

## Field Safety Notice

APH031 Pandora Profiling Bed

HPRA Ref: V30819

Type of action: Updated Instructions for Use & Warning Label

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Date: 24<sup>th</sup> January 2019

Attention: All users, installers and service engineers

### Details on affected devices:

This FSN affects all Pandora Profiling Beds currently used on the Irish market. These beds were purchased by the HSE from Lyncare and are serviced by Healthcare 21 on behalf of the HSE.

*Product / Model numbers:* APH031

*Serial Numbers:* HCP147700027-274, HCP771500001-120, HCP771600001-027 (inclusive)

### Description of the problem:

This FSN has been issued as a result of an incident that occurred whilst the product was in use with incorrectly installed accessories and with certain third-party accessories.

We have investigated the root cause of the incident and are aware of the circumstances that can lead to damaging the bed and ultimately to failure of the backrest mattress platform.

We are issuing this Field Safety Notice in response, to raise awareness of the need to ensure that appropriate product user awareness and in particular use of accessories with this product are in place prior to using any equipment.

Incorrect installation of accessories and/or use of third party accessories not strictly designed and manufactured for use with the Apollo Pandora bed can, in some instances, have a detrimental effect on the operation of the moving parts of the bed, in particular, the backrest mattress platform.

Certain accessories, if not installed correctly, can restrict the free movement of the backrest mattress platform, causing the backrest actuator mounting point to be subjected to a greater force than it is safely designed to do. Initially the paint can crack but with prolonged use, the metal frame itself can become bent or even torn.

This process is a gradual one i.e. there should be no sudden bending or tearing of the metal. It happens over a period of time, indicated by the backrest mattress platform not being able to be raised to its full angle of lift.

Our products have always been provided with user guides and instructions for use. It is important that this information is available and understood by users prior to putting the equipment into use. This information should be kept on file and made accessible to all users during the products life.

As part of this FSN the instructions for use have been revised to include a section on the correct installation of Apollo accessories and a warning about the use of third party accessories and the damage that they can cause. An electronic copy of the revised IFU is available to download from our website by clicking on the following link [http://www.apollo-ht.co.uk/uploads/File/downloads/Pandora\\_Bed\\_Manual\\_Rev\\_4\\_30-03-2017\\_217218.pdf](http://www.apollo-ht.co.uk/uploads/File/downloads/Pandora_Bed_Manual_Rev_4_30-03-2017_217218.pdf)

For further clarity the following warnings and sections were added to the IFU in the update:



**Use of non-Apollo Healthcare Technologies accessories is not advised. Installing third party accessories could restrict the moving parts of the bed. The warranty does not cover any damages caused by use of third party accessories and your warranty could be void if third party accessories are installed and used.**

#### 4.5 Bed Lever (additional accessory)

The Apollo Healthcare Technologies bed lever can be installed to aid the bed user move from a lying to a sitting and to a standing position.

##### Fitting

The bed lever can be fitted to either side of the bed frame where required. Secure the bed lever by unscrewing the hand screws and fitting the brackets over the frame. Fully tighten the hand screws when the lever is located correctly. The top of the bracket must be flush with the top of the bed frame with no movement possible up or along the frame.



**The Apollo bed lever is designed to not restrict any moving part of the bed including the side rails and backrest mattress platform. Do not install any third party bed lever as it may restrict the moving parts of the bed, especially the backrest mattress platform.**

#### 4.6 Dynamic Mattress (additional accessory)

Apollo Healthcare Technologies can supply a number of dynamic mattresses for use with the bed if required by the user. There are various ways in which the dynamic mattresses can be secured to the bed to stop it moving or slipping when the mattress platform is profiled but it is essential that in doing so, the movement of the mattress platform is not restricted in any way.

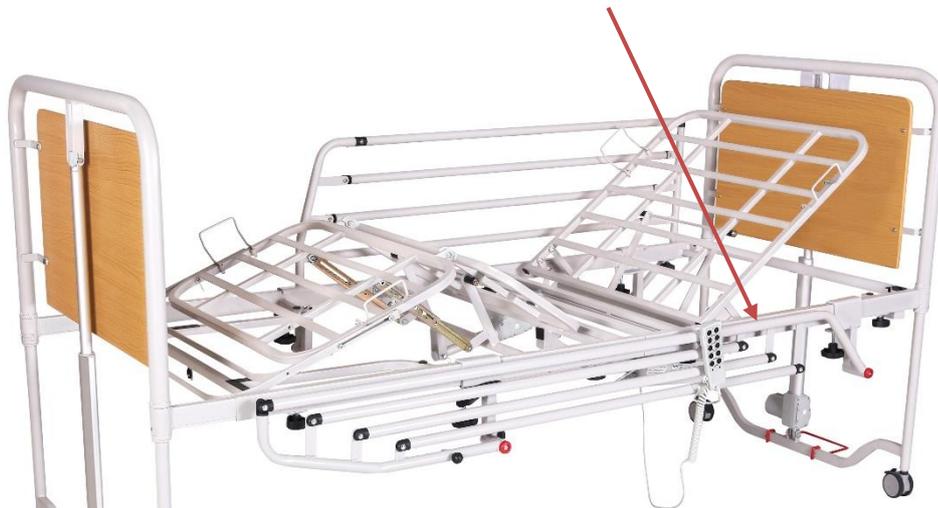
The example below shown in the images is of a dynamic mattress that utilises webbing straps in order to secure the mattress to the bed. The image on the right is the correct way where the straps are only secured to the moving part of the bed, namely the backrest mattress platform. The image on the left shown the incorrect way where the straps have also been secured around the non-moving frame of the bed.



Secondary to the revised IFU we have had a new label produced for the Pandora Profiling Bed to warn against the incorrect installation of accessories and the use of third party accessories. Please see image below:



The label will be available **for Irish users from the Irish distributor** HC21 and should be distributed by their engineers to all users of the Pandora Profiling Bed APH031 currently on the Irish market. The label should be placed on the outside of the bed frame in the most prominent place to where accessories could be installed and affect the backrest mattress platform.



**Advise on action to be taken by the user:**

If you are using, are installing or servicing a Pandora APH031 Profiling Bed, please obtain a copy of the revised IFU and the warning label.

It is very important that every user inspects the product thoroughly before each and every use, regardless of the age of product. You must ensure that particular attention is paid to the attachment of items that could prevent the correct operation of the product. If you are in any doubt about the use of accessories with the product, do not use, please place the product aside where it cannot accidentally be used by others and obtain additional advice from us.

In order to achieve best practice and of course follow health and safety guidelines, we insist that a thorough risk assessment and pre inspection of product suitability is conducted prior to use and that any additional items are used in a way that will not affect the correct operation of the product

**Transmission of this Field Safety Notice:**

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

**Contact reference points for the Irish market:**

Lyncare Ltd.  
Unit 3  
Shannonside Business Park  
Birdhill  
County Tipperary  
V94 V8W3  
Tel: +353 (0) 61 379 090

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Limerick Office  
Unit 1D  
Annacotty Industrial Estate  
Annacotty  
County Limerick  
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The undersign confirms that this notice has been notified to the appropriate Regulatory Agency

Signature



David Fletcher  
Business Manger

