

FOR FDA USE ONLY	DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service FOOD AND DRUG ADMINISTRATION REPORT OF ASSEMBLY OF A DIAGNOSTIC X-RAY SYSTEM	Form Approved: OMB No. 0910-0213. Expiration Date: March 31, 1998 See Reverse for OMB statement <div style="text-align: center; font-size: 2em; font-weight: bold;">D</div>
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1. EQUIPMENT LOCATION

a. NAME OF HOSPITAL, DOCTOR OR OFFICE WHERE INSTALLED	
b. STREET ADDRESS	
c. CITY	d. STATE
e. ZIP CODE	f. TELEPHONE NUMBER ()

2. ASSEMBLER INFORMATION

a. COMPANY NAME	
b. STREET ADDRESS	
c. CITY	d. STATE
e. ZIP CODE	f. TELEPHONE NUMBER ()

3. GENERAL INFORMATION

a. THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE (Check appropriate box(es)) <input type="checkbox"/> NEW ASSEMBLY-FULLY CERTIFIED SYSTEM <input type="checkbox"/> REASSEMBLY-FULLY CERTIFIED SYSTEM <input type="checkbox"/> REASSEMBLY-MIXED SYSTEM (Both certified and non-certified components) <input type="checkbox"/> REPLACEMENT COMPONENTS IN AN EXISTING SYSTEM <input type="checkbox"/> AN ADDITION TO AN EXISTING SYSTEM																					
b. INTENDED USE(S) (Check appropriate box(es)) <table style="width:100%; border: none;"> <tr> <td><input type="checkbox"/> GENERAL PURPOSE RADIOGRAPHY</td> <td><input type="checkbox"/> UROLOGY</td> <td><input type="checkbox"/> CT WHOLE BODY SCANNER</td> <td><input type="checkbox"/> RADIATION THERAPY SIMULATOR</td> </tr> <tr> <td><input type="checkbox"/> GENERAL PURPOSE FLUOROSCOPY</td> <td><input type="checkbox"/> MAMMOGRAPHY</td> <td><input type="checkbox"/> HEAD-NECK (Medical)</td> <td><input type="checkbox"/> C-ARM FLUOROSCOPIC</td> </tr> <tr> <td><input type="checkbox"/> TOMOGRAPHY (Other than CT)</td> <td><input type="checkbox"/> CHEST</td> <td><input type="checkbox"/> DENTAL-INTRAORAL</td> <td><input type="checkbox"/> DIGITAL</td> </tr> <tr> <td><input type="checkbox"/> ANGIOGRAPHY</td> <td><input type="checkbox"/> CHIROPRACTIC</td> <td><input type="checkbox"/> DENTAL-CEPHALOMETRIC</td> <td><input type="checkbox"/> BONE MINERAL ANALYSIS</td> </tr> <tr> <td><input type="checkbox"/> PODIATRY</td> <td><input type="checkbox"/> CT HEADSCANNER</td> <td><input type="checkbox"/> DENTAL PANORAMIC</td> <td><input type="checkbox"/> OTHER (Specify in comments)</td> </tr> </table>		<input type="checkbox"/> GENERAL PURPOSE RADIOGRAPHY	<input type="checkbox"/> UROLOGY	<input type="checkbox"/> CT WHOLE BODY SCANNER	<input type="checkbox"/> RADIATION THERAPY SIMULATOR	<input type="checkbox"/> GENERAL PURPOSE FLUOROSCOPY	<input type="checkbox"/> MAMMOGRAPHY	<input type="checkbox"/> HEAD-NECK (Medical)	<input type="checkbox"/> C-ARM FLUOROSCOPIC	<input type="checkbox"/> TOMOGRAPHY (Other than CT)	<input type="checkbox"/> CHEST	<input type="checkbox"/> DENTAL-INTRAORAL	<input type="checkbox"/> DIGITAL	<input type="checkbox"/> ANGIOGRAPHY	<input type="checkbox"/> CHIROPRACTIC	<input type="checkbox"/> DENTAL-CEPHALOMETRIC	<input type="checkbox"/> BONE MINERAL ANALYSIS	<input type="checkbox"/> PODIATRY	<input type="checkbox"/> CT HEADSCANNER	<input type="checkbox"/> DENTAL PANORAMIC	<input type="checkbox"/> OTHER (Specify in comments)
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c. THE X-RAY SYSTEM IS (Check one) <input type="checkbox"/> STATIONARY <input type="checkbox"/> MOBILE	d. THE MASTER CONTROL IS IN ROOM e. DATE OF ASSEMBLY <table style="width:100%; border: none;"> <tr> <td style="border: none;"> </td> </tr> <tr> <td style="border: none; text-align: center;">(mo.) (day) (yr.)</td> </tr> </table>		(mo.) (day) (yr.)																		
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4. COMPONENT INFORMATION (If additional space is needed for this section use another form, replacing the preprinted number with this Form Number, and complete Items 1, 4, and 5 only)

a. THE MASTER CONTROL IS <input type="checkbox"/> A NEW INSTALLATION <input type="checkbox"/> EXISTING (Certified) <input type="checkbox"/> EXISTING (Non-certified)	b. CONTROL MANUFACTURER	d. CONTROL SERIAL NUMBER	e. DATE MANUFACTURED
c. CONTROL MODEL NUMBER		f. SYSTEM MODEL NAME (CT Systems Only)	
Complete the following information for the certified components listed below which you installed. For beam limiting devices, tables and CT gantries enter the manufacturer and Model number in the indicated spaces. For other certified components, enter in the appropriate blocks how many of each you installed in this system.			
g. SELECTED COMPONENTS			h. OTHER CERTIFIED COMPONENTS (Enter number of each installed in appropriate blocks.)
BEAM LIMITING DEVICE	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
TABLES	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
CT GANTRY	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
<input type="checkbox"/> X-RAY CONTROL <input type="checkbox"/> HIGH VOLTAGE GENERATOR <input type="checkbox"/> VERTICAL CASSETTE HOLDER <input type="checkbox"/> TUBE HOUSING ASSEMBLY <input type="checkbox"/> DENTAL TUBE HEAD			<input type="checkbox"/> CRADLE <input type="checkbox"/> FILM CHANGER <input type="checkbox"/> IMAGE INTENSIFIER <input type="checkbox"/> SPOT FILM DEVICE <input type="checkbox"/> OTHER (Specify)

5. ASSEMBLER CERTIFICATION

I affirm that all certified components assembled or installed by me, for which this report is being made, were adjusted and tested by me according to the instructions provided by the manufacture(s), were of the type required by the manufacturer(s), were of the type required by the diagnostic x-ray performance standard (21 CFR Part 1020), were not modified to adversely affect performance, and were installed in accordance with provisions of 21 CFR Part 1020. I also affirm that all instruction manuals and other information required by 21 CFR Part 1020 for this assembly have been furnished to the purchaser and, within 15 days from the date of assembly, each copy of this report will be distributed as indicated at the bottom of each copy.		
a. PRINTED NAME	b. SIGNATURE	c. DATE

6. COMMENTS