UL 61010-2-020 (IEC 61010-2-020:2016)

STANDARD FOR SAFETY

Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-020: Particular Requirements for Laboratory Centrifuges

UL Standard for Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-020: Particular Requirements for Laboratory Centrifuges, UL 61010-2-020

Third Edition, Dated December 15, 2016

Summary of Topics

This revision of ANSI/UL 61010-2-020 dated February 4, 2022 is being issued to update the title page to reflect the most recent designation as a Reaffirmed American National Standard (ANS). No technical changes have been made.

Adoption of IEC 61010-2-020, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-020: Particular Requirements for Laboratory Centrifuges (third edition issued May 2016) as a new IEC-based UL standard, UL 61010-2-020, with no National Differences.

Text that has been changed in any manner or impacted by UL's electronic publishing system is marked with a vertical line in the margin.

The requirements are substantially in accordance with Proposal(s) on this subject dated December 17, 2021.

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UL 61010-2-020 (IEC 61010-2-020:2016)

Standard for Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-020: Particular Requirements for Laboratory Centrifuges

Third Edition

December 15, 2016

This ANSI/UL Standard for Safety consists of the Third Edition including revisions through February 4, 2022.

The most recent designation of ANSI/UL 61010-2-020 as a Reaffirmed American National Standard (ANS) occurred on February 4, 2022. ANSI approval for a standard does not include the Cover Page, Transmittal Pages, Title Page, or Preface. The IEC Foreword is also excluded from the ANSI approval of IEC-based standards.

Comments or proposals for revisions on any part of the Standard may be submitted to UL at any time. Proposals should be submitted via a Proposal Request in UL's On-Line Collaborative Standards Development System (CSDS) at https://csds.ul.com.

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Annex AA (normative) Dynamic microbiological test method for BIOSEALS

Annex BB (informative) General guidance and rationale for particular subclauses

Annex CC (informative) General guidance for an empirical method to determine the kinetic energy of a ROTOR

Bibliography

PREFACE

This UL Standard is based on IEC Publication 61010-2-020: third edition, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-020: Particular Requirements for Laboratory Centrifuges. IEC publication 61010-2-020 is copyrighted by the IEC.

Efforts have been made to synchronize the UL edition number with that of the corresponding IEC standard with which this standard is harmonized. As a result, one or more UL edition numbers have been skipped to match that of the IEC edition number.

This UL Standard 61010-2-020 Standard for Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-020: Particular Requirements for Laboratory Centrifuges, is to be used in conjunction with the third edition of UL 61010-1. The requirements for control equipment are contained in this Part 2 Standard and UL 61010-1.

Requirements of this Part 2 Standard, where stated, amend the requirements of UL 61010-1.

Where a particular subclause of UL 61010-1 is not mentioned in UL 61010-2-020, the UL 61010-1 subclause applies.

Note – Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the users of the Standard to judge its suitability for their particular purpose.

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FOREWORD

INTERNATIONAL ELECTROTECHNICAL COMMISSION

SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE – Part 2-020: Particular Requirements for LABORATORY CENTRIFUGES

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 nongovernmental 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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7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.

8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.

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

International Standard IEC 61010-2-020 has been prepared by IEC technical committee 66: Safety of measuring, control and laboratory equipment.

This third edition cancels and replaces the second edition published in 2006. It constitutes a technical revision and includes the following significant changes from the second edition:

a) This Part 2 is established on the basis of the third edition (2010) of IEC 61010-1.The changes listed in its foreword affect this Part 2, too.

b) The language has been updated to reflect current terminology for LABORATORY CENTRIFUGES used in the industry today.

It has the status of a group safety publication as specified in IEC Guide 104.

The text of this standard is based on the following documents:

CDV	Report on voting
66/542/CDV	66/565A/RVC

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

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

This Part 2-020 is intended to be used in conjunction with IEC 61010-1. It was established on the basis of the third edition (2010).

This Part 2-020 supplements or modifies the corresponding clauses in IEC 61010-1 so as to convert that publication into the IEC standard: *Particular requirements for LABORATORY CENTRIFUGES*.

Where a particular subclause of Part 1 is not mentioned in this part 2, that subclause applies as far as is reasonable. Where this part states “addition”, “modification”, “replacement”, or “deletion”, the relevant requirement, test specification or note in Part 1 should be adapted accordingly.

In this standard:

1) the following print types are used:

– requirements: in roman type;

– NOTES: in small roman type;

– *conformity and tests: in italic type;*

– terms used throughout this standard which have been defined in Clause 3: SMALL ROMAN CAPITALS.

2) subclauses, figures, and tables which are additional to those in Part 1 are numbered starting from 101; additional annexes are lettered AA, BB, etc.

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

A list of all parts of the IEC 61010 series, published under the general title *Safety requirements for electrical equipment for measurement, control, and laboratory use*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

• reconfirmed,

• withdrawn,

• replaced by a revised edition, or

• amended.

SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE – Part 2-020: Particular requirements for LABORATORY CENTRIFUGES

1 Scope and object

This clause of Part 1 is applicable except as follows:

1.1.1 Scope

Replacement:

This Part 2 is applicable to electrically powered LABORATORY CENTRIFUGES.

