URGENT FIELD SAFETY NOTICE

GE Healthcare
Vital Signs
20 Campus Road
Totowa, New Jersey
07512
USA

February 24th, 2011 GEHC Ref # 35002

To: Materials Manager / Central Supply Coordinator
Director Anesthesia / Anesthesia Technician Product Manager
Risk Manager

RE: **Greenlight II™ Laryngoscope Handle and Battery Cartridge**

Vital Signs, a GE Healthcare company, has become aware that the Greenlight II laryngoscope handle with a TOP Window battery cartridge may not function correctly. If the handle is subjected to a force perpendicular to the long axis of the handle, a battery may shift in the cartridge. This could result in an intermittent light source or loss of light source.

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issue

Difficulty in performing airway intubation due to intermittent light source or loss of light source.

Affected Product Details

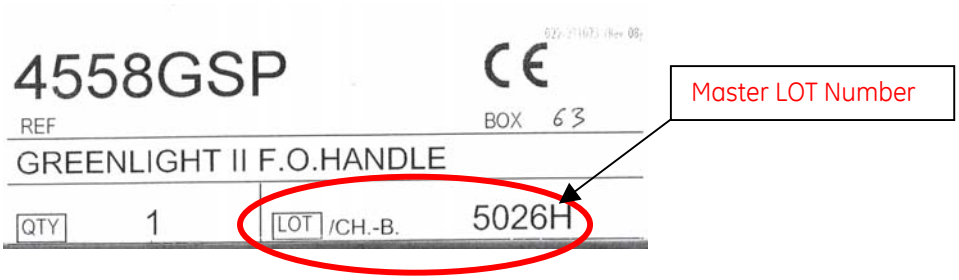
Affected product includes laryngoscope handle with cartridges and replacement cartridges manufactured between June 17, 2010 and September 7, 2010. Product codes and lot numbers affected can be found on the individual package as shown below. If the handle and cartridges have been placed into service, a visual check can be made to determine if cartridge in use is affected. See below.

- Product codes affected are 4558GSP and 4559LED.
- Lot numbers affected are:

5128F	**5140P**	**5161J**	**5184U**
5137P	**5144A**	**5180Z**	**5191X**
5139M	**5154Y**	**5183L**	

- This Field Correction does NOT affect cartridges with Bottom Window design (see below). Product with the bottom window design is fit for clinical use and should NOT be returned and will not be replaced.

Master LOT number



Cartridge Designs

TOP Window Design

Bottom Window Design NOT Affected

Safety Instructions

1. For TOP Window design, check that battery is properly seated before each use and verify handle is operational by engaging blade.
2. Standard intubation protocols should be followed, including having a back up handle always available.
3. Please complete the Confirmation Form attached and fax back per its instructions. This is required for us to confirm communication with all customers.

Product Correction

Replacement cartridges for TOP Window design will be provided at no charge when available. Please collect and return the number identified on Confirmation Form when replacements are available.

Contact Information

If you have any questions regarding this notice, please contact your local representative or Customer Service:

Linda Smith, UK Product Manager – VSD

71 Great North Road,

Hatfield Herts, AL9 5EN, UK

F: +44 (0) 7825714084 M: +44 (0)7768294511

linda.smith@ge.com

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.

Thank you.

James Dennison
Senior Executive QARA
GE Healthcare Systems
Mail Stop: RP2130
Wauwatosa, WI 53226 US

William Denman, M.D., FRCA
Chief Medical Officer
3000 N Grandview Blvd
Mail Stop W-440
Waukesha, WI 53188

URGENT FIELD SAFETY NOTICE

RE: CONFIRMATION FORM FOR MEDICAL DEVICE CORRECTION
Greenlight II™ Handle and Cartridges
ATTN: Paula Beckham

It is important that we confirm our customers have received this correction notice. As such, we require that you complete this Confirmation Form and **fax to: +1 (303) 799-0210** or send via **email to Paula.Beckham@ge.com.**

We have received your Correction Notice and alerted appropriate personnel at our facility regarding your Safety Instructions.

Number of Cartridges to be replaced : _____

Name of Dealer/Hospital : _____

Street Address : _____

City/State/Zip : _____

Telephone Number : _____

Email address : _____

Print Name : _____

Signature : _____ Title : _____

Date : _____

Thank you for your assistance with this matter.