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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 22615

Protective clothing — Performance requirements and test methods for protective clothing against infective agents

Vêtements de protection — Exigences de performance et méthodes d'essai pour les vêtements de protection contre les agents infectieux

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ISO/TC 94/SC 13

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This document is circulated as received from the committee secretariat.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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

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

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

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 94, *Personal safety - Protective clothing and equipment*, Subcommittee SC 13, *Protective clothing*.

This first edition has been draft based on the EN 14126:2003^[1].

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

Introduction

Protective clothing against infective agents has two main functions:

- To minimize or prevent infective agents from reaching the (possibly injured) skin;
- To prevent the spreading of infective agents to other people and other situations, e.g. eating or drinking, close contact with others when the person has taken his protective clothing off.

In many work situations, e.g. microbiological laboratories, biotechnological production, etc. the infective agents can be contained and the risk of exposure is limited to the occurrence of an accident. In these situations, the agents, to which the worker can be exposed, are usually well known. In other types of work, the organisms cannot be contained, exposing the worker continuously to the risk of infection by biological agents. This happens e.g. in sewage work, waste treatment, caring for animals infected with zoonotic agents, emergency clean-up, treatment of hospital risk waste etc. In these situations, the agents the workers are exposed to, may not be known, although possible risks can be assessed.

During pandemics, depending on the virus risk category, viral transmission means and the working environment, surgical gowns may not always necessarily provide adequate protection of the wearer (either due to the design or the nature of the material & seams).

Micro-organisms are a very heterogeneous group of organisms as to their size, shape, living conditions, infective dose, survival abilities and many other parameters. Their size alone can vary from 30 nm (poliovirus) to 5 µm to 10 µm (bacteria) and even larger (most fungi). A hazard classification of micro-organisms can be found in European Directive 2000/54/EEC (on the protection of workers from the risk related to exposure to biological agents at work).

Due to the heterogeneity of micro-organisms, it is not possible to define performance criteria on the basis of risk groups, nor on the type of micro-organism. Also it may not be possible to define exactly the organisms the worker is exposed to. Hence the test methods specified in this standard focus on the medium containing the micro-organism, such as a liquid, an aerosol or a solid dust particle. A risk analysis should determine which ones of these risks are present in a given situation.

This standard was inspired by EN 14126:2003^[1] and ANSI AAMI PB 70:2022^[2].

Protective clothing — Performance requirements and test methods for protective clothing against infective agents

1 Scope

This document specifies requirements and test methods for materials and seams of re-usable and single use protective clothing providing protection of the wearer against infective biological agents. Design criteria, mechanical requirements, and functional fit requirements are based on either the ISO 16602 series or on ISO/DIS 20384 as indicated in this document, while the barrier properties of this document will be additive to ensure the protection against infective biological agents.

NOTE This standard is a standalone standard but using requirements based on ISO 16602 series and ISO/DIS 20384.

For products intended for the dual use as both a PPE and as a medical gown, both this document and the ISO/DIS 20384 shall apply.

Clothing worn by surgical teams or drapes laid on patients to prevent cross-contamination during surgical interventions are not covered by the scope of this document, but are covered solely by ISO/DIS 20384.

This document is not applicable to components such as gloves, boots, eye/face protection devices and respiratory protective devices as their performance criteria are given in other standards. However, when these components are either an integral part of the protective clothing ensemble or are tested separately as partial body protection, supplementary requirements are provided in this standard. This document does not cover requirements for antimicrobial treatments for protective clothing.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 811:2018, *Textiles — Determination of resistance to water penetration — Hydrostatic pressure test*

ISO 11092:2014, *Textiles — Physiological effects — Measurement of thermal and water-vapour resistance under steady-state conditions (sweating guarded-hotplate test)*

ISO 11610:2023, *Protective clothing — Vocabulary*

ISO 11737-1:2018/Amd 1:2021, *Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products — Amendment 1*

ISO 13688:2013, *Protective clothing — General requirements*

ISO 13688:2013/Amd 1:2021, *Protective clothing — General requirements — Amendment 1*

ISO/DIS 16602-1, *Protective clothing for protection against chemicals — Classification, labelling and performance requirements — Part 1: General requirements*

ISO/CD 16602-1, *Protective clothing for protection against chemicals — Classification, labelling and performance requirements — Part 1: General requirements*

