

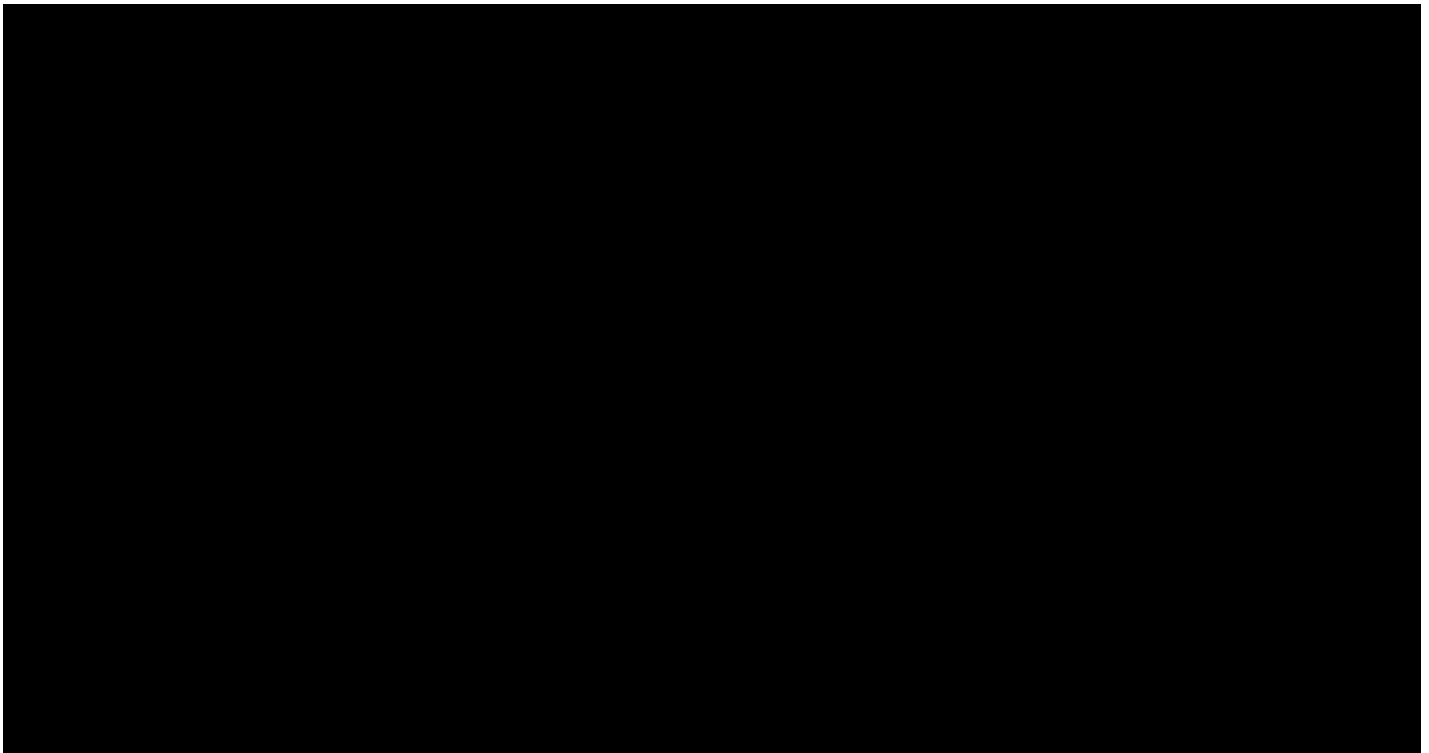


CONMED Hall® Small Lithium Battery L3000SM FIELD SAFETY NOTICE

July XX, 2018

CONMED Corporation is sending this communication to notify you of a product issue with the **Hall® Small Lithium Battery L3000SM**.

This action pertains only to Hall® L3000SM Batteries manufactured between March 15 and May 2, 2018, as listed below. The following serial numbers of L3000SM are affected.



The L3000SM Hall® Small Lithium Batteries are sold as non-sterile, reusable devices. They are used to power all the Hall® Cordless Handpieces except the PowerPro. Affected serial numbers are vulnerable to a premature battery failure which could result in an inability to provide power to the handpiece. If the battery fails, it will not power the Hall® Handpiece and will require replacement of the battery for the Hall® Handpiece to be used. This could cause a procedural delay. CONMED has received no reports that this premature failure has resulted in any illness or injury to patient or user.