This group safety publication is primarily intended to be used as a product safety standard for the products mentioned in the scope, but shall also be used by technical committees in the preparation of its publications for products similar to those mentioned in the scope of this standard, in accordance with the principles laid down in IEC Guide 104 and ISO/IEC Guide 51.

NOTE If all or part of the equipment falls within the scope of one or more other Part 2 standards of IEC 61010 as well as within the scope of this standard, it will also need to meet the requirements of those other Part 2 standards.

1.1.2 Equipment excluded from scope

Addition:

Add the following new item:

aa) IEC 60034 (Rotating electrical machinery);

1.2 Object

1.2.1 Aspects included in scope

Addition:

Add the following new items:

aa) contact with moving parts (see 7.3);

bb) LABORATORY CENTRIFUGE movement during any DISRUPTION (see 7.3.101);

cc) high energy chemical reaction after ROTOR DISRUPTION (see 7.7.2.2l));

dd) ineffectiveness of BIOSEALS (see 13.101)

1.2.2 Aspects excluded in scope

Addition:

Add the following new items:

aa) additional precautions which may need to be observed when centrifuging materials which are flammable or explosive (see 5.4.101);

bb) additional precautions which may need to be observed when centrifuging materials that could react chemically with sufficient vigour to cause a HAZARD (see 5.4.101).

1.4 Environmental conditions

1.4.1 Normal environmental conditions

Replacement:

Replace item c) by the following:

c) temperature 2 °C to 40 °C;

1.4.2 Extended environmental conditions

Replacement:

Replace item c) by the following:

c) ambient temperatures 2 °C or above 40 °C;

2 Normative references

This clause of Part 1 is applicable except as follows:

Addition:

ISO 3864 (all parts), *Graphical symbols – Safety colours and safety signs*

3 Terms and definitions

This clause of Part 1 is applicable except as follows:

3.1 Equipment and states of equipment

Addition:

Add the following new terms and definitions:

3.1.101 **LABORATORY CENTRIFUGE** apparatus intended for laboratory use that applies a centrifuging effect to sample materials

3.1.102 **CENTRIFUGE-ROTOR COMBINATION** LABORATORY CENTRIFUGE and ROTOR ASSEMBLY that are intended to operate together and which have to be evaluated together

3.1.103 **DISRUPTION** event in which the ROTOR ASSEMBLY, or part of it, fails or becomes detached during rotation

3.2 Parts and accessories

Addition:

Add the following new terms and definitions:

3.2.101 **CHAMBER** enclosed space within a LABORATORY CENTRIFUGE in which the ROTOR ASSEMBLY rotates

3.2.102 **ROTOR** primary component of a LABORATORY CENTRIFUGE which holds the material to be subjected to centrifugal force and which is rotated by the DRIVE SYSTEM

3.2.103 **BUCKET** sub-assembly of a ROTOR designed to support one or more containers

3.2.104 **PROTECTIVE CASING** casing which completely surrounds the ROTOR ASSEMBLY and which includes the LID and its securing devices

3.2.105 **LID** access cover of the CHAMBER

3.2.106 **ROTOR ASSEMBLY** ROTOR carrying a combination of ROTOR accessories specified by the manufacturer

Note 1 to entry: In the context of a ROTOR ASSEMBLY, ROTOR accessories include all components used with or in the CENTRIFUGE ROTOR for the purpose of holding samples, including adaptors, tubes and bottles.

3.2.107 **DRIVE SYSTEM** all components of the CENTRIFUGE associated with the provision of torque to, or the rotational support of, the ROTOR ASSEMBLY

3.2.108 **BIOSEAL** device or mechanism additional to, or integral with, a ROTOR or BUCKET and a closure assembly, and which is designed to prevent the escape of contents, for example microbiological material, during centrifuging

3.5 Safety terms

Addition:

Add the following new terms and definitions:

3.5.101 **CLEARANCE ENVELOPE** space around a LABORATORY CENTRIFUGE which is needed for safety

3.5.102 **CENTRIFUGE-ROTOR COMBINATION** LABORATORY CENTRIFUGE and ROTOR ASSEMBLY that are intended to operate together and which have to be evaluated together

4 Tests

This clause of Part 1 is applicable.

5 Marking and documentation

This clause of part 1 is applicable except as follows:

5.1 Marking

Replacement:

Replace item b) by the following:

b) serial number or other means to identify the production batch of the equipment.

Addition:

Add the following new subclause:

5.1.101 ROTORS and accessories

All OPERATOR-replaceable ROTORS and ROTOR ASSEMBLIES, including ROTOR ACCESSORIES, shall be marked with the manufacturer's or supplier's name or registered trade mark, and identification code.(such as id code, serial number or batch number)

If components are too small, or are not suitable for such marking, the required information shall be marked on the original packaging, as well as being stated in the documentation.

NOTE Packaging can be the outer box, an insert, etc.

If the manufacturer specifies that an individual part, for example a BUCKET, is to be fitted only to a specific ROTOR or in specific ROTOR positions for balance or some other reason, each BUCKET and ROTOR position should be identified by marking with corresponding numbers or letters..

