Protective Coatings for Non-Invasive Medical Devices for Real-World Reliability

Prevent Recalls, Warranty Issues, and Reputation Loss with Proven, Trusted Technology

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HZO.COM

Why HZO?

HZO is the global leader & innovator in protective solutions that keep the world running, delivering highly reliable nano conformal coating solutions that safeguard electronics, electrical products & critical applications in an ever-changing market. HZO works with some of the largest companies across industries from design through production, no matter the volume, complexity, or protection required, to deliver a better, more reliable, and more durable product.

Introduction

As growing geriatric populations and increasing incidences of chronic diseases converge with technological advances and internet penetration, less invasive medical devices that offer advanced monitoring of the body are in steady demand.

Smartwatches, activity trackers and monitors, smart hearing aids, and continuous glucose monitors (CGMs) fall into this market, all integrating complex software design with minimized, intricate components such as motion trackers, gyroscopes, skin temperature sensors, compasses, GPS components, and optical heart rate monitors.

An increasing number of consumers rely on non-invasive, connected medical products exposed to variable environments (including hazardous weather conditions, submersion, humidity, and pollution) to manage health conditions, and it is up to product design teams to design functional devices and make them reliable.

The FDA has identified the criticality of reliability, singling out design and reliability engineering as one of seven critical requirements to improve quality within the medical device industry. More specifically, the organization has emphasized a need for improved efforts in design-for-reliability and, perhaps most critically - validation of actual product use.

Connected medical device components have similar requisites for design-for-reliability; resiliency and long-term stability are necessary. However, the FDA's suggestion to validate actual product use may be easier said than done for medical devices worn on the body.

The difficulty is due to the fact that these products are bound to encounter two harsh environments – the human body and various operating environments. Devices worn on the human body will be subject to perspiration and other bodily fluids and endure frequent physical interactions. As such, wearable medical devices will experience vibration, shock and may be flexed, moved, and likely dropped.

The medical products will also go where users go. Consumers who depend on them for wellbeing may not be able to - or may not want to - remove them in swimming pools, showers, humid areas, and harsh weather conditions. They should be designed to reliably operate despite frequent chemical and corrosive exposure, as they will come into contact with cleaning fluids, airborne pollution, soap, other hygienical products, and an almost endless list of contaminants.

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Problems with Legacy Solutions

As someone tasked with designing and producing more reliable medical wearables, you have the option to use legacy protection methods such as seals and gaskets or thick conformal coating materials, such as acrylics, epoxies, urethanes, or silicones. While these may be appropriate solutions for some projects, many find they are no longer feasible from a medical device design or reliability standpoint.

Medical wearables entail minimized form factors to facilitate comfort and convenience, making the excessive use of seals and gaskets more difficult to integrate into designs than it used to be. Even thick conformal coatings may prove to be too bulky and heavy for products worn on the body.

In terms of reliability, seals and gaskets constantly exposed to vibration and shock common with wearables can become dislodged, creating opportunities for ingress. Additionally, medical wearables such as continuous glucose monitors require dependable connectivity, whether direct to the device or the system, through sensors that record changes in information gathered. These connections operate through cellular or radio waves, so the protection you choose must allow these signals to be transmitted without any interference.

Because it is your job to ensure consumers can depend on your medical wearables, it is your responsibility to envision and plan the entire product lifecycle. Simply testing to and meeting environmental specifications may provide temporary peace of mind, but the truth is that these specifications frequently do not represent the edges of the bell curve of the real world. If you do not plan and protect for the real world, consumers will become disillusioned with the product you created.

Worse, when product design teams settle for “good enough” reliability, it can cause product recalls, loss of critical medical data, liability, and repairs. If you see the benefits of producing a medical wearable capable of leaving the confines of the lab and remaining resilient in real life, this brochure is for you.

