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URGENT FIELD SAFETY NOTICE

1688 Camera Control Unit (CCU) (Part 2 out of 2)

May XX 2022

Attn / OR Director

Reference Number: RA2022-2912780

The purpose of this notification is to advise you that Stryker Endoscopy is conducting **Part 2** of a voluntary recall of the 1688 Camera Control Unit (CCU).
Please note, Part 1 only affected customers with a Pendulum Camera.
Part 1 is now closed and will be superseded by Part 2, which affects all customers with a 1688 CCU.
All affected consoles are required to install updated software.

Product Information:

Product Description	Part Number	GTIN	Software Revisions Affected
1688 Camera Control Unit (CCU)	1688010000 **or** 1688010000I	07613327420081	3.0.6, 4.0.13, and 4.0.18

Reason for the Voluntary Recall:

A software defect has been identified in the 1688 CCU that may cause the image on the monitor to flip upside-down into an incorrect orientation. This failure can only be seen when using a specific combination of products and set up, please see below:

The flip can occur with the following setup:

- 1688 CCU connected to Connected OR Hub through USB A-to-B Cable
- 1688 Pendulum or Standard Camera Head plugged into 1688 CCU

With the above setup, the following workflow will cause the 1688 image to flip:

1. Pendulum Camera Head or Standard Camera Head is inserted into the 1688 CCU
2. Advanced Menu is accessed and exited
3. Later, the opposite camera from previous (Standard or Pendulum) is connected to the CCU
4. "End Case" is selected on the Hub
5. Flip will occur

Potential Risks:

If the image on the monitor flips upside down it may cause user confusion. The highest potential harms are conversion to open procedure, additional medical intervention, or a revision surgery. **To date, there has been 1 report of an adverse event or serious injury.**

Actions needed:

1. Check inventory to see if you have an affected 1688 CCU by checking your CCU software version.
   The software version can be found on the bottom right corner of the screen during boot up.
   Please fill out our Customer Acknowledgement Form below confirming which software version is installed on your device.
   RESPONSE IS REQUIRED BY JUNE 24th 2022

2. If affected product is found in your inventory, please call your Stryker Sales Representative or contact your Stryker On Site Speacialist to upgrade CCU Software. Please use Temporary Solutions (section below) until software upgrade is complete.
   Temporary Solutions
   a. ***Preventing the Flip:***
   The only way to prevent the possibility of the image flip is to remove the USB A-to-B Cable from the CCU to Hub. However, this will cause the loss of device control through the CCU. ***Methods to Avoid/Correct Flip:***
   b. *Do not select "End Case" on the Hub while a camera head is inserted.*
   c. *If the flip does occur, unplugging and re-plugging the camera head will resolve the issue. However, this is only temporary, and this may occur again if "End Case" is selected*.

3. Maintain awareness of this communication internally until part 2 of 2 of this field action is completed.

4. Circulate this Field Safety Notice internally to all interested/affected parties.

5. Inform Stryker if any of the subject devices have been distributed to other organizations.
   a. Please provide contact details so that Stryker can inform the recipients appropriately.
   b. If you are a Distributor, note that you are responsible for notifying your affected customers.

6. Please inform Stryker of any adverse events concerning the use of the subject devices.
   a. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

7. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter.
   Therefore, **please complete even if you no longer have any of the subject devices in your physical inventory.**

8. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA

We request your support in finalizing the required steps within 14 calendar days from the date of receipt. Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Position: email:

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker, we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused.
We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Sincerely,

XXXXXXX XXXXXXX
RAQA Specialist

Business Reply Form

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Customer Acknowledgement Form

RA2022-2912780-1688 Camera Control Unit (CCU) (Part 2 of 2)

Actions needed:

1. Check inventory to see if you have an affected 1688 CCU by checking your CCU software version. **The software version can be found on the bottom right corner of the screen during boot up.** Please fill out our Customer Acknowledgement Form below confirming which software version is installed on your device.
2. Please return this form to your Stryker Sales Representative to organize the upgrade of CCU Software.

If affected inventory, please provide information below. (Attach additional sheet if needed.)

Product Description	Part Number	Serial Number	Software Revisions Installed (3.0.6 or 4.0.13 or 4.0.18)
1688 Camera Control Unit (CCU)	1688010000 or 1688010000I		
1688 Camera Control Unit (CCU)	1688010000 or 1688010000I		
1688 Camera Control Unit (CCU)	1688010000 or 1688010000I		

☐ If you no longer have affected product on hand, please check here.

- Please state disposition of product no longer on hand: _____

Customer information

Customer name _____

Name of person completing this form_____Title_____

Direct phone #_____Email_____

Address_____City_____State____ Postal code _____

Country _____

If you have further distributed any affected product, please indicate to whom:

Product(s) Distributed		**Quantity** Distributed	
Facility Name		**Contact Person**	
Full Address			

☐ ***Your signature indicates that you have read and acknowledge the purpose of this corrective action and the steps to be taken to update the CCU Software.***

Name (print)_____Signature_____Date ___

Return completed Business Reply Form to xxxxx@stryker.com.