PHILIPS

December 2021

Subject: SyncVision Co-Registration results scenario

Dear Valued SyncVision Customer,

Philips has identified a scenario where incorrect iFR/FFR Co-Registration results may be displayed on the SyncVision system. This unique situation may potentially cause a user to mistakenly use incorrect measurements leading to an inappropriate patient treatment if the physician is uninformed of the specific conditions resulting in an inaccurate iFR or FFR co-registration.

For this issue to occur, FFR measurement(s) must be made prior to an iFR/FFR co-registration in the same SyncVision procedural session. The user will be visually alerted with a warning message stating "Insufficient data, distal segment is not co-registered" on the display. The user may also notice the initial iFR/FFR co-registered distal value(s) will be higher than the correctly displayed distal iFR/FFR value(s), with high initial results displayed in the trendline.

Recommended Course of Action:
Philips recommends the following workflow alternatives to eliminate the impact of this scenario, when applicable.

If prior to the iFR/FFR Pullback on the IntraSight system, FFR measurement(s) were performed within the same SyncVision procedural session, the user needs to follow any one of the following steps just prior to the iFR/FFR pullback to mitigate the issue:

- Click on the "iFR Spot" button on the IntraSight system and perform at least one iFR Spot measurement.

OR:

- Go back to the "case menu" on the IntraSight system and then re-enter the LIVE screen to perform iFR pullback.

OR:

- Exit the SyncVision procedure and then re-enter the procedure using "Continue Procedure" option.

Philips is in the process of updating the Operators Manual to ensure the issue, mitigations, and workarounds are effectively highlighted to inform the user. Philips recommends notifying all SyncVision system users within your facility of this communication and retaining a copy available for reference.

If you need any further information or support concerning this issue, please contact your local Philips representative:

Philips IGTD Customer Service:
Email: IGTDCustomerService-Int@philips.com
Hours of Operation: Monday - Friday 8:00AM – 5:00PM CET

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APAC	+3222750171
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Belgium	+3222566604
CEE (excl. Poland)	+31202046550
Denmark	+4543310566
Finland	+358922943008
France	+33157324031
Germany	+494028991234
IIG (excl. Italy)	+31202046555
Italy	+390245281151
LATAM	+525515001184
META	+31202046527
Norway	+4722971709
Poland	+48223064475
Portugal	+351800785164
Spain	+34918362954
Sweden	+4687515241
Switzerland	+41445292374
The Netherlands	+31202046525
UKI	+442079490027

Philips regrets any inconveniences caused by this problem.

Sincerely,

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AFFECTED PRODUCTS	SyncVision Systems (400-0100.10, 30000485688x) with software version 4.2.x are affected. The issue is limited to cases when: • The SyncVision runs the current supported software version 4.2.x AND • The secondary modality (IntraSight IVUS) runs software version 5.x.
PROBLEM DESCRIPTION	Philips has identified a scenario where incorrect iFR/FFR Co-Registration results may be displayed on the SyncVision system. For this issue to occur, FFR measurement(s) must be made prior to an iFR/FFR co-registration in the same SyncVision procedural session.
HOW TO IDENTIFY AFFECTED PRODUCTS	All SyncVision systems interfaced to an IntraSight system are affected.

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ADVICE ON ACTIONS BY CUSTOMER / USER	Philips recommends notifying all SyncVision system users within your facility of this communication and retaining a copy available for reference. The user will be visually alerted with a warning message on the display about the distal segment not being co-registered. The user may also notice the initial iFR/FFR co-registered distal value(s) will be higher than the correctly displayed distal iFR/FFR value(s). **Issue:** The Co-Registered distal value is different than the distal value displayed in the Philips iFR/FFR System **Symptom / Error Message:** If the Co-Registered iFR/FFR-Initial value is significantly higher than the iFR/FFR distal value (difference > 0.02), the system shall indicate to the user: “Insufficient data, distal segment is not co-registered”. **Possible Cause:** FFR measurement(s) performed prior to the iFR/FFR pullback within the same SyncVision procedural session. **Recommended Course of Action:** If prior to the iFR/FFR Pullback on the IntraSight system, FFR measurement(s) were performed within the same SyncVision procedural session, the user needs to follow any one of the following steps just prior to the iFR/FFR pullback to mitigate the issue: • Click on the “iFR Spot” button on the IntraSight system and perform at least one iFR Spot measurement. OR: • Go back to the “case menu” on the IntraSight system and then re-enter the LIVE screen to perform iFR pullback. OR: • Exit the SyncVision procedure and then re-enter the procedure using “Continue Procedure” option.
ACTIONS PLANNED BY PHILIPS	Philips is in the process of updating the Operators Manual to include the information provided in the above section, “ADVICE ON ACTIONS BY CUSTOMER / USER”.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative:

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CUSTOMER RESPONSE FORM

Reference: SyncVision Co-Registration, 2021-IGT-IGTD-002

Instructions: Philips recommends notifying all SyncVision system users within your facility of this communication and retaining a copy available for reference. Please complete and return this form to Philips Healthcare promptly, upon receipt, and no later than 30 days from receipt. Completing this form confirms receipt of the Customer Information Letter and understanding of the issue.

Customer/Consignee/Facility Name:_____

Street Address:_____

City/State/ZIP/Country:_____

We acknowledge receipt and understanding of the accompanying Customer Information Letter and confirm that the information from this Notification has been properly distributed to all users that handle the SyncVision systems.

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

Please complete and return this Response Form to your local Philips representative or the following addresses:
Email: IGTD_INTL_FieldSafety@philips.com
Postal:
Philips Image Guided Therapy
Attention to: Emily Vandaele (2021C02)
Plesmanstraat 6, 3833
Leusden, Netherlands

It is important that your organization acknowledge receipt of this letter. Your organization's reply is the evidence required to monitor the progress of this corrective action.