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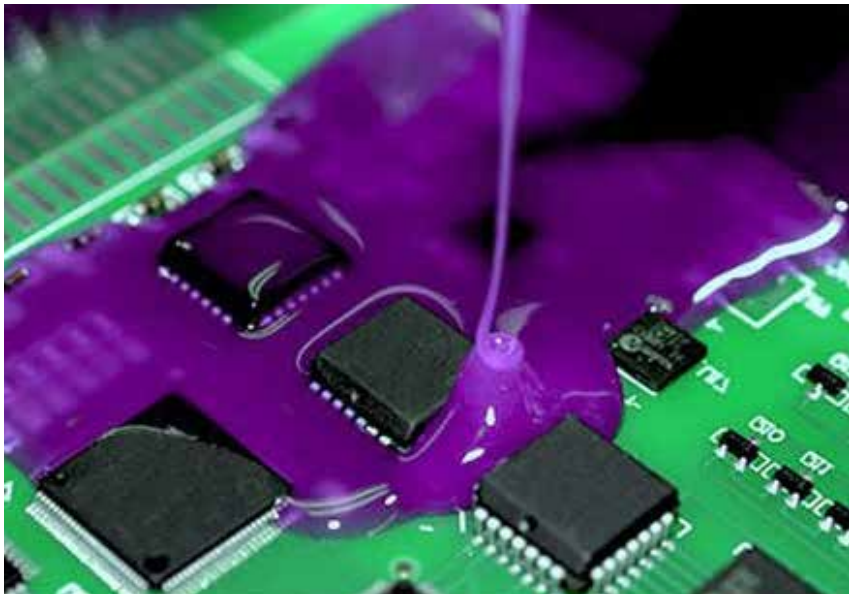


HZO's Parylene for Medical Wearables

HZO provides an alternative solution to seals and conventional conformal coatings ideal for medical wearables. Whether used in conjunction with seals as redundant protection or alone, our Parylene coatings can solve many reliability problems associated with harmful exposure to the human body and the operating environment.

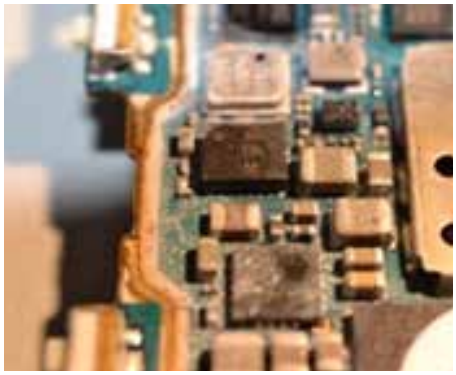
The images to the right compare the results of a mechanical seal breach with a component coated with HZO Parylene a week after exposure.

Parylene conformal coatings come in various types, including Parylene C, Parylene N, and Parylene F (VT-4). The coating is superior in uniform coverage, barrier properties, and performance at comparably thinner films, with less stress on mechanical structures and virtually no added weight. Due to its properties, Parylene has been trusted for decades in the medical industry to safeguard implants and other critical devices. Now, as HZO has engineered processes that cut costs and allow easy ramp-up to mass production with proven Parylene coatings, it may be time to revisit this solution for less-invasive medical products.

PARYLENE ADVANTAGES FOR MEDICAL WEARABLES

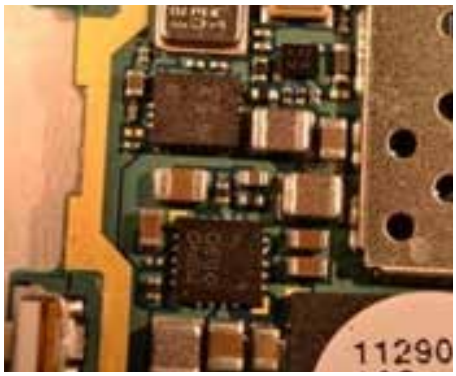
- Lightweight
- Optically clear
- Thermal stability
- Solvent-free, sustainable, no curing
- Non-irritating performance, can be worn on the skin
- FDA approved with a USP XII, Class VI biocompatibility rating
- Excellent moisture, chemical, and dielectric protection
- Reliable performance at normal body temperature, with a temperature range of -200° C through 80° C

Mechanical Seal Breach



HZO Parylene

One week after water exposure



HZO's Parylene for Medical Wearables

THINNESS

As wearable medical devices increase in capabilities and relevant applications, your products must be thinner, smaller, and more energy-efficient.

Our Guardian™ Series of Parylene conformal coatings have passed the IPC CC-830C test at 50% of the film thickness of conventional conformal coatings. The data prove that our coatings can provide as much - or more - flexibility, fungus resistance, flammability, dielectric withstanding voltage, thermal shock, moisture, and insulation resistance at a fraction of the mass.

