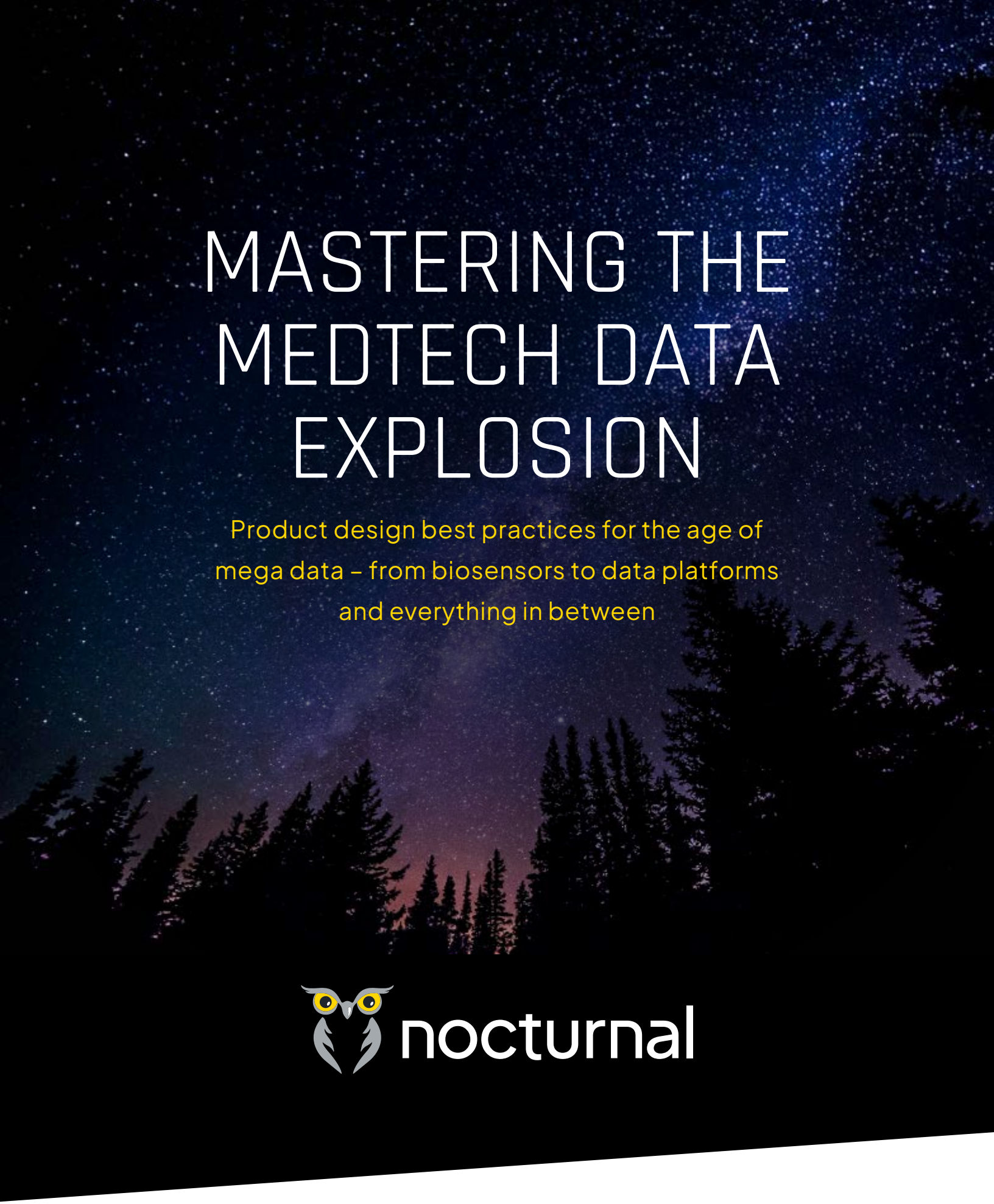

MASTERING THE MEDTECH DATA EXPLOSION

Product design best practices for the age of mega data – from biosensors to data platforms and everything in between

