Mortara Instrument, Inc.
7865 North 86th Street
Milwaukee, WI 53224
Tel: 414.354.1600
Fax: 414.354.4760
www.mortara.com

URGENT MEDICAL DEVICE CORRECTION

October 3, 2014

To: Health Care Administrator/ Risk Manager
Director of Biomedical/ Clinical Engineering

Re: Improper mounting of Mortara Surveyor S12 and Surveyor S19 Patient Monitors may result in a safety hazard.

Dear Customer,

Mortara Instrument, Inc. has recently become aware of a potential safety hazard involving our Surveyor S12 and Surveyor S19 Patient Monitors. A hazardous situation may be created when mounting these monitors using the 75mm VESA mounting hole pattern provided in the battery cover of these monitors. If the mounting screws provided by Mortara are not used and if the mounting screws used are longer than the provided screws, it is then possible for the longer screws to be driven completely through the battery cover and then possibly penetrate the protective casing of the lithium-ion battery which may result in a fire.

There have been no reported incidents of fire, injury or death due to this potential safety hazard.

A correction has been developed to eliminate the potential risk. The correction replaces the original battery cover with a new design incorporating a barrier that prevents mounting screws from penetrating into the battery compartment.

Please ensure that all potential users in your facility are made aware of this safety notification and that the required actions listed below are taken immediately.

1. Locate each Surveyor S12 and Surveyor S19 unit. The list of units delivered by Mortara to your organization is included.
2. For each unit, follow the included instructions (document number MIS-11-183-01) detailing the correction steps.
3. Complete and return the attached Medical Device Correction Return Response Acknowledgement and Receipt Form. A response is required for each device listed on the form.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions regarding this notice, please contact Technical Support at +1.414.354.1600 or TechSupport@mortara.com , or contact your local Service Representative.

Sincerely,

Timothy E. Field
Senior Vice President Quality

MEDICAL DEVICE CORRECTION RETURN RESPONSE
Acknowledgement and Receipt Form
Response is Required

Customer Information:
SAUDI HEALTH SERVICE CO,LTD
TASLEEH STREET, NEAR GIRLS SCHOOL
GUAIZA DISTRICT
JEDDAH, WR .. 21443
SAUDI ARABIA

Surveyor S12 and Surveyor S19 Patient Monitor Medical Device Correction

I have read and understand the recall instructions provided with the October 3, 2014 letter. ☐ Yes ☐ No

Were any adverse events associated with the recalled product? ☐ Yes ☐ No

If yes, please explain:

_____
_____
_____

Affected Product Information by Serial number:

Product Name	**Mortara Part Number**	**Device Serial Number**	**Correction Completed**
SURVEYOR	SUR12-BCF-AXXAD	114170207572	YES NO
SURVEYOR	SUR19-BCF-AXXAC	114170207577	YES NO

Signature of Receipt and Completion _____

Name/Title	
Telephone	
Email address	

FAX completed form to: +1.414.354.4760, ATTN: S12/S19 CORRECTION

OR e-mail completed form to: CORRECTIONS@MORTARA.COM

OR mail completed form to:
MORTARA INSTRUMENT, INC.
ATTN: S12/S19 CORRECTION
7865 NORTH 86TH STREET
MILWAUKEE, WI 53224