FLEXAVISION

Maintenance Report

Medical Systems Division
Shimadzu Corporation

Shimadzu Medical Systems Corporation

SVTS-0172D

No.

Report Date (M/D/Y):

Name of Institution:

Seal or Signature

Address

Telephone Number

Name of Room

Safety Management Supervisor for Medical Equipment

This is a report on the maintenance procedures, which were completed as noted in this document.

Name of System	System Component Described in the attached System Component List.
Management Registration No.	Installation Date (M/D/Y)
Inspection Date (/2) (M/D/Y)	Month of Next Inspection (M/Y)

Maintenance Engineers

Name

Name

Maintenance Company

Telephone Number

[Inspection Results]

Inspection Date: (1/2) (M) (D) (Y) to (M) (D) (Y)

Inspection Reporter:

Work Results:

Replacement Parts:

Part Name	Part No.	Qty	Part Name	Part No.	Qty

Measuring Instruments Used:

Name of Measuring Instrument	Control No.	Name of Measuring Instrument	Control No.

Inspection Date (2/2) (M) (D) (Y) to (M) (D) (Y)

Inspection Reporter:

Work Results:

Replacement Parts:

Part Name	Part No.	Qty	Part Name	Part No.	Qty

Measuring Instruments Used:

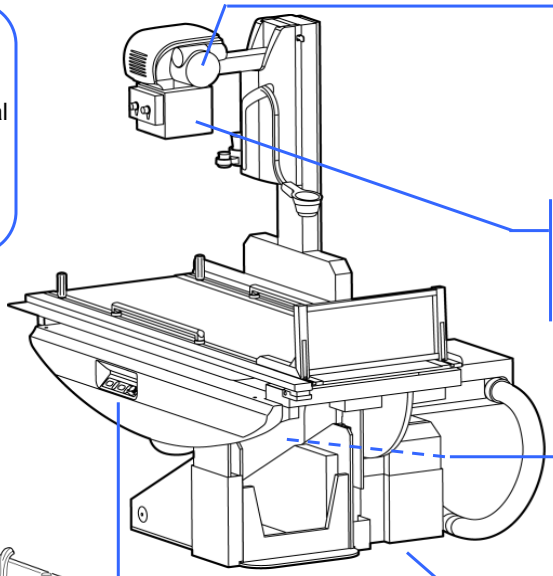
Name of Measuring Instrument	Control No.	Name of Measuring Instrument	Control No.

System Inspection Results Overview

Examination Room

<Air-Conditioning in the Examination Room>
Temperature/humidity
: ☐ Abnormal
: ☐ Normal
Special note:

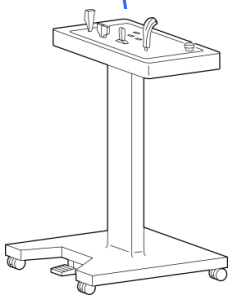
<X-Ray Tube Unit>
Image : ☐ Abnormal
: ☐ Normal
Special note:



<Irradiation Field Collimator>
Operation : ☐ Abnormal
: ☐ Normal
Special note:

<Local Console>
Operation : ☐ Abnormal
: ☐ Normal
Special note:

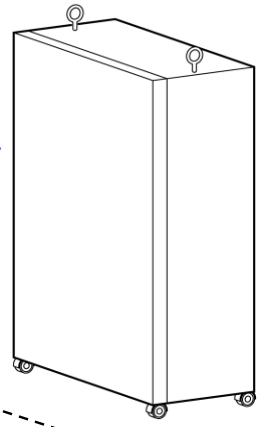
<FPD>
Operation : ☐ Abnormal
: ☐ Normal
Special note:



<Operation Switch>
Operation : ☐ Abnormal
: ☐ Normal
Special note:

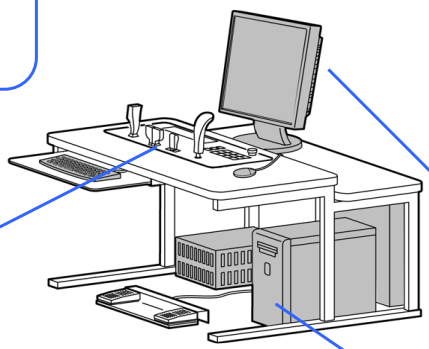
<R/F Table>
Operation : ☐ Abnormal
: ☐ Normal
Special note:

