



Date: Oct 2018

Dear Customer,

**FIELD SAFETY CORRECTIVE ACTION FSCA # 2018-04
MANDATORY HARDWARE UPDATE - PLEX ELITE 9000**

The purpose of this letter is to advise you that Carl Zeiss Meditec, Inc. (CZMI) is voluntarily performing a Field Safety Corrective Action on the PLEX® Elite 9000. This action involves a mandatory hardware update that applies to all PLEX Elite 9000 devices.

Problem Description

PLEX ELITE 9000 POWER TABLE UP/DOWN SWITCH: Under certain fault conditions, the existing design may expose the operator to a hazardous voltage when contacting the metal enclosure (including mounting screws) around the PLEX Elite 9000 Power Table Up/Down switch. Refer to Figure 1. A hazardous voltage from an electrical short circuit could occur as a result of damaged insulation on one of the wires inside the enclosure for the Power Table Up/Down switch.

Hazard Involved

There has been no report of serious injury, death, or unreasonable risk of substantial harm to public health. To date, there has been only one report of electric shock with no injury due to this failure mode. In any electrical discharge, there is potential for injury. In the remote chance that the malfunction was to occur, the likely possible effects range from no injury, to pain or neurological issues, to tissue burn.

Actions to be taken by ZEISS Service Department:

To correct the issue, our service staff will contact you to schedule a Field Service Engineer to perform a mandatory hardware update for your PLEX Elite 9000, s/n: XXX

We would appreciate it very much if you can acknowledge receipt of this letter by signing on the attached 'Acknowledgement of FSCA #2018-04 – Mandatory Hardware Update - PLEX Elite 9000' and return to us by either fax at +65-6842 7117 or email to our Regional Regulatory Affairs Manager at





Actions to be taken by the Customer/User

Until the mandatory hardware update has been performed, follow the procedure below in order to continue use of the PLEX Elite 9000:

- When adjusting the height of the Power Table, touch only the black plastic portion of the Up/Down switch. Avoid any contact with the entire metal enclosure (including mounting screws) surrounding the black plastic Up/Down switch. **Refer to Figure 1.**

Failure to follow this procedure may result in potential injury as discussed in the section **Hazards Involved**.

CAUTION: Operator(s) with an electrical implant are more sensitive to electrostatic discharge and must avoid use of the system prior to the hardware update.

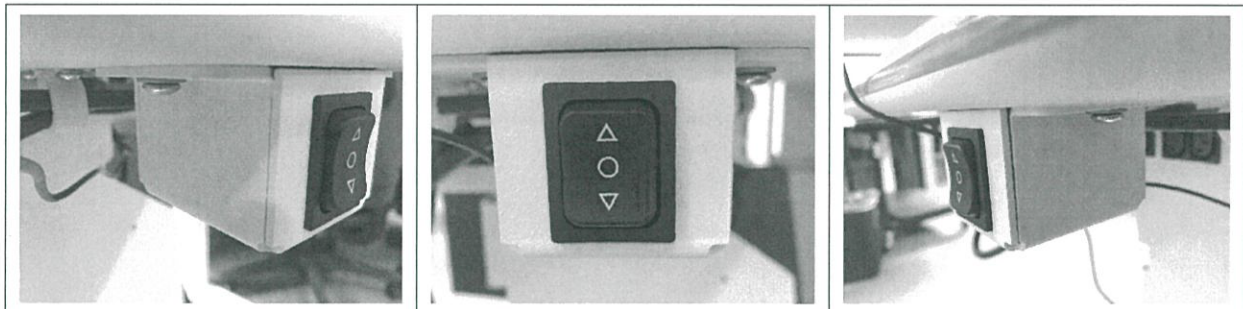


Figure 1. PLEX Elite 9000 Power Table Up/Down Switch. Avoid any contact with the metal enclosure (including mounting screws) surrounding the black plastic Up/Down switch.

We strive to ensure a high level of performance on any ZEISS device and an excellent experience for our customers. We apologize for any inconvenience you may experience. We will do our best to address your individual needs and concerns.


Thank you.

Yours Sincerely,


Sujay Debnath
Regional Director
Medical Business Group

cc: Chairman Medical Board and relevant Head of Departments

Acknowledgement of FSCA #2018-04 – Mandatory Hardware Update - PLEX Elite 9000

TO: Carl Zeiss Pte Ltd
50 Kaki Bukit Place
#05-01 Singapore 415926
Tel: 6741 9600, Fax: 6842 7117
Attn: Yuen Wai Leng


Product Serial Number(s): XXXX

We acknowledged receipt of the above notification from Carl Zeiss Pte Ltd.

Signature:

Name: _____

Date: _____

Hospital / Clinic Stamp: