



GE Medical Systems

OEC

GE OEC Medical Systems, Inc.
General Electric Company
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<http://www.ge.com/medicalsystems> 8878 '00 OCT 23 A9:56

October 18, 2000

Documents Management Branch (HFA-305)
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re: Variance Application

Attention: Documents Manager

In accordance with 21 CFR 1010.4, GE OEC Medical Systems hereby submits application for a variance from the source-skin distance requirement of the performance standard for fluoroscopic equipment [21 CFR1020.32(g)], as it applies to the *Miniview Mobile C-arm* (Formerly *Mini 6800* under 510(k) No. K992506).

The following information is provided in support of this application:

1. The Miniview Mobile C-arm (hereafter called Miniview), manufactured by GE OEC Medical Systems, is a small C-arm configuration, image-intensified fluoroscopic system. The Miniview is intended to provide the physician with fluoroscopic visualization of the patient during surgical orthopedic procedures and extremity examinations.

A summary of relevant Miniview specifications is provided as follows:

Monoblock X-ray Tube/ Generator	
High Voltage Range	40 to 80 kVp
Tube Current Range	20 to 160 μ A (0.020 to 0.160 mA)
Automatic Dose Rate Control	Normal and Low Dose settings
Entrance Exposure Rate (max.)	2.3 R/minute @ 20 cm SSD (with spacer) 9.0 R/minute @ 10 cm SSD (minimum)
Focal Spot	0.050 mm
Collimator	Circular two-position for selected field of view
Image Intensifier	Dual mode, 4/6-inch field of view
Source-Image Distance	45 cm (fixed)

OOP-1577

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2. Like the other commercially available mini C-arms (FluoroScan, Lunar, and GE OEC 6600), the Miniview offers a compact and economical imaging system that is well suited for orthopedic surgery and diagnostic examination of both the upper and lower extremities.

These surgical applications require that the open area between the x-ray head and the image intensifier be large enough to allow the physician to manipulate surgical tools (30-38 cm). This is not possible if the minimum source-skin distance (SSD) is limited to that required by the performance standard, i.e. 30 centimeters for mobile fluoroscopes or 20 centimeters for fluoroscopes intended for specific applications.

3. The Miniview deviates from the performance standard by providing a minimum SSD less than 20 centimeters as required for fluoroscopes intended for specific applications.

GE OEC proposes that the Miniview provide SSD not less than:

- 20 centimeters with the removable spacer attached to the x-ray head,
 - 10 centimeters with the spacer removed for surgical procedures as determined by the physician.
4. A reduction in the minimum SSD allows the Miniview to utilize a relatively short source-image distance (SID) of 45 centimeters. Consequently, the x-ray technique factors necessary to produce high quality diagnostic images are proportionately lower than those employed by a conventional fluoroscope (with 100 centimeter SID). For example, the x-ray tube current range of the Miniview is 0.020 to 0.160 mA (20-160 μ A) compared to 0.2 to 5.0 mA, typical of a conventional mobile C-arm. This results in comparable entrance dose rates when the patient anatomy is positioned as close as possible to the image intensifier. The table below shows the Miniview dose rates are actually lower for the same extremity examination when compared to either the GE OEC Series 9800 conventional C-arm or the GE OEC Mini 6600 C-arm (also see Attachment A).

Six-inch Field Dose Rates (mR/min)

Extremity	Thickness (cm)	Series 9800	Mini 6600	Miniview
Hand	3.40	137	53	44
Wrist	4.45	140	61	46
Forearm	5.38	172	56	51
Foot (lateral)	6.91	212	100	74
Foot (AP)	7.95	219	105	77
Ankle	7.29	264	108	88
Knee (lateral)	10.24	380	218	165
Knee (AP)	10.33	373	189	175
Shoulder	13.20	818	820	301

The 45 centimeter SID of the Miniview, like that of other commercially available mini C-arms, results in 35 centimeters of working space is when the skin spacer is removed for surgical procedures as determined by the physician. The working space is reduced to 25 centimeters with the skin spacer attached to the x-ray head for routine extremity examinations.

5. Suitable means of radiation protection is provided by constraints on the design and supplemental information provided to users.

The minimum SSD of 10 centimeters is established by the collimator enclosure that is permanently attached to the x-ray tube housing. The SSD increases to 20 centimeters with the skin spacer attached to the x-ray head. Prototype testing shows maximum dose rates to be around 8 R/minute at the 10 centimeter minimum SSD¹ (see Attachment B).

