



MEDICAL DEVICE RECALL NOTIFICATION

Date:

Product: ConMed Linvatec MicroChoice ® Footswitch, 5020-053 and/or
ConMed Linvatec 3 Pedal Footswitch, C9863

Serial Number(s): See attached list of affected serial numbers

Attention: RISK MANAGER, MATERIALS MANAGER, OR O.R. SUPERVISOR

Our distribution records indicate that your facility received the listed serial number(s) of the **ConMed Linvatec MicroChoice ® Footswitch, 5020-053 and/or ConMed Linvatec 3 Pedal Footswitch, C9863**. ConMed Linvatec Corporation has determined there is a possibility that the type of solder used by the supplier in the manufacture of the printed circuit board (PCB) contained in the footswitch was not as specified/approved by Linvatec. The use of this solder in the PCB component in the footswitches, when used with handpieces, could result in a system fault, which may cause a handpiece to self-activate, run intermittently, or revert to a default setting. Please do not use these footswitch products. This recall is being conducted at the distributor and user level.

We have corrected this issue and will send you a **NEW replacement footswitch** at no charge, for each affected footswitch product/serial number that your facility received from ConMed Linvatec. We are requesting the return of all affected serial number units to your ConMed Linvatec Distributor. Please perform the following immediately upon receipt of this information.

1. Please check your facility's inventory **immediately** for the catalog and serial numbers listed, inform the appropriate departments and personnel of this recall, and discontinue the use of the product. The serial number is located on the bottom of the footswitch.
2. Please complete the enclosed reply form and mail or fax the reply form to your ConMed Linvatec Distributor within 15 business days. Please return the product, with the assigned RG Number written on the outside of the shipping box to your ConMed Linvatec Distributor by **Federal Express Collect using Linvatec Account Number 033608306**.
3. Contact your ConMed Linvatec Distributor to order your **New Replacement** footswitch product(s).

If there is no product to be returned from your facility or you have already returned the affected product to Linvatec for repair or as a complaint, please complete the reply form and fax or mail to your ConMed Linvatec Distributor. A new replacement product will be sent to you at no charge if you have already returned the affected product to ConMed Linvatec for repair or as a complaint.

Please accept our sincere apology for any inconvenience this action may have caused. Should you have any additional questions, please contact me at 727-399-5276 or email dmahoney@linvatec.com or contact Linvatec Customer Service at 800-237-0169 or email custsvc@linvatec.com.

Sincerely,

Deborah Mahoney
Recall Coordinator
Linvatec Corporation



MEDICAL DEVICE RECALL NOTIFICATION
REPLY FORM

Date:

Product: ConMed Linvatec MicroChoice ® Footswitch, 5020-053 and/or
ConMed Linvatec 3 Pedal Footswitch, C9863
Serial Number(s): See attached list of affected serial numbers
Linvatec RG Number (add RG number here):

Please check/tick all that apply.

I verify that our facility has retired and discarded/disposed of the following product.
(Please attach additional sheets if required.)

Catalog Number: Serial Number:

Catalog Number: Serial Number:

The following product has already been returned as a repair or complaint, please send a new replacement product.
(Please attach additional sheets if required.)

Catalog Number: Serial Number:

Catalog Number: Serial Number:

The following product will be returned for a new replacement product. (Please attach additional sheets if required.)

Catalog Number: Serial Number:

Catalog Number: Serial Number:

Signature Title Date

Printed Name Telephone Fax

Please return the completed reply form within 15 business days and product to:

ConMed Linvatec Corporation RG No.
International Distributor