Date					
	URGENT: V	OLUNTARY	PRODUCT	RECALL O	F

Dear Valued Customer,

Data:

Reason for Recall: We have learned of potential for leaks affecting a limited number of lots of Eyesaline eyewash bottles. While these products are filled aseptically, the potential for a leak results in a low risk of contamination of the eyewash solution and possible damage to surrounding materials when used in First Aid Kits. The root cause has been addressed on the manufacturing production process and we are confident that the issue has been resolved. Safety is our priority, so we are initiating a voluntary recall of affected products you may have in inventory, as well as those sold to your customers and end-users.

EYESALINE EYEWASH AND FIRST AID KITS

Risk to Health: Although we have not received and are not aware of any reports of adverse health events related to this issue, exposure to infectious agents due to a compromised container barrier could result in infection and may require treatment with antibiotics.

Instructions to Customers:

Please take the following actions to help remove these items from usage:

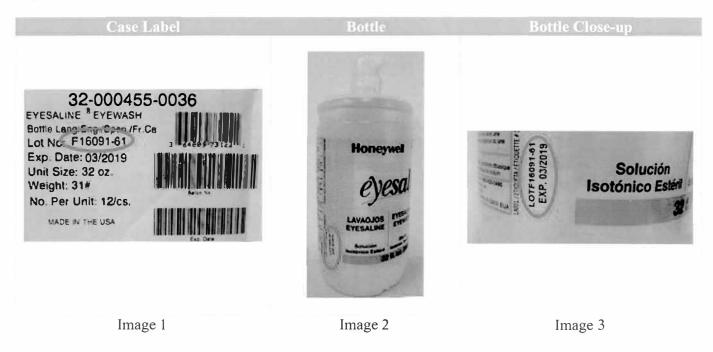
- 1. Identify if the product in your possession is affected by locating the lot number on the eyewash bottles or first aid kits and cross-referencing with the list of affected lots. Reference images 1 through 6 for assistance in locating the lot number.
- 2. Immediately segregate and stop sales and usage of any affected products.
- 3. If you have further distributed this product, please notify your customers of this recall at once. You can copy this notice for that purpose and post it in your branch outlining the requested customer action.
- 4. Contact 855.215.5028 to obtain a prepaid return label and Return Response Form.
- 5. A copy of the completed Return Response Form must be included with your return.
- 6. Follow steps 4 and 5 and Honeywell will issue replacement product directly to you.
- 7. Email list of customers you notified to <u>Honeywell3787@stericycle.com</u>. This information will be used strictly to track responses.
- 8. Please retain any undelivered notices for future reference.

We are conducting this recall in cooperation with Health Canada and the U.S. Food and Drug Administration. We sincerely appreciate your response by February 28th, 2018. If you have any questions, please do not hesitate to contact Customer Service at 855.215.5028, Monday – Friday, 8:00 AM – 5:00 PM EST.

Sincerely,				

LOCATING LOT NUMBERS - the below images highlight the most common locations for lot number location. Actual location may vary.

Eyesaline Eyewash Bottles



First Aid Kits





December 5, 2016

Dear Valued XGO Customer:

We just discovered—and want to alert you to—a potential problem with some of our 1FS59G fire-resistant (a/k/a "FR") shemaghs manufactured and distributed between April 5, 2016 and November 10, 2016.

As a result of an unauthorized yarn change by a supplier, some of these shemaghs fail to meet our specifications and will not offer the advertised level of fire-resistance protection and user safety. We have therefore chosen to issue an immediate recall of all 1FS59G fire-resistant shemaghs. Your safety is—and will always remain—our priority.

The limited number of non-compliant fire-resistant shemaghs can be easily detected by visible inspection but, rather than ask you to handle that task, we would ask you to return all XGO fire-resistant shemaghs for an immediate credit. We will immediately replenish your stock with compliant products and will, of course, reimburse you for freight costs.

Please note that these concerns are limited to woven fire-resistant shemaghs.

Our XGO FR fire-resistant base layer products meet—and continue to meet—all specifications and criteria. We are dedicated to providing you with products of outstanding quality and value.

Should you have any further questions, please contact me, President and Chief Executive Officer at (910) 673-5290 (extension 23), or Aloysius Donovan, XGO Director of Sales at (910) 673-5290 (extension 26), or Wendi Gatlin, Customer Service Manager at (910) 673-5290 (extension 24).

