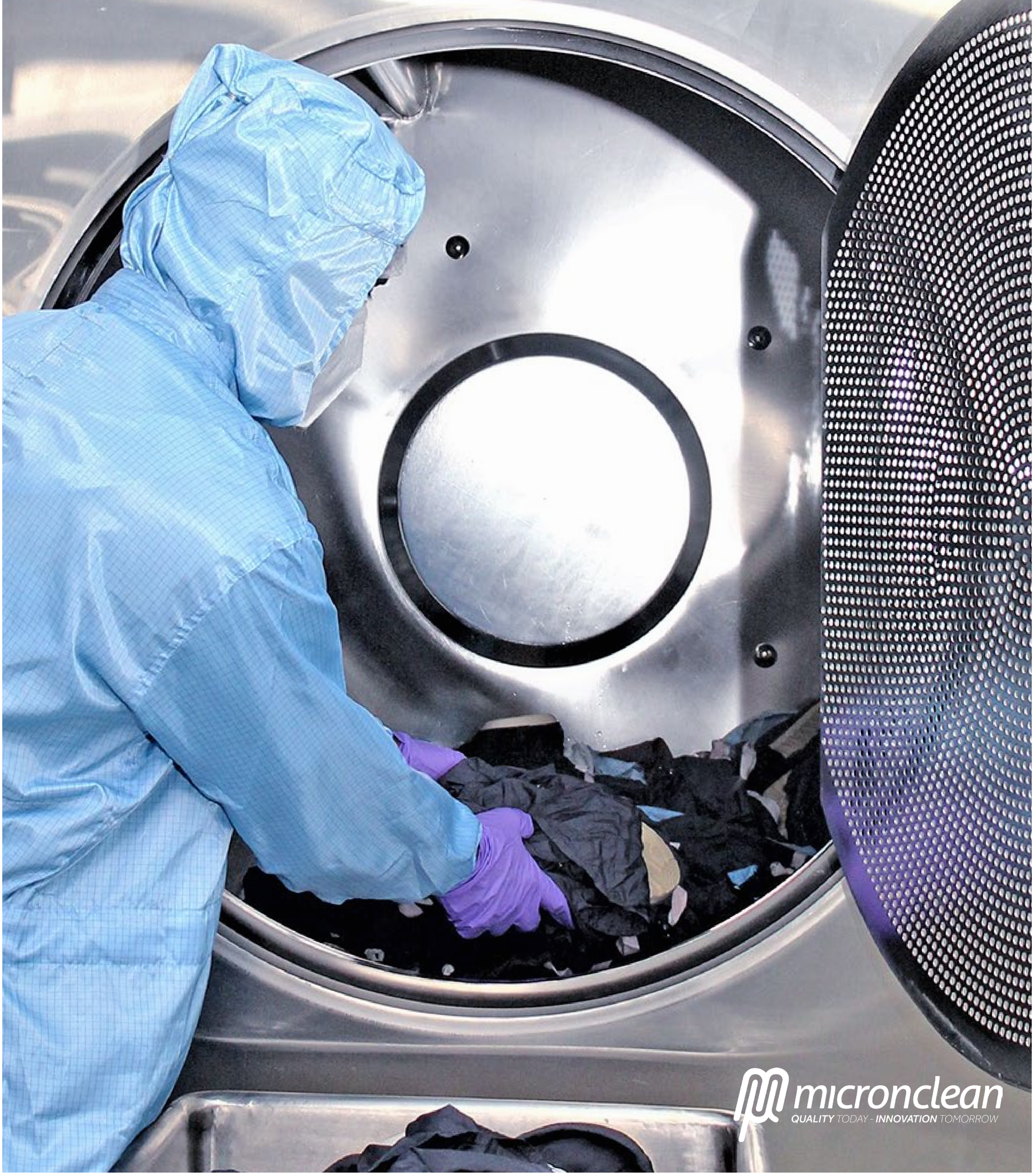
TECHNICAL OVERVIEW

NON-STERILE UNDERGARMENTS

FABRIC LIFE STUDY :: UK
(Buxton, Carsington, Sandwash)



micronclean
QUALITY TODAY - INNOVATION TOMORROW

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Revised:

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1	Document created	Sep-24	Marta Underwood Group Product Manager

EXECUTIVE SUMMARY

Cleanroom undergarments 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. Additionally, they provide an extra layer of protection between the wearer and the outer coverall.

Micronclean has extensive experience in the UK of delivering high quality, value for money cleanroom undergarments. Micronclean aims to provide the best cleanroom undergarments available on the market. This is achieved through knowledge of cleanroom undergarment technology, as well as expertise and innovation in cleanroom undergarment performance and optimisation of laundering cycles. Micronclean offers cleanroom undergarments via a rental service. Through this service model, Micronclean oversees and manages all aspects of cleanroom undergarment provision including selection of undergarment materials, undergarment design and construction and the laundry cycles.

High performing cleanroom undergarments must meet varying requirements. They must be made from a low shedding material and provide additional filtration to human made particulate, to reduce the particulate challenge to the outer garments. They must provide a high level of wearer comfort and be of a proper fit to increase the chance of the user donning the undergarments to provide a more effective cleanroom barrier.

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

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

Data is presented from such studies performed by Micronclean UK.

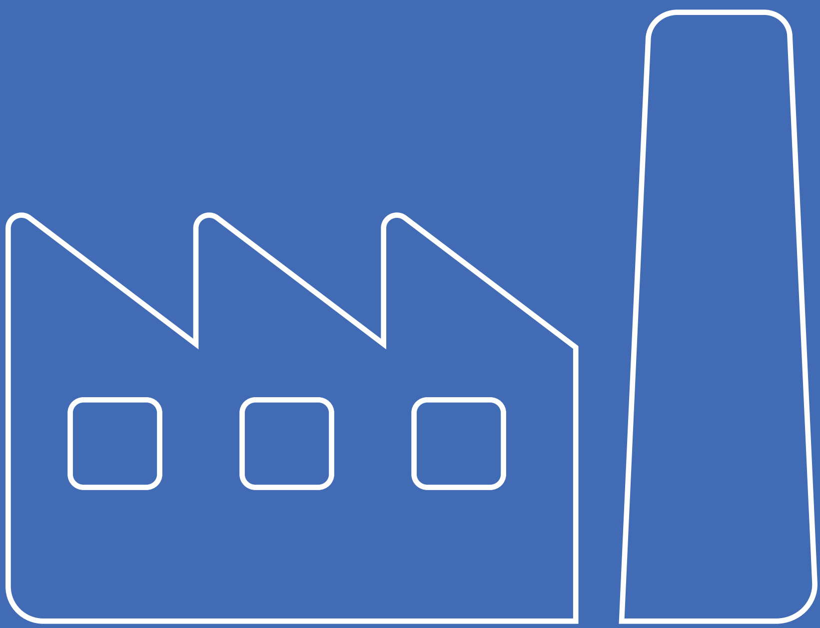
EXECUTIVE SUMMARY

Undergarment Tunic
Long Sleeve

Undergarment Trousers

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.

