

# PHILIPS

Philips Healthcare

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## Level 0 Documentation

**AIAT manual**

**for**

**DigitalDiagnost**

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**AIAT MANUAL –**

**DigitalDiagnost**

Type No:

File: AIAT for DigitalDiagnost

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**List of pages and drawings (LOPAD)**

**Manual Order No: 4512 988 02401**  
**released: 01/2011**

1...16	(11.0)
4512 983 11841	Replacement X-ray tube assembly
4512 983 11871	Replacement NICOL Collimator
4512 983 11911	Replacement Control Grip
4512 983 12181	Replacement Front cover 3-field / 5-field
4512 983 11971	Replacement for Single Sided Trolley TF-M
4512 983 11961	Replacement for Single Sided Table TH-S
4512 983 12001	Replacement Optimus RAD/RF/C
4512 983 12191	ComplianceTest Manual

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## 1. INTRODUCTION

### 1.1. PURPOSE OF MANUAL

This manual guides a trained and qualified service engineer in his activities as described in FDA rules clause 21 CFR1020.30(g), regarding Assembly, Installation, Adjustment and Testing (AIAT).

### 1.2. APPLICABILITY

This manual is applicable for the following systems:

- DigitalDiagnost
- DigitalDiagnost VM
- DigitalDiagnost VM Compact
- DigitalDiagnost VR

### 1.3. CERTIFIED COMPONENTS

The following devices are certified components in DigitalDiagnost systems

- Tube housing assembly:<sup>\*</sup>
- X-ray table:
  - Single Sided Table TH-S
  - Single Sided Trolley TF-M
- Wallstand:
  - Front cover 3-field/5-field
- Beam-limiting device:
  - NICOL collimator\*
- X-ray high voltage generator:
  - OPTIMUS 50/60/80\*
- Laser Product:
  - Control Grip

\* Assembly and/or installation of (parts of) the devices that are indicated with an asterix requires adjustments and/or tests for compliance with performance standards that are intended to reduce unnecessary X-ray exposure to the patient and operator.

## 1.4. SAFETY INFORMATION

### 1.4.1. Safety warnings

The general legal and factory safety recommendations for this X-ray equipment and the following recommendations must be strictly observed!

Start of installation, operation and maintenance work and especially electrical work must only be executed by trained and authorized persons. This equipment must only be serviced by properly educated service specialists who have received general and system-specific training as performed by Philips Medical Systems.



#### WARNING

*Procedures in this manual may only be carried out by a trained and qualified service engineer.  
Incorrect adjustments may lead to unacceptable risks for patient and operator.*

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#### WARNING

*The DigitalDiagnost equipment generates dangerous high voltages and should be handled with caution.*

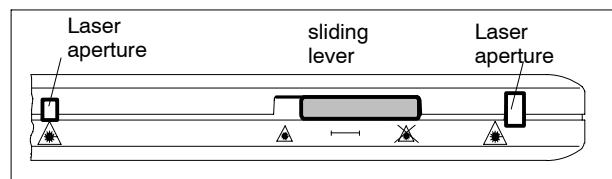
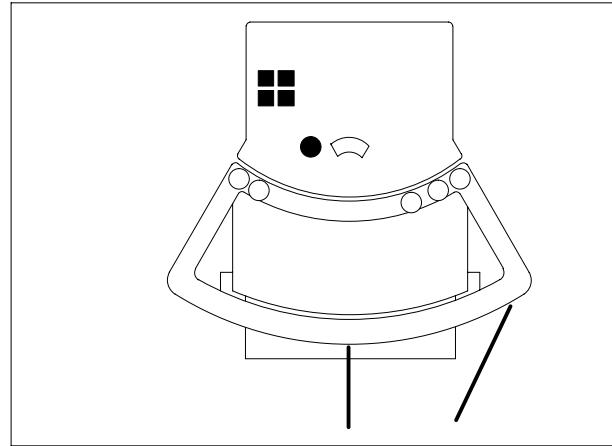
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### 1.4.2. Laser safety

For the Control Grips a class 2 Laser is used. The laser diode module, shows less than 1mW and is classified in laser class 2 regarding to the regulations of FDA DHHS 1040.10 and IEC 825-1. Up to the internal electronic stabilisation (automatic power control APC) the laser class 2 cannot exceed via the complete lifetime of the laser diode.

The laser light is used for orthopedic alignment and is fitted on the front cone cover. The laser produces a laser light crossbeam, which is visible red and projected directly through an aperture, at the top front cover, vertically downwards

The laser illuminates if the button  on the front PICU is activated.



**The laser light in the laser alignment tool should only be used under supervision of a medical trained person with knowledge of the hazards implied by the use of a laser light.  
It is the user's responsibility to fulfill the local safety regulations regarding laser light radiation.**



#### WARNING

*The light source of the light pointer is a Class II laser. Never look into the beam directly.*

*With Class II lasers the eye is protected from brief, random glances into the laser beam by the eyelid closure reflex. Class II lasers may therefore be used without taking any further precautions provided it is necessary neither to intentionally look into the beam for a period longer than 0.25s nor to repeatedly look into the laser beam or directly reflected laser beam.*

*For continuous duty Class II lasers the maximum limit for accessible radiation is 1mW. The laser light is emitted from openings in the lower side of the controlhandle. The laser apertures are marked by the yellow/black laser triangle in close proximity to the laser aperture.*

## 1.5. REGULATORY COMPLIANCE

Information regarding regulatory compliance of this medical device can be obtained at:

Philips Medical Systems Hamburg.  
Röntgenstraße 24  
22335 Hamburg  
Germany

## 1.6. ABBREVIATION AND DEFINITIONS

Abbreviation	Explanation
AIAT	Assembly, Installation, Adjustment and Testing
BIST	Build In Self Test
CCT	Comprehensive Compliance Testing
CFR	Code of Federal Regulations
EDL	Entrance Dose Limitation
FD, FDXD	Flat Detector
FDA	Food and Drug Administration
FRU	Field Replaceable Unit
FSE	Field Service Engineer
FSF	Field Service Framework
GEO	Geometry subsystem
PEE	Patient Entrance Exposure (limitation of patient dose e.g. 10 Roentgen)
PMS	Philips Medical Systems
POST	Power On Self Test
SMI	System Manual Installation
SRM	System Reference Manual
Velara	X-ray generator

## 1.7. CONTENTS OF STANDARD TOOL KIT TC 129

### SCREWDRIVERS

- Screwdriver (6x): 2.5mm (0) - 3.5mm (1) - 4mm (2) - 5.5mm (3) - 6.5mm (4) - 8mm (5)
- Stubby screwdriver (2x): 5.5mm (3) - 8mm (5)
- Screwholder slot, no. 2
- Crosshead screwdriver: no. 2
- Crosshead stubby screwdriver (2x): no. 0 - no. 2
- Screwholder crosshead: no. 1
- Double end offset screwdriver in line (0° and 90°) (2x): 4mm (2) - 6.5mm (4)
- Watchmakers screwdriver set (6): 0.6-2.5mm
- Parallel hexagon driver: 2.5mm
- Ball head hexagon driver (4x): 3mm - 4mm - 5mm - 6mm
- Torx driver + Torx-bits (10x): T-7 / T-8 / T-9 / T-10 / T-15 / T-20 / T-25 / T-27 / T-30 / T-40

#### ALLEN KEYS / SPANNERS

- Set hex metric keys (allen key) (5x): 0.71 - 0.89 - 1.27 - 1.5 - 2mm
- Set hex metric keys (allen key) (8x): 1.5 - 2 - 2.5 - 3 - 4 - 5 - 6 - 8mm
- Hex metric key (allen key): 9mm - 10mm
- Set hex inch keys (allen key) (9x): 1/16 - 3/32 - 1/8 - 5/32 - 3/16 - 7/32 - 1/4 - 5/16 - 3/8"
- Combination spanner set (ring/open), metric (17x): 6...22mm in 1mm steps
- Combination spanner set (ring/open), metric (2x): 5mm - 5.5mm
- Combination spanner set (ring/open), inch (11x): 1/4"-7/8" in 1/16" steps

#### PLIERS

- Long (chain) nose pliers (140mm)
- Long-nosed pliers (bent 60°)
- Side cutting pliers
- Side cutting pliers, small
- Water pump pliers 250mm
- Wire stripping pliers
- Spring ring pliers: outside / inside
- Hard-round file (medium grade) + handle
- Set of key files (6pcs.)
- Drill set (19x): 1mm....10mm (steps of 0.5mm)
- Masonry drill set (5x): 4 - 5 - 6 - 8 - 10mm
- Hammer 200gr. (iron)
- Hammer (nylon)
- Small hacksaw frame
- Spare blades for hacksaw (10x): 6"
- Cable knife
- Scissors
- Awl
- Pin punch (3x): 1.5mm - 2mm - 4mm
- Centre-punch no. 1
- Tap wrench with ratchet, no. 1: M3-M10
- Hand-machine tap (DIN 352B): M3 - M4 - M5 - M6 - M8 - M10
- 3/8" drive socket set: 6 - 7 - 8 - 9 - 10 - 11 - 13 - 14 - 17 - 19mm
- Tool kit carrying case (separately available; 12NC: 4522-980-32301)

#### SPECIAL APPLIANCES

- Hollow head potentiometer adjuster, 3.2mm dia
- Tweezers
- Strong insulated mirror plain (diff. type)
- Magnifying glass: 10x

#### MEASURING TOOLS

- Vernier callipers (1/125" - 0.05mm)
- Extending rule: 3m
- Flat precision steel rule: 300mm
- Spirit level: 400mm
- Plumb bob
- Plumb bob

## 1.8. CONFIGURATION SERVICE PC

### MINIMUM REQUIREMENTS

- Windows 2000
- 128 MB RAM
- 1GB ROM free
- 3.5" 1,44 MB floppy diskette drive
- CDRW drive
- one serial port of 9-pin connector

## 1.9. MANUAL HISTORY

Date	12NC	Reason of changes
December 2006	4512 988 02401 REV AA	Initial version
September 2009	4512 988 02401 REV AB	Update
November 2010	4512 988 02401 REV AC	Update
November 2010	4512 988 02401 REV AD	Update
January 2011	4512 988 02401 REV AE	Update

## **2. ASSEMBLY**

### **2.1. DEFINITION**

To fit together the parts or pieces of a component or system.

### **2.2. GUIDANCE FOR THE TRAINED AND QUALIFIED SERVICE ENGINEER**

Instructions for assembly of a complete system can be found in the System Manual Installation (SMI), which is delivered with the system.

Instructions for replacement of certified components (on FRU level) can be found in the Replacement documents, which are included in this AIAT manual.

### **3. INSTALLATION**

#### **3.1. DEFINITION**

To set up for use by verifying that proper assembly and adjustments were made to assure compliance with federal performance specifications.

#### **3.2. GUIDANCE FOR THE TRAINED AND QUALIFIED SERVICE ENGINEER**

Instructions for installation of a complete system can be found in the System Manual Installation (SMI), which is delivered with the system.

Installation activities that are required after replacement of certified components (on FRU level) can be found in the What-to-Do tables in the Replacement documents, which are included in this AIAT manual.

## 4. ADJUSTMENTS

### 4.1. DEFINITION

To bring various component parts up to a true or more effective relative position for performance purposes.

### 4.2. GUIDANCE FOR THE TRAINED AND QUALIFIED SERVICE ENGINEER

Instructions for adjustments that are required after installation of a complete system can be found in the System Manual Installation (SMI), which is delivered with the system.

Instructions for adjustments that are required after replacement of certified components (on FRU level) can be found in the What-to-Do tables in the Replacement documents, which are included in this AIAT manual.

## 5. TESTING

### 5.1. DEFINITION

A critical examination, observation, or evaluation of such conditions or operations through testing procedures provided by the manufacturer that will prove the unit meets specifications purposes.

### 5.2. GUIDANCE FOR THE TRAINED AND QUALIFIED SERVICE ENGINEER

Instructions for testing are described in the section “Testing”, which is included in this AIAT manual.

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# REPLACEMENTS

# X-ray tube assembly

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## 1. GENERAL REPLACEMENT PROCEDURES



### WARNING

*Before starting any of the replacement activities, SWITCH OFF the system, unless otherwise stated during the replacement procedure.*

---



### CAUTION

*Wear an Electro Static Discharge (ESD) bracelet during replacements.*

---



### NOTE

*Before disconnecting any cable, check the labeling, so the cable can be reconnected in the same position.*

---

### 1.1. GENERAL INFORMATION

The procedures stated in this replacement manual apply to the following systems:

- BuckyDiagnost Systems
- DigitalDiagnost Systems
- EasyDiagnost Overtable Systems

## 2. REPLACEMENTS

### 2.1. WHAT-TO-DO TABLE

This table lists the actions you have to perform to replace the defective part. The standard sequence is:

- Verify hardware programming (jumpers/cables etc.).
- Replace the item.
- Perform software programming.
- Perform adjustments.
- Execute the appropriate functional test.
- Update the Service Logbook (Specific System Functions > Service Log).
- Hand-over to the customer.

FRU	Activity	Reference to procedure
X-ray tube assembly	Info	N/A
SRO 2550 ROT 350 9890 000 8583x	Replacement	Chapter 2.6.
SRO 0951 ROT 350 9890 000 6318x	Adjustment	N/A (Pre-aligned assembly)
SRO 33100 ROT 360 9890 000 8610x	Verification	Refer to CCT
SRM 0612 ROT 504 9890 000 8500x		

### 2.2. TOOLS REQUIRED

- Standard Service Tool Kit (TC 129)

### 2.3. MATERIALS REQUIRED

- X-ray tube assembly

### 2.4. TIME / MANPOWER REQUIRED

	X-ray tube assembly replacement including removal of the collimator	
---	--	--

### 2.5. PRECONDITIONS

The X-ray tube assembly is provided with a tube alignment ring. Before starting the replacement procedure of the X-ray tube assembly, remove the collimator following the replacement procedure described in Chapter 2.6 in the Replacement Manual “Replacement of the Collimator”. Then start the replacement of the X-ray tube assembly.

## 2.6. REPLACEMENT PROCEDURES OF FRUs

### 2.6.1. FIXING THE WORKING POSITION



#### DANGER OF INJURY!

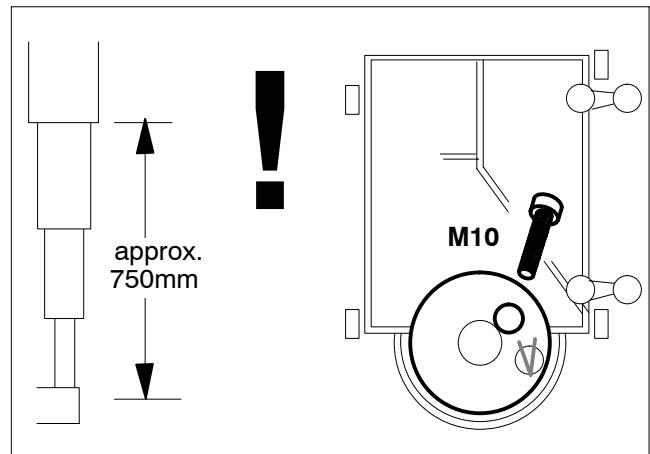
After removal of the collimator and the X-ray tube assembly the system is not weight balanced, so that the BuckyDiagnost CS/FS subsystem automatically moves up without fixing the working position.

For the following steps, the telescopic system has to remain locked in the middle of its range of movement (extension 750mm).

---

#### For BuckyDiagnost CS2/4:

- Position the telescopic tube.
- Lock the telescopic system by using the supplied screw M10.
  - Lock it via the hole into the thread.



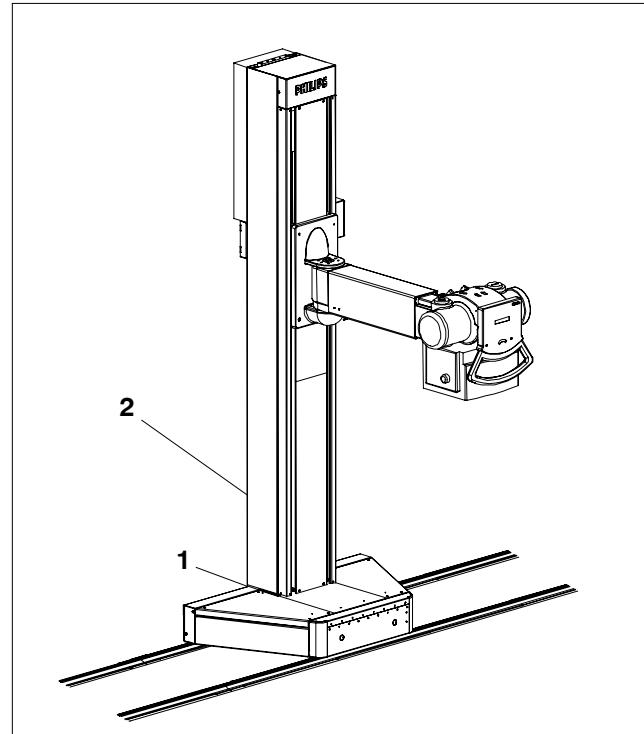
**For BuckyDiagnost FS:****DANGER OF INJURY!**

After removal of the collimator and the X-ray tube assembly the system is not weight balanced, so that the BuckyDiagnost CS/FS subsystem automatically moves up without fixing the working position.

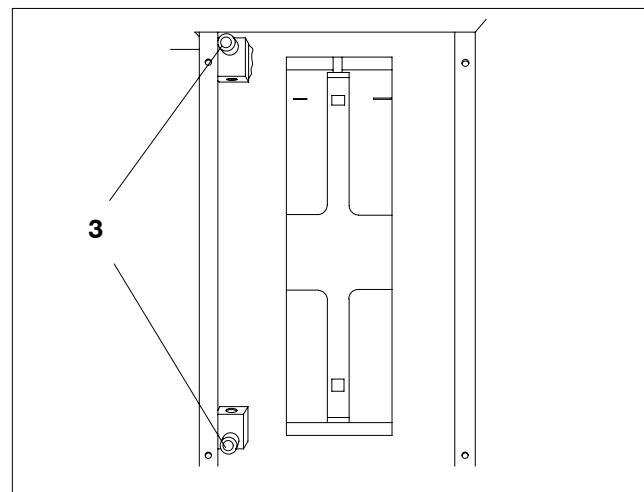
If the cover is removed, never put the hands or fingers inside until the system is blocked.

Insert the two "red headed" locking screws (3).

- Remove the rear bottom cover (1) of the stand.
- Remove the rear bottom cover (2) of the column.



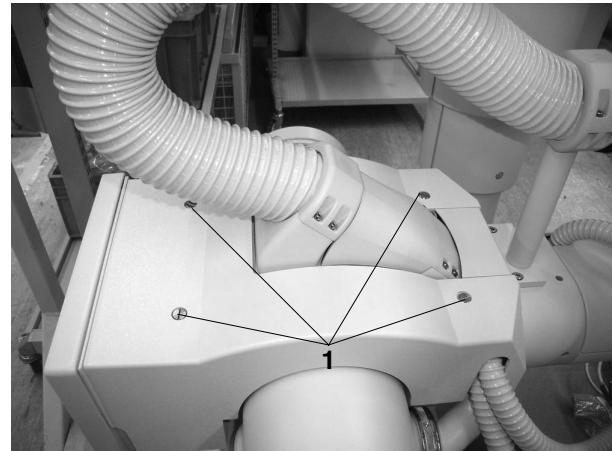
- The counterweight carriage must be left secured with two locking screws (3) until the new tube assembly and the collimator are completely installed!



Remove the locking screws(3) after the work is finished and place them back into their parking position.

## 2.6.2. DEMOUNTING THE TUBE COVER

- Demount the tube cover by loosening the two screws (1) on top of the X-ray tube assembly.



## 2.6.3. REMOVAL OF THE COLLIMATOR

For the removal of the collimator follow the instructions described in chapter 2.6 of the Replacement Manual "Replacement of the collimator". After having removed the collimator you can start deinstalling the X-ray tube assembly.

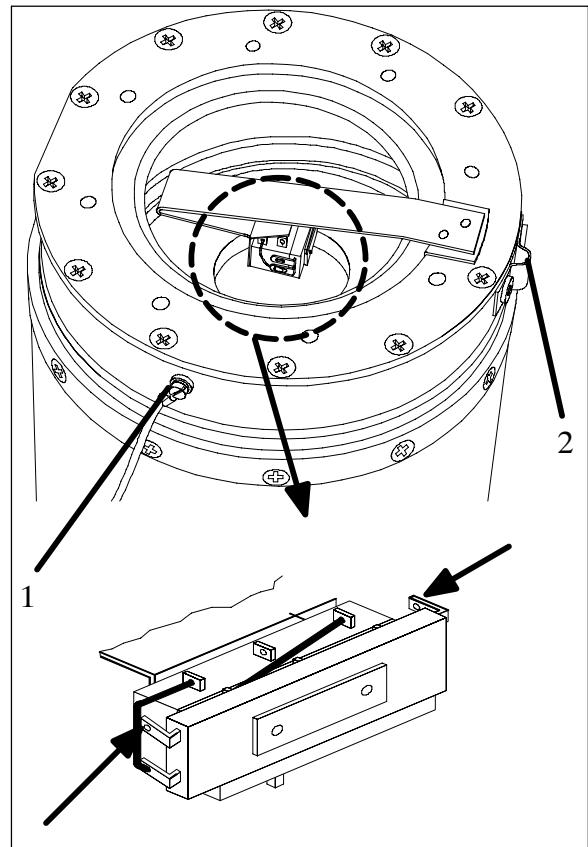
## 2.6.4. REPLACING THE X-RAY TUBE ASSEMBLY

For removing the X-ray tube assembly you have to disconnect all the electrical connections of the tube assembly before loosening the mechanical connections.

### 2.6.4.1. Electrical disconnections

#### a. Disconnection of the excess temperature switch

- Remove the protective cap from the cathode side of the X-ray tube assembly.
- Disconnect earth connection (1) from the protective cap.
- Release drag relief for the cable with the cable clamp (2) on the X-ray tube housing.
- Desolder the thermal contact cable from the two upper soldering lugs (↑) of the overload switch.



#### b. Disconnection of the fan (optional at SRO tube assemblies)

- Detach the end caps by loosening the three counter screws.
- Disconnect the anode and cathode end caps from the protective-earth connector.
  - Loosen the three special-type screws of the cap with the built-in fan and remove it.
- Disconnect the two leads of the fan.

### c. Disconnection of the X-ray tube Can (SRM tube assemblies)

The metal envelope of the X-ray tube, called "Can", is connected to the central earth point of the generator. During operation it is possible that the Can carries about 10% of the cathode current, the so-called "Can current".



*When the anode voltage fails the metal Can of the X-ray tube can take over the function of the anode. The resulting current flowing through the Can can destroy the X-ray tube irreversibly.*

- Before setting-to-work of an SRM X-ray tube assembly a conductor must be routed from the can of the X-ray tube to the earth connection of the high-voltage circuit.
- Disconnect the X-ray tube assembly from the X-ray tube housing. See drawing Z-12 in the Service Information (SI) delivered with the new X-ray tube assembly.

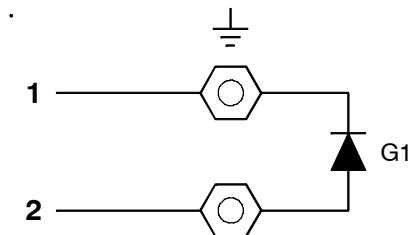
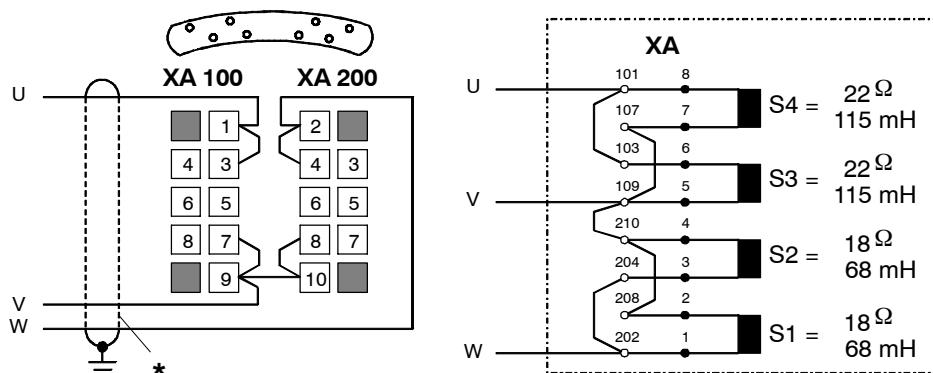


Figure 7    (1) PE conductor, green/yellow  
              (2) X-ray tube Can conductor

### d. Disconnection of the stator cable

- Disconnect the stator cable.



**e. Disconnection of the high-voltage cables****HV-DANGER OF INJURY!**

*HV cables have to be discharged every time they are removed. They act like capacitors.*

---



*During installation or replacement of an X-ray tube assembly, its plug connections are exposed to mechanical stress. Squeezing of the connector pins must be avoided under all circumstances!*

---

- Disconnect the HV cables carefully. Beware of deforming the connector pins.

**f. Disconnection of the protective-earth conductor**

- Dissolve the connection between the central earthing point of the X-ray tube assembly and the cover cab of the X-ray tube housing. See drawing Z-12 in the SI.

**2.6.4.2. Mechanical deinstallation**

*As loosening the screws causes the unit to disengage and to fall down, make sure to hold the X-ray tube assembly securely.*

---

**For BuckyDiagnost CS/FS:**

For the mechanical deinstallation of the X-ray tube assembly you have to loosen the four screws on top of the tube support.



## 2.6.5. INSTALLATION OF THE NEW X-RAY TUBE ASSEMBLY

For the installation of the X-ray tube assembly proceed in the reverse order or follow the instructions in the Service Information (SI) manual X-Ray Tube Assembly (delivered with replacement part). The “Setting-to-work” procedure and the “Return shipment process” of the defective tube assembly are also described in this manual.

## 2.7. ADJUSTMENTS AFTER REPLACEMENT

### 2.7.1. Tube conditioning

Refer to the Service Information (SI) manual X-Ray Tube Assembly for the respective tube (delivered with replacement part).

### 2.7.2. Tube adaptation



#### WARNING

*Radiation is released during the adaptation procedure!*

---

#### 2.7.2.1. General information

Tube adaptation is an automatic process which includes:

1. The measurement of the mA offset value that is caused by:
  - the kV measuring circuit
  - the emission current feedback circuit (VCO).
2. The measurement of the individual standby filament current (based on 100 $\mu$ A).
3. The emission current characteristic (kV, filament current).
4. The dynamic behavior (positive and negative boost adaptation) where the inertia of the filament with respect to heating up and cooling down is registered.

### 2.7.2.2. Preconditions / Program settings

- Switch OFF the generator.
- Disconnect the following plugs:

System	CXA/ISO Interface Connector		
	EZX23-1 signal bus	EZX42-1 system CAN	EZX43-1 system CAN
DigitalDiagnost	X	X	X

- Switch ON the generator.



The adaption procedure must not be started before relay ENK1 has been energized at least 2 minutes after the generator has been switched ON.

---

- The tube must be conditioned.

- Check the upper kV limit.

Select menu AGenT:

*Program / Tubes / Tube Limits / Max. Tube Voltage Limit [kV]*

The programmed value should match the nominal value of the tube connected or in case of older tubes the upper kV limit should be set to the max. application kV.

Once an adaptation is completed the new limit value is displayed as ADAPTED TO [kV].

- Perform the following program settings temporarily for each tube connected to one of the assigned RGDV = Free cassette

Select menu AGenT:

*Program / RGDV Set A + B / RGDV 1 ... 8 / Data Set A*

Program settings	Temporarily	Original Tube
Enable handswitch .....	YES	Verify the customized entries (refer to the SRM)
Syncmaster present	NO	
Exposure switch type	Double Step	
Exposure series / Tomo .....	YES	
Mounted radiographic .....	NONE	

### 2.7.2.3. Procedure

- Reset the generator.
- It is recommended that the high voltage be monitored during adaptation.

Connect the scope:

Channel1: kV AV HT at EZ130 X3 (1V/div), scale: 20kV/V

Trigger external: CTRL\_X\_C/ at backpanel EZ X74, negative slope

Time base: 2ms/div

- Select the RGDV = Free cassette for the tube to be adapted.
- Select menu AGenT:  
*Adjustment / Tube Adaptation*
- Select the tube and focus to be adapted, start with small focus!



*To avoid any malfunction make sure that READY is displayed on the desk before transmitting data by clicking on "Apply" with the left mouse button.*

*READY state disappears, ADAP is displayed on the desk.  
Wait until the generator turns back to the READY state.*

- Start the adaptation process by pushing the handswitch in PREP and EXP position and keep it depressed in the EXP position.  
The generator switches about 125 exposures for each focus. The radiation sign at the desk indicates exposures but there is no beep at the end of each exposure.  
The actual kV parameters are displayed during adaptation.  
The generator carries out the adaptation automatically. The procedure for one focus is completed when the desk indication changes from ADAP to TEST. At the end of the adaptation process the following message appears on the PC screen: "Before continuing the generator must be reset".
- Reset the generator.

- Run the adaptation for each focus (small and large) and tube.



*As there is no tube type with a physical third (middle) focus yet, the third focus cannot be adapted. VARIOFOCUS values are calculated by adapted small and large focus. APR programs using VARIOFOCUS can only be selected until small and large focus are both adapted.*

---

- Bring back the RGDV(s) program settings to the original status (refer to the SRM).
- Switch OFF the generator.
- Re-connect signal bus connector EZX23-1.
- Re-connect CAN connectors EZX42-1 and EZX43-1.
- Switch ON the generator.

### 2.7.3. Testing

The procedures corresponding to the requirements can be found in the Compliance Test Manual .

---

# REPLACEMENTS

# NICOL Collimator

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## Contents

### TEXT

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## 1. GENERAL REPLACEMENT PROCEDURES



### WARNING

*Before starting any of the replacement activities, SWITCH OFF the system, unless otherwise stated during the replacement procedure.*

---



### CAUTION

*Wear an Electro Static Discharge (ESD) bracelet during replacements.*

---



### NOTE

*Before disconnecting any cable, check the labeling, so the cable can be reconnected in the same position.*

---

### 1.1. GENERAL INFORMATION

The procedures stated in this replacement manual apply to following systems:

- BuckyDiagnost Systems
- DigitalDiagnost Systems
- EasyDiagnost Overtable Systems

## 2. REPLACEMENTS

### 2.1. WHAT-TO-DO TABLE

This table lists the actions you have to perform to replace the defective part. The standard sequence is:

- Verify hardware programming (jumpers/cables etc.).
- Replace the item.
- Perform software programming.
- Perform adjustments.
- Execute the appropriate functional test.
- Update the Service Logbook (Specific System Functions > Service Log).
- Hand-over to the customer.

FRU	Activity	Reference to procedure
NICOL RAD AUTOMATIC COLLIMATOR (98960102216x)	Info	N/A
	Replacement	Chapter 2.6
	Adjustment	N/A (Pre-aligned assembly)
	Verification	Refer to Compliance Test Manual

### 2.2. TOOLS REQUIRED

- Standard Service Toolkit (TC 129)

### 2.3. MATERIALS REQUIRED

- Collimator

### 2.4. TIME / MANPOWER REQUIRED

 4 h	Collimator replacement	
--	------------------------	--

### 2.5. PRECONDITIONS

The X-ray tube is provided with the tube alignment ring.

## 2.6. REPLACEMENT PROCEDURES OF FRUs

### 2.6.1. Fixing the working position



**WARNING**

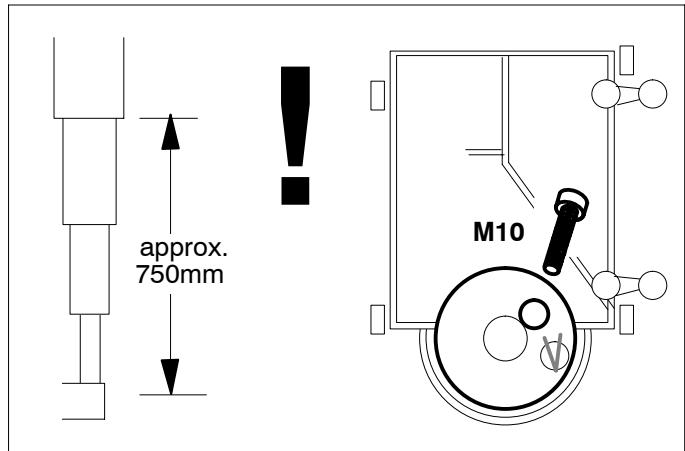
#### **DANGER OF INJURY!**

*After removal of the collimator the system is not weight balanced, so that the BuckyDiagnost CS/FS subsystem automatically moves up without fixing the working position.*

*To do the following steps, the telescopic system has to remain locked at the middle of its range of movement (extension 750mm).*

#### For BuckyDiagnost CS2/4:

- Position telescopic tube.
- Lock telescopic system by using the supplied screw M10.
- Lock it via the hole into the thread.



