

# Uncovering the Efficacy and Safety of Powder-Free Latex Examination Gloves and Powder-Free Nitrile Examination Gloves: A Post-Market Clinical Follow-up Study

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## ABSTRACT

This study evaluated the safety and performance of latex examination gloves powder free and nitrile examination gloves powder free. A total of 361 subjects participated in the study, with 181 using latex examination gloves powder free and 180 using nitrile examination gloves powder free. The performance of latex examination gloves powder free was rated as "satisfactory" (3.8) and that of nitrile examination gloves powder free as "good" (4.1). Clinical safety parameter analysis of latex examination gloves powder free showed that 87% of the users reported that the gloves did not fit perfectly. This may be due to the wrong size selection of gloves by the users for the procedure. No safety-related issues were reported by any of the users. No new risks were identified from the study for the products, and there was no addition to the residual risks that had already been identified in the Risk Management Report. None of the users reported any infection under normal condition of use, and there were no serious adverse events or adverse events reported.

**Keywords:** latex examination gloves powder free, nitrile examination gloves powder free,

safety, performance, clinical safety, risk management

## INTRODUCTION

Following the introduction of medical devices into the market, it is essential to conduct post-market surveillance studies to assess their long-term safety and performance. Latex Examination Gloves Powder Free and Nitrile Examination Gloves Powder Free are fundamental components of personal protective equipment (PPE) widely utilized in various healthcare settings. This scientific publication presents the outcomes of a comprehensive post-market clinical follow-up study aimed at evaluating the extended safety and performance of these two types of gloves.

The study design incorporates a monitoring period and a large cohort of healthcare professionals, enabling the collection of robust data in real-world clinical settings. Through subjective assessments, the study evaluates critical parameters such as glove integrity, resistance to puncture or tearing, ease of use, and overall user satisfaction.

Additionally, this study pays particular attention to the identification and analysis of potential adverse events associated with the use of Latex Examination Gloves Powder Free and Nitrile Examination Gloves Powder Free. These events include allergic reactions, irritant dermatitis, and any other complications that may arise during the glove usage.

By providing an in-depth analysis of the safety and performance characteristics of these gloves, this study aims to enhance the knowledge base of healthcare professionals, regulatory bodies, and manufacturers. The findings will inform evidence-based decision-making regarding the selection and utilization of Latex Examination Gloves Powder Free and Nitrile Examination Gloves Powder Free, thus fostering improved patient care and healthcare worker safety. Ultimately, this post-market clinical follow-up study contributes to the continuous refinement and optimization of PPE for healthcare settings.

### **Primary Objective**

The primary objective of this study was to confirm clinical performance and safety throughout the expected lifetime of the Examination Gloves, the acceptability and to assess the Safety and Performance of these medical devices. The primary objective is also measuring if the product had met its intended use as claimed by the manufacturer Primus Gloves Private Limited.

### **Secondary Objective**

The Secondary Objective was to determine any undesirable events under normal conditions of use and assess whether the risks outweigh the intended benefits of the device. This study tried to identify and analyze new emergent risks, known and unknown residual risks, and contraindications identified and formulated to address if any specific questions relating to the clinical safety or clinical performance of the device. The study also focused on

identifying possible systematic misuse or off-label use of the device.

## **MATERIALS & METHODS**

### **Study Design**

The study was conducted as per guidelines of MDR 2017/745, ANNEX XIV, Part B PMCF - A Guide for Manufacturers and Notified Bodies and MDCG 2020-7- Post-market clinical follow-up (PMCF) Plan A guide for manufacturers and notified bodies ISO 14155:2020 - Guidelines of Clinical Investigation of medical devices for human subjects. The study was a prospective, non-comparative, single-centre study. During the study, the healthcare workers in charge who used these gloves provided feedback regarding the safety and performance of Examination Gloves in the prescribed PMCF format –Case Report Form.

### **Performance Considerations**

The Performance characteristics listed below were assessed during the PMCF study:

1. Comfort of using the gloves
2. Easy of removal of gloves
3. Ease of handling objects
4. Resistance to tear and wear
5. Grip
6. Flexibility and Sensitivity
7. Fit of gloves
8. Thickness
9. Ability of gloves to prevent risk of contamination
10. Ability of gloves to prevent allergic reaction

### **Study Population and Enrollment**

This study was a prospective, randomized, non-comparative, single center study that aimed to enroll up to 360 subjects. The study was conducted in a hospital after getting the requisite ethics committee approval. The data was collected from the end users who have used these examination gloves for the following indications:

- Protection of the wearer from contamination with blood, secretions and excretions and the associated risk of

contamination with pathogens capable of reproduction.