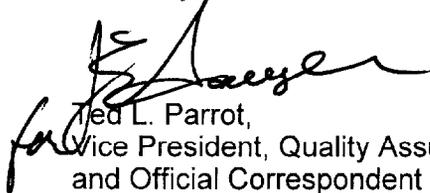
The user manuals contain supplemental information and precautions that may be necessary because of the shortened SSD.

The product labeling specifies that the Miniview is intended for extremity examinations and is not suitable for pediatric/infant whole-body imaging (see Attachment C).

6. GE OEC requests the variance be in effect for a five-year period, or when the proposed amendments to the Federal Performance Standard regarding small C-arm fluoroscopic systems becomes effective, whichever occurs first.

If you require additional information to evaluate and act upon this application, please contact me at 801-536-4694.

Sincerely,



Ted L. Parrot,
Vice President, Quality Assurance/Regulatory Affairs
and Official Correspondent

Enclosures:

Attachment A – Fluoroscopic Technique and Dose Rate for Extremity Examinations

Attachment B – Miniview Maximum Entrance Dose Rate

Attachment C – Product Labeling

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¹ This corresponds to entrance exposure rate of 3.5 R/minute at 30 centimeters distance from the image intensifier as measured in accordance with 21 CFR 1020.32(e)(2).

Miniview SSD Variance Application – Attachment A

Fluoroscopic Technique and Dose Rate for Extremity Examinations

GE OEC Miniview C-Arm

SID = 45 cm

HVL = 2.8 mm Al @ 80 kV

6 INCH FIELD

NORMAL ABS TABLE:

ANATOMY	kV	μA	DOSE RATE (mR/min)	ANATOMY DIMENSIONS in / cm
Hand	50	35.2	44	1.34 / 3.40
Wrist	50	36.5	46	1.75 / 4.45
Forearm	51	37.6	51	2.12 / 5.38
Foot (lateral)	53	45.4	74	2.72 / 6.91
Foot (AP)	54	47.4	77	3.13 / 7.95
Ankle	55	88.0	88	2.87 / 7.29
Knee (lateral)	59	65.0	165	4.03 / 10.24
Knee (AP)	58	65.0	175	4.07 / 10.33
Shoulder	64	78.4	301	5.20 / 13.20

LOW DOSE ABS TABLE:

ANATOMY	kV	μA	DOSE RATE (mR/min)	ANATOMY DIMENSIONS in / cm
Hand	48	29.9	35	1.34 / 3.40
Wrist	49	30.5	42	1.75 / 4.45
Forearm	50	32.1	42	2.12 / 5.38
Foot (lateral)	55	37.6	66	2.72 / 6.91
Foot (AP)	54	36.8	63	3.13 / 7.95
Ankle	55	38.4	66	2.87 / 7.29
Knee (lateral)	61	47.8	120	4.03 / 10.24
Knee (AP)	60	47.8	131	4.07 / 10.33
Shoulder	64	58.8	240	5.20 / 13.20

Miniview SSD Variance Application – Attachment A

Fluoroscopic Technique and Dose Rate for Extremity Examinations

GE OEC Mini 6600 C-Arm

SID = 40 cm SID

HVL = 2.3 mm Al @ 75 kV

6 INCH FIELD

NORMAL ABS TABLE:

ANATOMY	kV	μ A	DOSE RATE (mR/min)	ANATOMY DIMENSIONS in / cm
Hand	44	25.8	53	1.34 / 3.40
Wrist	46	28.2	61	1.75 / 4.45
Forearm	45	27.4	56	2.12 / 5.38
Foot (lateral)	51	30.5	100	2.72 / 6.91
Foot (AP)	52	30.5	105	3.13 / 7.95
Ankle	53	31.3	108	2.87 / 7.29
Knee (lateral)	59	36.0	218	4.03 / 10.24
Knee (AP)	58	36.0	189	4.07 / 10.33
Shoulder	67	59.6	820	5.20 / 13.20

LOW BONE DENSITY ABS TABLE:

ANATOMY	kV	μ A	DOSE RATE (mR/min)	ANATOMY DIMENSIONS in / cm
Hand	43	29.0	56	1.34 / 3.40
Wrist	43	31.3	57	1.75 / 4.45
Forearm	44	34.5	72	2.12 / 5.38
Foot (lateral)	46	39.2	100	2.72 / 6.91
Foot (AP)	46	40.0	102	3.13 / 7.95
Ankle	49	43.9	127	2.87 / 7.29
Knee (lateral)	54	54.1	268	4.03 / 10.24
Knee (AP)	53	54.1	232	4.07 / 10.33
Shoulder	62	69.8	834	5.20 / 13.20