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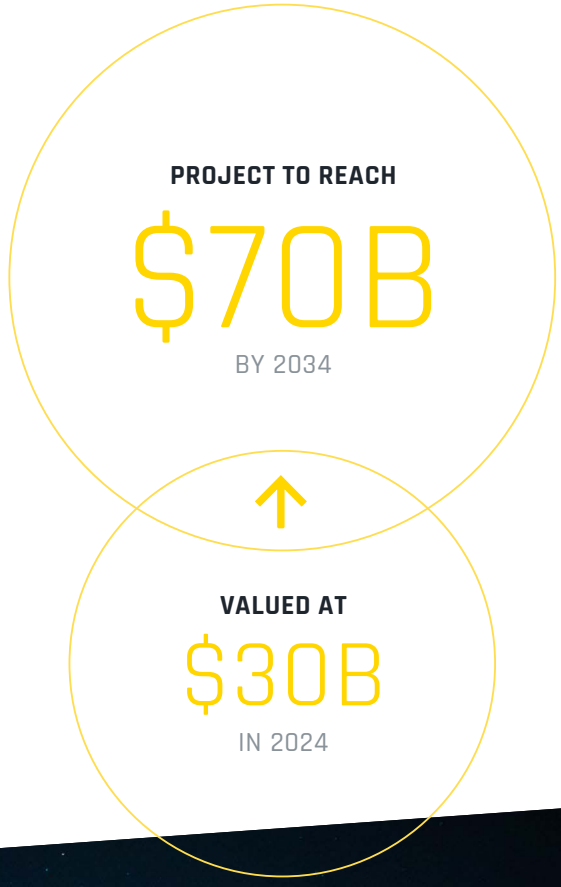
1 THE BIOSENSOR DATA EXPLOSION

The biosensors market is expanding rapidly, valued at $30 billion in 2024 and projected to reach $70 billion by 2034.[1] With this growth comes an overwhelming volume of biosensor-generated data, offering unprecedented insights into human health.

At the same time, this wealth of biosensor data presents new challenges in data collection, storage, processing, and interpretation.

Wearable and implantable devices now generate **millions of biosignal data points daily**, spanning heart rate variability, neural activity, glucose levels, and other critical physiological markers.



This surge in data volume doesn't automatically translate to improved clinical outcomes. Instead, the ability to **extract meaningful insights while maintaining device operational efficiency** is the true measure of success.

To fully leverage biosensor data, medical device manufacturers must implement robust data strategies from the earliest stages of development. The key challenge is striking the right balance between **data granularity, processing efficiency, and clinical relevance**.

[1] Source: Nova One Advisor

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2 DATA STRATEGY: MORE IS NOT ALWAYS BETTER

While the capacity to collect vast amounts of biosensor data presents exciting opportunities, excessive data collection can create unnecessary complexity and operational challenges, such as:

- **Power drain:** Continuous data streaming can significantly shorten device battery life.
- **Processing overload:** Large volumes of data require excessive computational resources to make them usable.
- **Increased noise:** Greater noise-to-signal ratio makes it harder to extract meaningful insights.
- **Regulatory challenges:** The more data collected, the more stringent security, compliance, and quality system requirements become.

THE SMARTER APPROACH TO CLINICAL DATA

A well-structured data strategy ensures that only high-quality, actionable data is collected, leading to more efficient processing and better decision-making.

Instead of capturing every possible data point, medical device developers should focus on:

- **Prioritizing clinically relevant information** over raw data volume.
- **Using intelligent monitoring and event-triggered recording** to capture timely meaningful signals.
- **Optimizing sensor placement and calibration** to ensure accurate data collection from the start.

3 QUALITY SIGNAL ACQUISITION

The foundation of effective biosensor data processing starts with **signal accuracy**. Without precise and reliable signal acquisition, even the most advanced data processing techniques cannot compensate for poor input.

Quality data acquisition ensures that every data point collected contributes to a clear and accurate picture of patient health. This means selecting the right sensors, reducing interference, and implementing mechanisms to validate the accuracy of collected signals.

KEY FACTORS IN HIGH-QUALITY SIGNAL CAPTURE

A well-designed biosensor system should focus on **accuracy over volume**, ensuring that the captured data is both **high-fidelity and clinically meaningful**.

- **Sensor selection:** Choose the right biosensors to capture the most relevant physiological signals.
- **Sensor location:** Place sensors in physiologic locations that balance the usability of all collected data for the application.
- **Noise reduction:** Reduce motion artifacts and environmental noise that can distort data.
- **Calibration and validation:** Ensure sensors are properly calibrated to maintain accuracy over time and across different environments.
- **Adaptive data collection:** Use dynamic sampling techniques that adjust collection frequency based on signal relevance.
- **Error detection and correction:** Implement robust mechanisms to detect and correct anomalies in real time.

