Boston Scientific International S.A.
ZAC Paris Nord II/Bât Emerson - 33 rue des Vanesses – 93420 Villepinte
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78960 Voisins le Bretonneux – France
Tel 33 (0)1 48 17 47 00
Fax 33 (0)1 48 17 47 01
www.bostonscientific.com

«Hospital_Name»
«Users_Name»
«Department»
«Customer_Address»
«Zip_Code» «City»
«Country_name»

<Reference: 92605381-FA> «Date_notif_sent»

Cover letter for Distributors – Urgent Medical Device Recall EKOS™ Control Unit 4.0

Dear «Users_Name»,

Boston Scientific Corporation is conducting a Medical Device Recall of EKOS Control Unit 4.0 (CU 4.0) consoles, on behalf of EKOS Corporation, the legal manufacturer of the products. Please find more information in the attached Field Safety Notice.

You are kindly requested to follow the below instructions:

1- **Check your Inventory for the products affected by this Field safety Notice**.
2- **Please segregate and do not distribute any of the affected products found in your inventory.**
3- **Please notify all your customers that have received affected product of the below Field Safety Notice.** To effectively manage this Field Safety Notice, your accounts are to communicate directly with you, not Boston Scientific. If any of your customers are distributors, please notify them that they must communicate this Field Action to the medical facility level.
4- **Your Boston Scientific Representative will coordinate with Customer Service to ship you new CU 4.0 units and accessories as well as new Instructions for Use.** Please retain the shipping box and packaging for use in returning the recalled units
5 - **Provide new Control Units and IFUs and collect all affected product from your customers.** Hold affected Control Units in your quarantine.
6- **Complete the attached Verification Form** for all affected product.
7- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number» on or before **04 December 2020**.
8- Please package the affected Control Unit 4.0 devices in the retained shipping boxes and **contact «Customer_Service_Tel»** of your local Boston Scientific office, to arrange return.

Your Competent Authority is being notified of this Field Safety Notice, unless if per local regulation, this task is to be performed by you as a Distributor.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.
Yours sincerely,

Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

Attachment: - Distributor Verification Form
- Field Safety Notice

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Reference: 92605381-FA «Date_notif_sent»

Urgent Field Safety Notice - Urgent Medical Device Recall
EKOS™ Control Unit 4.0

Dear «Users_Name»,

Boston Scientific is initiating a removal of EKOS Control Unit 4.0 (CU 4.0) consoles, on behalf of EKOS Corporation, the legal manufacturer of the products. These CU4.0 consoles can continue to be used in the interim. A Boston Scientific representative will contact your facility to exchange impacted consoles with new CU 4.0 consoles as part of the removal process. This action is being taken following an April 30, 2019 Field Safety Notice (FSN) released by EKOS Corporation regarding the console displaying errors 'E323' or 'E311' on either one or both channels, leading to a failure to deliver ultrasound therapy.

The most serious outcome reasonably foreseeable is a prolonged procedure to replace the CU 4.0 console or altered therapy to drug infusion without ultrasound. In most cases, no adverse health consequence is reasonably foreseeable. No complaints have been received related to this issue since the April 30, 2019 FSN was released.

The root cause of this issue was determined to be associated with operation of the console at lower temperatures, which caused the Radio Frequency (RF) board to fail. Since the April 30, 2019 FSN the RF board has been redesigned to prevent these occasional internal board failures and has been approved by appropriate regulatory bodies. As a result, all EKOS CU 4.0 consoles containing the old RF board design will be replaced with the newly designed CU 4.0 consoles.

Additionally, the EKOS CU 4.0 Instructions For Use (IFU) has been updated with guidance to avoid similar RF board failures. These updates are outlined in Appendix A.

Interim Recommendations until your EKOS CU4.0 console has been exchanged:

In order to avoid the channel errors described in this notice:

1- Store the Control Unit at room temperature, in a well-ventilated area.

2- The console should be plugged in and powered on for 30 minutes prior to making connections and starting therapy to allow the Control Unit to warm up to operating temperature (+15°C to +40°C)

Our records indicate that your facility received some of the concerned product. The **Attachment 1 below provides a complete list of all affected products**, including Product Description, Material Number (UPN), GTIN and Serial numbers. Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in this Field Safety Notice**.

INSTRUCTIONS:

1- Read this entire Field Safety Notice and ensure that all users of Control Unit 4.0 consoles are made aware of this Field Safety Notice.

2- Immediately post this information in a visible location near Control Unit 4.0 consoles to ensure this information is easily accessible to all users of these devices.

3- **Please complete the attached Verification Form** even if you do not have any product to return.

4- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number» on or before **04 December 2020**.

5- Please pass this notice to any health professional from your organization that needs to be aware and to any organization where the potentially affected devices have been transferred (If appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

Your Competent Authority is being notified of this Field Safety Notice.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,

Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

Attachment: Verification Form
Appendix A: IFU Updates
Attachment 1: Product List

Appendix A: IFU Updates

The following updates have been made to the EKOS™ Control Unit 4.0 Instructions For Use to address the issue noted in both the EKOS April 30, 2019 FSN and Medical Device Removal Notice.

