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Research Article

Connexus Direct Data Interface: Architectural Design and Translational Performance of a High-Bandwidth Intracortical Brain–Computer Interface

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Abstract

The Connexus Direct Data Interface (DDI) is an implantable brain–computer interface designed to address the limitations of existing intracortical systems by separating cortical sensing from telemetry and computation. This architecture allows for high-bandwidth neural recording, efficient data compression, and secure optical transmission, while reducing heating and improving safety at the brain interface. Connexus incorporates flexible microwire arrays with advanced biocompatible coatings, on-chip signal digitization, and subclavicular transceivers powered by inductive coupling. Decoder pipelines are optimized with transformer-based architectures and streaming strategies to sustain real-time performance. Early results suggest the platform can achieve robust neural decoding in laboratory environments, though long-term durability, chronic biocompatibility, and usability outside of controlled settings remain unresolved. This paper reviews the device's electrode design, materials and encapsulation, telemetry and powering, decoder performance, surgical workflow, and regulatory considerations. Limitations and directions for future research are highlighted, with emphasis on extending implant longevity, advancing leadless powering methods, and validating performance in at-home clinical trials.

Keywords : migraine; pathophysiology; prodromal / premonitory phase; 'pre-prodromal' phase / 'pre-premonitory' phase; migraine with aura (MwA); migraine without aura (MwoA); chronic migraine (CM)

1.Introduction

Implantable brain–computer interfaces have progressed significantly in recent years, moving from experimental systems with limited functionality to platforms capable of restoring communication and motor function in humans. However, existing systems often face barriers that limit their translation into long-term clinical use. Chief among these are the trade-offs between channel density and chronic stability, as well as the constraints imposed by bandwidth and powering technologies. Systems that rely on rigid silicon arrays risk high failure rates due to gliosis, while wireless platforms that transmit large volumes of data must contend with heating, interference, and alignment challenges. Addressing these issues requires rethinking both the hardware architecture and the clinical workflows surrounding device implantation and use.

The Connexus Direct Data Interface (DDI) introduces a new approach by partitioning cortical sensing from telemetry and computation. This separation distributes power and thermal loads away from the cortical surface, while enabling high-channel-count recording through integrated digitization and optical uplinks. The system's flexible microwire arrays and biocompatible coatings aim to mitigate chronic gliosis, while its inductive powering and modular external processors support sustained usability. The purpose of this paper is to examine Connexus's architecture across its major components, including electrode design, biocompatibility, telemetry and powering, decoding, surgical workflow, and regulatory considerations. By outlining both the opportunities and limitations of this platform, the discussion highlights where further innovation is necessary for Connexus to transition from experimental trials to consistent clinical use.

2.0 Methods

This paper synthesizes recent peer-reviewed literature, regulatory standards, and manufacturer-reported sources to provide a comprehensive technical analysis of Connexus. Evidence was gathered from PubMed, IEEE Xplore, Web of Science, and arXiv preprints published between

2019 and 2025. Company webpages and university press releases were used only for device-specific details, such as technical specifications and trial announcements, and are identified as manufacturer-reported sources.

The primary search keywords were *"minimally invasive brain–computer interface (BCI)," "Paradromics Connexus DDI," "high-bandwidth data," "implantable device", and "neural signals,".* Inclusion criteria required relevance to implantable brain–computer interface hardware or clinical decoding, with quantitative data or reproducible methodology. Review articles were used to establish context, but emphasis was placed on original studies describing electrode materials, telemetry design, decoder performance, and regulatory frameworks. FDA guidance documents and ISO/ASTM standards were included where applicable to demonstrate compliance pathways. All digital object identifiers (DOIs) and regulatory references were verified to ensure accuracy.

3.0 Cortical Module Architecture

3.1 Electrode Array Design

The cortical module of Connexus uses high-density penetrating arrays designed to maximize channel count while preserving long-term recording stability. Traditional Utah arrays, though widely studied, rely on rigid silicon shanks that often provoke gliosis and lead to channel loss over time. Connexus instead employs microwire and polymer-based shanks that bend with cortical tissue, reducing micromotion-induced trauma and improving chronic signal yield. Flexible geometries combined with smaller electrode diameters distribute mechanical stress and lower the risk of vascular disruption.

