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Class 2 Device Recall Spacelabs Healthcare Ventilator Flexport Interface

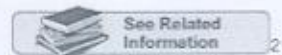


510(k)⁷|Registration & Listing⁸|Adverse Events⁹|Recalls¹⁰|PMA¹¹|Classification¹²|Standards¹³|Inspections¹⁴
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**Class 2 Recall
 Spacelabs Healthcare Ventilator
 Flexport Interface**



Date Posted	June 18, 2014
Recall Status¹	Open
Recall Number	Z-1824-2014
Recall Event ID	68374 ²²
Product	Spacelabs Healthcare Ventilator Flexport Interface, Model 90436A-07
Code Information	<p>Serial Numbers Distributed in the US: 436A000660, 436A000663, 436A000664, 436A000666, 436A000667, 436A000669, 436A004306, 436A004307, 436A004308, 436A004309, 436A004310, 436A006122, 436A006123, 436A006441, 436A006442, 436A006443, 436A006444, 436A006452, 436A006573, 436A006589, 436A006590, 436A006591, 436A006592, 436A006593, 436A006594, 436A006595, 436A006596, 6A006597, 436A006598, 436A006599, 436A006600, 436A006601, 436A006670, 436A006966 436A01020, 436A02086, 436A02087, 436A02088, 436A02234, 436A02246, 436A02247, 436A02281, 436A02282, 436A02283, 436A03237 and 436A03238. Serial Numbers Distributed Outside the US:</p> <p>436A003628, 436A003629, 436A003630, 436A003631, 436A003632, 436A003633, 436A003634, 436A003635, 436A003636, 436A003637, 436A003638, 436A003639, 436A003640, 436A003644, 436A003645, 436A003646, 436A003647, 436A004162, 436A004166, 436A004197, 436A004198, 436a005205, 436a005471, 436a005472, 436A005638, 436A005641, 436A005642, 436A006087, 436A006088, 436A006151, 436A006193, 436A006248, 436A006249, 436A006250, 436A006262, 436A006389, 436A006390, 436A006397, 436A006445, 436A006446, 436A006522, 436A006523, 436A006524, 436A006570, 436A006571, 436A006572, 436A006609, 436A006610, 436A006611, 436A006612, 436A006613, 436A006614, 436A006616, 436A006617, 436A006618, 436A006619, 436A006620, 436A006621, 436A006624, 436A006625, 436A006950, 436A006951, 436A01023, 436A01094, 436A01095, 436A01096, 436A01097, 436A01098, 436A01099, 436A01100, 436A01101, 436A01102, 436A01103, 436A01104, 436A01105, 436A01106, 436A01107, 436A01108, 436A01129, 436A01152, 436A01190, 436A01191, 436A01192, 436A01193, 436A01194, 436A01195, 436A01197, 436A01199, 436A01200, 436A01212, 436A01213, 436A01217, 436A01298, 436A02023, 436A02024, 436A02025, 436A02026, 436A02027, 436A02188, 436A02233, 436A02262, 436A02264, 436A02590, 436A02591, 436A02592, 436A03193, 436A03239, and 436A03500.</p>
Recalling Firm/ Manufacturer	Spacelabs Healthcare Inc 35301 SE Center St Snoqualmie, Washington 98065-9216
Manufacturer Reason for Recall	Spacelabs Healthcare is voluntarily recalling the Hamilton Galileo Ventilator Flexport, Model 90436A-07, where the monitored Minute Volumes (Vmin) 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.