rooms, heart catheterization rooms, intensive care rooms, angiographic examination rooms, premature baby rooms and intermediate care units.

Electrostatic control methods are required in G2 locations, where temporary losses of functions of medical equipment pose a significant risk to the life of patients and cannot, therefore, be tolerated. Electrostatic control methods can also be required in other medical locations depending on medical treatment or on manufacturer's specifications of medical equipment.

5.4 Service and maintenance

Unprotected ESD sensitive devices (ESDS) shall not be handled without an adequate ESD control programme. When unprotected ESDS are handled, the requirements of IEC 61340-5-1 shall be applied.

5.5 Administrative requirements and recommendations

5.5.1 Designing facilities

Precautions against electrostatic hazards in healthcare facilities are mainly based on passive control methods such as material selections and ground connections. Therefore, it is essential to take recommendations and requirements of this document into account in designing new facilities or refurbishing existing facilities. Active control measures such as optimizing dew point temperature, introducing bipolar ionization and optimizing room layouts and equipment locations as means to reduce individuals' exposures to excess charge and charged contaminants within the micro-environments they typically occupy should also be considered.

5.5.2 Operational responsibility

Organizations operating healthcare facilities are responsible for maintaining documentation and verification of the precautions against electrostatic hazards as well as considering any related training needs.

5.5.3 Qualification and verification

All new installations and materials used for electrostatic control shall be qualified before procurement. In addition, sample based acceptance testing at minimum is required for floorings and other installations. Periodic verifications or random checks of electrostatic control items are recommended.

Unless otherwise agreed, the atmosphere for conditioning and testing for qualification purposes shall be (23 ± 2) °C and (12 ± 3) % relative humidity, and the conditioning time prior to testing shall be at least 48 h. Verification testing shall be done under the range of ambient temperature and humidity conditions within the facility. For assessing the worst-case conditions humidity and temperature shall be measured at different times of the year when different humidity conditions can be experienced.

5.6 Technical requirements

5.6.1 Electrical safety

This document includes technical requirements for electrostatic control. These requirements shall not replace or supersede any requirements for personnel safety.

5.6.2 Material classification

5.6.2.1 General requirements for material classification

Materials for electrostatic control shall: limit the generation of electrostatic charge; quickly dissipate electrostatic charge; suppress or attenuate electrostatic field or electrostatic potential associated with residual electrostatic charge. To a certain extent, these functions are related. For example, a material that is able to dissipate charge faster than it is generated will appear to be one that limits the generation of charge. However, in some cases, the functions can be independent. Some materials that do not dissipate charge quickly, can show limited accumulation of charge or low measured surface potential.

Surface and volume resistance measurements (see 5.6.2.2) are one way to classify a material's ability to dissipate electrostatic charge and, in many cases, to limit electrostatic charge generation. If materials are to be used in the ground path for grounding personnel and other conductors, resistance measurements are essential. Nevertheless, there are materials that can be used for electrostatic control for which resistance measurements are not appropriate. Alternative test methods (see 5.6.2.3) shall be used for such materials.

Another option is for healthcare facilities to specify their own test methods and classification requirements, either based on other standards, or defined within their own facility specifications. Guidance on electrostatic test methods can be found in IEC TR 61340-1, IEC TR 61340-2-2 [7] and IEC 60079-32-2 [8].

Clothing worn by personnel that is intended to protect the wearer from hazards such as chemicals, heat or cold, impact, ignition of flammable atmospheres, etc. is classified as personal protective equipment (PPE) and is commonly subject to specific regulations. For example, in Europe, PPE must comply with the PPE Directive (PPE Regulation from 2018), and clothing materials for use in flammable atmospheres are normally tested and evaluated using the EN 1149 series of standards [9].

NOTE Guidance on the selection, use, care and maintenance of PPE for preventing electrostatic risks in hazardous areas is given in CEN TR 16832 [10].

5.6.2.2 Material classification based on resistive properties

5.6.2.2.1 Resistance measurements

Surface and volume resistance measurements shall be made according to IEC 61340-2-3.

5.6.2.2.2 Electrostatic conductive materials

Conductive materials may be surface conductive, volume conductive or both. A surface conductive material shall have a surface resistance < 1×10^4 Ω. Volume conductive materials shall have a volume resistance < 1×10^4 Ω. ~~ESD control~~ Electrostatic control items can have different limits depending on the standard.

5.6.2.2.3 Electrostatic dissipative materials

Dissipative materials may be surface dissipative, volume dissipative or both. Surface dissipative materials shall have a surface resistance ≥ 1×10^4 Ω and < 1×10^{11} Ω. Volume dissipative materials shall have a volume resistance ≥ 1×10^4 Ω and < 1×10^{11} Ω. ~~ESD control~~ Electrostatic control items can have different limits depending on the standard.

5.6.2.2.4 Electrostatic insulating materials

Electrostatic insulating materials may be surface insulating, volume insulating or both. Surface insulating materials have a surface resistance ≥ 1 × 10^{11} Ω. Volume insulating materials have a volume resistance ≥ 1 × 10^{11} Ω. ~~ESD control~~ Electrostatic control items can have different limits depending on the standard.

5.6.2.3 Material classification based on charge decay time and triboelectric charging

5.6.2.3.1 Charge decay time measurements

Charge decay time measurements shall be made according to IEC 61340-2-1.

5.6.2.3.2 Electrostatic dissipative materials

Electrostatic dissipative materials shall have a charge decay time of ≤ 2 s from an initial value between (200 ± 10) V and (1 000 ± 50) V to (100 ± 5) V. A material is also classified as electrostatic dissipative if on application of a corona voltage of at least 7 kV the maximum surface voltage is less than 190 V.

5.6.2.3.3 Low charging materials

Low charging materials shall meet one or more of the following requirements:

a) friction-charged electrostatic potential ≤ 1 000 V (ISO 18080-2 or ISO 18080-4)

b) friction charge density ≤ 2 μC/m^2 (ISO 18080-3)

NOTE The ISO 18080 series of test methods are primarily intended for textile materials. All the test methods described in the ISO 18080 series can be used to evaluate similar thin, flexible materials. ISO 18080-3 can also be used with minimum modification to evaluate many different types of material.

5.6.3 Selection of materials for ~~static~~ electrostatic control

5.6.3.1 Preferred materials

Electrostatic conductive or electrostatic dissipative materials are preferred for electrostatic control purposes.

