URGENT: FIELD SAFETY NOTICE

CONMED Corporation ThermoGard® Dual Dispersive Electrodes

May 25, 2016

CONMED Corporation is sending this communication to notify you of a product issue with the following catalog numbers of the ThermoGard® Dual Dispersive Electrodes:

Catalog Number	Device Name
51-7310	Adult ThermoGard® Dual Dispersive Electrodes (for patients >15 kg.), 10' (3.05m) Cable
51-7410	Adult ThermoGard® Dual Dispersive Electrodes (for patients >15 kg.), No Cable
51-7710	Pediatric ThermoGard® Dual Dispersive Electrodes (for patients 5-15 kg.), 10' (3.05m) Cable
7-382	Adult Dual Dispersive Electrodes (for patients >15 kg.), use with the Birtcher Pad Sensing System (PSS) on the Birtcher Systems 6000, 6400, 6500 and CONMED Systems 7500 and 7550 ABC® generators or conventional electrosurgery units with similar contact monitoring systems, 10' (3.05m) Cable
7-383	Pediatric Dual Dispersive Electrodes (for patients 5-15 kg.), use with the Birtcher Pad Sensing System (PSS) on the Birtcher Systems 6000, 6400, 6500 and CONMED Systems 7500 and 7550 ABC® generators or conventional electrosurgery units with similar contact monitoring systems, 10' (3.05m) Cable

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Most manufacturers of electrosurgical generators use a technology known as Contact Quality Monitoring (CQM) system as a safety feature incorporated in the design of their products.

However, some manufacturers of electrosurgical generators use a CQM technology which may rely on a preset upper limit (alarm limit) of the CQM impedance to detect pad lift. A version of the CONMED ThermoGard® Dual Dispersive Electrodes, manufactured between October 1, 2014, and July 5, 2015, may not be compatible with some of these generators, placing patients at risk for undetected pad lift and a potential burn. A customer alerted CONMED of this condition.

Beginning Manufacture Date	**Beginning Lot Code**	**Ending Manufacture Date**	**Ending Lot Code**
October 1, 2014	141001X	July 5, 2015	20150705X

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Based on this information, CONMED Corporation has decided to recall these ThermoGard® Dual Dispersive Electrodes to the user level, for all customers who do not use an electrosurgical generator that employs a Contact Quality Monitoring system listed on Attachment I, Table 2. If your electrosurgical generator **is not listed** on Attachment I, Table 2, that generator **should not be** used with the lot codes of the ThermoGard® Dual Dispersive Electrodes listed in Table 1.

Please review your inventory for any of the devices listed on Attachment I Table 1. If you use the ThermoGard® Dual Dispersive Electrodes in conjunction with an electrosurgical generator listed in Attachment I, Table 2, **no further action is required.** However, if your electrosurgical generator and CQM system is not listed on Attachment I, Table 2, **do not use the affected lot codes of ThermoGard® Dual Dispersive Electrodes.** Please note that ThermoGard® Dual Dispersive Electrodes produced after July 5, 2015, are not subject to this recall.

We ask that you contact all of those departments or organizations within your facility and any other facilities that you may have supplied or given these affected products to. It is imperative that all end users of these devices receive this notice and respond immediately. **If you have questions, please contact Patricia Cotter, ConMed Recall Coordinator +1 315-624-3237 or fax to +1 315-624-3225 or email thermog@CONMED.com.** You may also contact our Authorized Representative MDSS GmbH situated in Germany via email at info@mdss.com or via phone at +49 511 6262 8630.

If you HAVE any devices listed on Attachment I to return, please complete Attachment II and return it with the devices to:

CONMED Corporation
RGA Number (ref. Attach. II)
525 French Road
Utica, NY 13502 USA
Attn: Ed Kovac
Return via: UPS Account # W5Y243

Please process a commercial invoice for the return to the United States referencing your purchase price as a value for Custom's purposes and note on the commercial invoice that the return is for evaluation purposes only. Please include the following information on the invoice, with the returned product:

ConMed FDA Reg. # 1317214
MDL#: D223923
510K #: K140658

Please do not return used devices.

If you DO NOT HAVE any affected devices to return, please complete Attachment II, indicating you have no devices, and fax it to 315-624-3225, Attn: Patricia Cotter or scan and email to thermog@CONMED.com.

If you do not have any devices to return, please complete Attachment II, indicating you have no devices and fax it to +1 315-624-3225, Attn: Patricia Cotter.

We apologize for any inconvenience this will cause you or your staff.
The US Food and Drug Administration has been notified of this action. In addition, the appropriate foreign competent authorities have also been notified.

Sincerely,

Patricia Cotter
Recall Coordinator

ATTACHMENT I
PRODUCT CODES

FIELD SAFETY NOTICE

Table 1: Identification of Affected Devices and Lot Codes:

Catalog Number	Device Name
51-7310	Adult ThermoGard® Dual Dispersive Electrodes (for patients >15 kg.), 10' (3.05m) Cable
51-7410	Adult ThermoGard® Dual Dispersive Electrodes (for patients >15 kg.), No Cable
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Affected lot codes for ALL catalog numbers listed:

Lot codes for product manufactured to and including the dates listed below:

Beginning Manufacture Date	Beginning Lot Code	Ending Manufacture Date	Ending Lot Code
October 1, 2014	141001X	July 5, 2015	20150705X

Lot codes on boxes and packaging contain a lot code in the following form:

2014 10 01 X
2014 10 01 X
Or 14

- X — Manufacturing shift code 1, 2, 3, 4,5,6 or 9
- 01 — Day of the Month
- 10 — Month (October)
- 2014 — Year (20**14**)

Table 2: Identification of compatible CQM Electrosurgical Generators (ESU's):
(No need to return product for these generators)

Manufacturer	Mfr. CQM System Name	Model/Brand Name
CONMED	ARM™	Excalibur Sabre 180 Sabre 2400 System 6500 System 7500/7550 System 2500 System 5000 System 2450 Sabre Genesis Hyfresurge HelixAR Bicap III
Medtronic (Valleylab/Covidien)	REM™	Force 1B Force 1C Force 2 Force 300 Force 30 Force 40 Force 40S Force 4 Force 4B Force FX Force Triad FT10
ERBE	NESSY (Neutral Electrode Safety System)	ERBE VIO
KLS Martin Group	PCS (Patient Control System)	Beamer PCS
Birtcher Medical	PSS®	System 6400

ATTACHMENT II
EFFECTIVENESS CHECK

FIELD SAFETY NOTICE

BUSINESS REPLY FORM

Please check all that apply:

- □ We DO NOT have any stock of the suspect lots.
- □ We have notified our accounts to return their stocks of the product to us.
- □ We are returning: (Complete table below)

Catalog # being returned	Quantity per Case	Quantity of Eaches or Cases
51-7310	80/Case	
51-7410	80/Case	
51-7710	80/Case	
7-382	40/Case	
7-383	40/Case	

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 Patricia Cotter.
Return this completed form by fax to: Patricia Cotter at +1 315-624-3225.

If you are returning product, include a copy of this completed form with the devices.
Charge shipping to: UPS Account #

Return devices to: CONMED Corporation
RGA-
525 French Road
Utica, NY 13502 USA
Attn: Ed Kovac

Return via: UPS Account # W5Y243

Your Name: _____ Account #_____
(Please Print)
Signature:_____
Please complete at least one:
Phone:_____ Fax:_____Email:_____
Distributor/Hospital :_____
Address:_____
_____

Credit will be issued for recall goods being returned