Conformity is checked by inspection.

5.4.2 Equipment ratings

Addition:

Add the following new items:

aa) a list of all ROTORS and ROTOR accessories specified for use with a LABORATORY CENTRIFUGE, together with their RATED rotational frequencies;

bb) any restrictions by the manufacturer warning against the use of particular materials to be centrifuged;

cc) density and volume limits for ROTOR ASSEMBLY loading and, if applicable, derating instructions.

5.4.3 Equipment installation

Addition:

Add, after item a), the following sub-items:

i) floor or bench area required for the CLEARANCE ENVELOPE for the intended use (see 7.4.101);

ii) total weight of the CENTRIFUGE;

iii) instructions for site preparation;

iv) methods for levelling of the CENTRIFUGE;

v) means for securing to the mounting surface.

5.4.4 Equipment operation

Addition:

Add the following new items:

aa) loading and balancing procedures;

bb) ROTOR changing procedure;

cc) any specific requirement for an OPERATOR to be present at stated phases of the centrifuging procedure;

dd) necessary safeguards for personnel. Instructions shall include at least the following:

– not to lean on a LABORATORY CENTRIFUGE;

– not to stay within the CLEARANCE ENVELOPE longer than necessary for operational reasons;

– not to deposit any potentially hazardous materials within the CLEARANCE ENVELOPE;

– methods for safe operation during open LID procedures (see 7.3.102.2);

ee) instructions for use of BIOSEALS and other biocontainment components, including the proper closure techniques. These instructions shall indicate that BIOSEALS and related components are intended to be part of biocontainment systems, as specified in international and national biosafety guidelines. They are not to be relied on as the only means of safeguarding workers and the environment when handling pathogenic microorganisms.

5.4.5 Equipment maintenance

Addition:

Add the following new paragraph:

Where applicable, the instructions shall specify:

aa) inspection of any means of fixing the equipment to the mounting surface and the condition of the mounting surface itself;

bb) safeguards for the OPERATOR during cleaning;

cc) inspection of the PROTECTIVE CASING;

dd) inspection of the ROTOR ASSEMBLY, and safety considerations;

ee) checking the continuity of the PROTECTIVE BONDING;

ff) frequency of inspection, routine maintenance and the method of replacement of BIOSEALS and other biocontainment components.

Addition:

Add the following new subclauses:

5.4.101 Hazardous substances

The instructions for use shall state the precautions to be observed when the materials to be used with a LABORATORY CENTRIFUGE are known to be toxic, radioactive, or contaminated with pathogenic micro-organisms.

NOTE This information is relevant to the safety of both OPERATORS and service personnel.

The use within the LABORATORY CENTRIFUGE of the following materials shall be prohibited in the instructions for use:

a) flammable or explosive materials;

b) flammable or explosive materials;

materials which could react chemically with sufficient vigour to cause a HAZARD.

Conformity is checked by inspection.

5.4.102 Cleaning and decontamination

Documentation shall include:

a) a statement that, if hazardous material is spilt on or inside the equipment, the user has responsibility for carrying out appropriate decontamination;

b) manufacturer's recommendations for cleaning and, where necessary, decontaminating, together with the recognized generic names of recommended materials for cleaning and decontaminating:

c) the following statement:

"Before using any cleaning or decontamination methods except those recommended by the manufacturer, users should check with the manufacturer that the proposed method will not damage the equipment”

d) the following statement:

Cleaning and decontamination may be necessary as a safeguard before LABORATORY CENTRIFUGES, ROTORS, and any accessories are maintained, repaired, or transferred. Manufacturers may provide a format for users to document that such treatment has been carried out

NOTE Be advised, there are national guidelines and the internationally recognized "Laboratory Biosafety Manual", published in 1993 by the Wor5ld Health Organization in Geneva, which gives information on decontaminants, their use, dilutions, properties, and potential applications.

Conformity is checked by inspection.

5.4.103 Effects of chemicals and environmental influences

To ensure continued safe use of a LABORATORY CENTRIFUGE the documentation shall identify damage which could result from, for example:

a) the effect of chemicals;

b) environmental influences, including natural ultra-violet radiation likely to be encountered;

c) corrosion, and other weakening of construction materials that are part of the PROTECTIVE CASING or other protective components.

Conformity is checked by inspection of the documentation and the relevant data and/or additional testing (if needed).

6 Protection against electric shock

This clause of Part 1 is applicable.

7 Protection against mechanical HAZARDS

This clause of Part 1 is applicable except as follows:

7.1 General

Addition:

Add the following new note:

NOTE 101 A DISRUPTION, resulting in damage to a part of the PROTECTIVE CASING, for example a LID-locking mechanism, is considered to be a SINGLE FAULT CONDITION.

7.3 Moving parts

Addition:

Add the following new subclauses.

7.3.101 LID

7.3.101.1 Requirements

The LID shall be locked closed when the ROTOR drive is energized, and shall remain locked until the circumferential velocity of the ROTOR ASSEMBLY is not more than 2 m/s (see Annex BB).

