

1688 Camera Control Unit (CCU)

Date : May 17, 2022

Product Field Action number : PR 2879342

Dear Customer,

Cc: Chairman Medical Board and relevant Head of Departments



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 Part 1 is now closed and will be superseded by Part 2, which affects all customers with a 1688 CCU.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)	1688-010-000	07613327420081	3.0.6, 4.0.13, and 4.0.18
1688 Camera Control Unit (CCU) – International Kit	1688-010-000I	07613327588866	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 and return to asean.pms@stryker.com.
2. If affected product is found in your inventory, please call your Stryker Sales Representative or contact your Stryker OnSite Specialist to upgrade CCU Software. Please use Temporary Solutions (section below) until software upgrade is complete.
3. If no product is found at your account(s), ensure to complete Customer Acknowledgement Form, and return to asean.pms@stryker.com.

Temporary Solutions:

Preventing the Flip:

1. 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:

1. Do not select "End Case" on the Hub while a camera head is inserted.
2. 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.

If you have any questions or concerns, please email to asean.pms@stryker.com

On behalf of Stryker we thank you sincerely for your help and support in completing this action and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to high quality standards and meeting your expectations.

Sincerely,

Chia Nee Lim

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1688 Camera Control Unit (CCU) Customer Acknowledgement Form



Product Field Action number : PR 2879342

Product Description : 1688 Camera Control Unit (CCU)

1688 Camera Control Unit (CCU) – International Kit

Dear Customer,

Please complete the Customer Acknowledgement Form and return to ASEAN.PMS@stryker.com

Your signature below indicates you have received and understand this product field action notification.

Customer Name			
Form Completed by (Printed Name)		Title	
Signature		Phone	
Date		Email	
Stamp			

- If you no longer have affected product on hand, please check here.
- Please state disposition of product no longer on hand _____

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

Product(s) distributed		Quantity distributed	
Facility name		Contact person	
Full address			