TECHNICAL OVERVIEW

STERILE CLEANROOM OUTER GARMENTS

FABRIC COMPARISON LIFE STUDY :: UK

microngclean
QUALITY TODAY - INNOVATION TOMORROW

CONTENTS

Revised:

Issue Number	Reason for Change	Issue Date	Approved by
2	Title changed and reformatted to match layouts of most recent garment studies	Aug-24	Marta Underwood Group Product Manager
1	Document created	Jun-22	Greg Cochran Director

EXECUTIVE SUMMARY

Cleanroom garments play a critical role in cleanroom contamination control; they are designed to contain contamination generated by the greatest source of contamination in a cleanroom – the people.

Microncleanhas extensive experience in the UK of delivering high quality, value for money cleanroom garments. Microncleanaims to provide the best cleanroom garments available on the market. This is achieved through knowledge of cleanroom garment technology, as well as expertise and innovation in cleanroom garment performance and optimisation of laundering and sterilisation cycles. Microncleanoffers cleanroom garments via a rental service. Through this service model, Microncleanoversees and manages all aspects of cleanroom garment provision including selection of garment materials, garment design and construction and the laundry and sterilisation cycles.

High performing cleanroom garments must meet varying requirements. They must have high barrier properties to successfully retain contamination generated by the wearer. They must be durable to ensure they can withstand the stresses of use and repeat decontamination and sterilisation cycles. They must offer wearer comfort to increase the chance that the wearer will don and use the garments correctly. Finally, the garment system (including materials and garment designs) must work optimally as a whole in real cleanroom conditions.

Various guidelines are available that describe the considerations to be made in designing, selecting and using cleanroom garments. Further, standard test methods are available to demonstrate the performance of cleanroom garments against critical parameters.

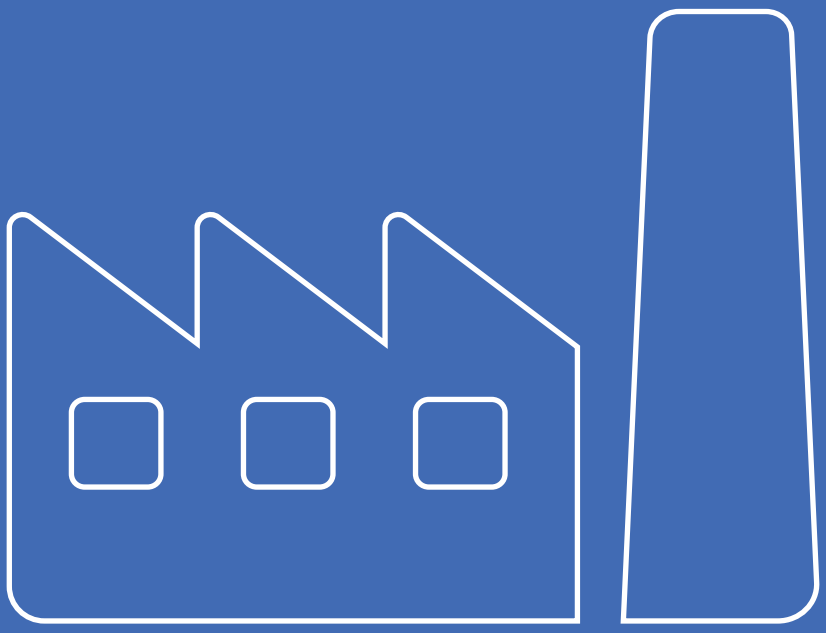
By performing extensive studies of cleanroom garment performance, Microncleanis able to select the best materials, garments designs and garment construction methods to work with, and is able to optimise its laundry and sterilisation processes to ensure that a high performing garment is delivered to the customer throughout a garment rental contract. These studies also allow Microncleanto select suitable alternatives and fabric backups to ensure supply chain security and continuity for our customers. Microncleanis also able to establish the safe, useful life of a cleanroom garment and design its contracts to ensure that customers receive high quality and good value for money.

Data is presented from such studies performed by Microncleanuk.

EXECUTIVE SUMMARY

MICRONCLEAN

OVERVIEW



MICRONCLEAN OVERVIEW

Micronclean is a UK company with a history dating back over 100 years. The company has been involved with the provision of textile rental and laundry services throughout its history. In the last 40 years Micronclean has specialised in the provision of cleanroom garments to various industries including pharmaceutical, biotechnology, microelectronics, aerospace and defence.

Micronclean is the UK market leader in the provision of cleanroom garment rental and laundry services. Micronclean has the privilege of providing cleanroom garments to over 65% of aseptic pharmaceutical / biotechnology production facilities in the UK.

Micronclean is known for its expertise in a number of aspects of cleanroom garment provision:

- Cleanroom garment technology – fabric, garment design;
- Cleanroom garment decontamination and sterilisation – laundry design, validation and process control;
- Development of IT solutions to provide market-leading tracking and traceability for cleanroom garments.

PURPOSE

Micronclean defines its company aims in its Purpose:

"At Micronclean our passion is to be the first to develop new technological solutions that change the shape of the markets we serve, creating quality and efficiency for our customers."

Figure 1 - Micronclean UK facility

SKIEs

Microncleanaspires to fulfil its Purpose through its core values – SKIEs:

STEWARDSHIP

We strive to leave more than we started with by creating lasting business structures that are enduring and act as a base for future, sustainable development. Stewardship enables us to do this and it is the management system by which we capture and embed our values and ethos into everyone and everything that we do.

Pride is at the core of our business; we do all we can to ensure everyone with the company feels, an integral part of something important and good, that we have helped to create. A high ethical integrity is at our heart and we aim to work with sincerity and honesty, treating everyone in a respectful and fair manner.

KNOWLEDGE

The foundation of our ability to serve our customers with Excellence and Innovation. Knowledge is the life blood of our business forming the backdrop against which all our activities are played out.

We aim to drive knowledge into our business by an openness of information and by consistently delivering training.

We strive to be experts in our business activities, allowing us the power and flexibility to exceed customer expectations. Being the best is aspirational and is achieved by a thirst for knowledge and betterment.

INNOVATION

Investment in change to create a better future for ourselves and our customers. It is the primary strategic choice of our company to position ourselves as the technological market leader. It is our investment in innovation that supports this and drives us into new markets. Innovation is core to what we do and defines our business. It ensures that we focus on 'how we can be the best'.

Our company strives to develop a management culture that encourages innovation and creative ideas from across the company. This enables all of us to feel a part of this process and allows innovation to become an intrinsic part of how we all think in our roles.

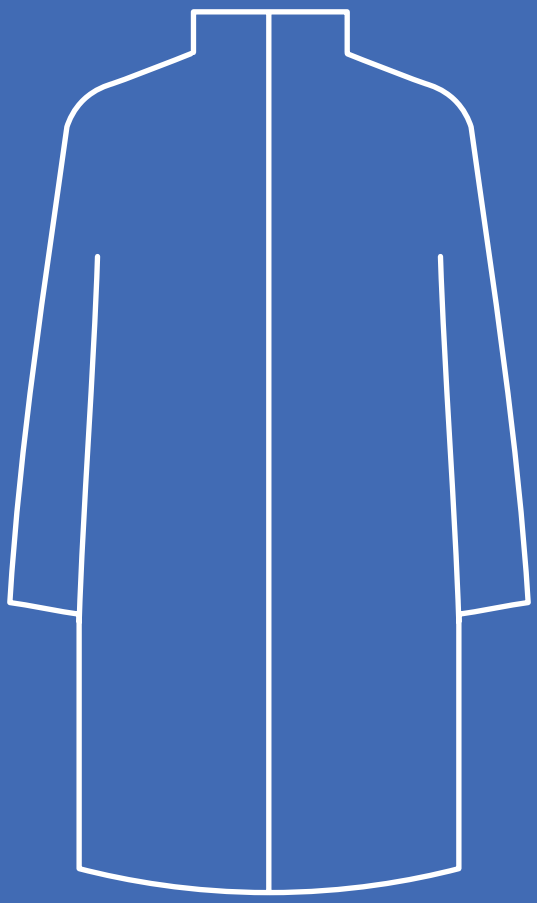
EXCELLENCE

The business process to continually improve the quality and cost base of our products and services. The key to achieving Excellence is a remorseless focus on being the best so that we can delight our customers and surpass their expectations. We achieve Excellence through the tight control of quality and the maintenance of an efficient cost base.

We achieve Excellence by simplifying our processes so that they are more logical and easily understood, then we train our staff to fully understand these systems. We are a company where any mistake is grasped as an opportunity for improvement. Creating an atmosphere where we are encouraged to bring forward mistakes enables us to learn from them and to make the changes that make us better than we were.

CLEANROOM GARMENTS

INTRODUCTION



CLEANROOM GARMENTS | INTRODUCTION

INTRODUCTION - CLEANROOM GARMENTS

This section provides an overview of the purpose and function of cleanroom garments, a comparison between a cleanroom garment rental service and alternative approaches to cleanroom garment provision, an introduction to cleanroom garment technology and an assessment of cleanroom garment performance through life.

THE ROLE OF CLEANROOM GARMENTS

Cleanroom garments must fulfil several important requirements:

1. Cleanroom garments must act as an effective contamination control measure, containing viable and non-viable particulate released from the wearer thus preventing cleanroom contamination.

2. Cleanroom garments must not themselves generate particulate or fibre contamination.

3. Cleanroom garments must be durable to ensure that it will not become easily damaged during use therefore presenting a contamination risk.

4. Cleanroom garments must be comfortable and practical for the wearer to allow the wearer to easily comply with cleanroom garment policies.

5. Cleanroom garments must be a cost-effective contamination control solution for the specified manufacturing operation.

6. The environmental impact of cleanroom garments must be as low as possible throughout its life cycle (from fabric and garment manufacture, through garment processing and use, to end of life).

Microncleanclean takes these requirements seriously. With several decades of experience, Microncleanclean has developed and optimised a number of aspects fundamental to delivering high quality cleanroom garments that perform consistently, including:

- Material and component selection
- Garment design
- Garment manufacture
- Garment laundering

CLEANROOM GARMENTS | INTRODUCTION

ASSURED CLEANROOM GARMENT PERFORMANCE

It is not enough to determine the performance of cleanroom garments in the 'as new' state. Cleanroom garments endure significant stresses from repeat cycles of use, decontamination and sterilisation. These activities cause wear and tear and therefore cause inevitable deterioration in performance of cleanroom garments. Indeed, the current draft of EU GMP Annex 1 states:

"Reusable garments (including eye coverings) should be replaced if damage is identified or at a set frequency that is determined during qualification studies. Damage to garments may not be identified by visual inspection alone, so the qualification should consider any necessary garment testing requirements."

Microncleanperforms extensive studies to measure the performance of its cleanroom garments through life.
The studies involve a comparison of market leading materials and components, optimised garment designs, and laundering and sterilisation using Microncleanʼs validated processes.

