

Maintenance Report

Angiography System Equipped with FPD (Single-Plane)

Trinias
BRANSIST *safire*
CVS Package
BRANSIST *alexa* C12L / F12L

Medical Systems Division
Shimadzu Corporation

Shimadzu Medical Systems Corporation

Report Date (M/D/Y):

Name of Institution:

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 Trinias Type C8	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 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

<FPD>

Image : ☐ Abnormal
☐ Normal
 Special note:

Examination Room

<Air-Conditioning in the Examination Room>

Temperature/humidity : ☐ Abnormal
☐ Normal

Special note:

<Monitor>

Degree of deterioration : ☐ Abnormal
☐ Normal

Special note:

<Operation Switch>

Operation : ☐ Abnormal
☐ Normal

Special note:

<Diagnostic Table>

Operation : ☐ Abnormal
☐ Normal

Special note:

<C-Arm>

Operation : ☐ Abnormal
☐ Normal
 Special note:

<X-Ray Tube Unit>

Operation : ☐ Abnormal
☐ Normal
 Special note:

Control Room

<Monitor>

Degree of deterioration : ☐ Abnormal
☐ Normal

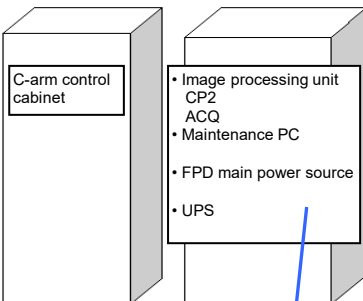
Special note:

<Image Processing Unit>

Display operation : ☐ Abnormal
☐ Normal

Special note:

Machine Room



<Air-Conditioning in the Machine Room>

Temperature/ humidity : ☐ Abnormal
☐ Normal

Special note:

<UPS Unit>

Operation : ☐ Abnormal
☐ Normal
 Recommended replacement time:

<X-Ray Tube Cooler>

Operation : ☐ Abnormal
☐ Normal
 Amount of cooling water: ☐ Abnormal
☐ Suitable
 Next cooling water replacement time:

<FPD Cooler>

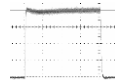
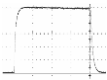
Operation : ☐ Abnormal
☐ Normal
 Amount of cooling water: ☐ Abnormal
☐ Suitable
 Next filter and cooling water replacement time:

[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)	Indicator during use	<input type="radio"/>	Lighting of the indicator during use					
(2)	Temperature and humidity	-		(First time)	(Second time)			
			Examination Room	Temperature: 20 to 27 °C		°C		°C
				Relative humidity: 15 to 75 %		%		%
			Machine Room	Temperature: 10 to 30 °C		°C		°C
			Relative humidity: 15 to 75 %		%		%	
2. Checking equipment usage status								
(1)	Equipment appearance	-	External appearance of each unit					
(2)	Nameplate	<input type="radio"/>	Appearance of caution and warning nameplates on each unit					
(3)	Surrounding environment of the equipment	<input type="radio"/>	Obstructions in the vicinity of the equipment					
3. Checking the power source and grounding								
(1)	Power supply voltage	-		(First time)	(Second time)			
			UD controller		V		V	
			DAR controller • Lo-L100:		V		V	
			MH controller		V		V	
(2)	Grounding wire connection	<input type="radio"/>	Status of the grounding wire					
4. X-ray generator								
(1)	Equipment interior	-	Clean the cabinet interior.					
(2)	Fluoroscopy operation	<input type="radio"/>	Operation and operation panel display					
(3)	Starter operation	-	Operation and operation panel display					
(4)	Radiography operation	<input type="radio"/>	Operation and operation panel display					
(5)	Tube voltage precision 	-	Radiography: 100 kV 630 mA 0.1 sec		kV			
(6)	Tube current precision 	-		(First time)	(Second time)			
			Radiography: 100 kV 10 mA 0.1 sec		mA		mA	
			FVR value					
			Radiography: 80 kV 630 mA 0.1 sec		mA		mA	
			FVR value					
(7)	Radiography time precision	-	Radiography: 100 kV 630 mA 32 msec		msec			
			Radiography: 100 kV 630 mA 0.1 sec		sec			

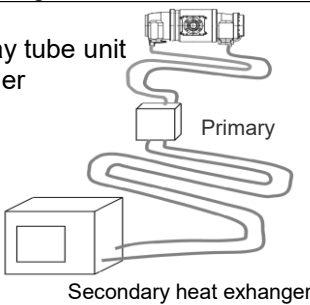
[Explanation about marks used in the Inspection Result column]

- 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 to be implemented next time and subsequently due to the inspection cycle

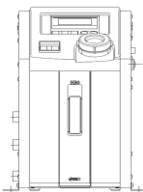
Safety Item: Inspection items related to safety are marked with a circle.

