Safety Customer Advisory Notice
CAN 008-2017

To: Director of the Radiology Department
Director of the Nuclear Medicine / PET Imaging Department
Risk Management Officer
Users of Siemens Healthineers Biograph Horizon systems running VJ10A, VJ10B, and VJ20A

Re: Biograph Horizon – UPMM, Waveform Sampling Issue

Dear Valued Siemens Healthineers Customer,

It has been brought to our attention that Biograph Horizon systems performing CT retrospective cardiac gating or PET cardiac gating examinations will experience a waveform sampling issue caused by a firmware change within the UPMM (Universal Physiological Measurement Module).

When does this malfunction occur and what are the potential risks?

Customers acquiring cardiac gating studies in the below affected areas will have a waveform that is out of sync with the acquisition. This could lead to a set of gated images that are partially or completely ungated.

If you have performed previous cardiac studies in the affected areas, please inform your Siemens Healthineers service representative.

The default protocols affected by this issue are the following:

- AverageCardiacGated
- CardiacGatedRestStress
- CardiacGated_Cardiacmatching
- CaScore
- CoronaryCTA_IR
- CoronaryCTARoutine

Please refer to Table 1 below to determine what imaging types are affected and not affected by this problem:

Software Version	PET Cardiac Gating	CT Prospective (Sequence) Cardiac Gating	CT Retrospective Cardiac Gating
VJ10A/B	Not Affected	Not Affected	Affected
VJ20A	Affected	Not Affected	Affected

Table 1

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How can you help to avoid the potential risk of this issue?

You should discontinue using your system for the cardiac imaging protocols listed above, until the resolution for this problem is installed on your system. Siemens Healthineers service organization will be contacting you in January 2018 to schedule the replacement of the UPMM on your Biograph Horizon system.

Please ensure that this customer advisory notice is placed in your Biograph Horizon Operator's Manual and this information is disseminated to all operators of the Biograph Horizon system. If this equipment is no longer in your possession, we kindly ask that you forward this letter to the new owner of the equipment, and please inform Siemens Healthineers about the change in ownership.

Adverse events or quality problems experienced with the use of this product should be reported to Siemens through the contact information provided below and may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

If you have any questions regarding this advisory notice, please contact your local Siemens representative at the contact numbers provided below.

- America: 1-800-888-7436
- Europe, Middle East, and Africa: +49 9131 940 4000
- Asia and Australia: +86 (21) 3811 2121

Sincerely,

Matt Shah
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