



March 23, 2004

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: Variance Request for Scanning Beam Digital X-ray (SBDX) System
Trade name: VASCO

References: FDA Docket No. 95V-0043/VAR 1 (8/22/95) (attached)
510(k) # K953113 (3/29/1995) (attached)
510(k) # K982345 (9/01/1998) (attached)
Restated Articles of Incorporation (CA)
(Corporate name change from "Cardiac Mariners" to "NexRay")

To Whom IT May Concern:

In accordance with 21 CFR 1010.4, NexRay, Inc. of Los Gatos CA requests a variance from provision 1020.32 (g) of the Performance Standards For Ionizing Radiation Emitting Products; that is, the source-skin distance limit of 38 cm.

Background:

NexRay, Inc., previously known as Cardiac Mariners, Inc., of Los Gatos CA, developed a C-arm-based, low dose, real time x-ray fluoroscopy system. This system (originally a mobile unit called "SBDX"; now a stationary unit referred to as "VASCO") is characterized by image quality comparable to conventional C-arm fluoroscopic systems but with a significant (up to 10X) reduction in radiation exposure. A 5-year variance (FDA Docket No. 95V-0043/VAR 1) for the source-skin distance provision detailed in 21 CFR 1020.32 (g) was granted by the FDA on August 22, 1995; marketing clearance was granted on March 29, 1995. After system redesign, subsequent marketing clearance was sought and received per 510(k) # K982345, September 1, 1998.

Unfortunately, the Company experienced severe financial duress in 1999, and was unable to secure financing for its planned production and product introduction activities in the latter part of that year. The workforce was reduced to only a handful of employees, and operations other than sustaining engineering essentially ceased. However, the company was able to stay afloat, and subsequently received a significant infusion of capital in late 2001. The corporate name was changed from "Cardiac Mariners" to "NexRay", and operations were resumed, but not before the original variance had lapsed. Therefore, the Company now requests to renew the variance before product introduction later this year. Details for this request are provided below in accordance with the numbered provisions of subparagraph 1010.4 (b).

1995V.0043

VAR 2



1. Product Description and Intended Use

The VASCO scanning beam digital x-ray system is a stationary, C-arm based, low-dose, real-time digital x-ray system intended for *real-time fluoroscopic applications where medically indicated*. The VASCO system has the same intended use as a conventional fluoroscope, but uses a different geometry. A large, distributed x-ray source replaces the conventional fluoroscope's point source, and a small detector array replaces the large diameter image intensifier and camera. The large x-ray source is created by scanning a target with an electron beam. The target emits x-rays that are then passed through a multi-hole collimator to allow only those x-rays directed at the detector to emerge. The effectiveness of this approach relies on placing the patient close to the source, rather than further away as with a conventional x-ray source. Moreover, as the patient is not close to the detector, the degrading effects of scattered radiation on SNR are substantially reduced, thus requiring less radiation and further reducing total received dose. This combination of factors allows entrance exposure reduction to the patient by a factor of up to 10X, while maintaining image quality comparable to a conventional system.

The NexRay, Inc. VASCO System comprises the following units: the C-arm and pedestal unit, the electronics equipment cabinets, a heat exchanger, a patient table, a power distribution/ isolation transformer, and requisite controllers, monitors, and parameter displays. *A detailed description of the System, its features, and dose reduction capabilities is included in Section 7 of 510(k) # K982345, appended to this document. This description is still valid for NexRay VASCO system.* Please note, however, that there are a number of differences between the SBDX of 1996 and the VASCO of 1998, as listed in Exhibit E of 510(k) # K982345.

2. Impact of Compliance

The NexRay VASCO scanning beam digital x-ray system is fully compliant with all performance standards detailed in 21 CFR Subchapter J with one exception; specifically, the requirements of subparagraph 1020.32 (g) which sets a source-skin distance minimum of 38 cm for stationary fluoroscopes.

Conventional C-arm-based fluoroscopy systems need the minimum source-skin distance to limit the exposure of patients to the high intensity x-rays near the point x-ray source that characterizes that technology. As illustrated in Figure 1 (appended to this letter), patient entrance exposure increases dramatically the closer the patient is positioned to the point x-ray source of the conventional system.

The NexRay VASCO system does not use a point x-ray source, but rather a distributed x-ray source with a target diameter of 25.4 cm, and a multi-hole collimator whose aperture output is positioned 5.0 cm above this target. The isocenter is 40 cm above the collimator surface, and the patient will be typically placed 15 cm to 25 cm above the collimator surface. As illustrated in Figure 2, radiation exposure decreases as distance to



the source is decreased, rather than increasing as with the conventional point x-ray source. In other words, the minimum amount of x-ray entrance exposure in the NexRay VASCO system occurs close to the source, rather than further away as with the conventional system. Positioning the patient in NexRay's VASCO system to satisfy the 38 cm source-skin distance would increase entrance exposure as compared to placing the patient closer to the source. Moreover, scatter radiation detected by the x-ray detector would also increase, thus reducing image contrast and requiring a further increase in x-ray exposure. In short, compliance with this standard is inconsistent with the VASCO system design principle, will diminish imaging effectiveness, and increase the entrance exposure to the patient.

Note

Measurements used to derive the graphs depicted in Figures 1 and 2 were taken in January, 2004 at the University of Wisconsin-Madison. The conventional system used for comparison is a Philips Optimus M200. Measurements were taken with a Solidose Model 300 Digital Dose meter with an R100 detector. There was nothing placed in the beam for these measurements, and AEC for both units was disabled. Distance was measured in centimeters from the top of the conventional system's source assembly and the top of VASCO's collimator surface, respectively.

3. Proposed Deviation

NexRay proposes that the VASCO scanning beam digital x-ray system deviate from the standard stated in 1020.32 (g) in that the source-skin distance be limited to 2.5 cm rather than 38 cm. This deviation will allow patient positioning adjacent to the source's collimator to minimize skin entrance exposure and optimize image quality, taking full advantage of the design principles involved.

4. Advantages

Reduced Patient Skin-Entrance Exposure

The proposed variance allows the VASCO system to operate at as it was designed, reducing patient skin entrance exposure levels and total patient dose.

Improved Image Contrast

The design of the VASCO system, characterized by a converging x-ray beam and small detector, results in reduced scatter radiation at the detector. Moreover, the greatest source of scatter, the patient, is located as far from the detector as possible.



5. Alternate Means of Radiation Protection

Location of the patient near the source of the VASCO system will, by the nature of the design principles of the system, minimize patient entrance exposure by up to 10X and total patient dose by up to 5X.

Users documentation shall contain procedures and cautions reflecting the unique features of the VASCO system, including recommended technique factors for a representative sample of fluoroscopic examinations and data on skin exposure for these factors.

6. Desired Time Period

NexRay requests that this variance be in effect for a period of five (5) years.

7. Equipment Location

The NexRay VASCO system received 510 (k) clearance (# K982345) on September 1, 1998. NexRay will file its Initial Report prior to anticipated production and distribution in the fourth quarter of 2004.

Kindly direct questions and comments regarding this request for variance to the undersigned at (408) 364-8603. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Bruce Floyd", written over a horizontal line.

Bruce Floyd
Director, Regulatory Affairs/Quality Assurance
Direct Line: (408) 364-8603

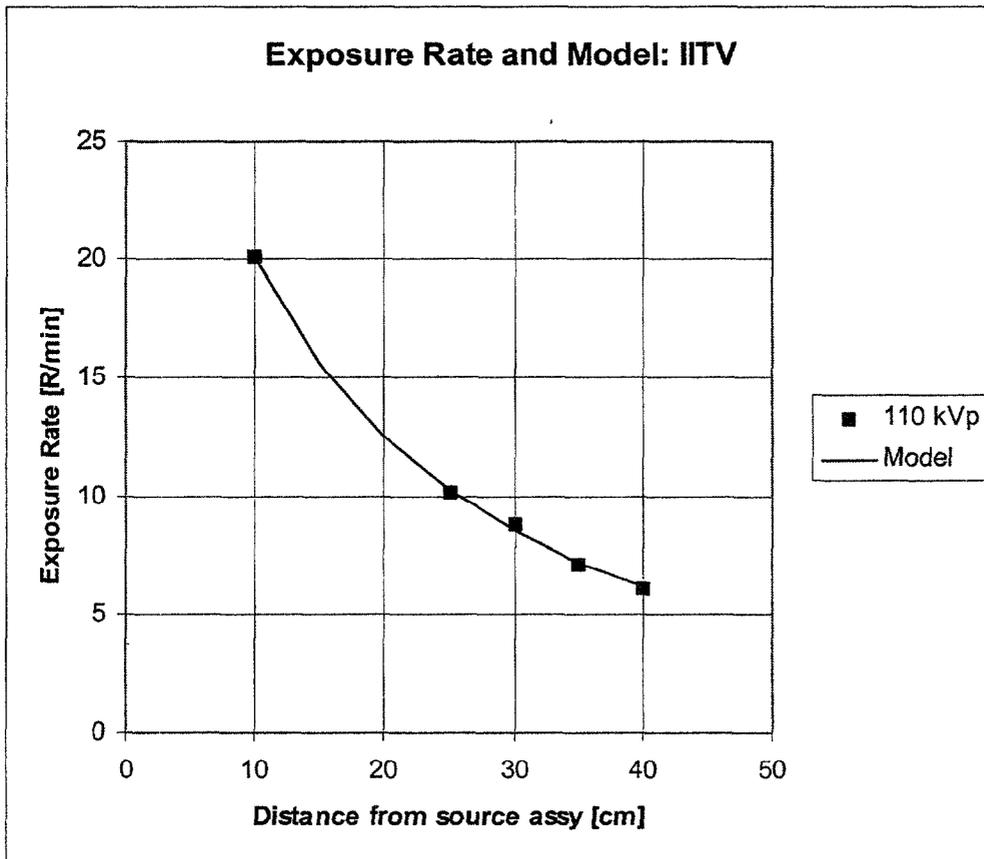


Figure 1: Data and Model of Exposure Rate from IITV system measured at various distances from the exit surface of the source assembly.

The model is a simply $\frac{a}{r^2}$, where “a” is a scale factor adjusted to match the data and “r” is the distance of the exposure measurement from the source focal spot for the IITV system, and from the detector position for VASCO (Figure 2).

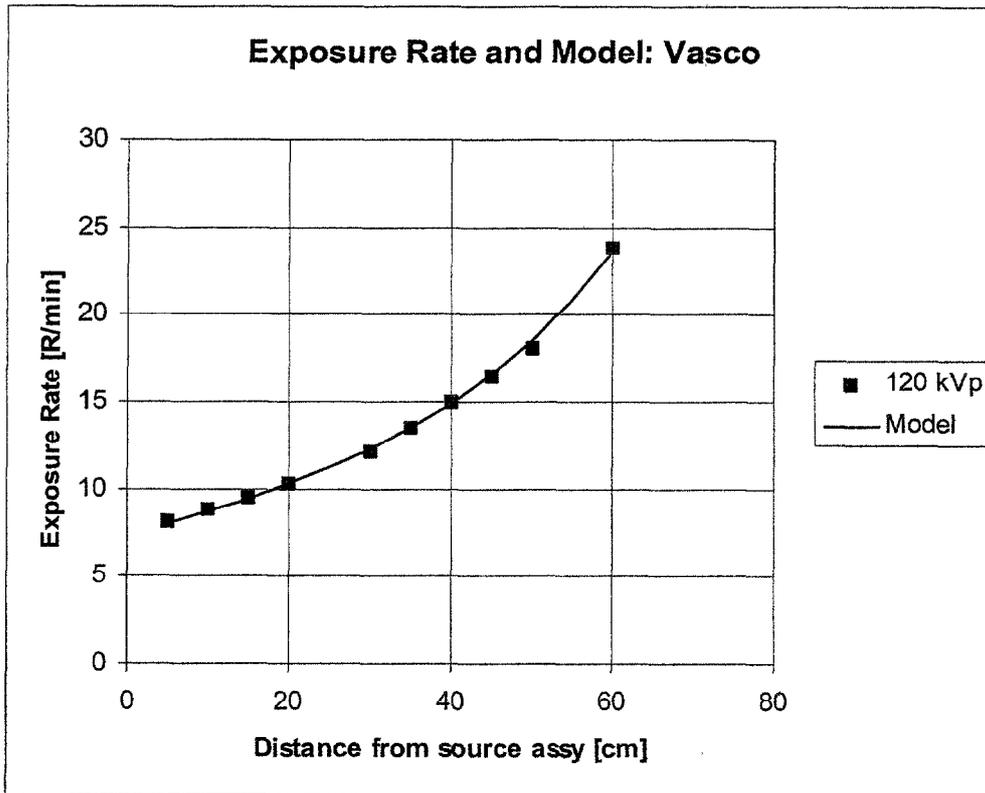


Figure 2: Data and Model of Exposure Rate from VASCO source measured at various distances from the surface of the collimator.

Reference Documents

1. FDA Docket No. 95V-0043/VAR 1 (8/22/95)
2. 510(k) # K953113 (3/29/1995) (Less Exhibits)
3. 510(k) # K982345 (9/01/1998) (Includes Exhibit "E")
4. Restated Articles of Incorporation (CA)
(Corporate name change from "Cardiac Mariners" to
"NexRay")



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 22 1995

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FDA Docket No. 95V-0043/VAR 1

Jack Moorman, President
Cardiac Mariners, Inc.
120-B Albright Way
Los Gatos, California 95030

Dear Mr. Moorman:

The Center for Devices and Radiological Health (CDRH) is approving, in accordance with 21 CFR 1010.4(c)(1), the petition Cardiac Mariners, Inc., filed on February 10, 1995, for Variance 95V-0043/VAR 1. The items of the variance are:

A. Variance Number

95V-0043/VAR 1

B. Effective Date

This variance shall become effective on the date of this letter in accordance with 21 CFR 1010.4(c)(1).