<table>
<tr><th colspan="2">Updates to the “Preparing for Ultrasound Use” Section</th></tr>
<tr><td colspan="2">4- Allow the Control Unit to warm up to operating temperature (see Specifications) with power on prior to starting ultrasound therapy.</td></tr>
<tr><th colspan="2">Updates to the “Starting Ultrasound” Section</th></tr>
<tr><th>Previous IFU Language</th><th>Updated IFU Language</th></tr>
<tr><td>After the physician has placed the EkoSonic™ Device into the patient, do the following:
1- If not already ON, press the Power button ⏻ on the front of the Control Unit.</td><td>After the physician has placed the EkoSonic™ Device into the patient, do the following:
1- If not already ON and at operating temperature, press the Power button ⏻ on the front of the Control Unit and allow it to warm up before starting ultrasound therapy. (See previous section, Preparing for Ultrasound Use.)</td></tr>
<tr><th colspan="2">Updates to the “Storing the Control Unit” Section</th></tr>
<tr><th>Previous IFU Language</th><th>Updated IFU Language</th></tr>
<tr><td>Storing the Control Unit
To store the Control Unit and the Connector Interface Cable(s), follow these guidelines:
1- Store the Control Unit at room temperature, in a well-ventilated area.
Caution Store the Control Unit in an area of good ventilation and under specified conditions. (See Specifications Section). Failure to store the Control Unit as specified could result in equipment failure leading to delay of ultrasound therapy.</td><td>Storing the Control Unit Within the Clinical Facility
To store the Control Unit and the Connector Interface Cable(s), follow these guidelines:
1- Store the Control Unit at room temperature, in a well-ventilated area.
Caution Failure to store and operate the Control Unit as specified could result in equipment failure leading to delay of ultrasound therapy.</td></tr>
<tr><th colspan="2">Updates to the “System Specifications” Section</th></tr>
<tr><th>Previous IFU Language</th><th>Updated IFU Language</th></tr>
<tr><td>Environmental Conditions:
Humidity 30% to 75%, non-condensing
Storage Temperature -20°C to +60°C
Operating Temperature +15°C to +40°C
Operating Atmospheric Pressure 73 kPa – 111 kPa</td><td>Environmental Conditions:
Humidity 30% to 75%, non-condensing
External Storage/Transport Temperature -20°C to +60°C
Operating Temperature +15°C to +40°C
Operating Atmospheric Pressure 73 kPa – 111 kPa</td></tr>
</table>

Attachment 1: Product List

Product Description	Material Number (UPN)	Serial Number	GTIN
EKOS™ Control Unit 4.0	600-40500	CU4.0-01062	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01063	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01066	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01068	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01069	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01070	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01072	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01073	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01074	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01076	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01078	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01079	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01081	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01083	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01084	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01086	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01088	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01089	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01090	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01091	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01093	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01094	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01095	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01096	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01097	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01100	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01101	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01102	00858593006462
EKOS™ Control Unit 4.0	600-40500	CU4.0-01103	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01104	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01106	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01107	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01108	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01110	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01113	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01114	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01115	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01116	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01117	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01119	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01121	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01123	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01124	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01126	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01127	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01128	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01129	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01130	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01131	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01132	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01133	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01134	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01135	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01138	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01141	

Product Description	Material Number (UPN)	Serial Number	GTIN
EKOS™ Control Unit 4.0	600-40500	CU4.0-01142	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01143	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01144	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01146	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01147	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01149	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01151	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01152	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01153	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01154	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01157	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01158	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01159	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01160	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01161	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01162	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01163	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01164	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01165	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01166	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01167	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01170	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01173	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01174	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01175	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01176	00858593006462
EKOS™ Control Unit 4.0	600-40500	CU4.0-01177	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01178	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01179	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01185	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01186	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01191	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01195	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01198	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01203	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01205	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01215	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01231	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01233	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01234	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01237	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01239	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01245	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01248	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01251	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01252	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01255	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01268	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01289	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01292	
EKOS™ Control Unit 4.0	600-40500	CU4.0-01299	

«Sold_to» - «Hospital_Name» - «City» - «Country_Name»

Please Complete the form even if you do not have any affected product & send it to Your Local Office:
«Customer_Service_Fax_Number»

Distributor's Verification Form – Urgent Medical Device Recall
EKOS™ Control Unit 4.0
92605381-FA

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1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated «Date_notif_sent».

2. **Boston Scientific records indicate you have received the following affected product** *(additionally please check inventory against complete list of affected product provided).*

Material N° (UPN)	Serial N°	Customer PO	Qty Sent	Qty to return

3. We confirm that all areas where affected product could be located, **including at our customers' location**, have been checked.

4. **TICK ONE OF THESE STATEMENTS***, **SIGN THIS FORM** and send it to «Customer_Service_Fax_Number»:

- ❑ We do not have any affected product.
- ❑ We have found affected product(s): Please confirm the quantity to return above. *If you are returning product not listed above, please **add the UPN, Lot/Batch number /Serial number and the quantity to return.***

NAME* _____Title _____

Telephone _____ Email _____

Distributor' **SIGNATURE*** _____ **DATE*** _____
dd/mm/yyyy

*** Required field**