

Safety Notice

Medical Devices

Opal, Opal Plus, Salisbury and Prime Overlay Mattresses and HH20 Active Seat System



Priority 2 – Warning

HPRA Safety Notice: SN2018(16)

Issue Date: 10th May 2018

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Harvest Healthcare Ltd.	V34743

ISSUE

Harvest Healthcare Ltd. have issued a field safety notice for devices manufactured using a HA200 Unipump. The pump's pressure indicator is designed to indicate if the pump has detected a pressure drop when connected to an active alternating system. Harvest Healthcare have identified situations in which the pressure indicator light did not illuminate as expected, when there is a drop in pressure.

Although the Manufacturer customer communication (attached) states that 2016 and 2017 models are affected, it is subsequently clarified that **all** devices incorporating this pump should have the recommended testing carried out, regardless of age. Harvest Healthcare have also updated their Instructions For Use for each device and are recommending that the pump's pressure sensor bag is replaced during annual service.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

- 1 Read and follow the instructions provided in the manufacturer's FSN.
- 2 Ensure that relevant personnel within your organisation receive a copy of the FSN.
- 3 Forward this HPRA Safety Notice to all those who need to be made aware within your organisation or to any organisation/person where these devices have been transferred.
- 4 Carry out the pump test as instructed by the FSN.
- 5 Ensure you have a copy of the updated IFU for each device.
- 6 Report any adverse events / incidents associated with this device to the manufacturer and the HPRA.

TARGET GROUPS

Risk managers

Nurses

Geriatric Departments

Hospice

Care at home staff

Patients

Nursing Homes

Community Care

Domiciliary Care Providers

Equipment stores

BACKGROUND

The Opal, Opal Plus, Salisbury and Prime Overlay mattresses are alternating overlays, used for the treatment and prevention of pressure ulcers. An Active Seat System (HH20) is used to provide pressure relief for patients who are not bed bound. Alternating air cells distribute patient weight throughout various cycles. This assists in treatment for existing problem areas.

A Unipump pump powers the mattress overlays. The pump is equipped with a low-pressure indicator to inform the patient/carer of a system failure and the potential for deflation of the mattress.

The Harvest Healthcare have outlined the procedure for testing these pump units in their customer communication (attached). Should testing identify faulty pump units they may be repaired or replaced by contacting Harvest's servicing team using the email provided in the FSN.

In a recent audit the company identified a pump unit manufactured in 2017 where the pressure indicator light failed to operate when tested for low pressure. The company have are advising that all pumps should be tested regardless of age and that the pressure sensor bag be replaced during the pumps annual service

Harvest Healthcare have updated their IFUs for these devices with recommendations for a weekly check and yearly replacement of the pressure sensor. These IFUs can be obtained from Harvest Healthcare customer service. The manufacturer are also advising that a visual inspection of the mattress to see if it has completely deflated as part of routine daily checks.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION (amend as required)

Enquiries to the **manufacturer** should be addressed to:

Harvest Healthcare Ltd.	Telephone:	+44 (0) 1709377172
Sheaf House.	Fax:	+44 (0) 1709377173
Bradmarsh Way,	E-mail:	customer.service@harvesthealthcare.co.uk
Bradmarsh Business Park.	Website:	www.harvesthealthcare.co.uk
Rotherham.		
England.		

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority	Telephone:	+353-1-6764971
Kevin O'Malley House	Fax:	+353-1-6344033
Earlsfort Centre	E-mail:	devicesafety@hpra.ie
Earlsfort Terrace	Website:	www.hpra.ie
Dublin 2		