

**Notice Information: - Warning  
20 April 2009**

**Part 1. Product Information**

- a) Title:
- b) Product Name/Type:
- c) Reference:
- d) Manufacturer/Supplier:

**Part 2. Target Audience**

- a) Target Audience:

**Part 3. Problem/Issue**

- a) Problem/Issue:

**Part 4. Background Information**

a) Background Information:

Spacelabs Healthcare issued an 'Urgent – Medical Device Correction' letter in August 2008 advising all customers of several circumstances where the device alarm fails. It also advised customers of new software V3.05.7 EN that would be provided to correct the problem.

The affected devices were supplied to the Irish market by Hospital Services Limited and Fannin Healthcare.

Hospital Services Ireland has been coordinating this action in Ireland. However, despite several rounds of communication, they have experienced problems locating all of the affected devices. A significant number of devices still require the software upgrade.

## Part 5. Action to be taken

a) Action to be taken:

<div style="margin: 0cm 0cm 0pt"> Ensure that the appropriate personnel are made aware of this notice. </div>

<div style="margin: 0cm 0cm 0pt"> Advise Hospital Services Ireland of the number and location of all affected devices in your hospital / health board. </div>

<div style="margin: 0cm 0cm 0pt"> Ensure that the software upgrade is completed on all devices. </div>

## Part 6. Enquiries

a) All enquiries should be made to:

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

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: [vigilance@imb.ie](mailto:vigilance@imb.ie)

Website: [www.imb.ie](http://www.imb.ie)

Enquiries to the manufacturer should be addressed to:

Barry Cripps

Spacelabs Healthcare Limited

Beech House, Chiltern Court

Asheridge Road , Chesham

Buckinghamshire HP5 2PX

United Kingdom

Telephone: +44-1494-784422

Fax: 44-1494-794414

E-mail: [barry.cripps@spacelabs.com](mailto:barry.cripps@spacelabs.com)

BrianCrotty Hospital Services Limited

BrianCrotty

Hospital Services Limited

Telephone: +353-1-2950500

E-mail: brian.crotty@hsl.ie

IMB Safety Notice SN2009(02): Spacelabs Ultraview Digital Telemetry  
Transmitter Model 90478

## Part 7. Keywords

a) Keywords:

IMB Safety Notice SN2009(02): Spacelabs Ultraview Digital Telemetry  
Transmitter Model 90478