

# **Market, Regulatory, Packaging, and Thermal Design Issues for Implantable Medical, Handheld, and Mobile Devices**

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## **Abstract**

A very wide range of different types of mobile, handheld, and wearable electronic devices now exist for consumer, security, and military applications. Similarly, an extensive array of medical electronic devices are now designed and manufactured for use in monitoring and improving human health. The overall market for all types of such mobile, handheld, wearable, and implantable devices has grown explosively and new developments continue. A specific area of significant growth, beyond such consumer products as smart phones and tablets, is the medical device market.

The market for medical devices intended to be worn externally, implanted in the body, or consumed orally is expected to be over \$50 billion worldwide over the next three years and growing rapidly. This presents opportunities for product design, material selection, and problem solving in order to achieve practical and beneficial electronic products. These devices must be developed, designed, and marketed within a complex range of regulatory requirements and meet consumer expectations for sports and health monitoring capabilities with the opportunity to impact clinical performance. These devices also potentially raise new questions at a societal level regarding privacy of data generated, data storage, and how “big data” rules and requirements may need to change to accommodate societal and privacy expectations. This presentation will outline the functional packaging, thermal, and materials requirements for handheld, mobile, wearable, and implantable electronic devices, the current regulatory landscape and impact on device design and functionality. Examining this market is useful for understanding materials requirements for energy storage and for power, RF, and integrated circuit components within such end products.

Discussion will follow this outline:

1. Product concepts
  - a. Needs analysis – fit, form, function
  - b. Current mobile, handheld, and wearable electronic devices: packaging, thermal characteristics by general product type
  - c. Implantable and ingestible medical electronic devices: packaging and thermal issues
  - d. Future developments for wearable and implantable medical electronic devices.
2. Regulatory environment and impact of regulation:
  - a. Principal U.S. and E.U. regulatory agencies and relevant regulations.
3. Societal expectations and potential issues for data generation, monitoring, storage, and use as “big data” for medical research and other uses.
4. Needs for materials and thermal solution developments for miniaturized wearable, implantable, and ingestible medical electronic devices.