Philips Healthcare

October 8, 2021

Mr. Adam Hodson
Coroner's Court
Birmingham & Solihull Districts
50 Newton Street
Birmingham 4B 6NE
Great Britain

[redacted]
Product = 866389 Patient Information Center iX (PIC iX) / MX40 Telemetry
Serial Number = 7COD-02P6-V / U5096A7490

Dear Mr. Hodson,

Thank you for bringing to our attention the incident involving the above cited product. The complaint details, subsequent investigation and resultant findings are described below.

Incident as reported to Philips Healthcare:

On August 27, 2021, Philips received the Coroner's report titled 'Regulation 28 Report to Prevent Future Deaths ' issued by you, Adam Hodson, HM Assistant Coroner. The following was reported:

> "On 1 April 2021 I commenced an investigation into the death of [redacted]. The investigation concluded at the end of the inquest. The conclusion of the inquest was: Death was a consequence of natural causes.
>
> The deceased was admitted to Good Hope Hospital on 26 February 2021 where [redacted] was treated for heart failure. [Redacted] was commenced on continual cardiac monitoring from 6th to 8th March, where two periods of ventricular standstill were recorded but were missed due to a combination of policy, staffing, workplace and equipment issues. [Redacted] suffered a cardiac arrest on 8 March 2021 and was treated on ICU for 22 days in total. Despite treatment, [redacted] deteriorated rapidly on [redacted] final day, and [redacted] died at 13:40, 30 March 2021. Had the periods of ventricular standstill been detected, [redacted] would have been admitted to CCU for monitoring, but [redacted] subsequent cardiac arrests could not have been prevented."

The report summarized concerns of a risk that future deaths will occur unless action is taken. Specifically, the report discussed a retrospective review of the telemetry monitoring carried out on this patient during the period of March 6-8, 2021. Two periods of ventricular standstill were noted: one at 12:43 on March 6, 2021 where the telemetry recorded a period of 4 seconds of ventricular standstill; and one at 13:09 on March 8, 2021 where the telemetry recorded a period of 10 seconds of ventricular standstill. The report further indicated that Medical Engineers were asked to analyse the telemetry and noted that on March 8, 2021 the monitor's alarm had triggered and that it was a self-terminating alarm as the heart rhythm had corrected itself. Medical Engineers and staff indicated there was no evidence that staff muted the alarm or that there was any fault with the equipment. Thus, it was concluded per the report that this self-correcting function is an intended function of the monitor.

Investigation:

Strip Review

As the Device Manufacturer, Philips' first contact from the Hospital in regard to this incident was on June 29, 2021. This was an informal request to investigate to a Philips Clinical Application Specialist (CAS) whilst visiting Heartlands Hospital on another matter. The question from the Matron was whether a Ventricular Standstill would cause an alarm and, if so, how long it would last for. A general ECG waveform strip and an Asystole Alarm strip, printed out around the time of the incident, was emailed to the CAS on July 18, 2021. The Asystole Alarm strip showed this alarm generated at the time of the Ventricular Standstill, but without the Clinical Audit Logs, the duration of this alarm and any other actions taken around the time of this alarm are unknown.

The configuration of the PIC iX was reviewed by the CAS at the time of this first site visit and found the systems functioning as designed. Red alarms were enabled and cannot be terminated without end user intervention.

Further review of the available information found that there was not a strip for the incident on March 6, 2021 to review. A strip was provided for March 8, 2021 13:09:13 that revealed an ECG waveform with beat labels. A (artifact), M (missed), ? (questionable), and one beat labeled N (normal) along with a period of ventricular standstill. The strips do not include the response taken by the user nor the length of time the alarm sounded. Philips was not notified of the March 2021 incidents until greater than three months following the events. As a result, Clinical Audit Logs required for a complete investigation were no longer available.

Self-Terminating Alarms

Per the report, hospital Medical Engineers were asked to review the Telemetry and the hospital Medical Engineers noted that on March 8, 2021, the monitors alarm had triggered and that it was a self-terminating alarm. Philips is interpreting this description as the alarm stopped on its own accord without user interaction. Any ventricular standstill of 4-10 seconds of duration would meet the definition of Asystole which is a red arrhythmia alarm. There is not a configuration to change Asystole or any other red arrhythmia alarm to self-terminate for a Telemetry / Central Station setup. In summary, the product is not designed to self-terminate red alarms nor is Philips able to reproduce the described behavior.

Good Hope Hospital Site Visit

Philips support personnel performed a site visit to Good Hope Hospital on September 24, 2021.

An ECG simulator was utilized to test the customer's system using the same equipment that was used on the patient in March. An Asystole alarm was generated, and the simulator was reset to normal sinus rhythm and the alarm continued even though the asystole condition had ended. Testing revealed no self-terminating of alarms. The devices were found to perform as expected.

The configuration was further reviewed by the Business Unit Clinical Specialist from the data collected during this site visit and the initial assessment of red alarms cannot be terminated without intervention was verified. While the original description of the issue was reported as the Information Center iX; this issue is with alarm detection and communication from the Telemetry to the PIC iX. When Telemetry is used with PIC iX, the alarm settings are sent from the PIC. Red alarms cannot be set to self terminate in the PIC configuration.

Complaint Review
Complaints were analyzed for the last 3 years world-wide and found one other similar complaint. This complaint was a non-adverse event, it was found that the alarm had been silenced by an end user initially and was giving an alarm reminder with brief audible alerts since alarm reminders were enabled. The equipment was operating as designed.

Conclusion:

Philips Healthcare investigated the reported incident and concluded that the device operates per specification.

- A full investigation into the alleged self-terminating alarm incident was not possible as the required logs were not obtained when the incident occurred.
- There is not a configuration available to enable asystole or any other red arrhythmia alarm to self-terminate for Telemetry / Central Station monitoring.
- Termination of asystole or other red arrythmia alarm with the current configuration requires end user intervention, as shown with the simulation test with NHS personnel present.
- Based on the current configurations of the system, if a red alarm is silenced by the user but persists, the expected behavior is for the audible alarm to end, the visual alarm to remain and a brief series of audible tones to be provided every 3 minutes, which stop after several seconds on their own as long as the condition remains.
- An on-site visit found the equipment to be operating as designed.

A full explanation of the configuration options is available in the Configuration Guide. Philips' clinical support continues to be available to assist with any changes to desired workflow.

Please be assured that Philips Healthcare is committed to providing quality products and solutions. If you have any questions on the investigation of this incident, please contact us.

Sincerely,

[redacted]

[redacted]
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Cc: Good Hope Hospital