These studies allow Microncleanto select the best materials and garment designs, but also provide evidence of performance. Microncleancan provide to customers assurance of cleanroom garment performance throughout life in the form of quantitative data.

Microncleanretains complete control of the materials, garments and the laundry and sterilisation cycles and can therefore manage risks associated with changes, including repeating studies as necessary.

By overseeing all aspects of cleanroom garment provision, and by extensively studying garment performance, Microncleancan deliver assurance of consistently high quality and value for money. For this reason, cleanroom garment rental from a specialist provider is considered best practice and has become the leading model of cleanroom garment provision in Europe, the USA and other leading markets.

The alternative approaches carry challenging risks:

- **Garment Purchase and On Premise Laundry**

  The garment manufacturer might provide performance data for garments as new. However, as the manufacturer cannot plan for all potential decontamination / sterilisation cycles, it is impractical for garment manufacturers to conduct through life studies. The user might therefore experience reduction in cleanroom garment performance over time, which presents a significant risk to cleanroom contamination.

  There are also risks from changes. The garment manufacturer might change a material or component that is not compatible with the laundry / sterilisation process, or the laundry might change the laundry / sterilisation process resulting in incompatibility with garments. This might result in contamination risks, issues with usability, or unforeseen escalation in costs.

  As well as contamination risks, premature degradation of cleanroom garments can result in unforeseen costs and therefore poor value for money.

- **Disposable Garments**

  The materials and manufacturing methods used in production of disposable cleanroom garments are necessarily low in cost. Compromises are necessarily made in performance, durability or comfort in order to achieve an appropriate price point. The pursuit of low manufacturing costs can lead to risks in quality and consistency of products.

CLEANROOM GARMENTS | INTRODUCTION

Non-woven materials naturally strike a poorer balance between barrier performance and wearer comfort. Although non-woven fabrics typically have very high barrier performance (e.g., particle filtration performance is excellent), this is combined with very low air permeability rates. This leads to two issues.
Firstly, garments are less breathable and therefore less comfortable to wear. This reduces the likelihood that wearers will consistently comply with gowning policies. Secondly, as the wearer moves, compressed air within the garment will be expelled from garment closures (e.g., cuffs, neck) rather than through the fabric. This 'pumping effect' presents a risk of cleanroom contamination, with contaminated air escaping from the suit rather than being filtered through the suit.

Cleanliness of disposable cleanroom garments is a further challenge. The act of manufacturing fabrics and then cutting and sewing these into garments inherently generates large amounts of particle and fibre contamination. Consideration must therefore be given of how to minimise contamination of garments during manufacture or, for high grade cleanroom applications, how to decontaminate garments (e.g. by laundering) prior to supply for use. Many disposable garments available on the market are not fit for use in cleanrooms due to the level of particle and fibre contamination.

Regarding life cycle, disposable garments present several key challenges. Overall, disposable garments have a greater environmental impact. Further, use of disposable garments presents significant risks and costs associated with supply chain, logistics, stock control and waste management.

Microncleanbelieves that the cleanroom garment rental model delivers the greatest possible quality assurance and value for money to cleanroom operators.

CLEANROOM GARMENT PERFORMANCE – GUIDANCE AND TEST METHODS

From a practical and technical perspective, there are several internationally used guidance documents that describe good practice approaches to the design and use of cleanroom garments.

ISO 14644-5: Operations includes a section and informative annex on the function, properties and practical considerations relating to cleanroom garments.

EU GMP Annex 1 describes personnel considerations in the manufacture of sterile medicines, including basic considerations for the use of cleanroom garments.

USP 797 outlines basic requirements for cleanroom garments in pharmaceutical compounding environments.

These documents are good sources of useful introductory information and indications for further reading. However, none of them intend to tackle cleanroom garment technology in any depth. For more detailed information and guidance the American Institute of Environmental Sciences and Technology (IEST) – Contamination Control Division has developed and published what is considered a recommended practice document – **IEST RP CC 003**. This document is considered to be the leading guideline on cleanroom garment technology and covers the key considerations for garment systems to be used in cleanrooms and controlled environments. Guidance is offered on the specification, design, construction, maintenance and use of cleanroom garments. Further, several test methods are described and referenced that can be used to measure the performance of cleanroom barrier fabrics and of cleanroom garment systems. This document is a good starting point for anyone wishing to learn about cleanroom garment technology.
Microncleanutilises these guidelines to assess cleanroom garment performance, and to design and plan it's through-life cleanroom garment performance studies. Below the key test methods incorporated in these studies are described. The test methods are divided into five groups – (i) barrier properties, (ii) durability, (iii) comfort, (iv) particle and fibre contamination, and (v) garment system performance.

[1] See - Vozzola E., Overcash M. & Griffing E. Life Cycle Assessment of Reusable and Disposable Cleanroom Coveralls. PDA J Pharm Sci Technol. 2018. 72(3). pp.236-248. (https://www.ncbi.nlm.nih.gov/pubmed/29444994)

CLEANROOM GARMENTS | INTRODUCTION

BARRIER PROPERTIES

The assessment of barrier properties provides an indication as to how a fabric will perform in the containment of contamination released from the wearer. Test methods are available to both directly and indirectly assess the barrier properties of a fabric.

PORE SIZE

Pore size is a key physical property of a fabric which is associated with adequately containing the contamination released by the wearer, and also the breathability of the fabric. In a woven fabric, the pore is the space between the yarns. The pore size is controlled by the construction of the yarn, and the tightness and consistency of the weave.

In simple terms, the smaller the pore size the increased barrier efficiency (i.e. greater containment of contamination) of the fabric. However, this may come with a compromise in breathability and therefore decreased comfort and increased risk of the 'pumping effect'. Having said this, it is also true to say that fabrics can – through their three-dimensional structure – achieve a 'depth filtration' effect. Weave patterns can create fabric pores that are convoluted, meaning the path for a particle through the fabric is more complex, thus increasing the chance of particle impaction within the fabric and thus increasing particle filtration efficiency.

IEST RP CC 003 refers to a British Standard – BS 3321, commonly referred to as the 'bubble point' method to measure pore size (this method is similar to the method used in the assessment of pore size in membrane filters).

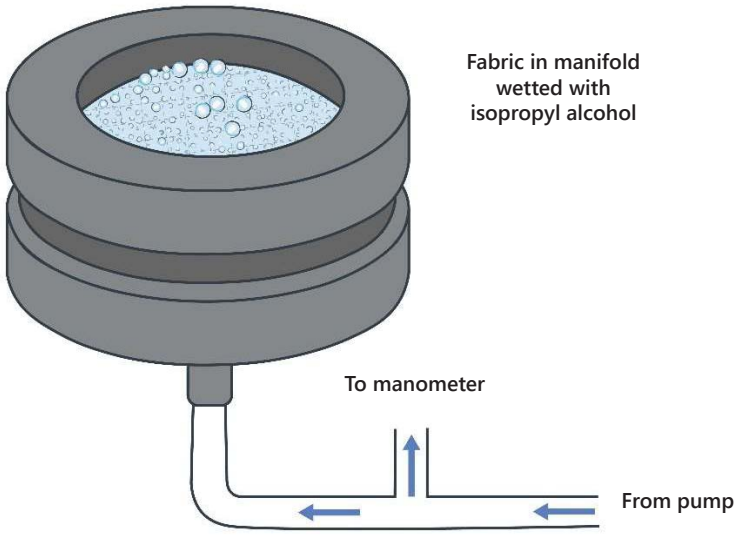


Figure 2 - Bubble point test apparatus to determine fabric pore size

Figure 2 shows a typical apparatus set up for the bubble point test method. The method involves placing the specimen fabric in a manifold, covering the fabric with a solvent of known surface tension (typically isopropyl alcohol), and applying increasing air pressure to the underside of the wetted fabric, until bubbles emerge from the fabric. The air pressure is proportional to the pore diameter.

As an indication, everyday polycotton fabrics (e.g. those used in shirts and blouses) have a pore size of 50 to 100µm, whereas a cleanroom fabric would typically have a pore size of 5 to 15µm.

CLEANROOM GARMENTS | INTRODUCTION

PARTICLE FILTRATION EFFICIENCY

Particle filtration efficiency is a direct measurement of how well a cleanroom fabric contains particulate contamination. IEST RP CC 003 describes a particle penetration test, whereby contaminated air is passed through a cleanroom fabric in controlled conditions and the amount of particle retention by the fabric is measured by comparing the particle concentration in the upstream and downstream air. The test can be conducted at different particle sizes and different exposure times to achieve a more complete assessment of how a fabric might perform in typical use conditions.

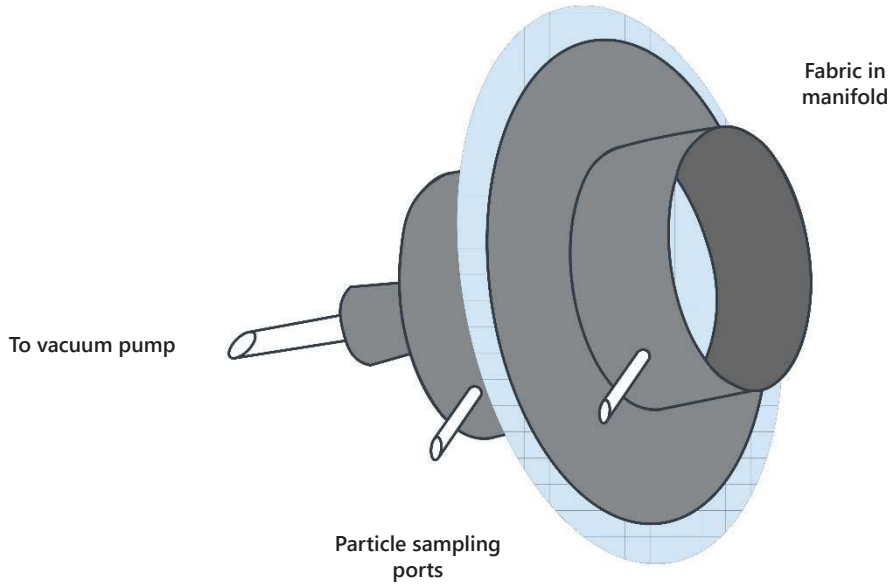


Figure 3 - Test apparatus to determine particle filtration efficiency of fabric

Figure 3 shows a typical apparatus set up for the particle filtration efficiency test method. Several laboratories have developed test methods according to the guidance in IEST RP CC 003. These methods typical involve preparation of contaminated air using silicon oxide particles of differing sizes.

A high-quality cleanroom fabric would typically be expected to achieve a particle filtration efficiency of >80% for particles greater than 0.5µm in size, and >90% for particles greater than 5.0µm in size.