C. Termination Date

This variance, unless renewed, shall terminate five years from the date of this letter.

D. Product for which Variance is Granted

This variance is applicable to the SBDX manufactured by Cardiac Mariners, Inc. The product is a mobile, C-arm based, low dose, real time x-ray fluoroscopy imaging system called the "SBDX" system. The intended use of this device is general purpose fluoroscopic imaging. This variance is for the SBDX as specifically described in the variance application. Any change in the dimensions, configuration, intended use or operating parameters will require the submission of a new variance request for the changes.

E. Provisions from which Variance is Granted

Variance is granted from a provision of 21 CFR 1020.32(f) requiring that the product shall be provided with a means to limit the source-skin distance (SSD) to not less than 38 centimeters on stationary fluoroscopes and to not less

Cardiac Mariners, Inc.

*120-B Albright Way
Los Gatos, CA 95030
408-379-6600*

February 10, 1995

Dockets Management Branch (HFA-305)
Food and Drug Administration, Rm 4-62
Parklawn Building 5600 Fishers Lane
Rockville, MD 20857

Attn:

Thomas M. Jakub
Office of Compliance
Diagnostic Devices Branch/CDRH

Subject: Variance Request for the Scanning
Beam Digital X-ray System (SBDX)

Dear Mr. Jakub:

In accordance with the provisions of 21 CFR 1010.4 Cardiac Mariners, Inc. requests a variance from certain provisions of the Diagnostic X-Ray Performance Standard set forth in 21 CFR 1020.30. The details of this request are provided below in accordance with the numbered provisions of subparagraph 1010.4(b).

I. Product Description and Intended Use

Cardiac Mariners, Inc. has developed a mobile, C-Arm based, low-dose, real time x-ray fluoroscopy imaging system called the "SBDX" system (Figure 1). This system is intended for general purpose fluoroscopic imaging. Compared to conventional C-Arm fluoroscopic system, the SBDX provides comparable image quality (Figure 2) with significant decrease in radiation exposure.

Typical fluoroscopic systems use a conventional x-ray tube which produces a point source x-ray beam. This beam is collimated and aligned to an image intensifier which, in conjunction with video imaging electronics, detects, amplifies, and displays the image. As shown in Figure 3, both scatter radiation produced by interaction of the x-ray beam with the patient and primary radiation is detected by the image intensifier. This scatter radiation tends to wash out the image resulting from the primary radiation thereby resulting in a reduction in image contrast. In radiography, grids are used to minimize the reduction in contrast due to patient scatter; however, similar methods are not generally used for conventional C-Arms.

The Cardiac Mariners Scanning Beam digital X-Ray system has the same intended use as conventional C-Arms but uses a different geometry. The SBDX system is based on an x-ray tube which produces a large distributed x-ray source which is collimated so as to converge at a small detector as shown in Figure 4. As shown in Figure 5, the large x-ray source is produced by an electron beam which is scanned across a liquid cooled tantalum target in a way which is similar to a television picture tube. The electron beam is produced by an electron gun operating at a maximum of 100 kVp and 30 mA. The target is composed of a 5 micron layer of tantalum on a 5mm beryllium substrate which is located 25.4 mm from the exit surface of the collimator. The circular collimator is 12.7 mm thick and 25.4 cm in diameter. Located within this 25.4 cm diameter are approximately 22,000 holes which are on 1.52 mm centers and which have diameters of 0.38 mm each. The axis of each hole is pitched so as to point towards the detector which is approximately 94 cm from the collimator. As the electron beam is scanned across the target each of the collimator holes is illuminated in turn so as to produce a tiny beam of radiation which, by virtue of the collimator, is aligned with the detector. As can be seen in Figure 6 the dimensions of the collimator hole and the detector are such as to assure that approximately 95% of the primary beam is detected.

The SBDX detector consists of a two-dimensional array of 96 scintillator crystals which are on 1.52 mm centers and are optically coupled to a 96 channel photomultiplier tube. The overall diameter of this 96 element array is approximately 1.8 cm. Each scintillator crystal is 5.0 mm thick and has a 90% detection efficiency as compared to a 50% detection efficiency for conventional fluoroscopes. This increased quantum efficiency compared to conventional fluoroscopes results in a reduction in required patient exposure by a factor of approximately 1.8 (0.9/0.5).

The scintillator array subdivides each beam into an array of smaller sub-beams as shown in Figure 7. The outputs from these crystal detector elements are summed by a mathematical reconstruction algorithm as shown in an exploded graphical representation in Figure 8. This approach uses all the x-ray energy incident on the detector array to produce images at a frame rate of 30 Hz and a spatial resolution corresponding to that of a single sub-beam.

The image reconstruction hardware collects 96 data samples for each collimator hole illuminated as the electron beam scans the target and performs the required image reconstruction in real time to produce 500 x 500 pixel images at a 30 Hz frame rate. Because

of the 96 element detector and the reconstruction algorithm a plane of best focus is created approximately 24 cm from the collimator. This focal plane has a diameter of 19 cm and a depth of field of approximately 7.6 cm. Objects at a distance from this focal plane are progressively blurred in a manner similar to a conventional radiographic tomo system.

The Cardiac Mariners SBDX system consists of two separate mobile units: the C-Arm cart and the Operator's Console. The C-arm cart houses the x-ray source assembly, its power supplies, control electronics, heat exchanger, detector, photomultiplier, a power positioning gantry, and various other control, sensor, and fail-safe modules. The Operator's Console contains the system control computer, user input devices, and both the system and image display monitors. Data and control communication between the C-arm cart and the Operator's Console is by means of a number of optical fibers encased in a single cable.

II. Impact of Compliance

The Cardiac Mariner's SBDX system will be fully compliant with all the performance standards prescribed in 21 CFR subchapter J with one exception. This application requests a variance from the requirements of subparagraph 1020.32(f) which sets a source-skin distance limit of 30 cm for mobile fluoroscopes. ✓

In a conventional C-Arm fluoroscopic system it is necessary to set a limit on the minimum source-skin distance to limit the exposure of the patient to the high intensity x-rays near the point x-ray source. Figure 9 illustrates the x-radiation exposure as a function of distance for a point x-ray source. As can be seen, patient exposure varies as a function of 1 over distance squared. Consequently, the patient exposure increases dramatically as the patient is positioned closer to the point source. For this reason it is desirable to position the patient as far as possible from the x-ray source. ✓

The Cardiac Mariners Scanning Beam Digital X-Ray (SBDX) System does not use a point source x-ray beam. Rather, it uses a distributed x-ray source having a diameter of 25.4 cm. The worst case radiation exposure (based on TLD measurements at 100 kVp and 15 mA, extrapolated to 30 mA) as a function of distance from the collimator is depicted in Figure 10. As can be seen, the radiation exposure decreases close to the collimator with the SBDX system rather than increasing as with a conventional C-Arm fluoroscopic system. For this reason the minimum patient exposure in the SBDX system occurs close to the collimator and x-ray source. (Note: As described above the exterior side of the collimator is 25.4 mm from the target.) Positioning the patient further away from the source will only increase his exposure. ✓

Positioning the patient in the SBDX system so as to meet the 30 cm source-skin distance would increase his skin entrance exposure (Figure 10) compared to positioning the patient adjacent to the collimator (assuming a 12" thick patient). In addition, the scatter radiation

being detected by the x-ray detector would be increased thereby reducing image contrast and requiring further increases in x-ray exposure. Moreover, the patient would be outside the plane of focus.

Requiring compliance of the SBDX system with the current source-skin distance standard would have the unintended effect of diminishing its imaging effectiveness while increasing patient exposure.

III. Proposed Deviation

It is proposed that the SBDX system deviate from the standard in that the source-skin distance be limited to 2.54 cm rather than 30 cm as currently required. This deviation will allow the patient to be positioned adjacent to the collimator so as to minimize skin entrance exposure and optimize image quality.

IV. Advantages

Reduced Patient Skin-Entrance Exposure

The proposed variance allows the system to operate at a patient skin entrance exposure which is one hundredth that of conventional C-Arm fluoroscopic systems (i.e. approximately 0.1 R/min rather than 10 R/min) with comparable image quality. As can be seen in Figure 10, the absolute radiation exposure at maximum technique factors (100 kVp and 30 mA) as extrapolated from TLD (LiF) measurements at 100 kVp and 15 mA is approximately 0.1 R/min in the vicinity of the collimator, gradually increasing to 0.3 R/min at 28.5 cm. Note: The distance from the collimator to the detector is 94 cm (37 inches). The patient cannot be positioned further than 35 inches from the collimator because of detector housing.

Reduced Total Patient Dose

The proposed variance results in less overall patient dose than conventional C-Arm fluoroscopic systems. Operating at 100 kVp/30 mA (maximum technique factors) and with a half-value layer of 2.5 mm Al the SBDX patient entrance exposure is approximately 100 mR/min as shown in ¹Figure 10. This Figure also shows that, regardless of his position, the patient cannot be exposed to radiation levels as high as

¹ Based on TLD measurements of SBDX exposure as a function of distance from the collimator.

conventional C-Arms (i.e. 10 R/min). As shown in ²Figure 11, exposure decreases as the convergent beam passes through the patient. As a result the patient exit exposure is significantly less than the entrance exposure.

In contrast, a conventional C-Arm operating at 100 kVp and maximum mA and with the same half-value layer (2.5 mm Al) results in patient entrance exposure as high as 10 R/min (approximately 100 times that of the SBDX) as shown in ³Figure 9. Similarly, exposure decreases as the divergent beam passes through the patient as shown in ⁴Figure 12. As a result the exit exposure is also significantly less than the entrance exposure.

Improved Image Contrast

The design of the SBDX system results in an improvement of contrast by reducing scatter radiation by a factor in excess of 100. This scatter reduction can be attributed to the SBDX system's use of a converging x-ray beam and an x-ray detector which has a surface area of only 1/100th of a conventional image intensifier. In addition, the greatest source of scatter, the patient, is positioned as far from the detector as possible thereby further reducing the scatter radiation which is detected.

Improved Quantum Efficiency

Each scintillator crystal is 5.0 mm thick and has a 90% detection efficiency. Compared to conventional fluoroscopes which typically have a quantum detection efficiency of approximately 50% the SBDX results in a reduction in required patient exposure by a factor of approximately 1.8 (0.9/0.5).

V. Alternate Mean of Radiation Protection

Location of the patient adjacent to the collimator will minimize patient exposure and allow realization of the other advantages described above. The design of the SBDX is such that the

² Based on radiation attenuation calculations in a simulated patient (12" water phantom) with confirmation using TLD measurements..

³ Based on theoretical calculations of exposure as a function of distance for a conventional C-Arm assuming a $1/r^2$ dependence and 10 R/min at 30 cm.

⁴ Based on radiation attenuation calculations in a simulated patient (12" water phantom) with the skin entrance located at 30 cm from the focal spot.

patient cannot be closer to the detector than 2 inches. As seen in Figure 10, the worst case radiation exposure to the patient cannot exceed that of conventional C-Arm fluoroscopic systems meeting the minimum SSD requirement (i.e. 10 R/min). For these reasons it is concluded that the SBDX system is by design inherently safer with respect to patient radiation exposure than conventional C-Arm systems.

VI. Desired Time Period

It is requested that this variance be in effect for a period of 5 years.

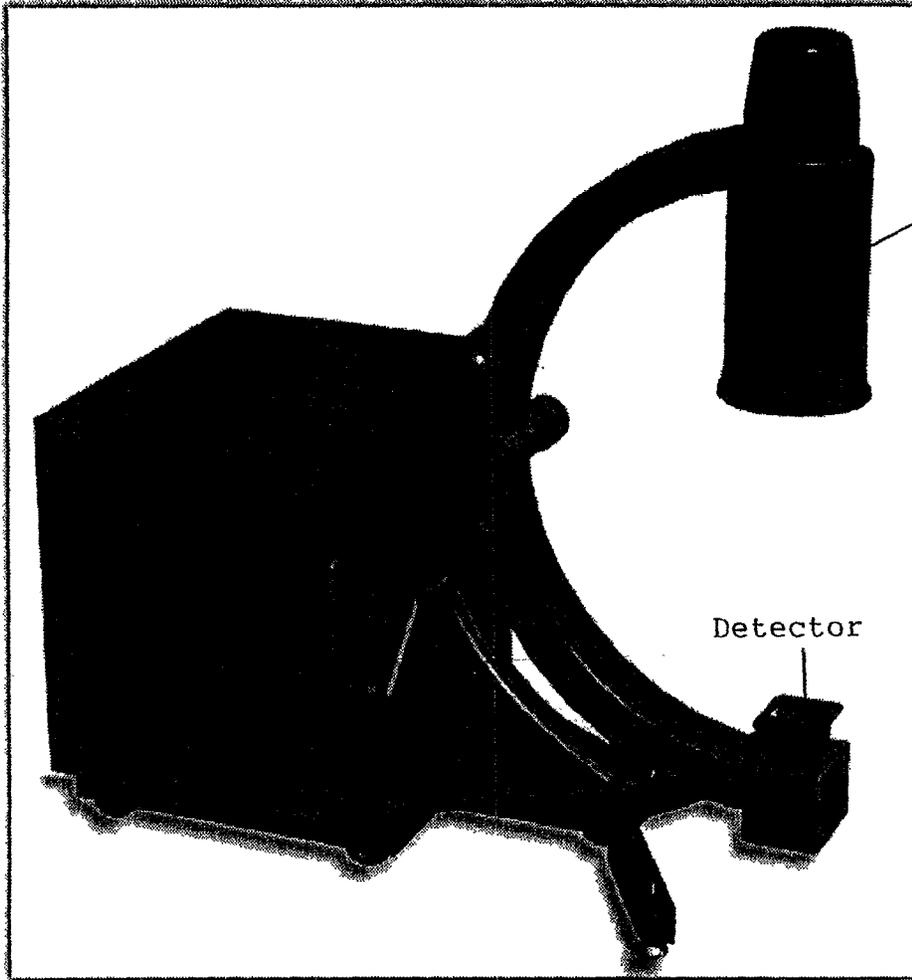
VII. Equipment Location

A 510(k) and initial report will be filed for the SBDX system in mid 1995 with manufacturing and distribution commencing upon 510(k) clearance.

