

Urgent Field Safety Notice

Commercial name of the affected product:	Keeler CRYOMASTER cryosurgical console – MOD 1, MOD 2 and MOD 3
FSCA identifier:	CAPA 1091 (MHRA ref 2013/012/016/081/003)
Type of action:	Advisory Notice
Date:	20/1/2014
Attention:	Distributors and Users
Transmission of this Field Safety Notice:	This notice must be passed on to all those who need to be aware within your organisation; This must include: Quality/Regulatory, Theatre, Maintenance

Keeler Cryomaster units labelled **MOD 4** or **MOD 5** are not affected.

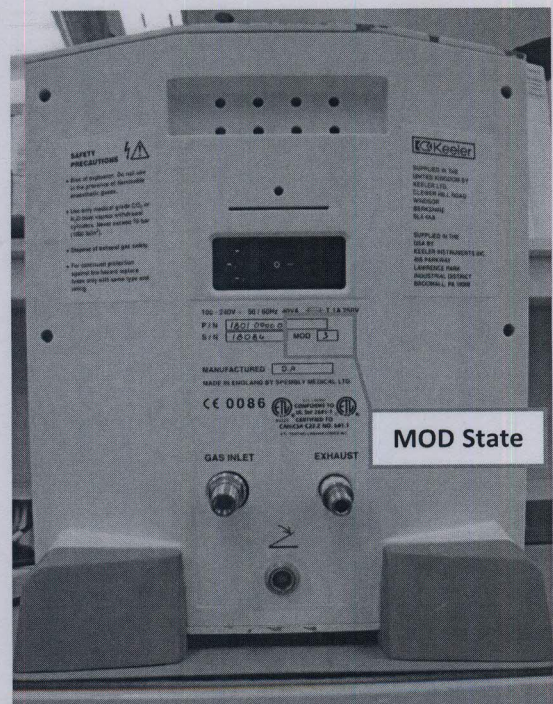
Description

Keeler Ltd has recently been made aware of a potential problem with certain versions of the Keeler Cryomaster whereby immediately after footswitch operation the device can revert to a purging state. During this time it may not be possible to easily break contact with the patient's eye, with the potential for damage to the affected surface of the eye.

Details of affected devices

Not all Keeler Cryomaster devices are affected.

Affected devices are labelled "**MOD 1**", "**MOD 2**" or "**MOD 3**" on the Serial Number label on the rear of the unit. See pictures below.



Cause

This behaviour is caused by a contact in the probe detection mechanism momentarily breaking a circuit. The unit then erroneously detects a probe disconnection and re-connection, and initiates an unwanted purge cycle.

Advice on action to be taken by user

For any Keeler Cryomaster units labelled “MOD 1”, “MOD 2” or “MOD 3” take the following actions:

1. Cease use of the Keeler Cryomaster unit with immediate effect.
2. Clearly label the device ‘**DO NOT USE**’, and remove from service.
3. Contact your supplier/dealer for assistance.
4. **PLEASE COMPLETE THE FORM ON THE FOLLOWING PAGE AND RETURN TO KEELER USING THE CONTACT DETAILS PROVIDED.**

Remedy

This problem can be remedied by replacement of the contact in the probe detection mechanism. This can be carried out by the Keeler Technical Services Workshop at its factory in Windsor.

For further information and to arrange replacement of the affected part please contact our Technical Services department as follows:

Keeler Technical Services Department.
Clewer Hill Road
Windsor, SL4 4AA
United Kingdom
Contact: Peter Stanley, Commercial Services Manager

Tel: + 44 (0)1753 827116
Email: techservices@keeler.co.uk

Keeler Contact for this notice

Phil Burridge
Keeler Ltd
Clewer Hill Road
Windsor
Berkshire
SL4 4AA
United Kingdom

0044 (0) 1753 827155

The undersigned confirms that this notice has been forwarded to the appropriate Regulatory Agency

Phil Burridge
Senior Quality Engineer