<High Voltage Generator>
Operation : ☐ Abnormal
: ☐ Normal
Special note:



Control Room

<Air-Conditioning in the Control Room>
Temperature/humidity : ☐ Abnormal
: ☐ Normal
Special note:



<Local Console>
Operation : ☐ Abnormal
: ☐ Normal
Special note:

<Monitor>
Degree of deterioration : ☐ Abnormal
: ☐ Normal
Special note:

<Image Processing Unit>
Operation : ☐ Abnormal
: ☐ Normal
Special note:

[System Component List]

Unit Name	Model	Serial Number	Remarks/Version
R/F table			
X-ray high voltage generator			
X-ray tube unit			
FPD			
Image processing unit			
Movable X-ray collimator	R-300		
Starter			
Monitor (1)			
Monitor (2)			
Monitor (3)			
Monitor (4)			

System Record:

[Inspection Report]

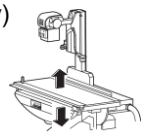
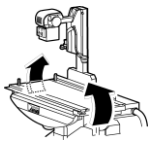
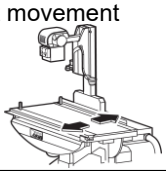
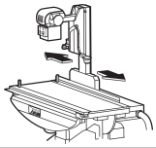
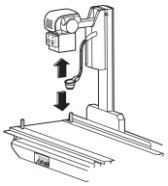
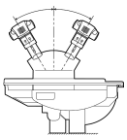
No.	Inspection Item	Safety Item	Details	Inspection Result: First Time	Inspection Result: Second Time
1. Checking installation environment					
(1)	X-ray exposure indicator	○	Confirm that the indicator lights up.		
(2)	Temperature and humidity	-	(First time) / (Second time) Exam. Room — Temperature: 10 to 35 °C: ____ °C / ____ °C Exam. Room — Relative humidity: 30 to 75 %: ____ % / ____ %		
			Control room — Temperature: 10 to 35 °C: ____ °C / ____ °C Control room — Relative humidity: 30 to 75 %: ____ % / ____ %		
2. Checking power supply					
(1)	Insulation resistance	-	(Second time) Between U and E: ____ MΩ Between V and E: ____ MΩ Between W and E: ____ MΩ (2 MΩ min. at 500 VDC) Between L100 and E: ____ MΩ Between L0 and E: ____ MΩ		
(2)	Power supply voltage	-	(First time) / (Second time) Between U and V: ____ V / ____ V Between V and W: ____ V / ____ V Between W and U: ____ V / ____ V (Power supply voltage ±10 %) Between L100 and L0: ____ V / ____ V		
(3)	Grounding wire connection	○	Confirm that the grounding wire is fixed.		
3. Checking equipment conditions					
(1)	Equipment appearance	-	Check the appearance.		
(2)	Equipment nameplate	-	Check the nameplate.		
(3)	Surrounding environment for equipment	○	Confirm that there are no obstructions in the vicinity of the equipment.		
(4)	Interphone operation	-	Check the connector connection and operations to send and receive audio signals.		
(5)	Caution displays	○	Check each equipment's operation to display cautions and warnings.		

Remarks

[Explanation about marks used in the Inspection Result column]

- **C** : **Checked** : Visual inspection or operation check has been performed. Measurement values have been confirmed to be within the standards.
- **M** : **Maintenance work performed** : Fixing parts have been re-tightened, lubrication and cleaning have been performed, and parts have been replaced.
- **A** : **Adjusted** : Settings have been changed and adjustment has been performed.
- **-** : **Not applicable** : There is no equipment subject to inspection or the item is not applicable.
- **N** : **Special note** : Detailed information is described in the Remarks section.
- **Next time** : Items not subject to inspection due to the inspection cycle

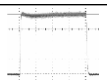
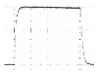
Safety Item: Inspection items related to safety are marked with a circle.