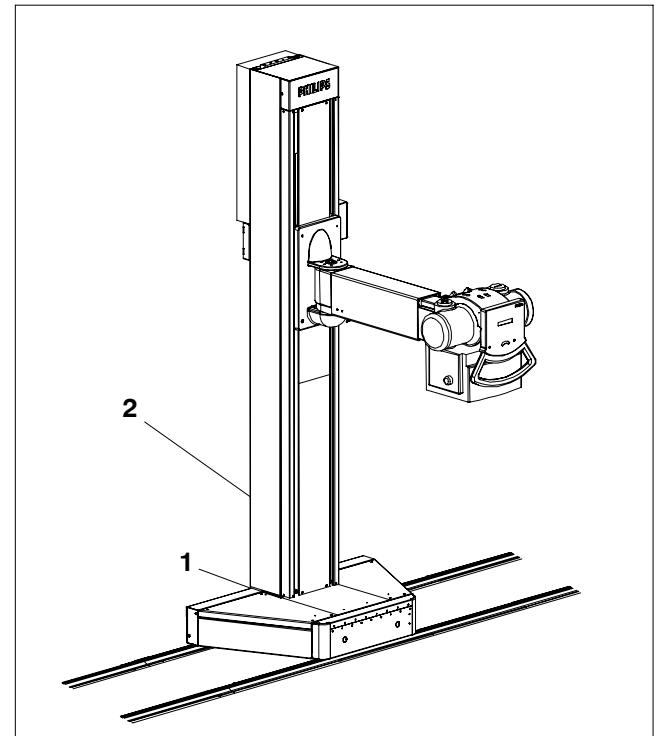
**For BuckyDiagnost FS:****DANGER OF INJURY!**

*After removal of the collimator the system is not weight balanced, so that the BuckyDiagnost CS/FS subsystem automatically moves up without fixing the working position.*

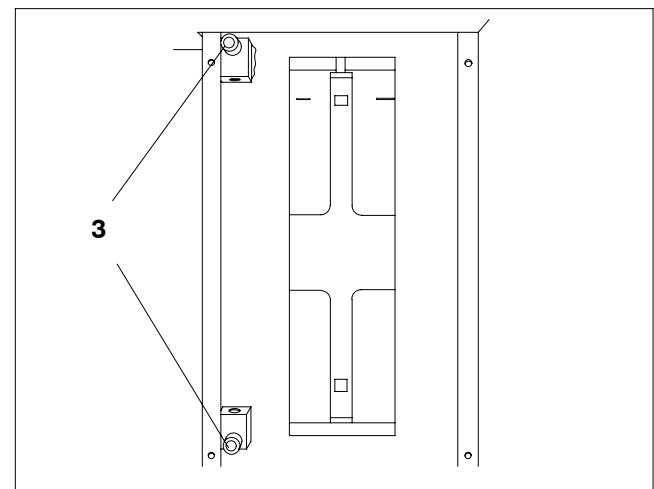
*If the cover is removed, never put the hands or fingers inside until the system is blocked.*

*Insert the two "red head" locking screws (3).*

- Remove the rear bottom cover (1) of the stand.
- Remove the rear bottom cover (2) of the column.



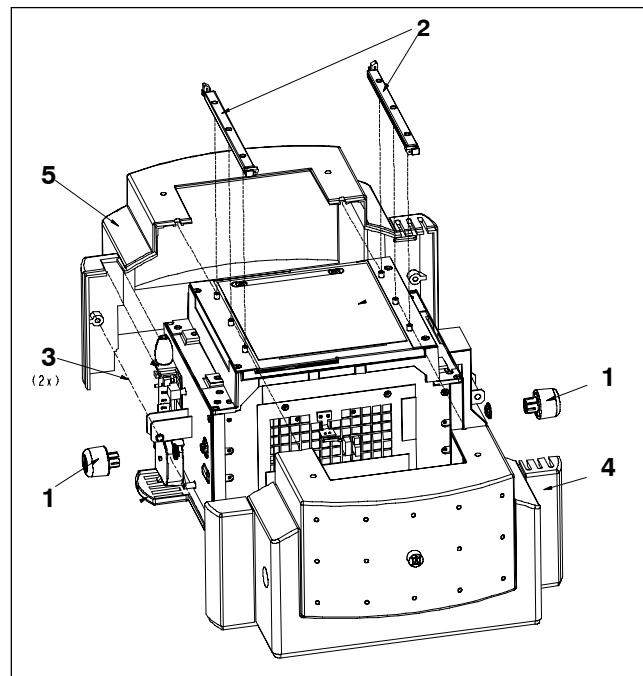
- The counterweight carriage must be left secured with locking screws (3) until the collimator is completely installed!



*Remove the locking screws (3) after the work is finished and place them back into their parking position!*

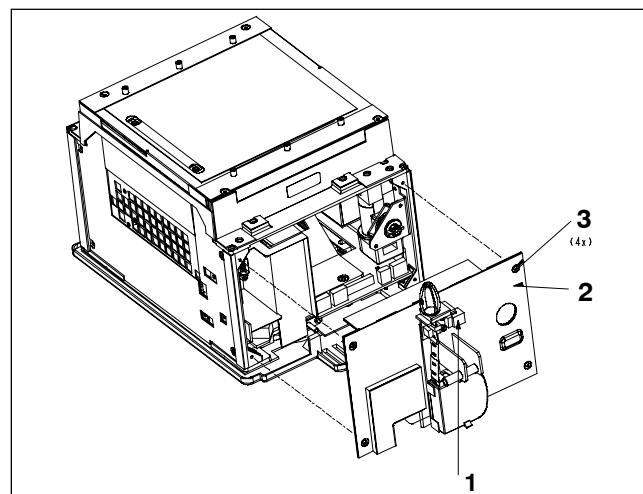
## 2.6.2. Removal of collimator covers

- Remove the DSC knobs by pulling the knobs (1) outward.
- Remove the accessory rails (2) by loosening the 6 screws.
- Remove the 2 screws (3),
- Remove the two collimator covers (4 and 5), first lift item 4, and then lift item 5.



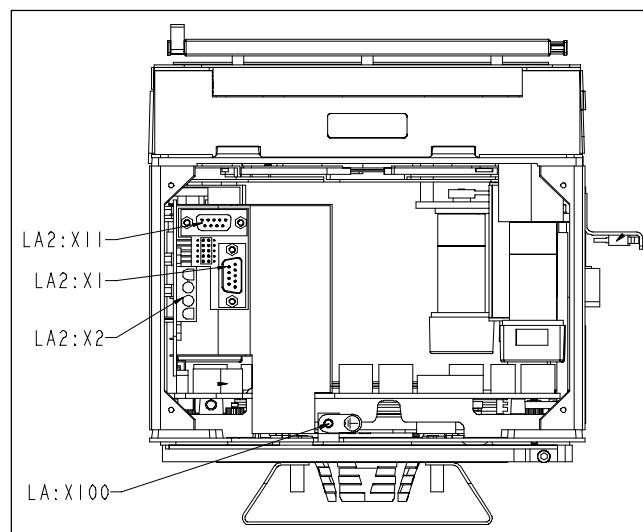
## 2.6.3. Removal of ruler side plate

- Disconnect the electronic ruler connector LA5X1 (1).
- Remove the side plate (2) using the 4 screws (3).



## 2.6.4. Removal of cable connections

- Disconnect male CAN cable 9p D-connector: LA2X1
- Disconnect female CAN cable 9p D-connector: LA2X11
- Disconnect power cable 4p Mate-N-Lock: LA2X2
- Disconnect yellow/green protective earth: LAX100



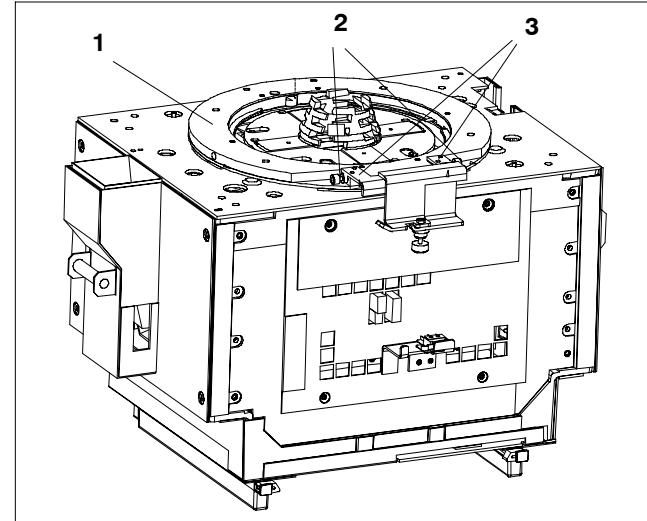
## 2.6.5. Exchanging the collimator



### CAUTION

*Exchange the collimator carefully in order not to DAMAGE the near focus shutters!*

- Unscrew the mounting ring (1) by loosening the two screws (2).
- Slide the two locking plates (3) outwards as far as possible.
- Remove the old collimator by turning the unit.
- Set the jumpers as on the collimator to be replaced.
- Reinstall the new collimator unit in reversed order.
- Check whether the collimator is properly secured.
- Attach the new identification label of the collimator unit (delivered by the FRU package).



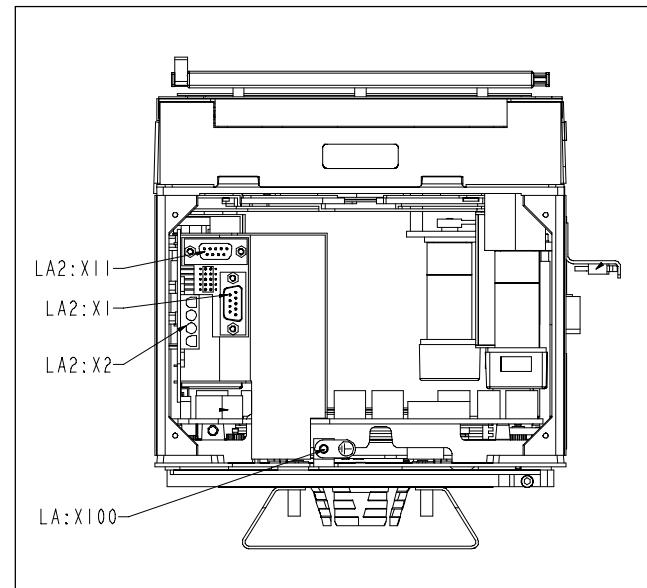
## 2.6.6. Electrical installation



### CAUTION

*The collimator MUST be connected to earth before power supply is switched ON. If not earthed – the collimator will be damaged.*

- Connect male CAN cable 9p D-connector: LA2X1
- Connect female CAN cable 9p D-connector: LA2X11
- Connect power cable 4p Mate-N-Lock: LA2X2
- Connect yellow/green protective earth: LAX100
- Reinstall the side plate



### 2.6.7. Reinstalling the collimator covers

- Refer to chapter 2.6.2 to reinstall the collimator covers in reversed order.



*Be sure that during reinstallation of the collimator covers, the micro-switch for the lamp is not damaged!*

---



*When reassambling the collimator covers, be sure that the ruler guidance is mounted correctly between front and rear covers.*

---

### 2.6.8. Finishing work

- Refer to chapter 2.6.1 to unlock the BuckyDiagnost CS/FS subsystem and reinstall covers in reversed order.

## 2.7. Adjustments after replacement

### 2.7.1. Adjustment



*The collimator flange is pre-aligned in the factory. No further centering is required.*

---

### 2.7.2. Testing

The procedures corresponding to the requirements can be found in the Compliance Test Manual.

---

# REPLACEMENTS

# Control Grip

---

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## 1. GENERAL REPLACEMENT PROCEDURES



### WARNING

*Before starting any of the replacement activities, SWITCH OFF the system, unless otherwise stated during the replacement procedure.*

---



### CAUTION

*Wear an Electro Static Discharge (ESD) bracelet during replacements.*

---



### NOTE

*Before disconnecting any cable, check the labeling, so the cable can be reconnected in the same position.*

---

### 1.1. GENERAL INFORMATION

The procedures stated in this replacement manual apply to following systems:

- BuckyDiagnost Systems
- DigitalDiagnost Systems
- EasyDiagnost Systems

## 2. REPLACEMENTS

### 2.1. WHAT-TO-DO TABLE

This table lists the actions you have to perform to replace the defective part. The standard sequence is:

- Verify hardware programming (jumpers/cables etc.).
- Replace the item.
- Perform software programming.
- Perform adjustments.
- Execute the appropriate functional test.
- Update the Service Logbook (Specific System Functions > Service Log).
- Hand-over to the customer.

FRU	Activity	Reference to procedure
CONTROL GRIP CS (2L) (yellow) (45122010231x) CONTROL GRIP CS (yellow) (45122010232x) CONTROL GRIP CS NICOL SID (yellow) (45122010233x) CONTROL GRIP CS NICOL (yellow) (45122010234x) CONTROL GRIP CS NICOL f. ED/OD/MD (yellow) (45122020119x)	Info	N/A
	Replacement	Chapter 2.6
	Programming	Chapter 2.6 (jumper settings)
	Adjustment	Chapter 2.7
	Verification	Refer to laser safety

### 2.2. TOOLS REQUIRED

- Standard Service Toolkit (TC 129)
- Antistatic kit

### 2.3. MATERIALS REQUIRED

- N/A

### 2.4. TIME / MANPOWER REQUIRED

 <b>1,5 h</b>	Control grip replacement	
---	--------------------------	--

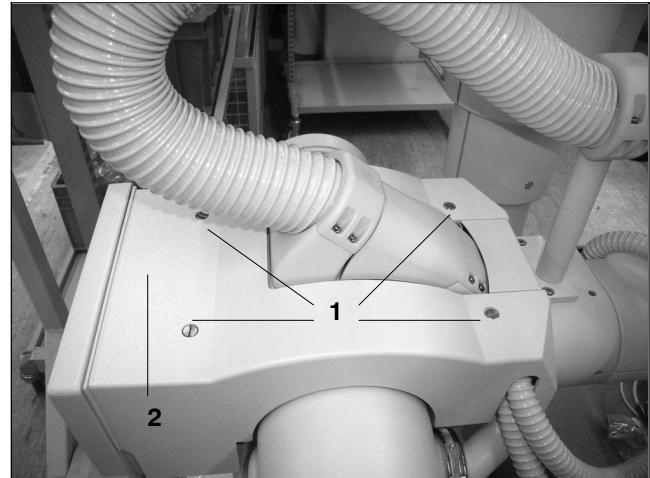
### 2.5. PRECONDITIONS

- N/A

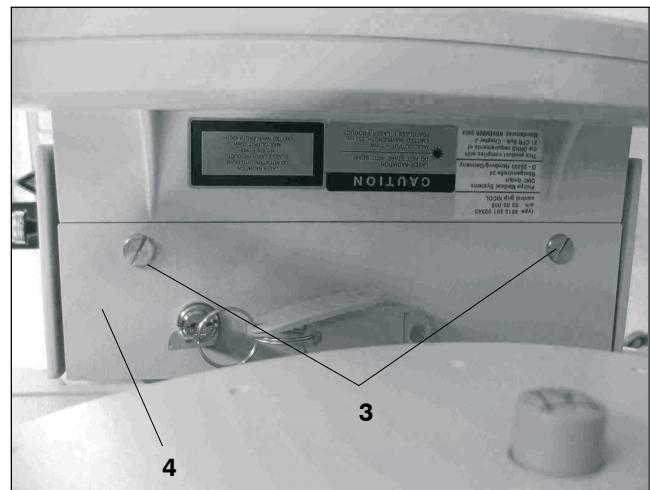
## 2.6. REPLACEMENT PROCEDURES OF FRUs

### 2.6.1. Removing the control grip from the tube support

- Unscrew the four mounting screws (1) to remove the tube cover (2).



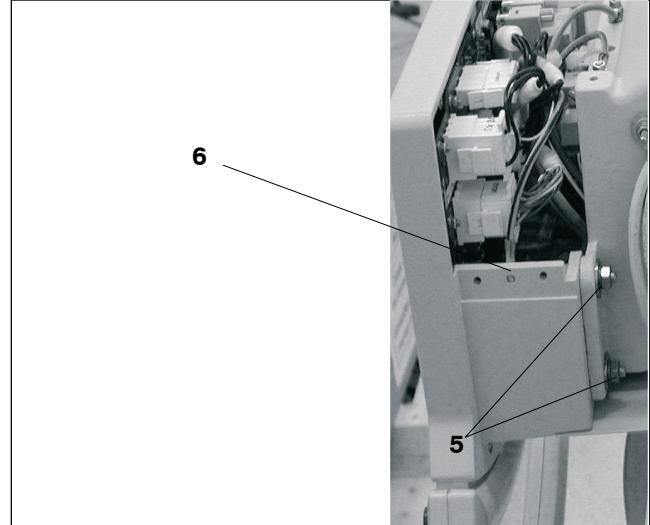
- Unscrew the two mounting screws (3) and remove the covering plate (4).





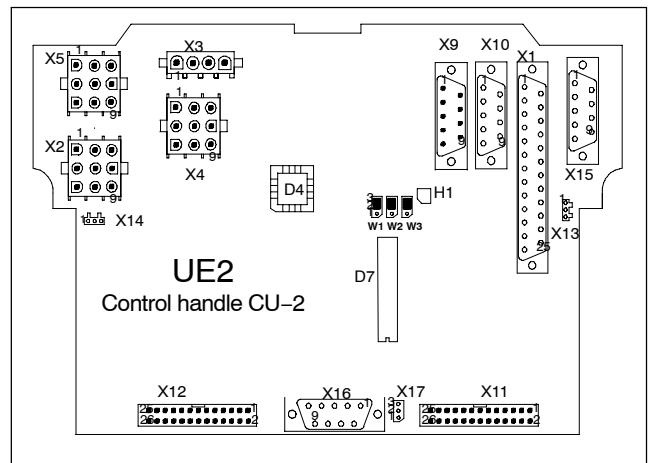
*Removing the four hexagonal nuts (5) may cause the level shims to fall down. Do not lose the level shims and consider their position in order to place them correctly when reinstalling the control grip.*

- Unscrew the four hexagonal nuts assembly (5).
- Disengage the control grip to get access to the electrical connections.



### 2.6.2. Disconnecting electrical connections

- Disconnect protective earth (6, see figure above).
- Disconnect the cable connections X1 – X16.



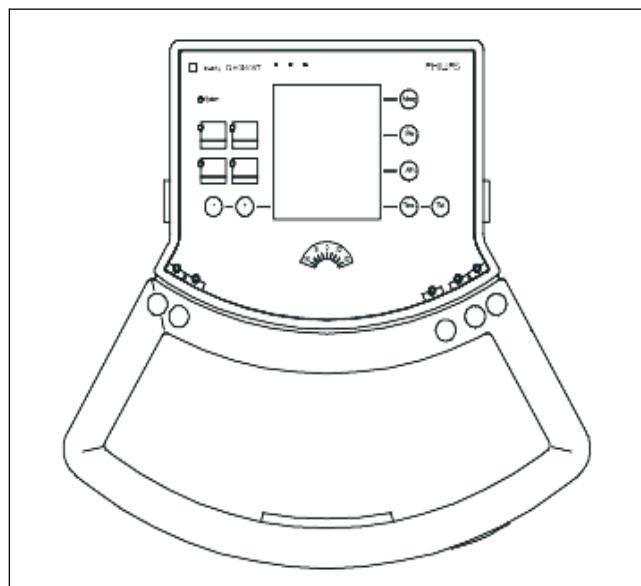
### 2.6.3. Exchanging the control grip

- Exchange the old control grip (the control grip design shown in this figure is exemplary).

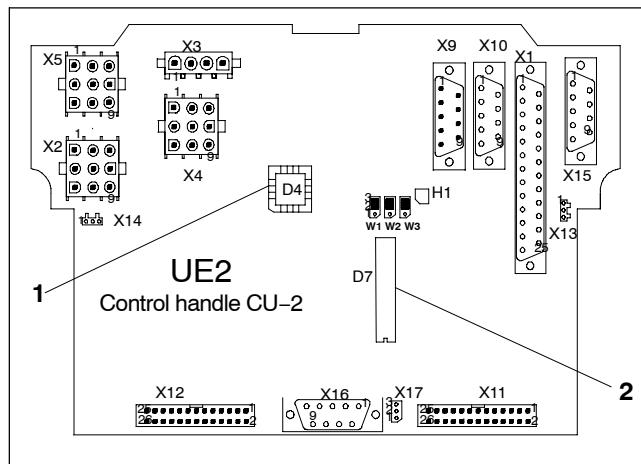


*Wear an Electro Static Discharge (ESD) bracelet during replacements.*

---



- Apply the firmware (1) of the old control grip.
- Apply the jumper settings (2) of the old control grip.
- Refer to chapter 2.6.2 to reconnect electrical connections.



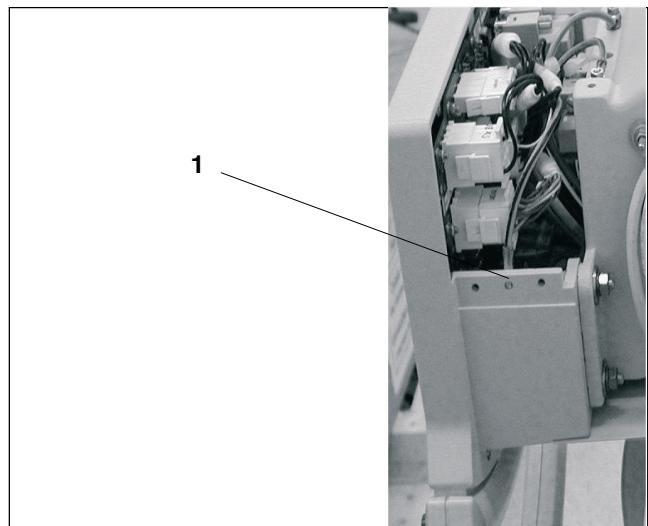
### 2.6.4. Mounting the control grip to the tube support

- Reconnect protective earth (1).
- Refer to chapter 2.6.1 to remount the control grip to the tube support in reversed order.



*Make sure that the level shims are placed correctly.*

---



- Refer to chapter 2.7 to perform the laser alignment.
- Reinstall the covering plate.
- Reinstall the tube cover.

## 2.6.5. Finishing work



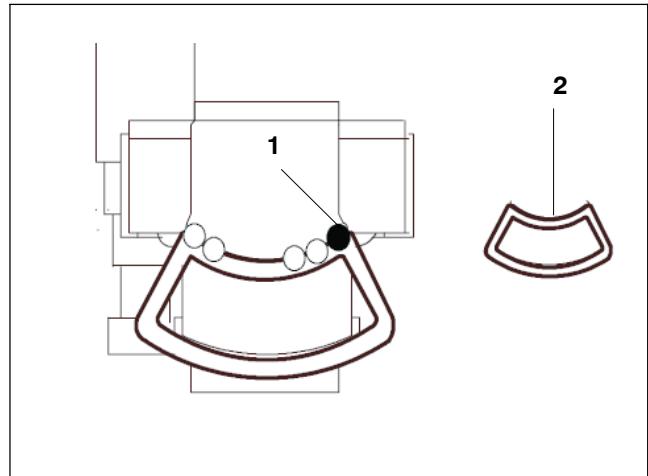
*Check the labeling. Add further labels if necessary.*

---

## 2.7. ADJUSTMENTS AFTER REPLACEMENT

### 2.7.1. Laser alignment

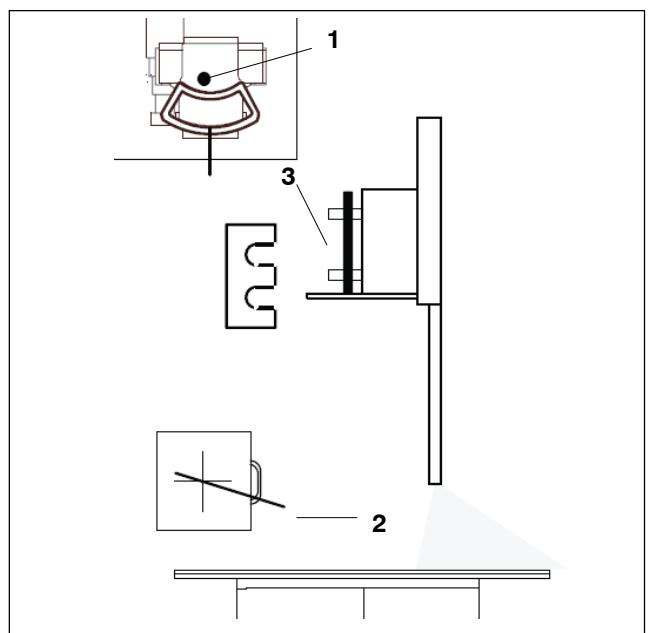
- Position the control grip on  $\alpha = 0^\circ$  position, LED (1) = **ON**
- Remove the control handle grip (2) on the rear side by loosening screws and nuts.



#### 2.7.1.1. Center laser alignment

##### Center laser alignment transverse (lateral):

- Press the button (1), to switch ON the center laser and collimator light.
- Raise the table top up and down.
- Observe the center laser light on the table top. If the beam wanders (2), adjust by adding level shims (3) between the tube support and the control grip.
- Tighten the screws and repeat the procedure.

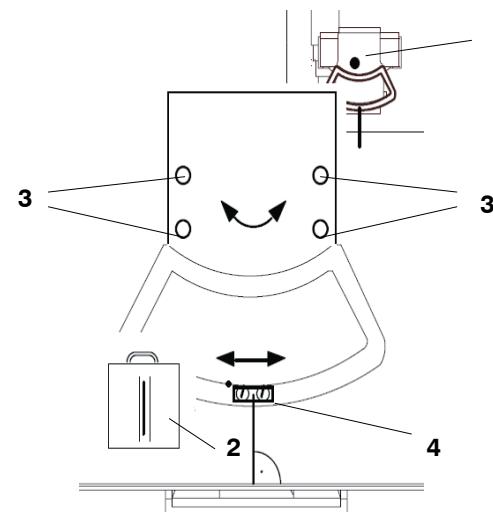


### Center laser alignment longitudinal:

- Press the button (1), to switch ON the center laser and collimator light.
- Raise the table top up and down.
- Observe the center laser light on the table top. If the beam wanders (2), rotate the control grip by loosening the four screws (3) on the rear side.
- Tighten the screws and repeat the procedure.

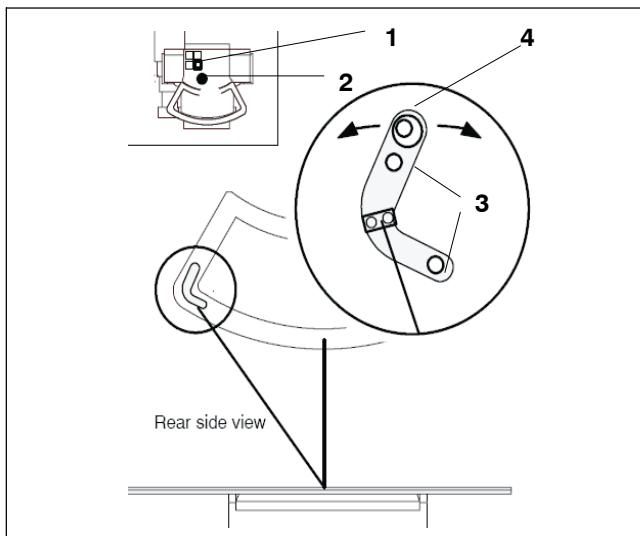
### Fine adjustment:

- Loosen the two fixing screws (4) of the center laser.
- Adjust the laser.
- Tighten the two fixing screws (4).



### 2.7.1.2. SID laser alingment (optional)

- Select the RGDV4 for free exposure (1), see manual for program X-Scope, SID selection.
- Raise the table top into the prefered value of the SID = 900 ... 1200 mm (default SID1100 mm).
- Press the button (2) to switch the center laser and pulsing SID laser and collimator light ON.
- Observe the center laser and the pulses SID laser on the table top. If the beams are not merged, loosen the two fixing screws (3) and adjust the SID laser with the eccentric screw (4).
- Tighten the two fixing screws (3).



### 2.7.1.3. Final work

- Install the removed control handle grip on the rear side.



*Pay attention that the laser wires are not damaged by attaching the grip! If necessary, fix the wires with adhesive tape.*

---

# REPLACEMENTS

---

# Front cover

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## 1. GENERAL REPLACEMENT PROCEDURES



### WARNING

*Before starting any of the replacement activities, SWITCH OFF the system, unless otherwise stated during the replacement procedure.*

---



### CAUTION

*Wear an Electro Static Discharge (ESD) bracelet during replacements.*

---



### NOTE

*Before disconnecting any cable, check the labeling, so the cable can be reconnected in the same position.*

---

### 1.1. GENERAL INFORMATION

The procedure stated in this replacement manual applies to the following systems:

- BuckyDiagnost systems
- DigitalDiagnost systems
- DuoDiagnost systems
- EasyDiagnost Eleva

## 2. REPLACEMENTS

### 2.1. WHAT-TO-DO TABLE

This table lists the actions you have to perform to replace the defective part. The standard sequence is:

- Verify hardware programming (jumpers/cables etc.).
- Replace the item.
- Perform software programming.
- Perform adjustments.
- Execute the appropriate functional test.
- Update the Service Logbook (Specific System Functions > Service Log).
- Hand-over to the customer.

FRU	Activity	Reference to procedure
front cover 5-field 4512 201 0279x	Info	N/A
front cover 3-field 4512 201 0413x	Replacement	Chapter 2.6.
	Programming	N/A
	Adjustment	N/A
	Verification	N/A

### 2.2. TOOLS REQUIRED

- Standard Toolkit TC 129

### 2.3. MATERIALS REQUIRED

### 2.4. TIME / MANPOWER REQUIRED

	Replacement of the front cover	
0.25 h		

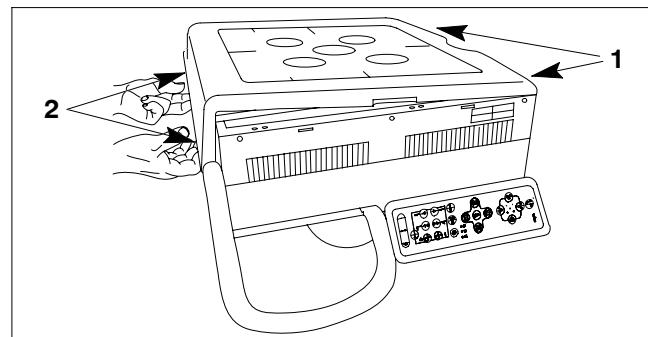
### 2.5. PRECONDITIONS

The use of the 3-field or the 5-field front cover depends on the use of the respective Amplimat chamber, 3-field or 5-field Amplimat chamber.

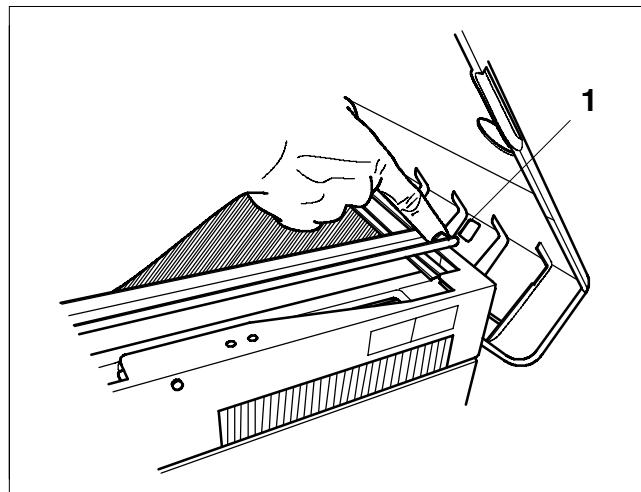
### 2.6. REPLACEMENT PROCEDURES OF FRUs

#### For Bucky Diagnost VS:

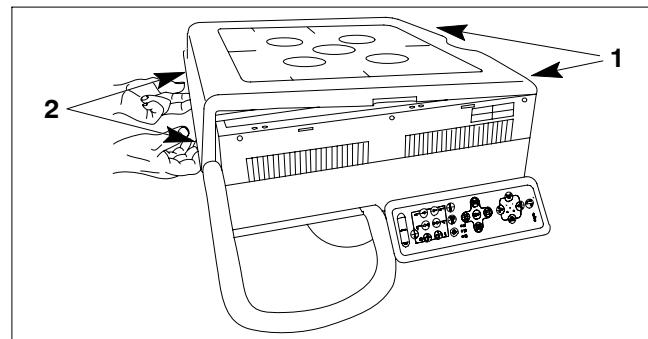
- Loosen both Allen screws (1).
- Remove both Allen screws (2).
- Remove the old front cover.



- Position the new front cover on the frame (1).



- Fix both Allen screws (1).
- Fix both Allen screws (2).



## 2.7. ADJUSTMENTS AFTER REPLACEMENT

N/A

---

# REPLACEMENTS

---

# Single Sided Table TH-S

---

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## 1. GENERAL REPLACEMENT PROCEDURES



### WARNING

*Before starting any of the replacement activities, SWITCH OFF the system, unless otherwise stated during the replacement procedure.*

---



### CAUTION

*Wear an Electro Static Discharge (ESD) bracelet during replacements.*

---



### NOTE

*Before disconnecting any cable, check the labeling, so the cable can be reconnected in the same position.*

---

## 2. REPLACEMENTS

### 2.1. WHAT-TO-DO TABLE

This table lists the actions you have to perform to replace the defective part. The standard sequence is:

- Verify hardware programming (jumpers/cables etc.).
- Replace the item.
- Perform software programming.
- Perform adjustments.
- Execute the appropriate functional test.
- Update the Service Logbook (Specific System Functions > Service Log).
- Hand-over to the customer.

FRU	Activity	Reference to procedure
Single Sided Table TH-S 9890 010 8430x	Info	N/A
	Replacement	Chapter 2.6.
	Programming	N/A
	Adjustment	Chapter
	Verification	N/A

### 2.2. TOOLS REQUIRED

- Allen keys, 3 mm and 10 mm

### 2.3. MATERIALS REQUIRED

### 2.4. TIME / MANPOWER REQUIRED

	Replacement of the tabletop	1/2 h
---	-----------------------------	-------

### 2.5. PRECONDITIONS

N/A

## 2.6. REPLACEMENT PROCEDURES OF FRUs

### 2.6.1. REPLACEMENT OF THE TABLETOP

To detach the three rail covers (1) of the tabletop (2) proceed as follows:

- Move the tabletop up to top position.
- Push the tabletop to end position.
- Detach the three covers of the X-guide rails and the brake rail.

The covers are connected to the tabletop only by magnets and secured by ground wires. Let them hang down – There is no need to remove the wires.

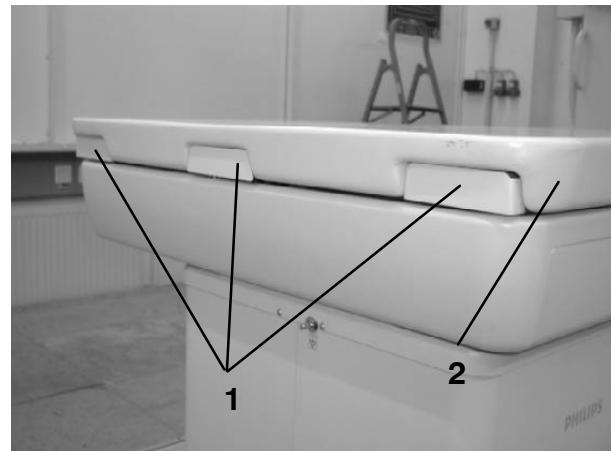
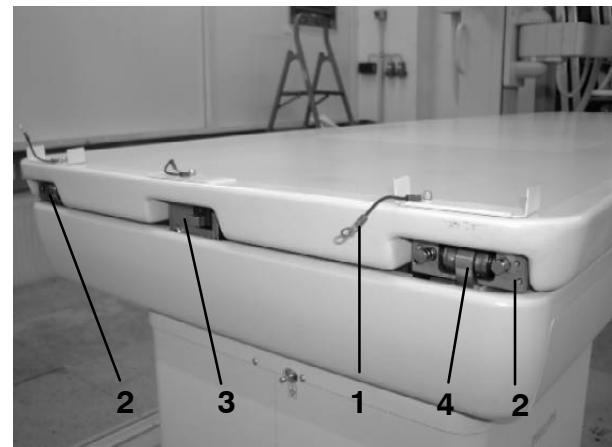


Fig. 1: Tabletop with rails

- (1): Ground wires of cover panel.
- (2): X-guide rails of the tabletop. There are safety brackets (see Fig. 3, mark1) mounted to the end of the rails, secured on each rail by 4 Allen screws (s/n: 05.00.160 and thereafter, or according to FCO 712 00013).
- (3): Brake rail of the tabletop.
- (4): Support block with roller bearings on the cross table, inside the X-guide rails.



