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## Class 2 Device Recall Terumo Advanced Perfusion System 1 Flow Module

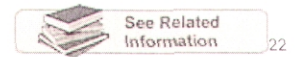


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### Class 2 Device Recall Terumo Advanced Perfusion System 1 Flow Module



<b>Date Initiated by Firm</b>	January 19, 2018
<b>Create Date</b>	April 20, 2018
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-1478-2018
<b>Recall Event ID</b>	<a href="#">79624</a> <sup>23</sup>
<b>510(K)Number</b>	<a href="#">K172220</a> <sup>24</sup>
<b>Product Classification</b>	Console, heart-lung machine, cardiopulmonary bypass <sup>25</sup> - <b>Product Code DTQ</b> <sup>26</sup>
<b>Product</b>	Flowmeter Module (accessory to Terumo Advanced Perfusion System 1).  Provides the interface between the flow sensor and the system.
<b>Code Information</b>	Catalog # - 802018, Serial #: 01662, 01672, 01680, 01681,01682, 01683 , and 01687., UDI: 00886799000687.
<b>Recalling Firm/Manufacturer</b>	Terumo Cardiovascular Systems Corporation 6200 Jackson Rd Ann Arbor MI 48103-9586
<b>For Additional Information Contact</b>	Mary Swift 734-741-6056
<b>Manufacturer Reason for Recall</b>	Inaccurate flow readings. Depending on the degree of inaccuracy, this issue may not be easy for the user to detect during setup or use (for example, following a Flow Probe relocation or manipulation).
<b>FDA Determined Cause<sup>2</sup></b>	Employee error
<b>Action</b>	The firm notified customers via phone alerting them of this affected device, issue, potential hazard, correction, and instructions. The communication also included scheduling an expedited service call for a Field Service Technician to replace the affected Flowmeter Module with a corrected Flowmeter Module. When necessary to avoid delaying or cancelling life-sustaining surgery, users can continue to use the Flowmeter Module while awaiting replacement. Once the issue is recognized by the user, if a replacement Flowmeter Module is available, replacement and reassignment of safety connections of the Flowmeter Module can be accomplished in less than 15 seconds. In the event that a replacement Flowmeter Module is not available, a less common mitigation is the use of a back-up stand-alone centrifugal pump or a stand-alone ultrasonic flowmeter system to provide flow data. Customers should receive a copy of the Urgent Medical Device Recall phone script by e-mail along with a Customer Response Form. The e-mail should be reviewed, and the form completed and returned as indicated. Questions or concerns can be directed Terumo CVS Customer Service at 1-800-521-2818.
<b>Quantity in Commerce</b>	7