

URGENT FIELD SAFETY NOTICE

Access 2 Family of Immunoassay Systems *

REF	Instrument Serial Number
81600N 386220 A25637 A25638	511527 – 511678; 511681 - 512212 (See attached list) 800999,801019 (See attached list)

* The Access 2 Family of Immunoassay Systems includes the Access 2, Access 2, Remanufactured and the UniCel DxH 600i SYNCHRON Access Clinical Systems

Attention Beckman Coulter Customer,

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

ISSUE:	Beckman Coulter has determined through internal investigation that a circuit board that controls motor functions in the instrument systems listed above can affect device positioning on the pipettor and incubator belt while the instrument is running.
IMPACT:	Users may experience the following errors that may cause a delay in the reporting of patient results: <ul style="list-style-type: none"> • An incubator belt motion error which can result in the instrument going into the Not Ready mode and cancellation of all in-process tests. • Z pipettor motion errors which can result in cancelled tests.
ACTION:	You can continue operating your system normally. <ul style="list-style-type: none"> • If you experience incubator belt motion errors, review the associated event on the Event Log screen and follow the provided troubleshooting instructions. Contact Technical Support if you need any assistance. • If you experience z pipettor motion errors, re-run any cancelled tests.
RESOLUTION:	Your service representative will contact you to schedule a service visit to replace the circuit board on your instrument.



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.

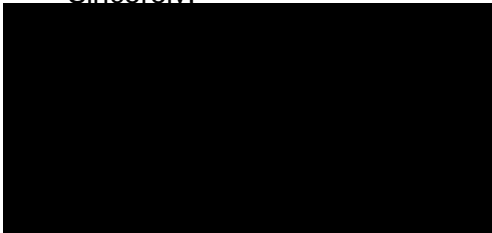
Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

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

- From our website: <http://www.beckmancoulter.com>
- By phone: call 1-800-854-3633 in the United States and Canada.
- Outside the United States and Canada, contact your local Beckman Coulter representative.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,



Enclosure: Response Form



REF	Instrument Serial Number
386220	501012,501110,501190,501224,501294,501371,501394,501403,501440,501443,501490,501501,501673,501681,501693,501861,501920,501926,501936,501970,502165,502196,502319,502331,502332,502368,502458,502475,502506,502543,502549,502556,502574,502640,502647,502651,502791,502843,502848,503153,503279,503313,503354,503384,503392,503424,503543,503627,503678,504046,504071,504072,504092,504112,504195,504322,504365,504370,504756,504767,504902,505042,505195,505251,505254,505644,505795,505840,505947,506002,506026,506108,506119,506153,506187,506371,506406,506560,506586,506664,506708,506766,506786,506837,506846,507039,507120,507161,507162,507214,507229,507248,507282,507353,507397,507480,507511,507604,507619,507842,507929,508019,508096,508179,508227,508313,508334,508412,508478,508509,508516,508767,509051,509087,509113,509164,509253,509297,509632,509837,510049,511042,511047,511180,511383,700024,800321,800341,800443,800608,800611,800650,800849
A25638	800995,800996,800997,800998,801000,801001,801002,801003,801004,801005,801006,801007,801008,801009,801010,801011,801012,801013,801014,801015,801016,801017,801018,801020,801021,801022,801023,801024,801025,801026,801027

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