Contact Lens Technologies for the Performance of MAX[1]

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KEY POINTS

Today's lifestyles	Lifestyles are often visually demanding, with many people directing their attention towards the screens of digital devices for many hours.[2]
The contact lens	ACUVUE® OASYS MAX 1-Day combines two technologies – TearStable™ Technology and the OptiBlue™ Light Filter[3] – for the performance of MAX.[1] A third technology, Pupil Optimized Design, is also employed for the multifocal lens.
TearStable™ Technology	TearStable™ Technology optimizes the distribution of the wetting agent (PVP) throughout the lens and at the surface, reducing evaporation, prolonging tear film stability,[†3–5] and contributing to the superior comfort and increased visual clarity MAX provides[*1].
OptiBlue™ Filter	The OptiBlue™ Filter provides the highest level of blue-violet light filtering[§#3,4]
Pupil Optimized Design	For presbyopic patients, ACUVUE® OASYS MAX 1-Day MULTIFOCAL uses a Pupil Optimized Design to tailor 100% of the optical designs to pupil-size variation across both age and refraction.[**7]

*Compared to ACUVUE® OASYS 1-Day.
†Versus DAILIES TOTAL1®, MyDay®, and INFUSE®, also significantly lower versus ACUVUE® OASYS 1-Day.
§Versus publicly available information for standard daily use contact lenses as of July 2022.
**Compared to competitor's designs, technology optimized for both the parameters of refractive error and add power.
#Filtering of high-energy visible light by contact lenses has not been demonstrated to confer any health benefit to the user, including but not limited to retinal protection, protection from cataract progression, reduced eye strain, improved contrast, improved acuity, reduced glare, improved low light vision, or improved circadian rhythm/sleep cycle. An eye care professional should be consulted for more information.

TearStable™ Technology

- Optimized distribution of wetting agent (PVP) throughout the lens and at the surface.[3-5]
- Patented combination of PVP with a self-hydrating silicone monomer.[8]

Provides:

- Less evaporation: 2x lower rate vs. DAILIES TOTAL1®, My Day® and INFUSE™.[^3,4]
- Prolonged tear film stability: 1.6 times more likely to have a long (>10 seconds) visual tear-film break-up time.[‡ 5]

The Comfort of MAX[1]

- Superior end-of-day comfort.[*1]
- 9 in 10 wearers experience all-day comfort.[1]
- Among heavy users of digital devices, 9 in 10 report a reduction in the feeling of tired eyes from using a computer.[1]

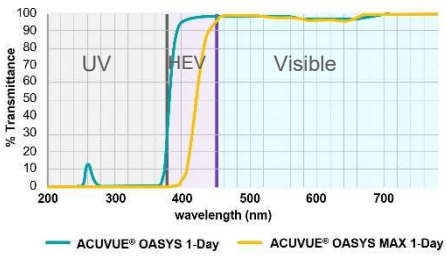
The Clarity of MAX[1]

- Superior clarity when using a computer.[*1]
- Nearly 100% of wearers reported clear, reliable vision.[1]
- Reduces light scatter.[*3,5]
- 9 in 10 wearers report they see comfortably when driving at night.[1]

OptiBlue™ Light Filter[#]

- Filters 60% of blue-violet light – the highest level of any contact lens.[§3,4]
- Preferential filtering within a range of shorter wavelengths.