If you have any questions regarding this variance, please contact our regulatory consultant, James M. Howard of Bio-Reg Associates, Inc. At 301-206-2214.

Sincerely,

Jack Moorman / *by James M Howard*
Jack Moorman
President



X-Ray Tube

The
Solution...

Low Dose
Digital X-ray

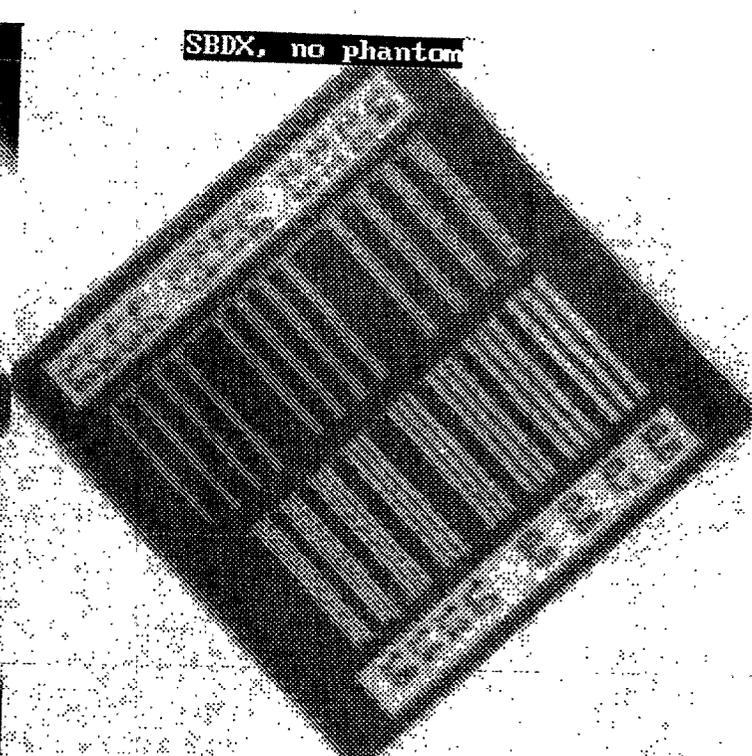
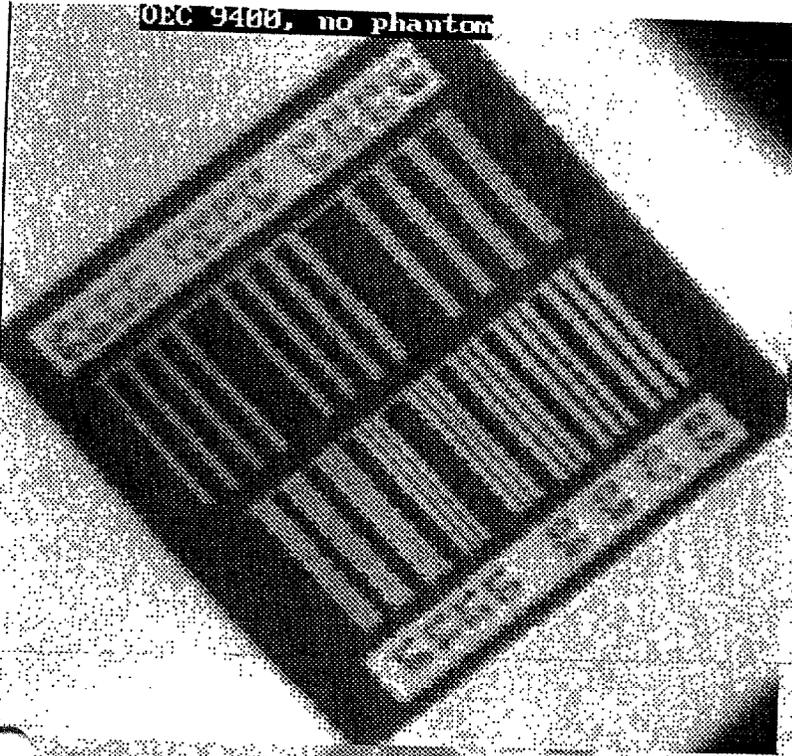
Figure 1

C-Arm

SBDX

OEC 9400, no phantom

SBDX, no phantom



OEC 9400 w/phantom (note fog from scattering)

SBDX w/ phantom

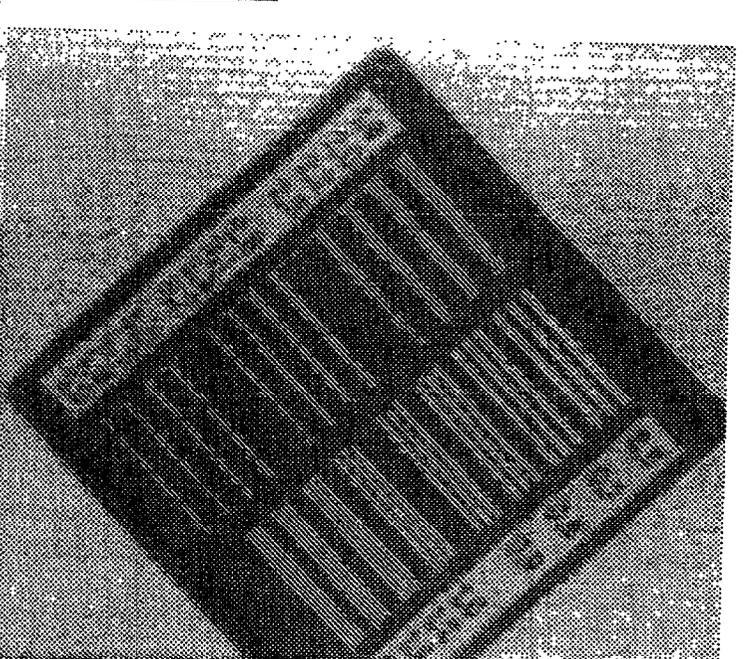
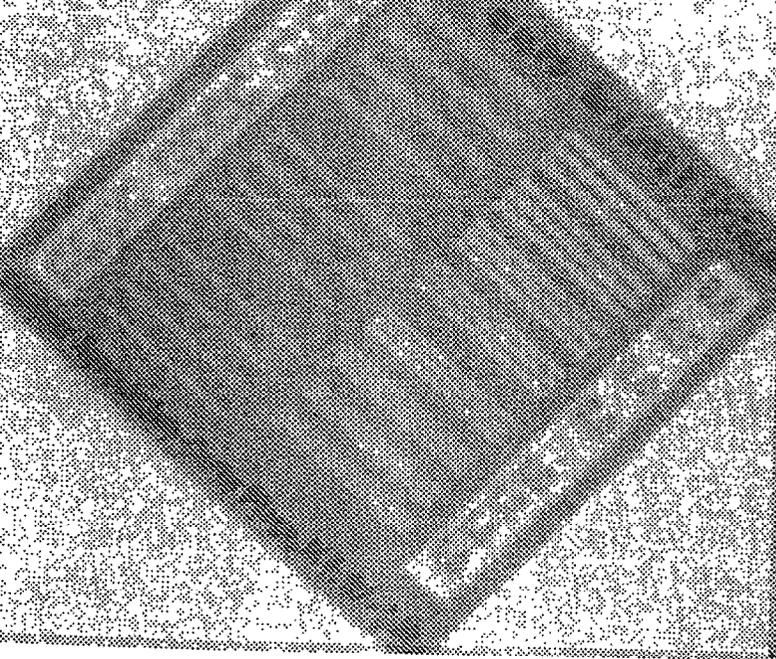


