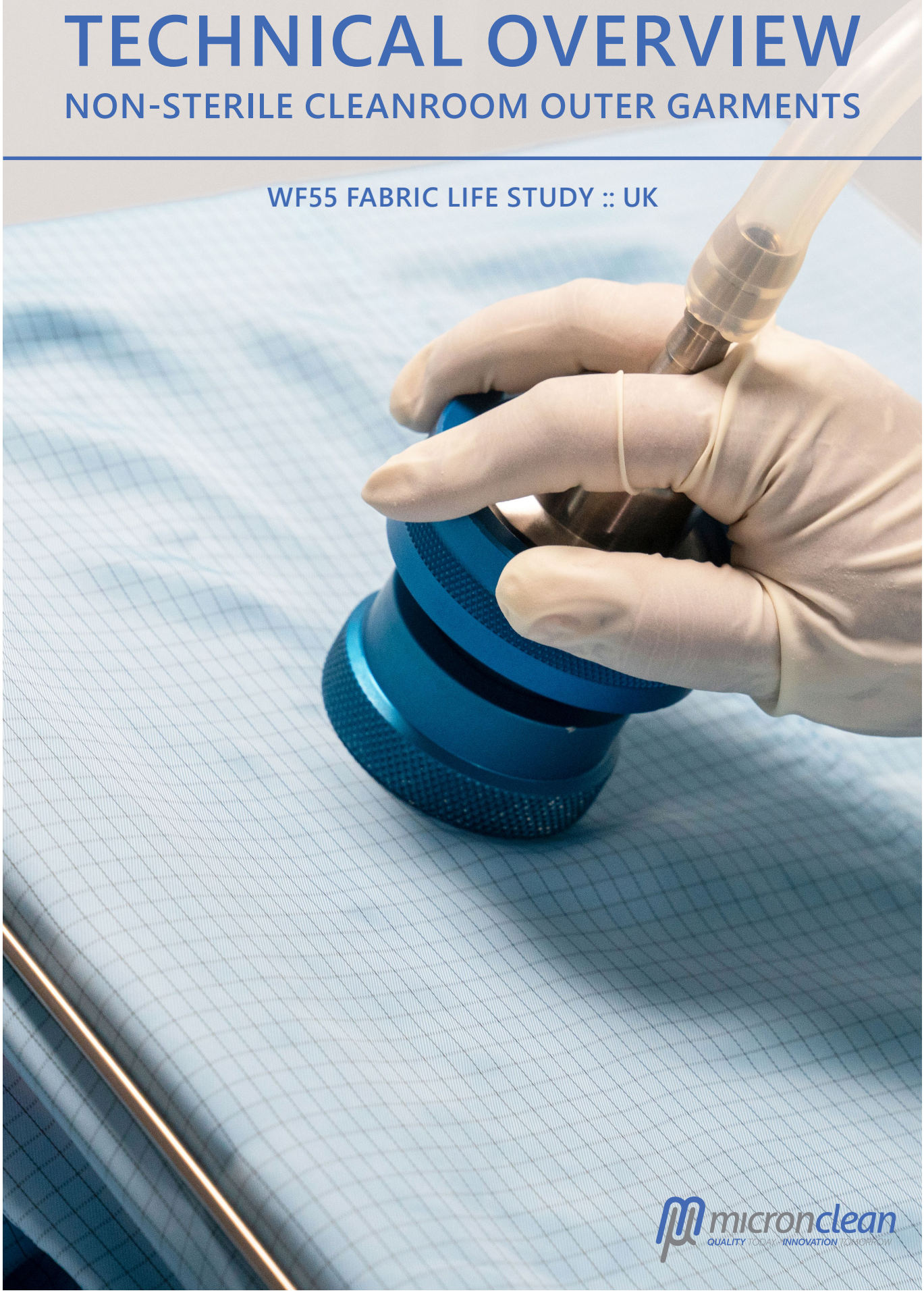
TECHNICAL OVERVIEW

NON-STERILE CLEANROOM OUTER GARMENTS

WF55 FABRIC LIFE STUDY :: UK



microngard
QUALITY TODAY :: INNOVATION TOMORROW

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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, garment designs and garment construction methods to work with, and can 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.

