Philips Healthcare

PHILIPS

January 7, 2012

Dear Valued Customer,

This letter is to inform you of an issue with Oridion's end tidal CO2 disposable Filterlines used with monitors and defibrillators incorporating Oridion's Microstream CO2 technology.

Following an FDA inspection in June, 2011, the FDA determined that Oridion products were not manufactured to Oridion's specifications. Therefore, per the FDA Quality System Regulation, these products are considered "adulterated". This finding resulted in an FDA warning letter issued to Oridion in October 2011 and a related import alert, which prohibits importation of some of the Microstream® Filterlines® into the U.S. On December 20, 2011, the FDA expanded the import alert to include all products manufactured by Oridion. Philips has initiated a voluntary ship hold on all Philips Filterlines® until FDA findings are adequately addressed by Oridion.

In Oridion's December 27, 2011 news release, Oridion indicated that "disruptions to product supply into the U.S. should not go beyond the first half of 2012."

Oridion has proactively initiated a health hazard evaluation and concluded from the evaluation that there are no product safety issues. Distributed product is not subject to recall.

For some products, Philips may be able to offer an alternative capnography solution from Philips Respironics. We are working diligently on programs and offerings to help address the clinical challenges that this issue may cause you. If you have any questions related to this situation, do not hesitate to contact your Philips sales representative.

We thank you for your patience as Oridion addresses the disposable Filterline® issues.

Sincerely,

Steve Smyth
Philips Healthcare
General Manager
Medical Consumables and Sensors