GE Healthcare

Date: June 26, 2019

Private and Confidential

Derek Winter DL
Senior Coroner for the City of Sunderland
Civic Centre
Burdon Road
Sunderland
SR2 7DN

Dear Mr. Winter

RE: Regulation 28 Report to Prevent Future Deaths – Mr. Thomas Smith Collings

GE Healthcare writes further to your correspondence dated April 15, 2019 regarding your concerns identified during the Inquest into Mr. Thomas Smith Collings' death.

As a medical device manufacturer, GE Healthcare takes patient safety and patient death reports very seriously. All death and serious injury reports received are thoroughly reviewed by GE Healthcare Medical Directors, product specialists and clinicians to determine whether the relevant patient monitoring system performed within specifications or if any further root cause investigation is required.

In the case involving Mr. Thomas Collings, following an investigation, GE Healthcare concluded that the automated ECG arrhythmia detection algorithm (EK-Pro), being used to monitor Mr Collings performed within specifications and ECG monitoring industry standards based on the available information and Full Disclosure data captured. The signal acquisition conditions combined with the extremely rare "Torsades de Pointes" ECG rhythm Mr. Collings presented with on the morning of August 2, 2018 prevented the algorithm from asserting a Ventricular Fibrillation ("VF") or Ventricular Tachycardia ("VT") arrhythmia alarm. Unfortunately, ECG tracings for leads I, II and V were not available for review to further the assessment.

The TRAM and Solar 8000M patient monitoring system used in the Sunderland Coronary Care Unit was state-of-the-art technology in 2004 when it was manufactured. If used in accordance with the operator's manual, the TRAM and Solar 8000M patient monitoring system is still an effective physiological patient monitoring device today.

Nevertheless, during the period since this equipment's manufacture date, there have been technology advances in digital signal processing hardware and software and medical industry standards, such as IEC 60601-1-8[1], which have improved the performance of patient monitoring equipment. In addition, GE Healthcare has a dedicated team of hardware and software engineers whose focus is improving the

[1] General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

sensitivity and specificity of the EK-Pro automated ECG arrhythmia algorithm based on clinical performance, customer feedback and ECG Full Disclosure data.

GE Healthcare has implemented ECG Technical Alarm notification improvements when the automated ECG algorithm detects noise and/or artifact. The current GE Healthcare CARESCAPE B850/B650/B450 Patient Monitoring platform provides escalating ECG Technical Alarms for "*Arrhythmia Paused"* and "*Leads Off"* states. These improvements allow clinicians to configure "*Arrhythmia Paused"* and "*Leads Off"* Technical Alarms to escalate to a high "red" alarm rather than a warning or advisory alarm. This functionality was introduced in the CARESCAPE product line in 2009. In Mr. Collings' case, based on the ECG tracings and log file information, the "*Arrhythmia Paused"* Technical Alarm would have escalated to a high "red" alarm at approximately 01:21:53, alerting caregivers to the loss of ECG monitoring and arrhythmia alarm detection capability.

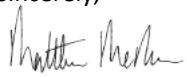
GE Healthcare has also implemented improvements in the signal processing specific to the detection of Ventricular Fibrillation. The current GE Healthcare CARESCAPE B850/B650/B450 Patient Monitoring platform uses a spectral analysis technique within the EK-Pro algorithm that was not possible in the previous generation platforms due to the computational demands. The primary performance benefits of the newer technology include a shorter average time to alarm and the capability to utilize the data in all available leads (e.g., I, II, III, V) when the analysis is updated each second. Testing of the algorithm improvements via the requirements of AAMI/ANSI EC-57 confirm the reduced alarm delay relative to the older technology. Furthermore, while the available EC-57 databases do not directly address Torsades de Pointes arrhythmias, the use of spectral analysis techniques would be expected to mitigate the primary challenge of the rapidly changing amplitude characteristics associated with these events. GE Healthcare expects to continue to invest in improvements in its algorithm detection capabilities in future versions of its software.

Following the incident involving Mr Collings where it became apparent that data for all leads had not been captured by the Trust at the time, GE Healthcare has also re-iterated to its complaint handling team to request data from all available monitoring leads when initiating an investigation, in an effort to ensure that as much data as possible is provided when reviewing a complaint or report requiring investigation.

Please be assured that maintaining a high level of safety and quality in our patient monitoring systems is GE Healthcare's highest priority.

We would like to take this opportunity to again offer our condolences to Mr Collings' family.

Sincerely,



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