

Name of Policy: <u>Warming devices and patient safety</u> Policy Number: 3364-100-50-44 Department: Hospital Administration Approving Officer: Chief Executive Officer - UTMC Responsible Agent: Chief Nursing Officer, Director of Pharmacy Scope: The University of Toledo Medical Center	 Effective Date: 10/1/2023 Initial Effective Date: 5/3/2011
<input type="checkbox"/> New policy proposal <input type="checkbox"/> Major revision of existing policy	<input type="checkbox"/> Minor/technical revision of existing policy <input checked="" type="checkbox"/> Reaffirmation of existing policy

(A) Policy Statement

All warming cabinets and similar devices used to heat patient care items will be appropriately monitored and meet standards for the safety of patients.

(B) Purpose of Policy

To ensure that patient care items that are warmed prior to use meet appropriate/safe temperature standards.

(C) Scope

The University of Toledo Medical Center

(D) Background

National standards are currently not established for this issue. Several organizations have published recommendations and are cited. The organization is establishing internal standards based on a review of the pertinent literature.

(E) Policy

1. Warming of Intravenous Fluids (I.V.)

Intravenous fluids are to be warmed exclusively by a device designed to warm I.V. solutions. Warming cabinets and microwave ovens are not to be used to warm I.V. solutions. They are to be warmed according to the device manufacturers' recommendations and must be consistent with the I.V. solution manufacturers' recommendations¹.

2. Warming of Fluids for Irrigation

Fluids for irrigation may be warmed in devices up to 110 degrees Fahrenheit (43 degrees Celsius)². Fluids should be cooled to approximate normal body temperature before use (98.6 degrees Fahrenheit, 37 degrees Celsius). Fluids will be rotated out of the warming device according to manufacturers' recommendations.

3. Warming of Blankets, Towels, Towelettes

Blankets, towels, towelettes and other items intended to contact the patient's skin can be warmed up to 130 degrees Fahrenheit, 54 degrees Celsius^{2,3}.

4. Warming Cabinets

Solutions and blankets (other items) should not be warmed in the same device **unless:**

¹ Letter from Baxter Corporation dated December 7, 2010 (attached)

² ECRI, "Hazard Report Update: ECRI Revises Its Recommendation for Temperature Limits on Blanket Warmers," *Health Devices*, July 2009, p230.

³ AORN Standards of Practice, Safe Environment of Care, In: *Perioperative Standards and Recommended Practices*. Denver, CO: AORN Inc; 2011; p222.



March 25, 2020

Anthony Eberly
OR Pharmacist
University of Toledo Medical Center

Dear Anthony,

Thank you for your recent inquiry to Baxter's Medical Information. Please see the enclosed information regarding;

- Warming parameters for Injection Solutions in VIAFLEX Plastic Containers
- Warming parameters for Irrigation Solutions in ARTHROMATIC and UROMATIC Containers
- Warming parameter for Irrigation Solutions in Plastic Pour Bottle

This letter is intended to provide pertinent data to assist you in forming your own conclusions and is not to be considered as medical advice. The information contained in this letter is applicable to products approved or cleared in the United States of America, unless specifically noted. Baxter does not advocate the use of its products outside of approved labeling. Please refer to Instructions for Use or Prescribing Information. This letter is provided as a service to Baxter customers, and it may not be reproduced without the prior written permission of Baxter Healthcare Corporation.

We hope that this information has been helpful. If you require further assistance, please contact Medical Information at Medinfo@baxter.com.

Sincerely,
Zuleida Hahn

Zuleida Hahn, RPh
Manager, Medical Affairs
US Medical Information

Case Number: US2020-02805

Warming parameters for Injection Solutions in VIAFLEX Plastic Containers

Per approved product labeling, Baxter recommends that Injection Solutions in VIAFLEX Plastic Containers should be stored at room temperature (25°C/77°F). Please refer to the respective product label for complete product prescribing information.

The following information has not been approved by the FDA.

If you choose to intentionally warm Injection Solutions in a VIAFLEX Plastic Container with plastic HDPE (High Density Polyethylene) Overwrap, Baxter recommends the use of controlled temperature warming cabinets. Baxter does not recommend the use of microwave radiation to warm any injection solutions.

The information below is applicable to 150 mL to 1000 mL Injection Solutions in VIAFLEX Plastic Containers in the plastic overwrap, including the following products:

Injection Solutions packaged in VIAFLEX Plastic Container

- o Dextrose Injection, USP
- o Dextrose and Sodium Chloride Injection, USP
- o Dextrose and Electrolyte No. 48 Injection, USP
- o Lactated Ringer's Injection, USP
- o Lactated Ringer's and 5% Dextrose Injection, USP
- o OSMITROL Injection (Mannitol Injection, USP)
- o PLASMA-LYTE A pH 7.4 and 148 Injection (Multiple Electrolytes Injection, Type 1, USP)
- o Potassium Chloride in Dextrose Injection, USP
- o Potassium Chloride in Sodium Chloride Injection, USP
- o Potassium Chloride in Dextrose and Sodium Chloride Injection, USP
- o Potassium Chloride in Lactated Ringer's and Dextrose Injection, USP
- o Ringer's Injection, USP
- o Sodium Chloride Injection, USP
- o Sterile Water Injection, USP, for drug diluent use only

For warming parameters for Injection Solutions in VIAFLEX Plastic Container in the plastic overwrap, see Table 1 below.¹

Table 1. Warming parameters for Injection Solutions in VIAFLEX Plastic Containers in the plastic overwrap

Injection Solution Fill Volumes	Warming Parameters
150 mL to 1000 mL	40°C (104°F) and for a period of no longer than 14 days if greater than or equal to 3 months expiry remain on the product

The warming cabinet storage times listed in Table1, are the amount of time the products can remain in the warmer during a single warming session. **Please note that products should not be warmed if there is less than 3 months expiry remaining.** Baxter has not tested these products in warm-cool-warm cycles. Once Injection Solutions in VIAFLEX Plastic Containers have been placed in the warming cabinet, they should be identified as having been warmed and used within the storage times listed on Table 1. period. If not used within the maximum warming period, the product should be discarded. The product should not be subsequently returned to room temperature storage or returned to the warmer. Baxter recommends that the integrity of the container be checked prior to use. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired.

