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Docket No. 99D-4910, Dockets Management Branch
Division of Management Systems & Policy
Office of Human Resources & Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

RE: CFR 900.12 (b)(8)(i)

To Whom It May Concern:

I would like to speak against the requirement for the fine adjustment compression controls operable from both sides of the patient.

The cost of this requirement is prohibitive. There is not some simple piece of all-on equipment that can make otherwise good machines compliant. Entire units would have to be replaced at a cost of approximately \$80,000 each. I truly believe that this cost is not justified for such a questionable benefit. This requirement could drive some privately owned breast imaging centers out of business, decreasing access to high-quality mammograms. It seems to me that this result is contrary to the goal of MQSA.

Thank you for considering my comments in drafting the final regulation. I would like to be personally contacted with your decision.

Most sincerely,

Vashti Hellein, M.D.
Radiologist

99D-4910

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BAPTIST
Gulf Breeze Hospital

The Women's Center
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