

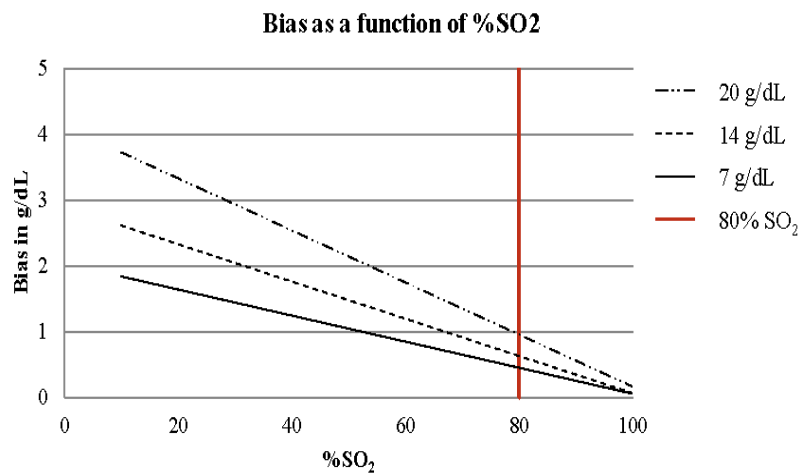
URGENT: FIELD CORRECTION NOTICE

GD7013, OPTI CCA-TS analyzer, GD7046, OPTI CCA-TS2 analyzer, GD7045, OPTI CCA analyzer & GD7031, OPTI R analyzer

Description

OPTI Medical investigated a report from the field where an OPTI CCA-TS2 was found to measure tHb high in whole blood. Internal investigation has reproduced this finding, showing a positive bias in tHb results in whole blood when saturated oxygen (SO₂) is low. This issue was found on all OPTI blood gas analyzers manufactured after July 2009.

Our investigation team has determined the root cause of this issue and is working to correct it. The root cause is due to a shift in the wavelength of one of the lasers used to measure tHb and SO₂. The shift occurred when OPTI switched suppliers of the laser. This shift in wavelength causes an increasing tHb bias as the %SO₂ decreases. The graph below shows typical bias on 3 levels of tHb as a function of SO₂. The bias is seen only in tHb measurements –the SO₂ measurement is not affected.



Affected Analyzers

OPTI analyzers affected by this issue were manufactured after July 2009. The serial numbers below are affected:

- **All** OPTI CCA-TS2 analyzers (GD7046)
- OPTI CCA-TS analyzers (GD7013) with serial numbers **2700 and above**
- OPTI CCA analyzers (GD7045) with serial numbers **8056 and above**
- OPTI R analyzers (GD7031) with serial numbers **1334 and above**

Corrective Action

Based on internal testing of multiple analyzers we have determined that when SO₂ is below 80%, the bias on the tHb is outside of our claims for measurement accuracy. As an immediate field corrective action we recommend that you **do not report tHb or use an alternative method to measure tHb when SO₂ is below 80%**. The Hct and O₂(ct) calculated parameters are significantly affected by the tHb issue as well. These calculated parameters should also not be reported when SO₂ is below 80%.

Please notify all users of the OPTI of this issue, and if possible, use your information system to block results for tHb if SO₂ is less than 80%.

We are working to fix the issue as quickly as possible with a software update. You will be notified once the update is available.

Regulatory Reporting

OPTI Medical is required to report this issue to the United States Food and Drug Administration (FDA). As part of our field correction, we are required to report any adverse events (improper treatment or harm to patients based on results) due to this issue. We strongly recommend customers review patient tHb results when SO₂ results were below 80% to determine if any adverse events occurred.

It is important that we are able to effectively communicate this issue and provide documentation of notification to all of our customers. Please fill out the field correction notice form attached and return it to OPTI Medical technical support.

On behalf of OPTI Medical, I apologize for any inconvenience that this issue may cause you.

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, or if you have any questions.

Best Regards,

Irene Richard

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April 14, 2015

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REPLY RESPONSE CARD

- Please fill out the form bellow, sign and date
- Please verify that no adverse events due to this issue have occurred
- Please return the response card to OPTI Medical as soon as possible

Fax: 770-510-4444
 Email: technicalsupport@optimedical.com
 Mail: 235 Hembree Park Drive
 Roswell, GA 30076

OPTI CCA-TS Serial Number(s): _____

OPTI CCA-TS2 Serial Number(s): _____

OPTI CCA Serial Number(s): _____

OPTI R Serial Number(s): _____

Do you report the tHb on your OPTI analyzer?

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 issue. I certify that reporting of tHb from patient samples when SO₂ is below 80% from all affected OPTI analyzers at my facility will be discontinued until further notice.

Signature: _____ Date: _____

Name: _____

Title: _____

Phone: _____ e-mail: _____

Facility Name: _____

Facility Address: _____