Contact Lens Spectral Transmittance



*Compared to ACUVUE® OASYS 1-Day.
^Also significantly lower verse ACUVUE® OASYS 1-Day.
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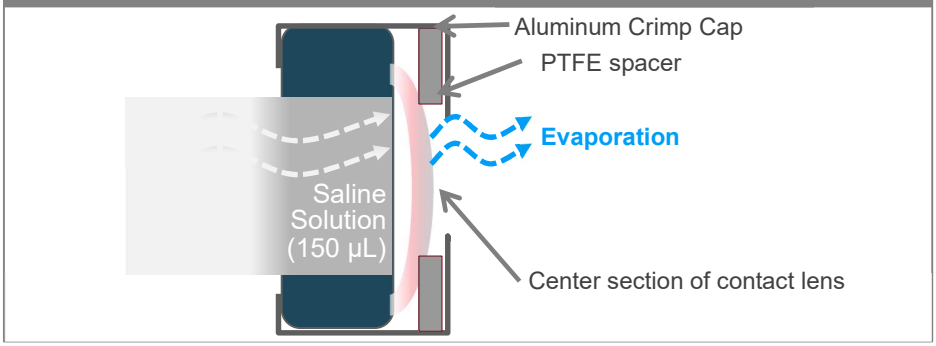
Introduction

In this age of digital technology, today's lifestyles often demand more from our vision. A persistent trend towards longer screen times – and the burden that this can put on eyes – is well documented. Over the last few years, the average time that adults spent using screens has increased by 33% to about 13.5 hours per day.[2] A recent change that may have contributed to this trend is the shift to remote working and the associated increase in video teleconferencing. The number and diversity of digital devices that people use is also on the rise; nowadays, a typical household owns around 25 connected devices.[9] The burden this puts on the eye can include symptoms of both ocular and visual discomfort; these symptoms are likely to be caused by altered blinking and accompanying tear-film issues at all ages,[10–12] accommodative and convergence demands,[13] and glare.[14]

Current Contact Lens Challenges

Given the increasing visual challenges presented by modern lifestyles, contact lens designs must adapt by providing further technological advancements that meet patients' needs. While contemporary contact lenses represent significant advancements compared to their historical counterparts, the scope remains for improving contact lens performance. End-of-day comfort is a key consideration among eye care practitioners, with 74% viewing it as the number-one performance gap for contact lenses.[15] Another important challenge is vision under various lighting conditions, especially dim light. Contact lens wearers can experience fluctuating vision throughout the day, and many patients have difficulties with the visual requirements of driving at night.[16] Lastly, the near vision provided by multifocal contact lenses could also be improved – as some wearers resort to using reading glasses over their contact lenses for particular tasks.[17]

Figure 1. Schematic representation of the pervaporation cell used to measure the pervaporation rates



The Technologies of MAX

To enhance both comfort and clarity, ACUVUE® OASYS MAX 1-Day (AOM1D) employs an unprecedented combination of two innovative technologies: TearStable™ Technology and the OptiBlue™ Light Filter.[3] A third novel technology – Pupil Optimized Design – is included in the multifocal lens. The performance benefits demonstrated by this combination of technologies in the lens shed light on factors that are essential for crisp, clear vision at all distances and in all lighting conditions, plus all-day comfort.[18]

Technology #1: TearStable™

The tear film works in concert with the ocular surface to continuously lubricate, moisturize, smooth, oxygenate, clean, and protect the ocular surfaces.[19] TearStable™ Technology supports a stable tear-film by mimicking the lubrication and moisturizing properties of the tear film.[3–5,20] To do this, AOM1D has a next-generation senofilcon A manufacturing technology which optimizes the distribution of wetting agent throughout the lens and at the surface.[3–5,20]

The lens' wetting agent, high molecular weight polyvinylpyrrolidone (PVP), has experienced longstanding use in the field of medicine, including ophthalmics.[21] PVP is considered to have mucin-like properties; crucially, both have amphiphilic properties (i.e., both hydrophilic and lipophilic properties) that allow both water and lipid components of the tear-film to spread over a surface, enabling moisture retention and lubrication.[22–24] This is designed to lock moisture throughout the lens and across the surface.[3]

A second key feature of this TearStable™ Technology is, like other ACUVUE® OASYS lenses, the patented combination of PVP with a self-hydrating silicone monomer (SiMMA).[25] The silicone monomer, interacts with PVP and water to create a hydrated and biocompatible material.[25]

Pervaporation describes the combination of permeation of fluid through a substance and its subsequent evaporation from the surface of the substance. Pervaporation rate can be determined gravimetrically, as depicted in Figure 1. In most cases, evaporation is the rate-limiting step compared to properties and clinical performance indicate benefits relating to reduced tear evaporation[†3,4] and enhanced tear-film stability.[‡5] With AOM1D, tear evaporation is almost halved when compared to competitor lenses (Figure 2).[†3,4]

† Versus DAILIES TOTAL1®, My Day® and INFUSE®, also significantly lower versus ACUVUE® OASYS 1-Day.
‡ More wearers achieved a visual tear break up time ≥ 10 seconds compared to ACUVUE® OASYS 1-Day.

