Specification and Testing of Radiographic Systems For Breast Biopsy

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Introduction

- Types of specimen radiography systems
- The procedure – getting the images
- Laws and regulations
- TG-209 Proposed specifications and testing
Why the sliced specimen

- Radiological and pathological size estimations of pure ductal carcinoma in situ of the breast, specimen handling and the influence on the success of breast conservation surgery: a review of 2564 cases from the Sloane Project.
- The agreement between pathological and radiological size of DCIS was poor in mastectomies but was improved by specimen slice radiography, suggesting specimen-handling techniques as a cause.

Stereotactic Breast Biopsy

- 3:1 Magnification
- 18x24 cm CR Cassette
Cabinet x-ray systems are used to perform radiography of breast specimens in both the stereotactic breast biopsy suite and in the operating room. What type of specimens are imaged in the operating room?

1. Stereotactic breast biopsy specimens
2. Mastectomy specimens
3. Segmental mastectomy specimens
4. Ultrasound guided biopsy specimens
5. Both segmental and full mastectomy specimens
Answer

5 – Both segmental and full mastectomy specimens

Ref: http://EzineArticles.com/?expert=Dr. Nitha Thejal

Regulations

- Current Regulations
  - FDA
  - State

FDA Statements

- Some cabinet x-ray systems are used for medical applications, such as analyzing tissue samples for tumor metastases. These systems are medical devices and subject to additional FDA regulations.

- Use of cabinet x-ray products is regulated either by the U.S. Occupational Safety & Health Administration or by State Government.
Who regulates the QC testing required to be performed on specimen x-ray systems?

1. Food and Drug Administration
2. Nuclear Regulatory Commission
3. Individual State Radiation Control Programs
4. Mammography Quality Standards Act
5. OSHA

Answer

• 3 – Individual State Radiation Control Programs

• Ref: 21 CFR 1020.40:

FDA – Code of Federal Regulations

• Cabinet X-ray Systems - FDA
  – 21CFR1020.40
    • Radiation Emission Limit
    • Floors
    • Ports and Apertures
    • Interlocks
    • Ground Faults
    • Controls and Indicators
    • Operating Procedures and Technical Manuals
Cabinet X-ray Systems

- Texas Regulations
  - 25 TAC 289.228
  - This section establishes requirements for the use of industrial radiation machines not otherwise covered by this chapter. For purposes of this section, industrial radiation machines include, but are not limited to, portable/handheld fluorescence x-ray (open beam), fluoroscopy hand held intensified, fluoroscopy x-ray, industrial accelerator, spectrography x-ray, flash x-ray, flash x-ray for bomb detection, educational facility (x-ray for non-human or not live animal use), diffraction x-ray, uncertified cabinet x-ray, and minimal threat radiation machines.

- No registrant shall permit any individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit.
  - Tests for proper operation of interlocks shall be conducted and recorded at intervals not to exceed 12 months.
  - The registrant shall perform an evaluation to determine compliance with §289.231(o)(1)-(3) of this title and Title 21, CFR, §1020.40 at intervals not to exceed one year. The registrant shall ensure that radiation emitted 5 centimeters from the external surface of the cabinet x-ray system does not exceed 0.5 millirem (5.0 mSv) in any one hour.

- (c) Requirements
  - (1) Emission limit. (i) Radiation emitted from the cabinet x-ray system shall not exceed an exposure of 0.5 milliroentgen in one hour at any point five centimeters outside the external surface.
• (ii) Compliance with the exposure limit in paragraph (c)(1)(i) of this section shall be determined by measurements averaged over a cross-sectional area of ten square centimeters with no linear dimension greater than 5 centimeters, with the cabinet x-ray system operated at those combinations of x-ray tube potential, current, beam orientation, and conditions of scatter radiation which produce the maximum x-ray exposure at the external surface, and with the door(s) and access panel(s) fully closed as well as fixed at any other position(s) which will allow the generation of x radiation.

