

Harvest Healthcare Ltd

Important Field Safety Notice

Date 25.01.18

HA200 Unipump - Fitted to the following systems: Opal & Salisbury overlay mattresses. Chatsworth, Opal Plus, Prime comfort active replacements mattresses. Seats cushion system HH20. Systems produced in 2016 and 2017 are affected

Affected part: Low pressure sensor indicator.

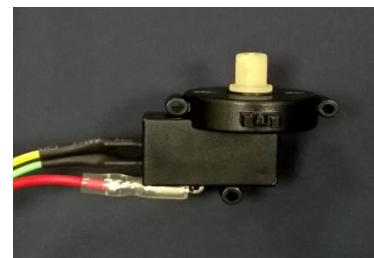
Part code UN-020

Description of the problem.

The pressure indicator is designed to indicate if the pump has detected a pressure drop when connected to an active alternating system. An audit has identified a failure on some units which are now in service. If the pressure indicator has stopped working, this will not activate if there is a deflation of the mattress. The Pump has been supplied with overlay systems and replacement systems. A visual inspection of the mattress to see if it has completely deflated is advisable as part of your routine daily checks.

Details on affected devices:

Models made in 2016 and 2017 are affected



The pump can be clearly identified by looking at the label situated on the underside of the pump. **EZ 16** indicates the year as 2016. These pumps have been supplied as individual units, or as part of active seat cushion and with alternating mattress systems.

It is important to inspect any pump you have regardless of its age to ensure the low pressure indicator is working correctly.

Advise on action to be taken by the owner/user.

How to test the pump for the fault, carry out the following action:

- Disconnect the pump from the mattress system.
- Allow the air to escape from both outlet ports.
- After 10 mins the low pressure light should have activated. This identifies that the pump is in good working order and no further action is required.
- If the low pressure light has not illuminated please follow the procedure below.



- Identify the faulty pump unit and repair or replace the affected item.
- Record the serial number.
- To repair or replace the pump unit contact Harvest servicing.
HH-Servicing (servicing@harvesthealthcare.co.uk)
- An Updated IFU with recommendations for a weekly check and yearly replacement of the pressure sensor can be obtained from customer service.
HH-Customer services (customer.service@harvesthealthcare.co.uk)

Transmission of this Field Safety Notice:

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

Contact reference person:

John Gerrard
Harvest Healthcare
Sheaf House, Bradmarsh Way, Bradmarsh Business Park, Rotherham, S60 1BW
Email john.gerrard@harvesthealthcare.co.uk

Signature



John Gerrard