Figure 2

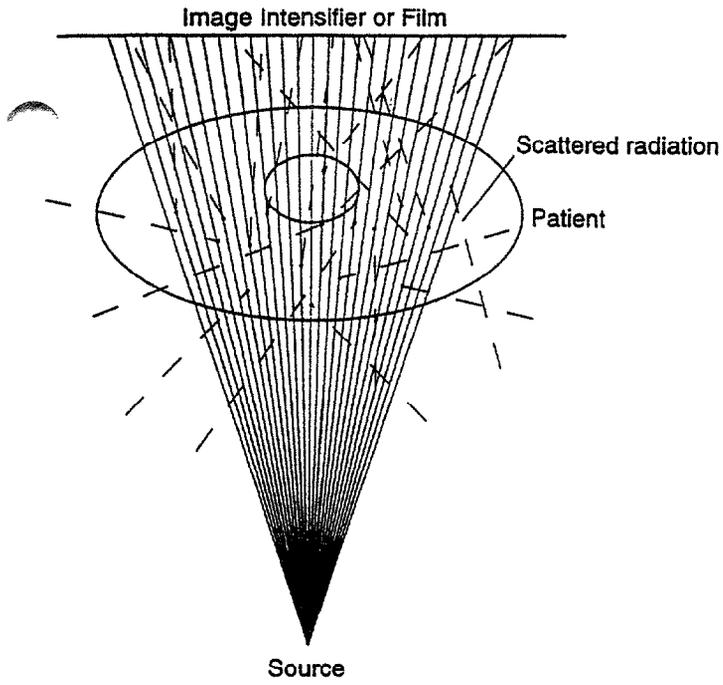


Figure 3 Conventional X-Ray System

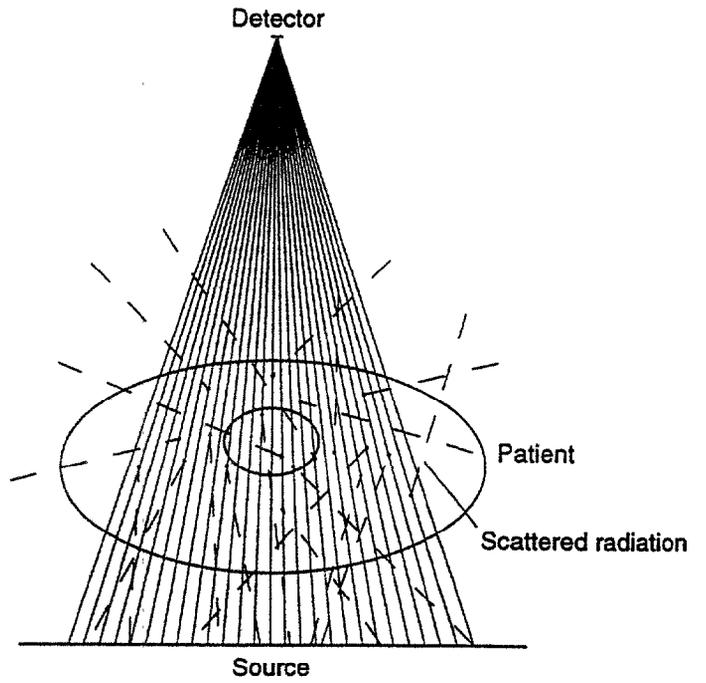


Figure 4 Scanning Beam Digital X-Ray System

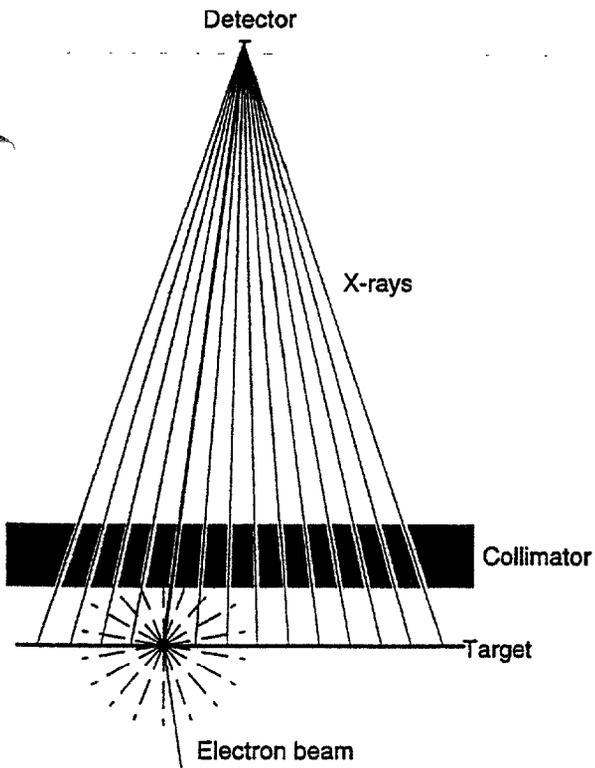


Figure 5 Scanning Beam X-Ray Source

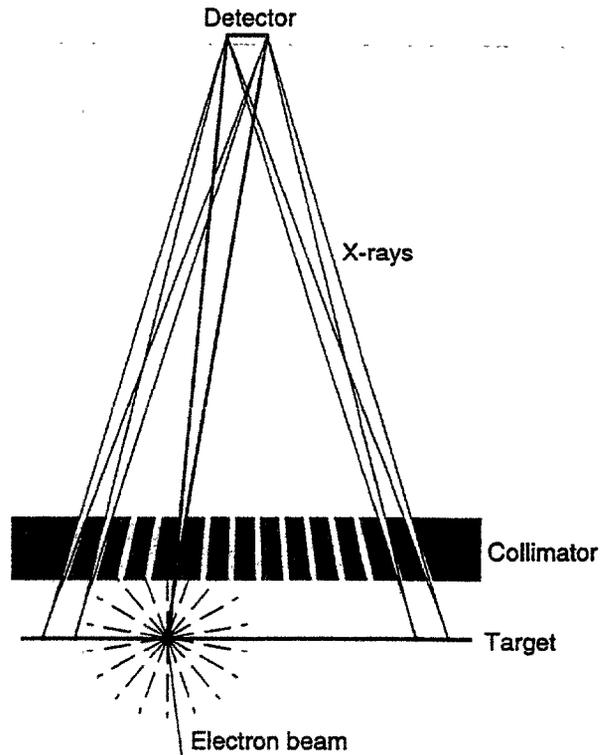


Figure 6 Beam Divergence through Collimator Holes

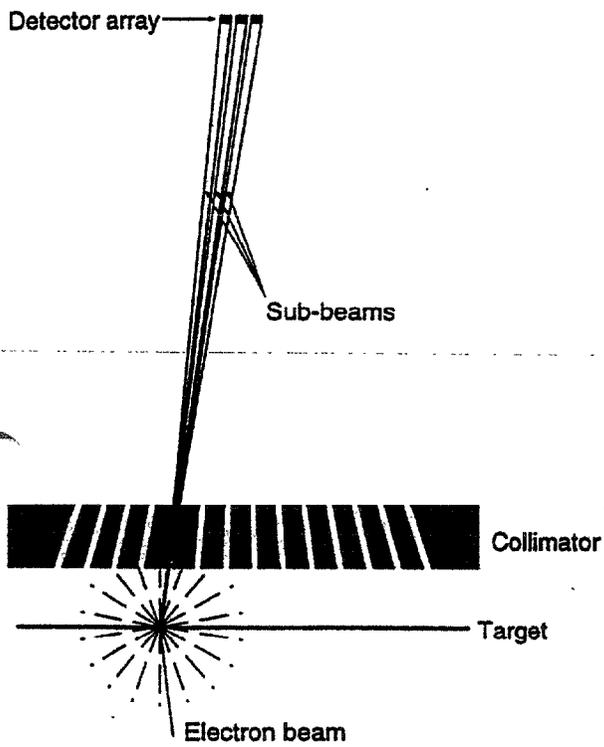


Figure 7 Detector Array Preserves Spatial Resolution by Breaking a Beam into Small Sub-Beams

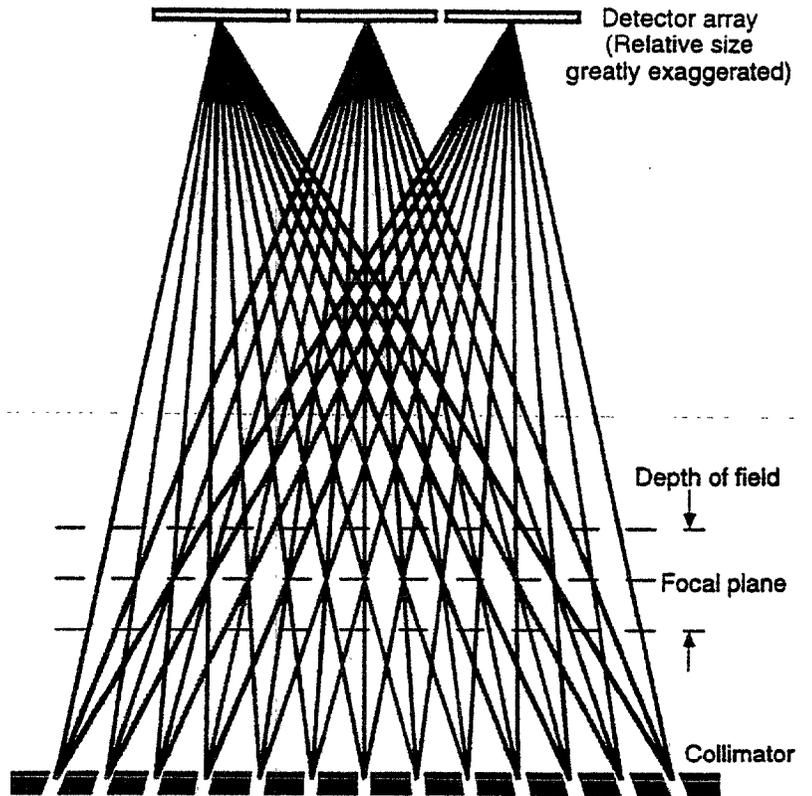


Figure 8 Image Reconstruction

Figure 9

C-Arm Fluoroscopic Exposure

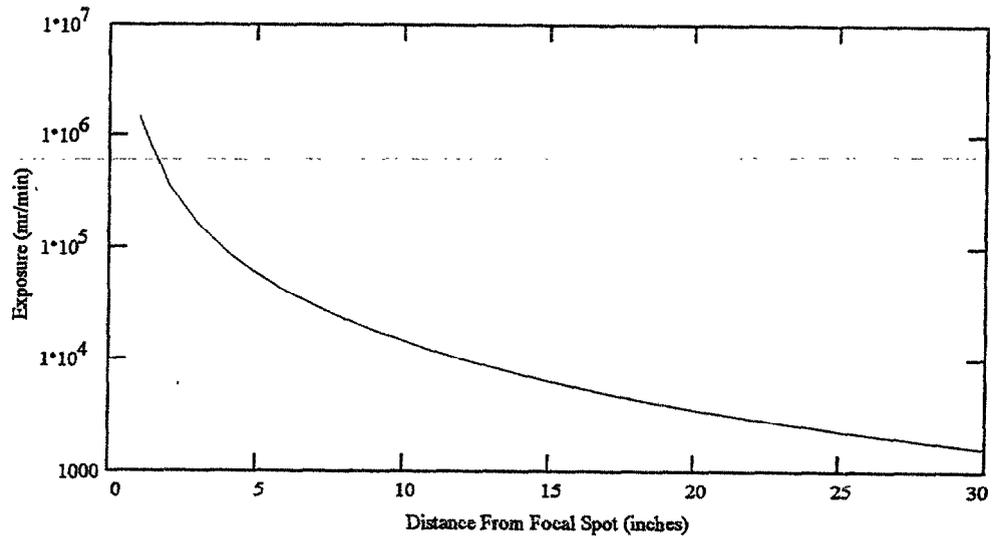


Figure 10

SBDX Fluoroscopic Exposure

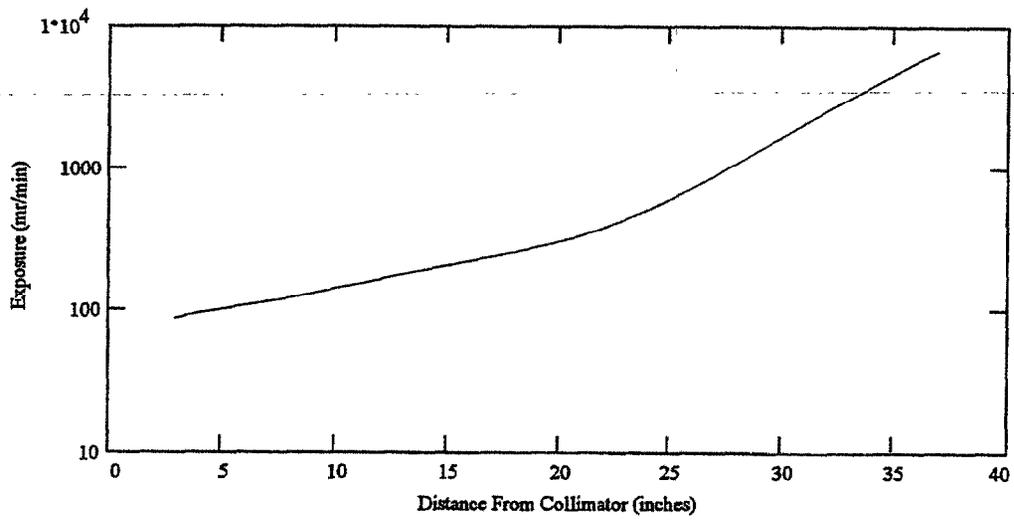


Figure 11

SBDX EXPOSURE
With 12" Water Phantom
Adjacent to Collimator

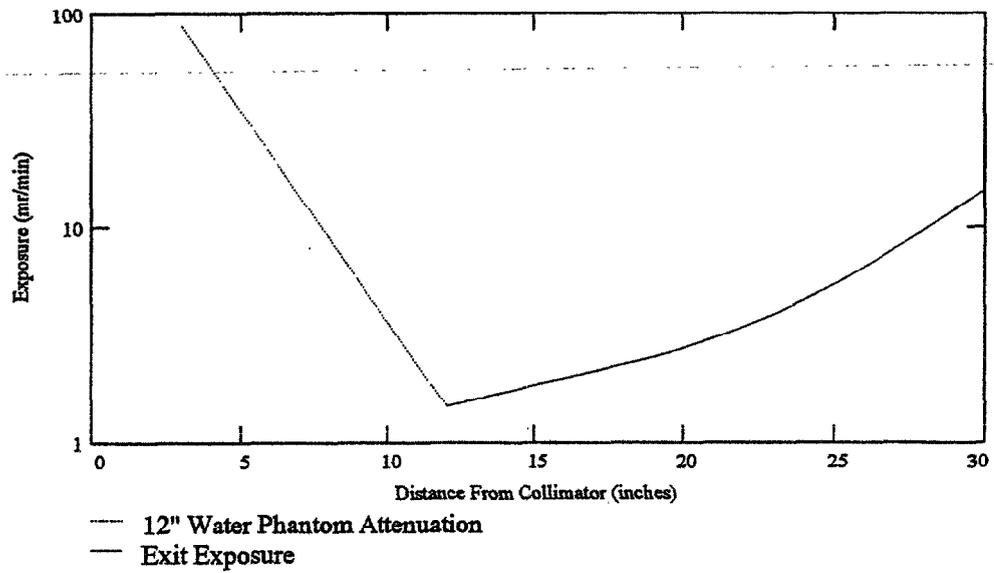
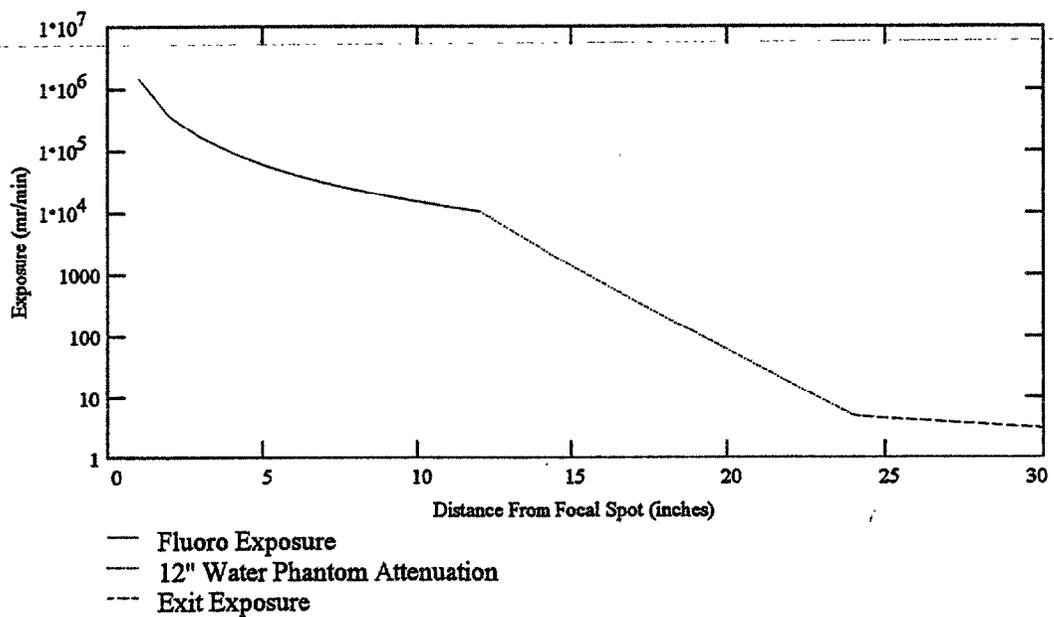


Figure 12

**Conventional C-Arm Exposure
with
12" Water Phantom**





MAR 29 1996

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850E. Boyd Floyd
Regulatory Affairs/QA
Cardiac Mariners, Inc.
120-B Albright Way
Los Gatos, CA 95030Re: K953113
Mobile Scanning Beam Digital X-Ray (SBDX) System
Dated: January 18, 1996
Received: January 19, 1996
Regulatory class: II
21 CFR 892.1650/Procode: 90 JAA

Dear Mr. Floyd:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug and Cosmetic Act (Act). You may therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you may have under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose, and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

June 30,1995

PMA Document Mail Center (HFZ-401).
Center for Devices and Radiological Health
U.S. Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

To Whom it May Concern:

In accordance with Subpart E of 21 CFR 807, Cardiac Mariners, Inc. of Los Gatos, CA is submitting this premarket [510(k)] notification of its intent to begin marketing a mobile fluoroscopy system. This data is organized as per the format described in 21 CFR 807.87.