In the event of a power failure, the LID-locking mechanism shall not release, and subsequent release shall require the use of a TOOL.

The LID shall be held closed with sufficient strength to withstand the results of testing according to 7.7.3. Fragments produced by any DISRUPTION shall be contained as specified in item a) of 7.7.

To evaluate which of the following points are appropriate for the CENTRIFUGE-ROTOR COMBINATION under consideration, information shall be recorded showing the tests conducted by the manufacturer or by a test facility:

a) mechanical abuse;

b) mislatching;

c) misalignment;

d) corrosion;

e) material degradation;

f) material defects;

g) vibration;

h) cleaning and decontamination;

i) environmental influences;

j) other considerations appropriate for the design.

Conformity is checked by visual inspection; by the review of recorded information, by the tests carried out under 7.7.3, and by any further tests considered appropriate for safety.

7.3.101.2 Exception

For LABORATORY CENTRIFUGES that satisfy all the following limitations, a device which merely interrupts motor power may be used instead of an interlock mechanism (see Annex BB):

a) the LABORATORY CENTRIFUGE incorporates a device which holds the LID closed;

b) the device which interrupts motor power does not permit the drive motor to be energized unless the LID is closed;

c) the rotational frequency of the ROTOR ASSEMBLY does not exceed 3 600 rpm;

d) the energy at maximum rotational frequency for the highest energy ROTOR ASSEMBLY when fully loaded does not exceed 1 kJ;

e) the maximum centrifugal force does not exceed 2 000 g;

f) the largest ROTOR ASSEMBLY diameter does not exceed 250 mm;

g) a switch is provided for disconnecting motor power, independent of the LID position;

h) the ROTOR ASSEMBLY is visible when the LID is closed, to permit observation of any rotation;

i) all ROTOR ASSEMBLIES used conform to 7.3 of Part 1;

j) if access is possible at a circumferential velocity of the ROTOR ASSEMBLY of more than 2 m/s, a warning label in accordance with ISO 3864 is provided on or near the access point, indicating that the LID should not be opened until rotation has stopped. Where there is insufficient space for such a label, symbol 14 of Table 1 is considered to be an acceptable marking.

Conformity is checked by visual inspection and by the review of data to confirm that all the above limitations are met.

7.3.102 ROTOR ASSEMBLIES

7.3.102.1 General

If a HAZARD could result from contact with moving parts of the ROTOR ASSEMBLY or DRIVE SYSTEM in NORMAL CONDITION or SINGLE FAULT CONDITION, suitable protective means shall be provided to prevent OPERATOR access, except as permitted by 7.3.101.2 and 7.3.102.2.

There shall be no holes or other openings in the top of the CHAMBER which permit the penetration of a 4 mm diameter pin.

Conformity is checked by inspection and by using the test fingers shown in Figures B.1 and B.2, and by checking openings in the top with a 4 mm diameter pin, in NORMAL CONDITION and SINGLE FAULT CONDITION.

The jointed test finger shown in Figure B.2 is applied in every possible position without applying any force. If it is possible to touch a part by applying a force, the rigid test finger shown in Figure B.1 is applied with a force of 10 N. The force is exerted against all outer surfaces, including the bottom, by the tip of the test finger so as to avoid wedge or lever action. The finger shall not touch any moving part that could cause a HAZARD.

7.3.102.2 ROTOR ASSEMBLIES requiring access during rotation

If the manufacturer supplies ROTOR ASSEMBLIES requiring OPERATOR interaction (e.g. zonal or continuous-flow ROTOR ASSEMBLIES), LABORATORY CENTRIFUGES are permitted to have an override control which allows the motor to be energized while the access LID is open, provided that:

a) the override control allows the motor to be energized only by use of a device (which can be a code or code-card) that makes it possible to override a protective system and functions by means that cannot be performed using other tools, or when a special guard plate allows only limited access to the rotor assembly;

b) means are provided to cancel the override function automatically when use of the rotor assembly requiring OPERATOR interaction is ended;

c) maximum speed while the LID is open is limited to 5 000 rpm.

Conformity is checked by inspection.

7.4 Stability

Addition:

Add a new third paragraph as follows:

No displacement of the LABORATORY CENTRIFUGE from its installed position shall be visible during NORMAL USE.

Addition:

Add the following new subclause:

7.4.101 LABORATORY CENTRIFUGE movement during malfunction

After installation according to the manufacturer's instructions, movement of a LABORATORY CENTRIFUGE as a result of ROTOR ASSEMBLY imbalance, ROTOR ASSEMBLY DISRUPTION, or drive failure (seizure), shall not present a HAZARD.

Movement shall be limited either by design, or by fastening to the mounting surface, or a combination of both, so that no part of the LABORATORY CENTRIFUGE moves outside a CLEARANCE ENVELOPE extending 300 mm, or less if stated by the manufacturer, in any direction from the outermost parts of the LABORATORY CENTRIFUGE in its original position (for rationale see Clause BB.6).

