



April 29, 2010

Renell Composto, RN, MSN
Director of Maternal Child Health Services
Provena Covenant Medical Center
1400 West Park Street
Urbana, IL 61801

Dear Ms. Composto:

Thank you for your inquiry regarding warming of Hospira's intravenous (I.V.) and irrigation solutions in polyvinyl chloride (PVC) and copolyester (CR3) plastic flexible containers, as well as our irrigation solutions in Aqualite® polyolefin plastic pour bottles (semi-rigid containers).

Hospira recommends that these fluids be stored according to the criteria specified in the individual product labeling. The labeling for these products indicates storage at 20-25°C (68-77°F). The expiration date assigned to each product is based on stability data derived from samples stored at 25°C (77°F). These data support the length of time a product may be stored under normal conditions while remaining pharmaceutically acceptable.

Some clinical situations may however warrant the use of solutions for injection and irrigation at higher temperatures than specified on the product label. For this purpose, we provide the following guidance:

Flexible PVC and CR3 Containers:

Solutions for injection and irrigation in PVC and CR3 plastic flexible containers, in their overwraps, may be warmed at a temperature not to exceed 40°C (104°F) (unless specified otherwise on the product label), and for a period no longer than two weeks (14 days). Once the product is removed from the warming cabinet, it should be clearly labeled with a revised expiration date. The revised expiration date for the maximum time period in the 40°C (104°F) warming cabinet of two weeks (14 days) is obtained by deducting eight weeks (56 days) from the original expiration date of the solution stored at 25°C (77°F). If the warmed product is not used immediately, it can be returned to 25°C (77°F) storage and used until the revised expiration date. Solutions should not be re-warmed.

Aqualite® polyolefin plastic pour bottles (Semi-rigid containers):

Solutions for irrigation in Hospira's Aqualite plastic pour bottles, with their plastic screw cap intact and unopened, may be warmed up to 40°C (104°F) (unless specified otherwise on the product label), and for a period no longer than two weeks (14 days). Once taken out of the warming cabinet, it should be clearly labeled with a revised expiration date. The revised expiration date for the maximum time period in the 40°C (104°F) warming cabinet of two weeks (14 days) is obtained

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by deducting eight weeks (56 days) from the original expiration date of the solution stored at 25°C (77°F). If the warmed product is not used immediately, it can be returned to 25°C (77°F) storage and used until the revised expiration date.

Alternatively, for specific clinical situations, irrigation solutions in the Aqualite plastic pour bottles may be warmed to temperatures **higher than 40°C (104°F) but not to exceed 66°C (150°F)** and for a period no longer than two weeks (14 days). Once removed from the warming cabinet, **solutions should be used within 24 hours or discarded and should not be re-warmed or returned to stock.**

Hospira recommends the use of a controlled temperature warming cabinet that is monitored by a calibrated temperature measurement device. This will assure that the temperature within the solution container will be no higher than the air that surrounds it. Containers should not come into direct contact with any heating elements or hot metal components within the warming cabinet. The use of a microwave oven for warming solutions is not recommended.

Hospira cautions against the handling of warmed I.V. and Irrigation solutions due to the possibility of scalding. Caution must be employed when using solutions that have been warmed to temperatures above the recommendations stated in the product labeling.

I hope this information is helpful. If you have any further questions, please contact Hospira Medical Information at 1-800-615-0187 or e-mail us at medcom@hospira.com.

Sincerely,

A handwritten signature in black ink that reads "Katie E. Anderson".

Kate Anderson
Assistant Medical Information Specialist
Medical Information
Hospira, Inc.

Reference Number: US2010-08103