

Maintenance Report

Fluoroscopy System

SONIALVISION G4

Medical Systems Division
Shimadzu Corporation

Shimadzu Medical Systems Corporation

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 SONIALVISION G4	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	<input type="checkbox"/> Inspection Engineer Certification No. MRC <input type="checkbox"/> Inspection Engineer Certification No. MRC
Maintenance Company Shimadzu Medical Systems Corporation	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

<X-Ray Tube Unit>

Operation : ☐ Abnormal
 : ☒ Normal
 Special note:

<R/F Table Unit>

Operation : ☐ Abnormal
 : ☒ Normal
 Special note:

<FPD>

Operation : ☐ Abnormal
 : ☒ Normal
 Special note:

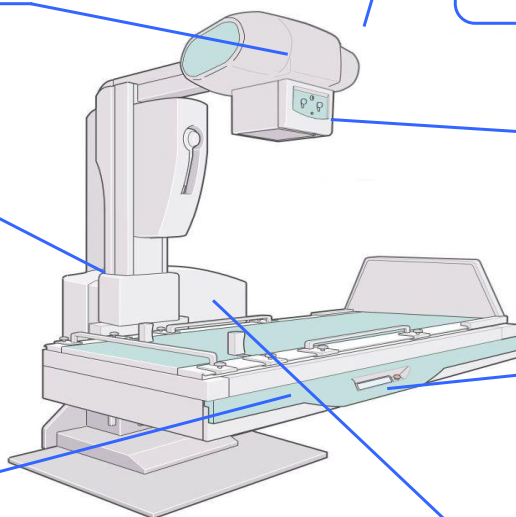
<R/F Table Controller>

Operation : ☐ Abnormal
 : ☒ Normal
 Special note:

<DR-300 EXAM CAB>

Operation : ☐ Abnormal
 : ☒ Normal
 Special note:

Examination Room



<Air-Conditioning in the Examination Room>

Temperature/humidity : ☐ Abnormal
 : ☒ Normal
 Special note:

<Collimator>

Operation : ☐ Abnormal
 : ☒ Normal
 Special note:

<Operation Switch>

Operation : ☐ Abnormal
 : ☒ Normal
 Special note:

<X-Ray Tube Heat Exchanger>

Operation : ☐ Abnormal
 : ☒ Normal
 Special note:

<UPS Unit>

Operation : ☐ Abnormal
 : ☒ Normal
 Recommended replacement time:

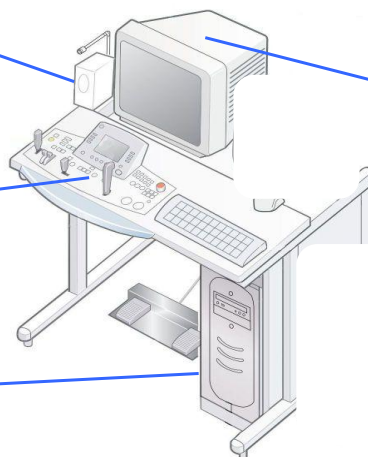
<Generator Controller>

Operation : ☐ Abnormal
 : ☒ Normal
 Special note:

<Intercom>

Operation : ☐ Abnormal
 : ☒ Normal
 Special note:

Control Room



<Control Console>

Operation : ☐ Abnormal
 : ☒ Normal
 Special note:

<Image Processing Unit>

Operation : ☐ Abnormal
 : ☒ Normal
 Special note:

<Monitor>


Degree of deterioration : ☐ Abnormal
 : ☒ Normal
 Special note:

[System Component List]

[illegible]

System Record:

[Inspection Report]