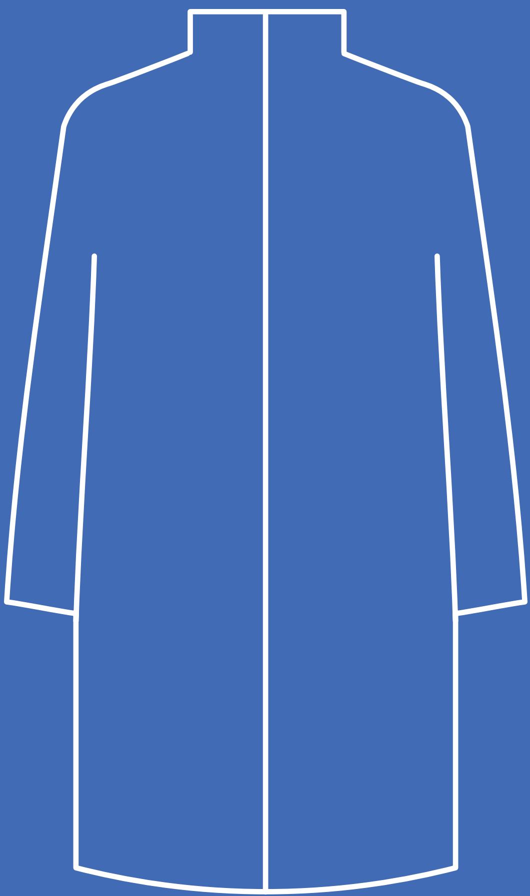
Micronclean is the UK market leader in the provision of cleanroom garment rental and laundry services. Micronclean has the privilege of providing cleanroom garments to over 65% of aseptic pharmaceutical / biotechnology production facilities in the UK.

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

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).

Micronclean takes these requirements seriously. With several decades of experience, Micronclean 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."

Micronclean has 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 Micronclean's validated processes.

These studies have allowed Micronclean to select the best materials and garment designs, but also provide evidence of performance. Micronclean can provide to customers assurance of cleanroom garment performance throughout life in the form of quantitative data.

Micronclean retains 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, Micronclean can 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.

Micronclean believes 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.

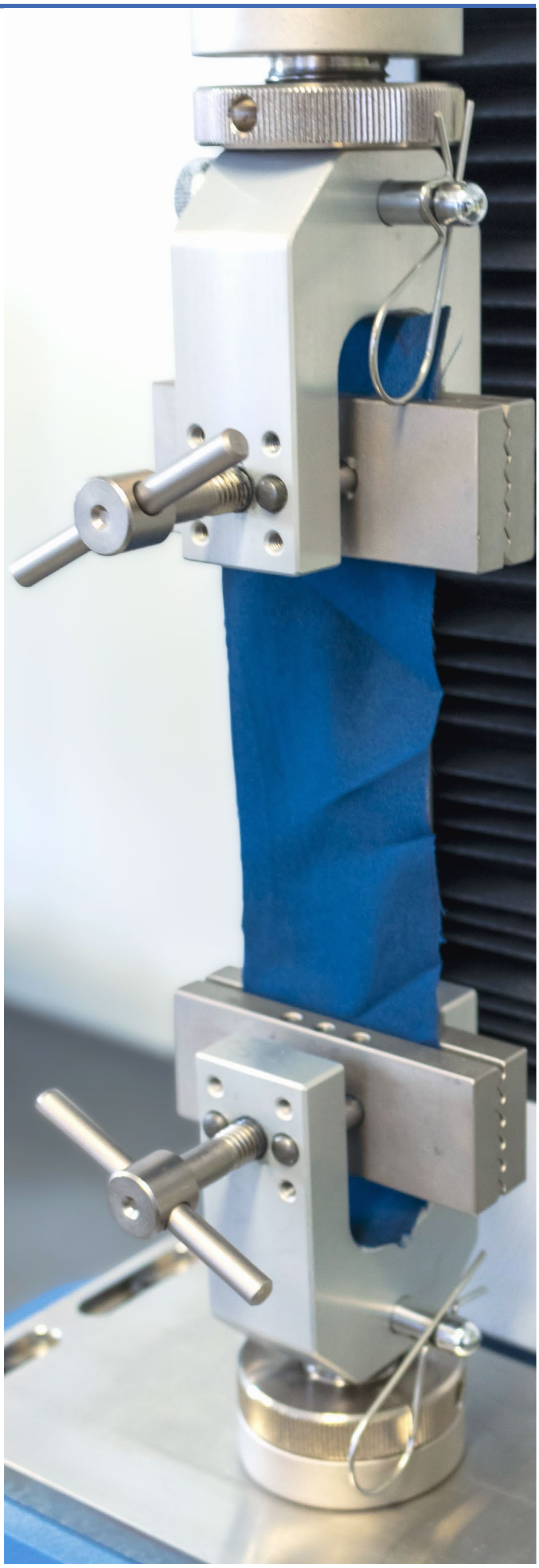
USP 797 outlines basic requirements for cleanroom garments in pharmaceutical compounding environments.

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.

Micronclean utilises 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.

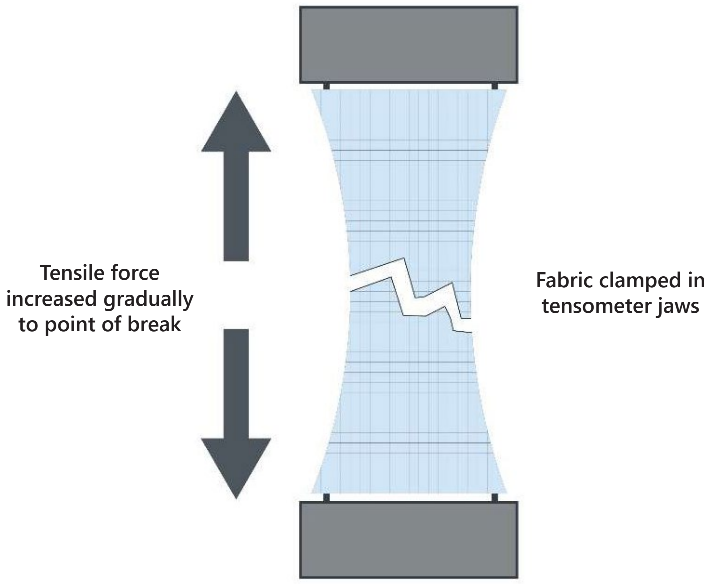


Figure 2. Test apparatus to measure tensile strength of fabric

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).

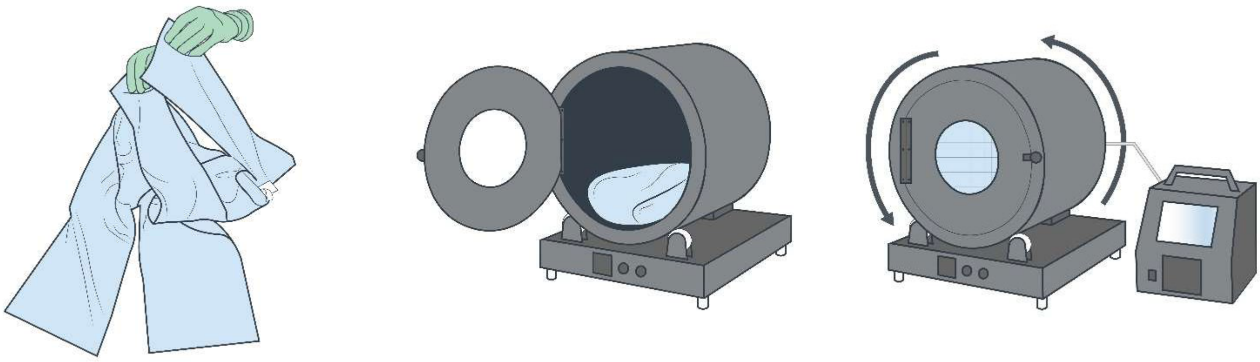
CLEANROOM GARMENTS PERFORMANCE

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.

