



April 24, 2020

URGENT FIELD SAFETY NOTICE

REMISOL Advance v 1.12

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field action for the product listed above. This letter contains important information that needs your immediate attention.

ISSUE:	Results from repeated run for the hematology test panels WBC, UWBC and PLT are deleted in RADV if certain options are set or the rerun was not ordered by Remisol Advance directly but manually on DxH 600 / 800 / 900 / 690T.
IMPACT:	In a worst case, re-run results may not be generated if ordered from the DxH analyzer and the original results would be reported, which may be erroneous.
ACTION:	If you are affected because your system includes one or more DxH Analyzers please ensure to order reruns through REMISOL and not through the analyzer until you receive the update.
RESOLUTION:	The issue will be addressed by updating to the next version of REMISOL Advance 1.12. You will be contacted by a Beckman Coulter Field Associate to arrange a date and time for the upgrade to the new version.

The national competent authority has been informed of this field safety corrective action.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter.

FA-20022

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Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact Beckman Coulter via:

- Our website: <http://www.beckmancoulter.com>
- By phone: contact your local Beckman Coulter representative.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

[Redacted signature block]

Enclosure: Response Form