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.

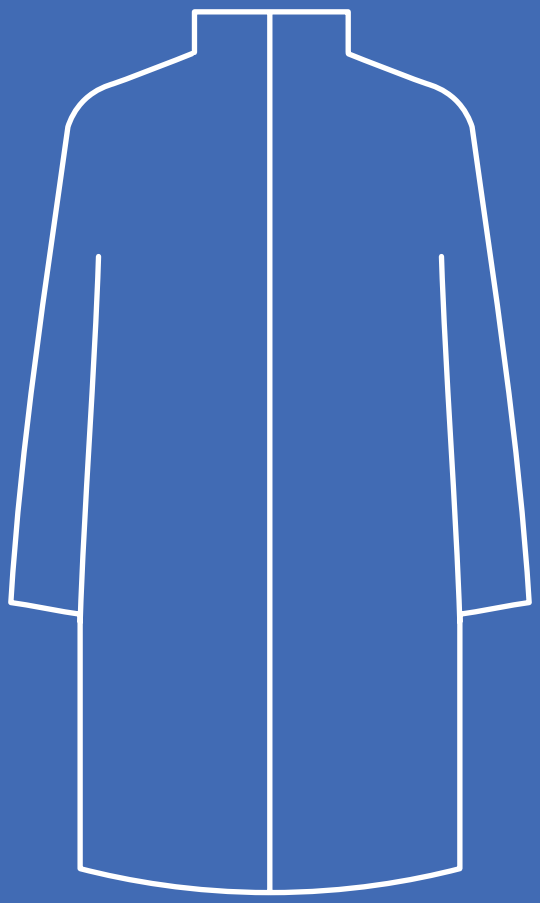
Micronclean is the UK market leader in the provision of cleanroom garment rental and laundry services. Micronclean has the privilege of providing cleanroom garments to over 65% of aseptic pharmaceutical / biotechnology production facilities in the UK.

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

Micronclean UK facility

CLEANROOM GARMENTS



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 | PERFORMANCE

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."

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

These studies have allowed 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.

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

CLEANROOM GARMENTS PERFORMANCE

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.

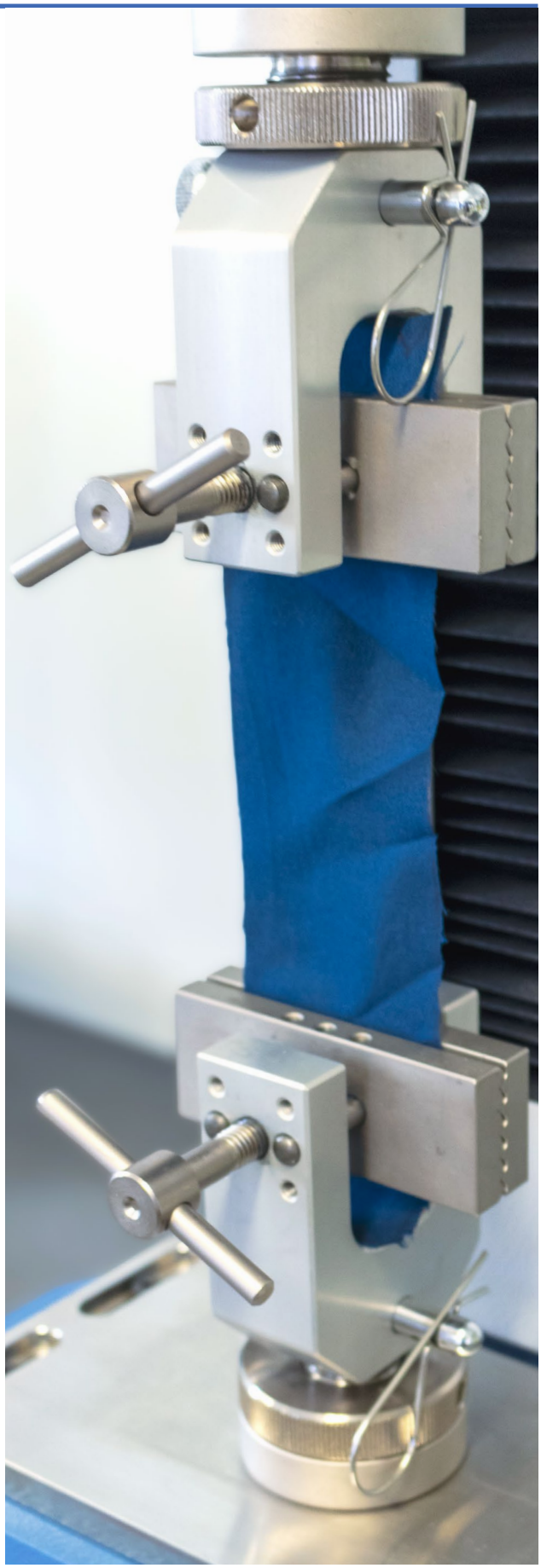
USP 797 outlines basic requirements for cleanroom garments in pharmaceutical compounding environments.