In the specifications for their products, manufacturers can sometimes include reference to different standards that specify requirements for electrostatic performance of products for general applications or for use other than in healthcare facilities. Some of these other standards can be consistent with the requirements of this document, but others are not because of different test methods, test conditions or performance requirements. In cases of conflict or doubt when considering materials for electrostatic control for healthcare facilities, materials complying with the testing and performance requirements of this document shall be used.

5.6.3.2 Flooring used to ground personnel and equipment

When flooring is required to ground personnel and equipment for electrostatic control purposes, resistance to ground shall be ≤ 1 × 10^9 Ω measured in accordance with IEC 61340-4-1.

Resistance to ground ≤ 1 × 10^6 Ω is required for flooring in locations where flammable anaesthetics and hyperbaric oxygen systems are used and where high electrostatic charging mechanisms are expected, for example rapid removal of sheets from beds or drapes from operating tables. If resistance to ground ≤ 1 × 10^6 Ω is not achievable, precautions shall be taken to eliminate high charging mechanisms. For example, bedding or drapes shall be removed slowly.

5.6.3.3 Footwear used to ground personnel

When footwear is required to ground personnel and handheld equipment for electrostatic control purposes, resistance shall be ≤ 1 × 10^9 Ω measured in accordance with ISO 20344 or IEC 61340-4-3. In compliance verification resistance to ground shall be ≤ 1 × 10^9 Ω measured in accordance with IEC 61340-5-1.

Resistance to ground ≤ 1 × 10^6 Ω is required for ~~footwear worn~~ flooring in locations where flammable anaesthetics and hyperbaric oxygen systems are used and where high electrostatic charging mechanisms are expected, for example rapid removal of sheets from beds or drapes from operating tables. If resistance to ground ≤ 1 × 10^6 Ω is not achievable, precautions shall be taken to eliminate high charging mechanisms. For example, bedding or drapes shall be removed slowly.

5.6.3.4 Person – footwear – flooring system

When electrostatic control is required, but it is not possible or necessary to ground patients or healthcare personnel via footwear and flooring, for example in unclassified rooms (see 5.3.2), flooring shall be used that generates a body voltage ≤ 2 000 V measured according to IEC 61340-4-5.

The footwear used for testing shall be representative of footwear typically worn in the facility, or which is considered to represent worst case charging conditions.

5.6.3.5 Mobile metal objects, electrical equipment and furniture

When electrostatic control is required, all the mobile metal objects such as patient beds, stretchers, intravenous stands, trolleys, delivery carts, over bed tables, and chairs shall be connected to ground. Resistance to ground shall be ≤ 1 × 10^9 Ω. Measurement is made according to IEC 61340-2-3 between the local functional ground and an electrode assembly placed, where possible, on a metal surface of the item. If it is not possible to use the electrode assembly specified in IEC 61340-2-3, a metal probe shall be used to contact the metal frame of the item.

When wheels are used for grounding in combination with flooring, at least two electrostatic conductive or dissipative wheels are recommended.

When electrostatic control is required, mobile battery operated electrical equipment shall be connected to a functional ground if the equipment has a built-in ground connection available.

NOTE Modification of medical devices/equipment can be subject to medical device regulations.

5.6.3.6 Textiles

When electrostatic control is required, textiles shall be made of electrostatic conductive, electrostatic dissipative or low charging materials, complying with at least one of the following requirements:

a) surface resistance < 1 × 10^{11} Ω, measured in accordance with IEC 61340-2-3;

b) charge decay time from initial value between (200 ± 10) V and (1 000 ± 50) V to (100 ± 5) V of less than or equal to 2 s measured in accordance with IEC 61340-2-1 (a material is also classified as electrostatic dissipative if on application of a corona voltage of at least 7 kV the maximum surface voltage is less than 190 V);

c) friction-charged electrostatic potential ≤ 1 000 V, measured in accordance with ISO 18080-2 or ISO 18080-4;

d) friction charge density ≤ 2 μC/m^2, measured in accordance with ISO 18080-3.

It is rare for textiles to be entirely conductive; it is more common for so called conductive textiles to be made from insulating materials that incorporate conductive fibres either as an

intimate blend or in a stripe or grid pattern. Irrespective of the method of construction, electrostatic conductive textiles shall be connected to ground during use in areas where ~~static~~ electrostatic control is required.

Electrostatic dissipative and low charging textile materials can be made from materials that are chemically treated or coated in such a way that the entire surface is electrostatic dissipative or low charging. It is also common for electrostatic dissipative and low charging textiles to be made from insulating materials that incorporate dissipative or core-conductive fibres. Grounding of electrostatic dissipative or low charging textiles is not always necessary, unless the surface resistance is less than 10^8 Ω.

In unclassified and G0 rooms, where patients are often ungrounded, and in other locations where grounding of personnel is not possible or practical, the occurrence of electrostatic hazards can be reduced by using low charging textiles for clothing, upholstery, bedding, curtains, and surgical drapes.

Whereas the test methods and requirements specified in 5.6.3.6 are useful for initial material selection and qualification, additional tests are required for final qualification of finished products. This is because triboelectric charging is dependent on several factors, including the nature of the contacting materials and the mechanism by which they contact, rub together and separate. Therefore, products can only be described as low charging within the specific context in which they are used. Test methods used to determine if products are low charging shall replicate, as near as possible, in-use charging conditions. Suitable test methods are specified in Annex A.

The use of electrostatic conductive, electrostatic dissipative or low charging material aprons is recommended. Such specification will help reduce likely deposition of microorganisms and other contaminants on apron surfaces and the magnitude of induced charge and contaminant deposition on nearby individuals and surfaces.

5.7 Packaging, containers and other electrostatic control items

Packages, containers and other items made from insulating materials can become highly charged. In many cases, functional requirements such as hygiene, barrier properties, etc. take precedence over electrostatic properties. Nevertheless, consideration should be given to replacing insulating materials, where possible and practical, with electrostatic conductive, electrostatic dissipative or low charging materials, complying with at least one of the following requirements:

a) surface resistance < 1×10^{11} Ω, measured in accordance with IEC 61340-2-3;

b) charge decay time from initial value between (200 ± 10) V and (1 000 ± 50) V to (100 ± 5) V of less than or equal to 2 s measured in accordance with IEC 61340-2-1 (a material is also classified as electrostatic dissipative if, on application of a corona voltage of at least 7 kV, the maximum surface voltage is less than 190 V);

c) friction-charged electrostatic potential ≤ 1 000 V, measured in accordance with ISO 18080-2 or ISO 18080-4;

d) friction charge density ≤ 2 μC/m^2, measured in accordance with ISO 18080-3.