- 1. **DEVICE NAME:** Image -Intensified Fluoroscopic X-ray System
COMMON NAME: Mobile C-Arm Fluoroscopy System
TRADE NAME: Mobile SBDX (Scanning Beam Digital X-ray) System
- 2. **CARDIAC MARINERS ESTABLISHMENT REGISTRATION NUMBER:** Initial Registration application will be submitted within 90 days.
MANUFACTURING LOCATION: Cardiac Mariners, Inc.; 120-B Albright Way; Los Gatos, CA 95030
- 3. **CLASSIFICATION:** CLASS II; 21 CFR 892.1650 (Classification by the Radiology Panel; Classification 90JAA)
- 4. **PERFORMANCE STANDARDS:** The Device and its labeling will comply with the standard for Radiological Health as detailed in 21 CFR Subchapter J; specifically:

- 1020.30(c) Certification of components
- 1020.30(e) Identification of x-ray components
- 1020.30(g) Information for assemblers
- 1020.30(h) Information for users
- 1020.30(j) Warning label
- 1020.30(k) Leakage radiation from source assembly
- 1020.30(l) Radiation from other than source assembly
- 1020.30(m) Beam quality
- 1020.32(a) Primary protective barrier
- 1020.32(b) Field limitation
- 1020.32(c) Activation of tube
- 1020.32(e) Entrance exposure rate limits
- 1020.32(f) Indication of tube potential and current
- 1020.32(g) *Variance Pending (Docket # 95V-0043/VAR 1; filed 2/21/95)*
- 1020.32(h) Fluoroscopic timer
- 1020.32(l) Mobile and portable fluoroscopes

Underwriters Laboratories, Inc. Standards UL 187 and UL 2601-1; specifically:

- | | |
|----------------------------|---------------------------------------|
| UL 187, Sections 5-20 | Electrical shock and fire |
| UL 187, Sections 21-31, 36 | Mechanical Safety and Stability |
| UL 187, Section 50 | Markings and Warnings |
| UL 2601-1, Section 3 | Protection Against Electrical Shock |
| UL 2601-1, Section 4 | Protection Against Mechanical Hazards |
| UL 2601-1, Section 10 | Constructional Requirements |

1. PERFORMANCE STANDARDS: (continued)

The required documents and reports will be provided to the appropriate oversight agency or organization to establish compliance with the applicable requirements as referenced above. ***The Cardiac Mariners, Inc. Mobile SBDX Scanning Beam Digital X-ray System will not be introduced into commerce until compliance with the standards referenced above has been certified.***

5. PROPOSED LABELING:

A) Device Characteristics

The scanning beam digital x-ray (SBDX) system is a C-arm based, low-dose, real-time digital x-ray system intended for general purpose fluoroscopic applications. The SBDX system has the same intended use as a conventional fluoroscope, but uses a different geometry. A large, distributed x-ray source replaces the conventional fluoroscope's point source, and one or more small detector arrays replace the large diameter image intensifier and camera. The large x-ray source is created by scanning a target with an electron beam. The target emits x-rays that are then passed through a collimator to allow only those directed at the detector to emerge.

The SBDX System consists of three separate units: the C-Arm Cart, the C-Arm Gantry Motion Control Stand, and the Operators Console. The C-Arm Cart houses the x-ray source and detectors. Gantry controls are located in the Motion Control Stand. The Operators Console contains the system computer, user input devices, and display monitors. Data and communication control is via fiber-optic cabling.

Please refer to Exhibit "A", the System Requirement Specification.

B) Software Version:

SBDX Application Software Version 1.X

C) Intended Use:

Intended use of the SBDX System is as a general purpose fluoroscopy system.

D) Proposed Labeling:

Labeling for the SBDX System is included in the Operators Manual; Exhibit "B". Please note that this is a Draft copy. No marketing literature has been developed at this time.

6. EQUIVALENCY INFORMATION

In the opinion of Cardiac Mariners, Inc., the Mobile SBDX System is of comparable type and substantially equivalent to currently marketed mobile C-arm fluoroscopy systems that comply with the same or equivalent standards and have the same intended uses. **[With exception as noted in pending Request for Variance; Docket # 95V-0043/VAR 1; filed 2/21/95, and included as Exhibit "C".]** Please refer to Exhibit "D", which includes comparisons and literature for systems currently marketed.

7. DETAILED DESCRIPTION

Note

Cardiac Mariners considers the following information proprietary and confidential.

A) X-ray Source and Collimator

The Cardiac Mariners Scanning Beam Digital X-Ray (SBDX) system is characterized by an x-ray source that is produced by raster scanning an electron beam (controlled by computer-generated beam deflection look-up tables) across a liquid-cooled target positioned behind a collimator. Please refer to Figures 1 and 2. The beam is produced by an electron gun operating between 70 kV / 60 mA and 100 kV / 30 mA. The target is 5 microns of tantalum on a 5 mm beryllium substrate, fixed in position 25.4 mm behind the exit surface of the collimator. The collimator is 12.7 mm thick and 25.4 cm in diameter. Located within this 25.4 cm diameter are approximately 22,000 holes, each with a diameter of 0.38 mm and spaced 1.52 mm center to center. The axis of each hole is pitched in order for each to point towards the detector, which is 94.5 cm from the source. Beam divergence is as illustrated in Figure 3.

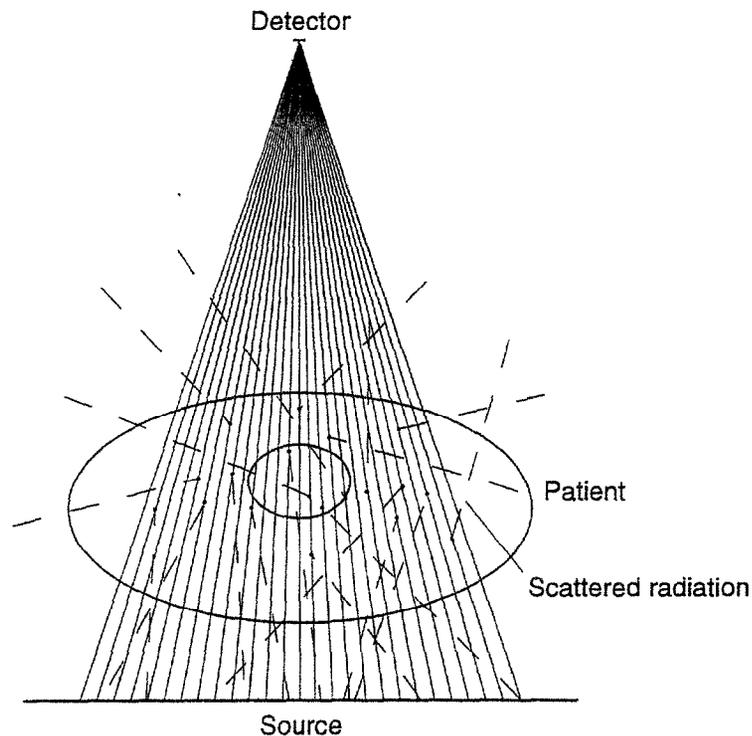


Figure 1. Scanning Beam Digital X-Ray System

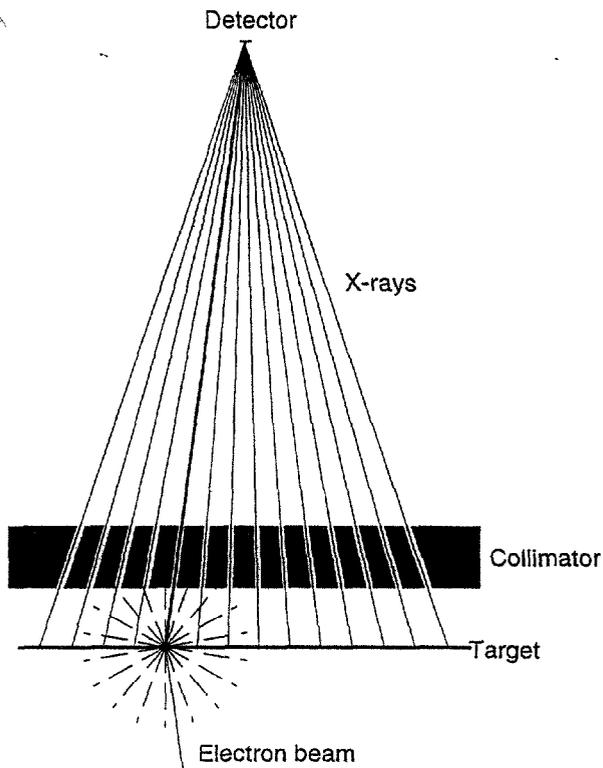


Figure 2. Scanning Beam X-Ray Source

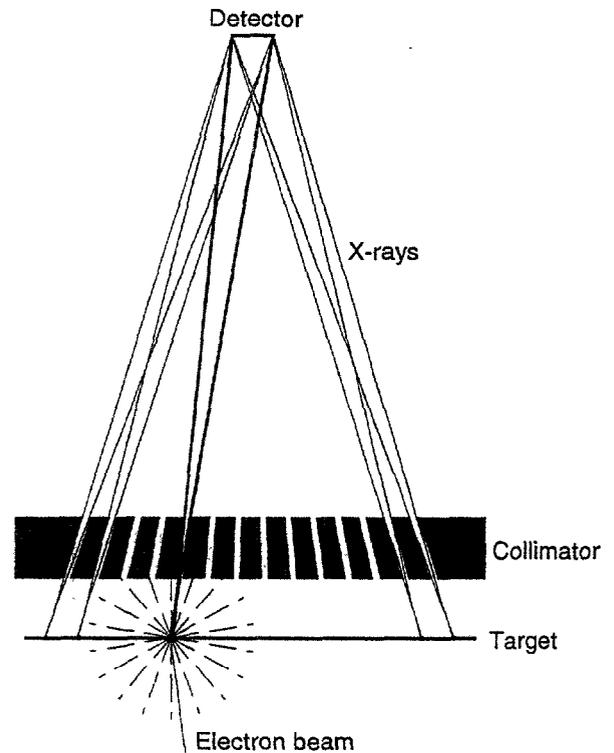


Figure 3. Beam Divergence through Collimator Holes

B) Detector

As mentioned above, the collimator holes have an 0.38 mm exit aperture 25.4 mm from the source, resulting in significant beam divergence. However, instead of a single detector, the SBDX system uses a two-dimensional array of 96 small detectors that can be thought of as breaking each beam emerging from a collimator hole into an array of smaller sub-beams, as shown in Figure 4. The outputs from the detector elements are then summed in a mathematical reconstruction algorithm shown graphically in figure 5, using all of the x-ray energy incident on the detector array to produce an image which has the spatial resolution corresponding to a single sub-beam. The two-dimensional detector array has a diameter of 1.8 cm and is made up of 96 scintillator crystals, located on 1.52 mm centers, optically coupled to a 96-channel photomultiplier tube. X-ray intensity is measured by counting x-ray photons, resulting in an image whose signal-to-noise ratio is determined almost entirely by quantum effects. The detector chain (scintillator, photomultiplier tube, and associated electronics) can discriminate single x-ray photons 20 keV or greater and count them up to a rate of approximately 10^7 photons per second. The scintillators are 2.0 mm thick and detect at least 90% of the incident x-ray photons, as compared to the approximately 50% that are stopped by a typical image-intensifier screen. This increased quantum efficiency of the SBDX detector system will reduce the required patient exposure by a factor of approximately 1.8; that is, 0.9/0.5.

The detector in the SBDX System is only 1.8 cm in diameter as compared to the 18 to 25 cm diameter of an image intensifier in a conventional fluoroscopy system, and is located further from the patient (the source of scatter radiation). This results in the SBDX detector seeing a scatter reduction of greater than 100-fold in comparison. Moreover, as the scatter has been virtually eliminated, there is no need for an anti-scatter grid.