What is the maximum allowable exposure limit for cabinet x-ray systems

1. 0.05 mR in one hour
2. 0.1 mR in one hour
3. 0.25 mR in one hour
4. 0.5 mR in one hour
5. 1.0 mR in one hour

Answer

• 4. 0.5 mR in one hour
• Ref: 21CFR1020.40(c)(1)(i)
Specification of Specimen X-ray systems

- Must be FDA Approved!!
  - Bioptics
  - Faxitron
  - Kubtec

Stereotactic Breast Biopsy Specimen X-ray System

- X-ray Tube
- Magnification
- Field Size

Field Size

- Large enough to image a 5 cm diameter specimen dish at the proposed magnification factor
- All systems at least 12 x 12 cm
- We use a 18 x 24 cm Mammography CR cassette
Specimen Dish

X-ray Tube Specifications Cabinet Systems

<table>
<thead>
<tr>
<th>Specification</th>
<th>Faxitron MX-20</th>
<th>Faxitron Biovision</th>
<th>Faxitron Spectre 40</th>
</tr>
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<tbody>
<tr>
<td>kVp</td>
<td>20 kVp - 35 kVp</td>
<td>5 kVp - 45 kVp</td>
<td>20 kVp - 50 kVp</td>
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<tr>
<td>mA</td>
<td>100 µA</td>
<td>5mA</td>
<td>5mA</td>
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<tr>
<td>focal Spot</td>
<td>&lt;25 µm</td>
<td>30 µm</td>
<td></td>
</tr>
<tr>
<td>window Filtration</td>
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<td>0.125 mm beryllium</td>
<td>0.005 mm beryllium</td>
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<td>resolution</td>
<td>10 lp/mm</td>
<td>10 lp/mm</td>
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</tr>
<tr>
<td>active imaging Area</td>
<td>9.2 cm x 9.2 cm</td>
<td>12 cm x 12 cm</td>
<td>10 cm x 10 cm up to 20 cm</td>
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<tr>
<td>magnification</td>
<td></td>
<td>1:1, 2:1, 4:1</td>
<td>up to 5x</td>
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</table>

Specifications Core Biopsy Systems

<table>
<thead>
<tr>
<th>Specification</th>
<th>Faxitron DX-50</th>
<th>Faxitron Core Vision</th>
<th>Faxitron Spectre 20</th>
</tr>
</thead>
<tbody>
<tr>
<td>kVp</td>
<td>20 kVp - 35 kVp</td>
<td>5 kVp - 30 kVp</td>
<td>20 kVp - 25 kVp</td>
</tr>
<tr>
<td>mA</td>
<td>0.1 mA</td>
<td>35 mA</td>
<td>100 mA</td>
</tr>
<tr>
<td>focal Spot</td>
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<td>50 µm</td>
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<tr>
<td>window Filtration</td>
<td>0.03&quot; beryllium</td>
<td>0.2 mm beryllium</td>
<td>0.005&quot; beryllium</td>
</tr>
<tr>
<td>resolution</td>
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<td>30 lp/mm</td>
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<tr>
<td>active imaging Area</td>
<td>5 cm x 5 cm</td>
<td>5 cm x 7 cm</td>
<td>5 cm x 5 cm</td>
</tr>
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</table>
What is smallest detector size provided by any of the vendors for stereotactic core biopsy imaging?

1. 3 cm x 7 cm (21 cm²)
2. 5 cm x 5 cm (25 cm²)
3. 10 cm x 10 cm (100 cm²)
4. 15 cm x 15 cm (225 cm²)
5. 20 cm x 20 cm (400 cm²)

Answer

• 1. 3 cm x 7 cm (21 cm²)

Ref: Bioptics Core vision technical specifications:
http://www.bioptics-inc.com/site/downloads/COREVISION_Brochure.pdf#zoom=60
Faxitron DX-50 Core Specimen Radiography System technical specifications:
Kubtec Xpert20 Specimen Radiography System technical specifications:
http://www.kubtec.com/xpert20.htm

QC Testing – AAPM TG 209

• Proposed testing
  – Safety Check
  – kVp
  – Exposure Rate
  – Resolution - Detector
  – Image quality phantom
  – Film Processor
  – CR Reader testing