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.

Garments were gathered across multiple customers, laundered and packed in the ISO Class4 cleanroom and tested at 0,25,50,60,70,80,90,100,110,120,130,140,150 processes (+/- 3 counts), using the following methods:

- Durability (Tensile Strength)
- Particulate Contamination (Helmke Drum)
- Colour Fade / Visual Test (Colorimeter)



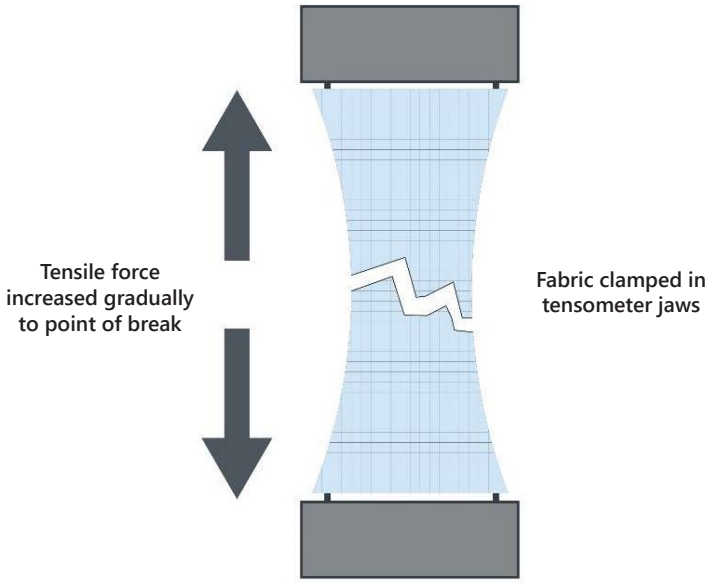
CLEANROOM GARMENTS PERFORMANCE

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 (Tensometer)

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.



Test apparatus to measure tensile strength of fabric

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.