ISO/DIS 16602-2, *Protective clothing for protection against chemicals — Classification, labelling and performance requirements — Part 2: Physical test methods, classification and requirements*

ISO/CD 16602-2, *Protective clothing for protection against chemicals — Classification, labelling and performance requirements — Part 2: Physical test methods, classification and requirements*

ISO/CD 16602-4, *Protective clothing for protection against chemicals — Classification, labelling and performance requirements — Part 4: Test methods, classification and requirements for specific designs and ensemble components including gloves, footwear, and respirators*

ISO/DIS 16602-4, *Protective clothing for protection against chemicals — Classification, labelling and performance requirements — Part 4: Test methods, classification and requirements for specific designs and ensemble components including gloves, footwear, and respirators*

ISO/CD 16602-5, *Protective clothing for protection against chemicals — Classification, labelling and performance requirements — Part 5: Garment test methods, classification and requirements*

ISO/DIS 16602-5, *Protective clothing for protection against chemicals — Classification, labelling and performance requirements — Part 5: Garment test methods, classification and requirements*

ISO 16604:2004, *Clothing for protection against contact with blood and body fluids — Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X 174 bacteriophage*

ISO 17491-4:2024, *Protective clothing — Test methods for clothing providing protection against chemicals — Part 4: Determination of resistance to penetration by a spray of liquid (spray test)*

ISO 18695:2007, *Textiles — Determination of resistance to water penetration — Impact penetration test*

ISO 18695:2007, *Textiles — Determination of resistance to water penetration — Impact penetration test*

ISO/CD 20384, *Surgical clothing and drapes — Requirements and test methods*

ISO/DIS 20384, *Surgical clothing and drapes — Requirements and test methods*

ISO/CD 20384, *Surgical clothing and drapes — Requirements and test methods*

ISO/DIS 22610, *Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Test method to determine the resistance to wet bacterial penetration*

ISO 22612:2005, *Clothing for protection against infectious agents — Test method for resistance to dry microbial penetration*

EN 13795-1:2019, *Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns*

3 Terms and definitions

For the purposes of this document, the *following terms and definitions* given in ISO 11610:2023, as well as the *following* apply.

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

— ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1

area

area of protective apparel

3.1.1

critical area

area where direct contact with blood, body fluids, and other potentially infectious materials is most likely to occur

3.1.2

less critical area

area less likely to be involved in the transfer of infective agents with the product

[SOURCE: EN 13795-1:2019, 3.5]

3.2

bacteriophage

type of virus which infects bacteria

Note 1 to entry: In this test method, the bacteriophage is Phi-X174. The Phi-X174 bacteriophage is not pathogenic to humans, but serves to simulate viruses that are pathogenic to humans.

3.3

body fluid

liquid produced (secreted or excreted) by the body

Note 1 to entry: For the purpose of this document, body fluids include those liquids potentially infected with blood-borne pathogens, including, but not limited to, blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid and peritoneal fluid, amniotic fluid, saliva in dental procedures, and any body fluid that is visibly contaminated with blood, and all body fluids in situation where it is difficult or impossible to differentiate between body fluids

[SOURCE: ISO 16604:2004, 3.6]

3.4

colony forming unit cfu

unit by which the culturable number of microorganisms is expressed

Note 1 to entry: The culturable number is the number of microorganisms, single cells or aggregates, able to form colonies on a solid nutrient medium.

3.5

infective biological agents

micro-organisms, including those which have been genetically modified, cell cultures and human endoparasites, that have been shown to potentially cause infections, acute disease or long-term damage to human health/human body

3.6

medical gown

gown used in health care facilities to provide various levels of protection to the wearer depending on the intended use

EXAMPLE Medical gowns include isolation gowns, surgical gowns, medical coveralls, patient gowns, etc.

3.7

point of attachment

area at which an attachment occurs providing a physical connection between one thing that is attached to another (e.g. areas where belts, ties, pockets, snaps, etc. are attached)

[SOURCE: ANSI AAMI PB 70:2022^[2]]

3.8

protective clothing against infective biological agents

combined assembly of garments, intended to afford protection to the skin against exposure to or contact with infective biological agents

3.9

surgical gown

gown worn by clinical staff to minimize transmission of infective agents during the peri-operative process, particularly within either the operating room or the Post Anaesthesia Care Unit (PACU)

Note 1 to entry: Medical gowns include surgical gowns. However some types of medical gowns e.g. Isolation gowns are not intended to be used as surgical gowns.