- (1): 10 mm Allen key
- (2): Recess
- (3): Cover Panel
- (4): Brake block
- (5): Stop bolt
- (A): Stop bolt is inactive, no stop function
- (B): Stop bolt is active
- To remove the tabletop, the stop bolt (5) (Allen screw 10mm) must be unscrewed from the brake block (4). This stop bolt is positioned in the bottom side of the brake block, behind the cover panel (3) of the cross table. A recess (2) at the bottom edge of the cross table cover panel provides access to the stop bolt.

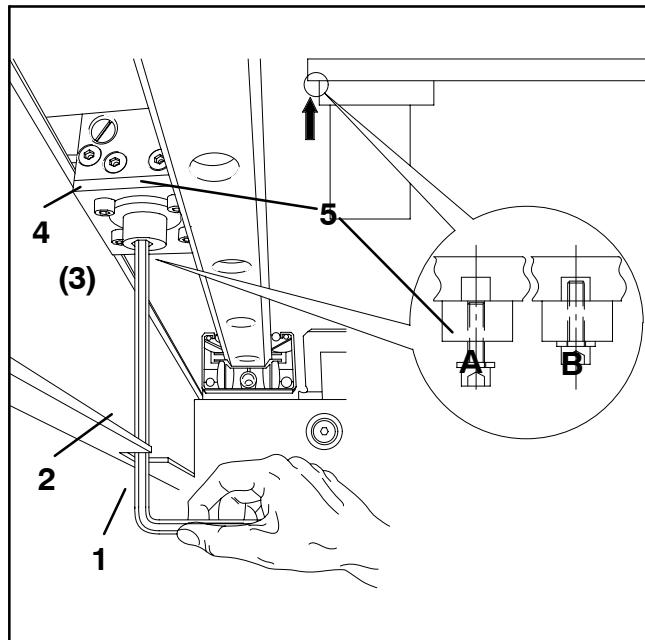


Fig. 3: Remove the safety brackets and the stop bolt

**WARNING**

*The tabletop is heavy!. 2-3 engineers are required.*

**Two persons:**

- Activate the floating (brake release) button on the foot switch
- Pull the tabletop in X-direction off the cross table
- Place the tabletop at a safe place and secure that it cannot tip over.

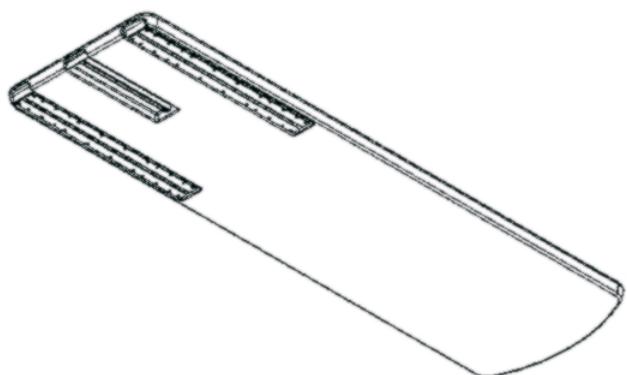


Fig. 4: tabletop lower side.

- Roller bearing for X-guide rails:
- (1) front-side
- (2) rear-side
- (3) Brake block X with stop bolt

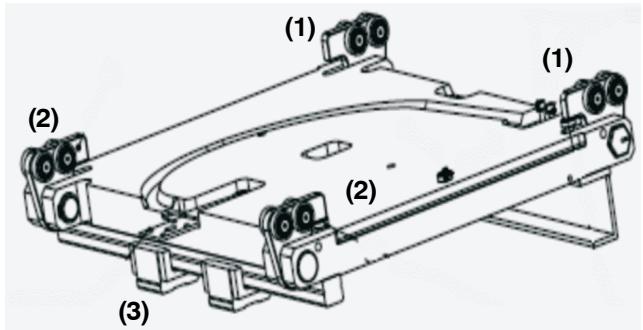


Fig. 5: Cross table without tabletop.  
X brake not shown.

### 2.6.2. REINSTALLATION OF THE TABLETOP

To reinstall the tabletop follow the steps above in reverse order.



*Make sure that the stop bolt (Allen screw 10mm) is fully screwed in into the brake block (X-direction) again (see Fig.3 ) so that it is impossible to pull the tabletop off the cross table during routine operation.  
Test the stop function.*

---

### 2.7. ADJUSTMENTS AFTER REPLACEMENT

When the tabletop is installed, perform a functional check of the X and Y-brake. Check that the tabletop moves easily without grinding noise.

---

# REPLACEMENTS

# Single Sided Trolley TF-M

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## 1. GENERAL REPLACEMENT PROCEDURES



### WARNING

*Before starting any of the replacement activities, SWITCH OFF the system, unless otherwise stated during the replacement procedure.*

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### CAUTION

*Wear an Electro Static Discharge (ESD) bracelet during replacements.*

---



### NOTE

*Before disconnecting any cable, check the labeling, so the cable can be reconnected in the same position.*

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## 2. REPLACEMENTS

### 2.1. WHAT-TO-DO TABLE

This table lists the actions you have to perform to replace the defective part. The standard sequence is:

- Verify hardware programming (jumpers/cables etc.).
- Replace the item.
- Perform software programming.
- Perform adjustments.
- Execute the appropriate functional test.
- Update the Service Logbook (Specific System Functions > Service Log).
- Hand-over to the customer.

FRU	Activity	Reference to procedure
Single Sided Trolley 4512 010 8414x	Info	N/A
	Replacement	Chapter 2.6.
	Programming	N/A
	Adjustment	N/A
	Verification	N/A

### 2.2. TOOLS REQUIRED

- Standard Toolkit TC 129
- Allen keys (3 mm, 4 mm, 5 mm, 6 mm)
- Torque spanner (9.8 Nm)

### 2.3. MATERIALS REQUIRED

### 2.4. TIME / MANPOWER REQUIRED

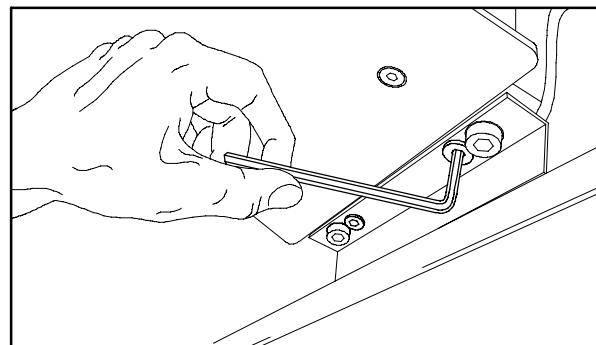
 2-3	Replacement of the tabletop	1/2 h
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### 2.5. PRECONDITIONS

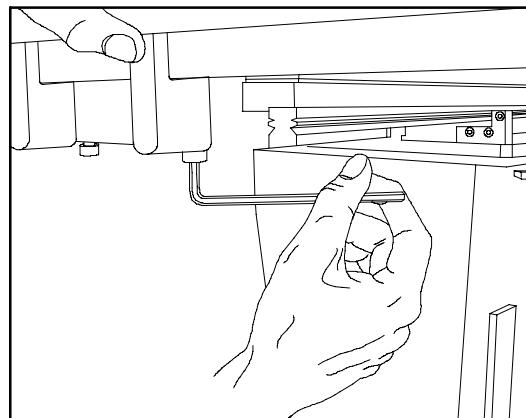
## 2.6. REPLACEMENT PROCEDURES OF FRUs

### 2.6.1. TABLETOP

- Dismantle the column cover by removing four hexagon socket screws at the bottom side of the cover.
- Put down the column cover carefully.



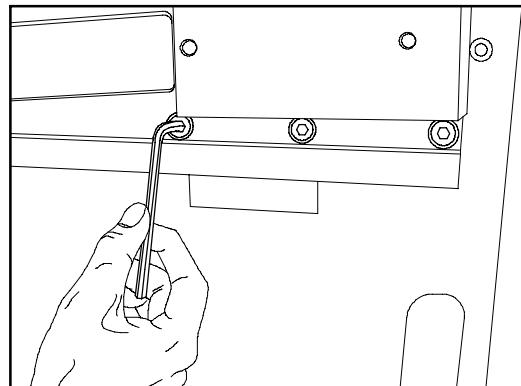
- Dismantle both accessory rails (four hexagon socket screws).



- Move the tabletop in transverse direction until it touches the end stop.
- Remove three hexagon socket screws at the bottom side of the tabletop.

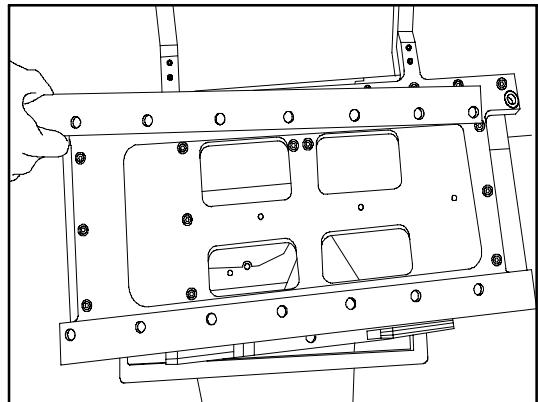


*A second person has to hold, or respectively to lift slightly the tabletop during this procedure.*

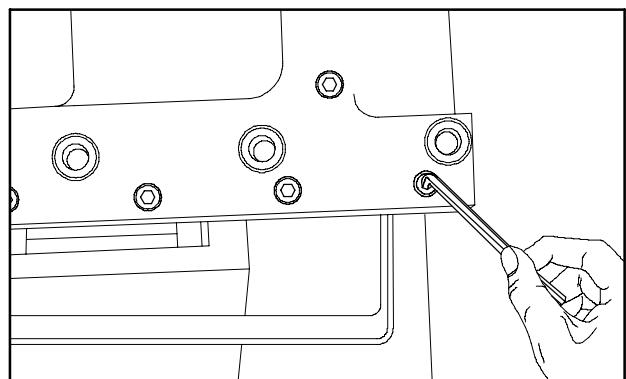


- Move the tabletop in transverse direction carefully until it touches the other end stop.
- Remove the remaining three hexagon socket screws.
- Put the tabletop aside.

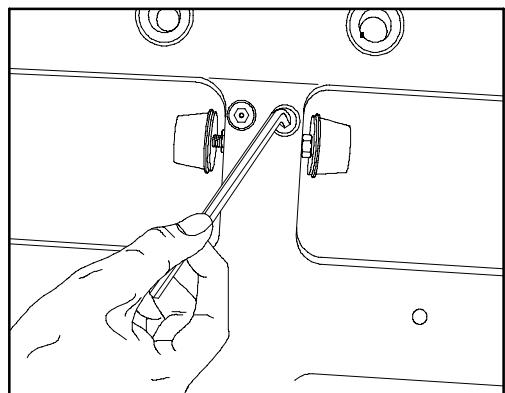
- Remove the lining.



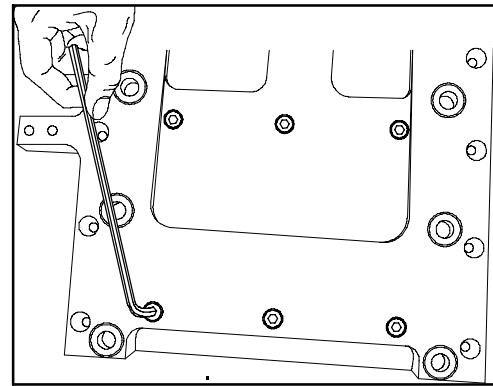
- Remove the hexagon socket screws (twenty pieces) from the guiding.
- Take away the leveling plate.



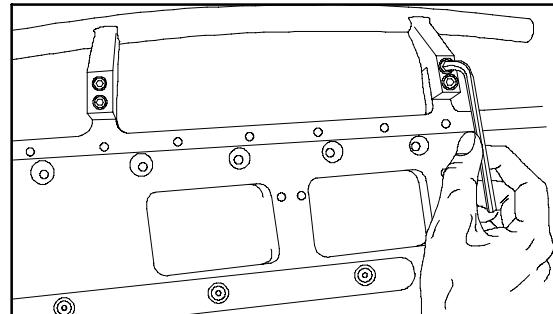
- Dismantle the end stop by removing two hexagon socket screws at the leveling plate.



- Remove the finger protection (nine hexagon socket screws).



- Turn the leveling plate and dismantle the hand grip (four hexagon socket screws).

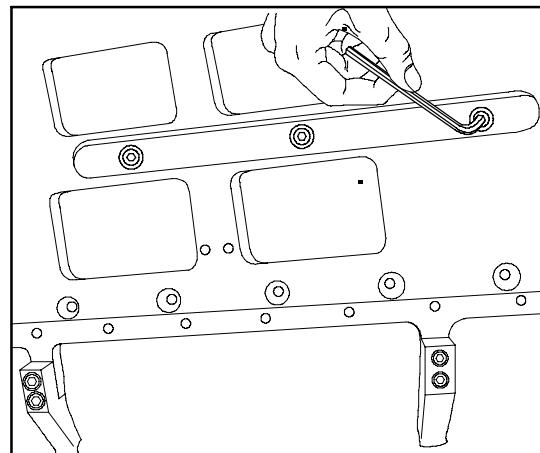


- Dismantle the brake angle (three hexagon socket screws).

**NOTE**

*The individual parts of the leveling plate will be reused.*

---



- Assembly of the new tabletop in reverse order.

**NOTE**

*The twenty hexagon socket screws for the fixation of the leveling plate at the linear guides must be fastened with a torque of 9.8 Nm!*

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# REPLACEMENTS

# Optimus RAD/RF/C

## Contents

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## 1. GENERAL REPLACEMENT PROCEDURES



### WARNING

*Before starting any of the replacement activities, SWITCH OFF the system, unless otherwise stated during the replacement procedure.*

---



### CAUTION

*Wear an Electro Static Discharge (ESD) bracelet during replacements.*

---



### NOTE

*Before disconnecting any cable, check the labeling, so the cable can be reconnected in the same position.*

---

### 1.1. GENERAL INFORMATION

The procedures stated in this replacement manual also apply to the following systems:

- BuckyDiagnost systems
- DuoDiagnost systems
- DigitalDiagnost systems

## 2. REPLACEMENTS

### 2.1. WHAT-TO-DO TABLE

This table lists the actions you have to perform to replace the defective part. The standard sequence is:

- Verify hardware programming (jumpers/cables etc.).
- Replace the item.
- Perform software programming.
- Perform adjustments.
- Execute the appropriate functional test.
- Update the Service Logbook (Specific System Functions > Service Log).
- Hand-over to the customer.

FRU	Replacement	Adjustment
H. V. generator	chapter 2.6	chapter 2.7

### 2.2. TOOLS REQUIRED

A standard service tool set is required for each replacement.

- Standard service tool set
- Service PC

### 2.3. MATERIALS REQUIRED

- AGenT SW

### 2.4. TIME / MANPOWER REQUIRED

For the required time and manpower see appropriate replacement chapter of the FRU.

## 2.5. PRECONDITIONS

N/A

## 2.6. REPLACEMENT PROCEDURES OF FRUs

In the case that a unit of the generator has to be replaced, the following steps have to be carried out first:

- Switch OFF the generator. Only switching OFF ENF1 is not sufficient.
- Move the generator cabinet E away from the wall.
- Remove all cover panels from the cabinet and if it is necessary to get access to the cable connections of the item which should be taken out, also remove their covers too.

### 2.6.1. H. V. generator

	Removal of the H. V. generator	
1.5 h		1.5 h

- Before the H. V. generator can be taken out of the generator cabinet E, all electrical connections to the H. V. Generator have to be removed.



### HV – Danger of injury

*HV cables have to be discharged every time they are removed. They act like capacitors.*

Always:            - E1         ----- GX1100 (ground)

                  - ZX12        ----- G100X15  
                   - ZX35        ----- G100X14

50 kW version:    - QC13:1        ----- GX1003  
                   - QC 3:1        ----- GX1002

Before GX1001 – GX1004 can be disconnected, the screening cap [figure] has to be removed.

Links or chokes of 1 ... 6 loops do not change:

                  - GX 1001        ----- GX 1003  
                   - GX 1004        ----- GX 1002

65/80 kW version: - QC13:1        ----- GX1001  
                   - QC 3:1        ----- GX1002  
                   - 2QC13:1        ----- GX1003  
                   - 2QC 3:1        ----- GX1004

- 2nd tube:
- WGX61 ————— GK1:1
  - WGX67 ————— GK1:2
  - WGX62 ————— GK2:1
  - WGX68 ————— GK2:2



*During removal observe the correct color coding on cables and connection terminals. Also observe the correct sequence of the connection terminals.*

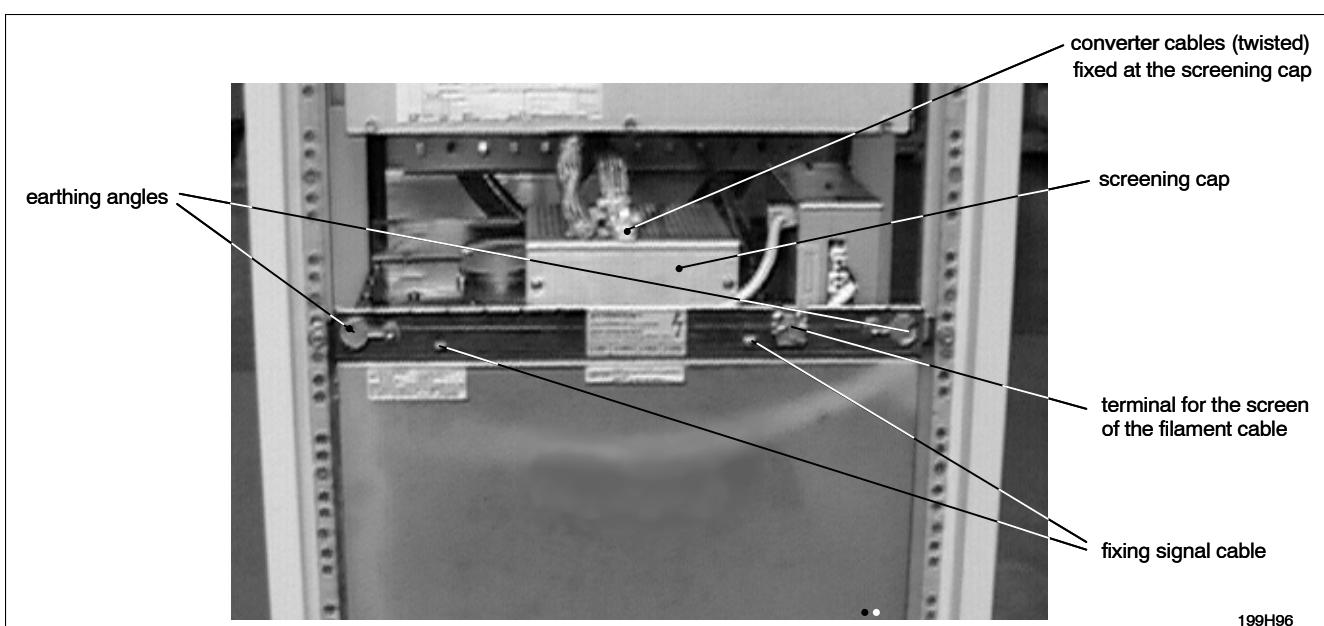
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- Remove the cables from the back panel (EN X12 and EN X35)
- Unscrew the earthing angles [figure] of the H. V. generator from the cabinet E and fold them to the inner side.
- Before lifting out the H. V. generator, fit in the deaerating screw.
- Check if all lines and cables of the H. V. generator are disconnected. To avoid damages, the cable ends should be fixed to the cable support at the rear side or with adhesive tape at the front side.
- To raise the H. V. generator, take the two transport bars from the rear side of the cabinet and push them through the mountings at the H. V. generator. !



*Due to its heaviness two persons are necessary to lift the H. V. generator out of the cabinet.*

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For the reinstallation of an H. V. generator proceed in the reverse order or follow the instructions in the System Manual Installation (SMI).

### 2.6.2. Final installation work

- Install the side panels of the generator cabinet.
- Take care that all cables inside the wall junction box are routed in **closed** loops with any kinks. Push the generator cabinet against the wall.



#### WARNING

*Block the two front wheels of the cabinet with the locking screws to guarantee that unauthorized persons cannot accidentally touch parts of the generator which might be dangerous.*

---

- if necessary, level the generator cabinet with the locking screws.
- Install the front cover to the generator cabinet.
- Remove the generator back to the wall.

## 2.7. Adjustments after replacement

### 2.7.1. Function unit kV

The alignment of the function unit kV must be repeated after replacing the H.V. generator.

#### 2.7.1.1. Connection and setting the scope

Channel 1 = EZ130 X3 ---> AV HT ---> 20kV/V ---> 1V/div ---> Zero-line at bottom of screen  
 Probe GND = one of the drilling holes at the front cabinet chassis

Channel 2 = EZ130 X26 --->  $U_{COMP}$  ---> 1V/div ---> Zero-line 2 div from bottom of screen  
 Probe GND = one of the drilling holes at the front cabinet chassis

Trigger = external (preferred) --->  $CTRL\_X\_C/$  ---> backpanel EZX74 / negative slope  
 or = internal channel 1 ---> AV HT ---> EZ130 X3 / positive slope at +3V  
 Probe GND = one of the drilling holes at the front cabinet chassis

Time base = 5 or 10ms/div ---> trigger delay -1div

#### 2.7.1.2. Deactivating the kV controller

Connect EZ130 X23  $GAIN\_IN$  and X6  $GNDA$  with a short link (use a short wire).

#### 2.7.1.3. Setting of exposure data

##### a) Set 141kV in case of

- of 65/80kW generators
- the tube limit (of at least one tube) is 150kV, perform this adjustment at the tube which has the highest kV limit programmed.

##### b) Set 125kV in case of

- of 50kW generators

and

- of 65/80kW generators if the programmed application limit of the tube limit is 125kV.

- Set kV and mA values according to the programmed tube limits:

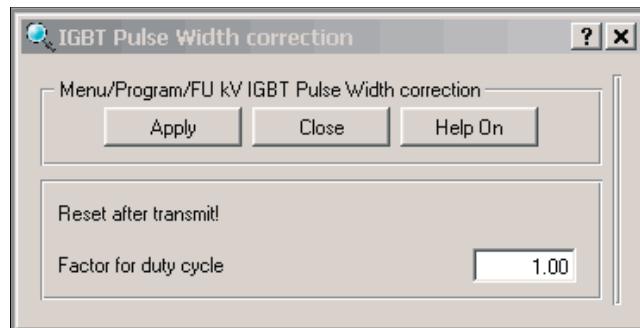
- **a) 141kV:** 200mA at kV\_4 (65/80kW)

- **b) 125kV:** 100mA at kV\_3 (50kW)  
 200mA at kV\_4 (65/80kW)

- Set the exposure time: 40ms

#### 2.7.1.4. Adjustment of the factor for duty cycle

- Start AGenT.
- Adjust the factor duty cycle via service software AGenT by measuring  $U_{COMP}$  with the scope.
- Connect the service PC and start AGenT:  
Select Menu: Program / FU kV IGBT Pulse Width Correction / IGBT Pulse Width Correction
- Set the starting value factor duty cycle to **1.00**:



- If the  $U_{COMP}$  value does not match the requirements type in another factor duty cycle value, transfer the factor by clicking on “Apply” with the left mouse button and push the active RGDV button to get the new value validated.
- Switch an exposure.  
The values are measured in the stationary condition. The transient behavior at the beginning of the exposure is not taken into account.

**Result:** In standby the  $U_{COMP}$  value is at about +11V, during exposure the mean value  $U_{COMP}$  must be as given in table 1 or 2.

**a) 141kV setting (65/80kW only)**

- Read the mean value of  $U_{COMP}$  for 141kV, correct the Factor Duty Cycle till  $U_{COMP}$  meets the required reference of +1V.

kV setpoint	mA setpoint	PCB type	$U_{COMP}$	Tolerance	kV peak of AV HT	Factor duty cycle:	Date
141kV	200mA	PCB kV_control 4:	+1V	$\pm 0.5V$	138kV		

Table 1: Factor duty cycle, settings 141kV (150kV limit)

Example how to correct the Factor Duty Cycle:

**PCB kV\_control 4:**

- If the mean value of  $U_{COMP}$  is:  $> +1.5V$       **increase** the factor duty cycle in steps of 0.01  
 $< +0.5V$       **decrease** the factor duty cycle in steps of 0.01
- Check also the kV peak value AV HT (not the overshoot), it must be **138kV** for **141kV** setpoint.
- Remove short link EZ130 X23 GAIN\_IN.
- Record the findings in table1.

**b) 125kV setting (50/65/80kW)**

- Read the mean value of  $U_{COMP}$  for 125kV.
- Correct the factor duty cycle till  $U_{COMP}$  meets the required reference of 0V.

kV setpoint	mA setpoint	PCB type	$U_{COMP}$	Tolerance	kV peak of AV HT	Factor duty cycle:	Date
125kV	100mA	PCB kV_control 3:	+0V	+1V / -0,5V	125kV		
125kV	200mA	PCB kV_control 4:	+0V	$\pm 0.5V$	125kV		

Table 2: Factor duty cycle, 125kV limit

Example how to correct the factor duty cycle:

**PCB kV\_control 3:**

- If the mean value of  $U_{COMP}$  is:  $> +1V$       **increase** the Factor Duty Cycle in steps of 0.01  
 $< -0.5V$       **decrease** the Factor Duty Cycle in steps of 0.01

**PCB kV\_control 4:**

- If the mean value of  $U_{COMP}$  is:  $> +0.5V$       **increase** the Factor Duty Cycle in steps of 0.01  
 $< -0.5V$       **decrease** the Factor Duty Cycle in steps of 0.01
- Check also the kV peak value AV HT (not the overshoot), it must be **125kV** for **125kV** setpoint.
- Remove short link EZ130 X23 GAIN\_IN.
- Record the findings in table 2.

### **2.7.2. Tube adaptation**

Having installed an H. V. Generator the adjustment of the tube is required.

- Refer to chapter Replacement for X-ray tube assembly.

### **2.7.3. Testing**

All FRU tests of the test manual have to be carried out.

- Refer to the Compliance Testing Manual.

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# Workbook

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## 1. INTRODUCTION

Diagnostic X-Ray systems or units subject to "FDA Standards 21CFR Part 1020" must be in compliance with these standards at all times. In this workbook the word "compliance" will always be used in the same context as above.

Equipment may go out of compliance as the result of the following three conditions:

1. Normal wear and tear
2. Equipment abuse or mis-use
3. Equipment breakdown

This workbook for component exchanges basically addresses condition 3 above (equipment breakdown) and is exclusively used for replacements or reinstallations—after—repair of the following components:

- X-Ray tube/housing assemblies of the SRO, SRM and SRC type only.
- Image intensifier tube/housing assemblies and
- Beam limiting devices used in combination with the above X-Ray tubes.

When carrying out a repair the service engineer should always strive to obtain full compliance with the minimum amount of testing, so that equipment repair costs and downtime are kept as low as possible.

In order to achieve this goal the test tables in this workbook have been simplified where possible (reduced number of test exposures etc.) as compared to the mandatory tests prescribed for new installations.

## 2. HOW TO USE THE WORKBOOK

It is the responsibility of the service engineer(s) to select and perform the proper tests to prove restoration of compliance. A table (see AIAT manual) has been prepared to assist the service engineer in selecting the proper tests of the compliance test manual.

For each exchanged component, required tests must be performed for each stand using the exchanged component. For example if an X-ray tube is exchanged on a ceiling crane used with a bucky table and a wall bucky, tests must be performed for both stands.

Use the following steps to select the tests from the table (AIAT manual):

- In the left hand column the table find the system containing the installed component.
- Out of the three component columns select the applicable one(s) and find the appropriate tests listed thereunder.
- Execute tests in accordance with the instructions in the compliance tests manual and any additional special instructions as noted with the individual tests in the Workbook for component exchanges.
- Decide whether the repair involves certified component replacement(s) resulting in serial number change(s). If so, then fill out PDA Form 2579. For example this means that all X-ray tube exchanges must be reported on Form 2579.
- Decide whether the repair involves component replacement(s) (certified and non-certified) resulting in serial number change(s). If so, then fill out the "Product Location Report" and send top sheet to:

Philips Medical Systems North America Inc.  
Installation Administration Department  
710 Bridgeport Avenue Shelton, CT 06484  
Attention: P. Ostrinski

The "Product Location Report" is required by Law for all component replacements and enables PMSNA to trace components in the event of re-call etc.

Take into account however that the tests listed in the table are only those directly related to the exchanged or re-installed component. For instance, an X-ray tube breakdown may be caused by normal wearing out of the insert itself but it could also be caused by a faulty timer. The latter will require repair and compliance check of the timer but timer tests do not appear in the table because timer failure is not a typical cause for tube breakdown.

All recorded and/or calculated test data must meet the specifications or be within the rejection limits as indicated in this Workbook.

Measuring instruments must be in proper state of maintenance and within their calibration dates.

### 3. GENERAL INFORMATION

Component exchanges or re-installations after repair should be carried out according to the standard equipment service manuals. Whenever the service engineer is instructed therein to execute tests specifically tailored to ensure FDA compliance, then such tests should not be repeated with equivalent tests of the test manual. In such cases, the service engineer should amend the particular test(s) in this Workbook with the note: "Tested as per instructions in service manual no:, Section, page and initial and date this statement. Any test results like films, parameter measurements etc., should be attached to this workbook.

It remains the responsibility of the service engineer(s) carrying out an X-ray equipment repair to ensure that any non-compliance resulting from the breakdown and subsequent repair activities is restored to full compliance before the equipment is turned over to the user again.

Whenever the service engineer cannot reasonably conclude, that a certain test need not to be done then he should perform the test.

The following symbols used in this Workbook mean:

- < = less than
- $\leq$  = less than or equal to
- > = greater than
- $\geq$  = greater than or equal to
- || = absolute value, sign of number which is ignored

## 4. TEST RESULTS



### CAUTION

*A copy of this yellow Workbook accompanies each X-ray tube housing assembly shipment originating from IPC Shelton. However this workbook must be used only when a tube assembly is exchanged in an existing X-ray unit or system.*

*Whenever the tube assembly is installed in a new X-ray unit or system the orange workbook must be used.*

---

### 4.1. TEST 1

Not applicable

### 4.2. TEST 2: PRODUCT LOCATION REPORT

#### INSTRUCTION

Whenever during a repair a component is removed from an X-ray system and replaced by a component with a different serial number a product location report must be filled out and send to:

Philips Medical Systems North America Inc.  
Installation Administration Department  
710 Bridgeport Avenue Shelton, CT 06484  
Attention: P. Ostrinski

If after a repair the original component is re-installed into the X-ray system then no product location report is required.

For detailed information how to complete a Product Location Report refer to the compliance test manual.

<b>TEST 2</b>	<b>PRODUCT LOCATION REPORT</b> PLEASE PRINT			PAGE 1 OF		
OA N*'S		DISTR. N*.		REPORT DATE		
CUSTOMER						
EQUIP. ADDRESS				INSTALL. DATE		
CITY		STATE	ZIP			
DEPARTMENT	PDA 2579 DATE N'.			TYPE OF SYSTEM		
	NAME EMPLOYEE SIGNATURE					
ROOM NUMBER						
DESCRIPTION	TYPE NUMBER	SERIAL NUMBER			LABELS	
		T/ S	D M	C		

#### 4.3. TEST 3

Not applicable

#### 4.4. TEST 4D: INDICATORS, VISUAL

SPECIFICATION
Where two or more radiographic tubes are controlled by one exposure switch, verify that the tube or tubes selected are indicated prior to exposure, both at the control desk and the tube housing.

Tube exchanged at tube station	Tube housing indicator is functional

INITIALS	DATE

#### 4.5. TEST 5: TUBE CURRENT AND KVP ACCURACY MANUAL FLUOROSCOPY FOR ALL GENERATORS EXCEPT CP

		SPECIFICATION LIMITS					
mA Dialed		mA		kV		kV	
		Max.	Min.	Max.	Min.	Max.	Min.
OPTIMUS	1.5	1.86	1.14	75.5	64.5	107.9	92.1
	2.5	3.10	1.90				
CLASSIC MCRT MOD- ULAR	1.5	1.80	1.20	77.0	63.0	110.0	90.0
	2.5	3.00	2.00				
MEDIO 5600	1.5	1.68	1.31	80.0	60.0	115.0	85.0
	2.5	2.81	2.19				

Tube station		
Selected		Measured
kVp	70	
mA	1.5	
kVp	70	
mA	2.5	
kVp	100	
mA	1.5	
kVp	100	
mA	2.5	

INITIALS	DATE

#### 4.6. TEST 6

Not applicable

#### 4.7. TEST 7

##### 4.7.1. TEST 7A: kVp ACCURACY RADIOGRAPHIC FOR ALL GENERATORS EXCEPT CP

kVp Dialed	60	80	110	140				
	SPECIFICATION LIMITS							
	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN
MEDIO 5600	65.0	55.0	85.0	75.0	118.8	101.2	151.2	128.8
MODULAR CLASSIC/MCRT	64.8	55.2	86.4	73.6	118.8	101.2	151.2	128.8
OPTIMUS	64.7	55.3	86.3	73.7	116.27	103.73	-	-
CINEPULSE	72.0	60.0	92.0	80.0	122.0	110.0	-	-

EXP	Tube station		
	Fixed mA at 0.1 sec	kVp	
		Dialed	Measured
1	200 or 250 mA* small focus	80	
2		140	
3	300 or 400 mA* large focus	60	
4		110	
5	Falling load 0.5 sec large focus (if present)	80	
6		110	

\* Use only one mA value/ whichever is available on generator control.

