



Biomedical device risk analysis could be a significant undertaking for an organization.

tw-Security's consultants are risk analysis experts and extremely efficient. When we are engaged to assist with biomedical devices risk analysis, we utilize our tools that support our risk analysis methodology based upon the guidance from the National Institute of Standards and Technology (NIST) developing the biomedical device risk management documentation foundation. We provide training to manage the findings, corrective action steps, as well as conducting risk profiles to address new inventory.

## **Classes of Biomedical Devices (Examples of devices that may store any type of PHI)**

1. Anesthesia Delivery Units
2. Analyzer (Lab Equipment)
3. Densitometer, Bone
4. EEG Machine
5. EKG Machine
6. Dialysis Machines
7. Fluoroscopic Unit, Portable
8. Image Digitization System, Computed Radiography, Reader
9. Infusion Pump, Sigma Spectrum Infusion Pump
10. Medication Dispensing Cabinet
11. Module, Data Transfer
12. Monitor, Anesthesia
13. Monitor, Bedside, Physiologic Monitor
14. Monitor, Central Station
15. Monitor, Stress Exercise
16. Printer, Dry-Processing
17. Radiographic System, Digital, Mammographic
18. Radiographic/Fluoroscopic System, Angiographic
19. Scanner, CT, Spiral
20. Scanner, Gamma Camera, Planar Image
21. Scanner, MRI, Full-Body
22. Ultrasound, Diagnostic
23. Ventilators

### **Reasonably anticipated threats:**

1. Hacking or tampering by an external person
2. Virus, worm, or malicious code
3. Program error, application bug, and/or operating system errors
4. Power failure
5. Theft or loss
6. Damage due to mishandling
7. Unauthorized access to confidential information
8. Hardware failure