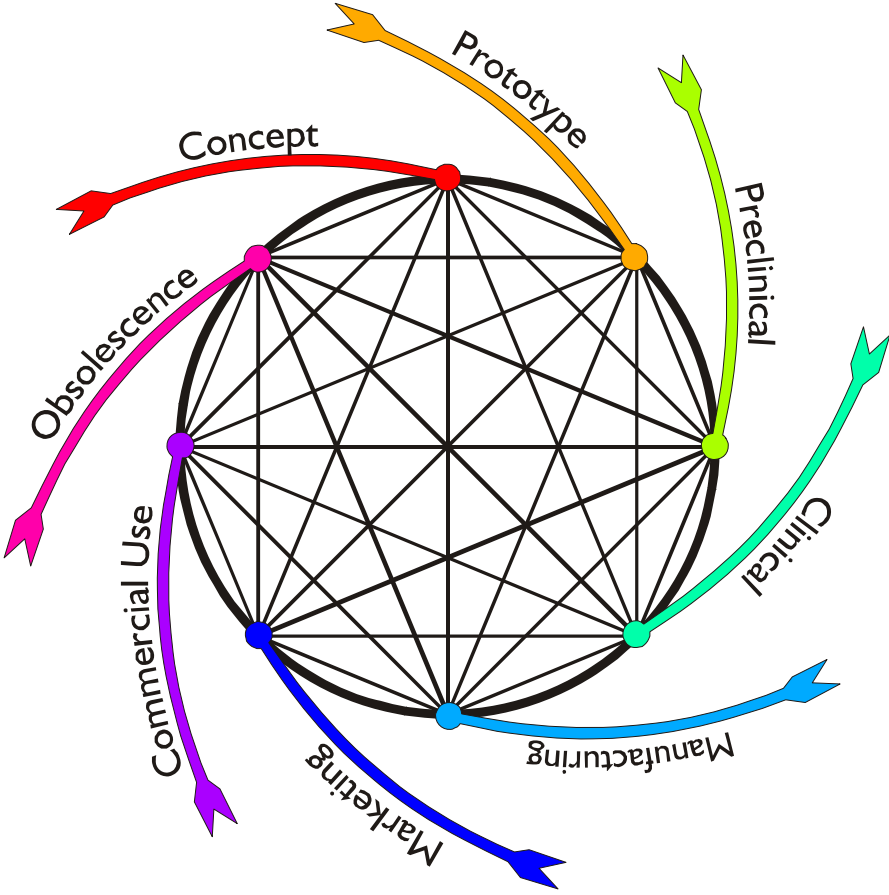


**iNEMI/FDA Forum on  
Component Reliability for  
Medical Electronics**

**Welcome**

# Introduction

# Total Product Life