NOTE The ISO 18080 series of test methods are primarily intended for textile materials. All the test methods described in the ISO 18080 series can be used to evaluate similar thin, flexible materials. ISO 18080-3 can also be used with minimum modification to evaluate many different types of material.

Annex A
(normative)

Test methods for low charging textiles

A.1 Test methods for clothing and upholstery

The test methods specified in IEC TS 61340-4-2 shall be used for triboelectric charging measurements relating to people, clothing and upholstery. With minimum modification, the test methods shall also be used for triboelectric charging measurements relating to people, bedding and surgical drapes.

In all cases the measured body voltage shall be ≤ 2 000 V. The resistance to ground of the person or mannequin shall be greater than 10^{13} Ω during all measurements. The additional measurements and calculations described in IEC TS 61340-4-2 are not essential for the purposes of this document.

Triboelectric charging tests require the product under test to be contacted by other materials, which shall either be representative of the materials most likely to come into contact with the product in use, or reference materials that are known to generate high levels of charge when rubbed against other materials. In the latter case, at least two reference materials shall be used: one electropositive and one electronegative. Examples of suitable material include (going from electropositive to electronegative) polyamide, wool, leather, polyester, polyvinylchloride and polytetrafluoroethylene.

Clothing shall be tested according to the method specified in IEC TS 61340-4-2:2013, Annex A, Annex B or Annex C. The clothing used shall be the combinations of clothing under test, for example a surgical apron and a surgical gown, or combinations of the clothing under test and reference clothing or materials.

Upholstery shall be tested according to the method specified in IEC TS 61340-4-2:2013, Annex B. The upholstery under test shall be installed on samples of the furniture to be used, or on representative reference furniture. The clothing used shall be representative of the clothing most likely to contact the upholstery in use or reference clothing.

A.2 Test methods for bedding, curtains, and surgical drapes

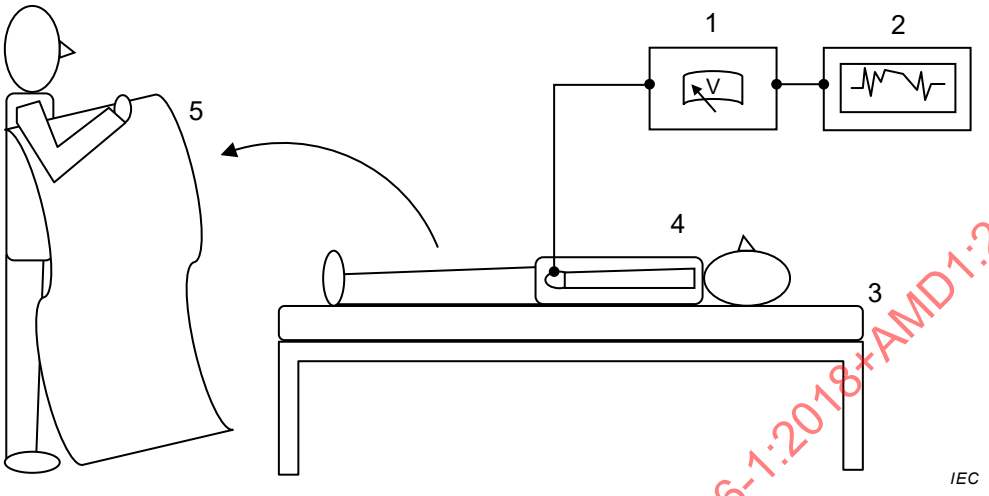
Bedding, curtains and surgical drapes shall be tested according to the method specified in IEC TS 61340-4-2 by replacing the seat with a bed or examination/operating table. The clothing used shall be representative of the clothing most likely to contact the product under test when in use or reference clothing. Alternatively, tests shall be made according to the following methods based on IEC TS 61340-4-2:2013, Annex A and Annex B, as illustrated in Figures A.1 to A.3.

In the example shown in Figure A.1, a person wearing clothing that is representative of clothing likely to be worn within the intended application, or reference clothing, lies on a bed or examination/operating table. A thin sheet of insulating material, for example polyethylene film, shall be placed beneath the person so that the resistance from the person to ground is greater than 10^{13} Ω. The product under test is placed over the person, who is then momentarily grounded. The product under test is then quickly removed and the body voltage of the person on the bed is recorded.

In the example shown in Figure A.2, the products under test can be the bedding or surgical drape removed, or the bedding or cover on the bed or examination/operating table, or both. In this example, the person conducting the test stands without footwear on a metal plate connected to the electrostatic voltmeter. The resistance from the metal plate to ground shall

be greater than 10^{13} Ω. After the item is removed, it is held close to the body and shall be prevented from touching anything else. The body voltage of the person is recorded.

In the example shown in Figure A.3, the two procedures are combined.