INITIALS	DATE

#### 4.7.2.TEST 7B: kVp AND mAs ACCURACY PMX MOBILE

SPECIFICATION mAs ±10%, 54 -80kV ± 5%, 81 -125kV ± 5 kVp					
kVp Diale d	SPECIFICATION LIMITS		mAs Dialed	SPECIFICATION LIMITS	
	Max.	Min.		Max.	Min.
60	63	57	16	17.6	14.4
110	115	105	64	70.4	57.6

EX P	kVp		mAs		
	Dialed	Meas.	Dialed	Meas.	
1	60		16		
2	60		64		
3	110		16		
4	110		64		

INITIALS	DATE

**4.8. TEST 8A, B, AND C**

Not applicable

**4.9. TEST 9: EXPOSURE PARAMETERS FOR ALL MEDIO AND SUPER CP GENERATORS INCLUDING THE OM 1050C.**

EXPOSURE NUMBER	DIAL	SPECIFICATION LIMITS	
		MEDIO CP	SUPER CP/OM1050C
1 FLUORO	90 kV	96. 5 > kVp > 82.5	95. 5 > kVp > 84.5
	2.5 mA	2.85 > mA > 2.15	2.73 > mA > 2.27
2 RADIOGRAPHY kV/mA/ms	81 kV	87. 0 > kVp > 75.0	85. 0 > kVp > 77.0
	250 mA	288. 5 > mA > 211.5	263. 5 > mA > 236.5
	100 ms	110. 0 > ms > 95.0	104. 0 > ms > 98.0
3 RADIOGRAPHY kV/mAs	125 kV	133. 2 > kVp > 116.8	131. 2 > kVp > 118.8
	80 mAs	93. 0 > mAs > 67.0	84.5 > mAs > 75.5

	EXP. NO.	PARAMETER VALUE DIALED	MEASURED VALUES					
			MEDIO CP		SUPER CP OM1050C			
			GEN. I	GEN. II	GEN. I	GEN. II		
FLUORO kV/mA	1							
RAD kV/ mA/ms	2						INITIALS	
KV/mAs	3						DATE	

#### 4.10. TEST 10: TUBE CURRENT ACCURACY (RADIOGRAPHIC FIXED CURRENT) FOR ALL GENERATORS EXCEPT CP

Dialed mA	50 or 60*			
SPECIFICATIONS	SPECIFICATION LIMITS			
	MAX	MIN	MAX	MIN
MODULAR	57.5	42.5	69.0	51.0
OPTIMUS	62.0	38.0	74.4	45.6
CLASSIC AND MCRT	52.5	37.5	69.0	51.0
MEDIO-5600	56.25	43.75	67.5	52.5

EXP	Tube Station			
	Dialed			Measured
	kVp	mA*	Time	mA
1	75	50 or 60		
2	125	50 or 60		

\* Select one mA value only, whichever is available on generator control.

INITIALS	DATE

**4.11. TEST 11: mAs ACCURACY, ALL GENERATORS EXCEPT CP**

E P O S U E	A		B	mAs Specification Limits						
			mA and Time	mAs Dialed	MEDIC- 5600		CLASSIC .....		MCRT	
	Dialed	Dialed			Pre- indicated/ Calculation	MAX.	MIN.	MAX.	MIN.	MAX.
1	125 or 150	0.2	Dialed, or 30	25.0	27.5 33.0	22.5 27.0	27.8 33.1	23.2 27.9	27 32	23 28
2	500 or 600	0.2	100 or 120	100.0 120.0	90.0 108.0	108.0 129.4	93.0 111.6	107.0 128.4	93.0 111.6	
				MODULAR						
1	125 or 150	0.2	25 or 30	25.0 30.0	30.0 36.0	20.0 24.0				
2	500 or 600	0.2	100 or 120	100.0 120.0	80.0 96.0					

EXP	Tube Station		
	Selected		Measured
	kVp	mAs	mAs
1	75	25 or 30	
2	100	100 or 120	

INITIALS	DATE

**4.12. TEST 12, 13, 14 AND 15**

Not applicable

**4.13. TEST 16****4.13.1.TEST 16A: BEAM QUALITY HALF LAYER FILTER INSPECTION**

<b>Tube station</b>	
<b>Tube/housing assembly serial numbers</b>	
<b>Filter and retaining ring in place</b>	

<b>INITIALS</b>	<b>DATE</b>

**4.13.2.TEST 16B: BEAM QUALITY – HALF VALUE LAYER (HVL) MEASUREMENT**

For tubes with operating range above 70 kVp.

This test is normally not required for Philips tubes, check the compliance test manual instructions.

<b>Dose measuring instrument</b>	
<b>Make:</b>	<b>Type No:</b>
<b>Probe type/size used:</b>	

**TUBE STATION:**

Actual Distance Focal Spot to Probe =						inch (cm)		
Added Filtration mm AL	Measured Dose (mR)					Total Dose 1 + 2 + 3 + 4 + 5		Average Dose
	Exp. 1	Exp. 2	Exp. 3	Exp. 4	Exp. 5			
						: 5 =		
						: 5 =		
						: 5 =		
						: 5 =		
						: 5 =		
						: 5 =		
						: 5 =		
						: 5 =		
						: 5 =		
						: 5 =		
Plotted HVL from graph = _____ mm AL > 3.6mm AL								

INITIALS	DATE

**4.14. TEST 17: FLUOROSCOPIC ENTRANCE DOSE RATE**

if another make of radiation monitor is used in lieu of the RADCAL 1015C it may be necessary to calculate new rejection limits. See instructions in the compliance test manual test 17A. List the used monitor and calculated rejection limits in the table below.

Radiation monitor type, No.	Ionization chamber type, No.	Combined accuracy of monitor and chamber	Specifications	
			A) 10 R/min	B) 5 R/min
			Rejection Limits R/min	
RADCAL 1015C	10 x5-6	±3%	9.7	4.85

TYPE OF DOSE CONTROL	STANDARD SYSTEMS	SYSTEMS WITH SID		
		CONTROLLED FLUOR - FLUOROSCOPIC OPTION (SEE CCT MANUAL TEST 17 PAR. 2C2 )		
IMAGE CHAIN	I	II	I	II
CHECK OFF (✓) IF DOSE RATE MEASURED IS IN COMPLIANCE	MANUAL			
	AUTOMATIC			
For systems with high level option verify and check off (✓) below that in High level mode:				
1) Continuous activation of fluoro switch is required .	-			
2) Continous sound audible to the fluoro-scopist is present.				

#### 4.15. TEST 18

Not applicable

#### 4.16. TEST 19: INDICATED X-RAY FIELD SIZE WITH OVERTABLE TUBE AN MOBILES (PMX)

The indicated field size and actual field size must be within 2% of the maximum SID. Allowable differences  $\pm 1.9\%$  SID.

BLD of tube station:		
TEST FILM	SID =	0.019 x SID =
Exposed length _____ - ideal length(10", 24cm) = _____ $\leq$ 0.019 SID		
Exposed width _____ - ideal width (8", 18cm) = _____ $\leq$ 0.019 SID		

INITIALS	DATE

**4.17. TEST 20**

Not applicable

**4.18. TEST 21: INTENSITY OF BLD LIGHT FIELD ILLUMINATION (ALL OVERTABLE TUBES)**

SPECIFICATION			
The minimum illumination requirement for the BLD light us 15 foot candles average at 100 cm from source, FDA 21 CFR 1020.31 (d)(2)(ii)			
<u>Philips Limits</u> Average light levels must be equal to or greater than 18 FC (193 Lux). (Includes correction for licht meder accuracy)			

TUBE STATION:	LIGHT LEVEL MEASURED		ACTUAL B.L.D. LIGHT LEVEL	AVERAGE B.L.D. LIGHT LEVEL
QUADRANT	TOTAL	AMBIENT	DIFFERENCE	Differences Total*0.25 =
1				≥ 18FC
2				
3				
4				
	DIFFERENCES TOTAL			
Supply Voltage at Lamp	=		VAC	Must be between 11.5 and 12 VAC

INITIALS	DATE

**4.19. TEST 22**

Not applicable

## 4.20. TEST 23: ALIGNMENT OF BLD LIGHT FILED AND X-RAY FIELD (RADIOGRAPHIC)

SPECIFICATION	REJECTION LIMIT
The total misalignment of the edges of the BLD light field with the respective edges of the X-ray field along either the width or the length of the light field shall not exceed 2% of the SID.	Max. misalignment: ≤ 1.% SID

Tube Station:

$$\text{SID} = 40" \text{ (100 cm)} \quad 1.8\% \times 40" \text{ (100cm)} = 0.72" \text{ (1.8cm)}$$

$$\text{Large Focus} \quad L_1 + L_2 = \underline{\hspace{2cm}} + \underline{\hspace{2cm}} = \underline{\hspace{2cm}} \leq 1.8\% \text{ SID}$$

$$W_1 + W_2 = \underline{\hspace{2cm}} + \underline{\hspace{2cm}} = \underline{\hspace{2cm}} \leq 1.8\% \text{ SID}$$

$$\text{Small Focus} \quad L_1 + L_2 = \underline{\hspace{2cm}} + \underline{\hspace{2cm}} = \underline{\hspace{2cm}} \leq 1.8\% \text{ SID}$$

$$W_1 + W_2 = \underline{\hspace{2cm}} + \underline{\hspace{2cm}} = \underline{\hspace{2cm}} \leq 1.8\% \text{ SID}$$

INITIALS	DATE

## 4.21. TEST 24: X-RAY FIELD CENTER ALIGNMENT (OVERTABLE TUBE)

SPECIFICATION	REJECTION LIMIT
The displacement between the X-ray film center and the X-ray field center must be ≤ 2% SID.	Max. displacement: ≤ 1.% SID

Perform this test for all image receptors served by the exchanged tube and if used at two different SIDs with one image receptor test both SIDs (tracking).

Displacement measured < 0.018 x SID			
Image receptor station	I	II	III
0.018 x SID1 =			
0.018 x SID2 =			

INITIALS	DATE

## 4.22. TEST 25: FIELD LIMITATION AND PBL OPERATING RANGE (OVERTABLE TUBE; RADIOGRAPHIC)

SPECIFICATION	REJECTION LIMIT
1. The total misalignment of the edges of the X-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the X-ray field in the plane of the image receptor shall not exceed 3% of SID.	Reject deviations: ≥ 2.7% SID*
2. The sum, without regard to sign of the above length and width misalignments, shall not exceed 4% of the SID.	≥ 3.6% SID*
3. FOR BLDs WITH BBL AND MANUFACTURED BEFORE DECEMBER 1 in 1983:  Positive beam limiting must be operational when X-ray beam is within $\pm 10^\circ$ of vertical or horizontal and SID is 65 cm to 200 cm inclusive. X-rays must be inhibited outside the SID ranges.	For Philips equipment PBL is operational: from 65 – 130 cm from 65 – 205 cm
4. FOR BLDs WITH PBL AND MANUFACTURED AFTER NOVEMBER 30 in 1983:  Positive beam limiting must be operational when: a) X-ray beam is within $\pm 3^\circ$ vertical and SID is 90 cm to 130 cm inclusive. b) X-ray beam is within $\pm 3^\circ$ of horizontal and SID is 90 cm to 205 cm inclusive.	

\*Includes allowance for measuring errors.

For wall bucky or wall cassette holders used at two different SIDs test both distances.

#### 4.22.1.IMAGE RECEPTOR STATION I

<b>A/IMAGE RECEPTOR STATION I</b>			
Table Bucky	SID =	0.027 SID =	0.036 SID =
Small cassette 8" x 10" (20 x 24 cm)		Large cassette 14" x 17" (32 x 43 cm)	
Measured length _____ x 2* = _____		Measured length _____ x 2* = _____	
Actual film length = _____ -		Actual film length = _____ -	
Misalignment (A) = _____ ≤ 0.027 SID		Misalignment (A) = _____ ≤ 0.027 SID	
Measured width = _____ x 2* = _____		Measured width = _____ x 2* = _____	
Actual film width = _____ -		Actual film width = _____ -	
Misalignment (B) = _____ ≤ 0.027 SID		Misalignment (B) = _____ ≤ 0.027 SID	
Total misalignment (A+B) = _____ ≤ 0.036 SID		Total misalignment (A+B) = _____ ≤ 0.036 SID	

<b>B: For beam limiting devices with PBL and manufactured before December 1, 1983, complete also the following box:</b>			
X-ray beam direction within 10° of:	Vertical	Verified ✓	
PBL range	65 to 200 cm inclusive		
X-rays inhibited outside the SID range			

<b>C: For beam limiting devices with PBL manufactured after November 30, 1983, complete also the following box:</b>			
X-ray beam direction within 3° of:	Vertical	Verified ✓	
PBL range	90 to 130 cm inclusive		

If optional test A1 is used ignore factor 2.

INITIALS	DATE

**4.22.2.IMAGE RECEPTOR STATION II**

<b>A/IMAGE RECEPTOR STATION II</b>			
Wall Bucky	SID =	0.027 SID =	0.036 SID =
Small cassette 8" x 10" (20 x 24 cm)		Large cassette 14" x 17" (32 x 43 cm)	
Measured length _____ x 2* = _____		Measured length _____ x 2* = _____	
Actual film length = _____ - Misalignment (A) = _____ ≤ 0.027 SID		Actual film length = _____ - Misalignment (A) = _____ ≤ 0.027 SID	
Measured width = _____ x 2* = _____		Measured width = _____ x 2* = _____	
Actual film width = _____ - Misalignment (B) = _____ ≤ 0.027 SID		Actual film width = _____ - Misalignment (B) = _____ ≤ 0.027 SID	
Total misalignment (A+B) = _____ ≤ 0.036 SID		Total misalignment (A+B) = _____ ≤ 0.036 SID	

**B: For beam limiting devices with PBL and manufactured before December 1, 1983, complete also the following box:**

X-ray beam direction within 10° of:	Vertical	Verified ✓	Horizontal	Verified ✓
PBL range	65 to 200 cm inclusive		65 to 200 cm inclusive	
X-rays inhibited outside the SID range	Vertical		Horizontal	

**C: For beam limiting devices with PBL manufactured after November 30, 1983, complete also the following box:**

X-ray beam direction within 3° of:	Vertical	Verified ✓	Horizontal	Verified ✓
PBL range	90 to 130 cm inclusive		90 to 130 cm inclusive	

\*1: or wall cassette holder

\*2: If optional test A1 is used ignore factor 2.

INITIALS	DATE

**4.23. TEST 26: FIELD LIMITATION AND CENTERING FOR SYSTEMS WITH ONE IMAGE RECEPTOR SIZE AND FIXED SID (E.G. PULMO DIAGNOST FILMCHARGER)**

SPECIFICATION	REJECTION LIMIT
1. The X-ray field at the plane of the image receptor shall have dimensions no greater than those of the image receptor. 2. The misalignment between the center of the X-ray field and the center of the image receptor shall be within 2% of the SID.	Reject deviations: $\geq 1.9\% \text{ SID}$

SID = \_\_\_\_\_ Max. allowable misalignment < SID x 0.019 = \_\_\_\_\_

	Verified ✓
1) BLD blades are just visible and parallel to film edges	
2) Measured misalignment = _____ < 1.9 SID	

INITIALS	DATE

**4.24. TEST 27: FLUOROSCOPIC X-RAY FIELD LIMITATION (OVERTABLE TUBE)**

SPECIFICATION	REJECTION LIMIT*
Neither the length nor the width of the X-ray field shall exceed of the visible area of the image receptor by more than 3% of the SID.	Max. Deviations $< 2.7\%$
The sum of the excess length and excess width shall not exceed 4% of the SID.	$< 3.6\%$

\*Specification percentages reduced to compensate for measuring errors.

**Table 1:**

FOR OVERTABLE TUBE CONFIGU- RATIONS ONLY	ACTUAL S.I.D.	MEASURED DISTANCE D	CALCULATE REJECTION LIMITS FOR TEST FILM AT DISTANCE D FROM FOCUS.		
			0.027 x D	0.036 x D	
Fixed or Maximum					
EXAMPLE	150 cm	80 cm	2.16 cm	2.88 cm	

The following tables provide for two different image intensifiers A and B (biplane II), each with up to three different modes.

For equipment with selectable SIDs, test maximum and minimum SID positions. Preferably, do all measurements in metric.



*Calculate length and width numerically without regard to sign of W1, W2, L1 and L2.*

### IMAGE INTENSIFIER STATION:

**Table2:**

MODE	II at FIXED or MAX SID								
WI	LI		+	L2		=	Lt		$\leq 0.027 D$
	WI		+	W2		=	Wt		$\leq 0.027 D$
				Lt	+	Wt	=		$\leq 0.036 D$
WI	LI		+	L2		=	Lt		$<0.027 D$
	WI		+	W2		=	Wt		$\leq 0.027 D$
				Lt	+	Wt	=		$\leq 0.036 D$
WI	LI		+	L2		=	Lt		$\leq 0.027 D$
	WI		+	W2		=	Wt		$\leq 0.027 D$
				Lt	+	Wt	=		$\leq 0.036 D$

**Table3:**

MODE	II at MINIMUM SID (if available)								
WI	L1		+	L2		=	Lt		$\leq 0.027 D$
	WI		+	W2		=	Wt		$\leq 0.027 D$
				Lt	+	Wt	=		$\leq 0.036 D$
WI	L1		+	L2		=	Lt		$\leq 0.027 D$
	WI		+	W2		=	Wt		$\leq 0.027 D$
				Lt	+	Wt	=		$\leq 0.036 D$
WI	L1		+	L2		=	Lt		<0.027 D
	WI		+	W2		=	Wt		<0.027 D
				Lt	+	Wt	=		<0.036 D
			INITIALS					DATE	

INITIALS	DATE

## 4.25. TEST 28/29 AND 34/35: X-RAY FIELD CENTERING AND X-RAY FIELD LIMITATION FOR SPOT FILM DEVICES WITH OVERTABLE AND UNDERTABLE TUBES

### A. X-ray tube/housing assembly replacement (existing BLD re-installed to new tube assembly)

In order to reduce the testing time for X-ray tube replacement proceed as outlined below.

- Install new tube assembly to table frame and align the central ray of the tube with the center of the spotfilm device in accordance to the instructions in the relevant installation manual(s).
- Re-install existing beam limiting device (BLD) to the new tube housing and carry out alignment instructions as per relevant installation manual(s).
- Perform the following limited compliance testing:
  - With “one cassette format spotfilm devices” take the following exposures:  
Exposure 1 program 1:1, as per compliance test manual instructions for test 28 or 34 whichever is applicable.  
Exposure 2 program 1:1, as per instructions for test 29 or 35.
  - With “multiple cassette format spotfilm devices” take the following exposures:  
Exposure 1: select smallest cassette format, program 1:1, as per instructions for test 28 or 34 whichever is applicable.  
Exposure 2: select largest cassette format, program 1:1, as per instructions for test 28 or 34.  
Exposure 3: select smallest cassette format, program 1:1, as per instructions for test 29 or 35 whichever is applicable.  
Exposure 4: select largest cassette format, program 1:1, as per instructions for test 29 or 35.
- For the Diagnost 92/Scopo 92 perform exposure 1 (2 films) and exposure 6 (2 films) as per test 30A.

If any of the above exposures are not in compliance recheck the alignment and adjustment procedures as per step 1 and 2 and repeat step 3 until compliance is obtained.

### B. Beam limiting device replacement (new BLD mounted to existing tube housing)

- Install BLD to tube housing and align calibrate and adjust in accordance with the instructions in the relevant installation manual(s).
- Perform the limited compliance testing as mentioned under A.



*If there is any reason (e. g. customer complaints) to suspect problems with either the automatic field limitation by the BLD or the field limitation by the shutters within the SFD than, after correction of the problem, the complete testing as per tests 28 and 34 or 29 and 35 for all cassette formats and divisions should be carried out rather than the limited testing as per A.*

#### **4.26. TEST 28 AND 34: ALIGNMENT OF X-RAY FIELD CENTER TO CENTER OF SELECTED PORTIONS OF THE IMAGE RECEPTOR (OVERTABLE AND UNDERTABLE TUBE)**

<b>SPECIFICATION</b>	<b>REJECTION LIMIT</b>
The center of the X-ray field in the plane of the film shall be aligned to the center of the selected portions of the film to within 2% of SID.	Max. deviation: $\geq 1.9\% \text{ SID}$

SID = \_\_\_\_\_  $\times 0.019 =$  \_\_\_\_\_ = Max. Deviation

Initial to confirm, that the test films taken as per instructions of the compliance test manual are in compliance with the above rejection limits. Number and date all films taken and file them with this workbook as proof of compliance.

INITIALS	DATE

#### **4.27. TEST 29 AND 35: X-RAY FIELD LIMITATION FOR SPOT FILM DEVICES**

<b>SPECIFICATION</b>	<b>REJECTION LIMIT</b>
1. The total misalignment of the edges of the X-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the X-ray field in the plane of the image receptor shall not exceed 3% of SID.	allowable difference: $\pm 2.7\% \text{ SID}^*$
2. The sum without regard to sign of the above length and width misalignments shall not exceed 4% of SID.	$\pm 3.6\% \text{ SID}^*$

\* Includes allowance for measuring errors.

<b>Calculation of allowable differences in mm</b>		
SID = _____	SID $\times 0.027 =$ _____	SID $\times 0.036 =$ _____
Measured distance test film to focal spot = _____ = A		
Correction factor "CF" = SID/A = _____		

<b>EXAMPLE</b>		
<b>Calculation of allowable differences in mm</b>		
SID = 900 mm	SID $\times 0.027 = 24 \text{ mm}$	SID $\times 0.036 = 32 \text{ mm}$
Measured distance test film to focal spot = 450 mm = A		
Correction factor "CF" = SID/A = 2		

**GENERAL REMARKS**

Measure all dimensions on metric and inch-size films in mm. When completing workbook tables use the (smaller) actual film sizes not the cassette format sizes for the "Ideal film dimensions" column. Of course in case of e. g. a 4:1 program use the width and length of actual film subdivisions are cone limited to the extent, that usage of the total available film area is not possible. In such cases the ideal dimensions are those as dictated by the cone rather than by the film in order to avoid unrealistic differences and possible non-compliance.

	1	2	3	4	5
CASSETTE SIZES	DIMENSIONS EXPOSED AREA			IDEAL	DIFF. =
CM	FROM TEST FILM	CORRECTION FACTOR	ACTUAL	DIMEN-SIONS	ACTUAL MINUS
INCH	Width Length Total	x CF =	L W T	L W T	
EXAMPLE	MEASUREMENTS IN MM				
Cassette 13x18cm L 1:1, Long Side Up W T	85 62 147	x 2	170 124 294	178 128 306	8 4 12
RESULTS:	L Diff = 8mm < 24mm W Diff = 4mm < 24mm T Diff = 12mm < 32mm				
L W T		x = x = x =			
L W T		x = x = x =			
L W T		x = x = x =			
L W T		X = x = X =			

INITIALS	DATE

# PHILIPS

Philips Medical Systems

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## COMPLIANCE TESTING Manual

**4512 983 12191**

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## 1. INTRODUCTION

### 1.1. PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

The U.S. Food and Drug Administration (FDA) regulates medical devices to assure their safety and effectiveness and develops and carries out a national program designed to control unnecessary exposures to, and assure safe and efficacious use of, ionizing radiation-emitting electronic products. The Center for Devices and Radiological Health (CDRH) is the component within the FDA that is responsible for this program. The FDA's legal authority to regulate both medical devices and electronic radiation-emitting products is the Federal Food Drug & Cosmetic (FD&C) Act. The FD&C Act contains provisions, that is, regulatory requirements, which define FDA's level of control over these products. To fulfill the provisions of the FD&C Act that apply to medical devices and radiation-emitting products, the FDA develops, publishes and implements regulations. These regulations are placed or codified into the Code of Federal Regulations (CFR) on an annual basis. Most of FDA's medical device and radiation-emitting product regulations are in Title 21 CFR Parts 800–1299. These final regulations codified in the CFR cover requirements regarding the X-radiation safety of diagnostic fluoroscopic X-ray systems and their components in sections 21CFR1020.30 and 21CFR1020.32. Philips Medical Systems' fluoroscopic diagnostic X-ray systems comply with these X-radiation safety requirements.

### 1.2. OBJECTIVE OF THIS MANUAL

Since the measure of compliance with these X-radiation safety requirements can be affected by both the logistic – and assembling process, the complete diagnostic X-ray system has to be verified upon compliance with certain of these requirements after installation of a new X-ray system or after an exchange of a certified component.

The following devices are certified components for BuckyDiagnost, DigitalDiagnost, EasyDiagnost Eleva and DuoDiagnost systems:

- X-ray tube housing assembly
- Beam-limiting device
- X-ray table
- X-ray high voltage generator
- X-ray control

This manual prescribes the necessary verifications (compliance tests) to be executed by the assembler, dependent on the nature of the assembly.

This manual also serves as a workbook to record the results of the necessary verifications.

The completed manual will form the basis for the report of assembly (FDA form 2579), to demonstrate the measure of compliance with the applicable X-radiation safety requirements.

### **1.3. APPLICABLE VERIFICATIONS**

It is mandatory to execute all applicable verifications, as prescribed in this manual, in case of:

- installation of a complete diagnostic X-ray system, or
- exchange, replacement or addition of one or more certified components.

The applicability of these verifications is determined by the nature of assembly.

In case a non-Philips made certified component has been assembled, the manufacturer's instruction for testing such component shall be followed.

## 1.4. CALCULATING ACCEPTANCE LIMITS (REPRODUCIBILITY)

The service engineer must calculate acceptance limits based on the accuracy of the measuring instrument. Use the following formulas:

### **1) When the accuracy is given as a relative value (e.g. percentage):**

$$\text{Upper acceptance limit} = \frac{\text{specified upper limit}}{1 + \text{measuring accuracy}}$$

$$\text{Lower acceptance limit} = \frac{\text{specified lower limit}}{1 - \text{measuring accuracy}}$$

#### Example:

- The specified upper limit for a test is 10 R/min.
- The specified accuracy of the measuring instrument is 0.03 (3%).
- The upper acceptance limit to guarantee compliance is then calculated as follows:

$$\text{Upper acceptance limit} = \frac{10}{1 + 0.03} = \frac{10}{1.03} = 9.71 \text{ R/min}$$

- This means that the test can be passed when the measured value is not more than 9.71 R/min.

### **2) When the accuracy is given as an absolute value:**

Upper acceptance limit = specified upper limit – measuring accuracy

Lower acceptance limit = specified lower limit + measuring accuracy

#### Example:

- The specified upper limit for a test is 10 R/min.
- The specified accuracy of the measuring instrument is  $\pm 0.2$  R/min.
- The upper acceptance limit to guarantee compliance is then calculated as follows:

$$\text{Upper acceptance limit} = 10 - 0.2 = 9.8 \text{ R/min}$$

- This means that the test can be passed when the measured value is not more than 9.8 R/min.

## 1.5. RADIATION PROTECTION



Verifications involving radiation are indicated by the radiation symbol. Take all necessary radiation protection precautions when executing such verifications.

## 2. VERIFICATION PROCEDURES



*Test involving radiation are indicated by the radiation symbol under the test number. Take all necessary radiation protection precautions when executing such verifications.*

---

### 2.1. TEST 1: OPERATORS MANUALS

Based on FDA regulation 21CFR1020.30(h).

1. Check that all required operator manuals (Instructions for use) are present.
2. Record all delivered operator manuals and let the customer sign for it.

### RESULTS

	VERIFIED (X)
Operator manuals present	

Delivered operator manuals			

(Customer representative title)	(Customer representative signature)		(Date)
---------------------------------	-------------------------------------	--	--------

## 2.2. TEST 2: SITE AUDIT FORM AND PRODUCT LABELLING CHECK

Based on FDA regulations 21CFR1010.2(b), 21CFR1010.3, 21CFR1020.30(e) and 21CFR1020.30(j).

### A. SITE AUDIT FORM

All components installed and/or replaced must be listed on the site audit form (test 2, workbooks). This includes all major components of Philips Medical imaging and diagnostic systems that are classified as a medical device or as a certifiable medical device. This also includes third party supplied devices, distributed by Philips and carrying the Philips logo type. Certified components are identified by a \* on the site audit form.

### B. LABELLING

All above mentioned major components must carry the "Type and Serial No." label (T/S), the "Date of Manufacture" label (DM) and, if the component is of the certified type, also the "Certification" label (C).

A generic list of components that require certification can be found in section 3 paragraph 2.2. of this manual.

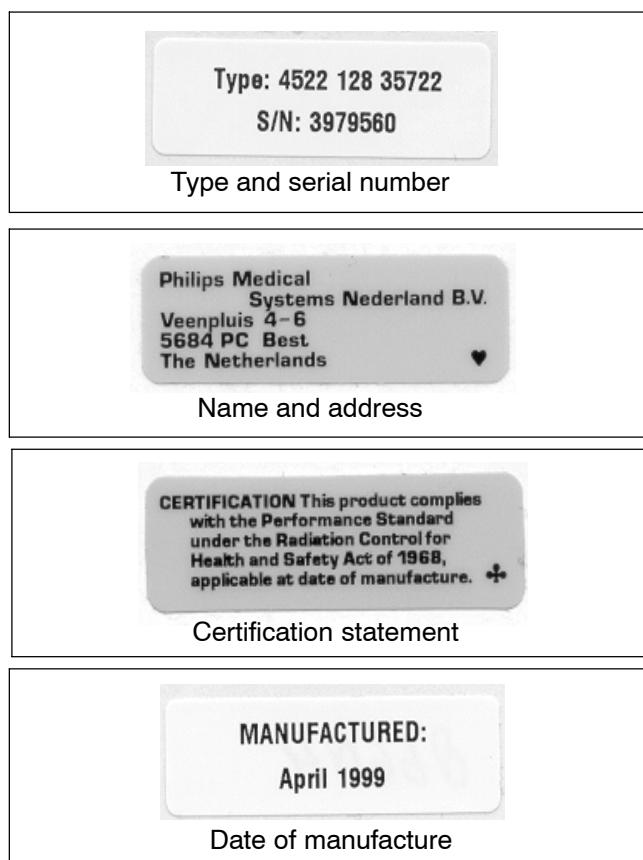
#### Required labels:

#### Label examples

(Actual size, text and layout can be different)

For all certified components:

- Type and serial number
- Name and address of manufacturer
- Certification statement
- Date of manufacture



For the control panel that contains the main power switch:

- Warning

**WARNING:**

THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS AND OPERATING INSTRUCTIONS ARE OBSERVED.

Warning

**TEST**

1. Obtain site audit form from the lead installer package.
2. Fill out all type and serial numbers as taken from the labels on the equipment next to the appropriate component description on the site audit form.
3. Verify that all required labels are present. (Use the labeling overview in section 6 of the system reference manual to locate labels.)

**RESULTS**

	<b>VERIFIED (X)</b>
Site audit form completed	
All required labels present	

	<b>INITIALS</b>	<b>DATE</b>

**C. INSTRUCTIONS TO FILL OUT THE REPORT**

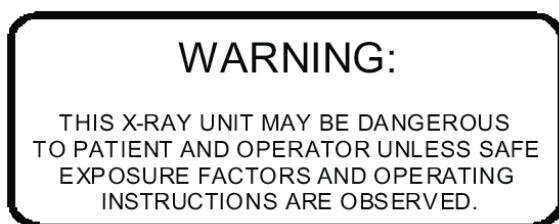
1. List all major components by name.
2. Fill out all type and serial numbers as taken from the labels on the equipment.
3. Check off the applicable label columns: "T/S" for type and serial no. label, "DM" for "DATE of MANUFACTURE" label, "C" for "CERTIFICATION" label.
4. Fill out all DATA boxes in the upper part of the site audit form.
5. Print and sign your name.
6. Tear off top sheet(s) and send to:  
 Philips Medical Systems North America Inc.  
 Installation Administration Department  
 710 Bridgeport Avenue  
 Shelton, CT 06484  
 Attention: P. Ostrinski
7. The site audit form copy pages remain in the workbook.

### 2.3. TEST 3: WARNING LABEL

Verify that "Warning Labels" are present on all X-ray control desks and initial the appropriate boxes in the workbook test 3.



The following warning label is used for Optimus generator.



## 2.4. TEST 4: INDICATORS AUDIBLE AND VISUAL

Based on FDA regulation 21CFR1020.31(a).



Verify that the following indicators are present and functional:

- a) X-ray beam on indicator
- b) Audible signal indicates the end of exposure.
- c) Automatic exposure control (amplimat) – When the amplimat is provided, the appropriate amplimat density and field select button must light up when selected.
- d) Multiple tubes – If applicable, where two or more radiographic tubes are controlled by one exposure switch, verify that the tube or tubes selected are indicated prior to exposure, both at the control desk and at the tube housing.

Check off and initial the appropriate boxes in the workbook test.

## 2.5. TEST 5: TUBE CURRENT AND KVP ACCURACY MANUAL FLUOROSCOPY (ALL GENERATORS EXCEPT CP)



*For fluoroscopy testing of CP generators see test 9.*

---



*Do not start this test until x-ray generator has been switched on for at least one hour.*

---

### TEST EQUIPMENT

- Keithley voltage divider with filter packs 32867C, 5C and 9C or equivalent
- Oscilloscope, storage
- Digital mA meter

### SETUP

1. Switch off generator/also switch off main disconnect breaker to system.
2. Connect digital mA meter as per instructions in relevant generator installation manual.
3. Set up the Keithley voltage divider complete with the appropriate filter as per Keithley instruction manual no. 3294 OIM.
4. Connect oscilloscope to the Keithley divider.



*Make sure that the oscilloscope has been calibrated with the aid of the Keithley divider as described in the Keithley instruction manual (par. 3.6 internal calibration) before starting any testing .*

---

5. For the specification limits see relevant generator documentation.  
The "Specification Limits" are based on the actual tolerances as listed in the generator operator's manuals.

These "Specification Limits" must be restricted to include the actual measuring instrument error. See also section 5 paragraph 3.1. regarding how to calculate rejection limits.