IPC CC-830C Results

Class	Type	Specimen - Avg. Coating Thickness (µm)			
		Specimen 1	Specimen 2	Specimen 3	Specimen 4
XY	Parylene N	25	25	23	23
XY	Parylene C	31	30	30	32
XY	Parylene F	46	36	43	29
AR/UR	Acrylic	73	73	69	72
SR	Silicone	102	99	114	154
AR/UR	Acrylated Polyurethane	91	91	107	107

HZO's Parylene passed all IPC CC-830C at 50% of the Film Thickness of the Traditional Conformal Coatings.

HZO's Parylene for Medical Wearables

MEET AND EXCEED INGRESS PROTECTION STANDARDS

Consumers often qualify medical device purchases with IP ratings when they make purchasing decisions. Therefore, it is often necessary to make marketing claims about ingress protection standards, such as passing IPX8 protection tests.

Our proven Parylene coatings can sustain electronics through liquid submersion, thereby allowing you to exceed any IP level of protection without the need for hours spent on customizing designs for seals or risking failure with conventional conformal coatings.

Liquid Ingress Protection Standards (e.g., IPX7)

Level	Protects Against	HZO Coating Protection
0	None	Exceeds
1	Dripping Water	Exceeds
2	Dripping Water When Tilted at 15º	Exceeds
3	Spraying Water	Exceeds
4	Splashing of Water	Exceeds
5	Water Jets	Exceeds
6	Powerful Water Jets	Exceeds
7	Immersion, Up to 1 Meter Depth for 30 Minutes	Exceeds
8	Immersion for Greater Time and Depth Than IPX7 (Typically 2 Meters for 1 Hour)	Exceeds

HZO's Parylene for Medical Wearables

RELIABLE CORROSION RESISTANCE

Electronic devices run on batteries and electricity, and medical wearable products are no exception. If they are not adequately protected, one drop in water can be a sufficient catalyst for the corrosion process, leading to unexpected premature failure.

Despite the thinness of HZO coatings, our Parylene performs exceptionally well as a barrier to corrosion caused by biofluids, moisture, and cleaning fluids. This is due to the material's ability to minimize the influence of the factors that affect coating lifetime and performance, including the following:

Uncoated PCBA with corrosion

Parylene Corrosion Resistant Properties

Oxygen permeability	Low oxygen permeability for a polymer coating
Water vapor permeability	Very low WVTR for a polymer coating
Liquid water uptake	Parylene absorbs very little water
Ionic permeability	Salts have a difficult time passing through the coating
Coating porosity	At a thickness of just 5 µm, Parylene forms a pinhole/pore-free coating

Parylene C is the most effective conformal coating available for corrosion protection at its thickness.

Water vapor transmission rate (WVTR) and gas permeability are properties that indicate barrier effectiveness for corrosion resistance. As the chart below shows, Parylene C's WTVR and gas permeability properties are extremely low. Medical wearable devices must endure various corrosive conditions, and corrosive damage can be particularly frustrating to consumers who come to depend on them. If they experience device failure immediately after a drop into liquid, it might be disappointing but expected. But because corrosion is a slower process, premature device failure may seem inexplicable and "out of the blue," leading to mistrust and damage to your brand. Fortunately, your customers can have conviction in the reliability of your product in part due to our coatings' strong corrosion resistance properties.

Uncoated PCBA with corrosion

Parylene C is the most effective conformal coating available for corrosion protection at its thickness.

Barrier Properties of Conformal Coatings

Polymer	Gas Permeability at 25 °C, (cc·mm)/(m²·day·atm)							WVTR, (cc·mm)/(m²·day·atm)
	N_2	O_2	CO_2	H_2	H_2S	SO_2	Cl_2	
Parylene C	0.4	2.8	3.0	43.3	5.1	4.3	0.1	0.08
Parylene N	3.0	15.4	84.3	212.6	313	745	29.2	0.59
Parylene F (VT-4)	-	-	16.7	-	-	-	0.28	-
Epoxy (ER)	1.6	4	3.1	43.3	-	-	-	0.94
Polyurethane (UR)	31.5	78.7	1,181	-	-	-	0.93	-
Silicone (SR)	-	19,685	118,110	17,717	-	-	-	-

Environmentally Friendly Support

Medical wearables OEMs feel increasing pressure to meet sustainability guidelines, such as REACH, RoHS, and Prop 65. The policies and regulations can have far-reaching effects, from raw material selection all the way through the manufacturing process. Parylene is a compliant solution with no cure time.

