

URGENT – VOLUNTARY PRODUCT RECALL

March 27, 2019

Re: Misoriented label on the EKOS Control System 4.0 Connector Interface Cable (CIC)

Product Name	Catalog Number	Lot Number	Serial Number
EKOS Control System 4.0 – Connector Interface Cable (CIC)	700-10410	180918052	180918052-012
		181116028	181116028-003
			181116028-005
			181116028-006
			181116028-007
			181116028-014
			181116028-016
			181116028-019

Dear Customer,

We are writing to notify you that EKOS is voluntarily recalling and replacing the above referenced component of the EKOS Control Unit 4.0 that is located at your facility. EKOS recently became aware that the indicator label affixed on the Connector Interface Cable (CIC; Catalog Number 700-10410) component of the EKOS Control Unit 4.0, may be misoriented. We have provided a side-by-side comparison of correct and incorrect orientation of the indicator label in Figure 1 below.

Correct
✓



Figure 1 (a) Correct orientation of CIC label with Channel B running



Wrong
x

Not lit
x

(b) Incorrect orientation of CIC label with Channel B running

The purpose of this secondary indicator label is to indicate the active running channel while administering therapy using the EkoSonic Endovascular Device. If the label is incorrectly oriented, as shown in Figure 1 (b), the 'blue' color would indicate the *incorrect* running channel. The primary indicators on the EKOS Control Unit

4.0, i.e., the timer and green highlighted active channel on the Control Unit 4.0 front panel are accurate; the incorrect orientation of the secondary indicator label does not affect these primary indicators. The schematic of the EKOS Control Unit 4.0 showing these primary indicators are shown in Figure 2.



Figure 2

On-screen indicators

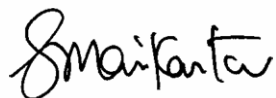
No patient injuries have been reported as a result of this incorrect label orientation, and the health hazard associated with this labeling discrepancy has been determined to be 'Low'. The cause of this discrepancy has been corrected and labels on all future units will be correctly oriented.

Our records indicate you have purchased one or more affected CIC unit(s), and EKOS wants to ensure you are notified of this labeling discrepancy. Your local BTG Representative/authorized distributor will contact you within a week to make an appointment to switch out your current Connector Interface Cable with a replacement component.

We sincerely regret any inconvenience this may cause to you or your facility.

If you have any questions or require additional documentation of this action, please do not hesitate to contact us at +44 1276 902 069

Sincerely yours,



Dr. Mani Shanmugham
Director, Quality
EKOS Corporation
11911 North Creek Parkway S.
Bothell, WA, USA 98011
D: +1 425 489 1279 | F: +1 425 415 3105
mani.shanmugham@ekoscorp.com