## TEST

1. Switch on system.
2. Select fluoroscopic X-ray tube and allow time for system to stabilize.
3. Select manual mode for fluoro kV and mA.
4. Switch on fluoroscopy and measure kVp and mA at the following settings:

1.5mA at 70 and 100kV  
2.5mA at 70 and 100kV

## RESULTS

Record measure kVp and mA values in workbook. Actual values must be within the calculated rejection limits.

## 2.6. TEST 6: FLUOROSCOPY TIMER

Based on FDA regulation 21CFR1020.32(h).



### TEST EQUIPMENT

- Stopwatch or digital wristwatch

### SETUP

The equipment completely assembled.

### TEST

1. Reset fluoro timer. Switch on fluoroscopy. With stop watch or digital wristwatch check fluoro timer by verifying that a signal audible to the fluoroscopist is produced within 5 minutes, or less.
2. After activation this signal must be audible any time fluoroscopy is being produced.
3. When reset button is pressed, timer should reset to zero and when fluoro is restarted, the audible signal must be present again, within 5 minutes or less.
4. Verify that X-ray ON light operates during fluoroscopy. Record test outcome in workbook.

### RESULTS

	VERIFIED (X)
Signal audible to the operator within 5 minutes	
Signal remains during fluoroscopy beyond 5 minutes	
Signal stops after reset and returns within 5 minutes	

	INITIALS	DATE

## 2.7. TEST 7

### 2.7.1. TEST 7A: kVp ACCURACY RADIOGRAPHIC (ALL GENERATORS EXCEPT CP)



SPECIFICATIONS								
1	MEDIO 5600		< 100kV : ± 5kV, > 100kV : ±8%					
2	MODULAR/CLASSIC/MCRT		±8%					
3	OPTIMUS		40–90kV : ± 7.9%, 91–125kV : ± 5.7%					
4	CINE PULSE		55–125kV : +12kV, -0kV					
S E C T I O N	kVp			DIALED				
	60	80		110		140		
SPECIFICATION LIMITS								
	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN
1	65.0	55.0	85.0	75.0	118.8	101.2	151.2	128.8
2	64.8	55.2	86.4	73.6	118.8	101.2	151.2	128.8
3	64.7	55.3	86.3	73.7	116.27	103.73	—	—
4	72.0	60.0	92.0	80.0	122.0	110.0	—	—

#### TEST EQUIPMENT

- Keithley voltage divider model # 35080 with filter packs 32867C, 5C, 9C, or equivalent.
- Oscilloscope (storage)



**NOTE**

*Do not start test until generator has been switched on for at least one hour.*

## SETUP

1. Set up the Keithley voltage divider complete with the appropriate filter as per Keithley instruction manual no. 3294 OIM.
2. Connect the oscilloscope to the Keithley divider.



*Make sure that the oscilloscope has been calibrated with the aid of the Keithley divider as described in the Keithley instruction manual before starting any testing (par. 3.6 internal calibration).*

---

3. Calculate rejection limits based on the exposure parameter "Specification Limits" shown in the table on previous page. The "Specification Limits" are based on the actual tolerances as listed in the generator operator's manuals. These "Specification Limits" must be restricted to include the actual measuring instrument error. See also section 5 paragraph 3.1. regarding how to calculate rejection limits.

## TEST

1. Select appropriate X-ray tube and allow time for system to stabilize.



*Allow for sufficient cooling off time between exposures as required per the relevant tube manual.*

---

2. Make exposures at kV selections as shown in specification block and for each of the five mA and time values below.
  - Fixed mA: 100mA at 0.1 sec/ small focus.
  - Fixed mA: 200mA or 250mA at 0.1 sec, small focus.
  - Fixed mA: 300mA or 400mA at 0.1 sec, large focus.
  - Small focus, falling load at 0.5\* sec. if present.
  - Large focus, falling load at 0.5\* sec. if present.

\*0.5 sec. to include falling load steps. On classic generators close collimator and interrupt exposure with handswitch after last step is observed.

3. Read the kVp's on the oscilloscope.

## RESULTS

Record measurements in workbook. Actual values must be within the calculated rejection limits.

## 2.7.2. TEST 7B: kVp and mAs ACCURACY PMX MOBILE



<b>mAs <math>\pm</math> 10%</b> <b>Specifications: 54 –80kV <math>\pm</math> 5%</b> <b>81 –125kV <math>\pm</math> 5 kVp</b>					
Dialed	Specification		Dialed	Specification	
	Max.	Min.		Max.	Min.
60	63	57	16	17.6	14.4
80	84	76	32	35.2	28.8
110	115	105	64	70.4	57.6

### TEST EQUIPMENT

- Keithley voltage divider model # 35080 with filter packs 32867C, 5C, 9C, or equivalent.
- Oscilloscope (storage)
- Digital mA/mAs meter.



*Do not start test until generator has been switched on for at least one hour.*

### SETUP

1. Switch off generator and also switch off main disconnect breaker to system.
2. Connect digital mAs meter as per instructions in the relevant service manual.
3. Set up the Keithley voltage divider complete with the appropriate filter as per Keithley instruction manual no. 3294 OIM.
4. Connect the oscilloscope to the Keithley divider.



*Make sure that the oscilloscope has been calibrated with the aid of the Keithley divider as described in the Keithley instruction manual before starting any testing (par. 3.6 internal calibration).*

---

5. Calculate rejection limits based on the exposure parameter "Specification Limits" shown in the table on previous page.

The "Specification Limits" are based on the actual tolerances as listed in the generator operator's manuals. These "Specification Limits" must be restricted to include the actual measuring instrument error. See also section 5 paragraph 3.1. regarding how to calculate rejection limits.

## TEST

1. Reconnect system to mains supply and switch on.
2. Allow system to stabilize.



*Allow for sufficient cooling off time between exposures as required in the relevant installation instructions.*

---

3. Make 9 exposures at the kVp and mAs combinations as shown in the workbook results table.
4. Read the kVp and mAs measurements and record in workbook.

## RESULTS

Actual kVp and mAs values must be within the calculated rejection limits.

## 2.8. TEST 8

### 2.8.1. TEST 8A: TIMER ACCURACY (SIX AND TWELVE PULSE GENERATORS ONLY)



MODULAR, CLASSIC, MCRT				
TIMER RANGE ms	SPECIFICATION	TIME SELECTED ms	SPECIFICATION LIMITS	
			MAX. ms	MIN. ms
1–10	±30%	5	6.5	3.5
11 – 40	±25%	25	31.2	18.8
41 – 100	±20%	50	60.0	40.0
101 – 1000	±15%	500	575.0	425.0
1000 – 6000	±10%	2000	2200.0	1800.0



*Do not start until generator has been switched on for at least one hour.*

---

#### TEST EQUIPMENT

- Keithley voltage divider model # 35080 with filter packs 32867C, 5C, 9C, or equivalent.
- Oscilloscope (storage)

#### SETUP

1. Set up the Keithley voltage divider complete with the appropriate filter as Keithley instruction manual no. 3294 OIM.
2. Connect the oscilloscope to the Keithley divider.
3. Calculate rejection limits based on the exposure parameter "Specification Limits" shown in the table above. The "Specification Limits" are based on the actual tolerances as listed in the generator operator's manuals. These "Specification Limits" must be restricted to include the actual measuring instrument error. See also section 5 paragraph 3.1. regarding how to calculate rejection limits.

**TEST**

1. Select suitable X-ray tube station and allow time for system to stabilize.
2. Make exposures of 5ms, 25ms, 50ms, 500ms and 2.0sec. at a fixed tube current of 150 or 200mA and 80kV.
3. Measure exposure time on oscilloscope, between the point where kV exceeds 75% of its max. value (kVp) and the point where kV decreases below 75% of its max. value.

**RESULTS**

Record actual exposure times in workbook. Results must be within the calculated rejection limits.

## 2.8.2. TEST 8B: TIMER ACCURACY (OPTIMUS 200)



SPECIFICATIONS					
TIMER RANGE	MAXIMUM DEVIATION		SELECTED TIME	SPECIFICATION LIMITS	
	+	-		MAX.	MIN.
0.32 – 1.0 ms	69 us	71 us	0.5 ms	0.569 ms	0.429 ms
1.2 – 10.0 ms	59 us	81 us	5.0 ms	5.059 ms	4.920 ms
12 – 100 ms	0	181 us	50 ms	50.00 ms	49.81ms
120 – 800 ms	0	1.2 ms	400 ms	400.0 ms	398.8 ms



*Do not start test until generator has been switched on for at least one hour.*

---

### TEST EQUIPMENT

- Keithley voltage divider model # 35080 with filter packs 32867C, 5C, 9C, or equivalent.
- Oscilloscope (storage)

### SETUP

1. Set up the Keithley voltage divider complete with the appropriate filter as per Keithley instruction manual no. 3294 OIM.
2. Connect the oscilloscope to the Keithley divider.
3. Calculate rejection limits based on the exposure parameter "Specification Limits" as shown in the table above. The "Specification Limits" are based on the actual tolerances as listed in the generator operator's manuals and must be restricted to include the actual measuring instrument error. See also section 5 paragraph 3.1. regarding how to calculate rejection limits.

### TEST

1. Select suitable X-ray tube station on control and allow system time to stabilize.
2. Make exposures of 0.5ms, 5ms, 50ms and 400ms at a fixed current of approx. 200mA at 80kV. Measure exposure time on oscilloscope.

### RESULTS

Record actual exposure times in workbook. Results must be within rejection limits.

**2.8.3. TEST 8C: TIMER ACCURACY (TWO-PULSE GENERATORS, MEDIO 5600 etc.)**

SPECIFICATION			SPECIFICATION LIMITS	
Selected Time	Pulses	Sec.	Max.	Min.
1/60 sec	2	–		
1/10 sec	12	–		
3/10 sec	36	–	exact	
0.5 sec	–	0.5		
2.0 sec	–	2.0		

**TEST EQUIPMENT**

- Keithley voltage divider model # 35080 with filter packs 32867C, 5C, 9C, or equivalent.
- Oscilloscope (storage)

**SETUP**

*Do not start test until generator has been switched on for at least one hour.*

1. Set up the Keithley voltage divider complete with the appropriate filter as per Keithley instruction manual no. 3294 OIM.
2. Connect oscilloscope to the Keithley divider.

**TEST**

1. Make exposures at 60kV and approximately 150mA at the selected times of 1/60, 1/10, 3/10, 1/2 and 2 seconds.
2. For the 1/2 and 2.0 sec. exposure time read on the oscilloscope the distance between the point that kV exceeds 75% of the kVp to the point that kV decreases below 75% of the kVp.  
For shorter exposure times count the pulses (see waveform section 5, paragraph 5).

**RESULTS**

Record the actual exposure times/pulse counts in workbook. Results must meet the specification.

## 2.9. TEST 9: EXPOSURE PARAMETERS FOR ALL MEDIO AND SUPER CP GENERATORS INCLUDING THE OM 1050C



CP generators are factory calibrated and checked for compliance with the parameter readout tolerances as stated in the relevant operator's manuals. Provided these generators are installed and set to work in accordance with the installation manuals only the following limited field compliance testing is required.

### TEST EQUIPMENT

- Keithley voltage divider model # 35080 with filter packs 32867C, 5C, 9C, or equivalent.
- Oscilloscope (storage)
- Digital mA, mAs meter.



- 1) *Do not start test until generator has been switched on for at least one hour.*
  - 2) *Direct (invasive) kVp measurements on CP generators with HV divider tanks normally available to the field service organization are not permitted.*
- 

### SET UP

1. Switch off generator and also switch off main disconnect breaker to system.
2. Connect digital mA meter as per instructions in the relevant service manual.
3. Set up the Keithley voltage divider complete with the appropriate filter as per Keithley instruction manual no. 3294 OIM.
4. Connect the oscilloscope to the Keithley divider.



*Make sure that the oscilloscope has been calibrated with the aid of the Keithley divider as described in the Keithley instruction manual before starting any testing (par. 3.6 internal calibration).*

---

5. Calculate rejection limits based on the exposure parameter "Specification Limits" shown in the table below.

## Compliance Testing

The "Specification Limits" are based on the actual tolerances as listed in the generator operator's manuals. These "Specification Limits" must be restricted to include the actual measuring instrument error. See also section 5 paragraph 3.1. regarding how to calculate rejection limits and paragraph 3.2. "Special considerations for CP generator testing".

### TEST

EXPOSURE NUMBER	DIAL	SPECIFICATION LIMITS	
		MEDIO CP	SUPER CP/OM1050C
1 FLUORO	90 kV	96.5 > kVp > 82.5	95.5 > kVp > 84.5
	2.5 mA	2.85 > mA > 2.15	2.73 > mA > 2.27
2 RADIOGRAPHY kV/mA/ms	81 kV	87.0 > kVp > 75.0	85.0 > kVp > 77.0
	250 mA	288.5 > mA > 211.5	263.5 > mA > 236.5
	100 ms	110.0 > ms > 95.0	104.0 > ms > 98.0
3 RADIOGRAPHY kV/mAs	125 kV	133.2 > kVp > 116.8	131.2 > kVp > 118.8
	80 mAs	93.0 > mAs > 67.0	84.5 > mAs > 75.5

1. Switch on system.
2. Make exposures 1, 2 and 3; read the kVp, mA, mAs and ms values. Repeat any exposure until you have obtained readouts of all parameters.
3. Verify that the measured values are within the calculated rejection limits and record same in workbook.

## 2.10. TEST 10: TUBE CURRENT ACCURACY (RADIOGRAPHIC FIXED CURRENT)

(Not applicable for CP generators)



SPECIFICATIONS	Dialed mA							
	20 or 25*				50 or 60*			
	MAX	MIN	MAX	MIN	MAX	MIN	MAX	MIN
MODULAR + 15%	23.0	17.0	28.75	21.25	57.5	42.5	69.0	51.0
OPTIMUS + 24%	24.8	15.2	31.0	19.0	62.0	38.0	74.4	45.6
CLASSIC AND MCRT ≤ 50 mA: + 5%, -25% > 50 mA: + 15%	21.0 —	15.0 —	26.25 —	18.75 —	52.5 —	37.5 —	69.0 —	51.0 —
MEDIO 5600 + 12.5%	22.5	17.5	28.1	21.9	56.3	43.8	67.5	52.5

\*Use 25mA and 60mA if 20 and 50mA are not available. For generators not allowing mA selection below 61mA mark workbook table "Not Applicable".



*Do not start test until generator has been switched on for at least one hour.*

### TEST EQUIPMENT

- Digital mA meter

### SETUP

1. Switch off generator, also switch off main disconnect breaker to system.



*Observe sufficient anode cooling off time between exposures as indicated in the relevant tube manual.*

---

2. Connect digital mA meter as instructed in relevant generator installation manual.
3. Calculate rejection limits based on the exposure parameter specification limits as shown in the table above (See also section 5, paragraph 3.1.).

## TEST

1. Switch on generator.
2. Select relevant X-ray tube.
3. Select mA values as per specifications block and make exposures at:  
75kV and 2.0 sec.  
100kV and 2.0 sec.

## RESULTS

Record actual mA in workbook. Results must meet the calculated rejection limits.

## 2.11. TEST 11: mAs ACCURACY

(Not applicable for CP generators)



SPECIFICATIONS										
MEDIO 5600: + 10%			CLASSIC: + 7%, + 1 mAs							
MCRT: + 2 mAs or 7%			MODULAR: + 20%							
E X P O S U R E	A	B	mAs Specification Limits							
	ma Dialed	Exp. Time Dialed	mAs Dialed	MEDIO 5600	CLASSIC	MCRT	MODULAR			
				MAX.	MIN.	MAX.	MIN.	MAX.	MIN.	MAX.
1	125 or 150	0.2	25 or 30	27.5 33.0	22.5 27.5	27.8 33.1	23.2 27.9	27 32	23 28	30.0 36.0
2	200 or 250	0.2	40 or 50	44.0 55.0	36.0 45.0	43.0 54.5	37.2 46.5	42.8 53.5	37.2 46.5	48.0 60.0
3	300 or 400	0.2	60 or 80	66.0 88.0	54.0 72.0	65.2 86.6	55.8 74.4	64.2 85.6	55.8 74.4	72.0 96.0
4	500 or 600	0.2	100 or 120	110.0 132.0	90.0 108.0	108.0 129.4	93.0 111.6	107.0 128.4	93.0 111.6	120.0 144.0
										80.0 96.0

## Compliance Testing

With generators providing 3 point technique only (kVp, mA and exp. time) select mA and time values as per specification table column A. For generators allowing 2 point technique (kVp, mAs) select mAs directly as per column B. For compliance testing always compare the pre-indicated mAs (on control dial or digital read out) with the actual mAs obtained.



*Do not start testing until generator has been switched on for at least one hour.*

---



*OBSERVE SUFFICIENT ANODE COOLING OFF TIME BETWEEN EXPOSURES AS INDICATED IN THE RELEVANT TUBE INSTALLATION MANUAL.*

---

### TEST EQUIPMENT

- Digital mA/mAs meter

### SET UP

1. Switch off generator and main disconnect breaker to system.
2. Connect mAs meter as per instructions in relevant installation manuals.
3. Calculate rejection limits based on the exposure parameter "Specification Limits" as shown in the table above (See also section 5, paragraph 3.4.).

### TEST

1. Switch on generator and allow time to stabilize.
2. Select X-ray tube station.
3. Select exposure parameters as per above table. For each exposure two mA values are shown. Select only one as available with the particular generator.
4. Complete 4 exposures for each of the three kVp values (75, 100 and 125 kVp) or twelve exposures per X-ray tube station.
5. Measure the mAs values and record in workbook.

### RESULTS

Actual mAs values must be within the calculated rejection limits.

## 2.12. TEST 12: MAXIMUM mAs FOR GENERATORS WITH AEC (ABOVE 50kVp)



SPECIFICATION	REJECTION LIMIT
<ol style="list-style-type: none"> <li>When <math>kVp \geq 50</math> the product of X-ray tube mA and exposure time shall not exceed 600mAs per exposure.</li> <li>A visible signal shall indicate when the exposure terminates at the limit.</li> <li>Manual resetting shall be required before further automatically timed exposures can be made.</li> </ol>	<p>For <math>\pm 2\%</math> mAs meter inaccuracy.</p> <p>Reject any exposures <math>&gt; 588\text{mAs}</math></p>

### TEST EQUIPMENT

- mAs meter
- Lead sheet

### SETUP

- Turn generator OFF. Also, shut off main disconnect breaker to system.
- Connect mAs meter to X-ray control according to instruction manual.

### TEST

- Turn generator ON.
- Select overtube tube and large focus.
- Select center field and darkest density of AEC operation.
- Manually close collimator shutters down to minimum.
- Place a lead sheet between the collimator and image receptor.
- For falling load generators set 50kV for fixed mA generators with AEC set 50kV and highest mA station.
- Make an exposure and read mAs.
- Check that a visible signal indicates that exposure has been terminated at the limit.
- Without resetting, check that generator will not make another exposure.

### RESULTS

Record actual mAs in workbook. Measurement may not exceed the rejection limit.

### LINEARITY AND REPRODUCIBILITY TESTS 13, 14 and 15

Factory testing of NEW generators ensures that generator linearity and reproducibility are in compliance with the FDA regulations. So for NEW installations field tests 13, 14 and 15 are not required. However, these tests are included here and must be performed whenever repairs are made that could adversely affect compliance.

## 2.13. TEST 13: LINEARITY TEST FOR ALL GENERATORS WITH mA STATIONS OR CONTINUOUS mA ADJUSTMENT



### SPECIFICATION

The difference between the average ratios of dose to mAs obtained at any two consecutive tube current settings shall not differ by more than 0.1 times their sum or:

$$|\bar{x}_1 - \bar{x}_2| \leq 0.1 (\bar{x}_1 + \bar{x}_2).$$

Where  $\bar{x}_1$  and  $\bar{x}_2$  are the average mR/mAs values obtained at each of two consecutive tube current settings.

### TEST EQUIPMENT

- Dosemeter
- Lead sheet
- Calculator
- mAs meter

### SETUP

1. Place dosemeter probe in center of x-ray field at a distance of 50cm (20") from tube focal spot.
2. Set collimator so that the size of the radiated area in the probe plane is twice the length and twice the width of the probe.
3. To avoid back scatter place lead sheet over image receptor.
4. Connect mAs meter as per relevant generator installation manual.
5. Select large focus.
6. Select technique factors for 80kV, 200 or 250 mA and 0.1 sec.



*Observe sufficient anode cooling off time between exposures as indicated in the relevant tube installation manual.*

---

## TEST

1. Make series of 10 exposures within one hour period. After each exposure, write down dose and mAs readings in workbook. During the exposure series the percent line-voltage-regulation must remain within  $\pm 1$  of the mean value for all measurements of the series. Repeat exposures that are out of line.
2. Repeat the above procedure but with generator technique factors for 80kV, 300 (400) mA, at 0.1 sec. Always select an adjacent mA station to the one used before. For generators with free mA selection (like MCRT) use identical technique factors as mentioned above. Always make sure that the mA settings for series I and II differ by a factor  $\leq 2$ .

## RESULTS

1. Calculate difference between the two average ratios.
2. Calculate the sum of the two average ratios divided by ten.
3. Complete calculation as shown in sample below. Outcome must meet specification.

Exp	SERIES I 80kV-200 (250mA), 0.1 sec			SERIES II 80kV-300 (400)mA, 0.1 sec		
	Dose in mR	mAs	$x_1 = \text{mR/mAs}$	Dose in mR	mAs	$x_2 = \text{mR/mAs}$
1	124.8	20.6	6.05	178.9	29.8	6.0
2	124.7	20.3	6.14	181.0	30.3	5.97
3	124.7	20.8	5.99	179.8	30.1	5.97
4	122.5	20.1	6.09	178.4	29.7	6.01
5	123.3	20.4	6.04	180.0	30.1	5.98
6	125.5	20.9	6.0	180.0	30.0	6.00
7	124.7	20.5	6.08	183.2	30.5	5.89
8	121.9	20.0	6.09	180.9	29.9	6.05
9	122.5	20.1	6.09	181.9	30.2	6.00
10	124.3	20.7	6.01	181.9	30.3	6.00
		Total = 60.58			Total = 59.87	

$$\ddot{\Omega}_1 = \text{Total Series I} : 10 = 6.058$$

$$\ddot{\Omega}_2 = \text{Total Series II} : 10$$

$$= 5.987$$

$$\text{Verified: } |\ddot{\Omega}_1| - |\ddot{\Omega}_2| = 0.071 \leq 0.1 \quad (\ddot{\Omega}_1 + \ddot{\Omega}_2) = 1.204$$

## 2.14. TEST 14: REPRODUCIBILITY FOR GENERATORS IN ABC MODE



SPECIFICATION
The coefficient of variation of radiation exposures shall not be greater than 0.05 for any specific combination of technique factors.
Calculation of the coefficient of variation "C" to be based on the following formula.
$C = \frac{1}{\bar{E}} \sqrt{\frac{\sum_{j=1}^n (X_j - \bar{E})^2}{n-1}} \leq 0.05$
in which: $\bar{E} = \frac{1}{n} \sum_{j=1}^n X_j$ Average Dose $n$ = number of test exposures $X_j$ = individual test exposure

### TEST EQUIPMENT

- Dosemeter
- Attenuation block of type 1100 AL alloy 20 x 20 x 3.8cm
- Calculator

### SETUP

1. Set tube at 40" (100cm) over image receptor.
2. Insert dosemeter probe in radiation field at distance of 20" (50cm) from, the tube focal spot.
3. Use BLD light to properly center probe in beam and to ensure that the size of the radiation field in the plane of the probe is at least twice the width and length of the probe.
4. Tape the attenuation block to the BLD opening.

**TEST**

1. Select large focus.
2. Set generator technique factors for falling load, and 80kV.

For fixed current only generators set technique factors for approx. 60mA, 80kV. Make sure that exposure factors selected always result in exposure times  $\geq 0.1$  sec.

3. Make a series of 10 exposures within a one hour period and measure the radiation dose after each exposure.

During the exposure series the percent line-voltage-regulation must remain within  $\pm 1$  of the mean value for all measurements of the series. Repeat exposures that are out of line.



*Observe sufficient anode cooling off time between exposures as indicated in the relevant tube installation manual.*

---



*For equipment manufactured after September 5, 1978, the technique factor controls must be moved from test setting and back again after each exposure.*

---

**RESULTS**

1. Record the ten measurements in workbook.
2. Calculate the coefficient of variation of radiation exposures. See example.

**EXAMPLE**

<b>EXP. NO.</b>	<b>RADIATION DOSE <math>X_i</math></b>	<b>AVERAGE DOSE <math>\bar{E}</math></b>	<b>DIFFERENCE <math>X_i - \bar{E}</math></b>	<b>DIFFERENCE SQUARED</b>
1	34.3	34.11	0.19	0.0361
2	33.9	34.11	0.21	0.0441
3	34.4	34.11	0.29	0.0841
4	34.4	34.11	0.29	0.0841
5	34.2	34.11	0.09	0.0081
6	34.1	34.11	0.01	0.0001
7	34.1	34.11	0.01	0.0001
8	34.1	34.11	0.01	0.0001
9	34.0	34.11	0.11	0.0121
10	33.6	34.11	0.51	0.2601
Total Dose	341.1	-	Differences Squared Total	0.529

**NOTE**

*Disregard minus signals for  $X_i - \bar{E}$  differences.*

---

Calculate: Average Dose  $\bar{E} = \text{Total Dose}/n = 341.1/10 = 34.11$

Calculate: Diff. Squared Total/ $n-1 = 0.529/9 = 0.05877 = A$

Calculate coefficient of variation  $C = \sqrt{A}/\bar{E}$

$$C = \sqrt{0.05877}/34.11 = 0.242/34.11 = 0.007$$

Result "C" must be smaller than or equal to 0.05.

## 2.15. TEST 15: REPRODUCIBILITY FOR GENERATORS IN MANUAL MODE (NONAEC)



### SPECIFICATION

The coefficient of variation of radiation exposures shall not be greater than 0.05 for any specific combination of technique factors.

Calculation of the coefficient of variation "C" to be based on the following formula.

$$C = \frac{1}{\bar{E}} \sqrt{\frac{n \sum_{j=1}^n (X_j - \bar{E})^2}{n-1}} \leq 0.05$$

in which:  $\bar{E} = \frac{1}{n} \sum_{j=1}^n X_j$  Average Dose

$n$  = number of test exposures

$X_j$  = individual test exposure

### TEST EQUIPMENT

- Dosemeter
- Lead sheet
- Calculator

### SETUP

1. Set tube at 40" (100cm) over image receptor.
2. Insert dosemeter probe in radiation field at distance of 20" (50cm) from focal spot.
3. Use BLD light to properly center probe in beam and to ensure that the size of the size of the radiation field in the plane of the probe is at least twice the width and length of the probe.
4. Place lead sheet over image receptor.

**TEST**

1. Select small focus.
2. Set generator technique factors for falling load, 20mA and 80kV.  
For generators with fixed current only set technique factors for 100mA, 80kV and 0.2 sec.
3. Make a series of 10 exposures within a one hour period and measure the radiation dose after each exposure.  
During the exposure series the percent line-voltage-regulation must remain within  $\pm 1$  of the mean value for all measurements of the series. Repeat exposures that are out of line.



*Observe sufficient anode cooling off time between exposures as indicated in the relevant tube installation manual.*

---



*For equipment manufactured after September 5, 1978, the technique factor controls must be moved from test setting and back again after each exposure.*

---

**RESULTS**

Record the ten measurements in workbook and complete calculations as shown under RESULTS item 2 of TEST 14. Test outcome must meet specification.

## 2.16. TEST 16: BEAM QUALITY-HALF VALUE LAYER (HVL) FOR X-RAY TUBES OPERATING ABOVE 70KV<sub>P</sub>

Based on FDA regulation 21CFR1020.31(g).

### PREFACE

All Philips X-ray tube/housing assemblies are factory equipped and tested for minimum HVL as required by the FDA, other national authorities and international standards.

Be aware that proper measurements of the HVL require a high precision setup that is only adequately available in the factory. Testing the HVL at the user's site will implicate inaccuracies that may induce misleading results, especially when looking for compliance with the FDA limits from June 2006. These limits are close to the Philips factory standard.

**It is not advised to measure the HVL routinely for acceptance testing.**

**Philips recommends a site inspection as per test 16A.**

In case a field measurement is performed anyhow(\*), the results have to be regarded as relative results. They can be used for future constancy measurements or for rough estimations when IQ or dose are off, or when an older tube is suspected to be worn out.

(\*) See description under 16B. Be aware that the test is time consuming.

Non-Philips tube housing assemblies should be tested in accordance with the manufacturer's instructions.

### SPECIFICATION

The half value layer (HVL) of the useful beam for a given X-ray tube potential shall conform to the HVL column below.

Designed operating range KV <sub>p</sub>	Measured operating potential KV <sub>p</sub>	Minimum HVL (mm of aluminum)
Above 70	71	2.5
	80	2.9
	90	3.2
	100	3.6
	110	3.9
	120	4.3
	130	4.7
	140	5.0
	150	5.4

### 2.16.1. TEST 16A: BEAM QUALITY – HVL FILTER INSPECTION

Inspect and confirm in workbook, that the tube housing's exit port filter and retaining ring are in place and in good order. Only in case of any sign of damage to, or tampering with, the filter and ring should the following test 16B be carried out.

## 2.16.2. TEST 16B: BEAM QUALITY – HVL CHECK



### TEST EQUIPMENT

- Set of high purity Al filters of appropriate thickness (Al purity min 99.9% – 1100 alloy is not sufficient!)
- Dosemeter (e.g. Unfors or Diados)
- Lead plate

### PRECONDITIONS

- Tube well adapted
- For an adequate reproducibility: Tube and generator well warmed up
- Any extra filtration removed from the beam

### TEST

1. Position the dose meter probe in the beam:
  - a) Protect the probe from backscatter by positioning it on a lead plate (or free in air).
  - b) Use BLD light to place dose meter probe in center of X-ray field.
  - c) Set a distance of 37" (100 cm) between probe and focal spot.
  - d) Adjust collimator shutters to a narrow field size – the sensitive probe area should just well be covered.
2. Set generator to the desired kVp for measurement (e.g. 100 kV).
3. Set focal spot and mAs such that a reasonable dosimeter reading is achieved and the exposure time is close to 100 ms (+/- 50 ms). Values must be set in a way that the dosimeter does not switch ranges during the measurements.
4. Make 5 exposures and record the dose values.
5. Calculate the average initial dose.
6. Add Al filtration to the Xray beam (filter layers to be placed as close to the tube as practical).
7. Make 5 exposures and record the dose values.
8. Calculate the average dose.
9. Repeat steps 6 to 8 until the meter reading is less than half of the initial value.
10. Pay special attention to the Al filtration that results in 50% of the initial reading: Make sure that you use Al thicknesses just above and below that value.
11. Note the readings and calculate the average per Al thickness. Values per reading should be accurate to +/- 2%.

#### Evaluation:

1. Plot the values into a diagram. MS Excel can be used for this.
2. In a semi log diagram, the plot should approximate a straight line.
3. Find the Al thickness that corresponds to 50% of the initial meter reading by interpolation between the adjacent points. This is the HVL.

Expectable accuracy (at 100 kV):

+/-	0.05 mm Al	Actual Aluminium thickness
+/-	0.2 mm Al	Actual kVp
+/-	0.1 mm Al	Meter reading
-	0.05 mm Al	Meter energy response

Increasing the measurement accuracy:

For a very accurate HVL measurement, the following modifications need to be made:

- use an air chamber dose meter (e.g. UNIDOS)
- invasively measure kVp with an accuracy better than +/- 0.5 kV and correct the kV setting to obtain the actual kVp as needed.



*None-invasively measured kV, e.g. by using the Unfors meter, are no improvement!*

---

Interpretation of results:

The results should be compatible with the limits shown in the specification table or slightly higher, taking the measurement accuracy into account. A tube should not be rejected if the deviation from acceptance limits is smaller than the measurement accuracy.

An older tube should be exchanged, if the limit is exceeded by 30%.

Hints:

- For a very fresh tube, the HVL value will increase slightly during the first days of operation.
- The HVL can also be directly determined using the Unfors meter. The Unfors meter is specified for a better than 10% accuracy in HVL, but by experience is accurate to about 5% in the 70 to 80 kV region, while it can be significantly off at high (140) or low (50) kV.
- There is usually no need to measure HVL over the full range. If the value is o.k. for e.g. 100 kV, then it is most probably also o.k. over the full range.

## 2.17. TEST 17: FLUOROSCOPIC ENTRANCE EXPOSURE RATE FOR ALL GENERATORS SERVING AN II

Based on FDA regulation 21CFR1020.32(e)(2).



### SPECIFICATION

- a) For units with automatic exposure rate control and no high level control the fluoroscopic dose rate must not exceed 10R/min, except during the recording of fluoroscopic images.
- b) For units with automatic exposure rate control and high level control the fluoroscopic dose rate must not exceed 5R/min unless the high level control is activated. Whenever high level mode is selected radiation is possible only by continuous manual activation by the operator, while a continuous signal audible to the fluoroscopist sounds.

## 1. GENERAL INFORMATION AND INSTRUCTIONS APPLICABLE TO ALL FLUOROSCOPIC STANDS AND TABLES

- a) The standardized instrument for the field service organization is the RADCAL radiation monitor 1015C with ion chambers (probes) model 10X5-6 and 10X5-60. For test 17 the 10X5-6 chamber should be used. The combined monitor/chamber accuracy is  $\pm$  3%. This leads to the following rejection limits:

Specification for units without high level control:  $\leq 10\text{R}/\text{min}$  rejection limit =  $10\text{R}/\text{min} + 1.03 = 9.7\text{R}/\text{min}$ .  
Specification for units with high level control:  $\leq 5\text{R}/\text{min}$  rejection limit =  $5\text{R}/\text{min} + 1.03 = 4.85\text{R}/\text{min}$ .

In case an instrument with a different accuracy percentage is used the service engineer must recalculate the rejection limits especially in case the instrument/probe combination is less accurate than  $\pm$  3%.