CLEANROOM GARMENTS | INTRODUCTION

DURABILITY

The assessment of durability is important to ensure that a fabric will withstand the normal wear and tear expected in the repeat cycles of garment use, laundering and sterilisation. A durable fabric will ensure a low risk of garment breach during use, and increased durability can also result in a longer life span, and therefore better value for money of cleanroom garments.

TENSILE STRENGTH

A tensile strength test measures the force required to break the fabric. Typically, a 'grab test' is used for fabrics, such as ISO 13934-2 or ASTM D5034.

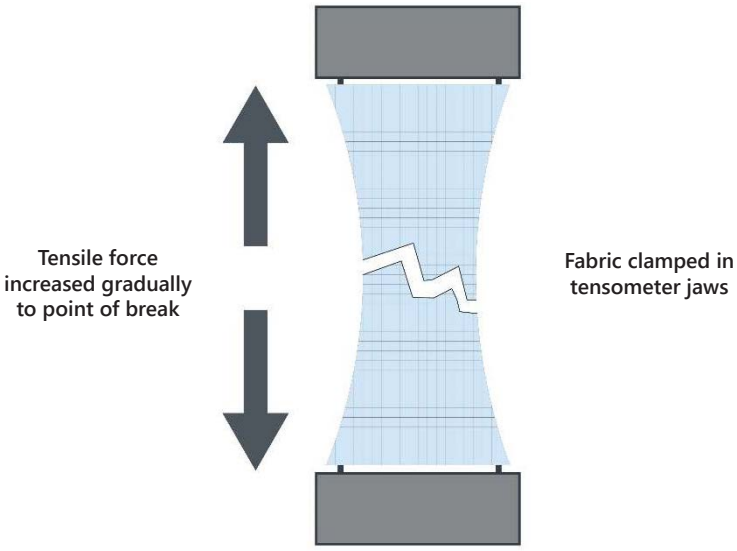


Figure 4 - Test apparatus to measure tensile strength of fabric

Figure 4 shows a typical apparatus set up for a fabric tensile strength test. A piece of fabric is gripped in the jaws of a tensometer, or universal test machine, and an increasing tensile force is applied, until the point at which the fabric breaks.

The tensile strength of a fabric is a useful indicator of a fabric's capability to withstand the rigours of repeat use, laundering and sterilisation, and a garment's likelihood of breach during use.

It is important to measure the tensile strength of a fabric through repeat laundering and sterilisation cycles as these processes can significantly degrade fabric strength. Poor fabric strength increases the risk of fabric breach during use and increases the cost of garment maintenance (e.g., more frequent repairs).

CLEANROOM GARMENTS | INTRODUCTION

ABRASION RESISTANCE

An abrasion resistance test measures a fabric's durability to rubbing and scuffing action. Standard test methods such as ISO 12947-1 and ASTM D3884 are commonly used.

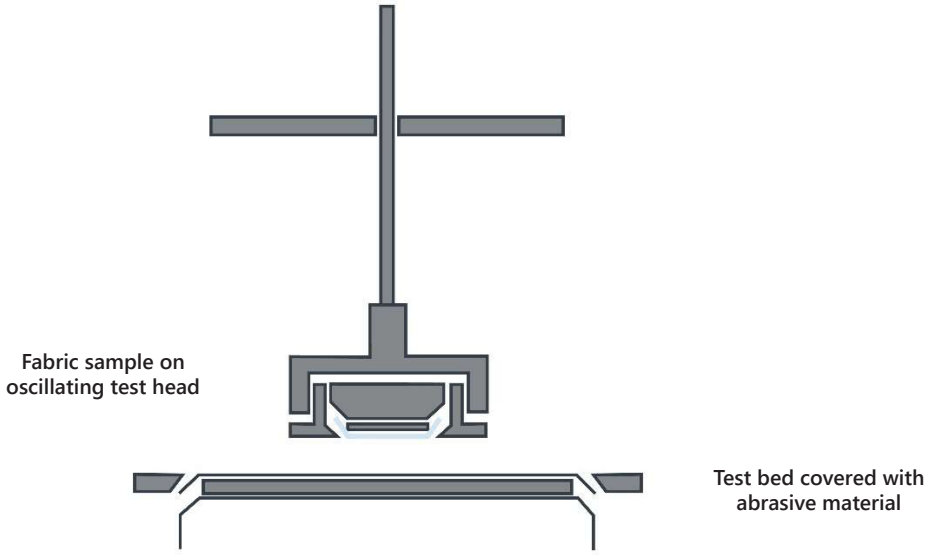


Figure 5 - Test apparatus to measure abrasion resistance of fabric

Figure 5 shows a typical apparatus set up for a fabric abrasion resistance test. Typically, an abrasion test will involve moving a sample of fabric over a standardised abrasive surface (e.g., sandpaper) in an oscillating pattern and counting the number of cycles the fabric can withstand, before showing signs of breakdown.

The abrasion resistance of a fabric is a useful indicator of how well the fabric will stand up to the stresses of repeat use. A low resistance to abrasion can indicate risks of rapid fabric degradation through use, which can lead to premature garment replacement and therefore unforeseen costs.

CLEANROOM GARMENTS | INTRODUCTION

COMFORT

In order to perform its function, cleanroom garments must be donned and worn according to strict procedures. There is a risk that contamination from the wearer will be released into the cleanroom, in greater, and unacceptable, quantities if their cleanroom garments are not worn and fastened correctly. Cleanroom garment comfort is therefore an important factor. If cleanroom garments are more comfortable then there is a greater chance they will be worn correctly.

AIR PERMEABILITY

Air permeability is a measure of how freely air can pass through a fabric; this is sometimes referred to as 'breathability' (although breathability is specifically the ability of a fabric to allow perspiration, evaporated by the body, to escape to the outside). Standard test methods, such as ASTM D737, are typically used. Breathability is important from a wearer comfort perspective as the more breathable the fabric, the quicker the temperature of the air inside the garment can equilibrate with the air outside the garment. Further, air permeability is critical from a contamination control perspective. The ideal cleanroom fabric has a high air permeability, with a small pore size; air can freely pass through the fabric and particulate will be filtered from the air as it passes through due to the small pores. A fabric with low air permeability increases the risk of 'pumping action'; as the wearer moves contaminated air within the garment is compressed. This contaminated air cannot easily pass through the fabric and will tend to escape from closures (e.g. cuffs, neck) in the garment, carrying with it contamination, and thus contaminating the cleanroom.

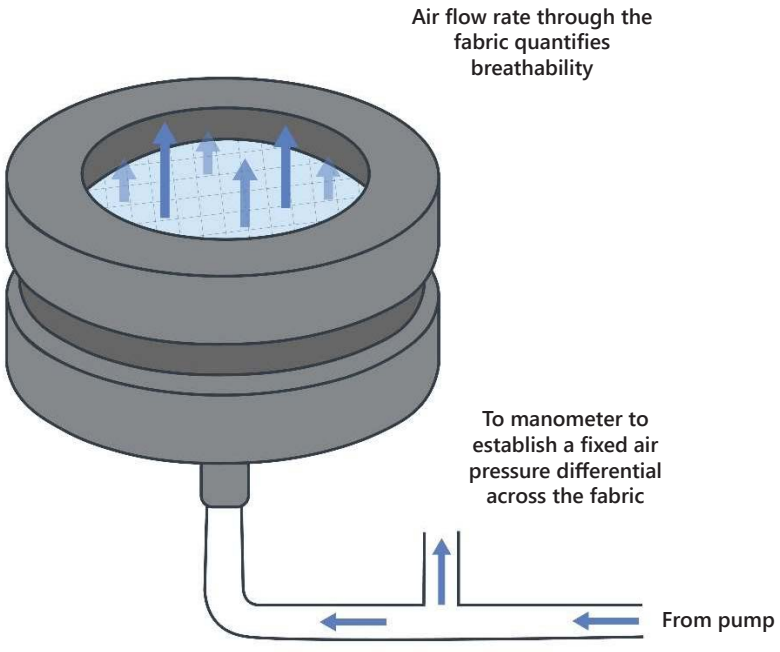


Figure 6 - Test apparatus to measure air permeability (or 'breathability') of fabric

Figure 6 shows a typical apparatus set up for a fabric air permeability test. An air permeability test is conducted at a fixed air pressure differential across the fabric. Air flow rate is measured at the exhaust side, and this quantifies the air permeability of the fabric. Air permeability is typically expressed as a volume of air that can pass through a fabric, per surface area of fabric, per unit of time (e.g. litres per square metre per second).

CLEANROOM GARMENTS | INTRODUCTION

Cleanroom fabrics, due to their small pore size, are less breathable than everyday fabrics. As an indication, everyday polycotton fabrics (e.g. those used in shirts and blouses) might have air permeability of 150 to 200 litres/m2/s, whereas a cleanroom fabric would typically have air permeability of 25 to 50 litres/m2/s. However, cleanroom fabrics, depending on their construction, can vary significantly in breathability. For reference, due to their construction (extremely small pore size and / or polymeric film lamination), non-woven materials used in cleanroom garments have a much lower air permeability, and therefore typically, offer a poorer comfort level to the wearer whilst significantly increasing the risk of 'pumping action'.

There is no specific rule regarding what level of breathability will lead to a comfortable garment. Many other factors influence operator comfort in a cleanroom (cleanroom garment design, primary garment attributes, cleanroom temperature and humidity, cleanroom air flow, physicality of work, etc.). However, the difference in breathability between cleanroom fabrics can provide a useful indication as to their relative contribution to achieving comfort for the wearer.

WATER VAPOUR TRANSMISSION

Water vapour transmission is a measurement of the free movement of moisture across a fabric. This is another important factor in the comfort of the wearer of a cleanroom garment and another measure of breathability. As the wearer perspires, they will be more comfortable the quicker that moisture can evaporate and escape through the fabric. Standard test methods, such as ASTM E96, are typically used.

Cleanroom fabrics have lower water vapour transmission rates than everyday polycotton fabrics. For reference, due to their construction (extremely small pore size and / or polymeric film lamination), non-woven materials used in cleanroom garments have a much lower water vapour transmission and therefore typically offer poorer comfort to the wearer.