Cycle

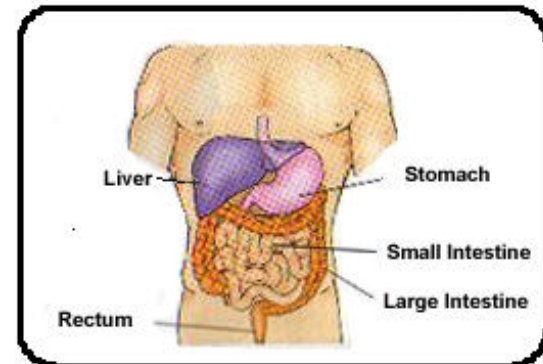
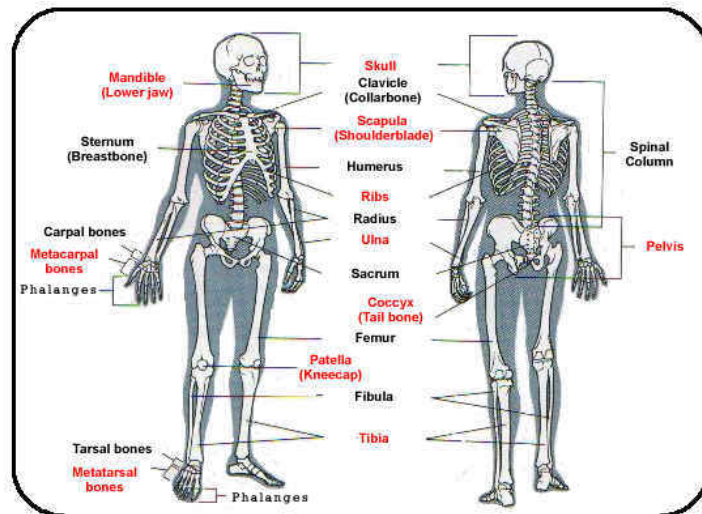
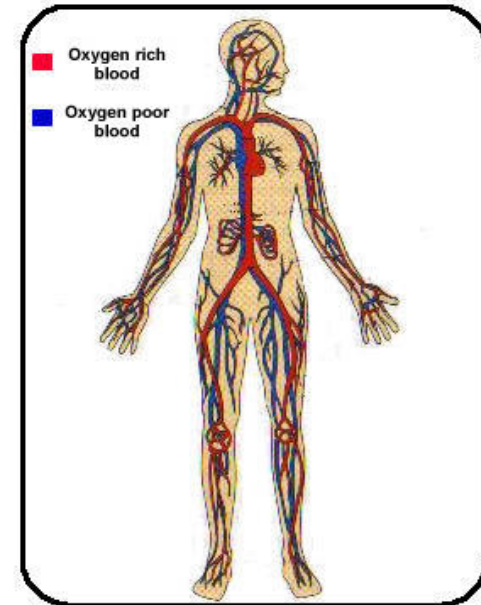
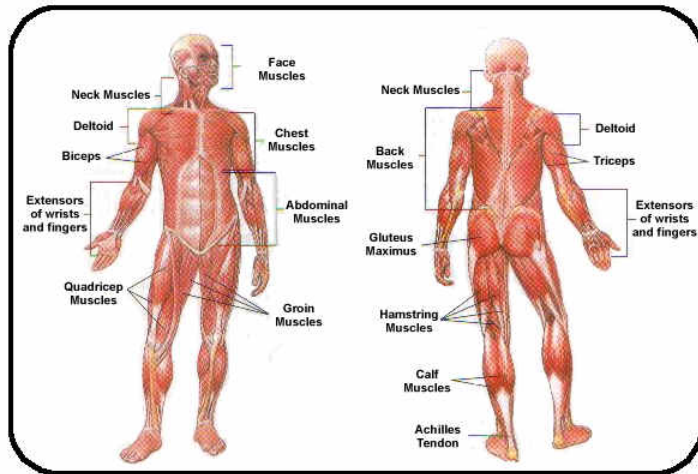