No.	Inspection Item	Safety Item	Details	Inspection Result First Time	Inspection Result Second Time
4. R/F table					
A. R/F table unit					
(1)	Table up/down mechanism (for ZS-5DS only) 	○	a. Check the motion/limit.		
			b. Check the chain (tension, joints).		
			c. Confirm that screws for mounting the sprocket, rack-and-pinion, motor, and other parts are tight.		
(2)	Table tilt mechanism 	○	a. Check the motion/limit.		
			b. Check the operations of the safety switch which prevents an operator's foot from getting caught.		
			c. Check the chain (tension, joints).		
			d. Confirm that screws for mounting the sprocket, rack-and-pinion, motor, and other parts are tight.		
(3)	Table left/right movement mechanism 	○	a. Check the motion/limit.		
			b. Check the guard plate.		
			c. Confirm that screws for mounting the motor and other parts are tight.		
(4)	F/R unit movement mechanism 	○	a. Check the motion/limit.		
			b. Check the chain (tension, joints).		
			c. Confirm that screws for mounting the sprocket, motor, and other parts are tight.		
(5)	Compression unit drive mechanism 	○	a. Compression operations		
			(Second time) b. Compression pressure — Vertical / Horizontal — 80 N max. — ____ N / ____ N		
			c. Check the tension of the chain.		
			d. Confirm that screws for mounting the motor and other parts are tight.		
(6)	X-ray tube extension mechanism	○	a. X-ray tube extension fastening		
			b. Check the motion/limit switch.		
(7)	X-ray tube oblique unit mechanism (option) 	○	a. Check the motion/limit.		
			b. Check the lubrication oil on the gear.		
			c. Confirm that screws for mounting the motor and other parts are tight.		
(8)	X-ray tube swiveling unit mechanism (option)	-	a. Check the motion/limit.		
			b. Confirm that screws for mounting the motor and other parts are tight.		
(9)	Shoulderrest	○	Install and check the shoulderrest.		
(10)	Footrest	○	Install and check the footrest.		

Remarks

No.	Inspection Item	Safety Item	Details	Inspection Result	
				First Time	Second Time
4. RF table (continued)					
(11)	Grip bar and grip	○	Install and check the grip bar and grip.		
(12)	Equipment cleaning	-	Clean the equipment using a cleaner.		
(13)	Cable conditions	-	Check the cables and connectors.		
(14)	Equipment fixing conditions	○	Check the equipment fixing conditions. Check for looseness in nuts and bolts.		
B. FPD tray					
(1)	FPD tray mechanism	-	Installation and check		
C. Collimator					
(1)	Open/close mechanism	-	Check the operation sound, wire rope, and linked operations.		
(2)	Dimensions of the effective irradiation field	-	Check the effective irradiation field.		
(3)	Equipment cleaning	-	Clean the equipment using a cleaner.		
(4)	Cable connectors	○	Check the cable connections.		
(5)	Installation	○	Check tightness of the mounting screws.		
D. Control panel and wiring					
(1)	Remote console 	○	a. Emergency stop switch operation		
			b. Operation switch operation		
(2)	Local console (option)	○	a. Emergency stop switch operation		
			b. Check the operation switch.		
			c. Check the cable.		
(3)	Main unit side console	○	a. Emergency stop switch operation		
			b. Check the operation switch.		
			c. Check the cable.		
(4)	Equipment cleaning	-	Clean the equipment using a cleaner.		
(5)	Cable connectors	○	Check the cable connections.		
E. Warning labels					
(1)	Warning labels	○	Check the condition of labels and tape.		

