

Urgent Field Safety Notice

FSCA-identifier: [bug 15757](#)

Type of action: Notification of ambiguous dialysate information being displayed when using Artis selectbags.

Date: June 8, 2016

Our Ref: [VIG-5](#)

Affected device: Diamant version v3.6, 3.8 or 3.9, all revisions.

Description of the problem:

From Diamant v3.6, in case of an Artis HD prescription using selectbag or citrate, the output of Diamant may contain ambiguous dialysate information. The dialysate as well as the selectbag is being displayed, where only the selectbag should have been visible.

This may result in patients having a too low/high blood-potassium level. If unattended this may lead to serious patient harm.

No actual occurrence of serious patient harm has been reported so far, other than patient discomfort.

Strong Advise on action to be taken by the user:

1. Inform staff of this undesired behaviour of the system.
2. Check every dialysate prescription (printed/on the SmartConnector for ambiguous dialysate information prior to setting up the treatment.
3. Check all centre-specific reports you may have on dialysate display.
4. Schedule an update as soon as Diasoft releases to a valid new Diamant v3.8 and v3.9. This is to be expected on June 30, 2016.
5. Workaround: All affected HD prescriptions can be modified to correct the problem by following the procedure below:
 - Set HD prescription in correction mode
 - Change concentrate combination to 'bicart'
 - Clear the dialysate
 - Change concentrate combination to 'bicart select'
 - Save HD prescription

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. This can be done by checking bug 15757 on our website.

Contact reference person:

Diasoft B.V.

Jan van den Berge

The sender confirms that this notice has been notified the appropriate Regulatory Agency