OPTIMIZE BIOSENSOR INTEGRATION FOR FASTER DEVICE DEVELOPMENT

Combining expertise in sensor manufacturing and product design, **Linxens** and **Nocturnal** have partnered to help device innovators fast-track the development of life-enhancing medical devices by integrating Linxens' electronic skin patches and biosensors with Nocturnal's design solutions.

→ Learn more about our partnership and contact us for additional details.

Image courtesy of Linxens

4 BALANCING POWER CONSUMPTION AND DATA COLLECTION

For implantable medical devices, power consumption is a critical factor impacting device longevity as well as patient comfort and compliance. Every additional data point collected has a direct impact on **battery life, processing time, and storage requirements**.

With these considerations in mind, implantable devices must be designed with an **efficient data acquisition model** to carefully balance the need for high-resolution data with power efficiency.

Achieving this balance requires smart data collection strategies, optimized hardware, and power-efficient processing methods that ensure long-term device operation without compromising functionality.

OPTIMIZING POWER WITHOUT COMPROMISING DATA QUALITY

A well-designed biosensor system should focus on **accuracy over volume**, ensuring that the captured data is both **high-fidelity and clinically meaningful**.

- **Event-based data collection:** Devices should record data only when specific physiologic thresholds are met.
- **Low-power signal processing:** Use efficient algorithms to filter and preprocess data only as much as truly necessary before transmitting it.
- **Precision over quantity:** Capture only the most relevant biosignals instead of streaming all available data continuously.
- **Hardware optimization:** Design sensors and circuits that consume minimal power while maintaining data fidelity.
- **Smart sleep and wake cycles:** Implement power-saving modes that enable devices to sleep as deeply as possible when data collection or transmission is unnecessary.

> By implementing smarter data collection techniques, device developers can extend battery life, enhance performance, and improve patient outcomes.

5 EFFICIENT AND EFFECTIVE DATA PROCESSING

Raw biosensor data is only valuable if it can be effectively processed and transformed into meaningful insights. High-resolution data, if not managed properly, can introduce unnecessary noise, increase computational load, and delay critical decision-making.

Effective data processing ensures that every captured signal is cleaned, analyzed, and structured to provide actionable intelligence. AI-driven algorithms can further refine this process, enhancing the ability to detect anomalies, predict patient outcomes, and deliver personalized therapies.

STEPS FOR EFFECTIVE DATA PROCESSING

By refining **the entire data pipeline**, biosensor data becomes **actionable, reliable, and clinically meaningful**.

- ☑ **Preprocessing:** Clean and filter raw data to remove noise and artifacts.
- ☑ **Data compression:** Reduce data size without losing critical information to optimize storage and transmission.
- ☑ **Resource allocation:** Process data off-device whenever possible to reduce power and storage overload.
- ☑ **Feature extraction:** Identify clinically significant patterns within the biosignal.
- ☑ **AI-driven analysis:** Apply machine learning models to detect trends, predict outcomes, and support real-time decision-making.

6 DATA MANAGEMENT COMPLIANCE AND CONTROL

Managing vast amounts of biosensor data presents significant challenges, including complying with regulatory standards, ensuring cybersecurity, and providing real-time accessibility.

Data management platforms provide a turnkey solution for securely processing, analyzing, and visualizing biosensor data in a compliant environment. These platforms accelerate time to market by allowing medical device companies to focus on innovation rather than building, maintaining, and securing their data infrastructure.

WHAT TO LOOK FOR IN YOUR DATA PLATFORM

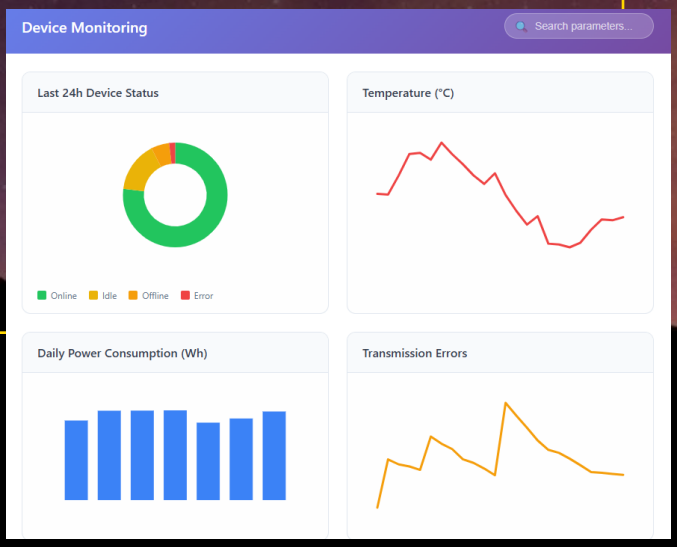
- **ISO 13485–certified storage:** Ensure compliance with medical device regulations.
- **HIPAA and cybersecurity compliance:** Protect patient data and simplify regulatory submissions.
- **IP protection:** Allow proprietary algorithms to process data securely without exposing intellectual property.
- **Built-in analytics and visualization:** Transform raw biosensor data into meaningful insights.
- **Data enrichment capabilities:** Allow layering of additional contextual information to improve decision-making.
- **Seamless data integration:** Enable smooth communication between device firmware, mobile applications, and cloud storage.
- **Scalability and flexibility:** Support device evolution from prototype to clinical trials and commercialization.