Key

1 electrostatic voltmeter

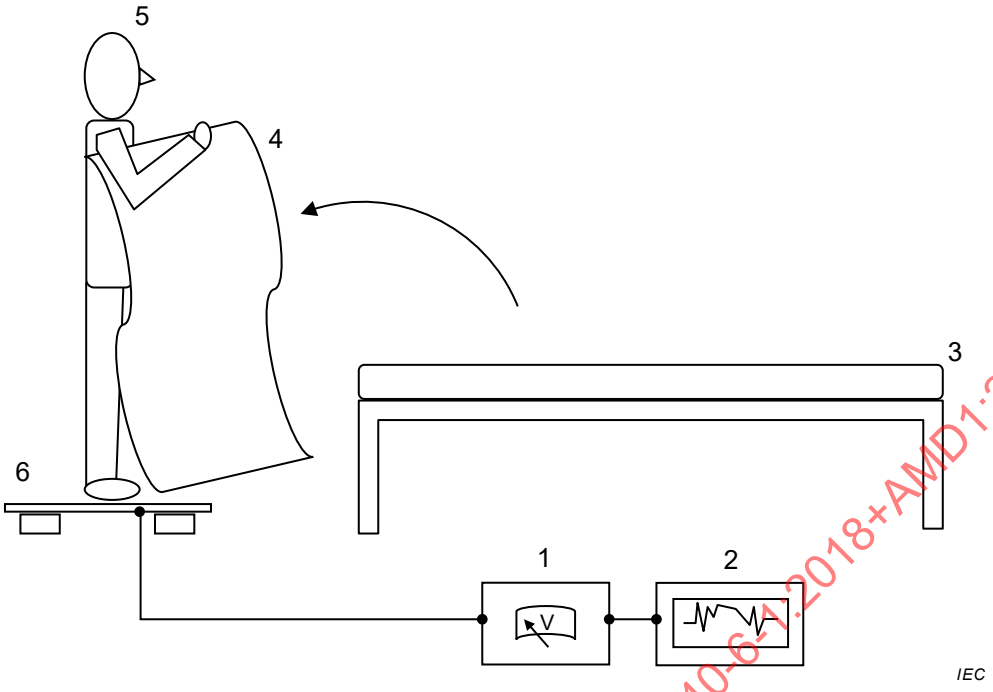
2 recording device

3 bed or examination/operating table

4 person wearing reference clothing, resistance to ground > 10^{13} Ω

5 bedding or surgical drape under test

Figure A.1 – Example of test equipment set up for measuring body voltage when removing item of bedding or surgical drape from person wearing reference clothing



Key

1 electrostatic voltmeter

2 recording device

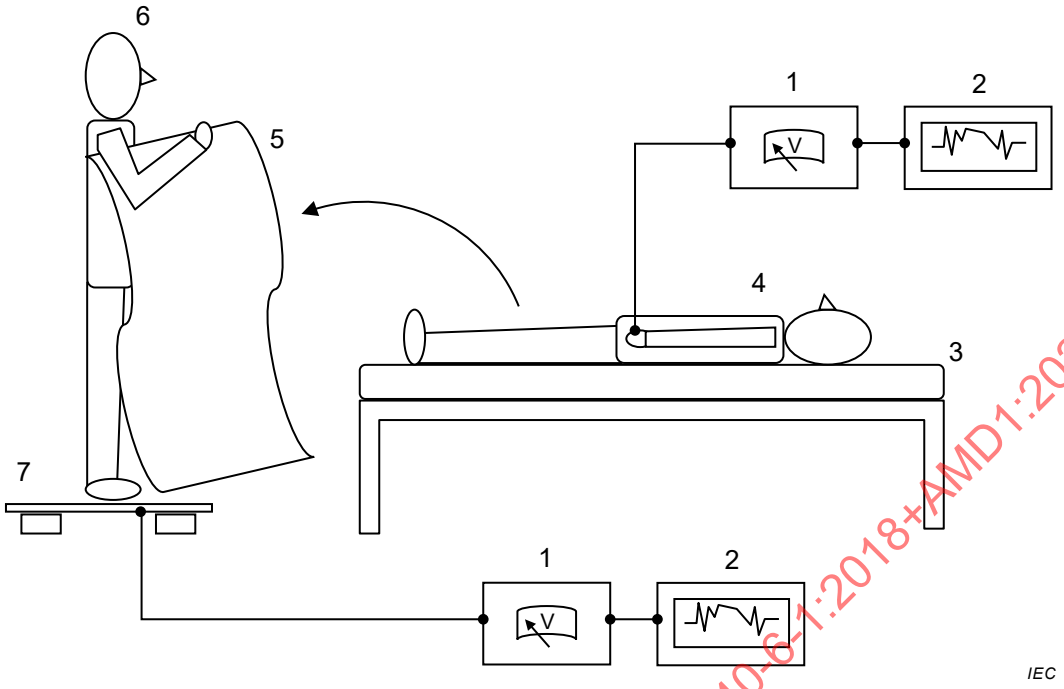
3 bed or examination/operating table

4 bedding or surgical drape under test

5 person without footwear

6 metal plate on insulating support, resistance to ground > 10^{13} Ω

Figure A.2 – Example of test equipment set up for measuring body voltage when removing item of bedding or surgical drape from bed or examination/operating table



Key

1 electrostatic voltmeter

2 recording device

3 bed or examination/operating table

4 person wearing reference clothing, resistance to ground > 10^{13} Ω

5 bedding or surgical drape under test

6 person without footwear

7 metal plate on insulating support, resistance to ground > 10^{13} Ω

Figure A.3 – Example of test equipment set up for measuring body voltage on two people when removing item of bedding or surgical drape

Annex B
(informative)

Ionization and other considerations

Ionization can be used as an optional method to limit electrostatic charge build-up on insulating materials where replacement with electrostatic control materials is not possible or practical. The need for ionization, and the specification of the ionizing equipment, should be considered based on the risks of ignition of flammable substances, deposition of particle contaminants, and sensitivity of electronic systems to ESD or excess electrostatic fields.

The main purpose of the ionization is to:

a) neutralize static charges on charged dielectric surfaces and remove static charges from electrically floating conductive materials;

b) reduce electrostatic attraction of airborne particles and other contaminants.

NOTE The presence of an ionizer does not substitute for the necessity to ground personnel or equipment.

Further guidance on ionization is given in IEC 61340-4-7 and IEC TR 61340-5-2.

Selected sources of information on the use of ionization, dew point temperature control and room layout optimization are listed in the bibliography.

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[3] IEC 60364 (all parts), *Low-voltage electrical installations*

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[6] ISO 6356, *Textile and laminate floor coverings – Assessment of static electrical propensity – Walking test*

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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ELECTROSTATICS –

Part 6-1: Electrostatic control in healthcare, commercial and public facilities – Healthcare

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 61340-6-1 edition 1.1 contains the first edition (2018-09) [documents 101/566/FDIS and 101/570/RVD] and its amendment 1 (2024-10) [documents 101/713/FDIS and 101/720/RVD].

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.

International Standard IEC 61340-6-1 has been prepared by IEC technical committee 101: Electrostatics.

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

A list of all parts in the IEC 61340 series, published under the general title *Electrostatics*, can be found on the IEC website.

The committee has decided that the contents of this document and its amendment will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

INTRODUCTION

Static electricity can be the source of several hazards to patients, staff and equipment in healthcare facilities. Such hazards include:

- electromagnetic disturbance or electrostatic discharge (ESD) disruption or damage to medical instrumentation and data processing equipment;
- damage to ESD susceptible electronic components and assemblies during service and maintenance;
- electrostatic attraction (ESA) and contamination;
- ignition of flammable gases, liquids and other materials, and
- electrostatic shocks to people.