- Prevention of pathogen release from the hand into sterile work area during aseptic duties
- Protection from chemicals
- Defined pathogen barrier as protection from biological agents.

### **Materials**

Protac Latex and Nitrile examination gloves, powder free manufactured by Primus Gloves private limited were used in the study.

### **Latex Examination Gloves Powder Free:**

The Latex Examination Gloves – Powder Free is made of natural rubber latex. The Latex Examination Gloves – Powder Free are sterile and disposable medical gloves. These are intended to use by healthcare professionals during medical procedures to help prevent cross-contamination between caregivers and patients. The Latex Examination Gloves – Powder Free are having precise sizing with better precision and complies as per the standards ASTM D 3578-19 and EN 455. The Latex Examination Gloves – Powder Free are sterilized by Ethylene Oxide or Gamma Irradiation as per the customer's requirement.

### **Nitrile Examination Gloves Powder Free:**

The Nitrile Examination Gloves – Powder Free are made of synthetic nitrile rubber latex. The Nitrile Examination Gloves – Powder Free are sterile and disposable medical gloves. These are intended to use by healthcare professionals during medical procedures to help prevent cross-contamination between caregivers and patients. The Nitrile Examination Gloves – Powder Free are more precise sizing with better precision and complies as per the standards ASTM D 6319-19 and EN 455. The Nitrile Examination Gloves – Powder Free are sterilized by Ethylene Oxide or Gamma Irradiation as per the customer's requirement.

### **Duration of Study**

The PMCF study was initiated on April 2022 and completed on June 2022.

### **Inclusion Criteria**

The inclusion criteria for the subjects of this study were as follows:

- Subjects consenting to be part of the study
- Subjects in which Examination Gloves are used during the examination, diagnostic and therapeutic procedures.

### **Exclusion Criteria**

The below Subjects are excluded from the study:

- Subjects without informed consent
- Subjects who are sensitive to natural latex rubber
- Subjects who are sensitive to synthetic latex

### **RESULT**

Overall, 361 subjects have participated in the PMCF study, out of which Latex Examination Gloves Powder Free were used by users on 181 cases. Nitrile Examination Gloves Powder Free was used by users on 180 cases.

### **Gender Distribution**

Below is the gender distribution of subjects in whom the gloves were used during the surgery.

### **Latex Examination Gloves Powder Free:**

Out of 181 subjects in the study 1(1%) of the subjects was Male and 180(99%) of the subjects were Female.

### **Nitrile Examination Gloves Powder Free**

Out of 180 subjects in the study 6 (3%) of the subjects were Male and 174(97%) of the subjects were Female.

### **Age distribution**

The age summary of the subjects whom the data is collected is represented below.

### Latex Examination Gloves Powder Free

117(65%) of the subjects were recruited from age groups 21-30 years and 64(35%) of the subjects were recruited from 31-40.

### Nitrile Examination Gloves Powder Free

134(74%) of the subjects were recruited from age groups 21-30 years. 46(26%) of the subjects were recruited from 31-40.

### Sizes of gloves used

The different sizes of gloves and the cuff sizes used in the study are given below in Table and Table 2.

**Table1: Sizes of gloves used**

Product Name	Glove Size	No of gloves
Latex Examination Gloves Powder Free	Small	17
	Medium	119
	Large	45
Nitrile Examination Gloves Powder Free	Small	41
	Medium	65
	Large	74

**Table 2: Cuff size of the gloves used**

Product Name	Variant Name	No: of use cases
Latex Examination Gloves Powder Free	Regular Cuff	06
	Long Cuff	175
Nitrile Examination Gloves Powder Free	Nil	180

Though the glove sizes are available in Ex small, Small, Medium, Large and Ex- large for Latex Examination gloves Powder Free and Small, Medium, Large and Ex- Large for Nitrile Examination Gloves Powder Free, under the clinical study only three glove sizes i.e., Small, Medium and Large for both Latex Examination gloves Powder Free and Nitrile Examination Gloves Powder Free were used. Since the study was conducted in India, the glove size matching the Indian population is these three sizes only. Hence, we considered these sizes for the clinical study. Since there is no change in the material or properties of the gloves the clinical outcome from the three sizes of the gloves would be considered for other sizes also.

