



Document Name: P21-094 Release Notes Hybrid Recon 5.0.0 Rev.1_EN
Document revision date: 2024-11-05
FSN ref: P21-092-02 Field Safety Notice FSN0066683

Additional Release Note (ARN)

Hybrid Recon 5.0.0

This Additional Release Note inform users of an issue in Hybrid Recon 5.0.0, that has been identified after release.

This is an electronic document, a copy of which can be downloaded from www.hermesmedical.com/ifu. Hard copies of Instructions for Use, System Environment Requirements, and Release Notes are available for free (as many as number of purchased licenses) upon request.

The Release Notes and the medical device software itself is copyrighted and all rights are reserved by Hermes Medical Solutions. Neither the software nor the manual may be copied or in any other way reproduced without prior consent in writing from Hermes Medical Solutions who reserve the right to make changes and improvements to the software and the manual at any time.

Hermes Medical Solutions*, HERMIA*, the HERMIA logotype* and SUV SPECT* are trademarks of Hermes Medical Solutions AB.

Third-party trademarks as used herein are the property of their respective owners, which are not affiliated with Hermes Medical Solutions.

*Subject to registration in some markets

Product Identification

Product name: Hybrid Recon

Marketing name: Hermia Reconstruction

Product version: 5.0.0

UDI = (01)00859873006196(8012)005000000

Identified problem

When reconstructing a SPECT/CT study, in some cases, the SPECT and CT series are not correctly aligned. This may be due to separately performed acquisitions, or due to the camera operator re-setting the reference point (landmark) between SPECT and CT acquisitions. Normally, the Hybrid Recon application warns the user if the Frames of Reference do not match, however in some configurations this warning message may be turned off.

If these conditions are met, then the SPECT reconstruction might not be properly aligned to the CT. This will often be obvious during the initial QC fused display and during final review, but there is a small chance that it might go unnoticed.

How to avoid the problem

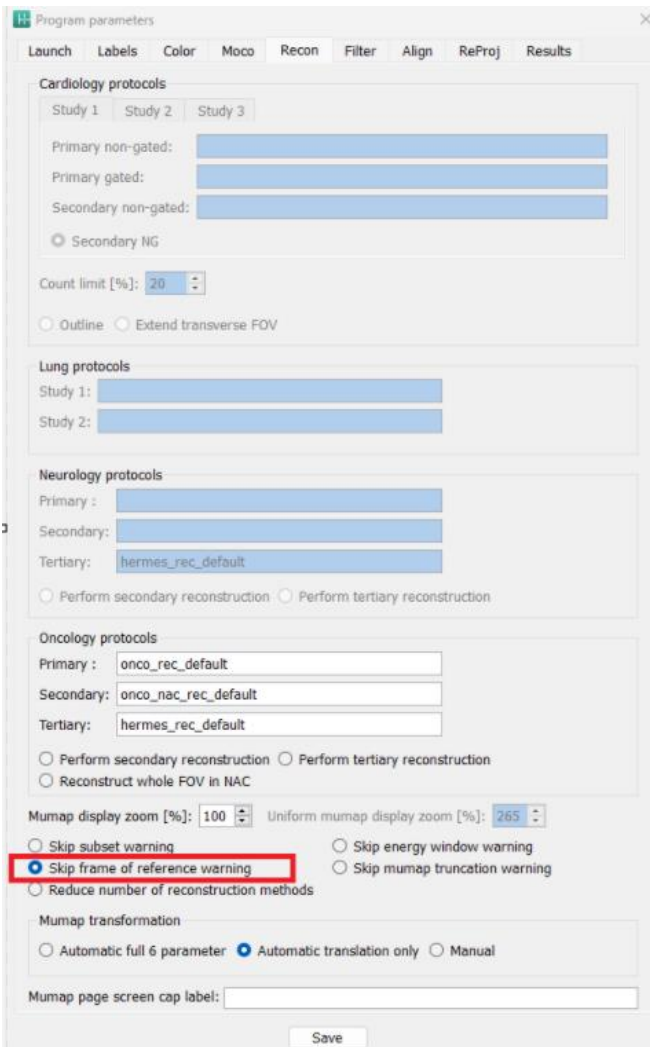
In all cases, the user must verify correct SPECT to CT alignment by careful inspection of the fused images during reconstruction.

To ensure that you are warned about possible SPECT to CT misalignment, the “Skip Frame of Reference warning” radio button shall not be activated.

The “Skip Frame of Reference warning” radio button can be found in the “Program Parameters” window. You can open the “Program Parameters” by clicking on the icon displayed bellow situated on the top right corner of the application.



Go to the “Recon” tab and find the “Skip frame of reference warning” radio button. If the button is “on” then this warning will not be shown to the users.



The setting of the “Skip Frame of Reference warning” radio button should be checked to ensure it is “off” for each workflow – Oncology, Neurology, Cardiology and Lung.

Please contact your Hermes Medical Solutions support if you do not have permission to make the changes required.

CONTACT INFORMATION

Contact any of the addresses below for service, support or if you have any other questions.

Manufacturer contact information



Head office
Hermes Medical Solutions AB
Strandbergsgatan 16
112 51 Stockholm
SWEDEN
Tel: +46 (0) 819 03 25
www.hermesmedical.com

General e-mail address:
info@hermesmedical.com

Support e-mail addresses:
support@hermesmedical.com
support.ca@hermesmedical.com
support.us@hermesmedical.com

Representatives

Authorized representatives

UK Responsible Person
Hermes Medical Solutions Ltd
Cardinal House
46 St. Nicholas Street
Ipswich, IP1 1TT
England, United Kingdom

CH Authorized Representative

CH	REP
----	-----

CMI-experts
Grellinger Str. 40
4052 Basel
Switzerland

Subsidiaries

Hermes Medical Solutions Ltd
7-8 Henrietta Street
Covent Garden
London WC2E 8PS, UK
Tel: +44 (0) 20 7839 2513

Hermes Medical Solutions, Inc
2120 E. Fire Tower Rd, #107-197
Greenville, NC27858
USA
Tel: +1 (866) 437-6372

Hermes Medical Solutions Canada, Inc
1155, René-Lévesque O., Suite 2500
Montréal (QC) H3B 2K4
Canada
Tel: +1 (877) 666-5675
Fax: +1 (514) 288-1430

Hermes Medical Solutions Germany GmbH
Robertstraße 4
48282 Emsdetten
Deutschland
Tel: +46 (0)819 03 25