# Warm Up to Clarity:

## ICONOGRAPHY IN TEMPERATURE COMMUNICATION ON COMBINATION PRODUCTS AND MEDICAL DEVICES

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## HIGH-LEVEL SUMMARY

**Relevant standards and on-market pharmaceutical product IFU's seldom specify guidance related to communicating warm-up time for temperature-sensitive medications.**

This presentation strives to discuss this existing gap, present relevant background information, and demonstrate a step forward in this space by showcasing a case study in which warm-up compliance labels were tested with n=45 representative users.

**Set users up for success by clearly communicating warm-up time with effective iconography.**

Adding labeling to pharmaceutical products that require refrigeration, and subsequent warm up periods can:

- Enhance product usability, and
- Improve users' mental models of product readiness

## INTRODUCTION

**Some medications, like insulin for example, are refrigerated prior to use and are then required to be left out at room temperature to "warm up" prior to drug delivery.**

- This process is done to ensure the medication works most effectively and the injection causes the patient the least amount of pain possible.

**Communicating warm-up time and temperature of a product prior to use** is an important topic for:

**Pharmaceutical manufacturers** who are developing medications that need to be warmed up prior to use, to support users in complying with instructions to warm a product prior to use.

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**Users** (patients, caregivers, healthcare providers) that need to warm a product prior to use.

One potential method of communicating warm-up time is to use **temperature-sensitive labels** on the packaging to indicate when the product has reached room temperature.

- These labels are small, so **iconography** is typically used to communicate temperature information.

For illustrative purposes, example icons that represent temperature were sourced from The Noun Project online design resource database.

**Example Temperature Icons from The Noun Project**

| | Warm /Too Warm | | | Cold / Too Cold | |
|---|---|---|---|---|---|
| Term Searched | "Sun" | "Warmth" | "Thermometer" | "Frost" | "Thermometer" |
| Icon Example |  |  |  |  |  |

**An assessment is needed,** of:

- Standards and regulations that provide guidance on communicating warm-up time and temperature of a product related to its use, and
- Existing temperature-sensitivity iconography and temperature-indicator labels in on-market products.

Learnings from this research may inform the design of device labeling and instructional materials related to warming up medication.

## OBJECTIVES

1. Present an evaluation of notable temperature-sensitivity symbols and icons, and ways of communicating warm-up time to users from:
   - Standards and regulations, and
   - On-market combination products.
2. Share user insights and lessons learned from a usability testing case study on a set of temperature-sensitive labels.

## METHODS

The standards and regulations listed in the below table were reviewed to identify applicable guidance related to iconography and "warm-up time" communication.

| International Standards | Regulations (US) |
|---|---|
| • ANSI/AAMI HE75<br>• ANSI Z535.4<br>• IEC 60601-1-6:2010/AMD1:2013<br>• IEC 60417<br>• IEC 62304:2006/A1:2015<br>• IEC 62366-1:2015<br>• IEEE 11073-10417<br>• ISO 15223-1:2021<br>• ISO 14971:2019 and ISO/TR 24971:2020<br>• ISO 11607-1:2019 | • 21 CFR Part 201 Labeling<br>• 21 CFR Part 801 Labeling<br>• 21 CFR Part 820 Quality System Regulation<br>• FDA, "Applying Human Factors and Usability Engineering to Medical Devices"<br>• FDA, "Instructions for Use — Patient Labeling for Human Prescription Drug and Biological Products — Content and Format"<br>• FDA, "Human Factors Implications of the New GMP Rule Overall Requirements of the New Quality System Regulation"<br>• FDA, "Application of Human Factors Engineering Principles for Combination Products: Questions and Answers"<br>• USP <659> Packaging and Storage Requirements<br>• USP <1079> Good Storage and Distribution Practices for Drug Products |

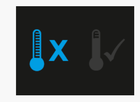
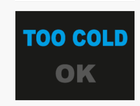
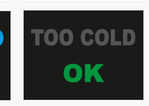
The labeling for notable on-market medicinal products that communicate information about the temperature of a product prior to use were reviewed to explore how warm-up is communicated to users (text instructions or using icons, symbols or labels):

- Lantus (insulin product),
- Pfizer-BioNTech Covid-19 (mRNA vaccine),
- Enbrel (biologic; tumor necrosis factor blocker),
- Humira (biologic; tumor necrosis factor blocker),
- Avonex (biologic; interferon beta- 1a),
- Orencia (biologic for autoimmune conditions), &
- Taltz (biologic for autoimmune conditions).

## A CASE STUDY

**A formative usability test was conducted to evaluate four design concepts for temperature sensitive warm-up compliance labels that are intended to visually indicate that the product has or has not reached room temperature.**

- A total of n=45 participants completed testing, including 18 adult patients, 17 adolescent patients, and 10 healthcare providers (HCPs).
- Each of the four design concept prototypes each contained two sets of temperature-sensitive labels, one that was visible when the product was below room temperature and one that was visible when the product had reached room temperature.

| Concept | <15°C | ≥15°C |
|---|---|---|
| A "thermometers" |  |  |
| B "stop sign/check mark" |  |  |
| C "not ready/ready" |  |  |
| D "too cold/ok" |  |  |

## RESULTS

**0/11 Of the 11 international standards reviewed, none provided standard guidance for communicating warm-up time or temperature-sensitivity of the product.**

- Focus of existing standards is on designing for safe and effective use, which includes storage and handling prior to use of the product.

**0/9 Of the 9 U.S. regulations reviewed, none prescribed specific icons or methods for conveying temperature sensitivity or warm-up time information.**

- The regulations generally mandate that any critical information for safe use (including instructions such as "warm-up time") be clearly communicated (see 21 CFR 201, 801, 820).

**0 to 1/7 Of the 7 on-market products that were reviewed to explore how warm-up time is communicated to users, none utilized temperature-sensitivity labels and only 1 used an icon to communicate warm up instructions (excerpt from Taltz IFU below).**

**Step 1a**

- **Take the TALTZ autoinjector from the refrigerator.**
- Remove the autoinjector from the package. Put the original package with any unused autoinjectors back in the refrigerator.
- Leave the base cap on until you are ready to inject.
- **Wait 30 minutes** to let the autoinjector warm to room temperature before you use it.
- **Do not** microwave the autoinjector, run hot water over it, or leave it in direct sunlight.
- **Do not** shake the autoinjector.


### Case Study User Insights

- Symbol-based labels were more frequently scored "best" when compared to text-based labels.
- The thermometer symbol was found to be more understandable to users.
- The words "OK" or "ready" lacked temperature-specific context, when presented on their own.
- Color primarily conveys meaning (i.e., green = go, red = stop). Red "ready" text was confusing to participants.

## CONCLUSIONS

- With limited standards and regulations to guide pharmaceutical manufacturers on communicating warm-up time for medical products prior to use, manufacturers often rely on text-based instructions.
- There are a variety of icons available to users in the public that manufacturers could leverage to communicate temperature sensitivity of a product, but without guidance and standards for such communication, it is difficult for manufacturers to be consistent, which can be confusing for users.
- Contextual factors play a role in iconography development (e.g., heating pad or fire symbol is not appropriate for warming at room temperature).
- **Ultimately, icons must be:**
  **Clear,**
  **Consistent,**
  **Culturally sensitive,** and
  **Compliant.**

### Implications for Practice

- **Adoption of standardized temperature icons across the industry through regulatory alignment can reduce confusion and enhance consistency in instructions, benefiting users, manufacturers, and regulators.**
- Insights from this work can inform the design of future device labeling and instructional materials, making them more user-friendly and effective in communicating critical information.

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