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## Class 2 Device Recall Terumo HX2 Temperature Management System



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### Class 2 Device Recall Terumo HX2 Temperature Management System



<b>Date Initiated by Firm</b>	April 16, 2021
<b>Create Date</b>	June 04, 2021
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-1789-2021
<b>Recall Event ID</b>	<a href="#">87834</a> <sup>23</sup>
<b>510(K)Number</b>	<a href="#">K071521</a> <sup>24</sup>
<b>Product Classification</b>	<a href="#">Controller, temperature, cardiopulmonary bypass</a> <sup>25</sup> - <b>Product Code</b> <a href="#">DWC</a> <sup>26</sup>
<b>Product</b>	<p>The Terumo HX2 Temperature Management System provides temperature control of two independent water circuits that directly controls the temperature of patient blood and cardioplegia solution during cardiovascular surgery. The system consists of a water tank, circulating pumps, heater manifolds, mercury free temperature sensors, water detectors, mixing valves and a tank divider which is provided to partition the tank into two separate channels (Left and Right).</p> <p>The system has the capacity to circulate water at a rate of up to 6.5 gal./min (25 L/min) with no load connected. The system is capable of heating and cooling for a single channel or for both channels.</p> <p>Device Name / Model Number: HX2 Temperature Management System (P/N 809810)</p> <p>Catalog Number: 809810</p>
<b>Code Information</b>	All lot numbers distributed from 05/02/1985 thru 06/10/2015
<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>	Terumo CVS has been unable to validate a cleaning protocol to satisfy current regulatory concerns and expectations. As a result, an updated cleaning protocol will not be developed by Terumo CVS and it has been determined that the

best course of action is for users to discontinue use of and dispose of HX2, TCM I and TCM II devices.

<b>FDA Determined Cause<sup>2</sup></b>	Device Design
<b>Action</b>	On 04/30/2021, Terumo issued an Urgent Medical Device Removal notice to customer via letter notifying users to discontinue the use of and dispose of HX2, TCM I and TCM II devices. Customers were instructed to confirm receipt of this communication by completing and returning the attached Customer Response Form as indicated on the form. For questions contact Terumo CVS Customer Service: 1-800-521-2818.
<b>Quantity in Commerce</b>	75 devices
<b>Distribution</b>	Domestic: Foreign: Australia, Belgium, Canada, Chile, China, Colombia, Dominican Republic, England, France, Germany, Greece, Hong Kong, India, Indonesia, Iran, Israel, Italy, Japan, Korea, Malaysia, Mexico, Netherlands, New Zealand, Norway, Philippines, Russia, Saudi Arabia, Singapore, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, UNITED ARAB EMIRATES (UAE), Vietnam
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report</a> <sup>27</sup>

<sup>1</sup> A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about [medical device recalls](#)<sup>28</sup>.

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

<sup>3</sup> The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

**510(K) Database** [510\(K\)s with Product Code = DWC and Original Applicant = TERUMO CARDIOVASCULAR SYSTEMS CORP.](#)<sup>29</sup>

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