Date: 21/11/2022 (Translated on 2022-12-08)

Urgent - Safety Notice

Reminder of the instructions for use of the infant radiant warmer for newborns FABIE (Ref. 4300) and the AMBIA care cradle (Ref. 4356 and 4357)

To the attention of:

The local materialovigilance correspondent
And/or the maternity and neonatal departments
And/or the Director of the establishment

Contact information for local representative
If you have any questions about this recall, please contact médipréma : Sales department : service.commercial.france@mediprema.com / +33 (0)2 47 28 23 86 After sales services : sav@mediprema.com / +33 (0)2 47 28 36 86 Quality department : qualite@mediprema.com / +33 (0)2 47 29 49 34

1. Information on the products concerned	
1.	**1. Type(s) of product**
	This safety notice applies to infant radiant warmer FABIE (Ref. 4300) and care cradles AMBIA (Ref. 4356 and 4357) for newborns. This notice does not apply to AMBIA (Ref. 4351, 4352, 4353, 4354, 4355).
1.	**2. Trade name**
	FABIE radiant incubator for newborns (Reference 4300). AMBIA care cradles for newborns (Ref. 4356 and 4357).
1.	**3. Primary clinical purpose of the device(s)**
	The FABIE-AMBIA radiant incubator is designed to maintain the thermal balance of a newborn by direct radiation of infrared energy.
1.	**4. Reference(s) of the device(s)**
	Catalog number: 4300, 4356, 4357
1.	**5. Software version**
	Software version 1.0 or 1.1
1.	**6. Serial numbers or batches concerned**
	All FABIE-AMBIA devices, References 4300, 4356, 4357 with a incline / decline system, put on the market.

2. Reason for the Corrective Action (FSCA)	
2.	**1. Description of the problem**
	Please be advised that an error in use has been reported during the nursing of a newborn with a FABIE radiant incubator (Ref.4300). The purpose of this safety notice is to remind you of the instructions for use of our FABIE-AMBIA devices, to permit you to assure the safety of the newborn, through the correct use of the incline / decline system and the correct positioning of the foldable screens.
2.	**2. Risk that caused this Safety Corrective Measure (FSCA)**
	Fall of a newborn resulting from the manipulation of the FABIE infant radiant warmer (Ref.4300) by a not intended user (parent).
2.	**3. Probability of occurrence of the problem**
	2 incidents involving two patients have been reported on 741 FABIE infant radiant warmer (Ref. 4300) put on the market since 2006 in France (1761 sales in the world). The risk associated with errors in using the infant radiant warmer was identified by médipréma in its risk analyses before the incident occurs.
2.	**4. Additional information to characterize the problem**
	Use of the infant radiant warmer by a user not intended by médipréma. Non-compliance with the instructions for use in the user manual.

2.	**5. Background of the problem**
	After the parents have placed the newborn on the infant radiant warmer's sleeping surface, the correct positioning and safety of the child has not been verified by the medical staff, including the use of the incline / decline system and the locking of the protective screens (foldable screens). The manipulation of the device by parents must be supervised by medical personnel previously trained in its use. When activation of the incline / decline system, it is necessary to make sure that the screen at the front of the sleeping surface is in the upright position and locked. The child must not be left unsupervised if the screen is opened.

3. Action to be taken to mitigate the risk

3. **1. Measures to be taken by the user**

☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device

☐ On-site device modification/inspection ☒ Follow patient management recommendations

☐ Take note of amendment/reinforcement of Instructions For Use (IFU)

☐ Other ☐ None

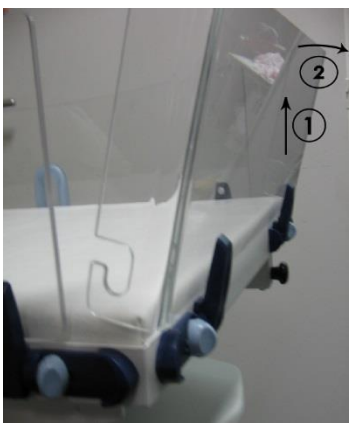
We would like **to remind you of the instructions for use**, available in your user manual:

- § 4.1 Foldable screens, for FABIE (Ref. 4300) et AMBIA (Ref 4356 & 4357)
- § 4.6 Bedding tray incline/decline, for FABIE (Ref.4300)
- § 4.8 Care cradle incline, for AMBIA (Ref. 4356 & 4357).

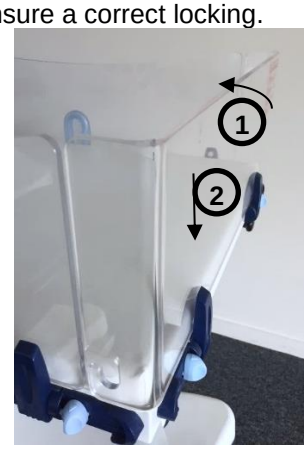
Foldable screens (FABIE-AMBIA care cradle)

The screens can be folded down or removed.

To fold the screens down, pull them slightly upwards (**1**) and then tilt them outwards (**2**).



To close the screens, proceed in the reverse order by folding up the screens (**1**) then make sure they go down (**2)** after reaching the vertical position to ensure a correct locking.



