

URGENT FIELD SAFETY NOTICE

1688 Camera Control Unit (CCU) (Part 1 out of 2)

February , 2022

Attn: OR Director
Reference Number: RA2022-2912780



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.

Response required by 01-April-2022

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

Product Description	Part Number	GTIN
1688 Pendulum Camera Head w/ Integrated Coupler	1688310130I	07613327501995
1688 Camera Control Unit (CCU)	1688010000I	07613327420081
Connected OR Hub	0240200100I	07613327413281
USB A-to-B Cable	0105187988	N/A

AND at least one of the following:

Product Description	Part Number	GTIN
1688 C-Mount Camera	1688210105I	07613327418989
1688 Integrated C-Mount Camera	1688610122I	07613327418996
1688 Inline C-Mount Camera	1688710105I	07613327419009
1688 Microscope C-Mount Camera	1688210080I	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 with the estimated timeline April – June this year.

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 return (Attachement A) the enclosed business reply form by email to xxxx@stryker.com to confirm receipt of this notification. **RESPONSE IS REQUIRED.**
3. Maintain awareness of this communication internally until part 2 of 2 of this field action is conducted.
4. Circulate this Field Safety Notice internally to all interested/affected parties.
5. Maintain awareness of this notice internally until all required actions have been completed within your facility.
6. 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.
7. 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.
8. 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.**
9. 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,

XXXXXXXX XXXXXXXX

RAQA Specialist

Attachment A

RA2022-2912780-1688 Camera Control Unit (CCU) (Part 1 of 2)

Temporary Solutions

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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 most quickly resolve the issue. However, this is only temporary, and this may occur again if "End Case" is selected.

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

Product Description	Part Number	Serial number	Quantity on hand
1688 Pendulum Camera Head w/ Integrated Coupler	1688310130I		
1688 Pendulum Camera Head w/ Integrated Coupler	1688310130I		
1688 Pendulum Camera Head w/ Integrated Coupler	1688310130I		

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

o 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 Temporary Solutions to prevent this failure from occurring. NO PRODUCT RETURN IS NECESSARY.

Name (print) _____ Signature _____ Date _____

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