

Dimension® Integrated Chemistry Systems

ELECTRICAL HAZARD WARNING: Dimension RMS Compressor Assembly Protective Electrical Cover Missing

Our records indicate that your laboratory has one of the Dimension® systems listed below.

Product	Siemens Material Number International
Dimension EXL with LM	10472176
Dimension EXL with LM STM	10639338
Dimension Reagent Management System (RMS)	10444833
Dimension RxL Max w/o HM	10444828
Dimension RxL Max HM	10444829
Dimension RXL MAX HM STM	10444831

Reason for Correction

Siemens Healthcare Diagnostics is notifying you of a potential safety issue regarding the Dimension Reagent Management System (RMS) refrigeration compressor. Siemens has identified RMS refrigeration compressors that are missing the safety cover on the electrical termination block. The exposed electrical hazard on the electrical termination block is located directly behind the RMS Waste Container.

Your Siemens Customer Service Engineer will contact you to schedule a visit to inspect your RMS refrigeration compressor.

Risk to Health

The absence of the safety cover results in a potential electrical hazard to the operator. This issue does not impact patient results.

Actions to be Taken by the Customer



WARNING

DO NOT TOUCH the electrical termination block on the refrigeration compressor within the Reagent Management System (RMS).

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1. Refer to Figures 1 and 2.

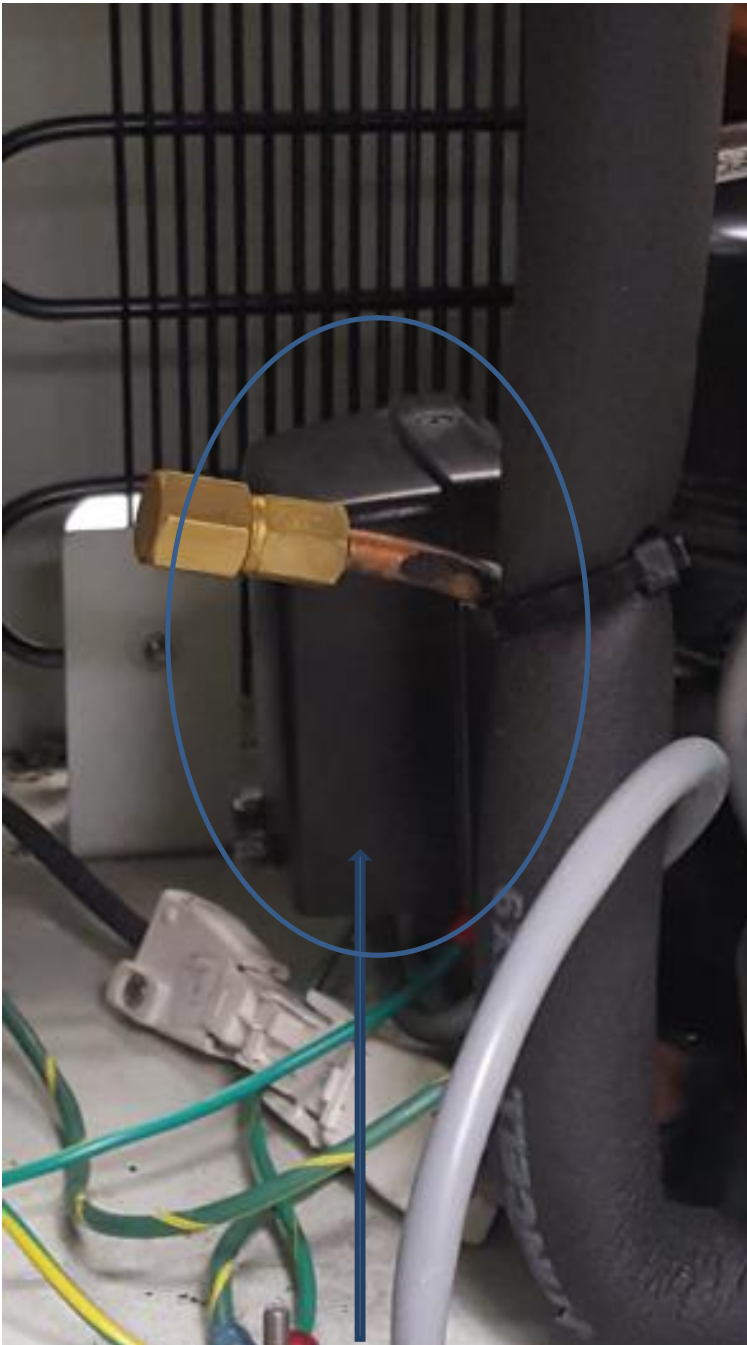


Figure 1. Cover in place

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Figure 2. Cover missing

Actions to be Taken by the Customer, continued.

