



June 30, 1999

Dallas District  
3310 Live Oak Street  
Dallas, Texas 75204-6191

Ref: 99-DAL-WL-19

**WARNING LETTER**

**VIA FEDERAL EXPRESS**

Mr. Matthew W. Prucka, President  
Prucka Engineering, Inc.  
13000 Executive Drive  
Sugar Land, Texas 77478

Dear Mr. Prucka:

During an inspection of your firm, on December 14, 1998, through January 26, 1999, our investigator determined that your firm manufactures multi-channel, electrocardiographic amplifiers, CardioLab EP System and CardioCath Catheterization Lab System software. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

These devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the current good manufacturing (CGMP) requirements of the Quality System Regulations, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The following Quality System Regulation deficiencies were noted:

1. Failure to validate manufacturing processes with a high degree of assurance, to approve the validation according to established procedures, and to maintain adequate documentation of validation activities and results, including the date and signature of the individual(s) approving the validation, as required by 21 CFR 820.75(a). For example:
  - a. The surface mount technology process used for the production of circuit boards was not validated; and
  - b. Validation testing procedures have not been approved.

2. Failure to establish and maintain procedures for validation of the device design, including software validation, and documentation of the validation, as required by 21 CFR 820.30(g). For example:
  - a. Standard operating procedures have not been established for software validation.
  - b. Review of the validation records for CardioLab Cath version 1.1 revealed:
    - i. The module entitled, "CO Worksheet" lacked complete documentation of testing in that the actual values under Section V. corresponding to the expected values of [redacted] [Hemoglobin] and [redacted] [O<sub>2</sub> capacity] were not documented.
    - ii. The module entitled "Measurements" does not identify test inputs and outputs.
  - c. Review of the validation records for CardioLab EP version 4.11 revealed:
    - i. The test record entitled, "Acquisition w/ Amps, HLT-CLAB II amp, 48 channels" under the Section entitled, "Testing sampling rates: [redacted] and [redacted]" documented that surface ECG channels 4, 5, and 6 were not available which is contrary to expected results.
    - ii. The test record entitled, "Stimset/Detect-Clab II amps (32 channels)" documented various instances in which the actual values generated did not meet established specifications.
3. Failure to establish and maintain adequate procedures for the acceptance of incoming products, including failure to inspect, test, or otherwise verify that incoming products conform to specified requirements, as required by 21 CFR 820.80(b). For example:
  - a. Your firm does not conduct any type of testing or evaluation of components. In addition, your firm does not maintain any written procedures covering acceptance testing of components.
  - b. Review of amplifier device history records for the period between 12/97 and 12/98 revealed 121 circuit boards did not meet specifications. The circuit boards were accepted, without justification, for integration into 206 finished amplifiers.

4. Failure to establish and maintain procedures to ensure that all purchased or otherwise received products and services conform to specified requirements, as required by 21 CFR 820.50. For example, your firm does not maintain purchasing control procedures.
5. Failure to evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements and to document the evaluation, as required by 21 CFR 820.50(a)(1). For example, your firm has not conducted formal evaluations of any suppliers.
6. Failure to establish and maintain procedures for and document changes to a specification, method, process, or procedure, verifying, or where appropriate, validating according to 21 CFR 820.75, before implementation. Failure to approve changes as required by 21 CFR 820.40 and 820.70(b). For example, the acceptance specification for the 16 Channel Amp Board changed from [REDACTED] mA to [REDACTED] mA in accordance with Release Change Notice #600-00144-00 dated 5/20/98. There is no documentation of verification or validation for this change in specification.
7. Failure to maintain complete device specifications, including software specifications in the Device Master Record, as required by 21 CFR 820.181(a). For example:
  - a. Complete Device Master Records have not been established for the CardioLab EP, CardioLab Cath, or CardioMapp software systems which include software specifications.
  - b. The document entitled "CardioCath Specifications" is incomplete in that the following parameters are not identified:
    - i. A description of all files to be created/accessed as well as all reports and or visual displays to be generated.
    - ii. A description of all limits and parameters to be measured, the frequency of measurement, and the points at which the user is to be alerted and/or data is to be rejected.
    - iii. A description of all error messages, their cause, and the corrective actions required.
8. Failure of the Device Master Record to include or refer to the location of quality assurance procedures and specification including acceptance criteria, as required by 21 CFR 820.181(c). For example, standard operating procedures have not been established for software quality assurance and acceptance activities.

