

Urgent Medical Device Correction Covidien Nellcor Bedside SpO2 Patient Monitoring System

Manufacturer name:	Medtronic																																			
About the Recall:	Medtronic Medical Surgical issues this notice of correction for their Covidian Nellcor Bedside SpO2 Patient Monitoring System due to customers reporting that the device alarm was not heard or recognized resulting in a delay to treatment or lack of response to low oxygen saturation, respiratory failure, or arrhythmia																																			
Products(s) numbers/models that are affected:	<table><tr><th colspan="4">Covidien Nellcor™ Bedside SpO2 Patient Monitoring System (All Serial Numbers)</th></tr><tr><th>Item Code</th><th>GTIN</th><th>Bundle Code</th><th>IFU Part Number</th></tr><tr><td>PM100N</td><td>10884521196728</td><td>PM100N-10 PM100N-2XMAXN PM100N-2XMAXN-CC PM100N-3DYS-CC PM100N-DYS PM100N-HC PM100N-MAXN PM100N-MAXN-CC PM100N-OXIAN-CC</td><td>PT00156509 - EN - English PT00156328 - EN - English</td></tr><tr><td rowspan="2">10005941</td><td>10884521163454</td><td>NELLSP02</td><td>PT00156324 - EN - English</td></tr><tr><td>A8845211634501</td><td>NA</td><td>NA</td></tr><tr><td>DLPM100N</td><td>10884521527607</td><td>NA</td><td>NA</td></tr><tr><td>DL10005941</td><td>10884521173293</td><td>NA</td><td>NA</td></tr><tr><td>DS10005941</td><td>DS10005941</td><td>NA</td><td>NA</td></tr><tr><td>DSPM100N</td><td>DSPM100N</td><td>NA</td><td>NA</td></tr></table>	Covidien Nellcor™ Bedside SpO2 Patient Monitoring System (All Serial Numbers)				Item Code	GTIN	Bundle Code	IFU Part Number	PM100N	10884521196728	PM100N-10 PM100N-2XMAXN PM100N-2XMAXN-CC PM100N-3DYS-CC PM100N-DYS PM100N-HC PM100N-MAXN PM100N-MAXN-CC PM100N-OXIAN-CC	PT00156509 - EN - English PT00156328 - EN - English	10005941	10884521163454	NELLSP02	PT00156324 - EN - English	A8845211634501	NA	NA	DLPM100N	10884521527607	NA	NA	DL10005941	10884521173293	NA	NA	DS10005941	DS10005941	NA	NA	DSPM100N	DSPM100N	NA	NA
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URL Link(s) to Manufacturer Notice/Web Site:	Medtronic.com																																			
Actions to be taken by customer/Patient:	<p>You may continue using the device, please ensure that monitoring alarms are safely heard and recognized.</p> <p>Metronic Medical surgical Quality Assurance (800) 255-6774</p>																																			