3.10

synthetic blood
challenge agent that is intended to simulate the liquid properties of blood

[SOURCE: AAMI PB 70:2022^[3]]

4 General

4.1 Basic requirements

Any garment and its components shall meet the relevant requirements of:

- ISO 13688:2013/ISO 13688:2013/Amd 1:2021 and ISO 16602 series, or
- ISO 13688:2013/ISO 13688:2013/Amd 1:2021 and ISO/DIS 20384, or
- ISO 13688:2013/ISO 13688:2013/Amd 1:2021, ISO 16602 series and ISO/DIS 20384,

in addition to the requirements set in this document.

The garment can provide either partial body protection or full body protection as defined in ISO/DIS 16602-1 sub-clause 7.2.1 and 7.3.1.

NOTE The ISO 13688:2013/ ISO 13688:2013/Amd 1:2021 and ISO/DIS 20384 route does not require chemical testing.

The value of each property defined in [4.2](#), [4.4](#) and [4.5](#) and which shall be used for performance classification, shall be determined in accordance with [Annex C](#)

Donning and doffing instructions shall be provided in the IFU in [clause 6](#), list item 3) based on the guidance given in [Annex F](#).

4.2 Barrier properties

4.2.1 General

The classification for the requirements of this document shall be based on the performance characteristics as defined in this document and in the minimum requirements of the standards mentioned in [4.1](#).

In addition, the classification for the requirements this document shall indicate the performance of the critical and less-critical areas of the garment. This document acknowledges the fact that not all areas of the product are involved in the transfer of infective agents to the same extent. [Annex D](#) explains how to indicate the location of the critical areas and less-critical areas that shall be marked in the garment according to [5](#), list item e).

4.2.2 Critical areas

Critical area properties are those properties which are considered critical for the intended risk against for which the product protects as defined in [6](#), list item 1). They shall meet all the requirements of [clauses 4.4](#), [4.5](#), and [4.6](#) in addition to the requirements of [4.2.3](#).

The performance of seams between and within critical areas shall meet the requirements for critical areas.

4.2.3 Less-critical areas

The less-critical area properties are those properties which are considered less-critical for the intended risk against which the product protects as defined in [6](#), list item 1). These areas shall meet the minimum requirements of the one of the standards as defined in [4.1](#) (ISO 16602 series, ISO/DIS 20384, or both). This document sets additional minimum requirements in [clauses 4.4.1](#), [4.4.2](#) and [4.5.6](#).

The performance of seams between critical and less-critical areas shall meet at least the requirements of the adjacent less-critical area.

4.3 Pre-treatment by cleaning and conditioning for testing

4.3.1 Cleaning

Before each test, all protective clothing against biological infective agents samples, with the exception of single use protective clothing, shall undergo pre-treatment by cleaning. For single use garments, testing shall be carried out on new material or a new garment.

For materials, which require pre-treatment by cleaning, the performance classification shall be based on the lowest/worst performance classification obtained on testing as new (not pre-treated) and pre-treated materials. If insufficient documented evidence (i.e. if there is no previous test data) is available to determine whether the test shall be performed as new or pre-treated, the test shall be performed in both conditions.

Where applicable according to manufacturer's instructions, the cleaning shall be in line with the manufacturer's instructions, on the basis of standardized procedures. If the number of cleaning cycles is not specified, the tests shall be carried out after 5 cycles of cleaning. Each cycle shall consist of one wash cycle and one dry cycle carried out as indicated by the manufacturer's instructions.

Manufacturer's instructions with regard to number of cleaning cycles, cleaning procedures shall be observed. Field decontamination or decontamination for disposal is excluded.

4.3.2 Deterioration of repellency by cleaning

Where the finishing, applied to improve or maintain the repellency for liquids resistance performance of the garment, can be deteriorated by the cleaning procedures indicated by the manufacturer, the manufacturer shall indicate the maximum number of cleaning cycles that can be carried out before the garment needs to be re-treated or re-impregnated to restore its performance.