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Tear film stability is also improved, with wearers of AOM1D being 1.6 times more likely to have a long (>10 s) visual tear-film break-up time (VBUT).‡[5] VBUT is a quantitative measure of the effect of tear-film stability on optical quality and is determined by changes in objective scattering index (OSI) over time. VBUT is the time elapsed from a complete blink to the point at which the subject's vision quality drops below a predefined threshold. Clinical observations suggest that a break-up time of less than 10 seconds is clinically significant.[26] Compared to a leading contact lens, AOM1D increased the proportion of patients with a VBUT >10 seconds, reflecting a superior tear-film stability and optical quality.‡*[5] Given the complexity of the ocular system, *in vivo* experiments such as this are the gold standard for evaluating the effect of contact lenses on tear-film parameters. In contrast, *in vitro* experiments that use model eyes struggle to accurately replicate the ocular surface, the tear film, and blinking.[27]

The prolonged tear-film stability provided by TearStable™ Technology may be a reason why the subjective contact lens experience of wearers is improved with respect to comfort and visual quality.‡‡[1]
Comfort may be improved because the tear-film moisturizes and lubricates the eye. AOM1D achieves superior end-of-day comfort,*[1] and 9 out of 10 wearers reported all-day comfort.[1] AOM1D also provides superior clarity of vision indoors and out,*[1] which may be due to the human tear-film creating an optically transparent, smooth, and highly refractive interface between the eye and the surrounding atmosphere.[1,5]

Technology #2: OptiBlue™ Light Filter#

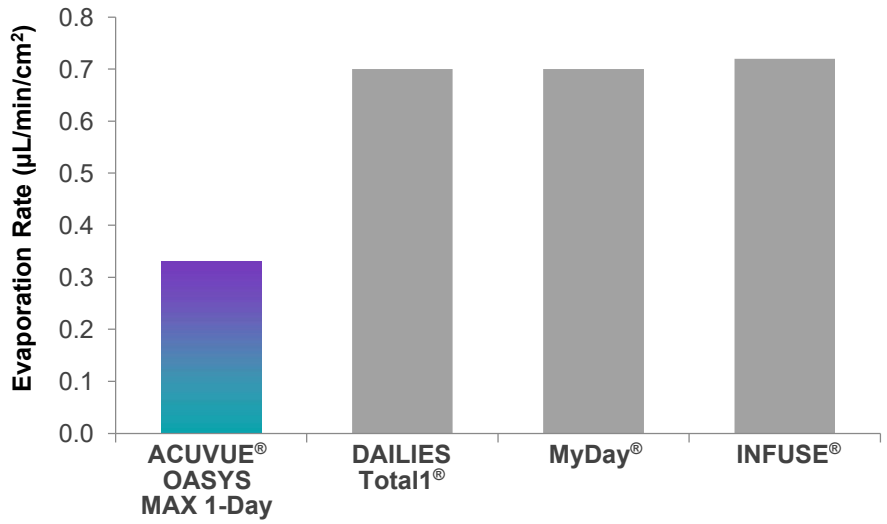
The electromagnetic spectrum spans a broad continuum of wavelengths; at one end of the spectrum, extremely-low-frequency radio waves can have wavelengths larger than planets; at the other end, the wavelengths of gamma rays are smaller than atoms.[28] Only a tiny part of the spectrum (0.0035%) is visible to the human eye.[29]

Shorter wavelengths within the visual spectrum are of particular interest; high-energy blue-violet light (380–450 nm) is more biologically significant than other visible light. Blue-violet light can be emitted from various sources, such as the sun, indoor lighting, car headlights, and digital devices. Depending on the precise wavelength, blue-violet light can have positive or negative effects.