Garments to be tested will have their particulate release (particles > 0.5 µm and > 5.0 µm) compared to the number of wash processes the garments have undergone. All results adjusted to reflect the size of the garment, using a medium frock from IEST RP CC 003 as the baseline size.



Cleanroom garment is folded | **Cleanroom garment is placed in test drum** | **Particle sampling is conducted while the drum tumbles the garment**

Figure 3. Test apparatus to test particulate release using a Helmke Drum

COLOUR FADE

COLORIMETER

Garments were tested to compare the colour fade of the undergarments using a colorimeter, to determine the colour difference between the baseline garments and the test garments. Colorimetry works by shining a spectrum of light wavelengths onto a surface. Some wavelengths of light will be absorbed by the surface and others reflected back to the colorimeters detector. The difference in the initial spectrum and the received spectrum will be reported by the colorimeter.

The color fade can be determined by using the colorimeter to create a baseline received spectrum for a zero-process garment. This can be compared to the received spectrum of a processed garment and the difference is reported as value called delta E (ΔE). The large the ΔE, the greater the difference in colour between the unprocessed and the processed garment.

Scans were performed at 5 different positions on the undergarment 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.

CLEANROOM GARMENTS PERFORMANCE

VISUAL ASSESSMENT

GARMENT REPAIRS

For the purpose determining the visual damage to garments as a function of process count, the repair data of undergarments was utilised. All active undergarments and withdrawn undergarments removed due to wear and tear was collected and organised by undergarments with 1 repair and undergarments with 2 or more repairs.

BUXTON UNDERGARMENTS RESULTS

Buxton garments were tested at the following process counts: 0, 1, 20, 40, 50, 60, 70, and 80 process, with 3 garments tested at each process count. The limited number of processes compared to other fabric types were due to the lack of garments in circulation.

HELMKE DRUM

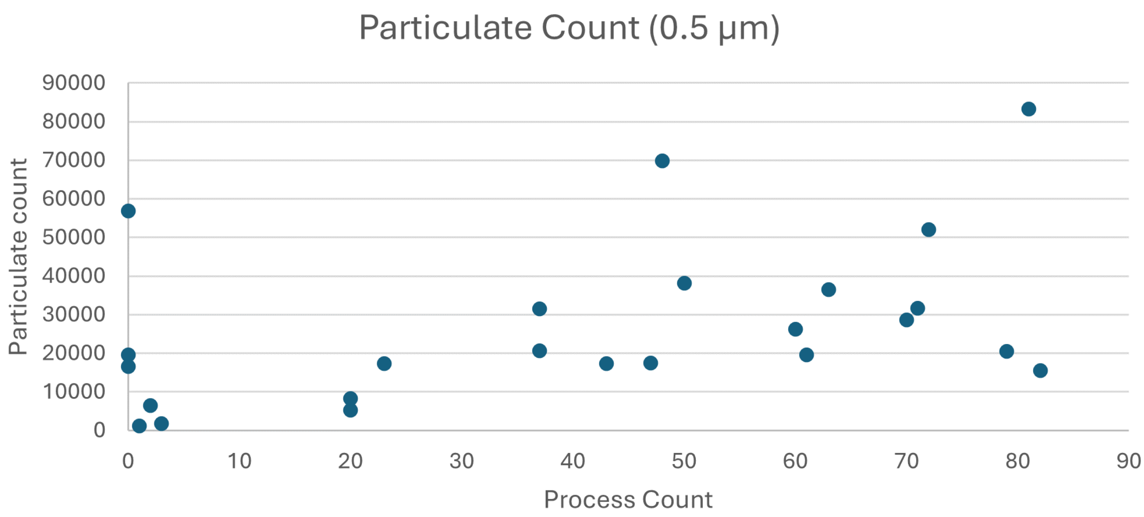


Figure 4. A graph to show the particulate count of size 0.5 μm or larger for Buxton undergarments at a given process count.

Figure 4 shows that unprocessed garment can release a large amount of particulate from manufacture. This shows the importance of the initial wash process of a garment before a customer takes the garment into their cleanroom.

A trend can be observed of increasing particulate counts as garment wash process count increases. After 60 wash processes, a number of garments can be observed reaching particulate counts higher than that of the unprocessed garments. Therefore, based on the particulate count >0.5 μm, Buxton garments should be replaced after 60 processes.

CLEANROOM GARMENTS PERFORMANCE

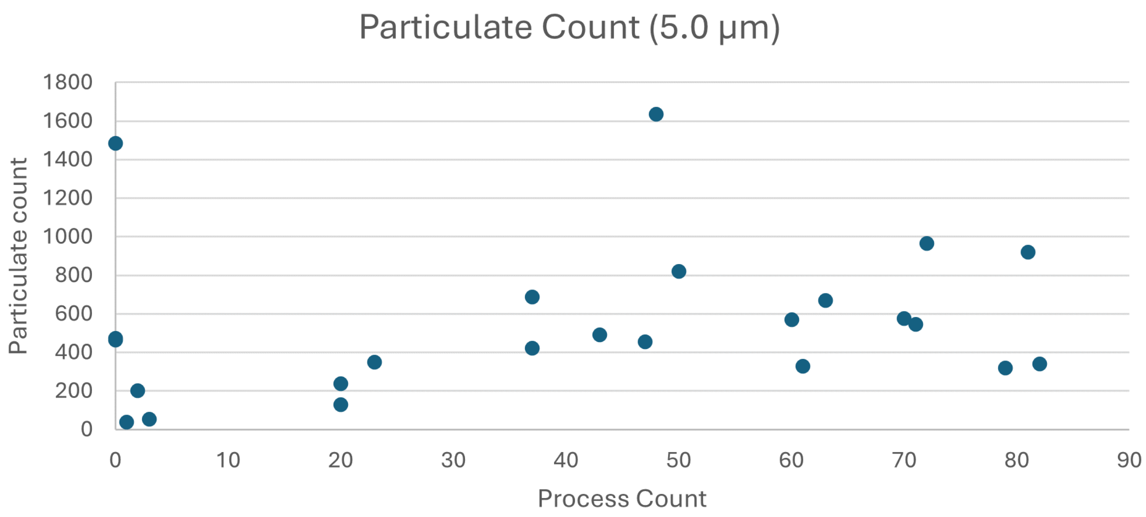


Figure 5. A graph to show the particulate count of size 5.0 µm or larger for Buxton undergarments at a given process count.

Similar to the data for particulate counts >0.5 µm, **Figure 5** shows unprocessed garments have high particulate levels and drops after an initial wash process. A rise in particulate level can also be observed as the process count increases.

The observed particulate count appears to slightly plateau as 60 wash processes is reached, and the peaks again 70 processes. This may indicate that the garment begins to become damaged at an increased rate and therefore garments should be replaced after 60 processes.

