COVIDIEN

URGENT MEDICAL DEVICE RECALL for PediCap™ End-Tidal CO2 Detectors

August 14, 2009

Dear Valued Customer,

We are informing you of an urgent voluntary medical device recall regarding the PediCap End-Tidal CO2 Detector (PediCap and PediCap 6).

We have received a customer report in which they experienced difficulty manually ventilating an intubated patient through the PediCap. While we continue to investigate, we believe that a recent modification to the PediCap End-Tidal CO2 Detector may result in increased resistance to airflow through the PediCap. This could result in ineffective ventilation of the patient and/or inadequate detection of CO2 levels, so that the indicator paper will not change color.

Although we have received no reports of patient injury, we have determined that all PediCap and PediCap 6 End-Tidal CO2 Detectors from the lots listed below must be returned. We are requesting your assistance in conducting this activity. Please review your inventory and segregate any product with the affected lot numbers and return affected product according to the directions below.

If you or your company has distributed PediCap or PediCap 6 End-Tidal CO2 Detectors to other persons or facilities, please promptly forward the recipients a copy of this letter and include the RGA provided at the top of this page as a reference.

The recall applies to the following 80 lot numbers.

8294199	**8301112**	**8301113**	**8315189**	**8315190**	**8319262**	**8319263**	**8322181**	**8322182**	**8326251**
8326252	**8326253**	**8326254**	**8329072**	**8329073**	**8330001**	**8333183**	**8350018**	**8350019**	**8354221**
8354224	**8357021**	**8357022**	**8361153**	**9005011**	**9005012**	**9012058**	**9012059**	**9026042**	**9026043**
9033128	**9033129**	**9040067**	**9040068**	**9047127**	**9047128**	**9054110**	**9054111**	**9061066**	**9061067**
9065209	**9068061**	**9068062**	**9072281**	**9075059**	**9075060**	**9079160**	**9082376**	**9082377**	**9086312**
9089126	**9089127**	**9103038**	**9103039**	**9110481**	**9110482**	**9117039**	**9117040**	**9124134**	**9124135**
9131188	**9131189**	**9138084**	**9138085**	**9138226**	**9145088**	**9145089**	**9152238**	**9152239**	**9159128**
9159129	**9170191**	**9170192**	**9170197**	**9176471**	**9176477**	**9184145**	**9191233**	**9191234**	**9204128**

To return the affected product for credit, please contact our Technical Services group at 1-800-635-5267, option 3, then option 1, and reference the Return Goods Authorization Number (RGA) noted at the top of this page. If product was purchased from a distributor, please contact your provider for their return process. Alternatively, you may complete the enclosed Verification Form and fax it to us at 925-463-4600 to initiate the return of your device(s).

Please report any issues with the PediCap End-Tidal CO2 Detectors to our Technical Services group to ensure proper device reporting procedures are followed. Please call 1-800-635-5267, option 3, then option 1, and you will be given further instructions.

This letter is being sent with the knowledge of the U.S. FDA.

Please be assured that we are working expeditiously to address this issue in future production and we are aware that this may create supply challenges for your facility. We sincerely apologize for any inconvenience this may cause and appreciate your prompt attention to this matter.

Sincerely,

Frances E. Harrison
Vice President, Regulatory Affairs
Respiratory and Monitoring Solutions
Covidien, formerly known as Tyco Healthcare

COVIDIEN

NELLCOR TECHNICAL SERVICES **FAX: 925-463-4600**
PediCap® End-Tidal CO2 Detector
Verification Form

Date:	
To: Nellcor Technical Services	**Page(s) – including this sheet:**
From (Facility Name): **Phone number:**	**Address:** **City:** **State:** **Country:**

Quantity Case or Each	Part Number	Lot Number

Name: (Please print):

Signature & Date:

Please fax this form to Technical Services. Please mark the RGA number prominently on the outside of the box, and return affected product(s) to the following address:
Covidien
Attention: PediCap End-Tidal CO2 Detector Returns
RGA #_____
3901 Rock Creek Blvd.
Joliet, IL 60431

Comments:

6135 GUNBARREL AVENUE
BOULDER, CO 80301
USA
800-635-5267 [T]