Wear Study

Evaluation of wear time for Flexcon® DermaFlex™ NWP 240 Flesh H-30 Spec 50K-8 wearable adhesive construction in a 30-day study

Abstract

This study investigates the adhesion performance of DermaFlex™ NWP 240 Flesh H-30 over a 30-day period. The primary objective was to assess the percentage of samples that maintained adhesion throughout the study duration. The results indicate acceptable levels of adhesion success with the given sample set, providing valuable insights for product development and optimization. This study shows that DermaFlex™ NWP 240 Flesh H-30 demonstrates the ability to meet long-term durability requirements and provides a reliable and stable performance for applications requiring extended wear.

1. Introduction

In the realm of medical devices, the importance of skin-friendly tapes cannot be overstated. These tapes play a crucial role in securing dressings, sensors, and other medical apparatus to the skin, ensuring they remain in place while minimizing discomfort and irritation. The development of skin-friendly tapes has been driven by the need to enhance patient comfort, reduce the risk of skin damage, and improve the overall effectiveness of medical devices. Adhesion performance is a critical factor in the effectiveness of patch-based products. This study aims to evaluate the long-term adhesion capabilities of DermaFlex™ NWP 240 Flesh H-30 for up to 30 days.

2. Methods

The in-house wear study was performed by applying non-sterile samples of DermaFlex™ NWP 240 Flesh H-30 on the upper arms (Figure 1) of 23 healthy participants (11 females and 12 males). The test adhesive was certified for ISO 10993-5 and ISO 10993-10 compliance for skin and body contact. The samples were worn for a 30-day period to assess their durability.

Participants had the opportunity to wear a sample of DermaFlex™ NWP 240 Flesh H-30 for an extended period of 30 days to explore the potential for longer wear time. The study monitored both the successful adhesion of samples to the skin and the occurrences of failure.

For each sample, the percentage of those that remained adhered by the end of the study was calculated. The adherent status of the patch and the wearing comfort were recorded by the participants daily.

Skin condition was evaluated upon removal of the samples, and any irritation experienced during the wear period and upon removal of the sample was recorded by the participants at the 30-day endpoint.

Participants were asked to refrain from applying moisturizers or skin products for 24 hours before attaching the samples and from applying skin products around the patches throughout the testing period. Participants were also asked to refrain from swimming, tub bathing, and submersion of samples. No additional activities were restricted for the 30-day wear period.

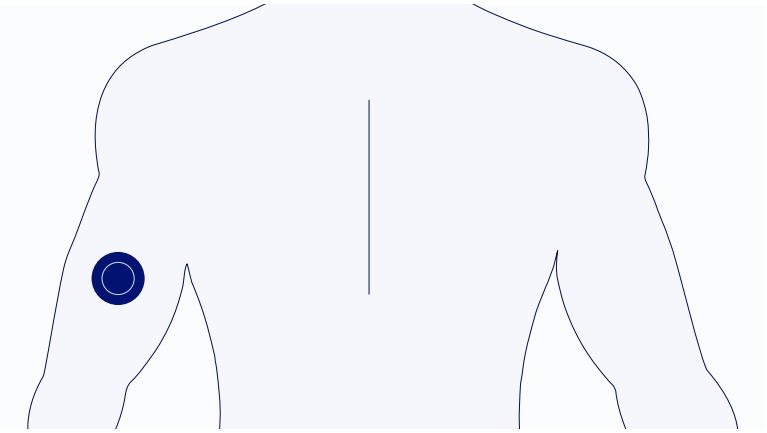


Figure 1.
Samples were worn on the back of the arm on a randomized position as shown in this picture

3. Results

Figure 2 tracks the percentage remaining adhered as a function of wear time. Table 3 details the status of DermaFlex™ NWP 240 Flesh H-30 samples that remained adhered to the skin at 0, 7, 14, 21, 28 and 30 days. Lift percentage was assessed for all participants and samples with any sample exhibiting a lift rate above 40% was classified as a failure in this study. Table 2 summarizes the participant list and sample attachment for each day of wear. Among the 23 DermaFlex™ NWP 240 Flesh H-30 samples, 14 samples maintained adhesion to the skin such that less than 40% of the sample was flagging from the skin, achieving a 61% adhesion rate at both 28 days and 30 days of wear.

These results suggest DermaFlex™ NWP 240 Flesh H-30 demonstrates long-term durability necessary for wearable medical device applications. DermaFlex™ NWP 240 Flesh H-30 Spec 50K-8 provides a reliable and stable performance for applications requiring extended wear. Furthermore, 96% of the participants did not show skin irritation upon completion of study.