Adequate electrostatic control can eliminate these hazards, or at least reduce residual risk to tolerable levels.

ELECTROSTATICS –

Part 6-1: Electrostatic control in healthcare, commercial and public facilities – Healthcare

1 Scope

This part of IEC 61340 applies to facilities that provide healthcare including hospitals, care centres and clinics.

This document provides technical requirements and recommendations for controlling electrostatic phenomena in healthcare facilities, which includes requirements for equipment, materials, and products used to control static electricity.

The requirements of this document do not apply to medical electrical equipment specified in IEC 60601-1 [1] [1] and in vitro diagnostic (IVD) medical equipment specified in IEC 61010-2-101 [2].

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.

IEC 60364-7-710, *Low-voltage electrical installations – Part 7-710: Requirements for special installations or locations – Medical locations*

IEC TR 61340-1, *Electrostatics – Part 1: Electrostatic phenomena – Principles and measurements*

IEC 61340-2-1, *Electrostatics – Part 2-1: Measurement methods – Ability of materials and products to dissipate static electric charge*

IEC 61340-2-3, *Electrostatics – Part 2-3: Methods of test for determining the resistance and resistivity of solid materials used to avoid electrostatic charge accumulation*

IEC 61340-4-1, *Electrostatics – Part 4-1: Standard test methods for specific applications – Electrical resistance of floor coverings and installed floors*

IEC TS 61340-4-2:2013, *Electrostatics – Part 4-2: Standard test methods for specific applications – Electrostatic properties of garments*

IEC 61340-4-3, *Electrostatics – Part 4-3: Standard test methods for specific applications – Footwear*

IEC 61340-4-5, *Electrostatics – Part 4-5: Standard test methods for specific applications – Methods for characterizing the electrostatic protection of footwear and flooring in combination with a person*

[1] Numbers in square brackets refer to the bibliography.

IEC 61340-5-1, *Electrostatics – Part 5-1: Protection of electronic devices from electrostatic phenomena – General requirements*

ISO 18080-2, *Textiles – Test methods for evaluating the electrostatic propensity of fabrics – Part 2: Test method using rotary mechanical friction*

ISO 18080-3, *Textiles – Test methods for evaluating the electrostatic propensity of fabrics – Part 3: Test method using manual friction*

ISO 18080-4, *Textiles – Test methods for evaluating the electrostatic propensity of fabrics – Part 4: Test method using horizontal mechanical friction*

ISO 20344, *Personal protective equipment – Test methods for footwear*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC TR 61340-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
acceptance test
test used to determine if systems or products meet specified requirements prior to installation or first use

Note 1 to entry: Acceptance tests may be the same as those used for qualification, or can be simpler tests more appropriate for use in a facility rather than a controlled test laboratory.

3.2
electrostatic attraction
ESA
force between two or more oppositely charged objects resulting in an increased deposition rate of particles onto charged surfaces or movement of charged particles

Note 1 to entry: This note applies to the French language only.

3.3
electrostatic discharge
ESD
transfer of electric charge between bodies of different electric potential in proximity or through direct contact

3.4
electrostatic discharge sensitive device
ESDS
sensitive devices, integrated circuit or assembly that can be damaged by electrostatic fields or electrostatic discharge

Note 1 to entry: This note applies to the French language only.

3.5
ESD protected area
EPA
area in which an ESDS can be handled with acceptable risk of damage as a result of electrostatic discharge or fields

Note 1 to entry: This note applies to the French language only.

3.6
electromagnetic compatibility
EMC
ability of an equipment or system to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to anything in that environment

3.7
functional ground
terminal used to connect parts to ground for reasons other than safety

Note 1 to entry: A functional ground can be a ground rod, stake or a separate wiring system that is bonded to the AC ground at the main service panel.

Note 2 to entry: In the absence of a dedicated functional ground, a protective earth can be used as a functional ground.

3.8
isolated conductors
non-grounded conductors

3.9
low charging material
materials with a tendency to minimize charge generation when contacting and rubbing against other materials

Note 1 to entry: As contact electrification and triboelectric charging are dependent on the nature of both contacting surfaces and the local environment, materials qualified as low charging under specific test conditions are not necessarily low charging under all possible conditions.

3.10
protective earth
terminal used to connect parts to earth for safety reasons

Note 1 to entry: Protective earth is also known as equipment grounding conductor.

3.11
qualification
process of evaluating test data or system/product data sheets to ensure that systems, materials or finished products meet specified requirements

4 Electrostatic hazards

4.1 General

Four different hazards of static electricity are generally recognized: ESD damaging or disrupting electrical equipment, contamination caused by ESA, ignition of flammable substances and electrostatic shock to people.

4.2 ESD effects on equipment

Electrostatic discharges can cause losses of the functions of instrumentation during patient care increasing the risks to human safety. Insufficient electrostatic control may also cause unnecessary repair costs of medical equipment, as well as corruption of data affecting the quality and reliability of medical operation.

Electrical installation requirements for medical equipment and locations are provided in the electrical safety rules specified in IEC 60364 (all parts) [3]. It is essential to recognize that electrical safety does not necessarily provide precautions for prevention of the risks of static electricity and electrostatic discharge (ESD). Local safety regulations shall be taken into account.

ESD immunity testing does not cover all the real discharge scenarios, such as those where metal parts having different electric potentials are touched together. A current limiting resistor used in the ESD testing specified in IEC 61000-4-2 [4] does not necessarily exist in such situations, resulting in higher discharge power in equipment under real stress. Charge accumulation in a mobile metal object can also result in high energies in uncontrolled environments. Especially in low humidity, discharge energies can exceed the stress levels used in IEC 61000-4-2 [4].

A completely integrated system in medical care is not necessarily tested against transients caused by ESD, although individual parts of the system have passed EMC qualification. Therefore, it does not always take into account all the realistic coupling and failure scenarios of the whole system.

Discharges from isolated conductors or from a human body can be prevented with grounding. Conductive parts of patient beds, intravenous stands, trolleys, delivery carts, over-bed tables, chairs, and other mobile metal objects are not normally connected to the protective earth. Therefore, grounding all conductive parts of every item through the flooring or with direct electrical connection to a functional ground becomes essential for electrostatic control.

