

Safety Notice

Medical Devices



IRISH MEDICINES BOARD

Kryo range of freezers

Priority 2 – Warning

IMB Safety Notice: SN2014(23)

Issue Date: 06 May 2014

MANUFACTURER / SUPPLIER	IMB CASE REFERENCE
Planer plc	V20007

ISSUE

Should the temperature probe to the chamber fail in a short circuit condition, the temperature will appear to be too cold, and the controller will attempt to compensate by warming the samples. Although this behaviour is the expected response of the control system, two software changes have been released to improve the resilience of the freezer systems to temperature probe faults. Planer has released new versions of the PID Engine firmware, PP007951 v6.85 and the MRV main application, CFG007954 v5.22.

ACTION OR RECOMMENDATIONS

The IMB advise that users:

- (1) Follow the instructions outlined by the manufacturer in the field safety notice (FSN) attached.
- (2) Forward this IMB Safety Notice to all those within your organisation that need to be aware of this information. Please also pass this Safety Notice and the attached FSN on to any end users or organisations where these devices may have been distributed.

TARGET GROUPS

All Hospital Staff	Purchasing / Procurement / Material Managers
Laboratory Staff	Risk Managers
Chief Executive Officers	Establishments authorised for the processing of
Healthcare professionals who use these devices	blood, tissues and cells
Hospital Managers	

BACKGROUND

Planer plc has issued a field safety notice relating to certain models of the Kryo range of controlled rate freezers. Such freezers are used to gradually freeze tissues and cells in the presence of cryoprotectants, in accordance with a programmed protocol. The models identified in the field safety notice are as follows:

- Kryo 1060-180
- Kryo1060-380
- Kryo3xx-1.7
- Kryo5xx-16
- Kryo750Plus
- MRV Controller, and
- Kryo-250

The IMB is working to ensure that all establishments which may cryopreserve tissues and cells using a controlled rate freezer are aware of the field safety notice.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

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

Service Manager
Planer plc,
110 Windmill Road,
Sunbury on Thames
Middlesex, TW167HD, UK

Telephone: +44 1932 755036
Fax: N/A
E-mail: service@planer.com
Website: N/A

Enquiries to the **manufacturer** should be addressed to:
(alternative contact details)

Quality Manager
Planer plc,
110 Windmill Road,
Sunbury on Thames
Middlesex, TW167HD, UK

Telephone: +44 1932 755072
Fax: N/A
E-mail: quality@planer.com
Website: N/A

IMB CONTACT INFORMATION

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

Irish Medicines Board
Human Products Monitoring
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie