

URGENT: FIELD SAFETY NOTICE

Affected Product:	Vision Sciences [®] Battery Charger and Rechargeable Lithium-Ion Batteries
Type of Action:	Advice to return of Battery Chargers and to dispose of Rechargeable Lithium-Ion Batteries
FSCA Identifier:	RGA CA14-011

Date: August 15th, 2014

Attention: Distributor

Details on affected devices:

The Vision Sciences[®] Battery Chargers included in this notice are model NOVACELL NV-LC02 and model VANSON V-95 and Rechargeable lithium-Ion Batteries. Please refer to the Attachment 1, Product Identification, for complete list of affected devices.

PLEASE NOTE: THIS FSCA ONLY CONCERNS THE BATTERY CHARGER and RECHARGEABLE LITHIUM-ION BATTERIES, NO ENDOSCOPES or LIGHT SOURCES are included in this Field Safety Notice.

Description of the problem:

Vision-Sciences Inc. has received a limited number of reports relating to over-heating and burning of the lithium-ion batteries being charged with the Vision-Sciences Battery Chargers. Since July 2011, there have been twenty three (23) incidents reported globally. As a result, Vision-Sciences Inc. has initiated a **Field Safety Corrective Action (FSCA) to put all Vision Sciences[®] Battery Chargers and Rechargeable Lithium-Ion Batteries out of service.**

Advice on action to be taken by Distributor:

Please check your stock to determine if you have any of the products listed in Attachment 1.

If product is identified, please complete the following steps:

- 1. Segregate Affected Product.** Please immediately remove all Battery Chargers and Rechargeable Lithium-Ion Batteries from use and your inventory (regardless of its location) and segregate this product in a secure location.
- 2. Complete Tracking/Verification/Return Goods Form.** This form must be completed and returned even if you do not have any Battery Charger and Batteries in stock.
 - a.** Please indicate how many battery chargers have you distributed; refer to attachment 1 to help you calculate this number.
 - b.** Fax the tracking/verification/return good form to **(+1)(845)365-0620** or scan in and e-mail to **batterycharger@visionsciences.com**

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3. **Return All Battery Chargers to Vision Sciences.** Package the Battery Charger(s) being returned in a shipping box or envelope. Place a signed original copy of the Tracking/Verification/Return Goods Form in the box, appropriately seal the box, and send it on or before September 30th 2014, to:

**Vision-Sciences, Inc.
40 Ramland Road
Orangeburg, NY 10962,
U.S.A**

Please indicate the reference number **RGA# CA14-011** when returning any product.

4. **Dispose of Batteries.** Please **DO NOT** ship recalled batteries. Most shipping companies do not permit the mailing of lithium-ion batteries. Please dispose of batteries per local regulations. Note on Tracking/Verification/Return Goods Form that this step has been completed.
5. **Provide Field Safety Notice (FSN)** to all your customers who have received battery chargers and rechargeable lithium-ion batteries; refer to attachment 1 for affected product. Please complete or utilize the enclosed "FSN for end users" template and send your customers the following documents:
 - a. Copy of the Customer Field Safety Notice
 - b. Copy of the Tracking/Verification/Return Goods Form

The Tracking/Verification/Return Goods form should be completed by your customer and returned to you.

As a distributor you are required to confirm to Vision-Sciences that you have completed the instructed activity for all your customers affected by this Field Action.

In case of any questions please Call (+1) 845-359-0276 from 9:00 a.m. to 5 p.m. (US EDT). Alternatively, you can e-mail batterycharger@visionsciences.com to obtain Return information.

Thank you for your support -- we are committed to delivering a replacement solution to this issue as soon as we believe that it meets the quality standards that you expect from Vision-Sciences.

In the meantime Distributors will be provided with a package of 10 disposable batteries (3.0V, Lithium Disposable, CR123A type) per charger reported. Please contact Vision-Sciences Customer Service if you have any questions regarding this FSCA, any of our products, or would like assistance with the FSCA.

We regret any inconvenience that this action may cause, but we appreciate your understanding as we take action to ensure patient/user safety and customer satisfaction.