The Examination Gloves were used for less than 60 minutes.

The below tables depict the categories of healthcare workers who have used these gloves.

**Table 3: Category of users of Latex examination gloves**

Type of Users	Number of use cases
Nurse	57
Doctors	124

**Table 4: Category of users of Nitrile Examination Gloves Powder free:**

Type of Users	Number of use cases
Nurse	77
Doctors	103

### Product Quality Analysis

The product quality analysis was evaluated by asking questions related to the quality parameters like ability to complete the procedure/ examination with a single pair of gloves, good dexterity, sweating or any other discomfort while using the gloves and colour variation in gloves.

All the users agreed that the product was meeting the product quality.

### Clinical Safety and Efficacy

The Clinical Safety and efficacy of the Examination Gloves was evaluated by asking questions related to the clinical parameters like

- Able to follow instruction for use on the package
- Perfect glove size/fit
- Discomfort in patients after the glove usage
- Holes or breakage in gloves while using or post usage

- Protection from risk of infection from pathogen
- Any adverse effects in patients after the examination
- Resistance to puncture from other medical devices
- Protection from blood and other body fluids of the patient
- Any high-risk reaction such anaphylaxis or other severe problems

**Latex Examination Gloves Powder Free:**  
From the clinical safety parameter analysis of Latex Examination Gloves Powder Free, in 87% of the use cases the users had reported that the gloves were not perfectly fit for them. This may be due to the wrong size selection of gloves by the users for doing the procedure. None of the users have reported safety related issues with the gloves.

**Nitrile Examination Gloves Powder Free:**  
From the clinical safety parameter analysis of Nitrile Examination Gloves Powder Free none of the users have reported safety related issues with the gloves.

All the users had agreed that the Latex Examination Gloves Powder Free and Nitrile Examination Gloves Powder Free had met the intended use.

### Clinical Performance

The clinical performance of the product was evaluated by asking the users to give satisfactory rating in the case report form for the performance category. The rating was done in Likert Scale. Likert scale consisted of “Excellent=5”, “Good=4”, “Satisfactory=3”, “Average=2” and “Unsatisfactory=1”. All ratings corresponding to each question were added together to find the product performance in each attribute.

**TABLE 5: Product performance of Latex Examination Gloves Powder Free**

Sl No	Product Performance	Rating
1.	Comfort of using the gloves	2.7
2.	Easy removal of gloves	3.8
3.	Ease of handling objects	2.7
4.	Resistance to tear and wear	4.4
5.	Grip	1.7
6.	Flexibility and sensitivity	4.3
7.	Fit of gloves	1.7
8.	Thickness	4.3
9.	Ability of gloves to prevent risk of contamination	4.7
10.	Ability of gloves to prevent allergic reaction	4.7
11.	Glove material	4.7
	<b>Overall Rating</b>	<b>3.8</b>

Overall performance rating was “3.8”, hence it was concluded that product is showing “Satisfactory” performance.

**Table 6: Product performance of Nitrile Examination Gloves Powder Free**

Sl No	Product Performance	Rating
1.	Comfort of using the gloves	4
2.	Easy removal of gloves	4
3.	Ease of handling objects	4
4.	Resistance to tear and wear	4
5.	Grip	4
6.	Flexibility and sensitivity	4
7.	Fit of gloves	4
8.	Thickness	4.8
9.	Ability of gloves to prevent risk of contamination	3.4
10.	Ability of gloves to prevent allergic reaction	4.1
11.	Glove material	4.9
	<b>Overall Rating</b>	<b>4.1</b>

Overall performance rating was “4.1”, hence it was concluded that product is showing “Good” performance.

There were no side effects/adverse events reported during the study.

Below mentioned risks were monitored during the PMCF Study:

#### **Latex Examination Gloves Powder Free**

• Infection • Anaphylaxis • Inflammation • Allergy • Itching

#### **Nitrile Examination Gloves Powder Free**

• Inflammation • Infection • Allergy • Itching

None of the users have reported any of the above-mentioned risks during the PMCF study.

