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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

August 2, 2000

CIN-XR-3937-0

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

REFERENCED TEST NO.: GI -62369

Mr. Peter R. George
Owner
Medical Technology Solutions, Inc.
2572 Sungale Court
Lexington, KY 40513

Dear Mr. George:

On July 27, 2000, a representative of the FDA performed a field test of a certified diagnostic x-ray system which your firm assembled on April 28, 2000 according to Report of Assembly of a Diagnostic X-Ray System, Form FDA 2579, Assembler Report No. C961118. We tested this system to determine its compliance with portions of the Performance Standard for Diagnostic X-Ray Equipment (Title 21 Code of Federal Regulations (CFR), sections 1020.30-32). Diagnostic x-ray equipment are devices as defined by section 201 (h) of the Federal Food, Drug and Cosmetic Act (the Act). This field test was performed at:

Cardinal Hill Hospital
2050 Versailles Rd.
Lexington, KY 40504

The system identification:

X-Ray Control Manufacturer	Innerscan, Inc.
X-Ray Control Model No.:	Concept - AP
X-Ray Control Serial No.:	1884
Room Number:	Room #2

This letter confirms our notification of July 27, 2000 to you at the above installation site regarding a serious noncompliance with the performance standard and our request that you immediately correct this violation:

The diagnostic x-ray failed to terminate exposure after a preset time interval or preset milliamperesecond (mAs). **21 CFR 1020.31(a)(2)**

Also our analysis of the field test data indicates that the system does not comply with the following item of the performance standard:

Actual vs., Indicated Field Size

The diagnostic x-ray system beam-limiting device had no means to indicate the dimensions of the x-ray field size. **21 CFR 1020.31 (e)(3)&(4)**

In addition to the above problems, we consider the compliance status of the following item to be suspect. Please verify the compliance status of this item when you correct the previously cited problems.

Accuracy of Indicated Source to Image Receptor Distance (SID)

Indicated SID = 91.4 cm (36 inches)
Measured SID = 87.1 cm
SID difference = 4.7%

The Performance Standard requires that the x-ray system indicate the SID to within two (2) percent. **21 CFR 1020.31 (e)(1)**

We request that you, as the responsible assembler, immediately investigate the deviations from the performance standard cited above 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 the noncompliance items at no charge to the user by either repairing the system, replacing it, or refunding the cost.
2. If you determine that the deviations are caused by the factory-based manufacturer, you must notify him of the noncompliance items 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 or defects do not exist or do not relate to the safety of the product, or are directly attributable to user abuse or lack of maintenance, you may submit such evidence in accordance with 21 CFR 1003.30 within 15 working days of receipt of this letter.

You must report the results of your investigation and follow-up to this office within 15 working days of receipt of this letter. Your response should include the date the corrective action was completed and copies of service records and/or other supportive documents. 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 (the 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).

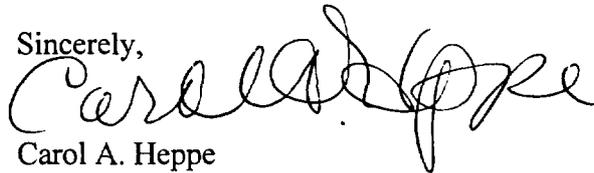
Please note that improper installation, including failure to follow installation instructions which cause the system to be noncompliant with the Performance Standard may cause the system to be adulterated. Under 501(c) of the Act, the system would not be of a quality represented by the labeling (including the certification statement).

Failure to promptly correct these violations can result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include seizure and/or injunction and/or the imposition of the civil penalties as provided 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 and up to a maximum of \$300,000.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your response should be sent to Mr. R. Terry Bolen, Radiological Health Specialist, Food and Drug Administration, 6751 Steger Dr., Cincinnati, OH 45237-3097.

If you have any questions, Mr. R. Terry Bolen can be contacted at 513-679-2700, extension 138.

Sincerely,



Carol A. Heppe
Acting District Director
Cincinnati District

c.
Ms. Sharon Davis, Radiologic Technologist
Cardinal Hill Hospital
2050 Versailles Rd.
Lexington, KY 40504