Class 2 Recall Spacelabs Healthcare Ventilator Flexport Interface

Date Posted: June 18, 2014
Recall Status: Open
Recall Number: Z-1824-2014
Recall Event ID: 68374

Product: Spacelabs Healthcare Ventilator Flexport Interface, Model 90436A-07
Recall Reason: Recall issued for a potential issue with the Spacelabs Healthcare Ventilator Flexport Interface, Model 90436A-07, where the monitored Minute Volumes (Ymin) has been reported at one time to reach ten times the actual value on the bedside monitor.

Manufacturer Reason: Spacelabs Healthcare is voluntarily recalling the Hamilton Galileo Ventilator Flexport, Model 90436A-07, where the monitored Minute Volumes (Ymin) has been reported at one time to reach ten times the actual value on the bedside monitor.

Action: Spacelabs recommends that customers immediately advise their staff of this situation and if they continue to use the Flexport, to please keep in mind: 1) Galileo Interface Protocol (GIP) version 1.0 and 1.1 do not affect the flexport readings. Only GIP version 1.2 is an issue. 2) If you have the GIP version 1.2, the ventilator alarms continue to work normally at the bedside and central station. The ventilator itself is available and working correctly. The reported x10 volumes would be an obvious error to the clinician. Spacelabs Field Service personnel will be contacting all customers to schedule a convenient time to install, at no cost, a software update that resolves this issue.

Quantity in Commerce: 46 units distributed within the US, 108 units distributed outside the US.


6/23/2014