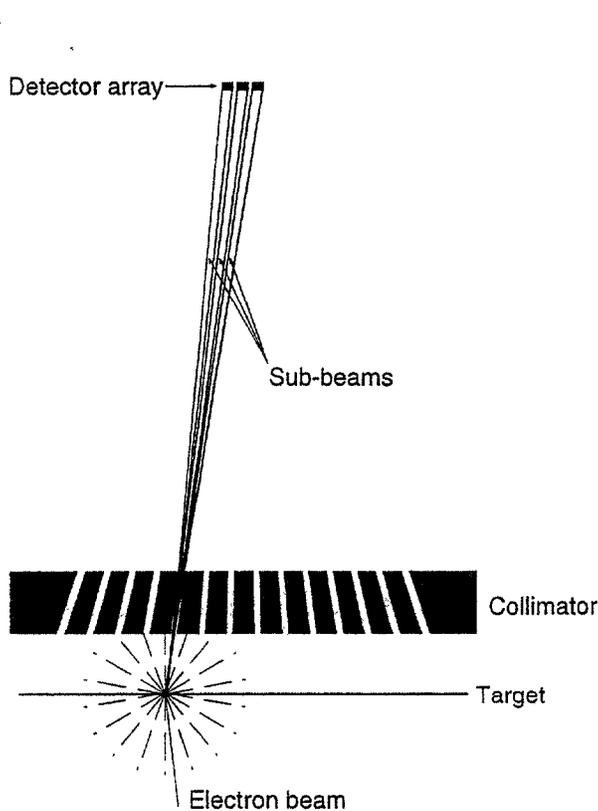


Figure 4. Detector Array Preserves Spatial Resolution by Breaking a Beam into Small Sub-Beams

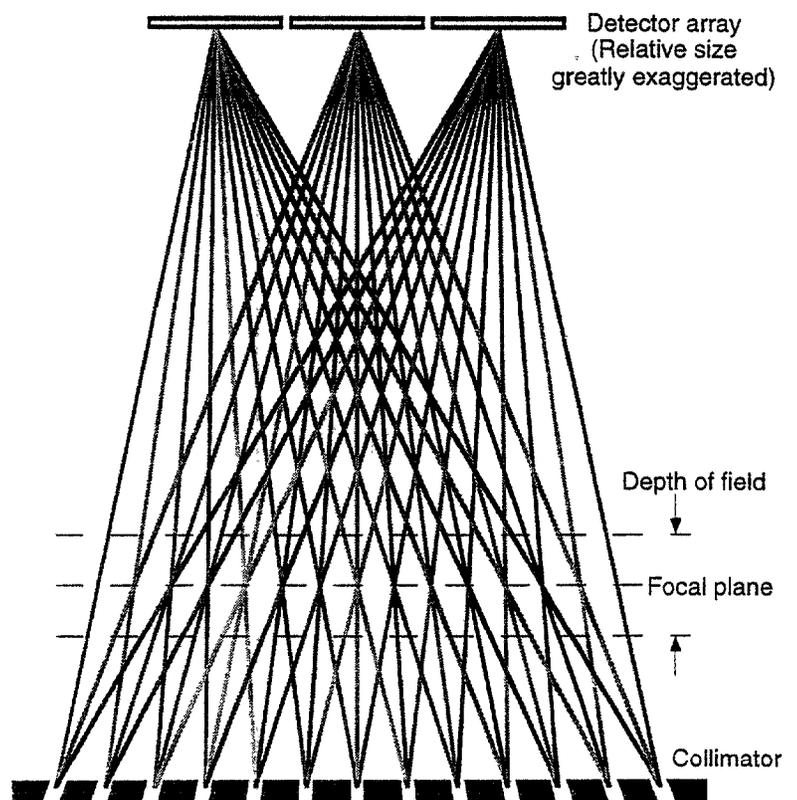


Figure 5. Image Reconstruction

C) *Reconstruction*

The image reconstruction hardware collects 96 data samples for each collimator hole illuminated, and performs the required reconstruction summation in real time to produce 500 x 500 pixel images at a 30 Hz frame rate. A key concept in the mathematical reconstruction is the creation of a plane of best focus. Again, please refer to Figure 5. The focal plane of the SBDX system is 24 cm from the source, has a field of view of 19 cm, and has a depth of field of approximately 7 cm. The system reconstructs 500 pixels across the 19 cm field of view and therefore has a pixel pitch of 0.38 mm in the focal plane. Objects at a distance from this plane are subject to tomographic blurring.

D) *Comparison of X-ray Flux from Conventional and SBDX Systems*

Conventional fluoroscopy systems operate at typically 70 kV and 2.5 mA for cardiac procedures. The SBDX system can operate at 70 kV and 60 mA; that is, at 24 times the power level. Assuming the source-detector distance is similar in the two systems, and since the beam emerging from any collimator hole illuminates a detector with a diameter of 1.8 cm as compared to (for example) an 18 cm image intensifier, the solid angle of the SBDX beam is only about 1/100th of that of a conventional image-intensifier-based system. Therefore, the increased power level of the SBDX source (24x) combined with the reduced solid angle of its output beam (1/100) results in the SBDX system producing only 24% of the flux of a conventional image-intensifier-based system. However, combined with a virtual elimination of scatter, an improved detector efficiency of approximately 1.8, and the elimination of the anti-scatter grid (a reduction factor of 1.5), there are still sufficient x-ray photons to build comparable 500 x 500 pixel images at a frame rate of 30 Hz.

E) *Summary of Exposure Reduction Comparison*

In summary, the four significant factors in the SBDX's exposure reduction are as follows:

1) Scattered Radiation:

The detection of scattered radiation results in a required increase in input flux by a factor equal to $1/(1-SF)$, where SF is the scatter fraction, in order to maintain signal-to-noise ratio in the face of decreased contrast. If the scatter ratio in a conventional image -- in the presence of an anti-scatter grid-- is assumed to be 0.5, then the exposure reduction of the SBDX will be 2x due to this factor.

2) Anti-Scatter Grid

If the primary transmission of an anti-scatter grid is assumed to be 66% , the exposure reduction for the SBDX will be 1.5x due to the absence of a grid.

3) Patient Entrance

If the diameter of the beam at the patient entrance of a 30 cm thick patient is assumed to be 14 cm for a conventional system with a 25.6 cm image intensifier; and that for the SBDX is 22 cm with a 25.6 cm source, then the exposure reduction for the SBDX will be $(22/14)^2$ squared; that is, 2.4 due to this factor.

4) Quantum Efficiency

If the quantum efficiency of the SBDX is assumed to be 0.9, and that of a conventional system is assumed to be 0.5, then the exposure reduction for the SBDX will be $0.9/0.5$; that is, 1.8 due to this factor.

5) Total Reduction Factor

The product of these exposure - reducing factors is nominally by a factor of approximately 13; that is, 2 (reduced scattered radiation) \times 1.5 (no grid) \times 2.4 (patient entrance) \times 1.8 (greater quantum efficiency).

Note

*Additional technical information is included in Exhibit "E", an extract from a Grant Application to the U.S. Public Health Service provided as **reference only**. Please refer to note on the Exhibit "E" cover sheet.*

F) *Implementation*

1) Hardware

The Cardiac Mariners, Inc. SBDX System comprises three separate mobile units; the C-arm Cart, the C-Arm Motion Control Stand, and the Operator's Console. Please refer to Exhibit "F", which includes a block diagram and dimensional drawings of the SBDX System; and Exhibit "G", the System Data Sheet.

The C-arm cart houses the x-ray source assembly, its power supplies, ion pump, control electronics and heat exchanger; the detector, photomultiplier tube, and image reconstruction engine; a powered positioning gantry and associated electronics; and various other control, sensor, and fail-safe modules.

Motion control devices for the C-Arm Gantry are located on the C-Arm Motion Control Stand, as is the Motion emergency off switch.

The Operator's Console contains the system control computer, tube controller, detector controller, user input devices, and both the system and image display monitors.

Data and control communication between the C-arm Cart and the Operator's Console is by means of optical fibers encased in a single cable. There are no electrical power connections between these two units.

2) Software

The SBDX System software comprises the Microsoft® Windows NT™ Operating System and the Cardiac Mariners Version 1.X Application software. The Application Software provides users capabilities to configure the system, control its operation, and manage the storage and output of imaging and other related data. It provides the following general capabilities:

- a) Configures and controls system hardware based upon user requests and internal system operational needs
- b) Monitors and tests the operational status of the system and its components

The software interacts with the hardware components in the system using the mechanisms provided by the Control Computer. User interaction is effected by a combination of on-screen graphics and dedicated controls. Please refer to Section 9 of this submittal for information regarding development and testing, and the Operators Manual included in Exhibit "B".

Note

*The Applications software does **not** control any mechanical motion of the SBDX C-Arm positioning gantry.*

3) Interlocks

The SBDX System includes hardware safety interlocks to prevent the occurrence of hazardous situations. System software is used only to verify the proper operation of these interlocks by simulating fault conditions and subsequently monitoring the system to ensure shutdown in the presence of these simulated faults. This method verifies the operational status of the interlocks and that there have been no "silent failures" in them. These tests commence upon system initialization and also at the request of the operator. Please refer to Exhibit "H" for the Fail-Safe Controller module specification.

8. SAFETY

There are no hazards inherent in the SBDX beyond those normally associated with this type of equipment. Please refer to the "Summary of Identified Hazards" in Exhibit "I", which identifies potential hazards and our approach to dealing with them.

9. SOFTWARE DEVELOPMENT AND VERIFICATION / VALIDATION PROCESS

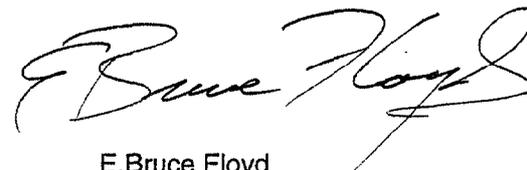
The Cardiac Mariners Software Development and System Verification Plans are included as Exhibits "J" and "K", respectively. Also, please see Software Certification attached to this submittal.

10. SAFETY AND EFFECTIVENESS STATEMENT

Data regarding the safety and effectiveness of the Mobile SBDX System will be made available to all interested parties upon written request to Cardiac Mariners, Inc. Please see 510(k) Statement certification appended to this submittal.

11. TRUTHFUL AND ACCURACY STATEMENT

I, E.Bruce Floyd, certify that, in my capacity as Regulatory Affairs/QA of Cardiac Mariners, Inc., I believe to the best of my knowledge that all data and information submitted in this premarket notification are truthful and accurate; and that no material fact has been omitted.



E. Bruce Floyd
Regulatory Affairs/QA
June 30, 1995

SOFTWARE CERTIFICATION

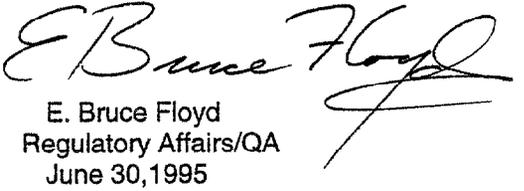
Cardiac Mariners, Inc. certifies that all stated procedures for the specification, design, development testing, and verification / validation of the SBDX System software will be strictly adhered to before commercial release of the product. Moreover, in the event of post-release (or post-distribution) discovery of any software problems ("bugs"), we will completely revalidate the affected software after the problem has been corrected.



E. Bruce Floyd
Regulatory Affairs / QA
June 30, 1995

**510 (K) STATEMENT
SAFETY AND EFFECTIVENESS DATA**

I certify that I, E. Bruce Floyd, Regulatory Affairs/QA of Cardiac Mariners, Inc, will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in this premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information as defined in 21 CFR 20.61.


E. Bruce Floyd
Regulatory Affairs/QA
June 30, 1995

SEP 1 1998

Rockville MD 20850

E. Bruce Floyd
Regulatory Affairs/Quality Assurance
Cardiac Mariners, Inc.
120-B Albright Way
Los Gatos, California 95030

Re: K982345
Vasco Scanning Beam
Dated: June 26, 1998
Received: July 6, 1998
Regulatory Class: II
21 CFR 892.1650/Procode 90 JAA

Dear Mr. Floyd:

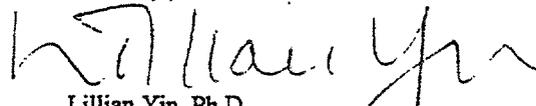
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Intended Use
Cardiac Mariners, Inc.

1702-11

VASCO SYSTEM

The Cardiac Mariners, Inc. VASCO scanning beam digital x-ray System is indicated for use in generating real time fluoroscopic images in patients where medically indicated.

David G. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K982345

PRESCRIPTION USE ✓
(PER 21 CFR 801.109)

Cardiac Mariners, Inc.

June 26, 1998

PMA Document Mail Center (HFZ-401).
Center for Devices and Radiological Health
U.S. Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

To Whom it May Concern:

Submitted herewith is a premarket [510(k)] notification of Cardiac Mariners, Inc., intent to market an image-intensified fluoroscopy system, the VASCO Scanning Beam Digital X-ray System. Two copies of descriptive data in the format prescribed by 21 CFR 807.87 are included. There is no clinical data requirement.

Please note that Cardiac Mariners, Inc., considers the information included in the "Detailed Description" of this submittal as confidential commercial information as defined in 21 CFR 20.61.

If there are any questions regarding this submittal, please contact the undersigned at (408) 364-8603 (direct line) or (408) 379-6600.

Sincerely,



E. Bruce Floyd
Regulatory Affairs / QA

**120-B Albright Way
Los Gatos, CA 95030
Tel: (408) 364-8603
Fax: (408) 379-6601**

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EXHIBITS

EXHIBIT A: SYSTEM REQUIREMENTS SPECIFICATION
EXHIBIT B: OPERATORS MANUAL (DRAFT)
EXHIBIT C: VASCO MARKETING LITERATURE
EXHIBIT D: SBDX VARIANCE (REFERENCE)
EXHIBIT E: PREDICATE DEVICE COMPARISON
EXHIBIT F: SYSTEM DESIGN SPECIFICATION SUMMARY
EXHIBIT G: SYSTEM BLOCK DIAGRAM & DIMENSIONAL DRAWINGS
EXHIBIT H: SYSTEM DATA SHEET
EXHIBIT I: FAIL-SAFE CONTROLLER SPECIFICATION
EXHIBIT J: HAZARDS SUMMARY
EXHIBIT K: SOFTWARE DEVELOPMENT PLAN
EXHIBIT L: SYSTEM VERIFICATION PLAN
EXHIBIT M: VASCO SOFTWARE ARCHITECTURE

June 26, 1998

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

To Whom it May Concern:

In accordance with Subpart E of 21 CFR 807, Cardiac Mariners, Inc. of Los Gatos, CA is submitting this premarket [510(k)] notification of its intent to begin marketing a fluoroscopy system. This data is organized as per the format described in 21 CFR 807.87.

