

# Allergan Aesthetics

an AbbVie company

July X, 2021

## URGENT FIELD SAFETY NOTICE

Commercial Name: CoolSculpting® Elite System  
Device Reference: CS-S3-001-D-00 or CS-S3-001-I-00  
FSCA/FSN Reference: FSCA-21-001-CSElite/FSN-21-001-CSElite  
Type of Action: Device retrofit (new software release)  
Serial Numbers: XXX  
Associated Devices: Surface 150 (S150) Applicator (CS-A3-15S-00)

Dear Customer,

At Allergan Aesthetics, our first priority is to our customers and patients. We are committed to ensuring the safe and effective use of our products. We are writing to advise you of a required software update correction for the CoolSculpting® Elite System.

### Description of the Issue:

This action is being conducted at the health care provider level. Updates are needed to the software to address the error messaging system. The possible outcomes that could arise include:

- An incorrect error message may be displayed on the machine following a thermal event that could lead a provider to re-treat the affected anatomic area within 24 hours.
- Another possible outcome may be that the system does not report a thermal event or any other error code. This means the treatment could continue without knowledge that a thermal event has occurred. To date, however, we have not been made aware of this error occurring in clinical practice.

In the event of this happening there is the possibility of a cold-induced injury leading to a 2<sup>nd</sup> and/or 3<sup>rd</sup> degree freeze burn.

### Actions to be taken:

The required software installation package, 3.1.0, has been deployed remotely to update all CoolSculpting® Elite units. A soft power cycle, using the touchscreen, is required to trigger the update process. After the system restarts, the update will start automatically—you cannot delay or defer the installation. On average, the install should take five minutes. Do not power off the system while the update is installing. Please allow the installation to complete, then follow instructions on the user interface to restart the system with the new software release. Once completed, you can verify the installation has been successful by pressing TOOLS – ABOUT, scroll to column 'Software Release'. This should now say 3.1.0. Refer to Appendix 1 for instructions for how to verify the software version.

**The software update must be completed before continuing to use the system. If you have already completed the software installation, no further action is needed.**

**If you did not receive the notification of the update on your CoolSculpting® Elite System or the update did not complete, please contact our Product Support team at +44 (0) 808-238-1500 between XX and XX or via email at [coolsculpting.emeasupport@allergan.com](mailto:coolsculpting.emeasupport@allergan.com)**

ZELTIQ™ Aesthetics, Inc.  
4410 Rosewood Drive  
Pleasanton, CA 94588, USA

AllerganAesthetics.com

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## **Transmission of this Field Safety Notice:**

Please ensure distribution of this Field Safety Notice to all those who need to be aware of it within the organisation and to maintain awareness until such time that all Coolsculpting Elite units in your organisation have the revised software installed.

If any such devices have been transferred outside of your organisation, please provide these details to the manufacturer and forward a copy of this Field Safety Notice.

The relevant national Competent Authorities have been informed of this Field Safety Corrective Action.

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Patient experience and customer satisfaction are of the utmost importance to us. We appreciate your support and apologize for any inconvenience this may cause.

**For adverse event reporting, medical information questions or to speak to our Product Support team, please contact +44 (0) 808-238-1500** between XX and XX or via email at [coolsculpting.emeasupport@allergan.com](mailto:coolsculpting.emeasupport@allergan.com)

Sincerely,

NAME

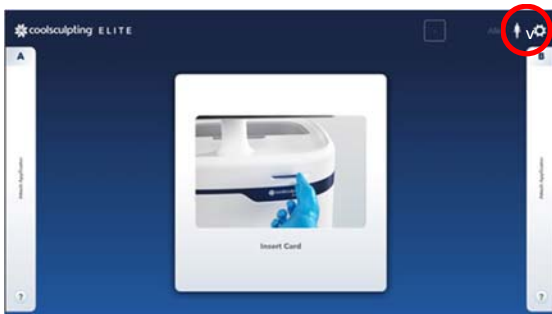
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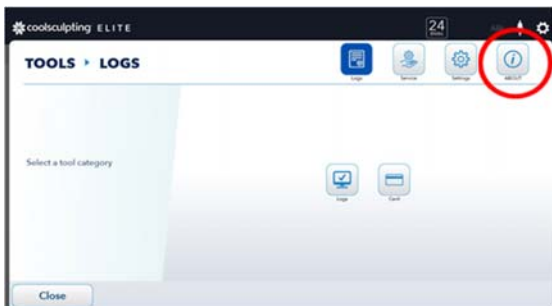
## APPENDIX 1

### Verifying your system has updated to version 3.1.0

1. Press the Tools icon on the top right of the screen.



2. After selecting Tools, select the ABOUT button.



3. Scroll if necessary and check that the Software Release field shows version 3.1.0.

