



July 2013

Re: Carestream Health X-ray films and intensifying screens for mammography

Carestream Health developers, fixers, and starter

The United States Food and Drug Administration (FDA) Mammography Quality Standards Act (MQSA) Final Regulations became effective April 28, 1999. The regulations require documentation on films and screens and processing chemicals used in mammography:

21 CFR 900.12(b)(11): X-ray film. The facility shall use X-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.

21 CFR 900.12(b)(12): Intensifying screens. The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.

21 CFR 900.12 (b)(13) *For processing mammography films, the facility shall use chemical solutions that are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.*

The FDA offers the following guidance in clarification of these rules:

- “designated by the film manufacturer as appropriate for mammography” simply means that the film manufacturer has established that the properties of the film are appropriate for mammography and markets it for such purposes, not that the film must be sold only for mammography. One mechanism to establish compliance would be to have documentation from the manufacturer, such as advertising material or specific literature, that clearly identifies the film and its intended use.
- The facility is responsible for matching the sensitivity of the film with the spectral output of the screen. Examples of acceptable methods to establish compliance would be to provide documentation from the screen and/or film manufacturer, such as advertising material or specific literature, that clearly identifies the appropriateness of the combination or specifies the screen output and the film sensitivity showing a match between them. Otherwise, the facility should independently show that matching has been established.
- the “facility must either have documentation from the chemical manufacturer/ supplier or the film manufacturer showing that the processing chemicals being used provide results consistent with the film manufacturer’s processing specifications, or the facility must establish that the film performance is sensitometrically equivalent to films developed according to the film manufacturer’s specific recommendations.”

As the manufacturer, Carestream Health, Inc. certifies the following:

These films are appropriate and marketed for use in mammography with green emitting intensifying screens:

- MIN-R EV
- MIN-R 2000 Plus
- MIN-R S

These intensifying screens are appropriate, and marketed, for use in mammography. They are composed of terbium activated gadolinium oxysulfide with primary emission in the green spectral region.

- MIN-R EV 150
- MIN-R EV 190

- MIN-R 2000
- MIN-R 2190

In addition, Carestream Health, Inc. certifies that any of the above films are spectrally matched to any of the above intensifying screens. **The MIN-R EV 150 and MIN-R EV 190 screens are specially designed to work with MIN-R EV Film.**

Although they have been specifically designed to produce optimal results in the above combinations, the above listed films would be spectrally matched with other commercial intensifying screens that are composed of terbium activated gadolinium oxysulfide, as these will have similar emission spectra and should provide acceptable results. Similarly, the above listed intensifying screens would be spectrally matched to films from other manufacturers that require green emission. Speed/ dose of the systems could be different.

Carestream Health, Inc. recommends the use of X-OMAT EX II Developer and Replenisher, RP X-OMAT Developer and Replenisher, RP X-OMAT LO Fixer and Replenisher and RP X-OMAT Developer Starter, for optimal results with the Carestream Health mammography films listed above. We do not recommend the use of X-OMAT MX Developer and Replenisher for use with Carestream Health mammography films due to the sensitometric and/or viewbox appearance of the film. Acceptable results are expected with the use of X-OMAT MX Fixer and Replenisher. It is important to follow Carestream Health's mixing and processing recommendations.

Acceptable results with mammography film from some other manufacturers are expected with the use of these Carestream Health chemical solutions.

Use of other manufacturers' developer and fixer combinations may adversely affect the sensitometric and/or viewbox appearance of the film.

Note: X-OMAT and MIN-R are trademarks of Carestream Health.