



PURGED *BJH*

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

cc. HFI-35

June 11, 1998

WARNING LETTER

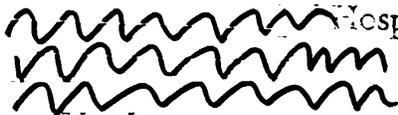
CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 36

David L. Melton
Manager
Alpha Imaging, Inc.
1601 N. Riverfront Drive
Mankato, Minnesota 56002

Dear Mr. Melton,

On May 29, 1998, the State of Minnesota (under contract with the Food and Drug Administration [FDA]) conducted field tests AR54654A and UF54654B of a certified diagnostic x-ray system which your firm assembled on December 15, 1997. The installation data is per a Report of Assembly of a Diagnostic X-ray System (FDA-2579) bearing number D042836. The system was tested to determine its compliance with portions of the Federal Performance Standard for Diagnostic X-ray Equipment (Performance Standard), Title 21, Code of Federal Regulations, Parts 1020.30-32 (21 CFR 1020.30-32). Diagnostic x-ray equipment is further defined as a medical device per Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

User Site:  Hospital

X-ray Control Manufacturer:  serial: A615317

Page Two

David A. Melton
June 11, 1998

Class A Non-compliance:

Fluoroscopic exposures were possible when the primary protective barrier was not positioned to intercept the entire useful beam. 21 CFR 1020.32(a) mandates that the entire x-ray beam be intercepted.

It is FDA's understanding that your firm has corrected this non-compliance per service order #33044 dated May 29, 1998. Please provide an assessment as to the cause of non-compliance, as detailed below.

Class B Non-compliance:

At 103 cm. SID, the spot film device was determined to be oversizing. Using a 4:1 technique with a 24 x 24 cm. film cassette, the resulting spot film was calculated to differ from the selected field size by:

- 6.958% in the across-table dimension
- 11.697% Sum of the along and across table differences (absolute value)

21 CFR 1020.31(h)(2) of the x-ray performance standard requires that the total misalignment of the edges of the x-ray field with the respective edges of the selected portion of the image receptor shall not exceed 3% of the SID, in either dimension, nor that the sum of these misalignments exceed 4% of the SID.

In addition to the above problems, we consider the compliance status of the following items to be suspect. Please verify the compliance status of these items when you correct the above problems.

- When the indicated SID (per digital display on the collimator) was 35.9 inches (91.2 cm), the actual SID was measured to be 94.8 cm. This discrepancy is -3.96% of the SID. 21 CFR 1020.31(e)(1) of the x-ray performance standard requires that the x-ray system indicate the SID to within 2%.
- The Positive Beam Limiting (PBL) collimator is mis-sizing. At 36 inches SID, a 43 x 35 cm. cassette was mis-sized:
 - 4.3% sum (absolute value) of along and across table dimensions

Page Three

David A. Melton
June 11, 1998

The x-ray performance standard, 21 CFR 1020.31(g)(1), states that neither the length nor width of the x-ray field in the plane of the image receptor can differ from the corresponding image receptor dimension by more than 3% of the SID. The sum of the length and width differences must not exceed 4% of the SID.

We request that you, as the responsible assembler, immediately investigate the above noted Class A and B deviations in accordance with 21 CFR 1003 and 1004 as follows:

1. If you determine that the deviations and/or defects are caused by improper assembly or installation, you must correct them at no charge to the user by either repairing the system, replacing it, or refunding the cost.
2. If you determine that the deviations and/or defects are caused by the factory-based manufacturer, you must notify them of the non-compliances and/or defects and send documentation of such notification to this office.
3. If you can establish that the system is compliant, that the alleged deviations and/or defects do not exist or do not relate to the safety of the product, or is directly attributable to user abuse or lack of maintenance, you may submit such evidence in accordance with 21 CFR 1003.30 within 30 working days of the receipt of this letter.

Report the results of your investigation and follow-up actions to this office within 15 working days of the receipt of this letter. Your response should include (a) the date the corrective action was completed and copies of service records and/or other supportive documentation, and (b) an explanation of specific steps your company has initiated to prevent the recurrence of similar violations.

If corrective action cannot be completed within 15 working days of the receipt of this letter, state the reason for the delay and the time within which the corrections will be completed.

If you do not respond within 15 working days the FDA may consider you to be in violation of the Federal Food, Drug, and Cosmetic Act, Sections 538(a)(2) and 538(a)(4) of Subchapter C -- Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968).

Page Four

David A. Melton
June 11, 1998

Please note that improper installation (including failure to follow installation instructions) which causes the system to be non-compliant with the Performance Standard may cause the system to be adulterated. Under Section 501(c) of the Act the system would not be of a quality represented by its labeling (including its certification label).

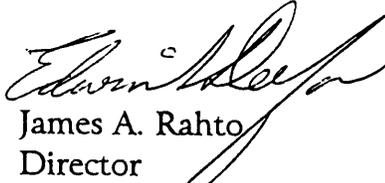
Failure to promptly correct this violation can result in regulatory action being initiated by the FDA without further notice. These actions could include seizure, injunction and/or civil penalties as provide for in Section 539 of the Act. Persons violating Section 538 of the Act are subject to civil penalties of up to \$1000 per violation up to a maximum of \$300,000.

Your response should be sent to:

Thomas W. Garvin
Radiological Health Specialist
Food and Drug Administration
2675 N. Mayfair Road, Suite 200
Milwaukee, WI 53226-1305

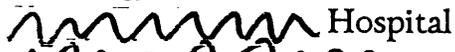
Any questions regarding the field test can be directed to Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,


James A. Rahto
Director
Minneapolis District

TWG/ccl

xc: Albert D. Perrico
President
Alpha Imaging, Inc.
4455 Glenbrook Road
Willoughby, OH 44049


Radiology
 Hospital



Regulatory Affairs



Judith A. Ball
Manager, Section of Radiation Control
MN Department of Health
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