9. Failure of the Device Master Record to include or refer to the location of installation and servicing procedures and methods, as required by 21 CFR 820.181(e). For example, standard operating procedures have not been established for installation and servicing.
10. Failure to document the evaluation of nonconformance and determine the need for an investigation, as required by 21 CFR 820.90(a). For example, there is no documentation of an evaluation or the need for an investigation for the following nonconformances:
  - a. The “Nonconforming Material Report/Deviation” report # [REDACTED] dated 4/30/98 documents that a printed circuit board had a trace open and pad lifted after production.
  - b. The “Nonconforming Material Report/Deviation” report # [REDACTED] dated 6/9/98 documents that a printed circuit board had been “damaged due to SMT process.”
  - c. The “Nonconforming Material Report/Deviation” report dated 9/9/98 documents that 39 components [integrated circuits] had failed.

Additionally, the devices comprising the CardioLab EP System are adulterated within the meaning of Section 501(f)(1)(B), in that they are Class III devices under Section 513(f) and they do not have a approved applications for premarket approval in effect pursuant to Section 515(a) or approved applications for an investigational device exemption under Section 520(g). The CardioLab EP system is also misbranded under Section 502(o), in that a notice or other information respecting the modification to include added functionality to the device was not provided to the FDA as required by Section 510(k) and 21 CFR 807.81(a)(3)(ii). New intended uses of the device not included in the original premarket notification include: RF Ablation Device Interface Module; Simultaneous Pace and Record Capability; CardioImage EP; and CardioMapp Integrated Software Module.

Further, the devices comprising the CardioCath Catheterization Lab System are adulterated within the meaning of Section 501(f)(1)(B), in that they are Class III devices under Section 513(f) and do not have approved applications for premarket approval in effect pursuant to Section 515(a) or approved applications for an investigation device exemption under 520(g). The CardioCath Catheterization Lab System is also misbranded under Section 502(o), in that a notice or other information respecting the modifications to include added functionality to the device was not provided to the FDA as required by Section 510(k) and 21 CFR 807.81(a)(3)(ii). The integration of different physiological devices, such as the: Nellcor (N180 and N200), Critikon (Dinamap), and Avox (Avoximeter 1000E), labeled for use with the CardioCath System constitute a major change in the intended use of the device.

The CardioLab EP System and the CardioCath Catheterization Lab System are further misbranded within the meaning of Section 502(f)(1) because these devices are prescription devices, which fail to bear the prescription legend required by 21 CFR 801.109(b)(1).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be system problems you must promptly initiate permanent corrective actions.

We have received your initial, undated response to the FDA-483 our investigator issued on January 26, 1999, as well as supplemental responses, dated February 26, 1999, and March 31, 1999. We have reviewed your responses and concluded that they do not completely address the inspectional observations:

Your response to FDA-483 observation #1 is inadequate in that it does not provide an assurance that these procedures are applied to all nonconforming products.

Your response to FDA-483 observation #2 is inadequate in that Document No. 005-11003-00 "Corrective and Preventative Action, Procedure 6.5-Verification/Validation," fails to establish specific criteria to be used to evaluate whether verification and/or validation are required. These criteria should also be included in the Discrepancy Report.

Your response to FDA-483 observation #3 is inadequate in that you did not specifically determine the reason for nonconforming product. For example, on the Nonconforming Material Report/Deviations (Exhibit F) Work Order #84534 for a CLAB II Amplifier the defect code was "Component wrong" yet your findings indicate "Investigation into the cause of the nonconformity did not discover any specific reason why the wrong component was applied." Several other reports were closed with similar findings. Further investigation as to the reasons the wrong component was selected, placed, and soldered should be conducted and documented.

Your response to FDA-483 observation #6 is inadequate in that the validation protocol fails to ensure that Release Change Notice #600-00144-00 includes a review of the specifications, methods, processes or procedures that accompany this change, and documentation that verification and/or validation were considered as part of the review.

Your responses to FDA-483 observations #11, 12, and 13 do not adequately address testing protocols and results. For example, normal, boundary, and out of range values are not described and test cases, potential operator errors, component failure conditions, sequences and combinations likely to uncover errors, and disaster recovery

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processes are not tested. Test plans for unit, integration, and system level testing should be included in these procedures.

Responses to FDA-483 observations 4, 5, and 7 through 10 appear to be adequate. We acknowledge your commitment to develop various specifications and standard operating procedures (SOP's). The adequacy of these specifications and SOP's will be verified upon re-inspection. Although many issues are addressed in your previous responses, there are additional issues noted in this letter that should be addressed in future responses.

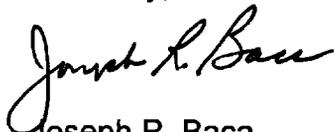
Until such corrections have been made, Federal agencies will be advised of the issuance of this Warning Letter so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct these violations, including an explanation of each step being taken to prevent the recurrence of similar violations.

Your response should be sent to Reynaldo R. Rodriguez, Jr., Compliance Officer, at the above letterhead address.

Sincerely,

A handwritten signature in cursive script that reads "Joseph R. Baca". The signature is written in black ink and is positioned above the printed name and title.

Joseph R. Baca  
Dallas District Director