There were no new risks were identified during the study.

### **DISCUSSION**

The medical field has witnessed the evolution of medical gloves to cater to its requirements. The surge in the usage of latex gloves gained momentum in the 1980s due to increased awareness of HIV/AIDS. The primary purpose of gloves is to establish an effective barrier that safeguards healthcare professionals and patients from infections. It is essential for healthcare workers to use gloves only once for each patient interaction and treatment, although prolonged and indiscriminate usage is advised against to minimize the risk of sensitization.<sup>(1,2)</sup>

Gloves are indispensable in various scenarios, including invasive procedures and when there is contact with non-intact skin, mucous membranes, or sterile sites. Consequently, it is crucial for gloves to exhibit minimal leakage, even if they appear undamaged. To ensure satisfactory performance regardless of the material used, several standards have been developed for gloves. They should be effortless to put on, comfortable to wear, and offer adequate and long-lasting protection.

Latex gloves were first introduced in the early 1900s and quickly became the standard in the medical field. However, latex allergies are relatively common, and some people may experience skin irritation

or even anaphylaxis when wearing latex gloves. Nitrile gloves were developed in the 1990s as an alternative to latex gloves for people with allergies. Nitrile gloves are more durable and resistant to chemicals than latex gloves, and they are also less likely to cause allergic reactions.<sup>(3-6)</sup>

Non-latex gloves, such as vinyl gloves, are effective in terms of protection and reliability. Each intact medical glove material, including natural latex rubber, vinyl or even polythene, prevents the passage of viruses, and viral penetration was found to be broadly equal for natural latex and vinyl medical gloves.<sup>(7)</sup>

Nitrile gloves are made of a synthetic polymer formed by combining the monomers acrylonitrile, butadiene and carboxylic acid. Each monomer contributes a unique property. For example, acrylonitrile provides penetration resistance from a number of solvents and chemicals such as hydrocarbon oils, fats, and solvents. The chemical resistance and stiffness of the gloves increase as the acrylonitrile concentration increases. Butadiene adds softness and flexibility and contributes to the elasticity of the glove. Carboxylic acid contributes to the tensile strength or the tear resistance of the glove. By changing the composition of these monomers, the characteristics of the glove can be altered.

Nitrile gloves that claim to be “powder-free” must undergo testing that demonstrates that the powder content is not more than 0.7 milligrams per gram of glove. In general, gloves in the ADA Acceptance Program must comply with American National Standard Institute/American Dental Association Specification No. 102.5. This specification requires testing of the following glove properties: biocompatibility of the polymer compound, dimensions (width, length, and thickness), water tightness, tensile strength, and ultimate elongation. Biocompatibility testing is intended to demonstrate that the glove material is non-toxic and non-carcinogenic. Physical property testing includes recording glove dimensions to ensure that optimal

tactile sensation is retained. Water tightness is tested to determine whether there are any perforations in the glove that would compromise its use as a protective barrier. Tensile strength is measured to determine the maximum force that the glove can bear before it breaks. Finally, ultimate elongation is evaluated to measure the length that the glove will stretch under maximum force before it breaks. The results of this testing for powder-free gloves must meet minimal requirements to be awarded the ADA Seal of Acceptance.

Several studies suggest that nitrile gloves perform better than latex gloves in terms of barrier integrity, especially in the presence of certain chemicals. Further, they are less likely to be torn or punctured during use while donning and wearing, and offer better resistance to chemical exposure. Nitrile gloves also produce less skin irritation than latex gloves in most individuals.<sup>(7-9)</sup>

While hypersensitivity reactions due to nitrile gloves are rare, there have been reported cases of contact urticaria, generalized pruritus, rhinitis, and dyspnea after using certain types of nitrile gloves. In some cases, natural rubber proteins were found in the nitrile gloves, causing these reactions. Therefore, the presence of latex in nitrile gloves should not be ruled out, and manufacturing companies should provide package inserts containing at least the total protein contents and allergenic latex protein levels and the measurement methods used.<sup>(3)</sup>