This action only concerns the listed serial numbers of the L3000SM Hall® Small Lithium Battery. There is no problem with any other Hall® Battery pack nor with any Hall® Cordless Handpieces.



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Based on this information, CONMED has decided to remove the devices listed above to the user level. **Therefore, please follow the steps below if you have received Hall® Small Lithium Battery L3000SM marked with any serial number listed above.**

Step 1: Please review your inventory for any of the affected L3000SM Hall® Small Lithium Batteries.

We ask that you contact all of those departments within your facility and any other facilities within your organization or any of your customers that may have received affected products. It is important that all end users of these devices receive this notice and respond immediately.

Step 2: If you have any L3000SM Hall® Small Lithium Batteries with serial numbers listed on page 1 of this letter:

- a. Pull all affected batteries from active use.
- b. Record the catalog and serial numbers of the affected batteries on the Business Reply Form (Attachment I) and complete this form.
- c. **Do not return these batteries to CONMED.** CONMED requests that you dispose of or destroy these batteries per your local regulations for lithium battery disposal.
- d. A 1) Certificate of Destruction or 2) an affidavit or receipt for disposal/recycling must be obtained and attached to the Business Reply Form (Attachment I). This documentation should show the number of batteries disposed of. It should include the date of product disposal.
- e. Indicate on the Business Reply Form (Attachment I) whether replacement product or credit is preferred. Credit for will be issued unless otherwise requested.
- f. If there is a charge to the customer for destruction/disposal, CONMED will reimburse the customer for this expense. A copy of the invoice for destruction/protocol must be attached to the Business Reply Form (Attachment I), for reimbursement to be approved.
- g. Please complete the Business Reply Form (Attachment I) and return it with the disposal/destruction documentation to:

CONMED Corporation

525 French Road

Utica, NY 13502 USA

Attn: L3000SM Support Team

- h. The Business Reply Form (Attachment I) and its attached documentation may also be scanned and forwarded to the L3000SM Support Team via email to L3000SM@conmed.com.
- i. Business Reply Form (Attachment I) may also be faxed to: L3000SM Support Team at +1 315-624-3225.

Step 3: If you DO NOT HAVE any affected L3000SM Hall® Small Lithium Batteries to return, please complete the Business Reply Form (Attachment I), indicating you have no batteries and return by one of the means listed below:

- a. Email to: L3000SM@conmed.com
- b. Fax to: L3000SM Support Team at +1 315-624-3225.




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If you have any questions or requests, please don't hesitate to contact the L3000SM Support Team at +1 1-800-448-6506, fax to +1 315-624-3225, or email L3000SM@conmed.com.

CONMED is dedicated to providing safe and reliable products to empower our customers to deliver exceptional outcomes for patients. We are committed to manufacturing product of the highest quality and sincerely apologize for any inconvenience this may cause you or your staff.

The appropriate international competent authorities have been notified of this action.

Sincerely,


Patricia Cotter
Senior Specialist, Regulatory Affairs



**ATTACHMENT I
EFFECTIVENESS CHECK
FIELD SAFETY NOTICE
BUSINESS REPLY FORM**

Please check all that apply:

- ☐ We DO NOT have any stock of the suspect serial numbers
- ☐ We have notified our accounts of this action and advised them of how to disposition product per CONMED's directions
- ☐ We have disposed of _____ (QTY OF L3000SM Batteries): (Complete table below)

CATALOG #	SERIAL NUMBERS				
L3000SM					
L3000SM					
L3000SM					
L3000SM					
L3000SM					
L3000SM					
L3000SM					
L3000SM					

Check one: ☐ Credit
☐ Replacement

All requests for credit or replacement must be accompanied by this completed form.

Please attach copy of 1) Certificate(s) of Destruction or 2) affidavit(s)/receipt(s) of disposal/recycling. Also attach any supporting documentation.

Have you received any reports of illness or injury related to this product? Yes____ No____

If yes-please document specific information. Include it when this form is returned to CONMED Corporation.

This form and all attachments can be faxed to +1 315-624-3225, Attn: L3000SM Support Team; or mailed to CONMED, 525 French Rd., Utica NY 13502, Attn: L3000SM Support Team; or emailed to

L3000SM@conmed.com

Return devices to:

CONMED Corporation
RGA-
525 French Road
Utica, NY 13502 USA
Attn: L3000SM Support Team

Your Name: _____ Account # _____

(Please Print)

Signature: _____

Please complete at least one:

Phone: _____ Fax: _____ Email: _____

Distributor/Hospital : _____

Address: _____