As a green manufacturer, HZO's support includes:

Material oversight

Responsible end-of-life management

Preparation for repair, reuse, and recycling

Corporate social responsibility

HZO Parylene coatings have:

Biostability
Stability within a biological operating environment.

Biocombatibility
Compatible within a biological operating environment.

No VOCs
No volatile organic compounds.

No Solvents
No solvents found within the material.

No Catalysts
Pure and free of trace ionic impurities.

No Disposal Issues
Ability to be disposed of safely and within regulation.

No Pollution Threats
No harmful pollutants found with the material.

No Cure Time
No additional time or equipment required for curing.

HZO's Parylene coatings are:

REACH Compliant

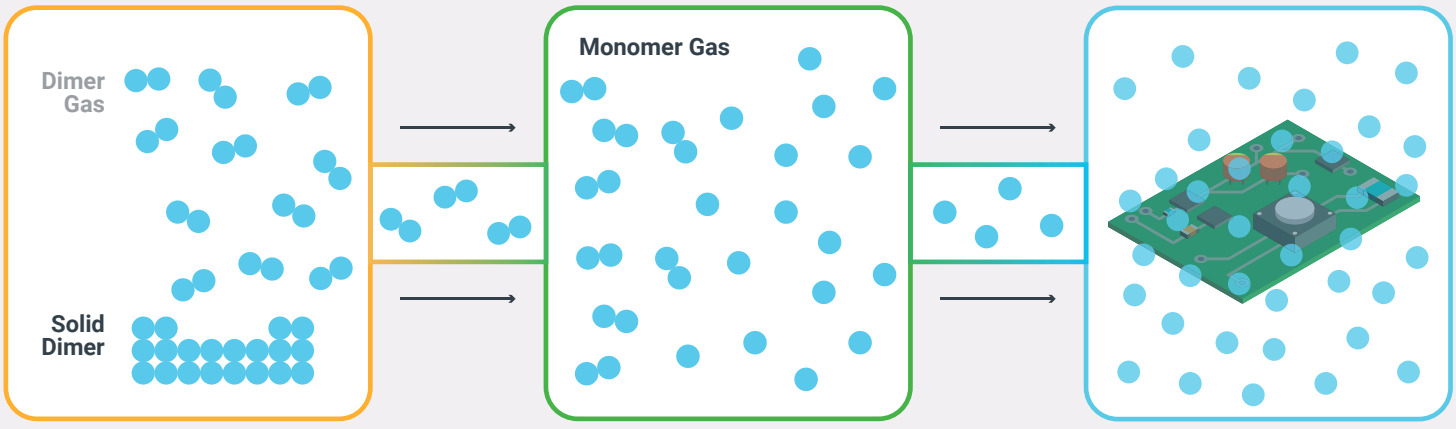
RoHS Compliant

Prop 65 Compliant

CVD – The Parylene Polymerization Process

Parylene coatings are ultra-thin, lightweight, and due to the chemical vapor deposition (CVD) application process, the coatings are highly conformal, wrapping around every edge available. The CVD process is performed under vacuum, with specialized equipment that includes a coating chamber. As a result, all surfaces are coated evenly regardless of chamber position, and the coating deposits the same thickness all around the objects being coated. This vapor phase coating process also leads to pinhole-free coatings free from defects.

Chemical Vapor Deposition (CVD) Coating Process



1. Parylene typically begins as a solid dimer, sublimated to gas.
2. The gas goes through a pyrolysis chamber that cracks the dimer into two di-radical monomers before entering the deposition chamber.
3. The monomers adsorb onto the substrate as a polymer.

More About Parylene's Conformality

Since it is deposited as a vapor that lands on and begins building up a thin film that wraps around components and substrates with little to no change in thickness, Parylene is a truly conformal coating that ensures protection from corrosive environments even at tight corners. Conversely, conventional conformal coatings leave uneven coatings, with much thinner layers at the corners of the component or substrate, unless the coating is made so thick that it starts adding size, weight, and potentially stressing components due to differences in thermal expansion.