COLOUR FADE

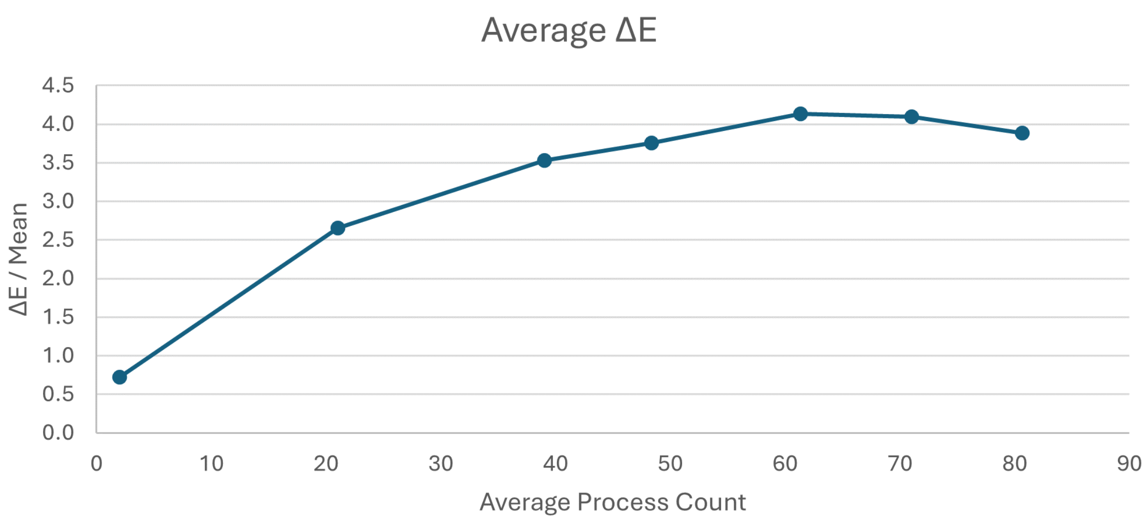


Figure 6. A graph to show the average colour fade (ΔE) against the average process counts of Buxton undergarments.

Figure 6 shows as the Buxton undergarments are washed, the greater the colour fade that is observed. This rate of colour fade is most rapid in the first 20 washes and gradually slows down after. The colour fade appears to peak at 60 wash processes before levelling out. Therefore, based on the colour fade, garments should be replaced after 60 wash processes.

CLEANROOM GARMENTS PERFORMANCE

VISUAL ASSESSMENT

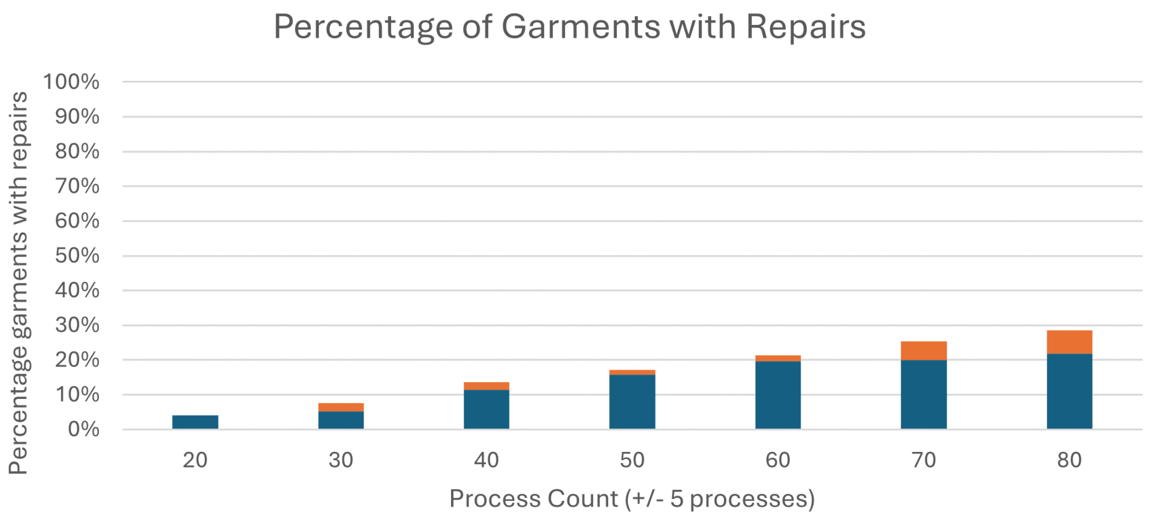


Figure 7. A graph to show the percentage of current and withdrawn undergarments (wear & tear) against the process count of Buxton undergarments (+/5 processes). Blue represents undergarments with 1 repair, orange represents garments with 2 or more repairs.

Figure 7 shows a general increase in garments with repairs performed on them as the process count of the garment increases. Once garments reach 70+ processes, the number of garments with 2 or more repairs increases more rapidly than seen at lower process counts. Based on this repairs data, Buxton garments should be replaced after 60 processes.

TENSILE STRENGTH

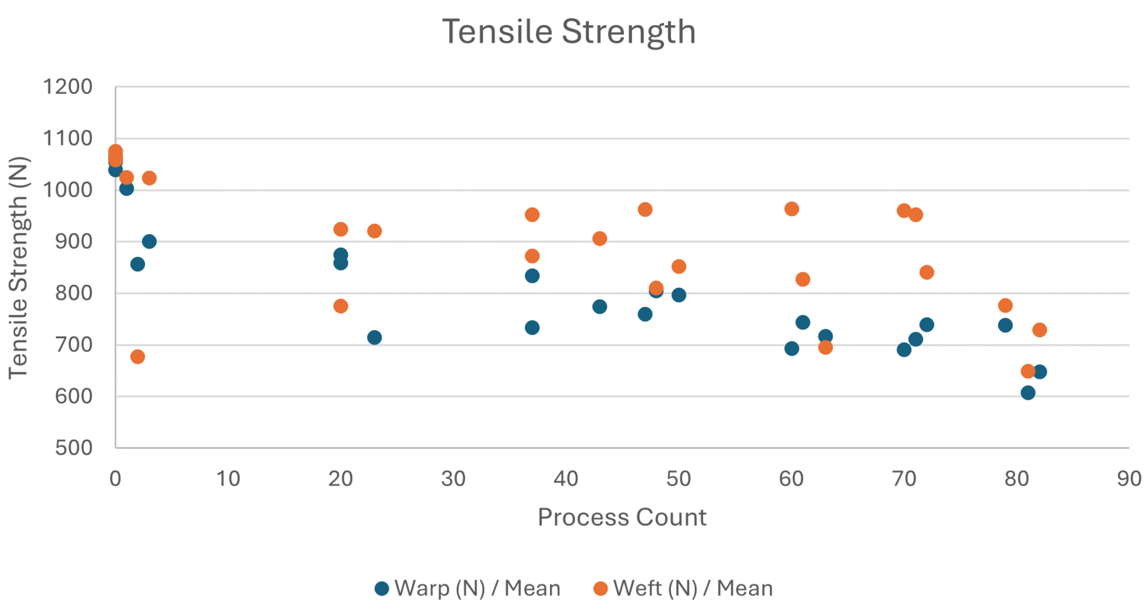


Figure 8. A graph to show the tensile strength of the average weft and average warp of Buxton undergarments at a given process count.