No.	Inspection Item	Safety Item	Details	Inspection Result		
				First Time	Second Time	
1. Checking installation environment						
(1)	X-ray exposure indicator	<input type="radio"/>	Lighting of the indicator during use			
(2)	Temperature and humidity	-		(First time)	(Second time)	
			Examination Room	Temperature: 20 to 27 (air-cooled to 30 °C)	°C	°C
				Relative humidity: 15 to 75 %	%	%
			Control Room	Temperature: 10 to 30 °C	°C	°C
			Relative humidity: 15 to 75 %	%	%	
2. Checking instrument usage conditions						
(1)	External appearance	-	External appearance, fastening status, and cable connection status of each unit			
(2)	Nameplates	<input type="radio"/>	Appearance of caution and warning nameplates on each unit			
(3)	Environment around the instrument	<input type="radio"/>	Obstacles around the instrument			
3. Checking the power source and grounding						
(1)	Power supply voltage	-		(First time)	(Second time)	
			Generator controller	• U-V phase	V	V
			R/F table controller	• Lo-L100:	V	V
			Image processing unit	• Single-phase 100 V	V	V
(2)	Grounding wire connection	<input type="radio"/>	Status of the grounding wire			
4. X-ray tube unit						
(1)	X-ray tube unit conditions	<input type="radio"/>	External appearance of X-ray tube unit and rotation noise (during normal rotation, double rotation, triple rotation, and braking)			
(2)	X-ray tube unit attachment	-	X-ray tube unit attachment			
(3)	High-voltage cables and bushing	-	External appearance, packing replacement, and greasing			
(4)	X-ray tube unit heat exchanger 	-	a. Heat exchanger pump and cooling fan operating noise			
		-	c. Check the oil hose.			
5. X-ray generator						
(1)	Instrument interior	-	Cleaning of the cabinet interior			
(2)	High-voltage cables and bushing	-	High-voltage transformer external appearance, packing replacement, and greasing			
(3)	Fluoroscopy operation		Operation and operation panel display			
(4)	Radiography operation	<input type="radio"/>	Operation and operation panel display			
(5)	Fluoroscopy tube voltage precision		Pulsed fluoroscopy: 80 kV	kV		

Remarks

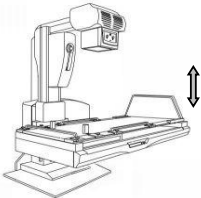
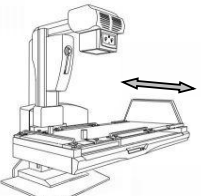
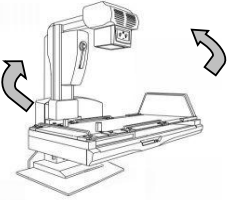
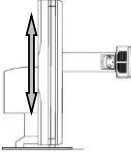
[Explanation about marks used in the Inspection Result column]

- 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.
NA : Items not subject to inspection due to the inspection cycle

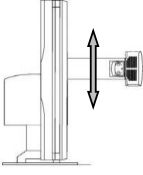
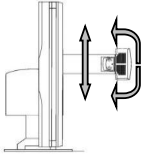
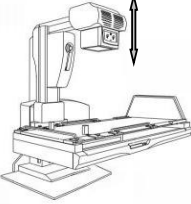
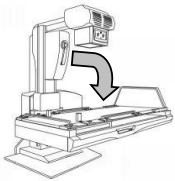
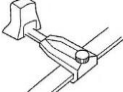




Inspection Report

No.	Inspection Item	Safety Item	Details	Inspection Result	
				First Time	Second Time
(6)	Fluoroscopy tube current precision	○	Pulsed fluoroscopy: 33.3 mA measurement value		
(7)	Tube voltage precision	-	Radiography: 100 kV 320 mA 0.1sec		
(8)	Tube current precision	-	(First time) Radiography: 100 kV 160 mA 0.1sec		
			FVR value		
			(Second time) Radiography: 80 kV 320 mA 0.1sec		
			FVR value		
(9)	Radiography time precision	-	Radiography: 100 kV 320 mA 32 msec		
			Radiography: 100 kV 320 mA 0.1 sec		
(10)	Control circuit	-	Connectors, control operation, standard voltage of the CPU (UD CONT) board		
			• +5 V V • +15 V V		
			• +3.3 V V • -15 V V		
(11)	Maximum fluoroscopy dose	○	Check that it does not exceed values regulated in the Medical Care Act.		
(12)	Automatic exposure	-	Operations in IBS automatic fluoroscopy and each radiography mode		
(13)	Area dosimeter	-	Check the area dosimeter.		
6. Image processing unit					
(1)	Instrument interior	-	Cleaning inside the image processing unit cabinet and PSU rack		
(2)	Image capture operation	-	Image capture operations		
(3)	Image evaluation	-	Evaluate image quality using the Image Quality Adjustment Manual.		
(4)	Image processing function	-	Image processing functions		
(5)	Reading and writing images	-	Reading and writing to/from the recording media		
(6)	Network connections	-	Obtain examination orders, send results information, and send images.		
(7)	Side station	-	Display images, send/receive images, and process images.		
(8)	Time settings	-	Time check, and conformity MPC DR ACQ DR REF ISYS GEN, RF_T, options		
7. Other optional functions					
(1)		-	Functional operation ()		
(2)		-	Functional operation ()		



