



July 22, 2026

URGENT MEDICAL DEVICE RECALL**BECKMAN COULTER CHEMISTRY ANALYZER AU480**

Analyzer	REF	Serial Number
BECKMAN COULTER CHEMISTRY ANALYZER AU480	Refer to Appendix A for the affected instrument	

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.

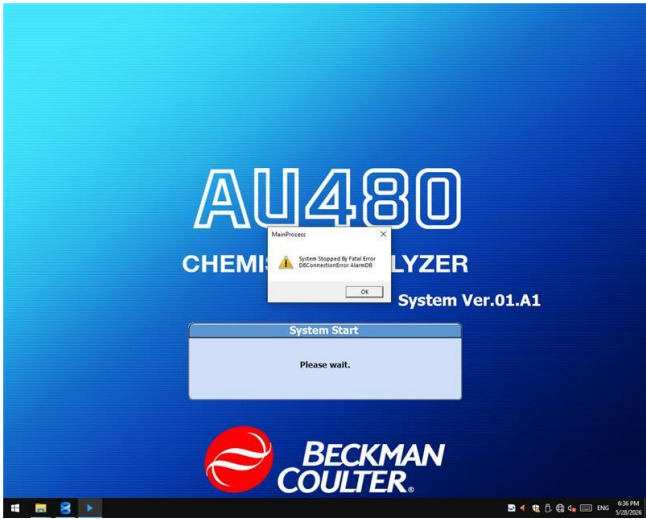
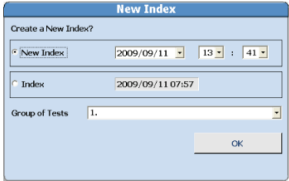
ISSUE:	Beckman Coulter has determined that CHEMISTRY ANALYZER AU480 with Windows 10 IoT Enterprise 2021 LTSC PCs listed above may output the message "System Stopped By Fatal Error: DBConnectionError AlarmDB" when launching the instrument software, using PC pre-installed with Microsoft® SQL Server® 2022 Express. (Refer to Picture.1) When this occurs, AlarmDB becomes unreadable and the instrument software cannot be started. This issue is caused by SQL Server processing associated with transaction log auto-growth. Our investigation has confirmed that this issue is more likely to occur when a new index is not created daily. This is because the alarm and operation logs are deleted when the index is switched, and deleting multiple days' worth of logs at once increases system load. Picture.1
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250 S. Kreamer Boulevard
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Telephone: (800) 854-3633
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www.beckmancoulter.com

FA-001553



	
IMPACT:	• If no alternative measurement method is available, in a worst-case scenario, delay in reporting patient results may lead to a delay in diagnosis and/or patient treatment. • This issue does not cause incorrect test results.
ACTION:	• Be sure to create a new index once or more per day at an appropriate time. Please refer to “5.1 Start the System” of the IFU to complete this action. Daily Startup 5 5.1 Start the System Figure 5.2  3 Select the Index and Group of Tests as needed. a. Select New Index to create a new index, or Index to return to the previous index. b. Select the group of tests to process from the "Group of Tests" drop-down list. c. Select OK. The Home menu displays. • Beckman Coulter recommends posting this letter on or near the affected analyzers.
RESOLUTION:	Beckman Coulter has identified the root cause and will resolve the issue by applying a Software solution to the impacted systems. BEC service team



	will contact you to schedule the Software solution application, and a Field Service Engineer (FSE) will perform the on-site work.
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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.

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 electronic system.
- 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>

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Signed by:

 Signer Name: Cheillan, Franck
 Signing Reason: I approve this document
 Signing Time: 22-Jul-2026 | 11:38:41 AM PDT
 6309FFDE61F340FA89FF6856007A4771

Franck Cheillan
 Vice President, International Quality Operations

Enclosure: Response Form

Beckman Coulter, the stylized logo and the Beckman Coulter product and service names mentioned herein are trademarks or registered trademarks of Beckman Coulter, Inc. in the United States and other countries.

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Appendix A

Serial numbers are shipped with Microsoft® SQL Server® 2022 Express pre-installed.

