**Class 1 Device Recall Continuous Ventilator**

<table>
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<tr>
<th>Date Posted</th>
<th>November 04, 2015</th>
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<tr>
<td>Recall Status</td>
<td>Open</td>
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<tr>
<td>Recall Number</td>
<td>Z-0151-2016</td>
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<td>Recall Event ID</td>
<td>72319</td>
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<td>Premarket Notification</td>
<td>K131744</td>
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<td>510(K) Number</td>
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<tr>
<td>Product Classification</td>
<td>HAMILTON-G5</td>
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<tr>
<td>Product</td>
<td>Ventilator, Continuous, Facility Use - Product Code CK27</td>
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<tr>
<td>Code Information</td>
<td>software versions between V2.00 and V2.31</td>
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</table>
Recalling Firm/Manufacturer
Hamilton Medical, Inc.
4980 Energy Way
Reno, Nevada 89502-4123

For Additional Information Contact
Daniel Belanger
775-742-2792

Manufacturer Reason for Recall
Ventilation and alarms of a HAMILTON-G5 ventilator can be suppressed unintentionally after the activation of a suctioning maneuver by the operator; this situation can occur regardless of the selected patient group (neonatal, pediatric and adult).

FDA Determined Cause 2
DESIGN: Device Design

Action
Hamilton Medical issued a letter dated April 22, 2014, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were notified that their Hamilton Medical Account Manager would contact them to coordinate the deactivation of the Ventilation Suppression feature. Customers were asked to review the Medical Device Field Safety Corrective Action. Customers with questions were instructed to call 800-426-6331, Ext. 215.

Quantity in Commerce
1128

Distribution
Nationwide Distribution

Total Product Life Cycle
TPLC Device Report 28

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1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 § 808.10
2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database
510(K)s with Product Code = CBK and Original Applicant = TERUMO BCT, INC. 30

Links on this page:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=140598
11/16/2015