Testing according to [4.5](#) shall be carried out before the cleaning cycle for which the manufacturer guarantees the performance.

For example, if the instructions state "re-impregnation during each third cleaning cycle", tests shall be performed after the second cleaning cycle, i.e. before re-impregnation. Then after reimpregnation is applied, the test should be performed again in order to demonstrate meeting the requirement.

If the instructions state "re-impregnation after each cleaning cycle", the tests shall be performed on new items. Later, the item shall be cleaned, reimpregnation is applied and test repeated again in order to demonstrate meeting the requirement.

In all cases, cleaning shall be according [4.3.1](#).

4.3.3 Sterile

Re-usable garments shall be tested for the requirements in [4.5](#) and to preconditioning according to [4.3.1](#) and [4.3.2](#) (if relevant) and after sterilization processing specified by the manufacturer.

Single use garment shall be tested for the requirements in [4.5](#) in sterile state as sold.

4.3.4 Conditioning

All samples shall be conditioned by storage at $(23 \pm 3) ^\circ\text{C}$ and $(60 \pm 10) \%$ relative humidity for at least 24 h. Testing of test specimen shall commence within 15 min of removing the sample or test specimen from the conditioning atmosphere.

This conditioning requirement takes priority over any conflicting conditioning requirements in the individual test method standards.

If the product is intended to be used after sterilisation, conditioning shall not be required prior to testing.

4.3.5 Testing temperature

Unless otherwise specified in this document, all testing shall be conducted at the same conditions used for conditioning specified in [4.3.4](#), with the exception for the ISO 18695:2007 in [clause 4.5.6](#).

4.4 Materials requirements

4.4.1 Material physical requirements

The materials shall be tested and meet at least class 1 for the core physical properties, described in [Table 1](#), in accordance with the requirements clause 5 of ISO/DIS 16602-1 and meeting the minimum class when tested in accordance to ISO/DIS 16602-2.

Table 1 — Core physical requirements

Core Physical Requirements

Abrasion
Flex cracking
Tear
Tensile
Puncture
Seam strength

4.4.2 Material ignition resistance requirements

The materials shall be tested for ignition resistance requirements of clause 4.10.2 of ISO/DIS 16602-2. If the materials do not meet this requirement this shall be reported in the manufacturer's instructions ([clause 6](#)).

4.4.3 Material cleanliness requirements (optional)

When the protective clothing is intended for use in laboratory environments or for use in health care settings, the garment shall additionally be tested to ISO 11737-1:2018/Amd 1:2021 for microbial cleanliness and the performance should be $< 300 \text{ CFU}/100 \text{ cm}^2$.

4.4.4 Material comfort indicator

Where the manufacturer claims the garment material to be breathable, the resistance to evaporative transfer (water vapour resistance) shall be tested according to ISO 11092:2014 (See [Annex B](#)). The mean R_{et} result shall be included in the manufacturer's instructions for use (see [6](#), list item i)).

NOTE The risk assessment of the end user is needed to determine the limited time of use, depending of the R_{et} result of the garment.

4.5 Performance requirements against penetration by infective biological agents

4.5.1 General

The test methods listed below focus on the medium containing the micro-organism, such as a liquid, an aerosol or a solid dust particle. The external side of the tested clothing material shall be facing the media containing the micro-organisms.

For the materials meeting critical area's properties that protect against the risk described in [4.2](#), these critical areas shall meet at least Class 1 of at least one of the tests/properties listed in the [4.5.2](#) - [4.5.5](#). Where for the [4.5.2](#) - [4.5.5](#) a Class 1 is not achieved or not tested, this should be indicated by "X". For the seam

requirement in 4.5.6, at least a Class 1 shall be achieved. Protective clothing made of multiple detachable layers, the lowest performance class of any of the layer materials shall be used.

4.5.2 Resistance to penetration by blood-borne pathogens using Phi-X174 bacteriophage under pressure

When tested in accordance with ISO 16604:2004 procedure C or D, three specimens of material shall be classified according to the levels of performance given in Table 2 as obtained in the bacteriophage test. Specimen shall exhibit no more than 10 PFU/mL of the Phi-X174 bacteriophage in the assay to pass the test.

Thin test specimens may be affected due to their deformation or creasing in the cell sealing area when 13.6 Nm torque is used on the bolts. Lower torque closure of the cell is permitted as long as no leakage occurs during testing.