Miniview SSD Variance Application – Attachment A

Fluoroscopic Technique and Dose Rate for Extremity Examinations

Series 9800 C-Arm

SID = 100 cm

HVL = 4.5 mm Al @ 80 kV

6 INCH FIELD (MAG 2)

NORMAL ABS TABLE:

ANATOMY	kV	mA	DOSE RATE (mR/min)	ANATOMY DIMENSIONS in / cm
Hand	52	1.6	137	1.34 / 3.40
Wrist	52	1.6	140	1.75 / 4.45
Forearm	53	1.7	172	2.12 / 5.38
Foot (lateral)	54	1.9	212	2.72 / 6.91
Foot (AP)	54	1.9	219	3.13 / 7.95
Ankle	56	2.2	264	2.87 / 7.29
Knee (lateral)	58	2.5	380	4.03 / 10.24
Knee (AP)	58	2.6	373	4.07 / 10.33
Shoulder	65	3.7	818	5.20 / 13.20

LOW DOSE ABS TABLE:

ANATOMY	kV	mA	DOSE RATE (mR/min)	ANATOMY DIMENSIONS in / cm
Hand	44	0.44	26	1.34 / 3.40
Wrist	52	0.56	49	1.75 / 4.45
Forearm	53	0.58	57	2.12 / 5.38
Foot (lateral)	54	0.60	67	2.72 / 6.91
Foot (AP)	57	0.69	85	3.13 / 7.95
Ankle	57	0.71	85	2.87 / 7.29
Knee (lateral)	59	0.78	126	4.03 / 10.24
Knee (AP)	59	0.76	109	4.07 / 10.33
Shoulder	66	1.1	275	5.20 / 13.20

Miniview SSD Variance Application – **Attachment A**
Fluoroscopic Technique and Dose Rate for Extremity Examinations

TEST PROCEDURE:

- Make exposures using the Series 9800, Mini 6600 and Miniview C-arm systems.
- Obtain the required extremity phantoms.
- Record all readings using six-inch field.
- Place phantom on the image intensifier.
- Set imaging system to auto fluoro mode – make an exposure.
- Record fluoroscopic technique.
- Lock technique in manual mode.
- Set probe height to phantom entrance dose position.
- Remove phantom from image intensifier.
- Place lead shield on image intensifier.
- Record dose rate at phantom entrance dose position.

EQUIPMENT USED FOR MEASUREMENTS:

Dosimeter

Radcal

Model: 9015
S/N: 91-0152
Cal due: 10/1/2001

Probe

Radcal

Model: 10X6-5CM
S/N: 15320
Cal due: 10/1/2001

Miniview SSD Variance Application – Attachment B

Miniview Maximum Entrance Dose Rate

Normal ABS Table								
kV / μ A	R/minute @ Source to Skin Distance							
	45 cm	40 cm	35 cm	30 cm	25 cm	20 cm	15 cm	10 cm
40 / 19.6	0.009	0.012	0.015	0.021	0.030	0.047	0.084	0.188
42 / 21.9	0.012	0.016	0.021	0.028	0.040	0.063	0.112	0.252
45 / 26.6	0.019	0.024	0.031	0.042	0.060	0.094	0.167	0.376
47 / 29.8	0.023	0.030	0.039	0.052	0.076	0.118	0.210	0.472
50 / 36.8	0.034	0.043	0.056	0.076	0.109	0.171	0.304	0.684
52 / 41.5	0.042	0.053	0.069	0.094	0.135	0.211	0.375	0.844
55 / 50.9	0.059	0.075	0.098	0.133	0.191	0.299	0.532	1.196
57 / 57.2	0.072	0.091	0.119	0.162	0.233	0.364	0.647	1.456
60 / 69.0	0.097	0.123	0.160	0.218	0.314	0.491	0.873	1.964
62 / 77.6	0.117	0.148	0.193	0.263	0.378	0.591	1.051	2.364
65 / 90.1	0.150	0.190	0.248	0.338	0.487	0.761	1.353	3.044
67 / 98.8	0.175	0.222	0.290	0.394	0.568	0.887	1.577	3.548
70 / 112.0	0.215	0.272	0.355	0.483	0.696	1.087	1.932	4.348
72 / 121.0	0.246	0.311	0.406	0.552	0.796	1.243	2.210	4.972
75 / 137.0	0.300	0.380	0.496	0.675	0.972	1.518	2.699	6.072
77 / 147.0	0.345	0.437	0.571	0.777	1.119	1.748	3.108	6.992
80 / 161.0	0.392	0.496	0.647	0.881	1.268	1.982	3.524	7.928