1. DEVICE NAME: Image -Intensified Fluoroscopic X-ray System
COMMON NAME: Fluoroscopy System
TRADE NAME: VASCO Scanning Beam Digital X-ray System ("VASCO")

2. CARDIAC MARINERS ESTABLISHMENT REGISTRATION NUMBER: Initial Registration application will be submitted prior to commencement of production.

MANUFACTURING LOCATION: Cardiac Mariners, Inc.; 120-B Albright Way; Los Gatos, CA 95030

3. CLASSIFICATION: CLASS II; 21 CFR 892.1650 (Classification by the Radiology Panel; Classification 90JAA)

4. PERFORMANCE STANDARDS: The Device and its labeling will comply with the standard for Radiological Health as detailed in 21 CFR Subchapter J; specifically:

1020.30(c)	Certification of components
1020.30(e)	Identification of x-ray components
1020.30(g)	Information for assemblers
1020.30(h)	Information for users
1020.30(j)	Warning label
1020.30(k)	Leakage radiation from source assembly
1020.30(l)	Radiation from other than source assembly
1020.30(m)	Beam quality
1020.32(a)	Primary protective barrier
1020.32(b)	Field limitation
1020.32(c)	Activation of tube
1020.32(e)	Entrance exposure rate limits
1020.32(f)	Indication of tube potential and current
1020.32(g)	<i>Will seek Variance as per 21 CFR 1010.4</i>
1020.32(h)	Fluoroscopic timer

Underwriters Laboratories, Inc. Standards UL 187 and UL 2601-1; specifically:

UL 187, Sections 5-20	Electrical shock and fire
UL 187, Sections 21-31, 36	Mechanical safety and stability
UL 187, Section 50	Markings and warnings
UL 2601-1, Section 3	Protection against electrical shock
UL 2601-1, Section 4	Protection against mechanical hazards
UL 2601-1, Section 10	Constructional requirements

4. PERFORMANCE STANDARDS: (continued)

The required documents and reports will be provided to the appropriate oversight agency or organization to establish compliance with the applicable requirements as referenced above. ***The Cardiac Mariners, Inc. VASCO Scanning Beam Digital X-ray System will not be introduced into commerce until compliance with the standards referenced above has been certified.***

5. PROPOSED LABELING:

A) *Device Characteristics*

The VASCO Scanning Beam Digital X-ray System ("VASCO System") is a C-arm based, low-dose, real-time digital x-ray system intended for real-time fluoroscopic applications where medically indicated. The VASCO System has the same intended use as a conventional fluoroscope, but uses a different geometry. A large, distributed x-ray source replaces the conventional fluoroscope's point source, and a small detector array replaces the large diameter image intensifier and camera. The large x-ray source is created by scanning a target with an electron beam. The target emits x-rays that are then passed through a collimator to allow only those directed at the detector to emerge.

The Cardiac Mariners, Inc. VASCO System comprises the following units: the C-arm and pedestal unit, the electronics equipment cabinets, a heat exchanger, a patient table, a power distribution/ isolation transformer, and requisite controllers, monitors, and parameter displays. Please refer to Exhibit "A", the VASCO System Requirement Specification.

B) *Software Version:*

VASCO Application Software Version 1.X

C) *Intended Use:*

The VASCO System is indicated for use in generating real time fluoroscopic images in patients where medically indicated. Please see attachment with this intended use statement.

D) *Proposed Labeling:*

Labeling for the VASCO System is included in the Operators Manual; Exhibit "B". Please note that this is a Draft copy. Marketing literature is included in Exhibit "C".

6. EQUIVALENCY INFORMATION

In the opinion of Cardiac Mariners, Inc., the VASCO Scanning Beam Digital X-ray system is of comparable type and substantially equivalent to currently marketed C-arm fluoroscopy systems that comply with the same or equivalent standards and have the same intended uses; and specifically, **the Cardiac Mariners, Inc. SBDX System, previously cleared for marketing by the FDA on March 29, 1996 [510(k) 953113]**. As with the *SBDX System*, Cardiac Mariners will seek a variance for the source-to-skin provision [21 CFR 1032(g)] of Subchapter J. For the *SBDX System*, this variance was granted in Docket # 95V-0043/VAR 1 (August 22, 1995). A copy of this variance is included in Exhibit "D" for reference purposes. The variance request for the VASCO System will be comparable in substance.

Please refer to Exhibit "E", which includes comparisons and literature for systems currently marketed.

7. DETAILED DESCRIPTION

Note

Cardiac Mariners considers the following information proprietary and confidential.

Please refer to Exhibit "F", the VASCO System Design Specification Summary, for the following discussion.

A) X-ray Source and Collimator

The Cardiac Mariners Scanning Beam Digital X-ray (VASCO) System has a source which produces x-rays by stepping an electron beam across a planar target positioned behind a converging collimator. Refer to Figures 1 and 2 for illustrations of this principle. The beam is produced by an electron gun operating between 70 kV / 126 mA avg and 120 kV / 74 mA avg and is deflected by look-up tables which control magnetic coils. The target is 12 microns of tungsten and 10 microns of niobium on a 5-mm beryllium substrate. The collimator is 43.5 mm thick with the collimator entrance located 6.5 mm from the target layer and the collimator exit located at 50 mm from the target layer. Cooling water flows in 1.5-mm channel between the beryllium substrate and the collimator to remove heat produced in the target. The collimator is 25.4 cm in diameter and has approximately 10,000 holes on a rectangular grid, each with an exit diameter of 1.90 mm and spaced 2.2 mm center-to-center at the collimator exit. The axis of each hole is aligned with the center of the detector which is 150 cm from the target. Beam divergence is illustrated in Figure 3.

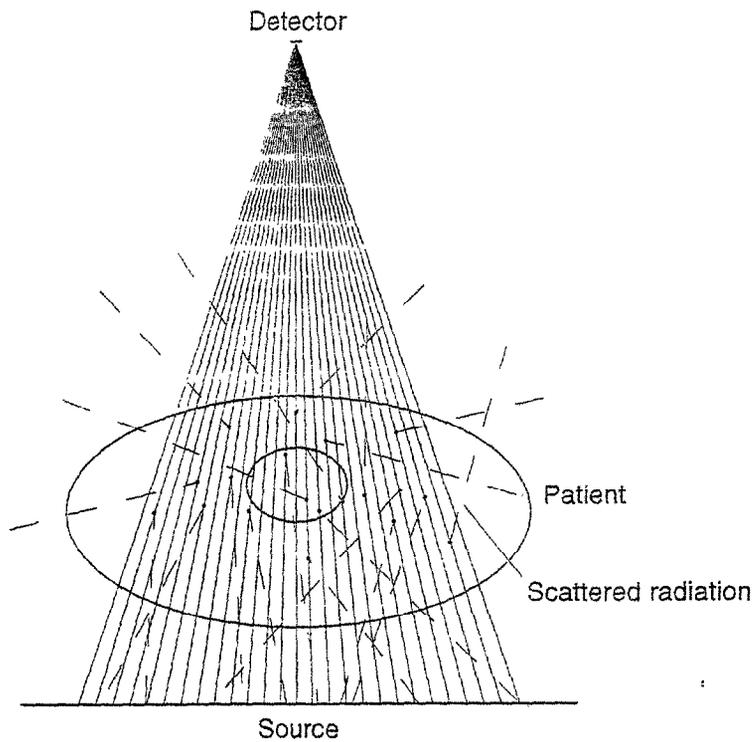


Figure 1. Scanning Beam Digital X-ray System

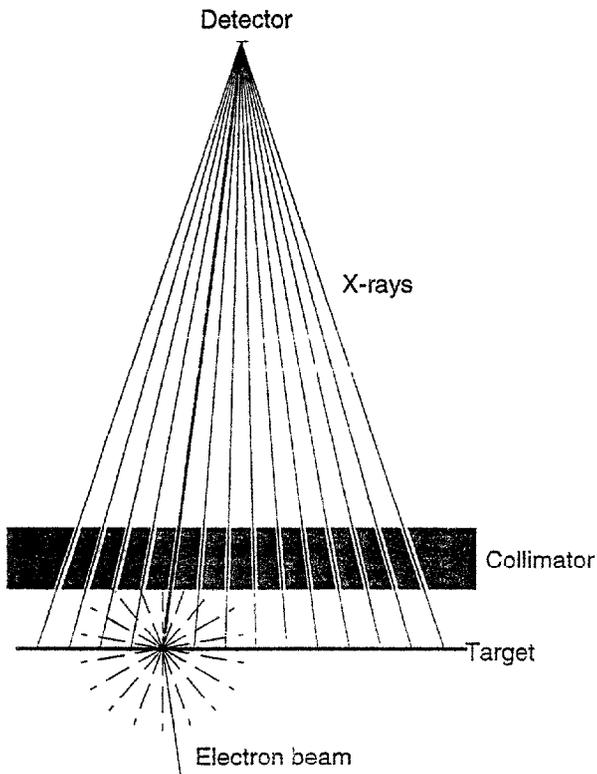


Figure 2. Scanning Beam X-ray Source

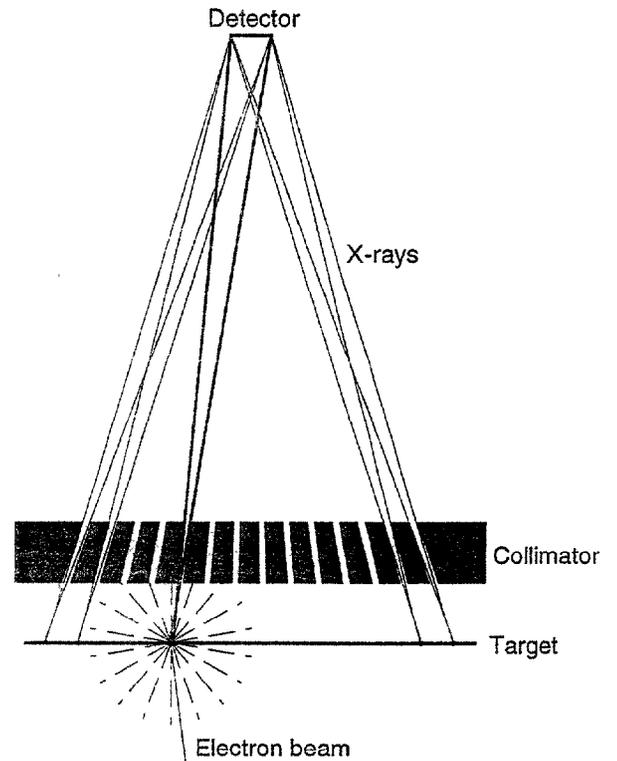


Figure 3. Beam Divergence through Collimator Holes

B) Detector

The VASCO System has a 54-mm square x-ray detector with 2304 photon-counting detector elements arranged in an array of 48 x 48 detector elements on a 1.125-mm rectangular pitch. Each 1.125-mm square detector element is subdivided into an array of 5 x 12 sub-elements. The sub-elements are binary x-ray detectors and the detector sub-element outputs are summed together to produce the photon-count for each detector element.

The x-ray detector is fabricated as 16 sensor hybrids arranged in a 4 x 4 pattern. Each sensor hybrid contains an array of 12 x 12 detector elements. These hybrids comprise a cadmium-telluride based tile with pixilated electrode pattern bump-bonded to an integrated circuit containing an amplifier and discriminator for each of the detector sub-elements.

Each element of the detector counts the number of x-ray photons striking it during the period the x-ray source delivers photons through a given collimator hole. The sensor array is connected to the detector processor which transmits the number of detected photons for each collimator hole to the imaging sub-system. Since each collimator hole may be illuminated more than once for each image frame, the detector processor sums the photon counts for each collimator hole / detector-element pair in a local memory before transmitting it to the imaging sub-system.

