भारतीय मानक
Indian Standard

IS/IEC 61010-2-020 : 2016

माप, नियंत्रण, और प्रयोगशाला के लिए उपयोगी विद्युत उपकरणों के लिए सुरक्षा आवश्यकताएँ

भाग 2-020 प्रयोगशाला अपकेंद्रित्र के लिए विशेष आवश्यकताएं

Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use

Part 2-020 Particular Requirements for Laboratory Centrifuges

ICS 19.080; 71.040.10

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
मानक भवन, 9 बहादुरशाह ज़फर मार्ग, नई दिल्ली – 110002
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI-110002
www.bis.gov.in www.standardsbis.in

June 2019

Price Group 10

Measuring Equipment for Basic Electrical Quantities Sectional Committee, ETD 12

NATIONAL FOREWORD

This Indian Standard (Part 2-020) which is identical with IEC 61010-2-020 : 2016 'Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-020: Particular requirements for laboratory centrifuges' issued by the International Electrotechnical Commission (IEC) was adopted by the Bureau of Indian Standards on recommendation of the Measuring Equipment For Basic Electrical Quantities Sectional Committee of the Electrotechnical Division Council.

The text of the IEC Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain terminologies and conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker, while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to the following International Standard for which Indian Standard also exists. The corresponding Indian Standard, which is to be substituted in its respective place, is listed below along with its degree of equivalence for the edition indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements	IS/IEC 61010-1 : 2010 Safety requirements for electrical equipment for measurement, control, and laboratory use: Part 1 General requirements	Identical to IEC 61010-1 : 2010

The technical committee has reviewed the provisions of the following international standard referred in this adopted standard, and decided that it is acceptable for use in conjunction with this standard.

International Standard	*Title*
ISO 3864 (all parts)	Graphical symbols — Safety colours and safety signs

Only English language text has been retained while adopting it in this Indian Standard, and as such, the page numbers given here are not the same as in the International Standard.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

SUPPLIED BY BSB EDGE UNDER THE LICENSE FROM BIS FOR GALGOTIAS UNIVERSITY, GREATER NOIDA - GREATER NOIDA (Librarian@galgotiasuniversity.edu.in) DATED 2021-07-17 AGAINST OUR ORD. REF. BIS-20210716-5

Indian Standard

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 7.7.2.2 l));

dd) ineffectiveness of BIOSEALS (see 13.101)

1.2.2 Aspects excluded from 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 below 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

SUPPLIED BY BSB EDGE UNDER THE LICENSE FROM BIS FOR GALGOTIAS UNIVERSITY, GREATER NOIDA - GREATER NOIDA (Librarian@galgotiasuniversity.edu.in) DATED 2021-07-17 AGAINST OUR ORD. REF. BIS-20210716-5

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 micro-biological 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
MCA
MAXIMUM CREDIBLE ACCIDENT
planned event chosen to represent worst-case conditions for a test that will evaluate the inherent mechanical safety of a CENTRIFUGE-ROTOR COMBINATION (see 7.7 and Annex BB).

4 Tests

This clause of Part 1 is applicable.

5 Marking and documentation

This clause of Part 1 is applicable except as follows.

5.1.2 Identification

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.

SUPPLIED BY BSB EDGE UNDER THE LICENSE FROM BIS FOR GALGOTIAS UNIVERSITY, GREATER NOIDA - GREATER NOIDA (Librarian@galgotiasuniversity.edu.in) DATED 2021-07-17 AGAINST OUR ORD. REF. BIS-20210716-5
IS/IEC 61010-2-020 : 2016

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 micro-organisms.

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) 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 WorSld 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).

SUPPLIED BY BSB EDGE UNDER THE LICENSE FROM BIS FOR GALGOTIAS UNIVERSITY, GREATER NOIDA - GREATER NOIDA (Librarian@galgotiasuniversity.edu.in) DATED 2021-07-17 AGAINST OUR ORD. REF. BIS-20210716-5

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:

SUPPLIED BY BSB EDGE UNDER THE LICENSE FROM BIS FOR GALGOTIAS UNIVERSITY, GREATER NOIDA - GREATER NOIDA (Librarian@galgotiasuniversity.edu.in) DATED 2021-07-17 AGAINST OUR ORD. REF. BIS-20210716-5
IS/IEC 61010-2-020 : 2016