The probability of ESD can efficiently be reduced by optimization of humidity levels, bipolar ionization, adequate material selection, personnel grounding, and grounding of mobile metal objects. In general, the prevention of static charge generation and ESD is preferable compared to enhancing medical equipment EMC immunity.

If a functional ground is used for electrostatic control purposes, it should be electrically bonded to protective earth where possible so as to avoid potential differences between the two systems.

4.3 Contamination caused by ESA

Electrostatically charged surfaces attract airborne particles. Increased deposition of microorganisms onto charged surfaces, including the airways, human skin, and open wounds, can contribute to the incidence of hospital infections. Electrostatic sources of contamination and nosocomial infection can be healthcare personnel, patients, or the environment. All objects that come into contact with patients can be considered as potentially contaminated.

Cleaning, disinfection and sterilizing can prevent transmission of infective agents. However, because of the human factor, complete certainty in cleanliness cannot be achieved without adequate control of the environment. Avoidance of electrostatic attraction (ESA) decreases airborne microbe contamination and improves overall cleanliness in healthcare. The reduction in charge carried by airborne submicron contaminants will additionally reduce the deposition of such contaminants in the airways, thereby reducing the load placed on the body's immune system. Charge accumulation and high surface charge densities can be reduced to tolerable levels by grounding of personnel and other conductors, and by correct selection of materials.

4.4 Ignition of flammable substances

The use of flammable substances in healthcare facilities has decreased, but the risk of fires and explosions can still occur especially in laboratories, intensive care units and operating rooms. For example, using alcohol based sterilizing substances has caused fires due to electrostatic discharge. ESD can be an ignition source in hyperbaric oxygen facilities and other locations where the oxygen concentration exceeds 23,5 % by volume.

The risk of incendiary ESD can be reduced to tolerable levels by grounding of personnel and other conductors, and by correct selection of materials.

4.5 Electrostatic shock to people

The incidence of unpleasant electrostatic shocks to people has increased due to the increased use of highly insulating materials such as plastics. An electrostatic discharge occurs when a human body approaches close enough to an object with different electric potential to exceed the electric breakdown field strength. ESD energy can be high enough to cause painful sensations to patients and healthcare personnel, resulting in involuntary movements, which can lead to accidents.

The risk of electrostatic shock can be reduced to tolerable levels by grounding of personnel and other conductors, and by correct selection of materials.

5 Electrostatic control requirements

5.1 General

Electrostatic control requirements in healthcare depend on the medical procedures, locations and activities such as service and maintenance of medical equipment.

5.2 Medical procedures

To ensure safety of patients from electrostatic hazards, protective measures shall be applied during medical examination and treatment.

Medical procedures can require specific electrostatic control actions that are dependent on the particular requirements of instrumentation, electric equipment or cleanliness. When protective measures have not otherwise been specified, the requirements in 5.3 to 5.7 shall be applied. Consideration shall also be given to applying the recommendations in 5.3 to 5.7 and Annex B.

5.3 Medical locations

5.3.1 Classification by groups

Locations that are intended for purposes of diagnosis, treatment, monitoring and care of patients shall be classified in the following groups, as defined in IEC 60364-7-710: unclassified, G0, G1 and G2.

Selection of materials to reduce residual charge levels is recommended in all locations. Grounding of personnel and other conductors is recommended in G0 locations, is conditionally required in G1 locations (see 5.3.4) and is required in G2 locations. Electrostatic control methods for each location are summarised in Table 1.

Table 1 – Summary of electrostatic control methods for specified locations

Location	Electrostatic control method			
	Ground personnel via footwear and flooring	Ground other conductors via flooring or direct connection	Use of conductive or dissipative materials	Use of low charging materials
Unclassified	Not mandatory	Not mandatory	Recommended[a]	Recommended
G0	Recommended	Recommended	Recommended[a]	Recommended
G1	Conditionally required[b]	Conditionally required[b]	Recommended[a]	Recommended
G2	Required	Required	Recommended[a]	Recommended

[a] Conductive and dissipative materials should only be used if grounding is provided.

[b] Electrostatic control methods are required in G1 locations if the humidity was less than 30 % RH (see 5.3.4).

5.3.2 Unclassified rooms

Waiting rooms, office areas, and corridors are not necessarily classified medical locations. It is recommended to use flooring and upholstery materials that limit human body voltage to below 2 000 V, thereby limiting occurrence of unpleasant electrostatic shocks, contaminant deposition, and errors in data processing. Temporary use of medical equipment shall be taken into account.

5.3.3 Group 0 – Electrostatic control recommended

Typical locations are massage therapy rooms.

Electrostatic control methods are recommended in G0 locations to reduce the risk of ESA based contamination, ignition accidents, unpleasant electrostatic shocks and ESD induced errors in data processing to tolerable levels.

5.3.4 Group 1 – Electrostatic control conditionally required

Typical locations are bedrooms, delivery rooms, electrocardiogram (ECG), electroencephalogram (EEG), electrohysterogram (EHG) rooms, endoscopic rooms, examination or treatment rooms, urology rooms, radiological diagnostic and therapy rooms, hydrotherapy rooms, physiotherapy rooms, haemodialysis rooms, MRI rooms and nuclear medicine rooms.

Electrostatic control methods are recommended in G1 locations to reduce the risk of ESA based contamination, ignition accidents, unpleasant electrostatic shocks and ESD induced errors in data processing to tolerable levels.

Electrostatic control methods are required in G1 locations if the humidity falls below 30 % RH, or below the humidity specified by equipment manufacturers, for a significant period of time (typically a continuous period of more than an hour), or if there is evidence of unacceptably high electrostatic charging. Evidence of unacceptably high charging can be the occurrence of any of the electrostatic hazards described in Clause 4, and can be confirmed by testing, see 5.6.2.3.3, 5.6.3.4 and 5.7 c) and d).

5.3.5 Group 2 – Electrostatic control required

Typical locations are anaesthetic areas, operating theatres, operating preparation rooms, operating plaster rooms, operating recovery rooms, heart catheterization rooms, intensive care rooms, angiographic examination rooms, premature baby rooms and intermediate care units.

Electrostatic control methods are required in G2 locations, where temporary losses of functions of medical equipment pose a significant risk to the life of patients and cannot, therefore, be tolerated. Electrostatic control methods can also be required in other medical locations depending on medical treatment or on manufacturer's specifications of medical equipment.