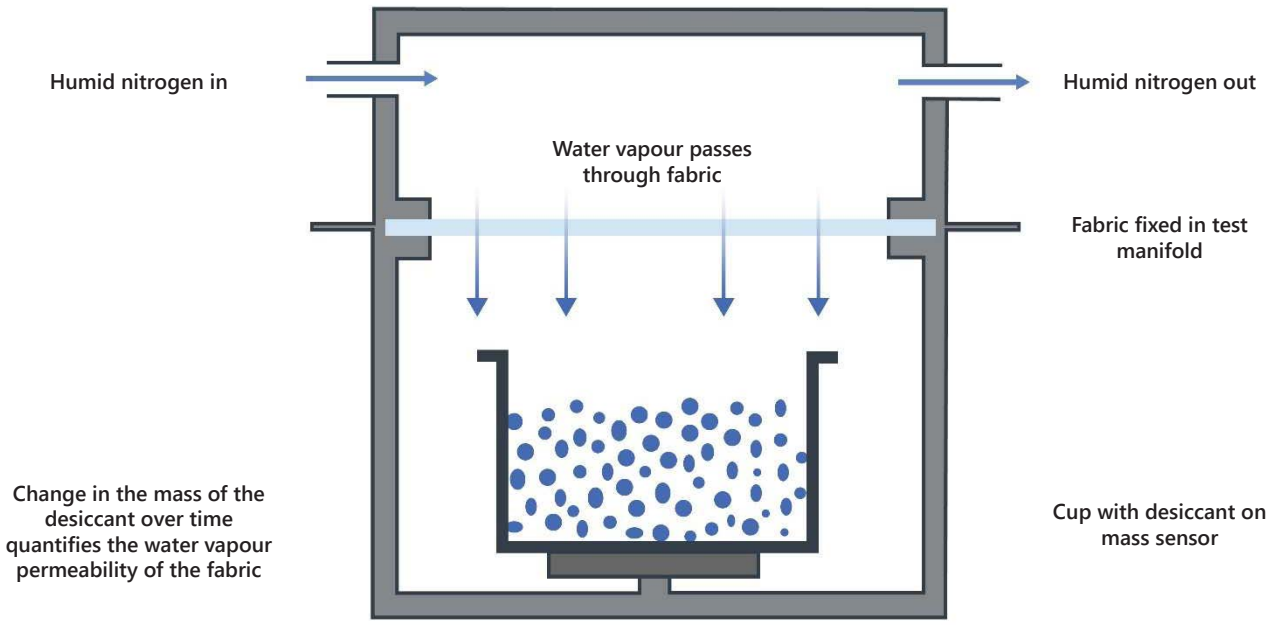


Figure 7 - Test apparatus to measure water vapour permeability of fabric

CLEANROOM GARMENTS | INTRODUCTION

Figure 7 shows a typical apparatus set up for a fabric water vapour permeability test. A fabric sample is held in a test manifold. In the space below the fabric a cup of desiccant is placed on a mass sensor. Humid nitrogen is supplied to the space above the fabric at a set rate. Water vapour passing across the fabric over time will be absorbed by the desiccant, thus changing its mass. The degree of mass change quantifies the water vapour permeability of the fabric. Water vapour transmission is typically expressed as mass of moisture moving across the fabric per surface area of fabric per unit of time (e.g. grams per square metre per 24hr).

As with air permeability, there is no specific rule regarding what level of water vapour transmission will lead to a comfortable garment. Many other factors influence operator comfort in a cleanroom (cleanroom garment design, primary garment attributes, cleanroom temperature and humidity, cleanroom air flow, physicality of work, etc.). However, the difference in water vapour transmission between cleanroom fabrics can provide a useful indication as to their relative contribution to achieving comfort for the wearer.

PARTICLE AND FIBRE CONTAMINATION

As well as containing contamination from the wearer, cleanroom garments must not generate contamination themselves during use. To achieve this, cleanroom garments incorporate a number of key features, including specialist yarns and garment construction methods. Further, cleanroom garments must be successfully decontaminated of particulate matter before they are first used (i.e. to remove particulate from garment manufacture) and after each use (i.e. to remove the particulate contamination collected by the garment during use). This decontamination is achieved using a cleanroom laundry with validated processes that can remove contamination from garments and prevent recontamination of garments prior to packaging.

Two standardised test methods are primarily used. They are intended to measure the amount of particulate matter releasable from the surface of a cleanroom garment in its 'ready for use' state. Both methods are outlined below with notes to describe their use cases.

ASTM F51

ASTM F51 describes a standard test method whereby releasable particulate is vacuumed from the surface of a cleanroom garment and impinged on a filter membrane. The filter is then visually inspected under the microscope to count the recovered particles and fibres. Two methods can be used; (i) the 5-point method whereby five small, discrete areas of the garment are sampled, and (ii) the frame method whereby a larger, 300mm x 300mm area of fabric is samples. The 5-point method is best suited for smaller items (e.g. headwear or footwear) or for garments where a high particulate level is expected. The frame method is best suited for larger items (e.g. coveralls or coats) especially where a low particulate level is expected and therefore a larger samples size contributes to a greater result accuracy.

CLEANROOM GARMENTS | INTRODUCTION

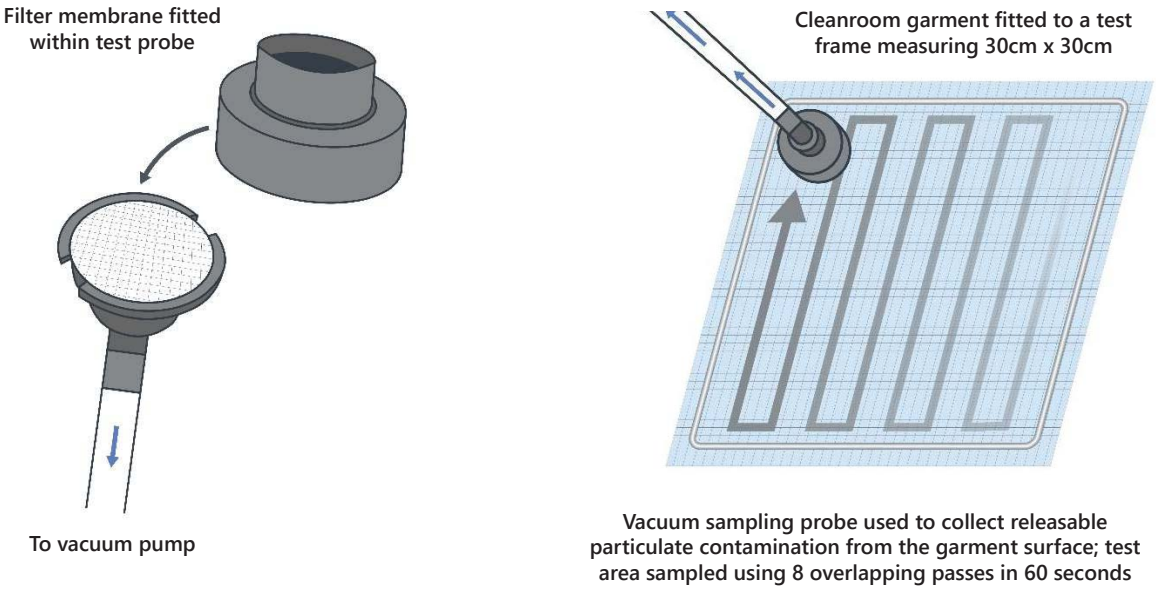


Figure 8 - Diagramatic representation of ASTM F51 test for garment particulate contamination

Figure 8 provides a diagrammatic representation of the ASTM F51 test to quantify garment particulate contamination. The test is performed in cleanroom conditions to prevent contamination of the garment prior to and during the test. The test apparatus consists of a stainless-steel test frame measuring 30cm x 30cm and a sampling probe attached to a vacuum line. A garment is laid over and fitted to the test frame. A filter membrane is fitted within the sampling probe and the vacuum pump switched on. The surface of the garment is sampled over a total of 60 seconds in 8 overlapping passes. Releasable particulate contamination from the surface of the garment is impinged on the filter membrane. The filter membrane is then inspected using an optical microscope and the particles and fibres are counted.

The test method samples particulate of 5.0µm and larger and fibres (particles greater than 100µm in length). These particles are more likely to be biologically active or be relevant to human physiology. The method is therefore suited to assessing the cleanliness of garments intended for use in the pharmaceutical and biotechnology industries.

The method can be used for woven (reusable garment) materials only. Non-woven (disposable garment) materials have insufficient air permeability to achieve the necessary vacuum-driven air flow through the fabric.

GARMENT SYSTEM PERFORMANCE

All of the above test methods measure fabric performance. The performance of a cleanroom fabric plays a critical role in the performance of a cleanroom garment system. However, cleanroom garment system performance is also significantly influenced by other key factors including garment construction; garment design; accuracy of donning and use by the wearer; and use of undergarments, which provide a coarse filtration of contamination from the wearer while themselves not producing contamination.

Assessing the performance of an entire garment system is therefore an important tool in ensuring cleanroom garments are fit for purpose.

CLEANROOM GARMENTS | INTRODUCTION

BODY BOX

IEST RP CC 003 describes a method by which the contamination control performance of the whole garment system can be assessed. The test is commonly referred to as the 'body box' method; it measures particle dispersion – both viable and non-viable – from a garment system in simulated use conditions. A person is asked to don cleanroom garments, enter a clean air booth, and then perform standardised action with a metronome. While the actions are being performed, an electronic particle counter and microbiological active air sampler are used to sample airborne contamination at close to floor level in the booth.

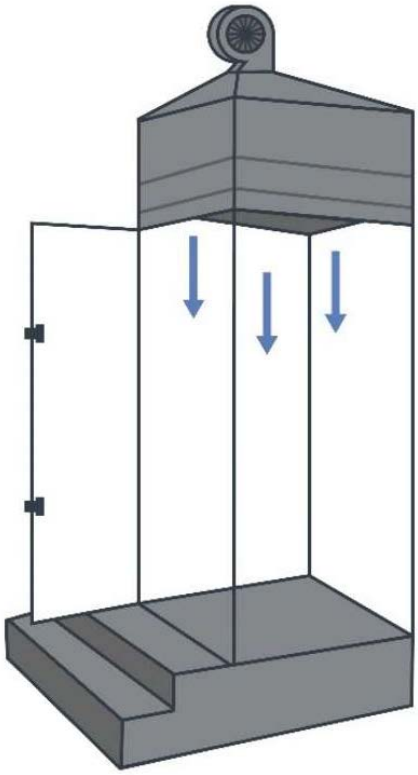


Figure 9 - Diagrammatic representation of a Body Box test apparatus

Figure 9 shows a typical Body Box test apparatus. The test is conducted in cleanroom conditions to prevent extraneous contamination impacting the test results. The test apparatus consists of a booth fed with cleanroom air and, at the base of the booth, an electronic particle counter and microbiological active air sample. A person is asked to aseptically don a set of cleanroom garments. They then enter the Body Box, and the door is closed. The person is asked to perform standardised exercises to the beat of a metronome (Phase A – an arm extension movement, Phase B – walking in place while moving arms). Simultaneously the particle counter and active air sampler are used to sample the air in the booth to quantify the particulate contamination and viable particulate contamination being released from the person into the air.

The test method does not produce absolute results. For example, the rate of particulate dispersion from the person is an uncontrolled variable as different people shed particulate contamination from their skin at significantly varying rates.

