

URGENT FIELD SAFETY NOTICE

Name of the Client
Address
City postal code

To the attention of the Material Vigilance Correspondent
Biomedical Services Department Manager

RE: Contrast media injector SBI 5002-CT

Dear Customer,

Following our notification last November, we are implementing a new software release version (5.3) for the SBI 5002-CT injector. This new version is intended to reduce situations of potential misuse (combined risks) during the preparatory stages of soft bags and purges in the case of bi-liquid injections. This update will be carried out by our technical department who will contact you shortly to upgrade your injector.

The changes in question consist mainly to:

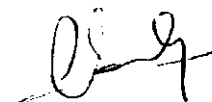
- Clarify the sequence of steps by the addition of messages and the modification of the position of some of them.
- Increase the flow of the slow purge in order to optimize the purge of air potentially present in the bags before purging.

MHRA have been informed of this approach.

Please forward this notice to all persons who may be affected by these changes within your organization.

For any additional questions regarding this safety information, please contact your local Medex sales representative or customer service at 04 72 79 20 50 or by email at the internet address cs.medex@guerbet-group.com. The UK Technical Services Manager can be contacted on +44 (0) 7837424246.

Medex thanks you for your cooperation and we apologize for any inconvenience caused by this procedure.



Catherine Vermeulen
Material Vigilance Correspondent
Regulations and Quality Manager

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