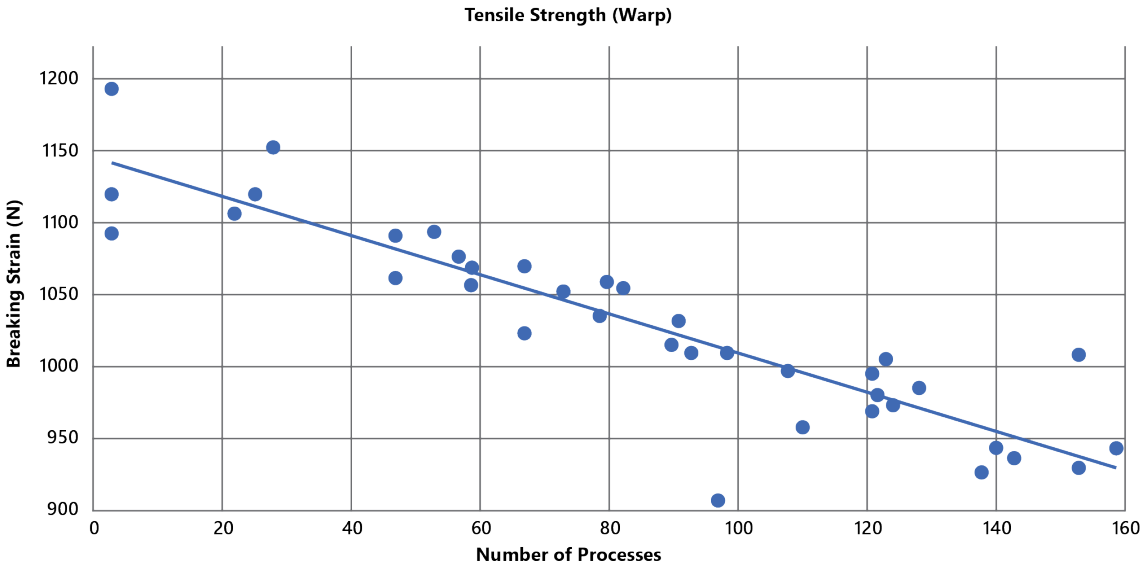
The tensile strength of a fabric is a useful indicator of a fabrics capability to withstand the rigours of repeat use and laundering, and a garment's likelihood of breach during use.

It is important to measure the tensile strength of a fabric through repeat laundering and wearing 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).

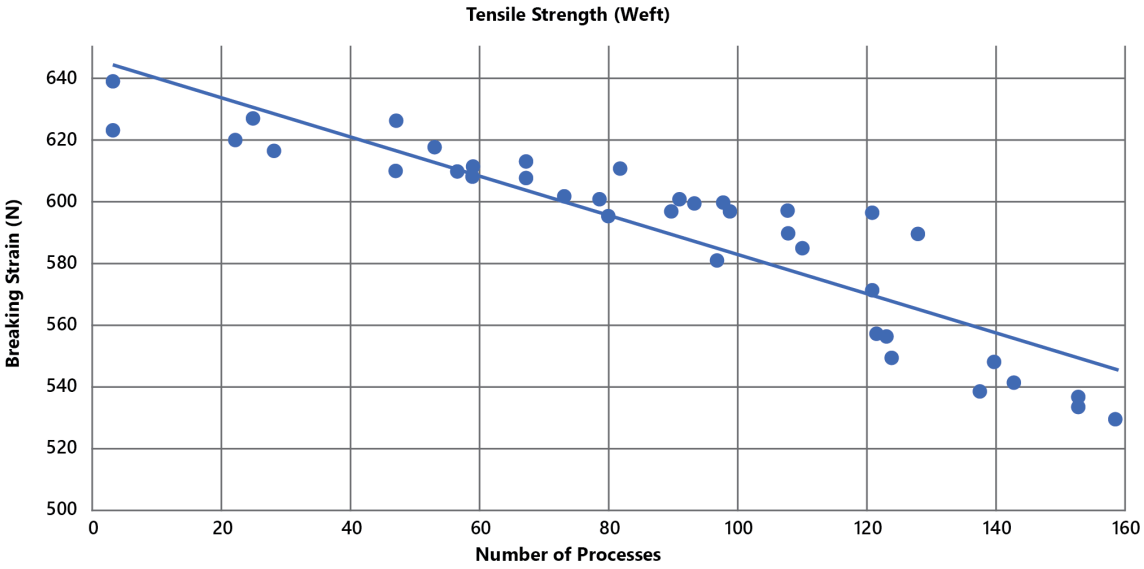
Each garment had three samples from each of the Weft and Warp direction taken for testing.