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 BB6.2)

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:

SUPPLIED BY BSB EDGE UNDER THE LICENSE FROM BIS FOR GALGOTIAS UNIVERSITY, GREATER NOIDA - GREATER NOIDA (Librarian@galgotiasuniversity.edu.in) DATED 2021-07-17 AGAINST OUR ORD. REF. BIS-20210716-5

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

SUPPLIED BY BSB EDGE UNDER THE LICENSE FROM BIS FOR GALGOTIAS UNIVERSITY, GREATER NOIDA - GREATER NOIDA (Librarian@galgotiasuniversity.edu.in) DATED 2021-07-17 AGAINST OUR ORD. REF. BIS-20210716-5

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	Corresponding steam temperature		Minimum hold time
kPa	Nominal °C	Range °C	min
325	136,0	134 to 138	3
250	127,5	126 to 129	10
215	122,5	121 to 124	15
175	116,5	115 to 118	30
NOTE "Minimum hold time" means the time the contaminant 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

The annexes of Part 1 are applicable except as follows.

Annex L

Index of defined terms

Additional defined terms:

Addition:

Add the following new annexes:

SUPPLIED BY BSB EDGE UNDER THE LICENSE FROM BIS FOR GALGOTIAS UNIVERSITY, GREATER NOIDA - GREATER NOIDA (Librarian@galgotiasuniversity.edu.in) DATED 2021-07-17 AGAINST OUR ORD. REF. BIS-20210716-5

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 $\geq 1 \times 10^{10}$ 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 micro-organism 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 colony-forming 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.

SUPPLIED BY BSB EDGE UNDER THE LICENSE FROM BIS FOR GALGOTIAS UNIVERSITY, GREATER NOIDA - GREATER NOIDA (Librarian@galgotiasuniversity.edu.in) DATED 2021-07-17 AGAINST OUR ORD. REF. BIS-20210716-5

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 the BIOSEALS of the BUCKETS or ROTOR would be while the LABORATORY CENTRIFUGE is running; and, when a sealed BUCKET is being tested, the surface of the ROTOR. In the case of sealed BUCKETS or canisters, additional swab samples of the seal are taken after the BUCKET has been inverted. Swab samples are also taken in areas of potential contamination.

AA.3.2.5 Centrifugation

After taking the control samples (see AA.3.2.4), the LABORATORY CENTRIFUGE is accelerated to the maximum speed for the ROTOR ASSEMBLY under test, maintained at that speed for 5 min, then decelerated to rest.

After the LABORATORY CENTRIFUGE has come to rest, the LID is opened and test swab samples are taken from the surfaces from which the control samples were taken (see AA.3.2.4).

AA.3.2.6 Decontamination

After each test, the test cabinet and contents are decontaminated by fumigation and the cabinet is thoroughly aired by means of the extractor fan.

The BUCKET or ROTOR under test is decontaminated according to the method recommended by the manufacturer.

AA.4 Pass and fail criteria

Each ROTOR or BUCKET is subjected to three separate and valid tests. A pass requires each of the individual tests carried out to be passed, and failure of any single valid test results in overall failure.

The test is only valid if either the maximum volume of additional test suspension, as described in AA.3.2.2, was added, or if a sample from immediately inside the BIOSEAL shows $> 1 \times 10^3$ colony-forming units more than the control sample from this location.

For the three separate tests, the numbers of colony-forming units recovered by swabbing after centrifugation (apart from immediately inside the BIOSEAL of the BUCKET or ROTOR) shall not exceed the numbers recovered from the control samples collected before a test by more than 1 colony-forming unit (this is to allow for sampling error at very low numbers). If more than five colonies are detected in any of the control samples then the test is void and shall be repeated.

Annex BB
(informative)

General guidance and rationale for particular subclauses

BB.1 Subclause 1.4 Environmental conditions

The lower limit of the ambient temperature at which equipment conforming to Part 1 should be safe to operate is +5 °C. For the purpose of LABORATORY CENTRIFUGES, the limit is lowered to +2 °C in this standard, since many LABORATORY CENTRIFUGES are used in cold-rooms. The nominal temperature at which such cold-rooms are maintained is +4 °C, but tolerances in the temperature control system inevitably mean that lower temperatures are experienced at times (but should never be as low as 0 °C). Therefore, the lower temperature of +2 °C has been chosen.