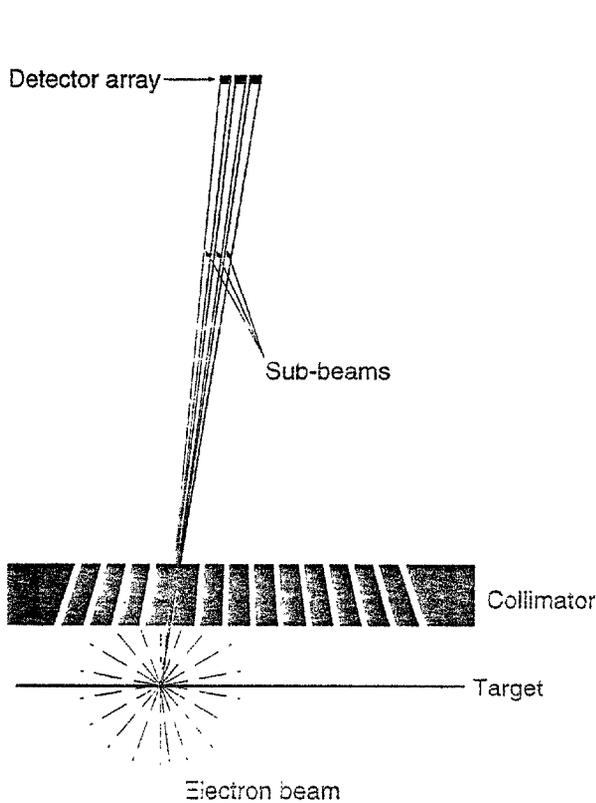


Figure 4. Detector Array Preserves Spatial Resolution by Breaking a Beam into Small Sub-Beams

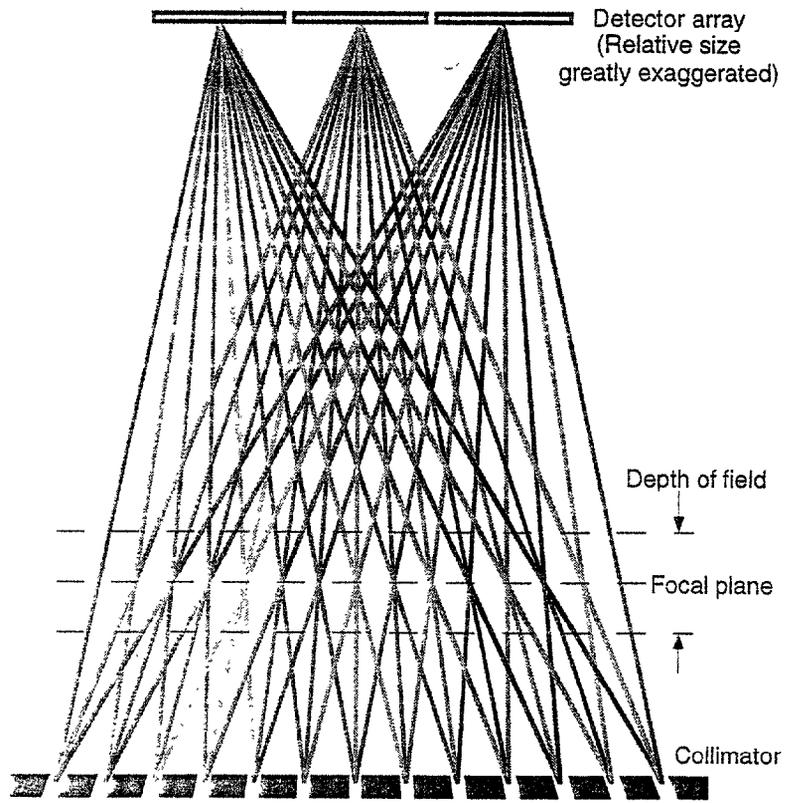


Figure 5. Image Reconstruction

C) Imaging Geometry

The x-ray source and detector are mounted on a C-arm with the x-ray detector at a fixed 1.500-m distance from the target layer of the x-ray source. The C-arm has two angular degrees of movement. The mechanical isocenter is at 0.450 m from the target layer of the x-ray source.

D) Reconstruction

The image-reconstruction hardware collects 2304 (48 x 48) data samples for each collimator hole illuminated. Using standard tomosynthesis techniques, the Vasco System calculates up to 16 simultaneous 1000 x 1000 pixel tomographic slices in each 33 ms period. The slices are spaced approximately 1.25 cm apart, and are evenly distributed around the mechanical isocenter of the gantry in order to cover the volume of interest. The field of view is 17.8 cm at isocenter. The multiple tomograms are combined to produce conventional 1000 x 1000 pixel projection images at a 30 Hz frame rate by combining areas from each tomogram which contain in-focus objects.

E) Summary of Exposure Reduction Comparison

In summary, the four significant factors in the VASCO System's exposure reduction are as follows:

1) Scattered Radiation

The detection of scattered radiation results in a required increase in input flux by a factor equal to $1/(1-SF)$, where SF is the scatter fraction, in order to maintain signal-to-noise ratio in the face of decreased contrast. If the scatter ratio in a conventional image -- in the presence of an anti-scatter grid-- is assumed to be 0.5, then the exposure

E) Summary of Exposure Reduction Comparison (continued)

reduction of the VASCO will be 2x due to this factor.

2) Anti-Scatter Grid

If the primary transmission of an anti-scatter grid is assumed to be 66%, the exposure reduction for the VASCO will be 1.5x due to the absence of a grid.

3) Patient Entrance

If the diameter of the beam at the patient entrance of a 30 cm thick patient is assumed to be 14 cm for a conventional system with a 25.6 cm image intensifier; and that for the VASCO is 22 cm with a 25.6 cm source, then the exposure reduction for the VASCO will be $(22/14)^2$ squared; that is, 2.4 due to this factor.

4) Quantum Efficiency

If the quantum efficiency of the VASCO is assumed to be 0.9, and that of a conventional system is assumed to be 0.5, then the exposure reduction for the VASCO will be $0.9/0.5$; that is, 1.8 due to this factor.

5) Total Reduction Factor

The product of these exposure - reducing factors is nominally by a factor of approximately 13; that is, 2 (reduced scattered radiation) x 1.5 (no grid) x 2.4 (patient entrance) x 1.8 (greater quantum efficiency).

F) Implementation

1) Hardware

The VASCO System comprises the following units: the C-arm and pedestal unit, three electronics equipment cabinets, a heat exchanger, a patient table, a power distribution/ isolation transformer, and requisite controllers, monitors, and parameter displays. Please refer to Exhibit "G", which includes a block diagram and dimensional drawings of the VASCO System; and Exhibit "H", the VASCO System Data Sheet.

The C-arm and pedestal houses the x-ray source assembly, the detector, beam deflection control electronics, and motion control circuitry. The electronics cabinets include the control computer, the high voltage power supply and controller, the imaging sub-system, the fail-safe controller/input-output controller and other requisite electronic assemblies. The patient table includes the motion control operator devices for the C-Arm. Ceiling-mounted monitors and parameter displays will display images and operational information. Control room units include the computer keyboard and mouse, x-ray parameter controller, operators monitor, and imaging controls.

2) Software

The VASCO System software comprises the Microsoft® Windows NT™ Operating System and the Cardiac Mariners Version 1.X Application software. The Application Software provides users capabilities to configure the system, control its operation, and manage the storage and output of imaging and other related data. It provides the following general capabilities:

- a) Configures and controls system hardware based upon user requests and internal system operational needs
- b) Monitors and tests the operational status of the system and its components

The software interacts with the hardware components in the system using the mechanisms provided by the Control Computer. User interaction is effected by a combination of on-screen graphics and dedicated controls. Please refer to Section 9 of this submittal for information regarding development and testing, and the Operators Manual

F) Implementation (continued)

included in Exhibit "B".

Note

The Applications software does **not** control any mechanical motion of the VASCO C-Arm positioning gantry.

3) Interlocks

The VASCO System includes hardware safety interlocks to prevent the occurrence of hazardous situations. System software is used to verify the proper operation of these interlocks by simulating fault conditions and subsequently monitoring the system to ensure shutdown in the presence of these simulated faults. This method verifies the operational status of the interlocks and that there have been no "silent failures" in them. These tests commence upon system initialization and also at the request of the operator. Please refer to Exhibit "I" for the Fail-Safe Controller specifications. Note that this circuitry is integrated into the I/O Controller Assembly.

8. SAFETY

There are no hazards inherent in the VASCO System beyond those normally associated with this type of equipment. Please refer to the "Summary of Identified Hazards" in Exhibit "J", which identifies potential hazards and the approach to dealing with them.

9. SOFTWARE DEVELOPMENT AND VERIFICATION / VALIDATION PROCESS

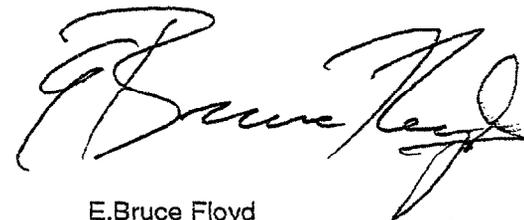
The Cardiac Mariners Software Development Plan, System Verification Plan, and VASCO Software Architecture are included as Exhibits "K", "L", and "M" respectively. Also, please see the Software Certification attached to this submittal. Although the Plans refer to the SBDX System, our procedural approach remains unchanged for development of the VASCO System.

10. SAFETY AND EFFECTIVENESS STATEMENT

Data regarding the safety and effectiveness of the VASCO System will be made available to all interested parties upon written request to Cardiac Mariners, Inc. Please see 510(k) Statement Certification appended to this submittal.

11. TRUTHFUL AND ACCURACY STATEMENT

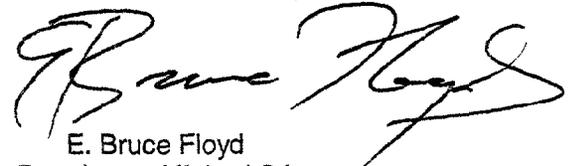
I, E.Bruce Floyd, certify that, in my capacity as Director, Regulatory Affairs/QA of Cardiac Mariners, Inc., I believe to the best of my knowledge that all data and information submitted in this premarket notification are truthful and accurate; and that no material fact has been omitted.



E. Bruce Floyd
Regulatory Affairs/QA
June 26, 1998

SOFTWARE CERTIFICATION

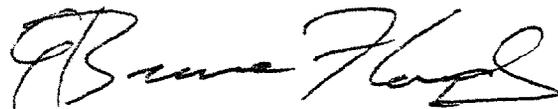
Cardiac Mariners, Inc. certifies that all stated procedures for the specification, design, development testing, and verification / validation of the VASCO System software will be strictly adhered to before commercial release of the product. Moreover, in the event of post-release (or post-distribution) discovery of any software problems ("bugs"), we will completely revalidate the affected software after the problem has been corrected.



E. Bruce Floyd
Regulatory Affairs / QA
June 26, 1998

**510 (K) STATEMENT
SAFETY AND EFFECTIVENESS DATA**

I certify that I, E. Bruce Floyd, Director, Regulatory Affairs/QA of Cardiac Mariners, Inc, will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in this premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information as defined in 21 CFR 20.61.



E. Bruce Floyd
Regulatory Affairs/QA
June 26, 1998

**Statement of Intended Use
Cardiac Mariners, Inc.**

VASCO SYSTEM

The Cardiac Mariners, Inc. VASCO scanning beam digital x-ray System is indicated for use in generating real time fluoroscopic images in patients where medically indicated.

EXHIBIT E

**PREDICATE DEVICE
COMPARISON DATA**

PREDICATE DEVICE COMPARISON TABLE

Manufacturer / Model	Cardiac Mariners VASCO	Cardiac Mariners SBDX
510 (k) Number		K953113
X-Ray Source:	Digital Scanning Beam	Digital Scanning Beam
Maximum output @ 208 V	74 mA @ 120 kVp	30mA @ 100 kVp
Heat Capacity	N/A; Rated for continuous operation with direct cooling of target	N/A; Rated for continuous operation with direct cooling of target
Focal spot size in mm (fluoro mode)	0.3	0.3
X-Ray Generator: (Fluoro Mode)	UVC™ High Frequency	Spellman™ SR6™ High Freq.
kV Range	70 kVp to 120 kVp	70 kVp to 120 kVp
mA Range (average)	74 mA to 126 mA	30 mA to 60 mA
Pulsed Fluoro	No	No
AEC	Yes	Yes
Image Intensifier:	Detector array; 10 inch FOV at source	Detector array; 10 inch FOV at source
Image Processing and Storage:		
Image Storage Capacity	Digital 3600	Digital (Optional) 3600
Image matrix size	1000 x 1000	512 x 512
Last-image Hold	Yes	Yes
C-Arm Gantry:		
Angulation	+ or - 45° from vertical	+ or - 45° from vertical
Rotation	120° RAO to 120° LAO	120° RAO to 120° LAO
HxWxD of C-Arm and pedestal (inches)	89x32x78	80x33x78
Weight	1000 lbs max.	1400 lbs max.
Power requirements	58A @208 VAC	30A @ 220 VAC 15 A @ 115 VAC

**RESTATED ARTICLES OF INCORPORATION
OF CARDIAC MARINERS, INC.,
a California Corporation**

ENDORSED - FILED
in the office of the Secretary of State
of the State of California

APR 07 2000

BILL JONES, Secretary of State

The undersigned, Marc C. Whyte, hereby certifies that:

- (1) He is the duly elected and acting President and Secretary of said corporation.
- (2) The Articles of Incorporation of said corporation shall be amended and restated to read in full as follows:

ARTICLE I

The name of this corporation is NexRay, Inc.

ARTICLE II

The purpose of this corporation is to engage in any lawful act or activity for which a corporation may be organized under the General Corporation Law of California other than the banking business, the trust company business or the practice of a profession permitted to be incorporated by the California Corporations Code.

ARTICLE III

A. Classes of Stock. This corporation is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares of Common Stock that this corporation is authorized to issue is Five Hundred Million (500,000,000), no par value, and the total number of shares of Preferred Stock that this corporation is authorized to issue is Three Hundred Million (300,000,000), no par value.

B. Rights, Preferences and Privileges of Preferred Stock. The Preferred Stock may be issued from time to time in series. There shall initially be one series of Preferred Stock designated and known as Series A Preferred Stock (hereinafter referred to as the "Series A Stock") The Series A Stock shall consist of Three Hundred Million (300,000,000) shares.

The Board of Directors is hereby authorized to fix or alter the rights, preferences, privileges and restrictions granted to or imposed upon additional series of Preferred Stock, and the number of shares constituting any such series and the designation thereof, or any of them. Subject to compliance with applicable protective voting rights which have been or may be granted to Preferred Stock or series thereof in Certificates of Determination or the corporation's Articles of Incorporation ("Protective Provisions"), but notwithstanding any other rights of any series of Preferred Stock, the rights, privileges, preferences and restrictions of any such additional series may be subordinate to, pari passu with (including, without limitation, inclusion