CLEANROOM GARMENTS PERFORMANCE

Figure 8 shows a decrease in tensile strength of the Buxton fabric as process count increases. This decrease in strength is more prominent for the warp than for the weft of the material. An increase in the rate of strength decline can be seen in both the warp and the weft from 70 processes to 80 processes, which indicates that after 70 processes the material starts to weaken more notably. Based on this, the Buxton garments should be replaced after 70 processes.

BUXTON RESULTS SUMMARY

Table 1 shows most of the testing for the Buxton undergarments recommends that undergarments be replaced after 60 processes, whereas tensile strength testing suggests the undergarments be replaced after 70 processes. Based on this, the overall recommended process count for which to replace Buxton undergarments is 60 wash processes.

Test	Recommended Process Count
Helmke drum particulate count	60
Colour fade	60
Garments with repairs	60
Tensile strength	70
Overall recommended process count	**60**

Table 1. A table to show the summary of test results performed on Buxton undergarments.

CLEANROOM GARMENTS PERFORMANCE

CARSINGTON UNDERGARMENTS RESULTS

Carsington garments were tested at the following process counts: 0, 20, 40, 50, 60, 70, 80, 100, 120 and 150 processes, with 3 garments tested at each process count.

HELMKE DRUM

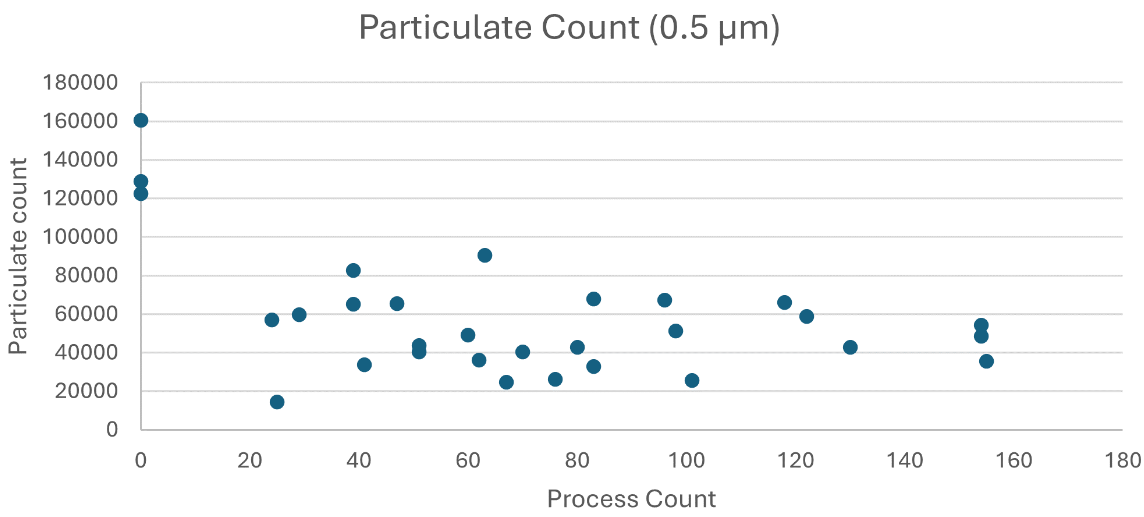


Figure 9. A graph to show the particulate count of size 0.5 µm or larger for Carsington undergarments at a given process count.

Figure 9 shows that the unprocessed garments have much higher levels of particulate that processes garments. This shows the importance of the initial wash process before sending customers their new garments.

As the wash process count of the garments increases, there is a slight upwards trend in particulate counts. However, to make a recommendation on the process limit for Sandwash undergarments, other testing data needs to be considered.

CLEANROOM GARMENTS PERFORMANCE

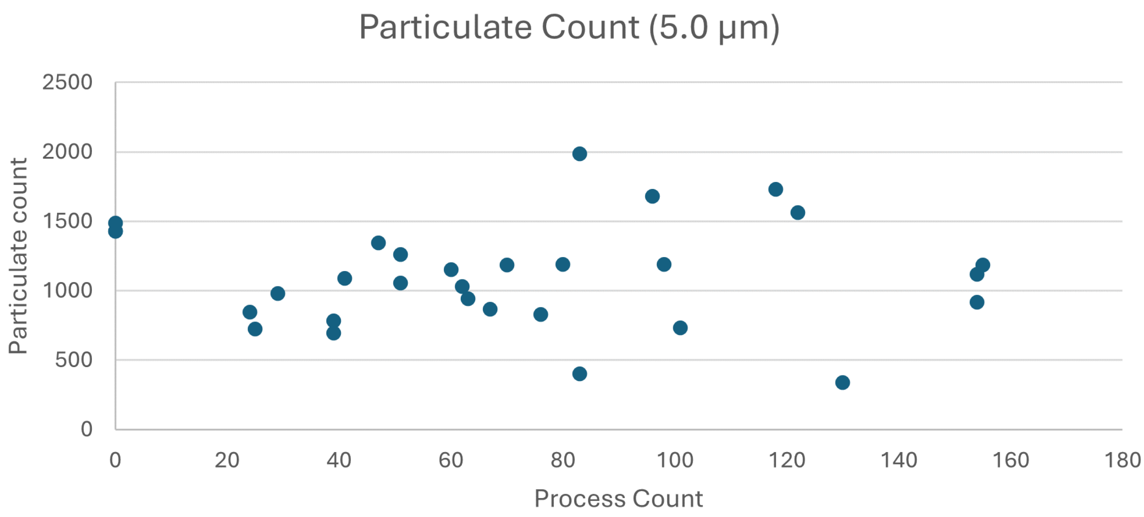


Figure 10. A graph to show the particulate count of size 5.0 µm or larger for Carsington undergarments at a given process count.

Figure 10 shows a similar trend in particulate count for >5.0 µm as for the >0.5 µm sized particles. However, once 100 wash process are reach, it can be observed that garments are releasing particulate counts similar to that of the unprocessed garments. This is still within acceptable particulate limits for cleanroom use, but based on this particulate data it can be recommended that Carsington undergarments be replaced after 100 wash processes.

COLOUR FADE

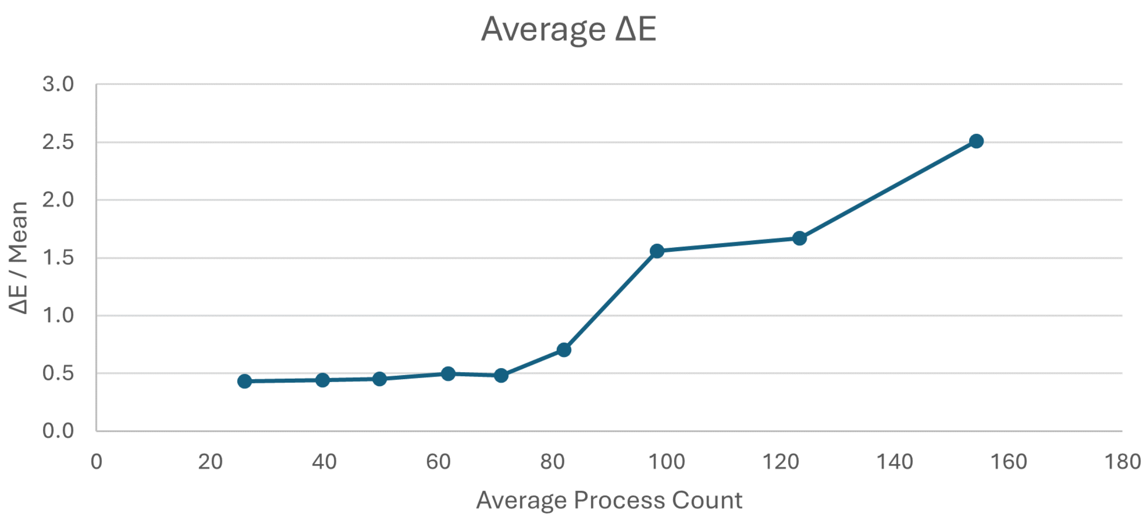


Figure 11. A graph to show the average colour fade (ΔE) against the average process counts of Carsington undergarments.