Conformity is checked by testing to confirm that the 300 mm limit, or any lower limit stated by the manufacturer, is not exceeded in NORMAL USE and after inducing the worst-case situation according to 7.7.2.2 for:

a) imbalance;

Use of an imbalance sensor is acceptable as a means for limiting movement. , but its possible failure should be considered when determining the worst-case condition unless examination of the equipment and design demonstrates conclusively that the sensor will not fail.

b) disruption of the ROTOR ASSEMBLY;

c) DRIVE SYSTEM failure;

d) seizure of the DRIVE SYSTEM.

NOTE The failure mode which will produce the greatest movement can be different from the failure mode of the MCA determined for testing the PROTECTIVE CASING according to 7.7.3. See Annex CC for additional guidance in determining the worst case rotor.

For these tests, the LABORATORY CENTRIFUGE is mounted on, or fixed to, a horizontal smooth concrete test surface of dimensions appropriate for the size of LABORATORY CENTRIFUGE being tested, and as specified in the manufacturer's instructions.

7.7 Expelled parts

Replacement:

Replace the title and text by the following new title and text.

7.7 Protection against expelled parts or projected parts

7.7.1 General

LABORATORY CENTRIFUGES shall be designed for safe operation in NORMAL USE and SINGLE FAULT CONDITION, when used with ROTOR ASSEMBLIES specified by the manufacturer.

In the event of a DISRUPTION:

a) no parts or fragments of the ROTOR ASSEMBLY exceeding 5 mm in any dimension shall completely penetrate the PROTECTIVE CASING. Smaller material (except for aerosols and liquids) shall remain within a trajectory extending 1 m in any direction from the outermost parts of the LABORATORY CENTRIFUGE; (See rationale in Annex BB.6)

b) no part of the LABORATORY CENTRIFUGE shall become detached or expelled in such a way as to present a HAZARD to personnel or the environment. In the case of parts detached or expelled from the centrifuge (not part of the ROTOR ASSEMBLY) this is to be evaluated in accordance with Clause 17.

c) the fastenings of the access LID shall not be loosened, and there shall be no distortion which could create an unimpeded path between any point on the ROTOR ASSEMBLY and any point outside the LABORATORY CENTRIFUGE.

Conformity of every CENTRIFUGE-ROTOR COMBINATION specified by the manufacturer is checked by testing as specified in 7.7.3, under MCA conditions, or by causing DISRUPTION by partially cutting the ROTOR, or by overloading the ROTOR ASSEMBLY, or by other appropriate means. If more than one worst-case ROTOR ASSEMBLY selection exists, each can be tested with a new PROTECTIVE CASING.

After the tests, the criteria of a) to c) above shall be met, and visible cracks shall be examined to determine whether or not the PROTECTIVE CASING would have contained the ROTOR parts irrespective of their trajectory. A questionable result shall require the test to be repeated once only, and a further questionable result is considered to be a failure. The equipment is checked to ensure that parts which are HAZARDOUS LIVE have not become ACCESSIBLE and that ACCESSIBLE conductive parts do not exceed the values of 6.3.2. In the event that the test causes the operation of an overcurrent protection device, if the device can not be reset without operating again, the unit is considered to have failed safe. (See rationale Annex BB.6.2)

NOTE 1 Consideration should be given to the presence of temporary gaps in containment during the MCA test in determining questionable results.

Alternatively, the safety of a CENTRIFUGE-ROTOR COMBINATION can be established by analytical evaluation based on comparison with one of more of the CENTRIFUGE-ROTOR COMBINATIONS already tested, to confirm that the PROTECTIVE CASING would have passed the relevant test of 7.7.3.

NOTE 2 CENTRIFUGE-ROTOR COMBINATIONS designed such that satisfactory evaluation by comparison with another CENTRIFUGE-ROTOR COMBINATION already tested cannot be made are tested as specified in 7.7.3.

7.7.2 Considerations for MCA tests

7.7.2.1 Information to be recorded

Recorded information shall include:

a) corrosion effects to be expected;

b) material fatigue behaviour;

c) material degradation considerations, including effects of inspection, maintenance, and component replacement schedules;

d) temperature limitation considerations;

e) material defect considerations;

f) improper BUCKET installation considerations;

g) relevant environmental considerations;

h) relevant maximum loading considerations;

i) electrical circuit diagram and functional descriptions;

j) material specifications and technical data;

k) pre-treatment methods to induce ROTOR ASSEMBLY failure;

l) traceability of all measuring instruments used during tests;

m) any other relevant information.

Conformity is checked by inspection of documentation relating to the above items.

7.7.2.2 Considerations for worst-case conditions

All combinations of the following that are possible shall be considered:

a) ROTOR selection: the worst-case specified ROTOR ASSEMBLY or ROTOR ASSEMBLIES; (for calculating the kinetic energy of rotors, refer to annex CC)

b) rotational frequency control setting: the maximum that an OPERATOR can select;

c) supply voltage: 10 % above the maximum RATED voltage marked on the equipment;

d) ROTOR ASSEMBLY load: the maximum specified load, partial load, and no load, including state and density of load (e.g. liquid, solid);

e) ROTOR accessories, worst case loading of specified accessories used with or in the ROTOR for the purpose of holding samples, including adaptors, tubes, and bottles;

f) ROTOR ASSEMBLY imbalance: the most severe condition;

g) altitude factors: the effect of reduced atmospheric pressure and density at increased altitude on ROTOR DRIVE SYSTEMS which rely on windage to limit maximum rotational frequency (see 1.4.1 b) and 1.4.2 b)).

