

Dear customer,

We are contacting you regarding a recent issue that was discovered in Ponemah v5.20 Service Pack 6 (v5.20-SP6).

### **Impact**

This issue may prevent starting an acquisition after loading a previously configured protocol file using the OpenART interface. The Jacket External Telemetry, PhysioTel Digital, MX2, ACQ-7700, and ACQ-16 interfaces are not impacted.

This issue does not cause loss or misrepresentation of data during acquisition and analysis. It also does not impact the software's GLP compliance, as it does not affect the software security and electronic records and signatures.

### **Issue Description**

If you do not use previously configured protocol files as described here in your processes, you will not be impacted by this issue.

To acquire data using the OpenART interface, users must define the configured implants that will be used for acquisition. This definition occurs during protocol setup within the **Select DSI Sources** dialog by moving implants from the **Available Sources** list to the **Selected Sources** list. Once these and other protocol settings have been defined, the acquisition may be started. Protocols can then be reused for subsequent acquisitions or added to a Study Protocol for acquisitions within Study.

Upon loading a previously configured protocol file in Ponemah v5.20-SP6, the defined implants will automatically be deselected from the protocol and reassigned to the **Available Sources** list, preventing the acquisition from being started. Users will be alerted of the issue when choosing **Start Acquisition**.

### **Interim Solution**

Reassign the implants to the **Selected Sources** list and start your acquisition.

For GLP systems, this solution is only applicable if the user initiating the acquisition also has permission to edit the **Select DSI Sources** dialog. If the user does not have these permissions, acquisition start will be delayed until a user with the appropriate permissions can perform the workaround.

### **Solution**

DSI has determined the root cause and has fixed the issue. We are currently performing formal testing of the fix. DSI will notify you once the fix is available.

This fix will be provided as a Hotfix to SP6 and will be fully integrated into the next full Ponemah Service Pack release.