Figure 11 shows that the Carsington undergarments hold on to their colour fastness up to 70 wash processes before colour fade increases. Therefore, it can be recommended based on the colour fade results that the garments be replaced after 70 wash processes.

CLEANROOM GARMENTS PERFORMANCE

VISUAL ASSESSMENT

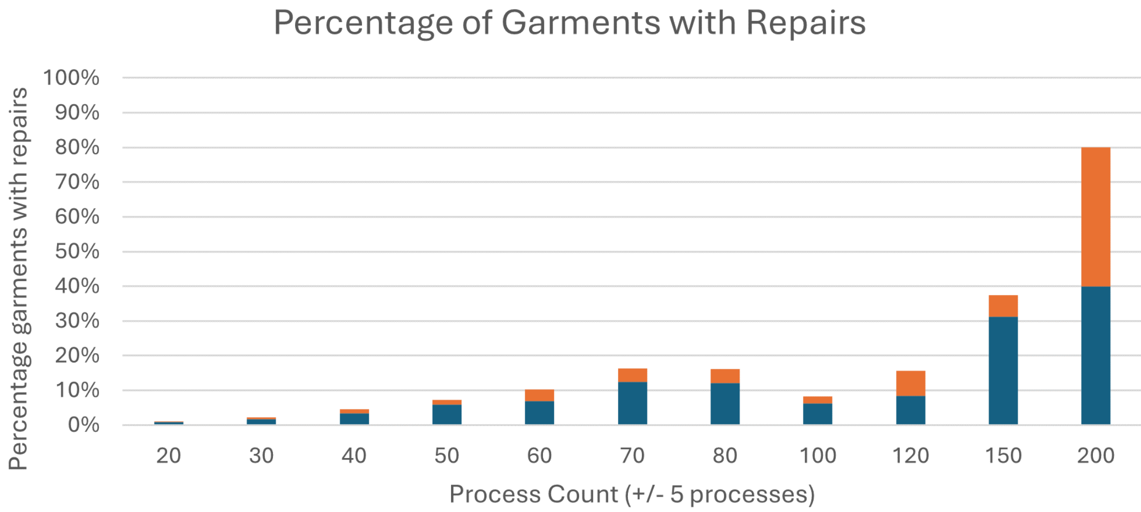


Figure 12. A graph to show the percentage of current and withdrawn undergarments (wear & tear) against the process count of Carsington undergarments (+/5 processes). Blue represents undergarments with 1 repair, orange represents garments with 2 or more repairs.

Figure 12 shows an increase in the percentage of Carsington undergarment with repairs increases with process count. Between 70 processes and 120 processes the percentage of garments with repairs remains consistent. However, after 120 processes the percentage of undergarments with 1 repair increase from 8.4% to 31.3% at 150 wash processes, and the total percentage of garments with repairs more than doubles at 150 wash processes. The large increase in garments with repairs indicates the performance of the undergarments begins to deteriorate at a faster rate after 120 wash processes. Therefore, Carsington undergarments should be replaced after 120 wash processes.

CLEANROOM GARMENTS PERFORMANCE

TENSILE STRENGTH

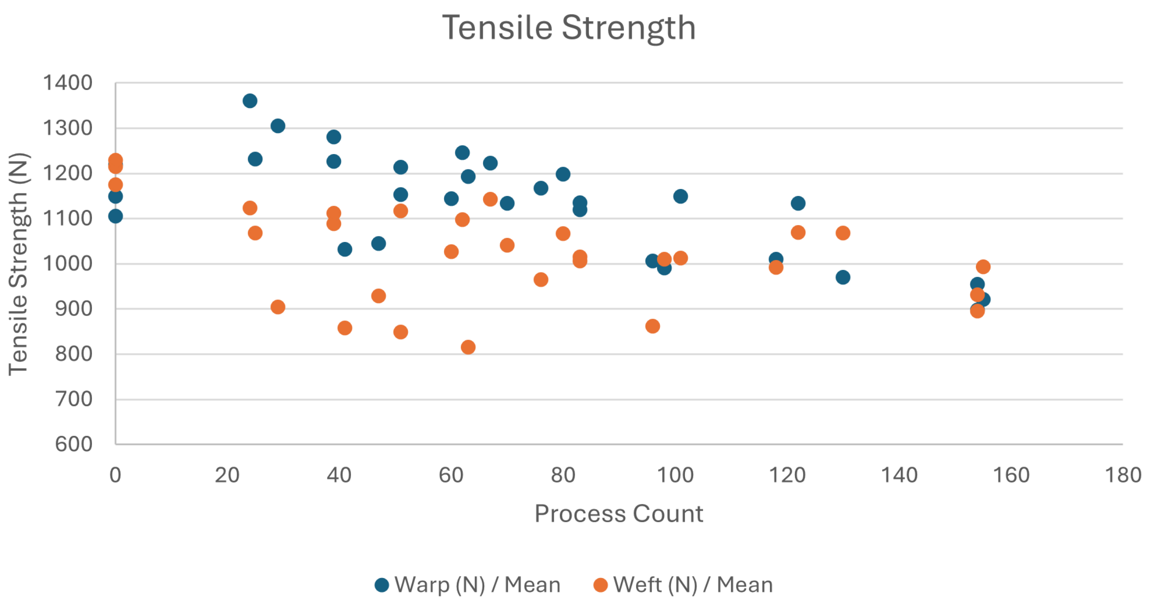


Figure 13. A graph to show the tensile strength of the average weft and average warp of Carsington undergarments at a given process count.

Figure 13 shows that the Carsington undergarment tensile strength increase between the unprocessed garments and 20 wash processes. This indicates that the laundry process causing and initial strengthening of the material. After 20 wash processes and steady decline in tensile strength performance up to 120 wash process where a further rate of decline can be observed between 120 and 150 wash processes. Therefore, based on tensile strength performance, Carsington undergarments should be replaced after 120 wash processes.

CARSINGTON RESULTS SUMMARY

Table 2 shows range of recommendations for the replacement process count for Carsington undergarments. The overall recommendation is based on the decline in performance in the strength of the material observed after 120 wash processes.

The particulate levels for the Carsington undergarments indicate replacement should occur at 100 processes as the particulate level rises to that of the unprocessed garments. However, for garments tested at 120 the particulate levels are still within acceptable limits for cleanrooms. The colour fastness at 120 wash processes is 3x poorer than the recommendation of 70 wash processes and would be a compromise for performance over visual quality.

Test	Recommended Process Count
Helmke drum particulate count	100
Colour fade	70
Garments with repairs	120
Tensile strength	120
Overall recommended process count	**120**

Table 2. A table to show the summary of test results performed on Carsington undergarments.