Wear Study

Figure 2: Wear Time Curves

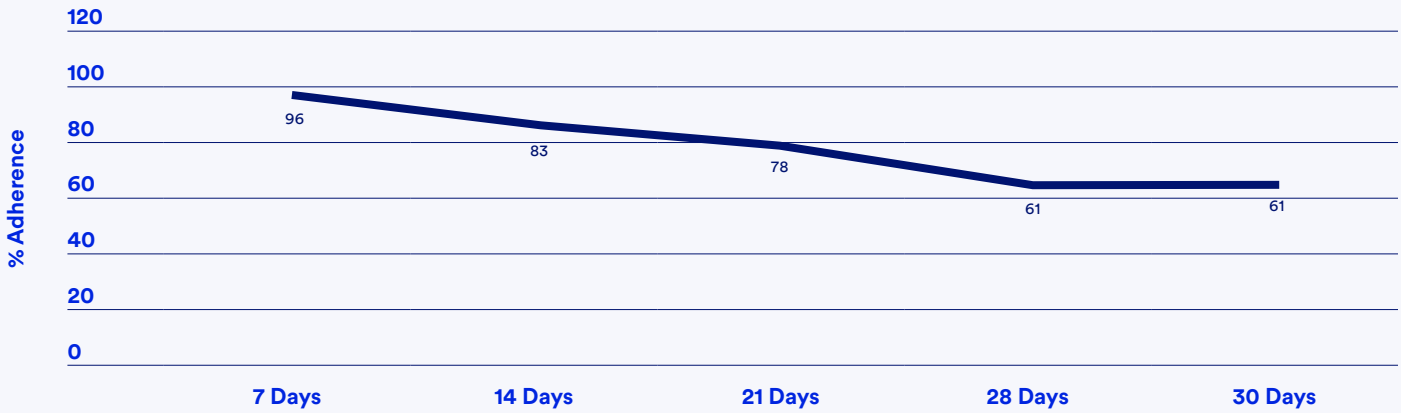


Table 1

Participant Number	Participant Gender	Test Day 0	Test Day 7	Test Day 14	Test Day 21	Test Day 28	Test Day 30
1	M	●	●	●	●	●	●
2	F	●	●	●	●	●	●
3	F	●	●	●	●		
4	F	●	●	●	●	●	●
5	M	●	●	●	●		
6	F	●	●	●	●	●	●
7	F	●	●	●	●	●	●
8	F	●	●	●	●	●	●
9	M	●	●	●	●		
10	F	●	●	●	●	●	●
11	M	●	●	●	●	●	●
12	F	●	●				
13	M	●	●				
14	M	●	●	●	●	●	●
15	F	●	●	●	●	●	●
16	M	●	●	●	●		
17	F	●	●	●	●	●	●
18	M	●	●	●	●	●	●
19	M	●	●	●	●	●	●
20	M	●					
21	F	●	●	●	●	●	●
22	M	●	●	●			
23	M	●	●				
Total Number Passed		**23**	**22**	**19**	**18**	**14**	**14**
% Adhered		**100**	**96**	**83**	**78**	**61**	**61**

Industry and Application Considerations

Wear time of medical tape as a leading indicator of performance in skin-worn devices.

In the design and deployment of wearable medical devices, adhesive performance is a critical determinant of both device functionality and patient comfort. Among the many metrics used to evaluate adhesive suitability, wear time is the duration a medical tape remains securely attached to the skin as a leading indicator of overall performance.

1. Wear time as a performance indicator
Wear time reflects the adhesive's ability to maintain skin contact over a defined period, often under controlled conditions. It serves as a primary metric for:

- Predicting clinical reliability (e.g., in long-term monitoring or drug delivery systems)
- Establishing baseline performance standards
- Informing adhesive selection during product development

Longer wear times typically imply stronger adhesion and sustained contact, which are vital for sensors requiring consistent signal acquisition or therapeutics needing controlled delivery.

2. Limitations of wear time alone
Despite its usefulness, wear time in isolation cannot fully represent adhesive performance due to several limitations:

Controlled vs. real-world conditions:

- Lab-tested wear times may not account for sweat, physical activity, environmental exposure, or skin movement.
- **Static weight testing:** Many tests do not include the additional load introduced by the wearable device itself, which can significantly affect adhesion.

3. Importance of additional testing variables
To ensure robust adhesive performance, testing must expand beyond standard wear time and include:

- **Device weight load testing:** Heavier devices exert greater shear and peel forces, potentially reducing effective wear time or causing premature detachment.
- **Use-case simulation:** Applications such as cardiac monitoring, wound healing, or diabetes management differ in their demands—requiring custom testing protocols that mirror expected activity levels, moisture exposure, and reapplication cycles.
- **Environmental and motion factors:** Temperature, humidity, and mechanical skin stress (e.g., bending or stretching) all influence tape performance and must be included in design-stage testing.