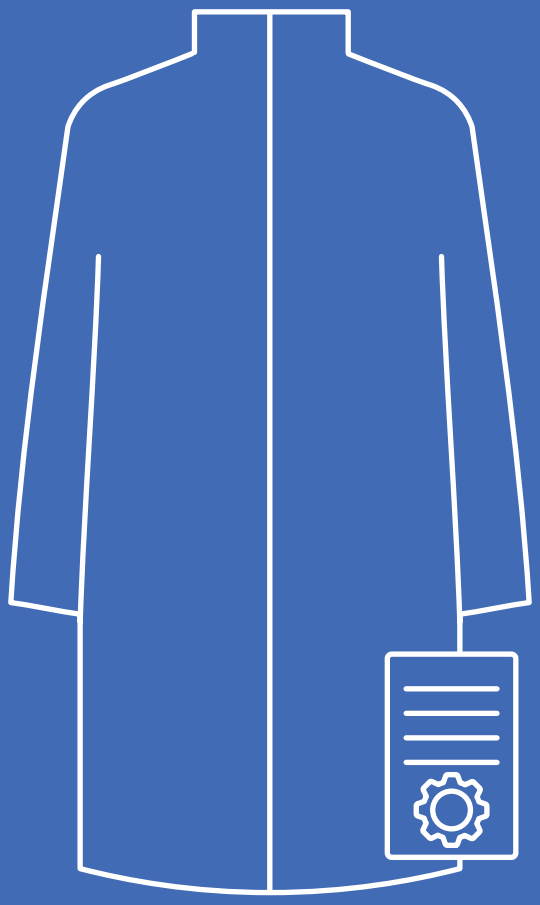
CLEANROOM GARMENTS | INTRODUCTION

The method is however useful in measuring the relative contamination control performance of different cleanroom garment systems, for example several garment systems of the same design but incorporating different fabrics (to test relative differences between fabric options), or several garment systems of different designs but incorporating the same fabric (to test relative differences between garment design options). Comparison tests are best performed using the same test subject (i.e. person) and in close time proximity to minimise the influence of uncontrolled variables on the results.

The test has also helped to establish the significance of other important cleanroom garment system factors, such as good garment decontamination practice prior to use, the contamination control benefits of using clean, low linting primary garments, and of proper maintenance of cleanroom garments (e.g. repair of even small areas of fabric or garment damage).

GARMENTS STUDY AND EXPERIENCE

MICRONCLEAN UK



MICRONCLEAN UK | GARMENT STUDY AND EXPERIENCE

MICRONCLEAN UK - GARMENT STUDY AND EXPERIENCE

By performing extensive studies of cleanroom garment performance, Micronclean is able to select the best materials, garment designs and garment construction methods to work with, and is able to optimise its laundry and sterilisation processes to ensure that a high-performing garment is delivered to the customer throughout a garment rental contract. Micronclean is also able to establish the safe useful life of a cleanroom garment and design its contracts to ensure that customers receive high quality and good value for money.

In this section, data from a UK cleanroom garment study is presented, demonstrating the important insight gained. The studies show that market-leading fabrics do not all perform equally. Despite approximately equal performance when new, some fabrics significantly outperform others when tested throughout life, offering higher performance levels, greater garment life, and better value for money.

The study presented in this section, exposed cleanroom garments of the same design, but constructed from four different fabrics, to repeat cycles of Micronclean's standard UK laundry and sterilisation (gamma irradiation) process. The fabrics were exposed to a maximum of 100 process cycles. At planned cycle intervals garments were removed from the study for analysis.

In the appendix the effect of steam sterilisation on garments is also explored.

The four fabrics in the study were (i) 'WF5505JG' – the fabric that Micronclean uses in its garments, (ii) Fabric B, (iii) Fabric C and (iv) Fabric D – three other market-leading cleanroom fabrics (see Table 1). For further details on WF5505JG please refer to Table 2.

TABLE 1 - COMPARISON OF THE FABRIC PHYSICAL PROPERTIES

Fabric	GSM	Construction	Weave	Fibre Type
WF5505JG	105	176 x 94	Plain	Polyester
B	98	168 x 100	Plain	Polyester
C	105	*	Plain	Polyester
D	102	165 x 99	Plain	Polyester

(* This information is unavailable due to commercial confidentiality).

TABLE 2 - SPECIFICATION AND BARRIER PERFORMANCE OF WF5505JG

Fabric Property	Result
Weight (g/m2)	105
Composition	98% Monofilament Polyester, 2% Conductive Yarn
Yarn Density (yarn/cm)	Warp = 69 - Weft = 37
Surface Resistivity (Ω)	108 – 109
Average Pore Size (µm)	4.01
Barrier Ability Against Airborne Particles >5.0µm (%)	93.4
Air Permeability (L/dm2/min)	8.0
Water Vapour Transmission (g/m2/24h)	5410
Dry Linting Propensity (Coefficient of Linting)	3.2

Results are shown for various key cleanroom fabric performance characteristics, for the 4 fabrics.

MICRONCLEAN UK | GARMENT STUDY AND EXPERIENCE

BARRIER PROPERTIES

PORE SIZE

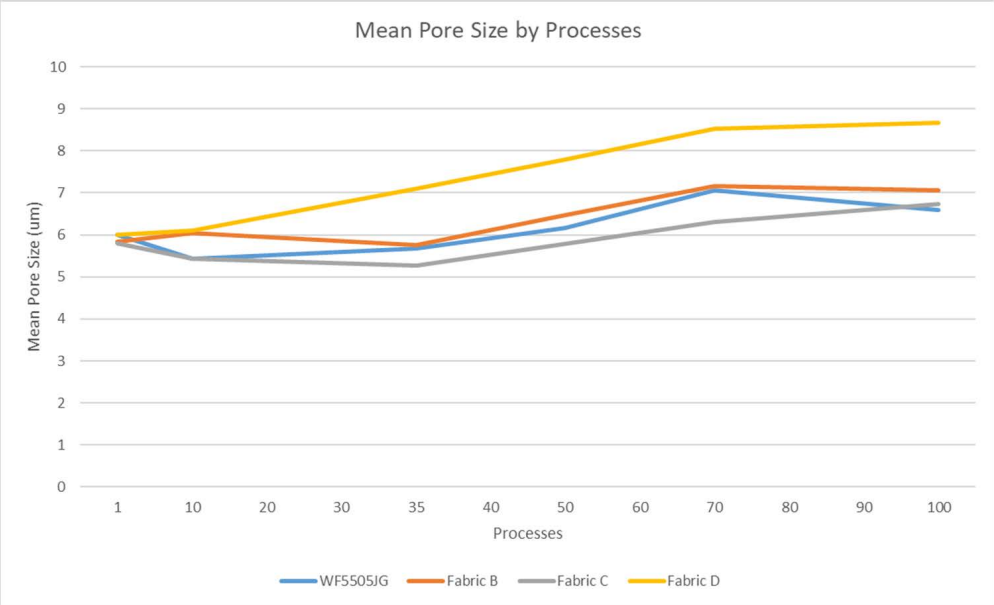


Figure 10 - Graph to show irradiated fabric pore size through life

In this test the pore size of the fabrics was measured. Results are expressed in micrometres.

All fabrics begin with a mean pore size of between 5.8-6.0µm. At 10 processes, the pore size of WF5505JG and Fabric C have slightly decreased, whilst Fabrics B and D have slightly increased. At processes beyond this all fabrics demonstrate a trend towards larger pore sizes.

TABLE 3 - TABLE SHOWING PORE SIZE INCREASE

Fabric	Highest Mean Pore Size (µm)	Mean Pore Size Increase from Initial (µm)
WF5505JG	7.1	0.6
Fabric B	7.2	1.3
Fabric C	6.7	0.9
Fabric D	8.7	2.7

The highest mean pore size was observed after the maximum number of processes for all fabrics, except WF5505JG. **Table 3** shows that Fabric D saw the highest increase overall with a 2.7µm increase from new to 100 processes. WF5505JG & Fabric C performed the best with similar final mean pore sizes.

MICRONCLEAN UK | GARMENT STUDY AND EXPERIENCE

PARTICLE FILTRATION EFFICIENCY

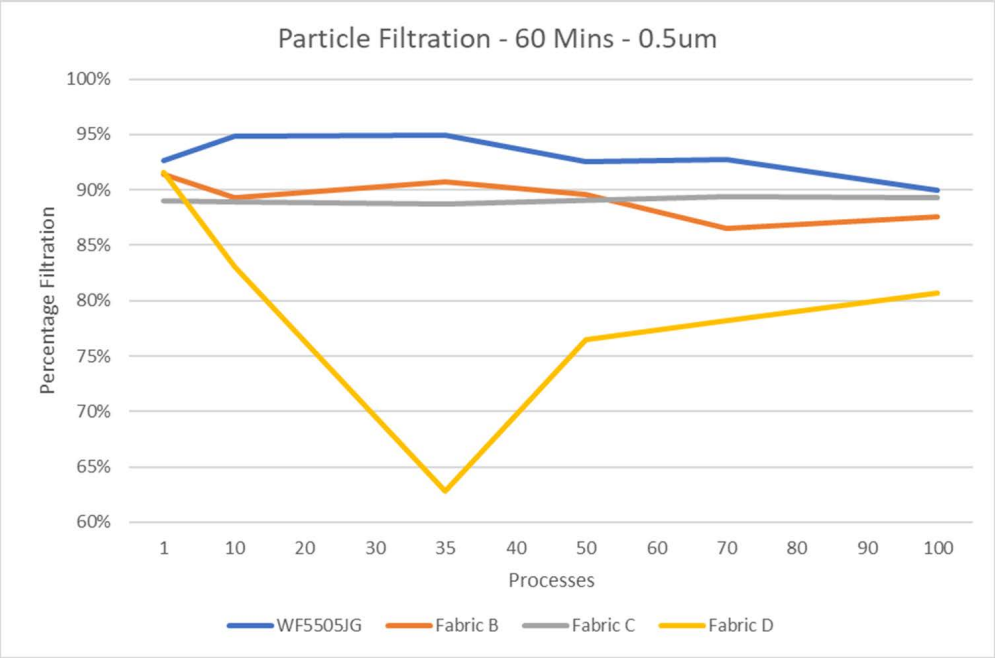


Figure 11 - Graph to show irradiated fabric particle filtration efficiency through life

In this test the particle filtration efficiency of the fabrics was measured. Test conditions were a particle size of 0.5µm, and a test time of 60 minutes. Results are expressed in percentage as a measure of particle filtration efficiency.

Figure 11 shows that all four fabrics begin with roughly equal levels of particle filtration efficiency, ranging between 89% and 93%. As the number of cycles increases a slight decline in particle filtration efficiency can be seen in Fabrics .

