

Medical Device Safety Notice

February 4, 2022

Recall Number: PR 2879342

Product Description : 1688 Camera Control Unit (CCU) (Part 1 of 2)

Dear Customer,



Product Issue

A software defect has been identified in the 1688 Camera Control Unit (CCU) that will cause the image on the monitor to flip upside-down into an incorrect orientation. Although the software defect is present in the Camera Control Unit (CCU), this failure can only be seen when using the combination of a Pendulum Camera Head and a Standard Camera Head (C-Mount, Integrated, Inline, Microscope) on the same CCU with the specific setup and workflow mentioned below. This will only affect customers with 1688 Pendulum Camera Heads, 1688 Standard Camera Heads, **AND** Connected OR Hubs.

For flip to occur, the setup must have ALL of the following:

Product Description	Part Number	GTIN
1688 Pendulum Camera Head w/ Integrated Coupler	1688-310-130	07613327501995
1688 Camera Control Unit (CCU)	1688-010-000	07613327420081
Connected OR Hub	0240-200-100	07613327413281
USB A-to-B Cable	0105-187-988	N/A

AND at least one of the following:

Product Description	Part Number	GTIN
1688 C-Mount Camera	1688-210-105	07613327418989
1688 Integrated C-Mount Camera	1688-610-122	07613327418996
1688 Inline C-Mount Camera	1688-710-105	07613327419009
1688 Microscope C-Mount Camera	1688-210-080	07613327481884

Potential Risks

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

The highest potential of harms are conversion to open procedure, additional medical intervention, or a revision surgery.

Temporary Solutions

These solutions are temporary while Stryker Endoscopy develops a software update to the 1688 Camera Control Unit to solve this issue. Part 2 of the field action will be a software update on all 1688 CCUs, which Stryker will install.

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.

Actions Needed

1. Check inventory to see if you have a 1688 Pendulum Camera. **NO PRODUCT RETURN IS NECESSARY.**
2. Please complete and return (Attachement A) the enclosed Business Reply Form within 5 business days and email a copy to by email to ASEAN.PMS@stryker.com to confirm receipt of this notification.
3. Maintain awareness of this communication internally until part 2 of 2 of this field action is conducted.

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,

Qi Fang Cheong

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Attachment A - Business Reply Form

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*Your signature indicates that you have read and acknowledge the Temporary Solutions to prevent this failure from occurring. **NO PRODUCT RETURN IS NECESSARY.***

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			