- b) Locate the ion chamber at the proper level as prescribed for each particular equipment configuration under "SPECIFIC EQUIPMENT TESTING AND SET UP INFORMATION" paragraphs 2.A thru 2.E.
- c) Use TV monitor to center the ion chamber in the radiation beam.
- d) Before carrying out the actual radiation measurements make sure that:
  - A LEAD SHEET FULLY COVERS THE FACE OF THE II. TO AVOID BURNING THE INPUT SCREENS OF THE II OR TV CAMERA.
  - Proper measurement procedure is selected:
    - see 1.e. for systems without high level option
    - see 1.f. for systems with high level option

### **1.e. RADIATION MEASUREMENTS ON INSTALLATIONS WITHOUT HIGH LEVEL FLUOROSCOPY OPTION (Specification dose rate < 10 R/min)**

1. Select manual fluoroscopic mode (if available) and set kV and mA parameters at maximum.
2. For dual and triple field II's select largest field mode and check that the BLD has opened fully to the image receptor size.
3. Switch on fluoroscopy and let system stabilize at highest dose rate.
4. Read the dose rate and switch off fluoroscopy.
5. Select automatic dose rate control mode and highest position of any manually controlled parameter if present.
6. Repeat steps 3 and 4.
7. The measured results cannot exceed the calculated rejection limits. Check off the appropriate boxes in workbook.

### **1.f. RADIATION MEASUREMENTS ON INSTALLATIONS WITH HIGH LEVEL FLUOROSCOPY OPTION (Specification: low level mode ≤ 5 R/min)**

1. Select manual non-high-level fluoroscopic mode (if available) and set kV and mA parameters at maximum value.
2. For dual and triple field II's select largest field mode and check that the BLD has opened fully to the image receptor size.
3. Switch on fluoroscopy and let system stabilize at highest dose rate.
4. Read the dose rate and switch off fluoroscopy.
5. Select automatic dose rate control mode and highest position of any manually controlled parameter if present.
6. Repeat steps 3 and 4.
7. The measured results cannot exceed the calculated rejection limits. Check off the appropriate boxes in workbook.
8. Select high-level fluoroscopic mode, switch on fluoroscopy and in this position check that:
  - radiation is produced only as long as continuous manual activation by the operator of the fluoroscopic control is occurring.
  - as long as radiation is produced a continuous signal audible to the fluoroscopist sounds.
9. Confirm conditions 8.a) and b) by checking off the appropriate boxes in workbook.

## **SPECIFICATIONS**

- In normal mode the fluoroscopic entrance exposure rate shall be limited to 10 R/min maximum.
- The high level control (HLC) mode shall:
  - Be limited to 20 R/min maximum.
  - Be selected by special means.
  - Be operable only by continuous manual activation.
  - Have an alarm that is audible whenever the mode is operational, regardless of the entrance exposure rate.

## **TEST EQUIPMENT**

- Dose / kVp meter TC261 (preferred) or TC142.
- Lead sheet 40 x 40 x 0.3 cm (to cover the entrance plane of the image receptor)

## SETUP

1. Set stand in 90 degrees rotation (beam horizontal).
2. Move table outside radiation beam.
3. Select largest image format.
4. Open the shutters.
5. Ensure that the wedge filter is out of the beam.
6. Position dose probe at 30cm from the entrance plane of image receptor.
7. Use fluoroscopy to center the dose probe in the radiation beam. Make sure that the entire surface of the dose probe is radiated!
8. Cover the entrance plane of the Image Receptor with a lead sheet.  
(To ensure that the maximum technique factors are achieved during fluoroscopy.)

## TEST

1. Set image receptor to minimum SID.
2. Select high level control (HLC) fluoro mode.
3. Start fluoroscopy and let system stabilize at highest dose rate.
4. Check that maximum technique factors are achieved, (e.g. 120 kV, 13 mA).  
If not, add additional absorption at the entrance plane of the image receptor.
5. Verify that the audible alarm for HLC mode can be heard at the tableside and at the control desk while HLC mode is active.
6. Read the HLC dose rate and write the value in the workbook.
7. Stop fluoroscopy.
8. Re-start fluoroscopy and verify that the system has automatically reverted to normal or low fluoroscopy mode.
9. Select normal fluoro mode.
10. Start fluoroscopy and let system stabilize at highest dose rate.
11. Read the normal dose rate and write the value in the workbook.
12. Repeat the test for SID = 100 cm and at maximum SID.



*Make sure that when changing the SID,  
the distance between dose probe and Image Receptor remains 30 cm.*

- 
13. Repeat the setup and test for the lateral channel (if present).

**RESULTS**

Used dose meter	
Specified accuracy of dose meter	
Acceptance limit* for HLC mode	
Acceptance limit* for Normal mode	

\* For calculation method see chapter 1.5.

Measured values [R/min]	Minimum SID		SID = 100 cm		Maximum SID	
	HLC	Normal	HLC	Normal	HLC	Normal
Frontal						
Lateral						

	VERIFIED (X) Frontal	VERIFIED (X) Lateral
Maximum exposure rate in normal mode		
Maximum exposure rate in HLC mode		
Audible alarm during HLC mode		
System returns to normal or low mode after stopping HLC mode		

	INITIALS	DATE

## 2. SPECIFIC EQUIPMENT TESTING AND SET UP INFORMATION

### 2.A. R/F TABLES WITH UNDERTABLE TUBE

1. Equipment completely assembled.
2. Set ion chamber in X-ray field at 1 cm above horizontal table top.

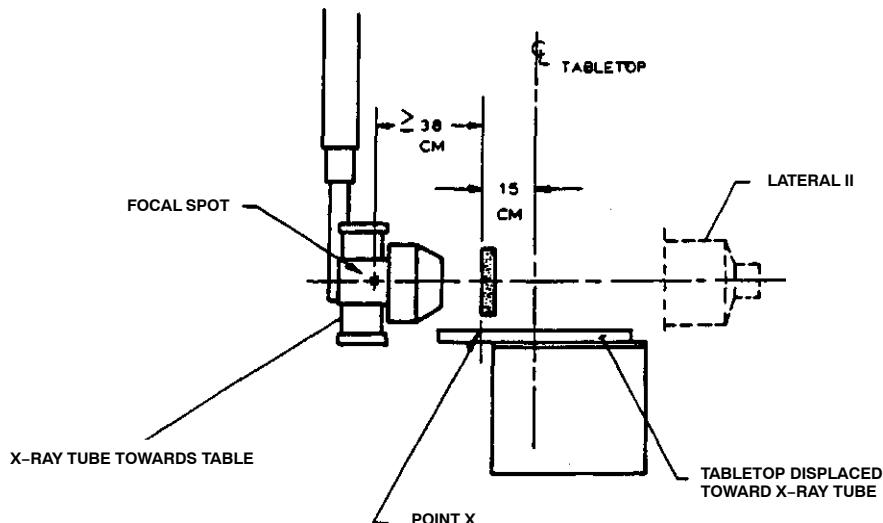
### 2.B. R/F TABLES WITH OVERTABLE TUBE

1. Equipment completely assembled with table top horizontal.
2. Raise table top to its highest position.
3. Move compression cone into parked position.
4. For equipment with variable SID set tube/BLD assembly as close as possible to point of measurement (shortest SID).
5. Set ion chamber in X-ray field at 30 cm above table top.

### 2.C. EXAMINATION STANDS INCORPORATING A LATERAL II

1. Equipment completely assembled and positioned.
2. Place X-ray tube assembly in its normal lateral working position as close as possible to the table top center line.
3. Extend tabletop laterally as close as possible towards the X-ray tube.
4. Measure 15cm (1/2 of patient's width) from table top center line in the direction of the X-ray tube and mark this point "X".
5. Measure distance from X to focal spot.
6. If distance is  $\geq 38\text{cm}$  then place ion chamber in field at X and carry out the measurement.

Be aware that distances  $<$  than 38cm represent illegal exposure positions (to close to patients skin). In such cases a spacer mounted to the front of the BLD or tube shroud must prevent distances  $<$  38cm or alternatively a mechanical or electrical device must prevent exposures at distances  $<$  38cm. The only exception to the 38 cm limit is in case of surgical applications requiring shorter working distances. In those cases the equipment may allow exposures at distances  $\geq 20\text{cm}$  provided this exception is available as an operators option only. Even if this  $\geq 20\text{cm}$  option is available the actual entrance dose rate measurement must be carried out with the ion chamber at a distance of 38cm from the focal spot.



## 2.18. TEST 18: ACTUAL TO INDICATED SID (OVERTABLE TUBE)

SPECIFICATION	REJECTION LIMIT
The visual SID indication must be within 2% of the actual SID	$\geq 1.8\%$ SID

### TEST EQUIPMENT

- Cassette
- Measuring tape, metric/inch

### SETUP

The equipment completely assembled with table in horizontal position.

### TEST

1. For tables with vertical tabletop adjustment set the top in lowest position.
2. Place unloaded cassette in table bucky tray and leave tray extended.
3. Set the focal spot of X-ray tube (red dot on housing) at exactly 100cm (40") from the film plane in bucky tray with the measuring tape as follows:
  - For tube arms with lateral movement, move arm until center of BLD is directly over center of the cassette in the extended tray and set an SID of 100cm (40").
  - For tube arms without lateral movement, measure distance "A" of film plane in tray to table top as accurately as possible. Then set focal spot of X-ray tube at a distance "B" from tabletop so that A & B is exactly 100cm (40").
  - For mobile radiographic units like PMX set focal spot of x-ray tube at exactly 100cm (40") above a suitable horizontal surface.
4. Verify the following requirements as indicated in table 1 below.
  - SID indicator on fl/c tube stand or ceiling crane suspension reads 100 cm (40")  $\pm 1.8\%$ .
  - Measuring tape in tube handle bar (if available) reads 100cm (40")  $\pm 1.8\%$  if extended to the table top. (Make sure that tape was shortened to cover the tabletop to film plane distance).
  - Measuring tape in tube handle bar reads 100cm (40")  $\pm 1.8\%$  if extended to the pre-set horizontal surface.
  - For installations equipped with an SID meter it should correspond with the measurement in b.
  - For applicable installations, that no SID indication is present on the ceiling suspension of the X-ray tube.

TABLE 1	a	b	c	d	e
Standard bucky tables with fixed top	X	X		X	
Horizontal Diagnost "H" 9870 404 60012		X			X
Horizontal Diagnost "H" 9870 404 60022 and other bucky tables with tabletop height adjustment		X		X	X
Mobile radiographic X-ray units like PMX			X		

### RESULTS

Verify in workbook that the equipment installed complies with the requirements "x" as specified in table 1 above.

## 2.19. TEST 19: INDICATED X-RAY FIELD SIZE WITH OVERTABLE TUBE AND MOBILES (PMX)



SPECIFICATION	REJECTION LIMIT
The indicated field size and actual field size must be within 2% of the maximum SID	Allowable difference: 1.9% SID

### TEST EQUIPMENT

- Loaded cassettes, 10" x 12" (24 x 30cm)
- Ruler metric/inch
- Washer

### SETUP

The equipment completely assembled and set to standard or maximum allowable SID. For PMX take SID of 40" (102 cm).

### TEST

1. Put loaded 10" x 12" (24 x 30 cm) cassette in bucky tray. Ensure that cassette is properly centered in the tray and insert tray into bucky cabinet.
2. Center overtable tube to bucky.
3. Using the dials on the BLD housing adjust BLD to 8" x 10" (18 x 24cm) opening at the SID selected.
4. Place washer in one quadrant of X-ray field at the anode end to identify film positioning.
5. Select overtable tube on control desk and make a 60kV, 5mAs exposure.
6. Develop film.
7. Measure length and width of X-ray image on test film.



*For mobile units like PMX, use loaded 10" x 12" (24 x 30cm) cassette positioned on a horizontal surface and center the PMX tube head perpendicular above it at an SID of 40" (100cm).*

*Adjust BLD to 8" x 10" (18 x 25cm) by using the dials on the BLD and proceed as mentioned above (steps 4, 5, 6 and 7).*

---

## RESULTS

Record the length and width measurements in workbook, calculate difference between ideal and measured length and width, date test film and file with workbook. Test results must be within the rejection limits.

**2.20. TEST 20:**

- 1) MINIMUM FIELD SIZE (OVERTABLE TUBE) AND**
- 2) EXPOSURE BLOCKING FOR INSUFFICIENT FILM COVERAGE**



SPECIFICATION
I. When the BLD is completely closed, the x-ray field must be 5 x 5cm or less at an SID of 100cm. II. Exposures must be blocked if total selected film area cannot be radiated.

**TEST EQUIPMENT**

- Ruler, (metric/inch)
- 14" x 17" loaded cassette

**SETUP**

The equipment completely assembled.

**TEST**

**I.**

1. Set X-ray tube at 100cm above tabletop.
2. Switch on BLD light.
3. Close both BLD shutters as far as possible.
4. Check size of light field, if any, is  $\leq 5 \times 5\text{cm}$  at 100cm.

For Bucky tables only:

**II.**

1. Place loaded 14" x 17" cassette in bucky tray and insert into the bucky.
2. Set tube BLD to minimum SID that still permits an exposure to be made.
3. Make an exposure at 60kV and 5mAs to expose entire film area. Remove cassette.
4. Develop film and measure length and width of radiated area.

**RESULTS**

Record results in workbook. Data must meet the specifications. Discard film.

## 2.21. TEST 21: INTENSITY OF BLD LIGHT FIELD ILLUMINATION (ALL OVERTABLE TUBES)

SPECIFICATION
The minimum illumination requirement for the BLD (collimator) light is 15 foot candles average at 100 cm from source, FDA 21 CFR, 1020.31 (d), (2), (ii).
PHILIPS LIMIT
Average light levels must be equal to or greater than 18 FC (193.6 Lux).



**NOTE**

*To convert foot candles to LUX, multiply foot candles by 10.8.*

---

### TEST EQUIPMENT

- Light meter
- Digital voltmeter

### SETUP

The equipment completely assembled.

### TEST



**NOTE**

*Measurements on the meter are sensitive to reflections from your clothing. Remain still and in the same relative position for each reading.*

---



**CAUTION**

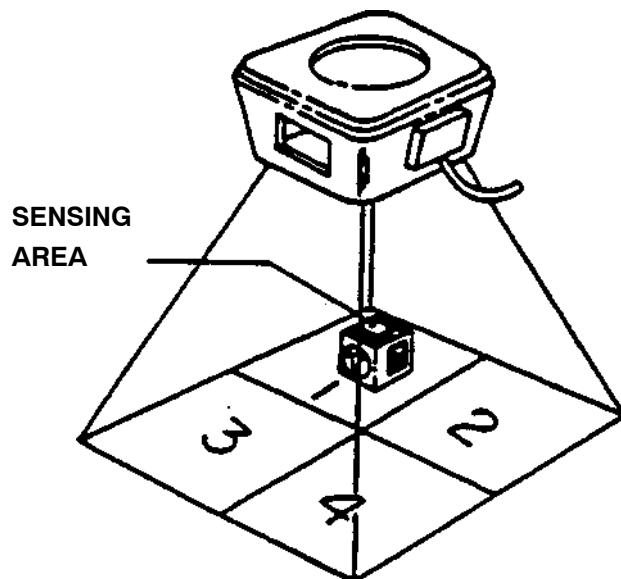
*Never touch glass bulb with bare fingers. If done so by accident clean bulb with alcohol.*

---

1. Measure supply voltage at the lamp and make sure it lies between 11.5 and 12 VAC.
2. Make certain that all surfaces in the light path are clean.

## Compliance Testing

3. Position light meter in the center of one of the four quadrants as shown.
4. Using tape in handlebar, set the distance from the X-ray tube focus to light meter's sensing area to 100cm.



5. Select proper light meter scale.
6. Reduce the ambient light level as much as possible.
7. Measure and record the ambient light level.
8. Switch on the BLD lamp.
9. Measure the total light level.
10. Repeat steps 3, 7, 8 and 9 for each of the four quadrants.

## RESULTS

Record in workbook:

The voltage measured in step 1,  
The ambient light levels measured,  
The total light levels measured.

Calculate and record the average BLD light level as the sum of the four differences between total and ambient light levels divided by four (see workbook).

The calculated average light level must be equal to or greater than 18 FC (193.6 Lux).

## 2.22. TEST 22: TABLETOP MODE EXPOSURE BLOCKING

SPECIFICATION
With the X-ray generator control in tabletop mode and a cassette or film present in any permanently mounted image receptor (such as bucky's, wall cassette holders or undertable spotfilms devices) all exposures must be blocked.

### TEST EQUIPMENT

- Cassette (any size that fits the device), unloaded.

### SET UP

The equipment completely assembled.



#### NOTE

*This test applies to all Bucky cabinets, cassette holders, film changers (Philips and non-Philips) that are an integral part of a fixed table or stand, as well as undertable spotfilm devices.*

---

### TEST

1. At the generator control select the "tabletop mode" auxiliary station (or any station permitting manually collimated exposures e.g. as used with stretcher patients, mobile film changers etc.)
2. Place a cassette in the exposure position of a Bucky cabinet or cassette holder, for Bucky Diagnost move a film in the exposure position.
3. Select exposure parameters well within the tube rating.
4. Press the exposure button. Exposure must be blocked.
5. Repeat the above test for all available permanently mounted image receptors.

### RESULTS

Compliance with the above mentioned specification must be confirmed in the workbook for all applicable image receptors.

## 2.23. TEST 23: ALIGNMENT OF BLD LIGHT FIELD AND X-RAY FIELD (RADIOGRAPHIC)



SPECIFICATION	REJECTION LIMIT
The total misalignment of the edges of the BLD light field with the respective edges of the X-ray field along either the width or the length of the light field shall not exceed 2% of the SID	Max. misalignment: ≤ 1.8% SID

### TEST EQUIPMENT

- Four copper strips
- Cassette 10" x 12" or 24cm x 30cm, loaded
- Cassette 8" x 10" or 18cm x 24cm, unloaded
- Metal washer
- Ruler, inch / metric



*This test is to determine that the X-ray field size and location is identical to the BLD light field for large and small focus.*

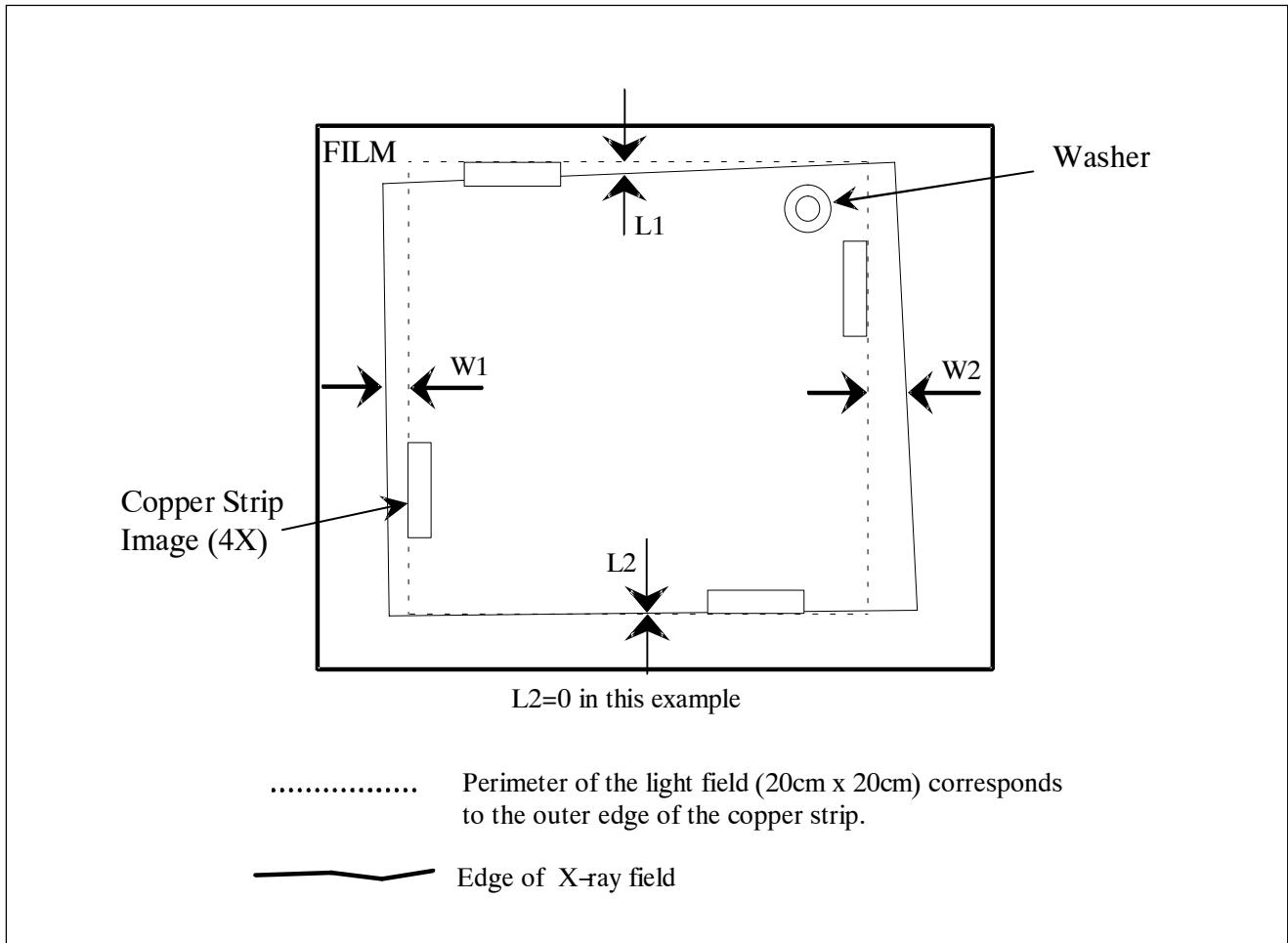
---

### SETUP

1. Place loaded 10" x 12" (24cm x 30cm) cassette on tabletop and center overtube directly above it at SID of 40" (100 cm).
2. Place empty 8" x 10" (18cm x 24cm) cassette in Bucky to enable exposure.

### TEST

1. Turn on BLD light.
2. Define light field perimeter by placing outer edges of copperstrips at the four light field sides, see figure below.



3. Place washer in one quadrant of film at anode end to identify positioning after development.
4. Select large focus and overtube tube at control desk and expose at 60kV, 5mAs.
5. Develop film.
6. Measure distances L1, L2, W1, and W2 between outside edges of metal markers and edges of X-ray field as shown.
7. Repeat test 13 for small focus.

## RESULTS

Record all measurements in workbook; number and date films and file with workbook. Measurements must comply with rejection limit.

**2.24. TEST 24: X-RAY FIELD CENTER ALIGNMENT (OVERTABLE TUBE)**

SPECIFICATION	REJECTION LIMIT
The displacement between the X-ray film center and the X-ray field center must be <del>&gt;2%</del> SID	Max. displacement: ≤ 1.8% SID



*This test must be performed for all table/Bucky stations as well as Bucky wallstands, cassette stands, etc.*

---

**TEST EQUIPMENT**

- Cassette (10" x 12") or (24 x 30 cm), loaded
- Ruler, metric/inch
- Tape measure
- Metal washer

**SETUP**

Equipment completely assembled.

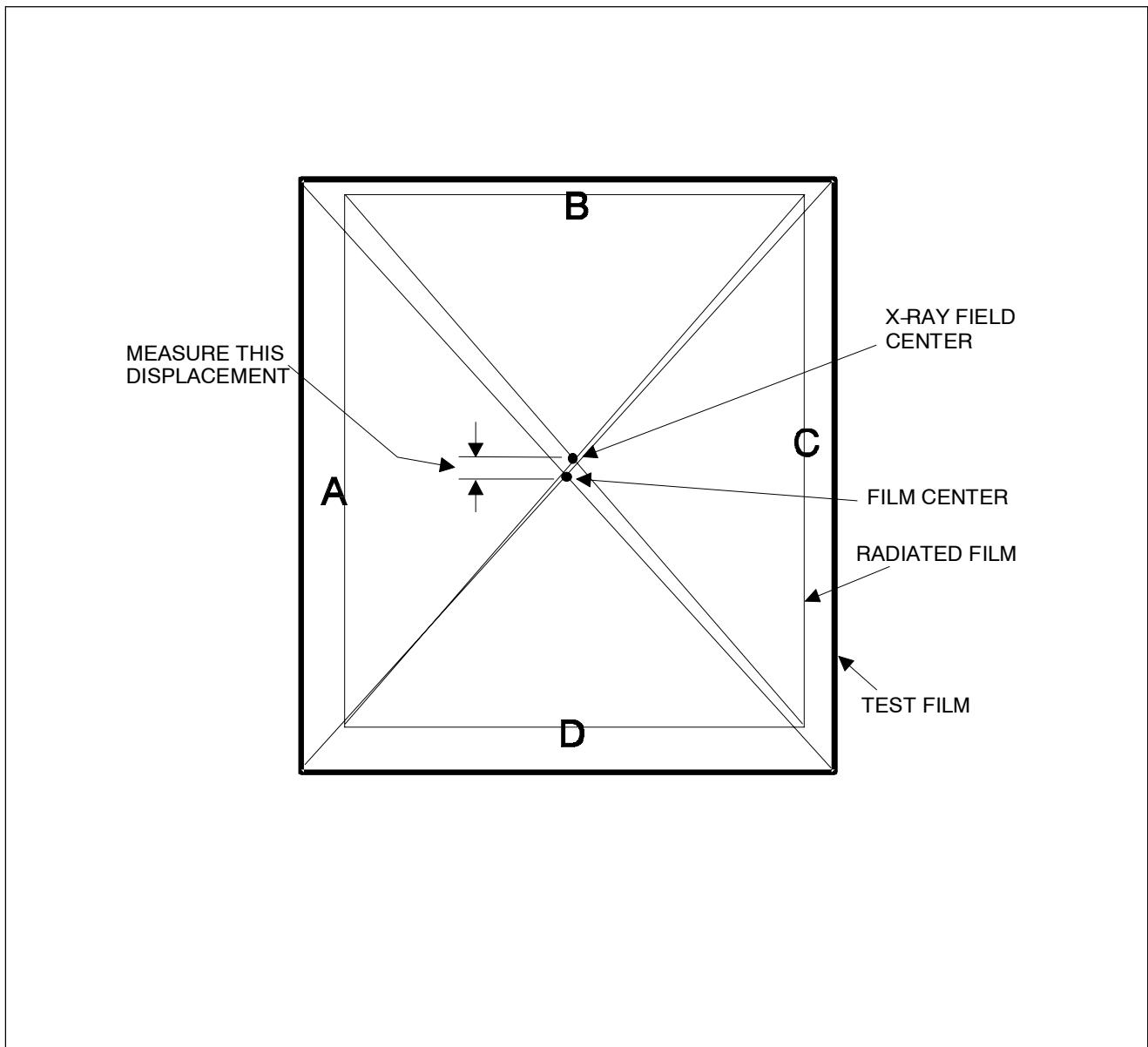
**TEST**

1. On control desk, select tube and image receptor station.
2. Center tube to image receptor by using available centering aids (centering stops on ceiling rails, centering light in tube control handle bar etc.). Set tube at max. SID: 40" (100cm) for table Bucky, up to 72" (180cm) for wall Bucky.
3. Tape metal washer in one quadrant of cassette at anode end for film orientation.
4. Place loaded 10" x 12" (24 x 30cm) cassette in bucky tray and ensure it is properly centered before inserting tray into Bucky.
5. Manually set BLD to slightly smaller (approx. 9" x 11") size than the size set by PLB so radiated area will be within the limits of the X-ray film.
6. Make exposure at 60kV and 5mAs.
7. Develop film.
8. On developed film, locate two points on each of the four sides of the exposed field as shown in figure below.
9. Draw straight lines through two points on each side. Extend lines till they intersect. The resulting rectangle will be a close approximation of the X-ray field.

10. Draw diagonals across this field. Crossing point of diagonals is X-ray field center. Also draw diagonals across X-ray film. Crossing point is X-ray film center.
11. Measure distance between both centers. This is the displacement (misalignment) of the X-ray field in relation to image receptor.

## RESULTS

Record displacement in workbook, write test number and date on film and file with workbook. Test result must be within rejection limit.



## 2.25. TEST 25: X-RAY FIELD LIMITATION AND PBL OPERATING RANGE (OVERTABLE TUBE - RADIOGRAPHIC)



SPECIFICATION	REJECTION LIMIT
<ol style="list-style-type: none"> <li>The total misalignment of the edges of the X-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the X-ray field in the plane of the image receptor shall not exceed 3% of SID</li> <li>The sum, without regard to sign of the above length and width misalignments, shall not exceed 4% of SID</li> <li>FOR BLD'S WITH PBL AND MANUFACTURED <u>BEFORE</u> DECEMBER 1, 1983: Positive beam limiting must be operational when X-ray beam is within <math>\pm 10\%</math> of vertical or horizontal and SID is 65 cm to 200 cm inclusive. X-rays must be inhibited outside the SID ranges.</li> <li>FOR BLD'S WITH PBL AND MANUFACTURED <u>AFTER</u> NOVEMBER 30, 1983 Positive beam limiting must be operational when:           <ol style="list-style-type: none"> <li>X-ray beam is within <math>\pm 3\%</math> of vertical and SID is 90 cm to 130 cm inclusive.</li> <li>X-ray beam is within <math>\pm 3\%</math> of horizontal and SID is 90 cm to 205 cm inclusive.</li> </ol> </li> </ol>	<p>Reject deviations:  <math>\geq 2.7\% \text{ SID}^*</math>  <math>\geq 3.6\% \text{ SID}^*</math></p> <p>For Philips equipment PBL is operational:  from 65 – 130 cm  from 65 – 205 cm</p>

\*Includes allowance for measuring errors.



*This test must be performed for all overtable tube/Bucky stations as well as Bucky wallstands, cassette stands, etc. Stands that are used at two different SID's must be tested at both distances.*

**TEST EQUIPMENT**

- Cassette unloaded, 8" x 10" (20 x 24cm) test A only
- Cassette loaded, 8" x 10" (20 x 24cm) test A/A1
- Cassette unloaded, 14" x 17" (35 x 43cm) test A only
- Cassette loaded, 14" x 17" (35 x 43cm) test A/A1
- Ruler, metric/inch
- 10' measuring tape

**SETUP**

The equipment completely assembled.

**TEST****A. FIELD LIMITATION TEST**

*If possible use simplified test A1.*

---

1. Select tube and relevant receptor station.
2. Center X-ray tube to image receptor and adjust to maximum SID that allows PBL or standard SID if max. SID with PBL is not applicable for the situation.
3. Insert empty 8" x 10" (18 x 24 cm) cassette in Bucky tray or cassette holder.
4. Locate a loaded 8" x 10" (18 x 24 cm) cassette halfway between tube focus and filmplane of image receptor (Bucky) and center cassette in X-ray beam with BLD light.  
Use non opaque material to support this cassette.
5. Make exposure at 60 kV and approximately 5mAs.
6. Develop film.
7. Repeat steps 3 thru 6 with loaded and unladen 14" x 17" (35 x 43 cm) cassettes.
8. Measure length "L2" and width "W2" of X-ray fields on both developed films and record in workbook.

Conditions:

$(L2 \times 2) - L1$	$\leq 0.027$ SID
$(W2 \times 2) - W1$	$\leq 0.027$ SID
SUM OF DIFFERENCES	
$\leq 0.036$ SID	

**A.1 OPTIONAL FIELD LIMITATION TEST**

1. Select tube and relevant receptor station.
2. Center X-ray tube to image receptor and adjust to maximum SID that allows PBL, or standard SID if maximum SID with PBL is not applicable for the situation.
3. Rotate BLD 45°.
4. Insert loaded 8" x 10" (18 x 24 cm) cassette in bucky tray of cassette holder.
5. Make exposure at approx. 60kV and 5mAs.

## Compliance Testing

6. Remove cassette and put in radiation safe place.
7. Repeat steps 4 thru 6 with loaded 14" x 17" (35 x 43 cm) cassette.
8. Develop both films.
9. Measure length "L2" and width "W2" of X-ray fields on both films and record in workbook.

### B/C PBL OPERATING RANGE TEST

1. Check date of manufacture of the BLD and make sure that PBL is operational within the limits as mentioned in the "SPECIFICATIONS" under item 3 or 4, whichever is applicable.

### D. FOR SYSTEMS WITH PBL OVERRIDE KEY SWITCH VERIFY THAT:

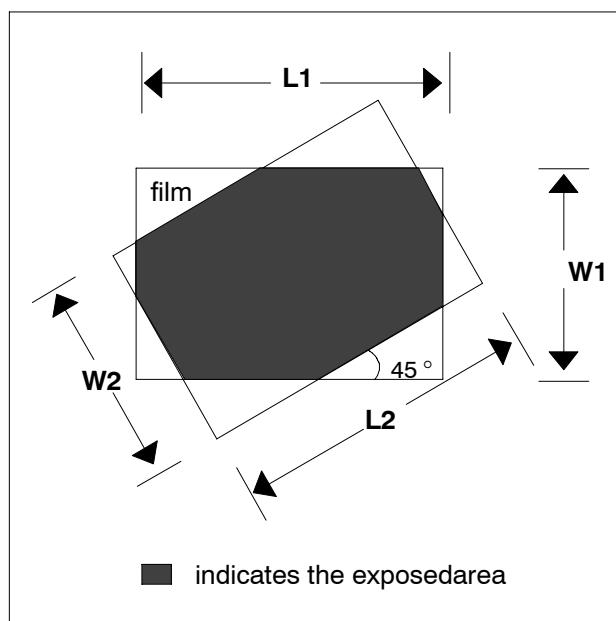
1. Key cannot be removed when PBL is overridden.
2. Key is clearly labeled: "FOR X-RAY FIELD LIMITATION SYSTEM FAILURE".

## RESULTS

Complete calculations as indicated in workbook.

Record and verify the outcome of steps B/C-1, and D1, 2 in workbook for as far as applicable to the particular equipment configuration.

Number and date test films and file together with the workbook. Test results must be within the rejection limits.



## 2.26. TEST 26: FIELD LIMITATION AND CENTERING FOR SYSTEMS WITH ONE IMAGE RECEPTOR SIZE AND FIXED SID (E.G. PULMO DIAGNOST FILM CHANGER)



SPECIFICATION	REJECTION LIMIT
<ol style="list-style-type: none"> <li>1. The X-ray field at the plane of the image receptor shall have dimensions no greater than those of the image receptor.</li> <li>2. The misalignment between the center of the X-ray field and the center of the image receptor shall be within 2% of the SID</li> </ol>	Reject deviations: $\geq 1.9\% \text{ SID}$

### TEST EQUIPMENT

- Ruler metric/inch

### SETUP

The BLD should have been installed and adjusted so that when at its maximum opening, the BLD blades will be just visible on the film.