Reference:

1. Internal data on file.

Warming parameters for Irrigation Solutions in ARTHROMATIC and UROMATIC Containers

Per approved product labeling, Baxter recommends that Irrigation Solutions in ARTHROMATIC and UROMATIC Plastic Containers should be stored at room temperature (25°C). Please refer to the respective product label for complete product prescribing information.

The following information has not been approved by the FDA.

If you choose to intentionally warm Irrigation Solutions in ARTHROMATIC and UROMATIC Plastic Container with plastic HDPE (High Density Polyethylene) Overwrap, Baxter recommends the use of controlled temperature warming cabinets. Baxter does not recommend the use of microwave radiation to warm any Irrigation Solutions.

The information below is applicable to 1000 to 5000 mL Irrigation Solutions in ARTHROMATIC and UROMATIC Plastic Containers in the plastic overwrap, including the following products:

Irrigation Solutions packaged in ARTHROMATIC and UROMATIC Plastic Container

- o Glycine for Irrigation, USP, UROMATIC Plastic Container
- o Lactated Ringer's for Irrigation, ARTHROMATIC Plastic Container
- o Sodium Chloride for Irrigation, USP, ARTHROMATIC Plastic Containers
- o Sodium Chloride for Irrigation, USP, UROMATIC Plastic Containers
- o Sorbitol Urologic Irrigation Solution, UROMATIC Plastic Container
- o Sterile Water for Irrigation, USP, UROMATIC Plastic Container

For warming parameters for Irrigation Solutions in ARTHROMATIC and UROMATIC Plastic Container in the plastic overwrap, see Table 1 below.¹

Table 1. Warming parameters for Irrigation Solutions in ARTHROMATIC or UROMATIC Plastic Containers in the plastic overwrap

Irrigation Solution Fill Volumes	Warming Parameters
1000 mL to 5000 mL	40°C (104°F) and for a period of no longer than 14 days if greater than or equal to 3 months expiry remain on the product
	50°C (122°F) and for a period no longer than 72 hours

The warming cabinet storage times listed in Table 1, are the amount of time the products can remain in the warmer during a single warming session. **Please note that products should not be warmed if there is less than 3 months expiry remaining.** Baxter has not tested these products in warm-cool-warm cycles. Once Irrigation Solutions in ARTHROMATIC or UROMATIC Plastic Containers have been placed in the warming cabinet, they should be identified as having been warmed and used within the storage times listed on Table 1. If not used within the maximum warming period, the product should be discarded. The product should not be subsequently returned to room temperature storage or returned to the warmer.

Baxter recommends that the integrity of the container be checked prior to use. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired.

Reference:

1. Internal data on file.

Warming parameter for Irrigation Solutions in Plastic Pour Bottle

Per the approved labeling, Baxter recommends that Irrigation Solutions in Plastic Pour Bottle be stored at room temperature (25°C). Please refer to the respective product label for complete product prescribing information.

If you choose to intentionally warm Irrigation Solutions packaged in Plastic Pour Bottle, Baxter recommends the use of controlled temperature warming cabinets. Baxter does not recommend the use of microwave radiation to warm any irrigation solutions.

Per the approved product labeling, irrigation solutions from 250 mL to 1500 mL in Plastic Pour Bottles listed below can be warmed as shown in Table 1.¹

Irrigation Solutions in Pour Bottle Plastic

- Acetic Acid Irrigation, USP, Plastic Pour Bottle
- Lactated Ringer's Irrigation, Plastic Pour Bottle
- Sodium Chloride Irrigation, USP, Plastic Pour Bottle
- Sterile Water Irrigation, USP, Plastic Pour Bottle
- Ringer's Irrigation, USP, Plastic Pour Bottle
- TIS-U-SOL Solution (Pentalyte Irrigation), Plastic Pour Bottle

Table 1. Warming parameters for Irrigation Solutions in Pour Bottle Plastic

Irrigation Solution Fill Volumes	Warming Parameters
250 mL to 1500 mL	50°C (122°F) for a maximum of 60 days

The warming cabinet storage times listed in Table 1, are the amount of time the products can remain in the warmer during a single warming session. Baxter has not tested these products in warm-cool-warm cycles. Once Irrigation Solutions packaged in the plastic Pour Bottle have been placed in the warming cabinet, they should be identified as having been warmed and used within the time listed in Table 1. If not used within the maximum warming period, the product should be discarded. The product should not be subsequently returned to room temperature storage or to the warmer.

If you wish to warm at a lower temperature, that is acceptable; however, storage longer than 60 days cannot be supported. Baxter has no recommendations or information regarding the appropriate temperatures for these solutions during actual administration/use.

Baxter recommend that the integrity of all containers be checked prior to use. If the protected seal is damaged, detached, or not present, discard container as solution path sterility may be impaired.

Reference:

1. Irrigation Solutions in Plastic Pour Bottle product label.