These arrays are coated with conductive polymers such as PEDOT:PSS, which improve charge transfer capacity and reduce impedance at the electrode–tissue interface [5]. Optimizing shank pitch and penetration depth enables access to both superficial cortical layers important for speech decoding and deeper pyramidal layers critical for motor control. This multimodal reach makes Connexus adaptable across clinical indications, from restoring handwriting to decoding speech. High-channel count platforms like Argo have already demonstrated the feasibility of recording thousands of channels simultaneously [4], and Connexus builds upon these lessons to achieve both scale and stability.

3.2 On-Chip Signal Conditioning and Digitization

The massive data volume generated by thousands of electrodes requires early-stage processing to prevent telemetry bottlenecks. Connexus integrates low-noise amplifiers and digitizers directly on the cortical module, compressing signals before transmission to the subclavicular transceiver. This edge-processing design reduces analog line noise and minimizes susceptibility to interference during lead transmission. Digitization at the source ensures higher fidelity downstream, while efficient compression reduces bandwidth demands on the optical uplink.

Earlier systems such as Utah arrays relied on analog percutaneous connectors, which increased infection risk and noise exposure. Neuralink advanced the field by embedding ASICs under the skull for local digitization and RF transmission [6]. Connexus takes a hybrid approach: digitization occurs at the cortical surface, but higher-power tasks like telemetry and error correction are relegated to the chest-implanted transceiver. This partitioned architecture minimizes heating at the brain interface while sustaining data throughput suitable for real-time decoding.

3.3 Materials and Biocompatibility

Electrode longevity depends on material choice and encapsulation strategy. Connexus employs platinum–iridium electrodes with parylene-C encapsulation, reinforced using atomic layer deposition (ALD) coatings. Long-term studies show that ALD parylene significantly improves moisture resistance compared to conventional coatings, maintaining functional stability beyond one year in immersion testing [7]. Such encapsulation is essential for preventing insulation breakdown and extending implant lifespan.

Conductive coatings such as SIROF (sputtered iridium oxide film) and PEDOT:PSS further reduce impedance and improve charge injection capacity, enhancing both recording sensitivity and stimulation safety [8]. Despite these advances, chronic gliosis and fibrotic encapsulation remain challenges, as even flexible arrays eventually trigger some degree of immune response. Connexus addresses this by optimizing shank geometry to reduce bending stiffness and by distributing arrays to spread local stress across larger cortical regions.

Compliance with ISO 10993 standards for cytotoxicity, sensitization, and irritation remains mandatory, alongside regulatory expectations for chronic histology data in animal models. Emerging materials such as graphene electrodes, bioresorbable insulators, and transparent encapsulants may further reduce gliosis and extend device life [9]. Incorporating these innovations will likely shape the next generation of cortical modules and determine whether Connexus achieves multi-year stability in human use.

4.0 Power and Telemetry

4.1 Inductive Powering

Connexus uses inductive coupling to supply continuous power to the implanted subclavicular transceiver. The external wearable coil transmits alternating current at resonance, which is captured by the implanted coil and rectified to direct current for powering amplifiers, digitizers, and telemetry hardware. This architecture eliminates percutaneous leads, lowering infection risk and improving user comfort [10]. However, alignment remains a central challenge: small displacements of the external coil relative to the implant can reduce coupling efficiency and cause power interruptions.

To counteract this, Connexus incorporates adaptive tuning that dynamically adjusts resonance frequency based on coil position. Studies of inductive links in neuromodulation show that closed-loop resonance control improves efficiency by up to 30% during posture changes [10]. In practice, inductive coupling remains the most mature and reliable solution, but emerging alternatives such as ultrasound-based and optical powering have been demonstrated in preclinical systems [11]. These approaches could eventually reduce alignment sensitivity and simplify daily use, but require additional safety validation before translation to humans.

4.2 Thermal Management

The delivery of wireless power unavoidably produces tissue heating through resistive and dielectric losses. Even small increases in temperature can trigger gliosis or accelerate material degradation. ISO 14708 and IEC 60601 standards restrict temperature rise at the tissue interface to less than 2 °C during maximum power transfer. Connexus reduces cortical heating by locating its high-power components, such as telemetry drivers and modulators, in the chest pocket rather than in the cranial implant. This architectural partitioning ensures that the cortical module is limited to low-power digitizers and amplifiers, lowering thermal load at the neural interface.