CLEANROOM GARMENTS PERFORMANCE

TENSILE STRENGTH TEST RESULTS



Baseline test garments had an average breaking strain of 1137.8N. Tensile strength test data across the Warp direction of the fabric also shows a linear decrease in strength as the garment is processed, with a sharp drop to 979.8N at 130 processes. This represents an approximate decrease in fabric integrity of 13.8%. From 130 to 150 processes breaking strain decreases further to 961.4N, representing a further 1.8% drop from baseline in the following 20 processes.



Baseline test garments had an average breaking strain of 633.6N. Tensile strength test data across the Weft direction of the fabric shows a linear decrease in strength as the garment is processed, with a sharp drop 565.6N to at 130 processes. This represents an approximate decrease in fabric integrity of 10.74%. From 130 to 150 Processes breaking strain decreases further to 533.4N, representing a further 5.06% drop from baseline in the following 20 processes.

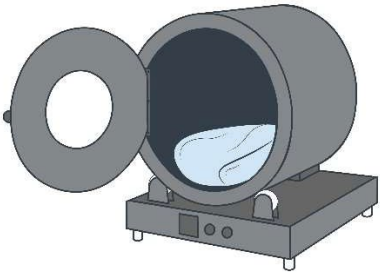
CLEANROOM GARMENTS PERFORMANCE

PARTICLE AND FIBRE CONTAMINATION

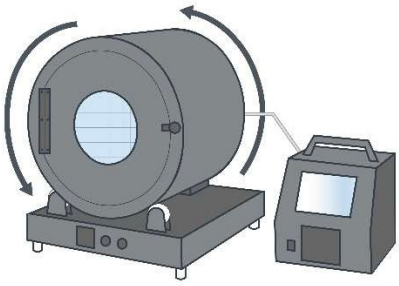
HELMKE DRUM

IEST RP CC 003 describes a method involving tumbling a garment inside a rotating drum, the test is sometimes referred to as the 'rotating drum method'. This action is intended to simulate particle shedding from the garment in normal use. As the garment tumbles inside the test drum, an electronic particle counter is used to sample the air within the drum to quantify the particulate matter released by the garment over a period of 10 minutes.

Cleanroom garment is folded



Cleanroom garment is placed in test drum



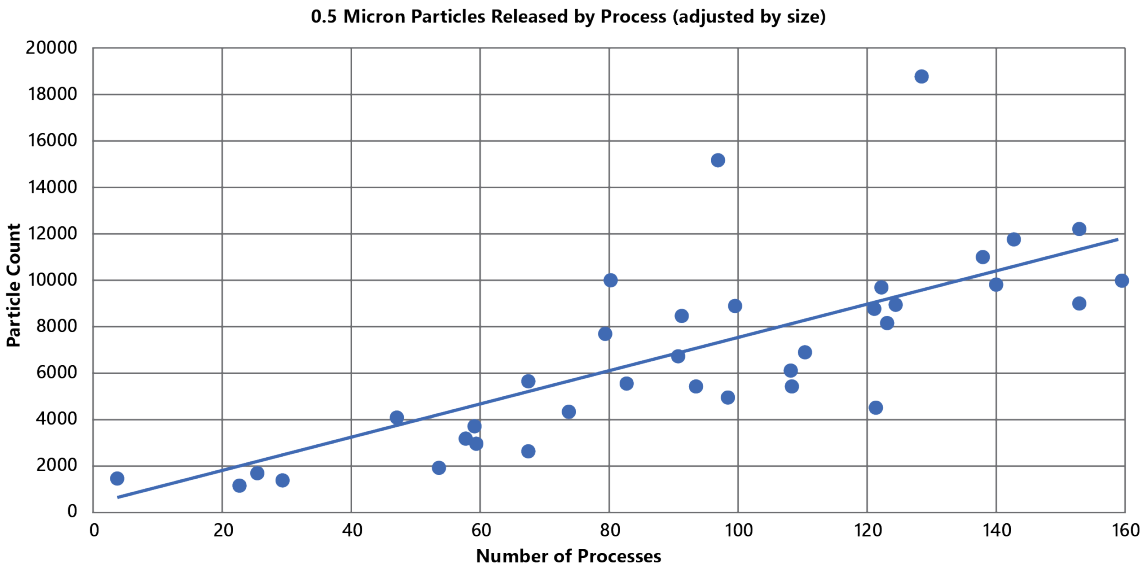
Particle sampling is conducted while the drum tumbles the garment