NOTE 1 The windage limitation can be determined by conducting a rotational frequency test in a cabinet or room in which the pressure is controlled to 80 kPa or less, or alternatively the rotational frequency n_2, which would be reached at 2 000 m altitude, can be determined from:

$$n_2 = n_1 \times \sqrt[3]{R}$$

where

n_1 is the maximum rotational frequency at standard atmospheric pressure at sea-level (101 kPa);

n_2 is the corresponding maximum rotational frequency at an atmospheric pressure equivalent to 2 000 m;

R = 1,27 (the ratio of the density of air at sea-level, to that at 2 000 m).

h) friction between the LABORATORY CENTRIFUGE or LABORATORY CENTRIFUGE feet and the surface on which the LABORATORY CENTRIFUGE is placed;

i) ambient temperature: the effect on components of working at any temperature in the permitted range from 2 °C to 40 °C;

j) a combination of ROTOR ASSEMBLY and drive unit causing an instability of the dynamic behaviour;

k) installation as specified by the manufacturer;

l) the possibility of high energy chemical reaction after DISRUPTION

NOTE 2 In LABORATORY CENTRIFUGES which develop energies of the order of 275 kJ and above, and which are refrigerated under vacuum, it is possible for a DISRUPTION to cause a chemical explosion if parts of the ROTOR ASSEMBLY are made of reactive material, such as aluminium and titanium. An explosion can occur due to interaction at high energies of the ROTOR ASSEMBLY fragments with refrigerants and water.

In such cases, the worst-case conditions can be achieved by the following combination of means:

i) disabling rotational frequency controls and limiting devices so that the highest rotational frequency is reached;

ii) selecting whichever ROTOR of reactive material has the highest rotational energy, and pretreating it so as to cause a DISRUPTION. The pre-treatment shall maximize the surface area of the resulting fragments;

iii) adjusting the refrigeration system to have the maximum amount of refrigerant in the evaporator which cools the CHAMBER;

iv) loading the ROTOR ASSEMBLY with water to 80 % of its nominal capacity;

v) running the LABORATORY CENTRIFUGE in worst-case conditions of all other unspecified factors until a DISRUPTION occurs.

NOTE 3 Test personnel should be aware that extraordinary energy release can result from the tests where a high-energy chemical reaction is possible after DISRUPTION. A remote bunker facility is recommended.

Conformity is checked by inspection of documentation relating to the above items.

7.7.2.3 SINGLE FAULT CONDITIONS to be considered

The following SINGLE FAULT CONDITIONS shall be considered:

a) rotational frequency control condition: whichever SINGLE FAULT CONDITION that results in the highest rotational frequency;

b) rotational frequency limiting system whichever SINGLE FAULT CONDITION permits the highest rotational frequency;

c) MAINS power interruption: intermittent or permanent loss of MAINS power, if either presents a hazardous condition;

d) drive seizure: the sudden application of the rotational energy to the frame and case of a LABORATORY CENTRIFUGE;

e) any component failure;

f) non-quantitative SINGLE FAULT CONDITIONS:

i) corrosion effects, for example corrosion at the bottom of a BUCKET or cavity, stress corrosion cracking of alloys, corrosion of welds in the PROTECTIVE CASING, environmental crazing of polymers, etc.;

ii) material fatigue behaviour, which may affect the mode of failure;

iii) material defects;

iv) improper installation of a BUCKET or any other component that is fitted in a swinging BUCKET system (e.g. the omission of a BUCKET), incorrect mounting of a BUCKET at its pivot points, use of an incorrect BUCKET, and overloading a BUCKET;

v) temperature effects, such as expected extremes during transportation, high ROTOR ASSEMBLY temperatures during operation, and any necessary treatment specified by the manufacturer.

Conformity is checked by inspection of documentation relating to the above items.

7.7.3 Testing the PROTECTIVE CASING

For each worst-case ROTOR ASSEMBLY selection in each MCA, determined according to 7.7.2.1 to 7.7.2.3, testing as necessary shall be carried out to prove the adequacy of the PROTECTIVE CASING, and to show that it would have contained the ROTOR parts irrespective of their trajectory. No parts or fragments shall be expelled from the PROTECTIVE CASING during the tests, other than those permitted by 7.7.1 a).

Each test may be carried out with a new PROTECTIVE CASING.

The ROTOR ASSEMBLY under test may first be appropriately weakened to induce it to fail during the test of the PROTECTIVE CASING in accordance with the MCA failure mode.

One of the more difficult fragments of a ROTOR ASSEMBLY to contain in a DISRUPTION is an approximate half ROTOR. Experience over the years has shown that many designs of ROTOR can disrupt to give such a size of fragment. This should be taken into account when determining an MCA, as well as other ROTOR failure modes.