BB.2 Subclause 3.5.102 mca (MAXIMUM CREDIBLE ACCIDENT)

Safety requirements which state specific construction parameters for LABORATORY CENTRIFUGES could limit innovation by the design engineer. This approach can unnecessarily increase the cost to the user without assurance that the construction methods will provide the necessary safety for the OPERATOR. This standard provides basic design considerations for safe design and proof of safety by mechanical testing.

The concept used is testing to an MCA. Choosing an MCA utilizes all information from the instrument, ROTOR, component designs and development tests. Although a single MCA is not considered statistically significant from the point of view of a number of tests, nevertheless it is very unlikely that such an event will ever happen during NORMAL USE.

BB.3 Subclause 5.4.102 relation to Table 101

While it is optional for a manufacturer to claim that an item can be decontaminated by steam sterilization, if such a claim is made, it is essential that such sterilization should be under realistic conditions to achieve decontamination.

Table 101 is included to provide an indication of the time-temperature conditions which are generally found suitable by microbiologists for autoclave decontamination of items which have been contaminated with hazardous biological agents. It should be noted, however, that it is the responsibility of the user to ensure that the time-temperature conditions chosen for use are appropriate to inactivate the particular biological agent(s) which may have contaminated the BUCKETS and/or ROTOR. (This is particularly important for any work with prions, which are not readily inactivated by either heat or chemical means.)

BB.4 Subclause 7.3.101.1 LID (first paragraph)

One of the purposes of this standard is to specify the protection needed to prevent an OPERATOR being injured by moving parts of a CENTRIFUGE. For practical reasons, neither limitation of the rotational frequency, nor limitation of the rotational energy of the ROTOR ASSEMBLY, can be used to provide such protection.

If the intention is to permit the OPERATOR to gain access to the ROTOR ASSEMBLY before rotation has completely stopped – such as is held to be necessary for some centrifuging work – a potential HAZARD exists. The HAZARD is significant if an OPERATOR attempts to slow down the ROTOR ASSEMBLY by hand while the rotational frequency is such that the hand cannot easily follow the movement of the ROTOR ASSEMBLY. Once the rotational frequency is low

SUPPLIED BY BSB EDGE UNDER THE LICENSE FROM BIS FOR GALGOTIAS UNIVERSITY, GREATER NOIDA - GREATER NOIDA (Librarian@galgotiasuniversity.edu.in) DATED 2021-07-17 AGAINST OUR ORD. REF. BIS-20210716-5

enough for the hand to follow the rotation, even if it was inserted "against" the direction of rotation, no injury should be caused. It has been shown that the circumferential velocity limit of 2 m/s which is specified, easily allows an OPERATOR to follow the rotation by hand.

BB.5 Subclause 7.3.101.2 Exception

Certain LABORATORY CENTRIFUGES are permitted to have an access LID with a power-interrupt system instead of an interlock mechanism that is dependent on rotational frequency.

A carefully restricted definition of these exempted LABORATORY CENTRIFUGES has been achieved by specifying restricted maximum values for rotational frequency, centrifugal force, ROTOR ASSEMBLY energy and ROTOR diameter. LABORATORY CENTRIFUGES that fall within these restricted limits are widely used throughout the world, with hundreds of thousands in service and tens of thousands sold each year.

The reason for permitting less stringent requirements for such LABORATORY CENTRIFUGES is that significant extra complexity would be involved in providing a LID interlock mechanism without providing additional reduction of HAZARD.

The working group experts have been unable to trace any accidents with such LABORATORY CENTRIFUGES that may be attributed to the lack of an interlock mechanism. They are of the opinion that, if the device which holds the LID closed is released while the ROTOR ASSEMBLY is at speed and the LID is opened slightly, any potential HAZARD to the OPERATOR, due to opening the LID, is immediately reduced by:

a) an increase in sound level that warns the OPERATOR of exposure of the ROTOR ASSEMBLY;
b) an air flow which tends to deflect dangling objects such as a tie or hair away from the ROTOR ASSEMBLY;
c) the immediate and rapidly progressive reduction in energy due to the power-interrupt. Access to the ROTOR ASSEMBLY, by hand or other object, first requires the time to release and open the LID and then to reach in to the ROTOR ASSEMBLY.