Longer blue wavelengths of around 460 nm to 500 nm are responsible for regulating pupillary light reflexes and circadian rhythm.[30] Intrinsically photosensitive retinal ganglion cells (ipRGCs) are sensitive to these wavelengths of light,[31] and exposure causes pupil constriction, irrespective of age.[32] These cells also play a key role in regulating circadian rhythm (the sleep-wake cycle),[33] with exposure to these wavelengths leading to reduced sleepiness,[34] increased alertness,[35] and increased cognitive function.[36] Therefore, filtering at these longer wavelengths may reduce or delay the associated biological processes.

Some shorter blue-violet wavelengths can have negative effects because of their higher energy. Wavelengths from around 415 to 455 nm have been shown to be particularly phototoxic to retinal pigment epithelial cells.[37] Shorter blue-violet light also has a negative effect on visual comfort and clarity. These wavelengths are more uncomfortable to view than the longer orange/red wavelengths (assuming equal luminous output),[38,39] which can lead to compensating behaviors to help mitigate exposure.[40–42] Shorter wavelengths are also scattered more easily than longer wavelengths – this phenomenon, known as Rayleigh scattering,[43] is responsible for the blue color of the sky during the day and the 'blue haze' observed when looking at distant objects. However, when light scatters within the eye, there is a reduction in retinal contrast

Figure 2. Least square mean pervaporation rate at 40% relative humidity for ACUVUE® OASYS MAX 1-Day, DAILIES TOTAL1®, MyDay®, and INFUSE®. $P \leq 0.0001$ when all lenses are compared to ACUVUE® OASYS MAX 1-Day.[3,4]



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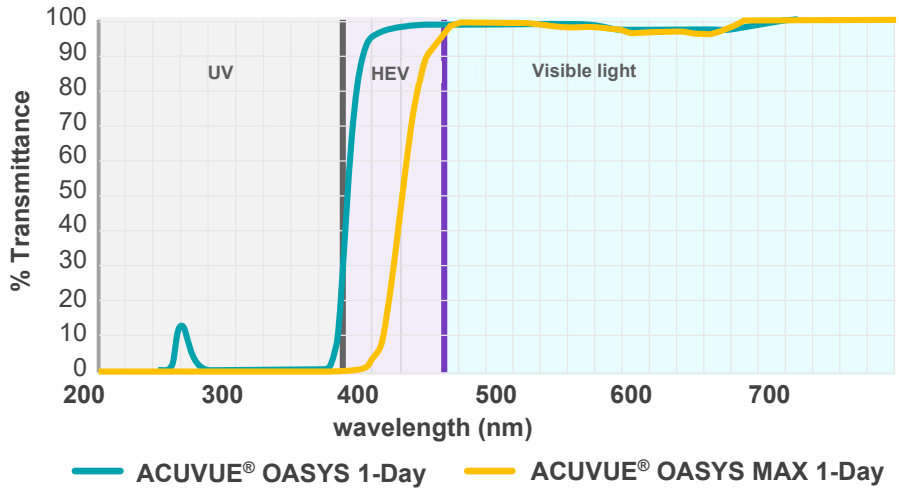
and, in turn, reduced visual clarity.[44]

Scientific literature suggests that filtering blue-violet light can reduce disability glare,[45–48] photostress recovery time,[45,48–52] halo and starburst diameters,[53–55] and eyelid squinting,[47–49,56,57] and improve visual comfort,[38,39,56,58–60] visual contrast,[48,58,59,61–67] chromatic contrast,[48,59,68] and brightness perception.[66,69–72] Not all blue-violet light filters are created equal; they can have different levels of filtering and can act on different regions of the light spectrum. The OptiBlue™ Filter has been developed to provide the highest level of blue-violet light filtering,[§#3,4] reducing blue-violet light transmission by 60% within a range of shorter wavelengths (Figure 3).[#3] This may be a contributing reason why AOM1D wearers experienced a significant improvement of vision indoors in bright light and outdoors,[*1] and they were able to see more comfortably and clearly while using a computer or digital device.*[1] Among heavy users of digital devices, 87% rated a reduction in the feeling of tired eyes from using a computer with AOM1D.[1] Wearers also report the ability to see comfortably while driving during the day and at night.[1] AOM1D reduces light scatter by nearly 20%, starbursts by 23%, and halos by 30%.*[3,5]

