Name of Policy: Warming Devices and Patient Safety UTOLEDO HEALTH **Policy Number**: 3364-100-50-44 **Approving Officer**: Chief Executive Officer Chief of Staff Effective date: Original effective date: 05/03/2011 **Responsible Agent**: Administrative Director of **Pharmacy Services Scope**: The University of Toledo Medical Center Key words: Warmer, Warming device, Patient, Temperature, Fluids, Cabinet  $\boxtimes$ New policy proposal Minor/technical revision of existing policy Major revision of existing policy 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' recommendations<sup>1</sup>.

## 2. Warming of Fluids for Irrigation

Fluids for irrigation may be warmed in devices up to 110 degrees Fahrenheit (43 degrees Celsius)<sup>2</sup>. 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<sup>2,3</sup>.

### 4. Warming Cabinets

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

- a. There are separate (dual) chambers with separate temperature controls and each chamber can be monitored independently, or
- b. The device temperature does not exceed 110 degrees Fahrenheit.
- 5. Warmed I.V. and irrigation solution bags should not be used to warm a patient's skin.

#### (F) Responsibilities

- 1. It is the responsibility of each department that warms patient care items to develop processes and procedures to monitor compliance to this policy.
- 2. Biomedical Engineering is responsible for device maintenance.

<sup>&</sup>lt;sup>1</sup> Letter from Baxter Corporation dated July 17, 2025(attached)

<sup>&</sup>lt;sup>2</sup> ECRI, "Hazard Report Update: ECRI Revises Its Recommendation for Temperature Limits on Blanket Warmers," Health Devices, July 2009, p230.

<sup>&</sup>lt;sup>1</sup> AORN Standards of Practice, Safe Environment of Care, In: *Perioperative Standards and Recommended Practices*. Denver, CO: AORN Inc; 2011; p222.

<sup>&</sup>lt;sup>1</sup> Letter from Baxter Corporation dated July 17, 2025(attached)

<sup>&</sup>lt;sup>2</sup> ECRI, "Hazard Report Update: ECRI Revises Its Recommendation for Temperature Limits on Blanket Warmers," Health Devices, July 2009, p230.

<sup>&</sup>lt;sup>3</sup> AORN Standards of Practice, Safe Environment of Care, In: *Perioperative Standards and Recommended Practices*. Denver, CO: AORN Inc; 2011; p222.

Approved by:	Policies Superseded by This Policy:
	• None
Daniel Barbee	Initial effective date: 05/03/2011
Chief Executive Officer	
	Review/Revision Date:
Date	5/3/2011 5/1/2014 5/1/2017 5/1/2020 5/1/2023
Puneet Sindhwani Chief of Staff	Next review date:
Date	
Review/Revision Completed by:	
Pharmacy	
HAS	
Chief Executive Officer	



July 17, 2025

Molly Holland University of Toledo Health 3000 Arlington Ave

Dear Molly,

Thank you for your enquiry regarding warming parameters for Injection Solutions in VIAFLEX Plastic Containers 250 mL to 1000 mL sizes.

Per approved product labeling, Baxter recommends that Injection Solutions in VIAFLEX Plastic Containers should be stored at room temperature (25°C/77°F). 1

Please refer to full prescribing information at National Library of Medicine's DailyMed.

The following information has not been approved by the FDA.

If you choose to intentionally warm Injection Solutions in a VIAFLEX Plastic Container, the solution bags should be warmed within their plastic HDPE (High Density Polyethylene) overwrap. Baxter recommends the use of controlled temperature warming cabinets to warm the solution bags. Baxter does not recommend the use of microwave radiation to warm any Injection Solutions.

The storage parameters for Injection Solutions in VIAFLEX Plastic Containers in their protective plastic overwrap during and after warming are summarized in Table 1. This information is applicable to 250 mL to 1000 mL bag sizes, and includes the following products:

#### Injection Solutions packaged in VIAFLEX Plastic Containers

- Dextrose Injection, USP
- Dextrose and Sodium Chloride Injection, USP
- Dextrose and Electrolyte No. 48 Injection, USP
- Lactated Ringer's Injection, USP
- Lactated Ringer's and 5% Dextrose Injection, USP
- OSMITROL Injection (Mannitol Injection, USP)
- PLASMA-LYTE A pH 7.4 (Multiple Electrolytes Injection, Type 1, USP)
- Potassium Chloride in Dextrose Injection, USP
- Potassium Chloride in Sodium Chloride Injection, USP
- o Potassium Chloride in Dextrose and Sodium Chloride Injection, USP
- Potassium Chloride in Lactated Ringer's and Dextrose Injection, USP
- o Sodium Chloride Injection, USP
- Sterile Water Injection, USP. For drug diluent use only. NDC 0338-0013-04 (product code 2B0304X)

Table 1. Storage parameters for Injection Solutions in VIAFLEX Plastic Containers in their plastic overwrap during and after warming<sup>28</sup>

Injection Solution Bag Sizes	Storage During Warming	Storage After Warming*
250 mL to 1000 mL	Up to 40°C (104°F) for a period of no longer than 14 days	Room Temperature (25°C/77°F) through labelled product expiry

<sup>\*</sup>Applies to solutions that have undergone one warming session.

The storage times listed in Table 1 reflect the amount of time the product can remain in the warmer during a single warming session and at room temperature after a single warming session. Once Injection Solutions in VIAFLEX Plastic Containers have been placed in the warming cabinet, they should be identified as having been warmed. If warmed solutions have not been used during the 14



day warming period, they may be returned to room temperature storage conditions and used within their labeled expiry period. Previously warmed bags should not undergo any additional warming sessions.<sup>2b</sup>

Selected injection solutions in VIAFLEX Containers have received FDA approval for shelf-life extension in response to solution shortages resulting from damage to Baxter's North Cove facility. These solutions can similarly be stored in the warmer for up to 14 days during the allowed expiry extension period.<sup>2b</sup> For a list of products with approved shelf-life extensions, please visit Hurricane Helene: Baxter's manufacturing recovery in North Carolina | FDA.

Baxter recommends 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 the inner bag firmly. If leaks are found, discard the solution as sterility may be impaired.<sup>1</sup>

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.

Elizabeth Downs

Elizabeth Downs, BSN, RN Manager, Medical Information Worldwide Medical Baxter Healthcare Corporation

Case Number: US2025-04768

#### References:

- 1. Injection Solutions, USP, in VIAFLEX Plastic Container prescribing information.
- 2. a,b Baxter internal data on file.