Regards,

Randy Black

President and Chief Executive Officer

Gendy Blow









September 27, 2016

URGENT PRODUCT RECALL – Major/Rugby Pharmaceutical Drug/Product Recall

North American Rescue has been notified that the Major/Rugby Pharmaceuticals Major Label Eye Wash and Rugby Label Eye Wash Irrigating Solution are being recalled by the manufacturer due to "concerns that product sterility may be potentially impacted".

NAR prides itself on providing safe and effective products and regrets this inconvenience. With this communication NAR wants to ensure that you have the recall information. *Please know this recall is for Major Pharmaceuticals Major Label Eye Wash and Rugby Label Eye Wash Irrigating Solution, only; all other components packaged in the kit are not affected by this recall.* The product codes are listed below.

Product Code	Item Description	Product Code	Item Description
85-0889	Range Trauma Kit - Hardcase	80-0209	K-9 Trauma Field Kit
85-0742	Advance Trauma Kit	85-0835	Mini Resupply Trauma Kit
85-0746	Advance Trauma Kit	80-0298	Range Trauma Kit - ORG
80-0211	K-9 Trauma Field Kit	80-0210	K-9 Trauma Field Kit
80-0213	Range Trauma Kit - ORG	85-0744	Advance Trauma Kit
80-0299	Range Trauma Kit - ORG	85-1274	Range Trauma Kit
85-0639	Amphibious Trauma Kit	80-0300	K-9 Trauma Field Kit
80-0304	K-9 Trauma Field Kit	85-0917	Aid Backpack Kit
85-0745	Advance Trauma Kit	80-0301	K-9 Trauma Field Kit
85-0639	Advance Trauma Kit	80-0353	USCG Boat Response Kit
85-0744	Advance Trauma Kit	85-0741	Advance Trauma Kit

This formal NAR communication is in cooperation with the recall efforts of the Major Pharmaceuticals. Please read the attached recall information in its entirety. If you have any questions about Major Pharmaceuticals recall, please contact Major/Rugby Pharmaceuticals, at (800) 645-2158. Included is a list of affected lot numbers, listed by product code.

Please review your inventory identifying on the enclosed form any affected lots. NAR will be pleased to provide a new eye wash packet at no cost to you. You may initiate the process to receive new eye wash, by contacting NAR Customer Service toll free at 1-888-689-6277; please have your customer order number available to reference.



Once again, we regret this situation and desire to make sure that a replacement eye wash is available to you without cost and with minimum inconvenience. North American Rescue remains committed to provide only the highest quality products and services for you, our valued customer.

Sincerely,

William Slevin

Director, QA/RA

North American Rescue, LLC

35 Tedwall Court

Greer, SC 29650

Enclosures (2)



Enclosure 1 Major Pharmaceuticals Eye Wash Recall

Please fill out and fax/email this form within 10 business days, even if you do not have the recalled product.

Please complete both pages of enclosure 1 and fax to 864-675-9880 or email to kward@narescue.com

Request for RGA Form

Account #:		
Account Name:	21.35.25	
Address:		_
Contact Name:	¥	_
	8	
Email and phone		



Enclosure 1

Inventory Information

☐ We have inspected our inventor	ory and have no product related to	this recall.
☐ We have inspected our invento	ory and have the following product	related to this recall.
Product Number	Lot Number	Quantity
		g
		~
	-	
Completed by	Date	



Enclosure 2

NAR Kit Number and Lot Number			
Kit Part #	Kit Lot #	Kit Part #	Kit Lot #
85-0639	85-0639080516	85-0889	85-0889082416
85-0639	85-0639060116	85-0889	85-0889071816
85-0639	85-0639061016	85-0889	85-0889071916
85-0639	85-0639071416	85-0889	85-0889071416
85-0639	85-0639072116	85-0889	85-0889052316
85-0639	85-0639050316	85-0889	85-0889050416
85-0639	85-0639050416	85-0889	85-0889042016
85-0639	85-0639051316	85-0889	85-0889041416
85-0639	85-0639082216	85-0889	85-0889090616
85-0639	85-0639090116	85-0889	85-0889090716
85-0639	85-0639090716	85-0889	85-0889060216
85-0639	85-0639080116	85-0889	85-0889062216
85-0639	85-0639091316	85-0889	85-0889080116
80-0213	80-0213080816W	85-0889	85-0889080816
80-0213	80-0213071316W	85-0835	85-0835061016
80-0213	80-0213041816W	85-0835	85-0835052416
80-0213	80-0213051716W	85-0835	85-0835051116
80-0213	80-0213050516W	85-0835	85-0835050216
80-0213	80-0213050916W	85-0835	85-0835042916
80-0213	80-0213081116W	85-0835	85-0835072616
80-0213	80-0213081716W	85-0835	85-0835072016
80-0213	80-0213082516W	85-0746	85-0746061016
80-0213	80-0213090216W	80-0211	80-0211070616
80-0213	80-0213090916W	80-0211	800-211051316
80-0213	80-0213070716W	80-0211	80-0211041816
80-0213	80-0213080316W	80-0211	80-0211030216
80-0213	80-0213080116W	80-0211	80-0211072216
80-0213	80-0213072716W	80-0210	80-0210070716
80-0213	80-0213090916W	80-0210	80-0210050416W
80-0299	80-0299080916W	80-0210	80-0210072216
80-0299	80-0299071116W	85-0744	85-0744072516
80-0299	80-0299060116W	85-0744	85-0744060916
80-0299	80-0299051916W	85-0744	85-0744052516
80-0299	80-0299081716W	85-1274	85-1274072516W
80-0299	80-0299050316W	80-0304	80-0304041916
80-0299	80-0299051016W	85-0917	85-0917041916
80-0299	80-0299082216W	85-0745	85-0745042516