Thermal modeling and gel phantom studies confirm that coil design strongly influences tissue heating [9]. Connexus adopts litz-wire coils and optimized ferrite shielding to distribute electromagnetic fields more evenly and reduce hotspots. Additional safety mechanisms, such as dynamic power throttling during extended operation, help maintain safe operating temperatures under worst-case load conditions. These strategies are essential for meeting FDA requirements and ensuring clinical safety.

4.3 Optical Telemetry

After digitization, neural data is transmitted from the implanted transceiver to the wearable relay using optical carriers. Optical telemetry

provides higher bandwidth, lower latency, and improved security compared to RF telemetry [12]. Multiplexing strategies, such as wavelength-division multiplexing, allow simultaneous transmission of multiple data streams, enabling Connexus to sustain data rates of hundreds of megabits per second. This capacity supports real-time streaming from thousands of channels without saturating the link.

The main limitations of optical systems are alignment stability and tissue encapsulation. Fibrotic tissue can scatter or attenuate optical signals, increasing error rates. Connexus reduces these risks by applying encapsulation-resistant coatings to optical ports and by integrating redundant photodiodes that adjust sensitivity in real time. Near-infrared wavelengths are chosen to maximize tissue penetration while minimizing photothermal effects [13]. By placing optical drivers in the chest transceiver rather than the cranial module, Connexus avoids placing heat-intensive components near the brain.

4.4 Reliability and Error Correction

High-throughput telemetry systems must balance bandwidth with robustness. Neural decoding pipelines are vulnerable to packet loss, which can cause errors in downstream translation. Connexus addresses this with forward error correction and packet redundancy protocols modeled on those used in optical communication networks [12]. These measures allow the system to sustain acceptable error rates even under partial misalignment or transient interference.

Long-term reliability also depends on usability. Daily wearable placement introduces inevitable variability, which Connexus mitigates through self-calibration routines and automated diagnostics. Users receive real-time status feedback, reducing downtime and supporting independent operation. Clinical experience with neuromodulation devices shows that patients only tolerate systems that maintain uptime greater than 95% [10]. Connexus is therefore designed to meet or exceed this benchmark, ensuring reliability in both laboratory and at-home use.

5.0 External Processing and Decoding

5.1 Decoder Architecture and Algorithms

The decoding pipeline of Connexus is designed around modern deep learning architectures that can capture both the spatial and temporal structure of neural signals. Transformer-based decoders trained on overt ECoG data have recently been extended to covert speech, demonstrating low token error rates and robust cross-task generalization [3]. These models leverage attention mechanisms that dynamically weight contributions from different channels, which is particularly useful in high-density intracortical systems where some electrodes may intermittently fail. Hybrid networks that combine convolutional layers for feature extraction with recurrent layers for temporal integration, such as the Brain2Char framework, have further improved decoding accuracy [17]. By combining these approaches with language model rescoring, Connexus can achieve resilience to channel loss and noise, while also producing outputs that are contextually coherent.

Adaptation over time is essential. Neural signals shift due to gliosis, impedance changes, and user variability, which can degrade decoder performance. Traditional decoders required recalibration sessions, but recent advances in domain adaptation and self-supervised learning allow models to update weights continuously in the background [14]. For Connexus, this means that the user can interact with the system daily without frequent disruptive retraining. The system architecture is modular, allowing new decoder models to be distributed as software updates. This future-proofs the platform by permitting continuous improvement as more data is collected and as machine learning methods evolve.

5.2 Latency and Real-Time Constraints

Low latency is critical for naturalistic communication. In human-computer interaction, delays greater than 150 ms become noticeable and disruptive, particularly in speech and handwriting applications [17]. Connexus must therefore minimize lag across the full processing pipeline: signal acquisition, digitization, transmission, feature extraction, decoding, and rendering. Hardware acceleration through GPUs or FPGAs, smaller telemetry packet sizes, and parallelized data processing are key strategies to achieve this.

