## BOSTON ENGINEERING™

# **Patient Monitoring Overview**

Boston Engineering solves complex product development and engineering challenges for patient monitoring, diagnostics, and medical device organizations. Our multidisciplinary teams combine innovative thinking with the technical and regulatory experience to drive product success.

Specializing in patient monitoring device development, we leverage our expertise to create cutting-edge solutions that enhance healthcare delivery. Our comprehensive range of engineering consulting covers the entire product development lifecycle, from concept to commercialization. With a team of experienced engineers and a deep understanding of the healthcare industry, we are committed to delivering innovative and reliable patient monitoring devices.

Boston Engineering applies its phase-gate development process to:

- Mitigate risk
- Optimize for manufacturability and service
- Comply with stringent regulatory requirements
- Accelerate time to market

# **Device Development to Save and Improve Lives**





## The Boston Engineering Advantage

Boston Engineering develops novel technology for commercialization that improves how people work and live. Examples:

#### Technology Areas:

- Sensing and analog-to-digital converters (ADCs)
- Embedded systems for computation and logging
- Packaging cleanable, sealed
- Batteries and low power design

#### Design Engineering:

- Manufacturability and assembly (DFM&A)
- Reliability (DFR) •
- Serviceability (DFS)
- Testability (DFT)
- Miniaturization •

#### Connected Capabilities:

- Internet of Things (IoT)
- Augmented Reality (AR)
- Communications IoT, BLE, etc.

#### Compliance and Standards:

- ISO 13485:2016-medical device development
- ISO 9001:2015-quality management systems
- Application of device design standards including IEC 62366 and IEC 60601
- IEC 62304 medical device software software life cycle processes
- Compliance to ISO 14971-risk management

#### Software

- Machine learning and AI
- User testing (use of simulation) throughout user interface (UI) and device development

### About Boston Engineering

Boston Engineering provides product design and engineering consulting from concept through commercialization and connectivity.

Certified for ISO 9001 and ISO 13485, the company's industry expertise includes commercial, defense, and medical. Founded in 1995, Boston Engineering is headquartered in Waltham, Mass.



## BOSTON **ENGINEERING**<sup>™</sup> Imagine the Impact

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