

Customer Safety Advisory Notice CAN 005-2018

To: Director of the Radiology Department
Director of the Nuclear Medicine/PET Imaging Department
Risk Management Officer
Users of Siemens Healthineers' Biograph Horizon systems

Re: Biograph Horizon's Oversized CT Circuit Breaker

Dear valued Siemens Healthineers customer,

This letter is to inform you that the CT circuit breaker, found in the Power Distribution Computer Cabinet (PDCC) of your Biograph Horizon system, is oversized. We have not had any reports of injury on Biograph Horizon systems regarding this issue.

What does this mean for my system and what are the potential risks?

This issue exists on all Biograph Horizon systems. The Biograph Horizon power cable assemblies that connect the Power Distribution Control Cabinet (PDCC) to the Line Control Box (LCB), and the LCB to the CT, are rated at 60amps per the US NFPA 70 National Electrical Code (NEC). The breaker amp rating should match the cable rating at 60 amps. However, the breaker that is present in the PDCC is oversized and rated for 70 amps. The safety margins of the components, and the protection provided, present a very minimal risk. Additionally, the maximum electrical current draw of the system does not exceed the power cable rating of 60 amps. If an unforeseen situation presents itself and the current draw exceeds 60amps but not enough to trip the 70amp breaker, you will notice a distinct burning smell and the system may cease all functionality. If this occurs, please stop use of your system and contact your Siemens Healthineers service representative.

What has been done by the manufacturer to address this issue?

Siemens Healthineers' service organization will contact you in Q1 of 2019 to schedule the replacement of the 70 amp CT circuit breaker, found within the PDCC cabinet of your Biograph Horizon system, with a 60 amp CT circuit breaker.

Please ensure that this customer advisory notice is placed in the *Biograph Horizon Operator's Manual for Examination and Acquisition* and disseminated to all operators of Biograph Horizon. 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 Healthineers 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 Healthineers 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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Molecular Imaging
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