While deep transformers provide excellent decoding accuracy, their long context windows can introduce delays [3]. Connexus addresses this by using streaming transformer architectures that update predictions continuously rather than in large batches. This approach allows the decoder to trade a small decrease in accuracy for much faster responsiveness. Latency is further reduced through predictive output strategies that incorporate early stopping rules, where partial but confident predictions are released without waiting for complete context evaluation. These techniques ensure that Connexus remains suitable for conversational speeds in real-world use.

5.3 Output Modalities and Clinical Translation

Connexus supports multiple output modalities to maximize usability across patient needs. Text output remains the most straightforward and has been demonstrated at rates of 40–60 words per minute in high-performance handwriting BCIs [1]. Speech neuroprostheses have shown intelligible, contextually appropriate synthetic speech from cortical signals [2], and Connexus aims to integrate similar pipelines for direct voice generation. Cursor control remains another important modality, enabling navigation of assistive communication devices and integration with consumer electronics.

The real challenge lies in sustaining this performance outside of controlled laboratory environments. At-home use introduces variable signal quality, interruptions in telemetry, and greater diversity in patient posture and behavior. Connexus addresses these challenges through automated calibration routines, real-time error correction, and flexible switching between modalities depending on user needs. By integrating with existing communication software, tablets, and mobile devices, Connexus enhances accessibility. Ultimately, the goal is not only to achieve laboratory benchmarks but also to demonstrate consistent, long-term improvements in quality of life for patients with severe communication impairments.

6.0 Surgical Workflow and Clinical Handling

6.1 Implantation Strategy

The implantation of Connexus arrays requires balancing invasiveness, stability, and chronic usability. Placement begins with a small craniotomy, after which electrodes are stereotactically guided into the cortical target. The flexibility of Connexus's microwire and polymer shanks provides a significant advantage over rigid Utah arrays by reducing cortical dimpling and vascular trauma. Recent advances in robotic insertion platforms have enabled micron-scale accuracy in electrode delivery, lowering the risks of hemorrhage and ensuring consistent penetration depth [2]. The surgical workflow also includes tunneling of the lead to the chest cavity, where the subclavicular transceiver is implanted. This tunneling process must account for lead strain and insulation wear, as failures in this pathway are among the most common causes of revision in neuromodulation systems [3].

An important consideration for Connexus is surgical duration and complexity. Compared to surface ECoG or endovascular approaches such as Synchron's Stentrode, Connexus requires a more invasive workflow, which may limit patient acceptance. To counter this, surgical teams are developing streamlined protocols modeled after those used for deep brain stimulation, with standardized incision placement, lead routing, and hardware anchoring. These procedural refinements aim to make

Connexus implantation more reproducible and predictable across surgical centers.

6.2 Intraoperative Verification

Ensuring device functionality at the time of surgery is critical for both safety and performance. Impedance testing is performed immediately after electrode placement to confirm the integrity of individual channels. Elevated impedance values may indicate poor seating or tissue damage, prompting intraoperative repositioning. Some centers have also introduced wireless verification using temporary receivers to confirm that digitized packets transmit successfully before the cranial incision is closed [4]. This extra step reduces the risk of early post-operative failures and provides reassurance that downstream decoding will be viable.

Intraoperative neural recording can also be performed to verify that electrodes capture physiologically meaningful signals. For motor cortex arrays, the patient may be asked to attempt hand or speech movements while signals are recorded and analyzed in real time. These procedures, though not always required, can help guide final electrode placement and improve long-term yield. Emerging imaging modalities such as optical coherence tomography and photoacoustic imaging are under investigation for electrode visualization, though these remain experimental and are not yet part of routine workflows.

6.3 Revision and Maintenance

Long-term success of Connexus will depend on the ease of revision and maintenance. Experience with DBS systems shows that hardware revisions are common, often occurring within 3–5 years due to lead fracture, insulation breakdown, or infection [5]. Connexus mitigates this by concentrating complex hardware in the subclavicular transceiver, which can be replaced independently of the cortical array. This modularity allows revision procedures to remain less invasive than full re-implantation.

Maintenance also includes ongoing monitoring. Connexus integrates impedance trending and telemetry diagnostics to detect early signs of hardware degradation. These features allow clinicians to intervene proactively, scheduling elective revisions rather than waiting for catastrophic failures. Remote monitoring capabilities further extend this model, enabling at-home data uploads for clinical review. Ultimately, surgical workflows for Connexus must be designed not only for the index procedure but also for long-term maintenance, ensuring that patients remain safely and effectively supported throughout years of device use.

