

Software:

16. Your description of your software is inadequate. Please address the following:
- a. Hazards Analysis: Please submit a more detailed Hazard Analysis which provides a description of the hazards presented by this device to the subject, the causes of these hazards, and the methods used to eliminate or mitigate them. This analysis should specifically identify the system hazards, and the components whose failure could cause those hazards and which are controlled by or interact with software. The analysis should identify this controlling or interacting software, and describe in greater detail how errors in this software are controlled or mitigated throughout the software development process.
  - b. Functional Requirements and System Specifications: Please provide a much more detailed description of the system and software requirements and specifications, including safety critical functions implemented because of the ongoing hazards analysis, and any applicable algorithms.
  - c. Software Design and Development: Please submit your written procedures, or at a minimum a very detailed description of your procedures, for designing and developing the software to be used in the device, from concept to delivery to the customer.
  - d. Verification, Validation, and Testing: Please submit a more detailed description of the software verification, validation, and testing process, including but not limited to the techniques and methods used at the module, integration and system level, the testing strategies and methodologies, and the test acceptance and completion criteria. Include examples and documentation of testing results.
  - e. Revision Control: Please submit the written procedures, or at a minimum, a very detailed description of the procedures, for your revision control process.

Advisory:

Although we requested the patient questionnaire be administered at times in addition to the ones you had originally proposed, we now believe that the subjects may become acclimated to the questionnaire, if it is presented too frequently. Therefore, you may revert to the times originally proposed in your IDE.