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

May 29, 2015

To: MORTARA INSTRUMENT GMBH

Re: Use of a specific workflow with the ELI 380 electrocardiograph may result in a safety hazard.

Dear Mortara Business Partner,

Mortara Instrument, Inc. has recently become aware of a potential safety hazard involving our ELI 380 electrocardiograph. When used in the workflow described below, acquired ECG waveforms for one patient may become associated with the patient demographics for a different patient when the record is transmitted to a records management system.

A hazardous situation may be created when the following workflow is used:

1. ECGs are ordered via an external records management system.
2. An order list is downloaded to the ELI 380 electrocardiograph.
3. An ECG technician selects an order from the list in the ELI 380, locates the patient, acquires and stores the ECG record on the ELI 380.
4. A new order list is subsequently downloaded to the same ELI 380 and the new order list differs from the previous order list.
5. An ECG associated with the original order list is retrieved from memory, edited and stored again.
6. The ECG record is transmitted to the records management system to fulfill the order.

In this workflow, editing and saving the record in step 5 may result in a wrong order number becoming associated with the ECG record in the ELI 380. When the ECG record is transmitted to the records management system to fulfill the order, the incorrect order number may cause the receiving system to associate the acquired ECG waveforms with the wrong patient demographics. Thus, when viewed on the records management system, the ECG may show the demographics for Patient A, but the ECG waveforms for Patient B.

This problem only occurs when using the ELI 380 in an orders-driven environment. Records with mismatched ECG waveforms and patient demographics only appear on the records management system after being received from the ELI 380. When viewed or printed on the ELI 380 itself, ECG waveforms and patient demographics are always matched properly.

There have been no reported incidents of patient injury due to this potential safety hazard.

A correction has been developed to eliminate the identified potential risk. The correction requires the ELI 380 system software to be upgraded to version 1.1.1. This new version of software corrects the handling of order numbers to ensure the correct order number is associated with the correct ECG, regardless of the workflow.

Although only affecting some records management systems and only under a specific workflow, Mortara has determined that the correction must be applied to all ELI 380 units to eliminate the potential safety hazard.

Please ensure that this safety notification is communicated to all customers that have received an ELI 380, that all potential users at customer facilities are made aware of this notification and that the required actions listed below are taken immediately.

1. Locate each ELI 380. The list of units delivered by Mortara to your organization is included with this notification.
2. In order to avoid possible use of the orders workflow described above, do not use the MWL/orders option to populate patient demographics with the ELI 380. It is safe to continue to use the ELI 380 when manually entering patient demographics. The MWL/orders feature can be used once the ELI 380 is updated to version 1.1.1.
3. For each unit, follow the included instructions (document number MIS-11-189-00) detailing the steps required to load the new version of software (provided), print the unit configuration page and verify the software has been loaded properly.
4. Complete and return the attached Medical Device Correction Return Response Acknowledgement and Receipt Form, along with the configuration page printout from each corrected unit. The configuration page printout 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,

[redacted]

Senior Vice President Quality

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

Customer Information:

MORTARA INSTRUMENT GMBH
ATTN: [redacted]
BONIFACIUSRING 15
ESSEN .. 45309
GERMANY

ELI 380 Medical Device Correction

I have read and understand the recall instructions provided with the notification 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?
ELI 380	ELI380-AAX12	115110249768	□ YES □ NO
ELI 380	ELI380-AAX12	115110249769	□ YES □ NO
ELI 380	ELI380-AAX12	115110249770	□ YES □ NO
ELI 380	ELI380-AAX12	115110249771	□ YES □ NO
ELI 380	ELI380-AAX12	115110249772	□ YES □ NO
ELI 380	ELI380-P-A	114360227774	□ YES □ NO
ELI 380	ELI380-P-A	114370228739	□ YES □ NO

Signature of Receipt and Completion _____

Name/Title	
Telephone	
Email address	

FAX completed form and configuration printouts for each unit to:
+1.414.354.4760, ATTN: ELI 380 CORRECTION

OR e-mail completed form and configuration printouts for each unit to:
CORRECTIONS@MORTARA.COM

BURDICK Mortara QUINTON

OR mail completed form and configuration printouts for each unit to:

MORTARA INSTRUMENT, INC.
ATTN: ELI 380 CORRECTION
7865 NORTH 86TH STREET
MILWAUKEE, WI 53224