The results are clear when conventional coatings are compared to Parylene coverage: Parylene coatings are superior in conformality and uniform coverage.

Parylene is a truly conformal coating that ensures protection from corrosive environments even at tight corners.

In figure 1 below, a conventional conformal coating has poor coverage, in which it is thinner on the top corners, thicker on the top than the sides, and much thicker at the bottom. A bubble trapped underneath the component shows the coating didn't push all the air from underneath as the coating was deposited. With so much coating at the bottom under the component, the coating may push up on the component or against the soldered leads as the electronic device is heated. After several hot-cold cycles, the coating may break the component's connection to the board, creating an electrical open. Figure 2 displays Parylene's truly conformal coverage, regardless of the complex geometry of the substrate it is applied to.

Parylene Conformality Compared to Conventional Conformal Coatings

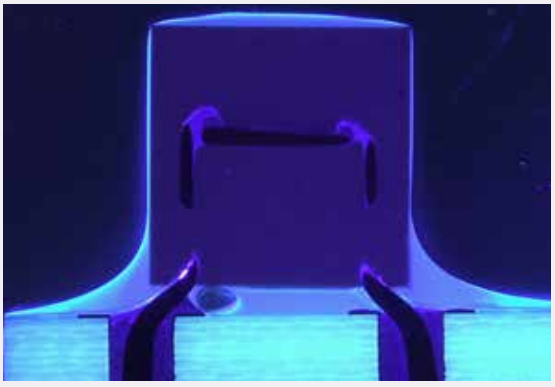


Fig 1: SEM image of conventional conformal coating coverage (Source: IPC-SMTA)

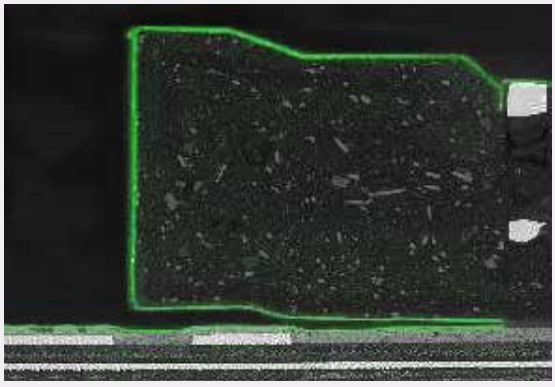


Fig 2: SEM image and chlorine map (combined) of Parylene conformal coating coverage (green line)

Applications

WEARABLES

The activity monitors and trackers market is growing. The demand is driven by the potential for wearable technologies to improve the quality of patient care while reducing cost in a non-invasive way. Medical wearables have expanded beyond simple, traditional monitors and hearing aids to sophisticated patient monitoring with connected software, biosensors, and smart trackers embedded into watches, rings, armbands, clothing, and glasses.

These devices require integrated systems that provide guaranteed reliability and accuracy, comfort and ease of use, aesthetics, and real-time results to meet customer expectations. At the core of this type of technology lie sensitive microelectronics and circuitry components that require superior levels of protection from humidity, temperature, and other environmental variables.

Achieving this level of protection can be a hurdle, as these devices endure consistent use in varying environments and need corrosion proofing to ensure reliability, long life, and durability. Liquid ingress is one of the most significant hazards from outdoor exposure. Long-term use without liquid protection can cause degradation, loss of reliability, or even device failure, which would affect users' wellbeing.

Currently, wearable PCBAs are typically protected with traditional liquid conformal coatings, which are thick and heavy, leading to discomfort. Furthermore, more robust corrosion protection solutions may be required to extend the product lifecycle, as many wearables are warrantied for one year and can be repaired and reused.

HZO Parylene's submersion protection levels capable of meeting any IP level make it ideal for devices that must remain on user for days/weeks at a time at a fraction of the mass or weight of alternatives. Additionally, our experience with high volume manufacturing and scalability allows us to tailor solutions to products of varying volume and complexity, suiting our customers' needs as this market continues to grow.