TAKE CONTROL OF YOUR CLINICAL DATA FROM DAY ONE WITH NO EXTRA COST, TIME, OR RESOURCES.

Early integration of a secure, regulatory-compliant data platform prevents costly delays and simplifies clinical validation.

Working with Nocturnal, medical device developers gain instant access to a scalable cloud platform for managing clinical data—without additional infrastructure costs.

→ Contact us to learn more.



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7 CYBERSECURITY CONSIDERATIONS

This section is contributed by CyberMed, security specialists helping medical device manufacturers meet FDA cybersecurity requirements.

Biosensor data transmission introduces potential vulnerabilities that could expose sensitive health information or disrupt device operation, leading to patient harm.

A strong cybersecurity strategy protects biosensor data while meeting regulatory requirements. The FDA's 2023 guidance for Cybersecurity in Medical Devices mandates robust security measures throughout the total product lifecycle (TPLC) to protect patients from cyber threats.

The FDA emphasizes that risk assessments must consider not only physical harm but also indirect consequences, such as data breaches and unauthorized device access. ANSI/AAMI SW96:2023 complements FDA guidance by providing a structured approach to security risk management, including threat modeling, vulnerability identification, and risk control throughout a device's lifecycle.

KEY CONSIDERATIONS FOR DEVICE SECURITY

- **Threat modeling and risk assessment:** Identify potential cybersecurity threats early in development and assess their impact on device safety and performance, as mandated by the FDA and detailed in SW96.
- **Secure data transmission:** Implement encryption and authentication to protect data as it moves from biosensors to processing platforms, ensuring compliance with HIPAA and FDA premarket submission requirements.
- **Software Bill of Materials (SBOM):** Generate an inventory of software components for analysis during development and post-market to enable rapid identification and patching of vulnerabilities.
- **Postmarket vigilance:** Establish processes for monitoring emerging threats and delivering timely patches, aligning with SW96's focus on lifecycle security and the FDA's emphasis on ongoing risk management.
- **Interoperability security:** Ensure safe integration with external systems, addressing the FDA's call for secure device interactions within broader healthcare networks.
- **Power efficiency:** Since encryption and authentication processes consume power, implementing security measures in energy-constrained implantable devices requires careful optimization to balance protection and efficiency.

By integrating these security practices into their design process, device manufacturers can mitigate risks such as unauthorized access and data tampering, ensuring that biosensor data remains trustworthy and clinically useful. Implementing these practices is also key to facilitating regulatory approval by demonstrating reasonable assurance of safety and effectiveness, a key FDA requirement.

8 KEY TAKEAWAYS

MORE DATA IS NOT ALWAYS BETTER – Focus on clinically relevant, high-quality data rather than excessive raw signals.

USE AI-DRIVEN DATA ANALYSIS – Transform raw biosignals into actionable insights through advanced algorithms.

OPTIMIZE POWER EFFICIENCY – Apply event-based data collection and efficient processing to reduce energy consumption.

LEVERAGE DATA PLATFORMS – Use secure, regulatory-compliant platforms to simplify storage, analytics, and regulatory approvals.

The future of biosensor-driven healthcare depends on **smarter, not just bigger, data**. By mastering **signal acquisition, processing, and management**, medical device developers can **improve patient outcomes, enhance device performance, and streamline regulatory compliance**.

WHAT YOU GET WHEN PARTNERING WITH NOCTURNAL

Hard-to-find expertise in biosensor data acquisition and processing
"Been there done that" makes a difference when it comes to complex medical device hardware and software development.

Cash-preserving result-based pricing
Our milestone-based pricing allows you to plan your budget with confidence and draw a viable path to commercial success.