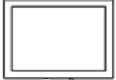




Remarks

No.	Inspection Item	Safety Item	Details	Inspection Result	
				First Time	Second Time
8. R/F table unit					
(1)	Control circuit		a. Clean the control cabinet interior.		
			○ b. Power supply voltage +5 V in the controller unit +24 V +15 V -15 V		
			c. Power supply voltage +5 V in the base unit +24 V +15 V -15 V		
(2)	<div>Table vertical movement mechanism</div> 	○	a. Check the roller chain tension and lubrication.		
			b. Check the chain link.		
			c. Operating noise and stopping position (limit switch and potentiometer operation)		
			d. Anti-pinching safety switch for downward movement		
		-	e. Belt status and tension		
			f. Rack and pinion fastening status and lubrication oil		
			g. Bearing rail status and fastening status		
		○ h. Confirm that fasteners and joints are tight for the motor, gear reducer, tension sprocket, etc.			
(3)	<div>Tabletop transverse movement mechanism</div> 	○	a. Operating noise and stopping position (limit switch operation)		
			b. Tabletop guard plate status (front and rear sides)		
		-	c. Check the gear status, lubrication oil, and retainer.		
			d. Rail status, fastening, and lubrication oil on head and foot ends		
			e. Bearing status and fastening status		
		○ f. Confirm that fasteners and joints are tight for the motor, etc.			
(4)	<div>Table tilt mechanism</div> 	○	a. Check the roller chain tension, status, and lubrication oil.		
			b. Check the chain link.		
			c. Operating noise and stopping position (limit switch and potentiometer operation)		
		-	d. Belt status and tension		
			e. Gear status and lubrication oil		
			f. Rail bearing status and fastening status		
			g. Rack and pinion status and lubrication oil		
		○ h. Confirm that fasteners and joints are tight for the motor, gear reducer, tension sprocket, and so on			
(5)	<div>Detection assembly vertical movement mechanism</div> 	○	a. Operating noise and stopping position (limit switch and AC servo operation)		
			b. Gear status and lubrication oil		
		-	c. Rail bearing status, fastening, and cleaning status		
			○ d. Confirm that the fasteners and joints are tight for the motor, gear reducer, etc.		

Remarks

No.	Inspection Item	Safety Item	Details	Inspection Result	
				First Time	Second Time
(6)	Support column assembly vertical movement 	○	a. Operating noise and stopping position (overrun limit switches and AC servo)		
			b. Movement of safety sensors and contact safety switches		
		-	c. Gear status and lubrication oil		
			d. Rail bearing status, fastening, and cleaning status		
		○	e. Confirm that the fasteners and joints are tight for the motor, gear reducer, etc.		
(7)	X-ray tube rotation movement (incidence) 	-	a. Operating noise and stopping position (AC servo operation)		
			b. Cable status and tension		
		○	c. Confirm that the fasteners and joints are tight for the motor, gear reducer, etc.		
(8)	X-ray tube vertical movement mechanism 	○	c. Operating noise and stopping precision (limit switch and potentiometer operation)		
		-	b. Belt status and tension		
			c. Gear status and lubrication oil		
			d. Rail bearing status and fastening status		
		○	e. Confirm that the fasteners and joints are tight for the motor, gear reducer, etc.		
(9)	Compression cone drive mechanism 	○	a. Check the compression force.		
		-	b. Check the external appearance and operating noise.		
			d. Chain status and tension		
			e. Rail bearing status and lubrication		
		○	f. Confirm that the fasteners and joints are tight for the motor, gear reducer, etc.		
(10)	Shoulder rest 	○	a. Check the fastening status.		
			b. Check the springs.		
(11)	Foot rest 	○	a. Check the fastener area.		
			b. Check the springs.		
			c. Shoe status		
(12)	Hand grip 	○	a. Check the fastener screws.		
(13)	Remote control console 	○	a. Check the emergency stop operation.		
		-	b. Check the operation of operating switches.		
(14)	Local control console 	○	a. Check the emergency stop operation.		
		-	b. Check the operation of operating switches.		

Remarks

No.	Inspection Item	Safety Item	Details	Inspection Result	
				First Time	Second Time
(15)	Main unit control console 	○	a. Check the emergency stop operation.		
		-	b. Check the operation of operating switches.		
(16)	Collimator 	○	a. Check the tightness of the mounting screws.		
		-	b. Check the irradiation field display lamp.		
		-	c. Manual operation		
9. Monitors					
(1)	Live 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)	Reference 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)	Live 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)	Reference 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.		
(5)	Monitor in the side station 	-	a. Check the contact of connectors and clean the monitor.		
		-	b. Check the grayscale.		
		-	c. Check the artifact and brightness.		
10. Other related devices					
(1)	Intercom	-	Check the connector connection and operations to send and receive audio signals.		
11. Checking system operations after inspection					
(1)	Overall operations after inspection	-	a. R/F table operations		
		-	b. Fluoroscopy and radiography operations		
		-	c. Check the displayed images.		
		-	d. Operation of MWM, storage, MPPS, etc.		

Remarks