35 Tedwall Court • Greer, South Carolina 29650-4791 Office: (864) 675-9800 • Fax (864) 675-9880 • Toll Free: (888) 689-6277 <u>www.NARescue.com</u>



Enclosure 2

NAR Kit Number and Lot Number				
Kit Part #	Kit Lot #	Kit Part #	Kit Lot #	
80-0299	80-0299082416W	80-0301	80-0301042916	
80-0299	80-0299090616W	80-0301	80-0301050316	
80-0299	80-0299090716W	80-0353	80-0353051916	
80-0299	80-0299090716W	85-0741	85-0741071416	
80-0299	80-0299080416W	85-0742	85-0742071816	
80-0298	80-0298081116W	80-0300	80-0300081216	
80-0298	80-0298060116W	80-0300	80-0300050916	
80-0298	80-0298062316W	80-0300	80-0300050316	
80-0298	80-0298090716W	80-0300	80-0300041916	
80-0209	80-0209082216	80-0300	80-0300082416	
80-0209	80-0209051816		ů.	
80-0209	80-0209051616			
80-0209	80-0209050316			
80-0209	80-0209041916			
80-0209	80-0209060316			

July 2015



Galls | Quartermaster 1340 Russell Cave Road Lexington, KY 40505 866-673-7643

Re: IMPORTANT PRODUCT REPLACEMENT NOTICE

The NIJ has issued an advisory concerning Galls' Model LXIIIA-1 ballistic package (Galls item BP964), and the product has been temporarily suspended from the NIJ Compliant Products List. A copy of the NIJ notice can be found at https://www.justnet.org/body_armor/active_advisory_notices.html.

As a precautionary measure, Galls and Point Blank, the manufacturer of this ballistics package, are undertaking a voluntary recall of the product. **Notwithstanding this voluntary recall, all Galls customers should continue wearing their vests until replacement panels are received.** Galls and Point Blank remain confident in the safety of this product, but will be replacing them so there are no concerns. Further, the NIJ has explicitly advised that customers should continue wearing their vests.

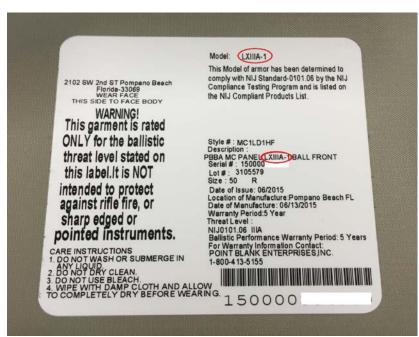
Galls and Point Blank have assembled a team to coordinate this replacement effort, which is already underway. To determine whether your ballistics package is subject to this voluntary recall, you should examine the label on your vest. If the model is LXIIIA-1, it is subject to the voluntary recall, and the ballistics panels will be replaced at no cost to you, our valued customer. See the photograph below for further guidance on where to identify the model number in order to determine whether your ballistics package is subject to the voluntary recall.

To obtain replacement panels, please fill out this <u>form</u> and return it to Point Blank at <u>returns@pbearmor.com</u>. Once your information is confirmed, Galls and Point Blank will work with you to facilitate the exchange of the ballistics panels, which are subject to the recall. If you have questions, you can contact Filipe Placucci at 1 (800) 413-5155.

Again, you should continue wearing your vest until you receive replacement ballistics panels. We truly apologize for any inconvenience this may cause. If you have any questions or concerns, please feel free to call the number above.

