



Field Safety Notice

Dear Beckman Coulter Customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the attached *in-vitro* diagnostics medical device.

We, hereby, enclosed the manufacturer's notification letter of this field corrective action with detailed information on the issue, impact, action need to be taken and resolution on this issue.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The **Medical Device Authority** will be informed of this notice.

Sincerely Yours,

Nur Aishah
Regulatory Affairs Specialist

Contact person of this notification	... Minella Liam.....
Department	... Marketing.....
Telephone	... 6017 2328 611.....
Fax	...603 7772 0551.....
E-mail	... lmliam@beckman.com

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September 25, 2025

URGENT MEDICAL DEVICE RECALL

UniCel Dxl 600 and 800 Analyzers

REF	Part Number
UniCel Dxl 600	A71460; A30260
UniCel Dxl 800	973100; A71456

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:	An internal investigation has determined that the pick-and-place (PnP) gantries in the UniCel Dxl analyzers listed in Appendix A may experience increased physical interference due to sub-components within the gantry assembly. This interference can result in more frequent Z-motion errors in the Wash PnP and/or Incubator PnP.
IMPACT:	Z-motion errors can cause the analyzer to enter a “Not Ready” or “Paused” state, which may lead to canceled tests and delays in reporting patient results. <ul style="list-style-type: none"> • Wash PnP: The analyzer enters “Not Ready,” stops sample processing, and cancels tests in progress. • Incubator PnP: The analyzer enters “Paused,” completes tests already in process, cancels queued samples, and then transitions to “Not Ready.” This may delay reporting patient test results to the physician. This issue does not affect test results.
ACTION:	If Wash PnP and/or Incubator PnP Z-motion errors appear in the analyzer event log, take the following steps: <ol style="list-style-type: none"> 1. Attempt to reinitialize the analyzer: <ol style="list-style-type: none"> a. Go to the <i>Diagnostics</i> screen on the User Interface. b. Select Initialize System. 2. If reinitialization is unsuccessful, contact Beckman Coulter Technical Support in your region. Beckman Coulter recommends posting this letter on or near the affected analyzers.
RESOLUTION:	Beckman Coulter has identified the root cause of this issue. A field service representative will contact your laboratory to schedule a time to replace the affected parts.

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 products listed above to another laboratory, please provide them a copy of this letter.



So that we are assured you have received this important communication, please respond within 10 days in one of the following ways:

- Electronically, if you received this communication via email.
- Manually, complete and return the enclosed Response Form.

If you have any questions regarding this notice, please contact our Customer Support Center:

- From our website: <http://www.beckmancoulter.com>

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Signed by:
Jennifer Chau
Signer Name: Jennifer Chau
Signing Reason: I approve this document
Signing Time: 25-Sep-2025 | 10:30:53 AM PDT
CC3CD3A8EA284A8CB13031EA135AA19D

Jennifer Chau
Vice President, US Quality Operations

Enclosure: Response Form

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Appendix A

610458	610670	902569	610600	610777	610561
610455	610721	902568	610565	610778	902532
610679	610580	610632	610558	610819	902509
610579	902557	610631	902570	610818	610597
610770	610752	610796	902571	610820	610638
610707	610444	610816	902530	610439	610669
610432	610704	610441	902531	610491	610628
610430	902513	610476	902538	610523	610630
610434	610586	610489	610557	610528	610445
902515	610684	610488	610543	610581	610440
610664	610589	610492	610617	610649	610567
610682	610588	610532	610618	610466	610596
610765	902507	610534	902581	610789	902555
610500	610493	610533	610551	610723	902558
610541	902543	610535	902553	902561	902564
610544	902526	610640	902552	902575	610497
610545	902527	902577	610527	610575	610774
610562	610659	902510	610685	610443	610454
902536	902523	610457	610730	610776	902520
610547	902522	610464	902504	902544	610426
902541	902560	610790	902514	610734	610431
610542	610782	610559	902525	610495	610442
610448	902562	610687	610722	610508	610433
610585	902524	610571	902535	610518	610435
902529	902506	610552	610686	610519	610486
902517	902508	610555	610494	610517	610485
902563	902505	610582	902512	610520	902519
610595	902574	610531	610753	610522	902521
902565	902533	610568	610815	610619	610612
610475	902572	610594	610817	610728	610690
610700	610570	610446	610779	610727	902559
610453	610498	610773	610780	610751	610548
610553	610748	610490	610590	902542	610549
610566	610496	610536	610593	610637	610599
610771	610560	610668	610546	610563	610606
610781	610573	610784	610724	610569	610604
610713	610574	610611	610538	610420	610603
610720	610577	610610	610540	902516	610591
610537	902578	610607	902539	902518	610592
610644	902579	902580	902566	610530	610447
610648	610601	610812	610620	610529	610539
610647	902540	902545	610625	902556	610578
610691	610651	610478	610627	610787	610554
610696	610680	610479	610624	610459	610509
610429	610666	610584	610635	610449	610418
610428	610642	610783	610636	610775	610483
610598	610641	610450	610643	610427	610484
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610452	610419	630150	902554	610658	630273
630104	630126	630151	902546	610660	630280
630105	610415	610587	902547	630224	610705
610526	610416	630153	902548	630234	610706
610602	610456	630163	902551	630228	630238
630160	610461	630148	902550	630220	630251
630159	610460	630147	610672	630225	630257
630162	610472	630138	610678	630229	630258
610481	630117	610639	610674	630204	630274
610487	630118	630194	610671	630212	610697
610482	610470	630197	610667	630213	630240
610507	630120	610614	610673	610725	630244
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630140	630119	630202	610677	610732	630262
630175	630121	630203	610650	610731	630237
610505	630122	610608	610662	610719	630266
610506	610471	610605	610692	610726	630236
610514	610463	630178	630219	610703	630261
630143	610462	630184	630208	630259	630245
630103	610467	630166	630217	630260	610710
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630099	630124	630176	610693	610718	610757
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610504	630129	610626	630232	630279	610769
630107	630128	630179	630201	630256	610768
610511	630130	630180	610652	630255	610785
610423	630131	630181	610661	630269	610788
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610525	630135	630187	630226	630248	610793
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610424	630172	610609	630233	610716	630307
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610480	630144	630193	630222	630271	630301
630132	630156	630191	610657	630267	610744
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630101	630157	630190	630215	630254	630315
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630139	630170	630168	630231	610714	630327
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630292	630323	630290	610745	630341	630326
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630305	610808	610735	630288	630344	610813
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630312	630317	630293	610824	630334	630185
610791	630308	630295	610823	610826	630352
630324	630306	630303	610829	630330	630329
610759	630318	610799	610832	610822	610821
610762	630299	630320	610833	630332	630277
610738	630314	630309	610830	630336	630283
610739	610761	610809	610831	630338	630297
610740	610763	610764	630328	630333	630349
610741	610798	630294	630337	630339	630200
610792	610803	630287	630351	630347	630239
630291	630302	630286	610827	630346	