Sincerely,

Diana Quintero-Avila

QA/RA Manager

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Attachment 1: Product Identification

PLEASE NOTE: THIS FSCA ONLY CONCERNS THE Vision-Sciences Battery Charger and Rechargeable Lithium-Ion Batteries

The Vision Sciences® Battery Chargers included in this notice are model NOVACELL NV-LC02 catalog numbers 07-3051 and 07-3051X and model VANSON V-95 catalog numbers 07-3058-EU, and 07-3058-UK.

List of Impacted Products from Vision-Sciences:

<u>VISION SCIENCES CAT. No.</u>	<u>ITEM Description</u>
07-3051	Battery Charger, Lithium-Ion
07-3051X	Battery Charger, Lithium-Ion*
07-3058-EU	Battery Charger, Lithium-Ion- Europe
07-3058-UK	Battery Charger, Lithium-Ion- United Kingdom
07-3052	Rechargeable Batteries, Lithium-Ion
07-3052X	Rechargeable Batteries, Lithium-Ion*
07-3059	Rechargeable Batteries, Lithium-Ion

The above devices were also sold as part of the following Light source kits and Vision-Sciences endoscopy systems sets, which contained one battery charger and a pair of rechargeable batteries. This **FSCA** affects **only** the Battery Charger and Rechargeable Lithium-Ion Batteries sold with these sets; no endoscopes or light sources BLS-1000 are included in this product FSCA:

<u>VSI PART No.</u>	<u>ITEM Description</u>	
07-3053	BLS-1000 Kit	(contains 1 charger 07-3051 and 2 batteries 07-3052)
07-3053X	BLS-1000 Kit*	(contains 1 charger 07-3051X and 2 batteries 07-3052X)
07-3053-EU	BLS-1000 Kit – Europe	(contains 1 charger 07-3058-EU and 2 batteries 07-3059)
07-3053-UK	BLS-1000 Kit – United Kingdom	(contains 1 charger 07-3058-UK and 2 batteries 07-3059)
02-2602	ENT-3000 Scope (Standard Set)	(contains 1 charger 07-3051 and 2 batteries 07-3052)
02-2602-IN	ENT-3000 Scope (Standard Set)*	(contains 1 charger 07-3051 and 2 batteries 07-3052)
02-4201	ENT-4000 Portable Set	(contains 1 charger 07-3051 and 2 batteries 07-3052)
02-4201X	ENT-4000 Portable Set*	(contains 1 charger 07-3051 and 2 batteries 07-3052)

** These products were distributed by Medtronic Xomed/ENT*

PLEASE NOTE: NO OTHER VISION-SCIENCES PRODUCTS ARE AFFECTED BY THIS FSCA.

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PRODUCT TO BE RETURNED TO VISION SCIENCES



Vision Sciences® Battery Charger NOVACELL NV-LC02



Vision Sciences® Battery Charger VANSON V-95

Important note: NO ENDOSCOPES or LIGHT SOURCES are included in this product FSCA so should not be returned to Vision Sciences.

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TRACKING/VERIFICATION/RETURN GOODS FORM

FSCA Identifier: RGA CA14-011

PRODUCT RECALL: Vision Sciences[®] Battery Charger and Rechargeable Lithium-Ion Batteries

Please fill out and return upon receipt

Vision-Sciences Catalog No.:

07-3051, 07-3051X, 07-3052, 07-3052X, 07-3058 and 07-3059 and extensions

- We do not have any stock of the above product.
- We have _____ units for a total of _____ units of the above product.
- We have discarded _____ number of batteries.
- We have distributed _____ number of chargers.

FACILITY/CUSTOMER NAME: _____

CONTACT PERSON: _____

ADDRESS: _____

CITY: _____ STATE: _____ ZIP CODE: _____

TELEPHONE: _____

EMAIL: _____

REMINDER: Return the Battery Charger ONLY. Dispose of all Rechargeable Lithium-Ion Batteries No other equipment or items are subjected to this FSCA.