



Digital *motion* x-ray®

To whom it may concern,

We are providing three comparison tables for exposure rates between a Standard Static X-ray System and a Digital Motion X-ray System (DMX).

1. The first table compares one lateral cervical static x-ray image taken with both systems.
2. The second table compares one lateral cervical static x-ray image using a standard x-ray system compared to a 15 second motion X-ray movie using a DMX System.
3. The third table compares seven static cervical x-ray images (Neutral Lateral, Lateral Flexion, Lateral Extension, Right Oblique, Left Oblique, A-P and A-P Open Mouth) using a standard x-ray system compared to a 90 second motion X-ray movie using a DMX System.

We are also providing the **FLUOROSCOPIC ENTRANCE EXPOSURE RATE** test. This test demonstrates the maximum exposure output reading of the DMX System.

Sincerely,

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SKIN EXPOSURE COMPARISON

1	Standard Static X-ray System	Digital Motion X-ray System (DMX)
Factors	1 Static Cervical X-ray	1 Static Cervical X-ray
KV	70 KV	70 KV
Ma	20 Ma	2 Ma
Radiation Dosage	111mR	7.46mR
Images	1 x-ray	1 spot view x-ray

Summary: 1 Static X-ray using a standard x-ray system exposes the patient to 111mR
 1 static spot view x-ray using a DMX System exposes the patient to 7.46mR

2	Standard Static X-ray System	Digital Motion X-ray System (DMX) for 15 Seconds of Continuous Exposure
Factors	1 Static Cervical X-ray	1 Cervical Range of Motion Repeated 3 times over 15 Seconds
KV	70 KV	70 KV
Ma	20 Ma	2 Ma
Radiation Dosage	111mR	112mR
Images	1 x-ray	Camera takes 30 frames per seconds X 15 seconds = 450 x-rays

Summary: 1 Static X-ray using a standard x-ray system exposes the patient to 111mR
 450 Static X-rays OR a 15 second motion X-ray movie using a DMX System exposes the patient to 112mR

3	Standard Static X-ray System	Digital Motion X-ray System (DMX) for 90 seconds of Continuous Exposure
Factors	7 View Davis Series	6 Different Cervical Ranges of Motion Repeated 3 times each over a total of 90 Seconds
KV	70 KV	70 KV
Ma	20 Ma	2 Ma
Radiation Dosage	777mR	672mR
Images	7 x-rays	Camera takes 30 frames per seconds X 90 seconds = 2700 x-rays

Summary: 7 Static X-rays using a standard x-ray system exposes the patient to 777mR
 2,700 Static X-rays OR a 90 second motion X-ray movie using a DMX System exposes the patient to 672mR

FLUOROSCOPIC ENTRANCE EXPOSURE RATE: 21 CFR 1020.32 (d) (4) (iii)

The chamber is placed at 15 cm (instead of 30 cm) from the image receptor as this is the position where the patient will be located during testing. The raw data readings are calculate to correspond to the 30 cm position.

Requirement: Fluoroscopic equipment that is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 5R/minute at the point where the center of the useful beam enters the patient, except: during recording of fluoroscopic images.

Critical Parameters and “Worst Case” Conditions:

Collimators are fully opened, with the maximum of 90 kV and 3 mA settings (peak tube potentials and tube currents)

Acceptance reading is 4.60 R/min. or less (calculated value). **FDA Regulations**

Rejection limit is 4.75 R/min or greater (calculated value)

Instrument: NERO 8000 (+/- 5% accuracy)

Sample Test Data: SKIN ENTRANCE EXPOSURES

Raw data readings taken at 15 cm from the image receptor.

40 KV		50 KV		60 KV	
ma	mR/min	ma	mR/min	ma	mR/min
1.0	52	1.0	93	1.0	171
1.5	73	1.5	132	1.5	241
2.0	100	2.0	180	2.0	330
2.5	121	2.5	218	2.5	400
3.0	142	3.0	256	3.0	470

70 KV		80 KV		90 KV	
ma	mR/min	ma	mR/min	ma	mR/min
1.0	270	1.0	363	1.0	473
1.5	380	1.5	512	1.5	665
2.0	520	2.0	700	2.0	910
2.5	630	2.5	848	2.5	1103
3.0	740	3.0	996	3.0	1295

Maximum exposure (worst case” condition) reading of 90 KV at a distance of 15 cm from the image receptor are 1295 mR/minute.

Inverse Square Calculation:

SID distance = 91 cm.
Readings distance from image receptor = 15 cm.
Reading distance from focal spot (image source) = 76 cm.
Calculated distance from image receptor = 30 cm.
Calculated distance from focal spot = 61 cm

FORMULA FOR CALCULATIONS:

$\frac{76\text{cm}}{61\text{cm}} = 1.24$ $(1.24 \text{ cm})^2 = 1.54 \text{ sq. cm.} \times 1.295 \text{ R/min} = 1.99 \text{ R/min (acceptable limit)}$

Our result is under half the acceptance for the FDA