BB.6 Subclause 7.4.101 LABORATORY CENTRIFUGE movement during malfunction

It is specified that the whole of a LABORATORY CENTRIFUGE shall remain inside a CLEARANCE ENVELOPE extending 300 mm from the outermost surface of the CENTRIFUGE. That dimension was selected after extensive examination of DISRUPTION data under MCA conditions. A requirement to have no movement at all during malfunction was considered, but was rejected because:

a) it could be attained by rigidly securing the LABORATORY CENTRIFUGE to a foundation with a mass many times the mass of the LABORATORY CENTRIFUGE. Present practice is that LABORATORY CENTRIFUGES are not rigidly fastened, so successful enforcement of a provision for fastening would be unlikely;
b) a requirement for rigid fastening would be a restriction of present practice. Bench-top LABORATORY CENTRIFUGES are frequently moved by an OPERATOR without involving service or maintenance staff. Most LABORATORY CENTRIFUGES may be moved for cleaning or relocated without elaborate work;
c) rigid fastening of a LABORATORY CENTRIFUGE would necessitate permanent changes to the mounting surface, and there is reluctance to make such permanent changes to laboratory benches and floors;
d) a review of accident data available to the working group did not provide any evidence of injury due to LABORATORY CENTRIFUGE movement.

The potential HAZARD of a LABORATORY CENTRIFUGE moving out of control and impacting personnel, as unlikely as that may be, has been considered. This risk has been reduced to an

acceptable level of injury by limiting the permitted motion in the event of an MCA that produces LABORATORY CENTRIFUGE motion. Setting that maximum movement at 300 mm is based on the following considerations:

- the 300 mm CLEARANCE ENVELOPE limit of movement is established from MCA testing and therefore is unlikely to be reached in NORMAL USE;
- the potential for injury is limited by the amount of energy available when movement is restricted to 300 mm and the probability of persons being within the CLEARANCE ENVELOPE during the event;
- aisles and passageways are normally wider than 600 mm. The HAZARD of kinetic energy transfer from a moving LABORATORY CENTRIFUGE to a person is therefore limited to the absorption of energy when a person is squeezed into the remaining 300 mm wide space.

It is recognized that many LABORATORY CENTRIFUGES, particularly bench-top models, will not be mounted on a concrete surface in NORMAL USE. The concrete test surface has been specified in order that test results obtained from different test locations may be expected to be consistent.

BB.6.1 Sub-clause 7.7.1 a) Protection against expelled parts or projected parts

LABORATORY CENTRIFUGES shall be designed for safe operation in NORMAL USE and SINGLE FAULT CONDITION, when used with ROTOR ASSEMBLIES specified by the manufacturer. The protective casing shall restrain the user from unintended access to the potentially hazardous moving parts inside the centrifuge and protect the user from any escaping hazard. Because of the need for ventilation, even under NORMAL CONDITIONS, the protective casing is not hermetically sealed. The function of the casing is to reduce the potential mechanical hazard of escaping parts to a safe limit.

The definition of safe limit is not obvious. Based on comprehensive research of injury biomechanics, a normalized energy value (energy per projected area) was found to be the best predictor for ocular injury after a direct hit by a projectile. Using this predictor, a level for a 50% injury risk of corneal abrasion after a direct hit was determined. This level is also used to limit the hazards of projectile toys in EN 71-1:2011-07.

As a general, simple evaluation method, a specified maximal size of 5 mm for parts or fragments, and a maximal distance of 1 m from the centrifuge, make it very unlikely that this value of normalized energy would be exceeded.

BB.6.2 Sub-clause 7.7.1 Conformity statement – paragraph 2

The MCA test is a catastrophic test, as such, at the end of this test the unit is not considered able to be put back into service. The dielectric voltage withstand test establishes whether a functioning unit is still providing adequate isolation for the user from hazardous voltages (refer to 6.7.1 – The nature of insulation). As the unit cannot be used beyond the MCA test, establishing whether the accessible parts still comply with the permissible limits of clause 6.3.2 ensures that the user is still protected if they touch the unit. If the MCA test causes the overcurrent protection device to operate and this device can not be reset, this implies that hazardous voltages cannot be applied to the unit and it is therefore considered to have failed safe.

