



Proposal for Product Development
Electronic Hardware and Embedded Control
Development Program
April, 2002

This product-development proposal considers the creation of all electronic hardware and control-system embedded software required to satisfy the requirements set forth by the Customer's Preliminary Product Specification (Appendix A). The proposal is divided into several Phases to keep the goals associated with each effort clearly in focus and to facilitate the tracking of progress on the program.

The Phases are envisioned to be as follows:

Phase I - Alpha Product Definition - This phase includes most of the major decision-making with respect to display sizes and orientation, options to be included and a continual check to ensure that the product cost-targets are satisfied. Once the display and user-selection interface is known, the client must create or at least work interactively with us to create the "story-board" for the sequence of displayed items. They will also be responsible for supplying text for and/or graphics for alternate languages. The major milestones in this phase include the following:

- Defining at least one method to implement each function (sensor inputs, menu selection methods, etc.)
- Creation of functional specification
- Selection of major components (display, microprocessors, keypads, batteries, etc.)
- Selection of Software methods and tools
- Identify Prototype & Production quantities of circuit-boards, models, etc.
- Identify Part Numbering System for PC Boards, Components, Cable Assemblies and Programmed Parts
- Obtain "story-boards" to define in detail the sequence of operation (LCD text, graphics, menus, etc.)
- Creation of IEC requirements specification
- Creation of preliminary costed BOM

Phase II - Alpha Circuit Design (4 weeks) - The PC Board circuit-design is the focus of this phase. Board-test and failure-test specifications are created and then used to verify that all required capabilities are included in the circuit design. This step also ensures that there all failure modes are "fail-safe" and that failure mechanisms are in accordance with regulatory agency guidelines as well as with the desires of the client. Circuit verification software is also written and used to debug and verify the operation of all circuits when the PC Boards are first tested. The Bill-of-Materials is now available with a much greater degree of accuracy and it must be carefully reviewed against the product cost target. The major milestones for this phase are listed below:

- Design Circuitry for PC Board
- Define PCB Footprint
- Embedded Software - generate initial board-verification test software
- Create test-ability specification
- Create failure-mode specification
- Create IEC Design Description
- Update / review costed BOM

Phase III - Alpha Prototype (4 weeks)- In this phase, the product-packaging effort drives the layout of the PC Board. Connectors will be located in convenient locations, wiring harnesses will be planned and PC Boards will be fabricated and assembled. The result of this phase is a physical circuit board that has been tested to prove proper operation of all circuitry. This Board may also be used to verify proper fit in a model enclosure once one is available. However, changes to the housing design may require that the PCB layout be revised and in that event, a subsequent pilot-run of boards would be built. The major milestones for this phase are as follows:

- Integration / Packaging Review
- Complete Electronic PCB Layout
- Create Internal Wiring Harness Drawings
- Build Prototype PCB Lot
- Test / Debug Control Board using board-test software.



Phase IV - Functional Prototype (4 weeks)- During this phase, the program is written for the client's specific application. An operational "test-configuration" called a breadboard is built for use in the programming lab. It includes all required elements of the system such as displays, indicators, keypads, switches, etc. This development breadboard is used to test and debug the application program. The result of this phase is a fully-functioning circuit board that is ready to test in a working (form/fit/function) prototype. The major milestones are listed below:

- Embedded Software - Create embedded application program
- Test / Evaluate function and performance in "bread-board" configuration
- Create IEC Failure Mode and effects Analysis

Phase V - Working Prototype - (2 weeks) This is the integration phase where the Electronics and the Mechanical configuration are assembled and evaluated for form, fit and function. The milestones associated with this phase are listed below:

- Integrate all components into actual housings
- Review service-ability and manufacturability issues
- Review functional and ergonomic issues
- Revise Embedded Software as required
- Creation of IEC Fault-Tree analysis and Validation Protocol

Phase VI - Agency Review and Approval (2 weeks) - With the prototype unit(s) available, units can be submitted to agencies for safety-certifications for Electro-static Discharge, Conducted and Radiated Emissions and for product safety approval. All costs associated with these product certification procedures will be the responsibility of the client.

- UL – Client responsible for costs associated with submitting unit for approval
- FDA – Client to prepare final documents for desired approval (510k, etc.) and submit revised application to FDA. Initial submission of FDA documents (510k) could be done as early as the end of Phase II.
- EMI / ESD - Client responsible for costs associated with submitting unit for testing and approval.

Phase VII - Engineering Changes (3 weeks) - Should any changes be required as a result of safety-certification testing and agency-approval testing, the electronic hardware and/or embedded software will be revised as required. Circuit boards will be built and the system will be validated to satisfy the new requirements.

- Electronic Hardware Revisions - update design and PC Board artwork as required
- Build revised PC Boards
- Test New boards with board-test software
- Validate Complete System Performance with Application Software

Phase VIII - Engineering Product Release (3 weeks) - In this final phase, all documentation is revised as required and revisions are updated to reflect the initial release level of each component. Typically, numeric revisions are used during development then components are revised to alpha-level revisions with a product-release Engineering Change Order (ECO). A complete Hardware reference manual will be created to include theory of operations, schematic diagrams, PC board layouts and a revision history. A software reference manual will include a copy of all source code as well as a complete listing of all tools and utilities that were used to create the software for this product system.

- Update all Drawings as required and Revise to Alpha-Level release
- Revise Bill-of-Materials
- Revise Software to Alpha-Level Release
- Create Hardware Reference Manual to include all materials in print and on disk.
- Create Software Reference Manual to include top-level software flow-diagram plus all source-code in printed form and on disk.