Figure 3 also shows the UV blocking characteristics of AOM1D with the lenses absorbing 100% of UVB and 99.9% of UVA radiation.[^,^^4] This is even higher than the existing AO1D family. Both of which qualify as Class 1 UV blocking contact lenses.[^,^^4]

Figure 3. Spectral transmittance curves for ACUVUE® OASYS 1-DAY (teal) and ACUVUE® OASYS MAX 1-DAY (yellow) across a range of wavelengths, including ultraviolet (UV) high-energy visible (HEV) and visible light.



Technology #3: Pupil Optimized Design

As well as reduced accommodation, tear-film stability reduces[73,74] and intraocular light scattering increases with age.[75,76] Of contact lens wearers over age 40, 94% expect to continue in contact lenses.[§§77] Despite this, half of patients over 45 will drop out of contact lens wear.[†] However, 9 out of 10 patients say they would try a new lens if it delivered more comfort and clarity.[78]

With the unprecedented combination of two innovative technologies,[3] AOM1D is well placed to meet the needs of the modern presbyopic patient. Wearers of AOM1D MULTIFOCAL reported high levels of comfort throughout the day and at the end of the day.[18] Wearers also experience crisp, clear vision at all distances and in all lighting conditions.[18]

In addition to TearStable™ Technology and the OptiBlue™ Filter, the multifocal lens of the AOM1D family incorporates Pupil Optimized Design. Pupil size varies with age and refraction: older and more hyperopic eyes tend to have smaller pupils.[80,79] By tailoring optical parameters to pupil-size variation across both near and distance powers, AOM1D MULTIFOCAL is designed for superior visual performance (Figure 4).[‡80] The Pupil Optimized Design also enables a high rate of fitting success, with 96% of patients successfully fit using two pairs of lenses or fewer.**[18]

Clinical Performance of ACUVUE® OASYS MAX 1-Day

Wearers of AOM1D report excellent outcomes for all-day comfort and all-day clarity.[18] These findings are based on the results from four randomized, subject-masked, 2-week dispensing studies: three studies were 2x2 crossover dispensing trials, and one was a two-arm parallel study. In total, the studies enrolled 767 subjects, and 731 subjects completed the studies.

AOM1D provides comfort all day long; compared to habitual lenses, AOM1D

§Versus publicly available information for standard daily use contact lenses as of July 2022.
*Compared to ACUVUE® OASYS 1-Day.
§§Those between the ages of 40 and 64 years old have intention to continue wearing contact lenses based on indicating "Definitely/ Probably would continue wearing contact lenses in the next 12 months".
†JJV Data on File 2021. Growth Levers analysis based on IPSOS Global/Appinio Incidence Tracker, retail outlet consumption data and national census population data covering the United States, United Kingdom, Russia, Japan, South Korea, and China.
‡Compared to prior JJVC multifocal design, technology optimized for both the parameters of refractive error and add power for a multitude of viewing distances and light levels.
**Four lenses in total.
^Helps protect against transmission of harmful UV radiation to the cornea & into the eye.
^^WARNING: UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV-absorbing eyewear as directed. NOTE: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.
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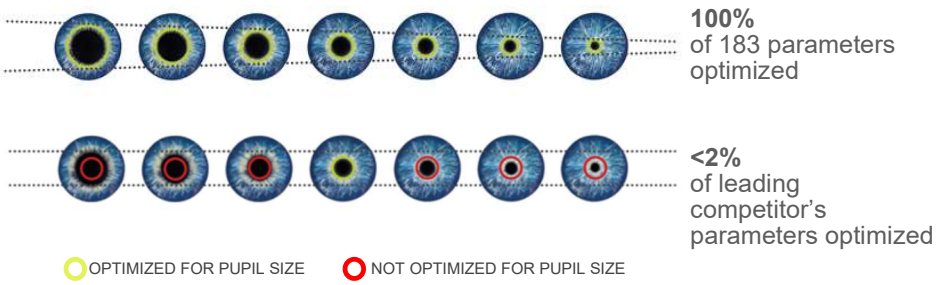
Figure 4. PUPIL OPTIMIZED DESIGN OF ACUVUE® OASYS MULTIFOCAL compared to leading competitor's design.**[7]



