November 22, 2021

Subject: Philips Infa-Therm Infant Transport Mattress

Dear Philips Distributor,

The enclosed Urgent Medical Device Recall notice is related to the Philips Infa-Therm Infant Transport Mattress. As part of the recall process, unused product(s) must be destroyed, regardless of expiration date. We sincerely regret this and apologize for the disruption this may cause your organization. You may request a credit for any unused and destroyed product(s).

The following link should be used by Philips Distributors only to submit both your acknowledgement of this recall and actions taken, as well as request for credit: https://forms.office.com/r/zdRPY0Fth9.

If you have a request for credit, please provide the information listed below when completing the credit section (last portion) of the on-line response.

1. Distributor Account Number.
2. Either the Purchase Order # or Sales Order # used for the purchase of the Philips Infant Transport Mattresses for which you are requesting credit.
3. Quantity (counted by each or individual) of Philips Infant Transport Mattresses to be credited. Please allow up to 4 weeks to receive your credit.

It is important that end-users with the affected Philips Infant Transport Mattresses as identified in the "AFFECTED PRODUCTS" section of the UMDR, receive this Notice. Because Philips sells these products through distributors, including your organization, we may not have the information to contact all users. Therefore, it is your responsibility to reach out to your customers. Please send them the enclosed Urgent Medical Device Recall Notice (UMDR) omitting the final page of UMDR which includes information for Distributors only. You may create your own response notification pathway for your customers.

Note: Philips has sent this notification to all customers to whom Philips shipped directly (i.e. customers in the "Ship To" field on the original invoice).

If you need any further information or support concerning this issue, please contact InfantWarming@Philips.com.

Unfortunately, Philips will no longer be offering this product. Again, we truly regret the inconvenience this may cause your organization and we deeply apologize.
Dear Customer,

Philips is initiating a voluntary recall of the Philips Infa-Therm Transport Mattress product.

The Infa-Therm Transport Mattress is a single use, exothermic moist heat pack activated by a healthcare professional within a hospital or institutional environment and intended to provide supplemental warming during transport of an infant.

This URGENT Medical Device Recall Letter is intended to inform you about:

1. The problem

After the device was cleared by the FDA, Philips made changes to the labeling that do not fall within the existing FDA clearance. These devices with the modified labeling cannot be distributed or sold without new 510(k) clearance. Since 2009, Philips has received 3 total complaints which were reportable events of accidental burns in the neonatal population; one of these was later determined not to involve a Philips device.

The main labeling changes were:

- Maximum activation temperature: Changed from 105°F to 117°F
- Expiration Dating: Added an Expiration date to the labels
- Warning in the IFU: Added “Use before expiration date to prevent risk of burn”
2. The hazard/harm associated with the issue

The potential for harm (infant skin burns) associated with the modified labeling content has not been reviewed and evaluated by the FDA. Philips’ assessment concluded that the labeling changes do not pose a safety or performance risk to the patient or user.

3. Affected products and how to identify them

<table>
<thead>
<tr>
<th>REF #</th>
<th>Product Description</th>
<th>Affected Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>989805616831</td>
<td>1015</td>
<td>Infa-Therm Transport Mattress</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All units are impacted</td>
</tr>
</tbody>
</table>

4. The actions that should be taken by the customer / user to prevent risks to patients or users

<table>
<thead>
<tr>
<th>Step Number</th>
<th>Infa-Therm Transport Mattress</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Identify all Infa-Therm Transport Mattress in your possession.</td>
</tr>
<tr>
<td>2</td>
<td>Destroy all Infa-Therm Transport Mattress, regardless if they are expired or not.</td>
</tr>
<tr>
<td>3</td>
<td>Please complete the Urgent Medical Device Recall Response Form online by using the URL provided on the form.</td>
</tr>
<tr>
<td>4</td>
<td>Identify and source an alternative device to meet your needs. Philips will no longer offer the Infa-Therm Transport Mattress.</td>
</tr>
<tr>
<td>5</td>
<td>Share this communication with your staff and other impacted departments and organizations.</td>
</tr>
</tbody>
</table>
5. Actions planned by Philips to correct the problem

We understand that this may be an inconvenience to you. Philips will reimburse you for the quantity of the Infa-Therm Transport Mattresses destroyed.

If you need any further information concerning this issue, please email InfantWarming@Philips.com (preferred communication path) or contact +1-629-215-7280 Monday through Friday, 8AM – 3PM Central Standard Time. If you email InfantWarming@Philips.com, you will receive an email response with the link to submit your Recall Acknowledgement form online, as well as a response to your inquiry.

This notice has been reported to the appropriate Regulatory Agencies.

If you experience any adverse reactions or quality problems with the use of our products, you may report adverse reactions or quality problems to the FDA’s MedWatch Adverse Event Reporting program either online https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=consumer.reporting1, by regular mail or by fax (1-800-332-0178).

Philips regrets any inconvenience caused by this problem.

Sincerely,

Jeffrey Hoebelheinrich

Head of Quality
Medical Consumables & Supplies
Philips Healthcare
URGENT MEDICAL DEVICE RECALL RESPONSE FORM

Reference: Infa-Therm Transport Mattress

Customer Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Medical Device Recall Letter, understanding of the issue, and required actions to be taken.

- Identify and destroy all Infa-Therm Transport Mattresses, regardless if they are expired or not
- Share this communication with your staff and other impacted departments and organizations
- Please provide the number of mattresses destroyed, acknowledge receipt and understanding of the accompanying Urgent Medical Device Recall Letter and confirm that the information from this Letter has been properly distributed to all users that handle the Infa-Therm Transport Mattress by visiting, https://forms.office.com/r/zdRPY0Fth9 to complete the Recall Response Form. Please complete form promptly and no later than 30 days from receipt of notice.

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