URGENT FIELD SAFETY NOTICE

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Depolyment>

GEHC Ref #36116

To: Chief of Nursing
Director of Biomedical Engineering
Healthcare Administrator / Risk Manager

Affected product: **PRN 50-M+ Digital Writer**

Dear Customer,

This letter is to notify you that JADAK (a GSI Group Company) is conducting a product recall.

A copy of the GSI Medical Device Correction Notice is included in this mailing. Please review the GSI notice and complete the "Medical Device Correction Confirmation" response form on the last page of the notice. Please **return the response form directly to GE by e-mailing it to mark.bender@ge.com.**

Please ensure that all potential users and supervisors at your facility are made aware of this correction notice immediately.

If you have any questions regarding this field correction or the identification of an affected PRN 50-M+ Digital Writer, please contact GE Healthcare Service or your local Service Representative.

Oxygen Care Ltd.
2 Holfeld Business Park,
Kilmacanogue,
Co. Wicklow,
Ireland .
Phone: ++353 1 276 9700
e-mail: k.long@oxygen-care.ie

We apologize for any inconvenience this action may have caused and thank you for your continued cooperation and support.

GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

Sincerely,

James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare

GSI Group Corp.
125 Middlesex
Turnpike
Bedford, MA 01730

MEDICAL DEVICE CORRECTION NOTICE

November 18, 2015

To: Healthcare Administrator / Risk Manager
Chief of Nursing
Director of Biomedical Engineering

RE: **Potential safety issue with outer enclosure material flammability rating and vulnerability to fluid ingress with the PRN 50-M+ Digital Writer that was purchased from GE Healthcare.**

GSI Group has recently become aware of a potential safety issue associated with the flammability and fluid ingress rating of the outer enclosure material. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issues

There is an increased user/patient risk of exposure to fire and/or electrical shock due to the failure of the PRN 50-M+ Digital Writer to meet its intended flammability and fluid ingress rating.

Safety Instructions

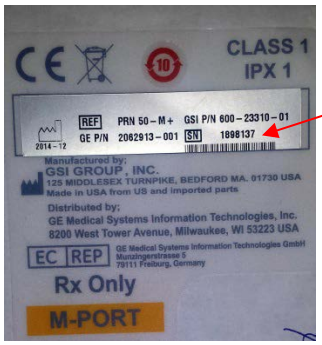
1) Follow all intended usage, cleaning and maintenance instructions that are found in the PRN 50-M+ Digital Writer Technical Manual.
2) Complete and return the attached Medical Device Correction Confirmation form.

Affected Product Details

Potentially affected product, **GE part number 2062759-001, manufacturer part number 600-23310-01** (Figure 1) were manufactured from May 28, 2013 through April 7, 2015 within the following serial number range: **1801405 through 1918761**. The serial number can be found on the back of the device (Figure 2).

Picture of the PRN50-M+ Digital Writer

Figure 1



Serial Number is located on the back of the printer

Figure 2

Product Correction

GSI Group will provide a correction at no charge. Once we receive the completed Medical Device Correction Confirmation form we will make arrangements to send you replacement(s).

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,

James Bowden
Director QA
GSI Group Company (JADAK Division)

MEDICAL DEVICE CORRECTION CONFIRMATION

CUSTOMER RESPONSE REQUIRED

PLEASE COMPLETE and RETURN

Customer Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

It is important that we confirm our customers have received this correction notice. To receive replacement product you must complete and return this confirmation form.

By sending back this notice, you acknowledge receipt of the Medical Device Correction Notice and have alerted the appropriate personnel at your facility regarding the safety issue and instructions. Please select one:

☐ We have received your Medical Device Correction Notice and no longer have this product.

☐ All products have been identified and the serial numbers listed below. **Power cords and instruction manuals will be saved and the old unit will be scrapped once replacements are received.**

Enter serial numbers below:

Reminder: Please SAVE the original power cord and Instruction Manual.

Please provide the name of the individual with responsibility for risk and compliance:

Signature:

_____

Printed Name/Title:

_____/_____

Date (DD/MMM/YY):

_____

Please Email Responses to: mark.bender@ge.com