Applications

CONTINUOUS GLUCOSE MONITORS (CGMS)

CGMs are one of the latest technological advancements related to the field of diabetes prevention and management. These devices monitor glucose by inserting a biosensor through a transcutaneous or subcutaneous route. This sensor measures glucose levels in the blood and transmits the information using a transmitter to a receiver/monitor for displaying the results.

Electronics used in these devices must withstand humidity, cleaning fluids, moisture, perspiration, and biofluids while maintaining biocompatibility. Components that must communicate, such as sending signals to instruct, track, or monitor the accuracy of drug delivery, must also have this level of protection without any signal distortion that could cause delivery failure. The ability to meet IP claims is an essential criterion for consumers when they make purchasing decisions.

Additionally, salt-fog protection, the capacity to perform even in high temperatures, and resilience against acids and alkali are valued properties of CGM protection. Most current units rely primarily on seals and encapsulation for this type of reliability, while some use seals and conventional conformal coating for redundant protection.

HZO Parylene protection has excellent moisture, chemical, and biofluid barrier properties. Because of its thinness, it can provide dielectric barrier protection without signal loss or transfer. Additionally, Parylene does not impede electrical communication, as its low dielectric constant ensures minimal energy loss in RF signals, and the thinness of the coating ensures signal transmission integrity.

Parylene thickness and Ingress Protection (IP rating) Correlation

Thickness (µm)	0.1 to 5	5 to 12.5	12.5 to 25
Relevant Standards	IEC 60529	IEC 60529	IEC 60529
Protection Level	IPX3 / IPX4	IPX4 / IPX7	IPX7 / IPX8

Our engineers have domain experience, having worked with these types of devices before, and our ability to scale ensures that we will deliver a reliable solution that can meet your needs as consumer demand grows.

More about HZO

Typically, Parylene is more costly than most other conformal coatings, requiring a batch-style coating process, and sometimes, a longer coating time. HZO addresses these Parylene shortcomings through engineering and manufacturing solutions - we can rise to mass-scale production within a specified budget or deadline.

HZO focuses on creating tight run-to-run repeatability with unique CVD attributes to ensure consistent protection, such as temperature customization, pressure, materials, coverage, and environmental considerations. With the combination of our in-house designed equipment, tested processes, and chemistry, our throughput can be two times faster than the industry standard.

Proprietary equipment with optimized cubed chambers can house more substrates and components than any other Parylene supplier in the industry, decreasing turnaround time and improving throughput. The chambers are larger in size, but the cubed shape also allows for high loading density so that not as much surface area is lost. The numbers of parts coated for medical devices vary, but HZO's manufacturing process allows for efficient high throughput. For reference, around 10,000 – 20,000 hearable device components or batteries may be coated in a single batch. The image below outlines our Parylene process for high-volume applications.

HZO Application Process

1. Pre-Processing

- Inspection of PCBAs/components for quality standards and control for product tracking
- Masking of areas and components where coating is not required
- Masking may be manual or automated depending on the needs of the customer

2. Production

- PCBAs/components situated on custom racks and placed in coating chamber
- Raw material sublimated from solid to vapor form, then heated to transform into an activated monomer
- Vapor forms uniform, thin-film polymer barrier around PCBA/components in coating chamber

3. Post-Processing

- Any previously applied masking material is removed from the PCBA/components
- Removal of masking may be manual or automated depending on the needs of the customer
- Manual or automated inspection of PCBAs/Components before final assembly

MORE ABOUT HZO

Our IP (intellectual property) backed equipment automates the required masking and demasking process to ensure that critical components such as connectors do not get coated. Automated and semi-automated masking and demasking effectively drive down costs associated with the Parylene process. Automated masking and demasking are complex, industry-leading, and somewhat unique to our company. However, if manual masking is your preference, our engineers have the required industry knowledge and expertise to craft an efficient process catered to your business needs and product.

We are also dedicated to quality assurance. Since HZO's inception, there has not been a single product return attributed to coating issues, although we have coated millions of components. Finally, we offer considerable convenience for medical device OEMs and their engineers, with highly configurable processes that integrate into many production points. Our turnkey solution, flexible business models, including factory-in-factory, and hands-on help from dedicated engineers help companies walk through solutions from beginning to end.

Contact one of our engineers for a DFM consultation or initiate a conversation if you want real-world reliability for your medical devices.

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