was preferred for overall comfort and for comfort throughout the day,‡‡[1] with 9/10 patients experiencing all-day comfort while wearing AOM1D.[1]

AOM1D also provides clear, comfortable vision across a wide range of lighting conditions. For example, wearers have comfortable vision while driving during the day and at night.[1] More than 90% of wearers report the ability to see comfortably when driving at night.[1] Furthermore, when compared to habitual lenses, AOM1D was preferred for overall vision.‡‡[1] Similarly, AOM1D was preferred over habitual lenses for clarity of vision from activity to activity.‡‡[1]

Likewise, the lens shows benefits for viewing digital devices. AOM1D lenses provide the ability to see comfortably while using a computer or other digital device.*[1] Nearly two-thirds of heavy computer users wearing AOM1D rated the reduction in the feeling of tired eyes from using a computer as 'very good' or 'excellent'. Additionally, AOM1D wearers were more likely to report excellent clarity of vision when using a computer or digital device.*[1]

Patient Characteristics

The AOM1D family is designed to help address contact lens needs throughout a lifetime. ECPs may consider prescribing AOM1D if patients report heavy digital devise use, if the patient is having comfort issues with their current contact lenses, if the patient has a compromised tear film (as evidenced by rapid tear break-up time, mild desiccation staining, or a reduced tear meniscus height), or if the patient is interested in blue violet light filtering. In addition, presbyopic patients may benefit from AOM1D MULTIFOCAL, particularly if they struggle with reading close up or in dim light.[18]

Conclusion

Many patients are straining to keep up with today's visually demanding lifestyles. ACUVUE® OASYS MAX 1-Day uses two innovative technologies to deliver the performance of MAX.[1] TearStable™ Technology is our first and only lens material specifically designed to prolong tear-film stability,[5] while OptiBlue™ is a precision light filter that provides the highest level of blue-violet light filtering.#§[3,4] Additionally, ACUVUE® OASYS MAX 1-Day MULTIFOCAL, combines these two technologies with Pupil Optimized Design. Together, these technologies result in a lens family that provides clear vision throughout the day and exceptional comfort.[1,18] Now is the time to offer your patients the performance of MAX.[1]

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Important safety information: ACUVUE® Contact Lenses are indicated for vision correction. As with any contact lens, eye problems, including corneal ulcers, can develop. Some wearers may experience mild irritation, itching or discomfort. Lenses should not be prescribed if patients have any eye infection, or experience eye discomfort, excessive tearing, vision changes, redness or other eye problems. Consult the package insert for complete information. Complete information is also available from Johnson & Johnson Vision Care, Inc. by calling 1-800-843-2020, or by visiting www.jnjvisionpro.com

^Helps protect against transmission of harmful UV radiation to the cornea & into the eye.

^^WARNING: UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses because they do not completely cover the eye and surrounding area. You should continue to use UV-absorbing eyewear as directed. NOTE: Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.

#Filtering of high-energy visible light by contact lenses has not been demonstrated to confer any health benefit to the user, including but not limited to retinal protection, protection from cataract progression, reduced eye strain, improved contrast, improved acuity, reduced glare, improved low light vision, or improved circadian rhythm/sleep cycle. An eye care professional should be consulted for more information.

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