

## Justification for 200 Equipment Units

The units needed reflect the current anticipated needs of the company to support the development and integration of RF telemetry into our implantable medical devices. Reasons for the need for so many units are reflected by:

1. Two product platforms are being developed which will utilize the RF telemetry system: pacemakers and ICDs. Each has unique requirements with respect to size, cost, and current consumption available. Two transceivers will be investigated to address this.
2. In addition to the products for implantation to be developed, an external device must also be developed as the other end of the RF telemetry link to serve as the implantable device interface. Since a single external device is required to potentially communicate with both transceivers, it may employ dual transceivers.
3. Another type of external device will be developed to provide home monitoring functions.
4. During the product development cycle, functional prototypes are built and tested. The prototypes communicate to a custom interface device, which will need to have functional RF telemetry. Generally, the interfaces are unique to a product platform and are not interchangeable.
5. A protocol for the RF telemetry needs to be developed and tested requiring functional transceivers.
6. Test vehicles will be developed using both transceivers to investigate propagation through various tissue models.
7. Test vehicles will be developed to allow characterization of both transceivers various performance parameters including bit error rates of the RF telemetry link.
8. Manufacturing floor functional production tests will need to be performed requiring the development of custom manufacturing RF test equipment using both transceivers.

Different design teams carry out the development process. Many times the work performed by one team is not suitable for reuse by other teams, due to design and implementation constraints.