

URGENT: FIELD CORRECTION NOTICE

BP7561 (OUS), BP7666 (USA), OPTI CCA B-Lac Cassettes **GD7046, OPTI CCA-TS2 Analyzer**

Description

OPTI Medical Systems, Inc. has discovered a low PO₂ bias on the OPTI CCA-TS2 B-Lac style cassettes. B-Lac style 66 cassettes are identified by the number 66 in the fourth and fifth lot digits (for example: 719**66**2). The **OPTI CCA-TS is not affected** by the PO₂ bias issue.

PO ₂ (mmHg)		
Target	Bias	TS2 result
40	-7	33
60	-8	52
80	-9	71
100	-13	87
200	-30	170
400	-50	350
600	-59	541

Affected Lot Numbers

All released style 66 lots are affected by the OPTI CCA-TS2 PO₂ bias:

- 651664
- 703660
- 715661
- 715664
- 717660
- 719662
- 719662

Corrective Action

As an immediate field corrective action, we recommend that you **destroy or dispose of any style 66 B-Lac cassettes in your inventory, and do not use any style 66 B-Lac cassettes on an OPTI CCA-TS2 instrument.**

Please contact OPTI Medical Technical Support at +1-800-490-6784 option 1 or technicalsupport@optimedical.com to return the response card, report any adverse events as a result of this issue, or if you have any questions.

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REPLY RESPONSE CARD

- Please fill out the form below, sign and date
- Please return the response card to OPTI Medical as soon as possible

Fax: 770-688-1541
Email: technicalsupport@optimedical.com
Mail: 235 Hembree Park Drive
Roswell, GA 30076
USA

B-Lac Lot Number(s): _____

Do you report PO₂ when utilizing the B-Lac test?

Yes _____ No _____

Are you aware of any adverse events that may have occurred due to this issue?

Yes _____ No _____

If yes, please provide further details below:

I have read and understand the attached notice and have notified the appropriate personnel of the OPTI CCA-TS2 issue and certify that any style 66 B-Lac cassette testing will be discontinued on the OPTI CCA-TS2 analyzer(s) until further notice.

Signature: _____ Date: _____

Name: _____

Title: _____

Phone: _____ e-mail: _____

Facility: _____

Facility Address: _____