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REVIEWER GUIDANCE FOR AUTOMATIC X-RAY FILM PROCESSOR 510(k)  
PREMARKET NOTIFICATIONS

The following issues are to be addressed in premarket notifications for Medical Film Automatic Processors:

1. Developer Temperature and Immersion Time
  - A. Developer Immersion Time
    - a. What is (are) the immersion time(s)?
    - b. What are the reproducibility and accuracy of the time(s)?
  - B. Developer Temperature
    - a. What is the temperature or range of temperatures at which the developer can be operated?
    - b. What are the reproducibility and accuracy of the temperature value(s)?
  - C. How are the developer temperature and immersion time regulated?
  - D. If more than one value of time and/or temperature is available:
    - a. How are the values changed?
    - b. Are changes in one variable coordinated with changes in the other?
    - c. If the answer to 2 is yes, what measures exist to assure that processing does not take place before the change is complete?
  - E. Total Cycle Time
    - a. What is the length of the total processor cycle?
    - b. What are the reproducibility and accuracy of the total cycle time?
    - c. How is the total cycle time regulated?
3. Identify settings of the subject processor to be used with at least one commonly used film and chemistry combination.
4. Assuming the film manufacturer's recommended chemistry or its equivalent is used, list the films that will perform according to their manufacturer's specifications if processed in your processor? (This will address mechanical problems (film too thick) as well as problems with chemicals.)

5. Must the processor be operated under safe lights only or is there any time during its processing cycle when the room lights can be on without causing unacceptable fogging?
6. Provide evidence that the emissions of all indicator lights are compatible with the films indicated in III and IV (that is, show that the indicator lights will not fog the films.)
7. What warm up time is required for the processor and how is readiness for use indicated to the operator? What safeguards exist to assure that it is not used before fully operational?
8. What information is provided to the user on:
  - A. How to measure the developer immersion time.
  - B. How to measure the developer temperature.
  - C. The effect of changing developer immersion time and/or temperature on film density and the exposure required to produce that density.
  - D. How to measure the dryer temperature.
  - E. The maximum dryer temperature that can be used without damaging the film.

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