A scientific study by Sawyer et al comparing the level of dexterity provided by latex gloves to that of nitrile gloves, which are used as a replacement for latex gloves to prevent latex allergy found that there was a statistically significant 8.6% increase in fine finger dexterity provided by latex gloves compared with nitrile gloves. However, there was no difference in gross dexterity between the two types of gloves. In the current study, the nitrile gloves were rated higher on these parameters compared to the latex gloves.<sup>(9)</sup>

According to the study, the dimensions of the participants' digits can have weak

correlations with the dexterity scores from various tests. Specifically, thinner and longer thumbs and index fingers were associated with improved dexterity. Additionally, the study mentions using statistical analysis to investigate any relationships between anthropometric measures, questionnaire data, and dexterity test scores, but it does not provide any specific findings related to these factors.<sup>(9)</sup>

The study by Mylon et al was conducted through semi-structured interviews with medical practitioners from various disciplines to determine the critical elements of glove performance and design appropriate tests. The results showed that participants had a preference for latex gloves over nitrile gloves, with glove fit being the main reason given. Additionally, satisfaction with surgical gloves (generally latex) was high, but less so with examination gloves (generally nitrile). Tactile sensation, comfort, and donning were also seen as major issues with glove use.<sup>(10)</sup>

The primary role of gloves is to prevent the spread of infection, so achieving good barrier integrity is important for glove design. Additionally, glove performance can affect safety, particularly in a surgical environment, where optimal frictional properties and tactile sensitivity are necessary for delicate procedures. Surgeons have resisted moves to replace surgical gloves with non-latex alternatives due to a perceived reduction in manual performance.<sup>(10)</sup>

Some users preferred latex gloves over nitrile gloves since they are more elastic and fit or conform better. Participants identified poor fit and less elasticity as the primary problems with nitrile gloves. Loss of dexterity and tactile sensation were also identified as the main effects of poor fit. Whereas some users stated that they did not have a preference for latex or nitrile, none expressed a preference for the nitrile over the latex (besides reasons of allergy). However, it is important to note that the study did not differentiate between

applications such as surgical or exam gloves. In this study, the users felt that the comfort of using gloves, ease of handling objects, the grip and the fit of gloves was better with the nitrile gloves compared to the latex gloves.<sup>(10)</sup>

The study described a two-stage experimental approach intended to develop criteria to optimize the design and manufacture of medical gloves that would encourage better performance and minimize user barriers. The first stage was interested in identifying which tasks are most difficult to perform with current gloves and how they are affected by glove characteristics. The second stage was intended to use the information gathered in experiments to create a series of standardized tests that predict how gloves may impact clinical performance. The study suggested that the resulting data would provide designers with functional performance requirements that include non-barrier considerations, such as basic requirements for dexterity, tactility, and comfort. While the study did not discuss specific interventions, it indirectly suggested that glove manufacturers should consider user needs and preferences when designing gloves for medical use.<sup>(10)</sup>

Murray et al discusses research on glove wearing and cross infection in healthcare settings, focusing on the increasing prevalence of hypersensitivity to latex proteins and the development of non-latex materials such as nitrile gloves. They describe a pilot investigation comparing the number of glove punctures occurring with latex and nitrile gloves used by dentists in general practice. The gloves were tested for punctures by a water inflation method. Wearing latex gloves in dental practice is not without risk to either dental clinician or patient, and the incidence of latex hypersensitivity appears to be increasing. It has been reported that 6.2% of operating theatre staff and 17% of hospital staff are hypersensitive to latex proteins. However, non-latex materials suitable for glove manufacture have been developed and introduced to address this issue.<sup>(11)</sup>

An investigation on the puncture resistance of recently introduced non-latex, nitrile dental glove in comparison with a latex glove worn during routine clinical dental procedures was conducted. The study showed that the nitrile gloves had a significantly lower incidence of punctures than the latex gloves. None of the users reported any punctures while using either gloves.<sup>(11)</sup>

The study by Rusell-Fell et al discusses the problems and risks associated with the use of medical gloves, specifically natural rubber gloves. It notes the risk of allergic reactions to the proteins and residual chemicals found in natural and synthetic rubber gloves, which can cause adverse effects on healthcare workers. The article compares different medical glove materials in terms of reliability and allergy, and suggests suitable alternatives for individuals who experience an adverse reaction.