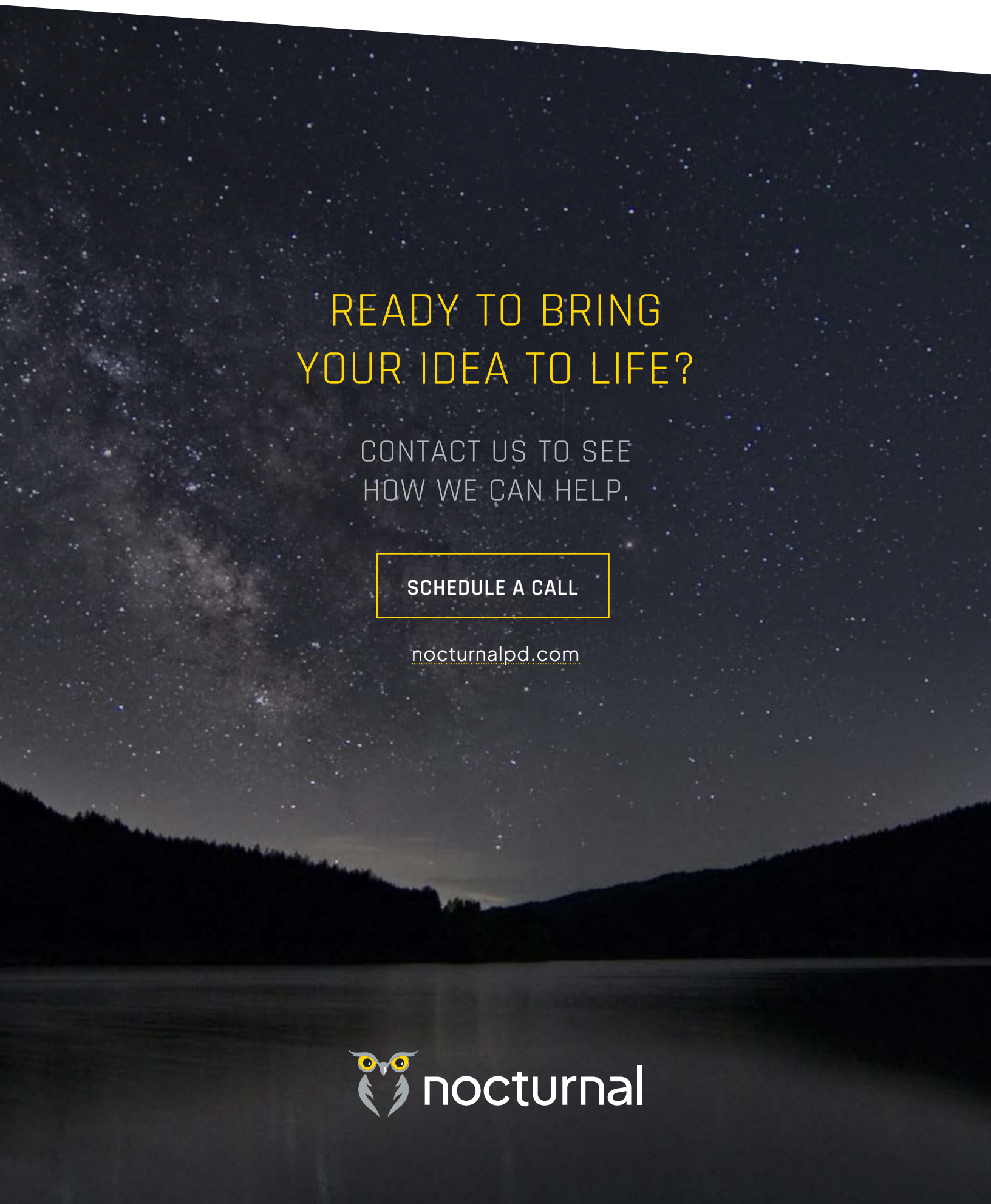
Device-ready building blocks for a quick head start
Using our rich library of hardware designs, software code, and documentation templates — we can get you faster to the finish line while minimizing project risk.

All hands on deck
We are a small team so you always work directly with our best and brightest, because that's all we have.

No surprises. Period.
Complete transparency throughout the project so you always know where you are.

"Working with Nocturnal has dramatically accelerated our time-to-market. In just one year, Nocturnal took our implantable cardiac monitor from a concept to a fully functional device with a mobile application and secure cloud connectivity."

JAESON BANG, FOUNDER AND CEO, FUTURE CARDIA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