Test data shall be recorded, including the following:

a) description of the LABORATORY CENTRIFUGE and ROTOR ASSEMBLY – model, ROTOR type, accessories and loading;

b) MCA conditions, with justification;

c) ROTOR ASSEMBLY failure inducement method with justification;

d) date and time of the test;

e) environmental conditions during the test;

f) photographs of the LABORATORY CENTRIFUGE and relevant parts before and after the test, with video-recording of the DISRUPTION;

g) rotational frequency at the time of ROTOR ASSEMBLY failure, and hence the energy involved;

h) type of ROTOR ASSEMBLY failure;

i) description of any damage caused to the PROTECTIVE CASING;

j) details of any movement of the LABORATORY CENTRIFUGE;

k) details of the escape of any debris.

8 Mechanical resistance to shock and impact

This clause of Part 1 is applicable.

9 Protection against the spread of fire

This clause of Part 1 is applicable.

10 Equipment temperature limits and resistance to heat

This clause of Part 1 is applicable.

11 Protection against HAZARDS from fluids

This clause of Part 1 is applicable except as follows.

11.2 Cleaning

Replacement:

Replace the second paragraph by the following:

Conformity is checked by cleaning the equipment 20 times if a cleaning process is specified and decontaminating the equipment once if a decontamination process is specified, in accordance with the manufacturer's instructions. If a manufacturer specifies only certain cleaning procedures, only these shall be applied. If no restriction is given in the instructions for use, a steam sterilization test at one of the time-temperature conditions of Table 101 (see 11.2.101) shall be repeated 20 times.

If, immediately after this treatment, there are any signs of wetting of parts likely to cause a HAZARD, the equipment shall pass the voltage test of 6.8 (without humidity preconditioning) and ACCESSIBLE parts shall not exceed the limits of 6.3.1.

Addition:

Add the following new subclause:

11.2.101 Steam sterilization

If a manufacturer claims that an item can be decontaminated by steam sterilization, it shall be capable of withstanding steam sterilization under at least one of the time-temperature conditions given in Table 101.

Table 101
Time-temperature conditions

Absolute pressure kPa	Corresponding steam temperature		Minimum hold time min
	Nominal °C	Range °C	
325	136,0	134 – 138	3
250	127,5	126 – 129	10
215	122,5	121 – 124	15
175	116,5	115 – 118	30
NOTE 'Minimum hold time' means the time the containment is at steam temperature.			

Conformity is checked by test.

11.3 Spillage

Modification:

Insert "or onto" after "into" in the first line.

Addition:

Add the following new subclause:

11.101 Refrigerated and water-cooled LABORATORY CENTRIFUGES

Refrigerated and water-cooled LABORATORY CENTRIFUGES shall not become hazardous while operated in elevated humidity and temperature conditions.

Conformity is checked by operating the LABORATORY CENTRIFUGE in an environmental cabinet which has been set at the maximum RATED humidity and temperature of the LABORATORY CENTRIFUGE. The equipment is operated in the standby mode, at the lowest settable CABINET temperature, for a period of 7 h.

Immediately after treatment, the equipment shall pass the voltage test of 6.8 (without further humidity preconditioning), and ACCESSIBLE parts shall not exceed the limits of 6.3.1.

12 Protection against radiation, including laser sources, and against sonic and ultrasonic pressure

This clause of Part 1 is applicable.

13 Protection against liberated gases and substances, explosion and implosion

This clause of Part 1 is applicable, except as follows.

Replacement:

Replace the title by the following new title:

13 Protection against liberated gases, explosion and implosion and escape of microbiological materials

Addition:

Add the following new subclause:

13.101 Microbiological materials

BIOSEALS in ROTORS and BUCKETS which are RATED by the manufacturer as being fit to contain microbiological specimens during centrifuging shall prevent the escape of biological materials, when operated and maintained in accordance with the manufacturer's instructions (see Annex AA).

Conformity is checked by testing the BIOSEAL as specified in Annex AA.

NOTE Additional test methods are under consideration for types of BIOSEAL for which the test of Annex AA is not applicable, and to cover much smaller micro-organisms (see also Annex BB, 13.101).

14 Components

This clause of Part 1 is applicable.

15 Protection by interlocks

This clause of Part 1 is applicable.

16 HAZARDS resulting from application

This clause of Part 1 is applicable.

17 RISK assessment

This clause of Part 1 is applicable.

Annexes

All annexes of Part 1 are applicable except as follows:

Annex L

Index of defined terms

Additional defined terms:

Addition:

Add the following new annexes:

Annex AA
(normative)

Dynamic microbiological test method for BIOSEALS

AA.1 General

This test method is based upon exposing the BIOSEAL of a BUCKET or ROTOR to a concentrated suspension of bacterial spores while the LABORATORY CENTRIFUGE is operating and testing to show that no spores escape. This test is designed to challenge the BIOSEAL design as a whole during a foreseeable event likely to occur when operated in accordance with the manufacturer's instructions (see 5.4) and with good laboratory practices associated with handling bio-hazardous materials.