CLEANROOM GARMENTS PERFORMANCE

SANDWASH UNDERGARMENTS RESULTS

Sandwash garments were tested at the following process counts: 0, 20, 40, 50, 60, 70, 80, 100, 120, 150 and 200 processes, with 3 garments tested at each process count.

HELMKE DRUM

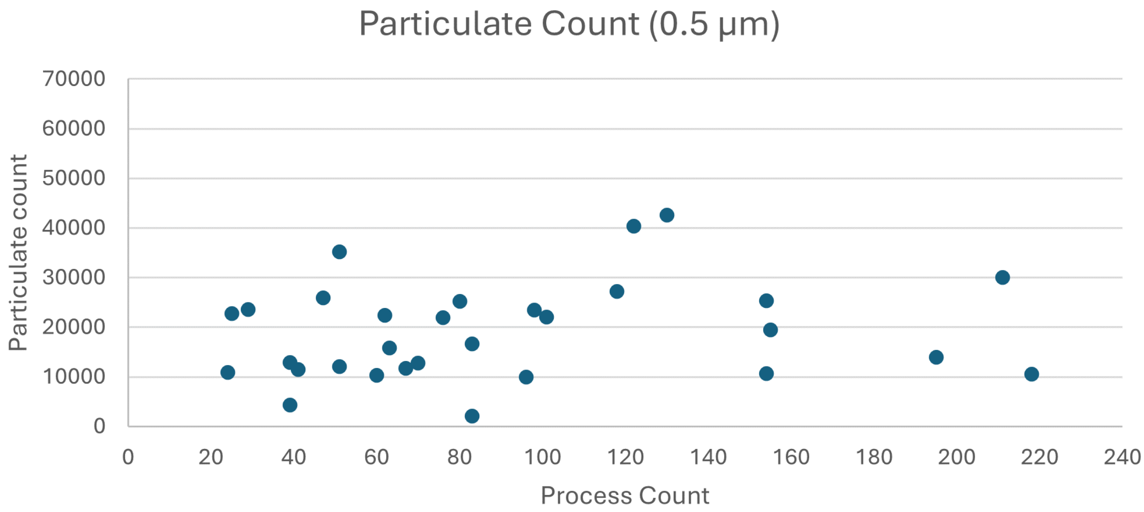


Figure 14. A scaled graph to show the particulate count of size 0.5 µm or larger for Sandwash undergarments at a given process count. 0 process garments counts are not displayed in this graph.

The particulate data for the Sandwash garments are 10x greater than those of the processed garments. **Figure 14** does not include these results so the trends in the particulate data can be observed.

The particulate data for >0.5 µm shows the particulate release from is similar across the tested process counts with a slight increase observed over 100 processes. The garments tested at 120 processes showed higher particulate counts than the trend suggested so additional testing was conducted for garments around 200 processes. This has helped to reinforce the trend observed prior to, and after 120 wash processes. The particulate data at >5.0 µm is needed to help establish a replacement count this point.

CLEANROOM GARMENTS PERFORMANCE

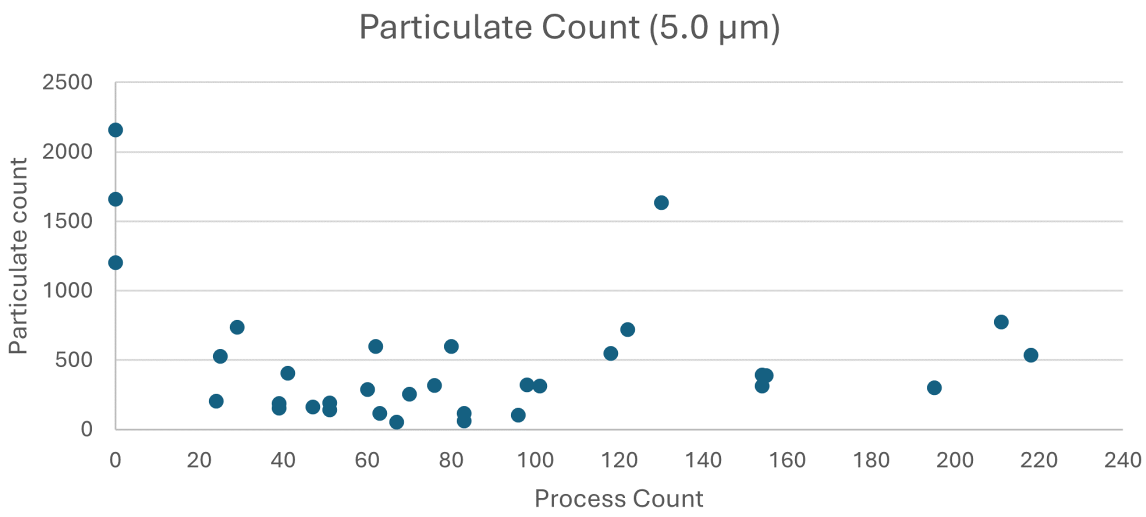


Figure 15. A graph to show the particulate count of size 5.0 µm or larger for Sandwash undergarments at a given process count.

Figure 15 shows a consistent level of particulate release for particulate sized >5.0 µm between 20 and 100 wash processes. A spike is seen at 120 wash processes, similar to what was observed for particulate counts >0.5 µm before returning to similar levels at 150 wash processes. **Figure 15** does show a rise in particulate levels once wash processes reach 200. Therefore, it can be recommended that Sandwash garments be replaced after 150 wash processes.

COLOUR FADE

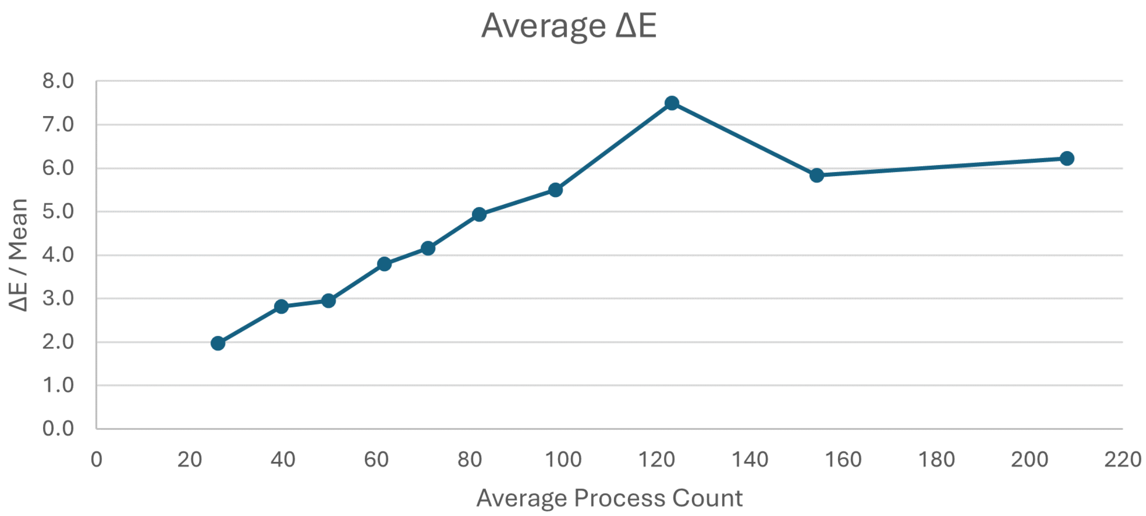


Figure 16. A graph to show the average colour fade (ΔE) against the average process counts of Sandwash undergarments.

