

MicroScan® WalkAway® Systems

Information Regarding MicroScan WalkAway plus Access Door Hinge

Our records indicate that your facility either had the WalkAway plus incubator door replaced or received one or more of the following product(s) from May 2013 to April 2014:

Table 1. MicroScan WalkAway Systems Affected Product

Product	Siemens Material Number (SMN)	Catalog Number
MicroScan WalkAway-40 plus Instrument	10444853	B1018-283
MicroScan WalkAway-96 plus Instrument	10444854	B1018-284

Reason for Field Correction

Siemens Healthcare Diagnostics is conducting a corrective action for the MicroScan WalkAway plus instruments to address a potential failure with the access door hinge. The failure can cause the springs to dislodge and be ejected towards the operator causing a potential safety issue for the customer. This notification is to inform you of the potential for injury to the WalkAway instrument operator if the access door hinge failure occurs when accessing the WalkAway plus instrument through the front access door.

Risk to Health

This failure does not impact patient results; therefore it is not necessary to review previous test results or to repeat testing.


This failure may result in bodily injury to the user. The severity of the injury ranges from minor or more serious depending on the body site involved and the proximity to the hinge at the time of failure.

An additional risk may be the exposure to reagents or inoculated panel fluids if the operator is adding or removing panels from the instrument at the time the springs are ejected.

Actions to be Taken by the Customer

- Wear personal protective equipment (PPE), including eye protection when accessing the WalkAway plus instrument through the front access door.

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- Take caution  when loading and unloading panels or performing maintenance or other activities through the WalkAway plus access door.
- Discuss the content of this letter with your laboratory director.
- Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.

A Siemens representative will contact you over the next few months to schedule a visit to correct this issue with the access door hinge. 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 Siemens Customer Care Center or your local Siemens technical support representative.

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FIELD CORRECTION EFFECTIVENESS CHECK

Information Regarding MicroScan WalkAway plus Instrument

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice MSI 14-01 dated May 2014 regarding MicroScan WalkAway plus access door hinge failure. 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 instructions provided in this letter. Yes No
2. Do you intend to take the recommended action as requested? Yes No

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Please fax this completed form to the Customer Care Center at XXX-XXX-XXXX. If you have any questions, contact your local Siemens technical support representative.