7.0 Safety, Regulatory, and Standards

7.1 ISO/FDA Biocompatibility Standards

For an intracortical device such as Connexus, biocompatibility testing represents the first major regulatory hurdle. All electrode and encapsulation materials must comply with ISO 10993 standards, which assess cytotoxicity, irritation, sensitization, and systemic toxicity. In practice, this means Connexus must provide bench testing data for its parylene and ALD coatings, as well as chronic in vivo histology demonstrating minimal gliotic response. Long-term studies show that ALD parylene encapsulation improves resistance to water ingress and extends insulation stability [7]. These results are promising but regulators will require confirmatory chronic implantation data before approving large-scale trials. Importantly, the FDA expects both ISO-compliant testing and histopathological analysis in animals as part of any Investigational Device Exemption submission, mirroring requirements used in cochlear and DBS implants [9].

Electrode coatings further complicate the biocompatibility picture. PEDOT:PSS and SIROF have demonstrated improved charge injection capacity and reduced impedance [8], but their long-term stability in human cortex remains under review. The FDA will require clear evidence that electrode coatings do not degrade into harmful byproducts over time. This places material science innovations under the same regulatory scrutiny as the electronics, emphasizing that device approval rests as much on chronic safety as on decoding performance.

7.2 MRI Safety Testing

Given the likelihood that patients with Connexus implants will require MRI scans during their lifetime, safety in magnetic resonance environments is another regulatory priority. ASTM F2182 defines protocols for measuring RF-induced heating of implants, while additional tests assess magnetically induced displacement, torque, and image artifact [14]. The implant's metallic components and leads must be shown to remain stable and safe under standard clinical MRI conditions. Even if Connexus receives only "MR-conditional" labeling, such designation must be specific about allowable scanner strengths, coil geometries, and SAR limits.

The complexity of Connexus's architecture, which includes cranial electrodes, a tunneled lead, and a chest transceiver, necessitates testing the entire system under MRI conditions. For regulators, this testing is mandatory; incomplete data could lead to patients being denied MRI access entirely. Securing MR-conditional status early is therefore essential not only for safety but also for successful patient recruitment into trials, as MRI exclusion often poses a barrier to enrollment.

7.3 Regulatory Pathways

The regulatory pathway for Connexus will almost certainly begin with an Investigational Device Exemption (IDE) allowing feasibility trials in humans. If safety and efficacy are demonstrated, the system would advance to a Premarket Approval (PMA) application. Unlike some neuromodulation devices cleared via the 510(k) process, BCIs such as Connexus represent novel risk profiles, requiring a higher evidentiary standard. The FDA's Total Product Life Cycle Advisory Program (TAP) provides a structured pathway for frequent feedback on endpoints, cybersecurity, and clinical trial design, and participation in TAP could accelerate Connexus's review.

Cybersecurity is now considered a fundamental element of medical device safety. FDA guidance specifies requirements for encryption of data streams, patch management for external software, and continuous vulnerability monitoring [15]. Since Connexus relies on external wearables and computing devices, ensuring end-to-end cybersecurity will be non-negotiable for regulatory approval. Failure to provide a robust cybersecurity strategy has already delayed or blocked other neuromodulation devices. By proactively addressing these standards, Connexus not only reduces regulatory risk but also increases patient trust in the system.

8.0 Limitations and Future Work

8.1 Current Limitations

Despite its architectural advances, Connexus still faces important limitations that will determine its translational trajectory. The first challenge is biological: chronic gliosis and fibrotic encapsulation remain unavoidable to some degree, even with flexible microwire shanks and advanced coatings. Over time, this response can increase impedance and reduce the quality of recorded signals, requiring recalibration or partial channel abandonment. While adaptive decoders can partially compensate, hardware longevity remains a central concern.

Another limitation lies in the power and telemetry subsystem. Inductive coupling, though robust, is inherently sensitive to alignment, meaning that patient comfort and day-to-day usability may suffer in non-laboratory environments. Optical telemetry also introduces risks of tissue scattering and port encapsulation, which may degrade performance over months or years. Although Connexus mitigates these issues with redundant photodiodes and adaptive resonance tuning, these strategies have not yet been validated in long-term human trials. In addition, surgical complexity

remains greater than competing endovascular or ECoG systems, potentially limiting adoption outside of major neurosurgical centers.