Most sincerely,

Galls, LLC



IMPORTANT SAFETY RECALL

Code 3° Announces Recall of Rechargeable LED Work/Utility Lamps



Model Number: CW2461CWR & CW2461-CAMO, manufactured from April 15, 2014

through November 19, 2015.

(The model and date of manufacture can be found on the lamp, as shown in the photos above.)

Product Label: If the box has a green sticker or if the label states "Rev B," it is not

part of this recall. If neither of these are present, you must still check the date code to determine whether it falls within the recall range.

Safety Concern: The product may overheat and present a risk of fire.

Remedy: Return the lamp to the retailer where you purchased it for a refund or

replacement (Subject to availability).

For more information:

(314) 426-2700 • C3-CS@code3esg.com • www.code3esg.com http://sodium.code3pse.com/web_files/CODE3_RecallPoster.pdf Monday - Friday, 7:30 am - 5:00 pm Central Time

Post Until 10/31/2016





February 16, 2018 FSN86100186

Medical Device Recall/Notification

HeartStart FRx, HeartStart Home, and Heartstart OnSite AEDs

Dear HeartStart AED Owner,

We are contacting you because our records show you are the owner of one or more Philips HeartStart FRx, HeartStart OnSite, or HeartStart Home automated external defibrillators (AEDs) manufactured between 2002 and 2013. Philips is voluntarily issuing this recall notification due to awareness of isolated failures with one of the device's electrical components (a resistor).

1. Reason for This Recall Notification:

Your Philips AED is used to treat ventricular fibrillation (VF), a common cause of sudden cardiac arrest (SCA), and certain ventricular tachycardias (VTs). These Philips AEDs have a low failure rate of less than ½ % per year.

To help ensure your AED will perform in the event of an emergency, Philips AEDs include self-tests that run automatically when the AED is not being used. Various tests occur at daily, weekly, and monthly intervals. These self-tests have been effective at catching over 99% of critical performance issues and alerting users through a series of audible chirps. However, isolated failures can occur that are not detected by these self-tests, and occur during use, putting patients at risk of not receiving adequate therapy for their VF or VT, potentially resulting in serious injury, or even death.

Philips has become aware of a specific issue with one of the electric components (a resistor) in approximately 660,000 AEDs that were manufactured between 2002-2013. Virtually all of these resistor-related failures were detected through the device's automatic self-testing, alerting the user by issuing audible chirps. The in-use reliability of these AEDs is greater than 99.9% when the AED determines a cardiac arrest victim is in need of shock therapy.

However, in rare instances, self-tests might not identify a problem and the device might not deliver a shock when needed. To date, Philips is aware of 13 instances in which this component failed during treatment, out of more than 45,000 uses in which shock therapy was delivered. In all these instances, the device delivered at least one shock before failure. Among the cases for which the patient outcome is known, 5 patients died and 2 patients were successfully resuscitated and survived. Importantly, when AEDs are used on patients suffering sudden cardiac arrest, not all patients survive. In published studies of public access defibrillation to treat sudden cardiac arrest, the typical indicated survival rates are approximately 25% when an AED is used by a bystander versus 10% if an AED is not used.

2. Risk to Health

Philips is sending this letter to remind customers about the nature and meaning of audible chirps, and to notify customers what to do in the extremely rare circumstances the automated tests fail to detect

Philips Healthcare



the AED's inability to function normally, and fail to deliver a shock when one is needed.

3. Actions To Be Taken By Customer/User

Understanding Audible Chirps from Your AED:

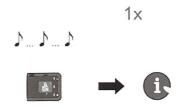
Your Philips AED tests itself at regular intervals to ensure it is ready for use. Issues identified during self- tests result in the sounding of audible single chirps or triple chirps. When an error is detected, the AED continues to chirp until the error is cleared. To help you better understand the difference between single and triple chirps, please view the instructional video on our website at:

www.philips.com/aedaudiblechirps

As stated in your HeartStart manual:

If your AED emits a series of single chirps ()...)...):

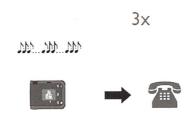
☐ Press the flashing blue i-button for information. Your AED will tell you what actions to take (such as replacing expired battery or pads).



If your AED emits a series of triple-chirps (), this could mean that a potentially serious problem was detected during self-test that could prevent your AED from delivering therapy in an emergency.

If you ever hear your AED emit a series of triple chirps:

□ <u>During Stand-By Mode:</u> *Please call Philips immediately* for technical support including delivery of a replacement unit and receipt of a Return Authorization (RA) number in accordance with the eligibility criteria described in the "Replacement or Rebate Opportunity" section below.