WF5505JG and B. Fabric C is the most consistent performing fabric showing no decline during the processing. WF5505JG retains an efficiency of above 89% throughout testing. Fabric B retains its efficiency up to approx. 35 processes but sees a decline to 88% by 100 processes. Fabric D sees an immediate decline below the baseline set by Fabrics B and C, reducing to 83% after 10 processes. The 35-process value of 63% is an outlier and assumed to be erroneous, the testing for this process point could not be repeated as the testing is destructive. The fabric continues a downward trend with 77% as the lowest value, 13 percentage points lower than its highest value.

This highlights that a cleanroom fabric should not be selected based on 'as new' performance data only. What appear to be similar fabrics in the 'as new' state, offer the user significantly different levels of performance over the course of garment life.

MICRONCLEAN UK | GARMENT STUDY AND EXPERIENCE

DURABILITY

TENSILE STRENGTH

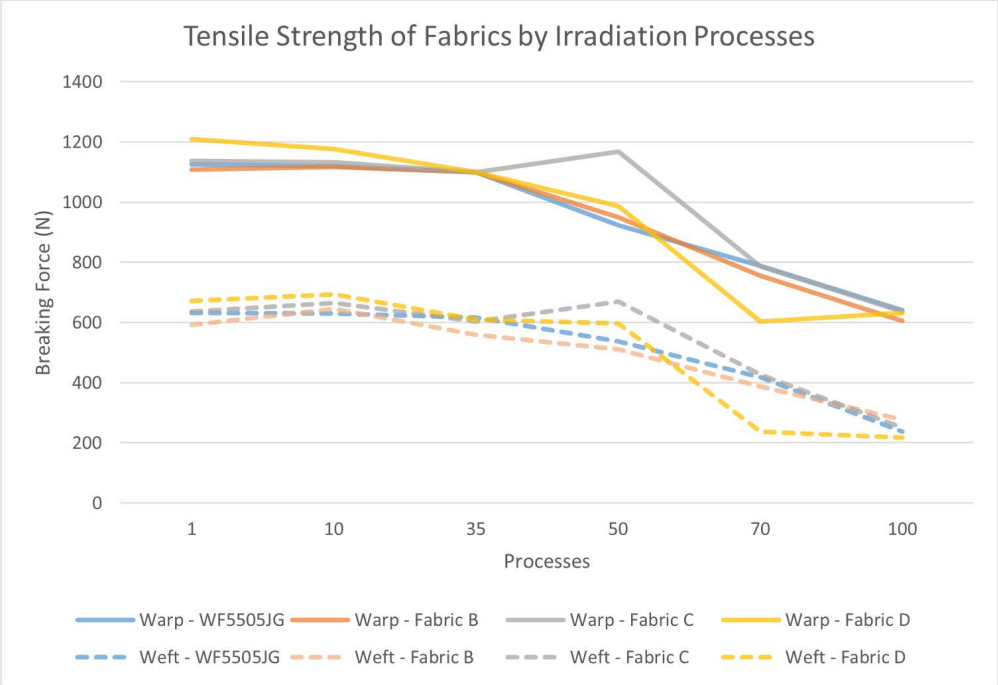


Figure 12 - Graph to show irradiated fabric tensile strength through life

In this test the tensile strength (force required to break the fabric) of the fabrics was measured. Results are expressed in Newtons of force, at the point of break.

As can be seen in **Figure 12**, all fabrics exhibit a reduction in tensile strength breaking force as the number of processes increases. The decline in breaking force required, reduces slowly from 1 to 35 process, but declines more rapidly at 50+ processes.

Fabric D begins with the highest tensile strength breaking force in both warp and weft directions. The warp starts at 1209N, by 35 processes it is on par with the remaining fabrics at 1100, and by 70 processes Fabric D is at 602N, with the next lowest being Fabric B with 755N. Both WF5505JG and Fabric C have the highest overall strength by the end of the test.

The results demonstrate the significant effect that repeat laundering and irradiation sterilisation has on the polyester fabrics used to manufacture cleanroom garments. However, not all fabrics degrade in the same way. The results suggest that Micronclean Fabric along with Fabric C will be more durable than the other 2 alternatives. They showed a fairly linear drop off, maintaining a good consistence performance.

MICRONCLEAN UK | GARMENT STUDY AND EXPERIENCE

ABRASION RESISTANCE

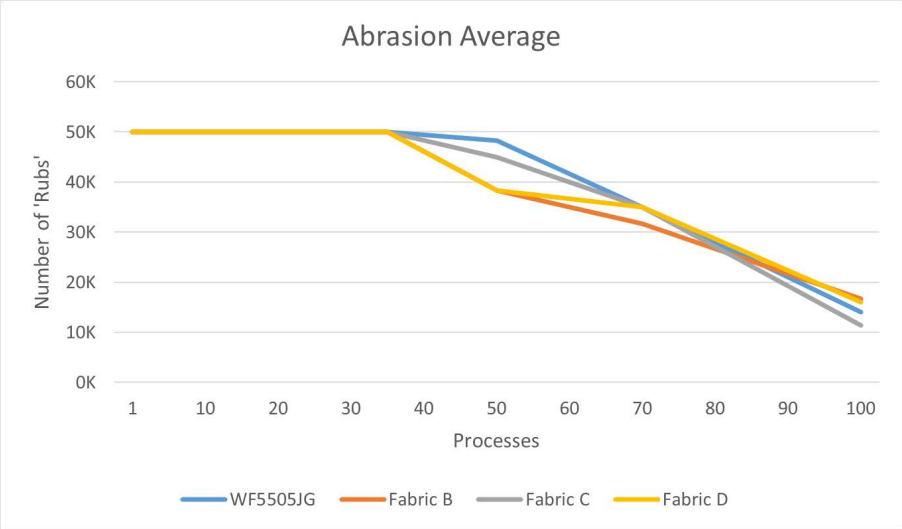


Figure 13 - Graph to show irradiated fabric abrasion resistance through life

In this test the abrasion resistance (cycles required before the fabric shows signs of breakage) of the fabrics was measured. Results are expressed in count of cycles at the point of break. Tests ran to a maximum of 50,000 cycles in each case, which for a cleanroom fabric is considered highly resistant to abrasion.

As can be seen in **Figure 13**, the 4 fabrics tested do not exhibit results below this cap until 35 processes. At this process point Fabrics D and B exhibit a reduction in abrasion resistance below 40,000 rubs, whilst WF5505JG, and Fabric C remain above 45,000. At 70 processes WF5505JG and Fabric C see a more rapid decline to 35,000 rubs. Fabric D reduces less than other fabrics between 50 and 70 processes, matching WF5505JG, and Fabric C with 35,000 rubs. At 100 processes the garments see a large decline in abrasion resistance, continuing the trend observed once results are lower than the 50,000 rub cap at 50 irradiation processes.

Like the observations for tensile strength, the results demonstrate the effect that repeat laundering and irradiation sterilisation has on the polyester fabrics used to manufacture cleanroom garments. The results suggest that Micronclean's fabric and Fabric C remain more durable than the other two alternatives, maintaining the highest results for the longest period of time (up until around 50 processes), before dropping significantly in its abrasion resistance.

MICRONCLEAN UK | GARMENT STUDY AND EXPERIENCE

COMFORT

AIR PERMEABILITY

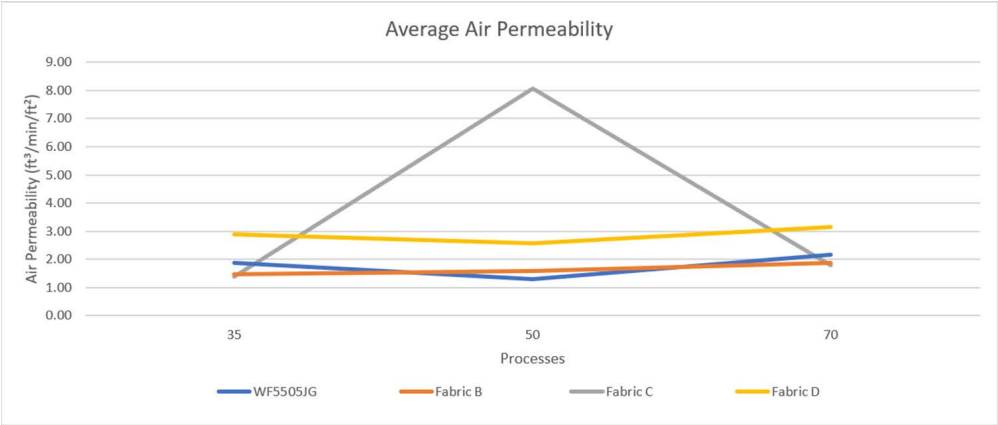


Figure 14 - Graph to show irradiated fabric air permeability through life

Looking at the differences between the garments in **Figure 14**, air permeability wasn't a useful comparative measure, and had a large experimental error associated with it. Therefore it was not tested on the full sample size.

WATER VAPOUR TRANSMISSION

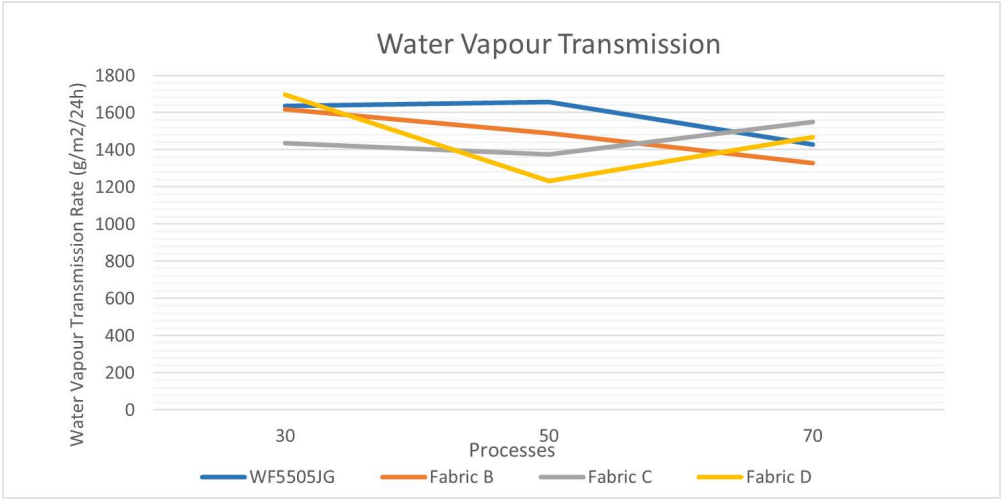


Figure 15 - Graph to show irradiated fabric water vapour transmission through life

As can be seen in **Figure 15**, over the majority of its lifetime, WF5505JG has the highest level of water vapour transmission. This means this fabric is likely to be more comfortable that the other fabrics, over its lifetime. Fabric C has the highest comfort level at the end of its lifetime.

