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Enforcement Report - Week of November 19, 2014
Product Detail

Product Description	Masimo SET uSpO2 Cable The Masimo SET uSpO2 Pulse Oximetry Cable is an in-line cable that provides continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate when installed in a compatible OEM host system. Shipping/Package: All Pulse Oximetry cables are shipped non-sterile in a cardboard carton. They are intended to be used non-sterile.
Recall Number	Z-0213-2015
Classification	Class II
Code Info	V35685 3636 V35686 3636 V35691 3636 V35693 3636 V35694 3636 V35696 3636 V35697 3636 V35698 3636 V35701 3636 V35702 3636 V35708 3636 V35716 3636 V35717 3636 V35726 3636 V35742 3636 V35743 3636 V35748 3636 V35750 3636 V35752 3636 V35756 3636 V35762 3636 V35765 3636 V35768 3636 V35769 3636 V35771 3636 V35773 3636 V36049 3636 V36054 3636 V36057 3636 V36058 3636 V36060 3636 V36061 3636 V36062 3636 V36063 3636 V36064 3636 V36066 3636 V36068 3636 V36070 3636 V36071 3578 V27744 3578 V27745 3578 V27746 3578 V27747 3578 V27748 3578 V27749 3578 V27750 3578 V27751 3578 V27752 3578 V27753 3578 V27754 3578 V27755 3578 V27756 3578 V27757 3578 V27758 3578 V27759 3578 V27760 3578 V27761 3578 V27762 3578 V27763 3578 V27764 3578 V27765 3578 V27766 3578 V27767 3578 V27768 3578 V27769 3578 V27770 3578 V27771 3578 V27774 3578 V27775 3578 V27776 3578 V27777 3412 V32427 3412 V32429 3412 V32443 3412 V32445 3412 V32449 3412 V32450 3412 V32457 3412 V32459 3412 V32467 3412 V32468 3449 V35327 3449 V35328 3449 V35329 3449 V35330 3449 V35331 3449 V35332 3449 V35333 3449 V35334 3449 V35335 3449 V35336 3449 V35337 3449 V35338 3449 V35339 3449 V35340 3449 V35341 3449 V35342 3449 V35343 3449 V35344 3449 V35345 3449 V35346 3449 V35347 3449 V35348 3449 V35349 3449 V35350 3449 V35351 3449 V35352 3449 V35353 3449 V35354 3449 V35355 3449 V35356 3449 V35357 3449 V35358 3449 V35362 3449 V35363 3449 V35364 3449 V35365 3449 V35366 3449 V35367 3449 V35368 3449 V35370 3449 V35371
Product Distributed Qty	21,754 units (21,222) in the U.S. and Puerto Rico)
Reason For Recall	Firm has identified a small number of Oximetry Cables with crossed-internal wires. The effect on performance when these wires are crossed is that when a low SpO2 value is measured, a high SpO2 value would be displayed on the monitoring device. Additionally when a high SpO2 value is measured, a low SpO2 value would be displayed on the monitoring device.

Event Detail

Event Id	69504
Product Type	Devices
Status	Ongoing
Recalling Firm	Masimo Corporation
City	Irvine
State	CA
Country	US
Voluntary / Mandated	Voluntary: Firm Initiated
Recall Initiation Date	2014-09-30
Initial Firm Notification of Consignee or Public	Letter
Distribution Pattern	Worldwide distribution including; nationwide (U.S. and Puerto Rico) and the countries of Argentina, Austria, Brazil, Canada, China, Denmark, France, Germany, Hong Kong, India, Italy, Japan, Jordan, Kuwait, Mexico, Netherlands, Poland, Portugal, South Korea, Spain, Switzerland, Turkey, and United Kingdom.

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