



**Mortara Instrument**

7865 North 86th Street  
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## URGENT: FIELD SAFETY NOTICE BURDICK 4250 HOLTER RECORDER

**Reference Number:** MOD1288  
**Action:** Device Exchange  
**Document Number:** 80024569 VER B

March, 11th 2019

Dear Distributors,

### **Background:**

The purpose of this notification is to inform you that Mortara recently became aware that product, Burdick 4250 Holter recorders, model number 92516-01, which no longer bears the CE Mark, were incorrectly shipped to European Distributors and placed onto the market.

### **Details on affected devices:**

Burdick 4250 Holter recorder  
Model number: 92516-01

### **Actions to be taken by Mortara:**

A replacement H3+ Holter Recorder will be provided free of charge.  
A list of impacted Burdick 4250 Holter recorders will be provided to you at the same time as receipt of this notification.

### **Action to be taken by distributors:**

You should contact the first consignee customer regarding this notification and schedule a service representative to replace the Burdick 4250 Holter Recorder with the H3+ Holter Recorder.  
Please confirm the following by email to [marco.manduchi@welchallyn.com](mailto:marco.manduchi@welchallyn.com):

1. Quantity and Serial Number on the list of impacted recorders provided to you
2. Complete the appendix A Field safety response form, and return to [marco.manduchi@welchallyn.com](mailto:marco.manduchi@welchallyn.com)

This notice needs to be passed on to all those who need to be aware within your organisation, or to any organisation where the potentially affected devices have been transferred.

This notice has been communicated to your local Regulatory Agency.

Yours sincerely,

Marco Manduchi  
RA Manager Mortara Instrument Inc.



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## **Appendix A**

# **URGENT: FIELD SAFETY NOTICE BURDICK 4250 HOLTER RECORDER**

By checking this box, you, on behalf of this distributor, are certifying that you have read and understand the attached BURDICK 4250 HOLTER RECORDER Urgent Field Safety Notice and have removed the Burdick 4250 Holter Recorders placed on to the market and replaced with the H3+ Recorder.

Signature: \_\_\_\_\_

Contact (First and Last Name): \_\_\_\_\_

Title: \_\_\_\_\_

Distributor Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

Locality Province/Abbreviation/Postal Code: \_\_\_\_\_

Phone Number: \_\_\_\_\_

email: \_\_\_\_\_

Return this Response Form to [marco.manduchi@welchallyn.com](mailto:marco.manduchi@welchallyn.com)