AA.2 Equipment and method

AA.2.1 CENTRIFUGE

The BUCKET or ROTOR is used as part of a ROTOR ASSEMBLY in conjunction with the type of LABORATORY CENTRIFUGE that is recommended by its manufacturer. BUCKETS, ROTORS and LABORATORY CENTRIFUGES are used in accordance with their manufacturer's instructions. Tests shall be carried out in CENTRIFUGES capable of reaching the maximum speed for the ROTOR as stated by the manufacturer. If possible, the LABORATORY CENTRIFUGE is operated from outside the test cabinet or test room during the tests.

AA.2.2 Test cabinet or test room

The cabinet is essentially airtight and of appropriate size for the LABORATORY CENTRIFUGE under test. It is fitted with high efficiency particulate air (HEPA) filters on both the inlet and outlet and a means of introducing the LABORATORY CENTRIFUGE and ROTOR ASSEMBLY to be tested. It is also provided with an electrical supply and facilities for operating the LABORATORY CENTRIFUGE from outside the test cabinet. The cabinet is fitted with an extractor fan capable of extracting air at a rate of approximately 2,8 m^3/min. If the CENTRIFUGE used is a floor standing model, then the cabinet or test room may have to be accessed by test personnel wearing full, clean room clothing including gloves and overshoes.

AA.2.3 Test suspension

An aqueous suspension of spores of the test organism, Bacillus subtilis var. niger (also referred to as B. atrophaeus Nakamura or B. globigii), containing ≥1 × 10^{10} spores/ml.

AA.2.4 Test plates

Sterile agar plates with appropriate medium for the growth of the test organism. The batch of agar plates shall be shown to be capable of recovering low concentrations of the test microorganism by plating out 0,1 ml of a 100 spore/ml to 1 000 spore/ml suspension on two plates with an accuracy of ±30 %.

AA.2.5 Sampling equipment

For all LABORATORY CENTRIFUGES, sampling equipment consists of sterile cotton swabs, moistened with sterile water, for sampling surfaces.

AA.2.6 Fumigation equipment

Equipment shall be suitable for appropriate fumigation of the test cabinet and its contents after each individual test, to kill the spores remaining from the test suspension. The effectiveness of the fumigation is verified by ensuring that there is no background contamination of the ROTOR or cabinet before testing. Care shall be taken to ensure that the fumigant is fully dispersed before testing is undertaken. The ventilation system of the test cabinet is inactivated and a measure of the fumigant concentration is taken

after a period equal to the relevant test period. If the concentration of the fumigant is appreciable (in the case of formaldehyde > 2 ppm) then the test is delayed, and ventilation is continued, until the level drops.

NOTE Fumigants are toxic by inhalation and care should be taken to avoid any exposure of personnel and also in the subsequent disposal of the vapour.

AA.2.7 Assessment of samples

All cultures are made on the surface of test plates. Swabs are rubbed over the surface of the test plates, which are incubated aerobically at 37 °C for between 18 h and 24 h. Bacillus subtilis var. niger colonies are recognized by their orange colour and are recorded as colonyforming units.

AA.3 Test procedure

AA.3.1 Checking of test suspension

Immediately before each test, appropriate dilutions of the test suspension are plated onto test plates.

AA.3.2 Test method

AA.3.2.1 Number of tests

Three separate tests, in which the BIOSEAL of the BUCKET or ROTOR is tested, are performed on each BUCKET or ROTOR. Control samples are taken before the test, as defined in AA.3.2.4.

AA.3.2.2 Fixed-angle ROTOR test method

Appropriate containers for the ROTOR under test are filled with the test suspension and placed, without capping or sealing, into every place in the ROTOR. All the ROTOR positions are filled to their RATED capacity, in accordance with the manufacturer's instructions.

Additional test suspension is pipetted carefully into the middle of the ROTOR, to simulate a ‘spill’. If possible, without overflowing the ROTOR, the volume of this ‘spill’ should be equivalent to or greater than the volume of one container for containers of volumes up to 5ml, or for ROTORS holding containers of larger volume it should be either 5 ml or 10 % of the volume of one of the containers, whichever is greater. A note shall be made if less than the full volume of test suspension is used to simulate the ‘spill’.

If canisters are used as the primary mode of protection in angle head ROTORS, then the BUCKET seal test method of AA.3.2.3 is used.

AA.3.2.3 BUCKET seal method

A different test method is required for sealed BUCKETS and canisters. The BUCKETS are filled with the test suspension to their rated capacity. After closing the cap, the BUCKET is slowly inverted twice to place the test suspension on the inside of the BUCKET seal.

Since BUCKETS and ROTORS come in many designs, the above test methods may not be appropriate for all designs. In these instances, other methods may have to be devised to achieve the same effect, such as challenging the BIOSEAL when used in accordance with the manufacturer’s instructions.

AA.3.2.4 Control samples

Surface samples are taken before each test to measure any background contamination with the test micro-organism. Initially, surface samples are taken from inside the "O"-ring of the BIOSEAL. After the test suspension is introduced into the BUCKET or ROTOR, surface samples are taken over the complete exterior of the BIOSEAL of the BUCKET or ROTOR and at multiple points around the inside of the CHAMBER at the height