<u>During an Emergency Rescue:</u> Press the flashing blue i-button and follow the voice prompts. Removing and reinserting the battery can clear some errors, and equip the device to deliver therapy in a rescue. *The battery removal and reinsertion procedure should only be done in an emergency situation. Once the emergency is over, call*

Philips Healthcare



Philips immediately for technical support including delivery of a replacement unit and receipt of a Return Authorization (RA) number.

WARNING: Removing and reinserting the battery one or more times when an AED emits a series of triple chirps may reset the device and cause it to report it is ready for use, though it may be unable to deliver therapy during a rescue. Removing and reinserting the battery when your AED is emitting a pattern of triple chirps should only be done during an emergency. If your device is emitting a series of triple chirps in stand-by mode, or after an emergency, please remove the AED from service and contact Philips immediately.

In the rare event that an AED fails during use and is unable to deliver shock therapy, you should:

- Ensure that 911 has been called.
- Continue CPR while waiting for Emergency Medical Services to arrive.
- If an additional bystander is available, send him/her to locate another nearby AED.

4. Specific Products Covered by This Notification

Philips AED Models: HeartStart FRx, HeartStart Home, and HeartStart OnSite AEDs manufactured from September 2002 through February 2013 are included within the scope of this notification because they may contain the type of resistor that has previously been associated with a failure. The year of manufacture can be identified by the 2nd and 3rd characters in the serial number on the back of the AED in the range:

Home/Onsite: A02I-xxxxx through A13B-xxxxx FRx: B04L-xxxxx through B13B-xxxxx

However, if your device was manufactured in 2013 and the 4th digit is the letter "C" or later (D, E, F...), it is not covered by this recall. For example, A<u>13G</u>-02375 is not covered by this recall because it does not contain the resistor associated with this recall notification.

Examples:

Serial number A $\underline{07C}$ -01002 was manufactured in 2007. It falls within this range and *is* covered by this notification.

Serial number A<u>13C</u>-00773 was manufactured after February 2013. It does *not* fall within this range and *is not* covered by this notification because it does not contain the resistor associated with this recall notification.

Serial number A13B-02375 is covered by this recall because it may contain the resistor associated with this recall notification, but A13G-02375 is not covered by this recall because it does not

Philips Healthcare



contain the resistor associated with this recall notification.

Some of the AEDs within the date ranges covered by this recall notification do not contain the resistor associated with the reported failures. Where Philips determined, based on its records, that a device within the date range covered by the notification does not contain a resistor previously associated with a failure, we did not send a notification. Nonetheless, if you wish to confirm whether your device contains the resistor at issue, please contact Philips at 1-800-263-3342, option 5.

5. Action Taken by Philips

Philips began notifying owners of this potential hazard in September 2012. With this mailing, we are providing additional information and have created an instructional video available at www.philips.com/aedaudiblechirps.

Philips carefully monitors the reliability of our AED products. If you experience an issue with your AED or if it is emitting triple chirps, please contact Technical Support (refer to following section).

6. For Technical Support

As noted above, and in your HeartStart AED owner's manual, if your Philips AED has ever emitted or begins to emit a pattern of triple chirps, please contact Philips for technical support at 1-800-263-3342, option 5. Live support is available Monday-Friday, 5:00AM-5:00PM Pacific Time. This number is available 24 hours a day, seven days a week for customer messages that will be promptly returned the next business day.

Adverse reactions or quality problems experienced during use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

7. Replacement or Rebate Opportunity

Your continued satisfaction with Philips AEDs is very important to us and we want to ensure your confidence in the reliability of our products. If your device is covered by this notification and is still under warranty, you are entitled to receive a refurbished exchange unit at no cost, in accordance with our standard warranty terms. If your device is no longer under warranty or if you desire to purchase a newer model replacement for your present AED, as an owner of a Philips HeartStart FRx, HS1 OnSite, and HS1 Home AED manufactured prior to 2013, you may be eligible for a trade-in rebate. Philips is offering trade-in rebates ranging from \$50 to \$625, depending on the age and model of your AED.

To request a warranty exchange unit or a trade-in rebate, or to obtain additional information, please contact your local Philips representative or contact Philips directly at 1-800-263-3342, option 5. Further information about the trade-in rebate program may be found at: www.philips.com/aedsupport.

Additionally, to help you get the most out of your AED and to help you ensure it is ready for use if needed, please refer to the online instructional video on AED pads and batteries:

www.philips.com/padsandbatteries