LOW DOSE ABS Table								
kV / μ A	R/minute @ Source to Skin Distance							
	45 cm	40 cm	35 cm	30 cm	25 cm	20 cm	15 cm	10 cm
40 / 20.3	0.009	0.012	0.015	0.021	0.030	0.047	0.084	0.188
42 / 22.7	0.013	0.017	0.022	0.029	0.042	0.066	0.117	0.264
45 / 26.6	0.019	0.024	0.031	0.042	0.061	0.095	0.169	0.380
47 / 29.0	0.023	0.029	0.038	0.051	0.074	0.115	0.204	0.460
50 / 32.1	0.029	0.037	0.049	0.066	0.095	0.149	0.265	0.596
52 / 34.5	0.035	0.044	0.057	0.078	0.112	0.175	0.311	0.700
55 / 38.4	0.044	0.056	0.073	0.100	0.143	0.224	0.398	0.896
57 / 40.7	0.051	0.064	0.084	0.114	0.164	0.257	0.457	1.028
60 / 47.0	0.066	0.083	0.109	0.148	0.213	0.333	0.592	1.332
62 / 54.1	0.081	0.103	0.134	0.183	0.263	0.411	0.731	1.644
65 / 67.4	0.112	0.142	0.186	0.253	0.364	0.569	1.012	2.276
67 / 76.0	0.135	0.171	0.223	0.303	0.436	0.682	1.212	2.728
70 / 91.7	0.176	0.222	0.290	0.395	0.569	0.889	1.580	3.556
72 / 103.0	0.209	0.265	0.346	0.471	0.678	1.060	1.884	4.240
75 / 124.0	0.273	0.346	0.452	0.615	0.886	1.384	2.460	5.536
77 / 138.0	0.319	0.404	0.527	0.718	1.034	1.615	2.871	6.460
80 / 160.0	0.389	0.493	0.643	0.876	1.261	1.970	3.502	7.880

Miniview SSD Variance Application – **Attachment B**

Miniview Maximum Entrance Dose Rate

Test Method:

The method used to determine the maximum entrance dose rates at different SSDs is described as follows:

The dose rate was measured with a Radcal model 9015 with 10X5-6 ion chamber, factory calibrated 2/29/2000, due 2/29/2001.

The readings were taken at 20 cm from the focal spot in order to obtain full x-ray beam coverage of the dosimeter ion chamber. The fluoroscopic technique was set at the highest available μA value for each of the selected kV settings.

The dose rate readings obtained at the 20 centimeter SSD for were used to plot the tables (above) at various SSDs using the following expression of the inverse square law:

$$\text{dose rate at SSD} = \text{exposure rate at 20 cm} * (20/\text{SSD})^2$$

The plotted values were spot-checked by measurement at various SSDs. The maximum deviation between the measured and plotted values was within 10%.

Miniview SSD Variance Application – **Attachment C**

Product Labeling

Sample of Use Limitation Label

***THIS DEVICE IS INTENDED FOR THE
EXAMINATION OF EXTREMITIES ONLY.
IT IS NOT TO BE USED FOR
PEDIATRIC/INFANT
WHOLE BODY IMAGING.***

Also top of FedEx PowerShip Label or ASTRA Label here

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KYLE STEADMAN

OEC MEDICAL SYSTEMS INC
384 WRIGHT BROTHERS DRIVE

SALT LAKE CITY, UT 84116

SHIP DATE: 20OCT00

SYSTEM #0689581 / CAFE2023

ACTUAL WGT: 0.2 LBS SCALE

TO: DOCUMENT MGMT. BRANCH HFA 305 (800) 874-7378

FOOD & DRUG ADMINISTRATION

12420 PARKLAWN DRIVE

ROOM 1-23

ROCKVILLE, MD 20857



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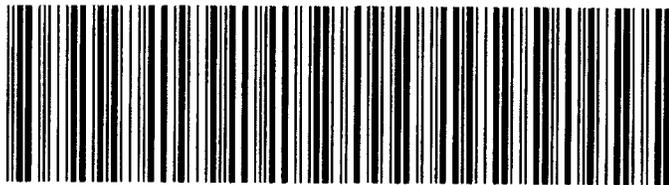
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