Analyzer: BECKMAN COULTER CHEMISTRY ANALYZER AU480

REF	Serial Number
B96692	2025061689, 2025071733, 2025071739, 2025081764, 2025081769, 2025081775, 2025081777, 2025081780, 2025081784, 2025081787, 2025081791, 2025091798, 2025091801, 2025091805, 2025091814, 2025101827, 2025101829, 2025101830, 2025101831, 2025101832, 2025101833, 2025101834, 2025101835, 2025101836, 2025101837, 2025101838, 2025101839, 2025101840, 2025111852, 2025111856, 2025111860, 2025111864, 2025121894, 2025121899, 2025121904, 2025121916, 2025121919, 2025121921, 2026011926, 2026011929, 2026021945, 2026021948, 2026031978, 2026031988, 2026031995, 2026031999, 2026042017, 2026042023, 2026042027, 2026052061, 2026052065
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	2026011925, 2026011927, 2026011928, 2026011930, 2026011931, 2026011932, 2026011933, 2026011934, 2026011935, 2026011936, 2026011937, 2026011938, 2026011939, 2026021941, 2026021942, 2026021943, 2026021944, 2026021946, 2026021947, 2026021949, 2026021950, 2026021951, 2026021952, 2026021953, 2026021954, 2026021955, 2026021956, 2026021957, 2026021958, 2026021959, 2026021960, 2026021961, 2026021962, 2026021963, 2026021964, 2026021965, 2026021966, 2026021967, 2026021968, 2026021969, 2026021970, 2026021971, 2026021972, 2026021973, 2026021974, 2026031975, 2026031976, 2026031977, 2026031979, 2026031980, 2026031981, 2026031982, 2026031983, 2026031984, 2026031985, 2026031986, 2026031987, 2026031989, 2026031990, 2026031991, 2026031992, 2026031993, 2026031994, 2026031996, 2026031997, 2026031998, 2026032000, 2026032001, 2026032002, 2026032003, 2026032004, 2026032005, 2026032006, 2026032007, 2026032008, 2026032009, 2026032010, 2026032011, 2026032012, 2026032013, 2026032014, 2026032015, 2026042016, 2026042018, 2026042019, 2026042020, 2026042021, 2026042022, 2026042024, 2026042025, 2026042026, 2026042028, 2026042029, 2026042030, 2026042031, 2026042032, 2026042033, 2026042034, 2026042035, 2026042036, 2026042037, 2026042038, 2026042039, 2026042040, 2026042041, 2026042042, 2026042043, 2026042044, 2026042045, 2026042046, 2026042047, 2026042048, 2026042049, 2026042050, 2026042051, 2026042052, 2026042053, 2026042054, 2026042055, 2026052057, 2026052058, 2026052059, 2026052060, 2026052062, 2026052063, 2026052064, 2026052066, 2026052067, 2026052068, 2026052069, 2026052070, 2026052071, 2026052072, 2026052073, 2026052075, 2026052076, 2026052077, 2026052078, 2026052079, 2026052080, 2026052081, 2026052082, 2026052083, 2026052084, 2026052085, 2026052086, 2026062087, 2026062088, 2026062089, 2026062090, 2026062091, 2026062092, 2026062093, 2026062094, 2026062095, 2026062096, 2026062097, 2026062098, 2026062099, 2026062100, 2026062101, 2026062102, 2026062103, 2026062104, 2026062105, 2026062106, 2026062107, 2026062108, 2026062109, 2026062110, 2026062112, 2026062113, 2026062114, 2026062115, 2026062116, 2026062117, 2026062118, 2026062119, 2026062120, 2026062121, 2026062122, 2026062123, 2026062124
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Serial numbers replaced with a new PC installed Microsoft® SQL Server® 2022 Express.

Analyzer: BECKMAN COULTER CHEMISTRY ANALYZER AU480

REF	Serial Number
N3660400	1040779, 1080921
N3151400	9060086
B11810	2016024859
B12183	2012091558, 2013022045, 2013042229, 2013062344, 2013072394, 2013102700, 2013112789, 2013122887, 2014043160, 2014073403, 2014093558, 2015033959, 2015104569, 2015104596, 2016040109, 2016060339, 2016090568, 2016090575
B96692	2017051172, 2018122391, 2020013334, 2023040477
B96693	2016110717, 2017020906, 2017081327, 2017081394, 2017101524, 2017111608, 2018031874, 2018082145, 2019012422, 2020013291, 2020013311, 2020033414, 2020043534, 2021024014, 2021024015, 2021044086, 2021084218, 2021084220,

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	2021084227, 2021094266, 2021094271, 2021104332, 2021104364, 2021124422, 2021124430, 2021124487, 2021124493, 2022014611, 2022014627, 2022034678, 2022034689, 2022090012, 2022090040, 2022120196, 2023010268, 2023020314, 2023030340, 2023030382, 2023030383, 2023040464, 2023040546, 2023090842, 2023100903, 2024021094, 2024071319, 2024101407, 2025031517, 2025041570
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