No.	Inspection Item	Safety Item	Details	Inspection Result	
				First Time	Second Time
(8)	High voltage cables and bushing	-	Tightening of the high-voltage connectors on the high-voltage transformer		
(9)	Control circuit	-	Connectors, control operation, standard voltage of the CPU board		
			• +5 V V • +15 V V		
			• -15 V V		
(10)	Maximum fluoroscopy exposure dosage	○	Check that it does not exceed values regulated in the Medical Care Act.		
(11)	Automatic exposure	-	Operations in IBS automatic fluoroscopy and each radiography mode		
(12)	Area dosimeter	-	Check the area dosimeter.		

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		
(3)	High voltage cables and bushing	-	External appearance, and tightening of the high-voltage connectors		
(4)	 X-ray tube unit cooler	-	a. Check the cooling water.		
			b. Cooler pump and cooling fan operating noise		
			c. Check the oil hose.		
			d. Clean the primary heat exchanger.		
			e. Clean the secondary heat exchanger's cooling water filter and cooling fan.		

6. FPD cooler

(1)	 FPD cooler	-	a. Cooling water status		
			b. Cooler pump and cooling fan operating noise		
			c. Set temperature of the cooling water		
			d. Clean the radiator and cooling fan.		

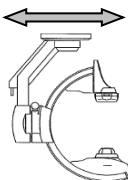
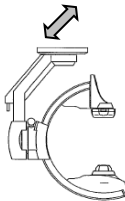
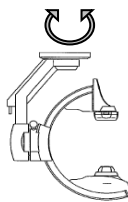
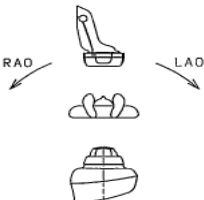
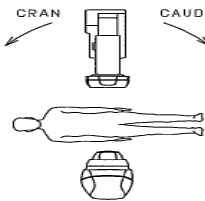
7. X-ray image processing unit

(1)	Equipment interior	-	Clean the PC cabinet interior (including REF PC).		
(2)	Image collection operation	-	Image collection 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)	Time settings	-	Time check, and conformity between units <div> <div></div> ACQ, <div></div> REF, <div></div> UD, <div></div> MH, <div></div> MPC, <div></div> options </div>		

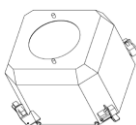




8. Other optional functions

(1)		-	Functional operation ()		
(2)		-	Functional operation ()		

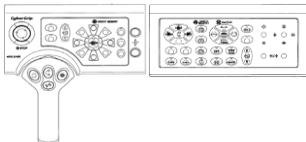
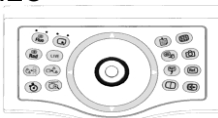
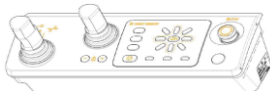
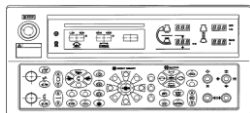
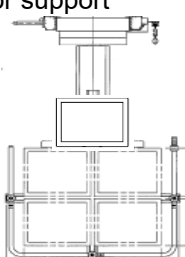
Remarks

No.	Inspection Item	Safety Item	Details	Inspection Result	
				First Time	Second Time
9-1. C-arm (MH-200S)					
(1)	Ceiling travel mechanism (longitudinal movement) 	-	a. Operation, noise, and stopping status		
			b. Status of drive surfaces and gears, and lubrication oil		
			c. Appearance and tension of belts		
			○ d. Limit switch		
(2)	Ceiling travel mechanism (lateral movement) 	-	a. Operation, noise, and stopping status		
			b. Status of drive surfaces and gears, and lubrication oil		
			c. Appearance and tension of belts		
			○ d. Limit switch		
(3)	Ceiling pivot mechanism 	-	a. Operation, noise, and stopping status		
			b. Status of drive surfaces and gears, and lubrication oil		
			c. Appearance and tension of belts		
			○ d. Limit switch		
(4)	C-arm rotation mechanism (rotation around body axis) 	-	a. Operation, noise, and stopping status		
			b. Status of drive surfaces and gears, and lubrication oil		
			c. Appearance and tension of belts		
			d. Check the cables and cable covers.		
		○ e. Limit switch			
(5)	C-arm sliding mechanism (rotation along body axis) 	-	a. Operation, noise, and stopping status		
			b. Status of drive surfaces and gears, and lubrication oil		
			c. Appearance and tension of belts		
			d. Check the cables and cable covers.		
		○ e. Limit switch			

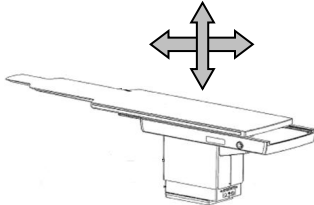
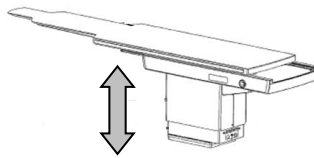
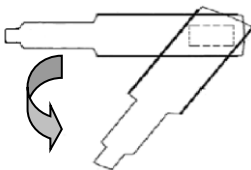
Remarks

