

**URGENT FIELD SAFETY NOTICE - UPDATE**

## DxA 5000 Automation System

Attention Beckman Coulter Customer,

Beckman Coulter is sending this update letter regarding the latest information on the Liquid Level Detection (LLD) function of the DxA 5000 Automation System. The changes are highlighted in blue below.

<b>ISSUE:</b>	<p>One of the functions of DxA 5000's Liquid Level Detection (LLD) is to detect the presence of gel in between layers of fluid. When configured to allow automatic centrifugation state (spun/unspun) detection, this information is used by the DxA 5000 system to determine whether samples loaded onto the system are un-spun (whole blood with no layers; gel at the bottom) and spun (gel presence in between layers). This detection of spun vs. unspun is used by the DxA 5000 system to determine whether further centrifugation by the DxA 5000 is required.</p> <p>Beckman Coulter has received and observed some reported instances where the system was not able to distinguish between spun and unspun samples.</p>
<b>IMPACT:</b>	<p>Unspun samples may be incorrectly identified as spun by the LLD and routed for analysis without centrifugation if automatic centrifugation state (spun/unspun) detection is configured.</p> <p>Although not observed or reported, there is also a potential risk that spun samples may be incorrectly identified as unspun, and centrifuged a second time before being routed for analysis.</p> <p>In a worst case scenario where a sample is presented to a connected analyzer in a condition that does not match analytical test requirements, the analyzer could generate erroneous but believable results.</p>
<b>ACTION:</b>	<p>In our original information, we instructed you to choose between the Options 1 and 2 listed below. After the last software update to version 1.2, and closed investigation we can now confirm that you can safely return to using the spun/unspun detection for your input drawers for <i>BD (Becton Dickinson)</i> and <i>Greiner</i> tube types with gel separator. We are therefore adding a third option for your convenience.</p> <p><b>Option 1:</b></p> <ul style="list-style-type: none"> <li>• Configure drawer settings to create spun and unspun drawers:       <ul style="list-style-type: none"> <li>• For unspun samples configure DxA 5000 settings to require centrifugation for all tubes.</li> <li>• For spun tubes with gel, configure DxA 5000 settings to skip centrifugation.</li> </ul> </li> <li>• Visually inspect all tubes before loading them onto the DxA 5000, loading them into the appropriately configured drawers as mentioned above.       <ul style="list-style-type: none"> <li>• For unspun samples (whole blood with no layers; gel at the bottom, or no gel detected) load into the drawer configured to require centrifugation for all tubes.</li> <li>• For spun tubes with gel, load into the drawer configured to skip centrifugation for all tubes.</li> </ul> </li> </ul>

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Beckman Coulter Biomedical GmbH

Sauerbruchstraße 50, 81377 München, Germany, Tel. +49 (0) 89 579589-0, Fax: +49 (0) 89 579589-3501

Geschäftsführer/Managing Directors: Piers Devereux, Dr. Christoph Möllers, Knud Müller

	<p><b>Option 2:</b></p> <ul style="list-style-type: none"> <li>If re-centrifugation of samples will not affect testing performed in your laboratory, you may configure the DxA 5000 settings to require centrifugation for all tubes.</li> </ul> <p><b>Option 3:</b></p> <ul style="list-style-type: none"> <li>Return to the use of the spun/unspun detection option for <i>BD</i> and <i>Greiner</i> tube types with gel separator. The system now detects the centrifugation status of these tubes with gel separator and identifies the need for centrifugation, calculating the route plan accordingly.</li> <li>If this Option is selected, the following limitations will now apply: <ul style="list-style-type: none"> <li>A reliable spun-state detection for spun sample tubes with gel separator can be performed only if a sample draw volume is equal to or larger than the gel separator volume. Sample tubes where the sample draw volume is less than the gel separator volume might be detected as unspun. To avoid recentrifugation, load pre-spun samples where the sample draw volume is lower than the gel separator volume to the Skip centrifuge region.</li> <li>An unspun sample tube might be falsely detected as pre-spun due to improper label placement. In this case, an unspun sample tube will not be centrifuged. Confirm that the bottom area of the sample tube containing gel is not covered by labels. Alternatively, for any unspun sample tubes with labels covering the bottom area containing gel, only use a configured Force centrifuge region.</li> </ul> </li> </ul> <p>This information is being added to the next version of the Instructions for Use. Your Beckman Coulter Field Service Engineer will contact you to configure your settings to the Option of your choice.</p>
<b>RESOLUTION:</b>	<p>An investigation to determine potential preventative actions has been performed and a software update has been released and installed by your Beckman Coulter Field Service Engineer. We can now confirm the possibility for Option 3 as described above for <i>BD</i> and <i>Greiner</i> tube types with gel separator.</p> <p>This investigation is now closed.</p>

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation.

If you are a centralized license holder, please provide the other affected laboratories of your organization or association with a copy of this letter.

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

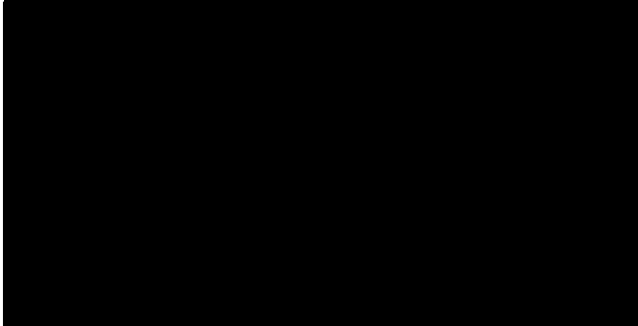
If you have any questions regarding this notice, please contact Beckman Coulter via:

- 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,



Enclosure: Response Form

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