5.4 Service and maintenance

Unprotected ESD sensitive devices (ESDS) shall not be handled without an adequate ESD control programme. When unprotected ESDS are handled, the requirements of IEC 61340-5-1 shall be applied.

5.5 Administrative requirements and recommendations

5.5.1 Designing facilities

Precautions against electrostatic hazards in healthcare facilities are mainly based on passive control methods such as material selections and ground connections. Therefore, it is essential to take recommendations and requirements of this document into account in designing new facilities or refurbishing existing facilities. Active control measures such as optimizing dew point temperature, introducing bipolar ionization and optimizing room layouts and equipment locations as means to reduce individuals' exposures to excess charge and charged contaminants within the micro-environments they typically occupy should also be considered.

5.5.2 Operational responsibility

Organizations operating healthcare facilities are responsible for maintaining documentation and verification of the precautions against electrostatic hazards as well as considering any related training needs.

5.5.3 Qualification and verification

All new installations and materials used for electrostatic control shall be qualified before procurement. In addition, sample based acceptance testing at minimum is required for floorings and other installations. Periodic verifications or random checks of electrostatic control items are recommended.

Unless otherwise agreed, the atmosphere for conditioning and testing for qualification purposes shall be (23 ± 2) °C and (12 ± 3) % relative humidity, and the conditioning time prior to testing shall be at least 48 h. Verification testing shall be done under the range of ambient temperature and humidity conditions within the facility. For assessing the worst-case conditions humidity and temperature shall be measured at different times of the year when different humidity conditions can be experienced.

5.6 Technical requirements

5.6.1 Electrical safety

This document includes technical requirements for electrostatic control. These requirements shall not replace or supersede any requirements for personnel safety.

5.6.2 Material classification

5.6.2.1 General requirements for material classification

Materials for electrostatic control shall: limit the generation of electrostatic charge; quickly dissipate electrostatic charge; suppress or attenuate electrostatic field or electrostatic potential associated with residual electrostatic charge. To a certain extent, these functions are related. For example, a material that is able to dissipate charge faster than it is generated will appear to be one that limits the generation of charge. However, in some cases, the functions

can be independent. Some materials that do not dissipate charge quickly, can show limited accumulation of charge or low measured surface potential.

Surface and volume resistance measurements (see 5.6.2.2) are one way to classify a material's ability to dissipate electrostatic charge and, in many cases, to limit electrostatic charge generation. If materials are to be used in the ground path for grounding personnel and other conductors, resistance measurements are essential. Nevertheless, there are materials that can be used for electrostatic control for which resistance measurements are not appropriate. Alternative test methods (see 5.6.2.3) shall be used for such materials.

Another option is for healthcare facilities to specify their own test methods and classification requirements, either based on other standards, or defined within their own facility specifications. Guidance on electrostatic test methods can be found in IEC TR 61340-1, IEC TR 61340-2-2 [7] and IEC 60079-32-2 [8].

Clothing worn by personnel that is intended to protect the wearer from hazards such as chemicals, heat or cold, impact, ignition of flammable atmospheres, etc. is classified as personal protective equipment (PPE) and is commonly subject to specific regulations. For example, in Europe, PPE must comply with the PPE Directive (PPE Regulation from 2018), and clothing materials for use in flammable atmospheres are normally tested and evaluated using the EN 1149 series of standards [9].

NOTE Guidance on the selection, use, care and maintenance of PPE for preventing electrostatic risks in hazardous areas is given in CEN TR 16832 [10].

5.6.2.2 Material classification based on resistive properties

5.6.2.2.1 Resistance measurements

Surface and volume resistance measurements shall be made according to IEC 61340-2-3.

5.6.2.2.2 Electrostatic conductive materials

Conductive materials may be surface conductive, volume conductive or both. A surface conductive material shall have a surface resistance $< 1 \times 10^4$ Ω. Volume conductive materials shall have a volume resistance $< 1 \times 10^4$ Ω. Electrostatic control items can have different limits depending on the standard.

5.6.2.2.3 Electrostatic dissipative materials

Dissipative materials may be surface dissipative, volume dissipative or both. Surface dissipative materials shall have a surface resistance $\geq 1 \times 10^4$ Ω and $< 1 \times 10^{11}$ Ω. Volume dissipative materials shall have a volume resistance $\geq 1 \times 10^4$ Ω and $< 1 \times 10^{11}$ Ω. Electrostatic control items can have different limits depending on the standard.

5.6.2.2.4 Electrostatic insulating materials

Electrostatic insulating materials may be surface insulating, volume insulating or both. Surface insulating materials have a surface resistance $\geq 1 \times 10^{11}$ Ω. Volume insulating materials have a volume resistance $\geq 1 \times 10^{11}$ Ω. Electrostatic control items can have different limits depending on the standard.

5.6.2.3 Material classification based on charge decay time and triboelectric charging

5.6.2.3.1 Charge decay time measurements

Charge decay time measurements shall be made according to IEC 61340-2-1.

5.6.2.3.2 Electrostatic dissipative materials

Electrostatic dissipative materials shall have a charge decay time of ≤ 2 s from an initial value between (200 ± 10) V and (1 000 ± 50) V to (100 ± 5) V. A material is also classified as electrostatic dissipative if on application of a corona voltage of at least 7 kV the maximum surface voltage is less than 190 V.

5.6.2.3.3 Low charging materials

Low charging materials shall meet one or more of the following requirements:

a) friction-charged electrostatic potential ≤ 1 000 V (ISO 18080-2 or ISO 18080-4)

b) friction charge density ≤ 2 μC/m^2 (ISO 18080-3)

NOTE The ISO 18080 series of test methods are primarily intended for textile materials. All the test methods described in the ISO 18080 series can be used to evaluate similar thin, flexible materials. ISO 18080-3 can also be used with minimum modification to evaluate many different types of material.

5.6.3 Selection of materials for electrostatic control

5.6.3.1 Preferred materials

Electrostatic conductive or electrostatic dissipative materials are preferred for electrostatic control purposes.

In the specifications for their products, manufacturers can sometimes include reference to different standards that specify requirements for electrostatic performance of products for general applications or for use other than in healthcare facilities. Some of these other standards can be consistent with the requirements of this document, but others are not because of different test methods, test conditions or performance requirements. In cases of conflict or doubt when considering materials for electrostatic control for healthcare facilities, materials complying with the testing and performance requirements of this document shall be used.

