OMB No. 0910-0025; Exp. May 31, 2010

Section: Diagnostic X-Ray Assembly

Introduction

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. 0910-0025
Expiration Date: May 31, 2010
See OMB statement below

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Attn: Diagnostic X-Ray Reports of Assembly
Document Mail Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number

Administrative Information

ADMINISTRATIVE INFORMATION

Note:	*Please answer the following administrative questions to ensure accurate filing of this assembly report.*

This Report of Assembly is for the following type of Diagnostic X-Ray System:	[L]

Is this submission a New report or a Correction to a previously submitted report?	[L]
Enter the Number of the previous report:	

Company Internal Reference ID:	

1.0 Equipment Location

Part 1	**EQUIPMENT LOCATION**

Note:	*Establishment Name is equivalent to the Installation Name.*
Name of Hospital, Doctor, or Office where Installed	
Establishment Information:	
Establishment Name	
Address	
Address	
Telephone Number	

2.0 Assembler Information

Part 2	**ASSEMBLER INFORMATION**

Note:	*Establishment Name is equivalent to the Company Name.*
Assembler Company Name	
Establishment Information:	
Establishment Name	
Address	
Address	
Telephone Number	

3.0 General Information

Assembly of Certified Component Types

Part 3	**GENERAL INFORMATION**

This report is for assembly of certified components which are (select appropriate option):
( ) New Assembly-Fully Certified System ( ) Reassembly-Fully Certified System

( ) Reassembly-Mixed System (Both certified and non-certified components)
( ) Replacement Components in an Existing System
( ) An Addition to an Existing System

Intended Uses

Part 3	GENERAL INFORMATION (continued)

Intended use(s) (check appropriate box(es), must select at least one)		
▪	General Purpose Radiology:	[ ]
▪	General Purpose Fluoroscopy:	[ ]
▪	Tomography (other than CT):	[ ]
▪	Angiography:	[ ]
▪	Podiatry:	[ ]
▪	Urology:	[ ]
▪	Mammography:	[ ]
▪	Chest:	[ ]
▪	Chiropractic:	[ ]
▪	CT Headscanner:	[ ]
▪	CT Whole Body Scanner:	[ ]
▪	Head-Neck (medical):	[ ]
▪	Dental-Intraoral:	[ ]
▪	Dental-Cephalometric:	[ ]
▪	Dental Panoramic:	[ ]
▪	Dental-CT:	[ ]
▪	Radiation Therapy Simulator:	[ ]
▪	C-arm Fluoroscopic:	[ ]
▪	Digital:	[ ]
▪	Bone Mineral Analysis:	[ ]
▪	Other:	[ ]
-	If "Other" has been selected, specify further:	
	[Multi-Line Plain Text]	

Other General Information

Part 3	GENERAL INFORMATION (continued)

X-Ray system is:	( ) Stationary ( ) Mobile

Master Control is in Room:

Date of Assembly (mm/dd/yyyy):	[Date]

4.0 Component Information

Part 4	Component Information

Note:	*Select "NEW" only if the control is unused. This would include controls previously installed into a mobile or portable system by the manufacturer requiring no on-site assembly by the assembler.*

Master Control:	( ) A New Installation ( ) Existing (Certified) ( ) Existing (Non-certified)

Control Manufacturer:
Control Model Number:
Control Serial Number:

Date Manufactured (mm/yyyy):	

CT System Model Name:

Selected Components

Note:	*Enter the requested information for each beam limiting device, table, or CT gantry newly installed under this Assembler Form. Enter the information exactly as it appears on the component labeling; if labeling is missing or obscured, then explain in the "COMMENTS" section.*

Beam Limiting Device

Item: 1 (could contain up to 4 items with none required)

Note:	*Complete the following information for the certified Beam Limiting Device installed under this Assembler Form. Enter the information exactly as it appears on the component labeling; if labeling is missing or obscured, then explain in the "COMMENTS" section.*

Manufacturer Name:	
Model Designation (Name and/or Number):	
Date Manufactured (mm/yyyy):	

Tables

Item: 1 (could contain up to 2 items with none required)

Note:	*Complete the following information for the certified Table component installed under this Assembler Form. Enter the information exactly as it appears on the component labeling; if labeling is missing or obscured, then explain in the "COMMENTS" section.*

Manufacturer Name:	
Model Designation (Name and/or Number):	
Date Manufactured (mm/yyyy):	

CT Gantry

Item: 1 (could contain up to 1 item but none are required)

Note:	*Complete the following information for the certified CT Gantry component installed under this Assembler Form. Enter the information exactly as it appears on the component labeling; if labeling is missing or obscured, then explain in the "COMMENTS" section.*

Manufacturer Name:	
Model Designation (Name and/or Number):	
Date Manufactured (mm/yyyy):	

Other Certified Components

Note:	*Complete the following information for the certified components below which you installed. For other certified components,*

	enter in how many of each you installed in the system.

Other Certified Components		
▪	X-Ray Control:	
▪	High Voltage Generator:	
▪	Vertical Cassette Holder:	
▪	Tube Housing Assembly:	
▪	Dental Tube Head:	
▪	Cradle:	
▪	Film Changer:	
▪	Image Intensifier:	
▪	Spot Film Device:	
▪	Fluoroscopic Imaging Assembly:	
▪	Cephalometric Device:	
▪	Image Receptor:	
▪	Image Receptor Support Device:	
▪	Fluorocopic Air Kerma Display Device:	
▪	Other:	[ ]
-	Specify Other Count:	
-	Specify Other Type:	

5.0 Assembler Certification

Part 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 CRF 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 on each copy.

Name	
Contact Name	

Date:	[Date]

6.0 Comments

Part 6	**Comments**

Provide additional comments below:
[Multi-Line Plain Text]

Completion

Error:	*You have not identified the type of Diagnostic X-Ray System for this Report of Assembly. Without this identification the form cannot be completed. Go back to the Administrative Information section and select the type of Diagnostic X-Ray System.*

Document Key: Specialized Response content is defined within straight brackets [ ]; Special code: [L] List of Values.