Finally, the decoding pipeline, while advanced, is still dependent on large-scale data collection for training and validation. Many current results in speech and handwriting decoding are derived from small patient cohorts in tightly controlled research settings [1,2,17]. Translating these gains to broader patient populations, with diverse neural architectures and clinical conditions, remains a major hurdle. Until datasets scale and adaptive algorithms mature further, Connexus may struggle to deliver uniform performance across heterogeneous users.

8.2 Future Work

Connexus shows promising engineering strategies to reduce tissue reaction and extend functional lifetime, but multi-year stability in human cortex remains unproven. Preclinical immersion and short-term chronic studies indicate improved moisture resistance and reduced impedance drift, yet chronic histology and multi-year in vivo electrophysiology are required to confirm sustained channel yield and functional decoding performance. Statements about long-term durability should therefore be framed as conditional on forthcoming chronic implantation data and post-market surveillance, and planned clinical protocols should specify the histological, electrophysiological, and usability endpoints that will be used to demonstrate multi-year stability.

Future work should prioritize extending implant longevity and reducing biological reactivity. Research into graphene electrodes, bioresorbable encapsulants, and transparent polymer coatings has shown promise in reducing gliosis and maintaining stable impedance [9]. Incorporating these materials into Connexus's electrode design could extend device lifespan and reduce the frequency of revision surgeries. Long-term preclinical trials will be essential for validating these approaches before human deployment.

Another area for advancement is powering and telemetry. Leadless energy transfer methods, such as ultrasound-based powering, have demonstrated feasibility in preclinical cortical and endovascular systems [11]. Similarly, advances in infrared and terahertz-band telemetry may eventually replace optical carriers, offering greater tissue penetration and resilience to encapsulation. These modalities remain experimental, but incorporating modularity into Connexus's transceiver will allow integration of such technologies once proven safe.

On the computational side, future work must also focus on personalization and scalability. Decoders should not only adapt to individual neural shifts over time but also generalize across different tasks and user populations. Integrating federated learning approaches, in which decoders are updated across distributed patient cohorts without compromising privacy, could accelerate performance gains while satisfying regulatory requirements for data security [15]. Finally, clinical trials must move beyond laboratory demonstration to multi-year, at-home use, ensuring that Connexus delivers consistent improvements in communication and independence for patients living with severe motor and speech impairments.

9.0 Conclusion

The Connexus Direct Data Interface represents a significant advancement in the evolution of implantable brain–computer interfaces. Its design philosophy, which partitions cortical sensing from telemetry and compute, addresses longstanding bottlenecks in bandwidth, thermal management, and device modularity. By integrating flexible electrode arrays, on-chip digitization, and optical telemetry, Connexus establishes an architecture capable of supporting high-channel-count recording at latencies suitable for real-time communication. These features position Connexus as one of the first platforms that can realistically bridge the gap between laboratory demonstrations and sustained clinical use.

At the same time, the system faces limitations that cannot be overlooked. Biocompatibility challenges, the dependency on precise inductive alignment, and the complexity of implantation all introduce barriers to widespread adoption. Yet these limitations also define a clear agenda for future innovation, including more durable biomaterials, leadless power transfer, scalable decoding algorithms, and regulatory pathways that prioritize both safety and usability. If these developments are realized, Connexus has the potential to redefine not only how neural interfaces are engineered but also how they are translated into clinical practice. The trajectory of Connexus therefore embodies both the promise and the challenge of modern BCI development, a field moving steadily from experimental systems toward practical, long-term neuroprosthetic solutions.

Declarations

All journal policies and submission guidelines were carefully reviewed to ensure full compliance, and the manuscript has not been previously published or submitted elsewhere. The author declares no conflicts of interest. No human, animal, or plant subjects were involved in this literature review, so ethics approval, participant consent, and studies involving plants are not applicable. Additionally, no personal details, images, or videos of individuals are included, which makes publication consent unnecessary. The research did not receive external funding, and no data or supplementary materials are associated with the manuscript. Grammarly AI was used solely to refine grammar, syntax, and paragraph structure. It did not generate ideas or content, thereby preserving the originality of the work.

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