MHRA
Medicines and Healthcare products Regulatory Agency
Safeguarding public health

# Medical Device **ALERT**

Ref. MDA/2003/033
**Issued: 09 October 2003**

| For: | | |
|---|---|---|
| | **IMMEDIATE ACTION** | ✓ |
| | ACTION | |
| | UPDATE | |
| | INFORMATION REQUEST | |



| | Further Information |
|---|---|
| **DEVICE:**<br>CBS Isothermal 'DRY' Cryogenic Storage Freezer – V-series | * |
| **PROBLEM:**<br>Loss of cooling because of liquid nitrogen depletion. | * |
| **ACTION BY:**<br>All laboratories using affected freezers to store patient's samples (for example fertility/andrology clinics, haematology/blood transfusion laboratories and microbiology laboratories). | |
| **ACTION:**<br>Ensure that daily checks of liquid nitrogen levels are carried out as recommended in the manufacturer's instructions for use. | * |
| **DISTRIBUTED to:**<br>NHS Trusts (England) – Chief Executives<br>National Care Standards Commission – Headquarters | |
| **CONTACTS:**<br>UK supplier's contact details, MHRA contacts for technical and clinical aspects. Change of address or removal from address list for services registered under the Care Standards Act 2000. | * |
| **FEEDBACK REQUIREMENTS:**<br>None. | |

*** Further information supplied in the following pages.**

The full text of this notice is on our website: **http://www.mhra.gov.uk**

## DEVICE:

CBS Isothermal 'DRY' Cryogenic Storage Freezers (V-series) manufactured by Custom Biogenic Systems (CBS) in the USA and supplied in the UK by PhiTec International.

## PROBLEM:

MHRA has been informed of an incident in which donated sperm, stored for in vitro fertilisation use, defrosted and was rendered non-viable. This incident resulted from failure to replenish the liquid nitrogen used as the cooling medium in a CBS Isothermal Cryogenic Freezer, model V1500. This issue can potentially affect all V-series ('DRY') models manufactured before April 2003.

CBS Isothermal Cryogenic freezers (V-series) can be automatically or manually filled with liquid nitrogen. A sensor tube regulates the automatic filling process. In some circumstances this can malfunction due to the formation of ice crystals from moisture or due to a build up of dust particles which enter the unit via the liquid nitrogen connector port. If the freezers are operating in automatic mode, a sensor tube malfunction will require the unit to be placed into manual mode, as soon as this is detected.

The manufacturer's instructions for use recommend that the liquid nitrogen level is checked daily regardless of whether the cryogenic freezer is being operated in automatic or manual fill mode.

CBS has informed MHRA that approximately 100 V-series Cryogenic freezers have been distributed in the UK. The manufacturer is aware of 21 incidents of sensor tube blockage in the UK. CBS has redesigned the sensor tube assembly in the V-series freezers to prevent this issue recurring. V-series freezers sold in the UK after April 2003 incorporate the redesigned sensor tube assembly.



## ACTION:

- Ensure that daily checks of liquid nitrogen levels are carried out in accordance with the manufacturer's instructions for use even when the cryogenic freezer is being operated in automatic fill mode.
- Consider replacing CBS Isothermal 'DRY' Cryogenic Storage Freezers (V-series) affected by this issue.
- Inform MHRA and the UK supplier of any similar incidents associated with this product.

## DISTRIBUTION:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution by:

**TRUSTS to:**

- Liaison officers (for onward distribution)
- Medical directors
- Nursing executive directors
- Directors of clinical oncology
- Directors of radiology
- Directors of urology
- Directors of obstetrics and gynaecology
- Directors of pathology
- Haematologists and microbiologists
- Blood transfusion laboratories
- Blood banks
- Health & safety officers
- Risk managers
- Clinical governance lead

**NATIONAL CARE STANDARDS COMMISSION to:**

- Hospitals in the independent sector

# CONTACTS:

Enquiries to the supplier should be addressed to:

Mr Andrew Young or Mr Philip Barker
PhiTec International
8 Canon Road
Old Wolverton
Milton Keynes, MK12 5TL

Tel: 01908 311175
Fax: 01908 311103

Enquiries to the MHRA should quote reference number **2003/007/017/091/003** and be addressed to:

**Technical aspects**

Dr Jennifer Cooke or Ms Samantha Baxter
Medicines & Healthcare products Regulatory Agency
Hannibal House
Elephant and Castle
London SE1 6TQ
Tel: 020 7972 8267 / 8242
Fax: 020 7972 8106
E-mail: jennifer.cooke@mhra.gsi.gov.uk
sam.baxter@doh.gsi.gov.uk

**Clinical aspects**

Dr Susanne Ludgate
Medicines & Healthcare products Regulatory Agency
Hannibal House
Elephant and Castle
London SE1 6TQ
Tel: 020 7972 8123
Fax: 020 7972 8111
E-mail: Susanne.Ludgate@mhra.gsi.gov.uk



**Change of address or removal from list for services registered under the Care Standards Act 2000.**

NCSC Customer Service Unit
St Nicholas Building
St Nicholas Street
Newcastle-upon-Tyne
NE1 1NB
Tel: 0191 233 3556
E-mail: enquiries@ncsc.gsi.gov.uk

**HOW TO REPORT ADVERSE INCIDENTS**

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents; on-line incident reporting facilities; and downloadable report forms are available from MHRA's website (http:// www.mhra.gov.uk).

Alternatively, further information and printed incident report forms are available from:
MHRA Adverse Incident Centre
Medicines and Healthcare products Regulatory Agency
Hannibal House, Elephant and Castle, London SE1 6TQ
Telephone 020 7972 8080 or Fax 020 7972 8109
or e-mail: AIC@mhra.gsi.gov.uk
(An answerphone service operates outside normal office hours)

**Medical Device Alerts are available in full text on the MHRA website:** http://www.mhra.gov.uk

MHRA is an Executive Agency of the Department of Health