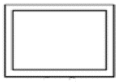
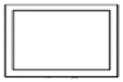
Remarks

No.	Inspection Item	Safety Item	Details	Inspection Result First Time	Inspection Result Second Time
5.	**X-ray tube unit**				
(1)	X-ray tube unit conditions	-	Appearance of the X-ray tube unit and rotation sound		
(2)	X-ray tube unit attachment	-	X-ray tube unit attachment		
6.	**X-ray high voltage generator**				
(1)	Control relay operation	○	Check the operations.		
(2)	PCB power voltage	-	TERMINAL-2005 (First time) J7 1–2 10.5 V ± 1 V ____ V J7 4–6 105 V ± 10 V ____ V J13 5–6 18 VAC ± 2 VAC ____ V INV. UNIT-2005 (First time) JM2 1–3 135 VAC ± 10 VAC ____ V UD CONT-2005 (First time) JPW 1–2 5 V ± 50 mV ____ V JPW 3–4 +15 V ± 400 mV ____ V JPW 5–6 -15 V ± 400 mV ____ V J124 1–2 24 V ± 600 mV ____ V		
(3)	Fluoroscopy operation	-	Tube voltage 115 kV Within ±10 % ____ kV Tube voltage 75 kV Within ±10 % ____ kV Tube current approx. 60 kV Within ± 20 % ____ mA		
(4)	Starter operation	-	Check the operations.		
(5)	Tube voltage precision and reproducibility 	-	60 kV 0.1 sec Max.mA*80 % ____ kV 100 kV 0.1 sec Max.mA*80 % ____ kV		
(6)	Tube current precision and reproducibility 	-	(First time) Radiography: 100 kV Min.mA 0.1 sec ____ mA ____ Radiography: 80 kV Max.mA*80 % 0.1 sec ____ mA ____		
(7)	Radiography time precision and reproducibility	-	Radiography: 100 kV (specific) mA 32msec ____ msec Radiography: 80 kV Max.mA*80 % 0.1 sec ____ msec		
(8)	mAs precision and reproducibility	-	Radiography: 100 kV 0.5 mAs ____ mAs Radiography: 60 kV 100 mAs ____ mAs		
(9)	High voltage cables and bushing	-	Fastening of the bushing on the high-voltage transformer		
(10)	Dose display value accuracy	○	Check that the calculated or measured dose display value is within the standard (±30%)		
(11)	Maximum fluoroscopy exposure dosage	○	Check that it does not exceed values regulated in the Medical Care Act.		
(12)	Automatic control	-	Operations in IBS automatic fluoroscopy and each radiography mode		
(13)	Check contactor screws	○	Check the screws that fasten the contactors and cables.		

Remarks

No.	Inspection Item	Safety Item	Details	Inspection Result	
				First Time	Second Time
7. FPD and power box					
(1)	Appearance	-	Check the appearance.		
(2)	Condition of connectors and cables	-	Check the connectors and cables.		
8. Image processing unit					
(1)	Pixel value (fluoroscopy/radiography)	-	Check the pixel value of fluoroscopy and radiography images.		
(2)	General image quality	-	Evaluate image quality using the Image Quality Adjustment Manual.		
(3)	Equipment cleaning	-	Clean the equipment using a cleaner.		
(4)	Cable connections	-	Check the connector of the cable.		
(5)	Image collection operation	-	Image collection operations		
(6)	Image processing function	-	Image processing functions		
(7)	Image read-out	-	Read images from the HDD.		
(8)	Print operation	-	DICOM print operation		

Remarks

No.	Inspection Item	Safety Item	Details	Inspection Result	
				First Time	Second Time
9. Monitors					
(1)	Fluoroscopy monitor in the examination room 	-	a. Check the contact of connectors and clean the monitor.		
			b. Check the grayscale.		
			c. Check the artifact and brightness.		
(2)	Radiography monitor in the examination room 	-	a. Check the contact of connectors and clean the monitor.		
			b. Check the grayscale.		
			c. Check the artifact and brightness.		
(3)	Fluoroscopy monitor in the control room 	-	a. Check the contact of connectors and clean the monitor.		
			b. Check the grayscale.		
			c. Check the artifact and brightness.		
(4)	Radiography monitor in the control room 	-	a. Check the contact of connectors and clean the monitor.		
			b. Check the grayscale.		
			c. Check the artifact and brightness.		
10. Checking overall system operations					
(1)	Overall operations after inspection	-	a. Fluoroscopy and radiography operations		
			b. Check the displayed images.		
			c. Operations such as DICOM MWM, printing, and storage		
			d. Linked operations with related equipment.		

Remarks