

May 20, 2019

URGENT FIELD SAFETY NOTICE

SUBJECT: Advice Given by the Manufacturer Regarding Operation of the EKOS Control System 4.0 (Part Number 600-40500)

Dear EKOS Customer,

EKOS Corporation is issuing this 'Field Safety Notice' to alert users of the appropriate use and storage conditions for the EKOS Control System 4.0. EKOS Corporation recently became aware of a few instances during which the EKOS Control System 4.0, within the first few minutes of turning on, displayed channel errors 'E323' or 'E311' either on one channel or both channels and subsequently failed to deliver ultrasound therapy. See Figure 1.

Our investigation showed that these units were most likely stored in a lower temperature location / area and not allowed to stabilize to room temperature prior to operation. Although the device fails to deliver ultrasound, this failure does not impact infusion of lytic or other physician specified fluids through the catheter. The patient will continue to receive the prescribed drug infusions.

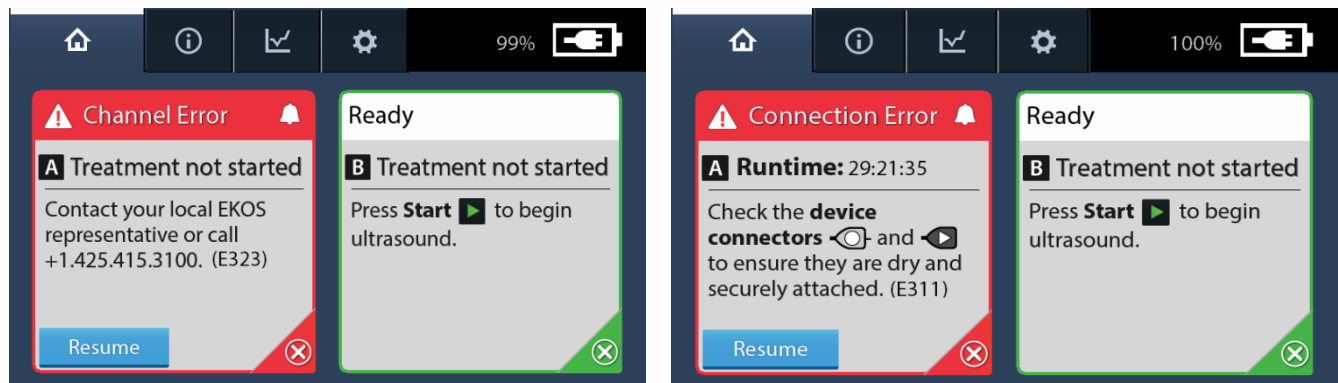


FIGURE 1 – Control Unit Display of E323 and E311 Channel Errors on Channel A

The IFU recommends the unit be stored and operated at controlled room temperatures for successful therapy delivery. Attempting to operate an EKOS Control System 4.0 without allowing sufficient time to stabilize to room temperature, may result in 'E323' or 'E311' error alarms and subsequently may not deliver ultrasound therapy. To prevent these error alarms, please ensure you always follow the IFU which recommends that the Control System 4.0 be kept at controlled room temperatures during use and storage. To reduce the likelihood of error alarms 'E323' or 'E311' and ensure ultrasound is available and delivered during therapy, EKOS Corporation recommends that the EKOS control System 4.0 be plugged in and powered on for 30 minutes prior to making



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connections and starting therapy. EKOS Corporation is in the process of providing supplementary clarifications in the IFU and implementing additional corrective actions as necessary.

Thank you for your attention to this notice. Should you have any questions or require additional information about this notification letter, please do not hesitate to contact EKOS Customer Service +1-425-415-3100 or your local EKOS representative.

Sincerely,

[Redacted signature]

[Redacted name]

[Redacted title]

EKOS Corporation, a BTG International group company
11911 North Creek Parkway S.
Bothell, WA, USA 98011

[Redacted address line]

[Redacted address line]

Please acknowledge receipt of this notice by signing below and returning to BTG Vascular (email: BTGvascularEMEA@btg-im.com; fax: +1 425 415 3105)

I, _____, have read and understand the Field Safety Notice concerning appropriate storage and operation of the EKOS Control System 4.0.

Signature

Date

CU4.0 Serial Number _____