MICRONCLEAN UK | GARMENT STUDY AND EXPERIENCE

GARMENT SYSTEM PERFORMANCE

BODY BOX

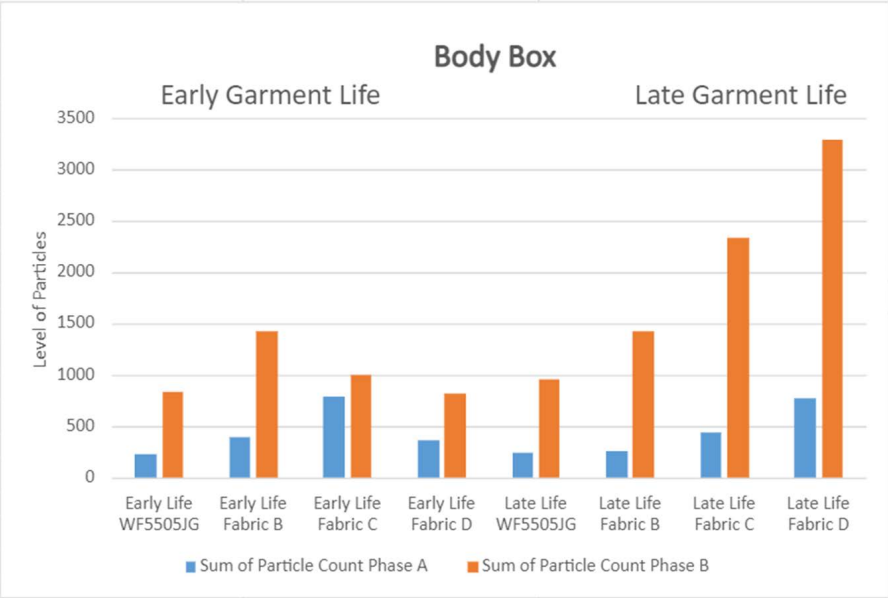


Figure 16 – Graph to show irradiated fabric particle dispersion in early and late garment life

The particle and micro results from the body box test are variable. However, there are a couple of conclusions that can be drawn from **Figure 16**. Particle levels appear to be increasing with higher movement levels (Phase A to B). It is also clear that more particles pass through the garments, later in life. Unfortunately, microbiological results were too variable to draw any meaningful conclusions.
Figure 16, shows that, overall, the Micronclean fabric WF5505JG performed better than the alternatives in both the early life and late life of the garment. Overall Fabric C performed the next best although results were highly variable.

MICRONCLEAN UK | GARMENT STUDY AND EXPERIENCE

DISCUSSION

By conducting these studies, encompassing a range of cleanroom garment fabrics, and with its controlled cleanroom laundering and sterilisation processes, Micronclean is able to select the best materials, garment designs and garment construction methods to provide to its customers. Further, Micronclean can optimise its laundry and sterilisation processes to ensure that a high-performing garment is delivered to the customer throughout a garment rental contract.

This study also provides data that supports the establishment of a safe useful life for cleanroom garments. This allows Micronclean to design cleanroom garment rental service contracts to ensure that its customers receive high quality and high performing garments throughout a contact term, as well as good value for money.

The tests used in this article are commonly provided in cleanroom garment fabric specifications when new and can be used as an assessment of a fabric's ability to perform, as required within a cleanroom environment. This study utilises those tests to evaluate how this performance changes as the garments are washed and dried in a commercial cleanroom laundry, and subsequently sterilised by irradiation. The impact of a user wearing a garment, made from the fabrics tested, was not investigated, but it is probable that this would have a negative impact on the garment performance over time. The effect of zippers, buckles and push buttons was not included as part of this study. These attachments can vary across garments and this study focused solely on the fabric of the garments, and the fabric's contribution to the performance of the garments.

The results for autoclave sterilisation can be found in Appendix 1.

The force required to break each fabric was observed to decline as the number of processes the fabric had experienced increased. Figure 12 shows that Fabric D has the highest tensile strength when new but has the lowest after 70 irradiation processes, highlighting the importance of understanding how a fabric will perform throughout its use and setting appropriate process limits for the fabric's use case. This difference reduces as the fabrics hit 100 processes, with all fabrics having tensile strength results between 615 and 670N. For WF5505JG, Fabric B, and Fabric C, the tensile strength declined more rapidly when the fabrics were irradiated compared with the fabrics which were autoclaved. The results indicate that autoclaved fabrics may retain adequate strength, and therefore remain more durable, for a higher number of process cycles, whereas irradiated fabrics show a progressive decline in strength. This may mean that autoclaved fabrics are more durable over time in comparison with irradiated fabrics.

The particle filtration efficiency of the fabrics was examined and compared when irradiating fabrics. WF5505JG and Fabric C demonstrated the potential for fabrics to consistently retain 'like new' values for PFE throughout 100 irradiation processes. Fabric B performed slightly worse than WF5505JG reducing by 4 percentage points by the end of testing. Fabric D continues the trend of starting strong at 92% PFE, dropping by 11 percentage points to 81% PFE after 100 processes. Fabric D is a market leading cleanroom fabric and when new, its performance is on par with the other market leading fabrics included in this study. However, it demonstrates significantly lower PFE after 100 processes, further reinforcing the importance of evaluating a fabric throughout its entire life expectancy, rather than relying on specifications when new.

Particle filtration when autoclaving showed a similar consistency up to 100 processes as with irradiation. WF5505JG, Fabric B, and Fabric C reduced by 5, 4.9, and 0.6 percentage points respectively from their highest observed values.
An additional 100 process test was carried out on the autoclave fabrics, these results follow the trend seen for the 1-70 process results.

Assessment of the mean pore size of the fabrics showed that after an initial reduction in pore size for WF5505JG and Fabric C, after 10 autoclave or irradiation processes, all fabrics trend towards larger pore sizes as they are processed, overall.

MICRONCLEAN UK | GARMENT STUDY AND EXPERIENCE

The pore sizes of WF5505JG, Fabric B, and Fabric C were slightly larger when autoclaving rather than irradiating. Pore sizes of garments were 0.5-0.8µm larger for each fabric at each process point when autoclaving. The slight increase in pore size when autoclaving correlates with the slight increase in PFE values when compared with irradiated garments, but care should be taken when drawing conclusions from small pore size changes.

The results indicate that pore size is correlated with particle filtration efficiency. Fabrics that saw the lowest increase in pore size, saw the lowest reduction in their PFE and tensile strength performance as processes increased. The mechanism for this correlation is not clear from this study. Further study into this correlation may give insight into whether pore size can be a good indicator of barrier performance and vice-versa.

Irradiated WF5505JG and Fabric C started to drop below the 50,000 rub upper abrasion limit of the test at 50 processes, while Fabrics B, and D dropped below 40,000 rubs. By 70 processes all fabrics had dropped below 35,000 rubs. At 100 processes the abrasion resistance of all irradiated fabrics drops significantly to less than 20,000 rubs. The testing makes clear that typical cleanroom fabrics should have process limits lower than 100 to avoid significant risk of fabric breach during use.

When autoclaved the fabrics retain their abrasion resistance for more processes, with WF5505JG remaining above 40,000 rubs and Fabrics B and C remaining above 30,000 rubs at 100 processes. Alongside improved tensile strength retention this testing suggests that fabrics may last longer when autoclaved rather than irradiated.

Overall, the study results reinforce that not all cleanroom fabrics are equal and stresses the importance of the EU GMP Annex 1 requirement to understand the performance of garment fabrics throughout their entire usable life, either by carrying out a fabric life study, or relying on a garment supplier to provide such data.

Fabric C exhibited a comparable performance to WF5505JG throughout this study. As a result of this work this fabric has been selected as Micronclean's 'second fabric' and has been introduced into Micronclean's garment supply chain to ensure supply chain security and continuity for Micronclean's customers.

In the study presented, the Micronclean fabric (WF5505JG) was shown to offer superior performance to the other market-leading cleanroom fabrics, in several areas. Importantly, the Micronclean fabric retains excellent particle filtration efficiency throughout the study (100 process cycles). This is fundamental to its performance in cleanroom contamination control. Coupled with this, the Micronclean fabric offers super breathability, and therefore greater comfort to the wearer; not only will the garment perform well, but it is more likely that it will be donned and worn correctly by the wearer. Further, the Micronclean fabric retains greater durability – both in terms of tensile strength and abrasion resistance – with repeat laundering and sterilisation cycles, leading to a reduced risk of damage through use and therefore better value for money through reduced frequency of garment repairs and replacements.

MICRONCLEAN UK | GARMENT STUDY AND EXPERIENCE

APPENDIX 1

The results for garments exposed to autoclave sterilisation.
Later in the study Fabric D was excluded due to poor results.

BARRIER PROPERTIES

PORE SIZE

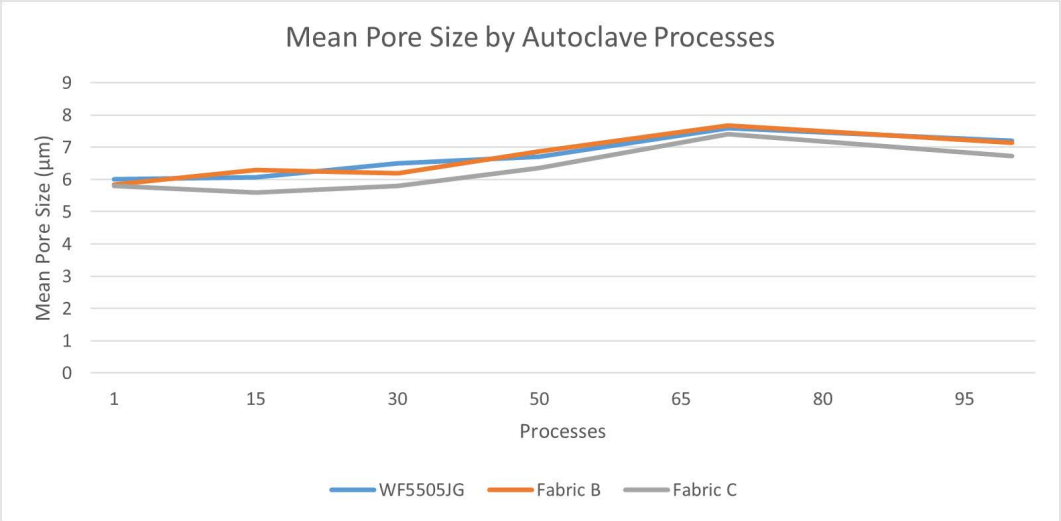


Figure 17 - Graph to show autoclaved fabric pore size through life

Figure 17 shows all fabrics begin with a mean pore size between 5.8-6.0µm. At 15 processes, WF5505JG and Fabric B slightly increase, whilst Fabric C slightly decreases. Up to 70 processes, all fabrics demonstrate a trend towards larger pore sizes. At 100 processes, the average pore size is slightly smaller than at 70 processes for all fabrics.