Device Manufacturers Need to  
Know What to Specify to OEM  
Suppliers

A Proper Design Analysis Must  
be Performed

Reliability can not be Tested into  
the Device

# The Intended Site of Use needs to be understood



# The Proper Function or Clinical Outcome for a New Material or Device needs to be Defined

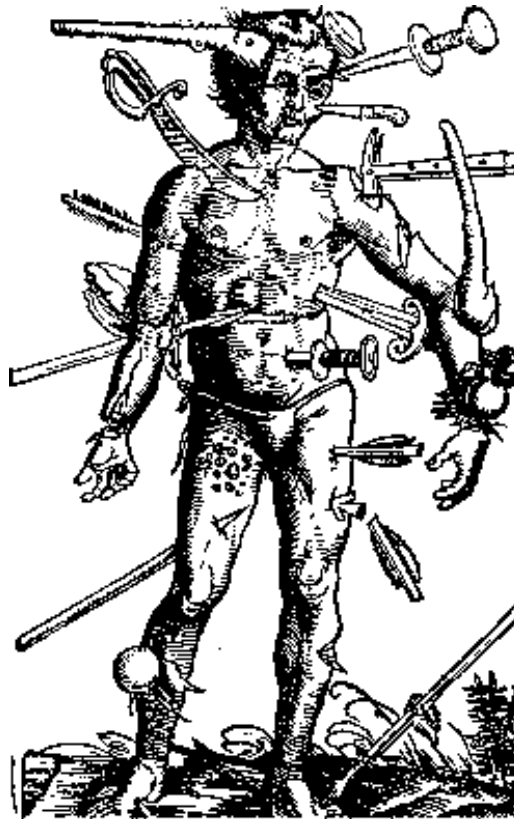


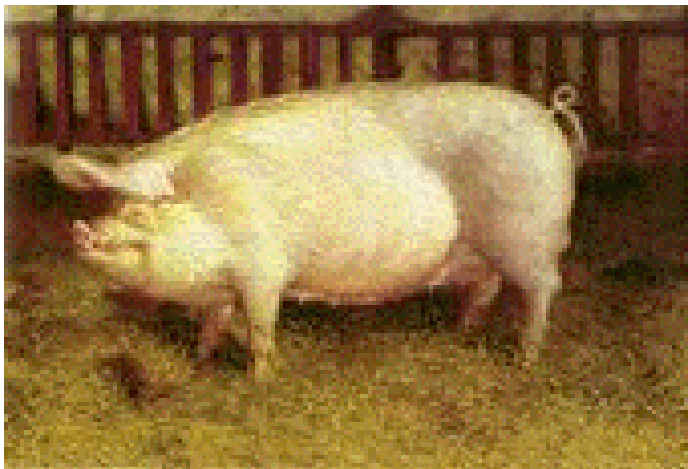
Figure 3-1-1. "Sound man."

The System needs to be evaluated under simulated use conditions





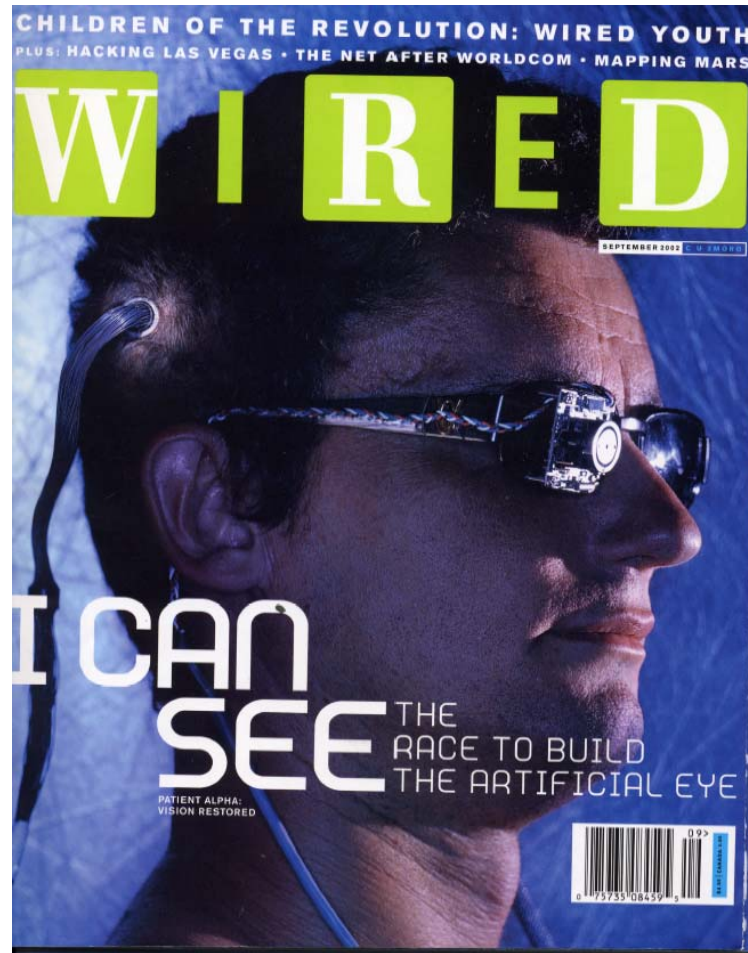
**Can the Proper Service Environment be Modeled *In-Vivo*?**



# Med-El's Combi 40+ (Ca 1994) Vs. Pulsar (Ca 2004)



# We have the Technology...



# NASA Pill