BB.7 Subclause 13.101

The use of BUCKETS and ROTORS with BIOSEALS is advocated by international [1][1)] and some national (such as [2] [3]) guidelines for work on microbiological material that require protection for workers and the environment. Accordingly, such equipment is in routine use in diagnostic microbiology laboratories, as well as other microbiological containment laboratories. The

1) Numbers in square brackets refer to Clause BB.8.

SUPPLIED BY BSB EDGE UNDER THE LICENSE FROM BIS FOR GALGOTIAS UNIVERSITY, GREATER NOIDA - GREATER NOIDA (Librarian@galgotiasuniversity.edu.in) DATED 2021-07-17 AGAINST OUR ORD. REF. BIS-20210716-5
IS/IEC 61010-2-020 : 2016

dynamic test, originally devised by Harper [4], has been adapted for more recent designs of LABORATORY CENTRIFUGE and ROTOR and is suitable for evaluation of BIOSEALS or parts of LABORATORY CENTRIFUGES, including those that have CHAMBERS that are sealed and evacuated.

The provision of BUCKETS and ROTORS with BIOSEALS is optional, but manufacturers who wish to make performance claims should be prepared to demonstrate that the BIOSEALS prevent escape of droplets and aerosols under dynamic test conditions that simulate the intended use. The choice of spores of Bacillus subtilis var. niger as the test agent is based upon long experience in the field of testing microbiological safety cabinets and similar equipment, which has shown them to be effective, and have also established that they neither infect those carrying out the tests nor have any adverse consequence for the environment. The spores are robust and do not significantly lose viability upon desiccation when a suspension is aerosolized, and even if leaked into an evacuated CHAMBER, and colonies of Bacillus subtilis var. niger have a characteristic colour which enables them to be distinguished from any contaminating organism. Although there is no single size of micro-organism to be contained by the BIOSEALS, and thus the spores will not correspond precisely to such a size, in practice leakage is found to occur in significant volumes and the ability to detect a single spore, once it has been grown into a colony on a test plate, gives the sensitivity for this to be an appropriate assay.

The requirement to provide specific instructions for the use of BIOSEALS and related components is based on the mandatory need for additional equipment and laboratory procedures to safeguard OPERATORS. These instructions to the OPERATOR are necessary to make clear that BIOSEALS alone are not adequate to provide complete protection, particularly as the seal can be compromised by wear or damage, for example to an "O"-ring.

BB.8 Reference documents

[1] WORLD HEALTH ORGANIZATION. *Laboratory Biosafety Manual*, 2nd Edition. Geneva, 1993.

[2] CENTERS FOR DISEASE CONTROL AND PREVENTION AND NATIONAL INSTITUTES OF HEALTH. *Biosafety in Microbiological and Biomedical Laboratories*, 4th Edition. Washington, 1999.

[3] ADVISORY COMMITTEE ON DANGEROUS PATHOGENS. *Categorisation of biological agents according to hazard and categories of containment*, 4th Edition. London, 1995.

[4] HARPER, G.J. Evaluation of sealed containers for use in centrifuges by a dynamic microbiological test method. *J. Clin. Pathol.* 1984, 37, pp. 1134–1139.

Annex CC
(informative)

General guidance for an empirical method to determine the kinetic energy of a ROTOR

Subclause 7.7.2.2 a) Determination of the kinetic energy

1) The rotor shall be loaded to the maximum and then it must be weighed.
   - fully loaded with samples as per maximum operated conditions
   - sample tubes / bottles will be loaded with test fluid.
2) Fasten the rotor with its axis of rotation to a rod. (Ensure that the rotor and the rod cannot be twisted against each other.)
3) Fasten a piece of fishing line with a tensile strength double the weight of the total assembly to ensure that there is no stretch to the rod and to the ceiling as per Figure 101. Ensure that the distances $s1$ and $s2$ are identical (approximately 50 mm each) and that the distance with regard to the ceiling is as long as possible (approximately 1 m to 1,5 m).
   - The vertical access shall be confirmed to be vertical.
4) Now, rotate the rotor through a small angle (approximate to but not greater than 30°) and release the rotor allowing it to rotate clockwise and anti-clockwise across a marked datum point. Ensure that the rotor does not wobble. Determine the time for one cycle with the aid of stopwatch. (One cycle corresponds to one rotation to and fro). We recommend measuring 10 cycles and then dividing the value by 10 in order to keep the error as small as possible.