4. Skin variability and patient population considerations
Human skin varies widely across individuals, impacting adhesive effectiveness:

- **Age and skin integrity:** Elderly or neonatal patients may have thinner, more fragile skin that is more susceptible to damage or may not adhere well.
- **Skin types and conditions:** Oily, dry, or sensitive skin, as well as conditions like eczema or dermatitis can reduce adhesive reliability or require special formulations.
- **Body location:** Adhesion on flat areas (e.g., back) differs from dynamic zones (e.g., joints), requiring location-specific evaluation.

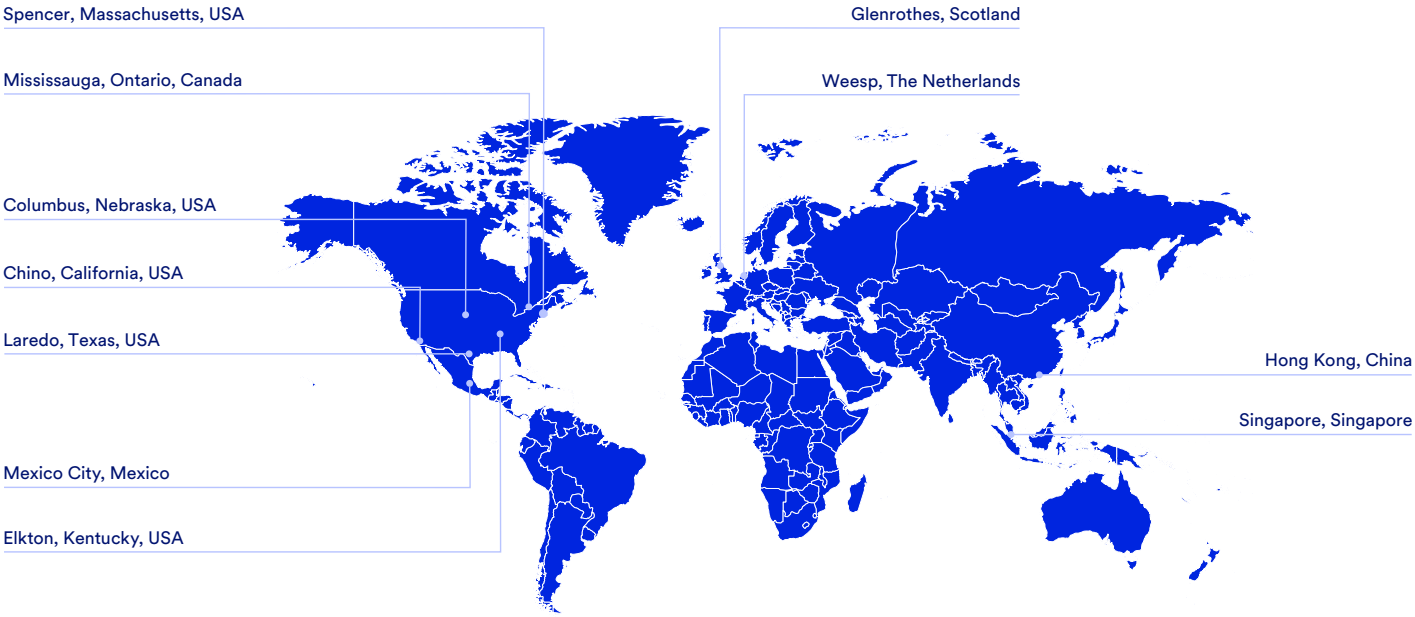
While wear time provides valuable baseline data, it does not alone capture the full complexity of real-world use. Additional testing that accounts for device weight, intended application, and diverse patient populations is essential for reliable, safe, and effective design.

Flexcon

Supporting Businesses Globally

In 1956, Myles McDonough pioneered the first pressure-sensitive film product in a Spencer garage, breaking away from the industry's focus on high-volume commodity products. His vision was to meet the unique needs of innovators seeking new applications for pressure-sensitive films.

Today, 70 years later, Flexcon continues this legacy, serving diverse industries such as packaging, electronics, durables, and healthcare. Flexcon is a trusted manufacturing partner, known for turning innovative ideas into reality. For over 35 years, Flexcon has been supplying the healthcare industry with adhesives, tapes, films, and coating technologies. Our products support applications in wearables, diagnostics, and labeling.



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