Garments to be tested will have their particulate release (particles of 0.5µm and 5µm) compared to the number of washes (Processes) the garments have undergone. Garments will be gathered, laundered and packaged, and tested at 0,25,50,60, 70,80,90,100,110,120,130,140,150 processes (+/- 3 counts).

HELMKE DRUM TEST RESULTS

All results were adjusted to reflect the size of the garment, using Medium as the baseline size.

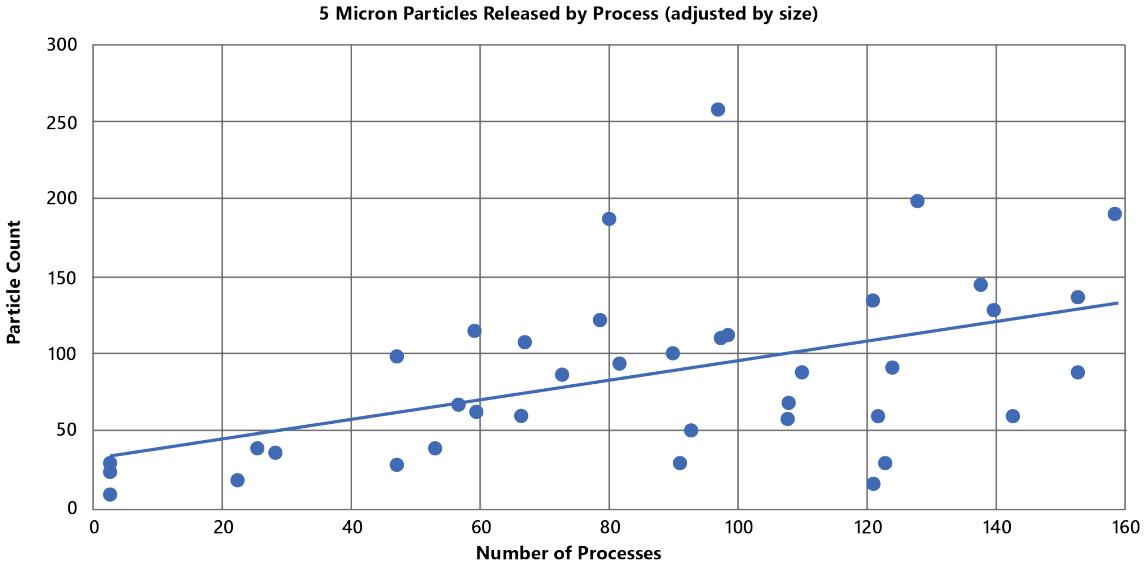
0.5µm PARTICLE RELEASE



CLEANROOM GARMENTS PERFORMANCE

Test data for release of 0.5µm particle release shows that garments at baseline (3 processes) shed an average of 1537 particles during the 10-minute test. Garments pass through 10000 particles shed (1000 particles per minute) at approximately 130 processes.

5µm PARTICLE RELEASE



Test data for release of 5µm particle release shows that garments at baseline (3 Processes) shed an average of 23 particles during the 10-minute test. Garments pass through 100 particles shed (10 particles per minute) at approximately 110 processes.

