# URGENT – FIELD SAFETY NOTICE

**Type of action: Software upgrade**

## ACTIV.A.C.™ Therapy Unit (All models and Serial Numbers)

**Date:** dd-mmm-yyyy

Dear Valued Customer,

The purpose of this letter is to advise you that KCI, now part of 3M, is implementing a voluntary Field Safety Corrective Action for all models and serial numbers of ACTIV.A.C™ Therapy Units. KCI has become aware that ACTIV.A.C™ Therapy Units may power off without notification to the user (i.e., no alarm or warning) resulting in a stoppage of negative pressure wound therapy. Since April 2017 KCI has reported 7 injuries globally (a rate of ≤0.001%) relating to maceration, localized infection, or wound deterioration as a result of the ACTIV.A.C.™ Therapy Unit unintentionally powering off.

KCI values the safety of our patients and quality of our products and is initiating a voluntary Field Safety Corrective Action for all models of this device that will be performed to implement a software change whereby the ACTIV.A.C.™ Therapy Unit software will provide a screen notification requiring acknowledgement by the user before the unit shuts down.

Our records indicate that you have purchased one or more ACTIV.A.C.™ Therapy Units affected by this voluntary field safety corrective action.

**Actions Required by Your Facility:**

1. Locate all ACTIV.A.C.™ Therapy Units.

2. **It is not necessary to discontinue therapy on patients using the ACTIV.A.C.™ Therapy Units. As per the Instructions for Use, replace V.A.C.® dressing with alternate dressing if therapy is interrupted or if the unit is powered off for more than two hours.**

3. Complete and sign the enclosed Customer Response Form and return this form to the KCI office at kci3mfieldactionresponse@mmm.com. Additional copies of the response form may be required based on the number of units in your facility.

4. Contact your local KCI representative who will work with you to schedule the software change of your ACTIV.A.C.™ Therapy Unit(s).

5. Ensure that all ACTIV.A.C.™ Therapy Units owned by your facility are returned for the software change according to the instructions provided by your KCI representative.

6. Make sure that all caregivers and users of the ACTIV.A.C.™ Therapy Unit are made aware of this Field Safety Corrective Action and of the need to be diligent to verify the unit is delivering therapy.

**Transmission of this Field Notice**

This ACTIV.A.C.™ Therapy Unit Field Safety Notice must be distributed to all individuals who need to be aware within your organization and to any organization where the potentially affected devices have been transferred or sold. Please notify any facilities that you may have transferred devices to by using this recall notification letter and acknowledgement form.

Please maintain awareness of this notice and resulting action for the use period of the device to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor, local KCI representative, or proper regulatory authority, if appropriate, as this provides important feedback.

**Additional Comment**

If you have any questions related to this Voluntary Field Safety Corrective Action, please contact your local KCI representative, call 0848 848 900 or visit http//www.Acelity.com/contact-us

This medical device field safety corrective action is made with the knowledge of the Regulatory Authorities where these products have been distributed

KCI takes the quality of our products seriously, and we always strive to meet or exceed our customers' expectations. We apologize for any inconvenience that this Voluntary Field Safety Corrective Action may cause. We greatly appreciate your understanding as we take actions to ensure correct product performance.

Sincerely,

James Halliday
Manager, Regulatory Compliance, EMEA
Email: kci3mfieldactionresponse@mmm.com

# Customer Response Form

**FIELD SAFETY NOTICE**

**ACTIV.A.C.™ Therapy Unit**

***Reference: Urgent Field Safety Notice ACTIV.A.C.™ Therapy Unit.***

Our records indicate that there have been ACTIV.A.C.™ Therapy Unit devices delivered to your location. Please provide a list of devices requiring the software upgrade.

| MODEL / PART NUMBER | SERIAL NO. | MODEL / PART NUMBER | SERIAL NO. |
|---|---|---|---|
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**Record the total number of affected devices currently located at your facility here please ➔ ___.**

Our records indicate that the ACTIV.A.C.™ Therapy Unit device shown below was delivered to your location. Please verify if you have any of the listed devices that are potentially affected and complete the information below.

| ORDER NO. | ITEM NO. | SERIAL NO. | MANUFACTURING DATE |
|---|---|---|---|
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Please check the appropriate boxes below:

☐ We have read the ACTIV.A.C.™ Therapy Unit Field Safety Notice and we understand the communication and the required actions.
**Please provide information where the affected devices are physically located, below.**

## Field Safety Notice Receipt and Customer Response Form Completion and Certification

| | | | |
|---|---|---|---|
| **Current Facility Name** | | | |
| **Contact Name / Title** | | | |
| **Address (no PO boxes, please)** | | | |
| **City, Region, Postcode** | | | |
| **Phone Number** | | **Fax:** | |
| **E-Mail Address:** | | | |

☐ We have sold/moved our ACTIV.A.C.™ Therapy Unit to another facility.
**Please provide new facility information, below.**

| | | | |
|---|---|---|---|
| **New Facility Name** | | | |
| **Contact Name / Title** | | | |
| **Address*** | | | |
| **City, Region, Postcode** | | | |
| **Phone Number** | | **Fax:** | |
| **E-Mail Address:** | | | |

**PLEASE RETURN YOUR COMPLETED FORM TO: kci3mfieldactionresponse@mmm.com**