2. Use caution when removing the RMS Waste Container. **DO NOT REACH HANDS INTO RMS CABINET BEYOND REMOVING THE WASTE CONTAINER. IF ANY FLEX CARTRIDGE FALLS OUTSIDE THE WASTE CONTAINER DO NOT REACH INSIDE THE RMS CABINET TO RETRIEVE IT.**
3. Securely attach the WARNING page within this Urgent Field Safety Notice on the outside of each RMS cabinet door as a temporary WARNING for all operators.
4. Return completed Field Correction Effectiveness form to Siemens Healthcare Diagnostics as instructed in the last page of this Notice.

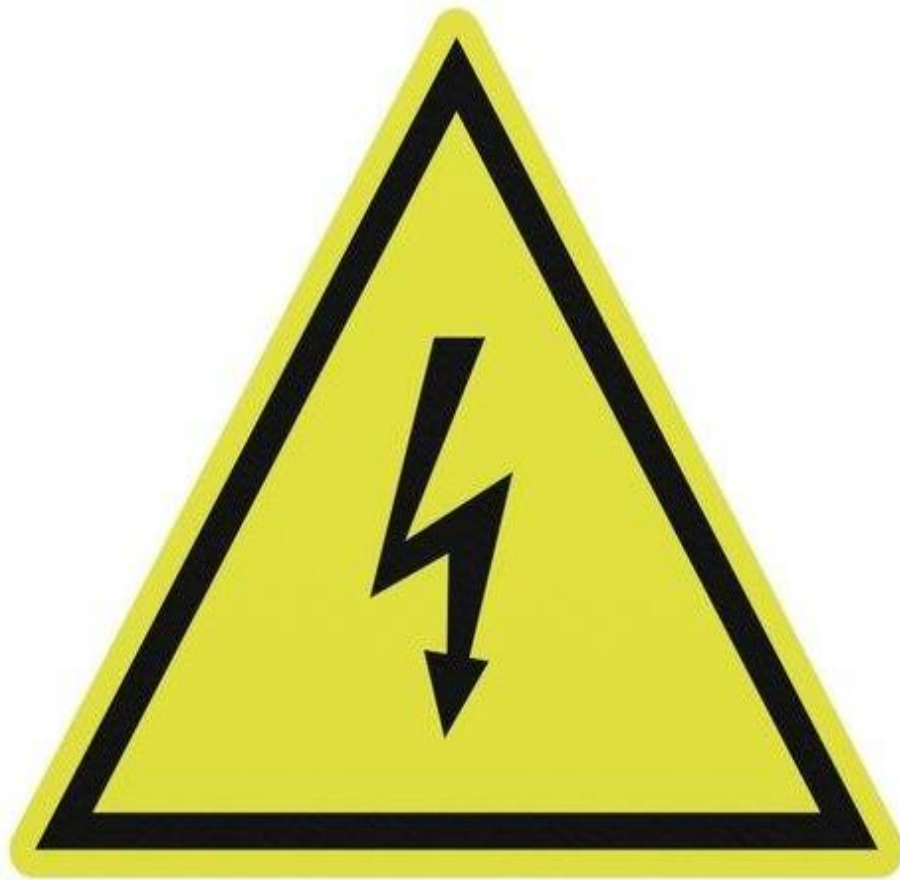
Note: If your laboratory does not have an RMS you are not affected. Please indicate this on the Field Correction Effectiveness form.

In addition, please perform the following:

- Review this letter with your Medical Director.
- Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation has caused. If you have any questions, please contact your local Siemens technical support representative.

Dimension is a trademark of Siemens Healthcare Diagnostics.



WARNING

ELECTRICAL HAZARD TO THE OPERATOR

DO NOT TOUCH the electrical termination block on the refrigeration compressor within the Reagent Management System (RMS). If any flex cartridge falls outside the waste container **DO NOT** reach into the RMS cabinet to retrieve it.

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FIELD CORRECTION EFFECTIVENESS CHECK

Dimension RMS Compressor Assembly Protective Electrical Cover Missing

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice DI-16-01.A.OUS dated November 2015 regarding **Dimension RMS Compressor Assembly Protective Electrical Cover Missing**. Please read the questions below and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice and instructions provided in this letter. Yes ☐ No ☐

2. Please check the box to the right if you do NOT have an RMS. ☐

3. I have posted the WARNING notice on the front of the cabinet door on each RMS at my site as a temporary WARNING for all operators. Yes ☐ No ☐

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Instrument Serial Number(s): _____

Customer Sold To #: _____

Customer Ship To #: _____

Please fax this completed form to the Customer Care Center – Technical Solutions at XXX-XXX-XXXX.

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