CC: Chairman of Medical Board &
Heads of Departments

Customer Safety Advisory Notice
CAN 004-2018

To: Director of the Radiology Department
Director of the Nuclear Medicine / SPECT Imaging Department
Risk Management Officer
Users of Siemens Evo Excel

Re: Evo Excel ECG Power Outlet

Dear Valued Siemens Customer,

Through product testing we have become aware that the External-ECG Power-Connection labeling is incorrect on the Evo Excel patient bed and in the Evo Excel Operating Instructions Manual. The outlet current limit is 0.55A but is incorrectly labeled as 1.0A. Our records indicate there are no complaints against the Evo Excel regarding this issue.

What are the potential risks?

We have conducted testing and determined that there is no risk to patient, operator or other person due to this issue. The system has an internal circuit breaker that disables the outlet in the event of a current overload. In the event of a current overload during an active scan, the scan will be interrupted and will need to be restarted once the system is back online.

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

Use external ECG power connections requiring a current of 0.55A or less, and only connect 1 ECG device to the system. The ECG device may be connected through either the gantry or the patient bed ECG power connection points.

You can expect to be contacted by Siemens service in the 1st quarter of 2019 to deliver a Symbia Evo Excel Addendum and DVD addendum with this updated information.

Always store the documentation in an easily accessible location in the vicinity of the system.

Please ensure that this customer advisory notice is placed in your Evo Excel Operator's Manual and disseminated to all operators of the Evo Excel 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 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.

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Sincerely,

[redacted]

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CAN 004-2018

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