### TEST

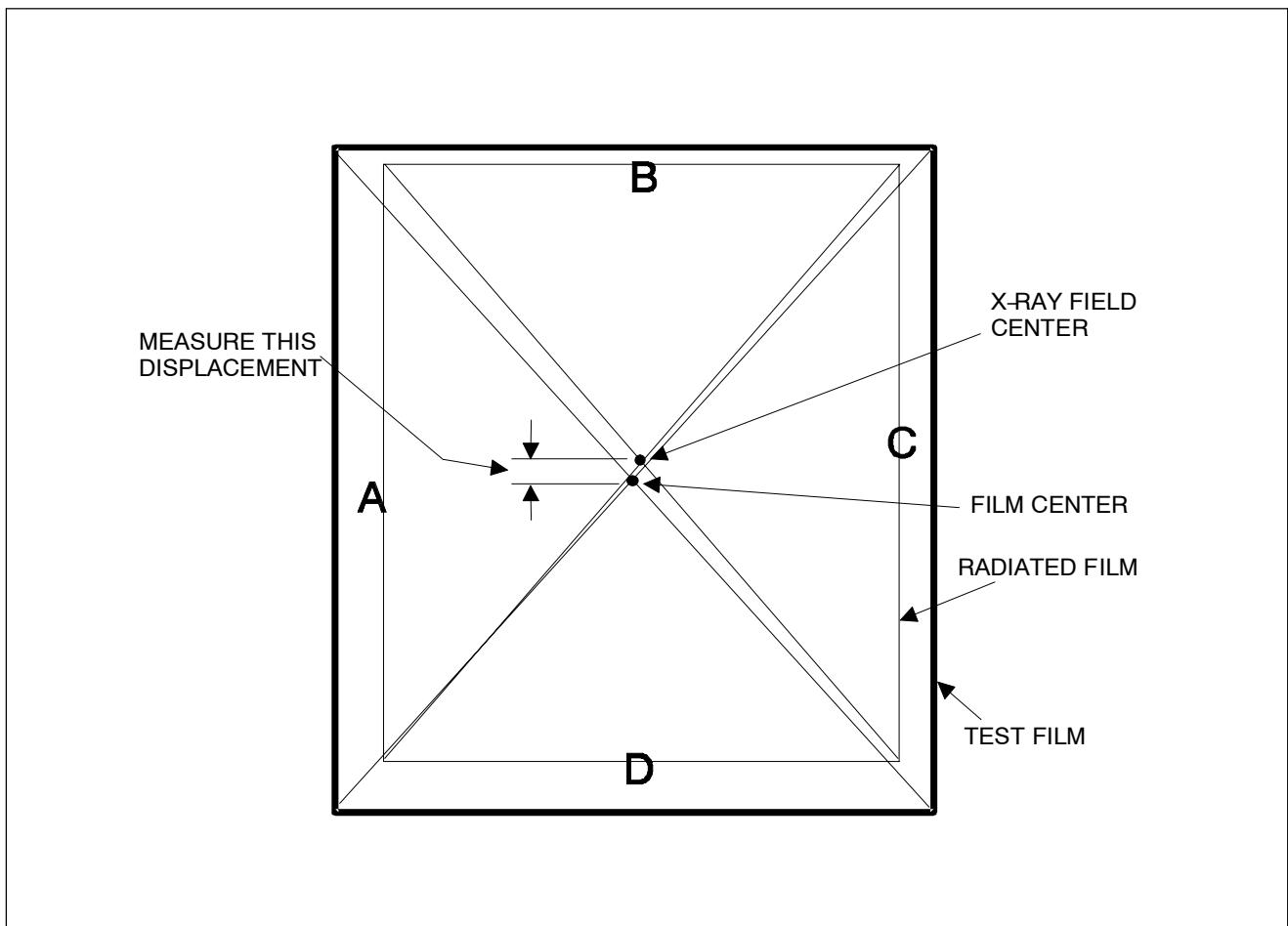
1. Load image receptor with film.
2. Make exposure at 60kV, 2mAs.
3. Develop film.
4. Check that field edges are just visible on the X-ray film and run parallel to the film edges. If so, proceed with 5.
5. Draw diagonals across the radiated field to find the center. Also draw diagonals across X-ray film to find its center.
6. Measure distance from X-ray field center to film center. (See figure below.)

## RESULTS

Record above distance (misalignment) in workbook. Write test number and date on film and file with workbook. Misalignment must be within rejection limit.



Radiated field sides A, B, C, and D should be parallel to and just visible within the edges of the X-ray film.



## 2.27. TEST 27: FLUOROSCOPIC X-RAY FIELD LIMITATION (OVERTABLE TUBE)



SPECIFICATION	REJECTION LIMIT
1. Neither the length nor the width of the X-ray field shall exceed that of the visible area of the image receptor by more than 3% of the SID	Max. deviations: < 2.7 % SID*
2. The sum of the excess length and excess width shall not exceed 4% of the SID (For rejection limits see workbook).	< 3.6 % SID*

\*Includes allowance for measuring error.

### TEST EQUIPMENT

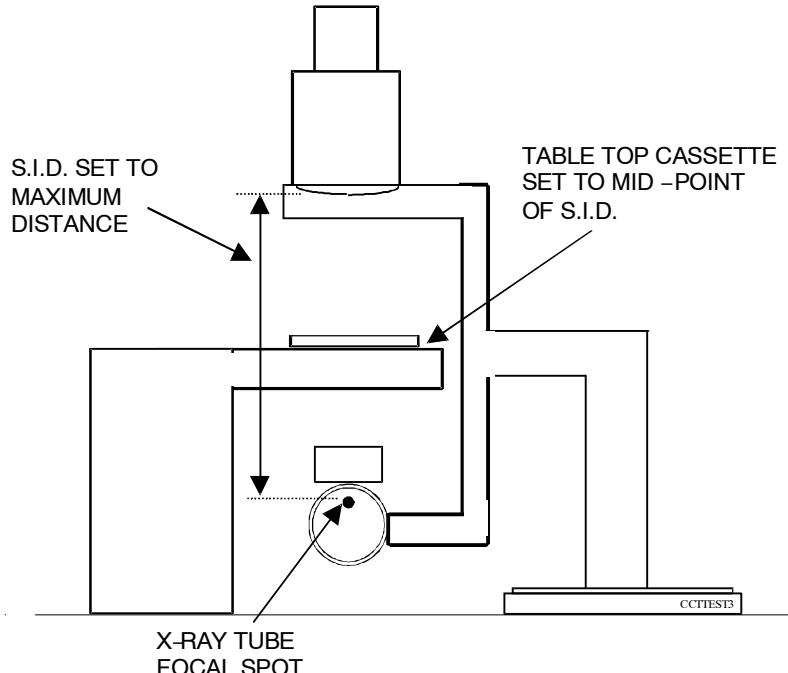
- Four copper strips
- Cassette 10" x 12" (24 – 30 cm) loaded
- Cassette tunnel for 10" x 12" cassette
- Ruler, metric/inch
- Measuring tape

### SETUP

The equipment completely assembled.

### TEST

1. For Bucky tables with built-in image intensifier set SID at 40" (100 cm) to the II input face.  
For remote controlled tables and other overtable tube configurations test maximum and minimum SID positions if available.
2. Utilize BLD light to position cassette tunnel on tabletop so that the center of the 10" x 12" film will coincide with the center of the BLD light field. See figure XXXX. Take care that  $D \geq 1/2$  SID



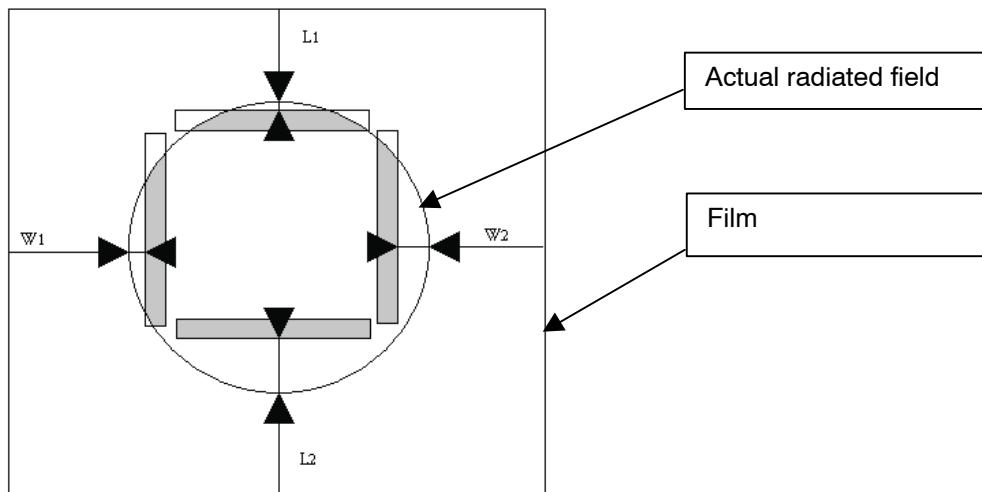
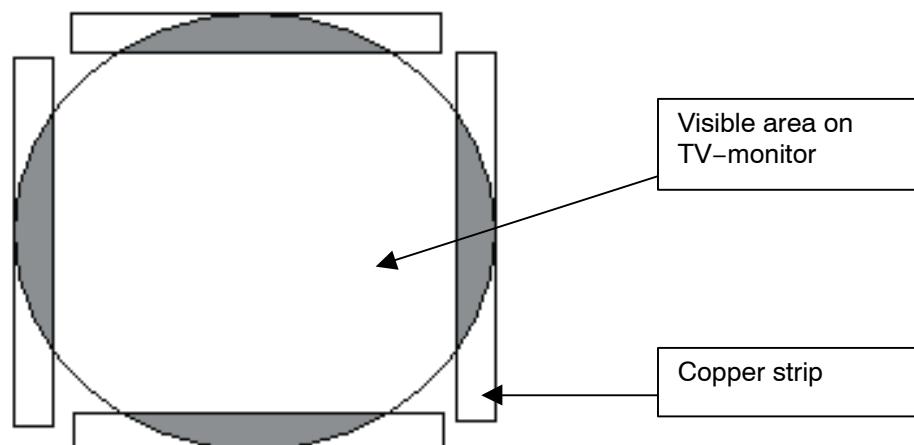
### WARNING

*Take all necessary radiation safety precautions when performing test.*

3. With no film cassette in tunnel switch on fluoroscopy. Position four copper strips on top of tunnel so that their outside edges are at the border of the visible area as viewed on TV monitor. See figure XXXX.  
When in position tape strips down to tunnel top and re-check their position under fluoroscopy.
4. Switch off fluoroscopy and insert loaded 10" x 12" cassette into tunnel.
5. Measure distance D from test film in tunnel to focal spot and record in workbook. Calculate rejection limits for test film and record in workbook table I.
6. Set manual fluoroscopy controls at 100kV and 3mA and switch on fluoroscopy for approximately 5 seconds.
7. Switch off fluoroscopy, remove film and develop.
8. Repeat procedure for all II modes available (9/5", 14/10"6" etc.) and at maximum and minimum SID if available.
9. From the developed films select the one showing the largest field extensions  $W_1 + W_2$  and  $L_1 + L_2$ . These largest extensions and the calculated  $W_t + L_t$  must meet the rejection limits. If not re-adjust the BLD and repeat the test.

## RESULTS

Record field extensions  $L_1 + L_2$ ,  $W_1 + W_2$  and  $L_t + W_t$  in workbook. All extensions must be within the rejection limits.



## 2.28. TEST 28: ALIGNMENT OF X-RAY FIELD CENTER TO THE CENTER OF SELECTED PORTIONS OF THE IMAGE RECEPTOR (OVERTABLE TUBE)



For certain spotfilm devices (serial changers) simplified testing, replacing the centering and field limitation tests 28/29 or 34/35 with one single test, may be available. These tests will be numbered 30A, 30B etc. Before proceeding check test 30-X whether such simplified testing is applicable, e.g.: Test 30-A for Diagnost.

SPECIFICATION	REJECTION LIMIT
The center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2% of the SID	Max. deviations: ≤ 1.9 % SID*

\*Includes allowance for measuring errors.

### TEST EQUIPMENT

- Ruler, metric/inch
- Cassettes, loaded for all sizes as required for SFD

### SETUP

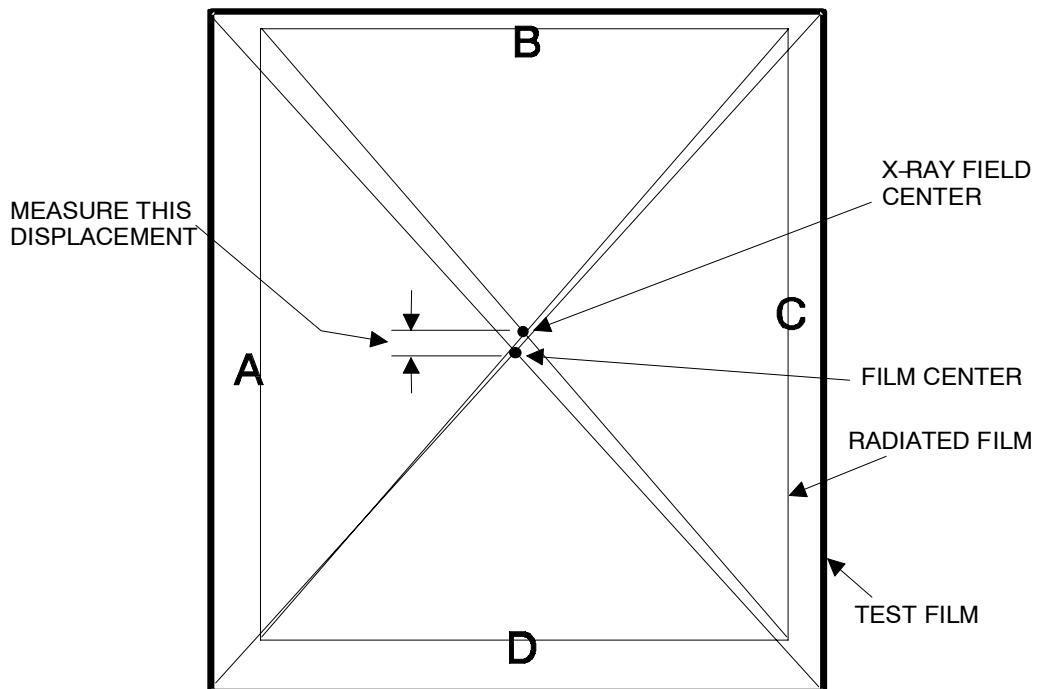
Equipment completely assembled (equipment with selectable SID use 40" (100 cm)).

### TEST

1. Insert loaded, minimum size, cassette into spot film device, short side in (long side up).
2. Select one on one format.
3. Turn on BLD light and slightly reduce the automatically set light field to ensure that all four blades of the BLD will be visible on the film.
4. Expose film at 60kV and approximately 5mAs.
5. Remove cassette, develop film.
6. Locate the center of the film or subdivision by drawing two diagonals from corner to corner. See figures.
7. Mark two points on each edge of the radiated area.
8. Draw four lines through each set of two points so that they intersect. The resultant rectangle represents the radiated area of the film.
9. Determine the center of the radiated area by drawing two diagonals connecting the corners of the radiated area (see figure).
10. Measure the distance "d" between the two centers.
11. Repeat the above procedure for all selected portions of all available cassette sizes and film formats.

**RESULTS**

Confirm in workbook Test 28 that all distances "d" measured are  $\leq$  the calculated maximum deviation. Number and date all test films taken. File all test films with the workbook as proof of compliance.



**2.29. TEST 29: X-RAY FIELD LIMITATION FOR SFD'S (OVERTABLE TUBE)**

For certain spotfilm devices (serial changers) simplified testing, replacing the centering and field limitation tests 28/29 or 34/35 with one single test, may be available. These tests will be numbered 30A, 30B etc. Before proceeding check test 30-X whether such simplified testing is applicable, e.g.: Test 30-A for Diagnost-92.

---

SPECIFICATION	REJECTION LIMIT
1. The total misalignment of the edges of the X-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the X-ray field in the plane of the image receptor shall not exceed 3% of SID	Allowable differences: ± 2.7 % SID*
2. The sum without regard to sign of the above length and width misalignments shall not exceed 4% of SID	± 3.6 % SID*

\*Includes allowance for measuring errors.

**TEST EQUIPMENT**

- Ruler metric/inch
- Measuring tape
- Cassettes: loaded 10" x 12" (24 x 30 cm) for tabletop plus a set of unloaded cassettes as required for the particular spot film device.
- Spacer material

**SETUP**

Equipment completely assembled with SID set at 40" (100 cm) for units with selectable SID

## TEST

1. Place a loaded 10" x 12" cassette on table with spacer so it will be at a distance from the focal spot equal to or greater than 1/2 SID
2. Switch on BLD and center tabletop cassette in light field.
3. Measure distance "A" focal spot to film in tabletop cassette and record in workbook. Record actual equipment SID in workbook.
4. Place empty, smallest format cassette in SFD and select one on one format.
5. Make exposure at 60kV, 5mAs and develop film.
6. Measure length and width of the radiated area on 10" x 12" developed film and record measurements in workbook.
7. Repeat steps 1 thru 6 and make one additional exposure of every kind of film subdivision available with cassette presently in SFD. For example, if this particular cassette offers 1:1, 2:1 and 4:1 formats, take one exposure at 4:1. Also if your checked a left hand side exposure on the 2:1 than go to a right hand side exposure on the 4:1 and do the same for upper and lower half exposures if you have that choice available in the program.
8. Repeat steps 1 thru 7 for all larger cassettes used with this SFD.

## RESULTS

Complete calculations as indicated in workbook, results must be within rejection limits stated. Number and date test films and file with workbook.

## 2.30. TEST 30

### 2.30.1. TEST 30A: X-RAY FIELD CENTERING AND LIMITATION FOR DIAGNOST/SCOPOMATIC 92 SPOTFILE DEVICE



SPECIFICATION	REJECTION LIMIT
1. The center of the X-ray field in the film shall be aligned with the center of the selected portion of the film to within 2% of the SID.	Max. deviations: < 1.9 % SID
2. The total misalignment of the edges of the X-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the X-ray field in the plane of the image receptor shall not exceed 3% of the SID.  The sum without regard to sign of the above length and width misalignments shall not exceed 4% of the SID.	< 2.7 % SID  < 3.6 % SID

Completion of this test satisfies both specifications 1 and 2 in one single test.

Pre-conditions for successful completion of this test are:

1. The completion of all calibration and adjustment instructions for the SFD and PBL as per relevant installation manuals.
2. The exact center of the spotfilm device has been established with the special tool supplied with the table and this center has been transferred to a lead cross fixed to the input of the Image Intensifier. See installation manuals for instructions.

#### TEST EQUIPMENT

- Ruler metric/inch
- Cassettes loaded as required per table 1
- Complete set of lead numbers to identify test films

#### SETUP

Equipment with SFD covers and tabletop in place. Table in horizontal position.

**TEST**

1. Fix a lead wire cross on the tabletop and align this cross with the lead cross already on the image intensifier input by means of the longitudinal and transverse tabletop movements during fluoroscopy.  
(Check the alignment also with the table upright, if necessary re-align.)
2. The following instructions refer to the exposure program shown in table 1.

**TABLE 1**

SID = 100 CM TABLE HORIZONTAL			
EXPOSURE NUMBER	CASSETTE FORMAT CM VERT X HOR	SELECTED PROGRAM	FOCUS
1	24 x 30	4:1	S
2			L
SID = 150 CM TABLE HORIZONTAL			
3	24 x 30	1:1	S
4			L
5	25 x 35	3:1	S
6			L
SID = 100 CM TABLE VERTICAL			
7			S
8			L
SID = 150 CM TABLE VERTICAL			
9			S
10			L
11			S
12			L

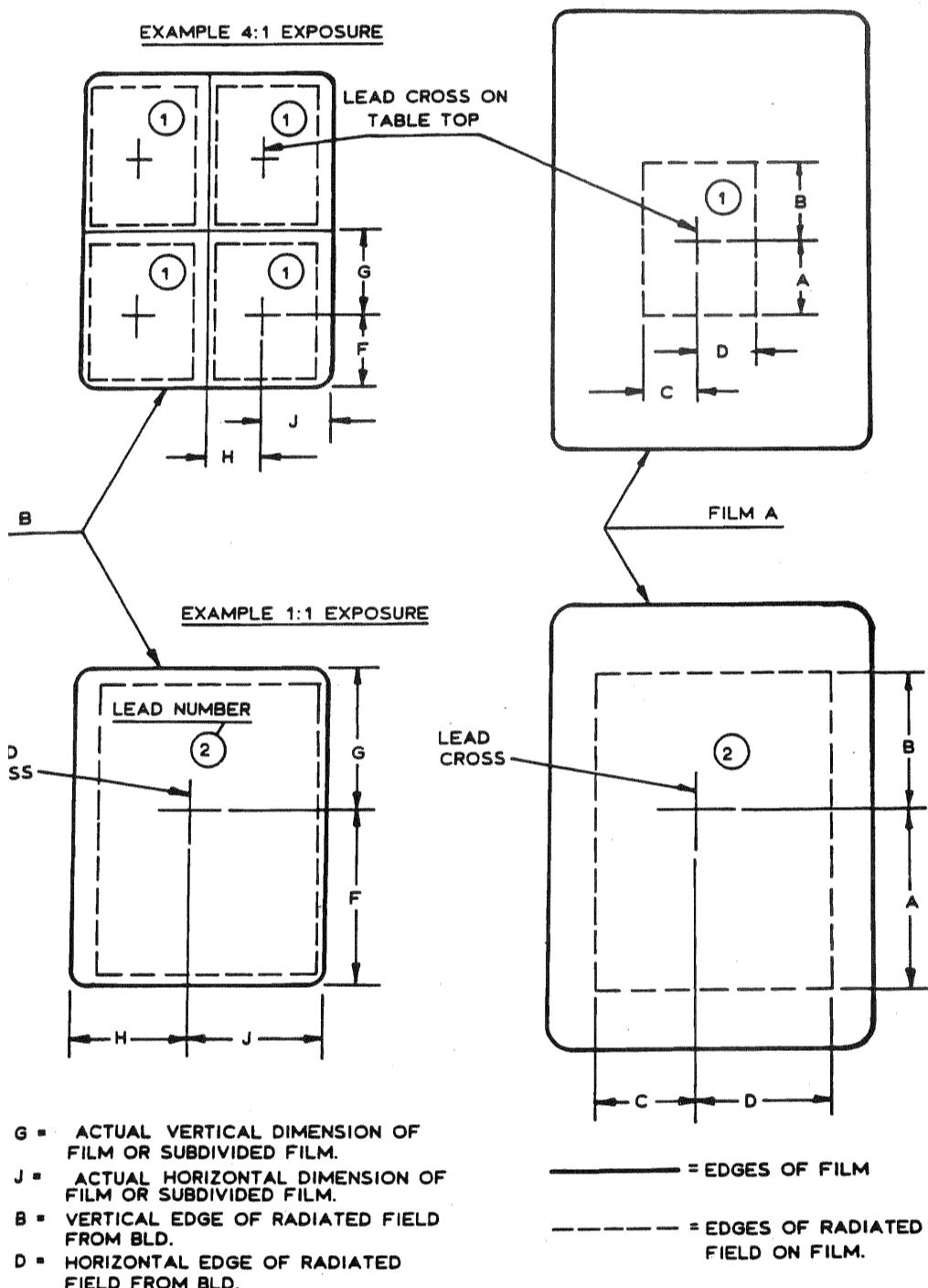
3. Mark each exposure 1 thru 12 with a lead number on the table so its image appears in the top right quadrant of the X-ray field, check with BLD light.
4. Insert 24 x 30 cm cassette into SFD and select program and focal spot as per Table 1 exposure no. 1.
5. After PBL has stabilized to the selected program set BLD to manual with the special H.H.S. (PBL override) key.
6. Complete all exposures for the selected program on the inserted cassette at 50 kV, 150mA, Amplimat. (Film B)
7. Remove cassette, store in radiation safe place and insert a larger format loaded cassette (e.g. 35 x 35 cm). Leave the same lead number in place. Expose this film which now will show the X-ray field as it comes from the BLD. (Film A)
8. Return to PBL by removing H.H.S. key.
9. Develop both films and measure distances A, B, C and D on film A and distances F, G, H, and J on film B. (See figures below). Fill out EXPOSURE – 1 Table in workbook and complete the field limitation error calculations in percentages of SID.
10. Repeat steps 3 thru 9 for exposures 2, 3, 4, and 6.
11. From the above exposures select the film with the largest percentages errors. If these are in compliance proceed with point 12, if not, re-adjust the SFD/PBL settings and repeat steps 1 thru 11 until compliance is obtained.
12. Use the cassette size and program of the film selected under 11 for all exposures 7 thru 12 in a identical way as mentioned under points 3 thru 9 for the different SID's and table positions as shown in table 1.

## Compliance Testing

13. Fill out the rest of the workbook tables and complete calculations for exposures 7 thru 12.

### RESULTS

Complete Table 1 in workbook. All horizontal and vertical error percentages must be < 2.7% and their sums < 3.6% of SID.



## 2.31. TEST 31: MINIMUM FIELD SIZE (UNDERTABLE TUBE)



### SPECIFICATION

When the BLD is completely closed, the field size must be less than 5 cm x 5 cm at maximum SID

### TEST EQUIPMENT

- Ruler, metric / inch

### SETUP

The equipment set at maximum SID

### TEST

1. Select undertable tube.
2. Select fluoroscopy and completely close BLD shutters.
3. Measure radiated field, if any, on TV monitor.
4. Correct measurements for any magnification factor (II input diameter to image diameter on monitor).

### RESULTS

Corrected length and width of radiated area must be < 5 x 5 cm. Check off workbook.

## 2.32. TEST 32:

**NOT APPLICABLE**

## 2.33. TEST 33: FLUOROSCOPIC X-RAY FIELD LIMITATION (UNDERTABLE TUBE)



### SPECIFICATION

Neither the length nor the width of the X-ray field shall exceed that of the visible area of the image receptor by more than 3% of the SID Also, the sum of the excess length and excess width shall not exceed 4% of the SID (See workbook for rejection limits.)

### TEST EQUIPMENT

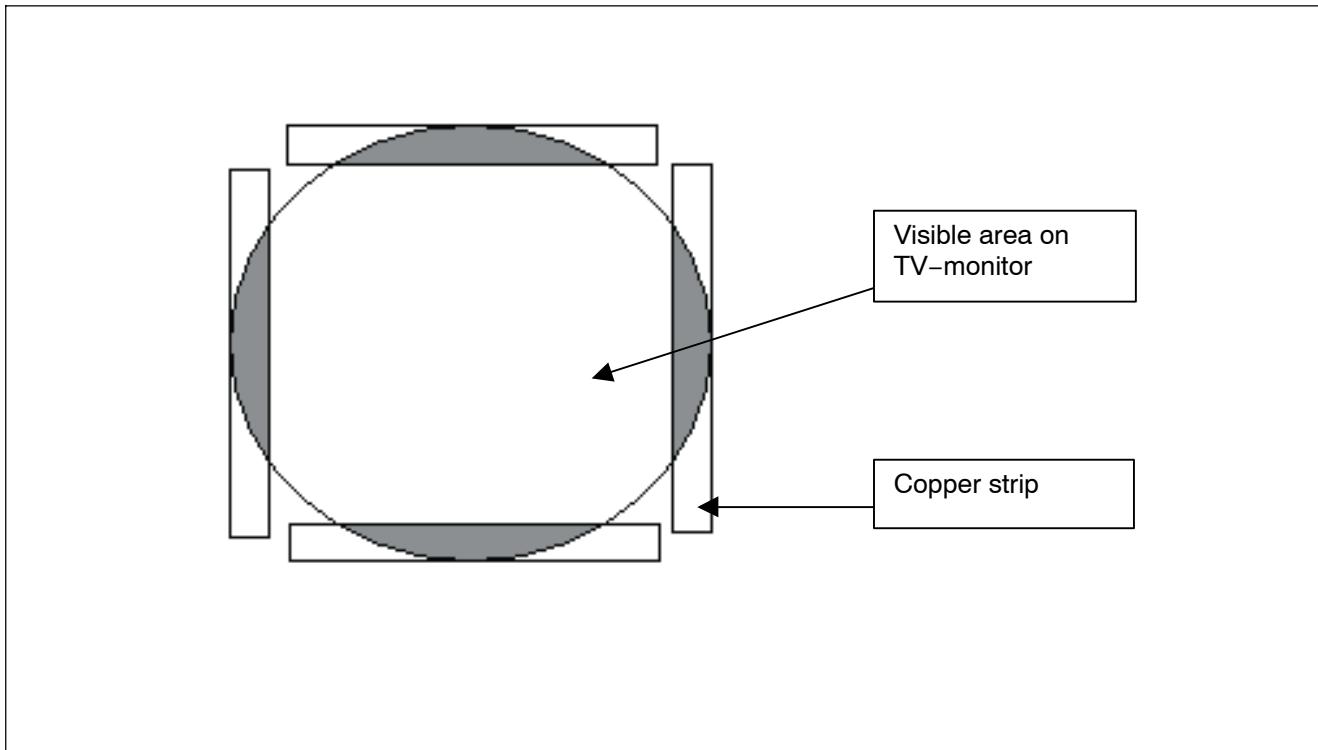
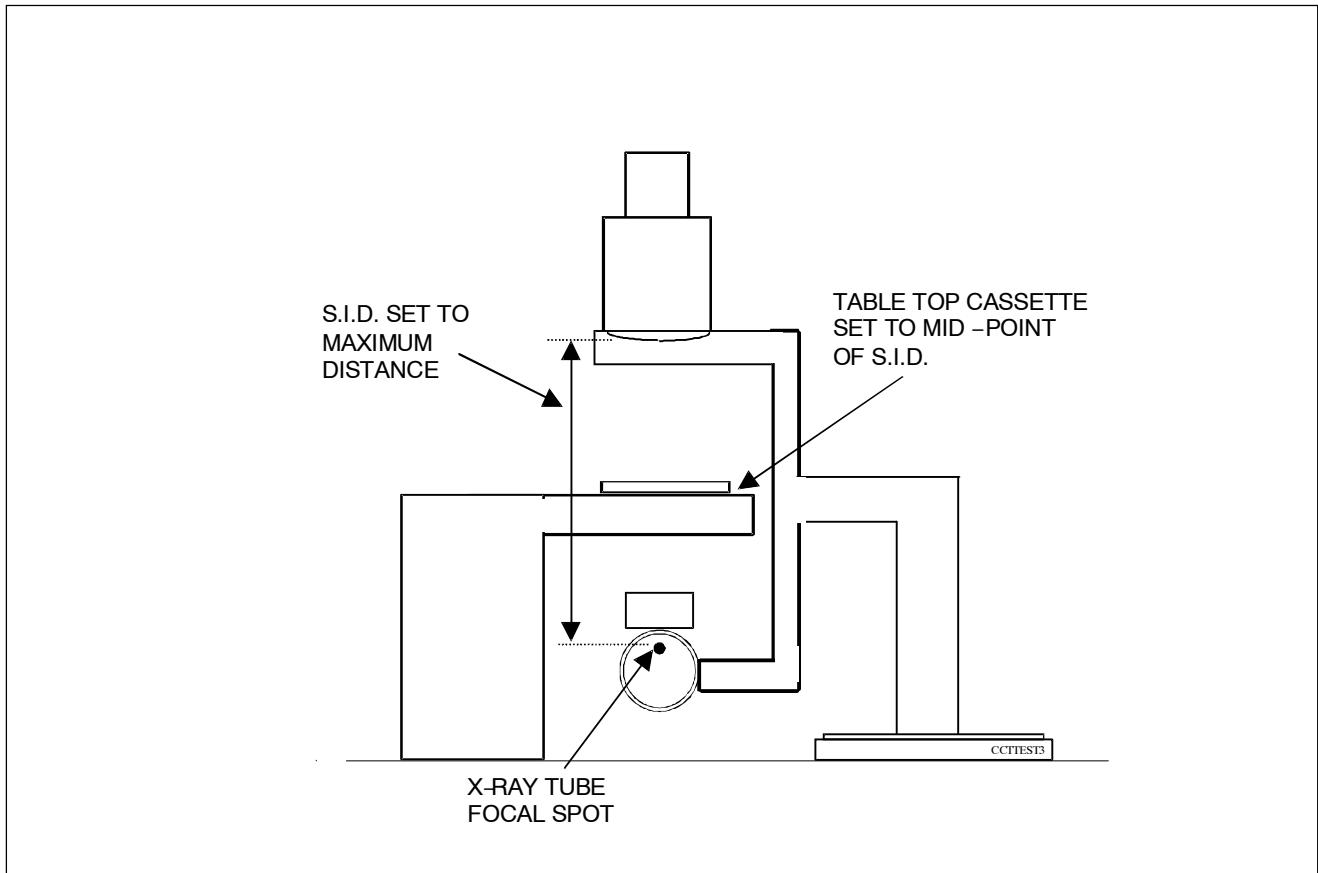
- Four copper strips
- Cassette, 9 1/2" x 9 1/2" or (24 x 30 cm), loaded
- Ruler, metric/inch

### SETUP

The equipment completely assembled.