According to the information provided, there was a low incidence of contact urticaria (CU) reaction to latex protein in gloves before 1979. However, the incidence increased significantly before the HIV pandemic caused wider use of medical gloves. Since 1980, the number of studies of adverse reaction to residual rubber chemicals in gloves indicates a higher incidence of delayed allergenic contact reaction than before. It is also suggested that a switch from reusable, resterilized latex gloves to the disposable types used from 1965-1975 may have been a previously overlooked causative factor for the increase in reactions to residual proteins and chemicals. Therefore, it can be inferred that the increased use of latex gloves has led to a higher prevalence of allergic reactions among healthcare workers. No allergic reaction was reported in the current study.<sup>(12)</sup>

A study that was conducted to compare the barrier effectiveness of medical examination gloves of different types of materials (vinyl, nitrile, copolymer, latex) and manufacturers found that nitrile examination gloves are a suitable alternative to latex, whereas vinyl



and copolymer examination gloves had the highest failure rate. Several authors have discovered that vinyl examination gloves have inferior barrier performance compared to latex and nitrile examination gloves.<sup>(2)</sup>

The study by Patel et al., discusses a study on the puncture resistance and stiffness of nitrile and latex dental examination gloves. Puncture resistance testing was carried out with both a steel puncture probe and a dental injection needle, with nitrile gloves proving to have higher resistance with the steel probe and latex gloves proving to have higher resistance with the dental injection needle. The stiffness (M100) of the gloves was also tested and was found to increase with age in the nitrile gloves. The study concludes that nitrile gloves offer similar puncture resistance to latex gloves and may be a good alternative for those who experience an adverse reaction to natural latex gloves.<sup>(8)</sup>

The study by Rego et al is a scientific article discussing the comparative barrier integrity of latex, vinyl, and nitrile gloves during simulated clinical conditions. The study evaluated 2000 gloves (800 latex, 800 vinyl, and 400 nitrile), and their failure rates were measured after manipulations mimicking patient care activities. The results showed that latex and nitrile gloves had lower failure rates than vinyl gloves. According to the study, nitrile gloves showed the lowest failure rate during manipulations mimicking patient care activities, while the standard vinyl gloves exhibited the highest in-use failure rate of 61%. Latex gloves demonstrated an in-use failure rate of 24%. The study results also suggested that stretch vinyl gloves had better in-use barrier integrity than standard vinyl gloves.<sup>(7)</sup>

The study by Pitten et al noted that the use of an alcoholic hand disinfectant before gloving was found to increase the frequency of perforations. Gloves applied to wet hands had a higher tendency to perforate.<sup>(13)</sup>

The study by Patrecke et al found that wearing gloves for longer than 90 minutes led to an increased risk of microperforations. The article states that

there was no significant difference in the rate of microperforation among surgeons and first assistants. No perforations were reported in this study.<sup>(14)</sup>

Hubner et al discusses the importance of gloves in preventing the transmission of infectious agents between patients and medical personnel in intensive care units (ICU). It presents a study that aims to determine the durability of examination gloves in two ICUs using two different brands and materials (latex and nitrile). The study concludes that medical gloves show marked differences in their durability. The paper suggests that changing gloves every 15 minutes can be a good compromise between feasibility and safety.<sup>(15)</sup>

## **CONCLUSION**

The conclusion of the above post-market clinical follow-up study is that latex examination gloves powder free and nitrile examination gloves powder free are both safe and effective for use in clinical settings. The performance of the latex examination gloves powder free was rated as "satisfactory" (3.8) and that of nitrile examination gloves powder free as "good" (4.1). No safety-related issues were reported by any of the users. No new risks were identified from the study for the products, and there was no addition to the residual risks that had already been identified in the Risk Management Report. These risks have been mitigated and are acceptable when weighed against the benefits to the patient. None of the users reported any infection under normal condition of use, and there were no serious adverse events or adverse events reported.

The study also found that 87% of the users of latex examination gloves powder free reported that the gloves did not fit perfectly. This may be due to the wrong size selection of gloves by the users for the procedure. The manufacturer should consider this finding when designing future studies and when making recommendations to users about how to select the correct size of gloves.

Overall, the results of this study suggest that latex examination gloves powder free and nitrile examination gloves powder free are both safe and effective for use in clinical settings. The manufacturer should continue to monitor the safety and performance of these products and make recommendations to users about how to select the correct size of gloves.

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