CLEANROOM GARMENTS PERFORMANCE

Figure 16 shows a steady increase in the colour fade of Sandwash undergarments from 20 to 100 wash processes. A spike in colour fade is observed at 120 wash processes, similar to the particulate counts from the Helmke drum testing, before returning to lower levels. As wash processes reach 150, the rate of colour fade appears to slow down before rising again towards 200 processes. To avoid the increase in colour fade increasing further, Sandwash undergarments should be replaced after 150 wash processes.

VISUAL ASSESSMENT

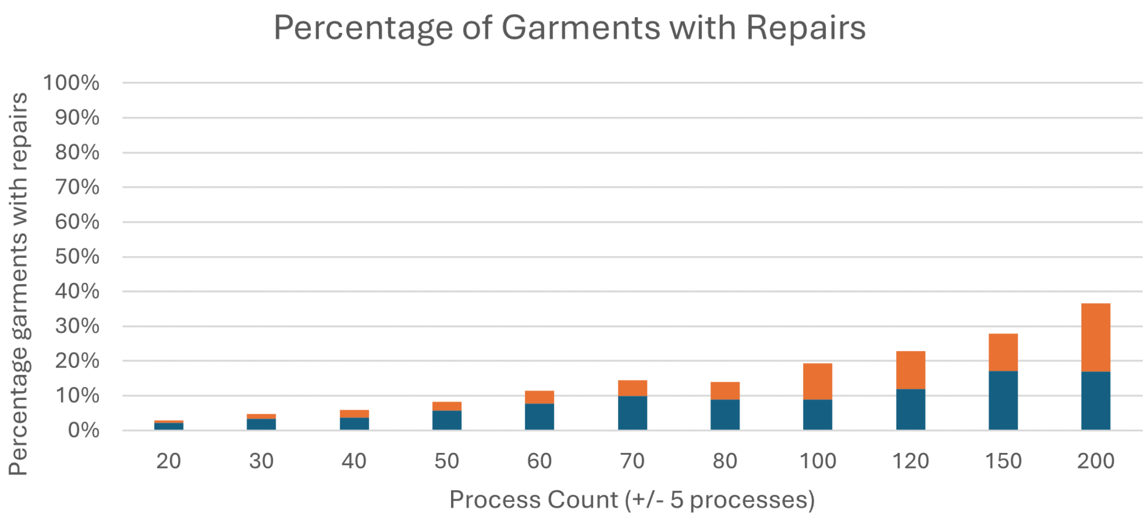


Figure 17. A graph to show the percentage of current and withdrawn undergarments (wear & tear) against the process count of Sandwash undergarments (+/5 processes). Blue represents undergarments with 1 repair, orange represents garments with 2 or more repairs.

Figure 17 shows an increase in the percentage of undergarments with repairs and process count increases. There is a steady increase in garments with repairs and this begins to rise more rapidly after 120 wash processes. Notably there is an increase in garments with 2+ repairs once 200 wash processes are reached, which indicates the garments begin to degrade in multiple places across the garment. Based on this data, Sandwash garments should be replaced after 150 wash processes.

CLEANROOM GARMENTS PERFORMANCE

TENSILE STRENGTH

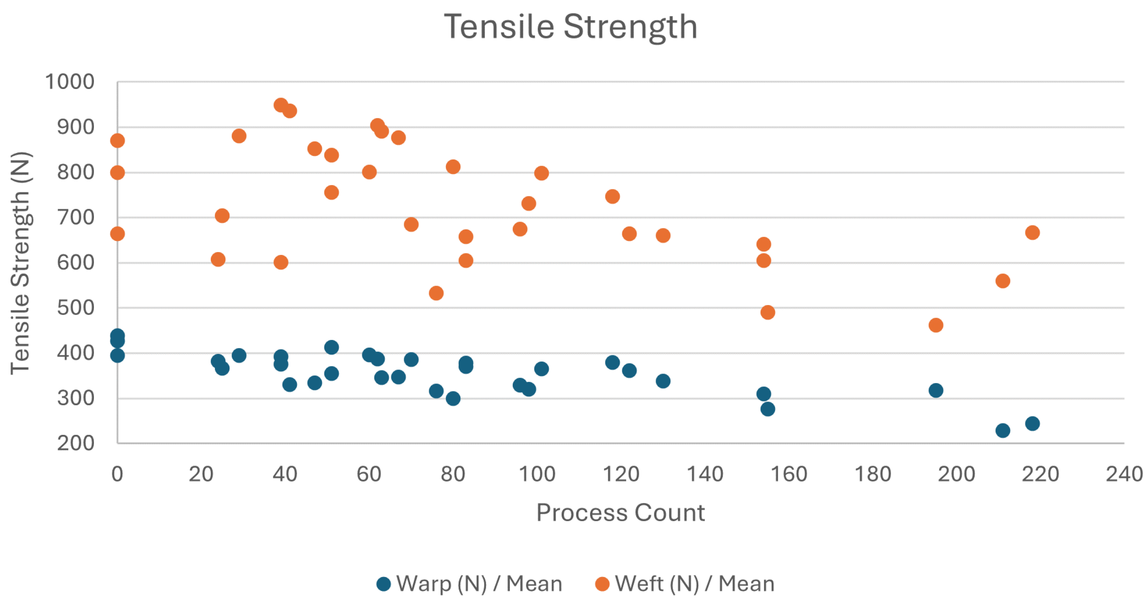


Figure 18. A graph to show the tensile strength of the average weft and average warp of Sandwash undergarments at a given process count.

Figure 18 shows a trend of the tensile strength of the warp and weft of the Sandwash undergarments decreasing as wash process count increases. This indicates that the garments are becoming weaker as they a washed and more likely to break and tear. There is a steady trend that can be observed across all wash processes. After 150 wash processes the strength of the garment is slightly more varied which may indicate that the certainty in the performance of the garment cannot be assured and therefore Sandwash garments should be replaced after 150 wash processes to avoid this.

SANDWASH RESULTS SUMMARY

Table 3 shows that all testing results for Sandwash undergarments are fit for purpose up to 150 wash processes and should be replaced after this count.

Test	Recommended Process Count
Helmke drum particulate count	150
Colour fade	150
Garments with repairs	150
Tensile strength	150
Overall recommended process count	**150**

CLEANROOM GARMENTS PERFORMANCE

TEST RESULTS SUMMARY

The recommended process counts for which to replace undergarments of differing materials can be found below in **Table 4.**

Garment Fabric Material	Recommended Replacement Process Count
Buxton	60
Carsington	100
Sandwash	100

Technical data assessing the performance of the fabrics was analysed and compared against the overall visual assessment of the garments and customer quality data to create the recommended process counts for each fabric.

Buxton undergarments should be replaced after 60 wash processes to avoid a large increase in particulate count and likelihood of the garments needing repairs.

Both Sandwash and Carsington undergarments should be replaced after 100 wash processes, as the overall quality of the garments deteriorates beyond this point. It was noted that after 100 processes, pilling, pulled threads, and small pinholes became more frequent, and the number of repairs began to increase. This is a sign that the overall quality of the garments is declining, even though the specific technical parameters of the fabric itself were within range.

NOTES

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