NOTE The synthetic blood test (ISO 16603:2004^[4]) is used for screening purposes to help predict the level where a penetration can be expected when performing the bacteriophage test (ISO 16604:2004).

Table 2 — Classification of resistance to penetration by blood-borne pathogens using Phi-X174 bacteriophage under pressure (ISO 16604)

Class	Pressure at which the material passes the test
6	20 kPa
5	14 kPa
4	7 kPa
3	3,5 kPa
2	1,75 kPa
1	0 kPa ^a

^a this means that the material is only exposed to the hydrostatic pressure of the liquid in the test cell

4.5.3 Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids.

When tested in accordance with ISO/DIS 22610, 5 specimens of the material shall be classified according to the levels of performance given in Table 3.

Table 3 — Classification of resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids

Class	I_B
3	$\geq 6,0$
2	$4,0 \leq I_B < 6,0$
1	$2,8 < I_B < 4,0$

NOTE I_B 6,0 for the purpose of this document means: no penetration. I_B 6,0 is the maximum achievable value.

4.5.4 Resistance to penetration by contaminated liquid aerosols

When the 8 specimens of the material are tested in accordance with Annex A, the average results of the material shall be used to classify according to the levels of performance given in Table 4.

Table 4 — Classification of resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids

Class	Penetration ratio (log)
3	$\text{Log} \geq 4,5$
2	$3,0 \leq \text{log} < 4,5$
1	$1,0 < \text{log} < 3,0$

4.5.5 Resistance to penetration by contaminated solid particles

When tested in accordance with ISO 22612:2005, 12 specimens of the material shall be tested. The classification, according to the levels of performance given in [Table 5](#) shall be based on the arithmetic mean of the valid results.

Test conditions: challenge concentration 10^8 CFU/g talcum and 30 min vibration time.

Table 5 — Classification of resistance to penetration by contaminated solid particles

Class	Penetration (log cfu)
3	$\text{Log cfu} \leq 1$
2	$1 < \text{log cfu} \leq 2$
1	$2 < \text{log cfu} \leq 3$

4.5.6 Fabric and seam requirement for penetration

In order to provide adequate biological protection, seams, points of attachment such as ties, and fabrics shall be tested and classified according to the levels of performance given for the Critical or Less-Critical area that indicated in [Table 6](#) and the paragraphs below.

The performance classification shall be determined based on the test method result calculation in [Table 6](#) using either the lowest single value for the ISO 16604:2004 and the average for the ISO 811:2018 and ISO 18695:2007. The results shall be provided in the IFU ([6](#), list item h)).

Table 6 — Classification of resistance to penetration

Class	Test method	Test Items	Performance classification	Critical Area	Less-Critical Area
6	ISO 16604	seams	lowest single value	Class 6 of Table 2	At least class 1 of Table 2
5	ISO 16604	seams	lowest single value	At least class 5 of Table 2	At least class 1 of Table 2
4	ISO 811	seams and fabric	average	$\geq 100 \text{ cm H}_2\text{O}$	$\geq 10 \text{ cm H}_2\text{O}$
3	ISO 811	seams and fabric	average	$\geq 50 \text{ cm H}_2\text{O}$	$\geq 10 \text{ cm H}_2\text{O}$
2	ISO 811	seams and fabric	average	$\geq 10 \text{ cm H}_2\text{O}$	$\geq 10 \text{ cm H}_2\text{O}$
1	ISO 18695	seams and fabric	average	$\leq 4,5 \text{ g}$	$\leq 10 \text{ g}$

NOTE 1 Class 5 and 6 are only tested for seams in this sub-clause as fabrics are already covered in sub-clause [4.5.2](#).

For Class 1 (Critical area and Less-Critical area), five specimens of both the seams and the fabric are to be tested and evaluated according to ISO 18695:2007, tested at a temperature of $(27 \pm 1) ^\circ\text{C}$.

For Class 2-4, the hydrostatic head according to ISO 811:2018 of 5 specimens, of both the seams and the fabric, shall be determined and by and applied under the following test conditions and supplementary instructions:

- the test area shall be 100 cm^2 ;
- the rate of increase of water pressure shall be $60 \text{ cm H}_2\text{O}/\text{min}$;