

David Clark,  
Assistant Coroner,  
Warwickshire Justice Centre,  
Newbold Terrace,  
Leamington Spa,  
Warwickshire.  
CV32 4EL

April 5<sup>th</sup>, 2016

**SUBJECT: Regulation 28 Report – Eileen Annie Thompson**

Dear Sir,


Firstly please let us state that we were very sorry to hear of the passing away of the lady involved in this incident and wish to pass our condolences onto the family. ArjoHuntleigh received your letter, via email, in regard to the above case on the 3<sup>rd</sup> March 2016.

ArjoHuntleigh utilises a global vigilance system for its distributed devices and as part of this Post Market Surveillance (PMS) system we have investigated this unfortunate incident and reviewed the recommendations from the inquest and would like to respond as documented below:

We have enquired with the supplier of the bed in question and it has been confirmed that all 4 brakes on the bed were working to specification. As the supplier had not been informed of the incident the actual bed in question had been out on loan another 4 times since the original incident.

We have recreated a simulation of the incident in a laboratory environment and are able to conclude the following:

- *It is possible to apply all four brakes on the bed castors, even when the bed is placed alongside a wall/s. After setting the bed in its intended position, it is still possible to access to the brakes that are next to the wall/s.*  
*One wall*

2.	Test has been performed to check if it is possible to apply brakes on castors located close to the wall when the bed is placed against one wall and in the lowest position	In situation as described, it is possible to apply all four brakes by approaching them, as shown by narrows, from the front or/and from the side. 
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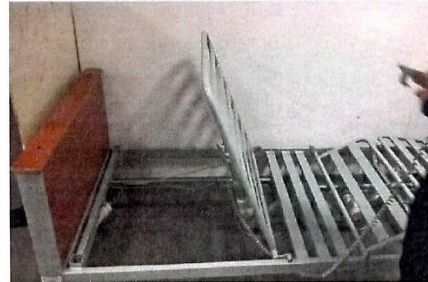
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## Two walls

3.

Test has been performed to check if it is possible to apply brakes closer to the wall when the bed is placed in between two walls

1. It is possible to raise the backrest to its maximum range of motion and, by going to the inside of the bed, brakes can be applied



- *The Instruction For Use (#746-396-UK rev.6 dated on February 2010) provides all necessary information regarding usage of the brakes. It also warns the user about necessity of applying all 4 brakes to prevent the bed from moving whilst in use with a patient.*

**Brakes and castors**

Each of the four castors is fitted with a separate brake.

**WARNING**

To prevent the bed from moving, apply the brakes on all four castors whenever the patient is moved to or from the bed.


**To apply the brake**      Press down on the brake operating lever (A) until it locks in the "down" position.

**To release the brake**      Push the upper end of the brake operating lever horizontally (B) until it springs back into the "up" position.

- *The lowest height level that the bed can be set to is approximately 28 cm. During the incident the bed was in use with a mattress (unknown what type). According to the Instruction For Use for the Minuet 2, it can be used with a mattress of maximum height 12,5 cm. Therefore the maximum height from which the patient could have fallen is established to be approximately 40 cm. Moreover, the IFU warns the user that the bed should be lowered to the minimum height position whenever the patient is left unattended.*
- *The force needed to move the bed from the wall is strictly correlated with an actual load applied on the bed and coefficient of the friction between castors and floor. With the limited information provided, we were unable to recreate the same conditions as during the event occurrence, but we did manage to perform a test to estimate the force needed to push the bed from the wall while an 80 kg person is lying on the bed, whilst the bed was situated on a hard and smooth surface offering low friction and resistance to castor movement. During the test, it was concluded that a relatively big force (450N) is needed to push the bed away from the wall and this activity was described as 'hard' by the person involved in the test.*
- *The Minuet 2 bed device can be used with safety side panels, which act as a mechanical barrier for the patient to reduce the possibility of unintentional exit from the bed. They are however not intended to restrain patients who make a deliberate attempt to leave the bed. Please note that this is an optional function proposed for this bed and the decision whether to use it or not should be made by a qualified personnel.*
- *As per the Instruction For Use provided for this particular bed (#746-396-UK rev.6 dated on February 2010) a clinically qualified person responsible is to consider the size, age and condition of the patient before allowing the use of safety sides.*

**Safety sides – all models, full length and folding**

**WARNING**



Only use ArjoHuntleigh safety sides that are designed and specified for use with this bed. Incompatible safety sides can cause a hazard.

Safety sides should be fitted either by a properly trained person or, due to the size and shape of these items, by two people if they are unfamiliar with the installation procedure.

Safety sides must always be used with a suitable mattress of the correct size; refer to page 12 for more information.

- The maximum recommended mattress thickness for use with standard height safety sides is 150mm.
- Extra-height safety sides can be used with mattresses or mattress combinations up to 172mm thick.
- Safety Side Height Extension and Full Length Standard Height Wooden Safety Sides can be used with a mattress and mattress overlay up to 265mm thick.


The clinically qualified person responsible should consider the size, age and condition of the patient before allowing the use of safety sides.

Safety sides are not intended to restrain patients who make a deliberate attempt to leave the bed.

Always run the cable from the control handset between the safety side and the frame of the bed.

Do not use the safety sides or safety side height extensions to move or lift the bed.

When using a powered air mattress system, the air supply tube for the mattress should be positioned between the safety side and the frame of the bed.



Safety side contact points are identified by this symbol. Take care to keep hands and fingers away from these areas.

Extract from IFU

We should also like to point out that we were informed of the incident on the 15<sup>th</sup> February 2016, which is approximately 6 weeks after the incident occurred and 3 days after the conclusion of the coroner's inquest.

We believe that our original risk assessment (as detailed in our product risk management files DHF 2400-304.2\_4 HTM Minuet 2) adequately addresses the hazardous situation identified. Based on the performed investigation, it seems that the patient was assessed as being unsuitable for safety side use due to her condition. Additionally, the user placed the bed in the lowest position and with mattresses on the floor. Putting the bed in lowest position is not an uncommon practice but placing mattresses on the floor is not considered normal clinical practice. It appears to indicate either the expectation from the user that the person would attempt to leave the bed intentionally or at minimum that there were circumstances relating to the use of the bed that were not shared with the manufacturer.

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In conclusion we believe that the root cause for this event is related to the combination of the use of the device and the patients' health state (including pre-existing conditions). Taking into the consideration that the patient, who was involved in this particular event, was diagnosed with dementia and had no upper body stability, it seems unlikely that a gap between the wall and bed frame could have been created in an immediate manner, without a significant effort from the patient side. We have reviewed the current warnings included with our products, which we feel are clear and fit for purpose and have also undertaken PMS reviews to highlight similar incidents globally (none) and therefore feel that no further action is required in this matter.

Yours Sincerely



Andy Ellis  
Director Quality & Regulatory Compliance – North Europe

On behalf of  
ArjoHuntleigh

cc: AHVigilance, UKSSUComplaintHandling