

# WHY MEDICAL GRADE?

### **EMI** Reduction

The most compelling factor in choosing a Medical Grade computer is reducing EMI. Tangent Medical Grade computers are UL60601-Certified. Certification ensures EMI compliance.

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH) and Association for the Advancement of Medical Instrumentation (AAMI) have established recommendations to minimize the risks associated with medical device EMI and promote electromagnetic compatibility (EMC) in healthcare facilities. Medical computers are medical devices.



The clinical and biomedical engineers and Safety Committee within a healthcare facility should ensure that all medical devices purchased reduce EMI.



#### FDA/CDRH RECOMMENDATIONS FOR **EMC/EMI IN HEALTHCARE FACILITIES**<sup>1</sup>



#### Manage

the electromagnetic environment, RF transmitters and all electrical and electronic equipment, including medical devices, to reduce the risk of medical device EMI and achieve EMC



# Coordinate the purchase,

installation, service, and management of all electrical and electronic equipment used in the facility to achieve EMC



# Educate

healthcare facility staff, contractors, visitors, and patients about EMC and EMI and how they can recognize medical device EMI and help minimize EMI risks



that document the intentions and methods of the healthcare institution for reducing the risk of medical device EMI and achieving EMC



# GUIDANCE ON ELECTROMAGNETIC COMPATIBILITY OF MEDICAL DEVICES FOR CLINICAL/BIOMEDICAL ENGINEERS<sup>2</sup>

#### **AAMI TIR 18 Summary Recommendations**

Because of their responsibility for the safe functioning of patient care equipment, clinical/biomedical engineers should be the focal point for EMC, EMI mitigation, and EMC/EMI education/training within the health care organization.



Electrically-powered medical devices purchased for use in the facility should meet EMC standards.



EMC/EMI should become a permanent responsibility of the health care organization's Safety Committee.

Purchase, installation, service, and management of all equipment (medical, communications, building systems, and information technology) used in the facility should be coordinated to assure EMC. Clinical/biomedical engineering, facility management, information systems, materials management, and risk management personnel should all be aware of the possibility for equipment interactions and the need for coordination.