

Company headed letter

To the Medical Devices Vigilances System Manager
To the Biomedical Departement

Adress

Tauxigny, 13th March 2018

Object : Important safety notice

Involved products : Radiant warmer Fabie – reference 4300

Involved services : Neonatal unit, maternity or obstetrical ward

Dear Sir, Dear Madam, Dear client

An event occurring on a radiant warmer Fabie 4300 came to our attention last July. A newborn fell from the bed placed in anti-Trendelenburg position.

Assessment has revealed that this event is linked to the two following conditions :

- Malfunction of the blocking actuator at the rear of the table, which extended under the load and didn't maintain the bedding surface in horizontal position.
- Front panel of the table left open or not properly closed by the user

According to the actuator manufacturer's analysis, the malfunction could be linked to the user(s) applying an excessive load on the actuator, without properly activating its release.

It's the first event of that sort that we know of since the product has been launched in 2006. Nevertheless, as a precaution, and to avoid any new incident, we would like to remind users of our instructions for use. Meanwhile, we are updating our control instructions during preventive maintenance.

Our traceability shows that you are the owner of the material listed below. We kindly ask you to communicate on this matter with the services involved.

Please confirm your receiving this letter by sending back the acknowledgment receipt here attached.

A copy of this note has also been forwarded to the biomedical engineer of your institution.

For any further information, please contact our customer service +33 (0)2 47 28 36 86.

We apologize for the inconvenience, and thank you in advance for your collaboration.

Yours sincerely,



Jean-Luc Vanhée
Medical Devices Vigilance Manager

Company headed letter

Client number : xxxxxxxxxxxx

Institution : xxxxxxxxxxxx

Our traceability shows that you are the owner of the following devices (Serial number) :

4300-xxxx ; 4300-xxxx ; 4300-xxxx ;

Reception acknowledgment, to be sent to +33 (0)2 47 27 35 85 (fax) or sav@mediprema.com

I hereby certify :

Title :

Institution's name :

Email :

Phone number :

Acknowledge receipt of MEDIPREMA's letter regarding the warming table FABIE sent on 13th March 2018.

Date and stamp :

CONTROL OF INCLINE/DECLINE

During preventive maintenance operations (at least once a year), check the operation of the table bed incline/decline (tilt) function as follows :

Operation check :

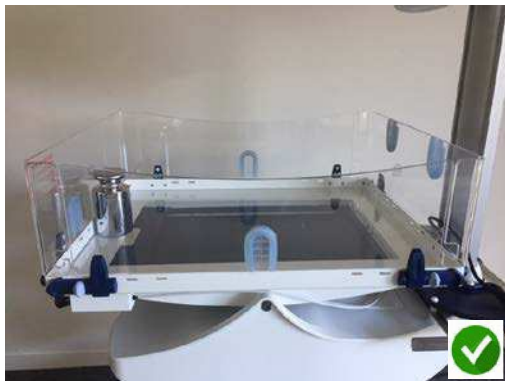
Adjust the bedding surface into tilt (incline/decline) position by holding the bed's handle with the left hand, and pulling with the right one on the knob located on the right side. Pull the knob (1) and adjust the tilt (incline/decline) without forcing (2). Release the knob to block the bed.



Bedding surface movement must be easy, without exerting pressure and must lock upon realeasing of the knob. If the bed doesn't tilt easily, isolate the device and call Médipréma or your dealer customer service.

Control of the actuator

Position a 5 to 10kg weight at the front of the bedding surface placed horizontally. Leave the bed with this weight on it for at least 1 hour. Check that it remained horizontal.

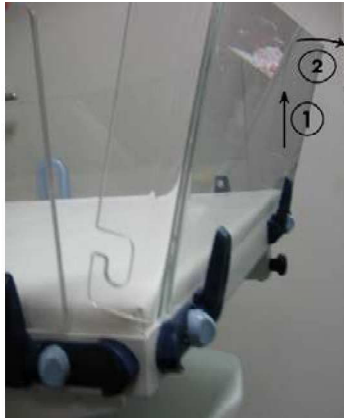


Bedding surface must stay in its original position. If you've noticed a shift in position, isolate the device and call Médipréma or your dealer customer service.

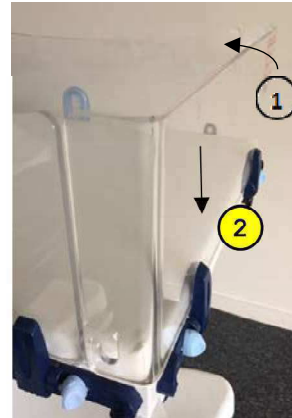
Please add this note to your instructions for preventive maintenance. Our customer service remains at your disposal for any further information.

Panels handling

To fold down the panels,
slightly pull upwards (1) and
then rotate them outwards (2).



To close the panels, do in
reverse order : rotate the
panel towards the inside of the
bed (1) and press it down to
lock it (2)



Never leave a newborn unattended if the panels are opened or removed (risks of falling).



Check that the panels are correctly locked before leaving the baby. Make sure no object (sheets, dressings...) prevents the panels from locking properly

Bedding surface maneuver for tilt

Adjust the bedding surface into tilt (incline/decline) position by holding the bed's handle with the left hand, and pulling with the right one on the knob located on the right side. Pull the knob (1) and adjust the tilt (incline/decline) without forcing (2). Release the knob to block the bed.



Bedding surface movement must be easy, without exerting pressure and must lock upon realeasing of the knob. If the bed doesn't tilt easily, isolate the device and call Médipréma or your dealer customer service.



In maximal tilted position, the child can slide. The side of the bed features provisions for retaining straps to prevent this. Using such devices or not is the responsibility of the medical staff.

Please add this note to the user manual issued when device was delivered. Our customer service remains at your disposal for any further information.