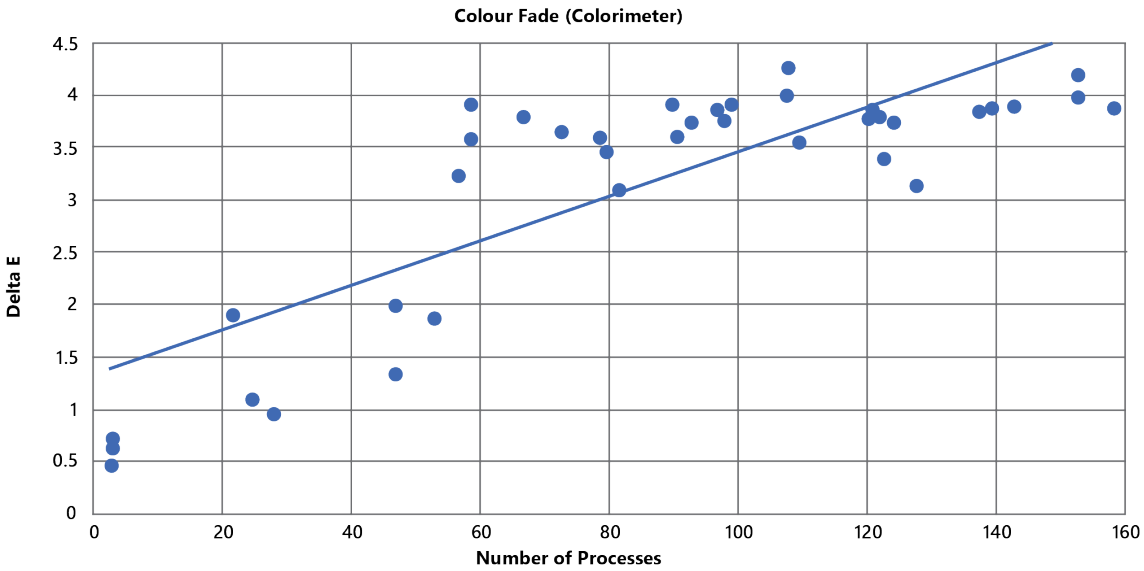
CLEANROOM GARMENTS PERFORMANCE

COLOUR FADE

COLORIMETER

Garments were tested to compare the colour fade of the non-sterile WF-55 garments using a colorimeter, to determine the colour difference between the baseline garments and the test garments. Baseline garments will be 3 x garments at 0 processes (+/- 3 processes), and 3 x garments at each count of 25,50, 60, 70, 80, 100, 110,120,130, 140 and 150 processes. (+/- 3 processes at each count). Scans were performed at 5 different positions on the garment using the following parameters: Illumination: D65, Observer: 2°, M2. The colorimeter will report a ΔE. This is the difference in colour between the baseline garment and test garment.

COLORIMETER TEST RESULTS



Colorimeter test results show a rapid fade in colour from the baseline garments over the first 60 processes. At process points 60 – 150, faded garment remains similar and shows very little further loss of remaining colour.

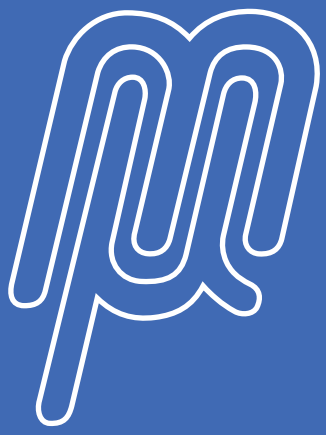
CLEANROOM GARMENTS PERFORMANCE

TEST RESULTS SUMMARY

Non-sterile WF55 fabric maintains a very high level of performance across the first 110 process and wear cycles. Garments were tested across a variety of customers with varied use cases and demands placed upon the material. The life cycle of this fabric is determined by its ability to resist breaching due to weakening of the fabric, prevent contamination from particulate shedding, remain cost-effective by not requiring excessive maintenance, and retain an acceptable appearance standard in a cleanroom environment.

Technical data assessing the performance of the fabric was analysed and compared against the overall visual assessment of the garments and customer quality data to create the recommended process count for non-sterile WF55 fabric. Therefore, to guarantee appropriate fabric performance and garment integrity, all non-sterile WF55 fabric garments should be replaced before the observed drop in performance, at 100 process cycles.

NOTES



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