



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.

Affected Serial Numbers of the L3000SM Lithium Battery								
1442030	1442065	1442098	1442122	1442142	1442165	1442195	1442217	1442262
1442032	1442066	1442099	1442123	1442143	1442166	1442196	1442218	1442263
1442034	1442067	1442100	1442124	1442144	1442169	1442197	1442219	1442264
1442035	1442068	1442101	1442125	1442147	1442170	1442198	1442220	1442265
1442036	1442069	1442102	1442126	1442148	1442171	1442199	1442222	1442266
1442038	1442072	1442104	1442127	1442149	1442172	1442200	1442223	1442267
1442039	1442073	1442105	1442128	1442150	1442173	1442201	1442228	1442268
1442040	1442076	1442106	1442129	1442151	1442174	1442202	1442229	1442269
1442041	1442077	1442107	1442130	1442152	1442175	1442203	1442240	1442271
1442042	1442078	1442108	1442131	1442153	1442176	1442204	1442241	1442272
1442043	1442079	1442109	1442132	1442154	1442177	1442206	1442242	1442275
1442050	1442085	1442111	1442133	1442155	1442178	1442207	1442243	1442277
1442053	1442091	1442112	1442134	1442156	1442179	1442208	1442244	
1442058	1442092	1442115	1442135	1442157	1442184	1442209	1442245	
1442060	1442093	1442116	1442136	1442160	1442188	1442210	1442246	
1442061	1442094	1442117	1442137	1442161	1442191	1442211	1442247	
1442062	1442095	1442119	1442138	1442162	1442192	1442213	1442248	
1442063	1442096	1442120	1442139	1442163	1442193	1442214	1442249	
1442064	1442097	1442121	1442141	1442164	1442194	1442216	1442260	

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,

A handwritten signature in black ink that reads 'Patricia Cotter'.

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: _____