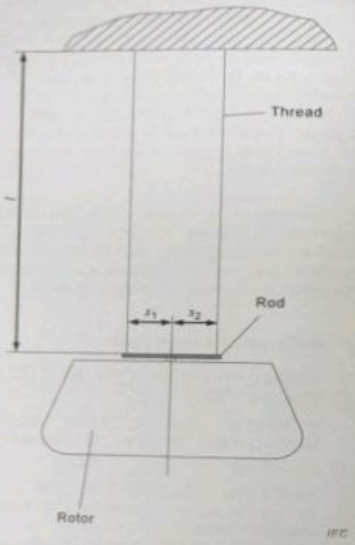

Figure 101 – Rotor test setup

5) The mass moment of inertia can be calculated with the aid of the following formula:

$$J_p = m \times g \times \frac{s1 \times s2 \times T^2}{l \times 4 \times \pi^2}$$

6) Then, the kinetic energy can be calculated as follows:

$$E_{kin} = \frac{1}{2} \times J_p \times \omega^2 \quad \omega = 2 \times \pi \times n$$

where

m is the mass in [kg]

g is 9,81 m/s²

$s1=s2$ is the thread distance with regard to the axis of rotation of the rotor in [m]

T is the cycle time in [s]

l is the thread length in [m]

J_p is the mass moment of inertia in [kgm²]

ω is the angular velocity in [1 / s²]

n is the speed in 1/s

E_{kin} is the kinetic energy in [Nm].

NOTE 1 Glycerine has a density of 1,26 and so the sample container is filled with glycerine until the rated load of the sample container is achieved.

NOTE 2 Examples of cords that could satisfy the requirements of the fishing line referenced above are those defined in the following standards:

- BS 4881:1993, *Polypropelene film cord, lines and twines*
- ISO 1873-1:1995, *Plastics – Polypropylene moulding and extrusion materials – Part 1: Designation systems and basic for specifications*
- ISO 1873-2:2007, *Plastics – Polypropylene moulding and extrusion materials – Part 2: Preparation of test specimens and determination of properties*
- EN ISO 1346:2004, *Fibre ropes – Polypropylene split film, monofilament and multifilament and polypropylene high tenacity multifilament – 3-, 4- and 8-strand ropes*
- EN 12423:1999, *Polypropylene twines*

Bibliography

Addition:

Add the following publication:

IEC 60034 (all parts), *Rotating electrical machines*

SUPPLIED BY BSB EDGE UNDER THE LICENSE FROM BIS FOR GALGOTIAS UNIVERSITY, GREATER NOIDA - GREATER NOIDA (Librarian@galgotiasuniversity.edu.in) DATED 2021-07-17 AGAINST OUR ORD. REF. BIS-20210716-5

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act*, 2016 to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Copyright

Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

This Indian Standard has been developed from Doc No.: ETD 12 (13580).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones: 2323 0131, 2323 3375, 2323 9402 *Website*: www.bis.gov.in

Regional Offices:

		Telephones
Central	: Manak Bhavan, 9 Bahadur Shah Zafar Marg NEW DELHI 110002	2323 7617, 2323 3841
Eastern	: 1/14 C.I.T. Scheme VII M, V.I.P. Road, Kankurgachi KOLKATA 700054	2337 8499, 2337 8561, 2337 8626, 2337 9120
Northern	: Plot No. 4-A, Sector 27-B, Madhya Marg CHANDIGARH 160019	265 0206, 265 0290
Southern	: C.I.T. Campus, IV Cross Road, CHENNAI 600113	2254 1216, 2254 1442, 2254 2519, 2254 2315
Western	: Manakalaya, E9 MIDC, Marol, Andheri (East) MUMBAI 400093	2832 9295, 2832 7858, 2832 7891, 2832 7892

Branches : AHMEDABAD. BENGALURU. BHOPAL. BHUBANESHWAR. COIMBATORE. DEHRADUN. DURGAPUR. FARIDABAD. GHAZIABAD. GUWAHATI. HYDERABAD. JAIPUR. JAMMU. JAMSHEDPUR. KOCHI. LUCKNOW NAGPUR. PARWANOO. PATNA. PUNE. RAIPUR. RAJKOT. VISAKHAPATNAM.

Published by BIS, New Delhi