

Customer Safety Advisory Notice
CAN 001-2021

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

Re: Improper use of the Patient Handling System (PHS) Pallet/Foot Extension

Dear valued Siemens Healthineers customer,

This letter is to inform you of the potential hazard associated with the improper use and/or operator assembly of the Patient Handling System (PHS) Pallet/Foot Extension.



Potential patient fall hazards could occur when the PHS Pallet/Foot Extension is improperly assembled by the operator. PHS Pallet/Foot Extension patient fall hazards could occur when the extension is improperly used to position the patient head-first. The Pallet/Foot Extension should only be used for positioning the patient's feet.

To avoid this issue, please ensure proper operator assembly of the PHS Pallet/Foot Extension as instructed in the Operator's Manual and as depicted on the extension label. Only use the PHS Pallet/Foot Extension for its intended purpose of feet first imaging as instructed in the Operator's Manual.



This letter is meant to serve as a reminder to follow the PHS Pallet/Foot Extension instructions for operator assembly and use in the existing Operators Manual.

Please ensure that this notice is placed in the Biograph Operator Manual and disseminated to all operators of the scanner.

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. Errors or problems that result in patient re-scan or re-dose should be reported to your local Siemens Healthineers representative.

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,

[Redacted Signature]

Siemens Healthineers
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