

Dimension Vista[®] 500
Dimension Vista[®] 1500

Vista Miswired Air Compressor

Our records indicate that your laboratory has the Dimension Vista[®] 500 or Dimension Vista[®] 1500 System.

Product	Siemens Material Number (SMN)
Dimension Vista[®] 500	Domestic: 10284473 International: 10488224
Dimension Vista[®] 1500	Domestic: 10444801 International: 10444802

Reason for Correction

Siemens Healthcare Diagnostics is notifying you of an issue with the Vista Air Compressor replacement part: SMN 10706557 Desc: SKIT Air Compressor Assy, used on the Dimension Vista[®] 500 and Dimension Vista[®] 1500 systems. Through internal investigation, Siemens Healthcare Diagnostics has confirmed that a small number of Vista Air Compressors we received from our vendor were miswired. If installed and powered up, these components could cause a fire, or become an electrical shock hazard.

Siemens is advising customers that this part: SMN 10706557 Desc: SKIT Air Compressor Assy is intended to be installed in the Dimension Vista 500 and Dimension Vista 1500 instruments by a trained Siemens Customer Service Engineer only.

Vista Air Compressors currently operating on a Vista instrument are not affected.

Risk to Health

There is no risk to patient health. The Dimension Vista system will be inoperable if failure of the air compressor occurs. Results cannot be generated.

There is a risk of injury to the operator if an attempt is made to install a Dimension Vista Air Compressor by untrained non-Siemens personnel. There is potential to receive an electrical shock or for the air compressor to catch fire.

Actions to be Taken by the Customer

1. If an Air Compressor has already been delivered to your laboratory, or is delivered in the future for installation by your Siemens Healthcare Customer Service Engineer, please do not make any attempt to install the Air Compressor by yourself.
2. Please notify your local Siemens Healthcare Diagnostics Customer Care Center when an Air Compressor is at your site so arrangements may be made for installation by a Siemens Healthcare Diagnostics Customer Service Engineer.

Please discuss the content of this letter with your Medical Director.

Please complete and return the Field Correction Effectiveness Check Form attached to this letter.

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.

Siemens Healthcare Diagnostics
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Newark, Delaware 19714-6101
www.siemens.com/diagnostics

Dimension Vista is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Vista Miswired Air Compressor

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 14-19 dated April 2014 regarding Vista Miswired Air Compressors. Please read each question 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 Medical Device Correction instructions provided in this letter. Yes No

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Street: _____

City: _____

State: _____

Phone: _____

Country _____

Customer Sold To #: _____

Customer Ship To #: _____

PLEASE FAX THIS COMPLETED FORM TO SIEMENS CUSTOMER CARE CENTER - TECHNICAL SOLUTIONS AT xxx-xxx.

If you have any questions, contact your local Siemens technical support representative.