To remove them, slide the two hinge pins out, one after the other (**1**), then remove the screen (**2**).

Never leave the device unattended while the screens are folded down: risk of the infant falling out.

Check that all screens are properly closed before leaving the newborn without supervision, especially after any intervention of a person not trained in the use of this medical device (parents, etc.).
Make sure that decline no item (blanket, cloth…) interfere with the locking of the screens.

FABIE - Bedding tray incline/decline

The tilt position is adjusted by holding the tray with the left hand, and pulling the lever located under the tray on the right with the right hand.

Pull completely the lever (**1**) then adjust the tilt of the tray (**2**), without applying excessive force on the tray. Release the lever (**1**) to lock the tilt.

When the lever is pulled, the tray should pivot effortlessly. Always completely pull the lever to ensure the gas spring is correctly unlocked before trying to adjust the tilt of the tray. If the tray pivot with difficulty although the lever is pulled, or if the tray does not lock when the lever is released, stop using the device and contact *Médipréma* Customer Service.

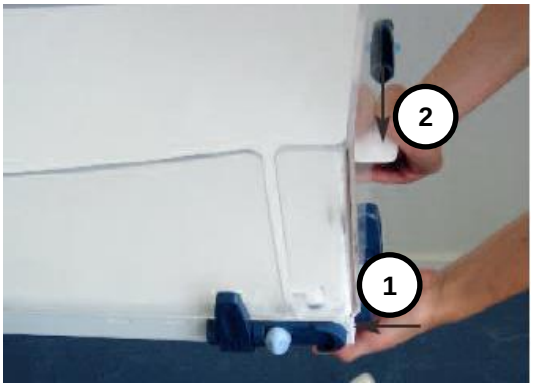
The baby can slip if the tray is in a highly tilted position. Loops are provided for use with retaining straps to prevent this. Medical personnel are responsible for deciding whether or not to use them. Always check the side screens are locked, falling hazard.

The Fabie Infant warmer is designed to distribute heat uniformly over the entire surface of the bedding when it is in the horizontal position. Obviously, during use when tilted, the temperature is greater at the highest point (and correspondingly lower at the lowest point). When the tray is in the maximum feet-up position, the temperature at the top edge is 3°C higher than the temperature at the center of the mattress. Consequently, the head or the feet of the newborn will be warmer (depending on his or her position); therefore, it is necessary to adjust the control temperature as a function of temperature reactions of the baby.

AMBIA - Care cradle incline

1 – Push the handle toward the inside
2 – Lower the bedding, without applying excessive force.

To raise the bedding just push on the handle. A gas spring will automatically raise the bedding.



When the handle is pushed, the tray should pivot effortlessly. Always completely push the handle to ensure the gas spring is correctly unlocked before trying to adjust the tilt of the tray. If the tray pivot with difficulty althoug the lever is pulled, or if the tray does not lock when the lever is released, stop using the device and contact *Médipréma* Customer Service.

The baby can slip if it is in the maximum tilt position. Loops are provided for use with retaining straps to prevent this. Medical personnel are responsible for deciding whether or not to use them.

Therefore, we inform you that all users of the device must be trained in its use. The use of the device is reserved for suitably trained persons and under the direction of qualified medical personnel who are informed of the risks and benefits associated with the use of the FABIE radiant incubator and AMBIA care cradle

Training sessions can be provided on request.
If you have any questions regarding user training, please contact the manufacturer, médipréma :

Sales department: service.commercial.france@mediprema.com / +33 (0)2 47 28 23 86
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3.	**2. Deadline** for implementation of these measures	January 23, 2023
3.	**3. Is a response from the client necessary?** (see acknowledgement of receipt form in attachment)	No
3.	**4. Measures taken by the manufacturer** ☒ Reminder of the instructions for use	
3.	5. Should the FSN be communicated to the patient/end user?	Yes, communication to the end user
3	6. If yes, has the manufacturer provided additional information tailored to the patient/user in an information letter?	
	No, reminder of the instructions for use already indicated in the user manual.	

	4. General information	
4.	**1. Type of notification FSN**	New
4.	**2. Other advice or information expected in the follow-up to this notification**	None
4.	**3. Manufacturer's information** (For the contact information of the local representative, see the first page of this security notice)	
	a. Name	**Médipréma**
	b. Address	**ZA Node Park Touraine** **470 rue Gilles de Gennes** **37310 Tauxigny** **France**
4.	**4. The competent (regulatory) authority in your country has been informed of this communication to customers:**	No
4.	**5. Attached document(s) :**	None
4.	**6. Name / Signature**	**Diana Gratade** **Quality and regulatory affairs manager**

	Transmission of this security notice
	This notice should be forwarded to all affected individuals within your facility or to any facility to which you have transferred affected products (if applicable). Please forward this notice to any other organization that may be impacted by these measures (if applicable). It is important that this information and the resulting actions are regularly reiterated for as long as necessary to ensure the effectiveness of the corrective actions taken. Please report any product-related incidents to the manufacturer, distributor or its local representative, and to the competent authority if applicable, as this provides important feedback.