No.	Inspection Item	Safety Item	Details	Inspection Result	
				First Time	Second Time
9-1. C-arm (MH-200S)					
(6)	Collimator rotation mechanism 	-	a. Operation, noise, and stopping status		
			b. Status of gears and lubrication oil		
		○	c. Attachment and tightening of motors and mechanisms		
(7)	Collimator front-panel switch 	○	a. Safety switch operation		
		-	b. Operation of front lid opening/closing check switch		
(8)	Collimator leaf open/close mechanism (H, V, C leaf, compensating filter) 	-	a. Operation and sound of each leaf and filter		
			b. Check interlock with field-of-view switching operation.		
(9)	BH filter switching mechanism	-	Operations		
(10)	Collimator control circuit	-	Terminals and connector contacts		
(11)	Collimator attachment	○	Tightness of the mounting screws		
(12)	FPD backward/forward movement mechanism 	-	a. Operation, noise, and stopping status		
			b. Status of drive surfaces and screw stocks, and lubrication oil		
		○	c. Limit switch		
(13)	FPD rotation mechanism 	-	a. Operation, noise, and stopping status		
			b. Status of gears and lubrication oil		
(14)	FPD front-panel switch	○	Safety switch operation		

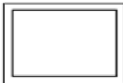




Remarks

No.	Inspection Item	Safety Item	Details	Inspection Result				
				First Time	Second Time			
9-2. C-arm unit, monitor support unit, IVR console (control, connections, and fastening)								
(1)	Equipment interior	-	Clean the cabinet interior.					
(2)	Control circuit	-	Connectors and control operation	• +5 V		V		
			a. (Standard voltage for CPU board)	• +15 V		V		
				• -15 V		V		
				• +5 V		V		
			b. (Standard voltage for Relay-I/F board)	• +15 V		V		
				• -15 V		V		
(3)	Local console (including CyberGrip) 	-		a. Operation and display of operating switches				
			b. Terminals and connector contacts					
			c. Appearance of console cables, and fastening of the console					
			○ d. Emergency stop operation					
(4)	IVR NEO 	-	a. Operation and display of operating switches					
			b. Terminals and connector contacts					
			c. Appearance of console cables, and fastening of the console					
(5)	Cyber console 	-	a. Operation and display of operating switches					
			b. Terminals and connector contacts					
			c. Appearance of console cables, and fastening of the console					
			○ d. Emergency stop operation					
(6)	Remote console 	-	a. Operation and display of operating switches					
			b. Terminals and connector contacts					
			○ c. Emergency stop operation					
(7)	Monitor support 	-	a. C-arm display unit					
			b. Brakes and their operation					
			c. Appearance of the rails, and bearing noise					
			d. Terminals, connector contacts, and appearance of cables					
			○ e. Fastening of the monitor, and attachment and tightening of the suspension part					
(8)	Fastening of the main unit to the floor and ceiling	○	Tightness of the mounting screws					

Remarks

No.	Inspection Item	Safety Item	Details	Inspection Result	
				First Time	Second Time
10. Table (diagnostic table)					
(1)	Tabletop lateral and transverse movement 	-	a. Operation, noise, and lock operation for lateral movement		
			b. Operation, noise, and lock operation for transverse movement		
			c. Appearance and fastening of the rails		
		○	d. Operation of the micro-switch for checking tabletop extension at the head end		
			e. Tightening of the tabletop mounting screws		
(2)	Tabletop vertical movement mechanism 	-	a. Vertical operation, noise, and stopping status		
			b. Appearance of rails and gears, and lubrication oil		
			c. Appearance and tension of belts		
		○	d. Limit switch		
(3)	Tabletop pivot mechanism 	-	a. Sensor operation		
			b. Pivot operation, noise, and braking operation		
			c. Appearance of gears, and lubrication oil		
		○	d. Tightening of attachment screws for clutches, etc.		
(4)	Control circuit	-	a. Foot switch operation		
			b. Operation of the operation switch on the side of the main unit		
			c. Connectors and control operation		
			d. Appearance of cables		
		○	e. Emergency stop operation		
(5)	Fastening of main unit	○	Fastening of table to the floor		
(6)	Fastening of accessories	-	Fastening of accessories situated on the tabletop side rails		

Remarks

No.	Inspection Item	Safety Item	Details	Inspection Result	
				First Time	Second Time
11. 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.		
(5)	Post processing monitor 	-	a. Check the contact of connectors and clean the monitor.		
			b. Check the grayscale.		
			c. Check the artifact and brightness.		
12. Other related devices					
(1)	Interphone	-	Check the connector connection and operations to send and receive audio signals.		
(2)	Contrast medium injector	-	Check the injector interlock operation.		
(3)	Bio-phenomena equipment	-	Check connections with the polygraph.		

13. Checking overall system operations					
(1)	Overall operations after inspection	-	a. Collection of DA, DSA, 3D, CTL, etc. b. C-arm and table control operations c. Check the displayed images. d. Operation of MWM, storage, MPPS, etc. e. Check linked operations with related equipment.		

Remarks