5.6.3.2 Flooring used to ground personnel and equipment

When flooring is required to ground personnel and equipment for electrostatic control purposes, resistance to ground shall be ≤ 1 × 10^9 Ω measured in accordance with IEC 61340-4-1.

Resistance to ground ≤ 1 × 10^6 Ω is required for flooring in locations where flammable anaesthetics and hyperbaric oxygen systems are used and where high electrostatic charging mechanisms are expected, for example rapid removal of sheets from beds or drapes from operating tables. If resistance to ground ≤ 1 × 10^6 Ω is not achievable, precautions shall be taken to eliminate high charging mechanisms. For example, bedding or drapes shall be removed slowly.

5.6.3.3 Footwear used to ground personnel

When footwear is required to ground personnel and handheld equipment for electrostatic control purposes, resistance shall be ≤ 1 × 10^9 Ω measured in accordance with ISO 20344 or IEC 61340-4-3. In compliance verification resistance to ground shall be ≤ 1 × 10^9 Ω measured in accordance with IEC 61340-5-1.

Resistance to ground ≤ 1 × 10^6 Ω is required for flooring in locations where flammable anaesthetics and hyperbaric oxygen systems are used and where high electrostatic charging mechanisms are expected, for example rapid removal of sheets from beds or drapes from operating tables. If resistance to ground ≤ 1 × 10^6 Ω is not achievable, precautions shall be

taken to eliminate high charging mechanisms. For example, bedding or drapes shall be removed slowly.

5.6.3.4 Person – footwear – flooring system

When electrostatic control is required, but it is not possible or necessary to ground patients or healthcare personnel via footwear and flooring, for example in unclassified rooms (see 5.3.2), flooring shall be used that generates a body voltage ≤ 2 000 V measured according to IEC 61340-4-5.

The footwear used for testing shall be representative of footwear typically worn in the facility, or which is considered to represent worst case charging conditions.

5.6.3.5 Mobile metal objects, electrical equipment and furniture

When electrostatic control is required, all the mobile metal objects such as patient beds, stretchers, intravenous stands, trolleys, delivery carts, over bed tables, and chairs shall be connected to ground. Resistance to ground shall be ≤ 1×10^9 Ω. Measurement is made according to IEC 61340-2-3 between the local functional ground and an electrode assembly placed, where possible, on a metal surface of the item. If it is not possible to use the electrode assembly specified in IEC 61340-2-3, a metal probe shall be used to contact the metal frame of the item.

When wheels are used for grounding in combination with flooring, at least two electrostatic conductive or dissipative wheels are recommended.

When electrostatic control is required, mobile battery operated electrical equipment shall be connected to a functional ground if the equipment has a built-in ground connection available.

NOTE Modification of medical devices/equipment can be subject to medical device regulations.

5.6.3.6 Textiles

When electrostatic control is required, textiles shall be made of electrostatic conductive, electrostatic dissipative or low charging materials, complying with at least one of the following requirements:

a) surface resistance < 1×10^{11} Ω, measured in accordance with IEC 61340-2-3;

b) charge decay time from initial value between (200 ± 10) V and (1 000 ± 50) V to (100 ± 5) V of less than or equal to 2 s measured in accordance with IEC 61340-2-1 (a material is also classified as electrostatic dissipative if on application of a corona voltage of at least 7 kV the maximum surface voltage is less than 190 V);

c) friction-charged electrostatic potential ≤ 1 000 V, measured in accordance with ISO 18080-2 or ISO 18080-4;

d) friction charge density ≤ 2 μC/m^2, measured in accordance with ISO 18080-3.

It is rare for textiles to be entirely conductive; it is more common for so called conductive textiles to be made from insulating materials that incorporate conductive fibres either as an intimate blend or in a stripe or grid pattern. Irrespective of the method of construction, electrostatic conductive textiles shall be connected to ground during use in areas where electrostatic control is required.

Electrostatic dissipative and low charging textile materials can be made from materials that are chemically treated or coated in such a way that the entire surface is electrostatic dissipative or low charging. It is also common for electrostatic dissipative and low charging textiles to be made from insulating materials that incorporate dissipative or core-conductive fibres. Grounding of electrostatic dissipative or low charging textiles is not always necessary, unless the surface resistance is less than 10^8 Ω.

In unclassified and G0 rooms, where patients are often ungrounded, and in other locations where grounding of personnel is not possible or practical, the occurrence of electrostatic hazards can be reduced by using low charging textiles for clothing, upholstery, bedding, curtains, and surgical drapes.

Whereas the test methods and requirements specified in 5.6.3.6 are useful for initial material selection and qualification, additional tests are required for final qualification of finished products. This is because triboelectric charging is dependent on several factors, including the nature of the contacting materials and the mechanism by which they contact, rub together and separate. Therefore, products can only be described as low charging within the specific context in which they are used. Test methods used to determine if products are low charging shall replicate, as near as possible, in-use charging conditions. Suitable test methods are specified in Annex A.

The use of electrostatic conductive, electrostatic dissipative or low charging material aprons is recommended. Such specification will help reduce likely deposition of microorganisms and other contaminants on apron surfaces and the magnitude of induced charge and contaminant deposition on nearby individuals and surfaces.

5.7 Packaging, containers and other electrostatic control items

Packages, containers and other items made from insulating materials can become highly charged. In many cases, functional requirements such as hygiene, barrier properties, etc. take precedence over electrostatic properties. Nevertheless, consideration should be given to replacing insulating materials, where possible and practical, with electrostatic conductive, electrostatic dissipative or low charging materials, complying with at least one of the following requirements:

a) surface resistance $< 1 \times 10^{11}$ Ω, measured in accordance with IEC 61340-2-3;

b) charge decay time from initial value between (200 ± 10) V and (1 000 ± 50) V to (100 ± 5) V of less than or equal to 2 s measured in accordance with IEC 61340-2-1 (a material is also classified as electrostatic dissipative if, on application of a corona voltage of at least 7 kV, the maximum surface voltage is less than 190 V);

c) friction-charged electrostatic potential ≤ 1 000 V, measured in accordance with ISO 18080-2 or ISO 18080-4;

d) friction charge density ≤ 2 μC/m^2, measured in accordance with ISO 18080-3.

NOTE The ISO 18080 series of test methods are primarily intended for textile materials. All the test methods described in the ISO 18080 series can be used to evaluate similar thin, flexible materials. ISO 18080-3 can also be used with minimum modification to evaluate many different types of material.