GE Healthcare
3000 N. Grandview Blvd.
Waukesha, WI 53188
USA

URGENT FIELD SAFETY NOTICE

June 10, 2009

To: CT Perfusion 4 Customers
Hospital Administrators / Risk Managers
Radiology Department Managers

Re: **Perfusion 4 Default settings**

GE Healthcare has recently become aware of the need to adjust default settings associated with the use of CT Perfusion 4 on your Advantage Workstation, CT and PET/CT consoles that may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue	The default parameter settings in CT Perfusion 4 may not be optimal in the case of data acquired with longer time sampling intervals such as axial scans with inter scan delay (ISD) greater than 2 seconds or VolumeShuttle data. This can result in reduced conspicuity of subtle perfusion defects due to increased noise in these types of data sets.
Affected Product Details	CT Perfusion 4 on Advantage Workstation, CT and PET/CT consoles.
Safety Instructions	Adjust the parameter settings when processing data with ISD greater than 2 seconds or VolumeShuttle data as described in the attached User Guide Addendum.
Product Correction	Please use the enclosed User Guide Addendum explaining how to adjust the parameter settings in cases with increased noise due to longer ISD. This should be used in addition to the existing User Guide. Please place it next to the system with your User Guide.
Contact Information	Please contact your local sales or service representative if you need additional information regarding this notification.

[redacted]
+44 (0)7825273426
Compliance Manager
352 Buckingham Avenue
Slough SL1 4ER
United Kingdom

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately.

Sincerely,

[redacted]

[redacted]
Executive, Regulatory Affairs
GE Healthcare
9900 W. Innovation Drive
Wauwatosa, WI 53226-4856
USA
Pam.Schaub@ge.com

English

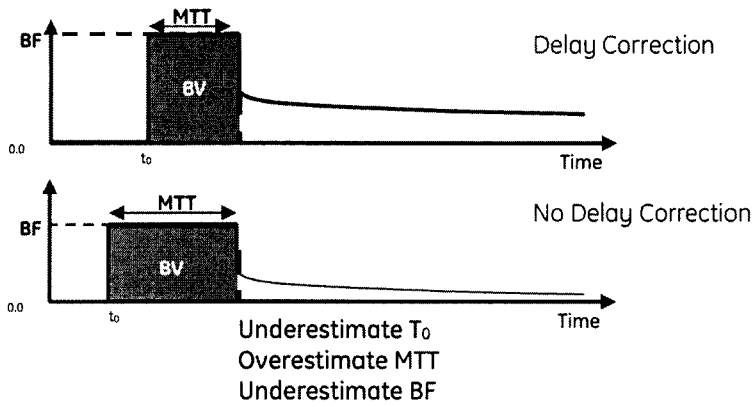
CT Perfusion 4 User Guide Addendum

Caution: CT Perfusion 4 default value settings may need adjustment when processing data with longer time intervals

This Addendum clarifies the methods described to maximize signal to noise ratio when using CT Perfusion 4 on data with longer time sampling intervals. **Ensure all potential users in your facility are aware of this additional information and store it with the existing CT user information.**

The default parameter settings in CT Perfusion 4 may not be optimal in the case of data acquired with longer time sampling intervals such as axial scans with inter scan delay (ISD) > 2sec or VolumeShuttle data. This can result in reduced conspicuity of subtle perfusion defects due to increased noise in these types of data sets.

The CT Perfusion 4 algorithm is designed to compensate for the delay in the arrival of blood (i.e. the contrast), which may be related to stenosis/blockage of a large proximal artery. Generally, the algorithms that do not compensate for this delay tend to overestimate the Mean Transit Time (MTT) and to underestimate the Blood Flow (BF) (see figure below), which may give an impression of a more pronounced perfusion defect.



These enhanced algorithmic changes improve the delay estimation and have the resultant effect of changing the maps, which may give the appearance of reducing the conspicuity of the abnormal region from the normal region, as well as properly introducing a change in the absolute values of the perfusion parameters. These changes are more evident for prior GE CT Perfusion users, so the Perfusion 3 algorithm was retained for comparison purposes as an integral part of Perfusion 4.

Per the instructions in the User Guide, it is recommended to modify the parameter settings when processing data with increased noise. Please refer to steps below to make necessary adjustments.

GE Healthcare recommends that users adjust time sampling (first phase) and spatial smoothing parameters when processing data acquired with longer time sampling step (axial scan with ISD > 2 seconds or VolumeShuttle). Additionally the data may also be analyzed using the Perfusion 3 algorithm, which will provide adjunct information for evaluation of scans with higher noise.

Adjusting parameter settings to compensate for noise

- Run CT Perfusion 4 on the dataset of interest.
- Adjust input parameters (registration, thresholds, artery, vein, or pre- and post-enhancement images) and re-compute functional maps if needed.
- Select **Advanced Settings** in the **Final Settings** panel, and adjust *Spatial Smoothing* to 7 or 9 under the **[Display] tab**, or as needed.
- Switch to the **[Time]** tab and adjust *Temporal Sampling (First Phase)* to 2.0 seconds.
- Click on *Done*.
- **In Final Settings** panel, click *Compute* and check the quality of the maps when computed.
- If satisfied with the results, these settings can be saved and used as new default parameters.

For comparative results using Perfusion 3 algorithm

- To switch to CT Perfusion 3 algorithm, select **Advanced Setting** in the **Final Settings** panel then select the **[Algorithm]** tab and enable the **Use CT Perfusion 3 Algorithm** option.
- Click on *Done*.
- In **Final Settings** panel, click *Compute* and check the quality of the maps when computed.
- If satisfied with the results, these settings can be saved and used as new default parameters.

Please refer to the CT Perfusion 4 User Guide Advanced Settings section in the Brain Stroke protocol for detailed instruction to execute the above mentioned.