MICRONCLEAN UK | GARMENT STUDY AND EXPERIENCE

PARTICLE FILTRATION EFFICIENCY

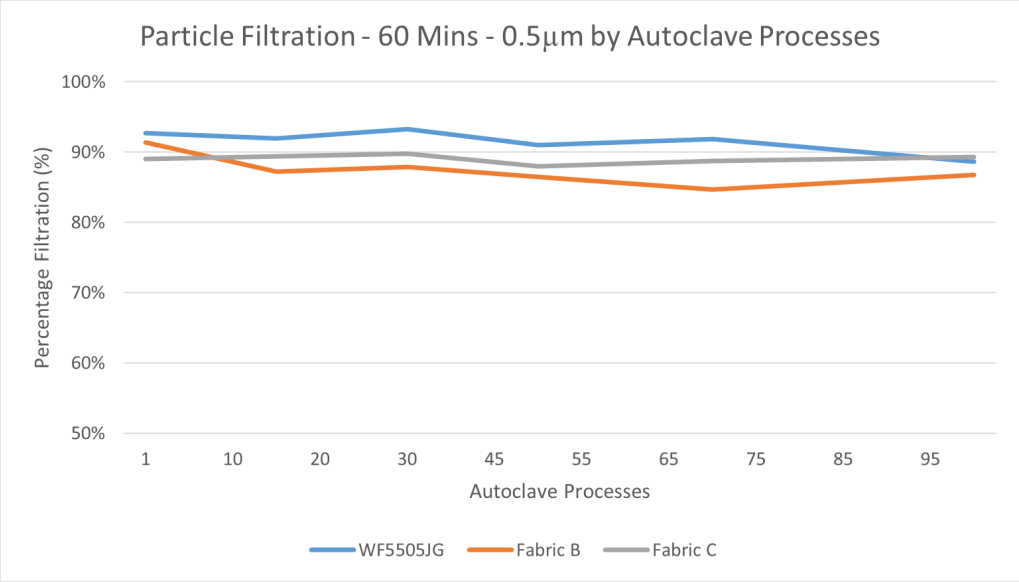


Figure 18 - Graph to show autoclaved fabric particle filtration efficiency through life

Figure 18 shows that PFE for all fabrics tested remains consistent throughout the entire garment life. WF5505JG begins at 93% PFE when new, falling to 89% at 100 processes. Fabric B begins at 91%, displaying a lowest PFE value of 85%. Fabric C begins at 89% and has a minimum value of 88%. Overall both WF5505JG and Fabric C perform comparably.

MICRONCLEAN UK | GARMENT STUDY AND EXPERIENCE

DURABILITY

TENSILE STRENGTH

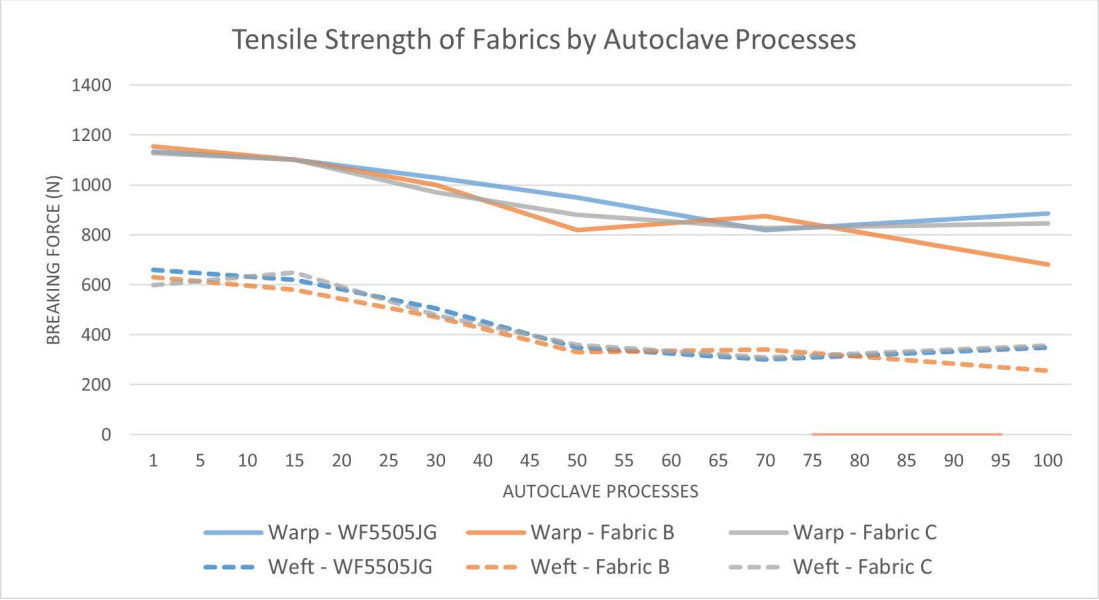


Figure 19 - Graph to show autoclaved fabric tensile strength through life

Figure 19 shows that, as with fabrics sterilised by irradiation, fabrics sterilised by autoclave demonstrate a reduction in tensile strength breaking force as the number of processes increases. All fabrics trend downwards towards 800N at 50 processes, from a starting point of 1100-1150N. WF5505JG remain above 800N up to 100 processes, while Fabric B dropped to 700N. Overall both WF5505JG and Fabric C perform comparably.

MICRONCLEAN UK | GARMENT STUDY AND EXPERIENCE

ABRASION RESISTANCE

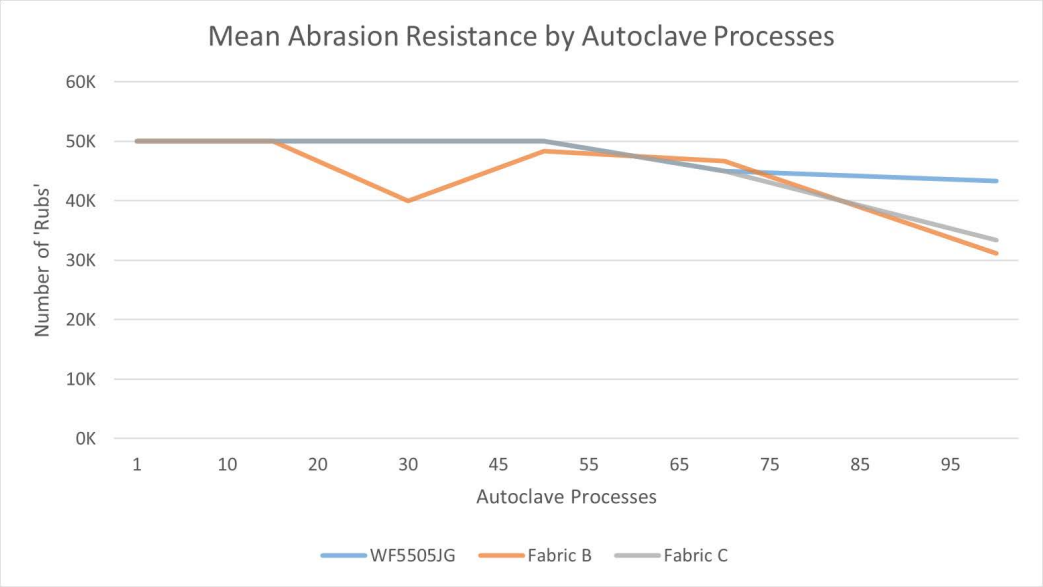


Figure 20 - Graph to show autoclaved fabric tensile strength through life

The maximum value in abrasion testing is artificially capped to 50,000 rubs, once a sample reaches this milestone the testing is ceased. **Figure 20** shows that WF5505JG and Fabric C remain at this cap until 50 processes, whilst Fabric B falls slightly below this at 50 processes. All fabrics then demonstrate a steady reduction in abrasion resistance, with WF5505JG remaining above 43,000 average rubs, and Fabrics B and C remaining above 30,000.

MICRONCLEAN UK | GARMENT STUDY AND EXPERIENCE

GARMENT SYSTEM PERFORMANCE

BODY BOX

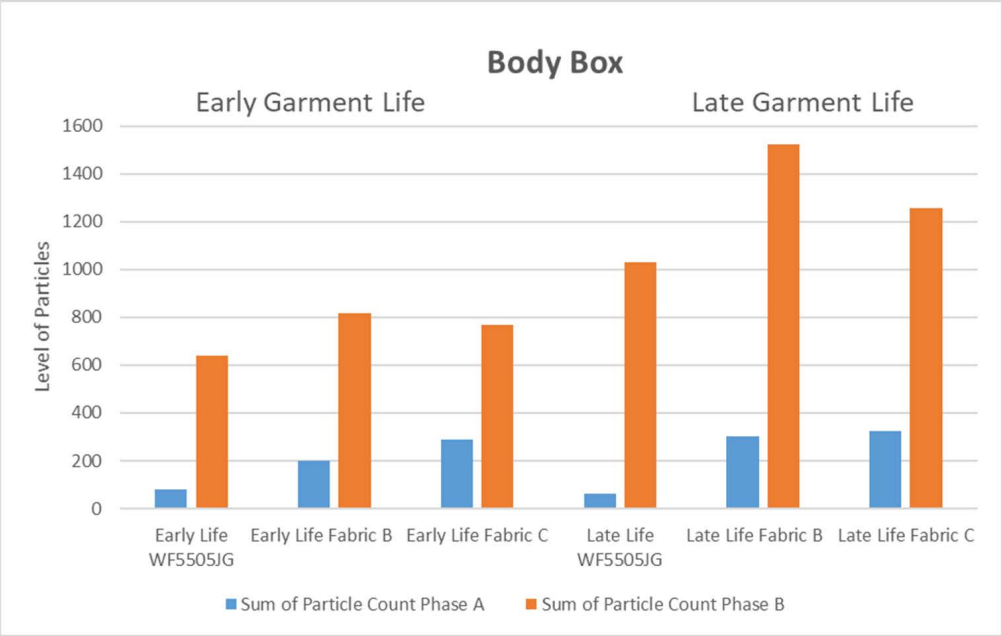
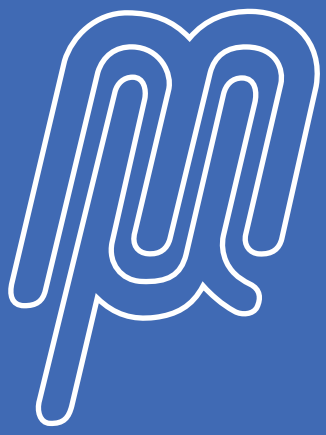


Figure 21 - Graph to show autoclaved fabric particle dispersion in early and late garment life

Autoclaved garments are showing a similar trend to the irradiated ones, with the Micronclean fabric WF5505JG performing better in all regards, and Fabric C with the next best performance, overall.

NOTES

NOTES



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