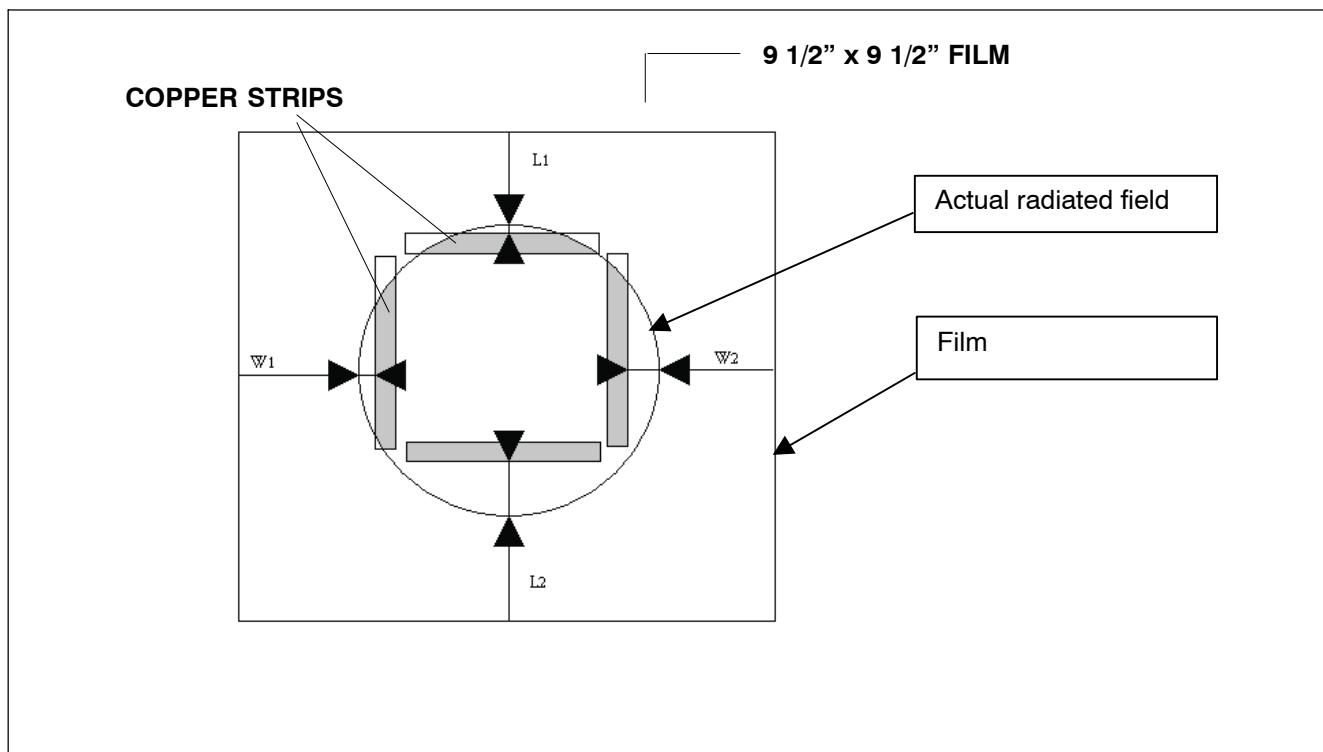
### TEST

1. Center a 9 1/2" x 9 1/2" (24 x 30 cm) cassette on horizontal tabletop and determine distance "A" from focal spot of undertable tube to film in 9 1/2" x 9 1/2" cassette (see sketch next page).
2. With R/F tables adjust spot film device so that distance "B" from input phosphor of image intensifier to film in tabletop cassette equals distance "A" and lock SFD in this position. With C- or U-arm assemblies use tabletop height adjustment to make distance A = B with II at max. SID. Measure exact SID and record in workbook.
3. Remove 9 1/2" x 9 1/2" cassette from tabletop and store in radiation safe place.
4. Switch on fluoroscopy and place 4 copper strips on the tabletop. While observing the TV monitor image position the copper strips at the edge of the visible area as shown below and tape the strips to the table.
5. Switch off fluoroscopy and center loaded 9 1/2" x 9 1/2" cassette face down over the copper strips on the tabletop.
6. Set generator at 100 kV and 2 mA and fluoroscope for 5 seconds.
7. Switch off fluoroscopy, remove cassette and develop film.
8. Repeat steps 4 thru 7 for all II modes (9/5", 14/10/6" etc.) available.
9. From the developed films select the one showing the largest field extensions  $W_1 + W_2$  and  $L_1 + L_2$ . These largest extensions and the calculated  $W_t + L_t$  must meet the rejection limits. If not re-adjust the BLD and repeat the test.



## RESULTS

Record field extensions  $L_1 + L_2$ ,  $W_1 + W_2$  and  $L_t + W_t$  in workbook. All extensions must be within the rejection limits.



## 2.34. TEST 34: ALIGNMENT OF X-RAY FIELD CENTER TO SELECTED PORTIONS OF IMAGE RECEPTOR (UNDERTABLE TUBE)



### NOTE

For certain spotfilm devices (serial changers) simplified testing, replacing the centering and field limitation tests 28/29 or 34/35 with one single test, may be available. Before proceeding check test 30-X whether such simplified testing is applicable, e.g.: Test 30-A for Diagnost-92.

SPECIFICATION	REJECTION LIMIT
The center of the X-ray field in the plane of the film must be aligned to the center of the film to within 2% of SID	Max. deviation: ≤ 1.9% SID*

\*Includes allowance for measuring errors.

### TEST EQUIPMENT

- Ruler, metric/inch
- Cassettes, loaded, for all sizes as required for SFD

### SETUP

Equipment completely assembled with SFD set at maximum SID Calculate allowable maximum deviation in mm:  
Max. S.I.D \_\_\_\_\_ X 0.019 = \_\_\_\_\_

### TEST

1. Insert loaded, minimum size, cassette in spot film device.
2. Select one on one format.
3. Manually reduce the automatically (PBL) set exposed area to ensure that all four blades of the BLD will be visible on the film.
4. Expose at 60 kV and approximately 5mAs.
5. Remove cassette, and develop film.
6. Locate center of film by drawing 2 diagonals connecting the film corners or film section in case of subdivided films.
7. Mark 2 points on each edge of the radiated field and draw lines so they intersect to form a rectangle (see figures, test 28).
8. Find center of the radiated area by drawing two diagonals connecting its corners.
9. Measure the distance "d" between the two centers.
10. Repeat steps 1 thru 9 for all selected portions of all available cassette sizes and film formats.



*For OT spotfilm devices installed after Sept. 24, 1986 a label must be present on the SFD or II housing showing the entire inch or metric cassette program to be used with the SFD exclusively.*

---

## RESULTS

Confirm in workbook test 28/34 block 1 that all distances "D" measured are  $\leq$  the calculated maximum deviation. Confirm in block 2 that the correct labelling is affixed. Number and date all testfilms taken. File all testfilms with the workbook as proof of compliance.

## 2.35. TEST 35: X-RAY FIELD LIMITATION FOR SFD'S (UNDERTABLE TUBE)



*For certain spotfilm devices (serial changers) simplified testing, replacing the centering and field limitation tests 28/29 or 34/35 with one single test, may be available. Before proceeding check test 30-X whether such simplified testing is applicable, e.g.: Test 30-A for Diagnost-92*

---

SPECIFICATION	REJECTION LIMIT
1. The total misalignment of the edges of the X-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the X-ray field in the plane of the image receptor shall not exceed 3% of the SID.	$\geq 2.7\% \text{ SID}^*$
2. The sum without regard to sign of the above length and width misalignments shall not exceed 4% of the SID.	$\geq 3.6\% \text{ SID}^*$

\*Includes allowance for measuring errors.

### TEST EQUIPMENT

- Ruler, metric/inch
- Cassettes: loaded 10" x 12" (24 x 30 cm) for tabletop plus a set of unloaded cassettes as required for the particular spot film device.

### SETUP

Equipment completely assembled with SID set at 37" (92.5 cm).

## TEST

1. Place loaded 10" x 12" cassette on tabletop in beam.
2. Adjust spot film device until distance from tabletop film to focal spot is equal to distance from tabletop film to film location in spot film device. (Correction factor "CF" = 2, see workbook.)
3. Lock in the compression movement in this position.
4. Remove 10" x 12" cassette from tabletop and store in radiation free spot.
5. Taking necessary radiation precautions, use fluoroscopy and TV monitor to position a solder cross on tabletop so its is in the center of the TV monitor image.
6. Tape cross to tabletop and check with fluoroscopy that it is still centered.
7. Switch off fluoroscopy.
8. Place a loaded 10" x 12" cassette face down on top of cross so center cross approximately coincides with center cassette.
9. Place empty, smallest format cassette in SFD and select one on one format. Make exposure at 60kV, 5mAs and develop film.
10. Measure length and width of the radiated area on the exposed film and record measurements in workbook.
11. Repeat steps 6 thru 9 and make one additional exposure of every kind of film subdivision (2:1, 4:1 etc.) available with the cassette presently in S.F.D.  
For example if this particular cassette size offers 1:1, 2:1 and 4:1 subdivisions then take one exposure at 1:1, one at 2:1 and one at 4:1. Also if you checked a left hand side exposure on the 2:1 than go to a right hand side exposure on the 4:1 and do the same for upper and lower half exposures if you have that choice available in the program.
12. Repeat steps 6 thru 9 for all larger cassettes used with this SFD.

## RESULTS

Complete calculations as indicated in workbook, results must be within the rejection limits stated. Number and date test films and file together with workbook.

## 2.36. TEST 36: PRIMARY BARRIER - X-RAY LOCKOUT FOR R/F TABLES WITH UT TUBE

SPECIFICATION
Exposure, DVI-exposure and fluoroscopy must be blocked if the X-ray beam axis is not perpendicular or aligned to the primary protective barrier

### TEST EQUIPMENT

- None

### SETUP

The equipment completely assembled.

### TEST

1. Verify the blocking of all exposures (fluoroscopy, fluorography, radiography and digital imaging) if the X-ray beam is not perpendicular or aligned to the primary protective barrier.
2. With the system misaligned verify also that all fluoroscopic and radiographic exposures are blocked when auxiliaries are tried.

### RESULTS

Complete workbook, test outcome must meet the specification.

## 2.37. TEST 41: STANDBY RADIATION FROM CAPACITOR DISCHARGE EQUIPMENT



### SPECIFICATION

Capacitor discharge equipment must not emit standby radiation of more than 2 mR/hr when the capacitors are fully charged.

### TEST EQUIPMENT

- Dosemeter

### SETUP

Equipment completely assembled.

### TEST

1. Place the dosimeter probe on the output face of the collimator. Set dosimeter to read on its lowest dose mR scale.
2. Set kVp to maximum and fully charge the capacitors.
3. With the dosimeter zeroed, measure the radiation output over a two minute period.



### NOTE

*If the capacitor charge drops by more than 5kV, recharge the capacitor and continue measuring.*

---

### RESULTS

Multiply the actual dose reading by 30 and record in workbook.

## 2.38. TEST 41

### 2.38.1. TEST 42A: DVI-1 TIMER ACCURACY



SPECIFICATIONS				
	DVI-1 WITH MODULAR GEN.	DVI-1 WITH OM200 GEN.	DVI-1 WITH MC850/MC1250	DVI-1 WITH SC 850
Mode	Spec.	Spec.	Spec .	Spec.
CONT. SUBT.	5.0 ±0.5sec	8.0sec + 0 ms -11 ms	6.0 ±0.6sec	6.0 ±0.6sec
SERIAL 8	320 ±48 ms	320 ms + 0 ms -1.1 ms	320 ±48 ms	330 ±49.5 ms
SERIAL 4	200 ±30 ms	200 ms + 0 ms -1.1 ms	200 ±30 ms	200 ±30 ms
SERIAL 2	130 ±19.5 ms	160 ms + 0 ms -1.1 ms	130 ±19.5ms	150 ±22.5 ms
SERIAL 1	80 ±16 ms	80 ms + 0 us -82 us	80 ±16 ms	90 ±18 ms



**NOTE**

*Do not start test unless timer accuracy of generator has already been checked and generator has been switched on for at least one hour.*

#### TEST EQUIPMENT

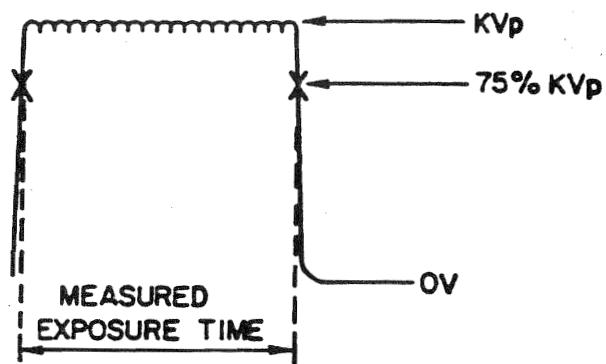
- Keithley voltage divider model # 35080 with filter packs 32867C, 5C, 9C or equivalent.
- Oscilloscope (storage)
- Lead sheet

#### SETUP

1. Calculate rejection limits based on the above specifications table.
2. Set up the Keithley voltage divider..
3. Connect the Keithley meter to the oscilloscope.
4. Protect image receptor with a sheet of lead.

## TEST

1. Select relevant X-ray tube and allow time for system to stabilize.
2. Select DVI auxiliary and switch on DVI.
3. Using the DVI handswitch, make a subtraction exposure (non-mask) in each DVI mode: CONTINUOUS, SERIAL 1, SERIAL 2, SERIAL 4, SERIAL 8. In each case, measure exposure time on oscilloscope between the point that kV exceeds 75% of the kVp and the point that kV decreases below 75% of the kVp. See waveform below.



## RESULTS

Record the actual exposure time for each DVI mode in the workbook.

## 2.38.2. TEST 42 B: DVI-2/S kV, mA, TIMER ACCURACY



SPECIFICATIONS		
	DVI-2/S with Modular	DVI-2/S with OPTIMUS
kVp	40 – 80 kV: $\pm 11.5\%$ 80 – 120 kV: $\pm 10.3\%$	40 – 90 kV: $\pm 7.9\%$ 90 – 125 kV: $\pm 5.7\%$
mA	20 – 3000mA: $\pm 15\%$	20 – 100 mA: $\pm 24\%$ 100 – 3000 mA: $\pm 5.2\%$
Exp. time	< 0.01 sec: $\pm 30\%$ < 0.04 sec: $\pm 25\%$ < 0.1 sec: $\pm 20\%$ > 1.0 sec: $\pm 15\%$ < 1.0 sec: $\pm 10\%$	0.32ms – 1ms: + 69 micro sec. 1.2ms – 10ms: + 59 micro sec. 12ms – 100ms: - 82 micro sec. 120ms – 800ms: - 1.1 m.sec.
	DVI-2/S with Classic/MCRT	
kVp	40 – 120 kV: $\pm 8\%$	
mA	$\pm 15\%$	
Exp. time	< 0.01 sec: $\pm 30\%$ < 0.04 sec: $\pm 25\%$ < 0.1 sec: $\pm 20\%$ < 1.0 sec: $\pm 15\%$ > 1.0 sec: $\pm 10\%$	



### NOTE

*Do not start this test unless kVp accuracy, tube current accuracy, and timer accuracy of the generator have already been checked and the generator has been switched on for at least one hour.*

### TEST EQUIPMENT

- Digital mA Meter
- Keithley voltage divider model #35080 with filter packs 32867C, 5C, 9C or equivalent
- Oscilloscope (storage)
- Lead sheet

## SETUP

The equipment completely assembled.

1. Calculate rejection limits based on the above specifications table.
2. Switch off generator\* also switch off main disconnect breaker to system.
3. Connect the digital mA meter.
4. Set up the Keithley voltage divider.
5. Connect the Keithley meter to the oscilloscope.
6. Protect image receptor with lead sheet.

## TEST

1. Switch on generator.
2. Switch on DVI-2 viewing console.
3. Select relevant X-ray tube and allow time for system to stabilize.
4. Select LIVE mode on Viewing Console.
5. Select APR #0 (top left button on DVI-2 operator console).
6. Depress the DVI handswitch to initiate exposure sequence.



*Handswitch must be held in expose position through the test shot sequence and programmed delay.  
Release the handswitch after the mask exposure is made.*

---

7. Measure and record exposure time on oscilloscope between the point that kVp exceeds 75% of its maximum value to the point that kVp decreases below 75% of its maximum value.
8. Measure and record the actual kVp on the oscilloscope waveform.
9. Measure and record the actual mA.
10. Read and record indicated exposure time/ kV and mA on the DV operator console LED readouts.
11. Select APR #1 on DVI-2 operator console and repeat steps 6 through 10 for another exposure.

## RESULTS

Record actual and indicated readings in Workbook.

### 3. TERMINOLOGY

In order to avoid misunderstandings in the interpretation of this manual the following definitions are given.

#### 3.1. TERMS AND DEFINITIONS

ACCESSIBLE SURFACE – The external surface of the enclosure or housing provided by the manufacturer.

ALUMINUM EQUIVALENT – The thickness of aluminum (type 1100 alloy) affording the same attenuation, under specified conditions, as the material in question.

ASSEMBLER – Any person engaged in the business of assembling, replacing, or installing one or more components into a diagnostic X-ray system or subsystem. This definition includes the owner of an X-ray system or his or her employee or agent who assembles components into an X-ray system that is subsequently used to provide professional or commercial services.

ATTENUATION BLOCK – A block or stack, having dimensions of 20 x 20 x 3.8 cm of type 1100 aluminum alloy or aluminum alloy having equivalent attenuation.

AUTOMATIC COLLIMATION – See Positive Beam Limitation.

AUTOMATIC EXPOSURE CONTROL (A. E. C) – A device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation.

BEAM AXIS – A line from the source through the center of the X-ray field.

BEAM-LIMITING DEVICE (B. L. D) – A device which provides a means to restrict the dimensions of the X-ray field. The word collimator will not be used in this manual.

BEAM-ON INDICATION – A visual indication which can be seen by the operator whenever X-rays are produced.

CERTIFICATION LABEL – The manufacturer's label affixed to each certified component which states the following: "CERTIFICATION This product complies with the Performance Standard of the Radiation Control for Health and Safety Act of 1968, applicable at date of manufacture."

CERTIFIED (BY ASSEMBLER) – The installer has certified, through filing the FDA 2579 form, that the complete system has been assembled and tested to all the requirements set forth in the various instructions supplied to him.

CERTIFIED (BY MANUFACTURER) – The manufacturer has taken all necessary steps to assure that a unit meets all of the requirements of the FDA performance standard when assembled and tested according to his instructions and has affixed a certification label to the unit.

CERTIFIED COMPONENT – A component type or model number for which the manufacturer has filed an initial report with the FDA. All certified components will bear a certification label.

CFR – Code of Federal Regulations. The CCT Manuals reflect rules and regulations as laid down in 21 CFR subchapter J "RADIOLOGICAL HEALTH" parts 1000 thru 1020.40.

COEFFICIENT OF VARIATION – The ratio of the standard deviation to the mean value of a population of observations. In this context, it is used to ensure compliance of reproducibility.

COLLIMATOR – See "Beam Limiting Device" BLD.

COMPLIANT – A product or component which meets all performance standards of the Radiation Control for Health and Safety Act of 1968.

CONTROL PANEL – Part of the X-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for setting the technique factors.

## Compliance Testing

COOLING CURVE – The graphical relationship between heat units stored and cooling time.

DHHS – The Department of Health and Human Services. The Secretary of DHHS reports to the President of the U. S.

DIAGNOSTIC SOURCE ASSEMBLY – The tube housing assembly with a beam limiting device attached.

DIAGNOSTIC X-RAY SYSTEM – An X-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

EQUIPMENT – X-ray equipment.

EXPOSURE – The production of radiation, dependent on preselected values of technique factors (kV, mA, time).

EXPOSURE RATE – The radiation dose per a given unit of time (e.g. R/ min), also called dose rate.

EXPOSURE RATE CONTROL – A system to automatically regulate the dose rate output of an X-ray tube in order to compensate for changes in object absorption, also called automatic dose rate control.

FLUOROSCOPIC IMAGING ASSEMBLY – A subsystem in which X-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

GENERAL PURPOSE X-RAY SYSTEM – Any radiographic X-ray system which by design is not limited to a radiographic examination of a specified anatomical region.

GRADUATED TEMPLATE – Any radiolucent sheet with permanently affixed radio opaque reference markings.

IMAGE RECEPTOR – Any device, such as a fluorescent screen or radiographic film, which transforms incident X-ray photons either to a visible image or into another form which can be made into a visible image by further transformations.

LEAKAGE RADIATION – Any radiation originating from the \*diagnostic source assembly except for:

1. Useful beam
2. Radiation produced when the exposure switch or timer is not energized (capacitor discharge units only.)

LEAKAGE TECHNIQUE FACTORS – The technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. They are defined as the maximum-rated peak tube potential and the maximum-rated continuous tube current at that peak tube potential.

LIGHT FIELD – That area of the intersection of the light beam from the beam limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

LINE-VOLTAGE REGULATION (Line Voltage Drop) – The difference between the no-load and the full load line potentials expressed as a percent of the full load line potential; that is,

$$\text{percent line voltage regulation} = \frac{V_n - V_i}{V_i} \times 100$$

where  $V_n$  = no-load line potential

$V_i$  = full load line potential

MANUFACTURER – Any person or firm who produces, assembles, or imports a diagnostic X-ray system or any of the previously listed certifiable (i.e., specified) components. Since the interconnection of specified components at the point of use to form an operational system and the adjustment and testing of the system are the final steps in the manufacturing process, an installer or assembler is, by definition, a manufacturer.

PEAK TUBE POTENTIAL (KVP) – The maximum value of the potential difference across the X-ray tube during an exposure.

POSITIVE BEAM LIMITATION (PBL) – The automatic adjustment of the X-ray field in the plane of the image receptor to the size of the image receptor in use. The word automatic collimation will not be used in this manual.  
\*See "Diagnostic source assembly"

PRIMARY PROTECTIVE BARRIER – The material, excluding filters, placed in the useful beam to reduce the radiation exposure for protection purposes.

RATING – The operating values specified by the manufacturer.

RECORDING – Producing a permanent form of an image resulting from X-ray photons (e.g. film, video tape).

RESPONSE TIME, INSTRUMENT – The time required for an instrument system to reach 90 percent of its final reading when exposed to a step change from zero sufficient to provide a steady state midscale reading.

SOURCE – The focal spot of the X-ray tube.

SOURCE-IMAGE RECEPTOR DISTANCE (SID) – The distance from the source to the center of the input surface of the image receptor.

SPOT FILM DEVICE (SFD) – A device to transport a radiographic image receptor (e.g. a film cassette) between the X-ray source and the fluoroscopic image receptor allowing one radiograph or a number of radiographs on a subdivided film to be made (also called serial changer). Also includes a clip on cassette holder in front of an image intensifier tube.

STATIONARY EQUIPMENT – Equipment installed in a fixed location.

TECHNIQUE FACTORS – Conditions of operation, as follows:

- For capacity energy storage equipment, kV and mAs.
- For field emission equipment rated for pulsed operation, kV and number of X-ray pulses.
- For all other equipment peak tube potential (kVp), tube current (mA), and exposure time, or the product of tube current and exposure time (mAs).

TUBE – X-ray tube. (See X-RAY TUBE)

TUBE RATING CHART – The set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

USEFUL BEAM – The radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

VARIABLE-APERTURE BEAM-LIMITING DEVICE – A beam-limiting device which has capacity for stepless adjustment of the X-ray field size at a given SID.

VISIBLE AREA – That portion of the input surface of the image receptor over which incident X-ray photons are producing a visible image.

X-RAY CONTROL – A device which controls input power to the X-ray high-voltage generator and/or the X-ray tube. It includes equipment such as timers, phototimers, automatic dose rate control systems, and similar devices, which control the technique factors of an X-ray exposure.

X-RAY EQUIPMENT – An X-ray system, subsystem, or component thereof.

X-RAY FIELD – That area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

X-RAY HIGH- VOLTAGE GENERATOR – A device which transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential. The device also include means for transforming alternating current to direct current, filament transformers for the X-ray tube(s), high-voltage switches, electrical protection devices, and other appropriate elements.

## Compliance Testing

X-RAY SYSTEM – The assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device, and all necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

X-RAY TUBE – Any electron tube which is designed for the conversion of electrical energy into X-ray energy.

1.2 The following symbols used in this manual and the workbook mean:

- < = less than
- $\leq$  = less than or equal to
- > = greater than
- $\geq$  = greater than or equal to
- | | = absolute value; ignore plus or minus sign of number within.

#### 4. TEST EQUIPMENT LIST

1.	High voltage divider tanks with cables	10.	Metal washers (10 mm or 1/2 inch ID)
2.	Digital mA/mAs meter	11.	Lead cross solder, (two pieces of 5" long solder)
3.	Dose/dose rate meter RADCAL 1015 CAB	12.	Cassettes and film in all sizes used in relevant equipment tested
4.	Lead sheet 40 x 40 x 0.3 cm or 16 x 16 x 1/8 inches	13.	Calculator that performs square root functions
5A.	Rulers 12" (30 cm); 2" (60 cm), metric and english	14.	Densitometer No: 331, Xrite
5B.	Metric scale (1 meter)	15A.	Copper filters 0.5 and 1.0mm Nuclear Associates No.: 07-431M
5C.	Tape measure 10' min, metric and english	15B.	Alum. filters: one 0.5 mm, four 1.0 mm Dimensions 6x6 inches Nuclear Associates No.: 07-430M
6.	Four (4) copper strips 2.5 x 10 x 0.05 cm or 1 x 4 x 1/4 inch	16.	Stopwatch or Wristwatch (Digital)
7.	Oscilloscope-storage Philips No: PM 3266, 3219 or 3311 with probes	17.	Cassette tunnel suitable for 10" x 12" (24 x 30 cm) cassette, (provide locally)
8.	Digital voltmeter	18.	Attenuation block of type 1100 Aluminum alloy 20 x 20 x 3.8 cm
9.	Light meter Min. range 10-30 foot-candles, e.g. G.E. type 214 triple range	19.	Keithley non-invasive kVp divider No: 35080 with filter packs or equivalent.

## 5. ACCURACY STATEMENTS AND REJECTION LIMITS

### 5.1. GENERATOR ACCURACY (ALL GENERATORS)

The "Specification Limits" for kVp, mA, ms and mAs as shown in the various tests in section 4 are based on the actual parameter tolerances as listed in the generator operator's manuals.

The Code of Federal Regulations (CFR-21) requires manufacturers and installers to comply with these listed tolerances. In order to achieve compliance the following is required:

1. The accuracy of the measuring instrument must be known for which there are basically two possibilities:
  - a) High precision laboratory calibration at regularly scheduled intervals, so that actual deviations for each individual instrument are known e.g. in the form of calibration graphs for all the measuring ranges.
  - b) Laboratory calibration at regularly scheduled intervals to confirm, that each instrument is functioning within the accuracy limits as stated by its manufacturer. Usually this means that the instrument is guaranteed to be accurate within certain limits like  $\pm 3\%$  of the read-out value. Type b calibration is the norm for field service instruments.
2. The service engineer must calculate parameter rejection limits based on the inaccuracy of his measuring instrument.

**Example:**

Generator accuracy for kVp as per operators' manual is  $\pm 8\%$ . Measuring instrument available is the Keithley voltage divider attached to a properly calibrated storage oscilloscope with a combined measurement system error of max.  $\pm 3\%$ .

Based on the generator accuracy of  $\pm 8\%$  the "Specification Limits" as shown in the kVp test of section 4 for a dialed kV of 100 would be 108 and 92 kV.

The rejection limits to guarantee compliance are calculated as follows: The upper rejection limit is  $108/1.03 = 104.85$  kVp. The lower rejection limit is  $92/0.97 = 94.84$  kVp.

Similar calculations apply to all the other exposure parameters as well.

Those service engineers, that use standardized sets of instruments for all their generator calibrations and compliance tests, can perform a one-time calculation of the rejection limits. These rejection limits can be re-used over and over again as long as identical measuring instruments are used that have been checked for proper calibration by means of a regular maintenance schedule. The tables for parameter testing have enough space available to write the calculated rejection limits under the relevant specification limits so it is available for future reference.

### 5.2. SPECIAL CONSIDERATIONS FOR CP GENERATOR TESTING

CP generators are factory calibrated and tested for CFR compliance. It is highly unlikely that a subsequent field, installation, when carried out in accordance with section C of the relevant service manual, could result in a non-compliance situation. For this reason a simplified combined parameter test has been developed (test 9). CP generators, are reliable and accurate devices and service engineers should question the readout accuracy of their measuring equipment first before rejecting the generator calibration.

In such cases re-check and if necessary exchange your test equipment.

### **5.3. X-RAY FIELD LIMITATION AND CENTERING**

Tests for X-ray field limitation and centering require the service engineer to measure certain distances like film plane to focal spot etc. Such measurements should always be done as accurately as possible even though some inaccuracy often cannot be avoided. Also measuring the dimensions on X-ray films will not be perfect due to penumbra effects etc. To compensate for these unavoidable inaccuracies the allowable FDA misalignments (expressed as a percentage of SID) have been reduced to cover for measuring errors.

### **5.4. RADIATION MEASUREMENTS**

4.1. Before doing any radiation measurements, always read the instrument operating manual and follow the instructions precisely.

4.2. Check due date for dose meter calibration.

4.3. Check meter operation with the calibration radiation source (if available).

4.4. Always remove any protective caps from chambers.

4.5. Follow probe positioning instructions as outlined in the various tests. Make sure the probe's sensitive surface is properly oriented in the radiation field. Generally the radiation field in the plane of the probe should be at least twice the length and twice the width of the probe's measuring surface.

4.6. If required in the manufacturer's instructions apply corrections for ambient temperature and barometric pressure.

4.7. Always check that probe in use can handle the peak radiation intensity to be measured in order to avoid probe saturation. This applies particularly to short radiation pulses. For example: Total dose measured during an exposure time of 10msec is 80mR. This is a dose rate of 80mR / 10msec or 8R / sec = 480R / min. Consequently the probe used must be able to handle a dose rate of 480R / min or higher.

4.8. Whenever dosimeters have been exposed to extreme cold be careful to avoid condensation. Wet instruments may require days to dry. Cold weather transport or storage should always be done with the instruments packed in air-tight containers or plastic bags. Never open packaging before the contents have been warmed up completely to the ambient temperature at the test location.

4.9. Never use a dosimeter: with past due calibration date, that behaves erratic, that may have been subjected to abuse (dropped, etc.).

### **5.5. HIGH VOLTAGE MEASUREMENTS**

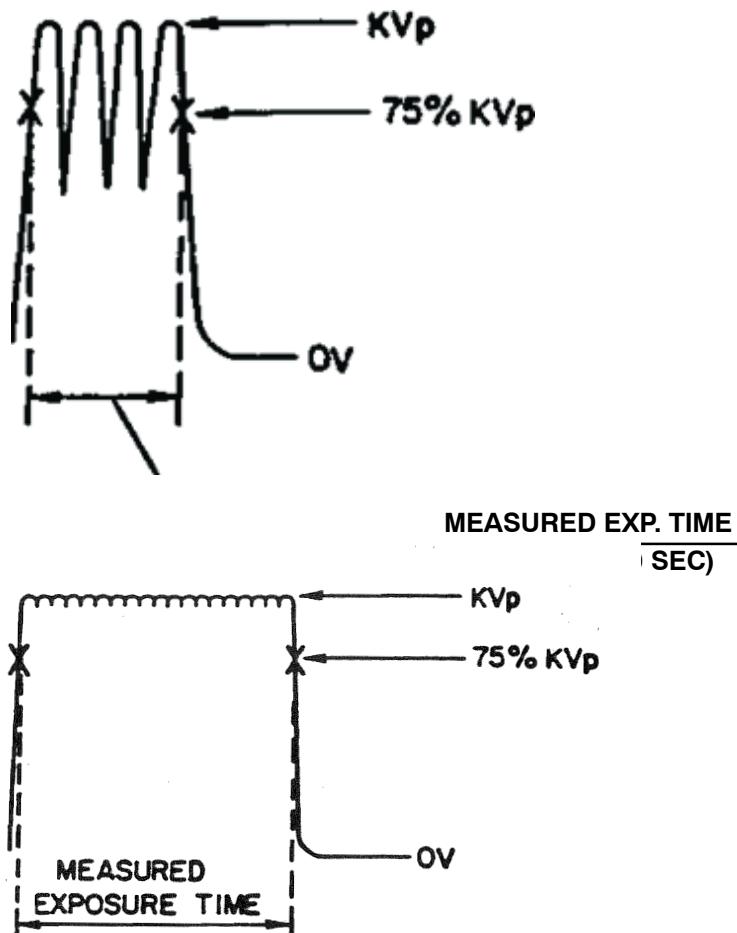
5.1. In case HV divider tanks are used for kVp measurements instead of the Keithley meter the following precautions apply:

In order to avoid additional resistance in the high voltage circuit, which could result in false mA readings the HV divider tanks should always be connected to a free outlet on the HV generator and operated by parallel switching of the solenoids of the relevant HV switches. If the third HV outlet is occupied, then disconnect one of the X-ray tubes at the generator side to provide a free HV outlet.

Whether you use HV divider tanks or the Keithley meter always use the oscilloscope for all kVp readouts, as digital meter read-outs could give false readings due to kV overshoot. Always read the kVp along the top of the wave, see waveforms for two-pulse and 12-pulse generators here-under. Neglect any kV overshoot at the beginning of the exposure when determining the kVp.

## 5.2. EXPOSURE TIME MEASUREMENTS

Whenever it is more convenient to do so exposure times may be measured with the oscilloscope and a properly enclosed and protected solid state photodetector positioned in the X-ray beam.



## 6. FURTHER TESTS

### 6.1. MINIMUM FIELD SIZE

Based on FDA regulation 21CFR1020.32(b)(2)(iv).



#### SPECIFICATIONS

When the beam limiting device (BLD) is completely closed, the X-ray field must be less than 5 x 5 cm at maximum SID.

#### TEST EQUIPMENT

- Ruler

#### SETUP

- The equipment set at maximum SID.

#### TEST

1. Select frontal (lateral) generator.
2. Select fluoroscopy and completely close collimator shutters.
3. Measure radiated field (if any) on viewing monitor.
4. Correct measurements for any magnification factor (image receptor input diameter to image diameter on monitor).
5. Repeat the setup and test for the lateral generator (if applicable).

#### RESULTS

	VERIFIED (X) Frontal	VERIFIED (X) Lateral
Minimum field size		

	INITIALS	DATE

## 6.2. FLUOROSCOPIC X-RAY FIELD LIMITATION

Based on FDA regulation 21CFR1020.32(b)(2)(i).



### SPECIFICATIONS

- Neither the length nor the width of the X-ray field shall exceed that of the visible area of the image receptor by more than 3% of the SID.
- Also, the sum of the excess length and excess width shall not exceed 4% of the SID.

### TEST EQUIPMENT

- Hardware key

### SETUP & TEST

1. Start the service procedure:  
**Adjustments > System > Detector Entranceplane Adjustment (Frontal)**
2. Check that all four shutters are within the image border margins as specified in the on-line procedure text.
3. Cancel the adjustment procedure.
4. Repeat the test for the lateral channel (if applicable).



*The test procedure does not measure the X ray field limitation directly, but when the detector entranceplane adjustment is correct, then it is guaranteed by design and manufacturing that the X-ray system meets the X ray field limitation specifications.*

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### RESULTS

	VERIFIED (X) Frontal	VERIFIED (X) Lateral
X-ray field limitation		

	INITIALS	DATE